

## The Importance of Using Wireless Engineers Who Understand Patient Care and RFID Technology

InfoLogix Response to *JAMA* Article by van der Togt et al on Radio Frequency Identification System-Induced Electromagnetic Interference with Hospital Equipment.



In the June 25, 2008, issue of the *Journal of the American Medical Association (JAMA)*, van der Togt et al reported results from a nonclinical study, completed in the Netherlands in May of 2006, demonstrating that active and passive radio frequency identification (RFID) systems can be manipulated to produce electromagnetic interference (EMI) with medical devices commonly used in hospital critical care units (e.g., infusion pumps, external pacemakers, defibrillators, monitors).<sup>1</sup> In some cases, the functionality of those devices was impaired to the extent that a patient relying on them for support would have been placed in jeopardy.

The safety of RFID technology in the hospital is understudied, and the paper by van der Togt and colleagues makes a valuable contribution to the scant available literature on the subject. However, reaction to the article in the lay press and on the Internet has been, in many cases, unscientific and irresponsibly alarmist. With all due respect to the Dutch researchers and their work, InfoLogix, as a leader in mobility solutions for 1,500 hospitals across North America, including the healthcare applications of RFID technology, feels a professional responsibility not to refute their findings, but to help contextualize the study for our present and potential customers who may have safety concerns arising from their publication:

- 1. The risk-benefit assessment of RFID technology in the hospital should fully consider the contributions RFID systems are making to better patient care and safety.** The paper by van der Togt et al correctly implies the need for a risk-benefit assessment of the use of RFID technology in hospitals but barely acknowledges the significant contributions of RFID technology to patient safety. RFID technology in hospital and other healthcare settings has many practical uses related to asset management and loss prevention, but RFID technology has also produced important advances in patient care and safety—reducing medical errors and saving lives. For example, RFID wristbands are used to track the movement of patients into and through hospital emergency departments and to ensure positive patient identification so surgical candidates do not end up in the wrong operating room or undergo the wrong procedure; RFID tags on blood products help ensure patients do not receive the wrong type of blood or plasma (a potentially lethal error) and to confirm the blood product has been properly stored; and RFID tags on drug packaging help prevent counterfeit products with potentially harmful contaminants from entering the supply chain.

**2. The problem described by van der Togt et al is not a real problem (to date); it is only a potential problem.** On the day the article was published, FDA spokeswoman Peper Long was quoted in RFID Journal saying that the Agency has never received a single report of injury directly caused by EMI with medical devices: “We certainly understand there is a potential for problems, and of course, we are looking into this.” She further stated that the FDA is currently working with standards organizations and device manufacturers to address the issue.<sup>2</sup>

**3. The study was a feasibility study, not a clinical study—no patients were involved, and the manner in which the tests were performed was not analogous to the way RFID systems are conventionally used in a modern hospital.** RFID tags and exciters were initially placed in close proximity (~6.5 feet) to the device under study. If no interference was noted, the RFID components were brought closer, to the point of physical contact with the device, until EMI (or no EMI) was observed. If EMI was observed at initial power-up, the device was moved farther from the device, until EMI ceased. The median distance between RFID exciter and device in all tests producing interference was 30 cm (range: 1–600 cm), i.e., less than 12 inches.

*InfoLogix RFID systems are primarily employed to track patients through admission and treatment in emergency departments and to track, locate and prevent the loss of valuable hospital equipment, including the kinds of devices tested by van der Togt et al. The exciters, which activate and/or read output from the RFID tag, are mainly installed in the ceiling and at hospital entrances and exits.*

**4. The RFID systems tested in the Dutch study were operated at maximal power to mimic a worst-case scenario.** The authors acknowledge this as a methodologic limitation in their concluding comments.

*The power range within which the RFID exciters used by InfoLogix operate is well below the levels employed in the JAMA study and well below test limits and the limits imposed by the FCC and FDA.*

**5. The paper by van der Togt et al does not adequately characterize the wireless industry’s commitment to the safe application of RFID technology to healthcare.** In the public discussion following publication of the study, much has been made of this passage from the authors’ closing commentary: “The lack of standardization of RFID in health care permits RFID systems originally designed for logistics [package tracking, inventory control, retail loss prevention] to enter the medical arena on the basis of requirements such as the range at which medical tagged items or individuals are to be detected.”

