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New RFID Study Finds No Interference With Medical Devices

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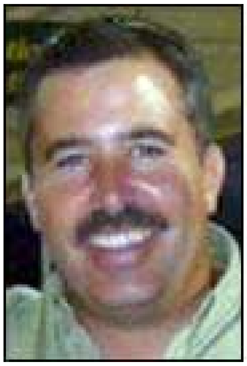
Researchers at Indiana University Purdue University Indianapolis and systems integrator BlueBean found no incidents of electromagnetic interference from passive UHF RFID systems.

By Beth Bacheldor

July 11, 2008—A new study on the effects of passive ultrahigh-frequency (UHF) RFID systems on medical equipment did not discover any problems with electromagnetic interference (EMI). The clinical study was conducted in March of this year at Community North Hospital in Indianapolis, by researchers at Indiana University Purdue University Indianapolis (IUPUI) and by RFID consulting and systems integration firm BlueBean. BlueBean, based in Carmel, Ind., initiated the study because there had been a scarcity of research on EMI and radio frequency identification, and the company hoped to have definitive answers for customers as it builds out an RFID practice for the health-care market.

The study, entitled "RFID Usage in the Patient-Care Environment," can be downloaded here, and also at BlueBean's Web site. Its publication comes just two weeks after a prior study was published in the *Journal of the American Medical Association* (*JAMA*) that found incidents of EMI by RFID on critical-care equipment in a non-clinical setting (see Researchers Warn RFID May Disrupt Medical Equipment). That study was conducted by researchers at the University of Amsterdam's Academic Medical Center in the Netherlands as part of a government research project.



Gregg Maggioli

Both studies examined whether electromagnetic radiation from RFID systems would disrupt infusion pumps, EKG monitors and other medical equipment. The Dutch group employed an active 124 kHz battery-powered tag and reader, as well as a passive 868 MHz tag and interrogator, to study RFID's effect on 41 medical devices. The IUPUI-BlueBean group studied RFID's effects on 25 medical devices and used only passive UHF (902-928 MHz) RFID tags and readers, which included one system (host computer, transceiver, antenna and tag) containing a near-field antenna operating in a "dense reader mode" and a near-field tag, and another system consisting of a far-field antenna operating in a "high-throughput" mode and a far-field tag. Researchers from both studies carried out their tests operating the RFID devices continuously at full power (2 to 4 watts).

The Dutch study was performed in a one-bed patient room with no patients present. The IUPUI-BlueBean study was conducted in a patient care room in a hospital, but was staged to best replicate the setting in which both antennas and clinical devices would be utilized. "Our layout was a real-life scenario, and we put the antenna where you'd expect to put an antenna, and the equipment where you'd expect the equipment to be," says Barbara Christe, associate professor and program director of IUPUI's biomedical engineering technology department, and the study's lead researcher. "Their test, while physically housed in a patient room, used a scenario where devices and systems were physically placed where you'd not expect them to be."

For the most part, Christe's group utilized patient simulators, though in some cases, test subjects were involved. The non-invasive blood pressure devices, for instance, were triggered to measure the blood pressure of a human subject during testing, but the EKG monitors were tested while connected to patient simulators.

Another critical difference is that while the Dutch study tested scenarios in which RFID systems were placed quite close (within centimeters) to the medical devices, none of the devices tested in the IUPUI-BlueBean study were ever closer than 1 foot (30.5 centimeters) to the RFID antennas during the test—a scenario that's much more consistent with real-world RFID system implementations, Christe says. The IUPUI study began each test at a distance of 6 feet, device performance was assessed and recorded, and the device was then moved closer to the antenna through 4-, 2- and 1-foot intervals, with the team verifying device performance at each interval.

In the Dutch study, the initial distances during testing were 200 centimeters (6.6 feet) between an RFID system and a medical device, and moving the RFID system in increments of 50 centimeters (1.6 feet) both toward and away from the device, depending on whether EMI was recorded. The median distance for all EMI incidents was 30 centimeters in a range of 0.1 to 600 centimeters (0.04 inches to 19.7 feet).

Christe believes the non-clinical setting and the close proximity of the RFID systems to the medical devices is the reason the Dutch researchers recorded so many incidents of EMI. "I believe differences, at this point, will ultimately depend on your testing methods. What we did, which is so different [than the Dutch study], is we created a much more use-case scenario," she says, using an analogy to compare the Dutch study with hers: "Do people get hurt if they fall out of buildings? Yes, but that isn't the use case we studied. The use case we studied is people using stairs and elevators. That's the difference."

According to Christe, the Dutch study was designed to determine whether there was any EMI at all with regard to RFID systems, and was never intended to mimic a clinical study. "In the *JAMA* article, it says this was a controlled, non-clinical study," she says. The IUPUI study, on the other hand, was designed to look for EMI with RFID in a clinical setting. "Our assumption, rightly so, is that there certainly should not be an antenna within a foot of a medical device. That is not good practice; that is not how you should design a system. Our study wasn't intended to find out, Is there ever interference? We know—even BlueBean agrees—that yes, there is likely to be some interference with devices when RFID systems are not used as intended."

There may be some applications, Christe says, in which an antenna might be closer than 1 foot, but in these applications—such as an RFID-enabled wand used to detect tags sewn into surgical sponges that may have inadvertently been left inside a patient—the system's power would only be on for a short time, while the patient is scanned, and not continuously.

Researchers with the Dutch study could not be reached by press time.

Gregg Maggioli, president and CEO of BlueBean, and one of the study's authors, says he wanted to conduct the EMI study simply because he could not find any research studies examining EMI and RFID systems. "I worked quite a few weeks trying to find EMI studies," he states, "and the more research I did, and in talking with a number of people—I called the FDA [U.S. Food and Drug Administration] and several other places—everyone pretty much told me the same thing: that they hadn't seen issues with interference." The FDA has publicly stated, in fact, that it has not received any reports of injuries directly caused by EMI with medical devices. But while that was good news to hear, Maggioli says, "there still hadn't been any studies that I was aware of, so I figured we should do one."

BlueBean wants to extend its consulting and systems integration services to the health-care market, Maggioli says—specifically with passive UHF RFID systems for tracking assets and drug dispensing and administering. Therefore, he got together with Christe and others at IUPUI (BlueBean had worked on previous projects with the university), and they applied for and received a small grant from the Multidisciplinary Undergraduate Research Institute (MURI) program established by IUPUI’s School of Engineering and Technology.

Although the Dutch study revealed most incidents of EMI when the RFID systems were quite close to the medical devices, there were also some incidents that occurred at greater distances. In fact, out of a total of 123 testing attempts, three resulted in EMI in which the reader/tag and the medical device were as far apart as 600 centimeters (19.7 feet)—the maximum distance at which EMI was observed. What's more, a ventilator exhibited an EMI incident beginning at a distance of 400 centimeters (13.1 feet).

Christe says it is unclear why the Dutch study discovered incidents at such great distances, but adds that three incidents out of 123 testing attempts "is not a statistical sample that meets the bar as a validity. Perhaps they were anomalies?" The Dutch study, she notes, does not detail what was done when a device first experienced an EMI incident. If, for instance, there was an incident at 200 centimeters (6.6 feet), Christe wonders, did they simply persist in increasing the distance and continue to see such incidents?

"The thought is that if a device malfunctions, you need to bring in a new device, or reset the device somehow, and then test that, rather than continue to test an already malfunctioning device," Christe states. "So, it might be that the malfunction was induced, and the reader was moved further way, and 'yep, it was still malfunctioning.' You really want a functioning device at every test interval. If that isn't what they did, then that certainly might explain why they had those results—and if that isn't what they did, then I question their testing methods."

Both studies recommend further testing as necessary. The IUPUI-BlueBean study indicates that "this study determined that RFID systems, including near- and far-field antennas and passive tags, did not influence the performance of commonly used medical devices such as physiological monitors and intravenous pumps," but adds that "as new RFID components and systems are introduced, further study may be necessary to evaluate evolving RFID technology and its impact on medical equipment."

Christe calls Maggioli a "pioneer" in examining RFID systems and interference. "It was good that Gregg brought it up and stirred the pot to get our study going," she says. "But the question remains: How do you differentiate from real use case, as we feel we studied, and all the potential hazards that might exist with interference?"

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