TRENDS IN MEDICAL DEVICE DESIGN AND MANUFACTURING

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ABSTRACT
An aging population in the US wants increased quality of life through more and better treatment options without being restricted to a hospital, clinic or doctor's office for the treatment of chronic conditions. And while house calls by a kindly old country doctor carrying his little black bag may be a thing of the past, home health care is coming back – albeit in a thoroughly modern way. Medical diagnostic and treatment devices today are increasingly sophisticated computer controlled electro-mechanical measurement instruments previously available only in the most advanced laboratories.

The trend in medical device design and manufacturing is toward smaller, more portable products that require more advanced components, manufacturing technologies and automation techniques. Medical products covering the range of patient monitors, drug delivery systems, therapeutic devices, and life assist devices all are shrinking in size while increasing in performance and features.

Wearable and even implantable devices that monitor, administer, treat and track patient conditions are increasingly common replacements to large, complex instruments that up until recently only a physician or technician would typically use. Since these new products are patient portable, patient wearable, or implantable, designers look for low-power components, long-life rechargeable batteries, rugged designs, simple user interfaces, and low overall cost. In addition, with the patient as the intended user (and in some cases, the buyer), these new products increasingly include design considerations typically associated with consumer-type products such as industrial design, ruggedness, user interface, portability and wireless connectivity.

Similarly, the manufacturing requirements for these new product designs are beginning to look more like those for consumer products, including fine pitch component placement, high volume automated assembly and sophisticated test techniques.

This paper presents several examples of patient wearable medical products, identifies the unique design and manufacturing considerations of such devices, and contrasts them to traditional medical device design and manufacturing practices. Observations about the consequent impact on component selection, design methodologies such as DFM and DFT, and manufacturing techniques are also presented.

DEMOGRAPHIC DRIVERS
The primary reason behind the trend towards smaller, more sophisticated medical equipment is the increasingly wide range of health care services being delivered at home to recovering, disabled, chronically ill, or terminally ill people.

Aging baby-boomers make up the largest segment of this patient population. According to a study conducted by Kaiser Permanente's Medical Care Program, the greatest users of home-health services are older people — and with some 76 million Americans born between 1946 and 1964 heading toward retirement, this is also the most rapidly growing segment of the population.

More and more older people are electing to live independent, non-institutionalized lives, and are receiving home-care services as their physical capabilities diminish. Two-thirds of Americans over 62 have at least one chronic disease, with heart disease, diabetes and respiratory problems topping the list of chronic diseases for this age group. Consequently, medical devices that target cardiac therapy, diabetes, patient monitoring and pain management are the most common.

But even younger adults who are disabled or recuperating from acute illnesses or diagnosed with a terminal illness are choosing home care over extended hospitalization. Even chronically ill infants and children are receiving sophisticated medical treatment in a familiar and secure home environment. In all cases, these patients receive earlier discharges from acute care settings to home even though they still may need daily care.

OVERALL TRENDS
The trend in medical device technology toward portability and delivery of care at the bedside or in the home is accelerating the development of a range of next-generation monitoring, display, diagnostic and therapeutic equipment designed to be more compact, accurate and versatile.

These systems are geared toward a prevention-oriented, consumer-driven model for health care that includes innovations such as smart devices that can "think" for themselves, customized wearable devices, electronic patient records, and wireless internet-linked systems – all expected to

deliver convenient, user-friendly, intelligent health care in the home.

The idea is to make patients independent of their physician, to give them the opportunity to conduct simple measurements on their own and to actively participate in their health care – all while leading a more normal life.

Patient wearable products in cardiac pacing, pain management, drug delivery, blood chemistry monitoring (blood pressure, glucose, oxygen), auditory therapy, and neural monitoring and stimulus are already on the market.

The GMP LifeSync™ Wireless Patient Monitor (Figure 1) is a good example of the new generation of patient wearable products. The LifeSync™ System is the first monitoring system that eliminates lead wires and trunk cables between patients and bedside 12-lead or transport ECG monitors. The system employs two-way Bluetooth radios that transmit and receive patient ECG and respiration data to existing ECG monitors, and replaces lead wires with a disposable LeadWear™ System.

