

Class 1 Recall: MRL/Welch Allyn AED 20™ Automatic External Defibrillators

Date Recall Initiated: August 24, 2007

Product: MRL/Welch Allyn AED 20™ Automatic External Defibrillators manufactured between October 2003 and January 2005, serial numbers 205787 through 207509.

Use: These devices are intended for use by emergency or medical personnel to treat adult and pediatric patients in cardiopulmonary arrest (heart attack). The devices analyze an unconscious patient's heart rhythm and automatically deliver an electrical shock to the heart if needed to restore normal heart rhythm.

Recalling Firm: Welch Allyn Protocol, Inc.
8500 Sw Creekside Pl
Beaverton, OR 97008

Reason for Recall: These recalled devices may display a "Defib Comm" error message on the device display during use which may result in a terminal failure of the device to analyze the patient's ECG and deliver the appropriate therapy.

Public Contact: Customers may call the company at 1-800-462-0777.

FDA District: Seattle

FDA Comments:

- Welch Allyn sent recall letters on August 29, 2007 to its customers who purchased these devices.
- Owners of this defibrillator should contact their local Welch Allyn representative to obtain a loaner AED 20™ at no cost while their unit is being serviced.
- Welch Allyn will pay all costs associated with the upgrade required to correct the issue as well as shipping and handling of the devices.

Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of the product will cause serious injury or death.

Health care professionals and consumers may report adverse reactions or quality problems experienced with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by FAX.

- **Online:** www.fda.gov/MedWatch/report.htm
- **Regular Mail:** use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm
Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- **FAX:** 1-800-FDA-0178