



The Dario glucose monitoring system works with a diabetic's smartphone to help monitor glucose levels and manage the disease by recording results and other user-entered information on a cloud-based data system.

Smart, New Medical Devices Coming to Market Faster

The FDA tries to keep up with medical device market shift to wearable devices that collect, analyze, transmit data

Karen Haywood Queen

Contributing Editor

The medical device industry is evolving to create better tools to help aging patients and their doctors manage chronic conditions outside of a hospital. Many of these devices and apps look like and/or work with smartphones. The goals are to lower costs, deliver value-based results and meet consumer demand.

Other trends that impact manufacturers include an aging population, improved quality inspections and the regulatory process, according to a recent report by EWI (Columbus, OH), a nonprofit engineering and applied R&D company. The Affordable Care Act also plays a role.

While the market for traditional metal parts used in implantable devices for knees and hips will be fairly stable in the year ahead, changes are coming, said Bryan Hughes, director of medical technology at P&M Corporate Finance in Chicago. Some parts used in medical devices that have historically been made of metal are being replaced by plastic components.

In some cases, the volume needed has finally increased to the point it made sense to transition from metal to plastic, he said.

“Volumes have gotten to a scale, creating a situation where it makes sense financially to invest in a mold to manufacture with molded plastic,” Hughes said.

Another driver in the trend has been concern over hospital-acquired infections. “Metal instruments have historically been a reusable item,” Hughes said. “They use the instrument, send it to central sterilization in the hospital, and then use it again. But the challenges and costs associated with instrument sterilizing have moved any number of products to single-use plastic.”

Meanwhile, a whole new wave of medical devices is also coming to market.

“There’s been a recognition that many medical devices were not designed with the consumer in mind,” said Brian Williams, director, strategy, Global Healthcare at PwC.

“We buy consumer devices driven partly by price but also by form, features and the software that powers those devices. We use smartphones to do our shopping, banking, read a book, bank, take photos. We are bringing those expectations of design, ease of use and convenience to healthcare. New medical devices won’t look as much like medical devices.”

Features and technology from consumer devices are making their way into medical devices in what Dale Robinson, business development director at EWI, calls technology fusion. Manufacturing technologies, such as printed flexible electronics will enable the next generation of health monitoring devices. Electronic circuitry is already being printed onto fabrics, he said.

Other technologies that will enable these trends include noninvasive sensors, onboard data analysis algorithms and wireless data transmission, Robinson said. The biggest areas for growth include patient monitoring through clothing or jewelry that seamlessly collects and transmits data to providers, family caretakers of the elderly and parents of newborns, Robinson said. The next generation of battery technology will be smaller, flexible and have a higher energy density.

The winners in the device market will design products that have a measurable value, provide a clear health outcome and integrate with devices consumers already use, Williams said. Stand-alone devices won’t likely be as common.

“Innovation has become more important in healthcare today, given changes that have occurred in the market driven by the Affordable Care Act,” Williams said. “One component of that is reimbursement models that are value based as opposed to fee based. That puts additional pressure on

Step 1: Revenue Estimates for Overall Medical Technology Market

- PMCF estimates total 2014 revenue at **\$365 billion**, with an annual growth rate of just under 6.0% to 2020.

Step 2: Gross Margin % Estimates for Overall Medical Technology Market

- Estimated at 60.5% by taking a weighted average of the gross margins of the largest “pure play” medical device OEMs shown in the adjacent chart.
- Given estimated medical device market revenue of \$365 billion in 2014 and a 39.5% COGS percentage, total cost of goods sold for the medical device market is estimated at **\$144 billion for the period**.

Step 3: Percentage of OEM Manufacturing Costs Outsourced

- Various market estimates assume medical OEMs outsource approximately 25% of manufacturing costs.
- Using this as a proxy, PMCF estimates the market size for medical contract manufacturing as roughly \$36.6 billion in 2014.

