

Reference: NC3946

November 2021: Follow up of the Field Safety Notice from December 2019

Field Safety Notice

Monitor-Defibrillator DEFIGARD Touch7

For the attention of operators of DEFIGARD Touch7

Local contact :
Customer assistance:

1. Device information
1. Type
DEFIGARD Touch7
2. Trade names
DEFIGARD Touch7
3. Main clinical use of device
Monitor Defibrillator
4. Models concerned by the notice
Reference 1-128-9900 Affected Serial Numbers in attachment Software Version below V08B20

2 Reason for safety notice
1. Description of problem
In rare cases, it is possible that a defibrillation shock cannot be delivered, the device shows an electrode failure, although no electrode failure is present. This results in an internal safety discharge, the shock delivery is canceled. The cause of the electrode fault message may be an impedance loop between the battery charge contacts of the defibrillator and the patient. This is possible when the device is placed on the patient during use (with the charge contacts in contact with the skin), or when the patient and the device are lying on wet ground, and charging contacts come into contact with the ground (for example, the patient and the device are on wet ground, or in the grass). 6 incidents have been identified since Market launch in 2015.
2. Risk
As long as this electrical connection is maintained, no shock delivery is allowed by the device.
3. Source of the problem
The connection between the battery circuits and the patient creates a loop impedance that disturbs the patient impedance measurement, that goes out of range of shock release limits (25-250 Ohms).



3. Action to mitigate the risk

Immediate measures :

You can continue to use your DEFIGARD Touch7 without restriction.
Identify the software version of your DEFIGARD Touch7, you can find it by the following procedure: Press (on the touch screen) the "Menu" key, then "Post intervention", then "stop patient monitoring", then "device info" "The software version is the one called" software package ".

Case 1: with software version lower than Soft 07B07:

If your DEFIGARD Touch7 cancels a shock for no apparent reason, at the same time displaying an electrodes failure, be sure to isolate the device from the ground and / or the patient, and start a new analysis.

Case 2: with software version Soft 07B07 and above:

If your DEFIGARD Touch7 prompts you to isolate it from the ground and / or from the patient (software version Soft07.B07 and above), move it accordingly, and start a new analysis.

However, in all cases, if your software version is lower than V08B ..., we invite you to update your DEFIGARD Touch-7 to the latest software version as soon as possible. This is available from your Distributor, and can be installed by following the instructions in paragraph 10.3 of the user manual.

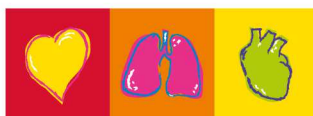
Corrective action :

An exchange of the electronic defibrillation board will be carried out, as part of your next annual maintenance, from the beginning of the year 2022. Your SCHILLER Distributor will contact you soon to plan this intervention, in the course of the year 2022. This new board eliminates the effects of the loop impedance described in 1.


Important note:

The occurrence situation described in 1 / must, however, be avoided as far as possible in the use of a defibrillator, as it is one of the hazardous situations described in the instructions for use. As a reminder, see the warnings below, included in the user manual:

- ▲ The user must make sure that there are no conductive connections between the patient and other persons during ECG analysis and defibrillation.
- ▲ Avoid defibrillation in very moist or wet surroundings.



Please attach a copy of this Safety Information to the User manual.

1. Reply required from the user Please see the modalities on the letter from your distributor		Yes
4. General information		
4.	1. Type of notice	Follow up
	2. additional information expected while monitoring the FSN?	No
	2. The competent (regulatory) authority of your country has been informed of this field safety notice.	
	3. Name/signature	Alain Weissinger Quality and Regulatory Affairs Director
		

Transmission of safety notice	
This notice is to be sent to those who need to be informed within your company or any other company where devices that are potentially concerned have been transferred.	

List of serial numbers:

