FSCA Ref: SAGQI-2335

Field Safety Notice (FSN)

ARGUS PB-3000

manufactured by

SCHILLER AG

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

Date: 2025-08-08

Attention: Schiller authorized system manufacturer and their customers

A problem related to blood pressure measurement has 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 system manufacturer/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 2025-09-30 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 system manufacturer.

SCHILLER AG apologizes for any inconvenience caused by this problem.

Sincerely,

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1. INFORMATION ON AFFECTED DEVICES	
COMMERCIAL NAME(S):	ARGUS PB-3000
PRIMARY CLINICAL PURPOSE OF DEVICE(S)*	Vital Signs Monitoring Instruments (EMDN Code: Z120302)
MODEL/CATALOGUE/ REF NUMBER(S):	3.921009 (GTIN: 07613365002782) 3.921012 (GTIN: 07613365002713) 3.921001 (GTIN: 07613365001709) 3.921000 (GTIN: 07613365001846) 3.921011 (GTIN: 07613365002799) 3.921003 (GTIN: 07613365002805) 3.921004 (GTIN: 07613365002829) 3.921013 (GTIN: 07613365002706) 3.921005 (GTIN: 07613365002812) 3.921030 (GTIN: 07613365003468) 3.921006 (GTIN: 07613365000115) 1A.701307 (GTIN: 07613365003024) 3.921007 (GTIN: 07613365002584) 3.921002 (GTIN: 07613365001914) 3.921031 (GTIN: 07613365003475)
AFFECTED SERIAL OR LOT NUMBER RANGE:	7010.000160 and lower 7011.000356 and lower 7012.000356 and lower 7013.000256 and lower 7014.000152 and lower
DEVICE TYPE:	The ARGUS PB-3000 is a vital data acquisition unit intended to be used within or connected to a medical device or a medical System (Host System) for acquiring, analyzing, and transmission of patient vitals and other pertinent clinical data of vital data of a patient.

2. REASON FOR FIELD SAFETY CORRECTIVE ACTION (FSCA)	
BACKGROUND INFORMATION AND PROBLEM DESCRIPTION	The ARGUS PB-3000 is a vital signs monitoring instrument intended to be integrated into a host system. The ARGUS PB-3000 may be used in operating suites, intensive care units, emergency medical device services environment, and road ambulances. During device testing, it was observed that certain units triggered an error message (Error Code: Pressure sensor defective [53]) during non-invasive blood pressure (NIBP) measurements, specifically when the initial inflation pressure was set in the high-pressure range (above 240 mmHg). The ARGUS PB-3000 is equipped with two pressure sensors:

	- a primary sensor used for the actual measurement of non-invasive blood pressure, and - a secondary sensor used for control purposes within the measurement circuit. The root cause of the issue was identified to be an improper adjustment of the secondary pressure sensor during manufacturing. This faulty adjustment may result in a measurement error detected by the device, leading to the observed error message (Error Code occurring in the ApPod Viewer: Pressure sensor defective [53]). Important: **The error message implemented by the host system may differ.**
HAZARD GIVING RISE TO THE FSCA	If the initial pressure is in the high-pressure range (above 240 mmHg), the non-invasive blood pressure measurement might become non-functional. This may lead to a slight delay that could have minor health impact. As an alternative method for determining the NIBP an secondary device would need to be utilized such as a sphygmomanometer or other automated NIBP measuring devices.
PROBABILITY OF PROBLEM ARISING	Based on statistical analysis, it is estimated that approximately 30% of the devices may show the error. Nevertheless, as the performance with an initial pressure within the low- and medium-pressure range up to 240mmHg is not affected, the probability of occurrence is remote.
PREDICTED RISK TO PATIENT/USERS	The accuracy of the measurement as well as the performance with an initial pressure within the low- to medium-pressure range up to 240 mmHg are not affected. As the device prompts an error message, in worst-case the problem may lead to an unusable NIBP measuring function of the device.

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3. TYPE OF ACTION TO MITIGATE THE RISK	
ACTION TO BE TAKEN BY THE MANUFACTURER	1) Adjust the NIBP sensors of the affected devices in accordance with the revised manufacturing instructions.
ACTION TO BE TAKEN BY THE HOST (SYSTEM) MANUFACTURER	1) Contact all identified users and provide them with a Field Safety Notice letter (FSN Letter) including defined additional actions to be taken by the user without delay. 2) Collect read confirmation from all users. 3) Complete and return the signed **Annex Ia – Initial System manufacturer Reply Form** to SCHILLER AG by **2025-09-30** to confirm that the content of the FSN Letter has been read and understood, and that the FSN Letter has been distributed to all relevant users. 4) For each device, verify whether it is affected by the issue described above based on the criteria defined in **Service Note "sn00740e". If** the device is affected, retrieve the devices from users. 5) Send the affected devices to SCHILLER AG. 6) Once the remediated devices are returned from SCHILLER AG, promptly deliver them back to the respective users. 7) Complete and return the signed **Annex Ib – Final System manufacturer Reply Form** to SCHILLER AG by **2026-08-07** to confirm that all required actions have been completed.
ACTION TO BE TAKEN BY THE USER	1) Read the Field Safety Notice (FSN) provided by the system manufacturer carefully 2) Wait until your system manufacturer contacts you for device testing or to arrange the remediation of your device(s).
DATE FOR COMPLETION:	**2026-08-07**
IS THE FSN REQUIRED TO BE COMMUNICATED TO THE PATIENT / LAY USER?	No
LIST OF ATTACHMENTS	ANNEX Ia – Initial System manufacturer Reply Form ANNEX Ib – Final System manufacturer Reply Form
TECHNICAL SUPPORT	For technical support, please contact your system manufacturer.

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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, system manufacturer or local representative, and the national Competent Authority / US FDA if appropriate, as this provides important feedback. *

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

Contact person of manufacturer:

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ANNEX Ia – Initial System manufacturer Reply Form

1. Field Safety Notice (FSN) information		
FSN Reference number*		SAGQI-2335
FSN Date*		2025-08-08
Product/ Device name*		ARGUS PB-3000
2. Manufacturer Details		
Company Name		SCHILLER AG
SRN		CH-MF-000012722
CHRN		CHRN-MF-20000372
Address		
Contact Name		
Email		
Telephone Number		
3. System manufacturer Details		
Company Name*		
Account Number		
Address*		
Shipping address if different to above		
Contact Name*		
Title or Function		
Telephone number*		
Email*		
4. System manufacturer (Tick all that apply)		
☐	*I confirm the receipt of this Field Safety Notice and that I read and understood its content.	System manufacturer to complete or enter N/A
☐	I checked my stock and quarantined inventory	System manufacturer 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 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*		System manufacturer print name here
Signature*		System manufacturer 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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The Art of Diagnostics

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ANNEX Ib – Final System manufacturer Reply Form

5. Field Safety Notice (FSN) information	
FSN Reference number*	SAGQI-2335
FSN Date*	2025-08-08
Product/ Device name*	ARGUS PB-3000
6. Manufacturer Details	
Company Name	SCHILLER AG
SRN	CH-MF-000012722
CHRN	CHRN-MF-20000372
Address	
Contact Name	
Email	
Telephone Number	
7. System manufacturer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

8. System manufacturer (Tick all that apply)		
☐	*I confirm the receipt of this Field Safety Notice and that I read and understood its content.	System manufacturer to complete or enter N/A
☐	I checked my stock and quarantined inventory	System manufacturer 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 carried out the actions for system manufacturer 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*		System manufacturer print name here
Signature*		System manufacturer 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.