

LIFEPAK[®] 20 MONITOR/DEFIBRILLATOR



Performance Inspection Procedure (PIP)



Performance Inspection Procedure (PIP)

This Performance Inspection Procedure (PIP) is a set of manual test procedures which are used as an operational closed-case evaluation of the LIFEPAK® 20 Defibrillator. This section describes contents of the test procedures you will perform to determine if the device is operating within the required specifications.

Perform the PIP as part of a regularly scheduled preventive maintenance routine. Also, perform the PIP after any repair, replacement, or calibration procedure. The **Performance Inspection Procedure Checklist** is provided as a tool for the recording of PIP test results.

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Scope and Applicability

The PIP applies to the LIFEPAK 20 Defibrillator exclusively. To complete the PIP, you must perform the manual test outlined in the **PIP - Instructions** below. All PIP tests must be performed from start to finish in the order presented.

Refer to the **PIP - Resource Requirements** for a listing of the necessary qualifications for PIP equipment, test equipment verification, workstation power.

Refer to the **PIP - Test Equipment Requirements** for a listing of test equipment, including specifications, required to complete the PIP. Use the **PIP - Checklist** to record your results.

Resource Requirements

This section describes the requirements for PIP equipment, PIP test equipment verification, PIP workstation power.

Test Equipment

To perform the PIP, you must use the equipment listed in the **PIP - Test Equipment Requirements** table. Although the table lists specific test equipment by manufacturer, test equipment with equivalent specifications may be substituted. Refer to the test equipment manufacturer's operating instructions for usage details where not specifically covered herein.

Test Equipment Verification

All test equipment used to perform the PIP must have a current calibration label. The calibration label must be issued by a certified calibration facility.

Workstation Power

The AC line power to the workstation must be connected to a grounded power source.

Test Equipment Requirements

| Equipment | Specification or Description | Manufacturer or Part number or Catalog number |
|---|--|---|
| Defibrillator analyzer with external noninvasive pacer measurements * | <p>Energy range: 0 to 450 J Load resistance: 50 ohms±1% Accuracy: +/- 2%, non-inductive</p> <p>Waveforms: Simultaneous 12-lead output Rates: 30 bpm, 120 bpm, with rate accuracy of ± 1% Amplitude: 1 mV ± 5%, based on Lead II ECG performance: Amplitudes of Lead II and Leads V1-V6 are equivalent. Lead I = 70% amplitude of Lead II. Sine wave: 10 Hz @ 1 mV ± 2%, based on Lead II</p> | Fluke [®] Biomedical Impulse 7000DP with QUIK-COMBO adapter accessory 16/7 D/P ADPT104** |
| Safety Analyzer | <p>90 V ac rms to 264 V ac rms mains voltage Current range: 0-1999 µA Current accuracy: 5% of reading or 1 digit (whichever is greater)</p> | Fluke Biomedical ESA612* |
| Decade resistance box | <p>0 to 9 MΩ resistance box Resolution: 1 Ω; accuracy: ± 1%</p> | IET RS-200 Resistance Substitute* |
| Remote Sync Test Pulse Generator *** | | 21300-007574 |
| SPO2 Leakage Cable | | 21300-007561, 21300-005487, 21300-007562 |
| AC Power Cable | | Commercial |
| Accessory –Test Plug, Quik-Combo | | 11113-000002 |
| Paddle Assembly - Detachable, LP20 | | 11130-000037 |
| QUIK-COMBO Therapy Cable | | 11110-000040 |
| 50 mm Recorder Paper | | 11240-000013 |

LIFEPAK® 20

Performance Inspection Procedure (PIP)

| Equipment | Specification or Description | Manufacturer or Part number or Catalog number |
|---|------------------------------|---|
| DB9 Male/DB 9 Female cable (optional) | | MXT100 |
| Masimo Oximeter Adult finger sensor (LNOP DCI, Adult SPO2 sensor, reusable) | | 11171-000007 |
| Massimo Extension Cable (PC04-Patient Cable, SPO2, 4ft) | | 11171-000006 |
| Cable Assembly, Fast Patch (use for 7000DP and RS200) | | 11110-000052 |
| Electrode test posts (use for 7000DP and RS200) | | 21330-001372 |
| Cable, Test, Service, LP CR2 | | 3323095 |
| Cable Assembly, 3 Lead ECG | | 11110-000029 11110-000030 |
| Cable Assembly, 5 Lead ECG | | 11110-000066 |
| Cable Assembly, Analog ECG Output | | 11110-000067 |
| Cable, QUIK-COMBO to Snap Termination | | 3009139 |
| Adapter -Test, Paddles, Leakage, LP12 & LP20 | | 3206631 |
| Cable, Test, ECG snap to banana plug | | 3305684 |
| QUIK-COMBO Leakage Cable | | 3207066 |
| 1210 Adapter (for ESA612) | | Fluke 1210 |
| BJ2 ECG Input Jack Adapter (1 for ESA612 and 2 for 1210 Adapter) | | Fluke - BJ2 |
| Banana plug cable (connect between ESA612 and Battery eliminators) | | Fluke ESA612 Accessory kit |
| <p>*Some energy meters are not accurate for biphasic waveforms; contact your defibrillator analyzer's manufacturer for more information.</p> <p>**Equivalent equipment is required to meet the specifications listed in the specification column.</p> <p>***A function generator can be used alternatively to the Remote Sync Test Pulse Generator.</p> | | |

Test Instructions

PIP - General Instruction

- This section lists the general instructions for performing the Performance Inspection Procedure (PIP).
- Perform the PIP in the order presented.
- Use the **Performance Inspection Procedure Checklist** to record your results.

WARNING

POSSIBLE EQUIPMENT DAMAGE

Only use accessories approved by Physio-Control.

PIP - Exterior Physical Inspection/Cleaning Paddles

To perform an exterior physical inspection:

1. Inspect the LIFEPAK 20 exterior for the following: Damage, excessive wear, improper mechanical function, and damaged connectors.
2. Pick up and turn over the device and listen for loose or rattling hardware. Locate any loose or rattling hardware, and then tighten or replace it.
3. Inspect the rubber feet on the underside of the lower enclosure. Reinstall or replace rubber feet as necessary.
4. Inspect the Therapy, ECG, SpO2 (if equipped), DB-9, DB-15, AED door, and IrDA connectors for damage and or cracks.
5. Inspect the keypads and overlays for damage, cracks, and separations.
6. Check all other accessory cables, Paddles, ECG, SpO2 sensors, and related items for expiration dates, general condition, and suitability for use.
7. Inspect carrying strap and mounts (if the device is equipped with them).

To perform Cleaning Paddles:

1. Disconnect the adult paddle plate from the paddle assembly.
2. Clean the spring contact of the adult paddle with alcohol.
3. Clean the pediatric electrode surface with alcohol.
4. Reattach the adult paddle plate to the paddle assembly.

PIP - Device Setup

WARNING

SHOCK HAZARD

The defibrillator delivers up to 360 joules of electrical energy. Unless properly used as described in these operating instructions, this energy may cause serious injury or death. Do not attempt to operate this device unless thoroughly familiar with these operating instructions and the function of all controls, indicators, connectors, and accessories.

1. Connect the AC Power cable into the device.
2. Install a roll of printer paper into the printer.

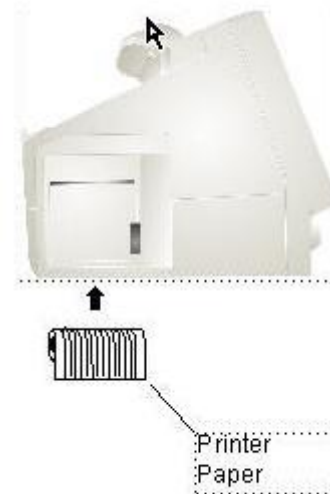


Figure 1.1: Device Setup

PIP - Manual Mode Access

It is recommended that the device be set up for Manual mode when performing the PIP.

Note: If you do not wish to change the setup for a device configured with manual access restrictions, it may be necessary to use the reserved technician passcode of 5433 to gain access to Manual mode.

Note: Be sure to make note of the customer settings to restore the device to the user-selected **MANUAL ACCESS** configuration at the completion of this PIP.

To perform the device for Manual mode access:

1. Access the Setup mode as follows:
 - a. Press and hold **OPTIONS** and **EVENT**, and then turn the device **ON**.
 - b. When the Setup mode passcode prompt appears enter 5433.
2. Select **MANUAL MODE** in the Setup menu.
3. In the Setup/Manual Mode submenu, set the Manual Access selection to **Manual/Direct** as shown in Figure 1.2.
4. Turn the device **OFF** by pressing **ON** for two seconds.

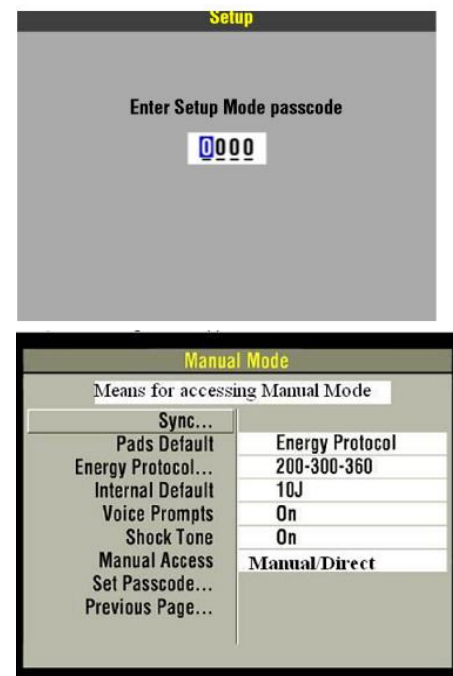


Figure 1.2: Manual Mode Access

PIP - Power Self-Test

To perform the Power On/Self-Test:

1. Press the **ON** button to initiate the device nominal five-second power-on self-test routine. Listen for a single tone from the speaker and then three distinct beeps from the sonalert (AC loss alert).
2. Verify that all lamps light momentarily except for the ON and AC mains indicators which remain on throughout self-test.
Note: The initial display indicates self-test in progress, as shown in Figure 1.3.
3. Verify that the device completes the Power On sequence.
4. Verify that AC Main indicator remains ON.
5. Verify that the SERVICE INDICATOR is OFF.

