REMOTE DIAGNOSTIC TECHNOLOGIES LTD

A Philips company

CUSTOMER INFORMATION LETTER

FIELD SAFETY NOTICE (FSN)

25 November 2020

Tempus LS

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

Incorrect ECG waveform and Pacing spikes possible when changing from Pacer Mode to Manual or AED Defibrillation Mode

Dear Valued Customer,

An intermittent problem has been detected in the **Tempus LS** that, if it were to recur, could affect the performance of the equipment. This Customer Information Letter 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 minimise the effect of the problem
- the actions planned by RDT to correct the problem.

We have reviewed our records and identified that you have been provided devices which are affected by the attached Field Safety Notice. We kindly ask that you read this notice carefully and send us written acknowledgement by **31 December 2020** that you have read and understood the contents of this notice. We will use the details provided in the acknowledgement to arrange correction of affected devices, via a software update.

Written acknowledgement can be sent to RDT via the details listed in the attached customer reply form.

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

<Country Distributor Contact Details>

RDT apologises for any inconveniences caused by this problem.

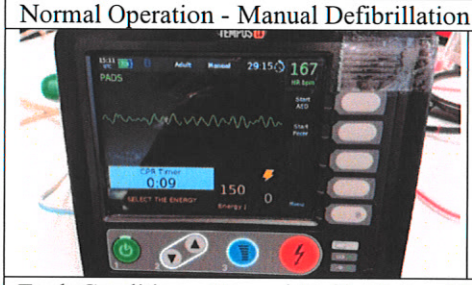
Sincerely,

Timothy Bubb
RA Manager
Remote Diagnostic Technologies Ltd

PHILIPS

CUSTOMER INFORMATION LETTER

AFFECTED PRODUCTS	Product Name: Tempus LS REF: 00-3010 UDI-DI: 07613365001693 Software Version Number: 1.3.4
PROBLEM DESCRIPTION	An inadvertent software error has been detected as part of internal production control activities for the Tempus LS. This issue affects all Tempus LS products with Software Version 1.3.4 installed. No customer complaints or adverse events have been reported from the field related to this issue. There is a risk when exiting Pacer mode back into Manual mode or AED mode, that the pacer pulse wave may put the ECG calibration out of calibration. This causes the waveform display to be a flat line, mimicking asystole. It cannot occur under any other interaction with the device. The root cause has been identified and it was introduced in the release of software V1.3.4. For this situation to occur, the user has to exit Pacer mode at the exact moment to coincide with a pacing pulse. The higher the pacing pulse rate frequency the higher the likelihood of occurrence. The incidence rate of the software error occurring is approximately 2-3% of mode changes from Pacer Mode to Manual Defibrillation Mode or Pacer Mode to AED Mode. **Manual Defibrillation Mode Fault Condition** This may result in a delay in therapy, as the clinician is not provided an ECG waveform on which a shockable rhythm decision can be made. The Tempus LS is still able to deliver a Manual defibrillation shock during the fault condition.

Normal Operation - Manual Defibrillation Mode	
	During normal operation, the device after changing from Pacer mode to Manual defibrillation mode will display the patients correct ECG waveform.
Fault Condition - Manual Defibrillation Mode	
	During the fault condition, the device after changing from Pacer mode to Manual defibrillation mode the screen shows inaccurate pacer markers and will display and mimic an asystole ECG waveform, which may not be representative of the patients true clinical condition.

