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

FSCA Ref: SAGQI-651, #1846729
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Field Safey Notice (FSN)

AT-102 / AT-102 plus / AT-10 plus /AT-104 PC / AT-104 PC ErgoSpiro MS-2007 / MS-2010 / MS-2015 / CS-200 / CS-200 ErgoSpiro

manufactured by
SCHILLER AG, Altgasse 68 CH-6341 Baar, Switzerland

www.schiller.ch

SRN: CH-MF-000012722 / CHRN: CHRN-MF-20000327

Date: 2023-01-27

Attention: SCHILLER AG authorized distributors and their customers.

A problem related to distorted representation of a pacemaker ECG signal

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 **03rd of March 2023** 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 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,

Eckard Glaser
Head of Quality Management
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):	CARDIOVIT AT-102 / AT-102 plus / AT-10 plus /AT-104 PC / CS-200 / MS-2007 / MS-2010 / MS-2015
PRIMARY CLINICAL PURPOSE OF DEVICE(S)*	Recording, analysis, and evaluation of ECG recordings.
CATALOGUE NUMBER(S) / MODEL NUMBER(S):	0.070000 (AT-102) / 3.912350 (Basic device AT-102 SAG 16) 0.070000 (AT-102) / 3.912360 (Basic device AT-102 Moni. SAG 16) 0.070000 (AT-102) / 3.912370 (Basic device AT-102 USA 16) 0.075000 (AT-102 plus) / 3.912300 (Basic device AT-102plus Standard) 0.075000 (AT-102 plus) / 3.912301 (Basic device AT-102plus WLAN) 0.075000 (AT-102 plus) / 3.912302 (Basic device AT-102plus 2013) 0.173000 (AT-10 plus) / 3.920603 (Basic device AT-10plus 2008) 0.173000 (AT-10 plus) / 3.920610 (Basic device AT-10plus 2014) 0.040000 (AT-104 PC) / 3.910454 (Basic device AT-104) 0.040000 (AT-104 PC) / 3.910456 (Basic device AT-104 2008 (USB)) 0.040100 (AT-104 PC ErgoSpiro) / 3.910454 (Basic device AT-104) 0.040100 (AT-104 PC ErgoSpiro) /3.910456 (Basic device AT-104 2008 (USB)) 0A.101000 (MS-2007) / 3.900790 (Basic device MS-2007 Standard) 0A.101000 (MS-2007) / 3.900792 (Basic device MS-2007 WLAN) 0.090000 (MS-2010) / 3.900800 (Basic device MS-2010 Standard) 0.090000 (MS-2010) / 3.900804 (Basic device MS-2010 WLAN/GSM) 0.090000 (MS-2010) / 3.900805 (Basic device MS-2010 WLAN) 0A.100000 (MS-2015) / 3.900829 (Basic device MS-2015 Standard 14) 0A.100000 (MS-2015) / 3.900830 (Basic device MS-2015 WLAN&GSM 14) 0A.100000 (MS-2015) / 3.900833 (Basic device MS-2015 WLAN) 0.030000 (CS-200) / 3.920250 (Basic device CS-200 classic) 0.030000 (CS-200) / 3.920200 (Basic device CS-200 B'Wehr) 0.030100 (CS-200 ErgoSpiro) / 3.920250 (Basic device CS-200 classic) 0.030100 (CS-200 ErgoSpiro) / 3.920200 (Basic device CS-200 B'Wehr)
AFFECTED SOFTWARE VERSIONS:	AT-102: all software versions AT-102 plus: software versions below 1.20 AT-10 plus: software versions below 2.60 AT-104 PC: all software versions AT-104 PC ErgoSpiro: all software versions MS-2007/2010/2015: software versions below 3.10 CS-200: all software versions CS-200 ErgoSpiro: all software versions
AFFECTED SERIAL OR LOT NUMBER RANGE:	All distributed devices (see the section above)

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UNIQUE DEVICE IDENTIFIER(S) (UDI-DI):	0.070000 (AT-102): - 3.912350 (Basic device AT-102 SAG 16): 07613365001662 3.912360 (Basic device AT-102 Moni. SAG 16): 07613365002249 3.912370 (Basic device AT-102 USA 16): 07613365001686 0.075000 (AT-102 plus): - 3.912300 (Basic device AT-102plus Standard): - 3.912301 (Basic device AT-102plus WLAN): - 3.912302 (Basic device AT-102plus 2013): 07613365001396 0.173000 (AT-10 plus): - 3.920603 (Basic device AT-10plus 2008): - 3.920610 (Basic device AT-10plus 2014): 07613365000054 0.040000 (AT-104 PC): - 0.040100 (AT-104 PC ErgoSpiro): - 3.910454 (Basic device AT-104): - 3.910456 (Basic device AT-104 2008 (USB)): 07613365001488 0A.101000 (MS-2007): - 3.900790 (Basic device MS-2007 Standard): 07613365001310 3.900792 (Basic device MS-2007 WLAN): 07613365001327 0.090000 (MS-2010): - 3.900800 (Basic device MS-2010 Standard): 07613365001334 3.900804 (Basic device MS-2010 WLAN/GSM): 07613365001365 3.900805 (Basic device MS-2010 WLAN): 07613365001358 0A.100000 (MS-2015): - 3.900829 (Basic device MS-2015 Standard 14): 07613365001372 3.900830 (Basic device MS-2015 WLAN&GSM 14): 07613365001389 3.900833 (Basic device MS-2015 WLAN): 07613365002287 0.030000 (CS-200): - 0.030100 (CS-200 ErgoSpiro): - 3.920250 (Basic device CS-200 classic): 07613365000047 3.920200 (Basic device CS-200 B'Wehr): -
DEVICE TYPE:	Electrocardiograph