It should be noted this study was completed more than 2 years ago, in May 2006. The manufacturing dates of the RFID systems tested are not stated. It is widely acknowledged in the industry that wireless technologies evolve rapidly, and it is doubtful the systems under study would qualify as state-of-the-art in 2008. More problematic, however, is the inaccurate suggestion that application of RFID technology in the hospital is governed solely by questions of ultimate functionality and is not the outcome of enterprise-specific research and development, or that this technology is deployed with no consideration of the environment in which it will operate. In 2008, WiFi and RF are integral parts of modern healthcare. Manufacturers are developing systems specifically for the healthcare environment and are mindful of the potential EMI-RFID hazards. EPCglobal, the organization leading the development of industry-driven Electronic Product Code (EPC) standards in connection with RFID, is well focused on the safe use of RFID technology in healthcare,<sup>3</sup> and as mentioned above, the FDA is already working with standards organizations and device manufacturers to address the issue.<sup>2</sup>

**6. The findings of van der Togt et al are not applicable to any brands or models of wireless device other than those tested and cannot be extrapolated to clinical scenarios involving patients.**

In the Dutch investigators' own words:  
"Our results apply only on the technology of 1 active and 1 passive RFID system from 2 specified manufacturers."

**7. A more robust and contemporary study conducted in 2008 under conditions analogous to contemporary hospital practice found no RFID-induced EMI of medical devices.**

A June 27, 2008, press release from Indiana University-Purdue University Indianapolis (IUPUI) announced the acceptance for publication by *Biomedical Instrumentation and Engineering* of a study from the Purdue School of Engineering and Technology.<sup>4</sup> Barbara Christe, director of the Biomedical Engineering Technology Program, and her colleagues completed a study in March 2008. According to the release:

*Christe noted, the Dutch study did not attempt to reproduce a setting that would typically be found in a hospital for the tests they conducted, as she did with her study. In fact, the conclusions of the Dutch study refer to a "controlled nonclinical setting."*

*In Christe's study, RFID antennas were placed as close as one foot from medical equipment. Even that distance, she said, is far closer than would typically be the case in a patient's room. No interference was found in 1,600 tests in Christe's study that were conducted in a patient room at Community North Hospital in Indianapolis. Christe tested pumps, non-invasive blood pressure monitors, pulse oximetry monitors, EKG monitors and sequential compression devices using two common RFID antennas, near field and far field.*

*The Dutch study tested the impact of RFID devices on medical equipment in a manner that was anything but a typical use setting, Christe said. "If I swallow my cell phone, I may have some type of hazardous interaction, but that is not an appropriate or typical use of a cell phone," she said.*

We respect the Dutch study and welcome its contribution to the healthcare community's growing understanding of the risks and benefits of RFID technology. We also believe that the study fundamentally implies that, to ensure maximum safety, healthcare providers should partner with a wireless mobility provider that understands the healthcare environment. InfoLogix has installed wireless mobility solutions, including RFID systems, in more than 1,500 hospitals nationwide.

In the *JAMA* editorial that accompanied publication of the Dutch study, Berwick notes, "Safety is not a condition, it is a process. It can only emerge continually in a culture that is alert, cooperative, transparent and resilient when the unexpected happens."<sup>5</sup> The Dutch study shows EMI from RFID systems is possible. The study by Christe et al, when it is published, will show that the risk of harm to patients from such interaction under normal hospital operating conditions is negligible. The FDA will continue to monitor for such events. And the industry, regulators, practitioners and researchers will continue striving to ensure that wireless technology in the hospital works to the benefit of all interested parties, beginning with patients.

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## About InfoLogix, Inc.

InfoLogix is a leading provider of enterprise mobility and advanced wireless asset tracking solutions for the healthcare and commercial industries. InfoLogix uses the industry's most advanced technologies to increase the efficiency, accuracy, and transparency of complex business and clinical processes. With 19 issued patents, InfoLogix provides mobile managed solutions, on-demand software applications, mobile infrastructure products, and strategic consulting services to over 2,000 clients in North America including Kraft Foods, Merck and Company, General Electric, Kaiser Permanente, MultiCare Health System and Stanford School of Medicine. InfoLogix is a publicly-traded company (NASDAQ: IFLG).