Top Pure-Play Medical Device OEMs	LTM Gross Margin %
bioMérieux SA (ENXTPA:BIM)	76.7%
Nipro Corporation (TSE:8086)	75.5%
Terumo Corporation (TSE:4543)	74.8%
Boston Scientific Corporation (NYSE:BSX)	73.3%
Hologic Inc. (NasdaqGS:HOLX)	72.9%
Smith & Nephew plc (LSE:SNL)	72.7%
Medtronic, Inc. (NYSE:MDT)	71.8%
Stryker Corporation (NYSE:SYK)	68.7%
Becton, Dickinson and Company (NYSE:BDX)	68.6%
Zimmer Holdings, Inc. (NYSE:ZMH)	66.2%
Coloplast A/S (CPSE:COLO B)	63.3%
Varian Medical Systems, Inc. (NYSE:VAR)	62.2%
CR Bard Inc. (NYSE:BCR)	54.7%
Biomet Inc.	54.3%
B. Braun Melsungen AG	52.2%
Edwards Lifesciences Corp. (NYSE:EW)	51.2%
Getinge AB (OM:GETI B)	51.1%
Hitachi Medical Corporation	50.5%
St. Jude Medical Inc. (NYSE:STJ)	49.6%
Abbott Laboratories (NYSE:ABT)	45.5%
Alcon, Inc.	42.7%
Baxter International Inc. (NYSE:BAX)	32.9%
DENTSPLY International Inc. (NasdaqGS:XRAY)	29.7%
Gross Margin Weighted Average	39.5%
Average COGS % of Revenue	60.5%

An aging global population will help power growth of just under 6% per year in medical device revenue.

manufacturers of devices to show the value of their product and tie that value to an outcome achieved by the patient.”

Pressure to lower costs plays a role. “The aging global population is huge in terms of overall medical device market growth,” Hughes of P&M said. “As you get above 70, the cost of treating chronic conditions such as COPD and congestive heart failure increases dramatically. To care for a patient per day in a hospital is \$3000, in a skilled nursing facility is \$450, at home is \$50.”

With home care in mind, companies that have in the past developed devices for use in hospitals are shifting their focus to the home health market, Hughes said.

Innovations that will make home care possible include improved and miniaturized implantable devices. Interventional cardiac defibrillators are now implanted and leadless—a great improvement over older technology, Robinson said. The devices are implanted into the heart and use much smaller batteries and electronic circuitry. The data processing chips will have higher density processing capabilities to enable better performance without increasing size. To assemble such

devices, manufacturing technology has improved to create hermetic seals to prevent fluids from leaking into the device and micro-joining processes to connect the battery tabs and microprocessor to the electronic circuitry, he said.

Growth in Smart Medical Devices

More devices will be worn, both on the wrist and as part of clothing using technology that prints circuitry onto fabric, said Jeffrey C. Rasmussen, market research manager at the Industrial Fabric Association International (Roseville, MN).

“In the past, sensors and circuitry embedded into fabric were too big and too clunky,” Rasmussen said. “Manufacturers have been able to make them miniaturized, more stretchable and comfortable. It’s exploded in the last year. Some of the big apparel players in the market are Adidas, Nike and Ralph Lauren.” Such clothing is improving in terms of washability, he said, although research continues in that area.

Sensors are becoming better and more sophisticated. Devices now entering the market have sensors that measure

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(in \$ millions)

Company Name	Medical Technology Revenue			Market Share 2014	CAGR 2010-2014
	2010	2013	2014		
Medtronic	\$ 16,897	\$ 18,200	\$ 28,229	7.8%	13.7%
	26,611	28,490	27,522	7.6%	0.8%
	16,897	18,200	18,299	5.0%	2.0%
	16,660	17,842	15,428	4.3%	-1.9%
	8,750	10,060	11,217	3.1%	6.4%
	11,410	12,719	11,147	3.1%	-0.6%
	10,020	11,308	10,988	3.0%	2.3%
	7,203	8,695	9,972	2.8%	8.5%
	7,320	9,021	9,675	2.7%	7.2%
	10,208	8,951	9,379	2.6%	-2.1%
Total Top 10	131,976	143,486	151,856	41.9%	3.6%
11-25	64,992	72,089	74,776	20.6%	3.6%
26-50	39,025	49,230	50,843	14.0%	6.8%
Remaining	42,137	71,887	85,041	23.5%	19.2%
Total Market	\$ 278,130	\$ 336,692	\$ 362,516	100.0%	6.8%

Source: Bloomberg, Company Filings, PMCF Analysis

From 2010-2014, medical device revenue growth increased nearly 7 %.

more physiological parameters such as 2-lead EKG and pulse oximetry, Robinson said. Circuitry and biosensors imprinted into fabric and worn close to the heart and lungs for monitoring a person's pulse and/or respiration rate tend to be more reliable than those worn on the wrist.

