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Chapter 1.

Introduction

How to Use This Guide

If you are a STERRAD® 100NX™ Sterilizer operator, you must read the “Safety Information” and the “Introduction,” “Load Preparation,” and “Operation” chapters prior to operating the sterilizer. This “Introduction” explains the features and parts of the sterilizer. “Load Preparation” explains how to prepare and package instruments for processing. “Operation” explains how to operate the sterilizer and obtain optimal results.

If you are a supervisor overseeing the STERRAD 100NX Sterilizer, you should read the entire user’s guide and pay particular attention to the chapter featuring “Access Levels and Supervisor Level Tasks.” This chapter describes tasks and options that are only available through “Supervisor Level” access.

If You Have Questions

If you are located in the United States and have questions about the STERRAD 100NX Sterilizer or questions about which items may be safely sterilized by the STERRAD Process, please call our Customer Care Center at 1-888-STERRAD (1-888-783-7723). Internationally, call your local Advanced Sterilization Products (ASP) Customer Support Representative. You may also wish to visit our website at www.sterrad.com.
Chapter 2.

Safety Information

Your safety is of primary concern to Advanced Sterilization Products (ASP). This chapter provides information on safely using the STERRAD® 100NX™ Sterilizer. **You must read and understand the safety information in this chapter before operating the sterilizer.** Always pay attention to the warnings, cautions and notes throughout this user’s guide. This information is for your safety and to ensure that you receive the most benefit from the safe operation of your STERRAD 100NX Sterilization System.

**Personal Safety and First Aid**

**WARNING! HYDROGEN PEROXIDE IS CORROSIVE**

Concentrated hydrogen peroxide is corrosive to skin, eyes, nose, throat, lungs, and the gastrointestinal tract. Always wear latex, PVC (vinyl), or nitrile gloves while removing items from the sterilizer following a cancelled cycle. Following a cancelled cycle, if items in the load show any visible moisture or liquid, hydrogen peroxide may be present.

**WARNING! HYDROGEN PEROXIDE IS AN OXIDIZER**

Avoid allowing hydrogen peroxide to contact organic materials, including paper, cotton, wood, or lubricants. Concentrated hydrogen peroxide is a strong oxidizer and may react with organic materials, causing ignition and fire.

**WARNING! RISK OF EYE INJURY**

Direct hydrogen peroxide contact with eyes can cause irreversible tissue damage. If contact with eyes occurs, immediately flush with large amounts of water. Consult a physician immediately.
Safety Information

WARNING! RISK OF SKIN INJURY
Direct hydrogen peroxide contact with the skin can cause severe irritation. If skin contact occurs, immediately flush with large amounts of water. If symptoms are severe or persist, consult a physician immediately.

WARNING! RISK OF RESPIRATORY IRRITATION
Inhalation of hydrogen peroxide mist can cause severe irritation of lungs, throat, and nose. If inhalation occurs, move to fresh air. Consult a physician immediately.

WARNING! CONCENTRATED HYDROGEN PEROXIDE IS TOXIC
Ingestion of hydrogen peroxide may be life-threatening. If swallowed, drink plenty of water immediately to dilute. Do not induce vomiting. Consult a physician immediately.

WARNING! HOT STERILIZATION SURFACES
At the end of a cycle, the interior of the sterilizer may be hot. Do not touch the inside of the chamber or door with your bare or gloved hands. Allow the sterilizer to cool before touching interior surfaces.

CAUTION: AVOID EXPOSURE TO ULTRAVIOLET LIGHT
The hydrogen peroxide monitor uses an ultraviolet light source located inside the chamber behind the door. To avoid eye injury, do not stare directly at the ultraviolet light source for an extended period of time.

Personal Protective Equipment

CAUTION: HYDROGEN PEROXIDE MAY BE PRESENT
Wear latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.

Device Safety

WARNING! RISK OF INJURY OR DAMAGE TO STERILIZER
The STERRAD 100NX Sterilizer should not be used stacked with other equipment.

CAUTION: RISK OF DAMAGE TO LOAD
Metal objects must not come into contact with the chamber walls, the door, or the electrode. Contact with the walls, door, or electrode could damage the sterilizer or the metal objects.
WARNING! KNOW WHAT YOU CAN PROCESS
Before processing any item in the STERRAD 100NX Sterilizer, make sure you know how the STERRAD Sterilization Process will affect the item. Read, understand, and follow the medical device manufacturers’ instructions for their products. The fold-out chart in this guide lists the certain types of items and materials that can be safely processed in the sterilizer. This guide is not intended to replace any medical device manufacturers’ instructions. If you have questions, or if you are in doubt about the materials in your devices, contact the medical device manufacturer or your ASP Customer Representative for more information.

CAUTION: RISK OF VIOLATION OF WARRANTY
Improper processing may limit our liability for damage to processed instruments. Improper processing may also violate your instrument warranty.

CAUTION: RISK OF DAMAGE TO LOAD – METAL OBJECTS
Metal objects must not come into contact with the chamber walls, the doors, or the electrode. Contact with the walls, doors, or electrode could damage the sterilizer or the metal objects.

CAUTION: RISK OF DAMAGE TO LOAD – VENTING CAPS
Take special care to confirm that venting caps are placed according to the manufacturers instructions. Venting caps are intended to prevent damage to flexible scopes that are being exposed to a vacuum, regardless of the sterilant used.

CAUTION: RISK OF DAMAGE TO LOAD – IMMERSION CAPS
You must remove the water-resistant immersion cap (if present) prior to processing in the sterilizer. If the immersion cap is not removed prior to processing in the STERRAD 100NX Sterilizer, it will damage the flexible scope due to the inability to properly vent.

CAUTION: KNOW WHAT YOU CAN PROCESS – FLEXIBLE ENDOSCOPES
Prior to processing flexible endoscopes in the STERRAD 100NX Sterilizer, you must read, understand, and follow the medical device manufacturer's instructions for use for the particular scope to be processed. Please contact the medical device manufacturer for more information on what can be processed in the STERRAD 100NX Sterilizer.

CAUTION: RF COMMUNICATIONS EQUIPMENT
Portable and mobile RF communications equipment can affect medical electrical equipment.
Guidance And Declaration-Electromagnetic Emissions

The STERRAD® 100NX™ Sterilizer is intended for use in the electromagnetic environment specified below. Assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The STERRAD 100NX Sterilizer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class A</td>
<td>The STERRAD 100NX Sterilizer is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/flicker emissions IEC 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>

Warnings, Cautions, and Notes

Warnings and cautions are accompanied by symbols surrounded by a triangle or a square and are printed in the text in **bold**. Warnings indicate events or conditions that can result in serious injury or death. Cautions indicate events or conditions that can result in severe damage to the equipment.

✔ Notes are printed in italics and have a checkmark in front of the word “Note.” Notes highlight specific information about the proper use and maintenance of the STERRAD® 100NX™ Sterilization System.
Symbols Used on the Sterilizer and in This Guide

- Hot surfaces present. Do not touch without protection.
- Hazardous chemical present. Use personal protective equipment.
- Corrosive chemical present. Use personal protective equipment.
- Oxidizing chemical present. Avoid exposure, contact, or ingestion. Use personal protective equipment.
- WEEE Symbol
- Toxic chemical present. Avoid exposure, contact, or ingestion.
- Ultraviolet (UV) light hazard. Do not look at the light without UV eye protection.
- High voltage hazard.
- I/O On/Off.
- Alternating current.
Safety Information
Chapter 3.

Sterilizer Overview

Intended Use

The STERRAD® 100NX™ Sterilization System is a general purpose, low temperature sterilizer which uses the STERRAD 100NX Process to inactivate microorganisms on a broad range of medical devices and surgical instruments. This sterilizer offers an effective, safe, fast, economical, easy to use, reliable, and flexible sterilization method.

When used as directed by the instructions in this user’s guide, the STERRAD 100NX Sterilization System will sterilize both metal and nonmetal medical devices at low temperatures. Please review the “How to Determine What Can Be Sterilized in the STERRAD 100NX Sterilizer” chart in the “Load Preparation” chapter. This chart contains details on recommended materials and lumen sizes.

The STERRAD® 100NX™ Sterilization Process

As a medical professional, you may already be familiar with general sterilization principles. However, the STERRAD 100NX Sterilizer represents a new technology, and it requires special attention to the ways in which it differs from other sterilizers.
The STERRAD 100NX Sterilizer sterilizes medical devices by diffusing hydrogen peroxide vapor into the chamber and then electromagnetically exciting the hydrogen peroxide molecules into a low-temperature plasma state. The combined use of hydrogen peroxide vapor and plasma safely and rapidly sterilizes medical instruments and materials without leaving toxic residues. All stages of the sterilization cycle operate within a dry environment at a low temperature, and thus the cycle is not damaging to compatible instruments that are sensitive to heat and moisture.

The STERRAD 100NX Sterilizer can be used for both metal and nonmetal devices, and can also sterilize instruments that have difficult-to-reach (diffusion-restricted) spaces, such as hinges on forceps. Refer to the “Safety Information” chapter for more information.

The sterilizer consistently provides a Sterility Assurance Level (SAL) of 10^-6, as defined by U.S. Food and Drug Administration (FDA) and international standards, for clinical use on all allowed substrates within the limits of the claims for materials and geometries when used in accordance with the directions in this user’s guide.

Overview of the STERRAD® 100NX™ Sterilization Cycle

The STERRAD 100NX Sterilization Cycle consists of two phases: Exposure 1 and Exposure 2. The following information provides a brief description for each of the steps.

**Exposure 1**

- **Delivery 1**: The hydrogen peroxide is transferred via vacuum from the cassette into the vaporizer.
- **Vaporization Pumpdown 1**: The pressure within the chamber and vaporizer/condenser is reduced. Water is removed from the hydrogen peroxide solution, leaving behind a concentrated hydrogen peroxide solution in the condenser.
- **Chamber Pumpdown 1**: The chamber is isolated from the vaporizer/condenser. The chamber pressure is reduced to remove air from the lumens.
Transfer 1: The concentrated hydrogen peroxide solution is transferred to the chamber where it penetrates throughout the load.

Diffusion 1: Chamber pressure is increased in order to drive hydrogen peroxide through the load packaging onto the surfaces of the devices and into the lumens of the load.

Plasma Pumpdown 1 / Plasma 1: Plasma power is applied to the electrode screen and the plasma is lit.

Vent 1: The chamber is vented to atmospheric pressure.

Exposure 2
The steps in Exposure 1 are repeated.

