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Researchers Warn RFID May Disrupt Medical Equipment

Topics/Verticals: Operations, Asset Tracking, Pharmaceutical, Health Care

Experts not involved with the study note that there have been no reports of injuries caused by electromagnetic interference with medical devices, though they do recommend further study.

By Beth Bacheldor

June 25, 2008—A new study published today in the Journal of the American Medical Association warns that radio frequency identification may disrupt the operation of defibrillators and other medical equipment, and occasionally induce "potentially hazardous incidents in medical devices." Experts not involved in the study note that no injuries related to electromagnetic interference (EMI) have been reported in an actual clinical setting, but recommend that before deploying a specific RFID system, a hospital should test it first to see if it has any effect on the medical devices the facility uses.

The study, conducted by Remko van der Togt, Erik Jan van Lieshout, and four of their colleagues at the University of Amsterdam's Academic Medical Center (AMC), in the Netherlands, was part of a research project entitled RFID in Health Care, initiated by the Dutch Ministry of Health in May 2006. That project has been focused on the use of RFID to track and trace blood products and expensive medical supplies in the operating rooms, intensive care unit (ICU) and blood transfusion lab at the 1,002-bed hospital.

Few formal studies have been conducted investigating whether RFID systems interfere with the operation of medical devices, but the technology's use has been growing in the health-care sector, particularly to track such devices. Many of those implementations involve Wi-Fi-enabled real-time location systems (RTLS), which the University of Amsterdam did not test during its study.

Additionally, the U.S. Food and Drug Administration (FDA) has been considering using RFID as a unique device identification (UDI) mechanism for tracking and tracing medical devices in the supply chain (see FDA Works on Draft ID System for Medical Devices, Supplies). In January 2007, the agency published a draft guidance document addressing issues and concerns relating to the use of RF wireless technology in medical devices, including whether RFID's electromagnetic waves could interfere with such devices. The FDA is currently evaluating the commentary and input it received on this issue last year.

According to Peper Long, a spokeswoman for the FDA, the agency has not yet received any reports of injuries directly caused by electromagnetic interference with medical devices. "We certainly understand there is a potential for problems," she says, "and, of course, we are looking into this." In fact, Long notes, the FDA is working with standards organizations and device manufacturers to evaluate RFID's impact on device performance, and to discern whether any vulnerabilities would create a public health concern.

The University of Amsterdam study was carried out in a controlled, nonclinical setting specifically to assess and classify incidents of EMI by RFID on critical care equipment. The researchers set up two RFID systems—one consisting of a 124 kHz battery-powered tag and a reader, the other a passive 868 MHz tag and interrogator. Both systems employed in the test (the active system is from Avonwood,

while the passive is made by Feig Electronic) comply with RFID standards set forth by the European Telecommunications Standards Institute (ETSI). Forty-one separate devices—such as defibrillators, infusion pumps, ventilators, fluid warmers and pacemaker programmers—from a variety of medical equipment manufacturers were included in the tests, which were conducted in a one-bed patient room at the hospital, though no patients were involved in the testing.

The researchers ran each device through three EMI tests: one involving the passive tag and reader, another involving the active tag and interrogator, and a third with the active tag but no reader). Each device test incorporated three procedures: the medical device was checked for normal operation; the device was tested when the RFID equipment was activated and the interrogator and tag were positioned at a distance of 200 cm (6.6 feet) from the medical device; and the device was tested once more with the RFID equipment turned on, and the distance between RFID equipment and medical device was increased by 50 cm (20 inches) if the device exhibited no effects of EMI, or decreased by that same amount if such effects were observed.

Once a detection of EMI appeared or vanished during a stepwise increment or decrement of 50 cm, the precise EMI distance was determined by moving the RFID equipment at a rate of approximately 1 cm (0.4 inch) every 3 seconds. Whenever an EMI incident was detected, the distance between the reader/tag and the device was measured in centimeters, with the type of incident categorized according to its severity.

