URGENT Field Safety Notification

HeartStart Intrepid Monitor/Defibrillator (867172)
Intermittent ECG Waveforms

01-JULY-2024

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 of this letter with your device's Instructions for Use.

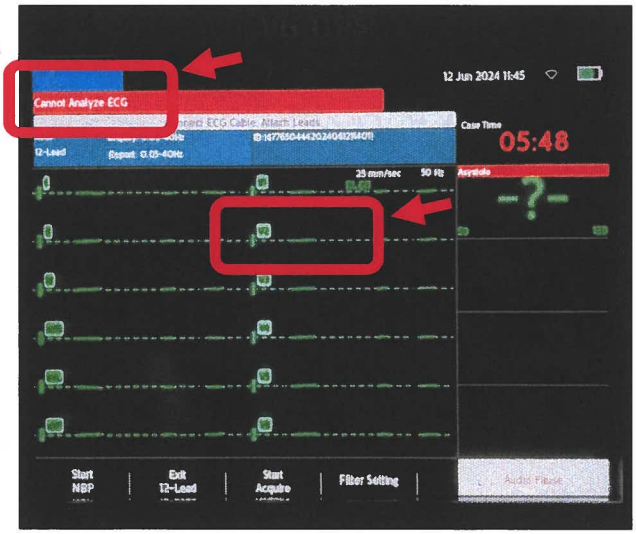
Dear Valued Distributor,

Philips has become aware of a potential safety issue where the HeartStart Intrepid Monitor/Defibrillator may display intermittent ECG waveforms when the fourth limb lead is placed on the patient using either a 5-Lead or 10-Lead ECG cable. This URGENT Field Safety Notice is intended to inform you about:

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

When monitoring ECG using either a 5-Lead or 10-Lead ECG cable, the HeartStart Intrepid Monitor/Defibrillator may display intermittent ECG waveforms when the fourth limb lead is placed on the patient. The ECG tracing is normal when only three limb leads are connected (right arm, left arm, and left leg). However, when there are one or more poor ECG lead connections to the patient, the ECG tracing either displays a dashed line or is intermittent between waveform and dashed line (see Figures 1-3 below). This failure may occur any time the HeartStart Intrepid Monitor/Defibrillator is being used to monitor 5-Lead or 12-Lead ECG.

Figure 1 – 12-Lead ECG



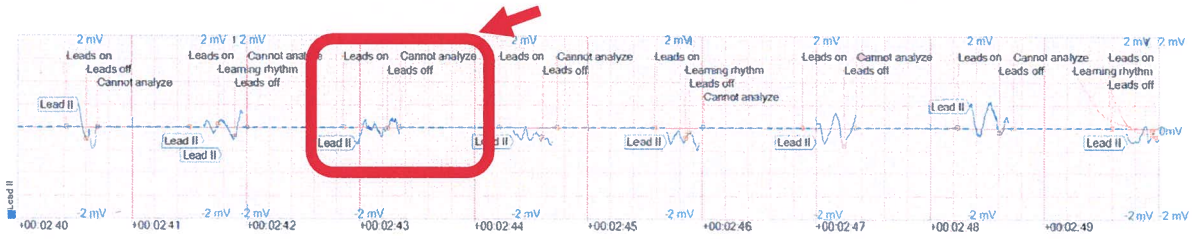
The ECG tracing is intermittent between waveform and dashed line.

Figure 2 – Monitor mode

The ECG tracing is intermittent between waveform and dashed line.

Figure 3 – ECG printout

The ECG tracing is intermittent between waveform and dashed line.



The issue was identified due to customer complaints.

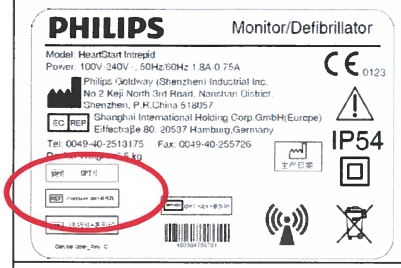
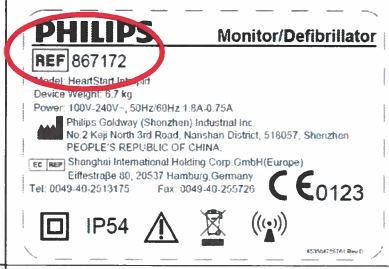
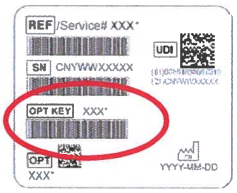
The HeartStart Intrepid is a monitor/defibrillator used in an emergency medical services or hospital environment by qualified medical personnel trained in its operation to provide pacing, defibrillation, and synchronized cardioversion therapies. It is intended to measure heart rate and rhythm; blood oxygen saturation; exhaled CO2; systolic, diastolic, and mean blood pressure; and temperature.

2. Hazard/harm associated with the issue

A failure to capture an ECG signal prevents Advanced Life Support (ALS) users from interpreting the cardiac rhythm (ECG) to determine the need for medical interventions or defibrillation therapy. The issue can occur in monitoring mode or using one of the following therapeutic modes of defibrillation therapy: Manual, Synchronized Cardioversion, or Pacing. The potential harms include: delays in assessing patient condition and possible delayed treatment.

