

Performance Inspection Procedure

The Performance Inspection Procedure (PIP) is a set of manual and computer-assisted test procedures used by authorized Physio-Control service representatives. It will be used as an operational closed-case evaluation of the defibrillator. This section describes the test procedures you will perform to determine if the device is operating within the required specifications.

Note: Use the [Performance Inspection Procedure Checklist](#) to record the results of each test to ensure compliance with each step of this process.

Note: Perform the procedures in the order presented.

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PIP – Scope and Applicability

The PIP applies to the LIFEPAK CR PLUS/EXPRESS Defibrillator exclusively. To complete the PIP, you must perform the combination of manual and computer assisted tests outlined in the **PIP – Instructions** section of this electronic service manual. All PIP tests must be performed from start to finish in the order presented.

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.

Use the **PIP – Checklist** to record your results.

PIP – Resource Requirements

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

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. The calibration label must be issued by a certified calibration facility.

PIP – Workstation Power

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

PIP – Test Equipment Requirements

Equipment	Specifications	Manufacturer
Defibrillator analyzer	Power range: 0-450 J Load resistance: 50 Ω Accuracy and/or guard banding must be sufficient to ensure test limits. Waveforms: NSR and VF	Fluke - Impulse 7000DP
Cable, Quik-Combo to Snap Termination		3009139
Decade resistance box	Range: 0-500 Ω, Resolution: 1 Ω Accuracy: 1%	IET Model RS-200
Safety analyzer	110 or 220 Vac line voltage Current range: 0-1999 μA Accuracy and/or guard banding must be sufficient to ensure test limits.	Fluke - ESA612
Cable Assembly, FAST-PATCH		3011030-00
Electrode Test Post Adapter (2 ea)		3205979
Test Software, LIFEPAK CR Series PIP-TCP		3202957 revision G

PIP – Test Equipment Requirements

Equipment	Specifications	Manufacturer
IrDA Dongle	IrDA FIR USB Adapter	iFoundry IFSYS-8003A
CHARGE-PAK/QUIK-PAK Replacement Kit		3201616

PIP – Instructions

PIP – General Instructions

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

- Perform the PIP in the order presented.
- Always start the PIP from the beginning of the procedure.
- Use the **Performance Inspection Procedure Checklist** to record your results.

PIP – Physical Inspection

Perform the exterior physical inspection, described as follows.

1. Inspect all exterior surfaces of the device for the following:
 - Damage
 - Excessive wear
 - Improper mechanical function
 - Damaged connectors

(Continued on next page)
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PIP – Instructions

PIP – Physical Inspection (continued)

2. Lift and turn over the device and listen for loose or rattling hardware. If loose hardware is suspected, investigate and correct or contact Physio-Control before performing this procedure.
3. Inspect the case for separation (integrity of case seal).
4. Check for debris or bent, broken, or corroded connectors or pins. Clean or replace damaged components.
5. Record the results of the physical inspection on the **PIP Checklist**.

PIP – Instructions

PIP – Initialization test

This test confirms the overall status of the device before you turn it on, and how to evaluate each step in the procedure.

Note: In some cases, it is acceptable to proceed with inspection when the **OK** symbol is not visible since the CHARGE-PAK battery charger and QUIK-PAK electrodes are replaced at the end of the inspection. Make a note in the PIP checklist of which symbols are visible and continue with inspection unless otherwise indicated in the chart.

SYMBOL VISIBLE	DEVICE HISTORY	INSTRUCTION
OK	n/a	Proceed with PIP
BATTERY	n/a	Proceed with PIP
BATTERY & ATTENTION	Device used to treat patient < 3 days ago.	Delay PIP
	Device used to treat patient > 3 days ago.	Proceed with PIP
	Device NOT used to treat patient.	ERROR - do not continue
ATTENTION	Device used to treat patient < 3 days ago and CHARGE-PAK replaced	Delay PIP
	Device used to treat patient > 3 days ago and CHARGE-PAK replaced	ERROR - do not continue
	Device NOT used to treat patient or CHARGE-PAK not replaced	ERROR - do not continue
WRENCH	n/a	ERROR - do not continue

PIP – Instructions

PIP – Initialization test (continued)

Note: Ensure a patient load is not connected to the device.

