LIFEPAK®15 MONITOR/DEFIBRILLATOR

PHYSIO CONTROL

Performance Inspection Procedure (PIP)



stryker

LIFEPAK®15
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® 15 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

This PIP applies to the LIFEPAK 15 Defibrillator exclusively. To complete the PIP, you must perform the tests 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 and 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 and PIP workstation power requirements.

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.

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/ Catalog number (REF)
Defibrillator analyzer with external noninvasive pacer measurements**	Energy range: 0 to 450 J Load resistance: 50 ±1% Accuracy: +/- 2%, non-inductive 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	Fluke® Biomedical Impulse 7000DP with QUIK-COMBO adapter accessory 16/7 D/P ADPT104*
Patient simulator (for Blood Pressure measurement)	Blood pressure accuracy: ± 1% full scale, ± 1 mmHg	Fluke Biomedical DNI 215A/217A or Fogg BP-28*
Safety Analyzer	90 V ac rms to 264 V ac rms mains voltage Current range: 0-1999 A Current accuracy: 5% of reading or 1 digit (whichever is greater)	Fluke Biomedical ESA612*
ESA612 adapter box	Provides addition ECG snap connections	Fluke Biomedical model 1210
Decade resistance box	0 to 9 MΩ resistance box Resolution: 1; accuracy: ± 1%	IET RS-200 Resistance Substitute*
Digital pressure meter	1% accuracy for pressure and vacuum	Fluke Biomedical DPM2Plus*
QUIK-COMBO therapy cable		11113-000004

Equipment	Specification or Description	Manufacturer or Part number/ Catalog number (REF)
FAST-PATCH cable assembly	Connects QUIK-COMBO to test posts	11110-000052or Physio-Control P/N 3323095
Electrode test posts (2 ea.)		21330-001372
Stop watch	Elapsed timer (minutes, seconds) Time accuracy: ± 0.5 Sec	ACCUSPLIT AX725*
3-lead ECG cable	Standard accessory with the 3-lead LP15 monitor/ defibrillator	11110-000029 11110-000030
5-wire ECG cable	Optional 5-wire cable for LP15 monitor/defibrillator	11110-000066 11110-000067
12-lead ECG cable	Standard accessory with the 12-lead LP15 monitor/ defibrillator	11110-000102, 11110-000103 11110-000104, 11110-000105
4-wire limb lead cable, 12-lead ECG	Standard accessory with the 12-lead LP15 monitor/ defibrillator	111111-000018 or 11111-000020
6-wire precordial cable, 12-lead ECG	Standard accessory with the 12-lead LP15 monitor/ defibrillator	11111-000022
General purpose oscilloscope	(Optional) Bandwidth: DC to 2 MHz Vertical accuracy: ± 3% (5 mv – 5 v/div.) Horizontal time base accuracy: ± 5%	Fluke 190*
SpO2/SpCO/SpMet sensor	Masimo Rainbow adult reusable sensor	11171-000007
Lithium-ion battery pak	Li-ion battery with fuel gauge, battery age is less than 2 years old.	21330-001176
NIBP calibration kit with syringe		40998-000153

Equipment	Specification or Description	Manufacturer or Part number/ Catalog number (REF)
NIBP hose	12ft straight hose	21300-007298, 21300-008146
Invasive pressure cable		3010-0116 (use with 217A) or Fogg 0365-2178 (use with BP-28)*
Tubing assembly - CO2 leak test		21330-000238
Tubing assembly - CO2 calibration		21330-000239
Calibration gas	5% CO2, balance N2	21300-001572
Filter Line H set, adult/pediatric		11996-000068
Analog ECG output cable	Connects to the System Connector	11110-000044
QUIK-COMBO to ECG snap terminator cable		Physio-Control P/N 3009139
ECG Snap to Banana Plug cable	For use in testing electrical safety	Physio-Control P/N 3305684
SpO2 Connector to ECG snap cable	For use in testing SpO2 electrical safety	Physio-Control P/N 3305685
Standard paddle	Optional therapy delivery accessory	11130-000061
Standard paddle leakage adapter	Optional - for use in testing Standard Paddle electrical safety	Physio-Control P/N 3206631
Standard paddle QC leakage cable	Optional - for use in testing Standard Paddle electrical safety	Physio-Control P/N 3207066
Laptop computer	Bluetooth wireless technology option installed	Dell 630*
CODE-STAT Reviewer software		Physio-Control P/N 3011520 Version 8.0 (minimum version required)
Battery leakage test adapter	Quantity 2, connection to exposed metal in battery well	Physio-Control P/N 3305682
Temperature probe simulator	Accuracy ± 0.05 degrees C for all settings	Fogg TP 400
Cable Assembly, Temperature Adapter		11140-000078
Fogg TP400 Interface cable		Physio-Control P/N 3308413

Equipment	Specification or Description	Manufacturer or Part number/ Catalog number (REF)
AC to DC Power Adapter		11140-000072
External Power Extension Cable		11140-000080
DC to DC Power Adapter, LP15		11140-000074
**Some energy meters are not accurate for biphasic waveforms; contact your defibrillator analyzer's manufacturer for more information. *Equivalent equipment is required to meet the specifications listed in the specification column		

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: Only use accessories approved by Physio-Control.

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.



Figure 1.1—Manual mode passcode

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.

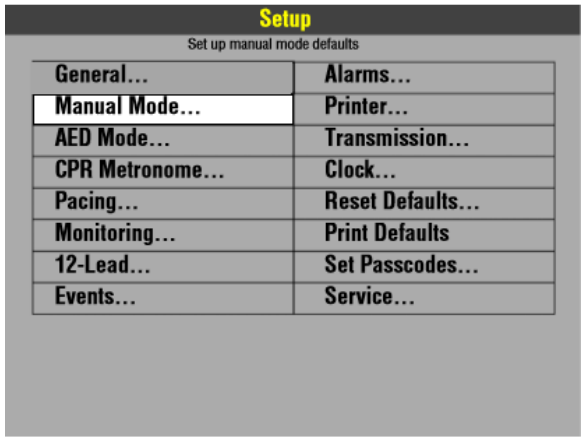


Figure 1.2—Manual mode menu selection

3. In the Setup/Manual Mode submenu, set the Manual Access selection to Manual/Direct.

4. Turn the device OFF by pressing ON for two seconds, and then continue with the next test.

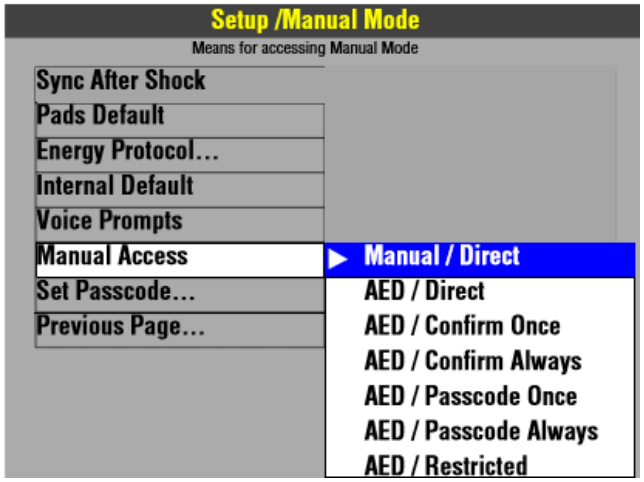


Figure 1.3—Manual mode submenu

PIP - Device Preparation



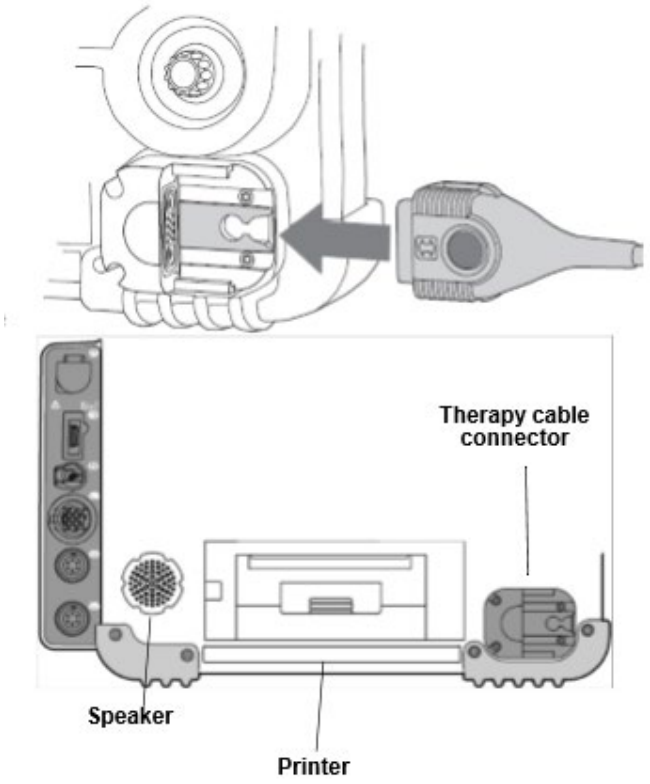
This section describes the inspection and setup procedures to prepare the device for the PIP.

- All required PIP tests applicable to the device configuration under test must be performed.
- The Performance Procedure Checklist is provided as a tool for the recording of test results.
- To correct failures, see Troubleshooting, and then repeat the PIP.

PIP - Exterior Physical Inspection

To perform an exterior physical inspection:

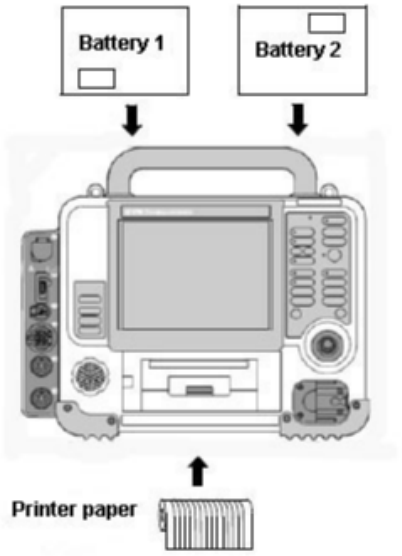
1. Inspect the device exterior for the following:
    - Damage
    - Excessive wear
    - Improper mechanical function
    - Damaged connectors
2. Pick up and turn over the device and listen for loose or rattling hardware. Locate any loose or rattling hardware, and then tighten or replace it.
3. Inspect the rubber feet on the underside of the lower enclosure. Reinstall or replace rubber feet as necessary.
4. Inspect the battery pins.
    - Tighten loose battery pins (see Battery Pin Replacement section of the LIFEPAK15 Service Manual).
    - Examine each leaf on the connector pins to make sure it is not cracked or broken.
    - Replace pins in accordance to the Scheduled Replacement Items section of the LIFEPAK15 Service Manual.
5. Inspect the pins and connector housings of all QUIK-COMBO, standard paddles, and other therapy cables for damage
6. Verify the spring button on the therapy connector is functional prior to engaging a therapy cable into the therapy connector
7. Inspect the ECG, SpO2*, CO2*, NIBP*, IP*, Temp* and system connectors for damage, cracks, or contamination (*if equipped).
8. Inspect the keypads and overlays for damage, cracks and separations.
9. Check all other accessory cables, ECG, SpO2 sensors, CO2 tubing, NIBP tubing, Temperature sensors and related items for expiration dates, general condition, and suitability for use.
10. Inspect carrying strap and mounts (if the device is equipped with them).



PIP - Device Setup

WARNING:
SHOCK HAZARD The device discharges up to 360 joules of electrical energy through the defibrillator cable. You must safely discharge this electrical energy as described in this PIP. Do not attempt to perform this procedure unless you are thoroughly familiar with the operation of the device.

1. Verify two, fully functional, charged, Lithium-ion batteries are showing more than two charge bars
   Note: A functional charged battery is one that does not return a LOW BATTERY message after turning on the device
2. Insert the two Li-ion batteries into the device.
3. Verify that each battery clicks into position in the battery wells.
4. Install a roll of printer paper into the printer.
5. Connect the QUIK-COMBO therapy cable (or optional standard paddles) to the therapy connector.
   Note: If the device is outfitted with standard paddles, perform the PIP tests specific to standard paddles instead of the tests specific to QUIK-COMBO.



PIP - Power Management

Perform the following Power Management tests:

PIP - Power On/Self-Test
PIP - Auxiliary Power Switching Test
PIP - Power Source Management Test

PIP - Power On/Self-Test:

To perform Power On/Self-Test:

1. Turn the device ON.
2. Verify the entire self-test completes in 10 seconds or less

   Note: The startup screen appears while the device is starting up and performing its self-test. The copyright is formatted as “Physio-Control Inc. (year).” The year shown will vary with software versions. The system software part number is also displayed at the bottom of screen.

3. Verify that the power ON LED remains illuminated after the self-test.
4. Verify that all front panel LEDs flash (except the ON LED, which glows steadily) for approximately 0.5 seconds during the self-test.
5. Verify that the speaker emits a clear, single-beep test tone.
6. Verify that the Service LED is OFF.
7. Verify that the display screen appears similar to figure 1.8 .
8. Turn the device OFF, and continue with the next test.

