STERRAD[®] 50 Sterilization System User's Guide

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

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a **Johnson Johnson** company Division of Ethicon. Inc.

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For warranty information, please visit our website or contact our Customer Care Center. For additional copies of this guide, please visit www.e-ifu.com

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About This Guide

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 contains 6 chapters, 1 appendix and a foldout chart. The 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 descriptions on preparing items to be sterilized, how to effectively package the load. It also contains a large, foldout chart detailing "How to Determine What Can be Sterilized in the STERRAD 50 System."

- 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 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 the ASP Customer Care Center for maintenance. The messages are listed in alphabetical order.
- **Appendix A. Specifications**-this appendix details the technical specification information for your sterilizer.

Additional Information

The information in the Safety Chapter (chapter 2) is repeated where appropriate throughout this guide for your safety and use. This information is 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.

Chapter 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 & 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.

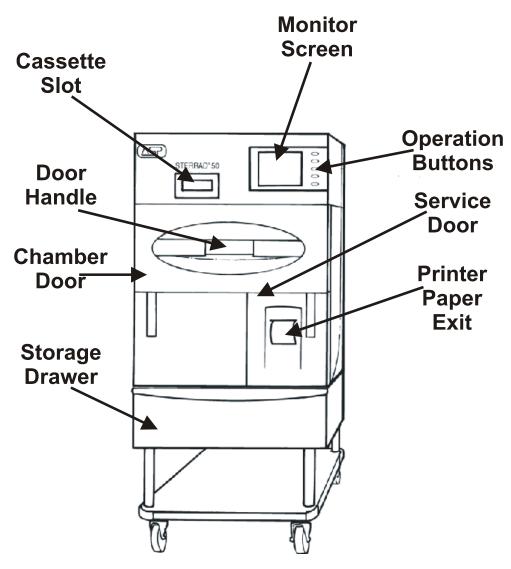


Figure 1. STERRAD[®] 50 Sterilizer

Chapter 2. For Your Safety

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 sterilizer.** 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 sterilizer, should repair or adjust the STERRAD 50 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 chemical resistant latex, PVC (vinyl) or nitrile gloves when removing items from the sterilizer following a cancelled cycle or if any moisture is noted on items in the load following a completed cycle.

♦ WARNING! HYDROGEN PEROXIDE IS AN OXIDIZER

Hydrogen peroxide is a strong oxidizing agent and poses a hazard for fire, explosion, or container rupture. Avoid allowing hydrogen peroxide to contact organic materials, including paper, cotton, wood, or lubricants. Do not use or store near heat or open flame. Shoes, clothing, or other combustible material that have come into contact with hydrogen peroxide must be immediately and thoroughly rinsed with water to avoid a potential fire hazard. In case of fire, use only water to extinguish.

WARNING! CONCENTRATED HYDROGEN PEROXIDE IS TOXIC

Ingestion of hydrogen peroxide may be life threatening. If swallowed, call a "poison control" center or physician immediately for treatment advice. Have the person drink plenty of water if the person is able to swallow. Do not give anything by mouth to an unconscious person. Do not induce vomiting unless instructed to do so by the poison control center or physician.

• WARNING! RISK OF EYE INJURY.

Direct hydrogen peroxide contact with eyes can cause irreversible tissue damage. If contact with eyes occurs, hold the eyes open and flush with large amounts of water for at least 15-20 minutes. Remove contact lenses, if present, and then continue rinsing the eyes. Consult a physician immediately after flushing the eyes.

WARNING! RISK OF RESPIRATORY IRRITATION

Inhalation of hydrogen peroxide mist can cause severe irritation of lungs, throat, and nose. If inhalation occurs, move the person to fresh air. If the person is not breathing, call for emergency medical attention, or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Consult a physician immediately.

• WARNING! RISK OF SKIN INJURY.

Direct hydrogen peroxide contact with the skin can cause severe irritation. Wear chemical resistant latex, PVC (vinyl) or nitrile gloves when handling used cassettes or ejected cassettes, items from a cancelled cycle, or items that have moisture present after a completed cycle. Immediately take off contaminated clothing and rinse thoroughly with water to avoid potential fire hazard and wash before re-use.

- WARNING! HEATED 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.
- ♦ WARNING! HYDROGEN PEROXIDE MAY BE PRESENT If white residue is visible on the load; this may be residue from the hydrogen peroxide stabilizer. Wear chemical resistant latex, PVC (vinyl) or nitrile gloves when removing a load with visible white residue. White residue can be minimized by making sure regular Planned Maintenance procedures are performed on your system. The system will inform you when Planned Maintenance is due. Please schedule your PM service in a timely manner.

♦ WARNING! RISK OF BREATHING DIFFICULTIES

On rare occasions, the outlet filter on the vacuum pump can prematurely fail. If this occurs, you may see mist or what some users have described as "haze" or "smoke" in the room where the sterilizer is operating. The chemical composition of the mist is primarily airborne mineral oil with trace amounts of other compounds. Oil mist exposure may, theoretically, pose an increased risk to people with certain respiratory conditions, such as asthma, and they should take special precautions not to be exposed to the mist. If you observe these conditions, personnel should leave the room as a precaution and discontinue use of the STERRAD System until the system is repaired. Personnel should avoid working in the room until the mist has cleared.

Please note that all STERRAD Sterilizers should be used and installed in a well-ventilated environment (a minimum of 10 air exchanges per hour).

Personal Protective Equipment

• WARNING! HYDROGEN PEROXIDE MAY BE PRESENT. Wear chemical resistant 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.

Cassette Handling

- WARNING! HYDROGEN PEROXIDE MAY BE PRESENT. 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.
- WARNING! HYDROGEN PEROXIDE MAY BE PRESENT. Do not remove used cassettes from the cassette collection box. Dispose of the sealed cassette collection box according to local was

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 chemical resistant latex, PVC (vinyl), or nitrile gloves. Do not touch gloves to face or eyes.

