Performance Inspection Procedures

The Performance Inspection Procedures (PIP) are a set of manual test procedures used for an operational closed-case evaluation of the LIFEPAK 20 defibrillator/monitor series.This section describes the test procedures you will perform to determine if the LIFEPAK 20 defibrillator/monitor series is operating within the required specifications. Investigate and correct any malfunctions or out-of-tolerance 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. Print the PIP Checklist to record the test results. Also refer to the **Operator Checklist** for additional items.

PIP – Scope and Applicability

The PIP applies to the LIFEPAK 20 Defibrillator/Monitor series 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 LIFEPAK 20 Defibrillator/Monitor series configuration under test must be performed.

Refer to the **PIP – Resource Requirements** for a listing of the necessary qualifications for PIP equipment, test equipment verification, workstation power, and personnel.

Refer to the **PIP – Test Equipment Requirements** for a listing of test equipment, including specifications, required to complete the PIP.

The **PIP – Checklist** is provided as an optional tool for recording test results.

PIP – Resource Requirements

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

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 specifications may be substituted.

PIP – Test Equipment Verification

All test equipment used to perform the PIP must have a current calibration label, issued by a certified calibration facility.

PIP – Workstation Power

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

PIP – Personnel

Service personnel who perform the PIP must be properly qualified and thoroughly familiar with the operation of the LIFEPAK 20 defibrillator/monitor series, meeting the requirements described in **Service Personnel Qualifications**.

PIP – Test Equipment Requirements

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

Equipment	Specifications	Manufacturer
Patient Simulator	Simultaneous 12-lead output Rates: 30 bpm, 120 bpm @ 1 mv Rate accuracy: ±1%	Fluke Biomedical Corp. 215A/217A or equivalent
Defibrillator Analyzer[a]	Energy range: 0 to 450 J Load resistance: 50 Ω ±1% Accuracy: ±2% +2 J Waveforms: NSR, VF, and Sine Wave	BIO-TEK® QED-6™, with test posts accessory (Software Version 2.07, or greater) or equivalent
Safety Analyzer	110 or 220 Vac line voltage Current range: 0-1999 pA Current accuracy: 5% of reading or 1 digit (whichever is greater)	Dale Model 600 (120 vac line input) or 600E (240 vac line input) or equivalent
Remote Sync Test Pulse Generator	A pulse train 5Vp-p (0-5V) , 5 to 200mS wide, 120 PPM (2Hz)	Physio-Control PN 3205653 or equivalent

a. Some energy meters are not accurate for biphasic waveforms; contact your defibrillator analyzer's manufacturer for more information.

PIP – Test Equipment Requirements

Equipment	Specifications	Manufacturer
Decade Resistance Box	0 to 9 MΩ resistance box Resolution: 1 Ω; Accuracy: ±1%	IET RS-200 Resistance Substituter or equivalent
Fixture Assembly, Impedance box to electrode adapter		Physio-Control PN 3205651
Analog ECG Output Cable (optional)	Connects to the DB-15 connector	Physio-Control PN 3202553
DB15 Cable	Connects to the DB-15 connector	
QUIK-COMBO test post adapter	Connects to QUIK-COMBO Therapy Cable	Physio-Control PN 3005302
3-Lead ECG cable		Physio-Control PN 3006218-02
5-Lead ECG cable		Physio-Control PN 3200496
General purpose oscilloscope (optional)	Bandwidth: dc to 2 MHz Vertical accuracy: ±3% (5 mV – 5 v/div.) Horizontal Time Base Accuracy: ±5%	Tektronix® 2232 or equivalent

PIP – Test Equipment Requirements

Equipment	Specifications	Manufacturer
Cable -Therapy, Quik-Combo, Short		Physio-Control PN 3006570
Accessory - Test Plug, QUIK-COMBO		Physio-Control PN 3201673
Standard Paddles (optional)		Physio-Control PN 3200585-00
Chassis Leakage Cable		Dale Model 600/100-2.4 m (8 ft)
LIFEPAK 20 SpO2 Leakage Cable		Physio-Control PN 3201832-004, -005, -006

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 LIFEPAK 20 defibrillator/monitor configuration under test must be performed.
- The **PIP Checklist** is provided as an optional tool for the recording of test results.
- Refer to **Troubleshooting** to correct failures, then repeat the PIP.

PIP – Exterior Physical Inspection

To perform an exterior physical inspection:

Note: Throughout the body of this PIP, the LIFEPAK 20 defibrillator/monitor is referred to as the Unit Under Test or UUT.

1. Inspect the UUT exterior for the following:
   - Damage
   - Excessive wear
   - Improper mechanical function
   - Damaged connectors
2. Pick up and turn over the UUT and listen for loose or rattling hardware. Locate any loose or rattling hardware and tighten or replace it.

PIP – Instructions

PIP – Exterior Physical Inspection (Continued)

3. Inspect the rubber feet on the underside of the lower enclosure. Reinstall or replace rubber feet as necessary.
4. Inspect the Therapy, ECG, SpO2 (if equipped), DB-9, DB-15, AED door, and IrDA connectors for damage, cracks, or contamination.
5. Inspect the keypads and overlays for damage, cracks, or separations.
6. Check all accessory cables, paddles, SpO2 sensors, and related items for expiration dates, general condition, and suitability for use.
7. Inspect carrying strap and mounts (if the UUT is equipped with them).
8. Record the results on the **PIP Checklist - Inspection**.

Cleaning Paddles

To clean the paddle connection:

1. Disconnect the adult paddle plate from the paddle assembly.
2. Clean the spring contact of the adult paddle with alcohol.
3. Clean the pediatric electrode surface with alcohol.
4. Reattach the adult paddle plate to the paddle assembly.

PIP – Instructions

PIP- Setup

WARNING!

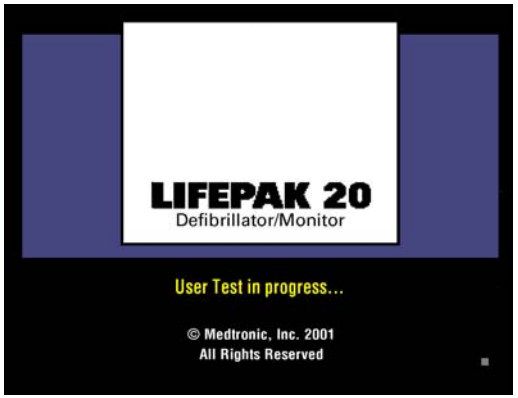
Shock hazard. The UUT discharges up to 360 J of electrical energy through the defibrillator cable. You must safely discharge this electrical energy as described in this PIP. Do not attempt to perform this procedure unless you are thoroughly familiar with the operation of the UUT.

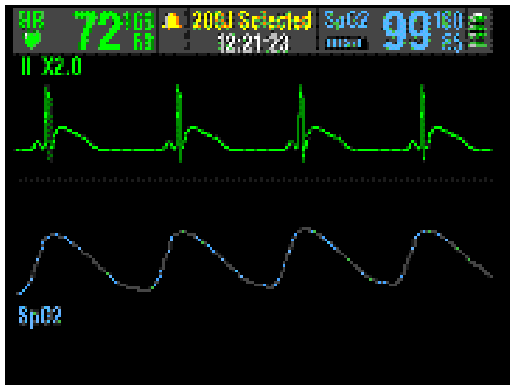
To set up the UUT in preparation for the PIP:

1. Install a roll of paper into the printer.
2. Connect the ac power cord into the UUT.

PIP – Instructions

PIP- Power On/ Self-Test





To perform the PIP Power On/Self-Test:

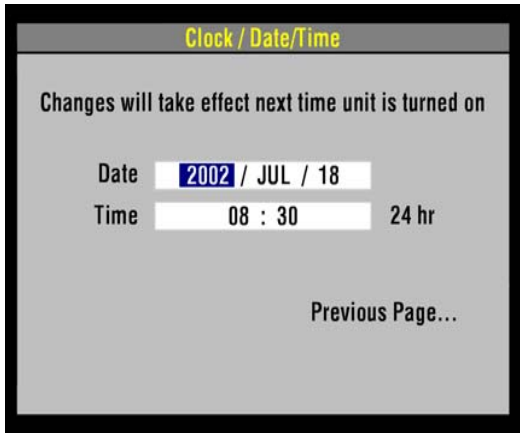
1. Press the ON button to initiate the UUT nominal five-second power-on self-test routine.

Note: The initial display includes Physio-Control Logo and LIFEPAK 20 defibrillator/monitor series, and the self test in progress, as shown to the upper left.

2. Verify that the UUT completes the Power On sequence.
3. Verify the AC Main indicator is ON.
4. Verify that the Service indicator is off.
5. Record the results in the **PIP Checklist**
6. Turn the UUT off.

PIP – Instructions

PIP- Date and Time



To test the UUT date and time:

1. Turn the UUT ON.
2. Press Options key.
3. Select **Date/Time**...from the Options menu.
4. Verify that the correct date and time values are displayed on the LCD.

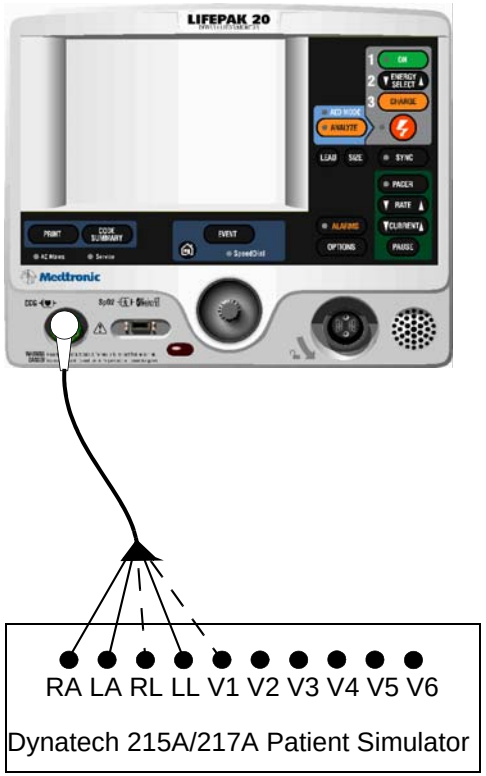
Note: If the date and time are incorrect, set date and time as needed.

5. Record the results on the **PIP Checklist**
6. Turn the UUT off.

PIP – Instructions

PIP- ECG Leads Characteristics setup

The ECG Lead Characteristics, set up the Patient Simulator, UUT as shown below. Continue to the PIP – ECG Lead Characteristics Procedure on the next page when you complete the setup.



