

Field Safety Notice

Device Commercial Name: FRED easyport plus®

Type of Action: Fixing a problem of managing periodic self-tests.

FSCA Ref: Manufacturer's ref number #1827674

Date: 01/03/2021

Notification: SCHILLER subsidiaries, distributors and customers.

Information on Affected Devices

Device Name: FRED easyport plus®

Affected devices

All FRED easyport plus® up to serial number 9000.001164



Primary clinical purpose of device(s)

The FRED easyport plus® is an external cardiac defibrillator that can deliver shock in manual, semi-automatic or fully automatic mode.

Reason for Field Safety Corrective Action (FSCA)

Description of the problem:

The FRED easyport plus defibrillator® can perform periodic self-tests.

The result of the last periodic self-test is indicated using the RTU LED (ready-to-use LED).

- Status OK: green blinking LED (Two second interval)
- Device failure status: LED OFF



The periodicity of these self-tests can be configured to a monthly, weekly or daily interval.

It has been reported that in the case of daily self-test configuration some self-tests are not performed within the allotted time.

The absence of a planned self-test results in the following behavior, depending on the software version of the device:

Version 1.0: The device will perform the self-test at the next turning on and turns off. It needs to be turned on again for use.

Version 1.1: The device displays the "Battery Test Error" message during startup but remains available for use. (Green blinking RTU LED)
The error message is a "false positive."

If the battery is below 10%, the Ready-to-use will not light and the device will start beeping until the battery is completely empty. When the device starts beeping, the device has still enough capacity to deliver at least 3 shocks.



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Risk:



With a FRED easyport plus® with software version **1.0**: Delay of treatment no more than one minute when starting up device, due to the execution of a self-test.

With a FRED easyport plus® with software version **1.1**: Ambiguous state, due to an erroneous error message. Indicated self-test error may be ignored as it does not compromise the normal functioning of the product.

Type of Action to mitigate the risk

Action to be taken by the user

Check which software version is installed:

1. Press and hold the  button while switching the device on.  The Configuration menu appears.
2. Select menu "Device Information" and check the SW Version.

Preventive actions:

1/ If your device has software version **1.0**, update immediately to the version **1.1**:

Service personnel: Follow the instruction in chapter '5 Update software' of the 2.540108a_EN_FRED easyport plus Service handbook (Art. no.: 2.540108 Rev. a).

End customer: Contact your SCHILLER authorized service representative.






2/ When your device has software version **1.1**, set your FRED easyport plus® to monthly frequency for self-tests, as followed:

Service personnel: Follow the instruction in chapter '4 Configuration' and '4.3.3 Self-test Settings' of the 2.540108a_EN_FRED easyport plus Service handbook.

End customer: Contact your SCHILLER authorized service representative.

If you want to check that your device is working at shorter intervals (daily or weekly), do use the manual testing procedure:

Performing manual self-test

1. Press and hold the  button while switching the device on.  The Configuration menu appears with the selected "Self-Test" menu.
2. Press the "OK" button  and select with the "Next" button  "Do Self-Tests" and start it with the "OK" button.  These tests take about 30 seconds.
3. Test in progress is displayed on the top of the display.

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4. After successful test "Self-Test Passed", switch off the device immediately to prevent discharging the battery.

Corrective action planned by the manufacturer

If you use your FRED easyport plus® configured with a monthly self-test, no action is required in the short to medium term. A correction will be made during your next maintenance, by your SCHILLER authorized service representative.

If you need to set up your FRED easyport plus® daily or weekly testing (for example, for frequent use), **please contact your SCHILLER authorized service representative to schedule an update.**

All action shall be completed by 31-May-2021.

List of attachments/appendages

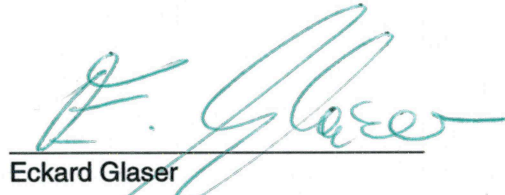
- ANNEX – ACKNOWLEDGE FORM


 Johann-Jakob Schmid

Senior Vice President

SCHILLER AG, Switzerland

Date: 01.03.2021


 Eckard Glaser

Head of Quality Management

SCHILLER AG, Switzerland

Date: 1.3.2021

Transmission of this Field Safety Notice

Please make sure that all users of the devices, and other relevant persons within your organization will be aware of this new field safety notice.
 If your organization passed the devices to third parties, please forward a copy of this information or inform the contact person mentioned below.
 Please maintain awareness of this notice and resulting actions at least until the corrective action has been completed.

The responsible National Authority has been informed about this communication of this field safety notice.

Contact details manufacturer:

SCHILLER AG
 Altgasse 68, CH-6341 Baar, Switzerland
 www.schiller.ch

Philipp Meier, Quality Assurance Manager
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quality@schiller.ch
 T: +41 41 766 42 42
 D: +41 41 766 43 44

ANNEX – ACKNOWLEDGE FORM

Please sign the completed form and return a copy by e-mail or mail to quality@schiller.ch not later than **31-May-2021**.

With the signature below the distributor / end customer confirms, that:

1. We have read and understood the Field Safety Notification #1827674 dated 01/03/2021.
2. We confirm that within our organization all users and other persons concerned have been informed about the content of the Field Safety Notification.
3. We confirm that if needed the requested tasks will be performed.

Fill out the list with the serial numbers (S/N) and the information of the end customer. Including the responsible person and the date the FSCA has been performed. Please write a justification if the tasks cannot be performed until the given due date.

S/N of Device	Customer	Address	Date of Update / Justification

Instead of filling out this table you can also provide this information in a separate Excel spreadsheet.

Distributor: _____

Contact Person: _____

Position: _____

Address: _____

Country: _____

Phone: _____

Comments/Notes: _____

Date / Signature _____