



Advancing Frontline Care™

AED 10 / MRL JumpStart Defibrillator Recall Frequently Asked Questions

When / how / who was notified of this recall?

We notified all affected customers and distributors of this recall via UPS Ground on 2/25. Each mailing had its own unique tracking number. We are also asking them to visit www.welchallyn.com/AED10Recall to determine which of the specific technical issues may pertain to their device.

Was this an FDA mandated recall?

No. This is a voluntary recall that is being conducted according to a plan reviewed by the FDA, and the FDA will monitor the recall as it progresses.

How are you replacing devices?

Customers' devices will be repaired / upgraded at no cost to the customer. Each customer will exchange its device for a similar device that has been upgraded, with the original warranty remaining in effect.

I have heard that there have been two deaths “linked” to AED 10 malfunctions. What happened?

In one instance, the AED 10 delivered a shock at the programmed energy level. It then delivered three more shocks each at approximately 75% of the programmed energy level. These shocks, although lower than the programmed energy level, were still high enough to be potentially clinically effective. The device had significant visible damage to the exterior casing, suggesting physical impact. The patient on which this device was used was not resuscitated.

There is one instance in which an AED 10 unexpectedly powered down during use on a patient, which prevented delivery of a shock. In this instance, the device was used in a way that was contrary to its directions for use, in that the device was not turned on before the pads were attached to the patient. This deviation from the directions in combination with other conditions rarely can cause the device to shut down. The patient on which this device was used was not resuscitated.

Did the defects on the device in these two cases contribute to the patient deaths? To our knowledge, the devices did not contribute. The AED 10 potentially can save lives when used promptly on patients with shockable ventricular fibrillation. Not all patients can be resuscitated, however. Many circumstantial factors determine the outcome, including length of time before the patient receives emergency treatment, the patient's age and medical condition, the quality of follow up emergency efforts, and so forth. In the two cases discussed above, it has not been established that these patients could have been revived.

Have there been any other patient incidents?

There was one other patient incident. In that case, an AED 10 unit was exposed to a high level of electromagnetic interference (beyond the level for which it is labeled) while analyzing the patient's heart rhythm. The interference appears to have caused the device to perform the analysis incorrectly and deliver a shock on a rhythm that should not have been shocked. Despite the shock, the event did not result in patient death.

The AED 10's resistance to electromagnetic interference conforms with industry safety standards. The level of this resistance is included in the directions for use. In fact, the AED 10 has a higher tested level of electromagnetic immunity than many competitive automatic defibrillators. Our recall is intended to strengthen the immunity of some of the older devices in the field by providing a software upgrade with enhanced filtering. Our more recent devices already have this improved filtering.

What about the 39 incidents mentioned in a recent Welch Allyn press release?

Our press release of March 11, 2009, states: "There have been 20 reported instances of low energy shock, 8 of electromagnetic noise interference, and 11 of unexpected device shutdown." Our ongoing recall is intended to correct all of these issues.

Three of these 39 instances involved patients, as described above. The remaining 36 of these 39 instances did not involve patients, and typically involved testing during which a unit did not perform to all specifications. Here is a detailed breakdown:

a) Low energy shock. There was one patient incident, as described above. Of the remaining 20 instances, 18 were uncovered by Welch Allyn servicing personnel during physical inspection and functional testing as part of unrelated servicing and/or routine software upgrades. An additional 2 incidents were reported in complaints from the field, although no patient was involved.

b) Unexpected device shutdown. There was one patient incident, as described above. The remaining 10 instances were all uncovered during factory quality testing of a new version of software. As a result of these 10 instances, this version of software was disapproved for release to the field. However, there were 89 AED 10 units already in the field that erroneously received this version of software as an upgrade. These 89 units were part of the recent recall discussed in the March 11 press release. (The one patient incident involving shutdown did not occur on one of these 89 units, but resulted from deviation from the directions in combination with other conditions that rarely can cause the device to shut down.)

c) Electromagnetic noise interference. There was one patient incident, as described above. The remaining 7 instances all involved the testing units on ungrounded simulators by biomedical personnel, which our subsequent investigation has shown to inject interference that exceeds the noise level permitted under the AED 10's labeling.

If my AED 10 is one of the recalled units, should I keep it in service?

The chance of any of these malfunctions occurring is rare. Therefore, you should keep your AED 10 in service until it is exchanged in the recall, as directed in the recall notice that you have received or will receive in the near future. If your device shows signs of damage from being dropped or other impacts, call the number in your recall notice and your device will be exchanged immediately, because physical damage can increase the chance of malfunction.

Was the MRL JumpStart also sold in the US/CAN and International? Yes. 80 percent in the US/CAN and 20% international.

Explain the difference between the MRL JumpStart and AED 10 defibrillators. Are there two different defibrillators being recalled? There is no difference between the two devices except the brand name. The MRL JumpStart AED was rebranded the Welch Allyn AED 10 when Welch Allyn acquired MRL in April, 2003.

How are defibrillator devices obtained?

AED 10s are sold in the US/CAN and internationally. They are prescription devices; sold only on the order of a doctor. They are to be used by end users trained in CPR and the use of the AED 10.

What is the difference between external and internal defibrillators?

An automated external defibrillator is a portable electronic device that automatically diagnoses the potentially life threatening cardiac arrhythmias of ventricular fibrillation and ventricular tachycardia in a patient, and is able to treat them through defibrillation—the application of electrical therapy which stops the arrhythmia, allowing the heart to reestablish an effective rhythm. Internal defibrillators (otherwise known as implantable cardioverter-defibrillator (ICDs) is a small battery-powered electrical impulse generator which is implanted in patients who are at risk of sudden cardiac death due to ventricular fibrillation. The device is programmed to detect cardiac arrhythmia and correct it by delivering an electric shock to the source.

The Welch Allyn AED 10 and MRL JumpStart devices are automated external defibrillators.