LIFEPAK® 35 monitor/defibrillator

Performance Inspection Procedure (PIP)

stryker

The Performance Inspection Procedure (PIP) is a set of manual test procedures used by service personnel. It will be used as an operational closed-case evaluation of the LIFEPAK 35 monitor/defibrillator. This section describes 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 repair, replacement, or calibration procedures are completed. The Performance Inspection Procedure Checklist is provided as an optional tool for the recording of PIP test results.

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PIP - Scope and applicability

This PIP applies to the LIFEPAK35 monitor/defibrillator exclusively. To complete the PIP, you must perform the combination of manual and computer assisted tests outlined in the PIP – Instructions below. All PIP tests should 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, software, and personnel.

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.

PIP - Glossary

PIP: Performance Inspection Procedure

TCP: Test Calibration Procedure

DUT: Device under test

PSST: Procare Services Support Tool

WCT: Wi-Fi Config tool

PIP - Resource requirements

This section describes the requirements for PIP equipment, PIP test equipment verification, PIP Computer with PSST and WCT installed, PIP workstation power, and PIP personnel qualifications.

PIP - 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 or better specifications may be substituted. Use only ECG, SpO2, CO2, Temp, IP, and NIBP cables that are specified for use with this device. Protection of the device against defibrillator discharge is dependent on the use of cables that are specified by Stryker.

PIP - 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.

PIP - Computer with PSST and WCT installed

To perform portions of the PIP, you must have access to a computer with the latest version of the PSST (ProCare Services Support Tool) application and the WIFI Config Tool (WCT) application installed from LIFENET® System.

Note: You do not need to install PSST or WCT application if you have the latest version already installed on your computer.

PIP - Workstation power

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

PIP - Personnel qualifications

Service personnel who perform the PIP must be thoroughly familiar with the operation of the LIFEPAK 35 monitor/defibrillator and must meet at least one of the following requirements (or the equivalent):

- Associate of Applied Science, with an emphasis in biomedical electronics.
- Certificate of Technical Training, with an emphasis in biomedical electronics.

  Note: Stryker Biomedical Training program does not provide a certificate.
- Equivalent biomedical electronics experience.

PIP - Test equipment requirements

Equipment	Specification or Description	Manufacturer	Part number/Catalog number (REF)
Defibrillator Analyzer	Power range: 0-450 J Load resistance: 50Ω Accuracy and/or guard banding must be sufficient to ensure test limits.	Fluke	Impulse 7000DP
Safety Analyzer	120 or 240 V AC line voltage Current range: 0-1999 µA. Accuracy and/or guard banding must be sufficient to ensure test limits.	Fluke	ESA612
Decade Resistance Box	Range: 0-9MΩ Resolution: 1Ω Accuracy: 1%	IET	Model RS-200
Digital Pressure Meter	1% accuracy for pressure and vacuum	Fluke	DPM2 Plus
Printer Cable	Cable Printer, LIFEPAK 35. Note: Optional, only needed if testing printer	Stryker	11330-000014
Printer	Optional Printer, 100mm, LIFEPAK 35	Stryker	11241-000016
Assy, QUIK-COMBO® Test Cable, Therapy	QUIK-COMBO Plug to Banana Plugs	Stryker	3335630-001
LIFEPAK Therapy Cable	Assy, Cable, Therapy, LIFEPAK 35	Stryker	11113-000007 or 11113-000008

Equipment	Specification or Description	Manufacturer	Part number/Catalog number (REF)
LIFEPAK 4-Wire ECG Cable, 1.5 m (5 ft), AHA or LIFEPAK 4-Wire ECG Cable, 2.4 m (8 ft), AHA	Assy, Cable, ECG, 4-Wire, AHA 5ft or 8ft Note: may use IEC equivalent	Stryker	11111-000036 or 11111-000035
12/15-Lead ECG Cable 6-Wire Precordial Attachment, AHA	Assy, Cable, ECG, 15-Lead, 6-Wire Cable, Precordial, AHA Note: may use IEC equivalent	Stryker	11111-000037
15-Lead ECG Cable 3-Wire Precordial Attachment	Assy, Cable, ECG, 15-Lead, 3-Wire Precordial, AHA, Optional 13 Wire	Stryker	11111-000041
NIBP Tubing, Straight, 2.7 m (9 ft) or NIBP Tubing, Straight, 3.7 m (12 ft)	ASSY - NIBP ROHS, 9FT, BAYONET, UDI or NIBP-Tubing, 12FT, Bayonet, UDI Note: Use either 9ft or 12ft NIBP hose	Stryker	11996-000391 Or 21300-008146
Service Kit - Cal/Press, Syringe, Locking, NIBP	NA	Stryker	3012432-003
Assy, Tubing, Leak Test, MDT CO_2	NA	Stryker	3335916-001
Assy, Tubing, Calibration Test, MDT CO_2	NA	Stryker	3335916-003
Chem- Gas, Mixture, Calibration, Aerosol	5% CO_2, 20.6 % O_2, BAL, N2	Stryker	21300-001572
Assy, Cable, Leakage Test, Masimo SpO_2	Use for ESA 612	Stryker	3335631-000
1210 Adapter (2 each)	Second adapter needed for 13 wire Leakage testing	Fluke	1210

Equipment	Specification or Description	Manufacturer	Part number/Catalog number (REF)
BJ2 ECG Input Jack Adapter	Use for 1210 Adapter (2 each)	Fluke	BJ2
Assy, Cable, Service Test, Leakage USB GND, LIFEPAK 35	Connect between Safety Analyzer and USB system GND	Stryker	3344955-000
Banana Plug Cable	Connect between Safety Analyzer and BJ2 ECG Input Jack Adapter.	Pomona or equivalent	B-24-2 or equivalent
LIFEPAK Access Port Cable	Assy, Cable, Access Port, LIFEPAK 35	Stryker	11330-000007
LIFEPAK FLEX Lithium-Ion Battery	Battery, LI-ION, LIFEPAK 35	Stryker	11335-000001
LIFEPAK 35 AC Power Adapter	Power Adapter, AC to DC, LIFEPAK 35	Stryker	41335-000001
Personal Computer	PC with internet access and Windows® 10 or above OS	HP or equivalent	EliteBook 840 or later/equivalent
Cable, Test, Fogg TP400 Interface	NA	Stryker	3308413-000
Assy, Cable, Service Test, IP, LIFEPAK 35	NA	Stryker	3344024-000
Temperature simulator	NA	FOGG	TP400 Temperature Probe Simulator.
Invasive Pressure Simulator	NA	FOGG	BP-28 Pressure Transducer Simulator.
ICU Invasive Pressure Adapter Cable, 2.44 m (8 ft)	Assy, Cable, Adapter, IP, ICU, LIFEPAK 35	Stryker	11230-000021

Equipment	Specification or Description	Manufacturer	Part number/Catalog number (REF)
ASSY, CABLE, ADAPTER, TEMPERATURE, LP35, 6FT or Temperature Adapter Cable, 3.0 m (10 ft)	ASSY, CABLE, ADAPTER, TEMPERATURE, LIFEPAK 35, 10FT or 6FT	Stryker	11230-000023 or 11230-000022
USB Flash Drive	Must be an empty USB storage device	SanDisk or equivalent	SDCZ60 or equivalent
CABLE, TEST, ECG SNAP TO BANANA PLUG	For use in testing electrical safety for 13-wire ECG only	Stryker	3305684-000
Rainbow 25-pin, Patient Cable, 1.2 m (4 ft)	CABLE, PATIENT, RNBOW25, RC4, RTANG, 4FT, MASIMO	Stryker	11996-000432 or Functional equivalent such as 11996-000429
Rainbow DCI Reusable Sensor, Adult	Rainbow DCI Adt Reusable Sensor, REF 2696,ROHS Used with CABLE, PATIENT, RNBOW25, RC4, RTANG, 4FT, MASIMO. Functional equivalents are acceptable	Stryker	11171-000049
AC Power Cord		Tripp Lite or equivalent	P007-L03 or equivalent
Cellular Modem	Cellular Modem, LIFEPAK 35 Note: any region modem can be used.	Stryker	11150-000020 or 11150-000021 or 11150-000022

PIP - Instructions

PIP - General instructions

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 listed in the PIP - Test equipment requirements table . Possible improper device performance.
-  Shock Hazard: Symbol and warning used throughout this document warning operator when high voltage is present during tests.

PIP - Entering service mode

The following describes how to set the LIFEPAK 35 monitor/defibrillator up to enter Service Mode.

1. Press the Main Menu button  at the bottom of the touchscreen and press Options.
2. Select “Service Mode”.

   Note: A pop up indicating a need to enter a 4-digit pin (default is 0000).
3. Allow the unit to cycle power, once complete, the unit will be in Service Mode.

PIP - Auxiliary power

This procedure has been written with the assumption that the device is configured with the standard AC power adapter connector to interface with the LIFEPAK 35 Power Adapter 41335-000001.

PIP - PSST access

The following describes how to access the Procare Services Support Tool (PSST) application to assist with varying calibrations/tests throughout the PIP and TCP.

Note: Only perform if you do not have the latest version of the PSST application installed on your computer

1. Log in to your LIFENET System account.
2. Pull down the **DOWNLOADS** menu.
3. Select ProCare Services Support Tool.
4. Click **Download** on the latest version.
5. After the Procare Services Support Tool has downloaded, double-click the **PSST_setup_xxxx.exe** file to install it. If you don't see the file, look in your Downloads folder.

   Note: If any security warnings appear, select the option to allow the file.
6. When the **INSTALLSHIELD WIZARD** appears, select your language and click **NEXT**.
7. When you see the **INSTALLSHIELD WIZARD COMPLETED** screen, make sure the **LAUNCH PSST TOOL** checkbox is selected, and then click **FINISH**. The application shall be installed in C:\ProgramData\Microsoft\Windows\Start Menu\Programs\Stryker\ProCare Service Support Tool
8. Once installed, launch PSST and follow the onscreen instructions to connect a device and proceed to the Services Commands menu.

PIP - Wi-Fi config tool access

The following describes how to access the LIFENET Wi-Fi Config Tool to assist with Bluetooth/Wi-Fi Functionality tests

Note: only perform if you do not have the latest version of WCT.

