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-2574

Field Safety Notice (FSN)

EASY PULSE

manufactured by

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

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

Date: 2025-10-17

Attention: Schiller authorized distributors and their customers

A problem related to the device failing to start mechanical CPR after the software update to version 1.1.3 occurred.

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 2025-11-14 that you have read and understood the contents of this notice. 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 inconvenience 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):	EASY PULSE
PRIMARY CLINICAL PURPOSE OF DEVICE(S)*	Mechanical CPR device
MODEL/CATALOGUE/ REF NUMBER(S):	3.940409 (GTIN: 07613365001853) 3.940410 (GTIN: 07613365001679)
SOFTWARE VERSION:	1.1.3
AFFECTED SERIAL OR LOT NUMBER RANGE:	All devices with software (SW) version 1.1.3
DEVICE TYPE:	The EASY PULSE is an active therapeutic device intended to do automatic multidirectional chest compression. It must only be used by medical personnel that has been trained on the device.

2. REASON FOR FIELD SAFETY CORRECTIVE ACTION (FSCA)	
BACKGROUND INFORMATION AND PROBLEM DESCRIPTION	SCHILLER AG was informed by an authorized distributor that after the SW update to version 1.1.3, the device does not start mechanical CPR when the start button is pressed. In such cases, the device emits both a visual and an audible warning and enters a defined error state as part of its safety mechanism. The root cause has been identified as excessive counterforce applied to the piston at start-up, which prevents the piston from initiating movement. With the release of software version 1.1.3, the initial acceleration of the piston was reduced. However, this adjustment has inadvertently increased the device's sensitivity to counterforces, resulting in premature activation of the safety stop under certain conditions.
HAZARD GIVING RISE TO THE FSCA	In case the device is mounted tightly, it may not be able to perform mechanical CPR.
PROBABILITY OF PROBLEM ARISING	The problem is expected to occur systematically in all devices operating with software version 1.1.3. The device will not initiate mechanical CPR if counterforce is present at start-up, as the safety mechanism is triggered. Nevertheless, the number of devices in the field with software version 1.1.3 is limited, as this version was available only for a short time period and devices are routinely tested following each software update.
PREDICTED RISK TO PATIENT/USERS	Worst case, the device cannot perform mechanical CPR. This loss or reduction of functionality may lead to a permanent impairment or irreversible injury.
OTHER INFORMATION RELEVANT TO FSCA	No device was produced with SW version 1.1.3. Only devices which received a SW update to 1.1.3 are affected by this FSCA. If the device with SW version 1.1.3 enters the error state, as it is mounted too tightly, slightly loosening the belt could resolve the issue and make the device operate as intended.

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3. TYPE OF ACTION TO MITIGATE THE RISK	
ACTION TO BE TAKEN BY THE DISTRIBUTOR / IMPORTER	1) Identify all potentially affected users and forward this FSN without delay. Additionally, inform the users which SW version is installed on their device. 2) Send the signed ANNEX Ia – Initial Distributor/Importer Reply Form back to SCHILLER AG by **2025-11-14** as confirmation that the content of this notice was read and understood and that this FSN was distributed. 3) Collect signed ANNEX II confirmations from the users. 4) Update all identified devices with SW version 1.1.3 to SW version 1.1.4 according to the Service Manual. In case SW version 1.1.4 is not yet available, downgrade the device to SW version 1.1.1. 5) Send the signed ANNEX Ib – Final Distributor/Importer Reply Form back to SCHILLER AG by **2026-04-17** as confirmation that all required actions have been performed.
ACTION TO BE TAKEN BY THE USER	1) Carefully read the content of this FSN 2) Send ANNEX II – Customer Reply Form back to your authorized distributor as confirmation that this Field Safety Notice was read and understood.
DATE FOR COMPLETION:	2026-04-17
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.
ADDITIONAL NOTE	In general, the manufacturer recommends keeping the devices up to date and have the newest SW installed.

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-2574
FSN Date*	2025-10-17
Product/ Device name*	EASY PULSE

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 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-2574
FSN Date*	2025-10-17
Product/ Device name*	EASY PULSE

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 attached the completed device list	
☐	*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-2574
FSN Date*	2025-10-17
Product/ Device name*	EASY PULSE

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.