

**LIFEPAK® 35 monitor/defibrillator**  
**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. Exterior physical inspection</b>				
a. Device exterior damage (general)	<input type="checkbox"/>	<input type="checkbox"/>		_____
b. Check device for loose/rattling hardware	<input type="checkbox"/>	<input type="checkbox"/>		_____
c. Check for missing fasteners, covers or other mechanical components	<input type="checkbox"/>	<input type="checkbox"/>		_____
d. Inspect therapy cable pins and connector	<input type="checkbox"/>	<input type="checkbox"/>		_____
e. Confirm spring button on therapy connector is functional	<input type="checkbox"/>	<input type="checkbox"/>		_____
f. Inspect device connectors for damage	<input type="checkbox"/>	<input type="checkbox"/>		_____
g. Inspect keypads and overlays for damage	<input type="checkbox"/>	<input type="checkbox"/>		_____
h. Check device accessories for condition and expiration dates	<input type="checkbox"/>	<input type="checkbox"/>		_____
i. Inspect carrying case and carrying strap for damage	<input type="checkbox"/>	<input type="checkbox"/>		_____
<b>2. Device setup</b>			<b>Complete</b>	<b>Comments</b>
a. Insert two fully charged Li-ion batteries into the device			<input type="checkbox"/>	_____
<b>3. 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>4. 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	<input type="checkbox"/>	<input type="checkbox"/>		_____
<b>5. Power source management</b>	<b>Pass</b>	<b>Fail</b>		<b>Comments</b>
a. Confirm battery status indicator switching	<input type="checkbox"/>	<input type="checkbox"/>		_____
<b>6. Modem functional test</b>	<b>Pass</b>	<b>Fail</b>	<b>NA</b>	<b>Comments</b>
a. Confirm DUT recognizes a modem has been installed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>7. Printer functional test</b>	<b>Pass</b>	<b>Fail</b>	<b>NA</b>	<b>Comments</b>
a. Confirm DUT recognizes a printer has been installed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>8. SHIFT check</b>	<b>Pass</b>	<b>Fail</b>	<b>NA</b>	<b>Comments</b>
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"/>	_____
<b>9. Auto test and date/time verification</b>	<b>Pass</b>	<b>Fail</b>		<b>Comments</b>
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"/>		_____
<b>10. USB functional test</b>	<b>Pass</b>	<b>Fail</b>		<b>Comments</b>
a. Confirm USB enumerates for each USB Port (Show mode populates)	<input type="checkbox"/>	<input type="checkbox"/>		_____

**Therapy testing**

		Pass	Fail	Comments	
<b>11. Patient impedance test</b>					
a.	Verify the PADDLES LEADS OFF message is not visible (50 ohms)	<input type="checkbox"/>	<input type="checkbox"/>	_____	
b.	Verify the device displays PADDLES LEADS OFF message (349 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"/>	_____	
<b>12. Delivered energy test</b>					
a.	10 J – Record delivered energy (tolerance 9.1 to 10.8 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?	Yes	No	NA	Comments
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>13. Charge time to 360J test</b>					
a.	Confirm device charges to 360 J in less than 10 seconds	<input type="checkbox"/>	<input type="checkbox"/>	_____	
<b>14. Synchronous cardioversion test</b>					
a.	Record Sync delay (maximum 60ms)	<input type="checkbox"/>	<input type="checkbox"/>	_____	
<b>15. Pacer option characteristics</b>					
a.	Confirm leads-off detection	<input type="checkbox"/>	<input type="checkbox"/>	_____	
b.	10 mA– Record current (tolerance 5 to 15 mA)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	_____
c.	100 mA – Record current (tolerance 90 to 110 mA)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	_____
d.	200 mA – Record current (tolerance 180 to 220 mA)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	_____
e.	Record pulse width (tolerance 19.2 to 20.8 ms)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>16. Therapy ECG characteristics</b>					
a.	Positive R-wave test	<input type="checkbox"/>	<input type="checkbox"/>	_____	
b.	Record ECG paddle lead gain (tolerance 1mV = 38 to 42 mm)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	_____