1. Log in to your LIFENET System account.
2. Pull down the **Downloads** menu.
3. Click **ADD OR UPDATE WI-FI CONFIGURATION TOOL**.
4. Click **Download** on the latest version.
5. After the Wi-Fi Configuration Tool has downloaded, double-click the **WCT.xxxx_Setup.exe** file to install it. If you don't see the file, look in your Downloads folder.

Note: If any security warnings appear, select the option to allow the file.

6. When the **INSTALLSHIELD WIZARD** appears, select your language and click **NEXT**.
7. When you see the **INSTALLSHIELD WIZARD COMPLETED** screen, make sure the **LAUNCH WI-FI CONFIGURATION TOOL** checkbox is selected, and then click **FINISH**. The application shall install in C:\ProgramData\Microsoft\Windows\Start Menu\Programs\Physio-Control\Wi-Fi Configuration Tool

*Note: The Wi-Fi Configuration Tool should launch automatically after installation. If you need to start the Wi-Fi Configuration Tool manually, open the **START** menu on your computer, open the **PHYSIO-CONTROL** folder, and click **WI-FI CONFIGURATION TOOL**.*

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 in the Service Manual, 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. Check for missing fasteners, covers or other mechanical components and replace as needed.
4. Inspect the pins and connector housings of all QUIK-COMBO, and other therapy cables for damage.
5. Verify the spring button on the therapy cable connector is functional prior to engaging a therapy cable into the therapy connector.
6. Inspect the ECG, SpO_2, CO_2, NIBP, Temp/IP*, USB ports, Access Port, Cellular modem port and DC connectors for damage, cracks, or contamination (*if equipped).
7. Inspect the keypad and overlays for damage, cracks, separations.
8. Check all other accessory cables, LIFEPAK ECG, LIFEPAK Invasive Pressure Adapter, LIFEPAK Temperature Adapter, SpO_2 sensors, CO_2 tubing, NIBP tubing and related items for expiration dates, general condition, and suitability for use.
9. Inspect LIFEPAK 35 storage bags and carrying strap for damage.

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, LIFEPAK FLEX Lithium-ion batteries are showing more than 50% charged.

Note: A functional charged battery is one that does not return a LOW BATTERY, unrecognized, or end of life 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. Connect access port cable to PC.
5. Connect auxiliary power to the device.

PIP - Power management

PIP - Power on/self-test and device indicator test

To perform the Power On/Self-Test and Device Indicator Test:

1. Press POWER button  to turn the device ON.
2. Verify that during the power on, the device momentarily illuminates all front panel LEDs, including the service LED.
3. Verify that the Service LED is OFF and no Service wrench  display.
4. Verify that the Battery Charging indicator display.

PIP - Auxiliary power switching test

To perform Auxiliary Power Switching Test:

1. In the Battery wells 1 and 2, insert each LIFEPAK FLEX Lithium-ion battery into the battery well until it clicks into place.
2. Supply Auxiliary power to the device.
3. Verify the Auxiliary Power indicator  display. Green LED illuminated when defibrillator is connected to auxiliary power adapter, whether defibrillator is turned on or off.

   Note: When the LIFEPAK 35 monitor/defibrillator is connected to the Power Adapter, the Auxiliary Power indicator illuminates, and batteries automatically begin charging. When the device is not in use, battery charge level is best maintained if the Power Adapter is connected to an AC outlet and the device is turned off.
4. Turn on the device and verify that the battery icons appear but neither is highlighted.

   Note: Battery indications may look slightly different.
5. Unplug the Auxiliary power cable from the device. Verify that one of the device battery icon's number labels is highlighted.

PIP - Power Source Management Test

To perform Power Source Management Test:

1. Ensure 2 LIFEPAK FLEX Lithium-ion batteries were installed into the device and the auxiliary power cable is connected.
2. Ensure the device turns on.
3. Remove Battery 1. Verify the device indicates no battery installed  in Well 1 and the device is being powered by Battery 2  .

Note: To remove a battery, pinch the clip towards the back of the device and remove battery from well.

4. Reinsert Battery 1 and remove Battery 2. Verify the device indicates no battery installed  in Well 2 and the device is being powered by Battery 1  .
5. Reinsert Battery 2.
6. Reinsert Auxiliary power cable.

PIP - Modem functional test

Note: Modem functional testing is an optional test depending on if one is available

1. Connect a LIFEPAK cellular modem to the DUT through the Cellular modem port (located bellow the Access port connector).
2. Press the Main Menu button  at the bottom of the touchscreen and press System to recognizes a modem has been connected.

PIP - Printer functional testing

Note: Printer functional testing is an optional test depending on if one is available.

1. Connect the LIFEPAK printer to DUT using a LIFEPAK printer cable.
2. Verify the device recognizes a printer has been connected.

Note: This can also be done by performing PIP-SHIFT check if a printer is connected at test start.

PIP - SHIFT check

SHIFT check is an internal diagnostic test that is recommended to be performed daily. This function will perform a series of tests to verify the following functions:

To Perform SHIFT Check:

1. Turn the device ON.
2. Press the Main Menu button  at the bottom of the touchscreen and press Options.
3. Select SHIFT Check and press OK on the attention popup.
4. Select SHIFT Check and follow the instructions prompted to perform the tests/checks listed above.
5. Verify no tests fail while running SHIFT Check.

PIP - Auto test and date/time verification

To perform Auto Test and date/time verification test:

1. Press the Main Menu button  at the bottom of the touchscreen and press Options.
2. Select SYSTEM.
3. Once System menu is displayed, verify the Data & Time field is correct.
4. Press the Main Menu button  at the bottom of the touchscreen and press Options.
5. Select Shift Check and press OK on the attention popup.
6. Select Auto Test. This is a daily automated test that performs several functional tests.

   Note: If the date and time are incorrect, you may reset by going to Setup mode and selecting "Date/Time" located at the bottom of the menu.
7. Navigate to the Test Logs tab and verify Auto Test passed.
8. Turn off the device.

PIP - USB port functional test

To perform the USB Port Functional Test:

1. Turn Device On.
2. Insert a USB Flash Drive into any of the 4 front facing USB ports as shown in the following Figure 1.

Note: Make sure no files are present on USB storage device

Figure 1

3. Press the Main Menu button at the bottom of the touchscreen and press Options.
4. Verify that “Show mode” is populated in the boot options menu tab.
5. Repeat steps 2 through 4 for the remaining USB ports.

PIP - Therapy testing

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.

Therapy testing includes the following:

- PIP - Patient impedance test
- PIP - QUIK-COMBO Defibrillator delivered energy test
- PIP - QUIK-COMBO Defibrillator charge time at 360J test
- PIP - QUIK-COMBO Defibrillator synchronous cardioversion test
- PIP - QUIK-COMBO Paddles ECG gain test
- PIP - QUIK-COMBO Defibrillator ECG restore test
- PIP - QUIK-COMBO R-wave polarity test
- PIP - Pacer Leads-off detection test
- PIP - Pacer output current test
- PIP - Pacer pulse width test

PIP - Patient impedance test

CAUTION

POSSIBLE EQUIPMENT DAMAGE

Do not defibrillate when connected to the Decade Resistance box.

To perform Patient Impedance Test:

1. Establish the Patient Impedance Tests setup as shown in the following Figure 2.

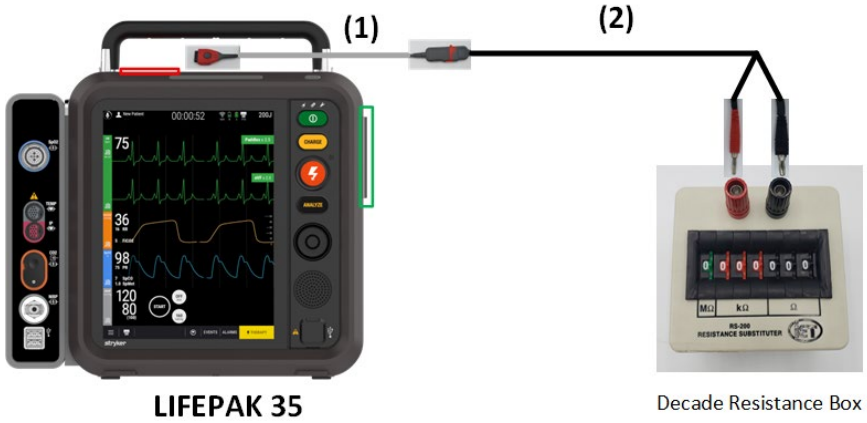


Figure 2

In Figure 2

Item 1: 11113-000007

Item 2: 3335630-001

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 is not visible.
5. Set the Decade Resistance box to 349 ohms.
6. Verify the device displays the PADDLES LEADS OFF message.
7. Set the Decade Resistance box to 254 ohms.
8. Verify the PADDLES LEADS OFF message is not visible.
9. Disconnect all the test cables from Decade Resistance box and the device.

PIP - QUIK-COMBO Defibrillator delivered energy test

To perform QUIK-COMBO Defibrillator Delivered Energy Test:

1. Establish the QUIK-COMBO Defibrillator Energy Tests setup as shown in the following Figure 3.

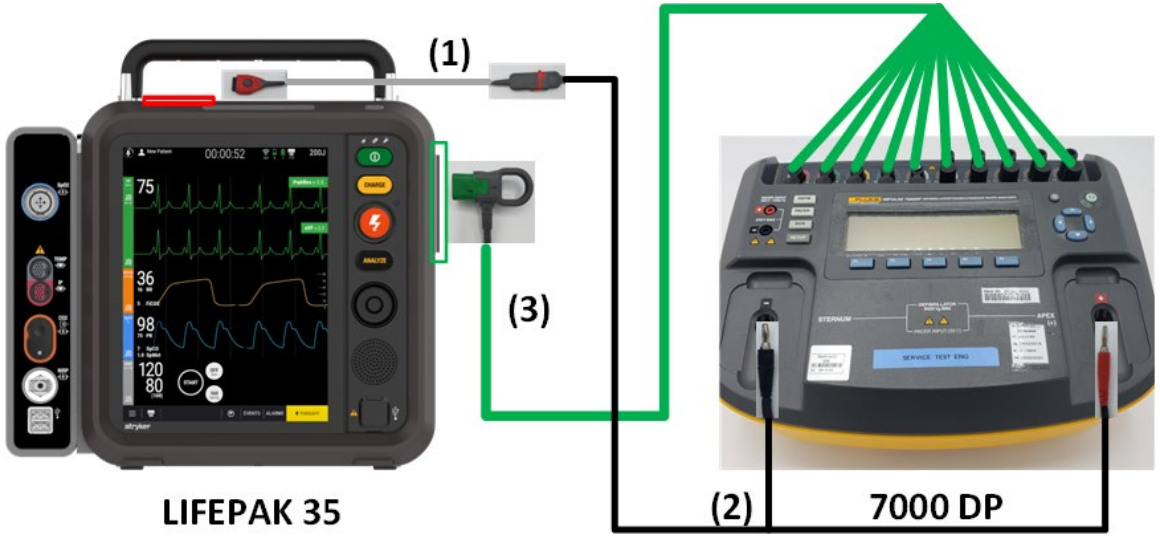


Figure 3

Item 1: 11113-000007

Item 2: 3335630-001

Item 3: 11111-000036, 11111-000037

and 11111-000041 (optional)

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. Access the Therapy Screen by pressing **THERAPY** in the lower-right corner of the touchscreen as shown in the following Figure 4.

