

LIFEPAK®15

Test Calibration Procedure (TCP)

LIFEPAK®15 MONITOR/DEFIBRILLATOR



Test Calibration Procedure (TCP)



Test Calibration Procedure (TCP)

This document contains the Test and Calibration Procedures (TCP) for the LIFEPAK 15. 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.

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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.*

TCP - Resource Requirements.

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

TCP - Equipment

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

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 - Workstation Power

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

Test Calibration Procedure (TCP)

TCP-Test Equipment Requirements

| Equipment | Specification or Description | Manufacturer or Part Number/ Catalog Number (REF) |
|---|--|--|
| Defibrillator analyzer with external noninvasive pacer measurements** | Energy range: 0 to 450 J Load resistance: 50 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 | 21330-001176 |
| Defibrillator isolation test load | Resistor test load: 200 ohms, 50 W, 5% | 21300-007736 |
| QUIK-COMBO therapy cable | | 11113-000004 |
| Fast-Patch cable assembly | Connects QUIK-COMBO to test posts | 11110-000052 or Physio-Control P/N 3323095 |
| Electrode test posts (2 ea.) | | 21330-001372 |
| Tubing assembly - CO2 calibration | | 21330-000239 |
| Calibration gas | 5% CO2, balance N2 | 21300-001572 |
| Filter Line H set, adult/pediatric | | 11996-000068 |
| Temperature probe simulator | Accuracy \pm 0.05 degrees C for all settings | Fogg TP 400 |
| Cable Assembly, Temperature Adapter | | 11140-000078 |
| Fogg TP400 Interface cable | | Physio-Control P/N 3308413 |
| **Some energy meters are not accurate for biphasic waveforms; for more information, contact your defibrillator analyzer manufacturer. | | |
| *Equivalent equipment is required to meet the specifications listed in the specification column | | |

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.

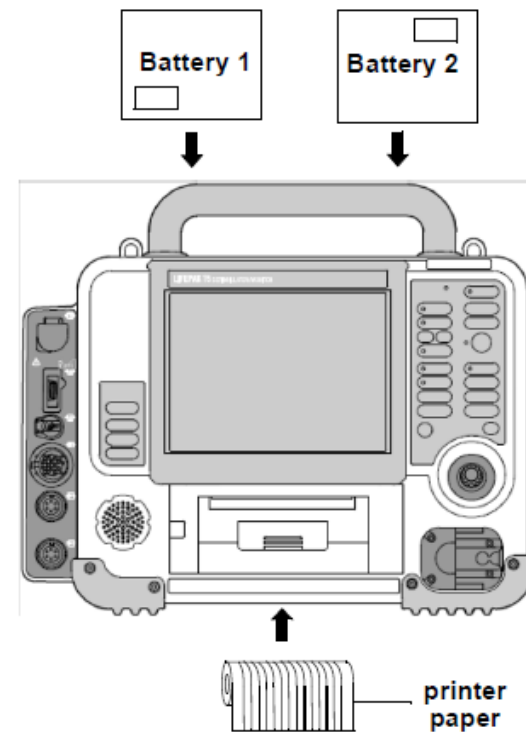


Figure 2.1—TCP setup

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 in Figure 2.2

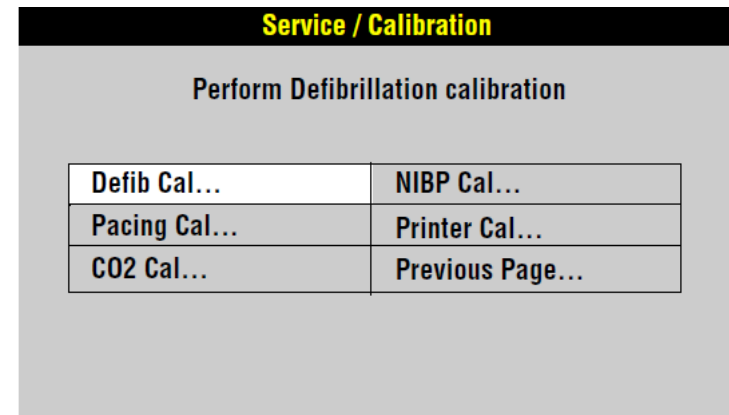


Figure 2.2—Calibration submenu

Test Calibration Procedure (TCP)

TCP - Temperature Calibration Test

To 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.
4. Select the Temperature Cal from the Service /Calibration menu as shown in Figure 2.3.

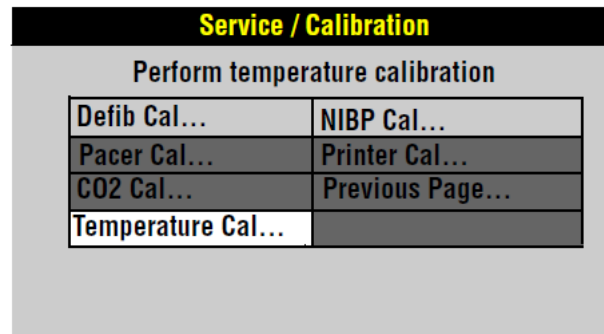


Figure 2.3—Calibration selection

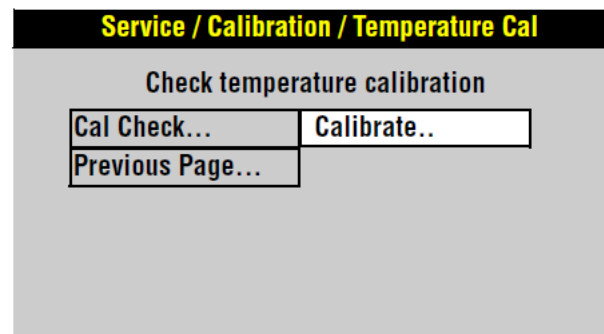


Figure 2.4—Temperature calibration selection

Test Calibration Procedure (TCP)

5. To initiate Temperature Calibration Check, select Calibrate from the Service / Calibration / Temperature Cal menu.
6. Connect the temperature sensor to the device and selected the Start button as shown in Figure 2.5.
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 in Figure 2.7.

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.

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.

Service / Calibration / Temperature Cal / Calibration

Start temperature calibration check

Start Previous Page..

Connect temperature sensor to simulator,
then select Start

Figure 2.5—Starting calibration check

Service / Calibration / Temperature Cal / Calibration

Perform calibration check

Next Previous Page..

Set simulator dial to 25.0° C,
then select Next

Figure 2.6—Calibration checking

Service / Calibration / Temperature Cal / Calibration

Return to main calibration screen

Exit Calibrate..

Check complete
37.04°

Figure 2.7—Calibration completion

TCP - Defibrillator Energy Tests

Defibrillator Energy Tests consist of:

[TCP-Defibrillator Energy Calibration](#)

[TCP-Defibrillator Energy Verification Test](#)

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 Energy Calibration :

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.
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.

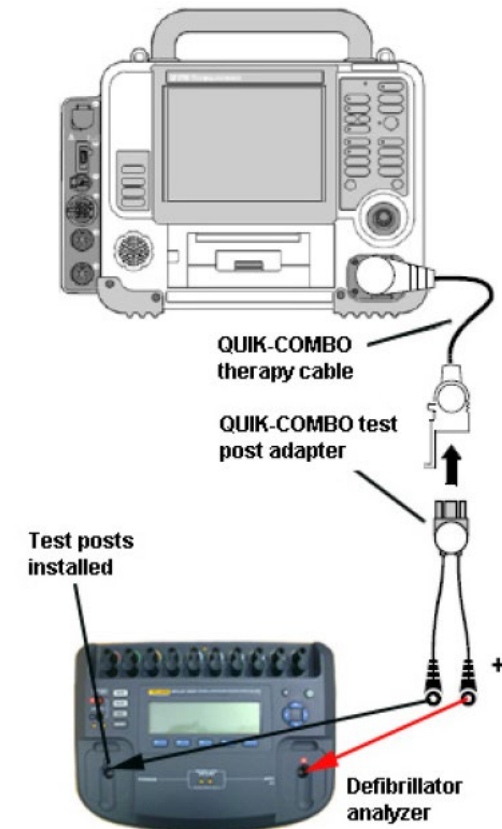


Figure 2.8—Energy calibration setup

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 perform the Defibrillator Delivered Energy Test:

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 |

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

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 perform the Defibrillator Output Waveform Test:

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.

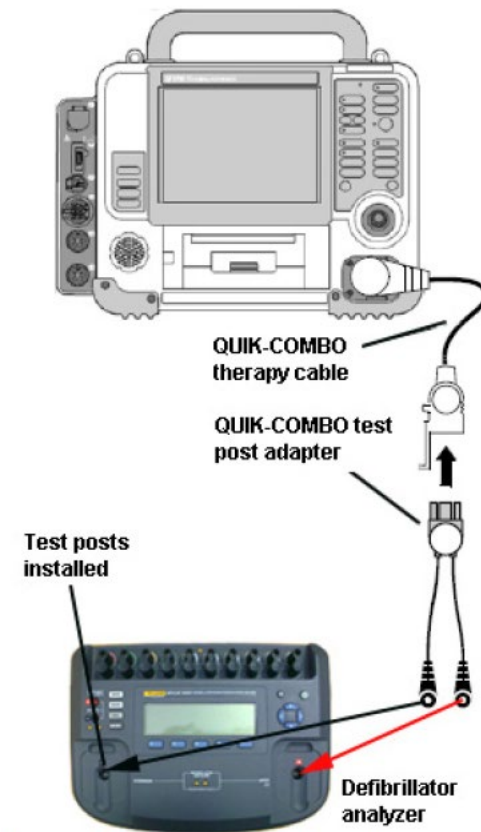


Figure 2.9—Output waveform test setup

Test Calibration Procedure (TCP)

- Verify that the waveform meets the specifications as shown in the following Figure 2.10 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 |

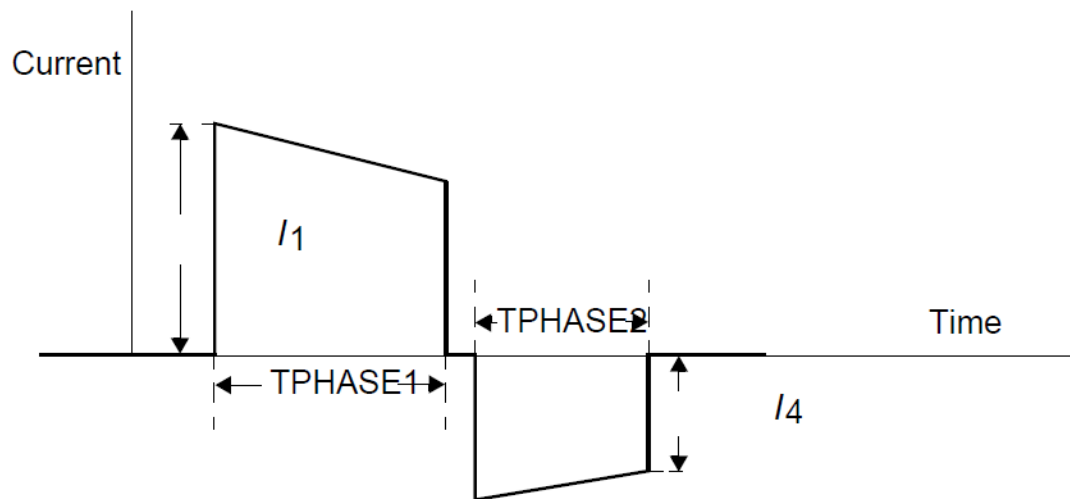


Figure 2.10—Output waveform specifications

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

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 perform Defibrillator Isolation Test after a therapy repair:

1. Establish the Apex setup as shown in Figure 2.19.
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.
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.

