



Quality Assurance & Regulatory Affairs
8500 SW Creekside Place
Beaverton, OR 97008

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.