Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

نتقدم بثقة
Moving Forward with Confidence

رؤية عُمان 2040
Oman Vision

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 176 **dated** 23/12/2024 **Regarding SFDA Field Safety Corrective Action of HeartStart Interpid from (mfr: Philips Healthcare).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC
مركز سلامة الدواء
Drug Safety Center

ISO 9001:2015 CERTIFIED

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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Ministry of Health
Drug Safety Center
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سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 176 **/ 2024**

22 -06-1446 H
23 -12-2024

Field Safety Corrective Action of HeartStart Interpid from Philips Healthcare.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/210
Product	HeartStart Intrepid.
Manufacturer	Philips Healthcare.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	867172.
Reason	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.
Action	1. Please follow (Actions that should be taken by the customer / user) provided in the attachment. 2. Philips distributor will contact you to arrange the software update 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

PHILIPS

URGENT Field Safety Notification

HeartStart Intrepid Monitor/Defibrillator (867172)
Intermittent ECG Waveforms

Update on Software Solution Release

30-Oct-2024

Dear Valued Customer/Distributor,

This communication is to inform you that the solution is now available to address the HeartStart Intrepid Monitor/Defibrillator Intermittent ECG Waveforms issue (where the device 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).

Philips will contact you to arrange the software update under FCO86100239.

If you need any further information or support, please contact your local Philips representative.
met.quality@philips.com

Sincerely,

Tanya DeSchmidt
Director of Quality

Tony She
Sr. QMS Manager

URGENT Field Safety Notification

Summary

01-JULY-2024

To: Users of HeartStart Intrepid Monitor/Defibrillators

WHAT IS THE PROBLEM?

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

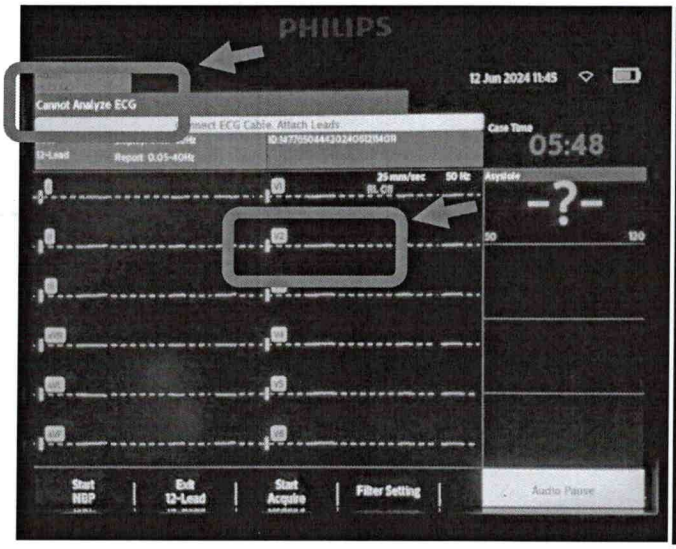


Figure 2 – Monitor mode

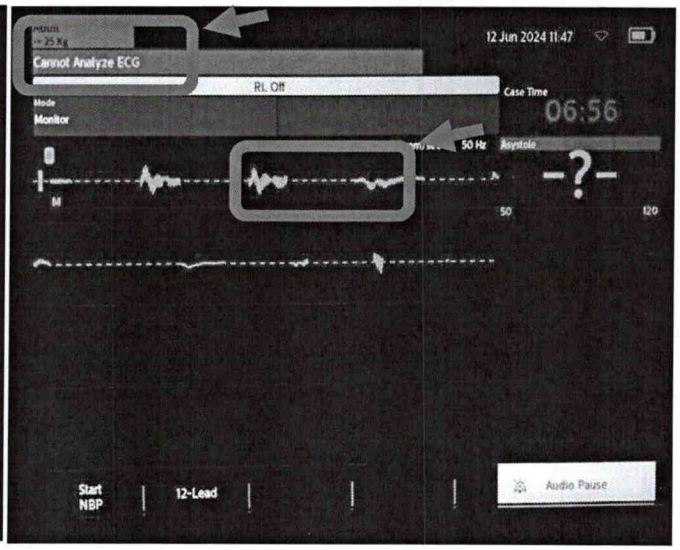
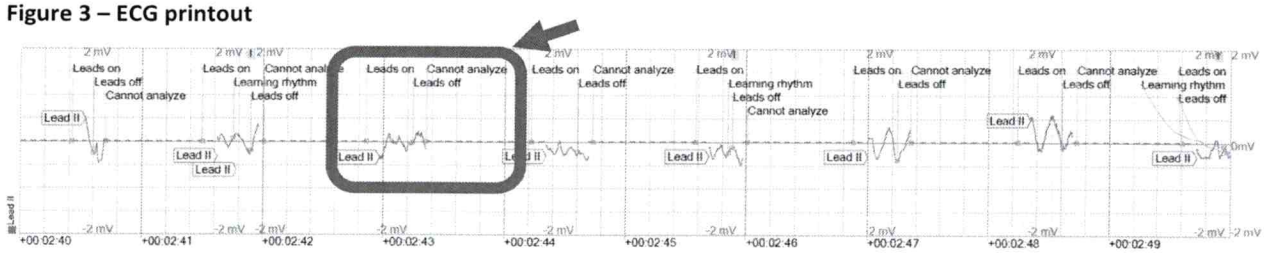


Figure 3 – ECG printout



WHAT SHOULD I DO?