PIP – Instructions

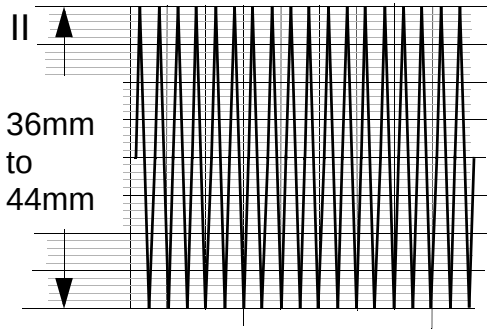
PIP- ECG Leads Characteristics

To test ECG Leads Characteristics:

1. Establish the PIP – ECG Lead Characteristics setup shown in the figure on the previous page.
2. Program the patient simulator output for a 60 BPM, NSR.
3. Turn the UUT on.
4. Set the UUT lead selection to LEAD II.
5. Remove the LL lead from the patient simulator.
6. Verify the UUT displays an LL LEADS OFF screen message.
7. Reconnect the LL lead.
8. Remove the RA lead from the patient simulator.
9. Verify the UUT displays an RA LEADS OFF screen message.
10. Reconnect the RA lead.
11. Set the UUT lead selection to LEAD I.
12. Remove the LA lead from the patient simulator.
13. Verify the UUT displays an LA LEADS OFF screen message.
14. Reconnect the LA lead.

PIP – Instructions

PIP- ECG Leads Characteristics (Continued)

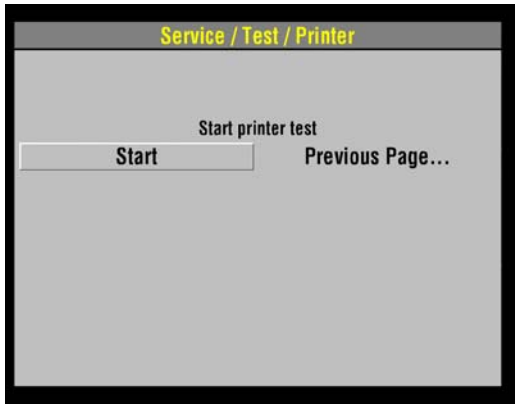


Lead	Printed Peak-to-Peak
I	18 mm to 22 mm
II	36 mm to 44 mm
C	36 mm to 44 mm

15. **For 5 Lead ECG only:** Set the UUT lead selection to LEAD II.
16. Remove the RL lead from the patient simulator.
17. Verify the UUT displays an ECG LEADS OFF screen message.
18. **For 5 Lead ECG only:** Set the UUT lead selection to LEAD C.
19. Remove the V1(C) lead from the patient simulator.
20. Verify the UUT displays a C LEADS OFF screen message.
21. Reconnect the V1(C) lead.
22. Program the patient simulator output for a 1 mV, 10 Hz sine wave.
23. Set the ECG size to 4.0 and lead selection to LEAD II.
24. Record five seconds of ECG Lead II and confirm the printed signal amplitude is 36 mm to 44 mm peak-to-peak.
25. Repeat Steps 23 and 24 for Lead I, substituting the signal amplitudes give in the table at the left.
26. **For 5 Lead ECG only:** Repeat Steps 23 and 24 for Lead C, substituting the signal amplitudes give in the table at the left.
27. Record the results on the **PIP Checklist**
28. Remove the ECG cable and turn the UUT off.

PIP – Instructions

PIP- Printer test

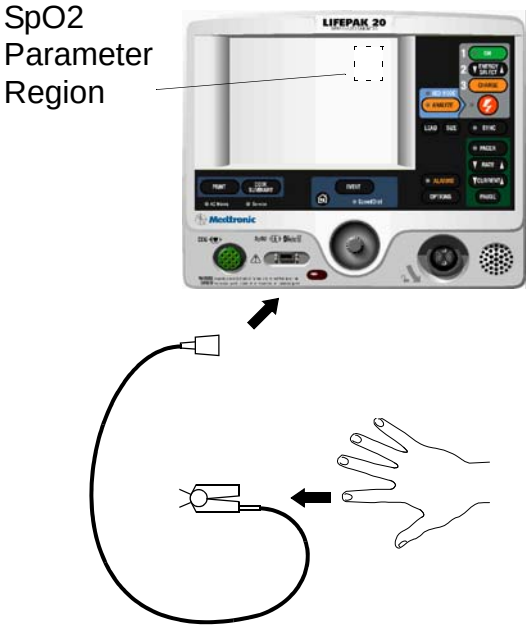


To test the 50 mm printer:

1. Hold down OPTIONS and EVENT controls and turn on the device. Hold the controls until Enter Passcode appears. Enter passcode 5433.
2. Select SERVICE from the Setup menu. Enter passcode 5433.
3. Select PRINTER from the on-screen Service/Test menu.
4. Select START from the Service/Test/Printer screen to print a test strip.
5. Inspect the test strip for the following attributes:
   - The large “X” form is printed without missing dots.
   - Four horizontal lines (one very close to the lower paper margin).
   - The character set is printed clearly without broken characters.
   - Vertical lines spaced 25 mm ±5% apart.
6. Open the printer door and verify the CHECK PRINTER message appears at the bottom of the screen.
7. Close the printer door.
8. Press the HOME key to return to Service menu. Turn the UUT off.
9. Record the results on the **PIP Checklist**

PIP – Instructions

PIP- Oximeter test



To test the SpO2 Oximeter:

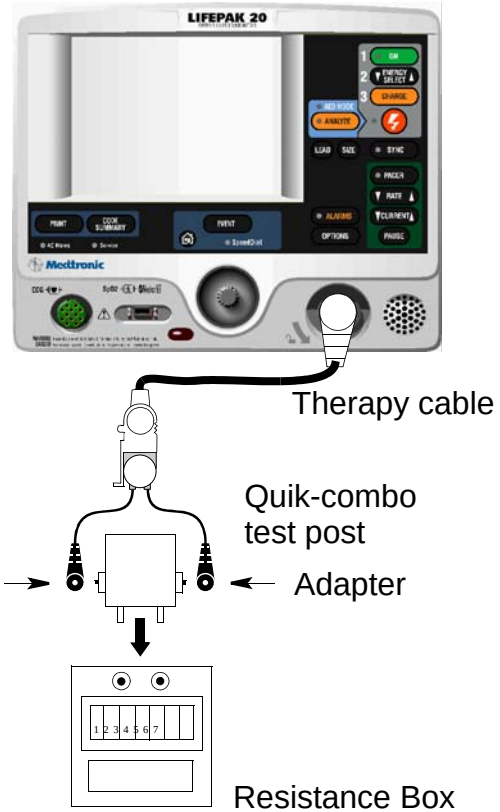
Note: Complete only if the UUT is equipped with the SpO2 Oximeter option.

1. Connect the Oximeter finger probe to the SpO2 connector as shown at the left.
2. Verify the SpO2 parameter region appears on the display.
3. Place your index finger into the SpO2 probe. Allow several seconds for the probe to find your pulse.
4. Confirm the SpO2 reading is between 90% and 100%.
5. Disconnect the SpO2 probe.
6. Record the results on the **PIP Checklist**
7. Turn the UUT off.

PIP – Instructions

PIP- Therapy-Impedance Sense setup

To perform the Therapy Impedance Sense test, set up the Resistance box and UUT as shown below. Continue to the PIP – Therapy Impedance Sense Procedure on the next page when you complete the setup.



PIP – Instructions

PIP- Therapy-Impedance Sense

To test Therapy Impedance Sense:

1. Establish the PIP – Therapy Impedance Sense setup shown in the figure on the previous page.
2. Set the decade resistance box to 50Z.
3. Turn on the UUT.
4. Set the UUT: manual mode, ECG Size to 1.0, lead selection to PADDLES.
5. Set the decade resistance box to 248 Z.
6. Verify the UUT display displays the PADDLES LEADS OFF message.
7. Set the decade resistance box to 182 Z.
8. Verify the PADDLES LEADS OFF message is removed from the UUT display.
9. Record the results on the **PIP Checklist**
10. Turn the UUT off.
11. Remove the decade resistance box.

PIP – Instructions

PIP- Therapy User Test

To test the Therapy User test:

1. **If the unit is equipped with Quik- combo cable:** Connect the Therapy cable between the UUT and the QUIK-COMBO test plug.

   If the unit is equipped with Standard Paddles: Install standard paddles into the UUT and place the UUT's paddles in the paddle wells.

   Note: Verify that the metal surfaces of the standard paddles and paddle test contacts in the device paddle wells are free of burn and arc marks. Also check that these surfaces are free of pits, scratches,insulating films, contaminants or raised nicks that can be felt with the finger tip. Check therapy connector for pin damage.
2. Set the UUT lead selection to PADDLES.
3. Press the OPTIONS button and select USER TEST from the Options screen.
4. Select YES from the Options/Users Test screen.
5. Push Speed Dial to initiate the self test and the user test. The self test and the user test are performed. The User Test Succeeded report is printed when test is complete.
6. Record the results on the **PIP Checklist.**

The unit automatically turns off after successfully completing the test.

PIP – Instructions

PIP- Therapy-Delivered Energy and Sync setup

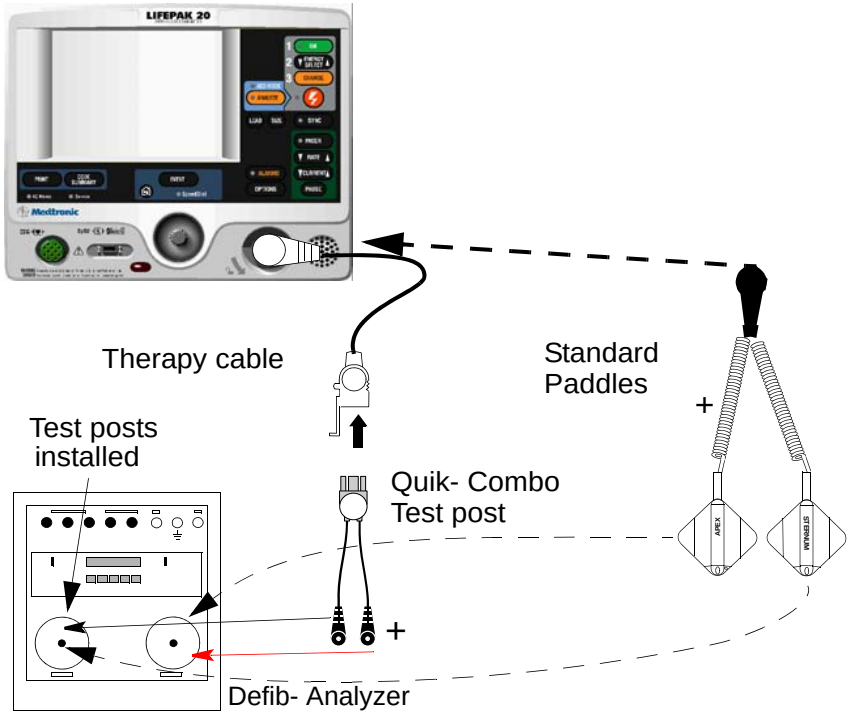
To perform the Therapy – Delivered Energy and Synchoronous cardioversion test, set up the defibrillator analyzer and UUT as shown on the next page. Continue to the PIP – Therapy Delivered Energy and Synchoronous cardioversion Procedure on the following page when you complete the setup.

