REMOTE DIAGNOSTIC TECHNOLOGIES LTD

A Philips company

CUSTOMER INFORMATION LETTER

MEDICAL DEVICE FIELD ACTION CUSTOMER INFORMATION

Tempus LS

Impedance out of Valid Range and Unexpected Safety Discharge Issues

25 November 2019

Dear Valued Customer,

A problem has been detected in the Tempus LS Defibrillator that, if it were to recur could affect the performance of the equipment. This Customer Information Letter and attached Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that you as a customer can take to minimize the effect of the problem
- the actions planned by RDT and Schiller AG to correct the problem.

The manufacturer has initiated a Field Safety Corrective Action to resolve impedance out of valid range and unexpected safety discharge issues with the device, which on rare occasions can result in a defibrillation not being possible. Further information can be found in the attached Field Safety Notice. RDT are working with the manufacturer on the actions required to resolve the safety issue with the device.

We will contact your organization to perform the safety upgrade, at no cost to the user, as soon as it is available. We are expecting stock of the upgraded hardware to be available in Q1 2020.

We kindly ask that you read this notice carefully and send us written acknowledgement by **12 December 2019** that you have read and understood the contents of this notice. Written acknowledgement can be sent to RDT via the contact details listed below.

Contact Details: RDT_Customerservice@philips.com or 01256 362400.

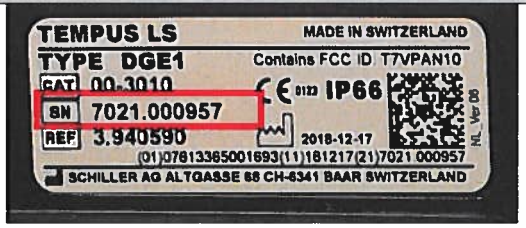
If you need any further information or support concerning this issue, please do not hesitate to contact RDT Customer Services.

RDT apologizes for any inconveniences caused.

Sincerely,

Martin Newman
Director of Quality & Regulatory Affairs

How to identify a Tempus LS Serial Number



The serial number label can be found on the top left hand corner of the device.

The serial number is shown next to the [SN] field, with a prefix of 7021.xxxxxx

PHILIPS

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Pavilion C2, Ashwood Park, Ashwood Way, Basingstoke, Hampshire, RG23 8BG, UK, www.rdtltd.com, Tel number +44 1256 362 400, Fax number +44 1256 362 415, Registered in England No.3321782, VAT No.692 9012 19.

Field Safety Notice

Tempus LS
FSCA-identifier 1816815-FSCA
Type of action: FSCA

Date: 21. 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.

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

M. Häfliger

Mr. Matias Häfliger
Quality Assurance Manager

Schiller AG, Switzerland
Date: 21.11.2019

i.V. J. J. Schiller
SENIOR VP.

Mr. Alfred E. Schiller
CEO

Schiller AG, Switzerland
Date: 21.11.2019

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.

Customer Reply Form
Tempus LS

Field Safety Notice (FSN) information	
FSN Reference number	1816815-FSCA
FSN Date	21st November 2019
Product/ Device name	Tempus LS
Product Code(s)	00-3010

Customer Details	
Please provide the relevant contact details for further correspondence regarding the hardware upgrade required to resolve this field safety corrective action. RDT will contact the identified organizational contact when the hardware upgrade is available. For further information on RDT's GDPR policy please visit https://www.rdtltd.com/privacy-policy or contact us on 01256 362400.	
Healthcare Organisation Name	
Organisation Address	
Department/Unit	
Location of Tempus LS equipment if different to above	
Contact name	
Title or Function	
Telephone number	
Email	
Please confirm quantity	
Please confirm /serial number(s)	7021.xxxxxx etc

Action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	To be completed or enter N/A
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Please provide details of relevant users or enter N/A
☐	I do not have any affected devices.	Please complete or enter N/A
Print Name		
Signature		
Date		

Return acknowledgement to sender	
Email	RDT_Customerservice@philips.com
Customer Helpline	01256 362400
Postal Address	Remote Diagnostic Technologies Ltd, Pavillion C2, Ashwood Way, Ashwood Park, Basingstoke, RG23 8BG, United Kingdom
Web Portal	https://www.rdtltd.com
Fax	01256 362415
Deadline for returning the customer reply form	12th December 2019

It is important that your organisation confirms receipt of the Field Service Notice and takes the appropriate actions detailed within. This ensures we can monitor the progress of the corrective actions.

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