PROCESS CONTROL AND DATA HANDLING IN CLINICAL CHEMISTRY BY A LABORATORY COMPUTER

By

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ABSTRACT OF THESIS

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Title of Thesis Process Control and Data Handling in Clinical Chemistry by a Laboratory Computer

The thesis describes the development and assessment of a clinical chemistry computer system based on the Elliott 903C computer obtained for the on-line monitoring of automated equipment and the subsequent processing of the data derived. The special hardware required for interfacing the automated equipment with the computer was designed and constructed by Elliott Medical Automation Limited. All the software required for the operation of the system was written by the manufacturer's programming staff and my part was to be closely involved with general systems analysis.

A detailed account is given of the evaluation of all the parameters required for the on-line monitoring of AutoAnalyzers and the provision of information required for calculation routines, checking quality control results, defining ranges for the automatic flagging of abnormal results, etc. The development work, including the testing, proving and where necessary, the modification of programs, was carried out in the Royal Infirmary, Edinburgh, with the assistance of the technical staff of the laboratory.

In the initial stages of development the computer system was run in parallel with the existing laboratory equipment to enable a full assessment of the system to be carried out. This included assessing the performance of process control functions and the chemical acceptability of the system. At a later stage an assessment was made of the routine operation of the computer system when interest was focused on the time taken to perform individual tasks and the reliability of the hardware components.

With the exception of one aspect of peak detection, the data acquisition programs were found to operate in a satisfactory manner, and the accuracy and precision of the computer system was at least as good as that of the routine laboratory methods; these latter involved manual reading and interpretation of recorder charts. The individual data processing programs were validated but when the programs were integrated to form a total software system, considerable delays in processing were encountered. Despite several attempts to reduce the time taken to perform processing routines, it was found impracticable to carry out the data handling activities of the laboratory within an acceptable time scale using the existing hardware configuration.

The computer system is currently in use on a seven-day week basis for monitoring analytical equipment and performing the following functions:-

(1) Acquisition of raw data from as many as 19 different determinations on up to 12 AutoAnalyzer channels at one time.

(2) Peak detection and validation.

(3) Calculation of results after correction for instrumental drift.

(4) Output of results identified by cup number.

(5) Calculation of mean and standard deviation of patient specimens.

The/

The present mode of operation removes the need for manual reading of AutoAnalyzer charts and hence reading errors, but it involves the transcription of results from the computer print-out to manually prepared work sheets, and the further transcription of results from work sheets to patient reports.

The benefits derived from the Elliott 903 computer in its present form of operation can be summarised as follows:-

(1) It has been possible to increase the laboratory throughput without a substantial increase in staff in spite of an increase in the numbers of technical staff attending classes of further education during working hours. This has resulted in an increase in productivity and a decrease in the average cost per determination.

(2) There is a decrease in the number of human errors by the elimination of reading of recorder charts.

(3) Quality control statistics are available while they are still relevant to the current situation.

The extension or modification of the hardware configuration and the additional software required to meet the needs of this laboratory have been investigated. Consideration has been given to the possibility of completely replacing the present computer system and to the feasibility of linking the laboratory system to a remotely situated data processing computer system.

SUMMARY

The number and range of analyses performed in clinical chemistry laboratories have increased considerably in the last twenty years. In order to contain this steadily rising work load, work simplification techniques and mechanised methods of analysis have been introduced. While mechanisation has relieved the strain on one part of the laboratory system, the actual chemical analysis of specimens, it has created new problems in other areas - by giving rise to a greatly increased amount of data. The handling of this data involves a large amount of repetitive calculation of results, and much clerical work in the preparation of reports for filing in patients' case folders. In addition, the use of mechanised procedures makes it more important to have an effective method of quality control; this in turn leads to an increase in the amount of information requiring inspection and interpretation.

Several attempts to reduce the amount of manual handling of data in clinical chemistry laboratories have involved the introduction of computers into the laboratory environment. In the earlier systems the raw data collected from mechanised equipment was processed in batch mode using an off-line computer.

This/

This method of operation greatly reduced the time spent in the laboratory on clerical routines but it did not provide facilities for process control of the analytical system nor for handling urgent test requests. These functions can, however, be performed by a computer dedicated to laboratory use and operating in on-line mode.

This thesis describes the assessment of a system based on an Elliott 903C computer obtained for the on-line monitoring of automated equipment and the subsequent processing of the data derived. The special hardware required for interfacing the automated equipment with the computer was designed and constructed by Elliott Medical Automation. All the software required for the operation of the system was written by Elliotts and my part was to be closely involved with general systems analysis; in performing this task I received much advice and guidance from members of the departmental staff. I was responsible for evaluating all the parameters required for on-line monitoring of AutoAnalyzers and for providing the information required for calculation routines, checking quality control results, defining ranges for the automatic flagging of abnormal/

abnormal results, etc. The development work was carried out in the Royal Infirmary, Edinburgh and I was assisted by the technical staff of the laboratory in the testing, proving, and where necessary, the modification of programs.

In the initial stages of development the computer system was run in parallel with the existing laboratory equipment to enable a full assessment of the system to be carried out. This included assessing the performance of process control functions and the chemical acceptability of the system. At a later stage an assessment was made of the routine operation of the computer system when interest was focused on the time taken to perform individual tasks and the reliability of the hardware components.

With the exception of one aspect of peak detection, the data acquisition programs were found to operate in a satisfactory manner, and the accuracy and precision of the computer system was at least as good as that of the routine laboratory methods; these latter involved manual reading and interpretation of recorder charts. The individual data processing programs were validated but when the programs were integrated to form a total software/

software system considerable delays in processing were encountered. Despite several attempts to reduce the time taken to perform processing routines, it was found impracticable to carry out the data handling activities of the laboratory within an acceptable time scale using the existing hardware configuration.

The computer system is currently in use on a seven-day week basis for monitoring analytical equipment and performing the following functions:-

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(4) Output of results identified by cup number.

(5) Calculation of mean and standard deviation of patient specimens.

The present mode of operation removes the need for manual reading of AutoAnalyzer charts and hence eliminates reading errors, but it involves the transcription of results from the computer print-out to manually prepared work sheets, and the further transcription/

transcription of results from work sheets to patient reports.

It has been suggested (Review for the National Health Service, 1971) that an important part of the evaluation of a computer system is a cost/benefit assessment. While such an assessment of a hospital-based system is of undoubted value for future computer developments, it presents many difficulties. The benefits derived from the Elliott 903 computer in its present form of operation can be summarised as follows:-

(1) It has been possible to increase the laboratory throughput without a substantial increase in staff in spite of an increase in the numbers of technical staff attending classes of further education during working hours. This has resulted in an increase in productivity and a decrease in the average cost per determination (Whitby, 1971).

(2) There is a decrease in the number of human errors by the elimination of reading of recorder charts.

(3) Quality control statistics are available while they are still relevant to the current situation.

The/

The extension or modification of the hardware configuration and the additional software required to meet the needs of this laboratory have been investigated. Consideration has been given to the possibility of completely replacing the present computer system and to the feasibility of linking the laboratory system to a remotely situated data processing computer system.

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SECTION I

INTRODUCTION

Clinical chemistry involves the application of chemical and biochemical analytical techniques to the study of the functions of the body in order to provide information for the prevention, diagnosis, prognosis and treatment of disease. The information is usually obtained by the analysis of blood; body fluids including urine, sweat, cerebrospinal fluid, pancreatic fluid, etc.; and other materials such as faeces, renal stones, etc. A wide range of analyses is performed on these materials. A succinct account of the work carried out in the clinical chemistry laboratory has been written by Watson (1968). Laboratory investigations, and in particular the chemical analysis of blood, are assuming an increasingly important role in hospital medicine. The introduction of new physical and chemical methods of analysis has greatly extended the range of investigations performed. Also, as a result of increased specialisation and the setting up of special clinics, clinicians now have a better knowledge of clinical chemistry and they are becoming increasingly dependent on the laboratory to assist in the diagnosis and treatment of disease (Gaddie, 1967).

The/

The analytical techniques employed in clinical chemistry laboratories have undergone a major transformation in the past 25 years with the introduction of colorimeters; spectrophotometers for use in the ultra-violet, infra-red and visible ranges of the spectrum; atomic absorption spectrophotometers; microglass electrodes for measuring pH, oxygen and carbon dioxide; paper, gas-liquid and thin layer chromatography; and electrophoretic techniques (Varley, 1967).

A measure of the increase in the clinical chemistry laboratory work load based on the number of analyses performed has shown that in the years 1958-63 the average annual increase in teaching hospitals was 21.7% while in non-teaching hospitals the figure was 16.7%; this represents a doubling of the technical work load every four to five years (Lathe and Mitchell, 1966). The fact that this trend has continued is indicated by a more recent estimate of the increasing work load in the Department of Clinical Chemistry, The Royal Infirmary of Edinburgh, where the number of laboratory determinations increased from 195,000 in 1963 to 646,000 in 1970 (Whitby, 1971); a similar growth rate has/

has been reported at University College Hospital, London (Flynn, 1969). It is unlikely that this growth in the number of analyses performed will reach a saturation level in the foreseeable future since the present interest in patient admission profiling, increased use of hospital services by general practitioners, and a progressive reduction in the duration of the patients' stay in hospital (Table I) will continue to produce a rise in the number of investigations required.

In an attempt to cope with this rapidly increasing number of analyses, work simplification techniques were introduced (Seligson, 1966; Laursen, 1966) in which automatic dispensers and other labour-saving devices were utilised. As the number of analyses continued to grow, automated or more correctly mechanised laboratory systems were developed. To date, the most successful and versatile system is based on the Technicon AutoAnalyzer (see Appendix I). Since its introduction in 1957 (Skeggs, 1957) the AutoAnalyzer has revolutionised the number and greatly improved the reproducibility of the estimations which can be undertaken; it is now in routine use in most clinical chemistry laboratories.

The/

TABLE I

DURATION OF PATIENTS' STAY IN HOSPITAL (*)

HALF-YEAR ENDING	MEAN STAY (DAYS)	
	SOUTH-EASTERN (SCOTLAND) REGION	ROYAL INFIRMARY, EDINBURGH
March 1966	19.4	17.9
September 1966	18.5	17.6
March 1967	19.2	17.4
September 1967	18.9	16.9
March 1968	19.2	16.8
September 1968	18.4	16.2
March 1969	18.9	16.9
September 1969	17.7	16.2
March 1970	17.7	17.0
September 1970	16.8	15.7

(*) Figures are reproduced from "Analysis of Form Statistics 8F 10" in the Hospital Statistics Report prepared by the Scottish Home and Health Department.

The continuous flow system used in AutoAnalyzers is capable of estimating the concentrations of as many as 18 constituents per blood sample at a sampling rate of up to 80 per hour.

A number of discrete analysis systems, in which the samples are treated and carried through the major part of the analytical process in separate containers, have recently been developed. These mechanised systems, which range from the relatively simple Analmatic Clinical Analysis System, Clino-Mak Mark II Analyzer, Griffin Bioanalyst Module, to the large and more complex Autochemist and Vickers Multichannel 300 System, have been reviewed by Northam (1969) and Broughton (1969). The sampling rates of these discrete analytical systems vary from 100 samples per hour in the case of the Mecolab System to a 24-channel machine operating at a rate of 135 samples per hour in the Autochemist system. The discrete systems have a faster sampling rate than continuous flow systems, and involve less cross-contamination between specimens; they are, however, more complex mechanically and hence the individual components must be of a high quality.

The/

The mechanisation of analytical procedures has enabled laboratories to analyse a much greater number of specimens with only a limited increase in the number of technicians, thereby increasing the productivity of the laboratory (Whitby and Simpson, 1969) but this in turn has created another problem by markedly increasing the amount of data handled in the laboratory. Hence, the bottleneck which previously existed at the analytical stage of the process has now been moved to other areas of the system including the collection, reception and preparation of specimens, acquisition of data from analysers, calculation of results and entry of results on forms, etc. Another problem posed by the greatly increased work load is the maintenance of satisfactory standards of accuracy and precision of the analytical results. When large batches of specimens are processed on AutoAnalyzers or other mechanised equipment, many repetitive operations have to be performed and hence there is a serious risk of mistakes occuring, e.g. the transposition of specimens on an analyzer sample plate, misreading of peak heights on recorder charts, etc.

In mechanised systems of the type described above, quality/

quality control assumes a very important role. Since electrical and electronic variations occuring in the system are outside the control of the operator, these forms of variations can produce significant changes in the results of analyses without necessarily interfering with the mechanical operation of the system. Not only is it important to monitor and control the performance of the analytical equipment but, when handling large numbers of specimens, it becomes extremely important to check the various transcription stages involved in the processing of information. A review of the methods of quality control in a routine clinical chemistry laboratory was published by Whitby, Mitchell and Moss (1967). The implementation of such quality control procedures results in a further increase in the number of specimens being analysed and hence increases the amount of data handled in the laboratory.

Before considering the way in which a computer system can reduce the problems of data handling in the clinical chemistry laboratory, it is necessary to consider in greater detail the individual components of the work flow through the laboratory. A representation of the work/

work flow through the various stages from the generation of a request to the issuing of reports is shown in Fig. 1, and the individual steps are discussed in the following sections.

(A) WORK FLOW IN THE CLINICAL CHEMISTRY LABORATORY

The first stage in the processing of a specimen is the generation of a request form in the ward, clinic or general practitioner's surgery. This document must provide the information necessary to identify the patient and to indicate which tests are to be performed: it is desirable that the form should also provide additional information required for the interpretation of results by the clinical chemist, e.g. diagnosis, age and sex.

Patient Identification Information

A wide range of information is currently in use for patient identification including the seventeen items listed below:-

1. Hospital number
2. Surname
3. Forename or initials
4. Hospital

5./

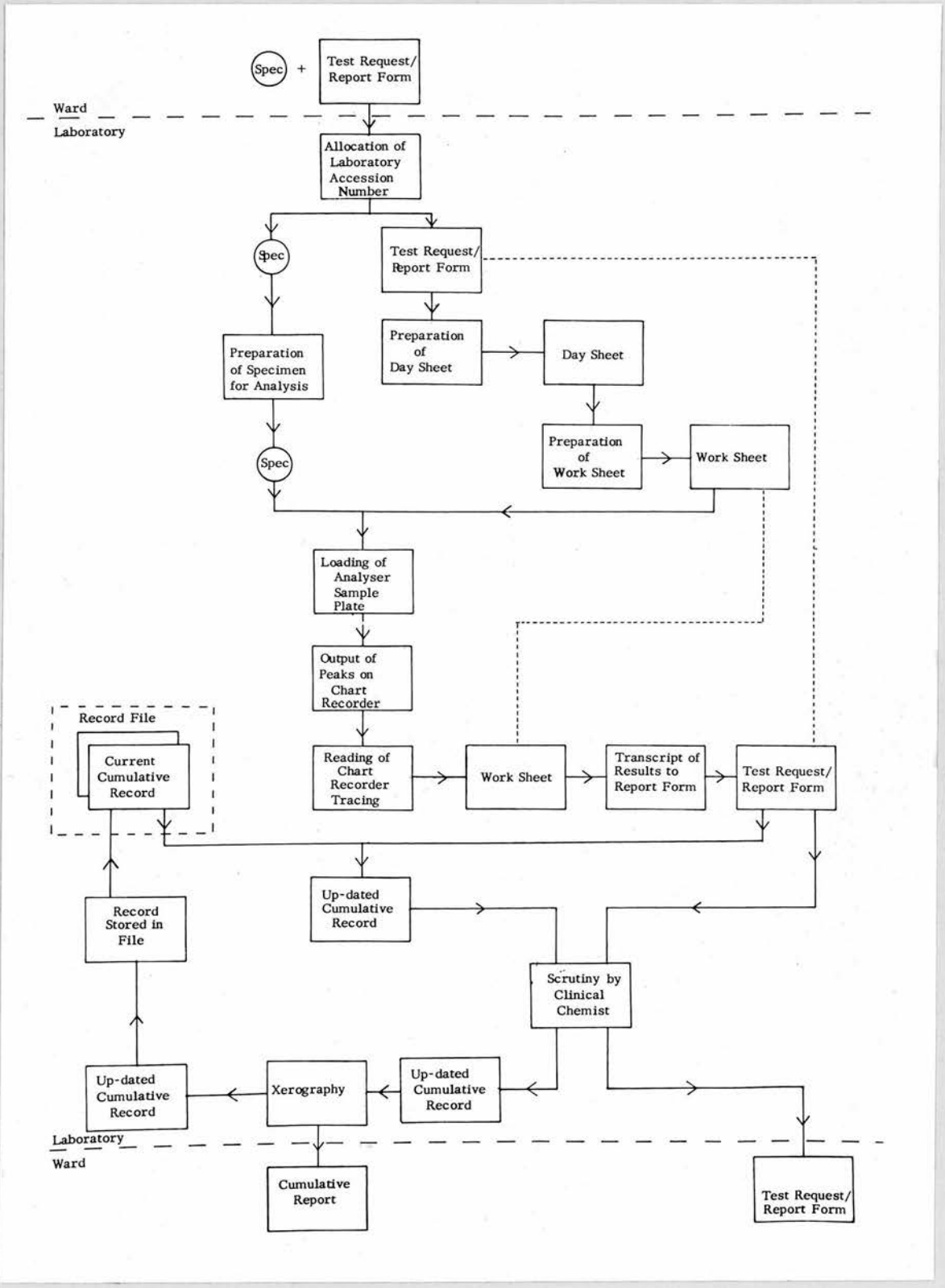

Fig. 1

Work flow in a clinical chemistry laboratory

5. Ward
6. Age
7. Sex
8. Date of birth
9. Home Address
10. Maiden name
11. Place of birth
12. Mother's maiden name
13. Ethnic group
14. General practitioner's name
15. General practitioner's address
16. Consultant's name
17. Consultant's address

Identification data must provide the information required to fulfil two basic functions. First, it must serve a 'homing' function to enable results to be returned to the place of origin. Secondly, if cumulative records are being maintained, it must serve a 'link' function so that results for an individual can be matched up with previous records. Items labelled 4,5 and 14-17 in the above list are 'homing' data while items 1 and 9-13 may be classified as 'link' data.

The/

The most efficient method of linking patient records is by means of an identification number, and Acheson (1967) has suggested that the information used for this purpose should satisfy the following requirements:-

1. Unique for the person concerned
2. Permanent
3. Universally existent in the population being considered
4. Easily available
5. Brief

The currently available Health Service number (e.g. SCPH/12/3) and the National Insurance number (e.g. 2K/00/70/09/A) satisfy the first three criteria, but few people are able to quote these numbers easily; furthermore, they consist of different sized groups of letters and numbers separated by a non-alphanumeric character. The numbers are therefore difficult to reproduce accurately and are not readily compatible with a computer based system of records. The use of a tattooed number or the patients' finger print as a means of identification has been suggested in the past, but a more/

more practicable suggestion by Thomas and Nicholas (1971) involves the use of a unique number implanted in the patient's finger. At present, however, the most satisfactory method of uniquely identifying a patient involves the use of a hospital registration number which should preferably include a check digit to ensure that transposition of digits has not occurred.

If a hospital registration number is not available, an alternative is to use a date of birth registration number which is formed by converting the date of birth into a number, e.g. a patient born on the 8th September, 1936 is given the number 080936. The information required to construct this number can usually be obtained from the patient, although it may be incorrectly quoted. Unlike the National Health Service and National Insurance numbers it can be checked for credibility in a computer system, but it is not unique and hence can serve only as a primary method of identification. It requires additional information, e.g. surname, initials, sex, etc. for complete identification. The date of birth registration number can be made more specific by adding the first letter of the surname (see Appendix II).

A date of birth registration number or a hospital identification/

identification number can easily be incorrectly reproduced on a hand-written request form or record card. For this reason it is desirable to use some form of printed label generated in a central records department at the time of admission of a patient. The use of printed information is even more important if identification is based on non-unique data including the surname, initials, sex, etc.

Even if identification is by means of a unique number, additional information is required by the laboratory. The surname and forename or initials are required for ease of communication between the laboratory and the ward or clinician, but they can also be used to supplement a non-unique registration number. If the surname and initials are used for patient identification in a computer-based system it is desirable to have the information on a pre-printed label because of variations in spelling, e.g. Profit, Proffit, Proffitt, Prophit, Prophet, Profitt. The hospital and ward descriptions are essentially 'homing' data, but they can be used to assist in the processes of identification. Sex and age or date of birth may form part of the identification data/

data; they are also important for the interpretation of results since they alter the normal range of certain constituents. It is preferable to use the date of birth rather than age for this purpose since the former is permanent; the age can readily be calculated from the date of birth.

Test Request Form

The tests being requested must be clearly indicated on the request form and for this purpose it is better to use a pre-printed form with check boxes. An example of such a form which also serves as a report form is shown in Fig. 2. As indicated on the form, the patient identification data can be provided by attaching an addressograph label but additional information, e.g. nature of specimen, time of collection and miscellaneous requests, must be hand-written. The form shown in Fig. 2 is restricted for tests performed on blood samples; a similar form is used for urine, faeces, etc. Results are entered in the space provided beside the name of the test and the form or a Xerox copy of the form can then be used as a ward report. Suitably mounted with case notes, a serial presentation of results can be built up.

Specimen/

THE ROYAL INFIRMARY OF EDINBURGH · DEPARTMENT OF CLINICAL CHEMISTRY

USE ADDRESSOGRAPH LABEL OR PRINT DETAILS CLEARLY

DATE OF BIRTH DAY	MONTH	YEAR	SURNAME	INITIALS	SEX
13	11	90		J	M

REPORT TO BE RETURNED TO:

WARD	HOSPITAL	LAB. USE
12	R.I.E.	

CONSULTANT/PRACTITIONER: A.I.S. MACPHERSON

SIGNATURE OF DOCTOR: [signature]

CLINICAL DETAILS AND RELEVANT TREATMENT

Post-op. carcinoma pancreas

E951

H870

List Miscellaneous blood requests here

Serum amylase
Urgent please phone.

W. & CO. 100M NO. 1

N.B.— Correct and complete information essential for computer input, otherwise only single reports can be issued. Do not wrap this form around specimens; it may be needed for reporting purposes. Tick tests requested in check boxes; use appropriate request form. See Departmental Handbook for details of specimens and normal ranges.

NATURE OF SPECIMEN (e.g. venous, fasting)	TIME OF COLLECTION (Use 24 hour clock)	DATE OF COLLECTION	NAME OF BLOOD TEST	UREA (mg./100 ml.)	SODIUM (meq./l.)	POTASSIUM (meq./l.)	CHLORIDE (meq./l.)	BICARBONATE (meq./l.)	BILIRUBIN (mg./100 ml.)	ALANINE AMINOTRANSFERASE (GPT) (units/ml.)	ALKALINE PHOSPHATASE (K.A. units/100 ml.)	CALCIUM (mg./100 ml.)	PHOSPHATE (mg./100 ml.)	CREATININE (mg./100 ml.)	URIC ACID (mg./100 ml.)	ASPARTATE AMINOTRANSFERASE (GOT) (units/ml.)	HYDROXYBUTYRATE DEHYDROGENASE (HBD) (units/ml.)	CHOLESTEROL (mg./100 ml.)	PROTEIN-BOUND IODINE (μg./100 ml.)	IRON (μg./100 ml.)	IRON-BINDING CAPACITY (μg./100 ml.)	11-HYDROXY-CORTICOSTEROIDS (μg./100 ml.)	TOTAL PROTEIN (g./100 ml.)	ALBUMIN (g./100 ml.)	FOR LAB. USE
	13.00	Day 4 Month 5 Year 72																							Amylase
	FOR LAB. USE ONLY		✓	✓	✓	✓	✓	✓	✓	✓	✓														
				38	136	3.5	100	25																	44

Fig. 2

Example of a combined request and report form

Specimen Identification and Preparation

It is not only necessary to identify the patient from whom blood or other fluid has been removed but it is equally important to identify the specimen or provide a link between the specimen and the corresponding request form. The specimen tube should be labelled with the basic identification data and it is desirable to place the tube and request form in a polythene envelope for delivery to the laboratory, thereby keeping specimen and form associated with one another.

On arrival in the laboratory the specimen tube and request form are labelled with an accession number and the patient's name, ward, laboratory accession number of specimen, and test requested entered on a day sheet. The specimen is then prepared for analysis. In the case of blood investigations, which in numbers exceed all others, each blood sample has to be centrifuged to separate the blood cells from the plasma; plasma is used for most chemical analyses on blood specimens.

Work Allocation

The day sheet provides a summary of all the tests to be performed and is used by the technical staff to prepare/

prepare work sheets which identify the specimens by laboratory number and list the order in which the specimens are to be analysed. It is desirable to include the patient's name and ward in the work sheet information for dealing with enquiries about results that have not reached patients' case folders. In preparing work sheets, priority is given to urgent requests, to specimens outstanding from the previous day and to the reallocation of specimens which on the first analysis gave rise to faulty peaks or peaks which were too high or too low for results to be calculated. The work sheets are used by staff operating AutoAnalyzers to load the appropriate specimens into the correct positions on the analyzer sample plate and the position on the plate (sample cup number) forms the link between a peak on the recorder chart and a patient result. Great care must be taken when loading analyzer plates since a simple transposition of specimens is likely to go undetected unless the calculated results show a marked inconsistency when compared with the previous results in an individual patient's record. If, however, the specimens are displaced by one cup, or if the analyzer pick-up/

pick-up device misses out a sample, then this error should be detected fairly quickly by the quality control system.

Acquisition of Data from AutoAnalyzers

The acquisition of data from AutoAnalyzers (Appendix I) is an important step in the flow of work through the laboratory. This mechanised equipment provides a simple method of reliably analysing specimens for a variety of constituents, but the manual acquisition of data from the chart recorder is prone to error particularly if large batches of specimens are being processed. In this department, over 300 specimens from patients are analysed daily for their content of electrolytes (sodium, potassium, chloride and bicarbonate) and urea and hence, before the introduction of a computer system, it was necessary to read off about 2,000 peaks from chart records for this group of tests alone; this represents about 60% of the number of results reported by the laboratory.

The procedure normally adopted when manually acquiring data from AutoAnalyzers is to have one member of staff read off the recorder peaks while a second person/

person records the concentrations on a work sheet. With this system of chart reading, errors can arise as a result of inaccurate reading of peak heights or as a result of mishearing. In addition to calculating concentrations, the technician must examine each individual peak to ensure that it has an acceptable shape; misshapen peaks frequently result from short-sampling and give erroneous results if not detected.

The uncorrected concentrations obtained by reading results directly from AutoAnalyzer charts have frequently to be adjusted to allow for instrumental drift; this is usually done by applying a linear correction to each group of test specimens for the amount of drift that has occurred between drift correction standards. The corrected values are checked to ensure that the calculated results for quality control specimens fall within acceptable limits of precision and, if so, the concentrations are transcribed on to report forms.

An investigation of the frequency of reading and recording errors when manually reading AutoAnalyzer peaks has been described by Flynn (1969). When results obtained from 5,086 AutoAnalyzer peaks by a computer system were compared with those produced by laboratory staff/

staff under routine conditions, 53 significant errors were detected in the manual results, only some of which were subsequently detected by routine checking procedures. Twenty-seven of the errors were attributed to inaccurate reading of the peak height, or inaccurate correction for instrumental drift, and the remainder were due to a transcription error. The error rate in performing calculations was much higher; out of 81 results checked 6 were found to be incorrect and of these two were of clinical significance.

Preparation of Patient Reports

The final stage in the progress of a request through the clinical chemistry laboratory is the preparation of a patient report. To facilitate the entry of results, the request/report forms or cumulative reports (Section IIf) can be stored in a definite order. For instance, laboratory number order can be used for request forms, while cumulative record cards are usually filed in alphabetical order of the surname or in registration number order. Having located the appropriate report form, the concentrations are transcribed manually from the relevant work sheets. This transcription step is/

is another possible source of error, and the subsequent checking of reports by a clinical chemist is of only limited value in detecting such errors. A Xerox copy of the completed report may be issued to the ward or clinician and the original record retained in the laboratory file.

Quality Control

The importance of quality control in mechanised systems has been stressed already. Throughout each analytical run the results obtained for quality control samples are examined to check that the analytical system is continuing to operate in a satisfactory manner. This information provides a continuous form of control on the operation of the analytical system, but a very useful retrospective form of quality control is afforded by calculating the mean and standard deviation of the patient specimens at the end of an analytical run. When the number of specimens in each batch is large, this is an additional and sensitive check that the system is in control (Whitby et al., 1967; Dixon and Northam, 1970). One important advantage of the use of the daily mean for all results from patients or of results falling within normal/

normal limits or a truncated range of values, is the fact that it does not increase the number of specimens being analysed. The main disadvantage of statistical methods of quality control is that the calculations are tedious and time-consuming when performed manually even with the aid of a desk calculator.

(B) COMPUTERS IN CLINICAL CHEMISTRY

In highly mechanised laboratories, where manual methods of data acquisition and processing are in use, it has been estimated that trained technical staff spend up to 30% of their time on routine clerical work including the preparation of day sheets and work sheets, acquisition of data from analytical equipment, calculation and correlation of results, transcription of information to report forms, and maintenance of laboratory and patient records (Rappoport, 1965). The employment of skilled staff for such work is not only wasteful but the repetitive nature of the work is conducive to errors in data handling. By introducing a computer into the laboratory system it should be possible to perform repetitive clerical work and calculation routines automatically, and hence give staff time/

time for other work such as increasing the reliability and improving the precision of existing techniques and developing new procedures.

A laboratory computer system can not only reduce the amount of clerical work carried out by technical staff but can increase the efficiency of the laboratory service by reducing the number of errors due to inaccurate reading of AutoAnalyzer peaks, eliminating errors of transcription, decreasing the time taken to perform calculations, improving quality control, and providing more compact storage of results and more rapid access to the stored data (Flynn, 1969). In addition, a computer system can improve the interpretation of results by marking the results falling outside a 'normal' range which takes into account refinements in the 'normal' range such as those associated with variations in age and sex; marks can also be used to indicate a significant change in the concentration of constituents. The use of marks that draw attention to results requiring scrutiny facilitates the checking of reports by a clinical chemist, and hence assists in the performing of a legally important quality control function.

The many advantages to be gained by using a computer based/

based system of quality control have been described by Whitehead (1965); Whitehead et al. (1968); Ressler and Whitlock (1967); Whitby et al. (1967) and Neil and Doggart (1970). Perhaps the greatest advantage is the ability of a computer to aid assimilation of information by converting a large amount of data into a form that can be readily comprehended and used.

In a recent report (Report of Working Party on Computers in Medicine, 1969) the benefits obtainable from computers in medicine came under four main headings:-

(i) Saving of direct costs of existing operations

(ii) Increased quality of work mainly through eliminating errors but also in terms of legibility, comprehensiveness, etc.

(iii) Saving of time and of work which are not readily translated into cash equivalents

(iv) Production of summaries, reports and evaluations of work done at a time when they are still topical.

The fundamental objective of any hospital computer system should be the provision of better patient care.

A clinical chemistry computer system can improve patient care by providing a quicker and more efficient service of reliable information required for the diagnosis/

diagnosis and treatment of disease. Such a service may have a beneficial effect if it can be shown to reduce the length of the patient's stay in hospital. A further benefit may be obtained from the analysis of computer-prepared cumulative records. The considerable amount of data held in the computer is readily accessible and able to be processed: it can theoretically be used to investigate the origin, circumstances and early detection of disease, which in turn should lead to advances in preventive medicine.

The many advantages to be gained by installing a computer system in a clinical chemistry environment must be balanced against the considerable capital investment involved. Small computers (4K-8K) suitable for data acquisition and simple data processing are available at a cost of £4,000 - £13,000. However, to this price must be added the cost of peripheral equipment including some form of backing store if cumulative records are to be maintained, and the not inconsiderable cost of software development. The provision of a software package as part of a computer system should reduce the overall cost of the system but experience has shown that, when software developed in one laboratory is introduced into another/

another laboratory, the software may require extensive modification. Even if the services of an experienced programmer are available in the laboratory, the fact that programs must be written in a low level machine-orientated language to make efficient use of the small computer means that program writing, testing and correction is a very slow process.

Sequential Multiple Analyzers

Before considering the use of computer systems in clinical chemistry it is appropriate to consider an alternative approach to the problem of the acquisition and processing of data from mechanised laboratory systems adopted by Technicon Instruments Corporation who developed sequential multiple analyzers. The SMA 12/60 analyzer (Smythe et al., 1968) performs 12 analyses on each sample of serum and has a sampling rate of 60 specimens per hour, i.e. 720 analyses per hour. By phasing the arrival of sample streams at the detectors involved it has been possible to read the output signals in sequence and hence to record the 12 results for each sample on a pre-printed chart. This chart record (Fig. 3) which is provided with calibration scales and/

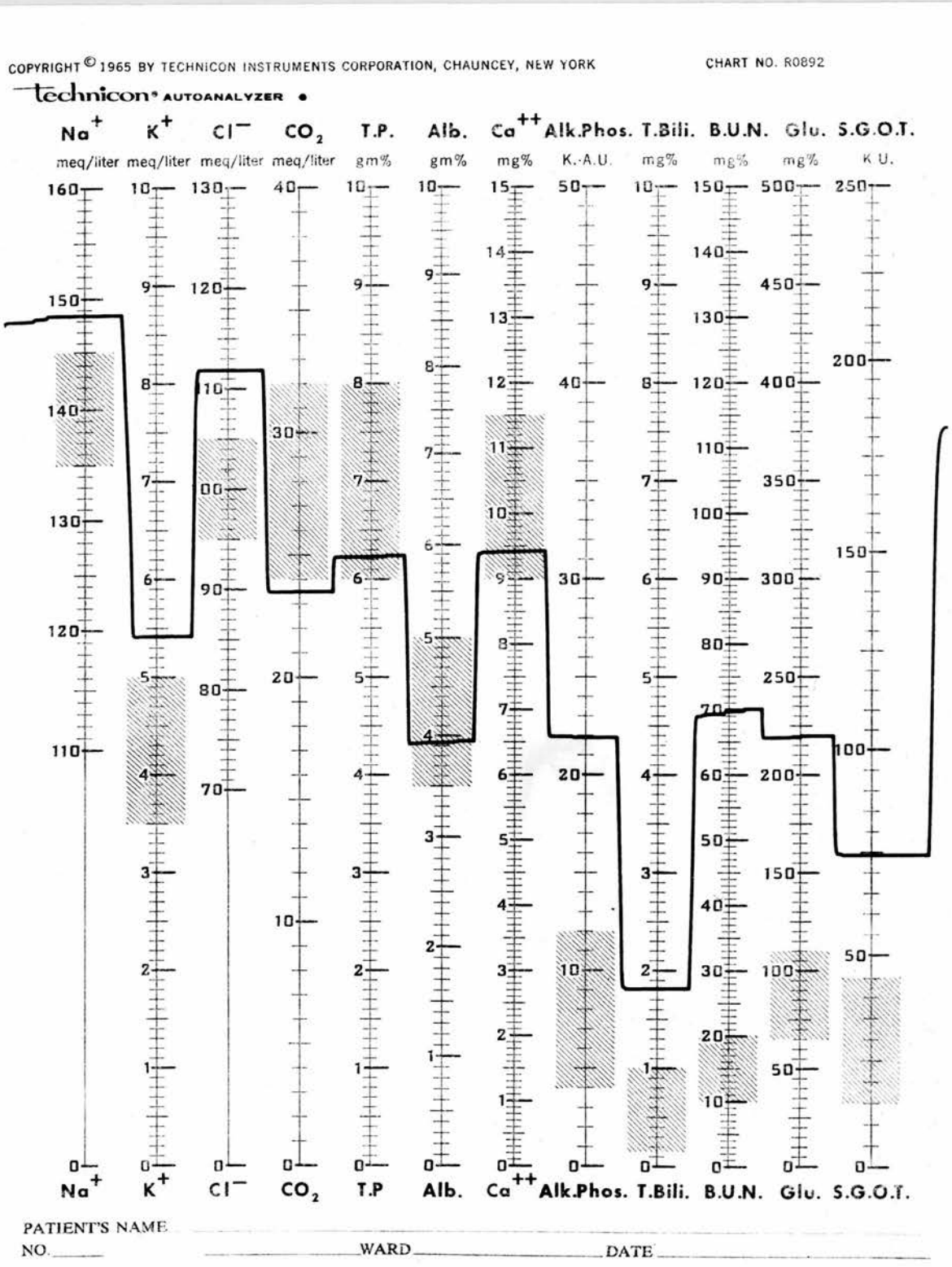

Fig. 3

Chart record obtained with a SMA 12/30 multi-channel analyser

and shaded areas corresponding to 'normal' ranges for each test can be sent to the ward as a report, thus eliminating any calculation or transcription procedures in the laboratory (Fig. 4 - flow path G).

An investigation of the operation of an earlier version of this analyzer, the SMA 12/30, was carried out by Broughton et al. (1968) who focussed attention on some of the important disadvantages of this approach. The most important problem is the standardisation of the multi-channel system for chemical analysis. The instrument is standardised using freeze-dried serum reconstituted with bicarbonate buffer; these materials are supplied by the manufacturers but they are assayed by another SMA 12 analyzer and, if the concentrations quoted are compared with results obtained by standard routine laboratory methods, considerable disagreement is observed for certain tests (Simpson et al., 1967). More recent assessments of the SMA 12/60 have been described by Finley et al. (1969), Makk et al. (1969) and Gardner (1971).

The use of the chart record as a report form greatly reduces the amount of data handling required in the laboratory and completely eliminates transcription errors by/

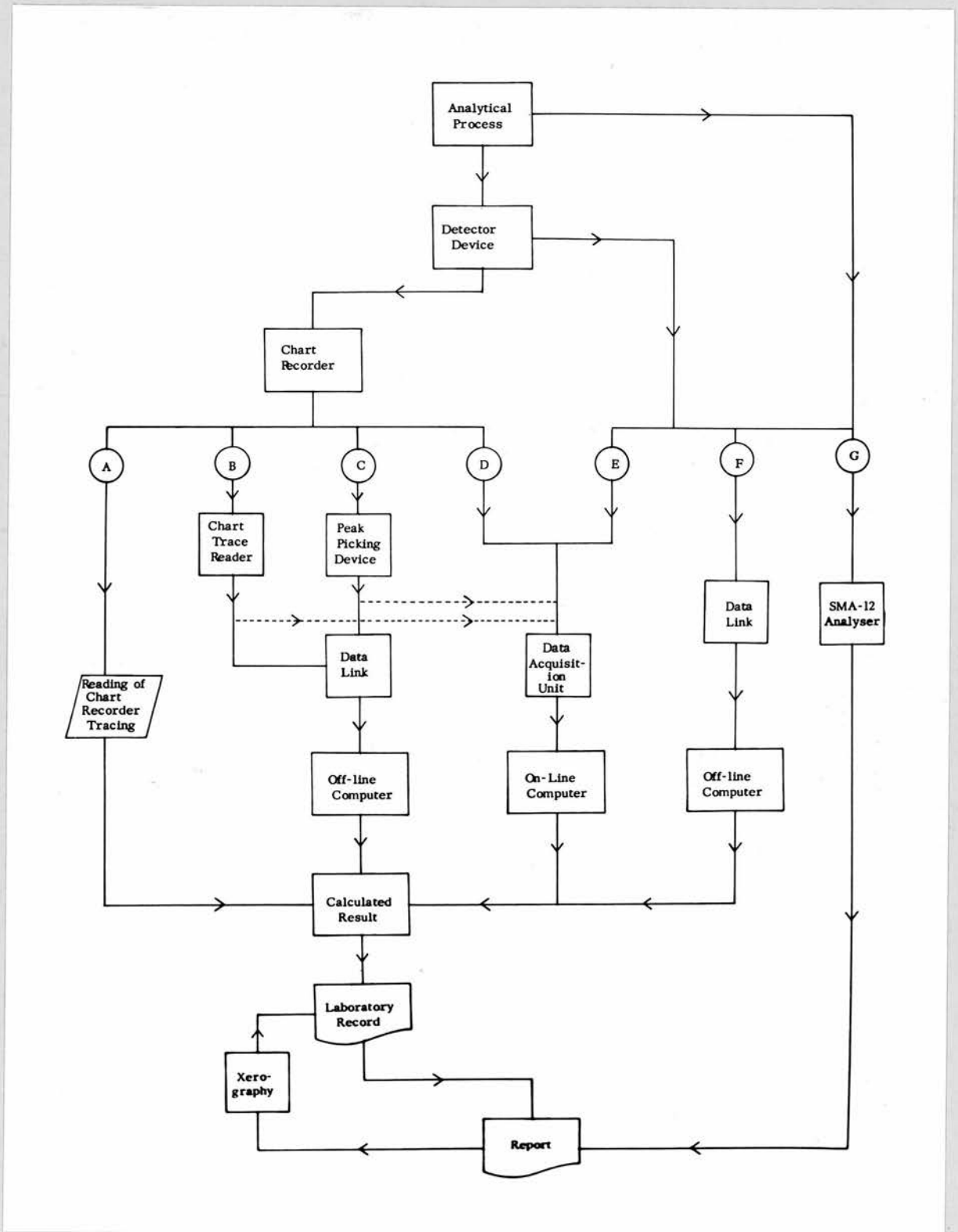

Fig. 4

Data acquisition and data processing in a clinical chemistry laboratory

by laboratory staff but it does not eliminate transcription or reading-off errors by clinical staff. This method of presentation of results is probably acceptable for single specimens from patients, provided the recorder charts are printed to suit the 'normal' ranges for methods used in individual laboratories. However, this method of reporting is inconvenient for the compilation of cumulative records, it does not provide a simple procedure for dealing with repeat analysis of specimens for which dilution is required and it is necessary to copy the chart record in order to maintain a laboratory file of results. Another disadvantage of the SMA 12 analyzer, as compared to a computer system, is that the SMA 12 does not automatically provide the statistical data required for efficient quality control; this information could be obtained by manual procedures but it is tedious and time-consuming. Even if the disadvantages listed were overcome the reporting system is designed to handle only a limited range of tests and hence a second system of reporting would be required. The SMA 12 fails to provide an acceptable alternative to a computer for data acquisition and processing in a routine clinical chemistry laboratory and/

and even for patient screening or admission profiling it is chemically imperfect in many respects.

Computer Systems

Computer systems in the clinical chemistry environment can be divided into two main groups depending on the method of acquiring data from mechanised analyzers. In on-line systems the computer is linked through an interfacing unit to the analytical equipment and receives electrical signals from the analyzer detector devices (Fig. 4). The system can therefore operate in a real time mode and hence can be used for process control functions. In off-line operation there is no direct link between the mechanised equipment and the computer; data to be processed are stored in some appropriate form, e.g. paper tape or punched cards, for later input to the computer. When operating in an off-line mode the computer may be sited in the laboratory or in another building with some form of data link to the laboratory.

Off-line computer systems usually involve the acquisition of data from chart recorders using a chart trace reader or peak-picking device (Fig. 4 - flow paths B and C). The chart trace reader consists of a metal base/

base plate which acts as a special reading surface on which the AutoAnalyzer chart is placed, and is fitted with a cross-wire or electric probe. Peaks are processed sequentially by operating a switch when the cross-wire is over the peak maximum, or by completing a circuit by piercing the chart paper at the point of the peak maximum with the electric probe. A paper tape punch is connected to the chart reader and each time the probe is used a signal that identifies its position is output on paper tape for subsequent batch processing.

Trace Readers

The Normalair-Garrett trace reader (1), which makes use of an electric probe, has been operated successfully at the Royal Postgraduate Medical School, London and Wootton (1968) reported that peaks can be processed at a rate of 50 - 60 per minute. A similar device, the d-Mac pencil follower (2) has been in use at University College Hospital, London, where it was found possible to convert 1,000 peaks into binary code in 30 minutes (Flynn, 1969).

In an extended system described by Maltby (1968) the signals from a Normalair-Garrett trace reader are transmitted on-line to an Olivetti Programma 101. By using/

(1) Normalair-Garrett, Yeovil, Somerset.
(2) d-Mac, 55 Kelvin Avenue, Glasgow, S.W.2.

using pre-recorded magnetic program cards it is possible to enter the concentrations of standard solutions via the computer keyboard, probe the calibration peaks and hence standardise the system. Calibration is based on linear interpolation between successive standards. It is also possible to apply drift correction to the calibration points by probing drift standard peaks.

The use of a similar system, in which a trace reader linked to a Digico micro 16 computer processes data from a SMA 12/60 and single-channel AutoAnalyzers, is being developed at Kings College Hospital, London (Gray and Walter, 1971). The computer system has a disc backing store and two remote Teletypes at other hospitals, and it is hoped to use it for work allocation and the preparation of cumulative reports.

A trace reader provides a relatively inexpensive and fairly rapid method of acquiring data from recorder charts; it eliminates transcription errors in chart reading although other operating errors can still occur. The visual checking of peaks eliminates the need for complicated programs and time-consuming computer procedures, but it is doubtful if a technician could sustain a high standard of peak validation when processing/

processing large numbers of recorder charts.

(C) OFF-LINE COMPUTER SYSTEMS

The Elliott Automation Laboratory Analysis (ALA) system and the IBM 1080 Laboratory Data Acquisition System (DAS) were developed for the acquisition of data from AutoAnalyzer chart recorders for subsequent processing by a computer operating in off-line mode (Fig. 4 - flow path C).

The ALA equipment was used to record peak heights from six AutoAnalyzer channels by attaching a peak-picking device to the chart recorder; the operation of this equipment has been described by Flynn et al. (1966). Signals from the detector unit were transmitted via translator and programmer components to a paper tape punch which output the data in binary form on 5-hole paper tape suitably coded to indicate the channel from which the signal was received. This paper tape and a second tape bearing patient identification information were processed by an Elliott 803 computer to produce reports for individual patients and a summary of quality control information.

A modified version of the ALA system was in operation in/

in The Royal Infirmary, Edinburgh, for the analysis of urea and electrolytes and has been described by Whitby et al. (1968). In the Edinburgh system, information from the data logging equipment was transmitted by a Westrex KSR 32 Teletype over a private telephone line to a computer centre situated about half a mile from the laboratory. The data was received on an identical Teletype unit which prepared a duplicate of the original punched tape for input to the computer. The computer-processed data were transmitted back to the laboratory over the Teletype link and the patient information and results typed out on continuous pre-printed stationery. Each set of results was accompanied by a computer-calculated ion difference and an alphabetical coding obtained by comparing the result with the 'normal' range for that test.

The main functions of the ALA system can be summarised as follows:-

(1) Monitoring of automated equipment

(a) Detection of sample peaks on AutoAnalyzer chart recorder

(b) Calibration of analytical system

(c) Correction of peak heights for instrumental drift

(d)/

(d) Calculation of concentrations by interpolation against standards

(2) Alphabetical coding of results and calculation of ion difference

(3) Provision of quality control information - mean value of determinations carried out on patient specimens

(4) Preparation of patient reports

The accuracy of results produced by the ALA system has been investigated by comparing computer-calculated results with manual results when excellent agreement was obtained (Flynn, 1965; Flynn et al., 1966). Operation of the system in University College Hospital showed that the equipment was reasonably reliable and less prone to failure than the AutoAnalyzers to which it was linked (Flynn et al., 1966). The main advantages of the ALA system included an appreciable saving in the time taken to process AutoAnalyzer results and the elimination of human errors in peak reading and transcription of results (Flynn, 1965).

The shortcomings of the ALA system, as operated in The Royal Infirmary, Edinburgh, have been described by Whitby et al. (1968). The least reliable components of the system were the two Teletypes which linked the laboratory and computer unit; failure in this part of the/

the system was of major importance since data processing was by off-line batch mode towards the end of the working day. When a breakdown occurred in the Teletype link, AutoAnalyzer record charts had to be processed manually and some of the laboratory staff had to stay on long after the end of the normal working day to complete this task. The shortcomings of this system have been summarised in tabular form by Whitby and Simpson (1969) and this summary is reproduced in Table II.

The Laboratory Data Acquisition System (DAS) installed at the Youngstown Hospital, Ohio (Rappoport et al., 1967) consists of an IBM 1081 control unit, 1082 card reader, 1084 sample reader and paper tape and card output devices. The control unit receives analogue signals from the slidewire potentiometers of AutoAnalyzer recorders and from other photoelectric instruments. It also receives digital voltages from timers and counters and specimen identification data from the sample reader. The raw instrumental readings and identification data are then output via a card or paper tape punch for off-line processing.

Specimen identification is based on a six-digit specimen number and this is linked to the patient's record/

TABLE II

SHORTCOMINGS OF THE ELLIOTT ALA SYSTEM OF DATA-ACQUISITION FROM AUTOANALYZERS FOR PROCESSING BY A COMPUTER OFF-LINE

A. Long chain of components involved, each liable to failure

(1) Mechanical peak (or trough) recognition system - shaft encoders.
(2) Translator timers and programmer unit for processing signals from shaft encoders.
(3) Paper-tape punch for collecting analytical data on punched tape.
(4) Teletype unit in laboratory, used for
    (a) preparing patient identification data on a second tape.
    (b) preparing a third tape detailing positions of standards and identification of errors.
    (c) transmitting these three tapes to another Teletype unit in the computer centre.
(5) Elliott 803 computer with output of results on paper tape.
(6) Transmission of results tape back to laboratory for print-out.

B. Consequences of large work load and resulting arrival of computed data near the end of the working day

(1) Disruptive effects of minor hold-ups in sequence of data-transmission and data-processing operations.
(2) Failure sometimes to detect faults in analytical operation until print-out able to be examined.
(3) Results required urgently to be calculated by laboratory staff and issued as preliminary reports.

C. Other shortcomings

(1) Inability to handle the full load of plasma urea and electrolyte analyses because data-acquisition from Auto-Analyzers has to stop about 3 pm.
(2) Capital cost of about £1,500 per channel for ALA equipment, i.e. apart from cost of the AutoAnalyzers themselves.
(3) Shaft-encoder too bulky to be fitted into a twin-channel recorder.

record by a six-digit hospital number. Laboratory tests are requested using a two-part column card interleaved with carbon paper. This card is pre-printed with the specimen number and patient identification information is imprinted using the patient's addressograph badge. The requisition document is sent to the laboratory where the top card is manually keypunched with the code numbers of tests requested and with the patient's hospital number. The bottom card, is taken to the ward, and, when the specimen is collected, a pre-printed and numbered stub is separated from the card and attached to the specimen tube. Specimens are loaded on to a Technicon Sampler 40 on which the stub card is read by a sample reader while the specimen is being aspirated.

Data cards were processed initially on an IBM 1440 computer, programmed to calculate the final results after correction for drift and interaction. Results are output on ward reports and also used to update patient master records held on a random access disc file; information stored on the disc is then used for the preparation of patient summary reports. Quality control information is output for checking before results are issued to wards.

The/

The Youngstown Hospital system has now been extended by the addition of IBM teleprocessing devices which link two unit laboratories. The extended system is used for the acquisition of data from 21 AutoAnalyzer channels performing chemical tests and also an SMA-4A analyzer used for haematological tests. Processing of laboratory data is now carried out in off-line batch mode on an IBM 360/30 computer (Rappaport, 1969).

Operation of the system for an eight month period has revealed that the benefits obtained by using the 1080 DAS system include the elimination of repetitive transcription of patient and specimen information and the enhancement of accuracy, precision and quality control of actual test performance.

One important feature of this system is the method of specimen identification which prevents errors due to sample cups being loaded on the sampler plate in the wrong order; this is one of the most difficult human errors to detect. The use of machine readable identification stubs offers another advantage in permitting the random insertion of specimens into cup positions and hence provides a simple method of giving priority to urgent specimens. One disadvantage

associated/

associated with this method of specimen identification is the fact that equipment supplied by two manufacturers, Technicon and IBM, is directly interfaced; this creates difficulties regarding the detection and correction of faults in the equipment.

A Computer Assisted Laboratory Information System (CALIS) based on the IBM 1440 computer and similar to the DAS system has been described by Cillo et al. (1968). In the CALIS system a patient master card is prepared for each patient on admission using a Standard Register Source Record Punch (SRP) model 1605 (*). The master card contains imprinted and punched identification information; a plastic impression plate which also contains the identification information is attached to the back of the master card. Laboratory request documents consisting of a three-part card imprinted and prepunched with patient identification data are generated at nursing stations using an SRP model 1605. The first part of the composite card is used as a request/results card, the second part serves as a specimen label and the third card is used for data processing. Results are punched on the request/results card and this document is used for the preparation of intermediate unit reports and/

(*) Standard Register Company, Dayton, Ohio, U.S.A.

and also for patient summary reports. A computer program checks all results and marks with an asterisk any result which falls outside the 'normal' range for that test. In addition the CALIS system provides a daily report list of all patients whose test results are either outside the 'normal' range for that hospital or are at wide variance from their previously recorded value.

Of the tests performed 96% can be ordered by using the 39 test codes listed on standard request cards, but a separate card is required for each test or group of tests selected and a special card must be used for tests not listed on the routine form. Each request/results card can accommodate up to four 4 digit results.

The advantages of operating this system are described by Cillo et al. (1968) include the computer preparation of orderly summaries which greatly simplify the interpretation of laboratory data and the generation of a variety of clerical and administrative reports. The on-site generation of a machine-readable requisition form is an obvious advantage, but its value is limited since it has been found necessary to have all cards checked by laboratory personnel; this procedure is not only/

only time-wasting but it is unlikely that all errors will be detected by such a process. The use of a single request card for each test or group of tests has been described as a positive advantage by Cillo *et al.* (1968), but this would appear to be likely to give rise to some confusion and to an appreciable increase in the amount of data processing at the generating station. The major disadvantage of the CALIS system is its restriction to the data processing area of clinical chemistry; it fails to provide any computer assistance for the acquisition of data from automatic analyzers. The computer facilities provided by the ALA, DAS and CALIS systems are compared in Table III.

The CALIS system like the DAS system is expensive and, if it is accepted that the extent to which they have been purchased for use elsewhere is a reasonable measure of the success or lack of success of a system, then these off-line computer systems have failed to provide an acceptable solution to the problem of data handling in a clinical chemistry laboratory.

A number of computer systems have been developed to perform quality control and statistical calculations on processed data from automated equipment and to prepare

ward/

TABLE III

OFF-LINE SYSTEMS - COMPARISON OF COMPUTER FUNCTIONS

SYSTEM	MACHINE-READABLE REQUESTS	SPECIMEN IDENTIFICATION	AUTOMATIC PEAK DETECTION	CORRECTION FOR INSTRUMENTAL DRIFT	QUALITY CONTROL AND PATIENT STATISTICS	PRINTED PATIENT REPORTS	CUMULATIVE RECORDS/ REPORTS	CODING/ MARKING OF RESULTS
Extended Trace Reader	No	No	No	Yes	No	No	No	No
ALA	No	No	Yes	Yes	Yes	Yes	No	Yes
DAS	No	Yes	Yes	Yes	Yes	Yes	Yes	No
CALIS	Yes	No	No	No	No	Yes	Yes	Yes

ward and laboratory reports. In the IBM 1130 system described by Neill and Doggart (1970) the computer is used for quality control calculations on data generated by a Technicon SMA-12 analyzer and a 6-channel Auto-Analyzer; the processed data from the analyzers is entered on punched cards for input to the computer. It is planned to extend this system to include the preparation of ward reports.

In the Clinical Chemistry Department of the Queen Elizabeth Hospital, Birmingham (Whitehead et al., 1968), laboratory data is entered on column cards using an IBM 870 system and the data is then processed on an IBM 1440 computer. Master punched cards containing patient identification data are prepared on an IBM 826 system situated in the registration department of the hospital. Request cards bearing the basic patient identification data in readable and punched (machine-readable) form are automatically generated from the master card and issued to wards. When a specimen is collected from a patient the tests requested are marked on the request card and the patient's name, registration number and date are written on the specimen tube.

On receipt in the laboratory, the request card is placed/

placed in the IBM 870 system and the patient identification data copied on to another card to which is added the date and test number of the analyses requested (Fig. 5). The cards generated in the laboratory are then used to prepare day sheets giving a list of all specimens received and tests requested; the cards are also used to prepare work sheets for each test or group of tests. Test results are calculated by the manual reading of recorder charts and the values are recorded by hand on the computer-prepared work sheets. Results on the work sheets are entered on to request cards by a punch operator using the IBM 870 system. The completed cards have been used to prepare salary-slip type reports for issue to wards and they are now being processed on the IBM 1440 computer in order to prepare cumulative reports (Whitehead, 1970). These cumulative reports, which are only produced if there are more than five results on the patient file or if the patient is being discharged, are

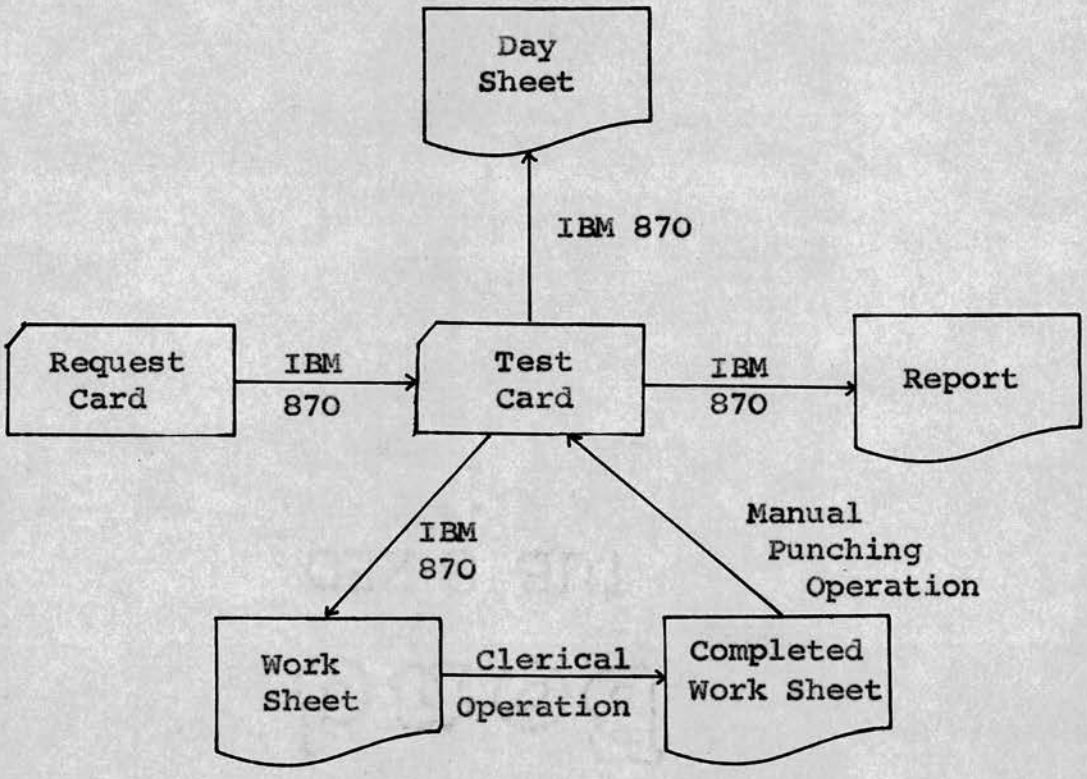

Fig. 5

Flow Diagram of Data Handling in Biochemistry Department, Queen Elizabeth Hospital

information.

While the system described above makes a considerable contribution to laboratory data handling, one major disadvantage is its dependence on manual methods of data acquisition from automated equipment and entry of results on punched cards; both processes are subject to human errors. It is envisaged that future development of the system will include automatic acquisition of data from analyzers and calculation of results using a dedicated IBM 1130 computer.

The use of an NCR/Elliott 4120 computer for the processing of raw data from AutoAnalyzers has been described by Wootton (1969). The system has been programmed to carry out quality control calculations, handle laboratory results, prepare cumulative reports and to perform significance tests on experimental data constructing frequency distributions and calculating population statistics.

(D) DEVELOPMENT OF AN ON-LINE SYSTEM FOR THE CLINICAL CHEMISTRY LABORATORY

The off-line computer systems described in the preceeding section either eliminated or considerably reduced the amount of repetitive transcription and greatly/

greatly simplified data processing in the laboratory but they did not provide real time process control facilities or special procedures for the immediate processing of results of urgently requested tests.

A computer linked directly to analytical equipment can theoretically be used for the real-time validation of output signals and calibration curves. Monitoring programs can then check each peak as it is formed, print our error messages to indicate the presence and nature of faults, or if appropriate smooth out spurious readings. This peak validation routine acts as an early-warning system so that remedial action can be taken immediately. While this scrutiny of each peak, using AutoAnalyzers, can be performed by a technician, it is very boring and it is very difficult to apply rigid criteria to the examination of peaks for long periods.

The validation of calibration curves at the start of an analytical run enables the technical staff to make any adjustments and repeat the standardisation if this is necessary before starting the day's run. In off-line batch processing systems the analytical run may have been completed before there is any indication of errors in calibration. An on-line monitoring system also provides/

provides information regarding instrumental drift as soon as a drift correction standard has been processed, and hence the system plays an important role in quality control by providing information while the analyzer is running. Taking a long-term view of computer systems, the on-line mode of operation is a step towards true automation (as distinct from mechanisation) in which computers can be used to control the operation of analytical equipment (Perone, 1971; Toren et al., 1972).

In an on-line system results of analyses of patient specimens are calculated in small batches and hence urgently requested results can be provided by the computer a few minutes after the actual analysis of the specimen. Although it has been suggested by computer consultants that only about 5% of test results are required urgently (Ockenden and Bodenham, 1970), if this facility is not provided by the computer system then it must be made available by having a separate analytical provision for urgently requested tests, with all the disadvantages that such an approach implies. An alternative solution to the problem involves the setting up of two units within the laboratory; one laboratory for handling urgent requests and another, factory-type laboratory/

laboratory, for the large bulk of routine analyses.

The main disadvantages of on-line monitoring systems are the relatively high capital cost, the complexity of programs required for this purpose, and the time-consuming nature of the data acquisition routines. In spite of these disadvantages, Ockenden and Bodenham (1970) suggested the use of a small dedicated computer for the on-line monitoring of output from AutoAnalyzers while pointing out that processing of clinical chemistry data could be carried out in batch mode.

Aim of Project

The aim of the project described in this thesis was to develop a dedicated computer system for on-line operation in the Clinical Chemistry laboratory in The Royal Infirmary, Edinburgh (RIE). The laboratory provides a routine service for the RIE and associated hospitals, the City Hospital, Edinburgh, situated several miles from the RIE, a number of smaller hospitals and the general practitioners in a considerable area of the city. The total number of hospital beds involved is about 6,500 of which 2,500 are acute beds. At the start of the project, the total work load in the laboratory/

laboratory was about 500,000 determinations per year.

As in any clinical chemistry laboratory the two major data handling areas were associated (1) with the reading of AutoAnalyzer charts and (2) with the processing of patient identification information and test results for the preparation of reports. These aspects of the laboratory's work are tedious, time-consuming, wasteful of skilled technician time and lead to unacceptably frequent errors in transcription. A computer system would need to be capable of greatly reducing or even eliminating manual intervention in these areas if it were to make a significant contribution to the data handling of the laboratory.

It was considered that the computer system to be installed in the Department should be able to perform the following functions, or have the undernoted features:-

(1) Accept the entry, after any necessary key-punching, of patient and test data from hand-written request forms (on a limited number of requests the patient identification information is printed on a label attached to the form but still requires key-board entry).

(2) The automatic preparation of documents required for work allocation, i.e. work sheets for all automated and manual tests and a statement of the current work load giving the number of specimens awaiting allocation to work sheets.

(3)/

(3) The acquisition of data from AutoAnalyzers and other forms of mechanised equipment.

(4) Perform individual peak detection and validation routines, and carry out standard curve identification and validation on all data from AutoAnalyzers.

(5) Calculate concentrations for specimens processed on AutoAnalyzers after correction for instrumental drift.

(6) Provide an input routine for entering into the computer the results of all tests performed by manual techniques.

(7) Output of certain quality control information in 'real time'.

(8) Compile cumulative records of results on individual patients and issue cumulative reports.

(9) Provide facilities for dealing with urgent specimens.

(10) The preparation of end-of-a-day summary of requests and results and a summary of test statistics, e.g. mean of patient specimens analysed for each channel.

(11) Incorporate adequate back-up facilities for use in the event of failure of one or more of the system components.

The definition of 'real time' used in this context is that given by Whitby and Lutz (1971) - "The operations proceed sufficiently quickly for the information output from the computer to affect and influence actions and decisions repeatedly within the overall system".

The/

The hardware chosen for this work was manufactured or marketed by Elliott Medical Automation Ltd. As a result of discussions involving the National Research and Development Corporation, an agreement was entered into whereby a collaborative attempt would be made to develop a British-manufactured system for use in clinical chemistry laboratories. The cost of the hardware was approximately £30,000, and the software development was to be the responsibility of Elliotts. The main tasks of the laboratory in this cooperative venture were to provide the analytical descriptions and detailed information about the performance of technical methods so as to allow systems design and programming to be undertaken, and thereafter to test, validate or reject the programs as they became available.

The purchase of the equipment was financed out of a grant to the South-Eastern Regional Hospital Board from the Scottish Home and Health Department. All the software required for the operation of the system was written by Elliotts and I was very closely involved with general systems analysis; other members of departmental staff were involved, but to a much smaller extent and mainly on a consultative basis. The initial testing of the/

the system was carried out at Borehamwood by the staff of Elliott Medical Automation Ltd. and myself using equipment from this laboratory.

After installation of the computer system, I was assisted by the technical staff of the laboratory in the testing, proving and modification of programs for the on-line monitoring of analytical equipment. To a lesser extent, I was involved with the staff of the Department in the testing and proving of software for the compilation of cumulative records and the preparation of patient reports. A general assessment of the operation of the overall system was undertaken and accounts have been published (Whitby and Simpson, 1969; Whitby and Simpson, 1970 and Simpson et al., 1971).

SECTION II

THE ELLIOTT AUTOMATED BIOCHEMICAL LABORATORY SYSTEM

BRIEF DESCRIPTION OF SYSTEM

The Automated Biochemical Laboratory (ABL) system is based on a standard Elliott 903C general purpose digital computer with a direct access store of 8K 18-bit words (expandable in increments of 8K words). The backing store consists of three industry-compatible Ampex TM7 tape handlers (9K c.p.s.), each carrying a 2,400 ft reel of 7-track half-inch magnetic tape linked to the central processor via a tape controller and multiplexer unit (Fig. 6).

The standard input devices consist of an on-line control teletype model 33 and paper tape reader (250 c.p.s.; 8-hole, I.S.O. code); in addition the central processor receives signals from AutoAnalyzers on-line to the computer via a data acquisition unit. The output voltages from the AutoAnalyzer detector units are first amplified by consoles situated on the laboratory bench and then transmitted to the data acquisition unit which is about 20 m. away in the computer room; these units of special hardware and features of their operation are described in detail in Appendix III.

Output from the computer is in several forms. High priority messages, e.g. error messages to which the operator/

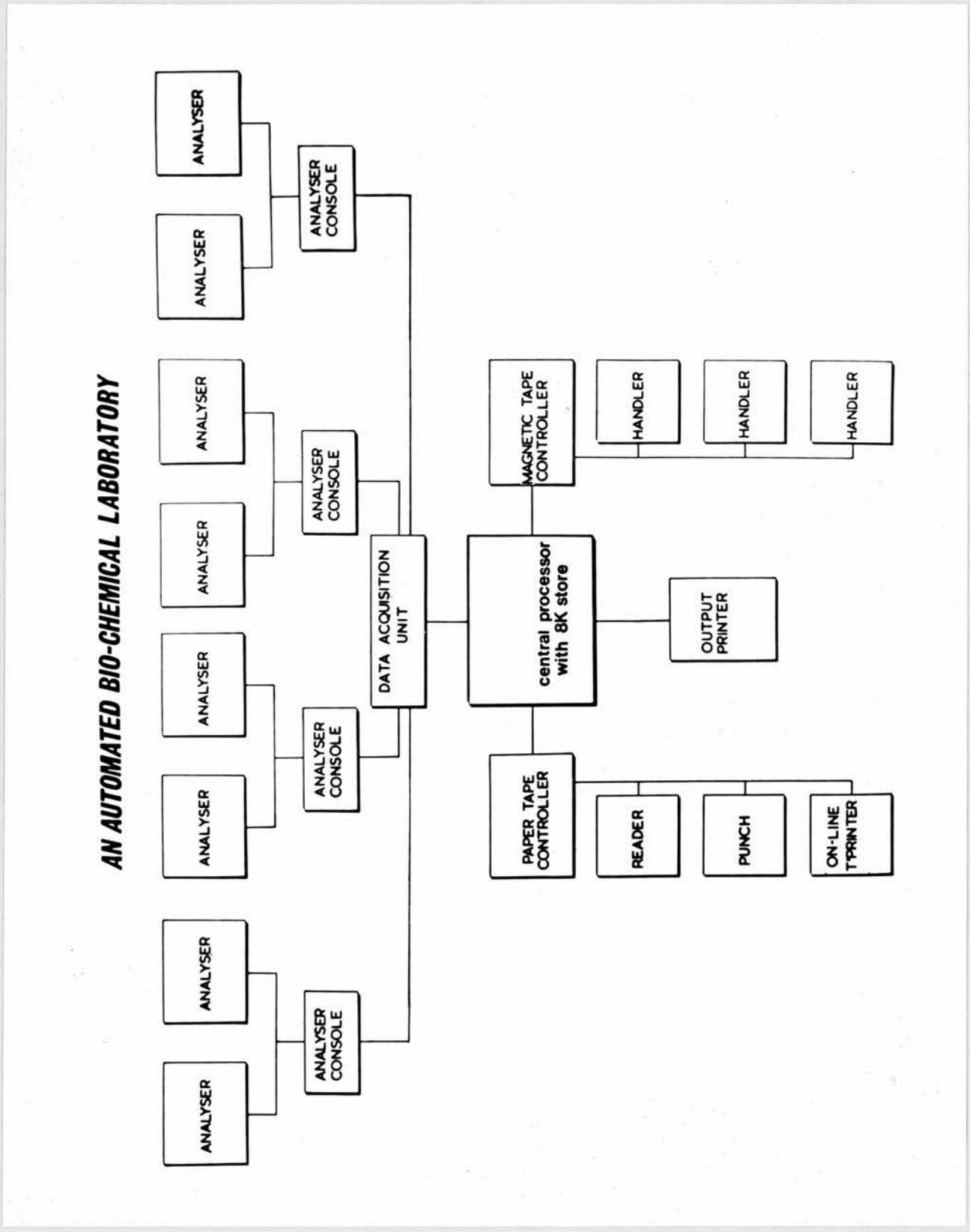

Fig. 6

Block Diagram of Elliott Automated Bio-chemical Laboratory System

operator must reply, results of urgently requested analyses, and results for quality control sera falling outside prescribed limits, are printed up on the on-line Teletype. Lower priority information, e.g. work load and work sheet data, results for patients' analyses, end-of-the-day summary and statistical calculations, is output via the paper tape punch (110 c.p.s.) for printing up off-line. Reports are output on paper tape and can be printed up on an IBM 731 printer (15 c.p.s.) on a time-sharing basis while the computer is being used for other activities, or printed up off-line on a model 35 Teletype (10 c.p.s.).

The 903 computer is provided with four priority interrupt levels (levels 1 - 4) for programming purposes (Table IV). If the computer is running on a low level and an interrupt signal is received for a higher priority program, the instruction currently being obeyed is completed but operation on the lower level is then temporarily suspended and control passed to the higher level program. When the higher level program work terminates, the computer reverts to the lower level program and continues from the point at which the interrupt was received. The system normally functions in level 4 but, when operating on-line to AutoAnalyzers, control/

TABLE IV

USE OF FOUR PRIORITY INTERRUPT LEVELS

INTERRUPT LEVEL	FUNCTION
1.	Input of programs through P/T reader and testing of system
2.	Input of readings from on-line test channels
3.	Input of messages from T/T and output of messages to T/T
4.	General systems programs in order of priority

control is passed to level 2 every two seconds and the on-line channels are read into the computer and stored. Normally control then returns to level 4, but if a message is waiting to be input on the teleprinter this takes priority as it has been programmed on level 3. The change from one programming level to another is achieved by a combination of hardware and software.

The programs which are run on level 4 are arranged in order of urgency in a level 4 queue so that the most urgent is processed first. The order of priority in the level 4 queue is as follows:-

(1) Output of error messages

(2) Calculation of concentrations

(3) Setting up procedures for analytical channels

(4) Output of emergency results and quality control messages

(5) Input of patient and specimen data, preparation of work sheets, output of results, etc. (Appendix IV).

The programming language used in the system is 903 Symbolic Input Routine (SIR). This is an assembly language which has a one to one correspondence with machine code and hence is efficient in computer space and time. SIR is more powerful than machine code, e.g. it/

it permits locations to be referred to by names instead of absolute addresses, constants can be referred to directly in the address part of an instruction, and programs can be divided into variable length blocks or modules, simplifying integration of routines written by different people.

The programs described in the following sections were written by Elliott Medical Automation Ltd. but I cooperated with Mr A.T. Gough and Mrs M. Harrison (Elliott Medical Automation Ltd.) in the general systems analysis; in performing this task we received advice and guidance from many members of the departmental staff. I was responsible for evaluating all the parameters required for on-line monitoring of AutoAnalyzers and for providing the information required for calculation routines, checking quality control results, ranges for the automatic flagging of abnormal results, etc. After preliminary debugging by Elliott Medical Automation Ltd., all programs were tested in the laboratory and many were modified as a result of experience gained in the routine operation of the system.

SOFTWARE AND OPERATIONAL PROCEDURES

At the start of a day's operation, a trigger program/

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program is input through the reader to open up the magnetic tape files (one master file and two work files) and transfer to the computer core store peak detection parameters, channel tables, standards concentrations, etc. Throughout the day the work file is updated by writing from one work file to the other, adding the latest request data input on the teleprinter. At the end of the day's run, request and results data relating to completed work are transferred to the master file and a new work file is prepared. A simplified flow diagram of the overall system is shown in Fig. 7 and the individual procedures are explained in greater detail in the following section.

The master file tape consists of three main sections: the programs, the patient identification records and the patient results records. The two work file tapes have programs, patient identification records and test request data, as well as results records for the current day's work and all specimens outstanding from previous days. Master and work file data are arranged in registration number order in variable length blocks (maximum 512 words) containing records also of variable length (Appendix VI).

The on-line systems programs are located on the first/

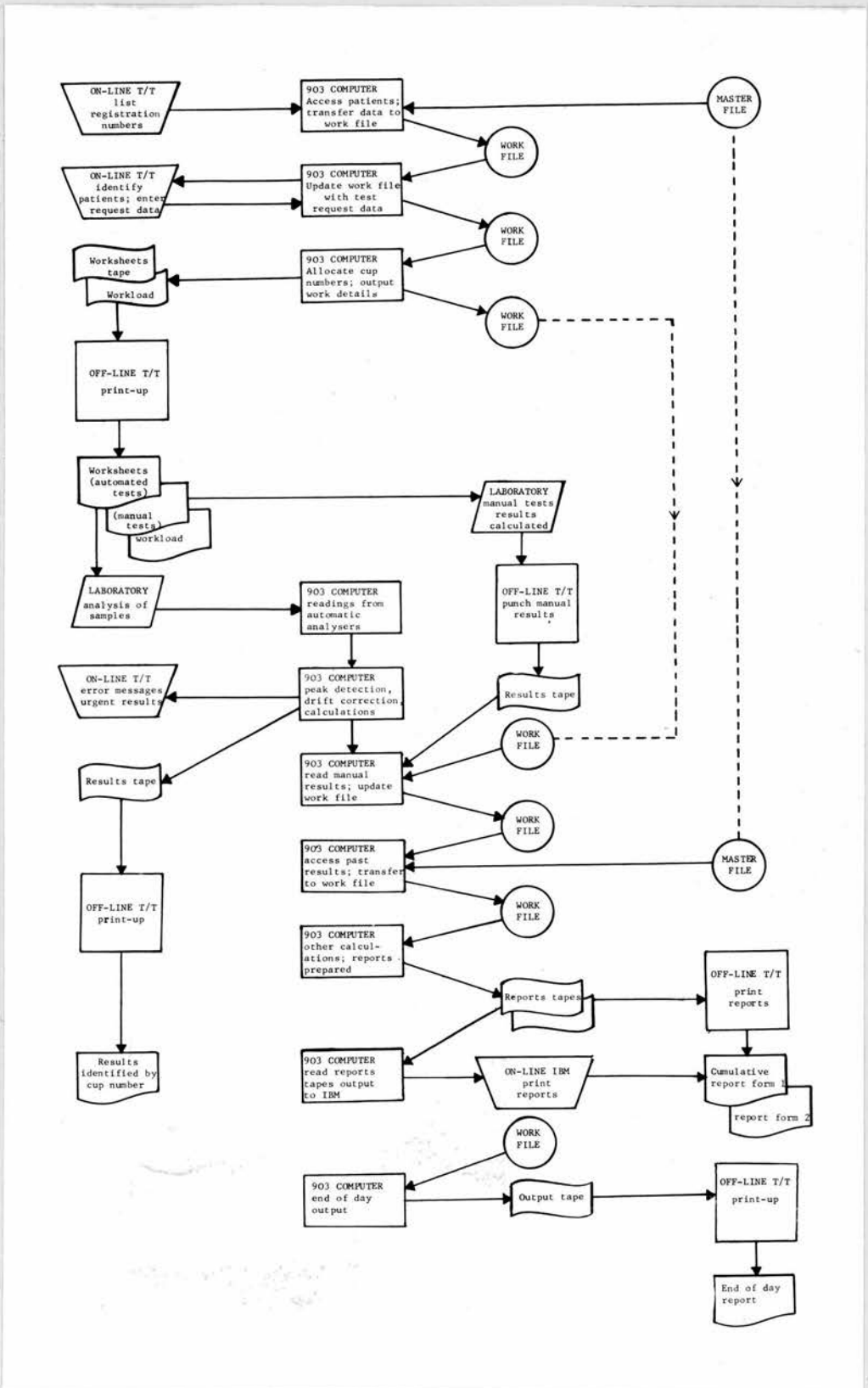


Fig. 7

Simplified flow diagram of the various operations carried out with an Elliott 903 computer working in a clinical chemistry laboratory

first 92 blocks of each magnetic tape file (Appendix VI). When a program is required a search routine selects one of the tape handlers, usually the handler containing the master file, reads the program and places it in the computer core store. The required program may be called by a previous program through the level 4 queue, as in the calculation of concentrations, or it may be called from the on-line teleprinter by input of the appropriate three-letter code as in the output of work sheets.

A summary of the system software, including the mode of entry into programs and the level of operation, is given in Appendix IV.

(A) SETTING-UP PROCEDURES

The program used for the input of the current date, number of first specimen received on this date, changes in AutoAnalyzer group and channel allocations, etc. is called down from magnetic tape by typing the appropriate code (SET>) on the on-line Teletype as indicated in Fig. 8. When the program is available for use, a message is automatically printed up and the date and the specimen number are then input from the Teletype. The specimen number, which consists of a letter and three figures (e.g. P001), links the sample with the request form/

```
SET>>

SETTING UP PROCEDURES READY

DATE 190570
LABNO P001

OUT>
  GROUP      1A   REDUNDANT
  GROUP      1B   ELU          12    16
  GROUP      2A   LFT          21    22
  GROUP      2B   REDUNDANT
  GROUP      3A   CC           31    31
  GROUP      3B   REDUNDANT
  GROUP      4A   COL          41    41
  GROUP      4B   FE           42    42
  CHANNEL    12   U      1B
  CHANNEL    13   NA     1B
  CHANNEL    14   K      1B
  CHANNEL    15   CL     1B
  CHANNEL    16   CO2    1B
  CHANNEL    21   ALP    2A
  CHANNEL    22   BIL    2A
  CHANNEL   C23   REDUNDANT
  CHANNEL    31   CC     3A
  CHANNEL   C32   REDUNDANT
  CHANNEL    41   COL    4A
  CHANNEL    42   FE     4B


GROUP 2A XXX
GROUP 2A EPH
21 TPA
22 LBM
23 TPB

END

FINISHED!
```

Input of Current Date and Number of First Specimen Received on this Date

Output of Channel Allocations

Re-allocation of Group

Fig. 8

Setting-up Procedures - Allocation of Test Channels, etc.

form and the letter is used by the computer program to differentiate between the current day's specimens and specimens from previous days. The current AutoAnalyzer group and channel allocations are output on the on-line Teletype in response to the input of a three-letter code (OUT>). The first part of the output (Fig. 8) gives the analyser console group number, test request code, and the first and last channels allocated to the group. The second part of the output gives the channel number, test request code and group allocated. If the channel number is preceded by a letter 'C', this indicates that the channel has been cancelled.

Changes in the allocation of channels can be carried out on the on-line teleprinter by a simple key-punching operation. For example, the lower part of Fig. 8 shows the cancellation of the group allocated to group A on analyser console 2 and its replacement by the EPH group; this consists of total protein (TPA), albumin (LBM) and protein blank (TPB) on channels 21-23. Analyser channels can be re-allocated at any time during the working day provided that, at the time of allocation, the channel being allocated is not on-line to the computer.

Commercial control sera are used for preparing calibration/

calibration and drift control standards for certain tests, e.g. for total protein and bilirubin. Since the composition of control sera varies from batch to batch, the ability to change the concentration of standards at the start of an analytical run is necessary; this may be effected by altering the values stored in the appropriate locations. The example in Fig. 9 shows the procedure used to change the concentration of the total protein calibration standards. The number '3278' is the absolute address of the location which contains the concentration of the first standard; the letter 'R' indicates that the value is stored as a real number. The first value in each line represents the concentration currently stored in the computer while the second value is the new concentration. At the end of the alteration procedure the new values have been recalled for checking (Fig. 9).

Computer-calculated concentrations for pooled sera used for quality control purposes are automatically checked against pre-determined values throughout an analytical run; hence the mean and standard deviation for each constituent of the serum must be entered at the start of a run. The information is entered as indicated in/

```
SETTING UP PROCEDURES READY

LOC>
SETTING UP PROCEDURES READY

A 3278 R
       0.899987 R

       1.799926 1.9 R

       3.599853 3.8 R

       5.699462 5.6 R

       7.598876 7.5 R

       9.099121 9.4

A 3278 RRRRRR
       0.899987
       1.899658
       3.799438
       5.599365
       7.500000
       9.396972
←

SET>>

SETTING UP PROCEDURES READY

POOLS>

SETTING UP PROCEDURES POOLS READY

U 50 2.0>>
NA 140 2.2>>
K 4.6 0.15>>
CL 102 2.2>>
CO2 19 0.9>>
TPA 5.6 0.14>>
LBM 3.8 0.13>>
CA 9.1 0.18>>
P 5.4 0.24>>

←
```

Input of concentration of new standards for total protein

Checking of concentration changes

Input of quality control data

Fig. 9

Setting-up Procedures - Changes in Concentration of Standards, etc.

in the lower section of Fig. 9 by using the appropriate sub-program of the setting-up procedures.

The setting-up procedures programs also provide facilities for the re-allocation of output or input to or from the on-line teleprinter and paper tape punch and for the re-allocation of magnetic tape handlers. In the event of punch failure the output of test results can be diverted to the on-line teleprinter until the faulty punch has been replaced by a spare peripheral. Similarly, if a fault develops on magnetic tape handler 0, which is normally used for the master file tape, this tape can be transferred to another handler and the necessary correcting information entered on the on-line Teletype.

The sub-program used to change the concentration of calibration standards can also be used to change peak detection and validation parameters, to output for inspection the contents of the peak table (i.e. the heights of all peaks awaiting processing), or to permit extrapolation of the calibration curve below the lowest standard, above the highest standard or in both directions.

All data entered in the setting-up procedures are checked by the computer software and the appropriate message/

message output on the on-line Teletype if an error in input is detected. A complete list of the setting-up procedures error messages (message numbers 84-98) is given in Appendix X.

(B) INPUT OF PATIENT IDENTIFICATION AND TEST REQUEST DATA

Initially, patient and test request information were input on the on-line Teletype using a conversational mode. At a later stage in development an off-line data preparation procedure was adopted but the input format was only slightly modified. The advantages and shortcomings of conversational mode are discussed in Section IV(A).

When operating in conversational mode, a list of date of birth registration numbers (date of birth converted to a six figure number, to which is added the first letter of the surname, e.g. 180692M) each separated by a space is entered on the teleprinter. Up to 8 numbers can be entered on one line and at the end of each line, i.e. after input of the 'carriage return' and 'line feed' instructions, the computer program checks the validity of each registration number. The number must consist of 6 figures followed by a letter: the/

the first two figures must be less than 32 and the second two figures must not exceed 12. To indicate to the operator which registration numbers have been accepted, the program outputs the symbol '/' for each accepted number and '↑' for each number not accepted (Fig. 10). Acceptable registration numbers are stored in the table of records, but if a number is rejected it must be input again in an acceptable form. A maximum of 24 registration numbers can be entered at one time and the end of input must be indicated by a terminator symbol (←).

If a specimen is received from a general practitioner, or if the date of birth is not entered on the request form, then a series of six zeros followed by the first letter of the surname is input instead of the date of birth registration number. In this case the patient record is not transferred to the master file at the end of the day's run and hence a cumulative record is not held on magnetic tape. The only permanent record of such results in the laboratory is on the end-of-the-day summary sheets.

After receiving the end of data symbol, the program enters a sort routine and the records are sorted into registration/

```
INN>>

START INPUT

180692M 090885H 191212H 000000M 260551L 000000R 130538T 271296F
/ / / / / / / /
040669D 000000M 150206F 160624D 00000R 140683H 204420S 240542Y
/ / / / ↑ / ↑ /
000000R 200442S
/ /
←

180692M MCFARLANE J M 29 - DMB>>
040669 R088 - ELU - S>>
- Z074 - CAP>>

090885H HAMILTON I F 15 RIE TIW  Y>>
- R117 31 ELU T0930>>

191212H HEANEY C F 5A CIT JMM>>
- R118 - RLU T0900>
 T= ELU>>

000000M/1 MITCHELL  J  F 3  CHA -  N>>
000000M/2 MCKAY  E  M 3  RIE -  N>>
000000M/3 MCLEOD E  F 5  RIE JCS  N>>
000000M/4 MATHIESON M  F - CP -  N>>
000000M/5 MAXWELL  E  F 1  LIB -  N>>

000000M MACPHERSON A F - LON ->>
- R189 - ELU - S>>
- Z149 - CAP>>

260551L LITLE H M 17 - - A>>
 N= LITTLE>>
- Z277 - C - S>>
- Z278 - CC V2700>>

000000R/1 RAC - - QCD RIE -  Y>>
- Z138 - FE,IBC>>
```

Fig. 10

Input of Patient Identification and Test Request Data Using Conversational Mode

registration number order. The program then searches the work file and master file, and outputs on the on-line teleprinter each patient registration number followed by all the available information (surname, initials, sex, ward, hospital or general practitioner, and consultant) on each of the patients whose registration number matches the number input. Originally the registration numbers were re-sorted and printed out in input order (Fig. 10) but to reduce the time taken to enter data, the second sort was eliminated and the numbers output in registration number order (see Section IV(A)). Using the information provided on the request form, the operator identifies the patient from whom a specimen has been received or, if no record exists, enters the complete identification data. If the correct patient record is output, acceptance is indicated by typing 'Y>'; if it is not the correct patient 'N>' is input and the computer program then outputs the next patient with the same registration number on the next line. If the correct patient record is output but part of the data requires amending, then 'A> ' is typed and the amendments input on the following line. If 'R> ' is entered the results of

all/

all tests performed on specimens received from the patient are output on the on-line Teletype.

The input of data for new patients is in the format shown in Fig. 10 and consists of eight fields each separated by a space. A detailed description of the contents of each field is given in Appendix V.

After identifying the patient or providing the required identification data, the test request information is entered on the on-line Teletype (Fig. 10). The test data consist of the date of the specimen, specimen number, ward (if different from that indicated in the patient identification data) and three-letter codes representing the test or test groups (a complete list of the test and test group codes is given in Appendix VIII). Additional information including the time of collection of the specimen, the volume and duration of collection of urine samples, and an indication if the result is required urgently can be entered, and a pre-dialysis or post-dialysis code may be used for patients undergoing haemodialysis in place of the time of collection.

Experience gained over a period of several months showed that the amendment of wards in the test request data/

data line was seldom used and, since this information can be amended in the patient identification line, the ward field was omitted from the test request information. The modified form of test request input consisting of five fields is described in Appendix V.

All the data input in respect of patient identification and test requests are checked by the computer software and error messages (see Appendix V) are output on the on-line Teletype when operating in conversational mode, or on the paper tape punch when using an off-line data preparation procedure.

(C) OUTPUT OF WORK LOAD AND WORK SHEETS

After entering data from a batch of up to 24 request forms, further batches can be input or a statement of the current work load can be requested by typing the program code (REQ>) on the on-line Teletype (Fig. 11). The program reads through the work file and checks each test request record to see if it has already been allocated to a work sheet (i.e. if the appropriate bit in the marker word is set to indicate that a cup number has been allocated) and, if not, a count is made of the location corresponding to the test requested. If the sample has been given a cup number and no results have/

```
REQ>>
                                    Request for work load statement
ISS>>

WORKSHEETS READY ELU>>

WORKSHEETS READY COL>>
                                    Request for work sheets
WORKSHEETS READY ←
END

TCN>>

CHANGE CUP NUMBERS READY
                                    Change cup numbers procedure
K298 1B 51>>

K299 1B 52>>

←
```

Fig. 11

Input/Output on Control Teletype -
Change Cup Numbers Procedure, etc.

have been received a count is made in another location. When the work file has been completely read the work load is output on paper tape for printing up off-line. The work load statement (Fig. 12) lists the number of specimens awaiting allocation to work sheets for each test channel, and the number of specimens allocated to work sheets for which results are not yet available.

Work sheets, which provide instructions for loading analyser sampler plates, are output on the paper tape punch in response to a message (ISS>) typed on the on-line teleprinter (Fig. 11). When the work sheets program has been transferred to the computer core store, the message 'WORKSHEETS READY' is output on the Teletype and the operator enters the test or group code for which the work sheet is required. The work file is then read through and a set of records consisting of patient registration number and sub-number, laboratory number of specimen, a space for computer allocated cup numbers to be inserted, and three markers assembled in store (see Appendix VI). The markers are used to indicate an emergency request, a re-allocated specimen (peak faulty or too high or too low on first analysis), and samples where the laboratory number has a letter other than/

WORKLOAD

TEST REQUEST CODE	NUMBER OF TESTS OUTSTANDING: CUP NUMBERS ALLOCATED NO	YES
U	57	24
NA	57	24
K	57	24
CL	57	24
CO2	57	24
COL	21	0
TPA	20	24
TPB	20	24
GA	4	20
GAA	4	20
GLB	4	20
GLG	4	20
LBM	20	24
C	30	0
CC	0	18
CA	9	24
P	7	24
UA	13	0

END

Fig. 12

Work Load Statement

than the current day's letter. The records are sorted and, after allowing for the places occupied by standards and quality control samples, the program allocates the remaining cup numbers to patient specimens in the following priority:-

(1) Emergency requests

(2) Re-allocated specimens

(3) Specimens held over from the previous day

(4) Current day's specimens in order of laboratory number

Each work sheet for an automated test or test group specifies the order of analysis of 20 samples, including calibration standards in prescribed positions followed by positions allocated for specimens from patients and control samples interspersed at regular intervals by a serum pool followed by a drift standard. Calibration standards are placed in cup positions 1 - 8, drift standards in cup positions 9, 10, 20, 30, etc. and pooled serum in positions 19, 29, 39, etc.

Computer-prepared work sheets provide the following information: the date of birth registration numbers, patients' surnames, laboratory specimen numbers, computer-allocated cup positions and a coded message to indicate/

indicate if the specimen needs to be diluted or concentrated (D/C), or if the result of the test is required urgently (EM!). An example of a work sheet for the analysis of cholesterol, output at the start of a day's run, is shown in Fig. 13. In subsequent work sheets the calibration standards in cup positions 1 - 8 are replaced by patient specimens while the drift standard in the 9th position is replaced by a sample of pooled serum, as shown in the work sheet for electrolytes and urea (Fig. 14). If there are insufficient specimens to complete a work sheet, the computer has been instructed to output 'blockfillers' to occupy the vacant cup positions.

Emergency requests are indicated by entering the code letter 'E' in the options field of the test request data (see Appendix V) and such requests receive priority in allocation to work sheets. For very urgent requests, a 'change cup numbers' routine can be used. The patient identification and test request data must first be input by on-line or off-line mode, and then the 'change cup numbers' program entered by typing the appropriate message (TCN>) on the on-line Teletype. This program allows the operator to input on the teleprinter, the/

COL WORKSHEET 04.09.69 SHEET 1

	STANDARD		1
	STANDARD		2
	STANDARD		3
	STANDARD		4
	STANDARD		5
	STANDARD		6
	STANDARD		7
	STANDARD		8
	STANDARD		9
	STANDARD		10
000009R	RAC	X963	11
290309T	TAYLOR	Z541	12
181200F	FERGUSON	Z620	13
000000S	SMART	A687	14
271131M	MITCHELL	A722	15
030303B	BROWN	A771	16
000000M	MCGILL	A841	17
000000Y	YOUNG	A854	18
	POOL		19
	STANDARD		20

Fig. 13

Work Sheet for Serum Cholesterol

ELU WORKSHEET 04.06.69 SHEET 7

000000D	DUFFY	R130	121		EM!				
151010R	ROBERTSON	R148	122		EM!				
240395R	ROSS	R149	123		EM!				
040669C	CALDER	R035	124	D/C	CUP	71	NA	CL	
110616P	PEACOCK	R036	125	D/C	CUP	72	U		
031108L	LOVE	R037	126	CUP		75	K		
180331U	URQUHART	R088	127						
130538T	TALLOCH	R089	128						
	POOL		129						
	STANDARD		130						
240421A	ANDERSON	R090	131						
141193W	WEAVER	R094	132	U					
050120H	HUNTER	R096	133						
131108G	COMM	R097	134						
300933M	MOORE	R098	135						
121238R	RUSSELL	R099	136	CL	CO2				
	BLOCKFILLER		137						
	BLOCKFILLER		138						
	POOL		139						
	STANDARD		140						

Emergency Requests

Re-allocated Specimens Requiring Dilution

K - Repeat Analysis, Peak Faulty on first analysis

U - Specimen to be Analysed for Urea Only

CL CO2 - Specimen to be analysed for Chloride and Bicarbonate

Fig. 14

Work Sheet for Plasma Urea and Electrolytes

the cup position on the sampler plate in which the specimen is to be placed (Fig. 11). The computer allocates the cup number as indicated and the specimen previously occupying this position is set for re-issue to a later work sheet. Up to four urgent specimens can be dealt with at one time.

Work sheets consisting of patient identification data, specimen number and computer-allocated 'cup number' can also be prepared by the computer for off-line tests; Fig. 15 shows a work sheet for protein electrophoresis. Analytical results for such tests are punched up on paper tape using the 'cup number' as a means of identification, and then input to the computer through the paper tape reader. Test data entered in this way are checked by the computer program and, if an unacceptable code is input, an error message (MSG 53) is printed on the on-line Teletype.

(D) MONITORING OF AUTOANALYZERS

(i) Data Acquisition and Peak Detection

The acquisition of data from AutoAnalyzers or other automated equipment depends on the computer processing of electrical signals taken directly from the analyser detectors/

GL	WORKSHEET	27.05.69	SHEET 1
281108G	GRAY	Y222	1
070120H	HAMILTON	Y359	2
200936H	HOLLAND	Z046	3
270307N	NISBET	Z049	4
071109R	ROBERTSON	Z064	5
200528H	HERD	Z091	6
281290I	IRVINE	Z110	7
140763H	HENDERSON	Z133	8
160916J	JOHNSTONE	Z211	9
151234R	RUSSELL	Z224	10
020926G	GALLOWAY	Z232	11

Fig. 15

Work Sheet for Manual Test (Protein Electrophoresis)

detectors or from a re-transmitting slide-wire fitted to a chart recorder. The reasons for using the recorder as a source of an electrical signal have been put forward by Gray and Owen (1969) and Whitby (1970) and are as follows:-

(1) The recorder provides a reliable method of obtaining differential signals from sample and reference channels.

(2) The recorder damps unwanted high frequency components of signals.

(3) A re-transmitting slide-wire provides signals of the same order of magnitude for all AutoAnalyzer channels.

(4) The recorders are required for back-up purposes and for monitoring, including the full-interpretation of error messages from the computer.

There are two main advantages in taking the input signal from the colorimeter or other detection device. Firstly, the signal is taken from the actual source and hence is unaffected by temporary electrical or mechanical malfunction of the recorder. Secondly, it is not necessary to modify the chart recorder; a standard chart recorder can be used for this purpose. The fact that the output from the detection device may be different for different tests does not normally present any real problem/

problem since the voltage to be transmitted to the computer can be brought in to the appropriate range by adjusting the amplification factor or, in the case of the reference voltage, by simply changing the aperture through which the reference light beam passes. It is, however, essential to use recorders for back-up and monitoring purposes, and hence part of the output signal from the detector must be diverted to the recorder. There is one possible disadvantage in taking signals from the detection device; the chart recorder tracing may not be an exact replica of the picture received by the computer because the amplified signal must be attenuated for transmission to the recorder and in addition the chart tracing can be affected by electrical noise in the recorder, but this is unlikely to interfere with the interpretation of errors due to faulty peaks, etc. If a scale expansion device is normally fitted to the chart recorder, it is still desirable to retain this in order to provide a chart tracing suitable for back-up use, but in this case the recorder tracing is essentially different from the pattern of signals transmitted to the computer.

In the ABL system, signals from AutoAnalyzer detector/

detector devices are transmitted to the central processor via the analyser console and the data acquisition unit (see Appendix III). The timer interrupts the current program every two seconds and the data acquisition program reads the output levels of the reference and measuring photocells. After checking that the reference output level is within prescribed limits of its original setting, the measuring cell reading is divided by the reference cell reading and the result stored for that channel. If the reference reading is outside the limits, or if the measuring reading is greater than the reference reading, the error message 'MSG 49 XY' or 'MSG 48 XY' (where XY represents the channel number) is output on the on-line Teletype.

In some instances the settings of the colorimeter controls when transmitting signals to the computer differ from the optimum settings selected for the usual operation of AutoAnalyzers. Examples of the extent of changes required in control settings on the colorimeters are summarised in Table V. The only channel in which the introduction of on-line monitoring has led to a significant modification in the appearance of the final chart record has been the sodium channel. With these analyses/

TABLE V

EXAMPLES OF COLORIMETER SETTINGS

METHOD	STANDARD AUTOANALYZER OPERATION			ELLIOTT ANALYSER CONSOLE INSERTED		
	NOMINAL APERTURE	AREA OF APERTURE (sq.cm.)	100% T CONTROL SETTING	NOMINAL APERTURE	AREA OF APERTURE (sq.cm.)	100% T CONTROL SETTING
Urea	9	1.61	644	3	0.50	220
Cholesterol	8	1.27	765	2	0.42	754
Uric acid	8	1.27	606	2	0.42	210
Phosphate	6	0.86	861	2	0.42	916
Bicarbonate	6	0.86	957	1	0.33	367

Settings unchanged

Chloride, Alkaline phosphatase, Calcium, Creatinine
(Also unchanged on Sodium, Potassium - flame photometer)

analyses, when the analyser console is in use, the display on the AutoAnalyzer recorder is no longer backed off with the result that the chart width for sodium, instead of covering the range from approximately 90 to 170 meq./l., runs from 0 to about 180 meq./l. (Whitby and Simpson, 1969). Despite this reduction in range there was no significant loss of precision when the operator had to read these charts and calculate results from the chart records from a run in which the computer had been set to monitor the sodium channel's performance.

The peak detection program examines successive readings from each channel and checks for a change from positive to negative in the slope obtained by plotting T/100 (where T is the percentage transmission) against time. In tests where the percentage transmission is inversely proportional to the concentration, e.g. urea, cholesterol, etc. the program detects 'troughs' instead of peaks, and hence the slope is obtained by plotting (I-T)/100 against time.

The basic program for peak detection and validation is applicable to all channels but its action on any particular channel is determined by a series of parameters or characteristics which must be evaluated for/

for each particular test. The peak detection routines have been described by Whitby and Simpson (1969) and a detailed description of the characteristics used in the program and the methods of evaluation are given in Section III.

(ii) Standards Identification and Validation

To determine the concentration of a constituent in specimens of blood or urine using the AutoAnalyzer, the system must first be calibrated to establish a relationship between peak height and concentration. A channel is calibrated by analysing a series of solutions containing known amounts of the particular constituent at the start of each analytical run. The computer program discussed here allows the use of up to 8 calibration standards: for most tests the standards are analysed in ascending order of concentration but in grouped analyses, where composite standards are used, this order can be varied and the number of standards for some channels may be reduced.

At the start of each run the computer program identifies and checks the calibration standards. Identification is based on a search procedure which examines/

examines the difference in transmission units between consecutive peaks and compares them with a pre-determined pattern of minimum differences (see Section III(B)).

When the program detects a calibration curve, the peaks are sorted into ascending order of concentration and the validity of the curve is checked by comparing the heights of the individual calibration standards, the gradients between successive peaks, and the change in gradient from one segment to the next with preset limits. The function of the curve validation characteristics and their evaluation is discussed in Section III(B) and the numerical values are listed in Appendix VII.

(iii) Correction for Instrumental Drift and Calculation of Concentrations

After acceptance of a calibration curve, the heights of the peaks relative to the base line or drift standard are calculated and stored for use in the calculation routines. Specimens from patients are analysed in batches of eight followed by a 'buffer' specimen, which can be a quality control pooled serum, and then a drift standard in every tenth position. On the completion of each batch of ten analyses, the computer checks the drift/

drift standards and calculates the difference between successive drift standards. It also compares each drift standard with the first drift standard for a run. As long as instrumental drift is within preset limits of acceptability, the program then applies a linear or percentage correction for drift to the nine samples analysed between adjacent drift standards. The drift correction procedure and the method of calculating concentrations is described in Section III(C).

When the concentrations of a batch of samples have been determined, the program reads the work file and stores the registration number for each of the cup numbers represented together with the set of results calculated. These are then sorted into registration order, merged with the results, and the work file read and rewritten with the concentrations in the appropriate records.

Two other operations are performed at the stage when results are written to the work file. In the first of these, each test result is checked to determine if the specimen is a sample of pooled serum used for quality control, or if the test request was input with an emergency code. If a result for a specimen of pooled serum/

serum differs from the mean value by more than a specified amount, the result is output on the on-line teleprinter. Emergency results are also output on the on-line Teletype.

In the second operation, work file records corresponding to high, low or faulty peaks detected by the computer program are marked so that the specimens can be output for repeat analysis on the next work sheet to be issued. In analyses for which there is a standard dilution or concentration procedure, peaks above the highest standard or below the lowest standard are re-allocated to the next available work sheet with a coded message to indicate whether dilution or concentration is required (Fig. 14). If no standard dilution or concentration procedure is used for the particular test, then the result is stored as greater than or less than the relevant standard value. In all cases the computer program prints out the appropriate message to inform the operator of the action taken. The error message output is in the following format:-

ERR 74 TTT XXX YYYYY CUP NNN

where/

where TTT is the channel test code, XXX is output as FTY if the peak is faulty, or HI or LO if the result is respectively too high or too low for calculation; YYYYY is output as REP or NOREP depending on whether the analysis is to be repeated or not, and NNN corresponds to the cup number of the specimen.

If a sample peak is faulty on a second analysis, the specimen is not re-allocated for further analysis and the code 'NR' (new request needed, analysis unsatisfactory) is stored in the patient's record in place of a result. A second result that is too high or too low is stored as greater than or less than the maximum or minimum standard concentration.

(E) INPUT OF MANUAL RESULTS

Results calculated manually for tests processed off-line can be input to the computer via the paper tape reader or typed on the on-line Teletype using a conversational mode of operation. The program for input of results from the reader is entered from the teleprinter keyboard and a paper tape containing the data loaded into the reader. The program can only be used for test requests which have previously been output by/

by the computer on work sheets.

The format of the results data is shown in Fig. 16. The first line consists of up to seven test request codes while the second and subsequent lines are composed of the computer allocated 'cup numbers' followed by the results of tests in the order of the test codes in the first line. When all the results have been typed the tape is terminated by carriage return, line feed instructions and an arrow (←). The result may be a real number, an integer, or a message. For instance, in Fig. 16, US and XX indicate 'specimen unsuitable for analysis' and 'test not performed', respectively. A real number can have up to 7 characters before and 6 characters after the decimal point; it may be preceded by a 'greater than' or 'less than' sign and/or followed by an asterisk to indicate an abnormal result.

Data tapes are checked by the computer program and a message output on the on-line teleprinter if errors are detected. If there is an error in the test request code line, e.g. if there are more than seven test codes in a line or one of the test codes is not identified by the computer, then an error message (MSG 77) is output and the operator must amend the data tape and re-input the/

```
GA  GAA  GLB  GLG
1  33  79  87  92
2  37  58  63  136
3  33  68  78  89
4  33  70  70  96
5  44  80  82  85
6  29  65  74  58
7  36  91  57  100
8  26  65  63  73
9  38  58  76  117
10 US  US  US  US  US
11 XX  XX  XX  XX  XX
←
```

Fig. 16

Entry of Manual Results for Protein Electrophoresis Using Off-line Mode for the Preparation of Paper Tape

the test request codes and their results in the correct form. A similar error message (MSG 78) indicates an error in the results line of the data and once again the test request codes and the corrected line of results must be re-input by the operator.

Manual results can also be entered into the computer by using the on-line program for input of patient and test request data. A maximum of six results or one comment can be input when entering the patient identification and test request data, as shown in the upper section of Fig. 17. If the patient identification and test request data have already been input, then manual results can be entered by using an amendment procedure as shown in the lower section of Fig. 17.

The results entered by the above procedures are read and stored in a format similar to the one adopted on the completion of the interpolation routine for tests processed on-line.

(F) OUTPUT OF RESULTS

If a test has been entered as an emergency request, or if it is a control serum result falling outside prescribed limits, the results are output on the on-line teleprinter/

```
INN>>

START INPUT


170543M
/
←


170543M MACD□NALD P.D M 17 - ALN>>
030670 B032 PH=7.38,PC2=58,SBC=29,□XY=94 T0915>>


END □F INPUT

INN>>

START INPUT


170543M
/
←


170543M MACD□NALD P.D M 17 RIE ALN  Y>>
030670 B132>>
PH =REQ
PC2=REQ
SBC=REQ
□XY=REQ
A>>
PH=7.39,PC2=38,SBC=23,□XY=96>>


END □F INPUT
```

Fig. 17

Input of Results for Blood Gases Using Conversational Mode

teleprinter as soon as they become available. The remaining results are output in groups of eight on the paper tape punch, identified here only by cup number. A printed copy of an output tape consisting of results for batches of plasma potassium, creatinine and cholesterol, interspersed by error messages is shown in Fig. 18. At this stage the results have not been rounded-off and hence are printed up to more decimal places than appear on the final reports. The format used for the output of emergency results on the on-line Teletype is shown in Fig. 19.

Cumulative reports are also output on the paper tape punch in batches of 45, on a demand entered from the on-line teleprinter keyboard. Before an output of reports is commenced, the past results on the master file must be accessed by typing the program code (TMF>) on the Teletype. When this routine has been completed the appropriate message is output and the operator can then enter the program code (OUT>) for the output of results. Additional calculations (e.g. ion difference, creatinine clearance, serum calcium concentration corrected for protein concentration) are performed by the computer program after receiving an 'output of results/

```
K
211 3.662
212 4.624
213 4.065
214 4.571
215 3.372
216 3.979
217 3.868
218 3.146

C
101 0.886
104 2.194
105 2.662
107 2.423
108 2.453

ERR 75  K              CUP 214   4.57

ERR 74  C   3A   HI   NOREP  CUP 102

ERR 74  C   3A  FTY   REP   CUP  103

ERR 74  C   3A   FTY  REP  CUP  106

COL
11 196.069
12 116.088
13 227.660
14 160.278
15 295.166
16 281.799
17 200.500
18 176.538
```

Fig. 18

Output of Test Results on the Paper Tape Punch

```
020402E EARSMAN D M 27 - DCF>>
241069 X547 - ELU E,T0925>>

020548K/1 KERR  S  M 21  RIE JSR  Y>>
- X542 - ELU T0900 S>
- X543 - CAP>>


EMERGENCY OUTPUT


000000B/1 BLACKLEY                M      F 5   RIE
  X561 U=175* NA=139 K=4.1 CL=103 CO2=26 TIM=0900 ID=14

150703W/1 WALL                    A      M 23  RIE
  X560 U=253* NA=134 K=3.9 CL=93 CO2=21 TIM=0900 ID=24

220795P/1 PRICE                   E      F     DEA
  X562 U=31 NA=138 K=3.8 CL=103 CO2=24 TIM=0900 ID=15

END OF FILE

ERR 83   K   CUP   39    3.96    4.01    3.94

ERR 83   CO2 CUP   39   13.23   13.19   13.46

END OF FILE

050601L LYLE A M - GP>>
- X550 - ELU T1815>>
```

Results for Emergency requests

Results for Pooled Serum

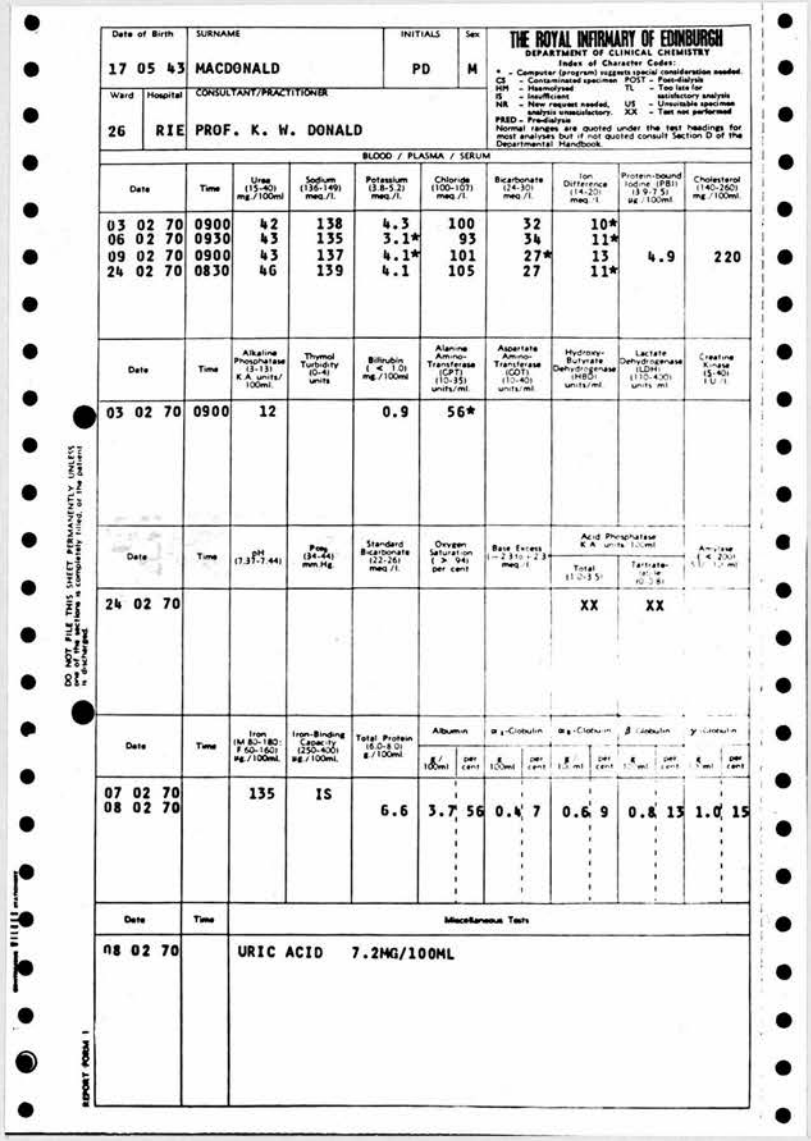
Fig. 19

Output of Results for Emergency Requests and Pooled Sera on the On-line Teletype

results' instruction.

The cumulative report output tape is re-input through the paper tape reader for printing up on the IBM printer on a time-sharing basis, or printed up off-line on the model 35 Teletype, using preprinted continuous stationery. Two report formats are used, one for analyses on blood specimens (Fig. 20) and the other mainly for analyses on urine specimens (Fig. 21). The report contains patient identification data, and includes spaces for the date and time of specimen withdrawal, duration of collection and volume of specimens for urine samples, test results and results of additional calculations. Character codes, as listed on the report form, may be used if a result has not been obtained, e.g. if there is insufficient specimen for a particular test or a specimen is haemolysed; a complete list of cumulative report character codes is given in Table VI. Comments can be printed in the miscellaneous section of both reports as shown in Fig. 21.

If a first test result on a cumulative report falls outside a pre-determined range of concentration, or if a subsequent result differs significantly from a previous result, then the result is marked with an asterisk to indicate/



Date of Birth	SURNAME	INITIALS	Sex
17 05 43	MACDONALD	PD	M

THE ROYAL INFIRMARY OF EDINBURGH
DEPARTMENT OF CLINICAL CHEMISTRY

Index of Character Codes:
* - Computer (program) suggests special consideration needed.
CS - Contaminated specimen
HM - Haemolysed
IS - Insufficient
NR - New request needed, analysis unsatisfactory
POST - Post-dialysis
TL - Too late for satisfactory analysis
US - Unsuitable specimen
XX - Test not performed
PRED - Pre-dialysis
Normal ranges are quoted under the test headings for most analyses but if not quoted consult Section D of the Departmental Handbook.

Ward	Hospital	CONSULTANT/PRACTITIONER
26	RIE	PROF. K. W. DONALD

BLOOD / PLASMA / SERUM

Date	Time	Urea (15–40) mg./100ml	Sodium (136–149) meq./l.	Potassium (3.8–5.2) meq./l.	Chloride (100–107) meq./l.	Bicarbonate (24–30) meq./l.	Ion Difference (14–20) meq./l.	Protein-bound Iodine (PBI) (3.9–7.5) µg./100ml.	Cholesterol (140–260) mg./100ml.
03 02 70	0900	42	138	4.3	100	32	10*		
06 02 70	0930	43	135	3.1*	93	34	11*		
09 02 70	0900	43	137	4.1*	101	27*	13	4.9	220
24 02 70	0830	46	139	4.1	105	27	11*		

Date	Time	Alkaline Phosphatase (3–13) K.A. units/100ml.	Thymol Turbidity (0–4) units	Bilirubin (< 1.0) mg./100ml	Alanine Amino-Transferase (GPT) (10–35) units/ml	Aspartate Amino-Transferase (GOT) (10–40) units/ml	Hydroxy-Butyrate Dehydrogenase (HBD) units/ml	Lactate Dehydrogenase (LDH) (110–430) units/ml	Creatine Kinase (5–40) I.U./l.
03 02 70	0900	12		0.9	56*				

Date	Time	pH (7.37–7.44)	Pco$_2$ (34–44) mm.Hg.	Standard Bicarbonate (22–26) meq./l.	Oxygen Saturation (> 94) per cent	Base Excess (−2.3 to +2.3) meq./l.	Acid Phosphatase K.A. units/100ml		Amylase (4–200) units/100ml
							Total (1.0–3.5)	Tartrate-ion (0–0.8)	
24 02 70							XX	XX	

Date	Time	Iron (M 80–180; F 60–160) µg./100ml.	Iron-Binding Capacity (250–400) µg./100ml.	Total Protein (6.0–8.0) g./100ml.	Albumin		α_1-Globulin		α_2-Globulin		β-Globulin		γ-Globulin	
					g./100ml.	per cent	g./100ml.	per cent	g./100ml.	per cent	g./100ml.	per cent	g./100ml.	per cent
07 02 70		135	IS											
08 02 70				6.6	3.7	56	0.4	7	0.6	9	0.8	13	1.0	15

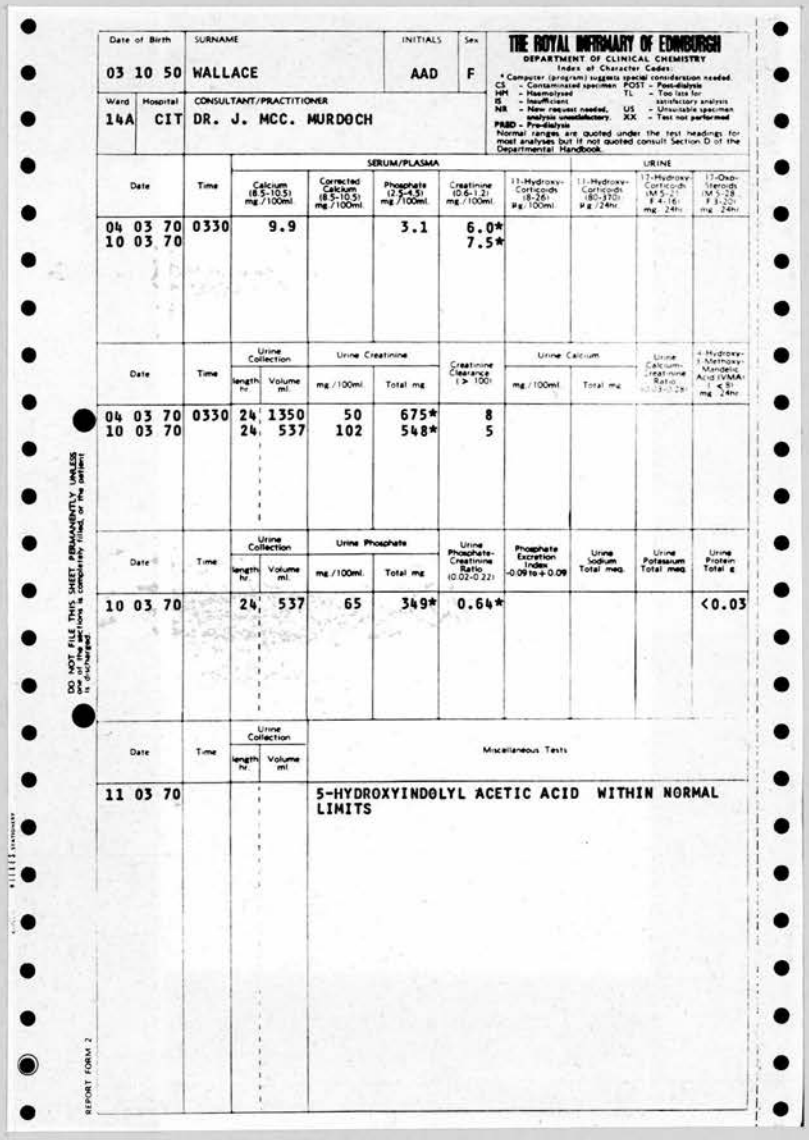
Date	Time	Miscellaneous Tests
08 02 70		URIC ACID 7.2MG/100ML

DO NOT FILE THIS SHEET PERMANENTLY UNLESS it contains a completely final, or the patient is discharged.

REPORT FORM 1

Fig. 20

Cumulative report for blood analyses



Date of Birth	SURNAME	INITIALS	Sex
03 10 50	WALLACE	AAD	F

Ward	Hospital	CONSULTANT/PRACTITIONER
14A	CIT	DR. J. MCC. MURDOCH

THE ROYAL INFIRMARY OF EDINBURGH
DEPARTMENT OF CLINICAL CHEMISTRY
Index of Character Codes:
* Computer (program) suggests special consideration needed.
CS - Contaminated specimen POST - Post-dialysis
HH - Haemolysed TL - Too late for satisfactory analysis
IS - Insufficient
NR - New request needed, analysis unsatisfactory. US - Unsuitable specimen
XX - Test not performed
PRED - Pre-dialysis
Normal ranges are quoted under the test headings for most analyses but if not quoted consult Section D of the Departmental Handbook.

Date	Time	SERUM/PLASMA: Calcium (8.5-10.5) mg./100ml.	Corrected Calcium (8.5-10.5) mg./100ml.	Phosphate (2.5-4.5) mg./100ml.	Creatinine (0.6-1.2) mg./100ml.	11-Hydroxy-Corticoids (8-26) µg./100ml.	URINE: 11-Hydroxy-Corticoids (80-370) µg./24hr.	17-Hydroxy-Corticoids (M 5-21 F 4-16) mg./24hr.	17-Oxo-Steroids (M 5-28 F 3-20) mg./24hr.
04 03 70	0330	9.9		3.1	6.0*				
10 03 70					7.5*				

Date	Time	Urine Collection: length hr.	Urine Collection: Volume ml.	Urine Creatinine: mg./100ml.	Urine Creatinine: Total mg.	Creatinine Clearance (> 100)	Urine Calcium: mg./100ml.	Urine Calcium: Total mg.	Urine Calcium-Creatinine Ratio (0.03-0.28)	4-Hydroxy-3-Methoxy-Mandelic Acid (VMA) (< 8) mg./24hr.
04 03 70	0330	24	1350	50	675*	8				
10 03 70		24	537	102	548*	5				

Date	Time	Urine Collection: length hr.	Urine Collection: Volume ml.	Urine Phosphate: mg./100ml.	Urine Phosphate: Total mg.	Urine Phosphate-Creatinine Ratio (0.02-0.22)	Phosphate Excretion Index -0.09 to +0.09	Urine Sodium Total meq.	Urine Potassium Total meq.	Urine Protein Total g.
10 03 70		24	537	65	349*	0.64*				<0.03

Date	Time	Urine Collection: length hr.	Urine Collection: Volume ml.	Miscellaneous Tests
11 03 70				5-HYDROXYINDOLYL ACETIC ACID WITHIN NORMAL LIMITS

DO NOT FILE THIS SHEET PERMANENTLY UNLESS one of the sections is completely filled, or the patient is discharged.

REPORT FORM 2

Fig. 21

Cumulative report for urine and miscellaneous analyses

TABLE VI

INDEX OF CHARACTER CODES FOR CUMULATIVE REPORTS

CODE	INTERPRETATION
*	Computer program suggests special consideration needed
CS	Contaminated specimen
HM	Haemolysed specimen
IS	Insufficient specimen
NR	New request needed, analysis unsatisfactory
PRED	Pre-dialysis specimen
POST	Post-dialysis specimen
TL	Too late for satisfactory analysis
US	Unsuitable specimen
XX	Test not performed

indicate that it may require special consideration. The use of asterisks on cumulative reports is discussed in greater detail in Section III(E), and the ranges and values used for calculating significant differences between results are listed in Appendix VII.

Cumulative reports in which results are marked with an asterisk and reports bearing results for quality control specimens are given priority in the output routine. All other results are output in registration number order. The maximum number of results in a test block is six: a seventh result appears on a new report, but all previous results are stored on the magnetic tape file record. It was considered desirable that patient records should be stored on magnetic tape files for at least three months after receipt of the last test request for the patient. After this time the record could be removed to a history file and stored for a much longer period; the programs required for the removal of patient records from a master file and the creation of a history file are still in a preliminary stage of preparation. While on the 'active' magnetic tape file, results can be recalled within several minutes but the recall of records from a magnetic/

magnetic tape history file would be an off-line operation and hence would be carried out after the end of a day's on-line operation. This particular aspect of the project has not been fully investigated because of the considerable delays encountered when operating the integrated computer system.

(G) QUALITY CONTROL

Before preparing reports containing results for analyses on specimens from patients, the results of quality control samples must be checked to ensure that the system is operating under proper control. Quality control procedures are based on the use of (1) pooled serum, (2) commercial control serum, (3) repeat analysis of patients' specimens and (4) information obtained by the statistical analysis of results for patients' specimens. The use of pooled serum is a method of 'within batch' quality control and provides a 'running' control or early warning system for the analytical channels (Whitby et al., 1967). Commercial control sera and repeat analysis of patient specimens act as a form of 'between batch' quality control while statistical results obtained at the end of a day's run are essentially a form of retrospective quality control (Whitby/

(Whitby et al., 1967).

A specimen of pooled serum is placed in the cup positions immediately preceding each drift standard, i.e. in cup positions 19, 29, 39, etc. Each time a result is obtained from these samples, it is compared with the mean and standard deviation for that particular pool value; these data have been input at the start of the analytical run (Section II(A)). If the calculated value differs from the mean value by more than two standard deviations, or if two consecutive results differ from the mean by more than 1.5 standard deviations in the same direction, or if three successive values differ from the mean by more than one standard deviation in the same direction, then a warning message is output on the on-line teleprinter. The message (Fig. 19) gives the calculated value for the current specimen together with the results for the two preceding pool specimens.

Patient specimens are interspersed with samples of commercial control sera and samples for repeat analysis. The quality control samples are identified by a word code (QCD for quality control department). Request data for commercial control sera is input to the computer using special registration numbers (010101A, 020202B, etc./

etc.), and cumulative records for these sera can thus be stored on the magnetic tape files and output on pre-printed cumulative reports. Information relating to patient specimens used for repeat analysis is entered using a pseudo registration number (000009R); this permits all the current day's repeat results to be output on a cumulative report but they are not transferred to the master file at the end of the day's run and hence are not stored in cumulative records. Since quality control samples are given priority in the output routine, some results are output with each batch of cumulative reports.

The fourth method of quality control makes use of the analytical results for patient specimens to calculate the patient mean and standard deviation. If the number of results is sufficiently large the average of 'normal' results and the standard deviation about this value are also calculated. The results of statistical analysis may be obtained on demand at any time during the day, but they also form part of an end-of-the-day summary (Fig. 22) which includes the estimated mean and standard deviations for the pooled sera together with the difference between the pre-determined mean and the estimated mean for plotting on a cusum chart (Whitby

et/

PATIENT STATISTICS 29.10.69

	TOTAL PATIENTS			NORMAL PATIENTS		
TRC	MEAN	STANDARD DEVIATION	COUNT	MEAN	STANDARD DEVIATION	COUNT
U	33.9	12.3	232	30.3	7.34	188
NA	139	6.66	261	140	4.96	204
K	4.11	.599	251	4.32	.342	152
CL	102	6.04	259	103	3.25	146
CO2	25.2	4.10	261	26.7	1.78	136
CA	9.18	.885	37	9.28	.367	27
P	3.51	1.15	33	----	----	---

END

POOL STATISTICS 29.10.69

TRC	MEAN	COUNT	STANDARD DEVIATION	CUSUM
U	46.8	33	1.03	-1.17
NA	141	33	2.00	.617
K	4.51	33	.070	.013
CL	103	33	1.66	.578
CO2	13.0	33	.566	-1.97
CA	9.72	5	----	----
P	3.09	4	----	----

END

Fig. 22

Patient and Quality Control Statistics

et al., 1967).

(H) ADDITIONAL CALCULATIONS

A set of sub-routines for performing additional calculations on results of manual or automated tests are called into the computer core store whenever an 'output of results' instruction is entered on the on-line Teletype. A complete list of the calculations carried out and the appropriate formulae are given in Appendix IX. If all the values required for the calculation of a ratio or clearance are available, the calculation is automatically performed by the computer program; for instance, if a specimen of urine has been analysed for calcium and creatinine, then the calcium/creatinine ratio can be calculated. For calculations involving the results of analyses of blood and urine specimens, e.g. creatinine clearance, the test requests for the blood and urine analyses must be input at the same time and must include a figure for the urine volume (see Appendix IX). Results of additional calculations are output on cumulative reports and values which may require special consideration are indicated by an asterisk. The asterisk ranges used for this purpose are given in Appendix VII.

(I)/

(I) END-OF-DAY SUMMARY

An end-of-day summary is output to the paper tape punch as part of a closedown procedure. In addition to providing statistical information and a final work load statement, the summary gives a list of patient identification and test request data for all requests entered on that particular day, together with results for the analyses that have been performed and results of additional calculations. The data are output in registration number order and can readily be consulted when answering enquiries about results that have not reached the patients' case folders. The end-of-day summary is the only permanent record of results for requests received from general practitioners, and for any other requests when registration numbers are unavailable and for which cumulative records are therefore not prepared. The format of the end-of-day summary is shown in Fig. 23.

(J) FILE UPDATING PROCEDURES

A paper tape program for updating magnetic tape files is read into the computer after completing the closedown procedures. In the first part of this routine all programs and cumulative records are read from/

```
      DAYS RESULTS          03.05.69          SHEET  5

260800R/1 ROBESON                    H        F 11   RIE
  L104 U=22* NA=135 K=3.6 CL=101 CO2=28* TIM=0815
       ID=9*

151100Y/1 YOUNG                      J        M 10   RIE
  L158 U=17* NA=135 K=3.5* CL=105 CO2=22* TIM=0900
       ID=12*

101200I/1 INGLES                     E        F 30   RIE
  L079 U=32 NA=140 K=3.2 CL=103* CO2=31* TIM=0900
  Y321 TPA=6.9 TPB=0.2 GA=41 GAA=94 GLB=65 GLG=99 LBM=3.1
       TP=6.7 LBP=46 GAC=0.5 GAP=7 G2C=1.1 G2P=17 GBC=0.8 GBP=12
       GGC=1.2 GGP=18
       ID=9*

151200S/1 STEELE                     H        -      HER
  L273 U=40 TIM=1230

310101A/1 ANDERSON                   A        F 30   RIE
  L098 U=25 NA=138 K=4.4* CL=107* CO2=26* TIM=0900
  Y340 COL=XX PBI=XX
       ID=10*

030601N/1 NISBET                     J        F 27   RIE
  L019 U=38 NA=137 K=3.9 CL=103 CO2=31 TIM=0900
       ID=7*

061201M/3 MCDONALD                   L        F      FDC
 Y352 COL=XX CA=8.9 P=3.5


230702M/1 MACK                       A        M 6    CIT
  L185 U=26* NA=127 K=4.2* CL=87* CO2=29*
       ID=15
```

Fig. 23

End-of-Day Summary of Patient and Test Data

from the current master file and updated by adding all records of completed work from the current work file to produce a new master file. In the second part of the updating procedure all incomplete test request data are read from the current work file and used to compile a new work file. The current files are stored for at least two days so that the file can be reconstituted in the event of magnetic tape failure.

At the end of the updating routine, the program prints up on the on-line Teletype, a statement of the number of blocks of information stored on the master file and an estimate of how long the file can be used before it is necessary to remove patient records to a history file (Fig. 24).

The programs section of the master file can be updated by writing new programs or new versions of programs currently on the file without having to rewrite all the programs to magnetic tape by using an edit procedure. This procedure can also be used to delete programs from the file, to change locations of programs currently on the file, or to make a copy of the program file on magnetic tape. To change a parameter or set of parameters for standard curve validation (e.g. limits of variation/

```
MASTER FILE IS       128  BLOCKS LONG

TAPE MUST BE CLEANED BEFORE     143  DAYS


NEW MASTER FILE ON HANDLER 2

UNLOAD HANDLERS 0 AND 2
LOAD SCRATCH TAPE ON HANDLER 2>>

NEW WORK FILE ON HANDLER 2

END OF UPDATING THE MASTER FILE
```

Fig. 24

Output of File Updating Information

variation of gradients or changes in gradients), the binary version of the original program on paper tape is read into the computer core store together with the appropriate program for changing parameters and the values are amended in a way similar to that used for changing parameters in Setting-up Procedures (Section II(A)). The amended data is output in binary form on the paper tape punch and the resulting tape, after validation by a checking program, is used to edit the master file. In the clinical chemistry laboratory where existing methods of analysis are modified, new methods introduced, sampling rates increased and the concentration of calibration standards altered from time to time, this simple procedure for amending parameters or characteristics has proved invaluable in the routine operation of the system.

(K) BREAKDOWN PROCEDURES

A breakdown procedures program is called into operation via the level 4 queue whenever a fault is detected in the operation of the magnetic tapes, on-line monitoring equipment, paper tape punch or on-line teleprinter. The program outputs a message on the on-line Teletype or, if this peripheral is not available,

on/

on the paper tape punch giving information about the nature of the fault, and the magnetic tape handler number or analyser console channel number on which the fault has been detected. If a fault develops on magnetic tape handler 0 then the program initiates the changes required to call down programming data from another tape file. In the event of failure of the paper tape punch the program re-directs all output to the on-line teleprinter: if a fault develops in the on-line teleprinter all output is re-directed to the paper tape punch.

If a fault develops in one of the analyser console units then the entire group, or at least one channel of the group, becomes inoperative. The breakdown procedures program will detect the loss of a signal from a channel or group of channels and print out a message on the Teletype. It may be possible to connect the channel or group of channels to another analyser console if one is available; if not, the analytical equipment can be disconnected from the console, the analyses carried out in off-line mode, and the results input on punched paper tape after reading off the recorder charts and calculating concentrations using/

using standard manual procedures.

If the ADC or any of the equipment common to all analytical channels develops a fault, it is necessary to operate the analytical equipment in an off-line mode. A paper tape containing manually calculated results can be input to the computer through the reader; patient and test request data can be input in the normal way and hence it is still possible to prepare cumulative reports, although extremely laborious.

In the event of total failure of the on-line equipment or the magnetic tape handlers or controller, the computer enters part one of a Rescue program which is part of the on-line system. If 2-second readings can still be input but no level 4 processing is possible, the peak table will eventually become too full. At this point, the Rescue program outputs the peak maxima on the paper tape punch and it is possible to continue this form of on-line operation of the system until the analytical runs have been completed. If a breakdown occurs which inhibits level 2 interrupts, then no peaks can be read into the computer but the peak heights already input and awaiting processing and the current work can be recovered by entering, through the paper tape/

tape reader, the second part of the Rescue program. This program outputs all the relevant sections of the store including standards parameters, unprocessed peaks, etc. on paper tape. When the hardware fault has been repaired, the output tape is entered through the reader and the results in cup-number order are output on the paper tape punch. The results should also be able to be transferred to the magnetic tape work file but this part of the program has not yet been fully validated.

(L) TESTING THE SYSTEM BEFORE USE

The computer and associated peripherals can be tested by a series of standard test programs provided by the manufacturers, but this is a time-consuming and tedious procedure. Because of this, a special test program was written to check the operation of the overall on-line system in about 10 minutes. The program is composed of a suite of six test programs; the tests can be performed sequentially under the control of a linking program, or called up individually by the operator if required for fault-finding or 'diagnostic' investigation.

A channel test program first measures the voltage of channel 0 (i.e. no switch selected) and outputs on the/

the on-line Teletype in octal form the largest of 256 readings. This value can be checked by the operator and compared with the maximum permitted value (2 mV). The test program then determines the mean, maximum and minimum readings of channel 1 (internal reference channel) and prints up the values in octal form; the mean should be within 0.1% of the nominal reference voltage (3.23 V) and the maximum and minimum should not differ from this by more than $\pm$ 1%. In the third part of this test, the program calculates the mean and standard deviation of 256 readings of the reference and measuring signals and the ratio for all AutoAnalyzer channels and outputs this information on the Teletype. If a result is suspect it is marked by an asterisk (Fig. 25).

On entry into the second program, the operator is instructed to switch on all channels in sequence and then switch off all channels in the same order and the status word is monitored throughout this procedure. The second part of this program checks that the correct status bit is set when a control bit is set (Appendix III).

In a pseudo reply test program two false addresses are/

```
ON LINE SYSTEM TEST


CH 0 MAX   &000003
CH 1 MEAN  &005003
CH 1 MAX   &005005
CH 1 MIN   &005002

 MEANS                                STANDARD DEVIATIONS

SW   CH   MEAS    REF     RATIO       MEAS     REF      RATIO
 2   12   46.1    47.9    96.2        0.00     0.00     0.01
 8   15   27.1    49.7    26.1*       0.24     0.00     0.21*
10   16   68.3    72.1    94.8        0.00     0.00     0.01
16   21    2.1    18.4    11.4        0.00     0.00     0.02
18   22   23.0    23.0    35.9*       0.00     0.00     0.48*
20   23   29.3    29.8    98.3        0.00     0.00     0.02

CHTEST END

ALL ACS OFF

ON IN SEQUENCE

OFF IN SEQUENCE

SCTEST END

PSTEST END

LOAD TAPE

END RTEST

END PTEST

TIMER ON

PRESS KEY   A
PRESS KEY   C
PRESS KEY   I
PRESS KEY   6
PRESS KEY   0
PRESS KEY   )
PRESS KEY   >

END TPTEST
```

Fig. 25

On-line Systems Test

are given, one for input and one for output, to check that pseudo reply is given and that the relevant bit of the status word is set. A reader-punch test is performed by reading a length of blank tape which has one character printed near the end of the tape. When the program is reading blanks, the reader 'busy' bit is checked; when a non-blank character is read, the program outputs 250 blanks on the paper tape punch.

The fifth test program checks the operation of the teleprinter, and in particular the setting and re-setting of the 'ready' and 'about to interrupt' bits, and the occurence and timing of the level 3 interrupt from the teleprinter. On entry to level 4 the program indicates that the timer is to be switched on, by printing a message on the teleprinter. The operator is then instructed to input characters from the Teletype keyboard for checking the setting and re-setting of the busy bit.

The timer program checks that the 'about to interrupt' bit is set for 260 m.sec. $\pm$ 10% prior to the level 2 interrupt, and that the interrupt period is 2 seconds. The processor obtains a 260 m.sec. warning of impending level 2 interrupts so that it is prevented from/

from entering a routine such as a block transfer to magnetic tape, which will take longer to complete than is permissable before the level 2 interrupt.

An example of the teleprinter output for the complete system test is shown in Fig. 25. If errors are detected, or if any test fails, the appropriate error message is printed up on the Teletype. A set of simple test routines for the paper tape reader and punch and the on-line Teletype have been developed in the department. These routines make use of the engineer's test panel and the operator's keyboard and hence do not depend on the satisfactory operation of other peripheral devices.

SECTION III

EVALUATION AND ASSESSMENT OF TEST CHARACTERISTICS AND CHECKING PROCEDURES

(A) PEAK DETECTION AND FAULT RECOGNITION CHARACTERISTICS

The computer program for the detection and validation of AutoAnalyzer peaks is based on a series of characteristics or parameters which have to be evaluated for each particular test channel. The elements of the peak detection program are shown in Fig. 26: the parameters used for the program are described below and the actual numerical values are tabulated in Appendix VII.

Parameter A Minimum Number of Rising Readings The number of rising 2-second readings before a peak maximum must be equal to or greater than a specified value.

Parameter B Minimum Number of Falling Readings The number of falling readings after a peak maximum must be equal to or greater than a specified value. If there are fewer than A rising readings or B falling readings the error message 'MSG 44 XY' (where XY is the channel number) is output on the Teletype.