WARNING! HYDROGEN PEROXIDE MAY BE PRESENT. 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.

Device Safety

• WARNING! RISK OF INJURY OR STERILIZER DAMAGE The STERRAD 50 Sterilizer should not be used stacked with other equipment.

KNOW WHAT YOU CAN PROCESS

Before processing any item in the STERRAD 50 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 foldout 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 STERILIZER

Do not change the power source without checking the electrical phase rotation. Prior to relocating the STERRAD 50 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.

• CAUTION: RISK OF DAMAGE TO STERILIZER

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.

PROPER USE OF BIOLOGICAL INDICATORS

Only ASP-approved biological indicators (BIs) 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 restarting the cycle. Call the ASP Customer Care Center (1-888-STERRAD) for information on approved biological indicators including the CycleSure[®] Biological Indicator.

• CAUTION: RF COMMUNICATIONS EQUIPMENT Portable and mobile RF communications equipment can affect medical electrical equipment.

Safe Maintenance

- **WARNING! RISK OF INJURY** Use of unauthorized parts for maintenance or repair could cause personal injury, result in costly damage or unit malfunction, and void the warranty.
- CAUTION: RISK OF DAMAGE TO THE STERILIZER Repairs and adjustments should only be attempted by experienced technicians who are fully trained to maintain and repair the STERRAD Sterilizer.

♦ CAUTION: RISK OF DAMAGE TO THE STERILIZER

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.

IMPORTANT! IMPORTANT PM PROCEDURE

If white residue is visible on the load; this may be residue from the hydrogen peroxide stabilizer. Wear chemical resistant latex, PVC (vinyl) or nitrile gloves when removing a load with visible white residue. White residue can be minimized by making sure regular Planned Maintenance (PM) procedures are performed on your sterilizer. The sterilizer will inform you when Planned Maintenance is due. Please schedule your PM service in a timely manner.

Guidance And Declaration-Electromagnetic Emissions				
The STERRAD [®] 50 Sterilities below. Assure that it is used		se in the electromagnetic environment specified ment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance		
RF emissions CISPR 11	Group 1	The STERRAD 50 Sterilizer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.		
RF emissions CISPR 11	Class A	The STERRAD 50 Sterilizer is suitable for use in all establishments other than domestic and those directly connected to the public low- voltage power supply network that supplies buildings used for domestic purposes.		
Harmonic emissions	Class A			
IEC 61000-3-2				
Voltage fluctuations/flicker emissions	Complies			
IEC 61000-3-3				

Chapter 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 Sterilizer" foldout 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.
- The STERRAD 50 Sterilizer can sterilize instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.

- Medical devices with only a single stainless steel lumen having the following dimensions can be processed in the STERRAD 50 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.
- Medical devices with a lumen made of Teflon[®]/Polyethylene (having the following dimensions) can be processed in the STERRAD 50 Sterilizer.
 - » an inside diameter of 6 mm or larger and a length of 310 mm or shorter.

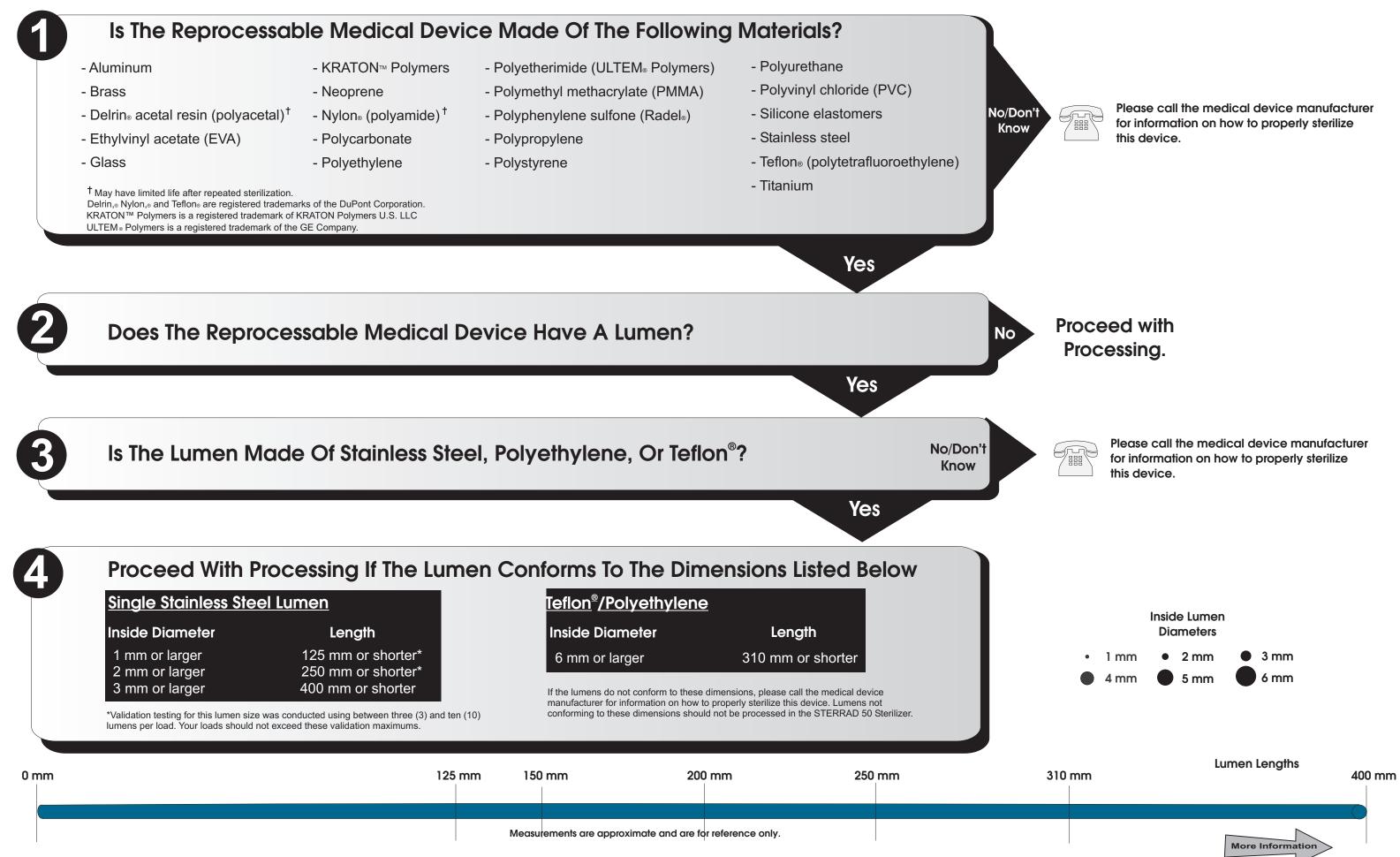
WARNING! DO NOT ATTEMPT TO STERILIZE ITEMS OR MATERIALS THAT DO NOT COMPLY WITH THE DIRECTIONS SPECIFIED IN THIS GUIDE. IN ADDITION YOU SHOULD READ THE MEDICAL DEVICE MANUFACTURER'S INSTRUCTIONS OR CALL THE ASP CUSTOMER CARE CENTER TO DETERMINE WHETHER AN ITEM CAN BE STERILIZED BY THIS STERILIZER.

How to Determine What Can be Sterilized in the STERRAD[®] 50 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 50 Sterilizer. Be sure to check with the medical device manufacturer's instructions before loading any new item in the STERRAD 50 Sterilizer.

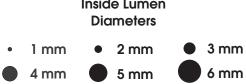
✓ Note: There is a wide variety of materials and devices that can be sterilized in the STERRAD 50 Sterilizer. Please contact the ASP Customer Care Center (1-888-STERRAD) for an up-to-date list of recommended materials, devices and/or device manufacturer information or visit the ASP website at www.sterrad.com.

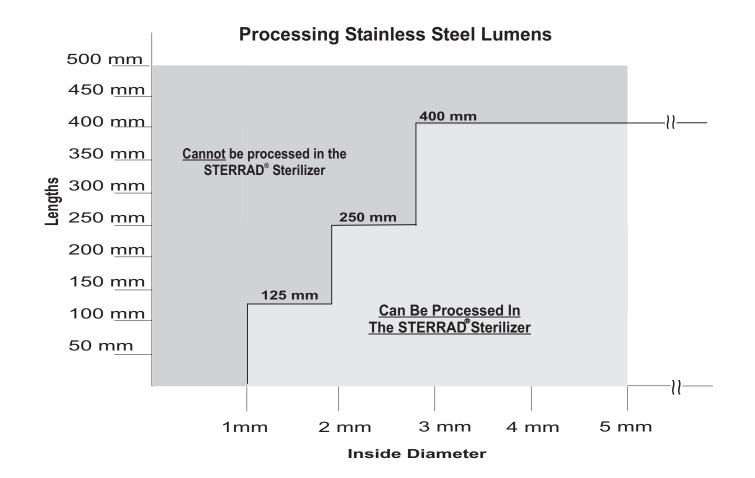
How To Determine What Can Be Sterilized In The STERRAD[®] 50 Sterilizer











Typical Devices Sterilized in the STERRAD[®] 50 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

Any devices processed in the STERRAD 50 Sterilizer must be within the claim limits for the sterilizer. 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.

Items Not Recommended

- Items made with copper or copper alloys (such as Monel), should not be used. Please contact ASP Customer Care Center at 1-888-STERRAD for more information.
- Instrument mats other than STERRAD Instrument Mats.
- Instrument trays other than STERRAD Instrument Trays or APTIMAXTM Instrument Trays.
- Any item that is not completely dry.
- Items or materials that absorb liquids.
- Single use items for which the manufacturer does not recommend resterilization.
- 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.
- 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.

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 including trays must be **thoroughly** cleaned, rinsed, and **dried** before loading into the sterilizer.
- Carefully inspect all instruments and devices for cleanliness and dryness prior to packaging. If visible soil is present, the item must be re-cleaned and dried prior to sterilization. If moisture is present, dry the item thoroughly prior to sterilization.
- Carefully inspect all instruments and devices for flaws or damage prior to packaging. Devices and instruments with flaws or damage should be replaced or repaired before using.
 - ✓ Note: Periodic careful inspection of the items after repeated exposure to disinfectant/cleaner/ sterilant is necessary, due to the potential damaging effects of the chemical agents on the items.

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. Sterilization then inactivates all remaining spores and live microorganisms.

- <u>Clean</u> your devices according to the medical device manufacturers' instructions. You must remove all blood, tissue, and soil from items using appropriate detergents, cleansers and/or methods.
- ♦ <u>Rinse</u> items thoroughly to remove detergent or cleanser residue. Use treated water that is of a quality that ensures hard water stains do not occur. Failure to remove all organic materials or detergents may result in the formation of light-colored residue on the devices. If residue is visible, you should clean, rinse, dry, and resterilize the device prior to use.

♦ <u>Dry all items thoroughly.</u> 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 manufacturers' 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.