- Verify the **OK** symbol appears in the Readiness Display.
- If the **WRENCH** symbol appears, the device must be serviced. Do not attempt to perform this inspection if the **WRENCH** symbol is illuminated.

OK



(Examples of symbols)

- Before you perform the initialization test, ensure that the device has been turned off for at least 60 seconds.
- If only the **ATTENTION** symbol is visible, the internal device battery is recharging from the CHARGE-PAK battery charger. Wait until the **ATTENTION** symbol is extinguished before continuing with the PIP.

PIP – Instructions

PIP – Initialization test (continued)

To perform the initialization test:

1. Make sure a CHARGE-PAK battery charger is installed in the device.
2. Press the **LID RELEASE/ON-OFF** button to open the lid and turn the device ON.
3. Verify that the **OK**, **BATTERY**, **ATTENTION**, and **WRENCH** symbols momentarily illuminate in the Readiness Display.
4. Verify that the **SHOCK** LED illuminates briefly in semi-auto unit. (Move the electrode packet to view LED.)
5. Verify that the Readiness Display shows three black squares at the end of the startup sequence. No other symbols will be visible during this interval.

Note: The **ATTENTION** symbol may be visible. Make a note in the PIP checklist but continue with procedure.

6. Verify that the electrode indicators flash red as the power cycles during startup.
7. Verify that an alert tone is heard and that voice prompts are clearly audible, which may include:

PIP – Instructions

PIP – Initialization test
(continued)

A- Original Voice Prompt Version:

- CALL FOR HELP NOW
- REMOVE CLOTHING FROM CHEST
- PULL RED HANDLE TO OPEN BAG
- PEEL EACH PAD OFF BLUE PLASTIC AND APPLY PADS TO EXPOSED CHEST

B- Current Voice Prompt Version:

- CALL FOR HELP NOW
- REMOVE ALL CLOTHING FROM PATIENT'S CHEST
- PULL RED HANDLE TO OPEN BAG
- LOOK AT PICTURES ON PADS
- PEEL ONE PAD OFF BLUE PLASTIC
- APPLY PAD TO BARE SKIN EXACTLY AS SHOWN IN THE PICTURE
- PRESS PAD FIRMLY
- PEEL OTHER PAD OFF BLUE PLASTIC
- APPLY PAD TO BARE SKIN EXACTLY AS SHOWN IN THE PICTURE
- PRESS PAD FIRMLY

Note: Actual voice prompts may vary depending on the device configuration.

PIP – Instructions

PIP – Initialization test (continued)

Note: These prompts will repeat approximately every seven seconds if no further action is taken.

8. Verify that the voice prompts are in the correct language.
9. Close the lid.
10. Verify the voice prompts cease as the device turns off.
11. Record the Initialization test results on the **PIP Checklist**.

PIP – Instructions

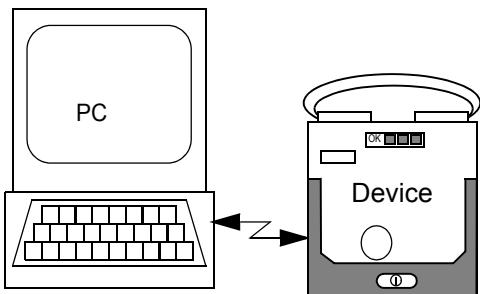
PIP – Computer Assisted tests

WARNING!

Shock hazard. When discharged, the defibrillator discharges up to 360 J of electrical energy through the therapy cable.

Perform these steps to test the device serial port communication link, verify the device serial number, perform the 03:00 auto test, perform defib verification, perform the defib charge time test, set the device time and date.