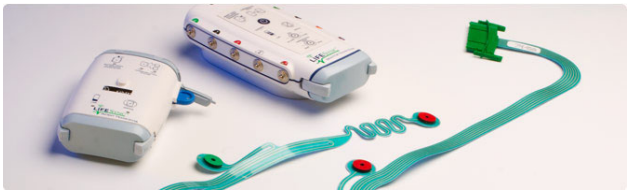

Figure 1: GMP LifeSync Patient Monitor

The next logical step is the further reduction from wearable devices to implants, again improving comfort for patients. Current day implantable medical electronic devices include pacemakers, ICDs, drug pumps, monitors and delivery systems, cochlear implants and neurostimulators.

Two common implantable devices are the hearing aid and the pacemaker. Today's state-of-the-art hearing aids incorporate the latest in DSP (digital signal processing) technology together with low-power analog amplification. Similarly, pacemakers (Figure 2) today take advantage of sophisticated microprocessor technology to monitor, analyze and control cardiac rhythm.

Figure 2: Medtronic and Guidant Pacemakers

Other advanced equipment used in diagnosis and patient care is migrating from the hospital emergency room, to the bedside, to the physician's office, to offices, and finally to the patient's home.

A good example is the Automatic External Defibrillator (Figure 3). An AED is a small, portable device that analyzes the heart's rhythm and prompts the user to deliver a defibrillation shock if it determines one is needed. Once turned on, the AED guides the user through each step of the defibrillation process by providing voice and/or visual

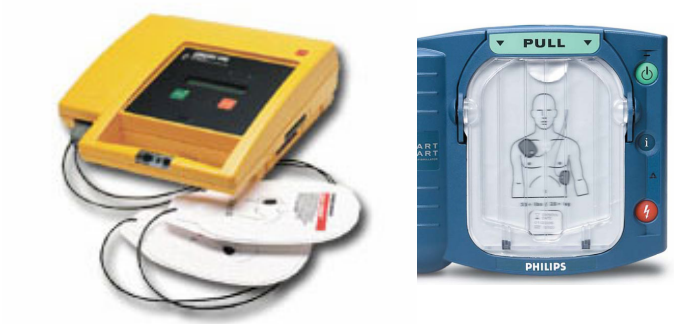

Figure 3: Medtronic and Philips Automatic External Defibrillators

prompts. Already offices, airports and airplanes carry AEDs.

Equipment that used to be the size of a tabletop box now mounts on a pole with the anesthesiologist's other equipment and shows the data on a computer screen, also attached to the pole.

Even products that have never been electronic, such as oxygen bottles, are getting a high-tech facelift. One Canadian company is developing a battery operated, wearable oxygen concentrator. Designed to fit into a belt pack, the system takes normal atmospheric air and strips out the nitrogen, delivering highly concentrated oxygen. The product relieves patients of the burden of carrying around bulky and heavy oxygen bottles.

Implantable microelectronic devices are being used for monitoring, control and treatment in implants and artificial prostheses for joints, hips, legs and spines. These microelectronic implants monitor temperature, pressure and strain to give orthopedic surgeons real-time data on healing and prosthesis efficacy.

Micro-array lab-on-a-chip products are improving point-of-care diagnostics. A micro-array lab-on-a-chip is an array matrix that lets doctors instantaneously analyze fluids, cells, and even DNA structure right in the office.

One method currently being developed uses an active semiconductor substrate that allows on-chip synthesis of molecules as well as on-chip electrochemical detection of

assay results. This technology can be applied to the detection of nucleic acids, proteins and small molecules. These semiconductor biochips are at the heart of development efforts to create compact instruments for hand-held diagnostic testing and point-of-care monitoring.

In addition to simply monitoring and reporting certain medical parameters, new medical devices are being developed that have the ability to measure, monitor, diagnose and treat specific conditions. Today's adaptive pacemakers and AEDs are good examples. In addition, there are patient wearable drug pumps that monitor blood glucose levels and administer the right level of insulin automatically.

Technology is also being developed that monitors the heart rate of a patient with congestive heart failure and triggers a timed heart assist cuff that provides a needed boost to the weakened cardiac output of the patient (Figure 4).

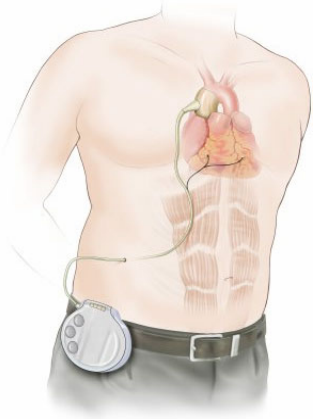

Figure 4: Sunshine Heart Heart Assist Device Concept

All of these products rely on advanced sensor technology and microprocessor-based decision-making algorithms to evaluate patient conditions and administer the appropriate therapy when needed.

