

Infusion Pump-Makers Look to Improve Safety Through Interoperability

ROBERT NEIL

New products, new players and new deals are attempting to alter the market for infusion pumps, which – unfairly or not – have a reputation as being one of the single biggest safety concerns in hospitals. While high demand for infusion pumps has led to a multibillion-dollar market, safety issues have created a need to improve product performance and user experience. Existing and new companies are working to meet those needs, which can be viewed as an opportunity to improve quality in a market that investors predict will maintain steady growth for the near future.

The worldwide market for infusion pump hardware is about \$1.5bn annually with an approximate annual growth rate of 4%, according to Eric Sato, vice president of infusion technologies at **Baxter International Inc.**, one of three companies that dominate the market. (See Figure 1).

Meanwhile, Ketan Patel, a partner with the venture capital firm **F-Prime Capital**, said with all segments considered, the US market could be worth about \$2bn, and the worldwide market could be as high as \$3bn-5bn with single-digit growth projected.

Infusion pumps come in various shapes, sizes and functionality, but essentially they are all designed to infuse fluids, medications or nutrients into a patient’s body. Large-volume infusion pumps make up about 50%-60% of the total market. They are also the primary focus of safety concerns, which have been documented by several organizations, including the ECRI Institute, the nonprofit organization that scientifically tests and evaluates medical devices and researches the evidence behind drugs, procedures and processes related to patient care. The organization is one of the most respected groups to independently evaluate devices for members, which include hospitals, health systems and payors, that rely on the reports when making purchasing and coverage decisions.

A special report, released November 2016 from ECRI’s *Health Devices*, ranked infusion pumps as the No. 1 problem in a list of “Top 10 Health Technology Hazards for 2017.” Specifically, the report said: “Most large-volume infusion pumps incorporate safety mechanisms for reducing the risks of potentially deadly intravenous (IV) infusion errors. These mechanisms have greatly improved infusion safety, but can’t eliminate all potential errors. And the mechanisms themselves have been known to fail.”

In some cases, issues with infusion pumps could be solved through low-tech solutions, according to ECRI Engineering Manager Erin Sparnon, who told *Medtech Insight* that errors – and their subsequent harm and death – could be avoided through three simple procedures.

First, nurses should use roller clamps, designed to prevent unintended flow of drugs. Second, nurses should look at the drip chamber after starting an infusion to make sure the actual flow rate corresponds to the expected flow rate. And finally, nurses should quickly inspect infusion pumps for signs of damage before programming to prevent dosing errors caused by broken or malfunctioning components.

AVOIDING ERRORS

The US FDA said, between 2005 and 2009, it received reports of 56,000 adverse infusion pump events – more reports than any other medical technology. These events resulted in 710 patient deaths; and 87 pumps were recalled during this time frame. Additionally, a 2007 report from the Institute of Medicine stated that dealing with patient safety issues resulting from infusion pumps costs the health system \$2bn annually (Also see “Hospitals Prefer Existing Mechanisms To Report Device Safety Issues, Says AHA” - *Medtech Insight*, 11 Jan, 2017.) (See Figure 2)

Meanwhile, nurses often complain that infusion pumps can

FIGURE 1

Leading Infusion Pump Manufacturers

COMPANY	SIGNATURE INFUSION PUMP PRODUCT	PRODUCT REVENUE RELATED TO INFUSION PUMPS
Baxter	Sigma Spectrum Infusion System	\$2.3bn from Hospital Products - Fluid Systems (2016)
Becton, Dickinson and Co.	Alaris System	\$2.21bn in Medication Management Solutions (2016)
Hospira/ICU Medical	Plum 360 Infusion System	\$1.45bn from all related infusion and IV products (pro forma from combined ICU Medical and Hospira sales)

Source: Medtech Insight, Company Reports

FIGURE 2

Safety Problems with Infusion Pumps

From 2005-2009 the FDA found:



Adverse events involving infusion pumps



The adverse event reports and device recalls

have not been isolated to a specific manufacturer, type of infusion pump, or use environment; rather, they have occurred across the board

A report from the Institute of Medicine found:



Annual health system costs from patient safety issues due to infusion pumps

FDA White Paper Infusion Pump Improvements 2010, Institute of Medicine Report Preventing Medication Errors, 2007

be too complicated, with interfaces that are not intuitive or easy to use, which, in turn, can lead to errors. Baxter's Sato said hospitals and nurses want infusion pumps that are safe for patients, simple to use, and reliable; and they want modern pumps that fit into a hospital's IT architecture. That integration includes secure connectivity with wireless networks and electronic medical records (EMR) systems, something not all pumps are capable of doing right now. For example, some pumps can connect to EMR systems, but cannot perform autoprogramming. Achieving connectivity between infusion pumps and hospital information systems is a key driver in the market right now, and ECRI finds that this kind of integration could mitigate most of the reported safety issues.

COMPETITIVE LANDSCAPE

Baxter, which is estimated to share roughly an equal portion of the market's leadership role with **Pfizer Inc.'s Hospira Infusion Systems**; and **Becton Dickinson & Co. (BD)**, has recently approached the market with integrated improvements. Like its competitors, Baxter produces smart pumps with software referred to as digital drug libraries, designed to help reduce medication errors by automating dosing calculations and delivery rates.

Smart pumps also allow hospitals with the proper IT infrastructure to integrate pump data with EMRs and order entry systems to achieve that extra layer of safety. As that movement continues to grow, it is important to note that even with those changes, infusion pumps are still listed as a major concern; however, sources of concern are not tied completely to the products themselves. The fact that the pumps are a vital device used in abundance to deliver essential medications in virtually all facilities places the pumps under extra scrutiny.

Smart pumps allow hospitals with the proper IT infrastructure to integrate pump data with EMRs and order entry systems to achieve that extra layer of safety.

Baxter's signature infusion pump is the *Sigma Spectrum Infusion System*, and last December, the company announced the launch of the *Sigma Safety Management System*, designed to increase safety and to make using the pumps easier. Sato said the infusion system was basically designed from the ground up with easy-to-use features such as the ability to automatically default to the drug library at the initial start of the system. He added, the improvements have helped users achieve a 97% drug library compliance rate within the first month of implementation, and noted the system is the only pump to include a built-in titration error prevention feature. He also pointed out that only 20 high-alert drugs are associated with an estimated 80% of all medication error-related deaths.

Dealing with titration is important, because the practice, which relates to making dose or rate changes after an infusion has started, is believed to be one of the biggest culprits in infusion pump safety.

In May 2016, Baxter presented results of a retrospective analysis from its Sigma Spectrum pumps that found 90% of programming events with IV "high-alert" drugs such as anesthetics, cardiovascular agents and insulin, are titrations. The results evaluated six-month data from 20,542 Sigma Spectrum pumps at 45 US hospital sites from October 2014 to July 2015 and were presented at the annual meeting of the Infusion Nurses Society in Ft. Lauderdale, FL.

Sigma Spectrum is the only pump on the market to include a built-in titration error prevention feature and the Safety Man-

agement System offers wireless connectivity to integrate data into a hospital's EMR system, including products from **Cerner Corp.** and **Epic Systems Corp.**, which make some of the industry's most widely used EMR systems. The connectivity allows data to be transferred to and from the infusion pump system for updating drug libraries and for continuous quality improvement reports.

Baxter competes in the market with BD, but recent acquisition deals could send changes through the market.

As mentioned, Baxter competes in the market with BD, but recent acquisition deals could send changes through the market. In the third quarter of 2015, BD acquired **CareFusion Corp.** in a deal estimated at \$12.2bn, and Pfizer on Feb. 6 announced it closed a billion-dollar deal to sell Hospira's **ICU Medical Inc.** (Also see "ICU Medical Completes Acquisition of Pfizer's Hospira Infusion Business" - *Medtech Insight*, 8 Feb, 2017.).

When the BD acquisition of CareFusion closed in August 2015, Vincent Forlenza, BD's Chairman and CEO, said the deal "significantly accelerates BD's strategy and builds scale and depth in medication management and patient safety solutions." Through the deal, BD acquired CareFusion's signature *Alaris System* infusion platform, which company officials boast as having "the most customers live with EMR integration."