Note: Record the device serial number before you execute the test software.



1. Position the device such that its IRDA port is aligned with the service personal computer (PC) infrared communication dongle.
2. Execute software P/N 3202957 revision G.
3. Verify the CRC value, in the lower left corner of the opening screen, is 0x54A3.
4. Select the **PIP** button on the opening screen and follow the instructions as prompted.
5. Verify the software P/N 3202957 PIP passed.

PIP – Instructions

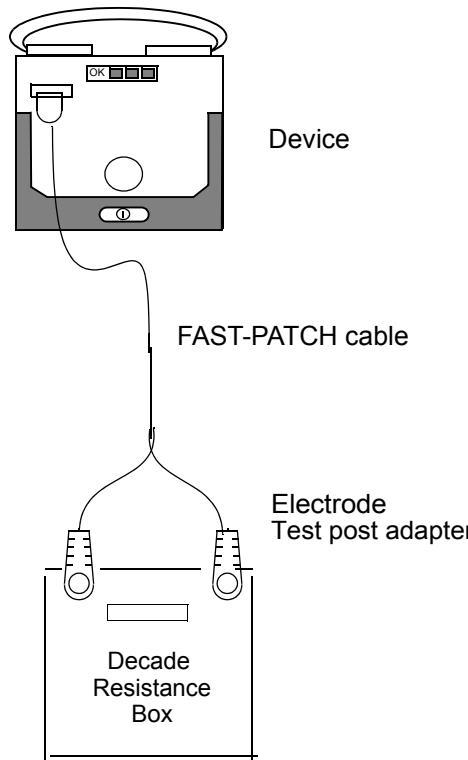
PIP – Computer Assisted tests (continued)

Note: If the defibrillator energy verification fails, execute the TCP using software P/N 3202957 to perform defibrillator energy calibration. After the TCP passes you must re-execute the PIP from software P/N 3202957 to obtain passing results for the PIP.

6. Record the Computer Assisted test results on the **PIP Checklist**.

PIP – Instructions

PIP – Electrode Impedance Test



This test verifies the relationship between electrode impedances and the device's responses.

1. Ensure the device is OFF.
2. Connect the device to the decade resistance box using the electrode test post adapter with FAST-PATCH cable.
3. Set the decade resistance box to 50Ω .
4. Press the **LID RELEASE/ON-OFF** button to turn the device ON.
5. The voice prompt sounds:

A- Original Voice Prompt Version:

- DO NOT TOUCH PATIENT/EVALUATING HEART RHYTHM.

B- Current Voice Prompt Version:

- DO NOT TOUCH PATIENT/EVALUATING HEART RHYTHM.

6. Turn the device OFF.
7. Repeat steps 1 through 6 with the decade resistance box set to each of the following values and verify the voice prompts at each value.

PIP – Instructions

PIP – Electrode Impedance Test (Continued)

Resistance Value (Ω)	Voice Prompt
3	<p>A- ORIGINAL VOICE PROMPT VERSION:</p> <p>CHECK PADS FOR GOOD CONTACT or CALL FOR HELP NOW - REMOVE CLOTHING FROM CHEST</p> <p>B-CURRENT VOICE PROMPT VERSION:</p> <p>CHECK PADS FOR GOOD CONTACT CHECK CONNECTOR or CALL FOR HELP NOW - REMOVE ALL CLOTHING FROM PATIENT'S CHEST</p>
11	<p>A- ORIGINAL VOICE PROMPT VERSION:</p> <p>DO NOT TOUCH PATIENT - EVALUATING HEART RHYTHM</p> <p>B-CURRENT VOICE PROMPT VERSION:</p> <p>DO NOT TOUCH PATIENT - EVALUATING HEART RHYTHM</p>

PIP – Instructions

PIP – Electrode Impedance Test (Continued)