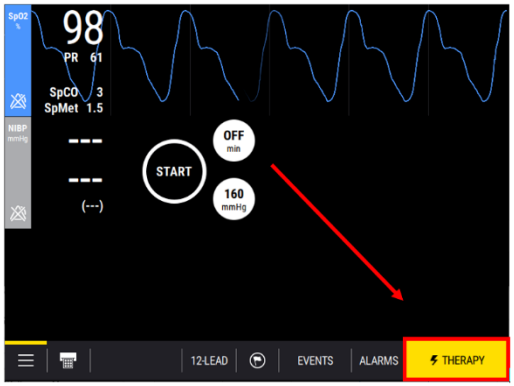


Figure 4

4. Select the desired energy up to 10J .
5. Push CHARGE button on the keypad and wait for the device to reach full charge.
6. Push the (shock) button on the keypad to discharge the device energy into the defibrillator analyzer.
7. Verify the defibrillator analyzer indicates the delivered energy is within the acceptable output limits as shown in the following table.

Delivered Energy	Low limits	High limits
10 J	9.1	10.9
50 J	46.6	53.4
200 J	186.0	214.0
360 J	334.8	385.2

8. Repeat steps 5 through 8 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.*

PIP - QUIK-COMBO Defibrillator charge time at 360J test

To perform QUIK-COMBO Defibrillator Charge Time at 360 J Test:

Note: Ensure proper power is being supplied to the device prior to testing. See PIP – Device setup for more details.

1. Select the desired energy to 360J by using the Up/Down arrows or dial on the touchscreen.
2. On the defibrillator analyzer, navigate to Defib>Charge Time>Measure.
3. When the countdown timer reaches 0 on the defibrillator analyzer, push CHARGE on the Keypad.
4. When the device reaches full charge at 360 J, immediately press the shock button when it starts flashing.
5. Verify that the time between on the defibrillator analyzer is less than 10 seconds.

PIP - QUIK-COMBO Defibrillator synchronous cardioversion test

To perform QUIK-COMBO Defibrillator Synchronous Cardioversion Test:

1. Set the defibrillator analyzer to measure synchronized cardioversion by pressing the Defib button, F2 Sync button.
2. Set the defibrillator analyzer Wave Form to Normal Sinus by pressing F1 and verify the Rate is set to 60 bpm.
3. Set the device Lead selection to LEAD II and ECG SIZE to 10 mm/mV.
4. Enter SYNC MODE by pressing SYNC on the Therapy Screen of the touchscreen as shown in the following Figure 5.

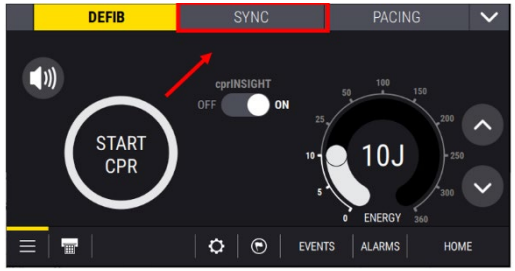


Figure 5

5. Verify that triangle sense (▼) markers appear on the ECG waveform as shown in the following figure.
6. Select the desired energy to 10J by using the Up/Down arrows or dial on the touchscreen.

7. Push Charge button on the keypad. Upon reaching full charge, push and hold the (shock) button on the keypad until the ENERGY DELIVERED message appears on the screen as shown in the following Figure 6.

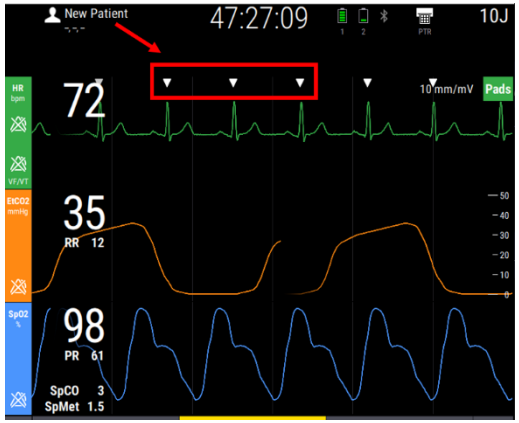


Figure 6

8. Verify the defibrillator analyzer measures a sync delay of 60 ms or less.

PIP - Pacer leads-off detection test

To perform Pacer Leads-Off Detection Test:

1. Establish the Pacer Tests setup as shown in the following Figure 7.

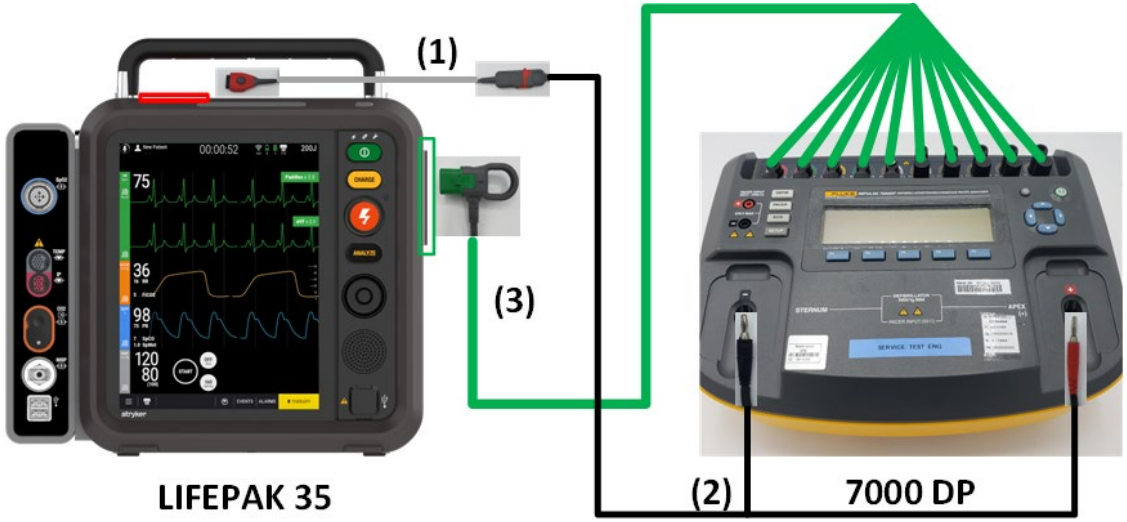


Figure 7

In Figure 7:

Item 1: 11113-000007

Item 2: 3335630-001

Item 3: 11111-000036, 11111-000037

and 11111-000041 (optional)

Note: ECG cables (item 3) is optional for Pacing tests

2. Disconnect APEX connection from Defib Analyzer.
3. Set the defibrillator analyzer to measure peak current pacing parameters.
4. Press PACING as shown in the following Figure 8.

Figure 8

5. Attempt to set the current to 10mA.
6. Verify the CONNECT PADS or APPLY PADS message appears.
7. Connect APEX lead to defib analyzer.

PIP - Pacer output current test

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

To perform Pacer Output Current Test:

1. Select Pacer button on Defibrillator Analyzer to measure pacing current.
2. In the menu screen, set the Brand to "LIFEPAK" Input Jacks to "Defib," and Load to "50 ohm" then “done”.
3. Using the RATE Up/Down arrows or dial on the touchscreen of the DUT, set pacer rate to 60 PPM.
4. Using the CURRENT Up/Down arrows or dial on the touchscreen, set a pacer current to (10 mA, 100 mA and 200 mA).
5. Verify the defibrillator analyzer indicates the pacer output current is within the acceptable output limits as shown in the following table.

Pacer Output Current	Low limits	High limits
10 mA	5	15
100 mA	90	110
200 mA	180	220

NOTE: If the Defibrillator Analyzer does not detect a pacing output current reading, then operate the Defibrillator Analyzer and device on battery power for the Pacer output current test.

PIP - Pacer pulse width test

To perform Pacer Pulse Width Test:

1. Set pacer rate on the device to 60 PPM.
2. Set a pacer current on the device to 200 mA.
3. Verify the measured pacer pulse width is between 19.8 and 20.8 ms.
4. Press the Stop button next to the PPM dial.
5. Press the “Home” button located on the bottom right of the DUT display.

PIP - QUIK-COMBO R-wave polarity test

To perform PIP – QUIK-COMBO R-Wave Polarity Test:

1. Program the defibrillator analyzer output for a 1-mV, ECG Normal Sinus Rhythm, 60 BPM.
2. On the Home Screen of the touchscreen, set the device Lead selection to PADDLES and ECG SIZE to 10 mm/mV.
3. Create a generic event by pressing the Flag icon at the bottom of the screen.
4. Navigate to the Events menu located at the bottom of the display (Events > View Patient Events > Generic Event at the bottom).
5. Confirm the positive R-wave referenced from baseline recorded on screen as shown in the following Figure 9

Note: Waveform can be verified by printing the waveform on printer paper.

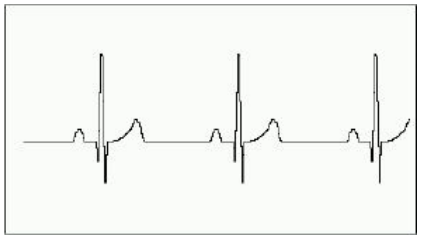


Figure 9

PIP - QUIK-COMBO Paddles ECG gain test

To perform QUIK-COMBO Paddles ECG Gain Test:

1. Program the defibrillator analyzer output for a 1-mV, 10-Hz sine wave.
2. On the Home Screen of the touchscreen, set the device Lead selection to PADDLES and ECG SIZE to 40 mm/mV.
3. Create a generic event by pressing the flag icon at the bottom of the screen.
4. Navigate to the Events menu located at the bottom of the display (Events > View Patient Events > Generic Event at the bottom).
5. Locate the event created and confirm the displayed signal amplitude is 38mm to 42 mm, peak-to-peak.