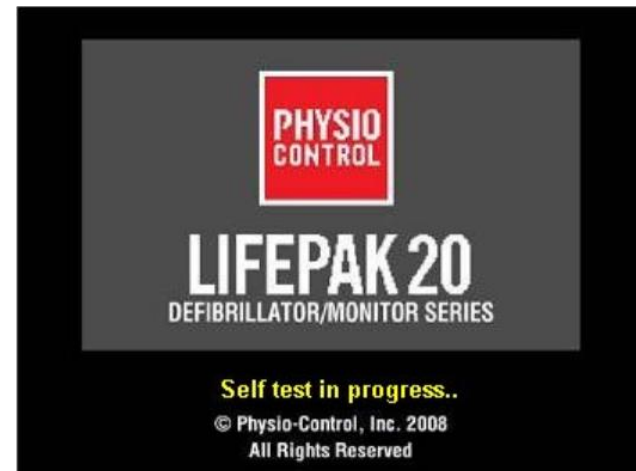


Figure 1.3: Power Self -Test

PIP - User Test and Date/Time Verification Tests

To perform the User Test and Date/Time Verification Tests:

1. Connect the Quik-Combo and Test Plug into the device.
2. Turn the device **ON**.
3. Press **OPTIONS** to access the Options menu.
4. Select **USER TEST** from the Option menu. When asked to Start user test. Select **Yes** and confirm using the Speed Dial.
5. Confirm the printed results that the device passes the user test and that the correct date and time values are displayed on the printout as shown in Figure 1.4.

Note: If the date and time are incorrect, reset using the Options/Date/Time menu.

6. Turn the device **OFF**.

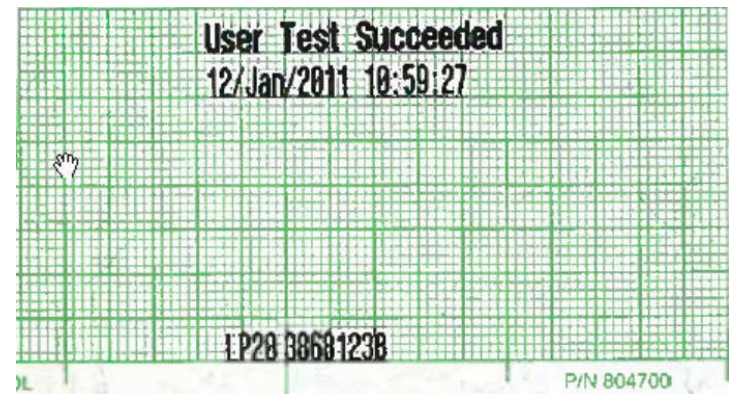


Figure 1.4: User Test and Date/Time Printout

PIP - SPO2 Test

To perform SPO2 Test:

1. Turn the device **ON**.
2. Connect the SpO2 finger probe to the SpO2 connector as shown in Figure 1.5.
3. Verify the **SpO2 parameter region** appears on the display.
4. Place your index finger into the SpO2 finger probe. Allow several seconds for the probe to find your pulse.
5. Confirm the SpO2 reading is between **50 % to 100 %**.
6. Remove finger from SpO2 finger probe. Message should display on screen: **SpO2 Check Sensor with audible alarm**.
7. Unplug SpO2 finger probe from the device; while on current patient record, message should display: **SpO2 No Sensor Detected**.
Note: Alarms will clear when device is turned off and new patient record started the next time the device is turned on again.
8. Turn the device **OFF**.

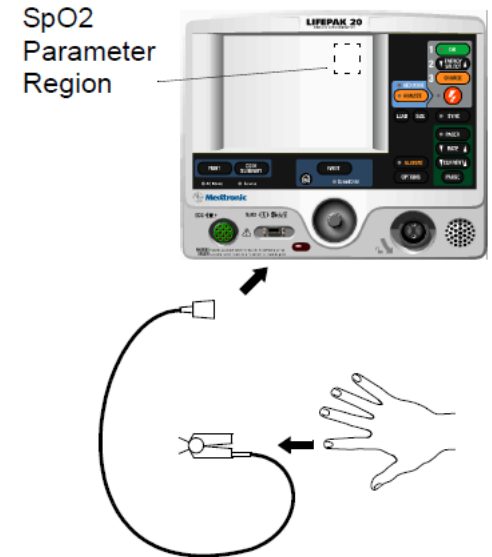


Figure 1.5: SPO2 Test

PIP - Keypad Verification Tests

To perform Keypad Verification Tests:

1. Select **TESTS** in the Service menu.
2. Select **BUTTONS** in the **Service/Tests** submenu as shown in Figure 1.6.
3. Press each front panel button when prompted by the flashing button legend (although you may press the buttons in any order).
4. Verify with each button pressed that its associated text box is highlighted.

Note: A failure is indicated by a text box that is not highlighted. It is normal for the buttons with up/down arrows to highlight only the arrows.
5. Press the switch located between the **OPTIONS** and **PAUSE** buttons.

Note: The switch is hidden in the elastomer keypad.
6. Verify the **TEST COMPLETE** message appears on the bottom of the screen and the **Service LED** is not on.
7. Press the **SPEED DIAL** to exit at the end of the test.
8. Continue with the next test while still in Service mode.

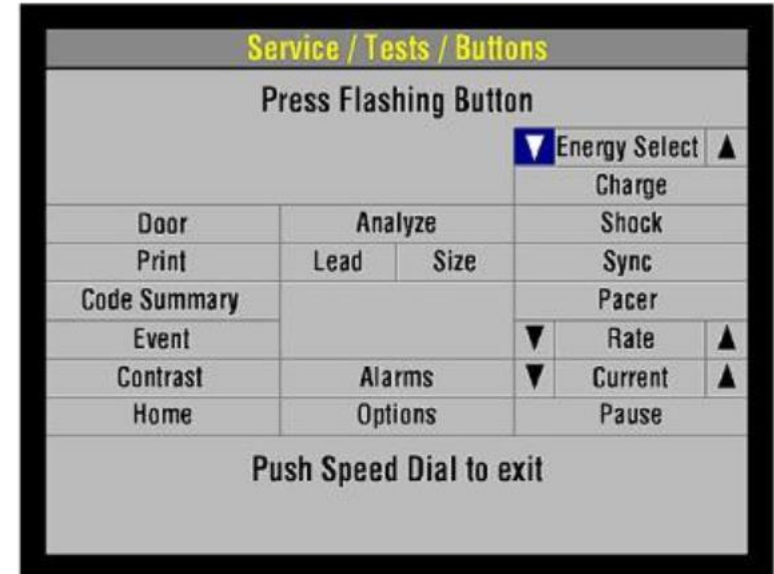


Figure 1.6: Keypad Test

PIP - Pixels Verification Test

To perform Pixels Verification Test:

1. Select **TESTS** in the Service menu.
2. Select **PIXELS** in the Service/Tests submenu. The pixels test screen appears, as shown in Figure 1.7.
3. Carefully examine the screen for any anomalies. Rotate **SPEED DIAL** to scroll through test screens.
4. Press the **SPEED DIAL** to exit the test.
5. Continue with the next test while still in Service mode.

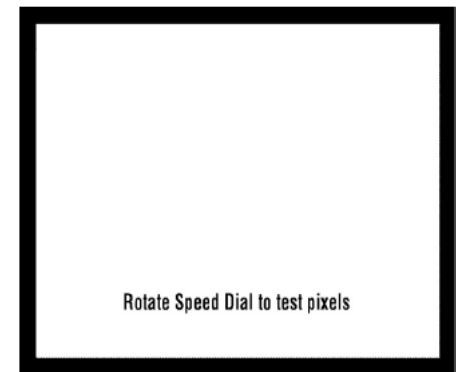


Figure 1.7: Pixels Test

PIP - Audio Verification Test

To perform Audio Verification Test:

1. Select **VOICE/TONE** from the Service/Tests submenu as shown in Figure 1.8.
2. Select **START** to produce voice prompts from the speaker.
3. Confirm that the voice prompts are clearly audible and reproduced without distortion.
Note: You can listen to a complete replay of all voice prompts and tones, but it is not required for verification of this function.
4. Continue with the next test while still in Service mode.

