

Safety notice reference: NC3489
March 2019

Safety notice

FRED Easy defibrillator

Electrode detection fault

For the attention of users of FRED Easy defibrillators

Local contact : Evolve Medical Pte Ltd Telephone - +65-6250 7108 Email - ra@evolvemedical.com.sg
Customer assistance: Same as above

1. Device information
1. Type
FRED Easy defibrillators
2. Trade names
FRED Easy FRED Easy Skity
3. Main clinical use of device
Automated external defibrillation
4. Models concerned by the notice
All FRED Easy and FRED Easy Skity devices

2 Reason for safety notice
1. Description of problem
During an analysis of the failure to recognise defibrillation electrodes, rare cases of the mechanical blocking of an internal relay to the FRED defibrillator were identified. The incident rate in relation to the number of devices in the market ranges from 0.001% to 0.005 %.
2. Risk
The defibrillator can no longer analyse the heart rhythm.
3. Source of the problem
These blocks are due to the device sustaining one or more violent mechanical impacts, such as in a fall from over a metre onto a hard floor. Such a stress can move a manoeuvring part of an electromagnetic relay and put it out of operation.



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3. Action to mitigate the risk

1. Action to be taken by the user

Operators/users are asked to take the following action as early as possible:

Operators/users must check the outside condition of their FRED Easy device to identify any signs of impacts or falls and make sure that no part is moving inside the FRED Easy, by turning it several times.
Examples of signs of impact



If the FRED Easy device shows cracks, impacts or deformation that could suggest that it has sustained a significant mechanical impact or contains a moving part, it should undergo maintenance.

Similarly, if a fall from over a metre is observed or suspected by the user, whether or not with the FRED Easy in its protective bag, users are strongly advised to subject it to preventive or corrective maintenance.

If your FRED Easy has experienced any of the above, the verification requires the use of a simulator for defibrillators, which is a device that generates an ECG rhythm and can receive a defibrillation shock.

The procedure consists in connecting the FRED Easy device to the simulator for defibrillators and delivering a defibrillation shock into the simulator. That confirms proper operation.

The check is to be carried out by the user, if they have such a simulator, or by any other maintenance third party approved by the manufacturer.

All repairs are to be made by a repairer approved by the manufacturer.

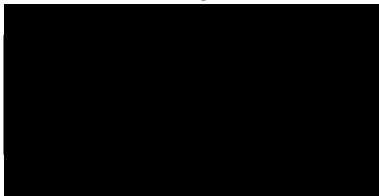
Any damaged housing must be replaced.

Important: Devices that do not have the faults described in this information must remain in use, and may continue to be used without restriction. Please enclose a copy of this safety notice to the instructions for use.



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Reminder: Defibrillators must necessarily undergo regular maintenance. Preventive maintenance operations (visual inspections, maintenance frequency) are described in the instructions for use, paragraph 7, Maintenance.	
2. Reply required from the user Please see the modalities on the letter from your distributor	YES

4. General information		
4.	1. Type of notice	Initial
	2. additional information expected while monitoring the FSN?	Not provided
	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

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.



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Cc: Chairman Medical Board and Relevant Head of Departments

Information confirmation form

Safety notice FRED Easy defibrillator Electrode detection fault

Please complete this document and send it back to us as soon as possible to the SCHILLER Distributor:

☐ I confirm the receipt of the Field Safety Notice, about my device(s):

Serial number

☐ I confirm the realization of the actions described in the Field Safety Notice

:

Name*: ----- Telephone*: -----

Position*: ----- Email*: -----

Signature*: (* required information)

Return by fax: 62507507

By email: admin@evolvemedical.com.sg



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