Note: Waveform can be verified by printing the waveform on printer paper.

PIP - ECG performance testing

Note: Perform the following ECG tests depending on what ECG cable assembly is available. It is recommended to perform the following tests with the most coverage such as 13 – wire ECG tests.

PIP - 13/10-Wire ECG leads-off detection test

To perform 13/10-Wire ECG Leads-Off Detection Test:

Note: Leaving therapy cable connected from previous testing is optional.

1. Establish the 10-Wire ECG Tests setup as shown in the following Figure 10:

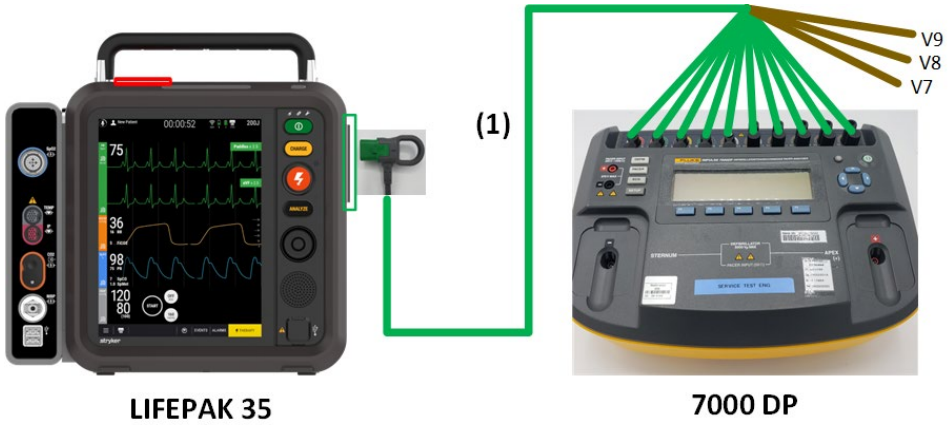


Figure 10

(Item 1 in Figure 10: 11111-000036, 11111-000037 and 11111-000041)

Note: DP7000 only supports testing 10 Wire at a time. If using a 13 Wire ECG cable, V7/A1-V9/A3 will be recognized as disconnected for steps 2-11.

2. Program the defibrillator analyzer output for a 1-mV, 10-HZ sine wave.
3. On the Home Screen of the DUT Touchscreen, set the device to LEAD II.

4. Remove the LL lead from the defibrillator analyzer and verify that the device displays the **LL LEAD DISCONNECTED** message and a repeating medium priority tone sounds when the lead is removed.
5. Reconnect the LL lead.
6. Repeat steps 4 and 5 for leads RA and RL.
7. On the Home Screen of the Touchscreen, set the device to LEAD I.
8. Remove the LA lead from the defibrillator analyzer.
9. Verify that the device displays the **LA LEAD DISCONNECTED** or ECG Leads disconnected message and a repeating Medium priority tone sounds when the lead is removed. Reconnect the LA lead.
10. Repeat steps 7 through 9 for V1 through V6 Leads.

Note: if the device is configured with the 12/15 lead analysis feature, you may use this function rather than setting the leads individually per step 7. If lead V7/A1 -V9/A3 were connected to the analyzer prior to this test, disconnect and reconnect the ECG cable to reset the device to 12 lead analysis.

11. Verify that the device displays a **LEADS OFF** message appears when each lead is removed (for example, **V1 LEAD DISCONNECTED** when the V1 lead is removed) and a repeating priority 3 tone sounds when the lead is removed.

Note: only proceed to next step if using a 13 Wire ECG cable.

12. Remove leads V4 through V6 and place V7/A1 through V9/A3 in the same order.
13. Repeat steps 11 – 13 for V7/A1 though V9/A3 Leads.
14. Verify that the device displays a **LEAD DISCONNECTED** message when each lead is removed (for example, **V7/A1 LEAD DISCONNECTED** when the V7/A1 lead is removed) and a repeating Medium priority tone sounds when the lead is removed.

PIP - 13/10-Wire ECG gain test

To perform 13/10- Wire ECG Gain Test:

Note: Leaving therapy cable connected from previous testing is optional.

1. Establish the 10-Wire ECG Tests setup as shown in the following figure.

   Note: DP7000 only supports testing 10 Wire *at a time. If using a 13* Wire *ECG cable, V7/A1-V9/A3 will be recognized as disconnected for steps 2-8.*

2. Program the defibrillator analyzer output for a 1-mV, 10-Hz sine wave.
3. On the Home Screen of the Touchscreen, set the device Lead selection to LEAD II and ECG SIZE to 40 mm/mV.
4. Create a generic event by pressing the Flag icon at the bottom of the screen.
5. Navigate to the Events menu located at the bottom of the display (Events > View Patient Events > Generic Event at the bottom).
6. Locate the event created and confirm the displayed signal amplitude is 38 mm to 42 mm, peak-to-peak, as shown in the following Figure 11:

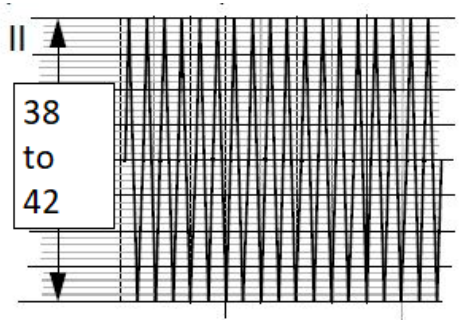


Figure 11

Note: Waveform can be verified by printing the waveform on printer paper.

7. Repeat steps 2, 3 and 4 for Lead I, substituting the signal amplitudes given in the following table.

Lead	Printed Peak- to - Peak
I	26 mm to 30 mm
II	38 mm to 42 mm
V1-V9/A3	36 mm to 44 mm

Note: Lead 3 is not required.

8. Repeat steps 2 and 3 for Lead V1 through V6, substituting the signal amplitudes given in the table above.

   Note: Only proceed if using a 13 Wire *ECG cable.*

9. Remove leads V4 through V6 and place V7/A1 through V9/A3 in the same order.
10. Repeat steps 2 and 3 for Lead V7/A1 through V9/A3, substituting the signal amplitudes give in the table above.
11. Disconnect all the test cables from Defibrillator Analyzer and the device.

PIP - SpO2/SpCO/SpMet tests

To perform SpO2/SpCO/SpMet Tests:

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 Index finger into the oximeter finger probe. The sensor sends wavelengths of light from the emitter to the receiving detector as shown in the following Figure 12.

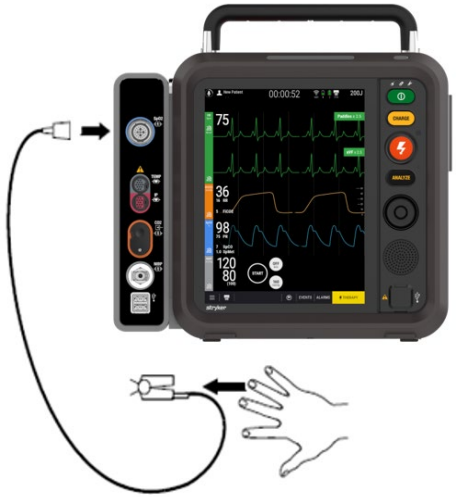


Figure 12

5. Confirm the SpO2 reading is in the range of 50% to 100%.
6. Verify the following if the device is configured to use SpCO and/or SpMet
   - Confirm the SpCO reading is in the range of 0% to 40%.
   - Confirm the SpMet reading is in the range of 0% to 15%.
7. Disconnect the oximeter finger probe.

PIP - Temperature tests

Note: Only perform test if Device is configured with the Temperature option.

To perform Temperature Test:

1. Establish the Temperature Tests setup as shown in the following Figure 13.

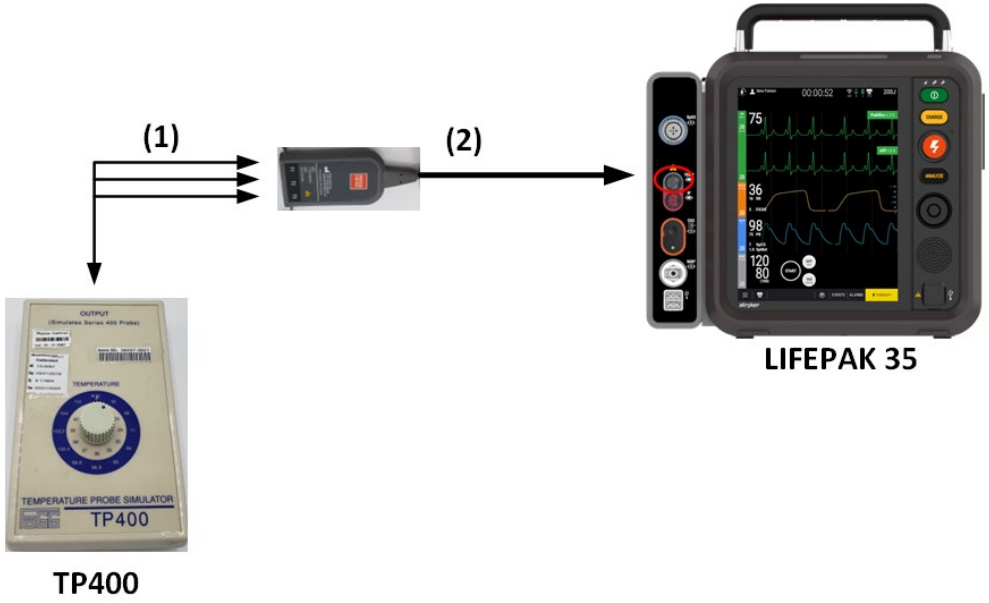


Figure 13

In Figure 13:

Item 1: 3308413-000

Item 2: 11230-000023

2. Connect 3308413-000 to Channel 1 “T1” on 11230-000022 and the Fogg TP 400 Simulator.
3. Rotate the dial on the Fogg TP400 Simulator to the following temperatures: 25C and 45C.
4. Verify the DUT temperature measurements are within the acceptable output limits as shown in the following table.