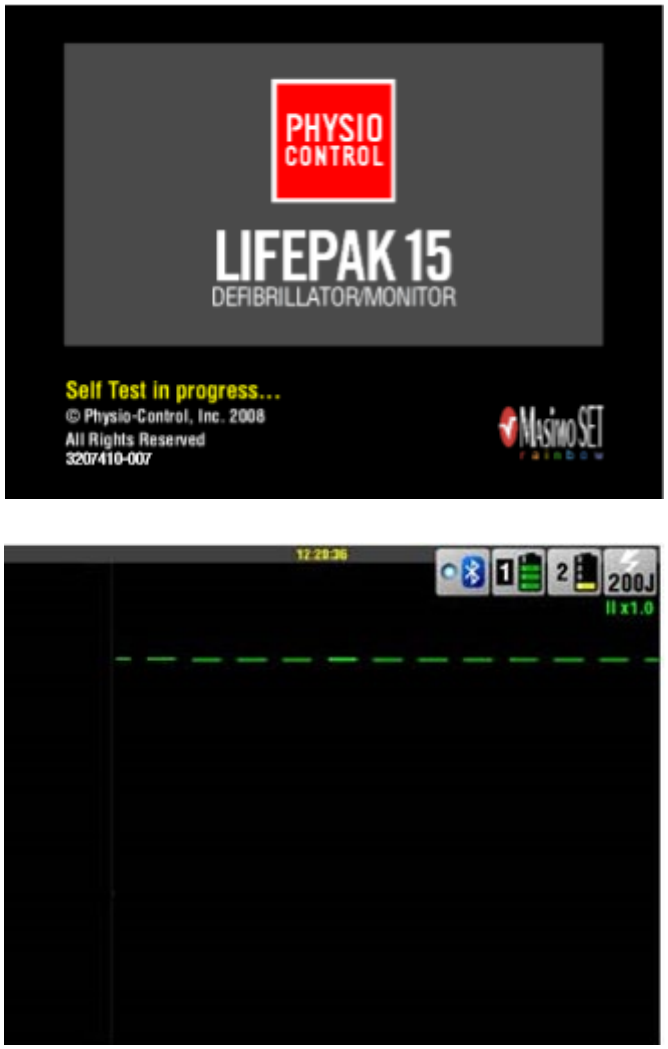
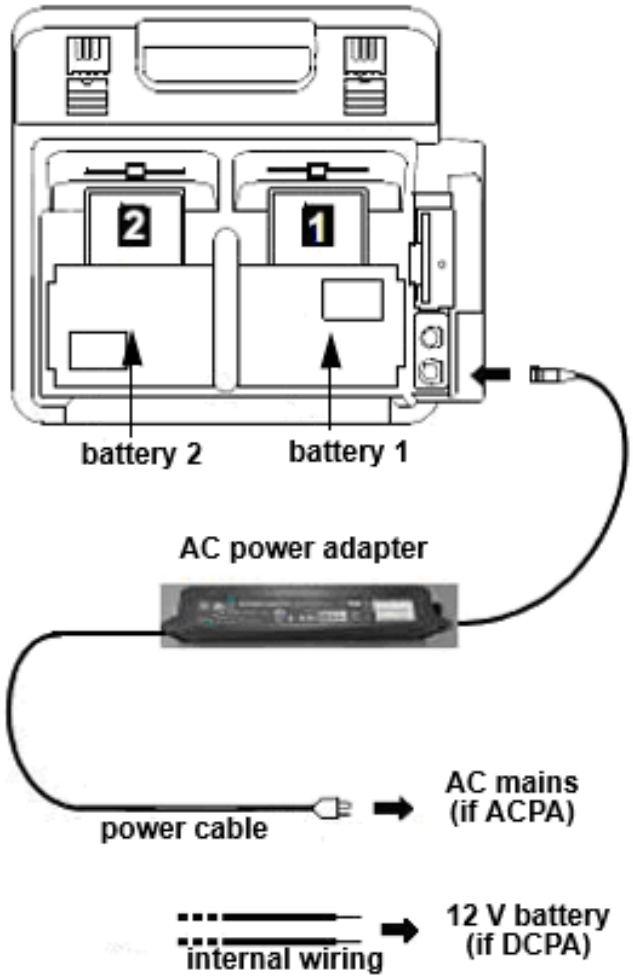


Figure 1.8—Display screen

PIP - Auxiliary Power Switching Test

To perform Auxiliary Power Switching Test:

1. Connect the power adapter to the power source and the output cable to the Auxiliary Connector at the rear of the device. See the Operating Instructions - AC and DC Power Adapters for more information.
2. Turn on the device and verify that the battery icons appear but neither is highlighted.
   Note: Battery indications may look slightly different.
3. Unplug the Power Adapter cable from the device Auxiliary Connector. Verify that one of the device battery icons is highlighted.



PIP - Power Source Management Test

To perform Power Source Management Test:

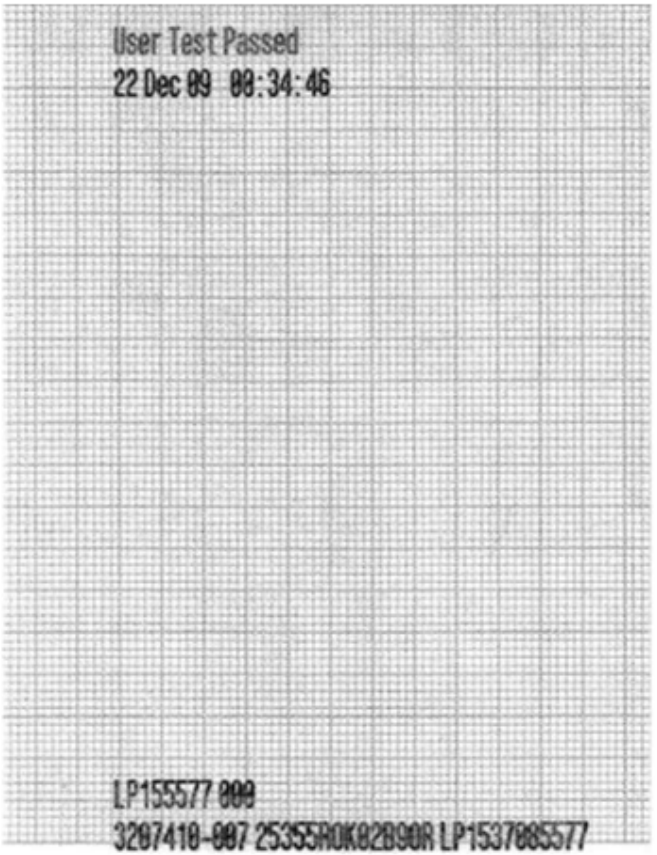
1. Turn the device ON.
2. Verify the device displays the battery status indicators showing the following information:
   - The presence of batteries in Battery Wells 1 and 2.
   - Which battery is being used (the battery in use is indicated by a white battery number in a black box).
   - The state of charge on each battery.
   - When two batteries are installed prior to turn ON, the device will use the battery with the lowest charge first.
3. Remove Battery 1. Verify the device indicates no battery is in Well 1 and the device is being powered by Battery 2.
4. Reinsert Battery 1 and remove Battery 2. Verify the device indicates no battery is in Well 2 and the device is being powered by Battery 1.
5. Reinsert Battery 2.
6. Turn the device OFF, and continue with the next test.



PIP - User Test and Date/Time Verification Tests

To perform User Test and Date/Time Verification Tests:

1. Turn the device ON.
2. Press OPTIONS to access the Options menu
3. Select USER TEST. The device automatically performs the following tasks:
    - Performs self-tests.
    - Charges to 10 joules and discharges internally (this energy is not accessible at the therapy connector).
    - Prints a Pass/Fail report.
4. Verify on the printout that the device passes the user test and that the correct date and time values are also displayed on the printout.
   Note: If the date and time are incorrect, reset using the Options/Date/Time menu.
5. Turn the device OFF, and continue with the next test.



PIP - Miscellaneous Functions

Miscellaneous function tests include:

PIP - Temperature Calibration Check
PIP - CO2 Tests
PIP - NIBP Tests

PIP - Temperature Calibration Check

Test Setup

To perform the Temperature Calibration Check Test:
Test Setup: This procedure requires the following equipment and test cables noted in Figure 1.12

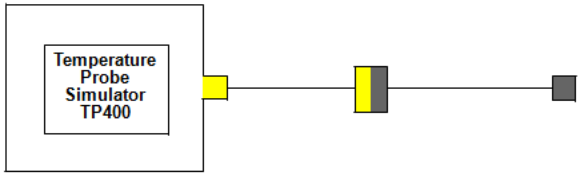


Figure 1.12—Temperature calibration check test setup

Temp Calibration Check Test

1. Turn the device ON.
2. Access the Service mode.
3. Select Calibration from the Service menu.

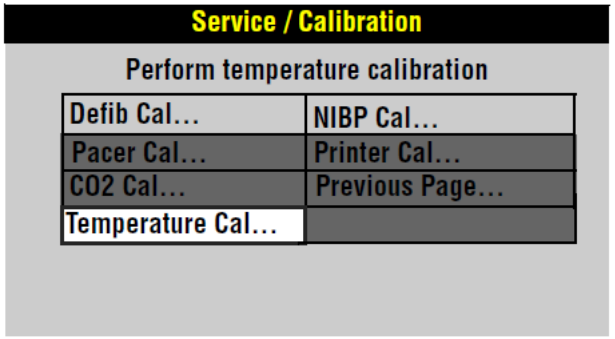


Figure 1.13—Calibration selection

4. Select the Temperature Cal from the Service /Calibration menu as shown in Figure 1.13.

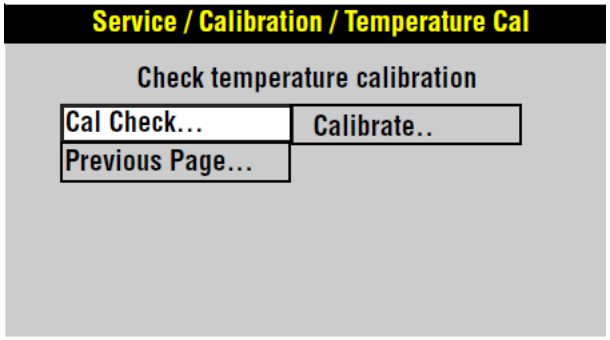


Figure 1.14—Temperature calibration selection

5. To initiate Temperature Calibration Check, select Cal Check from the Service / Calibration / Temperature Cal menu.

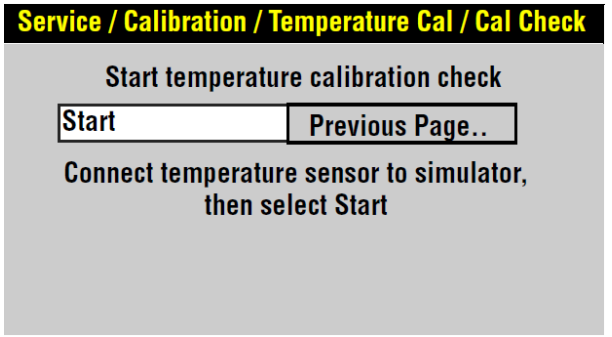


Figure 1.15—Starting calibration check

6. Connect the temperature sensor to the device and select the Start button as shown in Figure 1.15

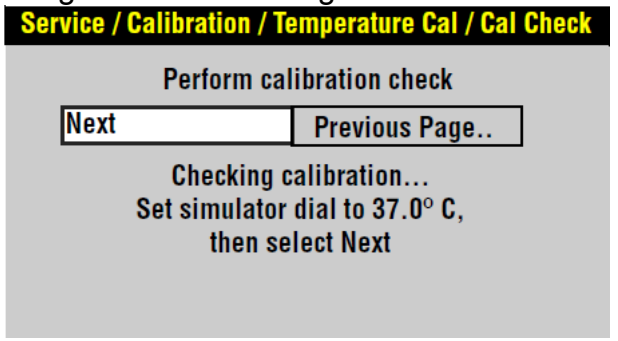


Figure 1.16—Calibration checking

7. When the calibration check is complete as shown in Figure 1.17.

   NOTE: Perform TCP - Temperature Calibration Test when the Temperature Calibration Check test fails.

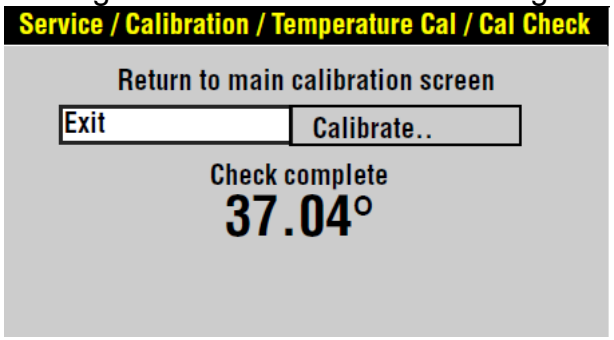


Figure 1.17—Cal check completion

PIP - CO2 Tests

NOTE: Perform the CO2 tests if the device is equipped with the CO2 option. Otherwise, skip to PIP- NIBP Tests.

CO2 tests consist of:

PIP - CO2 Leakage Test
PIP - CO2 Calibration Check

PIP – CO2 Leakage Test

To perform the CO2 monitoring system for leaks:

1. Set up the test equipment as shown in Figure 1.18.
   Note: Make sure the device is turned OFF and no tubing is connected to the device.
2. Open the hose clamp and depress the syringe fully.
3. Connect the tubing to the front panel CO2 connector and to the back panel CO2 gas outlet. Important: Press the fittings that connect to the device firmly to avoid leakage. All tubing ends should now be connected as shown in Figure 1.18.
4. Pull the syringe plunger out to induce a vacuum into the system. When the vacuum manometer indicates approximately -230 mmHg
   (-300 mBars), close the tubing clamp firmly.
5. Begin timing as the clamp is closed. Verify that after 30 seconds, the change in vacuum reading is less than 15 mmHg (20 mBars).
6. Open the tubing connection to the front panel CO2 connector to release the vacuum.
7. Continue to next test

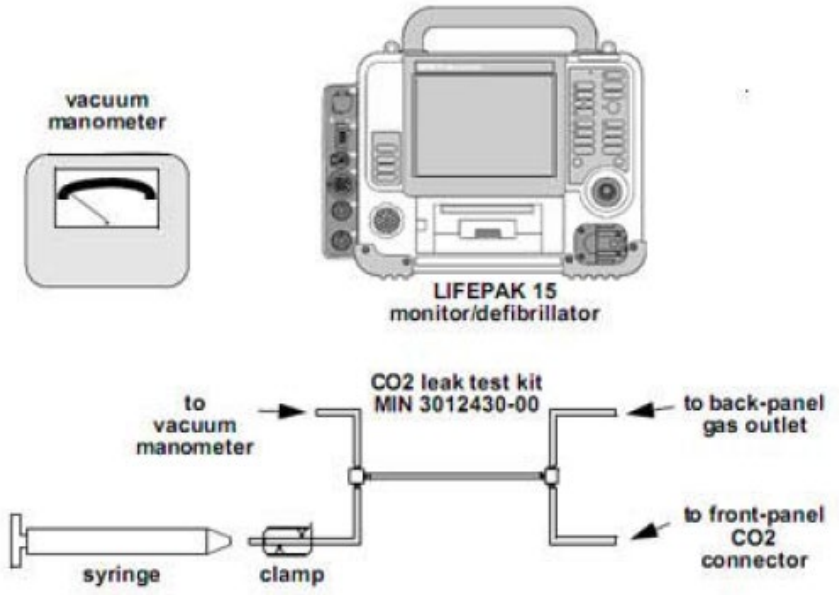


Figure 1.18—CO2 monitoring test setup

PIP – CO2 Calibration Check

To perform CO2 Calibration Check:

1. Turn the device ON.
2. Access the Service mode.
3. Select CALIBRATION from the Service menu.
4. Select CO2 CAL.

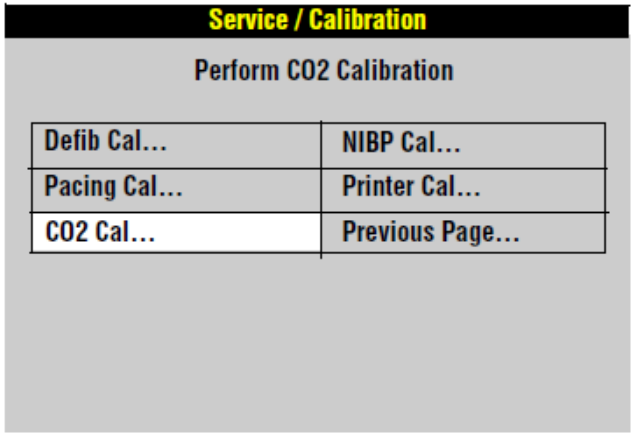


Figure 1.19—CO2 service calibration menus

5. Select CALCHECK.

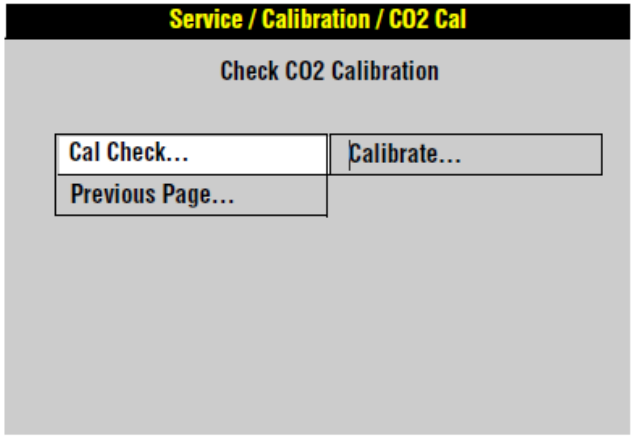


Figure 1.20—Service calibration Cal Check

6. Connect the calibration gas canister to the front panel CO2 connector using a standard CO2 Filter Line and the CO2 calibration kit as shown in Figure 1.21.
7. Press and hold the spray nozzle to apply the calibration gas. Release the spray nozzle when the device displays a stable value for the measured CO2 content of the calibration gas.

