

Performance Inspection Procedures

The Performance Inspection Procedures (PIP) are a set of manual test procedures used for an operational closed-case evaluation of the CodeManagement Module. This section describes the test procedures you will perform to determine if the CodeManagement Module is operating within the required specifications. Investigate and correct any malfunctions or out-of-tolerance test conditions detected during the PIP.

The PIP comprises safety and performance tests recommended by AHA/ASHE (American Hospital Association/American Society for Hospital Engineering) *Maintenance Management for Medical Equipment* and International Electrotechnical Commission (IEC) Technical Report 1288-2, *Maintenance of Cardiac Defibrillators-Monitors*.

Perform the PIP as part of a regularly scheduled preventive maintenance routine. Also, perform the PIP after any repair, replacement, or calibration procedure.

[PIP/TCP – Scope and Applicability](#)

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PIP/TCP – Scope and Applicability

The PIP applies to the CodeManagement Module exclusively. To complete the PIP, you must perform the combination of manual tests outlined in the PIP – Instructions section of this electronic service manual. All PIP tests applicable to the CodeManagement Module configuration under test must be performed.

Refer to the [PIP/TCP – Resource Requirements](#) for a listing of the necessary qualifications for PIP equipment, test equipment verification, workstation power, and personnel.

Refer to the [PIP/TCP – Test Equipment Requirements](#) for a listing of test equipment, including specifications, required to complete the PIP/TCP.

PIP/TCP – Resource Requirements

This section describes the requirements for PIP/TCP equipment, test equipment verification, workstation power, and personnel.

Equipment

To perform the PIP, you must use the equipment listed in the [PIP/TCP – 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, issued by a certified calibration facility.

Workstation Power

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

Personnel

Service personnel who perform the PIP must be thoroughly familiar with the operation of the LIFEPAK 20e defibrillator and CodeManagement Module and must meet at least one of the following requirements (or the equivalent):

- Associate of Applied Science, in the field of electronic technology.
- Certificate of Technical Training, in the field of electronic technology.
- Equivalent electronics experience with a preferred emphasis in biomedical electronics.

PIP/TCP – Test Equipment Requirements

The following is a list of test equipment required to conduct the PIP/TCP.

Equipment/Cable	Specifications	Manufacturer/Part Number/ Catalog Number
Safety Analyzer	110 or 220 Vac line voltage Current range: 0-1999 mA Current accuracy: 5% of reading or 1 digit (whichever is greater) Resistance range: 0-1.000 Ohm	Fluke Biomedical ESA612 (or equivalent)
ESA612 adapter box	Provides additional ECG snap connections.	Fluke Biomedical model 1210
Digital Pressure Meter	+/- 1% of full scale. Used as a vacuum manometer.	Fluke Biomedical DPM2Plus (or equivalent)
Alligator Clip	Used to access to LIFEPAK 20e defibrillator/monitor ground stud for electrical safety testing.	Fluke P/N AC220 (or equivalent)
Cable Assembly, 3 Lead, ECG	Standard accessory with the 3-Lead LIFEPAK 20e defibrillator/monitor.	11110-000029
Cable Assembly, 5 Lead, ECG	LIFEPAK 20e defibrillator optional accessory.	11110-000066
Cable Assy-Therapy, QUIK-COMBO		11110-000040
Cable, QUIK-COMBO to Snap Termination	For use in electrical safety testing with QUIK-COMBO therapy cable.	3009139-001

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PIP/TCP – Test Equipment Requirements

Equipment/Cable	Specifications	Manufacturer/Part Number/ Catalog Number
Cable Assy, LP20 SPO2 Test	For use in electrical safety testing.	3201832 (Multiple REF)
Paddle Assy-Detachable, LP20	LIFEPAK 20e defibrillator/monitor optional accessory.	3200936 (Multiple REF)
Adapter - Test, Paddles Leakage, LP12 & LP20	For use in electrical safety testing with standard paddles.	3206631
QUIK-COMBO Leakage Cable	For use in electrical safety testing with standard paddles.	3207066
Cable, Test, ECG Snap to Banana Plug	For use in electrical safety testing.	3305684
RS-232 (DB9 M/F) Cable		Commercial
USB to Serial Adapter (as required)		Commercial
Computer	OS, Windows XP, 7	Commercial
Software, CodeManagement Module Computer Assisted Test		3313963
Wireless network (WPA/WPA2 enterprise or personal)	Required to test Wireless functionality.	Commercial
LIFENET Device Agent Component (LDA)	Used to check and calibrate CO2.	21340-000836

