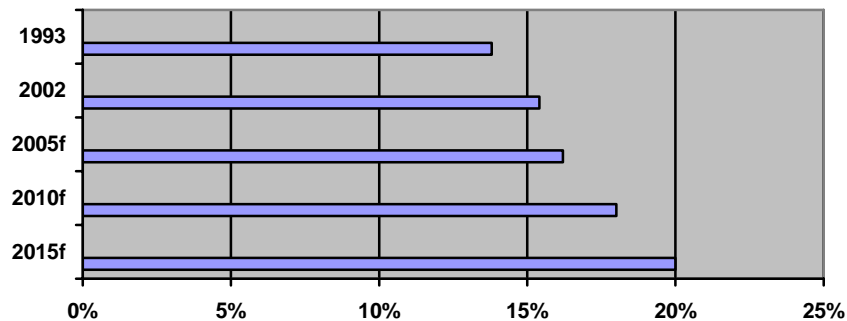


The Impact of Medical Applications on the Electronics Industry

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Increased spending on hospital care, home health services, drugs and public health programs will have a significant impact on the US economy over the next ten years. According to a recent issue of *BusinessWeek*, healthcare has added 1.7 million jobs since 2001. Growing from \$1.7 trillion in 2003, *Health Affairs* predicts the US will spend \$4 trillion on health care by 2015, or about \$12,320 per person annually. Likewise, the CMS National Health Statistics Group forecast an increase in health care spending from its current 16.2% of the US gross domestic product to 20% by 2015. By contrast, total manufacturing represents approximately 20% of the national output. Today, this nation spends a greater percentage of its domestic output on healthcare than any other country in the world.

Figure X
Health Expenditures as a Percentage of US GDP



The global population of 600 million senior citizens will double to 1.2 billion in the next 20 years according to Craig Barrett, Chairman of Intel Corporation. Citing America's 35 million seniors, in his keynote address to the White House Conference on Aging in December 2005, he stated, "This is a golden moment to bring government, health care professionals, industry and academia together to accelerate innovation and investment for this critical issue. No company, no industry, no country can afford to ignore the economic and social impact this wave of aging people will create."

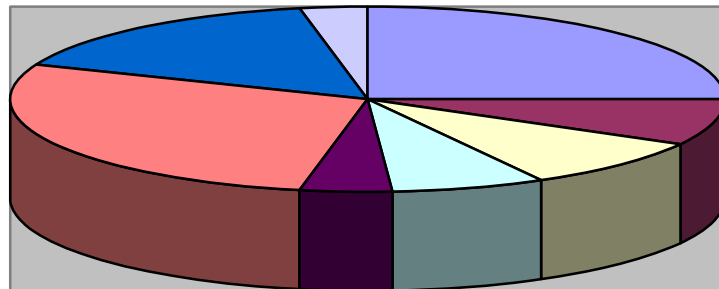
Better utilization of health-care technology offers a significant opportunity to help reduce costs and improve services. The application of biomedical engineering in









research, design and development of instruments and appliances that alleviate pain, restore health and extend life is an exciting area of future growth for the electronics industry.

The Medical Electronics Market

In response to these trends, the global market for medical electronics is expanding rapidly. According to Technology Forecasters Inc.(TFI), an Alameda, California based electronics consulting and research firm, the US medical device market has been growing at rates that are approximately twice the national GDP growth. The importance of new products and technological advancements is illustrated by the fact that the medical electronics industry invested over 11% of its sales in research and development in 2002. This level of spending is approximately three times that of an average US company.

Technology Forecasters estimates the global medical electronics market totaled \$44 billion in 2005 and forecast growth at an 8% annual growth rate to over \$65 billion by 2010. The breakout of the US medical device market by product type is shown in Figure X.X



 Surgical & Medical Instruments	 Electromedical
 Ophthalmic	 Lab Apparatus
 IVDs	 Surgical Appliances & Supplies
 Dental	 Irradiation

History of Medical Electronics

Two innovations, common in today's healthcare environment, evolved through the intersection of technical ingenuity and the deep compassion of medical professionals: the electronic pacemaker and the implantable defibrillator.