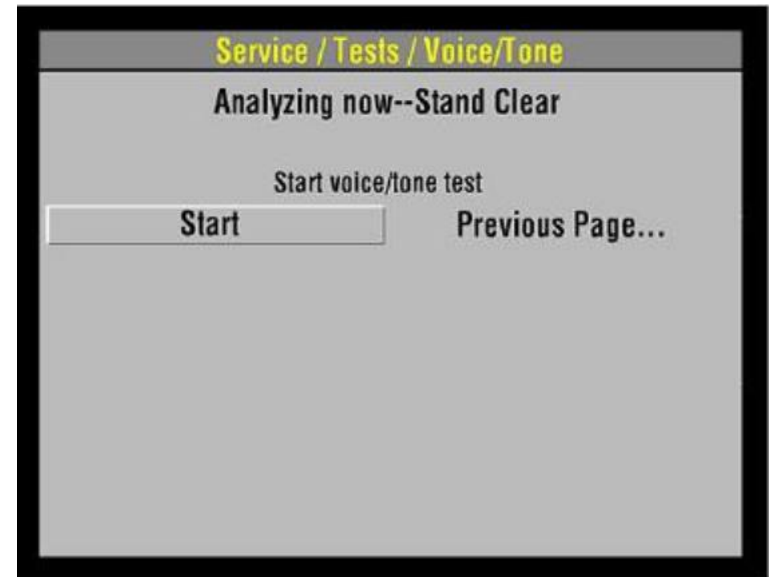


Figure 1.8: Audio Test

Printer Verification @ 25 mm/sec

1. Select **PRINTER** in the **Service/Tests** submenu.
2. Select **START** to print a test strip.
3. Inspect the test strip for the following attributes:
 - a. The large “X” form prints without missing dots.
 - b. Four horizontal lines print (one very close to the lower paper margin).
 - c. The character set prints clearly without broken characters.
 - d. Vertical lines spaced 25 mm \pm 1mm (approx. 24 to 26 mm.) apart print correctly.
4. Open the printer door and verify the **CHECK PRINTER** message appears at the bottom of the screen.
5. Remove the printer paper, and then close the printer door.
6. Verify the **CHECK PRINTER** message appears at the bottom of the screen.
7. Select **PREVIOUS PAGE** twice to return to the Service menu.
8. Continue with the next test.

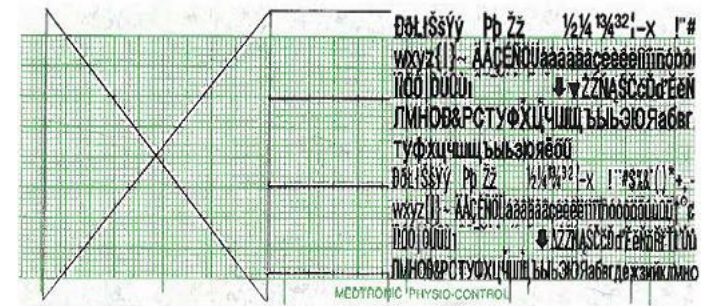


Figure 1.9: Printer Test

[PIP - ECG Performance Testing](#)

ECG Performance Testing consist of:

[PIP - ECG Performance Testing](#)

[PIP - 3-Lead ECG Tests](#)

[PIP - 3-Lead ECG Leads Off Detection Test](#)

[PIP - 3-Lead ECG Gain Test](#)

[PIP- 5-Lead ECG Tests](#)

[PIP - 5-Lead ECG Leads Off Detection Test](#)

[PIP - 5-Lead ECG Gain Test](#)

PIP - 3-Lead ECG Tests

Note: Perform this test if 3-lead ECG cable is used. Otherwise, skip to the next test.
The 3-Lead ECG tests consist of:

[PIP - 3-Lead ECG Leads Off Detection Test](#)

[PIP - 3-Lead ECG Gain Test](#)

PIP - 3-Lead ECG Leads Off Detection Test

1. Connect the 3-Lead ECG cable between the device and Impulse 7000DP as shown in Figure 1.10.
2. Set the Impulse 7000DP output to a 1-mV, 10-Hz sine wave.
3. Set the device **LEAD** selection to **Lead II**.
4. Remove the **LA lead** from the Impulse 7000DP, and verify the device displays the **ECG LEADS OFF** message and a repeating priority 3 tone shall sound when the Lead is removed. Reconnect the LA lead.
5. Remove the **RA lead** from the Impulse 7000DP, and verify the device displays the **RA LEADS OFF** message and a repeating priority 3 tone shall sound when the Lead is removed. Reconnect the RA lead.
6. Remove the **LL lead** from the Impulse 7000DP, and verify the device displays the **LL LEADS OFF** message and a repeating priority 3 tone shall sound when the Lead is removed. Reconnect the LL lead.
7. Continue with the next test with this setup in place.



Figure 1.10: 3 Lead ECG Leads Test Setup

PIP - 3- Lead ECG Gain Test

To perform 3-Lead ECG Gain Test:

1. Set the Impulse 7000DP output to a **1-mv, 10-Hz sine wave**.
2. Set the device **ECG SIZE to 4.0**.
3. Set the device **LEAD** selection to **LEAD I**.
4. Print five seconds of ECG Lead I, and confirm the printed signal amplitude is 25 mm to 31 mm, peak-to-peak as shown in Figure 1.11.
5. Set the device **LEAD** selection to **LEAD II**.
6. Print five seconds of ECG Lead II, and confirm the printed signal amplitude is 36 mm to 44 mm, peak-to-peak as shown in Figure 1.11.
7. Turn the printer **OFF**

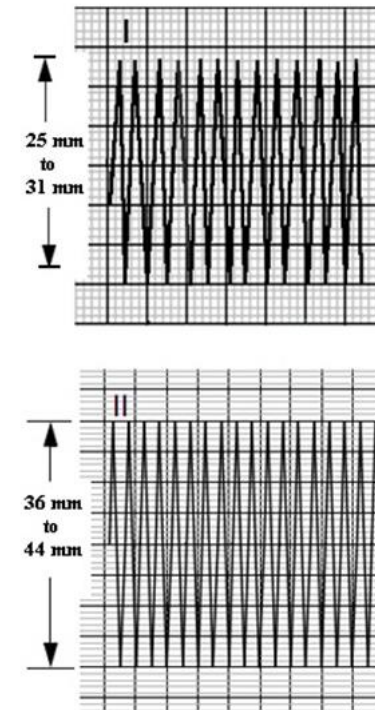


Figure 1.11: ECG Gain at Lead I and Lead II

Performance Inspection Procedure (PIP)

PIP - 5-Lead ECG Tests

Note: Perform this test if 5-lead ECG cable is used. Otherwise, skip to the next test.

The 5-Lead ECG tests consist of:

[PIP - 5-Lead ECG Leads Off Detection Test](#)

[PIP - 5-Lead ECG Gain Test](#)

PIP - 5-Lead ECG Leads Off Detection Test

1. Connect the 5-wire ECG cable between the device and Impulse 7000DP as shown in Figure 1.12.
2. Set the Impulse 7000DP output to a 1-mv, 10-Hz sine wave.
3. Set the device **Lead** selection to **LEAD II**.
4. Remove the RL lead from the Impulse 7000DP, and verify the device displays an **ECG LEADS OFF** message and a repeating priority 3 tones shall sound when the Lead is removed. Reconnect the RL lead.
5. Remove the RA lead from the Impulse 7000DP, and verify the device displays an **RA LEADS OFF** message and a repeating priority 3 tones shall sound when the Lead is removed. Reconnect the RA lead.
6. Remove the LL lead from the Impulse 7000DP, and verify the device displays an **LL LEADS OFF** message and a repeating priority 3 tones shall sound when the Lead is removed. Reconnect the LL lead.
7. Set the device lead selection to **LEAD I**.
8. Remove the LA lead from the Impulse 7000DP.
9. Verify the device displays an **LA LEADS OFF** message and a repeating priority 3 tones shall sound when the Lead is removed. Reconnect the LA lead.
10. Set the device **LEAD** selection to **C LEAD**.
11. Remove the C1/V1 Lead from the Impulse 7000DP.
12. Verify the device displays a **C LEADS OFF** message and a repeating priority 3 tones shall sound when the Lead is removed. Reconnect the C1/V1 lead.
13. Continue to the next test with this setup in place.



Figure 1.12: 5 Lead ECG Leads Test Setup

PIP - 5- Lead ECG Gain Test

To perform 5-Lead ECG Gain Test:

1. Set the Impulse 7000DP output to a **1-mv, 10-Hz sine wave**.
2. Set the device **ECG SIZE to 4.0**.
3. Set the device LEAD selection to **LEAD I**.
4. Print five seconds of ECG Lead I, and confirm the printed signal amplitude is 25 mm to 31 mm, peak-to-peak as shown in Figure 1.13.
5. Set the device LEAD selection to **LEAD II**.
6. Print five seconds of ECG Lead II, and confirm the printed signal amplitude is 36 mm to 44 mm, peak-to-peak as shown in Figure 1.13.
7. Repeat steps 5 and 6 for C Lead.
8. Turn the printer **OFF**.

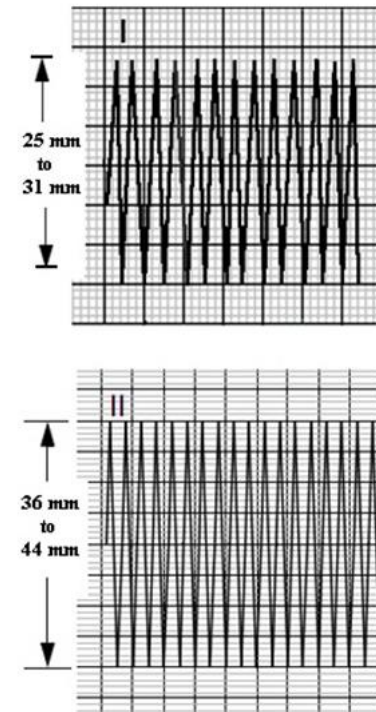


Figure 1.13: ECG Gain at Lead I and Lead II

PIP - Analog ECG Output Test (Optional)

Note: Perform this test if this feature is used by the customer. Otherwise, skip to the next test.

To perform Analog ECG Output Test:

1. Connect the device to the Impulse 7000DP and oscilloscope as shown in Figure 1.14.
2. Turn the device **ON**.
3. Using the ECG cable supplied with the device input a 1-mV, 10-Hz sine wave from the Impulse 7000DP.
4. Set device **LEAD** selection to **LEAD II**.
Note: The Analog ECG output is in real time at a nominal 1 V/mV and is not affected by the device ECG SIZE setting.
5. Verify the amplitude of the signal displayed on the oscilloscope is between 0.90Vp-p and 1.10Vp-p.
6. Disconnect the ECG output cable from the device and oscilloscope.
7. Turn the device **OFF**.