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PIP/TCP – Test Equipment Requirements

Equipment/Cable	Specifications	Manufacturer/Part Number/ Catalog Number
Paper clip, Large	Used to access the CodeManagement Module reset button.	Commercial
LIFEPAK 20e defibrillator/monitor with CodeManagement Module compatible software		Physio-Control, Inc.
Tubing Assy - CO2 Calibration	For use in CO2 calibration and calibration check.	21330-000239
Filterline H Set Adult/Pediatric	For use in CO2 calibration and calibration check.	11996-000068
Chemical - Gas, Mixture, Calibration, Aerosol	For use in CO2 calibration and calibration check.	21300-001572
Tubing Assy - Service, CO2	For use in CO2 leak testing.	21330-000238
Male Luer	Used to connect CO2 tubing assy to CO2 exhaust port.	Value Plastics MTLL250
Self powered 1.1 Compliant USB device	Used as part of the computer assisted test software, 3313963, to test the USB interface.	Belkin 4-Port Hub F5U021V (or equivalent)
AC power cable, hospital grade (USA)	International users - local hospital grade cable is an acceptable substitution.	Physio-Control 11140-000015
Stopwatch		Commercial

PIP – Instructions

PIP – General Instructions

This section lists the general instructions for performing the Performance Inspection Procedure (PIP).

- All required PIP tests applicable to the CodeManagement Module under test must be performed.
- The **PIP Checklist** is provided as an optional tool for the recording of test results.
- Throughout the body of this PIP, the LIFEPAK 20e defibrillator/monitor is referred to as the defibrillator.
- Throughout the body of this PIP, the CodeManagement Module is referred to as the Device Under Test or DUT.
- Unless specified in the test step, the DUT should have a battery installed and be connected to AC power.

PIP – Instructions

Warnings

WARNING!

Shock hazard. The LIFEPAK 20e defibrillator/monitor discharges up to 360 J of electrical energy through the defibrillator cable. You must safely discharge this electrical energy. Do not attempt to perform this procedure unless you are thoroughly familiar with the operation of the LIFEPAK 20e defibrillator/monitor and CodeManagement Module.



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PIP – Instructions

PIP – Exterior Physical Inspection

To perform an exterior physical inspection:

1. Inspect the DUT exterior for the following:
 - Damage
 - Excessive wear
 - Improper mechanical function
 - Damaged connectors
2. Pick up and turn over the DUT and listen for loose or rattling hardware. Locate any loose or rattling hardware and tighten or replace it.
3. Inspect the rubber feet on the underside of the DUT. Reinstall or replace rubber feet as necessary.
4. Inspect carrying strap and storage bags for damage (if equipped).



PIP – Instructions

PIP- Power Port and AC Mains LED

To test the Power Port and AC Mains LED:

1. Verify the DUT battery is installed.
2. Disconnect the AC power cable from the DUT to the power source.
3. Verify the DUT AC Mains LED is OFF.
4. Connect the AC power cable from the DUT to the power source.
5. Verify the DUT AC Mains LED is ON.
6. Verify the defibrillator AC Mains LED is ON.
7. Turn ON the defibrillator and verify the defibrillator turns ON.
8. Turn the defibrillator OFF.



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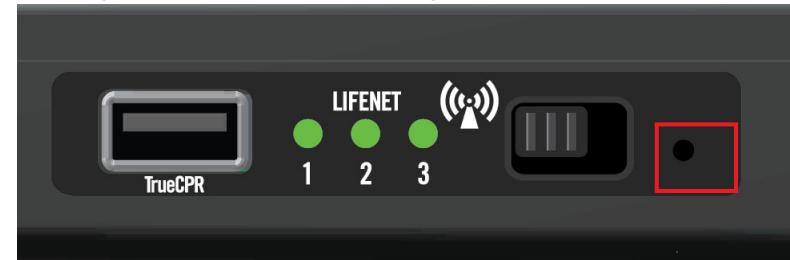
PIP – Instructions

PIP- Reset Button

To test the Reset Button:

1. Press and hold the reset button for a minimum of 1 second and release.

Note: Use the straightened end of a large paper clip to access the reset button.