The STERRAD® 100NX Sterilization Cycles

<table>
<thead>
<tr>
<th>Phase</th>
<th>Order</th>
<th>Stages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure 1</td>
<td>1</td>
<td>Delivery 1&lt;br&gt;Vaporization Pumpdown 1&lt;br&gt;Chamber Pumpdown 1&lt;br&gt;Transfer 1&lt;br&gt;Diffusion 1&lt;br&gt;Plasma Pumpdown 1 / Plasma 1&lt;br&gt;Vent 1</td>
</tr>
<tr>
<td>Exposure 2</td>
<td>2</td>
<td>Delivery 2&lt;br&gt;Vaporization Pumpdown 2&lt;br&gt;Chamber Pumpdown 2&lt;br&gt;Transfer 2&lt;br&gt;Diffusion 2&lt;br&gt;Plasma Pumpdown 2 / Plasma 2&lt;br&gt;Vent 2</td>
</tr>
</tbody>
</table>
The STERRAD® 100NX™ Sterilizer and Features

The cassette slot, the cassette drawer, the touch screen, PCMCIA slot (inside the access panel), the chamber door, the printer, and the foot pad are found on the input side of the sterilizer (the front of single-door units). On a two door unit the touch screen, chamber door, foot pad and printer are found on both the input and output sides. The main power switch is located on the left (your left) front side of the sterilizer. The I/O interface is located on the right (your right) front side of the sterilizer. See the sections on Data Transfer and Rebooting the System for locations of the power switch and USB port.

- The sterilizer is operated by using the touch screen to begin a cycle, enter load information, monitor the cycle and perform diagnostics.
- A cassette is inserted into the sterilizer through the cassette slot. The cassette will sterilize 5 loads.

![Figure 1. The STERRAD® 100NX™ Sterilizer. Not shown: The power switch is at the left and the USB port is at the right.](image)
The items to be sterilized are placed on the shelves and the door is closed using either the close door button on the touch screen or by tapping the foot pad with your foot. The foot pad is located on the lower portion of the front panel.

Load information and cycle notes are entered if desired, a cycle is selected and the chosen cycle is then started. Depending on your choice of cycle, the cycle duration is from about 42 minutes to about 47 minutes. At the conclusion of the cycle the items are removed and are ready for storage or immediate use.

If the system is equipped with 2 doors, the load is inserted from the input side and removed from the output side. On 2 door units, the touch screen and door can be used only from the active side; both doors cannot be opened at the same time.

Cassette

The cassette contains sealed capsules of hydrogen peroxide solution. Each cassette contains enough sterilant for five cycles. Each cassette has an identity device that is read by a scanner and provides details on the cassette expiration date, manufacturer, cell status and cycle completion information for each cell. The sterilizer pulls the cassette through the slot and moves it into the machine, keeping it there until the cassette has been used.

WARNING! HYDROGEN PEROXIDE IS CORROSIVE.

Concentrated hydrogen peroxide is corrosive to skin, eyes, nose, throat, lungs, and the gastrointestinal tract. Always wear latex, PVC (vinyl), or nitrile gloves while removing items from the sterilizer following a cancelled cycle. Following a cancelled cycle, if items in the load show any visible moisture or liquid, hydrogen peroxide may be present.
Cassette Disposal Box

After processing of the cassette, the sterilizer automatically discards it into the cassette disposal box. The cassette disposal box holds 2 used cassettes. When the box has the maximum number of cassettes, the sterilizer displays a message indicating that the box must be replaced. The cassette disposal box must be closed to permit safe disposal of cassettes. Refer to the “Maintenance” chapter for additional information.

Figure 3. Cassette Disposal Box.

Touch Screen and Speaker

The sterilizer displays information and accepts commands through a 10.4 inch LCD color touch screen display. By touching buttons displayed on the screen, you can enter letters and numbers, make selections, and start and stop the sterilizer.
Figure 4. Using the Touch Screen.

An internal loudspeaker emits “beep” tones to call for user attention or indicate errors. A single long beep indicates a successfully completed cycle. A series of ten short beeps indicates a canceled cycle.

Chamber

The load is placed in the chamber for sterilization. The chamber walls and doors contain heaters that keep the chamber interior warm during operation. When the chamber door(s) are closed, a vacuum-tight seal is created, allowing the chamber atmosphere to be evacuated during operation.

Figure 5. The STERRAD® 100NX™ Chamber Empty and With a Full Load Correctly Placed.

The chamber contains 2 slide-out shelves to permit efficient loading. Inside the chamber, surrounding the shelves is a metal screen (the electrode) that helps generate plasma during operation.
Printer

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 a second, external printer that is USB compliant and supports PCL protocol.)

- The handle is squeezed and the door is pulled toward you to open the printer door for printer replacement.
- The top button advances the paper.

Figure 6. STERRAD® 100NX™ Printer Paper Advance Button.
**Touch Screen Data Entry**

The following figure shows a typical data entry screen. The typewriter “keys” input the indicated character each time a key is touched. Touch the screen to move the cursor from place to place. The load list can be predefined and used repeatedly.

![Figure 7. Example of a Data Entry Screen.](image-url)
Function Buttons

Most screens provide function buttons that display other screens or select sterilizer functions. Common function buttons are shown in the following table.

<table>
<thead>
<tr>
<th>Button</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Checkmark]</td>
<td><strong>Done.</strong> Touch this button to indicate that you are finished using the screen.</td>
</tr>
<tr>
<td>![Arrow Left]</td>
<td><strong>Back.</strong> Touch this button to return to a prior screen.</td>
</tr>
<tr>
<td>![Image]</td>
<td><strong>View.</strong> Touch this button to view the selected report or file.</td>
</tr>
<tr>
<td>![Document]</td>
<td><strong>Print.</strong> Touch this button to print the selected report or file.</td>
</tr>
<tr>
<td>![Red Circle]</td>
<td><strong>Cancel.</strong> Touch this button to cancel the entry you just made.</td>
</tr>
</tbody>
</table>
Chapter 4.

Load Preparation

The STERRAD® 100NX™ Sterilizer is designed for sterilization of both metal and nonmetal medical devices at low temperatures. The STERRAD sterilization process is a multiphase sterilization process that utilizes a combination of exposure to hydrogen peroxide vapor and plasma to affect sterilization. Because the cycle operates within a dry environment and at low temperatures, it is especially suitable for instruments sensitive to heat and moisture.

**CAUTION: KNOW WHAT YOU CAN PROCESS**

Before processing items in the sterilizer, make sure you know how the STERRAD Sterilization Process will affect the item. If you have questions, or if you are in doubt about the materials in your devices, contact the medical device manufacturer or your ASP Customer Representative for more information.

**CAUTION: RISK OF VIOLATION OF WARRANTY**

Improper processing may limit our liability for damage to processed instruments. Improper processing may also violate your instrument warranty.

The STERRAD 100NX Sterilizer can sterilize instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.

Medical devices with the following materials and dimensions can be processed in the STERRAD 100NX Sterilizer **Standard cycle:**

**Single channel stainless steel lumens with**

- an inside diameter of 0.7 mm or larger and a length of 500 mm or shorter.†

†The validation testing for this lumen size was conducted using a maximum of 10 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing.
Medical devices, including most flexible endoscopes, with the following materials and dimensions can be processed in the STERRAD 100NX Sterilizer **Flex cycle:**

**Single channel polyethylene and Teflon® (polytetrafluoroethylene) flexible endoscope with**

- an inside diameter of 1 mm or larger and length of 850 mm or shorter.**

**Processing Tubing**

ASP has validated the processing of non-reusable polyethylene and Teflon® (polytetrafluoroethylene) medical grade tubing with the dimension and cycles listed below. (These tubing claims have not been reviewed by the Food and Drug Administration (FDA) as the FDA does not classify tubing as medical devices):

- An inside diameter of 1 mm or larger and a length of 1000 mm or shorter can be processed in the STERRAD 100NX Sterilizer **Standard cycle.**

**Recommended Materials and Lumen Chart**

**CAUTION: RISK OF DAMAGE TO LOAD OR STERILIZER.**

Do not attempt to sterilize items or materials that do not comply with the guidelines specified in this user’s guide. Consult the medical device manufacturer’s instructions or call the ASP Customer Care Center to determine if an item can be sterilized by the STERRAD 100NX Sterilization System.

This chapter includes a chart that unfolds to show you detailed lists of recommended items, materials, and some typical devices that can be sterilized in the STERRAD 100NX Sterilizer. Please refer to it whenever you need materials information.

Check the medical device manufacturer’s instructions before loading any item into the STERRAD 100NX Sterilizer.

**One or two flexible endoscopes can be processed per sterilization cycle. No additional load.**

**Sterilize without any additional load. Up to 20 pieces of tubing may be sterilized at one time.**
How To Determine What Can Be Sterilized In The STERRAD 100NX™ Sterilizer

Is The Reprocessable Medical Device Made Of The Following Materials?

- Aluminum
- Brass
- Polyacetal (Delrin acetal resin)
- Ethylvinyl acetate (EVA)
- Glass
- Liquid Crystal Polymer (LCP)
- Polyamide (Nylon)
- Polycarbonate
- Polyethylene
- Polyetheretherketone (PEEK)
- Polyetherimide (ULTEM Polymers)
- Polymethyl methacrylate (PMMA)
- Polymethylpentene (PMP)
- Polystyrene
- Polyurethane
- Polytetrafluoroethylene (Teflon)
- Polytetrafluoroethylene
- Polyvinyl chloride (PVC)
- Silicone elastomers
- Stainless steel
- Titanium

Does The Reprocessable Medical Device Have A Lumen?

If the lumens do not conform to these dimensions, U.S.A. customers please call the medical device manufacturer. International customers please call your local ASP representative for information on how to properly sterilize these devices. Lumen not conforming to these dimensions should not be processed in the STERRAD 100NX Sterilizer.

Inside Lumen Diameters

- 0.7 mm, 0.027 in, 2 Fr
- 1 mm, 0.039 in, 3 Fr
- 2 mm, 0.078 in, 6 Fr
- 3 mm, 0.118 in, 9 Fr
- 4 mm, 0.157 in, 12 Fr
- 5 mm, 0.196 in, 16 Fr
- 6 mm, 0.236 in, 18 Fr

Inside Diameter Cycle Selection Length

- Single Channel Stainless Steel Lumen
  - 0.7 mm or larger 500 mm or shorter
  - 1 mm or larger 1000 mm or shorter

- Single Channel Teflon / Polyethylene Lumens
  - 1 mm or larger 1000 mm or shorter

* The validation testing for this lumen size was conducted using a maximum of 10 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing.

Special Instructions

- Sterilize without any additional load. Up to 20 pieces of tubing may be sterilized at one time.
- One or two flexible endoscope can be processed per cycle with or without a silicone mat.
- No additional load. It is important to follow the medical device manufacturer's instructions for use prior to processing any scope in the STERRAD 100NX Sterilizer.

No/Don't Know

Yes

Proceed with Processing.
**Processing Polyethylene and Teflon® Lumens and Tubing In The STERRAD® 100NX™ Sterilizer®**

<table>
<thead>
<tr>
<th>Inside Diameter (ID)</th>
<th>Length</th>
<th>Can Be Processed in the STERRAD 100NX Standard Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.7 mm</td>
<td>1000 mm</td>
<td><strong>Cannot be processed</strong></td>
</tr>
<tr>
<td>1.0 mm</td>
<td></td>
<td><strong>Cannot be processed</strong></td>
</tr>
<tr>
<td>1.1 mm</td>
<td></td>
<td><strong>Cannot be processed</strong></td>
</tr>
<tr>
<td>1.2 mm</td>
<td></td>
<td><strong>Cannot be processed</strong></td>
</tr>
<tr>
<td>1.3 mm</td>
<td></td>
<td><strong>Cannot be processed</strong></td>
</tr>
<tr>
<td>1.4 mm</td>
<td></td>
<td><strong>Cannot be processed</strong></td>
</tr>
<tr>
<td>1.5 mm</td>
<td></td>
<td><strong>Cannot be processed</strong></td>
</tr>
<tr>
<td>1.6 mm</td>
<td></td>
<td><strong>Cannot be processed</strong></td>
</tr>
<tr>
<td>1.7 mm</td>
<td></td>
<td><strong>Cannot be processed</strong></td>
</tr>
<tr>
<td>1.8 mm</td>
<td></td>
<td><strong>Cannot be processed</strong></td>
</tr>
<tr>
<td>1.9 mm</td>
<td></td>
<td><strong>Cannot be processed</strong></td>
</tr>
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<td>2.0 mm</td>
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**WARNING:** This is a controlled proprietary and confidential document. Verify revision is current prior to use.

*These tubing claims have not been reviewed by the Food and Drug Administration.*
There are a wide variety of materials and devices that can be sterilized in the STERRAD 100NX Sterilizer. As more manufacturers complete testing of their products with the STERRAD 100NX Sterilizer, the list of compatible items continues to expand. Information in the chart included in this publication is updated as new information becomes available. ASP maintains this updated information and we are happy to share it with you. Please contact the ASP Customer Care Center for an up-to-date list of recommended materials, devices, and/or device manufacturer information. Information may also be obtained from the device manufacturer. In the U.S.A., call 1-888-783-7723, internationally call your local ASP Customer Care Representative or contact us through our website – www.sterrad.com.

**Items Not To Be Processed**

- Single use items for which the manufacturer does not recommend resterilization.
- Liquids and powders.
- Items or materials that absorb liquids.
- Items made of materials that contain cellulose, such as cotton, paper or cardboard, linens, huck towels, gauze sponges, or any item containing wood pulp.
- Paper instrument count sheets or lot stickers.
- Items with mated Nylon® surfaces.
- Instruments and devices that cannot withstand a vacuum and are labeled for gravity steam sterilization methods only.
- Items whose design permits the surfaces to collapse onto each other unless some method is used to keep the surfaces separated.
- Dead-end lumens must not be processed.
- Devices with internal parts, such as sealed bearings, that cannot be immersed, may present difficulties in cleaning and should not be processed in the STERRAD 100NX Sterilizer.
- Instrument mats other than STERRAD Instrument Mats.
- Instrument trays other than STERRAD Instrument Trays or APTIMAX® Instrument Trays.
- Implants for which the manufacturer has not specifically recommended sterilization in the STERRAD® 100NX™ Sterilizer.
Guidelines for Preparing Items to Be Sterilized

✅ **Note:** All items must be cleaned, rinsed, and thoroughly dried before being placed in the STERRAD 100NX Sterilizer. Loads containing moisture may cause cycle cancellations.

Cleaning, Rinsing, and Drying

Cleaning and sterilization are two separate processes. Proper cleaning of instruments and devices is a critical and necessary step prior to sterilization.

- All items must be thoroughly cleaned, rinsed, and dried before loading into the sterilizer.
- Carefully inspect all instruments and devices for cleanliness and dryness and for flaws or damage prior to packaging. If visible soil or moisture is present, the item must be re-cleaned and dried prior to sterilization.
- Devices and instruments with flaws or damage should be replaced or repaired before using.
The process of cleaning is necessary to remove organic and inorganic soil and debris from equipment. This process also removes many microorganisms from the surface of the items. The process of sterilization then inactivates all remaining spores and live microorganisms.

- Remove all blood, tissue, and soil from items by following the device manufacturer’s instructions using an appropriate detergent or cleanser.
- Rinse items thoroughly to remove detergent or cleanser residue.
- **Dry all items thoroughly.** An acceptable method for drying is to blow compressed air through the lumen until no moisture exits the distal end of the device. Please ensure that any method used to dry the devices is in accordance with the manufacturer’s instructions for use or contact the device manufacturer to obtain appropriate and safe procedures. It is necessary to remove moisture from all parts of the items. **Only dry items should be loaded into the sterilization chamber to prevent cycle cancellation.**
- Some complex reusable medical devices may require disassembly for proper cleaning and sterilization. It is very important that you follow the device manufacturers recommendations concerning cleaning and sterilization.

**WARNING! POSSIBLE NON-STERILE DEVICE**

*Loads containing moisture may result in either a non-sterile device or cycle cancellation.* Wear gloves when handling items from any load containing moisture.

✔ **Note:** Periodic careful inspection of items after repeated exposure to disinfectant/cleaner/sterilant is necessary, due to the potential damaging effects of the chemical agent on the items.
Packaging and Loading

If you choose to package the instruments (highly recommended), proper preparation of trays, pouches, and instruments can minimize or prevent cycle cancellations and positive biological indicator (BI) results due to load-related problems. All instruments must be cleaned, rinsed, and thoroughly dried before loading into the sterilizer.

In addition, special considerations for loading and processing flexible endoscopes are presented at the end of this chapter.

Instrument Trays

- Only STERRAD Instrument Trays, APTIMAX® Instrument Trays, and STERRAD accessories are recommended for use in the STERRAD 100NX Sterilizer. These instrument trays are specially designed to allow diffusion of hydrogen peroxide and plasma around every item in the load.

Tray Mats

- Instrument trays should only be padded with STERRAD Instrument Mats or polypropylene sterilization wrap. Never use linen, cellulose, or any materials listed in the “Items Not To Be Processed” section.
- Follow the Instructions for Use included with the STERRAD Instrument Mats to determine the number of mats that can be used at one time in the chamber. Do not use more than 174 square inches (1123 sq. cm) of mat material in the chamber at any time.
- Do not use foam pads in instrument trays as they may absorb the hydrogen peroxide.

Packaging

- Use only STERRAD Sterilizer-compatible polypropylene sterilization wrap and Tyvek® pouches.
- Do not use paper pouches or sterilization wraps containing cellulose or cotton.
- Do not use any wraps or packaging that are not approved by ASP or materials listed in the “Items Not To Be Processed” section.
- Properly arrange the items or the scope in a tray to ensure adequate diffusion of hydrogen peroxide throughout the load.
Load Preparation

- Place peel pouches on edge, if possible. Arrange them so that the transparent side of a pouch faces the opaque side of the next pouch. Do not stack pouches on top of each other.

- Do not stack instruments inside the trays. Do not stack trays. Do not stack trays within trays. Do not wrap instruments within a wrapped tray.

- If you are using rigid containers cleared by the FDA for use in the STERRAD 100NX Sterilizer, follow the same procedures that are recommended for use with the STERRAD Instrument Trays or APTIMAX® Instrument Trays. Do not stack instruments inside the containers. Do not stack containers. Do not stack containers within containers. Do not wrap instruments within the containers.

- Place STERRAD Chemical Indicator Strips inside trays and pouches as needed.

Loading

- Do not allow any item to touch the walls of the sterilization chamber, door, or electrode.

CAUTION: RISK OF DAMAGE TO LOAD OR STERILIZER.

Do not allow metal objects to come into contact with the walls of the chamber, door, or electrode. Contact with the walls, door, or electrode can cause a cycle cancellation, and/or damage the item or the sterilizer. Provide at least 1 inch (25 mm) of space between the load and the electrode.

Chemical Indicators

STERRAD Chemical Indicator Strips and STERRAD® SealSure® Chemical Indicator Tape offer a method to verify that the load has been exposed to hydrogen peroxide in the sterilizer. Chemical indicators are not a substitute for biological indicators.

If you use chemical indicator strips or chemical indicator tape, follow the Instructions for Use that accompany these items as you prepare the load.

- Place STERRAD Chemical Indicator Strips inside trays and Tyvek® pouches.

- Secure all wraps with STERRAD SealSure Chemical Indicator Tape.

- Do not use chemical indicators designed for other sterilization processes.
Special Considerations for Flexible Endoscopes

Flexible endoscopes are sensitive and complex medical instruments. Read the flexible endoscope manufacturer’s instructions for each endoscope before preparation and loading into the STERRAD 100NX Sterilizer. Take special care to confirm that venting caps are placed according to the manufacturers’ instructions. Venting caps are intended to prevent damage to scopes that are being exposed to a vacuum, regardless of the sterilant used.

In addition, if you are processing a flexible endoscope containing a water-resistant “immersion” cap in the sterilizer, you must remove the immersion cap prior to processing. If the immersion cap is not removed prior to processing in the STERRAD 100NX Sterilizer, it will damage the scope due to the inability to properly vent.

One or two flexible endoscope, with or without a silicone mat, can be processed per cycle. Do not add any additional items to the load.

CAUTION: RISK OF DAMAGE TO LOAD

Prior to processing flexible endoscopes in the STERRAD 100NX Sterilizer, please contact the medical device manufacturer, or the ASP Customer Care Center at 1-888-STERRAD, to ensure compatibility.
Chapter 5.

Operation

Before You Start

Each time you use the STERRAD® 100NX™ Sterilizer, follow the instructions provided in “Chapter 4, Load Preparation.” It is your responsibility to be familiar with the load preparation and safety information provided in this user’s guide.

Start and Warm-up

1. Turn on the main power switch located on left front side panel (as you face it) of the sterilizer.
2. The sterilizer begins by warming up. The warm-up can take up to 1 hour.

   ✔ Note: The sterilizer should not be turned off during warm-up.

3. “Touch Screen to Start” appears on the display when the sterilizer is ready for use.

Preparing the Load

While the sterilizer is warming up, you can use this time to prepare the load. Refer to the chapter detailing load preparation information.
Biological Indicators

Confirming that sterilizing conditions were achieved during a cycle is an important part of the sterilization process. Biological indicators are one way to ensure that your sterilizer is operating correctly. ASP recommends using the STERRAD® CycleSure® Biological Indicator. Contact your ASP Representative regarding biological indicators specifically designed for use in the STERRAD 100NX Sterilizer.

Place a STERRAD CycleSure® Biological Indicator in the chamber at the back of the bottom shelf. Biological testing should be performed at least once per day or as specified by your facility’s policy. Review the Instructions For Use included with the biological indicator to ensure its proper use.

Login

✔ Note: If your sterilizer has been configured not to require operator login, the login screen will not appear. Skip to the subsection titled Entering Load Information.

When you touch the “Touch Screen to Start” screen, the sterilizer displays the Operator Login screen.

![Operator Login Screen]

1 Touch the Operator field. The cursor appears in the field.

✔ Note: Operator and Password fields are case-sensitive.
2 Use the on-screen keyboard to type your assigned operator identification.
3 Touch the ENTER key. The cursor jumps to the Password field.
4 Type your password. The screen displays a series of "*" characters in place of the characters you type. This is done to keep others from reading your password.
5 When you have finished entering your password, touch the ENTER key.

**Entering Load Information**

✔ **Note:** If your sterilizer has been configured not to require load item data, this screen will not appear. Skip to the subsection titled Cycle Notes.

**Enter Load Item Data**

The Load Item Data screen allows you to enter information about the contents of the load. This can be done for tracking and traceability or may be useful for inventory purposes.

Items can be typed into the screen or selected from a predefined list of items. This information is stored and printed on a cycle report. It can also be transferred to a host computer over a network connection.

![Figure 9. Enter Load Item Data.](image)
1 To enter items not in the database, type the item information in the “Enter Items Here” field. Touch ENTER to accept the item. Repeat for additional items always touching ENTER after each item. Touch Done when the list is complete.

A barcode scanner can be used to enter load item data instead of entering them using the keyboard. Refer to the barcode scanner Instructions for Use if your sterilizer is equipped with this option.

**Select From List**

If a database has been established containing frequently used load information, you can select that information using the following steps:

1 Touch Select From List.
2 Scroll up or down the load item menu list to the desired item.
3 Touch the items you wish to add to your current list and touch Select.
4 Touch Done to complete the list.
5 Touch Keyboard to return to the keyboard entry fields or to use a barcode scanner.

**Cycle Notes**

✔ **Note:** If your sterilizer has been configured not to require cycle notes, this screen will not appear.

The Cycle Notes screen allows you to enter information about the cycle. For example; record information about biological indicators used in the cycle or other information that should be stored in the cycle history file. This information is printed on the cycle report, and can be transferred to a host computer over a network connection.
1 Touch the **Enter Notes for Cycle** field. The cursor appears in the field.

2 Use the on-screen keyboard to type your notes.

3 When data entry is complete, touch the **Done** button.

4 If conditions exist which prevent a sterilization cycle from starting; e.g., no cassette, hydrogen peroxide monitor is blocked, etc., a message is displayed on the screen.

5 The program displays the **System Ready** screen.

6 Touch **Back** to return to the previous screen.

---

**Figure 10. Cycle Notes.**

---

**Loading the Chamber**

✔ **Note:** The door is equipped with a safety mechanism that prevents it from closing if it encounters an obstruction. If this occurs, the door stops immediately. Open the door using the touch screen or foot pad.
1. Open the active chamber door by pressing the Open Door foot pad, or by touching **Open Door** on the display, and place your load on the shelves.

![Image of the foot pad being pressed](image1.png)

**Figure 11. Touch the Foot Pad to Open the door.**

✔ **Note:** If necessary, the top shelf can be removed to accommodate a large load placed on the bottom shelf.

![Image of the UV lamp and shelves](image2.png)

**Figure 12. Do Not Block the UV Lamp.**
2 When placing the load on the shelves, make certain that you do not block the ultraviolet lamp beam in the front right (your right) side of the chamber. Make sure the load is centered on the shelves and that the shelves are centered in the chamber.

![Figure 13. The Load Should NOT Touch the Electrode.](image1)

3 Do not allow any part of the load to touch the electrode, the back wall of the chamber, or the inside of the door.

4 Leave at least 1 inch (25 mm) of free space between the load and the electrode to allow hydrogen peroxide to diffuse around the load.

![Figure 14. Do NOT Stack Trays.](image2)
5 When you are finished loading the chamber, close the door by tapping the foot pad or pressing the **Close Door** button on the touch screen.

6 If a message requesting that the door be closed is displayed, the door is not securely closed. Make certain that nothing is caught in the door seal.

## Selecting and Starting a Cycle

When the load has been placed in the chamber, and the door has been closed, use the System Ready screen to start the cycle.

![System Ready screen](image)
The screen displays the message “Please Insert New Cassette” if a new cassette is required, if the cassette in the sterilizer is expired, or if there is no cassette installed in the sterilizer. Follow the instructions in the next section to insert a new cassette.

If the sterilizer is loaded with an unexpired cassette, touch your cycle choice, either STANDARD or FLEX, confirm to start the cycle; the cycle starts.

**System Ready Screen**

The System Ready screen displays a number of buttons allowing you to select various sterilizer functions:

- **Standard** cycle sterilizes the load in about 47 minutes.
- **Flex** cycle is specifically designed for flexible endoscopes and sterilizes the load in about 42 minutes.
- **Logout** is used when the current operator is finished using the sterilizer and the option is enabled. When Logout is selected, you must re-login to use the sterilizer.
- **Cycle History** displays the Select Cycle History screen. This screen allows you to select a cycle history file and view or print it.
- **Utilities** are available only to operators with Supervisor-level access. It displays the Additional Utilities Menu.
- **Door Open** opens the active door.
- **Door Close** closes the active door.

**Inserting a Cassette**

1. Take a new STERRAD 100NX Cassette out of the shipping carton.
2. Look at the package carefully before opening it. The indicator strip should be white. **If the indicator strip is red, or if you see droplets of moisture, do not open the package** – it is possible that hydrogen peroxide has leaked inside the package. Refer to the cassette Instructions for Use for proper handling instructions.
3. If the indicator strip is white, open the cassette package.
4. Position the cassette so that the arrows are pointing towards the sterilizer.
5. Insert the cassette into the cassette slot until it stops moving. **Do not use force** to push the cassette into the machine.
6 After a slight pause, the sterilizer pulls the cassette through the slot and the slot door closes. Cassette loading is now complete.

**Cycle in Progress**

When you touch the **Start Cycle** button (after selecting the cycle type), the sterilizer starts a “countdown clock” and begins the sterilization cycle.

![Figure 18. Cycle In Progress. The Countdown Clock is Displayed.](image)
The clock displays the estimated number of minutes and seconds remaining before the cycle is finished. The “Time Remaining” field updates as the sterilization cycle progresses. As each sterilization cycle stage runs, the screen displays the name of the stage. A moving bar graph also displays the percent of the cycle that is complete. For details about the current stage information, refer to the printouts in Chapter 7.

## Canceling a Cycle

There may be occasions when it is necessary to cancel a cycle before it is completed.

To cancel a cycle, do the following:

1. Touch the **Cancel Cycle** button. The screen displays a confirmation message.

![Figure 19. Cancel Cycle Confirmation. Touch Yes or No.](image)

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**WARNING:** This is a controlled proprietary and confidential document. Verify revision is current prior to use.
2  Touch the No button to continue with the cycle. Touch the Yes button to cancel the cycle. Once the cycle cancellation sequence begins, the screen turns red and the cancellation sequence cannot be interrupted. The cancellation sequence may take up to ten minutes to complete.

![Cycle In Progress](image)

**Figure 20. Cycle Cancellation In Progress. Cancellation Has Been Confirmed.**

Loads from canceled cycles should be rewrapped using new packaging materials, STERRAD® Chemical Indicator Strips, and STERRAD® SealSure® Chemical Indicator Tape. If a biological indicator was used in the canceled load, the previously used biological indicator must be discarded and a new biological indicator must be placed in the chamber before restarting the new cycle.

**WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.**

*If a cycle cancels and the items in the load appear wet, hydrogen peroxide may be present. Wear latex, PVC (vinyl), or nitrile gloves while removing the items from the chamber, and while wiping off the items with a damp cloth.*
Cycle Completed

When the cycle is complete, the Cycle Completed screen is displayed. The background of the screen is green to indicate a successfully completed cycle. The loudspeaker emits one long beep to indicate successful cycle completion.

![Cycle Completed Screen](image)

**Figure 21. Successful Cycle Completed.**

1. Touch the **View Details** button to display the cycle history file for the just-completed cycle.
2. Touch the **Done** button to proceed.
Processing a Sterilized Load

When you touch the **Done** button, how the sterilizer responds depends upon the configuration of your sterilizer.

- If login is required before the door can be opened, the Login screen is displayed. When this occurs, enter your operator identification and password and touch **Enter**. The door opens and the load can be removed. The operator’s name appears on the printout acknowledging the completion of the cycle.
- If no login is required for load removal, the door opens and the load can be removed.
- Refer to the cycle completion flowcharts for additional information.

Inspecting Chemical Indicators

After ensuring that the chemical indicators exhibit the correct color change, and the cycle printout shows that all the necessary cycle parameters were met, the sterilized load is ready for immediate use, following your facility’s policy. If the chemical indicators do not exhibit the correct color change, investigate the cause, repackage, and then reprocess the load.

Processing Biological Indicators

Remove the biological indicator from the load and process it per its **Instructions for Use**. Refer to the flow charts on the following pages for additional information.
Cycle Completion Flowchart

1. Steralization cycle completed.
2. Review printout.
3. Printout shows process complete.
   - Review Chemical Indicators from Load.
   - Chemical indicators show appropriate color change.
     - Are biological indicator results required by your facility prior to releasing load?
       - YES: Review BI flowchart.
       - NO: Release the load according to your site’s policy.
   - Chemical indicators do not show appropriate color change.
     - Reject cycle and resterilize all items.
4. Cancellation message shows parameters were not met.
   - Reject cycle and resterilize all items.
STERRAD® CycleSure® Biological Indicator Flowchart

CycleSure BI

- No color change (media remains purple) or turbidity.
  - Sterilization conditions have been achieved.

- Color change (purple to yellow) and/or turbidity as in the positive control BI.
  - Sterilization conditions have NOT been achieved.

  Follow facility policy for instrument recall/ quarantine.

  Test sterilizer with another CycleSure BI (No. 2).

  - No color change or turbidity.
    - Run another CycleSure BI as confirmation (No. 3).
      - Negative?
        - No color change or turbidity.
          - Sterilizer has not failed.
          - User error. Review procedures.
      - Positive?
        - Color change and/or turbidity.
          - International: Call your local ASP Representative. USA: Call ASP Clinical Support, 1-800-STERRAD. For information visit www.sterrad.com

  - Color change and/or turbidity.
    - International: Call your local ASP Representative. USA: Call ASP Clinical Support, 1-800-STERRAD. For information visit www.sterrad.com
Overview

Users with Supervisor-level access privileges (see below) are permitted to perform a set of restricted sterilizer functions. These functions are not used in daily sterilizer operation and some of them are designed to control access, manage system records, and perform advanced diagnostic functions.

Access Levels

The STERRAD® 100NX™ Sterilizer can be configured to require that all users enter a valid operator identification and password before operating the sterilizer. This access control is enabled through the System Configuration screen and user identifications, passwords, and access levels are assigned and maintained through the User Administration screens.

There are three levels of access available. Each is associated with a different subset of permitted operations.

**Operator-level access** is designed to permit a user to perform tasks associated with the daily operation of the sterilizer. These privileges allow a user to:

- Select, start, and cancel a cycle.
- Enter load item information and cycle notes.
- Print a cycle history report and view cycle history files.
- Run diagnostics when a cycle cancels.
**Supervisor-level access** includes all of the privileges of Operator-level access and additionally provides the ability to:

- Add, delete, and modify user names, passwords, and access levels.
- Select, view, and print all sterilizer files.
- Run diagnostic tests and print reports.
- Set date and time.
- Configure sterilizer options.
- Configure the network connection and upload data to the network.

