URGENT - Medical Device Recall
Philips IntelliVue TRx4841A and TRx4851A Telemetry Transceivers

Potential Loss of Arrhythmia Monitoring When Using Telemetry Transceivers with Philips Patient Information Center iX Release C

Dear Customer,

A problem has been detected when a Philips TRx4841A or TRx4851A Telemetry Transceiver is used with the Philips Patient Information Center iX (PIC iX) Release C.02.00, C.02.02, C.02.03 (all released versions of C.02, collectively referred to as 'C.02.xx') or C.03.01, which, if it were to occur, could pose a risk for patients.

This Field Safety Notice FSN86201907C is intended to inform you about:

- what the problem is and under what circumstances it can occur; and
- the actions that should be taken by the customer / user in order to prevent risks for patients or users.

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Heart rate and arrhythmia alarms from patients being monitored using a Philips TRx4841A or TRx4851A Telemetry Transceiver may not be generated or annunciated when the transceiver is used with a PIC iX Release C.02.xx or C.03.01. Philips has confirmed that this issue is not present when Philips TRx4841A and TRx4851A Telemetry Transceivers are used with PIIC Classic N.01.22, PIIC iX A.02.16, or PIIC iX B.02.18.

If you need any further information or support concerning this issue, please contact your local Philips representative:

<Philips representative contact details to be completed by the KM / country>

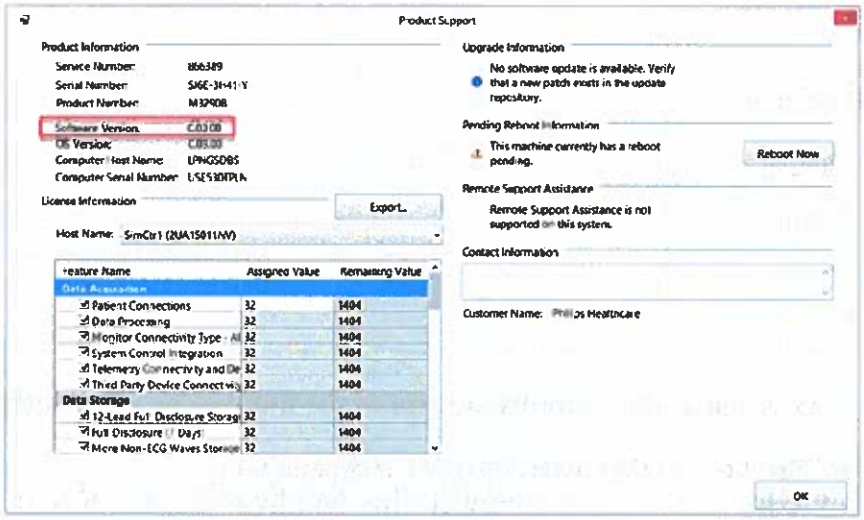
This recall will be reported to the appropriate regulatory agencies.

Philips apologizes for any inconvenience caused by this problem.

Sincerely,

Kristen Phillips
Head of Quality & Regulatory
Patient Monitoring Andover

AFFECTED PRODUCTS	Philips IntelliVue TRx4841A and TRx4851A Telemetry Transceiver at facilities that are operating Philips Patient Information Center iX (PIC iX) C.02.00, C.02.02, C.02.03 (all released versions of C.02 collectively referred to as 'C.02.xx') and C.03.01. 862439 TRx4841A 1.4 GHz IntelliVue Tele TRX 453564007261 - M4841 TRx w/SpO2 Refurbished 453564007271 - TELE-1.4 PWD ECG/SPO2 AAMI 453564007281 - TELE-1.4 PWD SPO2 UPGRADABLE AAMI 989803196951 - M4841 TRx w/SpO2 Refurbished 862231 TRx4851A 2.4 Ghz IntelliVue Tele TRX 453564052401 - ITS 2.4 PWD ECG ONLY AAMI 453564052411 - ITS 2.4 PWD ECG/SPO2 AAMI 453564052441 - ITS 2.4 PWD ECG ONLY IEC 453564052451 - ITS 2.4 PWD ECG/SPO2 IEC 453564166851 - ITS 2.4 PWD SP02 UPGRDBL AAMI 453564166861 - TELE-1.4 ITS 2.4 PWD SPO2 UPGRDBL IEC
PROBLEM DESCRIPTION	The ECG signal from patients being monitored using a Philips TRx4841A or TRx4851A Telemetry Transceiver may not be properly analyzed when the transceiver is used with a Philips Patient Information Center iX Release C.02.00, C.02.02, C.02.03 (all released versions of C.02, collectively referred to as 'C.02.xx') or C.03.01. If this occurs, the Information Center will not display a heart rate or generate, display or annunciate any heart rate or arrhythmia alarms. Alarming based on pulse oximetry (SpO_2) signals are unaffected by this issue.
HAZARD INVOLVED	Failure to generate and annunciate alarms for life-threatening arrhythmias could result in delay of urgently needed therapy.

HOW TO IDENTIFY AFFECTED PRODUCTS	A Philips IntelliVue TRx4841A or TRx4851A Telemetry Transceiver can be identified by the label on the front of the device:  To identify the revision of software on the Philips Patient Information Center iX surveillance: Access the Product Support screen from the Main Setup task bar button or by clicking the Philips icon. This will bring up the Product Support screen which identifies the software revision (see image below).  Philips TRx4841A and TRx4851A Telemetry Transceivers, when used with Patient Information Center iX C.02.xx or C.03.01, are at risk of potentially exhibiting this behaviour. Philips has confirmed that this issue is not present when Philips TRx4841A and TRx4851A Telemetry Transceivers are used with PIIC Classic N.01.22, PIIC iX A.02.16, or PIIC iX B.02.18.
ACTION TO BE TAKEN BY CUSTOMER / USER	• Confirm whether PIC iX Release C.02.xx and C.03.01 is used anywhere in your facility, and if so: o Identify Philips TRx4841A and TRx4851A Telemetry Transceivers in your facility by using the instructions provide in the HOW TO IDENTIFY AFFECTED PRODUCTS section above. o Immediately discontinue use of the Philips TRx4841A and TRx4851A Telemetry Transceiver. Philips support for these devices ended in 2017. • Complete, sign and return the reply form provided on the last page of this letter, as directed on the form.
ACTIONS PLANNED BY PHILIPS	Philips will contact you should further action be necessary.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>

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Customer Reply for FSN86201907C

Please complete and fax to: <Philips representative contact details to be completed by the KM / country>

Customer ID #	
Contact Name	
Telephone Number	
Email Address	
Facility Name	
Street Address City, State, Zip	

Please fax or email this completed form to the number or email address provided above.

CUSTOMER ACKNOWLEDGEMENT (Check One):
I acknowledge that I have reviewed this Medical Device Recall Notice, and

☐ My facility does not have Philips IntelliVue TRx4841A and TRx4851A Telemetry Transceivers.

- or -

☐ My facility does not run PIC iX Release C.02.xx or C.03.01 anywhere.

- or -

☐ My facility does run PIC iX Release C.02.xx or C.03.01 in at least one unit, and will discontinue use of its Philips IntelliVue TRx4841A and TRx4851A Telemetry Transceivers.

CUSTOMER CONTACT NAME (please print) **TITLE**

CUSTOMER CONTACT SIGNATURE **DATE**

Please email the completed reply form to: <Philips representative contact details to be completed by the KM / country>.
If you experience difficulty carrying out the instructions contained in this communication, contact your local Philips representative.