Note: Upon initial release of the reset button, all LEDs will glow steadily. After ~30-60 seconds, the AC mains LED will flash and then glow steadily.

2. Verify the DUT AC mains LED flashes, then glows steadily.



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PIP – Instructions

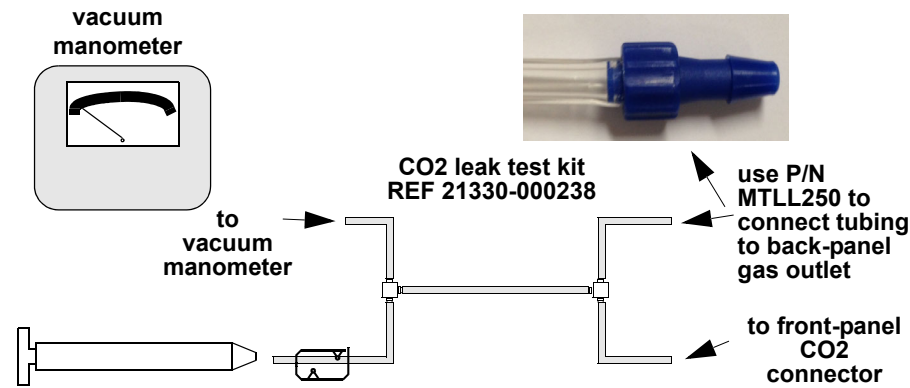
PIP- CO2 Leakage Test

Note: Perform the CO2 tests if the device is equipped with the CO2 option. Otherwise, skip to **PIP - Computer Assisted Tests**.

To test the CO2 monitoring system for leaks:

Note: Make sure the defibrillator is turned OFF and no tubing is connected to the device.

1. Open the hose clamp on the CO2 leak test kit and depress the syringe fully.
2. Connect the tubing to the front panel CO2 connector.
3. Use P/N MTL250 to connect the tubing to the back panel CO2 gas outlet.
4. Secure the fittings that connect to the device to avoid leakage.



DUT

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PIP – Instructions

PIP- CO2 Leakage Test (continued)

5. Pull the syringe plunger out to induce a vacuum into the system. When the vacuum manometer indicates approximately -250 mmHg +/- 50 mmHg, close the tubing clamp firmly.
6. Wait a minimum of three (3) seconds after closing the tubing clamp, then obtain an initial vacuum reading.
7. Verify that after 30 seconds, the change in vacuum reading is less than 15 mmHg (20 mBars).
8. Disconnect the tubing connection from the front panel CO2 connector to release the vacuum.
9. Disconnect the tubing connection from the back panel gas outlet and release the tubing clamp.

PIP – Instructions

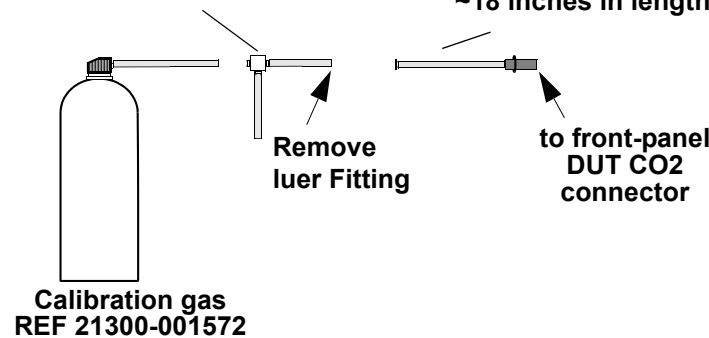
PIP- CO2 Calibration Check

To check CO2 calibration:

1. Connect the RS-232 (DB9 M/F) cable from the DUT to the test computer.
2. Launch the LIFENET Device Agent (LDA) from the test computer.
3. Follow instructions as prompted by the LDA to check CO2 calibration.

CO2 calibration kit
REF 21330-000239

Cut CO2 filter line
REF 11996-000068 to
~18 inches in length



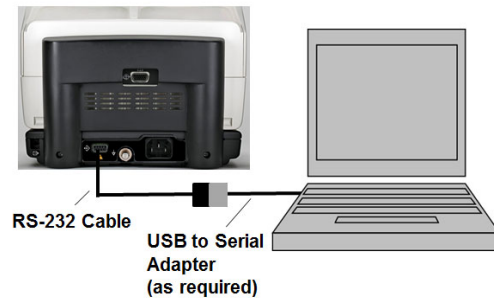
DUT

4. Verify that the measured gas concentration reads $5.0\% \pm 0.3\%$. If the measured value is incorrect, perform the **TCP – CO2 Calibration**.
5. Disconnect the CO2 filter line from the DUT.