That claim comes via a report from KLAS Research, the independent informatics research company providing objective vendor performance information. KLAS wrote in its August 2016 report entitled *Smart Pumps 2016: The Quest for Patient Safety* that BD has the most comprehensive pump platform. Additionally, BD officials said the report shows actionable insights are more highly valued over basic reporting and that BD is leading in this transformation. The *Alaris System* was also named "Best in KLAS" for smart pumps in the *2015 Best in KLAS: Medical Equipment Report*, which stated providers believe BD is better positioned for the future regarding interoperability with EMRs.

The data from KLAS is important for several reasons. The organization is well-respected, and like the reports from ECRI, is a trusted source for providers evaluating products for purchasing decisions. KLAS also highlights the importance providers place on connections to EMR systems and advanced drug libraries, stressing that an infusion pump without those features would not be of much interest to hospitals moving forward.

The touting of the KLAS reports also shows how marketing works in this space and highlights how difficult it is to show distinctions among products that actually have more in common than not. For example, Baxter was also listed in the report *Smart Pumps 2016: The Quest for Patient Safety* and was cited as the leader in drug library compliance and overall ease of use. Baxter's Sigma Spectrum was also named "2016 Best in KLAS for Smart

Pump – Large Volume Pumps" in the 2016 Best in KLAS report.

Meanwhile, a 2015 KLAS report, called *Smart Pump/EMR Integration*, said Hospira has "implemented integrated EMR technology at more hospitals than all other infuse pump providers combined, and with more major EMR platforms than any other company." Under Pfizer, Hospira has been able to establish itself as a leader in infusion pump/EMR connectivity, and a number of recent deals highlight that movement.

Last December, the company announced a partnership with the technology company **Iatric Systems Inc.** to develop interoperability between Hospira's smart infusion devices and Iatric's *Accelero Connect* integration software. The goal is to develop a system that allows two-way communication that makes automating pump programming possible with the validated EMR medication order. The system would also be able to send documentation of medication administration data back into the patient's EMR, and the companies are currently piloting the project at an undisclosed US hospital.

Also, in December, Hospira announced that Lancaster General Hospital in Pennsylvania had become the first health system to integrate a patient-controlled analgesia (PCA) infusion pump with an EMR system. Specifically, the connection involves an EMR from Epic and Hospira's *LifeCare PCA 7.0 Infusion System*, which the company launched last May under the billing "the next-generation infusion system." The product is the first PCA pump with integrated bar code identification of prefilled and pharmacy-filled vials, a feature designed to eliminate drug and concentration errors at the bedside.

Hospira is also working to improve the efficiency in responding to infusion pump alarms and has partnered with Cerner to route alerts to a clinician's mobile device. The first hospital to install the combined system is Sheridan Memorial Hospital in Wyoming, where, last December, Cerner's *CareAware Event Management system* began working with Hospira's *Alarm Forwarding* technology.

Hospira is also working to improve the efficiency in responding to infusion pump alarms and has partnered with Cerner to route alerts to a clinician's mobile device.

The hospital already receives alarm information from Hospira's *Plum A+ infusion system*, and the new system is seen as an essential secondary alert that, in addition to reaching mobile devices, can escalate alerts among clinicians, when necessary. Company officials see the upgrade as an important step in device interoperability that gives clinicians more control over monitoring smart pump alarms.

All of Hospira's recent improvements were made as the company was preparing to be sold by Pfizer to ICU Medical in a

deal priced at \$1bn with \$600m of that coming in cash and the remainder in newly issued ICU shares. Pfizer still owns about 16.6% of Hospira as it competes in the growing infusion pump market, but it also will allow Pfizer to concentrate on its core pharmaceutical business.

Pfizer had purchased Hospira in a \$17bn deal in September 2015, and that transaction actually netted Pfizer three business units from Hospira – injectable drugs, biosimilars and infusions systems.

