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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

NOTICE OF PESTICIDE:
x Registration
___ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
71871-3	FEB 1 2008

Term of Issuance: **Conditional**

Name of Pesticide Product: **Sterrad Hydrogen Peroxide**

Name and Address of Registrant (include ZIP Code):

Advanced Sterilization Products
33 Technology Drive
Irving, CA 92618

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

a. Revise the "EPA Registration Number to read, "EPA Reg. No. 71871-3".

Signature of Approving Official:

Marshall Swindell
Product Manager Team-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date: FEB 1 2008

EPA Form 8570-6

b. The User Guides must be revised in accordance with the comments listed on the 1/9/08 Efficacy Review. A copy is enclosed for your guidance.

2. Submit two (2) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the "accepted" label is enclosed for your records.

If you have any questions concerning this Notice, please contact Martha Terry at (703) 308-6217.

Sincerely,

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure

STERRAD®

HYDROGEN PEROXIDE

AQUEOUS SOLUTION STERILANT

FOR USE IN THE STERILIZATION OF
LABORATORY AND INDUSTRIAL EQUIPMENT

KEEP OUT OF REACH OF CHILDREN

DANGER

See Side Panel For Additional Precautionary Statements

STATEMENT OF PRACTICAL TREATMENT

If In Eyes: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
If On Skin or Clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.
If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.
If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Note To Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

ACTIVE INGREDIENT: Hydrogen peroxide	59.0%
INERT INGREDIENTS:	41.0%
TOTAL:	100.0%

EPA Registration No.: 71871-_____
EPA Establishment No.: _____

Net Contents:_____ LOT:_____

PRECAUTIONARY STATEMENTS

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear (goggles, face shield or safety glasses) and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.

PHYSICAL AND CHEMICAL HAZARDS.

Hydrogen peroxide is a strong oxidizing agent and poses a hazard for fire, explosion or container rupture. Avoid contact with contamination or combustible materials. Do not use or store near heat or open flame. Shoes, clothing, or other combustible materials that have come into contact with hydrogen peroxide must be immediately and thoroughly rinsed with water to avoid potential fire hazards. In case of fire, use only water. Contain spills and dilute with 20 parts of water. After diluting the contained spill, use sodium metabisulfide or sodium sulfite (1.9 lbs. SO_2 equivalent per 500 mL of spilled material) to deactivate the hydrogen peroxide.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, mammals, fish and aquatic invertebrates. Do not charge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System and the permitting authority has been notified in writing prior to discharge. Do not discharge this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Manufactured by:

ASP ADVANCED STERILIZATION PRODUCTS®
a Johnson & Johnson company
Division of Ethicon, Inc.
33 Technology Drive, Irvine, CA 92618-9824
(888) STERRAD

ACCEPTED
with COMMENTS
EPA Letter Dated:
FEB 1 2008
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 71871-3

CE

Authorized EC Representative
Ethicon GmbH
Gottstraße 1, D-22844 Norderstedt

©ASP, 2000

Expiration Date: (9 months from the date of manufacture will be inserted)

DO NOT REMOVE PLASTIC WRAP IF BAR HAS CHANGED FROM YE TO RED. EXP. Not for use or sale after (Insert Date Here) (NOTE TO REVIEWER: uration date will not exceed 9 months from manufacturing date)

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

STERRAD© Hydrogen Peroxide is intended for sterilizing:

- tissue culture equipment and materials
- laboratory equipment (including glassware) and instrumentation
- medical instruments and devices in veterinary facilities

STERRAD© Hydrogen Peroxide may be used for treating items made of aluminum, brass, Delrin, ethyl vinyl acetate (EVA), glass, Kraton, latex, neoprene, nylon, Monel, polycarbonate, polyethylene, polystyrene, polypropylene, polyurethane, polyvinyl chloride (PVC), silicone, stainless steel, Teflon/polytetrafluoroethylene (PTFE)

For Use In The STERRAD® 200 Sterilizer Only.

Two (2) Cycles/Cassette

- Each cell contains not less than 0.0868 oz. (0.898 ± 0.003 oz.) [2466 mg (2550 ± 84 mg)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® 200 Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine 8 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the originali sleeve and call ASP Customer Service.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 200 Sterilizer cycle time is approximately 75 minutes.
- **Refer to STERRAD® 200 Sterilizer System User's Guide for additional information.**

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- OR -

For Use In The STERRAD® NX Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 1750 ± 50 µL of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® NX Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read "Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine 8 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.

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- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® NX Sterilizer has two cycle times: the 28-minute Standard cycle is for most surgical instruments and the38-minute Advance cycle is for the flexible endoscope.
- **Refer to STERRAD® NX Sterilizer System User's Guide for additional information.**

- OR -

For Use In The STERRAD® 50 Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz) [([1750 µL (1800uL ± 50µL)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap from cassette sleeve. Do not remove cassette from the remaining cardboard packaging.
- Orient the arrow so that it is on top of the cassette sleeve and pointing away from you.
- Insert the cassette sleeve into the STERRAD® 50 Sterilizer.
- Push the cassette sleeve completely into the injector. Once properly positioned, the cassette will automatically be accepted and positioned for use by the Sterilizer. The monitor will read " Cassette Accepted." If the cassette is not accepted because the barcode cannot be read or the cassette has expired, the monitor will read "Please Remove Cassette." Should this occur, please insert a new cassette.
- When the cassette is empty or has reached its labeled expiration date, or has been in the machine 10 days (due to the higher temperature in the machine), it will automatically be re-inserted into the packaging and the monitor will display "Remove Cassette." Grasp and remove the sleeve containing the empty cassette. The chemical indicator on the cassette sleeve may have turned red due to the higher temperature in the machine.
- Discard the sleeves containing the empty cassettes as indicated in the disposal directions.
- If an UNUSED cassette extends or falls out of the sleeve, wear gloves to replace the cassette in the original sleeve and call ASP Customer Service.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 50 Sterilizer cycle time is approximately 45 minutes.
- **Refer to STERRAD® 50 Sterilizer System User's Guide for additional information.**

- OR -

For Use In The STERRAD® 100S Sterilizer Only.

Five (5) Cycles/Cassette

- Each cell contains not less than 0.592 fl. oz. (0.609 ± 0.017 fl. oz) [([1750 µL (1800uL ± 50µL)] of 59% hydrogen peroxide, which is a strong oxidizer and irritant.
- If the yellow indicator has turned red, the cassette might have been damaged. Do not remove plastic wrap. Call ASP Customer Service for Directions. Otherwise:
- Remove plastic wrap.
- Remove cassette from box.
- Insert the cassette sleeve into the STERRAD® 100S Sterilizer.
- The cassette will be accepted automatically.
- After the sterilization chamber has been properly loaded and the biological and chemical indicators are in place, you are ready to start the sterilization cycle. The STERRAD® 100S Sterilizer cycle time is approximately 55 minutes.
- **Refer to STERRAD® 100S Sterilizer System User's Guide for additional information.**

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This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Store upright at all times. Keep product in its original packaging at a controlled room temperature, between 15° - 30°C (59° - 86°F). Do not expose product to direct sunlight, radiant heat, powdered metals, permanganates, cyanide, hexavalent chromium compounds, other oxidizers, reducers, combustible materials or flammable vapors.

PESTICIDE DISPOSAL: Bottles: If bottle contains less than 50 mL, empty contents into sink with running water according to local regulatory agency requirements or dispose as hazardous waste. **Bottles and Cassettes:** Hydrogen peroxide is classified as a DOT oxidizer and a hazardous waste under US EPA hazardous waste regulation and it is a violation of Federal law to improperly dispose of pesticides. If these wastes cannot be disposed of by use or according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Cassettes: Discard empty container per the policy of the institution or facility. **Bottles:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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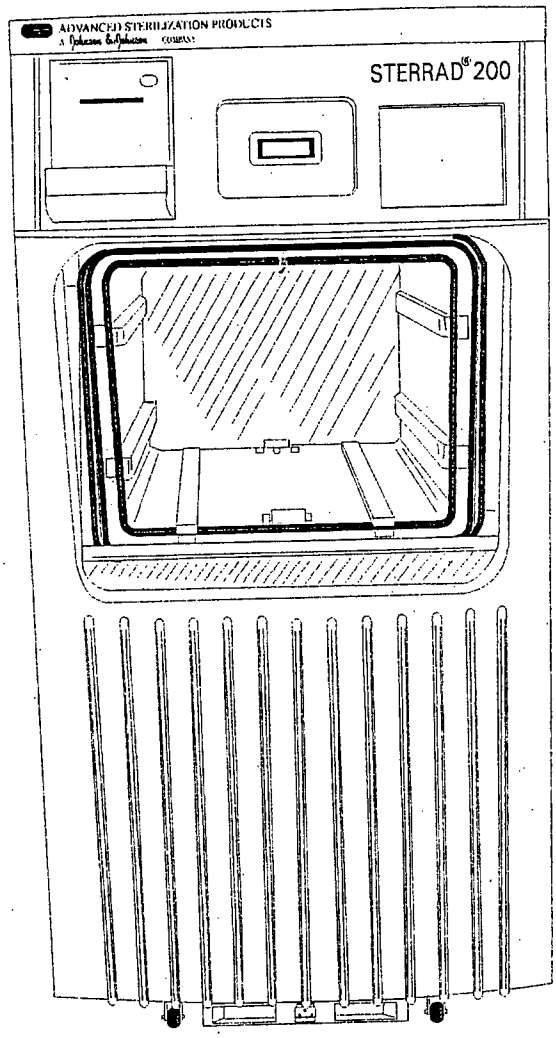
STERRAD® 200 Sterilization System

User's Guide



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User's Guide

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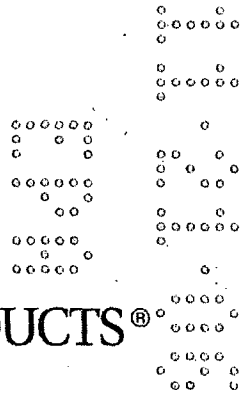

ADVANCED STERILIZATION PRODUCTS®

a Johnson & Johnson company

Division of Ethicon, Inc.

33 Technology Drive
Irvine, California 92618 USA
1-888-STERRAD
(1-888-783-7723)
949-581-5799

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About This Guide

In this chapter . . .

- *overview of this guide*

Overview

This guide is designed to provide useful and complete information on the day-to-day operation and routine maintenance of the STERRAD® 200 Sterilizer.

The guide is divided into 7 chapters and 2 appendices. These chapters provide information on using the sterilizer, load preparation, routine maintenance, and troubleshooting the system should problems arise. The appendices contain the system specifications and warranty information.

The chapters and appendices are:

- **About This Guide**-this section gives you important information on how to get the most use out of this guide.
- **Chapter 1. Introduction**-the first chapter of the guide has important details about the STERRAD 200 System including the major parts of the sterilizer and STERRAD Process information.
- **Chapter 2. For Your Safety**-this may be the most important chapter in the guide. You must read it thoroughly, understand the information, and follow all the safety procedures in this chapter. These safety procedures include safe handling of cassettes, safe transfer of sterilized materials using the two-tier shelf and carriage, and first aid information in case of possible hydrogen peroxide exposure.
- **Chapter 3. Preparing Items To Be Sterilized**-this chapter provides details on preparing items to be sterilized, packaging the load, using the two-tier shelf and carriage to transfer the load to the sterilizer and a brief description of the items that can be sterilized in the STERRAD 200 System.
- **Chapter 4. Day-to-Day Operation**-this chapter gives you detailed information on how to use the sterilizer. It shows you the typical displays that you will see as you use the sterilizer and the different screens available to the operator and administrator level passwords. It details how to use the touch screens and how to run cycles.
- **Chapter 5. Routine Maintenance**-the routine maintenance of the STERRAD 200 Sterilizer is very minimal. This chapter shows you how to change the printer paper and ribbon and what steps to follow to keep the sterilizer clean.

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- **Chapter 6. Troubleshooting**-the STERRAD 200 Sterilizer displays a number of messages to tell you what the system status is at any given moment. Many of these messages do not require any action from you. Others require that you call your ASP service representative.

- **Chapter 7. Compatible Devices**-this chapter provides you with information on how you can get an up-to-date list of compatible devices and device manufacturers.

- **Appendix A. Specifications**-this appendix provides tables detailing the technical data relevant to the STERRAD 200 Sterilizer. Size, electrical requirements, equipment rating and an explanation of the warning symbols used on the sterilizer are some of the information found in this appendix.

- **Appendix B. Warranty Information**- this appendix presents the commercial and service warranties.

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Chapter 1. Introduction

In this chapter . . .

- *system details*

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Overview

The STERRAD® 200 Sterilization System is a general purpose, low temperature sterilizer using the STERRAD 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.

The length of all cycle phases and the setpoints for all critical process parameters are controlled by a microprocessor and software. The system reliably sterilizes various material and load configurations, without leaving toxic residue.

The system consistently provides 10^{-6} sterility assurance level, as defined by international standards, for clinical use on all allowed substrates within the limits of the claims for materials and geometries.

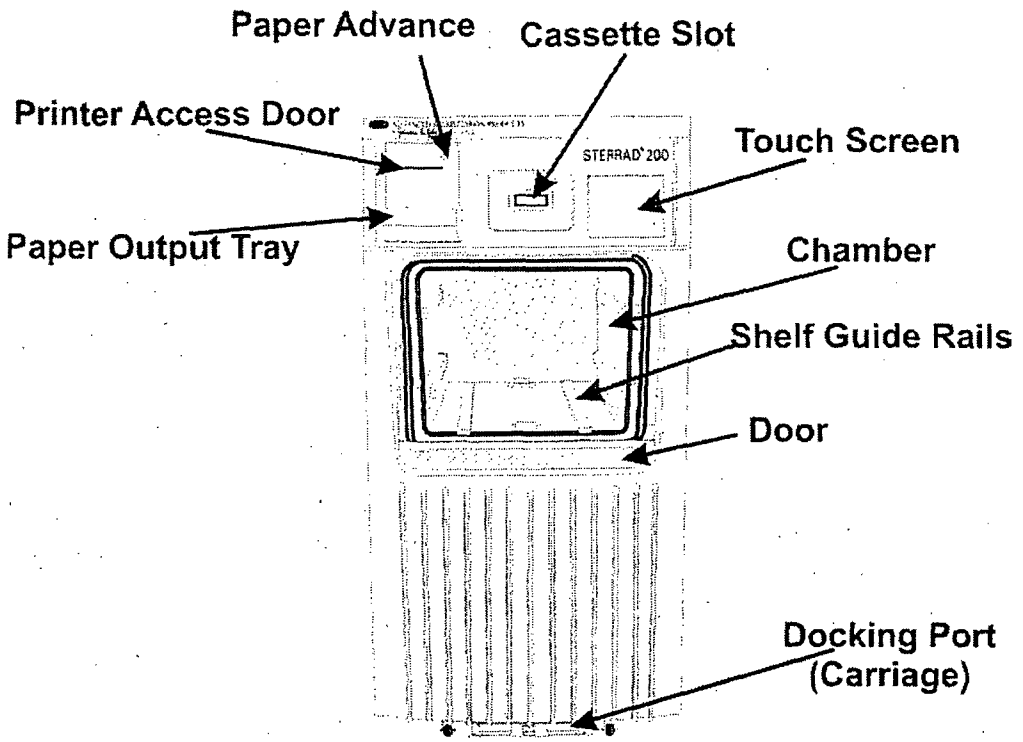

Figure 1. STERRAD® 200 Sterilizer input side on a two door unit, or front side on a one door unit.

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System Details

Here are details of the important parts of the STERRAD 200 Sterilizer.

- The items to be sterilized are placed on the two-tier shelf. The two tier shelf (see the following diagram) has 1 adjustable, removable shelf and a fixed bottom shelf. The packed two-tier shelf is easily moved, using the carriage, into or out of the sterilizer.

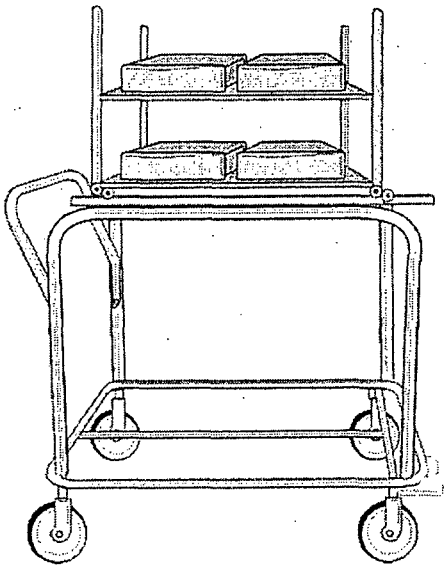

Figure 2. STERRAD® 200 Two-Tier Shelf and Carriage

- The carriage is used to move the two-tier shelf into position. This carriage is a wheeled unit that locks onto the front of the machine so that you can easily transfer a large load into or out of the sterilizer.

- Your system may have one or two doors. If you have a two-door unit, a door is located on each side of the unit. One side, the input side, is used for moving wrapped items to be sterilized into the sterilizer. The other side, the output side, is used to remove the sterile items from the sterilizer. These sterile items are then usually moved into a sterile storage area. On the one door unit, the door is used for both input and output.

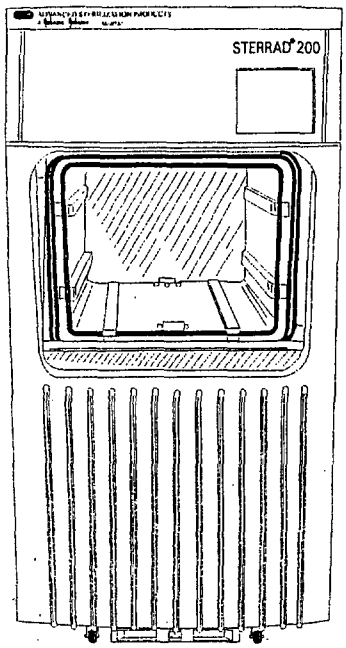

Figure 3. STERRAD® 200 Sterilizer–output side on a two door unit. Note the absence of a cassette slot.

- A touch screen computer display, mounted on the upper right front of the sterilizer, enables you to operate the sterilizer. There is a touch screen on each side of the double door unit.
- A printer, located on the upper left front panel of the unit, delivers printed messages, process parameters, and other information for your permanent records. There is usually only one printer on the unit regardless of the number of doors, however other printer options are available. Contact your ASP representative or ASP Customer Support for more details.
- There is an optional barcode scanner available for the sterilizer. The barcode scanner is used to conveniently enter barcoded data from product tags, labels or other items.
- The usable chamber capacity is approximately 150 liters.

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Chapter 2. For Your Safety

In this chapter . . .

- *personal safety and first aid*
- *device safety*
- *cassette handling*
- *safe maintenance*
- *additional information*

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Overview

Your safety is of primary concern to ASP. This chapter provides information on safely using the sterilizer. **You must read, understand and use the information in this chapter before operating the unit.** Also, always pay attention to the warnings, cautions and notes throughout this guide. This information is for your safety and to ensure that you receive the most benefit from the safe operation of your STERRAD® 200 Sterilization System.

Personal Safety and First Aid

- **WEAR LATEX OR VINYL GLOVES WHILE REMOVING THE ITEMS FROM THE STERILIZER AFTER A CANCELLATION. CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT.** If a cycle cancels and the items in the load have any visible moisture or liquid, hydrogen peroxide may be present.

- 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.

- Direct hydrogen peroxide contact with eyes can cause irreversible tissue damage. If eye contact occurs, immediately flush with large amounts of water and immediately consult a physician. Inhalation of mist can cause severe irritation of lungs, throat, and nose.

- If inhalation occurs, move to fresh air and consult a physician immediately. Ingestion can produce corrosion that may be life threatening. If swallowed, drink plenty of water immediately to dilute. Do not induce vomiting. Consult a physician.

- The vaporizer may be hot. Do not touch it with your bare or gloved hands.

Device Safety

- **DO NOT ATTEMPT TO STERILIZE ITEMS OR MATERIALS THAT DO NOT COMPLY WITH THE GUIDELINES SPECIFIED IN THIS GUIDE.** In addition, you should read the medical device manufacturer's instructions, or call ASP Customer Support to determine whether an item can be sterilized by this unit. Information may also be obtained from the device manufacturer.
- All items must be cleaned and thoroughly dried before loading into the sterilizer. Loads containing moisture may cause cycle cancellation.
- The chapter on preparing items to be sterilized contains information about the materials and devices that can be processed by the STERRAD 200 Sterilizer.
- 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 instruments.
- Do not change the power source without checking the electrical phase rotation. Prior to relocating the STERRAD 200 Sterilizer to a new power source, electrical phase rotation should be checked by a qualified technician. Failure to verify and match phase rotation may cause damage to the sterilizer and voids the warranty.
- If you plan to disconnect and store the sterilizer for any length of time, please contact your ASP service representative at 1-888-STERRAD (1-888-783-7723) for instructions.
- An ASP-approved biological indicator should be used to monitor the sterilization cycle. Should a cancellation occur when a biological indicator is in the chamber, discard the biological indicator and then use a new biological indicator when re-starting the cycle. Call ASP Customer Support for information on approved biological indicators.

Cassette Handling

- **STERRAD 200 CASSETTES CONTAIN CONCENTRATED HYDROGEN PEROXIDE, A STRONG OXIDIZER. CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT.** Direct 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. Direct contact with eyes can cause irreversible tissue damage. If eye contact occurs, immediately flush with large amounts of water and immediately consult a physician. Inhalation of mist can cause severe irritation of lungs, throat, and nose. If inhalation occurs, move to fresh air and consult a physician immediately. Ingestion can produce corrosion that may be life threatening. If swallowed, drink plenty of water immediately to dilute. Do not induce vomiting. Consult a physician.

- Do not remove the plastic wrapper from the cassette package if the indicator strip is red. Red indicates that the cassette might have been damaged. Call ASP Customer Support for credit.

- Do not remove used cassettes from the protective cardboard sleeve. Dispose of the cassette inside the protective sleeve according to your facility's procedures.

- If it is necessary to handle a used cassette that is not in the cardboard sleeve, wear latex or vinyl gloves. Do not touch your gloved hands to your face or eyes.

- Empty or expired cassettes must be replaced prior to starting the cycle.

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Safe Maintenance

- Repairs and adjustments should only be attempted by experienced technicians who are fully trained to maintain and repair the STERRAD 200 Sterilizer.
- Use of unauthorized parts for maintenance or repair could cause personal injury, result in costly damage or unit malfunction, and void the warranty.
- Do not clean the chamber door area with abrasives. The sterilization chamber uses an O-ring vacuum seal to maintain a vacuum in the chamber. Never use rough cleaning tools, such as a wire brush or steel wool, on the door housing or chamber assembly. This could damage the seal.

Additional Information

- The information contained in this chapter is repeated where appropriate throughout this guide for your safety and use. This information is subsequently labeled: WARNINGS, Cautions or Notes as appropriate.
- **WARNINGS** are shown in the text in all bold upper case letters. They indicate events or conditions that can result in serious injury or death.
- **Cautions** are shown in the text in bold letters. They indicate events or conditions that can result in damage to equipment.
- Notes are shown in the text with a check mark ✔. They highlight specific information about the proper use and maintenance of the STERRAD 200 Sterilizer.

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Chapter 3. Preparing Items To Be Sterilized

In this chapter . . .

- *indications for use*
- *how to determine what can be sterilized in the STERRAD® 200 Sterilizer*
- *items not recommended*
- *cleaning, rinsing and drying*
- *guidelines for wrapping and packaging*

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Overview

The STERRAD® 200 Sterilizer can process many of the items you commonly sterilize as well as instruments that are sensitive to heat and moisture. However, there are a few important exceptions. Please review the "How to Determine What Can be Sterilized in the STERRAD 200 System" fold-out page contained in this chapter. It contains details on recommended materials and lumen sizes.

Indications for Use

The STERRAD 200 Sterilizer is designed for sterilization of both metal and nonmetal medical devices at low temperatures. Because the cycle operates within a dry environment and at low temperatures, it is especially suitable for instruments sensitive to heat and moisture. The sections that follow contain more information on the types of items and materials that can be sterilized in the STERRAD 200 Sterilizer.

- The STERRAD 200 Sterilizer can sterilize instruments having diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Teflon® or polyethylene lumened instruments with inside diameters of 6 mm or larger and lengths of 310 mm or shorter can be processed in the STERRAD 200 Sterilizer.
- Medical devices with only a single stainless steel lumen with:
  - » an inside diameter of 1 mm or larger and a length of 125 mm or shorter,*
  - » an inside diameter of 2 mm or larger and a length of 250 mm or shorter,*
  - » an inside diameter of 3 mm or larger and a length of 400 mm or shorter.

  can be processed in the STERRAD 200 Sterilizer.

*Validation testing for this lumen size was conducted using a maximum of 12 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing.

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✔ *Note: The validation studies for this sterilizer were performed using the STERRAD cycle consisting of a 6-minute, 45-second injection phase followed by a 2-minute diffusion phase, and a 2-minute plasma phase. The validation studies were performed using a validation load consisting of four instrument trays, each weighing 9.12 lbs. (the total weight of the load was 36.48 lbs.).*

✔ *Note: Determination of true length is based upon actual instruments identified as intended for reprocessing and meet all other criteria for processing in the STERRAD 200 Sterilizer.*

WARNING! DO NOT ATTEMPT TO STERILIZE ITEMS OR MATERIALS THAT DO NOT COMPLY WITH THE GUIDELINES SPECIFIED IN THIS GUIDE. IN ADDITION, YOU SHOULD READ THE MEDICAL DEVICE MANUFACTURER'S INSTRUCTIONS, OR CALL ASP CUSTOMER SUPPORT TO DETERMINE WHETHER AN ITEM CAN BE STERILIZED BY THIS UNIT.

How to Determine What Can be Sterilized in the STERRAD® 200 System

The following page is a chart that unfolds to show you detailed lists of recommended items, materials, and some typical devices that can be sterilized in the STERRAD 200 Sterilizer. You should refer to it whenever you need materials information. Be sure to check with the medical device manufacturer's instruction before loading any item into the STERRAD 200 Sterilizer.

- **Important!** Stainless steel, polyethylene, and Teflon® are the only types of lumens that can be sterilized in the STERRAD 200 Sterilizer.

✔ *Note: There is a wide variety of materials and devices that can be sterilized in the STERRAD 200 Sterilizer. As more manufacturers complete testing of their products with the STERRAD 200 Sterilizer, the range of recommended and/or compatible items grows. Because of that, the information in the table included in this publication will be updated as new information becomes available. ASP maintains this updated information and we are happy to share it with you. Please contact ASP Customer Support for an up-to-date list of recommended materials, devices and/or device manufacturer information. Call 1-888-STERRAD (1-888-783-7723).*

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How To Determine What Can Be Sterilized In The STERRAD® 200 Sterilizer

1 Is The Reprocessable Medical Device Made Of The Following Materials?**

** This list of materials does not apply to trays and containers or other packaging materials. Please refer to the STERRAD® 200 User's Guide for information on appropriate packaging materials for use in the STERRAD System.

- Aluminum
- Brass
- Delrin® acetal resin (polyacetal)†
- Ethylvinyl acetate (EVA)
- Glass
- KRATON™ Polymers
- Neoprene†
- Non-mated Nylon® (polyamide)†
- Polycarbonate
- Polyethylene
- Polyetherimide (ULTEM® Polymers)
- Polymethyl methacrylate (PMMA)††
- Polyphenylene sulfone (Radel®)†
- Polypropylene
- Polystyrene
- Polyurethane
- Polyvinyl chloride (PVC)
- Silicone elastomers
- Stainless steel
- Teflon® (polytetrafluoroethylene)
- Titanium

† *May have limited life after repeated sterilization.*

Delrin®, Nylon®, and Teflon® are registered trademarks of the DuPont Corporation.
KRATON™ Polymers is a trademark of KRATON Polymers U.S. L.L.C.

ULTEM® Polymers is a registered trademark of the GE Company.

†† Contact ASP or the device manufacturer to determine the compatibility of any device manufactured from PMMA.

No/Don't Know → *Please call the device manufacturer for information on how to properly sterilize this device.*

Yes

2 Does The Reprocessable Medical Device Have A Lumen?

No → Proceed with Processing.

Yes

3 Is The Lumen Made Of Stainless Steel, Or Teflon®?

No/Don't Know → Please call the device manufacturer for information on how to properly sterilize this device.

Yes

4 Proceed With Processing If The Lumen Conforms To The Dimensions Listed Below

Stainless Steel Lumen	
Inside Diameter	Length
1 mm or larger	125 mm or shorter*
2 mm or larger	250 mm or shorter*
3 mm or larger	400 mm or shorter

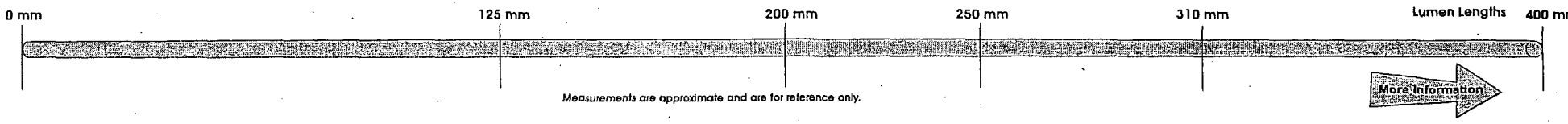
Teflon®/Polyethylene Lumens	
Inside Diameter	Length
6 mm or larger	310 mm or shorter

* Validation testing for this lumen size was conducted using a maximum of 12 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing.

If the lumens do not conform to these dimensions, please call the device manufacturer for information on how to properly sterilize these devices. Lumens not conforming to these dimensions should not be processed in the STERRAD 200 Sterilizer.

Inside Lumen Diameters

- 1 mm (0.039 inches)
- 2 mm (0.078 inches)
- 3 mm (0.118 inches)
- 4 mm (0.157 inches)
- 5 mm (0.196 inches)
- 6 mm (0.236 inches)



Measurements are approximate and are for reference only.

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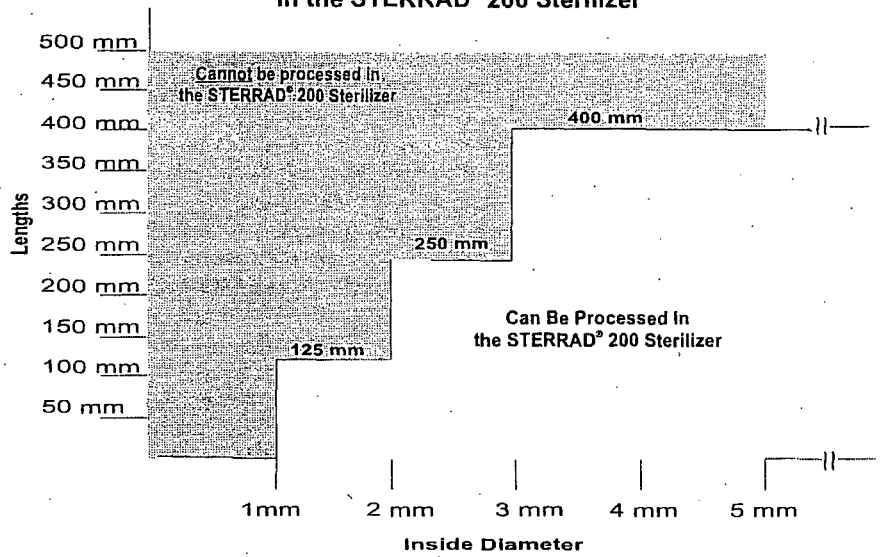
Processing Stainless Steel Lumens in the STERRAD® 200 Sterilizer



Typical Devices Sterilized in the STERRAD® 200 Sterilizer*

- Stereotactic equipment
- Defibrillator paddles
- Electrocautery instruments
- Esophageal dilators
- Cranial pressure transducer cables
- Metal instruments
- Patient lead cables
- Endoscopic instruments
- Rigid endoscopes
- Laryngoscope blades
- Trocar sheaths
- Cryoprobes
- Surgical power equipment and batteries
- Fiberoptic light cables
- Laser hand-pieces, fibers, and accessories
- Ophthalmic lenses (diagnostic, magnifying)
- Pigmentation hand-pieces
- Dopplers
- Shaver hand-pieces
- Radiation therapy equipment
- Ultrasound probes
- Video cameras and couplers
- Resectoscope/working elements and sheaths

If you have questions about whether your particular device can be sterilized in the STERRAD Sterilizer, please call the device manufacturer or call ASP at 1-888-STERRAD. Visit our website at www.sterrad.com.

* Any devices processed in the STERRAD 200 Sterilizer must be within the claim limits of the sterilizer.

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Items Not Recommended

- Items made with copper or copper alloys (such as Monel), should not be used. Please contact ASP Customer Support at 1-888-STERRAD for more information.
- Instrument mats other than STERRAD Instrument Mats.
- Instrument trays other than STERRAD Instrument Trays or APTIMAX® Instrument Trays.
- Any item that is not completely dry.
- 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.
- Liquids and powders.
- Items with mated, Nylon® surfaces.
- Single use items for which the manufacturer does not recommend resterilization.
- Implants for which the manufacturer has not specifically recommended sterilization in the STERRAD 200 Sterilizer.
- 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.
- 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 200 Sterilizer.

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Cleaning, Rinsing, Drying, and Loading

✔ *Note: All items must first be cleaned, rinsed, and thoroughly dried before being placed in the sterilizer.*

Cleaning and sterilization are two separate processes. Thorough cleaning is essential for assurance of sterilization by all sterilization methods, including the STERRAD 200 Sterilization System.

The process of cleaning is necessary to remove organic and inorganic soil and debris from equipment. In this process, many of the microorganisms are removed from the surface of the instrument. The process of sterilization inactivates all of the remaining spores and living 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. It is necessary to remove moisture from all parts of the items. Only dry items should be loaded into the sterilization chamber.

✔ *Note: Loads containing moisture may cause a cycle cancellation.*

✔ *Note: As with all sterilization methods, proper cleaning of instruments and devices is a critical and necessary step prior to sterilization. All items must be cleaned and thoroughly dried before loading into the sterilizer. You should carefully inspect all instruments and devices for cleanliness and dryness and for flaws or damage prior to packaging. If visual soil or moisture is present, then the devices and instruments should be re-cleaned and dried prior to sterilization in the STERRAD Process. Devices and instruments with flaws or damage should be replaced or repaired before using.*

Caution: ***As with any disinfectant/cleaning/sterilization system, periodic careful inspection of the devices after repeated exposure to the disinfectant/cleaner/sterilant is necessary, due to potential damaging effects of the chemical agent on the devices.***

Guidelines for Wrapping, Packaging, and Loading

Proper preparation of trays, pouches, and instruments can minimize or prevent cycle cancellation and positive BI results due to load-related problems.

- Only STERRAD and APTIMAX® Instrument Trays and STERRAD Accessories are recommended for use in the STERRAD 200 Sterilizer. STERRAD and APTIMAX® Instrument Trays are specially designed to allow diffusion of hydrogen peroxide and the plasma around all the items in the load. The trays should only be padded with STERRAD Instrument Tray Mats or polypropylene sterilization wrap. Do NOT use linen, cellulosic, or any materials shown in the "Items Not Recommended" list. Follow the instructions for use included with the STERRAD Instrument Tray Mats to determine the number of mats that can be used at one time in the chamber.

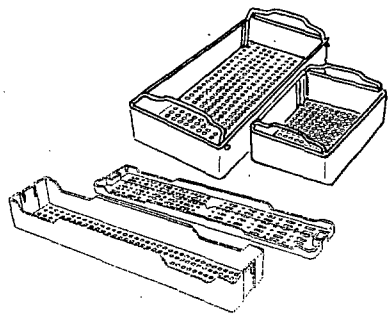

Figure 4. Use only STERRAD® Instrument Trays and APTIMAX® Instrument Trays

- Improper loading of the sterilizer may result in cycle cancellations and/or positive biological indicator results.
- Configure loads with a combination of metal and nonmetal items, and wrapped trays and pouches to maximize the efficiency of the cycle.
- Do not use foam pads in instrument trays. They may absorb the hydrogen peroxide.
- Do not use any wraps or packaging that are not approved by ASP and listed in the previous section on "items not recommended."

- Use only STERRAD 200 Sterilizer compatible polypropylene sterilization wrap and Tyvek® pouches. Do not use paper pouches or sterilization wraps containing cellulose or cotton.
- Place STERRAD Chemical Indicator Strips inside trays and Tyvek® pouches.
- Secure all wraps with STERRAD SealSure™ Chemical Indicator Tape.
- Arrange items to ensure that the hydrogen peroxide and plasma can contact all surfaces.
- Place peel pouches loosely 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 allow any item to touch the walls of the sterilization chamber, doors, or electrode.

✔ *Note:: 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.*

✔ *Note: If you are using rigid containers cleared by the FDA for use in the STERRAD System, follow the same procedures that are recommended for use with the STERRAD 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.*

Caution: ***Metal objects must not come into contact with the walls of the sterilization chamber, door, or electrode. Contact with the walls, door, or electrode can interrupt the plasma phase of the process, cause a cycle cancellation, and/or damage the item or the sterilizer.***

- Provide at least 25 mm (1 inch) of space between the ceiling of the electrode and the top of the load.
- Place STERRAD CycleSure™ Biological Indicator or an ASP-approved biological indicator in the chamber. Frequency of biological testing should be at least once per day or in accordance with your hospital policy. Review the instructions included with the biological indicator to ensure proper use.
- Proceed to "Chapter 4. Day-to-Day Operation" for information on starting a cycle.

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Chapter 4. Day-to-Day Operation

In this chapter . . .

- *safe operation*
- *sterilizer operation*
- *preparing the load*
- *biological indicators*
- *starting a cycle*
- *unloading and handling*
- *cassette control*
- *obtaining a cycle history*
- *administrative functions*

Safe Operation

Before operating the STERRAD® 200 Sterilizer, you must thoroughly *read, understand and follow* the information in "Chapter 2. For Your Safety" as well as "Chapter 3. Preparing Items for Sterilization."

Sterilizer Operation

The STERRAD 200 Sterilizer automatically monitors and controls the sterilization process. The STERRAD 200 Sterilizer reports its status in three ways:

- **Touch Screen (flat panel, high color VGA Display)**–The display indicates the status of the unit at all times the unit is powered on. It also indicates the time remaining to cycle completion. There is a display on each side of the sterilizer in the two door configuration. The display on the output side may not be active at all times and may not allow you to perform as many functions as on the input side.

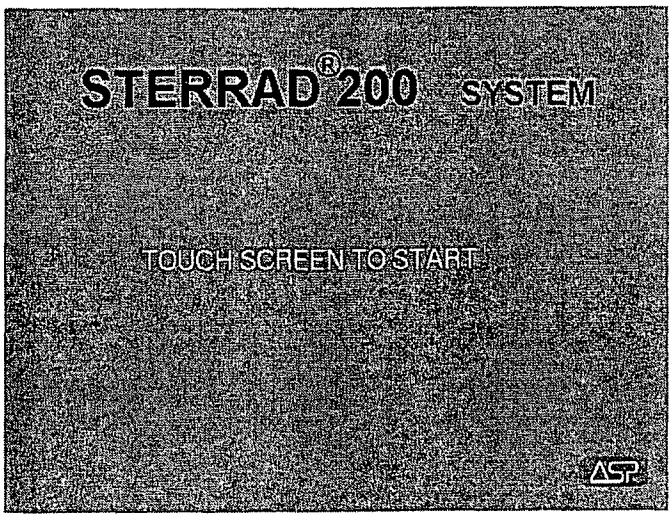

Figure 5. Main Display. Touch anywhere to begin.

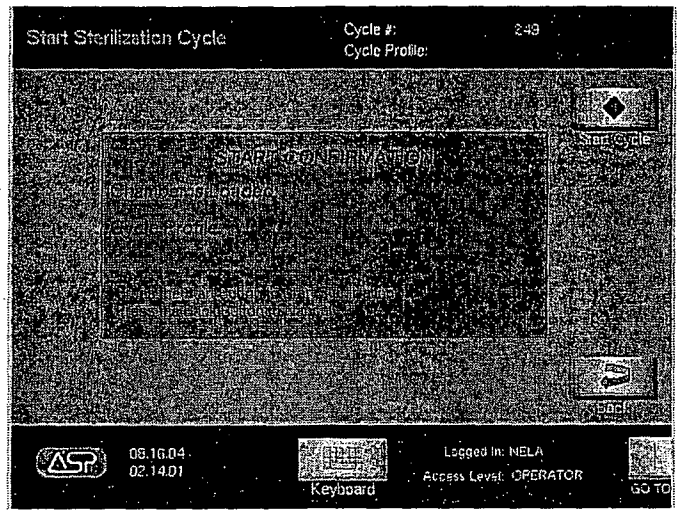

Figure 6. Touch Start Cycle to begin sterilization. This display is seen after log in and the Load Item Data display. Your display may be slightly different. Touch Back to return to the Load Item Data display.

- **Paper printout**–A printed record is produced after each cycle completion or cancellation. This is a record of the cycle parameters and may be kept for your records. The print should be completely black. Red print indicates a problem with the cycle. The printer is located behind the printer door on the upper left panel on the input side.

- **Beeps**–Beeps alert you when a cycle is complete, or a cancellation has occurred. A long beep indicates a complete cycle.

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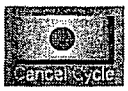
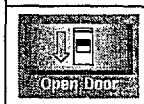
Display Sequence

Following is an abbreviated version of the displays that appear, and the steps required, during the start-up, processing, and the completion of a cycle.

- Log in on the input side (if login is enabled).
- Load items into the sterilizer.
- Enter load item data (if desired and if login is enabled).
- Start the cycle.
- Cycle completes. System logs the user out from the input side.
- Log in required on the output side (if enabled).
- Review the cycle summary results.
- Log out.

Using the Displays

The following table presents typical buttons that you use to perform tasks related to sterilizing your instruments or to actually starting the sterilization cycle. These buttons do not appear on all displays. On two door units, the current display is shown on both sides. However, only one side at a time has an active touch screen. The active side is the input side when items are being loaded, load item data is being entered and the cycle is in progress. The output side is the active side when a cycle has completed successfully and the load can be removed.

Button	Function
	Touch to begin the sterilization cycle.
	Touch to cancel a cycle or any other operation.
	Touch to open the sterilizer door. This button is only available when the cycle is not running. The door it controls is the door on the active side. You cannot open both doors at once. The Close Door button has the arrow pointing upwards.
	Touch to return to the previous display.
	Touch to confirm an action you have taken.
	Touch to open the Function Button Bar. This button bar has different button choices depending on whether the system is running a cycle, is being serviced, or is idle.
	Touch to log in to the system prior to running a cycle. Also, allows you to log out from the system.
	In the password administration display, touch this button to add a new user. You may not have access depending on your password level.

Button	Function
	In the password administration display, touch this button to modify existing information for the selected user; i.e., password, etc. You may not have access depending on your password level.
	Touch to open the system configuration display. You may not have access depending on your password level.
	Allows input of settings for connection to a computer network. You may not have access depending on your password level. You must contact your ASP service representative prior to performing this set-up.
	Touch to change the date and/or time. This button appears on the Function Button Bar on systems configured to operate without ID and password login.
	Touch to display the utilities menu. This menu includes, Cycle History, File Management, System Set-up and Diagnostics. You may not have access to all menus choices depending on your password level.
	Touch to open the Cycle Notes display. Enter text relevant to the load that is being processed. These notes are only applicable to the current cycle and can be printed.
	Touch to print the information displayed.
	Touch to collapse the Function Button Bar. (**GO TO...** is displayed when the Function Button Bar is closed.)
	Touch to expand or collapse the virtual keyboard. This button may not be available on all displays.

Function Button Bar Displays

The Login button is explained in the section on passwords. Touching **Close** collapses the Function Button Bar. The other buttons are explained in the preceding table. An alternate Function Button Bar is only seen when the system has been configured at installation to operate without an ID or a password. With this configuration, the date and time function is available to the operator. If the system is configured to require an ID and password, the date and time function is part of the system setup menu and is available to Administrator level passwords (or higher) by pressing the **Utilities** button.

- Pressing **Utilities** displays a login screen.
- The other buttons function in the same manner as previously explained.

Preparing the Load

Proper preparation of trays, pouches, and instruments can minimize or prevent cycle cancellation due to load-related problems. The two-tier shelf may be used in two ways: it can be used with the carriage to transfer the load into, and remove it from, the sterilizer. It may also remain in the sterilizer and the items to be sterilized can be placed on the two-tier shelf without the use of the carriage. Regardless of whether the carriage is used, the two-tier shelf *must* be used. Items cannot be placed in the sterilization chamber without using the two-tier shelf. More information on load preparation is found in "Chapter 3. Preparing Items for Sterilization."

- Arrange the items in a tray to ensure that the hydrogen peroxide and plasma can surround them. Do not stack basins within the trays.
- Place trays flat on the two-tier shelf. Do not stack trays.
- 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 allow any item to touch the walls of the sterilization chamber or the electrode.
- The load must not project above the top or beyond the edges of the two-tier.
- When needed, place an ASP-approved biological indicator in the sterilization chamber at the back of the bottom shelf.
- Provide at least 25 mm (1 inch) of space between the electrode and the top of the load.

✔ *Note: Do not stack instrument inside the trays. Do not stack trays. Do not stack trays within trays. Do not wrap instruments within the trays.*

✔ *Note: If you are using rigid containers cleared by the FDA for use in the STERRAD System, follow the same procedures that are recommended for use with the STERRAD 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.*

CAUTION: 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 instruments.

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. Frequency of biological testing should be at least once per day or in accordance with your facility's policy.

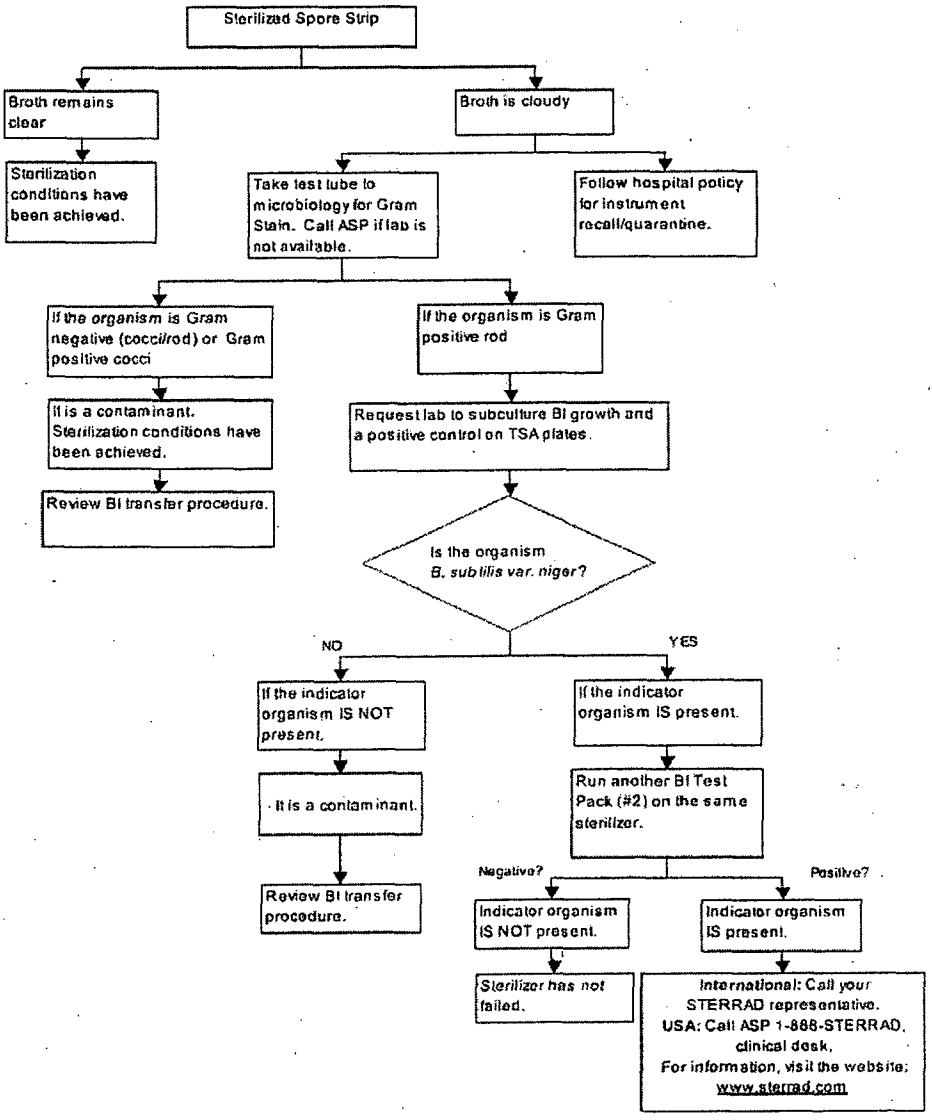
- Contact your ASP Representative regarding biological indicators specifically designed for use in STERRAD Sterilizers.

ASP Biological Indicators contain microorganisms that are known to be resistant to the sterilization process and are one way to verify proper processing. The biological indicator should be placed on the two-tier shelf, at the back part of the bottom shelf. Review the instructions that are included with the biological indicators for proper use. Should a cancellation occur when a biological indicator is in the chamber, discard the biological indicator and use a new biological indicator when starting the next cycle.

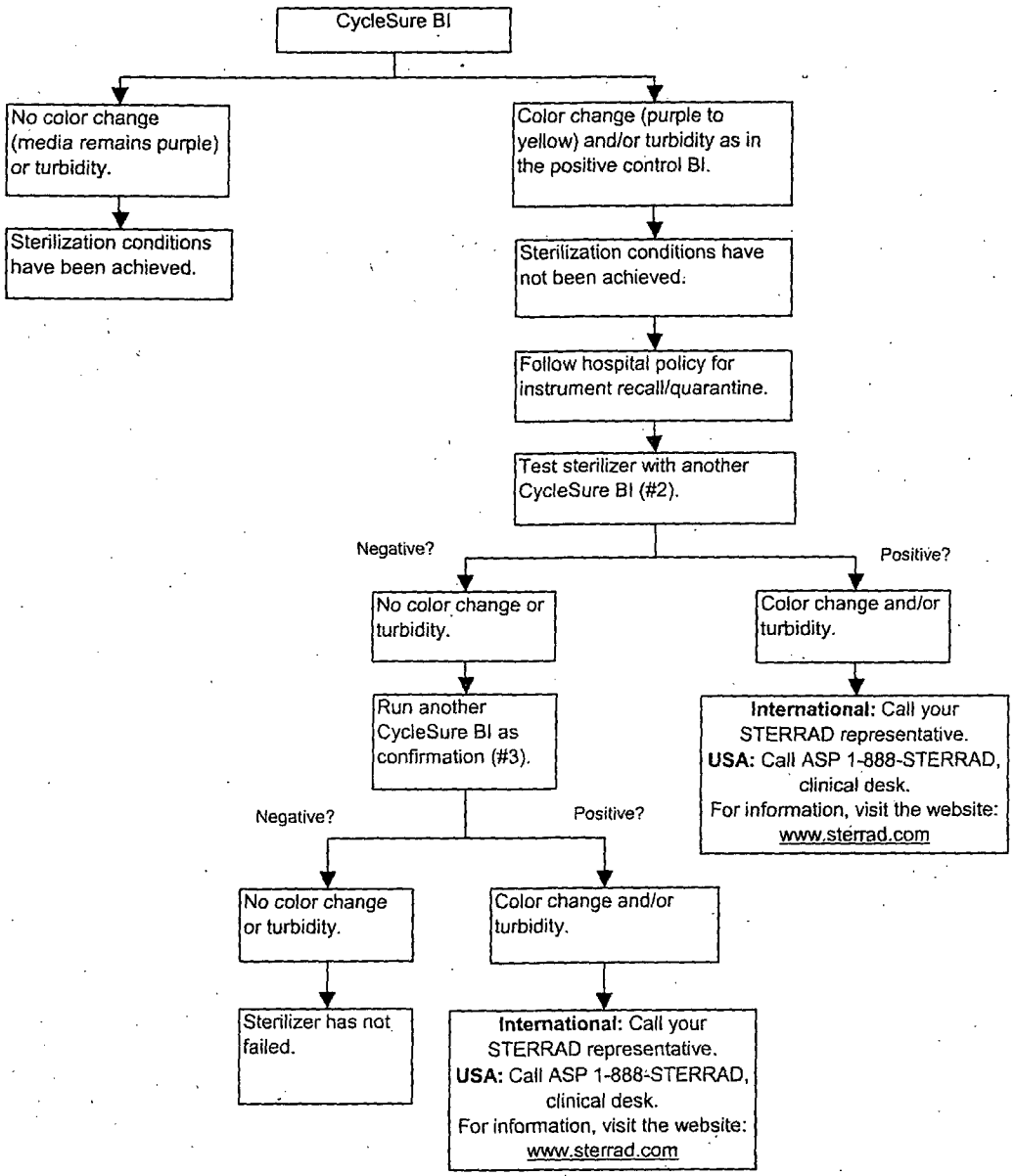
Suspected Positive BI

The following flowcharts detail the steps you need to follow when a positive biological indicator result is received. The flowcharts detail the procedures for both the STERRAD BI Test Pack and for the STERRAD CycleSure™ Biological Indicator.

STERRAD® BI Test Pack



STERRAD® CycleSure™ Biological Indicator



Chemical Indicators

STERRAD Chemical Indicator Strips and STERRAD SealSure™ Chemical Indicator Tape offer additional ways to verify processing in the sterilization cycle. They should be used in addition to, not in place of, the biological indicator. STERRAD Chemical Indicator Strips and STERRAD SealSure™ Chemical Indicator Tape *do not* indicate sterilization; they only indicate that the indicator has been exposed to the hydrogen peroxide. The color of the Chemical Indicator Strips and Tape changes from red to gold (or lighter) when exposed to hydrogen peroxide.

✔ *Note: Use only ASP biological indicators, STERRAD SealSure™ Chemical Indicator Tape, and/or STERRAD Chemical Indicator Strips. Do not use indicators designed for other sterilization processes.*

Using Chemical Indicator Strips

Place STERRAD Chemical Indicator Strips in trays and pouches to show exposure to hydrogen peroxide during the sterilization cycle. Please refer to the *Instructions for Use* included with the STERRAD Chemical Indicator Strips for more information.

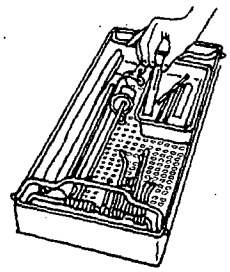


Figure 7. STERRAD® Chemical Indicator Strips should be used in each instrument tray.

Using Chemical Indicator Tape

STERRAD SealSure™ Chemical Indicator Tape should be used to secure the polypropylene sterilization wrap around the instrument tray.

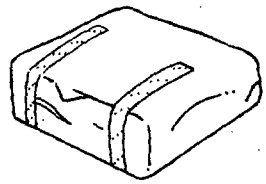


Figure 8. STERRAD® SealSure™ Chemical Indicator Tape should be used to secure the polypropylene wrap around each instrument tray.

Please refer to the *Instructions for Use* included with the STERRAD SealSure™ Chemical Indicator Tape for more information.

Preparing the Two-Tier Shelf

The procedures listed here must be followed for safe placement of the trays and pouches on the two-tier shelf when used with the carriage.

- Make sure the two-tier shelf is fully seated on the carriage and locked to the carriage before placing items on the two-tier shelf. The alignment wheels on the bottom of the two-tier shelf should be on the outside of the carriage rails.
- Place items on the two-tier shelf so that the items do not protrude from the sides, the back, the top, or the front. The two-tier shelf may be loaded from any position that is comfortable.
- Do not stack trays on top of each other.
- Do not place pouches directly on the shelves.
- When the carriage has been unloaded, it should be located in areas where it will not impede foot traffic. Follow your facility's policy for storage of such items.
- If the two-tier shelf is being used without the carriage, it must remain inside the sterilizer and be firmly locked in place.

Creating the Load Item Data List

The following steps assume that your sterilizer has been configured to use a password and a load list, and that you have logged into the system (see the section on "Starting a Cycle" for complete login information). If it does not require a load list, you may skip this section and go directly to the section on transferring the load into the sterilizer.

