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-3119

Field Safety Notice (FSN)

SEMA

manufactured by

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

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

Date: 2026-07-08

Attention: SCHILLER authorized distributors and their customers

A problem has occurred related to the representation of ECG signals in SEMA when used in combination with DEFIGARD Touch 7 and ARGUS PRO LifeCare 3.

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 at the latest by 2026-08-07 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

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-3119

1. INFORMATION ON AFFECTED DEVICES	
COMMERCIAL NAME(S):	SEMA (used in combination with DEFIGARD Touch 7 and ARGUS PRO LifeCare 3)
PRIMARY CLINICAL PURPOSE OF DEVICE(S)*	SEMA is a diagnostic data management system intended to be used by or under the direct supervision of a licensed healthcare practitioner in healthcare facilities for the reception, viewing, analyzing, editing, printing, and storing of cardiovascular, pulmonary, monitoring, defibrillation and patient demographic records.
MODEL/CATALOGUE/ REF NUMBER(S):	0A.602010 SEMA software package 0A.602030 SEMA Server 0A.602000 SEMA Client Office 0A.602020 SEMA Client Enterprise
SOFTWARE VERSION:	Below 25.10
AFFECTED SERIAL OR LOT NUMBER RANGE:	All SEMA Server and SEMA Client installations below version 25.10, which are used in combination with DEFIGARD Touch 7 with Software version 20B10_L05 or an ARGUS PRO LifeCare 3 with Software version 01B03_L01 as ECG acquiring devices.

2. REASON FOR FIELD SAFETY CORRECTIVE ACTION (FSCA)	
BACKGROUND INFORMATION AND PROBLEM DESCRIPTION	SCHILLER AG has identified that ECG recordings transmitted from DEFIGARD Touch 7 or ARGUS PRO LifeCare 3 devices to SEMA may not always be displayed identically in SEMA. The affected acquiring devices record, display, and print the ECG signal as intended. The issue may occur because DEFIGARD Touch 7 or ARGUS PRO LifeCare 3 transmit the ECG recording with a pre-applied CBS filter. This condition was not considered in affected SEMA versions, which may apply additional signal processing to the already filtered ECG signal. As a result, there might be some discrepancies between the ECG on the acquiring device and the ECG displayed or exported with SEMA. The issue only manifests when recordings taken with a DEFIGARD Touch 7 (Software version 20B10_L05) or with an ARGUS PRO LifeCare 3 (Software version 01B03_L01) are displayed or exported with SEMA versions below 25.10.
HAZARD GIVING RISE TO THE FSCA	SCHILLER AG performed a clinical review of the discrepancies on a large set of real-world ECG recordings. The clinical review concluded that despite visible differences, all paired ECG representations lead to the same clinical diagnosis and treatment decisions.

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

PROBABILITY OF PROBLEM ARISING	The issue may occur only when ECG recordings from DEFIGARD Touch 7 (Software version 20B10_L05) or ARGUS PRO LifeCare 3 (Software version 01B03_L01) devices are reviewed or exported in SEMA versions below 25.10. Other ECG acquiring devices, as well as DEFIGARD Touch 7 or ARGUS PRO LifeCare 3 with lower software versions, transmit the ECG signal without pre-applied CBS filter and are not affected by this issue.
PREDICTED RISK TO PATIENT/USERS	Based on the clinical review, no adverse health consequences are expected. Despite visible differences, all paired ECG representations lead to the same clinical diagnosis and treatment decisions. This FSN is intended to address and correct the technical issue described above and to ensure identical representation of the ECG recording across all SCHILLER devices.
OTHER INFORMATION RELEVANT TO FSCA	Recordings stored in the SEMA Server database are not affected. Using SEMA version 25.10, the representation of all stored recordings is identical to the original signal. The correction of this issue is included in SEMA version 25.10 or higher. Independently of this FSCA, SCHILLER AG strongly recommends keeping SEMA updated to the latest available software version.

