PHILIPS

HeartStart Intrepid Service Manual Addendum

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HeartStart Intrepid Service Manual Addendum

English

This document provides the information on how to conduct safety tests on the HeartStart Intrepid, based on the compliance requirements from IEC 60601 and IEC 62353.

NOTES: The information in this addendum applies to HeartStart Intrepid devices categorized as Class I equipment that meet any of the following conditions:

- FCO86100232 and/or FCO86100236 has been applied.
- Field upgrade option 867432 has been fitted.
- The device has a serial number higher than CN73904564.

For HeartStart Intrepid devices categorized as Class II equipment, see the corresponding sections in the *HeartStart Intrepid Service Manual.*

Safety Tests Compliance with IEC 60601

This section provides the guideline for conducting electrical safety tests on the HeartStart Intrepid to ensure compliance with IEC 60601.

This section is organized into the following topics:

Test Notes

The HeartStart Intrepid complies with the following international electrical safety standards:

– IEC 60601, Medical Electrical Equipment, General Requirements for Safety

To complete HeartStart Intrepid safety testing, do the following:

- Follow the procedures called out by the manufacturer of the safety analyzer in use.
- Only test the AC Mains (line) voltage used at customer's facility. There is no need to test both 120 VAC and 240 VAC.
- Test both normal and reverse polarity line connections for each test, and record the worst case value.
- If a chassis reference point is needed for the testing, connect to the inside metal shaft on the ECG Out (Sync) jack.

Test Method

To establish a maintenance routine, perform safety tests and update applicable maintenance records as follows:

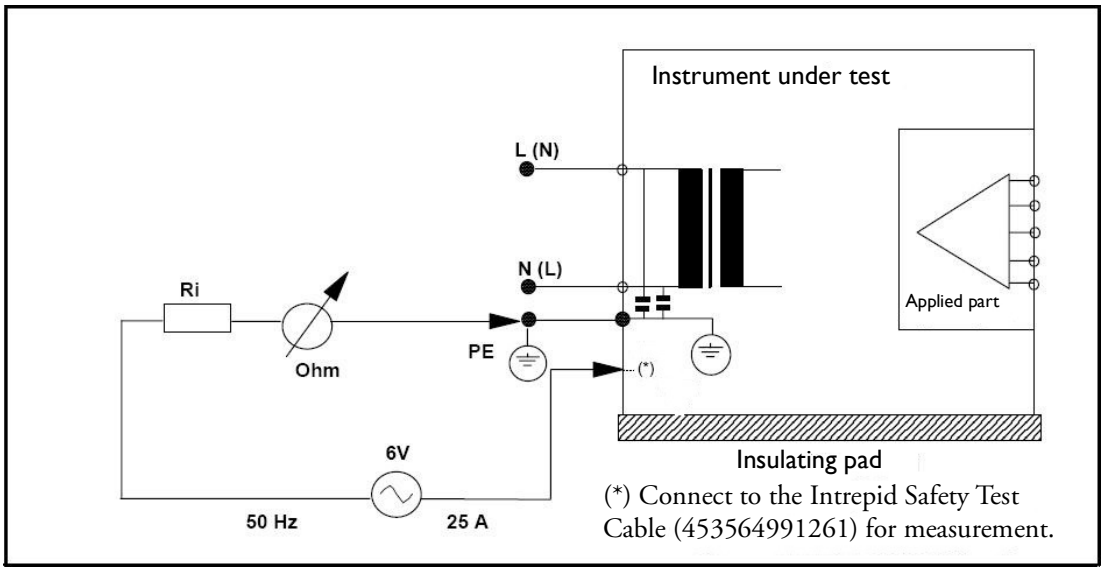
- Upon reception of the HeartStart Intrepid
- Whenever the HeartStart Intrepid is opened for repair
- Every year

The steps used for these tests and the acceptable ranges of values are based on local and international standards but may not be equivalent. These tests are not a substitute for local safety testing that is required for an installation or a service event.

Protective Earth Resistance

Figure 1 illustrates the protective earth resistance measurement of the HeartStart Intrepid.