**Service-level access** is only for use by ASP Service Representatives.

### Additional Utilities Menu

The Additional Utilities Menu is available only to users with Supervisor- or Service-level access privileges. If a user with Operator-level privileges touches an **Additional Utilities** button on any screen, the Login screen will be displayed with the message: “Supervisor- or Service-Level Login Required.”

The Additional Utilities Menu allows supervisors to configure the sterilizer and the network connection, set the date and time, set up and maintain user privileges, view and print files, perform diagnostic tests, and dispose of cassettes.

**Date & Time** allows you to set the date, time, time zone, and formats used for displaying and printing date and time.
System Config allows you to set sterilizer options.

User Admin allows you to add, delete, or modify operator identifications, passwords, and access levels.

Dispose Cassette moves the currently loaded cassette into the cassette disposal box.

Network allows you to configure a network connection.

Diagnostics starts a sequence of operator-assisted diagnostic tests and prints a diagnostic test report.

Service Functions are reserved for use by ASP Service Representatives.

File Management allows you to select, display, and print files.

Upload file reads the load items database file from a USB memory stick.

Input/Output door open opens the door on the input or output side.

Input/Output door close closes the door on the input or output side.

PCMCIA allows you to safely remove the PCMCIA card. Do not try to remove the PCMCIA card without using this feature.

The Back button returns you to the prior screen from which you originally selected the Additional Utilities Menu screen.

Date and Time Settings

Use the Date and Time Settings screen to set the date and time, and select the local time zone and display formats.

![Date and Time Setting](image)

Figure 23. Date and Time Setting.
Set Date

Use the MM box to set the month (01-12), the DD box to set the day (01-31), and the YY box to set the year.

Set Time

Use the HH box to set the hour (01-12 if 12-hour format is selected, 00-23 if 24-hour format is selected). Use the MM box to set the minute (00-59) and the SS box to set the second (00-59). If 12-hour format is selected, you may only select hours 01-12, and you must touch the AM or PM buttons to indicate the correct time.

Time Zone

Scroll through the selections until your time zone is displayed.

Date Format

Select the desired format for the date. The formats that include “YYYY” display a four-digit year.

Time Format

Select 12-hour or 24-hour format. If 12-hour format is selected, the AM and PM buttons on the Set Time line are enabled. If 24-hour format is selected, the AM and PM buttons are disabled.

Cancel/Done

To cancel the date or time setting, touch the Cancel button. When the date and time settings are correct, touch the Done button to return to the Additional Utilities menu.
System Configuration

Use the System Configuration screen to set sterilizer options. Selections on this screen allow you to set the volume of the alarm loudspeaker, the language used in displays and reports, and several access, report, and connection options. The sterilizer comes configured with factory-set defaults. If you want to change the default settings, select your preferred settings.

![Figure 24. System Configuration.](image)

Access Control Option

**User Login** requires that a user identification and password be entered before the sterilizer can be loaded and run. This is the factory default setting.

**No User Login** allows any person to operate the sterilizer.

IMS

**Enabled** causes the system to capture data with an IMS system (optional).

**Disabled** causes the system to not capture data with an IMS system (optional).

Vacuum Units

**Torr/mTorr** expresses vacuum measurements in torr and mtorr.

**kPa/Pa** expresses vacuum measurements in kilopascals and Pascals. This is the factory default setting.
Load Data Entry Option

**Enabled** causes the Enter Load Item Data screen to be displayed after login. This is the factory default setting.

**Disabled** skips the Enter Load Item Data screen.

Load Removal Option

**With Login** requires that a user enter a user identification and password to open the sterilizer door when a cycle is complete.

**Without Login** allows any person to open the sterilizer door when a cycle is complete. This is the factory default setting.

Notepad Option

**Enabled** causes the Cycle Notes screen to be displayed after login. This is the factory default setting.

**Disabled** skips the Cycle Notes screen.

Network Option

**Enabled** allows the sterilizer to transmit data on a network.

**Disabled** disables the network connection. This is the factory default setting.

Alarm Volume

Touch the + or - buttons to adjust the volume of the alarm loudspeaker. The factory default setting is in the middle of the scale.

Backlight Conservation (Minutes)

Touch the number of minutes; 15, 30, or 60, to indicate how long the splash screen remains visible in the idle state before starting screen saver mode.

Language Selection

Scroll through the list to select the language used in displays and printed reports. The factory default setting is English.
Sterilizer Settings

Touch Sterilizer Settings to display the following screen. The information entered here is included in the printout, but its use is optional. Touch **Done** to save the settings and return to the previous screen.

![Sterilizer Settings Screen](image)

**Figure 25. Sterilizer Settings.**

**Facility Name** – Enter the name of the hospital or medical facility.

**Department Name** – Enter the name of the department you wish to use as an identifier for the sterilizer.

**Sterilizer ID** – Enter an ID such as an asset tag number or other information used to identify the sterilizer.

**Sterilizer Serial Number** – This is configured by the manufacturer and cannot be altered.
Printer Settings

Touch **Printer Settings** to display the following screen: Touch **Done** to save the changes.

![System Configuration—Printer Settings](image)

**Figure 26. Printer Settings**

**Internal Printer Input Side** allows you to select the printer on the input side. This is the default.

**Internal Printer Output Side** allows you to select the printer on the output side (2 door configuration).

**External Printer** allows you to select an external printer connected to the USB port.

**Short Format** instructs the sterilizer to print only the short report when a cycle is complete. This is the factory default setting.

**Long Format** instructs the sterilizer to print only the long report when a cycle is complete.

**Parametric Format** instructs the sterilizer to print only the parametric report when the cycle is complete. This format is available only when an external printer is selected.

**Graphs** of various functions are available for printing if an external printer is selected. Touch the graph(s) desired.

**IMS Printout Enabled** printa the IMS information if an external printer is selected.

**IMS Printout Disabled** does not print the IMS information.
Transfer Settings

When you touch Transfer Settings from the System Configuration menu, the following screen appears. This screen displays selectable report types that automatically transfer via a network to a remote PC upon cycle completion. Touch Done to save the settings. Touch Cancel to return to the previous screen.

![Transfer Settings Screen](image)

**Figure 27. Transfer Settings**

Cancel/Done

To cancel system configuration (on the System Configuration Menu), touch the Cancel button. When the system configuration settings are correct, touch Done. Cancel and Done have the same function on all the other screens you can access through the System Configuration menu.
User Administration

Use the User Administration screen to add, modify, or delete user names, passwords, and access levels. A button on this screen allows you to upload user information to a USB memory stick. Supervisor-level access allows you to add, edit or delete a User or another Supervisor.

✔ Note: It is very important that you, as an administrator, keep track of your password. If you forget or lose your password, a service call is necessary for you to regain access to the supervisor area of the system.

Figure 28. User Administration.

Add User displays the Add User screen. On this screen you can set up a new user’s operator identification, password, and access level.

Modify User displays the Modify User screen. On this screen you can modify or delete an existing user’s identification, password, and access level. Touch Edit User on this screen to change information.

Upload User Data causes the sterilizer to receive a complete database file of user names, passwords, and access levels from a USB memory stick.

Back returns you to the Additional Utilities Menu.
Add User

Use the Add User screen to enter a new user’s identification, password, and access level.

![Add User Screen](image)

**Figure 29. Add User.**

1. Enter the user’s operator “identification” in the **Operator** field. The entry must be alpha-numeric and no more than 10 characters.

   ✔ **Note:** *Operator and Password fields are case-sensitive.*

2. Enter the user’s password in the **Password** field. The entry must be alpha-numeric, no more than 10 characters.

3. Scroll through the **Access Level** selections and select an appropriate access level. You may only choose “Operator” or “Supervisor.” Only Service Users can select “Service” level access.

4. Touch the **Cancel** button to exit this screen and return to the User Administration screen.

5. Touch the **Done** button when you have finished entering information for a new user.
Modify User

Use the Modify User screen to modify an existing user’s identification, password, and access level.

1. Touch the user’s name whose information you wish to edit or delete.
2. Touch **Delete User** to remove the user from the access list and revoke access to sterilizer operation.
3. Touch **Edit User** to change the user’s information including access level.
4 Touch **Done** to return to the previous screen.

![Figure 31. Edit User.](image)

- To modify the selected user’s information, touch the **Edit User** button.
- To change the user’s operator name, make changes in the **Operator** field.
- To change the user’s password, make changes in the **Password** field.
- To change the user’s access level, select the desired **Access Level**.
  You may only choose “Operator” or “Supervisor.” Only Service Users can select “Service” level access.

5 Touch the **Cancel** button to exit this screen and return to the Modify User screen.

6 Touch the **Done** button when you have finished – the Modify User screen is displayed.

### Upload User Data

You can also add up to 1000 user identifications by uploading them to the sterilizer from a USB memory stick.

The user data must be formatted to be compatible with the STERRAD 100NX Database format for user information. It must included the Access Level.

When the **Upload User Data** button is touched, the Upload User Data screen is displayed.

WARNING: This is a controlled proprietary and confidential document. Verify revision is current prior to use.
Figure 32. Upload User Data.

If the user data shown is acceptable, touch **Confirm**. The following section contains information on uploading user data.

**Steps to Upload a User Database**

To upload a list of user identifications and passwords, perform the following steps:

1. Create an ASCII text file called "users.rec" that contains the user identifications, passwords, and access levels. Use Microsoft Notepad to create the entry. Save the file as "users.rec" and in the “Encoding” drop down menu in Notepad Save, select UTF-8. Each entry should be separated by a comma only (no spaces). Example:

   USERNAME1,PASSWORD1,ACCESS-LEVEL1
   USERNAME2,PASSWORD2,ACCESS-LEVEL2
   USERNAME3,PASSWORD3,ACCESS-LEVEL3

   where:
   - **USERNAME** must be alpha-numeric, no more than 10 characters
   - **PASSWORD** must be alpha-numeric, no more than 10 characters
   - **ACCESS-LEVEL** must be either 1, 2 (1=Operator, 2 = Supervisor)

2. Copy users.rec file to a USB memory stick and insert the memory stick into the sterilizer’s port located on the lower right (your right) side of the sterilizer.
3 On the sterilizer, touch the **Upload User Data** button. The information in the file will be displayed with the password concealed by “*” characters.

You will receive an “INVALID STERRAD® 100NX DATABASE FILE” message if the password or user name is longer than the permissible length, you have specified an invalid access level, or you have used an invalid format.

4 Touch the **Confirm** button to accept the displayed data, logout the current user and return to the prior screen.

### Dispose Cassette

**CAUTION! HYDROGEN PEROXIDE MAY BE PRESENT.**

Wear latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation or when disposing of a cassette. Hydrogen peroxide liquid may be present on the cassette, the load or in the chamber.

