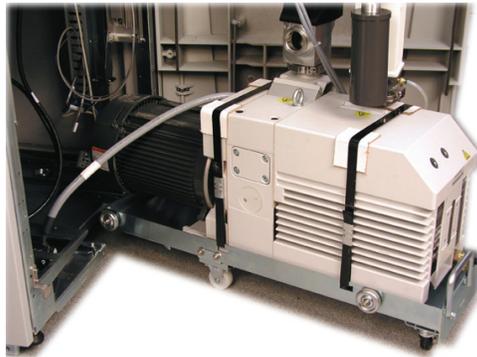
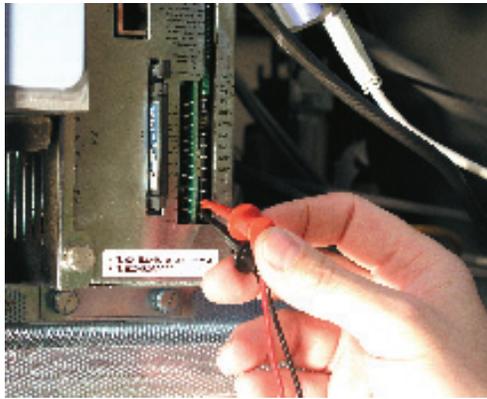


ASP<sup>®</sup>  
**STERRAD<sup>®</sup> 100NX<sup>®</sup>**

## **STERRAD<sup>®</sup> 100NX<sup>®</sup> Sterilization System**

### **Service Guide**



**ADVANCED STERILIZATION PRODUCTS**

Division of Ethicon, Inc.

a *Johnson & Johnson* company

TS-54155-04  
October 2011



# Sterilization System Service Guide



Division of Ethicon, Inc.

a *Johnson & Johnson* company

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## Chapter 1.

# Introduction

***IMPORTANT: The optional DUO Cycle is not available in the United States.***

## Overview

The STERRAD<sup>®</sup> 100NX<sup>®</sup> Sterilizer is a self-contained standalone system of hardware and software designed to sterilize medical instruments and devices using a patented hydrogen peroxide gas plasma process. Hydrogen peroxide vapor is generated by delivering aqueous hydrogen peroxide into the vaporizer where the solution is heated and vaporized. The hydrogen peroxide vapor is then introduced into the sterilization chamber, under sub-ambient pressure, where it is transformed into a gas-plasma by use of electrical energy.

The STERRAD<sup>®</sup> 100NX<sup>®</sup> Sterilizer is designed for sterilization of both metal and nonmetal medical devices at low temperatures. Because the cycle operates within a dry environment and at low temperatures, it is especially suitable for instruments sensitive to heat and moisture.

The STERRAD<sup>®</sup> 100NX<sup>®</sup> Sterilizer employs two different methods for delivering hydrogen peroxide to sterilize devices within the sterilization chamber:

- In the Standard and Flex cycles, the 59% hydrogen peroxide solution is concentrated to approximately 90% nominal hydrogen peroxide. By using the concentrated hydrogen peroxide solution, the sterilization cycle times have been reduced. The process is accomplished by selectively vaporizing and removing water prior to being delivered into the sterilization chamber.
- In the Express and DUO cycles, the 59% hydrogen peroxide is vaporized (not concentrated) and delivered into the sterilization chamber.

## Sterilant and Cassette

The sterilant used in the STERRAD<sup>®</sup> 100NX<sup>®</sup> Sterilizer is hydrogen peroxide. It is supplied in cassette form as a separate accessory.

The cassette contains 10 individually sealed cells. Each of the filled cells contains 5.4 ml of 59% nominal hydrogen peroxide. Each sterilization cycle uses two cells, except the DUO cycle; therefore, a cassette is labeled with the total volume available (54 ml).

## Hardware

The hardware for the sterilizer consists of a sterilization chamber and a variety of instruments and components housed in a covered frame. The sterilizer system also uses accessories such as a disposable sterilant cassette, reusable instrument trays, and printer paper.



Figure 1. STERRAD<sup>®</sup> 100NX<sup>®</sup> Sterilization System.

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# Software

The sterilization process is controlled automatically by software. The software controls and monitors the hardware through digital and analog signals. Functions managed by software include:

- Timing
- Temperature/pressure measurement and control
- Sterilant delivery and vaporization
- Plasma power generation and measurement
- Hydrogen peroxide monitor
- Access to chamber is through the automatic door or doors depending on system configuration.

Each parameter is part of a control loop in which information flows as input from one of many sensors to the computer, where it is processed and triggers an output signal that flows from the computer to an output device. Through this system of feedback signals (input), analysis, and response signals (output), the computer controls the entire sterilization process. If any process parameter falls outside allowable ranges, the software will cancel the cycle.