Pfizer still owns the first two businesses while ICU gained the infusion unit, which features the *Plum 360 Infusion System*, a smart pump launched in 2015 that is capable of connecting to electronic medical records other hospital IT systems. ICU officials said the deal gives the company a complete IV therapy product portfolio of pumps and non-dedicated infusion sets, and ICU will have about \$1.4bn in product revenue.

About \$457m of that will come from infusion pumps, sets and software with another \$482m in non-dedicated IV sales and accessories, and IV solutions are responsible for an additional \$462m with critical care adding \$52m, totaling \$1.45bn in revenues. The bulk of the revenue comes from the US market, which accounts for \$1.11bn, and the company's growing presence overseas is slated to bring in \$344m, according to ICU Medical. (See Figure 3)

With all the improvements the large companies are touting, there are still questions about whether those changes will be sufficient to improve safety. The CEO of one startup company, developing a next-generation infusion management platform, believes significant progress is more likely to come from outside the circle of the three manufacturers that dominate the market.

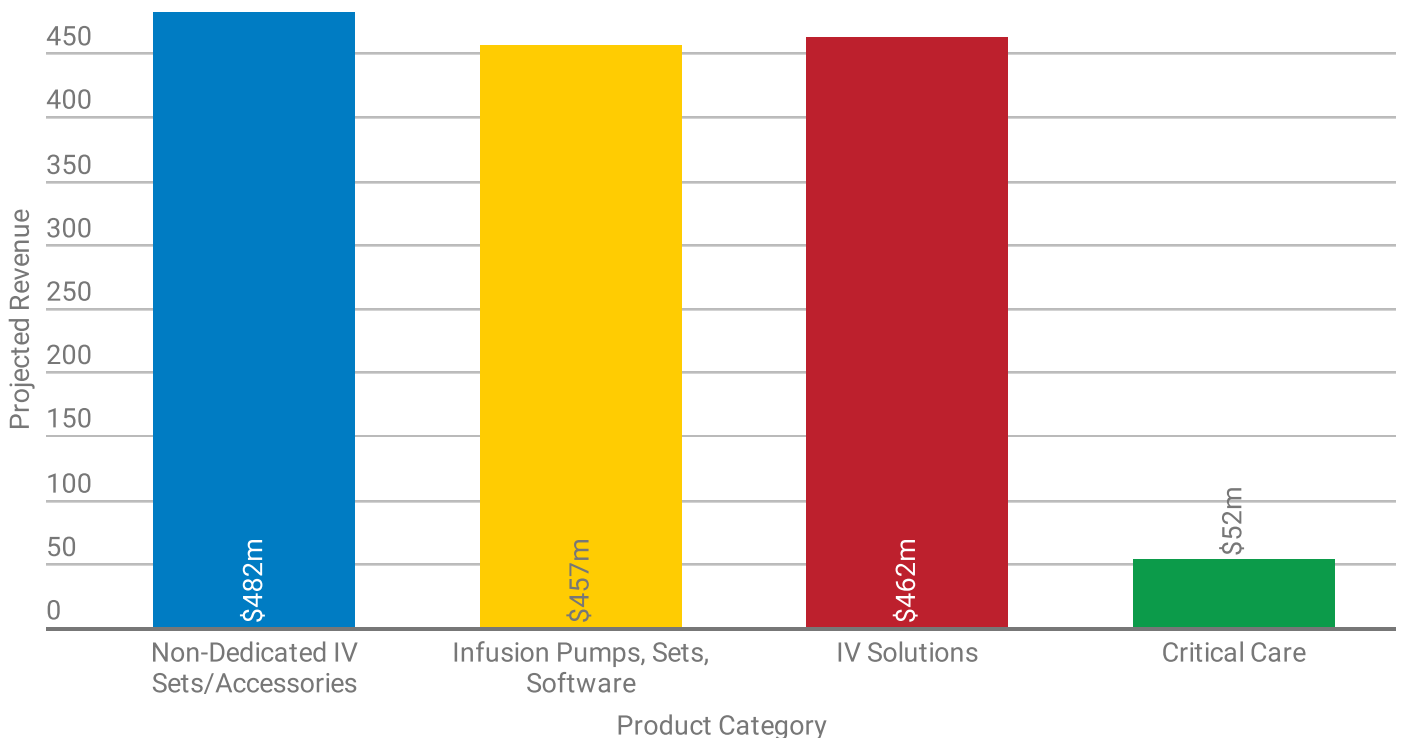
Stuart Randle, president and CEO of **Ivenix Inc.** said any market that operates under an oligopoly is going to face challenges in creating changes that require looking at solutions in a different way. Randle's company is in the final development stages of the *Ivenix Infusion Management System*, which he said is a re-design of legacy infusion pumps that will enhance dose accuracy and reduce the possibility of medication errors while also boosting clinician workflow. (See Figure 4).