1. Enter the ID and password information as shown later in this chapter. The item list entry or load list display is shown. The load list can be entered in three ways:

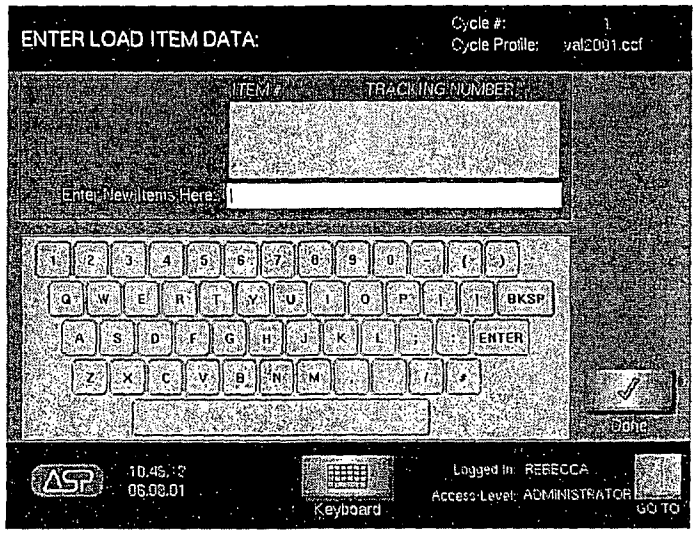


Figure 9. Type or scan load item data. Touch Keyboard to expand or collapse the keyboard display

WARNING! DO NOT LOOK DIRECTLY AT THE LIGHT IN THE SCANNER HEAD. DO NOT POINT THE SCANNER AT PEOPLE.

- Scan a pre-determined list using barcodes and the barcode scanner. Point the scanner head at the barcode and touch the button. An audible beep is heard when the barcode is successfully read. The red light must cover the barcode from left to right.

- Enter a list using the virtual keyboard and touching the "typewriter" keys on the display. After entering load item information touch **Enter**. A new line appears prompting you to enter the next item. As multiple items are entered, the list expands and up and down scroll arrows appear on the right hand side of the list.

- Use an external keyboard the same way as shown above to enter the information.

  ✔ *Note: The external keyboard must be attached and the system booted in order to function.*

2. Touch **Done** to complete the entry of the load list.

3. If you would like to enter additional information pertaining to the load such as the doctor's name, etc., follow this step. Otherwise you may go to step 5. Touch **GO TO...** to open the function button bar. Touch **Cycle Notes** to open the Notes display. Enter any text information that is exclusive to this load (use the up and down arrows to scroll through the information). This information can be printed separately by touching **Print**. It also prints as part of the process completion data.

4. Touch **Done** to complete the entry of the notes.

5. Touch **Start Cycle** to begin the cycle as shown in the "Starting a Cycle" section.

Transferring the Load into the Sterilizer

The load is easily transferred on the two-tier shelf into the sterilizer using the following steps:

1. Move the carriage containing the tray-filled two-tier shelf to the sterilizer.

   ✔ *Note: 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 instruments. The door should remain closed when not in use.*

2. Verify that the sterilizer status is ready to use and the door is open.

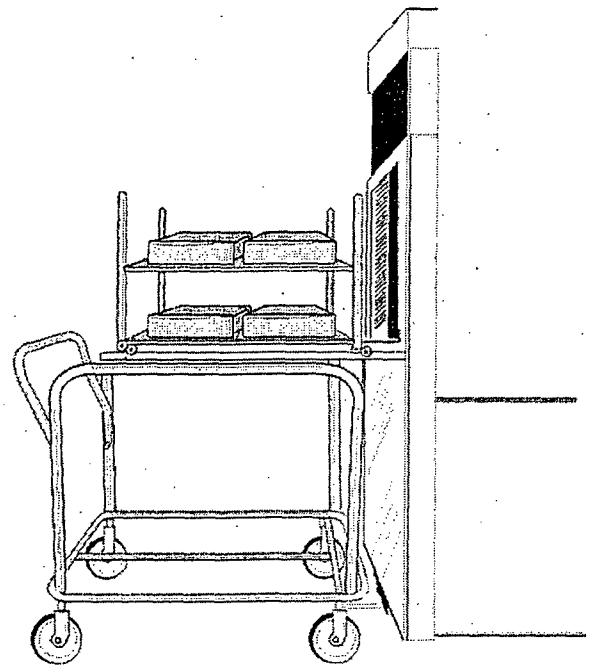


Figure 10. Make sure the carriage is completely seated and locked into the foot mechanism.

3. Gently push the carriage into the sterilizer so that the foot mechanism on the bottom of the sterilizer contacts and locks into the flange at the bottom of the carriage. The top front of the carriage rests just inside the chamber.

4. Release the two-tier shelf using the release. Gently push the two-tier shelf forward into the sterilizer. Make sure the alignment wheels are correctly positioned on the rails for smooth movement. Continue pushing until the two-tier shelf is completely inside the chamber and it engages the inside stop.

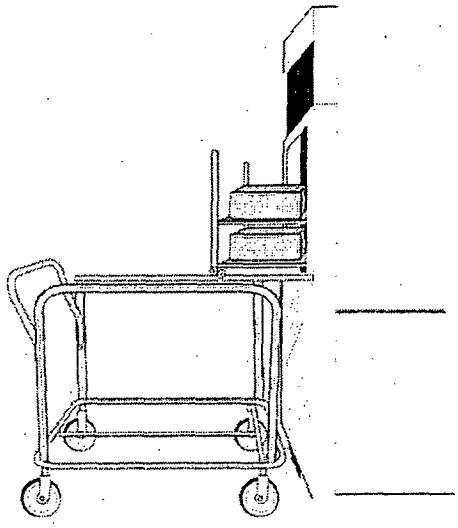


Figure 11. Push the two-tier shelf completely into the chamber.

5. Step on the carriage release and move the carriage to the desired location.

6. Verify that no part of the two-tier shelf or its contents comes in contact with the door or electrode. Close the door and begin your desired cycle or go to the section on "Inserting a Cassette."

Inserting a Cassette

The STERRAD 200 Sterilizer uses hydrogen peroxide, contained in special cassettes, to sterilize items placed into the sterilization chamber. Each STERRAD 200 Cassette provides enough hydrogen peroxide for 2 cycles. The message screen of the STERRAD 200 Sterilizer notifies you when a new cassette is needed.

WARNING! STERRAD 200 CASSETTES CONTAIN CONCENTRATED HYDROGEN PEROXIDE, A STRONG OXIDIZER. CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT. DIRECT 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.

DIRECT CONTACT WITH EYES CAN CAUSE IRREVERSIBLE TISSUE DAMAGE. IF EYE CONTACT OCCURS, IMMEDIATELY FLUSH WITH LARGE AMOUNTS OF WATER AND IMMEDIATELY CONSULT A PHYSICIAN.

INHALATION OF MIST CAN CAUSE SEVERE IRRITATION OF LUNGS, THROAT, AND NOSE. IF INHALATION OCCURS, MOVE TO FRESH AIR AND CONSULT A PHYSICIAN IMMEDIATELY.

INGESTION CAN PRODUCE CORROSION THAT MAY BE LIFE-THREATENING. IF SWALLOWED, DRINK PLENTY OF WATER IMMEDIATELY TO DILUTE. DO NOT INDUCE VOMITING. CONSULT A PHYSICIAN.

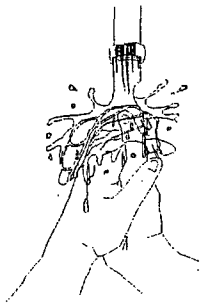


Figure 12. If skin contact occurs, immediately flush the area with water.

WARNING! DO NOT REMOVE THE PLASTIC WRAPPER FROM THE CASSETTE PACKAGE IF THE INDICATOR STRIP IS RED. RED INDICATES DAMAGE. CALL ASP CUSTOMER SUPPORT FOR CREDIT.

To insert a cassette, do the following:

5. Confirm that the sterilizer display indicates that a new cassette is needed.

6. Confirm that the chemical indicator strip on the cassette sleeve is NOT red; red indicates a damaged cassette and concentrated hydrogen peroxide may be present.

7. Confirm that the cassette expiration date has not passed.

✔ *Note: The system considers the cassette expired 8 days after insertion regardless of the printed expiration date. The cassette is ejected at that time. Once the cassette has been removed, even if it was not used, the barcode is rendered unreadable and the cassette cannot be reinserted.*

4. Remove the plastic wrapping from the cassette sleeve. Do NOT remove the cassette from the remaining cardboard sleeve.

5. Orient the arrow so that the top of the cassette sleeve is pointing away from you.

6. Hold the cardboard sleeve by its edges and insert it into the sterilizer.

7. Firmly push the cardboard sleeve in until it can go no further. If positioned properly, the cassette moves into place.

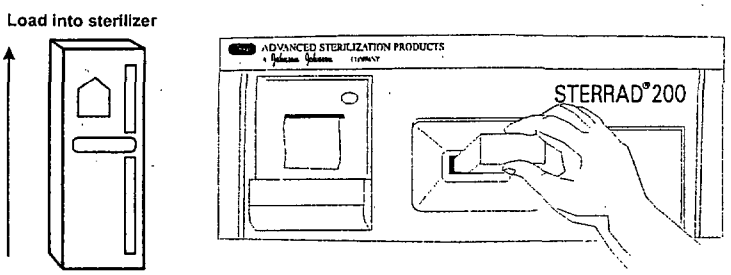


Figure 13. Insert the cassette and sleeve into the sterilizer. This illustration shows the printer on the input side. Your system may be different.

8. If the cardboard sleeve is not pushed in all the way, the monitor continues to read INSERT CASSETTE.

9. If the cardboard sleeve is properly positioned, the cassette is automatically accepted and positioned for use by the sterilizer. The display reads CASSETTE ACCEPTED.

10. If the cassette is not accepted because the barcode cannot be read or the cassette has expired, PLEASE REMOVE CASSETTE is displayed. Should this occur, remove that cassette and insert a valid one.

✔ *Note: The system microprocessor monitors the status of the cassette and informs the operator when the cassette is empty or expired. Empty or expired cassettes must be replaced prior to starting a cycle.*

WARNING! DO NOT REMOVE USED CASSETTES FROM THE PROTECTIVE CARDBOARD SLEEVE. DISPOSE OF THE CASSETTE INSIDE THE PROTECTIVE SLEEVE FOLLOWING YOUR FACILITY'S PROCEDURES. IF THE USED CASSETTE FALLS OUT OF THE SLEEVE, WEAR GLOVES TO PLACE THE PLASTIC CASSETTE BACK IN THE ORIGINAL SLEEVE.

Please refer to the *Instructions for Use* included with the STERRAD 200 Cassette for more information.

Starting a Cycle

✔ *Note: You must read, understand, and follow "Chapter 2. For Your Safety" prior to starting a cycle.*

This display appears following log out, or after power shut down. Touch the screen to view the displays needed to enter a password (if the system is configured for this function), enter a load item list (if the system is configured for this function), and start the sterilization process. The ability to perform certain functions prior to starting a cycle is determined by whether the system requires an ID and password. See the section on "Entering a Password" for more details.

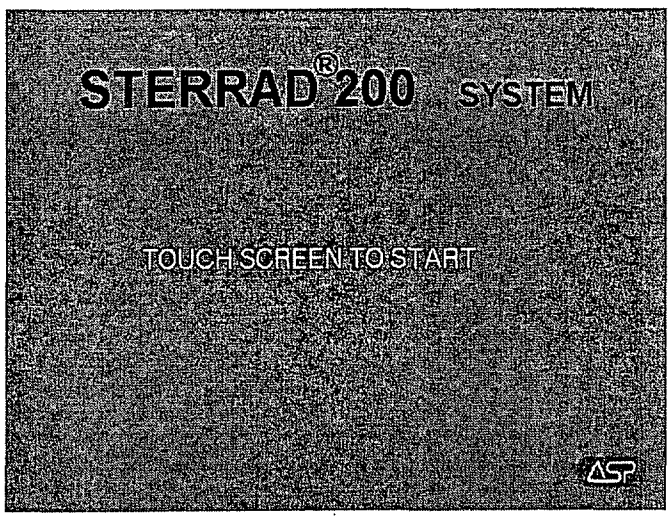


Figure 14. Touch the main display to begin.

Entering a Password

Your system administrator should assign you a log in ID and a password. You must use the ID and password in order to create a load list. You can log in to the system in 3 ways, (touch **Keyboard** to expand or collapse the virtual keyboard):

- Type your ID and password using the virtual keyboard and touching the keys.
- Type your ID and password using an external keyboard (the keyboard must be connected and then the system must be rebooted).
- Scan your ID and password using the external barcode scanner.

If your log in or ID is not recognized, you are prompted to repeat the log in procedure.

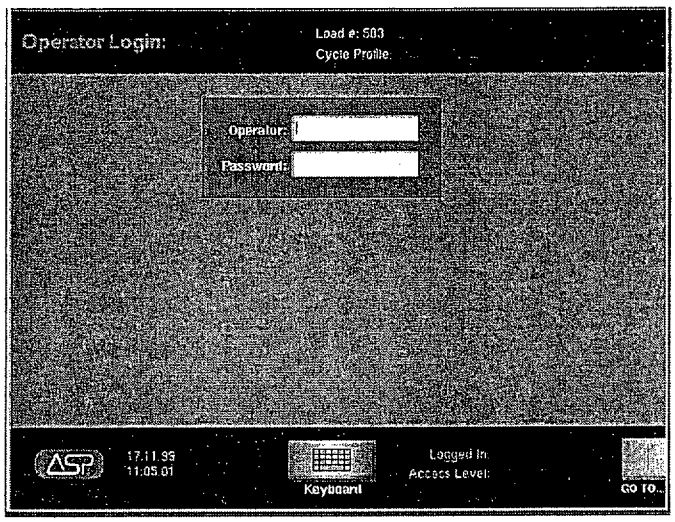


Figure 15. Enter ID and password

You would enter the load item list, if that function is available, at this point. Load item list information is shown previously in this chapter.

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Password Levels

Following are the various password levels assigned at installation. These levels can only be changed by someone with Administrator access (Level 3) or by an ASP Field Service Engineer (Level 4). Password levels are optional. They can be used (or not) if a password is set at installation.

Password Level	Function Access Capabilities
Level 4-Service	• All the functions of password levels 1-3. • Assign and change passwords of all levels. • Access to service menus.
Level 3-Administrator	• Assign/change passwords for level 1 and level 2 users. • Change the date and time. • Run a cycle. • Enter notes.
Level 2-Programmer	• Run a cycle. • Enter notes.
Level 1-Operator	• Run a cycle. • Enter notes.

When your ID and password are accepted, the following display is shown: Touch **Start Cycle** to begin or touch **Back** then **GO TO . . .** to display the Function Button Bar.

You are ready to start the cycle after the following has taken place: the load has been correctly placed on the two-tier shelf and transferred to the sterilizer; the biological and chemical indicators are in place; and the load list, if any, has been entered.

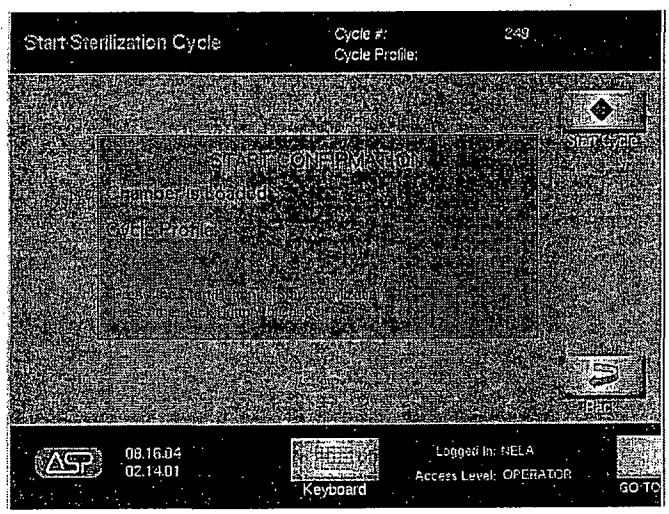

Figure 16. Touch Start Cycle to begin sterilization.

Cycle Notes

The Cycle Notes screen allows you to enter additional information about the current cycle.

To display Cycle Notes, first display the Function Button Bar, then touch **Cycle Notes.**

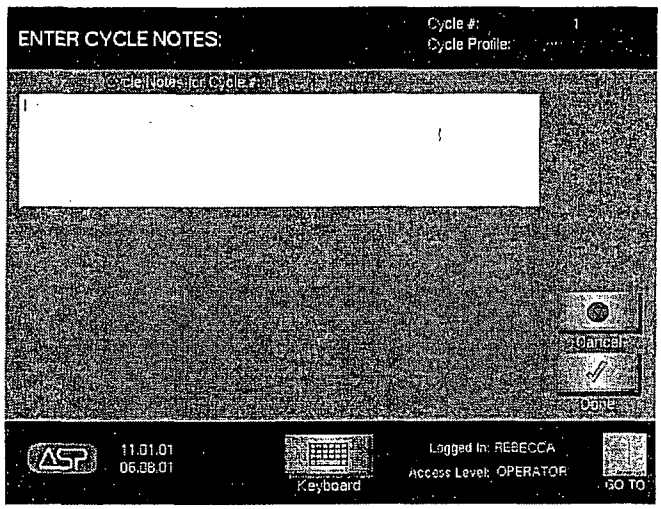

Figure 17. Enter additional cycle information.

Use the virtual keyboard to enter cycle notes information in the indicated field. When you are finished, touch **Done**. The information you entered is added to the cycle history file.

Watching a Cycle

You can monitor the progress of a cycle by watching the display; it indicates the phase of the cycle and certain process parameters. A long beep signals that the cycle is complete.

The display indicates the status of the unit at all times: the current stage of the sterilization cycle; the temperature in the chamber; the pressure in the chamber; the cycle start time, and the cycle estimated end time. You can change the display to show a graph or a numerical readout of the cycle. Each load goes through nine consecutive stages: vacuum, pre-plasma, injection, diffusion, plasma, injection, diffusion, plasma, and vent.

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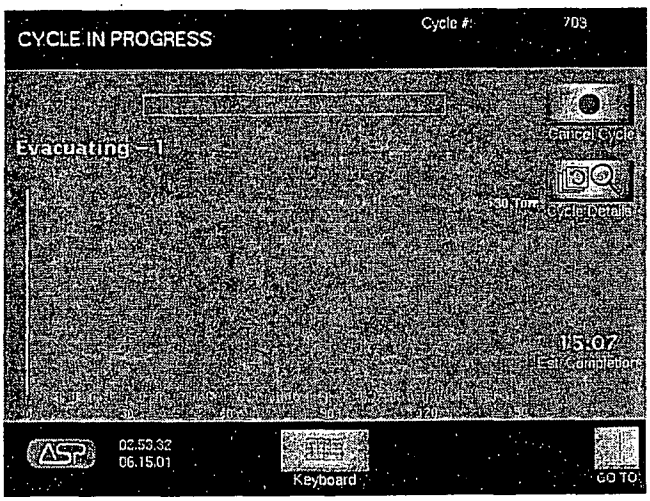


Figure 18. Cycle In Progress–Graph Display. Your display may look slightly different.

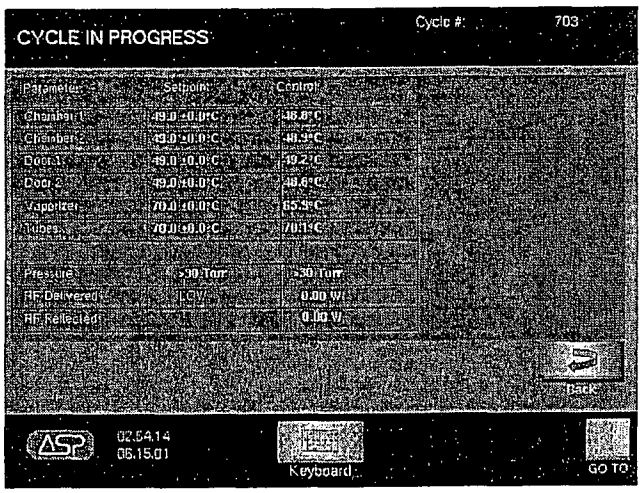


Figure 19. Cycle In Progress–Numerical Display.

Completing a Cycle

Cycle completion is signaled as follows:

- A long beep sounds.
- The paper printout (on the input side) shows the process parameters (in black letters only; red letters usually indicate a problem).
- For two door configurations requiring an ID and password: Cycle Completed Successfully is shown on the display. You are automatically logged out from the input side and must log in to the output side to open the door and remove the load. After the load is removed, touch **Done** and **Close Door** to log out from the output side.
- For one door configurations requiring an ID and password: Cycle Completed Successfully is shown on the display. After the load is removed, touch **Done** and **Close Door** to activate the log in screen for the next load.

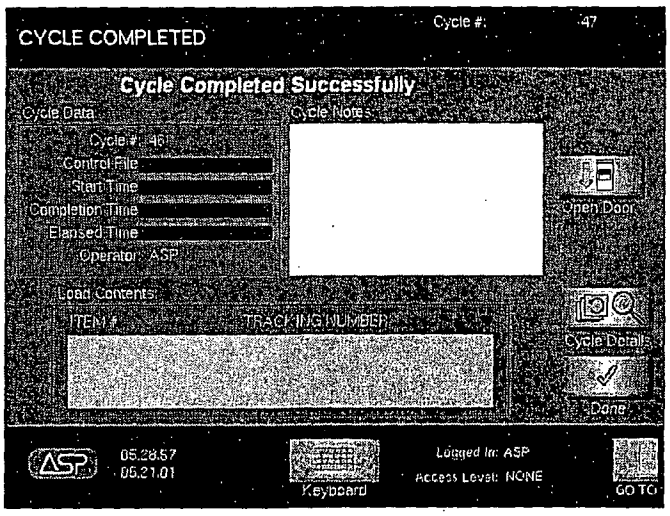


Figure 20. Cycle Complete display for systems requiring an ID and password.

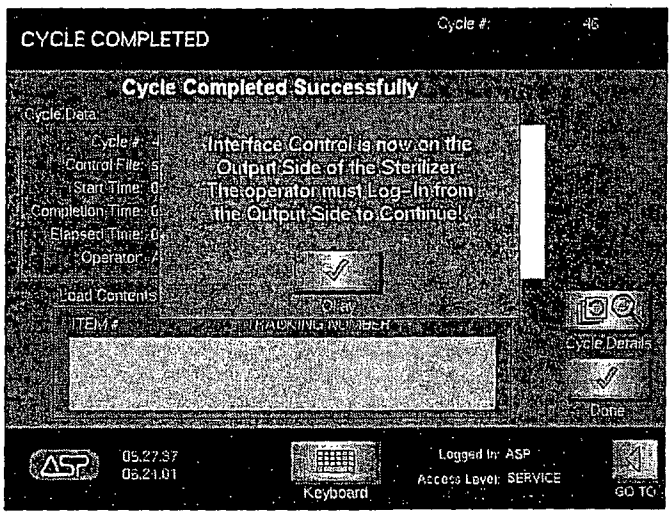


Figure 21. Cycle Complete-Touch Okay, then log in on the output side.

- For two door configurations where no log in has been set up: Cycle Completed Successfully is shown on the display and only the output side is active. You must touch **Open Door** FROM THE OUTPUT SIDE. Remove the load and touch **Done** and **Close Door** to activate the input side display.

- For one door configurations where no log in has been set up: Cycle Completed Successfully is shown on the display. Touch **Open Door**, remove the load and touch **Done** and **Close Door**.

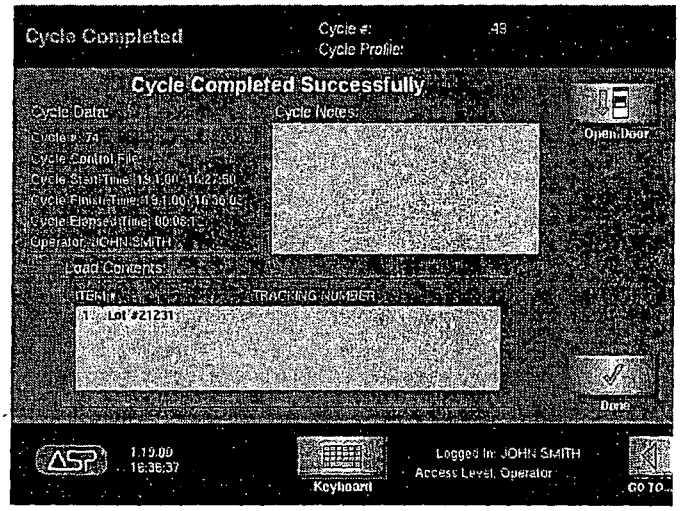


Figure 22. Cycle Completed Successfully.
This display may look different depending on your login.

Logging Out-Two Door Systems

After the sterile items have been removed from the output side, and no further review of the information is necessary, you should log out from the system. This returns control to the input side. To log out from the output side, do the following:

1. Touch **GO TO...** to open the toolbar. Touch **Login**.
2. Logout Confirmation is displayed.
3. Touch **YES** (or Confirm) to log out.
4. Touch **Cancel** to cancel the log out procedure and view the previous display.

Canceled Cycles

You can cancel a cycle at any time by touching **Cancel Cycle**, except during the final vent phase. The STERRAD 200 Sterilizer may also cancel a cycle if it detects a problem with the cycle. The load from a canceled cycle can only be removed from the input side.

To manually cancel a cycle:

1. Touch **Cancel Cycle**.
2. Cancel Confirmation is displayed.
3. Touch **YES** to confirm cancellation and cancel the cycle. Touch **NO** to return to the Cycle in Progress display.
4. Ten beeps sound and the Cycle Canceled/Operator Cancellation message is displayed.

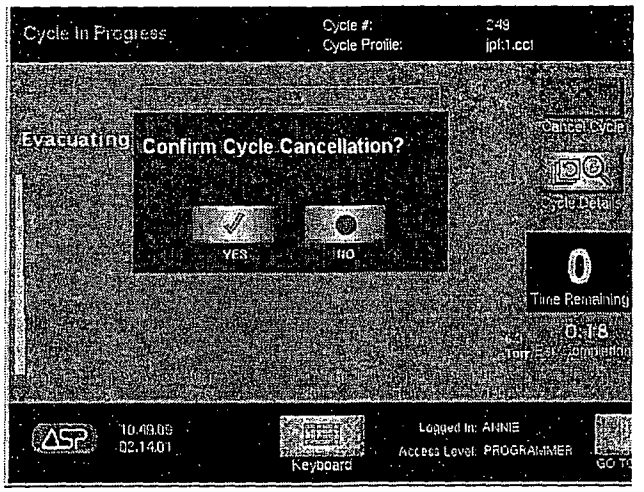


Figure 23. Touch Cancel to start a manual cancellation. The display requests confirmation of the cancellation. Touch YES to confirm. Touch NO to return to the previous display.

5. A paper printout exits the printer with a message in red ink.
6. The sterilizer automatically completes the cancellation process (which includes a short plasma stage during most phases of the process).

✔ *Note: The exact sequence of cancellation actions depends on which process was in operation at the time of cancellation.*

7. The display indicates when cancellation is complete and a summary display appears.

Loads from canceled cycles should be re-wrapped using new polypropylene wrap, STERRAD Chemical Indicator Strips, and STERRAD SealSure™ Chemical Indicator Tape. If a biological indicator was used in the canceled load, a new one should be placed in the chamber before restarting the new cycle.

WARNING! IF A CYCLE CANCELS AND THE ITEMS IN THE LOAD APPEAR WET, HYDROGEN PEROXIDE MAY BE PRESENT. WEAR LATEX OR VINYL GLOVES WHILE REMOVING THE ITEMS FROM THE CHAMBER, AND TO WIPE OFF THE ITEMS WITH A DAMP CLOTH.

Automatic Cancellation

If the sterilizer control system cancels a cycle, the display indicates when the cancellation process is complete. As with manual cancellation (above), the load should be repackaged using new polypropylene wraps, chemical indicators, etc. Note the messages on the display and on the paper printout, and refer to "Chapter 6. Troubleshooting" for more information.

Additional System Information

Under certain conditions the system may not perform normally and yet not generate a message. This is particularly true during power failures or low power situations. If there is a power failure, a leak in the pneumatic system can cause the door (doors) to open without power being present. It is possible that hydrogen peroxide would be present at that time. Take precautions when unloading a system in these situations. If it is anticipated that the power will be off for more than 24 hours, call your ASP service representative for additional instructions.

WARNING! CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT. IF A CYCLE CANCELS AND THE ITEMS IN THE LOAD HAVE ANY VISIBLE MOISTURE OR LIQUID, HYDROGEN PEROXIDE MAY BE PRESENT. YOU MUST FOLLOW ALL SAFETY PRECAUTIONS REQUIRED FOR DEALING WITH HYDROGEN PEROXIDE.

Unloading and Handling

After ensuring that the STERRAD Chemical Indicators exhibit the correct color change, the sterilized items are ready for immediate use, following your facility's policies and procedures. No additional time for aeration is required because the by products are water vapor and oxygen. Follow your facility's policy for release of sterilized items.

On a two door system, the input side displays are locked at the completion of a cycle. You must access the display from the output side in order to remove the load.

1. Log in to the system using your assigned ID and password as shown previously.
2. Touch Open Door.
3. Move the empty carriage to the sterilizer if you are using it to transfer the load.
4. Push the carriage gently into the sterilizer so that the foot mechanism on the bottom of the sterilizer contacts and locks into the flange at the bottom of the carriage. The top front of the carriage rests just inside the chamber and releases the latch holding the two-tier shelf in the sterilizer.
5. Gently pull the two-tier shelf onto the carriage. Make sure the alignment wheels are correctly positioned on the rails for smooth movement.

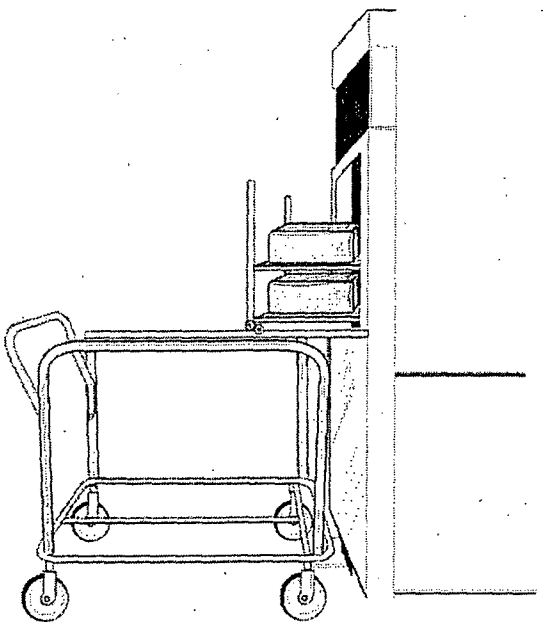


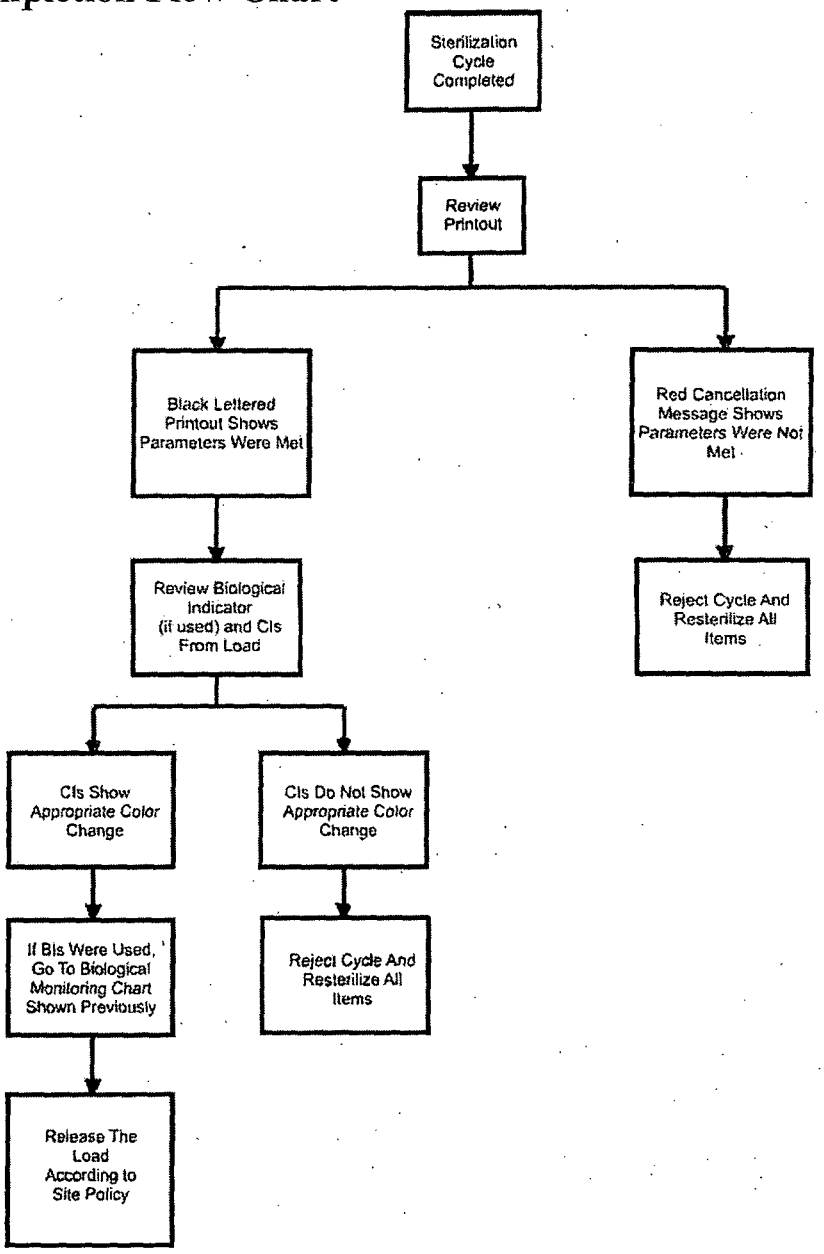
Figure 24. Make sure the carriage is correctly positioned and locked to the foot mechanism. Pull the two-tier shelf gently onto the carriage.

6. Continue pulling until the two-tier shelf is completely seated on the carriage and is locked in place.
7. Step on the carriage release and move the two-tier shelf and carriage to the desired location.
8. Touch Close Door.

Transferring the Load Without Using the Carriage

1. Touch **Open Door**.
2. Move a trolley or supply cart to the sterilizer.
3. Transfer the sterilized items to the trolley/cart.
4. Move the transferred items to the desired location.
5. Touch **Close Door.**

Cycle Completion Flow Chart



Cassette Control

From time-to-time it may be necessary to control the function of the cassette or to view the cassette barcode data. You may do that by using the H_2O_2 Control. This button is located on the Function Button Bar and is accessible to all password levels. To use the "Cassette Control" function, do the following:

1. Touch **GO TO . . .** to display the Function Button Bar.

2. Touch **H_2O_2 Control.** The following is displayed.

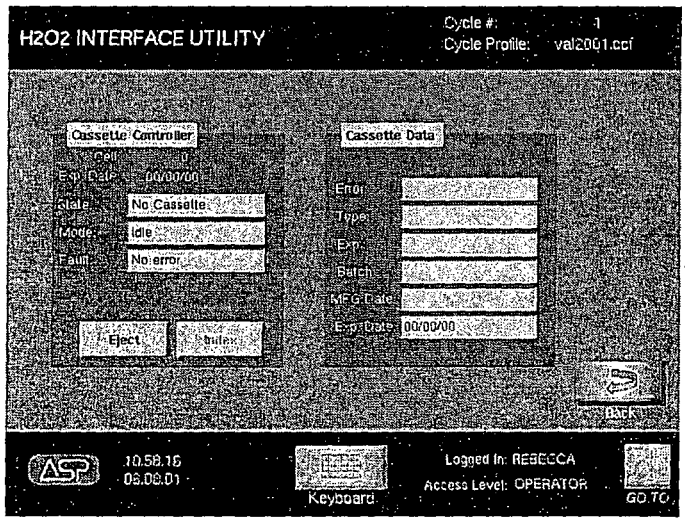


Figure 25. H_2O_2 Interface Utility or Cassette Control. Touch H_2O_2 Control on the Function Button Bar to view this display.

- Touch **Eject** to eject a cassette that is stuck in the chute.
- The Index function is only available to Service level passwords.
- State and Mode refer to the status of the sterilizer.
- Fault displays the sterilizer error message, if any.
- Cassette Data displays the information contained in the barcode which is automatically scanned when the cassette is inserted into the sterilizer. If the cassette is not usable, the error information is displayed in the error field.

Obtaining a Cycle History

Administrator access is needed to perform this function. To review the cycle history, do the following:

1. Touch **GO TO** to open the toolbar.

2. Touch **Utilities**, then touch **Cycle History**.

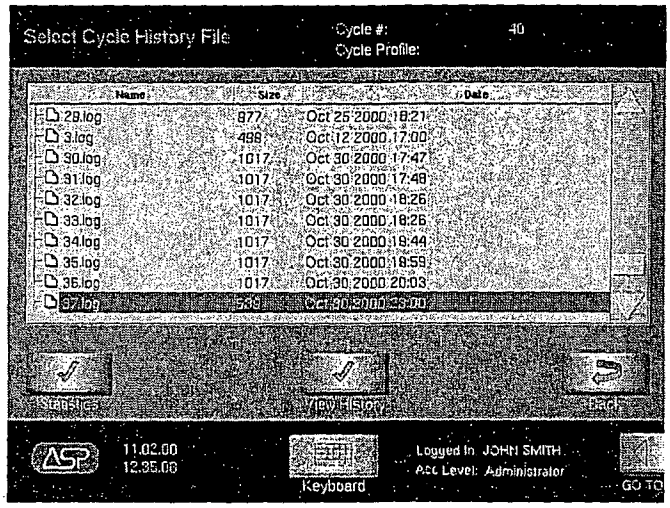


Figure 26. Cycle History Display. Depending on system configuration, the file size column may not be displayed.

3. The Cycle History display contains information about the previous 1500 cycles. The display shows the name of the cycle (assigned by the system), the size of the data file (not available on all configurations), and the cycle date and time. Touch the file name and then touch **View History** which shows details of the highlighted file including load item data. Touch **Statistics** to view cycle cancellation information. In addition, the View History display has a cycle history button that provides more detail on the particular cycle including a cycle graph and the ability to print the cycle information.

4. When you are done viewing a display, touch **Back** to return to the previous display.

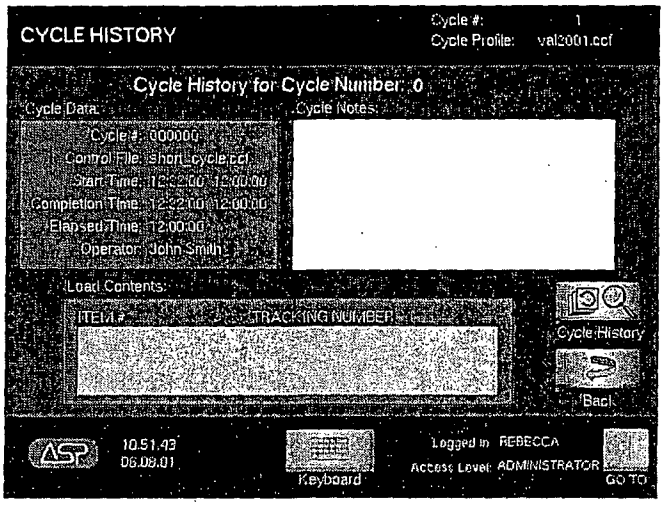


Figure 27. Touch View History to see this display.

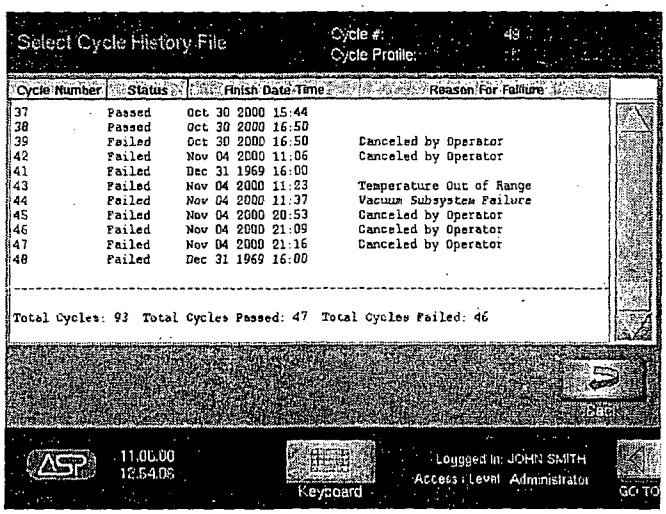


Figure 28. Touch Statistics to see this display.

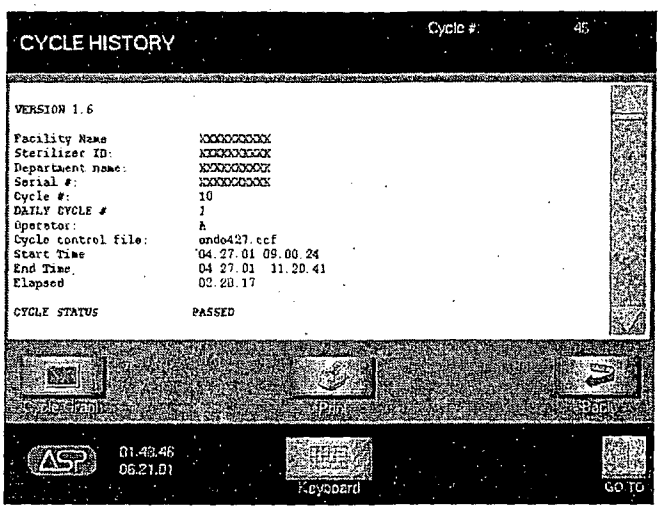


Figure 29. From the View History Display, Touch Cycle History to see this display. Touch Print to print the displayed information.

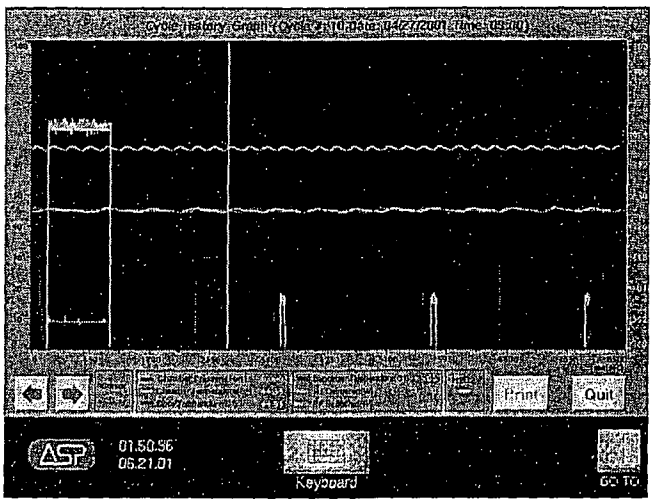


Figure 30. Touch Cycle Graph from the previous display to see this display. The arrows advance through the graph. Touch Print to print the displayed information. Touch Quit to return to the previous display.

Administrative Functions

The password level "Administrator" allows you to perform functions that are not available at the "Operator" level. These functions include: assigning and modifying passwords, changing the date and time displayed on the sterilizer, configuring the sterilizer to function on a network, and assigning the system ID information. These displays and descriptions of their functions are shown in this section.

System Setup

Touch **System Setup** on the Utilities Menu to display the Configuration Menu. The Configuration Menu allows you to select any of four configuration options.

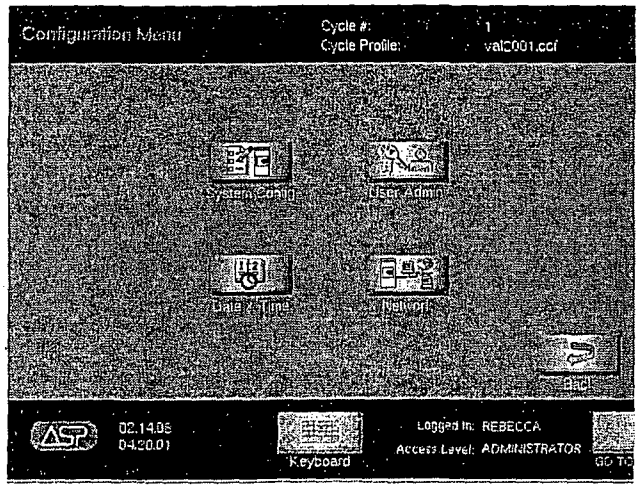


Figure 31. Touch System Setup to view this menu.

- Touch **System Config** to display basic configuration parameters for the STERRAD 200 Sterilizer.
- Touch **User Admin** to display user names, passwords, and privileges.
- Touch **Date & Time** to enter the display that allows you to change the date and time for the system clock and calendar.
- Touch **Network** to display and/or update the optional network connection parameters.

System Configuration Screen

To display the System Configuration screen, touch **System Config** on the Configuration Menu.

The System Configuration screen allows you to display and/or enter identifying and configuration information about the sterilizer. This information is typically entered at the factory or by an ASP service technician when the sterilizer is installed and is ordinarily not changed in the field.

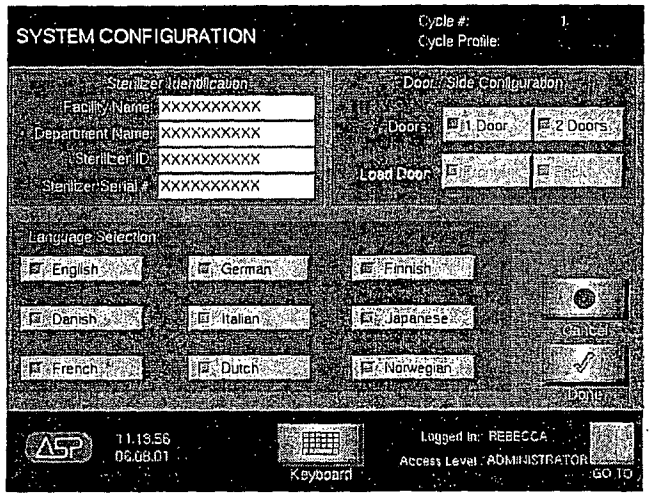


Figure 32. System Configuration.

- The Sterilizer Identification block allows you to enter the name of your facility and a label that identifies the individual machine. The serial number is displayed for information purposes and cannot be changed by the user.
- The Door/Side Configuration block indicates the number of doors and which door is used for cycle loading.
- The Language Selection block allows you to choose the language used on all sterilizer displays.
- Touch **Done** to return to the Configuration Menu.
- Touch **Cancel** to cancel any changes you made to fields in the System Configuration screen.

User/Password Administration Screen

To display the User/Password Admin screen, touch **User Admin** on the Configuration Menu.

The User/Password Administration screen allows you to add new users, modify users, and assign passwords and access privileges.

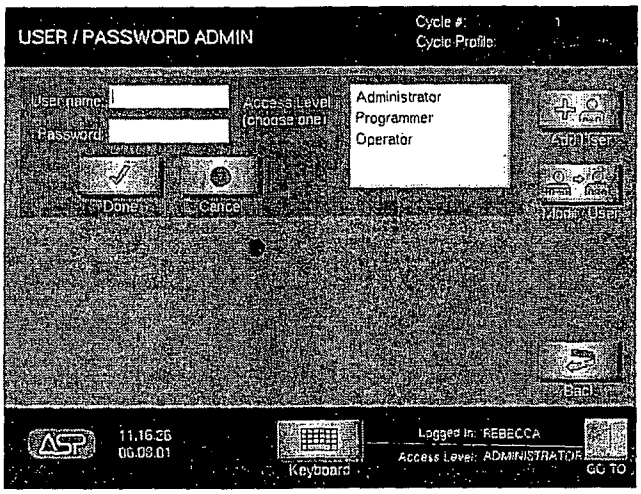


Figure 33. User/Password Administration.

Adding a New User

1. Touch **Add User** to add a new user to the system.
2. In the Username field, type the new user's name.
3. In the Password field, type the new user's password.
4. In the Access Level list box, choose the appropriate access level for the new user. You cannot assign a "Service" access level – this is reserved for ASP Service personnel only.
5. To cancel an addition, touch **Cancel**. To accept the new entry, touch **Done**. To return to the Configuration Menu, touch **Back**.

Modifying an Existing User's Information

1. Touch **Modify User** to change the password or access privileges of an existing user.
2. In the Username field, enter the name of the user to be modified.
3. In the Password field, enter the user's password.
4. In the Access Level list box, choose the appropriate access level for the user. You cannot assign a "Service" access level – this is reserved for ASP Service personnel only.
5. To cancel a change, touch **Cancel**. To accept the modified information, touch **Done**. To return to the Configuration Menu, touch **Back**.

Resetting the Date and Time

The date and time are set by your Service Representative at installation. If you have an administrator level password, you can change these settings at any time to conform to local standards.

✔ *Note: Date and Time is also available on the Function Button Bar on systems configured to operate without an ID or password login.*

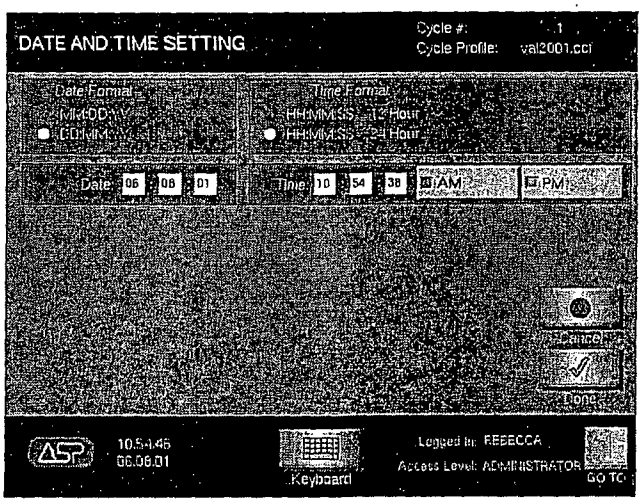


Figure 34. Date And Time Display.

To change the date

1. Touch **GO TO** , then touch **Utilities**.
2. Touch **System Setup**, then touch **Date and Time**.
3. Touch the **Date Format** you desire. The radio button (green dot) should light by your selection.
4. Touch the **Date** field. Touch **Keyboard** and using the number keys, enter the correct date.
5. Touch **Done** to accept and save the entered information. Touch **GO TO** to exit the display.
6. Touch **Cancel** (the red circle) at any time to cancel and exit without saving.

To change the time

1. Touch the **Time** format you desire. The radio button should be green by your selection.
2. Touch the **Time** field. Touch **Keyboard** and using the number keys, enter the correct time.
3. Touch **AM** or **PM** if applicable for your desired time format.
4. Touch **Done** (the check mark) to accept and save the entered information. Touch **GO TO...** to exit the display.
5. Touch **Cancel** (the red circle) at any time to cancel and exit without saving.

Network Settings Screen

✔ *Note: This function should not be performed arbitrarily. Please call your ASP service representative for help configuring these settings.*

The Network Settings screen allows the users with administrator level passwords access to configure the host name and port number when the sterilizer is connected to a network.

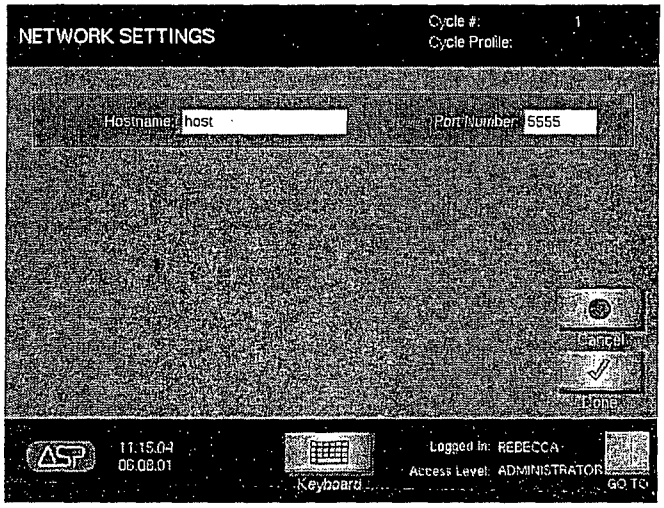


Figure 35. Network Settings.

1. Use the virtual keyboard to enter the host name in the "Hostname" field and the network port number in the "Port Number" field.

2. When you have entered the information, touch **Done** to update the network configuration.

3. To leave this screen without making any changes to the displayed data, touch **Cancel**.

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Chapter 5. Routine Maintenance

In this chapter . . .

- *replacing the printer ribbon cartridge*
- *replacing the printer paper*
- *cleaning the STERRAD® 200 Sterilizer*

Overview

This chapter is your guide to the following maintenance procedures for the STERRAD® 200 Sterilizer:

- Replacing the printer cartridge
- Replacing the printer paper
- Cleaning the STERRAD 200 Sterilizer

Contact ASP Technical Service for guidance on performing any other maintenance procedures.

WARNING! ONLY EXPERIENCED TECHNICIANS WHO ARE FULLY TRAINED TO MAINTAIN THE STERRAD 200 STERILIZER SHOULD REPAIR OR ADJUST THIS UNIT. USE OF UNAUTHORIZED PARTS FOR MAINTENANCE OR REPAIR COULD CAUSE PERSONAL INJURY, RESULT IN COSTLY DAMAGE OR UNIT MALFUNCTION, AND WILL VOID THE WARRANTY.

Maintaining the Printer

The printer requires that the ribbon cartridge be replaced whenever the print becomes too light to read easily. The paper should be changed when the colored bars begin to appear on the paper. This indicates the paper supply is running low.

Replacing the Printer Ribbon Cartridge

To replace a printer cartridge do the following:

1. Open the printer access service door on the upper left.
2. Remove the used cartridge by firmly, but carefully, pulling on the right side, as indicated by the arrow on the cartridge.
3. Discard the used cartridge.
4. Insert a new cartridge by aligning the left side of the cartridge in the printer. Push on the right side of the cartridge to snap it into place.

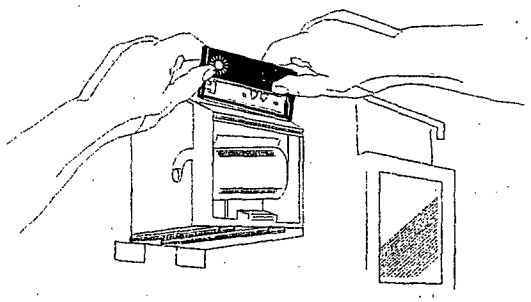

Figure 36. Tilt the ribbon cartridge into position and snap it in place.

5. Turn the knob on the cartridge clockwise to remove any slack from the ribbon.
6. Feed the printer paper through the printer paper slot in the service door and close the printer access service door.

Replacing the Printer Paper

To replace the paper roll do the following:

1. Open the printer access service door on the upper left.
2. Remove the empty paper core and discard the core. Retain the metal paper roller and insert it into the new roll of paper.

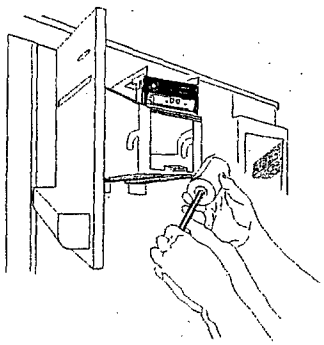

Figure 37. Retain the metal roller and insert it into the new paper core.

3. Place a new paper roll into position so that the paper feeds from the back of the roll. You may need to tilt the paper so that the roller fits securely into the grooves.

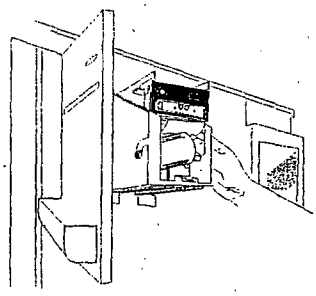

Figure 38. Tilt the paper roll into one side of the printer, then set it into the other side. The paper feeds from the back.

4. Feed the edge of the paper into the slot behind the printer. Press the **Paper Advance** button on the door until the mechanism begins to pull the paper. Continue pressing **Paper Advance** until about 150 to 160 mm (6 inches) of paper exits the printer cartridge.

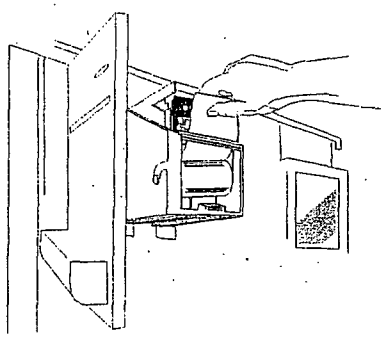

Figure 39. Feed the paper up through the mechanism and then through the slot in the door.

5. Feed the printer paper through the slot in the access door and close the door.

Cleaning the STERRAD® 200 Sterilizer

The outside surfaces of the sterilizer can be cleaned with water and a mild detergent. The inside of the sterilization chamber does not normally require cleaning. The chamber door and the chamber should not be cleaned with an abrasive, such as a wire brush or steel wool. If you have any questions regarding cleaning the STERRAD 200 Sterilizer, call your ASP service representative.

