

Safety notice reference: IM0499
May 2024

Safety notice

DEFIGARD HD-7 monitor and defibrillator

For the attention of users of DEFIGARD HD-7 monitors and defibrillators

Local contact
Customer assistance:

1. Device information
1. Type
DEFIGARD HD-7
2. Trade names
DEFIGARD HD-7
3. Main clinical use of device
Monitoring and automated external defibrillation
4. Models concerned by the notice
All DEFIGARD HD-7 devices

2 Reason for safety notice
1. Description of problem
Correction of software faults: 1) An automatic self-test time stamp fault (on 01/01/1970) can set off an alarm on the device without there being a technical fault. 2) In rare cases, there are reports that when the device is switched on for manual defibrillation, the defibrillator was in synchronised defibrillation mode instead of in direct mode.
2. Risk
Could lead to delayed patient treatment.
3. Source of the problem
The faults are software-related.



3. Action to mitigate the risk

Immediate steps

Until your DEFIGARD HD-7 is updated with the software version 02:

1) If there is a self-test alarm, please verify the dates of the latest self-tests. If you find a self-test dated 01/01/1970, the device memory must be reformatted, after first saving your data. The procedure is described in sections 8.1 Post-intervention and 9.1.1 Device settings menu.

2) After switching on in manual defibrillation mode, check that the defibrillator is in the defibrillation mode appropriate for the procedure to be applied. Change modes if needed.

Corrective action

Schiller Medical is releasing a new software version that corrects these faults.

With this Soft02 version and above, the time stamping of self-tests is made more reliable, and the manual defibrillator always starts in direct defibrillation mode.

Please update your DEFIGARD HD-7 as soon as possible, using the procedure described in paragraph 10.3 of the manual

Additional information: The software also includes another modification: the default energy for internal defibrillation (using defibrillation paddles) has been reduced to 10 Joules. It remains user-modifiable.

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

1. Response required from the user Please see the modalities in the letter from your distributor	YES
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4. General information

4.	1. Type of notice	Initial
	2. additional information expected while monitoring the FSN?	None
	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

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.