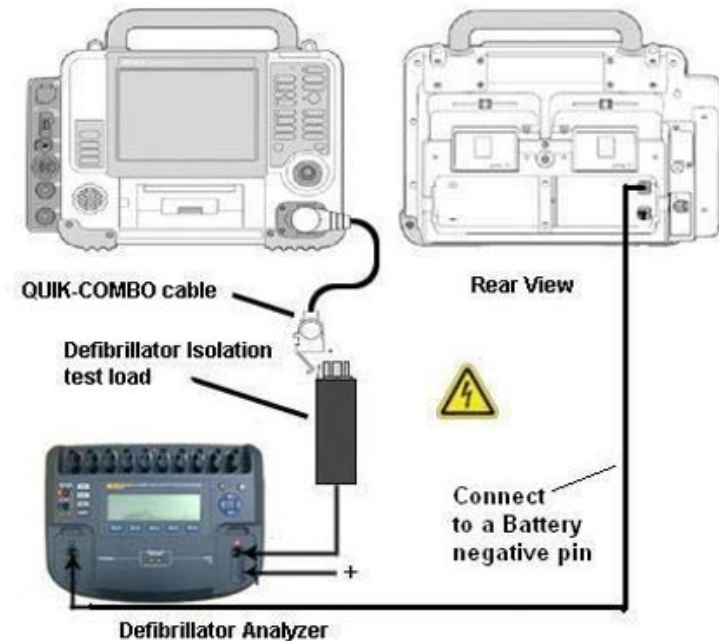


Figure 2.19 Defibrillator Isolation Setup

Test Calibration Procedure (TCP)

TCP - CO2 Calibration

To perform a calibration of 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.

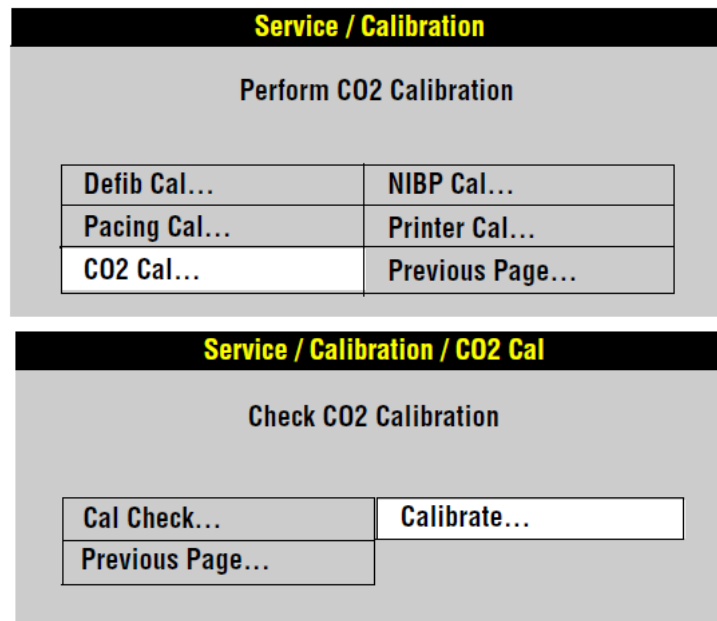


Figure 2.11—CO2 calibration submenus

Test Calibration Procedure (TCP)

- 4. Connect the calibration gas canister to the front panel CO2 connector using a standard CO2 Filter Line and the CO2 calibration kit as shown in Figure 2.13.

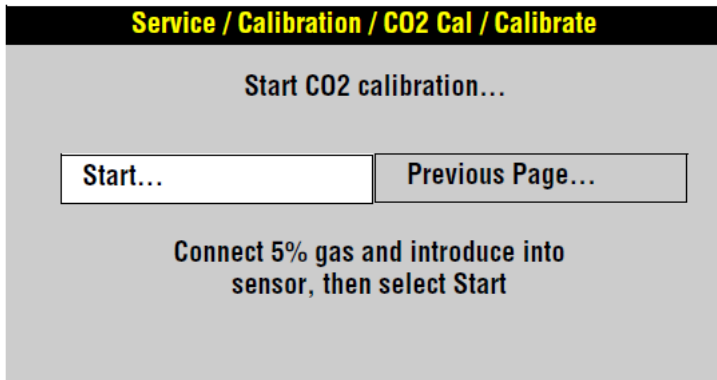


Figure 2.12—CO2 calibration overlay

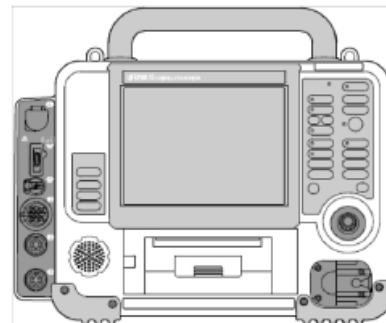
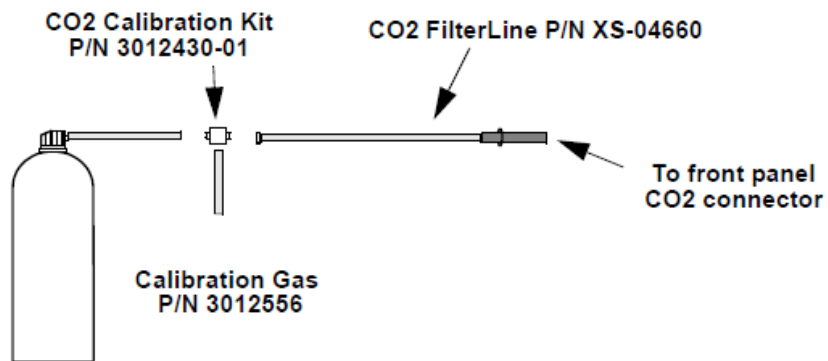


Figure 2.13—CO2 calibration connections

Test Calibration Procedure (TCP)

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

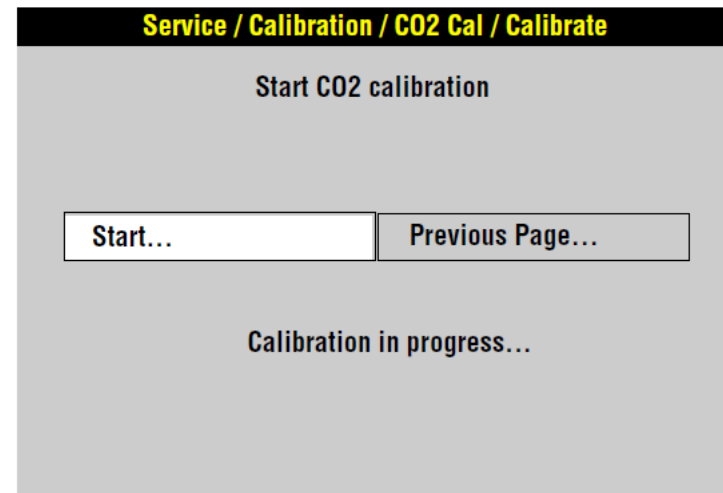


Figure 2.14—CO2 calibration start submenu

Test Calibration Procedure (TCP)

TCP - Printer Calibration Tests

The Printer Calibration tests consist of:

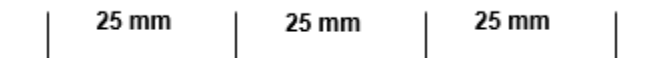
[TCP-Printer Calibration Test at 25mm](#)

[TCP-Printer Calibration Test at 12.5mm](#)

TCP - Printer Calibration Test at 25 mm

To perform the Printer Calibration Test 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.

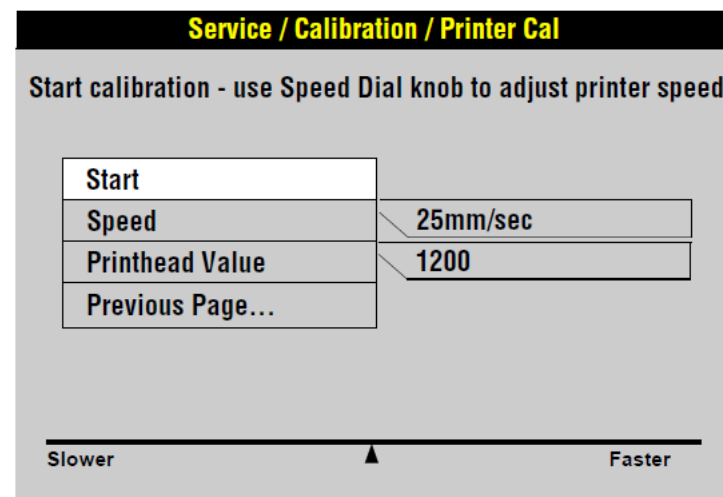


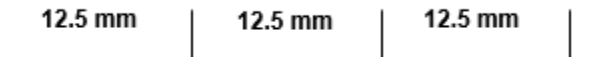
Figure 2.15—25 mm printer calibration submenu

Test Calibration Procedure (TCP)

TCP- Printer Calibration Test at 12.5mm

To perform the Printer Calibration Test 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 12.5 mm, press the SPEED DIAL to stop printing.
7. Turn the device OFF.