Note: Ensure proper test connections to the Defibrillator Analyzer. To avoid damage to the Analyzer or defibrillator;

1. Do NOT apply defibrillator pulses to the pacer inputs of the analyzer (if the analyzer is equipped with pacer inputs
2. If testing with standard paddles, verify that the metal surfaces of the paddlesare free of burn or arc marks and are free of pits, scratches, insulating films, contaminants or raised nicks that can be felt with the finger tips.

PIP – Instructions

PIP - Therapy - Delivered Energy and Sync Setup (Continued)



PIP – Instructions

PIP- Therapy- Delivered Energy and Sync

To test Therapy – delivered energy and Synchoronous cardioversion:

1. Establish the PIP – Therapy Delivered Energy and Synchoronous cardioversion setup shown in the figure on the previous page.
2. Turn on the UUT.
3. Set the UUT: manual mode, ECG Size to 1.0, lead selection to PADDLES.
4. Set the defibrillator analyzer to measure SYNC.
5. Press the SYNC button ON and select LOCAL, if Remote Sync is set to on.
6. Verify the SYNC LED turns on and R-wave markers appear on the ECG waveform.
7. Press the ENERGY SELECT button to select 2 J.
8. Press the CHARGE button and wait for the UUT to reach full charge. Then press the SHOCK button to discharge the UUT.

   Note: For standard paddles use the APEX PADDLE CHARGE button on the paddles.

9. Verify the defibrillator analyzer measures a sync R-wave of 60 ms or less.
10. Set the defibrillator analyzer to measure **ENRG** (press ESC, then ENRG).

PIP – Instructions

PIP- Therapy- Delivered Energy and Sync (Continued)

11. Repeat Steps 7 and 8 for the all energy levels specified in the table.
12. Verify the defibrillator analyzer indicates the delivered energy is within the acceptable output limits, shown below.

Energy Level (J)	Acceptable Output (J)
2	1.0 to 3.0
70	65.1 to 74.9
360	334.8 to 385.2

Note: Perform the **TCP – Defibrillator Calibration** if the delivered energy falls outside of the acceptable output range.

13. Press the Code Summary key. Verify that the Code Summary key is working properly.
14. Press Alarm key. Verify that the Alarm menu are displayed on the LCD.
15. Record the results on the **PIP Checklist**
16. Turn the UUT off.

PIP – Instructions

PIP- Therapy -Paddles ECG Gain and AED mode test

To test Therapy Paddles ECG gain and AED mode test :

1. To test Therapy Paddles ECG gain: Program the defibrillator analyzer output for a 1 mV, 10 Hz sine wave.
2. Set the UUT ECG Size to 4.0 and Lead selection to PADDLES.
3. Record 10 seconds of Paddles ECG and confirm the printed signal amplitude is 36 mm to 44 mm peak-to-peak.

Note: The BIO-TEK QED-6 produces a 1.1 mV output; confirm the printed signal amplitude is 38 mm to 50 mm peak-to-peak.

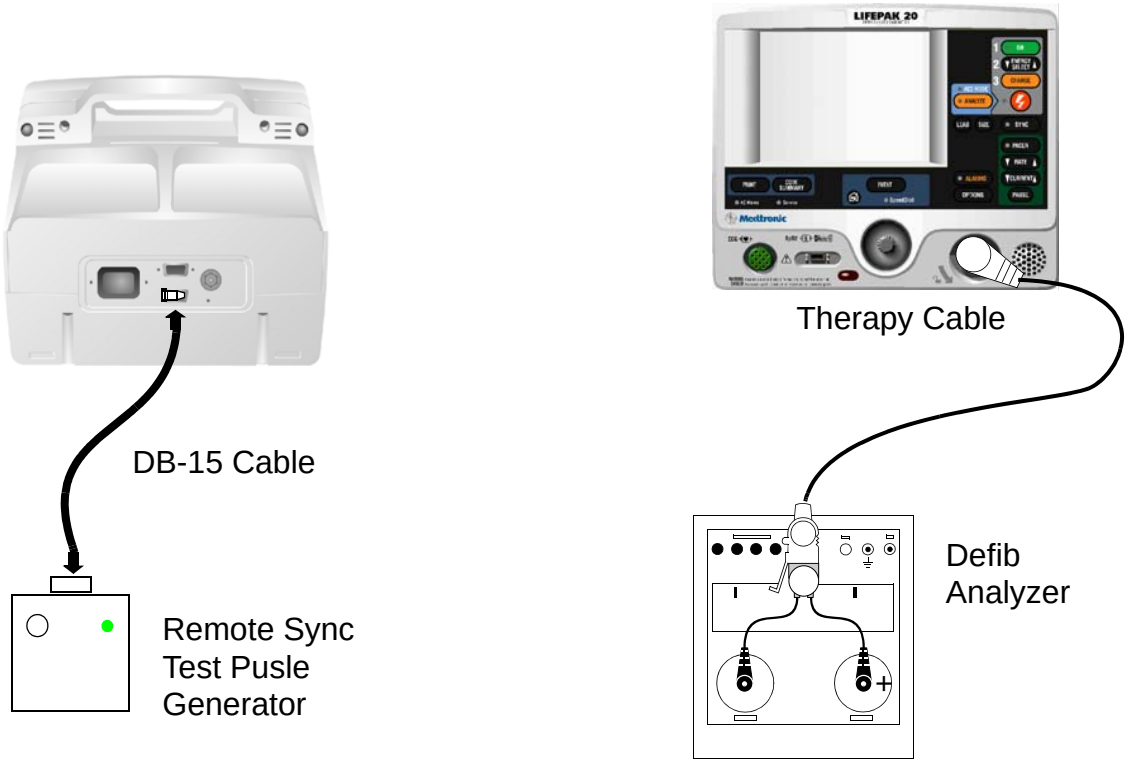
4. To test AED mode test : If the unit is equipped with standard paddles, remove standard paddles out of the UUT's therapy connector and connect the Therapy Quik-combo cable between the UUT and the Defib analyzer.
5. Press the ANALYZER key to turn the AED mode on. Verify that the AED mode on.
6. Verify that the voice prompts are clearly audible:

   •***ANALYZING NOW, STAND CLEAR.***
7. Press the ENERGY key. Verify that the UUT switches to Manual mode.
8. Record the results on the **PIP Checklist**

PIP – Instructions

PIP- Therapy- Remote Sync Test Setup

To perform the Therapy- Remote Sync test, set up the Defibrillator Analyzer, Remote Sync Test Pulse Generator, and UUT as shown below. Continue to the PIP – Therapy Remote Sync Test Procedure on the next page when you complete the setup.



PIP – Instructions

PIP- Therapy- Remote Sync Test

To test Therapy- Remote Sync :

1. Establish the PIP – Therapy- Remote Sync Test setup shown in the figure on the previous page.

   Note: A function generator can be used instead of a Remote Sync Test Pulse Generator. Set the function generator to provide a pulse train 5 Vp-p (0-5 V), 5 to 200 ms wide, 120 PPM (2 Hz).

2. Turn on the Remote Sync Test Pulse Generator.
3. On the Manual Mode Setup page, set the UUT to Remote Sync ON.
4. Turn the UUT off , then turn the UUT on.
5. Set the UUT: manual mode, lead selection to PADDLES.
6. Press the SYNC button on the UUT.
7. On the Sync Mode screen, select REMOTE.
8. Verify the SYNC LED is flashing.
9. Charge the UUT to 200 J.
10. Upon reaching full charge, press the SHOCK button to discharge the UUT.

PIP – Instructions

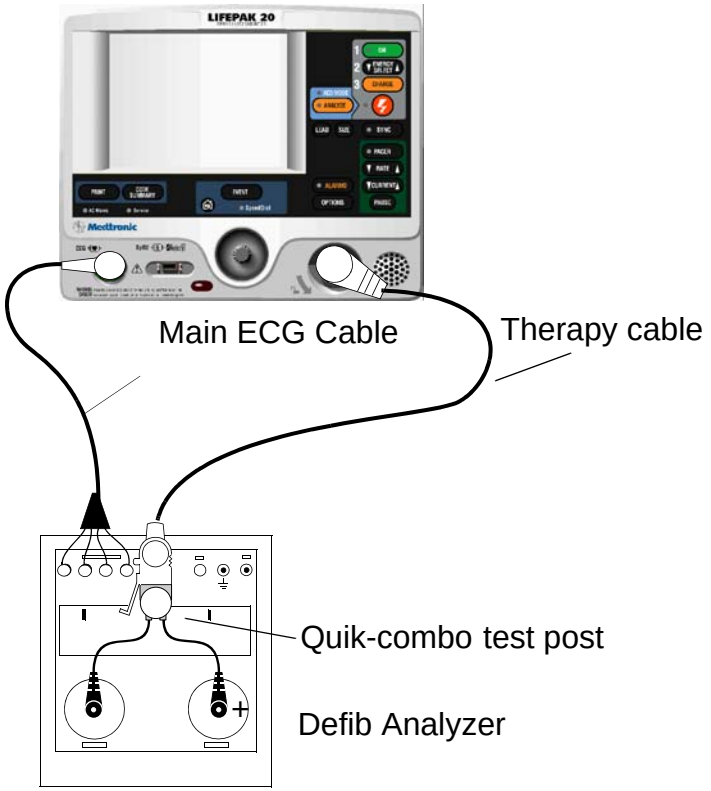
PIP-Therapy- Remote Sync Test (Continued)

11. Verify the UUT displays "ENERGY DELIVERED" screen message (for SW-20 version or below) or switches out of remote sync mode (for SW-26 version or above).
12. Record the results on the **PIP Checklist.** Turn the UUT off.

PIP – Instructions

PIP- Pacer Option Characteristics set up

1. To perform the Pacer Option Characteristics test, set up the Defibrillator Analyzer and UUT as shown below. Continue to the PIP – Pacer Option Characteristics Procedure on the next page when you complete the setup.



PIP – Instructions

PIP- Pacer Option Characteristics

To test Pacer Option Characteristics:

Note: Skip this test if using a nonpacing defibrillator.

1. Establish the PIP – Pacer Option Characteristics setup shown in the figure on the previous page.
2. Set the defibrillator analyzer to measure peak current pacing parameters.
3. Press the PACER control on the UUT.
4. Verify the PACER control LED lights and the PACER overlay appears.
5. Disconnect one of the Test Post Adapter snaps from the defibrillator analyzer.
6. Verify the PACING STOPPED/CONNECT ELECTRODES overlay appears accompanied by an audible alarm.
7. Reconnect the Test Post Adapter snap.
8. Verify the overlay CONNECT ELECTRODES disappears and the alarm stops.
9. Set the defibrillator analyzer to output PACE, MEAS.
10. Press all the keys on Pacer panel, verify that all keys are working properly.

PIP – Instructions

PIP- Pacer Option Characteristics (Continued).

11. At 40 PPM Rate, press the UUT CURRENT button to select a pacer current of 10 mA.
12. Verify the defibrillator analyzer indicates the pacer output current is within the acceptable output limits, shown below:

Peak Current Level (mA)	Acceptable Output (mA)
10	5 to 15
100	95 to 105
200	190 to 210

13. Repeat step 10 and 11 for the remaining peak pacer currents specified in the table.
14. At 40 PPM Rate and 200 mA, verify the defibrillator analyzer indicates the pacer pulse width is between 19.0 and 21.0 ms.
15. Press the UUT PACER control to terminate pacing.
16. Record the results on the **PIP Checklist**
17. Turn the UUT off.

PIP – Instructions

PIP- Leakage Current

Note: Each test result applies to a safety analyzer operating from a 120 vac source or 240 vac source, unless indicated otherwise. For exceptions, the test result includes the safety analyzer operating source. For example, 300 µA (120 vac) or 500 µA (240 vac). All test results are summarized in the **Leakage Current Specifications Summary Table**.

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.

PIP – Instructions

PIP- Leakage Current

Check the leakage current in accordance with the following industry standards:

- AAMI/ANSI (Association for the Advancement of Medical Instrumentation/ American National Standards Institute) DF2-1989, DF39-1993
- IEC (International Electrotechnical Commission) 601-1 and 601-2-4

Earth Ground: Third wire ground.

Normal Condition (N.C.): AC voltage is applied in either normal or reversed polarity i.e. measurements made with the POLARITY switch in both NORMAL and REVERSED positions. The earth ground is intact during these measurements (if LIFT GND switch is not pressed).

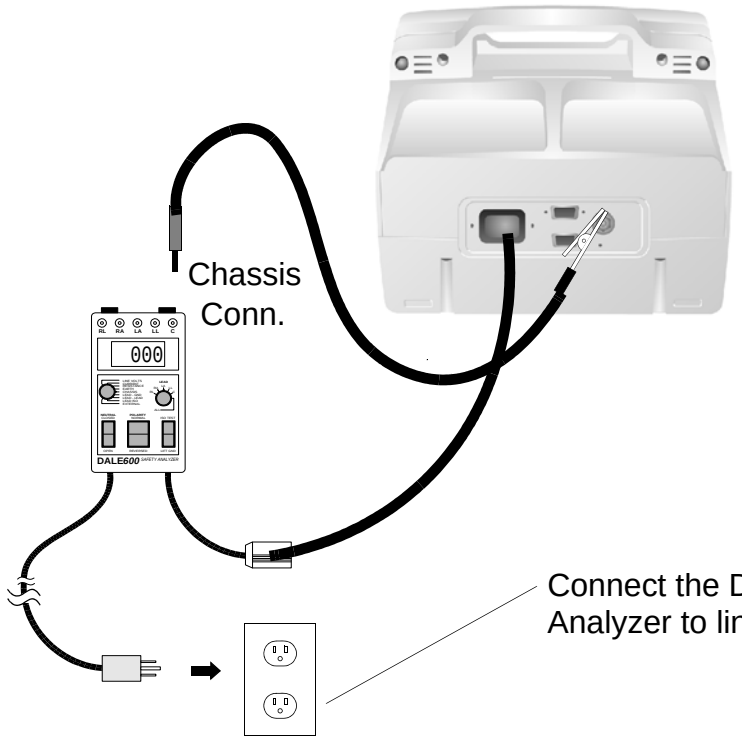
Single Fault Condition (S.F.C.): AC voltage is applied in either normal or reversed polarity i.e. measurements made with the POLARITY switch in both NORMAL and REVERSED positions. The earth ground is **NOT** intact during these measurements (if LIFT GND switch is pressed).

Note: Due to the variety of safety analyzers that may be used for these tests, this service manual provides only general instructions. For information about configuration and testing methods, refer to your safety analyzer operating instructions.

PIP – Instructions

PIP- Ground Resistance Test Setup

To test the Ground Resistance Test, set up the safety analyzer and UUT as shown below. Continue to the PIP – Ground Resistance Test Procedure on the next page when you complete the setup.



PIP – Instructions

PIP- Ground Resistance Test

To test Ground Resistance Test:

1. Establish the PIP – Ground Resistance Test Setup as shown in the figure on the previous page. **The UUT is off for this test.**
2. Set the safety analyzer controls to:

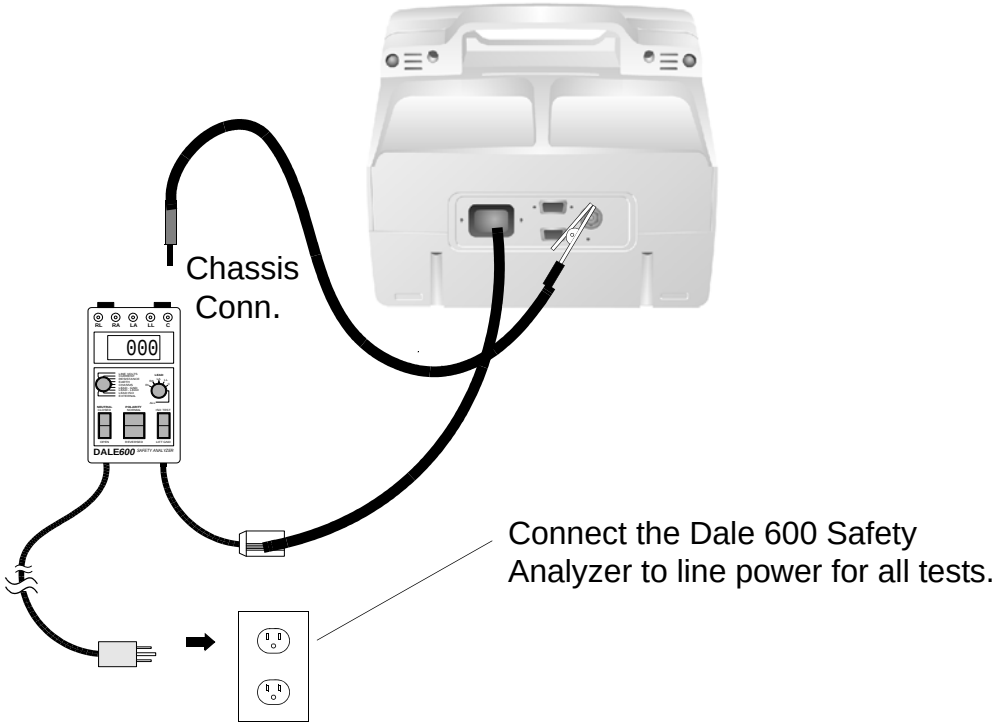
Neutral	Polarity	Mode		Lead
Any	Center	Ohms	Resistance	Any

3. Verify measured ground resistance test is less than 0.5 ohms.
4. Record the results in the **PIP Checklist**

PIP – Instructions

PIP- Chassis Leakage Current Setup

To test chassis leakage current, set up the safety analyzer and LIFEPAK 20 defibrillator/monitor (UUT) as shown below. Continue to the PIP – Chassis Leakage Current Procedure when you complete the setup.



PIP – Instructions

PIP- Chassis Leakage Current test

To test Chassis Leakage Current:

1. Establish the PIP – Chassis Leakage Current Setup as shown in the figure on the previous page.
2. Set the safety analyzer controls to:

Neutral	Polarity	Mode		Lead
Closed	Normal/Reversed	Leakage µA	Chassis	All

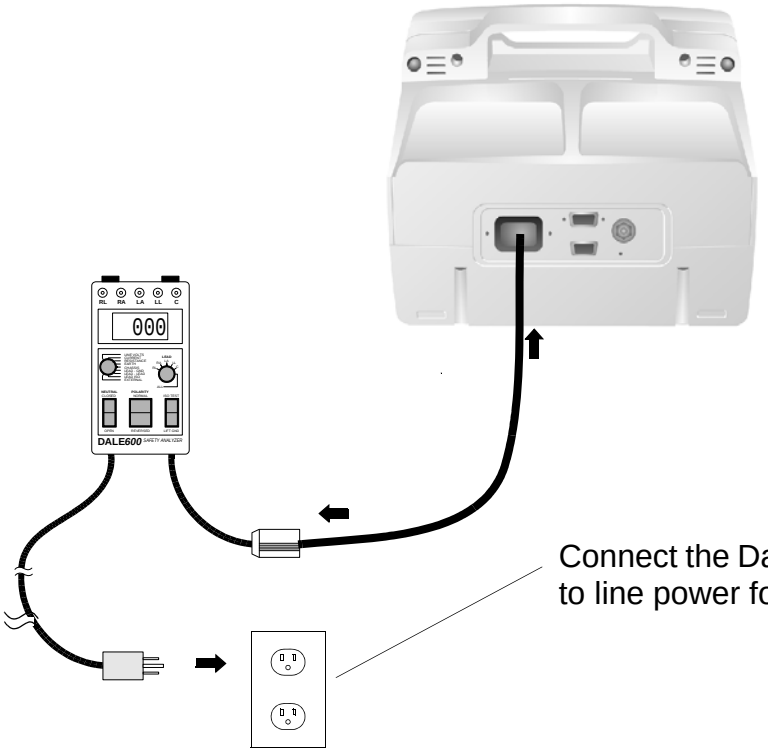
Note: When operating the Polarity Switch, be sure to pause in the Off (middle) position when switching between Normal and Reversed Polarities.

3. Connect the analyzer clip to the Ground stud and turn the UUT on.
4. Verify measured current is less than 90 µA.
5. Press the LIFT GND button on the safety analyzer.
6. Verify measured current is less than 270 µA (120 VAC) or less than 450 µA (240 VAC).
7. Release the LIFT GND button on the safety analyzer.
8. Record all results on the **PIP Checklist**

PIP – Instructions

PIP- Earth Leakage Current Setup

To test earth leakage current, set up the safety analyzer and UUT as shown below. Continue to the PIP – Earth Leakage Current Procedure when you complete the setup.



PIP – Instructions

PIP- Earth Leakage Current test

To test Earth Leakage Current:

1. Establish the PIP – Earth Leakage Current Setup shown in the figure on the previous page.
2. Set the safety analyzer controls to:

Neutral	Polarity	Mode		Lead
Closed	Normal/Reversed	Leakage µA	Earth	Any

Note: When operating the Polarity Switch, be sure to pause in the Off (middle) position when switching between Normal and Reversed Polarities.

