



STERRAD® 100NX®

Installation Requirements and Product Specifications



STERRAD® 100NX® SYSTEM

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| MODEL | <p>The STERRAD® 100NX® System is the latest sterilizer that utilizes ASP proprietary hydrogen peroxide gas plasma technology to deliver enhanced versatility plus improved performance in a single system that meets growing surgical demands.</p> <p>The STERRAD® 100NX® System uses a combination of hydrogen peroxide vapor and low-temperature gas plasma to rapidly sterilize a wide variety of medical instruments and materials and reduce residuals. There are four cycles available on the STERRAD® 100NX® System. The STANDARD Cycle time is approximately 47 minutes, the FLEX Cycle time is approximately 42 minutes, and the EXPRESS Cycle time is approximately 24 minutes, and the DUO Cycle time is 60 minutes.</p> <p>The STERRAD® 100NX® System offers several unique features, including the ability to terminally sterilize flexible endoscopes, a fully integrated hydrogen peroxide monitor for direct measurement of chamber sterilant volume, network connectivity, self-diagnostics capability for optimizing system up-time, and a foot activated door(s) for hands-free operation.</p> |
| HYDROGEN PEROXIDE GAS PLASMA PROCESS | <p>The STERRAD® 100NX® System sterilization process is a multiphase sterilization process that utilizes a combination of exposure to hydrogen peroxide vapor and plasma to safely sterilize medical instruments and materials without leaving toxic residue. Hydrogen peroxide is an oxidizing agent that affects sterilization by oxidation of key cellular components. Plasma is a state of matter distinguishable from a solid, liquid, or gas. Gas plasmas are highly ionized gases, composed of ions, electrons, and neutral particles that produce a visible glow. Hydrogen peroxide is a bactericidal, virucidal, sporicidal, and fungicidal agent, even at low concentration and temperature. Applying a strong electrical field then creates plasma. The plasma breaks down the peroxide into a “cloud” of highly energized species that recombine, turning the hydrogen peroxide into water and oxygen.</p> |
| VOLTAGE/ FREQUENCY/POWER | <p>The phase rotation is adjusted to match the system requirements at installation.</p> <p>208V 60 Hz Power: For versions employing 208V, 60 Hz power, the sterilizer requires a NEMA L21-30 five wire grounding twist-lock outlet attached to a dedicated 30-amp, 3-phase, 208V circuit with separate neutral and ground conductors.</p> <p>380-415V 50 Hz Power 380V, 398V and 415V: The sterilizer requires a five-wire grounding outlet attached to a dedicated 30-amp, 3-phase, 380V circuit with separate neutral and ground conductors.</p> <p>200V 50-60 Hz Power: The sterilizer requires a four-wire Delta configuration to a dedicated 30-amp circuit.</p> |
| SERVICE REQUIREMENTS | <p>In operation, the STERRAD® 100NX® System should not be placed closer than 2 inches from the rear wall. The sterilizer should be installed in a space of sufficient size to permit access to all four sides of the system. Service access requires approximately 39 inches, but can be less, if the system can be moved for servicing. The power receptacle should be positioned 12 inches to 24 inches (30.5 to 61 cm) above the floor.</p> |

SYSTEM INFORMATION

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| WHERE MARKETED | Worldwide |
| FDA CLEARANCE | Yes |
| LIQUID CHEMICAL AGENT | Hydrogen Peroxide The STERRAD® 100NX® System Cassette fill volume is 5400 ± 216 µl and the concentration is 58.0–59.5% hydrogen peroxide. |
| AGENT DELIVERY SYSTEM | Cassette |
| CYCLE TEMPERATURE RANGE | 116.6°F–132.8°F (47°C–56°C) |
| IONIZED SPECIES | Hydrogen Peroxide |
| CYCLE TIME | STANDARD Cycle: 47 minutes FLEX Cycle: 42 minutes EXPRESS Cycle: 24 minutes DUO Cycle: 60 minutes |
| PRIMARY BYPRODUCTS | Water Vapor and Oxygen |
| BIOLOGICAL INDICATORS | Self-Contained Biological Indicator: Incubate for time specified on the STERRAD® CYCLESURE® 24 Biological Indicator IFU |
| CHEMICAL INDICATORS | Chemical indicator tapes, strips, and peel pouches |
| TYPES OF POUCHES/WRAPPS | Tyvek® / Mylar Pouches and Polypropylene CSR wrap |
| CONNECTORS | Network: RJ45; Barcode reader: USB Printer: USB |
| DATA STORAGE | PCMCIA nonstandard compact flash, USB memory stick |
| RF GENERATION | Portable and mobile RF communications equipment can affect medical electrical equipment |
| APPROVED DEVICES | Metal, non-metal, heat- and moisture-sensitive instruments, single-channel flexible endoscopes, semi-rigid ureteroscopes, and longer-lumened devices (see User’s Guide for more information) |

Please refer to the STERRAD® 100NX® System User’s Guide for more detailed processing instructions.

SPACE PLANNING INFORMATION

CHAMBER

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| Shape | Rectangular |
| Dimensions (WxDxH) | 20.1 in x 28.9 in x 16.1 in (51 cm x 73.5 cm x 41 cm) |
| Usable Volume | Single shelf: 82.3 liters, 2.9 ft ³ Double shelves: 79.6 liters, 2.8 ft ³ |
| Two-Tiered Shelf (WxD) | 17.3 in x 25.2 in (440 mm x 640 mm) |

INSTALLATION

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| Space Requirements: | Service access requires a minimum clearance of 24 inches (61 cm) above the top and 8 inches on each side of the system. The system should not be placed closer than 2 inches from the rear wall. |
| Mobility: | On wheels |
| Venting Requirements: | None required |
| Gas Tank Requirements: | None required |
| Electrical Requirements: | Unit ships with electric cord attached and includes plug: 12 AWG, 3 m (9.84 feet) long, 5 conductors 208V, 60 Hz Power: requires a NEMA L21-30 five-wire grounding twist-lock outlet attached to a dedicated 30-amp, 3-phase, 208V circuit with separate neutral and ground conductors. Each country is responsible for installing an appropriate 3-phase plug according to their facility's power requirements. The plug must match the phase rotation. |
| Ethernet Port (optional): | Should be installed near STERRAD® 100NX® System units that will be connected to servers or networks. |
| Dimensions: | (HxWxD) 70.5 in x 30.5 in x 40 in (179.1 cm x 77.5 cm x 102 cm) |
| Weight: | 910 lbs (414 kg) – single door, 962 lbs (436 kg) – double door |
| Seismic Bracing: | "L" Bracket included with the unit |

ENVIRONMENTAL CONDITIONS

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| Air Exchanges | Minimum 10/hour |
| Altitude & Pressure: | Operating altitude up to 10,152 ft (3095 m) Atmospheric pressure 520-775 torr |
| Operating Temperature: | 64°F–95°F (18°C–35°C) |
| Storage Temperature: | -20°F–158°F (-29°C–70°C) |
| Heat Generation: | IDLE: 0.07 kW (239 BTU/h). STANDARD Cycle: 2.4 kW (8189 BTU/h). FLEX Cycle: 1.6 kW (5460 BTU/h). EXPRESS and DUO cycles do not exceed the FLEX Cycle. |
| Relative Humidity: | Operating: 10%–85% up to 30°C, linearly decreasing from 85% at 30°C to 70% at 40°C non-condensing |
| Storage: | 10%–100% (rainfall will be permitted) |

WARRANTY

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| Term: | The STERRAD® System supplied by Advanced Sterilization Products (ASP) is warranted to be free from defects in materials and workmanship for a period of one (1) year from the date of installation, when properly installed, maintained and used for its intended purpose. This warranty applies only to the original purchaser of the equipment and only if the equipment is used in the country to which it was originally shipped by Advanced Sterilization Products. |
| Repairs/Service: | Manufacturer |
| Service Network: | Regional with regional supply depots |
| Response Time: | Monday through Friday, 7:00am to 7:00pm. (Response time is dependent on selected service plan.) |

ACCESSORIES/OPTIONAL FEATURES

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| Supports external printers: | The sterilizer has an integrated internal printer located in the front panel. On two-door units, a printer is located in the main panel on each side. The printer prints cycle reports and other information on a roll of thermal paper. The printer features easy, drop-in paper loading and requires no ink cartridges. The system is also designed to interface to an external printer that is USB compliant and supports PCL protocol. |
| Independent Monitoring System (IMS): | For compliance with ISO 14937. The Independent Monitoring System (IMS) is an optional feature that may be purchased and installed on the sterilizer. It is an independent data collection system that can be used for system validation or requalification. All of the sensors are independent from the system sensors and the data collected from the IMS is identified separately from the system's one-second data. (Product Code: 10140) |