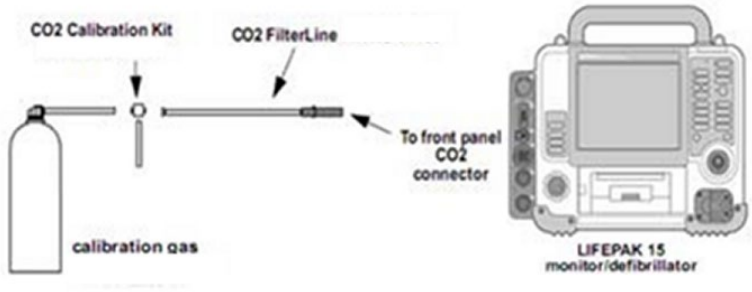


Figure 1.21—CO2 calibration connection

8. Verify that the measured gas concentration reads 5.0% ± 0.5% as shown in Figure 1.22. **NOTE:** If the measured value is incorrect, perform TCP - CO2 Calibration.
9. Select PREVIOUS PAGE twice to return to the Service/Calibration submenu.
10. Continue with the next test.

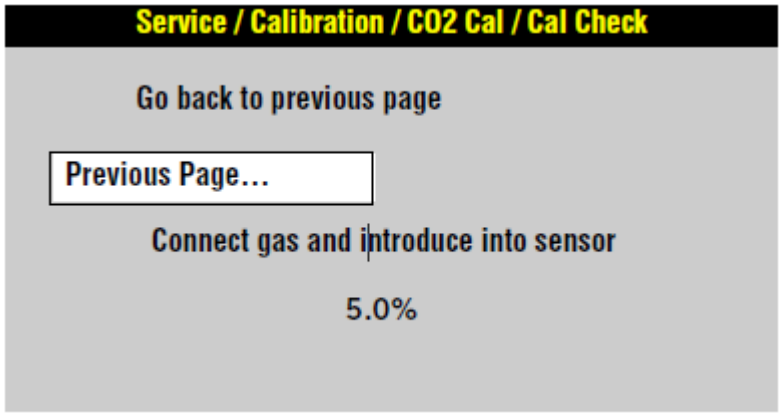


Figure 1.22—Service/Calibration submenu

PIP - NIBP Tests

NOTE: Perform the NIBP tests if the device is equipped with the NIBP option. Otherwise, skip to PIP - Invasive Pressure Verification - P1, P2

NIBP tests consist of:

PIP-NIBP Leakage Test
PIP-NIBP Calibration Check

PIP-NIBP Leakage Test

To perform the NIBP Leakage Test:

1. Access the Service mode.
2. Select NIBP CAL in the Service/Calibration submenu as shown in Figure 1.23.
3. Select LEAKAGE from the Service/Calibration/NIBP Cal submenu as shown.
4. Connect the 12 ft. straight NIBP hose to the NIBP connector.
5. Occlude the distal end of the NIBP tube by plugging it or folding it double and pinching it.
   Note: The pinch point is 6 inches from the open hose end (it is not the end of connected to NIBP connector).
6. Select START. The device pressurizes the tubing to approximately 200 mmHg. Verify that the message LEAKAGE TEST OK appears
7. Continue with the PIP – NIBP Calibration Check.

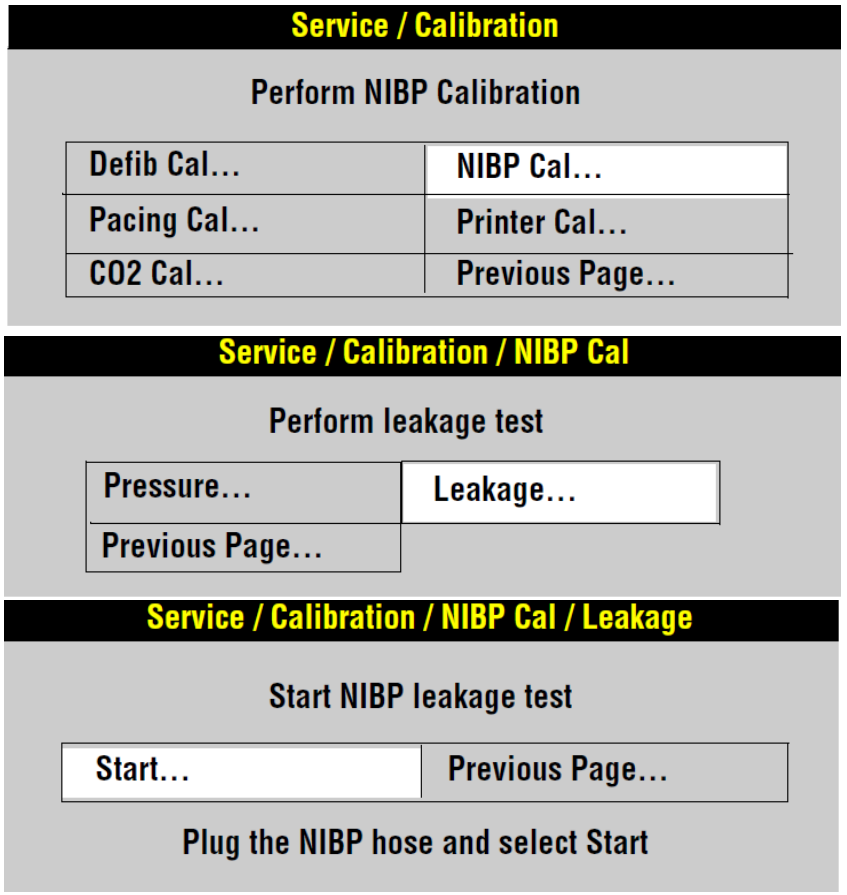


Figure 1.23—NIBP leakage menus

PIP – NIBP Calibration Check

CAUTION

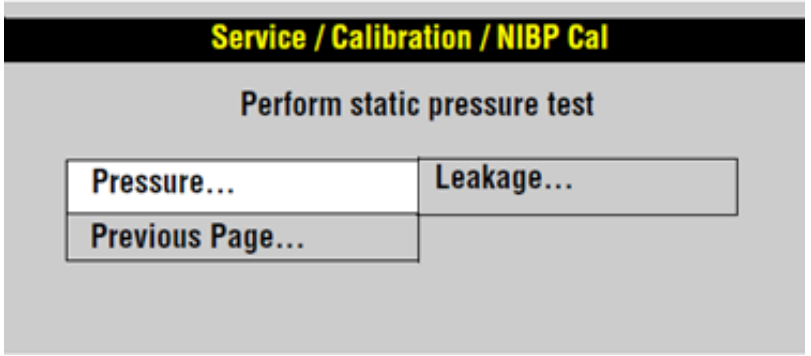
POSSIBLE EQUIPMENT DAMAGE Pulling out on the syringe plunger applies a vacuum to the NIBP connection and may damage the LIFEPAK 15 monitor/defibrillator. DO NOT pull on the plunger; only push in on the plunger to inflate the system per the instructions.

To perform the NIBP static pressure calibration:

1. Select PRESSURE to test the static pressure as shown.
2. Set up the NIBP calibration kit as shown in Figure 1.24.
3. Adjust the pressure meter, if necessary, to a zero initial pressure to ensure that the device and the pressure meter agree.
4. Using the syringe, inflate the system to each of the following pressures (as indicated on the manometer or pressure meter) :

50 mmHg	150 mmHg

5. Verify that the information displayed on the device screen and the external pressure meter agrees within ±20 mmHg.
6. Using the syringe, slowly inflate the system until the overpressure switch activates at 290 ±20 mmHg as displayed on the pressure meter.
7. Verify that the system depressurizes, and that the NIBP LED turns OFF. NOTE: This test fails if the system pressure reaches greater than 310 mmHg, as displayed by the pressure meter, prior to activating the overpressure switch.
8. Select PREVIOUS PAGE to return to the Service/ Calibration/NIBP Cal submenu.
9. Continue with the next test.



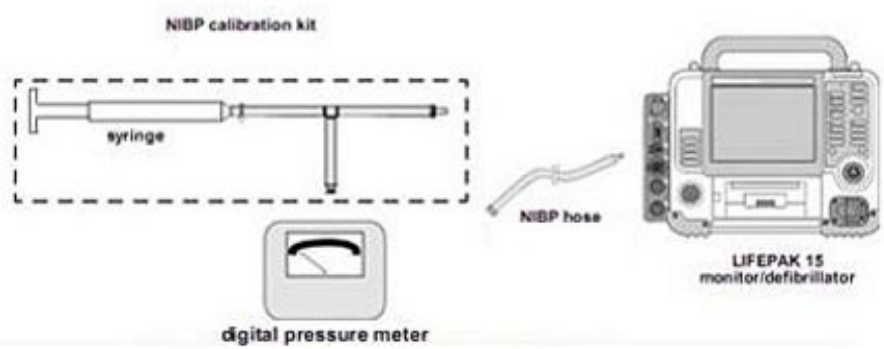


Figure 1.24—NIBP calibration setup

PIP – Printer Tests

Printer tests consist of:

PIP- Printer Speed Test at 25 mm/sec.

PIP- Printer Speed Test at 12.5 mm/sec

PIP- Printer Speed Test at 25 mm/sec.

To perform Printer Speed Test at 25 mm/sec Test:

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:
    - The large “X” form prints without missing dots.
    - Seven horizontal lines print (one very close to the lower paper margin).
    - The character set prints clearly without broken characters.
    - Vertical lines spaced 25 mm ± 1 mm (approx. 24 to 26 mm) a part print correctly.

    NOTE: Perform the TCP - Printer Calibration at 25 mm if the test results are unacceptable.

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. Install the printer paper and continue with the next test while still in Service mode.

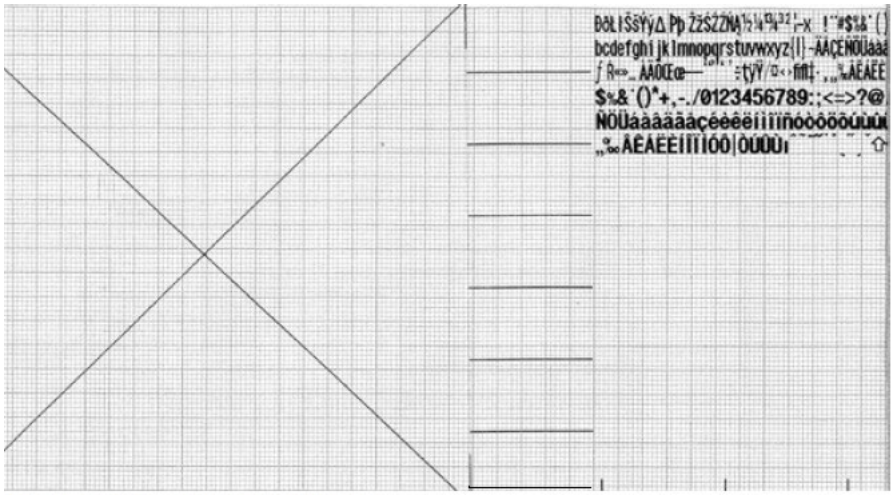


Figure 1.26—Printer test strip

PIP - Printer Speed Test at 12.5 mm/sec.

To perform Printer Speed Test at 12.5 mm/sec Test:

1. Select CALIBRATION in the Service menu.
2. Select PRINTER CAL in the Service/Calibration submenu.
3. Select 12.5 mm/sec for the speed
4. Select START and press the SPEEDDIAL to print a test strip.
5. Verify the interval between tick marks is spaced at 12.5 mm/sec.
   Note: Perform the TCP- Printer Calibration at 12.5 mm/sec if the test results fall outside of the acceptable range.
6. Press the SPEED DIAL to turn the printer off.
7. Continue with the next test while still in Service mode.

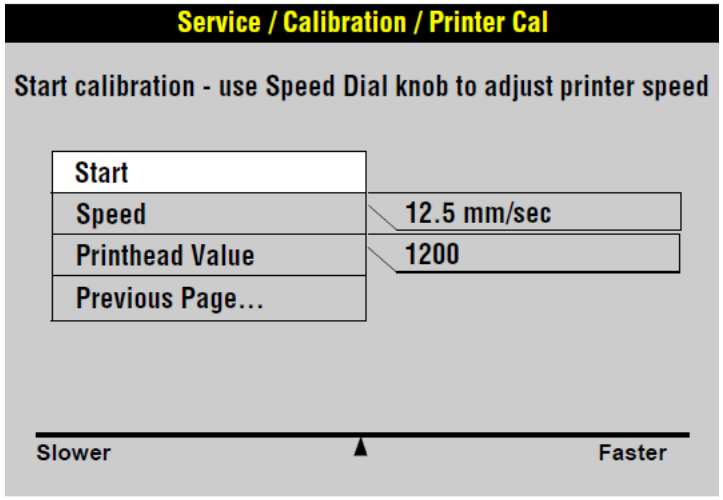


Figure 1.27—Printer speed test calibration submenu

PIP - Keypad Tests

To perform Keypad Tests:

1. Access the Service mode.
2. Select TESTS in the Service menu.
3. Select BUTTONS in the Service/Tests submenu as shown in Figure 1.28.
4. Press each front panel button when prompted by the flashing button legend (although you may press the buttons in any order).
5. 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.
6. Verify the TEST COMPLETE message appears on the bottom of the screen and the Service LED is not on.
7. Press SPEED DIAL to exit at the end of the test.
8. Continue with the next test while still in Service mode.

