interests pay the costs of operation. This scheme has the interesting prospect of allowing a market choice for consumers with regard to privacy. It also has the potential for cost reduction, as many a type 1 person could be transformed into a type 2 person when the costs were made explicit.

The quality of service is also important. While an information bit is binary, complex systems that handle and deliver information are subject to response degradation ranging from minor response delay to information "brownout" or even collapse. There is also a risk of irrecoverable losses of stored information.

Automobile recalls for safety, environmental impact, and consumer satisfaction are good examples of the far-reaching changes which are in store. In such systems statistical quality control is not enough. Records must be kept initially on the product identity and on the seller's identity and location. Records are also kept over time; as defects become apparent in use, the consequences are determined, and some subset of already sold items is called in for warranty repair. Indeed, with the built-in computer monitoring systems necessary to meet the stringent environment controls of 1980, it is possible that the decision to recall could, for some conditions, reside in the control computer of the individual car and be evoked when failure was detected in use.

This raises an interesting possibility for decentralization. As miniaturization continues and more powerful devices with memory become available, it will be possible to place monitors in all sorts of equipment (home appliances, and so forth) and to keep a log of activity. A record of demands and performance available to manufacturers and consumers would be a useful basis for warranty decisions, and it might relieve a burden of centralized data storage and retrieval.

A common thread in these examples is growth toward more complexity. We have mechanisms at hand that permit great expansion of bureaucratic regulation (public and private) and that may induce us to choose organizational forms of increasing complexity. We should be cautious about embracing these possibilities. Automobile recall requires considerable information. A matrix of interactions between dealers and owners extends over time and requires storage that increases at least linearly with time. Cost accounting for such information systems is not yet well developed, and storage without retrieval has been with us ever since man invented librarians, so it is unlikely that these systems will be well run.

Random isolated failures of complex information systems are expected and accepted. The social consequences of the general failure of such systems are less acceptable and less understood.

Any EFTS should be designed to be robust against general system collapse. Experiments with parallel systems should include careful tracing of costs and benefits. These systems should not be imposed on society before they have been thoroughly tested.

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The Impact of Integrated Electronics in Medicine

Robert L. White and James D. Meindl

Health care presents a singular opportunity to improve the quality of life in our society through electronics. In modern medical practice the premier diagnostic and monitoring tools are electronic instruments as illustrated by the x-ray and electrocardiograph. An electronic prosthesis, the implantable cardiac pacemaker, is essential to life for many patients. In medical research, a myriad of electronic instruments ranging from electron microscopes to pinpoint-size microelectrodes contribute enormously to the prevention, identification, and treatment of disease.

During the past 16 years the monolithic integrated circuit has had a revolutionary impact on electronics. Throughout this period the number of elements per chip, or the functional complexity of integrated circuits, has doubled annually. Today 64,000-element chips are commercially available. Because of their low cost, excellent performance, high reliability, and small size, integrated circuits have made possible whole new industries, and their impact pervades our lives. In particular, the unique capabilities of integrated electronics can be applied to medical instruments with enormous benefit to the quality and availability of health care. The purpose of this article is to illustrate through a number of examples how health care has been expanded through the new diagnostic, monitoring, and prosthetic instruments now possible through integrated electronics.

Diagnostic and Monitoring Instruments

The ideal diagnostic instrument provides definitive data on the patient's condition, causes him no harm or discomfort, and is convenient, reliable, and economical for the physician or his medical associates to operate. A monitoring instrument imposes the additional stringent requirement of virtually total freedom from the need for a human operator. Because of their noninvasive character, transcutaneous instruments such as computer-aided tomographic x-ray scanners, electrocardiographic monitoring units with automatic arrhythmia detection, and ultrasonic imaging and blood flowmeter systems offer the greatest possibilities of fulfilling these idealized specifications. However, in view of the limita-

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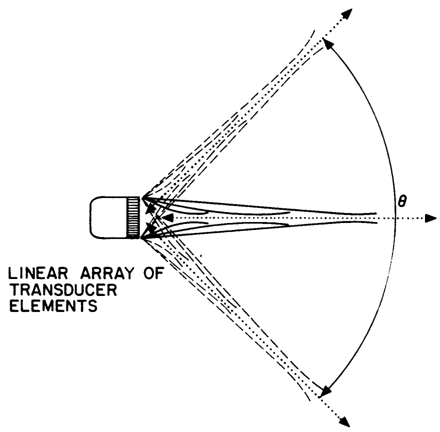

Fig. 1. Electronically scanned and focused piezoelectric transducer array.

tions of noninvasive techniques in medical research involving animal models of human disease, invasive instruments such as subcutaneously implanted telemetry systems for measurement of blood flow and pressure are invaluable in their ability to collect physiological data that would otherwise be unavailable. We now review several examples of both noninvasive and invasive diagnostic and monitoring instruments, with emphasis on capabilities possible only through integrated electronics.

Computer-aided x-ray tomography. In 1971, when a British company with no prior position in x-ray equipment (*1*) introduced the tomographic head scanner, the long-stagnant field of x-ray diagnostics was revolutionized. The order backlog for this scanner, and its instant competition, ran into the hundreds of units, although the instruments cost from \$300,000 to \$600,000 each. The new instrument (*2*) relies on a different approach from the conventional x-ray shadowgraph and gained instant acceptance because of its capability for resolving tissue densities on the order of ½ percent, as compared to the 25 percent difference resolvable by conventional techniques. Such resolution allows the location and identification of tumors as well as the distinction of body fluids from soft tissue, both difficult-to-impossible by shadowgraph techniques. The tomographic scanner operates by recording the attenuation of a narrow x-ray beam as it scans the patient from all angles in a single plane. Each element of tissue in this cross section is therefore observed from a number of directions, and it is possible, by computer processing of the totality of the recorded data, to separate the absorption coefficients, accurate to ½ percent for each small element. The absorption data is then converted to a brightness scale, and a tissue density map of the object plane is plotted. In this diagnostic technique, integrated electronics is used throughout the digital data processing system, without which computer-aided tomography would not exist. Indeed, if one takes the extreme view that computers have their present power, price, and pervasiveness only because of the advent of integrated circuits, one can argue that medical practice has been totally infiltrated by integrated electronics from appointment call to billing.

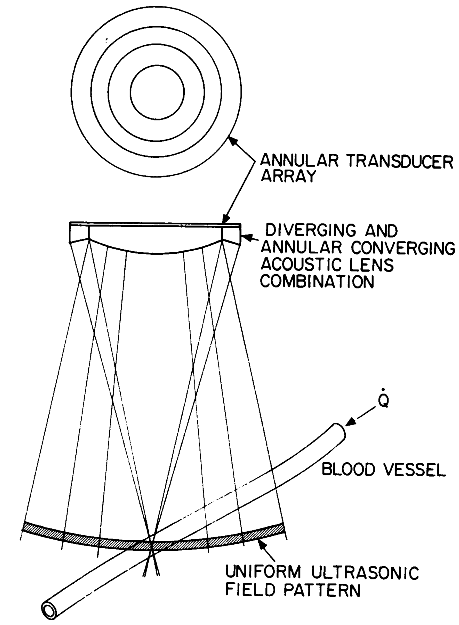

Fig. 3. Noninvasive volume blood flowmeter.