CAUTION: Do not clean the chamber door area with abrasives. The sterilization chamber uses an O-ring vacuum seal to maintain a vacuum in the chamber. Never use rough cleaning tools, such as a wire brush or steel wool on the door housing or chamber assembly. This could damage the seal. Use a damp, lint free cloth to clean the chamber door.

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Chapter 6. Troubleshooting

In this chapter . . .

- *rebooting the system*
- *message table*

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Overview

The STERRAD® 200 Sterilizer is a relatively trouble-free device, requiring only routine maintenance and care in load preparation to help prevent system cancellations.

WARNING! YOU MUST WEAR LATEX OR VINYL GLOVES WHEN REMOVING A LOAD AFTER A CYCLE CANCELLATION.

Rebooting the System

Rebooting is used in certain troubleshooting procedures. When power is turned off then back on, it causes the computer in the sterilizer to reload the software control program automatically; this action "reboots" the sterilizer. (Rebooting is used in certain troubleshooting procedures.) The display indicates sterilizer status after power has been reapplied.

The Power ON-OFF switch is located on the service side of the sterilizer (this is to the right as you face the input side of the sterilizer). If instructions indicate that you should reboot the system, flip the switch to the OFF position. Wait a few seconds for the system to completely power down, then flip the switch to the ON position. The display indicates sterilizer status after power has been reapplied.

Using the Message Table

To use this table, look at the message displayed and then find the same message in the table (it is in alphabetical order). The table shows the message, the printout associated with the displayed message, and suggests some actions to take. If you touch **Help** when any message is displayed, you receive additional solutions and actions to take. You may receive similar messages during different stages of the system cycle. The action you are to take is usually the same regardless of the cycle stage.

If your question was not answered either by the table below or by using the "Help" display, call ASP Customer Support for more information.

Message Table

Displayed Messages	Printed Messages	Condition/Action
Delivery Subsystem Failure	Delivery Subsystem Failure	The system was unable to successfully complete the injection. Call your ASP service representative.
H_2O_2 Delivery Failure	H_2O_2 Delivery Failure (System parameters are included on printout.)	An acceptable hydrogen peroxide concentration was not detected. One or more empty cassette cells is the most likely cause. Insert a new cassette and run the cycle again. If the problem persists, call your ASP service representative.
Insert New Cassette	No Printout	Insert a new cassette and restart the sterilizer.
Operator Cancellation	Operator Cancellation	The operator has cancelled the cycle. Restart the sterilizer.
Power Failure	Power Failure	The power was turned off during a cycle. Restart the sterilizer
RF Subsystem Failure	RF Subsystem Failure (RF system parameters are included on printout.)	**WARNING!** If plasma failed to light, please use extra caution when handling load. Check to see if two-tier shelf or other metal objects are in contact with the electrode, door, or chamber walls. Repackage and reprocess load. If problem persists, call your ASP service representative.

Temperature Has Not Risen Call ASP Technical Service	No Printout	The sterilizer is not at the temperature needed to run a cycle. Call your ASP service representative.
Temperature Out Of Range	Temperature Out Of Range (System temperature parameters are included on printout.)	The door, chamber, vaporizer, or tube temperatures are above or below the operating temperatures. Call your ASP service representative.
Timeout Failure	Timeout Failure	A timeout event occurred when the sterilizer was unable to complete a task within a preset timeout period. Run the cycle again, if the timeout problem persists, call your ASP service representative.
Vacuum System Failure	Vacuum System Failure (Vacuum system parameters are included on printout.)	The load may contain too much moisture contain cellulose material or there may be too many packages in the chamber. If problem persists, start a cycle with an empty chamber. If the vacuum stage is still not successful, call your ASP service representative.
Warming Up Please Wait	No Printout	You must wait until the system warms up to run a cycle.

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Chapter 7. Compatible Devices

In this chapter . . .

- *obtaining a list of compatible devices*

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Obtaining a List of Compatible Devices

There are a wide variety of devices that are compatible with the STERRAD® 200 Sterilizer. As more manufacturers complete testing of their products with the STERRAD 200 Sterilizer, the range of compatible items grows. Because of that, it is difficult to provide a comprehensive list of these devices in this publication. We do maintain this information, however, and are happy to share it with you. Please contact ASP Customer Support or your local representative for an up-to-date list of compatible devices and device manufacturer information. Check with the device manufacturer's instructions before processing any device in the STERRAD 200 Sterilizer.

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Appendix A. Specifications

In this chapter . . .

- *space requirements*
- *operation*
- *equipment rating*
- *electrical requirements*
- *protection*
- *serviceable assemblies*
- *i/o connection*
- *transport and storage*
- *explanation of warning symbols*

Technical Specifications

Space Requirements	
Sterilizer Size	Width: 915 mm (35 inches) Depth: 1130 mm (44 ½ inches) Height: 1754 mm (69 inches)
Weight	520 kg (1146 lbs)
Operation	
Ambient Temperature	+18°C to +40°C (+64°F to +103°F)
Relative Humidity	10% to 85% up to +30° C ambient and linearly decreasing from 85% at +30° C to +70% at +40° C noncondensing
Pollution Degree	2
Installation Category	II
Atmospheric Pressure	700 hPa to 1060 hPa
Altitude	Up to 2000 meters
Equipment Rating	
High Voltage	200V~, 3~, 50/60 Hz, 4 wire, 15 A 208V~, 3~, 50/60 Hz, 5 wire, 15 A 380V~/400V~/415V~, 3~, 50/60 Hz, 5 wire, 15 A
Electrical Requirements	
The STERRAD® 200 Sterilizer should only be plugged into outlets approved by a qualified technician. For further requirements, refer to the label on the back panel of the sterilizer or call your ASP service representative. Only a qualified technician can determine when the STERRAD 200 Sterilizer can be safely moved to a new power source.	
Protection	
Protection Class	Class 1
Protection Against Ingress of Water	Ordinary (IPXO)
Mode of Operation	Continuous

Serviceable Assemblies	
Circuit Diagrams	Contact ASP Customer Support*
Component Part Lists	Contact ASP Customer Support *
Descriptions	Contact ASP Customer Support *
Calibration Instructions	Contact ASP Customer Support *
I/O Connections	
Keyboard	DIN-5 Type
Barcode	D-SUB 9 Type
Transport and Storage	
Ambient Temperature	-40° C to +70° C (-40° F to +158° F)
Relative Humidity	10% to 100% non-condensing
Atmospheric Pressure	500 hPa to 1060 hPa
Explanation of Warning Symbols	
IEC 378-0300	Attention, consult accompanying documents
IEC 878-03-0	Dangerous voltage
	Caution: Mechanical crushing hazard. Do not touch
	Caution: Mechanical crushing hazard when door is closing.
	Protective earth
3N	Three phase neutral
I/O	On/Off
∿	Alternating current
DOOR STOPPER USE before Maintenance	The door must be blocked before maintenance is performed.

*ASP provides circuit diagrams, component part lists, descriptions, and calibration instructions on request to appropriately qualified personnel on the assemblies that ASP feels are serviceable by non-ASP personnel.

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Appendix B. Service and Warranty Information

In this appendix . . .

- *service warranty*
- *commercial warranty*

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 instrument. Replacement items can be either new or remanufactured. Defective parts replaced under warranty shall become the property of ASP.

THE EXPRESS WARRANTY ABOVE IS THE SOLE WARRANTY OBLIGATION OF ADVANCED STERILIZATION PRODUCTS, AND THE REMEDY PROVIDED ABOVE IS IN LIEU OF ANY AND ALL OTHER REMEDIES. THERE ARE NO OTHER AGREEMENTS, GUARANTEES OR WARRANTIES -- ORAL OR WRITTEN -- EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ADVANCED STERILIZATION PRODUCTS SHALL HAVE NO LIABILITY WHATSOEVER FOR ANY IMPROPER USE OR UNAUTHORIZED SERVICE OR REPAIR.

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ADVANCED STERILIZATION PRODUCTS
Commercial Warranty

The STERRAD® Sterilizer and reusable accessories supplied by ADVANCED STERILIZATION PRODUCTS (ASP) are 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 their 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 null and void if service is attempted or performed by persons who are not authorized to do so by ADVANCED STERILIZATION PRODUCTS. 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 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/replacement in its own factory, at any authorized repair station, or at the facilities of the purchaser of the instrument. Replacement items can be either new or remanufactured. Defective parts replaced under warranty shall become the property of ASP.

ACCEPTED
with COMMENTS
EPA Letter Dated:

FEB 1 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

71871-3

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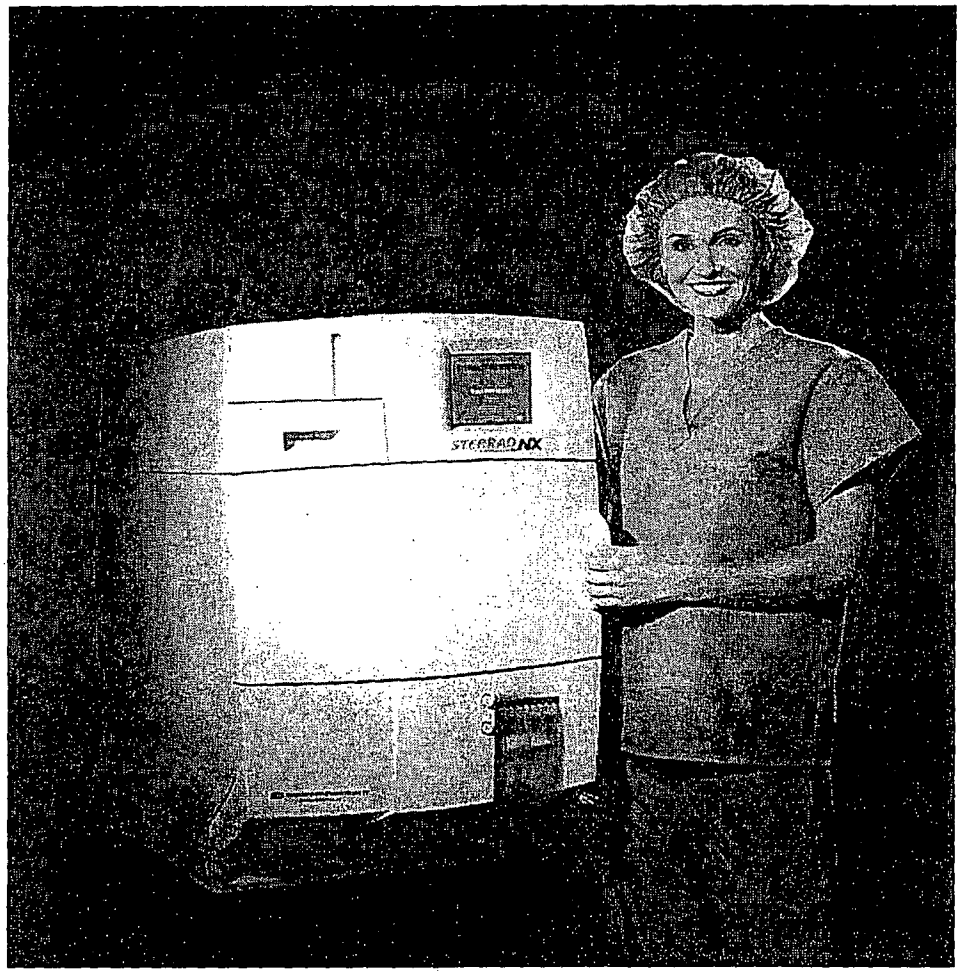
STERRAD® NX™ Sterilization System

User's Guide



ADVANCED STERILIZATION PRODUCTS®

a Johnson & Johnson company

Division of Ethicon, Inc.

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EPA Letter Dated:

FEB 1 2008

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STERRAD® NX™ Sterilization System

User's Guide

REF 99920

ADVANCED STERILIZATION PRODUCTS®
a Johnson & Johnson company
Division of Ethicon, Inc.
33 Technology Drive, Irvine, CA 92618-9824
Authorized EC Representative
Ethicon GmbH
Oststraße 1, D-22844 Norderstedt
CE 0123

USA	Irvine, CA 92618	IT	Johnson & Johnson Medical S.p.A. Via del Mare, 56 - 00040 Pomezia, Roma
FR	92787 Issy-les-Moulineaux	ES	28042 Campo de las Naciones, Madrid
DE	22844 Norderstedt	GB	Ascot, SL5 9EY
CH	8957 Spreitenbach	CA	Johnson & Johnson Medical Products Markham, ON, L3R 0T5
NL	3600 AD Amersfoort	JP	ジョンソン・エンド・ジョンソン 株式会社
GR	15125 Marousi, Athens	A	1190 Wien
SE	19184 Sollentuna	BR	Rodovia Presidente Dutra, Km 154 S.J. Campos-S.P 12240-908
B	1700 Dilbeek	PT	2745-555 Barcarena
CZ	Johnson & Johnson, s.r.o. Karla Engliše 3201/6 150 00 Praha 5	PL	Szyszkowa 20, 02-285 Warszawa
SK	Plynárenská 7/B 824 76 Bratislava 26	HU	Johnson & Johnson Kft. H-2045 Törökbálint, Tó Park

1-888-STERRAD
ASP U.S.A. Customer Care Center 949.581.5799

ASP International Customer Support
(Call your local ASP Customer Support Representative)

www.sterrad.com

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Chapter 1.

Introduction

How to Use This Guide

If you are a STERRAD® NX™ 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 NX Sterilizer, you should read the entire user's guide and pay particular attention the chapter featuring "Access Levels and Supervisor Level Tasks." This chapter describes tasks and options that are only available through "Supervisor Level" access.

The chapters on "Maintenance," "Troubleshooting," and the Appendices are designed as references. Keep this user's guide available so that if a question arises, you can quickly locate the information you need.

Warnings, Cautions, and Notes

Warnings and cautions are accompanied by symbols surrounded by a triangle and are printed in the text in boldface italics. 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 accompanied a check mark ✔and are printed in italics. Notes highlight specific information about the proper use and maintenance of the STERRAD® NX 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.

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.

If You Have Questions

If you are located in the United States and have questions about the STERRAD NX 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 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® NX™ 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 NX 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 or if any moisture is noted on items in the load following a completed 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.

WARNING! RISK OF SKIN INJURY.
Direct hydrogen peroxide contact with the skin can cause severe irritation. Wear gloves when handling used cassettes, ejected cassettes, items from a cancelled cycle or items that have moisture present after a completed cycle.
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! 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 used cassette, an ejected cassette, a load after a cycle cancellation, or if any moisture is noted on a load following a completed cycle. Hydrogen peroxide liquid may be present on the load or in the chamber.

Device Safety

KNOW WHAT YOU CAN PROCESS

Before processing any item in the STERRAD NX 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 door, or the electrode. Contact with the walls, door, 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 NX 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 NX 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 NX Sterilizer.

Chapter 3.

Sterilizer Overview

Intended Use

The STERRAD® NX™ Sterilization System is a general purpose, low temperature sterilizer which uses the STERRAD NX 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 NX 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 NX Sterilizer" chart in the "Load Preparation" chapter. This chart contains details on recommended materials and lumen sizes. When selecting reusable medical devices to be processed in the STERRAD NX Sterilizer, reprocessing information should be obtained from the manufacturer of the medical device in accordance with international norms (such as ISO 17664 or AAMI TIR12).

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The STERRAD® NX™ Sterilization Process

As a healthcare professional, you may already be familiar with general sterilization principles. However, the STERRAD NX Sterilizer represents a new technology, and it requires special attention to the ways in which it differs from other sterilizers.

The STERRAD NX 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 sensitive to heat and moisture. (Refer to Chapter 4 for more information on compatible instruments.)

The STERRAD NX 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.

The devices have been pre-validated to an SAL of 10^{-6} based upon worst-case conditions, including lumens within the claim lengths and mated surfaces. If additional technical information concerning validation is needed, please contact your ASP Representative.

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Overview of the STERRAD® NX™ Sterilization Cycle

The STERRAD NX 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 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: Chapter pressure is increased in order to drive hydrogen peroxide is 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.

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Exposure 2

The steps in Exposure 1 are repeated.

The STERRAD® NX Sterilization Cycle

Phase	Order	Stages
Exposure 1	1	Delivery 1 Vaporization Pumpdown 1 Chamber Pumpdown 1 Transfer 1 Diffusion 1 Plasma Pumpdown 1 / Plasma 1 Vent 1
Exposure 2	2	Delivery 2 Vaporization Pumpdown 2 Chamber Pumpdown 2 Transfer 2 Diffusion 2 Plasma Pumpdown 2 / Plasma 2 Final Vent

The STERRAD® NX™ Sterilizer and Features

The cassette slot, the cassette drawer, the touch screen, the chamber door, the printer, and the main power switch are found on the front of the sterilizer.

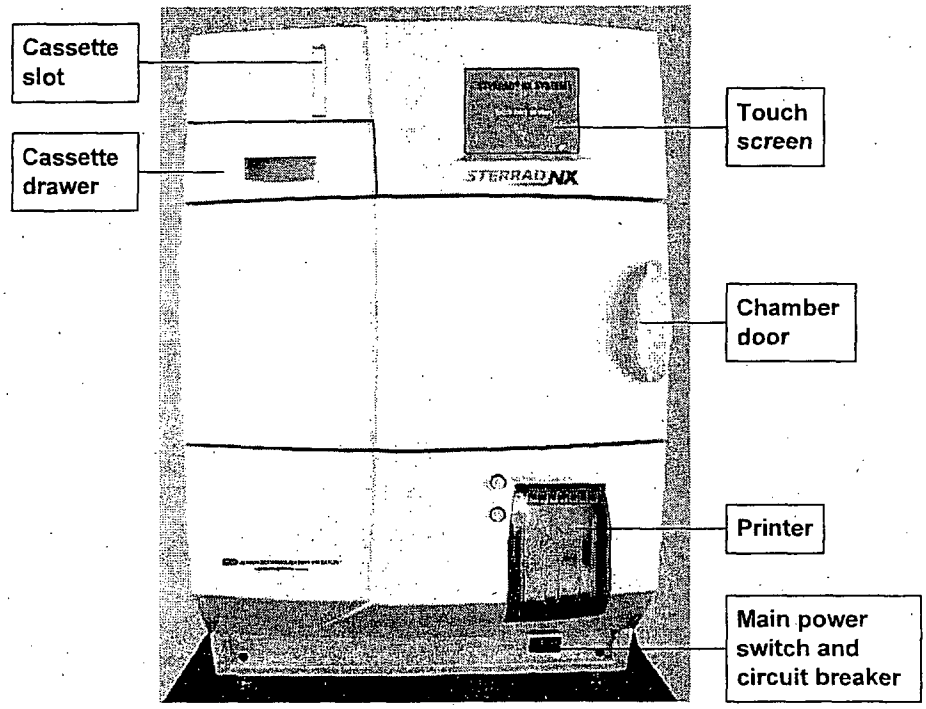


Figure 1. The STERRAD® NX™ Sterilizer.

Cassette

The cassette contains sealed capsules of precisely measured amounts of hydrogen peroxide solution. Each cassette contains enough sterilant for five cycles. Cassettes are inserted into the sterilizer through the cassette slot. The sterilizer pulls the cassette through the slot and moves it into the machine, keeping it there until the cassette has been processed.

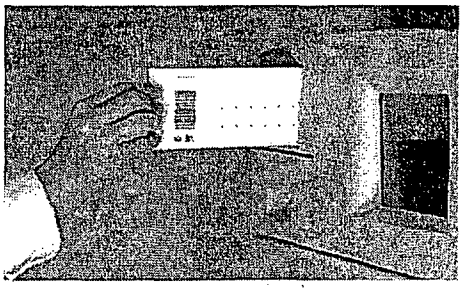


Figure 2. Inserting a Cassette.

Cassette Drawer

After processing of the cassette, the sterilizer automatically discards it into the cassette disposal box in the cassette drawer. **Wear gloves when handling used or ejected cassettes.**

Cassette Disposal Box

The cassette drawer contains a cassette disposal box for used cassettes. The box holds three cassettes. When the box is full, the sterilizer displays a message indicating that the drawer must be emptied. The cassette disposal box must be closed to permit safe disposal of cassettes. Refer the "Maintenance" chapter for additional information.

Touch Screen and Speaker

The sterilizer displays information and accepts commands through a color touch screen. By touching buttons displayed on the screen, you can enter letters and numbers, make selections, and start and stop the sterilizer.

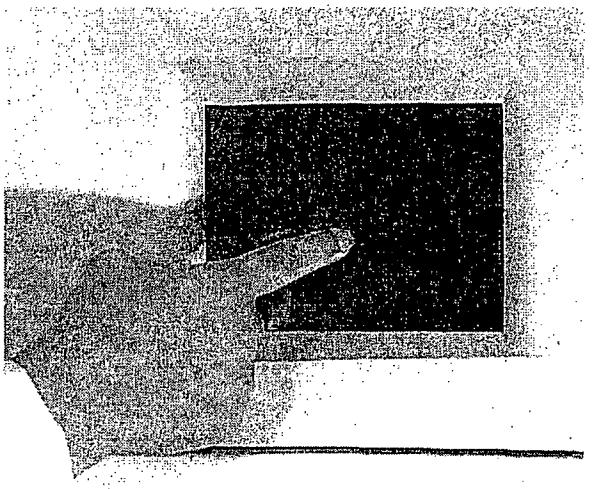


Figure 3. Using the Touch Screen

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 chamber is where the load is sterilized. The chamber walls and door contain heaters that keep the chamber interior warm during operation. When the chamber door is closed, a vacuum-tight seal is created, allowing the chamber to be evacuated during operation. A locking mechanism prevents the door from being opened when a sterilization cycle is in progress.

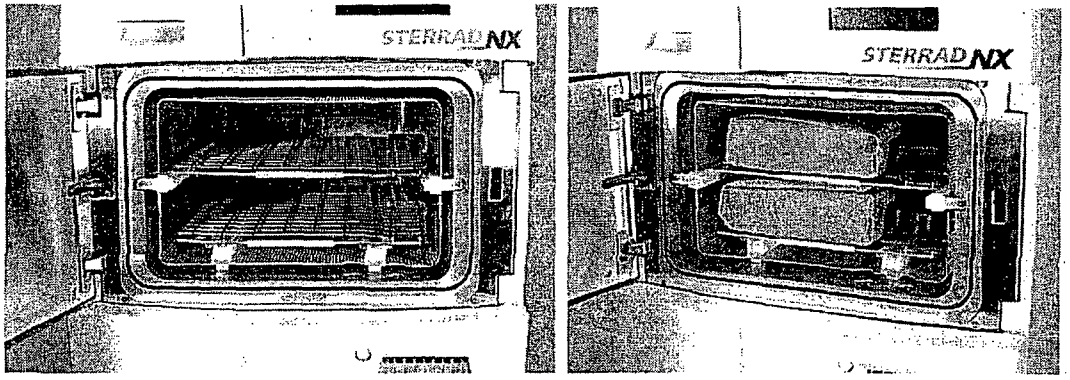


Figure 4. The STERRAD® NX™ Chamber Empty and With the Load Correctly Place.

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

Printer

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. When the sterilizer power is on, the printer interior is illuminated with a blue light.

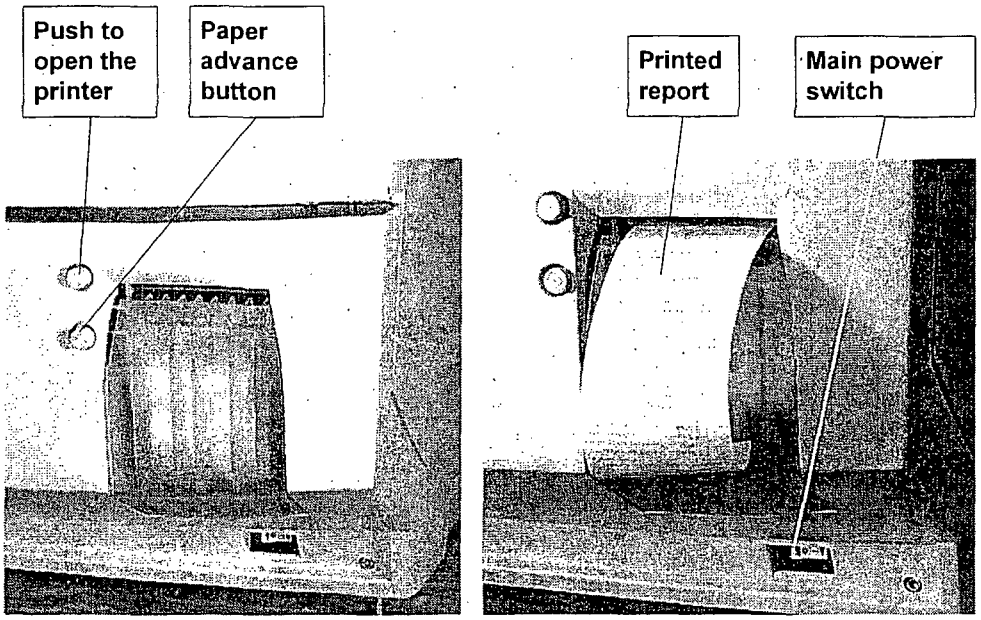


Figure 5. STERRAD® NX™ Printer, Paper Advance Button and Power Switch Details.

The top button opens the printer for paper replacement. The bottom button advances the paper when pressed. Note the location of the main power switch under the printer.

Rear Panel

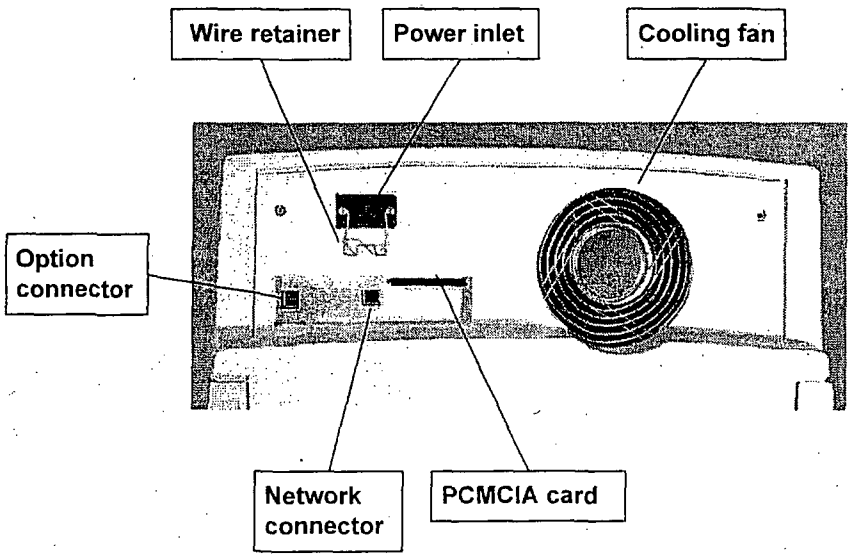


Figure 6. Rear Panel.

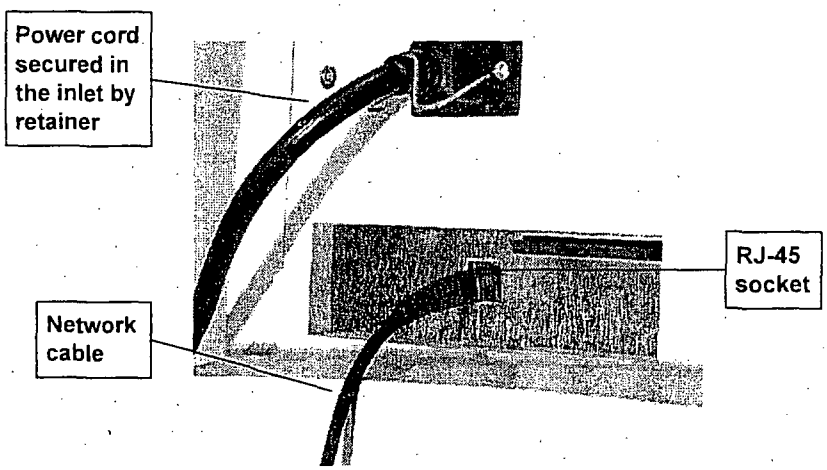


Figure 7. Connection Panel Located on the Lower Rear of the Sterilizer.

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. You can touch the screen with your finger or with a stylus to move the cursor from place to place.

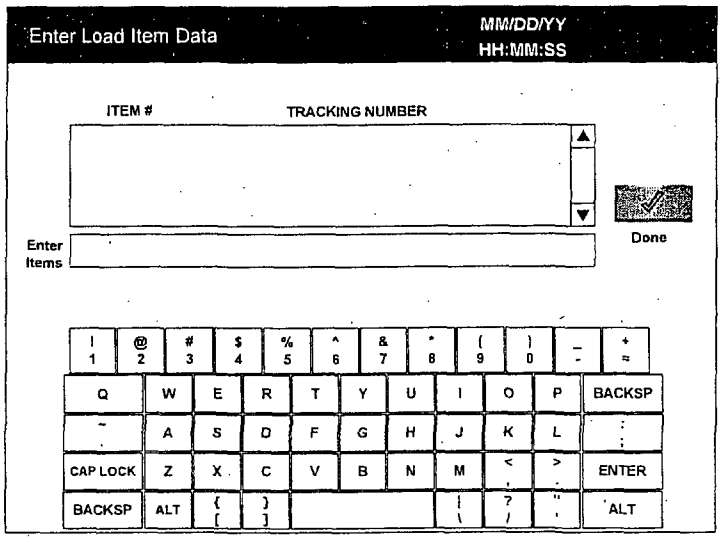


Figure 8. Example of an Information Entry Screen.

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

Function Buttons

Button	Function
	Done. Touch this button to indicate that you are finished using the screen.
	Back. Touch this button to return to a prior screen.
	View. Touch this button to view the selected report or file.
	Print. Touch this button to print the selected report or file.
	Cancel. Touch this button to cancel the entry you just made.

Sterilizer Cart

The Sterilizer Cart is an optional accessory that may be used to hold the STERRAD® NX™ Sterilizer. The following figure shows the sterilizer placed upon the cart.

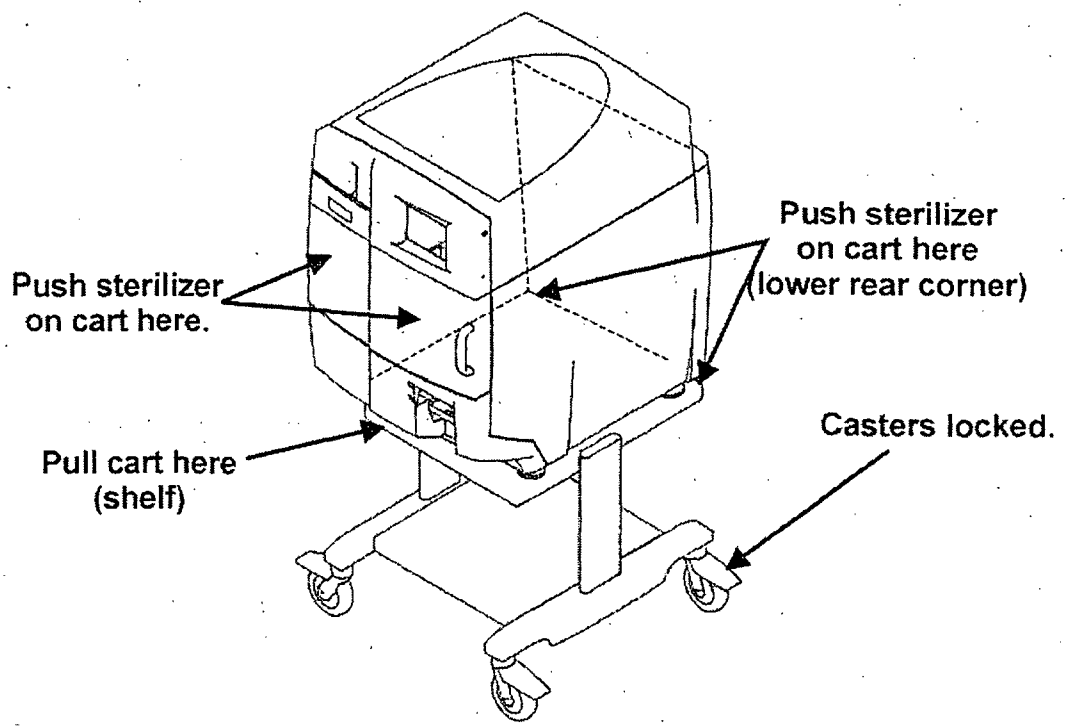


Figure 9. Sterilizer Cart

The casters may be locked and unlocked by pressing on caster levers. In order for the cart to have maximum stability, the casters should be oriented in the locked position as shown in the figure above.

The sterilizer may be *pulled* and *pushed* as shown in the figure above. DO NOT push or pull the sterilizer sideways as this is the least stable orientation. DO NOT move the sterilizer with the door open. DO NOT use the door handle to move the sterilizer.

The next chapter describes how to use the STERRAD NX Sterilizer to sterilize your items.

Chapter 4.

Load Preparation

Indications for Use

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

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.

Standard Cycle Processing

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

- Single-channel stainless steel lumens with an inside diameter of 1 mm or larger and a length of 150 mm or shorter.†
- Single-channel stainless steel lumens with an inside diameter of 2 mm or larger and a length of 400 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.

Advanced Cycle Processing

Medical devices, including most flexible endoscopes, with the following materials and dimensions can be processed in the STERRAD NX Sterilizer **Advanced cycle**:

- Single-channel stainless steel lumens with an inside diameter of 1 mm or larger and a length of 500 mm or shorter.†
- Single-channel PE/PTFE flexible endoscopes with an inside diameter of 1 mm or larger and a length of 850 mm or shorter.*

✔ *Note: With the exception of the 1 x 850 mm flexible endoscopes, the validation studies were performed using a validation load consisting of one instrument tray weighing 10.7 lbs. The 1 x 850 mm flexible endoscopes were validated without any additional load.*

†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.

*Only one flexible endoscope per cycle with or without a silicone mat. No additional load.

Determining What Can be Sterilized in the STERRAD® NX™ Sterilizer

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 NX Sterilization System.

Recommended Materials and Lumen Chart

The following page 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 NX Sterilizer. Please refer to it whenever you need materials information.

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

There are a wide variety of materials and devices that can be sterilized in the STERRAD NX Sterilizer. As more manufacturers complete testing of their products with the STERRAD NX 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.

How To Determine What Can Be Sterilized In The STERRAD® NX™ Sterilizer

1 Is The Reprocessable Medical Device Made Of The Following Materials?**

** This list of materials does not apply to trays and containers or other packaging materials. Please refer to the STERRAD® NX User's Guide for information on appropriate packaging materials for use in the STERRAD System.

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

† May have limited life after repeated sterilization.

Delrin®, Nylon®, and Teflon® are registered trademarks of the DuPont Corporation. ULTEM® Polymers is a registered trademark of the GE Company. KRATON™ Polymers is a registered trademark of KRATON Polymers U.S. L.L.C. Radel® is a registered trademark of Solvay S.A.

No/Don't Know

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.

Yes

2 Does The Reprocessable Medical Device Have A Lumen?

No

Proceed with Processing.

Yes

3 Is The Lumen Made Of Stainless Steel, Polyethylene, Or Teflon®?

No/Don't Know

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.

Yes

4 Proceed With Processing If The Lumen Conforms To The Dimensions Listed Below

No

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® NX™ Sterilizer

Single Channel Stainless Steel Lumen

Inside Diameter	Length	Cycle Selection
1 mm or larger	150 mm or shorter	Standard cycle*
2 mm or larger	400 mm or shorter	Standard cycle*
1 mm or larger	500 mm or shorter	Advanced cycle*

*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.

Single Channel Teflon®/Polyethylene Lumens

Inside Diameter	Length	Cycle Selection	Special Instructions
1 mm or larger	350 mm or shorter	Standard cycle.	Tubing only.*†
1 mm or larger	1000 mm or shorter	Advanced cycle.	Tubing only.†*
1 mm or larger	850 mm or shorter	Advanced cycle.	Single channel flexible endoscopes.*†

Standard cycle = 28 minutes • Advanced cycle = 38 minutes

† These tubing claims have not been reviewed by the Food and Drug Administration.

* Sterilize without any additional load. Up to 10 pieces of tubing may be sterilized at one time.

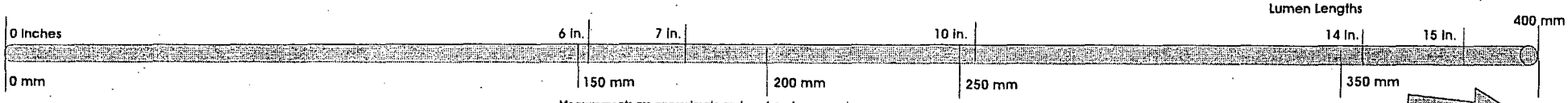
†† Only one flexible endoscope can be processed per cycle with or without a silicone mat. No additional load. It is important to follow the medical device manufacturer's instructions for use prior to processing any scope in the STERRAD NX Sterilizer.

Inside Lumen Diameters

- 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

mm= millimeter, in = inch, Fr = French

Lumen Lengths

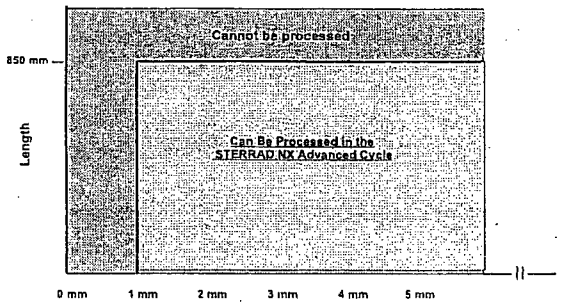


Measurements are approximate and are for reference only.

More Information

11 & 359

Processing Single-Channel Flexible Endoscopes With Polyethylene and Teflon® Lumens Only In The STERRAD® NX™ Sterilizer*



*Only one single-channel flexible endoscope can be processed per cycle with or without a silicone mat. No additional load.

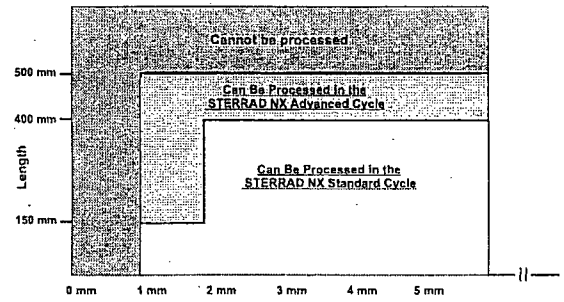
It is important to follow the medical device manufacturer's instructions for use prior to processing any scope in the STERRAD NX Sterilizer.

Inside Lumen Diameter

Millimeters	Inches	French Size	Gauge
.667	.026	2.0	22
.833	.033	2.5	21
1.0	**.039**	**3.0**	**20**
1.333	.052	4.0	18
1.667	.065	5.0	16
1.767	.069	5.3	15
2.0	**.078**	**6.0**	**14**
2.1	.082	6.3	14
2.167	.085	6.5	14
2.333	.091	7.0	13
2.5	.098	7.5	13
2.667	.104	8.0	12
2.833	.111	8.5	12
3.0	**.117**	**9.0**	**11**
3.333	.130	10.0	10
3.667	.143	11.0	9
4.0	**.156**	**12.0**	**8**
4.333	.169	13.0	7
4.667	.182	14.0	
5.0	.195	15.0	
5.333	.210	16.0	
5.667	.223	17.0	
6.0	.236	18.0	

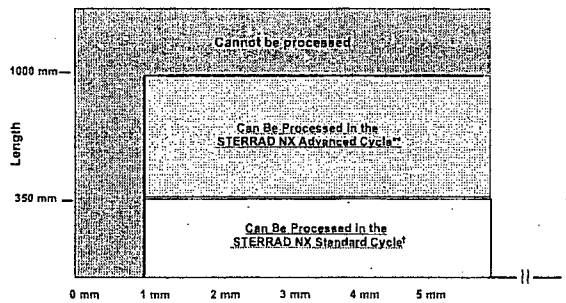
* Not indicated

Processing Single Channel Stainless Steel Lumens In The STERRAD® NX™ Sterilizer*



* 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.

Processing Polyethylene and Teflon® Tubing In The STERRAD® NX™ Sterilizer*



These tubing claims have not been reviewed by the Food and Drug Administration.

**Sterilize without any additional load. Up to 10 pieces of tubing may be sterilized at one time.

†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.

Typical Devices Sterilized in the STERRAD® NX™ Sterilizer*

- Stereotactic equipment
- Defibrillator paddles
- Electrocautery instruments
- Esophageal dilators
- Cranial pressure transducer cables
- Metal instruments
- Patient lead cables
- Endoscopic instruments
- Rigid endoscopes
- Laryngoscope blades
- Trocar sheaths
- Cryoprobes
- Surgical power equipment and batteries
- Fiberoptic light cables
- Laser hand-pieces, fibers, and accessories
- Ophthalmic lenses (diagnostic, magnifying)
- Pigmentation hand-pieces
- Dopplers
- Shaver hand-pieces
- Radiation therapy equipment
- Ultrasound probes
- Video cameras and couplers
- Resectoscope/working elements and sheaths
- Single Channel Flexible Endoscopes

If you have questions about whether your particular device can be sterilized in the STERRAD NX Sterilizer, please call the device manufacturer, your local ASP Representative, or in the U.S.A. call ASP at 1-888-STERRAD. Visit our website at www.sterrad.com.

* Any devices processed in the STERRAD NX Sterilizer must be within the claim limits of the sterilizer.

1/8 & 359

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

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 NX 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® NX Sterilizer.

†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.
*Sterilize without any additional load. Up to 10 pieces of tubing may be sterilized at one time.

Guidelines for Preparing Items to Be Sterilized

✔ *Note: All items must be cleaned, rinsed, and **thoroughly dried** before being placed in the STERRAD NX 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 gas 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, 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 NX 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.
- Arrange the items or the scope in a tray to ensure proper diffusion of hydrogen peroxide throughout the load.
- 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 NX 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 top of 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 NX 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 NX Sterilizer, it will damage the scope due to the inability to properly vent.

Only one flexible endoscope, with or without a silicon mat, can be processed per cycle. Do not add any additional items to the load.

Caution: ***Prior to processing flexible endoscopes in the STERRAD NX 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® NX™ Sterilizer, follow the instructions provided in the chapter on load preparation. It is the operator's responsibility to be familiar with the information provided in this user's guide.

Start and Warm-up

1. Turn on the main power switch–it is located at the front of the sterilizer, below the printer.
2. Close the door. The sterilizer begins by warming up. The warm-up can take up to 30 minutes.
3. "Touch Screen to Start" appears on the display.

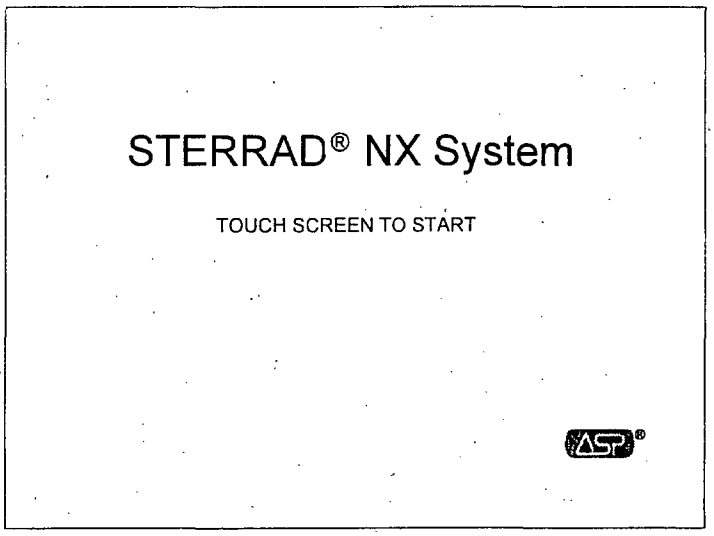


Figure 10. Touch the Screen to Start Your Cycle

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, skip to the subsection titled "Preparing the Load."

Inserting a Cassette

1. Take a new STERRAD NX Cassette out of the shipping carton.
2. Look at the package carefully before opening it. The indicator strip should be a yellow color. **If the indicator strip is red, 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 yellow, open the cassette package.
4. Insert the cassette into the cassette slot until it stops moving as shown in the following figure. **Do not use force** to push the cassette into the machine.

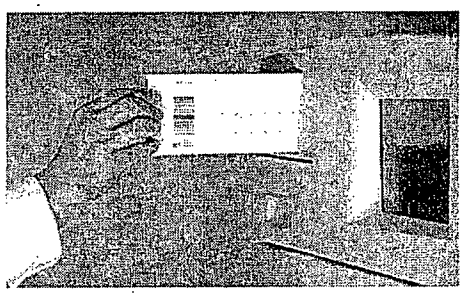


Figure 11. Inserting the Cassette into the Slot.

5. After a slight pause, the sterilizer pulls the cassette through the slot and the slot door closes. Cassette loading is now complete.

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 NX Sterilizer.

Biological testing with the STERRAD CycleSure Biological Indicator should be performed at least once per day or as specified by your facility's policy. Biological indicators should be processed in the cycle type (standard or advanced) that you are using during the day. If you use both cycles, process a biological indicator in each cycle type. Place the STERRAD CycleSure Biological Indicator in the chamber at the back of the bottom shelf for each test you perform. 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.

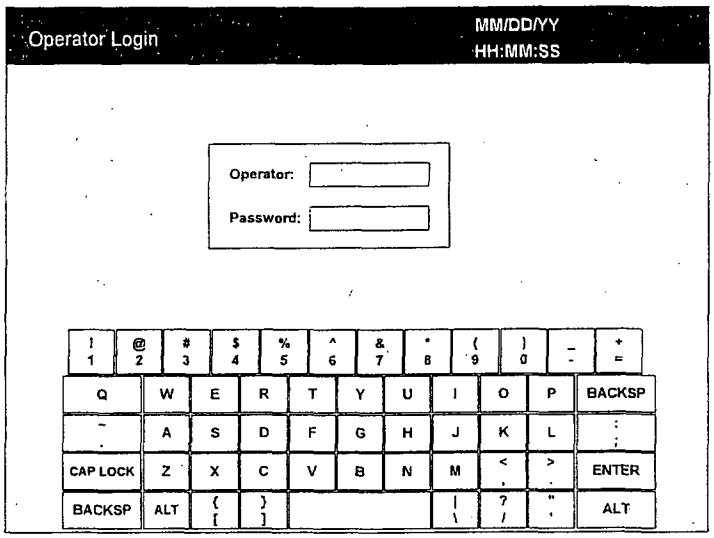


Figure 12. Operator Login Screen.

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.

The Load Item Data screen allows you to enter a list of items in your load and their associated tracking numbers (if any). This information is stored by the sterilizer and is printed on a cycle report (and can be transferred to a host computer over the network connection).

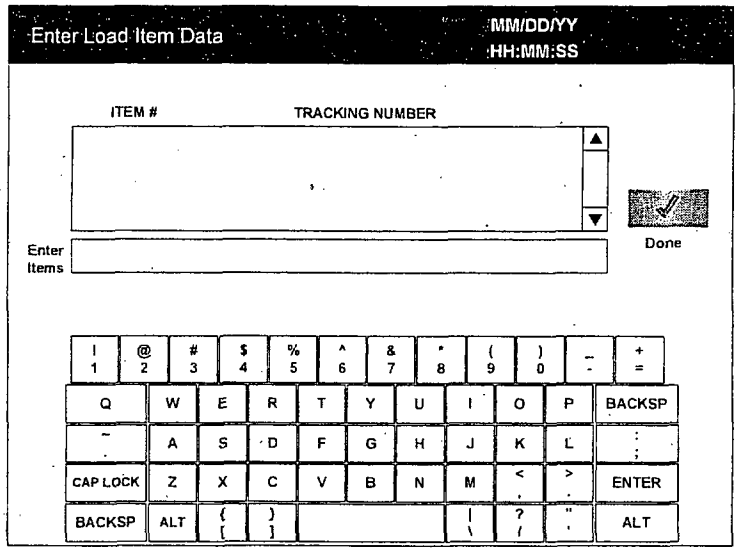


Figure 13. Enter Load Item Data

1. Touch the **Enter Items** field. The cursor appears in the field.
2. Use the on-screen keyboard to type a description of each item or its tracking number.
3. When you have entered an item, touch the **Enter** key. The line you typed moves to the list box.
4. Continue entering information, one line at a time, until you are finished.

5. When data entry is complete, touch the **Done** button.
6. The program displays the Enter Cycle Notes screen.

A barcode scanner can also be used to enter load item data. Refer to the barcode scanner *Instructions for Use* if your sterilizer is equipped with this option.

Cycle Notes

✔ ***Note:*** *If your sterilizer has been configured not to require cycle notes, this screen will not appear. Skip to the subsection titled* "Loading the Chamber."

The Cycle Notes screen allows you to enter information about the cycle. This screen can be used to record information about biological indicators used in the cycle or any other information that should be stored in the cycle history file. This information is printed out on the cycle report (and can be transferred to a host computer over the network connection).

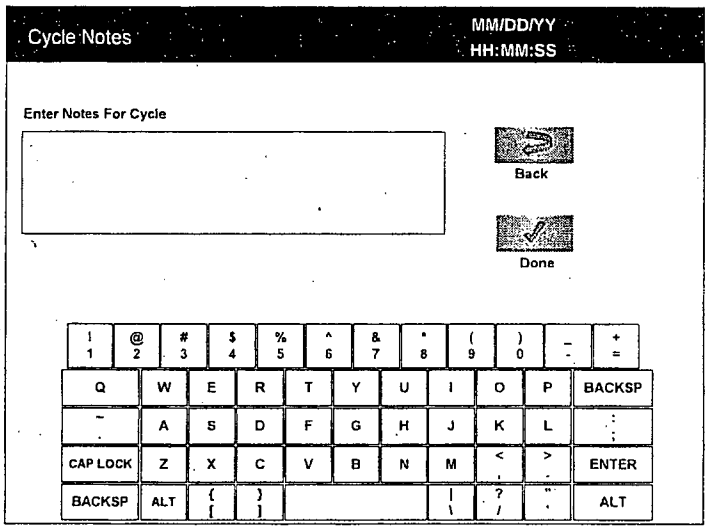


Figure 14. Cycle Notes.

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 blocked), a message is displayed on the screen.
5. The program displays the System Ready screen.

Loading the Chamber

1. Open the chamber door and place your load on the shelves.

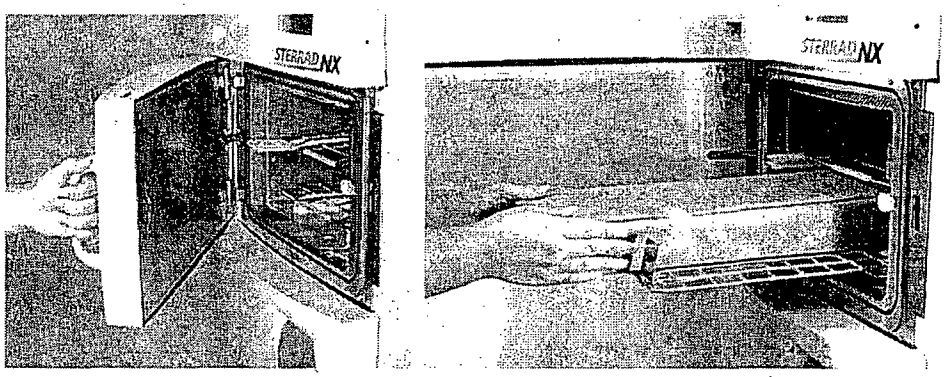


Figure 15. Open the Door and Place your Load on the Shelf.

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

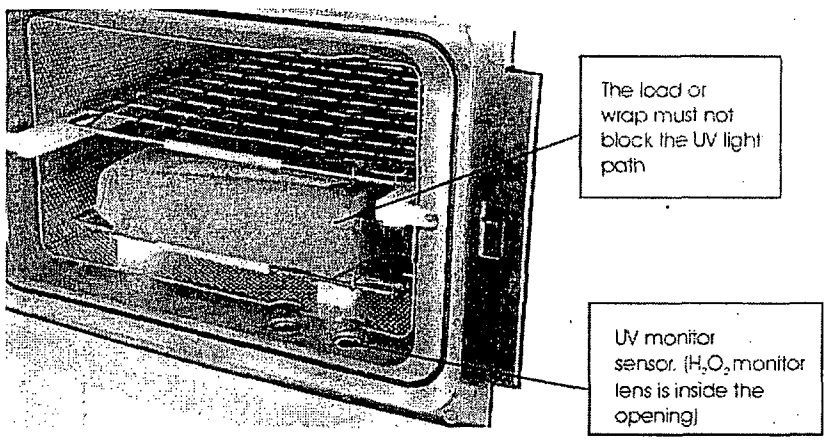


Figure 16. Do Not Block the UV Lamp.

2. When placing the load on the shelves, make certain that you do not block the beam of the ultraviolet lamp in the front right corner of the chamber.

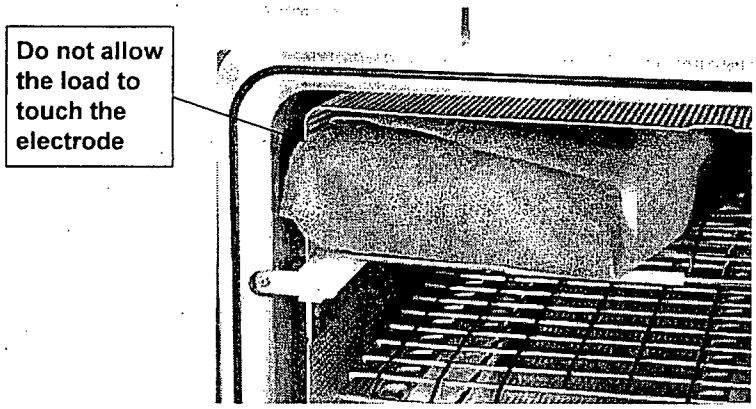


Figure 17. The Load Should NOT Touch the Electrode.

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.

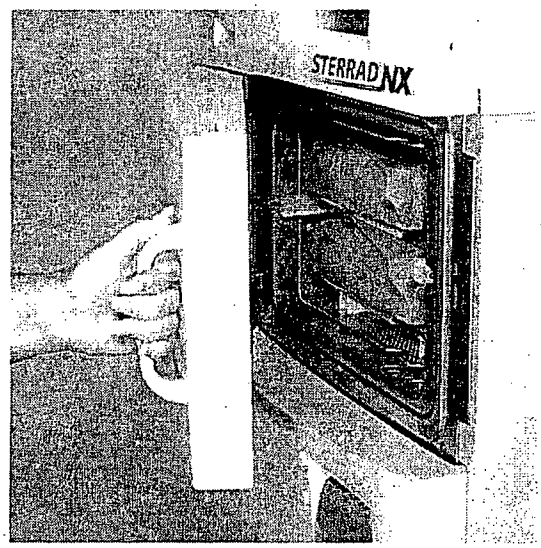


Figure 18. Close the Door.

5. When finished loading the chamber, close the door tightly.
6. If the message "Please Close Door" 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 tightly closed, use the System Ready screen to select the sterilization cycle appropriate for the load.

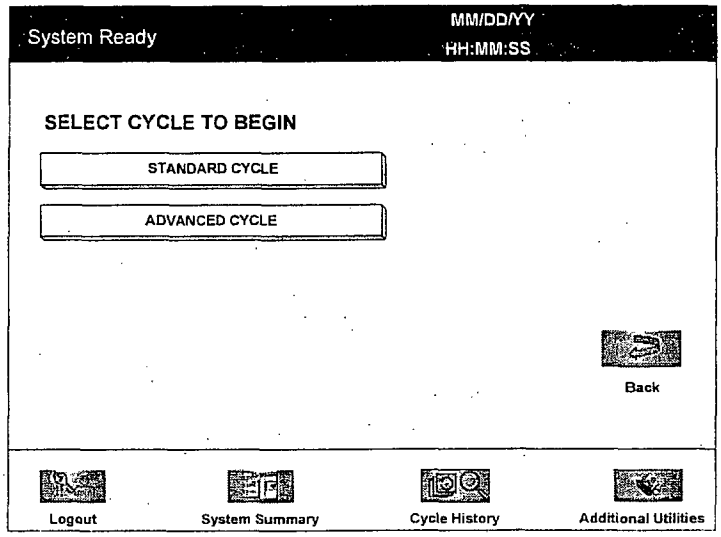


Figure 19. System Ready.

