

LIFEPAK 15 Test Calibration Procedure (TCP)

This section contains the Test and Calibration Procedures (TCP). Perform the procedures in this section as necessary after replacing device components or to correct out-of-specification conditions detected during the PIP. The following procedures may be performed in any order.

NOTE: Whenever the device is calibrated or opened for repair or component replacement, it must successfully pass all portions of the closed-case Performance Inspection Procedures .

- TCP -Scope and Applicability
- TCP - Resource Requirements
- TCP - Test Equipment Requirements
- TCP - Setup
- TCP - Service/Calibration Submenu Access
- TCP – Temperature Calibration Test
- TCP - Defibrillator Energy Tests
- TCP -Defibrillator Output Waveform Test
- TCP - Defibrillator Isolation Test
- TCP - CO2 Calibration
- TCP- Printer Tests
- TCP- Pacer Characteristics
- TCP – LIFENET Device Communications Setup

LIFEPAK 15 Test Calibration Procedure (TCP)

TCP- Scope and Applicability

This TCP applies to the LIFEPAK 15 monitor/defibrillator exclusively. You may perform the procedures outlined in this section in any order.

Note: Prior to its return to active use, the LIFEPAK 15 monitor/defibrillator must successfully pass all portions of the closed-case Performance Inspection Procedures (PIP) anytime the device is opened for repair, component replacement, upgrade, or after calibration.

See TCP – Resource Requirements for necessary equipment, test equipment verification, workstation power, and qualifications of the TCP personnel.

See TCP – Test Equipment Requirements for a list of test equipment, including specifications, required to complete the TCP.

TCP – Resource Requirements

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

TCP – Equipment

To perform the TCP, you must use the equipment listed in **TCP – Test Equipment Requirements** table. Although the table lists specific test equipment by manufacturer, test equipment with equivalent specifications may be substituted.

NOTE: Using test equipment other than that specified in the Test Equipment Requirements table may provide test results that are different from those specified in this manual. It is the responsibility of the biomedical personnel who maintain this device to determine test equipment equivalency.

Use only Physio-Control device accessories, including cables, batteries, and the appropriate Physio-Control battery charger.

TCP – Test Equipment Verification

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

TCP – Personnel

Technicians who perform the PIP must be properly qualified and thoroughly familiar with the operation of the LIFEPAK 15 monitor/defibrillator, meeting the requirements described in Service Personnel Qualifications.

LIFEPAK 15 Test Calibration Procedure (TCP)

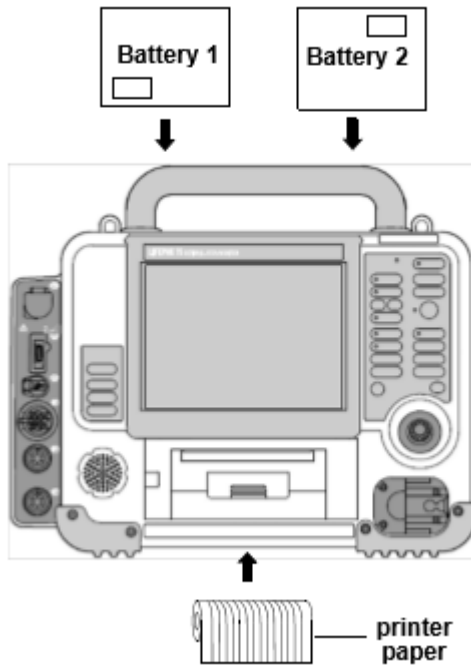
TCP-Test Equipment Requirements

Equipment	Specification or Description	Manufacturer or Part Number
Defibrillator analyzer with external noninvasive pacer measurements ^a	Energy range: 0 to 450 J Load resistance: 50 Ω \pm 1% Accuracy: \pm 2% +2 J Waveforms: NSR, VF, and sine wave Amplitude: 1.1mV \pm 10%	Fluke [®] Biomedical Impulse 7000DP with QUIK- COMBO adapter accessory 16/7 D/P ADPT104*
Lithium-ion battery pak	Li-ion battery with fuel gauge	Physio-Control P/N 3206735
Defibrillator isolation test load	Resistor test load: 200 ohms, 50 W, 5%	Physio-Control P/N 3205570
QUIK-COMBO therapy cable		Physio-Control P/N 3207047
Fast-Patch cable assembly	Connects QUIK-COMBO to test posts	Physio-Control P/N 3011030
Electrode test posts (2 ea)		Physio-Control P/N 3205979
Tubing assembly - CO2 calibration		Physio-Control P/N 3012430-01
Calibration gas	5% CO2, balance N2	Physio-Control P/N 3012556
FilterLine H set, adult/pediatric		Physio-Control P/N 3012176/XS-04660
Temperature probe simulator	Accuracy \pm 0.05 degrees C for all settings	Fogg TP 400
Cable Assembly, Temperature Adapter		Physio-Control P/N 3303938-000
Fogg TP400 Interface cable		Physio-Control P/N 3308413
<p>a. Some energy meters are not accurate for biphasic waveforms; for more information, contact your defibrillator analyzer manufacturer.</p> <p>*Equivalent equipment is required to meet the specifications listed in the specification column</p>		