Parameter C Maximum Irregularity in Rise or Fall In some tests the readings remain near the peak maximum for 6 - 8 seconds and small fluctuations in the percentage transmission may occur (Fig. 27). One of the highest readings/

ELEMENTS OF PEAK RECOGNITION PROGRAM

Signals digitized every 2 seconds

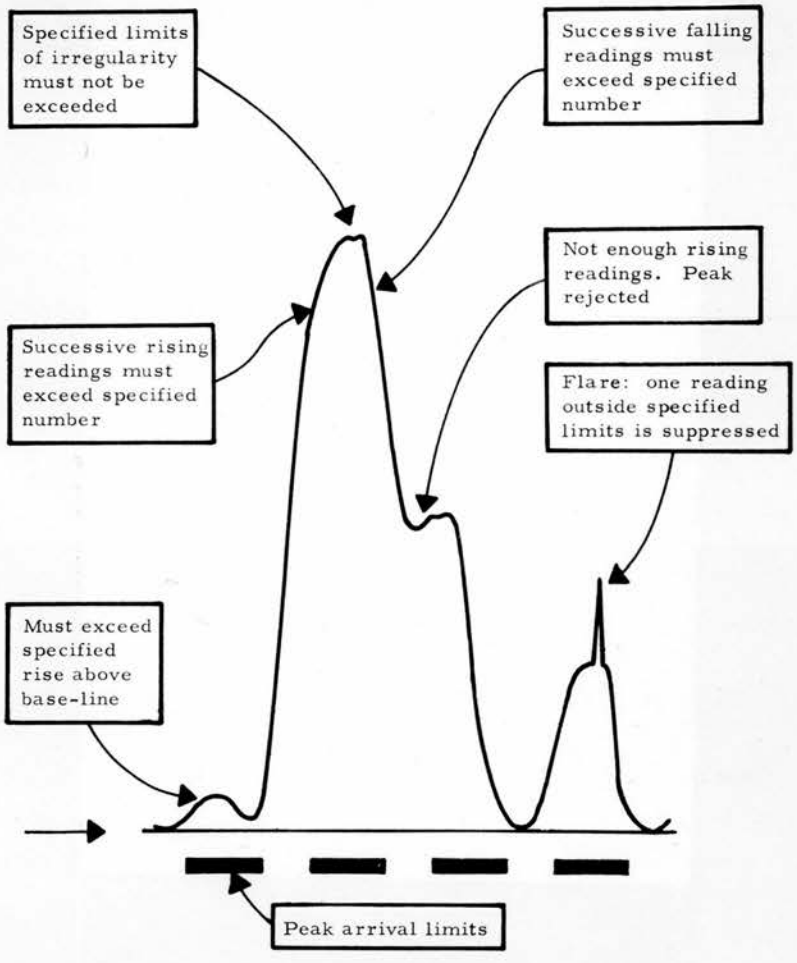


Fig. 26

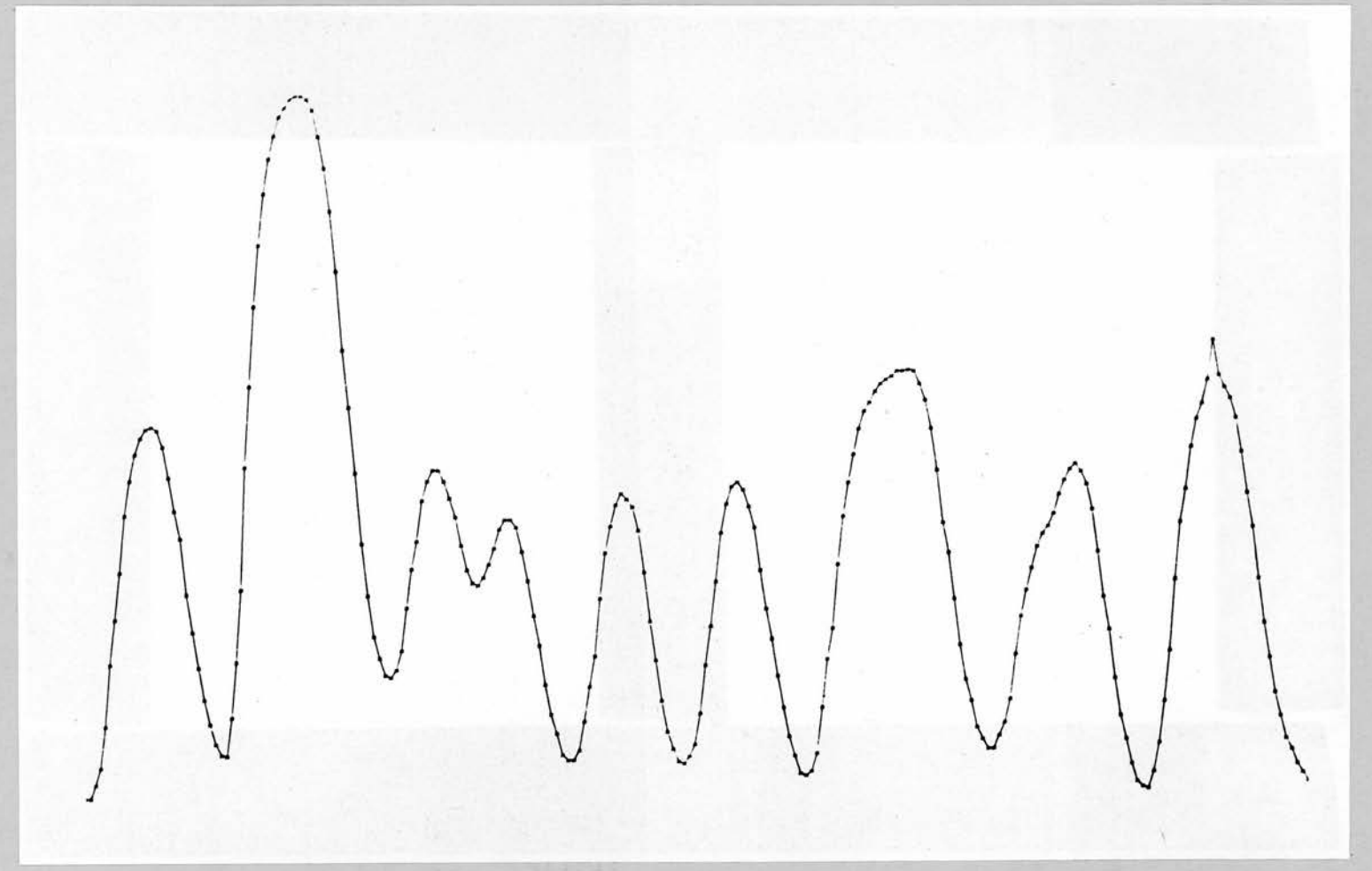


Fig. 27

Graphical representation of 2-second peak readings for serum phosphate (60 samples/hr; 1:1 sample to wash ratio)

readings may be 0.5 of a transmission unit below the readings on either side of it but if the variation is small it does not affect the peak height sufficiently to require rejection of the peak. Parameter C is the value in units of (1 - T/100) of the greatest fall in the rising section of A readings or the greatest rise in the falling section of B readings that can be ignored by the program. This parameter is used in the detection of double peaks and peaks affected by carry-over from a previous peak. If the observed irregularity in rise or fall is greater than C transmission units then the error message 'MSG 43 XY' is output.

Parameter D Maximum Difference between Successive Readings

If a peak is deformed on the chart record by the appearance of a flare (usually due to an air bubble passing through the colorimeter), then as long as there is only one irregular signal generated this is unlikely to affect the peak maximum and hence the program allows for the acceptance of the peak. Parameter D is the height in 1 - T/100 units of a single reading above the average of the preceding and succeeding readings for it to be counted as a flare and the single reading suppressed.

If/

If the duration of the flare is such that two or more readings are affected then the peak is rejected as faulty and the error message 'MSG 40 XY' printed on the on-line Teletype.

Parameter E Minimum Rise Required Small fluctuations in the base line could conceivably satisfy the criteria of parameters A and B and hence for a peak to be accepted there must be a rise of at least E transmission units (1 - T/100) over the A rising readings. If there are fewer than E units over the rising readings then error message 'MSG 44 XY' is output.

Parameter F Expected Number of Readings Between Peaks

The expected number of 2-second readings between the maxima of two peaks depends on the sampling rate and, at 60 samples per hour, the value is 30. When a peak is detected the expected position of the next peak X' is defined in relation to the expected position of the current peak X and its actual position P:-

$$X' = aX + (1 - a)\ P + F$$

where F is the expected number of readings; the value of 'a' is/

is usually 0.75 but it can have any value in the range $0 \leq a \leq 1$. The value of 'a' varies the dependence of X'' on the actual position of the previous peak and its expected position which is based on the previous peaks.

Parameter H Width of Time Window In addition to defining the expected position of the next peak maximum, it is necessary to define the range about that position in which the peak can be accepted. Parameter H is the width of the time window in 2-second readings, i.e. the maximum reading for acceptable peaks must arrive within the range $X' \pm (H - 2)/2$ readings (Fig. 28). If the maximum value coincides with the first or last reading specified by parameter H or if no peak is detected then the appropriate error message is output on the on-line teleprinter. Early or late arrival of a peak is indicated by message 'MSG 41 XY' or 'MSG 42 XY', respectively, and the program looks for the next peak after an interval of F readings. The use of a time window enables two particular sampling errors to be detected:-

(1) Sampling time too short - there is a thin early peak which does not fall inside the window of H readings.

The/

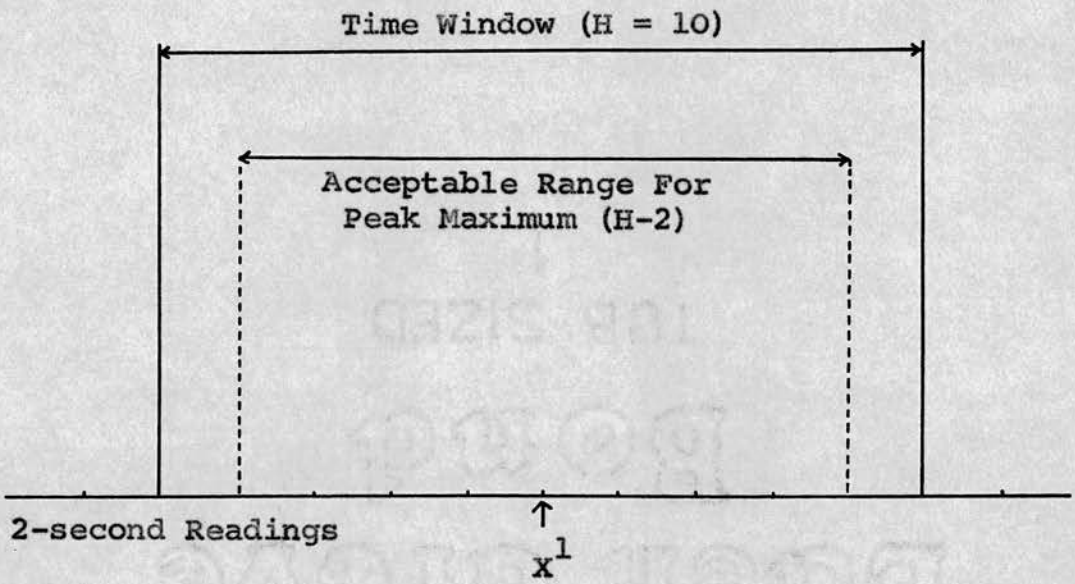


Fig. 28

Peak Detection Time Window

The usual cause of thin peaks is insufficient specimen in the sample cup or a partial block in the sample probe.

(2) Sampling time too long - there is a fat late peak which falls outside the window. The occurrence of fat peaks is much less frequent than that of thin peaks and it is usually caused by a fault in the AutoAnalyzer sampler unit.

Parameter G Waiting Time for First Peak At the start of an analytical run the arrival of the first peak may occur at any time after switching on the equipment. The program reads in (A + H + B) readings and then begins peak detection on the H readings in the middle. If a peak is not found, the H readings are cancelled and the window moved up. This procedure continues until a peak is finally detected. If after G readings no peak has been found a warning message (MSG 46 XY) is output on the on-line Teletype. This message is repeated after an interval (2G) and finally if after 3G readings no peak is detected a different message (MSG 47 XY) is output and the channel is cancelled.

Parameter I Peak or Trough This parameter indicates if the analyser peak is a 'trough' (concentration

inversely/

inversely proportional to percentage transmission) or a 'peak' (concentration proportional to percentage transmission).

Peak detection parameters are transferred to the computer core store at the start of a run. They can be changed by entering the setting-up procedures routine, typing the address of the appropriate location on the on-line Teletype and altering the value stored in this location (Section II(A)).

Whenever a peak fails to conform to the peak validation requirements, an error message is output on the on-line teleprinter and the fault lamps on the analyser console and data acquisition unit are switched on; the lamps are extinguished when the next acceptable peak is detected on that channel. If the computer detects four consecutive faulty peaks, a special error message (MSG 69 XY) is output on the teleprinter to which the operator must reply by typing W>, U>, R> or C> to indicate respectively, wait, use, restart or cancel the channel. The fault could be due to a block in the sample pick-up line in which case the use option is selected and the computer continues to search for peaks/

peaks while the block is cleared; provided the sampler plate is not stopped, the timing sequence is maintained and when acceptable peaks are once more obtained they can be detected by the computer program. If a peak is faulty or is not detected by the computer, the corresponding specimen is automatically re-allocated to a later work sheet.

When an acceptable peak is detected the peak maximum, i.e. the maximum transmission reading within the time window, is stored in the computer until there are sufficient values for calculation of concentrations. This means that the raw peak values are stored until after the next drift correction standard has been analysed satisfactorily.

A preliminary evaluation of the above peak detection parameters was carried out before installation of the 903 computer system by using peak monitoring equipment similar to that described by Flynn et al. (1966). A peak-picking device fitted to the shaft on an AutoAnalyzer chart recorder was connected via translator, timer and programmer units to a paper tape punch. The equipment was linked to each AutoAnalyzer channel in turn and the percentage transmission recorded at/

at two second intervals for a series of calibration standards and patient specimens. During the analytical run faulty peaks were deliberately introduced by varying the aspiration time of samples, introducing air bubbles into the colorimeter flow cell, creating a partial block in the sample line, placing low concentration samples immediately after high concentration samples to produce marked interaction, and by having insufficient specimens in some sample cups. The data collected in this way were printed up, and were also converted to graphical form to facilitate the retrieval of relevant information. Fig. 27 shows the graphical representation obtained for samples analysed for serum phosphate concentration (60 samples/hour; 1:1 sample to wash ratio).

The minimum number of rising and falling readings required to define an acceptable peak (parameters A and B, respectively) were determined by visual inspection of the graphical output. The expected number of 2-second readings between the maxima of two consecutive peaks (parameter F) was calculated from the sampling rate, e.g. F = 45 if the sampling rate is 40 per hour. The calculated value for parameter F was then/

then applied to the 2-second tracing to determine the width of the time window (parameter H). Parameters used to specify the greatest fall in the rising section of a peak or rise in the falling section (parameter C), the height of a single reading above the average of the preceding and succeeding values for it to be counted as a flare (parameter D), and the minimum rise over the A readings for the peak to be accepted (parameter E) were evaluated from the printed output of 2-second transmission readings. Parameter G, the number of readings accepted at the beginning of the run without a peak being detected, was calculated from the delay on the AutoAnalyzer between the time of aspiration of a sample and the arrival of the sample in the colorimeter or flame photometer.

The 903 computer was installed several months after the preliminary evaluation of parameters and during the intervening period several changes were made in the analytical procedures and equipment. The Technicon flame photometer Mark II was replaced by the Mark III module, some of the sampler and pump units were replaced by later models, and the sampling rates for several tests were altered. As a result of these changes it was necessary/

necessary to re-evaluate the peak detection parameters and this was carried out using a 2-second reading routine provided with the 903 computer software. In this case the signals were taken from the detector instead of the chart recorder. The data printed on the on-line Teletype were used together with the corresponding graphical output to compile tables of channel parameters. From time to time the values of parameters have since been altered to improve peak detection or as a result of changes in analytical methods - for instance, the colorimetric calcium method was superseded by a fluorometric technique. The procedure for changing the values of program parameters or characteristics stored on magnetic tape has been described in Section II(A); the values currently in use are listed in Appendix VII.

After evaluating the program parameters, the performance of the peak detection and fault recognition routines was assessed by testing their ability to determine the peak maxima for all properly formed peaks while rejecting any faulty peaks deliberately introduced into the analytical system. The chart record for the urea channel shown in Fig. 29 represents an experiment in/

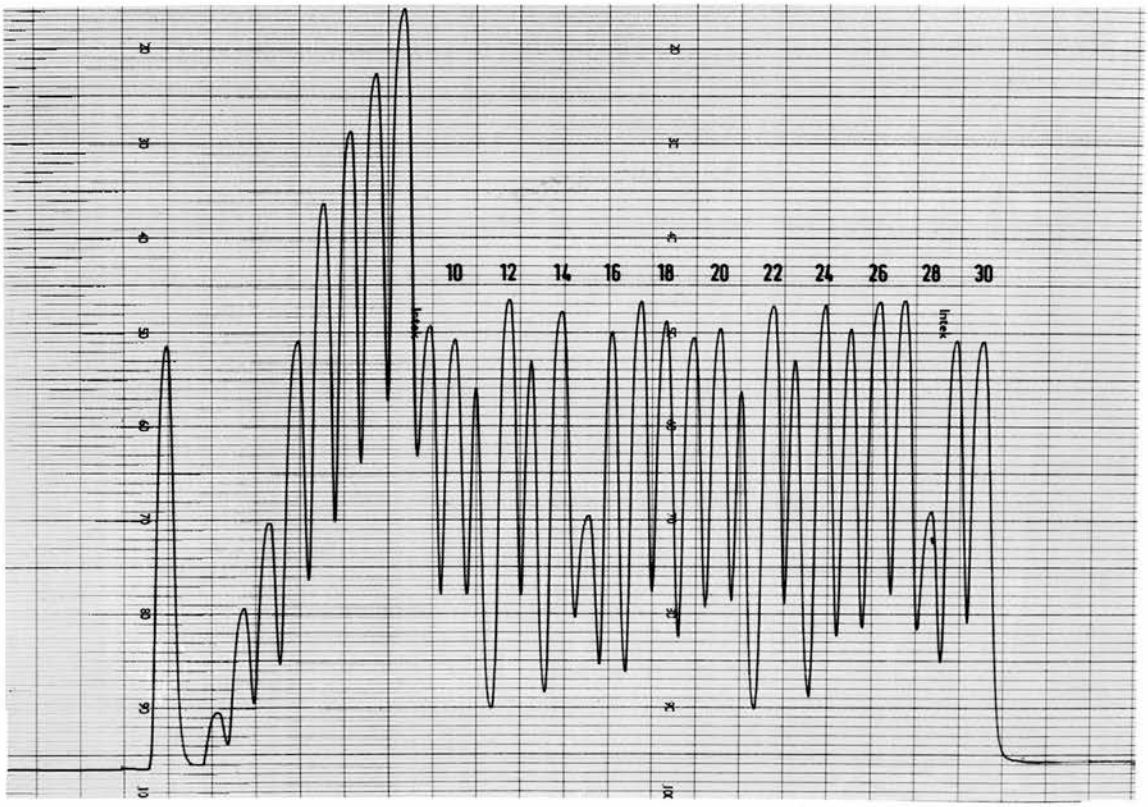


Fig. 29

An example of a chart record obtained with a single channel AutoAnalyzer. The tracing begins with a 'trigger' peak to set the computer's peak detection program in operation, followed by a series of calibration standards (1-8), drift correction standards (10, 20 and 30), quality control serum pool (19 and 29) and patients' specimens (the rest of the peaks). Some of the peaks (11, 13, 21 and 23) are sharp-topped, due to deliberately inadequate sampling (see Table VII); they should all have been the same height as peaks 12, 14, 22 and 24.

in which some of the specimens being analysed for their content of urea, sodium, potassium, chloride and bicarbonate had their sampling times deliberately shortened; Table VII compares the ability of the computer and of a technician who worked in another laboratory to detect unsatisfactory peaks. The information in Table VII indicates that the computer has been no less successful than the technician, except in the case of urea, but the computer would be unaffected by the numbers of tests being performed and would maintain this standard of validation in a much longer run. The recorder tracing for urea peaks (Fig. 29) considered in conjunction with the data in Table VII reveals that the computer had failed to reject peaks that appeared unduly sharp on the chart record. This failure to reject faulty peaks was attributed to the wide limits set for the time window, and the experiment was then repeated after reducing the time window from 10 to 8 two-second readings. The ability of the computer program to detect unsatisfactory peaks in this repeat experiment was compared with that of a technician; the results in Table VIII showed an improvement in the computer fault recognition routine.

A/

TABLE VII

RECOGNITION OF INSUFFICIENT SPECIMENS

SAMPLE	ASPIRATION TIME (SECONDS)	UREA (mg/100ml)		SODIUM (meq./l.)		POTASSIUM (meq./l.)		CHLORIDE (meq./l.)		BICARBONATE (meq./l.)	
		C[1]	T[2]	C	T	C	T	C	T	C	T
11	20	E[3]	R[4] (85)	E	R (115)	E	R (4.4)	E	R (70)	E	R (15)
12	40	114	112	142	142	5.4	5.4	93	94	18	19
13	25	93	R (92)	E	R (121)	E	R (4.6)	E	R (80)	E	E (17)
14	40	108	107	142	142	5.4	5.4	96	96	19	19
15 (QC)	40	50	48	139	138	4.6	4.6	104	104	11	13
16	30	100	100	E	127	E	4.8	87	89	E	17
17	40	111	108	143	141	5.4	5.3	97	97	19	19
18	35	103	102	136	135	5.1	R[5](5.1)	94	95	18	19
19 (Drift)	40	-	98	-	139	-	3.9	-	102	-	20
20 (Drift)	40	-	100	-	140	-	4.0	-	104	-	20
21	20	E	R (81)	E	R (110)	E	R (4.3)	E	R (71)	E	R (15)
22	40	109	107	142	142	5.5	5.4	95	95	19	19
23	25	92	R (91)	E	R (120)	E	R (4.6)	E	R (79)	E	R (17)
24	40	110	108	143	143	5.4	5.5	95	96	18	19
25	30	102	102	126	129	E	R[5](5.0)	87	89	17	18
26	40	112	111	143	143	5.5	5.5	98	98	19	19
27	35	113	113	138	138	5.3	R[5](5.3)	98	98	18	19
28 (QC)	40	52	52	138	139	4.6	4.7	103	103	11	13
29 (Drift)	40	-	100	-	139	-	3.8	-	104	-	20
30 (Drift)	40	-	100	-	140	-	4.0	-	104	-	20

Concentrations for the rejected peaks calculated by a technician are shown in brackets. Except where noted (drift and QC = quality control) all samples were from the same pool of plasma. Rate of analysis is 60/hour; normally sample:wash ratio, 2 : 1

[1] C = Computer
[2] T = Technician
[3] E = Error message
[4] R = Peak rejected by technician
[5] Rejected by technician because of irregularity on top of peaks

TABLE VIII

RECOGNITION OF INSUFFICIENT SPECIMENS

SAMPLE	ASPIRATION TIME (SECONDS)	UREA (mg/100ml)	
		C[1]	T[2]
11	20	E[3]	R[4] (73)
12	40	96	96
13	25	E	R (79)
14	40	97	95
15 (QC)	40	48	48
16	30	86	86
17	40	96	95
18	35	92	91
19 (Drift)	40	-	102
20 (Drift)	40	-	100
21	20	E	R (70)
22	40	95	95
23	25	E	R (77)
24	40	94	93
25	30	87	R (87)
26	40	96	96
27	35	89	89
28 (QC)	40	46	45
29 (Drift)	40	-	101
30 (Drift)	40	-	100

Concentrations for the rejected peaks calculated by a technician are shown in brackets. Except where noted (Drift and QC = quality control) all samples were from the same pool of plasma. Rate of analysis is 60/hour; normally sample:wash ratio, 2 : 1

[1]C = Computer
[2]T = Technician
[3]E = Error message
[4]R = Peak rejected by technician

A further assessment of the peak detection and fault recognition routines was made by recording peak error messages while operating AutoAnalyzers under routine laboratory conditions, and examining carefully all peaks on the chart recorder tracing at the end of each analytical run. In carrying out this examination of AutoAnalyzers peaks I was assisted by the technical staff and, in order to avoid bias, the fault recognition performed by the technicians was used as the basis of the assessment. The findings were classified according to the error message number and are summarised in Tables IX - XIII. Examination of the figures in these tables reveals that, with the exception of uric acid, serum phosphate and serum creatinine, the peak detection and validation routines operated in a satisfactory way. After this assessment had been carried out, the width of the time window for urea and uric acid was reduced from 8 to 6 and 10 to 8 readings, respectively, and several changes in analytical method were made in the serum phosphate and serum creatinine assays.

It is interesting to note that the overall percentage of faulty peaks in the 4,909 AutoAnalyzer peaks examined was 4.6%: the value for specific tests varied from 1.2% for chloride to 29.2% in the case of

TABLE IX

ASSESSMENT OF FAULT RECOGNITION PARAMETER D - PEAK ERROR BECAUSE OF FLARE (ERROR MESSAGE NO. 40)

TEST	TOTAL NO. OF ANALYSES	COMPUTER	ASSESSMENT BY TECHNICIAN		
		NO. OF FAULTY PEAKS	NO. OF FAULTY PEAKS	NO. OF FAULTY PEAKS ACCEPTED BY COMPUTER	NO. OF ACCEPTABLE PEAKS REJECTED BY COMPUTER
Urea	670	-	-	-	-
Sodium	670	-	-	-	-
Potassium	670	-	-	-	-
Chloride	330	-	-	-	-
Bicarbonate	670	-	-	-	-
Total protein	136	-	-	-	-
Protein blank	112	2	2	-	-
Albumin	136	-	-	-	-
Alkaline phosphatase	78	-	-	-	-
Bilirubin	78	-	-	-	-
Calcium	112	-	-	-	-
Phosphate	180	-	-	-	-
Creatinine	164	-	-	-	-
Iron	142	-	-	-	-
Iron-binding capacity	130	2	2	-	-
Cholesterol	160	-	-	-	-
Uric acid	262	-	-	-	-
Urine phosphate	94	-	-	-	-
Urine creatinine	115	-	-	-	-

TABLE X

ASSESSMENT OF FAULT RECOGNITION PARAMETER H - PEAK EARLY ERROR (ERROR MESSAGE NO. 41)

TEST	TOTAL NO. OF ANALYSES	COMPUTER	ASSESSMENT BY TECHNICIAN		
		NO. OF FAULTY PEAKS	NO. OF FAULTY PEAKS	NO. OF FAULTY PEAKS ACCEPTED BY COMPUTER	NO. OF ACCEPTABLE PEAKS REJECTED BY COMPUTER
Urea	670	8	9	1	-
Sodium	670	6	7	1	-
Potassium	670	9	10	1	-
Chloride	330	3	3	-	-
Bicarbonate	670	12	12	-	-
Total protein	136	2	2	-	-
Protein blank	112	3	3	-	-
Albumin	136	2	2	-	-
Alkaline phosphatase	78	-	-	-	-
Bilirubin	78	-	-	-	-
Calcium	112	4	4	-	-
Phosphate	180	5	8	3	-
Creatinine	164	19	21	2	-
Iron	142	4	4	-	-
Iron-binding capacity	130	4	4	-	-
Cholesterol	160	3	3	-	-
Uric acid	262	17	21	4	-
Urine phosphate	94	-	-	-	-
Urine creatinine	115	2	2	-	-

TABLE XI

ASSESSMENT OF FAULT RECOGNITION PARAMETER H - PEAK LATE ERROR (ERROR MESSAGE NO. 42)

TEST	TOTAL NO. OF ANALYSES	COMPUTER	ASSESSMENT BY TECHNICIAN		
		NO. OF FAULTY PEAKS	NO. OF FAULTY PEAKS	NO. OF FAULTY PEAKS ACCEPTED BY COMPUTER	NO. OF ACCEPTABLE PEAKS REJECTED BY COMPUTER
Urea	670	-	-	-	-
Sodium	670	4	3	-	1
Potassium	670	-	-	-	-
Chloride	330	1	1	-	-
Bicarbonate	670	-	-	-	-
Total protein	136	-	-	-	-
Protein blank	112	3	3	-	-
Albumin	136	-	-	-	-
Alkaline phosphatase	78	-	-	-	-
Bilirubin	78	-	-	-	-
Calcium	112	-	-	-	-
Phosphate	180	-	-	-	-
Creatinine	164	12	10	-	2
Iron	142	7	6	-	1
Iron-binding capacity	130	3	3	-	-
Cholesterol	160	-	-	-	-
Uric acid	262	4	4	2	2
Urine phosphate	94	-	-	-	-
Urine creatinine	115	-	-	-	-

TABLE XII

ASSESSMENT OF FAULT RECOGNITION PARAMETER C - DOUBLE PEAK ERROR (ERROR MESSAGE NO. 43)

TEST	TOTAL NO. OF ANALYSES	COMPUTER	ASSESSMENT BY TECHNICIAN		
		NO. OF FAULTY PEAKS	NO. OF FAULTY PEAKS	NO. OF FAULTY PEAKS ACCEPTED BY COMPUTER	NO. OF ACCEPTABLE PEAKS REJECTED BY COMPUTER
Urea	670	-	-	-	-
Sodium	670	-	-	-	-
Potassium	670	-	-	-	-
Chloride	330	-	-	-	-
Bicarbonate	670	-	-	-	-
Total protein	136	1	1	-	-
Protein blank	112	4	4	-	-
Albumin	136	-	-	-	-
Alkaline phosphatase	78	-	-	-	-
Bilirubin	78	-	-	-	-
Calcium	112	-	-	-	-
Phosphate	180	-	-	-	-
Creatinine	164	1	1	-	-
Iron	142	-	-	-	-
Iron-binding capacity	130	-	-	-	-
Cholesterol	160	-	-	-	-
Uric acid	262	-	-	-	-
Urine phosphate	94	-	-	-	-
Urine creatinine	115	-	-	-	-

TABLE XIII

ASSESSMENT OF FAULT RECOGNITION PARAMETERS A, B & E - VERY LOW RISE TO PEAK (ERROR MESSAGE NO. 44)

TEST	TOTAL NO. OF ANALYSES	COMPUTER	ASSESSMENT BY TECHNICIAN		
		NO. OF FAULTY PEAKS	NO. OF FAULTY PEAKS	NO. OF FAULTY PEAKS ACCEPTED BY COMPUTER	NO. OF ACCEPTABLE PEAKS REJECTED BY COMPUTER
Urea	670	19	19	-	-
Sodium	670	1	1	-	-
Potassium	670	-	-	-	-
Chloride	330	-	-	-	-
Bicarbonate	670	3	3	-	-
Total protein	136	-	-	-	-
Protein blank	112	-	-	-	-
Albumin	136	2	2	-	-
Alkaline phosphatase	78	1	1	-	-
Bilirubin	78	6	6	-	-
Calcium	112	-	-	-	-
Phosphate	180	4	2	-	2
Creatinine	164	16	16	-	-
Iron	142	3	3	-	-
Iron-binding capacity	130	4	4	-	-
Cholesterol	160	-	-	-	-
Uric acid	262	8	7	-	1
Urine phosphate	94	4	4	-	-
Urine creatinine	115	3	3	-	-

serum creatinine. The high percentage of faulty peaks for serum creatinine could be explained by carry-over from specimens having a high concentration of this constituent. The most important factor to be considered when assessing the performance of fault recognition routines is the number of peaks rejected by a technician but accepted by the computer software (column 5 in Tables IX - XIII); the overall percentage of such peaks accepted by the computer was found to be 0.3%.

The ability of the fault recognition programs to detect faulty peaks due to short-sampling of specimens or a partial block in a sample line depends mainly on the peak maximum falling outside the time window. A peak validation procedure based on this criterion restricts the latent ability of a computer system to reject faulty peaks, and on several occasions peaks have been accepted when the maximum was within the time window but the general peak shape indicated that there had been inadequate sampling. In an effort to improve fault recognition procedures, the variation in peak height within the window and over the rising and falling readings has been investigated and this is described in Section V(A).

The/

The information summarised in Tables IX - XIII provides some measure of the usefulness of the individual peak detection error messages. The proportion of faulty peaks detected by the 'peak early' and 'peak late' routines indicates the extent to which the system depends on the time window for fault recognition. Parameters A,B and E also play an important role in fault recognition by detecting a 'very low rise to peak', but parameter E could be made more meaningful and more easily evaluated if it were based on the total rising readings instead of the 'A' rising readings. The program routines for detecting double topped peaks and flares, although used infrequently, are an essential part of a fault recognition system.

(B) STANDARDS IDENTIFICATION AND VALIDATION

The analytical system is calibrated by analysing a series of standards at the start of each run. This set of calibration standards must be identified by the computer program and identification is based on the difference in transmission units between the height of consecutive standard peaks. The differences detected by the computer are compared with a prescribed pattern of/

of minimum differences which form the characteristics of a standards search procedure.

The minimum differences used to define this pattern are expressed in units of (1 - T/100) for 'troughs' and (T/100) for 'peaks', where T is the percentage transmission reading for the peak maximum. The numerical value stored as a parameter is preceded by a positive or negative sign to indicate an increase or decrease in transmission units. For the minimum difference to be checked both peaks must be acceptable; if one peak is faulty the appropriate error message is output on the on-line Teletype.

The first calibration standard may be preceded by a standard to trigger off the peak timing sequence followed by a sample of water to prevent carry-over to the first standard (Fig. 29); the computer has been programmed to ignore these samples when performing a standards search routine. The use of a 'trigger' standard to start the peak timing is more satisfactory than the use of the first calibration peak for this purpose as the latter is frequently small and rounded in shape. The water sample, in addition to preventing interaction, serves to check the error message routine, as/

as there should be a fault recognition message reporting a delay in finding a peak following the 'trigger' sample.

The minimum differences used for standards identification were evaluated by analysing a large number of calibration curves, each assessed and considered to be acceptable for calibration purposes, and which had been produced during several months routine operation of the AutoAnalyzer system. The minimum values for the first 7 differences in peak height between successive standards were used as the minimum difference characteristics. The eight difference in peak height which is the difference in transmission units between the eight calibration standard and a buffer sample placed between the final calibration standard and the drift correction standard (Fig. 29), was set to a small negative value to indicate a decrease in peak height and facilitate the standards search procedure. For total protein, albumin and protein blank channels, only six standards are used for calibration and hence the sixth difference is set to a negative value.

When composite calibration standards are used, two consecutive standards may have the same concentration, in which case the minimum difference is given the value

+0/

+0 to indicate that the difference is approximately zero. A minimum difference code of +1 is used to indicate that the difference between two peaks is not checked but both peaks must be checked for acceptability since they form part of the calibration curve. The code +2 indicates that no checking is required and one or both peaks can be faulty since they are not used in the calibration of the test channel. The minimum differences search routine is terminated by a value of +3. A complete list of the minimum differences used for each AutoAnalyzer test is given in Appendix VII.

When the program detects a calibration curve, the peaks are sorted into ascending order of concentration and the validity of the curve is checked by applying the following criteria:-

(1) The heights of individual calibration standards measured in transmission units (1 - T/100) must fall within specified limits.

(2) Gradients between the peak maxima of adjacent pairs of standards forming part of the overall curve must fall within specified limits; these gradients express the relationship between the change in signal generated/

generated as a result of analysing pairs of standards and the difference in concentration between the corresponding pairs of standards (shown in the left-hand inset to Fig. 30 as $\triangle$ T/$\triangle$C).

(3) Changes in gradients between successive segments of the calibration curve must fall within specified limits (shown in the right-hand inset to Fig. 30).

If a calibration curve falls within acceptable limits, a message is output on the on-line teleprinter (e.g. 'CHN 12 ACCEPTED') indicating that the standard curve for the test channel (channel 12) has been accepted and the peak values have been stored. The program allows for the possible use of a calibration curve in which either the top or the bottom standard is rejected, or else one of the intermediate standards is faulty. The nature of the fault is output on the Teletype - 'MSG 62 XY' (end standard faulty) or 'MSG 63 XY' (middle standard faulty) and the operator must reply to indicate whether the imperfect calibration curve is to be used, repeated or cancelled. If a middle standard is faulty and the calibration curve is used, then the faulty/

ELEMENTS OF CALIBRATION CURVE VALIDATION PROGRAM

Each peak is examined by the peak recognition program

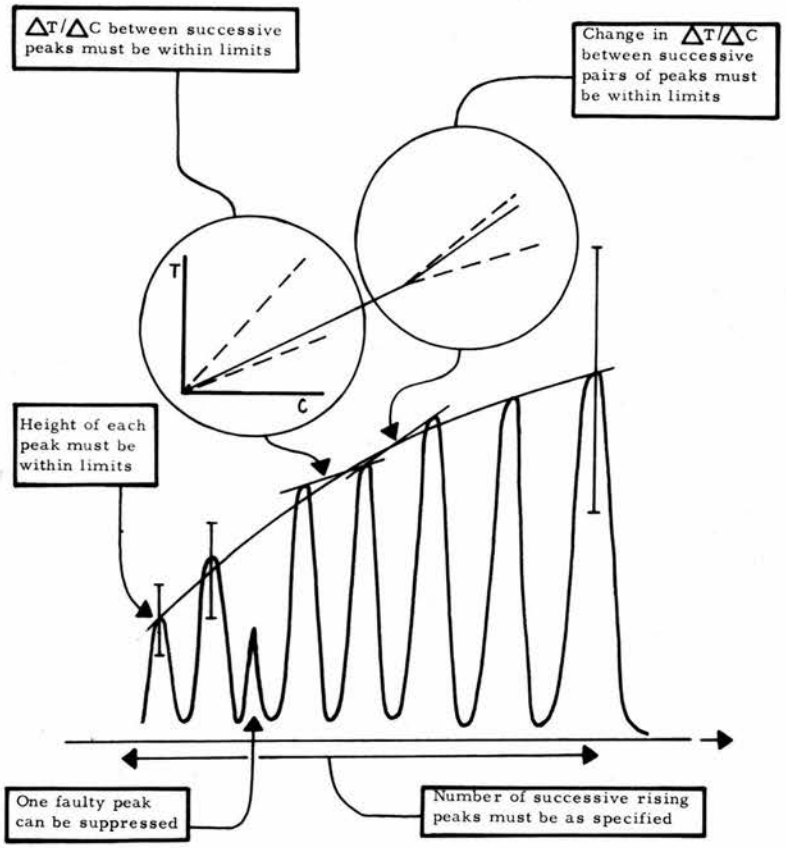


Fig. 30

faulty peak is replaced by a peak estimated by linear interpolation. If an end standard (first or last standard) is faulty and the curve is used, then the peak is rejected and a shortened standard curve is used for that particular run of analyses. This means that if the lowest standard is faulty, any patient specimen that is lower than the second lowest standard is treated as too low. Similarly, if the highest standard is faulty, any specimen that is higher than the second highest standard is treated as too high.

If the peak heights, gradients or changes in gradients are outside prescribed limits, the operator is informed by a message on the on-line teleprinter, e.g. 'MSG 64 XY ABC' where XY is the channel number and ABC indicates the parameter where the check failed (Fig. 31). For peak position low or high AB = PL or PH, for gradient low or high AB = GL or GH, and for difference in gradient low or high AB = DL or DH. The value of C gives the number of the parameter where the check failed (C = 1 - 8). In this case the calibration curve is inspected on the chart record and a decision taken whether to instruct the computer to use this curve or to discontinue monitoring the channel.

If/

```
<<CHN 32 ACCEPTED >>

MSG  41  12>

MSG 64 31 CL5 U>>

<<CHN 31 ACCEPTED >>

MSG 69 12 R><<RESTART SPECIMENS AT CUP 241>>

SET>>

SETTING UP PROCEDURES READY

GROUP 1B XXX
GROUP 1B ELU 230
12 U
13 NA
14 K
15 CL
16 CO2
←

FINISHED !
```

Standards Check Error Message

Change in Cup Number for Restart

Fig. 31

Input/Output on Control Teletype - Standards Check and Restart Messages

If the computer fails to detect a standard curve (i.e. two or more standards are faulty, or if one or more peak differences are less than the specified minimum values), then an error message (MSG 61 XY) is output and the calibration curve must be repeated using new standards. If four consecutive faulty peaks are detected before the standard curve has been accepted, the appropriate message (MSG 65 XY) is printed up on the on-line Teletype.

When error messages relating to calibration curve detection and validation (MSG 61-65) are output on the on-line teleprinter, the program waits for one minute for a reply by the operator. The reply is typed on the same line as the message in coded form (W>, C>, R> or U>) to indicate the wait, cancel, restart or use option that has been selected. This procedure is illustrated in Fig. 31 where the calibration curve on test channel 31 has been accepted after an error message indicating that the fifth gradient was too low (GL5).

If the operator has not been informed which option is to be selected and he wishes to be given another opportunity to reply to the message, then the wait option is entered and the standards search or check is temporarily/

temporarily abandoned by the computer until a further five peaks for that test have been read. In the case of error message 61 or 65, the search is then repeated for the standards, including in this search the new peaks; if a set of peaks corresponding to the standards still cannot be found, the error message is repeated. If the error message is 62-64, the standard check is repeated on the same peaks: the five later peaks read into the computer are not used at this stage. A second wait message causes the program to wait for five more peaks to be read, but after the third wait message the program waits for only one more peak. If the fourth wait option is selected, or if no reply is given, then the cancel option is taken and the message <<CHN XY CANCELLED>> is output on the Teletype.

If the cancel option is selected by the operator, on-line monitoring on the particular channel is discontinued and all unprocessed peaks for that channel are cancelled. The rest of the channels in the particular group carry on as usual. If the restart option is taken, the on-line switch on the analyser console must be switched off when all unprocessed peaks for the channels in the particular group are cancelled and/

and the message <<RESTART SPECIMENS AT CUP N>>, where N is the cup number of the first specimen, is printed up on the Teletype (Fig. 31). The operator may amend the number N if he wishes to restart at a cup number which is different from that output by the computer program (Fig. 31).

The action taken by the computer in response to a 'use' option depends on the particular error message. If 'use' is typed in reply to error message 61, the first three peaks are cancelled and the search for the standards is temporarily abandoned until a further three peaks have been read in. The search for the standards is then repeated and, if unsuccessful, the error message is repeated. Unless some spurious peaks have been detected at the start of the run, or some peaks have been left from a previous restart (i.e. if the analyser console was switched off too late), 'restart' and 'cancel' are the only useful options for error message 61.

If the 'use' option is taken after an error message 62, the faulty end peak is ignored and the reduced set of standards is checked. Providing the rest of the standards check, the reduced set is used. This means that, if the lowest standard is faulty, any patient sample/

sample that is lower than the second lowest standard is treated as too low. In the case of tests where extrapolation is allowed, e.g. total protein blank, no results for patient samples are lost if the end standard is faulty although the results may be slightly less accurate.

If 'use' is selected after an error message 63, the faulty peak is replaced by a peak estimated by linear interpolation. The revised set of standards is then checked and used if accepted. Input of a 'use' option after error message 64 indicates to the program that the standards found are acceptable and are to be used as they stand. If a 'use' option is selected after error message 65, all peaks up to and including these faulty peaks are cancelled and the search for the standards repeated when sufficient peaks have been read.

If an unacceptable reply is given to an error message 61-65 the letters 'XXX' are output and the error message is repeated on a new line. Failure to reply within a minute, or a gap of a minute between input of characters, causes the program to print out a reply 'N>' and select the 'wait' option.

Six sets of parameters are used for the validation of/

of calibration standards for each test channel (see Fig. 30): the parameters are classified as follows:-

(1) PKLOW — The lowest peak height for each standard measured in units of (1 - T/100) for 'troughs' or units of (T/100) for peaks.

(2) PKHIGH — The highest peak height for each standard measured in the same units as PKLOW.

(3) PKGLOW — The lowest value of the gradient between one peak and the next, i.e. $\triangle T/\triangle C$ where $\triangle T$ = difference in transmission units between successive peaks and $\triangle C$ = difference in concentration between successive standards.

(4) PKGHIG — The highest value of $\triangle T/\triangle C$ for each gradient.

(5) PKDLOW — The lowest value for the change in gradient between one gradient and the next.

(6) PKDHIG — The highest value for the change in gradient between one gradient and the next.

The/

The number of individual parameters in each set depends on the number of standards used for calibrating the test channel.

The limiting values for the standards validation parameters were initially determined by using data from at least 20 calibration curves for each channel; the curves were obtained during the routine operation of AutoAnalyzers over a period of several weeks before the computer system was installed in the laboratory. All curves used for this purpose were first scrutinised to ensure that they were analytically acceptable. Subsequently a considerable part of the data was modified on the basis of experience gained during the on-line monitoring of AutoAnalyzers with the computer system. The parameters in current use for the validation of calibration curves are listed in Appendix VII.

If the gradients and changes in gradients fall inside the prescribed limits, then the computer program outputs an acceptance message and proceeds with the processing of data from the analytical channel. In view of the heuristic approach adopted for the evaluation of calibration curve parameters, it is important/

important to obtain an estimate of the maximum error in concentration which could conceivably occur as a result of variation within permissible limits. The procedure employed for estimating the maximum error in concentration is illustrated in Fig. 32. The gradient between standards 1 and 2 must lie between the minimum value AG and the maximum value AD, and similarly the gradient between standards 2 and 3 must be between GC and DC. However, the 'change in gradient' parameters does not permit a gradient change of AG to GC nor of AD to DC and hence, as a result of this constraint, the peak maximum of standard 2 must fall within the range EF or the computer program will enter an error routine. It is possible to convert this difference in peak height ($\triangle T = E - F$) measured in transmission units (T/100 for peaks, 1 - T/100 for troughs) to a difference in concentration units ($\triangle X$) by constructing the appropriate calibration curve or using a simple mathematical relationship. The permissible range of concentration can then be expressed in the form $Y \pm \triangle X/2$, where Y is the true concentration. The value of $\triangle X/2$ expressed as a percentage of the true concentration (Y) has been calculated at several levels

of/

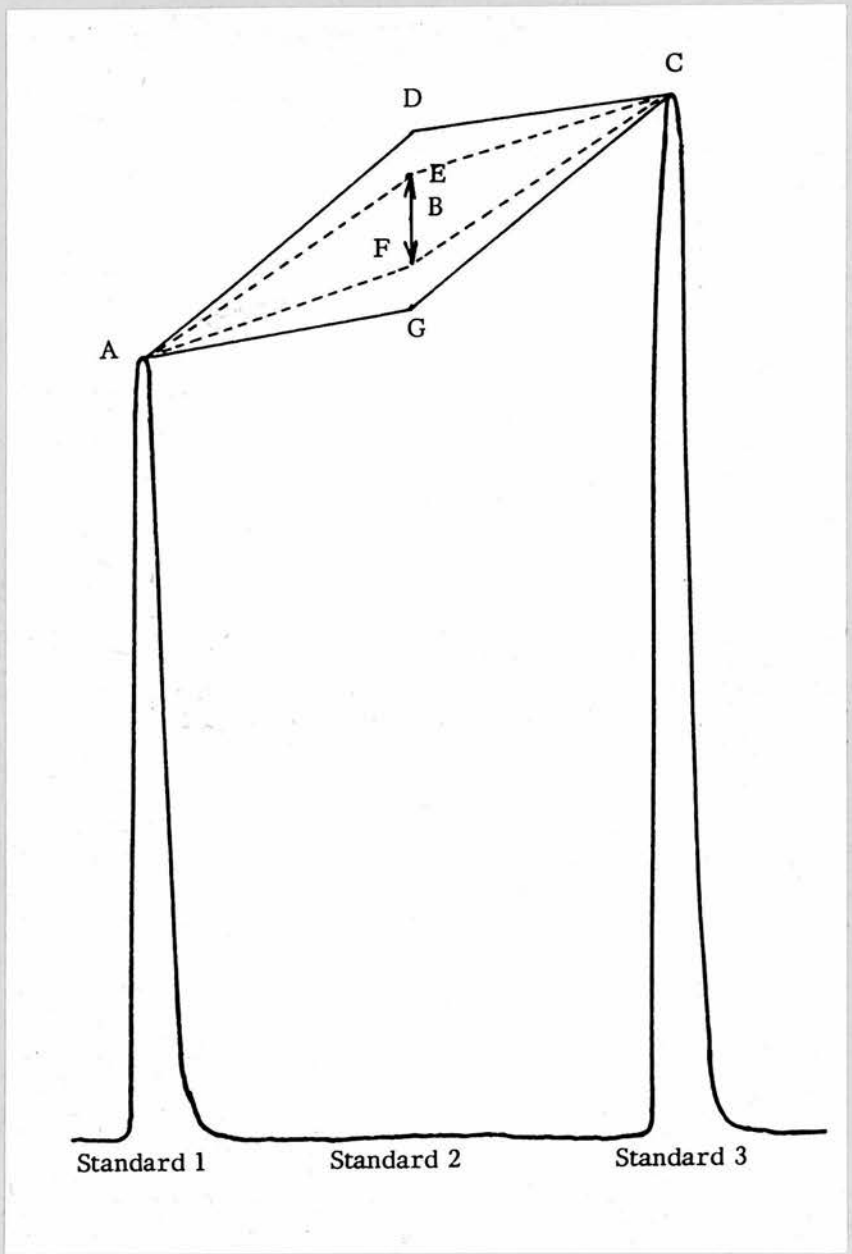


Fig. 32

Estimation of maximum variation in the peak height of calibration standards

of concentration for each analytical test channel monitored by the computer system, and the resulting figures are recorded in Table XIV.

Inspection of Table XIV reveals that for several tests the maximum error in the concentration of the calibration standards permitted by the 'change in gradient' parameters is appreciable by comparison with the coefficient of variation of the method. There are two main reasons for these relatively high values for the percentage error. Firstly, the day-to-day variability of AutoAnalyzer calibration curves due to changes in reagents, changes in the characteristics of pump tubes, dialyser membranes, etc., and possibly also due to variation in electrical and electronic components, makes it necessary to set fairly wide limits for check parameters. Secondly, wide limits are also required for tests which are calibrated by commercial control sera, e.g. total protein and albumin, since the concentration and hence the gradients and changes in gradients vary from one batch of serum to another. There are in addition several examples of isolated percentage errors which are grossly elevated, e.g. at the 2.0 meq./l. concentration level for potassium and the 50 mg/100 ml level/

TABLE XIV

CALCULATED MAXIMUM ERROR IN CONCENTRATION OF STANDARDS PERMISSIBLE BY CHECK PARAMETERS

Test (units)	Precision of Method *	Level of Conc.	Max. % Error in Conc.	Level of Conc.	Max. % Error in Conc.	Level of Conc.	Max. % Error in Conc.	Level of Conc.	Max. % Error in Conc.	Level of Conc.	Max. % Error in Conc.	Level of Conc.	Max. % Error in Conc.
Sodium meq./l.)	1.5%	100	2.4	110	1.6	120	1.9	130	1.5	140	1.1	150	1.4
Potassium (meq./l.)	2.2%	2.0	15.3	4.0	3.7	6.0	0.9						
Chloride (meq./l.)	2.1%	81	2.9	88	2.6	96	2.2	104	3.2	114	2.2		
Bicarbonate (meq./l.)	3.3%	10	2.7	20	4.1	30	6.6						
Urea (mg/100ml)	4.0%	30	4.8	50	12.8	100	4.5	150	5.2	200	5.0	250	4.6
Calcium (mg/100ml)	2.1%	4.0	6.1	6.0	6.6	8.0	4.8	10.0	2.1	12.0	3.6	14.0	2.5
Phosphate (mg/100ml)	5.4%	2.5	5.8	4.0	5.7	6.0	6.8	8.0	7.8	12.0	2.6	16.0	4.3
Alkaline Phosphatase (K.A. units/100ml)	5%	8	2.5	11	7.9	15	8.4	23	9.4	30	2.8	34	2.8
Bilirubin (mg/100ml)	8%	1.6	4.9	2.4	6.4	3.2	4.2	4.7	6.0	6.3	1.2	7.2	2.1
Total Protein (g/100ml)	1.9%	1.9	18.2	3.7	6.2	5.6	4.9	7.5	3.9				
Albumin (g/100ml)	2.4%	1.1	18.9	2.2	6.5	3.4	1.6	4.5	8.9				
Iron (µg/100ml)	6%	50	9.9	100	5.8	150	2.5	200	2.8	300	2.9	650	4.2
Iron-binding Capacity (µg/100ml)	6%	150	15.5	300	3.3	450	2.8	600	4.8				
Uric Acid (mg/100ml)	4%	3.0	4.7	4.5	1.7	6.0	2.4	7.5	1.7	9.0	4.5	120	2.8
Cholesterol (mg/100ml)	5%	100	4.8	150	4.5	200	4.4	250	5.6	300	6.9	400	3.9
Serum creatinine (mg/100ml)	7%	0.9	25.0	1.8	7.4	2.7	5.4	3.6	9.7	5.4	10.0	7.2	5.2
Urine creatinine (mg/100ml)		40	7.2	60	4.9	80	6.9	100	4.8	120	4.4	160	2.5

* Precision expressed as coefficient of variation calculated at mid-point of normal range

level for urea. This would appear to be a function of the shape of the calibration curve in the case of urea, but it is more difficult to explain this finding for potassium.

The information gathered by this experiment indicates that there are limitations to the usefulness of computer validation of calibration curves based on a system of linear interpolation. It must be emphasised, however, that the data collected in Table XIV had been obtained by theoretical considerations, and the probability of such errors occurring in practice is low. Nevertheless, it would appear that the checking of calibration curves by visual inspection is an important part of curve validation.

(C) DRIFT CORRECTION

Before calculating the concentration of patient specimens, the computer program corrects the height of the peaks for instrumental drift. The drift correction procedure makes use of drift standards placed at regular intervals (cup positions 10,20,30, etc.) throughout the analytical run. In the original version of the drift correction program the drift standard had

to/

to have the same concentration as one of the standards in the calibration curve, but this has since been modified to permit the use of pooled serum for drift correction.

On the completion of each batch of ten analyses, the computer program compares the height of the latest drift standard with the previous drift standard and also with the first drift standard for the run. The two differences in peak heights are then compared with preset maximum limits for instrumental drift and, if the observed values fall within acceptable limits, the height of each peak relative to the drift standard is calculated.

If no drift occurs between two adjacent drift standards the peak heights of the nine specimens between the drift standards are reduced to the drift standard base line by subtracting the height of the drift standard (Fig. 33). The peak height now becomes (P - S) where P and S are in transmission units: the values obtained are used for the calculation of concentrations.

If drift takes place, the drift slope in the interval between adjacent drift standards D_1 and D_2 is computed, and the height of each peak in the interval between these standards is reduced or increased by an amount depending on the drift slope AB (Fig. 34). If

a/

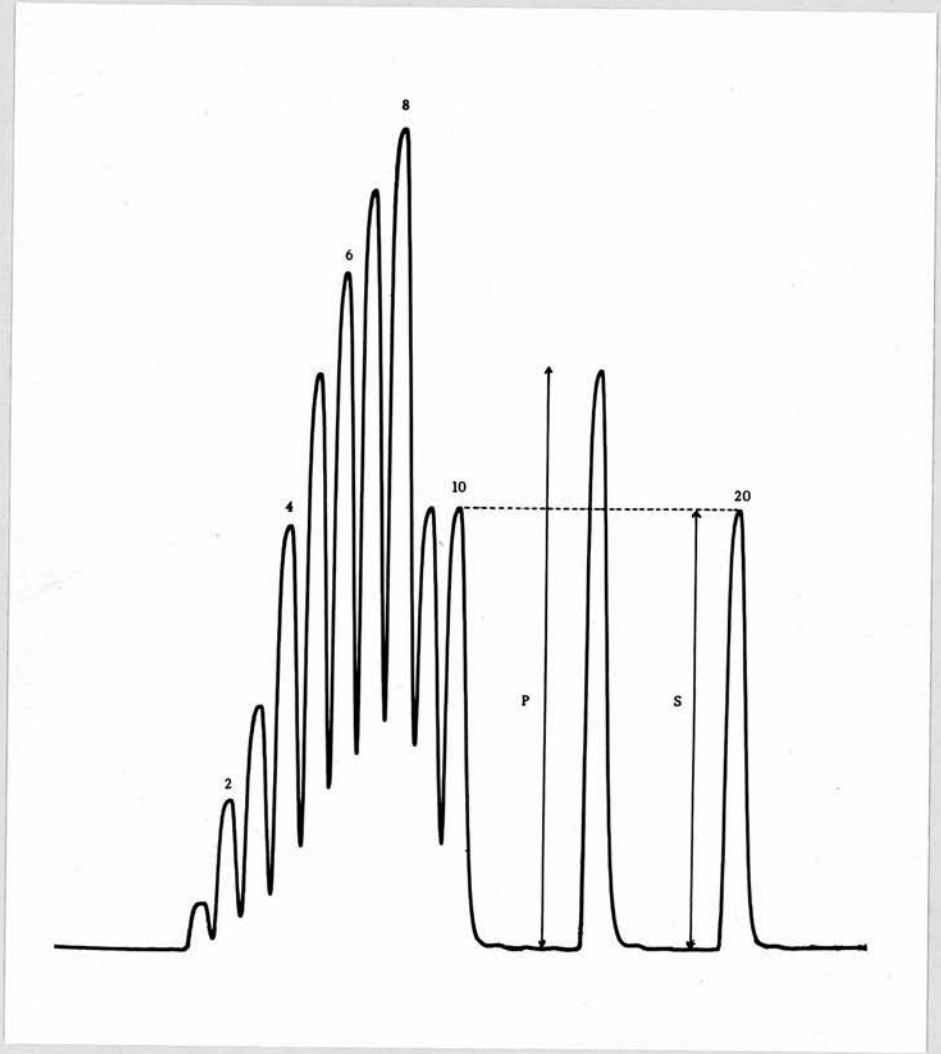


Fig. 33

Calibration of AutoAnalyzer
Test Channel

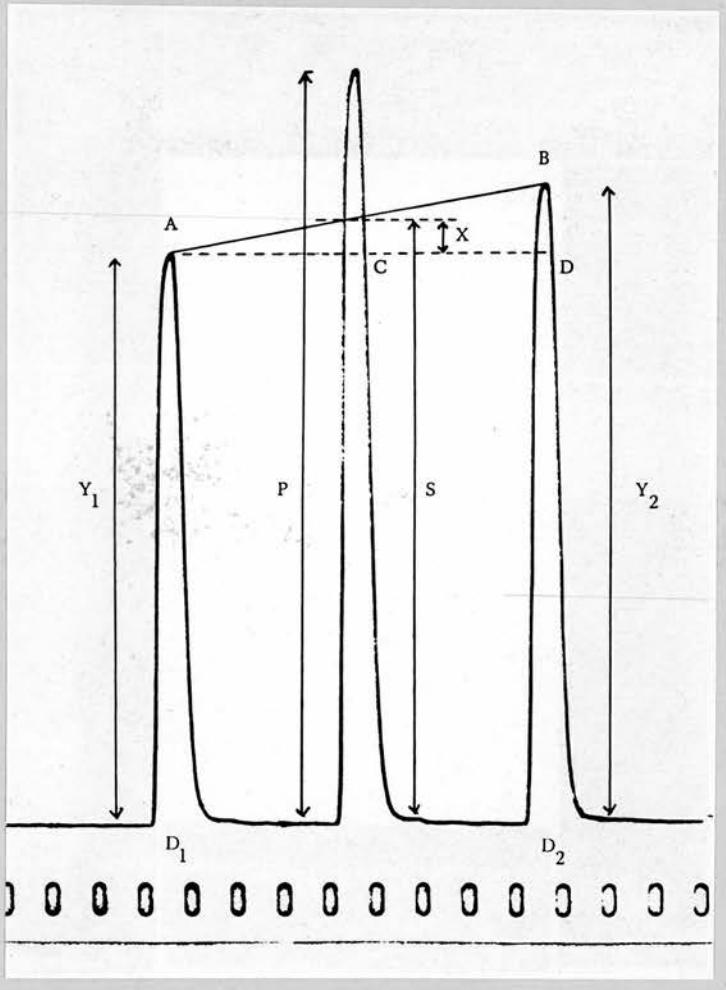


Fig. 34

Correction of peak height for instrumental drift

a linear correction based on peak height is used, the drift corrected peak height (P') can be calculated as follows:-

$$P' = P - S = P - Y_1 - X$$

$$\text{but } \frac{X}{(Y_2 - Y_1)} = \frac{AC}{AD} \quad \text{(similar triangles)}$$

$$\therefore \quad P' = P - Y_1 - \frac{AC}{AD} \times (Y_2 - Y_1)$$

where AC represents the time interval between D_1 and the patient specimen, and AD is the time interval between D_1 and D_2. A percentage correction based on peak height may be carried out in a similar manner by using the following relationship:-

$$P' = P - Y_1 - \frac{AC}{AD} \times (Y_2 - Y_1) \times \frac{(1 - P)}{(1 - Y_1)}$$

where P and Y_1 are the peak heights in (1 - T/100) units.

The drift corrected peak heights are then interpolated against the calibration standards using a linear interpolation procedure, and the concentrations of the specimens calculated as follows:-

$$C = \frac{(P' - H_1)}{(H_2 - H_1)} \times (C_2 - C_1)$$

where/

where C is the calculated concentration, P' is the drift corrected peak height, H_1 and C_1 are the peak height and concentration of the standard below the specimen, and H_2 and C_2 are the peak height and concentration of the standard above the specimen (Fig. 35).

If the peak height of a drift standard is outside allowable limits, a message is output on the on-line Teletype to which the operator must reply by indicating whether to wait, use, restart or cancel. The wait, restart and cancel options have the same effect as in the case of standards check error messages 62-64 (see Standards Identification and Validation), but the effect of the use option depends on the particular error message. Drift correction error messages provide the following information:-

(1) The first drift standard, i.e. the drift standard in cup number 10, is faulty (MSG 67). If 'use' is typed, drift correction is applied between the standard in the calibration curve with the same concentration as the drift standard, and the second drift standard.

(2) The peak height of the latest drift standard is too/

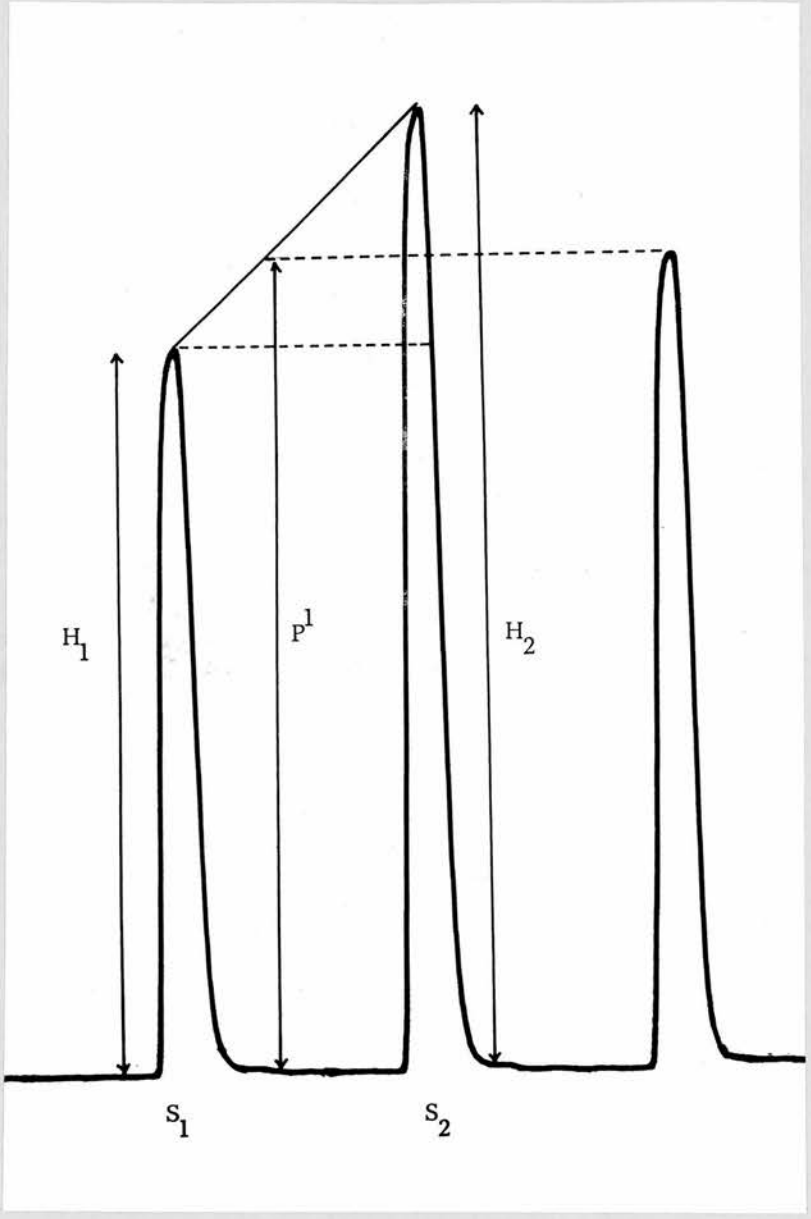


Fig. 35

Calculation of concentration
from peak height

too high by comparison with the height of the first drift standard of the run (MSG 70). If the use option is selected the drift standard is treated as a faulty peak and the calculations are delayed until the next drift standard is read in; the concentrations are then calculated over the double interval. If a double interval is already being used, the calculations are performed assuming zero drift from the last correct drift standard. This option should be selected only after careful inspection of the chart record.

(3) The peak height of the latest drift standard is too low by comparison with the height of the first drift standard of the run (MSG 71). The effect of the use option is the same as described for error message 70.

(4) The difference between the current drift standard and the latest acceptable drift standard is too great (MSG 72). The use option has the same effect as for error message 70.

(5) The latest drift standard is faulty and a double interval cannot be assumed since this has already been used (MSG 68). The use option which assumes zero drift from the last correct drift standard should be selected only after inspection of the chart record.

It is essential to exercise care in the application of the 'use' option to drift errors. This reply should be selected only when a drift standard is faulty or when, as a result of a plate-loading error, the wrong sample has been placed in the position normally occupied by a drift correction standard. If the 'use' option is taken when instrumental drift has exceeded the permissible limits then the assumption of zero drift will lead to incorrect results. The magnitude of the errors will depend on the degree of instrumental drift, but they could give rise to significant errors in the calculated concentrations.

In order to check for instrumental drift the computer software makes use of two parameters:-

(1) DRFDIF, twice the maximum drift allowable between a drift standard and the first drift standard in the calibration curve.

(2) MAXDRF, the maximum drift allowable between consecutive drift standards. The cup number of the drift standard in the calibration curve must also be specified in the list of parameters.

The/

The drift correction parameters are different for different channels, and they were evaluated initially by using data collected during routine operation of the AutoAnalyzers over a period of several months. As in the case of peak detection and standards validation parameters, drift correction parameters were modified after gaining practical experience of the routine operation of the computer system. The drift correction parameters currently in use are recorded in Appendix VII.

(D) ASSESSMENT OF CHEMICAL ACCEPTABILITY

The analytical acceptability of the computer system was assessed by several methods including paired comparisons between the results of analyses of patient specimens and quality control samples, the analyses being carried out first with AutoAnalyzers operating under routine laboratory conditions and then repeated on a second AutoAnalyzer system which was monitored by the computer. The standard deviations based on the difference between the pairs of analyses performed, the corresponding correlation coefficients and the slope and intercept of the regression lines were determined and are listed in Table XV. The calculated coefficients indicate/

TABLE XV

PAIRED COMPARISONS OF ANALYTICAL PERFORMANCE[1]

Analysis	Method *	No. of Paired Observations (n)	Standard Deviation (SD) $SD = \sqrt{\frac{(\Sigma \text{difference}^2)}{2n}}$	Correlation Coefficient	Regression Equation Y = MX + C		Concentrations Over Which Paired Comparisons Made
					Slope (M)	Intercept (C)	
Plasma or Serum							
Urea	A	553	3.31 mg/100ml	0.99	0.96	2.34	10-300
Sodium	N21BII	604	1.38 meq./l.	0.92	1.00	0.05	114-156
Potassium	N21BII	594	0.15 meq./l.	0.98	1.01	0.06	2.4-7.7
Chloride	N21BII	302	2.20 meq./l.	0.94	1.04	-4.63	84-115
Bicarbonate	N8B	601	2.78 meq./l.	0.96	0.86	-0.08	10-36
Alkaline Phosphatase	B	54	0.28 K.A. units/100ml	0.99	0.95	0.43	5-30
Bilirubin	N12	56	0.07 mg/100ml	0.99	0.94	0.10	0.2-8.0
Calcium	C	80	0.18 mg/100ml	0.90	0.96	0.27	8.0-12.0
Phosphate	D	145	0.25 mg/100ml	0.99	0.95	0.08	1.9-11.4
Total Protein	N14B	124	0.11 g/100ml	0.99	0.99	0.18	1.8-9.3
Total Protein Blank	N14B	71	0.03 g/100ml	0.90	1.03	0.01	0.1-1.1
Albumin	E	124	0.10 g/100ml	0.98	0.94	0.28	1.3-5.2
Creatinine	N11B	104	0.16 mg/100ml	0.99	0.99	-0.08	0.5-9.4
Cholesterol	N24A	113	6.6 mg/100ml	0.98	0.96	9.91	119-365
Uric Acid	F	111	0.38 mg/100ml	0.99	1.03	-0.12	2.6-13.9
Iron	G	107	6.2 µg/100ml	0.99	0.99	-1.45	22-455
Iron-binding Capacity	G	111	14.4 µg/100ml	0.98	1.00	-7.66	165-645
Urine - Creatinine	N11B	76	1.9 mg/100ml	0.99	1.05	-0.97	29-198
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

(1) [illegible] by the department's routine methods, in response to requests received by the laboratory. Analyses were repeated the next day, using AutoAnalyzers on-line to the Elliott 903 computer and the computer-calculated results were compared with the previous day's results. The overnight delay before repetition of analyses partly accounts for the discrepancies between pairs of bicarbonate analyses.