1. Touch the button that corresponds to the cycle that is appropriate for the load you wish to sterilize.
2. The sterilizer loads the cycle program and displays the **Start Cycle** button.
3. If an incorrect cycle has been selected, touch the **Cancel** button and then select the correct cycle.
4. Touch the **Start Cycle** button to start the selected cycle.

Cycle Warm Up

When changing from one type of cycle to another; i.e., from Standard to Advanced or from Advanced to Standard, the sterilizer requires time to warm up.

1. The sterilizer displays the System Warming Up message.

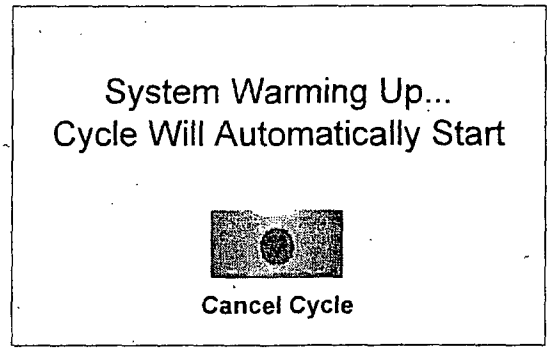


Figure 20. System Warming Up,

2. The message provides a cancel button to allow the user to cancel the cycle.
3. If the sterilizer temperature does not reach the setpoints within 10 minutes, the sterilizer returns to the System Ready screen and the display directs you to the proper action.
4. Once the temperatures are within the correct range, the sterilizer begins a "count down clock" as described in the "Cycle In Progress" section.

System Ready Screen

The System Ready screen displays a row of buttons along the bottom of the screen. These buttons select sterilizer functions:

- **Logout** is used when the current operator is finished using the sterilizer. When Logout is selected, you must login to use the sterilizer.
- **System Summary** displays the System Summary file and allows you to print a copy.
- **Cycle History** displays the Select Cycle History screen. This screen allows you to select a cycle history file and view or print it.
- **Additional Utilities** is available only to operators with Supervisor-level access. It displays the Additional Utilities Menu.

Cycle in Progress

When you touch the **Start Cycle** button, the sterilizer starts a "countdown clock" and begins the sterilization cycle.

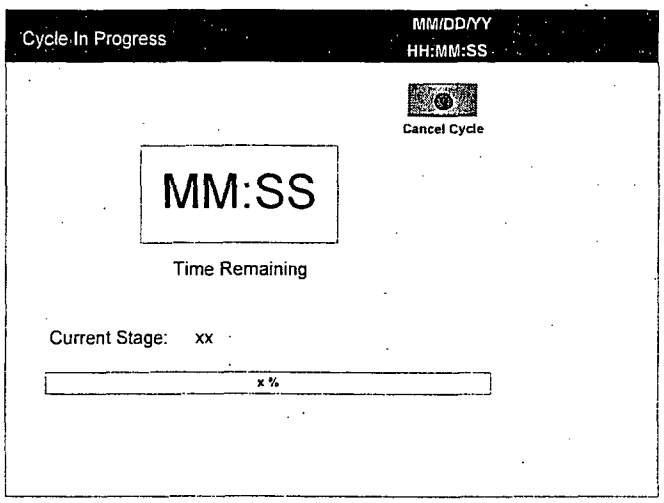


Figure 21. Cycle In Progress. The Countdown Clock is Displayed.

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 Long Report printout in the "Reports and Files" chapter.

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.

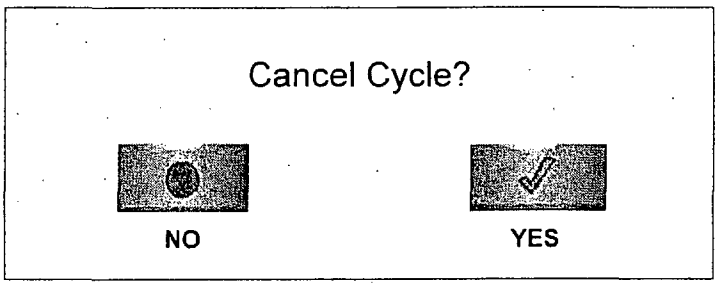


Figure 22. Cancel Cycle Confirmation. Touch Yes or No.

2. Touch the **No** button to proceed 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.

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 or if 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.

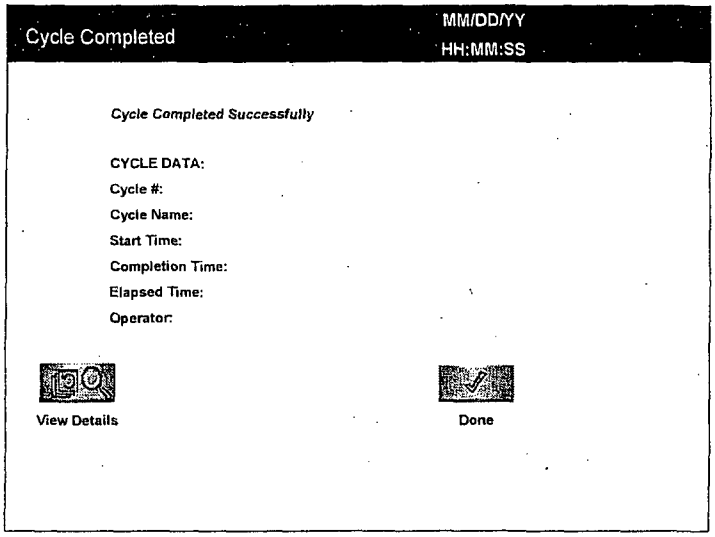


Figure 23. Cycle Completed.

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 the **Done** button. The door unlocks and the load can be removed.
- If no login is required for load removal, the door unlocks and the load can be removed.
- Refer to the cycle completion flowchart on the next page for additional information.

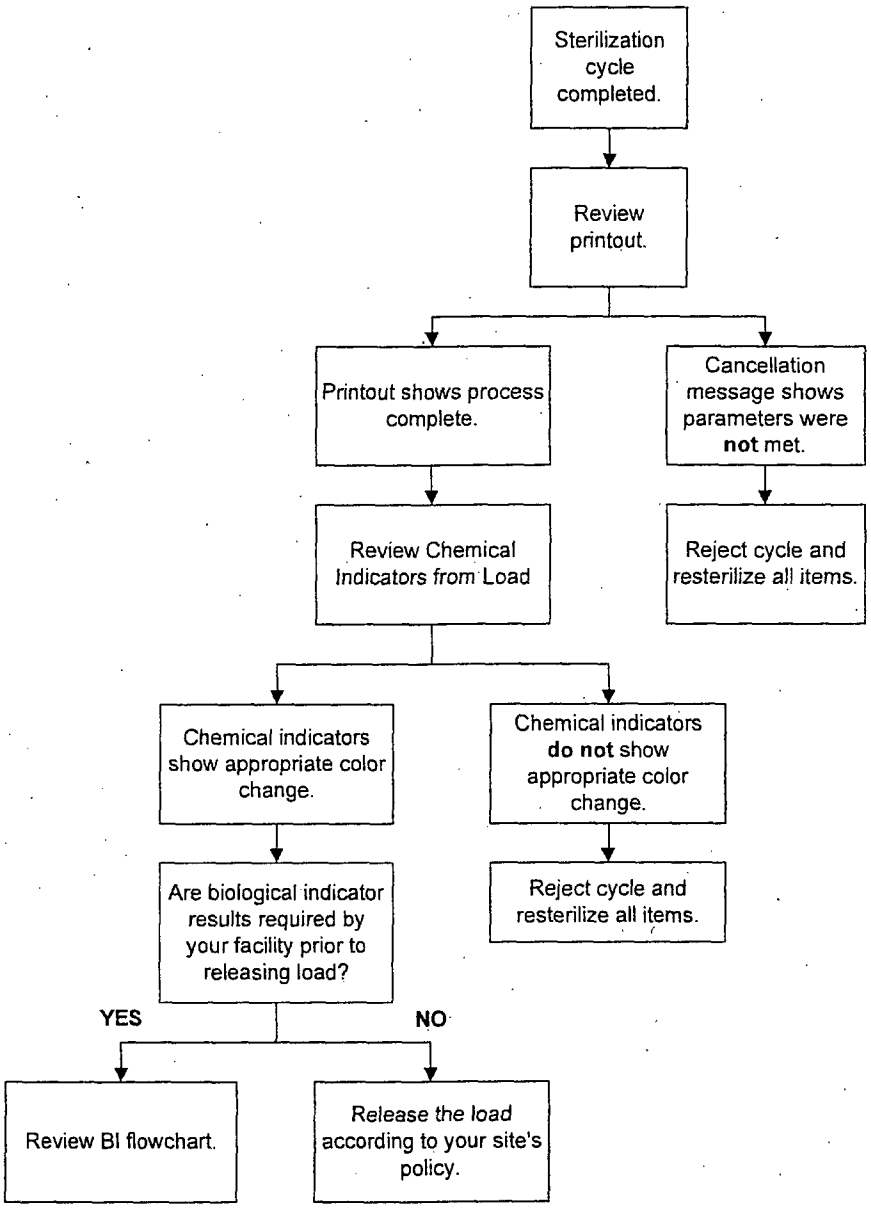
Inspecting Chemical Indicators

After ensuring that the chemical indicators exhibit the correct color change, and the cycle printout shows that all 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 and repackage and reprocess the load.

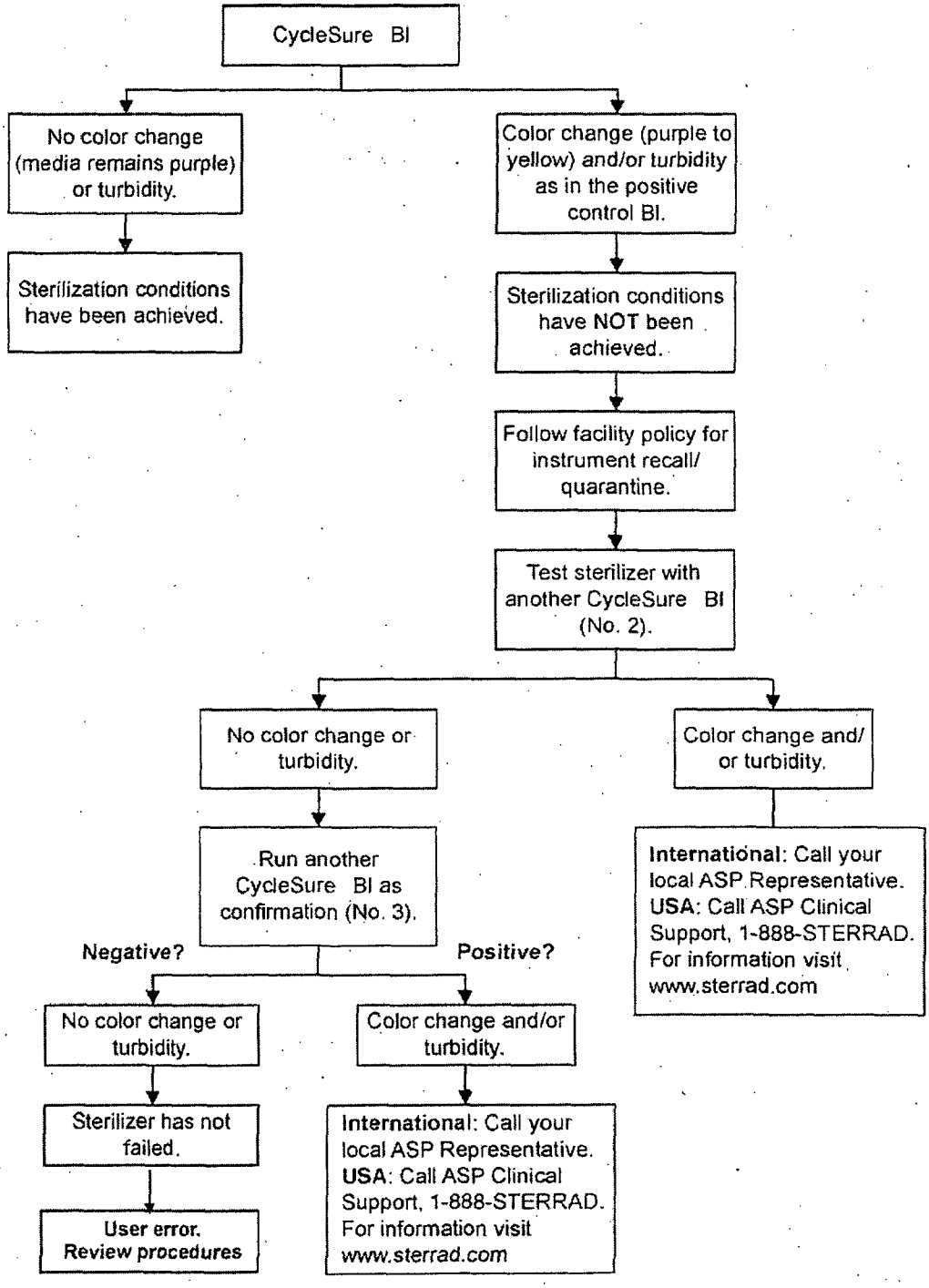
Processing Biological Indicators

Remove the biological indicator from the load and process it per its *Instructions for Use*. Refer to the biological indicator flow chart on the next page for additional information.

Cycle Completion Flowchart



STERRAD® CycleSure® Flowchart



Chapter 6.

Access Levels and Supervisor Tasks

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® NX™ 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

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.

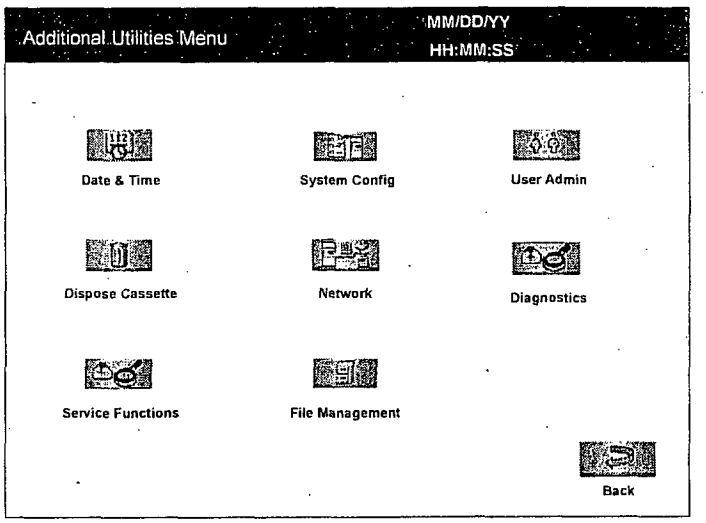


Figure 24. Additional Utilities Menu.

Date & Time allows you to set the date, time, time zone, and formats used for displaying and printing date and time.

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

Service Functions are reserved for use by ASP Service Representatives.

System Config allows you to set sterilizer options.

Network allows you to configure the network connection.

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

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

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

The **Back** button returns you to the screen from which you selected "Additional Utilities."

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.

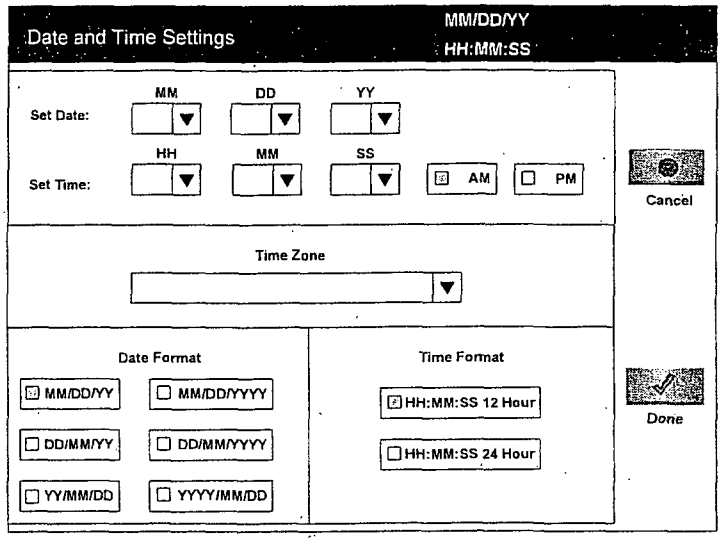


Figure 25. Date and Time Setting

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.

Dispose Cassette

Touch the **Dispose Cassette** button when you want to dispose of a cassette that is currently loaded in the sterilizer. The Dispose Cassette function moves the cassette from inside the sterilizer to the cassette drawer. Once a cassette is disposed, the sterilizer will not allow it to be inserted again.

Service Functions

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

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 time interval before the screen backlight is turned off, 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.

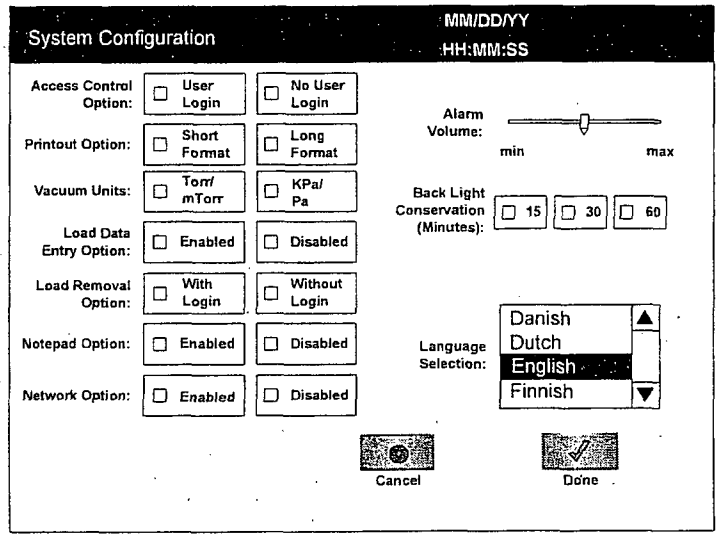


Figure 26. System Configuration.

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.

Printout Option

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.

144 7 359

Vacuum Units

torr/mtorr expresses vacuum measurements in torr and millitorr.

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 be connected to a network.

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

Alarm Volume

Touch the slider to adjust the volume of the alarm loudspeaker. Move the slider to the far left end to turn the alarm speaker off. The factory default setting is in the middle of the scale.

Backlight Conservation

The lifetime of the touch screen backlight can be considerably increased if the sterilizer automatically turns it off when it is not in use.

Select **15**, **30**, or **60** minutes to set the length of time the backlight remains on after the screen was last touched. When the selected interval expires, the backlight is automatically turned off. Touch the screen to turn the backlight on again. The factory default setting is 15 minutes.

Language Selection

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

Cancel/Done

To cancel system configuration, touch the **Cancel** button. When the system configuration settings are correct, touch the **Done** button on the second System Configuration screen.

File Management

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

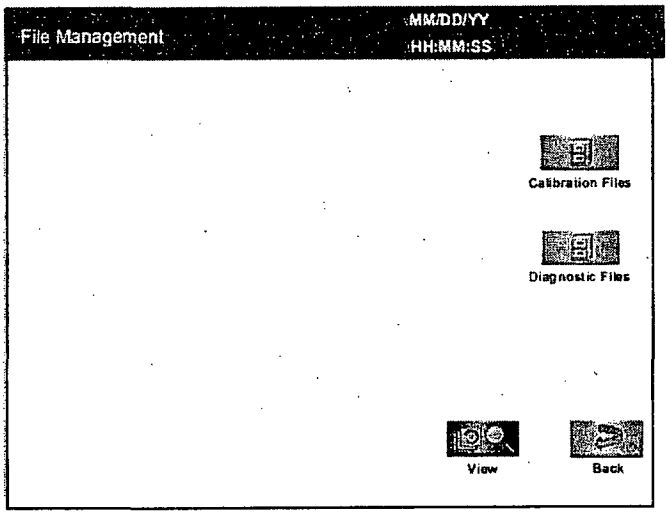


Figure 27. File Management.

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.

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 over your network from a remote host (if configured for network connection).

✔ *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.*

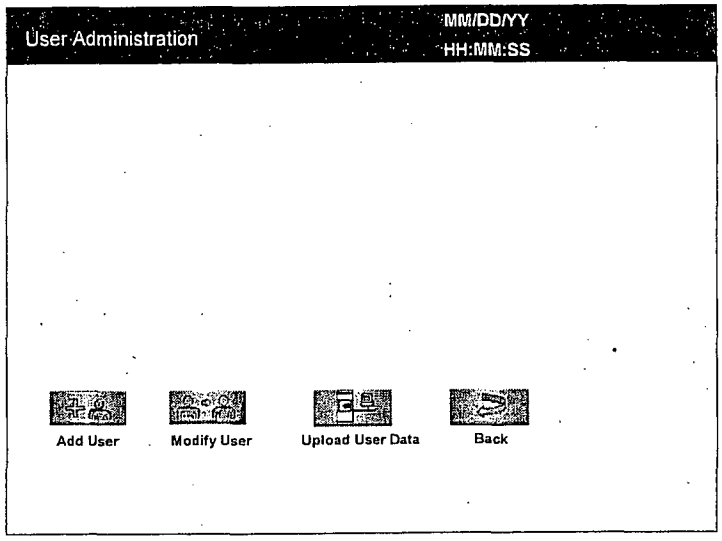


Figure 28. User Administration.

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.

Upload User Data causes the sterilizer to receive a complete database file of user names, passwords, and access levels from a remote host over the network. (This function does not work if your sterilizer is not configured for a network connection.)

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.

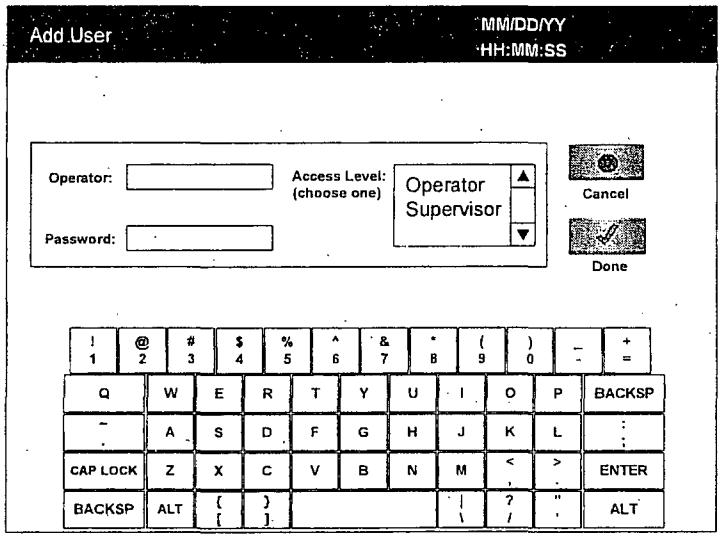


Figure 29. Add User.

1. Enter the user's operator "identification" in the **Operator** field. The entry must be alpha-numeric, 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."

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.

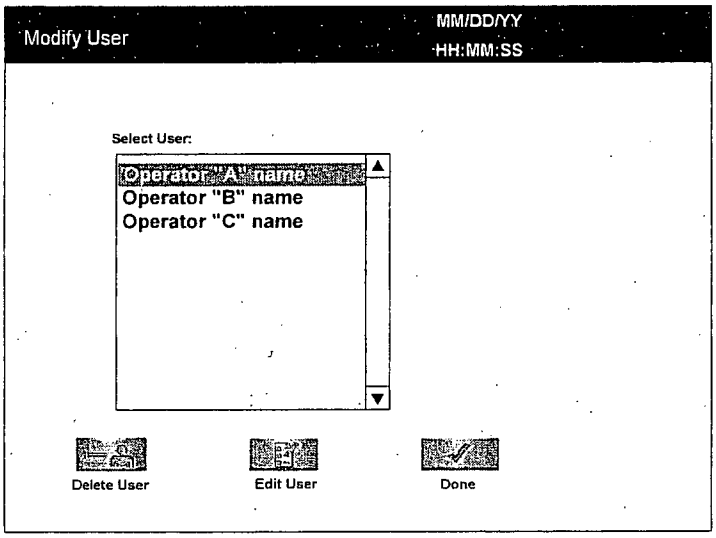


Figure 30. Modify User.

1. Select the user's name whose information you wish to modify.
2. The selected user's information is displayed in the Edit User screen.

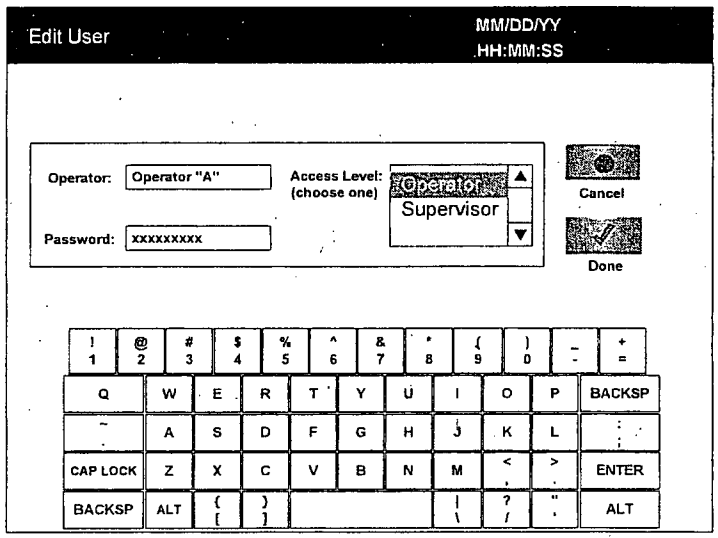


Figure 31. Edit User

- 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."

3. Touch the **Cancel** button to exit this screen and return to the Modify User screen.
4. Touch the **Done** button when you have finished – the Modify User screen is displayed.
5. To delete a user (revoke access to the sterilizer), select the user name and touch the **Delete User** button.

Upload User Data

If your STERRAD® NX Sterilizer has been configured for network connectivity, you can also add up to 1000 user identifications by uploading them to the sterilizer from a remote computer or hospital network.

If you are not familiar with MS-DOS® applications, do not attempt to upload the user data. Contact your facility's network administrator for more information.

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

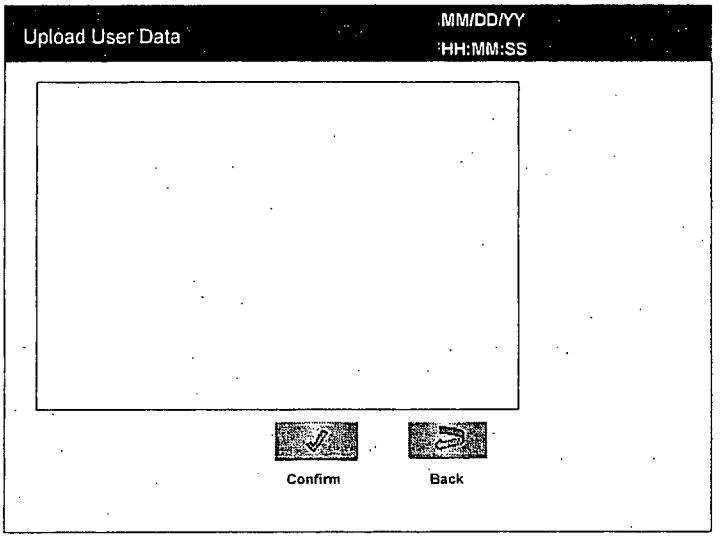


Figure 32. Upload User Data

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. 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. From a PC running Microsoft® Windows, open the command prompt application (emulation of an MS-DOS® shell).
3. Type: **cd <path>**

   where <path> is the pathname to the **users.rec** file.
4. Determine the sterilizer's IP address (refer to the *Network Settings* screen).

5. Transfer the **users.rec** file to the sterilizer by typing: **TFTP <sterilizer IP address> PUT users.rec**
   where <sterilizer IP address> is the address obtained from the Network Settings screen.
6. 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® NX 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.
7. Touch the **Confirm** button to accept the displayed data, logout the current user and return to the prior screen.

Diagnostics

Touch the **Diagnostics** button to start automatic diagnostic testing of the sterilizer. When started, the diagnostics function prompts you to select one of two types of tests (either *Temperature* 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 following table in the order in which they occur.

Diagnostic Tests

Order	Test Name	What is tested	Average Time to Run*
1	Power Supply Test	High- and low-voltage power supplies and sensors.	30 sec.
2	Vacuum Test	Vacuum pump and pressure sensors.	2 min. 20 sec.
3	Plasma Test	Plasma electrical subsystem. Electrode integrity.	3 min. 40 sec.
4	Cassette Test	Cassette mechanical subsystem. Barcode reader.	5 min.
5	Door Test	Electric door lock.	20 sec.
6	H_2O_2 Sensor Test	Ultraviolet lamp and detector.	20 sec.
7	Display Test	Touch screen calibration and function.	20 sec.
8	Printer Test	Printer function.	10 sec.
9	Fan Test	Fan speed and function.	10 sec.
10	Sound Test	Loudspeaker function and volume.	40 sec.

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

The ten tests take approximately 13 minutes and 30 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.

Chapter 7.

Reports and Files

Displayed Reports

Users with Operator-level access can display the System Summary file and Cycle History files. Users with Supervisor-level access can display the System Summary file, 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.

System Summary

The System Summary lists the configuration settings and factory-set parameters of the sterilizer and the control program.

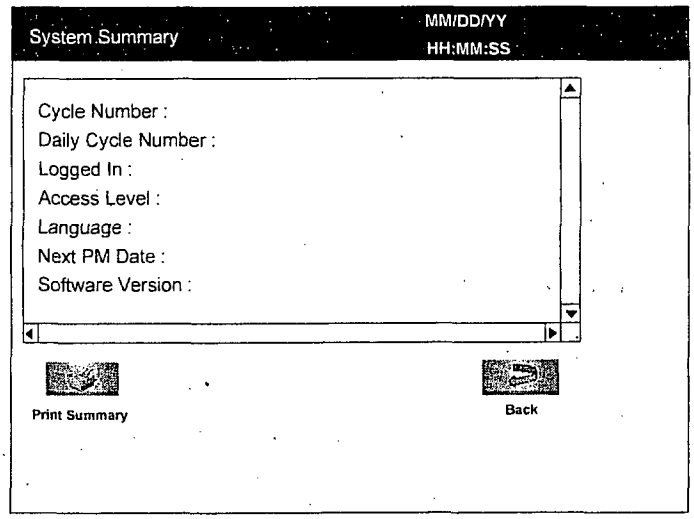


Figure 33. System Summary

Print Summary prints the contents of the System Summary file. Touch the scroll bars to scroll through the file. An explanation of the System Summary file is provided in the following table

Back returns you to the previous screen.

System Summary File

Summary Item	Description	Comments
Cycle Number	Number of cycles since sterilizer was installed	Determined by sterilizer operation
Daily Cycle Number	Number of cycles since start of day (midnight)	Determined by sterilizer operation
Logged In	Name of currently logged-in operator	Determined by operator
Access Level	Access level of currently logged-in operator	Configurable by supervisor
Language	Current language setting	Configurable through System Configuration screen
Next PM Date	Date next planned maintenance service is due	Set by ASP Service
Software Version	Version of the sterilizer software	Set by factory; modifiable by ASP Service only
Cassette Position	Current position of the cassette	Determined by sterilizer operation
Cassette Exp. Date	Expiration date of currently installed cassette	Read from barcode on currently installed cassette
Cassette Barcode	Barcode data from currently installed cassette	Read from barcode on currently installed cassette
Access Control	Indicates whether user login is required	Configurable through System Configuration screen
Printout Option	Indicates print option – short or long format must be selected	Configurable through System Configuration screen
Vacuum Units	Scaling used to indicate vacuum: torr/millitorr or kilopascals/Pascals	Configurable through System Configuration screen
Load Data Entry	Indicates whether Load Item Data entry is required	Configurable through System Configuration screen
Load Removal	Indicates whether users must login to remove a load	Configurable through System Configuration screen
Notepad	Indicates whether Cycle Notes	Configurable through System

Summary Item	Description	Comments
	entry is required	Configuration screen
Alarm Volume	Current setting of alarm volume	Configurable through System Configuration screen
Backlight Conservation	Current setting of backlight conservation timer	Configurable through System Configuration screen
Facility Name	Name of your facility	Configurable through System Configuration screen
Department Name	Name of your department	Configurable through System Configuration screen
Sterilizer ID	A unique identifier of your sterilizer	Configurable through System Configuration screen
Sterilizer Serial #	Serial number of your sterilizer	Set by ASP Service
Date Format	Current setting of date format	Configurable through Date and Time Settings screen
Time Format	Current setting of time format	Configurable through Date and Time Settings screen
Time Zone	Current setting of time zone	Configurable through Date and Time Settings screen
Remote Hostname*	Current setting of remote hostname	Configurable through Network Settings screen
Remote Port Number*	Current setting of remote port number	Configurable through Network Settings screen
Sterilizer Host Name*	Current setting of sterilizer host name	Configurable through Network Settings screen
Sterilizer IP Address*	Current setting of sterilizer IP address	Configurable through Network Settings screen
Name Server IP Address*	Current setting of name server IP address	Configurable through Network Settings screen
Gateway*	Current setting of gateway	Configurable through Network Settings screen
Resolver Domain Name*	Current setting of resolver domain name	Configurable through Network Settings screen
Subnet Mask*	Current setting of subnet mask	Configurable through Network Settings screen
System Board Revision	Revision number of system circuit	Determined by sterilizer

Summary Item	Description	Comments
	board	operation
Network Option	When enabled, network connection is supported	Configurable through System Configuration screen
Pressure Zeroing	Current setting for the pressure zeroing procedure	Set by ASP Service
Pressure Zeroing Time Interval	Current setting of the time interval of when to start the pressure zeroing procedure	Set by ASP Service
Pressure Zeroing Time of day	Current setting of the time of day to start the pressure zeroing procedure	Configurable through System Configuration screen
Pressure Zeroing Printout	Indicates whether printout is required	Configurable through System Configuration screen
IMS† Hardware	Current IMS hardware configuration of the sterilizer	Set by ASP Service
IMS Mode	Current setting of the IMS option	Set by ASP Service
IMS Printout	Indicates whether printout is required	Configurable through System Configuration screen

* Not applicable if Network Option is disabled.
† Independent Monitoring System.

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.

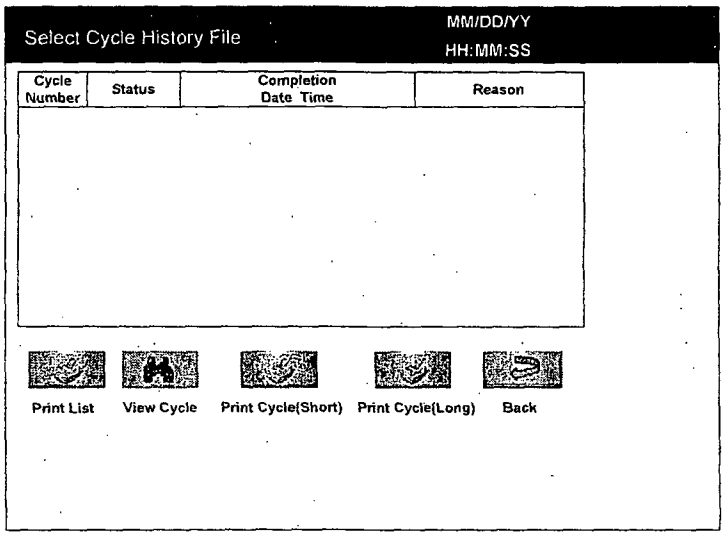


Figure 34. Select Cycle History File.

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.

Back returns you to the previous screen.

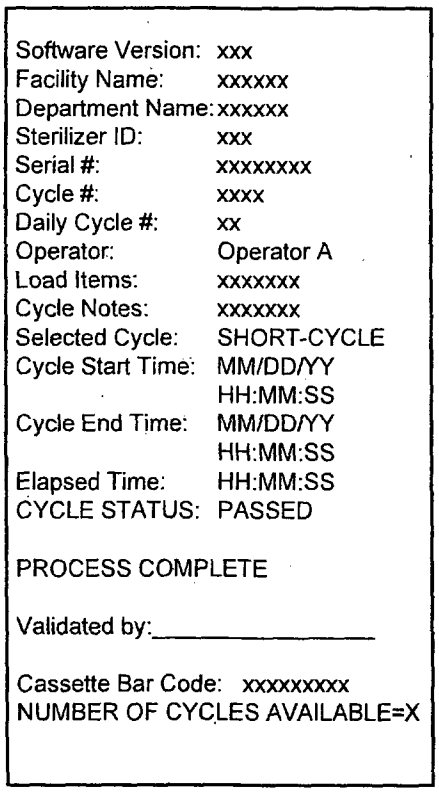
158 7 359

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 or a long-format report. Both reports extract 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 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. An example of a short-format report is illustrated in the following figure.



Software Version: xxx
Facility Name: xxxxxx
Department Name: xxxxxx
Sterilizer ID: xxx
Serial #: xxxxxxxx
Cycle #: xxxx
Daily Cycle #: xx
Operator: Operator A
Load Items: xxxxxxx
Cycle Notes: xxxxxxx
Selected Cycle: SHORT-CYCLE
Cycle Start Time: MM/DD/YY
HH:MM:SS
Cycle End Time: MM/DD/YY
HH:MM:SS
Elapsed Time: HH:MM:SS
CYCLE STATUS: PASSED

PROCESS COMPLETE

Validated by:_____

Cassette Bar Code: xxxxxxxxx
NUMBER OF CYCLES AVAILABLE=X

Figure 35. Short Formal Report

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.

An example of a long-format report is illustrated in the following three figures.

Software Version: xxx
Facility Name: xxxxxx
Department Name: xxxxxx
Sterilizer ID: xxx
Serial #: xxxxxxxx
Cycle #: xxxx
Daily Cycle #: xx
Operator: Operator A
Load Items: xxxxxxxxxx
Cycle Notes: xxxxxxxxxx
Selected Cycle: STNX-SHORT-CYCLE
Cycle Start Time: MM/DD/YY HH:MM:SS
Cycle End Time: MM/DD/YY HH:MM:SS
Elapsed Time: HH:MM:SS
Cycle Status: Passed

(Warm Up Start)

Start Time	End Time	Stage Time
XX:XX:XX	XX:XX:XX	XX:XX:XX
Sensor	Max	Min
---	---	---
Pressure:	>30Torr	>30Torr
Chamber Temp:	xx.xC	xx.xC
Door Temp:	xx.xC	xx.xC
Vaporizer Temp:	xx.xC	xx.xC
Condenser Temp:	xx.xC	xx.xC

(Delivery)

Start Time	End Time	Stage Time
XX:XX:XX	XX:XX:XX	XX:XX:XX
Sensor	Max	Min
---	---	---
Pressure:	xxxTorr	xxxTorr
Chamber Temp:	xx.xC	xx.xC
Door Temp:	xx.xC	xx.xC
Vaporizer Temp:	xx.xC	xx.xC
Condenser Temp:	xx.xC	xx.xC
H2O2 Monitor(mg/l):	x.x	x.x

(Vaporization Pumpdown 1)

Start Time	End Time	Stage Time
XX:XX:XX	XX:XX:XX	XX:XX:XX
Sensor	Max	Min
---	---	---
Pressure:	xxxTorr	xxxTorr
Chamber Temp:	xx.xC	xx.xC
Door Temp:	xx.xC	xx.xC
Vaporizer Temp:	xx.xC	xx.xC
Condenser Temp:	xx.xC	xx.xC

(Chamber Pumpdown 1)

Start Time	End Time	Stage Time
XX:XX:XX	XX:XX:XX	XX:XX:XX
Sensor	Max	Min
---	---	---
Pressure:	xxxTorr	xxxmTorr
Chamber Temp:	xx.xC	xx.xC
Door Temp:	xx.xC	xx.xC
Vaporizer Temp:	xx.xC	xx.xC
Condenser Temp:	xx.xC	xx.xC

(Transfer 1)

Start Time	End Time	Stage Time
XX:XX:XX	XX:XX:XX	XX:XX:XX
Sensor	Max	Min
---	---	---
Pressure:	xxxmTorr	xxxmTorr
Chamber Temp:	xx.xC	xx.xC
Door Temp:	xx.xC	xx.xC
Vaporizer Temp:	xx.xC	xx.xC
Condenser Temp:	xx.xC	xx.xC

(Pressure Check 1)

Start Time	End Time	Stage Time
XX:XX:XX	XX:XX:XX	XX:XX:XX
Sensor	Max	Min
---	---	---
Pressure:	xxxTorr	xxxmTorr
Chamber Temp:	xx.xC	xx.xC
Door Temp:	xx.xC	xx.xC
Vaporizer Temp:	xx.xC	xx.xC
Condenser Temp:	xx.xC	xx.xC

(Diffusion 1)

Start Time	End Time	Stage Time
XX:XX:XX	XX:XX:XX	XX:XX:XX
Sensor	Max	Min
---	---	---
Pressure:	xxxTorr	xxxTorr
Chamber Temp:	xx.xC	xx.xC
Door Temp:	xx.xC	xx.xC
Vaporizer Temp:	xx.xC	xx.xC
Condenser Temp:	xx.xC	xx.xC

Figure 36. Long Format Report

(Plasma Pumpdown 1)

Start Time	End Time	Stage Time
XX:XX:XX	XX:XX:XX	XX:XX:XX
Sensor	Max	Min
Pressure:	>30Torr	>30Torr
Chamber Temp:	xx.xC	xx.xC
Door Temp:	xx:xC	xx.xC
Vaporizer Temp:	xx.xC	xx.xC
Condenser Temp:	xx.xC	xx.xC
Max. Delivered Power:		xxx Watts
Min. Delivered Power:		x Watts
Plasma Time:		x:xx

(Plasma 1)

Start Time	End Time	Stage Time
XX:XX:XX	XX:XX:XX	XX:XX:XX
Sensor	Max	Min
Pressure:	xxxTorr	xxxTorr
Chamber Temp:	xx.xC	xx.xC
Door Temp:	xx.xC	xx.xC
Vaporizer Temp:	xx.xC	xx.xC
Condenser Temp:	xx.xC	xx.xC
Max. Delivered Power:		xxx Watts
Min. Delivered Power:		x Watts
Plasma Time:		x:xx

(Vent 1)

Start Time	End Time	Stage Time
XX:XX:XX	XX:XX:XX	XX:XX:XX
Sensor	Max	Min
Pressure:	xxxmTorr	xxxmTorr
Chamber Temp:	xx.xC	xx.xC
Door Temp:	xx.xC	xx.xC
Vaporizer Temp:	xx.xC	xx.xC
Condenser Temp:	xx.xC	xx.xC

(Delivery)

Start Time	End Time	Stage Time
XX:XX:XX	XX:XX:XX	XX:XX:XX
Sensor	Max	Min
Pressure:	xxxTorr	xxxTorr
Chamber Temp:	xx.xC	xx.xC
Door Temp:	xx.xC	xx.xC
Vaporizer Temp:	xx.xC	xx.xC
Condenser Temp:	xx.xC	xx.xC
H2O2 Monitoring(mg/l):	x.x	x.x

(Vaporization Pumpdown 2)

Start Time	End Time	Stage Time
XX:XX:XX	XX:XX:XX	XX:XX:XX
Sensor	Max	Min
Pressure:	xxxTorr	xxxTorr
Chamber Temp:	xx.xC	xx.xC
Door Temp:	xx.xC	xx.xC
Vaporizer Temp:	xx.xC	xx.xC
Condenser Temp:	xx.xC	xx.xC

(Chamber Pumpdown 2)

Start Time	End Time	Stage Time
XX:XX:XX	XX:XX:XX	XX:XX:XX
Sensor	Max	Min
Pressure:	xxxTorr	xxxmTorr
Chamber Temp:	xx.xC	xx.xC
Door Temp:	xx.xC	xx.xC
Vaporizer Temp:	xx.xC	xx.xC
Condenser Temp:	xx.xC	xx.xC

(Transfer 2)

Start Time	End Time	Stage Time
XX:XX:XX	XX:XX:XX	XX:XX:XX
Sensor	Max	Min
Pressure:	xxxmTorr	xxxmTorr
Chamber Temp:	xx.xC	xx.xC
Door Temp:	xx.xC	xx.xC
Vaporizer Temp:	xx.xC	xx.xC
Condenser Temp:	xx.xC	xx.xC

(Pressure Check 2)

Start Time	End Time	Stage Time
XX:XX:XX	XX:XX:XX	XX:XX:XX
Sensor	Max	Min
Pressure:	xxxTorr	xxxTorr
Chamber Temp:	xx.xC	xx.xC
Door Temp:	xx.xC	xx.xC
Vaporizer Temp:	xx.xC	xx.xC
Condenser Temp:	xx.xC	xx.xC

Figure 37. Long Format Report (continued).

(Diffusion 2)

Start Time	End Time	Stage Time
XX:XX:XX	XX:XX:XX	XX:XX:XX

Sensor	Max	Min
Pressure:	xxxTorr	xxxTorr
Chamber Temp:	xx.xC	xx.xC
Door Temp:	xx.xC	xx.xC
Vaporizer Temp:	xx.xC	xx.xC
Condenser Temp:	xx.xC	xx.xC

(Plasma Pumpdown 2)

Start Time	End Time	Stage Time
XX:XX:XX	XX:XX:XX	XX:XX:XX

Sensor	Max	Min
Pressure:	xxxTorr	xxxTorr
Chamber Temp:	xx.xC	xx.xC
Door Temp:	xx.xC	xx.xC
Vaporizer Temp:	xx.xC	xx.xC
Condenser Temp:	xx.xC	xx.xC

(Plasma 2)

Start Time	End Time	Stage Time
XX:XX:XX	XX:XX:XX	XX:XX:XX

Sensor	Max	Min
Pressure:	xxxmTorr	xxxmTorr
Chamber Temp:	xx.xC	xx.xC
Door Temp:	xx.xC	xx.xC
Vaporizer Temp:	xx.xC	xx.xC
Condenser Temp:	xx.xC	xx.xC
Max. Delivered Power:		xxx Watts
Min. Delivered Power:		x Watts
Plasma Time:		x:xx

(Final Vent)

Start Time	End Time	Stage Time
XX:XX:XX	XX:XX:XX	XX:XX:XX

Sensor	Max	Min
Pressure:	xxxTorr	xxxmTorr
Chamber Temp:	xx.xC	xx.xC
Door Temp:	xx.xC	xx.xC
Vaporizer Temp:	xx.xC	xx.xC
Condenser Temp:	xx.xC	xx.xC
Max. Delivered Power:		xxx Watts
Min. Delivered Power:		x Watts
Plasma Time:		x:xx

Process Complete

Validated by: _____

Cassette Bar Code: XXXXXXXXXX
Number of Cycles Available=X

Figure 38. Long Format Report (continued).

Files

The STERRAD® NX™ Sterilizer creates, stores, displays, prints, and can upload over a network several files of sterilizer and cycle-related data. These files include cycle history files. Each file is explained in the following sections.

Cycle History Files

Cycle history files contain very detailed information about each sterilization cycle. The files include identifying information about the operator, load, time, date, cycle duration information, stage-by-stage data from the sensors and controls, and related technical items. Information is extracted from the cycle history file to produce the short-format report and the long-format report. The cycle history file contains information that is vital to a facility's recordkeeping and traceability procedures. The sterilizer's memory holds data from the last 50 cycles.

Cycle history files can be viewed and printed by users with Operator-level access.

The following figure features an example of a Cycle Profile Graph that may be viewed for each cycle run by the sterilizer. This graph depicts plots of the chamber pressure, vaporizer pressure and hydrogen peroxide pressure. From the Select Cycle History File screen, pressing the **View Cycle** button will display the Cycle History screen. This screen shows the cycle data for the sterilization cycle. The Cycle History screen also contains a **Cycle History Graph** button that will display the Cycle Graph.

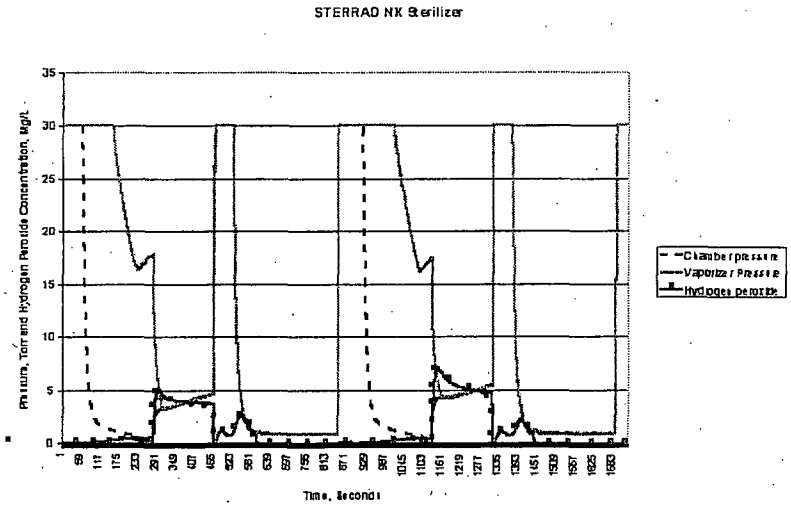


Figure 39. Cycle Profile - Standard Cycle.

Calibration Files

Calibration files are generated every time the sterilizer is recalibrated. The files contain details about the inputs and outputs from calibrated sensors. This information ensures that the sterilizer is operating within its calibration limits and is useful to ASP Service Representatives when performing maintenance or service.

Calibration files can only be viewed and printed by users with Supervisor-level access.

Examples of a temperature calibration report, a thermistor resistance adjustment report, and a hydrogen peroxide monitor calibration report are illustrated in the following three figures.

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Temp Calibration/Verification Report

File Name:		/xxxxxxxxxxxx
CH1 Heater	R:	xxxxxxxxxxxx
CH1 Heater	A:	xxxxxxxxxxxx
CH1 Heater	B:	xxxxxxxxxxxx
CH1 Heater	C:	xxxxxxxxxxxx
50C Verify Point(C):		xx.x
70C Verify Point(C):		xx.x
CH1 Htr Status:		XXXXXX
Last Verified:		MM/DD/YY HH:MM
CH2 Heater	R:	xxxxxxxxxxxx
CH2 Heater	A:	xxxxxxxxxxxx
CH2 Heater	B:	xxxxxxxxxxxx
CH2 Heater	C:	xxxxxxxxxxxx
50C Verify Point(C):		xx.x
70C Verify Point(C):		xx.x
CH2 Htr Status:		XXXXXX
Last Verified:		MM/DD/YY HH:MM
Door Heater	R:	xxxxxxxxxxxx
Door Heater	A:	xxxxxxxxxxxx
Door Heater	B:	xxxxxxxxxxxx
Door Heater	C:	xxxxxxxxxxxx
50C Verify Point(C):		xx.x
70C Verify Point(C):		xx.x
Door Htr Status:		XXXXXX
Last Verified:		MM/DD/YY HH:MM
Vap Heater	R:	xxxxxxxxxxxx
Vap Heater	A:	xxxxxxxxxxxx
Vap Heater	B:	xxxxxxxxxxxx
Vap Heater	C:	xxxxxxxxxxxx
50C Verify Point(C):		xx.x
70C Verify Point(C):		xx.x
Vap Htr Status:		XXXXXX
Last Verified:		MM/DD/YY HH:MM

Cond Heater	R:	xxxxxxxxxxxx
Cond Heater	A:	xxxxxxxxxxxx
Cond Heater	B:	xxxxxxxxxxxx
Cond Heater	C:	xxxxxxxxxxxx
50C Verify Point(C):		xx.x
70C Verify Point(C):		xx.x
Cond Htr Status:		XXXXXX
Last Verified:		MM/DD/YY HH:MM

Figure 40. Temperature Calibration Report Example.

Thermistor Resistance
Adjustment Report

File Name:	temprxxxxxxxx
Last Verified:	MM/DD/YY
	HH:MM
Door:	
Rprecision:	xxxxx Ohm
Rmeasured:	xxxxx Ohm
Rdiff:	xxxxx Ohm
Status:	Passed
Chamber 1:	
Rprecision:	xxxxx Ohm
Rmeasured:	xxxxx Ohm
Rdiff:	xxxxx Ohm
Status:	Passed
Chamber 2:	
Rprecision:	xxxxx Ohm
Rmeasured:	xxxxx Ohm
Rdiff:	xxxxx Ohm
Status:	Passed
Vaporizer:	
Rprecision:	xxxxx Ohm
Rmeasured:	xxxxx Ohm
Rdiff:	xxxxx Ohm
Status:	Passed
Condenser:	
Rprecision:	xxxxx Ohm
Rmeasured:	xxxxx Ohm
Rdiff:	xxxxx Ohm
Status:	Passed

Figure 41. Thermistor Resistance Adjustment Report Example.

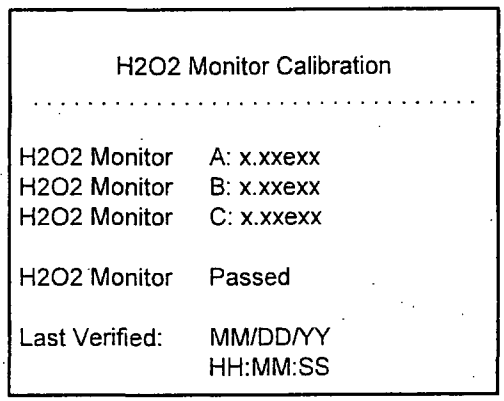

Figure 42. Hydrogen Peroxide Monitor Calibration Report Example.

Diagnostic Files

Diagnostic files are created by the diagnostics tests that are available only to users with Supervisor-level access. The files contain details about the tests and the outcomes (Passed or Failed) of each. This information is useful to ASP Service Representatives when performing maintenance or service.

Diagnostic files can only be viewed and printed by users with Supervisor-level access.

An example of a Diagnostic file is illustrated in the following figure.

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DIAGNOSTICS REPORT

File Name: /xxxxxx
Power Supply Test
3.3 Volts Power Supply: x.x
5 Volts Power Supply: x.x
12 Volts Power Supply: xx.x
15 Volts Power Supply: xx.x
24 Volts Power Supply: xx.x
POWER SUPPLY TEST PASSED/FAILED
Time Stamp: MM/DD/YY
HH:MM:SS

Pressure Test
PRESSURE TEST PASSED/FAILED
Time Stamp: MM/DD/YY
HH:MM:SS

Plasma Test
PLASMA TEST PASSED/FAILED
Time Stamp: MM/DD/YY
HH:MM:SS

Cassette Test
CASSETTE TEST PASSED/FAILED
Time Stamp: MM/DD/YY
HH:MM:SS

H2O2 Sensor Test
H2O2 SENSOR TEST PASSED/FAILED
Time Stamp: MM/DD/YY
HH:MM:SS

Display Test
DISPLAY TEST PASSED/FAILED
Time Stamp: MM/DD/YY
HH:MM:SS

Printer Test
PRINTER TEST PASSED/FAILED
Time Stamp: MM/DD/YY
HH:MM:SS

Fan Test
FAN TEST PASSED/FAILED
Time Stamp: MM/DD/YY
HH:MM:SS

Sound Test
SOUND TEST PASSED/FAILED
Time Stamp: MM/DD/YY
HH:MM:SS

Character Set

ABCDEFGHIJKLMNOPQRSTUVWXZY
abcdefghijklmnopqrstuvwxyz
!#$%&'()*+,_./:;<>?@[]^_{|}
0123456789

Display Test
DISPLAY TEST PASSED/FAILED
Time Stamp: MM/DD/YY
HH:MM:SS

Temperature Test
Door Rate: x.x c/min
Chamber Low Rate: x.x c/min
Chamber High Rate: x.x c/min
Vaporizer Rate: x.x c/min
Condenser Heat Rate: x.x c/min
Condenser Cool Rate: x.x c/min

Figure 43. Diagnostic File Example.

Chapter 8.

Maintenance

✔ *Note: Repairs and adjustments should only be attempted by experienced technicians who are fully trained to maintain and repair the STERRAD® NX ™ 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

Some maintenance procedures are performed automatically by the sterilizer software. The user does not have to perform any task to start an automatic maintenance procedure. There are two automatic maintenance procedures controlled by the software, they are:

- Pressure Zeroing
- Automatic Lamp Adjustment

Pressure Zeroing

Periodically, the sterilizer will need to adjust the pressure transducers to ensure that they are operating within the required parameters.

When the operator presses the **Touch Screen to Start** screen, and if the sterilizer is within two days of its automatic pressure zeroing function, a "Pressure Zeroing Recommended" warning message will be displayed, notifying the operator that the Pressure Zeroing function should be run. If a Pressure Zeroing procedure has not been performed by the operator within the required time interval, a "Pressure Zeroing Required" warning message will be displayed on the **System Ready** screen. If this occurs, the operator will be unable to start a cycle. A Supervisor will be required to successfully perform the Pressure Zeroing procedure.

