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URGENT Field Safety Notice

LIFEPAK® 20 and LIFEPAK 20e Defibrillator/Monitors
Medical Device Correction

Medtronic reference: FA473

Dear Customer,

Physio-Control, Inc., a division of Medtronic Inc., is notifying you of two potential power supply issues associated with the LIFEPAK 20/20e defibrillator/monitors. The purpose of this communication is to make you aware of this situation, provide you with instructions in case you encounter either of these issues, and communicate the plan to update affected devices. The failure of the power supply could delay or prevent delivery of defibrillation therapy.

What are the issues?

The LIFEPAK 20/20e defibrillator/monitor has a dual power supply system and is designed to operate on AC (line) power and/or DC (battery) power. We have received reports of separate and unique issues associated with both power supply sources as explained below.

No AC (line) Operating Power

AC power failures have been attributed to specific component failures due to a line over voltage condition preventing AC power operation and preventing battery charging capability. Over an eight (8) year period of time and with 53,480 devices in use for an average of 54 months, there have been 367 AC power failures reported with no adverse patient related events or deaths. Most of these AC power failures were identified during the recommended Operating Instruction device checks.

- *If loss of AC power occurs while the device is in use, the AC Main LED will turn off and the device will automatically switch to DC (battery) power. A fully charged battery will provide full device operation for two (2) hours or for approximately 40 days in stand-by mode. When the DC (battery) is low; the Low Battery message will display. Once the battery is fully depleted, this failure will prevent the recharging of the battery and all device power will be lost.*
- *If the device is not in use and the loss of AC power occurs, the AC Main LED will turn off and the AC loss Alert will sound after 15 minutes (default setting), it will then continue until the battery is depleted.*

No DC (battery) Operating Power

DC power failures have been attributed to residual solder flux under a component causing electrical current leakage that prevents operation on DC power. Over the same eight (8) year

period of time, and for a subset of 42,943 of the same devices described in the "No AC" issue above, and in use for an average of 62 months there have been 400 DC power failures reported including one unconfirmed report of an adverse patient related event in 2006 in which the device did not work on DC power and was not subsequently plugged into AC power. Most of these DC power failures were identified during recommended Operating Instruction device checks

- *If your defibrillator fails to power on with DC (battery) power or shuts down while operating on DC power, immediately connect the defibrillator to AC (line) power. AC power will be the only power source. If no AC power is available, it can result in a delay of defibrillation therapy.*

Am I affected by this issue and what is the action plan?

Our records show that LIFEPAK 20 and/or LIFEPAK 20e defibrillator/monitor(s) that have the potential to experience a power supply issue have been distributed to your facility and are identified on the enclosed list by serial number.

The plan is to update all affected power supplies at no charge in one service update that will address both issues. The plan will be completed in two phases. Phase 1 identifies devices at a higher risk that account for 92% of all DC (battery) power failures. We expect to complete this phase in 9 to 12 months. Phase 2 identifies the remaining lower risk devices that will be updated upon completion of Phase 1. We expect Phase 2 will take an additional 9 to 12 months to complete. Your local Medtronic Physio-Control service representative or Agent/Distributor will begin scheduling updates with you in due course.

What should I do?

The probability that you will experience either of these issues is extremely remote. Additionally, failure of the AC or DC power supply can be detected during routine daily checks. Therefore, until your device is repaired, it is important to keep your defibrillator/monitor(s) in service while we schedule the updates. We recommend the following:

- Keep normally functioning LIFEPAK 20/20e defibrillators/monitors in service connected to AC power and continuously charging DC power whenever possible.
- Follow the recommended daily Operator's Checklist steps in accordance with LIFEPAK 20/20e defibrillator/monitor Operating Instructions – Section 7 – Maintaining the Equipment – Appendix D. These daily checks will identify any potential AC or DC power failure prior to use. A copy of the daily operator's checklist can also be downloaded from our website at www.physio-control-notices.com/LP20power.
- Visit the website above for additional useful information regarding the probability of experiencing a power supply malfunction over the next two years and the relative impact that the frequency of routine device checks has on the likelihood that a malfunction could potentially interfere with a defibrillation event.
- Identify failed units for repair or replacement as quickly as possible.

If your LIFEPAK 20/20e defibrillator/monitor exhibits any power issues that cannot be resolved, immediately call your Medtronic Physio-Control service representative or Agent/Distributor at the number provided below.

In line with requirements of the Irish Medicines Board we need confirmation of receipt of this letter. Please complete the enclosed fax-back form and return it to Medtronic Physio-Control on +44 (0)1923 225 273. Alternatively it can be scanned and e-mailed to david.dunham@medtronic.com. Please return the form within 15 days of receipt of this letter.

What if I don't have LIFEPAK 20/20e defibrillator/monitor(s) any longer?

If you no longer own the LIFEPAK 20/20e defibrillator/monitors on the enclosure list, please contact 01 2769 700 as soon as possible to ensure accurate updating of your account. We recommend customers forward this notification to all of your sites that may have a LIFEPAK 20/20e defibrillator/monitor.

The Irish Medicines Board has been notified of this action.

If you have any questions regarding this notification, please visit our website at www.physio-control-notices.com/LP20power or call 01 2769 700.

Yours sincerely

D. G. Dunham.

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