The key to a nationwide capability for computer analysis of medical signals:

The dedicated medical signal processor*

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INTRODUCTION

The Medical Systems Development Laboratory has demonstrated a system of computer analysis that encourages wider use of medical signals, reduces unit costs, and alleviates the shortage of physician manpower while concurrently improving the quality of interpretations. It is adaptable to hospital wards, outpatient departments, routine physical examinations, and health screening programs. Its development anticipates the worsening shortage of professionals able to analyze medical data.

A large number of those concerned with the practice of medicine recognize that automated analysis is the only feasible answer. At the same time, most medical-service groups are reluctant to install systems in their own institutions because existing computer hardware has not been adapted to meet their needs. Existing systems are expensive, bulky, and because of the flexibility for which they were designed require scarce computer technicians to operate and maintain. The need of most potential medical users is for quite the opposite: a small computer system that requires minimal maintenance and that can be operated by the personnel usually available to medical groups.

The aim of this paper, after a brief review of the background, is to describe a model for a compact computer system designed for the needs of medical-service groups. The model is based on an existing “breadboard” system.

Background of need

The electrocardiogram was chosen as the model signal for automated pattern recognition and interpretation by computer because physicians are familiar with it and have 50 years of experience in relating its waveforms to specific meanings. But almost any other physiological signal—brain waves, vital capacity, heart sounds, and others—could have been selected. In fact, we have since demonstrated that each of these signals is subject to automated measurement and interpretation. The computer measurements are accurate, and clinicians can accept the interpretations as readily as they accept those of other clinicians.

Approximately 50 million electrocardiograms are interpreted annually in the United States by medical personnel. It is probable that changes in population age-groups and the impact of health legislation will double the volume of electrocardiograms long before it is possible to train the required specialists. Conventional techniques of electrocardiography would make the cost of the projected increase prohibitive for disease control and prevention purposes in terms of physician-technician man-years.

From a manpower viewpoint the most important factor is total reading time, including measurement and interpretation time by interns, residents, technicians, and finally that of the physician who signs the electrocardiogram report. Although some tracings can be read by cardi-
ographers in a few minutes, total reading time—
for problem as well as routine cardiograms—
averages close to 15 minutes. Thus the reading
of 50 million electrocardiograms, in terms of a
2,000-hour man-year, takes up an estimated 6,250
ECG reader man-years. In conventional systems,
reading time accounts for 75\% of the cost. Use
of a computer system can reduce reading time
5- to- 7 fold and facilitates the reduction of secre­
tarial (bookkeeping, filing) and technician (re­
cording) time.

The current computer system prints out all the
significant measurements with a verbal diagnostic
statement based on the criteria of a consensus of
cardiologists. Electrocardiograms and spiromgrams
are now being taken from patients in hospitals
and clinics evaluating benefits of immediate on­
line analysis by a computer system.

More than 300 groups on their own initiative
have asked the Medical Systems Development
Laboratory to make available to them the use of
the computer program currently available for
electrocardiogram analysis. Consultation has been
given, but serious hardware limitations have re­
stricted utilization within the medical setting.
Duplication of laboratory type facilities such as
our existing “breadboard” system is not generally
practical in medical care units. Nevertheless, one
group with a large staff (the Missouri Regional
Medical Program), for lack of any other “off the
shelf” alternative, has replicated the basic essen­
tials of the breadboard processing configuration
used at the Medical Systems Development Labora­
tory.

Alternative routes

It is possible to construct, from products now
on the market, large regional centralized multi­
purpose, multi-signal computer facilities. How­
ever, these would be impractical for routine cli­
cinal medical-signal analysis at this time because
of their defects: staffing difficulties, the continu­
ing high expense of non-local analog telemetry,
high acquisition and maintenance costs, the ab­
sence of a workable time-sharing system for medi­
cal-care purposes, and the changing character of
medical systems due to computer use itself. Al­
though the technological problems can be solved,
largely because of the last reason it may not be
economical to expend great effort for an overall
solution until 10 years hence.

This does not mean that we oppose large, re­
gionally centralized computer centers now. On
the contrary they are to be encouraged, but as
central storage and retrieval centers serving net­
works of small, dedicated computer systems.
Translation of patient-care computer programs
to the assembly, compiler, or machine languages
of small computers for service-oriented hospitals
of average size is thus a pressing vital step.

This concept implies a need for development
of small single-purpose computers for processing
medical signals. Our experience with prototype
systems adapted for general-purpose computers
has proved that a specially designed dedicated
computer can best meet the anticipated needs of
regional medical programs, multiphase screening
programs, medium-to-large hospitals, and
local health departments.¹

Our experience with commercial groups sug­
gests that the systems dedicated to medical-data
processing can be commercially available in 2
years. A prototype, the Control Data Corporation
“MESA” system, was developed from our speci­
fications within a 6-month period about 1965
and served to clarify our concepts of the systems
required for the ‘70s. The proposed systems
should be of office-desk size, completely modular
self-contained units.