Pacemakers

In Minneapolis in the late 1940's Earl Bakken founded a small medical equipment service company, Medtronic. He worked with the heart surgeons at the University of Minnesota repairing their electronic equipment. After heart surgery, patients would often require an external system to pace the heart while recovering from the surgery. During a thunderstorm in the late 1950's, a power failure at the hospital resulted in an external pace system stopping and a young child dieing. Dr. C. Walton Lillehei asked Bakken if he could develop a pacing system that was both battery operated and portable.

While reading an article of *Popular Electronics* on an electronic metronome which contained a schematic diagram of the electronic circuit, Bakken immediately saw the similarity of a metronome to the heart. Based on this concept he developed a small, battery operated circuit that could be rate adjusted. He used a 9volt mercury battery to power this first external pacemaker. It was tested at the University of Minnesota lab and the following day was attached to a pediatric heart patient. It immediately restored the patient's heartbeat to normal. From this beginning, Medtronic later partnered with Wilson Greatbach and Dr. William Chardack to develop and market a new invention, the implantable pacemaker. Today Medtronic is the worlds leading medical technology company with over 37,000 employees in 120 countries.

Implantable Defibrillator

In another example of human compassion driving medical innovation occurred in the 1980's at Johns Hopkins. A close friend of Michael Mirowski suffered a cardiac arrest and the ambulance did not arrive in time to resuscitate him. Heartbroken, Mirowski envisioned the concept of an implantable automatic defibrillator. Miniaturizing an external defibrillator into an implantable package was a challenge. Dr. Mir Imran, with degrees from Rutgers University in electrical engineering and bioengineering, and also a graduate of Rutgers Medical School was asked to form an engineering team for the project.

This engineering group faced numerous challenges – define the normal heart rhythm, calculating how to detect a heart attack, determine when to shock or not to shock, method of implementing a safety system because false positive and negatives are not tolerable. The team borrowed some concepts from the pacemaker industry, but electronics and battery technologies had to be developed. As Dr. Imran stated, "It was another amazing experience, literally bringing patients back from the brink of death when seconds counted." This innovation eventually evolved into Guidant, another major medical electronics provider.

Electronic Treatments for Chronic Diseases

Of US healthcare spending, 78% was for treatment of patients with chronic illness. Today we see a proliferation of electronic products to diagnose and treat chronic diseases. In a presentation at the IPC's Technical Market Research Council in October 2005, Dr. Mark Phelps, Senior Director for Electronics Systems Technology of the Medtronic Micro Electronics Center discussed the future of medical electronics and emerging technologies. His presentation included a discussion of the variety of medical electronics products produced by his company for these treatments:

Heart Failure

Two conditions can lead to problems for heart patients: with the condition known as Bradycardia, the heart rate is too slow, and in Tachycardia, the rate is too fast or irregular which can lead to sudden cardiac arrest. Over 22 million people worldwide suffer from heart failure, where unsynchronized beating of the heart results in insufficient blood flow to meet the body's needs. This is a major healthcare expense in the US with spending estimated at \$40 billion. Multiple electronic therapeutic and monitoring devices for the heart are in use today.

Atrial Fibrillation

With atrial fibrillation, the upper chamber of the heart, the atria, beats rapidly and inconsistently. This affects 5 million people on a global basis and requires the most hospitalizations of all Arrhythmias. Multiple electronic therapy options are now available.

Central Nervous System Disorders

Movement disorders, such as Parkinson's disease, epilepsy, Dystonia, and chronic pain can be the result of disorders of the Central Nervous System. Today electronic technology offers multiple therapeutic options for these disorders including electrical stimulation and programmable pumps for drug delivery.

Diabetes

Today over 150 million people in the world have diabetes, the inability to produce or properly use insulin. This number is anticipated to double to 300 million by 2025. In America 4.6 million diabetics are insulin dependent. Today electronic glucose monitoring systems and programmable insulin delivery pumps are in common use.

Gastroenterological and Urological Disorders

Gastroenterological and urological conditions represent some of the world's most widespread medical problems. Stimulation therapy is becoming a standard method of care for urinary control. In addition, electronic stimulation devices are now being used for treatment of prostate problems and acid reflux disease.

Ear, Nose and Throat

Medical electronics is also being used in diagnosis and treatment of diseases and conditions affecting the ears, nose and throat. Power tissue removal

systems, nerve monitors, instruments, instruments, implants, image-guided surgery systems and portable pressure-pulse generators are a few examples.