***Note:** The hydrogen peroxide monitor does not provide feedback control to the sterilizer. However, the monitor will cancel the cycle if the area under the hydrogen peroxide concentration-time curve or hydrogen peroxide rate constant does not meet specifications.*



## Chapter 2.

# Safety Information

Your safety is of primary concern to Advanced Sterilization Products. This chapter provides information on safely servicing the STERRAD® 100NX® Sterilizer. **You must read and understand the safety information in this chapter before performing service on the sterilizer.** Always pay attention to the warnings, cautions, and notes throughout this *Service Guide*.

## Personal Safety and First Aid



**ASP FIELD SERVICE ENGINEER REQUIREMENT  
ALL ASP FIELD SERVICE ENGINEERS MUST WEAR SAFETY  
GOGGLES WHEN SERVICING ASP PRODUCTS.**



**WARNING! HYDROGEN PEROXIDE IS CORROSIVE.**

Concentrated hydrogen peroxide is corrosive to skin, eyes, nose, throat, lungs, and the gastrointestinal tract. Always wear chemical resistant 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, or when handling used cassettes, or when handling used vacuum pump oil.



**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.

## 2 Safety Information

---



### **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 PVC (vinyl) or nitrile gloves when handling used cassettes, ejected cassettes, items from a cancelled cycle, items that have moisture present after a completed cycle, or used vacuum pump oil. Immediately take off contaminated clothing and rinse thoroughly with water to avoid potential fire hazard and wash 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. Under certain circumstances the outer surfaces of the vacuum pump may reach temperatures above 70° C (158° F). Allow the sterilizer to cool before touching interior surfaces.



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

If white residue is visible on a processed load, this is residue from the hydrogen peroxide stabilizer. Wear chemical resistant 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 the system. The system informs the customer when Planned Maintenance is due.



### **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. Use UV-specific protective eyewear if necessary.

**WARNING! ELECTRIC SHOCK HAZARD.**

High voltages are present inside the sterilizer. Contact with electrically energized parts can cause injury or death. Turn OFF and unplug the sterilizer before performing service tasks.

**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 sterilizer until it is repaired. Personnel should avoid working in the room until the mist has cleared. Please note that all STERRAD<sup>®</sup> Sterilizers should be used and installed in a well-ventilated environment (a minimum of 10 air exchanges per hour).

## Safe Maintenance/Device Safety

**WARNING! TURN OFF THE STERILIZER PRIOR TO SERVICING**

Always turn off the sterilizer prior to servicing unless the particular service procedure requires electrical power.

**WARNING! RISK OF INJURY OR DAMAGE TO THE VACUUM PUMP AND STERILIZER.**

Do not operate the vacuum pump if the outlet port is blocked or restricted in any way. Failure to do so may result in over-pressurization of the oil housing and cause it to rupture and violently release stored energy causing injury and damage to the sterilizer.

**WARNING! RISK OF INJURY OR DAMAGE TO THE VACUUM PUMP**

Do not operate the vacuum pump without a metal blanking flange, or the bellows and vacuum control valve properly connected to the chamber. Failure to do so may result in contact with large quantities of exhausted vacuum pump oil, severe over-heating, or seizure of the vacuum pump.

**WARNING! RISK OF INJURY**

Do not expose any part of your body to vacuum generated at the vacuum pump port during pump-down, a severe injury may result.

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

The sterilizer should not be used stacked with other equipment.

## 2 Safety Information

---



### **CAUTION: RISK OF DAMAGE TO THE STERILIZER. REPAIRS MUST BE PERFORMED BY AUTHORIZED PERSONNEL**

Repairs and adjustments should only be attempted by experienced technicians who are fully trained to maintain and repair the STERRAD® 100NX® Sterilizer. Do not attempt to perform any adjustments or procedures on the sterilizer if you have not been trained in an ASP-approved training facility by an ASP trainer.



### **CAUTION: RISK OF DAMAGE TO STERILIZER – VOIDING OF WARRANTY**

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



### **CAUTION: RISK OF DAMAGE TO STERILIZER – NEED DEDICATED POWER SOURCE**

Warn the customer that they must not change the power source or relocate the sterilizer to a new power source because the STERRAD® 100NX® Sterilization System requires a dedicated power source.



### **RISK OF DAMAGE TO STERILIZER– USE PROPER CLEANING TOOLS**

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

## Cassette Handling



### **CHECK FOR CASSETTE DAMAGE**

Do not remove the cassette from the package if the indicator strip is red. Red indicates that the cassette might have been damaged.