WARNING! POSSIBLE RESIDUAL HYDROGEN PEROXIDE CONTACT! FAILURE TO ENSURE THAT INSTRUMENTS ARE COMPLETELY DRY BEFORE THEY ARE PROCESSED IN THE STERRAD[®] STERILIZER MAY RESULT IN RESIDUAL HYDROGEN PEROXIDE BEING PRESENT ON THE OUTER SURFACE OF THE LOAD. THIS MAY CAUSE CONTACT BURNS WHEN THE SURFACE OF THE LOAD IS HANDLED.

• 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. In the absence of STERRAD System-specific instructions, please contact the relevant medical device manufacturer.

WARNING! POSSIBLE NON-STERILE DEVICE! LOADS CONTAINING MOISTURE MAY RESULT IN EITHER A NON-STERILE DEVICE OR CYCLE CANCELLATION. WEAR CHEMICAL RESISTANT LATEX, PVC (VINYL) OR NITRILE 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.

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, APTIMAXTM Instrument Trays, and STERRAD Accessories are recommended for use in the STERRAD 50 Sterilizer. STERRAD Instrument Trays and APTIMAXTM 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.

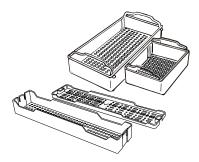


Figure 2. Use Only STERRAD[®] Instrument Trays And APTIMAX[™] Instrument Trays

- 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 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 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 allow any item to touch the walls of the sterilization chamber, door, or electrode. Provide at least 25 mm (1 inch) of space between the electrode and 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 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.
- Place a STERRAD CycleSure[®] Biological Indicator (BI) in the chamber. Frequency of biological testing should be at least once per day or in accordance with your facility's 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.

Chapter 4.

Day-to-Day Operation

Safe Operation

Before operating your STERRAD[®] 50 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 50 Sterilizer" foldout 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.

Using The 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.



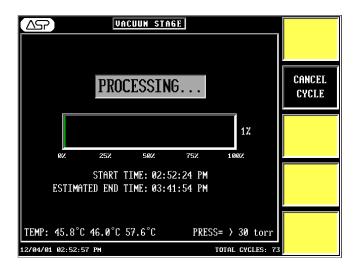
Figure 3. Main Display. Ready To Use.

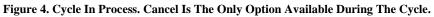
START

To begin the sterilization process, you must start the cycle. Be sure that the chamber has been properly loaded 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 **START**. The display changes to show the progress and status of the cycle.





The status bar identifies the cycle stage. At the center is a graphic depicting the percentage of the sterilization cycle completed. Below this are shown the cycle start time, the estimated end time, the pressure in the chamber and the temperature within the chamber. The right side of the display shows the CANCEL CYCLE button.

HELP

Help is available for every display on the sterilizer. To get help, do the following:

- 1. Press **HELP**. The Help display shows detailed information for the current display.
- 2. Press **EXIT HELP** 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 CANCEL. The sterilizer starts the cycle cancellation process.

CYCLE CANCELED	
OPERATOR CANCELLATION	
1002	
07. 257. 507. 757. 1007.	
START TIME: 12:28:18 PM COMPLETION TIME: 12:28:50 PM	HELP
TEMP: 45°C 45°C 54°C PRESS= > 30 torr 09/13/96 12:29:05 PM TOTAL CYCLES: 65	UNLOCK Door

Figure 5. Display Showing Cancelled Cycle Information.

2. When the cycle cancellation process is complete, you MUST press **UNLOCK DOOR** to return to the main display.

CAUTION: If UNLOCK DOOR is not pressed, the door will remain locked and will require a service call to open. Rebooting the system will not unlock the door. System Functions Display



Figure 6. Pressing SYSTEM FUNCTIONS Displays This Screen.

To access the system functions display, do the following:

- 1. Press **SYSTEM FUNCTIONS**. The right side of the display shows five buttons: DATE/TIME, CYCLE HISTORY, SYSTEM TOOLS, HELP, and EXIT.
- 2. Press **DATE/TIME** to open the Date/Time display to change date and time settings.
- 3. Press CYCLE HISTORY to access cycle history information.
- 4. Press SYSTEM TOOLS to open the System Tools display.
- 5. Press **HELP** to open the Help display.
- 6. Press **EXIT** 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 **DATE/TIME.** 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.

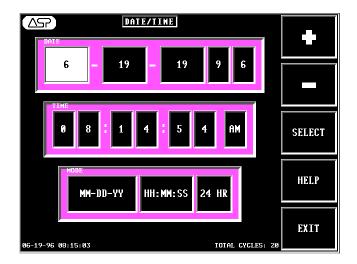


Figure 7. Use This Display To Change The Date And/Or The Time.

- 2. Press the + or buttons to change the highlighted character.
- 3. Press **SELECT** to move the cursor through the fields.
- 4. Press **HELP** to display the Help display for the current display.
- 5. Press **EXIT** to return to the main display.

CYCLE HISTORY

To review the cycle history from the System Functions display, do the following:

1. Press CYCLE HISTORY.

	CYCLE HISTORY				
STATUS	E	END TIM	START TIME	DATE	
AM PROCESS COMPLETE	9 AM	09:59:29	09:12:37 AM	09/13/96	
AM PROCESS COMPLETE	6 AM	09:03:26	08:16:20 AM	09/13/96	
PM PROCESS COMPLETE	6 PM	05:07:56	04:21:04 PM	09/12/96	
AM PROCESS COMPLETE	6 AM	11:09:56	10:22:57 AM	09/12/96	
AM PROCESS COMPLETE	4 AM	10:18:24	09:31:12 AM	09/12/96	
AM PROCESS COMPLETE	5 AM	01:20:25	12:33:29 AM	09/12/96	
AM PROCESS COMPLETE	9 AM	12:32:29	11:45:33 PM	09/12/96	
PM PROCESS COMPLETE	3 PM	11:44:33	10:57:31 PM	09/11/96	
PM PROCESS COMPLETE	1 PM	10:56:31	10:09:14 PM	09/11/96	
	4 PM	10:08:14	09:20:51 PM	09/11/96	
PM PROCESS COMPLETE OPEN	1 PM	04:40:01	Ø3:53:22 PM	09/09/96	
PM PROCESS COMPLETE	2 PM	03:52:22	03:05:41 PM	09/09/96	
PM PROCESS COMPLETE	1 PM	03:04:41	02:17:59 PM	09/09/96	
PM PROCESS COMPLETE	9 PM	02:16:59	01:30:20 PM	09/09/96	
PM PROCESS COMPLETE	ØPM	01:29:20	12:42:41 PM	09/09/96	
PM PROCESS COMPLETE HELP	8 PM	06:36:28	Ø5:49:48 PM	09/08/96	
PM PROCESS COMPLETE	8 PM	05:48:48	05:02:06 PM	09/08/96	
PM PROCESS COMPLETE	6 PM	05:01:00	04:14:25 PM	09/08/96	
PM PROCESS COMPLETE	5 PM	04:13:2	03:26:47 PM	09/08/96	
PM PROCESS COMPLETE	7 PM	03:25:47	02:39:09 PM	09/08/96	
PM POWER INTERRUPTED	5 PM	02:38:4	02:37:04 PM	09/08/96	
PM PROCESS COMPLETE EXIT	6 PM	01:41:46	12:55:06 PM	09/06/96	

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 (↑) and DOWN (↓) arrows, OPEN, HELP, and EXIT.
- 3. Press the UP (\uparrow) or DOWN (\downarrow) arrows to scroll to and highlight a cycle.
- 4. Press **OPEN** to see a more detailed history of a particular cycle. Press **PRINT** to obtain a printout of the cycle information.
- 5. Press **HELP** to open the Help display.
- 6. Press **EXIT** 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 **OPEN** . 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 **CLOSE** to return to the original Cycle History display.
- 3. Press **PRINT** to print a cycle record, according to facility policy.
- 4. Press **HELP** to open the Help display.
- 5. Press **EXIT** to return to the main display.

SYSTEM TOOLS

To use the System Tools from the System Functions display, do the following:

1. Press **SYSTEM TOOLS**. 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 **CONFIGURE** to open a display that lets you use the ID String Editor.
- 3. Press CASSETTE FUNCTIONS.
- 4. Press **HELP** to open the Help display.
- 5. Press **EXIT** 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 CONFIGURE.
- 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 **ID STRING EDITOR** 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 (\uparrow) and DOWN (\downarrow) arrows, SELECT, HELP, and EXIT.



Figure 11. You May Use Your Own Identification In This Field.

- 4. Press the UP (\uparrow) or DOWN (\downarrow) arrows to change the highlighted character.
- 5. Press **SELECT** to move through and highlight the characters.
- 6. Press **HELP** to open the help display.
- 7. Press **EXIT** to return to the main display.

Preparing the Load

Proper preparation of trays, pouches, and instruments can minimize or prevent cycle cancellation due to load-related problems. Below is a brief overview of load preparation. More detailed 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.
- 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 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 ASPapproved 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.

- ✓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.

Biological Indicators

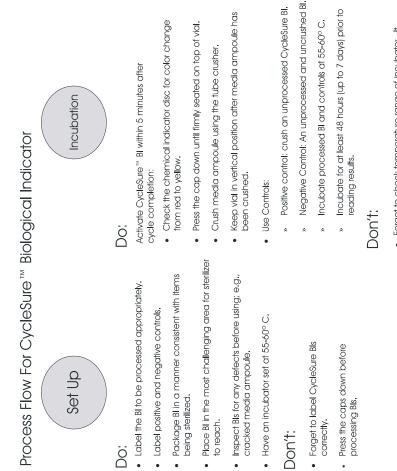
Biological indicators (BIs) help you to assure that your sterilizer is operating correctly. Confirming that sterilizing conditions were present during a cycle is an important part of the sterilization process. Frequency of biological testing should be at least once per day or in accordance with your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

• Contact ASP Customer Care Center (1-888-783-7723) 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 the best way to verify proper processing. The biological indicator should be placed at the back of the chamber, with the opening facing the back. Review the instructions that are included with the biological indicators for proper use.

The following chart details the transfer process and a flow chart shows the biological indicator procedure.

✓ 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.





- 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:

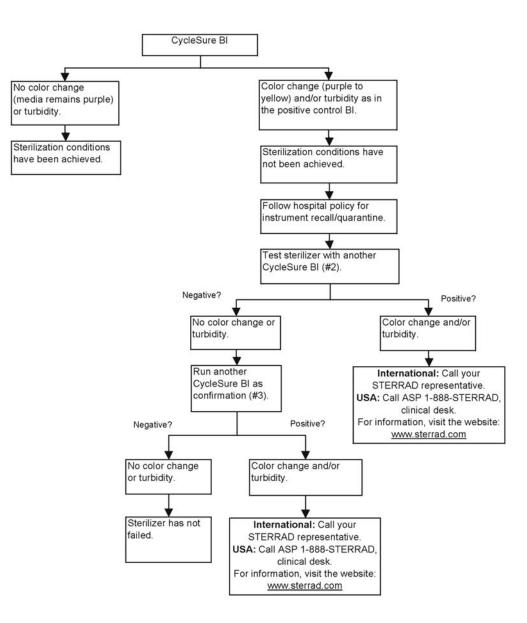
- Observe for color change in the processed BI and controls.
- Processed BI: no growth (no color change, media remains purple).
- Positive Control: growth (color change in media from purple to yellow).
 - Negative Control: no growth (media shall remain purple).