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PIP – Instructions

PIP - Computer Assisted Tests



The CodeManagement Module Computer Assisted Test software automatically tests the serial communication to the defibrillator, the USB interface, battery power, battery I²C, Wireless and Wireless switch functionality.

1. Ensure that an operational wireless network (WPA/WPA2 enterprise or personal) signal is being broadcasted.
2. Launch the CodeManagement Module Test software P/N 3313963 from the test computer and follow instructions as prompted.

Note: Use a USB to Serial adapter as required to connect the DUT to the test computer.

Note: If the DUT does not communicate with the test computer, remove both the battery and AC power from the DUT. Wait ~ 1 minute. Reinstall both the battery and AC power. Try the test again as necessary.

3. Verify all tests PASS.

Note: If any difficulty is observed during communication between the PC and the CodeManagement Module while using a USB to Serial adapter, in particular during the Wireless communications test, it is possible that the Serial to USB adapter is configured incorrectly, or is incompatible with the PC and/or its operating system. Replace the Serial to USB adapter with an alternate model as necessary.

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PIP – Instructions

PIP - Computer Assisted Tests (continued)

Note: A wireless communications test failure could be the result of the wireless signal. Retry the test as necessary.

4. Turn off the defibrillator and disconnect the RS-232 cable from the DUT.
5. Press the reset button on the side of the DUT to reboot the DUT.

Note: Ensure the DUT completes the reboot before continuing (~1 min).

PIP – Instructions

Electrical Safety Tests

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

- IEC (International Electrotechnical Commission) 62353
- IEC (International Electrotechnical Commission) 60601-1 and 60601-2-4

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.

Note: Ensure the RS-232 cable is not connected to the DUT during electrical safety testing.

Note: Safety analyzer setup instructions are specific to the Fluke Biomedical ESA612.

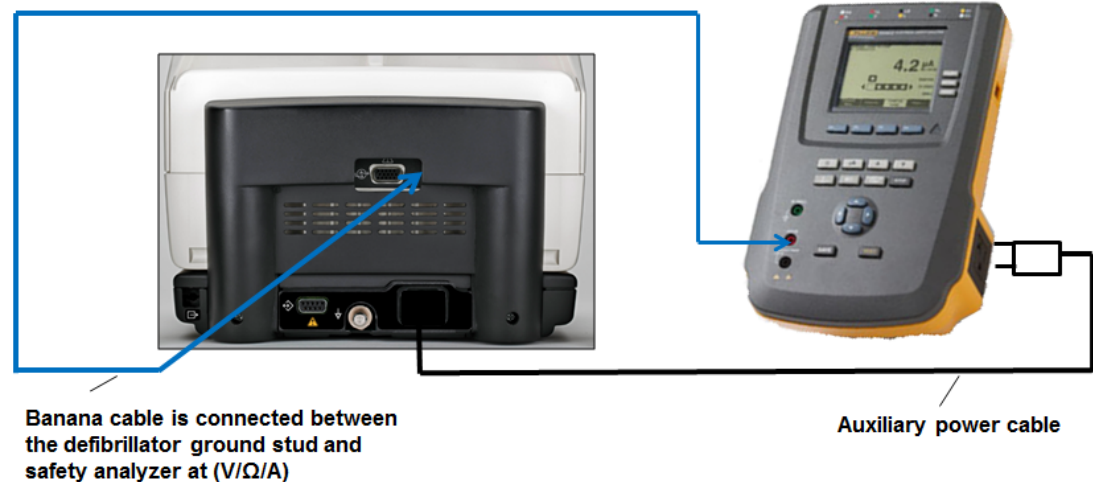
PIP – Instructions

PIP- Protective Earth Resistance - LIFEPAK 20e Defibrillator Ground Stud

To test the Protective Earth Resistance from the defibrillator ground stud:

1. Turn the defibrillator OFF.
2. Set up the test as shown below.

Note: Use Alligator Clip P/N AC220 (or equivalent) to access the defibrillator ground stud through the DUT bridge opening for the DB15 port.



3. Set the safety analyzer controls to measure Ohms by selecting the Ohm button on the safety analyzer.
4. Verify the measured protective earth resistance is less than 0.3 Ohms (120 and 240 Vac).

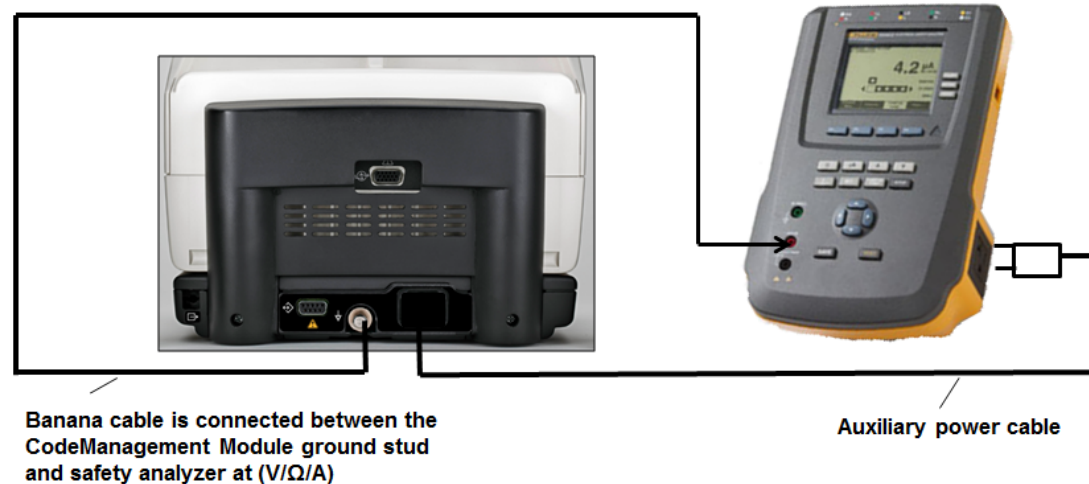
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PIP – Instructions

PIP- Protective Earth Resistance - CodeManagement Module Ground Stud

To test the Protective Earth Resistance from the CodeManagement Module ground stud:

1. Turn the defibrillator OFF.
2. Set up the test as shown below.



3. Set the safety analyzer controls to measure Ohms by selecting the Ohm button on the safety analyzer.
4. Verify that the measured protective earth resistance is less than 0.3 Ohms (120 and 240 Vac).

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PIP – Instructions

PIP- Leakage Current Setup

To set up the remaining leakage current tests:

Note: Reference the figures below for test setup using QUIK-COMBO therapy cable and test setup using STANDARD PADDLES.

1. Connect a banana cable between the CodeManagement Module ground stud and the safety analyzer V/Ohm/A output.
2. Connect the customer ECG Lead (5-wire or 3-lead) cable between the defibrillator and the 1210 box.
3. Connect the 1210 box to the safety analyzer at RA snap with an ECG snap to banana plug cable.
4. Connect the Therapy cable (QUIK-COMBO or Standard Paddles) between the defibrillator and the safety analyzer at LL and LA snaps.
5. Connect the AC power from the CodeManagement Module to the safety analyzer AC output.
6. Connect the SpO2 Leakage cable (if equipped) between the defibrillator and the safety analyzer at RL snap.