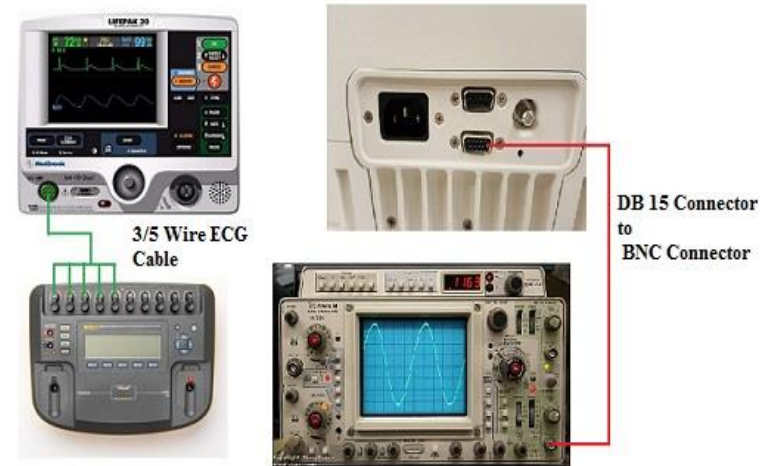


Figure 1.14: Analog ECG Output Test Setup

PIP- Defibrillator/Pacing Testing

The Defibrillator/Pacing Testing consist of:

[PIP - Quik-Combo Defibrillator Sync Tests at 2J](#)

[PIP - QUIK-COMBO Defibrillator Delivered Energy Tests at 2J and 70 J](#)

[PIP - Quik-Combo Defibrillator Delivered Energy and Charge Time Tests at 360 J \(Battery Powered\)](#)

[PIP - Quik-Combo Defibrillator ECG Characteristic Tests](#)

[PIP - QUIK-COMBO Defibrillator ECG Gain Test](#)

[PIP - QUIK-COMBO Defibrillator a Positive R-wave Test](#)

[PIP - Quik - Combo Sync Remote Test](#)

[PIP - Standard Paddles Users Test](#)

[PIP - Standard Paddles Defibrillator Sync Test at 2J](#)

[PIP - Standard Paddles Defibrillator Delivered Energy Tests at 2J and 70J](#)

[PIP - Standard Paddles Defibrillator Delivered Energy and Charge Time Tests at 360 J \(Battery Powered\)](#)

[PIP - Standard Paddles ECG Characteristic Tests](#)

[PIP - Standard Paddles Defibrillator ECG Gain Test](#)

[PIP - Standard Paddles Defibrillator a Positive R-wave Test](#)

[PIP - Standard Paddles Sync Remote Test](#)

[PIP - Pacer Characteristic Tests](#)

[PIP - Pacer Leads-Off Detection Test](#)

[PIP - Pacer Output Current Test](#)

[PIP - Pacer Pulse Width Test](#)

PIP - QUIK-COMBO Defibrillator Sync Test at 2J

To perform QUIK- COMBO Defibrillator Sync Test at 2J:

Note: Perform this test if Quik-Combo cable is used. Otherwise, skip to the next test.

To perform Quik-Combo Defibrillator Sync Test at 2 J:

1. Establish the setup as shown in Figure 1.15.

Note: Ensure proper test setup connections to the Defibrillator Analyzer. To avoid damage to the Analyzer or defibrillator, do NOT apply defibrillator pulses to the pacer inputs of the analyzer.

2. Turn the device **ON**.
3. Set the device: **Manual** mode, **ECG Size** to 1.0, **LEAD** selection to **Lead II**.
4. Set the Defibrillator Analyzer to measure **SYNC**.
5. Press the **SYNC** button **ON** and select **LOCAL**, if Remote Sync is set to on.
6. Verify the Sync LED turns on and R-wave markers appear on the ECG waveform.
7. Press the **ENERGY SELECT** button to select 2J.
8. Press the **CHARGE** button and wait for the device to reach full charge. Then push the **SHOCK** button to discharge the device.
9. Verify the defibrillator analyzer measures a sync R-wave is within 1.0 ms to 60ms.
10. Continue to the next test with this setup in place.

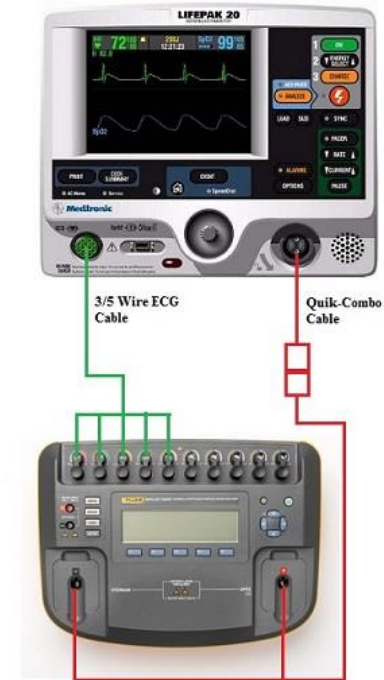


Figure 1.15: Quik-Combo Defibrillator Delivered Energy Setup

PIP - QUIK-COMBO Defibrillator Delivered Energy Tests at 2J and 70 J

To perform QUIK- COMBO Defibrillator Delivered Energy Test at 2J and 70J:

1. Set the Defibrillator Analyzer to measure **ENRG**
2. Press **ENERGY SELECT** on the device and select 2 J.
3. Press the **CHARGE** button and wait for the device to reach full charge. Then push the **SHOCK** button to discharge the device.
4. Verify the defibrillator analyzer indicates the delivered energy is within 1.0 J to 3.0J.
5. Repeat steps 2 and 3 for the energy level at 70J.
6. Verify the defibrillator analyzer indicates the delivered energy is within 59.5 J to 80.5J.

Note: Perform the **TCP- Defibrillator Energy Calibration** if the delivered energy falls outside of the acceptable output range.

PIP - QUIK-COMBO Defibrillator Delivered Energy and Charge Time Tests at 360J (Battery Powered)

Note: Perform this test if Quik-Combo cable is used. Otherwise, skip to the next test.

WARNING

SHOCK HAZARD

Electrical energy is discharged during this procedure. Do not allow the electrodes to contact any person or conductive surface except as described below.

To perform Quik-Combo Defibrillator Delivered Energy and Charge Time Tests at 360 J (Battery Powered)

1. Establish the setup as shown in Figure 1.16.
2. Disconnect the AC power cable from the device and turn the device ON by battery.
3. Press ENERGY SELECT on the device and select 360 J.
4. Start a Stop Watch, then press the CHARGE button and wait for the device to reach full charge. Stop a Stop Watch, and then press the SHOCK button to discharge the device.
5. Verify the defibrillator analyzer indicates the delivered energy is within 306.0J to 414.0 J.
6. Verify the Charge Time is within 1s to 10 s.

Note: Perform the TCP- Defibrillator Energy Calibration if the delivered energy falls outside of the acceptable output range.

7. After testing is complete reconnect the AC power cable to the device.

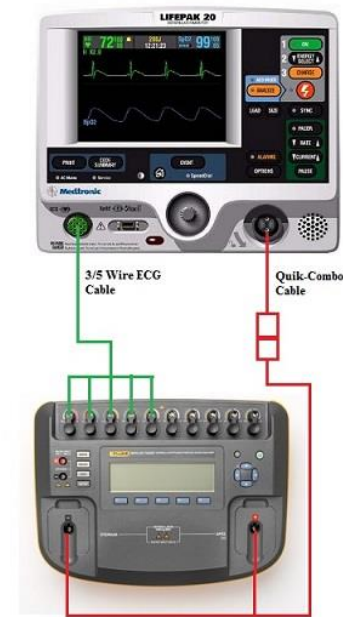


Figure 1.16: Quik-Combo Defibrillator Energy and Charge Time Test Setup

PIP - Quik-Combo Defibrillator ECG Characteristic Tests

Note: Perform this test if Quik-Combo cable is used. Otherwise, skip to the next test.

The ECG characteristic tests consist of ECG gain and a positive R-wave test. These two tests are included here as a single procedure and step numbers are continuous from one step to the next.

[PIP - QUIK-COMBO Defibrillator ECG Gain Test](#)

[PIP - QUIK-COMBO Defibrillator a Positive R-wave Test](#)

PIP - Quik-Combo Defibrillator ECG Gain Test

To perform ECG Gain Test:

1. Set the Impulse 7000DP output to **ECG**, Performance, **1-mv, 10-Hz sine wave**.
2. Set the device **ECG SIZE** to **4.0**.
3. Set the **LEAD** selection to **PADDLES**.
4. Print 10 seconds of paddles ECG and confirm the printed signal amplitude is 36 mm to 44 mm, peak-to-peak as shown in Figure 1.17.

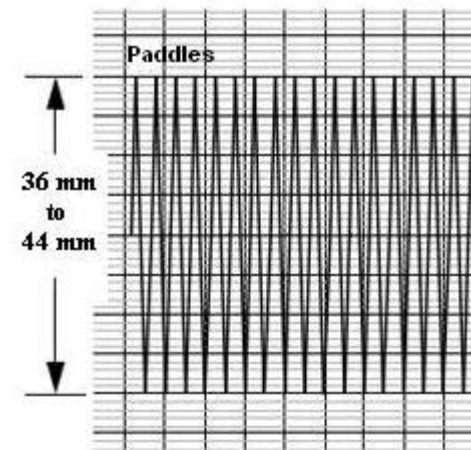


Figure 1.17: ECG Gain at Paddles Lead

PIP - Quik-Combo Defibrillator a Positive R-Wave Test

To perform A positive R-wave test:

1. Set the Impulse 7000DP to a **1mV, Normal Sinus, 60 BPM.**
2. Set the device **ECG SIZE** to **1.0.**
3. Set the **LEAD** selection to **PADDLES.**
4. Print 10 seconds of paddles ECG recorded on printer paper.
5. Turn the printer **OFF.**
6. Confirm the R-Wave polarity on the paper matches image as shown in Figure 1.18.

