Medical devices come home:

How to address the challenges

A white paper by Plexus Corp.

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Executive Summary

The use of electronic medical devices is increasingly migrating from health care centers to homes. A new set of challenges faces device designers and manufacturers. In the past, it was nearly impossible to conceive of a patient undergoing dialysis in his or her own home, linking remotely to his or her physician for daily blood pressure or glucose checks, or downloading pacemaker activity via a telephone line. Today, all possibilities are in development, and the advancement of innumerable more in-home medical devices is on the health care horizon. The accessibility of wireless technology, mobile applications and other connectivity platforms facilitates device manufacturers' ability to make complex medical devices available for home use. This trend offers beneficial new opportunities to multiple , including added convenience for health care providers; improved care for patients; and cost savings for insurers and government payers.

Taking these devices out of the security of a hospital setting also introduces significant HIPAA, FCC and FDA regulations. Thus, regulatory and technical requirements for bringing these devices to market are still catching up with the eager anticipation of health care suppliers and providers.

This paper explores the impact of recent market trends surrounding the large-scale introduction of medical devices in the home. It outlines challenges of pursuing this opportunity in product development and offers insight from key industry insiders and corporate stakeholders on the oft-conflicting expectations of patients, health care providers, device designers and regulatory bodies.

Section 1: Demand Driven by Demographics

The shift in the demand for medical devices for the home is a global trend. The global market for consumer medical devices is expected to grow at a steady rate with revenue forecasted to reach $8.9 billion by the end of 2014 (see figure 1).

According to IHS, a global scientific, technical and medical information company, revenue expansion for the next several years will range from five to nine percent, with industry revenue amounting to $10.6 billion by 2017, as shown in figure 1. (Source IHS, Inc., September 2013)

So what is driving this multibillion dollar growth?

1.1 Global Drivers Increasing Need for Medical Care

Three global drivers for the increased demand of consumer medical devices stand out:

1. An increasingly aging global population and the associated rise in chronic illness, leading to more long term care.

2. Patient expectations of ubiquitous and constantly accessible healthcare.

3. Cost pressure on healthcare system

First, let's discuss aging demographics and rise of chronic care...

Roeen Roashan, Analyst for Consumer Medical Devices and Digital Health at IHS Research recently explained, "One important reason for the consistent rise in revenue over the years (in the consumer medical device sector) is that the worldwide population of those age 65 and above will continue to grow. As a result, there will be an increased need for health monitoring."

In his book, The Creative Destruction of Medicine, cardiologist, author and healthcare technologist Eric Topol, M.D. writes of the phenomenon of Aging in Place: "The concept of wireless monitoring to create a 'smart' medical

Figure 1: Forecast for Consumer Medical Devices (billions of US Dollars)

Global Revenue Forecast for Consumer Medical Devices (Billions of U.S. Dollars)

	2012	2013	2014	2015	2016	2017
Billions of US Dollars	7.9	8.2	8.9	9.3	10.0	10.6
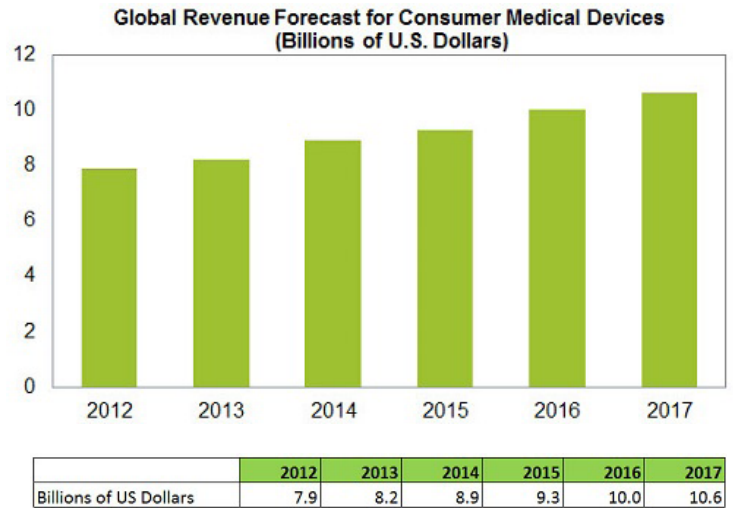
home may be particularly well suited for select seniors, preserving their ability to stay at home by providing a greater safety margin. Nearly all seniors, more than 95 percent in surveys, want to stay in their own homes rather than move to an assisted living facility or nursing home."