3. TYPE OF ACTION TO MITIGATE THE RISK

ACTION TO BE TAKEN BY THE DISTRIBUTOR / IMPORTER

1) Identify and inform all potentially affected users who are using SEMA in combination with a DEFIGARD Touch 7 or an ARGUS PRO LifeCare 3.
2) Before **2026-08-07,** send the signed **ANNEX Ia – Initial Distributor/Importer Reply Form** back to SCHILLER AG as confirmation that the content of this notice was read and understood and that this FSN was distributed.
3) Collect acknowledgements from the affected users that this notice was read and understood.
4) Make sure that all affected SEMA installations are updated to the newest Version (at least 25.10).
5) Regularly provide a status update to SCHILLER AG about the progress.
6) Before **2027-07-08**, or upon completion of all actions, send the signed **ANNEX Ib – Final Distributor/Importer Reply Form** back to SCHILLER AG as confirmation that all required actions have been performed.

Please ensure that all future installations have the latest SEMA version, particularly when used in combination with DEFIGARD Touch 7 or ARGUS PRO LifeCare 3.
Also, please ensure that SEMA is updated to the newest version in case a DEFIGARD Touch 7 or ARGUS PRO LifeCare 3 is newly incorporated in an already existing setup.

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-3119

ACTION TO BE TAKEN BY THE USER	1) Carefully read the content of this notice. 2) Provide an acknowledgement to your local distributor that this notice has been read and understood. 3) If you are using SEMA in combination with a DEFIGARD Touch 7 or an ARGUS PRO LifeCare 3, coordinate with your local distributor that SEMA is updated to the latest version. 4) Please note that there might be affected pdf exports. It is recommended to review them and if necessary, generate new exports with SEMA version 25.10 or higher. Until the update has been implemented, be aware of the above-described issue when interpreting ECG recordings from DEFIGARD Touch 7 or ARGUS PRO LifeCare 3 devices in affected SEMA versions and if necessary, verify the ECG with help of the acquiring device or its printout.
DATE FOR COMPLETION:	**2027-07-08**
COMMUNICATION TO THE PATIENT / LAY USER NECESSARY?	No
LIST OF ATTACHMENTS	ANNEX Ia – Initial Distributor/Importer Reply Form ANNEX Ib – Final Distributor/Importer 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 to all those who need to be aware within your organization, or to any organization to which potentially affected devices have been transferred. (As appropriate)
Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the correction.
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

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-3119

ANNEX Ia – Initial Distributor / Importer Reply Form

Mandatory fields are marked with*

1. Field Safety Notice (FSN) information	
FSN Reference number *	SAGQI-3119
FSN Date *	2026-07-08
Product/ Device name *	SEMA
2. Manufacturer Details	
Company Name	SCHILLER AG
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*	
Address*	
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 have identified customers that have or may have installed this device *	
☐	I have attached the completed customer list *	
☐	Neither I nor any of my customers have any affected installations	
Print Name *		Distributor/Importer print name here
Signature *		Distributor/Importer sign Here
Date *		

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.

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-3119

ANNEX Ib – Final Distributor / Importer Reply Form

Mandatory fields are marked with*

1. Field Safety Notice (FSN) information	
FSN Reference number *	SAGQI-3119
FSN Date *	2026-07-08
Product/ Device name *	SEMA
2. Manufacturer Details	
Company Name	SCHILLER AG
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*	
Address*	
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 have identified customers that have or may have installed this device *	
☐	I have attached the completed customer list *	
☐	I have carried out the actions for DISTRIBUTOR / IMPORTER as requested by this FSN. *	Note Qty., Date of completion
☐	I have received the completed reply form from all identified customers *	
☐	Neither I nor any of my customers have any affected installations	
Print Name *		Distributor/Importer print name here
Signature *		Distributor/Importer sign Here
Date *		

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.