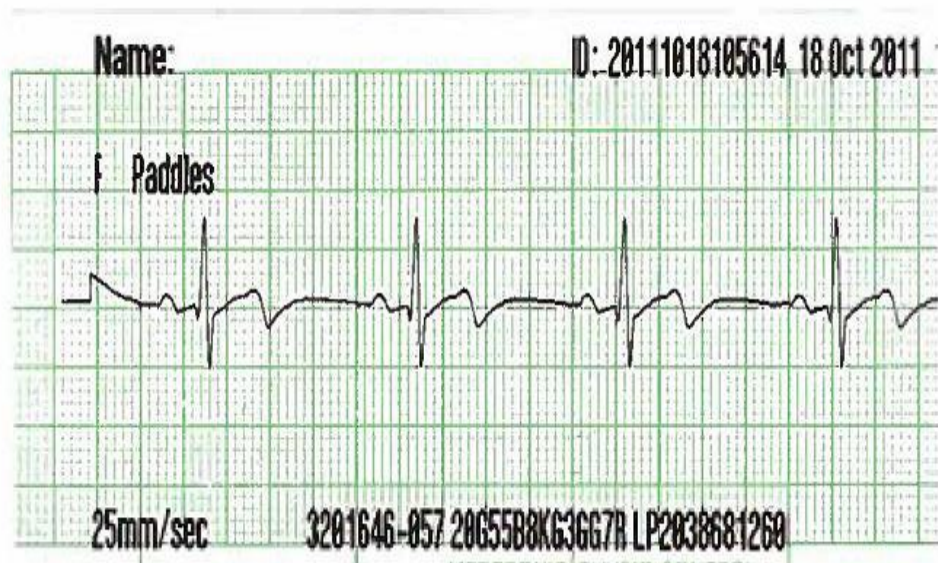


Figure 1.18: A Positive R-Wave

PIP - Quik-Combo Sync Remote Test

Note: Perform this test if Quik-Combo cable is used. Otherwise, skip to the next test.

To perform Quik-Combo Sync Remote Test:

1. Establish the setup as shown in Figure 1.19.
2. Turn on the Remote Sync Test Pulse Generator.

Note: A function generator set to provide a pulse train 5 Vp-p (0-5 V), 5 to 200 ms wide, 120 PPM (2 Hz) can be used alternatively to the Remote Sync Test Pulse Generator.

3. On the Manual Mode setup page; set the device to Remote Sync ON.
4. Turn the device **OFF** and then turn the device **ON**.
5. Set the device: **Manual mode**, lead selection to **PADDLES**.
6. Press the **SYNC** button on the device.
7. On the Sync mode screen, select **REMOTE**.
8. Verify the **SYNC LED** is flashing.
9. Charge the device to 200 J.
10. Upon reaching full charge, press the **SHOCK** button to discharge the device.
11. Verify the device displays "**ENERGY DELIVERED**" screen message (for SW-20 version or below) or switches out of remote sync mode (for SW-26 or above).
12. On the Manual Mode setup page, set the device to Remote Sync **OFF**.
13. Turn the device **OFF**.



Figure 1.19: Quik-Combo Sync Remote Test Setup

PIP - Standard Paddles User Test

Perform this test if STANDARD paddles are used. Otherwise, skip to the next test.

Note: Use the customer's standard paddles (when available). Remove the paddles and check that the paddle surfaces and paddle wells are clean and dry and free of any debris. Verify that the metal surface of the standard paddles and paddle test contacts in the device paddle wells are free of burn and arc marks. Also check that these surfaces are free of pits, scratches or raised nicks that can be felt with the finger tip. Check the therapy connector interface for pin damage.

WARNING

SHOCK HAZARD

The conductive gel (wet or dry) on the paddle handles and in the paddle wells may allow the electrical energy to arc between paddles during discharge. Thoroughly clean and dry the paddles and the paddle wells after use and before performing the Standard Paddles User Test.

1. Connect the standard paddles to the device. Place the paddles in the paddle wells as shown in Figure 1.20.
2. Turn the device **ON**.
3. Set the device Lead selection to **PADDLES**.
4. Press the **OPTIONS** button and select **USER TEST** from the Option screen.
5. Select **YES** from the Option/User Test screen.
6. Push Speed Dial to initialize the Self-Test and the User Test. The Self-Test and the User Test are performed. The User Test Succeeded report is printed when test is complete. **Note:** The Device will automatically turn off after successfully completing the test.
7. Proceed to next test.



Figure 1.20: Standard Paddles User Test Setup

[PIP- Standard Paddles Defibrillator Sync Test at 2J](#)

Perform this test only if the device is equipped with the standard paddles option.

WARNING

SHOCK HAZARD

Electrical energy is discharged during this procedure. Do not allow the electrodes to contact any person or conductive surface except as described below.

Note: Ensure that the Standard Paddles is connected between the device and the Impulse 7000 DP, using the appropriate adapters.

Note: Verify that the metal surface of the paddles are free of burn or arc marks and are free of pits, scratches, insulting films, contaminants or raised nicks that can be felt with the finger tip.

Note: To avoid damage to the Defibrillator Analyzer, do not apply any defibrillator pulses to the pacer inputs of the analyzer.

To perform Standard Paddles Sync Test at 2J

1. Establish the setup as shown in Figure 1.21.
2. Turn the device **ON**.
3. Set the device: **MANUAL MODE**, **ECG Size to 1.0**, **LEAD** selection to **LEAD II**.
4. Set the Defibrillator Analyzer to measure **SYNC**.
5. Press the **SYNC** button **ON** and select **LOCAL**, if Remote Sync is set to on.
6. Verify the Sync LED turns on and R-wave markers appear on the ECG waveform.
7. Press the **ENERGY SELECT** button to select 2J.
8. Press the **CHARGE** button on Standard Paddles and wait for the device to reach full charge. Then push both **SHOCK** buttons on Standard Paddles to discharge the device.
9. Verify the defibrillator analyzer measures a sync R-wave is within 1.0 ms to 60ms.
10. Continue to the next test with this setup in place.

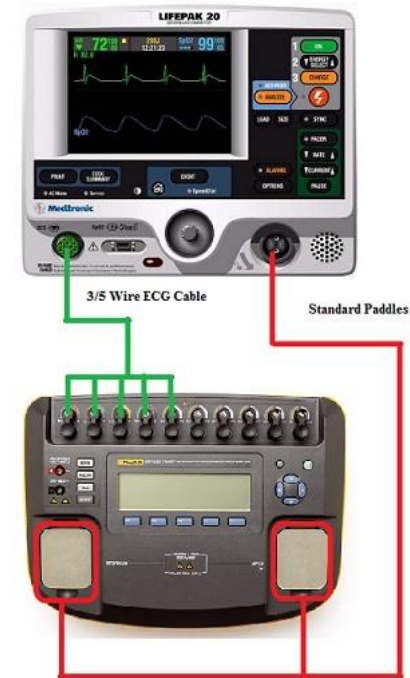


Figure 1.21: Standard Paddles Defibrillator Energy Test Setup

PIP - Standard Paddles Defibrillator Delivered Energy Tests at 2 J and 70 J

To perform Standard Paddles Defibrillator Delivered Energy Test at 2J and 70J:

1. Set the Defibrillator Analyzer to measure ENRG
2. Press **ENERGY SELECT** on the device and select 2 J.
3. Press the **CHARGE** button on Standard Paddles and wait for the device to reach full charge. Then push both **SHOCK** buttons on Standard Paddles to discharge the device.
4. Verify the defibrillator analyzer indicates the delivered energy is within 1.0 J to 3.0J.
5. Repeat steps 2 and 3 for the energy level at 70J.
6. Verify the defibrillator analyzer indicates the delivered energy is within 59.5 J to 80.5J.

Note: Perform the **TCP- Defibrillator Energy Calibration** if the delivered energy falls outside of the acceptable output range.

PIP - Standard Paddles Defibrillator Delivered Energy and Charge Time Tests at 360J (Battery Powered)

WARNING

SHOCK HAZARD

Electrical energy is discharged during this procedure. Do not allow the electrodes to contact any person or conductive surface except as described below.

To perform Standard Paddles Defibrillator Delivered Energy and Charge Time Tests at 360J (Battery Powered)

1. Establish the setup as shown in Figure 1.22.
2. Disconnect the AC power cable from the device and turn the device **ON** by battery.
3. Press the **ENERGY SELECT** button to select 360 J.
4. Start a Stop Watch, then press the **CHARGE** button on Standard Paddles and wait for the device to reach full charge. Stop a Stop Watch, and then push both **SHOCK** buttons on Standard Paddles to discharge the device.
5. Verify the defibrillator analyzer indicates the delivered energy is within 306.0 J to 414.0 J.
6. Verify the Charge Time is within 1s to 10 s.

Note: Perform the TCP- Defibrillator Energy Calibration if the delivered energy falls outside of the acceptable output range.

7. After testing is complete reconnect the AC power cable to the device.



Figure 1.22: Standard Paddles Defibrillator Energy and Charge Time Test Setup

PIP - Standard Paddles Defibrillator ECG Characteristic Tests

Note: Perform this test if Standard Paddles cable is used. Otherwise, skip to the next test.

The ECG characteristic tests consist of ECG gain and a positive R-wave test. These two tests are included here as a single procedure and step numbers are continuous from one step to the next.

[PIP - Standard Paddles Defibrillator ECG Gain Test](#)

[PIP - Standard Paddles Defibrillator a Positive R-wave Test](#)

PIP - Standard Paddles Defibrillator ECG Gain Test

To perform ECG Gain Test:

1. Set the Impulse 7000DP output to ECG, Performance, 1-mv, 10-Hz sine wave.
2. Set the device ECG SIZE to 4.0.
3. Set the **LEAD** selection to **PADDLES**.
4. Print 10 seconds of paddles ECG and confirm the printed signal amplitude is 36 mm to 44 mm, peak-to-peak as shown in Figure 1.23.