Closely associated, the global healthcare system will see a rise is expenses associated with aging people living with chronic diseases that require consistent monitoring. Chronic conditions such as cardiovascular disease, diabetes and obesity continue to increase and are no longer diseases primarily prevalent in Western societies. According to the World Health Organization, cardiovascular disease or hypertension is responsible for more than 30 percent of annual deaths worldwide. (Source: World Health Organization Report on Global Health Estimates, 2000-2011)

Growth rates for consumer medical devices also look promising due to government initiatives in preventive care. Efforts from public and private health organizations result in increased awareness among consumers of the benefits of consistent health monitoring, especially for chronic

conditions. Due to the rising number of consumers investing in their physical well-being, personal care devices such as activity monitors, body composition analyzers and heart-rate monitors are among the fastest-growing consumer medical devices.

"I want my medical treatment to fit my lifestyle and not the other way around."

Secondly, patient expectations about the convenience of their medical treatment are driving the growth in demand for in-home medical devices. Patients expect more from their medical treatment options deriving in large part from their comfort and experience with computers, tablets and smartphones.

Keely Wagner, Senior Hardware Design Engineer at Plexus comments on changing patient expectations:

"Because technology is now an integral part of our daily routine, people have come to expect it in every part of their lives. Wireless technology specifically has been at the forefront of that expectation. We don't want to have to wheel around medical devices with wires strung from them and having to connect them to local ethernet connections. We as consumers expect them to be mobile and connected."

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Finally, recent seismic changes in U.S. healthcare legislation, most notably the Affordable Care Act, puts pressure on hospitals and healthcare facilities to reduce costs which, by extension also puts pressure on device OEMs.

Reducing service time, or time spent with patients by health care providers, can reduce overall cost for healthcare facilities; therefore, some experts expect in-home medical

devices will fulfill that desire. Jack Levin is a Partner at Venetia Systems, a consulting firm specializing in helping product manufacturers be more solutions focused with M2M and the Internet of Things. Levin explains, "In the medical sector, the traditional doctor-patient monitoring element is one of the highest cost factors in the healthcare system. For instance, after surgery, mobile health devices such as home monitors allows patients to be placed in a much lower-cost treatment environment while ensuring the patient is in compliance with his or her prescribed treatment. This ends up relieving a lot of financial stress on the healthcare system."

1.2 Preparation and Early Engagement Ensures Success

Motivated by all the technology available, engineers and product managers are eagerly exploring how to bring these consumer-driven devices to market. Given the complexities of patient and provider expectations and regulatory compliance, product developers must thoughtfully build time and testing into their earliest attempts at product realization.

Jeffrey Newhouse, Senior Quality Engineer at Plexus Corp., explains: "Performance standards are now recognizing the importance that risk management and essential performance has on the device under evaluation. As such, Safety Agencies are now required to review your risk management file and evaluate essential performance during test. In order to successfully design a device to meet these requirements it is essential to have a well-organized risk management strategy and conduct early engagement activities with your Safety Agency in order to assure a successful certification during your official submission."

Section 2: Enabling Technologies: Opportunities and Challenges

2.1 Wireless Communication

The two most common benefits of wireless communication are mobility and access to real-time data. Patient mobility allows them to move freely within a hospital setting, but more importantly, leave the hospital while still being monitored. An example of such a product is an implantable device that monitors glucose levels while a patient is in the comfort of his or her own home. This same device transmits real-time data to a networked computer in the patient's home, allowing healthcare professionals access to the data remotely. (Source: The Wireless Revolution in Medical Devices, http://www.medicaldevice-network.com/projects/wireless_revolution)

Wireless communication solutions are largely accessible. Keely Wagner of Plexus said, "There are a range of wireless modules readily available for manufacturers to integrate into their products requiring minimal engineering efforts." However, the complexities of wireless medical devices still pose challenges that engineers and project managers need to overcome.