LIFEPAK 15 Test Calibration Procedure (TCP)

TCP – Setup

The following describes the LIFEPAK 15 monitor/defibrillator setup for the TCP.
To set up the device for the TCP:



1. In the Battery wells 1 and 2, insert each LP15 Lithium-ion battery into the battery well until it clicks into place.
2. Connect the AC power cable into the device as needed

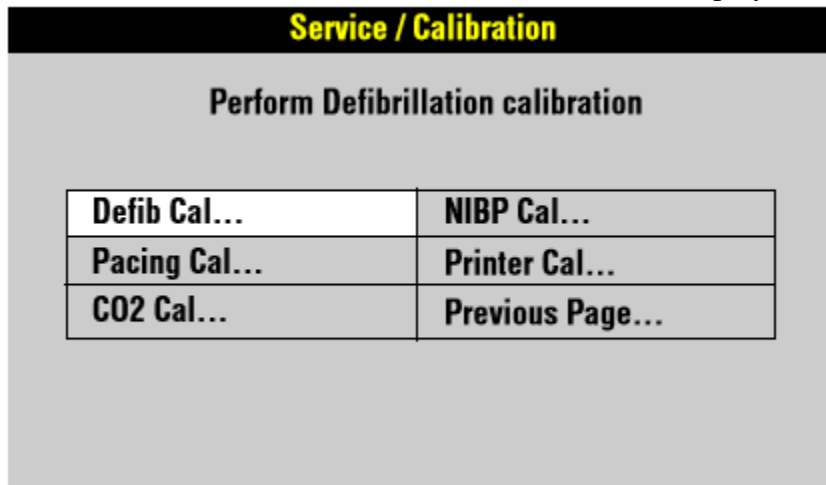
NOTE: Do not connect anything to the device therapy connector except as directed during these procedures.

LIFEPAK 15 Test Calibration Procedure (TCP)

TCP – Service/Calibration Submenu Access

To display the Service/Calibration submenu after performing TCP –Setup.

1. Access the service mode as described in Entering Service Mode.
2. Select CALIBRATION from the Service menu to display the Service/Calibration submenu as shown below.

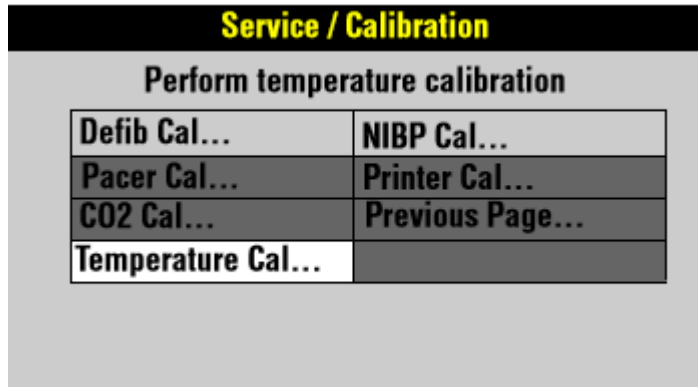


LIFEPAK 15 Test Calibration Procedure (TCP)

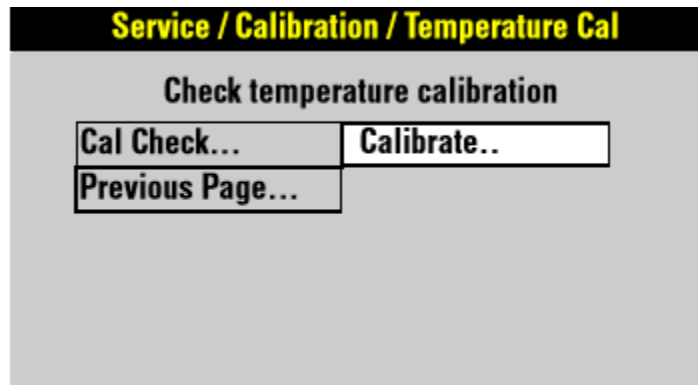
TCP – Temperature Calibration Test

Perform the temperature calibration test:

1. Turn the device ON.
2. Access the Service mode (see Entering Service Mode).
3. Select CALIBRATION from the Service menu as shown below.