2. REASON FOR FIELD SAFETY CORRECTIVE ACTION (FSCA)	
PROBLEM DESCRIPTION	SCP compression/decompression algorithm may distort the ECG signal if "Pacemaker detection" function is not activated (in this case, pacemaker pulses are not suppressed, and a detected QRS onset may occur in the middle of the pacing pulse) ECG distortion only occurs when a such recorded ECG is compressed and sent to data management device.
HAZARD GIVING RISE TO THE FSCA	Faulty transmission: mismatch of ECG recording information transferred from an ECG device to a storage device/server.

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PROBABILITY OF PROBLEM ARISING	ECG distortion only happens in extremely rare cases when an ECG is compressed and sent to the data management device. The ECG detected by an electrocardiograph has no distortions.
PREDICTED RISK TO PATIENT/USERS	The problem described above may lead to distortion of recording and thus, may result in diagnosis error.

3. TYPE OF ACTION TO MITIGATE THE RISK	
ACTIONS BEING TAKEN BY THE MANUFACTURER	1) Distribute this **Field Safety Notice** to all authorized distributors / importers by **27th of January 2023** together with the Addendum to IFU of the affected devices with instructions on how to activate the pacemaker detection function so that the issue does not occur. 2) Update the IFU of AT-102 in English by **31st of January 2023**.
ACTION TO BE TAKEN BY AUTHORIZED DISTRIBUTOR / IMPORTER	1) Distribute this Field Safety Notice to all identified users. 2) Send the signed ANNEX I – Distributor/Importer Reply Form back to SCHILLER AG by **03rd of March 2023** as confirmation that the content of this notice was read and understood and that this Field Safety Notice was distributed, read and understood by all users.
ACTIONS TO BE TAKEN BY THE USER	1) Read carefully and follow the instructions in this Field Safety Notice and the attached Addendum. 2) This FSN including the Addendum to IFU must be attached to the IFU and kept with the IFU. 3) Send the signed ANNEX II – Customer Reply Form back to your authorized distributor as confirmation that this Field Safety Notice was read and understood.
DATE FOR COMPLETION:	**03rd of March 2023**
IS THE FSN REQUIRED TO BE COMMUNICATED TO THE PATIENT / LAY USER?	No
FURTHER INFORMATION AND SUPPORT	SCHILLER AG recommends keeping the software up-to-date at all times. If you need any further information or support concerning this issue, please contact SCHILLER AG Customer Services: support@schiller.ch

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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, 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:

Eckard Glaser
Head of Quality Management
Altgasse 68, CH-6341 Baar, Switzerland
vigilance@schiller.ch
T: +41 41 766 42 42

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ANNEX I - Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	SAGQI-651
FSN Date*	2023-01-20
Product/ Device name*	CARDIOVIT AT-102 / AT-102 plus / AT-10 plus /AT-104 PC / AT-104 PC ErgoSpiro / MS-2007 / MS-2010 / MS-2015 / CS-200 / CS-200 ErgoSpiro

2. Manufacturer Details	
Company Name	SCHILLER AG
SRN	CH-MF-000012722
CHRN	CHRN-MF-20000327
Address	Altgasse 68 6341 Baar, Switzerland
Contact Name	Eckard Glaser
E-Mail	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, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	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	
☐	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		
Signature*		
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

1. Field Safety Notice (FSN) information	
FSN Reference number*	SAGQI-651
FSN Date*	2023-01-20
Product/ Device name*	CARDIOVIT AT-102 / AT-102 plus / AT-10 plus /AT-104 PC / AT-104 PC ErgoSpiro / MS-2007 / MS-2010 / MS-2015 / CS-200 / CS-200 ErgoSpiro

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 the attention of all relevant users and executed.	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
☐	I sold my device(s)	Device serial number(s) and contact information of the new owner
☐	The device(s) is/are no longer in use	Device serial number(s)
Print Name*		
Signature*		
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.