3. Verify measured current is less than 450 µA.
4. Set the safety analyzer controls to:

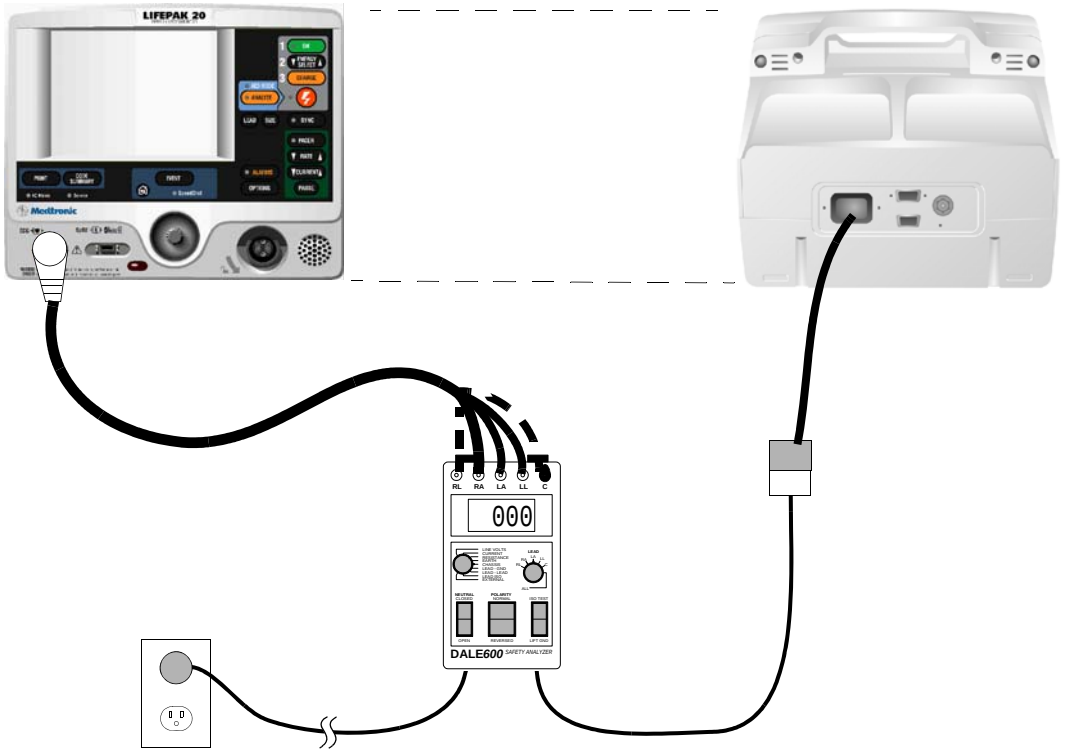
Neutral	Polarity	Mode		Lead
Open	Normal/Reversed	Leakage µA	Earth	Any

5. Verify measured current is less than 900 µA.
6. Record the results in the **PIP Checklist**.

PIP – Instructions

PIP- ECG Lead Leakage Setup

To perform the ECG Lead Leakage Current test, set up the safety analyzer and UUT as shown below. Continue to the PIP – ECG Lead Leakage Current Procedure on the next page when you complete the setup.



PIP – Instructions

PIP- ECG Lead Leakage Current test

To test ECG Lead Leakage Current :

1. Establish the PIP – ECG Lead Leakage Current Setup shown in the figure on the previous page.
2. Turn on the UUT.
3. Set the safety analyzer controls to:

Neutral	Polarity	Mode		Lead
Closed	Normal/ Reversed	Leakage µA	Lead – Gnd	ALL

Note: When operating the Polarity Switch, be sure to pause in the Off (middle) position when switching between Normal and Reversed Polarities.

4. Verify the measured current is less than 10 µA.
5. Press the LIFT GND button on the safety analyzer.
6. Verify the measured current is less than 50 µA.
7. Release the LIFT GND button.
8. Set the safety analyzer controls to:

Neutral	Polarity	Mode		Lead
Closed	Normal/ Reversed	Leakage µA	Lead – Lead	RA

PIP – Instructions

PIP- ECG Lead Leakage Current test (Continued)

9. Repeat steps 4 through 7 for the remaining (RA and LL).
10. **For 5-Lead ECG**:Repeat steps 4 through 7 for the remaining (RL and C)
11. Turn the UUT off.
12. Set the safety analyzer controls to:

Neutral	Polarity	Mode		Lead
Closed	Normal	Leakage µA	Lead Iso	All

WARNING!

Shock hazard. During sink leakage tests high voltage is present on the safety analyzer electrode snaps. Do not touch the analyzer snaps or UUT connections during these tests.

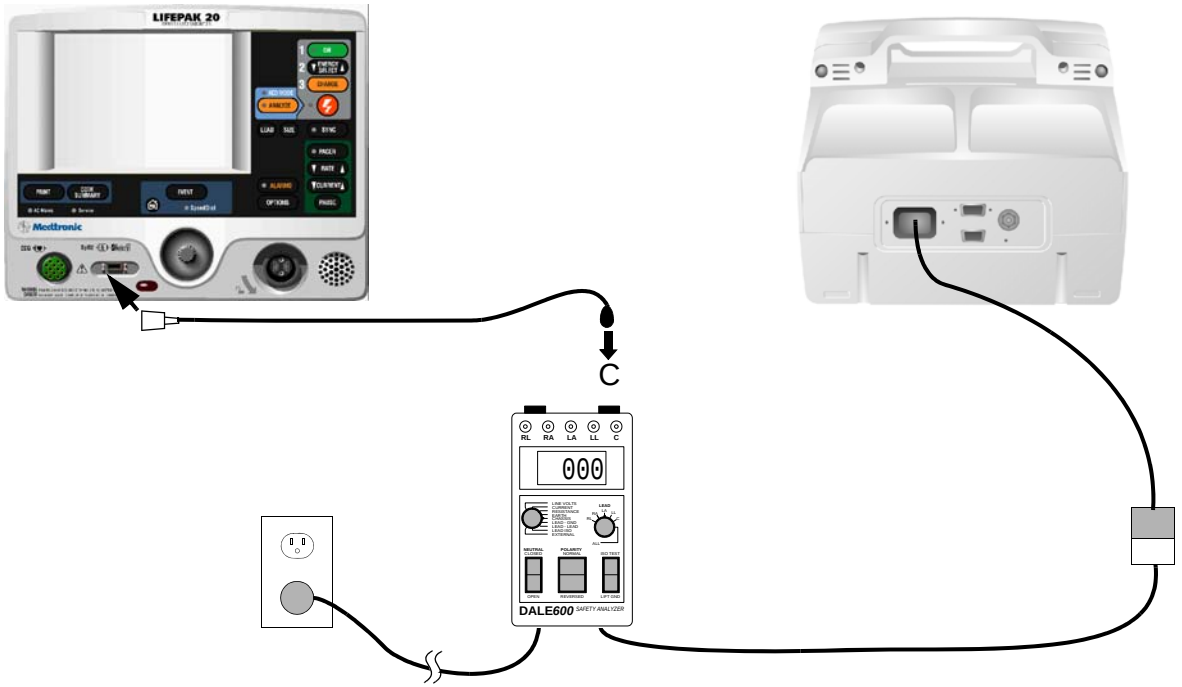
13. Momentarily press the ISO TEST button on the analyzer and observe the current reading.
14. Release the ISO TEST button.
15. Verify the measured current is less than 45 µA.
16. Record all results on the **PIP Checklist**.

PIP – Instructions

PIP- SpO2 Leakage Current Setup

Note: Complete the following only for UUTs equipped with the SpO2 option.

The SpO2 Leakage Current, set up the safety analyzer, UUT as shown below. Continue to the PIP – SpO2 Leakage Current Procedure when you complete the setup.



PIP – Instructions

PIP- SpO2 Leakage Current

To test SpO2 Leakage Current:

1. Establish the PIP – SpO2 Leakage Current Setup shown in the figure on the previous page.
2. Set the safety analyzer controls to:

Neutral	Polarity	Mode		Lead
Closed	Normal	Leakage µA	Lead Iso	C

WARNING!

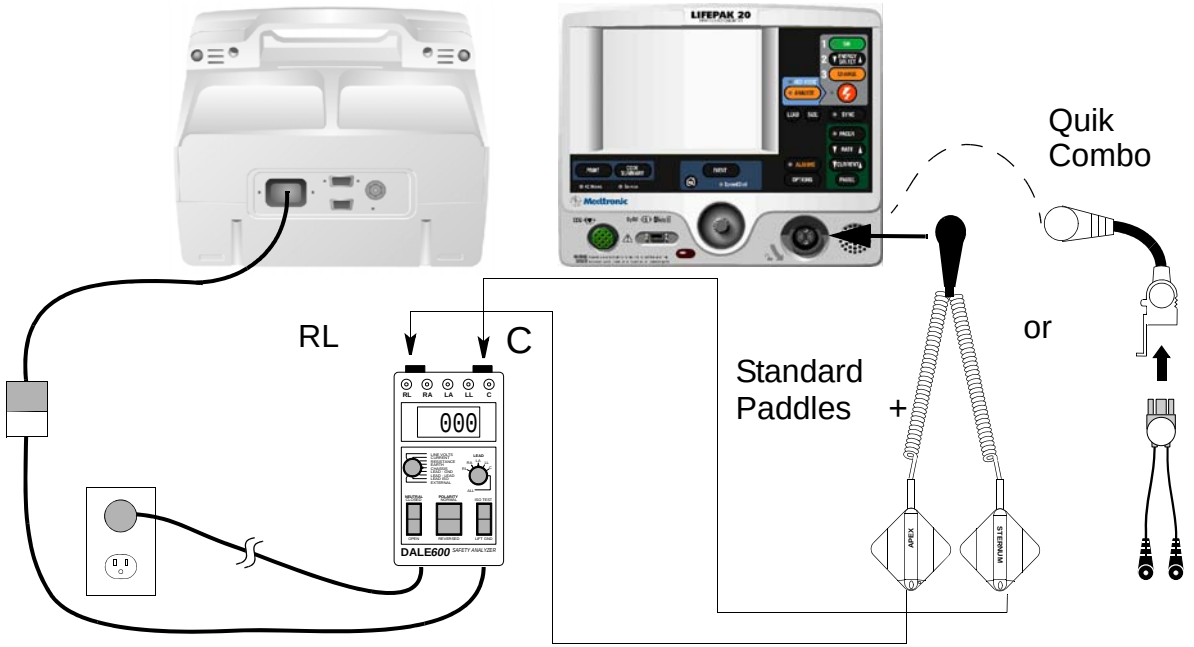
Shock hazard. During sink leakage tests high voltage is present on the safety analyzer electrode snaps. Do not touch the analyzer snaps or UUT connections during these tests.

3. Momentarily press the ISO TEST button on the safety analyzer and observe the measured current reading.
4. Release the ISO TEST button.
5. Verify the measured current is less than 90 µA (120 vac) or 450 µA (240 vac).
6. Record the results on the **PIP Checklist**.

PIP – Instructions

PIP- Therapy Leakage Current Setup

To perform the Therapy leakage current test, set up the safety analyzer and UUT as shown below. Continue to the PIP – Therapy Leakage Current Procedure on the next page when you complete the setup.



PIP – Instructions

PIP- Therapy Leakage Current test

To test Therapy Leakage Current :

Establish the PIP – Therapy Leakage Current Setup shown in the figure on the previous page.

