Reprinted from –
AFIPS – Conference Proceedings, Volume 33

Computer system for research and clinical application to medicine

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INTRODUCTION AND GENERAL PHILOSOPY

Since June, 1964, a Control Data 3200 computer system has been installed in the Latter-day Saints Hospital in Salt Lake City, Utah, under support from NIH grant FR-00012. This system in its inception was used to develop research programs and time-sharing software for use by the medical community in the Salt Lake City area. As a result, a software and hardware system called MEDLAB has been developed. Using this system, research programs were developed for cardiovascular studies. It soon became apparent that the programs which were being developed could also be used in a clinical environment.

The first clinical application of the system was used in the heart catheterization laboratory. These programs involved pressure analysis, oxygen saturation analysis, dye dilution studies, etc. With the system in the catheterization laboratory new needs arose to satisfy the routine day-to-day clinical application of the computer. It was not now possible to make the program and hardware changes necessary in research without disrupting the 24 hour clinical service.

Without a memory protect system available on the 3200, programs being debugged could easily destroy the results and programs of another user, frustrating particularly the clinical user, who might be unaware of the problems involved in developing new programs.

As development continued new clinical programs rapidly became available, such as intensive care monitoring and patient screening programs. A new system design had to be developed. For the clinical applications to become effective in patient care situations, maximum reliability is required and can be provided only with back-up hardware.

The computer system described in this paper was developed to serve the two needs of this facility. A description of both the hardware and software and two clinical applications presently in operation at the facility are presented.

Hardware configuration

The system used for both research and clinical applications is made up of three computers located at the L. D. S. Hospital. A block diagram of the system is shown in Figure 1 which shows the two computers—a CDC 3200 and 3300, the 3200 being used for research and program debugging while the 3300 is used strictly for operational clinical applications; the small Digital Equipment Corporation PDP-8/S computer is used as a teletype buffer driver to provide hard copy at distant hospital sites. Although the 3300 has expansion capabilities which the 3200 does not have such as paging memory, memory protect, etc., the 3300 used has essentially the same capability as the 3200 computer. Therefore, both machines are hardware and software compatible and communciate through common disc units.

There are three pieces of equipment identical on each machine which are critical for hardware and software interchangeability. These are:

(1) The disc storage units.
(2) The REDCOR Corporation read and write interfaces, which are the adapters for communicating with the remote terminals and the handling of the physiological signals coming either from a patient or an experimental set up. The read interfaces for both machines are identical and analog signals are presented in parallel to the analog multiplexers of both interfaces. Thus, a program can be debugged, checked out and made operational on the 3200 research system then transferred to the clinical system with no change of channels or program. If the analog-to-digital (A-to-D) converter or computer system for the

clinical system fails, the clinical operating system can be transferred to the 3200 machine with a minimum of rewiring (approximately ten minutes required for change over after the problem is diagnosed) and the assurance that the analog signals will be correct.

(3) The write interfaces on both machines are identical and are connected such that they can be transferred from one machine to the other with a minimum of difficulty (approximately ten minutes).

The two machines are different in their hardware configurations since the 3200 is used for program compilation, printing and magnetic tape capability for program and data storage. The extra peripheral equipment on the research machine includes a 1,000 card per minute card reader, a 1,000 line per minute printer, three high-speed magnetic tapes and one special-purpose high-speed A-to-D converter. The 3300, or clinical machine, on the other hand, has a special output interface for the small PDP-8/s computer used to drive teletypes at the remote sites for hard copy reporting of clinical and experimental information. Both machines are capable of operating remote terminals both from sites within the hospital and remote sites at other hospitals, experimental laboratories and clinics.

Figure 2 shows a photograph of a typical remote terminal through which an operator communicates with the computer. This remote terminal consists of a Tektronix 601 memory display unit, control and timing circuits for operation of this display unit, a decimal keyboard and two 12-bit octal thumbwheel switches for coding information into the computer. Also shown on the front panel are indicator lights which tell the operator the state of the computer, the state of his program and various other indications.

