

ASP
STERRAD® 100NX®

STERRAD® 100NX® Sterilization System

User's Guide

Ref 99994



ADVANCED STERILIZATION PRODUCTS

Division of Ethicon, Inc.

a *Johnson & Johnson* company

M-99994_02
April 2012

STERRAD® 100NX® Sterilization System User's Guide

 **ADVANCED STERILIZATION PRODUCTS**

Division of Ethicon, Inc.

a **Johnson & Johnson** company

33 Technology Drive, Irvine, CA 92618



EC REP

Johnson & Johnson Medical GmbH
Oststraße 1, 22844 Norderstedt, Germany

US	Irvine, CA 92618	IT	Johnson & Johnson Medical S.p.A. Via del Mare, 56 - 00040 Pomezia, Roma
FR	92787 Issy-les-Moulineaux	ES	Johnson & Johnson Medical Paseo de las Doce Estrellas, 5-7 28042 Madrid
DE	22844 Norderstedt	GB	Wokingham, RG40 3EW
CH	8957 Spreitenbach	CA	Johnson & Johnson Medical Products Markham, ON, L3R 0T5
NL	3800 AD Amersfoort	JP	ジョンソン・インフ・ジョンソン 株式会社 〒101-0065 東京都千代田区西神田3丁目5番2号
GR	15125 Maroussi, 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. Karta Engliš 3201/6 150 00 Praha 5	PL	Itzecka 24, 02-135 Warszawa
SK	Plynárenská 7/B 824 78 Bratislava 26	HU	Johnson & Johnson Kft. H-2045 Törökbálint, Tó Park

1-888-STERRAD ASP U.S.A. Professional Services

ASP International 949-581-5799

Please visit www.aspji.com

For warranty information, please visit our website or contact ASP Professional Services.

ASP International Customer Support; call your local ASP Representative)

©. 2008-2012 Division of Ethicon. All rights reserved. STERRAD® is a registered trademark of Advanced Sterilization Products (ASP). Teflon®, Delrin®, and Tyvek® are registered trademarks of E.I. du Pont de Nemours and Company. Radel® is a registered trademark of Solvay SA. Kraton® is a registered trademark of Kraton Polymers LLC. Santoprene™ is a trademark of ExxonMobil Corporation. Ultem® is a registered trademark of SABIC. da Vinci® is a registered trademark of Intuitive Surgical, Inc. Other products mentioned in this publication are trademarked by their respective owners. **Please note:** the screen displays shown in this

guide are for reference only. The actual displays on your system may be slightly different depending on your system's configuration and software revision. Reproduction, adaptation, or translation of this publication without prior written permission is prohibited. Printed in the U.S.A.

Contents

Chapter 1. Introduction 5

- How to Use This Guide 5
- Intended Use 5
- The STERRAD® Sterilization Process 6
- If You Have Questions 6

Chapter 2. Load Preparation 7

- Load Weight Requirements 7
- Cycles and Materials Processing 10
- Recommended Materials 14
 - Thermoplastics 14
 - Thermoplastic Elastomers 14
 - Thermosetting Elastomers 15
 - Glass 15
 - Metal 15
- Items Not To Be Processed 15
 - Do Not Process in the EXPRESS Cycle 16
 - Do Not Process in the DUO Cycle 16
- Guidelines for Preparing Items to Be Sterilized 17
- Cleaning, Rinsing, and Drying 17
- Packaging and Loading 19
 - Instrument Trays 19
 - Tray Mats 19
 - Packaging 19
 - Loading 20
 - Chemical Indicators 21
 - Special Considerations for Flexible Endoscopes 21

Chapter 3. Operation 23

- Before You Start 23
- Start and Warm-up 23
- Biological Indicators 23
- Login 24
- Entering Load Information 25
 - Enter Load Item Data 25
 - Cycle Notes 26
- Loading the Chamber 28

Selecting and Starting a Cycle	32
System Ready Screen	33
Inserting a Cassette	33
Cycle in Progress	34
Canceling a Cycle	35
Cycle Completed	37
Processing a Sterilized Load	38
Inspecting Chemical Indicators	38
Processing Biological Indicators	38

Chapter 4. Troubleshooting 41

Running Diagnostics	41
System Message Table	42
Temperature Messages	42
Messages Not In This Table	42
Call Your ASP Representative	46

Chapter 5. Sterilizer Overview 47

Sterilizer Cycles	47
Sterilizer Features	48
Cassette	49
Cassette Disposal Box	50
Touch Screen and Speaker	50
Chamber	51
Printer	52
Touch Screen Data Entry	53

Chapter 6. Maintenance 55

Automatic Maintenance	55
Automatic Lamp Adjustment	55
Manual Maintenance	56
Disposing of Cassettes	56
Removing a Cassette Disposal Box	57
Replacing the Printer Paper	58
Cleaning the Sterilizer Exterior	61
Cleaning the Hydrogen Peroxide Monitor Detector Lens	62
PCMCIA Card Handling and Replacement	63
Data Transfer Using a Memory Stick	64
Rebooting the System	65
Sterilizer Disposal	65

Chapter 7. Reports and Files 67

- Displayed Reports 67
 - Cycle History 67
- Printed Reports 69
 - Short Report 69
 - Parametric Report 69
 - Long Report 69

Chapter 8. Access Levels and Supervisor Tasks 71

- Overview 71
- Access Levels 71
- Additional Utilities Menu 72
- Date and Time Settings 73
 - Set Date 74
 - Set Time 74
 - Time Zone 74
 - Date Format 74
 - Time Format 74
 - Cancel/Done 74
- System Configuration 75
 - Access Control Option 75
 - IMS 75
 - Vacuum Units 75
 - Load Data Entry Option 76
 - Load Removal Option 76
 - Notepad Option 76
 - Network Option 76
 - Alarm Volume 76
 - Backlight Conservation (Minutes) 76
 - Language Selection 76
 - Sterilizer Settings 77
 - Printer Settings 78
 - Transfer Settings 79
 - Cancel/Done 79
- User Administration 80
 - Add User 81
 - Modify User 82
 - Upload User Data 83
 - Steps to Upload a User Database 84
- Cassette Functions 85
 - Dispose Cassette 86
 - Peroxide Clearance 87
- Network 88
- Diagnostics 88
 - Diagnostic Tests 89
- Service Functions 89

File Management 90
 Calibration Files 90
 Diagnostic Files 90
Upload File 91
Input/Output Doors 92
Product Options 92

Appendix A. Safety Information 95

Personal Safety and First Aid 95
Personal Protective Equipment 97
Device Safety 97
Warnings, Cautions, and Notes 100
Symbols 101

Appendix B. Consumables, Accessories, and Additional Parts 103

Appendix C. Sterilizer Specifications 105

Chapter 1.

Introduction

How to Use This Guide

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

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

Intended Use

The STERRAD® 100NX® Sterilization System is a general purpose, low temperature sterilizer which uses the STERRAD® 100NX® Process to inactivate microorganisms on a broad range of medical devices and surgical instruments.

When used as directed by the instructions in this user’s guide, the STERRAD® 100NX® Sterilization System will sterilize both metal and nonmetal medical devices at low temperatures. Please review “How to Determine What Can Be Sterilized in the STERRAD® 100NX® Sterilizer” in the “Load Preparation” chapter along with the cycle information to make sure you follow the directions for processing items in each type of cycle.

The STERRAD® Sterilization Process

The STERRAD® 100NX® Sterilizer sterilizes medical devices by diffusing hydrogen peroxide vapor into the chamber and then electromagnetically exciting the hydrogen peroxide molecules into a low-temperature plasma state. The combined use of hydrogen peroxide vapor and plasma safely and rapidly sterilizes medical instruments and materials without leaving toxic residues. All stages of the sterilization cycle operate within a dry environment at a low temperature, and thus the cycle is not damaging to compatible instruments that are sensitive to heat and moisture.

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

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.

If You Have Questions

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

Chapter 2.

Load Preparation

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



CAUTION: KNOW WHAT YOU CAN PROCESS

Before processing items in the sterilizer, make sure you know how the STERRAD® Sterilization Process will affect the item. When constructing your load, the total weight of the load to be sterilized should not exceed the load requirements for the specific cycle. 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 void your instrument warranty.

Load Weight Requirements

The weight of the items to be sterilized must conform to the weights used for validating the sterilizer processes. These weights are listed in the following table. The weight of the load depends on the cycle selected and whether one or both shelves are used.

Cycle Type	Weight	Shelves
STANDARD Cycle	9.7 kg (21.4 lbs) total weight	1 or 2 shelves
DUO Cycle	6.0 kg (13.2 lbs) total weight	1 or 2 shelves
EXPRESS Cycle	4.9 kg (10.7 lbs) total weight	Bottom shelf only
FLEX Cycle	9.7 kg (21.4 lbs) total weight	1 or 2 shelves

STANDARD Cycle Processing

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

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

- ◆ Single channel stainless steel lumens with an inside diameter of 0.7 mm or larger and a length of 500 mm or shorter.†

Processing Tubing

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

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

DUO Cycle Processing

Medical devices, including many flexible endoscopes with accessory devices such as light cords and cameras with the following material and dimensions can be processed in the STERRAD® 100NX® DUO Cycle.

- ◆ Single channel polyethylene and Teflon® (polytetrafluoroethylene) flexible endoscopes with an inside diameter of 1 mm or larger and a length of 875 mm or shorter.
- ◆ Cameras.
- ◆ Accessory light cords.
- ◆ Flexible endoscopes without lumens.

- ✓ *Note: Do not include more than 2 flexible endoscopes per load.*

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

*Sterilize without any additional load. Up to 20 pieces of tubing may be sterilized at one time.

EXPRESS Cycle Processing

The following types of medical devices can be sterilized in the **EXPRESS** Cycle:

- ◆ General medical devices requiring surface sterilization, or sterilization of mated titanium and stainless steel surfaces.
- ◆ Rigid or semi-rigid endoscopes without lumens; for example da Vinci® endoscopes.

FLEX Cycle Processing

Medical devices, including most flexible endoscopes, with the following materials and dimensions can be processed in the STERRAD® 100NX® Sterilizer **FLEX** cycle:

- ◆ Single channel polyethylene and Teflon® (polytetrafluoroethylene) flexible endoscope with an inside diameter of 1 mm or larger and length of 850 mm or shorter.**
- ◆ Non-lumened flexible endoscopes.

✓ *Note: Do Not process more than 2 flexible endoscope per load.*

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

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

Cycles and Materials Processing



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 ASP Customer Support to determine if an item can be sterilized by the STERRAD® 100NX® Sterilization System.

This chapter includes cycle information regarding recommended items, materials, and some typical devices that can be sterilized in each of the cycles on the STERRAD® 100NX® Sterilizer. Please refer to these pages whenever you need materials information.

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

There is a wide variety of materials and devices that can be sterilized in the STERRAD® 100NX® Sterilizer. Please contact ASP Professional Services for more information. Information may also be obtained from the device manufacturer. In the U.S.A., call 1-888-783-7723 or contact us through our website at www.aspjj.com. Internationally, call your local ASP Customer Support Representative.

STERRAD® 100NX™ Cycle Selection Table

STANDARD CYCLE: 47 Minutes*

The STANDARD Cycle should be selected for instruments that meet the criteria below:

- General medical instruments (metal and nonmetal, including hinged devices).
- Instruments with single-channel stainless steel lumens having an internal diameter 0.7 mm or larger and a length of 500 mm or shorter.
- Polyethylene and Teflon® lumen tubing with an internal diameter of 1 mm or larger and length of 1000 mm or shorter.

Instrument sets that can be sterilized in the STANDARD Cycle include, but are not limited to:

- > Arthroscope and laparoscopic instrument sets
- > Eye instruments
- > Cystoscope instruments
- > Rigid or semi-rigid ureteroscopes
- > Cameras and light cords
- > Rechargeable batteries
- > Doppler cords and defibrillator paddles
- > Orthopedic drills and saws
- > Ultrasound probes/transducers

EXPRESS CYCLE: 24 Minutes*

The EXPRESS Cycle should be selected for instruments that meet the criteria below:

- General medical devices requiring surface sterilization, or sterilization of instruments with hinged stainless steel and titanium surfaces.

Items that should NOT be processed in the EXPRESS cycle:

- Items made of nylon, polyurethane, or Kraton®.
- Items with mated/hinged surfaces made of Delrin®, Ultem®, Radel®, or anodized aluminum.

Instruments that can be sterilized in the EXPRESS Cycle include, but are not limited to:

- > da Vinci® endoscopes
- > Rigid or semi-rigid endoscopes without lumens
- > General surgery devices without lumens
- > Rechargeable batteries
- > Eye instruments without lumens
- > Ultrasound probes/transducers

*Cycle times are approximate.

DUO CYCLE: 60 Minutes*

The DUO Cycle should be selected for instruments that meet the criteria below:

- Single channel flexible endoscopes with an internal diameter of 1 mm or larger and a length of 875 mm or shorter, or non-lumened scopes.
- Process a maximum of 2 scopes with light cords at one time.
- Place venting/immersion caps on flexible scopes according to the manufacturer's instructions.
- Accessory light cords and cameras.