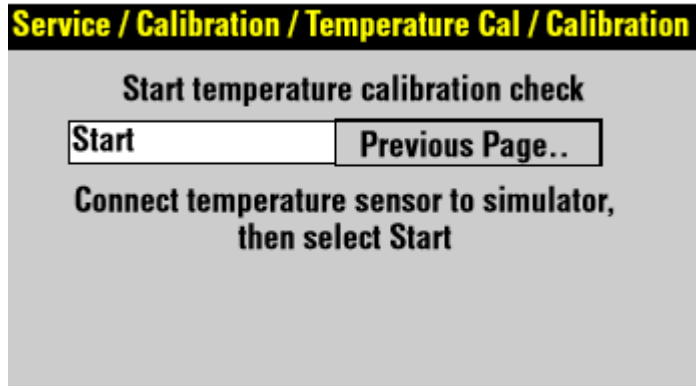


4. Select the Temperature Cal from the Service /Calibration menu as shown below.

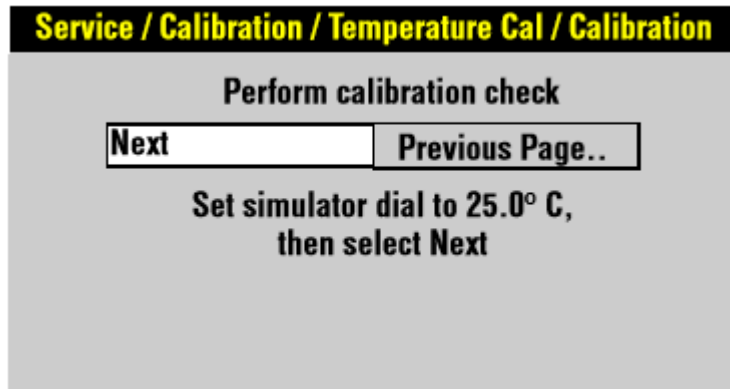


5. To initiate Temperature Calibration Check, select Calibrate from the Service / Calibration / Temperature Cal menu as shown below..

LIFEPAK 15 Test Calibration Procedure (TCP)

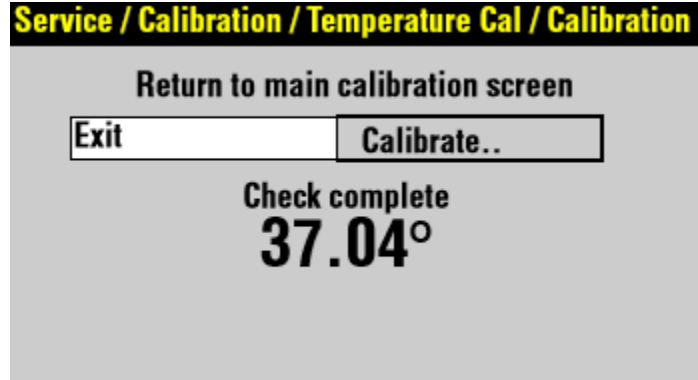


6. Connect the temperature sensor to the device and selected the Start button as shown below.



7. After NEXT is selected, the test, CALIBRATING... appears on the screen centered about the SET SIMULATOR text.
8. The CALIBRATING.... text is removed when calibration at 25.0° is complete and step 7 is repeated, but with 45.0° instead of 25.0°.
9. The CALIBRATING.... text is removed when calibration at 45.0° is complete and step 7 is repeated AGAIN, but with 37.0°.
10. When the calibration is complete as shown below.

LIFEPAK 15 Test Calibration Procedure (TCP)



Note:

- If the calibration fails, the screen will look like the previous screen except that the text message above the temperature value will be CALIBRATION FAILED.
- An XXX will appear in the Temperature parameter region in place of the Temperature value and will remain through power cycles until the module is no longer disabled.
- This failure will not generate a service light when the device is powered up in the normal operating mode.
NOTE: Temperature calibration will be left unchanged if the calibration fails because the user steps through the process without a simulator, or uses incorrect settings. This prevents the temperature channel from being disabled accidentally as a result of improper calibration procedures

LIFEPAK 15 Test Calibration Procedure (TCP)

TCP – Defibrillator Energy Tests

Defibrillator energy tests include:

- TCP – Defibrillator Energy Calibration Test
- TCP – Delivered Energy Verification Test

LIFEPAK 15 Test Calibration Procedure (TCP)

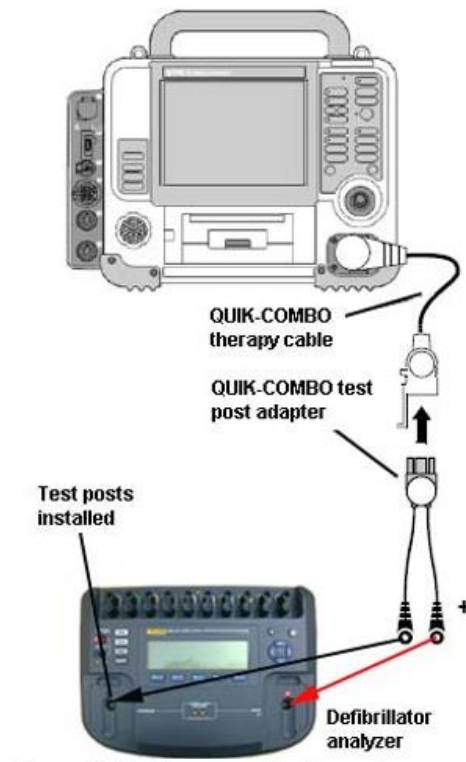
TCP – Defibrillator Energy Calibration



Avoid contact with the energy meter. Dangerous voltages are present on energy meter electrode plates/posts.