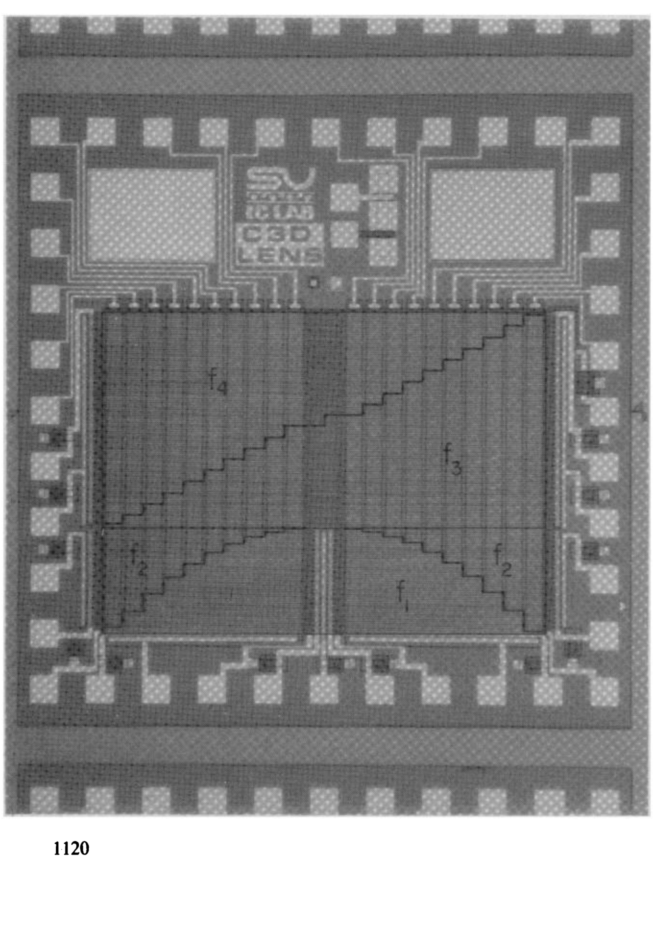

Fig. 2. Cascade charge coupled device (C3D) photomicrograph. Chip size is 3 by 3 mm.

Coronary care heart monitors. It is imperative that cardiac performance be monitored continuously for patients recovering from a heart malfunction. To have a nurse or technician continuously watching an electrocardiograph display is both unacceptably expensive and insufficiently reliable, since the significant warning events are occasional irregular beats (arrhythmias) out of hundreds or thousands of regular beats. The solution has been provided by computer monitoring of the patient's electrocardiogram (*3*). The computer can be programmed to analyze each heartbeat in a multivariate fashion, identifying such features as the height and duration of the principal electrical event (the QRS complex) and the interval between beats, and on the basis of these data classify each beat as normal or abnormal. The computer then displays at a central monitoring station of the coronary care unit such information as heartbeat rate and the number of abnormal events occurring in a given interval, perhaps sounding an alarm if abnormal events exceed a predetermined rate. Such monitoring systems, which provide patient care more reliable than a human observer, are possible only because of the computational power provided by integrated circuits.

Ultrasonic imaging systems. In comparison to x-rays, ultrasound is a recent noninvasive diagnostic modality that offers superior characteristics in some circumstances and inferior ones in others. Applications in which ultrasound frequently provides advantages include (i) imaging moving targets, such as the heart or the fetus, (ii) imaging the pregnant uterus where minimal x-ray exposure is advisable, and (iii) imaging soft tissues such as muscles and blood, with very similar densities but very different acoustic properties. Typical applications in which x-rays are often more useful include imaging the lungs or the brain where air passages and the skull, respectively, severely attenuate ultrasound.

The basic principle of operation of most ultrasonic imaging systems is similar to that of sonar or radar. A short pulse of high frequency 1.0 to 5.0 megahertz ultrasound is emitted by a piezoelectric transducer contained in a handheld probe, in contact with the patient's skin. As the packet of ultrasonic energy propagates through the body, most of it is lost through tissue absorption; but a small amount is reflected at boundaries between tissues of differing acoustic impedance. It is the reflected component, which returns to the transducer, that provides useful information. Until recently, images were generated from these reflections by manually scanning a single transducer element attached to a mechanical arm equipped with several potentiometers providing electrical signals describing probe position and orientation. Feeding these potentiometer signals along with the returning echo signals to a cathode-ray tube display produces a cross-sectional image. Typically, such images are low in resolution as a result of the use of a single, large-diameter transducer element emitting a collimated acoustic beam. In addition, manual scanning precludes real-time imaging of moving targets, such as the heart. Integrated electronics can be used to overcome these two limitations and compose echoes for image formation (Fig. 1). All transducer elements in the linear array are used in a controlled time sequence for both electronic focusing and electronic scanning in a sector pattern to produce a real-time cross-sectional image. The special features of this approach are high resolution at virtually all ranges, since "electronic zoom" is used dynamically to adjust the focus to each depth, and, in addition, a large sector angle, $\theta = \pm 35°$, provides a panoramic field of view. This scheme is particularly suited to high-resolution dynamic cardiac and abdominal imaging.

In addition to the transducer array, integrated electronics provides several other key contributions to this system. Each transducer element must have an associated transmitter circuit, and these must be triggered in a carefully timed burst to permit launching an acoustic wave in any specified direction within the $\pm$ 35° sector. A carefully matched set of preamplifiers must be connected to the transducer array to receive returning echoes. The output signals from these preamplifiers are fed to a corresponding set of electronically variable time delay lines which form the heart of this system. In essence, focusing on a particular point in the target sector consists of equalizing the time delays from that point to the common output node (or summation point) of the delay lines. That is, differences in acoustic path delays from a particular target point to various transducer elements must be compensated precisely by a complementary set of electronic time delays preceding signal summation.