This feature is used to remove the currently loaded cassette from the sterilizer to resolve an error message or to move a cassette that may be stuck in place. The Dispose Cassette function moves the cassette from inside the sterilizer to the cassette box. The remaining volume of hydrogen peroxide is displayed on the screen. Once a cassette is disposed, it should not be reinserted into the sterilizer.

Touch **Dispose Cassette** to move the cassette into the cassette disposal box.

![Dispose Cassette](image)

**Figure 33. Press Dispose Cassette to Move the Cassette Into the Cassette Disposal Box.**
Access Levels and Supervisor Tasks

Network

STERRAD® 100NX™ Sterilizer can be configured to communicate with a remote personal computer over a network. If you need to use this feature, please contact Advanced Sterilization Products for details on performing this setup.

Diagnostics

The diagnostics function prompts you to select one of two types of tests (either Temperature Test or Other Tests). If Other Tests is selected, the sterilizer runs ten operator-assisted tests of the sterilizer subsystems. You may skip one or more tests in the automatic sequence by touching the Cancel button when a test begins. This causes the program to advance to the next test in the sequence.

The ten tests and the sterilizer elements that are tested are listed in the order in which they occur in the following table.

Touch the Diagnostics button to start automatic diagnostic testing of the sterilizer.

✔ Note: The duration of the Temperature Test is a minimum of 11 minutes.
# Diagnostic Tests

<table>
<thead>
<tr>
<th>Order</th>
<th>Test Name</th>
<th>What is tested</th>
<th>Average Time to Run*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Power Supply Test</td>
<td>DC power supply</td>
<td>30 sec.</td>
</tr>
<tr>
<td>2</td>
<td>Vacuum Test</td>
<td>Vacuum pump, pressure sensors and valves (vacuum control, vent, inlet, transition, delivery, and oil return)</td>
<td>12 min.</td>
</tr>
<tr>
<td>3</td>
<td>Door Test</td>
<td>Door Motor and sensors</td>
<td>20 sec.</td>
</tr>
<tr>
<td>4</td>
<td>Plasma Test</td>
<td>Plasma electrical subsystem&lt;br&gt;Electrode integrity</td>
<td>3 min. 20 sec.</td>
</tr>
<tr>
<td>5</td>
<td>Cassette Test</td>
<td>Cassette electro-mechanical subsystem RFID Reader</td>
<td>5 min.</td>
</tr>
<tr>
<td>6</td>
<td>H₂O₂ Sensor Test</td>
<td>Ultraviolet lamp and detector</td>
<td>20 sec.</td>
</tr>
<tr>
<td>7</td>
<td>Display Test</td>
<td>Touch screen and display function</td>
<td>20 sec</td>
</tr>
<tr>
<td>8</td>
<td>Printer Test</td>
<td>Printer function</td>
<td>10 sec.</td>
</tr>
<tr>
<td>9</td>
<td>Fan Test</td>
<td>Fan function</td>
<td>10 sec.</td>
</tr>
<tr>
<td>10</td>
<td>Sound Test</td>
<td>Loudspeaker function and volume</td>
<td>1 min.</td>
</tr>
</tbody>
</table>

* Times are approximate. If a failure is detected, the time may be extended.

The ten tests take approximately 23 minutes and 10 seconds to complete. When the series of tests is complete, the sterilizer creates and stores a diagnostics file and prints a report. When printing is complete, the Additional Utilities menu is displayed.

# Service Functions

The Service Functions button is reserved for use by ASP Service Representatives.
File Management

Use the File Management screen to select and display calibration files or diagnostic report files.

**Figure 35. File Management.**

**Calibration Files**

Touch the **Calibration Files** button to display a list of calibration files created during a sterilizer calibration. Scroll through the list and touch the file name you wish to view. Touch the **View** button to display the selected calibration file. Touch the **Back** button to return to the Additional Utilities menu.

**Diagnostic Files**

Touch the **Diagnostic Files** button to display a list of reports created by the Diagnostics function. Scroll through the list and touch the report you wish to view. Touch the **View** button to display the selected report. Touch the **Back** button to return to the Additional Utilities menu.
Upload File

This screen allows you to upload item information from a separate database to the sterilizer using the USB memory port.

1 Using Microsoft “Notepad,” create a list of load items similar to the example shown in the figure. To obtain the above display; i.e., ENDOSCOPE1, ENDOSCOPE2, etc., each item must start on a new line and end with a comma. Up to 1000 load items can be defined.

2 Save the file with the file name “loaditems.txt” and use the “encoding” drop down in Notepad to save the file encoded as UTF-8.

3 Insert the USB memory stick with the file loaditems.txt resident on the stick into the sterilizer’s USB port located on the lower right side of the front panel.

4 Follow the instructions on the display to upload the file.
Input/Output Doors

The doors can be opened or closed via the foot pad that you tap with your foot or by touching the Input or Output Door buttons. If the system has only one door, only the Input Close Door and Input Open Door buttons are available for use. Only one door can be opened at a time. For example, if the Input Door is open, the Output Door cannot be opened at the same time.

The Input Open Door and Input Close Door buttons open and close the input side of the sterilizer. That is the side where you load your instruments for processing.

The Output Open Door and Output Close Door buttons open and close the output or clean side of the sterilizer. This is the side, on a two door unit, where you would remove your sterilized items. When the door is moving, the door open and close buttons, and the foot pad, are disabled until the door has completed its movement.
Chapter 7.  

Reports and Files

Displayed Reports

Users with Operator-level access can display the Cycle History files. Users with Supervisor-level access can display the Cycle History files, as well as Calibration files and Diagnostic files.

All files that are displayed can be printed by touching the **Print** button on the file display screen.

Cycle History

Cycle history data is stored in the sterilizer’s memory. The memory holds data from the last 50 cycles. After 50 cycles are completed, the oldest cycle history record is overwritten with new data from the 51st cycle. If your sterilizer is configured with the optional network connection, cycle history data can be periodically uploaded to a host computer and preserved permanently if desired.

When you touch the **View Cycle History** button on any screen where the button appears, the program displays the Select Cycle History screen. The list box shows the cycle number, status, completion date and time, and reason for cancellation (if applicable) for all cycle history records currently in the sterilizer’s memory.
Touch the scroll bars to scroll through the list. Touch the line you wish to select.

![File Management](image)

**Figure 36. Select Cycle History File.**

**Print List** prints a list of all cycle history files stored in the sterilizer.

**View Cycle** displays the selected Cycle History file on the screen.

**Print Cycle (Short)** prints a short-format report of the selected cycle history file.

**Print Cycle (Long)** prints a long-format report of the selected cycle history file.

**Parametric Print** prints a parameter format report of the selected cycle history file.

**Data Transfer** – allows you to transfer the cycle information to a USB memory stick or to a networked PC.

**Back** returns you to the previous screen.
Printed Reports

Every time a cycle is completed, a cycle completion report is printed. Depending upon how your sterilizer has been configured, the report will either be a short-format report, a parametric report, or a long-format report. Each report extracts data from the cycle history record created by the cycle. The short-format report indicates the cycle status (Passed or Failed), date, time, operator and load information. The parametric report contains much more detail than the short report, but is less extensive than the long-format report. The long-format report includes all of the data in the short report plus detailed information about each stage of the sterilization cycle.

Short Report

The short-format report lists identifying information about the cycle, shows the cycle status, lists the date and duration of the cycle, and shows operator and load identifying information. The short-format report is useful for recordkeeping purposes and providing traceability of sterilized loads.

Parametric Report

The parametric format report shows single-point values for a certain number of parameters. It is a more confined report than the long printout and contains a table of all critical parameters and their values. It is only available if an external printer is attached.

Long Report

The long-format report lists detailed information about the cycle, shows the cycle status, lists the date and duration of the cycle, shows operator and load identifying information, and provides detailed data about the operation of the sterilizer, including temperatures, pressures, plasma measurements, and sterilant concentrations throughout the cycle. The long-format report is useful for detailed cycle quality control and contains valuable diagnostics information for ASP Service Representatives.
Chapter 8.

Maintenance

✔ Note: Repairs and adjustments should only be attempted by experienced technicians who are fully trained to maintain and repair the STERRAD® 100NX™ Sterilizer. Use of unauthorized parts for maintenance or repair could cause personal injury, result in costly damage, or sterilizer malfunction and voids the warranty.

Automatic Maintenance

The adjustment of the hydrogen peroxide monitoring lamp is performed automatically by the sterilizer software. The user does not have to perform any task to start this procedure.

Automatic Lamp Adjustment

When the sterilizer shows the System Ready screen, the message “Auto Adjustment in Progress” will be displayed while the sterilizer adjusts the intensity of the UV lamp. This function can take approximately 5 minutes to complete. The automatic adjustment will take place if the lamp voltage is below a preset limit.
Manual Maintenance

The following maintenance procedures are performed by the user:

- Disposing of cassettes.
- Inserting a new cassette disposal box.
- Replacing the printer paper roll.
- Cleaning the sterilizer exterior.
- Cleaning the hydrogen peroxide monitor detector lens.
- Replacing the air filter.
- Replacing the PCMCIA card (if desired).
- Disposing of a sterilizer.

These tasks are performed when needed. The printer paper is replaced when the roll is empty. The sterilizer exterior should be cleaned only when necessary. This chapter provides step-by-step instructions on how to perform these maintenance tasks. Information on inserting a cassette box follows the disposal section.

Disposing of Cassettes

When a cassette is empty the sterilizer automatically moves it to the cassette disposal box. The screen displays a message instructing you which actions to take next. When the cassette disposal box contains 2 cassettes, it is full, and you must dispose of the full cassette disposal box. For safety reasons, you must use the cassette disposal box to dispose of cassettes. Never reuse a cassette disposal box. Once a cassette disposal box has been removed, a new cassette disposal box must be inserted.

Removing a Cassette Disposal Box

CAUTION: HYDROGEN PEROXIDE MAY BE PRESENT.

Wear latex, PVC (vinyl), or nitrile gloves. This will protect you from contact with any residual hydrogen peroxide that may be present in the cassettes.
1 Open the cassette access door. Pull the tab on the cassette disposal box to more easily slide it completely out.

![Figure 37. Open the Access Panel and Remove the Used Cassette Box.](image1)

2 Close the lid by pinching it shut along the edge.

![Figure 38. Pinch the Edge of the Lid to Close the Box.](image2)

3 Dispose of the closed cassette box according to your facility’s policy.
4 Insert a new box making sure the tab is facing you and the lid is open and not caught in the opening.

Figure 39. Insert the New Cassette Box with the Lid Open so the Tab is on the Left.

5 Close the access panel.

Figure 40. Cassette Box. Note the Illustration. The Lid is Open and the Tab is on the Left.
Replacing Printer Paper

When the printer paper roll is empty, the sterilizer displays a message “Printer is out of paper. Please load a new roll.”

1. Open the printer by pushing or squeezing up on the handle as shown. The printer door opens toward you.

2. The empty paper roll rests on the bottom of the printer door. Remove the empty roll.
3 Insert a new paper roll as shown in the following figure. The paper should feed from the top of the roll.

