

STERILIZATION GUIDELINES



Medtronic
PHYSIO-CONTROL

LIFEPAK® 9 Defibrillator/Monitor

Therapy Paddle Accessories

The following paragraphs provide current sterilization guidelines for the therapy paddle accessories compatible with the LIFEPAK 9 defibrillator/monitor. Please keep this guideline document with your LIFEPAK 9 operating instructions manual and in your sterilization department. The therapy paddle accessories covered by this guideline are:

	Prevacuum (Wrapped)	Gravity (Wrapped)	Flash Gravity (Unwrapped)
Preconditioning Pulses	4 pulses	N/A	N/A
• Internal handles with discharge control (PN 805249)	10.0 inHg maximum	N/A	N/A
• Prevacuum	10.0 inHg maximum	N/A	N/A
• External sterilizable paddles (PN 804503)	30.5 psig maximum	30.5 psig maximum	30.5 psig maximum
• Posterior paddle (PN 802461)	4 minutes	30 minutes	12 minutes
• Internal handles without discharge control (PN 800441)	Up to 30 minutes	Up to 30 minutes	Up to 30 minutes
• Dry Time	Up to 30 minutes	Up to 30 minutes	Up to 30 minutes
• 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.
- between prevacuum sterilization and gravity displacement sterilization.

Ethylene Oxide Gas Sterilization (All Paddle Accessories)

Medtronic Physio-Control has tested and approved LIFEPAK 9 therapy paddle accessories: internal handles (PN 805249), internal paddles (PN 805355), external sterilizable paddles (PN 804507), posterior paddle (PN 802461), internal handles (PN 804441), internal paddles (PN 802154), 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 9 therapy paddle accessories: internal handles (PN 805249), internal paddles (PN 805355), external sterilizable paddles (PN 804507), posterior paddle (PN 802461), internal handles (PN 800441), internal paddles (PN 802154), 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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