Field Safety Notice (FSN)

Tempus LS
FSCA-identifier 1816815-FSCA rev02 **(this revision, replaces the FSN from 21. November 2019)**
Type of action: FSCA

Date: 28. November 2019

Attention:
Remote Diagnostic Technologies Ltd
Pavilion C2, Ashwood Park
Ashwood Way, Basingstoke
Hampshire RG23 8BG, UK

Details on affected devices:

Product:	Tempus LS
Article Number:	3.940590
Serial Number:	See on page 4 for all affected devices

Device Type and Intended Use:

The Tempus LS defibrillator is used for the treatment of ventricular fibrillation (VF) and ventricular tachycardia (VT) in AED or manual defibrillation and a Cardioversion mode to convert abnormally fast heart rate (tachycardia) or other cardiac arrhythmias to a normal rhythm. The pacemaker module stimulates the heart with two operation modes, "Fix" or "Demand".

The Tempus LS is for use for termination of ventricular fibrillation and ventricular tachycardia. The device is for the use of qualified medical personnel who are trained in the use of the device and in basic and advanced life support.

This FSN includes the solution for two current issues that have been highlighted to SCHILLER AG by Tempus LS users.

Issue 1: Impedance out of valid range

Description of the problem:
SCHILLER AG received notice that under certain circumstances a defibrillation will not be possible.
It's possible that an impedance change between patient and device causes an impairment of the impedance measurement. If the impedance is out of a valid range, a defibrillation is not possible.
The impedance change can be created by any ground contact between device and patient (e.g. docking station, wet floor etc.)
In this case the device shows "Error: too high impedance", "check electrodes".

Solution of the problem:
SCHILLER has implemented a hardware change to eliminate the possibility of this impedance impairment. This change has been implemented on the latest devices, while all products listed in the appendix still can have this issue.

Implementation in the field:
Customers facing this issue, should act as following:

a. If the device shows "Error: Too high Impedance", but clearly the electrodes are well connected, the device should be isolated (lifted from the ground, no contact between device and patient, taken out of the docking station etc.). After this, the device will work as expected.
b. SCHILLER AG will provide a hardware modification to eliminate this issue. For the implementation of this modification, the device will need to be returned to the manufacturer for repair/exchange.

Issue 2: Unexpected safety discharge

Description of the problem:
SCHILLER AG received notice that under certain circumstances the device performs an unexpected safety discharge.
Our investigations have shown, that in rare circumstances, the device detects a voltage variation triggering the safety circuit to perform an internal discharge.

Solution of the problem:
SCHILLER AG has implemented a hardware change to eliminate this issue (currently under verification)

Implementation in the field:
Customers facing this issue, should act as follows:

a. If the device shows this behaviour, the device should be switched off and restarted immediately.
b. SCHILLER AG will provide a Hardware modification to eliminate this issue. For the implementation of this modification, the device will need to be returned to the manufacturer for repair/exchange.

Recommendation for Issue 1 and Issue 2

The end customer should consider using another defibrillator than the Tempus LS if possible and available, till the hardware modification has been done.

Transmission of this Field Safety Notice:

Please make sure that all users of the devices aforementioned and other relevant persons within your organisation are aware of this new Field Safety Notice.

If your organisation passed the devices to third parties, please forward a copy of this FSN or inform the below mentioned contact person.

Please maintain awareness of this notice and resulting actions at least until the corrective actions have been completed.

End users must sign of and return the acknowledgement form provided by the distributor not later than 20 December 2019

Distributors must sign off and return the "Acknowledgement Form A" not later than 31. December 2019

Distributors must sign off and return the "Acknowledgement Form B" not later than 31. July 2020

The responsible National Competent Authority, Swissmedic, has been informed about this Field Safety Notice. As SCHILLER AG has knowledge about incidents in Netherlands and United Kingdom, Health and Youth Care Inspectorate, NL and MHRA, UK has also been informed.

Contact Person for National Competent Authority / Distributor:
SCHILLER AG
Matias Häfliger, Quality Assurance Manager
Altgasse 68, CH-6341 Baar, Switzerland
T +41 41 766 42 42 / D +41 41 766 43 52
Email: quality@schiller.ch

Mr. Matias Häfliger
Quality Assurance Manager

Schiller AG, Switzerland
Date: 28. Nov 2019

i.V. THOMAS KABIR
Mr. Alfred E. Schiller
CEO

Schiller AG, Switzerland
Date: 28. Nov 2019

ANNEX 1 - List of affected serial numbers Tempus LS

Issue 1: Impedance out of valid range

All Tempus LS on the market within listed s/n range are affected;

7021.000100 up to 7021.001215

All those devices require modification A or B as described in ANNEX 3, or a justification why the device has not been modified.

Issue 2: Unexpected safety discharge

All Tempus LS on the market within listed s/n range are affected;

7021.000100 up to 7021.001509

All those devices require modification A or C as described in ANNEX 3, or a justification why the device has not been modified.

ANNEX 2 – ACKNOWLEDGE FORM A

Confirmation Safety Notification

Advice on action to be taken by SCHILLER AG distributors:

- Identify the location of the affected devices
- Update customers about the possible problems with above specified actions.
- Sign off and return this acknowledgement form not later than 31. December 2019

With the signature below the distributor confirms, that:

a.) We have read and understood the safety notification from 21. November 2019.

b.) We confirm that within our organization all users and other persons concerned have been informed about the content of the safety notification.

c.) We confirm that we have informed all costumer about the Field Safety Notification and that they are aware of the required Field Safety Correction.

Fill out the list with the serial numbers (s/n) ranges and the information to whom in what country this device(s) has been sold. Including the Responsible person and the date they confirmed this.
If you do not get a confirmation until the due date, please write a justification.

S/N of Device	Customer	Country	Responsable Person / e-mail address	Date of Confirmation / Justification

Remote Diagnostic Technologies Ltd
Pavilion C2, Ashwood Park
Ashwood Way, Basingstoke
Hampshire RG23 8BG, UK
T +44 (0) 1256 362400

Name: Martin Newman
Position: Director of Quality & Regulatory Affairs

Date / Signature

Company Stamp

Please sign the completed form and return a copy by e-mail or mail to quality@schiller.ch
not later than 31. December 2019

Thank you for your cooperation!

ANNEX 3 – ACKNOWLEDGE FORM B

Confirmation Field Safety Corrective Action (FSCA)

Advice on action to be taken by SCHILLER AG distributors:

- Update all affected devices according SCHILLER AG Service Note 323e (detailed work instructions for the required HW/SW modification)
- Sign off and return this acknowledgement form not later than 31. July 2020

With the signature below the distributor confirms, that:

a.) We have read and understood the Service Note 323e for the FSCA from 21. November 2019.

b.) We confirm that we have updated all the devices on the field according the Service Note 323e

Fill out the list with the serial numbers (s/n) ranges and the information to whom in what country this device(s) has been sold and what modifications have been performed.
For not updated devices we need a justification.

S/N of Device	Customer	Country	Performed modification*	Date of modification / Justification

* Modification:
A: Returned to SCHILLER AG for modification
B: Modifications done for Issue 1 (Impedance out of valid range) and Issue 2 (Unexpected safety discharge)
C: Modification done for Issue 2 (Unexpected safety discharge)
X: No modification done, see justification

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Name: Martin Newman
Position: Director of Quality & Regulatory Affairs

Date / Signature

Company Stamp

Please sign the completed form and return a copy by e-mail or mail to quality@schiller.ch
not later than 31. July 2020

Thank you for your cooperation!