![Figure 43. Insert a New Paper Roll.](image)

4 Pull a short length of paper over the top of the printer door.

5 Align the paper so that it fits between the two paper guides on the top of the printer door.

6 Push the door shut making sure the paper stays in place.

![Figure 44. Make sure the Printer Door Latches Securely and the Paper is in Place.](image)

7 Press the paper advance button. Check the alignment of the paper and make certain it does not jam or misfeed.
Figure 45. Press the Paper Advance Button.

8 When the paper has advanced normally, tear off the used strip in an upward direction. Paper replacement is now complete.

Cleaning the Sterilizer Exterior

✔ Note: Do not attempt to clean the chamber, door, interior surfaces, shelves, or electrode. If these items need cleaning, in the U.S.A. call the ASP Customer Care Center. Outside the USA, call your local ASP Customer Support Representative for assistance.

The sterilizer exterior can be cleaned with a soft cloth and a mild, nonabrasive detergent solution if necessary. When cleaning the sterilizer exterior, follow these guidelines:

1 Turn off the power to the sterilizer before cleaning the exterior.
2 Never allow cleaning solution or water to enter the interior or chamber. Moisten a cloth with nonabrasive detergent solution and use the damp cloth to clean the surfaces.
3 Do not spray cleaning solution directly on the touch screen. Use a dampened cloth to clean the screen.
4 If you have any questions about proper cleaning techniques, in the U.S.A. please call the ASP Customer Care Center. Outside the USA, call your local ASP Customer Support Representative before proceeding. Failure to follow these guidelines may result in damage to the sterilizer and may void the warranty.
Cleaning the Hydrogen Peroxide Monitor Detector Lens

The hydrogen peroxide monitor lens is located on the input side of the sterilizer. The lens must be kept clean. Wipe off the lens once every three months or when an accumulation of debris is noted. This is shown in the following figure.

- Always use a lint-free cloth to clean the lens.
- Moisten the cloth with isopropyl alcohol. Never use an abrasive cleanser.
- Wipe the lens to remove any accumulated debris.

Figure 46. Cleaning the Hydrogen Peroxide Monitor Lens.
PCMCIA Card Handling and Replacement

The PCMCIA card contains the flash memory used to store cycle data. The following steps contain information on removing and replacing the PCMCIA card:

1. Turn off the sterilizer.
2. Open the cassette access door.
3. Eject the PCMCIA card by pressing the eject button on the left of the card slot (see the following figure).

To reinsert the PCMCIA card, do the following:

1. Examine the PCMCIA card and note the location of the label.
2. Orient the PCMCIA card so that the side of the card with the label faces left.
3 Insert the card into the PCMCIA card slot.

4 Press the end of the PCMCIA card until the card is firmly seated in the slot (you will feel a “click” as the card is seated in the connector). A properly seated card is shown in the following figure.

![Insert the PCMCIA Card Correctly](image1)

✔ Note: The STERRAD 100NX Sterilizer will not operate unless the PCMCIA card is properly installed.

Data Transfer Using a Memory Stick

A memory stick can be inserted in to the USB port located on the right (your right) side of the sterilizer. Go to the Cycle History screen and select **Data Transfer**, then **USB Save**. Select cycle data to be transferred and data type.

![Insert the Memory Stick into The USB Port](image2)
Rebooting the System

If it becomes necessary to reboot the system, flip the main switch on the sterilizer to turn off the system and then turn it back on.

Sterilizer Disposal

In the event that disposal of the STERRAD 100NX Sterilizer is necessary, the sterilizer may be returned to ASP or recycled with a local recycler. Disposal of infectious waste, electronic circuit boards, and cathode ray tubes (CRTs) are regulated by the U.S. Environmental Protection Agency and most international environmental agencies. Please ensure compliance with all International, Federal, State, and Local regulations before disposal. Contact your ASP Customer Care Representative for additional information.
Note: Repairs and adjustments should only be made by ASP trained and authorized personnel.

Most sterilizer operating problems are accompanied by a system message. These messages are useful in determining the source of the problem. In many cases you can take remedial actions to return the sterilizer to normal operation. Because load related issues are the most frequent cause of cycle cancellation, the easiest solution is to repackage the load and restart the sterilizer when a cycle cancels. Be sure to replace biological and chemical indicators with new ones. In other cases, the problem may be caused by a component failure that requires adjustment or repair by an ASP Service Representative. Call the ASP Customer Care Center at 1-888-STERRAD (1-888-783-7723). Outside the USA, call your local ASP Customer Support Representative.

In the following table are messages that are displayed by the system. The messages are listed in alphabetical order. Some messages do not require action on your part and are merely statements of the system status. Other messages require that you insert a cassette, remove the cassette disposal box, or other such action. The display directs you what steps to take. If the cycle had cancelled, WEAR GLOVES when removing the load.

Running Diagnostics

If the sterilizer or the information in the following table directs you to run diagnostics, remove the load and touch Other Tests from the Diagnostics menu. If you have received a message containing the word “temperature,” touch Temperature Tests. (See the section on “Access Levels and Supervisor Tasks” for information on how to navigate to the Diagnostics menu.) If you run Diagnostics and the tests show that there are errors, contact your ASP Representative and report the diagnostic results. If the diagnostic tests pass with no errors, you can run cycles with your normal load.
System Message Table

Temperature Messages

**WARNING! HOT SURFACES.**

When a temperature message is displayed, this may mean that the interior of the sterilizer may be very hot. Do not touch the inside of the chamber, electrode, or doors with your bare or gloved hands.

A number of displayed messages concern the temperature of the system; i.e., doors, vaporizer, electrode, etc. These messages contain the word “temperature” and require that you run the temperature test in diagnostics. If the temperature test fails, or if the message is repeated, call your ASP Representative for further action.

Messages Not In This Table

If a displayed message is not found in the following table, there is no remedy available that you may safely perform. Call your ASP Representative for further action.

<table>
<thead>
<tr>
<th>If this message appears . . .</th>
<th>Do this . . .</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannot Dispose Cassette, Run Diagnostics</td>
<td>The cassette did not drop into the disposal box. Remove the load and run diagnostics.</td>
</tr>
<tr>
<td>Cannot Eject Cassette, Run Diagnostics</td>
<td>The cassette did not eject out the cassette slot. Remove the load and run diagnostics.</td>
</tr>
<tr>
<td>Cassette Accepted, Positioning</td>
<td>No action required.</td>
</tr>
<tr>
<td>Cassette Detected, Verifying</td>
<td>No action required.</td>
</tr>
<tr>
<td>Cassette Did Not Index</td>
<td>A cassette was unable to advance to the next cell. Remove the load and run diagnostics.</td>
</tr>
<tr>
<td>Cassette Expired, Disposing Cassette</td>
<td>Insert a new cassette.</td>
</tr>
<tr>
<td>Cassette Expiry Found During Start Cycle</td>
<td>The cassette was found to be expired when the Start Cycle button was pressed. Dispose of the cassette and insert new cassette.</td>
</tr>
<tr>
<td>Cassette Out Of Date, Disposing Cassette</td>
<td>The cassette has been in the sterilizer for 10 days or the cassette has expired. Insert new cassette.</td>
</tr>
<tr>
<td>Cassette System Timeout When Piercing</td>
<td>The delivery subsystem is not responding. Remove the load and run diagnostics.</td>
</tr>
<tr>
<td>Cassette Used, Disposing</td>
<td>The inserted cassette does not have any unused cells remaining. Insert a new cassette.</td>
</tr>
<tr>
<td>If this message appears . . .</td>
<td>Do this . . .</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Control Available On Other Side</td>
<td>Use the other side of the sterilizer to access the touch screen.</td>
</tr>
<tr>
<td>Cycle Canceled By Operator</td>
<td>The operator canceled the cycle. Repackage the load. Restart the cycle after cancellation is complete.</td>
</tr>
<tr>
<td>Delivery System Not Ready</td>
<td>Delivery system not responding. Remove the load and run diagnostics.</td>
</tr>
<tr>
<td>Disposing Cassette</td>
<td>No action required.</td>
</tr>
<tr>
<td>Door Opened</td>
<td>Door open sensor malfunction. Remove the load and run diagnostics.</td>
</tr>
<tr>
<td>Door Sensor Fault</td>
<td>Door malfunction. Reboot the system. If the message persists, call your ASP Representative.</td>
</tr>
<tr>
<td>Function Available on Other Side Only</td>
<td>Control of the sterilizer is on the other side of the unit.</td>
</tr>
<tr>
<td>H₂O₂ Adjustment In Progress</td>
<td>The intensity of the UV lamp is being adjusted. Wait 5 minutes for adjustment to be completed.</td>
</tr>
<tr>
<td>H₂O₂ Bulb Warming Up, Please Wait…</td>
<td>No action needed.</td>
</tr>
<tr>
<td>H₂O₂ Bulb/Detector Fault</td>
<td>H₂O₂ detector malfunction. Run diagnostics.</td>
</tr>
<tr>
<td>H₂O₂ Curve Area Too Low</td>
<td>Load is absorbing too much peroxide. Remove absorbing materials from the load, repackage, and restart the cycle. If the problem persists, call your ASP Representative.</td>
</tr>
<tr>
<td>H₂O₂ Monitor Failure</td>
<td>H₂O₂ bulb or detector malfunction. Remove the load and run diagnostics.</td>
</tr>
</tbody>
</table>

**CAUTION! HYDROGEN PEROXIDE MAY BE PRESENT.**

Wear latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.

<table>
<thead>
<tr>
<th>H₂O₂ Peak Too Low</th>
<th>The load is absorbing too much peroxide. Remove the absorbent materials from the load, repackage, and restart the cycle. If the problem persists, call your ASP Representative.</th>
</tr>
</thead>
<tbody>
<tr>
<td>H₂O₂ Rate Constant Too High</td>
<td>The load is decomposing the H₂O₂. Check the load for absorbent materials. Repackage, and restart the cycle. If the problem persists, call your ASP Representative.</td>
</tr>
<tr>
<td>If this message appears . . .</td>
<td>Do this . . .</td>
</tr>
<tr>
<td>-----------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>H$_2$O$_2$ Rate Outside the Calibrated Range</td>
<td>Reboot the system. If the problem persists, call your ASP Representative.</td>
</tr>
<tr>
<td>H$_2$O$_2$ Sensor Fault</td>
<td>Reboot the system. If the problem persists, call your ASP Representative.</td>
</tr>
<tr>
<td>High Plasma Power</td>
<td>The plasma power is out of specification. Remove the load and run diagnostics.</td>
</tr>
<tr>
<td>Invalid Key Code. Please Enter A Valid Code</td>
<td>Press the OK button and reenter a valid key code.</td>
</tr>
<tr>
<td>Invalid Load Items File</td>
<td>Press the Back button and reinsert the USB memory stick.</td>
</tr>
<tr>
<td>Less Number of Cells Available, Please Dispose the Cassette</td>
<td>The system will automatically move the cassette to the disposal box.</td>
</tr>
</tbody>
</table>

**CAUTION! HYDROGEN PEROXIDE MAY BE PRESENT.**

Wear latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.

| Load May Contain H$_2$O$_2$                               | Residual peroxide may be present on the load or chamber walls due to a cancelled cycle or system malfunction. Wearing latex, PVC (vinyl), or nitrile gloves, repackage the load and restart the cycle. If the problem persists, call your ASP Representative. |

**CAUTION! HYDROGEN PEROXIDE MAY BE PRESENT.**

Wear latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.