### **WARNING! RISK OF HYDROGEN PEROXIDE EXPOSURE**

Do not remove the plastic wrapper from the cassette package if the indicator strip is red. Red indicates that the cassette might have been damaged.



### **WARNING! RISK OF HYDROGEN PEROXIDE EXPOSURE**

Do not handle used cassettes in the cassette collection box. Dispose of the cassettes inside the cassette collection box per your facility's procedures. If it is necessary to handle a used cassette that is not in the cardboard sleeve, wear chemical resistant gloves. Do not touch your gloved hands to your face or eyes.



**FOR ROUTINE HANDLING, MINIMUM PPE REQUIREMENTS INCLUDE APPROVED; (e.g., ANSI Z87.1), CHEMICAL SPLASH GOGGLES, NITRILE CHEMICAL RESISTANT GLOVES, AND A CHEMICAL RESISTANT; (e.g., polyolefin fiber), LAB COAT. Where there is a risk of product contact with shoes, chemical resistant shoe**



coverings are recommended. Where there is risk of product splashing into eyes, an independent face shield must be worn in addition to chemical splash goggles as authorized in 29 CFR 1910.133, applicable U.S. State regulations, or the appropriate standards of Canada and its Provinces or EC Member States (per European Standard EN 166).

## Device Safety



### **WARNING: RISK OF INJURY OR DAMAGE TO THE STERILIZER**

The STERRAD<sup>®</sup> 100NX<sup>®</sup> Sterilizer should not be used stacked with other equipment.



### **CAUTION: RISK OF DAMAGE TO THE STERILIZER.**

Do not bend, nick, or damage the counterbalance metal tape in any way. Do not use any tool to clamp it to another part. If the tape is damaged, it will bind in the housing slit, further damage the part, and disrupt the door motion.



### **CAUTION: RISK OF DAMAGE TO THE 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.



### **KNOW WHAT CAN BE PROCESSED**

Before processing any item in the sterilizer, make sure you and your customers know how the STERRAD<sup>®</sup> Sterilization Process will affect the item. Read, understand, and follow the medical device manufacturers' instructions for their products. This guide is not intended to replace any medical device manufacturers' instructions. If you or your customers have questions, or if you are in doubt about the materials in any device, contact the medical device manufacturer or an ASP Customer Representative for more information. Improper processing may limit our liability for damage to processed instruments. Improper processing may also violate the instrument warranty.



### **CAUTION: RF COMMUNICATIONS EQUIPMENT**

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

## 2 Safety Information

Guidance And Declaration-Electromagnetic Emissions		
The STERRAD <sup>®</sup> 100NX <sup>®</sup> 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 <sup>®</sup> 100NX <sup>®</sup> 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 <sup>®</sup> 100NX <sup>®</sup> 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	

## Warnings, Cautions, and Notes



Warnings and cautions are accompanied by symbols surrounded by a triangle or a square and are printed in this manual 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*. Notes highlight specific information about the proper use and maintenance of the STERRAD<sup>®</sup> 100NX<sup>®</sup> Sterilization System.

## Symbols Used on the Sterilizer or in This Guide



Hot surfaces present.  
Do not touch without protection.



Corrosive chemical present.  
Use personal protective equipment.



Oxidizing chemical present  
Use personal protective equipment. Do not expose to excessive heat or open flame. Keep separate from flammable chemicals.



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



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



High voltage hazard.

I/O

On/Off.



Alternating current.

## Safety Standards Compliance

The STERRAD<sup>®</sup> 100NX<sup>®</sup> Sterilizer meets the following safety standards:

- CAN/CSA-C22.2 No. 61010-1/R: 2009; Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use.
- UL 61010-1/R: 2008; Standard for Safety for Electrical Equipment for Laboratory Use.
- IEC/EN 61010-1: 2001; Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use.
- IEC/EN 61010-2-240: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials, 1<sup>st</sup> Ed., 2005.
- IEC/EN 60601-1-2: 2007 CLASS A; Medical Electrical Equipment, Part 1: General Requirements for Safety, Section 2: Collateral Standard: Electromagnetic Compatibility.
- EN 55011, Group I Class A limits, based on CISPR 11:2009, Group I Class A limits (subset of EN 60601-1-2).

## Chapter 3.

# Functional Description

## Overview of the Sterilization Process

The STERRAD<sup>®</sup> 100NX<sup>®</sup> Sterilizer software interfaces with the hardware through digital/analog input and output signals and through serial communications via serial ports. The inputs monitor the sterilization process while the outputs control the process. The process occurs as follows:

1. The items to be sterilized are placed in the sterilization chamber, the chamber door is closed, and a vacuum pump reduces the pressure in the chamber.
2. A 59% aqueous solution of hydrogen peroxide is transferred from the cassette and delivery system into the vaporizer/condenser where it is concentrated and vaporized (Standard and Flex cycles) or vaporized (Express and optional DUO cycles) before it is introduced into the chamber.
3. A low frequency electric current is delivered to the chamber electrode, causing the formation of a low-temperature gas plasma in the chamber.
4. In the plasma state, the hydrogen peroxide vapor breaks apart into reactive molecules that include free radicals.
5. The combined use of hydrogen peroxide and plasma safely and rapidly sterilizes most medical instruments and materials without leaving toxic residues.

## Hydrogen Peroxide Concentration and Delivery

### Standard and Flex Cycles

During the hydrogen peroxide delivery step, hydrogen peroxide solution is delivered into the vaporizer bowl after the system pumps below 200 torr. Additional air is removed from the chamber and from the vaporizer/condenser by pulling a vacuum to a controlled pressure in the vaporizer/condenser. At this time, the transfer valve is closed. Water is removed from the 59% hydrogen peroxide solution by reducing the pressure in the condenser. The pressure differential between the chamber and the condenser creates the driving force to remove the water. During this concentration step, the flow of H<sub>2</sub>O<sub>2</sub> vapor is restricted by an orifice between the condenser and the chamber, creating lower chamber pressure.

Once the controlled pressure is achieved in the condenser, the chamber pressure is further reduced by closing the orifice with the transition valve. The condenser temperature is increased and the concentrated hydrogen peroxide vapor is then transferred into the chamber by opening the transfer valve and the transition valve. This transfer step is followed by the diffusion step (which occurs at atmospheric pressure), followed by pressure reduction and plasma. The vent step then occurs which returns the chamber to atmospheric pressure. This process occurs twice during a complete sterilization cycle.

### Express and Optional DUO Cycles

During the hydrogen peroxide delivery step, hydrogen peroxide solution is delivered into the vaporizer bowl after the system pumps below 200 torr. Additional air is removed from the chamber by pulling a vacuum to a controlled pressure in the chamber. During this time, the transfer and transition valves are closed.

Once the controlled pressure is achieved in the chamber, the condenser temperature is increased and 59% hydrogen peroxide vapor is then transferred into the chamber by opening the transfer valve and the transition valve. This transfer step is followed by the diffusion step (which occurs at atmospheric pressure), followed by pressure reduction and plasma. The vent step then occurs which returns the chamber to atmospheric pressure. This process occurs twice during a complete sterilization cycle.

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# Process Monitoring and Control

The monitoring and control systems regulate the following:

- Temperature
- Pressure
- Hydrogen peroxide monitor
- Plasma power
- Time
- Process status
- IMS

## Temperature

Temperature monitoring and control are involved in two aspects of the STERRAD<sup>®</sup> 100NX<sup>®</sup> Process: heating and cooling of the condenser that condenses hydrogen peroxide during vaporization, and heating the vaporizer, chamber walls and doors. The temperature control loop consists of heaters and temperature sensors. There are 7 temperature sensors in the system. They are located on the: vaporizer; condenser; doors; and chamber front, middle, and rear.

## Pressure

Pressure monitoring and control are performed by a control loop which includes the vacuum pump, vacuum control valve, vent valve, three pressure transducers, and an atmospheric pressure switch. The control system interacts with these components during chamber evacuation, pressure monitoring, and venting to atmosphere. Two chamber pressure transducers monitor and control the vacuum process; one ranges from 0-30 torr and the other ranges from 0-200 torr. The pressure transducers are attached to a port in the top of the chamber. The vaporizer pressure transducer monitors and controls the vacuum during the vaporization pumpdown step; its range is from 0-30 torr. The pressure transducer is attached to a port in the vaporizer/condenser assembly. The atmospheric pressure switch is a differential pressure sensor. Its function is to signal the control system that the interior of the chamber is at or very near atmospheric pressure.

## Hydrogen Peroxide Monitor

During the hydrogen peroxide transfer step, hydrogen peroxide concentration data are collected from the monitor. The ultraviolet lamp assembly sits at the top front of the chamber and delivers UV light across the chamber to the detector mounted at the bottom of the chamber. Hydrogen peroxide vapor absorbs UV light – reducing the intensity of

## 3 Functional Description

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light reaching the detector by an amount proportional to the amount of hydrogen peroxide present in the light path. A photodiode detector measures the amount of light coming from the lamp, before and during hydrogen peroxide transfer to the chamber, allowing a calculation of the hydrogen peroxide concentration. The area under the concentration-time curve and the hydrogen peroxide rate constant are calculated and compared by the controller to specifications. If the limits are exceeded, the cycle will be cancelled.

