SCHILLER
The Art of Diagnostics

SCHILLER | Altgasse 68 | 6341 Baar, Switzerland
Tel: +41 41 766 42 42 | vigilance@schiller.ch | www.schiller.ch
CHE-105.868.779 MWST

FSCA Ref: SAGQI-1082

Field Safety Notice (FSN)

FRED easyport

manufactured by

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

SRN: CH-MF-000012722 / CHRN: CHRN-MF-20000372

Date: YYYY-MM-DD

Attention: Schiller authorized distributors and their customers

A problem related to the FRED easyport has been detected.

This notice is intended to inform you about:
- what the problem is and under what circumstances it can occur.
- the actions that you as a distributor/customer can take to minimize the effect of the problem.
- the actions planned by SCHILLER AG to correct the problem.

We kindly ask that you read this notice carefully and send us immediate written acknowledgement no later than **2025-05-29** that you have read and understood the contents. Written acknowledgement can be sent to SCHILLER AG via the contact details listed below.

If you need any further information concerning this FSN, please do not hesitate to contact the SCHILLER AG Vigilance Team: vigilance@schiller.ch

For technical support, please contact your local distributor.

SCHILLER AG apologizes for any inconveniences caused by this problem.

Sincerely,

Stefan Bigler
Head of Regulatory Affairs
vigilance@schiller.ch
T: +41 41 766 42 42

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1. INFORMATION ON AFFECTED DEVICES	
COMMERCIAL NAME(S):	FRED easyport
PRIMARY CLINICAL PURPOSE OF DEVICE(S)*	The FRED easyport is an automated external defibrillator (AED) used for the treatment of ventricular fibrillation (VF) and ventricular tachycardia (VT).
MODEL/CATALOGUE/ REF NUMBER(S):	3.940050 / 0.900000
AFFECTED DEVICES:	All devices
UNIQUE DEVICE IDENTIFIER(S) (UDI-DI):	07613365001075
DEVICE TYPE:	Non-rechargeable professional semi-automated external defibrillator
2. REASON FOR FIELD SAFETY CORRECTIVE ACTION (FSCA)	
BACKGROUND INFORMATION AND PROBLEM DESCRIPTION	SCHILLER AG has identified isolated cases where the FRED easyport failed routine maintenance tests due to defective IGBT modules. Failure of the IGBT module may result in the device failing the maintenance by being unable to deliver a shock. However, it may be possible to deliver a limited number of shocks before failing to deliver further shocks. This issue has occurred exclusively during maintenance, and no incidents involving patients have been reported.
HAZARD GIVING RISE TO THE FSCA	If regular maintenance is not carried out at the intervals specified in the IFU, a defective IGBT module may go undetected. As a result, excessive leakage current in the module could prevent the device from fully charging the capacitor, thereby limiting the number of shocks it can deliver before failing to deliver further shocks.
PROBABILITY OF PROBLEM ARISING	Since its market launch, a total of 18,958 FRED easyport devices have been distributed worldwide. To date, SCHILLER AG has identified 15 incidents linked to defective IGBT modules, equating to an occurrence rate of approximately 0.08% of all distributed devices.
PREDICTED RISK TO PATIENT/USERS	Defective IGBT modules are reliably detected during the mandatory maintenance procedure and therefore do not pose a risk to patients or users when maintenance is performed as specified. However, if the mandatory maintenance procedure is not carried out, an undetected defective IGBT module could potentially cause the device to lose functionality if initial shocks do not result in successful treatment.

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	According to the risk analysis, such a loss or reduction of functionality is classified as severity level S3. In a worst-case scenario, this: • Results or may result in permanent impairment or irreversible injury, • or requires or may require immediate medical or surgical intervention to prevent permanent organ damage, • or reduces or may reduce the probability of survival, • or results or may result in unnecessary or preventable surgical intervention
3. TYPE OF ACTION TO MITIGATE THE RISK	
GENERAL ACTIONS	All USERs are requested to read the current valid Instruction for Use (EN: Ver.: p) and take note of the lifetime in chapter 7.2 Safety standard. To ensure the reliable operation of the device and detect potential IGBT module defects and other vital component defects at an early stage, always perform the required maintenance actions at the intervals specified in IFU chapter 6.1 Maintenance Intervals: • A function test every four months, conducted by the device user. • A prescribed safety and measurement check every four years, performed by service staff authorized by SCHILLER. Both maintenance actions are crucial in identifying a defect of the IGBT module.
ACTION TO BE TAKEN BY THE DISTRIBUTOR / IMPORTER	1) Send the FSN to all identified USERs. 2) Provide USERs with the latest version (EN: Ver.: p) of the Instruction for Use. 3) Send the signed ANNEX Ia – Initial Distributor/Importer Reply Form back to SCHILLER AG by **2025-05-29** as confirmation that the content of this notice was read and understood and that this Field Safety Notice was distributed to all USERs. 4) Identify all devices within the eight-year lifetime of which the mandatory four-year safety and measurement check is overdue. 5) Request these devices from the USER and perform the four-year safety and measurement check. Inform SCHILLER AG about these devices once the four-year safety and measurement check has been performed. 6) Investigate all devices which failed the four-year safety and measurement check or the function test defined in section ACTION TO BE TAKEN BY THE USER, 2). 7) Inform support@schiller.ch regarding the investigation findings to define the appropriate remediation. 8) Send the signed ANNEX Ib – Final Distributor/Importer Reply Form back to SCHILLER AG by **2026-04-01** as confirmation that all required actions have been performed.