Other technology in this sector includes smart socks that send an alert if a baby stops breathing, a vest defibrillator, and smart blankets that can send alerts if a patient is developing bedsores.

Smart fabrics manufacturer Eeonyx has developed a patented formulation that allows it to apply conductive polymer coatings to textiles, fibers, and yarns—making them piezo-resistive, which means they are sensitive to and react to touch, Rasmussen said. This creates a custom pressure

touch sensor in the fabric. In 2014, Eeonyx partnered with BeBop Sensors, which now uses co-designed proprietary Eeonyx smart fabric to create flexible electronics/circuits that can be incorporated into a single piece of fabric. Using DuPont designed conductive inks, BeBop Sensors' stretchable circuits can be printed onto fabric, such as a shirt or jacket for a variety of purposes including wearable controllers.

"Instead of wearing sensors in the shirt, the shirt is the sensor," Rasmussen said.

Self-Monitoring

With these devices in hand, consumers will monitor their own health, perhaps consulting with a medical provider by video or a smart device. "I can use my smartphone to gain access to a clinician in real time through video consulting," Williams said. "In that distributed-care environment, innovation needs to advance to support convenient care."

These new devices will be easier to use at home and easier on the eyes. For example, ResMed and other companies focused on oxygen treatment are developing better devices to effectively provide patients with oxygen at home—instead of in a hospital on a ventilator, Hughes said. "People don't want a huge oxygen concentrator that takes up a lot of room and is loud," he said. "We're working with a company that has a pretty big, ugly device. They want us to make it look cooler."

Some aren't technically medical devices as defined by the Food and Drug Administration because they simply

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collect data. These wearable devices to monitor health information include products such as the Fitbit or Apple Watch, Robinson said.

Technology fusion will come into play again as tech companies such as Google, Fitbit and Verizon are moving into medical device territory, said Chris Schorre, vice president of global marketing at medical device consultancy Emergo in Austin, TX. "You are also going to see more companies that are making traditional medical devices looking for ways to add a wireless monitoring component to their products so they can connect to a smartphone or tablet. Consumers want their devices to do more than simply count steps or measure their heart rate, and doctors increasingly appreciate the benefits of remote patient monitoring."

For example, Verily, formerly Google Life Sciences, has gone aggressively into life sciences, he said, citing the company's research and development with Swiss manufacturer Novartis of a contact lens with a chip embedded in it to measure blood glucose (BG) levels.

"There are definitely going to be winners and losers," Schorre said. "A lot of this technology will connect via a smartphone, tablet or other system. If Verily succeeds in getting its contact lens with an embedded glucose sensor cleared by the FDA, and users can constantly monitor their glucose levels with alerts on their smartphones, it's going to have an impact on companies making traditional meters ... at least among the 10—15% of people wearing contacts."

As companies such as Google move into medical device territory, medical device companies will have to return the favor, Schorre said. "You are going to see more companies that are traditional medical device com-

panies developing wireless technology to connect their products to a smartphone."

When devices are designed to collect and transmit data to healthcare providers for diagnostic analysis and therapeutic

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advice from a physician, they turn a corner to become FDA-regulated medical devices, Robinson said.

One leader in that space is Glooko Inc. (Palo Alto, CA). Glooko was founded in 2011 by a mobile app developer, a technologist, and a then-Facebook senior executive. Its diabetes management platform, Glooko MeterSync, downloads readings from more than 40 of the most popular blood glucose meters, insulin pumps and continuous glucose monitoring systems to Android and iOS mobile devices.

Other companies are moving into that sector. Late last year, the FDA granted 510(k) clearance for LabStyle Innovations Corp.'s Dario Blood Glucose Monitoring System. The system includes a device housing that includes a blood glucose meter, lancing device, test strips, lancets, control solutions and a mobile application. The mobile app allows the user to look at glucose test results using Apple's iOS 6.1 or above smart mobile device technology. It helps manage the disease by recording the BG results and other user-entered information such as carbohydrates, activity, and insulin use.