Pressure Zeroing Report	
Time Stamp	MM/DD/YY HH:MM
Result:	[PASS/FAIL]
Chamber Offset:	xx mTorr
Vaporizer Offset:	xx mTorr
Chamber 1 Temperature:	xx.x C
Chamber 2 Temperature:	xx.x C
Vaporizer Temperature:	xx.x C
Door Temperature:	xx.x C
Condenser Temperature:	xx.x C
Chamber Pressure:	xx mTorr
Vaporizer Pressure:	xx mTorr
Reference Pressure:	xx mTorr

Figure 44. Pressure Zeroing Report.

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 between 5 and 40 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. 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 in the collection drawer. The screen displays a message instructing you which actions to take next. When the cassette disposal box contains three 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 from the drawer, a new cassette disposal box must be assembled and inserted in the drawer.

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. Pull open the cassette drawer.
2. Lift the disposal box of used cassettes out of the drawer.
3. Fold the flaps over the top of the box. Push the tab of one flap into the slot of the other flap.

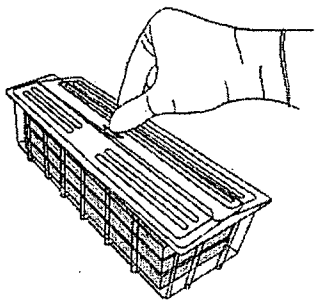

Figure 45. Push Tab Into Slots

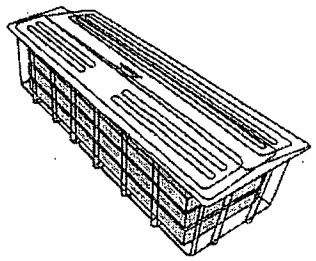

Figure 46. Closed Box Can Now Be Discarded

4. The closed box is now ready for disposal. It can be discarded as directed by your facility's hazardous waste disposal procedures following local and federal requirements.
5. Install a new cassette disposal box in the cassette drawer.

Inserting a New Cassette Disposal Box

After disposing of a used cassette disposal box, following your facility's policy, a new box must be assembled and inserted into the cassette collection drawer.

1. Remove a new, unused cassette disposal box from the packaging.
2. Place the box inside the drawer making sure the arrow on the bottom of the box faces away from you.

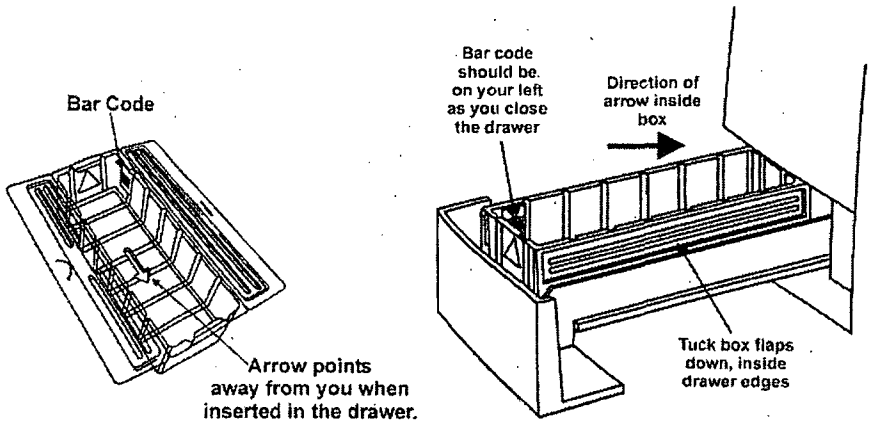

Figure 47. Correct Placement of Cassette Box in Drawer. Notice the Direction of the Arrow in the Box.

3. Tuck the flaps on the box inside the drawer edges. Close the drawer.

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 pressing the top button. The printer door drops forward.

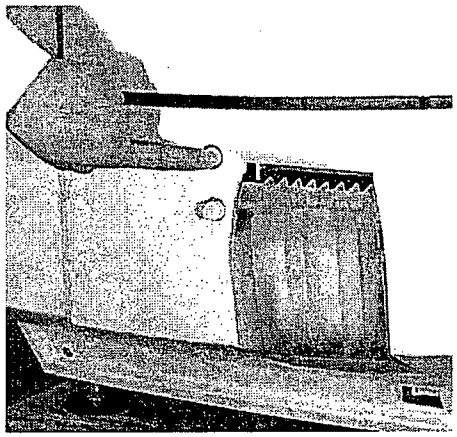

Figure 48. Open the Printer Door.

2. The empty paper roll rests on the bottom of the printer door. Remove the empty roll.

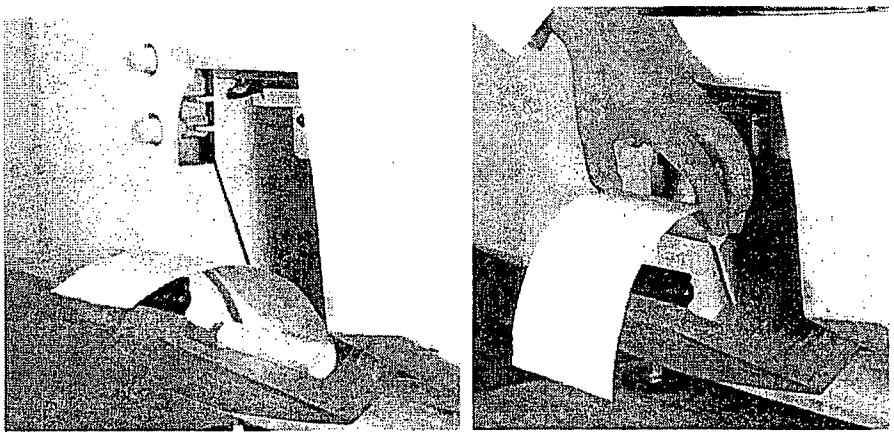

Figure 49. Remove the Empty Paper Roll.

3. Insert a new paper roll as shown in the following figure. The paper should feed from the top of the roll.

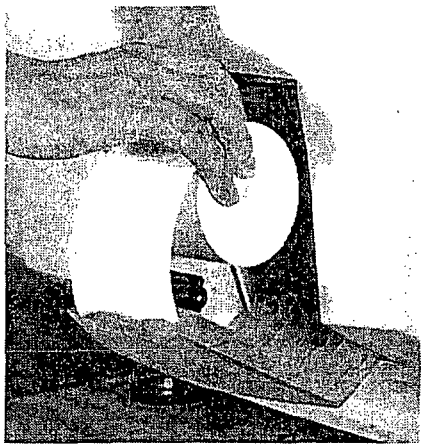

Figure 50. Insert a New Paper Roll.

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.

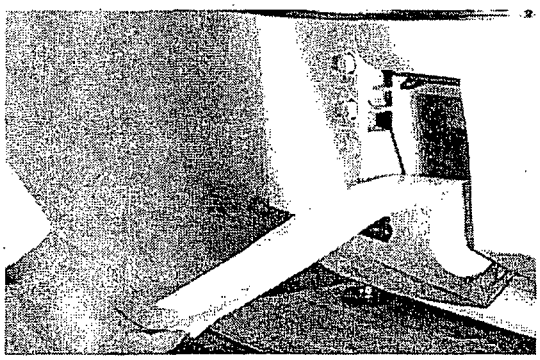

Figure 51. and Pull the Paper Over the Top of the Door and Align the Paper Between the Guides.

6. Hold the paper in place as you push the door shut.

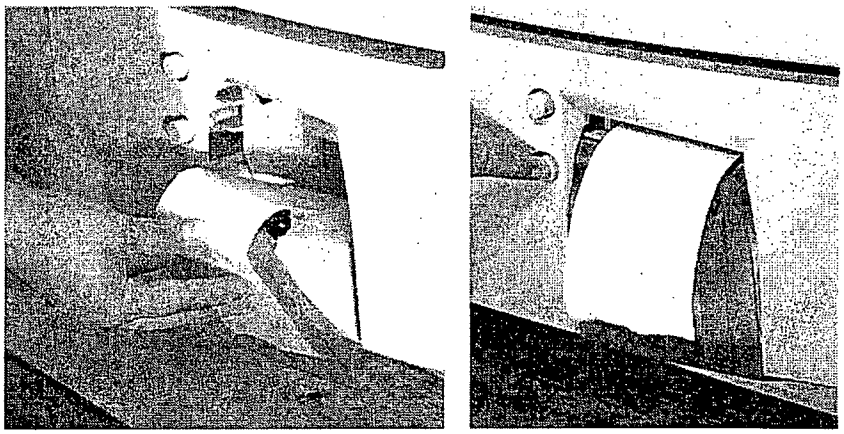

Figure 52. Hold the Paper as You Shut the Printer Door. Press the Paper Advance Button.

7. Push the bottom button to advance the paper. Check the alignment of the paper and make certain it does not jam or misfeed.
8. When the paper has advanced normally, tear off the used strip in an upward direction. Paper replacement is now complete.

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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. Internationally, 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. Internationally, 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 must be kept clean. Clean the lens once every three months or when an accumulation of debris is noted. The lens is shown in the following figure.

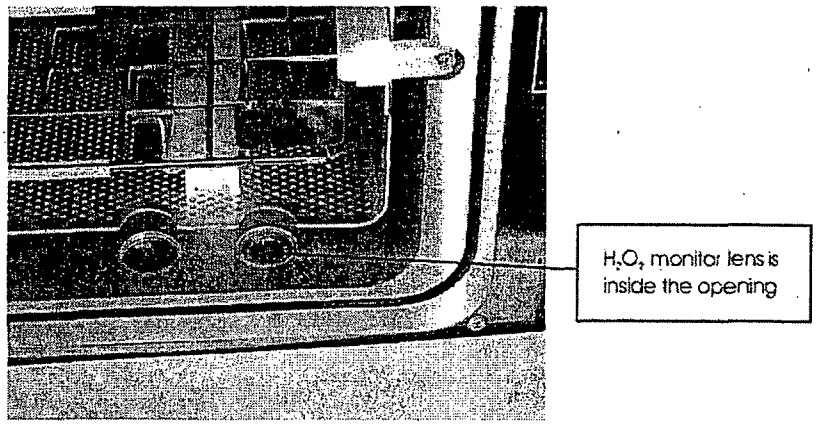

Figure 53. Hydrogen Peroxide Monitor Lens.

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

Replacing the Air Filter

The air filter should be replaced when it is clogged with dust or debris. Periodically check the air filter for dust and debris. Refer to Appendix B for information on purchasing air filters for the STERRAD® NX™ Sterilizer.

To replace the air filter follow these guidelines:

1. Remove the nut that holds the flange of the air filter to the sterilizer. Save the nut.
2. Pull the air filter straight out. Do not pull it up or bend it (see the following figure).
3. Orient the new air filter as shown in the following figure.

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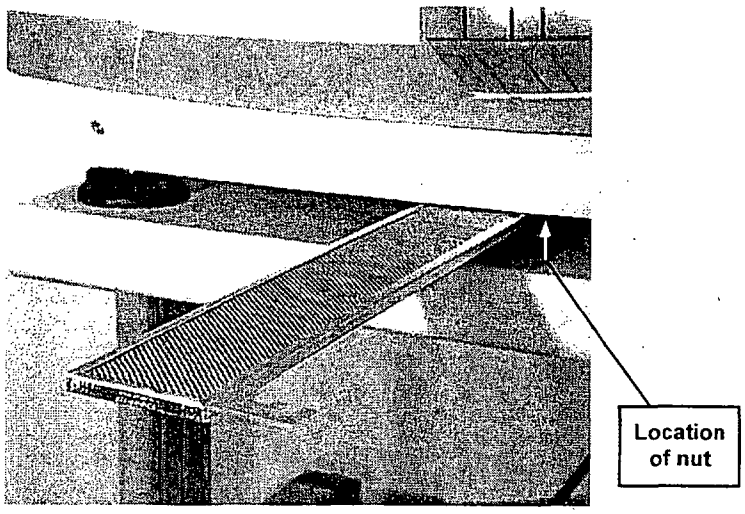

Figure 54. Air Filter.

4. Slide the new air filter into the sterilizer until it is firmly seated.
5. Replace and tighten the nut that attaches the air filter to the sterilizer.
6. Discard the used air filter as directed by your facility's policy.

PCMCIA Card Handling and Replacement

The PCMCIA card contains the flash memory used to store cycle data. If you wish to save cycle data and do not have a network connection, the cycle data can be transferred directly from the PCMCIA card to a computer equipped with a PCMCIA card slot. To access the cycle data, perform the following steps:

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

The card can now be inserted into a computer to transfer the files. Refer to the operating instructions of your computer before installing a PCMCIA card in your computer. Once the cycle data is transferred, the PCMCIA card must be reinserted in the sterilizer by following these steps:

1. Examine the PCMCIA card.

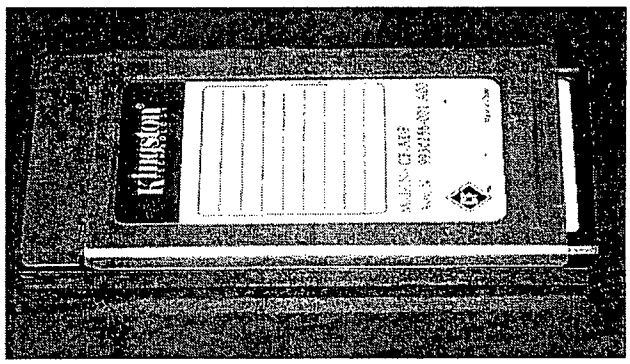

Figure 55. PCMCIA Card.

2. Orient the PCMCIA card so that the side of the card shown in the following figure faces up.
3. Insert the card into the PCMCIA card slot as shown below.

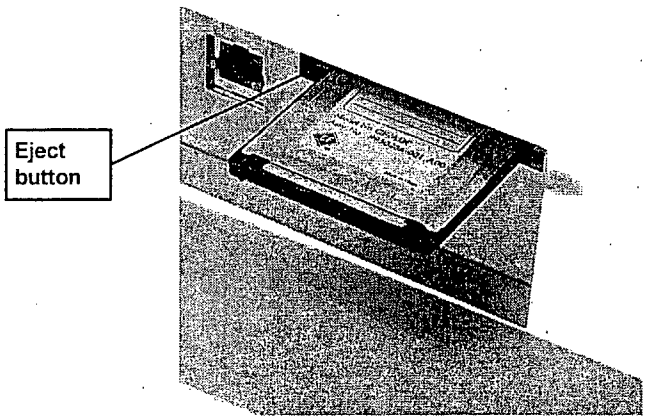

Figure 56. PCMCIA Card Partially Inserted.

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.

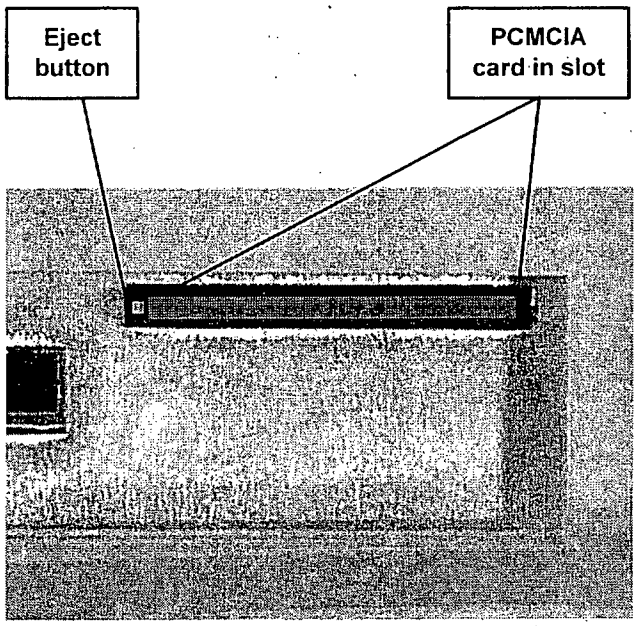

Figure 57. PCMCIA Card Seated in the Slot.

Alternatively, you may choose to save the PCMCIA card for your records. If you wish to save the card, replace the PCMCIA card in your sterilizer with a new card. Replacement cards are available from ASP and ordering information is provided in Appendix B of this user's guide.

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

Sterilizer Disposal

In the event that disposal of the STERRAD NX Sterilizer is necessary, the machine may be returned to ASP, recycled with a local recycler, or disposed of in a local landfill. 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.

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Chapter 9.

Troubleshooting

✔*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 correct the source of the problem and thereby return the sterilizer to normal operation. In other cases, the problem is 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). Internationally, call your local ASP Customer Support Representative.

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System Messages

Some system messages indicate conditions that you may be able to remedy. Refer the following table for details.

✔ *Note: If a system message is not found in the following table, there is no remedy available that you may safely perform. Call the ASP Customer Care Center for assistance.*

System Message	Probable Cause	Suggested Remedy
CASSETTE ACCEPTED, POSITIONING...	The barcode has been read and the cassette has been positioned at cell 1.	None required.
CASSETTE DETECTED, VERIFYING...	A cassette has been detected and the barcode data is being read.	None required.
CASSETTE DID NOT INDEX	A cassette error occurred or the cassette did not index.	Run diagnostics.
CASSETTE EXPIRY FOUND DURING START CYCLE	The cassette was found to be expired when the Start Cycle button was pressed.	Dispose cassette and insert new cassette.
CASSETTE SYSTEM TIMEOUT	A timeout occurred in the cassette system.	Run diagnostics.
CASSETTE SYSTEM TIMEOUT ON INDEXING	The cassette could not index to the next cell.	Run diagnostics.
CYCLE CANCELED BY OPERATOR	The operator canceled the cycle.	None required.
DISPOSING CASSETTE...	A user disposed of the cassette or there are no remaining cells in the cassette.	None required.
H2O2 ADJUSTMENT FAILED	The maximum intensity of the UV lamp has been reached.	Call your ASP Customer Care Representative.
H2O2 ADJUSTMENT IN PROGRESS	The intensity of the UV lamp is being adjusted.	None required.
H2O2 BULB WARMING UP	The UV lamp is warming up.	None required.

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System Message	Probable Cause	Suggested Remedy
H2O2 CURVE AREA TOO LOW	The calculated H_2O_2 area under the time-temperature curve is less than the threshold value set in the CCF.	Run diagnostics. Call your ASP Customer Care Representative.
H2O2 RATE CONSTANT TOO HIGH	The calculated rate constant for H_2O_2 is greater than the threshold value set in the CCF.	Run diagnostics. Call your ASP Customer Care Representative.
INJECT SETUP TIMEOUT	The time needed to initialize the injection stage has expired.	Run diagnostics. Call your ASP Customer Care Representative.
INJECT TIMEOUT	The time needed to inject hydrogen peroxide into the chamber has expired.	Run diagnostics. Call your ASP Customer Care Representative.
MEMORY CARD FULL	More than 50 cycle records are contained on the PCMCIA card. The next cycle record will overwrite the oldest cycle record.	Store cycle record information from PCMCIA card on an external PC.
PLEASE CLOSE DOOR	The door was opened while the system was warming up.	Close the door.
PLEASE INSERT NEW CASSETTE	No cassette was detected.	Insert a valid cassette.
PLEASE OPEN DOOR	Displayed after cycle completion. The load is ready for removal.	Open the door.
POWER FAIL CANCELLATION	A power failure occurred during a cycle.	Call your ASP Customer Care Representative.
POWER SUPPLY OUT OF RANGE	A power supply voltage is 20% higher or lower than specified.	Run diagnostics.
PRESSURE OUT OF RANGE (Low)	There is a pressure problem with the vacuum system.	Run diagnostics. Call your ASP Customer Care Representative.
SYSTEM FAILURE - CALL ASP.	A software error has occurred.	Call your ASP Customer Care Representative.
SYSTEM PROBLEM - CALL ASP!	A system error has occurred.	Call your ASP Customer Care Representative.

System Message	Probable Cause	Suggested Remedy
UNABLE TO LIGHT PLASMA. USE EXTRA CAUTION WHEN HANDLING THIS LOAD.	The plasma did not light during canceled cycle.	Run diagnostics. Call your ASP Customer Care Representative.
UNABLE TO OPEN ONE SECOND DATA FILE	A bad or missing PCMCIA compact flash memory.	Call your ASP Customer Care Representative.
VACUUM TIMEOUT	The time needed to evacuate the chamber has expired.	Run diagnostics. Call your ASP Customer Care Representative.
VENTING PLEASE WAIT...	The chamber is venting until it reaches atmospheric pressure.	None required.
WARMING UP, PLEASE WAIT...	The sterilizer is warming up.	None required.

Diagnostic Messages

If an error occurs during operation, the sterilizer may allow you to run a diagnostic test immediately. When prompted to do so, touch the **Confirm** button to perform the diagnostic test. A diagnostic test displays and prints a diagnostic message when the test is completed. Some diagnostic messages indicate conditions that you may be able to remedy.

✔**Note:** *If a diagnostic message is not found in the following table, there is no remedy available that you may safely perform. Call the ASP Customer Care Center for assistance.*

Message	Probable Cause	Suggested Remedy
12 VOLT SUPPLY HIGH	12 volt DC supply > 14.4 volts.	Call your ASP Customer Care Representative.
12 VOLT SUPPLY LOW	12 volt DC supply < 9.6 volts.	Call your ASP Customer Care Representative.
15 VOLT SUPPLY HIGH	15 volt DC supply > 18 volts.	Call your ASP Customer Care Representative.
15 VOLT SUPPLY LOW	15 volt DC supply < 12 volts.	Call your ASP Customer Care Representative.
24 VOLT SUPPLY HIGH	24 volt DC supply > 28.8 volts.	Call your ASP Customer Care Representative.
24 VOLT SUPPLY LOW	24 volt DC supply < 19.2 volts.	Call your ASP Customer Care Representative.

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Message	Probable Cause	Suggested Remedy
3.3 VOLT SUPPLY HIGH	3.3 volt DC supply > 3.96 volts.	Call your ASP Customer Care Representative.
3.3 VOLT SUPPLY LOW	3.3 volt DC supply < 2.64 volts.	Call your ASP Customer Care Representative.
5 VOLT SUPPLY HIGH	5 volt DC supply > 6 volts.	Call your ASP Customer Care Representative.
5 VOLT SUPPLY LOW	5 volt DC supply < 4 volts.	Call your ASP Customer Care Representative.
AIR PUMP SENSOR READ OFF	Air pump mechanical failure or air pump sensor failure.	Call your ASP Customer Care Representative.
AIR PUMP SENSOR READ ON	Air pump mechanical failure or air pump sensor failure.	Call your ASP Customer Care Representative.
ALARMS NOT HEARD	Alarms not functioning.	Verify annunciation of alarms. If the problem persists, call your ASP Customer Care Representative.
ATM SWITCH STUCK AT ATMOSPHERE	Atmospheric switch failure.	Call your ASP Customer Care Representative.
ATM SWITCH STUCK AT VACUUM	Atmospheric switch failure.	Call your ASP Customer Care Representative.
BAD MONITOR	UV monitor not functional.	Verify pathway between UV lamp and monitor is blocked. If the problem persists, call your ASP Customer Care Representative.
BARCODE FAILURE	Barcode scanner did not read barcode label.	Verify cassette is inserted correctly. Verify barcode. If the problem persists, Call your ASP Customer Care Representative.
CANNOT TURN PLASMA OFF	Plasma power out of specification.	Call your ASP Customer Care Representative.
CARRIAGE SENSOR FAILURE	Carriage sensor not functional.	Verify cassette is inserted all the way in. If problem persists, call your ASP Customer Care Representative.

Message	Probable Cause	Suggested Remedy
CASSETTE MOTOR FAILURE	Cassette motor not functional.	Verify cassette is inserted all the way in. If problem persists, call your ASP Customer Care Representative.
CASSETTE SYSTEM TIMEOUT	System could not communicate with delivery subsystem.	Call your ASP Customer Care Representative.
CHAMBER 1 TEMPERATURE RAILED HIGH	Thermistor circuit failure.	Call your ASP Customer Care Representative.
CHAMBER 1 TEMPERATURE RAILED LOW	Thermistor disconnected.	Call your ASP Customer Care Representative.
CHAMBER 2 TEMPERATURE RAILED HIGH	Thermistor circuit failure.	Call your ASP Customer Care Representative.
CHAMBER 2 TEMPERATURE RAILED LOW	Thermistor disconnected.	Call your ASP Customer Care Representative.
CHAMBER DELTA TOO BIG	The chamber temperature difference was larger than expected. A sensor or heater may have failed.	Call your ASP Customer Care Representative.
CHAMBER LOW/HIGH SELECT FAILURE	Chamber heater not functioning within specification.	Call your ASP Customer Care Representative.
CHAMBER PRESSURE RAILED HIGH	Chamber pressure always reads 30 torr.	Call your ASP Customer Care Representative.
CHAMBER PRESSURE RAILED LOW	Chamber pressure always reads 0 torr.	Call your ASP Customer Care Representative.
CHAMBER1 TEMPERATURE DID NOT DROP	Chamber heater will not shut off.	Call your ASP Customer Care Representative.
CHAMBER1 TEMPERATURE DID NOT RISE	Chamber heater/sensor not functioning within specification.	Call your ASP Customer Care Representative.
CHAMBER2 TEMPERATURE DID NOT DROP	Chamber heater will not shut off.	Call your ASP Customer Care Representative.

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Message	Probable Cause	Suggested Remedy
CHAMBER2 TEMPERATURE DID NOT RISE	Chamber heater/sensor not functioning within specification.	Call your ASP Customer Care Representative.
COLLECTION BOX FAILURE – FULL	Collection box is not present or properly positioned.	Verify collection box is present and positioned properly. If problem persists, call your ASP Customer Care Representative.

WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.

Wear latex, PVC (vinyl), or nitrile gloves whenever handling disposed cassettes. Hydrogen peroxide liquid may be present on the cassettes.

COLLECTION BOX FAILURE - NOT FULL	Disposed cassette did not end up in collection box.	Wear gloves and open collection box drawer and free up any jammed cassettes. If problem persists, call your ASP Customer Care Representative.
CONDENSER FAN NOT OFF	Condenser fan electrical failure.	Call your ASP Customer Care Representative.
CONDENSER FAN NOT ON	Condenser fan not functioning.	Call your ASP Customer Care Representative.
CONDENSER TEMPERATURE DID NOT DROP	Condenser heater will not shut off.	Call your ASP Customer Care Representative.
CONDENSER TEMPERATURE DID NOT RISE	Condenser heater/sensor not functioning within specification.	Call your ASP Customer Care Representative.
CONDENSER TEMPERATURE TOO HIGH	The condenser temperature was higher than expected. A sensor or heater may have failed.	Run diagnostics.
CONDENSER TEMPERATURE TOO LOW	The condenser temperature was lower than expected. A sensor or heater may have failed.	Run diagnostics.
CONDENSER TEMPERATURE RAILED HIGH	Thermistor circuit failure.	Call your ASP Customer Care Representative.

Message	Probable Cause	Suggested Remedy
CONDENSER TEMPERATURE RAILED LOW	Thermistor disconnected.	Call your ASP Customer Care Representative.
DELIVERY VALVE SENSOR READ CLOSED	Delivery valve mechanical failure.	Call your ASP Customer Care Representative.
DELIVERY VALVE SENSOR READ OPEN	Delivery valve mechanical failure.	Call your ASP Customer Care Representative.
DISPLAY TEST FAILURE	Touch panel not functioning.	Verify pressing of specified target. If problem persists, call your ASP Customer Care Representative.
DISPOSE FAILURE	Collection box not present.	Verify cassette was disposed into the collection box. If problem persists, call your ASP Customer Care Representative.
DOOR FAN STUCK OFF	Door fan not functioning.	Call your ASP Customer Care Representative.
DOOR FAN STUCK ON	Door fan not functioning.	Call your ASP Customer Care Representative.
DOOR SENSOR STUCK CLOSED	Door sensor electrical failure.	Call your ASP Customer Care Representative.
DOOR SENSOR STUCK OPEN	Door sensor electrical failure.	Call your ASP Customer Care Representative.
DOOR TEMPERATURE DID NOT DROP	Door heater will not shut off.	Call your ASP Customer Care Representative.
DOOR TEMPERATURE DID NOT RISE	Door heater/sensor not functioning within specification.	Call your ASP Customer Care Representative.
DOOR TEMPERATURE RAILED HIGH	Thermistor circuit failure.	Call your ASP Customer Care Representative.
DOOR TEMPERATURE RAILED LOW	Thermistor disconnected.	Call your ASP Customer Care Representative.
EJECT FAILURE	Cassette did not eject.	Verify cassette is not ejected. If problem persists, call your ASP Customer Care Representative.
FAILED TO EXTEND NEEDLE	Needle motor not functional.	Verify needles extend. If problem persists, call your ASP Customer Care Representative.

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Message	Probable Cause	Suggested Remedy
FAILED TO RETRACT NEEDLE	Needle motor not functional.	Verify needles retract. If problem persists, call your ASP Customer Care Representative.
HIGH PLASMA POWER	Plasma power out of specification.	Run diagnostics. Call your ASP Customer Care Representative.
INLET COMMAND ALWAYS CLOSED	Inlet valve electrical failure.	Call your ASP Customer Care Representative.
INLET COMMAND ALWAYS OPEN	Inlet valve electrical failure.	Call your ASP Customer Care Representative.
LOW PLASMA POWER	Plasma power out of specification.	Run diagnostics. Call your ASP Customer Care Representative.
MAIN FAN STUCK OFF	Main fan not functioning.	Call your ASP Customer Care Representative.
NO PLASMA POWER	Plasma power out of specification.	Call your ASP Customer Care Representative.
OIL RETURN VALVE STUCK CLOSED	Oil return valve mechanical failure.	Call your ASP Customer Care Representative.
OIL RETURN VALVE STUCK OPEN	Oil return valve mechanical failure.	Call your ASP Customer Care Representative.
PRINTER TEST FAILURE	Printer not printing.	Verify data printed. If problem persists, call your ASP Customer Care Representative.
PUMP ALWAYS OFF	Vacuum pump electrical failure.	Call your ASP Customer Care Representative.
PUMP ALWAYS ON	Vacuum pump electrical failure.	Call your ASP Customer Care Representative.
UNABLE TO LOCK DOOR	Door lock mechanical failure.	Call your ASP Customer Care Representative.
VACUUM COMMAND ALWAYS OPEN	Vacuum valve mechanical failure.	Call your ASP Customer Care Representative.
VACUUM CONTROL VALVE STUCK CLOSED	Vacuum control valve mechanical failure.	Call your ASP Customer Care Representative.
VACUUM CONTROL VALVE STUCK OPEN	Vacuum control valve mechanical failure.	Call your ASP Customer Care Representative.

Message	Probable Cause	Suggested Remedy
VACUUM INSUFFICIENT FOR PLASMA	Leak in chamber or wet load in chamber.	Remove load. Verify door is closed. If problem persists, call your ASP Customer Care Representative.
VACUUM SENSOR STUCK CLOSED	Vacuum valve sensor failure.	Call your ASP Customer Care Representative.
VACUUM SENSOR STUCK OPEN	Vacuum valve sensor failure.	Call your ASP Customer Care Representative.
VAPORIZER PRESSURE RAILED HIGH	Vaporizer pressure always reads 200 torr.	Call your ASP Customer Care Representative.
VAPORIZER PRESSURE RAILED LOW	Vaporizer pressure always reads 0 torr.	Call your ASP Customer Care Representative.
VAPORIZER TEMPERATURE DID NOT DROP	Vaporizer heater will not shut off.	Call your ASP Customer Care Representative.
VAPORIZER TEMPERATURE DID NOT RISE	Vaporizer heater/sensor not functioning within specification.	Call your ASP Customer Care Representative.
VAPORIZER TEMPERATURE RAILED HIGH	Thermistor circuit failure.	Call your ASP Customer Care Representative.
VAPORIZER TEMPERATURE RAILED LOW	Thermistor disconnected.	Call your ASP Customer Care Representative.
VENT SENSOR STUCK CLOSED	Vent valve sensor failure.	Call your ASP Customer Care Representative.
VENT SENSOR STUCK OPEN	Vent valve sensor failure.	Call your ASP Customer Care Representative.
VENT VALVE COMMAND ALWAYS CLOSED	Vent valve electrical failure.	Call your ASP Customer Care Representative.
VENT VALVE COMMAND ALWAYS OPEN	Vent valve electrical failure.	Call your ASP Customer Care Representative.
VENT VALVE PARTIALLY OCCLUDED	Filter on vent valve needs cleaning or replacement.	Call your ASP Customer Care Representative.
VENT VALVE STUCK CLOSED	Vent valve mechanical failure.	Call your ASP Customer Care Representative.

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Message	Probable Cause	Suggested Remedy
VENT VALVE STUCK OPEN	Vent valve mechanical failure.	Call your ASP Customer Care Representative.

ASP Customer Care Center

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

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Appendix A.

Warranties and Software License

Advanced Sterilization Products Commercial Warranty

The STERRAD® Sterilizer and reusable accessories supplied by Advanced Sterilization Products (ASP) are 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 their 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 null and void if service is attempted or performed by persons who are not authorized to do so by Advanced Sterilization Products. 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 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/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

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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.

THE EXPRESS WARRANTY ABOVE IS THE SOLE WARRANTY OBLIGATION OF ADVANCED STERILIZATION PRODUCTS, AND THE REMEDY PROVIDED ABOVE IS IN LIEU OF ANY AND ALL OTHER REMEDIES. THERE ARE NO OTHER AGREEMENTS, GUARANTEES OR WARRANTIES – ORAL OR WRITTEN – EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ADVANCED STERILIZATION PRODUCTS SHALL HAVE NO LIABILITY WHATSOEVER FOR ANY IMPROPER USE OR UNAUTHORIZED SERVICE OR REPAIR.

Advanced Sterilization Products Software License

Please read this license carefully.

You are purchasing the Advanced Sterilization Products (ASP) STERRAD Sterilization System. This system provides the STERRAD Operational Software in a magnetic media format that is designed to be used on the STERRAD® Sterilizer System only.

The STERRAD® Operational Software is protected by international copyrights, and is licensed to you for use only in the terms set forth below. Opening the packaging and/or using the STERRAD® Operational Software indicates your acceptance of these terms.

ASP grants you permission to use, annotate, copy, and print any single or multiple text portions, from the STERRAD® Operational Software, only for personal use, as needed to service or document the STERRAD® Sterilization System operation.

No other use of the STERRAD® Operational Software is granted. Unauthorized uses include, but are not limited to: incorporation into another software program or application, dissemination, reverse engineering, decompilation, modification, sub-licensing, selling, renting, leasing, lending, giving or in any other way transferring, by any means or in any medium, including telecommunication.

This license agreement is terminated if you tamper with the hydrogen peroxide container or use sources of hydrogen peroxide other than Certified ASP Hydrogen Peroxide containers in your STERRAD® Sterilizer. Any

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warranties associated with this STERRAD® Sterilizer are hereby disclaimed if such non-certified sources are used in your STERRAD® Sterilizer.

Your use of the STERRAD Operational Software in any unauthorized manner will constitute a breach of this agreement and subject you to civil penalties for such breach.

Advanced Sterilization Products
a Johnson & Johnson company
Division of Ethicon, Inc.
33 Technology Drive
Irvine, California 92618

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

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Appendix B.

Consumables, Accessories, and Additional Parts

Consumable Products	Product Code	Description
STERRAD® NX™ Cassette	10133	5 cycles per cassette, 5 cassettes per case.
Thermal Printer Paper Roll	10305	12 rolls of replacement printer paper.
Cassette Disposal Box	10306	10 collection boxes per case.

Accessories	Product Code	Description
Barcode Reader	10308	Optional barcode scanner for tracking instruments and other information in the cycle history file.
Independent Monitoring System (IMS)	10307	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.
Sterilizer Cart	10301	Cart with locking wheels.
Sterilizer Table	10303	Stationary table.

Additional Parts	Part Number
Air Filter	25-52153-801
PCMCIA Card	40-51513-001
Stylus	61-52645-001

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B Appendix

STERRAD® Consumables	Product Code
CycleSure® Biological Indicator	14324
STERRAD® SealSure® Chemical Indicator Tape	14202
STERRAD® Chemical Indicator Strips	14100
Tyvek® Pouches and Rolls with STERRAD® Chemical Indicator	Visit www.sterrad.com for a complete list of pouches, rolls, instrument trays and accessories
APTIMAX® Instrument Trays and accessories	
STERRAD® Instrument Trays and accessories	

ASP also offers a full line of other consumables and accessories which have been fully tested and validated for use with the STERRAD® NX Sterilizer. For more information on any of these products, in the U.S.A. contact the ASP Customer Care Center at 1-888-STERRAD. Internationally, contact your local ASP Customer Support Representative.

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Appendix C.

STERRAD® NX™ Sterilizer Specifications

Power	Single phase, offered in two voltage ranges: 99-132 VAC~, 47-63 Hz, 16A 180-264 VAC~, 47-63 Hz, 10A
Dimensions	H 33 in. (84 cm), W 22 in. (56 cm), D 32 in. (81 cm). Footprint: fits onto 23 in. (58.5 cm) deep countertop.
Service clearances	Front 39 in. (100 cm), Rear 1 in. (25 mm), Top 24 in. (61 cm). Left side 2.4 in. (6 cm), Right side 24 in. (61 cm).
Weight	275 lb. (125 kg).
Chamber volume	30 liters. H 6.2 in. (15.7 cm), W 12.6 in. (32 cm), D 23.6 in. (60 cm).
Chamber shelves	Two shelves, W 12.3 in. (31.2 cm), D 23.6 in. (60 cm). Shelf capacity: 25 lb. (11.4 kg) uniformly distributed. Top shelf is removable.
Temperature	Operating: 18 °C – 35 °C (64 °F – 95 °F). Storage: -40 °C to +70 °C (-40 °F to +158 °F).
Humidity	Operating: 10% – 85% up to 30 °C,

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	linearly decreasing from 85% at 30 °C to 70% at 40 °C. Storage: 10% – 100% (rainfall will be permitted).
Altitude/Pressure	Operating altitude up to 3048 m (10,000 ft). Atmospheric pressure 70 kPa – 106 kPa (700 mbar – 1060 mbar), (20.7 in. Hg – 31.3 in. Hg).
Cycle temperature	46 °C – 55 °C (115 °F – 131 °F)
Cycle time	Standard cycle: approx. 30 min. Advanced cycle: approx 40 min.
Cycles per cassette	5
Connectors	Network: RJ45; Barcode reader: USB.
Data storage	PCMCIA nonstandard compact flash.
Cordset and plug	12 AWG, 98 cm (38.6 inches) long. NEMA 5-20P, IEC-320-C19.
RF Generation	Portable and mobile RF communications equipment can affect medical Electrical Equipment.

ACCEPTED
with COMMENTS
EPA Letter Dated:
FEB 1 2008
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.
71871-3

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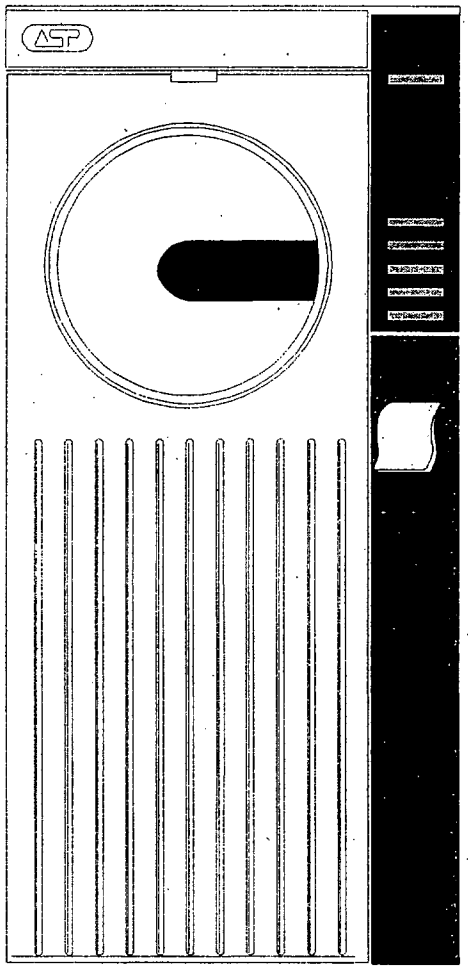
STERRAD® 100S Sterilization System

User's Guide



ACCEPTED
with COMMENTS
EPA Letter Dated:

FEB 1 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

71871-3

200 # 359

STERRAD® 100S Sterilization System
User's Guide

REF 99008

ADVANCED STERILIZATION PRODUCTS®
a Johnson & Johnson company
Division of Ethicon, Inc.

33 Technology Drive
Irvine, California 92618
1-888-STERRAD
(888-783-7723)
www.sterrad.com

ACCEPTED
with COMMENTS
EPA Letter Dated:

FEB 11 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

71871-3

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About This Guide

In this chapter . . .

- *how to use this guide*

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Overview

This guide is designed to provide useful information on the day-to-day operation and routine maintenance of the STERRAD® 100S Sterilizer.

The guide is divided into 6 chapters, 2 appendices, and includes a fold-out chart in Chapter 3. These chapters provide information on using the sterilizer, load preparation, routine maintenance, and troubleshooting the system should problems arise.

The features of this guide are:

- **About This Guide**-this section gives you important information on how to get the maximum use out of this guide.
- **Chapter 1. Introduction**-the first chapter of the guide contains important details about the STERRAD 100S System, including the major parts of the sterilizer and STERRAD Process information.
- **Chapter 2. For Your Safety**-this may be the most important chapter in the guide. You **must** read it thoroughly, understand the information, and follow all the safety procedures in this chapter. These safety procedures include safe handling of cassettes, safe handling of the load, and first aid information in case of possible hydrogen peroxide exposure.
- **Chapter 3. Preparing Items To Be Sterilized**- this chapter provides descriptions on preparing items to be sterilized, how to effectively package the load, and a large, fold-out chart detailing "How to Determine What Can be Sterilized in the STERRAD 100S Sterilizer."
- **Chapter 4. Day-to-Day Operation**-this chapter gives you detailed information on how to use the sterilizer, how to load the chamber, how to use the control panel, how to run cycles, and how to interpret biological indicator test results.
- **Chapter 5. Routine Maintenance**-the routine maintenance of your STERRAD 100S Sterilizer is very minimal. This chapter shows you how to change the vaporizer plate, printer paper, printer ribbon, and the steps to follow to keep your sterilizer clean.

- **Chapter 6. Troubleshooting**-the STERRAD 100S Sterilizer displays a number of messages to tell you what the system status is at any given moment. Many of these messages do not require any action from you. Others require that you call the ASP Customer Care Center for maintenance. The messages are listed in alphabetical order.

- **Appendix A. Specifications**-details the technical specification information for your sterilizer.

- **Appendix B. Service and Warranty Information**-this appendix contains the detailed system warranty and our guarantees to you regarding your STERRAD 100S Sterilizer.

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Chapter 1. Introduction

In this chapter . . .

- *operating information*

Overview

This guide provides basic information on how to operate your sterilizer safely and efficiently. The STERRAD® 100S Sterilization System is a general purpose, low temperature sterilizer using the STERRAD 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.

You **must** read, understand, and follow the safety information presented in Chapter 2 and throughout this guide. The safety information is provided for your benefit and for the benefit of your instruments and equipment.

Operation Information

The STERRAD 100S Sterilizer has been developed by Advanced Sterilization Products, (ASP) a Johnson and Johnson company, a division of Ethicon, Inc., to sterilize medical devices by diffusing hydrogen peroxide into the chamber and then "exciting" the hydrogen peroxide molecules into a 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, including the plasma stage, operate within a dry environment at a low temperature, and thus the cycle is not damaging to compatible instruments sensitive to heat and moisture. The 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.

When selecting reusable medical devices to be processed in the STERRAD 100S Sterilizer, reprocessing information should be obtained from the manufacturer of the medical device in accordance with international norms (such as ISO 17664 or AAMI TIR12).

The system consistently provides a sterility assurance level (SAL) of 10^{-6}, as defined by the Food and Drug Administration 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 guide.

The devices have been pre-validated to a SAL of 10^{-6} based upon worst-case conditions, including lumens within the claim lengths and mated surfaces. If additional technical information concerning validation is needed, please contact the ASP Customer Care Center (1-888-STERRAD).

Overview of Sterilizer Components

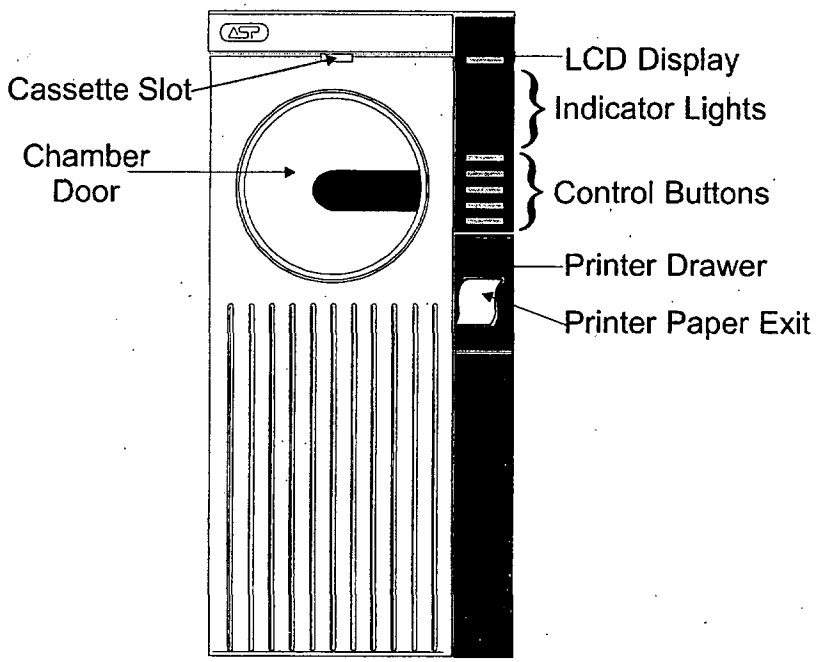

Figure 1. STERRAD System. Your Sterilizer May Be Slightly Different in Appearance.

The main sterilizer components are shown in the preceding illustration: The sterilizer operates as follows:

- the system indicates that sterilization can be started by displaying the "Ready to Use" message on the LCD display.
- the items to be sterilized are placed in the chamber.
- a cassette is inserted (if needed).
- START is pressed.
- the door automatically closes and the sterilization process begins.

The sterilization process is complete in about 55 minutes. The load can then be used immediately or stored according to your facility's procedures.

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Chapter 2. For Your Safety

In this chapter . . .

- *personal safety and first aid*
- *device safety*
- *cassette handling*
- *safe maintenance*
- *additional information*

Overview

Your safety is of primary concern to ASP. This section provides information on safely using the sterilizer. **You must read, understand, and use the information in this chapter before operating the unit.** Also, always pay attention to the warnings, cautions, and notes throughout this guide. This information is for your safety and to ensure that you receive the most benefit from the safe operation of your STERRAD® 100S Sterilization System. Only trained, experienced technicians, who are fully acquainted with the unit, should repair or adjust the STERRAD 100S System.

Personal Safety and First Aid

- **WEAR LATEX, PVC (VINYL) OR NITRILE GLOVES WHILE REMOVING ITEMS FROM THE STERILIZER AFTER A CYCLE HAS CANCELLED. CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT.** If a cycle cancels and the items in the load have any visible moisture or liquid, hydrogen peroxide may be present.
- 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.
- Direct hydrogen peroxide contact with eyes can cause irreversible tissue damage. If eye contact occurs, immediately flush with large amounts of water and immediately consult a physician.
- Inhalation of vapor or mist can cause severe irritation of lungs, throat, and nose. If inhalation occurs, move to fresh air and consult a physician immediately.
- Ingestion can produce corrosion that may be life threatening. If swallowed, drink plenty of water immediately to dilute. Do not induce vomiting. Consult a physician.
- Do not insert your hand into the sterilizer when the door is closing.

Device Safety

- **DO NOT ATTEMPT TO STERILIZE ITEMS OR MATERIALS THAT DO NOT COMPLY WITH THE DIRECTIONS SPECIFIED IN THIS GUIDE.** In addition, you should read the medical device manufacturer's instructions, or call the ASP Customer Care Center (1-888-STERRAD) to determine whether an item can be sterilized by the STERRAD 100S Sterilizer.
- All items must be cleaned and thoroughly dried before loading into the sterilizer. Loads containing moisture may cause cycle cancellation.
- The chapter on preparing items to be sterilized contains information about which materials and devices can be processed by the sterilizer.
- 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 instruments.
- Do not change the power source without checking the electrical phase rotation. Prior to relocating the STERRAD 100S Sterilizer to a new power source, electrical phase rotation should be checked by a qualified technician. Failure to verify and match phase rotation may cause damage to the sterilizer and voids the warranty.
- Do not leave the sterilizer unplugged or turned off for longer than 24 hours. If the sterilizer must be turned off for longer than 24 hours, call the ASP Customer Care Center (1-888-STERRAD) for instructions.
- Only ASP-approved biological indicators should be used to monitor the sterilization cycle. Should a cancellation occur when one of these biological indicators is in the chamber, it should be discarded and a new biological indicator should be used when re-starting the cycle. Call the ASP Customer Care Center (1-888-STERRAD) for information on approved biological indicators including the CycleSure® Biological Indicator.
- Portable and mobile RF communications equipment can affect medical Electrical Equipment.

Cassette Handling

- **STERRAD CASSETTES CONTAIN CONCENTRATED HYDROGEN PEROXIDE, A STRONG OXIDIZER. CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT.** Direct 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. Direct contact with eyes can cause irreversible tissue damage. If eye contact occurs, immediately flush with large amounts of water and immediately consult a physician. Inhalation of vapor or mist can cause severe irritation of lungs, throat, and nose. If inhalation occurs, move to fresh air and consult a physician immediately. Ingestion can produce corrosion that may be life threatening. If swallowed, immediately drink plenty of water to dilute. Do not induce vomiting. Consult a physician.

- Do not remove the plastic wrapper from the cassette package if the indicator strip is red. Red indicates that the cassette might have been damaged. Call the ASP Customer Care Center (1-888-STERRAD) for credit.

- Do not remove used cassettes from the cassette collection box. Dispose of the sealed cassette collection box according to local waste regulations. Cassettes with unused hydrogen peroxide are hazardous waste as defined by the US Environmental Protection Agency and should be disposed of accordingly. If it is necessary to handle a used cassette, wear latex, PVC (vinyl), or nitrile gloves. Do not touch gloves to face or eyes.

- Empty or expired cassettes must be replaced prior to starting the cycle as directed by a message on the sterilizer display. Cassettes with unused hydrogen peroxide are hazardous waste as defined by the US Environmental Protection Agency and should be disposed of accordingly.

Safe Maintenance

- Repairs and adjustments should only be attempted by experienced technicians who are fully trained to maintain and repair the STERRAD Sterilizer.

- Use of unauthorized parts for maintenance or repair could cause personal injury, result in costly damage or unit malfunction, and void the warranty.

- Do not clean the chamber door area with abrasives. The sterilization chamber uses an O-ring vacuum seal to maintain a vacuum in the chamber. Never use rough cleaning tools, such as a wire brush or steel wool, on the door housing or chamber assembly. This could damage the seal.

Additional Information

The information in this chapter is repeated where appropriate throughout this guide for your safety and use. This information is subsequently labeled: **WARNINGS, Cautions,** or Notes as appropriate.

- **WARNINGS** are shown in the text in all bold, upper case letters. They indicate events or conditions that can result in serious injury or death.
- **Cautions** are shown in the text in bold letters, and they indicate events or conditions that can result in damage to equipment.
- Notes are shown in the text with a check mark 4. They highlight specific information about the proper use and maintenance of the sterilizer.

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Chapter 3. Preparing Items To Be Sterilized

In this chapter . . .

- *indications for use*
- *recommended items*
- *typical items sterilized*
- *items not to be processed*
- *cleaning, rinsing, and drying*
- *guidelines for wrapping, packaging, and loading*

Overview

STERRAD 100S Sterilizers can process many of the items you commonly sterilize as well as instruments that are sensitive to heat and moisture. However, there are a few important exceptions. Please review the "How to Determine What Can be Sterilized in the STERRAD 100S Sterilizer" fold-out chart contained in this chapter. It contains details on recommended materials and lumen sizes.

Indications for Use

- The STERRAD 100S Sterilizer is designed for sterilization of both metal and nonmetal medical devices at low temperatures. Because the cycle operates within a dry environment and at low temperatures, it is especially suitable for instruments sensitive to heat and moisture.
- The STERRAD 100S Sterilizer can sterilize instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Metal and nonmetal lumened instruments with inside diameters of 6 mm or larger and lengths of 310 mm or shorter can be processed in the STERRAD 100S Sterilizer.
- Medical devices with only a single stainless steel lumen which have the following dimensions can be processed in the STERRAD 100S Sterilizer:
  - » an inside diameter of 1 mm or larger and a length of 125 mm or shorter
  - » an inside diameter of 2 mm or larger and a length of 250 mm or shorter
  - » an inside diameter of 3 mm or larger and a length of 400 mm or shorter

WARNING! DO NOT ATTEMPT TO STERILIZE ITEMS OR MATERIALS THAT DO NOT COMPLY WITH THE DIRECTIONS SPECIFIED IN THIS GUIDE. YOU SHOULD READ THE MEDICAL DEVICE MANUFACTURER'S INSTRUCTIONS OR CALL THE ASP CUSTOMER CARE CENTER (1-888-STERRAD) TO DETERMINE WHETHER AN ITEM CAN BE STERILIZED BY THIS STERILIZER.

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Determining What Can be Sterilized in the STERRAD® 100S Sterilizer

The following page is a chart that unfolds to show you detailed lists of recommended items, materials, and some typical devices that can be sterilized in the STERRAD 100S Sterilizer. Be sure to check with the medical device manufacturer's instruction before loading any new item in the sterilizer.

Note: *There are a wide variety of materials and devices that can be sterilized in the STERRAD 100S Sterilizer. As more manufacturers complete testing of their products with the STERRAD 100S Sterilizer, the range of recommended and/or compatible items grows. Because of that, the information in the tables included in this publication will be 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 (1-888-STERRAD) for an up-to-date list of recommended materials, devices and/or device manufacturer information or visit the ASP website at www.sterrad.com.*

Items Not To Be Processed

- Instrument mats other than STERRAD Instrument Mats
- Instrument trays other than STERRAD Instrument Trays or APTIMAX® Instrument Trays
- Any item that is not completely dry
- Items made of Monel
- Items or materials that absorb liquids
- Dead end lumens
- Items made of materials containing 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
- Liquids and powders
- Items with mated, Nylon® surfaces
- Single use items
- Implants for which the manufacturer has not specifically recommended sterilization in the STERRAD 100S Sterilizer
- Instruments and devices that can not 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
- 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 100S Sterilizer

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Cleaning, Rinsing, and Drying

As with all sterilization methods, proper cleaning of instruments and devices is a critical and necessary step prior to sterilization. All items must be cleaned and thoroughly dried before loading into the sterilizer. User should carefully inspect all instruments and devices for cleanliness and dryness and for flaws or damage prior to packaging. If visual soil or moisture is present, then the devices and instruments should be recleaned and dried prior to sterilization in the STERRAD process. Devices and instruments with flaws or damage should be replaced or repaired before using.

Cleaning and sterilization are two separate processes. Thorough cleaning is essential for assurance of sterilization by all sterilization methods, including the STERRAD 100S Sterilization System.

The process of cleaning is necessary to remove organic and inorganic soil and debris from equipment. In this process, many of the microorganisms are removed from the surface of the instrument. The process of sterilization inactivates all remaining spores and living 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. It is necessary to remove moisture from all parts of the items. Only dry items should be loaded into the sterilization chamber.
- 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.

4 *Note: Loads containing moisture may cause a cycle cancellation.*

CAUTION: As with any disinfectant/cleaning/ sterilization system, periodic careful inspection of the devices after repeated exposure to the disinfectant/cleaner/ sterilant is necessary, due to potential damaging effects of the chemical agent on the devices.

Guidelines for Wrapping, Packaging, and Loading

Proper preparation of trays, pouches, and instruments can minimize or prevent cycle cancellation due to load-related problems.

- Only STERRAD Instrument Trays and APTIMAX Instrument Trays and STERRAD Accessories are recommended for use in the STERRAD 100S Sterilizer. STERRAD Instrument Trays and APTIMAX Instrument Trays are specially designed to allow diffusion of hydrogen peroxide and the plasma around all the items in the load. The trays should only be padded with STERRAD Instrument Tray Mats or polypropylene sterilization wrap. Do NOT use linen, cellulosic, or any materials shown in the "Items Not To Be Processed" list.