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ACTION TO BE TAKEN BY THE USER	1) Always use and follow the current instruction for use (EN: Ver.: p) For devices within the defined lifetime of eight years: 2) Immediately perform a function test on your device, as outlined in IFU Chapter 6.1.2, regardless of the scheduled maintenance or function test status. **Important: always use a full battery!** 3) Send the devices which **failed** the function test **to your authorized distributor** for further investigation by **2025-12-12**. For devices which passed the function test, no further immediate actions are required. Follow the maintenance interval as specified in the IFU Chapter 6.1. 4) Send ANNEX II – Customer Reply Form back to your authorized distributor as confirmation that this Field Safety Notice was read and understood and all required actions have been performed.
DATE FOR COMPLETION:	**2026-04-01**
IS THE FSN REQUIRED TO BE COMMUNICATED TO THE PATIENT / LAY USER?	No
LIST OF ATTACHMENTS	ANNEX Ia – Initial Distributor/Importer Reply Form ANNEX Ib – Final Distributor/Importer Reply Form ANNEX II - Customer Reply Form
TECHNICAL SUPPORT	For technical support, please contact your local distributor.

Transmission of this Field Safety Notice
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)
Please transfer this notice to other organisations on which this action has an impact. (As appropriate)
Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback. *

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

Contact person of manufacturer:

Stefan Bigler
Head of Regulatory Affairs
vigilance@schiller.ch
T: +41 41 766 42 42

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ANNEX Ia – Initial Distributor / Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	SAGQI-1082
FSN Date*	Pre-filled by manufacturer
Product/ Device name*	FRED easyport

2. Manufacturer Details	
Company Name	SCHILLER AG
SRN	CH-MF-000012722
CHRN	CHRN-MF-20000372
Address	Altgasse 68 6341 Baar, Switzerland
Contact Name	Stefan Bigler
Email	vigilance@schiller.ch
Telephone Number	+41 41 766 42 42

3. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

4. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt of this Field Safety Notice and that I read and understood its content.	Distributor/Importer to complete or enter N/A
☐	I checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
☐	*I have identified customers that received or may have received this device	
☐	*I have attached the completed device list	
☐	*I have informed all identified users	
☐	I returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number, Date Returned
☐	I destroyed affected devices	Add quantity, Lot/Serial Number, Date destroyed
☐	Neither I nor any of my customers have any affected devices in inventory	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

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ANNEX Ib – Final Distributor / Importer Reply Form

5. Field Safety Notice (FSN) information	
FSN Reference number*	SAGQI-1082
FSN Date*	Pre-filled by manufacturer
Product/ Device name*	FRED easyport

6. Manufacturer Details	
Company Name	SCHILLER AG
SRN	CH-MF-000012722
CHRN	CHRN-MF-20000372
Address	Altgasse 68 6341 Baar, Switzerland
Contact Name	Stefan Bigler
Email	vigilance@schiller.ch
Telephone Number	+41 41 766 42 42

7. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

8. Distributors/Importers (Tick all that apply)		
☐	*I have carried out the actions for DISTRIBUTOR / IMPORTER as requested by this FSN.	Note Qty., Lot/Serial Number(s), Date of completion
☐	*I have received the completed reply form from all identified customers	
☐	I returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number, Date Returned
☐	I destroyed affected devices	Add quantity, Lot/Serial Number, Date destroyed
☐	Neither I nor any of my customers have any affected devices in inventory	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

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ANNEX II - Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	SAGQI-1082
FSN Date*	Pre-filled by manufacturer
Product/ Device name*	FRED easyport

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	*I confirm the receipt of this Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A
☐	*I have identified all affected devices	Note quantity, Lot/Serial Number(s)
☐	*The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A
☐	*I have carried out the actions for USER as requested by this FSN.	Note Qty., Lot/Serial Number(s), Date of completion
☐	I have returned affected device(s)	Note Qty., Lot/Serial Number(s), Date of return of all returned devices.
☐	I have destroyed affected device(s)	Note Qty., Lot/Serial Number(s), Date of destruction of all destroyed devices.
☐	I sold my device(s)	Note device serial number(s) and contact details of the new owner.
☐	I do not have any affected devices.	Customer to complete or enter N/A
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.