To perform the defibrillator calibration procedure:

1. Establish the Defibrillator Energy Tests setup as shown in the following figure. Make sure the therapy cable (+) terminal is connected to Apex (+) as shown below.



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. Set the defibrillator analyzer to measure ENERGY, using the appropriate scale.

LIFEPAK 15 Test Calibration Procedure (TCP)

3. Turn the device ON.
4. Select DEFIB CAL from the Service/Calibration submenu. See TCP – Service/Calibration Submenu Access .
5. Select START to initiate the calibration routine.
6. Follow the instructions on the device screen.
7. Turn the device OFF when the calibration procedure is complete.
8. Continue with the TCP – Delivered Energy Verification Test with this setup in place.

LIFEPAK 15 Test Calibration Procedure (TCP)

TCP – Delivered Energy Verification Test

Perform the delivered energy verification test at 2 J, 10J, 100J, 200J, and 360J.
Instructions here are for all energy levels.



Avoid contact with the energy meter. Dangerous voltages are present on energy meter electrode plates/posts.

To verify the defibrillator delivered energy:

1. Turn the device ON.
2. Select the desired energy to 2 J, 10J, 100J, 200J and 360J.
3. Push CHARGE button on the keypad and wait for the device to reach full charge.
4. Push the ⚡ (shock) button on the keypad to discharge the device energy into the defibrillator analyzer.
5. Verify that the defibrillator analyzer shows an energy level between as specified in the following table.

Delivered Energy	Low Limits	High Limits
2 J	1.0	3.0
10 J	9.1	10.9
100 J	97.75	102.25
200 J	195.5	204.5
360 J	352	368

7. When testing is complete, turn the device OFF and disconnect the test setup.

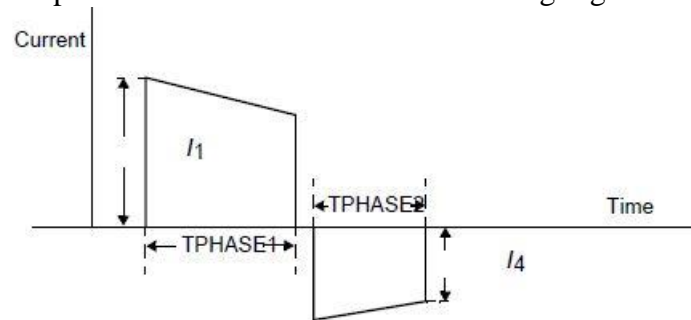
LIFEPAK 15 Test Calibration Procedure (TCP)

TCP – Defibrillator Output Waveform Test

This test is optional and is intended to aid in troubleshooting the A13 Transfer Relay Assembly or the A15 Energy Storage Capacitor. Use fully charged batteries when performing this procedure.

To test the defibrillator output waveform:

1. Connect the device to the defibrillator analyzer as described in TCP – Defibrillator Energy Calibration .
2. Turn the device ON.
3. Select the desired energy to 360J.
4. Push CHARGE button on the keypad and wait for the device to reach full charge.
5. Push the ⚡ (shock) button on the keypad to discharge the device energy into the defibrillator analyzer.
6. Verify that the waveform meets the specifications as shown in the following Figure and Table .



Phase 1 Peak Current		Phase 1 Pulse Width		Phase 2 Pulse Width	
Min	Max	Min	Max	Min	Max
35A	42A	6.9ms	7.8 ms	4.5 ms	5.4 ms

5. When testing is complete, turn the device OFF and disconnect the test setup.

LIFEPAK 15 Test Calibration Procedure (TCP)

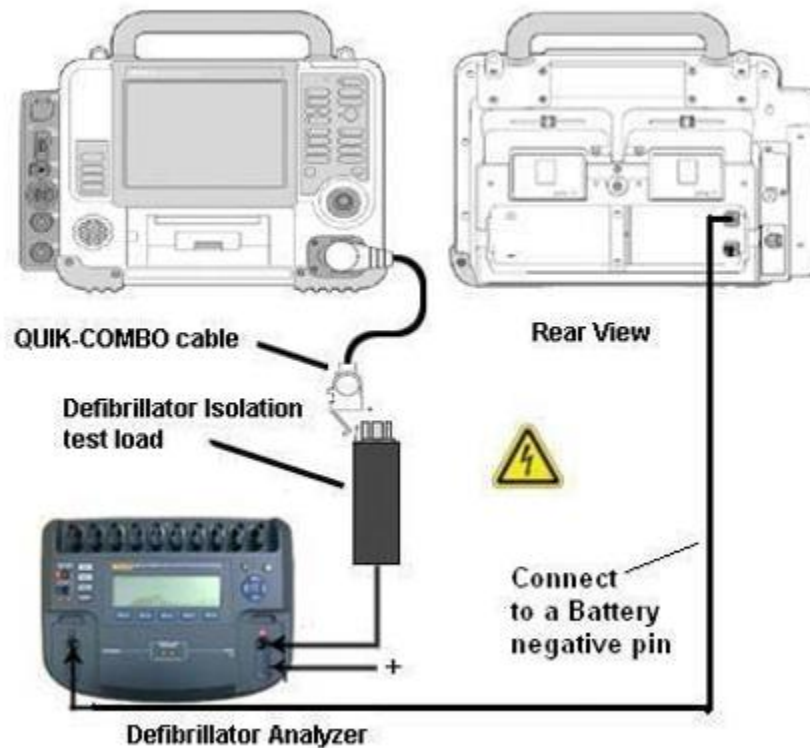
TCP – Defibrillator Isolation Test



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

To test defibrillator isolation after a therapy repair:

1. Establish the Apex setup as shown below.



2. Verify the defibrillator analyzer is on and set to measure ENERGY. If it is not set to ENERGY, press the ENRG softkey.
3. Turn the device ON.

LIFEPAK 15 Test Calibration Procedure (TCP)

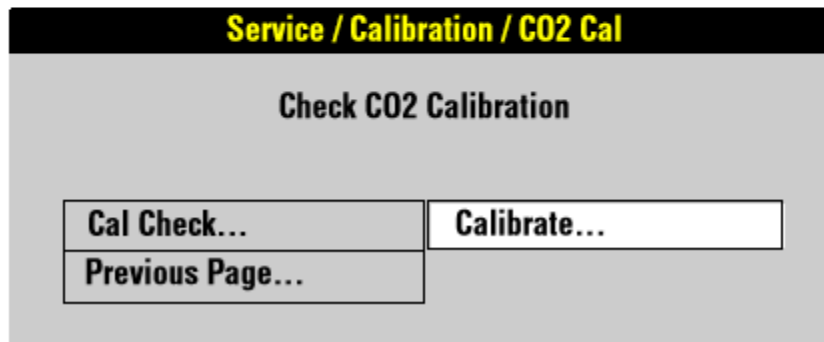
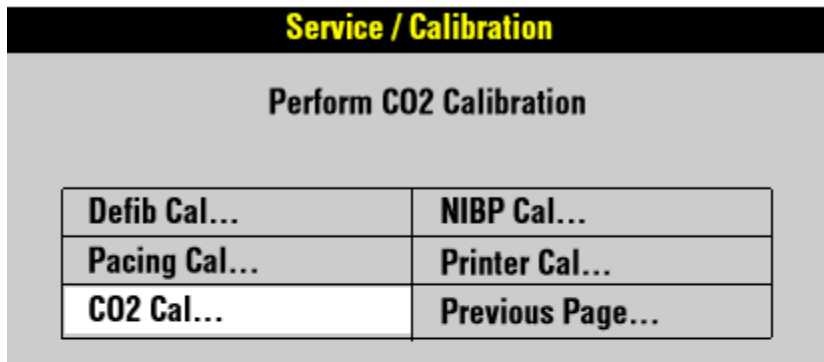
4. Select the desired energy to 360J by using the Up/Down arrows or dial on the touchscreen .
 5. Push CHARGE button on the keypad and wait for the device to reach full charge.
 6. Push the ⚡ (shock) button on the keypad to discharge the device energy into the defibrillator analyzer.
 7. Verify device displays message “Energy Delivered”.
 8. Verify the defibrillator analyzer indicates a delivered energy of less than 2J.
- NOTE:** The Impulse 7000DP may not detect any energy reading.
9. Turn the device OFF and disconnect the test setup.

LIFEPAK 15 Test Calibration Procedure (TCP)

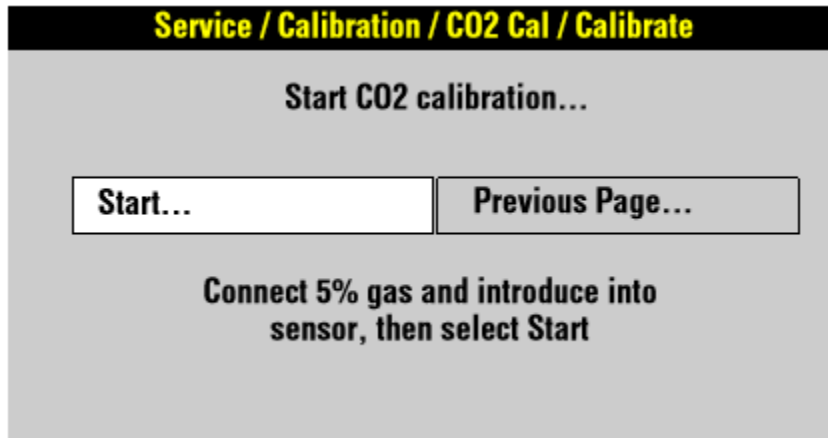
TCP – CO2 Calibration

To calibrate the CO2 module:

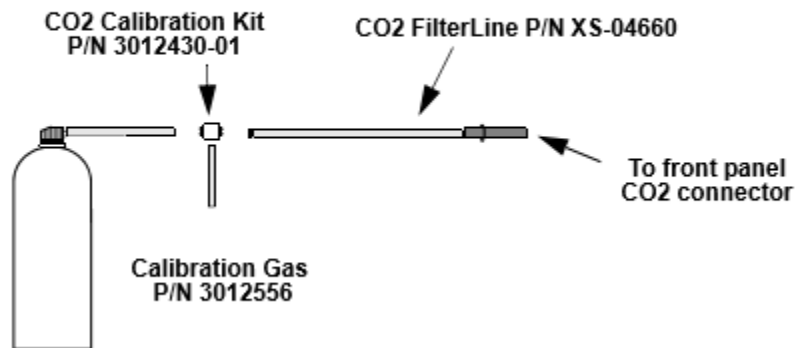
1. To complete the warm-up period, the device must be on for a total of 20 minutes before proceeding with the calibration of the CO2 module.
2. Turn the device ON and select CO2 CAL from the Service/ Calibration submenu as described in TCP – Service/Calibration Submenu Access .
3. Select CALIBRATE in the Service/Calibration/CO2 Cal submenu.



LIFEPAK 15 Test Calibration Procedure (TCP)

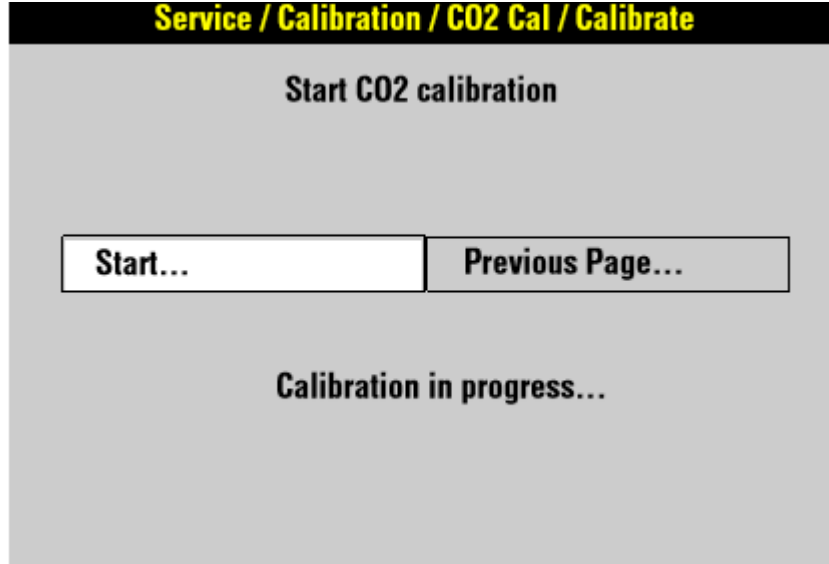


4. Connect the calibration gas canister to the front panel CO2 connector using a standard CO2 FilterLine and the CO2 calibration kit as shown below.



5. Press and hold the spray nozzle to apply calibration gas.
6. Select START and verify that the CALIBRATION IN PROGRESS message appears.

LIFEPAK 15 Test Calibration Procedure (TCP)



7. Continue pressing the spray nozzle until the DISCONNECT GAS message appears.

8. Release the spray nozzle.

9. Verify that the CALIBRATION OK message appears.

Note: Do not disconnect the FilterLine until the CALIBRATION OK message appears.

10. If the CALIBRATION FAILED message appears, an error code is written into the device Service Log and the front panel Service LED illuminates.

LIFEPAK 15 Test Calibration Procedure (TCP)

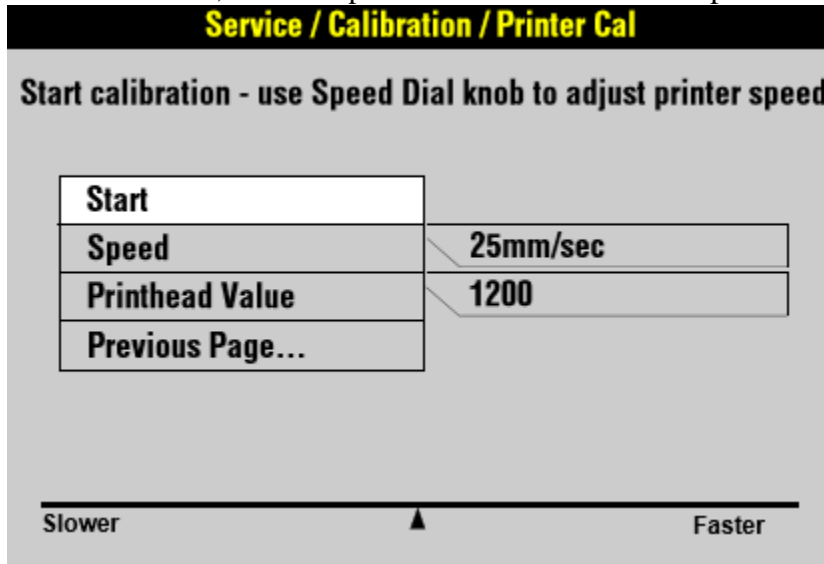
TCP – Printer Calibration Tests

Perform the following printer calibration tests:

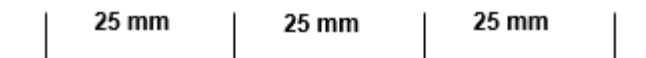
- TCP – Printer Calibration at 25 mm
- TCP – Printer Calibration at 12.5 mm

To perform the printer calibration procedure at 25mm:

1. Disconnect all front panel cables from the device.
2. Display the Service/Calibration submenu as described in TCP – Service/Calibration Submenu Access.
3. Select PRINTER CAL
4. Select START, and then press the SPEED DIAL. The printer begins printing horizontal tick marks.



