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Field Safety Notice

Product Name: AED 10
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Type of Action: Advice given by Welch Allyn regarding the use of the device

Date: 9th April, 2008

Attention: Health Care Provider

Details on Affected Devices: Automated External Defibrillator: Welch Allyn AED 10

Description:

Welch Allyn have received 14 complaints from throughout Europe (with a total distribution in excess of 5,500 devices) regarding our AED 10 defibrillators, in which customer(s) have received an audible and visual "low battery" indication while deploying the device to deliver therapy. The low battery indicator can be caused by: 1) a persistent drop in voltage generated by a battery in the later stage of its useful life, or 2) a transient drop in voltage generated by environmental or other episodic use conditions. In some cases, the low battery indicator (visual and audible) can further deplete the battery. Some battery packs can trigger the low battery indicator at an earlier stage of depletion than other battery packs, due to differences in internal resistance and variability of internal resistance.

User Actions:

In the event you should experience a "low battery" message from your AED10 upon power up, continue with therapy. The indication is a reminder to replace the battery with a new battery, but the device is capable of delivering at least 15 discharges at 360 joules of shocks of therapy, and often considerably more than this after the low battery indicator first appears. The purpose of the low battery indicator is to provide you with ample time to obtain a replacement battery pack before the current one is exhausted. Please refer to the enclosed Battery Management Best Practices Welch Allyn AED10 Technical Note that will help you understand your AED10 power characteristics

Additionally please note: Welch Allyn have partnered with Panasonic as our battery cell provider due to obsolescence of the battery packs from the previous supplier. Welch Allyn's R&D facility in Chicago, IL, fully verified and validated the Panasonic battery packs, and they are less prone to trigger an early low battery indicator.

If for any reason you wish to exchange your AED10 battery pack please contact any one of our Customer Support Centers and we will provide you one under warranty at a discounted price.

Respectfully,

Mr. Paul Reynolds
Sr. Manager Quality Assurance & Regulatory Affairs (EMEA)

Battery Management Best Practices Welch Allyn AED10

Background

Welch Allyn introduced the AED10 (previously branded MRL Jumpstart) automated external defibrillator in December 2002. The device employs a single non-rechargeable, Lithium (LiMnO₂) battery pack which is specified to provide approximately five years of standby performance.

Depending upon environmental conditions, patterns of use, and age, AED10 batteries will eventually begin to indicate a low battery condition, but this can occur at varying times. For example, activities such as “Power On” or extended idle operation of devices, when performed frequently, will shorten an otherwise longer timeframe before the AED10 indicates “Low Battery.”

Welch Allyn takes this opportunity to re-emphasize various important points described in the AED10 User Manual regarding battery management, including advising users to inspect / verify the device battery status using scheduled inspections and to employ battery management best practices to ensure readiness.

Verifying Readiness

To ensure the readiness of your AED10, it is important to respond immediately to low battery status indicators – regardless of when they occur. In addition to the self-test performed by the device, the AED10 should be inspected weekly or monthly, depending on the frequency of its use. An “Operator’s Checklist,” found in the Welch Allyn AED10 User Manual, should be maintained according to the schedule outlined below.

Frequency of Use	Inspection Schedule
Monthly	Weekly
Infrequent (e.g., once a year)	Monthly

Check battery readiness by verifying that the AED10 status indicator, located left of the device green power button, is in a “ready to use” state (solid black icon). If the status indicator is flashing a red circle with a slash through it, this indicates a “Low Battery” situation. A low battery condition does not render the unit non-functional but does indicate that the battery is beginning to weaken. Continue to use the AED10 if needed but replace the battery at the first opportunity. If a solid “red circle with slash” symbol appears, turn on the AED 10 and note the self-test results. If the unit powered on and a “Self-Test Failure” is indicated, remove the AED 10 from service and contact Welch Allyn technical service immediately. If AED 10 will not power on, replace the battery as it may be drained. Again, attempt to power on the AED10. If the AED10 successfully powered on and a “Self-Test Failure” is indicated, or if the AED 10 will still not power on, remove the AED10 from service and contact Welch Allyn technical support immediately.

Length of Use of Battery

Length of use of the battery before a “Low Battery” indication is dependant on proper power management. Several variables can affect duration of battery performance. The most common contributors to shorter timeframes are:

- Frequent device power ups to check the status of the device. As provided in the User Manual, battery capacity is diminished with every activation or “power up” of the device. Remember the device performs ‘automatic’ self-tests on a weekly and monthly basis and therefore additional power ups are not required.

Technical Note

Battery Maintenance (continued)

Harsh use or storage conditions, e.g., hot or cold environments, <0C or >50C for use or storage, or near the specified operating limits as provided in the User Manual. . Battery capacity may also be diminished by other environmental extremes such as humidity >95%, moisture IPX4 and altitude <-150 to >4750 m.



Best Practices

To ensure readiness and lengthen use of an AED battery before a “Low Battery” indication, we recommend the following as provided in the User Manual:

- Rely solely on the device’s “status indicator” to identify the operational readiness of the device rather than powering up the device. Only attempt to power up the device after a solid red circle with a slash appears in the battery indicator as described under “Verifying Readiness” above.

Solid Black = **Ready**, Flashing Red Circle = **Low Battery**, Solid Red Circle = **Do Not Use**.



- Always check the status indicator after each use and replace the battery at the first opportunity if low. A low battery condition does not render the unit non-functional but indicates that the battery is beginning to weaken.
- Always have a fully charged battery (backup) available for use
- Always replace the battery every five (5) years due to degradation of battery chemistry
- Perform regular maintenance checks of your device to ensure it is ready when needed.
 - Establish periodic inspections of your device on a weekly or monthly basis depending on frequency of use (see above)
 - An Operator’s Checklist is also provided in the manual for your convenience

Full Information

Full information on battery maintenance and installation are available in the AED10 User Manual. For any service related issues, please contact your local Welch Allyn authorized service center. A list of Welch Allyn offices worldwide is available on our web-site: www.welchallyn.com.