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



Internet: http://www.schiller-medical.com

E.mail: info@schiller.fr

Field Safety Notice

Monitor / Defibrillator DEFIGARD Touch 7

Description:

During long-term operating tests, SCHILLER Medical detected on a DEFIGARD Touch7 device, an internal power failure, manifested by its shutdown when charging the defibrillation capacitor. The Monitoring function remains functional.

The origin of this dysfunction is the degradation of one contact of the main battery of the DEFIGARD Touch7.

At this stage of testing, this fault is considered as premature aging of this element.

For the moment, no similar issue has been reported from a user.

Affected Devices:

Are affected by this safety information, all devices bearing the serial number between 128995000101 and 128996000623

Solution:

SCHILLER Medical will preventively change all battery contacts of the devices listed above. You will be contacted by our distributor, for the update schedule

Interim Measures:

Waiting the update of your DEFIGARD Touch 7, you can continue to use it without restriction.

Wissembourg, April 22, 2016



Alain Weissinger Quality Manager