<table>
<thead>
<tr>
<th>Low Plasma Power</th>
<th>The plasma power is out of specification. Remove the load and run diagnostics.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Memory Card Full</td>
<td>Initiate backup to the memory card or press OK and the system will delete the oldest file.</td>
</tr>
<tr>
<td>No File Found</td>
<td>Press OK. Reinsert the USB memory stick.</td>
</tr>
<tr>
<td>Other Door Is Open</td>
<td>Close the door on the other side of the sterilizer. You cannot use the sterilizer if both doors are open.</td>
</tr>
<tr>
<td>Please Close Door</td>
<td>Touch the close door display or the door foot pad to close the door.</td>
</tr>
<tr>
<td>Please Enter Valid User Name and Password</td>
<td>After the valid user name and password are entered, press OK.</td>
</tr>
<tr>
<td>Please Insert New Cassette</td>
<td>Insert a new, unused cassette.</td>
</tr>
<tr>
<td>If this message appears . . .</td>
<td>Do this . . .</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Please Remove Cassette And Verify Cassette Type</td>
<td>Wrong cassette type. Confirm that the cassette is a STERRAD 100NX cassette.</td>
</tr>
<tr>
<td>Please Wait While Graph Loads</td>
<td>No action required.</td>
</tr>
<tr>
<td><strong>CAUTION! HYDROGEN PEROXIDE MAY BE PRESENT.</strong></td>
<td>Wear latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.</td>
</tr>
<tr>
<td>Power Fail Cancellation</td>
<td>A power failure occurred during a cycle. Repackage the load and restart the cycle. If the problem persists, call your ASP Representative.</td>
</tr>
<tr>
<td><strong>CAUTION! HYDROGEN PEROXIDE MAY BE PRESENT.</strong></td>
<td>Wear latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.</td>
</tr>
<tr>
<td>Pressure Check Failed</td>
<td>Load is absorbing too much peroxide. Remove absorbing materials from the load, repackage, and restart the cycle. If the problem persists, call your ASP Representative.</td>
</tr>
<tr>
<td>Pressure Out Of Range (High)</td>
<td>Vacuum system malfunction. Remove the load and run diagnostics.</td>
</tr>
<tr>
<td>Pressure Out Of Range (Low)</td>
<td>Vacuum system malfunction. Remove the load and run diagnostics.</td>
</tr>
<tr>
<td>Printing Is In Progress</td>
<td>No action required.</td>
</tr>
<tr>
<td>RFID Data Error, Ejecting Cassette, Verify Cassette Orientation</td>
<td>Cassette will automatically eject. Insert a valid cassette</td>
</tr>
<tr>
<td>Stage Timeout</td>
<td>Remove the load and run diagnostics.</td>
</tr>
<tr>
<td><strong>CAUTION! HYDROGEN PEROXIDE MAY BE PRESENT.</strong></td>
<td>Wear latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.</td>
</tr>
<tr>
<td>Unable to Evacuate Chamber</td>
<td>Remove the load and run diagnostics. Reboot the system. If the problem persists, call your ASP Representative.</td>
</tr>
<tr>
<td>Unable to Open One Second Data File</td>
<td>Replace the PCMCIA card with a new one.</td>
</tr>
</tbody>
</table>
Troubleshooting

<table>
<thead>
<tr>
<th>If this message appears...</th>
<th>Do this...</th>
</tr>
</thead>
<tbody>
<tr>
<td>UV Path Is Blocked, Open Door And Clear Pathway</td>
<td>Object is blocking the UV path. Verify that the shelves and/or the load are not blocking the path. If the problem persists, call your ASP Representative.</td>
</tr>
<tr>
<td>Warming Up, Please Wait...</td>
<td>No action needed.</td>
</tr>
<tr>
<td>CAUTION! HYDROGEN PEROXIDE MAY BE PRESENT.</td>
<td>Wear latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.</td>
</tr>
<tr>
<td>Would You Like to Troubleshoot?</td>
<td>Remove the load and run diagnostics. If the problem persists, call your ASP Representative.</td>
</tr>
</tbody>
</table>

Call Your ASP Representative

If you encounter a problem or a system message that is not covered in this user’s guide, do not attempt to perform repairs or adjustments to the STERRAD® 100NX™ Sterilizer. Call the ASP Customer Care Center for assistance in the USA at 1-888-STERRAD (1-888-783-7723) and outside the USA, call your local ASP Customer Support Representative.
## Consumables, Accessories, and Additional Parts

### Consumable Products

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10144</td>
<td>5 cycles per cassette, 2 cassettes per case.</td>
</tr>
<tr>
<td>10305</td>
<td>Used with the thermal printer to record sterilizer information.</td>
</tr>
<tr>
<td>20227</td>
<td>This box is used to collect cassettes for disposal.</td>
</tr>
<tr>
<td>20228</td>
<td>Contains the trays, mats, and BI validation supplies.</td>
</tr>
</tbody>
</table>

### Accessories

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10308</td>
<td>Optional barcode scanner for tracking instruments and other information in the cycle history file.</td>
</tr>
<tr>
<td>10140</td>
<td>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.</td>
</tr>
</tbody>
</table>
ASP also offers a full line of other consumables and accessories which have been fully tested and validated for use with the STERRAD® 100NX™ Sterilizer. For more information on any of these products, in the U.S.A. contact the ASP Customer Care Center at 1-888-STERRAD. Outside the USA contact your local ASP Customer Support Representative.
Appendix B.

STERRAD® 100NX™
Sterilizer Specifications

Power
The phase rotation is adjusted to match the system requirements at installation.

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 208 Volt circuit with separate neutral and ground conductors.

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.

200V 50-60 Hz Power (Japan): The sterilizer requires a four wire Delta configuration to a dedicated 30 AMP circuit.

Dimensions
H: 70.5 in. (179.1 cm), W: 30.5 in. (77.5 cm), D: 40 in. (102 cm).

Service clearances
Front: 39.5 in. (100 cm); Back: 39.5 in (100 cm); Top: 39.5 in. (100 cm)
Left side: 39.5 in. (100 cm); Right side: 39.5 in. (100 cm).

Weight
414 kg, 910 lbs

Chamber volume
152 liters.W20.7 in. (51 cm), H16.1 in. (41 cm), D28.93 in. (73.5 cm).
Usable volume: 93.4 liters (3.3 cubic feet)

Chamber shelves
Two shelves, W 17 in. (42.5 cm), D 28 in. (70 cm).
Shelf capacity: 55 lb. (25 kg) uniformly distributed.
Both shelves are removable.
<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature Operating</td>
<td>18°C - 35°C (64° - 95°F)</td>
</tr>
<tr>
<td>Storage</td>
<td>-29°C - 70°C (-20°F - 158°F)</td>
</tr>
<tr>
<td>Humidity Operating</td>
<td>10% – 85% up to 30°C. Linearly decreasing from 85% at 30°C to 70% at 40°C non-condensing</td>
</tr>
<tr>
<td>Storage</td>
<td>10% – 100% (rainfall will be permitted).</td>
</tr>
<tr>
<td>Altitude/Pressure</td>
<td>Operating altitude up to 3095 m (10,152 ft.).</td>
</tr>
<tr>
<td></td>
<td>Atmospheric pressure 520-775 torr</td>
</tr>
<tr>
<td>Cycle temperature</td>
<td>47°C – 56°C (116.6°F – 132.8°F)</td>
</tr>
<tr>
<td>Cycle time</td>
<td>42 minutes – Flex Cycle</td>
</tr>
<tr>
<td></td>
<td>47 minutes – Standard Cycle</td>
</tr>
<tr>
<td>Cycles per cassette</td>
<td>5</td>
</tr>
<tr>
<td>Connectors</td>
<td>Network: RJ45; Barcode reader: USB.</td>
</tr>
<tr>
<td></td>
<td>Printer: USB</td>
</tr>
<tr>
<td>Data storage</td>
<td>PCMCIA nonstandard compact flash.</td>
</tr>
<tr>
<td>Main Power Cable</td>
<td>12 AWG (4 mm²), 3 m (9.84 feet) long, 5 conductors</td>
</tr>
<tr>
<td></td>
<td>NEMA L21 - 30P (USA and Canada.)</td>
</tr>
<tr>
<td>RF Generation</td>
<td>Portable and mobile RF communications equipment can affect medical</td>
</tr>
<tr>
<td></td>
<td>Electrical Equipment.</td>
</tr>
</tbody>
</table>

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Appendix C.

Warranties and Software License

Advanced Sterilization Products Commercial Warranty

The STERRAD® Sterilizer 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.

This warranty is hereby disclaimed, null and void if service is attempted or performed by persons who are not authorized to do so by Advanced Sterilization Products. This warranty is hereby disclaimed null and void if non-certified sources of hydrogen peroxide are used in your STERRAD Sterilizer. If, after examination by an ASP Service Representative, any portion of the unit is found to be defective within the period specified above, and ASP is satisfied that the failure was due to its use of defective materials and/or workmanship, ASP will, at its option, repair or replace the defective parts without charge. This warranty is not valid for repair or replacement for defects due to external factors including, but not limited to, defective electrical installation or electrical/atmospheric disturbances, the use of non-certified sources of hydrogen peroxide, or damage cause by unauthorized service representatives or improper use of the equipment. ASP reserves the right to make the necessary repair/replacement in its own factory, at any authorized repair station, or at the facilities of the purchaser of the equipment. Replacement items can be either new or remanufactured. Defective parts replaced under warranty shall become the property of ASP.
Advanced Sterilization Products Service Warranty

Service repairs are warranted to be free from defects in materials and workmanship for a period of 90 days after the date of repair when serviced by an ASP Representative or authorized dealer.

This warranty is null and void if service is performed by persons who are not authorized to do so by Advanced Sterilization Products. If, after examination by an ASP Service Representative, the previously repaired portion of the unit is found to be defective within the period specified above, and ASP is satisfied that the failure was due to defective materials and/or workmanship, ASP will, at its option, repair or replace the defective parts without charge. This warranty is not valid for repair or replacement for defects due to external factors including, but not limited to, defective electrical installation or electrical/atmospheric disturbances. ASP reserves the right to make the necessary repair in its own factory, at any authorized repair station, or at the facilities of the purchaser of the equipment. Replacement items can be either new or remanufactured. Defective parts replaced under warranty shall become the property of ASP.

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Division of Ethicon, Inc.
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Irvine, California 92618

1-888-STERRAD (1-888-783-7723)
+ 1-949-581-5799 (internationally)