

**Performance Inspection Procedure (PIP) Checklist**

**Model #** \_\_\_\_\_ **Department/location** \_\_\_\_\_  
**Serial #** \_\_\_\_\_ **Performed by** \_\_\_\_\_  
**Type of PIP** \_\_\_\_\_ **Post-repair**  **Annual**  **Date** \_\_\_\_\_

Exterior physical and basic function inspection	Pass	Fail	Comments
<b>1. Loose Hardware Inspection</b>			
a. Loose or rattling hardware	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>2. Inspect Front of DUT</b>			
a. Broken or scratched display	<input type="checkbox"/>	<input type="checkbox"/>	_____
b. Broken or cracked keypad	<input type="checkbox"/>	<input type="checkbox"/>	_____
c. Broken or cracked bezel	<input type="checkbox"/>	<input type="checkbox"/>	_____
d. Missing USB cover	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>3. Inspect Right Side of DUT</b>			
a. Damage, cracks or case separation.	<input type="checkbox"/>	<input type="checkbox"/>	_____
b. ECG connection port damage free	<input type="checkbox"/>	<input type="checkbox"/>	_____
c. ECG cable works properly	<input type="checkbox"/>	<input type="checkbox"/>	_____
d. Batteries work properly in both battery wells.	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>4. Inspect Top of DUT</b>			
a. Damage, cracks or case separation.	<input type="checkbox"/>	<input type="checkbox"/>	_____
b. Damage to handle	<input type="checkbox"/>	<input type="checkbox"/>	_____
c. Therapy connects and releases properly	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>5. Inspect Bottom of DUT</b>			
a. Damage or cracks to the skid plate	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>6. Inspect Parameter Module of DUT</b>			
a. Damage, cracks or case separation.	<input type="checkbox"/>	<input type="checkbox"/>	_____
b. Damage or missing CO2 cover	<input type="checkbox"/>	<input type="checkbox"/>	_____
c. Damaged or missing USB cover	<input type="checkbox"/>	<input type="checkbox"/>	_____
d. Accessories and connect and release properly	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>7. Device setup</b>	<b>Complete</b>		<b>Comments</b>
a. Insert two fully functional LP35 batteries into the DUT	<input type="checkbox"/>		_____
<b>8. Power on/self - test</b>	<b>Pass</b>	<b>Fail</b>	<b>Comments</b>
a. All items are conforming	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>9. Auxiliary power switching</b>	<b>Pass</b>	<b>Fail</b>	<b>Comments</b>
a. Auxiliary Power indicator was Green	<input type="checkbox"/>	<input type="checkbox"/>	_____

- b. Battery icons appear but neither is highlighted   \_\_\_\_\_
- c. Battery icons appear and one is highlighted   \_\_\_\_\_

10. Power source management		Pass	Fail	Comments	
a.	Confirm battery status indicator switching	<input type="checkbox"/>	<input type="checkbox"/>	_____	
11. Modem functional test		Pass	Fail	NA	Comments
a.	Confirm DUT recognizes a modem has been installed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
12. Printer functional test		Pass	Fail	NA	Comments
a.	Confirm DUT recognizes a printer has been installed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
13. SHIFT check		Pass	Fail	NA	Comments
a.	Confirm device passes SHIFT check	<input type="checkbox"/>	<input type="checkbox"/>		_____
b.	Confirm device passes SHIFT check with Printer (optional)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
14. Auto test and date/time verification		Pass	Fail	Comments	
a.	Confirm device passes Auto Test	<input type="checkbox"/>	<input type="checkbox"/>	_____	
b.	Confirm Time and Date are correct	<input type="checkbox"/>	<input type="checkbox"/>	_____	
15. USB functional test		Pass	Fail	Comments	
a.	Confirm USB enumerates for each USB Port (Show mode populates)	<input type="checkbox"/>	<input type="checkbox"/>	_____	

Therapy testing					
16. Patient impedance test		Pass	Fail	Comments	
a.	Verify the device displays PADDLES LEADS OFF message (349 ohms)	<input type="checkbox"/>	<input type="checkbox"/>	_____	
b.	Verify the PADDLES LEADS OFF message is not visible (50 ohms)	<input type="checkbox"/>	<input type="checkbox"/>	_____	
c.	Verify the PADDLES LEADS OFF message is not visible (254 ohms)	<input type="checkbox"/>	<input type="checkbox"/>	_____	
d.	Verify the PADDLES LEADS OFF message is visible (open condition)	<input type="checkbox"/>	<input type="checkbox"/>	_____	
17. Delivered energy test		Pass	Fail	Comments	
a.	10 J – Record delivered energy (tolerance 9.1 to 10.9 J)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	_____
b.	50 J – Record delivered energy (tolerance <b>46.6 to 53.4 J</b> . If TCP energy calibration was performed, tolerance <b>47.5 to 52.5J</b> )	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	_____
c.	200 J – Record delivered energy (tolerance <b>186.0 to 214.0 J</b> . If TCP energy calibration was performed, tolerance <b>195 to 205J</b> )	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	_____
d.	360 J – Record delivered energy (tolerance <b>334.8 to 385.2 J</b> . If TCP energy calibration was performed, tolerance <b>351 to 369J</b> )	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	_____
e.	Was a successful Defibrillator Energy Calibration performed?	<b>Yes</b>	<b>No</b>	<b>NA</b>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