Flexible endoscopes and accessories that can be sterilized in the DUO Cycle include, but are not limited to:

- > Bronchoscopes
- > Hysteroscopes
- > Cystoscopes
- > Flexible ureteroscopes
- > Choledochoscopes
- > Thorascopes
- > Intubation fiberscopes
- > Light cords
- > Cameras

FLEX CYCLE: 42 Minutes*

The FLEX Cycle should be selected for flexible endoscopes that meet the criteria below:

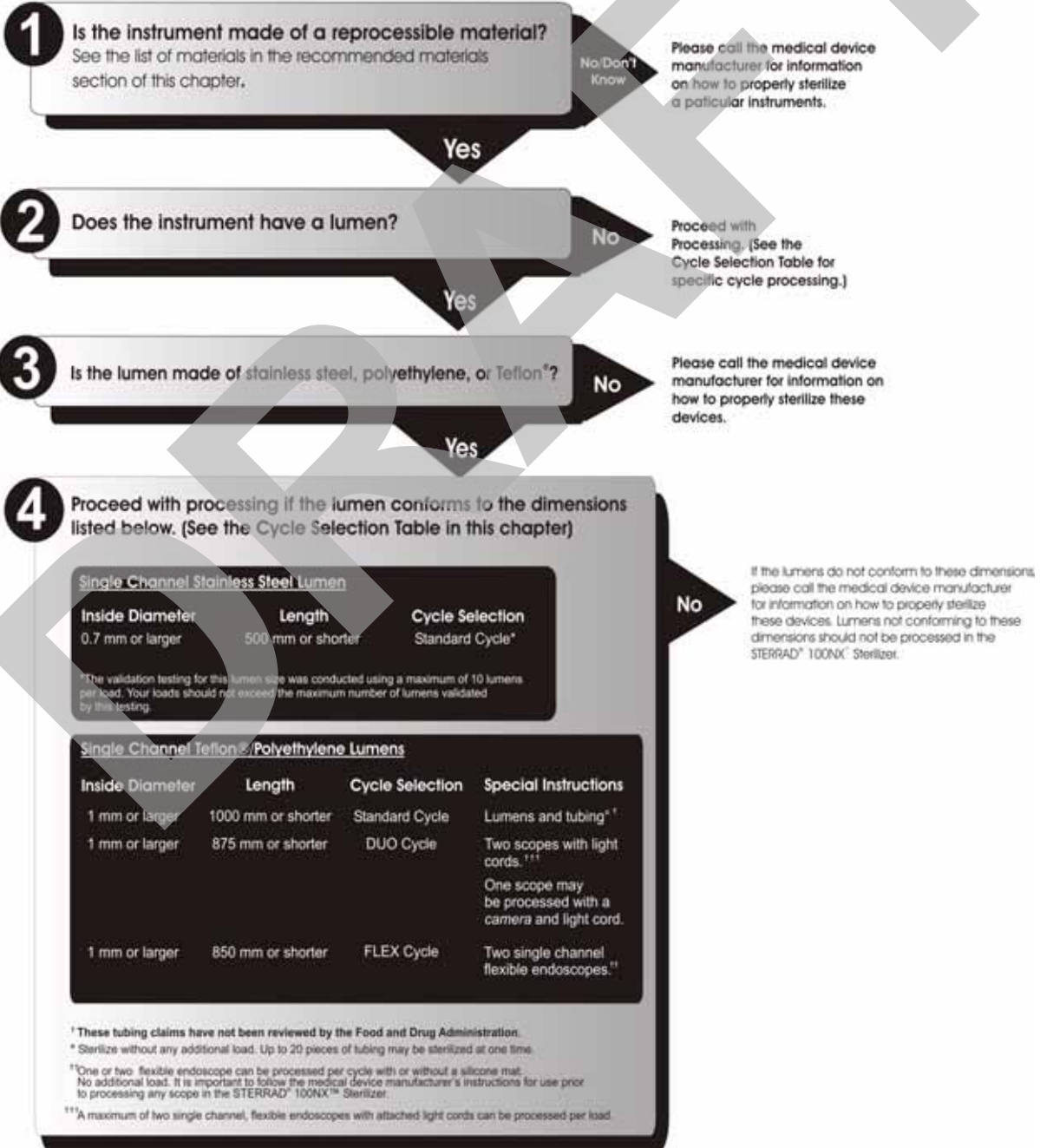
- Single channel or non-lumened endoscopes only.
- Internal diameter 1 mm or larger and a length of 850 mm or shorter.
- Process a maximum of 2 scopes at one time.
- No additional items may be processed with the scopes.
- Place venting/immersion caps on flexible scopes according to the manufacturer's instructions.

Flexible endoscopes that can be sterilized in the FLEX Cycle include, but are not limited to:

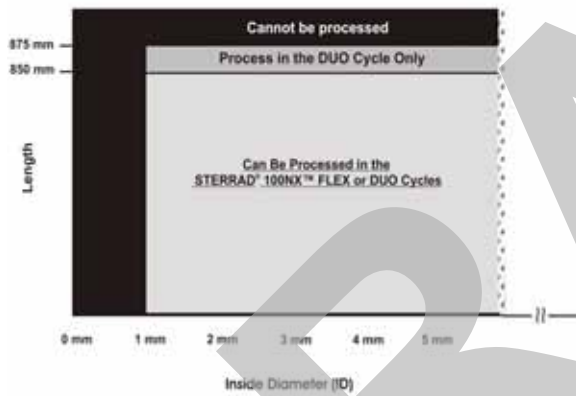
- > Bronchoscopes
- > Hysteroscopes
- > Cystoscopes
- > Flexible ureteroscopes
- > Choledochoscopes
- > Thorascopes
- > Intubation fiberscopes

2 Load Preparation

How To Determine What Can Be Sterilized In The STERRAD® 100NX™ Sterilizer



Processing Single-Channel Flexible Endoscopes With Polyethylene and Teflon® Lumens Only In The STERRAD® 100NX™ Sterilizer*



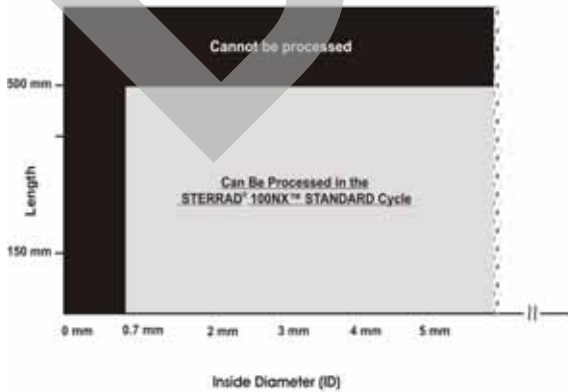
*One or two single-channel flexible endoscope can be processed per cycle with or without a silicone mat. No additional load (Flex Only). It is important to follow the medical device manufacturer's instructions for use prior to processing any scope in the STERRAD® 100NX™ Sterilizer.

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	.118	9.0	11
3.333	.130	10.0	10
3.667	.143	11.0	9
4.0	.157	12.0	8
4.333	.169	13.0	7
4.667	.182	14.0	*
5.0	.197	15.0	*
5.333	.210	16.0	*
5.667	.223	17.0	*
6.0	.235	18.0	*

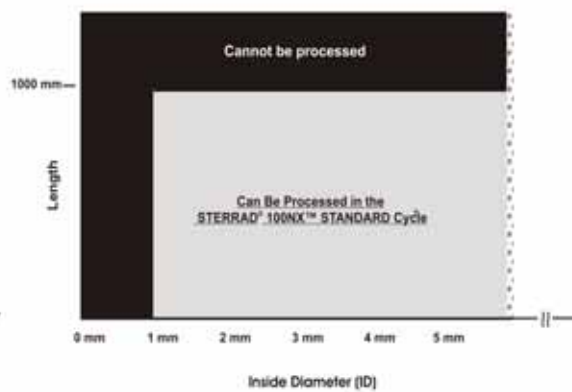
* Not Indicated

Processing Single Channel Stainless Steel Lumens In The STERRAD® 100NX™ Sterilizer*



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

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



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

Recommended Materials

There is a wide variety of materials and devices that may be sterilized in the sterilizer. The materials listed below are commonly found in medical devices and represent typical classes of materials used to construct medical devices. The items marked with an asterisk (*) may have limited life after repeated sterilization.

Please contact ASP Professional Services for more information. Information may also be obtained from the device manufacturer. In the U.S.A., call 1-888-783-7723 or contact us through our website at www.aspjj.com. Internationally, call your local ASP Customer Support Representative.

Thermoplastics

- ◆ Ethylvinyl Acetate (EVA)
- ◆ Kraton® Polymers
- ◆ Liquid Crystal Polymer (LCP)
- ◆ Polyacetal (Delrin® acetal resin)*
- ◆ Polyamide (Nylon)*
- ◆ Polycarbonate
- ◆ Polyetheretherketone (PEEK)
- ◆ Polyetherimide (ULTEM® Polymers)
- ◆ Polyethylene
- ◆ Polymethyl methacrylate (PMMA)*
- ◆ Polyphenylene sulfone (Radel®)*
- ◆ Polypropylene
- ◆ Polystyrene
- ◆ Polytetrafluoroethylene (Teflon®)

Thermoplastic Elastomers

- ◆ Santoprene™

Thermosetting Elastomers

- ◆ Silicone
- ◆ Polyurethane
- ◆ PVC

Glass

Glass

Metal

- ◆ Aluminum
- ◆ Brass
- ◆ Gold
- ◆ Stainless steel
- ◆ Titanium

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 hinged/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.
- ◆ Devices with dead-end lumens.

- ◆ Devices with internal parts, such as sealed bearings, that cannot be immersed, may present difficulties in cleaning and should not be processed in the STERRAD® 100NX® Sterilizer.
- ◆ Implants for which the manufacturer has not specifically recommended sterilization in the STERRAD® 100NX® Sterilizer.

Do Not Process in the EXPRESS Cycle

- ◆ Items made of nylon cannot be processed in the EXPRESS Cycle.
- ◆ Items made of Kraton® cannot be processed in the EXPRESS Cycle.
- ◆ Items made of Polyurethane cannot be processed in the EXPRESS Cycle.
- ◆ Items with mated Delrin® surfaces cannot be processed in the EXPRESS Cycle.
- ◆ Items with mated anodized aluminum surfaces cannot be processed in the EXPRESS Cycle.
- ◆ Items with mated Radel® surfaces cannot be processed in the EXPRESS Cycle.
- ◆ Items with mated Ultem® surfaces cannot be processed in the EXPRESS Cycle.
- ◆ Items with lumens cannot be processed in the EXPRESS Cycle.

Do Not Process in the DUO Cycle

- ◆ Items with mated anodized aluminum surfaces cannot be processed in the DUO Cycle.

Guidelines for Preparing Items to Be Sterilized

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

Cleaning, Rinsing, and Drying

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

- ◆ All items including accessories must be thoroughly cleaned, rinsed, and dried before loading into the sterilizer.
- ◆ Carefully inspect all instruments, devices, and accessories 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, devices, and accessories for flaws or damage prior to packaging. Items with flaws or damage should be replaced or repaired before using.
- ✓ *Note: Periodic careful inspection of items after repeated exposure to disinfectant/cleaner/sterilant is necessary, due to the potential damaging effects of the chemical agents.*

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.

- ◆ **Clean** 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.
- ◆ **Rinse** 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.

- ◆ **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 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 surface of the load after the cycle is complete. 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 gloves when handling items from any load containing moisture.

Packaging and Loading

If you choose to package the instruments (highly recommended), proper use and 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.

Special considerations for loading and processing flexible endoscopes are presented at the end of this chapter.

Instrument Trays

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

Tray Mats

- ◆ Instrument trays should only be padded with STERRAD® Instrument Mats or polypropylene sterilization wrap. **Never use** linen, cellulose, or any materials listed in the “Items Not To Be Processed” section.
- ◆ Follow the *Instructions for Use* included with the STERRAD® Instrument Mats to determine the number of mats that can be used at one time in the chamber. Do not use more than the recommended amount of mat material in the chamber at any time.

<u>Cycle Name</u>	<u>Square Centimeters</u>	<u>Square Inches</u>
STANDARD	2250	349
DUO	2774	430
FLEX	2250	349
EXPRESS	1387	215

- ◆ 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. Tyvek® Pouches and Rolls with STERRAD® Chemical Indicators are the only pouches and rolls available on the market that are validated by ASP. They are the only pouches and rolls validated by ASP for efficacy and stability.

- ◆ 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. In the USA, use only FDA-cleared polypropylene wraps.
- ◆ Properly arrange the items or the scope in a tray to ensure adequate 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® 100NX® Sterilizer, follow the Instructions for Use provided by the rigid container manufacturer. Verify that the rigid containers are cleared for use in each sterilization cycle. Remember the following:
 - ◆ 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.

STANDARD and FLEX Cycles Loading Preparation

- ◆ The STERRAD® 100NX® Sterilizer STANDARD and FLEX Cycles were validated using a load weight of 4.9 kg (10.7 lbs) per shelf. When constructing your load, the total weight of the load to be sterilized should not exceed 9.7 kg (21.4 lbs).

DUO Cycle Loading Preparation

- ◆ The STERRAD® 100NX® Sterilizer DUO Cycle was validated using a total load weight of 6.0 kg (13.2 lbs). When constructing your load, the total weight of the load to be sterilized should not exceed 6.0 kg (13.2 lbs).

EXPRESS Cycle Loading Preparation

- ◆ The STERRAD® 100NX® Sterilizer EXPRESS Cycle was validated using a load weight of 4.9 kg (10.7 lbs) on the bottom shelf only. When constructing your load, the total weight of the load to be sterilized should not exceed 4.9 kg (10.7 lbs).



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 25 mm (1 inch) of space between the load and the electrode.