This highly specialized requirement of medical imaging systems has been met by a unique integrated circuit. It is a cascade charge coupled device (C3D) which consists of a monolithic set of variable delay lines whose time delay is the product of the number of stages (or length) and the electronically controlled transfer rate of a signal charge packet from stage to stage (*4*). A photomicrograph of this C3D is shown in Fig. 2. The section of the chip labeled f_4 accepts a separate preamplifier output for each of its 20 parallel delay lines. The sections f_4 and f_3 correspond to acoustic (or optical) prisms whose two acute angles, or height, are electronically variable by changing the C3D transfer rates which control the scan angle of the imaging system. Sections f_2 and f_1 correspond to an acoustic (or optical) lens doublet whose radii of curvature are electronically variable by changing the transfer rates, which control the range of focus of the imaging system. The output of section f_1 represents the signal summation point. This remarkable integrated circuit zoom lens provides the basis for extremely high performance ultrasonic imaging systems in the future.

Ultrasonic blood flowmeters. The capability to perform harmless, repeated, accurate, noninvasive measurements of volume flow is necessary in the diagnosis and treatment of countless medical prob-

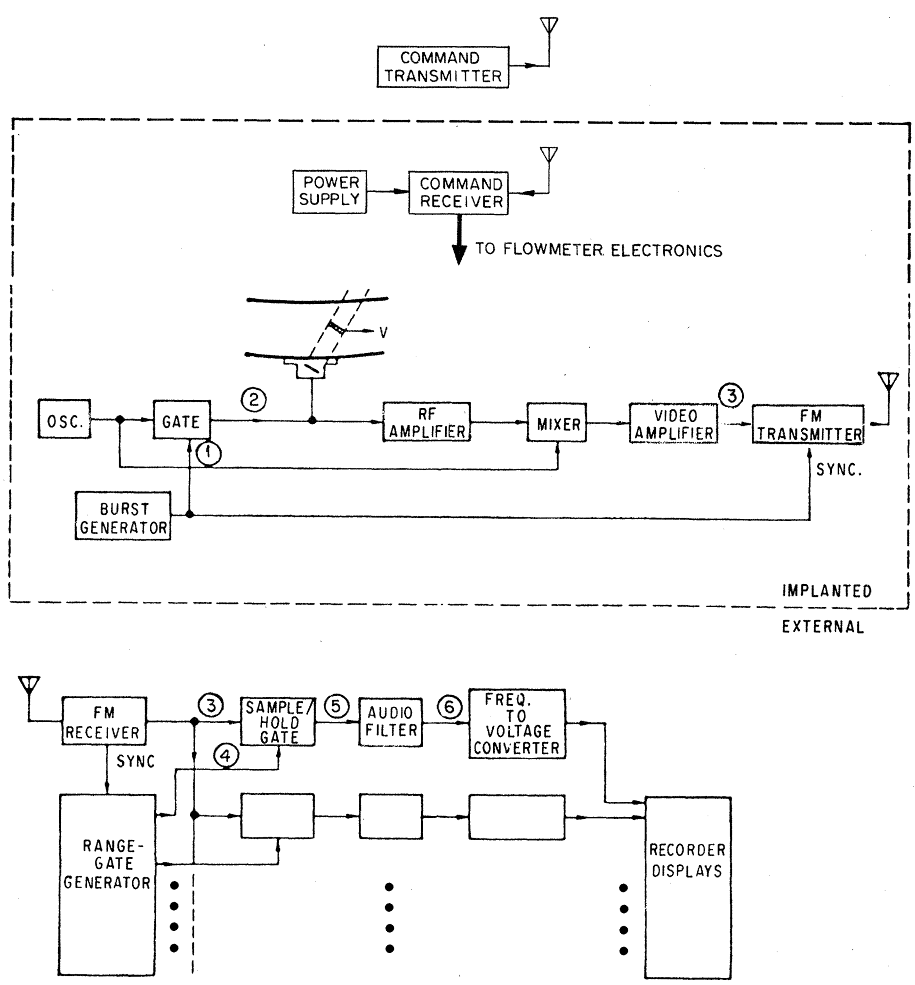

Fig. 4. Implantable flowmeter block diagram.