Ivenix acknowledges that the adoption of IT capabilities to pumps currently on the market are a welcome improvement, but Randle said a more comprehensive approach is needed to truly fix the safety problems in the market. User errors need to be addressed, and he noted part of the problem has been that nurses are so busy that they lack the time to engage an infusion pump that is not intuitive.

The Ivenix system, which will be submitted for FDA clearance later this year, features a large color touchscreen user interface, designed to address user errors. Randle said the Ivenix system

FIGURE 3

ICU Medical's Projected Revenue After Hospira Aquisition



Source: ICU Medical

FIGURE 4

Snapshot of Ivenix Inc.

PRODUCT	IVENIX INFUSION MANAGEMENT SYSTEM
President and CEO	Stuart Randle
Founded	2007
Investors	Cardinal Partners, CICA Inc., Easterly Capital, F-Prime, SCP Vitalife Partners, WuXi Healthcare Ventures
Funding	\$42m raised in Sept. 2015

Source: Ivenix Inc.

was designed as an intuitive system with an interface that operates like a smartphone and relies on menus and a big screen rather than buttons and switches found on other products in the market.

The system also has a unique, pneumatic pumping mechanism that can measure the flow of fluid and automatically adjusts to ensure accuracy. The technology features a mechanism that, unlike other pumps, delivers fluid independent of gravity, which means nurses don't have to worry about the height of the medication bag in relation to the pump.

Randle said he considers Ivenix more of a health care IT company than an infusion pump manufacturer, and the company's product – its first – reflects that. The actual infusion portion of the system incorporates many elements of an information system within it, and that allows the device to either interact with larger health information systems or to function as a standalone device. Overall, the system includes a remote software upgrade and security patches that do not require the pump to be physically removed from hospital floors.

Additionally, the pump has adaptive technology that eliminates the need for ongoing calibration. The system also allows for a fleet of pumps to be remotely monitored to manage asset utilization and maintenance across a health care system. The pump is designed to have pluggable and scalable integration with EMR and other hospital systems, and it features an advanced drug library with built-in dose protection and drug incompatibility alerts.

Ivenix is backed by investors, including the previously mentioned F-Prime, as well as **Cardinal Partners, CICA Inc., Easterly Capital, SCP Vitalife Partners** and **WuXi Healthcare Ventures**. Meanwhile, Ivenix is planning to demonstrate its system at the 2017 HIMSS Conference & Exhibition on Feb. 19-23 in

“A more comprehensive approach is needed to truly fix the safety problems in the [infusion pump] market. User errors need to be addressed, and part of the problem has been that nurses are so busy that they lack the time to engage an infusion pump that is not intuitive,”
Ivenix CEO Stuart Randle says.

Orlando, and show attendees how its Infusion Management System communicates in real time with EMR systems and other health information technologies.

For a market that has been dominated by major companies for a while, the recent activities could signal an opportunity for players with new solutions that address the long-running safety issues. The movement to reduce medical errors is certainly a catalyst that is pushing hospitals to look for better alternatives, and like a number of areas in health care, connectivity to IT systems has emerged as a major component. Infusion pumps that work seamlessly with EMR and order entry systems not only offer enhanced safety features, but are also more efficient to run and maintain.

Hospitals are on a path toward interoperability with many of their medical devices and items as vital as infusion pumps will be no different, and, in fact, the sheer volume and sensitive nature of their function should put infusion pumps near the top of the list for connectivity. ▶