PHILIPS

URGENT Field Safety Notice

Possible loss of ECG signal when using the 12-lead ECG Monitoring Interface Notification: 2021-CC-EC-019

31-JAN-2022

This document contains important information tor 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 this communication.

Please retain a copy with the equipment Instruction for Use.

Dear Customer,

Philips determined that the Philips HeartStart Intrepid Monitor/Defibrillator (Intrepid) 12-Lead ECG feature could pose a risk for patients. Philips is releasing this field action to inform affected customers and describe actions to be taken by the customer to reduce any potential risk. Please refer to the following sections for more information.

1. What is the problem and under what circumstances can it occur.

The HeartStart Intrepid 12-Lead ECG feature may lose the ECG signal when (a) it is connected to the patient and (b) the Right Leg (RL) connection becomes intermittent. This loss of ECG signal can occur without generating a 'leads off' warning. Instead, this issue appears as a dashed line on all channels of the ECG display on the device.

This issue occurs bath when (a) initially placing leads ECG electrode on the patient to capture a 12-Lead ECG and (b) intermittently during 12-lead ECG patient monitoring use. **If** the error occurs during placement of ECG leads, the monitor display will say 'leads off' or a dashed line on all channels of the display will appear. If the error occurs intermittently during 12-lead monitoring without generating a 'leads off warning, this could go undetected unless the user is actively observing the 12-lead ECG on screen.

As of 24-Jan-2022, Philips received one adverse event complaint, which resulted in a death and was possibly related to this issue.

2. Describe the hazard/harm associated with the issue.

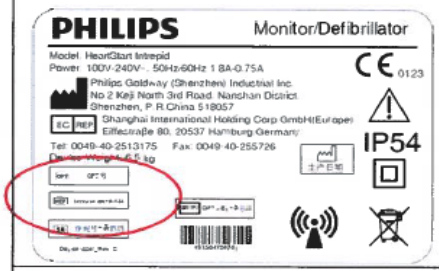
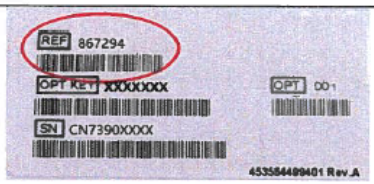
12- Leads ECG signal loss may lead to:

- A delay in diagnosis or therapy due to losing ECG signal during monitoring or while troubleshooting the 12-Leads 'leads off' warning or dashed lines, specifically:

- 12-lead ECG interpretation (as an adjunct to qualified Physician interpretation), including:
  - Measurements and Interpretive Statements describing the patient's cardiac rhythm and waveform morphology
  - Critical Values Statements to aid in quickly identifying an interpretation that may mean the patient needs immediate attention
  - ECG Severity assessments including - Normal ECG, Otherwise Normal ECG, Borderline Normal ECG, Abnormal ECG and Detective ECG
- Demand Mode Pacing, if utilizing a 10-lead cable set
- Cardioversion, if utilizing a 10-lead cable set

3. Affected products and how to identify them

The model number (867172) of the Philips HeartStart Intrepid Monitor/Defibrillator is printed on the primary tabel on the bottom of the device.

Label Description	Label Sample	Remarks
Device Regulatory label	Rev C: 	Confirm code "B03" is listed in OPT box. Or device has 867294 field upgrade label.
	Rev D: 	Confirm code "B03" is listed in OPT box. Or device has 867294 field upgrade label.
Device Primary Label (UDI)		Confirm code "B03" is listed in OPT box. Or device has 867294 field upgrade label.
Field Upgrade Label		Confirm code "B03" is listed in OPT box. Or device has 867294 field upgrade label.

4. Describe the actions that should be taken by the customer / user to prevent risks for patients or users.

You can continue to use your HeartStart Intrepid Monitor/Defibrillator if you follow its Instructions tor Use (IFU) and take the following precautions:

- 12-Lead ECG Monitoring (via 10-lead cable set):
  - When initiating 12-Lead functionality and a loss of signal appears (either a 'leads off' warning or dashed lines appear), adjust the leads to get a proper reading, starting with the RL lead connection
- Demand Mode Pacing:
  - Utilize 3-lead monitoring cable sets to ensure a continuous ECG monitoring source
- Cardioversion:
  - Utilize 3-lead monitoring cable sets or pads to ensure a continuous ECG monitoring source
- Place this Urgent Field Safety Notice with the documentation of the system
- Circulate this notice to all users of this device so they are aware of the product issue
- Complete and return the Urgent Field Safety Notice Response Form included with this letter

5. Describe the actions planned by Philips Emergency Care to correct the problem.

While a solution tor this issue is developed, Philips is providing this Urgent Field Safety Notice to inform affected customers. Philips will notify you again to arrange a permanent resolution immediately upon release.

If you need further information or support concerning this issue, please contact your local Philips representative: *<Philips representative contact details to be completed by the Market>*

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this problem.

Sincerely,

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URGENT FIELD SAFETY NOTICE RESPONSE FORM

Reference: The HeartStart Intrepid 12-Lead ECG feature may lose the ECG signal when it is connected to the patient and the RL connection becomes intermittent. This loss of ECG signal can occur without generating a 'leads off' warning. HeartStart Intrepid. CR#- 2021-CC-EC-019.

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

Customer/Consignee/Facility Name:_____

Street Address:_____

City/State/ZIP/Country:_____

Customer Actions:

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  - When initiating 12-Lead functionality and a loss of signal appears (either a 'leads off' warning or dashed lines appear), adjust the leads to get a proper reading, starting with the RL lead connection
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  - Utilize 3-Lead monitoring cable sets to ensure a continuous ECG monitoring source
- Cardioversion:
  - Utilize 3-Lead monitoring cable sets or pads to ensure a continuous ECG monitoring source

I acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this Letter has been properly passed to those who need to be aware.

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

Please return this form to Philips by email or fax. <provide. fax#, email address. >