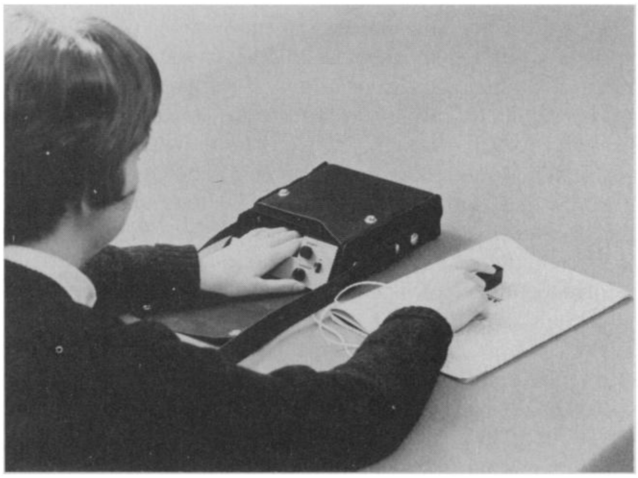

Fig. 5. The Optacon in use.

lems. A new concept for transcutaneous measurement of volume flow which utilizes an integrated annular array of piezoelectric transducers is illustrated in Fig. 3 (5). In this scheme, a short burst of high-frequency excitation is applied to the three inner elements of the array at three unequal amplitude levels, so that in combination with the diverging acoustic lens, the transducers generate a uniform ultrasonic field pattern within a given range interval. This interval must include the entire lumen of the blood vessel in which flow is to be measured. Following the transmit pulse, the three inner elements are connected in parallel to receive returning ultrasonic energy which is backscattered and Doppler-shifted in frequency an amount Δf by the moving red cells in the blood vessel. This Doppler frequency shift is directly proportional to the velocity of blood flow. In addition, the outer annular transducer is used to receive returning ultrasonic energy which emanates from only a portion of the lumen (that is, the "small area") as defined by the annular converging lens.

To convey the fundamental principle of operation, it is convenient to assume that the "small area" is known as a result of the characteristics of the converging lens. Hence, by electronically forming a ratio of the Doppler signal power returning to the three inner transducers to the Doppler signal power returning to the outer transducer, the area of the lumen is determined. Furthermore, by computing the centroid of the power spectrum of the Doppler signals returning to the three inner transducers, in essence, one can determine the average velocity of blood flow in the lumen. The product of lumen area and average velocity is volume flow $\dot{Q}$.

Careful analysis of this approach indicates that the instantaneous volume flow measurement is independent of the angle of orientation of the transducer relative to the vessel, the blood velocity profile within the lumen, and the shape of the lumen (5). Extensive medical applications of this new system are anticipated.

Implantable telemetry systems. The ability to prevent and treat disease in man has depended on animal research. In cardiovascular research, for example, it is now widely recognized that acute physiological measurements in anesthetized, open-chest animals often cannot be duplicated in intact awake animals. It follows that concepts derived from such experiments are not necessarily applicable to intact unanesthetized man. Therein lies the rationale for implantable telemetry systems in animal research. These unique instruments simply provide the means for continuous physiological measurements that otherwise cannot be achieved. Because of the complex functional capability, small size, high reliability, and low power drain required of implantable units, integrated electronics must be used.

Two of the most useful measurements that can be made in cardiovascular research are blood flow and pressure. A block diagram of an implantable, ultrasonic flowmeter capable of measuring instantaneous blood velocity profiles and hence volume flow is illustrated in Fig. 4 (6). In this system, the exciter provides a short (1.0 microsecond) burst of high-frequency (6.0 megahertz) excitation to the single piezoelectric transducer. For a relatively long interval (50 microseconds) after each transmit pulse, the scattered and Doppler-shifted signals returning to the transducer as the ultrasonic pulse traverses the vessel are processed by the receiver circuit and telemetered to the external electronics. Because the velocity of sound in blood is well known, the Doppler frequency shift in the returning signals at any instant corresponds to blood velocity at a particular point in the lumen. Consequently the external electronics can provide an instantaneous blood velocity profile whose integral over the lumen diameter can give an accurate estimate of volume flow.