Resistance Value (Ω)	Voice Prompt
238	<p>A- ORIGINAL VOICE PROMPT VERSION: DO NOT TOUCH PATIENT - EVALUATING HEART RHYTHM</p> <p>B-CURRENT VOICE PROMPT VERSION: DO NOT TOUCH PATIENT - EVALUATING HEART RHYTHM</p>
370	<p>A- ORIGINAL VOICE PROMPT VERSION: CHECK PADS FOR GOOD CONTACT or CALL FOR HELP NOW - REMOVE CLOTHING FROM CHEST</p> <p>B-CURRENT VOICE PROMPT VERSION: CHECK PADS FOR GOOD CONTACT CHECK CONNECTOR or CALL FOR HELP NOW - REMOVE ALL CLOTHING FROM PATIENT'S CHEST</p>

PIP – Instructions

PIP – Electrode
Impedance Test
(Continued)

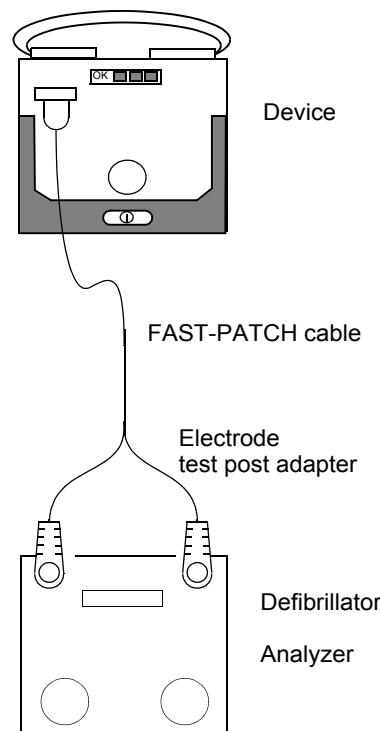
Resistance Value (Ω)	Voice Prompt
Open	<p>A- ORIGINAL VOICE PROMPT VERSION:</p> <p>CHECK PADS FOR GOOD CONTACT or CALL FOR HELP NOW - REMOVE CLOTHING FROM CHEST</p> <p>B-CURRENT VOICE PROMPT VERSION:</p> <p>CHECK PADS FOR GOOD CONTACT CHECK CONNECTOR or CALL FOR HELP NOW - REMOVE ALL CLOTHING FROM PATIENT'S CHEST</p>

Note: Actual voice prompts may vary depending on the device configuration.

8. Disconnect the FAST-PATCH cable and Electrode test post adapter from the decade resistance box.
9. Record the electrode impedance test results on the **PIP Checklist**.

PIP – Instructions

PIP – Defibrillator Automatic Advisory Operation



To test the defibrillator automatic advisory system:

1. Establish the set-up as shown. Set the Defibrillator Analyzer to output a Normal Sinus Rhythm waveform.
2. Press the **LID RELEASE/ON-OFF** button to turn the device ON.
3. Verify that the electrode indicators turn steady green.
4. Verify that the voice prompts are clearly audible. They may include:

A- ORIGINAL VOICE PROMPT VERSION:

- CALL FOR HELP NOW
- DO NOT TOUCH PATIENT — EVALUATING HEART RHYTHM
- NO SHOCK ADVISED
- CHECK FOR PULSE (or SIGNS OF CIRCULATION)
- IF NO PULSE (or IF NO SIGNS OF CIRCULATION), START CPR
- CONTINUE CARE (NOTE: AFTER 15 SEC, REPEAT “CONTINUE CARE” EVERY 15 SEC).

PIP – Instructions

PIP – Defibrillator Automatic Advisory Operation (continued)

B- CURRENT VOICE PROMPT VERSION:

- CALL FOR HELP NOW
- DO NOT TOUCH PATIENT — EVALUATING HEART RHYTHM
- NO SHOCK ADVISED
- CHECK FOR BREATHING
- IF NOT BREATHING/PROVIDE RESCUE BREATHS AND CHEST COMPRESSIONS
- CONTINUE CARE (NOTE: AFTER 15 SEC, REPEAT “CONTINUE CARE” EVERY 15 SEC).