**Note:** if TCP energy calibration is performed, delivered energy test will have tighter limit per 3340123, Specification, Field Test, Manual PIP-TCP, LIFEPAK 35

18. Charge time to 360J test		Pass	Fail	Comments
a.	Confirm device charges to 360 J in less than 10 seconds	<input type="checkbox"/>	<input type="checkbox"/>	_____

  

19. Synchronous cardioversion test		Pass	Fail	Comments
a.	Record Sync delay (maximum 60ms)	<input type="checkbox"/>	<input type="checkbox"/>	_____
	Measured Value _____ms			

  

20. Pacer option characteristics		Pass	Fail	Comments
a.	Confirm leads-off detection	<input type="checkbox"/>	<input type="checkbox"/>	_____
b.	10 mA- Record current (tolerance 5 to 15 mA)	<input type="checkbox"/>	<input type="checkbox"/>	_____
	Measured Value _____			
c.	100 mA - Record current (tolerance 90 to 110 mA)	<input type="checkbox"/>	<input type="checkbox"/>	_____
	Measured Value _____			
d.	200 mA - Record current (tolerance 180 to 220 mA)	<input type="checkbox"/>	<input type="checkbox"/>	_____
	Measured Value _____			
e.	Record pulse width (tolerance 19.2 to 20.8 ms)	<input type="checkbox"/>	<input type="checkbox"/>	_____
	Measured Value _____			

  

21. Therapy ECG characteristics		Pass	Fail	Comments
a.	Positive R-wave test	<input type="checkbox"/>	<input type="checkbox"/>	_____
b.	Record ECG paddle lead gain (tolerance 1mV = 38 to 42 mm)	<input type="checkbox"/>	<input type="checkbox"/>	_____
	Measured Value _____			

ECG performance testing					Pass	Fail	NA	Comments
<b>22. ECG tests (3, 5, 12 or 15-LEAD ECG tests)</b>					<input type="checkbox"/>	<input type="checkbox"/>		_____
a.	Confirm LEADS-OFF screen messages				<input type="checkbox"/>	<input type="checkbox"/>		_____
b.	Record Lead II gain (tolerance 38 to 42 mm)	Measured Value _____			<input type="checkbox"/>	<input type="checkbox"/>		_____
c.	Record Lead I gain (tolerance 26 to 30 mm)	Measured Value _____			<input type="checkbox"/>	<input type="checkbox"/>		_____
d.	Record Lead III gain (tolerance 11 to 13 mm) (3-wire)	Measured Value _____			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
e.	Record Lead V1/C gain (tolerance 36 to 44 mm) (13- wire, 10-wire, 5-wire)	Measured Value _____			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
f.	Record Lead V2 gain (tolerance 36 to 44 mm) (13- wire, 10- wire)	Measured Value _____			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
g.	Record Lead V3 gain (tolerance 36 to 44 mm) (13- wire, 10- wire)	Measured Value _____			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
h.	Record Lead V4 gain (tolerance 36 to 44 mm) (13- wire, 10- wire)	Measured Value _____			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
i.	Record Lead V5 gain (tolerance 36 to 44 mm) (13- wire, 10- wire)	Measured Value _____			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
j.	Record Lead V6 gain (tolerance 36 to 44 mm) (13- wire, 10- wire)	Measured Value _____			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
k.	Record Lead V7/A1 gain (tolerance 36 to 44 mm) (13- wire)	Measured Value _____			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

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- l. Record Lead V8/A2 gain (tolerance 36 to 44 mm) (13- wire) Measured Value \_\_\_\_\_    \_\_\_\_\_
- m. Record Lead V9/A3 gain (tolerance 36 to 44 mm) (13- wire) Measured Value \_\_\_\_\_    \_\_\_\_\_

**Patient parameter function**

23. SpO <sub>2</sub> /SpCO/SpMet Tests	Pass	Fail	NA	Comments
a. Confirm SpO <sub>2</sub> reading is between 50% and 100%	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
b. Confirm SpCO reading is between 0% and 40% (if SpCO is installed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
c. Confirm SpMet reading is between 0% and 15% (if SpMet is installed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