For the purpose of the tests, the term *incident* was defined as "every unintended change in function of a medical device," and was characterized as being hazardous, significant or light. *Hazardous* was defined as having "direct physical influence on a patient by unintended change in equipment function" (for instance, the total stopping of a syringe pump, or incorrect pacing by an external pacemaker). *Significant* was defined as having an "influence on monitoring with significant level of attention needed, causing substantial distraction from patient care" (for example, an incorrect alarm or inaccurate monitoring of blood pressure). *Light* denoted "without significant level of patient influence or change in equipment function" (such as a disturbed display).

During the tests—of which there were 123 altogether (three per medical device)—a total of 34 EMI incidents occurred. Of those, 22 were hazardous, two were significant and 10 were light. The passive system produced more incidents than the active system (26 versus eight). Some of the "hazardous" incidents recorded included the shutdown and restart of mechanical ventilators tested, as well as the shutdown of syringe pumps.

For the 34 EMI incidents, a total of eight were initiated at a distance of more than 50 cm. The median distance at which *hazardous* EMI-related incidents occurred was 25 cm (10 inches), and the median distance for all incidents was 30 cm (12 inches). Only three tests resulted in incidents in which the reader/tag and the medical device were as far apart as 600 cm (19.7 feet)—the maximum distance at which EMI was observed. One medical device (a ventilator) exhibited an EMI incident beginning at a distance of 400 cm (13.1 feet), causing it to exhibit behavior classified as hazardous—in this case,

triggering ventilation erroneously and at a higher frequency.

The published study compares the EMI caused by RFID to that of EMI from mobile phones, which have been studied and been known to disrupt medical devices, though newer generations of phones are much less problematic since they can operate at much lower power levels. The study's findings do not surprise John Collins, the director of engineering and compliance with the American Society for Healthcare Engineering (ASHE), a professional membership group within the American Hospital Association (AHA). The AHA is a national organization that represents and serves all types of hospitals, health-care networks, and their patients and communities.

"There needs to be a growing awareness among hospitals that problems can occur," Collins says. "And it is difficult to say if something, such as an RFID system, will interfere with critical care equipment unless you do a study. Hospitals need to do a risk assessment of every wireless device that comes into the hospital, because [the wireless devices] all create a greater noise level in terms of radio frequency waves. You really don't know what to expect until they are tested."

Power coming from the RFID system, Collins says, may have more of an impact on devices than the type of frequency used—something the university's study revealed. According to the study, in fact, the number of EMI incidents increased with higher output power of transmitting RFID systems.

Collins deems the study well conducted, praising the researchers' disclosure that they conducted a worst-case scenario by using the maximal output power of both RFID systems. "Most devices don't operate at their highest power," he explains, adding that hospitals should test any RFID system—regardless of frequency—because any frequency may or may not impact devices. "You just don't know," he says.

According to the study's authors, although the two systems utilized in the test could be considered as a representative sample of RFID equipment used for applications in health care, the testing of one RFID system on EMI in a medical device "does not implicate immunity or vulnerability to other RFID systems if based on different signal characteristics or deployments."

AeroScout, one of several vendors that supplies Wi-Fi-based tracking technology to a number of hospitals, reports that not only are hospitals deploying Wi-Fi-enabled real-time location systems to track assets, but they are also increasingly using Wi-Fi-enabled equipment such as laptops. Executives from AeroScout claim their devices have been tested and certified as meeting regulations of the U.S. Federal Communications Commission (FCC) and ETSI, as well as the IEC6100/CE60601 standard that specifically defines electromagnetic compatibility rules for operation in a health-care environment.
As for the University of Amsterdam's study, its authors recommend that anyone implementing RFID in health-care environments take additional precautions, including on-site EMI tests. They further suggest that "the intensity of electronic life-supporting medical devices in this area requires careful management of the introduction of new wireless communications such as RFID."