  4 *Note: Do not stack instruments inside the trays. Do not stack trays. Do not stack trays within trays. Do not wrap instruments within the trays.*

  4 *Note: If you are using rigid containers cleared by the FDA for use in the STERRAD System, follow the same procedures as are recommended for use of the STERRAD 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 container*

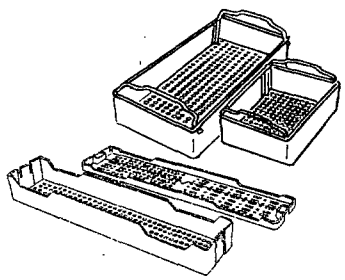

Figure 2. Use only STERRAD® Instrument Trays and APTIMAX® Instrument Trays

- Improper loading of the sterilizer may result in cycle cancellations and/or positive biological indicator results.

- Configure loads with a combination of metal and nonmetal items.
- Do not use foam pads in instrument trays. They may absorb the hydrogen peroxide.
- Do not use any wraps or packaging that are not approved by ASP and listed in the previous section on "Items Not To Be Processed."
- Use only STERRAD 100S Sterilizer compatible polypropylene sterilization wrap and Tyvek® pouches. Do not use paper pouches or sterilization wraps containing cellulose or cotton.
- Place STERRAD Chemical Indicator Strips inside trays and Tyvek® pouches.
- Secure all wraps with STERRAD SealSure® Chemical Indicator Tape.
- Arrange items to ensure that the hydrogen peroxide and plasma can make contact with all surfaces.
- Place peel pouches loosely on edge, if possible. Arrange them so that the transparent side of a pouch faces the opaque side of the next pouch.
- Do not allow any item to touch the walls of the sterilization chamber, door, or electrode.

CAUTION: Metal objects must not come into contact with the walls of the sterilization chamber, door, or electrode. Contact with the walls, door, or electrode can interrupt the plasma phase of the process, cause a cycle cancellation, and/or damage the item or the sterilizer.

- Provide at least 1 inch (25 mm) of space between the electrode and the load.
- Place a STERRAD CycleSure® Biological Indicator or STERRAD Biological Indicator Test Pack in the chamber. Frequency of biological testing should be at least once per day or in accordance with your hospital policy. Review the instructions included with the biological indicator to ensure proper use.
- Proceed to "Chapter 4, Day-to-Day Operation" for information on starting a cycle.

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Chapter 4. Day-To-Day Operation

In this chapter . . .

- *safe operation*
- *sterilizer operation*
- *preparing the load*
- *loading the sterilization chamber*
- *inserting cassettes*
- *sterilization cycles*
- *unloading and handling*

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Safe Operation

Before operating your STERRAD® 100S Sterilizer, you **must** thoroughly *read, understand, and follow* the information in "Chapter 2. For Your Safety" as well as "Chapter 3. Preparing Items To Be Sterilized" and the "How to Determine What Can be Sterilized in the STERRAD 100S Sterilizer" fold-out in Chapter 3.

Sterilizer Operation

The STERRAD 100S Sterilizer automatically monitors and controls the sterilization process. The sterilizer reports its status in 4 ways:

- **Message screen (LCD)**-The screen indicates the status of the unit at all times. It also indicates the time remaining to cycle completion. Chapter 6 has details on understanding system messages.
- **Status indicator lights**-These lights clearly indicate the current stage of the sterilization cycle. Indicator lights help you monitor the cycle stages (vacuum, injection, diffusion, plasma, and vent) and respond to any problems.
- **Paper printout**–A paper printout exits the front panel after each cycle completion or cancellation. This is a record of the cycle parameters and may be kept for your records. The print should be completely black. Red print indicates a problem with the cycle. (If two-part paper is used, a second copy is printed at the same time; but instead of exiting the front panel, the copy is rolled up inside the printer mechanism. See Chapter 6 for printout interpretation.) A duplicate copy of the printout can be obtained by pressing CANCEL before the next cycle is started.
- **Beeps**–These alert you when a cycle is complete or a cancellation has occurred. A long beep indicates a complete cycle.

Preparing the Load

Proper preparation of trays, pouches, and instruments can minimize or prevent cycle cancellation due to load-related problems. More information on load preparation is found in "Chapter 3. Preparing Items To Be Sterilized."

- Arrange the items in a tray to ensure that the hydrogen peroxide and plasma can surround them. Do not stack trays.
- 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 allow any item to touch the walls or door of the sterilization chamber or electrode.
- Provide at least 1 inch (25 mm) of space between the electrode and the load.
- Place the STERRAD CycleSure® Biological Indicator or other ASP-approved biological indicator in the sterilization chamber.

CAUTION: Metal objects must not come into contact with the walls, door, or electrode. Contact with the walls, door, or electrode can interrupt the plasma phase of the process cycle, cause a cycle cancellation and/or damage the item or the sterilizer.

4 *Note: Do not stack instruments inside of the trays. Do not stack trays. Do not stack trays within trays. Do not wrap instruments within trays.*

4 *Note: If you are using rigid containers cleared by the FDA for use in the STERRAD System, follow the same procedures as are recommended for use of the STERRAD 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.*

Biological Indicators

Biological indicators help you to assure that your sterilizer is operating correctly. Confirming that sterilizing conditions were present during a cycle is an important part of the sterilization process. Frequency of biological testing should be at least once per day or in accordance with your facility's policy.

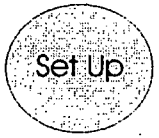
- Contact the ASP Customer Care Center (1-888-STERRAD) regarding CycleSure Biological Indicators and other biologicals specifically designed for use in the STERRAD 100S Sterilizer.

ASP CycleSure Biological Indicators contain microorganisms that are known to be resistant to the sterilization process and are the best way to verify proper processing. The biological indicator should be placed at the back of the chamber, on the bottom shelf with the opening facing the back of the chamber. Review the instructions that are included with the biological indicators for proper use.

The following charts detail the transfer process and a flow chart showing the entire biological indicator procedure for both ASP-approved biological indicators.

4 ***Note:*** *If a cancellation occurs when a biological indicator is in the chamber, the biological indicator should be discarded and a new CycleSure Biological Indicator should be used when starting the next cycle.*

BI Transfer Process for STERRAD®BI Test Pack



Do:

- Clean the transfer area with sporicidal solution.
- Have 2 sterile forceps (individually wrapped).
- Use a new, sterile catalase vial.
- Label 4 TSB tubes (processed BI, positive control, catalase, and TSB).
- Have an incubator set at 30-35° C.

Don't:

- Use damaged or leaking test tubes.
- Re-use the catalase vial.
- Forget to label each tube correctly.

Do:

- Have a trained individual perform the transfer within 5 minutes of cycle completion.
- Add a drop of catalase to all tubes except the tube labeled "TSB," 15 minutes before cycle completion.
- Check to see if the CI of the processed BITP changed color.
- Unscrew lids on all 4 test tubes. Rest lids on the tubes.
- Transfer the processed BI strip to the labeled tube first.
- Use different sterile forceps to transfer the positive control.
- If BI strip is dropped on the counter, make a note of it.

Don't:

- Place test tubes lids on the counter.
- Allow skin contact with any components.
- Use the same forceps to transfer the processed BI and the positive control.
- Perform transfer in a turbulent area (people traffic, AC vents, etc.).
- Wait more than 5 minutes to transfer, hydrogen peroxide residual activity inactivates spores.

Do:

- Loosen test tube lids 1/2 turn for oxygen.
- Incubate test tubes at 30-35° C.
- Incubate for at least 48 hours prior to reading results.

Don't:

- Over tighten lids. Spores are aerobic and need oxygen to grow.
- Forget to check temperature range of incubator. It should be 30-35° C.

Desired Results:

- **Processed BI strip:** no growth.
- **Control BI strip:** growth (turbidity and/or orange color particles).
- **Catalase control:** no growth.
- **TSB control:** no growth.

Other Results:

- Processed BI strip: growth (turbidity and/or orange color) (See BI Flowchart.)
- Control BI strip: no growth
  - » lid too tight.
  - » incubator temperature out of range.
  - » strip inactivated during storage.
  - » media does not support growth.
- Catalase control: growth (turbidity)
  - » contaminated catalase.
  - » no aseptic transfer.
- TSB control: growth (turbidity)
  - » contaminated media.

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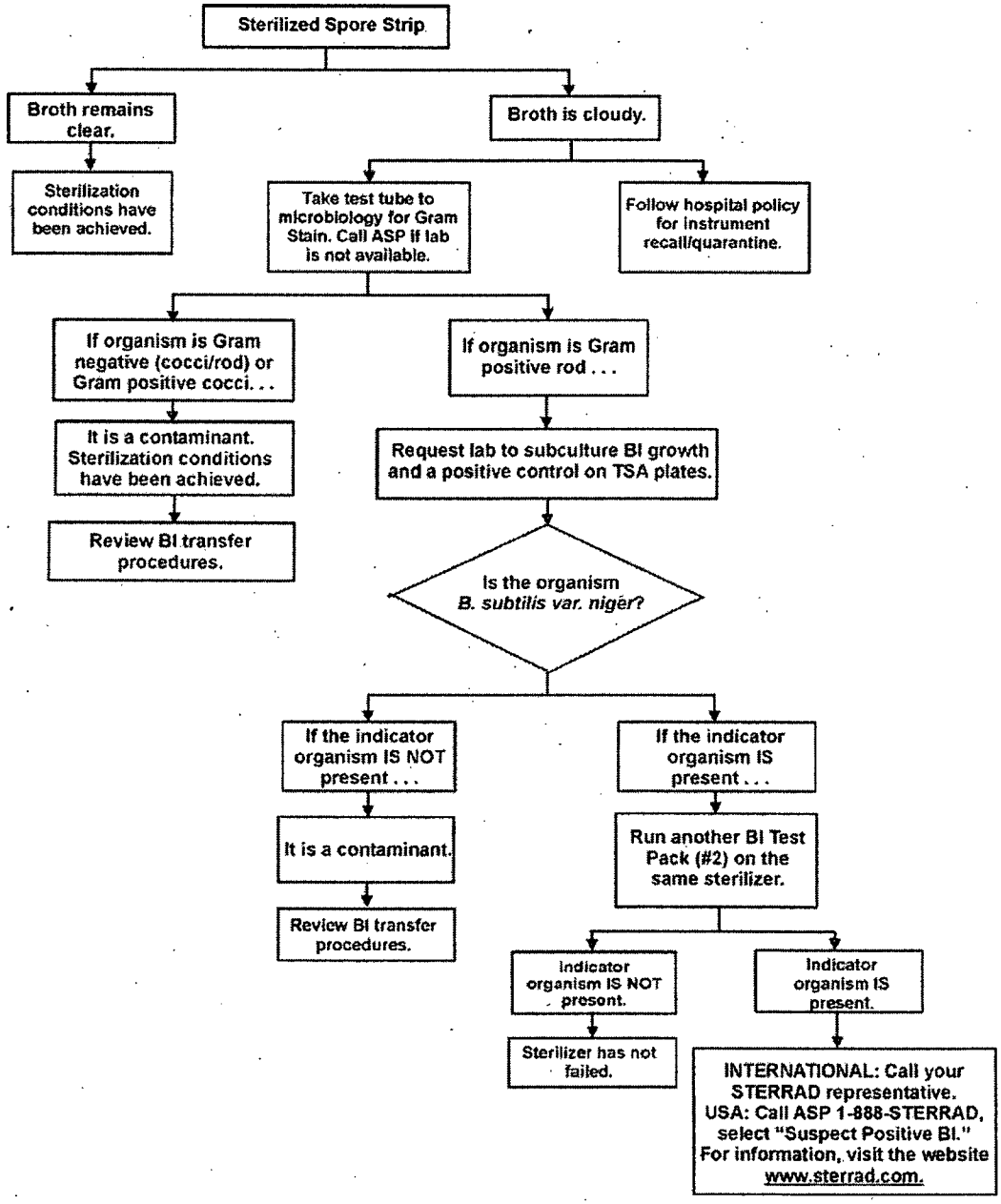
Biological Monitoring Results-Biological Indicator Test Pack



Process Flow For CycleSure™ Biological Indicator

Do:

- Label the BI to be processed appropriately.
- Label positive and negative controls.
- Package BI in a manner consistent with items being sterilized.
- Place BI in the most challenging area for sterilizer to reach.
- Inspect BIs for any defects before using; e.g., cracked media ampoule.
- Have an incubator set at 55-60° C.

Don't:

- Forget to label CycleSure BIs correctly.
- Press the caps down before processing BIs.

Do:

Activate CycleSure™ BI within 5 minutes after cycle completion:

- Check the chemical indicator disc for color change from red to yellow.
- Press the cap down until firmly seated on top of vial.
- Crush media ampoule using the tube crusher.
- Keep vial in vertical position after media ampoule has been crushed.
- Use Controls:
  - » Positive control: crush an unprocessed CycleSure BI.
  - » Negative Control: An unprocessed and uncrushed BI.
  - » Incubate processed BI and controls at 55-60° C.
  - » Incubate for at least 48 hours (up to 7 days) prior to reading results.

Don't:

- Forget to check temperature range of incubator. It should be between 55-60° C.
- Forget to crush media ampoule for processed BI and positive control.
- Forget to press caps down on BIs before incubating to prevent dehydration.

Desired Results:

- Observe for color change in the processed BI and controls.
- Processed BI: no growth (no color change, media remains purple).
- Positive Control: growth (color change in media from purple to yellow).
- Negative Control: no growth (media shall remain purple).

Other Results:

- Processed BI: growth (color change in media from purple to yellow). See CycleSure™ BI flow chart.
- Positive Control: no growth (no color change)
  - » Incubator temperature out of range.
  - » BI inactivated during storage.
  - » media does not support growth.
- Negative Control: growth (color change in media from purple to yellow)
  - » contaminated media ampoule.

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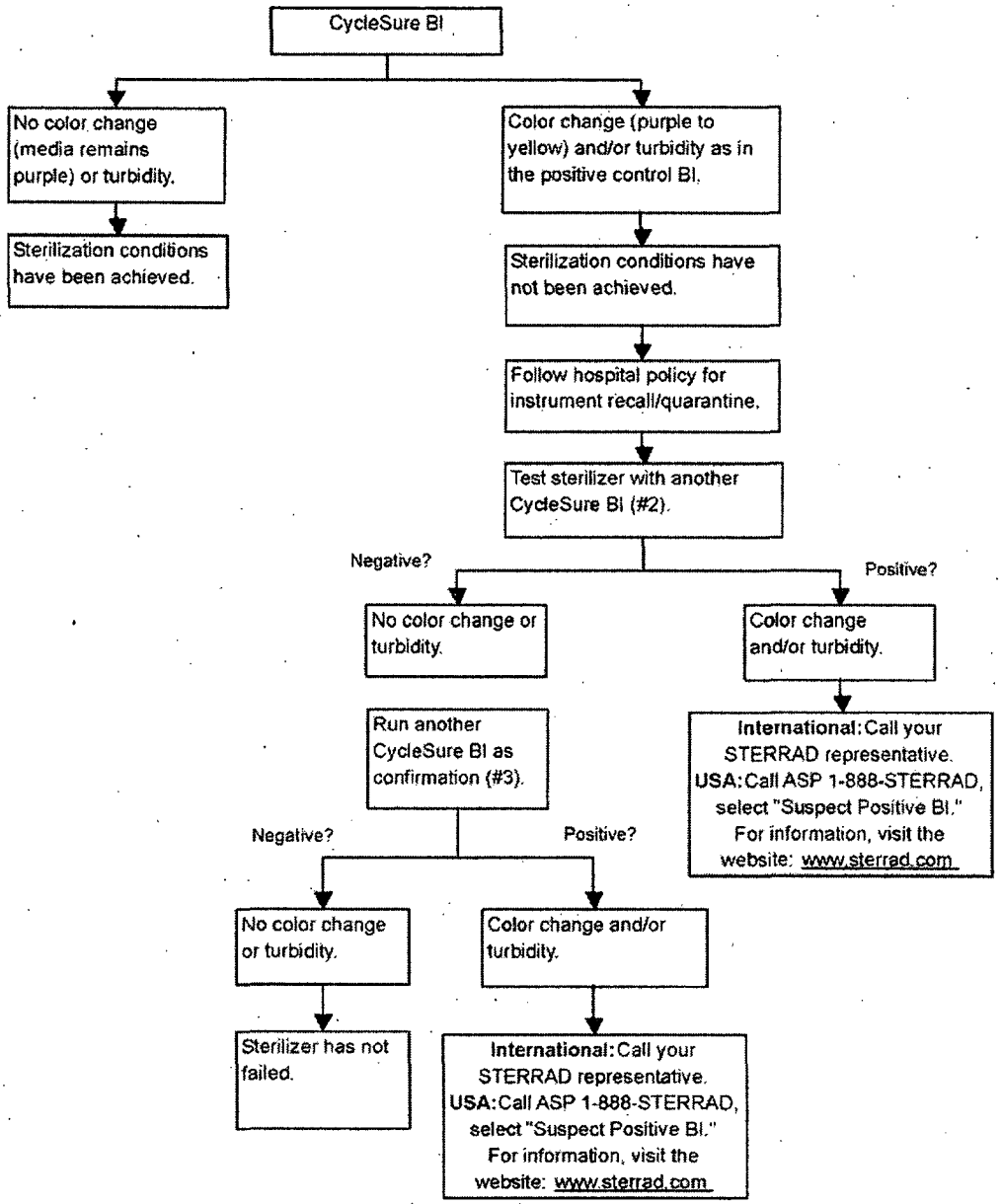
Biological Monitoring Results-CycleSure® Biological Indicator



Chemical Indicators

STERRAD Chemical Indicator Strips and STERRAD SealSure Chemical Indicator Tape offer additional ways to verify processing in the sterilization cycle. They should be used in addition to, not in place of, the CycleSure biological indicator. STERRAD Chemical Indicator Strips and STERRAD SealSure Chemical Indicator Tape *do not* indicate sterilization; they only indicate that the indicator has been exposed to the hydrogen peroxide. The color of the indicator strips and tape changes from red to gold (or lighter) when exposed to hydrogen peroxide vapor.

4 ***Note:*** *Use only STERRAD SealSure Chemical Indicator Tape, and/or STERRAD Chemical Indicator Strips. Do not use indicators designed for other sterilization processes.*

Using Chemical Indicator Strips

Place STERRAD Chemical Indicator Strips in trays and pouches to show exposure to hydrogen peroxide during the sterilization cycle. Please refer to the *Instructions for Use* included with the STERRAD Chemical Indicator Strip for more information.

Using STERRAD® SealSure® Chemical Indicator Tape

STERRAD® SealSure® Chemical Indicator Tape should be used to secure the polypropylene sterilization wrap around the instrument tray.

Please refer to the *Instructions for Use* included with the STERRAD SealSure Chemical Indicator Tape for more information.

Loading the Sterilization Chamber

- A fully loaded sterilization chamber has trays or packaged items on both shelves of the STERRAD 100S Sterilizer. Trays must be placed flat on shelves. Do not stack trays within trays. Do not stack trays on top of trays.
- Arrange the items in the trays to ensure that the hydrogen peroxide and plasma can surround them.
- Place peel pouches on edge, if possible.
- Do not allow any metal items to touch the walls, door, or electrode of the sterilization chamber or electrode.
- Provide at least 1 inch (25 mm) of space between the electrode and the load.

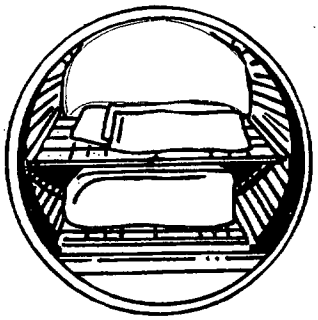


Figure 3. Properly loaded sterilization chamber.

4 *Note: Do not stack instruments inside of trays. Do not stack trays. Do not stack trays within trays.*

4 *Note: If you are using rigid containers cleared by the FDA for use in the STERRAD System, follow the same procedures as are recommended for use of the STERRAD 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.*

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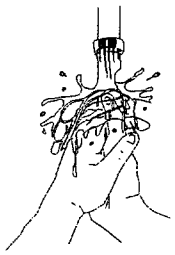
Inserting Cassettes

The STERRAD 100S Sterilizer uses concentrated hydrogen peroxide, contained in special cassettes, to sterilize items placed into the sterilization chamber. Each STERRAD 100S Cassette provides enough hydrogen peroxide for 5 cycles. The sterilizer message screen notifies you when a new cassette is needed.



WARNING! STERRAD CASSETTES CONTAIN CONCENTRATED HYDROGEN PEROXIDE, A STRONG OXIDIZER. CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT. DIRECT 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.

DIRECT CONTACT WITH EYES CAN CAUSE IRREVERSIBLE TISSUE DAMAGE. IF EYE CONTACT OCCURS, IMMEDIATELY FLUSH WITH LARGE AMOUNTS OF WATER AND IMMEDIATELY CONSULT A PHYSICIAN.

INHALATION OF VAPOR OR MIST CAN CAUSE SEVERE IRRITATION OF LUNGS, THROAT, AND NOSE. IF INHALATION OCCURS, MOVE TO FRESH AIR AND CONSULT A PHYSICIAN IMMEDIATELY.

INGESTION CAN PRODUCE CORROSION THAT MAY BE LIFE-THREATENING. IF SWALLOWED, DRINK PLENTY OF WATER IMMEDIATELY TO DILUTE. DO NOT INDUCE VOMITING. CONSULT A PHYSICIAN.

WARNING! DO NOT REMOVE THE PLASTIC WRAPPER FROM THE CASSETTE PACKAGE IF THE INDICATOR STRIP IS RED. RED INDICATES THAT THE CASSETTE MIGHT HAVE BEEN DAMAGED. CALL the ASP CUSTOMER CARE CENTER (1-888-STERRAD) FOR CREDIT.

To insert a new cassette do the following:

1. Confirm that the message screen on the front panel of the sterilizer indicates that a new cassette is needed.

2. Confirm that the chemical indicator strip on the cassette box is NOT red; red indicates the cassette might have been damaged.

3. Confirm that the expiration date has not passed.

   4 *Note: The STERRAD 100S Sterilizer considers the cassette is expired 10 days after insertion, and ejects it, regardless of the printed expiration date on the package.*

4. Remove the plastic wrapping and the box from the cassette.

5. Observe the direction arrow on the cassette.

6. Hold the cassette by its edges and insert it into the cassette door located above the sterilization chamber. The sterilizer automatically completes the insertion and positions the cassette for the next sterilization cycle.

   4 *Note: Please refer to the "Instructions for Use" included with the STERRAD 100S Cassettes for more information.*

Sterilization Cycle

Starting a Cycle

After the sterilization chamber has been properly loaded, and the biological and chemical indicators are in place, you are ready to start the cycle. The display should read either "READY TO USE," or, if the chamber has not reached operating temperature, the display reads "WARMING UP CYCLE WILL START." When the chamber has reached operating temperature, the cycle automatically starts.

1. Press **START**. The sterilizer door closes automatically and the cycle begins.

2. After you press **START**, and when all cycle parameters stay within their limits, the cycle is completed automatically. A long beep signals when the cycle is complete.

4 *Note: If you need to stop the cycle at any time, press **CANCEL**. The sterilizer automatically cancels the cycle. The door of the sterilization chamber opens automatically when the cancellation procedure is complete (in about 10 minutes).*

Watching a Cycle

You can monitor the progress of a cycle by watching the message screen and the status indicator lights on the front panel. The message screen indicates the status of the unit at all times. It also indicates the time remaining to cycle completion.

Status indicator lights indicate the current stage of the sterilization cycle. Each cycle goes through eight consecutive stages: vacuum, injection, diffusion, plasma, injection, diffusion, plasma, and vent. The following table shows the approximate times of each cycle stage.

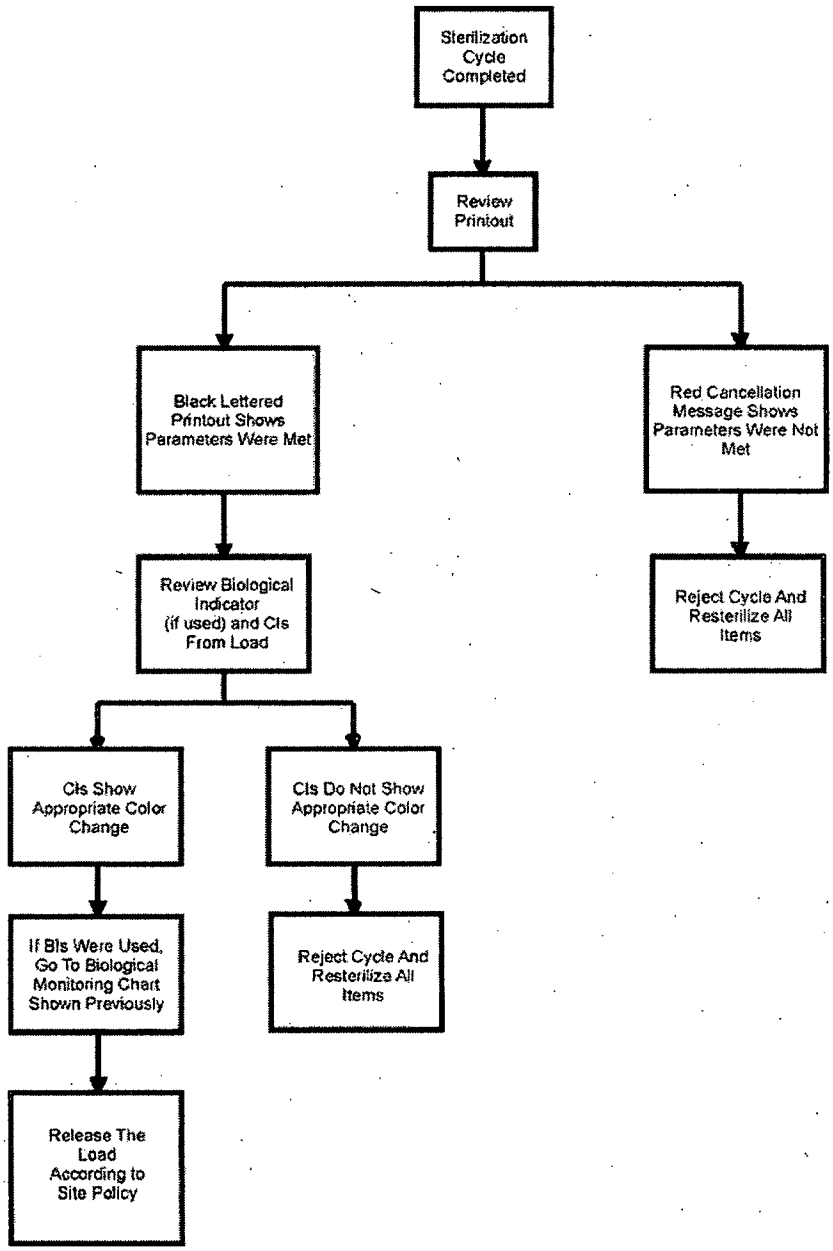
Cycle Stage	Minimum Duration	Maximum Duration
Vacuum	15 minutes	35 minutes
Injection	6 minutes	6 minutes, 20 seconds
Diffusion	1 minute, 59 seconds	2 minutes, 1 second
Plasma	5 minutes	19 minutes
Injection	6 minutes	6 minutes, 20 seconds
Diffusion	1 minute, 59 seconds	2 minutes, 1 seconds
Plasma	5 minutes	14 minutes
Vent	Less than 1 minute	2 minutes

Completing a Cycle

Cycle completion is signaled in four ways:

- A long beep.
- "PROCESS COMPLETE" is displayed on the message screen.
- The paper printout shows the process parameters (in black ink only; red ink indicates a problem).
- After cycle completion, the door of the sterilization chamber remains closed until you press **OPEN DOOR**. You may open the door as soon as the cycle is complete.
- Close the door to maintain the operating temperature and to keep the chamber clean.

Cycle Completion Flow Chart



Canceling A Cycle

Manual Cancellation

You can cancel a cycle at any time by pressing **CANCEL**. To manually cancel a cycle, do the following:

1. Press **CANCEL**.

   - The alarm indicator light illuminates, ten beeps are produced, and the message screen shows "CYCLE CANCELED."
   - A paper printout exits the front panel with a message in red ink.
   - The sterilizer automatically completes the cancellation process (which includes a short plasma phase at most stages of the cycle).
   - The chamber door opens automatically when cancellation is complete.

Loads from canceled cycles should be repackaged using new polypropylene wrap, STERRAD Chemical Indicator Strips, and STERRAD SealSure Chemical Indicator Tape. If a CycleSure Biological Indicator was used in the canceled load, it should be discarded and a new one should be placed in the chamber before starting the new cycle.

WARNING! IF A CYCLE CANCELS AND THE ITEMS IN THE LOAD HAVE ANY VISIBLE MOISTURE OR LIQUID, HYDROGEN PEROXIDE MAY BE PRESENT. WEAR LATEX, PVC (VINYL), OR NITRILE GLOVES WHILE REMOVING THE ITEMS FROM THE CHAMBER, AND WHEN WIPING OFF ITEMS WITH A DAMP CLOTH.

Automatic Cancellation

The sterilizer may automatically cancel a cycle if it detects a problem with a cycle. The sterilizer completes the same steps as shown above for manual cancellation. The chamber door opens automatically when the cancellation process is complete. Note the messages on the message screen and on the paper printout, and refer to "Chapter 6. Troubleshooting" for further instructions.

4 *Note: Loads from canceled cycles should be repackaged, using new polypropylene wrap and Tyvek® pouches, STERRAD Chemical Indicator Strips, and STERRAD SealSure Chemical Indicator Tape. If an ASP-approved biological indicator was placed in the canceled load, it should be discarded and a new biological indicator should be placed in the chamber before starting the new cycle.*

Unloading and Handling

Items processed by the STERRAD 100S Sterilizer can be used as soon as the sterilization cycle is complete. Sterilized items are then ready to be handled according to your post-sterilization process. No additional aeration time is required.

To unload the chamber, do the following:

1. Press **OPEN DOOR.**
2. Remove chamber contents.
3. Press **CLOSE DOOR.**
4. After confirming appropriate color change of the STERRAD Chemical Indicators in the load, the sterilized items are ready for immediate use, following your facility's post-sterilization process.

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Chapter 5. Routine Maintenance

In this chapter . . .

- *changing the cassette collector box*
- *replacing the vaporizer plate*
- *printer maintenance*
- *resetting the date and time*
- *setting the pressure units*
- *using the history menu*
- *cleaning the sterilizer*
- *master reset*

Overview

This chapter is your guide to the maintenance procedures for the STERRAD® 100S Sterilizer.

- Changing the cassette collection box.
- Replacing the injector valve vaporizer plate.
- Replacing the printer ribbon rolls or cartridge.
- Replacing the printer paper.
- Resetting the time and date display.
- Setting the pressure units.
- Using the history menu.
- Cleaning the sterilizer.
- Master Reset

Contact the ASP Customer Care Center (1-888-STERRAD) for guidance on all other maintenance procedures.

WARNING! ONLY EXPERIENCED, ASP-TRAINED TECHNICIANS SHOULD REPAIR OR ADJUST THIS UNIT. REPAIRS AND ADJUSTMENTS SHOULD ONLY BE ATTEMPTED BY EXPERIENCED TECHNICIANS WHO ARE FULLY TRAINED TO MAINTAIN AND REPAIR THE STERRAD STERILIZER.

USE OF UNAUTHORIZED PARTS MAY BE DANGEROUS AND VOIDS THE WARRANTY. USE OF UNAUTHORIZED PARTS FOR MAINTENANCE OR REPAIR COULD CAUSE PERSONAL INJURY, RESULT IN COSTLY DAMAGE OR UNIT MALFUNCTION, AND VOIDS THE WARRANTY.

CAUTION: Do not leave the sterilizer unplugged or turned off for longer than 24 hours. If the sterilizer must be turned off for longer than 24 hours, call the ASP Customer Care Center (1-888-STERRAD) for instructions.

Changing the Cassette Collection Box

The cassette collection box holds 30 used cassettes; this constitutes 145 cycles. The vaporizer plate is also changed every time you put in a new cassette collection box.

If the cassette collection box is not replaced at the proper cycle intervals, the sterilizer does not run any more cycles and the paper printout shows:

CHANGE COLLECTION BOX
NO FURTHER CYCLES CAN BE RUN.

If this occurs, change the cassette collection box immediately. At the same time, change the vaporizer plate.

WARNING! AVOID HANDLING USED CASSETTES. IF IT IS NECESSARY TO HANDLE A USED CASSETTE WEAR LATEX, PVC (VINYL), OR NITRILE GLOVES. DO NOT TOUCH GLOVES TO FACE OR EYES. DISPOSE OF THE CASSETTE COLLECTION BOX IN REGULAR TRASH OR FOLLOW HOSPITAL PROCEDURES.

Figure 4. Do not remove used cassettes from the collection box.

To replace the cassette collection box, do the following:

1. Unlock and open the door on the right side-panel.

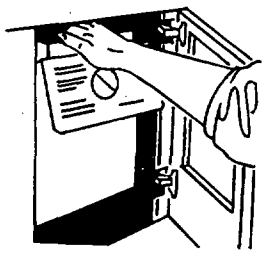

Figure 5. Open the door and remove the cassette collection box.

2. Remove the filled box and close it. Secure both ends with tape. Dispose of the cassette collection box according to local waste regulations. Cassettes with unused hydrogen peroxide are hazardous waste as defined by the Environmental Protection Agency and should be disposed of accordingly.

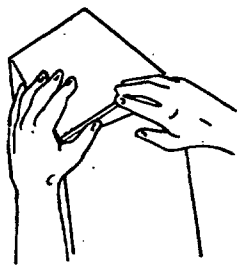

Figure 6. Close the cassette collection box and seal it with tape.

3. Inspect the chute from which the used cassettes slide into the box. It should be free of obstructions. If you must remove a used cassette from the chute, wear latex, PVC (vinyl), or nitrile gloves.

4. Unfold a new cassette collection box. Fold down the lids along the outside of the box. Insert it into the sterilizer. Be sure the instructions face the door and can be read easily.

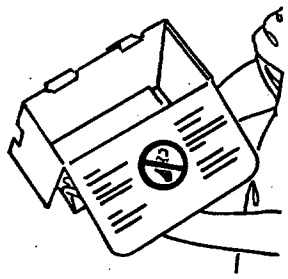

Figure 7. New cassette collection box with lids correctly folded.

5. Close and lock the side-panel door. Go to the following section for details on replacing the vaporizer plate.

4 *Note: The microprocessor in the system monitors the time needed for changing the cassette collection box. A new box should be inserted within 10 minutes. At least 10 seconds must pass before the microprocessor accepts that a new box has been loaded. A single beep sounds at 10 seconds.*

Replacing the Vaporizer Plate

A vaporizer plate is installed in all STERRAD® 100S Sterilizers. This vaporizer plate minimizes the risk of liquid hydrogen peroxide coming into contact with the load in the chamber. It also helps keep the load and the chamber clean. Operation of the STERRAD 100S Sterilizer without the vaporizer plate in place may result in hydrogen peroxide remaining on the load after a successfully completed cycle. Residual hydrogen peroxide remaining on the load can result in operator contact and/or injury.

Removing the Vaporizer Plate

WARNING! YOU MUST WEAR EYE PROTECTION AND GLOVES WHILE PERFORMING THIS PROCEDURE

1. Replace the vaporizer plate every 30 days or 145 cycles, whichever occurs first.

2. Reach into the sterilizer and grasp the protruding end of the vaporizer plate that is closest to you. Pull firmly on the plate; outward and downward so that the lips of the plate unhook from the electrode. You may also want to squeeze the plate slightly and move it outward and downward. Remove the plate from the sterilizer and discard it according to your facility's policy.

Installing a New Vaporizer Plate

CAUTION: Please make sure you follow the steps below and hold the vaporizer plate as shown in the picture. It is very important that the vaporizer plate be correctly installed so that it functions properly.

WARNING! YOU MUST WEAR EYE PROTECTION AND GLOVES WHILE PERFORMING THIS PROCEDURE.

1. Remove the vaporizer plate from its packaging. Hold the plate and insert it as shown in the following figures.

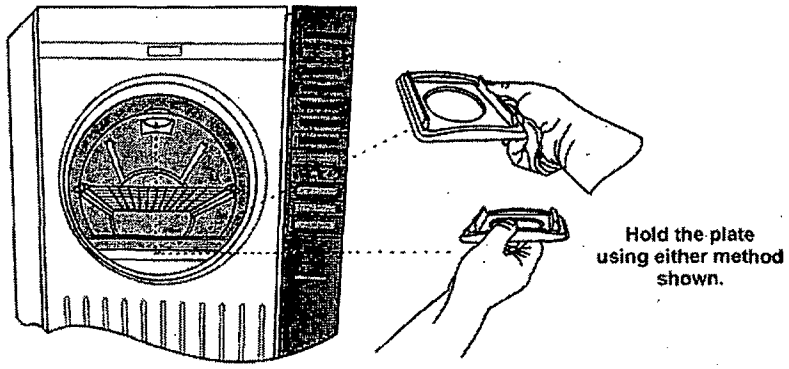

Figure 8. There are two ways to hold the plate for insertion. Choose the one that is most comfortable for you.

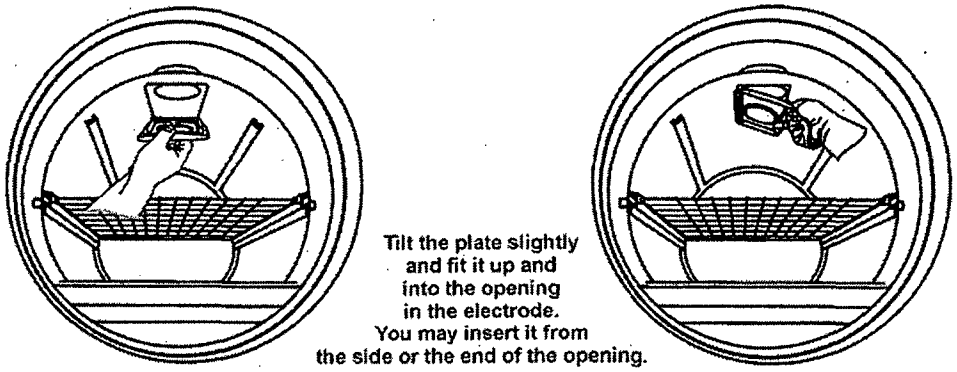

Figure 9. Insert the plate from either side of the opening. The plate fits snugly.

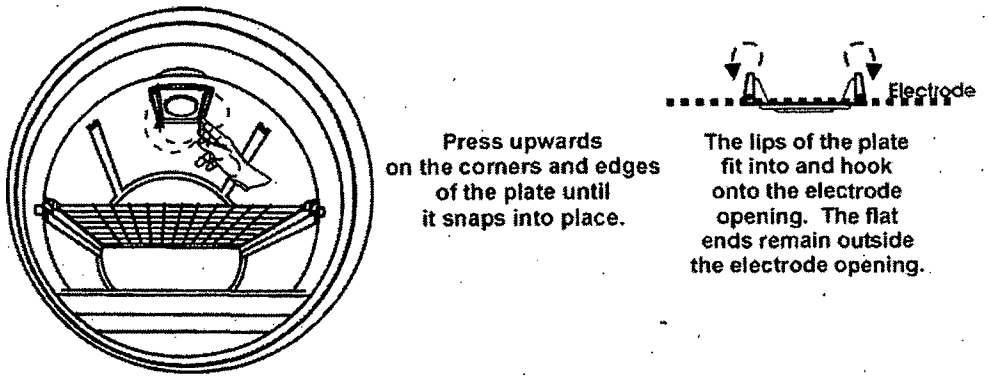

Figure 10. Make sure the plate is correctly placed before using the sterilizer.

Replacing the Printer Ribbon Rolls or Cartridge

To replace the **printer ribbon rolls,** do the following:

1. Open the printer drawer on the control panel.

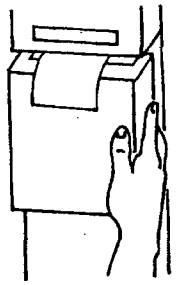

Figure 11. Opening the printer drawer.

2. Hold back the left and right security clips and pull carefully to remove the used ribbon rolls and discard them.

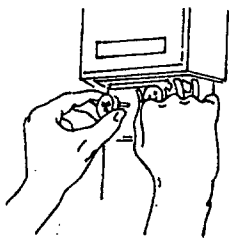

Figure 12. Holding back the security clip to remove the old ribbon roll.

3. Remove the new ribbon rolls from the packaging. Unroll the ribbon about 6 inches (150 mm). Hold back the left security clips and insert the ribbon into the printer slot (red half inside).

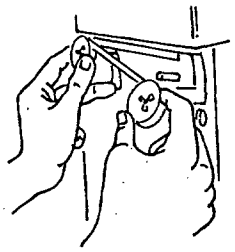

Figure 13. Unrolling the ribbon before mounting the second roll.

4. Hold back the right security clip and insert the other roll into the printer.
5. Turn the right roll clockwise to remove any slack from the ribbon.
6. Close the printer drawer, taking care to ensure that the printer paper exits the printer paper slot.

To replace a **printer ribbon cartridge,** do the following:

1. Open the printer drawer on the control panel.
2. Remove the used cartridge by firmly, but carefully, pulling on the right side, as indicated by the arrow on the cartridge.

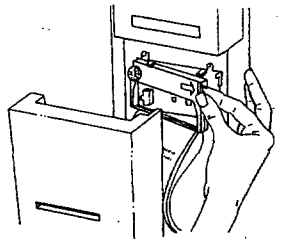

Figure 14. Removing the used printer cartridge.

3. Discard the used cartridge.
4. Insert a new cartridge by aligning the left side of the cartridge with the bracket on the machine. Push on the right side of the cartridge to snap it into place.

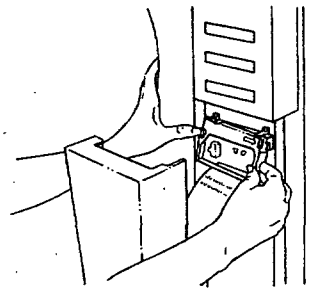

Figure 15. Inserting a new printer cartridge.

5. Turn the knob on the cartridge clockwise to remove any slack from the ribbon.

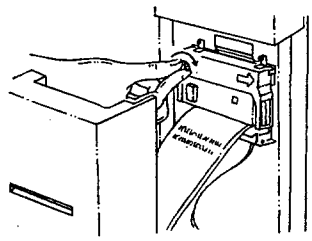

Figure 16. Removing slack from the printer ribbon.

6. Close the printer drawer, taking care to ensure that the printer paper exits the printer paper slot.

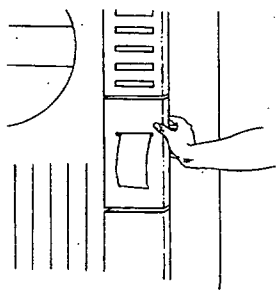

Figure 17. Closing the printer drawer.

Replacing the Printer Paper

To replace the **single roll printer paper**, do the following:

1. Open the printer drawer on the control panel.

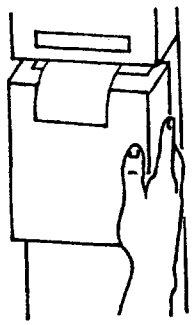

Figure 18. Opening the printer drawer.
(Early version of STERRAD 100S System shown.)

2. Remove the metal rod from the empty paper core and discard the core.

3. Insert the rod into the core of the new paper roll.

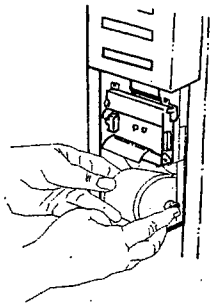

Figure 19. Placing a new paper roll into the retaining slots.

4. Insert the new paper roll so that the paper feeds from the back of the roll. Set the rod in the metal retaining clips.

5. Make sure the paper is smooth and the edge is cut clean.

6. Feed the edge of the paper into the slot behind the printer ribbon until firm resistance is felt. Push up gently on the paper and press **PAPER ADVANCE** until the mechanism begins to pull the paper. Continue pressing **PAPER ADVANCE** until about 3 or 4 inches (70 to 80 mm) of paper exits the slot above.

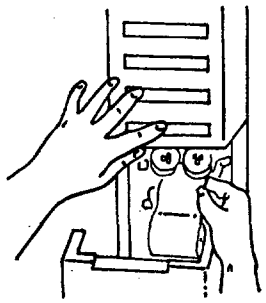

Figure 20. Feeding the paper into the mechanism.

7. Close the printer drawer, taking care to ensure the paper exits the printer paper slot.

To replace the **double roll printer paper,** do the following:

1. Open the printer drawer on the control panel and remove the large take-up reel containing the yellow backup copies of the cycles.

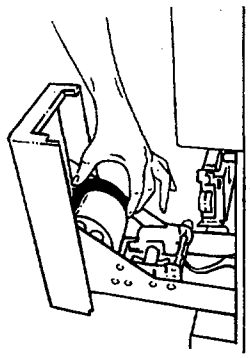

Figure 21. Removing the take-up reel containing the yellow backup copies.

2. Hold the black side of the take-up reel in one hand and, with the other hand, pull off the metal side of the reel.

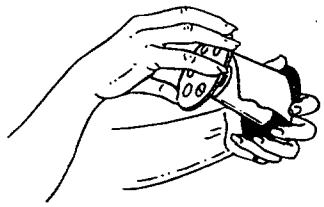

Figure 22. Removing the metal side of the take-up reel.

3. Remove the roll of yellow backup copies and save per your facility's policies/procedures.

4. Snap the metal side back onto the reel and replace the reel into the holder.

5. Remove the empty paper core and discard the core.

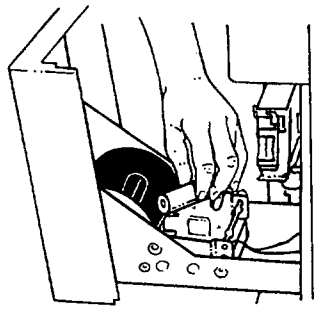

Figure 23. Removing the empty paper core.

6. Place a new paper roll into position so that the paper feeds from the back of the roll.

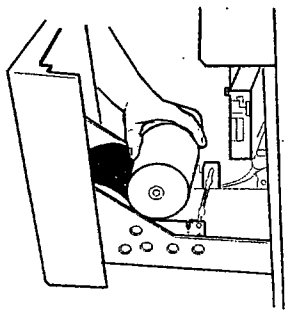

Figure 24. Placing a new paper roll into the proper position.

7. Feed the edge of the paper roll under the metal rod located just behind the paper roll.

8. Feed the edges of both the white and yellow papers into the slot behind the printer.

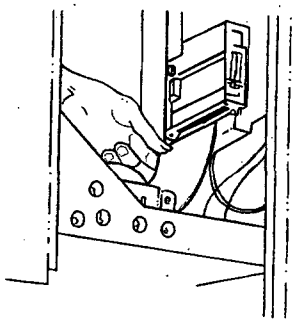

Figure 25. Feeding the paper into the slot leading to the printer cartridge.

9. Push up gently on the paper and press **PAPER ADVANCE** until the mechanism begins to pull the paper. Continue pressing **PAPER ADVANCE** until about 6 to 7 inches (150 to 160 mm) of paper exits the printer cartridge.

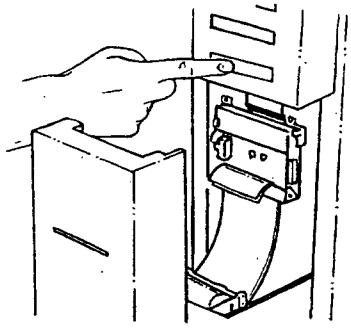

Figure 26. Advancing the paper.

10. Feed the edge of the yellow paper into the slot located on the core of the take-up reel.

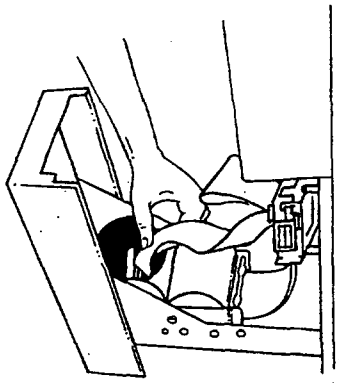

Figure 27. Inserting the yellow paper into the slot on the take-up reel.

11. Press **PAPER ADVANCE** to begin winding the yellow paper around the reel.

12. Feed the white printer paper through the slot in the printer drawer and close the drawer.

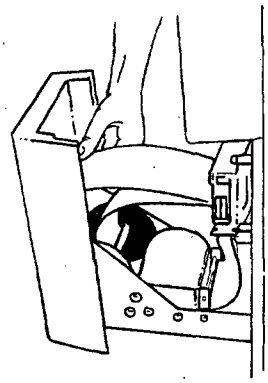

Figure 28. Feeding the white paper through the slot in the printer drawer.

4 *Note: To use a single (white paper only) roll, follow the steps above but ignore all references to yellow paper and the take-up reel.*

Resetting the Date and Time

The STERRAD 100S Sterilizer is set-up at installation to display the time in 12- or 24-hour mode. Be sure to let your ASP service engineer know the time method you prefer. You also can change the date and time as needed.

4 *Note: If you are changing the date or time, you must have completed your change before a cycle can be started. You may want to open the door so that you cannot accidentally start a cycle.*

To change the **date,** do the following:

1. Press **START** and **CANCEL** at the same time.
2. The message screen shows the date:

   DATE = MON 02/14/99

3. A flashing cursor appears at the day-of-the-week entry.
4. Press **OPEN DOOR** to change the name of the day of the week.
5. Press **CLOSE DOOR** to accept the desired day of the week. The cursor moves to the next field.
6. Press **OPEN DOOR** to change the displayed numbers.
7. Press **CLOSE DOOR** to accept the desired entry. The cursor moves to the next field.
8. Press **OPEN DOOR** to change the display.
9. Press **CLOSE DOOR** to accept the information. The display changes to the time editing mode.

   4 *Note: If you are also going to change the time, skip step 10 below, and step 1 in the following section.*

10. At the same time, press **START** and **CANCEL** to exit the date and time editor.

To change the **time,** do the following:

Note: You may want to open the door so that you do not accidentally start a cycle.

1. Press **START** and **CANCEL** at the same time.
2. Press **CLOSE DOOR** until the time display appears:

   TIME = 01:10:32 PM or 13:10:32

3. A flashing cursor appears at the hour field.
4. Press **OPEN DOOR** to change the displayed hour.
5. Press **CLOSE DOOR** to accept the desired hour. The cursor moves to the minutes field.
6. Press **OPEN DOOR** to change the displayed minutes.
7. Press **CLOSE DOOR** to accept the desired minutes. The cursor moves to the seconds field.
8. Press **OPEN DOOR** to change the displayed seconds.
9. Press **CLOSE DOOR** to accept the desired seconds. The display changes to date.
10. At the same time, press **START** and **CANCEL** to exit the time and date editor.

Clock Mode

1. Press **CANCEL** at any time during the previous date/time setting to set the clock mode. Clock mode selects either a 12-hour clock or a 24-hour clock.
2. Press **OPEN** to select the clock mode.
3. Press **CLOSE** or **CANCEL** in Clock Mode to go to the Pressure Units menu.

   CLOCK MODE XX
   OPEN(chng)-CLOSE(accept)

Setting Pressure Units

The "Pressure Units" menu on the STERRAD 100S Sterilizer displays the pressure units in torr or Pascal. The selected units are also printed at cycle completion.

PRESSURE UNITS = TORR
OPEN(chng)-CANCEL(next)

1. Press **OPEN** to switch the pressure units between torr and Pascal. The pressure units are set to torr by default, whenever a loss of battery power is detected or the number of total machine cycle is reset to zero.
2. Press **CANCEL** to transfer to the History Menu.

Using the History Menu

The History Menu on the STERRAD 100S Sterilizer allows you to print any or all of the following:

- A report of the last 10 cycle cancellations.
- A report of the last 10 barcode read failures.
- A report of the RF reflected power level.
- All three reports at once.

The History Menu displays the following:

HISTORY: PRINT ALL
OPEN(Select)-CLOSE(Prnt)

1. Press **CLOSE** to print: the last 10 cycle cancellations; the last 10 barcode read failures; and the RF reflected power history.
2. Press **OPEN** to display the following:

HISTORY: CANCELLATION
OPEN(Select)-CLOSE(Prnt)

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3. Press **CLOSE** to print the last 10 cycle cancellations report. Press OPEN to display the following:

   HISTORY: CASSETTE
   OPEN(Select)-CLOSE(Prnt)

4. Press **CLOSE** to print the last 10 barcode read failures report. Press OPEN to display the following:

   HISTORY: PRINT RF REFL.
   OPEN(chng)-CLOSE(accept)

5. Press **CLOSE** to print the RF reflected power history report. The display shows the PRINT ALL history menu. Press OPEN to switch between the previous display and the following:

   HISTORY: CLEAR RF REFL.
   OPEN(chng)-CLOSE(accept)

6. Press **CLOSE** while the above message is displayed, and the RF Reflected Power history records are cleared. The display shows the PRINT ALL history menu.

Cleaning the Sterilizer

The outside surfaces of the STERRAD 100S Sterilizer can be cleaned with a mild detergent. The inside of the sterilization chamber does not normally require cleaning. The chamber door and the chamber should not be cleaned with an abrasive, such as a wire brush or steel wool. If you have any questions regarding cleaning the sterilizer, call the ASP Customer Care Center (1-888-STERRAD).

CAUTION: Do NOT clean the chamber door area with abrasives. The sterilization chamber uses an o-ring vacuum seal to maintain a vacuum in the chamber. Never use rough cleaning tools, such as a wire brush or steel wool, on the door housing or chamber assembly. This could damage the seal.

Master Reset

The master reset *must only* be done when specifically directed in the Troubleshooting chapter or by an ASP Service Engineer. The master reset is accomplished by two people. There is NO danger to the operator or the system when performing this operation.

To perform a master reset, do the following:

1. One person remains at the front of the system, the second person moves to the rear of the system.

2. The person at the rear of the system turns the system main power circuit breaker to the OFF (DOWN) position. The circuit breaker resembles a large on/off light switch and is located at the bottom, right side of the system back.

3. The person at the front of the system presses and holds **CANCEL** on the control panel and instructs the person at the rear of the system to switch the circuit breaker to the ON (UP) position while continuing to hold the **CANCEL** button for 10 seconds or until the system beeps. When the system beeps, the master reset is complete.

4. The person at the front of the system verifies the master reset was successful by viewing the message on the display. The display may show a series of numbers/letters in the following format XX-XXXXX-X-XXX, the words "Ready to Use" or "Please Insert Cassette." If none of these messages is seen, please inform the ASP Customer Care Center (1-888-STERRAD).

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Chapter 6. Troubleshooting

In this chapter . . .

- *using system messages to troubleshoot the system.*

Overview

The STERRAD® 100S Sterilizer is a relatively trouble-free device, requiring only routine maintenance and care in load preparation to help prevent system cancellations. Proper preparation of the load can help to ensure a minimal amount of cycle cancellations. You **must** read, understand and follow all the safety procedures detailed in Chapter 2, and the load preparation procedures in Chapter 3.

WARNING! YOU MUST WEAR LATEX, PVC (VINYL), OR NITRILE GLOVES WHEN REMOVING OR INSERTING THE LOAD BECAUSE OF A CANCELED CYCLE.

Using System Messages To Troubleshoot The System

The messages in this table are in alphabetical order. You may receive similar messages during different stages of the system cycle. The action you are to take is usually the same regardless of the cycle stage. Depending on the software version installed in your sterilizer, you may see messages containing "See User Guide" instead of "See Op Manual"; and "Call Customer Support" instead of "Call Technical Support (ASP Technical Service.) The different wording does not affect your handling of the message.

STERRAD® 100S Message	Printed Message	Action
CASSETTE ACCEPTED	No Printout	Cassette is of the correct type and date, and is positioned correctly. No action required.
CASSETTE INSERTED INCORRECTLY	No Printout	Barcode cannot be read. Cassette ejected out of the front panel. Insert cassette as directed on the cassette. If problem persists, call the ASP Customer Care Center.
CASSETTE OUT-OF-DATE	No Printout	Shelf-life of cassette expired or date on sterilizer is not current. Cassette automatically exits to the collection box. Insert new cassette or verify date.
CHANGE COLLECTION BOX	145 Cycles Change Collection Box	29 cassettes have been captured in the cassette collection box. Replace this box. (See "Chapter 5. Routine Maintenance.")
CHANGE COLLECTION BOX NO MORE CYCLES CAN RUN	Change Collection Box No Further Cycles Can Be Run	30 cassettes have been captured in the cassette collection box. The box is now full and must be replaced. (See "Chapter 5. Routine Maintenance.")