* Where the method used does not differ from the Technicon N-method description, the code number is given in full. References for the others as follows:-

A. Marsh, W.H., Fingerhut, B. and Miller, H. (1965). Clin. Chem., 11, 624-627.
B. Sterling, R.E., Wilcox, A.A., Ware, A.G. and Umehara, M.K. (1964). Clin. Chem., 10, 1112-1116.
C. Gitelman, H.J. (1967). Analyt. Biochem., 18, 521-531.
D. Young, D.S. (1966). J. clin. Path., 19, 397-399.
E. Northam, B.E. and Widdowson, G.M. (1967). Assoc. clin. Biochem., Tech. Bull. No. 11.
F. Crowley, L.V. (1964). Clin. Chem., 10, 838-844.
G. Young, D.S. and Hicks, J.M. (1965). J. clin. Path., 18, 98-102.

indicate very good correlation between the two sets of results while the regression slopes, with the exception of the values for bicarbonate and urine phosphate, closely approach unity. In the case of bicarbonate the diminished slope can be attributed to the fact that the second analysis was performed on the next day and, although the specimen cups were capped and stored overnight in a refrigerator, no special action was taken to prevent the escape of carbon dioxide. There does not appear to be any satisfactory explanation for the low regression slope for urine phosphate, particularly in view of the fact that this phenomenon is not observed in the case of serum phosphate which was assayed by the same automated procedure. The values for the regression intercepts are variable but for most analyses are small; where the intercept is of appreciable magnitude, e.g. cholesterol and iron-binding capacity, the scatter diagram reveals a wide distribution of results.

A measure of the precision of the computer system can be obtained by comparing the standard deviations based on the difference between pairs of analyses performed, first by the department's routine methods and repeated next day using AutoAnalyzers on-line to the computer with

between/

between-batch comparisons for analyses carried out by routine methods and repeated the next day using the same methods (Table XVI). The standard deviations listed in Table XVI show good agreement between the two sets of analytical data, indicating that the computer-calculated results are at least as precise as the results obtained by manual reading of recorder charts.

A similar set of comparisons of computer-calculated results with results obtained by the standard methods of processing data from AutoAnalyzers, in which both groups of results were derived from the same analytical run, were also carried out and the results are given in Table XVII. The importance of this latter set of comparisons lies in the fact that the chart records provide the back-up system in the event of computer failure. The results in Table XVII indicate that changes in the optimum settings of the colorimeter controls (Section II(D)) do not appear to affect the manual processing of AutoAnalyzer peaks on the chart recorder tracing. The decrease in the magnitude of the standard deviation in Table XVII, as compared to the values given in Table XV, indicates closer agreement in the set of analytical comparisons in Table XVII; these

latter/

TABLE XVI

PRECISION OF PAIRED COMPARISONS BETWEEN COMPUTER-CALCULATED AND ROUTINE RESULTS AND BETWEEN REPEAT ANALYSIS BY ROUTINE METHODS

ANALYSIS	COMPUTER CALCULATED/ROUTINE RESULTS			REPEAT ANALYSIS BY ROUTINE METHODS		
	NO. OF PAIRED OBSERVATIONS (n)	STANDARD DEVIATION (SD)*	RANGE OF CONCNS. OVER WHICH PAIRED COMPARISONS MADE	NO. OF PAIRED OBSERVATIONS (n)	STANDARD DEVIATION (SD)*	RANGE OF CONCNS. OVER WHICH PAIRED COMPARISONS MADE
Plasma or Serum						
Urea	553	3.31 mg/100ml	10-300	90	2.8 mg/100ml	14-80
Sodium	604	1.38 meq./l	114-156	121	1.6 meq./l	122-148
Potassium	594	0.15 meq./l.	2.4-7.7	120	0.15 meq./l.	2.5-7.6
Chloride	302	2 20 meq./l.	84-115	107	1.5 meq./1.2 2 meq./l.	77-116
Bicarbonate	601	2.78 meq./l.	10-36	121	2.2 meq./l.	13-37
Alkaline phosphatase	54	0.28 K.A. units/100ml	5-30	76	0.97 K.A. units/100ml	5-30
Bilirubin	56	0.07 mg/100ml	0.2-8.0	87	0.13 mg/100ml	0.2-8.0
Calcium	80	0.18 mg/100ml	8.0-12.0	40	0.37 mg/100ml	7.3-12.2
Phosphate	145	0 25 mg/100ml	1.9-11.4	42	0.28 mg/100ml	2.0-14.1
Total protein	124	0.11 g/100ml	1.8-9.3	92	0.14 g/100ml	4.3-8.4
Total protein blank	71	0.03 g/100ml	0.1-1.1	-	-	-
Albumin	124	0.10 g/100ml	1.3-5.2	91	0.13 g/100ml	1.5-5.0
Creatinine	104	0.16 mg/100ml	0.5-9.4	27	0.17 mg/100ml	0.6-5.8
Cholesterol	113	6.6 mg/100ml	119-365	45	10.1 mg/100ml	140-420
Uric acid	111	0.38 mg/100ml	2.6-13.9	27	0.28 mg/100ml	2.4-14.1
Iron	107	6 2 µg/100ml	22-455	38	7.8 µg/100ml	15-480
Iron-binding capacity	111	14.4 µg/100ml	165-645	33	24.3 µg/100ml	185-615

$$*SD = \sqrt{\frac{(\Sigma \text{difference}^2)}{2n}}$$

TABLE XVII

PAIRED COMPARISONS OF METHODS OF CALCULATING RESULTS [1]

ANALYSIS	NO. OF PAIRED OBSERVATIONS (n)	STANDARD DEVIATION (SD) $SD = \sqrt{\frac{(\Sigma difference^2)}{2n}}$	RANGE OF CONCENTRATIONS OVER WHICH PAIRED COMPARISONS MADE
Plasma or Serum			
Urea	584	2.26 mg/100ml	10-300
Sodium	600	0.66 meq./l.	114-156
Potassium	589	0.05 meq./l.	2.4-7.7
Chloride	298	0 74 meq./l.	84-115
Bicarbonate	572	0.53 meq./l	10-36
Alkaline phosphatase	57	0.47 K.A. units/100ml	3-20
Bilirubin	47	0 05 mg/100ml	0.4-3.3
Alanine aminotransferase	103	1 42 Reitman Frankel units	11-94
Calcium	167	0.16 mg/100ml	3.9-13.3
Phosphate	87	0.11 mg/100ml	2.1-10.8
Total protein	89	0.11 g/100ml	3.7-9.0
Total protein blank	43	0.03 g/100ml	0.1-0.9
Albumin	64	0.05 g/100ml	1.5-5.5
Creatinine	55	0.06 mg/100ml	0.5-8.6
Cholesterol	192	4.13 mg/100ml	124-465
Uric acid	95	0.15 mg/100ml	2.4-10.7
Iron	40	2.03 µg/100ml	51-312
Iron-binding capacity	71	5 4 µg/100ml	151-800
Urine - Creatinine	67	1.23 mg/100ml	37-195
Phosphate	26	0.63 mg/100ml	17-60

(1) Standard deviations between paired calculations of results for single specimens when the Hilger analyser console was being used to transmit signals to the Elliott 903 computer. The comparisons are between (1) results calculated from the chart records by standard methods of calculation, and (2) results printed out after the computer had performed its calculation. The close agreement shows that the chart records can be used for back-up purposes.

latter are not subject to between-batch variation.

A comparison of the accuracy of the computer processed results with results obtained by reading off peaks from the recorder charts is reflected in the correlation coefficients and regression constants in Table XV. This aspect was further investigated by comparing the mean values obtained for patient specimens, commercial control sera and laboratory pooled serum analysis, first by AutoAnalyzers operating under routine laboratory conditions and then repeated with the computer system in operation. The mean values for patient specimens and samples of pooled serum assayed for urea and electrolytes are given in Table XVIII. The lower mean values for bicarbonate can be explained by the fact that the analyses using the computer were carried out on the day after the analyses performed on the equipment in routine laboratory use. The two sets of mean values show excellent agreement indicating comparable accuracy by the two methods.

All the statistical calculations described above were performed on the 903 computer using a SIR statistical program written by the author.

(E)/

TABLE XVIII

COMPARISON OF MEAN VALUES FOR SAMPLES ANALYSED BY COMPUTER AND ROUTINE METHODS

TEST	PATIENT SPECIMENS			POOLED SERUM		
	NO. OF PAIRED OBSERVATIONS	MEAN VALUES		NO. OF PAIRED OBSERVATIONS	MEAN VALUES	
		COMPUTER SYSTEM	ROUTINE METHODS		COMPUTER SYSTEM	ROUTINE METHODS
Sodium	602	139.4	139.0	50	139.1	139.0
Potassium	595	4.24	4.24	50	4.60	4.60
Chloride	603	102.0	102.0	50	102.2	102.6
Bicarbonate	536	21.6	25.1	43	15.2	17.7
Urea	501	38.4	37.6	44	46.2	46.5

(E) MARKING SELECTED RESULTS ON CUMULATIVE REPORTS

The computer program automatically checks all results before output to cumulative reports, and prints an asterisk to mark results which may require special attention. If a first test result falls outside a prescribed range of concentration, or if a subsequent result differs significantly from a previous result, then the result is marked with an asterisk. The concentration ranges used for first results were initially based on the patient mean $\pm$ (2 x 'analytical' standard deviation + 2 X 'patient' standard deviation) where the 'analytical' standard deviation is a measure of the methodological precision and the 'patient' standard deviation is the value used to calculate the 'normal' range for the particular test. Some of the ranges have been modified to accord more closely with the clinical interpretation of results.

In defining a significant difference between successive results a change of $\pm$ (4 x 'analytical' standard deviation) was selected as this represents the maximum change possible within 95% probability limits. The calculated value does not take into account any physiological variation; if this variation is small compared/

compared to methodological variation then the suggested asterisk level should be satisfactory, but if the reverse is true then the asterisk denoting a significant change will be of limited value.

The frequency with which results are marked with an asterisk using the above criteria was estimated by checking a sample of 1,240 report forms having one set of results. It was observed that 46% of the reports had at least one result marked by an asterisk, while in a similar sample of cumulative reports 88% had at least one asterisk. A more detailed investigation was carried out on the number of individual results marked by asterisks and this information is summarised together with the appropriate asterisk ranges in Tables XIX and XX.

A large proportion of patients admitted to hospital have a sample of blood collected for the analysis of electrolytes, and hence the percentage of results marked by an asterisk is low (4-17%). This percentage tends to increase (6-36%) for subsequent results since more patients in this group are likely to have developed some form of electrolyte imbalance (e.g. postoperatively) and may be receiving therapy. The relatively high proportion of urea results marked with an asterisk is probably/

TABLE XIX

USE OF ASTERISKS TO MARK FIRST TEST RESULT

TEST	UNITS	ASTERISK RANGE	TOTAL NO. OF RESULTS	NO. OF ASTERISKS	%
Urea	mg/100ml	<14 or >50	376	131	35
Sodium	meq./l.	<130 or >153	376	16	4
Potassium	meq./l.	<3.4 or >5.6	379	65	17
Chloride	meq./l.	<92 or >111	376	35	9
Bicarbonate	meq./l.	<18 or >34	377	43	11
Ion difference	-	<12 or >24	368	55	15
Iron	µg/100ml	M <60 or >200 F <45 or >180	174	81	47
Iron-binding capacity	µg/100ml	<200 or >450	143	24	17
Cholesterol	mg/100ml	<120 or >290	114	22	19
Uric acid	mg/100ml	M <2.0 or >8.0 F <2.0 or >7.0	154	47	31
Total protein	g/100ml	<5.5 or >8.5	181	62	34
Albumin	g/100ml	<3.0 or >5.0	183	72	39

M = Male
F = Female

TABLE XX

USE OF ASTERISKS TO MARK SUBSEQUENT TEST RESULTS

TEST	UNITS	4 x ANALYTICAL STANDARD DEVIATION	TOTAL NO. OF RESULTS	NO. OF ASTERISKS	%
Urea	mg/100ml	± 16% (C of V)	284	134	47
Sodium	meq./l.	8.8	287	18	6
Potassium	meq./l.	0.4	288	104	36
Chloride	meq./l.	8.8	287	18	6
Bicarbonate	meq./l.	3.6	287	73	25
Iron	µg/100ml	28	20	6	30
Iron-binding capacity	µg/100ml	96	17	7	41
Cholesterol	mg/100ml	36	10	6	60
Uric acid	mg/100ml	0.6	82	39	48
Total protein	g/100ml	0.5	42	7	17
Albumin	g/100ml	0.4	42	8	19

probably mainly due to the hospital population including a renal clinic and a considerable number of geriatric patients. The other tests listed in Tables XIX and XX are less likely to be performed as a routine procedure and hence a greater number of 'abnormal' results is observed than in the case of electrolytes.

Ranges used for exception marking must be set in such a way that the number of results requiring special attention which are not marked by an asterisk is very small while the number of 'normal' results so marked is reduced to a minimum. If a large proportion of the results are marked by an asterisk then the indicator will lose its value and will fail to serve a useful function. The figures in Tables XIX and XX indicate that in terms of the percentage results marked the asterisk ranges appear to be satisfactory although it would be desirable to have a clinical assessment of the usefulness of the indicators. If the asterisk limits used for subsequent results were based on physiological variation in addition to methodological variation then the indicator would probably be more meaningful. The interpretation value could also be improved by using ranges adjusted for age and sex. At present, no correction is made for age/

age, and sex differences are used in only two ranges - serum iron and serum uric acid.

An alternative approach to the use of indicators is based on the percentage of results marked by an asterisk. A percentage, say 40%, is selected and asterisk ranges adjusted to satisfy this requirement; while such a procedure ensures that only a limited number of results are marked, the interpretation of the asterisk could be extremely difficult.

SECTION IV

OPERATION OF COMPUTER SYSTEM

(A) OPERATION AND DEVELOPMENT OF SYSTEM

The computer system was installed in June, 1968 and after software and hardware testing and development, the system was successfully used for the on-line monitoring of AutoAnalyzers in August of the same year. Throughout the period August to December, 1968, the computer system was operated in parallel with the routine laboratory methods and the information obtained used for an analytical assessment of the system (see Section III). In this initial stage of development, programs and test parameters were stored on paper tape and input to the computer via the paper tape reader. In December, 1968, the programming data was transferred to the magnetic tape backing store and work commenced on the input of patient and test request data by conversational mode and the preparation of work sheets. By April, 1969, this extended system was operational and up to 11 AutoAnalyzer channels on 4 analyser consoles were being successfully monitored at one time on-line to the computer.

An assessment of the performance of the computer system at this stage revealed that several processes occurred too slowly when the computer was attempting to carry out several functions on a time-sharing basis.

Substantial/

Substantial delays occurred when attempting to enter data from request forms once the computer was on-line to AutoAnalyzers, and these delays prevented the computer-dependent preparation of work sheets from keeping up with the AutoAnalyzer's rate of operation. Delays also occurred in the output of error messages if the computer was doing more than on-line monitoring and output via the tape punch of small batches of results unmatched with patient identification. The average time taken to input patient identification and test request data for 24 patients while monitoring 6-9 AutoAnalyzer channels was 23 minutes. The cup number of the specimen being sampled when a standards validation message was printed on the on-line teleprinter was in the range 15-23 and hence excluding the calibration and drift correction standards, 5-9 patient specimens had been sampled before the message was output. Even at this early stage of development it became apparent that the use of a conversational mode input would give rise to unacceptable delays in the operation of the system.

All the programs required for the system including those required for the preparation of cumulative records, checking of quality control samples, change cup numbers, etc./

etc. were tested and validated in the department by June, 1969. When an attempt was made to operate the fully integrated system there were unacceptable delays in the input of patient identification and test request data, and hence in the preparation of work sheets. These hold-ups were of sufficient magnitude to render impracticable the operation of the integrated system, and it was found necessary to abandon temporarily the preparation of cumulative reports; computer processing was therefore restricted to the preparation of work sheets for a limited number of tests, on-line monitoring of up to 11 AutoAnalyzer channels and the output of results, identified by cup number, on the paper tape punch.

A measure of the major delays encountered when using the fully integrated system is given by the time taken to input patient identification and test request data, issue computer-prepared work sheets, output cumulative reports, etc. The average time taken to input information from 24 request forms while monitoring 1-5 AutoAnalyzer channels increased to 36 minutes with a maximum of 58 minutes (Table XXIa). The values in Table XXIa show that the input time depends not only on the number of analyser channels/

channels being monitored but also on the length of the magnetic tape work file, the input time increasing with an increase in the number of blocks of data on the file. The average time taken for the preparation of work sheets was 4 minutes (Table XXIIa) and the number of patient specimens sampled before a standards validation message was output, increased to 7-10 specimens (Table XXIIIa). This number is only slightly affected by an increase in the number of channels being monitored or by an increase in the length of the work file. The average time taken to output 32 cumulative reports on the paper tape punch while monitoring 6-9 AutoAnalyzer channels was 11 minutes (Table XXIVa) but since this was not a time-sharing routine it was neither affected by the number of channels on-line to the computer nor by the number of blocks of data on the work file. Another 11 minutes were taken to print up a batch of 32 reports on the IBM printer when the computer was not doing on-line work (Table XXVa).

In an attempt to minimise the delays described above, the input and output programs and magnetic tape handling procedures were extensively modified.

Modifications/

TABLE XXI

TIME TAKEN TO INPUT PATIENT IDENTIFICATION AND TEST REQUEST DATA BY CONVERSATIONAL MODE

(A) Before Modification

NO. OF AUTOANALYZERS ON-LINE TO COMPUTER	TIME BETWEEN INPUT OF 'INN ' AND OUTPUT OF 'END OF INPUT'			APPROXIMATE NUMBER OF PATIENTS ON WORK FILE	
	AVERAGE (MINS.)	MINIMUM (MINS.)	MAXIMUM (MINS.)	START OF DAY'S RUN	END OF DAY'S RUN
0	19	14	22	0	300
1-5	22	14	27	0	300
6-9	24	21	27	0	300
0	30	25	37	70	350
1-5	36	22	58	70	350
6-9	*	*	*	70	350

(B) After Modification

NO. OF AUTOANALYZERS ON-LINE TO COMPUTER	TIME BETWEEN INPUT OF 'INN ' AND OUTPUT OF 'END OF INPUT'			APPROXIMATE NUMBER OF PATIENTS ON WORK FILE	
	AVERAGE (MINS)	MINIMUM (MINS)	MAXIMUM (MINS)	START OF DAY'S RUN	END OF DAY'S RUN
0	12	10	14	0	300
1-5	17	12	23	0	300
6-9	21	15	26	0	300
0	12	10	15	70	350
1-5	17	12	23	70	350
6-9	21	17	35	70	350

* No data available

TABLE XXII

TIME TAKEN FOR THE OUTPUT OF WORK SHEETS

(A) Before Modification

NO. OF AUTOANALYZERS ON-LINE TO COMPUTER	TIME BETWEEN INPUT OF 'WRK ' & OUTPUT OF PRINTED WORK SHEET			APPROXIMATE NUMBER OF PATIENTS ON WORK FILE	
	AVERAGE (MINS.)	MINIMUM (MINS.)	MAXIMUM (MINS.)	START OF DAY'S RUN	END OF DAY'S RUN
0	4	3	4	0	300
1-5	4	4	5	0	300
6-9	4	4	5	0	300
0	4	3	4	70	350
1-5	4	3	6	70	350
6-9	*	*	*	70	350

(B) After Modification

NO. OF AUTOANALYZERS ON-LINE TO COMPUTER	TIME BETWEEN INPUT OF 'ISS ' & OUTPUT OF PRINTED WORK SHEET			APPROXIMATE NUMBER OF PATIENTS ON WORK FILE	
	AVERAGE (MINS.)	MINIMUM (MINS.)	MAXIMUM (MINS.)	START OF DAY'S RUN	END OF DAY'S RUN
0	3	3	4	0	300
1-5	4	3	9	0	300
6-9	5	3	9	0	300
0	3	3	4	70	350
1-5	4	3	9	70	350
6-9	5	4	9	70	350

* No data available

TABLE XXIII

TIME TAKEN TO OUTPUT STANDARDS VALIDATION INFORMATION WHILE MONITORING AUTOANALYZER CHANNELS

(A) Before Modification

NO. OF UTOANALYZERS ON-LINE TO COMPUTER	CUP NO. OF SPEC. BEING SAMPLED WHEN 'CHN ACCEPTED' OUTPUT	NO. OF PATIENT SPEC. SAMPLED BEFORE 'CHN ACCEPTED' OUTPUT	APPROXIMATE NO. OF PATIENTS ON WORK FILE	
			START OF DAY'S RUN	END OF DAY'S RUN
1-5	17	7	0	300
6-9	17-19	7-8	0	300
1-5	17-19	7-8	70	350
6-9	20-22	8-10	70	350

(B) After Modification

NO. OF UTOANALYZERS ON-LINE TO COMPUTER	CUP NO. OF SPEC. BEING SAMPLED WHEN 'CHN ACCEPTED' OUTPUT	NO. OF PATIENT SPEC. SAMPLED BEFORE 'CHN ACCEPTED' OUTPUT	APPROXIMATE NO. OF PATIENTS ON WORK FILE	
			START OF DAY'S RUN	END OF DAY'S RUN
1-5	15-18	5-8	0	300
6-9	19-20	8	0	300
1-5	16-19	6-8	70	350
6-9	19-21	8-9	70	350

TABLE XXIV

TIME TAKEN TO OUTPUT CUMULATIVE REPORTS ON THE PAPER TAPE PUNCH

(A) Before Modification

NO. OF AUTOANALYZERS ON-LINE TO COMPUTER	TIME TAKEN FOR OUTPUT OF 32 REPORTS			APPROXIMATE NUMBER OF PATIENTS ON WORK FILE	
	AVERAGE (MINS.)	MINIMUM (MINS.)	MAXIMUM (MINS.)	START OF DAY'S RUN	END OF DAY'S RUN
0	*	*	*	0	300
1-5	11	10	13	0	300
6-9	11	10	13	0	300
0	11	10	13	70	350
1-5	11	10	13	70	350
6-9	11	10	13	70	350

(B) After Modification

NO. OF AUTOANALYZERS ON-LINE TO COMPUTER	TIME TAKEN FOR OUTPUT OF 45 REPORTS			APPROXIMATE NUMBER OF PATIENTS ON WORK FILE	
	AVERAGE (MINS.)	MINIMUM (MINS.)	MAXIMUM (MINS.)	START OF DAY'S RUN	END OF DAY'S RUN
0	13	12	16	0	300
1-5	13	12	16	0	300
6-9	13	12	16	0	300
0	13	12	16	70	350
1-5	13	12	16	70	350
6-9	13	12	16	70	350

* No data available

TABLE XXV

TIME TAKEN TO PRINT CUMULATIVE REPORTS ON IBM PRINTER

(B) Before Modification

NO. OF AUTOANALYZERS ON-LINE TO COMPUTER	TIME TAKEN FOR OUTPUT OF 32 REPORTS			APPROXIMATE NUMBER OF PATIENTS ON WORK FILE	
	AVERAGE (MINS.)	MINIMUM (MINS.)	MAXIMUM (MINS.)	START OF DAY'S RUN	END OF DAY'S RUN
0	11	10	13	0	300
1-5	-	-	-	0	300
6-9	-	-	-	0	300
0	11	10	13	70	350
1-5	-	-	-	70	350
6-9	-	-	-	70	350

- Reports could not be printed when computer was being used for other work)

(B) After Modification

NO. OF AUTOANALYZERS ON-LINE TO COMPUTER	TIME TAKEN FOR OUTPUT OF 45 REPORTS			APPROXIMATE NUMBER OF PATIENTS ON WORK FILE	
	AVERAGE (MINS.)	MINIMUM (MINS.)	MAXIMUM (MINS.)	START OF DAY'S RUN	END OF DAY'S RUN
0	15	14	16	0	300
1-5	32	22	40	0	300
6-9	*	*	*	0	300
0	15	14	16	70	350
1-5	32	22	40	70	350
6-9	*	*	*	70	350

* No data available

Modifications to the System

The modifications to the system can be summarised as follows:-

(1) Re-organisation of program blocks on magnetic tape was undertaken so that commonly used programs, e.g. 'Issue Work Sheets', were placed nearer the beginning of the file and programs which are normally used one after another, e.g. 'Input Patient Data' and 'Issue Work Sheets' were placed near each other on the magnetic tape master file. A complete list of the programs in re-arranged order is given in Appendix VI.

(2) The length of the first block of a program on magnetic tape was reduced from 1120 words to 512 words so that the program could be found and the first block transferred to the core store without an 'interrupt' from the central processor. When program blocks were 1120 words long, there were frequent delays because of 'interrupts' causing missed data transfers. Subsequent blocks of a program are not read so often and hence a block length of up to 2047 words was used.

(3) To prevent backspacing by too many blocks on magnetic tape, an internal reference was introduced. This/

This reference was used by the program search routine for checking how many blocks to backspace instead of using a fixed formula.

(4) The program search routine was modified to include a check of the program currently in store to prevent unnecessary re-reads of the same program from magnetic tape.

(5) The number of store locations available for programs and processing of patient data was increased by decreasing the fixed area of the store used for coding and shortening the level 4 queue by allowing options to be input from the teleprinter, e.g. 'Issue Work Sheets' and 'Output Cumulative Reports'.

(6) The number of patient records processed on each update of the work file was increased by 50% from 10 to 15.

(7) All patients with six-zero registration numbers (general practitioners' patients or patients for whom no registration number was available) were assumed to be new patients. In the initial phase of development all the current day's results for tests performed on specimens from a patient identified by a six-zero registration number were output on one report form.

When/

When a six-zero number was input the program searched the work file for all patients with this number and the identification data for each patient was printed out one set at a time for comparison with the request form. This procedure proved to be very slow and time-consuming especially towards the end of a day's run when up to 12 patients were identified by some of the codings, especially OOOOOOM and OOOOOOS, and hence the daily merging routine for these patients was discontinued.

(8) After the input of a batch of patient registration numbers, the numbers and any available identification data were output in registration number order instead of re-sorting to input order. This second sort was eliminated to reduce the time taken to input patient identification and test request data, but as a result of this modification the request forms had to be manually sorted by the operator. An example of the input of data by this modified procedure is shown in Fig. 36.

As a result of the modification in the procedure for handling records for patients identified by a six-zero number, two or more report forms each containing one/

```
INN>>

START INPUT


090323D 310193S 150508T 000000L 121018S 270943C 000009R 190833A
/ / / / / / / /
000000M 080642G 090212H 0202020
/ / / /
←


000000L LAW T M 13 - MFW>>
060270 L133 ELU T0900>>


000000M MANSON E F 9 ->>
- L134 ELU T0930>>


0202020/1 QCD - - QCD RIE -  Y>>
- L139 CAP>>

150508T/1 TALLOCH  F  M 21  RIE JSR  Y>>
- L121 C - S>>
- L122 CC V2400>>


000009R/1 RAC - - QCD RIE -  Y>>
- L102 C>>


090212H HUTTON M 18>
S=M>>
- L118 ELU>>


121018S SUTHERLAND M F - GP>>
050270 L100 PBI>>


090323D/1 DALLAS W  M 3  RIE HJM  Y>>
060270 L124 ELU T0830,E>>
```

Fig. 36

Input of Patient Identification and Test Request Data Using Modified Form of Conversational Mode

one set of results were output if two or more requests were received on any day from a patient identified in this way. However, only one request per day is received for most patients identified by a six-zero number, so the modified procedure has a negligible effect on the output while greatly reducing the time taken for the input of data. One disadvantage of the present system is the inability of the program to recall patient records identified by six-zero numbers for amendment of identification data or results, e.g. overwriting a high potassium result with a code to indicate that the specimen was haemolysed, before the preparation of printed reports.

An assessment of the effect of the modifications to the system revealed that the average input time for 24 patients while monitoring 6-9 AutoAnalyzer channels was reduced to 21 minutes (Table XXIb). The time taken to output 45 cumulative reports on the paper tape punch was 13 minutes (Table XXIVb); before modification the time taken to output 32 reports was 11 minutes, which is equivalent to 45 reports being output in 15.5 minutes. The average time taken to print up 45 reports on the IBM printer when the computer was monitoring 1-5 AutoAnalyzer/

AutoAnalyzer channels was 32 minutes, but this reduced to 15 minutes when the computer was not doing other work (Table XXVb); before modification of the systems programs this time-sharing facility for printing reports was not available. Modifications to the system software did not affect the output of work sheets (Table XXIIb) or AutoAnalyzer operation (Table XXIIIb).

Further Modification to the System

A further modification to the output procedure was made at a later date when the sorting of cumulative reports by the computer was greatly reduced. Previously reports had been sorted according to ward and hospital but this was found to be very time-consuming and of relatively limited value. Reports for quality control samples and patient reports marked with asterisks continued to be given priority but all other reports were output in registration number order. This modification reduced the average time taken to output reports on the punch by more than 50%, from 13 to 6 minutes, and there was also a considerable reduction in the time taken for the overall output routine, i.e. from the input of the program code on the on-line Teletype/

Teletype to the end of output on the punch (Table XXVI). The first part of the overall output routine, unlike the punching component, is dependent on the number of AutoAnalyzer channels on-line to the computer and the number of blocks of data on the work file.

Operation of the System

The modifications described above produced a significant decrease in the time taken for several procedures, as shown in Tables XXI - XXVI, but the overall saving in time was still not sufficient to permit the use of the fully extended system for all routine laboratory work. An analysis of the time taken for the various computer activities, excluding the monitoring of AutoAnalyzer channels, on an average working day on which 8 AutoAnalyzer channels were monitored simultaneously on-line to the computer, but the preparation of cumulative reports restricted to specimens for urea and electrolyte determinations, is given in Table XXVII. The data in Table XXVII was collected at a time when there were approximately 3,000 patient records on the master file. At the start of the day's operation there were 30 patient records on the work file and/

TABLE XXVI

OUTPUT OF CUMULATIVE REPORTS ON THE PAPER TAPE PUNCH

	NO. OF AUTOANALYZER CHANNELS ON-LINE TO COMPUTER	TIME TAKEN TO OUTPUT 45 REPORTS					
		BEFORE MODIFICATION			AFTER MODIFICATION		
		AVERAGE (MINS.)	MINIMUM (MINS.)	MAXIMUM (MINS.)	AVERAGE (MINS.)	MINIMUM (MINS.)	MAXIMUM (MINS.)
TIME FROM START OF OUTPUT ON PUNCH TO END OF OUTPUT	*	13	12	16	6	4	9
Time from input of program code on T/T to end of output	0	18	15	22	10	7	14
	1-5	20	17	26	12	8	19
	6-9	26	24	30	18	15	20

* The actual punching time is independent of the number of AutoAnalyzer channels on-line to the computer (see Table XXIV)

TABLE XXVII

AN ANALYSIS OF ONE DAY'S OPERATIONS PERFORMED BY THE COMPUTER
(USING CONVERSATIONAL MODE)

The computer is switched on at 0800 and switched off at approximately 1830. The data presented in this Table were collected at a time when there were approximately 3,000 patients on the master file. At the start of the day's operations there were 30 patients on the work file, and at the end of the day's analytical work there were 310 records on the work file prior to updating of the master file.

Activities indicated with an asterisk represent off-line activities. The column headed 'Percentage of total time' does not add up to 100%, since it does not include timings for the routine carried out when searching for and checking standard curves, nor for peak evaluation and output of peak detection and other error messages on the on-line Teletype, nor for updating of magnetic tape work files with test results. The detailed assessment of time spent in on-line monitoring of various aspects of AutoAnalyzer operation would also be difficult to assess.

PROCESS	TIME (HOURS MIN.)	PERCENTAGE OF TOTAL TIME
Testing and cleaning of computer and peripheral equipment	0.29	*
Setting-up procedures and reallocation of channels	0.30	4.7
Idle time (before specimens arrive in laboratory)	0.30	4.7
Input of patient and test request data (conversational mode)	3.14	30.4
Output of work load and work sheets	0.42	6.6
Pools error messages, emergency output, and change cup numbers routine	0.06	0.9
Input of manual results	0.12	1.9
Amendment to data on files (e.g. alterations in identifying data)	0.05	0 8
Accession of master file before output of cumulative reports	0.11	1.7
Output of results on paper tape punch	0.12	1.9
Output of cumulative reports to paper tape punch (270 reports)	1.30	14.1
Printing up of reports on IBM printer (time for a batch of 45 reports)	0.16	2.5
Printing up of reports on Teletype 35 (time for a batch of 45 reports)	0.32	*
Output of end of day summary to paper tape punch	0.25	3.9
Printing up of end of day summary on Teletype 35	1.10	*
Update master file and work file routine	0.24	3.8
Total time computer switched on	10.39	

and at the end of the day, this had increased to 310 before updating of the master file. The figures indicate that the two most time-consuming procedures in on-line operation are the input of patient data by conversational mode (30.4% of the total time) and the output of cumulative reports on the paper tape punch (14.1% of the total time). The third bottleneck, the transfer of data to and from the magnetic tape files, was closely associated with the input and output timing difficulties.

Off-line Data Preparation

In a final modification to the system the conversational mode of input was replaced by an off-line routine for the preparation of patient and test request data. The data were punched up off-line on to paper tape, using a format almost identical to that used in the on-line conversational mode procedure (Fig. 37), and the data input to the computer via the paper tape reader. The average time taken for the preparation of a tape containing identification and test request data for 24 patients was 5.5 minutes, and a further 2.3 minutes were required for the input of the information through the reader/

```
120999O OBRIEN E F 28
290571 V249 CAP T1130>

220518W WHITSON E F 28 - JHC
- V254 CAP T1130>

080590H HOGG J M 6
- E258 ELU - S
- V311 CAP T1430>

100752W WOOD A M 23 - RHG
- E260 ELU - S
- V315 CAP - S
- V314 UA T1400>

280354D DUNN E F 33 - JIS
- E355 ELU - S
- V458 LFT T0900>

050724L LIVINGSTONE J M 21 - JSR
- V469 LFT T1700>

261132F FRECKLETON E F 21 - JSR
- V470 LGT T1700)))))
- V470 LFT T1700>

000000D DEWAR C M 21 - JSR
- V471 LFT - S
- V472 EPH T1700>

040649F FERGUSON C M 21 - JSR
- V473 LFT T1700>

←
```

Fig. 37

Off-line Preparation of Patient Identification and Test Request Data

reader, validation of the data by the computer and transfer of the validated data to magnetic tape. The time taken to input a similar batch of data using the conversational mode was 12-21 minutes depending on the number of AutoAnalyzer channels on-line to the computer at the time. The output procedure on the IBM printer was also altered; previously the computer program could interrupt the printing of reports to output results, etc., but the interruption of the printing was restricted to error messages on the on-line teleprinter. The average time taken to print up 45 reports was thus reduced to 16 minutes irrespective of the number of AutoAnalyzer channels being monitored by the computer.

Data entered into the computer by the off-line procedure are checked in the same way as in the on-line conversational mode but, if an error is detected in the identification or test request data for a patient, all the data together with the appropriate error message are output on the paper tape punch. A new tape with the corrected information must then be prepared; to do this it may be necessary to go back to the original request form, and it is thus more difficult to correct errors when made in the off-line mode of operation.

Another/

Another disadvantage of off-line operation is the increase in the number of key depressions required, since all identification and test request data must be entered by the operator on each occasion a request is received for a patient. This repeated input of identification information increases the number of errors which cannot be detected by computer software, e.g. misspelling of surname, incorrect initials or sex, etc.; these result in the mismatching of patient records on the work file and master file and the creation of more than one record for the same patient as shown in Fig. 38. The average percentage of records created as a result of mismatching of patient identification data was found to be 12%.

The multiplicity of records is not only due to typing errors but also to incorrect information on request forms. This source of error could be eliminated or greatly reduced if a unique registration number were available since it would then not be necessary to use the surname, initials, sex, etc. for record linkage purposes. If a unqiue number is not available, the number of key depressions (and hence the error rate) could be minimised by using edge-punched cards/

```
180155C/1 GILLIES  A  M 21  RIE -
180155C/2 GILS  A  M 21  RIE JSR
180155C/3 GILLES  A  M 21  RIE JSR

180755C/1 GILLES  A  M 21  RIE JSR
180755C/2 GILLIES  A  M 21  RIE JSR
180755C/3 GILLIS  A  M 21  RIE JSR
180755C/4 GILLIS  A  F 21  RIE JSR


170743C/1 GREASELY  S  F 21  RIE JSR
170743C/2 GREASLEY  S  F 21  RIE JSR

170793C/1 GREASLEY  S  F 21  RIE JSR


120495S/1 SNEDDON  W  M 32  RIE LJD

121195S/1 SNEDDON  W  M 32  RIE LJD
```

Fig. 38

Multiplicity of Patient Records when Using Off-line Mode for Data Preparation

cards containing the patient identification information in machine-readable form for the preparation of input data tapes. An example of an edge-punched card used for this purpose at University College Hospital, London is shown in Fig. 39.

An analysis of the typing errors detected by manual checking of the input data, but not detected by the computer, is summarised in Table XXVIII. The total error rate of 0.5% is relatively low but to this figure must be added errors in the information provided on request forms; this could more than double the total error rate. When using the conversational mode of input, the items of information labelled 1-7 (Table XXVIII) are entered only on the first occasion that a request is received for a patient; on subsequent occasions these data are checked by the operator. When using the off-line mode, items 1-7 have to be entered each time a request is received, and hence errors in this information give rise to multiplicity of records and reports. Errors in items 8-9 do not affect patient identification and are frequently detected by the laboratory staff before the specimen is analysed.

One point of special interest in Table XXVIII is the relative/

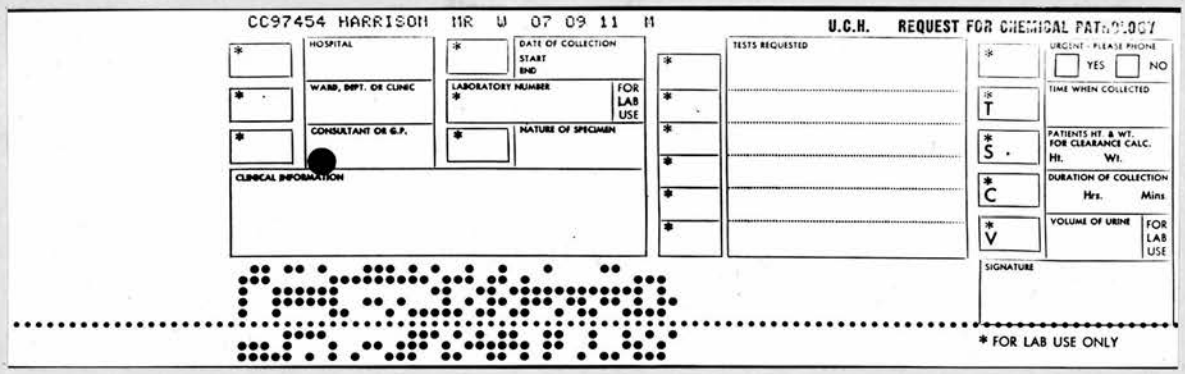


Fig. 39

Example of the use of an edge-punched card for patient identification and test request data

TABLE XXVIII

SUMMARY OF INPUT ERRORS WHEN USING OFF-LINE MODE

Total number of entries of patient and test data - 432
Average number of characters per entry - 30

	TOTAL NO.	%
Errors in surname (1)	28	.22
Errors in date of birth registration number (2)	12	.09
Errors in initials (3)	7	.05
Errors in sex (4)	2	.02
Incorrect ward (5)	1	.01
Incorrect hospital (6)	-	-
Incorrect consultant code (7)	1	.01
Incorrect test code (8)	11	.09
Errors in laboratory number (9)	4	.03
TOTAL	66	.51

relative frequency of errors in alpha and in numeric characters. The error rate for the surname, i.e. all alpha characters, is more than twice that for the date of birth registration number which is composed mainly of numeric characters. It is generally assumed that errors are more likely to occur in the reproduction of numbers than names. Although the sample described in Table XXVIII is fairly small this fact was observed consistently throughout the computer project.

An analysis of one day's operations performed by the computer when using an off-line procedure for the preparation of data tapes is given in Table XXIX. On this occasion 13 AutoAnalyzer channels were monitored on-line with a maximum of 8 at any one time, and cumulative reports were prepared for specimens analysed for urea and electrolytes. At the start of the day's operation there were no patient records on the work file and at the end of the run the file contained 280 records. The number of records on the master file before updating was about 4,800.

A comparison of the times given in Tables XXVII and XXIX indicates a decrease of about 23% in the percentage of computer time used for the input of patient identification/

TABLE XXIX

AN ANALYSIS OF ONE DAY'S OPERATIONS PERFORMED BY THE COMPUTER USING AN OFF-LINE MODE FOR THE INPUT OF PATIENT AND TEST REQUEST DATA

PROCESS	TIME (HOURS MIN.)	PERCENTAGE OF TOTAL TIME
Testing and cleaning of computer and peripheral equipment	0.15	*
Setting-up procedures and re-allocation of channels	0.22	3.5
Idle time (before specimens arrive in laboratory)	0.30	4.7
Input of patient and test request data (paper tape reader)	0.44	6.9
Output of workload and work sheets	0.46	7.2
Pools error messages, emergency output and change cup number routine	0.23	3.6
Input of manual results	0.09	1.4
Amendment to data on files (e.g. alterations in identifying data)	0.05	0.8
Accession of master file before output of cumulative reports	0.32	5.0
Output of results on paper tape punch	0.13	2.0
Output of cumulative reports to paper tape punch (280 reports)	1.08	10.7
Printing up of reports on IBM printer (time for a batch of 45 reports)	0.16	2.5
Printing up of reports on Teletype 35 (time for a batch of 45 reports)	0.32	*
Output of end of day summary to paper tape punch	0.19	3.0
Printing up of end of day summary on Teletype 35	1.02	*
Update master file and work file routine	0.20	3.1
Off-line preparation of patient and test request data	1.08	*
Total time computer switched on	10.36	

Activities indicated with an asterisk represent off-line activities

identification and test request data. The most time-consuming on-line operation in the modified system, as shown in Table XXIX, is the output of cumulative reports on the paper tape punch (110 c.p.s.). A much more important source of delays is, however, the transfer of data to and from magnetic tape; this is more difficult to measure and is not included as a separate item in the list of computer activities shown in Table XXIX although it contributes to some of the times quoted. The off-line printing of reports on a Teletype (10 c.p.s.) created another major bottleneck in the overall system.

One factor not forming part of the computer system, but which has a considerable effect on its efficient operation, is the delay in the delivery of specimens to the laboratory by hospital porters, and in the case of outside hospitals, by van service. It is frequently necessary to use cup blockfillers or even to stop the urea and electrolytes AutoAnalyzer channels while awaiting delivery of the next batch of specimens.

(B) RELIABILITY OF HARDWARE COMPONENTS

The reliability of the various components of the computer/

computer system was first assessed at the end of a 20-month period of operation and the results reported by Simpson et al. (1971). A further assessment of reliability was carried out over a period of 40 months and this information is collected in Table XXX. In comparing the results for the preliminary assessment with those obtained at the end of the longer period, a significant change was noted in two of the values for percentage down-time. The percentage computer time had increased from 0.4 to 0.6% as a result of two periods of 22 and 12 hours down-time while the magnetic tape controller down-time had decreased from 3.1 to 1.8%.

A percentage down-time for the computer of 0.4 to 0.6% would appear to be an acceptable value although it is still difficult to obtain comparable figures for other similar systems. Abernethy et al. (1970) reported on the hardware reliability of the PDP8/5 system, but they did not give figures for the percentage down-time. Figures included in the Edinburgh Regional Computing Centre Newsletter (1971) indicated that the central processor down-time for IBM 360/50 and ICL 4/75 systems were 0.8 and 1.0% respectively.

The total down-time for peripheral equipment of 5.8%/

TABLE XXX

SUMMARY OF OPERATION OF SYSTEM FOR 40 MONTH PERIOD (PART 1)

TIME (HOURS)	1968				1969											
	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUNE	JULY	AUG	SEPT	OCT	NOV	DEC
Total time computer switched on	168	208	237	190	196	213	216	248	269	239	250	227	214	259	229	242
Total time computer in use	166	145	172	182	189	198	203	232	256	239	248	195	213	256	228	241
Total computer down time	-	-	-	-	-	-	1	-	8	-	-	9	-	-	-	-
Peripheral Down Time																
(1) D.A.U. down time	-	6	-	-	-	-	12	16	-	-	-	10	-	-	-	-
(2) Reader " "	-	11	9	-	-	-	-	-	-	-	-	-	-	2	-	-
(3) Punch " "	2	-	-	1	-	12	-	-	-	-	-	-	-	-	-	-
(4) Teletype " "	-	-	-	-	7	-	-	-	-	-	-	10	-	-	-	-
(5) Magnetic tape controller down time	-	46	56	-	-	-	-	-	-	-	-	-	-	-	-	-
(6) Magnetic tape handler down time	-	-	-	7	-	3	-	-	5	-	2	3	1	1	-1	1
Total peripheral down time	2	63	65	8	7	15	12	16	5	-	2	23	1	3	1	1
Routine service by engineer	-	-	-	-	-	-	-	-	-	9	-	13	-	18	-	17
Out-of-hours servicing engineer	-	12	51	-	-	6	-	-	11	3	-	4	-	2	-	3
Modifications to hardware	-	-	8	-	-	-	17	-	-	-	-	-	-	-	-	-
Cleaning and testing by operator	6	8	6	15	16	21	22	19	12	17	12	10	7	11	6	3

TABLE XXX

SUMMARY OF OPERATION OF SYSTEM FOR 40 MONTH PERIOD (PART 2)

TIME (HOURS)	1970											
	JAN	FEB	MAR	APR	MAY	JUNE	JULY	AUG	SEPT	OCT	NOV	DEC
Total time computer switched on	230	241	266	250	223	227	260	262	243	275	283	286
Total time computer in use	211	220	266	212	184	199	256	237	243	178	267	286
Total computer down time	-	-	-	-	-	-	-	-	-	22	-	-
Peripheral Down Time												
(1) D.A.U. down time	-	4	-	-	8	20	4	-	-	-	-	-
(2) Reader " "	-	-	-	-	-	-	-	-	-	-	7	-
(3) Punch " "	-	-	-	-	-	-	-	-	-	-	-	-
(4) Teletype down time	-	-	-	-	12	-	-	25	-	2	-	-
(5) Magnetic tape controller down time	-	-	-	38	18	3	-	-	-	-	-	-
(6) Magnetic tape handler down time	19	17	-	-	1	5	-	-	-	73	9	-
Total Peripheral Down Time	19	21	-	38	39	28	4	25	-	75	16	-
Routine servicing by engineer	-	10	-	9	-	-	9	7	-	-	9	-
Out-of-hours servicing engineer	-	3	-	12	5	-	-	-	-	-	-	-
Modifications to hardware	-	-	-	-	-	-	-	-	-	-	-	-
Cleaning and testing by operator	2	3	2	2	3	3	3	2	2	2	3	3

TABLE XXX

SUMMARY OF OPERATION OF SYSTEM FOR 40 MONTH PERIOD (PART 3)

TIME (HOURS)	1971													
	JAN	FEB	MAR	APR	MAY	JUNE	JULY	AUG	SEP	OCT	NOV	DEC	TOTAL	%
Total time computer switched on	212	211	254	214	234	222	217	213	218	221	225	266	9358	
Total time computer in use	212	211	243	214	215	216	217	213	218	221	193	265	8760	93.6
Total computer down time	-	-	-	-	-	-	-	-	-	-	12	-	52	0.6
Peripheral Down Time														
(1) D.A.U. down time	-	-	11	-	-	-	-	-	-	-	-	-	91	1.0
(2) Reader " "	-	-	-	-	-	-	-	-	-	-	-	-	29	0.3
(3) Punch " "	-	-	-	-	-	-	-	-	-	-	-	-	15	0.2
(4) Teletype " "	-	-	-	-	-	6	-	-	-	-	-	-	62	0.7
(5) Magnetic tape controller down time	-	-	-	-	10	-	-	-	-	-	-	-	171	1.8
(6) Magnetic tape handler down time	-	-	-	9	-	-	-	-	-	-	20	1	178	1.9
Total Peripheral Down Time	-	-	11	-	19	6	-	-	-	-	20	1	546	5.8
Routine servicing by engineer	6	-	6	7	9	5	-	8	3	-	1	7	153	
Out-of-hours servicing by engineer	-	-	-	-	4	-	-	-	-	-	-	-	116	
Modifications to hardware	-	-	-	-	-	-	-	1	-	-	-	-	26	
Cleaning and testing by operator	4	4	4	2	4	4	4	3	5	5	4	5	269	

5.8% was high even when account was taken of the fact that a significant proportion of this down-time occurred in the early stages of operation. The figures given in Table XXX do not include several periods of up to 3 days when the system was operating in crippled mode, e.g. a simplified version of the system using paper tape for the input of programming data was used when the magnetic tape handlers were faulty. All the peripheral components of the system have developed faults on several occasions, but the frequency and duration of breakdown of the different components has varied considerably. The duration of a breakdown has been closely related to the ease with which the fault could be detected, but the time taken to secure the services of an engineer and the availability of replacement components have also been important features.

The first two periods of computer down-time, of 1 and 8 hours duration, were caused by overheating of transistor boards as a result of faults in the computer cooling fan. The system could not be used for a further period of 9 hours when the block transfer facilities failed to function properly, giving rise to errors in data transfer to the magnetic tape files. A

period/

period of down-time amounting to 22 hours occurred when a fault developed in a rectifier in the central power unit; an appreciable part of this down-time was caused by a delay in obtaining a replacement unit. On three occasions, in November, 1971, the voltage supplied to the central processor dropped below the acceptable limit; this caused system failure and a total down-time of 12 hours.

The on-line monitoring facility of the system has been out of action for several periods, as a result of faults in the data acquisition unit caused mainly by failure of a transistor board or the power unit. The analyser consoles, although sited in the laboratory in close proximity to the analytical equipment and hence in an atmosphere containing chemical fumes and vapours, have proved to be very reliable requiring only minor adjustments to the potentiometers on the amplifier boards and periodical cleaning of electrical contacts.

There have been numerous short periods of down-time on the magnetic tape handlers as a result of faulty fuses or photosensor lamps. Fortunately, these minor troubles have usually been detected at the start of a day's operations and, since the components can be readily replaced/

replaced by laboratory staff, have not seriously interfered with routine operation of the system. Much longer periods of down-time on the magnetic tape handlers have resulted from a faulty diode, failure of a rewind switch, and from an incorrect voltage on the magnetic tape logic boards, while a delay of 73 hours occurred when it was necessary to replace carbon brushes in the vacuum pump motors.

A design deficiency in the magnetic tape controller was detected initially in October, 1968, when an attempt was made to use magnetic tape files for storing systems programs. The fault was corrected after a total down-time of 46 hours but, in the following month, the controller was modified to meet the manufacturer's latest specifications and, as a result of faulty re-wiring, the magnetic tape system could not be used for a further period of 56 hours extending over 9 working days. The controller continued to function in a satisfactory manner until April, 1970 when a fault occurred which corrupted the transfer of data from the magnetic tapes. The fault was traced to the magnetic tape controller but the exact nature of the fault was not discovered and, after some minor adjustments, the system became operational/

operational again. The period of down-time in May, 1970 was caused by a fault in the controller power unit.

The lengths of down-time for the reader, punch and Teletype quoted in Table XXX, each relate to periods when both the particular peripheral and its associated spare peripheral were faulty, and hence the overall system could not be operated. The reader down-time in October and November, 1968 was due to a faulty earth line in the socket connecting the reader and the computer. The paper tape punch could not be used for a total period of 12 hours in February, 1969 because a logic fault had developed in the central processor punch control board. As in the case of the off-line system described by Whitby et al. (1968), the least reliable component of the system has been the teleprinter. The computer system was inoperable for five periods of from 2-25 hours because of simultaneous failure of the on-line control Teletype (Westrex model 33) and the spare Teletype (Data Dynamics model 33). Both Teletypes had to be removed for major servicing after about 2 years' operation.

A model 35 Teletype was added to the off-line equipment in November, 1969 but in the first 5 months of/

of use this allegedly more reliable Teletype was out of action for 55 hours. The various controls were re-adjusted on several occasions and the drive mechanism removed for repair but, even after 11 months operation, intermittent errors still occurred when punching or copying paper tapes and the instrument could not be used for this purpose; the printing of data from the keyboard or paper tape reader appeared to be unaffected by this fault. In October, 1969 the manufacturers admitted that the drive mechanism had an inherent fault and this was replaced by another unit after which the teleprinter operated in a satisfactory manner.

The IBM printer has been reliable but it has been used for shorter periods than the other printing equipment. However, servicing difficulties have occurred with the IBM printer also, since there was a delay of three weeks in replacing the drive motor when this developed a fault. On another occasion when the printer was being used to print analytical results, a fault occurred which resulted in the incorrect printing of numeric characters, e.g. sodium results of 142, 123 and 140 meq./l. were printed as 152, 133 and 151 meq./l., respectively/

respectively, while chloride results of 100 and 105 were printed as 111 and 115 meq./l. This fault was not detected by the running quality control system since the results for the analysis of pooled sera are printed on the on-line teleprinter, but the fault was discovered by the clinical chemist who was checking reports for results on patients. On examining the output of results, it was found that at the start of the day the error rate was low but this rate increased gradually throughout the day and the overall error rate was about 10% although many of the errors were not clinically significant. This incorrect printing of characters proved to be due to a mechanical fault in the printing mechanism. A fault of this nature is extremely difficult to detect while the analytical system is in operation and would not be detected by calculating the mean of the patient specimens at the end of the analytical run since this information is output on paper tape for printing off-line.

On several occasions during the past 40 months there have been voltage reductions in the power supply in excess of the legally permissable 6% level. These reductions of up to 10% had little or no effect on the operation/

operation of the 903 computer itself but resulted in occasional faults on the magnetic tape handlers. Voltage 'spikes' of up to 25% had a more serious effect on the system, interfering not only with the operation of the magnetic tapes but also with the level 2 interrupts and hence with the on-line monitoring of AutoAnalyzers. This problem of voltage fluctuations can be overcome by installing a voltage regeneration unit (costing up to £1,000) or, if the computer establishment is sufficiently large, a stand-by electric generator with the necessary electronic devices for automatic transfer from the mains power supply in the event of excessive voltage fluctuations (T.S.U. Note No. 1119 and Watson, 1972).

Faulty magnetic tapes have been a frequent source of short delays at the start of a day's operation, and on several occasions they have given rise to corrupted records. The useful lifetime of magnetic tapes varies considerably depending on the individual tape and also on the nature of the job for which it is used, for instance the first 90 blocks of a master tape are used almost continually throughout the day but the remainder of the tape is used infrequently. The entire length

of/

of the work file tape is used during the day but for each section the reading and writing routines occur about four times per day. Two tapes are still in use after 19 months although they have been cleaned and recertified once during this time, while one master file tape has been in use for 16 months without requiring cleaning. Care must be taken when loading reels of tape on the Ampex TM7 handlers or the edge of the tape may be distorted. Failure to ensure that the tape reel was properly mounted resulted in the rejection of 3 tapes after 5-7 months operation because of a wavy edge throughout the length of the tape. A brief resume of the use made of magnetic tapes is given in Table XXXI.

The importance of regular cleaning and testing of magnetic tapes, even in installations with expensive air conditioning, has been stressed by Hutchings (1970) and Walker (1970). The limited use made of tape cleaning and recertification services by this department does not permit a proper evaluation of this service, but it would appear that the useful life of a cleaned tape (i.e. the time for which it can be used before rejection or further cleaning) is at least as long as for a new tape. The cost of the cleaning service is about £3 per/

TABLE XXXI

RECORD OF USE AND CLEANING OF MAGNETIC TAPES

MAGNETIC TAPE NO.@	USE (*)	PERIOD OF USE (MONTHS)	NO. OF TIMES CLEANED	REASON FOR REJECTION
10	WF/MF	11-	1	-
11	WF	5	1	Wavy edge throughout
12	WF	5	-	1,500 permanent errors
16	WF	18-	1	-
17	MF	12-	2	-
20	WF	4	1	Spasmodic drop out for 1,200 ft.
21	WF	7	-	Wavy edge throughout
22	WF	7	-	Wavy edge throughout
23	MF	15-	-	-
24	WF/MF	19-	1	-
25	WF	10	1	Oxide deposit, 110 temp. errors
26	MF/WF	19-	1	-
27	WF	16-	1	-
28	MF/WF	14-	2	-
29	WF	13-	2	-
30	MF	16-	-	-
31	WF	12-	1	-
32	WF	4-	1	-
33	MF	13-	-	-
34	WF	12-	1	-
35	WF/MF	12-	-	-
36	WF	12-	-	-
37	WF	12-	1	-
38	WF/MF	11-	-	-

* WF = Work file; MF = Master file

@ Tapes 4-9, 13-15 and 18-19 were part of a faulty batch of tapes and were returned to the manufacturers

per tape while the price of a new tape is about £10 and hence tape cleaning is an economic proposition. If a large number of magnetic tapes are in use then the cost of cleaning could be reduced by purchasing a tape cleaner (cost about £600) and perhaps a certifier. The importance of having magnetic tapes fully certified before purchase has been underlined by the fact that a complete batch of 12 tapes was found to be faulty; the batch was replaced by the manufacturer but, since the system was in a development and testing phase at the time, it was several weeks before the operational troubles were traced to the magnetic tapes.

The frequency with which tapes are cleaned can be reduced by careful handling, loading and thorough cleaning of the computer room environment to prevent the accumulation of dirt. A list of the common magnetic tape faults and their causes has been prepared by Hutchings (1970).

(C) COMPUTER ROOM ENVIRONMENT

In providing a suitable environment for the efficient operation of a computer system and conditions acceptable to the operating staff, it is necessary to control/

control the room temperature and humidity, to prevent the collection of dust, and to minimise the noise produced by the computer, its peripherals and associated equipment.

The computer room temperature is normally controlled by air conditioning equipment which may also regulate the atmospheric humidity. In calculating the required cooling capacity of air conditioning equipment, consideration must be given to not only the heat-generating computer equipment but also to the heat produced by lighting, the presence of operating staff, and the siting of the computer room in the building. The heat generated by the 903 computer system can be summarised as follows:-

Central processor	4,124	B.Th.U./hr.
Data acquisition unit	510	" "
Magnetic tape handlers	6,500	" "
Magnetic tape controller	860	" "
Controller for IBM printer	860	" "
Total	12,854	B.Th.U./hr.

To this had to be added 200-300 B.Th.U./hr. for the heat generated by Teletypes, and on this basis it appeared that a Stewart King AKS 151 unit, with a cooling/

cooling capacity of 14,500 B.Th.U./hr., could be used to control the room temperature at 70°F. One of these units was installed, but experience has since shown that this is not adequate, and the air conditioning equipment is unable to control the room temperature in a satisfactory manner. This failure has been attributed to an inadequate allowance for the heat emanating from other sources. In addition the AKS 151 equipment has two distinct disadvantages; firstly it is a wall-mounting unit and hence makes a considerable contribution to the noise level in the computer room and also in the surrounding area; secondly it does not include a device for regulating humidity. Ideally, the noisy circulating equipment should be sited outside the building, and the air should be supplied to the computer room through ventilation ducts.

Adequate control of the computer room temperature is required to provide suitable working conditions for the operating staff, to prevent over-heating of computer transistor boards and Teletype mechanisms, and to obtain optimum efficiency from the Ampex TM7 magnetic tape assembly. Faults have occurred in transistor boards and Teletypes and on magnetic tapes as a result

of/

of excessively high temperatures in the computer room, in spite of the fact that the ambient air temperature for the TM7 tape transport is quoted by the manufacturers as ranging from 40° to 110°F.

The proper control of atmospheric humidity is important in tape based computer systems. If the atmosphere is too dry, when passing through a punch roller/capstan drive the tape tends to generate static electricity. On the other hand a high atmospheric humidity can cause dimensional changes in paper tape. Ideally, paper tape is read at the same humidity at which it is punched. Regulation of humidity also assists in the control of dust.

The accumulation of dust in the computer room is harmful to magnetic tapes and can cause errors in reading data by photoelectric devices. The problem of dust can be minimised by adopting the following procedures:-

(1) Filtration of the air circulated by air conditioning equipment.

(2) The use of an air conditioning system which maintains the air in the computer room at slightly/

slightly above atmospheric pressure, to reduce the entry of unfiltered air when people come in and out of the room.

(3) The provision of dust adhesive mats at the door of the computer room.

(4) Regular cleaning of the computer room using a vacuum cleaner and impregnated dusters.

A considerable amount of dust is generated in the paper tape punch and this tends to be circulated by the punch fan. Dust from this source can be significantly reduced by fitting a filter to the fan output vent. Computer room cleaning is the subject of a paper produced by the Technical Support Unit of the Department of Trade and Industry (T.S.U. Note No. 1191).

Noise in computer installations can reach hazardous levels and in addition to interfering seriously with the efficiency of operation of the system can lead to occupational deafness. Exposure to noise levels in excess of 150 dB can cause permanent damage to hearing but continued exposure to lower but still/

still intense noise can also cause deafness (T.S.U. Note No. 1170). It has been suggested (Report on the National Bureau of Standards Investigation, 1970; Griffiths et al., 1970) that there is a significant risk of physiological damage to hearing if a person is exposed to levels of noise in excess of 90 dB with any regularity: exposure for a full working day should not exceed a level of 85 dB. If the noise is pure tone then this level could be considerably reduced depending on the frequency of the tone, but at 1,000 Hz the safe level is about 80 dB. The overall noise level in a computer room in which an Elliott 903C computer and two Teletypes are situated has been measured by Griffiths et al. (1970) and found to be 74-76 dB (A).

The noise levels of the main components of the Elliott ABL system and the associated air conditioning equipment installed in the clinical chemistry laboratory have been measured using a Kudelski tape recorder (model Nagra 1V-S) with a Sennheiser microphone (model MD 211). A calibration signal of 90 dB was recorded on the tape so that the correct level could be obtained on playback. The tape was processed/

processed by a Bruel and Kjaer real time analyser type 3347 which enabled a 1/3-octave band analysis and an A weighting level to be obtained.

The noise produced by the basic 903C computer was 66 dB (A) and octave band analysis indicated a modal frequency band of 500-630 Hz. Throughout the entire working day the basic computer, air conditioning fan and magnetic tape assembly are in operation giving a total noise level in the computer room of 71 dB (A); the frequency histogram (Fig. 40) shows that the noise level is $>$ 60 dB (A) over the range 100-800 Hz. The noise level in the computer room is increased to 74-80 dB (A) when the off-line Teletype (model 35) and the on-line Teletype (model 33), paper tape punch or the IBM printer are in operation (Fig. 41). The wall-mounted air conditioning equipment generates a noise level of 71 dB (A) in the corridor and in the room immediately adjacent to the unit; the maximum frequency ($>$ 65 dBA) occurs in the range 160-315 Hz. The background noise in the routine laboratory was found to be 67 dB (A). The computer room noise (Fig. 41) differs from the laboratory noise (Fig. 42) in having a higher level in the 0.8-16 KHz frequency range.

The/

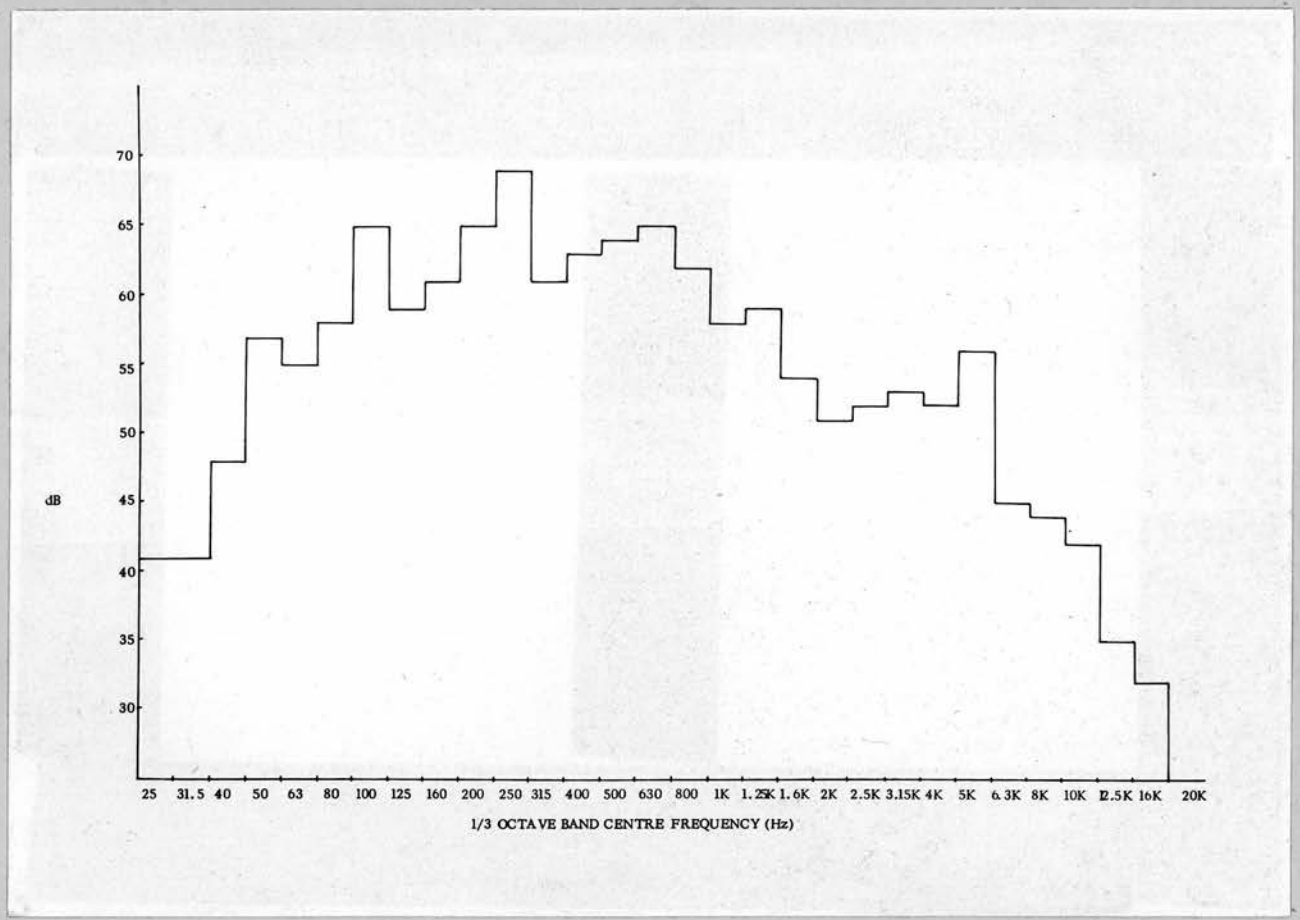


Fig. 40

Noise level produced by basic computer, air-conditioning equipment and magnetic tape assembly

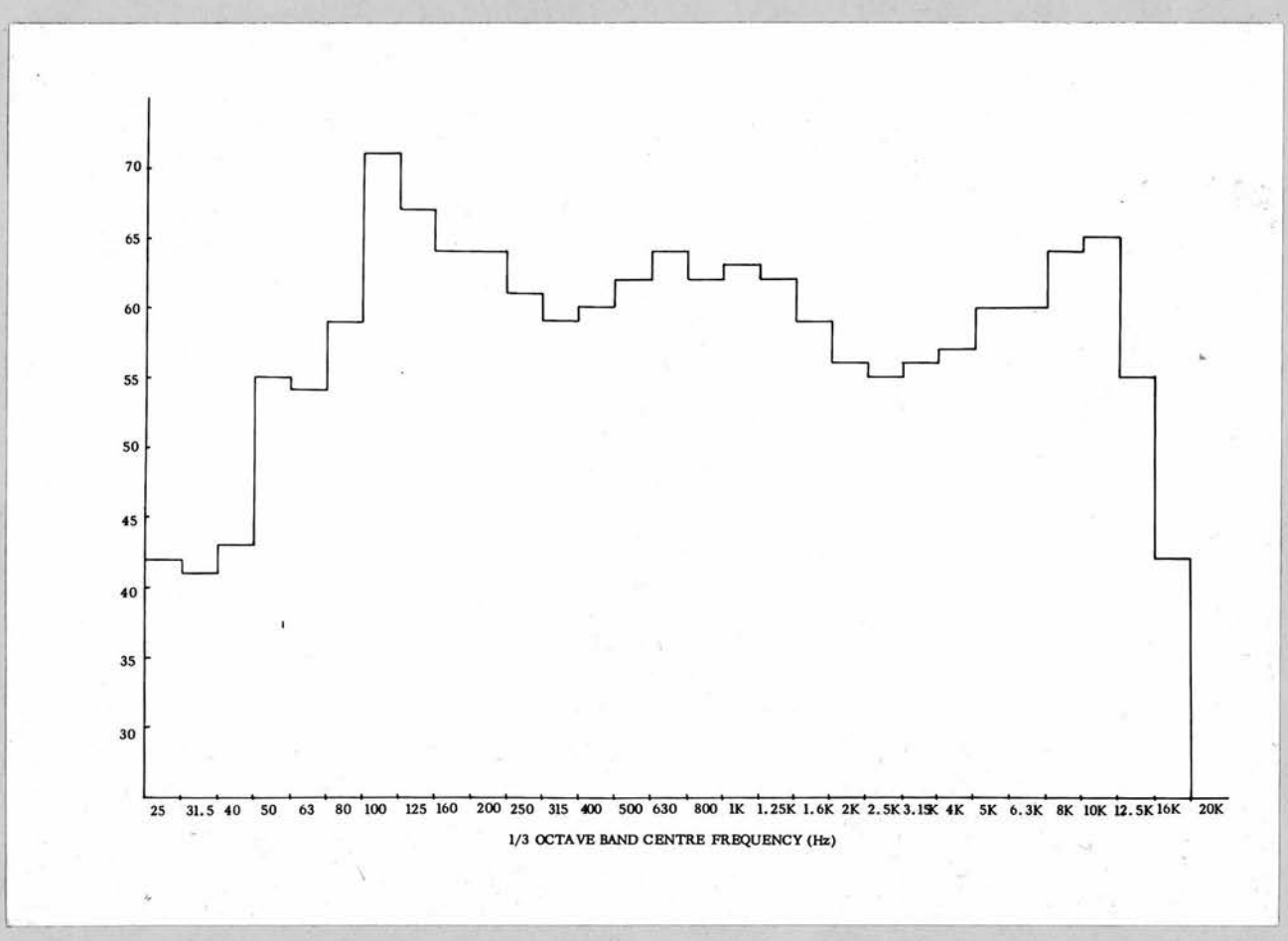


Fig. 41

Noise level produced by basic computer, air-conditioning equipment and paper tape punch

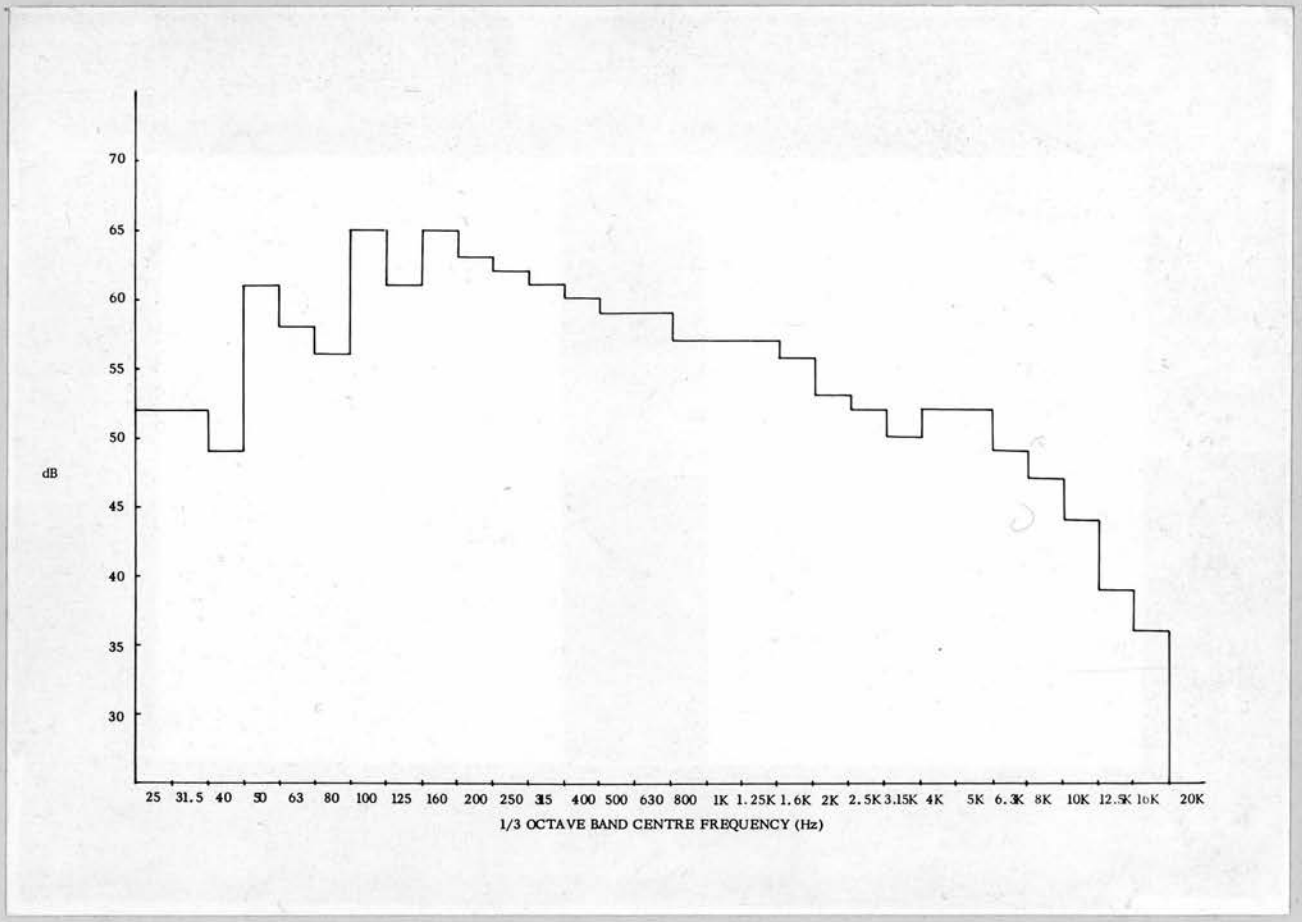


Fig. 42

Background noise in the laboratory

The measured values indicate that the noise levels in the computer room environment are not physiologically harmful but are of sufficient magnitude to interfere with communication within the computer room and between the computer room and the laboratory. The calculated speech interference level (S.I.L.) of noise that just permits conversation with marginal reliability when operating the basic computer, air conditioning equipment and the magnetic tape assembly is 64 dB; the actual noise level is 71 dB (A). The S.I.L. value for the computer room when Teletypes and a paper tape punch or IBM printer is operating is about 70 dB.