An additional feature of prime importance in this system is the integrated circuit command receiver which, under control of the external command transmitter, serves to disconnect the battery power supply from the flowmeter electronics per se during periods when data are not required. In this manner, the useful operating life of the implantable unit can be enormously prolonged since the power drain of the command receiver is approximately 0.1 percent of that of the flowmeter.

For blood pressure telemetry, a thin silicon diaphragm approximately 1.0 millimeter in diameter and 5 micrometers thick is used (7). Tiny silicon resistors formed in this diaphragm using integrated circuit fabrication processes are sensitive in value to the blood pressure deflecting the diaphragm. One or more of these silicon piezo-resistive pressure transducers can be implanted along with signal processing and telemetry electronics similar to the electronics used in the Doppler flowmeter, to monitor blood pressure at various sites in the cardiovascular system. Such implantable telemetry systems offer considerable promise in medical research involving animal models of human disease.

Prostheses

For many humans the quality of life is greatly diminished by loss of some natural function. Blindness, deafness, paralysis, and loss of limb are afflictions suffered by many. The powerful and compact sensory, computational, and display capabilities of integrated electronics make possible exciting new avenues for prostheses to remedy these functional deficiencies. Some prostheses, especially sensory prostheses, operate transmodally, mapping the information normally gathered by the impaired sense onto an unimpaired sense. The optical-to-tactile reading aid described below is such a prosthesis. Others, such as the cardiac pacemaker, inject synthetic signals into the nervous system to replace missing natural signals. We now present examples of modern prostheses, possible only through integrated electronics, which are harbingers of things to come.

A transmodal sensory prosthesis. In principle, the Optacon is a direct translation reading aid for the blind which converts an optical image of a printed character on a page of an ordinary book, magazine, or newspaper to a vibrating tactile facsimile (*8*). By means of a simple optical system contained in a hand-held camera, an image of the printed character is focused on an integrated circuit array of phototransistors. Output signals from the phototransistor image sensor array are processed in a simple electronic system, and then used to control a corresponding array of piezoelectric tactile stimulators or bimorphs. Tiny pins cemented to the tips of the bimorphs protrude slightly through perforations in a rectangular plastic plate. A blind reader whose fingertip is resting over the perforations can then feel an exact tactile facsimile or vibrating image of the original printed character.

A photograph of the Optacon is shown in Fig. 5. The tiny camera in the right hand of the reader is scanned freehand across a line of print. Batteries and electronics are contained in the portable carrying case. The left index finger of the reader is covering the tactile display. Custom integrated electronics is crucial in two features of this instrument. The first is the 6 by 24 phototransistor image sensor array for the camera, and the second is the high-voltage driver circuits that are necessary to excite the piezoelectric transducers of the tactile display. Several thousand Optacons are now in daily use by blind individuals in many countries.

Neural substitutes. The signals that travel the nervous system are electrical in character, so it should in principle be possible to replace defective nervous tissue with an electronic substitute. The two major technological difficulties are (i) interfacing with the nervous tissue so that signals may be inserted or extracted and (ii) achieving in acceptably small volume and at acceptably low power the signal processing function of the tissue to be replaced. The impact of integrated electronics on both these obstacles has been revolutionary.

That electronic substitution for defective neural tissue is in practice feasible is proved by the success of the cardiac pacemaker. Approximately 100 cardiac pacemakers are installed daily in the United States, and their manufacture and sale is a $100-million business. The cardiac pacemaker, however, is required to achieve only a relatively simple function, that of assuring the arrival of a periodic stimulation at a single extended site. It was possible to achieve this

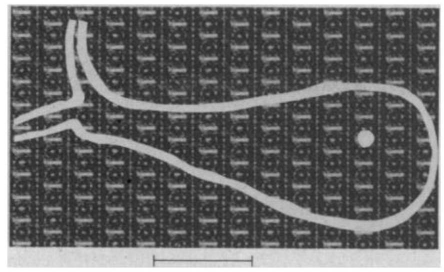

Fig. 6. Photomicrograph of semiconductor memory chip with image of cerebral neuron superimposed. The bar represents 50 μm.

simple function in an acceptable volume and at an acceptable power level even before the advent of integrated circuits. So also was it possible to achieve a pacemaker for the lung (*9*) for those paralyzed by a spinal cord injury or suffering from sleep apnea, and to develop a peroneal nerve stimulator (*10*) to remedy foot drop and improve the gait of hemiplegics. In all these cases a simplified version of the neural function replaced suffices to achieve an important or vital objective. One may now ask, however, to what degree our horizons in neural prosthesis have been extended by the advent of integrated electronics.