STERRAD® 100S Message	Printed Message	Action
CHECK CASSETTE CHUTE NO MORE CYCLES CAN RUN	Wear Gloves Remove Cassette See Op Manual	Cassette is stuck at top of exit chute. Open door on right side-panel. Wearing latex, PVC (vinyl), or nitrile gloves, remove cassette from chute, and place in collection box. OR Check to see if collection box is full. If full, change the collection box.
CLOSE DOOR TIME-OUT CALL TECHNICAL SERVICE	No Printout	Call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT..	Cycle Canceled Moisture In Load Dry And Repackage Load Restart Sterilizer	Too much water remains in the load. Check the instruments to be sure they are dry. Replace all indicators and restart the sterilizer.
CYCLE CANCELED PLEASE WAIT . . .	Cycle Canceled Operator Cancellation Repackage Load Restart Sterilizer	Operator canceled during the first part of the vacuum stage of the cycle. Repackage load and restart sterilizer.
CYCLE CANCELED PLEASE WAIT . . .	Cycle Canceled Power Interrupted See Op Manual	Power was interrupted during the first part of the vacuum stage of the cycle. Cycle canceled. Repackage load and restart sterilizer. If problem persists, call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT...10 MIN	Cycle Canceled Pressure Out Of Range In Vacuum See Op Manual	Pressure in the chamber did not stabilize in the range required for the plasma state. Load may be releasing gases from plastic-like materials, or load may be wet. Check load, repackage, and restart the sterilizer. If the problem reoccurs, start the cycle with the chamber empty. If the stage is not successful Call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT...	Cycle Canceled Temperature Below Threshold Call ASP Technical Service	Call the ASP Customer Care Center.

STERRAD® 100S Message	Printed Message	Action
CYCLE CANCELED PLEASE WAIT..	Cycle Canceled Vacuum System Interrupted Call ASP Technical Service	Call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT..	Cycle Canceled Vacuum Insufficient See Op Manual	Vacuum was not reached. Check load for: moisture, cellulosic materials, too many packages in chamber. Repackage load and restart the sterilizer. OR If problem reoccurs, start a cycle with the chamber empty. If the vacuum stage is then successful, problem is the load. If the vacuum stage is not successful, call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT..	Cycle Canceled Valve Open Time-Out Call ASP Technical Service	Call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT..	Cycle Canceled Valve Close Time-Out Call ASP Technical Service	Call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT...10 MIN.	[Printout May Show With Any Cycle Canceled Message.] Please Inspect Load Carefully See Op Manual	**Hydrogen peroxide may be present on wet items. Wear latex, PVC (vinyl), or nitrile gloves when removing items from the chamber and while checking the items for moisture.** If moisture is found, wipe off moisture with a damp cloth. Repackage load and restart the sterilizer.
CYCLE CANCELED PLEASE WAIT...10 MIN.	Cycle Canceled Injection System Interrupted See Op Manual	Not enough cells in cassette to complete cycle, or faulty cassette detected. Cassette ejects into the cassette collection box. Insert new cassette, repackage load and restart the sterilizer.

STERRAD® 100S Message	Printed Message	Action
CYCLE CANCELED PLEASE WAIT...10 MIN.	Cycle Canceled Insufficient Plasma Pressure See Op Manual	Vacuum did not reach the level required for the plasma stage. Load may be releasing gases from plastic-like materials. Check load, repackage, and restart the sterilizer. If the problem persists start a cycle with the chamber empty. If the problem persists Call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT...10 MIN	Cycle Canceled Low Pressure In Diffusion Call ASP Technical Service	Call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT...10 MIN	Cycle Canceled Low Pressure In Injection See Op Manual	Low peroxide pressure. Load may contain cellulose, linen, paper pouch, or other absorbent materials. Check load, repackage, and restart the sterilizer. OR If the cycle cancels again, run another cycle with the chamber empty. If injection stage is successful, problem is the load. Readjust and repackage the load, restart the sterilizer. If the empty cycle cancels due to low injection pressure, call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT...10 MIN.	Cycle Canceled Low RF Power See Op Manual or Cycle Canceled Low RF2 Power See Op Manual	RF or RF2 generator power too low. Check to see if shelves or other metal is in contact with chamber walls, electrode, or door. Repackage load, and restart sterilizer. If problem persists, call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT...10 MIN	Cycle Canceled Low RF Power In Vacuum See Op Manual or Cycle Canceled Low RF2 Power In Vacuum See Op Manual	RF or RF2 generator power too low. Check to see if shelves or other metal in load is in contact with sterilizer chamber walls, electrode, or door. Repackage load and restart the sterilizer. If problem persists, call the ASP Customer Care Center.

STERRAD® 100S Message	Printed Message	Action
CYCLE CANCELED PLEASE WAIT...10 MIN.	Cycle Canceled No RF Power See Op Manual	No generator power. Check to see if shelves or other metal is in contact with chamber walls, electrode, or door. Repackage load, and restart sterilizer. If problem persists, call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT...10 MIN	Cycle Canceled No RF Power In Vacuum See Op Manual	No RF generator power. Check to see if shelves or other metal in load is in contact with sterilizer chamber walls, electrode, or door. Repackage load and restart the sterilizer. If problem persists, call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT...10 MIN	Cycle Canceled Operator Cancellation Repackage Load Restart Sterilizer	Operator canceled cycle during a critical stage. Repackage load and restart the sterilizer.
CYCLE CANCELED PLEASE WAIT...10 MIN.	Cycle Canceled Over Pressure In Injection See Op Manual	Possible air leak in system. Run a cycle with the chamber empty. If injection stage is successful, repackage load and restart the sterilizer. If the problem persists, call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT...10 MIN.	Cycle Canceled Pressure Out Of Range Call ASP Technical Service	Call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT...10 MIN.	Cycle Canceled Power Interrupted See Op Manual	Power was interrupted during a critical stage of the cycle. Cycle canceled. Repackage load and restart the sterilizer. If problem persists, call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT...10 MIN.	Cycle Canceled Process Time Exceeded Call ASP Technical Service	Call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT...10 MIN.	Cycle Canceled Temperature Over Threshold Call ASP Technical Service	Call the ASP Customer Care Center.

STERRAD® 100S Message	Printed Message	Action
CYCLE CANCELED PLEASE WAIT...10 MIN	Cycle Canceled Temperature Below Threshold Call ASP Technical Service	Call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT...10 MIN	Cycle Canceled Temperature Sensor Below Limit Call ASP Technical Service	Call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT...10 MIN	Cycle Canceled Vacuum Not Low Enough For Injection See Op Manual	Vacuum was not reached. Check load for: moisture, cellulosic materials, too many packages in chamber. Repackage load and restart the sterilizer. OR If problem reoccurs, start a cycle with the chamber empty. If the vacuum stage is then successful, problem is the load. If the vacuum stage is not successful, call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT...10 MIN.	Cycle Canceled Valve Close Time-Out Call ASP Technical Service	Call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT...10 MIN.	Cycle Canceled Valve Open Time-Out Call ASP Technical Service	Call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT...10 MIN.	Cycle Canceled Vent Time-Out Call ASP Technical Service	Call the ASP Customer Care Center.
CYCLE CANCELED PLEASE WAIT...10 MIN	Cycle Canceled Vaporizer Out Of Range Call ASP Technical Service	Call the ASP Customer Care Center.
DOOR IS BEING BLOCKED	No Printout	Remove item blocking the door.
DOOR WILL CLOSE AUTOMATICALLY	No Printout	No action required. The door is closing normally after START has been pressed.

STERRAD® 100S Message	Printed Message	Action
EJECT TIME-OUT PERFORM MASTER RESET	No Printout	Perform a Master Reset as shown in the Routine Maintenance Chapter. If the problem persists, call the ASP Customer Care Center.
INCORRECT CASSETTE TYPE	No Printout	Incorrect type of cassette is inserted. Insert a STERRAD® 100S Cassette.
INSERT NEW CASSETTE NO CYCLES CAN BE RUN	No Printout	No cassette is in the machine. Insert a new cassette.
INSERT NEW CASSETTE CALL TECHNICAL SERVICE	No Printout	Insert new cassette. The planned maintenance is past due. Call the ASP Customer Care Center immediately.
INSERT NEW CASSETTE MAINTENANCE DUE (L1)	No Printout Or PM Interval Due (Level 1): XX	Insert a new cassette. The Level 1 planned maintenance is due soon. Call the ASP Customer Care Center to schedule service.
INSERT NEW CASSETTE MAINTENANCE DUE (L2)	No Printout Or PM Interval Due (Level 2) XX	Insert a new cassette. The Level 2 planned maintenance is due soon. Call the ASP Customer Care Center to schedule service.
NO DISPLAY	Software Anomaly SP = XXXXXX Call ASP Technical Service	Call the ASP Customer Care Center.
OPEN DOOR TIME-OUT CALL TECHNICAL SERVICE	No Printout	Call the ASP Customer Care Center.
OVER CENTER TIME-OUT CALL TECHNICAL SERVICE	No Printout	Call the ASP Customer Care Center.
PLEASE REMOVE CASSETTE	No Printout	Remove the cassette and reinsert. If the message persists, try a new cassette.
POSITIONING CASSETTE	No Printout	Cassette is being positioned. No action required.
PRINTER BUFFER FULL SEE OP MANUAL	No Printout	Perform Master Reset. ("See Chapter 5. Routine Maintenance.")
PROCESS COMPLETE CALL TECHNICAL SERVICE	Level 1 PM Interval Past Due XXX Call ASP Technical Service	Process complete. The Level 1 planned maintenance is past due. Call the ASP Customer Care Center immediately.

STERRAD® 100S Message	Printed Message	Action
PROCESS COMPLETE CALL TECHNICAL SERVICE	Level 2 PM Interval Past Due XXX Call ASP Technical Service	Process complete. The Level 2 planned maintenance is past due. Call the ASP Customer Care Center immediately.
PROCESS COMPLETE	STERRAD® 100S Sterilizer [Printout Contains All Process Parameters] Process Complete Validated By:_____ Biological Indicator:_____ Number Of Cycles Available = X Cassette Expiration Date XX/XX [Printout May Show: Insert New Cassette, PM Interval Due, Or Level 1/Level 2 PM Interval Past Due, Vent Time-Out] *Trademark	Cycle complete. Door may be opened and load removed from sterilizer.
PROCESS COMPLETE MAINTENANCE DUE (L1)	PM Interval Due (Level 1): XX	The Level 1 planned maintenance is due soon. Call the ASP Customer Care Center to schedule service.
PROCESS COMPLETE MAINTENANCE DUE (L2)	PM Interval Due (Level 2): XX	The Level 2 planned maintenance is due soon. Call the ASP Customer Care Center to schedule service.
READY TO USE	No Printout or RF Reflected Power > 50 Watts Please Call ASP Technical Service to Schedule Preventative Maintenance.	System is ready for a new cycle. No action required. or Call the ASP Customer Care Center to schedule maintenance.

STERRAD® 100S Message	Printed Message	Action
READY TO USE CALL TECHNICAL SERVICE	No Printout	Ready to use. The planned maintenance is past due. Call the ASP Customer Care Center immediately.
READY TO USE MAINTENANCE DUE (L1)	No Printout	The Level 1 planned maintenance is due soon. Call the ASP Customer Care Center to schedule service.
READY TO USE MAINTENANCE DUE (L2)	No Printout	The Level 2 planned maintenance is due soon. Call the ASP Customer Care Center to schedule service.
RECOVERING FROM POWER INTERRUPT PLEASE WAIT . . .	No Printout	No action required.
START OPEN DOOR TIME-OUT CALL TECHNICAL SERVICE	No Printout	Call the ASP Customer Care Center.
TEMP. OVER THRESHOLD NO MORE CYCLES CAN RUN	Temperature Over Threshold Call ASP Technical Service	Call the ASP Customer Care Center.
TEMP. SENSOR BELOW LIMIT NO MORE CYCLES CAN RUN	Temperature Sensor Below Limit Call ASP Technical Service	Call the ASP Customer Care Center.
TEMPERATURE HAS NOT RISEN	Temperature Has Not Risen. Call ASP Technical Service	Call the ASP Customer Care Center.
UNABLE TO VERIFY INSERT NEW CASSETTE	No Printout	Barcode cannot be read for the second time. Insert new cassette. If problem persists, call the ASP Customer Care Center. To receive credit for the cassette, call the ASP Customer Care Center.
VENT TIME-OUT CALL TECHNICAL SERVICE	Vent Time-Out Call ASP Technical Service	Call the ASP Customer Care Center.
VERIFYING CASSETTE PLEASE WAIT. . .	No Printout	The system is trying to read the barcode; it tries twice. No action required.
WARMING UP	No Printout	Chamber is not at operating temperature.
WARMING UP CYCLE WILL START AUTOMATICALLY	No Printout	Chamber is not at operating temperature. Cycle starts automatically. To remove load before cycle starts, press CANCEL.

STERRAD® 100S Message	Printed Message	Action
WARMING UP PLEASE CLOSE DOOR	No Printout	Chamber is not at operating temperature. Please close the door.

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Appendix A.

In this appendix . . .

- *sterilizer specifications*

Specifications

Protection	
Protection Class	Class 1
Protection Type	Type B
Protection Against Ingress of Water	Ordinary (IPXO)
Mode of Operation	Continuous
Explanation of Warning Symbols	
IEC 348	Attention, consult accompanying documents
IEC 878-03-01	Dangerous voltage
Serviceable Assemblies	
Circuit Diagrams	Contact ASP Technical Service*
Component Part Lists	Contact ASP Technical Service*
Descriptions	Contact ASP Technical Service*
Calibration Instructions	Contact ASP Technical Service*
Environmental Conditions/Transport and Storage	
Ambient Temperature	-40°C to +70°C (-40° to 158° F)
Relative Humidity	10% to 100%, including condensation
Atmospheric Pressure	50 kPa to 106 kPa
Altitude	Up to 2000 meters (6562 feet)
Environmental Conditions/Operation	
Ambient Temperature	+10°C to +40°C (50 to 104° F)
Relative humidity	30% to 75%, noncondensing
Atmospheric pressure	70 kPa to 106 kPa

*ASP provides the circuit diagrams, component part lists, descriptions, and calibration instructions on request to appropriately qualified personnel on the assemblies that ASP feels are serviceable by non-ASP personnel.

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Appendix B.

In this appendix . . .

- *service and commercial warrantees*

Service and Commercial Warranties

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 (ASP). 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 instrument. Replacement items can be either new or remanufactured. Defective parts replaced under warranty shall become the property of ASP.

THE EXPRESS WARRANTY ABOVE IS THE SOLE WARRANTY OBLIGATION OF ADVANCED STERILIZATION PRODUCTS, AND THE REMEDY PROVIDED ABOVE IS IN LIEU OF ANY AND ALL OTHER REMEDIES. THERE ARE NO OTHER AGREEMENTS, GUARANTEES OR WARRANTIES -- ORAL OR WRITTEN -- EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ADVANCED STERILIZATION PRODUCTS SHALL HAVE NO LIABILITY WHATSOEVER FOR ANY IMPROPER USE OR UNAUTHORIZED SERVICE OR REPAIR.

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Advanced Sterilization Products Commercial Warranty

The STERRAD® Sterilizer and reusable accessories supplied by Advanced Sterilization Products (ASP) are 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 their 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 null and void if service is attempted or performed by persons who are not authorized to do so by Advanced Sterilization Products. 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 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/replacement in its own factory, at any authorized repair station, or at the facilities of the purchaser of the instrument. Replacement items can be either new or remanufactured. Defective parts replaced under warranty shall become the property of ASP.

THE EXPRESS WARRANTY ABOVE IS THE SOLE WARRANTY OBLIGATION OF ADVANCED STERILIZATION PRODUCTS, AND THE REMEDY PROVIDED ABOVE IS IN LIEU OF ANY AND ALL OTHER REMEDIES. THERE ARE NO OTHER AGREEMENTS, GUARANTEES OR WARRANTIES -- ORAL OR WRITTEN -- EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ADVANCED STERILIZATION PRODUCTS SHALL HAVE NO LIABILITY WHATSOEVER FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF ANY DEFECT, IMPROPER USE OR UNAUTHORIZED SERVICE OR REPAIR.

ACCEPTED
with COMMENTS
EPA Letter Dated:

FEB 11 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

71871-3

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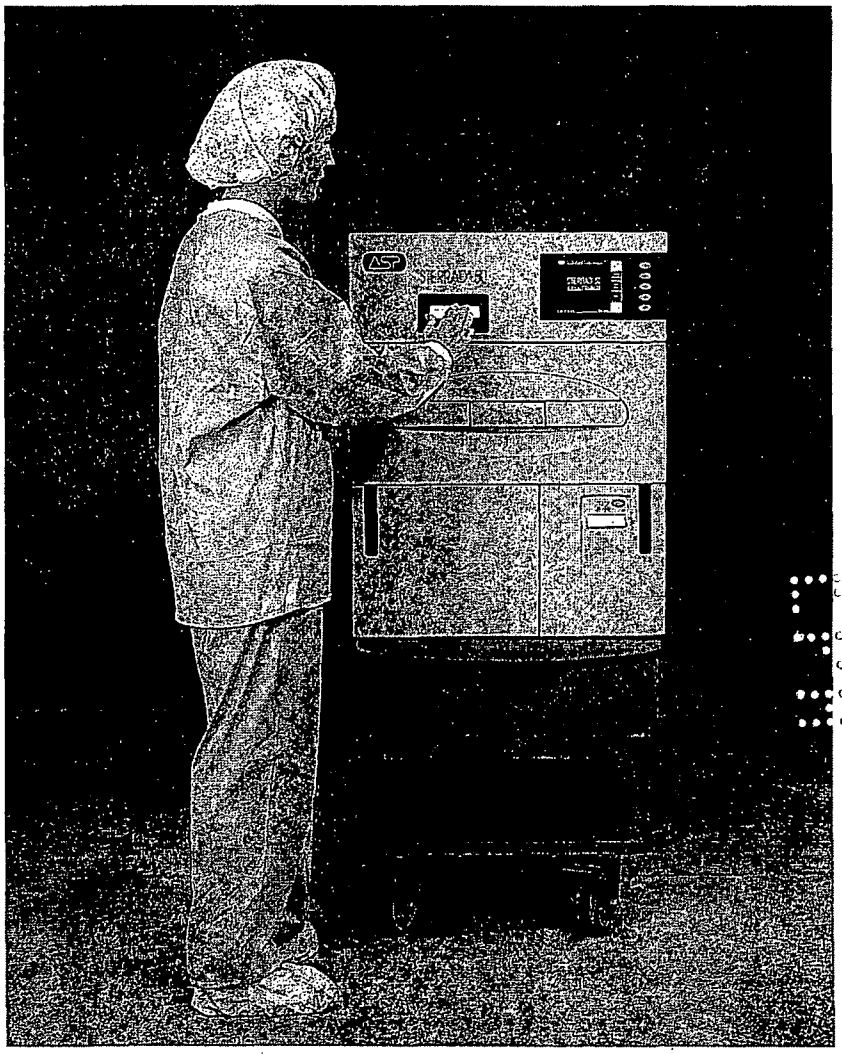
STERRAD® 50 Sterilization System

User's Guide



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71871-3

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STERRAD® 50 Sterilization System

User's Guide

REF 99015

Manufacturer:

ADVANCED STERILIZATION PRODUCTS®

a Johnson & Johnson company

Division of Ethicon, Inc.

33 Technology Drive, Irvine, CA 92618-9824

Authorized EC Representative

Ethicon GmbH

Oststraße 1, D-22844 Norderstedt

CE 0123

USA Irvine, CA 92618	I 00040 Pomezia, Roma
F 92787 Issy-les-Moulineaux	E 28042 Campo de las Naciones, Madrid
D 22844 Norderstedt	GB Ascot, Berks
CH 8957 Spreitenbach	CDN Johnson & Johnson Medical Products Markham, ON, L3R 0T5
NL 3800 AD Amersfoort	J 東京都江東区新砂6-3-2 ㈱ジョンソン・エンド・ジョンソン 株式会社
BR Rodovia Dutra, Km 154 S.J. Campos S.P. 12237-350	A 1190 Wien
S 19184 Sollentuna	GR 15125 Maroussi, Athens

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ASP USA Customer Support 01.949.581.5799

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About This Guide

- *In this chapter . . .*
  - *information about this user's guide*

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Overview

This guide is designed to provide useful information on the day-to-day operation and routine maintenance of the STERRAD® 50 Sterilizer.

The guide is divided into 6 chapters and 2 appendices and two fold-out pages. These chapters provide information on using the sterilizer, load preparation, routine maintenance, and troubleshooting the system should problems arise.

The chapters are:

- **About This Guide**-this section gives you important information on how to get the most use out of this guide.
- **Chapter 1. Introduction**-the first chapter of the guide has important details about the STERRAD 50 Sterilizer, including the major parts of the sterilizer and STERRAD Process information.
- **Chapter 2. For Your Safety**-this may be the most important chapter in the guide. You should read this chapter thoroughly, understand the information, and follow all the safety procedures. These safety procedures include safe handling of cassettes, safe handling of the load and first aid information in case of possible hydrogen peroxide exposure.
- **Chapter 3. Preparing Items To Be Sterilized**-this chapter provides a brief description on preparing items to be sterilized, and how to effectively package the load.
- **Chapter 4. Day-to-Day Operation**-this chapter gives you detailed information on how to use the sterilizer, how to load the chamber, how to use the control panel, how to run cycles and how to interpret BI test results.
- **Chapter 5. Routine Maintenance**-the routine maintenance of the STERRAD 50 Sterilizer is very minimal. This chapter shows you how to change the printer paper and ribbon, and what steps to follow to keep the sterilizer clean.

- **Chapter 6. Troubleshooting**-the STERRAD 50 Sterilizer displays a number of messages indicating system status at any given moment. Many of these messages do not require any action from you. Others require that you call your ASP Service Representative for maintenance. The messages are listed in alphabetical order.

- **Appendix A. Specifications**-this appendix details the technical specification information for your sterilizer.

- **Appendix B. Service and Commercial Warrantees**-this appendix contains the detailed system warranty and our guarantees to you regarding your STERRAD 50 Sterilizer.

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Chapter 1. Introduction

In this chapter . . .

- *operation information*

1 Introduction

Overview

The STERRAD® 50 Sterilization System is a general purpose, low temperature sterilizer using the STERRAD 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.

It is your responsibility to read, understand, and follow the safety information presented in chapter 2 and throughout this guide. The safety information is provided for your benefit and for the benefit of your instruments and equipment.

Operation Information

This guide provides basic information on how to operate the STERRAD 50 Sterilizer safely and efficiently. As a medical professional, you may already be familiar with general sterilization principles. However, the STERRAD 50 Sterilizer represents a new technology, and it requires special attention to the ways in which it differs from other sterilizers.

The STERRAD 50 Sterilizer has been developed by Advanced Sterilization Products, a Johnson and Johnson Company, a division of Ethicon, Inc., to sterilize medical devices by diffusing hydrogen peroxide into the chamber and then "exciting" the hydrogen peroxide molecules into a 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, including the plasma stage, operate within a dry environment at a low temperature, and thus the cycle is not damaging to compatible instruments sensitive to heat and moisture. The STERRAD 50 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.

The system consistently provides a sterility assurance level (SAL) of 10^{-6}, as defined by 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 guide.

The length of all cycle phases and the setpoints for all critical process parameters are controlled by a microprocessor and software. The system reliably sterilizes various materials and load configurations, without leaving toxic residue when used in accordance with the directions in this guide.

✔ *Note: The following paragraph presents a simplified overview of the sterilizer components. Chapters 3 and 4 detail loading and sterilizer operation.*

The main sterilizer components are shown in the following illustration: The sterilizer operates as follows:

- the system indicates that sterilization can start by displaying the "Ready to Use" message on the system display.
- the items to be sterilized are placed in the chamber.
- the door is manually shut.
- a cassette is inserted (if needed).
- START is pressed.

The sterilization process is complete in about 45 minutes. The load can then be used immediately or stored according to your procedures.

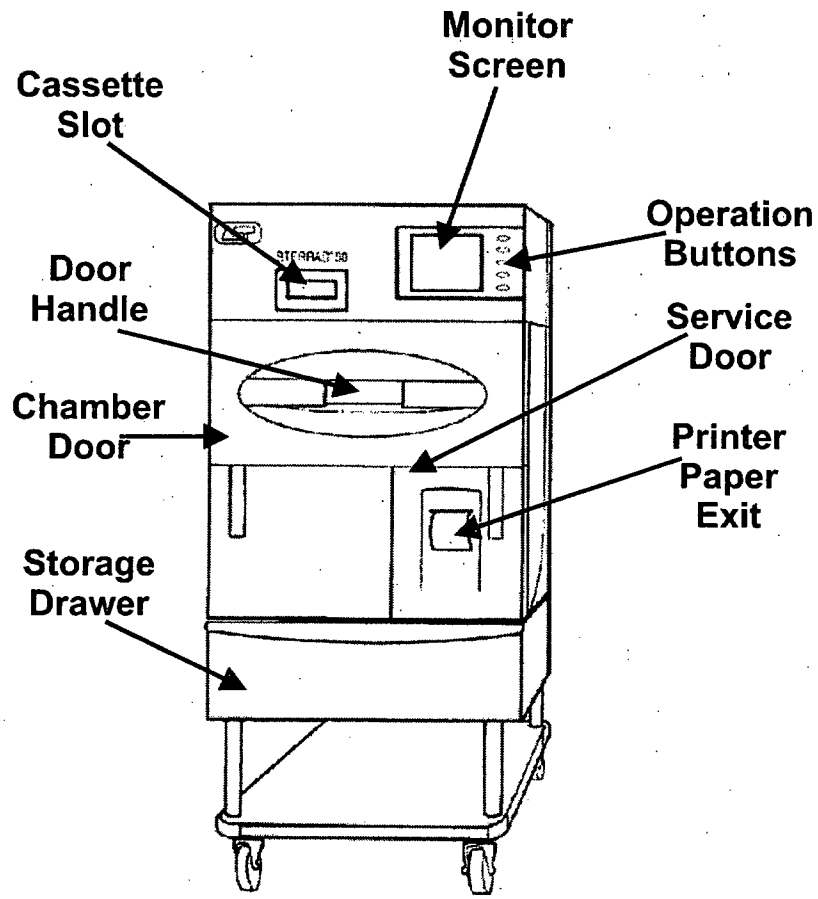

Figure 1. STERRAD® 50 Sterilizer

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Chapter 2. For Your Safety

In this chapter . . .

- *personal safety and first aid*
- *device safety*
- *cassette handling*
- *safe handling*

Overview

Your safety is of primary concern to ASP. This section provides information on safely using the sterilizer. **You must read, understand and use the information in this chapter before operating the unit.** Also, always pay attention to the warnings, cautions and notes throughout this guide. This information is for your safety and to ensure that you receive the most benefit from the safe operation of your STERRAD® 50 Sterilization System. Only trained, experienced technicians, who are fully acquainted with the unit, should repair or adjust the STERRAD 50 System.

Personal Safety and First Aid

- **WEAR LATEX, PVC (VINYL) OR NITRILE GLOVES WHILE REMOVING ITEMS FROM THE STERILIZER AFTER A CYCLE HAS CANCELLED. CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT.** If a cycle cancels and the items in the load have any visible moisture or liquid, hydrogen peroxide may be present.

- 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.

- Direct hydrogen peroxide contact with eyes can cause irreversible tissue damage. If eye contact occurs, immediately flush with large amounts of water and immediately consult a physician.

- Inhalation of vapor or mist can cause severe irritation of lungs, throat, and nose. If inhalation occurs, move to fresh air and consult a physician immediately.

- Ingestion can produce corrosion that may be life threatening. If swallowed, drink plenty of water immediately to dilute. Do not induce vomiting. Consult a physician.

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Device Safety

- **DO NOT ATTEMPT TO STERILIZE ITEMS OR MATERIALS THAT DO NOT COMPLY WITH THE DIRECTIONS SPECIFIED IN THIS GUIDE.** In addition, you should read the medical device manufacturer's instructions, or call your ASP representative to determine whether an item can be sterilized by this unit.
- All items must be cleaned and thoroughly dried before loading into the sterilizer. Loads containing moisture may cause cycle cancellation.
- The chapter on preparing items to be sterilized contains information about which materials and devices can be processed by the STERRAD Sterilizer.
- 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 instruments.
- Prior to relocating the STERRAD Sterilizer, make sure the new power source has a dedicated line with the correct power requirements for your location (see Appendix A for electrical information.)
- Do not leave the sterilizer unplugged or turned off for longer than 24 hours. If the sterilizer must be turned off for longer than 24 hours, call your ASP Service Representative for instructions.
- Only ASP-approved biological indicators should be used to monitor the sterilization cycle. Should a cancellation occur when one of these biological indicators is in the chamber, it should be discarded and a new biological indicator should be used when re-starting the cycle. Call your ASP representative for information on approved biological indicators.

Cassette Handling

- **STERRAD 50 CASSETTES CONTAIN CONCENTRATED HYDROGEN PEROXIDE, A STRONG OXIDIZER. CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT.** Direct 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. Direct contact with eyes can cause irreversible tissue damage. If eye contact occurs, immediately flush with large amounts of water and immediately consult a physician. Inhalation of vapor or mist can cause severe irritation of lungs, throat, and nose. If inhalation occurs, move to fresh air and consult a physician immediately. Ingestion can produce corrosion that may be life threatening. If swallowed, drink plenty of water immediately to dilute. Do not induce vomiting. Consult a physician.

- Do not remove the plastic wrapper from the cassette package if the indicator strip is red. Red indicates that the cassette might have been damaged. Call your ASP Representative for credit.

- Do not remove used cassettes from the protective cardboard sleeve. Dispose of the cassette inside the protective sleeve in normal waste or follow your facility's procedures. Empty or expired cassettes must be replaced prior to starting the cycle.

- If the USED cassette falls out of the cardboard sleeve, wear latex, PVC (vinyl), or nitrile gloves to place the plastic cassette back in the original sleeve. Discard the cassette according to your hospital procedures. Do not touch gloves to face or eyes.

Safe Maintenance

- Repairs and adjustments should only be attempted by experienced technicians who are fully trained to maintain and repair the STERRAD 50 Sterilizer.

- Use of unauthorized parts for maintenance or repair could cause personal injury, result in costly damage or unit malfunction, and void the warranty.

- The power cord of the STERRAD 50 Sterilizer should only be plugged into outlet that have been approved by a qualified technician. For further

requirements, refer to the label on the back panel of the sterilizer or call your ASP service representative.

- Do not clean the chamber door area with abrasives. The sterilization chamber uses an O-ring vacuum seal to maintain a vacuum in the chamber. Never use rough cleaning tools, such as a wire brush or steel wool, on the door housing or chamber assembly. This could damage the seal.

Additional Information

The information in this chapter is repeated where appropriate throughout this guide for your safety and use. This information is subsequently labeled: **WARNINGS,** Cautions or Notes as appropriate.

- **WARNINGS** are shown in the text in all bold upper case letters. They indicate events or conditions that can result in serious injury or death.
- **Cautions** are shown in the text in bold letters, and they indicate events or conditions that can result in damage to equipment.
- Notes are shown in the text with a check mark ✔. Notes highlight specific information about the proper use and maintenance of the STERRAD 50 Sterilizer.

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Chapter 3. Preparing Items To Be Sterilized

In this chapter . . .

- *indications for use*
- *recommended materials*
- *typical items sterilized*
- *items not recommended*
- *cleaning, rinsing, and drying*
- *guidelines for wrapping, packaging, and loading*

3 Preparing Items To Be Sterilized

Overview

This chapter briefly describes the materials and devices that can be sterilized by the STERRAD® 50 Sterilizer. It also provides information on how to prepare items for sterilization.

STERRAD 50 Sterilizers can process many of the items you commonly sterilize as well as instruments that are sensitive to heat and moisture. However, there are a few important exceptions. Please review the "How to Determine What Can be Sterilized in the STERRAD 50 System" fold-out page contained in this chapter. It contains details on recommended materials and lumen sizes.

Indications for Use

The STERRAD 50 Sterilizer is designed for sterilization of both metal and nonmetal medical devices at low temperatures. Because the cycle operates within a dry environment and at low temperatures, it is especially suitable for instruments sensitive to heat and moisture. (See the list of recommended materials.)

The STERRAD 50 Sterilizer can sterilize instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.

Devices with Metal Lumens

Medical devices that have a single stainless steel lumen that has:

- an inside diameter of ≥1 mm and a length of ≤125 mm,
- an inside diameter of ≥2 mm and a length of ≤250 mm,
- an inside diameter of ≥3 mm and a length of ≤400 mm,

can be processed in the STERRAD 50 Sterilizer without a STERRAD Booster/Adaptor.

Medical devices that have a single stainless steel lumen that has:

- an inside diameter of ≥1 mm and a length >125 mm and ≤500 mm,
- an inside diameter of ≥2 mm and a length >250 mm and ≤500 mm,
- an inside diameter of ≥3 mm and a length of >400 mm and ≤500 mm,

must be processed in the STERRAD 50 Sterilizer with a STERRAD Booster/Adaptor.

Medical devices with a lumen made of copper containing alloys, such as Monel, having an inside diameter of ≥3 mm, and a length of ≤500 mm, **must** be processed with a STERRAD Booster/Adaptor in the STERRAD 50 Sterilizer.

Devices with Nonmetal Lumens

Reprocessable medical devices that have a polyethylene or Teflon® (PTFE) lumen (medical tubing) having the following dimensions can be processed in the STERRAD 50 Sterilizer:

- an inside diameter of ≥1 mm and a length of ≤1000 mm can be processed without a STERRAD Booster/Adaptor,
- an inside diameter of ≥1 mm and a length of ≤2000 mm **must** be processed with a STERRAD Booster/Adaptor.

Flexible endoscopes with lumens made from polyethylene or Teflon® and an inside diameter of ≥1 mm and a length of ≤2000 mm **must** be processed in the STERRAD 50 Sterilizer with a STERRAD Booster/Adaptor attached to each lumen.

WARNING! DO NOT ATTEMPT TO STERILIZE ITEMS OR MATERIALS THAT DO NOT COMPLY WITH THE DIRECTIONS SPECIFIED IN THIS GUIDE. IN ADDITION YOU SHOULD READ THE MEDICAL DEVICE MANUFACTURER'S INSTRUCTIONS OR CALL YOUR ASP REPRESENTATIVE TO DETERMINE WHETHER AN ITEM CAN BE STERILIZED BY THIS STERILIZER.

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How to Determine What Can be Sterilized in the STERRAD® 50 System

The following page is a chart that unfolds to show you detailed lists of recommended items, materials, and some typical devices that can be sterilized in the STERRAD 50 Sterilizer. Be sure to check with the medical device manufacturer's instruction before loading any new item in the STERRAD 50 Sterilizer.

✔ *Note: There are a wide variety of material and devices that can be sterilized in the STERRAD 50 Sterilizer. As more manufacturers complete testing of their products with STERRAD Sterilizers, the range of recommended and/or compatible items grows. Because of that, the information in the table included in this publication will be updated as new information becomes available. ASP maintains this updated information and we are happy to share it with you. Please contact your ASP Representative for an up-to-date list of recommended materials, devices and/or device manufacturer information or visit the ASP website at www.sterrad.com.*

Items Not Recommended

- Instrument mats other than STERRAD Instrument Mats.
- Instrument trays other than STERRAD Instrument Trays or APTIMAX™ Instrument Trays.
- Any item that is not completely dry.
- 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.
- Liquids and powders.
- Items with mated, Nylon® surfaces.
- Single use items for which the manufacturer does not recommend resterilization.
- Implants for which the manufacturer has not specifically recommended sterilization in the STERRAD 50 Sterilizer.
- Instruments and devices that can not withstand a vacuum and are labeled for gravity steam sterilization methods.
- Items whose design permits the surfaces to collapse onto each other unless some method is used to keep the surfaces separated.
- 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 50 Sterilizer.

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Cleaning, Rinsing, and Drying

✔*Note: All items must first be cleaned, rinsed, and thoroughly dried before being placed in the sterilizer*

Cleaning and sterilization are two separate processes. Thorough cleaning is essential for assurance of sterilization by all sterilization methods, including the STERRAD Sterilization System.

The process of cleaning is necessary to remove organic and inorganic soil and debris from equipment. In this process, many of the microorganisms are removed from the surface of the instrument. The process of sterilization inactivates all of the remaining spores and living 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. It is necessary to remove moisture from all parts of the items. Only dry items should be loaded into the sterilization chamber.

✔*Note: Loads containing moisture may cause a cycle cancellation.*

CAUTION: As with any disinfectant/cleaning/ sterilization system, periodic careful inspection of the devices after repeated exposure to the disinfectant/cleaner/sterilant is necessary, due to potential damaging effects of the chemical agent on the devices.

Guidelines for Wrapping, Packaging, and Loading

Proper preparation of trays, pouches, and instruments can minimize or prevent cycle cancellation due to load-related problems.

- Only STERRAD Instrument Trays, APTIMAX™ Instrument Trays and STERRAD Accessories are recommended for use in the STERRAD 50 Sterilizer. STERRAD Instrument Trays and APTIMAX™ Instrument Trays are specially designed to allow diffusion of hydrogen peroxide and the plasma around all the items in the load. The trays should only be padded with STERRAD Instrument Tray Mats or polypropylene sterilization wrap. Do NOT use linen, cellulosic, or any materials shown in the "Items Not Recommended" list.

- Do not stack trays. Do not stack trays within trays.

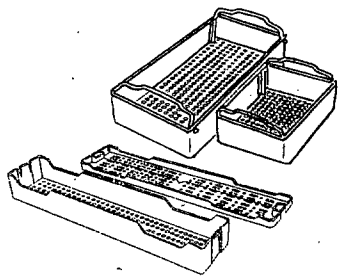

Figure 2. Use only STERRAD® Instrument Trays and APTIMAX™ Instrument Trays

- Improper loading of the sterilizer may result in cycle cancellations and/or positive biological indicator results.

- Do not use foam pads in instrument trays. They may absorb the hydrogen peroxide.

- Do not use any wraps or packaging that are not approved by ASP and listed in the previous section on "items not recommended."

- Use only STERRAD 50 Sterilizer compatible polypropylene sterilization wrap and Tyvek® pouches. Do not use paper pouches or sterilization wraps containing cellulose or cotton.
- Place STERRAD Chemical Indicator Strips inside trays and Tyvek® pouches.
- Secure all wraps with STERRAD Chemical Indicator Tape.
- Arrange items to ensure that the hydrogen peroxide and plasma can contact all surfaces.
- Place peel pouches loosely on edge, if possible. Arrange them so that the transparent side of a pouch faces the opaque side of the next pouch.
- Do not allow any item to touch the walls of the sterilization chamber, door, or electrode.

CAUTION: Metal objects should not come into contact with the walls of the sterilization chamber, door, or electrode. Contact with the walls, door, or electrode can interrupt the plasma phase of the process, cause a cycle cancellation, and/or damage the item or the sterilizer.

- Provide at least 25 mm (1 inch) of space between the electrode and the load.
- Place a STERRAD CycleSure™ Biological Indicator or STERRAD Biological Indicator Test Pack in the chamber. Frequency of biological testing should be at least once per day or in accordance with your hospital policy. Review the instructions included with the biological indicator to ensure proper use.
- Proceed to "Chapter 4. Day-to-Day Operation" for information on starting a cycle.

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Chapter 4. Day-to-Day Operation

In this chapter . . .

- *safe operation*
- *sterilizer operation*
- *system displays*
- *preparing the load*
- *loading the sterilization chamber*
- *inserting a cassette*
- *sterilization cycles*
- *unloading and handling*
- *rebooting/ power switch*

Safe Operation

Before operating your STERRAD® Sterilizer, be sure you thoroughly *read, understand, and follow* the information in "Chapter 2. For Your Safety" as well as "Chapter 3. Preparing Items To Be Sterilized" and the "How to Determine What Can be Sterilized in the STERRAD System" fold-out in Chapter 3.

Sterilizer Operation

The STERRAD 50 Sterilizer automatically monitors and controls the sterilization process. The STERRAD 50 Sterilizer reports its status in three ways:

- **Monitor Screen (VGA Display)**–The display indicates the status of the unit at all times the unit is powered on. It also indicates the time remaining to cycle completion. When not in use, the screen saver engages, resulting in a blank display. Press any button to activate the display.

- **Paper printout**–A paper printout exits the printer after each cycle completion or cancellation. This is a record of the cycle parameters and may be kept for your records. The print should be completely black. Red print indicates a problem with the cycle. The printer is located on the lower right side of the unit. The paper advance button is on the printer door near the paper exit slot.

- **Beeps**–Beeps alert you when a cycle is complete, or a cancellation has occurred. A long beep indicates a complete cycle.

System Displays

This section is your guide for navigating the displays of the STERRAD 50 Sterilizer. Each display shows you the date and time at the bottom left of the screen, and the total number of cycles completed at the bottom right of the screen. At the right of the screen is a list of five functions, and to the right of these are corresponding buttons used to activate each function. The displays shown here are the only ones accessible to you. Your Field Service Engineer has access to a number of other displays that perform various tests and diagnostics on your system. These "Service Mode" displays should only be used by ASP trained and experienced service personnel.

Main Display

The main display of the STERRAD 50 Sterilizer is the starting point for all the functions you will be using. When you press the EXIT button on any subsequent display, you are returned to the main display. The right side of the display shows three buttons: START CYCLE, SYSTEM FUNCTIONS, and HELP. If the door is not closed and secured, the START CYCLE indication is not present.

✔ *Note: If the display is blank upon approaching the sterilizer, the screen saver is probably engaged. Press any button to activate the display.*

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Figure 3. Main Display. Ready to Use.

START

To begin the sterilization process be sure that the chamber has been properly loaded and that all necessary biological and chemical indicators are in place according to the instructions in the previous chapter. Make sure the door is closed and secure.

To start a cycle, do the following:

1. Press the START button. The display changes to show the progress and status of the cycle.

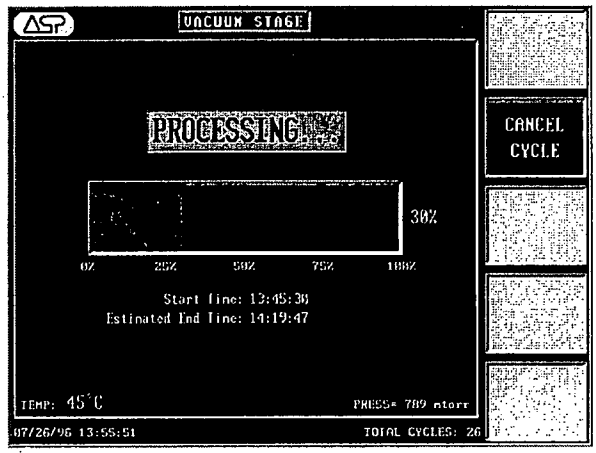

Figure 4. Cycle in process. Cancel is the only option available during the cycle.

The status bar at the top center of the display identifies the cycle stage. The graphic shows the cycle progress in percentage completed. Below this are the cycle start time, the estimated end time, and the chamber pressure and temperature. The right side of the display shows the CANCEL button.

HELP

Help is available for every display on the sterilizer. To get help, do the following:

1. Press the HELP button to view detailed information for the current display.

2. Press the EXIT HELP button to close the Help display.

CANCEL

You can cancel a cycle at any time by pressing the CANCEL button, except during the final vent phase. The STERRAD 50 Sterilizer may also cancel a cycle if it detects a problem with the cycle.

To cancel a cycle, do the following:

1. Press the CANCEL button. When the sterilizer completes the cycle cancellation process, the main display reappears.

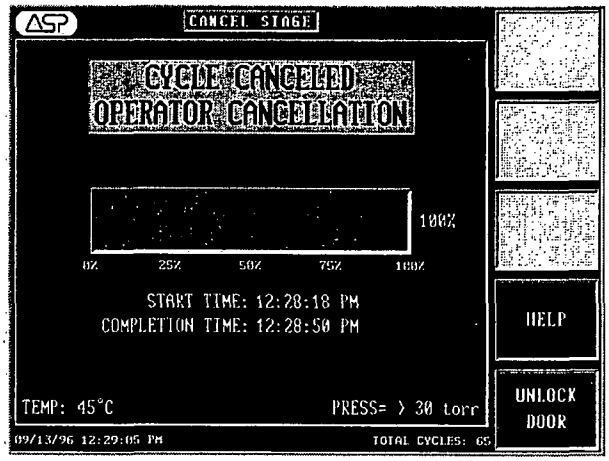

Figure 5. Display showing cancelled cycle information.

2. After the sterilizer has completed the cycle cancellation, you must press UNLOCK DOOR to release the door lock and then pull up on the handle to open the door and remove the sterilized items.

System Functions Display

Figure 6. Pressing SYSTEM FUNCTIONS displays this screen.

To access the system functions display, do the following:

1. Press the SYSTEM FUNCTIONS button. The right side of the display shows five buttons: DATE/TIME, CYCLE HISTORY, SYSTEM TOOLS, HELP, and EXIT.
2. Press the DATE/TIME button to open the Date/Time display to change date and time settings.
3. Press the CYCLE HISTORY button to access cycle history information.
4. Press the SYSTEM TOOLS button to open the System Tools display.
5. Press the HELP button to open the Help display.
6. Press the EXIT button to return to the main display.

DATE/TIME

To change the date or time from the System Functions display, do the following:

✔ *Note: More detailed instructions on setting the date or time are shown in the Routine Maintenance chapter.*

1. Press the DATE/TIME button. The Date/Time display shows three fields: Date, Time, and Mode. The right side of the display shows five buttons: + (plus), – (minus), SELECT, HELP, and EXIT. Time can be displayed in a 24-hour or 12-hour format.

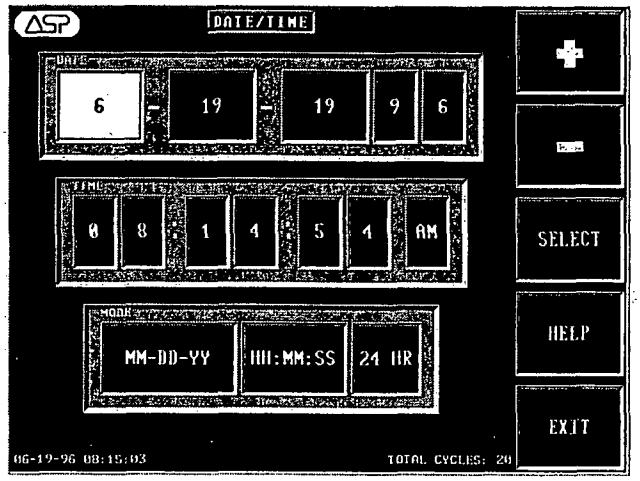

Figure 7. Use this display to change the date and/or the time.

2. Press the + or – buttons to change the highlighted character.
3. Press the SELECT button to move the cursor through the fields.
4. Press the HELP button to display the Help display for the current display.
5. Press the EXIT button to return to the main display.

CYCLE HISTORY

To review the cycle history from the System Functions display, do the following:

1. Press the CYCLE HISTORY button.

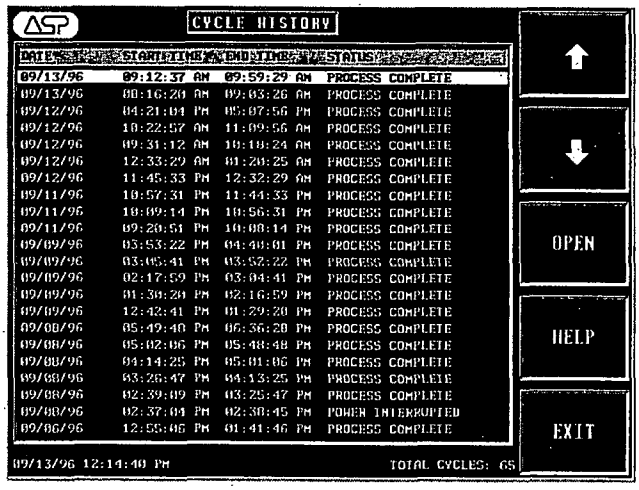

Figure 8. CYCLE HISTORY display.

2. The Cycle History display contains information about the previous 1500 cycles. The display shows, from left to right: Date, Start Time, End Time, and Status of each cycle. The right side of the display shows five buttons: ↑ (up arrow), ↓ (down arrow), OPEN, HELP, and EXIT.

3. Press the ↑ or ↓ button to scroll to and highlight a cycle.

4. Press the OPEN button to see a more detailed history of a particular cycle. Press the PRINT button to obtain a printout of the cycle information.

5. Press the HELP button to open the Help display.

6. Press the EXIT button to return to the main display.

To see a detailed history of the highlighted cycle from the Cycle History display, do the following:

1. Press the OPEN button. The top row of this display shows the Date, Start Time, End Time, Elapsed time, and Cycle number. Subsequent rows show the following information:
    - A list of cycle stages, Start time, End time, Total time, and Pressure and Temperature for each stage.
    - The Cycle Status field displays the final status of the cycle.
    - The Total Cycles, number Passed, and the number Failed.
    - The right side of the display shows four buttons: CLOSE, PRINT, HELP, and EXIT.
2. Press the CLOSE button to return to the original Cycle History display.
3. Press the PRINT button to print a cycle record, according to facility policy.
4. Press the HELP button to open the Help display.
5. Press the EXIT button to return to the main display.

SYSTEM TOOLS

To use the System Tools from the System Functions display, do the following:

1. Press the SYSTEM TOOLS button. The right side of the display shows four buttons: CONFIGURE, CASSETTE FUNCTIONS, HELP, and EXIT.

Figure 9. Press CONFIGURE to gain access to the ID String Editor.

2. Press the CONFIGURE button to open a display that lets you use the ID String Editor.

3. Press the CASSETTE FUNCTIONS button.

4. Press the HELP button to open the Help display.

5. Press the EXIT button to return to the main display.

ID STRING EDITOR

Use the ID String Editor to personalize the sterilizer. This is normally done upon initial installation and set up, but is accessible by you. From this display, you can specifically identify each STERRAD 50 Sterilizer by location or other specific information. This information is printed by the sterilizer on completion of a cycle.

To use the ID String Editor from the System Tools display, do the following:

1. Press the CONFIGURE button.

2. The right side of this new display shows three buttons: ID STRING EDITOR, HELP, and EXIT.

Figure 10. Press ID STRING EDITOR, HELP or EXIT from this display.

3. Press the ID STRING EDITOR button to open the ID String Editor display. The ID String Editor display has two fields. The first field displays only the currently highlighted character. The second field displays the entire ID string or name. The right side of the display shows five buttons: ↑ (up arrow), ↓ (down arrow), SELECT, HELP, and EXIT.

Figure 11. You may use your own identification in this field.

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4. Press the ↑ or ↓ button to change the highlighted character.
5. Press the SELECT button to move through and highlight the characters.
6. Press the HELP button to open the help display.
7. Press the EXIT button to return to the main display.

Cassette Functions Tools

The cassette function tools, available on newer systems and systems with upgraded software, allow you to control some of the actions of the cassette. The Cassette Functions display shows EJECT CASSETTE, INDEX CASSETTE (not available on all systems), and RESET BARCODE. Each of these features is described below.

To access the cassette function tools, do the following:

1. From the main menu press SYSTEM FUNCTIONS.
2. From the System Functions display press SYSTEM TOOLS.
3. From the System Tools display press CASSETTE FUNCTIONS.

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Figure 12. CASSETTE FUNCTIONS display. View this display from the system tools display. Press CASSETTE FUNCTIONS to view the next display.

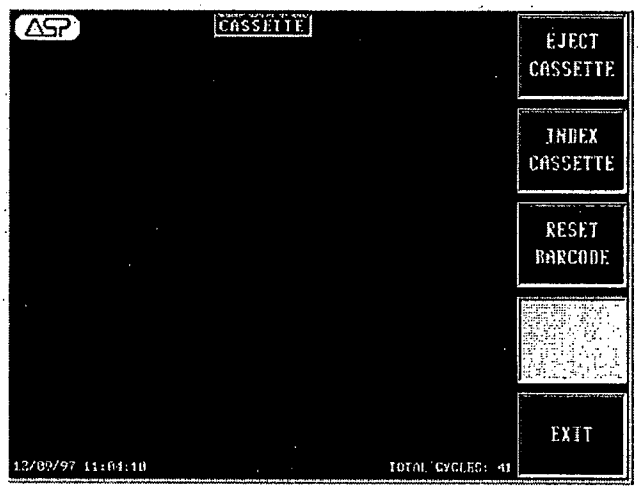

Figure 13. This display is shown when you press CASSETTE FUNCTIONS. INDEX CASSETTE is not available on all systems.

Eject Cassette

After inserting a cassette, you may see the message Cassette System Interrupted. At this time the cassette is still in the sterilizer and needs to be removed. Do the following to remove the cassette:

1. Access CASSETTE FUNCTIONS as shown above. Press EJECT CASSETTE. The following display appears and the cassette is ejected into the sleeve. Insert a new, valid cassette. The ejected cassette can NOT be reused. The cassette barcode is not readable after it has been inserted and removed from the sterilizer.

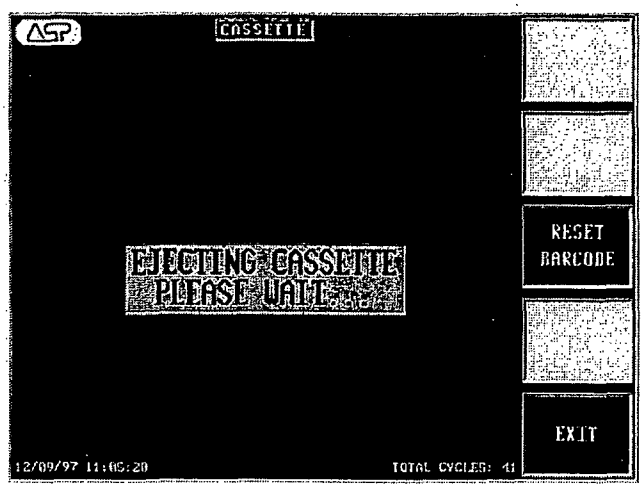

Figure 14. The cassette is being ejected. EJECT CASSETTE has been pressed on the cassette functions display.

✔*Note: If you need to remove a cassette from the sterilizer, use this procedure. Do not try to remove cassettes during a cycle.*

Index Cassette

✔ *Note: This feature is not available on all systems.*

CAUTION: Manually indexing the cassette results in the loss of at least one cycle capacity of the cassette.

If you suspect that a cassette failed to index properly (advance to the next cell) after injection or a cassette has gotten stuck in the system, do the following:

1. Access CASSETTE FUNCTIONS as shown previously. Press INDEX CASSETTE. The following display appears and the cassette advances to the next available cell.

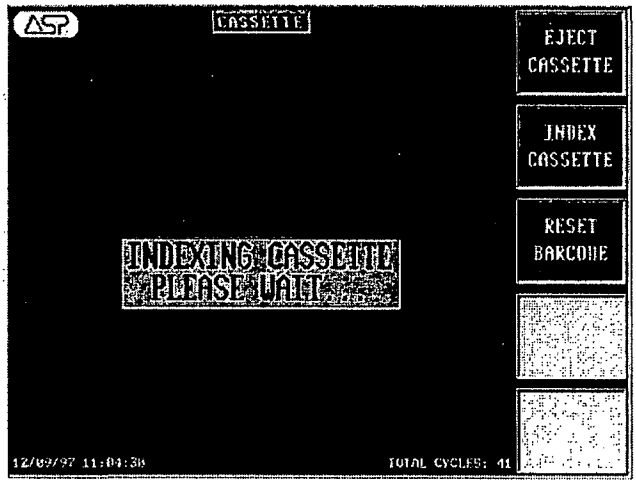

Figure 15. Pressing INDEX CASSETTE advances the cassette to the next available cell.

2. After indexing has been successful, the system is available to run a cycle.

3. If indexing is not successful, try ejecting the cassette. If this fails, please call your ASP Service Representative for technical service or to schedule a repair procedure.

Reset Barcode

The system stores barcode information in a file called a buffer. On rare occasions this buffer may retain too much data and produce a false error. That is, it displays a barcode error when there is, in fact, nothing wrong with the barcode on your cassette. If you have inserted two or more new cassettes and received barcode error messages, do the following:

1. Access CASSETTE FUNCTIONS as shown previously. Press RESET BARCODE. This clears the barcode reader transmission buffer.