5. Notice the spacing of the printed tick marks. The correct interval between marks is 25 mm \pm 1 mm (approx. 24 to 26 mm). Use the SPEED DIAL to adjust the printer speed SLOWER or FASTER.

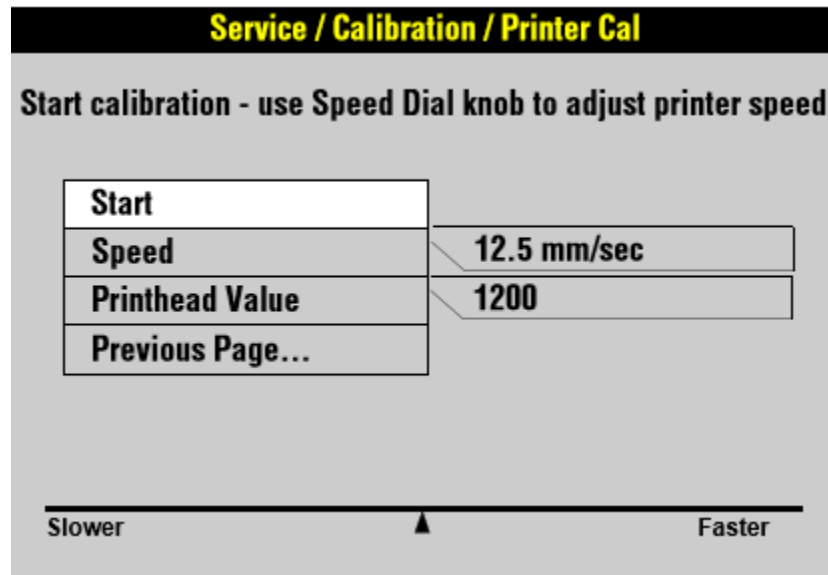


6. When the marks are spaced at 25 mm, press the SPEED DIAL to stop printing.
7. Turn the device OFF.

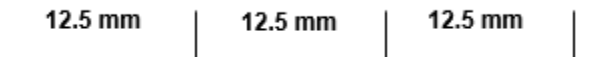
LIFEPAK 15 Test Calibration Procedure (TCP)

To perform the printer calibration procedure at 12.5mm:

1. Disconnect all front panel cables from the device.
2. Display the Service/Calibration submenu as described in TCP – Service/Calibration Submenu Access.
3. Select PRINTER CAL.



4. Select START, and then press the SPEED DIAL. The printer begins printing horizontal tick marks.
5. Notice the spacing of the printed tick marks. The correct interval between marks is 12.5 mm \pm 1 mm (approx. 12 to 13 mm). Use the SPEED DIAL to adjust the printer speed SLOWER or FASTER.



6. When the marks are spaced at 25 mm, press the SPEED DIAL to stop printing.
7. Turn the device OFF.

LIFEPAK 15 Test Calibration Procedure (TCP)

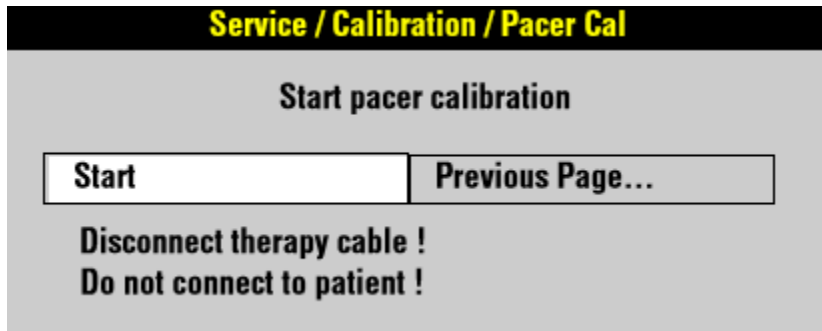
TCP – Pacer Characteristics Tests

Pacer characteristics tests include:

- TCP – Pacer Self-Calibration
- TCP – Pacing Verification Test

To perform the pacer self-calibration procedure:

1. Disconnect all front panel cables from the device.
2. Select PACING CAL from the Service/Calibration submenu as described in TCP – Service/Calibration Submenu Access.



3. Select START to initiate the calibration routine
4. In less than 60 seconds, the CALIBRATION COMPLETE message appears.
5. Turn the device OFF.
6. Continue with the TCP – Pacing Verification Test.

NOTE: This test is not applicable to devices containing the service reference number 4 icon.