Note: Actual voice prompts may vary depending on the device configuration.

WARNING!

Shock hazard. When discharged, the device discharges up to 360 J of electrical energy through the therapy cable.

5. Set the Defibrillator Analyzer to output a Ventricular Fibrillation waveform.
6. Cycle power on the device.
7. Verify that the voice prompts are clearly audible. They may include:

PIP – Instructions

PIP – Defibrillator
Automatic Advisory
Operation (continued)

A- ORIGINAL VOICE PROMPT VERSION:

- DO NOT TOUCH PATIENT DELIVERING SHOCK
- EVALUATING HEART RHYTHM
- STAND BY
- PREPARING TO SHOCK

B- CURRENT VOICE PROMPT VERSION:

- DO NOT TOUCH PATIENT
- EVALUATING HEART RHYTHM
- STAND BY
- PREPARING TO SHOCK

Note: Actual voice prompts may vary depending on the device configuration.

8. When the device is charged, verify that the voice prompts are clearly audible. They may include:

A- ORIGINAL VOICE PROMPT VERSION:

- EVERYONE CLEAR
- PRESS FLASHING BUTTON

B- CURRENT VOICE PROMPT VERSION:

- EVERYONE CLEAR

PIP – Instructions

PIP – Defibrillator Automatic Advisory Operation (continued)

- DO NOT TOUCH PATIENT
- DELIVERING SHOCK

Note: Actual voice prompts may vary depending on the device configuration.

9. Verify that a ready tone is audible.

WARNING!

Fully automatic models will discharge automatically.

Note: Fully automatic models will discharge automatically; the SHOCK button will flash for semi-automatic models.

10. Press and hold the **LID RELEASE/ON-OFF** button to turn the device OFF.
11. Disconnect the Fast Patch cable from the device and the Defibrillator Analyzer
12. Record the successful completion of the automatic advisory operation test on the **PIP Checklist**.

PIP – Instructions

PIP – Leakage Current

Check to ensure the leakage current meets the following industry standards:

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

WARNING!

Shock Hazard. Failure to properly perform these tests could result in a failure to detect excessive leakage current. Make sure you are familiar with your test equipment and these test performance procedures.

Note: This test procedure provides specific instructions for use of the Fluke Biomedical ESA612 Safety Analyzer. Use of equivalent test equipment is acceptable.

PIP – Instructions

PIP – Leakage Current (continued)

1. Use the QUIK-COMBO to snap termination cable to connect the device to the ESA612 Safety Analyzer at the RA and LL snaps of the ESA612.

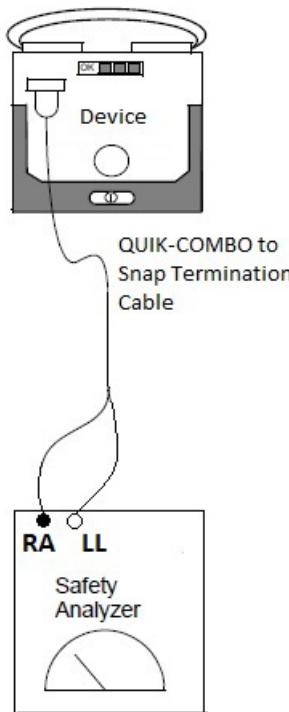
2. Turn the device ON.

3. Turn the Fluke ESA612 ON, press the μ A button then the F3/Patient Auxiliary button.

Note: The ESA612 must be setup to measure IEC 60601 under the Setup menu.

4. Verify the test setup and confirm the ESA612 is properly configured to measure Patient Auxiliary leakage.

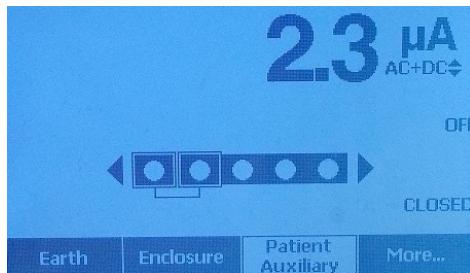
5. Verify that the Patient Auxiliary Leakage Current from the RA snap to the LL snap does not exceed the leakage current limit, shown below.