Figure 1 **HeartStart Intrepid Protective Earth Resistance Test Diagram**



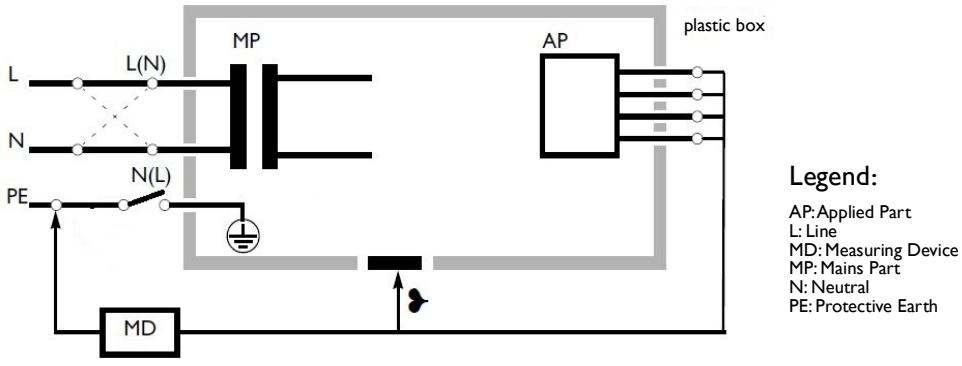
Acceptable test results:

Maximum impedance x ≤ 100 mΩ (IEC 60601-1 and UL 60601-1). Record as “aaa”.

Leakage Currents

Check for the touch current (enclosure leakage current) from the accessible conductive parts, but not for protective earth resistance since the conductive parts are not connected to the protective earth. Figure 2 illustrates the HeartStart Intrepid circuitry.

Figure 2 **HeartStart Intrepid Leakage Current Test Diagram**



AC Mains (Ground Leakage)

Leakage through earth (ground) wire of AC power cord.

- Normal Condition (Open ground), both AC line connections intact
  - Should be ≤ 300 µA (UL 120 VAC).
  - Should be ≤ 500 µA (IEC 240 VAC).
  - Record as “bbb”.
- Single Fault Condition (Open ground line, open neutral line), one AC line connection open.
  - Should be ≤ 1000 µA. Record as “cccc”.

Chassis (Enclosure Leakage)

Use the ECG Out (Sync) jack to measure enclosure leakage current.

- Normal Condition
  - Should be < 100 µA. Record as “dd”.
- Single Fault Condition (Open Neutral)
  - Should be < 300 µA (UL).
  - Should be < 500 µA (IEC).
- Reverse the polarity and repeat the test. Record the higher value as “eee”.
- Single Fault Condition (Open Earth)
  - Should be < 300 µA (UL).
  - Should be < 500 µA (IEC).
- Reverse the polarity and repeat the test. Record the higher value as “fff”.

Patient Leakage Current

Leakage out of (Source) or into (Sink) patient-connected inputs (Applied Parts).

CAUTION: Do not touch the ECG leads during the test.

ECG Leads (IEC Type CF)

- Source (out of the ECG leads into the HeartStart Intrepid)
  - Normal Condition (both AC line connections and earth ground intact)
    Should be ≤ 10 µA. Record as “ff”.
  - Single Fault Condition (separately open neutral and open earth, each in turn)
    Should be ≤ 50 µA. Record as “gg”.
- Sink (out of the HeartStart Intrepid into the ECG leads)
  - Single Fault Condition with AC Mains voltage on Applied Parts (both AC line connections and earth ground intact)
    Should be ≤ 50 µA. Record as “hh”.

Internal Paddles (IEC Type CF)

Test internal paddles only if the device is used in internal defibrillation.

- Source (out of the internal paddles into the HeartStart Intrepid)
  - Normal Condition (both AC line connections and earth ground intact)
    Should be ≤ 10 µA. Record as “ii”.
  - Single Fault Condition (separately open neutral and open earth, each in turn)
    Should be ≤ 50 µA. Record as “jj”.
- Sink (out of the HeartStart Intrepid into the internal paddles)
  - Single Fault Condition with AC Mains voltage on Applied Parts (both AC line connections and earth ground intact)
    Should be ≤ 50 µA. Record as “kk”.

SpO_2 Cable (IEC Type CF)

- Source (out of the SpO_2 cable into the HeartStart Intrepid)
  - Normal Condition
    Should be ≤ 10 µA. Record as “mm”.
  - Single Fault Condition (separately open neutral and open earth, each in turn)
    Should be ≤ 50 µA. Record as “nn”.
- Sink (out of the HeartStart Intrepid into the SpO_2 cable)
  - Single Fault Condition (with AC Mains voltage on Applied Parts)
    Should be ≤ 50 µA. Record as “pp”.

External Paddles or Pads (IEC Type BF)

- Source (out of the external paddles or pads into the HeartStart Intrepid)
  - Normal Condition (both AC line connections and earth ground intact)
    Should be ≤ 100 µA. Record as “ggg”.
  - Single Fault Condition (separately open neutral and open earth, each in turn)
    Should be ≤ 500 µA. Record as “hhh”.
- Sink (out of the HeartStart Intrepid into the external paddles or pads)
  - Single Fault Condition with AC Mains voltage on Applied Parts (both AC line connections and earth ground intact)
    Should be ≤ 500 µA. Record as “iii”.

Temperature Cable (IEC Type CF)

- Source (out of the temperature cable into the HeartStart Intrepid)
  - Normal Condition (both AC line connections and earth ground intact)
    Should be ≤ 10 µA. Record as “qq”.
  - Single Fault Condition (separately open neutral and open earth, each in turn)
    Should be ≤ 50 µA. Record as “rr”.
- Sink (out of the HeartStart Intrepid into the temperature cable)
  - Single Fault Condition with AC Mains voltage on Applied Parts (both AC line connections and earth ground intact)
    Should be ≤ 50 µA. Record as “ss”.

CPR meter 2 Cable (IEC Type BF)

- Source (out of the CPR meter 2 cable into the HeartStart Intrepid)
  - Normal Condition (both AC line connections and earth ground intact)
    Should be < 100 µA. Record as “ttt”.
  - Single Fault Condition (separately open neutral and open earth, each in turn)
    Should be < 500 µA. Record as “uuu”.
- Sink (out of the HeartStart Intrepid into the CPR meter 2 cable)
  - Single Fault Condition with AC Mains voltage on Applied Parts (both AC line connections and earth ground intact)
    Should be < 500 µA. Record as “vvv”.

Safety Tests Compliance with IEC 62353

Some countries require service personnel to follow IEC 62353 when examining the device before returning it back to the user, after maintenance, inspection, or repair. Service personnel must assess the safety of medical electrical equipment and medial electrical system and comply with IEC 60601-1.

This section describes how to conduct electricity safety tests on the HeartStart Intrepid to ensure compliance with IEC 62353. For facilities that follow IEC 62353, follow the instructions provided in this section.

This section is organized into the following topics:

Test Method

To establish a maintenance routine, perform safety tests and update applicable maintenance records as follows:

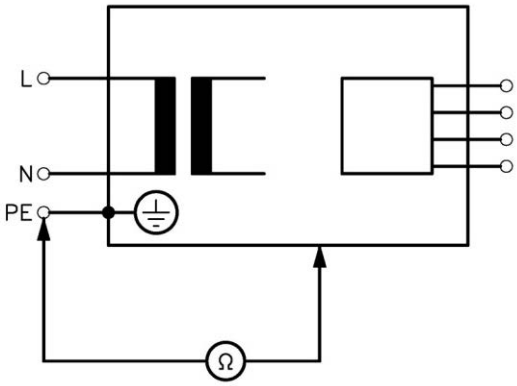
- Upon reception of the HeartStart Intrepid
- Whenever the HeartStart Intrepid is opened for repair
- Every year

The steps used for these tests and the acceptable ranges of values are derived from local and international standards but may not be equivalent. These tests are not a substitute for local safety testing where it is required for an installation or a service event.

Protective Earth Resistance

Figure 3 illustrates the protective earth resistance measurement of the HeartStart Intrepid.

Figure 3 **HeartStart Intrepid Protective Earth Resistance Test Diagram**



Acceptable test results (Maximum impedance):

With detachable power supply cord, x ≤ 200 mΩ (IEC 62353).

Detachable power supply cord, x ≤ 100 mΩ (IEC 62353).