Other Results:

- Processed BI: growth (color change in media from purple to yellow). See CycleSure¹¹⁴ 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.

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 hydrogen peroxide vapor. 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 12. 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.

Loading the Sterilization Chamber

- Trays must be placed flat on the shelf.
- Arrange the items in the trays to ensure that the hydrogen peroxide and plasma can surround them. Do not stack trays within 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 peel pouches on top of each other.
- 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.
 - ✓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.

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 FOR AT LEAST 15 MINUTES 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 13. 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 CUSTOMER CARE 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.
 - ✓ Note: Do not remove the plastic wrapping until ready to insert the cassette.
- 4. Remove the plastic wrapping from the cassette sleeve. Do NOT remove the cassette from the remaining heavy paper sleeve.
- 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 14. Note The Orientation Of The Arrow On The Heavy Paper Sleeve (The End Of The Sleeve That Is Inserted First Is Shown Above.) 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 YOUR FACILITY'S PROCEDURES OR IN NORMAL WASTE. IF THE RETAINER HOLDING THE PLASTIC CASSETTE IN THE CARDBOARD SLEEVE IS DAMAGED AND THE USED CASSETTE FALLS OUT, WEAR CHEMICAL RESISTANT LATEX, PVC (VINYL) OR NITRILE GLOVES TO PLACE THE PLASTIC CASSETTE BACK IN THE ORIGINAL SLEEVE. DISCARD THE CASSETTE INSIDE THE SLEEVE, FOLLOWING FACILITY'S PROCEDURES OR IN NORMAL 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 START.
- 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.

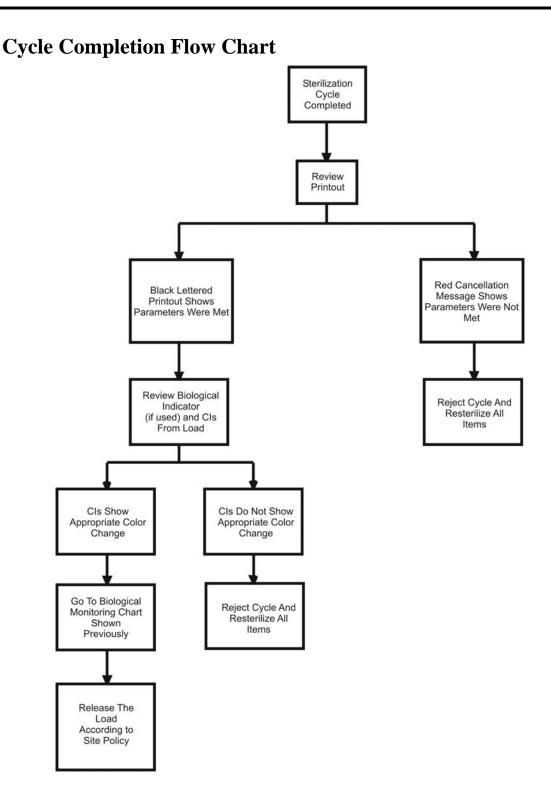
The display indicates the status of the unit at all times: the current stage of the sterilization cycle, the temperature in the chamber, the pressure in the chamber, the cycle start time and the cycle estimated end time. Each load goes through eight consecutive stages: vacuum, injection, diffusion, plasma, injection, diffusion, plasma, and vent.

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).



Canceling A Cycle

You can cancel a cycle at any time by pressing CANCEL, except during the final vent phase. The STERRAD 50 Sterilizer may also cancel a cycle if it detects a problem with the cycle.

To manually cancel a cycle, do the following:

- 1. Press CANCEL.
- 2. Ten beeps sound, and the message display shows CYCLE CANCELED/OPERATOR CANCELLATION.
- 3. A paper printout exits the printer with a message in red ink.
- 4. The sterilizer automatically completes the cancellation process (which includes a short plasma stage during most phases of the process).
- 5. The display indicates when cancellation is complete.

Loads from canceled cycles should be rewrapped using new polypropylene wrap, STERRAD Chemical Indicator Strips, and STERRAD Chemical Indicator Tape. If a biological indicator was used in the canceled load, discard it and place a new one in the chamber before starting the new cycle.

WARNING! HYDROGEN PEROXIDE MAY BE PRESENT. IF THERE IS A CYCLE CANCELLATION AND THE ITEMS IN THE LOAD APPEAR WET, HYDROGEN PEROXIDE MAY BE PRESENT. WEAR CHEMICAL RESISTANT 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

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.

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:

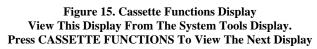
- 1. Lift the handle of the door of the STERRAD 50 Sterilizer, then pull the door towards you and downward to open the sterilizer.
- 2. Remove chamber contents.
- 3. Close the door and press down on the handle latch to secure the door.
- 4. After ensuring that the STERRAD Chemical Indicators exhibit the correct color change, the sterilized items are ready for immediate use, following facility policies and procedures.

Cassette Functions Tools

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.





The Cassette Functions display shows EJECT CASSETTE, INDEX CASSETTE, and RESET BARCODE. Each of these features is described below.

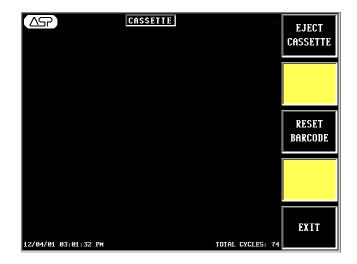
	IE	EJECT Cassette
		INDEX Cassette
		RESET BARCODE
12/09/97 11:04:10	TOTAL CYCLES: 41	EXIT

Figure 16. This Display Is Shown When You Press CASSETTE FUNCTIONS. INDEX CASSETTE May Not Be 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 17. 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

CAUTION: Manually indexing the cassette results in the loss of at least one cycle capacity of the cassette.