A system with a processing capacity of 60,000
or more medical signals annually could be mar­
keted by industry for a cost under $100,000 (or
rented for about $36,000 per year). With sup­
port for the development of prototypes, a net­
work of such computers could be established
within 5 years to make routine computer analysis
of electrocardiograms, spiromgrams, or other medi­
cal signals available anywhere in the United
States. These could aid in increasing the quality
of medical care and in controlling the rising cost
of medical tests.

These single-purpose medical computers would
facilitate the creation of storage and retrieval
centers at strategic locations for much-needed
medical data pools. This storage and retrieval is
of course of secondary importance to immediate
display for action. With data extracted by the
dedicated clinical terminal from the human source
and analyzed with defined accuracy, the analysis
can be displayed, prepared for insertion in the
patient’s record, and put to immediate use. This
is the basic reason for considering storage and
retrieval centers as secondary in any service­
oriented medical computer project.
Preliminary estimates of the basic cost of an electrocardiogram with a dedicated system, assuming a 10-year equipment amortization and 60,000 patients a year, show a unit processing cost of a few cents contrasted to dollars today. With mass volume, costs of the equipment are small when contrasted with costs of manpower training and utilization.

The breadboard system

At the Medical Systems Development Laboratory we have, as part of our work in automation of medical signals analysis, experimented with several different preprocessing and processing systems. We have kept in mind that in medicine, users or even combinations of users often do not generate sufficient quantities of data to warrant processing on large, fast computer systems. Costs for processing equipment are low as long as the system is kept busy, but are apt to be exorbitant if input rates are slower than throughput capabilities. Therefore we have chosen to work initially with dedicated, single-input systems.

Because computer personnel are not readily available at most hospitals or clinics, the system should not require skills beyond those of hospital technicians and nurses. Our experience indicates that processing can become medically reliable in nearly any properly equipped computer room, but even there only if the system is exceedingly simple to operate. Accordingly, our system specifications require no more of the technician than to load and start an analog tape playback and then check that a monitor light goes on.

Before we could begin to specify requirements for routine service equipment, it was necessary to determine many system requirements, for example, the sampling rate, the filter settings, etc. An experimental processing system was constructed having variable settings for nearly every component. After the first approximations were determined and necessary corrections made, there still remained the tasks of statistical validation, reliability and maintainability studies, human factors engineering, and analysis of operational problems encountered. To complicate matters, the original signal (the ECG) became only one of many undergoing automation at our lab. The system grew and changed, all the while becoming more versatile, but also more complex and difficult to operate and maintain. We recognized that this system would allow almost limitless variations in experimental and research techniques but was not applicable to clinical processing.

In routine operation the most difficult problem was with trouble shooting and maintenance. Basically the engineering solution hinges on the use of replaceable modules which can easily be exchanged in the event of failure. No wiring or special effort to connect the modules should be required. Repairs of components should be made at remote sites with well-equipped maintenance facilities while the user enjoys uninterrupted service. Basically the hospital or clinic should be unconcerned about maintenance except for acceptance of a preventive maintenance contract. The system must be no more complex to operate than a home television set. It should be operable with the same amount of instruction, since hospital personnel do not have the specialized skills of electronic technicians or computer operators.

The signal from the data acquisition devices is given to the first section of the system (the input unit), which contains an analog tape playback deck and monitor indicator. The tape deck uses 1/4-inch-wide tape on 7-inch reels and operates at 3¾ inches per second. After set-up, start/stop is initiated by computer control. The monitor indicator automatically glows if the tape being played was not recorded on a properly aligned data acquisition system. If the recorder head was not aligned to specifications, a 6750-Hertz flutter compensation signal used in our data acquisition systems will not be played back with sufficient amplitude. If the head is unaligned, the tape deck should stop automatically. Filter bandwidth for processing clinically used medical signals is DC to 45 Hz. The 3-db point should be at 45 Hz. Rolloff above 45 Hz should be 24 db/octave.

To enable heart sound processing, a bandwidth of 40 to 1000 Hz (± 1 db) is usually suggested. A filter with the 3 db points at 20 and 2000 Hz with rolloff of 6 db/octave is recommended. Parenthetically we can state that the envelope resulting from the rectified signals may be adequate for analysis and brings all medical signals to the same range.

Amplifiers should be provided to compensate for losses incurred during transit of the signals through the filter networks and other media such as telephone lines, and to condition the signal strength and circuit impedance to the optimum values required by the analog-to-digital converter. One, a high input impedance amplifier (minimum
10 megaohms), can be provided at the input to the filter networks. The second can be a signal level compensating amplifier at the output of the filter network. A calibrated gain control should be available with the compensating amplifier to enable adjustment of signal voltages to proper levels.

The experience gained from our experiments suggests commercial incorporation of some of the above listed functions either as the terminal end of a digital data-acquisition device (instead of an analog one) or the initial part of the dedicated computer as described here. The tape playback demodulator, amplifiers, filters, and/or telephone jacks are also in the input unit. An automatic answering feature can enable acceptance and recording of the telephone data without operator intervention. Automated control circuits must be provided to coordinate the various functions.

The second section is the medical-signal processor. Its stored programs should have the capability of modification by a procedure not normally available to the usual medical user. The system must utilize a minimum of external switches and human decisions. The hardware in this section consists of an analog-to-digital conversion unit, a central processing unit, data and program storage unit, printer, and the control panel. Our oscillator drives the analog-to-digital converter at a fixed sampling rate of 500 cycles per second per channel used. This sampling rate is adequate for most medical signals. An unsigned 10-bit output is adequate for accuracy purposes over the range of ± 2.5 volts. A control circuit causes the analog-to-digital converter to send a 10-bit word through the computer input register upon computer request. Initial input requests start and computer commands stop the analog tape deck.

The sub-modules must be packaged in a single housing that need occupy a space of not more than 20 square feet. The cabinet should resemble a desk and have a top usable as such. Weight of the unit, excluding the optional attachments, should not exceed 1,000 pounds, to be suitable for normal hospital and clinical building floor load.

The minimal functions that need be included are: input/output, arithmetic operations, peripheral control, logical and/or, shift, conditional and unconditional transfers, and interrupts or timing devices.

A typewriter or other low-cost printing device, capable of a printout speed of at least 720 characters per minute, is all that is necessary for conventional work. The unit should operate under program control, with buffering a desirable feature.

An incremental plotter also under computer control could be utilized to produce a graphic output.

A capability should be provided for attachment of a telephone for transmission of digital data (i.e., the medical results obtained by the processor) to central storage and retrieval computers.

The internal memory can contain as little as a 16,000 18-bit word memory core. This would suffice for the operational program.

Provision for program entry or modification must be preplanned. Dedicated analysis systems must therefore be compatible with an existing commercially and readily available computer, to enable manufacturers to make program modifications to incorporate medical advances.

A random access storage unit can replace part of the core memory specified. Economy for the individual manufacturer should dictate the storage medium. The storage capacity will be dependent on the peripheral equipment and the computer's instruction repertoire. Approximately 16,000 18-bit word or 32,000 12-bit word capacity or equivalent would be ample.

The system should incorporate executive programs to control program selection and the flow of information between input and output devices, patient code recognition, and data formatting. Checkout programs for the on-line equipment and the data acquisition system should also be part of the software.

Utility programs to facilitate fault detection, modification of programs, and the addition of new programs are needed only by the manufacturer's checkout or maintenance crew.

The MSDL electrocardiogram program for the 160A consists of two parts. The first (pattern recognition) is approximately 6,000 lines in the OSAS assembly language. The second (diagnostic) is 8,000 assembly statements. The MSDL spirogram program consists of approximately 5,000 assembly statements. The generality and numerous logic paths incorporated in these pro-
grams indicate why translation and validation are time consuming.

SUMMARY AND CONCLUSIONS

Several factors should be considered to evaluate the system's adequacy for medical operations. The medical signal processor must permit easy installation and keep maintenance requirements to a minimum. The unit must be capable of being maintained by replacement of easily removed components and modules. Reliability of operation must be considered to be of prime importance in the design and manufacture of any medical signal processor. Commercial sales cannot be expected to be great without due emphasis on this aspect. The validation must demonstrate the ability of the system to handle approximately 60,000 medical signals over a 1-year period when operated on a continuous basis (exclusive of preventive maintenance time).

Large-scale screening or research projects both require utilization of more than one signal. In lieu of "simultaneous" processing with one device or a serial system, small dedicated systems used in parallel can achieve the high throughput rates required to keep up with voluminous data. Currently we believe these will offer the most economic courses to follow to solve existing volume problems. A central storage and retrieval system can then collate the data.

The medical community can be provided with a standardized processing system for medical signals to meet volume requirements of health care needs. Diagnostic printouts can be made in the standard format and terminology familiar to every physician. This alone will provide invalu­able quality control of medical service delivery. Combinations of small machines can be effective in producing the required volume and quality on a sound economic basis.

REFERENCES

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