SCHILLER MEDICAL
4, rue Louis Pasteur
67160 Wissembourg – France

Safety notice reference: SG5404
April 2023

Safety notice
Defibrillator FRED PA-1

For the attention of users of FRED PA-1 defibrillators

Local contact
Customer assistance:

1. Device information
1. Type
FRED PA-1
2. Trade names
FRED PA-1
3. Main clinical use of device
Automated external defibrillation
4. Models concerned by the notice
Automatic defibrillators made between 7 December 2022 and 25 January 2023 bearing a serial number in the enclosed list

2 Reason for safety notice
1. Description of problem
During internal tests, SCHILLER Medical has identified a nonconforming component batch that could affect the working of the PA-1 defibrillator in automatic defibrillation mode.
2. Risk
The first defibrillation shock is always delivered, but one or more subsequent shocks could be cancelled by the defibrillator. The issue occurs randomly. Estimated frequency of adverse event: 0.08% of uses, with the potentially affected devices. No incident has been reported.
3. Source of the problem
Faulty component batch. Indeed, an increased fault rate was found in production in this component batch. Laboratory tests indicate a reliability risk in the medium or long term. The devices manufactured using that batch have been identified.

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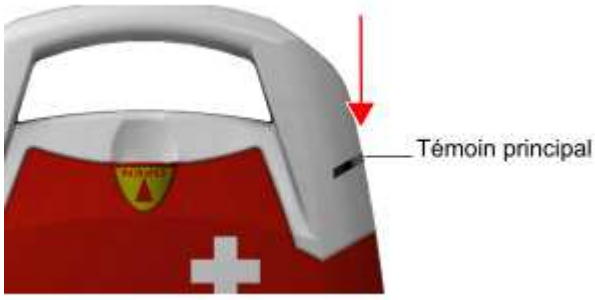
3. Action to mitigate the risk

Corrective action

SCHILLER will recall the FRED PA-1 devices containing the components from the batch identified as potentially faulty, and will replace the component.

Immediate steps

You may continue to use your FRED PA-1 with no restrictions, providing you follow the instructions below:
Your FRED PA-1 is monitored by periodic self-tests.
If a fault is detected, the main indicator no longer flashes in green, but remains off and a sound alarm is emitted:



If your FRED PA-1 is in such a condition, please inform your SCHILLER distributor immediately to schedule corrective maintenance as early as possible. However, the randomness of the fault makes detection uncertain.

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

4. General information

4.	1. Type of notice	Initial
	2. additional information expected while monitoring the FSN?	
	2. The competent (regulatory) authority of your country has been informed of this notice to customers.	
	3. Surname/signature	[redacted] 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.