Medical Device Market Speeds Up

"There have been big changes in the speed of innovation," Williams said. "We are seeing more new products, new apps, new solutions that meet consumers where they are than we saw even a few years ago. It's driven by an innovation cycle associated with technology. It doesn't take long to develop a new piece of software that does something novel."

That innovation cycle is moving much faster than the regulatory environment for traditional healthcare infrastructure is accustomed to, Williams said. The FDA has continued to tweak the process in an effort to keep up with changes while maintaining safety.

Producing or launching an innovative product in the US has been challenging compared to releasing the same product in Europe because the FDA's system of approval and clearance depends on predictive devices—comparing a new device to one that has already been cleared or approved by the agency, Schorre said.

The FDA classifies medical devices as Class I, II and III. Class I devices, such as dental floss, are deemed to be low risk. Class II devices, such as condoms, are higher risk than Class I and are subject to more controls to reasonably assure the device is safe and effective. Class III devices are the highest risk—"anything where failure of the device would injure or kill a patient or user," Schorre said—and require the greatest regulatory controls. Active implantable devices, such as pacemakers, are Class III.

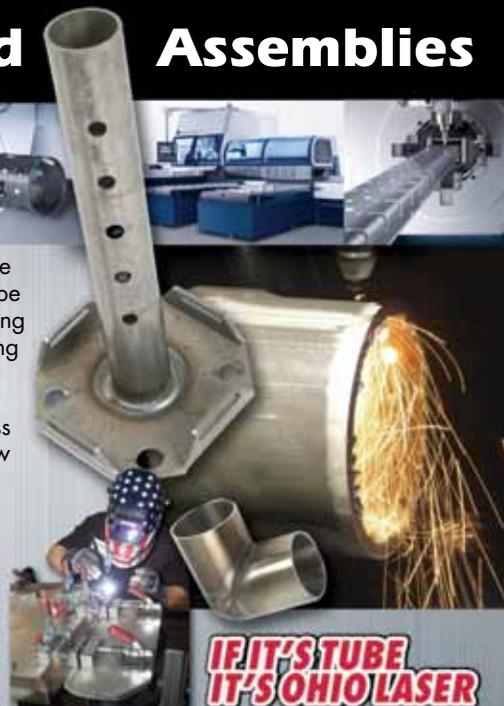
Some Class I devices, nearly all Class II devices and a few Class III devices must be cleared by the FDA via a 510(k) process, also known as Pre-Market Notification. Most Class III devices are subject to the far more stringent PreMarket Approval (PMA) requirements, which involve clinical trials.

Launching an innovative product in the US market is sometimes challenging compared to releasing the same product in the European market. That's because the FDA has a predicate-based regulatory system, which relies on comparing

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a new device to one that has already been cleared for sale by the agency. "The problem with that system is, if your device is new, innovative and quite a bit different from one already cleared by the FDA, then the FDA is going to treat it as a new device," Schorre said. "They will initially default to classifying it as 'high risk.' You may have to [clear] significant hurdles so it can be a Class II product—to convince the FDA that it's not high risk and doesn't require clinical trials. But obviously, just because a device is innovative and new doesn't mean it's high risk."

US Regulators Try to Catch Up

Because of the different European approval system, "We sometimes advise clients to seek approval for their innovative products in Europe first," he said. "The regulatory system in Europe is rules-based and is therefore more flexible [G]oing to Europe first can be faster and cheaper because the manufacturer might avoid having to jump through unexpected hoops that would be required for FDA clearance of an innovative but lower risk device," Schorre said. "Getting approval in Europe first will not necessarily make getting approval in the United States easier. The primary benefit is that companies making new technology can generate sales more quickly and be generating post market clinical use data that might eventually support a FDA submission."

In the future, clearance for mobile medical apps might be more well-defined in the United States. "The FDA is leading the charge in developing standards for mobile medical apps, but some want the FDA to take the next step in being more specific about what is allowed and what is not," Schorre said. "That has not been happening in the rest of the world. Other countries will look at how the United States is regulating apps and issuing guidance

and most likely will emulate what the FDA has been doing. To their credit, the FDA understands they will always be a step behind in regulating mobile medical technology and do not want to be the ones to hinder its development." ➔

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