In a typical operation, the user calls a program by dialing a code into the octal switches, then presses the CALL button which interrupts the computer. The computer reads the octal switch and displays instructions back to the operator on the face of the memory display unit. The display unit is capable of displaying 400 characters in a 25 column by 16 row pattern or graphical information with a capability of 512 horizontal and 512 vertical dots. In addition to its capacity as a remote computer display terminal, the terminal can also be used as a conventional three-channel memory oscilloscope by pressing a pushbutton switch on the front panel. This feature allows the operator to quickly check signal level qualities to be presented to the computer and insure that they are within range of the A-to-D converter and of adequate quality for the desired computer analysis. The display will revert from a conventional oscilloscope to a computer display terminal upon receiving an erase pulse from the computer; thus assuring that no computer generated information is lost while the operator is viewing waveforms.

The processing of analog signals is presently carried out independent of the display terminal. As a standard package, each laboratory or clinical area is assigned three analog channels. These three channels are used for multiple purposes. For example, the three channels could be carrying pressure information, electrocardiographic information, densitometry information, etc., depending on the requirement of the user. This three channel requirement was primarily determined by electrocardiographic analysis program where three simultaneous lead signals are necessary. A second reason for making three analog channels a standard configuration is that three channel data sets for telecommunication

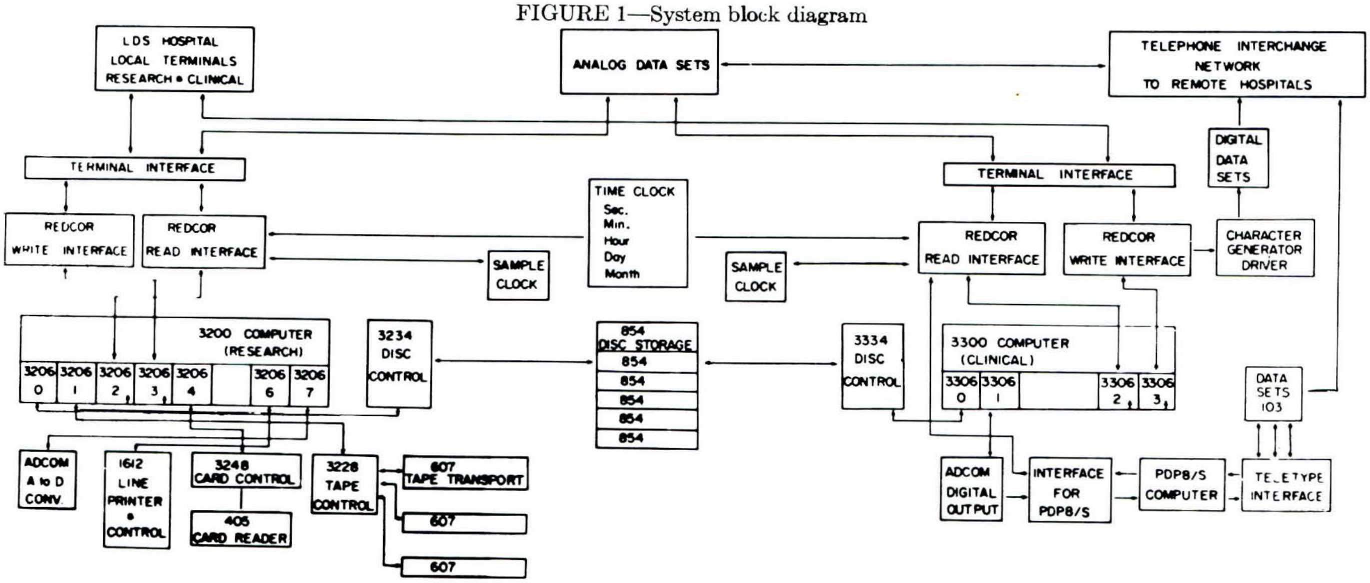


FIGURE 1—System block diagram

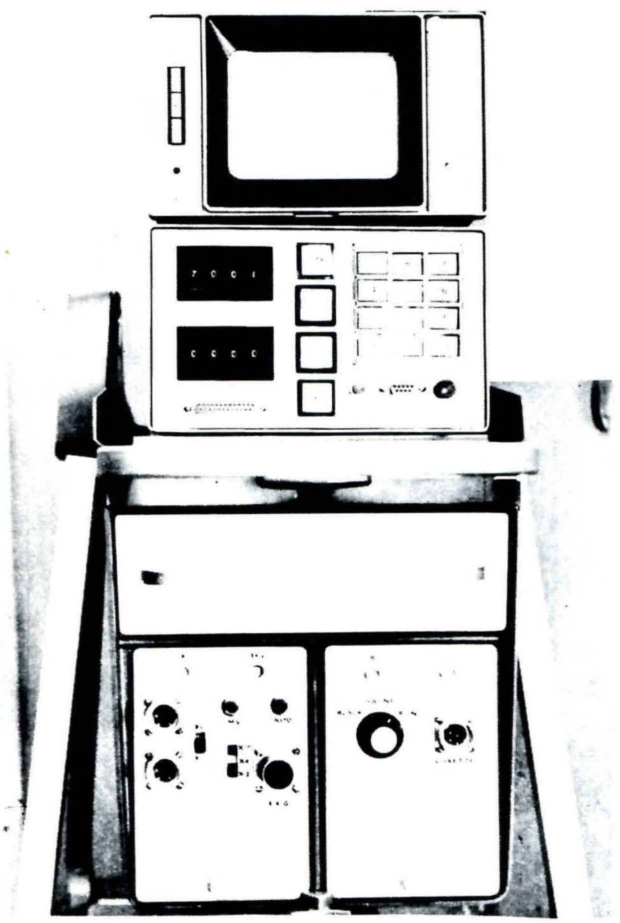


FIGURE 2—Remote terminal with instrumentation

to distant sites are available for processing of data from remote hospitals.

The remote terminals with instrumentation can be constructed for a cost of about $3,000; a character generator added for operation of remote sites costs an additional $1,200. With the capability of both alphanumeric and graphical functions, this terminal becomes an extremely flexible convenient module for use in both clinical and experimental applications.