3. Affected products and how to identify them

All HeartStart Intrepid Monitor/Defibrillators may be affected by this issue. The issue is more likely to occur in devices with the 12-Lead (B03) option. HeartStart Intrepid Monitor/Defibrillators can be identified by model number 867172 printed on the primary label on the bottom of the device. HeartStart Intrepid Monitor/Defibrillators with the 12-Lead (B03) option can be identified as shown below:

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: 	For Rev D label confirm "B03" shown on Device Primary Label (UDI) or has an 867294 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. Actions that should be taken by the customer / user in order to prevent risks for patients or users

If you follow the Instructions for Use (IFU) and take the following precautions, you can continue to use your HeartStart Intrepid Monitor/Defibrillator:

- Should you experience gaps in the ECG waveform, removal of the Right Leg and Chest connections will force the device to default to 3-Lead measurement and ensure a continuous ECG during monitoring, pacing, or cardioversion.
- Continue to follow the Instructions for Use (IFU) for proper use of ECG electrodes and their application to patients, including skin preparation. Use only Philips approved lead sets listed in the IFU with the HeartStart Intrepid. Failure to do so may introduce noise and result in intermittent 'Cannot Analyze' or 'Leads on/Leads off' ECG messages.
- Use only Philips monitoring electrodes, multifunction electrode pads, battery, and accessories listed in the IFU. Substitutions may cause the HeartStart Intrepid to function improperly and cause patient injury.
- Keep a copy of this Urgent Field Safety Notification letter with your device's Instructions for Use until you receive the correction.
- Complete and return the Urgent Field Safety Notice Response Form included with this letter.

Complete and return the Urgent Field Safety Notification response form included within 30 days of receipt. Please pass this notice on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred (if appropriate).

5. Actions that should be taken by the Distributors

- Please modify the URGENT FIELD SAFETY NOTICE RESPONSE FORM found on the last page of the URGENT Field Safety Notice letter (Document Identification: FSN-2024-CC-EC-016) to substitute your firm's own email and fax information (an electronic copy will be provided.)
- Please send a copy of the URGENT Field Safety Notice letter (Document Identification: FSN-2024-CC-EC-016) with modified response form to each customer with an affected device as soon as practical and not more than 30 days from receipt of this letter. If you have any HeartStart Intrepid Monitor/Defibrillators in stock, please distribute this letter with the device.
- Please complete and send to Philips the URGENT FIELD SAFETY NOTICE RESPONSE FORM found on the last page of this letter (Document Identification: DISTRIBUTOR-2024-CC-EC-016) within 30 days of receipt.

After the letters have been sent to customers with affected devices, please take steps to ensure customers received the letters. Please pass this notice on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred (if appropriate). Please transfer this notice to other organizations on which this action has an impact.

6. Actions planned by Philips Emergency Care (CN-MF-000003921) to correct the problem

While a solution for this issue is in development, 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. Philips anticipates that the solution will be available in Q4 2024.

If you need any further information or support concerning this issue, please contact your local Philips representative. < Key Markets insert contact information here >

This notice has been reported to the appropriate Regulatory Agencies. Be sure to report any occurrence of this issue to Philips, your Philips representative, or your local Regulatory authority.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Tanya DeSchmidt
Director of Quality

Tony She 02JUL 2024
Tony She
Sr. QMS Manager

PHILIPS

DISTRIBUTOR URGENT FIELD SAFETY NOTIFICATION RESPONSE FORM

Reference: HeartStart Intrepid Monitor/Defibrillator (867172) Intermittent ECG Waveform

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 Field Safety Notification and understanding of the issue and required actions to be taken.

Customer / Consignee / Facility Name: _____

Street Address: _____

City / State / Zip / Country: _____

Distributor Actions:

- Please modify the URGENT FIELD SAFETY NOTICE RESPONSE FORM found on the last page of the URGENT Field Safety Notice letter (Document Identification: FSN-2024-CC-EC-016) to substitute your firm's own email and fax information (an electronic copy will be provided.)
- Please send a copy of the URGENT Field Safety Notice letter (Document Identification: FSN-2024-CC-EC-016) with modified response form to each customer with an affected device as soon as practical and not more than 30 days from receipt of this letter. If you have any HeartStart Intrepid Monitor/Defibrillators in stock, please distribute this letter with the device.
- Please complete and send to Philips the URGENT FIELD SAFETY NOTICE RESPONSE FORM found on the last page of this letter (Document Identification: DISTRIBUTOR-2024-CC-EC-016) within 30 days of receipt.

Complete and return the Urgent Field Safety Notification response form included within 30 days of receipt. We acknowledge receipt and understanding of the accompanying Field Safety Notification and confirm that the information from this Notification has been properly distributed to all users that handle the HeartStart Intrepid devices.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD-MMM-YYYY): _____

Please return this form to Philips by email or fax < Key Market Insert reply information >