Welch Allyn®

Advancing Frontline Care™

March 5, 2009

Dear Competent Authority,

We wish to inform you that we will be voluntarily recalling certain Welch Allyn AED 10 and former MRL JumpStart Automated External Defibrillators manufactured between October 3, 2002 and July 11, 2005. There is a remote chance of a device malfunction due to one or more of the following problems as described in Appendix A:

- Low energy shock
- Electromagnetic noise interference
- Unexpected shutdown during use
- Blown fuse
- Loss of voice prompts
- Shutdown in cold temperatures

With the possibility of a failure, Welch Allyn is offering to our customers the exchange of the affected Welch Allyn AED 10 or MRL JumpStart defibrillator for a new device.

Should you have any questions, please contact me at xinli.lin@welchallyn.com or (65) 6419 8100.

Sincerely,

Lin Xinli
Asia Pacific Regulatory Affairs
Welch Allyn, Inc

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APPENDIX A

1. Low energy shock

There is a remote chance that your Welch Allyn AED 10 or MRL JumpStart defibrillator may have a defect that can result in delivery of less than the programmed energy of a defibrillating shock (between 25% and 100%), which could result in failure to resuscitate a patient. The defect consists of cracked or imperfect solder joints that attach four transformers to their circuit board. These cracks or imperfections may be caused by weak joints and/or by damage from excessive physical impacts or vibration. There has been one death during an event in which a device with visible damage to the outside case delivered a low energy shock. The issue has also been observed in 17 additional units during routine servicing. The 14,012 units that may have this defect were manufactured between October 3, 2002 and July 11, 2005.

It is not possible to test the unit in advance to determine whether this issue is present. The outside case of the unit involved in the one known death was visibly damaged. We recommend that you safeguard the unit to avoid excessive physical impacts and vibration pending the recall. If your unit or the outside case has visible damage, please let us know immediately at **888-345-5356.**

If your unit gives a low energy warning during use, it is important that you continue to use the device in accordance with its voice prompts and the directions for use. A shock of less than programmed energy is often clinically effective in defibrillating a patient, and furthermore, the diminished energy delivery may be intermittent so that a full energy shock can follow a low energy shock.

2. Electromagnetic Noise Interference

All Welch Allyn AED 10 devices comply with applicable standards as to sensitivity and specificity for detecting shockable arrhythmias in the presence of a 10 amp per meter electromagnetic field. There has been one known incident in which a shock was delivered to a patient with a non-shockable rhythm possibly in the presence of an electromagnetic field exceeding 10 amps per meter. In addition, there have been 7 known incidents where the device has failed to recognize a shockable rhythm during routine bench tests using an ungrounded simulator.

10,735 units manufactured between October 3, 2002 and December 30, 2004 will receive a revised version of software with improved electromagnetic noise filtering.

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3. Unexpected Shutdown

There is a remote possibility that your AED 10 could unexpectedly shut down during use. This remote possibility can exist only if **both** of the following conditions are met:

A. The pads are attached to the patient **prior to** turning on the device (contrary to the instructions for use on the back of the unit and also in the Quick Reference material inside the AED 10 case.); **and**

B. The device is set to deliver an initial shock of 150 Joules energy.

The unexpected shutdown described above cannot occur if the AED 10 is set to deliver an initial shock of 200 Joules energy. There has been one known death during an event in which the combination of these conditions caused the device to shut down. The 10,735 units that may have this defect were manufactured between October 3, 2002 and December 30, 2004.

All of the recalled units will be upgraded with software that corrects the unexpected shutdown problem. In the meantime, until your device is upgraded, if the initial shock is set to 150J, it is **vital** to follow the step 1-2-3 operating procedure which directs attachment of the pads after the device has been turned on. This procedure is described on the back of your device and also in the Quick Reference material inside the AED 10 case. Some pages in the user's manual may erroneously describe or show illustrations of an operating procedure in which the pads are attached before the device is turned on. Please disregard these erroneous instructions; a corrected user's manual will be distributed by separate correspondence.

Please be advised that all U.S. units and most international units have a factory default setting of 200J initial shock that can only be changed using the password-protected supervisor menu. Only units sold outside the U.S. with the British voice option have a factory default setting of 150J initial shock.

4. Blown Fuse

4,568 units manufactured between May 18, 2004 and December 30, 2004 have experienced 23 blown F1 fuses. The blown fuse would render the AED 10 inoperable and cause a visual system status indicator warning of the inoperable condition. This issue may be identified during the unit's weekly self-test by a "do not use" red circle with a red line through it in the system status indicator of the AED 10; an example is shown on the back of the device. The blown fuse also could occur unexpectedly during use, which would prevent delivery of therapy. There are no known injuries or deaths associated with this issue. Recalled units will receive an improved fuse.

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5. **Voice Prompt**

5,336 units manufactured between October 3, 2002 to July 26, 2004 have the potential for loss of voice prompts due to intermittent speaker connection. There have been 10 reports of voice prompt failure. It is not possible to test the unit in advance to determine whether this issue is present. If this issue arises, the visual prompts are not affected, and the delivery of therapy also is not impaired. There are no known injuries or deaths associated with this issue. An upgraded speaker connection will be provided to recalled units.

6. **Shutdown in Cold Temperatures**

89 units serviced in 2007 and upgraded with software version 02.06.00 have a remote possibility of shut down during use in cold environmental conditions. There are no known injuries or deaths associated with this issue. The units will be updated with the current version of software.