For instance, commercial product time cycles differ greatly from those of medical devices. Wi-Fi technology changes quickly and a durable medical device has an average life cycle of seven years. Designers and engineers need to be sure to incorporate technology that can accommodate and adapt to the changes that surround it. Currently, astute Wi-Fi module makers are aware of the discrepancy in end-device requirements and provide solutions that are designed for these longer product life cycles.

2.2 Smart Phone Technology and mHealth Applications

Smart phone technology is quickly evolving into medical device technology. Jack Levin said that smartphones, or mobile devices, are already playing an important role in health care in what has become known as mHealth. "We see more and more healthcare applications working in combination with mobile devices, with companies leveraging their medical devices or services around the smartphone."

Remote patient monitoring will provide the most cost savings to the healthcare industry when it results in less time in hospitals and fewer outpatient visits. These benefits are further enhanced by the combination of smartphone apps and mHealth attachments in collecting data, delivering information directly to patients and providers, and real-time monitoring.

One example of this is the development of cardiac monitoring systems. Sensors are attached to the body, yet the technology utilizes the patient's phone for all its communication. Instead of building the communication capabilities into the medical device, the system is taking advantage of the fact that the majority of the technical features required to enable its communication features are already integrated parts of the smartphone.

2.3 The Rise of mHealth and its Current Limitations

The integration of mobile devices into a patient's life is more accessible today thanks to the wide availability of mHealth applications. This can range from applications that support a healthy diet, to applications that provide education about surgical procedures. However, many pressing questions remain:

- To what extent can apps support a patient's medical condition or his or her treatment?
- Can advice and treatment be given via a smartphone and expect to be implemented properly?
- Is the data that is being transferred secure and properly documented in the patient's records

How do physicians, nurses and other healthcare professionals see the advent of mHealth devices and apps that transfer care from the clinic to the home?

Dr. Orrin Franko is an orthopedic surgery resident at University of California, San Diego. Dr. Franko is also the Founder and CEO of TopOrthoApps.com, a website that educates physicians on benefits and limitations of apps along with providing reviews.

Franko stated, "Today, patients expect more when it comes to accessibility of their medical care. Many patients feel physicians should be available at their disposal prepared with clear information to make complex disease and treatment easily understandable to them." According to Franko, apps have been able to assist in meeting some of these demands by providing illustrations of a surgical procedure or by providing patients with a post-surgical treatment plan to follow. "These are beneficial tools for patients and may help to minimize health care costs, but still don't relieve the workload for physicians themselves." In Franko's opinion, the best mobile apps are ones designed or developed jointly with physicians and are geared towards supporting treatment, improving patient insight and ultimately contributing to the success of the care objectives.

However, Franko cautions of several challenges that mHealth devices and apps present to the healthcare system. He opines, "Simply collecting more data won't automatically lead to better patient care." For example, Franko is concerned that even though devices are capable of collecting patient monitoring data like vital signs or glucose level on a 24/7 basis, databases and case histories don't exist yet that help physicians understand this data deluge. Furthermore, Franko feels, "There is always risk when diagnosing or proposing a treatment plan without physically seeing the patient."

Chad Walters, Senior Industrial Designer at Plexus, comments: "When we are designing products or applications we empathize with the target audience of that device. We will spend an entire day with physicians to understand how they interact with current devices and what needs are unmet or what challenges they see with the new product we are developing."

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A good example of an application Franko would recommend is one that is a complete resource for patients considering knee replacement surgery. The in-app features include a calendar with reminders of surgery-specific details and checklists, e-mail alerts to remind patients what to do and when, and location-based resources for local hospitals and surgeons with quality outcome data and more.