Figure 6 is a photomicrograph of a commercially available integrated circuit memory chip; superimposed is the image of a cerebral neuron. Dozens of active semiconductor elements fit within the area of the cell body. The two-dimensional density of semiconductor memory or logic elements of advanced but current design is more than an order of magnitude higher than the corresponding density of cerebral nervous tissue. Even allowing for less efficient packing in the third dimension, it is now possible to attain a volume density of integrated circuit logic elements which is comparable to that of natural nervous tissue and to execute logical functions of similar complexity at similar energy cost. It is now technologically feasible to replace defective nervous tissue with synthetic neural

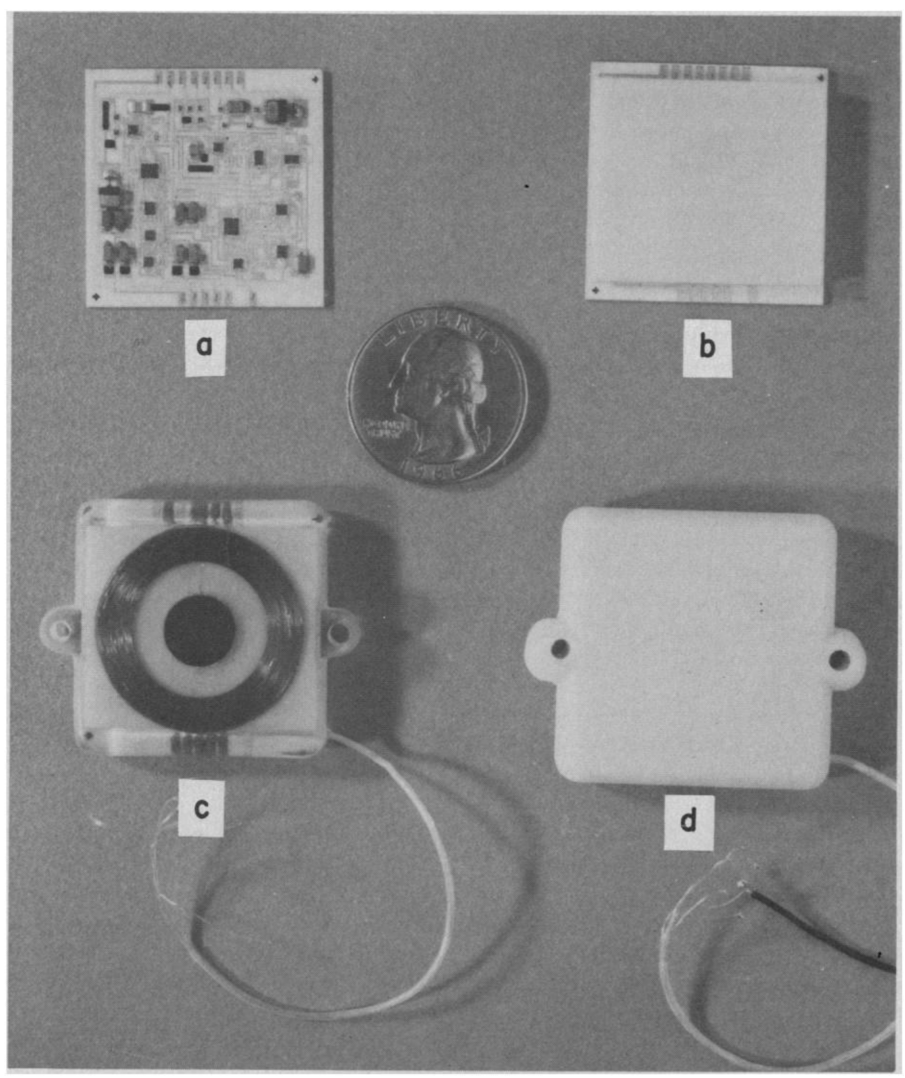

Fig. 7. The STIMULISS IV B auditory prosthesis implantable receiver-stimulator unit. (a) Hybrid microcircuits, (b) hermetically sealed, (c) with radio-frequency and ultrasonic receiver antennas, and (d) fully encapsulated.

circuits of similar size and power needs; the implied possibilities for prostheses are countless.

