URGENT Field Safety Notification

HeartStart Intrepid Monitor/Defibrillator (867172)
Service Manual Electrical Safety Test Issue

10-OCT-2023

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 identified a potential safety and compliance issue: The HeartStart Intrepid Monitor/Defibrillator's Service Manual does not detail electrical safety test verification methods as required by International Electrotechnical Commission (IEC) requirements for Class I devices. This URGENT Field Safety Notice is intended to inform you about:

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

The current HeartStart Intrepid Service Manual does not detail IEC Class I electrical safety test verification methods. The lack of this testing does not introduce a failure, but it may prevent a failure from being detected. This could occur when an IEC Class I device is tested as a Class II device after a servicing event.

The issue was identified as the result of a service provider's inquiry. There have been no reports of patient harm.

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 and deliver external cardiac pacing.

2. Describe the hazard/harm associated with the issue

If the missing IEC Class I electrical safety test conditions are not executed by the user and a component fails that could have been identified in the Class I device required testing, then safety and performance tests may not verify actions were properly conducted related to servicing. As such, a component failure may not be identified, contributing to potential risks to service technicians or users during clinical use. The user will assume the device is safe to use once the device has returned from servicing and is in the clinical setting. The device's Operational Check may not detect all potential component failures.

The lack of instructions in the Service Manual for maintenance and safe replacements of parts related to the supply of electrical power to the Intrepid may expose the patient, user, or bystander to unsafe electrical

voltages or current. This could result in a delay of therapy, no therapy, or an irregular heart rhythm due to electric shock. The critical factors that must occur for an electric shock hazard or a delay in therapy to occur, depend on whether testing was appropriate, whether the patient/user/bystander is in contact with a conductive part (USB port and ECG Output port) of the device, and whether a fault condition occurs.

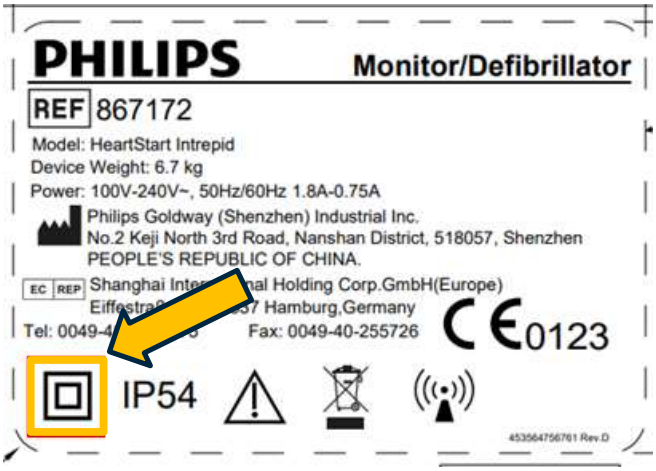
3. Affected products and how to identify them

HeartStart Intrepid Defibrillator/Monitor devices with the new Class I power supply are potentially affected. This includes devices that received the new power supply via field upgrade (option part number 867432 installed) or were shipped with it (serial numbers above CN73904564) and have undergone subsequent servicing that required the device being opened. HeartStart Intrepid devices that shipped with the Class I power supply and have not been serviced have not had the risk introduced.

A Class I HeartStart Intrepid power supply can be identified by having a three-pin power socket and via the label on the bottom of the device.

A three-pin power socket will be visible on Class I HeartStart Intrepids as shown below:

If the bottom label on your HeartStart Intrepid has the highlighted symbol below, it is currently a Class II device. The highlighted symbol will not be on the bottom label of Class I HeartStart Intrepid devices:



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

You may continue to use your HeartStart Intrepid Monitor/Defibrillator. Philips advises you take the following precautions:

- If you have a Class I device that has been opened and serviced, test your HeartStart Intrepid device(s) using the attached Service Manual Addendum.
- A hard copy of the Service Manual Addendum is included with this notification. A copy should be kept with each HeartStart Intrepid Service Manual. If you use a CD version of the Service Manual, ensure that the additional instructions from the hard copy are followed.

Complete and return the Urgent Field Safety Notification response form included, no later than 30 days from 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. Describe the actions planned by Philips Emergency Care (CN-MF-000003921) to correct the problem

Philips has released an addendum to the HeartStart Intrepid Service Manual for devices categorized as IEC Class I equipment describing how to conduct electrical safety tests in accordance with IEC 60601 and IEC 62353. It is included with this notification and may be used immediately. Philips will contact you to arrange complimentary retesting to Class I as necessary.

If you need any further information or support concerning this issue, please contact your local Philips representative at the Philips Customer Care Service Centre on:

Telephone: +448000260086
NI: +448000260430
ROI: +3531800832340

ukpcmsfco@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) Service Manual Electrical Safety Test Issue

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, understanding of the issue, and required actions to be taken.

Customer / Consignee / Facility Name: _____

Street Address: _____

City / State / Zip / Country: _____

Customer Actions:

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Complete and return the Urgent Field Safety Notification response form included, no later than 30 days from 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 to **safetynoticeuki@philips.com**