Chemical Indicators

STERRAD® Chemical Indicator Strips and STERRAD® SEALSURE® Chemical Indicator Tape offer a method to verify that the load has been exposed to hydrogen peroxide in the sterilizer. Chemical indicators are not a substitute for biological indicators. If you use chemical indicator strips or chemical indicator tape, follow the *Instructions for Use* that accompany these items as you prepare the load.

- ◆ Place STERRAD® Chemical Indicator Strips inside trays and Tyvek® pouches or follow your facility's procedures.
- ◆ Secure all wraps with STERRAD® SEALSURE® Chemical Indicator Tape.
- ◆ Do not use chemical indicators or tape 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 sterilizer. Take special care to confirm that venting caps are placed according to the manufacturer's 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, you *must remove* the immersion cap prior to processing. If the immersion cap is not removed prior to processing, it will damage the scope due to the inability to properly vent.

2 *Load Preparation*

FLEX Cycle: A maximum of 2 flexible endoscopes can be processed per load, with or without silicone mats. Do not add any additional items to the load.

DUO Cycle: A maximum of 2 flexible endoscopes can be processed per load, with or without silicone mats. You can also process 1 flexible endoscope with its light cord and a camera.



CAUTION: RISK OF DAMAGE TO LOAD

Prior to processing flexible endoscopes in the STERRAD® 100NX® Sterilizer, please contact the medical device manufacturer, or ASP Professional Services at 1-888-STERRAD.

Chapter 3.

Operation

Before You Start

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

Start and Warm-up

1. Turn on the main power switch located on left front side panel (as you face it) of the sterilizer.
2. The sterilizer begins by warming up. The warm-up can take up to 1 hour.
✓ Note: *The sterilizer should not be turned off during warm-up.*
3. “Touch Screen to Start” appears on the display when the sterilizer is ready for use.

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® 24 Biological Indicator. Contact your ASP Representative regarding biological indicators specifically designed for use in the STERRAD® 100NX® Sterilizer.

Place a STERRAD CYCLESURE® 24 Biological Indicator in the chamber at the back of the bottom shelf. Biological testing should be performed at least once per day or as specified by your facility’s policy. Review the *Instructions For Use* included with the biological indicator to ensure its proper use.

Login

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

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

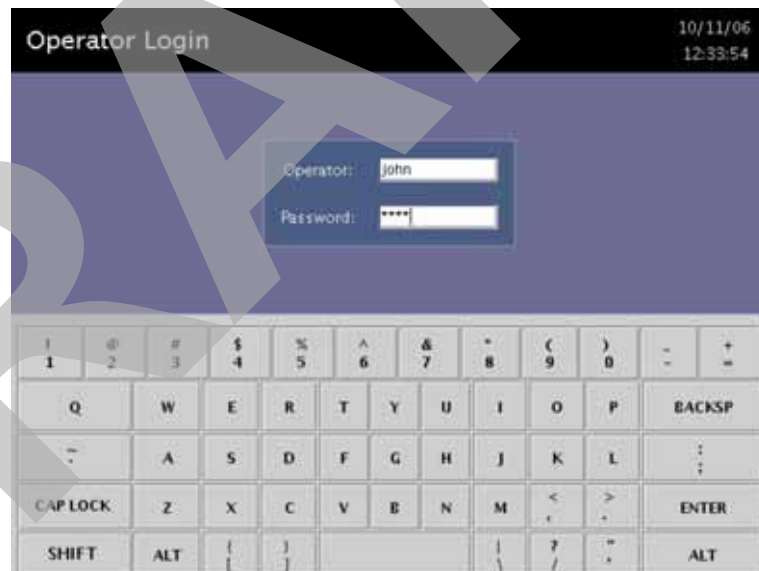


Figure 1. Operator Login Screen.

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

Entering Load Information

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

Enter Load Item Data

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

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

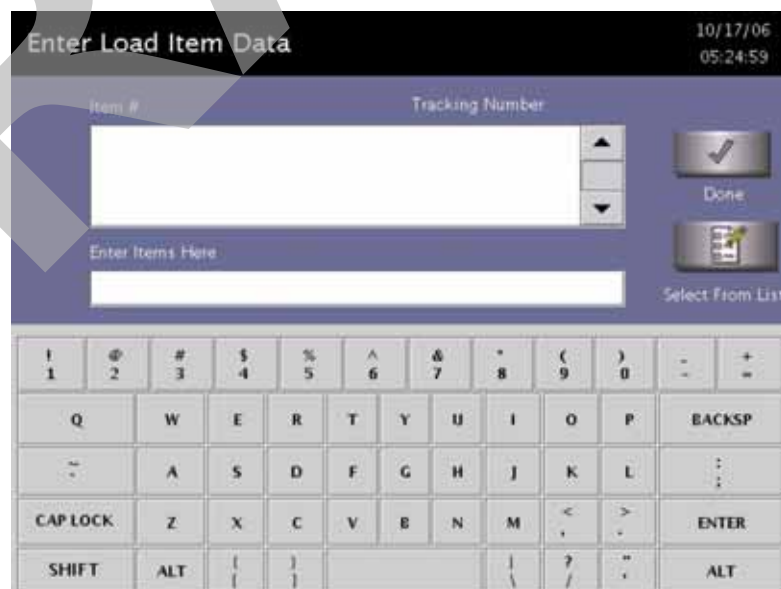


Figure 2. Enter Load Item Data.

1. To enter items not in the database, type the item information in the “Enter Items Here” field. Touch **ENTER** to accept the item. Repeat for additional items always touching **ENTER** after each item. Touch **Done** when the list is complete.
2. An optional barcode scanner can be used to enter load item data. You may use this feature if your sterilizer is equipped with this option.

Select From List

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

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

Cycle Notes

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

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



Figure 3. 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 is blocked, etc., a message is displayed on the screen.
5. The program displays the **System Ready** screen.
6. Touch **Back** to return to the previous screen.

Loading the Chamber

✓ *Note: The door is equipped with a safety mechanism that prevents it from closing if it encounters an obstruction. If this occurs, the door stops immediately. You must use the touch screen to open the door.*

1. Open the active chamber door by pressing the Open Door foot pad, or by touching **Open Door** on the display, and place your load on the shelves.



Figure 4. Touch the Foot Pad to Open the door.

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

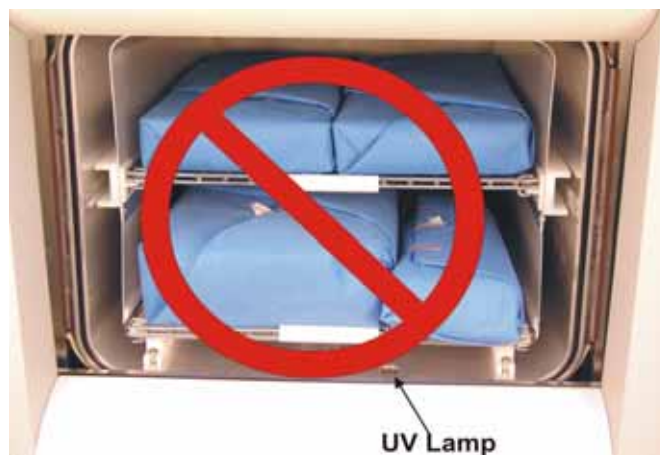


Figure 5. Do Not Block the UV Lamp.

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



Figure 6. 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 7. Do NOT Stack Trays.



Figure 8. Load Correctly Placed for STANDARD Cycle Processing



Figure 9. Load Correctly Placed for DUO and FLEX Cycle Processing

5. When you are finished loading the chamber, close the door by tapping the foot pad or pressing the **Close Door** button on the touch screen.
6. If a message requesting that the door be closed is displayed, the door is not securely closed. Make certain that nothing is caught in the door seal.

Loading Requirements for the EXPRESS Cycle

Only the bottom shelf of the STERRAD® 100NX® Sterilizer should be used when processing loads in the EXPRESS Cycle. The following figure shows a correctly placed load.



Figure 10. Load Correctly Placed for EXPRESS Cycle Processing

Selecting and Starting a Cycle

When the load has been placed in the chamber, and the door has been closed, use the System Ready screen to start the cycle. The following display shows all the cycles available for the STERRAD® 100NX® Sterilizer. You may have one or more cycles installed and enabled on your system. Make sure you understand the differences in the cycles and what types of materials can be sterilized in each cycle

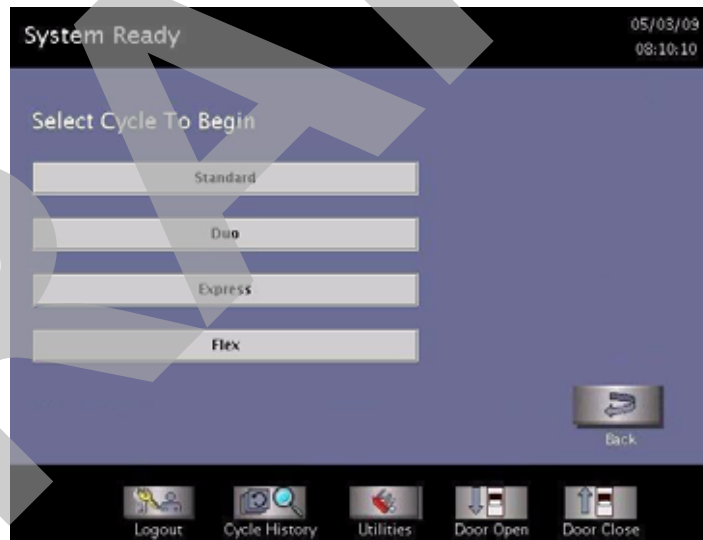


Figure 11. Touch the Screen to Start Your Cycle.

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.

Touch your choice of cycle from those displayed and then touch confirm to start the cycle; the cycle starts.

- ✓ *Note: When alternating between cycle types, the system needs a few minutes to adjust. This adjustment period does not apply when processing consecutive STANDARD and FLEX, or DUO and EXPRESS Cycles.*
- ✓ *Note: If a cycle installed on your system does not appear on the cycle selection screen, this cycle may have been disabled by the supervisor. See Supervisor Level information to learn how to enable/disable an installed cycle.*

System Ready Screen

The System Ready screen displays a number of buttons allowing you to select cycles based on the cycles that are loaded and enabled on your sterilizer.

Cycle Types

- ◆ **STANDARD** cycle sterilizes the load in about 47 minutes. This cycle is installed on all systems.
- ◆ **DUO** cycle is for sterilization of flexible endoscopes with their light cords and cameras. It sterilizes the load in about 60 minutes.
- ◆ **FLEX** cycle is specifically designed for flexible endoscopes and sterilizes the load in about 42 minutes.
- ◆ **EXPRESS** cycle is for surface sterilization of general medical devices, rigid and semi-rigid endoscopes without lumens; and sterilization of mated stainless steel and titanium devices. It sterilizations the load in about 24 minutes.

Functions

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

Inserting a Cassette

1. Take a new STERRAD® 100NX® Cassette out of the shipping carton.
2. Look at the package carefully before opening it. The indicator strip should be white. **If the indicator strip is red, or if you see droplets of moisture, do not open the package** – it is possible that hydrogen peroxide has leaked inside the package. Refer to the cassette *Instructions for Use* for proper handling instructions.
3. If the indicator strip is white, open the cassette package.
4. Position the cassette so that the arrows are pointing towards the sterilizer.

5. Insert the cassette into the cassette slot until it stops moving. **Do not use force** to push the cassette into the machine.



Figure 12. Inserting the Cassette into the Slot.

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

Cycle in Progress

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

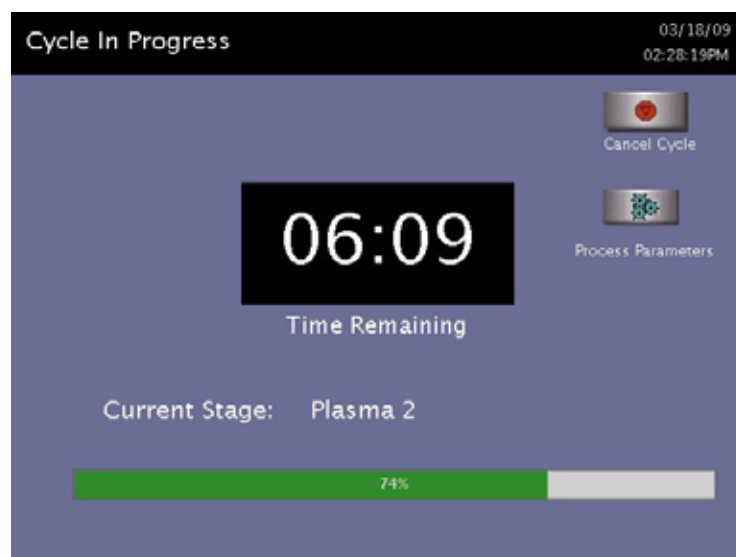


Figure 13. Cycle In Progress. The Countdown Clock is Displayed.

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 printouts 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.

