

URGENT NOTIFICATION

FDA Recall of MRL/Welch Allyn AED 20 Automated External Defibrillators

September 20, 2007

The AHA is relaying the following information from the FDA as a service to its provider members and all health care consumers. The AHA has not made an independent determination of the information reported in the FDA alert.

FDA alert and link to more information:

FDA issued a Class I recall for MRL/Welch Allyn AED 20 Automatic External Defibrillators manufactured between October 2003 and January 2005, serial numbers 205787 through 207509.

These devices are used by emergency or medical personnel to treat adult and pediatric patients in cardiopulmonary arrest (heart attack). The 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.

FDA advises healthcare professionals and patients to stop using the recalled product and contact the manufacturer for a replacement.

Read the complete MedWatch 2007 Safety Summary including a link to the FDA recall notice: (<http://www.fda.gov/medwatch/safety/2007/safety07.htm#mrl>)

Per the FDA (CDRH), these devices are "intended to be used in healthcare or EMS environments"; however, some may also be used in public access defibrillation programs. The American Heart Association does not comment on specific brands or models of automated external defibrillators. We recommend that anyone who has purchased or who uses the devices in question to contact the FDA (<http://www.fda.gov/medwatch/feedback.htm>) and/or Welch Allyn (800.462.0777) for more information.