SCHILLER
The Art of Diagnostics

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

FSCA Ref: SAGQI-137
FSN_with_acknowledgment_form_Tempus LS_SAGQI-137.docx

Field Safety Notice (FSN)

Tempus LS

manufactured by

SCHILLER AG, Altgasse 68 CH-6341 Baar, Switzerland
www.schiller.ch

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

Date: 2023-03-24

Attention: SCHILLER authorized distributors and their customers

A problem related to the pacing function of the device.

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 2023-04-21 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.

[redacted]

PRRC / Head of Quality

Vice President of Global Product Management
Corporate Management

SCHILLER
The Art of Diagnostics

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

FSCA Ref: SAGQI-137
FSN_with_acknowledgment_form_Tempus LS_SAGQI-137.docx

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:	All serial numbers below 7021.002164
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 a pacing problem with the Tempus LS where the defibrillator/pacemaker module (DPM) encounters a problem and communication from the Mainboard to the DPM fails. In this case, the device stops pacing and displays the error message "HW failure DPM".
HAZARD GIVING RISE TO THE FSCA	This failure leads to no or ineffective pacing which, in worst case, may result in reduction of probability of survival.
PROBABILITY OF PROBLEM ARISING	There have been 56 reported cases of pacing problems with 1736 devices on the market, 23 of which are confirmed to be intermittent communication problems of the DPM modules.
PREDICTED RISK TO PATIENT/USERS	**Cardiac pacing issues during** device **use on a** patient Clinical outcome of cardiovascular emergencies involving cardiopulmonary resuscitation (CPR) critically depends on overall health (including past medical history and surgeries) and age of the patient. In the present case, a patient was involved, however insufficient specific clinical information about the patient's overall health, previous history, medications etc. is available. As with any risks associated with partial or complete failure of a defibrillator, pacing device, or electrotechnical CPR device this risk can be mitigated by initiating/resuming high-quality CPR / chest compressions. The current 2020/2021 international resuscitation guidelines published by the European Resuscitation Council (https://www.cprguidelines.eu/assets/guidelines/European-Resuscitation-Council-Guidelines-2021-Ad.pdf), the European Society of Cardiology (https://academic.oup.com/eurheartj/article/42/14/1289/5898842), the UK Resuscitation Council (https://www.resus.org.uk/library/2021-resuscitation-guidelines/adult-advanced-life-support-guidelines and https://www.resus.org.uk/print/pdf/node/11317), the American Heart Association (https://cpr.heart.org/en/resuscitation-science/cpr-and-ecc-guidelines and https://cpr.heart.org/-/media/CPR-Files/CPR-Guidelines-Files/Highlights/Hghlghts_2020_ECC_Guidelines_English.pdf and https://cpr.heart.org/en/r

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

	esuscitation-science/cpr-and-ecc-guidelines/algorithms), and the Australian Resuscitation Council (https://resus.org.au/guidelines/index/) all list CPR as the first mandatory, immediate step and method of choice in advanced life support for cardiopulmonary resuscitation. In fact, according to the current guidelines CPR must be initiated even before any device (defibrillator, electrotechnical CPR device or pacer, etc.) is applied to the patient. This also applies for pediatric cardiac arrests or cardiac arrests during pregnancy (https://cpr.heart.org/-/media/CPR-Files/CPR-Guidelines-Files/Highlights/Hghlghts_2020_ECC_Guidelines_English.pdf). High-quality CPR must also be resumed and maintained if a device is not functioning as intended. Importantly, as already pointed out above, success of any resuscitation efforts (IV drugs, defibrillation, pacing, CPR) on patient outcome will critically depend on the patient's overall chronic and acute health status, independently of whether a functional device is available or not. Patients with chronic heart diseases are at high risk to develop a cardiac arrest (coronary artery disease/history of myocardial infarction, heart failure, genetic predisposition to develop ventricular tachyarrhythmias, incl. Brugada syndrome, Long QT-syndrome etc.). **General pacing issues during** device **operation** The device may not perform as intended, even no patient is present and nor cardiac pacing is required (e.g., device self-testing or other) and no patient would be harmed. Potential risks associated with partial or complete failure of the device, should a patient be involved, will be mitigated by immediately starting CPR / chest compressions in case of device dysfunction/failure in keeping with current resuscitation guidelines (European Resuscitation Council Guidelines 2021: Adult advanced life support https://www.cprguidelines.eu/assets/guidelines/European-Resuscitation-Council-Guidelines-2021-Ad.pdf), European Resuscitation Council Guidelines 2021: Cardiac arrest in special circumstances https://www.cprguidelines.eu/assets/guidelines/European-Resuscitation-Council-Guidelines-2021-Ca.pdf), UK Resuscitation Council Adult Advanced Life Support Guidelines https://www.resus.org.uk/library/2021-resuscitation-guidelines/adult-advanced-life-support-guidelines https://www.resus.org.uk/print/pdf/node/11317), and the 2020 American Heart Association Guidelines for CPR and ECC https://cpr.heart.org/en/resuscitation-science/cpr-and-ecc-guidelines https://cpr.heart.org/-/media/CPR-Files/CPR-Guidelines-Files/Highlights/Hghlghts_2020_ECC_Guidelines_English.pdf). According to the Guidelines CPR remains the first step and method of choice in advanced life support due to a cardiac arrest and must be initiated before any device (defibrillator, pacer, etc.) is applied to the patient. Patients with chronic heart diseases are at high risk to develop a cardiac arrest (coronary artery disease/history of myocardial infarction, heart failure, genetic predisposition to develop ventricular tachyarrhythmias, incl. Brugada syndrome, Long QT-syndrome etc.).