To perform the pacing verification test for currents at 10mA, 50mA, 100mA, and 150mA.

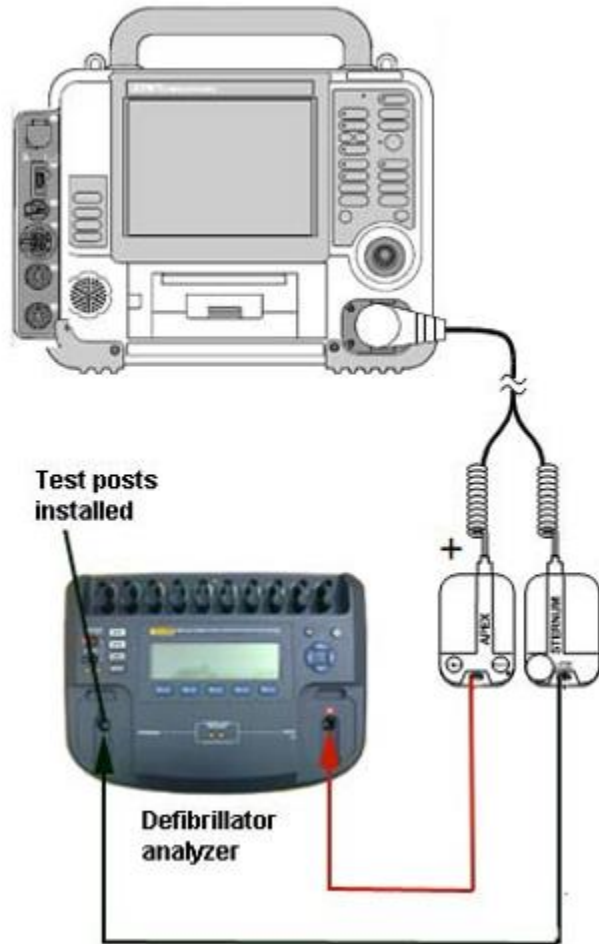
WARNING

SHOCK HAZARD Avoid contact with the energy meter. Potentially dangerous voltages will be present on energy meter electrode plates/ posts.

To verify the pacer current levels:

LIFEPAK 15 Test Calibration Procedure (TCP)

1. Connect the device to the Impulse 7000DP. Make sure the QUIK-COMBO (+) terminal is connected to apex (+).



2. Select Pacer button on Impulse 7000DP to measure pacing current.

3. In the menu screen, set the Brand to "Physio-Control" Input Jacks to "Defib," and Load to "50 ohm".

4. Turn the device ON.

5. Press PACER to activate pacing.

LIFEPAK 15 Test Calibration Procedure (TCP)

6. Set pacer rate on the device at 60 PPM.

7. Press CURRENT, and then use the SPEED DIAL to select the current being tested (test for 10 mA, 50 mA, 100 mA, and 150 mA).

8. Verify the measured pacer current is between the values specified in Table below

Set Current (mA)	Output (mA)
10	5.2 to 14.8
50	45.2 to 54.8
100	95.5 to 104.8
150	142.7 to 157.3

NOTE: Press CURRENT, as required, to maintain the CURRENT overlay on the screen.

9. When testing is complete, turn the device OFF and disconnect the test setup.

LIFEPAK 15 Test Calibration Procedure (TCP)

TCP – LIFENET Device Communications Setup

NOTE: The LIFENET[®] Device Communications for CODE-STAT Reviewer setup procedure is for testing the *Bluetooth* wireless technology option on the LIFEPAK 15 monitor/defibrillator. If the Bluetooth wireless technology option is not installed, ignore this procedure.


NOTE: It is assumed that the computer is using Microsoft[®] Bluetooth Enumerator as the driver for the Bluetooth hardware.

NOTE: If LIFENET Device Communications for CODE-STAT Reviewer is being used for the first time, you need to set up communication ports on your computer.

To set up Bluetooth communication ports on your computer:

1. Right-click the Bluetooth icon on the computer's taskbar (lower right location).
2. Select OPEN BLUETOOTH SETTINGS.
3. Select the COM PORTS tab.
4. Add an incoming COM port on the COM Ports tab and click OK.
5. Write down the COM port name for use in the next section.

To set up the COM port to operate with CODE-STAT Reviewer:

1. Open the CODE-STAT Reviewer application on your computer, and select the DEMO database.
2. Enter "physio" for the user ID and "control" for the password (case-sensitive).
3. Select UTILITIES, and then select SYSTEM CONFIGURATION.
4. Select the DEVICE DATA RECEPTION tab in the LIFENET System Configuration dialog box.
5. Click MODIFY at the bottom of the Communication Ports section.
6. In the Available window on the left side of the Communication Ports dialog box, select the COM port added previously on the COM Ports tab.
7. Click  to transfer the highlighted ports to the Use window on the right.
8. Click OK in the Communication Ports dialog box to return to the LIFENET System Configuration dialog box.
9. Click OK again. Your computer is now ready to receive data from a device.

NOTE: Do not close the CODE-STAT Reviewer application