Temperature	Low limits	High limits
25C	24.8C	25.2C
45C	44.8C	45.2C

5. Repeat steps 2-4 with channel 2 and 3.

PIP - Invasive pressure tests

Note: Only perform test if Device is configured with the Invasive Pressure option.

To perform Invasive Pressure Test:

1. Establish the Invasive Pressure Tests setup as shown in the following Figure 14.

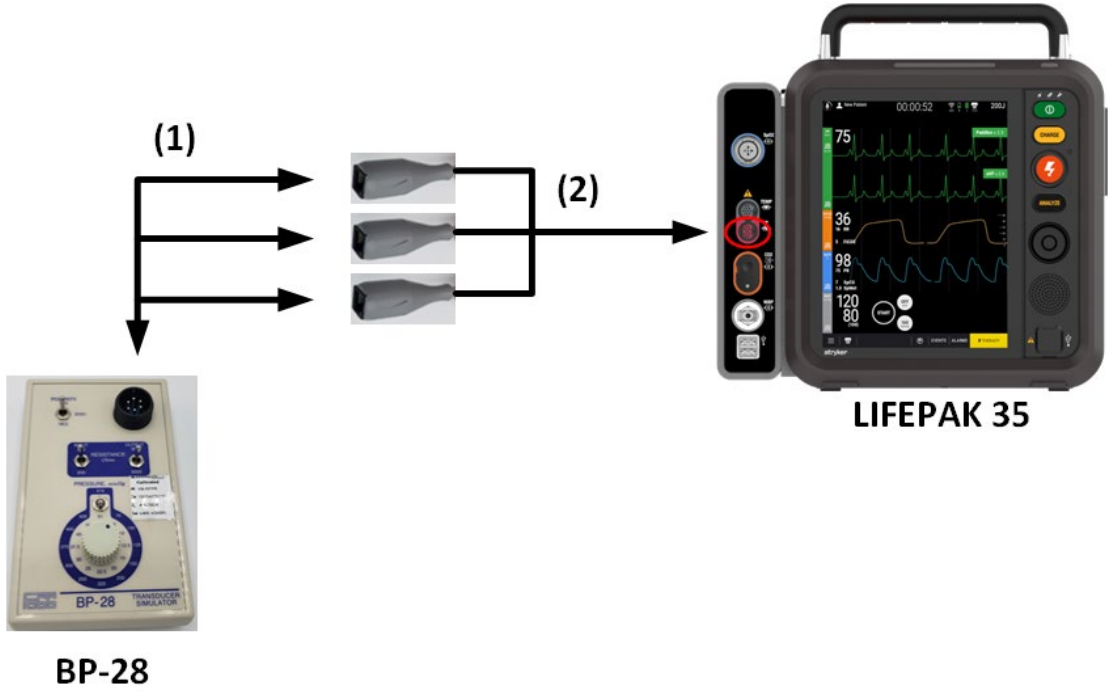


Figure 14

In Figure 14:

Item 1: 3344024-000

Item 2: 11230-000021

2. Select “ART” on the Invasive Pressure menu.
3. Set the polarity switch on the Fogg simulator to “zero” in the middle position.
4. On the DUT screen, navigate to the IP options menu and press “Settings”, then ‘Zero”.
5. Once “IP1 Zeroed” is displayed at the top left of the DUT screen, set the polarity switch and pressure dial to -30mm/Hg on the simulator.
6. Verify the DUT Invasive pressure measurements are within the acceptable output limits as shown in the following table.

Pressure	Low limits	High limits
-30mm/Hg	-34mm/Hg	-26mm/Hg
20mm/Hg	16mm/Hg	24mm/Hg
100mm/Hg	96mm/Hg	104mm/Hg
300mm/Hg	288mm/Hg	312mm/Hg

7. Repeat steps 2- 6 with channel 2 & 3.

PIP - CO_2 tests

CO2 testing includes the following:

- PIP – CO_2 leakage test
- PIP – CO_2 calibration check

PIP - CO_2 leakage test

To perform CO_2 Leakage Test:

1. Establish the CO_2 Leakage Test setup by using Assy, Tubing, Leak Test, MDT CO2 P/N 3335916-001 as shown in the following Figure 15.

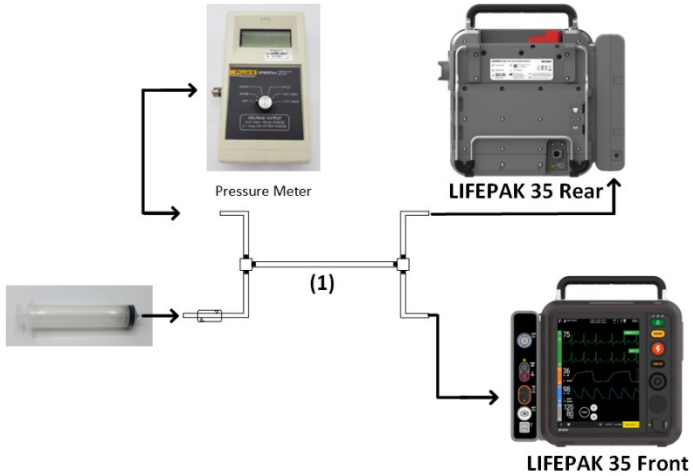


Figure 15

(Item 1 in Figure 15: 3335916-001)

Note: Make sure the device is turned OFF and the syringe is fully depressed before connecting to DUT.

2. Connect the tubing to the front panel CO_2 connector and to the back-panel CO_2 gas outlet. *(Important: Press and or screw the fittings that connect to the device firmly to avoid leakage. All tubing ends should now be connected as shown in the figure above).*
3. Pull the syringe plunger out to induce a vacuum into the system. When the vacuum manometer indicates approximately -230 mmHg close the tubing clamp firmly.
4. Begin timing as the clamp is closed. Verify that after 30 seconds, the change in vacuum reading is less than 15 mmHg.
5. Open the tubing connection to the front panel CO_2 connector to release the vacuum.

PIP - CO_2 calibration check test

To perform CO_2 Calibration Check Test:

1. Turn the device ON.
2. Access the Service Commands screen within PSST. See PIP – PSST access.
3. Select CO_2 Calibration Check in the Service Commands screen.
4. Connect the calibration gas canister to the front panel CO_2 connector using Assy, Tubing, Calibration Test Masimo CO2 P/N 3335916-002 or Assy, Tubing, Calibration Test, MDT CO2 P/N 3335916-003 as shown in the following Figure 16.

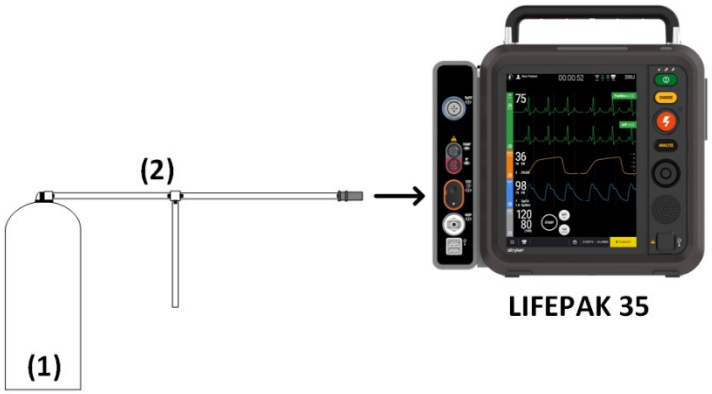


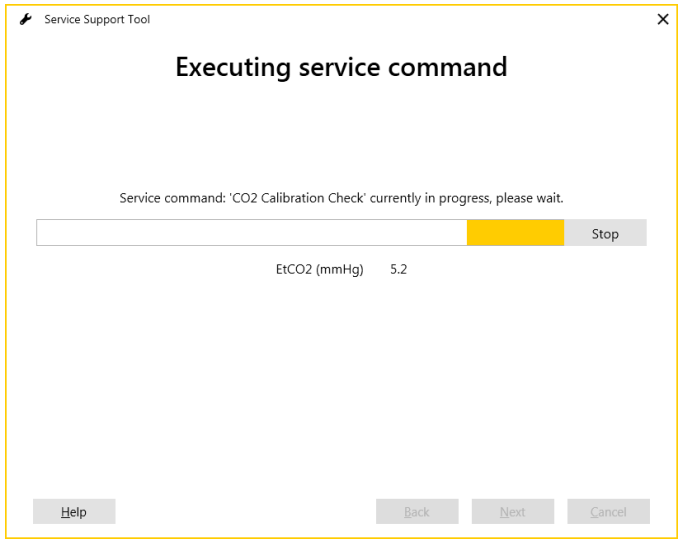
Figure 16

In Figure 16:

Item 1: 21300-001572

Item 2: 3335916-003

5. Follow the PSST on screen instructions to perform the CO2 Calibration Check.



6. Verify that the measured gas concentration reads 5.0% ± 0.82% mmHg.

NOTE: PSST does not determine pass/fail criteria, only that the device executed its remote commands as expected. If the measured value is incorrect, perform TCP – CO_2 Calibration.