"The rise of mHealth applications has certainly helped enable independent patient care and given patients more freedom and control. I see the healthcare system overall accepting this trend as they hope to see cost reductions. But on the flip side, I see hesitation with physicians giving up face-to-face interaction with their patients. It's risky," Franko concludes.

2.4 Security Challenges: Intermittent Wi-Fi Networks and Medical Bands

The rise of wireless communications in the medical space immediately raises security-specific challenges. Cellular networks like 3G or 4G are still relatively vulnerable ways of transporting data, which piques the interest of regulatory bodies.

The network's wireless signal is a big concern relating to the performance of the medical device. To overcome intermittent signal strength, current available techniques include buffering and queuing. The configuring of a mobile device to work on Wi-Fi is a real challenge, especially if it is moved in and out of various Wi-Fi networks and initiates new manual logins each time. Overall, Wi-Fi and cellular networks present relatively unstable connections for medical devices, which can bear significant security risks as reliability is crucial to their operation.

One alternative in the medical sector is the use of previously unlicensed frequency bands. Medical telemetry bands are available from the Federal Communications Commission (FCC) and are specifically designed to provide secure options for monitoring patient developments, making the use of the device much more safe and reliable. (Source: Federal communication commission, wireless medical telemetry service, http://www.fcc.gov/encyclopedia/wireless-medical-telemetry-service-wmts)

Working with a product realization company that is aware of these challenges in wireless applications is imperative. The Food and Drug Administration (FDA) ensures that before all wireless medical devices are introduced into the market, that they be properly tested and that the manufacturers have considered, outlined and tested the potential limitations associated with wireless connectivity (Source: Cutting the Wires: FDA Provides Industry Guidance, http://blogs.fda.gov/fdavoice/index.php/2013/08/cutting-the-wires-fda-provides-industry-guidance)

2.5 Privacy Challenges and Related Regulation

Not only do OEMs and device manufacturers have to keep tabs on FDA regulations, but when collecting patient data, they also have to make sure they are HIPAA and HITECH compliant. Both of these acts ensure that protected health information (PHI) is confidential and secure when it is transferred, received, or shared.

The security of data being transferred over Wi-Fi is being studied and as a result additional regulations are being developed to address these issues. Doug Biette, Vice President of Medical Device Development and Manufacturing at United Therapeutics commented, "Regulations are not keeping up with technology. Data protection is a big topic in the medical industry, but all of the hoops manufacturers have to jump through to get products approved are limiting innovation."

Bluetooth technology wireless protocol in the medical space and provides a bit more data protection than traditional Wi-Fi methods. An article on the wireless revolution in medical devices shares that Bluetooth was designed to allow small groups of up to eight devices to communicate with each other over a Personal Area Network (PAN). These ad hoc networks have the potential to make seamless the integration between medical equipment in hospitals and at home. Patient privacy can easily be designed into products, since Bluetooth supports many security features, including password protection and encryption. (Source: The Wireless Revolution in Medical Devices, http://www.medicaldevice-network.com/projects/wireless_revolution)

3.1 Designing for the Home vs. Professional Environment

The home environment is less uniform and much more unpredictable than a hospital or medical facility. Medical device designers have to incorporate feature sets that overcome those obstacles while ensuring proper device function.

"Incorporating the proper feature set into a medical device that will be used in a patient's home is the most challenging hurdle an industrial designer has to face when designing a new product," says Chad Walters, Senior Industrial Designer at Plexus . "The challenge is what does the device actually need and why?"

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Industrial designers have to be cognizant that they are designing devices which will be used by a wide range of patients with varying levels of proficiency. Simple and straightforward is best, Walters believes. "Just because we have the technology to incorporate a feature set, doesn't always mean we should," he explained. "We should only be adding features to the device if they are required to make the device functional or add value to the patient's care."

There has been a strong demand for devices featuring touchscreen capabilities. Yet despite their modern look and feel, this feature can unnecessarily prolong the development of the product and add unwarranted costs. It is ultimately the decision of the manufacturer, but often the technology the patient demands isn't feasibly integrated into his or her medical device.

It is the responsibility of an industrial designer to incorporate the proper feature sets while meeting the requirements of the product and keeping it easy to use. "This is how the method works at Plexus." Walters described, "We are involved early and work closely with the project team throughout the whole process to ensure our customer's needs are being met and that we are delivering a product that will improve the lives of patients."

- An industrial designer ensures the right questions are being asked about the required performance of the product and the environment in which the product will be used.

- The designers then work closely with software, electrical, and other engineers to discuss the types of technology that can be incorporated.

- This is followed up by end-user research which may involve the use of 3-D models and watching actual patients interact with a to-scale model of the product.

3.2 Usability and FDA Regulations

It is critical for the success of the product to get the end-user of the device involved early. This is true both for medical devices designed for a hospital setting and individual homes. Gathering end-user feedback isn't just for successful device function—it is also required documentation for the FDA.

Companies need to demonstrate that the feedback they receive from test groups of end- users is being taken into account at each step in the design process and that these changes are ultimately improving the functionality or usability of the device. Failing to actively seek end-user feedback throughout the development process is frowned upon by official regulatory bodies. A well-informed product realization partner will know this.

3.3 Changing Landscapes in Medical Device OEM Business Models

Medical OEMs have to get creative with their business model strategies because of recent significant changes in the medical industry. Stricter regulations and cost constraints are making it more difficult to design products that previously would have been an easy sell. The growth potential with in-home medical devices and mHealth shows signs of hope for device OEMs whose current or previous business model is struggling.

As Doug Biette of United Therapeutics stated, "We have invested a significant amount of money in human factors engineering to align with products that now need to be more personalized for at-home patient use. We also added to our market research budget to ensure we are aligning with end-user needs."

Full product realization companies are of added value to OEM's changing their business model because they provide access to a broad spectrum of key resources that all work in tandem to meet the customer's requests such as:

- Quality engineers who keep tabs on regulatory standards

- Hardware and software engineers who are on top of newest technology advancements

- Industrial designers who specialize in human factor engineering

The value of working with one company is the cohesion of all resources aligning to produce the best possible product.

Today's medical electronics market has seen an explosion of technologies that will have a lasting impact on the way patients and providers experience health care. The combination of rapid technology developments together with the expectations of increasingly tech savvy patients is driving lasting changes in the medical device space.

The impact of bringing more medical devices into the private realm of the patient's home environment will be felt across the entire healthcare sector, driving changes in hospitals, homes, the economy and society as a whole. Working with a partner that supports product developers at each point in the process is key to success.

> *"As a partner to many of the leading global medical device companies, it is exciting to be a part of and to see the positive outcomes made possible by remote patient care. Industry cost pressures are inevitable but cost savings can never come at the expense of patients. Remote patient care empowers patients, ultimately resulting in both reduced cost to the healthcare system and improved patient care." Michael Tendick, Market Sector Vice President at Plexus*

Seek out tightly integrated industrial design and engineering relationships with specialist teams working across all disciplines to create beneficial intersections where ideas and innovation happen. The medical device market will become increasingly complex, more specialized and more heavily regulated. With the right support, insights and infrastructure, companies can use new technologies to stay on top and lead the market in new medical device development.

About Plexus Corp. – The Product Realization Company

Plexus (www.plexus.com) delivers optimized Product Realization solutions through a unique Product Realization Value Stream service model. This customer-focused services model seamlessly integrates innovative product conceptualization, design, commercialization, manufacturing, fulfillment and sustaining services to deliver comprehensive end-to-end solutions for customers in the America, European and Asia-Pacific regions.

Plexus is the industry leader in servicing mid-to-low volume, higher complexity customer programs characterized by unique flexibility, technology, quality and regulatory requirements. Award-winning customer service is provided to over 140 branded product companies in the Networking/Communications, Healthcare/Life Sciences, Industrial/Commercial and Defense/Security/Aerospace market sectors.