

Welch Allyn Ltd.
Navan, Co. Meath
Ireland

URGENT: FIELD SAFETY NOTICE

WELCH ALLYN Portable Intensive Care (PIC50)

Dear Welch Allyn PIC 50 Customer:

Previously you will have received a similar communication to this from Welch Allyn - in the format of a "Product Alert Letter". Welch Allyn's Lead Competent Authority in Europe considers this customer communication a Field Safety Corrective Action, and we have been requested to issue this PIC 50 communication in the Field Safety Notice format per MEDDEV 2.12-1 rev 6.

Therefore, you are receiving this communication once again, but with the naming convention 'Field Safety Notice' in place of previous 'Product Alert'. The content of the remainder of this letter is unchanged from the previous version distributed; the only exception being the additional statement advising your National Competent Authority has been notified.

Welch Allyn wishes to inform that it has identified a low potential likelihood for the PIC 50 display to malfunction or fail. The screen displays a patient's ECG to assist in determining whether defibrillation is indicated. Loss of the ability to view the patient's ECG (and other vital signs) on the display could cause the user to delay or fail to administer defibrillation needed to resuscitate a patient.

This malfunction occurs due to partial or complete dislodging of the cable connecting the display to its circuit board such that the connection to the circuit board is lost or compromised. Physical damage to the device due to impact may increase the likelihood of a cable becoming disconnected. All PIC 50s can be affected, regardless of age or condition.

To minimize the likelihood of this malfunction occurring, you must follow the instructions in the PIC 50 user's manual which requires routine daily checks or at each shift change. These checks ensure that the PIC 50 and its components (including the screen display) are fully operational and undamaged. Our analysis indicates that such checks will assist in discovering this potential malfunction, and thus timely maintenance and repair.

The screen display does not affect the ability to obtain a printout of the patient's ECG and other preconfigured parameters by use of the print function. If the Semi-Automatic Defibrillation (SAED) option is activated should the display fail, the voice prompts and defibrillation operation tones would not be affected.

User Actions:

Follow the instructions for use and carry out routine daily and shift checks of the PIC 50. These are in Section 16.1 of the PIC 50 User's Manual. A copy of Section 16.1 is enclosed for your convenience. The entire User Manual is available on line at www.welchallyn.com (search PIC50 Manual).

Remove PIC 50 devices from service; should they appear to have screen display problems or damage, and please arrange for repair.

Although Welch Allyn has discontinued sales of the PIC 50, we have arranged for ZOLL Medical Corporation to provide continued support and service. If your PIC50 experiences a display issue or other device function problems requiring service, please contact ZOLL Technical Support at +49-6441-38331-153.



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We have notified your National Competent Authority of our intended action and will be reporting to them on the effectiveness of this Field Safety Corrective Action.

If you have questions, please call Welch Allyn at +353 (0) 46 9092135 during normal business hours or e-mail fieldsafetynotice@welchallyn.com

Sincerely,

Mr. 
Director, International Quality & Regulatory Affairs
Welch Allyn



Welch Allyn Ltd.
Navan, Co. Meath
Ireland

RESPONSE FORM

Welch Allyn WA10-02-02 - PIC50

To be completed:

We have read and understand the instructions provided in the field safety notice:

Name (please print):	
Signature/Date	
Title:	
Telephone No.	
Email Address:	
Firm Name:	
Address:	
City/State:	

**PLEASE FAX COMPLETED RESPONSE FORM WITHIN (5) WORKING DAYS TO:
FAX 00353 4690 67755**

**Alternatively e-mail a scanned copy of the completed form to:
fieldsafetynotice@welchallyn.com**

**Regulatory Department
Welch Allyn Ltd.
IDA Business Park,
Dublin Road
Navan,
Co. Meath
Republic of Ireland.**

CONSIGNEE REF NUMBER:	
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