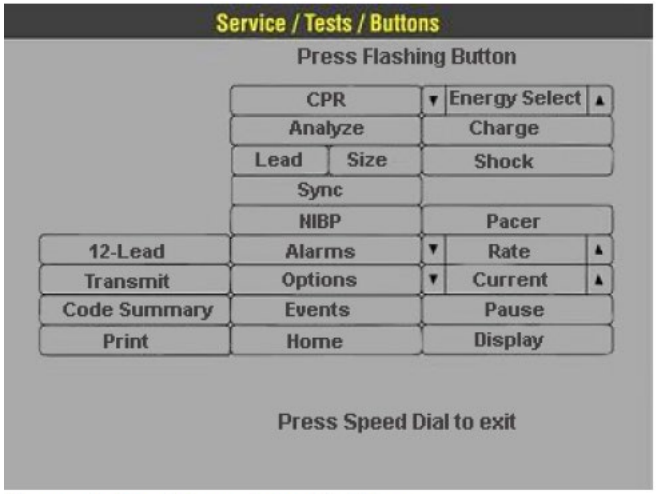


Figure 1.28—Keypad test buttons

PIP - Audio Test

To perform Audio Test:

1. Select VOICE/TONE from the Service/Tests submenu.
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.

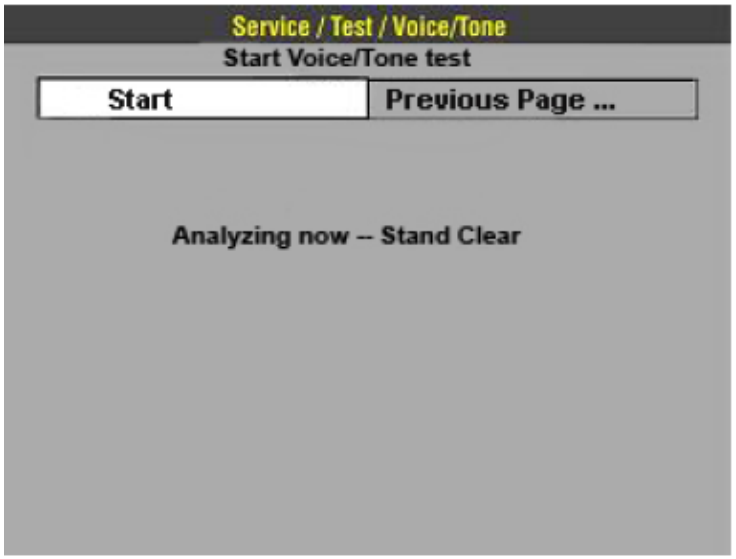


Figure 1.29—Audio test submenu

PIP - Invasive Pressure Verification -P1, P2 Testing

NOTE: Perform this test if the device is equipped with the invasive pressure option. Otherwise, skip to PIP - SpO2/SpCO/SpMet Test.

To perform the invasive pressure tests:

1. Turn the device ON.
2. Use the invasive pressure cable to connect the patient simulator to the P1 connector on the device parameter bezel.
3. Turn the patient simulator ON, and set the simulator pressure output to ZERO.
4. Use the SPEED DIAL on the device to select P1 in the Mean Arterial Pressure (MAP) display area to display the pressure waveform.
5. On the P1 menu, verify that the scale is set to AUTOSCALE. Select ZERO to zero the P1 pressure channel.
6. Set the patient simulator to produce Static blood pressures.
7. Select 250 mmHg. Verify that the Mean Arterial Pressure (MAP) displays and the pressure waveform reads 250 ±8 mmHg within a few seconds.
8. Repeat step 7, using the following simulated pressures.
   - 100 mmHg (±5 mmHg)
   - 20 mmHg (±3 mmHg)
9. With a simulated pressure input of 20 mmHg, use the SPEED DIAL to select P1 in the Mean Arterial Pressure (MAP) display area, and then select ZERO to zero the P1 pressure channel again.
10. Verify that the pressure waveform and the MAP display return to zero.
11. Set the simulator pressure output to ZERO.
12. Verify that the device displays -20 ±3 mmHg within a few seconds.
13. Disconnect the invasive pressure cable from the P1 connector and connect it to P2.



Figure 1.30—Pressure waveform

14. Select CHANNEL 2, and assign P2 to the display.
15. Repeat steps 4 through 12 above for the P2 pressure channel.
16. Disconnect the invasive pressure cable from the P2 connector.
17. Turn the device OFF, and continue with the next test.

PIP - SpO2/SpCO/SpMet Testing

NOTE: Perform this test if the device is equipped with any combination of the SpO2/SpCO/SpMet options. Otherwise, skip to PIP - Recording Operating Data (Optional)

To perform the SpO2/SpCO/SpMet:

1. Turn the device ON.
2. Connect the oximeter finger probe to the SpO2/SpCO/SpMet connector.
3. Verify the SpO2/SpCO/SpMet parameter region appears on the display.
4. Place your ring finger into the oximeter finger probe.
5. Allow several seconds for the probe to find your pulse.
6. Confirm the SpO2 reading is in the range of 50% to 100%.
7. Highlight SpO2 on the screen and press SPEED DIAL twice.
8. Highlight the parameter and press the SPEED DIAL to select:
   - Confirm the SpCO reading is in the range of 0% to 40%
   - Confirm the SpMet reading is in the range of 0% to 15%.
9. Disconnect the oximeter finger probe.
10. Turn the device OFF.
11. Continue with the next test.

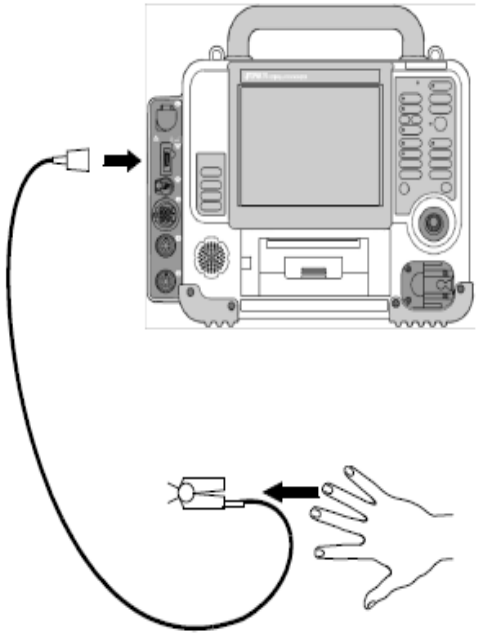


Figure 1.31—Sp02/SpCO/SpMet setup

PIP - Recording Operating Data Testing

To perform Recording Operating Data:

1. Press and hold OPTIONS and EVENT, and then turn the device ON.
2. When the Setup mode passcode prompt appears, enter 5433.
3. Select SERVICE from the Setup menu, and enter 5433 for the password again.
4. Select STATUS in the Service menu.
5. Select COUNTERS in the Service/Status submenu.
6. Record the shocks since last reset (in the boxes) and total shocks in last built. (Select CLEAR ALL to reset boxed counter, if necessary)
7. Select PREVIOUS PAGE.
8. Select DEVICE LOG and record the following items:
    - Fault Messages
    - Power Cycle
    - Count Pacing
    - Count Shock
    - Count Power on
    - Time Printer on
    - Time.SpO2
    - Operating Time (if SpO2 option is installed)
    - CO2 Operating Time (if CO2 option is installed)
    - NIBP Inflation Cycles (if NIBP option is installed.
9. Press SPEED DIAL to exit. Press HOME SCREEN to return to the Service menu.

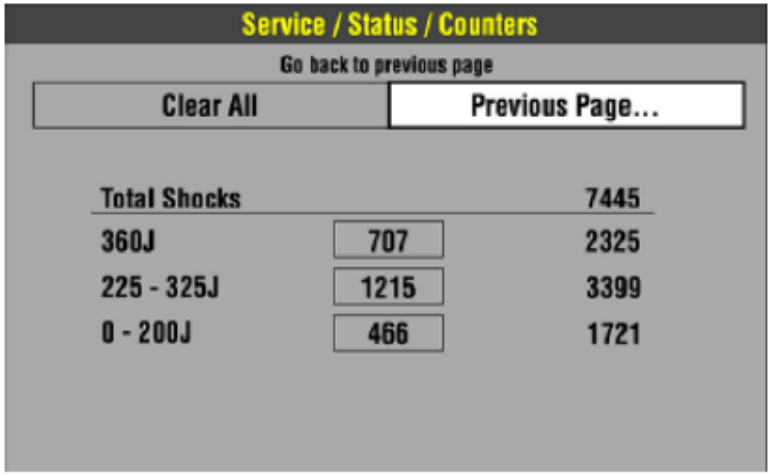


Figure 1.32—Counters submenu

PIP - ECG Performance Testing

Perform the following ECG Performance Testing:

PIP - ECG Performance Testing
- PIP-12-Lead ECG Tests
  - PIP-12-Lead ECG Leads Off Detection Test
  - PIP-12-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
  - PIP-3-Lead ECG Leads Off Detection Test
  - PIP-3-Lead ECG Gain Test

PIP -12-Lead ECG Tests

NOTE: If your device is not equipped with a 12-LEAD button on the small keypad, perform the PIP - 5-Lead ECG Tests or PIP - 3-Lead ECG Tests instead.

The 12-Lead ECG tests consist of:

PIP-12-Lead ECG Leads Off Detection Test
PIP-12-Lead ECG Gain Test

PIP-12-Lead ECG Leads-Off Detection

To perform 12-Lead ECG Leads Off Detection (using the customer's ECG cable, if available):

1. Connect the main ECG cable with the limb lead and precordial lead attachments, and connect all 10 ECG leads to the Impulse 7000DP as shown in Figure 1.33.
2. Set the Impulse 7000DP output to a 1-mv, 10-HZ sine wave.
3. Turn the device ON.
4. Set the device lead selection to Lead II.
5. Press the 12-LEAD button, and then press the SPEED DIAL twice until the ACQUIRING 12 LEAD message appears.
6. Remove the RL lead from the Impulse 7000DP.
7. Verify that the device displays an ECG LEADS OFF message and a repeating priority 3 tone sounds when the Lead is removed.
8. Reconnect the RL Lead.
9. Remove the RA Lead from the Impulse 7000DP.
10. Verify the device displays an RA LEADS OFF message and a repeating priority 3 tone sounds when the lead is removed.
11. Reconnect the RA lead.
12. Repeat step 5 (as needed) and steps 9 through 11 for the LA, LL, and all V Leads.



Figure 1.33—ECG lead connections

13. Verify the device displays an individual LEADS OFF message when each lead is removed (for example, LA LEADS OFF when the LA lead is removed) and a repeating priority 3 tone sounds when the lead is removed.
14. Continue to the next test with this setup in place.

PIP- 12-Lead ECG Gain Test

To perform 12-Lead ECG Gain Test:

1. Program the Impulse 7000DP output for 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 1.34.
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 1.34.
7. Repeat steps 5 and 6 for Lead V1, V2, V3, V4, V5, and V6.
8. Turn the printer off.
9. Continue with the next test.

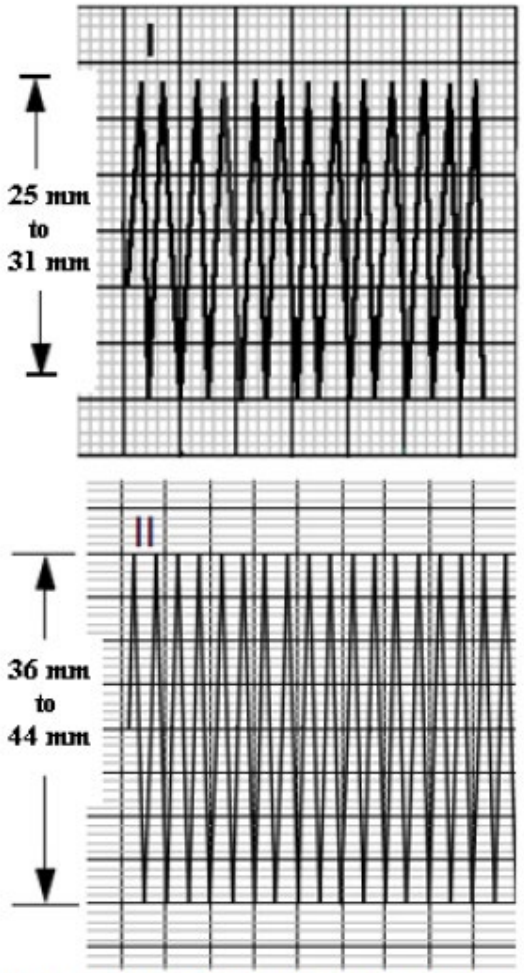


Figure 1.34—Signal amplitude for 12-lead gain test

PIP-5-Lead ECG Tests

NOTE: If your device is not equipped with a 12-Lead button on the small keypad, and the customer does not use 5-wire cable, perform the PIP - 3-Lead ECG Tests instead.

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

To perform 5-Lead ECG Leads Off Detection (using the customer's ECG cable):

1. Connect the 5-wire ECG cable to the Impulse 7000DP.
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 LL Lead from the Impulse 7000DP, verify that the device display an LL LEADS OFF message and repeating priority 3 tone sounds when the lead is remove.
5. Remove the LL lead from the Impulse 7000DP, and verify that the device displays an LL LEADS OFF message and a repeating priority 3 tone sounds when the lead is removed.
6. Reconnect the LL lead.
7. Remove the RA lead from the Impulse 7000DP, and verify that the device displays an RA LEADS OFF message and a repeating priority 3 tone sounds when the lead is removed.
8. Reconnect the RA lead.
9. Remove the RL lead from the Impulse 7000DP, and verify that the device displays an ECG LEADS OFF message and a repeating priority 3 tone sounds when the lead is removed.
10. Reconnect the RL lead.
11. Set the device lead selection to LEAD I.
12. Remove the LA lead from the Impulse 7000DP.
13. Verify that the device displays an LA LEADS OFF message and a repeating priority 3 tone sounds when the lead is removed
14. Reconnect the LA lead.
15. Set the device LEAD selection to LEAD V1/C.
16. Remove the V1/C lead from the Impulse 7000DP.
17. Verify that the device displays a CHEST LEADS OFF message and a repeating priority 3 tone sounds when the lead is removed.
18. Reconnect the V1/C lead.
19. Continue to the next test with this setup in place.



