GANSHORN
SCHILLER GROUP GANSHORN Medizin Electronic GmbH
Industriestraße 6-8, D-97618 Niederlauer, Germany
FSCA Ref: QI-69

Field Safety Notice (FSN)

Spirometry-Sensor "SP Plus"

manufactured by

GANSHORN Medizin Electronic GmbH, Industriestraße 6-8, D-97618 Niederlauer, Germany

website www.ganshorn.de

SRN: DE-MF-000006566

Date: 2023-02-16

Attention: Ganshorn authorized distributors and their customers

A problem related to accuracy of volume calibration during volume verification procedure which is obliged prior to use of the **SP Plus** spirometry sensor has been reported to Ganshorn. The spirometry-sensor **SP Plus** is used exclusively with, **CARDIOVIT AT-102 G2, SPIROVIT SP-1 G2** and **CARDIOVIT CS-104**.

The described error pattern shows an inaccuracy of the volume measurement outside the given specifications. In case the described error pattern occur and user ignore error message of "the verification has failed, it might lead to the false volume measurement results and finally, this could lead to misdiagnosis and overtreatment of respiratory diseases.

Please check the user manual for trouble shooting" and further use the device, this might lead to conduction of measurements with false volume measurement results. Therefore, it could be possible that physician make his decision for a diagnosis based on false volume measurement results. Finally, this may could lead to misdiagnosis and overtreatment of respiratory diseases. If User / Authorized Distributor followed the recommended FSCA the risk as described above could be eliminated completely.

The actions that you as a distributor/customer can take to minimize or eliminate the residual risk is to check your potentially affected device on-site remotely with an error pattern correction software. This software can check whether the error pattern is present and if so, directly makes a correction of the gain factor. To perform the action, please follow the manufacturer's instructions for installing the error pattern correction software and checking your potentially affected device.

We kindly ask that you read this notice carefully and send us written acknowledgement by **01.03.2023,** that you have read and understood the contents of this notice. Written acknowledgement can be sent to SCHILLER AG and Ganshorn via the contact details listed below.

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

SCHILLER: support@schiller.ch
Ganshorn: support@ganshorn.de

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SCHILLER AG and Ganshorn Medizin Electronic GmbH apologizes for any inconveniences caused by this problem.

Sincerely,

GANSHORN
SCHILLER GROUP

GANSHORN Medizin Electronic GmbH
Industriestrasse 6-8 • D-97618 Niederlauer
Tel: +49 9771 6222 0 • Fax: +49 9771 6222 55

Felix Ciokan
Head of Quality Management
quality@ganshorn.de

Stefan Ponto
Co- Chief Executive Officer

1. INFORMATION ON AFFECTED DEVICES	
COMMERCIAL NAME(S):	SP Plus
PRIMARY CLINICAL PURPOSE OF DEVICE(S)*	Measurement of lung function parameters, flow and volume over time;
MODEL/CATALOGUE/ REF NUMBER(S):	013400563
SOFTWARE VERSION:	USCntl 2.26.1
AFFECTED SERIAL OR LOT NUMBER RANGE :	D22661878 up to D21661180; D19660346, D19660394, D19660463, D19660495, D20660809, D21661079, D19660362, D20660868, D20661058, D19660404, D20660861, D20660922, D20660956, D21661482, D20660654, D20660666, D20660971, D19660343, D19660396, D19660503, D19660532, D19660549, D20660800, D20660995, D20661014, D20661049;
UNIQUE DEVICE IDENTIFIER(S) (UDI-DI):	0 7613365 50003 5
DEVICE TYPE:	handheld spirometry sensor as additional measurement option to SCHILLER ECG, providing spirometry measurement parameters such as Flow and Volume.

2. REASON FOR FIELD SAFETY CORRECTIVE ACTION (FSCA)	
PROBLEM DESCRIPTION	A problem related to accuracy of volume calibration during volume verification procedure which is obliged prior to use of the SP PLUS spirometry sensor has been reported to Ganshorn. The described error pattern shows an inaccuracy of the volume measurement outside the given specifications. In case where the device will be used disregard of the failed prescribed verification, it might lead to the false volume measurement results and finally, this could lead to misdiagnosis and overtreatment of respiratory diseases. In detail there has been reported two cases with the following SCHILLER products, where spirometry-sensor SP Plus is used exclusively with, CARDIOVIT AT-102 G2, SPIROVIT SP-1 G2 and CARDIOVIT CS-104. .
HAZARD GIVING RISE TO THE FSCA	In case the described error pattern occur and user ignore error message of "the verification has failed. Please check the user manual for trouble shooting" and further use the device, this might lead to conduction of measurements with false volume measurement results. Therefore, it could be possible that physician make his decision for a diagnosis based on false volume measurement results. Finally, this may could lead to misdiagnosis and overtreatment of respiratory diseases. If User / Authorized Distributor followed the recommended FSCA the risk as described above could be eliminated completely.