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

3. TYPE OF ACTION TO MITIGATE THE RISK

ACTION TO BE TAKEN BY THE MANUFACTURER	1) Provide the rework instruction to the relevant SCHILLER AG authorized repair locations.
ACTION TO BE TAKEN BY THE DISTRIBUTOR / IMPORTER	1) Send this FSN to all identified USERs. 2) **Send the signed ANNEX Ia** – Initial Distributor / Importer Reply Form including a list of all USERs back to SCHILLER AG **by 21st April 2023** as confirmation that the content of this notice was read and understood and that this Field Safety Notice was distributed to all USERs. 3) Contact the USER(s) to arrange the rework of the USER's device(s). 4) Send the loaner device(s) to the USER(s). 5) Send the USER's device(s) to a SCHILLER AG authorized repair location. 6) After the device(s) has/have been returned from the rework, send back the device(s) to the USER. 7) **Send the signed ANNEX Ib** – Final Distributor/Importer Reply Form back to SCHILLER AG by **31st December 2024** as confirmation that all defined actions for IMPORTER / DISTRIBUTOR have been completed.
ACTION TO BE TAKEN BY THE USER	8) Wait until your local distributor contacts you to arrange the rework of your device(s). 9) Delete all patient data stored on the device(s). 10) Decontaminate the device(s). 11) Declare additional defects/damages, if applicable. 12) Send your device(s) to your local distributor after having received the loaner device(s). 13) After the device(s) has/have been returned from the rework, delete all patient data stored on the loaner device(s), decontaminate the loaner device(s) and send back the loaner device(s) to your local distributor. 14) Send ANNEX II – Customer Reply Form back to your authorized distributor as confirmation that this Field Safety Notice was read and understood.

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

FSCA Ref: SAGQI-137
FSN_with_acknowledgment_form_Tempus LS_SAGQI-137.docx

REMEDIAL ACTION TO BE TAKEN BY THE USER	In case of encountering any pacing issues during clinical application, immediately carry out the actions of the resuscitation guidelines applicable to the country you're located in. **European Resuscitation Council** https://www.cprguidelines.eu/assets/guidelines/European-Resuscitation-Council-Guidelines-2021-Ad.pdf **European Society of Cardiology** https://academic.oup.com/eurheartj/article/42/14/1289/5898842 **UK Resuscitation Council** https://www.resus.org.uk/library/2021-resuscitation-guidelines/adult-advanced-life-support-guidelines https://www.resus.org.uk/print/pdf/node/11317 **American Heart Association** https://cpr.heart.org/en/resuscitation-science/cpr-and-ecc-guidelines https://cpr.heart.org/-/media/CPR-Files/CPR-Guidelines-Files/Highlights/Hghlghts_2020_ECC_Guidelines_English.pdf https://cpr.heart.org/en/resuscitation-science/cpr-and-ecc-guidelines/algorithms **Australian Resuscitation Council** https://resus.org.au/guidelines/index/
DATE FOR COMPLETION:	31st December 2024
IS THE FSN REQUIRED TO BE COMMUNICATED TO THE PATIENT / LAY USER?	No
LIST OF ATTACHMENTS	ANNEX Ia – Initial Distributor / Importer Reply Form ANNEX Ib - Final 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 organization or to any organization where the potentially affected devices have been transferred. (As appropriate)
Please transfer this notice to other organizations 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:

[redacted]
PRRC / Head of Quality Management
Altgasse 68
CH-6341 Baar
vigilance@schiller.ch
T: +41 41 766 42 42

SCHILLER
The Art of Diagnostics

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

FSCA Ref: SAGQI-137
FSN_with_acknowledgment_form_Tempus LS_SAGQI-137.docx

ANNEX Ia – Initial Distributor / Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	SAGQI-137
FSN Date*	24.03.2023
Product/ Device name*	Tempus LS

2. Manufacturer Details	
Company Name	SCHILLER AG
SRN	CH-MF-000012722
CHRN	CHRN-MF-20000372
Address	Altgasse 68 6341 Baar, Switzerland
Contact Name	[redacted]
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 checked my stock and quarantined inventory.	Distributor/Importer to enter quantity and date
☐	*I have identified all customers that received or may have received this device and informed all customers about this FSN.	
☐	*I have attached the completed device list.	
☐	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.

SCHILLER
The Art of Diagnostics

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

FSCA Ref: SAGQI-137
FSN_with_acknowledgment_form_Tempus LS_SAGQI-137.docx

ANNEX Ib – Final Distributor / Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	SAGQI-137
FSN Date*	24.03.2023
Product/ Device name*	Tempus LS

2. Manufacturer Details	
Company Name	SCHILLER AG
SRN	CH-MF-000012722
CHRN	CHRN-MF-20000372
Address	Altgasse 68 6341 Baar, Switzerland
Contact Name	[redacted]
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 have carried out all the actions for DISTRIBUTOR / IMPORTER 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
Print Name *		Distributor/Importer print name here
Signature *		Distributor/Importer sign Here
Date *		

SCHILLER
The Art of Diagnostics

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

FSCA Ref: SAGQI-137
FSN_with_acknowledgment_form_Tempus LS_SAGQI-137.docx

ANNEX II - Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	SAGQI-137
FSN Date*	24.03.2023
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 and that I read and understood its content.	Customer to complete or enter N/A
☐	*I have identified all affected devices	Note quantity, Lot/Serial Number(s)
☐	*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 have carried out the actions for USER as requested by this FSN.	Note Qty., Lot/Serial Number(s), Date of completion
☐	My device(s) has/have additional defects/damages.	Note Qty., Lot/Serial Number(s), Description of the defect
☐	I have returned affected device(s)	Note Qty., Lot/Serial Number(s), Date of return of all returned devices.
☐	I have destroyed affected device(s)	Note Qty., Lot/Serial Number(s), Date of destruction of all destroyed devices.
☐	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.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.