Figure 1.35—ECG 5-wire connection

PIP-5-Lead ECG Gain Test

To perform 5-Lead ECG Gain Test:

1. Program the Impulse 7000DP output for 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 1.36.
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.
7. Repeat steps 5 and 6 for Lead VI.
8. Turn off the printer.
9. Continue with the next test.

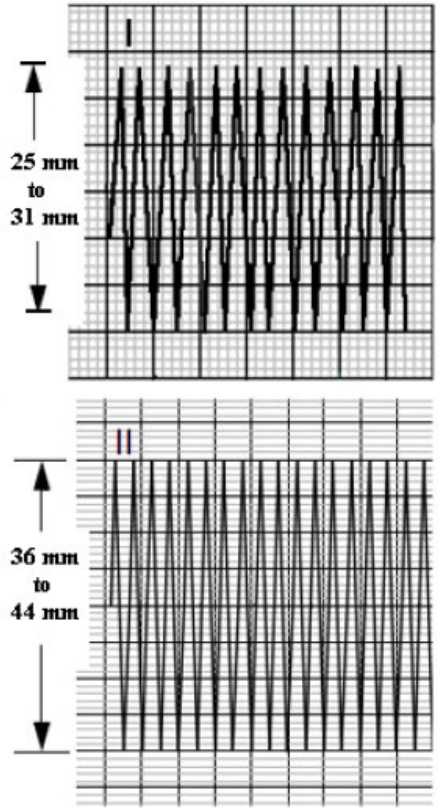


Figure 1.36—Signal amplitude for 5-lead gain test

PIP - 3-Lead ECG Tests

NOTE: If your device is equipped with a 12-LEAD button on the small keypad, perform the PIP - 12-Lead ECG Tests instead

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

To perform 3-Lead ECG Leads Off Detection (using the customer's ECG cable):

1. Connect the 3-lead ECG cable between the device and Impulse 7000DP as shown in Figure 1.37.
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 LL lead from the Impulse 7000DP, and verify that the device displays the LL LEADS OFF message and a repeating priority 3 tone sounds when the lead is removed.
5. Reconnect the LL lead.
6. Remove the RA lead from the Impulse 7000DP, and verify that the device displays the RA LEADS OFF message and a repeating priority 3 tone sounds when the lead is removed. Reconnect the RA lead.
7. Remove the LA lead from the Impulse 7000DP, and verify that the device displays the ECG LEADS OFF message and a repeating priority 3 tone sounds when the lead is removed. Reconnect the LA lead.
8. Continue with the next test with this setup in place.



Figure 1.37—ECG 3-wire connection

PIP-3-Lead ECG Gain Test

To perform 3-Lead ECG Gain Test:

1. Program the Impulse 7000DP output for a 1-mv, 10-Hz sine wave.
2. Set the device ECG SIZE to 4.0.
3. Set the 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 1.38.
5. Set the 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.
7. Turn the device OFF, and continue with the next test.

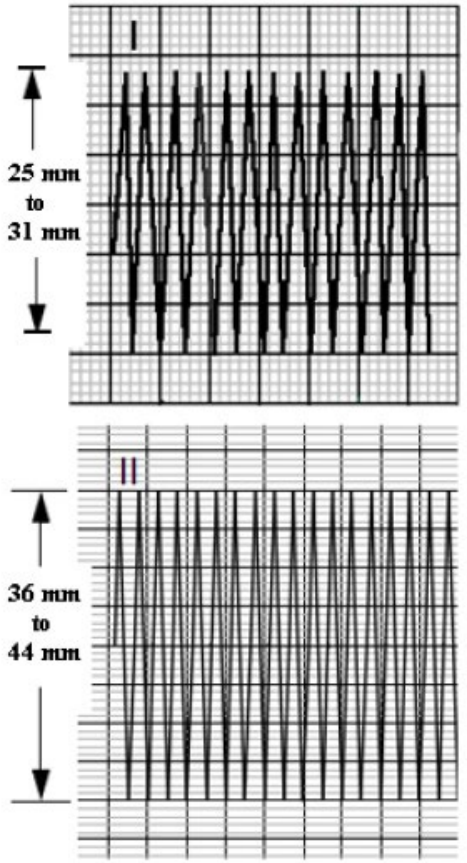


Figure 1.38—Signal amplitude for 2-lead gain test

PIP – Analog ECG Output Test (Optional)

NOTE: Perform this test if this feature is used by the customer.
Otherwise, continue with PIP – QUIK-COMBO Defibrillator Delivered Energy Test.

To perform the ECG analog output:

1. Connect the device to the Impulse 7000DP and oscilloscope as shown in Figure 1.39.
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 the device LEAD selection to LEAD II. (The ECG analog 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 0.90 Vp-p and 1.10 Vp-p.
6. Disconnect the ECG cable from the device and oscilloscope.
7. Turn the device OFF.
8. Continue with the next test.

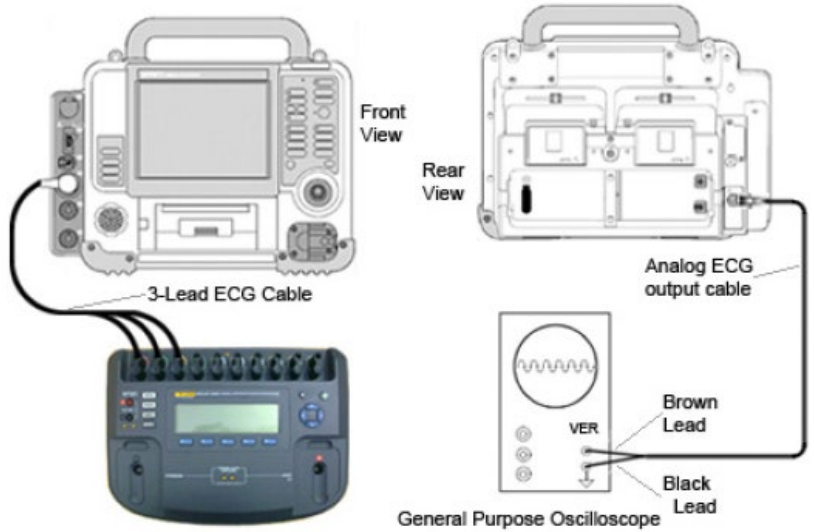


Figure 1.39—Analog ECG output test setup

PIP - Defibrillator/Pacing Testing

PIP - QUIK-COMBO Defibrillator Delivered Energy Test
PIP - QUIK-COMBO Defibrillator Charge Time Test and Sync Tests
- PIP- QUIK-COMBO Defibrillator Charge Time Test
- PIP- QUIK-COMBO Defibrillator Sync Test

PIP - QUIK-COMBO Defibrillator ECG Characteristic Tests
- PIP - QUIK-COMBO Defibrillator ECG Gain Test
- PIP - QUIK-COMBO Defibrillator ECG Restore Test
- PIP - QUIK-COMBO Defibrillator a Positive R-wave Test

PIP – Standard Paddles User Test
PIP – Standard Paddles Defibrillator Delivered Energy Test
PIP - Standard Paddles Defibrillator Charge Time Test and Sync Tests
- PIP- Standard Paddles Defibrillator Charge Time Test
- PIP- Standard Paddles Defibrillator Sync Test

PIP - Standard Paddles Defibrillator ECG Characteristic Tests
- PIP - Standard Paddles Defibrillator ECG Gain Test
- PIP - Standard Paddles Defibrillator ECG Restore Test
- PIP - Standard Paddles Defibrillator a Positive R-wave 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 Delivered Energy Test

To perform Quik-Combo Defibrillator Delivered Energy Test:

1. Connect the therapy cable between the device and defibrillator analyzer as shown in Figure 1.40.
   NOTE: Ensure proper 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. Program the defibrillator analyzer to measure an Energy output.
3. Turn the device ON.
4. Press ENERGY SELECT and select 10 J.
5. Press CHARGE and wait for the device to reach full charge.
6. Press SHOCK to discharge the device into the defibrillator analyzer.
7. Verify the defibrillator analyzer indicates the delivered energy is within the acceptable output limits shown in Table Delivered Energy Levels below:

Energy Level (J)	Acceptable Output (J)
10	9.1 to 10.9
200	186.0 to 214.0
360	334.9 to 384.9

8. Repeat steps 4 through 7 for the remaining energy levels specified in the table.
   Note: Perform TCP- Defibrillator Energy Calibration if the delivered energy falls outside the acceptable output range.
9. Continue to the next test with this setup in place.

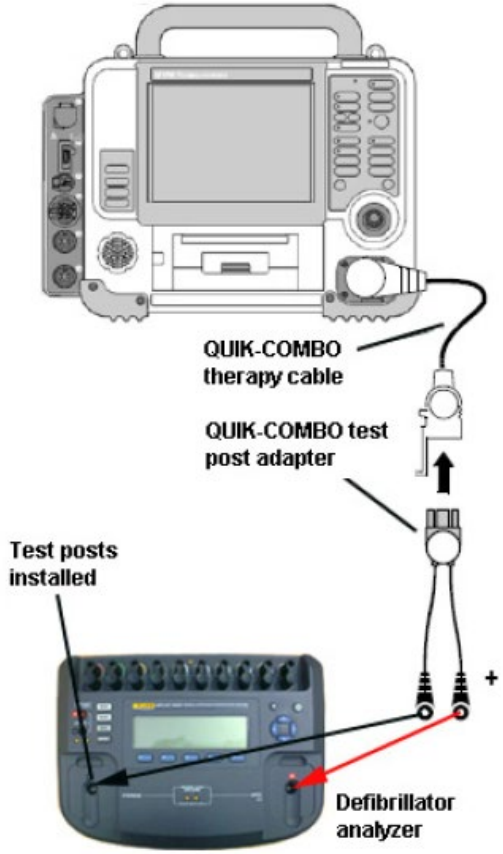


Figure 1.40—QUIK-COMBO delivered energy test setup

PIP – QUIK-COMBO Defibrillator Charge Time Test and Sync Tests

QUIK-COMBO PIP tests consist of::

PIP- QUIK-COMBO Defibrillator Charge Time Test
PIP- QUIK-COMBO Defibrillator Sync Test

PIP- Quik-Combo Defibrillator Charge Time Test

To perform the device charge time using a stopwatch:

1. Press ENERGY SELECT on the device and select 360 J.
2. Press CHARGE and start the stopwatch timer at the same time.
3. Stop the timer when the device reaches full charge at 360 J.
4. Verify that the charge time is less than 10 seconds.
5. Continue with the next test with this setup in place.

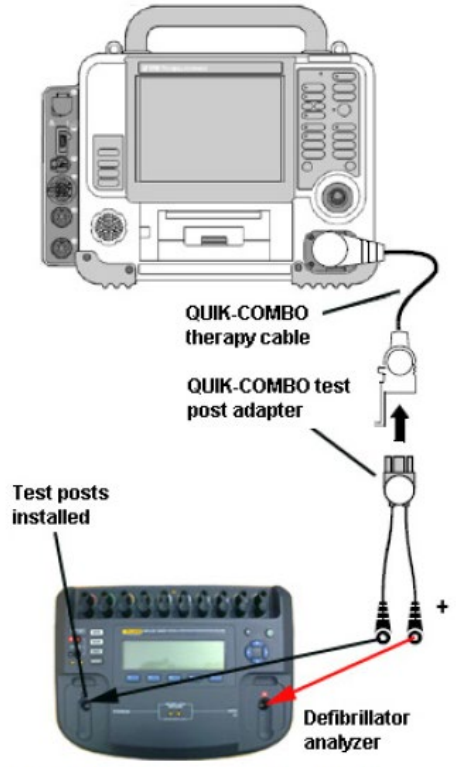


Figure 1.41—Charge time test setup

PIP – QUIK-COMBO Defibrillator Sync Test

To perform Quik-Combo Defibrillator Sync Test:

1. Connect the main ECG cable between the device and the defibrillator analyzer as shown in Figure 1.42.
2. Set the device ECG SIZE to 1.0.
3. Set the LEAD selection to LEAD II.
4. Set the defibrillator analyzer to measure SYNC, and then press the SYNC button on the device.
5. Verify that the SYNC LED is on and R-wave markers appear on the ECG waveform.
6. Charge the device to 10 J. Upon reaching full charge, press SHOCK to discharge the device.
7. Verify the defibrillator analyzer measures a sync delay of 60 ms or less.
8. Disconnect the ECG cable from the device and the defibrillator analyzer.
9. Continue with the next test with this setup in place.

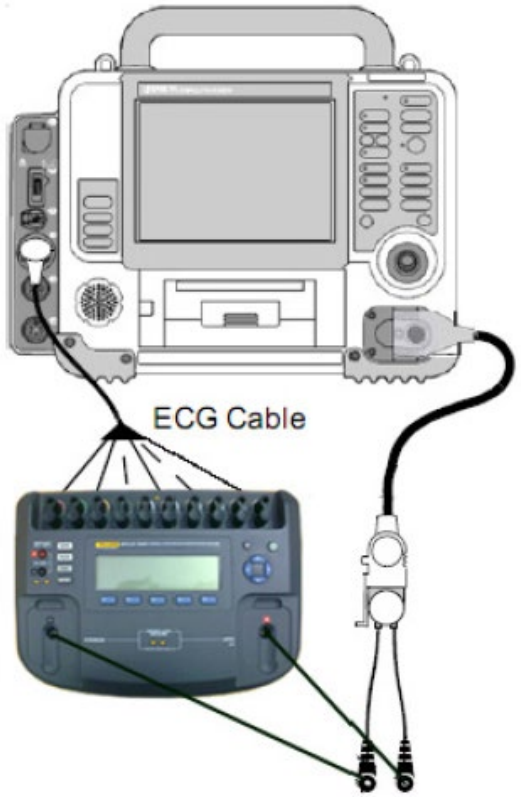


Figure 1.42—Synchronous cardioversion test setup

PIP – QUIK-COMBO Defibrillator ECG Characteristic Tests

The ECG characteristic tests consist of ECG gain, ECG restore, and a positive R-wave test. These three 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 ECG Restore Test
PIP - QUIK-COMBO Defibrillator a Positive R-wave Test

PIP – Quik-Combo Defibrillator ECG Gain

To perform ECG Gain Test:

1. Program the defibrillator analyzer output for a 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. Confirm printed signal amplitude is between 36mm to 44mm, peak to peak.
5. Turn the printer OFF.

