

Safety notice reference: NC4140  
June 2022

## Safety notice

# DEFIGARD Touch7 monitor and defibrillator

For the attention of users of DEFIGARD Touch7 monitors and defibrillators

Local contact
<b>Customer assistance:</b>

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 the notice
All DEFIGARD Touch7 devices

2 Reason for safety notice
1. Description of problem
In rare cases, cancellations of heart rate analyses after 30 seconds were reported.
2. Risk
Failure to analyse can lead to delayed patient treatment.
3. Source of the problem
Sometimes, when the device is switched on directly in manual or semiautomatic defibrillation mode, the wrong ECG lead is selected, and the patient ECG signal is not analysed by the SAS shock advice system.



### 3. Action to mitigate the risk

#### Immediate steps

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

While your DEFIGARD Touch7 has not been upgraded with SOFT 09 software:

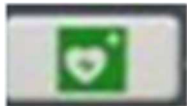
**We strongly recommend to configure your DEFIGARD Touch-7 to start in Monitoring Mode, until upgrade to Soft 09**

DG Touch7 is configurable to start with different mode via SCHILLER Update Server (SUS); See operating instructions, 12.6 Device configuration.

1. DEFIGARD Touch7 has not been upgraded with SOFT09 software:
  - a. DEFIGARD Touch7 is configured for starting up in Monitoring mode, when it is switched on using the On/Off soft key



- b. Do not start it with the direct defibrillator mode starting soft key



2. If your DEFIGARD Touch7 is configured to start in Defibrillator mode (AED or manual defibrillator):

- a. Do not start it using the On/Off key



- b. start it with the monitoring key




- c. The AED or Manual Defibrillator modes can be selected freely from the Monitoring mode.
  - d. If the device is all the same started in Defibrillator mode straightaway, and if an analysis is interrupted, restarting the device in Monitoring mode restores all its features.



**Corrective action**

Schiller Medical is developing a new software version which will prevent the risk of incorrect ECG lead selection.  
From that software version, SOFT09 and above, the device may be used once again after it is started directly in Defibrillator mode.  
The software will be available in the fourth quarter of 2022. The update will follow the usual procedure, described in paragraph 10.3 of the operating instructions.  
You will receive information from your distributor as soon as the software becomes available.

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

1. Response required from the user Please see the modalities in the letter from your distributor		YES
<b>4. General information</b>		
4.	1. Type of notice	Initial
	2. additional information expected while monitoring the FSN?	Fourth quarter of 2022: software update information.
	2. The competent (regulatory) authority of your country has been informed of this notice to customers.	
	3. Surname/signature 	Alain Weissinger Quality and Regulatory Affairs Director

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