7. Disconnect all the test cables from the device.

PIP - NIBP tests

NIBP testing includes the following:

- PIP – NIBP leakage test
- PIP – NIBP calibration check test

PIP - NIBP leakage test

To perform NIBP Leakage Test:

1. Set up the NIBP calibration kit as shown in the following Figure 17.

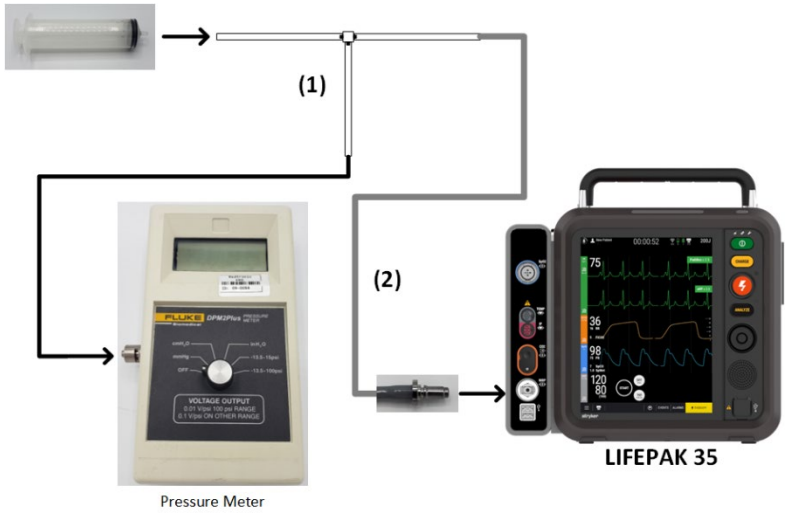


Figure 17

In Figure 17:

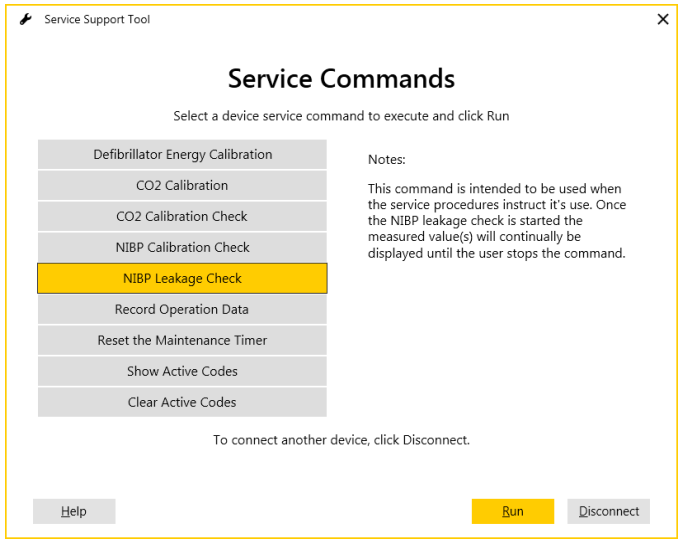
Item 1: 3012432-003

Item 2: 11996-000391

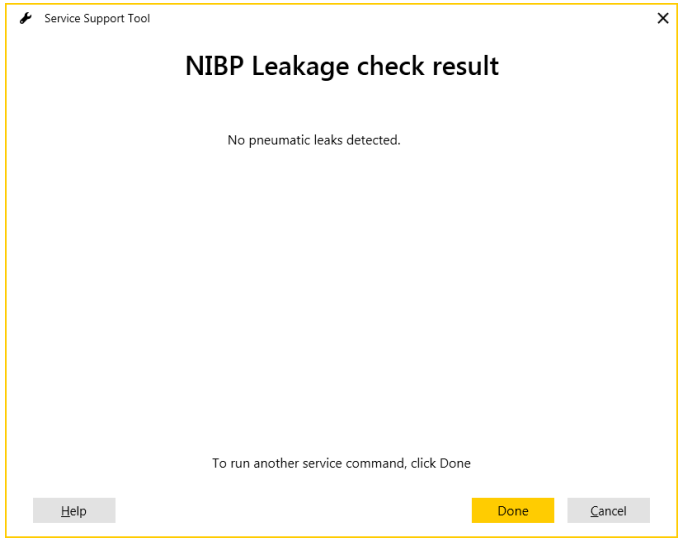
Note: Fully retract the syringe plunger prior to setup.

2. Access the Service Commands screen within PSST. See PIP – PSST access.

3. Select NIBP Leakage Check in the Service Commands screen.



4. Select RUN on the SST screen.



5. After test completion, verify that the message “No pneumatic leaks detected” appears on the SST screen.
6. Select DONE on the SST screen.

PIP - NIBP calibration check test

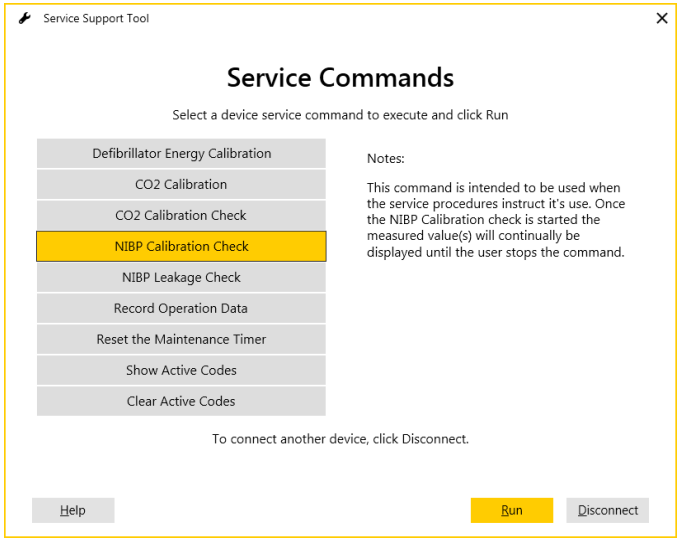
CAUTION

POSSIBLE EQUIPMENT DAMAGE

Pulling out on the syringe plunger applies a vacuum to the NIBP connection and may damage the LIFEPAK 35 monitor/defibrillator. DO NOT pull on the plunger; only push in on the plunger to inflate the system per the instructions.

To perform NIBP Calibration Check Test:

1. Select NIBP Calibration Check from the Service Commands screen.



2. Set up the NIBP calibration kit as shown in the following Figure 18.

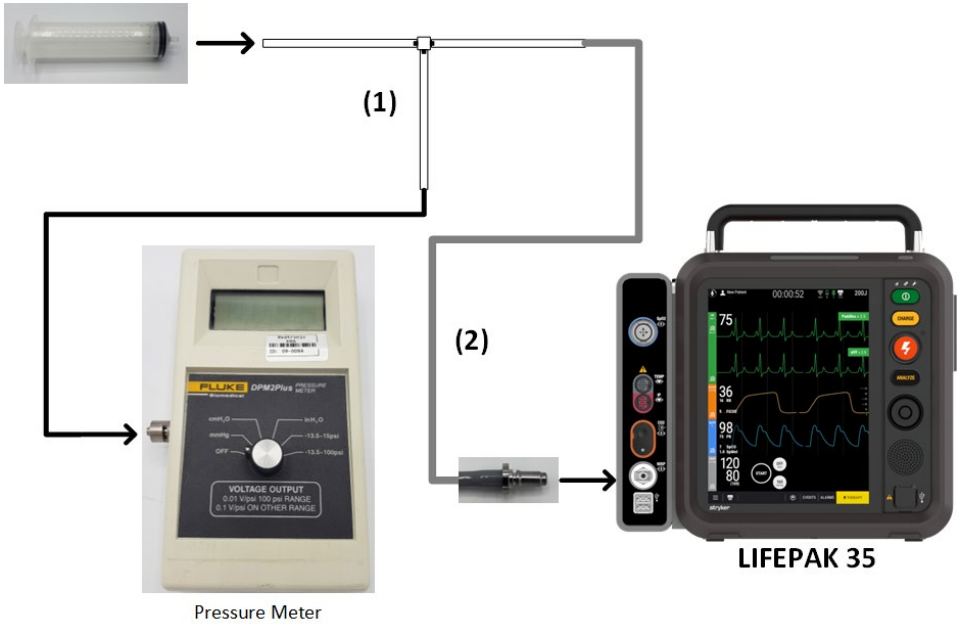


Figure 18

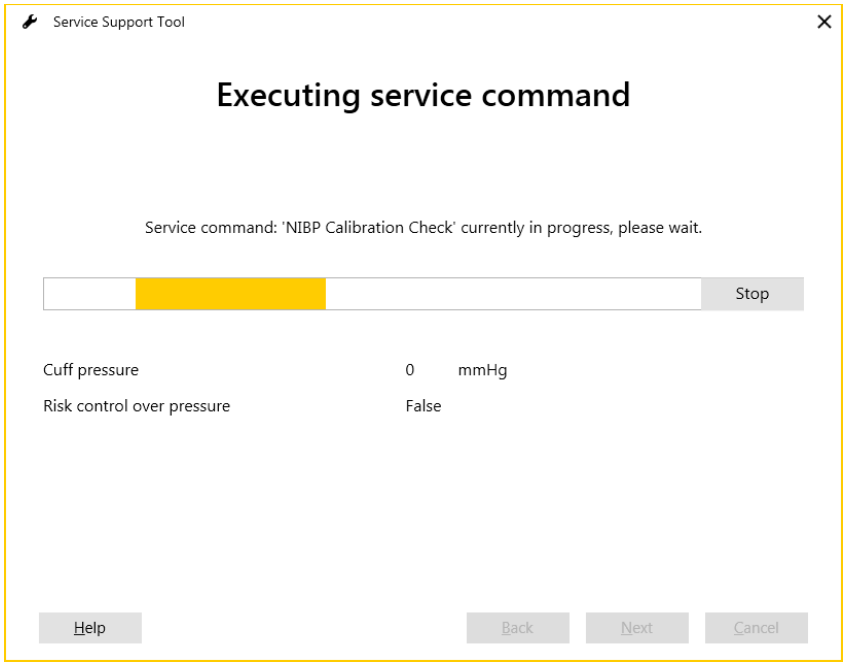
In Figure 18

Item 1: 3012432-003

Item 2: 11996-000391

Note: Fully retract the syringe plunger prior to setup.

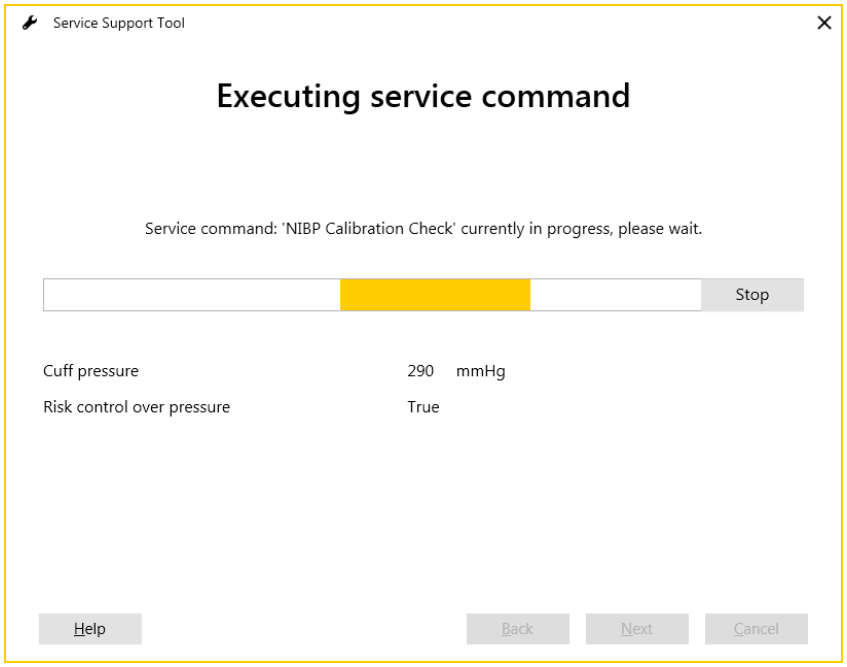
3. Select RUN on the SST screen.