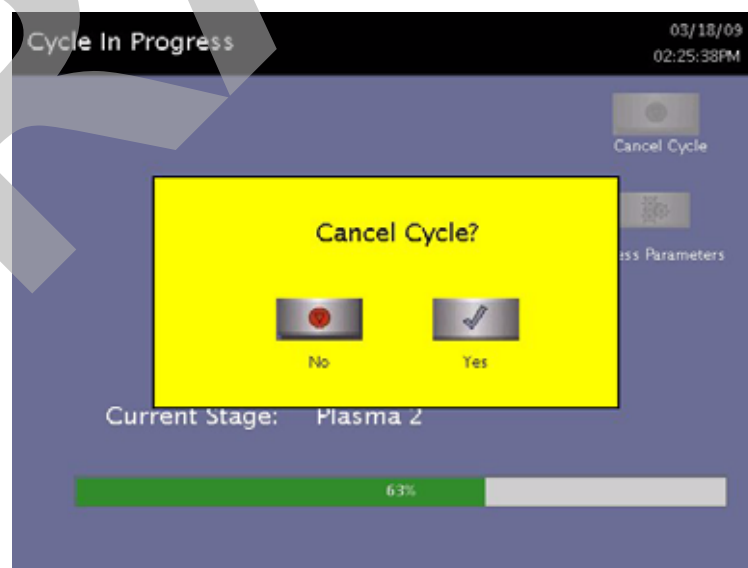


Figure 14. Cancel Cycle Confirmation. Touch Yes or No.

2. Touch **No** to continue with the cycle. Touch **Yes** 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.

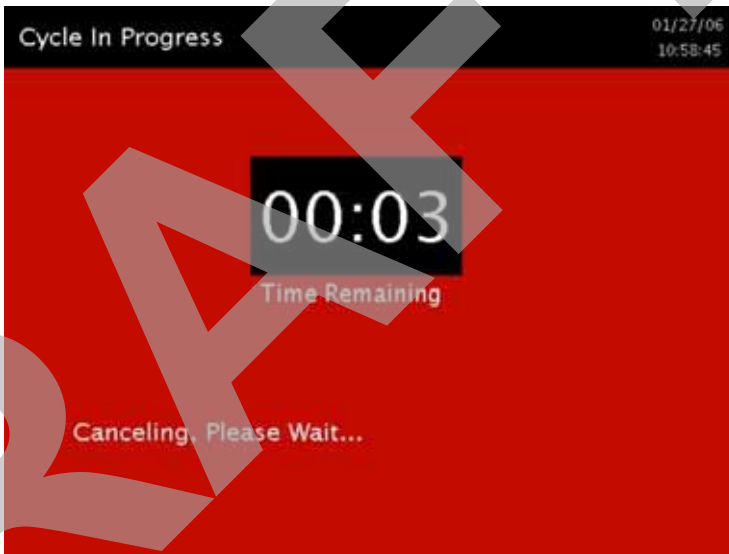


Figure 15. Cycle Cancellation In Progress. Cancellation Has Been Confirmed.

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



WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.

If a cycle cancels and the items in the load appear wet, hydrogen peroxide may be present. Wear chemical resistant latex, PVC (vinyl), or nitrile gloves while removing the items from the chamber, and while wiping off the items with a damp cloth. Discard contaminated cloth according to your facility's procedures.

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.

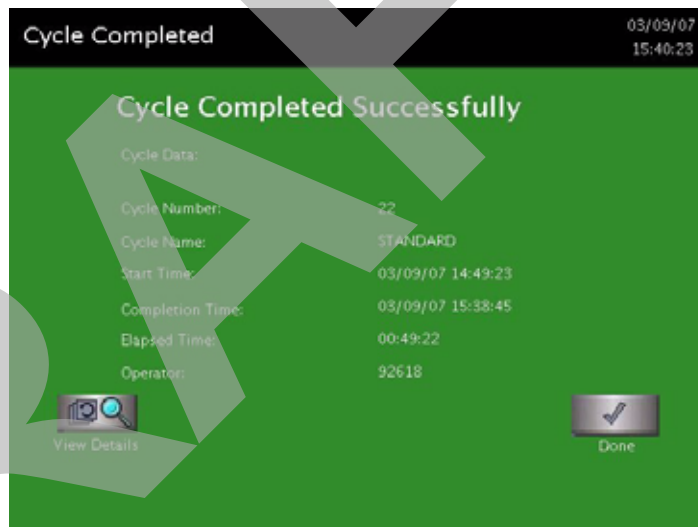


Figure 16. Successful STANDARD Cycle Completed.

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

Processing a Sterilized Load

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

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



WARNING! HYDROGEN PEROXIDE MAY BE PRESENT

If white residue is visible on the load, this is 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.

- ◆ Refer to the cycle completion flowcharts for additional information.

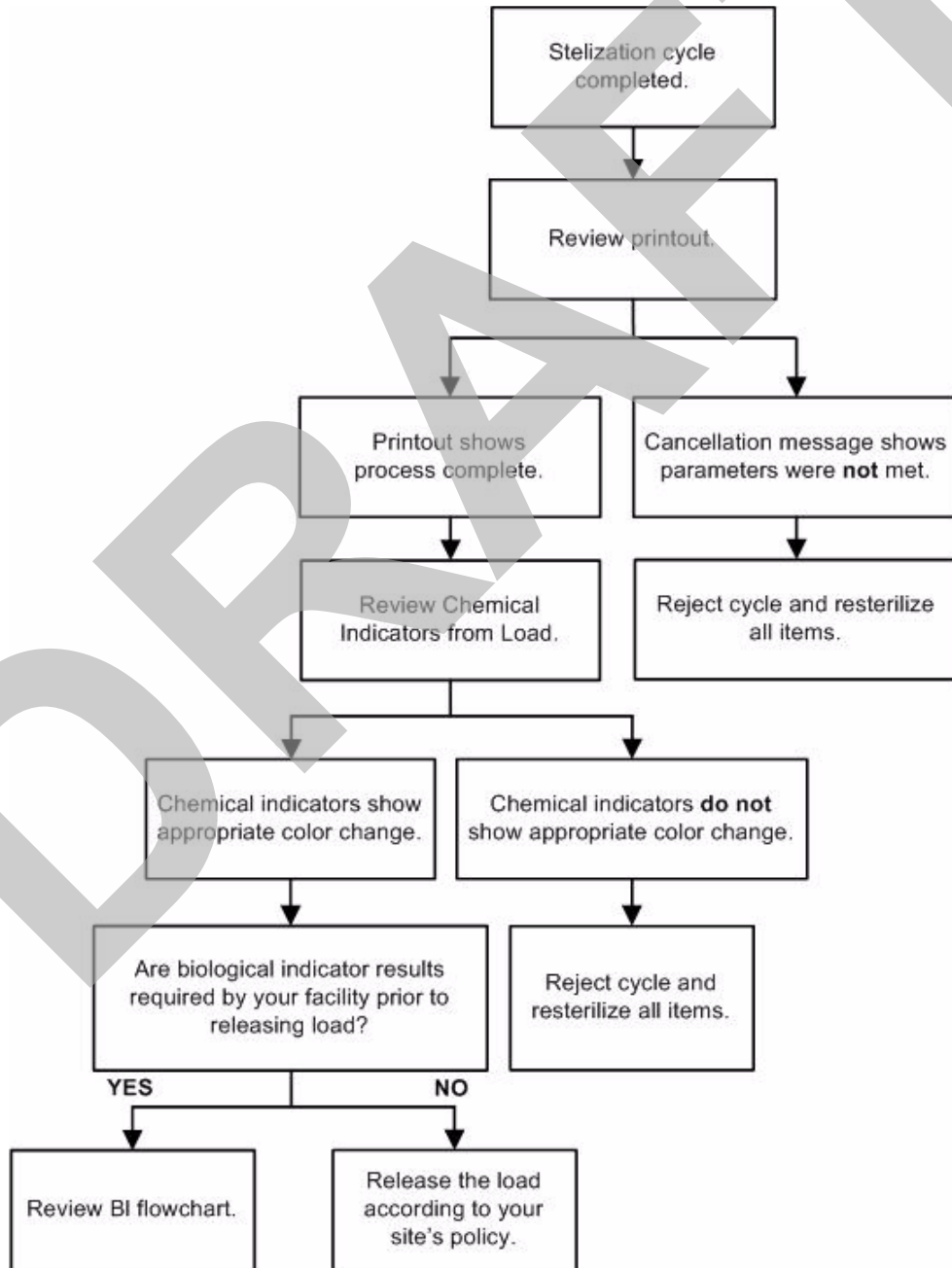
Inspecting Chemical Indicators

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

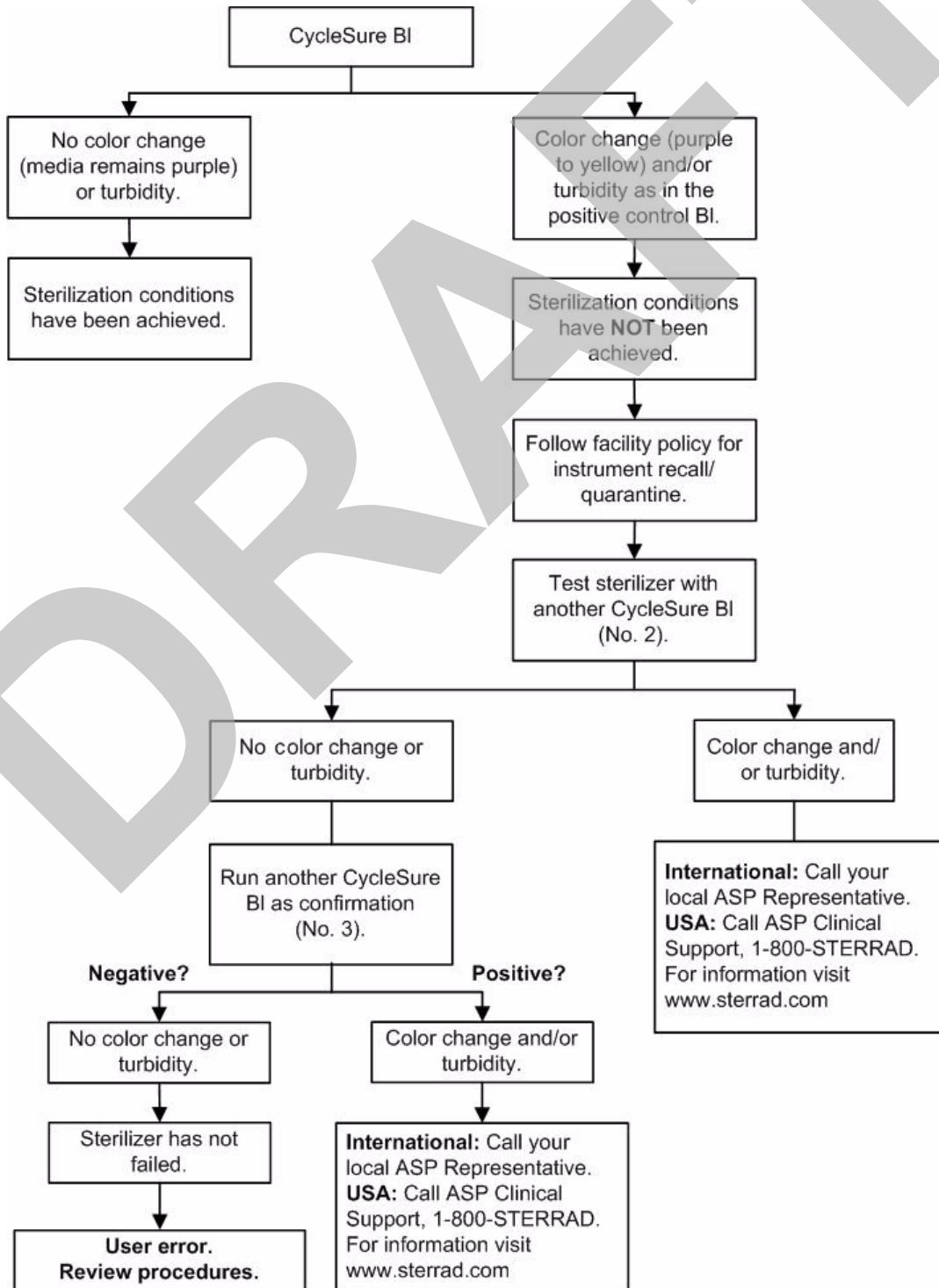
Processing Biological Indicators

Remove the biological indicator from the load and process it per its *Instructions for Use*. Refer to the flowcharts on the following pages for additional information.

Cycle Completion Flowchart



STERRAD® CYCLESURE® 24 Biological Indicator Flowchart



Chapter 4.

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 return the sterilizer to normal operation. Because load related issues are the most frequent cause of cycle cancellation, the easiest solution is to repackage the load and restart the sterilizer when a cycle cancels. Be sure to replace biological and chemical indicators with new ones. In other cases, the problem may be caused by a component failure that requires adjustment or repair by an ASP Service Representative. Call ASP Professional Services at 1-888-STERRAD (1-888-783-7723). Outside the USA, call your local ASP Customer Support Representative.

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

Running Diagnostics

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

System Message Table

Temperature Messages



WARNING! HOT SURFACES.


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

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




Messages Not In This Table




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

If this message appears . . .	Do this . . .
Cannot Dispose Cassette, Run Diagnostics	The cassette did not drop into the disposal box. Remove the load and run diagnostics.
Cannot Eject Cassette, Run Diagnostics	The cassette did not eject out the cassette slot. Remove the load and run diagnostics.
Cassette Accepted, Positioning	No action required.
Cassette Detected, Verifying	No action required.
Cassette Did Not Index	A cassette was unable to advance to the next cell. Remove the load and run diagnostics.
Cassette Expired, Disposing Cassette	Insert a new cassette.
Cassette Expiry Found During Start Cycle	The cassette was found to be expired when the Start Cycle button was pressed. Dispose of the cassette and insert new cassette.
Cassette Out Of Date, Disposing Cassette	The cassette has been in the sterilizer for 10 days or the cassette has expired. Insert new cassette.