**ECG performance testing**

		Pass	Fail	NA	Comments
<b>17. ECG tests</b> (13-Wire or 10-Wire ECG tests)					
a. Confirm LEADS-OFF screen messages		<input type="checkbox"/>	<input type="checkbox"/>		_____
b. Record Lead I gain (tolerance 26 to 30 mm)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>		_____
c. Record Lead II gain (tolerance 38 to 42 mm)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>		_____
d. Record Lead V1/C gain (tolerance 36 to 44 mm) (10-wire, 13- wire)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>		_____
e. Record Lead V2 gain (tolerance 36 to 44 mm) (13- wire, 10- wire)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>		_____
f. Record Lead V3 gain (tolerance 36 to 44 mm) (13- wire, 10- wire)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>		_____
g. Record Lead V4 gain (tolerance 36 to 44 mm) (13- wire, 10- wire)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>		_____
h. Record Lead V5 gain (tolerance 36 to 44 mm) (13- wire, 10- wire)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>		_____
i. Record Lead V6 gain (tolerance 36 to 44 mm) (13- wire, 10- wire)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>		_____
j. Record Lead V7/A1 gain (tolerance 36 to 44 mm) (13- wire)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
k. Record Lead V8/A2 gain (tolerance 36 to 44 mm) (13- wire)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
l. Record Lead V9/A3 gain (tolerance 36 to 44 mm) (13- wire)	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

**Patient parameter function**

		Pass	Fail	NA	Comments
<b>18. SpO<sub>2</sub>/SpCO/SpMet Tests</b>					
a. Confirm SpO <sub>2</sub> reading is between 50% and 100%		<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"/>	_____

**19. Temperature sensor verification** (if Temp option is installed)

		Pass	Fail	NA	Comments
a. Record T1 pressure reading of 25 ±0.2 C	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
b. Record T1 pressure reading of 45 ±0.2 C	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
c. Record T2 pressure reading of 25 ±0.2 C	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
d. Record T2 pressure reading of 45 ±0.2 C	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
e. Record T3 pressure reading of 25 ±0.2 C	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
f. Record T3 pressure reading of 45 ±0.2 C	Measured Value _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

		Pass	Fail	NA	Comments
<b>20. Invasive blood pressure verification</b> (if IP option is installed)					
a.	Confirm P1 pressure channel zero	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
b.	Record P1 pressure reading of -30 ±4 mmHg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Measured Value _____
c.	Record P1 pressure reading of 20 ±4 mmHg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Measured Value _____
d.	Record P1 pressure reading of 100 ±4 mmHg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Measured Value _____
e.	Record P1 pressure reading of 300 ±12 mmHg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Measured Value _____
f.	Confirm P2 pressure channel zero	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
g.	Record P2 pressure reading of -30 ±4 mmHg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Measured Value _____
h.	Record P2 pressure reading of 20 ±4 mmHg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Measured Value _____
i.	Record P2 pressure reading of 100 ±4 mmHg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Measured Value _____
j.	Record P2 pressure reading of 300 ±12 mmHg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Measured Value _____
k.	Confirm P3 pressure channel zero	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
l.	Record P3 pressure reading of -30 ±4 mmHg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Measured Value _____
m.	Record P3 pressure reading of 20 ±4 mmHg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Measured Value _____
n.	Record P3 pressure reading of 100 ±4 mmHg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Measured Value _____
o.	Record P3 pressure reading of 300 ±12 mmHg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Measured Value _____
<b>21. CO<sub>2</sub> tests</b>		<b>Pass</b>	<b>Fail</b>		<b>Comments</b>
a.	Confirm change in vacuum reading is less than 15 mmHg	<input type="checkbox"/>	<input type="checkbox"/>		_____
b.	Record CO <sub>2</sub> concentration reading is 5.0% ±0.82%	<input type="checkbox"/>	<input type="checkbox"/>		Measured Value _____
		<b>Yes</b>	<b>No</b>	<b>NA</b>	<b>Comments</b>
c.	Was a successful CO <sub>2</sub> Calibration performed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>22. NIBP tests</b>		<b>Pass</b>	<b>Fail</b>		<b>Comments</b>
a.	Confirm LEAKAGE TEST OK message	<input type="checkbox"/>	<input type="checkbox"/>		_____
b.	Confirm 50 mmHg readings agree within ±3 mmHg	<input type="checkbox"/>	<input type="checkbox"/>		_____
c.	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"/>		_____

23. 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**

24. 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"/>	_____
25. 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**

26. 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"/>	_____

<b>27. LIFEPAK 35 maintenance instruction</b>	<b>Completed</b>
a. Maintenance prompt disabled or reset	<input type="checkbox"/> _____

Comments: