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Defibrillator recall and company's demise create dilemma for emergency officials

By AP Staff Writer

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BOSTON - The sudden closure of a Concord-based manufacturer of external defibrillators amid its recall of the potentially lifesaving devices has created a dilemma for emergency response officials nationwide.

Some are debating whether to shelve potentially defective units covered under the recall of about 11,000 of the devices - as recommended by the manufacturer - or keep them in use in case they are needed in an emergency and there is no alternative equipment available to revive a heart attack victim.

“This is an obviously unsettling situation,” fire chief Steve Bane said Thursday in West Allis, Wis. “You’re potentially carrying a device which is not going to function in a lifesaving situation.”

The department in the Milwaukee suburb chose to box up 11 recalled automated defibrillators made by Access CardioSystems Inc. To ensure an adequate supply in fire trucks and ambulances, the department swapped out some of the three dozen defibrillators produced by other manufacturers that were recently placed in public buildings including schools and shopping malls.

But because there may be only a small likelihood that a unit covered under the recall is actually defective, the Wisconsin EMS Association is advising that recalled units be kept in service if there’s no immediate way to replace them.

Access CardioSystems says no patient has died because of either of two types of malfunctions that led to the recall: either devices fail to deliver a shock, or they mysteriously turn themselves on, which in turn can cause the device to fail to defibrillate.

The company’s recall notice, sent Nov. 3, said the company has received 11 complaints of the first type, a problem that could occur in 1,450 recalled units. The company received 33 of the latter reports, with that problem possible in 9,580 units. The company said failure rates were less than 1 percent.

“If we remove them from service, we have taken a 1 percent chance that they won’t defibrillate and made it a 100 percent chance,” said Don Hunjadi, executive director of the Wisconsin EMS Association.

“We’re telling them (emergency responders), ‘As soon as you can, swap them out,’ he said.

Hunjadi said 800 to 1,000 Access CardioSystems defibrillators were in service in Wisconsin, mostly in public buildings. Most of the state’s agencies use defibrillators from other manufacturers.

In Texas, police at El Paso Community College on Wednesday shelved nine defibrillators bought last year for \$13,000.

“We’re going to be getting quotes from other companies to replace them,” Police Chief J.R. Grijalva said. “But that’s a lengthy process, and it’s not done overnight. It’s going to leave a gap in coverage.”

“This is a life-threatening situation, and they (Access CardioSystems) leave us holding the bag.”

A notice of the voluntary recall was posted Wednesday by the U.S. Food and Drug Administration, a week after the company said it began notifying customers.

The company’s Web site was temporarily down Thursday. When it resumed operating, a message was posted reading, “Due to reasons beyond the company’s control, Access CardioSystems Inc. is no longer able to continue in business.”

Calls to the company’s main number yielded a recording to that effect, and Keith Proctor, the company’s vice president of regulatory affairs and quality assurance, declined to comment.

The three-year-old, privately held company’s recall notice said the company had stopped making and marketing all defibrillator models and cannot provide parts such as disposable battery packs or offer service for units already sold.

That has left some public agencies wondering how long they can continue using defibrillators the company did not include in the recall.

``We're looking at various possibilities for the future,' said Javier Sambrano, a police spokesman in El Paso, which bought 105 Access CardioSystems defibrillators over the past two years for \$106,000. The department inspected all its units and found none had either failed to work or had serial numbers covered by the recall, Sambrano said.

Dun & Bradstreet, which evaluates companies' creditworthiness, assigned Access CardioSystems its highest credit risk rating on a five-point scale. The company frequently pays its bills late and is slower to pay than the average in its industry, the Dun & Bradstreet report said.

The company sustained a \$7.4 million loss last year, with \$9.8 million in sales, the report said.

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