Insulation Resistance (Not Mandatory)

Figure 4 to Figure 8 illustrate the insulation resistance measurements of HeartStart Intrepid. For acceptable test results, see Table 1 “Insulation Resistance Acceptable Test Results” on page 8

Figure 4 **HeartStart Intrepid Insulation Resistance Test Diagram - Mains Part and Protective Earth**

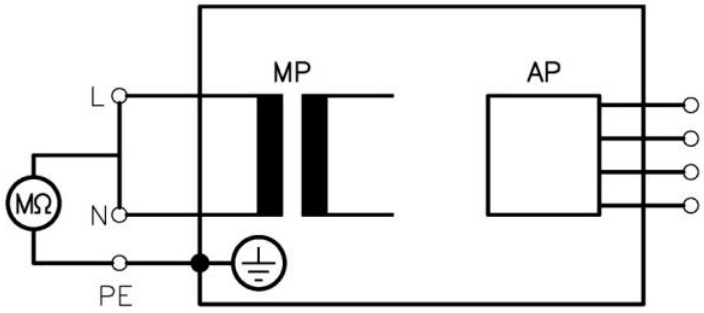


Figure 5 **HeartStart Intrepid Insulation Resistance Test Diagram - Mains Part and Non-Earthed Accessible Conductive Parts**

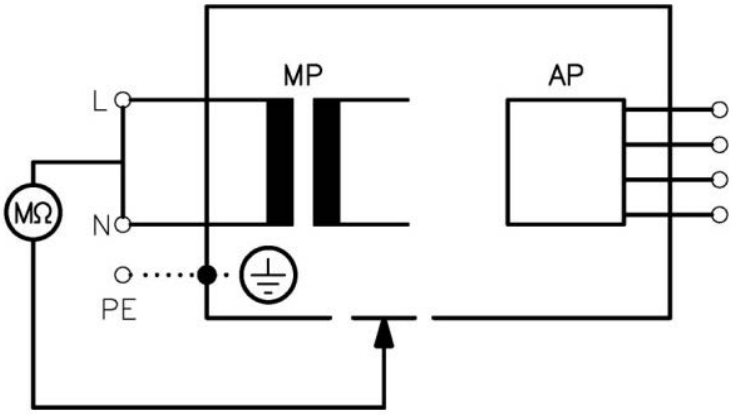


Figure 6 **HeartStart Intrepid Insulation Resistance Test Diagram - Mains Part and Applied Parts**

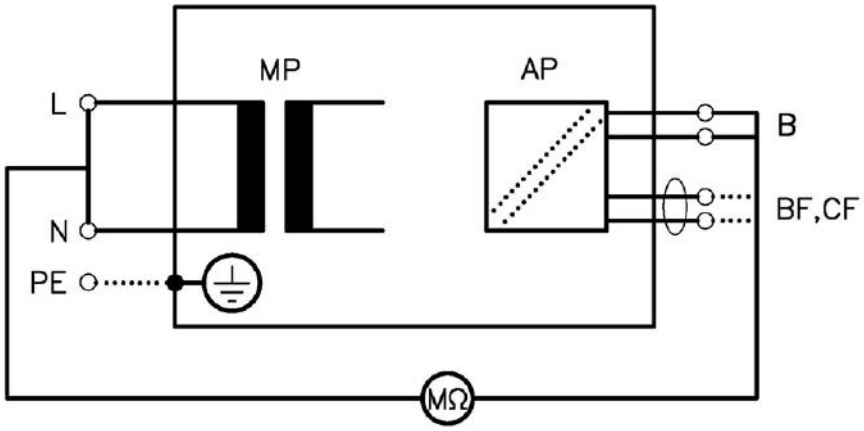


Figure 7 **HeartStart Intrepid Insulation Resistance Test Diagram - F-Type Applied Parts and Protective Earth**

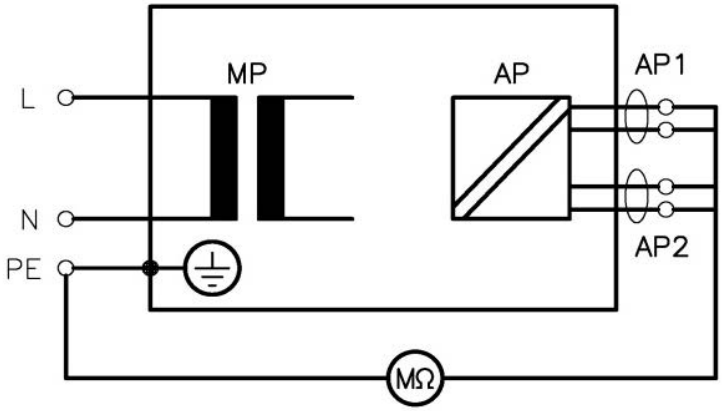


Figure 8 **HeartStart Intrepid Insulation Resistance Test Diagram - F-Type Applied Parts and Non-Earthed Accessible Conductive Parts**