The measured noise levels also have a psychological effect by annoying and hence reducing the efficiency of the computer room staff. The noise produced by Teletypes, paper tape reader and punch contains a high frequency component which is likely to cause annoyance to the operating staff.

A significant reduction in the noise levels in the computer room could probably be achieved by the use of acoustic tiles (T.S.U. Note No. 1110); other methods for reducing computer noise have been described in recent/

recent publications (National Bureau of Standards Investigation, 1970; T.S.U. Note No. 1172) and they include the following:-

(1) Cover all openings around card punches, readers and printers with one-quarter-inch clear lucite shields edged with soft rubber gaskets to effect an airtight seal.

(2) Wherever possible, vibration mount all drive motors, cooling fans, etc., on rubber pads or use rubber sleeves on mounting bolts.

(3) All console panels should be treated with viscoelastic material for vibration damping and lined internally with fibreglass to reduce the noise build-up in reverberant cavities.

If the suggested methods fail to reduce computer room noise to acceptable levels, then operating staff should wear ear protectors.

SECTION V

INVESTIGATION OF POSSIBLE MODIFICATIONS TO SOFTWARE

(A) PEAK DETECTION PROCEDURES

The method of peak detection employed in the Elliott 903 system makes use of readings of measuring and reference signals taken every two seconds from colorimeter photocells and relies mainly on three characteristics or parameters (Section IIIA) - the minimum number of rising readings before a peak maximum (A readings), the minimum number of falling readings after a peak maximum (B readings), and the width of a time window (H readings) within which peak maxima for acceptable peaks must fall. Faulty peaks resulting from short-sampling of specimens usually have a peak maximum which falls outside the time window, and are rejected for this reason by the computer program.

Routine operation of the computer system has revealed that a certain number of misshapen peaks produced by short-sampling have a peak maximum which falls inside the time window and, if the other criteria are satisfied, then the peak is accepted. It has been estimated that, as a result of the failure of the current peak detection system to reject a particular type of short-sampling, 0.1-0.2% of

AutoAnalyzer results are incorrect. The magnitude of the error in terms of concentration lies in the range of 1-12% (Section IIIA); a proportion of these errors are not statistically significant, therefore, and an even greater number are not clinically significant.

The type of faulty peak described above can be detected by careful visual inspection of the Auto-Analyzer recorder chart, and could be detected by the computer if the time window were sufficiently narrow. However, there is some variation in the position of maximum transmission or absorption for acceptable peaks and hence a decrease in the width of the time window could give rise to the rejection of acceptable peaks.

There are several well established methods for detecting misshapen peaks on chart recorder tracings based on the overall peak shape. For instance, it is possible to set limits for the ascending or descending gradients, or to measure the breadth of the peak at half the maximum height and compare the value obtained with a calculated range. One such method, described by Blaivas and Mencz (1968), makes use of a proportionality factor between peak height and peak area.

We/

We have endeavoured to find some method which makes use of the information already available in the computer core store, viz. the 2-second peak readings. The suggested parameter (P) has the following value:-

$$P = \frac{(M - X) + (M - Y)}{M},$$

where M is the maximum 2-second peak reading, X is the first of the A rising 2-second readings before the peak maximum and Y is the last of the B falling readings after the peak maximum (Fig. 43). If there is an inverse relationship between concentration and transmission, then the parameter (P) for the resulting 'trough' is calculated as follows:-

$$P = \frac{(X - M) + (Y - M)}{(1 - M)}$$

This parameter was evaluated by collecting 2-second readings for each test channel and using the values obtained to set maximum acceptable limits. The performance of the parameter was assessed by artificially producing thin peaks, by reducing the sampling period by as much as 25% of the normal sampling time. The concentrations corresponding to the heights of the thin peaks were calculated manually and compared/

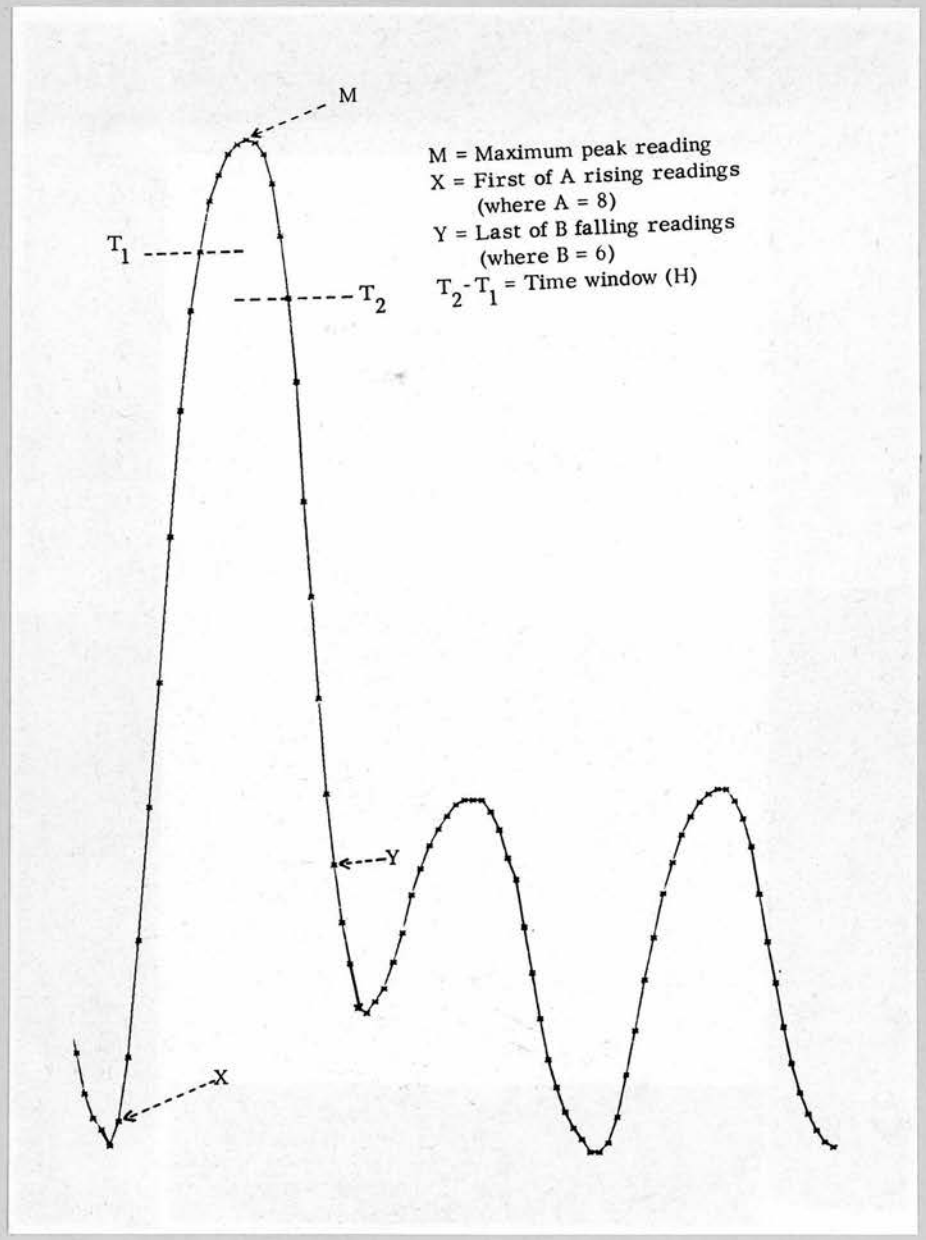


Fig. 43

Peak detection based on
2-second readings

compared with predetermined values for the specimens being analysed.

The results of this assessment are summarised in Table XXXII, which reveals a considerable variation, from 11-100%, in the percentage of faulty peaks rejected by the application of this additional characteristic. Further investigation has shown that the level of success is low if there is a marked change of peak shape with concentration. For example, if the rate of change of gradient at the top of a peak increases markedly with an increase in peak height, then the average value of the parameter increases with concentration and hence the detection of faulty peaks at lower levels of concentration is unsatisfactory. A detailed study of the application of this parameter to serum iron revealed that the 'success level' could be increased from 11% to 90% by using a modified parameter in which the power of the denominator is raised to compensate for the effect of concentration:-

$$P = \frac{(X - M) + (Y - M)}{(1 - M)^{3/2}}$$

This parameter does, however, have two important disadvantages/

TABLE XXXII

RECOGNITION OF SHORT SAMPLED SPECIMENS

TEST	RANGE OF CONCENTRATION	% ERROR IN CALCULATED CONCENTRATION	% FAULTY PEAKS REJECTED
Sodium	100-150 meq./l.	1.4-10.0	100
Potassium	1.0-8.0 meq./l.	3.3-12.5	80
Chloride	72-122 meq./l.	2.4-13.5	11
Bicarbonate	10-40 meq./l.	3.3-10.5	33
Urea	30-250 mg/100ml	2.7-13.5	89
Calcium	4.0-14.0 mg/100ml	4.4-14.3	93
Phosphate	2.5-16.0 mg/100ml	1.7-12.5	50
Serum creatinine	0.9-9.0 mg/100ml	3.5-11.1	78
Urine creatinine	40-200 mg/100ml	2.0-10.0	89
Total protein	1.8-8.9 g/100ml	2.2-16.6	91
Albumin	1.1-5.6 g/100ml	0.2-9.5	33
Alkaline phsophatase	9-45 K.A. units/100ml	3.7-14.8	11
Bilirubin	1.5-7.6 mg/100ml	0.3-8.7	89
Iron	50-400 µg/100ml	1.3-11.5	11
Uric acid	4.5-15.0 mg/100ml	3.3-8.3	43
Cholesterol	100-500 mg/100ml	1.0-10.0	40

disadvantages - it involves the calculation of square roots, which is wasteful of processing time, and it involves different calculation procedures for different test channels since the index 3/2 is applicable to serum iron but not to some other tests such as urea and sodium.

An alternative approach is the use of a parameter to limit variation inside the time window. If the mean of the 2-second readings within the window is determined, then values can be calculated for maximum permissible variation from this mean. This approach, and several other methods based on 2-second readings, were investigated but were found to be less efficient than the procedure described above for the detection of short-sampling. Another method of peak detection, which also makes use of 2-second readings, involves the calculation of either ascending or descending peak gradients; these gradients can be related to the peak height and then compared with pre-set values. The procedure is at present under investigation.

(B) CALIBRATION OF ANALYTICAL EQUIPMENT

There are several possible advantages in the use of a polynomial expression to relate concentration to peak height, as compared to linear interpolation between/

between successive standards. The advantages may be summarised as follows:-

(1) Increase in precision. Investigation has indicated that if the number of standards is sufficiently large (e.g. 5-8), depending on the shape of the calibration curve, then the increase in precision is small. However, the use of a polynomial may permit the number of standards to be reduced while retaining an acceptable level of precision. This would permit more frequent re-calibration of the system without producing a marked increase in the sample-to-test ratio.

(2) The use of a polynomial would simplify the programming required for calculating concentrations from peak height, and would reduce the time taken to perform calculation routines.

(3) Polynomial expressions would simplify procedures for the validation of calibration curves.

(4) The use of polynomials could permit the use of a more sophisticated method of correcting for calibration drift. For instance, it might be possible to change the shape of the calibration curve on the basis/

basis of the change in peak height of one or two drift standards.

In order to investigate the possible use of polynomials, the data from a large number of standard curves was punched on column cards and processed on an I.C.L. 4-75 computer using a program provided by the Edinburgh Regional Computing Centre. All calibration curves used for this purpose were carefully examined and considered to be of acceptable shape.

The computer program calculated the polynomial coefficients for 1st, 2nd, 3rd and 4th order expressions of the following type:-

$$Y = Ao + A_1T + A_2T^2 + A_3T^3 + A_4T^4$$

where Y represents the concentration, T the peak height and A_1 etc. the polynomial coefficients. An assessment of the goodness-of-fit of the calculated polynomial is provided by the standard deviation:-

$$S.D. = \sqrt{\frac{(Y - Yc)^2}{N}}$$

where N is the number of data points, Y is the concentration input, and Yc is the calculated value of Y.

The/

The polynomial coefficients were evaluated using data from between 15 and 30 calibration curves for each test studied, and the mean value and range of the standard deviation were calculated (Table XXXIII). The values obtained indicate that, for most of the tests, a third order polynomial expression can be used for calibration. For some tests, such as serum iron and uric acid, a second order expression could probably be used without having any significant effect on the precision of the method. Calibration of assays performed by flame photometry should in theory be based on first order polynomials; this was found to be true for potassium and possibly for sodium, although for the latter test some degree of non-linearity was observed at the lower end of the 90-160 meq./l. concentration range. This apparent non-linearity can be eliminated by reducing the calibration range to 100-160 meq./l. The use of a third order polynomial for urea may not be adequate, while it is doubtful if even a fourth order expression would be satisfactory for serum creatinine.

Considerable variation in the values of polynomial coefficients was noted for several tests. Variation

was/

TABLE XXXIII

GOODNESS-OF-FIT OF POLYNOMIAL EXPRESSIONS

TEST	S.D. OF METHOD	STANDARD DEVIATION OF FITTED POLYNOMIAL							
		1st ORDER		2nd ORDER		3rd ORDER		4th ORDER	
		RANGE	MEAN	RANGE	MEAN	RANGE	MEAN	RANGE	MEAN
Sodium	2.2	0.6 - 1.8	1.2	0.2 -1.0	0.6	0.1 -1.0	0.5	0.1 -1.0	0.4
Potassium	0.1	0.01- 0.11	0.04	0.01-0.08	0.02	0.00-0.03	0.01	-	-
Chloride	2.2	3.3 - 4.1	3.8	1.5 -2.5	1.9	0.8 -2.1	1.1	0.7 -2.0	1.0
Bicarbonate	0.9	1.9 - 2.9	2.3	0.7 -1.0	0.8	0.1 -0.4	0.2	-	-
Urea	4%*	18.4 -23.3	21.4	5.3 -8.5	6.9	0.6 -3.5	2.3	0.2 -1.2	0.8
Calcium	0.18	0.15- 0.48	0.25	0.09-0.26	0.19	0.06-0.15	0.09	0.05-0.15	0.06
Phosphate	0.24	0.59- 1.36	1.16	0.16-0.90	0.33	0.05-0.15	0.08	0.02-0.15	0.06
Serum creatinine	0.09	0.35- 0.49	0.41	0.04-0.37	0.12	0.02-0.30	0.09	0.02-0.27	0.07
Urine creatinine	2.0	5.5 -14.6	9.8	0.6 -7.2	2.5	0.2 -4.8	1.2	0.1 -4.2	0.8
Total protein	0.12	0.53- 0.69	0.59	0.12-0.22	0.18	0.02-0.07	0.05	0.00-0.07	0.03
Albumin	0.1	0.25- 0.45	0.39	0.10-0.20	0.14	0.02-0.10	0.06	0.00-0.08	0.02
Iron	7	5.2 -14.6	11.4	1.4 -3.7	2.4	0.9 -3.1	1.9	0.7 -3.1	1.6
Uric acid	0.15	0.30- 0.54	0.41	0.06-0.14	0.09	0.01-0.09	0.06	0.01-0.07	0.04
Cholesterol	9	17.7 -39.2	30.6	7.8 -19.8	12.0	2.4 -17.7	7.2	1.1 -15.1	5.4

* Precision calculated as coefficient of variance

was observed not only when comparing standardisation curves run on different days but also when comparing curves obtained at the start and at the end of one day's analytical run; some examples of this variation are shown in Table XXXIV. The magnitude of this variation is such that it would be necessary to set very wide limits for the coefficients in order to prevent the rejection of curves which on visual examination appeared to be acceptable. Further, the use of polynomials in an attempt to improve drift correction seems unlikely to be successful. While carrying out this investigation several calibration curves were rejected on visual assessment because of irregular shape or non-linearity; in most cases the calculated coefficients and standard deviations were within the limits based on data from acceptable curves. These observations would appear to indicate that the use of polynomial expressions is of limited value for curve validation. However, Bennet et al. (1970) report the use of third order polynomials for the AutoAnalyzer calibration data for 16 tests. In addition, routine measurement of the exactness of fit has proved useful in detecting errors in the calibration standards.

(c)/

TABLE XXXIV

VARIATION OF POLYNOMIAL COEFFICIENTS

TEST	RUN	ORDER OF POLYNOMIAL	POLYNOMIAL COEFFICIENTS					S.D. OF FIT
			1	2	3	4	5	
Urea	1. Start	3rd	-14.95	296.7	-368.0	554.2	-	1.2
	End		-16.04	279.7	-348.0	540.9	-	2.0
	2. Start	3rd	-13.60	259.4	-303.2	390.3	-	2.1
	End		-16.38	280.5	-351.9	417.3	-	2.3
	3. Start	3rd	-84.59	669.6	-981.3	711.8	-	0.9
	End		-114.6	829.3	-1237.1	834.5	-	0.6
Potassium	1. Start	1st	-1.263	10.56	-	-	-	0.04
	End		-1.279	9.93	-	-	-	0.05
	2. Start	1st	-2.339	11.66	-	-	-	0.03
	End		-2.105	10.73	-	-	-	0.05
	3. Start	1st	-1.415	10.65	-	-	-	0.03
	End		-1.496	10.78	-	-	-	0.01
Iron	1. Start	2nd	-47.23	672.8	145.6	-	-	1.7
	End		-31.94	567.8	264.6	-	-	1.4
	2. Start	2nd	-34.21	397.1	215.5	-	-	2.8
	End		-28.20	376.3	242.5	-	-	2.8
	3. Start	2nd	-33.00	604.5	240.2	-	-	1.8
	End		-24.66	612.3	278.3	-	-	3.3

(C) CORRECTION FOR INSTRUMENTAL DRIFT

In most AutoAnalyzer systems there is a small random variation in the height of drift standard peaks but quite frequently, particularly during long analytical runs, there is a systematic drift throughout part or all of the run. Instrumental drift can affect calibration curves in a number of different ways but there are two basic factors involved - baseline drift which produces a linear displacement of the calibration curve, and a change in sensitivity which alters the shape of the curve. It is probable that in practice both factors contribute to instrumental drift although one may predominate in certain circumstances.

There are four methods of drift correction in general use; a linear correction based either on peak height or on concentration, or a percentage correction based on peak height or concentration. Linear correction of the peak height is the method which has been used in the present investigations. This form of correction is acceptable if the drift is mainly of the baseline type. However, Bennet et al. (1970) suggest that drift correction based on concentration is in general better than correction based on peak height; this/

this will be the case if a change in shape of the calibration curve takes place.

In order to determine the effect of instrumental drift on the standardisation curve in routine operation, the system was recalibrated at the end of each analytical run. When the drift standards indicated that systematic drift had occurred, the final curve was compared with the initial curve. This comparison was carried out for all the AutoAnalyzer channels studied using between 12 and 32 calibration curves for each test. The type of drift was classified by visual examination of the curves. For instance, in the case of sodium (Fig. 44), it is predominantly baseline drift whereas for potassium (Fig. 45) it is predominantly a sensitivity change. In several instances the instrumental drift appeared to involve both baseline and sensitivity changes. These observations indicate that linear correction may not be suitable for potassium, nor possibly for bicarbonate, total protein and chloride (Table XXXV). Similar findings for bicarbonate and total protein have been reported by Bennet et al. (1970), who also found that the chloride calibration was significantly affected by changes/

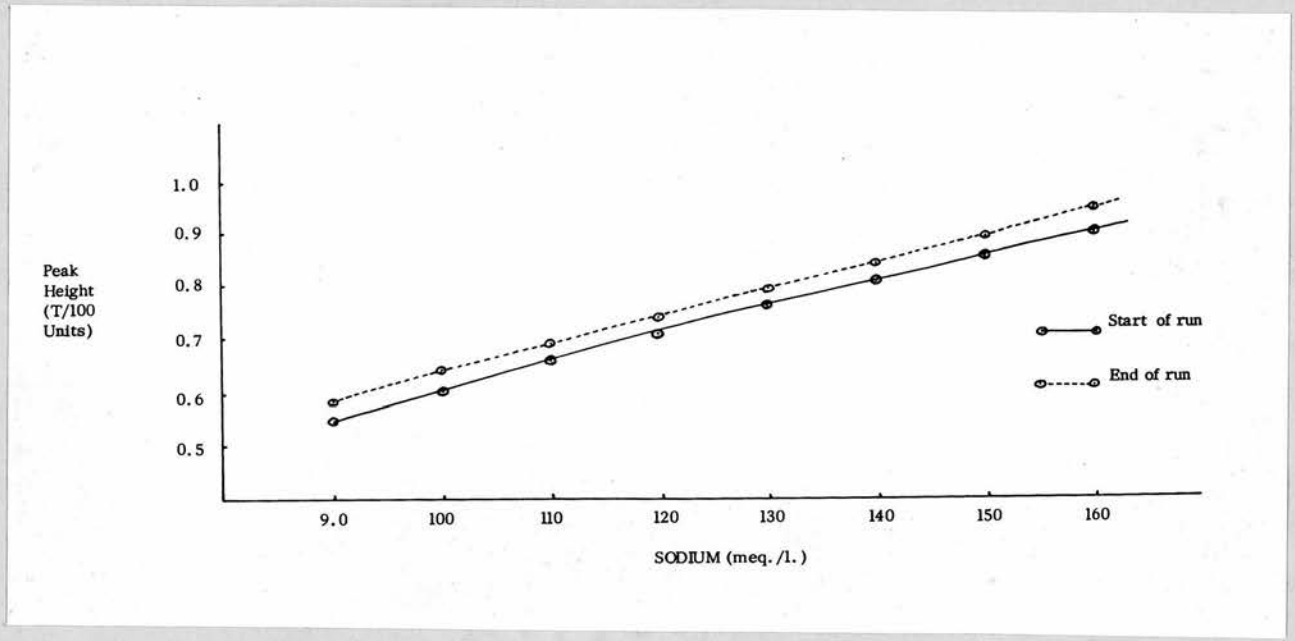


Fig. 44

Instrumental drift - sodium channel

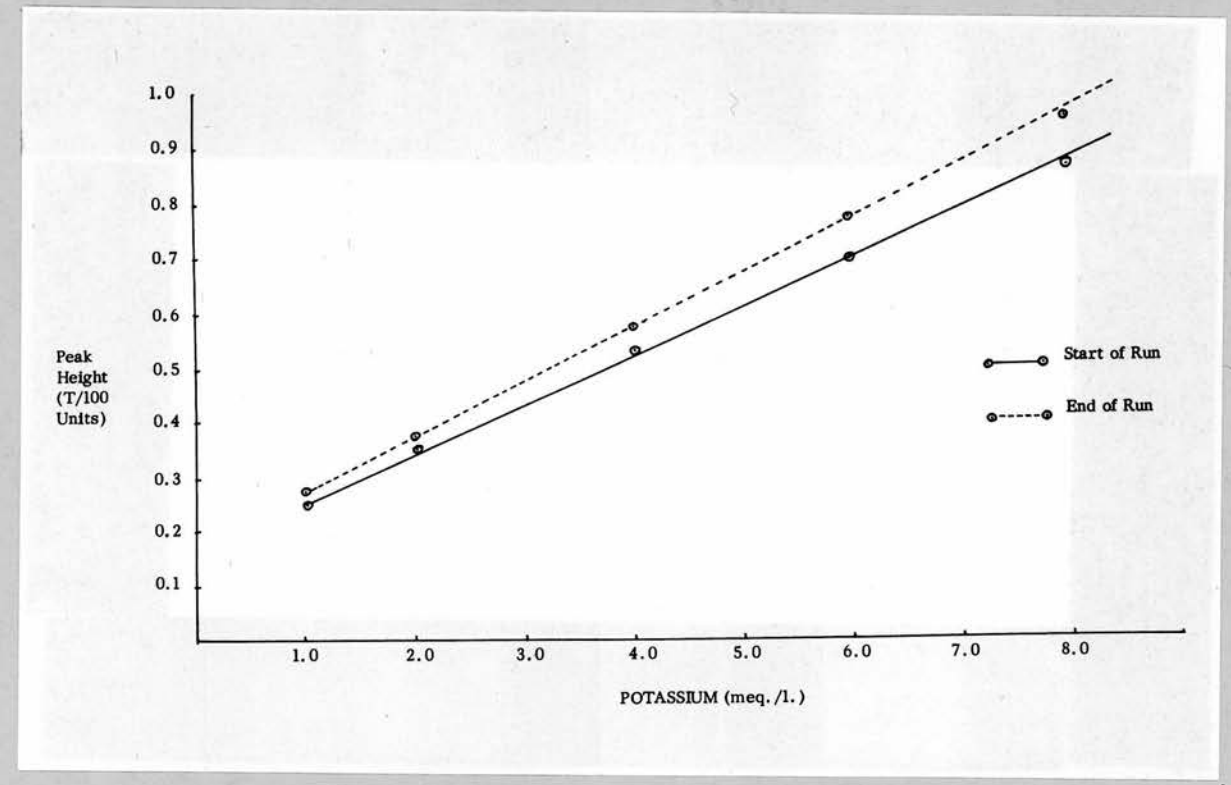


Fig. 45

Instrumental drift - potassium channel

TABLE XXXV

CLASSIFICATION OF AUTOANALYZER INSTRUMENTAL 'DRIFT'

TEST	PREDOMINANTLY BASELINE DRIFT	PREDOMINANTLY SENSITIVITY CHANGE	COMBINED BASELINE & SENSITIVITY CHANGE
Urea	100%	-	-
Sodium	100%	-	-
Potassium	-	75%	25%
Chloride	17%	-	83%
Bicarbonate	45%	45%	10%
Calcium	93%	-	7%
Phosphate	62%	-	38%
Creatinine	67%	-	33%
Albumin	86%	-	14%
Total protein	25%	-	75%
Iron	88%	-	12%
Cholesterol	100%	-	-
Uric acid	100%	-	-

changes in room temperature. However, it is important to obtain some measure of the error introduced by using the simpler but 'incorrect' linear form of drift correction to determine if this has a significant effect on the precision of the method.

The magnitude of errors in concentration arising from linear correction is given in Table XXXVI. The error in concentration for potassium can be significant at low and high concentrations but the effect was small within the 'normal range' (3.8-5.2 meq./l.) since the drift correction standard has a value of 4 meq./l. In contrast, the application of linear correction appears to have had little effect on bicarbonate although 45% of the instrumental drift observed in this method was classified as involving predominantly a sensitivity change. Mainly baseline drift was observed with the cholesterol and urea methods and drift correction errors were small; this was also true for total protein. Instrumental drift in the calcium method appeared to be mainly of the baseline type, but linear correction procedures gave rise to significant errors particularly at the lower end of the concentration range. As in the case of potassium, the error was least in the 'normal range' (8.5-10.5 mg/100 ml) since drift correction was based on a 10 mg/100 ml standard.

TABLE XXXVI

MAGNITUDE OF ERRORS IN CALCULATED CONCENTRATION USING LINEAR DRIFT CORRECTION

TEST	UNITS	DRIFT STANDARD	CONC. LEVEL	ERROR IN CALCULATED CONCENTRATION		S.D. OF METHOD
				MEAN	RANGE	
Potassium	meq./l.	4.0	1.0	0.23	0-0.5	0.1
			2.0	0.16	0-0.4	
			6.0	0.22	0-0.6	
			8.0	0.45	0-1.4	
Bicarbonate	meq./l.	20	5	0.8	0-1	0.9
			30	0.9	0-2	
			40	0.7	0-2	
Total protein	g/100ml	5.6	0.9	0.13	0-0.2	0.12
			7.1	0.04	0-0.1	
			9.3	0.06	0-0.2	
Urea	mg/100ml	100	30	0.7	0-3	2.9(20-50)
			50	1.5	0-4	
			150	2.3	0-4	6.5(100-250)
			250	3.8	0-10	
Calcium	mg/100ml	10.0	2.0	0.42	0-1.2	0.18
			6.0	0.27	0-0.7	
			12.0	0.21	0-0.6	
			16.0	0.23	0-1.0	
Cholesterol	mg/100ml	200	50	7	0-15	9
			100	4	0-10	
			300	2	0-5	
			500	4	0-15	

SECTION VI

DISCUSSION

(A) SUCCESSES AND FAILURES OF ELLIOTT ABL COMPUTER SYSTEM

The Elliott 903 computer system has been used successfully since July, 1969 to monitor on-line as many as 19 different determinations on up to 12 AutoAnalyzer channels at one time, performing peak detection and validation, channel calibration and calculation of concentrations after correction for instrumental drift. The allocation of AutoAnalyzer tests to computer channels throughout a normal working week is summarised in Table XXXVII. While monitoring AutoAnalyzers the system performs a process control function by checking and printing error messages on the on-line Teletype to indicate the detection of faulty peaks, unacceptable calibration standards, excessive instrumental drift, and the concentrations calculated for quality control samples if these fall outside prescribed limits. With the exception in certain cases of the detection of short-sampled specimens (Sections IIIA and IVA), the system software developed for data acquisition routines has worked well; a preliminary account of the chemical acceptability and efficiency of fault recognition procedures was published by Whitby and Simpson (1969), and this assessment has been described/

TABLE XXXVII

ALLOCATION OF AUTOANALYZER TEST CHANNELS AND TEST GROUPS TO COMPUTER CHANNELS

DAY	TIME	AUTOANALYZER TEST CHANNELS AND TEST GROUPS				
		GROUP 1B (CHN 12-16)	GROUP 2A (CHN 21-23)	GROUP 3A (CHN 31-32)	GROUP 4A (CHN 41)	GROUP 4B (CHN 42)
Monday	AM	ELU	LFT	C,CC	FE	-
	PM	ELU	EPH	CAP	IBC	COL
Tuesday	AM	ELU	LFT	-	UA	-
	PM	ELU	LFT	CAP	-	-
Wednesday	AM	ELU	LFT	C,CC	FE	-
	PM	ELU	EPH	CAP	IBC	-
Thursday	AM	ELU	LFT	-	UA	-
	PM	ELU	LFT	CAP	-	COL
Friday	AM	ELU	LFT	C,CC	FE	-
	PM	ELU	EPH	CAP	IBC	COL
Saturday	AM	ELU	-	-	-	-
	PM	ELU	-	-	-	-
Sunday	AM	ELU	-	-	-	-
	PM	-	-	-	-	-

ELU = Sodium, potassium, chloride bicarbonate and urea
LFT = Alkaline phosphatase, bilirubin and bilirubin blank
EPH = Total protein, albumin and protein blank
CAP = Calcium and phosphate

C = Serum creatinine
CC = Urine creatinine
FE = Serum iron
IBC = Iron-binding capacity
UA = Uric acid
COL = Cholesterol

described in detail in Section III.

In the area of laboratory data processing the computer system has been less successful. All the software provided for the input of patient and test request data, preparation of work sheets, compilation of records on magnetic tape and the printing of cumulative reports, etc., has been tested. Where necessary it has been modified by the manufacturers in the light of experience in this laboratory and operated on a trial basis. Cumulative records for all requests for urea and electrolytes have been maintained for two periods of about six months, and a similar compilation of records has been carried out for all requests for liver function tests over a limited period. However, it has not been possible to operate the integrated system within an acceptable timescale to process all the analytical work of the laboratory, and hence it has not been possible to issue computer-prepared reports to the wards and departments in the hospital.

Substantial delays with the input of data were encountered in the preliminary stages of development. These were reduced by changing from conversational to off-line mode (Section IVA), but there are still long hold-ups/

hold-ups in the transfer of data to and from magnetic tape files resulting in delays in the preparation of work sheets. In addition, the present printing facilities are inadequate to handle the preparation of cumulative reports.

The computer system is currently in use on a seven-day week basis for monitoring analytical equipment and performing the following functions:-

(1) Acquisition of raw data from up to 12 AutoAnalyzer channels at one time.
(2) Peak detection and validation.
(3) Calculation of results after correction for instrumental drift.
(4) Output of results identified by cup number.
(5) Calculation of mean and standard deviation of patient specimens.

By comparison with the basic requirements set out in Section I, the system has been unable to perform within the normal working day, the following functions as part of an integrated system:-

(1) Input of patient and test data for all requests received in the department.

(2)/

(2) Preparation of work sheets for automated and manual tests.

(3) Compilation of cumulative records on magnetic tape.

(4) Preparation of cumulative patient reports.

The present mode of operation removes the need for manual reading of AutoAnalyzer charts and hence eliminates reading errors, but it involves the transcription of results from the computer print-out to manually prepared work sheets, and the further transcription of results from work sheets to patient reports. The system in its present form fails to reduce, let alone to eliminate, human transcription errors which can occur at two stages in the processing of data from AutoAnalyzers.

In order to meet the current data acquisition and data processing requirements of this laboratory, which had a work load of 646,000 determinations per year in 1970, it would be necessary to extend and modify the existing hardware configuration or replace the present computer system. The ability of an extended system based on the 903 computer, the Elliott "A" system installed at University College Hospital, London, to cope/

cope with a work load of about 300,000 determinations is described in Section VI(C).

(B) SUGGESTED MODIFICATIONS AND EXTENSIONS

The delays in data handling experienced with the Elliott ABL system are associated with the input of information, with the transfer of information to and from the magnetic tape backing store, and with the printing of computer output. Any modifications and extensions of the system should therefore remove, or at least greatly reduce, the bottlenecks which exist in these areas of operation of the computer system.

The input of patient and test data by off-line mode is much less wasteful of computer time than normal conversational mode operation, but off-line preparation of data involves a considerable amount of repetitive key-punching and hence the possibility of a large number of typing errors (Section IVA). The number of key depressions can be appreciably reduced by the use as request forms of edge-punched cards (Fig. 39, Section IVA) coded with printed and punched data to identify the patients. Equipment for the generation of edge-punched cards could be sited in the/

the laboratory, but preferably in a centrally placed hospital records office where master cards could be prepared at the time of first registration of patients. The transfer of data from cards to paper tape, which would be necessary if using a paper tape based computer such as the Elliott 903, could be carried out by a Westrex Model 35 Teletype fitted with an edge-punched card reader and punch attachment. Alternatively, the printing and reading of cards could be performed on a Friden Flexowriter.

Most of the advantages of conversational and off-line mode (Section IVA) can be obtained by using keyboard-to-magnetic tape data preparation equipment (T.S.U. Note No. 0274). If the equipment includes a small computer then it can be used for storing and editing information, correcting errors and file searching. The input of data is simplified by using equipment in which the keyboard is linked to a visual display device. Once the validated information has been assembled on the data preparation tape it can be rapidly transferred to the computer magnetic tape backing store.

Magnetic tape has a number of advantages over other forms of input. The data can be recorded on tape in high-density/

high-density form and hence will take up little storage space. Also, the cost of materials is low since magnetic tape can be used over and over again, the generation of paper dust is eliminated and the computer room environment is improved by the quietness of operation. The main disadvantages of magnetic tape encoders are the high initial capital cost of the equipment and the fact that records are not readable visually (T.S.U. Note No. 0274).

A wide range of key-to-tape, key-to-cassette and key-to-disc machines are now available on the market and many of these machines have a display facility. However, there is one problem associated with the use of tape encoding equipment, namely compatibility with a particular computer's magnetic tapes. It is possible to obtain several tape preparation devices compatible with ICL and IBM computer systems, but special translator programs would be required to make this equipment compatible with the Elliott 903 system.

Delays in processing due to the slow transfer of data to and from magnetic tape could be alleviated by increasing the size of the core store. This would increase the buffer capacity, and thereby reduce the number/

number of times it was necessary to transfer data. However, it is doubtful if the increase in core store would eliminate all delays in processing, and the solution to this problem would appear to be the incorporation into the system of a rapid access backing store such as magnetic disc or drum, for storing programs and for holding the work file. A disc would greatly reduce the transfer times but the Elliott 903 computer cannot be linked to a disc system since it does not have an autonomous transfer facility. To make use of software developed for the Elliott 903 computer but at the same time meet the need for a faster access store, it would be necessary to replace the 903 computer by a more modern machine; the Elliott 905 computer could fulfil this requirement.

Experience has shown that for the printing of cumulative reports a line printer is essential. This finding is supported by a report issued by P.M.A. Consultants (1968), who considered the printing requirements of a hospital laboratory with a work load in excess of 500,000 determinations per annum. If a line printer with a printing speed of about 300 l.p.m. were added to the hardware configuration, the time taken

to/

to print a cumulative report would be about 0.2 min. as compared to a total punching and printing time of about 0.7 min. on the present system.

One of the main bottlenecks in the present system is associated with the use of computer-prepared work sheets. Even if all the suggested modifications described above were fully implemented, the preparation of work sheets could hold up the start of analytical runs and make it necessary to stop and restart test channels. There are two main disadvantages in using computer-prepared work sheets - it causes delays in the plate-loading area of the laboratory and it is not readily compatible with a central plate-loading system which greatly simplifies the handling of specimens in the laboratory. In this simplified system all specimens arriving in the laboratory are prepared for analysis and aliquots of the specimens placed on the appropriate AutoAnalyzer sample plates in a central area.

The delays caused by the computer preparation of work sheets could be eliminated by reverting to manually prepared work sheets, and allowing laboratory staff to allocate cup numbers to specimens, but all the/

the relevant information would still have to be input to the computer in order to prepare cumulative records and patient reports. If the manually allocated cup number was entered on the request form then it could be input together with the patient identification and test request information, but this procedure would be complicated and prone to error especially when more than one specimen was received with a single request form. Alternatively, the manually allocated cup numbers could be entered into the computer as a separate function; this would simplify the entry of data but would almost double the time taken in file searching routines.

The main advantages of using computer-prepared work sheets are the arrangement of specimens in priority order on the work sheets, the automatic re-allocation to work sheets of those specimens which produced faulty peaks on a first analysis or require dilution and the correction for dilution when calculating results. One of the advantages of manually prepared work sheets is the removal of any restriction on the cup number positions used for quality control samples. This facility could be extended to computer-prepared work sheets/

sheets but it would involve a considerable increase in the complexity of the software required to sort out patient specimens from other samples.

The object of modifications and extensions such as those outlined above would be to overcome the time delays which occur in various areas of the system. The possibility of extensions to the data acquisition hardware, to allow the number of AutoAnalyzer channels to be increased from 12 to about 24 channels, also needs to be considered. Also to be taken into account are the modifications in hardware and software that would be required to permit acquisition of data from Mark II AutoAnalyzer detector devices (output voltage up to 60 mV as compared to 0-10 mV for Mark I modules), from multichannel analysers such as the SMA 12/60 and 6/60, and from other automatic analysers including the LKB reaction rate analyser and discrete analysers such as the Vickers 300 instrument.

To extend the monitoring capability of the 8K Elliott 903 computer system to 24 channels of AutoAnalyzer equipment and to provide for monitoring two LKB reaction rate analysers, it would be necessary to provide additional computer transistor boards, high level/



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level switches, analyser console amplifier boards and additional core store. The on-line acquisition of data from an SMA 12/60 analyser by a 903 computer has been described by Carter and Griffiths (1971); for this purpose it was found necessary to increase the frequency of level 2 interrupts from once every two seconds to once every half second.

As in the case of computer-prepared and manually prepared work sheets, the advantages and disadvantages of taking signals from the AutoAnalyzer detector device as compared to the chart recorder are almost evenly balanced (Section IID). One disadvantage of the use of input signals from the detector has become apparent in the past two years; the manufacturers frequently change the design of detector devices resulting in changes in the nature and voltage of output signals. These changes in detector output require corresponding changes to be made in the amplification factors of analyser console transistor boards. They do not, however, affect signals taken from the chart recorder.

After discussions with the manufacturers of the Elliott 903 computer it was concluded that, in order to perform laboratory organisation, process control and the/

the preparation of cumulative records and reports, the 8K 903 computer would need to be replaced by an Elliott 905 system provided with a 32K core store. Further, the hardware configuration required to be extended to include a 896,000 word disc, a line printer (300 l.p.m.), a Friden Flexowriter fitted with edge-punched card equipment, and an up-graded data acquisition unit (24 analytical channels).

There are several alternative solutions to the problem of data processing in this department. For example, the present system could be linked to a larger computer system, or to a small data processing computer, or the Elliott 903 computer could be replaced by another computer system. Before considering the possible use of other computer systems to extend or replace the present system it is worth comparing the performance and capabilities of the existing system with other small computer systems in routine operation.

(C) COMPARISON OF ELLIOTT A.B.L. SYSTEM WITH OTHER COMPUTER SYSTEMS

On-line computer systems developed in the past few years include the IBM 1710 Process Control System (Blaivas, 1966), the Laboratory Instrument Computer (LINC)/

(LINC) system described by Hicks et al. (1966), the Clinical Laboratory Automation System (CLAS) Spear 300 computer system (Pribor et al., 1968), systems based on PDP-8 and PDP-8/S computers described by Potter (1968) and Gray and Owen (1969), respectively, and the Elliott 903 A system in operation at University College Hospital (U.C.H.), London (Flynn and Piper, 1971). In addition IBM systems are currently being developed at the Queen Elizabeth Hospital, Birmingham, and the Royal Victoria Hospital, Belfast, while work is still proceeding on the Modular One system at Dundee Royal Infirmary and on the Digico Micro 16 system at King's College Hospital, London. The various systems are described in this section and details of the systems are summarised in Tables XXXVIII and XXXIX.

IBM 1710 System

The IBM 1710 system (Blaivas, 1966) is used for the on-line monitoring of up to 20 AutoAnalyzer channels, the preparation of results cards and for the compilation of patient and test data on a disc file. Blaivas and Mencz (1967) next reported that the number of Auto-Analyzer channels on-line had been increased to 30, and stated/

TABLE XXXVIII

ON-LINE COMPUTER SYSTEM - SUMMARY OF HARDWARE FACILITIES

	ELLIOTT ABL SYSTEM	ELLIOTT 903 A SYSTEM	PDP 8/S	PDP 12 (CLINI-LAB 12)	LINC 8	SPEAR CLAS 300	IBM 1130	IBM 1710	DIGICO MICRO 16
Length of computer word (bits)	18	18	12	12	12	12	16	*	16
Core store (K)	8	8	8	8	2	4	8	*	16
Cycle time (μS) +	6	6	1.5	1.6	*	*	3.6	*	1.9
Storage of programs	M/T	M/T	DISC (32K)	DISC (534K words)	M/T	M/T	DISC	DISC	DISC
Input device	P/T Reader or T/T (C)	P/T Reader	P/T Reader	T/T (C)	*	VDU (C)	Card Reader	Card Reader	T/T
Process control device	T/T	T/T	T/T	VDU	VDU	VDU	*	*	T/T
Output device	IBM Printer (15 c.p.s.)	L/P (300 l.p.m.)	T/T	L/P (300 l.p.m.)	T/T or VDU	*	*	*	T/T
Storage of patient records	M/T	M/T	-	DISC	M/T	M/T	DISC	DISC	DISC
Cost	£33,000	*	*	*	*	£20,000	*	*	£23,000

* = Information not available; (C) = Conversational mode; (+) = Cycle times are reproduced from "Small Computer Supplement", Dataweek, 15th August, 1970 and "Minicomputers", Computer Weekly, 27th January, 1970.

TABLE XXXIX

ON-LINE COMPUTER SYSTEM - SUMMARY OF COMPUTER FUNCTIONS

FUNCTION	ELLIOTT ABL SYSTEM	ELLIOTT 903 A SYSTEM	PDP 8/S	PDP 12 (CLINI-LAB 12)	LINC 8	SPEAR CLAS 300	IBM 1130	IBM 1710	DIGICO MICRO 16
Preparation of patient and test data	T/T	E.P.C. to P/T	No	-	No	-	Yes	Punched cards	-
Input of patient and test data	P/T Reader or T/T(C)	P/T Reader	No	T/T(C)	No	VDU(C)	Card Reader	Card Reader	T/T(C)
Work allocation	Yes (+)	Yes	No	Yes	No	Yes	*	Yes	Yes
On-line monitoring of AutoAnalyzers	12 channels	24 channels	12 channels	24 channels	15 channels	SMA-12 SMA-4	*	30 channels	No
Method of calibration	Linear interpolation	Linear interpolation	3rd order polynomial	*	Linear interpolation	Linearised plot	*	Linear-ised plot	-
Correction for instrumental drift	Yes	Yes	Yes	*	Yes	Yes	*	Yes	-
Correction for interaction	No	No	Yes	*	*	*	*	Yes	-
On-line monitoring of other equipment	No	No	No	SMA-12 and Robot chemist	SMA-12	Beckmann Densitometer	*	No	Trace Reader
Cumulative records and reports	Yes (+)	Yes	No	Yes	No	Yes	*	No	Yes
Marking of 'abnormal' results	Yes (+)	Yes	No	*	-	Yes	*	-	*
End of day summaries	Yes (+)	Yes	*	Yes	*	Yes	Yes	*	*
Quality control and patient statistics	Yes	Yes	*	Yes	Yes	Yes	Yes	*	*
Laboratory management information	No	Yes	*	Yes	Yes	Yes	*	*	*

* Information not available; E.P.C. - Edge-punched cards; (+) - Function is operational but not in routine use; (C) - Conversational mode

stated that the system as modified was capable of monitoring up to 200 AutoAnalyzer channels. Request cards are prepunched with the physician's name and his identification number; on receipt in the laboratory, the data, tests to be performed and a laboratory accession number are entered on the card. The identification and test data are read into the computer and stored on disc files. The analyser monitoring programs perform peak validation routines and output on the control Teletype, messages relating to the acceptance or rejection of standards and quality control specimens and a list of specimens on which repeat analyses are required. After correcting for baseline drift and specimen interaction the test results are calculated and written away to the disc files. Information stored on the files is used to generate punched cards, printed results cards and laboratory report sheets.

Blaivas and Mencz (1968) also described an improved method of peak detection. This included the calculation of a proportionality factor between peak height and peak area. The method of standardisation was also modified, a linear calibration procedure making/

making use of one standard and the baseline. They checked the validity of this linear plot by using two commercial control sera.

LINC System

The LINC system (Hicks et al., 1966) consists of a 2K core store, two magnetic tapes with a capacity of 130,000 test results per tape, data acquisition equipment, a Teletype and an oscilloscope screen linked to an input keyboard. Programs for the on-line monitoring of up to 16 analogue channels are stored on magnetic tape. Data is entered on the keyboard/ oscilloscope device using conversational mode and the information is stored on magnetic tape.

The system is used to calculate test results and to perform additional calculations on the results obtained. For instance, protein electrophoretic fractions are calculated from the total protein and integrator scan readings taken directly from a densitometer and entered on the keyboard. Two types of data files are used - files containing the date and test results which can be used for quality control, statistical analysis and census reports, and files containing/

containing only the dates and numbers of tests performed from which census reports can be prepared. Statistical data provided by the computer include the average, median, standard deviation and a histogram of test results; the histogram is displayed on the oscilloscope screen.

The extension of the LINC computer system to include the acquisition of data from an SMA-12 analyser was reported by Evenson et al. (1968). This is one of the few publications describing clinical chemistry systems which include a comparison of the precision of a manual reading procedure and computer-calculated results; an investigation of glucose, urea and calcium results revealed that the precision of computer readings was comparable to that of strip chart readings.

Spear CLAS 300 System

The Spear CLAS 300 computer system has a 4K core store, input keyboard, magnetic tape backing store and visual display unit (VDU); it accepts signals from up to 12 analogue channels. The system has been linked to SMA-12 and SMA-4 Technicon multi-channel analysers, and to a Beckmann scanning densitometer. Laboratory test/

test requests are entered into the computer via the keyboard using a conversational mode. For new patients, the first test request is accompanied by patient identification data (name, age, sex, etc.), these being used to create a permanent file on magnetic tape. Subsequent tests are requested by entering each patient's hospital number and the test code.

The computer program calculates the concentration of each constituent in the patient's specimen and enters the figures into the appropriate magnetic tape record. Serum protein electrophoresis strips are scanned by the densitometer and the readings transferred directly to the computer; this information is displayed on the VDU and the components marked electronically by a technician. Electrophoretic patterns are compared with disease patterns stored in the computer memory and two diagnostic statements are output - the conditions in which this pattern most frequently occurs and those in which the pattern may also be found. On demand, the computer provides complete cumulative reports for each patient, with the appropriate normal ranges for the patient's age and sex. The computer also/

also provides a daily list of all patients with abnormal results, quality control information including histograms for all tests, and laboratory management information.

PDP-8 Systems

The CLINDATA system, based on the PDP-8 computer (Potter, 1968), consists of an on-line Teletype for the input of test request data by a conversational mode, and data input consoles for the acquisition of test readings from colorimeters, cell counters, etc. When all the tests on an individual patient are completed, the computer automatically prints out a report.

The PDP-8/S system described by Gray and Owen (1969) has a 4K core store, a 32K disc file used for storing AutoAnalyzer programs, and peripheral Teletype equipment. An interface device attached to the computer receives signals from the re-transmitting slide wires in AutoAnalyzer chart recorders. The system has been used routinely to acquire data from a 5-channel AutoAnalyzer complex; it performs drift correction by a linear interpolation procedure based on peak height. Specimens are assayed in batches of up to 80, each batch/

batch containing calibration standards, drift correction standards, and serum or urine pools used for quality control purposes. Results identified by cup number are printed out shortly after each specimen has been analysed.

Gray and Owen (1969) have assessed the analytical performance by comparing results obtained by the computer with results obtained by manual chart reading and also by comparing the results of quality control materials. The authors gave a brief report of the reliability of the computer hardware during a six-month period of routine operation.

In a later publication, Abernethy et al. (1970) reported on the operation of an extended system having an 8K core store and an interface device capable of receiving data from up to 12 test channels. The modified system makes use of improvements suggested by Bennett et al.(1970) for calibration by a third-order polynomial, drift correction based on assay values instead of on peak heights, and correction for specimen interaction.

Elliott/

Elliott 903 A System

The Elliott A system installed at University College Hospital, London, (Flynn and Piper, 1971) is similar to that in the Royal Infirmary, Edinburgh but the data acquisition unit can be used for the on-line monitoring of up to 24 AutoAnalyzer channels, the hardware configuration includes a Potter chain printer (310 l.p.m.) and the software has been modified and extended to provide additional on-line and off-line facilities.

Patient identification and test request data are provided on an edge-punched card generated in the hospital records office, or on a hand-written request form. At the present time less than 20% of the 300-500 requests forms received each day are on edge-punched cards, but on a considerable proportion of the hand-written forms the patient identification is printed by an addressograph-type plate. When a written request is received, a record file containing all the cards prepared in the department is manually checked to ascertain if the patient has a record on magnetic tape. If a master card is found for a patient, this card is used to transfer the identification data relating/

relating to that patient on to an input data tape to which is added the test request information. If no record is available for a patient, a master card is generated in the laboratory by key-punching using a Friden Flexowriter. The transfer of patient identification data from edge-punched cards to paper tape is also carried out on a Friden Flexowriter and this is followed by entry from the keyboard of the diagnosis and test request data. The rate of processing patient requests is up to 3 requests per minute.

Computer procedures have been developed for the preparation of work sheets, the input of manual results, comments and amendments, and the output of quality control and test request form statistics. Results are output as cumulative records on pre-printed continuous stationery. Three report formats are used; two for analyses on blood specimens, and one for urine and miscellaneous tests. In addition, the results of glucose tolerance tests are output in graphical form on a graph plotter. On cumulative reports, results are marked by an asterisk if they fall outside 'normal limits' or show a significant change from a previous result/

result. Results are also marked by a letter to indicate how they compare with a 'normal range' based on the patient's age and sex. Cumulative reports are printed up on the Potter printer at a printing rate of 6-7 reports per minute.

A visual link between the computer room and the laboratory stations, in the form of a television camera and display terminals, when used in conjunction with an audio link, has proved to be of considerable value for communicating error messages to the laboratory staff.

The computer system at University College Hospital has been fully operational for several months. Its operations give a much more comprehensive amount of computer involvment in laboratory work than with the Royal Infirmary system, but it has been found necessary to extend the normal working day by several hours in order to carry out all the computer operations using existing hardware (Flynn and Piper, 1971).

Comparison of Systems

The information in Table XXXIX indicates the measure of success achieved by clinical chemistry laboratory/

laboratory systems. However, because of the lack of detail in published reports, it is impossible to make more than a superficial comparison of these systems. Most publications on computer systems fail to distinguish clearly between software still at the flow-charting stage, software written but not fully tested and debugged, and programs being used routinely in laboratory procedures. Comparisons are made even more difficult by the scanty information available regarding the number of determinations per year, the total cost of software and hardware, the duration of the computer working day, reliability of hardware components, etc. In spite of these difficulties an attempt is made here to provide some form of comparison of the various systems.

The Elliott 903 A system installed at University College Hospital is currently performing all the functions required by the laboratory with the exception of on-line monitoring of LKB reaction rate analysers. However, it is unable to carry out this work within the normal working day even with a work load of 300,000 determinations per year. In order to meet the requirements of the laboratory at the Royal Infirmary, which/

which has a work load in excess of 670,000 determinations on specimens from patients each year, the system would have to be extensively modified.

The PDP 8/S system described by Abernethy et al. (1970), and the LINC-8 system (Evenson et al., 1968), do not provide facilities for work allocation and the preparation of cumulative records and reports; these are essential parts of a laboratory's requirements for assistance from a computer. The Clini-lab 12 system, based on the PDP 12 computer, and the Digico Micro 16 system are still in the developmental stage, but it is unlikely that the latter will provide the necessary computing facilities for departments with work loads in excess of 500,000 determinations per year.

The Spear CLAS 300 system (Pribor et al., 1968) appears to provide a wide range of facilities for a laboratory where the work load is up to 600,000-800,000 determinations per year. It uses a remarkably small hardware configuration. This system provides patient reports carrying normal values for the patients' age and sex, and suggests differential diagnoses based on the results of certain tests, notably/

notably protein electrophoresis. One limitation of this system is the fact that it is restricted to a maximum of 12 analogue channels.

The IBM 1710 system (Blaivas, 1966; Blaivas and Mencz, 1967; Blaivas and Mencz, 1968) appears to be capable of providing most of the facilities required by a laboratory with a work load of about 500,000 determinations per year, but it does not include the preparation of cumulative reports and very little information is available in the literature regarding the compilation of records.

(D) ALTERNATIVE SYSTEMS REQUIRING CONSIDERATION

There are four different types of solution to the data handling problem in the clinical chemistry laboratory at the Royal Infirmary, Edinburgh:-

(1) The extension of the existing Elliott 903 system.

(2) The replacement of the 903 computer by another system.

(3) The use of the present computer as a device for data acquisition, with a link to another small dedicated computer for data processing.

(4)/

(4) The use of the present computer for data acquisition with a link to a large remote computer for data processing on a time-sharing basis.

The advantages and disadvantages of each solution are discussed in the following section.

(1) Extension of the Elliott 903 System

The extension of the present system has been discussed in Section VI(B) where the additional hardware components have been enumerated. The main advantage of this approach is the availability of fully tested software, but this advantage is more than offset by the fact that the 903 computer cannot be linked to a magnetic disc or drum system. This means that the access time of the backing store cannot be significantly reduced even by additional core store. In view of this limitation, it is most unlikely that even an extended 903 system could perform all the necessary computer functions within an acceptable timescale. Furthermore, the manufacturers would not advocate this extension which would create a 'one-off' system with all its attendant disadvantages.

(2)/

(2) Replacement of the Elliott 903 Computer

There are several computers which can be considered as possible replacements for the 903 system. These include the Elliott 905 computer, Computer Technology's Modular One system, the PDP12, one of the range of PDP11 computers and the Digico Micro 16 system.

One important factor in favour of the Elliott 905 computer would be the fact that its programming would not involve a major change in software; current programs could be used although they would require some modification for use with the new hardware. The advantage of available software must be set against some of the obvious disadvantages - the 905 computer is expensive, it is several years since the computer was designed and hence the hardware is out of date, and the disc system is not fully operational.

The Modular One computer (cycle time = 0.75 μs) is faster than the Elliott 905 computer (cycle time = 1 μs) and has up-to-date hardware. However, only a very limited amount of general software is available from the manufacturers, and although systems software is being developed at the Royal Infirmary, Dundee, this work is still in a preliminary phase. It would appear/

appear that it will be many months, if not years, before the clinical chemistry software for the Modular One computer is comparable to that presently available for the Elliott 905 computer. A current assessment would indicate that, in the short term, the Modular One is a poor alternative to the Elliott 905 system, but the former appears to be a better long term investment. However, great care must be exercised in making such predictions since the rapid development of computer hardware could render the Modular One system obsolete even before the software is fully developed.

In contrast to the Modular One system, a large amount of general software is available for the Digital Equipment Company's PDP computers, and software for use in clinical chemistry laboratories has been developed on an 8/S computer in Alfred Hospital, Melbourne (Gray and Owen, 1969; Abernethy et al., 1970); similar software is at present being developed on a PDP 12 at the Royal Infirmary, Aberdeen. The PDP 12 computer is appreciably slower (cycle time = 1.6 μS) than the Elliott 905 and Modular One computers; the cycle times for the PDP 11 range of computers are in the range 1.2-0.3 μS.

Experience/

Experience gained in using the Elliott 903 system has revealed several factors which merit special consideration when selecting a computer system. These include the following:-

(a) The previous experience gained by the manufacturers in developing clinical chemistry systems.

(b) The willingness and ability of the manufacturers to design the special hardware required for the acquisition of signals from laboratory equipment.

(c) The extent to which the manufacturers are willing to write special purpose software required for the system.

(d) The cost. A comparison of the costs of computer systems is difficult since a higher price for hardware may be balanced by an increased amount of software available, and what is to be standard hardware in one system may be 'optimal extras' in another system.

(e)/

(e) The availability of software documentation. This information must be comprehensive and of a reasonably high standard if it is to be used for future in-house modification of software.

(f) The provision of adequate maintenance and servicing facilities is of paramount importance.

(g) The availability of fully tested and proven standard software and compilers for a range of high level languages, e.g. ALGOL and FORTRAN; COBOL could also be of value for laboratory management and stock control programs.

(h) The availability and size of store modules for increasing the core store, and the availability of suitable interfaces for linking additional peripheral equipment such as magnetic tape or disc backing store, visual display units, etc.

(3) Link to another Small Computer for Data Processing

It is doubtful if any small computer could be directly/

directly linked to the Elliott 903 system without creating major problems in the construction of suitable hardware interfaces. The incompatibility of software would also present great difficulties, and these problems would require for their solution a considerable outlay of capital. It would, however, appear to be feasible to link a small computer such as the Modular One or IBM 1130, to the present system using paper tape to transfer data. The paper tape containing results calculated by the 903 computer could be input to the data processing computer for the compilation of records and generation of reports.

The advantages and disadvantages of the Modular One system have been discussed above. The IBM 1130 series of computers are slow (cycle time = 3.6 μS), but the company has wide experience of data processing and a large amount of fully tested software is available.

The use of a system involving two digital computers suffers from the inherent disadvantages of a mixed system. These include a considerable amount of manual intervention by the operators, increased error rates because of the use of paper tape when transferring information from one process to the next, and/

and the difficulty of locating faults in the system.

If a Modular One computer was selected, after completing development of the data processing part of the system, the 903 computer could be phased out and the Modular One configuration extended to include data acquisition. The manufacturers of the IBM 1130 do not consider that this computer is suitable for on-line data acquisition although the development of hardware interfaces to enable the IBM 1130 to fulfil this function is being carried out at the Queen Elizabeth Hospital, Birmingham and at the Royal Victoria Hospital, Belfast.

(4) Link to a Large Computer System

The possibility of a magnetic tape link between the Elliott 903 system and an ICL 1900 series computer situated in the Regional Hospital Board computer unit has been investigated and the difficulties encountered can be summarised as follows:-

(a) There is a parity difference between the two systems, but the parity setting can be altered on the 1900 computer.

(b)/

(b) Differences in the speed of reading data from magnetic tape (I.C.L. system - 40 K.C.S.; Elliott system - 9 K.C.S.) and in packing density do not appear to interfere with the reading of data from magnetic tape, although this disparity may increase the read/write error rate.

(c) The I.C.L. computer has a 24-bit word; the Elliott computer has an 18-bit word.

(d) Octal codes used in the I.C.L. system differ from those used in the Elliott system.

(e) The tape header format used in the Elliott system is not recognised by COBOL programs operating in the I.C.L. system.

The incompatibilities outlined in (c) and (d) could possibly be overcome by using a translator program written in 1900 assembly language (PLAN), to convert the magnetic tape data into a suitable form for processing by COBOL programs, but such a system would be cumbersome, prone to error and time-consuming.

A direct link between a dedicated ICL-compatible laboratory computer and a large ICL system sited in the Regional/

Regional Board computer unit or in the projected computer unit serving the Royal Infirmary could offer important advantages if the large system was also linked to the hospital records department. If the patient identification information was input through a terminal in the records office at the time of admission of each patient, then a unique number could be allocated at this stage and this number used for a variety of purposes including the requesting of laboratory tests. The additional information required by the laboratory could be obtained from the large computer using the unique number as a data link. Such a system would greatly reduce the amount of data to be input in the laboratory. If a link of this nature was considered, it would be necessary to replace the Elliott 903 computer by an ICL-compatible computer, e.g. a PDP 12 or a Modular One computer; the Elliott 905 computer is not readily compatible with ICL 1900 series systems.

One important problem associated with the use of a remote computer for storing patient records is the time taken to access past results and, if only a number is used for patient identification when entering test data, the time taken to report the results of urgent/

urgent analyses. In order to achieve an acceptable access time, it would probably be necessary to receive the patient identification data from the remote computer and to file patient records on a backing store linked to the dedicated computer in the laboratory.

(E) SELECTION OF COMPUTER SYSTEM

In deciding upon the most suitable computer system for the clinical chemistry laboratory at the Royal Infirmary, Edinburgh, it is necessary to restate and review the list of requirements set out at the start of the Elliott ABL project (Section ID) in the light of experience gained, and taking into account the recent developments in automated laboratory equipment and in computer peripherals. A future computer system in this laboratory should include the following facilities:-

(1) A rapid method of entering patient identification and test request data involving a minimum number of key depressions and some form of validation of the data. This could be achieved by the use of edge-punched card equipment or a display/keyboard-to-magnetic tape device. The input of patient identification information could be greatly simplified by/

by the use of a unique registration number and by a link, possibly via a Royal Infirmary or Regional Hospital Board computer, with the hospital records office, provided rapid access to patient information could be guaranteed.

(2) The system should provide a work allocation function, although this need not necessarily depend on the issue of computer-prepared work sheets.

(3) The data acquisition hardware should be capable of extension to handle an increasing number of channels of automated equipment. In addition to AutoAnalyzers (Mark I, Mark II and Sequential Multiple Analyzers), the system must be capable of performing the on-line acquisition of signals from other forms of automated equipment including LKB reaction rate analysers, multichannel analyzers and discrete analysers, e.g. the Vickers 300 system.

(4) Computer software is required for the calculation of concentrations after correction for instrumental drift and specimen interaction, and for the performance of simple additional calculations such as creatinine clearances and phosphate excretion indices.

(5)/

(5) Even in a highly automated laboratory, a number of tests are performed manually, e.g. blood gases and certain steroid assays; a simple method of entering results obtained in this way is therefore essential. A keyboard-to-magnetic tape device, or a visual display unit on-line to the computer, could be used for this purpose. Once again it is important to reduce the number of key depressions to a minimum by using carefully designed input formats, and to perform validation checks on all data being entered.

(6) The system should include a process-control function, a running assessment of quality control data, and the provision of this information in 'real time' if the values fall outside prescribed limits.

(7) An important function of the computer system is the compilation of patient records. Current records should be stored in a rapid access medium, e.g. magnetic discs or drums; historical records could be held on discs or on magnetic tape.

(8) It should be possible to prepare printed cumulative reports for issue to wards and departments. For this purpose it is essential to extend the hardware configuration to include a fast printer or a line printer/

printer. Consideration should be given to the use of non-cumulative reports for issuing to general practitioners and outside hospitals and as an important form of back-up in the event of failure of the data processing section of the computer system.

(9) Results on cumulative reports should be compared with normal ranges corrected for each patient's age and sex, and compared with previous results. The latest result should be marked by the computer program if special attention is needed.

