PHILIPS

<Name and Address of Hospital>

<Date>

TO: WHOM IT MAY CONCERN
CC: Chairman Medical Board and relevant Head of Department

Attached is a Field Safety Notice/Field Change Order pertaining to the Philips Hemodynamic system due to FCO 2018-IGTBST-019_ 72200439. Please note that the serial number of the units affected are stated below:

Affected Serial Numbers: <Affected serial numbers>

If you need any further information or support concerning this issue, please contact your local Philips Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).

This is a mandatory requirement based on 21CFR Part 820 by USA FDA, thus we seek your cooperation to acknowledge that you are thus notified of the above within 5 working days from the issuance of this letter.

Acknowledged By:

Customer Name/Signature:

Company Name/Stamp:

Date:

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www.philips.com.sg

Reg. No 199705989C

IGT Systems FSN for 2018-IGTBST-019 2018-Dec-13

URGENT - Field Safety Notice
Medical Device Correction

Philips Hemodynamic Application R1.0.1

Cardiac Output Hemo

Dear Customer,

A problem has been detected in the Philips Hemodynamic Application R1.0.1, that, if it were to re-occur, could pose a risk for patients.

This Field Safety Notice is intended to inform you about:

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

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.

Please retain a copy with the equipment Instruction for Use until the problem is solved by Philips.

Following a complaint received on the value of the cardiac output when performing a Thermodilution Cardiac Output Measurement, Philips initiated an investigation and confirmed a problem in the algorithm used by the Philips Hemodynamic Application R 1.0.1 for this measurement. No patient harm has been reported to Philips.

In the following pages, detailed information and actions required are provided.

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

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

[redacted]
Rajesh Kathuria
Head of Q&R
Image Guided Therapy Systems

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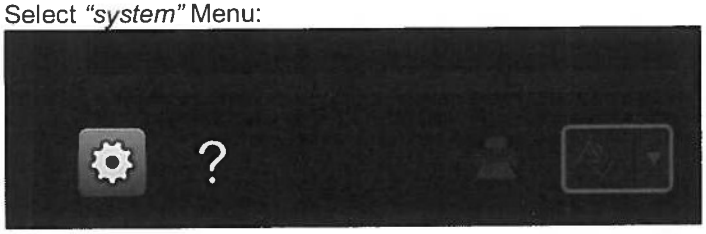
AFFECTED PRODUCTS	Philips Hemodynamic system (product code:722463) with Philips Hemodynamic Application in Release 1.0.1
PROBLEM DESCRIPTION	To perform Thermodilution Cardiac Output measurements, the Philips Hemodynamic-Application (PHA) has an algorithm to detect the onset of a cold bolus passing and to determine the baseline temperature of the blood (the temperature before the onset of the bolus). It has been identified that when the cold bolus injection is slower than the detection threshold used in the algorithm, the Philips Hemodynamic Application will detect the onset of the bolus too late resulting in the baseline temperature being determined at a too low value. This will result in a wrong value of the Cardiac Output (i.e. overestimation, high variability). Only the cardiac output measurements are affected by this issue.
HAZARD INVOLVED	A wrong value, (i.e. overestimation, high variability) of the Cardiac Output measurements might result in: • The patient not getting the required treatment. • A delay in treatment. No patient harm has been reported to Philips.
HOW TO IDENTIFY AFFECTED PRODUCTS	Philips will contact customers with affected products directly. To confirm the release of the Philips Hemodynamic Application: • Select *"system"* Menu:  OR 

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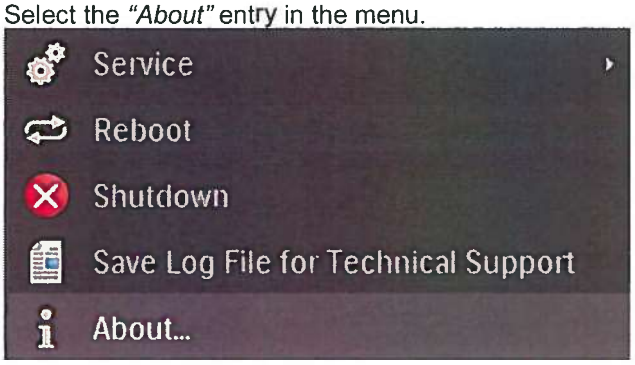
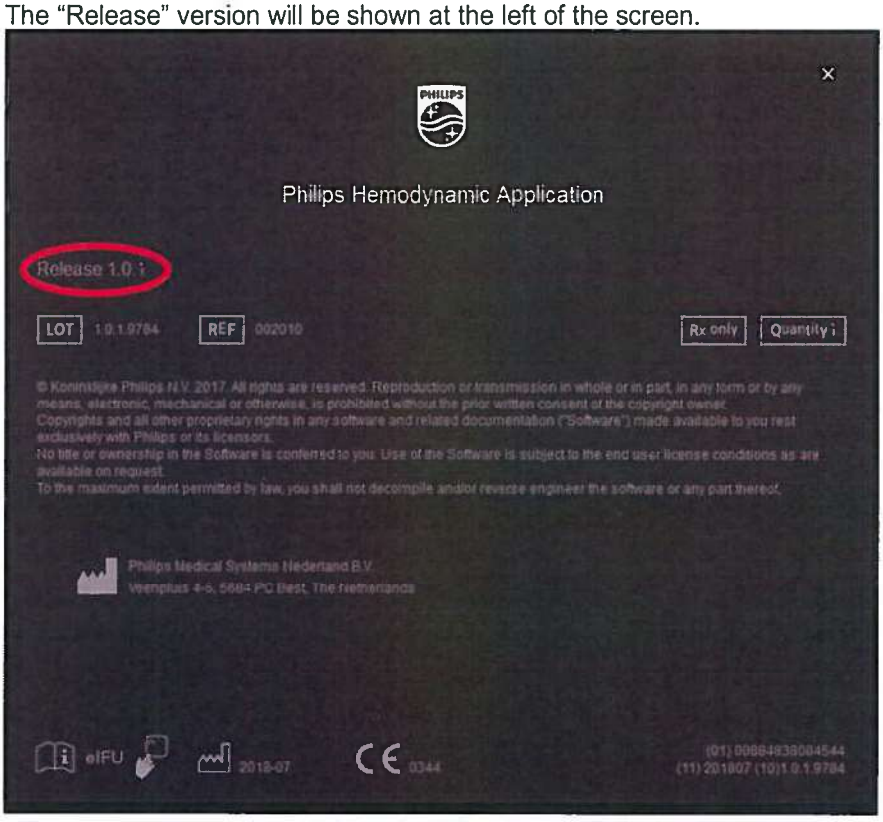
- Select the *"About"* entry in the menu.



- The "Release" version will be shown at the left of the screen.



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ACTION TO BE TAKEN BY CUSTOMER / USER	Until Philips installs a software update: • **Do not** perform cardiac output measurements. As an alternative a patient monitor with cardiac output option can for instance be used. • Please ensure that all staff with access to the affected systems are informed of the content of this Field Safety Notice. • Include this Field Safety Notice together with the documentation of the system until the system has been corrected by Philips.
ACTIONS PLANNED BY PHILIPS	The problem will be resolved by a software update, which is planned to be available by the end of December 2018. You will be notified by your local Philips representative when the software update is available for installation.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: