

Safety Alert Bulletin

22 June 2006

MRL, Inc. a Welch Allyn Company, Issues a Voluntary Worldwide Recall of Selected AED20 Automatic External Defibrillators

MRL Inc.

1-800-462.0777 or 1-847-520-0300

FOR IMMEDIATE RELEASE

Buffalo Grove, MRL, Inc., a Welch Allyn Company, today announced it is initiating a voluntary worldwide Class I recall of 580 AED20 Automatic External Defibrillators manufactured in Buffalo Grove, IL between April and October of 2003, with serial numbers 205199 through 205786. These 580 AED20's may experience failure or unacceptable delay in analyzing the patient's ECG and may fail to deliver appropriate therapy, which possibly could result in failure to resuscitate the patient. This will occur in combination with an error message on the device display reading "DEFIB COMM FAIL SELF TEST FAILED." This problem occurs because of an intermittent electrical connection within the device.

The company has received 30 related complaints about devices in this group of AED20's, corresponding to 5 percent of the 580 recalled devices which the company deems an unacceptable risk. In one instance the "Defib Comm" error delayed patient resuscitation. The company has taken corrective action and no other devices besides those manufactured between the above dates are subject to this recall.

MRL, Inc initiated notification via certified mail on June 14, 2006 to its customers who purchased AED20's in this group of devices 369 of which were sold within the US and 211 outside of the US. Owners of this defibrillator should contact MRL, Inc. to obtain a loaner AED20 at no cost while their unit is being serviced. MRL, Inc. will pay all costs associated with shipping, handling and replacement of the units "DEFIB" board. This recall is being conducted with the full knowledge of the U.S. Food and Drug Administration (FDA). FDA has determined that this action is a Class I recall. The FDA defines Class I as a situation in which there is reasonable probability that the use of or exposure to the product will cause serious adverse health consequences or death.

FDA classifies medical device recalls into three categories, representing their potential risk to public health:

Class I: high risk

Class II: less serious risk

Class III: low risk.

Customers with questions may contact the company at 1.800.462.0777 or 1.847.520.0300 for more information. Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at :

1-800-FDA-1088

by Fax at 1-800-FDA-0178

by mail at:

MedWatch

HF-2, FDA

5600 Fishers Lane

Rockville, MD 20852-9787

On the MedWatch website at:

http://www.fda.gov/oc/po/firmrecalls/mr106_06.html



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