

Safety notice reference: IM01159
November 2025

Field Safety Notice

DEFIGARD Touch7 monitor and defibrillator

For the attention of owners and users of DEFIGARD Touch7 monitor/defibrillators

Local contact
Customer assistance:

1. Device information
1. Type
DEFIGARD Touch7
2. Trade names
DEFIGARD Touch7
3. Main clinical use of device
Monitoring and automated external defibrillation
4. Models concerned by this notice
DEFIGARD Touch7 devices with software version SOFT10B17 or SOFT10B18 and a serial no. lower than 128960006000

2 Reason for safety notice
1. Description of problem
Cases have been reported of technical alarms appearing randomly during use. These alarms take the form of a message on the screen "ECG Module inoperative" or "DEFI Module inoperative" and malfunctioning of the ECG or Defibrillation functions.
2. Risk
Could delay the treatment of the patient.
3. Source of the problem
Following an operating software update, from SOFT10B17 onwards a compatibility fault appeared with the first versions of the DEFIGARD Touch7 hardware which could lead to internal communication failures.



3. Action to mitigate the risk

Immediate steps

You can continue to use your DEFIGARD Touch7 with no restrictions, providing you follow the instructions below:

Case 1/ The software version of your DEFIGARD Touch7 is lower than SOFT10B17: it is not affected by this potential malfunction.

Case 2/ The software version of your DEFIGARD Touch7 is SOFT10B17 or SOFT10B18 and its serial no. is lower than 128960006000: If the fault occurs during use, restart the device immediately to return to normal operation.

Corrective action

SCHILLER Medical has developed a new software version to correct this fault. From this software version SOFT10B19 and in all future versions, full compatibility with all the hardware versions will once again be guaranteed.

If your DEFIGARD Touch7 falls within Case 2 above, please update it to version SOFT10B19 without delay.

If your DEFIGARD Touch7 falls within Case 1 above, please update it to version SOFT10B19, as soon as possible to integrate the maintenance test described above.

This new version is available from your SCHILLER distributor, and they will provide any assistance you need with installing it.

Please attach a copy of this safety notice to the instructions for use, and insert one copy in each Defigard Touch-7 bag to inform its users.

Further information concerning maintenance

SCHILLER Médical has also included a predictive maintenance test for the defibrillation circuits in this software to allow early detection of any premature ageing of an essential component. This test intended for use exclusively during the annual maintenance check-ups will be carried out by personnel trained in the maintenance of the DEFIGARD Touch7. No action by the user is required.

The first test will be done during your next scheduled maintenance check-up.

User response required
 See the letter from your distributor for the correct procedure.

YES



4. General information		
4.	1. Type of notice	Initial
	2. additional information expected in the follow-up to the FSN?	
	2. The competent (regulatory) authority of your country has been informed of this notice to customers.	
	3. Name/signature	Alain Weissinger Quality and Regulatory Affairs Director

Circulation of this safety notice	
This notice is to be passed on to all those who need to be informed within your organisation or any other organisation to which devices that are potentially concerned have been transferred.	