Since most of the physiologic signals are analog, it was necessary to develop extensive front-end signal conditioning equipment for the computer operation. An objective in the development of the front end equipment was to provide extremely stable, highly reliable instrumentation such that a person with a minimum of instruction and training could use it. The lower part of Figure 2 shows the front panel of a typical instrumentation package. Note that there are no control knobs for adjusting gain or bias of the analog signals from the transducers and that there are a minimum number of control switches for operator use.

The analog front-end system is made up primarily of integrated circuit operational amplifiers with all signals being amplified from their low level condition to a high level (± 10 volt) condition for transmission to the computer, either over hardwire connection or a telecommunication link. In each case, signals are conditioned for optimum use by the computer and by the telecommunication link by amplifying and adjusting the offset for full scale capability of computer and communication link.

Experience has shown that minimizing the number of controls and adjustments makes the system easier to use, both by experienced and nonexperienced operators, and also increases the confidence of the operating personnel. As a typical example of an instrumentation application where this type approach has been used, consider the pressure transducer amplifier which amplifies signals from a balanced Wheatstone bridge strain gage. The gage itself can be balanced, the amplifier or amplifiers could each have a separate off-set control, the gage excitation could be varied, the amplifier gain could be varied, and so on. To minimize the problems in set up of a pressure transducer, only one control is provided and is made an integral part of the transducer system. The excitation voltage on the gage is fixed, the sensitivity of all the strain gages have been calibrated to a standard level and all pressure amplifiers are set up with the standard gains. A fixed off-set has been programmed into the amplifying system and the only adjustment that need be made by the user is gage balance which compensates for varying fluid levels of the patient. Therefore, a pressure system which is usually complicated and difficult to handle becomes a simple set up procedure which a nurse or inexperienced technician can adequately handle and get results that are technically adequate and, in fact, as good as an experienced operator can obtain.

As can be seen from the foregoing discussion, the computer system has been designed with both a research investigator and a clinical investigator in mind with standard packages designed and constructed which aid both. The system is also easily adaptable to special purpose experimentation with signal levels that can be conditioned with a great amount of flexibility for the occasional user who has special requirements for signal levels, sampling rates and timing.