Warning

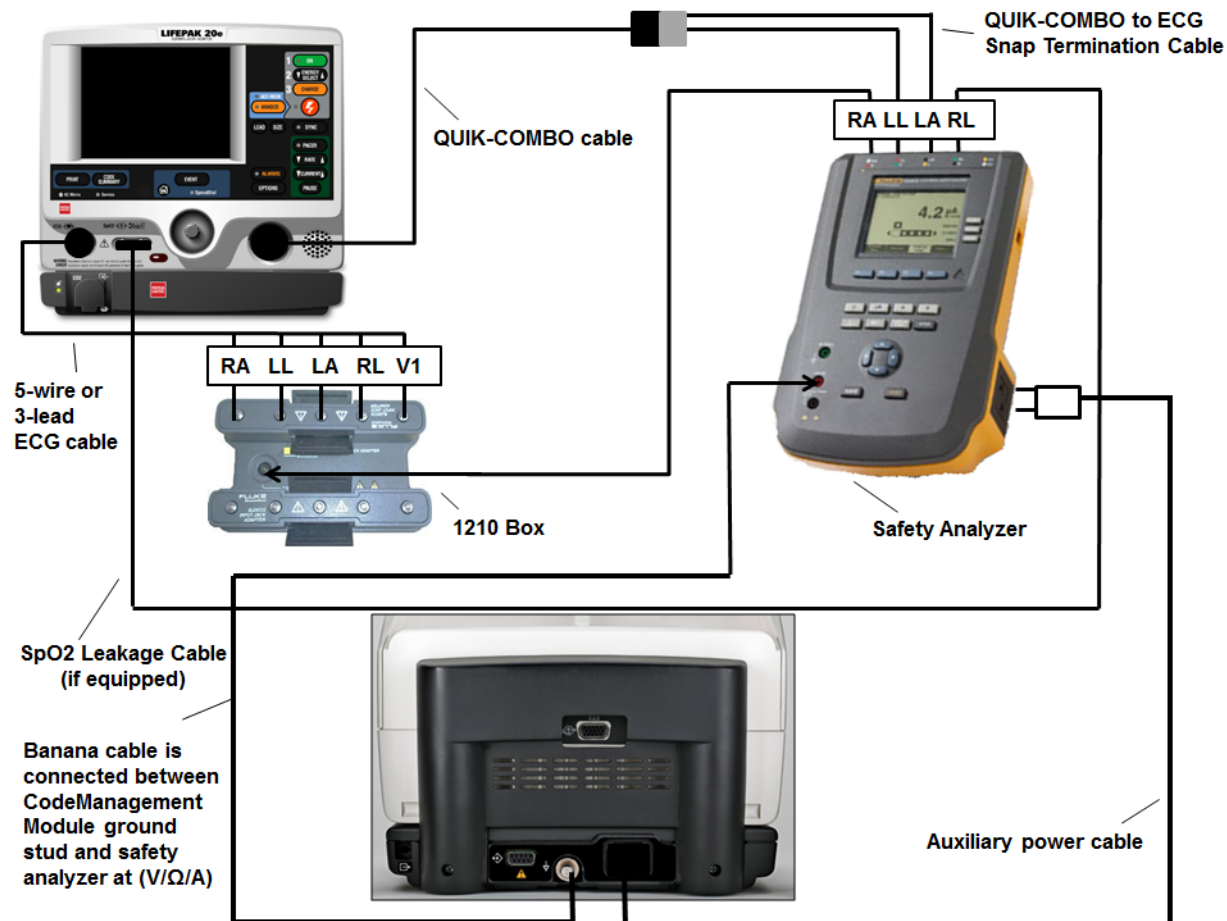
SHOCK HAZARD. Do not defibrillate when connected to the safety analyzer.