DESIGN IMPLICATIONS

Medical device design practices are subject to audit by the US Food and Drug Administration (FDA). The guidance document titled "Design Control Guidance For Medical Device Manufacturers" provides a good introduction to FDA oversight of medical device design practices and can be found at www.fda.gov/cdrh/comp/designgd.html.

The introduction to this document reads:

> *To ensure that good quality assurance practices are used for the design of medical devices and that they are consistent with quality system requirements worldwide, the Food and Drug Administration revised the Current Good Manufacturing Practice (CGMP) requirements by incorporating them into the Quality System Regulation, 21 CFR Part 820. An important component of the revision is the addition of design controls.*
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> *Because design controls must apply to a wide variety of devices, the regulation does not prescribe the practices that must be used. Instead, it establishes a framework that manufacturers must use when developing and implementing design controls. The framework provides manufacturers with the flexibility needed to develop design controls that both comply with the regulation and are most appropriate for their own design and development processes.*

In addition to the FDA regulations, five significant trends in medical device designs: Smaller, Wearable/Implantable, Wireless, Reliable, and Intelligent, impose a variety of constraints and sometimes conflicting design challenges on medical device designers today.

Smaller: Patient wearable devices must be small and light enough to be worn unobtrusively on the body (such as hearing aids), hidden under or incorporated into articles of clothing, or disguised as everyday accessories such as a watch, disc player or belt pack. To accommodate this, the overall package dimensions must be minimized due to the size and weight restrictions.

At the same time, designers want to add more functions to the devices. This directly conflicts with the desire for smaller packages. New patient wearable medical devices are being developed that have many of the following capabilities:

- High speed microprocessors or microcontrollers for onboard intelligence, analysis and control
- Datalogging memory to store and download patient measurements
- Advanced electrical, chemical, physical or optical sensors to monitor patient parameters
- Wired and wireless communication, including Ethernet, USB, RS-232, WMTS, BlueTooth, WiFi (802.11), IR, GSM, and GPRS
- Battery operated, with rechargeable batteries
- Simple, iconic, numeric or graphical user interface with either a monochrome or color LCD display

Putting all these features into a small package is no small task.

All this added functionality requires space, consumes power and generates heat. The electronics, display, battery, and interconnects for sensors, power, and communications all compete for limited space, power and cooling. Component selection (size), power consumption, packaging techniques and thermal management all become part of the design considerations and trade-offs.

Advanced discrete component packages such as 0402 and 0201 SMT components, and component mounting and chip scale packaging technologies such as BGAs, Flip Chips, flex circuitry and COB are required to meet the overall size constraints. When production volumes permit, higher levels of customization and integration such as FPGAs and ASICs become viable.

In order to pack as much functionality as possible into as small as space as possible, component placement technology also has to support higher density designs: flip chips with I/O pitch as tight as 250 microns, chip scale packaging down to 0.5mm package pitch, COB with 60 micron die pitch, and 0201 SMT component placement accuracies down to +/- 12 micron.

The need for micro miniaturization extends beyond just the electronics and includes areas such as micro-fluidics and small-scale mechanical and optical components. Emerging technology such as Micro Electro-Mechanical Systems (MEMS), and even nanotechnology components are being developed for medical and biomedical applications.

Fortunately, many of these technologies have been developed and perfected for small consumer electronics products, such as cell phones where volumes and overall economies of scale make the investment in technology development worthwhile.

Wearable/Implantable: Patient wearable or implantable medical devices typically rely on batteries as the primary power source. After size, the overall power budget for the device directly affects the size of the battery and service life of the device. Wearable devices can have rechargeable batteries, but for implanted devices that use a battery for their primary source of power, battery life is critical: every replacement requires a surgical procedure. Inductive charging might be an option, but relies on the user/patient having access to a charging device whenever necessary, which is an inherent risk factor.

Typically, a rechargeable battery power supply should support a minimum of 8 hours normal use without recharging. In some cases this is being extended to 16 hours or more. For non-rechargeable devices such as implants and other long-term-use devices, battery life of upwards of 3-5 years is required.

Apart from selecting low-power components such as low voltage CMOS and high efficiency mechanical components like pumps, motors and valves, reducing the duty cycle or initiating a sleep mode can help reduce the power consumption of continuously operated equipment.

Implantable devices, or even patient wearable devices that come in contact with the skin, have additional design constraints.

All medical devices that come in contact with the body must be biocompatible. Biocompatible materials must be stable in the physiological environment, with no deterioration. They must be non-toxic for the cells or be encapsulated with a non-toxic material that serves as an insulation barrier. Materials must have smooth surfaces to prevent induced trauma of tissue and nerves. They should not be brittle or heavy-weighted, and should be flexible enough to conform to the natural soft tissue.

Examples for biocompatible materials are solid materials such as chirurgic steel, gold, certain types of ceramics and glasses, coatings like silicone and parylene, molding plastics such as macrolone, polystyrene and PMMA.

Implanted devices must also be hermetically sealed so as not to allow ingress of bodily fluids or contaminants, or allow internal compounds, chemicals or liquids to escape. Still, the outer shell of the sealed device must use biocompatible materials. The human body is a harsh environment, more corrosive than one might think. Biocompatibility is necessary to protect the device as much as it is to protect the patient.

Wireless: Whether in the hospital, at a physician's office, or at home, medical devices are going wireless. A variety of technologies are being deployed, including WMTS, BlueTooth, WiFi (802.11), GPRS, GSM, and IR. The reason is simple: untethered ambulation; allowing the patient the freedom to move about the hospital room or at home without being tied up in cables.

The wireless links are two-way: for downloading programming or calibration data to the device, and for extracting measurement data from the device. In many cases the patient data is fed into a PC for analysis, and may even be transferred to a central patient records database in the hospital or doctor's office.

Some new products can be monitored and controlled from a remote location, allowing a physician direct access to the patient information without having to be present. These devices record patient information such as blood pressure measurements, and then transmit that information either over a computer line or wirelessly to the patient's healthcare provider.

Especially with implantable devices, wireless communication with external readers/programmers is mandatory for programming, calibration and data extraction purposes.

The primary design consideration in adding wireless capability to a device is that it typically requires a much higher power budget: to power the transceiver plus the associated microprocessor and support electronics (data storage) that wireless capability implies. This in turn reflects back on the earlier two design considerations of size and battery power.

Conversely, a wired configuration adds mechanical issues including large, expensive hardware that can impact the overall device size and cost.

Reliable: Medical devices, particularly those that are life-sustaining, must have high reliability. Useful product life can extend to 3-5 years. Implantable devices cannot be repaired; they must be replaced if they fail, and replacement requires surgery. Even wearable devices may not be repairable.

Now with more patient wearable devices (as opposed to clinical or laboratory devices) the need for ruggedness is increasing. Once outside the protective confines of a hospital or clinic, the use environment is hostile. Many of these devices undergo constant use, 24x7. They are subjected to shock, vibration, dropping, misuse, sweat, dirt, contaminants and water (shower, bath or pool). For many devices an IP rating of 65 or better is desirable.

Aside from simple product reliability, another important aspect of reliability is operator error. With more medical devices targeted for individual patient use in the home, operation of the device must be simple. Instructions must be clear, easy to follow, and non-technical so the anticipated users – often senior citizens – can operate the products safely and effectively. There is no trained, experienced technician there to make sure the device is worn or operated properly. The device itself must also be easy to manipulate – sort of the opposite of child-proof caps on medicine bottles. Patients with limited dexterity, visual acuity or mental faculty must be able to use the device properly by themselves.

For this reason, the FDA through CDRH (Center for Device and Radiological Health) has provided human factors guidance to manufacturers on device design that will reduce the likelihood of user error. This guidance document, titled "Medical Device Use Safety: Incorporating Human Factors Engineering Into Risk Management," can be found on CDRH's Web site at www.fda.gov/cdrh/humfac/1497.html (the document is also available as a PDF).

Intelligent: Medical devices are getting smarter. Embedded microprocessors, SOC (System On a Chip), SBC (Single Board Computers), integral PDAs and advanced sensor technology are all common elements of today's medical devices. The computing power is required to support the sensor management, signal processing, data collection and analysis, wired and wireless communications, and user interface displays used on new devices.

As clock speeds increase with advances in microprocessor design, the higher frequencies make EMI and EMC compliance more difficult to achieve. Shielding and noise immunity become a bigger challenge.