Operation of terminals from remote hospitals is made over voice grade direct distance dial compatible telephone communication link. As far as the user is concerned, operation from a remote hospital is essentially the same as operating a local terminal. Figure 3 shows a block diagram of the communication link where the data sets shown are Bell system designations. As can be seen from this diagram, there are three types

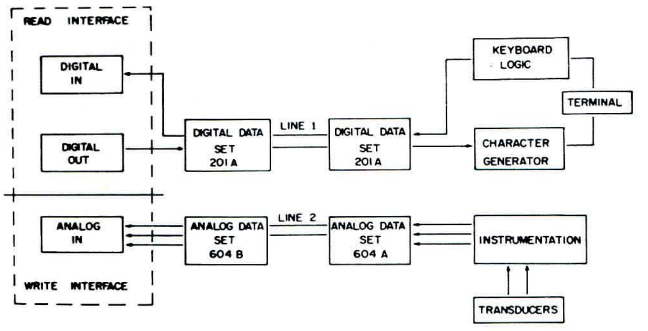


FIGURE 3—Block diagram of communication link used for remote hospitals

of data the computer system must handle for the remote terminal: (1) digital input and control information; (2) digital output used to drive a character generator and provide control outputs; and (3) analog input signals presently sent over a second telephone line.

Typical operation of the scheme might be as follows. Initially 201 data sets which connect the central processor and the remote hospital are both in the receive mode. Upon pressing a button at the remote terminal, the 201 data set at the terminal end goes into the transmit mode, after a settling time required by the data set, it transmits a serial 14-bit code to the receiver at the computer site. The data set at the computer site receives the serial data which is converted to a parallel 12-bit code and read into the computer. For the usual operation a keyboard entry is followed by an alphanumeric reply to the terminal. The data set at the computer end becomes a transmitter and transmits data back down the line to the remote console. Using a character generator scheme (developed jointly by the authors and Beehive Electrotech of Salt Lake City) alphanumeric and graphical data are presented on the remote storage display unit. The present transmission scheme uses a 14-bit word consisting of one sync bit, a parity bit and 12 data bits. The 12 data bits are broken down into nine bits of display data with three control bits which determine whether the character generator writes alphanumeric characters, using the ASCII code, plots graphical information, sets up control functions or outputs nine bits in parallel to remote control devices.

With the rate of 2,000 bits per second available with the Bell system's 201 data set, the character generator scheme will output characters at approximately 130 characters per second and plot graphs at approximately 130 points per second, being limited by the data set bit rate. With faster data sets correspondingly faster write-out rates could be obtained. After a transmission is completed both data sets return to the receive mode and are free for the operator to again enter some type of digital information or a piece of control equipment outboard from the remote terminal to access the computer.

The basic remote terminal, which is not much larger than the 201 data set (Figure 2), is completely transportable and can be taken anywhere telephone communication facilities are availiable and used to communicate with the MEDLAB system. Applications for stand-alone communication terminals of this type are expected in tumor registry programs, radiation treatment planning and other areas where analog signals are not necessary. When analog signals are required, Bell system data sets 604A and 604B, which are analog transmitter, receiver respectively, are used to send three channels of analog information simultaneously. The analog data bandwidth of these FM multiplexed channels is DC to 100 cycles for each channel. Cross-talk and signal-to-noise characteristics and bandwidth of these channels is adequate for transmission of most clinical physiologic information. The requirements for three channels is dictated by the vectorcardiographic system which requires three simultaneous channels of ECG. With a slight modification of this system it is possible to use touch-tone telephone keyboard and a 604A=B, 401J data set configuration to transmit electrocardiograms and other physiological data from any patient room within a hospital by installing phone jacks in the rooms and using the internal television distribution system of the hospital to transmit instructions and results to the operator on the television receiver located in the patient room.

A "program-line" connection is operational between the neurophysiology research laboratory at a remote hospital. This type line is one which is commonly used by FM music stations and is conditioned to have "flat" frequency response from 50Hz to 8KHz making it ideally suited for transmission of action potentials.

Presently there are systems in four hospitals using the communications terminals and one additional hospital using a hardwire connection. Plans call for region-wide screening clinics to be conducted by State, local and private health organizations. With these terminals, health services can be provided to remote communities that heretofore were available only to patients at major hospitals.