### Plasma Power

The plasma power monitoring and control system controls the plasma power during the two plasma steps of the STERRAD® 100NX® Sterilizer process. The plasma power is monitored and controlled by a plasma power sensor. This sensor interacts in a control loop with the computer and plasma power unit to control the process within the specified limits.

### Time

Time monitoring and control are performed by the computer and affect numerous steps in the process. An interval timer measures process step duration and the computer uses time inputs to control the various devices in the process sequence.

## System Software

STERRAD® 100NX® Sterilizer software controls and monitors the sterilizer through digital and analog signals. When a sterilization cycle is not in process, the software monitors and controls the sterilizer temperature, responds to operator touch panel inputs (Select Cycle and Start Cycle), verifies cassettes upon insertion, controls printer output, and allows the operator to set the system date and time. When a sterilization cycle is in process, the software controls and monitors the timing, temperature, pressure, delivery and vaporization processes, application of plasma power, printer output, and responds to an operator input of CANCEL (all other operator inputs are disabled during the cycle). If sterilization process parameters fall outside allowable ranges, the software will cause the cycle to cancel, and will control the cancellation process.

Each sterilizer subsystem is part of a control loop in which information flows as input from one or more sensors to the computer, where it is processed and triggers an output signal which flows from the computer to an output device. Through this system of feedback signals (input), analysis, and response signals (output), the computer controls the entire sterilization process.

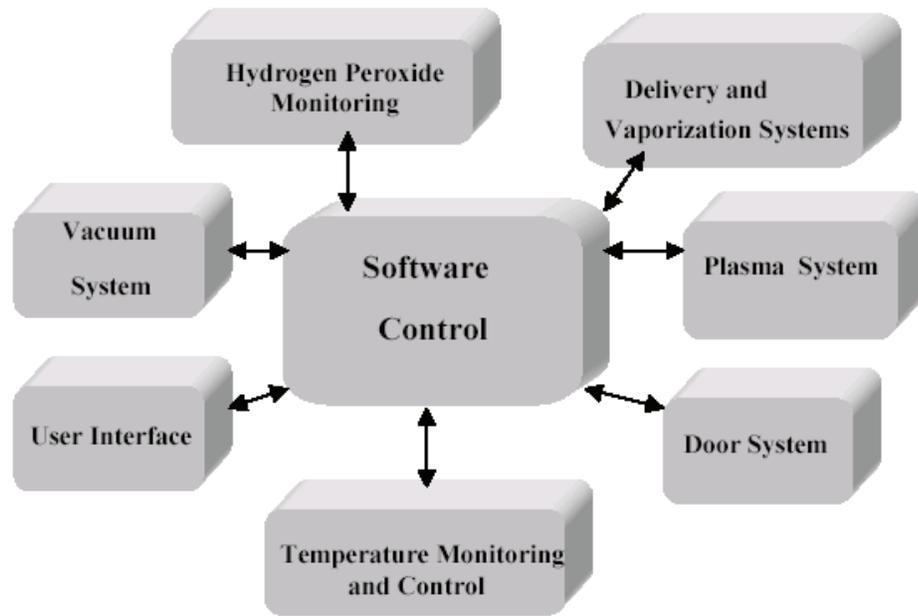


Figure 2. Software Control Diagram.

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## Subsystems

### Delivery System

The hydrogen peroxide delivery assembly transfers hydrogen peroxide solution from the cassette assembly to the vaporizer assembly. The delivery process involves: accepting a valid cassette from the user via an RFID, positioning the cells in the hydrogen peroxide extractor assembly, delivering hydrogen peroxide solution from a cell to the vaporizer, isolating the vaporizer from atmosphere, and disposing of a used cassette.

### Vacuum Subsystem

The vacuum subsystem evacuates the chamber during the vacuum steps of the cycle, controls chamber pressure, and admits filtered air into the chamber during venting. The vacuum subsystem is found in the lower portion of the system; below the chamber. The vacuum pump can be removed using an included caster system.

### Plasma Subsystem

The plasma subsystem generates electrical energy creating a gas plasma in the chamber that reduces residual hydrogen peroxide from the chamber atmosphere and in the materials of the load.

The plasma subsystem consists of the LFPS II, an electrode assembly and an integrated plasma energy feedthrough. The door open/close sensor functions as a safety switch to prevent the LFPS II from operating when the door is open.

### Hydrogen Peroxide Monitor Subsystem

The hydrogen peroxide monitor measures the concentration of hydrogen peroxide vapor at a fixed location in the chamber during the transfer stage of the sterilization process. The UV lamp and the lamp manager are located in the top section of the sterilizer; the UV detector assembly is located underneath the chamber just behind the input door.