If this message appears. . .	Do this . . .
Cassette System Timeout When Piercing	The delivery subsystem is not responding. Remove the load and run diagnostics.
Cassette Used, Disposing	The inserted cassette does not have any unused cells remaining. Insert a new cassette.
Control Available On Other Side	Use the other side of the sterilizer to access the touch screen.
Cycle Canceled By Operator	The operator canceled the cycle. Repackage the load. Restart the cycle after cancellation is complete.
Delivery System Not Ready	Delivery system not responding. Remove the load and run diagnostics.
Disposing Cassette	No action required.
Door Opened	Door open sensor malfunction. Remove the load and run diagnostics.
Door Sensor Fault	Door malfunction. Reboot the system. If the message persists, call your ASP Representative.
Function Available on Other Side Only	Control of the sterilizer is on the other side of the unit.
H ₂ O ₂ Adjustment In Progress	The intensity of the UV lamp is being adjusted. Wait 5 minutes for adjustment to be completed.
H ₂ O ₂ Bulb Warming Up, Please Wait. . .	No action needed.
H ₂ O ₂ Bulb/Detector Fault	H ₂ O ₂ detector malfunction. Run diagnostics.
H ₂ O ₂ Curve Area Too Low. Verify That The Load Is Not Blocking The UV Light Path	Load is absorbing too much peroxide. Remove absorbing materials from the load, repackage, and restart the cycle. If the problem persists, call your ASP Representative.
H ₂ O ₂ Monitor Failure	H ₂ O ₂ bulb or detector malfunction. Remove the load and run diagnostics.
 <p>WARNING! HYDROGEN PEROXIDE MAY BE PRESENT. <i>Wear chemical resistant latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.</i></p>	
H ₂ O ₂ Peak Too Low	The load is absorbing too much peroxide. Remove the absorbent materials from the load, repackage, and restart the cycle. If the problem persists, call your ASP Representative.
H ₂ O ₂ Rate Constant Too High	The load is decomposing the H ₂ O ₂ . Check the load for absorbent materials. Repackage, and restart the cycle. If the problem persists, call your ASP Representative.

4 Troubleshooting

If this message appears. . .	Do this . . .
 <p>WARNING! HYDROGEN PEROXIDE MAY BE PRESENT. <i>Wear chemical resistant latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.</i></p>	
H ₂ O ₂ Rate Outside the Calibrated Range	Reboot the system. If the problem persists, call your ASP Representative.
H ₂ O ₂ Sensor Fault	Reboot the system. If the problem persists, call your ASP Representative.
High Plasma Power	The plasma power is out of specification. Remove the load and run diagnostics.
Invalid Key Code. Please Enter A Valid Code	Press the OK button and reenter a valid key code.
Invalid Load Items File	Press the Back button and reinsert the USB memory stick.
Less Number of Cells Available, Please Dispose the Cassette	The system will automatically move the cassette to the disposal box.
 <p>WARNING! HYDROGEN PEROXIDE MAY BE PRESENT. <i>Wear chemical resistant latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.</i></p>	
Load May Contain H ₂ O ₂	Residual peroxide may be present on the load or chamber walls due to a cancelled cycle or system malfunction. Wearing chemical resistant latex, PVC (vinyl), or nitrile gloves, repackage the load and restart the cycle. If the problem persists, call your ASP Representative.
 <p>WARNING! HYDROGEN PEROXIDE MAY BE PRESENT. <i>Wear chemical resistant latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.</i></p>	
Low Plasma Power	The plasma power is out of specification. Remove the load and run diagnostics.
Memory Card Full	Initiate backup to the memory card or press OK and the system will delete the oldest file.
No File Found	Press OK. Reinsert the USB memory stick.
Other Door Is Open	Close the door on the other side of the sterilizer.
Please Close Door	Touch the close door display or the door foot pad to close the door.

If this message appears. . .	Do this . . .
Please Enter Valid User Name and Password	After the valid user name and password are entered, press OK.
Please Insert New Cassette	Insert a new, unused cassette.
Please Remove Cassette And Verify Cassette Type	Wrong cassette type. Confirm that the cassette is a STERRAD® 100NX® cassette.
Please Wait While Graph Loads	No action required.
 <p>WARNING! HYDROGEN PEROXIDE MAY BE PRESENT. <i>Wear chemical resistant latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.</i></p>	
Power Fail Cancellation	A power failure occurred during a cycle. Repackage the load and restart the cycle. If the problem persists, call your ASP Representative.
 <p>WARNING! HYDROGEN PEROXIDE MAY BE PRESENT. <i>Wear chemical resistant latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.</i></p>	
Pressure Check Failed	Load is absorbing too much peroxide. Remove absorbing materials from the load, repackage, and restart the cycle. If the problem persists, call your ASP Representative.
Pressure Out Of Range (High)	Vacuum system malfunction. Remove the load and run diagnostics.
Pressure Out Of Range (Low)	Vacuum system malfunction. Remove the load and run diagnostics.
Printer Is Out Of Paper. Please Load A New Roll.	Load paper into the printer.
Printing Is In Progress	No action required.
RFID Data Error, Ejecting Cassette, Verify Cassette Orientation	Cassette will automatically eject. Insert a valid cassette
Stage Timeout	Remove the load and run diagnostics.
 <p>WARNING! HYDROGEN PEROXIDE MAY BE PRESENT. <i>Wear chemical resistant latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.</i></p>	

4 Troubleshooting

If this message appears. . .	Do this . . .
Unable to Evacuate Chamber . . . Ensure Load is Dry before Starting Cycle	Remove the load and run diagnostics. Reboot the system. If the problem persists, call your ASP Representative.
Unable to Open One Second Data File	Replace the PCMCIA card with a new one.
UV Path Is Blocked, Open Door And Clear Pathway	Object is blocking the UV path. Verify that the shelves and/or the load are not blocking the path. If the problem persists, call your ASP Representative.
Warming Up, Please Wait...	No action needed.
 <p>WARNING! HYDROGEN PEROXIDE MAY BE PRESENT. <i>Wear chemical resistant latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.</i></p>	
Would You Like to Troubleshoot?	Remove the load and run diagnostics. If the problem persists, call your ASP Representative.

Call Your ASP Representative

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

Chapter 5.

Sterilizer Overview

Sterilizer Cycles

The following display shows all the cycles available for the STERRAD® 100NX® Sterilizer. This guide contains detailed instructions for each cycle. Make sure you understand the differences in the cycles and what types of instruments can be sterilized in each cycle.

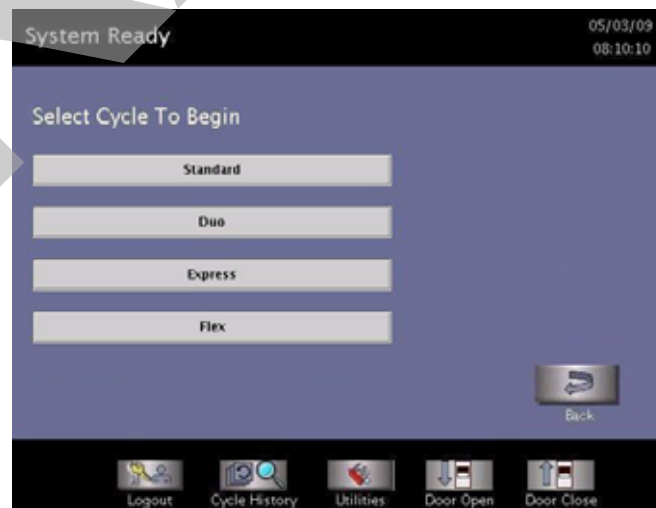


Figure 17. Select Cycle Display Showing All Cycles. Your display may be different depending on the cycles installed and enabled for use. Supervisor Access is required to enable installed cycles.

Sterilizer Features

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

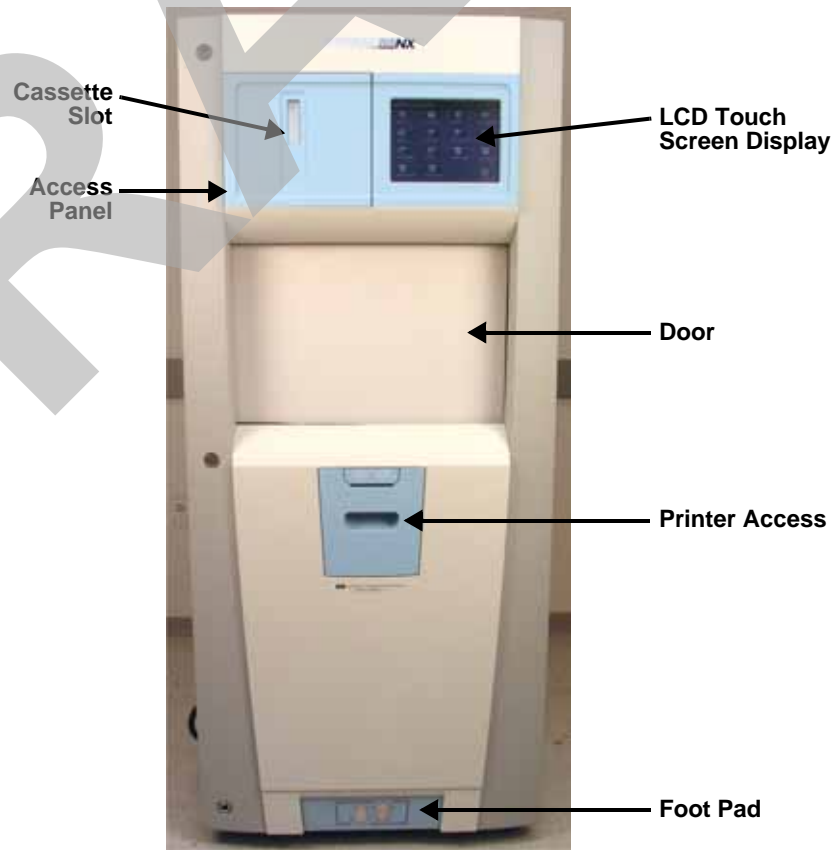


Figure 18. The STERRAD® 100NX® Sterilizer.
Not shown: The power switch is at the lower left and the USB port is at the lower right.

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

- ◆ The items to be sterilized are placed on the shelves and the door is closed using either the close door button on the touch screen or by tapping the foot pad with your foot. The foot pad is located on the lower portion of the front panel.

Load information and cycle notes are entered if desired, a cycle is selected and the chosen cycle is then started. At the conclusion of the cycle the items are removed and are ready for storage or immediate use.

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

Cassette

The cassette contains sealed capsules of hydrogen peroxide solution. Each cassette has coded information that provides displayed details on the cassette expiration date, manufacturer, and cell status including cycle completion information. The sterilizer pulls the cassette through the slot and moves it into the machine, keeping it there until the cassette has been used.



Figure 19. Inserting a Cassette.



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 while removing items from the sterilizer following a cancelled cycle. Following a cancelled cycle, if items in the load show any visible moisture or liquid, hydrogen peroxide may be present.

Cassette Disposal Box

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



Figure 20. Cassette Disposal Box.

Touch Screen and Speaker

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



Figure 21. Using the Touch Screen.

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

Chamber

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



Figure 22. The STERRAD® 100NX® Chamber Empty and With a Typical Standard Cycle Load Correctly Placed.

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

Printer

The sterilizer has an integrated internal printer located in the front panel. On two door units, a printer is located in the main panel on each side. The printer prints cycle reports and other information on a roll of thermal paper. The printer features easy, drop-in paper loading and requires no ink cartridges. (The system is also designed to interface to a second, external printer that is USB-compliant and supports PCL-3 protocol.)

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



Figure 23. STERRAD® 100NX® Printer Paper Advance Button.

Touch Screen Data Entry

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

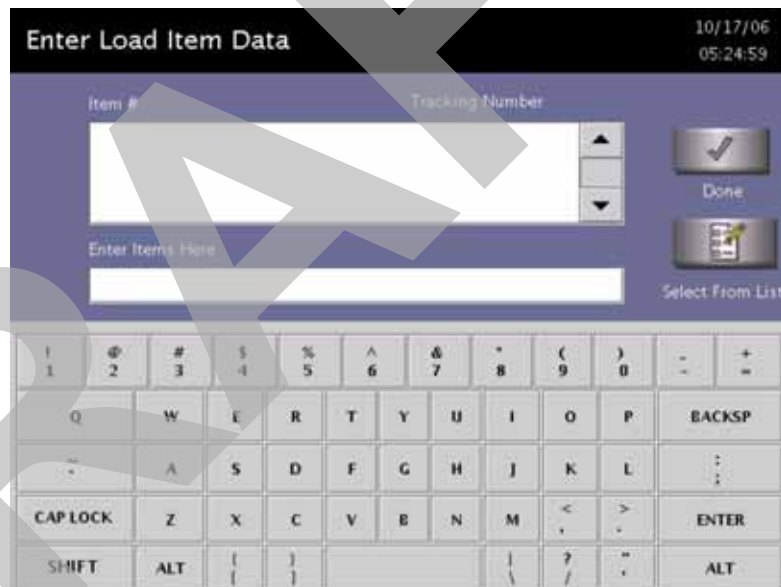







Figure 24. Example of a Data Entry Screen.

Function Buttons

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

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.

Chapter 6.