IEC 60601 Parameter	Current Mode	Leakage Current Limit
Patient Auxiliary (QUIK-COMBO Leads, Lead-to-Lead)	AC + DC	9 μ A

PIP – Instructions

PIP – Leakage Current (continued)



Note: As the current flow from the Apex to the Sternum is identical to the flow from the Sternum to the Apex, only one leakage measurement is required.

Note: When using the Fluke ESA612, Polarity, Neutral, and Earth settings are irrelevant as the device operates via battery power only.

6. Record the leakage current test results on the **PIP Checklist**.
7. Turn the device OFF.

PIP – Instructions

Replenishment of QUIK-PAK Electrodes and CHARGE-PAK Battery Charger

The QUIK-PAK electrodes and the CHARGE-PAK battery charger have the same Use By dates. They must both be replaced at the end of this inspection to ensure the device is ready for use.

QUIK-PAK Electrodes Installation and CHARGE-PAK installation

Perform the following steps to replace the QUIK-PAK electrodes:

1. Remove the electrode packet anchor pin from the slot in the device.
2. Slide the replacement electrode anchor pin into the slot on the device.
3. Plug in the new electrode connector.
4. Ensure that the new electrode packet is centered on the device and is tucked behind the lip before closing the lid.
5. Proceed to the CHARGE-PAK battery charger installation procedure on the next page.

PIP – Instructions

QUIK-PAK Electrodes Installation and CHARGE-PAK installation (continued)

Note: The defibrillator internal battery may be partially depleted (the **ATTENTION** symbol will appear) at the end of the inspection. This is considered normal operation but the device must not be placed back into active service until the **OK** symbol is visible. (This may take approximately 10 days, depending on the state of the battery.)

Perform the following steps to remove and replace the CHARGE-PAK battery charger used during this inspection.

1. Remove the used CHARGE-PAK battery charger by pressing down on its latch. The CHARGE-PAK battery charger will spring outward from the device.
2. Insert the new CHARGE-PAK battery charger into the device until you hear it “click” into position. If it is not completely inserted, it will spring back out.
3. Verify that the **OK** symbol appears on the Readiness Display.
4. Deplete the used CHARGE-PAK battery charger using the discharger provided in the replacement kit and following the instructions provided.
5. Record the installation of the new QUIK-PAK electrodes and CHARGE-PAK battery charger test results on the **PIP Checklist**.

PIP – Instructions

PIP – Final Status

This test confirms the overall status of the device after replacing the CHARGE-PAK battery charger and QUIK-PAK electrodes.

Note: Ensure a patient load is not connected to the device.

- Turn the device ON and wait for the self-test to finish.
- Turn the device OFF.
- Verify the **OK** symbol appears in the Readiness Display.
- If the **OK** symbol does not appear and the **ATTENTION** symbol is visible, the CHARGE-PAK battery charger is charging the internal battery and the device must not be placed back in active service.
- If the **WRENCH** symbol appears, the device must be serviced.



(Examples of symbols)

- Record the Final Status test result on the **PIP Checklist**.

Test and Calibration Procedures

This section covers the Test and Calibration Procedures (TCP). You should complete the relevant TCP to correct out-of-specification conditions detected during the **Performance Inspection Procedure** (PIP). Also follow TCP as necessary after replacement of device components. The listed procedures may be performed in any order.

Note: The two PCBs in this device must be changed as a calibrated set. The analog and digital PCBs cannot be replaced individually.

Note: Any time the device is opened for repair, component replacement, or calibration, the device must successfully pass all portions of the closed-case **PIP** before being returned to active service. If a device exhibits a fault code, contact Physio-Control; do not place it back in service.