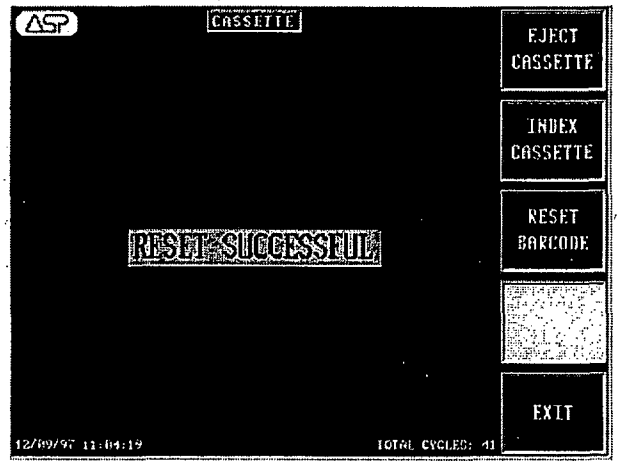

Figure 16. Press RESET BARCODE to clear the buffer of excess data.

2. If the reset is successful, you may run a cycle as usual.

3. If the reset is unsuccessful, then there is a problem within the system. Please call your ASP Service Representative for technical service or to schedule a repair procedure.

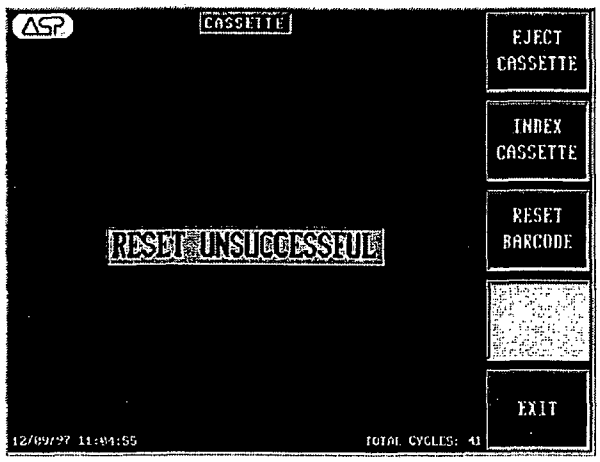

Figure 17. If the reset is unsuccessful, you must schedule a repair procedure.

Preparing the Load

Proper preparation of trays, pouches, and instruments can minimize or prevent cycle cancellation due to load-related problems. More information on load preparation is found in "Chapter 3. Preparing Items To Be Sterilized."

- Arrange the items in a tray to ensure that the hydrogen peroxide and plasma can surround them. Do not stack trays.
- 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 allow any item to touch the walls or door of the sterilization chamber or electrode.
- Provide at least 25 mm (1 inch) of space between the electrode the load.
- Place the STERRAD CycleSure Biological Indicator or other ASP-approved biological indicator in the sterilization chamber.

CAUTION: Metal objects must not come into contact with the chamber walls, door or electrode. Contact with the walls, door or electrode can cause a cycle cancellation and/or damage the items or the sterilizer.

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Biological Indicators

Biological indicators help you to assure that your sterilizer is operating correctly. Confirming that sterilizing conditions were present during a cycle is an important part of the sterilization process. Frequency of biological testing should be at least once per day or in accordance with your hospital policy.

- Contact your ASP representative regarding biologicals specifically designed for use in STERRAD Sterilizers.

ASP biological indicators contain microorganisms that are known to be resistant to the sterilization process and are the best way to verify proper processing. The biological indicator should be placed at the back of the chamber, on the bottom shelf with the opening facing the back of the chamber. Review the instructions that are included with the biological indicators for proper use.

The following charts detail the transfer process and a flow chart showing the entire biological indicator procedure for both ASP-approved biological indicators.

✔ *Note: Should a cancellation occur when a biological indicator is in the chamber, it should be discarded and a new biological indicator should be used when starting the next cycle.*

BI Transfer Process for STERRAD®BI Test Pack

Do:

- Clean the transfer area with sporicidal solution..
- Have 2 sterile forceps (individually wrapped).
- Use a new, sterile catalase vial.
- Label 4 TSB tubes (processed BI, positive control, catalase, and TSB).
- Have an incubator set at 30-35° C.

Don't:

- Use damaged or leaking test tubes.
- Re-use the catalase vial.
- Forget to label each tube correctly.

Do:

- Have a trained individual perform the transfer within 5 minutes of cycle completion.
- Add a drop of catalase to all tubes except the tube labeled "TSB," 15 minutes before cycle completion.
- Check to see if the CI of the processed BITP changed color.
- Unscrew lids on all 4 test tubes. Rest lids on the tubes.
- Transfer the processed BI strip to the labeled tube first.
- Use different sterile forceps to transfer the positive control.
- If BI strip is dropped on the counter, make a note of it.

Don't:

- Place test tubes lids on the counter.
- Allow skin contact with any components.
- Use the same forceps to transfer the processed BI and the positive control.
- Perform transfer in a turbulent area (people traffic, AC vents, etc.).
- Wait more than 5 minutes to transfer, hydrogen peroxide residual activity will inactive spores.

Do:

- Loosen test tube lids 1/2 turn for oxygen.
- Incubate test tubes at 30-35° C.
- Incubate for at least 48 hours prior to reading results.

Don't:

- Over tighten lids. Spores are aerobic and need oxygen to grow.
- Forget to check temperature range of incubator. It should be 30-35° C.

Desired Results:

- **Processed BI strip:** no growth.
- **Control BI strip:** growth (turbidity and/or orange color particles).
- **Catalase control:** no growth.
- **TSB control:** no growth.

Other Results:

- Processed BI strip: growth (turbidity and/or orange color) (See BI Flowchart.)
- Control BI strip: no growth
  - » lid too tight.
  - » incubator temperature out of range.
  - » strip inactivated during storage.
  - » media does not support growth.
- Catalase control: growth (turbidity)
  - » contaminated catalase.
  - » no aseptic transfer.
- TSB control: growth (turbidity)
  - » contaminated media.

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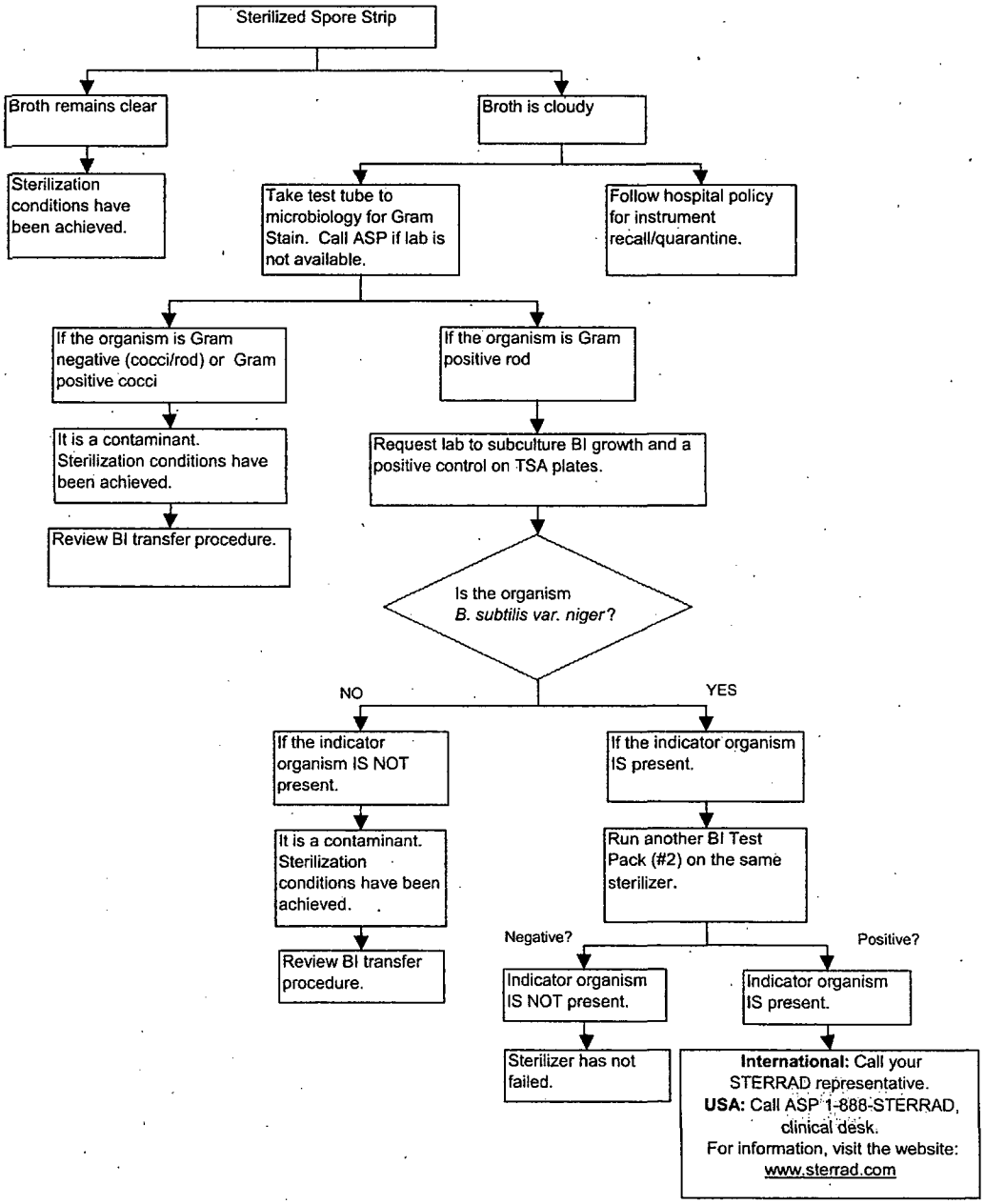
Biological Monitoring Results-Biological Indicator Test Pack



Process Flow For CycleSure™ Biological Indicator

Do:

- Label the BI to be processed appropriately.
- Label positive and negative controls.
- Package BI in a manner consistent with items being sterilized.
- Place BI in the most challenging area for sterilizer to reach.
- Inspect BIs for any defects before using; e.g., cracked media ampoule.
- Have an incubator set at 55-60° C.

Don't:

- Forget to label CycleSure BIs correctly.
- Press the caps down before processing BIs.

Do:

Activate CycleSure™ BI within 5 minutes after cycle completion:

- Check the chemical indicator disc for color change from red to yellow.
- Press the cap down until firmly seated on top of vial.
- Crush media ampoule using the tube crusher.
- Keep vial in vertical position after media ampoule has been crushed.
- Use Controls:
  - » Positive control: crush an unprocessed CycleSure BI.
  - » Negative Control: An unprocessed and uncrushed BI.
  - » Incubate processed BI and controls at 55-60° C.
  - » Incubate for at least 48 hours (up to 7 days) prior to reading results.

Don't:

- Forget to check temperature range of incubator. It should be between 55-60° C.
- Forget to crush media ampoule for processed BI and positive control.
- Forget to press caps down on BIs before incubating to prevent dehydration.

Desired Results:

- Observe for color change in the processed BI and controls.
- Processed BI: no growth (no color change, media remains purple).
- Positive Control: growth (color change in media from purple to yellow).
- Negative Control: no growth (media shall remain purple).

Other Results:

- Processed BI: growth (color change in media from purple to yellow). See CycleSure™ BI flow chart.
- Positive Control: no growth (no color change)
  - » Incubator temperature out of range.
  - » BI inactivated during storage.
  - » media does not support growth.
- Negative Control: growth (color change in media from purple to yellow)
  - » contaminated media ampoule.

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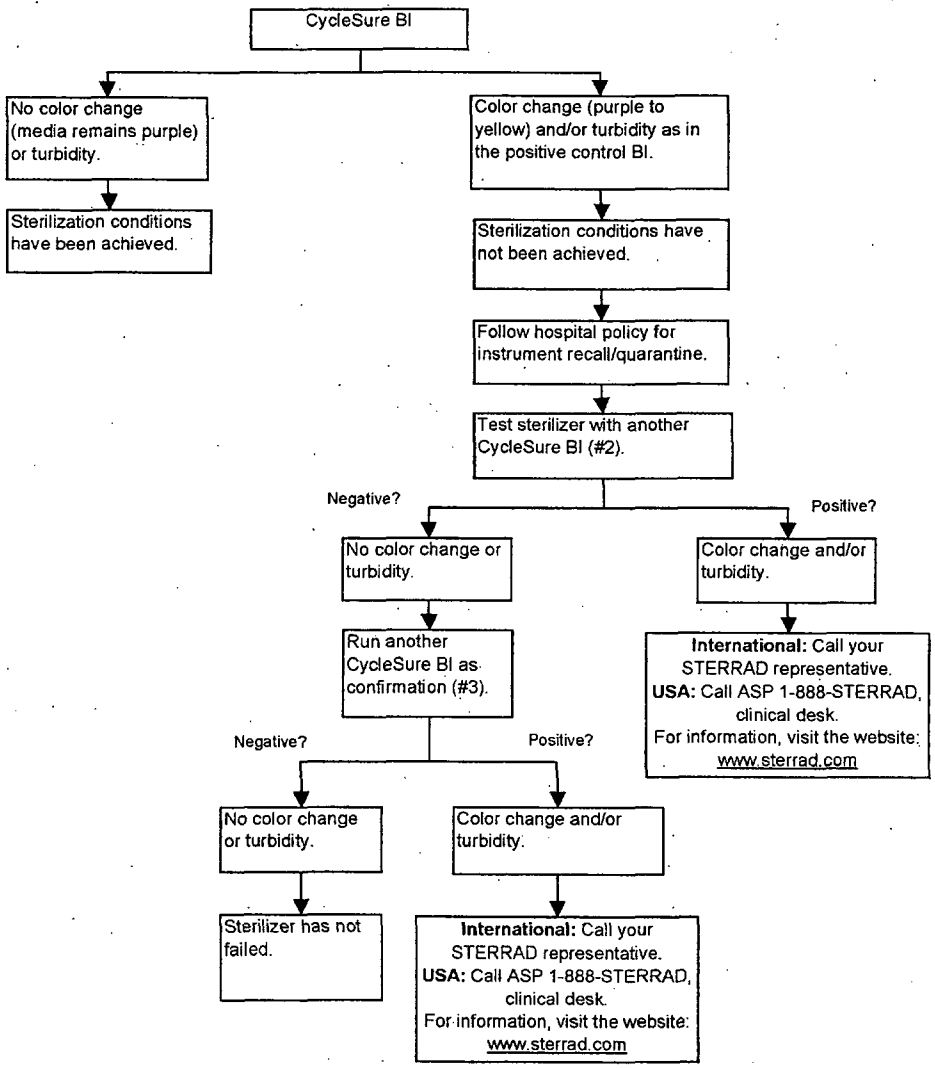
Biological Monitoring Results-CycleSure™



Chemical Indicators

STERRAD Chemical Indicator Strips and STERRAD Chemical Indicator Tape offer additional ways to verify processing in the sterilization cycle. They should be used in addition to, not in place of, the biological indicator. STERRAD Chemical Indicator Strips and STERRAD Chemical Indicator Tape *do not* indicate sterilization; they only indicate that the indicator has been exposed to the hydrogen peroxide. The color of the indicator strips and tape changes from red to yellow (or lighter) when exposed to hydrogen peroxide vapor.

✔ *Note: Use only STERRAD Chemical Indicator Tape, and/or STERRAD Chemical Indicator Strips. Do not use indicators designed for other sterilization processes.*

Using Chemical Indicator Strips

Place STERRAD Chemical Indicator Strips in trays and pouches to show exposure to hydrogen peroxide during the sterilization cycle. Please refer to the *Instructions for Use* included with the STERRAD Chemical Indicator Strip for more information.

Using Chemical Indicator Tape

Chemical Indicator Tape should be used to secure polypropylene sterilization wrap around the Instrument Tray.

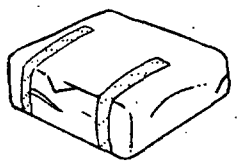


Figure 18. STERRAD® Chemical Indicator Tape should be used to secure the polypropylene wrap around each instrument tray.

Please refer to the *Instructions for Use* included with the STERRAD Chemical Indicator Tape for more information.

Loading the Sterilization Chamber

- Arrange the items in the trays to ensure that the hydrogen peroxide and plasma can surround them. Do not stack trays within trays.
- Trays must be placed flat on shelf.
- Place peel pouches on edge, if possible.
- Do not allow any metal items to touch the walls, door, or electrode of the sterilization chamber or electrode.
- Provide at least 25 mm of space between the electrode and the load.

Inserting a Cassette

The STERRAD 50 Sterilizer uses hydrogen peroxide, contained in special cassettes, to sterilize items placed into the sterilization chamber. Each STERRAD 50 Cassette provides enough hydrogen peroxide for 5 cycles. The message display of the STERRAD 50 Sterilizer notifies you when a new cassette is needed.

WARNING! STERRAD 50 CASSETTES CONTAIN CONCENTRATED HYDROGEN PEROXIDE, A STRONG OXIDIZER. CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT. DIRECT 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.

DIRECT CONTACT WITH EYES CAN CAUSE IRREVERSIBLE TISSUE DAMAGE. IF EYE CONTACT OCCURS, IMMEDIATELY FLUSH WITH LARGE AMOUNTS OF WATER AND IMMEDIATELY CONSULT A PHYSICIAN.

INHALATION OF VAPOR OR MIST CAN CAUSE SEVERE IRRITATION OF LUNGS, THROAT, AND NOSE. IF INHALATION OCCURS, MOVE TO FRESH AIR AND CONSULT A PHYSICIAN IMMEDIATELY.

INGESTION CAN PRODUCE CORROSION THAT MAY BE LIFE-THREATENING. IF SWALLOWED, DRINK PLENTY OF WATER IMMEDIATELY TO DILUTE. DO NOT INDUCE VOMITING. CONSULT A PHYSICIAN.

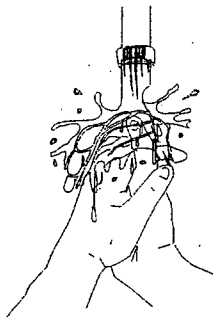


Figure 19. If skin contact occurs, immediately flush the area with water.

WARNING! DO NOT REMOVE THE PLASTIC WRAPPER FROM THE CASSETTE PACKAGE IF THE INDICATOR STRIP IS RED. RED INDICATES DAMAGE. CALL YOUR ASP REPRESENTATIVE FOR CREDIT.

To insert a cassette, do the following:

1. Confirm that the sterilizer display indicates that a new cassette is needed.
2. Confirm that the chemical indicator strip on the cassette sleeve is NOT red; red indicates that the cassette may be damaged.
3. Confirm that the cassette expiration date has not passed.

✔***Note:*** *The system considers the cassette expired 10 days after insertion regardless of the printed expiration date. The cassette is ejected at that time.*

4. Remove the plastic wrapping from the cassette sleeve. Do NOT remove the cassette from the remaining heavy paper sleeve.

   ✔ *Note: Do not remove the plastic wrapping until ready to insert the cassette.*

5. Orient the arrow so that the top of the cassette sleeve is pointing away from you.

6. Hold the paper sleeve by its edges and insert it into the sterilizer.

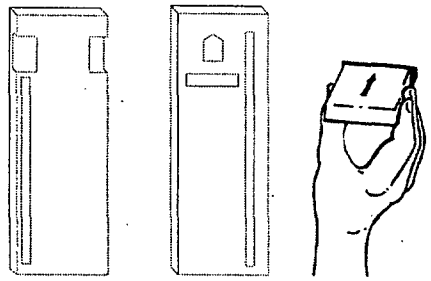


Figure 20. Note the orientation of the arrow on the heavy paper sleeve. Insert the entire cassette sleeve into the sterilizer.

7. Push the paper sleeve in firmly until it can go no further. If positioned properly, the cassette snaps into place.

8. If the paper sleeve is not pushed in all the way, the monitor continues to read INSERT CASSETTE.

9. If the paper sleeve is properly positioned, the cassette is automatically accepted and positioned for use by the sterilizer. The display reads CASSETTE ACCEPTED.

10. If the cassette is not accepted because the barcode cannot be read or the cassette has expired, PLEASE REMOVE CASSETTE is displayed. Should this occur, remove that cassette and insert a valid one.

    ✔ *Note: The system microprocessor monitors the status of the cassette and informs the operator when the cassette is empty or expired. Empty or expired cassettes must be replaced prior to starting the cycle.*

WARNING! DO NOT REMOVE USED CASSETTES FROM THE PROTECTIVE CARDBOARD SLEEVE. DISPOSE OF THE CASSETTE INSIDE THE PROTECTIVE SLEEVE FOLLOWING HOSPITAL PROCEDURES OR IN NORMAL HOSPITAL WASTE. IF THE RETAINER HOLDING THE PLASTIC CASSETTE IN THE CARDBOARD SLEEVE IS DAMAGED AND THE USED CASSETTE FALLS OUT, WEAR LATEX, PVC (VINYL) OR NITRILE GLOVES TO PLACE THE PLASTIC CASSETTE BACK IN THE ORIGINAL SLEEVE. DISCARD THE CASSETTE INSIDE THE SLEEVE, FOLLOWING HOSPITAL PROCEDURES OR IN NORMAL HOSPITAL WASTE.

Please refer to the *Instructions for Use* included with the STERRAD 50 Cassette for more information.

Sterilization Cycles

Starting a Cycle

✔ *Note: Make sure you read, understand, and follow "Chapter 2. For Your Safety," and the sections in this chapter on preparing the load, and using biological and chemical indicators before starting a cycle.*

In order to start a cycle, and to perform many other functions of the STERRAD 50 Sterilizer, you must press the appropriate button next to the display. The button labels are outlined on the display and change according to the type of display shown.

After the load has been properly placed into the sterilizer, and the biological and chemical indicators are in place, you are ready to start the cycle.

1. Close the door to the sterilization chamber by lifting up on the handle and pulling the door upward until the door is closed. Press the handle down to secure the door.

2. Press the START button.

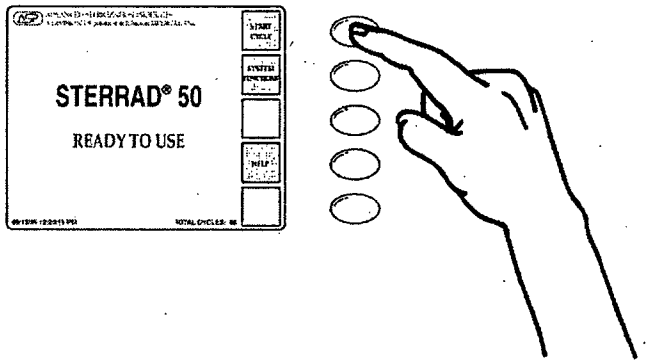


Figure 21. Press the START button to start a cycle.

3. The door locks and the cycle begins. If all cycle parameters stay within their limits, the cycle is completed in approximately 45 minutes.

Watching a Cycle

You can monitor the progress of a cycle by watching the display; it indicates the phase of the cycle and certain process parameters. A long beep signals that the cycle is complete.

The display indicates the status of the unit at all times: the current stage of the sterilization cycle, the temperature in the chamber, the pressure in the chamber, the cycle start time and the cycle estimated end time. Each load goes through eight consecutive stages: vacuum, injection, diffusion, plasma, injection, diffusion, plasma, and vent. These stages always follow the same order, but some take longer than others.

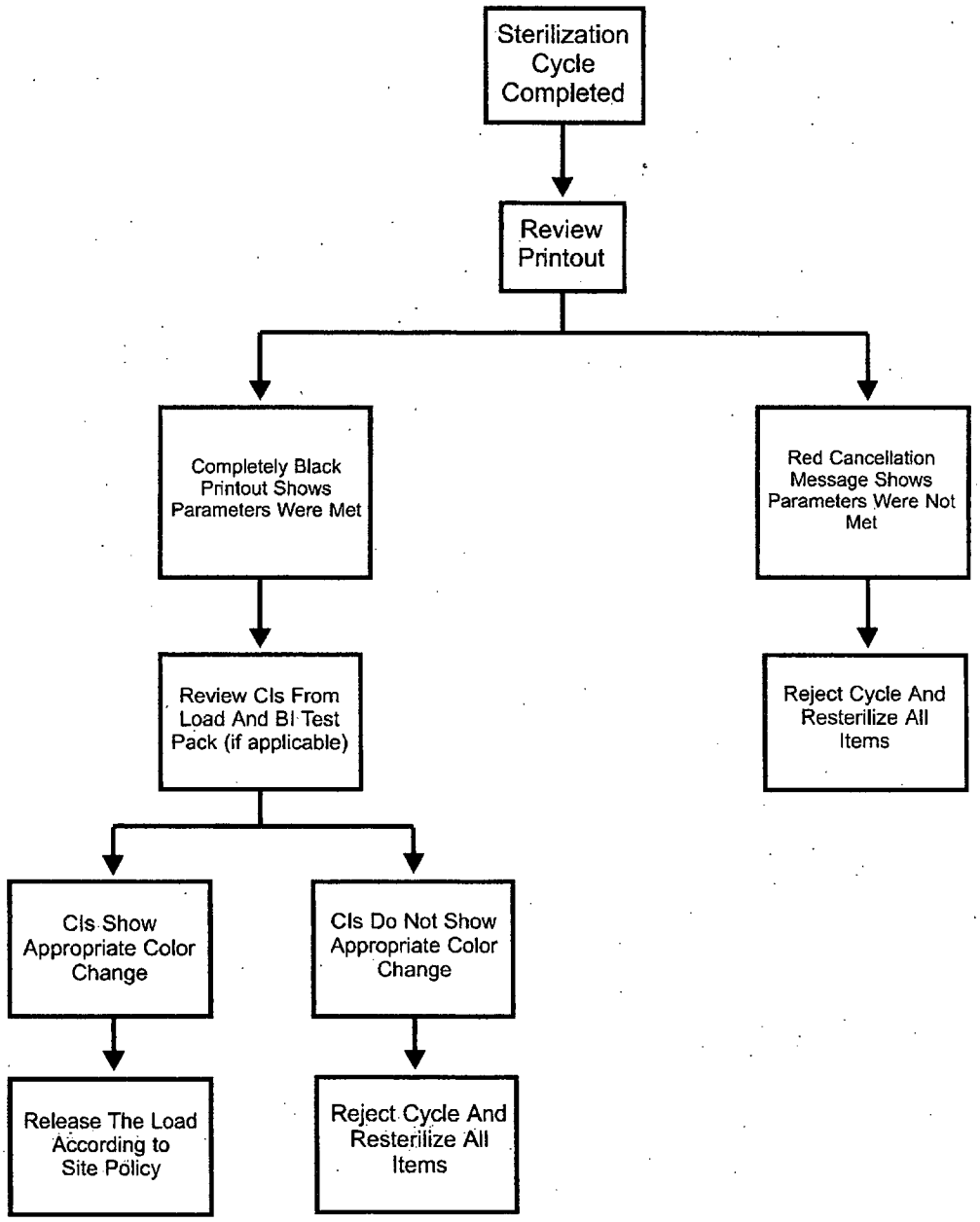
Order	Stage	Duration (Approx.)
1	Vacuum	20 minutes
2	Injection	6 minutes
3	Diffusion	2 minutes
4	Plasma	4 minutes
5	Injection	6 minutes
6	Diffusion	2 minutes
7	Plasma	4 minutes
8	Vent	1 minute

Completing a Cycle

Cycle completion is signaled in four ways:

- A long beep sounds.
- PROCESS COMPLETE is displayed on the monitor.
- OPEN DOOR TO REMOVE LOAD is displayed on the monitor.
- The paper printout shows the process parameters (in black ink only; red ink indicates a problem).

Cycle Completion Flow Chart



Canceling a Cycle

Manual Cancellation

You can cancel a cycle at any time by pressing the CANCEL button, except during the final vent phase.

To manually cancel a cycle, do the following:

1. Press the CANCEL button.
    - Ten beeps sound, and the message display shows CYCLE CANCELED/OPERATOR CANCELLATION.
    - A paper printout exits the printer with a message in red ink.
    - The sterilizer automatically completes the cancellation process (which includes a short plasma stage during most phases of the process).
    - The display indicates when cancellation is complete.

Loads from canceled cycles should be repackaged using new polypropylene wrap, STERRAD Chemical Indicator Strips, and STERRAD Chemical Indicator Tape. If a STERRAD Biological Indicator was used in the canceled load, it should be discarded and a new one should be placed in the chamber before starting the new cycle.

WARNING! IF THERE IS A CYCLE CANCELLATION AND THE ITEMS IN THE LOAD APPEAR WET, CONCENTRATED HYDROGEN PEROXIDE MAY BE PRESENT. WEAR LATEX, PVC (VINYL) OR NITRILE GLOVES WHILE REMOVING THE ITEMS FROM THE CHAMBER, AND TO WIPE OFF THE ITEMS WITH A DAMP CLOTH.

Automatic Cancellation

The STERRAD 50 Sterilizer may also cancel a cycle if it detects a problem with the cycle. If the sterilizer control system cancels a cycle, the display indicates when the cancellation process is complete. As with manual cancellation (above), the load should be repackaged using new polypropylene wraps, biological indicators, chemical indicators, etc. Note the messages on the display and on the paper printout, and refer to "Chapter 6. Troubleshooting" for more information.

Unloading and Handling

Items processed by the STERRAD 50 Sterilizer can be used as soon as the sterilization cycle is complete according to facility procedures. No additional time for aeration is required.

To unload the chamber:

1. Press UNLOCK DOOR to release the locking mechanism.
2. Lift the handle of the door of the STERRAD 50 Sterilizer, then pull the door towards you and downward to open the sterilizer.
3. Remove chamber contents.
4. Close the door and press down on the handle latch to secure the door.
5. After ensuring that the STERRAD Chemical Indicators exhibit the correct color change, the sterilized items are ready for immediate use, following facility policies and procedures.

Power ON-OFF Switch/Rebooting the System

The Power ON-OFF switch is located at the back of the sterilizer. Flip the switch to the OFF position to shut off power to the sterilizer. Turning the power switch to ON returns power to the sterilizer and causes the computer in the sterilizer to reload the software control program automatically; this action reboots the sterilizer. Rebooting is used in certain troubleshooting procedures. The display indicates that the system is READY TO USE.

Chapter 5. Routine Maintenance

In this chapter . . .

- *maintaining the printer*
- *resetting the date and time*
- *cleaning the sterilizer*
- *cleaning the injector valve vaporizer bowl and deflectors*

5 Routine Maintenance

Overview

This section is your guide to the maintenance procedures for the STERRAD® 50 Sterilizer: Contact ASP Technical Service for guidance on all other maintenance procedures.

WARNING! ONLY ASP-TRAINED TECHNICIANS SHOULD REPAIR OR ADJUST THIS UNIT. REPAIRS AND ADJUSTMENTS SHOULD ONLY BE ATTEMPTED BY EXPERIENCED TECHNICIANS WHO ARE FULLY TRAINED TO MAINTAIN AND REPAIR THE STERRAD 50 STERILIZER.

USE OF UNAUTHORIZED PARTS MAY BE DANGEROUS AND WILL VOID THE WARRANTY. USE OF UNAUTHORIZED PARTS FOR MAINTENANCE OR REPAIR COULD CAUSE PERSONAL INJURY, RESULT IN COSTLY DAMAGE OR UNIT MALFUNCTION, AND WILL VOID THE WARRANTY.

Maintaining the Printer

The printer requires that the ribbon cartridge be replaced whenever the print becomes too light to read easily. The paper should be changed when the colored bars begin to appear on the paper. This indicates the paper supply is running low. The illustration below shows the printer installed on the printer door. Your system may or may not have this configuration. The ribbon cartridge and paper changing routines shown in this chapter are the same regardless of the location of the printer.

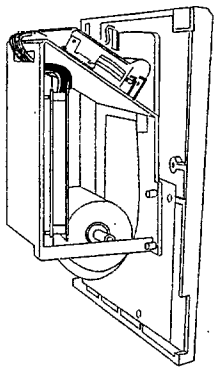


Figure 22. Printer mounted on printer door.

Replacing the Printer Ribbon Cartridge

To replace a printer ribbon cartridge do the following:

1. Open the right service door by pressing on the corner to release the door. Pull the printer assembly drawer forward (if present).

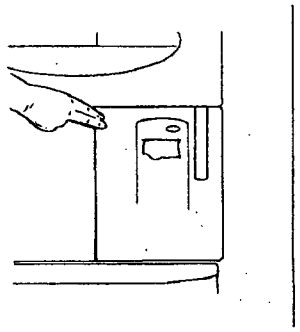


Figure 23. Press the corner to open the service door.

2. Firmly, but carefully, pull on the right side of the used ribbon cartridge, as indicated by the arrow on the cartridge. Remove the used cartridge and discard.

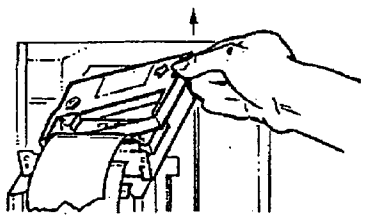


Figure 24. Removing the used ribbon cartridge.

3. Insert a new cartridge by aligning the left side of the cartridge with the bracket in the printer. Push on the right side of the cartridge to snap it into place.

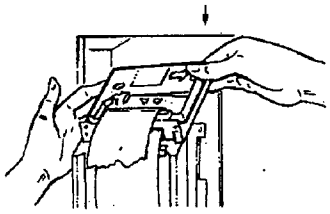


Figure 25. Inserting a new ribbon cartridge.

4. Turn the knob on the cartridge clockwise to remove any slack from the ribbon.

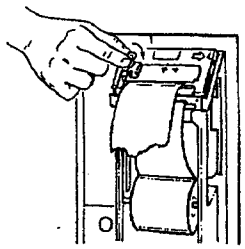


Figure 26. Turn the knob on the cartridge to remove slack from the ribbon.

5. Push the printer assembly drawer back into place. Make sure the printer paper feeds through the printer paper slot in the service door. Close the service door.

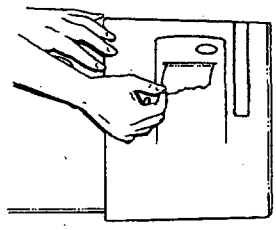


Figure 27. Feed the printer paper through the slot in the printer service door.

Replacing the Printer Paper

To replace the paper roll do the following:

1. Open the right service door and pull printer assembly drawer forward. (Not done on systems with the printer mounted on the door.)

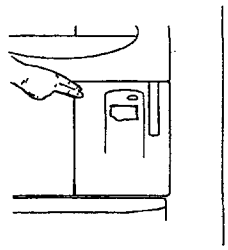


Figure 28. Press the corner to open the service door.

2. Remove the empty paper core and discard the core.

3. Place a new paper roll into position so that the paper feeds from the back of the roll.

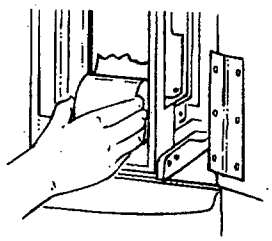


Figure 29. Place a new paper roll into the printer.

4. Feed the edge of the paper under the gray metal bar located in front of the printer cartridge and into the slot behind the printer. Push up gently on the paper and press PAPER ADVANCE until the mechanism begins to pull the paper. Continue pressing PAPER ADVANCE until about 150 to 160 mm (about 6 inches) of paper exits the printer cartridge.

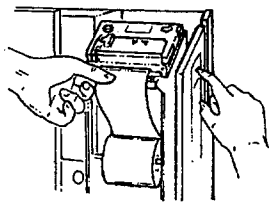


Figure 30. Advance the paper through the printer mechanism and the ribbon cartridge.

5. Make sure the printer paper feeds through the slot in the printer door. Close the door.

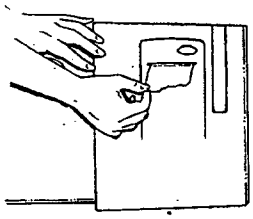


Figure 31. Feed the printer paper through the slot in the printer door.

Resetting the Date and Time

The date and time are set by your ASP service representative at installation. You can change these settings at any time to conform to local standards.

To change the date, do the following:

1. Press SYSTEM FUNCTIONS, as indicated on the display, then press DATE/TIME.

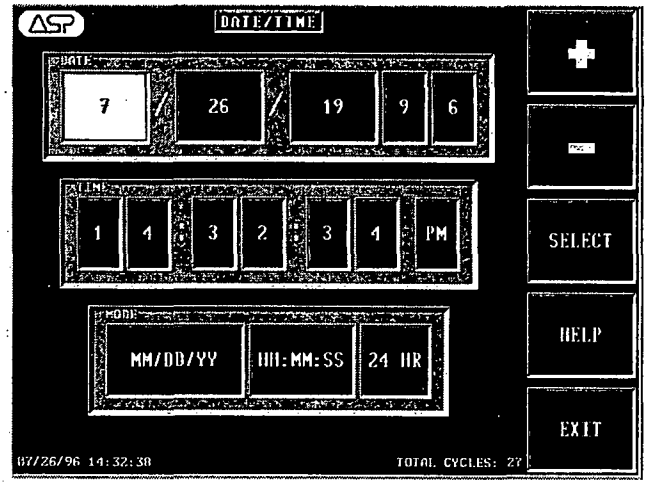


Figure 32. Date/Time Display

2. Press SELECT until the DATE box inside the mode block is lit, then press + (plus) or – (minus) until the desired date format appears in the date box. Note that the date style in the lower left corner changes as you change the mode.

3. Press SELECT until the month, day, or year inside the date block is lit, then press + or – until the desired number appears.

4. To accept all current settings and to exit this mode, press EXIT.

To change the time, do the following:

1. Press SYSTEM FUNCTIONS, as indicated on the display, then press DATE/TIME.

2. Press SELECT until the TIME box inside the mode block is lit, then press + or – until the desired time format appears in the time box. Note that the time style in the lower left corner changes as you change the mode.

3. Press SELECT until the 12/24 HR box inside the mode block is lit, then press + or – until the desired format appears in the box.

4. Press SELECT until the hour, minute, second or AM/PM box in the time block is lit, then press + or – until the desired number appears in the box.

5. To accept all current settings and to exit this mode, press EXIT.

Cleaning the STERRAD® 50 Sterilizer

The outside surfaces of the sterilizer can be cleaned with a mild detergent. The inside of the sterilization chamber does not normally require cleaning. The chamber door and the chamber should not be cleaned with an abrasive, such as a wire brush or steel wool. If you have any questions regarding cleaning the STERRAD 50 Sterilizer, call your ASP representative.

CAUTION: Do not clean the chamber door area with abrasives. The sterilization chamber uses an O-ring vacuum seal to maintain a vacuum in the chamber. Never use rough cleaning tools, such as a wire brush or steel wool, on the door housing or chamber assembly. This could damage the seal.

Cleaning the Deflector and Injector Valve Vaporizer Bowl

Your system has one of two types of deflectors: a deflector attached to the vaporizer bowl, or a deflector plate fitted into the electrode (also called a "vaporizer plate.") To clean the injector valve vaporizer bowl and deflectors, do the following:

1. Wearing latex, PVC (vinyl), or nitrile gloves and eye protection, remove the attached deflector by turning the locking nut counterclockwise. If your system has the deflector plate, remove it by slightly pinching the sides and pulling down on the plate to remove it.

2. Clean the exterior surface of the bowl and both sides of the attached deflector by wiping them with a clean, damp cloth. Rinse the deflector plate under running water. Dry it thoroughly.

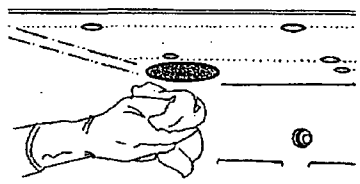


Figure 33. Clean the exterior surface of the bowl.

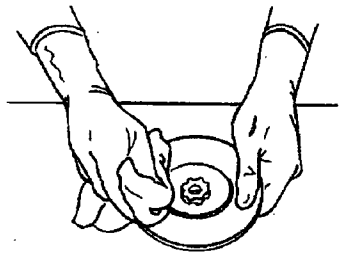


Figure 34. Cleaning the Attached Deflector.

3. Replace the attached deflector by turning the nut clockwise.

4. Replace the deflector plate by placing it diagonally in the square opening of the electrode. The bowl faces downward. Rotate it 1/8 turn until the oval wings seat on top of the electrode and the top lip is against the inside of the electrode. Move the plate backwards or forwards until you feel the vertical lip stop against the edge of the electrode.

CAUTION: Always reattach the deflector and reinstall the deflector plate. The sterilization cycle will not process correctly without the deflector.

Chapter 6. Troubleshooting

In this chapter . . .

- *system message table in alphabetical order*

6 Troubleshooting

Overview

The STERRAD® 50 Sterilizer is a relatively trouble-free device, requiring only routine maintenance and care in load preparation to help prevent system cancellations.

Proper preparation of the load can help to ensure a minimal amount of cycle cancellations. Be sure you read, understand and follow all the safety procedures in Chapter 2 and the load preparation procedures in Chapter 3.

WARNING! YOU MUST WEAR LATEX, PVC (VINYL) OR NITRILE GLOVES WHEN REMOVING OR REINSERTING THE LOAD BECAUSE OF A CANCELED CYCLE.

Message Table

The messages in this table are in alphabetical order. You may receive similar messages during different stages of the system cycle. The action you are to take is usually the same regardless of the cycle stage. Also, some messages may end with slightly different wording than shown in the message table; this does not affect your handling of the message. Pressing HELP when a message is received provides you with more detailed instruction on resolving the system message.

Many system messages are the result of problems with the materials in the load. If you received one of these types of messages, be sure to inspect the load, and repackage if necessary. Be sure to replace all cycle indicators and biological indicators if they are being used. Remember, you can always press HELP for more information.

Displayed Message	Printed Message	Action
CASSETTE ACCEPTED	No printout.	Cassette is of the correct type and date, and is positioned correctly.
CASSETTE DID NOT INDEX	No printout.	Cassette did not successfully move to the next cell. Remove the cassette and insert a new one. If the message persists, call your ASP Service Representative.
CASSETTE NOT DETECTED	No printout.	Remove the cassette. Reinsert the same cassette or a new one. If the message persists, call your ASP Service Representative.
CASSETTE OUT-OF-DATE PLEASE REMOVE CASSETTE	Cassette out of date Cassette Exp _____(Date)	Ten days have passed since the cassette was inserted into the sterilizer and it is assumed to have expired. Insert a new cassette, or if you know that the cassette has NOT expired, press HELP when this message appears and follow the instructions.
CASSETTE SYSTEM INTERRUPTED	No printout.	Call your ASP Service Representative.
CASSETTE VERIFICATION UNSUCCESSFUL PLEASE REMOVE CASSETTE	Verification Unsuccessful Refer To Help Screen	The barcode cannot be read. Press HELP for more information or call your ASP Service Representative.
CYCLE CANCELED [may show any cycle canceled message] PLEASE WAIT... 10 MIN	[Printout May Show Any Cycle Canceled Message.] Please Inspect Load Carefully Refer To Help Screen	The instruments may have contained too much moisture before they were placed in the sterilizer. **WARNING! WEAR LATEX, PVC (VINYL) OR NITRILE GLOVES WHEN REMOVING THE LOAD FROM THE CHAMBER AND WHILE CHECKING ITEMS FOR MOISTURE.** Press HELP for more information or call your ASP Service Representative.

Displayed Message	Printed Message	Action
CYCLE CANCELED INJECTION SYSTEM INTERRUPTED PLEASE WAIT... 10 MIN	Cycle Canceled Injection System Interrupted Call ASP Technical Service	Call your ASP Service Representative.
CYCLE CANCELED INSUFFICIENT PLASMA PRESSURE PLEASE WAIT... 10 MIN.	Cycle Canceled Insufficient Plasma Pressure Refer To Help Screen.	Vacuum did not reach the level required for the Plasma Stage. Load may be releasing gases from plastic-like materials. Press HELP for more instructions. If the cycle cancels again, call your ASP Service Representative.
CYCLE CANCELED LOW PRESSURE IN DIFFUSION PLEASE WAIT... 10 MIN.	Cycle Canceled Low Pressure In Diffusion Call ASP Technical Service	Atmospheric pressure has not been reached during diffusion. Unit fails to vent. Run an empty chamber cycle. If the cycle cancels again, call your ASP Service Representative.
CYCLE CANCELED LOW PRESSURE IN INJECTION PLEASE WAIT... 10 MIN	Cycle Canceled Low Pressure In Injection Refer To Help Screen	The peroxide pressure is too low due to a possible problem with the materials in the load. Press HELP for detailed instructions on how to resolve this problem. If you run an empty chamber cycle and the cycle cancels again, call your ASP Service Representative.
CYCLE CANCELED LOW RF POWER PLEASE WAIT... 10 MIN	Cycle Canceled Low RF Power In Vacuum. Refer To Help Screen or Cycle Canceled Low RF Power Refer To Help Screen or Cycle Canceled Low RF2 Power In Vacuum. Refer To Help Screen	Plasma power is too low. This may be caused by the load coming into contact with the electrode, the door or the chamber. Press HELP for information on how to resolve this problem. If the cycle cancels after an empty chamber cycle has been run, call your ASP Service Representative.

Displayed Message	Printed Message	Action
CYCLE CANCELED NO RF POWER PLEASE WAIT... 10 MIN.	Cycle Canceled No RF Power In Vacuum. Refer To Help Screen or Cycle Canceled No RF Power Refer To Help Screen or Cycle Canceled No RF2 Power In Vacuum. Refer To Help Screen	No RF or RF2 generator power. This may be caused by the load touching the electrode, the door, or the chamber. Press HELP for more information. If the cycle cancels after an empty chamber cycle has been run, call your ASP Service Representative.
CYCLE CANCELED OPERATOR CANCELLATION PLEASE WAIT...	Cycle Canceled Operator Cancellation Repackage Load Restart Sterilizer	The operator canceled the cycle. Press HELP for more information.
CYCLE CANCELED OVER PRESSURE IN INJECTION PLEASE WAIT... 10 MIN	Cycle Canceled Over Pressure In Injection Refer To Help Screen	Possible air leak in system or there is a problem with the load. Press HELP for more information. If you run an empty chamber cycle and the cycle cancels, call your ASP Service Representative.
CYCLE CANCELED POWER INTERRUPTED PLEASE WAIT...10 MIN	Cycle Canceled Power Interrupted	Power was interrupted during a critical phase of the cycle. Call your ASP Service Representative.
CYCLE CANCELED PRESSURE OUT OF RANGE PLEASE WAIT... 10 MIN	Cycle Canceled Pressure Out Of Range In Plasma Call ASP Technical Service or Cycle Canceled Pressure Out Of Range In Vacuum Refer To Help Screen	The pressure in the chamber did not stabilize in the range necessary to create a vacuum or a plasma state. There may be wet items in the load. **WARNING! WEAR LATEX, PVC (VINYL) OR NITRILE GLOVES WHEN REMOVING THE LOAD FROM THE CHAMBER AND WHILE CHECKING ITEMS FOR MOISTURE.** Press HELP for more information, or, if you have

Displayed Message	Printed Message	Action
		run an empty chamber cycle and the cycle cancelled, call your ASP Service Representative.
CYCLE CANCELED RF INTERRUPTED PLEASE WAIT... 10 MIN.	Cycle Canceled RF Interrupted In Vacuum Refer To Help Screen or Cycle Canceled RF Interrupted Refer To Help Screen	RF generator reflected power is too high. RF delivered power is too low. Something may be touching the electrode, door or the chamber walls. Press HELP for more information or if you have run an empty chamber cycle and the cycle cancelled, call your ASP Service Representative.
CYCLE CANCELED TEMPERATURE BELOW THRESHOLD PLEASE WAIT... 10 MIN.	Temperature Below Threshold Call ASP Technical Service	Call your ASP Service Representative.
CYCLE CANCELED TEMPERATURE OVER THRESHOLD PLEASE WAIT... 10 MIN.	Cycle Canceled Temperature Over Threshold Call ASP Technical Service	Call your ASP Service Representative.
CYCLE CANCELED VACUUM INSUFFICIENT PLEASE WAIT...	Cycle Canceled Vacuum Insufficient Refer To Help Screen	The items in the load may have contained too much moisture before they were placed in the sterilizer. **WARNING! WEAR LATEX, PVC (VINYL) OR NITRILE GLOVES WHEN REMOVING THE LOAD FROM THE CHAMBER AND WHILE CHECKING ITEMS FOR MOISTURE.** Press HELP for more information, or if you have run an empty chamber cycle and the cycle cancelled, call your ASP Service Representative.

Displayed Message	Printed Message	Action
CYCLE CANCELED VACUUM NOT LOW ENOUGH PLEASE WAIT... 10 MIN.	Cycle Canceled Vacuum Not Low Enough For Injection Refer To Help Screen	The items in the load may have contained too much moisture before they were placed in the sterilizer. **WARNING! WEAR LATEX, PVC (VINYL) OR NITRILE GLOVES WHEN REMOVING THE LOAD FROM THE CHAMBER AND WHILE CHECKING ITEMS FOR MOISTURE.** Press HELP for more information , or if you have run an empty chamber cycle and the cycle cancelled, call your ASP Service Representative.
CYCLE CANCELED VACUUM SYSTEM INTERRUPTED PLEASE WAIT...	Cycle Canceled Vacuum System Interrupted Call ASP Technical Service	Call your ASP Service Representative.
CYCLE CANCELED VAPORIZER BELOW THRESHOLD PLEASE WAIT... 10 MIN.	Cycle Canceled Vaporizer Below Threshold Call ASP Technical Service	Call your ASP Service Representative.
INCORRECT CASSETTE TYPE PLEASE REMOVE CASSETTE	No printout.	The cassette you are using is not recognized by the system. Insert a STERRAD® 50 Cassette.
INSERT NEW CASSETTE	No printout.	You have tried to start a cycle without inserting a cassette. Insert a new cassette and press START.
INSERT NEW CASSETTE CALL ASP TECHNICAL SERVICE	No printout.	Insert a new cassette. The specified planned maintenance is due now. Call your ASP Service Representative immediately.
INSERT NEW CASSETTE MAINTENANCE DUE (XXX)	No printout or Maintenance Due (XXX): NN	Insert a new cassette. The specified planned maintenance is due. Call your ASP Service Representative to schedule service.

Displayed Message	Printed Message	Action
PLEASE CLOSE DOOR	No printout.	Close and latch the door.
PLEASE REMOVE CASSETTE	No printout.	Remove the cassette. If the message persists, try a new cassette.
POSITIONING CASSETTE	No printout.	The cassette is being positioned.
PROCESS COMPLETE OPEN DOOR TO REMOVE LOAD	Maintenance Due (XXX): NN	The specified planned maintenance is due. Call your ASP Service Representative to schedule service.
PROCESS COMPLETE OPEN DOOR TO REMOVE LOAD	XXX PM Interval Past Due Call ASP Technical Service (NN)	The specified planned maintenance time is due now. Call your ASP Service Representative.
PROCESS COMPLETE OPEN DOOR TO REMOVE LOAD	STERRAD® 50 STERILIZER [Printout contains all process parameters.] PROCESS COMPLETE Validated By:_____ Biological Indicator:_____ CASS. LOT # XXXX EXP. DATE: MM/YYYY NUMBER OF CYCLES AVAILABLE = X REMOVE CASSETTE	The cycle is complete with no error. The door may be opened and the load removed and used or stored according to your facility's procedures.
READY TO USE	No printout.	The system is ready for a new cycle.
READY TO USE CALL ASP TECHNICAL SERVICE	No printout.	The specified planned maintenance is due now. Call your ASP Service Representative immediately.
READY TO USE MAINTENANCE DUE (XXX)	No printout.	The specified planned maintenance is due. Call your ASP Service Representative to schedule service.

Displayed Message	Printed Message	Action
SOFTWARE FAULT PLEASE WAIT...	Software Fault Call ASP Technical Service	Call your ASP Service Representative.
SYSTEM CANCEL PLEASE WAIT... 10 MIN.	System Cancel Call ASP Technical Service	Call your ASP Service Representative.
SYSTEM DATA UNREADABLE	No printout.	Call your ASP Service Representative.
TEMPERATURE HAS NOT RISEN CALL ASP TECHNICAL SERVICE	Temperature Has Not Risen Call ASP Technical Service	Call your ASP Service Representative.
TEMPERATURE OVER THRESHOLD CALL ASP TECHNICAL SERVICE	Temperature Over Threshold Call ASP Technical Service	Call your ASP Service Representative.
TEMPERATURE SENSOR BELOW THRESHOLD CALL ASP TECHNICAL SERVICE	Temperature Sensor Below Threshold Call ASP Technical Service	Call your ASP Service Representative.
UNABLE TO POSITION CASSETTE	No printout.	The cassette could not be positioned properly. If the cassette has ejected, remove the cassette and insert a new one. If the cassette did not eject, press the EJECT CASSETTE button. If the cassette ejects successfully, insert a new one. If this does not resolve the problem, call your ASP Service Representative.
VENT TIME-OUT CALL ASP TECHNICAL SERVICE	Vent Time-Out Call ASP Technical Service	Call your ASP Service Representative.
VERIFYING CASSETTE PLEASE WAIT...	No printout.	The system is trying to read the barcode; it tries twice. No action is required.
WARMING UP PLEASE WAIT	No printout.	The chamber is not yet at operating temperature. No action required, however if the message has not changed within 1 hour, call your ASP Service Representative..

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6 Troubleshooting

Appendix A.

In this appendix . . .

- *sterilizer specifications*

Specifications

Space Requirements	
Size including cart	1 meter x 1 meter (3 feet x 3 feet)
Operation	
Electrical	120 VAC, 60 Hz, 15 Amps 220-240 VAC, 50/60 Hz, 10 Amps 100 VAC, 50/60 Hz, 20 Amps
Ambient Temperature	+15°C to +40°C (58-103° F)
Relative Humidity	10% to 80%, non-condensing
Pollution Degree	2
Overvoltage Category	II
Equipment Rating	
High Voltage	220-240 VAC, 50/60 Hz, 10 Amps
Low Voltage	120 VAC, 60 Hz, 15 Amps 100 VAC, 50/60 Hz, 20 Amps
Electrical requirements	
The STERRAD® 50 Sterilizer should only be plugged into outlets that have been approved by a qualified technician. For further requirements, refer to the label on the back panel of the sterilizer or call your ASP Service Representative. Only a qualified technician can determine when the STERRAD 50 Sterilizer can be safely moved to a new power source.	
Transport and Storage	
Ambient Temperature	+5°C to +60°C (40-139° F)
Relative Humidity	10% to 85%
Maximum Altitude	2,000 meters (6,561.6 feet)

Protection	
Protection Class	Class 1
Protection Type	Type B
Protection Against Ingress of Water	Ordinary (IPXO)
Mode of Operation	Continuous
Explanation of Warning Symbols	
IEC 378-03-0	Attention, consult accompanying documents
IEC 878-03-0	Dangerous voltage
Serviceable Assemblies	
Circuit Diagrams	Contact ASP Customer Support*
Component Part Lists	Contact ASP Customer Support*
Descriptions	Contact ASP Customer Support*
Calibration Instructions	Contact ASP Customer Support*

* ASP provides servicing information only to appropriately qualified personnel and only for assemblies that ASP feels are serviceable by non-ASP personnel. This information is available on request and may consist of circuit diagrams, component part lists, descriptions, and calibration instructions.

Appendix B.

In this appendix . . .

- *service and commercial warrantees*

Service and Commercial Warrantees

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 instrument. Replacement items can be either new or remanufactured. Defective parts replaced under warranty shall become the property of ASP.

THE EXPRESS WARRANTY ABOVE IS THE SOLE WARRANTY OBLIGATION OF ADVANCED STERILIZATION PRODUCTS, AND THE REMEDY PROVIDED ABOVE IS IN LIEU OF ANY AND ALL OTHER REMEDIES. THERE ARE NO OTHER AGREEMENTS, GUARANTEES OR WARRANTIES -- ORAL OR WRITTEN -- EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ADVANCED STERILIZATION PRODUCTS SHALL HAVE NO LIABILITY WHATSOEVER FOR ANY IMPROPER USE OR UNAUTHORIZED SERVICE OR REPAIR.

Advanced Sterilization Products Commercial Warranty

The STERRAD® Sterilizer and reusable accessories supplied by Advanced Sterilization Products (ASP) are 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 their 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 null and void if service is attempted or performed by persons who are not authorized to do so by Advanced Sterilization Products. 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 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/replacement in its own factory, at any authorized repair station, or at the facilities of the purchaser of the instrument. Replacement items can be either new or remanufactured. Defective parts replaced under warranty shall become the property of ASP.

ACCEPTED
with COMMENTS
EPA Letter Dated:
FEB 1 2008
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.
71871-3