

Urgent Field Safety Notice
LIFEPAK® 15 Monitor/Defibrillator and LIFEPAK® 12 Defibrillator/Monitor with
End-Tidal CO₂ option



Physio-Control Operations Netherlands B.V. | Lifesaving starts here.™

ADRES

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Urgent– Please bring this letter to the immediate attention of the person(s) responsible for maintaining/monitoring your LIFEPAK® 15 and LIFEPAK® 12 Monitor/Defibrillators.

February 2017

Dear Valued Customer,

This communication is a notification to specific owners of LIFEPAK 12 and LIFEPAK 15 devices with End-Tidal CO₂ (EtCO₂) functionality. Physio-Control is conducting a voluntary **Field Correction** of these LIFEPAK 12 and LIFEPAK 15 devices.

The attached Confirmation Sheet includes the list of affected device serial numbers that according our files, are in your possession and are impacted by this Field Correction.

Description of Issue

Physio-Control has become aware of an issue where the EtCO₂ reading can intermittently show a value of “XXX” after start-up or during device operation (see example below).



During the investigation, the manufacturer of the EtCO₂ module found that compressed air may have contaminated filters within in the EtCO₂ module. As a result of the contamination of the filter, the EtCO₂ display on the LIFEPAK 12 or LIFEPAK 15 will provide a reading of “XXX”. There may be solid or dashed lines present on the device display in the place of an EtCO₂ waveform and the SERVICE LED will be illuminated. In this situation, the EtCO₂ monitoring functionality will no longer be available.

If the above issue occurs, immediately contact Physio-Control at the phone number below. If the above issue does not occur, please continue to perform the daily device self-tests as indicated in the Operating Instructions and the device is safe to use.

Physio-Control's Planned Actions

Physio-Control is contacting customers with affected devices to schedule the correction of their device(s), which will include replacing the EtCO₂ module.

Required Customer Actions

1. Please forward this information to all of your sites, trainers and users that may have affected LIFEPAK 12 or LIFEPAK 15 device(s).
2. Please follow the instructions on the Confirmation Sheet for each serial number listed in your possession. Promptly return the completed Confirmation Sheet to Physio-Control.
3. If you experience the “XXX” after power-up or during device operation, please contact Physio-Control to arrange for servicing of your device.

Should you have any questions about this subject, please contact your local Physio-Control distributor.

Sincerely,



Rod J. Rylands
Vice President, Quality
PHYSIO-CONTROL, INC.