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Stuart Randle, Pres.
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YEAR FOUNDED

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WHO'S BEHIND IT

Stuart Randle, senior manager of several medical technology companies in sales and marketing roles with experience in the infusion market; COO Jesse Ambrosina, who led the medical division of global product development firm Foliage Systems and personally holds over 30 US patents; CTO & VP of Research & Development George Gray, once Senior Architect at Philips Healthcare and founder of Envision Solutions Inc., a provider of clinical analytics and data integration solutions; and Chief Nursing Officer Sue Niemeier, MHA, BSN, RN, who formerly held a similar title and role at Capsule Tech Inc.

UNMET CLINICAL NEED

Improving the safety and reliability of infusion pumps and seamlessly integrating a patient's infusion information with the electronic medical record and other hospital information systems

SOLUTION

The *Ivenix Infusion System*, a modern, touchscreen, user-friendly pump with an advanced pumping technology, designed with an IT perspective in mind to improve patient safety

IVENIX: A MODERN INFUSION SOLUTION FOR AGE-OLD CHALLENGES

For twenty years, the world of infusion has seen little change despite the constant evolution of technology. Ivenix is seeking to give the industry a substantial, long-overdue update and bring infusion pumps into the modern age of connected healthcare.

by
COLIN MILLER,
CONTRIBUTOR

Infusion pumps are far and away the most error-prone devices used in hospitals, accounting for more incident reports to the FDA than any other apparatus. From 2005 to 2009 alone, 56,000 adverse infusion pump events were reported, resulting in over 700 patient deaths and 87 pump recalls. The Institute of Medicine estimates that malfunctioning pumps cost hospitals \$2 billion every year, with frequent issues, including inaccurate software for registering the intended drug dose, problems with alarms that

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signal the need for staff attention, unintuitive user interfaces and easily damaged parts. Plus, a more recent report by the ECRI lists infusion pumps as the #1 health technology hazard for hospitals and suggests that more effective hospital IT system integration could mitigate as much as three quarters or more of documented safety issues. Ivenix is now seeking to give the infusion market a desperately needed upgrade.

Stuart Randle, the president and CEO of **Ivenix Inc.** and former CEO of **GI Dynamics** and **ACT Medical Inc.**, has been in the life sciences industry for over two decades, serving in senior

management roles at a variety of companies, including Baxter Healthcare's IV infusion business. He points out that the infusion pump arena is all but dominated by three large medical device manufacturers: CareFusion Corp. (a recent acquisition by **Becton, Dickinson and Company**), **Baxter International** and Hospira Inc. (recently acquired by **ICU Medical Inc.**). In all his time selling and marketing IV pumps, Randle saw no substantive improvements to core designs despite the increasing complexity of drug dosing regimens, a demand for electronic medical record (EMR) integration and heightened concern around patient safety issues. Most improvements so far have been incremental at best, Randle says, doing little to tackle the fundamental retooling that current infusion offerings require to adapt to modern standards of care. As Randle puts it rather succinctly, "As a big company it's much easier to keep doing what you're doing than to disrupt it yourself."

A publication issued by the FDA in December of 2014 entitled "Infusion Pumps Total Product Life Cycle Guidance for Industry and FDA Staff" was the start of an initiative intended to give the industry a quality overhaul, but the team behind Ivenix had already begun working on its sophisticated system two years earlier. The founders' original concept was bold but well-defined, according to Randle. "They wanted to revolutionize the space both from a pump standpoint and, more importantly from an IT standpoint," he says, adding that "IV pumps in particular

came out of large companies that used electrical and mechanical engineers to design them. Now software along with human factors engineering are very important elements in that space.” He believes that with software engineering and information system architecture at its core, Ivenix is better suited to address today’s clinical needs than the largely stagnant major players.

The *Ivenix Infusion System’s* functionality is an impressive leap in the right direction, in the same way that the iPhone dwarfed the processing power of an early 2000s desktop computer, Randle notes. Three major features set it apart from the competition: adaptive pump technology, a smart phone-inspired user interface, and advanced web-based architecture for remote viewing and analysis. Starting with the pump itself, it continuously measures and adapts flow regardless of bag position, viscosity or back pressure, to ensure consistent fluid delivery.

At the heart of the *Ivenix Infusion System* is its signature menu-driven touch screen interface that Randle asserts is “very intuitive to pick up and start using right out of the box.” The simplicity with which pumps can be configured and operated via the device’s robust IT platform is a point of company pride, and a facet that aims to minimize dosing errors—good news for patients, nurses and hospital budgets. With remote viewing of their patient’s infusions using a web-based dashboard, nurses will be able to view the pump status when they are away from the bedside, leaving no patient ignored.

While exact pricing information is still unavailable, Randle predicts a positive economic impact from the Ivenix system, which will generate savings not only by avoiding costly pump overhauls, but also enabling wireless software updates and secu-

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rity patches. Instead of having to pull individual units out of service, users can install updates on Ivenix pumps while they remain in operation. Pursuing interoperability as a central objective, Ivenix has enabled its system to work with an extensive drug library, to enable interoperability with EMRs, and to record accurate time-stamped infusion data, making it possible to review and analyze specific events.

EMR integration is crucial for infusion pumps because it allows auto-programming of infusions with the pharmacy verified physician orders, eliminating the number of error prone keystrokes used to program a pump manually. This redirects healthcare staff attention and effort from impersonal, tedious, error rectifying tasks to work that’s best handled by a human; the machine takes care of the grunt work, so to speak. Additionally, EMR capability makes it possible for pumps to auto-document infusion values and view the patient’s infusion status remotely. Furthermore, while cybersecurity is a natural concern when private health information is on the line, Randle confidently spoke to advanced protection measures designed into the *Ivenix Infusion System*.

Despite infusion pump errors being associated with more than half of all medication errors and 61% of life-threatening adverse events according to the ECRI Institute, Ivenix promises to make most of the IV experience. From the system’s ease of use and automation—curbing human error to produce more satisfied patients and nursing staff—to its seamless compatibility with hospital IT for precise analysis, every aspect represents a previous performance gap filled. Ivenix is preparing for FDA submission, and Randle hopes to begin commercial operations by 2018. “This is really an extraordinary company,” he says. “We’ve got a spectacular team culture unlike anything I’ve seen in twenty years in the medtech industry.” 🍌