Maintenance

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

Automatic Maintenance

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

Automatic Lamp Adjustment

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

Manual Maintenance

The following maintenance procedures are performed by the user:

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

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

Disposing of Cassettes

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

Removing a Cassette Disposal Box



WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.

Wear chemical resistant latex, PVC (vinyl), or nitrile gloves. This will protect you from contact with any residual hydrogen peroxide that may be present in the cassettes.

1. Open the cassette access door. Pull the tab on the cassette disposal box to more easily slide it completely out.



Figure 25. Open the Access Panel and Remove the Used Cassette Box.

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



Figure 26. Pinch the Edge of the Lid to Close the Box.

3. Dispose of the closed cassette box according to your facility's policy.

4. Insert a new box making sure the lid is open and not caught in the opening, and the tab is facing you.

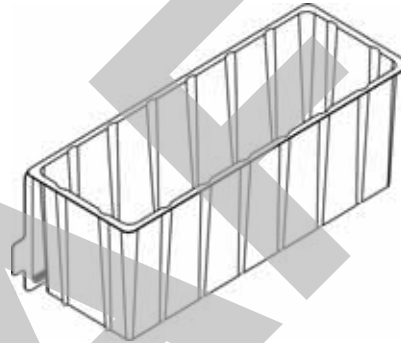


Figure 27. Insert the New Cassette Box with the Lid Open so the Tab is on the Left.

5. Close the access panel.

Replacing the Printer Paper

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

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



Figure 28. Open the Printer.

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



Figure 29. 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 30. 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.

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

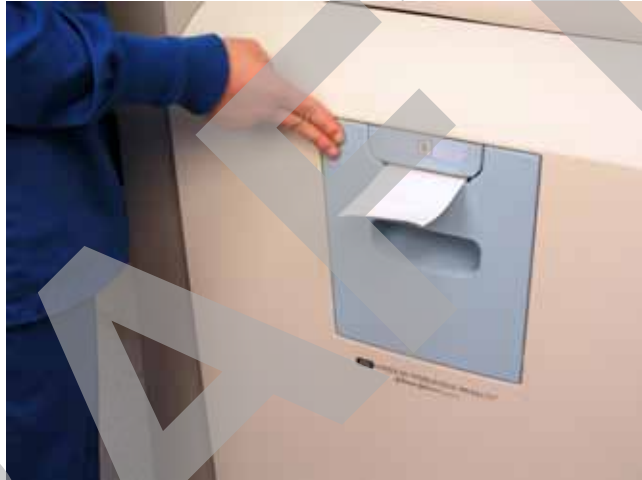


Figure 31. Make sure the Printer Door Latches Securely and the Paper is in Place.

7. Press the paper advance button. Check the alignment of the paper and make certain it does not jam or misfeed.



Figure 32. Press the Paper Advance Button.

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

Cleaning the Sterilizer Exterior

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

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

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

Cleaning the Hydrogen Peroxide Monitor Detector Lens

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



Figure 33. Cleaning the Hydrogen Peroxide Monitor Lens.

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

PCMCIA Card Handling and Replacement

The PCMCIA card contains the flash memory used to store cycle data. It should not be removed arbitrarily. If you need to remove or replace it, use the following steps:

1. Turn off the sterilizer, or go to the “Additional Utilities” menu and press the PCMCIA button. Either method allows you to safely remove the PCMCIA card.
2. Open the cassette access door.
3. Eject the PCMCIA card by pressing the eject button on the top of the card slot (see the following figure).



Figure 34. Press the Button at the Top of the Card Slot to Eject the PCMCIA Card.

To reinsert the PCMCIA card, do the following:

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

3. Insert the card into the PCMCIA card slot.
4. Press the end of the PCMCIA card until the card is firmly seated in the slot (you will feel a “click” as the card is seated in the connector).



Figure 35. Insert the PCMCIA Card Correctly.

- ✓ *Note: The STERRAD® 100NX® Sterilizer will not operate unless the PCMCIA card is properly installed.*

Data Transfer Using a Memory Stick

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



Figure 36. Insert the Memory Stick into The USB Port.

Rebooting the System

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



Main Circuit Breaker



Figure 37. The Main Power Switch/Circuit Breaker is Located on the Side of the Sterilizer at your Left.

Sterilizer Disposal



Applicable in the EU: All electrical and electronic equipment (including batteries) must be returned to a waste collection system or treatment and recycling facility. Follow decontamination instructions before returning waste. Contact your ASP Representative if you need assistance.

Other Countries: Prior to disposal of the sterilizer, user must follow decontamination instructions. The disposal of infectious waste, electronic circuit boards and other electronic components (including batteries) are regulated in many countries; (e.g., by the US Environmental Protection Agency). Please ensure compliance with all International, Federal, State, and Local regulations before disposal. Contact your ASP Representative for additional information.

DRAFT

Chapter 7.

Reports and Files

Displayed Reports

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

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

Cycle History

Cycle history data is stored in the sterilizer's memory. The memory holds data from the last 200 cycles. After 200 cycles are completed, the oldest cycle history record is overwritten with new data from the 201st 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 38. Select Cycle History File.

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

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

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

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

Parametric Print prints a parameter format report of the selected cycle history file (external printer required).

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

Back returns you to the previous screen.

Printed Reports

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

Short Report

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

Parametric Report

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

Long Report

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

DRAFT

Chapter 8.

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

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

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

- ◆ Select, start, and cancel a cycle.
- ◆ Enter load item information and cycle notes.
- ◆ Print a cycle history report and view cycle history files.
- ◆ Run diagnostics when a cycle cancels.

Supervisor-level access includes all of the privileges of Operator-level access and additionally provides the ability to:

- ◆ Add, delete, and modify user names, passwords, and access levels.

- ◆ Select, view, and print all sterilizer files.
- ◆ Run diagnostic tests and print reports.
- ◆ Set date and time.
- ◆ Configure sterilizer features.
- ◆ 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 39. Additional Utilities Menu.

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

System Config allows you to set sterilizer features.

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

Cassette Functions allows you to automatically dispose a cassette into the collection box or perform the peroxide clearance procedure.

Network allows you to configure a network connection.

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

Service Functions are reserved for use by ASP Service Representatives.

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

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

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

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

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

Product Options allows you to enable or disable certain feature upgrades.

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

Date and Time Settings

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



Figure 40. Date and Time Setting.

Set Date

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

Set Time

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

Time Zone

Scroll through the selections until your time zone is displayed.

Date Format

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

Time Format

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

Cancel/Done

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

System Configuration

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

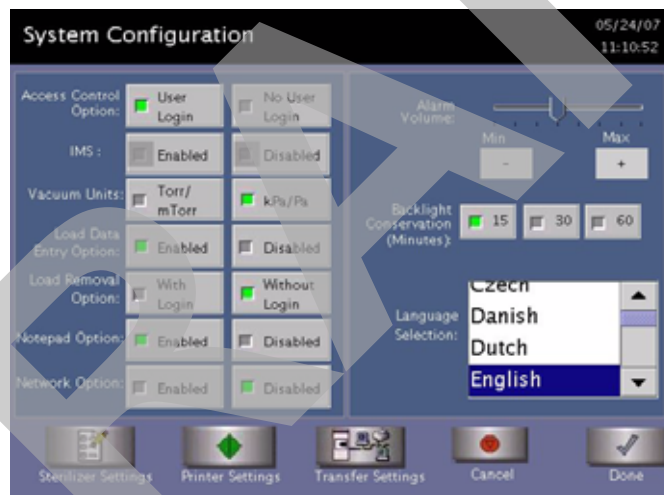


Figure 41. System Configuration.

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.

IMS

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

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

Vacuum Units

Torr/mTorr expresses vacuum measurements in torr and mtorr.

kPa/Pa expresses vacuum measurements in kilopascals and Pascals. This is the factory default setting.

Load Data Entry Option

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

Disabled skips the Enter Load Item Data screen.

Load Removal Option

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

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

Notepad Option

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

Disabled skips the Cycle Notes screen.

Network Option

Enabled allows the sterilizer to transmit data on a network.

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

Alarm Volume

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

Backlight Conservation (Minutes)

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

Language Selection

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

Sterilizer Settings

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

The screenshot shows a mobile application interface titled "System Configuration - Sterilizer Settings". At the top right, the date "05/24/07" and time "11:11:14" are displayed. The main area contains a "Sterilizer Identification" form with four input fields: "Facility Name:", "Department Name:", "Sterilizer ID:", and "Sterilizer Serial #:". To the right of the form are two buttons: "Cancel" (with a red circle icon) and "Done" (with a checkmark icon). Below the form is a full QWERTY keyboard. A large, semi-transparent "DRAFT" watermark is overlaid diagonally across the entire page.

Figure 42. Sterilizer Settings.

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

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

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

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

Printer Settings

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

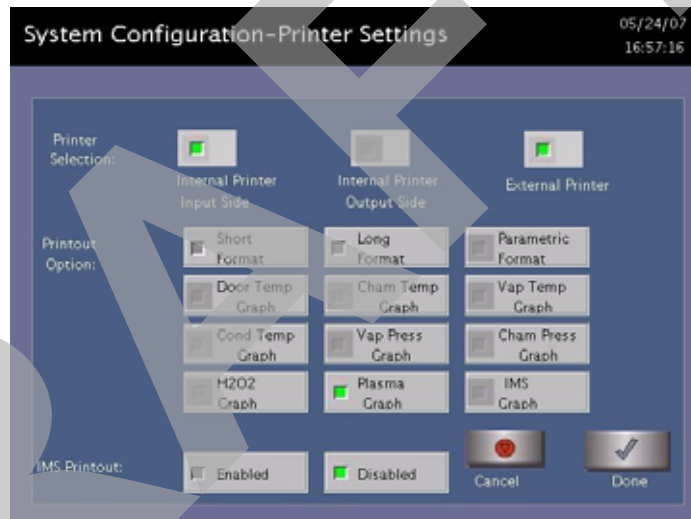


Figure 43. Printer Settings

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

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

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

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

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

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

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

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

IMS Printout Disabled does not print the IMS information.

Transfer Settings

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

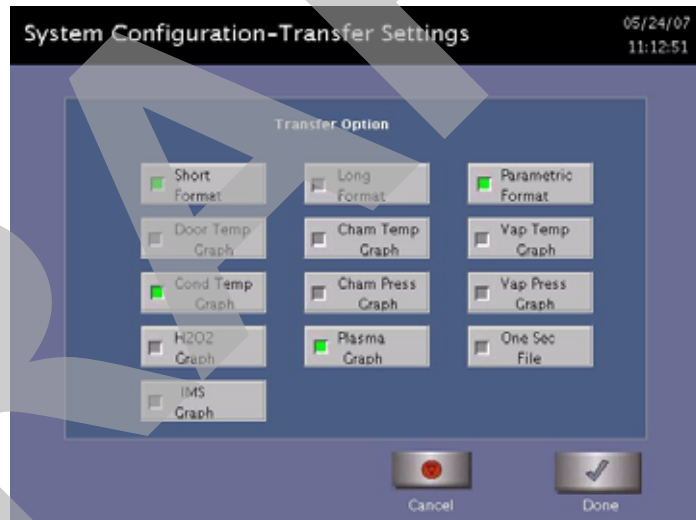


Figure 44. Transfer Settings

Cancel/Done

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

User Administration

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

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

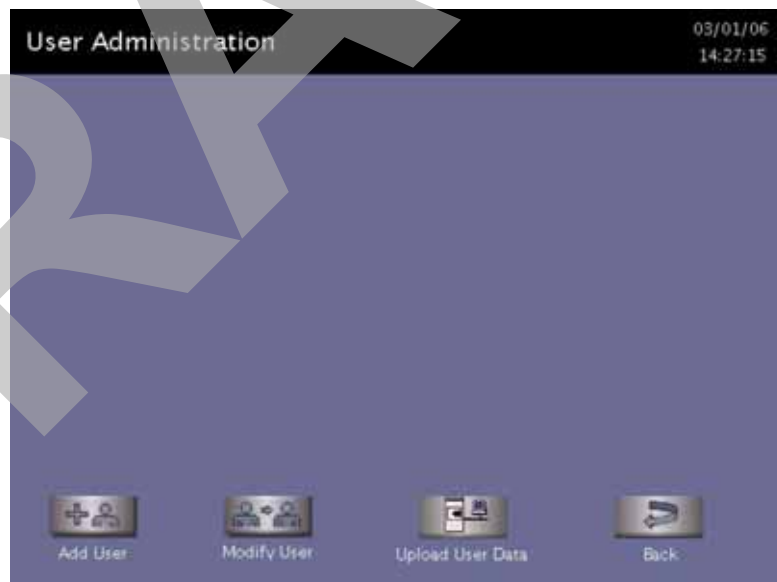


Figure 45. User Administration.

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

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

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

Back returns you to the Additional Utilities Menu.

Add User

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



Figure 46. Add User.

1. Enter the user's operator "identification" in the **Operator** field. The entry must be alpha-numeric and no more than 10 characters.
✓ *Note: Operator and Password fields are case-sensitive.*
2. Enter the user's password in the **Password** field. The entry must be alpha-numeric, no more than 10 characters.
3. Scroll through the **Access Level** selections and select an appropriate access level. You may only choose "Operator" or "Supervisor." Only Service Users can select "Service" level access.
4. Touch the **Cancel** button to exit this screen and return to the User Administration screen.
5. Touch the **Done** button when you have finished entering information for a new user.

Modify User

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



Figure 47. Modify User.

