Patient Safety Alert

veterans Health Administration Warning System Published by VA Central Office

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Item: Automated External Defibrillators (AED) manufactured by Access

Cardiosystems, Inc. -- failure to operate correctly.

Specific Incident:

1. Units with serial numbers ranging from 075690 to 077140 may experience a malfunction in the shock delivery circuit and fail to deliver therapeutic shocks.

- 2. Units with serial numbers ranging from 075180 to 084760 may turn on unexpectedly and cannot be turned off when the power switch becomes inoperable. This may lead to failure of the device to defibrillate properly.
- Access Cardiosystems, Inc. announced they are no longer able to continue in business and will be unable to provide service, parts or consumables for any AED with their name.

Action:

- 1. Immediately check your inventory to determine if you have any Access Cardiosystems AEDs and remove units from service affected by items 1 and 2 above.
- 2. Other Access Cardiosystems units can remain in service only as long as you have consumables on hand to support them or until February 1, 2005, then they must be removed from service and replaced with AEDs from other manufacturers.
- 3. If you are affected, plan for emergency replacement of any Access Cardiosystems defibrillators in stock.

Source: VA Center for Engineering, Occupational Safety & Health (CEOSH),

Manufacturer and FDA

Contact: Access Cardiosystems, Inc. Recall Coordinator at (978)-405-1057.

Company Recall Notice, Press Release, FAQ and Updates available at:

http://accesscardiosystems.com

You may also contact Paul Sherman, CEOSH at (314)-543-6700.