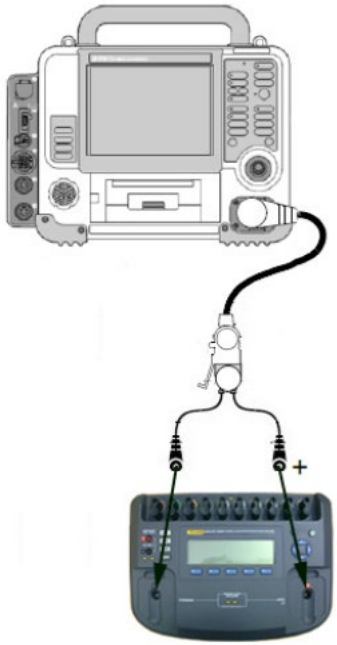


Figure 1.43—QUIK-COMBO ECG characteristics test setup

PIP – Quik-Combo Defibrillator ECG Restore

To perform ECG Restore Test:

1. Press ENERGY SELECT on the device and select 360 J.
2. Press PRINT to begin recording.
3. Press CHARGE.
4. Upon reaching full charge, press SHOCK to discharge the device into the defibrillator analyzer.
   Note: Allow the printer to run until the defibrillation event and associated sine waveform finish printing.
5. Turn the printer OFF.

6. Verify the Shock # marker and Energy Delivered event marker are recorded on the Paddles printout as shown in Figure 1.44.
7. Verify the signal baseline on the Paddles printout restores to zero offset within 0.5 seconds of transfer.
8. Verify the amplitude on the Paddles printout restores to >50% of the amplitude restored within 3 seconds.

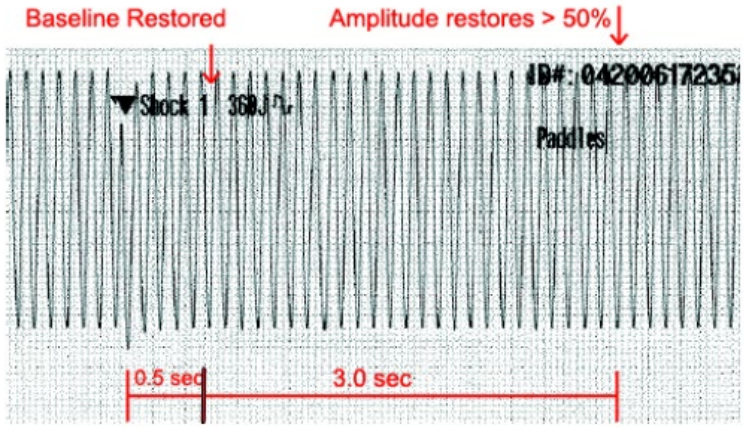


Figure 1.44—QUIK-COMBO ECG restore test printout

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

To perform a positive R-wave tests:

1. Impulse 7000DP is programmed for a 1-mv, ECG Normal Sinus Rhythm, 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 positive R-wave referenced from baseline recorded on printer paper as shown in Figure 1.45.
7. Turn the Device OFF.

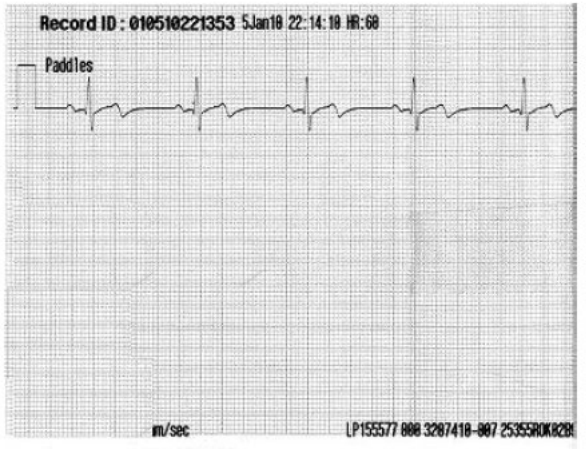


Figure 1.45—QUIK-COMBO ECG A positive R-wave test printout

PIP – Standard Paddles User 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 paddle wells after use and before performing the Standard Paddles User Test.

To perform Standard Paddles User Test:

1. Connect the standard paddles to the device.
2. Place the paddles in the paddle wells.
3. Turn the device ON.
4. Rotate the Sternum paddle ENERGY SELECT dial to select 10 J.

   Note: Discharging >10 J into the paddle wells may damage the defibrillator.

5. Press CHARGE on the Apex paddle.
6. Press only the Apex paddle's SHOCK button and confirm that the defibrillator does not discharge. Release the SHOCK button.
7. Press only the Sternum paddle's SHOCK button and confirm that the defibrillator does not discharge. Release the SHOCK button.
8. With the paddles still in the paddle wells, press both SHOCK buttons simultaneously.
9. Confirm the message ABNORMAL ENERGY DELIVERED displays on the screen.

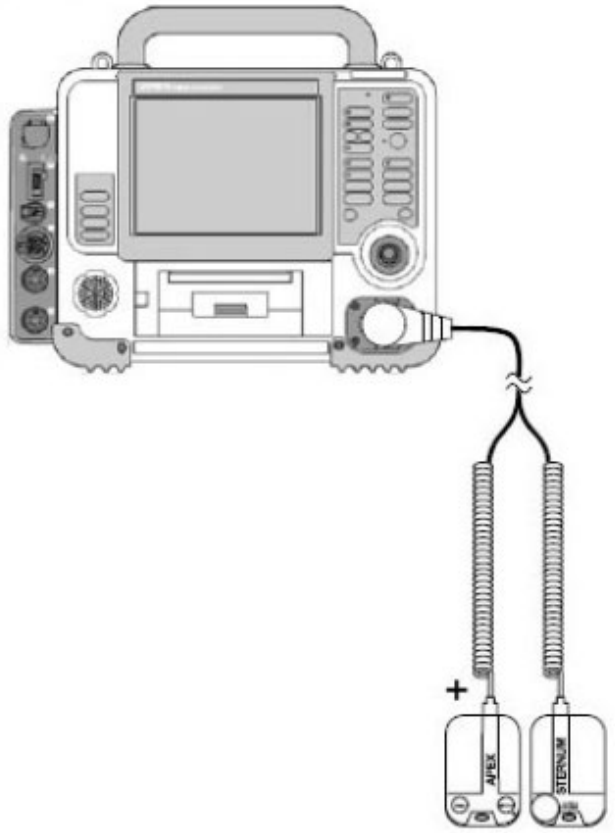


Figure 1.46—Standard paddles test diagram

PIP - Standard Paddles Defibrillator Delivered Energy Tests

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 surfaces except as described below.

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

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 Defibrillator Delivered Energy Test:

1. Place Standard Paddles onto the defibrillator analyzer as shown in Figure 1.47.
2. Program the Defibrillator Analyzer to measure an Energy Output.
3. Turn the Deice ON.
4. Rotate STERNUM PADDLE ENERGY SELECT dial to the level being tested (10J, 200J and 360J).
5. Press CHARGE Button on Standard Paddles and wait for the device to reach full charge.
6. Press SHOCK on Standard Paddles to discharge the device energy.
7. Verify the measured delivered energy is between the values for each test level as list in Table below

Energy Level (J)	Acceptable Output (J)
10	9.1 to 10.9
200	186.0 to 214.0
360	334.9 to 384.9

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

8. Continue with the next test.

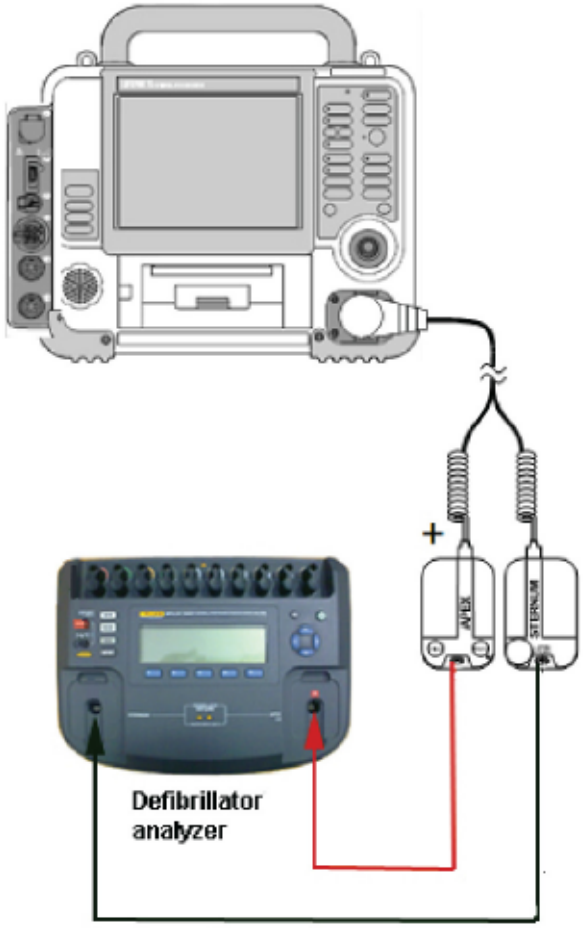


Figure 1.47—Standard paddles defibrillator delivered energy setup

PIP- Standard Paddles – Defibrillator Charge Time and Sync Tests

The Standard Paddles Defibrillator Charge Time and Sync Test consist of:

PIP- Standard Paddles Defibrillator Charge Time Test
PIP- Standard Paddles Defibrillator Sync Test

PIP- Standard Paddles – Defibrillator Charge Time Test

To perform Standard Paddles Defibrillator Charge Time Test:

1. Place Standard Paddles onto the defibrillator analyzer as shown in Figure 1.48, using the appropriate adapters.
2. Rotate STERNUM PADDLE ENERGY SELECT dial to 360 J.
3. To test the device charge time using a stopwatch:
   - Press CHARGE and start the stopwatch timer at the same time.
   - Stop the timer when the device reaches full charge at 360 J.
4. Verify the charge time is 10 seconds or less.

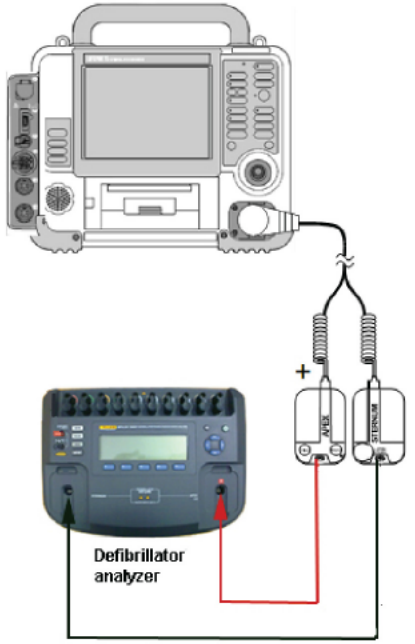


Figure 1.48—Standard paddles defibrillator charge time test setup

PIP –Standard Paddles Defibrillator Sync Test

To perform Standard Paddles Defibrillator Sync Test:

1. Establish the setup as shown in Figure 1.49.
2. Set the device ECG SIZE to 1.0.
3. Set the LEAD selection to Lead II.
4. Set defibrillator analyzer to measures SYNC.
5. Press the SYNC button on the device.
6. Verify that the SYNC LED is on and R-wave markers appear on the ECG Waveform.
7. Press ENERGY SELECT on the device and select 10 J.
8. Charge the device to 10 J. Upon reaching full charge, press and hold SHOCK key to discharge the device.
9. Verify the measured sync delay is 60 ms or less.

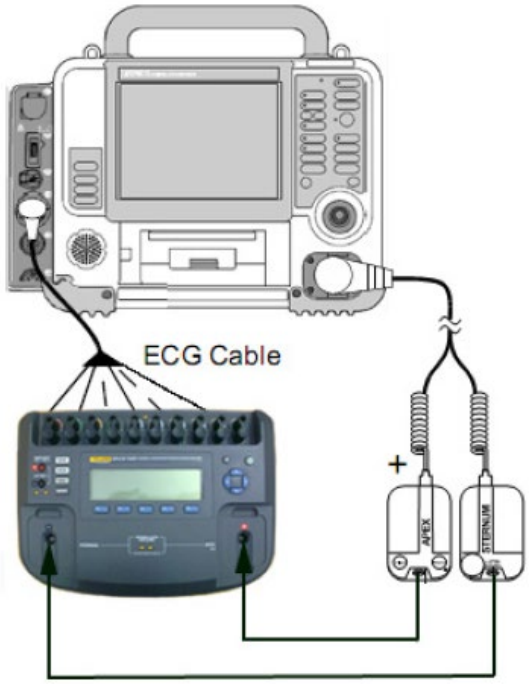


Figure 1.49—Standard paddles defibrillator sync test setup

PIP – Standard Paddles Defibrillator ECG Characteristics Tests

The standard paddles ECG characteristics tests consist of three tests combined into this one PIP. The tests are ECG gain, ECG restore, and a positive R-wave. Step numbers are continuous from one step to the next.

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

PIP - Standard Paddles Defibrillator ECG Gain Test
PIP - Standard Paddles Defibrillator ECG Restore Test
PIP - Standard Paddles Defibrillator a Positive R-wave Test

PIP- Standard Paddles Defibrillator ECG Gain Test

To perform ECG Gain Test:

1. Program the defibrillator analyzer output for a 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.
5. Turn the printer OFF.

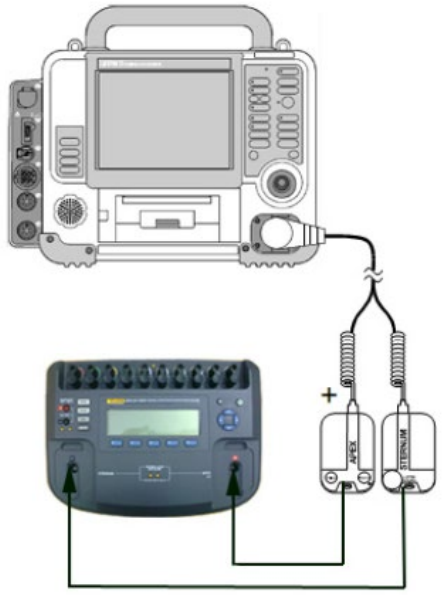


Figure 1.50—Standard paddles ECG characteristics test setup

PIP- Standard Paddles Defibrillator ECG Restore Test

To perform ECG Restore Test:

1. Press ENERGY SELECT on the device and select 360 J.
2. Press PRINT to begin recording.
3. Press CHARGE.
4. Upon reaching full charge, press SHOCK to discharge the device into the defibrillator analyzer.
   NOTE: Allow the printer to run until the defibrillation event and associated sine waveform finish printing.
5. Turn the printer OFF.
6. Verify the Shock # marker and Energy Delivered event marker are recorded on the Paddles printout.
7. Verify the signal baseline on the Paddles printout restores to zero offset within 0.5 seconds of transfer.
8. Verify the amplitude on the Paddles printout restores to >50% of the amplitude restored within 3 seconds.

