SCHILLER MEDICAL SAS ZAE SUD BP 90050 4, rue Louis Pasteur F-67162 Wissembourg Cedex



Internet : <u>http://www.schiller-medical.com</u> E.mail : <u>info@schiller.fr</u>

Field Safety Notice Battery for defibrillator FRED easy

Description:

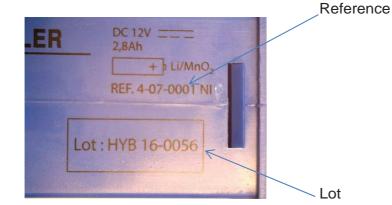
Users have reported some new batteries causing the failure "BATTERY EMPTY" when inserted into a defibrillator FRED easy.

Risk:

Batteries with this fault can not be used. The fault is detected automatically by the FRED easy when the battery is inserted into the device.

Affected Devices:

This Field Safety Notice is intended for the batteries for FRED easy, reference 4-07-0001, with Lot Number HYB 16-0056, HYB 16-0057, HYB 16-0058 and HYB 16-0059.



Interim Measures:

If you purchased a battery reference 4-07-0001, or a FRED easy, between October 1, 2016 and January 15, 2017, you have potentially received a battery impacted by this Field Safety Notice. The batteries of these Lots must be tested, using the procedure described below, to verify that they can be used in your FRED easy.



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Solution: Test procedure:

Insert the battery into your FRED easy (see section 3.1 "Inserting the battery" in the FRED easy user manual).

The unit performs its self-test. At the end of the self-test, it shuts down and its green LED flashes:



In this case, your battery is free from defects and can be used without limitation.

However, if after the self-test of your FRED easy the green light remains off and the display shows:

EMPTY BATTERY >REPLACE BATTERY

Defective battery

Your battery is defective.

In this case, contact your SCHILLER Distributor immediately, to get replacement.

Wissembourg, January 17, 2017

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