The most striking of the neural prosthesis possibilities opened by the high intelligence density of integrated circuits are sensory prostheses for hearing and vision. In both cases, the information flow rate is high, and the stimulation pattern which must be generated is complex in both space and time. One of the first cases to which integrated circuit technology has been seriously applied is that of an auditory prosthesis, an implantable inner ear for the profoundly deaf.

Basically the ear is a transducer that converts the mechanical energy of a sound wave (in which information is encoded) into a patterned array of electrical impulses traveling up the auditory nerve. In a significant number of cases of profound deafness the transduction machinery of the cochlea is defective, but the auditory nerve itself remains viable. It has been known for some time that electrical stimulation of the auditory nerve produces the sensation of sound in such cases. Considerations based both on auditory physiology and on speech theory indicate that, given the restricted bandpass characteristic of a single neural channel, the independent stimulation of eight to ten subsets of nerve fibers of the auditory nerve is required to convey the information content of speech. An eight- to ten-electrode array of stimulation microelectrodes must therefore be inserted into the auditory nerve. Because of the danger of infection, the microelectrode array cannot be driven on a permanent basis by wires running through the skin, but must be driven by a fully implantable receiver-stimulator unit. A series of cochlear prostheses are under development to achieve these functions (*11*). Integrated electronics technology is crucial to the fabrication of a small low-power implantable receiver-stimulator microelectrode array and a small low-power supercutaneous speech processor-transmitter. A prototype four-channel implantable unit has been developed and tested in vitro and in animals, and the fabrication of microelectrode arrays using photolithographic techniques as well as the design of the speech processing algorithm is in progress. Figure 7 shows the first-generation four-channel unit in several stages of construction. Power is transmitted on a radio-frequency link; the receiver coil is apparent. Data are transmitted in digital form over an ultrasonic link for noise and misalignment immunity; the receiver crystal is also visible (in Fig. 7) within the radio-frequency coil.

The development of a visual prosthesis for the blind offers even greater technological challenge, since the data acquisition rate is two orders of magnitude greater than that for the ear and there are the dimensions of color, flicker, and relative position of the eye to the head to be dealt with (*12*). The greatest obstacles to the visual prosthesis at present are, however, probably not technological but physiologic. One major obstacle is that the optic nerve is not viable in most cases of blindness (in contrast to the auditory case where nerve survival is common). Stimulation of the surface of the visual cortex produces bright spots (phosphenes) in the visual field, and most of the efforts on visual prostheses have been based on this phenomenon. There are, however, two basic problems confronting the cortical visual prosthesis. First, that part of the cortical surface corresponding to the central high-acuity portion of the retina is buried deep in a cortical fold, making surgical access all but impossible. Second, the cortex is the site of the final stages of optical signal processing and is not in principle a good place to insert what is essentially input data on the visual field. It is possible that the required electronic function for a visual prosthesis can be accomplished within the appropriate space and power constraints if the physiologic and anatomical problems of appropriate insertion point can be solved.

Sensory prostheses have been singled out as being complex and requiring the capabilities that integrated circuits offer. In addition, sophisticated skeletal muscle prostheses could require comparably complex signal processing (*10*). Consider, for instance, a prosthesis which might operate a paralyzed arm through neural stimulation. An array of muscles would have to be stimulated in a programmed fashion, and in a manner influenced by sensory feedback on limb position, grasp pressure, and the like. Some progress has been made in this direction, but only with the development of integrated circuits can the technological problems involved be surmounted.

Summary

There are two salient points which convey the essence of the impact of integrated electronics in medicine. First, the quality and availability of health care are becoming increasingly dependent on radically new diagnostic, monitoring, and prosthetic instruments provided by electronics. Second, many of these new instruments, such as ultrasonic imaging systems, blood flowmeters, and artificial inner ears, impose very stringent performance requirements, which can be met only through innovative application of integrated electronics. In summary, the initial impact of integrated electronics on health care is now visible, and consequently it is apparent that we are beginning a new era of revolutionary advances in medical instrumentation. Health care may indeed present the most promising opportunity to improve the quality of life in our society through electronics.

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