4. Adjust the pressure meter, if necessary, to a zero initial pressure to ensure that the device and the pressure meter agree, within ±3 mmHg.
5. Using the syringe, inflate the system to each of the following pressures (as indicated on the manometer or pressure meter): 50 mmHg +/- 15 mmHg and 150 mmHg +/- 15 mmHg.
6. Verify that the information displayed on the SST screen and the external pressure meter agree within ±3 mmHg.
7. Using the syringe, slowly inflate the system until the overpressure switch activates at 290 ±20 mmHg, as displayed on the pressure meter.
8. Verify that the system depressurizes, and that the SST screen displays Risk Control Over Pressure as “True”.

NOTE: This test fails if the system pressure reaches greater than 290 mmHg, as displayed by the pressure meter, and does not activate overpressure switch.

9. Select STOP to display the NIBP Calibration check result screen.
10. Select DONE to return to the Service Commands screen.



11. Turn off the device.

NOTE: PSST does not determine pass/fail criteria, only that the device executed its remote commands as expected.

PIP - Record operating data (optional)

1. Access the Service Commands screen within PSST. See PIP – PSST access.
2. Select Record Operating Data and make note of the total Pacing count, 0-200J shock count, 225-325J Shock count and 360J shocks

PIP - Data management

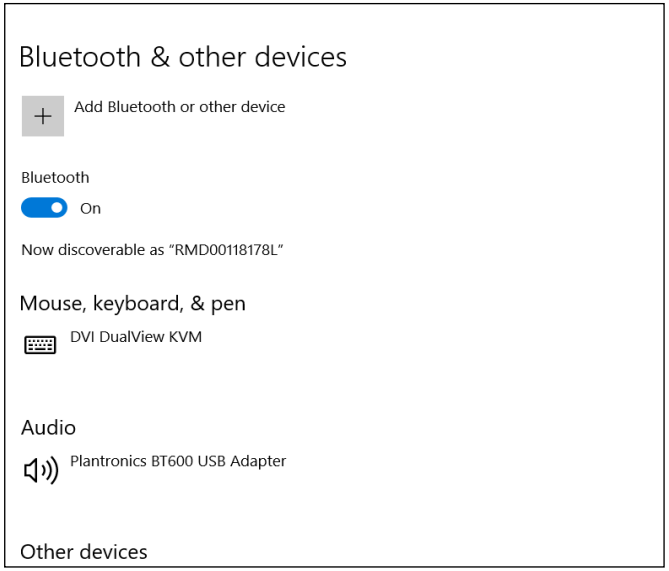
Data Management testing includes the following:

- PIP-Bluetooth functional test.
- Wi-Fi functional test.

PIP - Bluetooth functional test

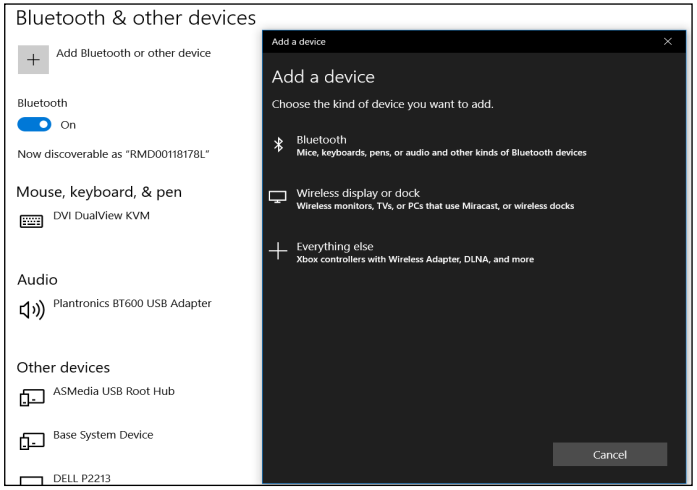
Prepare PC to connect with DUT:

1. Disconnect the access port cable from the device.
2. On your PC, go to windows start menu and search for “Bluetooth and other devices”.
3. Turn Bluetooth antenna On.



Note: Step 3 only needs to be performed if the DUT has not been connected to the operator’s PC prior. If this DUT has been connected previously, navigate to “other devices” and remove the device from the Bluetooth device list and re-add per step 3.

4. Select “Add Bluetooth or other device” then select “Bluetooth”.



To perform the PC to DUT setup through Bluetooth to the Wi-fi Config tool:

Note: Make sure access port cable is disconnected.

1. Launch Wi-Fi config tool application (Make sure Wi-Fi config tool is installed (see section PIP-Wi-Fi config tool access and launch the tool).
2. Sign into Wi-Fi Config tool using LIFNET credentials.
3. Select “Can’t see your device on list?”.
4. Select “Bluetooth” button.
5. Follow bellow steps to go into SETUP MODE.
    a. Press the Main Menu button at the bottom of the touchscreen and press options. Select SETUP MODE.
    b. Enter your default passcode if prompted.
    c. Wait until your device is fully rebooted.

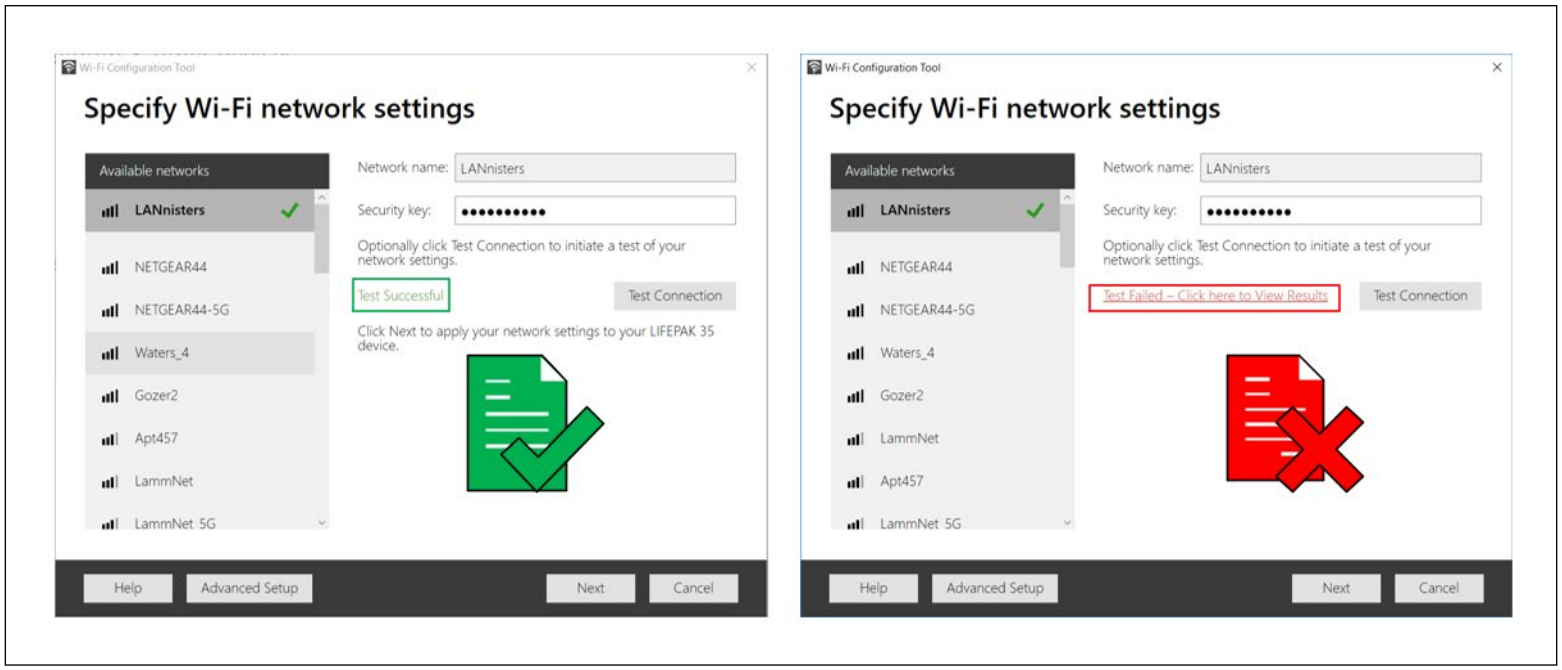
6. When in SETUP MODE, click next on Wi-Fi config tool.
7. Select the “Bluetooth” Button on the DUT screen located towards the bottom .
8. Turn on Bluetooth Antenna on DUT.
9. When on the device screen it says, “Discoverable as LIFEPAK 35 SN XXXXXXXX ….” Press next on the Wi-Fi config tool.
10. When you see the device, SN populated on the Wi-Fi config tool window, select it and press next.
11. When prompted on the device, press “Connect”.
12. Verify the SN, ID and the Code that is populated on the Wi-Fi config tool matches what’s on the device screen. Press confirm on Wi-Fi config tool and the device screen.

PIP - Wi-Fi functional Test

To perform the setup DUT to Wi-Fi:

Note: This assumes you have completed the Bluetooth setup. If Bluetooth connection is not desired, connect an access port cable and connect to Wi-Fi config tool.

1. Select “Wi-Fi” in Wi-Fi config tool. The tool will continue to read its current configured setting.
2. Select an available network on the Wi-Fi config tool to connect to.
3. Enter network’s security key and press Test Connection.
4. Verify the “Test Successful” is populated.



PIP - Leakage current tests

Note: the following leakage tests can be performed if the device is in Setup mode from previous testing.

Leakage Current testing includes the following:

- 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

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

IEC (International Electrotechnical 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.

Earth Ground – Third wire ground.