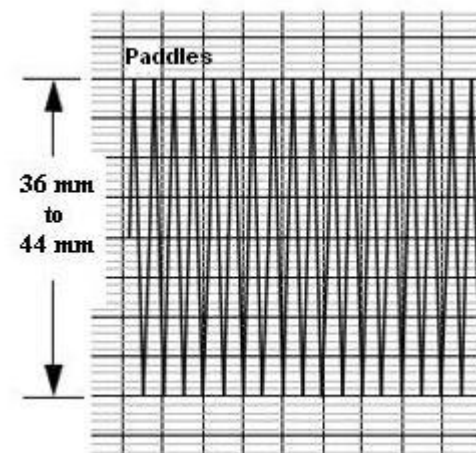


Figure 1.23:
ECG Gain of STD Paddles

PIP - Standard Paddles Defibrillator a Positive R-Wave Test

To perform A positive R-wave test:

1. Set the Impulse 7000DP to a 1mV, Normal Sinus, 60 BPM.
2. Set the device ECG SIZE to 1.0.
3. Set the **LEAD** selection to **PADDLES**.
4. Print 10 seconds of paddles ECG recorded on printer paper.
5. Turn the printer OFF.
6. Confirm the R-Wave polarity on the paper matches image as shown in Figure 1.24.

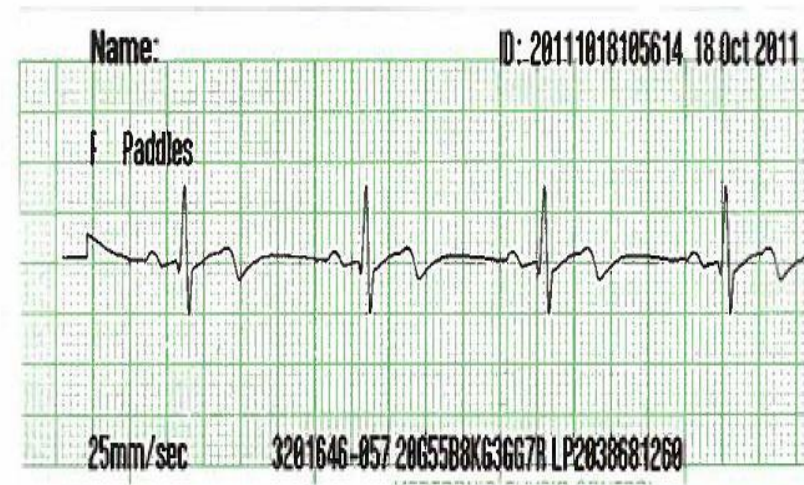


Figure 1.24: A Positive R-Wave

PIP - Standard Paddles Sync Remote Test

Note: Perform this test if Standard Paddles is used. Otherwise, skip to the next test.
To perform Standard Paddles Sync Remote Test:

1. Establish the setup as shown in Figure 1.25.
2. Turn on the Remote Sync Test Pulse Generator.

Note: A function generator set to provide a pulse train 5 Vp-p (0-5 V), 5 to 200 ms wide, 120 PPM (2 Hz) can be used alternatively to the Remote Sync Test Pulse Generator.

3. On the Manual Mode setup page; set the device to Remote Sync **ON**.
4. Turn the device **OFF** and then turn the device **ON**.
5. Set the device: **Manual mode**, lead selection to **PADDLES**.
6. Press the **SYNC** button on the device.
7. On the Sync mode screen, select **REMOTE**.
8. Verify the SYNC LED is flashing.
9. Charge the device to 200 J.
10. Upon reaching full charge, press the **SHOCK** button to discharge the device.
11. Verify the device displays "**ENERGY DELIVERED**" screen message (for SW-20 version or below) or switches out of remote sync mode (for SW-26 or above).
12. On the Manual Mode setup page, set the device to Remote Sync **OFF**.
13. Turn the device **OFF**

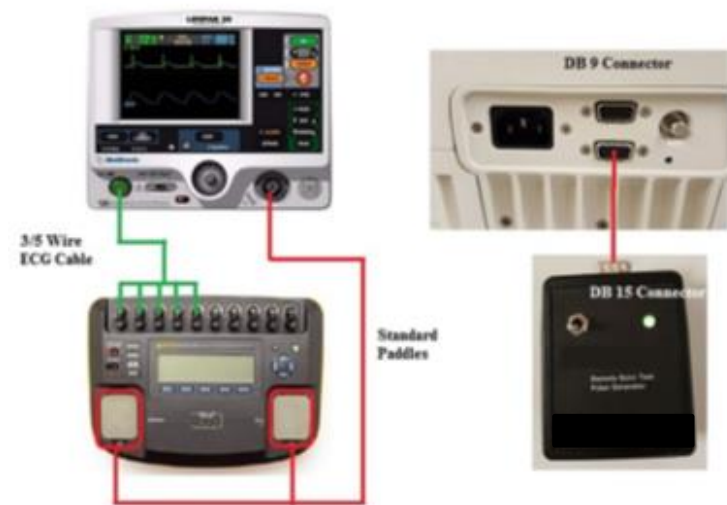


Figure 1.25: Standard Paddles Sync Remote Test Setup

[PIP – Pacer Characteristic Tests](#)

The pacer characteristics consist of:

[PIP – Pacer Leads-Off Detection Test](#)

[PIP – Pacer Output Current Test](#)

[PIP – Pacer Pulse Width Test](#)

PIP – Pacer Leads-Off Detection Test

To perform Pacer Leads-Off detection:

1. Establish the setup as shown in Figure 1.26.
Note: Can use any type of ECG Lead cable in the setup.
2. Turn the device **ON**.
3. Set the Impulse 7000DP to measure Pacer
4. Press **PACER** button, press F1/Brand to Physio Control, press F2/Input to Defib, and press F3/Load to 50 ohms.
5. Press **PACER** on the device.
6. Verify the PACER LED is on and the Pacer overlay appears.
7. Disconnect one of the test post adapter snaps from the Impulse 7000DP.
8. Verify the Pacing/Connect Electrodes overlay appears, accompanied by an audible alarm.
9. Reconnect the test post adapter snap.
10. Verify the Pacing/Connect Electrodes overlay disappears and the alarm stops.

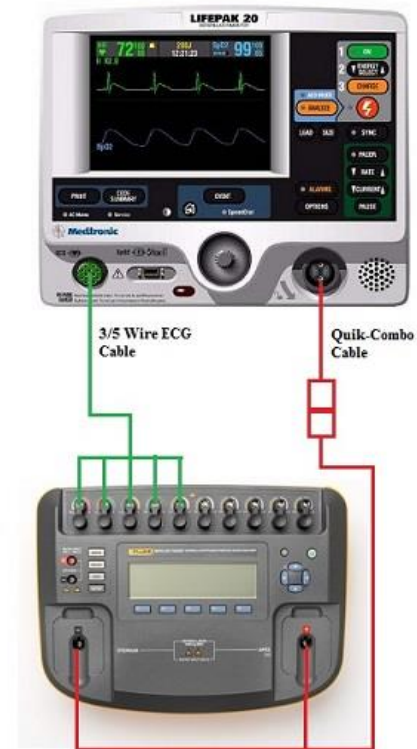


Figure 1.26: Pacer Test Setup

PIP - Pacer Output Current Test

To perform the pacer output current:

Note: Perform the pacer output current test at 10 mA, 100 mA and 200 mA. You must repeat the test for each current level.

1. Select Pacer button on Impulse 7000DP to measure pacing current.
2. In the menu screen, set the Brand to "Physio-Control" Input Jacks to "Defib," and Load to 50 ohms.
3. Set Pacer Rate at 60PPM.
4. Press CURRENT on the device, and select a pacer current (10 mA, then 100 mA, and then 200 mA).
5. Verify the defibrillator analyzer indicates the pacer output current is within the acceptable output limits shown in Table below (results may appear as negative numbers).

Note: If the Impulse 7000DP does not detect a pacing output current reading, then operate the Impulse 7000DP and device on battery power for the Pacer output current test.

Note: Perform TCP – Pacer Self-Calibration if the peak pacer current falls outside the acceptable output range.

| Peak Current Level (mA) | Acceptable Output (mA) |
|--------------------------------|-------------------------------|
| 10 | 0 to 20 |
| 100 | 90 to 110 |
| 200 | 180 to 220 |

PIP - Pacer Pulse Width Test

To perform the pacer pulse width test:

1. Set pacer rate on the device at 60 PPM.
2. Press **CURRENT** on the device, and select a pacer current of 200 mA.
3. Verify the measured pacer pulse width is between 19.0 and 21.0 ms.

Note: Perform TCP - Pacer Self-Calibration if the peak pacer current falls outside the acceptable output range.

PIP - Patient Impedance Test

To perform patient impedance sense circuitry:

WARNING

POSSIBLE EQUIPMENT DAMAGE

Do not defibrillate into the decade resistance box!

1. Establish the setup as shown in Figure 1.27.
2. Set the decade resistance box to **50 ohms**.
3. Turn the device ON, and set the lead selection to **PADDLES**.
4. Verify the **PADDLES LEADS OFF** message are **not visible**.
5. Set the decade resistance box to **248 ohms**.
6. Verify the device displays the **PADDLES LEADS OFF** message.
7. Set the decade resistance box to **182 ohms**.
8. Verify the **PADDLES LEADS OFF** message are **not visible**.
9. Remove the decade resistance box.
10. Turn the device OFF.



