FSCA Ref: SAGQI-874
FSN_with acknowledgment form_Tempus LS_SAGQI-874_EN.docx

Field Safety Notice (FSN)

Tempus LS

manufactured by

SCHILLER AG,

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

Date: 2024-04-10

Attention: SCHILLER authorized distributors and their customers

A problem related to missing information in the instructions for use.

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 2024-11-15 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 inconveniences caused by this problem.

Sincerely,

1. INFORMATION ON AFFECTED DEVICES	
COMMERCIAL NAME(S):	Tempus LS
PRIMARY CLINICAL PURPOSE OF DEVICE(S)*	The Tempus LS defibrillator is a battery-powered, small, lightweight device designed for use in prehospital and clinical settings. The Tempus LS defibrillator is used for the treatment of ventricular fibrillation (VF) and ventricular tachycardia (VT) by manual and automatic defibrillation, and in cardioversion mode for the treatment of atrial fibrillation.
MODEL/CATALOGUE/ REF NUMBER(S):	3.940590 Tempus LS Base unit (part of 1A.702100 Tempus LS Package RDT)
SOFTWARE VERSION:	Not applicable, as this issue is not caused by the device software.
AFFECTED SERIAL OR LOT NUMBER RANGE:	Not applicable, as this issue is not related to serial numbers
UNIQUE DEVICE IDENTIFIER(S) (UDI-DI):	07613365001693
DEVICE TYPE:	Physiologic-monitoring defibrillation system

2. REASON FOR FIELD SAFETY CORRECTIVE ACTION (FSCA)	
BACKGROUND INFORMATION AND PROBLEM DESCRIPTION	SCHILLER AG has identified missing information in the instructions for use for the Tempus LS. The information was missing that simultaneous ECG measurements with multiple devices on the same patient may lead to distortions of the ECG signal
HAZARD GIVING RISE TO THE FSCA	Distortions may lead to no or ineffective pacing or no or inappropriate defibrillation pulse.
PROBABILITY OF PROBLEM ARISING	This behaviour can potentially affect all devices and can occur in any situation in which two devices with ECG amplifiers are used simultaneously on the same patient.
PREDICTED RISK TO PATIENT/USERS	The distortion of the ECG and the resulting lack of functionality of the device, in worst case: • Results or may result in permanent impairment or irreversible injury, • or requires or may require immediate medical or surgical intervention to prevent permanent organ damage, • or reduces or may reduce the probability of survival, • or results or may result in unnecessary or preventable surgical intervention

3. TYPE OF ACTION TO MITIGATE THE RISK	

ACTION TO BE TAKEN BY THE MANUFACTURER	1) Update instructions for use with the information that two ECG amplifiers must not be connected to the same patient at the same time. Schiller AG is in the process of updating the instructions for use and will provide them in Q2-2024
	• Chapter 1.1.6/10 will be updated as follows:
	  ◦ Connecting two ECG device (e.g. Tempus Pro and Tempus LS ECG cables) at the same patient, may cause electrical noise and interference that will affect the quality of ECG recordings. This can cause the ECG waveforms to be unreadable or distorted.
	• Chapter 3.4.2 will be updated as follows:
	  ◦ While the Tempus LS ECG leads are applied to a patient, do not apply a second set of ECG leads to the patient (e.g., from Tempus Pro). Connecting a second set of ECG leads simultaneously may cause the ECG signals to be distorted or unreadable. This may also cause the pacing function to not work as intended.

ACTION TO BE TAKEN BY THE DISTRIBUTOR/ IMPORTER	1) Send this FSN to all identified USERs 2) Provide users with the latest version of the instructions for use. 3) Send the signed ANNEX I – Distributor/Importer Reply Form back to SCHILLER AG by 2024-11-15 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.
ACTION TO BE TAKEN BY THE USER	1) Always use and follow the current instructions for use. 2) Send ANNEX II – Customer Reply Form back to your authorized distributor as confirmation that this Field Safety Notice was read and understood.
DATE FOR COMPLETION:	2024-11-15
IS THE FSN REQUIRED TO BE COMMUNICATED TO THE PATIENT/ LAY USER?	No
LIST OF ATTACHMENTS	ANNEX I – Distributor / Importer Reply Form ANNEX II - Customer 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 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.

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ANNEX I – Distributor / Importer Reply Form

(To be filled out for each country)

1. Field Safety Notice (FSN) information	
FSN Reference number*	SAGQI-874
FSN Date*	2024-04-10
Product/ Device name*	Tempus LS

2. Manufacturer Details	
Company Name	SCHILLER AG
SRN	CH-MF000012722
CHRN	CHRN-MF-20000372
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*	
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 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 received or may have received this device	Distributor/Importer to complete or enter N/A
☐	*I attached the completed device list	Distributor/Importer to complete or enter N/A
☐	*I have carried out the actions for DISTRIBUTOR / IMPORTER as requested by this FSN.	Distributor/Importer to complete or enter N/A
☐	*I have received the completed reply form from all identified customers of the country X	Distributor/Importer to note applicable country
☐	Neither I nor any of my customers have any affected devices in inventory (In this case ANNEX Ib must not be completed)	
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 - Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	SAGQI-874
FSN Date*	2024-04-10
Product/ Device name*	Tempus LS

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 the receipt of this Field Safety Notice as well as the updated IFU and that I read and understood the content.	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
☐	I sold my device(s)	Note device serial number(s) and contact details of the new owner.
☐	I do not have any affected devices.	Customer to complete or enter N/A
Print Name*		Customer print name here
Signature*		Customer 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.

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