PROBABILITY OF PROBLEM ARISING	Probability is evaluated and is stated with Occasional. Occasional is defined as an occurance as calculated within Risk Estimation Propability Level QI-69
PREDICTED RISK TO PATIENT/USERS	Risk for user and patient is evaluated and is stated S1 – Lowest level of severity. The error pattern may result in reversible impairment or injury that is transient and that does not require medical intervention.
BACKGROUND ON ISSUE ***(if not applicable – remove this row)***	The error pattern described has the following root cause determined by Ganshorn. There is a drift of the gain factor for the reference breathing tube, which is used for the factory setting of the gain factor. The gain factors obtained with this reference breathing tube in the root cause analysis are not in the mean compared to batches that were manufactured and measured later. Thus, the error can be eliminated by calculating an average value for the gain factor used for the factory setting.
OTHER INFORMATION RELEVANT TO FSCA ***(if not applicable – remove this row)***	N/A

3. TYPE OF ACTION TO MITIGATE THE RISK	
ACTION TO BE TAKEN BY THE USER or AUTHORIZED DISTRIBUTOR / CUSTOMER	☒ Identify Device ☒ Quarantine Device ☐ Return Device ☐ Destroy Device ☒ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other Factory setting will be reset by Software Update. Software could be downloaded under the following LINK https://nc.ganshorn.de/s/SyfJQxzzPer25jE **Password:** *aFSN16022023* , Installation must be conducted according to Service Note and SP Plus Configuration Tool Instruction for use which could be downloaded by the LINK User or Authorized distributor will get a software which is able to check the potentially affected devices and implement an optimized gain factor if necessary. Until this measure is not conducted the potentially affected devices must be in Quarantine and is not allowed for intended use. For further information please contact your Service partner.
DATE FOR COMPLETION:	The FSCA should be completed by user, authorized distributor the latest at end of March 2023.

ACTIONS BEING TAKEN BY THE MANUFACTURER	☐ Product Removal ☐ On-site device modification/inspection ☒ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None • Stock of potentially affected devices is checked and if necessary reworked. • New calculated average value for the gain factor is implemented in a timely manner after getting aware the error pattern, in the production of SP PLUS spirometry sensors. • Provide a software to user and authorized distributors to check all potentially affected devices with respect to the reported error pattern.
DATE FOR COMPLETION:	End of March 2023
IS THE FSN REQUIRED TO BE COMMUNICATED TO THE PATIENT / LAY USER?	no
	If yes, has manufacturer provided additional information suitable for the patient / lay user in a patient/lay or non-professional user information letter/sheet? No
FURTHER INFORMATION AND SUPPORT	To evaluate if the potentially affected devices suffer the error pattern a check with a software must be conducted by the user / authorized distributor. In the attachment of this FSN, the Instruction manual for installation and procedure of evaluation of potentially affected devices with the software is described. I Anything is unclear do not hesitate to contact your Service or Sales person at SCHILLER AG.

4. GENERAL INFORMATION	
FSN TYPE	Final Version
FOR UPDATED FSN, REF NUMBER AND DATE OF PREVIOUS FSN	N/A

FOR UPDATED FSN, KEY NEW INFORMATION AS FOLLOWS:	N/A
IF FOLLOW-UP FSN EXPECTED, WHAT IS THE FURTHER ADVICE EXPECTED TO RELATE TO:	N/A
ANTICIPATED TIMESCALE FOR FOLLOW-UP FSN	N/A
THE COMPETENT (REGULATORY) AUTHORITY OF YOUR COUNTRY HAS BEEN INFORMED ABOUT THIS COMMUNICATION TO CUSTOMERS.	
	If extensive consider providing web-link instead.
LIST OF ATTACHMENTS/ APPENDICES:	ANNEX I – Potentially affected SP Plus spirometry-sensors list with country of final destination. ANNEX II - Template for a Field Safety Notice Customer Reply Form/Customer Reply Form

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:

Felix Ciokan, Head of Quality Management, PRRC
Industriestraße 6-8, D-97618 Niederlauer, Germany
quality@ganshorn.de
T +49 9771 6222-0

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CHECK FOR FORMATING BEFORE SIGNING

ANNEX I

Template for a Field Safety Notice Distributor/Importer Reply Form

Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	QI-69
FSN Date*	Pre-filled by manufacturer
Product/ Device name*	Spirometry sensor SP Plus
Product Code(s)	1 2 3
Batch/Serial Number (s)	1 2 3

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

3. Return acknowledgement to Sender	
Email	Quality@ganshorn.de
Distributor/Importer Helpline	support@ganshorn.de
Postal Address	Industriestrasse 6-8,97618 Niederlauer
Web Portal	www.ganshorn.de
Deadline for returning the Distributor/Importer reply form*	End of March 2023

4. 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 (same information as requested by the Customer Reply form
☐	Neither I nor any of my customers has 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 II

Template for a Field Safety Notice Customer Reply Form

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	QI-69
FSN Date*	16.02.2023
Product/ Device name*	Spirometry-sensor SP Plus
Product Code(s)	REF:013400563
Batch/Serial Number (s)	D22661878 up to D21661180 D19660346, D19660394, D19660463, D19660495, D20660809, D21661079, D19660362, D20660868, D20661058, D19660404, D20660861, D20660922, D20660956, D21661482, D20660654, D20660666, D20660971, D19660343, D19660396, D19660503, D19660532, D19660549, D20660800, D20660995, D20661014, D20661049;

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 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	Customer to complete or enter N/A

	the attention of all relevant users and executed.			
☐	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:	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:	
		N/A	Comments:	
☐	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*				

4. Return acknowledgement to sender	
Email	Quality@ganshorn.de
Customer Helpline	support@ganshorn.de
Postal Address	Industriestrasse 6-8, 97618 Niederlauer
Web Portal	www.ganshorn.de
Fax	+49 9771 6222-55
Deadline for returning the customer reply form*	End of March 2023

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.