Figure 1.27: Patient Impedance Test Setup

[Electrical Safety](#)

[PIP-Safety Analyzer Setup for IEC62353 Testing](#)

WARNING

POSSIBLE EQUIPMENT DAMAGE

Do not defibrillate when connected to the safety analyzer!

To perform the Direct Equipment Leakage, Direct Applied Part Leakage and Protective Earth Resistance tests in accordance with IEC 62353, set up the Safety Analyzer as follows:

Press the SETUP button on the Safety Analyzer.

1. Press the SETUP button on the Safety Analyzer.
2. Press the F4/MORE button.
3. Press the F2/INSTRUMENT button.
4. Press the F1/STANDARD button.
5. Press the UP/DOWN arrows to select the 62353 Standard.
6. Press the DONE button.

PIP- Protective Earth Resistance Test

To perform the Protective Earth Resistance Test in accordance with IEC 62353:

1. Ensure the Safety Analyzer set to the IEC 62353 standard.

Note: Consult your safety analyzer user manual to perform a “Lead Zeroing” operation to eliminate test lead resistance from your measurements.

2. Set the Safety Analyzer controls to measure Ohms by selecting the Ohm button on the Safety Analyzer.
3. Establish the setup as shown in Figure 1.30a.

Note: Ensure all connectors and connection points are clean and are firmly attached. If not, you will see higher readings from the safety analyzer.

4. Measure the resistance of AC power cord **ground conductor** per figure 1.30a. Record the resistance value on the PIP checklist. The measured value must be below 0.1 ohms.

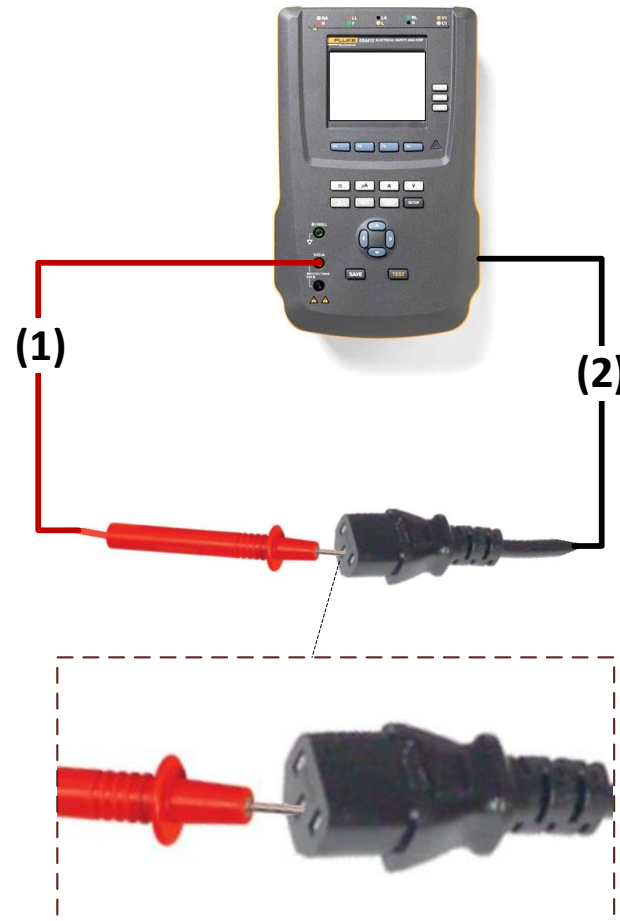


Figure 1.30a

5. Establish the setup as shown in Figure 1.30b.

Note: Ensure all connectors and connection points are clean and are firmly attached. If not, you will see higher readings from the safety analyzer.

6. Ensure the device is off.
7. Measure the resistance of device with the AC power cord per figure 1.30b. Record the resistance value on the PIP checklist.
8. Calculate the resistance of device only by subtracting the value obtained in Step 4 from the value obtained in Step 7. The calculated value must be less than 0.2 ohms. Record the calculated value on PIP checklist.

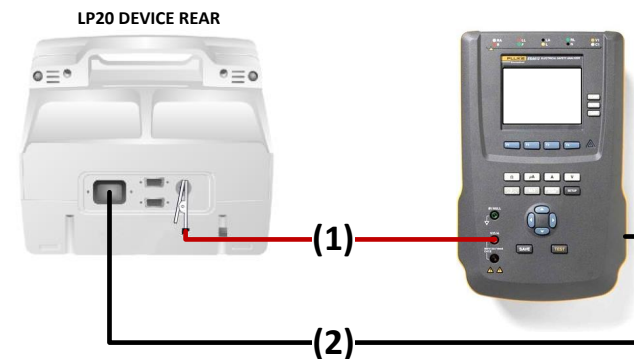


Figure 1.30b

PIP - Leakage Current Tests

Perform leakage current testing in accordance to the following electrical safety standards:

IEC (International Electro technical Commission) 62353.

WARNING

SHOCK HAZARD

Failure to properly perform these tests could result in a failure to detect excessive leakage current. Make sure you are familiar with your test equipment and these test performance procedures.

Leakage – Current flow induced by the application of high voltage to a material or object with high dielectric strength.

Normal Condition (N.C.) – AC voltage is applied in either normal or reversed polarity (that is, measurements made with the POLARITY switch in both NORMAL [NC] and REVERSED [RM] positions). The earth ground is intact during these measurements.

Single Fault Condition (S.F.C.) – AC voltage is applied in either normal or reversed polarity (that is, measurements made with the POLARITY switch in both NORMAL [NC] and REVERSED [RM] positions). The earth ground is NOT intact during these measurements.

Safety Analyzer setup instructions are specific to the Fluke Biomedical ESA612.

PIP - Leakage Current Test Setup

Establish the Leakage Current Test setup as shown in Figure 1.28:

WARNING

POSSIBLE EQUIPMENT DAMAGE

Do not defibrillate when connected to the safety analyzer!

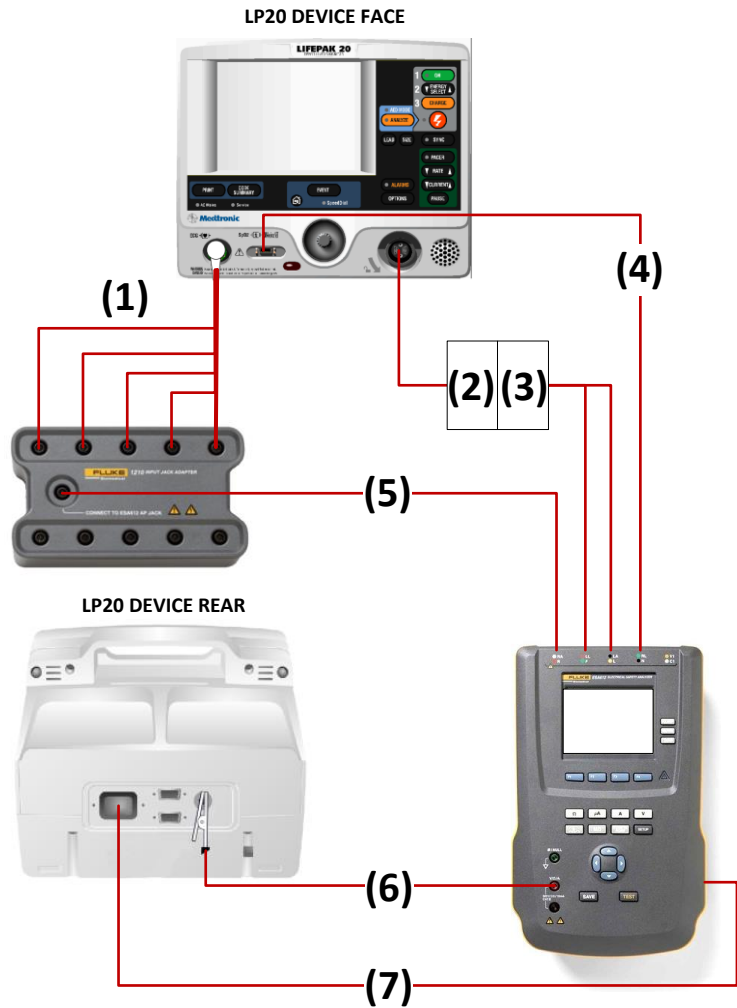
1. Connect the Banana cable (Item 6) between the Safety Analyzer ESA612 (at V/ohms/A) and the Ground stud.
2. Connect the customer ECG Lead cable (Item 1) between the LIFEPAK 20 and the 1210 box. Connect Item 5 between the 1210 box and the Safety Analyzer ESA612 at RA snap.

Note: The customer ECG cable is 5-Wire or 3-Lead.

3. Connect the Therapy cable (Quik Combo (Items 2 and 3) or Standard Paddles (Item 8) between the LIFEPAK 20 and the Safety Analyzer ESA612 at LL and LA snaps.
4. Connect the SPO2 cable (Item 4) between the LIFEPAK 20 and the Safety Analyzer ESA612 at RL snap.
5. Connect the AC power cable (Item 7) between the device and the Safety Analyzer ESA612 at AC output.

