

Covidien to Pilot Its RFID-enabled System This Summer

Using passive high-frequency tags, the company's contrast media delivery system for CT scans will alert radiology technicians if they inadvertently try to administer an expired or previously used syringe.

By Claire Swedberg

June 10, 2008—Health-care products firm Covidien says its Covidien Imaging Solutions division expects to carry out tests of its RFID-enabled contrast media delivery system during the next few months, with a commercial launch scheduled by summer's end. The new system, which gained approval from the U.S. Food and Drug Administration (FDA) on May 6, employs passive 13.56 MHz RFID tags and interrogators to ensure that empty, previously used or expired syringes are never administered to a patient during a computed tomography (CT) scan.

Contrast agents are utilized to make blood vessels, organs and other non-bony tissues more visible on an X-ray image. Covidien's contrast delivery system consists of the company's unit-dose Ultraject syringes prefilled with contrast agent, as well as its Optivantage DH power injectors. With the RFID technology, the system will not operate unless the power injector's built-in RFID interrogator recognizes the ID number of the tag attached to the syringe, and determines that the syringe has not expired.

The new system, says Brian Straeb, Covidien's VP of U.S. marketing for imaging solutions, is the first of several steps being taken toward using RFID for greater safety management of the company's contrast media. The initial system only prevents a used or incorrect syringe from being utilized. In the future, however, Covidien intends to employ RFID to enable the system to regulate the amount of dosage, and perhaps to link that data with a health-care facility's back-end system for use with such functions as invoicing, as well as for tracking methods used during contrast media application for a specific patient.

"What RFID does," Straeb says, "is it combines the prefilled syringe with the power injector to create an intelligent interface that allows a radiology technologist to ensure there is no misadministration of contrast media."

The majority of prefilled CT scan contrast agents sold in the United States are manufactured by Covidien's Imaging Solutions subsidiary. The viscous material, usually offered in dosages of 50 to 150 milliliters, requires a power injector and syringe to more readily administer it to patients intravenously. Health-care facilities must ensure that they don't reuse a syringe, which could be empty or have air bubbles in it, or use a fresh syringe containing the incorrect substance, such as saline solution. One possible scenario might involve a technologist leaving a used syringe on a table when leaving for the day, and the next thinking it had been laid out for an upcoming patient. Because contrast media is clear, it can be difficult to determine if a syringe is full or empty.

Since 2004, health-care facilities must also comply with the Joint Commission on Accreditation of Healthcare

Organizations (JCAHO) requirements to regulate the use of contrast media as they would a drug (see Bayer HealthCare Pharmaceuticals' Smart Cabinet Tracks Contrast Agents).

A hospital typically tracks the administration of contrast media through handwritten reports detailing how much of a particular product was administered, then adding those reports to a specific patient's file. With Covidien's new RFID-enabled system, a technologist would attach a syringe, prefilled with contrast media, to the power injector. The injector's built-in RFID interrogator would capture the data encoded to the syringe's tag, which complies with the ISO 15693 standard and would be encoded with a unique ID number, as well as the contrast media's lot number, expiration and manufacture dates, product name and fill volume, concentration and National Drug Code (NDC) number.

If the interrogator reads the tag and determines that the syringe has never been utilized before—and that its expiration date has not yet passed—the injector would become operable and the reader would encode the tag to indicate that syringe has been used. After administering the contrast agent to the patient, the technician would use the system's label printer to print the volume and concentration of the contrast media that had been in the syringe, and to attach that label to the patient's file.

If the syringe has been used or has reached its expiration date, the interrogator would read that data on the tag. The system would then issue an alert indicating the syringe's expired or used status, and would not enable the injection of the syringe's contents into a patient. If a syringe contains the wrong substance, it would not have the proper RFID tag on it. Consequently, the injector would not operate and the system would issue an alert to the technician.

In the future, Straeb says, Covidien intends to expand the system to include other types of data, such as the various phases of the injection (for instance, some injections are administered more rapidly at first, then slowed down). This information would be transmitted to the health-care facility's back-end system and printed as well, so that if the patient were to require the procedure again, there would be records regarding how the previous contrast media injection was administered. "This is the first step—to have the injector communicate with the syringe," he states.

RELATED_ARTICLES Those using Covidien's current power injector can purchase an upgrade with an RFID reader and a standard thermal label printer. Contrast media will be sold either as RFID-enabled, or not. "This is a system that helps to reduce the risk of potentially life-threatening errors," Straeb says. He does not indicate what the cost of the system would be, nor the price of upgrades or syringes.

Thus far, Straeb says, there are no customers piloting the project, though Covidien plans to begin testing it this summer, then make it commercially available by the end of the summer. He expects any facility that offers CT scans could be a potential customer.

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