LIFEPAK® 35 monitor/defibrillator

Test Calibration Procedure (TCP)

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This document contains the Test and Calibration Procedures (TCP) for the LIFEPAK 35 monitor/defibrillator. 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 Procedure****.*

CONTENTS

TCP - Scope and applicability

This TCP applies to the LIFEPAK 35 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 35 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 - Glossary

PIP: Performance Inspection Procedure

TCP: Test Calibration Procedure

DUT: Device under test

PSST: Procare Services Support Tool

WCT: Wi-Fi Config tool

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. Use only Stryker device accessories, including cables, batteries, and the appropriate Stryker 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 qualifications

Service personnel who perform the TCP must be thoroughly familiar with the operation of the LIFEPAK 35 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.

TCP - Test equipment requirements

Equipment	Specification or Description	Manufacturer	Part number/Catalog number (REF)
Defibrillator Analyzer	Power range: 0-450 J Load resistance: 50 Ω Accuracy and/or guard banding must be sufficient to ensure test limits.	Fluke	Impulse 7000DP
LIFEPAK Therapy Cable	Assy, Cable, Therapy, LIFEPAK 35	Stryker	11113-000007 or 11113-000008
Assy, QUIK-COMBO Test Cable, Therapy	QUIK-COMBO Plug to Banana Plugs	Stryker	PN: 3335630-001
Defibrillator Isolation Test Load	NA	Stryker	PN: 21330-007736
Assy, Cable, Service Test, Leakage USB GND, LIFEPAK 35	Use to perform Defib Isolation test	Stryker	PN: 3344955 -000
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
LIFEPAK Access Port Cable	Assy, Cable, Access Port, LIFEPAK 35	Stryker	11330-000007
Personal Computer	PC with internet access and Windows® 10 or above OS	HP or equivalent	EliteBook 840 or later/equivalent

Assy, Tubing, Calibration Test, MDT CO2	NA	Stryker	PN: 3335916-003
Chem- Gas, Mixture, Calibration, Aerosol	5% CO2, 20.6 % O2, BAL, N2	Stryker	21300-001572
AC Power Cord	NA	Tripp Lite or equivalent	P007-L03 or equivalent

TCP - 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 TCP. Do not attempt to perform this procedure unless you are thoroughly familiar with the operation of the device.

1. Verify two, fully functional, charged, LIFEPAK FLEX Lithium-ion batteries are showing more than two charge bars.
2. Insert the two Li-ion batteries into the device.
3. Verify that each battery clicks into position in the battery wells.
4. Connect LIFEPAK access port cable between DUT and PC.

TCP - PSST access

The following describes how to access the Procare Services Support Tool (PSST) to assist with varying calibrations/tests throughout the PIP and TCP. *Note: only perform if you do not have the latest version of PSST*

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 Service Commands menu.

TCP - Service log

The following steps outline how to access the device Service Log:

1. Device On.
2. Select the menu button at the bottom left of the screen.
3. Press “Options” and then “Shift Check”.
4. Allow the device to reboot.
5. Once the device has re-booted, select the “Service Log” tab near the top of the screen.

TCP – Defibrillator energy tests

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 TCP. Do not attempt to perform this procedure unless you are thoroughly familiar with the operation of the device.

Defibrillator energy tests include the following:

- TCP – Defibrillator energy calibration
- TCP – Delivered energy verification test
- TCP – Delivered output waveform test
- TCP – Defibrillator isolation test

TCP – Defibrillator energy calibration

To perform the defibrillator calibration procedure:

1. Establish the Defibrillator Energy Tests setup as shown in the following Figure 1.

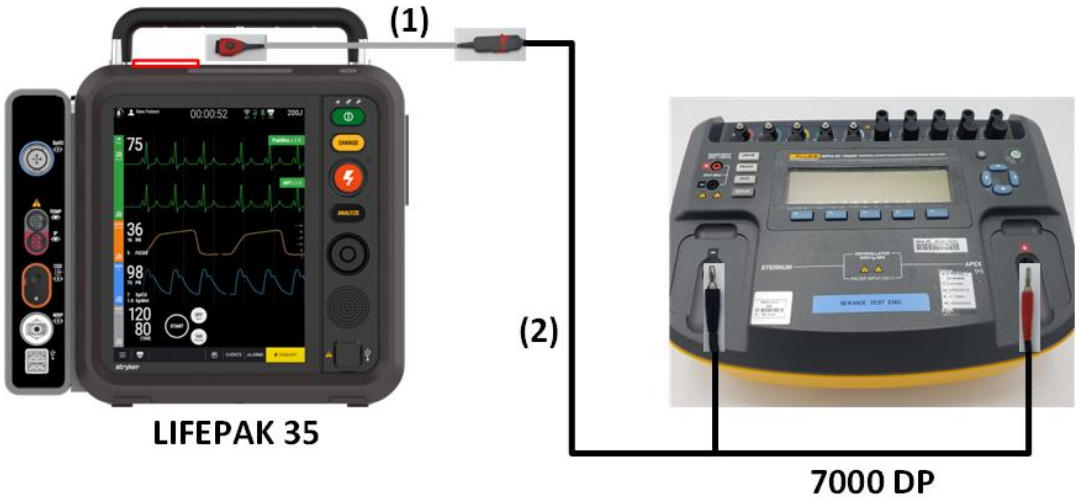


Figure 1

In Figure 1

Item 1: 11113-000007

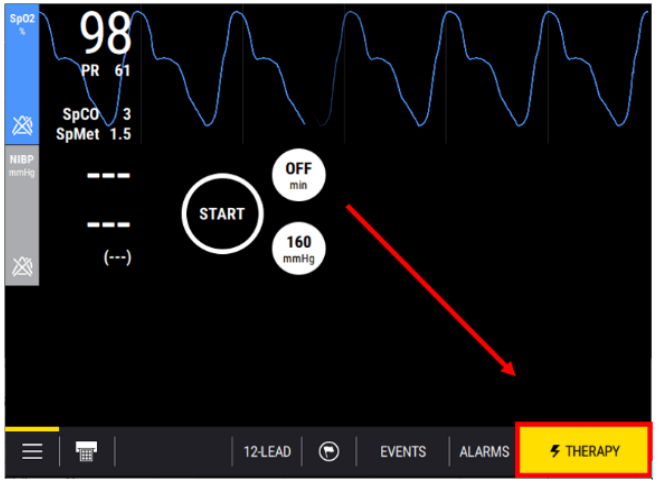
Item 2: 3335630-001

2. Make sure the therapy cable (+) terminal is connected to Apex (+).

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.*

3. Set the defibrillator analyzer to measure ENERGY, using the appropriate scale.
4. Turn the device ON.

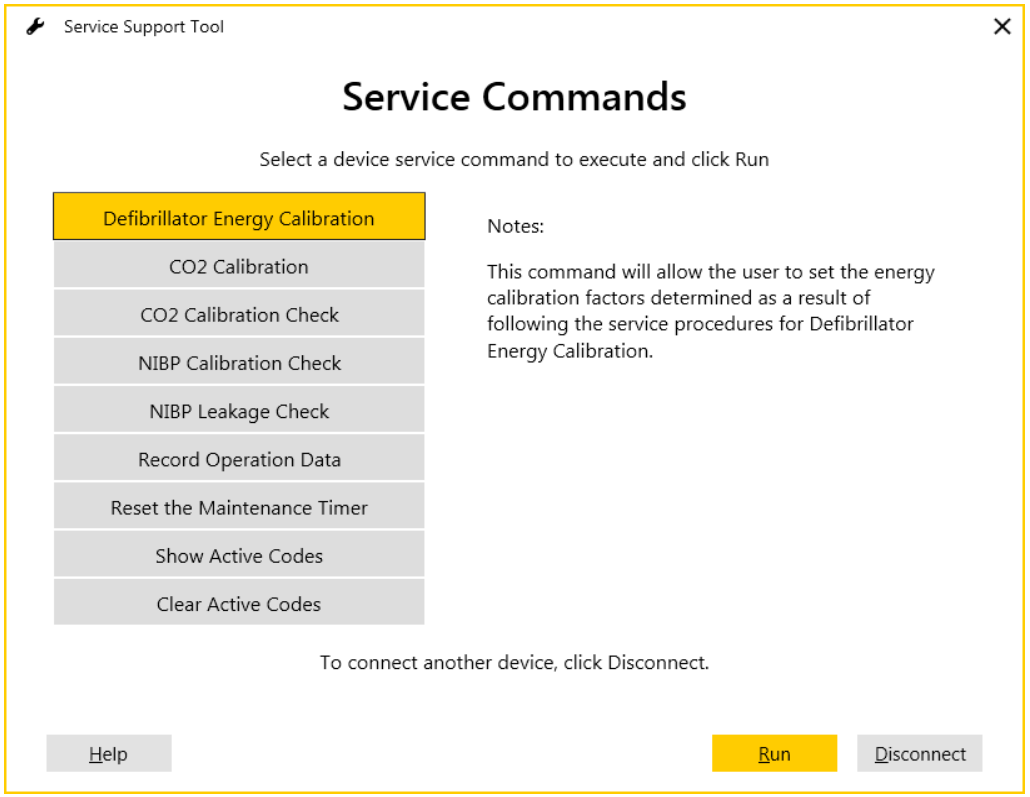
5. Access the Therapy Screen by pressing **THERAPY** in the lower-right corner of the touchscreen as shown in the following figure.



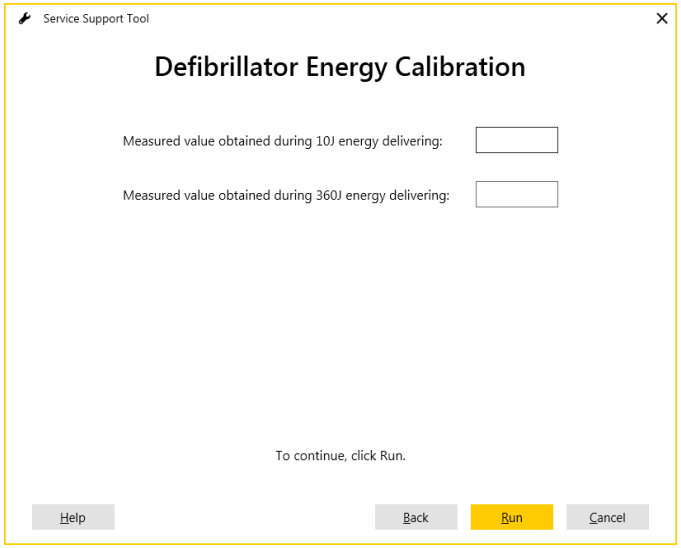
***NOTE**: If the device starts in AED mode, tap MANUAL DEFIB to access the Therapy Screen.*

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 and wait for the device to reach full charge.
8. Push the (shock) button on the keypad to discharge the device energy into the defibrillator analyzer.
9. Take note of the delivered energy values shown on the defibrillator analyzer. Repeat steps 5-7 for 360J.
10. Access the Service Commands screen within SST. See TCP – PSST Access.
11. Select Defibrillator Energy Calibration in the Service Commands screen.

12. Select RUN on the Service Commands screen.



13. Enter the defibrillation energy values from step #6 for both 10J and 360J, in the respective fields on the SST screen.

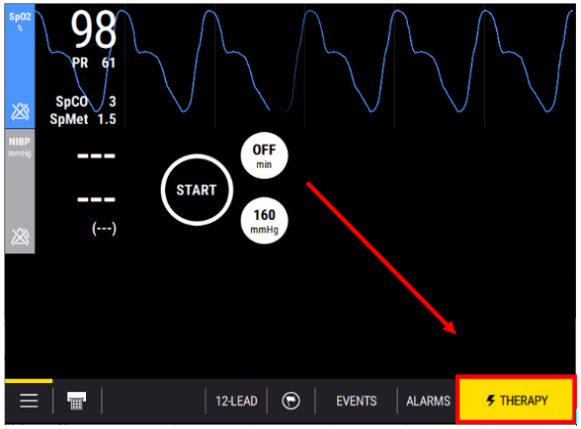


14. Select RUN on the SST screen.
15. Verify that the SUCCESS screen appears.
16. If the Energy Calibration Error message appears, an error code is written into the device Service Log and the front panel Service LED illuminates.
17. Select DONE on the SST screen.
18. Turn the device OFF when the calibration procedure is complete.

TCP – Delivered energy verification test

To verify the defibrillator delivered energy:

1. Turn the device ON.
2. Access the Therapy Screen by pressing THERAPY in the lower-right corner of the touchscreen as shown in the following figure.



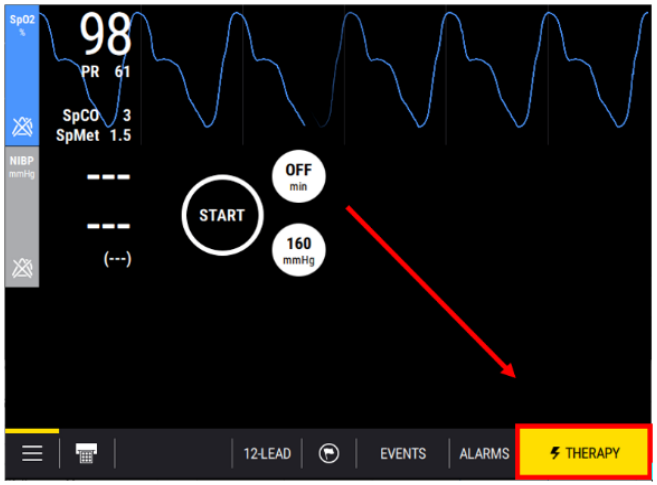
3. Select the desired energy to 10J, 100J, 200J and 360J by using the Up/Down arrows or dial on the touchscreen.
4. Push CHARGE button on the keypad and wait for the device to reach full charge.
5. Push the shock button on the keypad to discharge the device energy into the defibrillator analyzer.
6. Verify that the defibrillator analyzer shows an energy level as specified in the following table.

Delivered Energy	Low Limit	High Limit
10 J	9.1	10.8
50 J	47.6	52.4
200 J	196	204
360 J	352	368

TCP – Defibrillator output waveform test (optional)

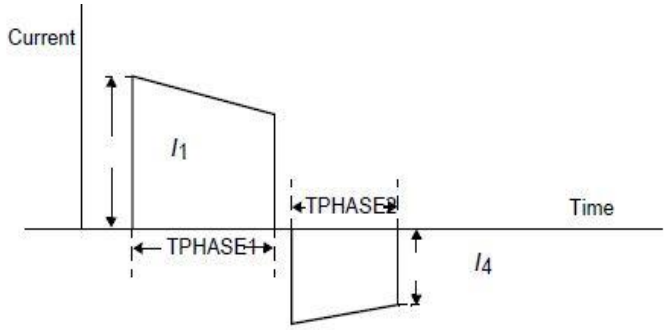
To test the defibrillator output waveform:

1. Connect the device to the defibrillator analyzer as described in TCP – Defibrillator energy calibration.
2. Turn the device ON.
3. Access the Therapy Screen by pressing **THERAPY** in the lower-right corner of the touchscreen as shown in the following figure.



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 that the waveform meets the specifications as shown in the following table.



Phase 1 Peak Current		Phase 1 Pulse Width		Phase 2 Pulse Width	
Min	Max	Min	Max	Min	Max
35A	42A	6.85ms	7.85 ms	4.4 ms	5.5 ms

TCP – Defibrillator isolation test

To test defibrillator isolation after a therapy repair:

1. Establish the Apex setup as shown in the following figure.

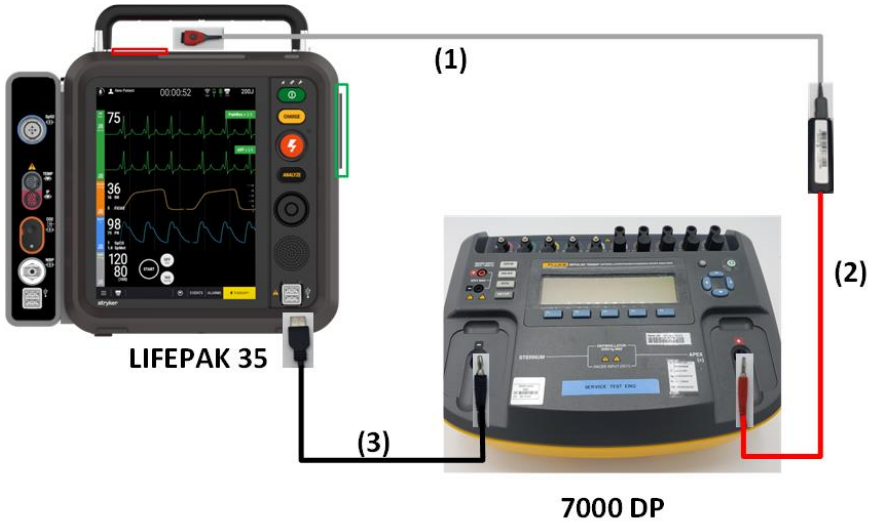


Figure 2

In Figure 2:

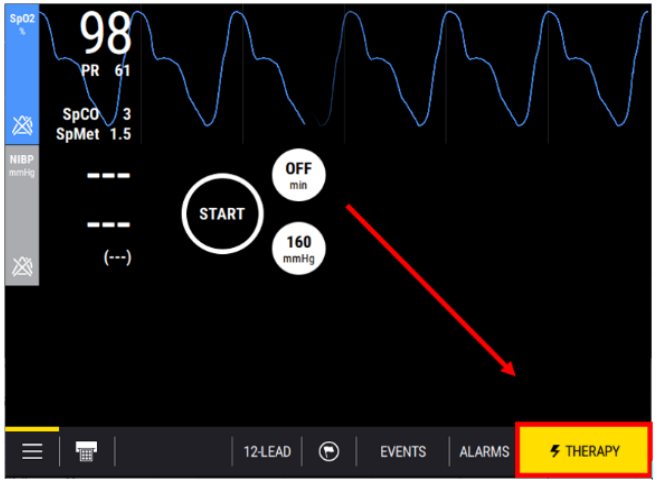
Item 1: 11113-000007

Item 2: 3205570-000

Item 3: 3344955-000

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



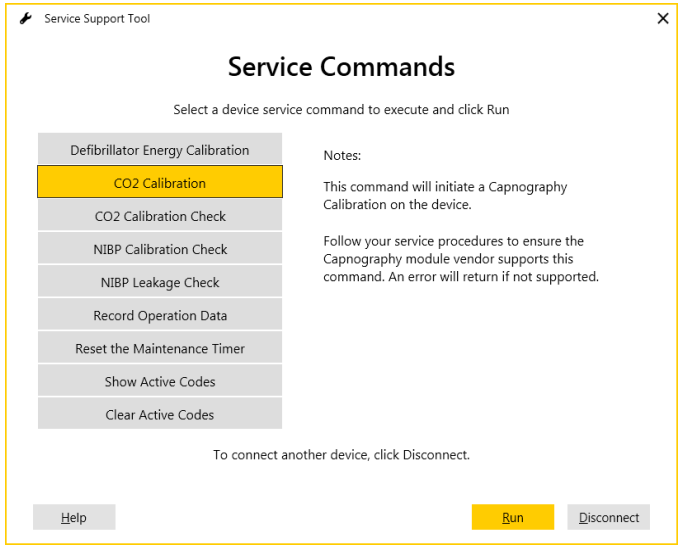
5. Select the desired energy to 360J by using the Up/Down arrows or dial on the touchscreen.
6. Push CHARGE button on the keypad and wait for the device to reach full charge.
7. Push the shock button on the keypad to discharge the device energy into the defibrillator analyzer.
8. Verify device displays message “Energy Delivered”.
9. Verify the defibrillator analyzer did not detect any energy reading.

TCP – CO2 calibration

To calibrate the MDT-CO2 module:

Note: 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.