1. Set the safety analyzer controls to:

Neutral	Polarity	Mode		Lead
Closed	Normal/Reversed	Leakage µA	Lead – GND	ALL

Note: When operating the Polarity Switch, be sure to pause in the Off (middle) position when switching between Normal and Reversed Polarities.

2. Verify the measured current is less than 10 µA.
3. Press the LIFT GND button on the safety analyzer.
4. Verify the measured current is less than 50 µA.
5. Release the LIFT GND button.
6. Set the safety analyzer controls to:

Neutral	Polarity	Mode		Lead
Closed	Normal/Reversed	Leakage µA	Lead – Lead	RL or C

PIP – Instructions

PIP- Therapy Leakage Current test (Continued)

Note: When operating the Polarity Switch, be sure to pause in the Off (middle) position when switching between Normal and Reversed Polarities.

7. Repeat steps 2 through 5.
8. Turn the UUT off.
9. Set the safety analyzer controls to:

Neutral	Polarity	Mode		Lead
Closed	Normal	Leakage µA	Lead Iso	All

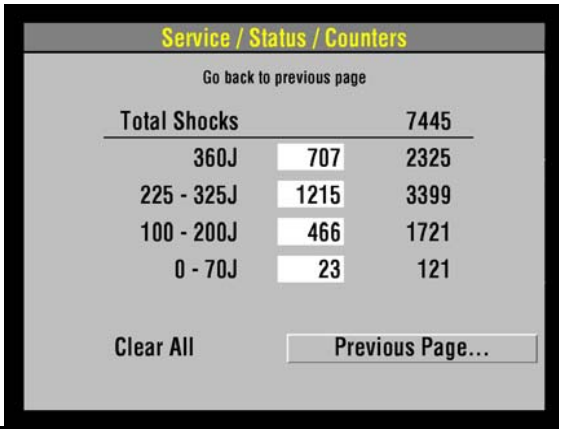
WARNING!

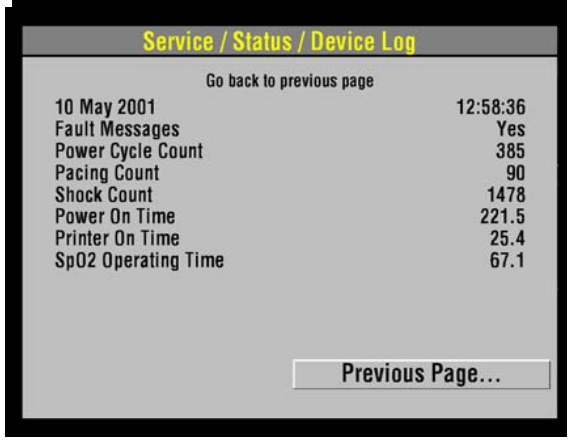
Shock hazard. During sink leakage tests high voltage is present on the safety analyzer electrode snaps. Do not touch the analyzer snaps or UUT connections during these tests.

10. Momentarily press the ISO TEST button on the safety analyzer and observe the measured current reading.
11. Release the ISO TEST button.
12. Verify the measured current is less than 90 µA (120 vac) or 450 µA (240 vac).
13. Record the results on the **PIP Checklist**.

PIP – Instructions

PIP- Record Operating Data (optional test)



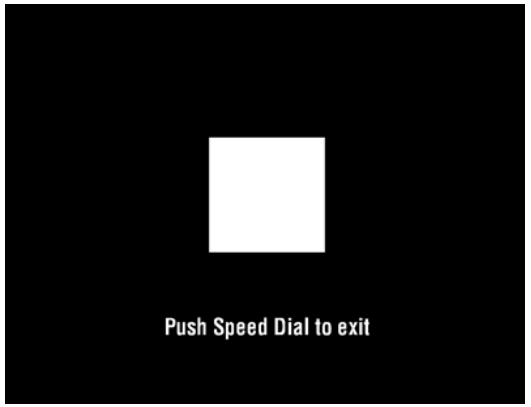


To record the operating data:

1. Hold down OPTIONS and EVENT controls and turn on the device. Hold the controls until Enter Passcode appears. Enter passcode 5433.
2. Select SERVICE from the Setup menu. Enter passcode 5433.
3. Navigate to the Service/Status/Counters screen. On the **PIP Checklist** record the shocks since last reset (in boxes) and total shocks since the device was built. Select CLEAR ALL to reset box counters (if desired).
4. Select PREVIOUS PAGE.
5. Select DEVICE LOG. record the following on the **PIP Checklist**:
   - Power Cycle Count
   - Pacing Count
   - Shock Count
   - Power On Time
   - Printer On Time
   - SpO2 Operating Time
6. Turn the UUT off.

PIP – Instructions

PIP- Contrast Test — LCD (optional test)



To test screen contrast:

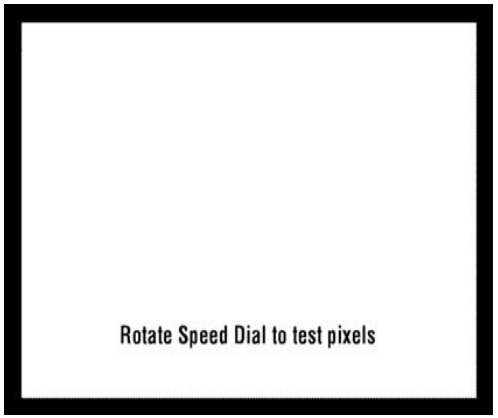
1. Hold down OPTIONS and EVENT controls and turn on the device. Hold the controls until Enter Passcode appears. Enter passcode 5433.
2. Select SERVICE from the Setup menu. Enter passcode 5433.
3. Enter the Service/Tests screen and select Contrast. The LCD changes to display a square block in the center of the screen, as shown in the figure on the left.
4. For passive LCD only: rotate the Speed Dial. The background changes from white to black. After five seconds the PUSH SPEED DIAL TO EXIT message appears on the screen.
5. Press the Speed Dial to exit the test.

Note: If you accidentally select a pure white or pure black background when exiting the contrast test, press the CONTRAST button ◐, rotate the Speed Dial to the desired display, and press the Speed Dial.

6. Record the results in the **PIP Checklist**
7. Turn the UUT off.

PIP – Instructions

PIP- Pixels test (optional test)

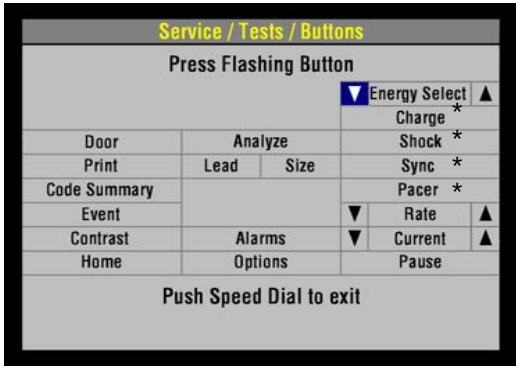


To test the display pixels:

1. Hold down OPTIONS and EVENT controls and turn on the device. Hold the controls until Enter Passcode appears. Enter passcode 5433.
2. Select SERVICE from the Setup menu. Enter passcode 5433.
3. Enter the Service/Tests screen and select pixels. The pixels test screen appears, as shown in the figure on the left.
4. Carefully examine the screen for any anomalies. After five seconds, the **ROTATE SPEED DIAL TO TEST PIXELS** message appears on the screen.
5. Press the Speed Dial to exit the test.
6. Record the results in the **PIP Checklist**.
7. Turn the UUT off.

PIP – Instructions

PIP- Keypad test (optional test)



* The button is not available on nonpacing models. Press the keypad in the button's location to verify the button.

To test the keypad:

1. Hold down OPTIONS and EVENT controls and turn on the device. Hold the controls until Enter Passcode appears. Enter passcode 5433.
2. Select SERVICE from the Setup menu. Enter passcode 5433.
3. Select TESTS… from the on-screen Service menu. Navigate to the Service/ Tests/Buttons screen.
4. Press each front panel control when prompted by the flashing control legend (although you may press the controls in any order).
5. Verify with each control pressed that its associated text box is highlighted. All buttons must be tested regardless of defibrillator configuration.

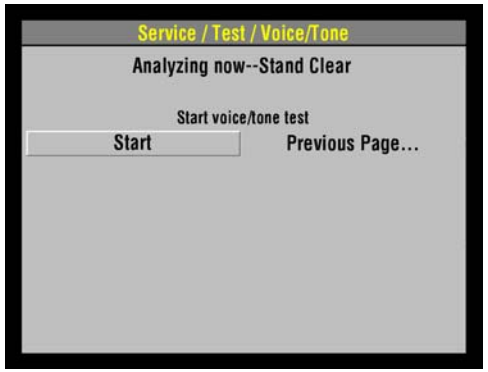
Note: Door button is hidden in the elastomer keypad and it is located between the OPTION and PAUSE buttons.

Note: A failure is indicated by a control text box that is not highlighted. It is normal for the controls with up/down arrows to highlight only the arrows.

6. Verify the key check sound indicating that the button is working.
7. Press the Speed Dial at the end of the test.
8. Record the results on the **PIP Checklist**.

PIP – Instructions

PIP- Audio test (optional test)



To test the UUT voice prompts and tones:

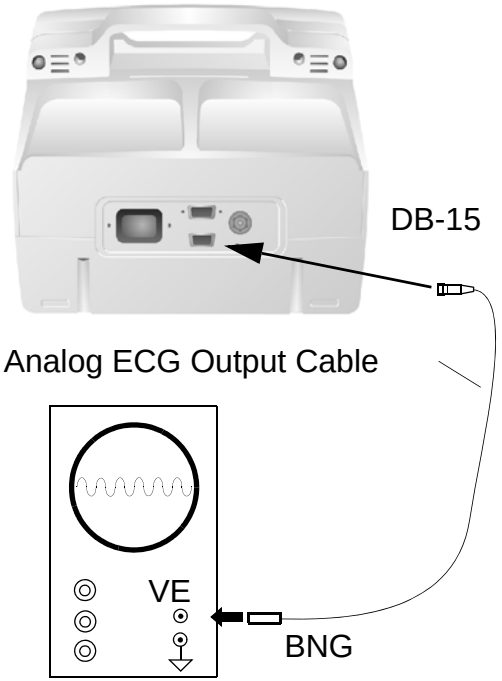
1. Hold down OPTIONS and EVENT controls and turn on the device. Hold the controls until Enter Passcode appears. Enter passcode 5433.
2. Select SERVICE from the Setup menu. Enter passcode 5433.
3. Select VOICE/TONE... from the Service/Tests sub-menu.
4. Select START. Voice prompts sound in the speaker.
5. When satisfied that the voice prompts are clearly audible and reproduced without distortion, turn off the device.

Note: You may listen to a complete replay of all voice prompts and tones, but it is not required for verification of this function.