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

4. Touch **Done** to return to the previous screen.



Figure 48. 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." Only Service Users can select "Service" level access.
5. Touch the **Cancel** button to exit this screen and return to the Modify User screen.
 6. Touch the **Done** button when you have finished – the Modify User screen is displayed.

Upload User Data

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

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

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

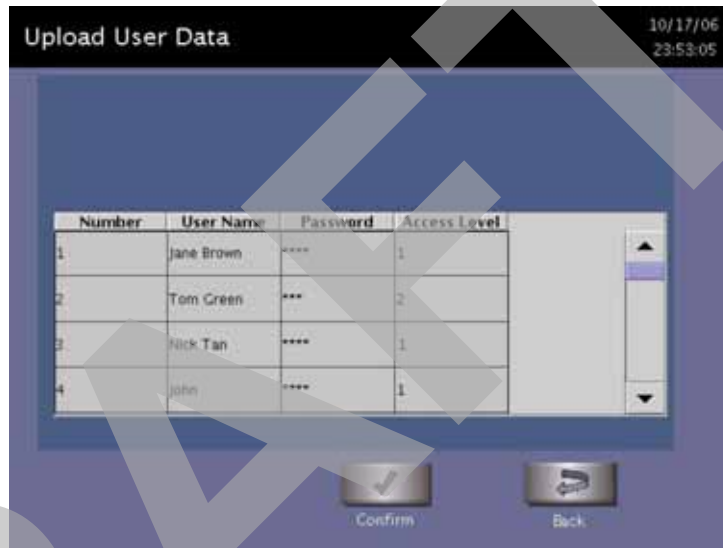


Figure 49. Upload User Data.

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

Steps to Upload a User Database

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

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

```
USERNAME1,PASSWORD1,ACCESS-LEVEL1  
USERNAME2,PASSWORD2,ACCESS-LEVEL2
```

where:

- ◆ **USERNAME** must be alpha-numeric, no more than 10 characters
 - ◆ **PASSWORD** must be alpha-numeric, no more than 10 characters
 - ◆ **ACCESS-LEVEL** must be either 1, 2 (1=Operator, 2 = Supervisor)
2. Copy users.rec file to a USB memory stick and insert the memory stick into the sterilizer’s port located on the lower right (your right) side of the sterilizer.

3. On the sterilizer, touch the **Upload User Data** button. The information in the file will be displayed with the password concealed by “*” characters.
You will receive an “INVALID STERRAD® 100NX® DATABASE FILE” message if the password or user name is longer than the permissible length, you have specified an invalid access level, or you have used an invalid format.
4. Touch **Confirm** to accept the displayed data, logout the current user and return to the prior screen.

Cassette Functions



WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.

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

This function has two options: **Dispose Cassette** which is used to remove the currently loaded cassette from the sterilizer to resolve an error message or to move a cassette that may be stuck in place; and **Peroxide Clearance** which is used to dispose of peroxide remaining in the sterilizer reservoir when the peroxide has expired. Peroxide in the system expires after 10 days. The system displays a message indicating that either of these functions need to be performed.

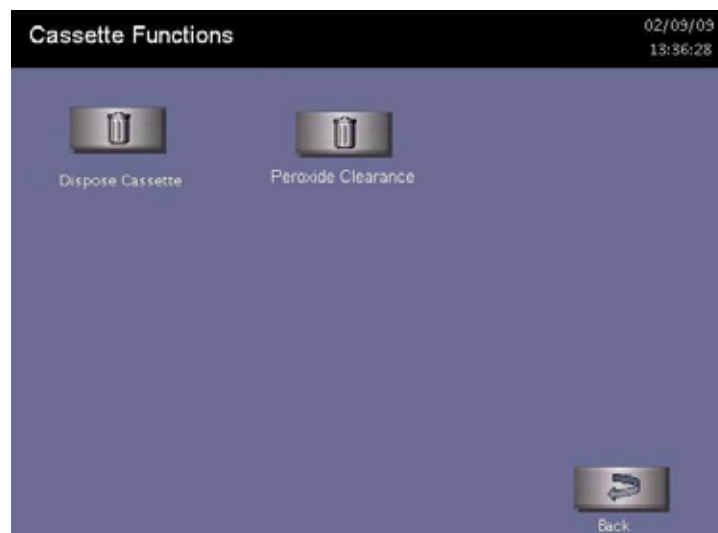


Figure 50. Touch Cassette Functions to display this screen. Touch Dispose Cassette or Peroxide Clearance.

Dispose Cassette

The Dispose Cassette function moves the cassette from inside the sterilizer to the cassette box. The remaining volume of hydrogen peroxide is displayed on the screen.

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

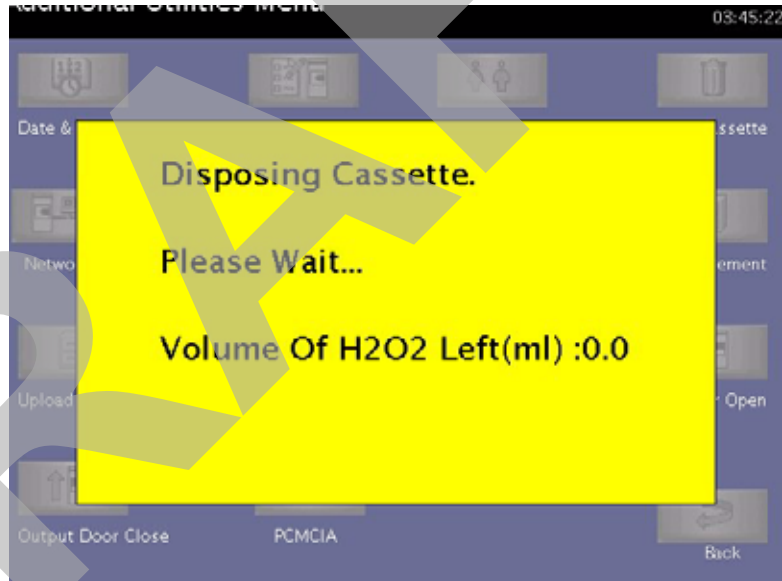


Figure 51. Press Dispose Cassette to Move the Cassette Into the Cassette Disposal Box.

Peroxide Clearance

The DUO Cycle requires the sterilizer to hold peroxide in a reservoir to optimize sterilization. If this peroxide expires, you must dispose of the peroxide remaining in the system. “Peroxide Clearance,” must be performed when a message appears or no subsequent DUO cycles can be run.

- ✓ **Note:** Before you start *Peroxide Clearance*, ensure the chamber is empty.

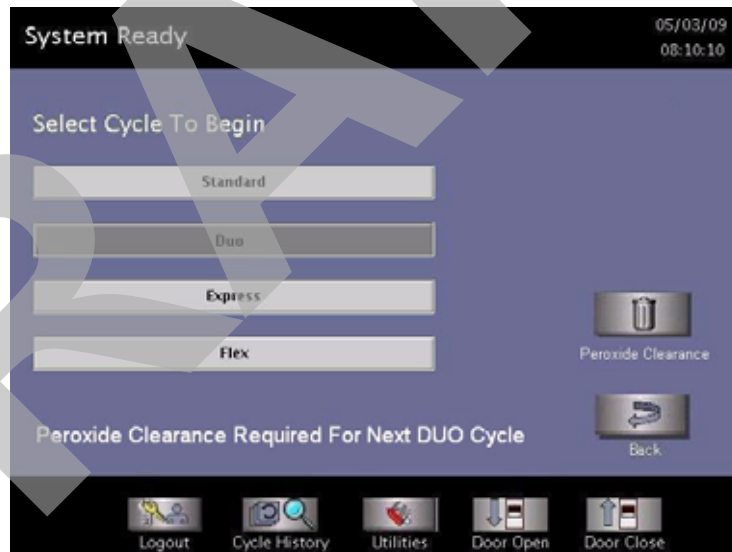


Figure 52. Typical Peroxide Clearance Message

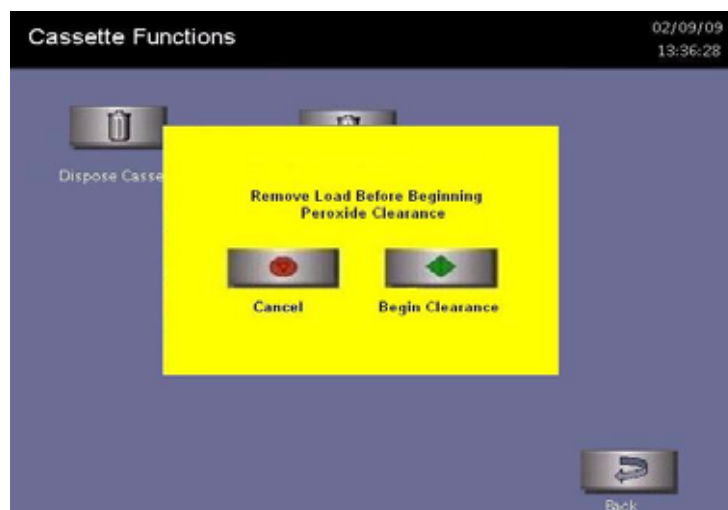


Figure 53. Touch Peroxide Clearance to begin the procedure.

Network

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

Diagnostics

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

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

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

- ✓ *Note: The duration of the Temperature Test is a minimum of 11 minutes.*

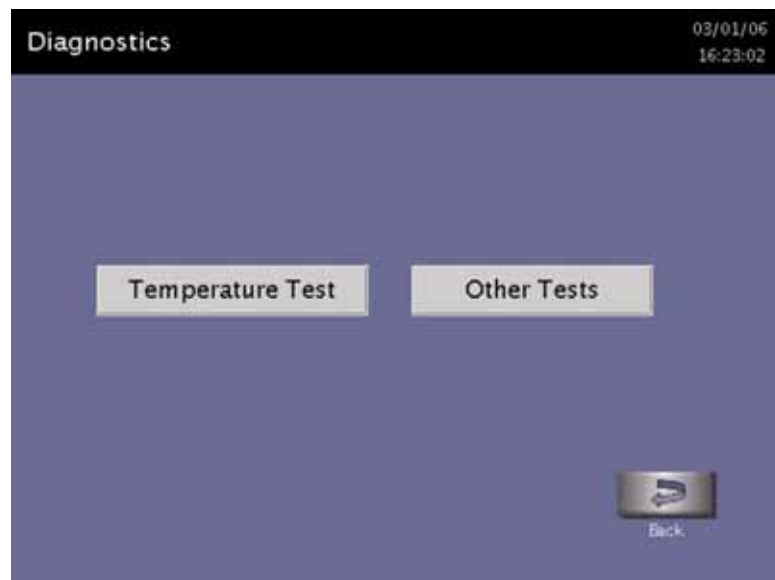


Figure 54. Touch Either Button to Run Tests Than Can Help You Resolve System Messages.

Diagnostic Tests

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

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

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

Service Functions

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

File Management

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

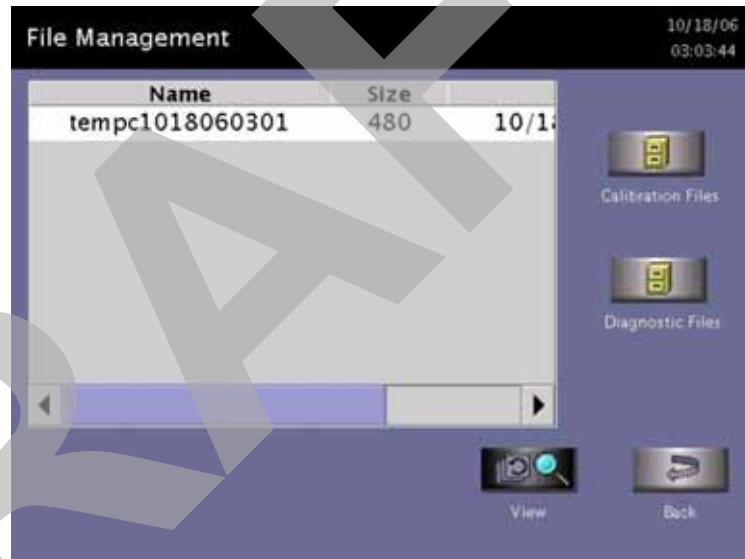


Figure 55. File Management.

Calibration Files

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

Diagnostic Files

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

Upload File

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

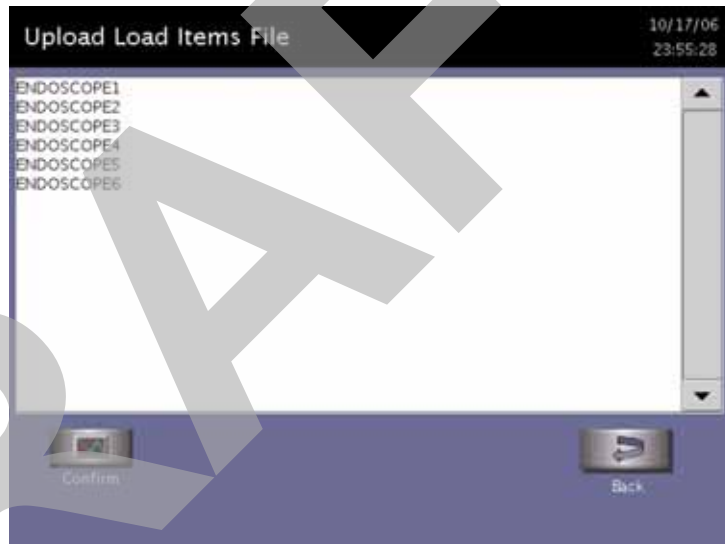


Figure 56. Load Items Files

1. Using Microsoft “Notepad,” create a list of load items similar to the example shown in the figure. To obtain the above display; i.e., ENDOSCOPE1, ENDOSCOPE2, etc. Each load item must be entered on the same line separated by a comma with no spaces before or after the comma. Be sure to include a comma after the last load item. Up to 1000 load items can be defined.
2. Save the file with the file name “loaditems.txt” and use the “encoding” drop down in Notepad to save the file encoded as UTF-8.
3. Insert the USB memory stick with the file loaditems.txt resident on the stick into the sterilizer’s USB port located on the lower right side of the front panel.
4. Select “Upload File” for the Additional Utilities menu.
5. Review the database displayed on the screen and press **Confirm** to accept the database into the sterilizer or press **Back** to cancel.