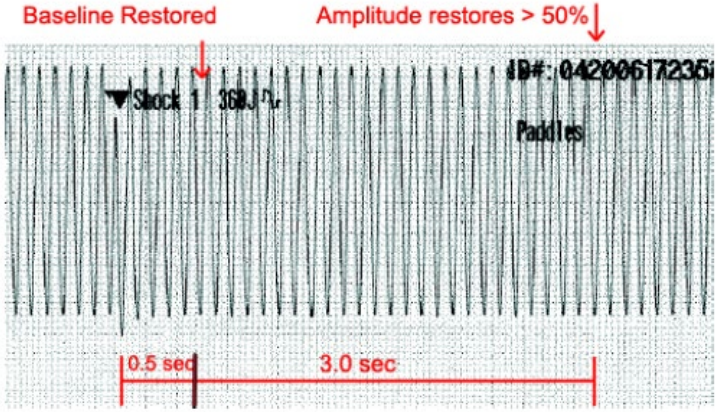


Figure 1.51—Standard paddles ECG restore test printout

PIP – Standard Paddles Defibrillator a Positive R-Wave Test

To perform a positive R-wave tests:

1. Set defibrillator analyzer for a 1-mv, ECG Normal Sinus Rhythm, 60BPM.
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 positive R-wave referenced from baseline recorded on printer paper.
7. Turn the device OFF.

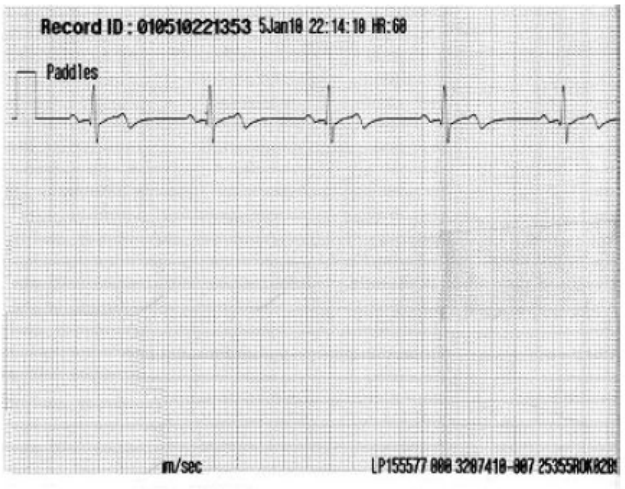


Figure 1.52—Standard paddles ECG A positive R-wave printout

PIP - Pacer Characteristic Tests

The pacer characteristics Tests consist of:

PIP- Pacer Leads-Off Detection Test
PIP- Pacer Output Current Test
PIP- Pacer Pulse Width Test

PIP - Pacer Leads-Off Detection

To perform pacer leads-off detection:

1. Establish the setup as shown in Figure 1.53.
2. Turn the device ON.
3. Set the defibrillator analyzer to measure peak current pacing parameters.
4. Press PACER button on the device.
5. Verify the PACER LED is on and the Pacer overlay appears.
6. Disconnect one of the therapy cable connections from the defibrillator analyzer.
7. Verify the Pacing/Connect Electrodes overlay appears, accompanied by an audible alarm.
8. Reconnect the therapy cable connection. Verify the Pacing/Connect Electrodes overlay disappears and the alarm stops.



Figure 1.53—Pacer leads-off 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.

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.

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 60BPM.
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)

Peak Current Level (mA)	Acceptable Output (mA)
10	5 to 15
100	91 to 109
200	181 to 219

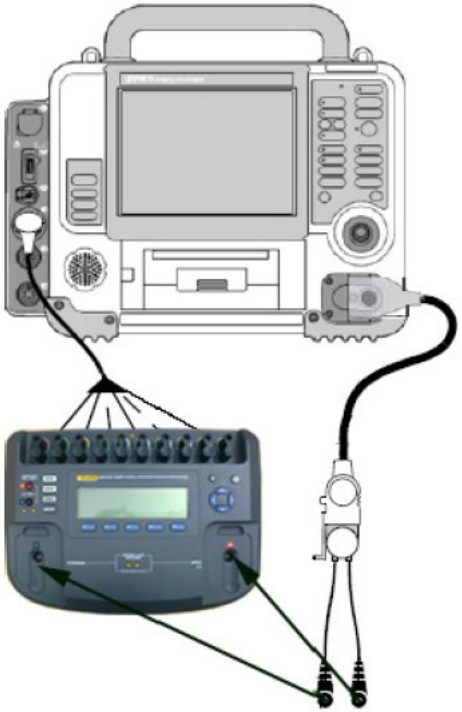


Figure 1.54—Pacer output current test setup

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 19.2 and 20.8 ms.

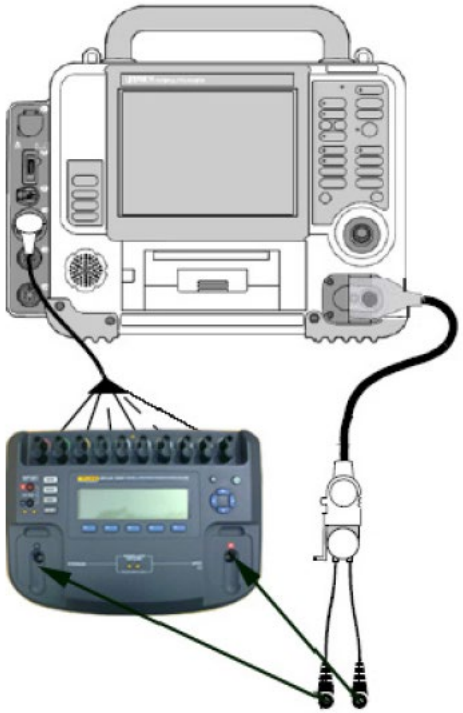


Figure 1.55—Pacer pulse width test setup

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

NOTE: TCP - Pacer Self-Calibration is not applicable to devices containing the service reference number 4 icon. 

PIP - Patient Impedance Test

To perform patient impedance sense circuitry:

1. Connect the QUIK-COMBO therapy cable to the QUIK-COMBO test post adapter cable.
2. Connect the QUIK-COMBO test post snaps to a decade resistance box, using the appropriate adapters as shown in Figure 1.56.
3. Set the decade resistance box to 50 ohms.
4. Turn the device ON, and set the lead selection to PADDLES.
5. Verify the PADDLES LEAD OFF message is not visible.
6. Set the decade resistance box to 370 ohms.
7. Verify the device displays the PADDLES LEADS OFF message.
8. Set the decade resistance box to 238 ohms.
9. Verify the PADDLES LEAD OFF message not visible.
10. Remove the decade resistance box.
11. Turn the device OFF and continue with the next test.

CAUTION
POSSIBLE EQUIPMENT DAMAGE

Do not defibrillate when connected to the Decade Resistance box.

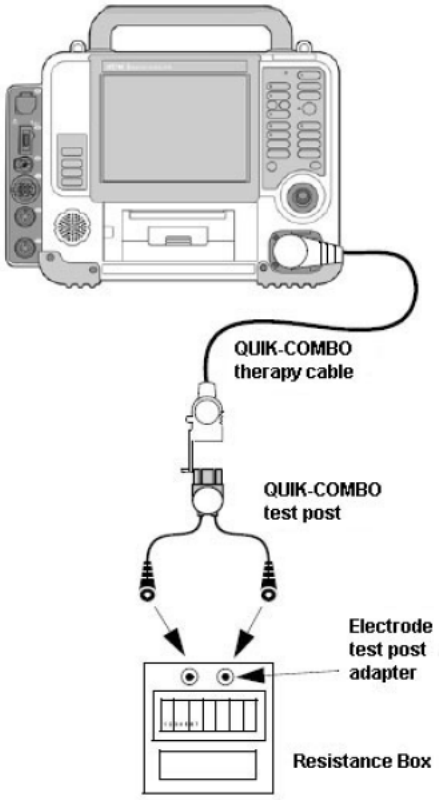


Figure 1.56—Patient impedance test setup

PIP - Data Management

PIP- Bluetooth Wireless Technology

To perform these tests if the device is equipped with the Bluetooth wireless technology option.

NOTE: If LIFENET Device Communications for CODE-STAT is being used for the first time, perform the TCP-CODE-STAT Device Communication Setup on your PC first.

To pair your computer to the device using Bluetooth wireless technology:

1. Ensure the CODE-STAT Reviewer application is open on your PC.
2. Select DOWNLOAD WIZARD.
3. Double-click the LIFEPAK 15 icon.
4. On the LIFENET Download Wizard dialog box, select the SKIP AUDIO DOWNLOAD Checkbox (if available) and the click NEXT.
   Note: Do not close CODE-STAT Reviewer application
5. Set up your computer as follows:
   a. Double –click the BLUETOOTH DEVICES icon in the taskbar.
   b. Select the OPTIONS tab.
   c. Select the TURN DISCOVERY ON checkbox in the Discovery section. Discovery can now be enable/disable using the Fn F2 keyboard combination.
   d. In the Connection section, select the ALLOW BLUETOOTH DEVICES TO CONNECT TO THIS COMPUTER checkbox and the ALERT ME WHEN A NEW BLUETOOTH DEVICE WANTS TO CONNECT checkbox.
   e. Select the SHOW THE BLUETOOTH ICON IN THE NOTIFICATION AREA Checkbox in the Options section.
   f. Click APPLY.
   Note: Do not exit the Bluetooth wireless technology application on your PC.

6. Rename your computer to the Physio Service Class (PSC) name as follows:
   a. Rename your computer to the Physio Service Class (PSC) name as follows:
   b. Select BLUETOOTH MODULE and click PROPERTIES.
   c. Select the ADVANCED tab.
   d. Insert “B_” before the current computer name (for example, change SMITHJ1- L2 to B_SMITHJ1-L2).
   e. Click OK, and then click OK again to exit the Bluetooth wireless technology application on your PC.

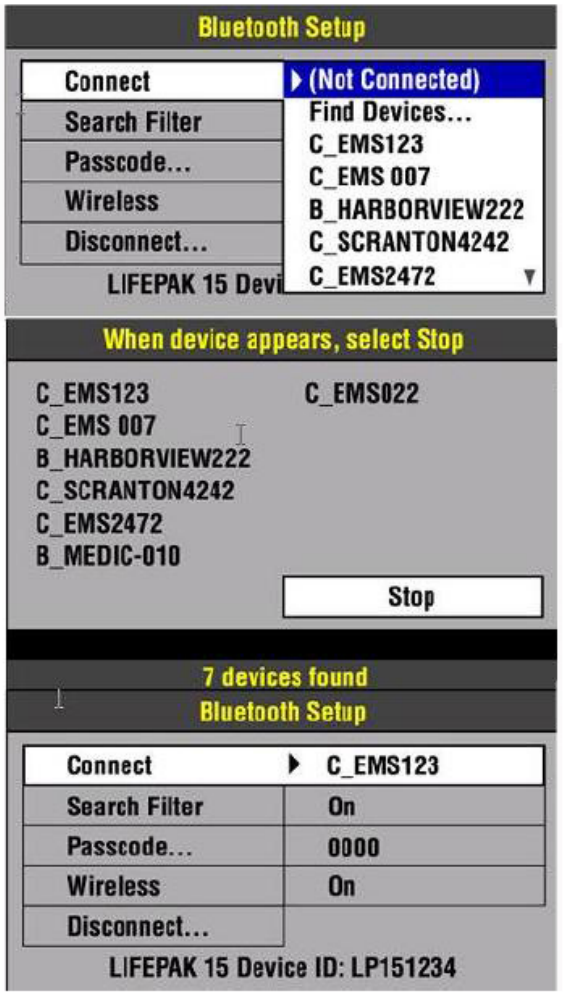


Figure 1.57—Bluetooth menus

7. Pair the device to your computer as follows:
   a. Turn the device ON.
   b. Rotate the SPEED DIAL to select the BLUETOOTH icon on the HOME SCREEN, and then press the SPEED DIAL to display the Bluetooth Setup menu.
   c. Set SEARCH FILTER to ON if you want to find only devices that have the PSC (Physio Service Class); otherwise, set SEARCH FILTER to OFF.
   d. Make sure WIRELESS is set to ON
      Note: When Bluetooth wireless technology is installed, the default settings for WIRELESS and SEARCH FILTER are ON.
   e. Select CONNECT and then select FIND DEVICES.
   f. The Find Devices menu appears.
      Note: The LP15 begins searching for products in the area that are equipped with Bluetooth wireless technology and meet the search filter criteria. The products are displayed under OTHER FOUND, with the most recently found product appearing at the top of the list. If the device is set to WIRELESS OFF, the wireless status changes to WIRELESS ON when FIND DEVICES is selected.
   g. When your computer name (for example, B_SMITHJ1-L2) appears in the list use the SPEED DIAL to select STOP and return to the Bluetooth Setup menu.
   h. Use the SPEED DIAL to scroll through the list and select the computer that you want to connect to using Bluetooth wireless.
   i. When Bluetooth wireless technology passcode (default password is 0000).
      Note: The passcodes on the LP15 and the PC must match.
   j. When the connection is made, verify that an alert tone sounds, the Bluetooth wireless technology LED on the Bluetooth icon on the HOME SCREEN is illuminated, and the CONNECTED TO (YOUR PC NAME) message briefly appears in the message area.
8. Turn the device OFF to exit the Bluetooth Setup menu.
9. Continue to the next test.

PIP - Leakage Current Tests

Leakage Current tests consist of:

PIP - Leakage Current Test Setup
- PIP-Leakage Current Battery Powered Test Setup
- PIP-Leakage Current ACPA Powered Test Setup

PIP - Direct Equipment Leakage and Direct Applied Part Leakage Test Setup
PIP - Direct Equipment Leakage Test - Single Fault Condition (SFC)
PIP - Direct Applied Part Leakage Test Setup
PIP - Direct Applied Part Leakage Test – ECG
PIP - Direct Applied Part Leakage Test - Therapy
PIP - Direct Applied Part Leakage Test - SpO2
PIP- Leakage Current Test Limits

Leakage Current Introduction

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 the following figures:

WARNING

Do not defibrillate when the leads are connected to the ESA-612.