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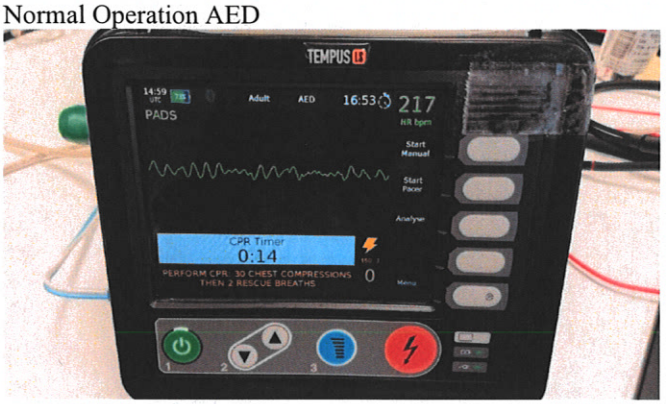
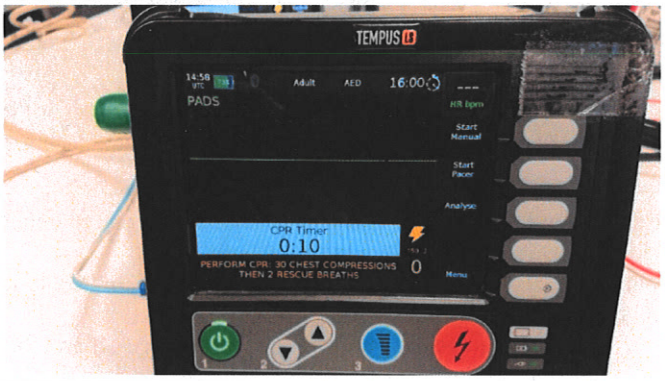
AED Defibrillation Mode Fault Condition

This may result in inability to deliver therapy. When the problem exhibits itself the device inadvertently displays and mimics Asystole for the connected patient, when another heart rhythm may be present. The device identifies the patient as being Asystole, and therefore in AED mode does not recommend a shock and a shock is not possible to deliver.

Normal Operation AED



Fault Condition AED



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HOW TO IDENTIFY AFFECTED PRODUCTS	The software version on the Tempus LS can be verified by selecting Menu -> System -> Device Info The "Device Info" displays "SW Version" and will show "V1.3.4-10732" on affected devices. 
ADVICE ON ACTIONS BY CUSTOMER / USER	For devices at V1.3.4, when changing from Pacer mode to either Manual defibrillation mode or AED mode, the user must: - Manually exit Pacer mode into the default (Manual or AED mode) and then must power cycle the device by: - Holding the power button to turn the device off and then power on again using the power button. The device will restart in the default Manual or AED defibrillation mode. Alternatively, the user may switch to a different Defibrillator to monitor ECG waveform and perform a defibrillation shock.
ACTIONS PLANNED BY THE MANUFACTURER	The root cause of the software error has been identified and a fix will be made available in Tempus LS Software Version: 1.3.5. This software update will be made available to users as a field correction via the exclusive Distributor Remote Diagnostic Technologies Ltd, a Philips company. RDT will contact affected customers to arrange a field update of device software.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact RDT Customer Services or your account manager: <Country Distributor Contact Details>

Please send the Customer Reply form below by **31 December 2020.**

REMOTE DIAGNOSTIC TECHNOLOGIES LTD

CUSTOMER INFORMATION LETTER

Customer Reply for

Tempus LS

Incorrect ECG waveform and Pacing spikes possible when changing from Pacer Mode to Manual or AED Defibrillation Mode

Please complete, sign, and return this form at your earliest convenience, and no later than 31 December 2020.

Customer Name:		
Contact Name:		
Telephone Number:		
Email Address:		
Facility Name:		
Street Address:		
City, State, Postal Code:		
Country:		
Preferred corrected software distribution method (select one)	☐	**Corrected Software as a Digital Download** Email address to send download link if different from the above:
	☐	**Corrected Software on a USB Flash Drive** Contact/Address to send USB Flash Drive with corrected software if different from the above:

CUSTOMER ACKNOWLEDGEMENT

I certify the Field Safety Notification was received, read, and understood by staff who may use the Tempus LS.

Signature: _____ Date: _____

Please return your completed form at your earliest convenience by either method below;

- Email completed and signed form to RDT.Recall.Response@Philips.com
- Fax completed and signed form to **+44 1256 362 415**