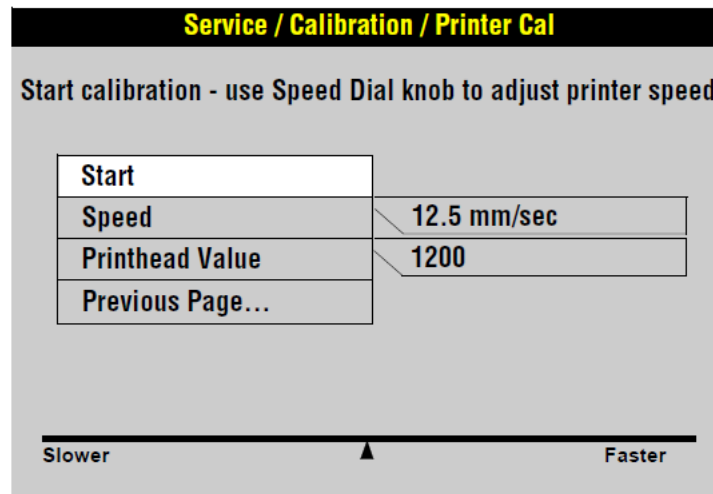


Figure 2.16—12.5 mm printer calibration submenu

Test Calibration Procedure (TCP)

TCP - Pacer Characteristics Tests

Pacer characteristics tests consist of:

[TCP-Pacer Self Calibration Test](#)

[TCP-Pacer Verification Test](#)

WARNING

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

TCP – Pacer Self-Calibration Test

1. To perform the Pacer Self-Calibration Test:
 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 appear.
 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.

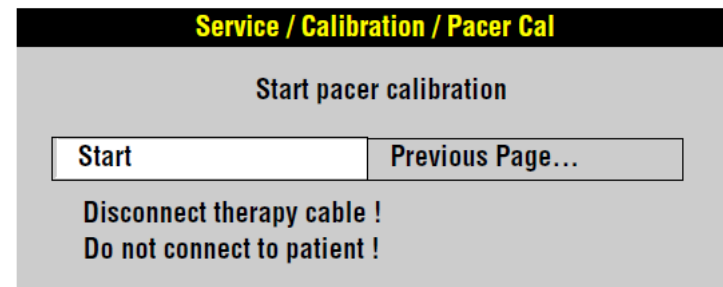


Figure 2.17—Pacer self-calibration submenu

Test Calibration Procedure (TCP)

TCP- Pacer Verification Test

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

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.
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.

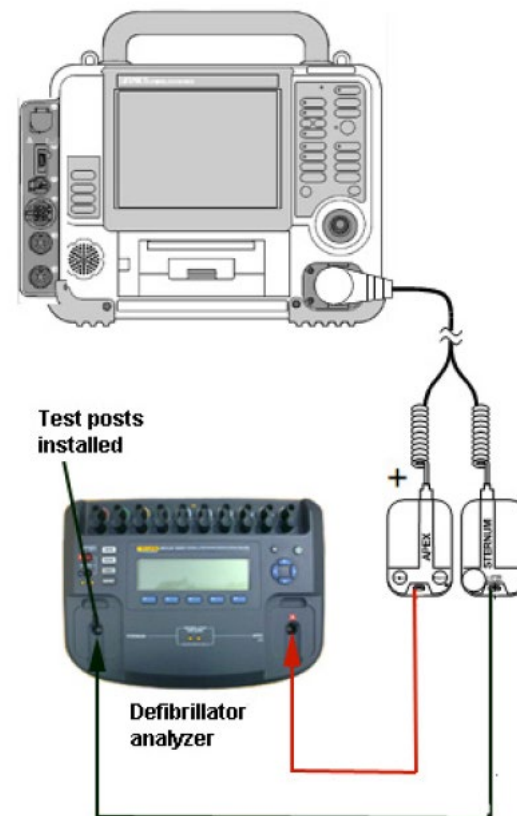


Figure 2.18—Pacing verification setup

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.


NOTE: 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. 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.

Test Calibration Procedure (TCP)

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.



LIFEPAK[®]15 MONITOR/DEFIBRILLATOR

Test Calibration Procedure (TCP)

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

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