The Leakage Current Test Setup consist of:

PIP-Leakage Current Battery Powered Test Setup
PIP-Leakage Current ACPA Powered Test Setup

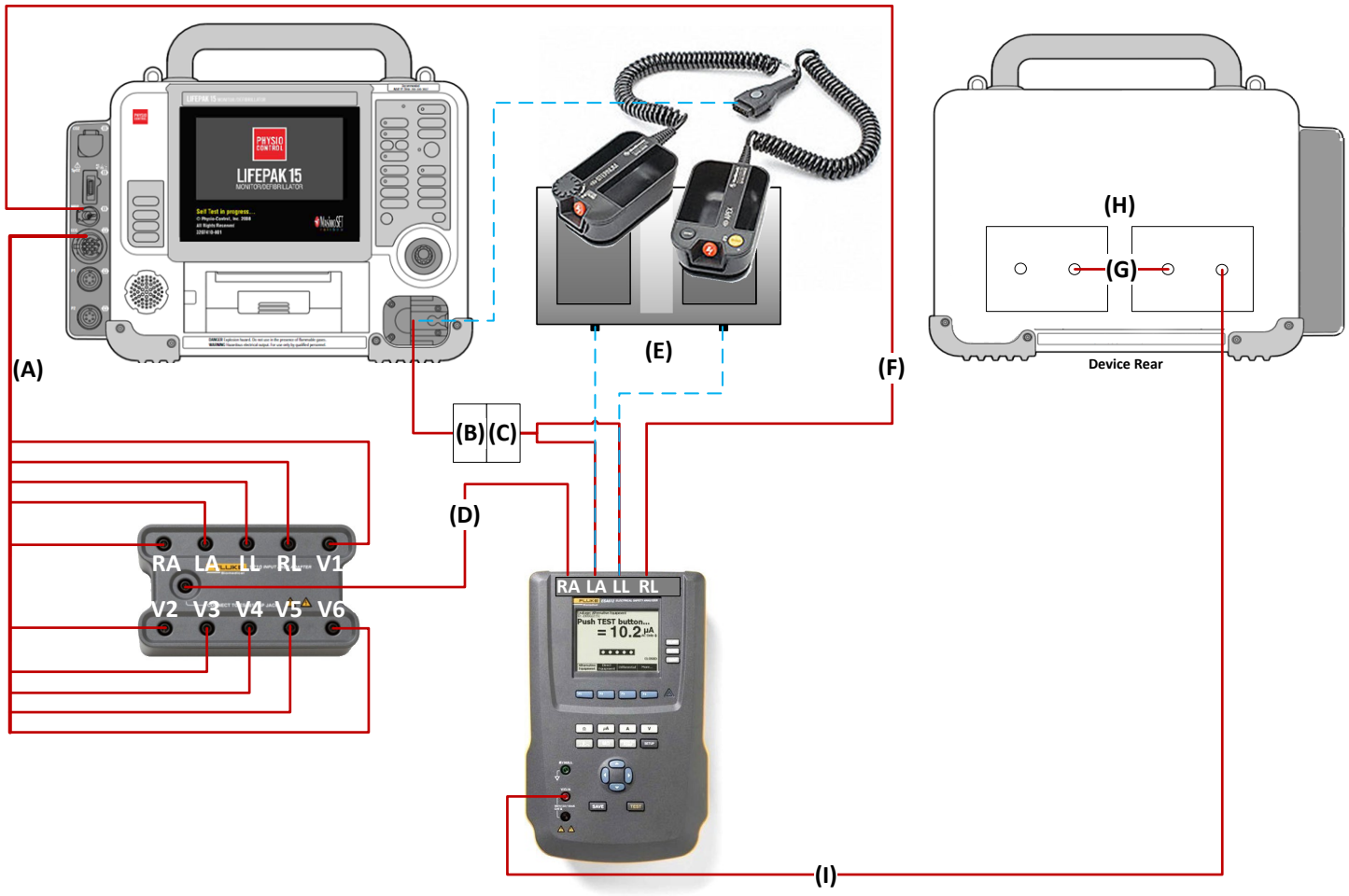
PIP-Leakage Current Battery Powered Test Setup

To perform Leakage Current Test for Battery Powered:

NOTE: Perform leakage current tests for the following applicable conditions when Battery powered for Direct Applied Parts at 120 or 240 VAC. Complete the setup (Leakage Current Test Setup Battery Powered).

1. Install 2 battery adapters to 2 battery wells of the device.
2. Connect 2 battery adapters together by using the appropriate connection.
3. Connect the Banana cable between the Safety Analyzer ESA-612 (at V/ohms/A) and the Battery Adapter.
4. Connect the customer ECG Lead cable between the device and the 1210 box. Connect the 1210 box to the Safety Analyzer ESA-612 at RA snap.
   Note: The customer ECG cable is 12 Lead or 5 Lead or 3 Lead.
5. Connect the Therapy cable (Quik Combo or Standard Paddles) between the device and the Safety Analyzer ESA-612 at LL and LA snap.
6. Connect the SpO2 Leakage cable between the device and the Safety Analyzer ESA-612 at RL snap (if equipped with SpO2 feature).

A. 3/5/12 Lead ECG Cable
B. Quick-Combo Cable
C. Quick-Combo to ECG snap or banana cable.
D. Banana Cable.
E. Optional Hard Paddles in test fixture.
F. Cable, test, LP15 SPO2 connector to ECG snap or banana plug.
G. Banana cable is connected between two battery adapters
H. Battery adapters at rear of device.
I. Banana cable connected between battery adapter and ESA-612 at (V/Ohms/A)



1.58 Leakage Currents Battery Powered Setup

PIP- Leakage Current ACPA Powered Test Setup

To perform Leakage Current Test for AC Powered:

NOTE: Perform leakage current tests for the following applicable conditions when AC powered for Direct Equipment Leakage and Direct Applied Parts at 120 or 240 VAC. Complete the setup (Leakage Current Test Setup AC Powered (ACPA)

1. Install 2 battery adapters to 2 battery wells of the device. Connect 2 battery adapters together by using the appropriate connection.
2. Connect the Banana cable between the Safety Analyzer ESA-612 (at V/ohms/A) and the Battery Adapter.
3. Connect the customer ECG Lead cable between the device and the 1210 box. Connect the 1210 box to the Safety Analyzer ESA-612 at RA snap.
   Note: The customer ECG cable is 12 Lead or 5 Lead or 3 Lead.
4. Connect the Therapy cable (QUIK-COMBO or Standard Paddles) between the device and the Safety Analyzer ESA-612 at LL and LA snaps.
5. Connect the SpO2 Leakage cable between the device and the Safety Analyzer ESA-612 at RL snap (if equipped with SpO2 feature).
6. Connect the ACPA power cable between the ACPA and the Safety Analyzer ESA-612 at AC output.
7. Connect the ACPA Aux connector to the device.

WARNING

Do not defibrillate when the leads are connected to the ESA-612.

A. 3/5/12 Lead ECG Cable
B. Quick-Combo Cable
C. Quick-Combo to ECG snap or banana cable.
D. Banana cable
E. Optional Hard Paddles in test fixture..
F. Cable, test, LP15 SPO2 connector to ECG snap or banana plug
G. Banana cable is connected between two battery adapters
H. Battery adapters at rear of device.
I. Banana cable connected between battery adapter and ESA-612 at (V/Ohms/A)
J. ACPA plugged into ESA-612 AC receptacle.
K. AC Power Adapter (ACPA)
L. ACPA plugged into device power connector

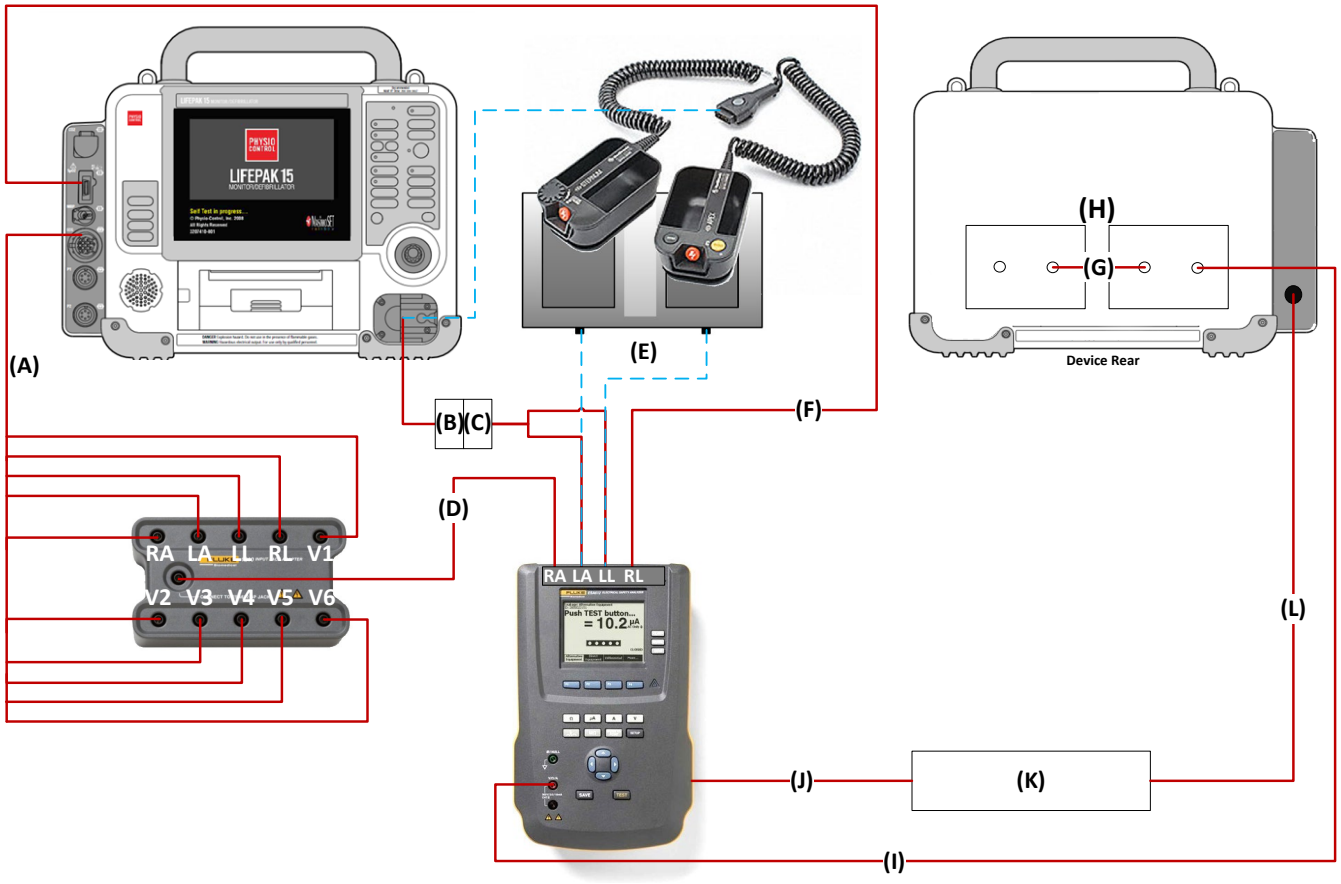


Figure 1.59 Leakage Currents AC Powered Setup

PIP - Direct Equipment Leakage and Direct Applied Part Leakage Test Setup

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

- Press the Setup button on the safety analyzer
- Press the F4/More button
- Press the F2/Instrument button
- Press the F1/Standard button
- Press the Up/Down arrows to select the 62353 standard as shown in Figure below
- Press the Done button

WARNING

Do not defibrillate when the leads are connected to the ESA-612.

PIP - Direct Equipment Leakage Test - Single Fault Condition (SFC)

WARNING

Do not defibrillate when the leads are connected to the ESA-612.

1. Press the **µA** button on the safety analyzer.
2. 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

3. Verify the measured current is between 15 µA and 270 µA (120 Vac) or between 15 µA and 450 µA (240 Vac).

PIP - Direct Applied Part Leakage Test Setup

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.

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

- Press the **µA** button on the safety analyzer
- Press the **F4/MORE** button
- Press the **UP/DOWN** arrows to select the appropriate A.P. groups as shown in Figure 1.60.
- Press **F1/SELECT** then F1/Direct A.P.

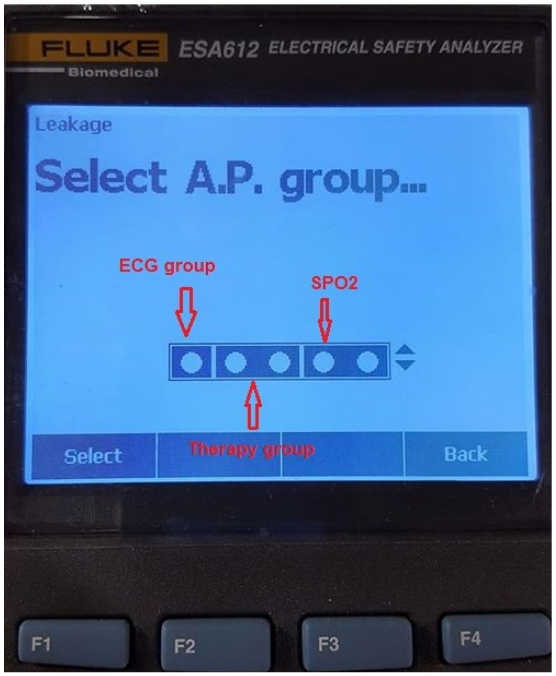


Figure 1.60 D.A.P Leakage Test Setup

PIP - Direct Applied Part Leakage Test – ECG  (Type CF)

WARNING

Do not defibrillate when the leads are connected to the ESA-612.

1. 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)

2. Press the **TEST** button to measure the Direct Applied Part Leakage current.
3. Verify the measured current is between 5 µA and 45 µA (120 and 240 Vac).

PIP - Direct Applied Part Leakage Test - Therapy  (Type BF)

1. 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)

2. Press the **TEST** button to measure the Direct Applied Part Leakage current.

3. Verify the measured current is between 5µA and 2625 µA (120 and 240 Vac).

PIP - Direct Applied Part Leakage Test - SpO2  (Type BF)

Note: Execute this test if the LIFEPAK 15 is equipped with SpO2.

1. 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)

2. Press the Test button to measure the Direct Applied Part Leakage current.
3. Verify the measured current is between 5µA and 2625 µA (120 and 240 Vac).

PIP- Leakage Current Test Limits

The test limits listed in the table below apply to safety analyzers operating on 120 or 240 VAC. Test limits apply to AC or DC leakage tests.

TABLE - IEC 62353 Leakage Test Limits

Leakage Test to be Performed	Test Conditions	Range at 120V, 60HZ	Range at 240V, 50HZ
ECG Direct Applied Part	Normal Reversed	5 - 45 µA 5 - 45µA	5 - 45 µA 5 - 45µA
Therapy (Apex, Sternum) Direct Applied Part	Normal Reversed	5 - 2625µA 5 - 2625µA	5 - 2625µA 5 - 2625µA
SPO2 Direct Applied Part	Normal Reversed	5 - 2625µA 5 - 2625µA	5 - 2625µA 5 - 2625µA
Direct Equipment Leakage	Normal, Open Earth Reversed, Open Earth	15 - 270µA 15 - 270 µA	15 -450 µA 15 - 450 µA

PIP – Disabling/Resetting Maintenance Prompt

To disable or reset the maintenance prompt, see Disabling/Resetting the Maintenance Prompt Interval in the Preventive Maintenance section.

LIFEPAK®15 MONITOR/DEFIBRILLATOR

Performance Inspection Procedure (PIP)

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

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