24. Temperature sensor verification (if Temp option is installed)	Pass	Fail	NA	Comments
a. Record T1 reading of 25C (tolerance 24.8C to 25.2C) Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
b. Record T1 reading of 45C (tolerance 44.8C to 45.2C) Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
c. Record T2 reading of 25C (tolerance 24.8C to 25.2C) Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
d. Record T2 reading of 45C (tolerance 44.8C to 45.2C) Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
e. Record T3 reading of 25C (tolerance 24.8C to 25.2C) Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
f. Record T3 reading of 45C (tolerance 44.8C to 45.2C) Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

25. Invasive blood pressure verification (if IP option is installed)	Pass	Fail	NA	Comments
a. Confirm P1 pressure channel zero	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
b. Record P1 pressure reading of - 30 mmHg (tolerance -34 mmHg to -26 mmHg) Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
c. Record P1 pressure reading of 20 mmHg (tolerance 16 mmHg to 24 mmHg) Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
d. Record P1 pressure reading of 100mmHg (tolerance 96 mmHg to 104 mmHg) Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
e. Record P1 pressure reading of 300mmHg (tolerance 288 mmHg to 312 mmHg) Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
f. Confirm P2 pressure channel zero	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
g. Record P2 pressure reading of -30 mmHg (tolerance -34 mmHg to -26 mmHg) Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
h. Record P2 pressure reading of 20 mmHg (tolerance 16 mmHg to 24 mmHg) Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
i. Record P2 pressure reading of 100 mmHg (tolerance 96 mmHg to 104 mmHg) Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
j. Record P2 pressure reading of 300 mmHg (tolerance 288 mmHg to 312 mmHg) Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

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k. Confirm P3 pressure channel zero		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
l. Record P3 pressure reading of -30 mmHg (tolerance -34 mmHg to -26 mmHg)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
m. Record P3 pressure reading of 20 mmHg (tolerance 16 mmHg to 24 mmHg)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
n. Record P3 pressure reading of 100 mmHg (tolerance 96 mmHg to 104 mmHg)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
o. Record P3 pressure reading of 300 mmHg (tolerance 288 mmHg to 312 mmHg)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

26. CO <sub>2</sub> tests		Pass	Fail		Comments
a. CO <sub>2</sub> Leakage Test: Confirm change in vacuum reading is less than 15 mmHg		<input type="checkbox"/>	<input type="checkbox"/>		_____
b. CO <sub>2</sub> Calibration Check Test: Record CO <sub>2</sub> concentration reading is 5.0% ±0.82%	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>		_____
		Yes	No	NA	Comments
c. Was a successful CO <sub>2</sub> Calibration performed?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

27. NIBP Tests		Pass	Fail		Comments
a. NIBP Leakage Test: Confirm the message: Service command "NIBP Leakage Check" has been completed successfully		<input type="checkbox"/>	<input type="checkbox"/>		_____
b. NIBP Calibration Test: Confirm 50 mmHg readings agree within ±3 mmHg		<input type="checkbox"/>	<input type="checkbox"/>		_____
c. NIBP Leakage Test: Confirm 150 mmHg readings agree within ±3 mmHg		<input type="checkbox"/>	<input type="checkbox"/>		_____
d. Confirm the overpressure switch activates at 290 ±20 mmHg		<input type="checkbox"/>	<input type="checkbox"/>		_____

28. Record Operating Data (Optional) Total Shocks:		Comments
a. Pacing Count	<input type="text"/>	_____
b. 0-200J Shock Count	<input type="text"/>	_____
c. 225-325J Shock Count	<input type="text"/>	_____
d. 360J Shocks	<input type="text"/>	_____

**Data Management**

29. Bluetooth Wireless Technology (if Bluetooth option is available)	Pass	Fail	NA	Comments
a. Verify Bluetooth Pairing Successful	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

30. WIFI Wireless Technology (If WIFI Option is available)	Pass	Fail	NA	Comments
a. Verify WIFI Network connection Successful	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

**Leakage current test**

31. Leakage test AC powered device at 120VAC or 240 VAC	Pass	Fail	Comments	
a. Direct Equipment Leakage Polarity NC/RM, Condition Open Earth, (15 µA - 490 µA)	Measured Value_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
b. ECG Direct Applied Part Polarity NC/RM, Condition Normal, (5 µA - 50 µA)	Measured Value_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
c. Therapy Direct Applied Part Polarity NC/RM, Condition Normal, (5 µA - 5000 µA)	Measured Value_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
d. SpO2 Direct Applied Part Polarity NC/RM, Condition Normal, (5 µA - 5000 µA)	Measured Value_____	<input type="checkbox"/>	<input type="checkbox"/>	_____

32. LIFEPAK 35 maintenance instruction	Completed	Comments
a. Maintenance prompt disabled or reset	<input type="checkbox"/>	_____