Software

The software available on the 3200 (research) system and that on the 3300 (clinical) system are quite similar but some important differences exist. A major difference is the type of program which can run under either system. On the 3300 system, which is used for the clinical applications, there are 12 partitions within core memory, each partition being approximately 2,000 words in length. Only those programs which are designated clinical real-time programs and have been written in assembly language are allowed to run within any of the 12 partitions. Since the user can have only 2,000 words of core at any time most programs are written as a series of overlays to be read in as needed into the same partition. These programs must have reached a high degree of reliability before being allowed to run on the clinical system. The clinical executive monitor contains a dictionary of the programs allowed and if a program is not in that dictionary, a message is written on the display unit at the terminal indicating that the program is not allowed. No debugging of programs is allowed on the clinical system. All debugging must be performed on the research system.

Within the 3200 (research system) there are only four partitions for real-time programs and a 16,000 word area of core set aside for background programs. These background programs consist mainly of compilations, statistical analysis programs, report generation programs and other nonreal-time programs. There is also available on the research system a program designated DEBUG which allows for on-line debugging of real-time programs from any remote terminals. Upon calling this program from a research terminal, the programmer may then use it to aid in debugging his program. This program allows the user, within his program, to execute instructions, change instructions, look at data in memory, etc., in an on-line situation.

Software-wise there is no interaction between the research system and the clinical system. The research system is unaware of whether the data generated on any disc is generated by a program being run on the research or the clinical system. All data which are generated by either machine and stored on disc are accessible by the research system for report generation on the line printer.

The time-sharing of the programs on either machine is accomplished by a series of tables which are stored in the executive monitor. These tables correspond to either external station interrupts or internal clock interrupts. As an example, assume that a user desires to sample a pressure waveform at the rate of 100 samples per second. Within his program he branches to a subroutine in the executive monitor with the rate he desires to sample and the location within his program where control is to be given at the time of his clock interrupt. This subroutine then searches through the tables to determine the minimum time for the next interrupt and sets the appropriate hardware interrupt registers to generate an interrupt at that particular time. On the occurrence of the clock interrupt, the system determines which station caused the interrupt and branches to that program via the clock interrupt JUMP table which had been previously set by the program.

Similar action takes place with operator interaction from a remote terminal. Within his program the user will use the routines and tables within the monitor to set the addresses he wishes to branch to when he presses one of the interrupt buttons at his remote terminal. When an external interrupt is generated in this way, the system decodes it to determine which station has interrupted and branches to the appropriate table. If the code read from the terminal is a program call code, the system will load the user's program from disc and branch to the beginning of his program. Interaction continues with the program writing instructions on the storage display unit and waiting for a reply from the operator.

With the present hardware configuration on the clincial system there are 12 terminals connected to the 3300 and, thus, with the 12 partitions available within core there is no swapping of programs required. In the research system, however, this is not true since there are only four partitions available and 12 remote stations connected to the computer system. Algorithms have been developed to determine whether a station is inactive; that is, it is either not sampling any real-time data, it is not accessing the disc or performing some other I/O function. When these conditions exist, this program may then be transferred to a disc and another user's program brought into core at that location. When the user interrupts to initiate some action from the system, the monitor determines if his program is in core. If not, it checks to see if that partition of core is busy and then loads the program from disc or writes a message on the scope indicating that core is being used at that time.

Within the 3200 system there is available the larger area (16,000 words) in lower core for background programs. This program may, however, be linked to a real-time program in upper core. This is usually done when the program has need to sample analog data from some station. Fortran programs, which have been linked to one of the assembly language programs, are given the priority one whereas compilations and Fortran programs run through the card reader in a batch-processing manner are given a lower priority, priority two, and will be swapped out when request from a terminal is made for that area by a priority one Fortran program. Many of the present assembly language programs are developed using this capability; that is, writing the program, or at least portions of it initially in Fortran to get the basic logic developed. Then once the program has been debugged, it is converted to assembly language for use on the clinical machine.

Resident in core within both systems are a series of re-entrant subroutines which may be accessed by any user's program. These subroutines are used to write messages on the display terminals, to store or retrieve data on the disc, to convert from binary to floating point or BCD, etc. Resident also are special clincal routines which are used by most of the users.