(10) Special facilities must be available for handling urgent requests. Results for such tests should be output as soon as the analyses have been completed, so that the results can be conveyed to the doctor as quickly as possible.

(11) An end-of-the-day summary of test requests and results is not only useful for dealing with telephone enquiries but is an important hard copy record for the laboratory of work carried out, whether or not the data are also stored in the computer's magnetic records. If the format of this print out is designed properly it can also form part of a back-up system of reporting.

(12)/

(12) A summary of test and quality control statistics including the mean values both for patient specimens and for samples of laboratory pooled serum should be output at the end of each run. Preferably this information should be provided in easily understood form, as histograms, cusum charts or some other form of graphical representation.

(13) It is essential to provide adequate back-up facilities for use in the event of failure of one or more components of the computer system. If no on-line monitoring is possible the heights of AutoAnalyzer peaks could be recorded on paper tape using a trace reader and the resulting tape input to the computer via the paper tape reader. If a fault in the backing store prevents access to patient record files, it should be possible to prepare non-cumulative reports.

(14) Results stored in cumulative records should be in such a form that they are readily accessible for retrospective statistical analysis. For this purpose it is desirable to include the diagnosis in the list of information stored.

(15) The computer system should provide laboratory management statistics including the number of/

of specimens received for each test, number of requests from each ward, etc. Consideration should be given to the use of the computer for stock control, allocation of duties to laboratory staff, preparation of duty biochemist rotas, etc.

(16) The method of communication between the computer room and the laboratory is an important feature of a clinical chemistry system. This could take the form of a television camera or visual display unit in the computer room linked to display terminals in the laboratory. The visual display unit is more expensive but it is more reliable and can also be used for editing computer programs, etc. In addition to the visual link it is essential to have some form of audio link.

Work on the present project has served to underline the importance of several aspects of software development. The programs for this project were written by the manufacturers and provided in the form of binary tapes for testing and validation. Only a very limited amount of documentation was provided for data acquisition programs and no program documentation was/

was provided for data processing routines. The documentation and operating instructions supplied by the manufacturers lacked clarity and were difficult to comprehend without frequent reference to the programming staff. As a result it was extremely difficult to correct simple errors and make even minor amendments to systems programs without the assistance of the manufacturers. This caused considerable delays in the testing and development of software. Frequent changes in the manufacturer's programming staff were another source of frustration, giving rise to misunderstandings and difficulties in the correction of programming errors.

In the development of the Elliott ABL system there were numerous unacceptable delays in the writing of systems software. Even at the present time, several programs have not been provided by the manufacturers, e.g. Preparation of History Files, while other programs are not fully operational, e.g. Rescue Procedures, although it is 5 years since the computer system was installed in the department.

In spite of the many disadvantages, a high standard of programming can be achieved by the manufacturers as

a/

a result of the software expertise available and a more intimate knowledge of the performance of the computer. However, this may be offset by a failure to understand clearly the detailed nature of the tasks to be performed by computer programs.

If a manufacturer is providing systems software, it is essential to have on the site an experienced programmer with a good knowledge of the software so that errors can be corrected and modifications carried out quickly to prevent frustration and enable debugging to proceed without delay. It is important that the on-site programmer should have a close link with the manufacturer's programming staff. An equally important requirement is the provision of programs in low level language, as well as in binary form, and full documentation for all programs supplied by the manufacturers, to enable a resident programmer to modify programs if this proves to be necessary. Full documentation for all in-house and manufacturer's programs is essential for future development of the systems software.

APPENDICES

APPENDIX I

The Technicon AutoAnalyzer

The AutoAnalyzer system of continuous flow analysis was described by Skeggs (1957); it has been developed and marketed by Technicon Instruments Corporation (1). It consists of a number of individual modules which carry out different analytical functions such as sampling, mixing, dialysing, heating, etc. and which can be connected as required for the analysis of a particular constituent. Samples for analysis are placed in disposable polystyrene cups arranged round the circumference of a turntable which forms part of a sampler module (Fig. 46). The sample turntable rotates at a speed representing 20-80 analyses per hour, and a probe attached to a pick-up arm dips into each cup in turn aspirating its contents for a specified length of time; it aspirates water before passing on to the next sample. This water wash interposes a column of water between successive samples and hence reduces cross-contamination between samples.

The removal of an aliquot of the sample and addition of measured quantities of reagents is performed by/

(1) Technicon Instruments Corporation, Tarrytown, New York

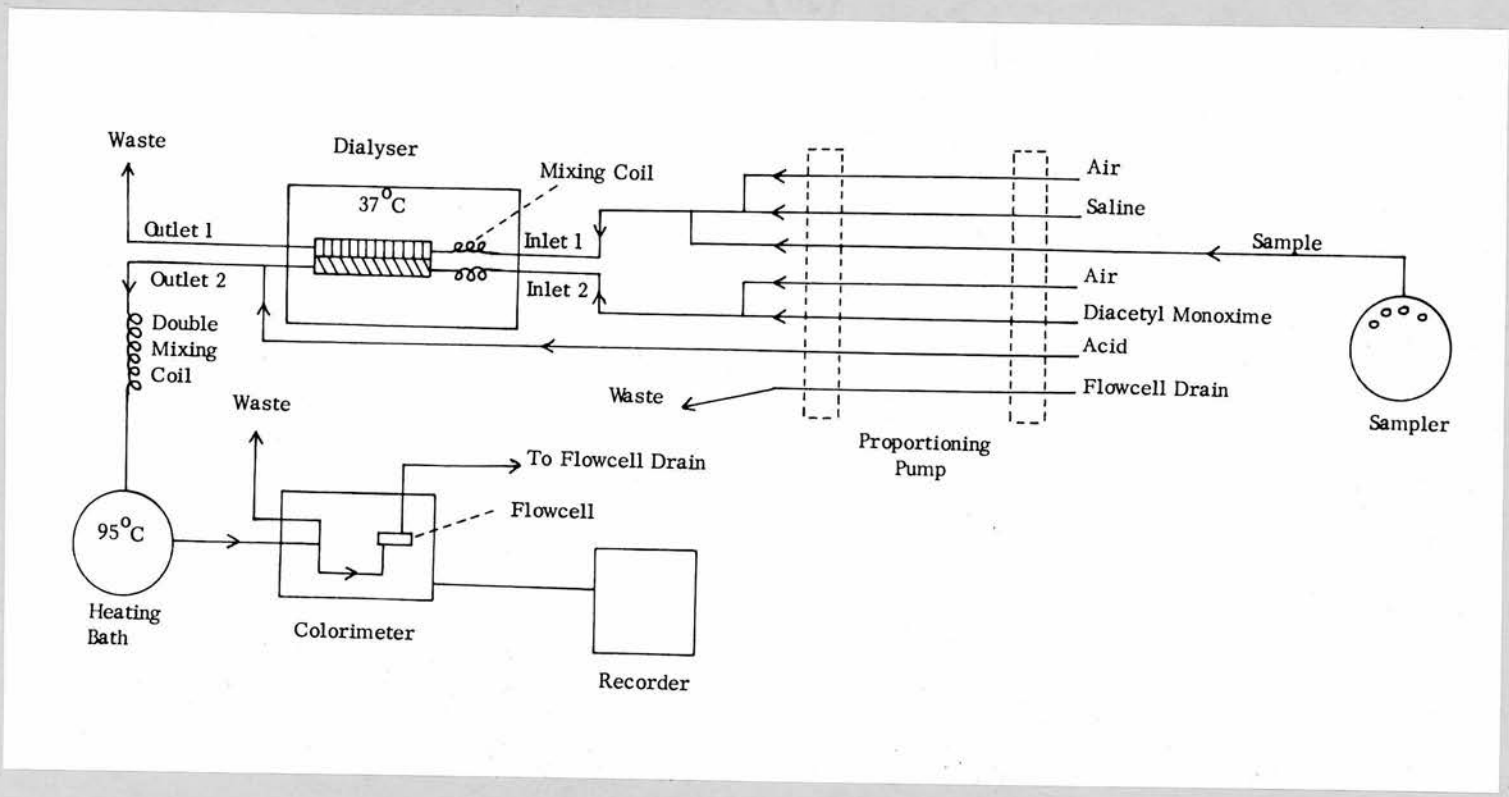

Fig. 46

Flow diagram for urea AutoAnalyzer

by a proportioning pump which may be considered to be the heart of the AutoAnalyzer. The Mark I pump consists of two parallel steel roller chains which compress a set of flexible plastic tubes down against a spring-loaded pump platen. In the Mark II module the roller assembly is mounted below the pump tubes while a cover plate and platen is positioned above the tubes. The cover plate and platen are attached together by a hinged pivot bar assembly and when the platen is lowered and latched, the rotation of the rollers applies a steady pressure to the pump tubes. An aliquot of sample, reagent and diluting fluids are sucked in and forced through the plastic tubes by the peristaltic action of the rollers; the rate of flow through each tube depends on the bore of the tube. The volume of sample introduced into the flow system depends not only on the tube bore but also on the sampling rate and the sample-to-wash ratio selected on the sampler module.

After passing through the pump assembly, the different liquid streams are combined by using a variety of glass connecting pieces. Air is injected into each stream by an air line which also passes through the pump/

pump, dividing the stream into short segments of liquid separated by air bubbles. The air bubbles keep the individual samples separate, clean the walls of the tubes preventing formation of a stationery liquid film, and play an important role in the mixing of sample and reagent streams. Mixing is effected by passing the air-segmented streams through helical glass coils when the segments of liquid are repeatedly inverted and hence the heavier liquid falls down through the less dense medium.

If it is necessary to remove proteins the stream from the mixing coil is passed through a dialyser module (Fig. 46) which consists, in the case of a Mark I module, of a matching pair of plastic plates, each having a spiral groove with a cellophane membrane stretched between the two plates. In the Mark II dialyser, the grooves on two small polystyrene plates are aligned to form a continuous tube that is divided lengthwise by the membrane. The liquid stream flows along one side of the membrane and the diffusible components pass through into the recipient reagent stream. Transfer of the constituents across the membrane is not complete, but since the standard solutions are subjected/

subjected to the same conditions proportional dialysis occurs and it is not necessary to reach dialysis equilibrium. In order to standardise the conditions of dialysis, the dialyser unit is immersed in water maintained at a constant temperature of 37°C and the streams entering the unit pass through temperature equilibrating coils placed in the water.

The stream leaving the dialysis module may pass through further mixing coils and through a glass helix immersed in a bath of diethylene glycol which serves as a heating bath. Finally, the liquid stream passes through a detector module in which the absorption or emission of light by the standards and samples is measured. The detector can be a dual-beam colorimeter in which one beam of light falls on a reference photoelectric cell while a second beam passes through the sample and falls on a measuring cell. Other detecting devices used in AutoAnalyzer systems include a flame photometer for sodium and potassium, and a fluorimeter for calcium. The reference and measuring signals from the detector are transmitted to a chart recorder which acts as a null balancing indicator in which the signals from standards and samples are represented as a series of peaks (see Fig. 29, Section IIIa).

A/

A flow diagram for the AutoAnalyzer system used for the analysis of urea in plasma is shown in Fig. 46. An aliquot of the specimen (0.1 ml) is diluted with saline, the stream of liquid segmented by air and pumped into a dialyser unit. The protein-free component passes into an air-segmented recipient stream containing diacetyl monoxime which is then mixed with a solution of ferric chloride and thiosemicarbazide in phosphoric and sulphuric acids. The reagents are passed through a double-length mixing coil and the aqueous mixture is heated to 95°C before passing into the colorimeter module. The chemistry of the reaction is uncertain but in the strongly acid solution, diacetyl monoxime reacts with urea in the presence of ferric chloride to form triazine derivatives by an oxidative condensation reaction; the thiosemicarbazide intensifies the final colour. The intensity of the colour produced by the reaction is measured at 505 nm.

At the start of each analytical run, the Auto-Analyzer system is calibrated by running a series of standards. A calibration curve is constructed by plotting the peak heights against the known concentrations of the standards. The concentration of the constituent in/

in test specimens can then be determined by reading off the appropriate value from the calibration curve. If the test specimens are intersperced with drift correction standards it is possible to adjust the position of the calibration curve to compensate for instrumental drift (see Section IIIC).

APPENDIX II

Date of Birth Registration Number

The main problem associated with the use of a patient identification system based on the date of birth registration number stems from the fact that two or more patients can have the same date of birth and hence the same identification number. The probability of two persons having been born on any specified date (day and month) of a year is 1 in 365. The probability that a patient admitted to hospital or attending an out-patient clinic has a particular date of birth is proportional to the number of people of that age in the community; for instance, one is much more likely to find a patient with a date of birth 010160 (1st January, 1960) than 010180 (1st January, 1880). The proportion in each age-group in the Edinburgh area can be taken as being roughly the same as for the whole of Scotland, an estimate of the proportions can be obtained from the estimated Scottish Population for 1968 (Registrar General's Report, 1968) which is listed in Table XL.

The probability of a patient having a date of birth on a specified day within any 5-year period is $(^{1}/[5 \times 365])/$

TABLE XL

ESTIMATED SCOTTISH POPULATION - 1968

AGE	NO.	AGE	NO.
0-4	470,600	45-49	328,100
5-9	466,900	50-54	295,300
10-14	418,700	55-59	317,900
15-19	398,800	60-64	286,100
20-24	395,000	65-69	235,700
25-29	318,000	70-74	166,700
30-34	295,200	75-79	111,400
35-39	303,800	80-84	62,600
40-44	313,600	85+	32,600

Total population - 5,217,400

($^{1}/[5 \times 365]$); the probability that the patient is in the age-group 0-4 is (470,600/5,217,400) and hence the probability that a patient A has a date of birth on a specified day in the last five years is given by the following expression:-

$$P_A = \frac{1 \times 4,706}{5 \times 365 \times 52,174}$$

The probability that a second patient (patient B) has this same date of birth is also given by the above expression and therefore the probability that both A and B have this date of birth is P_A^2. There are 5 x 365 days in the 5-year period in which A and B could coincide, so that the probability of two patients, born within the last 5 years, having the same date of birth is given by the expression P_{AB}:-

$$P_{AB} = \frac{5}{365} P_A^2 = \frac{1}{5 \times 365} \left(\frac{4,706}{52,174}\right)^2$$

Similarly for the 5-9 age group, the probability of two patients having the same date of birth is given by P_{CD}:-

$$P_{CD} = \frac{1}{5 \times 365} \left(\frac{4,669}{52,174}\right)^2$$

and similarly for all the other age groups. The total probability that two patients have the same date of birth/

birth is given by P_T:-

$$P_T = \frac{1}{5 \times 365 \times (52,174)^2} [(4,706)^2 + (4,669)^2 + ...(326)^2]$$

$$= 0.000036$$

i.e. the probability that two patients have the same date of birth is 1 in 28,000, approximately.

To this must be added the probability that three or more patients have the same date of birth. The probability that 3 patients have the same date of birth is of the order of 0.0000025 and this brings the total probability up from 1 in 28,000 to 1 in 26,000. For 4 or more patients with the same date of birth the probability is so small that it can be ignored.

The Clinical Chemistry Department in The Royal Infirmary of Edinburgh produces a service for a total of 6,500 hospital beds and receives patients from a total population of about 600,000 and hence a probability of 1 in 26,000 is comparatively high. In order to reduce this probability the first letter of the surname was added to the date of birth to form the patient identification number. The magnitude of this reduction in probability depends on the surname initial - there are many more people in Scotland with surnames beginning with/

with M than with X. One method of getting an estimate of this probability for each surname initial is to count the number of columns occupied by each letter in a telephone directory; as local authorities and many other organisations are included in these lists the figures are not accurate but they can be used as a rough guide.

In the Edinburgh area directory the distribution and the probabilities of each initial are shown in Table XLI. For any specified initial, the probability of two or more patients having the same identification number can be obtained by multiplying 1 in 26,000 by the appropriate probability; for instance, the probability for the surname initial A is given by P_N:-

$$P_N = \frac{1}{26,000} \times \frac{1}{26} = \frac{1}{675,000}$$

The values of the probability vary from 1 in 37,960,000 for surname letter Z to a maximum of 1 in 182,000 for the letter M. The addition of the first letter of the surname thus represents a considerable reduction in the probability of one or more patients having the same identification number.

TABLE XLI

DISTRIBUTION OF SURNAME INITIALS IN EDINBURGH AREA TELEPHONE DIRECTORY AND CORRESPONDING PROBABILITIES

INITIAL	NO. OF COLUMNS	PROBABILITY	INITIAL	NO. OF COLUMNS	PROBABILITY
A	55	.038	O	12	.008
B	130	.089	P	54	.037
C	114	.078	Q	2	.001
D	73	.050	R	84	.058
E	35	.024	S	139	.095
F	59	.040	T	55	.038
G	72	.049	U	6	.004
H	93	.064	V	6	.004
I	12	.008	W	93	.064
J	25	.017	X	-	-
K	33	.023	Y	10	.007
L	62	.042	Z	1	.001
M	206	.141			
N	29	.020	TOTAL	1460	

APPENDIX III

Description of Computer Hardware

Two units of special hardware were designed for the system by Elliott Medical Automation Limited. These units are interposed between the laboratory instruments and the computer - the analyser consoles, used in close proximity to the AutoAnalyzers, and the Data Acquisition Unit (DAU) placed beside the computer. A third unit, the magnetic tape controller, is interposed between the computer and the magnetic tape handlers.

(1) The Analyser Consoles

The analyser consoles are connected by two-core screened leads to the analytical instruments on the laboratory bench. Their main function is to raise the output voltage level from the measuring instruments to a level suitable for transmission to the DAU. In addition, the consoles provide switches for initiating the input of data from the analysers linked on-line to the computer; they have display lights (green and red respectively) to indicate if the data have been accepted or not. The analyser consoles have so far been used for transmitting signals from the standard AutoAnalyzer tubular/

tubular flow-cell colorimeter, from the Mark III and Mark IV flame photometer modules, and from the Mark I fluorimeter to the computer. Signals are taken separately from the reference and from the measuring photocells of these detector units (output voltage 0.5 to +10 mV) and amplified a thousand times if the maximum output is +10 mV or amplified ten thousand times if the maximum output is only +1 mV. The 0 to 10 V analogue d.c. levels are transmitted to the DAU, which has a capacity to accept signals from up to 31 analytical channels (a total of 62 analogue input signals). The analyser console also attenuates the amplifier output to corresponding levels between 0 and 20 mV at plugs provided for its connection to standard AutoAnalyzer recorders.

With the exception of the first console, each analyser console can accommodate eight amplifier boards and can be connected to two groups of analysers made up of various channel combinations; for instance, five in group A and three in group B. The first console is restricted to a maximum of seven channels since one channel is used for internal reference and standard voltage measurements. Each amplifier board has two amplifiers/

amplifiers; the input of one is connected to the reference photocell and the input of the other to the measuring photocell. The analyser console and AutoAnalyzer configuration in current use in the laboratory is shown in Fig. 47.

The control panel on the front of the analyser console (Fig. 48) includes a power switch, a central 9-position switch, two on-line switches, a further switch that selects either the reference or measuring signal, and a voltmeter. The power switch connects the power supply from the DAU to the analyser console when set in either the 'run' or 'offset' position. In the 'run' position an external resistive shunt is connected; this converts the meter range from 0-750 mV to 0-10 V. With this switch in the 'run' position, the central switch can be used in conjunction with the reference/measuring switch and the meter to observe the output levels of the reference and measuring photocells of the various instruments on-line to the console. If the power switch is in the 'offset' position, by using the central switch and the meter the amplifier offset can be observed and, if necessary, adjusted to a minimum by adjusting the corresponding potentiometer on/

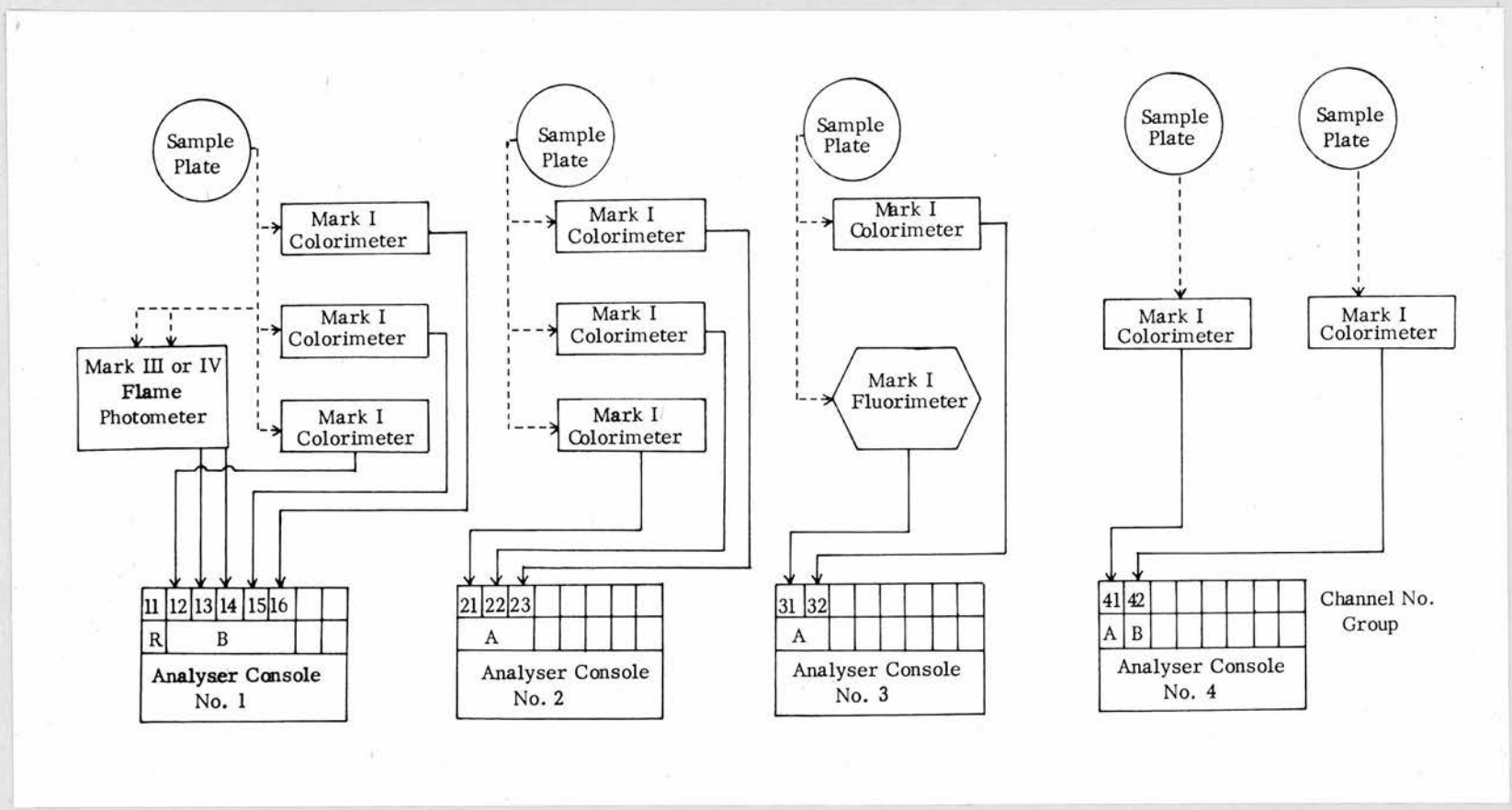

Fig. 47

Analyser console and AutoAnalyzer configuration



Fig. 48

Analyser console control panel

on the amplifier board. A green 'OK' lamp and a red 'FAULT' lamp are associated with each on-line switch: one switch is used for Group A and the other for Group B.

On-line monitoring of a particular group of analysers is initiated by depressing the appropriate on-line switch. If a fault is detected by the computer in the operation of one of the analyser channels, the red light associated with the appropriate on-line switch is illuminated for one minute; at other times, when on-line monitoring is taking place, the green light shows a set of analytical channels is on-line. The operation of the lights is duplicated on the control panel of the DAU cabinet in the computer room.

(2) The Data Acquisition Unit

The DAU has special circuits which convert the d.c. levels from a maximum of 24 analogue channels into their binary equivalents. So far, the largest number of analysers operated simultaneously on-line to the computer has been 12 channels (24 analogue input signals). The maximum number of analogue channels linked to the DAU can be increased to 62 by increasing the number of transistor/

transistor boards and associated components. The DAU is built up from a number of related components including a multiplexer and multiplexer controller, analogue selection unit, timer, status word and fault registers, high level switches and the analogue-to-digital converter (ADC).

The Elliott 903C computer has a peripheral interface for the connection of an on-line teleprinter, paper tape station and only one other peripheral device. The multiplexer enables the central processor to be connected to the magnetic tape controller and to the IBM 731 printer, and to receive the 12-bit binary representations of the outputs of the analytical instruments. Control data is transferred to and from the central processor and this is decoded by the multiplexer controller and transmitted to the analogue selection unit, which selects the required channel and connects it via the high level switches to the ADC (Fig. 49).

The timer unit outputs a pulse every 2 seconds; this is used as a level 2 interrupt to hold up for about 15 milliseconds the program currently being processed on level 4. The computer then reads the measuring/

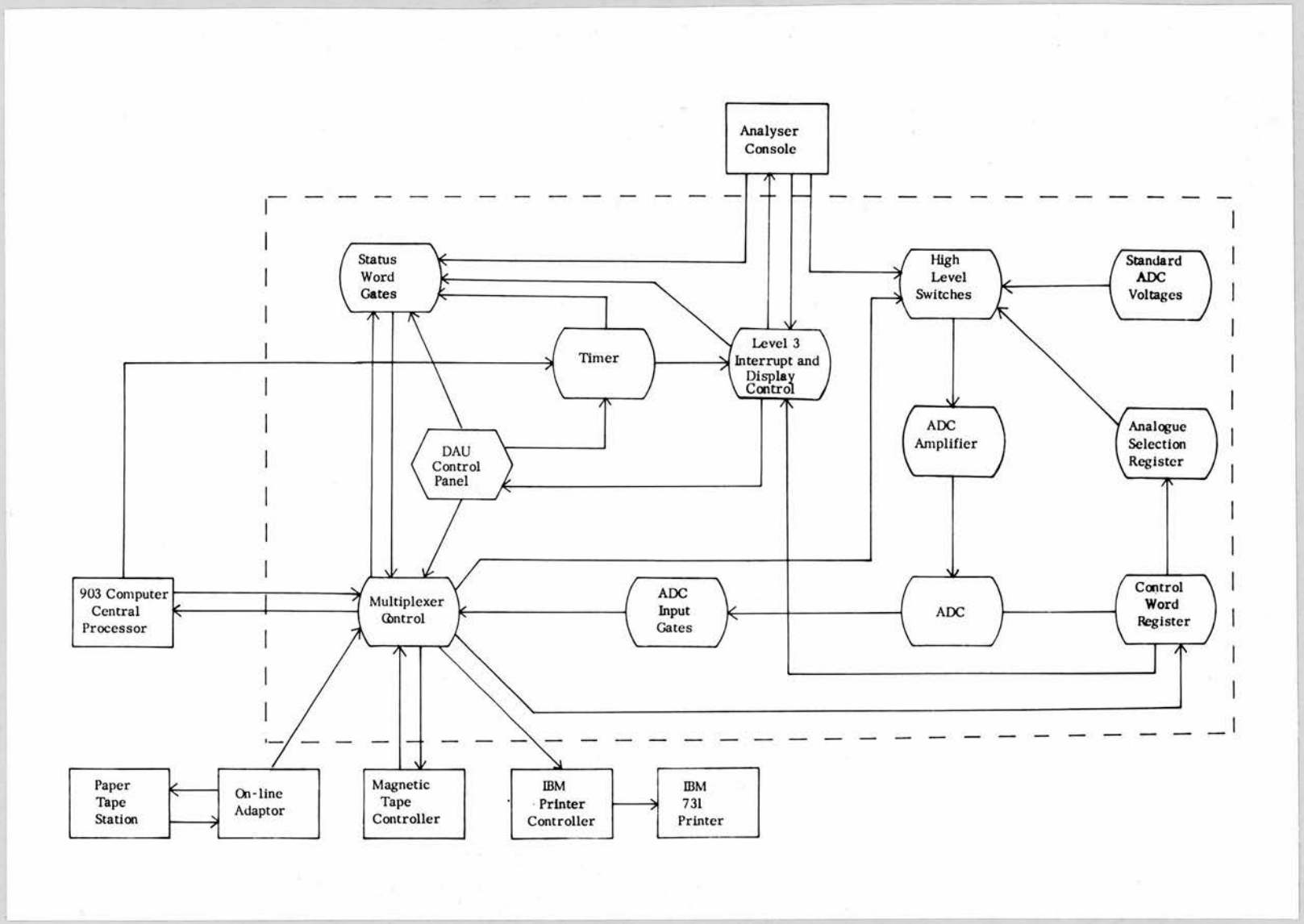

Fig. 49

Block diagram of data acquisition unit

measuring and reference signals from those analyser photocells connected on-line before returning to level 4 operation.

The reference and measuring sub-channels of the first channel of the first analyser console are used for internal reference and standard voltage measurements. A digital output of the ADC and its pre-amplifier for a known input voltage is obtained by earthing the measuring sub-channel and connecting the reference sub-channel to a 6.2 V $\pm$ 5% output; this is derived from a constant current circuit.

A status word register consisting of an 18-bit gate board monitors the switches on the analyser consoles, timer and paper tape equipment and passes this information to the multiplexer controller. The significance of the 18 bits in the status word is given in Table XLII.

As each channel is read, the 0 to +10 V analogue signal is inverted and halved in the ADC amplifier, and the 0 to -5 V output is converted in about 100 µS into a 12-bit digital representation by the ADC. After this 12-bit representation has been examined by the software, the computer addresses the control word register/

TABLE XLII

STATUS WORD BIT SIGNIFICANCE

BIT	SIGNIFICANCE WHEN BIT = 1
1(l.s.)	Analyser Console No. 1 Group A On Line
2	Analyser Console No. 1 Group B On Line
3	Analyser Console No. 2 Group A On Line
4	Analyser Console No. 2 Group B On Line
5	Analyser Console No. 3 Group A On Line
6	Analyser Console No. 3 Group B On Line
7	Analyser Console No. 4 Group A On Line
8	Analyser Console No. 4 Group B On Line
9	Peripheral Expansion Channel 2 Ready
10	Peripheral Expansion Channel 1 Ready
11	Multiplexed Output Select 1 Busy
12	Multiplexed Output Select 2 Busy
13	About to Interrupt (Level 2)
14	Punch Not Ready
15	Reader Not Ready
16	Teleprinter Input Not Ready
17	Teleprinter Output Not Ready
18 (m.s.)	Pseudo Reply Given

l.s. - least significant bit of word
m.s. - most significant bit of word

register which activates the indicator lamps on the analyser consoles and on the control panel of the DAU. If a fault is indicated the software gives details of the fault on the on-line teleprinter.

When the computer is on-line to analytical equipment, if the processor addresses a faulty peripheral device and does not receive a reply, the whole system could remain idle for a considerable time before the fault was noticed. To prevent this, a pseudo-reply circuit has been designed to limit the waiting time to 300 μS, after which a message is printed out by the software on the on-line teleprinter.

The control panel on the DAU cabinet includes (1) an on/off power switch which controls the supplies to the unit and to the analyser consoles; (2) a timer switch which allows the timer to interrupt on level 2 and the on-line teleprinter to interrupt on level 3; and (3) an on-line adaptor switch which permits a pseudo-reply when set to the 'on-line' position.

(3) The Magnetic Tape Controller

The magnetic tape controller outputs information from the computer to a backing store consisting of 3 handlers/

handlers (capable of extension to 4). The controller is designed to operate from a 903 standard peripheral interface and may be placed up to 25 feet from the magnetic tape handlers.

Data is transferred from the central processor to the controller as an 18-bit word. The word is then split into three 6-bit characters such that bits 18 to 13 inclusive form the first character written on the tape, bits 12 to 7 inclusive form the second character, and bits 6 to 1 inclusive form the third character. For each character a seventh parity bit is generated; the parity may be odd or even depending on the mode currently selected. Thus each 18-bit word is written on the tape as three consecutive 7-bit characters. The backing density is 200 characters per inch, the inter-block gap 0.75 inch, and the block length is between 5 and 2047 words. When the 7-bit characters are read from magnetic tape, the parity bit is checked and then discarded, and the six data bits are reassembled into an 18-bit word. A block of data must be read in the same parity mode as it was written.

Read, write, erase and backspace instructions are output from the accumulator to the controller by using

a/

a control word. The control word also indicates if interrupts are permitted or inhibited, and selects odd or even parity. The block transfer facilities of the 903 system may or may not be used for reading or writing on tape, and this is indicated by a write-a-word or write-a-block instruction. Each handler has a status word which indicates the state of the handler (e.g. handler busy, handler in manual, parity error, etc.). All the status word bits are reset by the control word when it selects a different handler, or by pressing a 'reset' switch on the controller.

The control panel of the controller console includes (1) 'ON' and 'OFF' power switches, (2) a 'SELECTED' light which indicates that the controller is being addressed by the computer, and (3) a 'RESET' switch which will reset the controller and all the status bits.

APPENDIX IV

Summary of System Software

The programs which make up the system software may be classified under the following headings - basic software, magnetic tape routines, executive programs, processing of patient and test request data, on-line acquisition of data, calculation routines, presentation of results and ancillary programs. The basic software provides the necessary facilities for the input and output of data and the operation of real numbers and integers in interpretative routines. Executive programs are mainly concerned with the order of operation in program level 4, but they are also required for the decoding, allocation of priorities and accession of programs called by input from the on-line teleprinter. The ancillary programs used in the system include setting up and closing down procedures, breakdown procedures, various checking routines, etc.

A detailed list of all the constituent programs of the system software giving a brief description of the function of each program, the program level on which it operates and the mode of entry into the program is given in Table XLIII. A system of priorities operates within program/

program level 4; the priority given to programs is indicated by the sub-level number, where no sub-level number is listed the program operates on the base level with no priority in the level 4 queue.

The arrangement of programs on magnetic tape files, the length of each program in terms of the number of words (3 characters per word), and the number of blocks is given in Appendix VI.

TABLE XLIII

SUMMARY OF SYSTEM SOFTWARE (PART I)

LEVEL NO.	USE	SUB-LEVELS	PROGRAMS	PROGRAM FUNCTIONS	MODE OF ENTRY
1	Input of P/T programs	-	Systems trigger	Open magnetic tape files, transfer peak detection parameters, standards concentrations, etc. to core store	P/T Reader
			Update Master File and Work File	Updating of Master File by adding records of completed work Transfer of incomplete test data to new work file	
			Edit Master tape program file	Amendment of programs, standards search and standards check parameters, etc.	
2	Monitoring of AutoAnalyzers	-	Peak detection and validation	(1) Inputs signals from reference and measuring photocells, tests that reference level is within prescribed limits and if so calculates ratio - measured/reference voltage (2) If acceptable peak is detected, the peak height and channel number are stored in peak table. If peak is not detected, marker is set in level 4 queue for output of message on on-line T/T. (3) Processed peaks are removed from peak table after calculation routine.	Entered every 2 seconds when timer unit sets level 2 active
3	Input of coded messages	-	Message decoding	Reads in message designator and makes an entry in level 4 queue so that required program will be run when processing time is available.	On-line T/T
4	General programming operations	I	Output of error messages	(1) Outputs error messages on on-line T/T (2) Switches on fault lamps on analyser console and D.A.U.	
		II	Calculation of concentrations	(1) Standards search and check routines (2) Check drift standards, if drift outside prescribed limits output message to on-line T/T (3) If drift within limits, correct set of 9 peak heights for drift and interpolation against standards	Level 4 queue

TABLE XLIII

SUMMARY OF SYSTEM SOFTWARE (PART II)

LEVEL NO.		SUB-LEVELS	PROGRAMS	PROGRAM FUNCTIONS	MODE OF ENTRY
4	General programming operations (Contd.)	II	Calculation of concentrations (Contd.)	(4) Concentrations and cup numbers output to P/T punch (5) Concentrations stored on M/T work file in appropriate patient records. High, low or faulty peaks marked for re-allocation to work sheets.	Level 4 queue
		III	Setting up procedures for analytical channels (on-line T/T)	(1) Input of date and number of first specimen received (2) Re-allocation of analytical channels (3) Input of mean and S.D. for quality control sera (4) Input of standards concentrations for tests using commercial control sera for calibration (5) Amendment of peak detection parameters (6) Re-allocation of input/output to reader/punch/Teletype	Level 4 queue
		IV	Output of emergency results and quality control messages (on-line T/T)	(1) Reads work file and outputs all completed results marked as emegencies (2) Outputs value for current quality control specimen and results for two preceeding pool specimens if calculated value is outside prescribed limits.	Level 4 queue
		V	Input of patient and specimen data (on-line T/T)	(1) Input list of registration numbers - output check on T/T and store if correct. (2) Sort list into registration number order - access work file and Master File. (3) Output registration number and identification data if available. (4) Input identification data and amendments - check and store (5) Input test request data - check and store (6) Merge into new work file.	Level 4 queue

TABLE XLIII

SUMMARY OF SYSTEM SOFTWARE (PART III)

LEVEL NO.	USE	SUB-LEVELS	PROGRAMS	PROGRAM FUNCTIONS	MODE OF ENTRY
4	General programming operations (Contd.)	V	Output work load (P/T punch)	(1) Read M/T work file and store counts of all incomplete tests. (2) Output test request codes and counts.	Level 4 queue
			Output work sheets (P/T punch)	(1) Sort test requests into priority order. (2) Allocate cup numbers. (3) Update M/T work file with cup numbers. (4) Output work sheets.	Level 4 queue
			Change cup numbers (On-line T/T)	(1) Input patient and test data (2) Input specimen number, group code and cup number. (3) Search M/T work file for specimen previously allocated to cup position and re-issue on a later work sheet.	Level 4 queue
			Input manual results (P/T reader)	(1) Input test code, cup numbers and results on P/T (2) Search M/T work file for patient records and merge into new work file.	Level 4 queue
			Access master file	(1) Read work file and check if previous records on master file. (2) Read past results and merge with existing work file to form new work file.	Level 4 queue
			Output cumulative reports (P/T punch)	(1) Perform additional calculations and set markers to indicate abnormal results. (2) Determine number of reports and output count on on-line T/T. (3) Select first 45 reports giving priority to reports bearing asterisks and reports for quality control specimens. (4) Output reports in registration number order.	Level 4 queue

TABLE XLIII

SUMMARY OF SYSTEM SOFTWARE (PART IV)

LEVEL NO.	USE	SUB-LEVELS	PROGRAMS	PROGRAM FUNCTIONS	MODE OF ENTRY
4	General programming operations (Contd.)	V	Printing cumulative reports (IBM printer)	(1) Input reports P/T through reader. (2) Output to IBM printer.	Level 4 queue
			Closing down procedures (P/T punch)	(1) Close down analyser channels and output any outstanding results. (2) Output final work load. (3) Output in registration number order, a list of patient and test data and results, if available, for day's run. (4) Output patient and quality control statistics. (5) Re-write work file immediately after programs on one tape. (6) Close file and output handler number of final work file on on-line T/T.	Level 4 queue

APPENDIX V

Input of Patient and Test Request Data

The input of patient identification data on the on-line Teletype using conversational mode, or via the paper tape reader after the off-line preparation of a data tape, is in a format consisting of eight fields each separated by a space (see Section IIB). The data fields contain the following information:-

FIELD 1 Date of birth registration number.

FIELD 2 Surname. Only letters, apostraphe and hyphen are allowed in this field.

FIELD 3 Initials. Only letters and full stop (.) are allowed. Any number of initials may be input but only the first three letters, ignoring full stops, are stored in the computer.

FIELD 4 Sex. M, F or minus sign (-) allowed.

FIELD 5 Ward/Department. Royal Infirmary and City Hospital patients have this code checked against a full list held in the computer (Appendix VIII). Other hospitals normally have a minus sign (-) entered in this field but any three characters are accepted and stored.

FIELD 6/

FIELD 6 Hospital/General Practitioner. Only recognised hospital codes (Appendix VIII) are allowed but 'GP' may be input to indicate a general practitioner. In this field a minus sign (-) is taken to mean Royal Infirmary.

FIELD 7 Consultant. Up to three letters may be input and these are checked against a list held in the computer (Appendix VIII). If the three letter code is identified, the consultant's full name, title and initials are output on report forms, otherwise the letters are output in the same form.

FIELD 8 End of line indicator. The end of data is specified by the 'greater than' symbol (>), but if the operator notices an input error at this point the letter 'A' may be input before the terminator to indicate an amendment.

In all fields except number 6, absence of information is denoted by a minus sign (-). It is not necessary to input a minus sign for fields 6 and 7 if the hospital is the Royal Infirmary and the consultant's name has not been provided: the end of data symbol may be/

be input after field 5.

The computer software checks each field and, if the check fails when using conversational mode, a code letter indicating the faulty field and an equals sign (=) are output to enable the operator to enter the correct information on the on-line Teletype. The field to be corrected is specified as follows:-

N = Surname

I = Initials

S = Sex

W = Ward/Department

H = Hospital/General Practitioner

C = Consultant

Amendments initiated by the operator are specified by typing the above characters followed by the new data and terminated with a '>' symbol. When a line of data has been accepted the computer program outputs a 'greater than' symbol (>) followed by 'carriage return', 'line feed' instructions.

If any errors are detected in the patient identification information on data tapes prepared off-line then the input is rejected. An error message is output to/

to the punch indicating which field or fields are faulty followed by the rejected data line. The faulty field is indicated by the codes indicated on page 247: an error in the registration number is indicated by the output of the letter 'R'.

The test request input (see Section IIB) consists of the following five fields, each separated by a space:-

FIELD 1 Date. This must consist of six figures, but if the date for the request currently being processed is the same as for the last request then a minus sign (-) can be input instead of the date.

FIELD 2 Laboratory number. This must consist of one letter and three figures.

FIELD 3 Tests requested. Single tests or groups may be requested using the test codes listed in Appendix VIII; test codes must be separated by a comma. All codes are checked against a full test list held in the computer store. This field can also be used to input single test results using the following format:-

U = 32, NA = 135, K = HM

The/

The number of results that can be entered in this way is limited to six, or alternatively one test can be input as a comment such as BAR = 'NONE DETECTABLE'.

FIELD 4 Options. The following options are available:-

E for emergency request
V1000 for volume in millilitres
L12 for length of collection in hours
(24 hours is assumed if the length is not input)
T1200 for time of collection (24 hour clock)
PRED for pre-dialysis specimen (input in place of time)
POST for post-dialysis specimen (input in place of time)

Any number of options is allowed as long as they are each separated by commas.

FIELD 5 End of line indicator. The end of data is specified by a 'greater than' symbol (>), but if a second line of test request data is required the letter 'S' must be input before the terminator; in this case the computer outputs 'carriage return', 'line feed' instructions and the operator must input the additional/

additional data. If the operator wishes to amend the data, the letter 'A' must be input before the '>' symbol; the computer then outputs 'carriage return', 'line feed' instructions and the operator enters the first letter of the field to be amended followed by an equals sign and the amended data. If 'C>' is entered, the test request data are cancelled and the next registration number is output.

The end of data symbol (>) may be entered after field 3 if no options have been selected, unless 'S>', 'A>' or 'C>' is input in which case all the fields must be specified or represented by a minus sign (-) if not present.

The computer software checks all the fields input and, in the case of errors detected in conversational mode, the computer outputs a letter indicating the field and an equals sign (=). The operator can then re-input the information in its correct form followed by a 'greater than' symbol. When operating in off-line mode, the detection of an error in the test request line results in the cancellation of the complete patient identification and test request input. The identification data and any test/

test request lines already accepted are output to the punch followed by an error indication denoting which field is faulty. The field to be corrected is specified as follows:-

D = Date

L = Laboratory number

T = Test or test group code

O = Options

If, while operating in conversational mode, the computer detects a format error in a line of data, an error message (MSG 51) is output and the operator must re-input the last complete line of data.

APPENDIX VI

Structure of Magnetic Tape Files

The master tape file consists of blocks of programs followed by patient identification records and then patient results records, each section separated by data labels. The work file tapes contain programs and successive versions of the work file, which consists of patient identification, request and results records. Each version of the work file is separated by data labels.

The programs occupy the first 92 blocks on each magnetic tape file. A complete list of the programs in the order in which they are stored on magnetic tape is given in Table XLIV. This table also provides information regarding the length of each program in terms of the number of words (3 characters per word) and the number of blocks.

The format of the patient identification records stored on magnetic tape is shown in Fig. 50. The record is of variable length but has a maximum length of 25 words, i.e. 75 characters. The date of birth registration number is stored in words 0 and 1 of the patient identification record. The registration sub-number stored in word 1 is used to distinguish between patients with/

TABLE XLIV

LIST OF PROGRAMS ON MAGNETIC TAPE FILES

PROGRAM CODE	PROGRAM	NO. OF BLOCKS	NO. OF WORDS
AAA	Systems trigger	4	6308
AAB-AAD	System and open files		
CAL-CAM	Calculation of concentrations	2	2559
CAP-CAS	Write concentrations to the work file	4	3661
CAT-CAU	Check quality control pools	2	2233
CAV-CAW	Write extra calculations to the work file	2	1663
CAX-CAL	Check abnormal results and output emergency results	4	4362
INC-INJ	Input patient data	22	16915
ISS-ISX	Issue work sheets	6	4785
OUT-OVD	Output of patient reports	12	11281
PRT	IBM print routine	1	282
REQ-RER	Output work load of test requests	2	1875
RMR-RMS	Input of manual results	2	1807
SEP-SE↑	Setting-up procedures	9	7656
STA-STC	Standards programs	3	3100
TCN-TCQ	Change cup numbers routine	4	2826
TER	Terminate day's run	1	123
TMF-TMG	Access master file for past results	2	1553
TPO-TPP	Output end of day summary	2	2554
VAR-VAV	Statistical procedures	4	4862
XIT-XIU	Closedown procedures	2	973

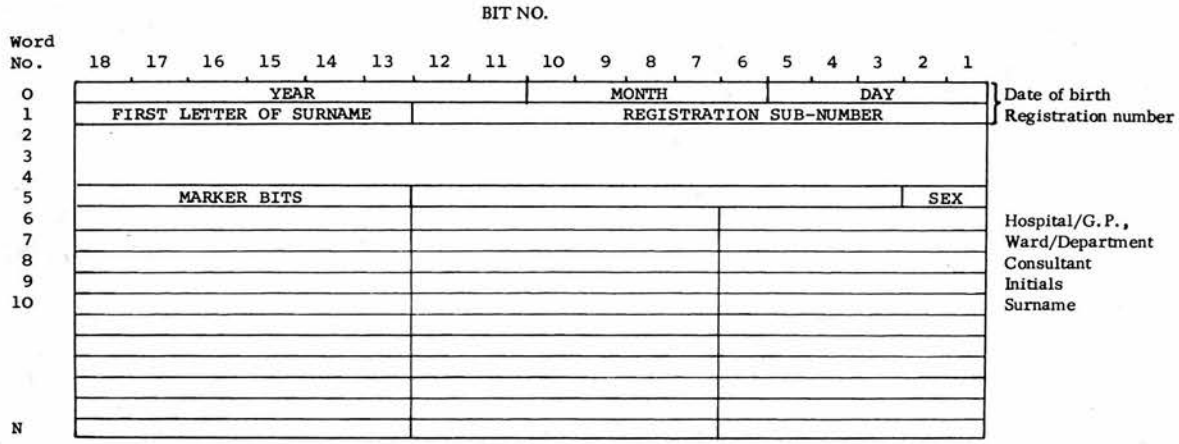

Fig. 50

Patient identification record format

with the same registration number, e.g. 130522N/1 and 130522N/2. Each new patient is given the sub-number 1 unless there already exists on the file one or more patients with the same registration number in which case the next sub-number is issued. Word 2 is reserved for the date of birth in systems where a hospital number occupies words 0 and 1. Words 3 and 4 in results and requests records contain the specimen number, but in identification records these words are left blank so that the marker bits which indicate the type of record are stored in equivalent positions (bits 15-18 of word 5) on identification, results and requests records; hence the records can be sorted in the same way. The bits of the marker word are used to indicate if the patient results have been obtained from the master file, if the record is an identification or request record, etc., while bits 1-2 of word 5 are used to denote the sex.

Three characters can be stored in the hospital, ward, consultant and initials words, and the code 'GP' can be placed in word 6 if the request is received from a general practitioner. The patient surname is packed three characters to a word and can consist of up to 15 words, i.e. 45 characters.

The/

The results and request records format is shown in Fig. 51. Bits 15-18 of the marker word are used in the same way as in the patient identification record, while bits 3 and 12-14 in the request record are used to indicate if cup numbers have been issued for all requests in the record, or if results have been output for all requests in the record, of if one of the requests in the record is an emergency, etc. The marker bits in word 0 of the results and requests section of the record are used to indicate if dilution of a specimen is required, or if a result is abnormal, or if a result is a real number or a comment, etc. Real number results are stored as the exponent (word 0) and the mantissa (word 1). If the result is a comment the format of the record is modified so that bits 1-6 of word 0 are used to store the numbers of words required for the comment. The comment is packed three characters per word and may occupy any number of words. The marker bits in word 2 of the request section of a record are set to indicate if the cup number has been issued for this request, or if the result was too high or too low and needs to be re-output to work sheets, or if the result has been output for this request, etc.

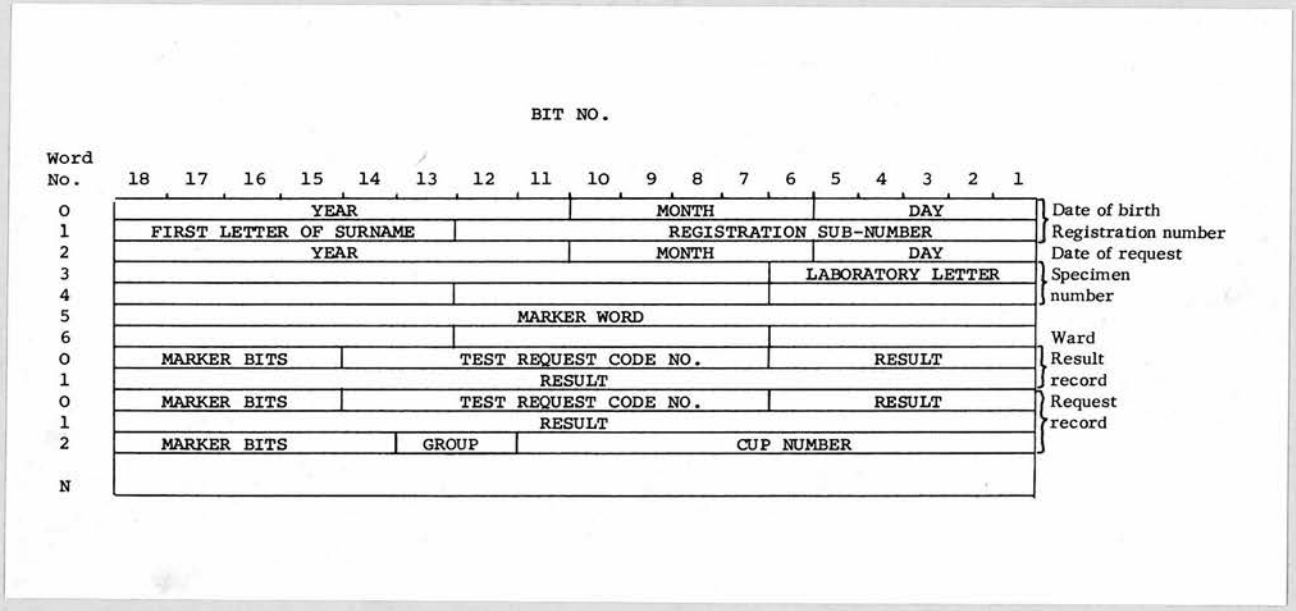

Fig. 51

Results and request records format

APPENDIX VII

Test Parameters and Asterisk Ranges

The current values of parameters used for peak detection, fault recognition, standard curve validation and drift control are summarised in Tables XLV - LXIII. The peak height recorded in the tables is a positive decimal fraction, where 0 represents 0% transmission and 1.0 represents 100% transmission (i.e. peak height = T/100). In the case of 'troughs', the value is inverted so that the peak height is represented by (1 - T/100) where T is the percentage transmission. The mode of action of each parameter and the methods used to evaluate parameters are discussed in detail in Section III(A-C).

Tables XLV - LXIII also give information about the analytical procedures including sampling rate, analytical precision, standard dilution, etc. adopted for each test channel monitored by the computer system.

The use of asterisks on cumulative reports to mark a first result falling outside prescribed limits is based on the use of the patient mean and the patient and analytical standard deviation (Section IIIE). The marking/

marking of significant changes in results is based on the analytical standard deviation. The concentration ranges and standard deviations used for this purpose are listed in Table LXIV, while the application of this exception marking routine to cumulative reports is described in Section IIIE.

TABLE XLV

Test: Urea
Test Code: U
Test No.: 12
Program Identifiers:
Sampling Rate: 60/hr
Units: mg/100 ml
Normal Range: 15-40
Asterisk Range: 14-50
Maximum Digits: >000*

Precision (± SD):
Precision (C of V): ± 4%
Standard Diln.: 1/5
Dilution Calc.: 5 x OBS
Standard Conc.:
Form to be Output On:

Date

Twice the maximum drift allowable between a drift standard and the first drift standard: 0.20

Maximum drift allowable between drift standards: 0.6

Concentration of drift standard: 100 Cup No. of Drift Standard: 4

Peak Detection Parameters		Standard Search Parameters		
Meaning of Parameter	Value	Cup No.	Conc.	Min. Diff.
				+2
A. Minimum no. of rising readings	10	1	10	.08
B. Minimum no. of falling readings	4	2	30	.06
C. Maximum irregularity in rise or fall	0.01	3	50	.13
D. Maximum difference between successive readings	0.05	4	100	.07
E. Minimum rise required	0.01	5	150	.02
F. Expected no. of readings between peaks	30	6	200	.01
G. Waiting time for first peak	240	7	250	.01
H. Width of window + 2	8	8	300	-.01
I. Peak -1 or trough +0	0	9		+3
NOTES		10		

STANDARD CHECK PARAMETERS

Conc. in Ascending Order	Peak Heights		Gradients		Change in Gradients	
	PKLOW	PKHIGH	PKGLOW	PKGHIG	PKDLOW	PKDHIG
1	.04	.27	.0037	.0066		
2	.10	.35	.0037	.0064	-.0014	+.0004
3	.20	.45	.0033	.0047	-.0028	-.0002
4	.35	.65	.0020	.0033	-.0016	-.0002
5	.50	.80	.0013	.0024	-.0017	-.0003
6	.60	.90	.0009	.0020	-.0013	+.0003
7	.65	.95	.0005	.0017	-.0011	+.0001
8	.70	.99				

TABLE XLVI

Test: Sodium
Test Code: NA
Test No.: 13
Program Identifiers:
Sampling Rate: 60/hr
Units: meq./l.
Normal Range: 136-149
Asterisk Range: 130-153
Maximum Digits: > 000*

Precision (± SD): 2.2
Precision (C of V):
Standard Diln: 1/5 (fluid)
5x OBs - 560
Dilution Calc.: 1/5 (fluid)
Standard Conc.: 5 x OBS - 560
Conc. Calc.:
Form to be Output On:

Date:

Twice the maximum drift allowable between a drift standard and the first drift standard: 0.16

Maximum drift allowable between drift standards: 0.03

Concentration of drift standard: 140 Cup No. of drift standard 6

Peak Detection Parameters		Standard Search Parameters		
Meaning of Parameter	Value	Cup No.	Conc.	Min. Diff.
				+2
A. Minimum no. of rising readings	8	1	90	0.02
B. Minimum no. of falling readings	5	2	100	0.02
C. Maximum irregularity in rise or fall	0.01	3	110	0.02
D. Maximum difference between successive readings	0.05	4	120	0.02
E. Minimum rise required	0.05	5	130	0.02
F. Expected no. of readings between peaks	30	6	140	0.02
G. Waiting time for first peak	180	7	150	0.03
H. Width of window + 2	6	8	160	-0.01
I. Peak -1 or trough +0	-1	9	140	+3
NOTES		10	140	

STANDARD CHECK PARAMETERS

Conc. in Ascending Order	Peak Heights		Gradients		Change in Gradients	
	PKLOW	PKHIGH	PKGLOW	PKGHIG	PKDLOW	PKDHIG
1	0.40	0.70	0.0040	0.0085		
2	0.45	0.75	0.0040	0.0070	-0.0027	+0.0020
3	0.50	0.80	0.0040	0.0085	-0.0016	+0.0037
4	0.55	0.85	0.0035	0.0075	-0.0032	+0.0007
5	0.60	0.90	0.0025	0.0055	-0.0032	+0.0012
6	0.65	0.95	0.0025	0.0075	-0.0024	+0.0032
7	0.70	0.97	0.0030	0.0080	-0.0012	+0.0027
8	0.75	0.99				

* Standards used for calibration

TABLE XLVII

Test: Potassium
Test Code: K
Test No.: 14
Program Identifiers:
Sampling Rate: 60/hr
Units: meq./l.
Normal Range: 3.8-5.2
Asterisk Range: 3.4-5.6
Maximum Digits: >0.0*

Precision (± SD): 0.15
Precision (C of V):
Standard Diln.:
Dilution Calc.:
Standard Conc.:
Conc. Calc.:
Form to be Output On:

Date:

Twice the maximum drift allowable between a drift standard and the first drift standard: 0.10

Maximum drift allowable between drift standards: 0.03

Concentration of drift standard: 4.0 Cup no. of drift standard: 6

Peak Detection Parameters		Standard Search Parameters		
Meaning of Parameter	Value	Cup No.	Conc.	Min. Diff.
				+2
A. Minimum no of rising readings	10	1	1.0	+2
B. Minimum no. of falling readings	6	2*	1.0	.05
C. Maximum irregularity in rise or fall	.02	3	2.0	+1
D. Maximum difference between successive readings	.05	4*	2.0	.05
E. Minimum rise required	.02	5	4.0	+1
F Expected no. of readings between peaks	30	6*	4.0	.14
G. Waiting time for first peak	180	7*	6.0	.14
H Width of window +2	10	8*	8.0	-.01
I. Peak -1 or trough +0	-1	9	4.0	+3
NOTES		10	4.0	

STANDARD CHECK PARAMETERS

Conc. in Ascending Order	Peak Heights		Gradients		Change in Gradients	
	PKLOW	PKHIGH	PKGLOW	PKGHIG	PKDLOW	PKDHIG
2	.10	.45	.050	.125		
4	.20	.55	.075	.125	-.006	+.020
6	.35	.75	.083	.130	-.008	+.016
7	.50	.90	.080	.135	-.009	+.013
8	.70	.99				

* Standards used for calibration

TABLE XLVIII

Test: Chloride
Test Code: CL
Test No.: 15
Program Identifiers:
Sampling Rate: 60/hr
Units: meq./l.
Normal Range: 100-107
Asterisk Range: 92-111
Maximum Digits: > 000*

Precision (± SD): 2.2
Precision (C of V):
Standard Diln.: 1/5
Dilution Calc.: 5 x OBS - 480
Standard Conc.: 1/5
Conc. Calc.: 5 x OBS - 480
Form to be output on:

Date:

Twice the maximum drift allowable between a drift standard and the first drift standard: .2

Maximum drift allowable between drift standards: .05

Concentration of drift standard: 104 Cup no. of drift standard 6

Peak Detection Parameters		Standard Search Parameters		
Meaning of Parameter	Value	Cup No.	Conc.	Min. Diff.
				+2
A. Minimum no. of rising readings	7	1	81	+1
B. Minimum no. of falling readings	5	2*	81	-0.0
C. Maximum irregularity in rise or fall	0.01	3*	72	+0.29
D. Maximum difference between successive readings	0.06	4*	122	-0.01
E. Minimum rise required	0.05	5*	114	
F. Expected no. of readings between peaks	30	6*	104	-0.01
				-0.03
G. Waiting time for first peak	240	7*	96	-0.02
H. Width of window +2	6	8*	88	0.01
I. Peak -1 or trough +0	0	9	104	+3
NOTES		10	104	

STANDARD CHECK PARAMETERS

Conc. in Ascending Order	Peak Heights		Gradients		Change in Gradients	
	PKLOW	PKHIGH	PKGLOW	PKGHIG	PKDLOW	PKDHIG
3	0.10	0.50	0.0046	0.0220		
2	0.20	0.60	0.0062	0.0200	-0.0058	+0.0081
8	0.35	0.75	0.0059	0.019	-0.0095	+0.0025
7	0.42	0.82	0.0040	0.015	-0.0055	+0.0005
6	0.50	0.90	0.0030	0.010	-0.0040	+0.0002
5	0.55	0.95	0.0021	0.0073	-0.0045	+0.0008
4	0.60	0.99				
8						

* Standards used for calibration

TABLE XLIX

Test: Bicarbonate
Test Code: CO2
Test No.: 16
Program Identifiers:
Sampling Rate: 60/hr
Units: meq./l.
Normal Range: 24-30
Asterisk Range: 18-34
Maximum Digits: > 00*

Precision (± SD): 0.9
Precision (C of V):
Standard Diln.: 1/5 (fluid)
Dilution Calc.: 5 x OBS-80
Standard Conc.:
Conc. Calc.:
Form to be Output On:

Date:

Twice the maximum drift allowable between a drift standard and the first drift standard: 0.20

Maximum drift allowable between drift standards: 0.05

Concentration of drift standard: 20 Cup no of drift standard: 6

Peak Detection Parameters		Standard Search Parameters		
Meaning of Parameter	Value	Cup No.	Conc.	Min. Diff.
A. Minimum no. of rising readings	10	1*	5	+2
B. Minimum no. of falling readings	6	2*	10	.01
C. Maximum irregularity in rise or fall	.01	3	20	+1
D. Maximum difference between successive readings	.04	4	-	+2
E. Minimum rise required	.01	5	10	+2
F. Expected no. of readings between peaks	30	6*	20	.04
G. Waiting time for first peak	200	7*	30	.05
H. Width of window +2	8	8*	40	.09
I. Peak -1 or trough +0	-1	9	20	-.01
NOTES		10	20	+3

STANDARD CHECK PARAMETERS

Conc. in Ascending Order	Peak Heights		Gradients		Change in Gradients	
	PKLOW	PKHIGH	PKGLOW	PKGHIG	PKDLOW	PKDHIG
1	.05	.25	.004	.011		
2	.07	.27	.0085	.018	+.0030	+.0075
6	.15	.45	.017	.0315	+.0065	+.016
7	.30	.70	.019	.035	-.0100	+.0110
8	.50	.94				

* Standards used for calibration

TABLE L

Test: Alkaline Phosphatase
Test Code: ALP
Test No.: 21
Program Identifiers:
Sampling Rate: 60/hr
Units: K.A. units
Normal Range: 3-13
Asterisk Range: 2-16
Maximum Digits: 000*

Precision (± SD): 0.7
Precision (C of V): +5%
Standard Diln.: 1/5
Dilution Calc.: 5 x OBS
Standard Conc.:
Conc. Calc :
Form to be Output On:

Date:

Twice the maximum drift allowable between a drift standard and the first drift standard: .10

Maximum drift allowable between drift standards: .01

Concentration of drift standard: 8 Cup no. of drift standard (base) 2

Peak Detection Parameters		Standard Search Parameters		
Meaning of Parameter	Value	Cup No.	Conc.	Min. Diff.
				+2
A. Minimum no. of rising readings	8	1	4	.03
B. Minimum no. of falling readings	7	2	8	.03
C. Maximum irregularity in rise or fall	.01	3	13	.03
D. Maximum difference between successive readings	.02	4	17	.06
E. Minimum rise required	.01	5	25	.05
F. Expected no. of readings between peaks	30	6	34	.02
G. Waiting time for first peak	300	7	38	.02
H. Width of window +2	12	8	42	-.01
I. Peak -1 or trough +0	0	9		+3
NOTES		10		

STANDARD CHECK PARAMETERS

Conc. in Ascending Order	Peak Heights		Gradients		Change in Gradients	
	PKLOW	PKHIGH	PKGLOW	PKGHIG	PKDLOW	PKDHIG
1	.03	.25	.010	.030		
2	.04	.30	.007	.035	-.011	+.008
3	.05	.35	.007	.025	-.011	+.005
4	.08	.40	.006	.025	-.006	+.006
5	.10	.50	.006	.020	-.008	+.002
6	.15	.70	.006	.020	-.005	+.006
7	.20	.80	.006	.020	-.005	+.006
8	.25	.90				

TABLE LI

Test: Bilirubin
Test Code: BIL
Test No.: 22
Program Identifiers:
Sampling Rate: 60/hr
Units: mg/100 ml
Normal Range: 1.0
Asterisk Range: 1.4
Maximum Digits: 00.0*

Precision (± SD):
Precision (C of V): ± 8%
Standard Diln.: 1/5
Dilution Calc.: 5 x OBS
Standard Conc.:
Conc Calc.:
Form to be Output On:

Date:

Twice the maximum drift allowable between a drift standard and the first drift standard: .04

Maximum drift allowable between drift standards: .01

Concentration of drift standard: 1.6, Cup no. of drift standard (base) 2

Peak Detection Parameters		Standard Search Parameters		
Meaning of Parameter	Value	Cup No.	Conc.	Min. Diff.
				+2
A. Minimum no of rising readings	8	1	0.8	.03
B. Minimum no. of falling readings	4	2	1.6	.03
C. Maximum irregularity in rise or fall	.01	3	2.4	.025
D. Maximum difference between successive readings	.01	4	3.2	.05
E. Minimum rise required	.005	5	4.7	.04
F. Expected no. of readings between peaks	30	6	6.3	.02
G. Waiting time for first peak	100	7	7.2	.015
H. Width of window +2	10	8	8.0	-.01
I. Peak -1 or trough +0	+0	9		+3
NOTES		10		

STANDARD CHECK PARAMETERS

Conc. in Ascending Order	Peak Heights		Gradients		Change in Gradients	
	PKLOW	PKHIGH	PKGLOW	PKGHIG	PKDLOW	PKDHIG
1	.02	.25	.040	.090		
2	.03	.28	.050	.100	-.010	+.019
3	.04	.30	.040	.075	-.035	+.008
4	.06	.35	.040	.080	-.015	+.012
5	.08	.45	.035	.060	-.025	-.001
6	.10	.55	.025	.055	-.020	+.005
7	.15	.70	.025	.065	-.020	+.020
8	.20	.80				

TABLE LII

Test: Bilirubin Blanks
Test Code:
Test No.: 23
Program Identifiers
Sampling Rate: 60/hr
Units: mg/100 ml
Normal Range:
Asterisk Range:
Maximum Digits:

Precision (± SD):
Precision (C of V):
Standard Diln.:
Dilution Calc.:
Standard Conc.:
Conc. Calc.:
Form to be Output On:

Date:

Twice the maximum drift allowable between a drift standard and the first drift standard: 0.06

Maximum drift allowable between drift standards: 0.02

Concentration of drift standard: 0.12 Cup no of drift standard (base): 2

Peak Detection Parameters		Standard Search Parameters		
Meaning of Parameter	Value	Cup No.	Conc.	Min. Diff.
				+2
A. Minimum no. of rising readings	6	1	0.05	+.002
B. Minimum no. of falling readings	4	2	0.10	+.002
C. Maximum irregularity in rise or fall	0.1	3	0.15	+.002
D. Maximum difference between successive readings	0.1	4	0.20	+.005
E. Minimum rise required	.001	5	0.30	+.005
F. Expected no. of readings between peaks	30	6	0.35	+.002
G. Waiting time for first peak	120	7	0.40	+.002
H. Width of window +2	16	8	0.45	-.001
I. Peak -1 or trough +0	0	9		+3
NOTES		10		

STANDARD CHECK PARAMETERS

Conc. in Ascending Order	Peak Heights		Gradients		Change in Gradients	
	PKLOW	PKHIGH	PKGLOW	PKGHIG	PKDLOW	PKDHIG
1	.02	.20	0.080	0.40		
2	.025	.25	0.040	0.25	-0.10	+0.07
3	.030	.30	0.050	0 30	-0.09	+0.11
4	.035	.35	0.050	0.25	-0.08	+0.11
5	.040	.40	0.050	0.25	-0.09	+0.04
6	045	.45	0.030	0.25	-0.07	+0.08
7	.050	.50	0.050	0.25	-0.12	+0.09
8	.055	.55				

TABLE LIII

Test: Total Protein
Test Code: TPA
Test No.: 21
Program Identifiers:
Sampling Rate: 60/hr
Units: gm/100 ml
Normal Range: 6.0-8.0
Asterisk Range: 5.5-8.5
Maximum Digits: >00.0*

Precision (+ SD): 0.13
Precision ($\bar{C}$ of V): 1/2
Standard Diln.:
Dilution Calc.:
Standard Conc.: 2 x OBS
Conc. Calc.: Form to
Form to be Output On:

Date:

Twice the maximum drift allowable between a drift standard and the first drift standard: 0.06

Maximum drift allowable between drift standards: .01

Concentration of drift standard: 5.5 Cup no. of drift standard: 4

Peak Detection Parameters		Standard Search Parameters		
Meaning of Parameter	Value	Cup No.	Conc.	Min. Diff.
	10 ⊗			+2
A. Minimum no. of rising readings	13	1*	0.9	.08
B. Minimum no. of falling readings	4	2*	1.9	.12
C. Maximum irregularity in rise or fall	.01	3*	3.8	.08
D. Maximum difference between successive readings	.05	4*	5.5	.05
E. Minimum rise required	.04	5*	7 4	.02
F. Expected no. of readings between peaks	30	6*	9.2	-.01
G. Waiting time for first peak	120	7	7.4	+2
H. Width of window +2	12	8	5.5	+2
I. Peak -1 or trough +0	0	9	5.5	+3
NOTES ⊗ For paper tape version only		10	5.5	

STANDARD CHECK PARAMETERS

Conc. in Ascending Order	Peak Heights		Gradients		Change in Gradients	
	PKLOW	PKHIGH	PKGLOW	PKGHIG	PKDLOW	PKDHIG
1	.04	.30	0.08	.166		
2	.18	.45	.09	.130	-.040	+.007
3	.32	.60	.057	.084	-.045	-.010
4	.45	.85	.035	.060	-.045	-.008
5	.50	.90	.030	.055	-.025	+.007
6	.55	.95				

* Standards used for calibration

TABLE LIV

Test: Albumin
Test Code: LBM
Test No.: 22
Program Identifiers:
Sampling Rate: 60/hr
Units: gm/100 ml
Normal Range: 3.6-4.7
Asterisk Range: 3.0-5.0
Maximum Digits: > 0.0*

Precision (± SD): 0.1
Precision (C of V):
Standard Diln.: 1/5
Dilution Calc.: 5 x OBS
Standard Conc.:
Conc. Calc.:
Form to be Output On:

Date:

Twice the maximum drift allowable between a drift standard and the first drift standard: 0.04

Maximum drift allowable between drift standards: 0.01

Concentration of drift standard: 3.0 Cup no. of drift standard: 4

Peak Detection Parameters		Standard Search Parameters		
Meaning of Parameter	Value	Cup No.	Conc.	Min. Diff.
A. Minimum no. of rising readings	11⊗ 12	1*	0.5	+2
B. Minimum no. of falling readings	5⊗ 6	2*	1.0	.04
C. Maximum irregularity in rise or fall	.01	3*	2.0	.09
D. Maximum difference between successive readings	.03	4*	3.0	.06
E. Minimum rise required	.025	5*	4.0	.03
F. Expected no. of readings between peaks	30	6*	5.1	.02
G. Waiting time for first peak	150	7	4.0	-.01
H. Width of window +2	10	8	3.0	+2
I. Peak -1 or trough +0	0	9	3.0	+2
NOTES		10	3.0	+3

STANDARD CHECK PARAMETERS

Conc. in Ascending Order	Peak Heights		Gradients		Change in Gradients	
	PKLOW	PKHIGH	PKGLOW	PKGHIG	PKDLOW	PKDHIG
1	.04	.45				
2	.08	.50	.08	.22	-.060	+.002
3	.16	.60	.090	.160	-.060	-.010
4	.24	.70	.070	.120	-.050	-.010
5	.36	.80	.040	.110	-.040	-.010
6	.42	.90	.020	.060		

⊗ Paper tape version only
* Standards used for calibration

TABLE LV

Test: Protein Blank
Test Code: TPB
Test No.: 23
Program Identifiers:
Sampling Rate: 60/hr
Units: gm/100 ml
Normal Range:
Asterisk Range:
Maximum Digits:

Precision (± SD):
Precision (C of V):
Standard Diln.:
Dilution Calc.:
Standard Conc.:
Conc. Calc.:
Form to be Output On:

Date:

Twice the maximum drift allowable between a drift standard and the first drift standard: .06 (DRFDIF)

Maximum drift allowable between drift standards: .01 (MAXDRF)

Concentration of drift standard: 0.2 Cup no. of drift standard: 4

Peak Detection Parameters		Standard Search Parameters			STANDARD CHECK PARAMETERS						
					Conc. in Ascending Order	Peak Heights		Gradients		Change in Gradients	
Meaning of Parameter	Value	Cup No.	Conc.	Min. Diff		PKLOW	PKHIGH	PKGLOW	PKGHIG	PKDLOW	PKDHIG
				+2							
A. Minimum no. of rising readings	4	1	0.05	+2	3	0.02	.30	0.01	0.60		
B. Minimum no. of falling readings	4	2	0.10	+.001	4	0.02	0.30	0.01	0.60	-0.1	+0.1
C. Maximum irregularity in rise or fall	0.1	3*	0.125	+ 001	5	0.02	0.30	0.01	0.60	-0.1	+0.1
D. Maximum difference between successive readings	0.1	4*	0.20	+.001	6	0.02	0.30				
E. Minimum rise required	.001	5*	0.25	+.001							
F. Expected no. of readings between peaks	30	6*	0.30	-.001							
G. Waiting time for first peak	120	7	0.25	+2							
H. Width of window +2	16	8	0.20	+2							
I. Peak -1 or trough +0	+0	9		+3							
NOTES		10									

* Standards used for calibration

TABLE LVI

Test: Calcium
Test Code: CA
Test No.: 31
Program Identifiers:
Sampling Rate: 40/hr
Units: mg/100 ml
Normal Range: 8.5-10.5
Asterisk Range: 8.1-10.9
Maximum Digits: >00.0*

Precision (± SD): 0.2
Precision (C of V):
Standard Diln.: 1/2
Dilution Calc. 2 x OBS
Standard Conc.:
Conc. Calc.
Form to be Output On:

Date:

Twice the maximum drift allowable between a drift standard and the first drift standard: .16

Maximum drift allowable between drift standards: .03

Concentration of drift standard: 10 Cup no of drift standards: 5

Peak Detection Parameters		Standard Search Parameters		
Meaning of Parameter	Value	Cup No	Conc.	Min. Diff.
				+2
A. Minimum no. of rising readings	12	1	2.0	0.05
B. Minimum no. of falling readings	6	2	4.0	0.04
C. Maximum irregularity in rise or fall	0.03	3	6.0	0.04
D. Maximum difference between successive readings	0.02	4	8.0	0.03
E. Minimum rise required	0.04	5	10.0	0.02
F. Expected no. of readings between peaks	45	6	12.0	0.02
G. Waiting time for first peak	150	7	14.0	0.02
H. Width of window +2	8	7	16.0	-0.01
I. Peak -1 or trough +0	-1	9	10.0	+3
NOTES		10	10.0	

STANDARD CHECK PARAMETERS

Conc. in Ascending Order	Peak Heights		Gradients		Change in Gradients	
	PKLOW	PKHIGH	PKGLOW	PKGHIG	PKDLOW	PKDHIG
1	0.05	0.25	.026	0.060		
2	0.10	0.35	0.032	0.068	+.001	+.020
3	0.20	0.48	0.032	0.068	-.022	+.016
4	0.30	0.60	0.042	0.070	-.015	+.018
5	0.40	0.72	0.038	0.075	-.015	+.015
6	0.50	0.85	0.035	0.075	-.022	+.020
7	0.55	0.93	0.032	0.075	-.014	+.022
8	0.60	0.95				

TABLE LVII

Test: Serum Phosphate
Test Code: P
Test No.: 32
Program Identifiers:
Sampling Rate: 40/hr
Units: mg/100 ml
Normal Range: 2.5-4.5
Asterisk Range: 2.1-5.5
MaximumDigits: >00.0*

Precision (± SD): 0.19
Precision (C of V):
Standard Diln.: ½
Dilution Calc.: 2 x OBS
Standard Conc.:
Conc. Calc.:
Form to be Output On:

Date:

Twice the maximum drift allowable between a drift standard and the first drift standard: 0.10

Maximum drift allowable between drift standards: 0.02

Concentration of drift standard: 8.0 Cup no. of drift standard: 5

Peak Detection Parameters		Standard Search Parameters		
Meaning of Parameter	Value	Cup No	Conc.	Min. Diff.
A. Minimum no. of rising readings	Ø10 12	1*	1.0	+2 .03
B. Minimum no. of falling readings	6	2*	2.0	.03
C. Maximum irregularity in rise or fall	.01	3*	3.0	.04
D. Maximum difference between successive readings	.02	4*	4.0	.04
E. Minimum rise required	.015	5*	5.0	.07
F. Expected no. of readings between peaks	45	6*	8.0	.06
G. Waiting time for first peak	120	7*	12.0	.03
H. Width of window +2	10	8*	15.0	-.01
I. Peak -1 or trough +0	+0	9		+3
NOTES		10		

STANDARD CHECK PARAMETERS

Conc. in Ascending Order	Peak Heights		Gradients		Change in Gradients	
	PKLOW	PKHIGH	PKGLOW	PKGHIG	PKDLOW	PKDHIG
1	0.5	.25	.035	.065		
2	.10	.30	.030	.063	-.015	+0.010
3	.20	.45	.023	.060	-.025	+.005
4	.25	.55	.025	.045	-.012	+0.015
5	.30	.60	.023	.035	-.018	+0
6	.40	.70	.013	.027	-.014	-.002
7	.45	80	.013	.028	-.011	+.008
8	.50	.85				

Ø For paper tape versions only
* Standards used for calibration

TABLE LVIII

Test: Serum Creatinine
Test Code: C
Test No.: 32
Program Identifiers:
Sampling Rate: 50/hr
Units: mg/100 ml
Normal Range: 0.6-1.2
Asterisk Range: 0.5-1.4
Maximum Digits: >00.0*

Precision (± SD): 0.08
Precision (C of V): ±7%
Standard Diln.: 1/5
Dilution Calc.: 5 x OBS
Standard Conc.:
Conc. Calc.:
Form to be Output On:

Date:

Twice the maximum drift allowable between a drift standard and the first drift standard: .06

Maximum drift allowable between drift standards: .02

Concentration of drift standard: 1.8 Cup no. of drift standard: 3

Peak Detection Parameters		Standard Search Parameters		
Meaning of Parameter	Value	Cup No.	Conc.	Min. Diff.
				+2
A. Minimum no. of rising readings	10	1	.45	.02
B. Minimum no. of falling readings	4	2	.90	.05
C. Maximum irregularity in rise or fall	.01	3	1.8	.03
D. Maximum difference between successive readings	.02	4	2.7	.04
E. Minimum rise required	.01	5	3.6	.03
F. Expected no. of readings between peaks	36	6	5.4	.05
G. Waiting time for first peak	360	7	7.2	.02
H. Width of window +2	8	8	9.0	-.01
I. Peak -1 or trough +0	0	9	3.6	+3
NOTES		10	1.8	

STANDARD CHECK PARAMETERS

Conc. in Ascending Order	Peak Heights		Gradients		Change in Gradients	
	PKLOW	PKHIGH	PKGLOW	PKGHIG	PKDLOW	PKDHIG
1	.03	.25	.028	.135		
2	.05	.30	.056	.120	-.028	+.040
3	.10	.35	.070	.125	-.030	+.024
4	.15	.45	.040	.099	-.046	+.018
5	.25	.55	.031	.080	-.042	+.014
6	.30	.60	.042	.077	-.025	+.036
7	.40	.75	.028	.049	-.033	-.001
8	.50	.85				

TABLE LIX

Test: Creatinine (Urine)
Test Code: CC
Test No.: 32
Program Identifiers:
Sampling Rate: 50/hr
Units: mg/100 ml
Normal Range:
Asterisk Range:
Maximum Digits: >.000

Precision (± SD): 2 0
Precision (C of V):
Standard Diln.: 1/2
Dilution Calc.: 2 x OBS
Standard Conc.:
Conc. Calc.:
Form to be Output On:

Date:

Twice the maximum drift allowable between a drift standard and the first drift standard: .06

Maximum drift allowable between drift standards: .02

Concentration of drift standard: 100 Cup no. of drift standard: 5

Peak Detection Parameters		Standard Search Parameters		
Meaning of Parameter	Value	Cup No.	Conc.	Min. Diff.
				+2
A. Minimum no. of rising readings	10	1	20	.05
B. Minimum no. of falling readings	4	2	40	.02
C. Maximum irregularity in rise or fall	.01	3	60	.02
D. Maximum difference between successive readings	.02	4	80	.03
E. Minimum rise required	.01	5	100	.02
F. Expected no. of readings between peaks	36	6	120	.04
G. Waiting time for first peak	360	7	160	.03
H. Width of window +2	6	8	200	-.01
I. Peak -1 or trough +0	0	9	100	+3
NOTES		10	100	

STANDARD CHECK PARAMETERS

Conc. in Ascending Order	Peak Heights		Gradients		Change in Gradients	
	PKLOW	PKHIGH	PKGLOW	PKGHIG	PKDLOW	PKDHIG
1	.10	.25	.0040	.0083		
2	.15	.40	.0033	.0065	-.0030	0
3	.25	.55	.0032	.0073	-.0018	+.0025
4	.30	.60	.0025	.0053	-.0035	+.0005
5	.35	.70	.0020	.0038	-.0023	+.0002
6	.40	.80	.0017	.0033	-.0010	+.0005
7	.50	.90	.0010	.0025	-.0010	+.0001
8	.60	.99				

TABLE LX

Test: Cholesterol
Test Code: COL
Test No.: 41
Program Identifiers:
Sampling Rate: 40/hr
Units: mg/100 ml
Normal Range: 140-260
Asterisk Range: 120-290
Maximum Digits: >0000*

Precision (± SD): 9.0
Precision (C of V): ± 5%
Standard Diln.: ½
Dilution Calc.: 2 x OBS
Standard Conc.:
Conc. Calc.:
Form to be Output On:

Date:

Twice the maximum drift allowable between a drift standard and the first drift standard: 0.12

Maximum drift allowable between drift standards: 0.03

Concentration of drift standard: 200 Cup no. of drift standard: 4

Peak Detection Parameters		Standard Search Parameters		
Meaning of Parameter	Value	Cup No	Conc.	Min. Diff.
A. Minimum no. of rising readings	12	1	50	+2
B. Minimum no. of falling readings	Ø8 10	2	100	0.05
C. Maximum irregularity in rise or fall	0.01	3	150	0.03
D. Maximum difference between successive readings	0.02	4	200	0.03
E. Minimum rise required	0.02	5	250	0.02
F. Expected no. of readings between peaks	45	6	300	0.02
G. Waiting time for first peak	100	7	400	0.02
H. Width of window +2	8	8	500	0.02
I. Peak -1 or trough +0	0	9	200	-0.01
NOTES		10	200	+3

STANDARD CHECK PARAMETERS

Conc. in Ascending Order	Peak Heights		Gradients		Change in Gradients	
	PKLOW	PKHIGH	PKGLOW	PKGHIG	PKDLOW	PKDHIG
1	0.05	0.35	0.0011	0.0028		
2	0.20	0.50	0.0017	0.0026	-0.0006	+0.0008
3	0.30	0.60	0.0013	0.0022	-0.0009	+0.0004
4	0.40	0.70	0.0010	0.0019	-0.0008	+0.0002
5	0.45	0.75	0.0011	0.0018	-0.0006	+0.0005
6	0.50	0.85	0.0009	0.0013	-0.0007	+0.0001
7	0.60	0.95	0.0006	0.0010	-0.0006	0
8	0.65	0.99				

Ø For paper tape version only

TABLE LXI

Test: Iron Binding Capacity
Test Code: IBC
Test No.: 42
Program Identifiers:
Sampling Rate: 40/hr
Units: µg/100 ml
Normal Range: 250-400
Asterisk Range: 200-450
Maximum Digits: > 000*

Precision (± SD): 24
Precision (C of V): ± 6%
Standard Diln.:
Dilution Calc.
Standard Conc.:
Conc. Calc.:
Form to be Output On:

Date:

Twice the maximum drift allowable between a drift standard and the first drift standard: .06

Maximum drift allowable between drift standards: .01

Concentration of drift standard: 300 Cup no. of drift standard: 3

Peak Detection Parameters		Standard Search Parameters		
Meaning of Parameter	Value	Cup No.	Conc.	Min. Diff.
A. Minimum no. of rising readings	12	1*	60	+2
B. Minimum no. of falling readings	6	2*	150	.01
C. Maximum irregularity in rise or fall	.01	3*	300	.03
D. Maximum difference between successive readings	.02	4*	450	.02
E. Minimum rise required	.005	5*	600	.02
F. Expected no. of readings between peaks	45	6*	900	.02
G. Waiting time for first peak	240	7	1200	+2
H. Width of window +2	12	8	1500	+2
I. Peak -1 or trough +0	0	9	600	-.01
NOTES		10	300	+3

STANDARD CHECK PARAMETERS

Conc. in Ascending Order	Peak Heights		Gradients		Change in Gradients	
	PKLOW	PKHIGH	PKGLOW	PKGHIG	PKDLOW	PKDHIG
1	.02	.20	.0001	.0004		
2	.03	.25	.0002	.0005	-.0002	+.0002
3	.05	.35	.0001	.0004	-.0003	+.0001
4	.10	.40	.0001	.0004	-.0002	+.0002
5	.13	.45	.0001	.0004	-.0001	+.0002
6	.17	.60				

* Standards used for calibration

TABLE LXII

Test: Iron
Test Code: FE
Test No.: 42
Program Identifiers:
Sampling Rate: 40/hr
Units: µg/100 ml
Normal Range: male 80-180, female 60-160
Asterisk Range: male 60-200, female 45-180
Maximum Digits: > 000*

Precision (± SD): 7.0
Precision (C of V): ±8%
Standard Diln.:
Dilution Calc.:
Standard Conc.:
Conc. Calc.:
Form to be Output On:

Date:

Twice the maximum drift allowable between a drift standard and the first drift standard: 0.06

Maximum drift allowable between drift standards: 0.01

Concentration of drift standard: 100

Cup no. of drift standard: 3

Peak Detection Parameters		Standard Search Parameters			Conc. in Ascending Order	STANDARD CHECK PARAMETERS					
						Peak Heights		Gradients		Change in Gradients	
Meaning of Parameter	Value	Cup No.	Conc.	Min. Diff.		PKLOW	PKHIGH	PKGLOW	PKGHIG	PKDLOW	PKDHIG
				+2							
A. Minimum no. of rising readings	12	1	20	.01	1	0.02	0.20	.0004	.0013		
B. Minimum no. of falling readings	6	2	50	.02	2	0.03	0.25	.0006	.0015	-.0004	+.0005
C. Maximum irregularity in rise or fall	.01	3	100	.02	3	0.05	0.35	.0005	.0012	-.0004	+.0004
D. Maximum difference between successive readings	.02	4	150	.02	4	0.10	0.40	.0005	.0012	-.0004	+.0004
E. Minimum rise required	.005	5	200	.02	5	0.13	0.45	.0005	.0012	-.0002	+.0004
F. Expected no. of readings between peaks	45	6	300	.02	6	0.17	0.60	.0005	.0012	-.0004	+.0004
G. Waiting time for first peak	240	7	400	.02	7	0.25	0.70	.0002	.0010	-.0008	+.0003
H. Width of window +2	12	8	500	-.01	8	0.30	0.80				
I. Peak -1 or trough +0	0	9	200	+3							
NOTES		10	100								

TABLE LXIII

Test: Uric Acid
Test Code: UA
Test No.: 42
Program Identifiers:
Sampling Rate: 50/hr
Units: mg/100 ml
Normal Range: male 2.0-7.0, female 2.0-6.0
Asterisk Range: male 2.0-8.0, female 2.0-7.0
Maximum Digits: >00.0*

Precision (± SD): 0.15
Precision (C of V): ± 4%
Standard Diln.: 1/2
Dilution Calc.: 2 x OBS
Standard Conc.:
Conc. Calc.:
Form to be Output On:

Date:

Twice the maximum drift allowable between a drift standard and the first drift standard: 0.04

Maximum drift allowable between drift standards: 0.01

Concentration of drift standard: 6.0

Cup no. of drift standard: 4

Peak Detection Parameters		Standard Search Parameters			Conc. in Ascending Order	STANDARD CHECK PARAMETERS					
						Peak Heights		Gradients		Change in Gradients	
Meaning of Parameter	Value	Cup No.	Conc.	Min. Diff.		PKLOW	PKHIGH	PKGLOW	PKGHIG	PKDLOW	PKDHIG
				+2							
A. Minimum no. of rising readings	10	1	1.5	0.03	1	0.05	0.35	0.041	0.072		
B. Minimum no. of falling readings	4	2	3.0	0.02	2	0.08	0.38	0.039	0.062	-0.015	+0.011
C. Maximum irregularity in rise or fall	0.01	3	4.5	0.02	3	0.10	0.40	0.031	0.062	-0.018	+0.008
D. Maximum difference between successive readings	0.02	4	6.0	0.02	4	0.15	0.45	0.031	0.055	-0.015	+0.008
E. Minimum rise required	0.02	5	7.5	0.02	5	0.20	0.50	0.028	0.053	-0.014	+0.011
F. Expected no. of readings between peaks	36	6	9.0	0.03	6	0.25	0.55	0.018	0.037	-0.022	-.001
G. Waiting time for first peak	200	7	12.0	0.03	7	0.30	0.60	0.013	0.030	-0.019	+0.009
H. Width of window +2	10	8	15.0	-0.01	8	0.35	0.70				
I. Peak -1 or trough +0	0	9	9.0	+3							
NOTES		10	6.0								

TABLE LXIV

LIST OF ASTERISK RANGES

TEST	UNITS	NORMAL RANGE	S.D. (PATIENT)	S.D. ⊕ (ANAL)	ASTERISK RANGE
Albumin	g/100ml	3.6-4.7	0.28	0.1	<3.0 or >5.0
Alkaline phosphatase	K.A.U./100ml	2-13	2.8	0.7 (5%)	<2 or >16
Bicarbonate	meq./l.	24-30	1.5	0.9	<18 or >34
Bilirubin	mg/100ml	<1.0	-	±8% (cv)	>1.4
Calcium	mg/100ml	8.5-10.5	0.5	0.2	<8.1 or >10.9
Corrected calcium	mg/100ml	8.5-10.5	0.5	0.2	<8.1 or >10.9
Chloride	meq./l.	100-107	1.8	2.2	<92 or >111
Cholesterol	mg/100ml	140-260	30	9.0 (±5%)	<120 or >290
Creatinine (serum)	mg/100ml	0.6-1.2	0.15	0.08 (±7%)	<0.5 or >1.4
Alanine aminotransferase	U/ml	10-35	6.3	1.8 (±5%)	>40
Aspartate aminotransferase	U/ml	10-40	7.5	1.8 (±5%)	>45
Iron - Males	µg/100ml	80-180	25	7.0 (±6%)	<60 or >200
Females	µg/100ml	60-160	25	7.0 (±6%)	<45 or >180
Total iron-binding capacity	µg/100ml	250-400	37.5	24.0 (±6%)	<200 or >450
Phosphate	mg/100ml	2.5-4.5	0.5	0.19	<2.1 or >5.5
Potassium	meq./l.	3.8-5.2	0.35	0.1	<3.4 or >5.6
Protein bound iodine	µg/100ml	3.9-7.6	0.9	0.6	<3.5 or >8.0
Sodium	meq./l.	136-149	3.5	2.2	<130 or >153
Total protein	g/100ml	6.0-8.0	0.5	0.13	<5.5 or >8.5
Urea	mg/100ml	15-40	8.3	±4%	<14 or >50
Uric acid - Males	mg/100ml	2-7	1.3	0.15 (±4%)	<2.0 or >8.0
Females	mg/100ml	2-6	1.0	0.15 (±4%)	<2.0 or >7.0
Calculations					
Urine calcium (total)	mg/24hr	100-300	-	*	<50 or >300
Urine creatinine (total)	mg/24hr	1000-2000	-	*	<800 or >2200
Urine phosphate (total)	mg/24hr	500-1500	-	*	<400 or >1600
Creatinine clearance	ml/min.	>100	-	*	70
Calcium/creatinine ratio	-	0.03-0.28	-	*	<0.02 or >0.39
Phosphate/creatinine ratio	-	0.02-0.22	-	*	>0.30
P.E.I.	-	-0.09-+0.09	-	*	<-0.14 or >0.14
Ion difference	-	-	-	*	<12 or >24

⊕ - Percentages indicate precision expressed as coefficient of variance

* - No comparison between first result and a subsequent result

APPENDIX VIII

Lists of Test, Test Group, Ward, Department, Hospital and Consultant Codes

In order to simplify the input of patient identification and test request data, computer codes consisting of up to three alphanumeric characters have been assigned to all tests (Tables LXV - LXVII), test groups (Table LXVIII), wards and departments (Table LXIX), hospitals (Table LXX) and consultants (Table LXXI).

All codes entered on the on-line Teletype or paper tape reader are checked by the computer program. The same character codes are used for departments and hospitals when printing cumulative reports, but the consultant's name and title as shown in Table LXXI are printed in full. Most of the commonly requested tests are printed in the pre-printed section of the cumulative report (Section IIF) but the names of tests appearing in the miscellaneous section of the report are printed out in full. The nature of the specimen on which the analysis is to be performed is indicated by the test code; for instance, NA, NAC, FNA and SNA indicate respectively the analysis of sodium in blood, urine, other fluids and faeces.

Wherever/

Wherever possible contracted forms of names currently in use for tests, wards, hospitals, etc. were used for computer codes, but an attempt was made to ensure that codes which were in frequent use were sufficiently different to reduce the likelihood of input errors; for instance, LBM was used for albumin instead of ALB to prevent confusion with the code for alkaline phosphatase (ALP).

TABLE LXV

LIST OF TEST REQUEST CODES (PLASMA OR SERUM)

Acid phosphatase (total)	ACT	5-Nucleotidase	NUC
Acid phosphatase (tartrate labile)	TL	Glucose	GLU
Alanine aminotransferase	GPT	Globulin	GLO
Albumin	LBM	Hydroxybutyrate dehydrogenase	HBD
Alkaline phosphatase	ALP	Iron	FE
Ammonia	NH3	Iron-binding capacity	IBC
Amylase	AMY	Isocitrate dehydrogenase	ICD
Ascorbic acid	VC	Lactate dehydrogenase	LDH
Aspartate aminotransferase	GOT	Leucocyte ascorbic acid	LVC
Barbiturate	BAR	Magnesium	MAG
Base excess	BEX	Miscellaneous	MIS
Bicarbonate	CO2	Oxygen saturation	OXY
Bilirubin (total)	BIL	Pco_2	PC2
Bilirubin (conjugated)	BIC	pH	PH
Bromsulphthalein	BSP	Phosphate	P
Caeruloplasmin	CAE	Po_2	PO2
Calcium	CA	Potassium	K
Calcium (corrected)	CCA	Protein-bound iodine	PBI
Carboxyhaemoglobin	CO	Pseudo cholinesterase	PSC
Chloride	CL	Pyruvic acid	PY
Cholesterol	COL	Salicylate	SAL
Cortisol (11-hydroxycorticosteroids)	COR	Sodium	NA
Creatine	CR	Standard bicarbonate	SBC
Creatinine	C	Total protein	TP
Creatine kinase	CK	Toxicology	TOX
Cycloserine	CYS	Urea	U
Dibucaine number	DBN	Uric acid	UA
Fibrinogen	FBR	Xylose	XY

TABLE LXVI

LIST OF TEST REQUEST CODES (URINE AND FLUIDS)

(A) URINE			
Amino acids	AA	Miscellaneous	MUS
Ammonia	UNH	Nitrogen	N
Amylase	UAM	17-Oxosteroids	XST
Ascorbic acid	UVC	pH	UPH
Bence Jones protein	BJ	Phosphate	PC
Calcium	CAC	Porphyrins (copro)	POC
Chloride	CLC	Porphyrins (uro)	POU
Chromatography	CHR	Potassium	KC
Copper	CU	Protein	PRC
Creatine	CRC	Salicylate	USA
Creatinine	CC	Sodium	NAC
Cycloserine	CS	Titratable acidity	TA
Cystine	UCY	Toxicology	UTX
Glucose	UGL	Urea	UU
11-Hydroxycorticoids	OHS	Uric acid	UUA
17-Hydroxycorticosteroids	HYD	Urobilinogen	URO
Hydroxyindolyl acetic acid	HAA	Vanillylmandelic acid	VMA
Iodine	I	Volume	VOL
Iron	UFE	Xylose	XYT
Lead	LED		
(B) CEREBROSPINAL FLUID			
Globulin	PAN	Miscellaneous	MSC
Glucose	CGL	Total protein	CTP
(C) OTHER FLUIDS			
Amylase	FAM	Lipase	LIP
Amylase (pancreatic function test)	PFT	Miscellaneous	MSF
		pH	FPH
Bicarbonate	FC2	Potassium	FK
Bilirubin	FLB	Sodium	FNA
Calcium	FCA	Total acidity	FTA
Chloride	FCL	Total protein	FTP
Cholesterol	FCO	Toxicology	FTX
Free acid	HCL	Trypsin	FTR
Glucose	FGL	Urea	FU

TABLE LXVII

LIST OF TEST REQUEST CODES (FAECES AND STONES)

(A) FAECAL ANALYSES			
Calcium	SCA	Porphyrin	POR
Fat	FAT	Sodium	SNA
Nitrogen	NIT	Stercobilinogen	STE
Occult blood	OB	Tryptic activity	STR
Potassium	SK		
(B) STONE ANALYSIS			
Chemical analysis	CEM		

TABLE LXVIII

LIST OF TEST GROUP CODES

(A) PLASMA OR SERUM	
Acid phosphatase (total and tartrate labile)	AP = ACT + TL
Calcium and phosphate	CAP = CA + P
Electrolytes and urea	ELU = U + NA + K + CL + CO2
Enzymes	ENZ = GOT + HBD
Gases	GAS = PH + PC2 + SBC
Liver function tests	LFT = ALP + BIL + GPT
Protein	PRT = TP + LBM
Protein electrophoresis	EPH = GA + GAA + GLB + GLG + TP + LBM
(B) URINE	
Acidification test	UAT = UPH + TA + UNH
Calcium-creatinine ratio	CCR = CC + CAC
11-Hydroxycorticoids and creatinine	UHC = OHS + CC
17-Hydroxycorticosteroids and creatinine	HCS = HYD + CC
17-Oxosteroids and creatinine	OSD = XST + CC
Phosphate-creatinine ratio	PHC = PC + CC
Electrolytes	UEL = NAT + KT
Vanillylmandelic acid and creatinine	VMC = VMA + CC

TABLE LXIX

LIST OF WARDS AND DEPARTMENTS

(A) WARDS

Royal Infirmary wards - 3 and 5-54 inclusive (coded by ward number)

Royal Infirmary Outpatient ward clinics - 3, 4-18 and 21-23 inclusive (coded by ward number followed by 'P')

City Hospital wards - 2-4, 5 and 5A - 8 and 8A, 14 and 14A - 16 and 16A, 17, 19, 19A, 20, 21 (coded by ward number and letter)

(B) DEPARTMENTS

Blood Clinic	BIC	Nurses' Sick Room	NSR
Blood Transfusion Service	BTS	Orthopaedic Outpatient dept.	OOP
Cardiology	CAR	Oral Surgery dept.	ORS
Coronary Care Unit	CCU	Psychological Medicine	PSY
Coagulation Laboratory	COG	Peripheral Vascular Clinic	PVC
Department of Medicine	DOM	Quality Control dept.	QCD
Diabetic Outpatient dept.	DOP	Rheumatic Clinic	RHC
Department of Surgical Neurology	DSN	Renal Isolation Unit	RIU
Ear, Nose and Throat Outpatient dept.	ENT	Surgical Consultation dept.	SCD
Eye Outpatient dept.	EYE	Skin Outpatient dept.	SKN
Anaesthetics department	GAS	Simpson Maternity Outpatient dept.	SMP
Gynaecology Outpatient dept.	GOP	Surgical Outpatient dept.	SOP
Medical Outpatient dept.	MOP	Therapeutic dept.	THE
Endocrine Clinic	NDO		

TABLE LXX

LIST OF HOSPITAL CODES

Andrew Duncan Clinic	ADC	Longmore Hospital	LON
Astley Ainslie Hospital	AAH	Mackenzie House	MCK
Bangour Hospital	BAW	Medical Reception Station	MRS
Beechmount Hospital	BMT	Northern General Hospital	NGH
Bruntsfield Hospital	BFD	Peel Hospital	PEH
Chalmers Hospital	CHA	Perth Royal Infirmary	PRI
Chalmers Hospital Annexe	CHX	Princess Margaret Rose Hospital	PMR
City Hospital	CIT	Queensberry House	QUB
Corstorphine Hospital	COR	Roodlands Hospital	ROO
Deaconess Hospital	DEA	Rosslynlee Hospital	ROS
Eastern General Hospital	EGH	Royal Dispensary	RDY
East Fortune Hospital	EFO	Royal Edinburgh Hospital	REH
Edenhall Hospital	EDN	Royal Hospital for Sick Children	RSC
Elsie Inglis Hospital	EIH	Royal Infirmary	RIE
Family Doctor Centre	FDC	Royal Victoria Dispensary	RVD
Fife District Laboratory	FIF	Royal Victoria Hospital	RVH
Gogarburn Hospital	GOG	St Triduanas Hospital	STT
Herdmanflat Hospital	HER	Southfield Hospital	SOU
Leith Hospital	LEI	Western General Hospital	WGH
Liberton Hospital	LIB	West House	WHO
Livingstone House	LIV		

TABLE LXXI

LIST OF CONSULTANT CODES

Dr D.M.F. Batty	DMB	Mr A. Logan	ALN
Sir John Bruce	SJB	Mr D. McIntosh	DMI
Mr J. Chalmers	JCS	Mr T.J. McNair	TMN
Dr B.F. Clark	BFC	Mr A.I.S. MacPherson	AIM
Prof. J.W. Crofton	JWC	Mr W.M. McQuillan	WMQ
Dr S.H. Davies	SHD	Dr R.M. Marquis	RMM
Dr A. Doig	ADG	Dr H.J.S. Matthew	HJM
Prof. K.W. Donald	KWD	Dr J.D. Matthews	JDM
Dr L.J.P. Duncan	LJD	Dr C. Mawdsley	CMY
Mr E.L. Farquharson	ELF	Dr J.McC. Murdoch	JMM
Dr D.C. Flenley	DCF	Mr B. Nolan	BNN
Prof. J Gillingham	JGM	Dr M.F. Oliver	MFO
Dr J. Halliday Croom	JHC	Dr J. Richmond	JRD
Dr J.G.M. Hamilton	JGH	Dr J.G. Robertson	JGR
Dr N.W. Horne	NWH	Dr J.S. Robson	JSR
Dr J. Innes	JIS	Dr D.J.C. Shearman	DJS
Dr W.J. Irvine	WJI	Mr I.S.R. Sinclair	ISS
Dr D.G. Julian	DGJ	Mr J.W.W. Thomson	JWT
Prof. R.J. Kellar	RJK	Mr T.I. Wilson	TIW
Dr A. Lambie	ALB	Sir Michael Woodruff	MFW

APPENDIX IX

Details of Additional Calculations

The following additional calculations are carried out on test results before the output of cumulative reports (see Section IIJ):-

(1) Urine Phosphate (Total) PT

$$PT = \frac{PC}{100} \times VOL \text{ mg/24 hr}$$

where PC = urine phosphate (mg/100 ml) and VOL = 24 hour urine volume (ml).

(2) Urine Calcium (Total) CAT

$$CAT = \frac{CAC}{100} \times VOL \text{ mg/24 hr}$$

where CAC = urine calcium (mg/100 ml) and VOL = 24 hour urine volume (ml).

(3) Urine Creatinine (Total) CT

$$CT = \frac{CC}{100} \times VOL \text{ mg/24 hr}$$

where CC = urine creatinine (mg/100 ml) and VOL = 24 hour urine volume (ml).

(4) Creatinine Clearance CCL

$$CCL = \frac{CC \times VOL}{60 \times L \times C} \text{ ml/min.}$$

where CC = urine creatinine (mg/100 ml), C = plasma creatinine/

creatinine (mg/100 ml), L = length of collection (hr) and VOL = urine volume (ml/L hr)

(5) Calcium/Creatinine Ratio CCR

$$CCR = \frac{CAC}{CC}$$

where CAC = urine calcium (mg/100 ml) and CC = urine creatinine (mg/100 ml)

(6) Phosphate/Creatinine Ratio PHC

$$PHC = \frac{PC}{CC}$$

where PC = urine phosphate (mg/100 ml) and CC = urine creatinine (mg/100 ml)

(7) Phosphate Excretion Index PEI (Nordin and Fraser, 1960)

$$PEI = \frac{PC \times C}{CC \times P} - 0.055P + 0.07$$

where PC = urine phosphate (mg/100 ml), C = plasma creatinine (mg/100 ml), CC = urine creatinine (mg/100 ml) and P = plasma phosphate (mg/100 ml)

(8) Protein Electrophoresis EPH

$$\% \text{ Albumin} = \frac{LBM}{TP} \times 100$$

$$\alpha_1\text{-globulin (GAC)} = \frac{RI}{RT} \times (TP - LBM) \text{ g/100 ml}$$

$$\% \ \alpha_1\text{-globulin (GAP)} = \frac{GAC}{TP} \times 100$$

$$\alpha_2\text{-globulin (G2C)} = \frac{R2}{RT} \times (TP - LBM) \text{ g/100 ml}$$

%/

$$\% \alpha_2\text{-globulin (G2P)} = \frac{G2C}{TP} \times 100$$

$$\beta\text{-globulin (GBC)} = \frac{R3}{RT} \times (TP - LBM) \text{ g/100 ml}$$

$$\% \beta\text{-globulin (GBP)} = \frac{GBC}{TP} \times 100$$

$$\gamma\text{-globulin (GGC)} = \frac{R4}{RT} \times (TP - LBM) \text{ g/100 ml)}$$

$$\% \gamma\text{-globulin (GGP)} = \frac{GGC}{TP} \times 100$$

where TP = total protein (g/100 ml), LBM = albumin (g/100 ml), R_1, R_2, R_3 and R_4 are the integrator readings obtained by scanning the electrophoretic strip, and RT = $R_1 + R_2 + R_3 + R_4$.

(9) Corrected Calcium CCA (Dent and Watson, 1968)

$$CCA = CA - \frac{0.25}{0.30} (TP - 7.2)$$

$$= CA + 6.00 - 0.83\ TP$$

where CA = serum calcium (mg/100 ml) and TP = total protein (g/100 ml).

(10) Ion Difference ID

$$ID = (NA + K) - (CL + CO2)$$

where NA = plasma sodium (meq./l.), K = plasma potassium (meq./l.), CL = plasma chloride (meq./l.) and CO2 = plasma bicarbonate (meq./l.).

(11)/

(11) Dilution or Concentration of Patient Specimens

If the concentration of sodium, chloride or bicarbonate in a patient specimen falls outside the range of the calibration standards then the request is re-allocated to work sheets and the analysis repeated after mixing the specimen with a diluting-concentrating fluid (1 volume of specimen to 4 volumes of fluid). This fluid brings the concentration into the standards range by reducing the concentration if it is elevated or increasing the concentration if it is low. The diluting-concentrating fluid contains sodium chloride (7.014 g NaCl per litre) and sodium carbonate (1.059 g Na_2CO_3 per litre) i.e. [Na] = 140 meq./l., [Cl] = 120 meq./l. and [CO_3] = 20 meq./l. The calculation required to determine the actual concentration of the constituent in the plasma specimen is performed by the computer program using the following formulae:-

Actual NA = (5 x observed NA) - 560

Actual CL = (5 x observed CL) - 480

Actual CO2 = (5 x observed CO2) - 80

If/

If the concentration of urea, alkaline phosphatase, bilirubin, serum creatinine, alanine aminotransferase or aspartate aminotransferase in a specimen is higher than the highest calibration standard, the request is allocated for repeat analysis after 1:5 dilution with 0.9% sodium chloride solution and the computer program makes the necessary correction when calculating the result. Similarly, if the concentration of specimens for phosphate, uric acid, or urine creatinine is outside the calibration range then the analysis is repeated after a 1:2 dilution of the serum.

APPENDIX X

List of Program Error Messages

An abbreviated list of computer error messages is given in Table LXXII. All the error messages are printed out on the on-line control Teletype (see Section II) and the information is passed on to the laboratory staff by using a simple 'intercom' link between the computer room and the analyser console station. The laboratory staff become conversant with the more commonly used error numbers within a short period, but a list of on-line monitoring messages (i.e. errors in peak detection, standards validation, drift correction, etc.) is displayed at each analyser console. The detection of faulty peaks is also indicated by the red 'fault' light on the console, but this does not by itself attract much notice and was found to be of only limited value.

TABLE LXXII

ABBREVIATED LIST OF MESSAGES

MESSAGE NO.	PROGRAM	REPLY	MEANING, ACTION, etc.
1	14.24	No	More than 120 characters in a line
2	14.24	No	Wrong parity or illegal character
3	14.24	No	(Internal) No reply to request for input
4	14.51	No	IBM Printer has been busy for three minutes
10	19.1	No	"PSEUDO REPLY" set. Ignore unless excessive
11	15 5	C, R, U >	Error exit taken from one of the 900 Library Magnetic Tape routines. Program code, handler, action code and status word output
12	15.4	No	A program not found on the magnetic tape. The identifier is printed
13	15.7	No	Start Master File Read entered wrongly
14	15.9	No	Final work file not written correctly
16	15.6	No	Cannot open files. Reallocate the magnetic tapes
28	22.1	No	All handlers in manual or files incorrect
29	22.1	No	Block read has the wrong label
30	22.1	No	Magnetic tape error - status printed
38	19.1	No	High level switch zero wrong. All on-line work stopped
39	19.1	No	High level switch one wrong. All on-line work stopped
40	19.2	No	Peak error because of flare
41	19.2	No	Peak early error
42	19.2	No	Peak late error
43	19.2	No	Double top peak error
44	19.2	No	Very low rise to peak
45	19.2	No	(Internal) Too many consecutive errors
46	19.2	No	Long wait for first peak
47	19.2	No	Excessively long wait for first peak, channel switched off
48	19.2	No	Off-scale reading, measuring greater than reference, peak rejected
49	19.2	No	Reference reading outside limits, peak rejected
50	19.1	No	"PSEUDO REPLY" set, ignore unless excessive
51	18.1-6	Repeat	Format error in last line. Repeat complete identification or request data input
52	18.6	Repeat	Error in the last input line. Re-input the full line
53	18.12	No	Test request for work sheets not known or none found on the work file
54	18.12	No	Record not found on work file. Processing error
55	18.12	No	There are no outstanding requests on the work file for the work sheet requested

56	18.4-6	Repeat	The record space in store is full. Data is written away then last patient must be restarted
61	20.2	W,C,R,U>	Standards cannot be found. Differences wrong or two or more faulty peaks, or the two drift standards are both faulty
62	20.3	W,C,R,U>	One of the end standards is faulty. If U > then the reduced set of standards is used
63	20.3	W,C,R,U>	One of the middle standards is faulty. If U> the peak is interpolated
64	20.3	W,C,R,U>	The standards do not check for position, etc.
65	20.2	W,C,R,U>	Too many consecutive faulty peaks or the console has been switched off before standards are accepted
66	20.12	No	Output of pool result when processing without the work file
67	20.3	W,C,R,U>	The first drift standard in the standards is faulty. U> means assume zero drift from the final drift standard
68	20.11 & 20.3	W,C,R,U>	The latest drift standard is faulty, and a double interval cannot be assumed. U> means assume zero drift
69	20.12	W,C,R,U>	Too many consecutive faulty peaks, or the console has been switched off
70	20.11	W,C,R,U>	Drift peak now too high (relative to first drift standard). U> means act as if drift standard were a faulty peak
71	20.11	W,C,R,U>	Drift peak now too low. See 70
72	20.3 or 20.11	W,C,R,U>	Difference between the current drift standard and the latest acceptable drift standard is too great See 70
73	20.11	No	One drift peak faulty. Computer goes on to use a double interval
74	20.14	No	Faulty, too high, or too low result received for given test and cup. REP means automatic repeat
75	20.14	No	No record has been found on the work file for the results output. The test, group, cup number, and result is printed
76	20.12	No	Faulty, too high, or too low result received for a given test and cup when processing without the magnetic tape work file
77	20.21	No	Error in test request code line of input of manual results. Operator should correct and re-input
78	20.21	No	Error in line of manual results. See 77
79	21.10	No	Tape Reader busy for longer than one minute. Program stopped
80	21.6	No	Past results not yet brought down. Go on to next patient.
81	21.6	No	Patient cannot be found on the work file. Go on to next patient
82	21.2	No	Patient cannot be found on the work file. Go on to next patient
83	21.5B	No	Abnormal Pools result
84	22.2	Repeat	Line of Pools data wrong
85	22.2	No	Insufficient data to create a Pools record on magnetic tape.
86	22.2	Repeat	Channel requested to be set up not allocated to a group. Use GROUP subprogram
87	22.2	Repeat	Sub-program identifier not recognised
88	22.2	Repeat	Channel still allocated to another group
89	22.2	Repeat	MAGTAPE identifier not WRI, REA, or MST.
90	22.2	Repeat	Handler numbers not -1, 0, 1, or 2
91	22.2	Repeat	Test request code is not an automated test
92	22.2	Repeat	External channel number or group code not recognised
93	22.2	Repeat	Test request code (group or channel) not recognised.
94	22.2	Repeat	Paper tape sub-program identifiers not PUN, TPO, TPI, REA, or IBM
95	22.2	Repeat	Attempt to alter a location outside the correct area of store or the letter input not A, I, O, R, F, E, or X
96	22.2	Repeat	Error reported from Basic Software (see 1, 2, or 3)
97	22.2	Repeat	Input of today's date is not six digits only
98	22.2	Repeat	Laboratory number is not one letter and three digits
99	22.3	No	(Internal) Switch off a fault lamp

Eden Grove
Bond
TUB SIZED

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Experience with on-line computing in clinical chemistry

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The scientific practice of medicine is making increasing demands upon clinical chemistry departments and it is the experience of these laboratories, both in teaching and non-teaching hospitals, that their work loads double every four to five years (Lathe and Mitchell, 1966). The use of AutoAnalyzers[1] has markedly increased the capacity of these laboratories for carrying out repetitive types of analytical work (Table I), and at the same time introduced a degree of much needed uniformity into the methods of performing analyses. Developments in automatic chemical equipment may further increase the work capacity of these departments, but already a different set of problems has emerged. These can be summarized under several interrelated headings: (1) specimen collection and unequivocal identification of samples with the correct patient throughout the subsequent procedures; (2) accession procedures in the laboratory; (3) maintenance of reliable standards of analytical performance in large-scale operations; (4) processing of instrumental readings; (5) report preparation and presentation; (6) uses made of laboratory data (*a*) by the clinicians and (*b*) by the laboratory; (7) records storage and arrangements for their retrieval for various purposes.

This paper will concentrate particularly on experience gained so far with computer-dependent systems designed to help with problems 2 to 5.

Blaivas and Mencz (1967, 1968), reporting upon an extension of their earlier system (Blaivas, 1966), described how an IBM 1710 computer had been routinely used for process control, linked on line to as many as 30 AutoAnalyzers performing up to 20 different analyses. The reasons for wishing to develop an alternative to the system in use at King's County Research Laboratories included the substantial cost (capital or hire) of the IBM system, and the desire to incorporate additional features such as records storage and cumulative reporting of laboratory results using the computer. The system recently installed in this laboratory is intended ultimately to help with problem 7 also, by storing records of laboratory work in a way that will allow the issue of cumulative reports similar to those previously prepared manually (Whitby and Owen, 1965).

TABLE I

THE PRODUCTIVITY OF A CLINICAL CHEMISTRY LABORATORY[1]

Year	*Work Load (Determinations)*	*Technicians*	*AutoAnalyzers (Number of Channels)*	*Productivity*[2]
1955	57,000	14	—	4,000
1960	106,000	18	1	6,000
1963	195,000	23	3	8,500
1966	407,000	30	12	13,500
1968	506,000	33	15	15,300

[1]Data from the Department of Clinical Chemistry, Royal Infirmary, Edinburgh.
[2]Productivity is expressed as the average number of determinations performed annually by each member of the technical staff.

With AutoAnalyzers other than the SMA-12 series, an important data-acquisition and calculation problem exists in the need to convert raw analytical data, as represented by long series of peaks on chart records, into numerical results for entry on reports. This demands the examination of each peak, since variations in shape may indicate instrumental malfunction or faulty chemical analysis, the reading and checking of peak heights, the application of corrections for instrumental drift, the interpolation of corrected readings in relation to the appropriate pairs of standards, calculation of concentrations, and entry of calculated results into the laboratory's records and on to report forms. With several AutoAnalyzer channels operating at 40 or 60 samples/hour, the number of repetitive processes involving checking and calculation to be performed daily in a busy laboratory is formidable.

To help with these computations, in 1966 this department installed an Elliott Automatic Laboratory Analysis[2] (ALA) system for data acquisition from five channels of AutoAnalyzer equipment and processing by an Elliott 803 computer. The features of the ALA system have been fully described (Flynn, 1965, 1966; Flynn, Piper, and Roberts, 1966), and this laboratory's experience with the equipment has been reported (Whitby, Proffitt, and McMaster,

[1]Technicon Instruments Co., Chertsey, Surrey.

[2]Elliott Automation Ltd, Borehamwood, Herts.

TABLE II

SHORTCOMINGS OF THE ELLIOTT ALA SYSTEM OF DATA ACQUISITION FROM AUTOANALYZERS FOR PROCESSING BY A COMPUTER OFF-LINE[1]

A *Long chain of components involved, each liable to failure*
- (1) Mechanical peak (or trough) recognition system—shaft encoders
- (2) Translator timers and programmer unit for processing signals from shaft encoders
- (3) Paper-tape punch for collecting analytical data on punched tape
- (4) Teletype unit in laboratory, used for
  - (*a*) preparing patient identification data on a second tape
  - (*b*) preparing a third tape detailing positions of standards and identification of errors
  - (*c*) transmitting these three tapes to another Teletype unit in the computer centre
- (5) Elliott 803 computer with output of results on paper tape
- (6) Transmission of results tape back to laboratory for printout

B *Consequences of large work load and resulting arrival of computed data near the end of the working day*
- (1) Disruptive effects of minor hold ups in sequence of data-transmission and data-processing operations
- (2) Failure sometimes to detect faults in analytical operation until printout able to be examined
- (3) Results required urgently have to be calculated by laboratory staff and issued as preliminary reports.

C *Other shortcomings*
- (1) Inability to handle the full load of plasma urea and electrolyte analyses because data acquisition from AutoAnalyzers has to stop about 3 pm
- (2) Capital cost of about £1,500 per channel for ALA equipment, *ie*, apart from cost of the AutoAnalyzers themselves
- (3) Shaft-encoder too bulky to be fitted into a twin-channel recorder

[1]From Whitby *et al* (1968).

1968); the advantages described by Flynn and his colleagues were confirmed, but these had to be offset against the disadvantages inherent in the acquisition of data from AutoAnalyzers for batch processing at the end of an analytical run by a remote computer off-line (Table II). Experience gained with the off-line ALA system was, however, valuable in helping to define features that should be incorporated into the Elliott Automatic Biochemical Laboratory (ABL) system. The ABL system was delivered in May 1968, and installation and manufacturers' standard acceptance tests were completed in July 1968. Since then investigations have been in progress to evaluate, step by step, the programs which had been written on the basis of detailed systems analysis and specifications carried out jointly by the staff of Elliott Automation Systems Ltd and the staff of this laboratory in the previous 18 months.

The components of hardware installed in the laboratory are detailed in Table III. One room, area 200 sq ft and centrally placed, required minor modification with provision of an intake of filtered air; it accommodates these various items, with the exception of the analyser consoles which are placed on the laboratory benches. The individual components were all standard products apart from the data-acquisition unit and the analyser consoles; these had to be developed as well as the systems programming, the development being carried out with the support of the National Research Development Corporation.

TABLE III

HARDWARE CONFIGURATION

Central processor	Elliott 903 computer; 8k core store (18-bit word)
Backing store	Magnetic tape controller and three handlers (Ampex TM7; 9 kch/sec).
Input devices	On-line Teletype (model 33) Paper tape reader (250 ch/sec) Data-acquisition unit, receiving signals on-line from AutoAnalyzers via (up to four) analyser consoles
Output devices	On-line Teletype (same unit as input Teletype; 10 ch/sec) On-line IBM output writer (15 ch/sec) Paper tape punch (100 ch/sec) Off-line Teletype (model 33; 10 ch/sec)
Spare units	Paper tape reader and punch Off-line Teletype can serve as spare for on-line unit.

MONITORING AUTOANALYZERS ON-LINE TO THE COMPUTER

MONITORING OF EQUIPMENT Previously described methods of data acquisition on-line from AutoAnalyzers (Blaivas, 1966; Blaivas and Mencz, 1967, 1968; Gould, 1968; Gray and Owen, 1968) have all taken their signals from the chart recorder, but the ABL system takes its signals from the standard AutoAnalyzer colorimeter or flame photometer: so far, other detector units, such as the multichannel colorimeter used in the SMA-12 system or the fluorimeter unit, have not been linked to the Elliott data-acquisition unit. Instead of the signal from the colorimeter being transmitted direct to the recorder, as in the standard method of operating AutoAnalyzers, the separate signals from the reference and measuring photocells in the colorimeter are led to an analyser console, developed by Elliott Automation; here they are each amplified for transmission to the data-acquisition unit (the length of linking cable is about 60 feet). The analyser console also attenuates part of the amplified signals for separate transmission to the AutoAnalyzer recorder-amplifier unit; a visible record of each channel's operation is thereby retained. (The importance of retaining these chart records will be discussed later.)

The optimum settings of the colorimeter controls

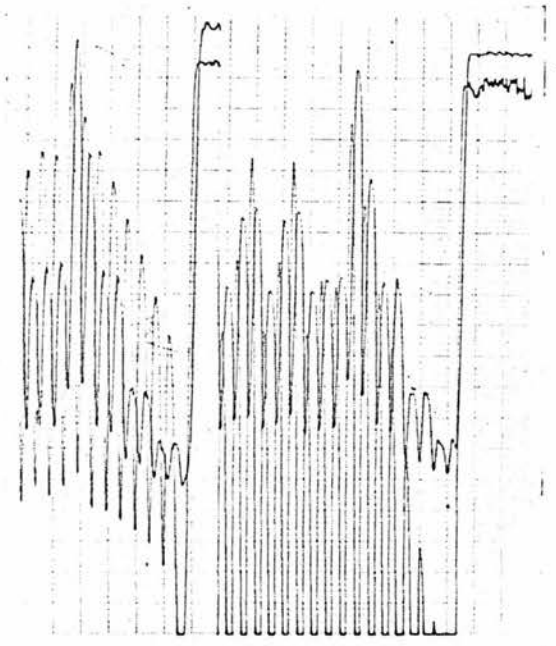


FIG. 1.

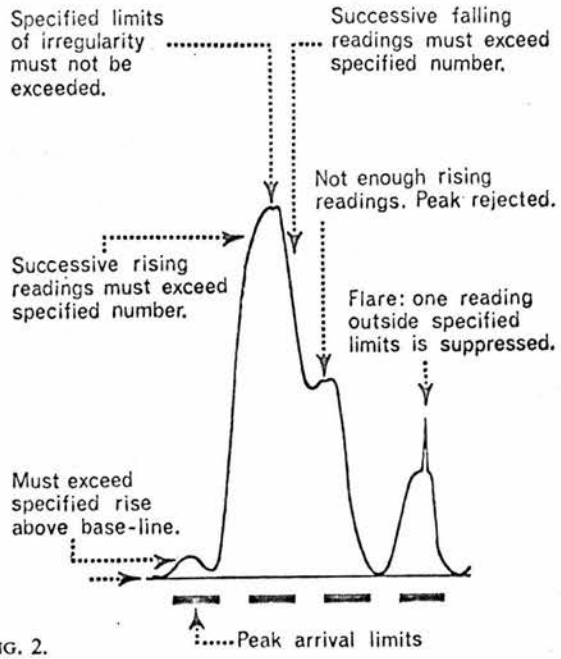


FIG. 2.

FIG. 1. *AutoAnalyzer chart records of calibration curves for sodium and potassium determinations (a) with the usual backing off on the sodium channel (lowest standard on scale 100 m-equiv/l), and (b) without backing off when the signals reached the recorder via the Elliott analyzer console.*

FIG. 2. *Elements of the peak recognition program. Signals from the reference and measuring photocells are read and digitized every two seconds (for details, see text and Table V).*

when signals are to be transmitted to the computer differ in some instances from those selected for the usual operation of AutoAnalyzers. Details of the analytical methods are included in Table VIII; all the methods, except sodium and potassium determinations, employed tubular flow cells, and examples of the extent of changes required in control settings on the colorimeters are summarized in Table IV. The only channel in which the introduction of on-line monitoring has led to a significant modification in the appearance of the final chart record has been the sodium channel. With these analyses, when the Elliott analyser console is in use, the display on the AutoAnalyzer recorder is no longer backed off with the result that the chart width for sodium, instead of covering the range from approximately 90 to 170 m-equiv/l, runs from 0 to about 180 m-equiv/l (Fig. 1); this gives rise to some loss of precision if the operator has to read these charts and calculate results from the chart records from a run in which the computer has been set to monitor the sodium channel's performance.

PEAK RECOGNITION BY COMPUTER Several of the features of the peak recognition programs are similar to those previously described (Blaivas, 1966;

TABLE IV

EXAMPLES OF COLORIMETER SETTINGS

	Standard AutoAnalyzer Operation			*Elliott Analyser Console Inserted*		
Method	*Nominal Aperture*	*Area of Aperture (sq cm)*	*100% T Control Setting*	*Nominal Aperture*	*Area of Aperture (sq cm)*	*100% T Control Setting*
Urea	9	1·61	644	3	0·50	220
Cholesterol	8	1·27	765	2	0·42	754
Uric acid	8	1·27	606	2	0·42	210
Phosphate	6	0·86	861	2	0·42	916
Bicarbonate	6	0·86	957	1	0·33	367

Settings unchanged: Chloride, alkaline phosphatase, calcium, creatinine (also unchanged on sodium, potassium; flame photometer).

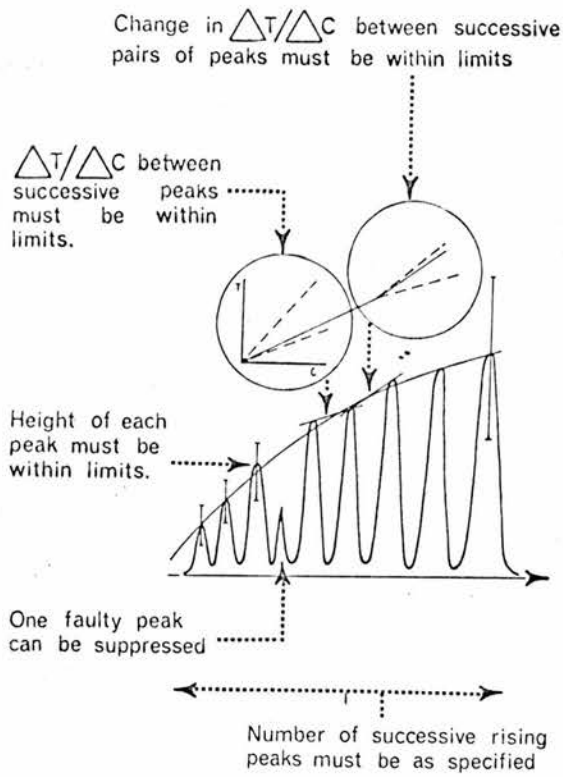


FIG. 3. *Elements of the calibration curve validation program. Each peak is examined by the peak recognition program. The change in peak height between successive peaks is expressed as the difference in percentage transmission for the stated increment of concentration, and thus represents the gradient Δ T/ Δ C of a straight line.*

Blaivas and Mencz, 1967, 1968; Gould, 1968), and are summarized in Figure 2. The continuously varying electrical voltages from the measuring and the reference photocells corresponding to each analytical channel are amplified in the analyser consoles for transmission to the computer, and the data-acquisition unit receives these two signals from each channel regularly every two seconds. The analogue signals are then digitized for input into the computer.

As shown in Fig. 2, for a peak to be recognized, the height of the peak must exceed a specified minimum distance above the baseline. Except for a few analyses, *eg*, protein blank, this minimum rise is derived from the usual analytical behaviour of the lowest standard on the calibration curve, and the specification of a minimum rise means that peaks with heights lower than the first standard are rejected for calculation purposes. With protein blanks, readings for calculations are taken on a timed basis, starting from a first peak of easily recognized proportions, and linear extrapolation between the baseline and the lowest standard is permitted, *ie*, no minimum rise is stipulated for protein blanks.

Each peak, to be accepted, must have a number of rising readings and a number of falling readings each of which exceed a specified number, and acceptable limits of irregularity on the ascending and descending limbs of a peak as well as across the top of a peak are specified. Collectively these limits serve to detect and reject peaks swamped by carryover from the preceding analysis and double peaks. The program allows for the acceptance of a peak that is deformed on the chart record by the appearance of a flare (usually due to an air bubble passing through the colorimeter), as long as there is only one irregular signal generated by this disturbance. One further criterion laid down is the time limit within which peaks can arrive at the colorimeter for them both to be recognized and accepted. Examples of the data required in specifying the peak recognition program for each channel are shown in Table V.

CALIBRATION CURVE VALIDATION Each run of analyses begins with a set of calibrating standards, and the computer program searches for and attempts to validate the calibration curves, basing this validation on several criteria (Fig. 3). The individual criteria have been given wide limits, but collectively they make up a demanding set of requirements, summarized as follows: (1) Each peak is examined for acceptability by the peak recognition program.

TABLE V

EXAMPLES OF PEAK RECOGNITION PARAMETERS

		Calcium	*Cholesterol*	*Uric Acid*	*Alkaline Phosphatase*	*Bilirubin*
A	Rate of analysis (samples/hour)	40	40	50	60	60
B	Expected number of readings between peaks	45	45	36	30	30
C	Width of window (seconds)	12	12	20	20	16
D	Minimum number of rising readings	10	10	10	8	8
E	Minimum number of falling readings	6	10	4	7	4
F	Maximum irregularity in rise or fall[1]	3·0	1·0	1·0	1·0	1·0
G	Maximum difference between successive readings	2·0	2·0	2·0	2·0	1·0
H	Minimum rise required	5·0	2·0	2·0	1·0	0·5

[1]The units for columns F to H are the number of transmission lines on the chart record.

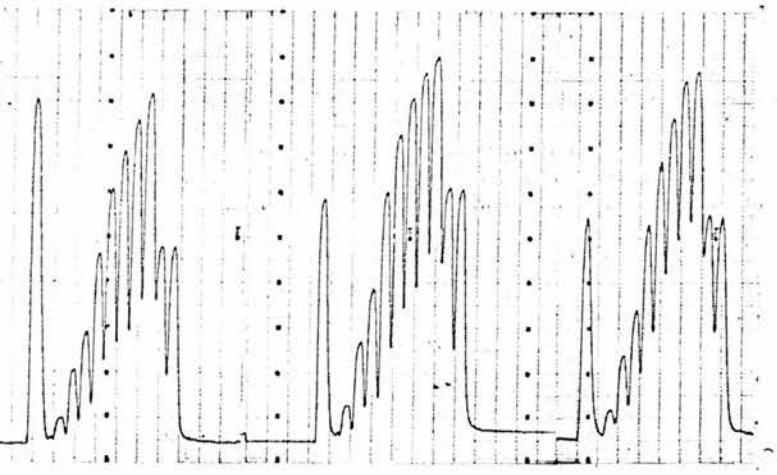


FIG. 4. *Examples of calibration curves for urea analyses. Left: curve close to lower limit of acceptable height. Middle: high curve accepted after operator's instruction. Right: curve with one faulty standard accepted after operator's instruction.*

(2) The heights of individual calibration standards must fall within specified limits. (3) Gradients between adjacent pairs of standards forming part of the overall curve must fall within specified limits; these gradients express the relationship between change in signal generated as a result of analysing pairs of standards and the difference in concentration between the corresponding pairs of standards (shown in the left-hand inset to Fig. 3 as $\Delta T/\Delta C$). (4) Changes in gradients between successive segments of the calibration curve must not exceed specified limits (shown in the right-hand inset to Fig. 3). (5) Overall recognition of the appropriate number of peaks, occurring in the prescribed sequence. (With multichannel analyses, calibrating standards for each analysis cannot always be analysed in progressively rising order of concentration.)

Data describing the characteristics of each calibration curve were defined initially from study of at least 20 curves for each channel, obtained with standard AutoAnalyzers during analytical runs on different days; some of these data were modified on the basis of experience gained later during on-line monitoring of the AutoAnalyzers with the Elliott 903 computer.

As Fig. 3 indicates, the individual calibrating standards can be accepted within wide limits as long as they satisfy the peak recognition program, but the gradient between successive pairs of peaks must fall within defined limits, and flat calibration curves have been rejected because these minimum differences between standards have not been exceeded; similarly, excessively steep calibration curves have been rejected by this criterion. If the gradient observed between one pair of peaks differs from the mean of the stipulated values, the extent to which the gradient on the succeeding segment of the calibration curve can be accepted is narrowed, a set of criteria for acceptable changes in gradients between adjacent segments having also been defined. These points about gradients are shown diagrammatically in Fig. 3, and a selection of calibrating curves illustrating some of these points is shown in Figure 4.

The program allows for the use of a faulty calibration curve in which either the top or the bottom standard is rejected, or else one of the intermediate standards is faulty (Fig. 4). However, before the curve can be used for calculation purposes, an error message appears on the on-line Teletype; after inspection of the recorder trace, the computer can be instructed to use the imperfect calibration curve, but this decision may carry disadvantages. If an end standard has been lost and the computer is instructed to use the curve, it thereafter calculates on the basis of a reduced set of standards; this will have the effect that more results for specimens are unable to be calculated if their concentrations fall outside the shortened calibrating curve. With loss of an intermediate standard (Fig. 4), the computer applies linear interpolation over a wider interval, with possible loss of accuracy over the affected part of the curve.

Immediately following acceptance of a calibration curve, a message to this effect appears on the on-line Teletype. If the computer fails to find the calibration curve by the expected time, however, it continues to search for the pattern of standards that together make up the calibration curve, and it cannot be used to monitor the analysis of samples from patients until the curve has been found. Since the operator is informed immediately the calibration curve has

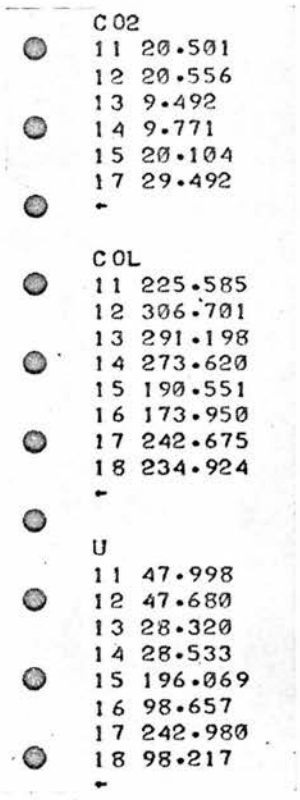


FIG. 5. *Results for batches of bicarbonate, cholesterol and urea results printed up off line by Teletype. Computed results processed in batches of 10, with results only printed out for the first eight positions*, ie, *those allocated to patients' specimens or control samples (specimens 16 and 18 on bicarbonate channel had been rejected).*

been accepted, there is normally no delay at this stage in starting the analysis of patients' specimens, assuming the curve was satisfactory.

CORRECTION FOR DRIFT AND CALCULATION OF CONCENTRATIONS Following acceptance of a calibration curve, the computer continues to search for and validate peaks and the analysis of samples from patients proceeds, except that positions 10 and 20, and every 10th position thereafter, contain a drift correction standard. At the completion of each batch of 10 analyses, assuming that the drift standard was satisfactory, the computer program applies a linear correction for any drift that has occurred to each acceptable intervening peak. This correction is applied to the highest single reading (excluding flairs) observed on each peak, and the program thereafter uses the corrected values for calculation purposes, interpolating these in relation to the appropriate pairs of standards on the calibration curve.

In due course, calculated concentrations are to be held on the magnetic tape backing store but, at the present stage of assessment, results are punched out in batches by the paper-tape punch and printed up off line on the Teletype (Fig. 5). The acceptability of the drift standard in each 10th position is assessed against the peak height of the corresponding standard in the calibration curve, and error messages are printed out if drift has exceeded specified limits either upwards or downwards. Under these circumstances, a decision has to be taken by the operator whether to continue analyses on that channel; while awaiting the instruction, the computer continues to search for the peaks that follow the faulty drift standard. Assuming that a decision to continue analyses is taken, the reading for the faulty drift is cancelled and concentrations are then calculated over a double interval, with application of a linear correction for drift to the previous 20 peaks after the peak corresponding to the succeeding drift standard has been recognized and accepted. It is possible to continue monitoring peaks after failing to detect two successive drift standards by typing in the appropriate instruction, but this is regarded as an unlikely requirement, quite apart from the doubtful validity of such an instruction on analytical grounds.

Immediately preceding the drift standards (in cup positions 19, 29, 39, etc), samples from a pool of quality control serum can now be placed. The program does not provide for the concentrations observed with this pool to be printed out unless a value is observed which differs by more than a specified amount from the figures stored in the computer. When the acceptable limits are exceeded, the latest set of observations together with the two preceding sets of values are to be printed out on the on-line Teletype. This feature of the program has not yet been fully tested, and the printout (Fig. 5) corresponds to an analytical run in which positions 19, 29, etc, were occupied by drift correction standards identical in composition with those occupying positions 20, 30, etc. It is important to standardize the conditions under which the drift correction standards in positions 20, 30, etc, are analysed, and this can either be achieved by placing another identical sample in the preceding cups, as was the practice adopted with the ALA system (Flynn, 1965), or by standardizing for a run the composition of the samples in positions 19, 29, etc, for instance by using a quality control pool of specified composition, and of composition sufficiently close to the drift correction standard for the latter not to be affected adversely by carryover.