Input/Output Doors

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

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

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

Product Options

When you select Product Options from the Additional Utilities Menu, and the EXPRESS or DUO cycles are installed, the following is displayed after the installation is complete, and every time you select Product Options after installation. ENABLED is the default option. This feature is only available with Supervisor-Level access.

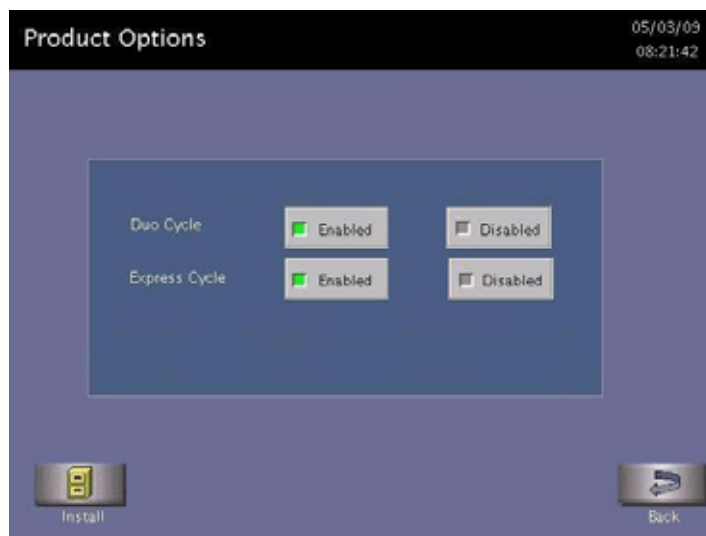


Figure 57. Product Options

Install guides you to install any newly purchased features.

Back returns you to the Additional Utilities Menu.

Enabled displays any cycle in your sterilizer which can be selected (enabled). The choices appear on the Start Cycle display.

Disabled removes the selected cycle buttons from the Start Cycle Screen. These cycles are still available for future use by selecting Enabled on the Product Options screen.

DRAFT

Appendix A.

Safety Information

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

Personal Safety and First Aid

**WARNING! HYDROGEN PEROXIDE IS CORROSIVE**

Concentrated hydrogen peroxide is corrosive to skin, eyes, nose, throat, lungs, and the gastrointestinal tract. Always wear chemical resistant 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.

**WARNING! HYDROGEN PEROXIDE IS AN OXIDIZER**

Hydrogen peroxide is 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! 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 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 was before re-use.



WARNING! RISK OF RESPIRATORY IRRITATION

Inhalation of hydrogen peroxide mist can cause severe irritation of lungs, throat, and nose. If inhalation occurs, move to 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! 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! 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! 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.



WARNING! HYDROGEN PEROXIDE MAY BE PRESENT

If white residue is visible on the load, this is 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 load after a cycle cancellation. Hydrogen peroxide liquid may be present on the load or in the chamber.

Device Safety

**WARNING! RISK OF INJURY OR DAMAGE TO STERILIZER**

The STERRAD® 100NX® Sterilizer should not be used stacked with other equipment.

**CAUTION: RISK OF DAMAGE TO LOAD**

Metal objects must not come into contact with the chamber walls, the door, or the electrode. Contact with the walls, door, or electrode could damage the sterilizer or the metal objects.



CAUTION: KNOW WHAT YOU CAN PROCESS

Before processing any item in the STERRAD® 100NX® Sterilizer, make sure you know how the STERRAD Sterilization Process will affect the item. Read, understand, and follow the medical device manufacturers' instructions for their products. This guide lists certain types of items and materials that can be safely processed in certain cycle choices. Make sure you understand the parameters of each cycle type before processing your items. This guide is not intended to replace any medical device manufacturers' instructions. If you have questions, or if you are in doubt about the materials in your devices, contact the medical device manufacturer or your ASP Customer Representative for more information.



CAUTION: RISK OF VIOLATION OF WARRANTY

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



CAUTION: RISK OF DAMAGE TO LOAD – METAL OBJECTS

Metal objects must not come into contact with the chamber walls, the doors, or the electrode. Contact with the walls, doors, or electrode could damage the sterilizer or the metal objects.



CAUTION: RISK OF DAMAGE TO LOAD – VENTING CAPS

Take special care to confirm that venting caps are placed according to the manufacturers' instructions. Venting caps are intended to prevent damage to flexible scopes that are being exposed to a vacuum, regardless of the sterilant used.



CAUTION: RISK OF DAMAGE TO LOAD – IMMERSION CAPS

You *must remove* the water-resistant immersion cap (if present) prior to processing in the sterilizer. If the immersion cap is not removed prior to processing in the STERRAD® 100NX™ Sterilizer, it will damage the flexible scope due to the inability to properly vent.



CAUTION: KNOW WHAT YOU CAN PROCESS – FLEXIBLE ENDOSCOPES

Prior to processing flexible endoscopes in the STERRAD® 100NX® Sterilizer, you must read, understand, and follow the medical device manufacturer's instructions for use for the particular scope to be processed. Please contact the medical device manufacturer for more information on what can be processed in the STERRAD® 100NX® Sterilizer.



CAUTION: RF COMMUNICATIONS EQUIPMENT

Portable and mobile RF communications equipment can affect medical electrical equipment.

Guidance And Declaration-Electromagnetic Emissions		
The STERRAD® 100NX® Sterilizer is intended for use in the electromagnetic environment specified below. Assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The STERRAD® 100NX® Sterilizer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The STERRAD® 100NX® Sterilizer is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

FCC ID: AXJ100NXRFID

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

This device complies with part 15 of the FCC Rules.

Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

IC Certification Number: 10207A-100NXRFID

This Class A digital apparatus has been tested and found to comply with Canadian ICES-003.



CAUTION: RISK OF NON-COMPLIANCE

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Warnings, Cautions, and Notes



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

- ✓ Notes are printed in italics and have a checkmark in front of the word “Note.” Notes highlight specific information about the proper use and maintenance of the sterilizer.

Symbols



Hot surfaces present.
Do not touch without protection.



Hazardous chemical present.
Use personal protective equipment.



Corrosive chemical present.
Use personal protective equipment.



Oxidizing chemical present.
Avoid exposure, contact, or ingestion.
Use personal protective equipment.



WEEE Symbol



Toxic chemical present.
Avoid exposure, contact, or ingestion.



Ultraviolet (UV) light hazard.
Do not look at the light without UV eye protection.



High voltage hazard.



On/Off.



Alternating current.

DRAFT

Appendix B.

Consumables, Accessories, and Additional Parts

Consumable Products	Product Code	Description
STERRAD [®] 100NX [®] Cassette	10144	2 cassettes per case.
Thermal Printer Paper Roll-Case	10305	Used with the thermal printer to record sterilizer information. 12 rolls/case
Cassette Disposal Box - Case	20227	This box is used to collect cassettes for disposal. 10 boxes/case.
STERRAD [®] 100NX [®] Validation Kit	20228, 20229	Contains the trays, mats, and BI validation supplies. (20228 international, 20229 US domestic.)
STERRAD [®] CYCLESURE [®] 24 Biological Indicator	14324	Used as a standard method for frequent monitoring of the STERRAD [®] Sterilizer cycles.
STERRAD [®] SEALSURE [®] Chemical Indicator Tape	14202	Used to seal packaged instruments, the tape changes color when exposed to hydrogen peroxide.
STERRAD [®] Chemical Indicator Strips	14100	Placed inside instrument packages, the chemical indicator strips change color when exposed to hydrogen peroxide.
Tyvek [®] Pouches and Rolls with STERRAD [®] Chemical Indicator		Contact your ASP Representative for a complete list of pouches, rolls, instrument trays and accessories.
APTIMAX [®] Instrument Trays and accessories		Contact your ASP Representative for a complete list of pouches, rolls, instrument trays and accessories.

B

Consumables, Accessories and Additional Parts

Accessories	Product Code	Description
Barcode Reader	11142	Optional barcode scanner for tracking instruments and other information in the cycle history file.
Independent Monitoring System (IMS)	10140	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.

Additional Parts	Part Number
Compact Flash Card and Adapter	04-53004-0-001

ASP also offers a comprehensive line of other consumables and accessories which have been fully tested and validated for use with the STERRAD® 100NX® Sterilizer. For more information on any of these products, in the U.S.A. contact ASP Professional Services at 1-888-STERRAD. Outside the USA contact your local ASP Customer Support Representative.

Appendix C.

Sterilizer Specifications

Power	<p>The phase rotation is adjusted to match the system requirements at installation.</p> <p>208V 60 Hz Power: For versions employing 208V, 60 Hz power, the sterilizer requires a NEMA L21-30 five-wire grounding twist lock outlet attached to a dedicated 30 Amp 3 phase 208 Volt circuit with separate neutral and ground conductors.</p> <p>380 - 415V 50/60 Hz Power: The sterilizer requires a five-wire grounding outlet attached to a dedicated 30 AMP, 3 phase, (200-240VAC, 380-415V) $\pm 10\%$, 50/60 Hz $\pm 5\%$ circuit with separate neutral and ground conductors.</p> <p>200V 50/60 Hz Power (Japan): The sterilizer requires a four-wire Delta configuration to a dedicated 30 AMP circuit.</p>
Dimensions	H: 70.5 in. (179.1 cm), W: 30.5 in. (77.5 cm), D: 40 in. (102 cm).
Service clearances	Front: 39.5 in. (100 cm); Back: 39.5 in (100 cm); Top: 39.5 in. (100 cm) Left side: 39.5 in. (100 cm); Right side: 39.5 in. (100 cm).
Weight	425 kg, 938 lbs 1-Door system 457 kg, 1,006 lbs 2-Door system
Chamber volume	152 liters. W20.7 in. (51 cm), H16.1 in. (41 cm), D28.93 in. (73.5 cm). Usable volume: 93.4 liters (3.3 cubic feet)
Chamber shelves	Two shelves, W 17 in. (42.5 cm), D 28 in. (70 cm). Shelf capacity: 55 lb. (25 kg) uniformly distributed. Both shelves are removable.
Temperature	Operating: 18°C - 35 °C (64° - 95°F). Storage: -29°C - 70°C (-20°F - 158°F)

Humidity	<p>Operating: 10% – 85% up to 30°C. linearly decreasing from 85% at 30°C to 70% at 40°C non-condensing</p> <p>Storage: 10% – 100% (rainfall will be permitted).</p>
Altitude/Pressure	<p>Operating altitude up to 3095 m (10,152 ft.).</p> <p>Atmospheric pressure 520-775 torr</p>
Cycle temperature	47°C – 56°C (116.6°F – 132.8°F)
Cycle time	<p>STANDARD Cycle - 47 minutes</p> <p>DUO Cycle - 60 minutes</p> <p>EXPRESS Cycle - 24 minutes</p> <p>FLEX Cycle - 42 minutes</p>
Connectors	<p>Network: RJ45; Barcode reader: USB.</p> <p>Printer: USB</p>
Main Power Cable	<p>12 AWG (4 mm²), 3 m (9.84 feet) long, 5 conductors</p> <p>NEMA L21 - 30P (USA and Canada.)</p> <p>Each country is responsible for installing an appropriate 3 phase plug according to their facility's power requirements. The plug must match the phase rotation.</p>
Mobility	On wheels
Venting Requirements	None required
Gas Tank Requirements	None required
Heat Generation	<p>Idle: 289 BTU/hour</p> <p>In operation: 8,189 BTU/hour maximum</p>
RF Generation	Portable and mobile RF communications equipment can affect medical Electrical Equipment.

Medical Device Requirements and Guidelines

Medical Device Directive 2007/47/EC
 IEC/EN 61010-1: Safety Requirements For Electrical Equipment For Measurement, Control, And Laboratory Use – Part 1: General Requirements
 EN 61010-2-040: Safety Requirements for Electrical Equipment, Control and laboratory Use. Particular requirements for sterilizer and washer-disinfectors used to treat medical devices.
 IEC 60601-1: Medical Electrical Equipment – Part 1: General Requirements For Safety (Japan Requirement)
 EN 60601-1-2: Medical Electrical Equipment - electromagnetic Compatibility - Requirements and Tests.
 ANSI/AAMI/ISO 14937: Sterilization Of Health Care Products – General Criteria For Characterization Of A Sterilizing Agent And Development, Validation, And Routine Control Of A Sterilization Process
 CAN/CSA C22.2 No. 61010-1.
 UL 61010-1.

Medical Device Agencies

US: FDA (Food and Drug Administration)
 EU: TUV Product Service (ASP's Notified Body)
 Japan: MHLW (Ministry of Health, Labor and Welfare)
 Canada: TPP (Therapeutic Products Programme)
 Australia: TGA (Therapeutic Goods Administration)

DRAFT