PHILIPS

URGENT Field Safety Notice

RE: Cardiac Workstation 5000 and 7000 – Potential Incorrect Measurements When Putting the Device in and Returning the Device from "Standby" Mode

DD-MMM-YYYY

To: Customer Name
Customer Street Address
City, State, Zip Code

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 this letter for your records.

Dear Customer,

Philips has become aware of a potential safety issue with Cardiac Workstation 5000 and 7000 – Potential Incorrect measurements when putting the device in and returning the device from "Standby" mode. This URGENT Field Safety Notice is intended to inform you about:

What the problem is and under what circumstances it can occur

Philips has received multiple complaints indicating that the Cardiac Workstation can intermittently provide inaccurate data related to the patient's native heart rate. Healthcare providers were able to recognize that secondary review was needed because the patient's clinical presentation and symptoms were not consistent with the elevated heart rate displayed by the Cardiac Workstation. Although the elevated heart rate may serve as an indicator to the clinician that the data is inaccurate, the issue also impacts the accuracy of the entire ECG report, including waveform data, measurements, and interpretive statements.

This issue is related to the Wired PIM accessory used with the Cardiac Workstation. In rare cases, when the Cardiac Workstation is returned from Standby mode, the system may not set the ECG sampling rate in the Wired PIM correctly. This can cause the ECG waveform and interpretation to be inaccurate.

Hazard/harm associated with the issue

The misinterpretation of ECG data can contribute to a short-term delay in recognition, assessment, or evaluation of a cardiac condition.

Affected products and how to identify them

#	Product Name	Product Number	UDI or UPC Number
1	Cardiac Workstation 5000	860439	(01)00884838094826
2	Cardiac Workstation 7000	860441	(01)00884838094833

The Wired PIMs involved in the issue are the following:
a. 12-Lead AAMI Wired PIM, PN 453665074741
b. 15/16-Lead AAMI Wired PIM, PN 453665074761
c. 12-lead-IEC Wired PIM, PN 453665074751
d. 15/16-lead IEC Wired PIM, PN 453665074771

Actions that should be taken by the customer / user in order to prevent risks for patients or users

- Continue the use of the device but refer to the information in this notice.
- Disable the automatic "Standby" feature on the Cardiac Workstation and avoid manually putting the Cardiac Workstation in "Standby" mode to minimize the inaccurate heart rate value from occurring.
- Pass this notice to all those who need to be aware within your organization or to any organization where affected devices have been potentially transferred.
- Place this Urgent Field Safety Notice with the documentation of the Philips Cardiac Workstation and associated devices in a place where it is most likely to be seen and viewed.
- Complete the URGENT Field Safety Notice Response Form at the end of this notification to submit both acknowledgment of this URGENT Field Safety Notice and confirm understanding of actions to be taken.

Actions planned by Philips to correct the problem

- Philips representative will contact you to arrange an upgrade to the Cardiac Workstation Release 1.2.0.7.

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 Market/Business>*

This notice has been reported to the appropriate Regulatory Agencies. Adverse reactions or quality problems experienced with the use of this product(s) may be reported to *< Markets to insert to whom the customer should report>*.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Deborah Currlin
Head of Quality, Hospital Patient Monitoring
Philips Healthcare

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Reference: Cardiac Workstation 5000 and 7000 – Potential Incorrect Measurements When Putting the Device in and Returning the Device from "Standby" Mode

Instructions: Please complete and return this Response Form to Philips promptly and no later than 30 days from receipt. Completing this Response Form confirms receipt of the URGENT Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Continue the use of the device but refer to the information in this notice.
- Disable the automatic “Standby” feature on the Cardiac Workstation and avoid manually putting the Cardiac Workstation in “Standby” mode to minimize the inaccurate heart rate value from occurring.
- Pass this notice to all those who need to be aware within your organization or to any organization where affected devices have been potentially transferred.
- Place this Urgent Field Safety Notice with the documentation of the Philips Cardiac Workstation and associated devices in a place where it is most likely to be seen and viewed.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this letter has been properly distributed to all users that handle the affected product(s).

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please email this completed form to Philips at: <Response Form return details to be completed by the KM/country>