



Quality Assurance & Regulatory Affairs
1000 Asbury Drive
Buffalo Grove, IL 60089-4551

July 14th, 2006

URGENT: MEDICAL DEVICE RECALL

WELCH ALLYN PIC 50

(Part Numbers: 971081, 971082, 971083, 971084)

Dear PIC 50 Customer,


We are writing to inform you that your Welch Allyn PIC 50 monitor-defibrillator is being recalled to correct a condition that could result in a malfunction that prevents or unacceptably delays the delivery of a defibrillating shock, which possibly could result in failure to resuscitate the patient. This recall is being conducted with the full knowledge of the U.S. Food and Drug Administration (FDA) and the European Competent Authorities.

The condition is caused by an intermittent connection between a pin and socket on a circuit board inside the device, and is isolated to devices made with a unique population of sockets. The problem develops over time and is unpredictable. The PIC 50 has a self-monitoring feature that detects this problem and displays a "Defib Comm" error message. The problem is usually identified while the PIC 50 is being tested before use, or while the PIC 50 is being used as a vital signs monitor on non-cardiac patients, but there is a possibility that the problem could occur during use without previous warning on a patient in cardiac arrest and delay or prevent defibrillation therapy. We received 18 related complaints about devices in this group of PIC 50's, corresponding to 1.6 percent of the 1,160 recalled devices and in two instances this Defib Comm problem occurred during use on a patient in cardiac arrest and delayed defibrillation therapy.

Not all PIC 50s are affected by this recall. The affected PIC 50s are those with the serial numbers identified in Appendix 1 of this notice. You will find the serial number located on a label on the lower left hand corner of the back panel of the device, along with the model and part numbers. Our records indicate that you purchased a PIC 50 affected by this potential problem, and you should verify this by matching the serial number of your unit with one identified in Appendix 3.

With the possibility of a failure, Welch Allyn - MRL is taking this precautionary measure to service your PIC 50 to address this issue. Welch Allyn - MRL will provide you with a loaner device during servicing. PIC 50s that have exhibited the Defib Comm error message will be given priority in scheduling of remedial service, and we ask that you complete and return Appendix 2 to assist us in determining if your device should receive priority service.

Please respond as soon as possible to this notification by faxing (00353469067755) or mailing the response form found in Appendix 2 to Welch Allyn-MRL at the identified address or fax number. Please respond within 5 days if your PIC 50 has displayed the Defib Comm error message, and even if your device has not displayed the Defib Comm error message, respond to us within 30 days so that we can schedule your PIC 50 for preventive service. We will be ready to answer any questions you may have regarding this letter.

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After we receive the Appendix 2 response form from you, we will promptly contact you and schedule the service for your PIC 50. We will furnish you with a loaner PIC 50 device to use while your device is being serviced as well as instructions for shipping your device to us for the service.

During the period before your PIC 50 is serviced, it should be checked before each shift by using the self-test, which automatically is initiated by powering up the device. If a Defib Comm error is displayed, or has been previously displayed, the device should be removed from service, if possible, and you should contact us to obtain priority servicing of your device and a loaner. If the Defib Comm error occurs during use, cycling the power off-on may clear the error. Even if power cycling clears the device, you should contact us to obtain priority servicing of your PIC 50.

We greatly appreciate your cooperation and understanding in this matter.

Respectfully,



European Regulatory Manager



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