Scope and Applicability

Resource Requirements

Test Equipment Requirements

Defibrillator Energy Calibration

Scope and Applicability

The TCP applies to the device exclusively. You may perform the procedures outlined in this section in any order.

Note: Any time the device is opened for repair or component replacement, or after calibration, the device must successfully pass the entire **Performance Inspection Procedure** before it is returned to active service.

Refer to **Resource Requirements** for necessary equipment, test equipment verification, and workstation power.

Refer to **Test Equipment Requirements** for a listing of test equipment, (including specifications) required to complete the 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 **Test Equipment Requirements** table. 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 line power to the workstation must be connected to a grounded power source. The workstation must have Electrostatic Discharge (ESD) protection.

Test Equipment Requirements

Equipment	Specifications	Manufacturer
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
Cable Assembly, FAST-PATCH		3011030-00
Electrode Test Post Adapter (2 ea)		3205979
Test Software, LIFEPAK CR Series PIP-TCP		3202957 revision G

Defibrillator Energy Calibration

WARNING!

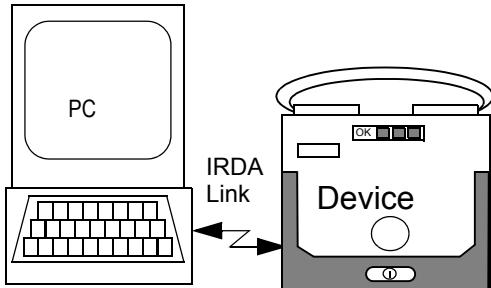
Shock hazard. Avoid contact with the energy meter. Dangerous voltages will be present on energy meter electrode plates/posts.

Perform the following steps to calibrate all defibrillator-delivered energy levels:

1. Position the device such that its IRDA port is aligned with the PC infrared communication dongle.
2. Execute program P/N 3202957 revision G. Select TCP button from the opening screen and follow the instructions as prompted.

Note: Use a 50Ω patient load for defibrillator energy calibration.

Note: The CHARGE-PAK battery charger must be replaced after defibrillator energy calibration.



Performance Inspection Procedure (PIP) Checklist

Model # _____

Department/Location _____

Serial # _____

Performed By _____

Date _____

Service Report # _____

Inspection		Pass	Failed	Comments
A	Physical Inspection			
	Confirm the results of physical inspection.	<input type="checkbox"/>	<input type="checkbox"/>	
Testing				
1	Initialization Test			
	Confirm the results of Initialization test.	<input type="checkbox"/>	<input type="checkbox"/>	
2	Computer Assisted Tests			
	a- Record the results of the Defibrillation Delivered Energy tests.			
	Shock # 1	Observed (J)	_____	
	Shock # 2	Observed (J)	_____	
	Shock # 3	Observed (J)	_____	
	b- Confirm the result of Computer assisted tests.	<input type="checkbox"/>	<input type="checkbox"/>	
3	Electrode Impedance			
	Confirm the results of Electrode impedance test.			
	50Ω – Do not touch patient			
	3Ω – Check pads/Call for help/Check Connector			
	11Ω – Do not touch patient			
	238Ω –Do not touch patient			
	370Ω –Check pads/Call for help/Check Connector			
	Open –Check pads/Call for help/Check Connector	<input type="checkbox"/>	<input type="checkbox"/>	
4	Automatic Advisory Operation			
	Record the results of Automatic Advisory Operation tests.	<input type="checkbox"/>	<input type="checkbox"/>	
5	Leakage Current			
	Record the result of Leakage current test. (0 µA - 9 µA)	Observed (µA)	_____	
6	Installation of New QUIK-PAK Electrodes and CHARGE-PAK battery charger			
	Confirm the result of Installation of new QUIK-PAK electrodes and CHARGE-PAK battery charger.	<input type="checkbox"/>	<input type="checkbox"/>	
7	Final Status			
	Confirm the result of Final status test.	<input type="checkbox"/>	<input type="checkbox"/>	