6. Record the results on the **PIP Checklist**.
7. Turn the UUT off.

PIP – Instructions

PIP- ECG Analog Output (optional test)



To test the ECG analog output:

Note: This test is optional. Perform only if this feature is used.

1. Establish the test setup as shown at the left.
2. Using the ECG cable supplied with the UUT, input a 1 mV 10 Hz sine wave from the patient simulator.
3. Set the UUT lead selection to LEAD II. (The ECG analog output is in real time at a nominal 1 v/mV and is not affected by the device ECG size setting.)
4. Verify the amplitude of the signal displayed on the oscilloscope is between 0.85 Vp-p and 1.15 Vp-p.
5. Disconnect the Analog ECG Output Cable from the UUT and oscilloscope.
6. Record the results on the **PIP Checklist**.
7. Turn the UUT off.

PIP – Summary of Leakage Current Specifications

The following summarizes leakage current specifications.
NC=Normal Condition SFC = Single Fault Condition

Leakage Test		Maximum Leakage Current Specifications	
Type of Test	**Lead Test**	**Analyzer @ 120 vac**	**Analyzer @ 240 vac**
Chassis Leakage	Contact of Ground Stud	NC: 90 µA	NC: 90 µA
		SFC: 270 µA	SFC: 450 µA
Earth Leakage	Closed Neutral	450 µA	450 µA
	Open Neutral	900 µA	900 µA
3-Lead ECG Source LEAD-GND	All-GND	NC: 10 µA	NC: 10 µA
		SFC: 50 µA	SFC: 50 µA
3-Lead ECG Source LEAD-LEAD	RA	NC: 10 µA	NC: 10 µA
		SFC: 50 µA	SFC: 50 µA
	LA	NC: 10 µA	NC: 10 µA
		SFC: 50 µA	SFC: 50 µA
	LL	NC: 10 µA	NC: 10 µA
		SFC: 50 µA	SFC: 50 µA
3-Lead ECG Sink Leakage	ISO Test	45 µA	45 µA

PIP – Summary of Leakage Current Specifications

Leakage Test		Maximum Leakage Current Specifications	
Type of Test	**Lead Test**	**Analyzer @ 120 vac**	**Analyzer @ 240 vac**
5-Lead ECG Source LEAD-GND	ALL	NC: 10 µA	NC: 10 µA
		SFC: 50 µA	SFC: 50 µA
5-Lead ECG Source LEAD-LEAD	RA	NC: 10 µA	NC: 10 µA
		SFC: 50 µA	SFC: 50 µA
	RL	NC: 10 µA	NC: 10 µA
		SFC: 50 µA	SFC: 50 µA
	LA	NC: 10 µA	NC: 10 µA
		SFC: 50 µA	SFC: 50 µA
	LL	NC: 10 µA	NC: 10 µA
		SFC: 50 µA	SFC: 50 µA
	C	NC: 10 µA	NC: 10 µA
		SFC: 50 µA	SFC: 50 µA
5-Lead ECG Sink Leakage	ISO Test	45 µA	45 µA

PIP – Summary of Leakage Current Specifications

Leakage Test		Maximum Leakage Current Specifications	
Type of Test	**Lead Test**	**Analyzer @ 120 vac**	**Analyzer @ 240 vac**
SpO2 Sink Leakage	ISO Test	90 µA	450 µA
Paddles Source LEAD-GND	All–GND	NC: 10 µA	NC: 10 µA
		SFC: 50 µA	SFC: 50 µA
Paddles Source LEAD-LEAD	RL or C	NC: 10 µA	NC: 10 µA
		SFC: 50 µA	SFC: 50 µA
Paddles Sink Leakage	ISO Test	90 µA	450 µA
QUIK-COMBO Source LEAD-GND	All–GND	NC: 10 µA	NC: 10 µA
		SFC: 50 µA	SFC: 50 µA
QUIK-COMBO Source LEAD-LEAD	RL or C	NC: 10 µA	NC: 10 µA
		SFC: 50 µA	SFC: 50 µA
QUIK-COMBO Sink Leakage	ISO Test	90 µA	450 µA

Instrument Calibration

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

Note: Anytime the device is calibrated or opened for repair or component replacement, it must successfully pass all portions of the closed-case **Performance Inspection Procedure (PIP).**

TCP – Scope and Applicability

This TCP applies to the LIFEPAK 20 defibrillator/monitor exclusively. You may perform the procedures outlined in this section in any order.

Note: Prior to its return to active use, the LIFEPAK 20 defibrillator/monitor must successfully pass all portions of the closed-case Performance Inspection Procedure (PIP) anytime the device is opened for repair, component replacement, or after calibration.

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

Refer to **TCP – Test Equipment Requirements** for a listing 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 the TCP – Test Equipment Requirements table on the next page. Although the table lists specific test equipment by manufacturer, test equipment with equivalent specifications may be substituted.

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

TCP – Personnel

Technicians who perform the TCP must be properly qualified and thoroughly familiar with the operation of the LIFEPAK 20 defibrillator/monitor, meeting the requirements described in **Service Personnel Qualifications**.

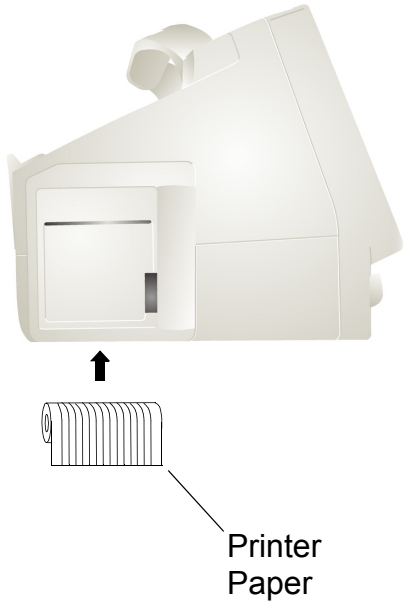
TCP – Test Equipment Requirements

You need the following test equipment, or equivalent, to conduct the TCP.

Equipment	Specifications	Manufacturer
Defibrillator Analyzer[a]	Energy range: 0 to 450 J Load resistance: 50 Z ±1% Accuracy: ±2% +2 J Waveforms: NSR, VF, and Sine Wave	BIO-TEK® QED-6™, with test posts accessory (software version 2.07, or greater) or equivalent
QUIK-COMBO test post adapter	Connects to QUIK-COMBO therapy cable	Physio-Control PN 3005302
Cable -Therapy, Quik-Combo Pretest		Physio-Control PN 3011517
Defibrillator Isolation test load	Resistor - Test Load, 200Z, Silicon Coated, 50 Watt, 5%	Physio-Control PN 3205570
General purpose oscilloscope	Bandwidth: dc to 2 MHz Vertical accuracy: ±3% (5 mV – 5 v/div.) Horizontal Time Base Accuracy: ±5%	Tektronix® 2232 or equivalent

a. Some energy meters are not accurate for biphasic waveforms; contact your defibrillator analyzer's manufacturer for more information.

TCP – Setup



The following describes the LIFEPAK 20 defibrillator/monitor setup for the TCP.

WARNING!

Shock hazard. When discharged during this TCP, the device discharges up to 360 J 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.

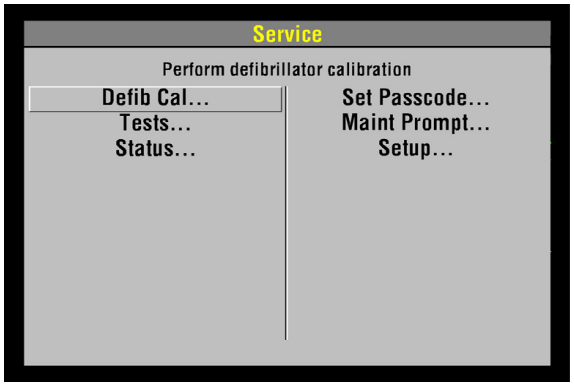
To set up the LIFEPAK 20 defibrillator/monitor for the TCP: Install a roll of paper into the printer.

Note: Ensure that the LOW BATTERY screen message does not appear when the device is turned on and during defibrillator calibration by installing a fully functional battery in the UUT.

Note: If the A12 Printer was replaced, save the piece of paper inside the printer that has the printhead resistance written down.

Note: Do not connect anything to the therapy connector, except as directed during this procedure.

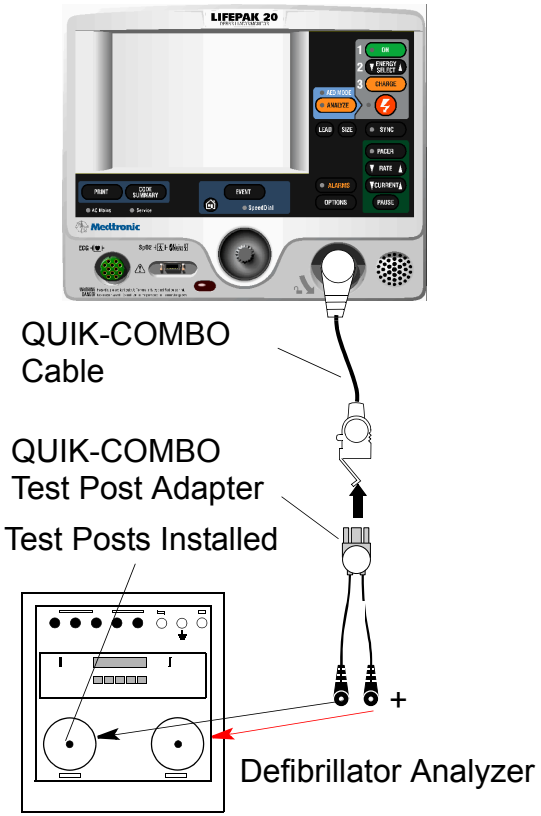
TCP – Defibrillator Calibration Menu Access



To enter the Service screen:

1. Complete the TCP – Setup.
2. Place the UUT in service mode.
3. Select DEFIB CAL.. from the Service screen. The Service/Calibration screen appears.

TCP – Defibrillator Calibration



To perform the defibrillator calibration procedure:

1. Connect the UUT to the defibrillator analyzer. Make sure the QUIK-COMBO (+) terminal is connected to apex (+).

   Note: Adapt this procedure to use standard paddles, if desired.

   Note: Ensure proper test setup 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 (if the analyzer is equipped with pacer inputs).