1. Turn the device ON.
2. Access the Service Commands screen within SST. See TCP – PSST access.
3. Select CO2 CALIBRATION on the Service Commands screen.



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 the following Figure.

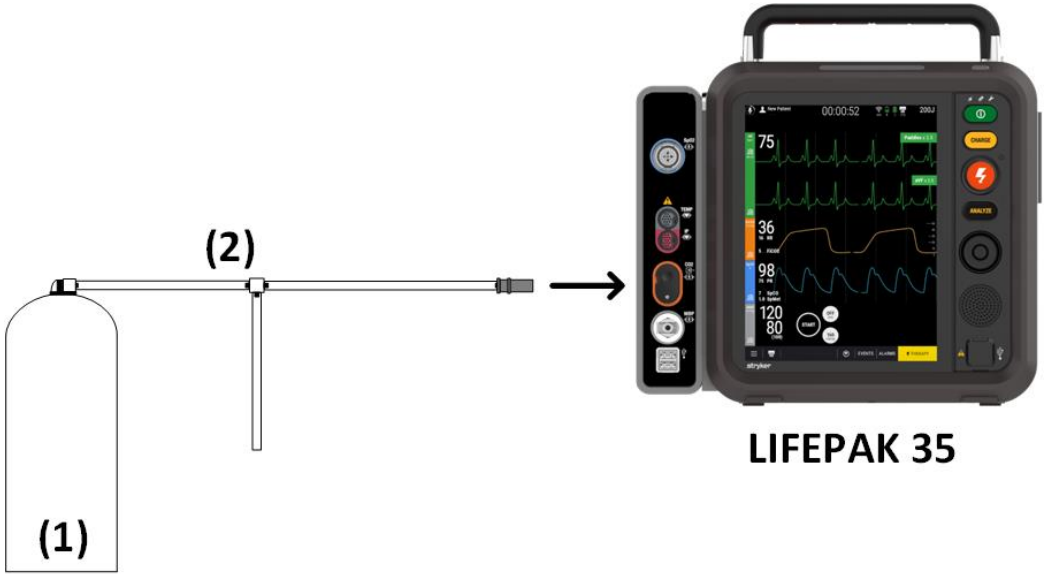


Figure 3

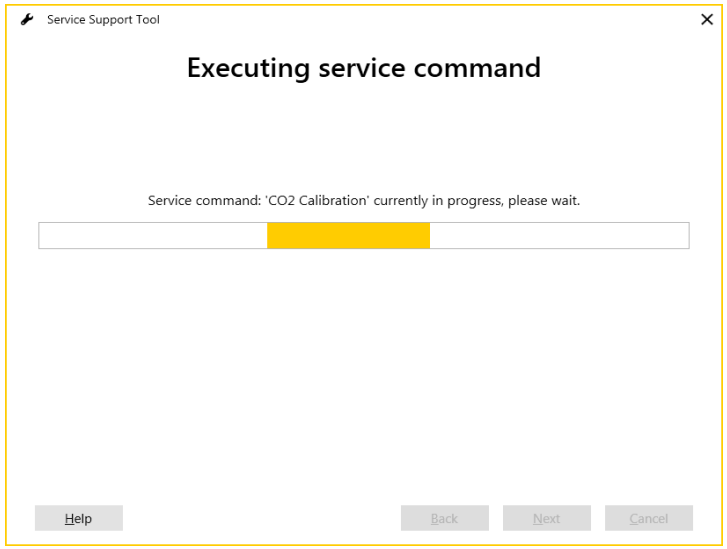
In Figure 3:

Item 1: 21300-001572

Item 2: 3335916-003

5. Press and hold the spray nozzle to apply calibration gas.

6. Select RUN on the SST screen, and verify that Executing Service Command screen appears, as shown in the figure below.



7. Continue pressing the spray nozzle until the DISCONNECT GAS message appears.
8. Release the spray nozzle.
9. Verify that the SUCCESS screen appears.
10. If the CO2 Calibration Error message appears, an error code is written into the device Service log and the front panel Service LED illuminates.
11. Power off DUT.

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Specifications are subject to change without notice.

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

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