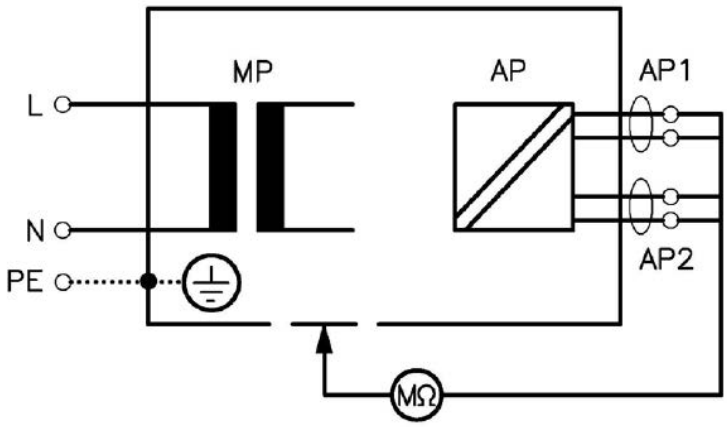


Table 1 **Insulation Resistance Acceptable Test Results**

Insulation Resistance Measurements Between	Acceptable Test Results for Class I Equipment
Mains Part and Protective Earth	≥ 2 M Ohms
Mains Part and Non-Earthed Accessible Conductive Parts	≥ 7 M Ohms
Mains Part and Applied Parts	≥ 70 M Ohms
F-Type Applied Parts and Protective Earth	≥ 70 M Ohms
F-Type Applied Parts and Non-Earthed Accessible Conductive Parts	≥ 70 M Ohms

Leakage Currents

Check for the touch current (enclosure leakage current) from the accessible conductive parts, but not for protective earth resistance since the conductive parts are not connected to the protective earth.

For the test diagram on conducting leakage currents test, see Figure 2 “HeartStart Intrepid Leakage Current Test Diagram” on page 2.

AC Mains (Ground Leakage)

Leakage through earth (ground) wire of AC power cord.

- Normal Condition (Open ground), both AC line connections intact
  - Should be ≤ 500 µA.

Chassis (Enclosure Leakage)

Use ECG Out (Sync) jack to measure enclosure leakage current.

- Normal Condition
  - Should be ≤ 100 µA.

Patient Leakage Current

Leakage out of (Source) or into (Sink) patient-connected inputs (Applied Parts).

ECG Leads (IEC Type CF)

- Source (out of the ECG leads into the HeartStart Intrepid)
  - Normal Condition (both AC line connections and earth ground intact)
    Should be ≤ 50 µA.

Internal Paddles (IEC Type CF)

Test internal paddles only if the device is used in internal defibrillation.

- Source (out of the internal paddles into the HeartStart Intrepid)
  - Normal Condition (both AC line connections and earth ground intact)
    Should be ≤ 100 µA.

External Paddles (IEC Type BF)

- Source (out of the external paddles into the HeartStart Intrepid)
  - Normal Condition (both AC line connections and earth ground intact)
    Should be ≤ 5000 µA.

SpO_2 Cable (IEC Type CF)

- Source (out of the SpO_2 cable into the HeartStart Intrepid)
  - Normal Condition (both AC line connections and earth ground intact)
    Should be ≤ 50 µA.

Temperature Cable (IEC Type CF)

- Source (out of the temperature cable into the HeartStart Intrepid)
  - Normal Condition (both AC line connections and earth ground intact)
    Should be ≤ 50 µA.

CPR meter 2 Cable (IEC Type BF)

- Source (out of the CPR meter 2 cable into the HeartStart Intrepid)
  - Normal Condition (both AC line connections and earth ground intact)
    Should be < 5000 µA.

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