

LIFEPAK® 12 Defibrillator/Monitor Series

Therapy Paddle Accessories



The following paragraphs provide current cleaning and sterilization guidelines for therapy paddle accessories compatible with the LIFEPAK 12 defibrillator/monitor series. *Please keep this guideline document with your LIFEPAK 12 operating instructions manual and in your sterilization department.* The therapy paddle accessories covered by this guideline are:

- Internal handles with discharge control (PN 3010901)
- Internal paddles (PN 805355)
- External sterilizable paddles (PN 3009166)
- Posterior paddle (PN 802461)
- Pediatric paddles (PN 800418)

Cleaning

After each use:

- Remove paddle(s) from handle(s), except for pediatric and external sterilizable paddles.
- Manually wipe or rinse paddles, handles, cables, and connectors with mild soap and water or disinfectant using damp sponge, towel, or brush. Do not immerse or soak (except for removable internal and posterior paddle electrodes).
- Dry thoroughly.
- Individually protect paddles before and after cleaning to prevent damage to paddle surfaces.
- Examine handles, cables, and connector for damage or signs of wear (that is, loose cable connections, damaged pins, exposed wires, and cable connector corrosion). Examine paddles for scratched, pitted, or chipped electrode surfaces and bubbled, scratched, or chipped epoxy coating. If any of these conditions are found, remove the affected component from use immediately.

Steam Sterilization (Internal Handles and Paddles Only)

Medtronic Physio-Control has tested and approved LIFEPAK 12 therapy paddle accessories: internal handles (PN 3010901) and internal paddles (PN 805355) for material compatibility and sterilization efficacy up to 200 cycles of steam sterilization, wrapped and unwrapped, using the following parameters.

	Prevacuum (Wrapped)	Gravity (Wrapped)	Flash Gravity (Unwrapped)
Sterilization Temperature	132°-135°C (270°-275°F)	132°-135°C (270°-275°F)	132°-135°C (270°-275°F)
Preconditioning Pulses	4 pulses	N/A	N/A
Prevacuum	10.0 inHg maximum	N/A	N/A
Pressure	30.5 psig maximum	30.5 psig maximum	30.5 psig maximum
Sterilization Exposure Time	4 minutes	30 minutes	12 minutes
Dry Time	Up to 30 minutes	Up to 30 minutes	Up to 30 minutes

The accessories were wrapped using sequential wrapping with single 26"x16" woven cotton first wrap (square wrapped) and 24"x24" nonwoven, bonded double thickness final wrap (envelope wrapped). Do not use peel packaging.

These sterilization parameters are valid only with equipment properly maintained and calibrated. Sterilization cycle times and efficacy vary depending on equipment, wrapping, and load configuration.

Internal handles must be positioned in the sterilizer to allow recessed paddle socket (lumen) area to drain.

Coil cables loosely away from handles during sterilization. Damage may occur if cables have tight bends or are wrapped around the handles. Individually protect internal paddles before and after sterilization to prevent damage to paddle surfaces.

The useful life of internal paddles is affected by the number of cycles rather than age. Paddle cycle life may be different between prevacuum sterilization and gravity displacement sterilization.

Ethylene Oxide Gas Sterilization (All Paddle Accessories)

Medtronic Physio-Control has tested and approved LIFEPAK 12 therapy paddle accessories: internal handles (PN 3010901), internal paddles (PN 805355), external sterilizable paddles (PN 3009166), posterior paddle (PN 802461), and pediatric paddles (PN 800418) for material compatibility and sterilization efficacy to 100 cycles of ethylene oxide gas sterilization, wrapped (peel package) using the following parameters.

	100% EO (Wrapped)	12/88% EO (Wrapped)
Temperature	55°C (131 ±5°F)	55°C (131 ±5°F)
Humidity	40-80% RH	50-60% RH
Sterilant Gas	100% ethylene oxide	12% ethylene oxide/88% Dichlorodifluoromethane
Concentration (ethylene oxide)	725 ±5% mg/L	600 ±5% mg/L
Sterilization Exposure Time	60 minutes	120 minutes
Aeration Time	11 hours (minimum) at 110-130°F	11 hours (minimum) at 110-130°F

STERRAD® Hydrogen Peroxide Gas Plasma Sterilization (All Paddle Accessories)

Medtronic Physio-Control has tested and approved all LIFEPAK 12 therapy paddle accessories: internal handles (PN 3010901), internal paddles (PN 805355), external sterilizable paddles (PN 3009166), posterior paddle (PN 802461), and pediatric paddles (PN 800418) for material compatibility and sterilization efficacy to 100 cycles of hydrogen peroxide gas plasma sterilization (STERRAD system), wrapped (STERRAD tray with double thickness SPUNGUARD® wrap or peel package) using the following parameters.

Vacuum Phase:	Chamber evacuation to 300 mTorr pressure. Duration: 5-20 minutes
Injection Phase:	Automatic injection of 1.8 ml aqueous H ₂ O ₂ solution and vaporization. Duration: 6-12 minutes
Diffusion Phase:	Diffusion of H ₂ O ₂ in chamber and throughout load. Duration: 42 minutes
Plasma Phase:	Low temperature gas plasma with 400W power at 500 mTorr pressure. Duration: 15 minutes
Vent Phase:	Chamber returned to atmospheric pressure.
Chamber Temperature:	Maintained at 45°C to 55°C (113°F to 131°F).
Total Cycle Time:	Approximately 75 minutes

The STERRAD System is an automated process with nonadjustable cycle parameters.



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