ANALYSIS OF SPECIMENS: SUMMARY OF PROGRESS Peak recognition, calibration curve validation, and drift correction programs have been assessed for 20 analytical channels (listed in Table VII); these features have all been satisfactorily validated except

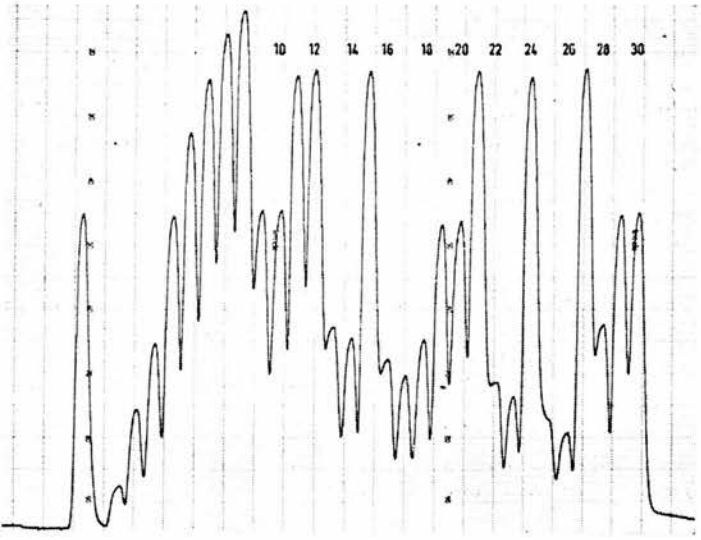


FIG. 6. *Recognition of interaction between specimens by the computer (urea analyses, 60/h; sample: wash ratio, 2:1). Positions 11, 12, 15, 21, 24, and 27 occupied by a pool of plasma having a high concentration of urea. Positions 13 and 14, 16 and 17, 22 and 23, 25 and 26 occupied by pairs of plasma samples having progressively lower concentrations of urea. Drift correction standards in positions 19 and 20, 29 and 30. Quality control samples in 18 and 28. Results for analyses (concentrations in mg/100 ml) are set out below.*

Peak number	11	12	13	14	15	16	17	18	19	20
Chart record result	201	206	57	52	208	46	42	53	99	100
Computer's result	201	207	55	51	210	Error	41	52	—	—
Peak number	21	22	23	24	25	26	27	28	29	30
Chart record result	211	—	36	204	—	25	211	59	100	100
Computer's result	215	Error	34	204	Error	24	210	56	—	—

with alanine aminotransferase; monitoring of this channel on line still gives rise to occasional difficulties. Up to 10 analytical channels have been monitored simultaneously, signals being transmitted to the data-acquisition unit through the four analyser consoles (for instance, console 1: sodium potassium, chloride, bicarbonate, and urea; console 2: total protein and albumin; console 3: calcium and phosphate; console 4: cholesterol), to test the multiplexing capability of the system. The efficiency of the computer in recognizing faults in the operation of AutoAnalyzers and the chemical acceptability of computer-calculated results have also been investigated.

ANALYSIS OF SPECIMENS: FAULT RECOGNITION Fault recognition programs relating to the acquisition of data on line from AutoAnalyzers have been assessed by testing their ability to reject faulty peaks, deliberately introduced (*eg*, Fig. 5); to reject unacceptable calibration curves; to detect faulty calibration curves which can nevertheless be used if the operator instructs the computer appropriately (*eg*, Fig. 4); and to detect unacceptable degrees of instrumental drift.

When a peak is rejected as faulty by the computer, it may fail to meet more than one of the specified criteria (Fig. 2 and Table V) but only one error message appears on the on-line Teletype. For instance, a peak affected by carryover from the previous sample (Fig. 6) could be rejected on the basis of insufficient rising readings (error 38), or the peak may appear early (error 35), or no peak may appear within the time window due to excessive carryover and a 'peak late' message may be printed out (error 36). This has prevented a detailed individual analysis of each fault recognition program, and the assessments have been restricted to determining the efficiency with which faults have been detected, without specifying in detail the nature of the fault on each occasion. In general, these programs have worked efficiently, and faults have been detected much more rapidly than by the human operator.

Occasionally the computer has failed to reject peaks that appear unduly sharp on the chart record, the usual causes for these sharp peaks being specimens insufficient for satisfactory analysis, or a temporary block on the sample line. It may be possible to reject these faulty peaks by narrowing the time window within which peaks can be accepted; Table V shows that the time windows have been set wide, so as to allow for considerable variation in the arrival of the top of a peak. An alternative method might be to include in each peak recognition program a specification for the number of readings required within, for instance, ± 3% of the peak reading, instead of basing peak recognition and

TABLE VI

RECOGNITION OF INSUFFICIENT SPECIMENS

Sample	Aspiration Time (seconds)	Urea (mg/100 ml)		Sodium (m-equiv/l)		Potassium (m-equiv/l)		Chloride (m-equiv/l)		Bicarbonate (m-equiv/l)	
		C[1]	T[2]	C	T	C	T	C	T	C	T
11	20	E[3]	R[4] (85)	E	R (115)	E	R (4·4)	E	R (70)	E	R (15)
12	40	114	112	142	142	5·4	5·4	93	94	18	19
13	25	93	R (92)	E	R (121)	E	R (4·6)	E	R (80)	E	R (17)
14	40	108	107	142	142	5·4	5·4	96	96	19	19
15 (QC)	40	50	48	139	138	4·6	4·6	104	104	11	13
16	30	100	100	E	127	E	4·8	87	89	E	17
17	40	111	108	143	141	5·4	5·3	97	97	19	19
18	35	103	102	136	135	5·1	R[5](5·1)	94	95	18	19
19 (Drift)	40	—	98	—	139	—	3·9	—	102	—	20
20 (Drift)	40	—	100	—	140	—	4·0	—	104	—	20
21	20	E	R (81)	E	R (110)	E	R (4·3)	E	R (71)	E	R (15)
22	40	109	107	142	142	5·5	5·4	95	95	19	19
23	25	92	R (91)	E	R (120)	E	R (4·6)	E	R (79)	E	R (17)
24	40	110	108	143	143	5·4	5·5	95	96	18	19
25	30	102	102	126	129	E	R[5](5·0)	87	89	17	18
26	40	112	111	143	143	5·5	5·5	98	98	19	19
27	35	113	113	138	138	5·3	R[5](5·3)	98	98	18	19
28 (QC)	40	52	52	138	139	4·6	4·7	103	103	11	13
29 (Drift)	40	—	100	—	139	—	3·8	—	104	—	20
30 (Drift)	40	—	100	—	140	—	4·0	—	104	—	20

Concentrations for the rejected peaks calculated by a technician are shown in brackets. Except where noted (drift and QC = quality control) all samples were from the same pool of plasma. Rate of analysis is 60/hour; normally sample: wash ratio, 2 : 1

[1]C = Computer

[2]T = Technician

[3]E = error message

[4]R = peak rejected by technician

[5]Rejected by technician because of irregularity on top of peaks

acceptance mainly on the minimum numbers of rising and falling readings and on an acceptable arrival time. These shortcomings of the present program should not be overstressed, however, as Fig. 7 shows the chart record for the urea channel in an experiment where some of the specimens being analysed for their content of urea, sodium, potassium chloride, and bicarbonate had their sampling time deliberately shortened, and Table VI compares the ability of the computer and of a technician who

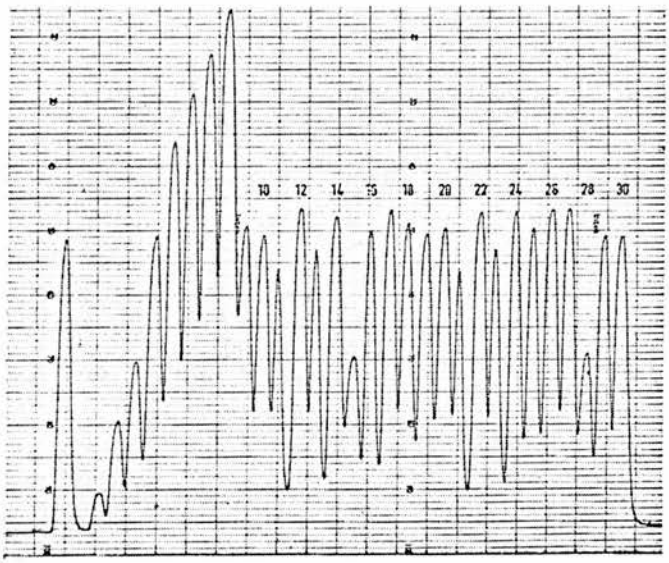
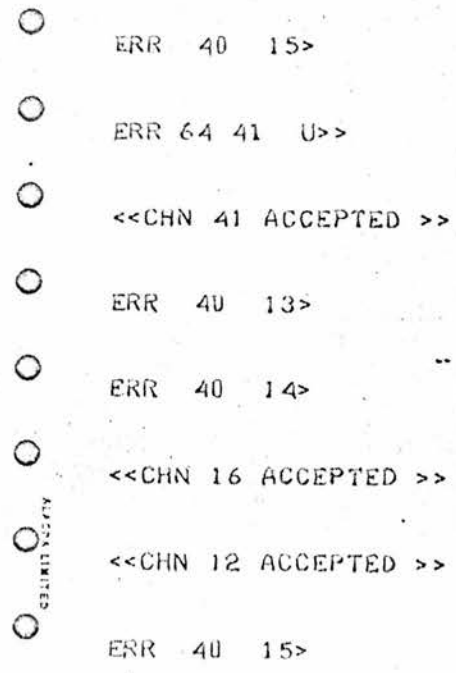


FIG. 7. *Recognition of samples that are insufficient for proper analysis. Urea analyses (60/hr; sample: wash ratio, 2:1). Specimens in some positions have been analysed for periods shorter than 40 seconds. Comparisons between concentrations calculated by computer and by a technician unaware of which peaks were faulty are given in Table VI.*



IG. 8. *Messages appearing on the Teletype in an xperiment where the computer was on line to channels 12 urea), 16 (bicarbonate), and 41 (cholesterol); channels 13, 4, and 15 were not in operation, but the computer was rogrammed to receive signals from these channels. The rror messages represent long waits for the arrival of peaks error 40), each followed by a channel identification umber. Error 64 reported a fault on the calibration curve or which the operator typed in a 'use' instruction, and the omputer immediately printed out a message to say that hannel 41 was accepted. Channels 12 and 16 had their alibration curves accepted without difficulty.*

orks in another laboratory to detect unsatisfactory eaks; the computer has been no less successful than ne technician, but the computer would not tire over ne examination of peaks by rigid criteria in a onger run.

Examples of calibration curve acceptance messages nd error messages appearing on the on-line eletype are given in Figure 8. When faults occur, addition to an error message appearing on the n-line Teletype, a red light glows on the analyser onsole on the laboratory bench, and another on the ont panel of the data-acquisition unit. These lights ay on for one minute, unless another fault appears relation to the succeeding peak. For some faults o action is required by the operator. However, if e error message requires a decision but no instruc-on is given, the message is typed out again five minutes later and again after 10 and finally after 11 minutes if still no instruction has been typed in; thereafter, if no action is taken, the computer stops monitoring the channel. Examples of faults where the error messages demand an answer include faults detected on the calibration curves and on the drift correction standards. Some of the faults on calibration curves cannot be overcome by an instruction from the operator, and the relevant analytical channel must be closed down or restarted; both the close-down and restart routines have been tested and can be carried out satisfactorily. The computer also automatically ceases to monitor a channel if four faulty peaks occur in succession.

ANALYSIS OF SPECIMENS: CHEMICAL ACCEPTABILITY Assessment of acceptibility on analytical grounds has included paired comparisons between the results of analyses of patients' specimens and quality control samples, the analyses being carried out first with AutoAnalyzers operating under routine laboratory conditions and then repeated on a second AutoAnalyzer system where the signals from the photocells were being monitored by the computer. For these paired analyses, agreement (Table VII) between the two sets of analytical runs has been at least as good as for between-batch comparisons on the routine analytical methods.

The results calculated and printed out from the computer have also been compared with the results obtained by the standard methods of processing data from AutoAnalyzers, involving the reading off of peaks from the chart records and calculation of concentrations for specimens; in this set of comparisons, both groups of results derived from the same analytical run. The importance of this latter set of comparisons lies in the fact that the chart records will provide the back-up system when the laboratory is using the computer routinely, since the chart records allow these processes of calculation and reporting to be performed, if necessary, independently of the computer itself. Closer agreement has been obtained in this set of analytical comparisons (Table VIII), which are not subject to between-batch errors, but the computer has been very much quicker at applying the appropriate drift corrections and punching out the results of each batch of analyses for printing up the results on the off-line Teletype (Fig. 5) than the technicians responsible for reading and processing the data from the chart records.

ANALYSIS OF SPECIMENS: OUTPUT OF RESULTS The output of calculated results at first appeared on the keyboard of the on-line Teletype, but latterly the amount of information from the computer appearing

TABLE VII

PAIRED COMPARISONS OF ANALYTICAL PERFORMANCE[1]

Analysis	*Method*[2]	*Number of Paired Observations (n)*	*Standard Deviation* $\sqrt{\frac{(\Sigma\ difference^2)}{n}}$	*Range of Concentrations over which Paired Comparisons Made*
Plasma or Serum				
Urea	A	553	3·31 mg/100 ml	10-300
Sodium	N21B II	604	1·38 m-equiv/l	114-156
Potassium	N21B II	594	0·15 m-equiv/l	2·4-7·7
Chloride	N21B II	302	2·20 m-equiv/l	84-115
Bicarbonate	N8B	601	2·78 m-equiv/l	10-36
Alkaline phosphatase	B	54	0·28 King-Armstrong units/100 ml	5-30
Bilirubin	N12	56	0·07 mg/100 ml	0·2-8·0
Alanine aminotransferase	N44	—	No results	—
Calcium	C	80	0·18 mg/100 ml	8·0-12·0
Phosphate	D	145	0·25 mg/100 ml	1·9-11·4
Total protein	N14B	124	0·11 g/100 ml	1·8-9·3
Total protein blank	N14B	71	0·03 g/100 ml	0·1-1·1
Albumin	E	124	0·10 g/100 ml	1·3-5·2
Creatinine	N11B	104	0·16 mg/100 ml	0·5-9·4
Cholesterol	N24a	113	6·6 mg/100 ml	119-365
Uric acid	F	111	0·38 mg/100 ml	2·6-13·9
Iron	G	107	6·2 µg/100 ml	22-455
Iron-binding capacity	G	111	14·4 µg/100 ml	165-645
Urine				
Creatinine	N11B	76	1·9 mg/100 ml	29-198
Phosphate	D	102	1·8 mg/100 ml	3-59

[1]Standard deviations between pairs of analyses performed on specimens obtained from patients. Analyses were first carried out by the department's routine methods, in response to requests received by the laboratory. Analyses were repeated the next day, using AutoAnalyzers on line to the Elliott 903 computer and the computer-calculated results were compared with the previous day's results. The overnight delay before repetition of analyses partly accounts for the discrepancies between pairs of bicarbonate analyses.

[2]Where the method used does not differ from the Technicon N-method description, the code number is given in full. References for the others as follows:—

A Marsh, W. H., Fingerhut, B., and Miller, H. (1965). *Clin. Chem.*, **11**, 624-627.
B Sterling, R. E., Wilcox, A. A., Ware, A. G., and Umehara, M. K. (1964). *Ibid.*, **10**, 1112-1116.
C Gitelman, H. J. (1967). *Analyt. Biochem.*, 18, 521-531.
D Young, D. S. (1966). *J. clin. Path.*, 19, 397-399.
E Northam, B. E., and Widdowson, G. M. (1967). *Ass. clin. Biochem.*, Tech. Bull. No. 11.
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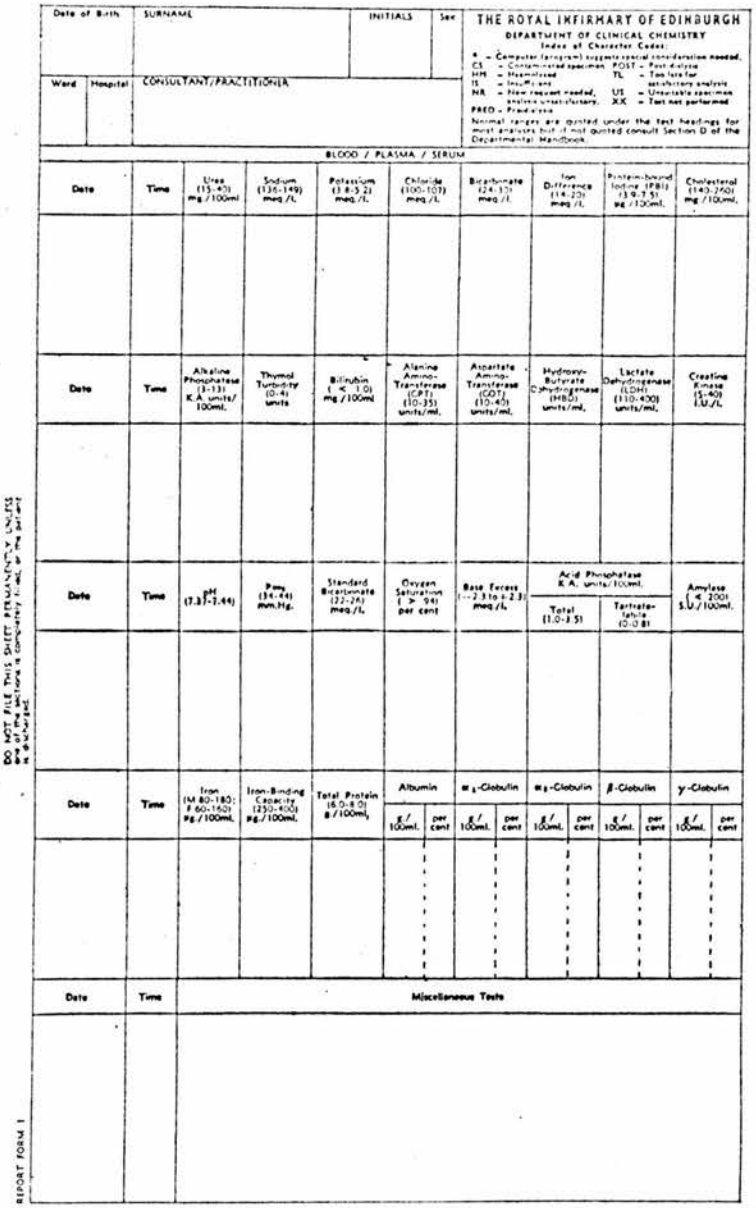
G Young, D. S., and Hicks, J. M. (1965). *J. clin. Path.*, 18, 98-102.

TABLE VIII

EXAMPLES OF PAIRED COMPARISONS OF METHODS OF CALCULATING RESULTS[1]

Analyses	*Number of Paired Observations (n)*	*Standard Deviation* $\sqrt{\frac{(\Sigma\ difference^2)}{n}}$	*Range of Concentrations over which Paired Comparisons Made*
Urea	584	2·26 mg/100 ml	10-300 mg/100 ml
Sodium	600	0·66 m-equiv/l	114-156 m-equiv/l
Potassium	589	0·05 m-equiv/l	2·4-7·7 m-equiv/l
Chloride	298	0·74 m-equiv/l	84-115 m-equiv/l
Bicarbonate	572	0·53 m-equiv/l	10-36 m-equiv/l
Creatinine	55	0·06 mg/100 ml	0·5- 8·6 mg/100 ml
Calcium	167	0·16 mg/100 ml	3·9-13·3 mg/100 ml
Phosphate	87	0·11 mg/100 ml	2·1-10·8 mg/100 ml
Iron	40	2·03 µg/100 ml	51-312 µg/100 ml

[1]Standard deviations between paired calculations of results for single analyses when the Elliott analyser console was being used to transmit signals to the Elliott 903 computer. The comparisons are between (1) results calculated from the chart records by standard methods of calculation, and (2) results printed out after the computer had performed its calculations. The close agreement shows that the chart records can be used for back-up purposes.



Date of Birth	SURNAME	INITIALS	Sex	THE ROYAL INFIRMARY OF EDINBURGH DEPARTMENT OF CLINICAL CHEMISTRY Index of Character Codes: * – Computer (program) suggests special consideration needed. CS – Contaminated specimen POST – Post-dialysis HM – Haemolysed TL – Too late for satisfactory analysis IS – Insufficient NR – New request needed, analysis unsatisfactory. US – Unsuitable specimen XX – Test not performed PRED – Pre-dialysis Normal ranges are quoted under the test headings for most analyses but if not quoted consult Section D of the Departmental Handbook.
Ward	Hospital	CONSULTANT/PRACTITIONER		

BLOOD / PLASMA / SERUM

Date	Time	Urea (15-40) mg/100ml	Sodium (136-149) meq/l.	Potassium (3.8-5.2) meq/l.	Chloride (100-107) meq/l.	Bicarbonate (24-30) meq/l.	Ion Difference (14-20) meq/l.	Protein-bound Iodine (PBI) (3.9-7.5) µg/100ml.	Cholesterol (140-260) mg/100ml.

Date	Time	Alkaline Phosphatase (3-13) K.A. units/100ml.	Thymol Turbidity (0-4) units	Bilirubin (< 1.0) mg/100ml	Alanine Amino-Transferase (GPT) (10-35) units/ml.	Aspartate Amino-Transferase (GOT) (10-40) units/ml.	Hydroxy-Butyrate Dehydrogenase (HBD) units/ml.	Lactate Dehydrogenase (LDH) (110-400) units/ml.	Creatine Kinase (5-40) I.U./l.

Date	Time	pH (7.37-7.44)	P_{CO_2} (34-44) mm.Hg.	Standard Bicarbonate (22-26) meq/l.	Oxygen Saturation (> 94) per cent	Base Excess (−2.3 to +2.3) meq/l.	Acid Phosphatase K.A. units/100ml. Total (1.0-3.5)	Acid Phosphatase K.A. units/100ml. Tartrate-labile (0-0.8)	Amylase (< 200) S.U./100ml.

Date	Time	Iron (M 80-180; F 60-160) µg/100ml.	Iron-Binding Capacity (250-400) µg/100ml.	Total Protein (6.0-8.0) g/100ml.	Albumin g/100ml.	Albumin per cent	α_1-Globulin g/100ml.	α_1-Globulin per cent	α_2-Globulin g/100ml.	α_2-Globulin per cent	β-Globulin g/100ml.	β-Globulin per cent	γ-Globulin g/100ml.	γ-Globulin per cent

Date	Time	Miscellaneous Tests

DO NOT FILE THIS SHEET PERMANENTLY UNLESS one of the sections is completely filled, or the patient is discharged.

REPORT FORM 1

FIG. 9. *Preprinted continuous stationery showing layout adopted for cumulative reports. Output programs for these reports have not yet been tested. This format is for analyses on blood.*

on this keyboard has been greatly reduced following the writing of the on-line monitoring and calculation programs on to magnetic tape; output of computed data at present occurs via the paper-tape punch (Fig. 5). These results are printed up to more decimal places than will appear on the final reports, and individual sets of results have still to be identified by their positions on the AutoAnalyzer sampler turntables. At a later stage, the output of results is planned to appear as cumulative records on preprinted stationery (Figs 9 and 10), printed up either on line (IBM output writer) or off line after initial output on paper tape; investigation of this aspect of the overall programme of work has to wait until after the programs for laboratory accession procedures and the organization of records on file have been evaluated fully.

Results for analyses of serum total protein and

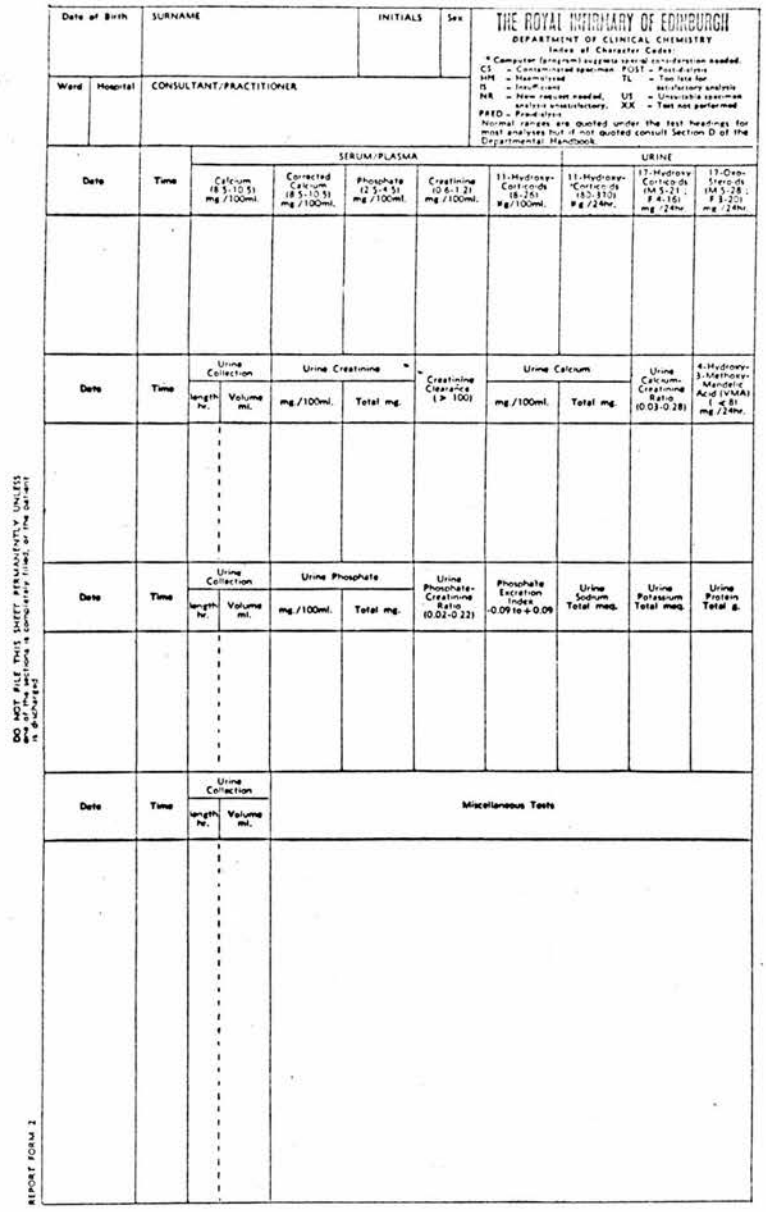


FIG. 10. *Preprinted continuous stationery showing layout adopted for cumulative reports. This format is mainly for analyses on urine.*

their corresponding blank determinations are at present calculated separately and printed up separately; the program which allows for the automatic subtraction of blanks by interrelating the results of these two separate analytical runs has not yet been tested.

LABORATORY ACCESSION PROCEDURES

INPUT OF DATA TO THE COMPUTER FROM REQUEST FORMS

Information carried on request forms is at present entered via the keyboard of the on-line Teletype, and the computer applies several checks to the accuracy of these operations. Thereafter, when instructed to do so, the computer sorts this information into work sheets and issues these via the tape punch for printing up off line. Figures 11 and 12 show the pattern of keyboard entries and the appearance of a computer-prepared work sheet. Steps in the present program for preparing work sheets are summarized in the succeeding paragraphs.

Date of birth registration numbers (six figures and first letter of surname) for up to 24 patients are entered;

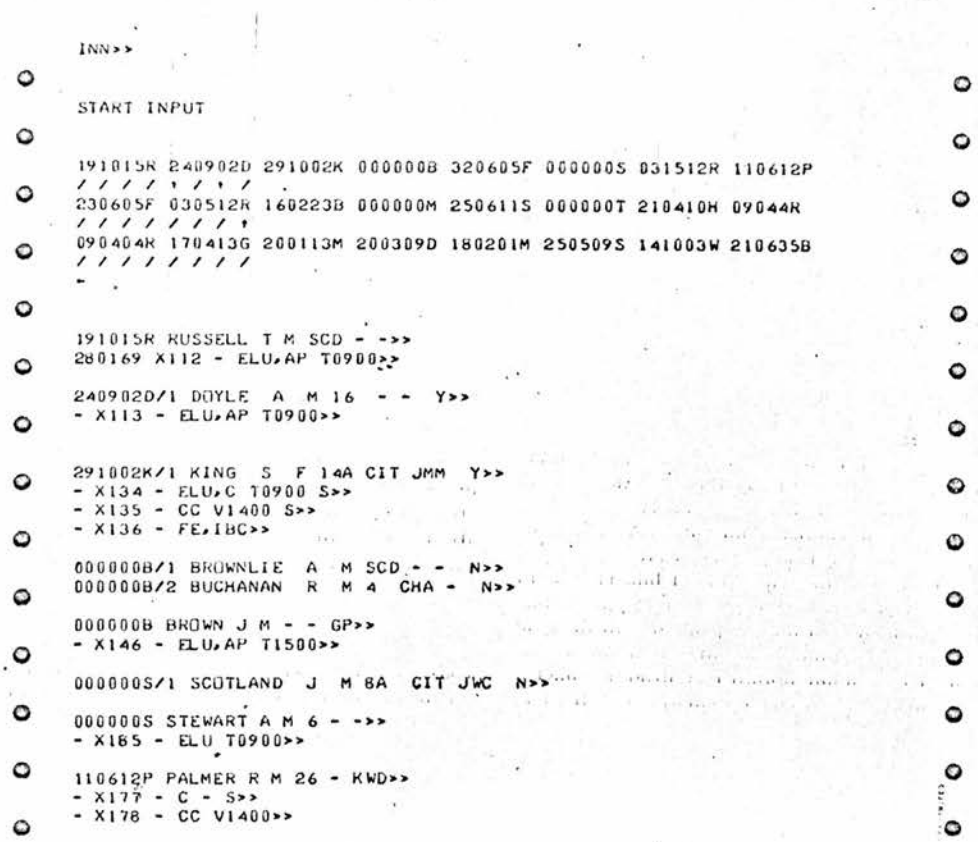


FIG. 11. *Entry of information from request forms. A series of registration numbers consisting of the date of birth and first letter of surname (the Royal Infirmary uses the date of birth for identification purposes; it does not issue a unique identifying number for each patient). These numbers are examined a line at a time (eight numbers each) and acceptable numbers are indicated by a | mark; rejected numbers (two examples in first line) are entered again at the start of the second line. At the end of the entry (24 numbers maximum), the computer prints these numbers back one at a time together with full identification of any patient on file who has the number under consideration. If the identifying data match up, the operator types in Y followed by the information relating to the specimen (second and third patients in this list). If the patient is not on file (fourth patient), the operator types in N and the number is printed back again. For patients new to the computer's records, full identification data and test request information are key punched. The computer also applies checks to test request codes (Table IX) and queries any unacceptable codings. S indicates a further specimen for the same patient.*

each line on the Teletype carriage accommodates eight of these numbers. On completion of a line of input, the computer rapidly checks the acceptability of these numbers, as dates of birth, before the typist proceeds to enter the next line, acceptance of a number being indicated by a slash mark (Fig. 11). If the date of birth is not known, a series of six zeros and the initial of the surname is entered as the 'registration number'.

When up to 24 registration numbers have been entered, the computer searches its records and prints these numbers back one at a time on the keyboard of the on-line Teletype. If there is already a patient on file corresponding to a particular registration number, the complete identification of that patient is printed back and the keyboard operator signifies whether the patient's data entered on the request form correspond with the information retrieved from the magnetic tape file; an opportunity exists at this stage for modifying individual items, *eg*, change of ward. Since the registration number is not unique, if the details for the patient retrieved by the

TABLE IX

EXAMPLES OF TEST REQUEST CODES

Analysis on Plasma or Serum	*Code*	*Analysis on Urine*	*Code*
Acid phosphatase (total and tartrate-labile)	AP	5-hydroxy-indole acetic acid	HAA
Creatinine	C	Creatinine concentration[3]	CC
Cholesterol	COL	Calcium concentration[4]	CAC
Electrolytes[1] and urea	ELU	11-hydroxycorticosteroids	OHS
Iron	FE	17-hydroxycorticosteroids	HYD
Iron-binding capacity	IBC	Uric acid	UUA
Potassium	K	*Analysis on faeces*	
Liver function tests[2]	LFT	Calcium	SCA
Urea	U	Fat	FAT
Uric acid	UA	Potassium	SK

[1]Electrolytes = sodium, potassium, chloride, and bicarbonate
[2]Liver function tests = bilirubin, alkaline phosphatase, alanine aminotransferase, and thymol turbidity
[3]Clearance to be calculated automatically if the entries C and CC made for same patient and 24-hour volume of urine sample supplied, *eg.* third patient in Figure 11
[4]Twenty-four-hour output calculated if 24-hour volume entered

computer do not match with the information on the request form, the operator instructs the computer accordingly and the computer then prints out the registration number again on a new line. If there are already two or more patients on file with this registration number, their full identifying data are printed out one set at a time for comparison with the request form. If the patient is a new patient, after the computer has completed its search of past records for that particular registration number, the operator keys in the full identifying data following the printing back by the computer solely of the registration number.

After the patient has been identified as one previously on file, or the full identifying data have been entered, the date of the request and the details relating to the specimen (laboratory identification number followed by the investigations that have been requested) are entered, using codes for the tests (examples shown in Table IX); other relevant details, such as the length of collection of a sample of urine or an indication that the request is urgent, complete the entry. The computer then checks the entry for acceptability, and prints back queries in respect of illegal or incomplete entries; mispunchings of test codings, for instance, can be corrected.

These steps finish the entry of data for one request form, and the computer signifies that it has accepted each complete entry by automatically printing back the next registration number in the batch currently being processed. In this way, the data on a batch of request forms are progressively entered, it being important to keep the request forms in their correct order so as to expedite the process. It is essential to work systematically as otherwise test codes for one patient may be entered in relation to identifying data corresponding to another.

OUTPUT OF WORK SHEETS When data for one batch consisting of up to 24 request forms have been entered, further batches can be entered or the computer can be instructed, on completion of a batch of entries, to sort the information on tests that have been requested and prepare specified work sheets; these are then punched out for printing up off line on the Teletype (Fig. 12). Each work sheet specifies the order of analysis for 20 specimens, the first work sheet listing the standards to be analysed before

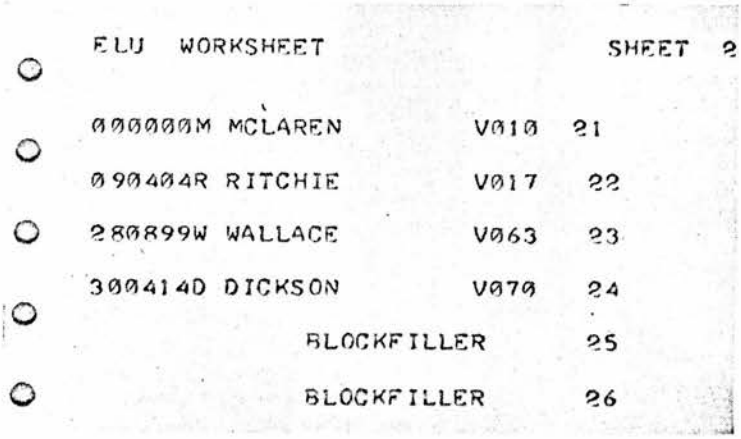


FIG. 12. *Part of a computer-prepared work sheet for plasma electrolyte (sodium, potassium, chloride, and bicarbonate) and urea analyses. The work sheet is issued on punched tape and printed up on the off-line Teletype.*

```
141219M/1 MURRAY R   M 21   - JSR  Y>>
- C012 - ELU,LFT T0700>>

080621D DAVIDSON S F 21 - JSR>>
- C013 - ELU,LFT T0700>>

ERR  36  21>

ERR  36  23>

ERR 69 21  N>

ERR 69 23  U>>

150336H HISLOP C F 17 - ->>
151268 J024 - ELU,LFT>>
```

FIG. 13. *Part of the printout appearing on the on-line Teletype when information was being entered from request forms at the same time as the computer was on line to protein (channel 21) and protein blank (channel 23) analyses. Immediately after a block of input (eight requests) had been completed a series of error messages appeared that had been held up by the input procedures.*

proceeding to print out the identifications for patients' specimens. If there are insufficient specimens to complete a work sheet, the computer has been instructed to designate the vacant spaces as 'blockfillers'.

EXPERIENCE WITH LABORATORY ACCESSION PROCEDURES

The present system of entry of information from request forms suffers from the major drawback that no part of the data can be read into the computer until after a key-punching operation. This drawback, which is primarily a criticism of the request forms rather than of the method of entering information into the computer, will be considered in the discussion.

The entry of requests and the calling down of work sheets has been tested both with the computer performing no other functions, and with the computer simultaneously monitoring AutoAnalyzers, so as to simulate the conditions that obtain at the start of the day and later on. The ability to correct mispunchings, and the amendment of identifying information for patients already on file have also been tested.

The preparation of work sheets has not yet been fully evaluated as work has been temporarily held up by a fault that has been detected in the magnetic tape controller; this has been preventing the reading of the status of the controller during a back-space operation. It is, however, possible to comment on certain aspects relating to the input of data from request forms and the preparation of work sheets on the basis of experience gained so far.

The computer can successfully detect the entry of impossible dates of birth and of illegal test request codes, and the correction of these errors has been achieved satisfactorily. Some errors, *eg*, misspellings of names, entry of the wrong ward, or of a code corresponding to another test in place of the one requested, cannot be detected by the computer; if the operator sees these mistakes, the entry can be amended or else cancelled and re-entered. Obviously difficulties can arise if incorrect but computer-acceptable entries are made and the error is not detected until later; these errors can be made good, but the extent of the correction required will depend on whether or not work sheets have already been prepared that include the incorrectly entered request, and the various correction procedures have not all been tested yet.

The sorting of details from request forms and the preparation of work sheets has also begun to be evaluated, but the fault on the tape controller means that work sheets cannot be obtained when the on-line adapter on the data-acquisition unit is switched on, and even at other times the recall of work sheets has not been uniformly successful. The preliminary experiments have already shown, however, that unacceptable delays can occur in the output via the on-line Teletype of messages relating to the operation of AutoAnalyzers, when the entry of information from request forms is also taking place. Figure 13 shows that a series of error messages was held up until the entry of a block of information about requests had been completed, and these hold ups have resulted in the computer automatically ceasing to monitor some channels when it has failed to receive the necessary instruction relating to certain categories of error message sufficiently quickly. Similar delays in the output of error messages may be anticipated when the computer is organizing requests for the output of work sheets, but this possibility cannot be tested until the preparation of work sheets can take place at the same time as the monitoring of the AutoAnalyzers.

DISCUSSION

The computer system described in this paper has been used successfully for on-line acquisition of data from up to 10 channels of AutoAnalyzer equipment at one time. Programs for peak recognition, calibration curve validation, and drift correction have

been evaluated, and the acceptability on analytical grounds of the computer-calculated results established for 19 different chemical analyses performed on AutoAnalyzers. Since acquisition of signals from AutoAnalyzers for transmission to the computer involves modification to the colorimeter settings for some of the analytical channels, the demonstration that these modifications did not adversely affect the reliability of the chemical analyses (Table VII), and that the chart records could still be used for back-up purposes (Table VIII) was important.

On those days when the programme of development work allows it, the computer-calculated results are now used for reporting purposes, but this involves transcription from the Teletype printout on to report forms, and the computer will not become a regular component of the laboratory's operation until the other aspects of the overall system have been fully evaluated, particularly the programs for work sheet preparation and for records storage with output of cumulative reports. The reliability of the AutoAnalyzer-monitoring part of the system has begun to be tested under daily working conditions, and a big advantage of on-line real-time acquisition of data from AutoAnalyzers has already been clearly demonstrated, namely, the rapid printout by the computer of fault-recognition messages. The checks on analytical performance are applied rapidly and systematically by the computer, and the weak link in the process-control loop is now clearly seen to be the AutoAnalyzer operator; the correction of instrumental malfunction by human intervention is very slow in comparison with the speed of fault recognition by the computer. Ideally, the loop will eventually be closed by servocontrol mechanisms operating appropriately in response to fault-recognition procedures carried out by the computer.

It would be premature to comment upon the reliability of different components of the computer system on the basis of experience gained so far. There has been a substantial amount of down time, particularly on the data-acquisition unit and the magnetic tape unit, but some down time has to be accepted with a system involving development. At a later stage, under routine working conditions, temporary faults can be anticipated and arrangements have been made to minimize the effects of some of these by the purchase of a spare Teletype, tape reader, and tape punch. Until the output programs have been tested, no decision has been taken about the purchase of additional output printing equipment; it is forecast, however, that the present equipment will prove insufficiently rapid for the task of preparing cumulative reports. Only experience will show whether a second IBM output writer (interfaced to the computer for on-line printing), or a battery of Teletypes (for off-line printing) or a line-printer can best overcome any deficiencies in the speed of output, particularly as encountered at peak periods of reporting.

Experience already gained with the on-line conversational method of entering information from request forms shows that there could be unacceptable delays in the printing out of messages detailing the nature of faults occurring with the operation of AutoAnalyzers, particularly when the number of request forms to be handled is increased from the present pilot scale up to about 500 each day. This congestion on the on-line Teletype provides one important reason for rewriting the input programs so as to allow the preparation of information on request forms for entry to the computer as an off-line operation, but another advantage that could derive from this would be the possibility of introducing machine-readable request forms. The request forms currently in use (Whitby *et al*, 1968) provide a simple back-up system for reporting purposes, but they have serious disadvantages as source documents for the computer as their use involves so much accurate transcription. It is, for instance, impossible for the computer to match up a new request with previous work done for the same patient if the date of birth is incorrectly entered on the form, or is omitted, or is key punched wrongly and the error not detected. Much of this repetitive key punching in the laboratory would be eliminated, and the problem of correct and consistent identification of patients greatly reduced, if the records department were to provide each case-record folder at the time of registration with a set of machine-readable laboratory request forms bearing full personal identification data. These forms could, for instance, be 80-column punched cards (Whitehead, 1965, 1968) or edge punched cards, which would be more appropriate for the Elliott 903 computer system; on receipt of such a request form with its specimen, the key punching in the laboratory would be restricted to entering the variable data detailing the nature of the request, and even this could be further reduced if suitable mark-sensing procedures could be introduced for doctors to detail at source the tests requested in a machine-readable way.

This report is necessarily incomplete because it describes the progress achieved so far in the introduction of a small computer into a large clinical chemistry laboratory. The programme of development work could stop now and the system be used for routine monitoring and calculation of results from several AutoAnalyzer channels; this would in itself achieve a major reduction in the repetitive chart-reading and calculation procedures carried out by technicians. However, to stop the programme

of work at this stage would leave untouched the problem of matching up results with their report forms, and would mean the acceptance of transcription of results from the Teletype printout which deals with only one analytical channel at a time; the preparation of reports and records of laboratory work would remain largely a manual process. At present, therefore, many additional advantages that may be derived from this computer system still remain to be explored, such as the preparation of printed reports matching the analytical findings with the appropriate patient, and the preparation of cumulative summary reports for patients undergoing repeated investigation. Specifications have been drawn up so that the computer printout will automatically attach an asterisk to results that fall outside prescribed limits, or to draw attention to significant changes occurring in serially performed determinations. At a later stage, when the computer files hold sufficient data, detailed assessments of the different patterns of use made of the laboratory should be much more practicable than the present limited manually performed reviews.

SUMMARY

An Elliott 903 computer system has been used for six months for the on-line real time acquisition of data from AutoAnalyzers operating in parallel with the equipment used to perform the hospital's routine chemical investigations. Signals are led from the colorimeter or flame photometer to an analyser console, sited on the laboratory bench, and are here amplified for transmission to the data-acquisition unit for input to the computer. Programs for peak recognition, calibration curve validation, drift correction, and calculation routines have been tested for 19 chemical analyses. Fault recognition programs have also been investigated.

The results computed for analyses performed on specimens from patients showed close agreement with the corresponding results obtained from a second analytical run in which the specimens were analysed by AutoAnalyzers that were not on line to the computer, the chart records being processed by standard methods for the calculation of results.

With several methods, it is necessary to adjust the settings on the AutoAnalyzer colorimeter so that signals will fall within the range required for amplification and transmission to the computer. Part of the amplified signals are also attenuated for transmission to the AutoAnalyzer recorder amplifier, and it has been shown that the chart records can be used for back-up purposes.

The multiplexing capability of the data-acquisition unit has been tested. Ten AutoAnalyzer channels have been monitored simultaneously on line, the signals being transmitted to the data-acquisition unit from four analyser consoles, each of which has the capacity to accept signals from up to eight channels.

The output of calculated results from the computer is at present on punched paper tape for printing up off line. Results are identified by sample cup position, and are issued separately for each analytical channel. These computer-calculated results have begun to be used for reporting purposes, but at present require transcription on to standard laboratory report forms.

Information carried on request forms is entered via the on-line Teletype in a conversational mode. Evaluation of this process and of the programs for sorting this information into work sheets has begun, and experience so far indicates that the preparation of the input should be reprogrammed as an off-line operation, preferably combining this with the use of machine-readable request forms.

It is a pleasure to acknowledge the contribution of many members of the staff of Elliott Automation Ltd, and particularly the close involvement and interest of Mr G. E. Sims and Mr A. T. Gough. The project has been generously supported by a grant from the South-Eastern Regional Hospital Board, Scotland, and has been carried out under the auspices of the National Research Development Corporation. Many of the departmental staff have helped greatly with this work, and our thanks are due particularly to Dr D. W. Moss, Mr J. Proffitt, Miss A. Nicoll, and Mr R. S. McMaster.

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Equipment for linking the AutoAnalyzer on-line to a computer

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Equipment for linking the AutoAnalyzer on-line to a computer

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SYNOPSIS An Elliott 903 computer with 8K central core store and magnetic tape backing store has been operated for approximately 20 months in a clinical chemistry laboratory. Details of the equipment designed for linking AutoAnalyzers on-line to the computer are described, and data presented concerning the time required by the computer for different processes. The reliability of the various components in daily operation is discussed.

Limitations in the system's capabilities have been defined, and ways of overcoming these are delineated. At present, routine operations include the preparation of worksheets for a limited range of tests (five channels), monitoring of up to 11 AutoAnalyzer channels at a time on a seven-day week basis (with process control and automatic calculation of results), and the provision of quality control data. Cumulative reports can be printed out on those analyses for which computer-prepared worksheets are provided but the system will require extension before these can be issued sufficiently rapidly for routine use.

Flynn, Piper, and Roberts (1966) described a system for peak recognition and analogue to digital conversion that enabled the raw output from five AutoAnalyzer[1] channels to be collected in a form suitable for processing by an off-line computer. Experience with the system in this laboratory drew attention to the disadvantages of off-line batch processing by a computer of the output from automatic analysers (Whitby, Proffitt, and McMaster, 1968), and a dedicated computer system was later obtained to meet this laboratory's principal requirements. The chemical validation of this latter system has been reported (Whitby and Simpson, 1969), and this paper describes the performance of the system in daily operation. Technical features of the special hardware, developed with support from the National Research Development Corporation, are detailed; a preliminary account of the special hardware has been published (Griffiths and Carter, 1969).

Description of the System

The central processor is a standard Elliott[2] 903C general purpose digital computer with an 8192 18-bit word store, with a backing store of three industry-compatible Ampex TM7 tape handlers (9 kch/sec) linked to the central processor via a tape controller and multiplexer control.

The standard input devices consist of an on-line Teletype and a paper tape reader (250 ch/sec; 8-hole, ISO code). The central processor also receives signals on-line from AutoAnalyzers, these signals being amplified by analyser consoles situated on the laboratory bench and transmitted to the data-acquisition unit which is about 20 m away in the computer room; these units of special hardware, and features of their operation, will be described later.

Output from the computer is in several forms. High priority messages (eg, error messages requiring a decision by the operator, emergency results) are printed up on the on-line Teletype keyboard. Lower priority messages (eg, worksheets or statistical calculations) are issued via the paper tape punch for printing up off-line. Reports are output initially on paper tape and are then either read in again for printing up on-line on an IBM (15 ch/sec) printer or off-line on a model 35 Teletype (10 ch/sec).

The computer has four priority interrupt levels for programming purposes. Level 1 is used for entering programs and for testing the system. When operat-

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[1]Technicon Instruments Co Ltd, Hanworth Lane, Chertsey, Surrey.
[2]Elliott Medical Automation Ltd, Elstree Way, Borehamwood, Herts.

ing, the system is normally functioning at the base level, level 4. Every two seconds, however, when on-line to AutoAnalyzers, the base level program is halted temporarily and control passed to level 2, when the on-line channels are read into the computer and validated peaks stored; level 2 programs are held in the core store. Normally control then returns to level 4, where the original program is continued, but if a message is waiting to be input on the Teletype this takes priority on level 3. The programs which are run on level 4 are either held in the core store or on magnetic tape, and transferred to the core store when required. Programs to be run on level 4 are arranged in order of urgency in a level 4 queue, the output of error messages being followed in order of priority by calculation of concentrations, setting up procedures for analytical channels, output of emergency results and quality control messages, input of patient and specimen data, preparation of worksheets, and output of results, etc. The change from one level of priority to another is achieved by a combination of hardware and software. The allocation of programs to the various priority levels, and their order of priority within these levels, differs in several ways from the system described by Griffiths and Carter (1969) in which there was no magnetic tape backing store.

The programming language used in the system is 903 symbolic input routine (SIR). This is an assembly language which has a one to one correspondence with machine code, so is efficient in computer space and time. It is more powerful than machine code, eg, locations can be referred to by names instead of numbers, constants can be referred to directly in the address part of an instruction, and programs can be divided into variable length blocks or modules, simplifying integration of routines written by different people.

SPECIAL HARDWARE

Analyser consoles

These tap signals separately from the reference and measuring photocells of the detector units and the voltages are amplified a thousand times if the maximum output is +10 mV, or ten thousand times if the maximum output is +1 mV; the amplification unit has very low drift characteristics. The consoles also attenuate these amplified outputs to levels within the range 0-20 mV, for transmission to standard AutoAnalyzer strip-chart recorders required for back-up purposes and for the full interpretation of error messages issued by the computer. With the exception of the first, each console can be provided with eight amplifier boards and be connected to two groups of analysers made up of various channel combinations, eg, five in group A and three in group B. The first console has one channel used for internal reference and standard voltage measurements.

The controls on the analyser console allow the individual output levels of the reference and measuring photocells on-line to the console to be displayed in turn on the meter, or the performance of the corresponding amplifier boards to be inspected and adjusted when equipment is being set up. On-line monitoring of analysers is then initiated with the 'on-line switch', and a green light indicates that a set of channels is on-line. If a fault is detected, the red light associated with that switch glows for one minute and an explanatory message is issued by the computer; the operation of these lights is duplicated on the control panel of the data acquisition unit.

Data acquisition unit

The data acquisition unit receives the 0 to +10 V analogue DC voltages from the analyser consoles. It includes a multiplexer and multiplexer controller, analogue selection unit, timer, status word and fault registers, and analogue-to-digital converter, and it converts these voltages to their binary equivalents. Up to 11 channels (22 analogue inputs) of AutoAnalyzer equipment have been operated simultaneously on-line (Whitby and Simpson, 1969).

The multiplexer in the data acquisition unit expands the computer's single standard peripheral interface into two such interfaces and into a special interface for the connexion of the on-line printer. Input to and output from the computer is decoded by the multiplexer and controller and transmitted to the analogue selection unit, which selects the required channel and connects it to the analogue-to-digital converter.

The reference and measuring subchannels from the first analyser console are used for checking purposes. The reference subchannel is connected to a precision voltage reference source to monitor the accuracy of the analogue-to-digital converter, and the input to the measuring subchannel is disconnected so that any switch leakage, noise, or drift in the analogue-to-digital converter may be detected.

A status word register, consisting of an 18-bit gate board, monitors the switches on the analyser consoles, timer, and paper tape equipment, and passes this information to the multiplexer controller. The timer unit outputs a pulse every 2 s; this is used as a level 2 interrupt to hold up the program currently being processed for about 15 ms. During this time, the computer reads the measuring and reference signals from the photocells that are on-line before returning to its previous level of operation. As each channel is read, the 0 to +10 V analogue signal is inverted and halved in the analogue-to-

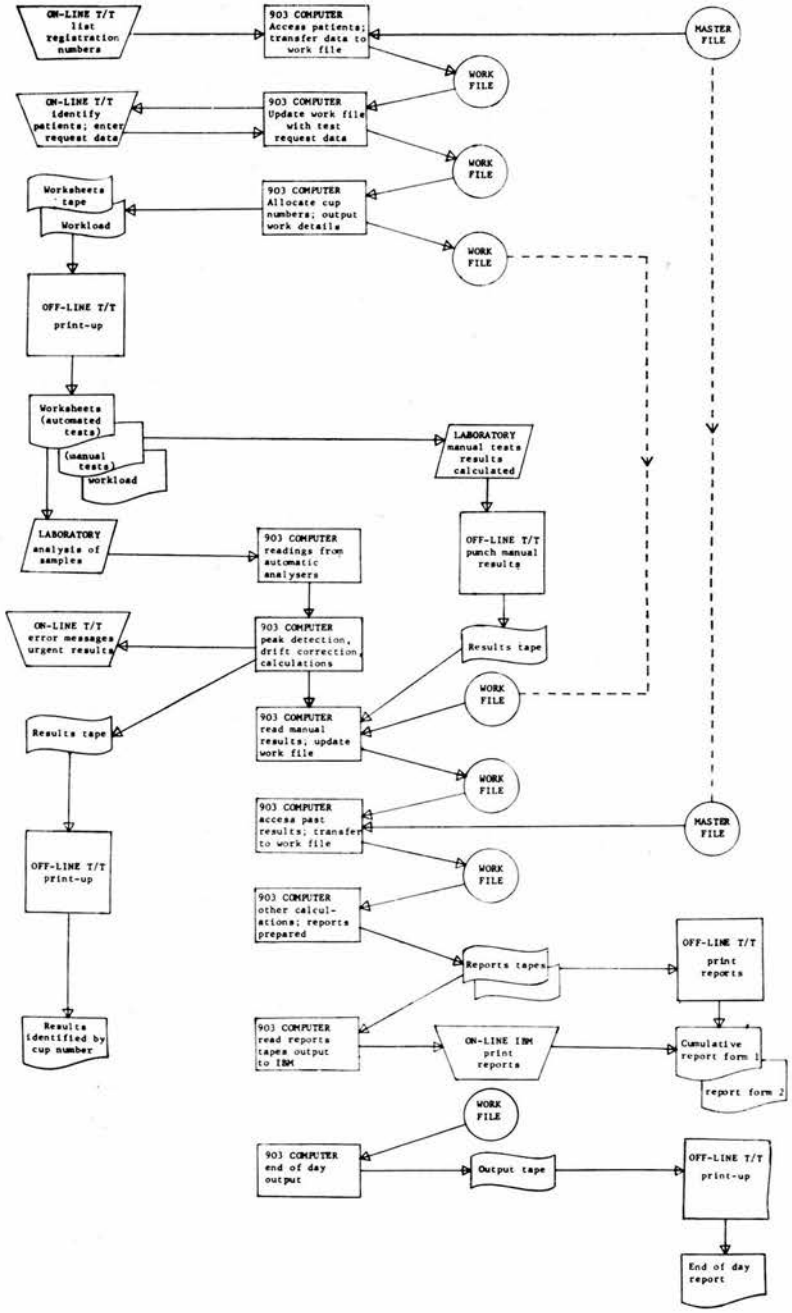

Fig. 1. *Simplified flow diagram of the various operations carried out with an Elliott 903 computer working in a clinical chemistry laboratory.*

digital converter amplifier, and the 0 to -5 V output is converted in about 100 μs into a 12-bit digital representation by the analogue-to-digital converter. After this representation has been examined by the software, the computer addresses the fault register which activates the indicator lamps. With the computer on-line to analytical equipment, if the processor were to address a faulty peripheral and receive no reply, the whole system could remain idle for a considerable time before the fault was noticed; to prevent this, a pseudo-reply circuit limits the waiting time to 300 μs, after which a message is printed out by the software on the on-line Teletype.

Software and Operational Procedures

The on-line system programs are located on the first few blocks of each magnetic tape file. When a program is required a search routine selects one of the handlers, reads the program, and places it in the computer core store. The required program may be called by a previous program through the level 4 queue, as in the calculation of concentrations, or it may be called from the on-line Teletype by input of the appropriate code.

The master file tape consists of three main sections: programs, patient identification records, and patient results records. The work file tapes have in addition test request data for all specimens with work still to be completed. Master and work file data are arranged in registration number order in variable length blocks (maximum 512 words) containing records also of variable length.

At the start of a day's operation, a trigger program is input through the reader to bring into store the system program, which includes the level 2 and 3 programs and level 4 queue processing program as well as peak detection parameters, channel allocations, standards concentrations, etc: it also opens up the magnetic tape files. Throughout the day the work file is updated by writing from one work file tape to the other, adding the latest request data entered on the Teletype. At the end of the day's run, request and results data relating to completed work are transferred to the master file and a new master file is prepared. A simplified flow diagram of the overall system is shown in Fig. 1 and the individual procedures are explained in greater detail in the following sections.

SETTING-UP PROCEDURES

The program used for input of the date, number of first specimen received on this date, changes in AutoAnalyzer group and channel allocations, etc, is called down from magnetic tape by typing in a message. Channels may be re-allocated via the on-line Teletype at any time during the day provided that, at the time of re-allocation, the channel is not on-line to the computer.

Commercial control sera are used for preparing calibration and drift control standards for certain tests, eg, for total protein and for bilirubin. Since the composition of control sera varies from batch to batch, the facility to change the concentration of standards at the start of an analytical run is essential; this is effected by altering the value stored in the appropriate location. Other pooled sera are used for quality control purposes, and the computer-calculated concentrations are checked against predetermined values throughout an analytical run; the mean and SD for the constituents of the serum are entered at the start.

INPUT OF PATIENT AND TEST REQUEST DATA

This can occur via the on-line Teletype in two stages using a conversational mode (Whitby and Simpson, 1969). These data are stored until a block of patient and test request data has been entered when they are written to the magnetic tape files. The conversational mode of input proved too slow for routine use, partly because of shortcomings in the method of identifying patients, and an alternative off-line method of input is now being developed.

OUTPUT OF WORKLOAD AND WORKSHEETS

Statements of the outstanding workload are output to the paper tape punch when requested via the on-line Teletype, and worksheets printed up on the basis of this information. Calibration standards occupy positions 1-8, drift standards positions 9, 10, 20, 30, etc, and pooled serum positions 19, 29, 39, etc. Samples from patients are allocated to worksheets automatically in a priority order: emergency requests, followed by specimens requiring their analysis repeated because of a fault on first analysis, then samples held over from the previous day, and finally the day's samples in order of accession number. A 'change cup number' routine can be used for very urgent specimens. Worksheets can be provided for analyses carried out off-line as well as for on-line work.

DATA ACQUISITION AND PEAK DETECTION

The program reads the output of the reference and measuring photocells, checks that the reference value is within prescribed limits of its original setting, divides the measuring cell reading by the reference cell reading, and stores the result for that channel. When a series of readings for a particular channel has been stored, the program enters a peak detection routine. The basic program for peak detection and validation is applicable to all channels but

its action on any particular channel is determined by a series of parameters evaluated for each particular test (Whitby and Simpson, 1969); these are transferred to core at the start of a run. Parameters can be changed by entering the setting-up procedures routine, typing the address of the appropriate location, and changing the value stored in this location.

If a peak fails to conform to the peak validation requirements, an error message is output and the fault lights show for that channel until the next acceptable peak is detected. If four consecutive faulty peaks are detected (eg, due to a block in the sample line), a special message is output but the computer can be instructed to continue its search for peaks while the block is cleared—provided the sampler plate is not stopped, the timing sequence is maintained and if satisfactory peaks are once more obtained they can still be accepted by the computer program.

STANDARDS IDENTIFICATION AND VALIDATION

The maximum number of calibration standards is eight. Identification is based on a search procedure which examines the difference in transmission units between consecutive peaks and compares them with a predetermined pattern of differences (Whitby and Simpson, 1969).

CALCULATION OF CONCENTRATIONS

The program calculates the difference between successive drift standards, and compares each with the first drift standard for a run. As long as drift is within preset limits, the program then applies a linear correction for drift to the nine specimens analysed between adjacent drift standards. If a drift standard falls outside allowable limits, a message is output, and the operator must indicate whether to use, restart, or cancel; if the use option is selected, this suppresses the faulty drift standard and drift is calculated over a double interval. The drift-corrected peak heights are interpolated against the calibration standards and the concentration of the samples is determined.

OUTPUT OF RESULTS

Emergency tests, and results for a control serum (position 19, 29, etc) falling outside prescribed limits, are output on the on-line Teletype as soon as they become available. Other results are output in groups of eight via the tape punch identified by cup number, and are available for back-up reporting purposes in the event of subsequent system failure (when they could be printed up off-line); they are also written on to the work file and associated with the appropriate records.

Cumulative reports are output via the tape punch in batches of 45 in response to a message on the on-line Teletype; these reports can only be provided for those analyses that have computer-prepared worksheets. Additional calculations (eg, anion-cation differences, creatinine clearances) are carried out by the program after receiving an 'output of reports' instruction. The tape bearing the reports can be read in again for printing up on the on-line printer on a time-sharing basis or printed up off-line on preprinted continuous stationery (Whitby and Simpson, 1969).

QUALITY CONTROL

Real time quality control depends on the results obtained for the specimens of pooled serum placed in positions 19, 29, etc.; these are compared with the mean and SD values input at the start of the analytical run. If the calculated and stated values differ by more than 2 SD, or if two consecutive results differ from the stated value by more than 1·5 SD in the same direction, or if three successive values by more than 1 SD in the same direction, a warning message is output and the value for the current pool printed together with the two preceding pool values. Other quality control specimens are analysed during each analytical run as if they were samples from patients, and values suitable for cusum plots are available at the end of each batch of determinations.

END-OF-DAY OUTPUT

A summary is output to the paper tape punch as part of a closedown procedure. This gives statistical information, a statement on workload, a list of all requests entered that day, and results for completed analyses and certain additional calculations, eg, creatinine clearances. The data are output in registration number order and can be readily consulted when answering enquiries.

FILE UPDATING PROCEDURES

A paper tape program for updating files is input after the closedown procedures. In the first part of this routine, all programs and cumulative records are read from the master file and updated by adding records of completed work from the work file to produce a new master file. In the second part, all incomplete tests are read from the work file to produce a new work file. At the end of the updating routine, the program outputs to the Teletype the number of blocks of information stored on the master file and an estimate of how long the file can be used before having to remove patients to a history file.

Process	*Time (hr min)*	*Percentage Total Time*
Testing and cleaning of computer and peripheral equipment	0·29	*
Setting-up procedures and re-allocation of channels	0·30	4·7
Idle time (before specimens arrive in laboratory)	0·30	4·7
Input of patient and test request data (conversational mode)	3·14	30·4
Output of workload and worksheets	0·42	6·6
Pools error messages, emergency output, and change cup numbers routine	0·06	0·9
Input of manual results	0·12	1·9
Amendment to data on files (eg, alterations in identifying data)	0·05	0·8
Accession of master file before output of cumulative reports	0·11	1·7
Output of results on paper tape punch	0·12	1·9
Output of cumulative reports to paper tape punch (270 reports)	1·30	14·1
Printing up of reports on IBM printer (time for a batch of 45 reports)	0·16	2·5
Printing up of reports on Teletype 35 (time for a batch of 45 reports)	0·32	*
Output of end-of-day summary to paper tape punch	0·25	3·9
Printing up of end-of-day summary on Teletype 35	1·10	*
Update master file and work file routine	0·24	3·8
Total time computer switched on	10·39	

Table I *Analysis of one day's operations performed by the computer*[1]

[1]Activities indicated with an asterisk represent off-line activities. The column headed 'Percentage Total Time' does not add up to 100%, since it does not include timings for the routine carried out when searching for and checking standard curves, nor for peak evaluation and output of peak detection and other error messages on the on-line Teletype, nor for updating of magnetic tape work files with test results. The detailed assessment of time spent in on-line monitoring of various aspects of AutoAnalyzer operation would also be difficult to assess.

Operation of the System

The validation of several individual aspects of the system, particularly the chemical validation, has already been described (Whitby and Simpson, 1969) and the data presented here are mainly concerned with the operation of the integrated system. Although the computer has contributed greatly to the operation of the laboratory, some procedures are carried out too slowly with the present hardware configuration for them to be taken over by the computer as routine operations. The two most time-consuming procedures in on-line operation on an average working day are the input of patient data by the conversational mode and the output of cumulative reports. The third bottleneck, transfer of data to and from magnetic tape files, is closely associated with the input and output timing difficulties.

Table I sets out an analysis of one day's operations. The computer is switched on at 08.00 and switched off at approximately 18.30. The data presented in this table were collected at a time when there were approximately 3,000 patients on the master file. At the start of the day's operations there were 30 patients on the work file, and at the end of the day's analytical work there were 310 records on the work file before updating the master file.

The time taken to enter data for 24 patients when the computer is monitoring six to nine AutoAnalyzer channels is 21 minutes (range 17-35 minutes), and similarly the time to output a batch of 45 cumulative reports to the tape punch is 13 minutes (range 12-16 minutes). The time for printing up 45 reports on the on-line printer when the computer is monitoring up to 11 AutoAnalyzer channels is 16 minutes; this reduces slightly, to 15 minutes, when the computer is not doing other work. The slowness of these input and output operations means that the system cannot be used routinely for the issue of cumulative reports; non-cumulative reports using combined request and report forms (Whitby *et al*, 1968) are still being prepared by hand, which means a lot of transcription.

The reliability of the various components has been assessed over a period of 20 months (Table II). A percentage down time for the computer of 0·4% would appear to be an acceptable value, but the peripheral down time of 6·6% is high; this reduces to 4·1% if the effect of an initial design deficiency on the magnetic tape controller is discounted. All the peripherals have developed faults; the frequency and duration of breakdown for the different components has varied considerably. The length of each breakdown has been closely related to the ease with which the fault could be detected, but the time to secure the services of an engineer and the availability of replacement components have also been important features.

Discussion

The on-line system described in this paper has several advantages compared with the off-line system which used an Elliott 803 computer in a batch-processing mode (Flynn *et al*, 1966; Whitby *et al*, 1968). It incorporates process control features which permit real time detection of faults in the operation of the analytical equipment, starting with the valida-

Time (hr)	1968				1969												1970				Total
	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	
Total Time																					
Total time computer switched on	168	208	237	190	196	213	216	248	269	239	250	227	214	259	229	242	230	241	266	250	4,592
Total time computer in use	166	145	172	182	189	198	203	232	256	239	248	195	213	256	228	241	211	220	226	212	4,272
Total computer down time	—	—	—	—	—	—	1	—	8	—	—	9	—	—		—	—	—	—	—	18
Peripheral Down Time																					
DAU	—	6	—	—	—	—	12	16	—	—	—	10	—	—	—	—	—	4	—	—	48
Reader	—	11	9	—	—	—	—	—	—	—	—	—	—	2	—	—	—	—	—	—	22
Punch	2	—	—	1	—	12	—	—	—	—	—	—	—	—	—	—	—	—	—	—	15
Teletype	—	—	—	—	7	—	—	—	—	—	—	10	—	—	—	—	—	—	—	—	17
Magnetic tape controller	—	46	56	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	38	140
Magnetic tape handler	—	—	—	7	—	3	—	—	5	—	2	3	1	1	1	1	19	17	—	—	60
Total peripheral down time	2	63	65	8	7	15	12	16	5	—	2	23	1	3	1	1	19	21		38	302
Servicing																					
Routine servicing by engineer	—	—	—	—	—	—	—	—	—	9		13	—	18	—	17	—	10	—	9	76
Out-of-hours servicing by engineer	—	12	51	—	—	6	—	—	11	3	—	4	—	2	—	3	—	3	—	12	107
Modifications to hardware	—	—	8	—	—	—	17	—	—	—	—	—	—	—	—	—	—	—	—	—	25
Cleaning and testing by operator	6	8	6	15	16	21	22	19	12	17	12	10	7	11	6	3	2	3	2	2	200

Table II *Summary of operation of system for 20-month period*

tion of calibration curves and continuing with the assessment of individual peaks, the measurement of drift, and the monitoring of concentrations observed when a control serum is analysed repeatedly; with the off-line system none of these assessments could be performed automatically until the end of an analytical run and only some could be included in the off-line programs. With the on-line system, also, when analyses are urgently requested, not only can the specimen be automatically advanced in the queue, but the results are printed out on-line for immediate reporting; with the off-line system, interchange of specimens could be performed (with the risk of confusing their identity) but urgent calculations had to be performed without the computer. Fault-recognition procedures have worked well with the on-line system, and simple restart procedures can be performed, unlike with the off-line system where it was necessary to begin with a new set of calibration standards. Whenever the on-line system rejects a peak (eg, faulty, too high a concentration, etc), the specimen is automatically allocated a place with high priority on the next worksheet; these reallocation procedures could not be carried out automatically with the off-line system.

Some components of the present system operate too slowly, and the computer's routine tasks are at present restricted to the preparation of worksheets for a limited range of laboratory tests (five channels), the monitoring of up to 11 AutoAnalyzer channels at a time on a seven-day week basis (with process control and automatic calculation of results), and the provision of quality control data. On the input side, the conversational mode of entering data from request forms via the on-line Teletype proved to be slower than had been anticipated; this is being replaced by an off-line batch method of entry, which should later allow the use of request forms bearing patient identification data in machine-readable form. On the output side, the equipment prints up cumulative reports too slowly, but delays are also due to the limited space available in the central processor for drawing up each cumulative report before output. The present intention is to enlarge the core store to 16K and to attach a line printer to overcome these hardware limitations.

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