✓ Note: "Index Cassette" may not be an option on your system, depending on the software version.

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.

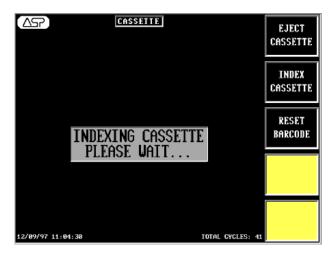


Figure 18. Pressing INDEX CASSETTE Indexes Or Advances The Cassette To The Next Available Cell.

- 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 1-888-STERRAD 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.

	EJECT Cassette
	INDEX Cassette
RESET SUCCESSFUL	RESET BARCODE
12/89/97 11:84:19 TOTAL CYCLES: 43	EXIT

Figure 19. 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 1-888-STERRAD for technical service or to schedule a repair procedure.



Figure 20. If The Reset Is Unsuccessful, You Must Schedule A Repair Procedure With ASP Customer Care Center.

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. Flipping 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

Overview

This section is your guide to the maintenance procedures for the STERRAD[®] 50 Sterilizer: Contact ASP Customer Care Center for guidance on all other maintenance procedures.

WARNING! RISK OF INJURY.

ONLY EXPERIENCED TECHNICIANS SHOULD REPAIR OR ADJUST THIS STERILIZER. 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 STERILIZER MALFUNCTION, AND WILL VOID THE WARRANTY.

Caution: White residue can be minimized by making sure regular Planned Maintenance (PM) procedures are performed at the interval specified on the system. Make sure you schedule a service call in a timely manner when notified that a PM is due.

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.

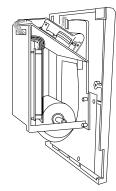


Figure 21. Printer Mounted On Printer Door.

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 22. 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.

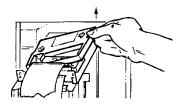


Figure 23. Removing The Used Ribbon Cartridge.

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.

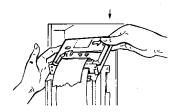


Figure 24. Inserting A New Ribbon Cartridge.

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



Figure 25. 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 26. 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 27. 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 28. 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.

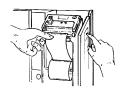


Figure 29. Advance The Paper Through The Printer Mechanism And The Ribbon Cartridge.

5. Make sure the printer paper feeds through the slot in the printer door. Close the door.

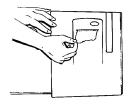


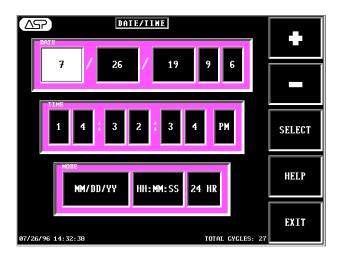
Figure 30. Feed The Printer Paper Through The Slot In The Printer Door.

Resetting the Date and Time

The date and time are set by your Field Service Engineer 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.





- 2. Press **SELECT** until the DATE box inside the mode block is lit, then press + or 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 the ASP Customer Care Center.

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 or Injector Valve Plate

Your system has one of two types of deflectors: a deflector attached to the vaporizer bowl or a injector valve plate fitted into the electrode. To clean the injector valve vaporizer bowl and deflectors, do the following:

- 1. Wearing chemical resistant 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.

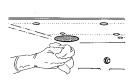


Figure 32. Clean The Exterior Surface Of The Bowl.





- 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.

Chapter 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! HYDROGEN PEROXIDE MAY BE PRESENT. YOU MUST WEAR CHEMICAL RESISTANT 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 (use a new biological indicator) if they are being used. Remember, you can always press **HELP** for more information or call the Advanced Sterilization Products (ASP) Customer Care Center at 1-888-STERRAD.

Displayed Message	Printed Message	Action
CASSETTE ACCEPTED	No printout.	The cassette is the correct type and date, and is positioned correctly. No action required.
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 the ASP Customer Care Center.
CASSETTE NOT DETECTED	No printout.	Remove the cassette. Reinsert the same cassette or a new one. If the message persists, call the ASP Customer Care Center.

CASSETTE OUT-OF-DATE PLEASE REMOVE Cassette out of date Cassette Exp Ten days have passed since the cassette was inserted into the

Displayed Message	Printed Message	Action
CASSETTE	(Date)	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 the ASP Customer Care Center.
CASSETTE VERIFICATION UNSUCCESSFUL PLEASE REMOVE CASSETTE	Verification Unsuccessful Refer To Help Screen	The barcode cannot be read. Press Help for more information or call the ASP Customer Care Center.
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 CHEMICAL RESISTANT 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 the ASP Customer Care Center.
CYCLE CANCELED INJECTION SYSTEM INTERRUPTED PLEASE WAIT 10 MIN	Cycle Canceled Injection System Interrupted Call ASP Technical Service	Call the ASP Customer Care Center.

CYCLE CANCELED INSUFFICIENT PLASMA	Cycle Canceled Insufficient Plasma	Vacuum did not reach the level required for the Plasma Stage.
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Displayed Message	Printed Message	Action
PRESSURE PLEASE WAIT 10 MIN.	Pressure Refer To Help Screen.	Load may be releasing gases from plastic-like materials. Press Help for more instructions. If the cycle cancels again, call the ASP Customer Care Center.
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 the ASP Customer Care Center.
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 the ASP Customer Care Center.
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	Generator 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 the ASP Customer Care Center.