Some of the more sophisticated sensor technology being used today requires extremely low-level measurements – electrical, optical, thermal, chemical and biological. Noise immunity, suppression and isolation become significant challenges, requiring complex algorithms and DSP.

Patient wearable devices often record patient data into memory for later download and analysis. In some cases, the data is analyzed by the device itself in order to modify the ongoing therapy, as in the case of adaptive pacemakers or drug pumps. Data storage and analysis requires memory, processor power, on-board intelligence and external communications.

The implications on software development are also significant. A single device may require development of embedded code (firmware), application software that runs on a host or connected PC, and a variety of custom or semi-custom device drivers.

MANUFACTURING CHALLENGES

The design trends discussed previously present a number of significant challenges. In general, these challenges fall into three areas: assembly, test and compliance.

Assembly: Small component dimensions make manual assembly and inspection essentially impossible, so special automated equipment is required for handling, placing and attaching the components during assembly operations. Keeping machinery current and compatible with the latest component geometries can be expensive.

Once medical products successfully pass the FDA approval process, ramp to production is fast. Complete and accurate manufacturing documentation and assembly instructions are critical to achieve successful pilot runs and quick ramp to volume. Products that have been designed with DFM/DFT (Design for Manufacturing, Design for Test) stand a much better chance of ramping to volume successfully.

New technology advances in semiconductors and SMT components can create obsolete parts problems. Time to market for a new medical device may take years, including the FDA approval process. With some parts available only for a few years, parts originally designed into the product may no longer be available once the product actually receives FDA market approval. Mitigation strategies include part obsolescence planning, lifetime buys, and ultimately redesign efforts to accommodate part shortages.

With more individual user-patient devices coming on the market, manufacturing volumes will increase. Some devices can reach volumes similar to consumer electronics products. Higher volumes also dictate automated assembly to achieve throughput goals and lower unit costs.

Manufacturing process controls and Six Sigma quality practices are increasingly important to ensure product quality, especially since many new devices are intended for single use and are not repairable (e.g. hermetically sealed).

Test: Small board sizes may limit physical access to test points so in-circuit test (ICT) is more difficult, and sometimes is impossible. Other manufacturing defect detection schemes become necessary, such as AOI, X-Ray, BIST and Boundary Scan.

Here again, high production volumes dictate TAKT times that preclude manual test operations. Automated test, including final product performance test is required.

Compliance: Medical device manufacturers must be registered with the Food and Drug Administration (FDA). Registration entails establishing and documenting cGMP procedures compliant with 21 CFR 820 appropriate to the device classification to be manufactured, and successfully passing an audit by the FDA.

The FDA has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties. Each of these generic types of devices is assigned to one of three regulatory classes (Class I, II or III) based on the level of control necessary to assure the safety and effectiveness of the device.

Device classification depends on the intended use of the device and indications for use. For example, a scalpel's intended use is to cut tissue. Indications for use can be found in the device's labeling, but may also be conveyed orally during sale of the product.

In addition, classification is risk based, that is, the risk the device poses to the patient and/or the user is a major factor in the class it is assigned. Class I includes devices with the lowest risk and Class III includes those with the greatest risk.

CONCLUSIONS

The market demand for medical products that are smaller, wearable/implantable, wireless, reliable and intelligent impose a variety of constraints on medical device designers today. These design challenges are sometimes conflicting, and require compromises between desired device functionality and design capability.

Careful consideration must be given to the impact additional functionality will have on component selection, packaging technologies, power budget and ultimate product size. Choosing the correct balance between these factors can significantly impact development cost, manufacturing cost, and ultimately, market acceptance.

Aside from technical challenges, medical device designers must also consider the regulatory requirements imposed by the FDA on medical product design and manufacturing. As medical products move out of the hands of trained physicians and into the hands of individual patients, greater care must be given to human factors engineering, including design considerations of form, fit, and interaction with the human body, user interface, and instructions for proper use.

Manufacturing tools, processes, and equipment must keep pace with the latest advances in components and component packaging.

In order to meet cost and quality goals, design and manufacturing engineers must incorporate rigorous manufacturing quality programs using Six Sigma methodologies. In addition, DFSS, Design for Six Sigma, a data-driven quality approach to designing new products or processes for six sigma quality, typically using a DMAIC or DMADV five-step process, should also be considered.

This includes using design practices such as DFM/DFT/DFA (Design for Manufacturability, Design for Test, Design for Assembly) as part of the standard approach to design.

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