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PIP – Instructions

PIP- Leakage Setup

QUIK-COMBO Therapy Setup

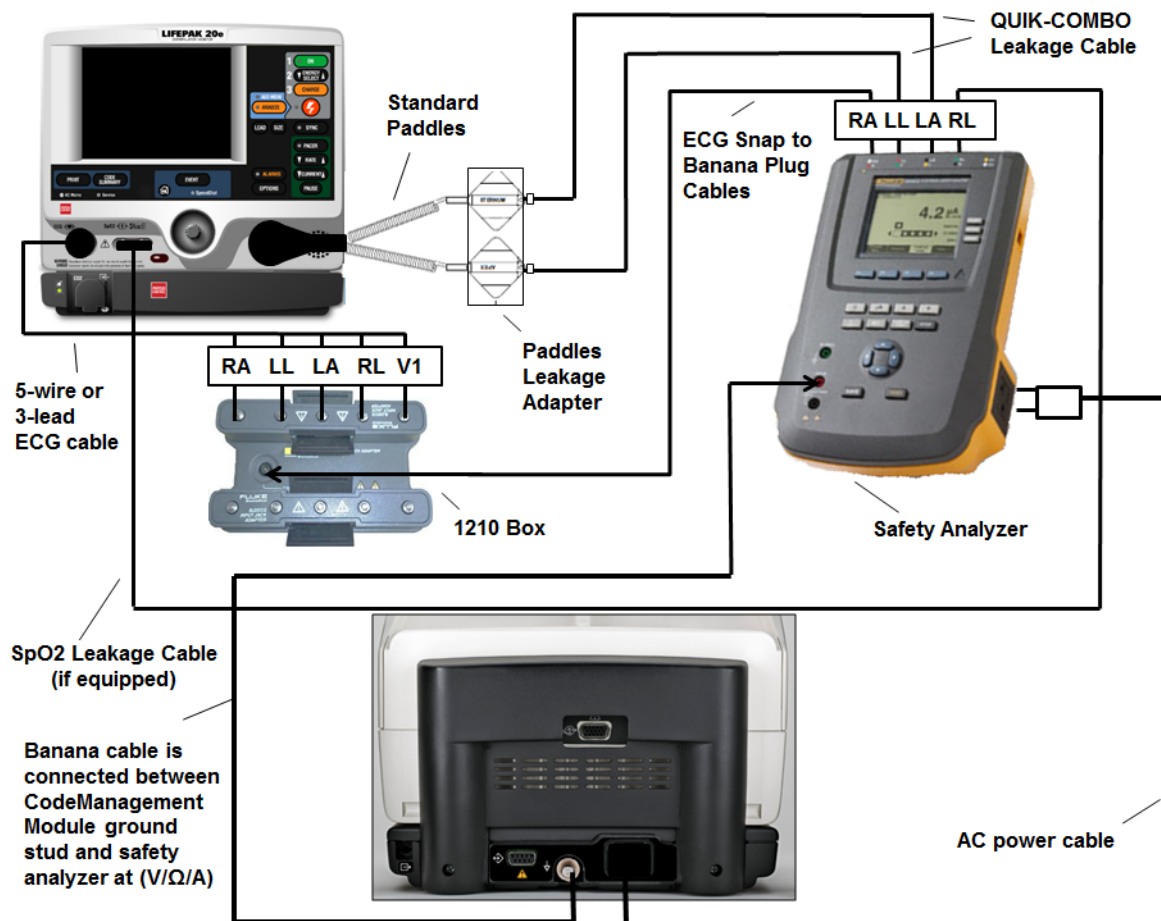


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PIP – Instructions

PIP- Leakage Setup

Standard Paddles setup



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PIP – Instructions

Earth Leakage Test Setup

To perform the Earth Leakage test in accordance with IEC 60601, 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 60601 standard
- Press the **DONE** button

PIP – Instructions

PIP - Earth Leakage Test - Normal Condition (NC)

1. Turn the defibrillator ON.
2. Press the μA button on the safety analyzer.
3. Press the **F1/EARTH** button on the safety analyzer and set the safety analyzer controls as follows:

Neutral	Polarity	Current Mode
Closed	Normal/Reverse	AC only

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

4. Verify the DUT AC Mains LED is ON.
5. Verify the defibrillator AC Mains LED is ON.
6. Verify the measured current is between 15 μA and 300 μA (120 Vac) or between 15 μA and 500 μA (240 Vac).

PIP – Instructions

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

1. Verify the defibrillator is ON.
2. Press the μA button on the safety analyzer.
3. Press the **F1/EARTH** button on the safety analyzer and set the safety analyzer controls as follows:

Neutral	Polarity	Current Mode
Open	Normal/Reverse	AC only

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

4. Verify the DUT AC Mains LED is OFF.
5. Verify the defibrillator AC Mains LED is OFF.
6. Verify the measured current is between 15 μA and 1000 μA (120 and 240 Vac).

PIP – Instructions

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
- Press the **DONE** button

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

1. Verify the defibrillator is 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 DUT and defibrillator AC Mains LEDs are ON.
5. Verify the measured current is between 15 μA and 300 μA (120 Vac) or between 15 μA and 500 μA (240 Vac).

PIP – Instructions

Direct Applied Part Leakage Test Setup

PIP - Direct Applied Part Leakage Test - ECG

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

1. Verify the defibrillator is ON.
2. Press the **LEFT/RIGHT** arrows to select the RA lead, and set the safety analyzer controls as follows:

Polarity	Lead
Normal/Reverse	RA (ECG group from Fluke 1210 adapter)

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.

3. Press the **TEST** button to measure the Direct Applied Part Leakage current.
4. Verify the DUT and defibrillator AC Mains LEDs are ON.
5. Verify the measured current is between 2 μA and 45 μA (120 and 240 Vac).

