SCHILLER AG | Altgasse 68 | 6341 Baar, Switzerland
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info@schiller.ch | www.schiller.ch

Field Safety Notice (FSN)

FRED easyport plus

manufactured by

SCHILLER AG, Altgasse 68 CH-6341 Baar, Switzerland
www.schiller.ch
SRN: CH-MF-000012722 / CHRN: CHRN-MF-20000327

Date: 2022-03-02

Attention: Schiller authorized distributors and their customers.

Issues related to the functionality of FRED easyport plus has been identified:
➔ Misleading Ready-To-Use Status and Analysis interruption.

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 written acknowledgement **by 15th of April 2022** that you have read and understood the contents of this notice. Written acknowledgement can be sent to SCHILLER AG via the contact vigilance@schiller.ch.

If you need any further information or support concerning this issue, please do not hesitate to contact SCHILLER AG Customer Services: support@schiller.ch

SCHILLER AG apologizes for any inconveniences caused by this problem.

Sincerely,

Valentina Shcherba
Head of Regulatory Affairs
Altgasse 68, CH-6341 Baar, Switzerland
vigilance@schiller.ch
T: +41 41 766 42 42

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1. INFORMATION ON AFFECTED DEVICES	
COMMERCIAL NAME(S):	FRED easyport plus
PRIMARY CLINICAL PURPOSE OF DEVICE(S)*	The FRED easyport plus® is a defibrillator with the possibility to deliver a shock in semi-automatic, fully automatic or manual mode. FRED easyport plus® is intended to be used to terminate cardiac arrhythmia such as Ventricular Fibrillation (VF) or Ventricular Tachycardia (VT) with a defibrillation shock.
MODEL/CATALOGUE/ REF NUMBER(S):	REF : 3.940060, 3.940066, 3.940063 Catalogue number: 0A.900000
SOFTWARE VERSION:	All software versions below 1.2.2
AFFECTED SERIAL OR LOT NUMBER RANGE :	See list of affected products in Annex III
UNIQUE DEVICE IDENTIFIER(S) (UDI-DI):	07613365001921
DEVICE TYPE:	Automated-External defibrillator (AED)

2. REASON FOR FIELD SAFETY CORRECTIVE ACTION (FSCA)	
PROBLEM DESCRIPTION	The device sets the RTU (Ready-To-Use) state to OK by default unless the self-test fails. This results in the RTU state being incorrectly set to OK if the device crashes during the self-test or shuts off (e.g., because of insufficient battery capacity).
	If the device is operated with the volume set to the maximum the audio amplifier consumes more energy and generates more noise on the internal supply voltage. The devices can (depending on absolute patient impedance and language setting) recognize that noise as an ongoing chest compression and therefore can interrupt the analysis and does not recommend delivering a shock.
Hazard giving rise to the FSCA	Possible loss or reduction of the device's functionality.
PROBABILITY OF PROBLEM ARISING	The probability of the occurrence is unlikely, but expected for the devices during lifetime, when the battery gets a very low battery capacity and will be not exchanged as required by maintenance instructions or in case of specific languages where a language audio file volume is set to maximum.
PREDICTED RISK TO PATIENT/USERS	Delay to treatment is possible in case the user is misled by the device readiness status. An interruption of the analysis and no shock delivery might affect probability of survival.
	However, this risk of no shock delivery can be mitigated by mechanical resuscitation (chest compressions) by trained medical personnel / users of the device who will always need take into account the current clinical condition of the patient as per BLS instructions and guidance and perform clinical measures as needed, including CPR.

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3. TYPE OF ACTION TO MITIGATE THE RISK	
ACTION TO BE TAKEN BY THE USER or AUTHORIZED DISTRIBUTOR / CUSTOMER	1) Send the Annex I - Distributor Reply Form / Annex II - Customer Reply Form back to SCHILLER AG **by 15th of April 2022** that the content of this notice was read and understood. 2) Update the affected devices according to the Service Instructions **by 15th of June 2022.** Please note: The new Software version 1.2.2 and its Service Release Notes on how to perform the update are available **on SCHILLER Service website:** Software (schiller.ch) : https://extra.schiller.ch/products/Rescue/Pages/software.aspx?productId=367 3) Send the Annex I - Distributor Reply Form / Annex II - Customer Reply Form including the confirmation about the updated devices back to SCHILLER AG **by 15th of June 2022.**
DATE FOR COMPLETION:	**15th of June 2022**
ACTIONS BEING TAKEN BY THE MANUFACTURER	☒ Software upgrade A new version of the software will be provided for the update of the device.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact SCHILLER AG Customer Services: support@schiller.ch

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:
Valentina Shcherba
Head of Regulatory Affairs
Altgasse 68, CH-6341 Baar, Switzerland
vigilance@schiller.ch
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ANNEX I
Distributor/Importer Reply Form

FRED easyport plus

SCHILLER AG, Altgasse 68 CH-6341 Baar Switzerland

Please complete, sign, and return your acknowledgement by 15th of April 2022 to vigilance@schiller.ch

1. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

For the list of affected products, see ANNEX III

2. Distributors/Importers (Tick all that apply)		
☐	***I confirm the receipt, the reading and understanding of the Field Safety Notice.**	Distributor/Importer to complete or enter N/A
☐	I have 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 customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number, Date Returned (same information as requested by the Customer Reply form
☐	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number, Date Returned/Destroyed (same information as requested by the Customer Reply form
☐	Neither I nor any of my customers has any affected devices in inventory	

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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 II
Customer Reply Form

FRED easyport plus

SCHILLER AG, Altgasse 68 CH-6341 Baar Switzerland

Please complete, sign, and return your acknowledgement by 15th of June 2022 to vigilance@schiller.ch

1. 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*	

For the list of affected products, see ANNEX III

2. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.*	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.*	Customer to complete or enter N/A		
☐	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 returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number: Or provide a separate list	Date Returned (DD/MM/YY):
		N/A	Comments:	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number: Or provide a separate list	
		N/A	Comments:	

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☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A
☐	Other Action (Define):	
☐	I do not have any affected devices.	Customer to complete or enter N/A
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
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.

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Annex III
List of affected devices

Serial Nummer	Date of the Update / Comments
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