Since there is no memory protect on either machine, some software features have been developed, especially for the clinical system, to attempt to eliminate errors which might result in the running of any program. Since the basic cause of errors in running of the clinical programs at this facility results from generating external interrupts from the terminal at inappropriate times, measures have been placed within the executive monitor system to allow for external interrupts from a remote terminal only during those times when they may be serviced by the program without causing interference with other activities going on within that same program. Some of these times are specifically when the program is sampling data, using the disc or writing on a scope, etc. This does not, however, exclude other remote terminals from generating external interrupts and performing functions within their program but only excludes the user from interrupting himself at these times.

Applications

Patient screening

One of the newer projects using the system at this facility is a patient screening admission program. Every patient who is admitted to the L. D. S. Hospital, with the exception of maternity and emergency patients, are screened using this program. When the patient arrives at the hospital and registers in the Admitting Office he is given a hospital record number. This number is used by the computer system to generate a file of data for the patient. Once the patient has received his registration forms he is brought to an admitting laboratory where two samples of blood and a urine sample are taken for analysis in the Chemistry Laboratory. Upon leaving the admitting laboratory the patient is brought to the computer screening laboratory. A file is initiated on the patient by entering the patient's hospital number on the decimal keyboard at the terminal. A nurse measures the patient's blood pressure, temperature, respiration rate and enters these parameters along with age, height and weight in the patient's file.

Two on-line computer tests are then performed on the patient. The first is a maximun breathing test where the patient is required to take a deep breath and blow into a spirometer which measures both the total volume expired by the patient (Forced Vital Capacity), the volume expired after one second and two flow rates during the maximum expiration. The analog signal generated by a potentiometer connected to the spirometer is sent directly to the computer. Corrections for temperature, barometric pressure and calibration factors are made by the computer and the results presented on the display unit within two seconds after the test. Once the patient has successfully performed this test, which usually requires blowing into the spirometer at least twice in order to obtain the best possible results, the patient is given a computerized electrocardiogram (ECG) with the computer sampling the output of the three vector signals from the ECG amplifier. This test requires a series of eight electrocardiographic leads to be connected to the patient. These leads are resolved by the amplifier into an orthogonal lead system used for the measuring of the electrical activity of the heart. The program performs a pattern recognition on the data collected and reports back to the screening technicians a classification of an ECG pattern. This information is also stored on the patient's file. Once the patient has completed his electrocardiogram he is taken to his room. Total time for these two tests is approximately five minutes with the computer being used for about one minute.

Other information entered into the pateint's file includes the results of the urine analysis and the hematology analysis, and the blood chemistry tests run on a 12-channel autoanalyzer. The 12-channel autoanalyzer is operated as an on-line terminal which allows the computer to sample its output and store the results directly into the patient's file. The urinalysis, as well as the hematology results, are entered into the patient's file through the keyboard at a remote terminal.

At the end of the day the technicians generate a report from the patient's data by punching a card with the patient's name and hospital number. The report generated for each patient contains all the data which had been entered, either automatically by the computer or keyed in from one of the remote terminals. The program prints out the test results as well as a problem list; that is, a listing of all values which are outside of normal limits. The reports are then distributed to the nurses' stations and placed on the patient's charts. Subsequent data gathered on the patient during his stay in the hospital are also recorded on the patient's file by the computer. At time of discharge the file is taken from the active file, which is stored on one of the magnetic discs, and transferred to magnetic tape in the inactive file. At this time, or shortly after, a discharge diagnosis is placed on the patient's record. When the patient is readmitted to the hospital his record is retrieved and pertinent information returned to the disc in the active file. This screening procedure has been performed on several hundred patients and although results are preliminary, significant numbers of patient abnormalities have been observed.