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PIP – Instructions

Direct Applied Part Leakage Test - Therapy

1. Verify the defibrillator is 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	Lead
Normal/Reverse	LL-LA (Therapy group)

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

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.

4. Verify the DUT and defibrillator AC mains LEDs are ON.
5. Verify the measured current is between 2 μ A and 5000 μ A (120 and 240 Vac).

PIP – Instructions

Direct Applied Part Leakage Test - SpO2

Note: Execute this test if the LIFEPAK 20e defibrillator/monitor is equipped with SpO2.

1. Verify the defibrillator is ON.
2. Press the **LEFT/RIGHT** arrows to select the RL lead and set the safety analyzer controls as follows:

Polarity	Lead
Normal/Reverse	RL (SpO2 group)

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

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.

4. Verify the DUT and defibrillator AC Mains LEDs are ON.
5. Verify the measured current is less than 5000 μ A (120 and 240 Vac).

PIP - Leakage Current Test Limits

Leakage Current Test Limit Summary

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	2 - 45 μ A	2 - 45 μ A
	Reversed	2 - 45 μ A	2 - 45 μ A
Therapy (Apex, Sternum) Direct Applied Part	Normal	2 - 5000 μ A	2 - 5000 μ A
	Reversed	2 - 5000 μ A	2 - 5000 μ A
SPO2 Direct Applied Part	Normal	0 - 5000 μ A	0 - 5000 μ A
	Reversed	0 - 5000 μ A	0 - 5000 μ A
Direct Equipment Leakage	Normal, Open Earth	15 - 300 μ A	15 - 500 μ A
	Reversed, Open Earth	15 - 300 μ A	15 - 500 μ A
Protective Earth Resistance	Measured from CodeManagement Module ground stud	0.3 Ohms	0.3 Ohms
Protective Earth Resistance	Measured from LIFEPAK20/20e defibrillator ground stud	0.3 Ohms	0.3 Ohms

TABLE - IEC 60601 Leakage Test Limits

Leakage Test to be Performed	Test Conditions	Range at 120V, 60HZ	Range at 240V,50HZ
Earth Leakage Current	Normal Condition	15 - 300 μ A	15 - 500 μ A
	Single Fault Condition	15 - 1000 μ A	15 - 1000 μ A

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TCP – Scope and Applicability

Test and Calibration Procedure

This section contains the Test and Calibration Procedures (TCP). Perform this section as necessary after replacing components or to correct out-of-specification conditions detected during the PIP.

Refer to the [PIP/TCP – Resource Requirements](#) for a listing of the necessary qualifications for PIP equipment, test equipment verification, workstation power, and personnel.

Refer to the [PIP/TCP – Test Equipment Requirements](#) for a listing of test equipment, including specifications, required to complete the PIP.

Throughout the body of this TCP, the CodeManagement Module is referred to as the Device Under Test or DUT.

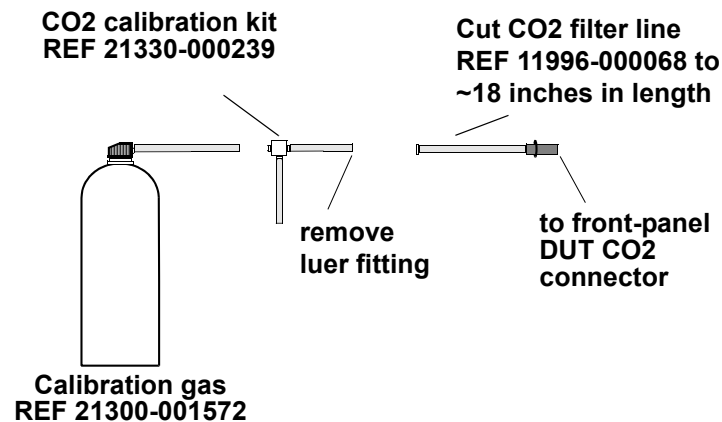
TCP – Instructions

TCP – CO2 Calibration

Note: Perform this test only if **PIP- CO2 Calibration Check** fails or if required by the LIFENET Device Agent (LDA).

To calibrate CO2:

1. Connect the RS-232 (DB9 M/F) cable from the DUT to the test computer.
2. Launch the Lifenet Device Agent (LDA) from the test computer.
3. Follow instructions as prompted by the LDA to calibrate CO2.



DUT

4. Verify that the CO2 calibration was successful.