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 (10 wire)

Establish the Leakage Current Test setup as shown in the following Figure 19:

⚠ ***CAUTION: POSSIBLE EQUIPMENT DAMAGE*** ***Do not defibrillate when connected to the safety analyzer.***

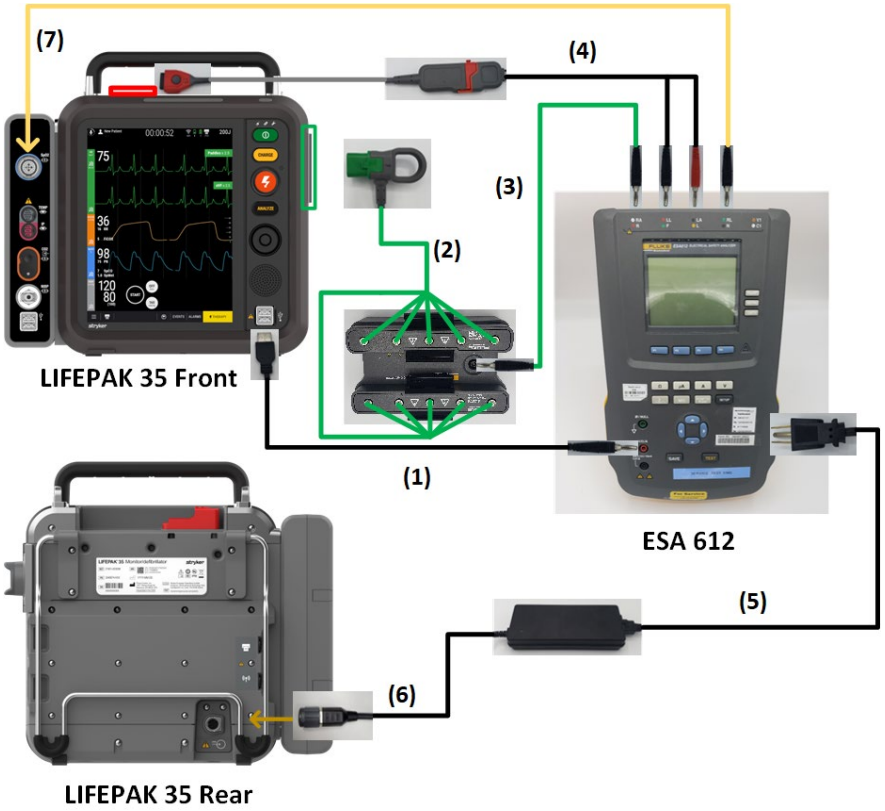


Figure 19

LIFEPAK 35 Leakage Current test Setup with 10-Wire ECG

1. Connect a banana cable between the device SYS GND (3344955-000) and the Safety Analyzer V/Ohm/A output.
2. Connect the customer 10 wire (11111-000036 and 11111-000037) cable between the device and the 1210 box.
3. Connect the 1210 box to the Safety Analyzer at RA jack with the banana plug cable (Pomona P/N B-24-2 or equivalent).
4. Connect the Therapy cable (11113-000007 and 3335630-001) between the device and the Safety Analyzer at LL and LA jacks.
5. Connect the AC power (P007-L03 or equivalent) from the device power adapter to the Safety Analyzer AC output.
6. Connect the Auxiliary power adapter (41335-000001) from the device power adapter to the back of the DUT.
7. Connect the SpO2 Leakage cable (3335631-000) between the device and the Safety Analyzer at RL jack.
8. Install 2 LIFEPAK FLEX batteries into the device.
9. Power on DUT

PIP - Leakage current test setup (13 wire)

Establish the Leakage Current Test setup as shown in the following Figure 20:

CAUTION

POSSIBLE EQUIPMENT DAMAGE

Do not defibrillate when connected to the safety analyzer.

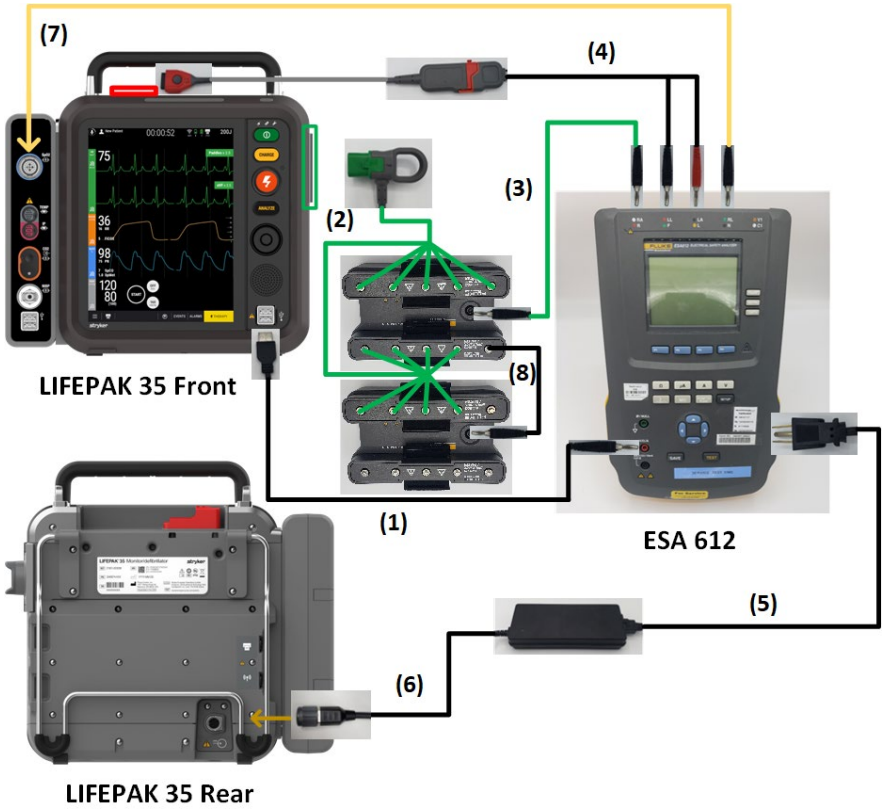


Figure 20

LIFEPAK 35 Leakage Current test Setup with 13 Wire ECG

1. Connect a banana cable between the device SYS GND (3344955-000) and the Safety Analyzer V/Ohm/A output.
2. Connect the customer ECG 13 wire cable (11111-000036, 11111-000037 and 11111-000041) between the device and the 2 1210 boxes shown above.
3. Connect the 2 1210 boxes as shown above by using 3305684-000.
4. Connect the 1210 box to the Safety Analyzer at RA jack with the banana plug cable (Pomona P/N B-24-2 or equivalent).
5. Connect the Therapy cable (11113-000007 and 3335630-001) between the device and the Safety Analyzer at LL and LA jacks.
1. Connect the AC power (P007-L03 or equivalent) from the device power adapter to the Safety Analyzer AC output.
2. Connect the Auxiliary power adapter (41335-000001) from the device power adapter to the back of the DUT.
3. Connect the SpO2 Leakage cable (3335631-000) between the device and the Safety Analyzer at RL jack.
4. Install 2 LIFEPAK FLEX batteries into the device.
5. Power on DUT

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 standards.
- Press the **DONE** button.

PIP - Direct equipment leakage test - single fault condition (SFC)

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

4. Verify the device power adapter LED is ON.
5. Verify the measured current is between 15 µA and 490 µA (120 Vac) or between 15 µA and 490 µA (240 Vac).

PIP - Direct Applied Part Leakage Test Setup

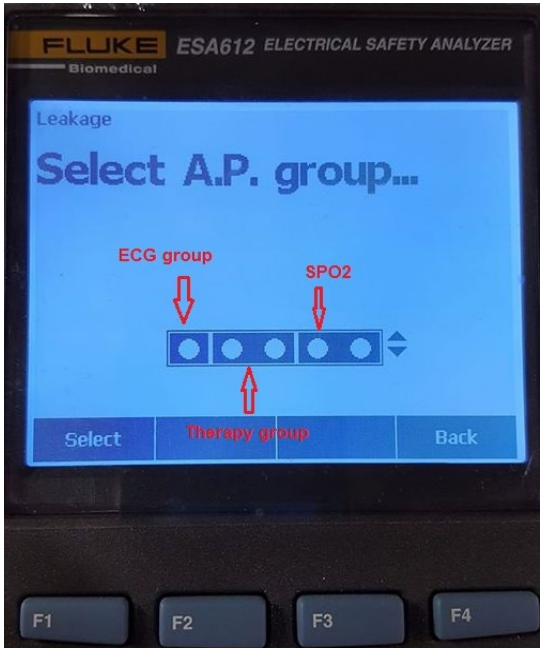
WARNING:

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.
- Press **F1/SELECT** then F1/Direct A.P.



PIP - Direct applied part leakage test - ECG  (type CF)

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 power adapter LED is ON.
5. Verify the measured current is between 5 µA and 50 µA (120 and 240 Vac).

PIP - Direct applied part leakage test - Therapy  (type BF)

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 power adapter LED is ON.
5. Verify the measured current is between 5 µA and 5000 µA (120 and 240 Vac).

PIP - Direct applied part leakage test - SpO2  (type BF)

Note: Execute this test if the LIFEPAK 35 is equipped with SpO_2.

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 power adapter LED is ON.
5. Verify the measured current is between 5 µA and 5000 µA (120 and 240 Vac).

PIP - Leakage current test limits

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 - 50 µA 5 - 50µA	5 - 50 µA 5 - 50µA
Therapy (Apex, Sternum) Direct Applied Part	Normal Reversed	5 - 5000 µA 5 - 5000 µA	5 - 5000 µA 5 - 5000 µA
SPO_2 Direct Applied Part	Normal Reversed	5 - 5000 µA 5 - 5000 µA	5 - 5000 µA 5 - 5000 µA
Direct Equipment Leakage	Normal, Open Earth Reversed, Open Earth	15 - 490 µA 15 - 490 µA	15 - 490 µA 15 - 490 µA

PIP - Reset maintenance timer

Access the Service Commands screen within PSST. See PIP – PSST access.

Select Reset Maintenance Timer in the Service Commands screen.

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LIFEPAK® 35 monitor/defibrillator

Performance Inspection Procedure (PIP)

Specifications are subject to change without notice.

For further information, call Stryker at 1 800 STRYKER or visit stryker.com

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