CYCLE CANCELED NO RF POWER PLEASE WAIT 10	Cycle Canceled No RF Power In	No RF or RF2 generator power. This may be caused by
MIN.	Vacuum. Refer To Help	the load touching the

Displayed Message	Printed Message	Action
	Screen or Cycle Canceled No RF Power Refer To Help Screen or Cycle Canceled No RF2 Power In Vacuum. Refer To Help Screen	electrode, the door, or the chamber. Press Help for more information. If the cycle cancels after an empty chamber cycle has been run, call the ASP Customer Care Center.
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 the ASP Customer Care Center.
CYCLE CANCELED POWER INTERRUPTED PLEASE WAIT10 MIN	Cycle Canceled Power Interrupted	Power was interrupted during a critical phase of the cycle. Call the ASP Customer Care Center.
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 CHEMICAL RESISTANT 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 the ASP Customer Care Center.
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 the ASP Customer Care Center.
CYCLE CANCELED TEMPERATURE BELOW THRESHOLD PLEASE WAIT 10 MIN.	Temperature Below Threshold Call ASP Technical Service	Call the ASP Customer Care Center.
CYCLE CANCELED TEMPERATURE OVER THRESHOLD PLEASE WAIT 10 MIN.	Cycle Canceled Temperature Over Threshold Call ASP Technical Service	Call the ASP Customer Care Center.
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 CHEMICAL RESISTANT 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 the ASP Customer Care Center.
CYCLE CANCELED	Cycle Canceled	The items in the load may

Displayed Message	Printed Message	Action
VACUUM NOT LOW ENOUGH PLEASE WAIT 10 MIN.	Vacuum Not Low Enough For Injection Refer To Help Screen	have contained too much moisture before they were placed in the sterilizer. WARNING! WEAR CHEMICAL RESISTANT 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 the ASP Customer Care Center.
CYCLE CANCELED VACUUM SYSTEM INTERRUPTED PLEASE WAIT	Cycle Canceled Vacuum System Interrupted Call ASP Technical Service	Call the ASP Customer Care Center.
CYCLE CANCELED VAPORIZER BELOW THRESHOLD PLEASE WAIT 10 MIN.	Cycle Canceled Vaporizer Below Threshold Call ASP Technical Service	Call the ASP Customer Care Center.
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. Planned maintenance is due now. Call the ASP Customer Care Center immediately.
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Displayed Message	Printed Message	Action
INSERT NEW CASSETTE MAINTENANCE DUE (XXX)	No printout or Maintenance Due (XXX): NN	Insert a new cassette. The specified planned maintenance is due. Call the ASP Customer Care Center to schedule service.
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 the ASP Customer Care Center 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 the ASP Customer Care Center.
PROCESS COMPLETE OPEN DOOR TO REMOVE LOAD	STERRAD [®] 50 STERILIZER [Printout contains all process parameters.]	The cycle is complete with no error. The door may be opened and the load removed and used or stored according to your
	PROCESS COMPLETE	facility's procedures.
	Validated By: Biological Indicator:	
	CASS. LOT # XXXX	
	EXP. DATE: MM/YYYY NUMBER OF CYCLES AVAILABLE = X	
	REMOVE CASSETTE	
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 the ASP Customer Care Center

Displayed Message	Printed Message	Action	
		immediately.	
READY TO USE MAINTENANCE DUE (XXX)	No printout.	The specified planned maintenance is due. Call the ASP Customer Care Center to schedule service.	
SOFTWARE FAULT PLEASE WAIT	Software Fault Call ASP Technical Service	Call the ASP Customer Care Center.	
SYSTEM CANCEL PLEASE WAIT 10 MIN.	System Cancel Call ASP Technical Service	Call the ASP Customer Care Center.	
SYSTEM DATA UNREADABLE	No printout.	Call the ASP Customer Care Center.	
TEMPERATURE HAS NOT RISEN CALL ASP TECHNICAL SERVICE	Temperature Has Not Risen Call ASP Technical Service	Call the ASP Customer Care Center.	
TEMPERATURE OVER THRESHOLD CALL ASP TECHNICAL SERVICE	Temperature Over Threshold Call ASP Technical Service	Call the ASP Customer Care Center.	
TEMPERATURE SENSOR BELOW THRESHOLD CALL ASP TECHNICAL SERVICE	Temperature Sensor Below Threshold Call ASP Technical Service	Call the ASP Customer Care Center.	
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 EJECT CASSETTE. If the cassette ejects successfully, insert a new one. If this does not resolve the problem, 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 is required.
WARMING UP PLEASE WAIT	No printout.	The chamber is not yet at operating temperature. No action required; however if the

Displayed Message	Printed Message	Action
		message has not changed within 1 hour, call the ASP Customer Care Center.

Appendix A. Specifications

Space Requirements		
Size including cart	1 meter x 1 meter (3 feet x 3 feet)	
Weight	300 kg/660 lbs	
Installation		
Space Requirements	57 in x 30 in x 36 in(HxWxD)(144.8 cm x 75 cm x 91 cm)	
Mobility	Movable (includes cart)	
Venting Requirements	None required	
Gas Tank Requirements	None required	
Electrical Requirements	3 m/10 ft. power cord	
Operation		
Electrical	120 VAC, 60 Hz, 15 Amps 220-240 VAC, 50/60 Hz, 10 Amps 100 VAC, 50/60 Hz, 20 Amps	
	Single phase dedicated line. NEMA L5-20 receptacle. 20 Amp circuit. Wire gauge to be of sufficient size to maintain 108-132 VAC with the following: 12 Amps continuous current; 34 Amps momentary current.	
Ambient Temperature	15° C to 40° C (59° F to 104° F)	
Relative Humidity	10% to 80%, non-condensing	
Altitude	-100 m to 3000 m msl (-330 ft. to 10,000 ft. msl)	
Air Exchanges Minimum	10/hour	
Heat Generation	1919 BTU/Cycle	

Pollution Degree	2	
Overvoltage Category	П	
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 the ASP Customer Care Center. 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	

✓ Note: 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.