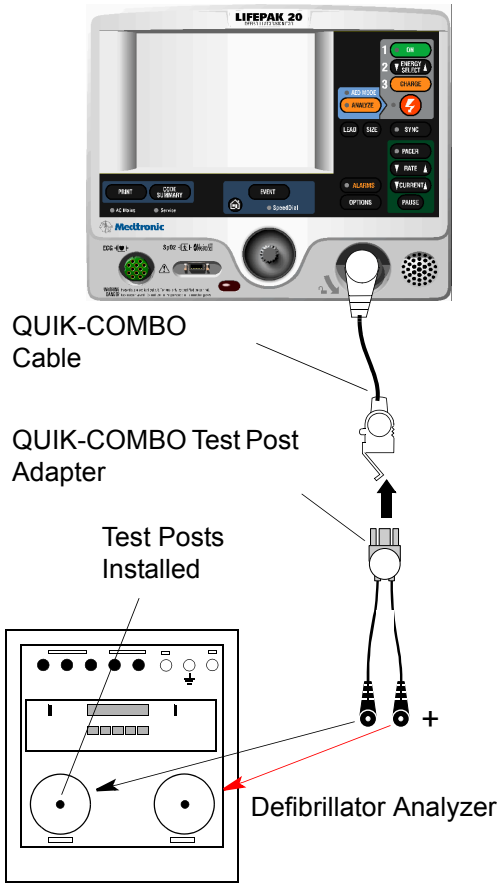
   Note: If testing with standard paddles, verify that the metal surfaces of the paddles are free of burn or arc marks and are free of pits, scratches, or raised nicks that can be felt with the finger tips.

2. Set the defibrillator analyzer to measure energy, with the appropriate scale.
3. Access the Defib Calibration submenu.
4. Select DEFIB CAL from the Service Screen.
5. Select START to initiate the calibration routine.
6. Follow the instructions on the UUT screen.

TCP – Defibrillator Calibration

7. Turn off the UUT.
8. Continue directly to TCP – Delivered Energy Test on the next page.

TCP – Delivered Energy Test



WARNING!

Shock hazard. Avoid contact with the energy meter. Dangerous voltages will be present on energy meter electrode plates/posts.

To verify the defibrillator delivered energy:

1. Connect the UUT to the defibrillator analyzer. Make sure the QUIK-COMBO (+) terminal is connected to apex (+).

   Note: Adapt this procedure to use standard paddles, if desired.

2. Set the defibrillator analyzer to measure energy, with the appropriate scale.
3. Turn on the UUT. Verify that the ADVISORY indicator is off. If not, refer to **Entering Manual Mode**.
4. Press the ENERGY SELECT control to select 2 J.
5. Press the CHARGE control and wait for the UUT to reach full charge. Press the SHOCK control to discharge the UUT energy.

   Note: Verify that the defibrillator analyzer shows an energy level between 1.0 and 3.0 J.Not all energy levels listed in the Delivered Energy Test table (below) are available on every UUT.

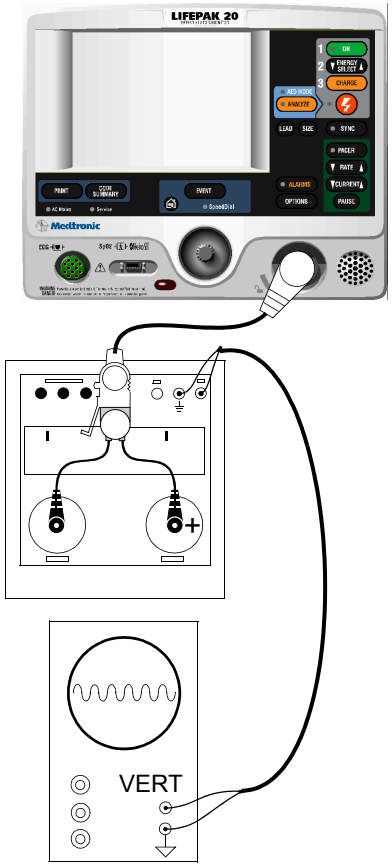
TCP – Delivered Energy Test

6. Repeat Steps 4 through 6 for the remaining available energy levels specified in the Delivered Energy Test table below.

Energy Level (J)	Acceptable Output (J)	Energy Level (J)	Acceptable Output (J)
2	1.0 to 3.0	70	66.5 to 73.5
10	9.0 to 11.0	100	97.5 to 102.5
15	14.0 to 16.0	360	351.0 to 369.0
50	47.5 to 52.5		

(Continued on next page)

TCP – Defibrillator Output Waveform Test (Optional)



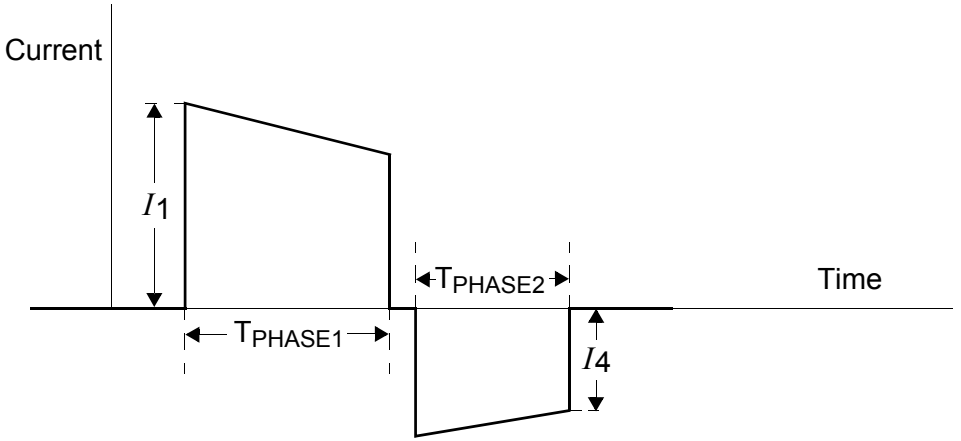
The Defibrillator Output Waveform Test is an optional test.

1. Connect the UUT to a defibrillator analyzer using the QUIK-COMBO electrode cable. Set the defibrillator analyzer to ENERGY, 1000 J scale.
2. Connect the DEFIB and GND terminals on the defibrillator analyzer to an oscilloscope vertical channel input and ground input. Set the oscilloscope to 0.5 V/div, 2 ms/div, + slope, store mode, and single sweep.

   Note: 1 V on the oscilloscope = 29 A defibrillator output current using the QED-6 energy meter. When using other energy meters, refer to the manufacturer's specifications. You may need to slow down the horizontal sweep and/or turn on the triggering high-frequency reject to successfully capture the waveform.
3. Turn on the UUT. Press the ENERGY SELECT control and select 360 J.
4. Press the CHARGE control. After the capacitor charges (the SHOCK indicator is blinking), press the SHOCK control to deliver the energy to the analyzer.
5. Verify that the waveform meets specifications.
6. When testing is complete, turn off the UUT and disconnect the test setup.

(Continued on next page)

TCP – Defibrillator Output Waveform Test (Optional)

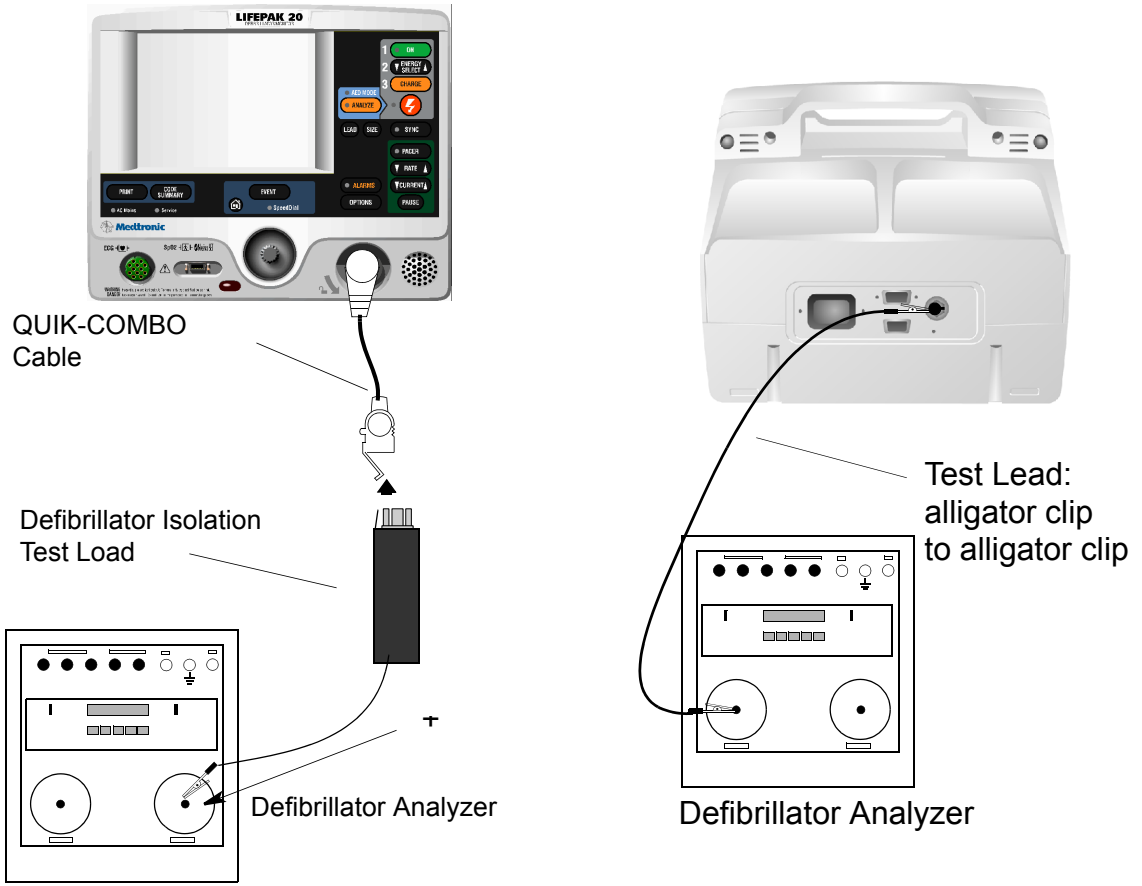


Patient Impedance (Ω)	T_{PHASE1} (ms)		T_{PHASE2} (ms)		Tilt	
	Min	Max	Min	Max	Min	Max
50	6.8	7.9	4.5	5.3	63.9	71.0

1. Delivered waveform at 360 J into given resistive load.
2. Discharge polarity is APEX positive, STERNUM negative for Phase 1.
3. $\text{Tilt} = \frac{+I1 - |I4|}{I_1}$,

TCP – Therapy Defibrillation Isolation Test

TCP- Therapy- Defibrillation Isolation Setup



TCP – Therapy Defibrillation Isolation Test

TCP- Therapy-Defibrillation Isolation

To test for therapy defibrillation isolation after a therapy repair:

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

1. Establish the setup shown in the figure on the previous page.
2. Verify the defibrillator analyzer is on and the display displays ENERGY. If not, turn on the defibrillator analyzer and press the ENRG softkey.
3. Turn on the UUT.
4. Press the ENERGY SELECT control and select 360 J.
5. Press the CHARGE control. After the capacitor charges (the SHOCK indicator is blinking), press the SHOCK control to deliver the energy to the analyzer.
6. Verify the defibrillator analyzer indicates a delivered energy of less than 2J.
7. Turn off the device.