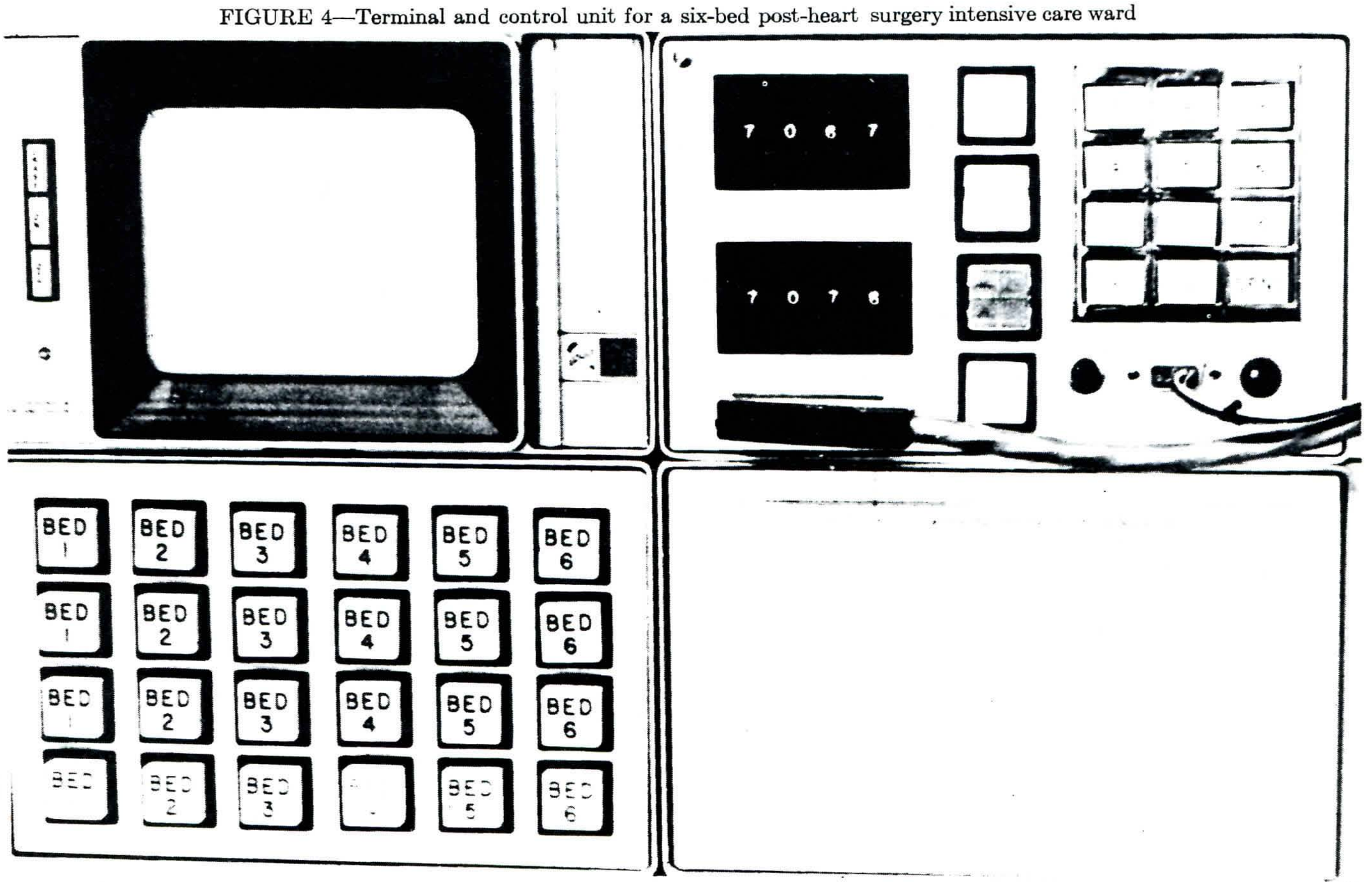
Intensive care ware

A six-bed intensive care ward for monitoring of patients who have had open-heart surgery has been in operation at the L. D. S. Hospital since March, 1966. The system is currently used routinely by the surgeons and nurses for monitoring cardiovascular function and entering nurses' notes for each patient on the intensive care ward. A picture of the central console used for control of all six beds is shown in Figure 4 and consists of a terminal similar to those discussed earlier as well as an input/output control box used to control switching of signals from each of the six beds in the ward.

The column of four lights for each bed in the intensive care ward are colored red, yellow, green and white and are controlled by the computer. A green light is turned on when the computer is actively sampling data from the respective bed. The red light indicates a change in patient status while the yellow light is an indicator to the nurse that some procedure is required on the patient, such as scheduled drug injections. The bottom row of lights are used to display the analog inputs from each bed on the memory display unit. Pressing BED 1 on this row for example would cause the display unit to go into the sweep mode and simultaneously display arterial pressure waveform, electrocardiogram and venous pressure waveform. The display unit will erase at the end of each sweep and revert to a computer display anytime the computer begins to write out information.