Mental Disorders

An emerging field is electronic stimulators for the use in treatment of some mental disorders. Nerve stimulators involve the use of devices that are similar to pacemakers and heart deliberators, but are attached to the brain or other parts of the nervous systems. A nerve stimulation device has been approved to treat severe chronic depression in patients who did not respond to other therapies. The manufacturer estimated the potential market for this device at 4.4 million Americans. In another application, a vergus nerve stimulator has been developed to treat obesity. This implanted electrical stimulator is attached to the vargus nerve, a pathway from the brain down into the abdomen with branches to other major organs.

Telehealth

In conjunction with these technologies used to treat chronic illness, telehealth is coming to the forefront of medical technology. Teleheath combines telecommunications, information technology and conventional health education to improve health care quality and efficiency. Joseph Coughlin, director of the Massachusetts Institute of Technology's AGE Lab calls for a nationwide system to apply medical technologies. "The center of gravity of health care has been moving for some time from the hospital and doctors office to the home and the individual" says Coughlin.

Electronic systems are being developed aimed at assisting a "demographic tidal wave" of aging baby boomers. Innovations to help the seniors live independently are utilizing a wide range of technologies including sensor networks, artificial intelligence, robotics, location-based services, and user interfaces. Intel recently demonstrated three electronic innovations aimed at the older population: an in-home system to monitor Parkinson's disease patients, an automated system for making sure seniors take their proper prescription medications, and a system to keep Alzheimer patients socially active. In the future they hope to announce a home health care platform that lets health care professionals diagnose and treat patients remotely.

It is most interesting to note the evolution of Intel into the medical electronics arena. Five years ago, being the global leader in semiconductor technology and manufacturing, they conducted an in-depth marketing study to identify future needs in electronics. But to their initial surprise, when consumers were asked what they hoped was on the horizon, it was not a need for a larger flat-screen high-definition television or a smaller, sexier, cell phone. The emerging wish was "How can you help me take care of my aging parents?"

Today many advances are being made in this merging of telecommunication, computing and health care technology. The following offers some of the more interesting examples in development or existence today.

Lab-on-a Chip

STMicroelectronics of Switzerland has developed a “lab-on-a-chip” to provide a swift, low cost test for avian flu. Such innovation could decrease the possibility of a deadly pandemic. In less than one hour the semiconductor can compare synthetic DNA which mirrors flu types with a blood sample. In case of a match, the electronic chip emits a burst of energy which an optical sensor detects. The portable kit works with both human and avian samples. Costing less than \$10,000 the kit cost about a tenth of a comparable lab set-up.

Capsule Endoscopy

Given Imaging, an Israeli medical electronics firm, has developed the PillCam – a bullet-size capsule containing a tiny blinking camera set to transmit two photos per second to a computer hard drive. The PillCam routinely explores the tight, twisted area of the small intestine, which traditional invasive tube-and-lens endoscopes can not reach. Reviews conclude the PillCam is twice as effective as other diagnostic tools – including colonoscopies and push enteroscopies- at identifying disorders. The PillCam, which is swallowed by the patient and passes the natural way, sells for about \$450.

Implantable, Wireless Cardiac Monitor

Biotronik Inc, a German medical electronics firm, has developed the Lumos, an implantable cardioverter defibrillator. In addition to responding to irregular heart beats by shocking the heart back into rhythm, the Lumos automatically sends data on the patient’s heart to his doctor. Using wireless technology, the portable transmitter, which resembles a cell-phone, sends data automatically as long as the patient is within 20 feet of the unit. Physicians using the system have reported of being aware of a patient’s heart abnormalities, before the patient themselves know they have had an episode.

Implantable Identification

Hackensack University Medical Center has implemented a project to implant radio frequency ID (RFID) chips the size of a grain of sand in Alzheimer’s and lung disease patients, who might not be able to identify themselves during emergency. Using the RFID chips and an electronic wand to read them, and Hackensack hopes to eliminate medical errors and duplicate medical test.

Advances in Defense Medical Electronics

The Impact of International Military and Security Issues on the Electronics Industry, a report available from Technology Forecasters Inc., identified the increasing innovations in medical electronics developed for defense purpose. As

ironic as it seems, wartime economies can contribute to the development of technologies that will benefit the overall betterment of society. Many such examples can be found today in the field of medical technology.

Robotic Surgical System

The Robotic Surgical system would allow doctors to treat a wounded soldier on the battlefield from a remote location using advanced diagnostics and tele-operated instruments. The robot would not perform surgery on its own, but it would carry out commands of a surgeon controlling the process. The doctor, receiving a video feed from the robot, would use a system of surgical manipulators to perform the operation. As he moves his hands in manipulators, his actions and voice commands would be communicated wirelessly to the automated system, which would replicate his actions.

Advanced Prosthetics

There is a surge in the number of troops in Iraq and Afghanistan who have lost hands and arms. DOD has recently funded a research program to revolutionize upper-body prosthetics. The purpose is to develop improved artificial arms, aiming for one that will “feel, look and perform” like a real arm guided by the central nervous system. In July 2005, a major break-through in prosthetic-limb technology was demonstrated at the Rehabilitation Institute of Chicago as an injured electrician demonstrated the advanced robotic arm, using his thoughts alone to maneuver it.

Retinal Implant

The Naval Research Laboratory will soon begin clinical trials of a 3,200-pixel retinal implant that could restore vision to certain blind patients. This technology will give people with macular degeneration or retinitis pigmentosa the ability to recognize faces, read large print and navigate rooms.

Exoskeleton System

This system will develop an artificial skeleton which will help soldiers run faster, jump higher, and lift more weight. While the final systems is years away, the US Army has funded MIT and industrial partners to develop nanomaterials that can act as exterior support muscles.

Electrically Powered Artificial Muscles

These artificial muscles can exceed the performance of natural muscles by generating 100 times their force and elongate twice as fast. DARPA has awarded a study to the University of Texas at Dallas to enhance these for military use.

Smart Military “Medical Dog Tags”

New “medical dog tags” have been developed to facilitate rapid and more effective treatment of wounded personnel. They provide rapid RF linked contact that can access the injured medical data while in the field, enter the patient’s status, actions taken in the field and recommended treatment information. This

immediate radio link to the field hospital expedites follow-on treatment. Navy field test have indicated a potential reduction of 30% in field losses.

Battlefield Medical Response: The Virtual Soldier

DARPA has initiated a program called the virtual soldier. This project will develop a computational representation of the individual soldier that can be used to augment medical care off and on the battlefield. The system contain various sources of data including X-rays, CTs, MRI, ultrasound and vital signs data and will display in an integrated fashion the soldiers physiological and anatomical information with model results that predict outcome of a wound.

The Future of Medical Electronics

One of the greatest challenges in the medical electronics field is obtaining regulatory approval. It can takes up to six years to get a new medical electronic product to market. Once a device gets the approval from regulators, it has the twin challenge of persuading doctors to prescribe the devices use and getting insurers to pay for the product. It must demonstrate that such systems will have a positive impact on health care. Gaining approval and providing such evidence is a key piece of the new-product development cycle in medical electronics.

Emerging medical products will be thinner, lighter, flexible devices with more emphasis on patient comfort. Products will also be a combination of biological and electronic systems and smarter devices with closed loop sensors. The following technologies will be on the leading edge in the developments in medical electronics.

Leading Technologies in Medical Electronics
Communications technologies (wireless-low power)
Information management and advanced user interfaces
Sensors and smart devices
Visualization and navigation technologies
Diagnostics
Biotechnology
Device miniaturization technologies
Electromagnetic therapy
Advanced materials and tissue engineering

However, there is still much to be done in research in medical electronics. The Center for Aging Services Technologies (CAST) is a group founded in 2003 by the American Association of Homes and Services for the Aging in conjunction with a number of universities and electronics companies including Intel, IBM, Honeywell and Medtronic. And in testimony before Congress last year, Martha E. Pollack, a professor of electronics engineering and computer science at the

University of Michigan, stated, "There is foundational work still to be done, and it is work that must be done by multidisciplinary teams that include not only computer scientist, roboticist and electrical and mechanical engineers, but also psychologist, physicians, nurses, occupational therapist, privacy experts and representatives of the care-giving community."