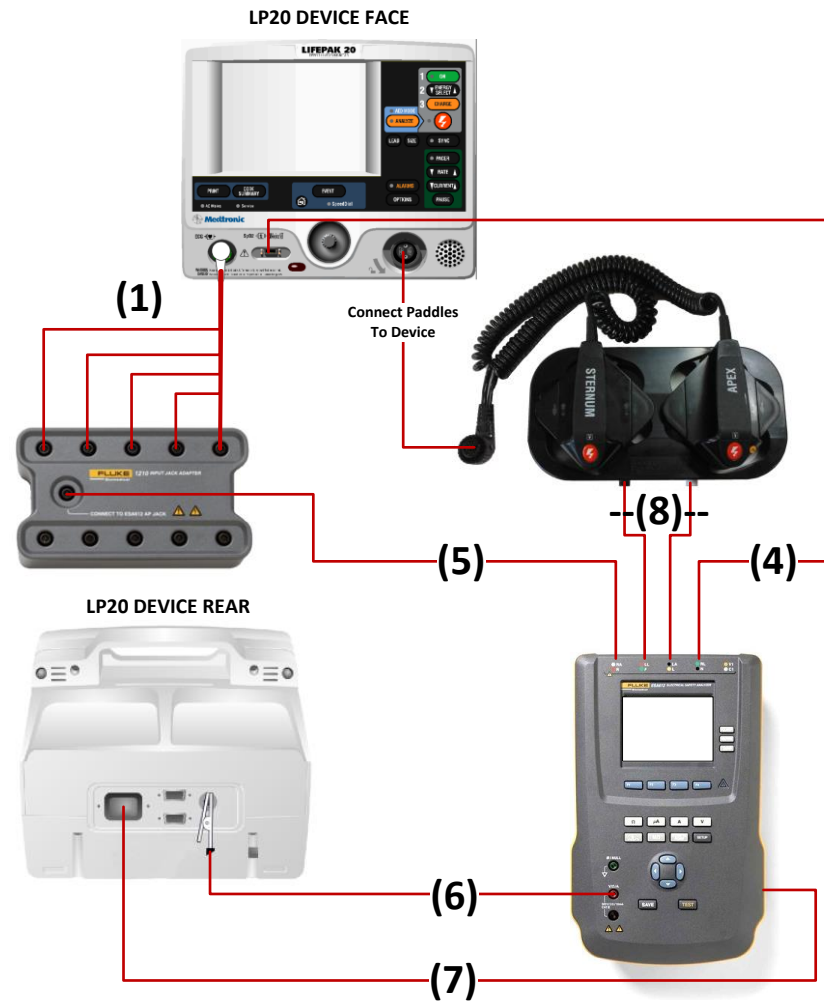
LP20 LEAKAGE CURRENT TEST SETUP

Quik-Combo Cable



LP20 LEAKAGE CURRENT TEST SETUP

Std Paddles



OR

Figure 1.28: LP20 Leakage Current Test Setup

PIP-Direct Equipment Leakage Test - Single Fault Condition (SFC)**WARNING****POSSIBLE EQUIPMENT DAMAGE**

Do not defibrillate when connected to the safety analyzer!

1. Turn the device ON.
2. Press the μA button on the Safety Analyzer.
3. Press the F1/DIRECT EQUIPMENT button on the Safety Analyzer and set the Safety Analyzer controls as follows:

| Earth | Polarity | Current Mode |
|--------------|-----------------|---------------------|
| Open | Normal/Reverse | AC only |

Note: Pause briefly between switching polarity to prevent damage to the defibrillator.

4. Verify the device AC Mains LED is ON.
5. Verify the measured current is between 15 μA and 270 μA (120 VAC) or between 15 μA and 450 μA (240 VAC).

[PIP-Safety Analyzer Setup on Direct Applied Part Leakage Tests](#)

WARNING

SHOCK HAZARD

During Direct Applied Part Leakage tests, high voltage is present on the Safety Analyzer electrode snaps. Do not touch snaps or device connections during these tests.

WARNING

POSSIBLE EQUIPMENT DAMAGE

Do not defibrillate when connected to the safety analyzer!

To set up the Safety Analyzer to measure Direct Applied Part Leakage:

1. Press the μ A button on the Safety Analyzer.
2. Press the F4/MORE button.
3. Press the UP/DOWN arrows to select the appropriate A.P groups as shown in Figure 1.29.
4. Press F1/SELECT then F1/Direct A.P.

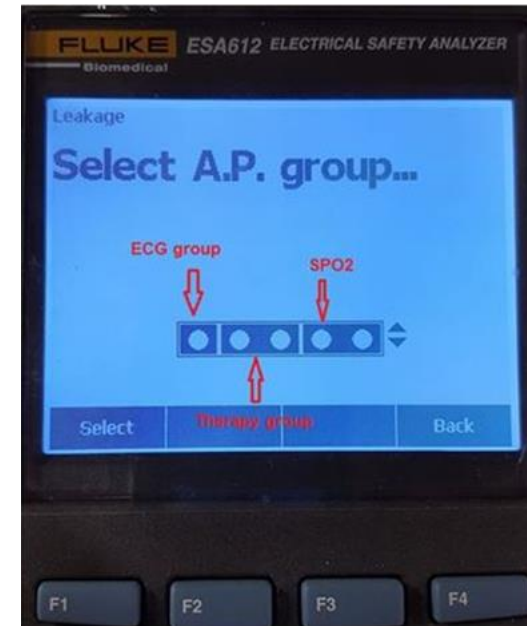


Figure 1.29: Direct Applied Part Leakage Setup

PIP-Direct Applied Part Leakage Test-ECG**WARNING****POSSIBLE EQUIPMENT DAMAGE**

Do not defibrillate when connected to the safety analyzer!

1. Turn the device ON.
2. Press the LEFT/RIGHT arrows to select the RA lead, and set the Safety Analyzer controls as follows:

| Polarity | Current Mode | Lead |
|-----------------|---------------------|--|
| Normal/Reverse | AC only | RA (ECG group from Fluke 1210 adapter) |

3. Press the TEST button to measure the Direct Applied Part Leakage current.
4. Verify the device AC Mains LED is ON.
5. Verify the measured current is between 2 μ A and 45 μ A (120 and 240 VAC).

PIP-Direct Applied Part Leakage Test-Therapy**WARNING****POSSIBLE EQUIPMENT DAMAGE**

Do not defibrillate when connected to the safety analyzer!

1. Turn the device ON.
2. Press the LEFT/RIGHT arrows to select the LL and LA leads, and set the Safety Analyzer controls as follows:

Note: The A.P. group should be set up to measure the combined leakage of the LL and LA leads.

| Polarity | Current Mode | Lead |
|-----------------|---------------------|--------------------------|
| Normal/Reverse | AC only | LL-LA (Therapy group) |

3. Press the TEST button to measure the Direct Applied Part Leakage current.
4. Verify the device AC Mains LED is ON.
5. Verify the measured current is between 2 μA and 2625 μA (120 VAC and 240 VAC).

PIP-Direct Applied Part Leakage Test-SPO2

Note: Execute this test if the LIFEPAK 20 is equipped with SpO2

WARNING

POSSIBLE EQUIPMENT DAMAGE

Do not defibrillate when connected to the safety analyzer!

1. Turn the device ON.
2. Press the LEFT/RIGHT arrows to select the RL lead, and set the Safety Analyzer controls as follows:

| Polarity | Current Mode | Lead |
|-----------------|---------------------|--------------------|
| Normal/Reverse | AC only | RL (SpO2 group) |

3. Press the TEST button to measure the Direct Applied Part Leakage current.
4. Verify the device AC Mains LED is ON.
5. Verify the measured current is less than 2625 μ A (120 VAC and 240 VAC).

[PIP-Safety Analyzer Setup - Earth Leakage Test](#)**WARNING****POSSIBLE EQUIPMENT DAMAGE**

Do not defibrillate when connected to the safety analyzer!

To perform the Earth Leakage test in accordance with IEC 60601, set up the Safety Analyzer as follows:

1. Press the SETUP button on the Safety Analyzer.
2. Press the F4/MORE button.
3. Press the F2/INSTRUMENT button.
4. Press the F1/STANDARD button.
5. Press the UP/DOWN arrows to select the 60601 Standard.
6. Press the DONE button.

PIP-Earth Leakage Test - Normal Condition (NC)**WARNING****POSSIBLE EQUIPMENT DAMAGE**

Do not defibrillate when connected to the safety analyzer!

1. Turn the device ON.
2. Press the μA button on the Safety Analyzer.
3. Press the F1/EARTH button on the Safety Analyzer and set the Safety Analyzer controls as follows:

| Neutral | Polarity | Current Mode |
|----------------|-----------------|---------------------|
| Closed | Normal/Reverse | AC+DC |

Note: Pause briefly between switching polarity to prevent damage to the defibrillator.

4. Verify the device AC Mains LED is ON.
5. Verify the measured current is between $15\ \mu\text{A}$ and $2250\ \mu\text{A}$ (120 VAC and 240 VAC).

PIP-Earth Leakage Test - Single Fault Condition (SFC)

1. Turn the device ON.
2. Press the μA button on the Safety Analyzer.
3. Press the F1/EARTH button on the Safety Analyzer and set the Safety Analyzer controls as follows:

| Neutral | Polarity | Current Mode |
|----------------|-----------------|---------------------|
| Open | Normal/Reverse | AC +DC |

Note: Pause briefly between switching polarity to prevent damage to the defibrillator.

4. Verify the device AC Mains LED is ON.
5. Verify the measured current is between $15\ \mu\text{A}$ and $2625\ \mu\text{A}$ (120 VAC and 240 VAC).

[PIP-Restore Customer Settings](#)

Restore customer settings...

1. Enter **SETUP** menu.
2. Choose **MANUAL MODE**.
3. Choose **MANUAL ACCESS**.
4. Choose **CUSTOMER'S NORMAL SETTINGS**.



LIFEPAK[®] 20 MONITOR/DEFIBRILLATOR

Performance Inspection Procedure (PIP)

For further information, please call Stryker at 1.800.442.1142 or visit www.strykeremergencycare.com

Stryker
11811 Willows Road NE
Redmond, WA 98073-9708 USA
Tel: 425.867.4000
Fax: 425.458.1404
www.strykeremergencycare.com

Stryker Australia Pty Ltd
8 Herbert Street
St Leonards
NSW 2065
Australia



Physio-Control, Inc., 11811 Willows Road NE, Redmond, WA 98052 USA



Stryker European Operations B.V., Herikerbergweg 110, 1101 CM Amsterdam, The Netherlands

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