



LIFEPAK®1000 MEDICAL DEVICE CORRECTION

Physio-Control, Inc. | Lifesaving starts here.™

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Dear Valued Customer,

In January 2017, Physio-Control began sending Notifications to consignees of a LIFEPAK 1000 defibrillator that the company had received reports of a device shut down unexpectedly during patient treatment. This unexpected shut down was due to an intermittent connection between the battery and device contacts. At the time, the company was developing an engineering solution that would correct the issue. The design change was released on June 2, 2017 for the Field Correction of LIFEPAK 1000s.

Physio-Control is in the process of performing Field Corrections for the LIFEPAK 1000 Defibrillators. The information below is a description of the actions Physio-Control is taking.

Field Correction

The Field Corrections that are planned for LIFEPAK 1000 devices include updates to the Device and applying dielectric lubricant to the primary non-rechargeable batteries.

There is a subset of the primary batteries that were produced with insufficient gold on the contacts. These batteries are referred to as Thin-gold batteries. Thin-gold batteries (PN: 3205379-004 and 3205379-005) that have lot code numbers 1422 to 1636 will be replaced.

The Field Correction consists of the following:

1. Installing a new device-side battery interface PCBA with a revised design to increase the gold plating thickness from 30 microinches to 50 microinches.
2. The contacts on the device-side battery interface PCBA were relocated to create a new mating connection with the battery.
3. Adding dielectric lubrication on the battery contacts for primary and rechargeable batteries.
4. Installing foam to restrict motion of the battery installed in the LIFEPAK 1000.
5. Replacing primary batteries that may have insufficient gold with new primary batteries.

In the January 2017 notification Physio-Control provided instructions to remove and reinsert the battery on a weekly basis, which is no longer required after items 1 through 4 are completed. Physio-Control recommends that regular maintenance be performed by following the instructions in the LIFEPAK 1000 Operating Instructions.



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Should you have any questions about this subject, please contact me at 1-425-867-4660, 8:00 A.M. to 5:00 P.M. (Pacific), Monday – Friday.

Sincerely,
PHYSIO-CONTROL, INC.



Kathryn Janecke
Sr. Director, Quality

cc: Chairman Medical Board and relevant of Departments