Two modes of data collection are available. A "measure-once" option allows the nurse to call the program, inidicate the bed number and initiate measurements on the patient. Sixteen heart beats are analyzed and the average value for each of ten variables (heart rate, stroke volume, cardiac output, peripheral vascular resistance, duration of contraction, maximum pressure, minimum pressure, mean venous pressure, respiratory rate and amplitude) is immediately displayed on the memory display unit and stored on magnetic disc by the computer, along with the time and date of the measurement. The second mode involves setting up a schedule of measurements. When the nurse chooses this option, measurements are made on 50 successive hearbeats and for each variable the mean and standard ert ror of the mean are determined. This statistical description of the state of the patient forms a base from which subsequent measurements are evaluated thus eliminating the need for the nurse or doctor to decide

FIGURE 4—Terminal and control unit for a six-bed post-heart surgery intensive care ward



arbitrarily on upper or lower limits for each variable to initiate an alarm condition. Four minutes after the base line measurements are made on a patient, a scheduled measurement is initiated automatically and consists of determining a mean value for each of the ten variables over 16 heart beats. A red light is turned on if any one of the mean values exceeds its base value by more than three standard errors of the mean. To determine which variable has deviated from its base line, the nurse, at her earliest convenience, merely presses the red switch light which interrupts the computer and sends a code identifying the bed number and causes the computer to display a message indicating the variable furthest out of tolerance. The value of the last reading and the time of the reading are shown together with the mean, standard error of the mean and time of the base line measurement for comparison. At this point the nurse may choose one of several options; she may explain or verify the alarm indication, determine a new base line, or review the wave-forms. If the change in status detected by the computer represents the establishment of a new steady-state, the nurse establishes a new base line at this point. All subsequent measurements will then be referred to this new base.

The interval between scheduled measurements is under computer control and is dependent on the state of the patient. If the first measurement made four minutes after a base line is not statistically different from the base line, the next scheduled measurement will occur in eight minutes. If the red light is turned on, however, the next measurement is made in two minutes. Thus, the interval between measurements will vary between two minutes, when the patient is unstable, up to 16 minutes when successive readings coincide consistently with the base values.

Since the computer system is not continually sampling all six beds but is merely scanning from one bed to another depending on patient status, there is a possibility that a patient could get into trouble, say within the 16 minute interval. Two of the more common problems encountered are related to frequency of contraction of the heart. These are ventricular fibrillation (speeding up of the heart) and cardiac arrest (heart stopped). Since this could happen at any time and detection from the arterial pressure wave-form would require continuous monitoring, the electrocardiogram or arterial pressure signal are used to drive a rate meter. Upper and lower heart rate limits are set for each patient. If the patient s heart rate goes beyond a limit, the red warning lamp for that bed begins to flash on and off and an interrupt and bed code are sent to the computer causing it to record the event and start making measurements of cardiovascular function. Remote hospitals also have similar intensive care wards with complex control features made possible by the communications system described above.

There are a variety of physiologic variables which would undoubtedly contribute additional useful information to patient care. Some of these, such as blood chemistry determinations, blood gas analysis, are measured periodically on these patients but at present the information is entered into the computer only semiautomatically from other laboratories in the hospital. The intensive care service is provided on a seven day a week, 24 hour a day basis and requires a maximum of computer reliability and up-time. To achieve the confidence of the doctors and nurses involved in patient's care, the system was designed with complete back-up of all the critical signal measuring and reduction systems. There is a possibility that a card reader or printer could fail, eliminating hard copy, but the information is still available to the user through his remote terminal. The hard copy could be printed later after repair time of the printer or card reader.

Results of the use of the computer system in the intensive care ward have been very encouraging. At present patients are automatically put on the monitoring system unless the attending physician requests that they not be monitored. The surgeons schedule their surgery around the computer system (i.e., if the computer system is not operational, surgery is rescheduled for a time when the computer service is available).

CONCLUSIONS

The dual system just described has been in operation since September, 1967, and presently services 20 terminals. These terminals are located in six separte medical areas at distances from a few miles to 50 miles from the central facility. The system is used in diverse areas as heart catheterization, nervous system studies, screening clinics and others. Experience to date has shown that the system performs both clinical and research functions well.