- 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.

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.

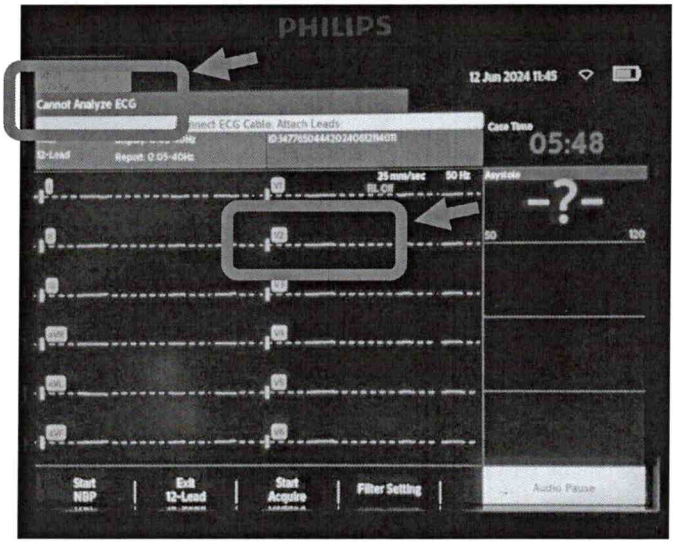
Dear Valued Customer,

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

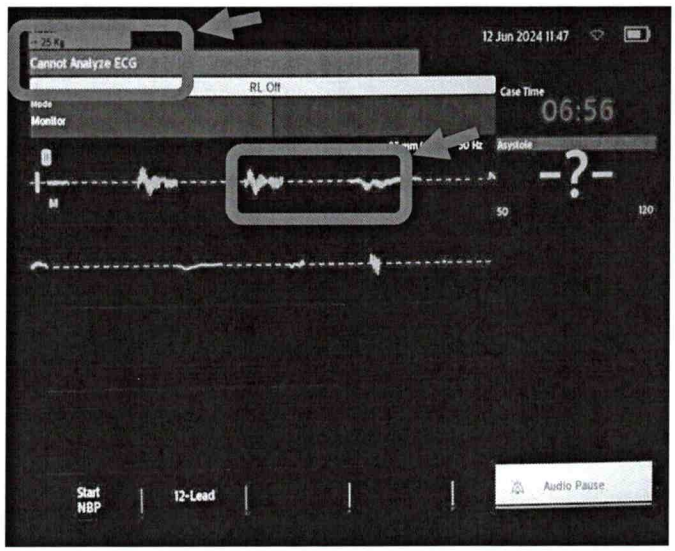
When monitoring ECG using either a 5-Lead or 10-Lead ECG cable, the HeartStart Intrepid **Monitor/Defibrillator may display intermittent ECG waveforms when the fourth limb lead is placed on the** patient. The ECG tracing is normal when only three limb leads are connected (right arm, left arm, and left 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



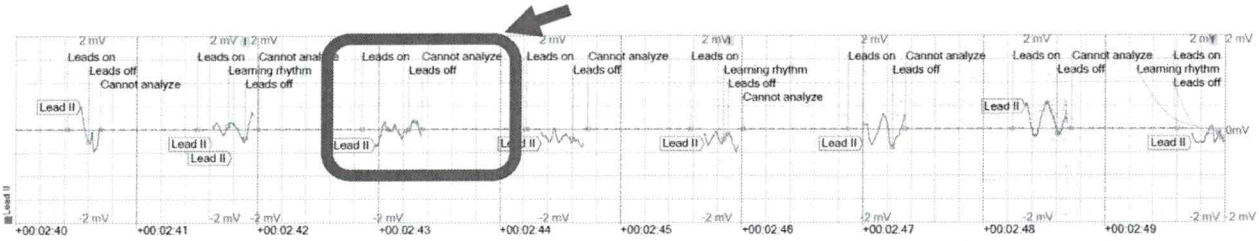
The ECG tracing is intermittent between waveform and dashed line.

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.

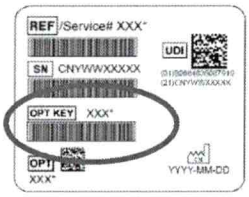
The HeartStart Intrepid is a monitor/defibrillator used in an emergency medical services or hospital environment by qualified medical personnel trained in its operation to provide pacing, defibrillation, and synchronized cardioversion therapies. It is intended to measure heart rate and rhythm; blood 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 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. met.quality@philips.com

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
Sr. QMS Manager

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: _____

Customer Actions:

If you follow the Instructions for Use (IFU) and take the following precautions, you may 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. 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 met.quality@philips.com.