### Display Assembly

The display assembly provides the graphical user interface. You can interact with the sterilizer by reading system information and cycle status information and entering information and configuring the system through the touch-screen.

## **Cassette Disposal Box**

The cassette disposal box holds 2 depleted sterilant cassettes when full. It is located behind the access panel. The cassette disposal box is removed, closed, and discarded according to the facility's procedures.

## **Vaporizer/Condenser**

The vaporizer/condenser subsystem is connected between the delivery system and the chamber. The vaporizer receives hydrogen peroxide solution from the delivery system and vaporizes the liquid hydrogen peroxide and water. The condenser condenses the hydrogen peroxide vapor while allowing the water vapor to pass through the chamber. The condenser vaporizes the hydrogen peroxide and delivers the vapor to the chamber. The vaporizer pressure transducer monitors the pressure of the vapor in the vaporizer/condenser assembly.

## **AC Distribution**

The AC distribution assembly provides On/Off power control and power distribution to the sterilizer. It interfaces with system software to provide AC power distribution to the following subsystems: Heaters for the chamber, door, and vaporizer; DC power supplies; vacuum pump; and plasma.

The AC distribution assembly contains, inside the enclosure, configuration switches that must be set to match the input voltage to be used by the sterilizer (low voltages: 200V-208V; high voltages: 380V-415V). The voltage setting is determined by the switch positions.

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## DC Power Supplies

Two DC power supplies convert AC power to six different DC voltages. One power supply is 24 VDC only. The second power supply voltages are +3.3V, +5V, +12V, and  $\pm 15V$ . All output voltages are regulated and the DC power supplies have built-in overcurrent protection. The input to the DC power supplies is supplied by AC power from the AC distribution assembly.

## System Control Enclosure

The system control enclosure consists of the ETX board and the system interface board. The system software resides in the Compact-Flash card on the ETX board. The system control enclosure provides all necessary electrical interconnections to components, provides software control to operate and monitor the sterilizer, provides external connections and access, and provides a control interface for the operator to input cycle information and access the sterilizer's functions.

The system control enclosure is configured as two circuit boards mounted together, inside a metal-shielded enclosure. Access to test pins is provided by removing a small cover on the end of the enclosure.

## Fan

The system fans are mounted on the top of the frame assembly. The fans exhaust heat from the sterilizer. Fresh air is pulled through an air filter secured to the inside bottom surface of the frame.

## Door Assembly

The chamber doors use a gear motor worm drive and timing belt assembly. A one-door unit includes a back plate bolted onto the chamber. A two-door unit includes two motorized doors. The motorized door can be opened, without power present, by attaching a special tool to the gear motor and manually rotating it. The door is manually placed in the service position.

A safety latch is also attached to the bottom of the door to prevent the door from moving during shipment. This latch needs to be disabled before the door can be opened. This latch should also be used to secure the door if needed during service.

Heaters with an integrated thermostat provide the heat input to the door to maintain its temperature at a predetermined control point. A temperature sensor is used to monitor the door temperature and provide feedback to the computer to properly control the heaters. Thermostats will cut off the power to the heaters if temperature limits are exceeded.

## Chamber and Shelves

The chamber functions as the container where sterilization of a load takes place. The chamber assembly includes the chamber, electrode, shelves, heaters, three temperature sensors, thermostats, and insulation.

The chamber is heated using three independent heating zones; each controlled by a heater, thermostat, and temperature sensor. These are used to maintain its temperature at a predetermined control point. Temperature sensors are used to monitor the chamber temperature and provide feedback to the computer to properly control the heaters. Thermostats will cut off the power to the heaters if temperature limits are exceeded.

The two shelves are mounted on rails and can be pulled out of the chamber partially or completely. Each shelf has two detents to aid you in centering the shelves inside the electrode.

## Electrode

The electrode resides inside the chamber and is isolated from the chamber walls, door(s), and shelves and is used in the generation of plasma. The electrode distributes electrical energy uniformly throughout the chamber causing hydrogen peroxide molecules in the chamber to break apart and form plasma.

## Feedthrough

A feedthrough conductor, which is electrically isolated from the chamber wall, connects the electrode to the plasma power supply, which delivers power to the electrode.

## Circuit Breaker

A magnetic-hydraulic automatic circuit breaker/switch is mounted on the AC power supply and is accessible on the lower left side of the input panel. The circuit breaker/switch is used to turn power on and off and will trip open to protect the sterilizer if a current overload occurs.

## Printer

The printer produces a paper record of cycle information including process parameters, warning and error messages, troubleshooting information, machine and cycle identification information, and validation signature locations for the operator's confirmations.

The printer assembly is mounted in the center of the input panel and the output panel, if equipped with a second door. Access to the printer paper roll is provided by a flip-open door.

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## Functional Description

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### **Vacuum Pump Assembly**

The vacuum pump assembly consists of a vacuum pump, in a tray assembly, exhaust oil mist filter, exhaust catalytic converter, oil return valve, vacuum control valve, and related components. The vacuum pump assembly is mounted on the input side of the unit. The vacuum pump assembly can be removed from the sterilizer and be serviced or replaced using the supplied caster assembly that is manually attached to the tray.

### **I/O Panel**

The I/O panel provides external communication connection from the system control enclosure including: Ethernet and USB. The I/O panel is mounted to the frame and is accessible on the lower right side of the input panel.

### **DUO Delivery Module (Optional)**

The DUO delivery module is an optional hardware upgrade that allows a low temperature terminal sterilization cycle with metered H<sub>2</sub>O<sub>2</sub> delivery within the current STERRAD® 100NX® Sterilizer and uses the same consumables for the current STERRAD® 100NX® Sterilizer. The add-on hardware is a delivery module or subsystem that is inserted between the existing STERRAD® 100NX® Sterilizer delivery system and vaporizer to support the DUO cycle.

## Diagnostic Functions and Tests

The diagnostic function of the system software provides an automatic link between a failed cycle (cancelled cycle) and a specific subsystem function and performance test. The service personnel can access the diagnostic functions independent of the cycle.

The STERRAD<sup>®</sup> 100NX<sup>®</sup> system software also provides predefined test sequences to determine the functionality and behavior of each subsystem. The diagnostic features of the system software provide service personnel detailed information about system performance.

The system diagnostic tool is designed to provide the following information:

- The result of the diagnostic test provides specific corrective action for the service person.
- The diagnostic test identifies a failed individual component or a group of components.
- Tests can better isolate failures to the subsystem level.

The following table lists the components and subsystems covered by the diagnostic tests.

### Subsystems and Components

Subsystem	Components
<b>Power Supply</b>	AC distribution system DC power supply (+ 3.3, +5, +12, ±15, +24 volts DC)
<b>Temperature</b>	Door temperature sensor (input/output) Door heater (input/output) Chamber front temperature sensor and heater Chamber center temperature sensor and heater Chamber back temperature sensor and heater Vaporizer temperature sensor Vaporizer heater Condenser temperature sensor

# 3 Functional Description

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<b>Subsystem</b>	<b>Components</b>
	Condenser heat/cool Condenser fans
<b>Vacuum</b>	Vacuum pump Vacuum control valve Vent valve Atmospheric pressure switch Chamber pressure sensors (2) Vacuum control valve current sensor Vent valve current sensor Inlet valve Inlet valve current sensor Transition valve Transition valve current sensor Vaporizer pressure sensor Oil return valve Oil return valve current sensor
<b>Plasma</b>	LFPS II power supply
<b>Delivery</b>	Carriage sensor RFID reader Cassette motor Delivery valve sensor
<b>Doors</b>	Open/close sensors Door direction sensors
<b>Hydrogen Peroxide Monitor</b>	Hydrogen peroxide detector Ultraviolet lamp

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Subsystem	Components
<b>Display</b>	VGA display
	Touch panel
<b>Printer</b>	Printer
<b>Fan</b>	Fan
	Fan current sensor
<b>Sound</b>	Alarm enunciator

### Chamber Heater Resistance

Wire Color	Ohms
Red to black	56.9 +3.0/-5.1

### Door Heater Resistance

Wire Color	Ohms
Red to black	121.0 +6.4/-11.0

## Process Variables and Cancellation Limits

The following table lists the control parameters and cancellation limits for the Standard and Flex cycles.

Variable	Cycle Parameters		Cancellation Limits
	Standard	Flex	
	Standard	Flex	Standard/Flex
Cycle time	47 minutes	42 minutes	Not applicable
Chamber wall temperature	50° C	50° C	<47° C or >56° C
Pressure at delivery to vaporizer	190 torr	190 torr	<120 torr or >195 torr
Pressure before delivery to chamber	150 mtorr	150 mtorr	<1 mtorr or >190 mtorr
Transfer time	8 minutes	8 minutes	>8 minutes
Diffusion time	0.5 minutes	0.5 minutes	>0.5 minutes
Plasma time	7.5 minutes	5 minutes	>7.5 min. Standard cycle > 5 min. Flex cycle.
Plasma pressure	500 mtorr	500 mtorr	<200 mtorr or >1300 mtorr
Plasma power	500 Watts	500 Watts	<450 W or >550 W

The following table lists the control parameters and cancellation limits for the Express and optional DUO cycles.

Variable	Cycle Parameters		Cancellation Limits
	Express	DUO	
Cycle time	24 minutes	60 minutes	Not applicable
Chamber wall temperature	50° C	50° C	<47° C or >56° C
Pressure at delivery to vaporizer	190 torr	300 mtorr	<120 torr or >195 torr, Express cycle <200 mtorr or >400 mtorr, DUO cycle
Pressure before delivery to chamber	400 mtorr	150 mtorr	<300 mtorr or >500 mtorr, Express cycle <200 mtorr or >400 mtorr, DUO cycle
Transfer time	2.5 minutes	6 minutes	>2.5 min, Express cycle >6.0 min, DUO cycle
Diffusion time	0.5 minutes	1.0 minutes	>0.5 min, Express cycle > 1.0 min, DUO cycle
Plasma time	7.5 minutes	2 minutes	>7.5 min, Express cycle > 2 min, DUO cycle
Plasma pressure	500 mtorr	500 mtorr	<200 mtorr or >1300 mtorr
Plasma power	500 Watts	400 Watts	<450 W or >550 W, Express cycle <350 W or >450 W, DUO cycle

## Access Levels and Supervisor Tasks

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.

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

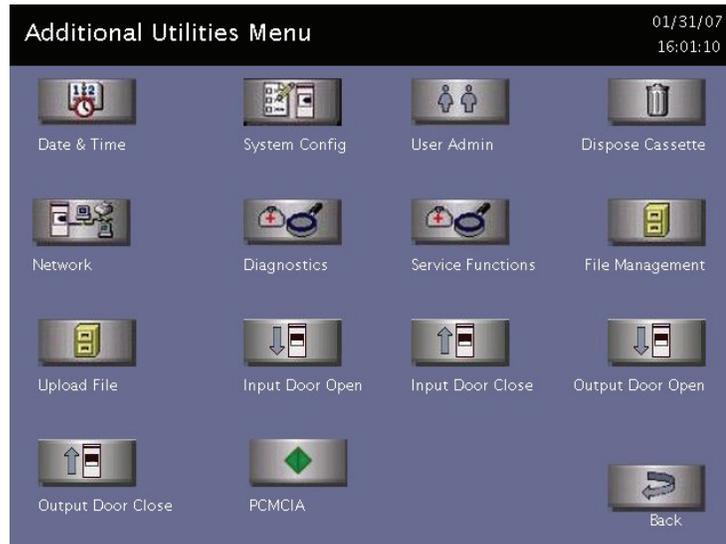
- Add, delete, and modify user names, passwords, and access levels.
- Select, view, and print all sterilizer files.
- Run diagnostic tests and print reports.
- Set date and time.
- Configure sterilizer options.
- Configure the network connection and upload data to the network.

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

### Additional Utilities Menu

The Additional Utilities Menu is available only to users with Supervisor- or Service-level access privileges. If a user with Operator-level privileges touches **Additional Utilities** 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 3. 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 options.

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

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

**Network** allows you to configure the 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.

**Back** returns you to the screen from which you selected “Additional Utilities.”

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## 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.

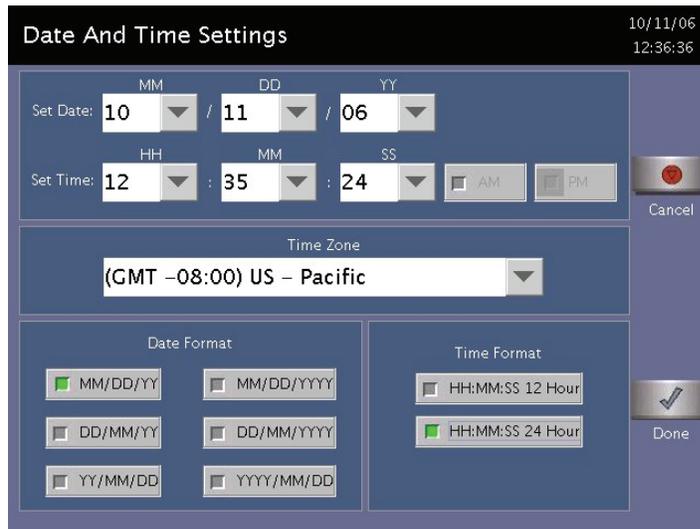


Figure 4. Date and Time Setting.

### 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 **AM** or **PM** 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, **AM** and **PM** are disabled.

### Cancel/Done

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

## System Configuration

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

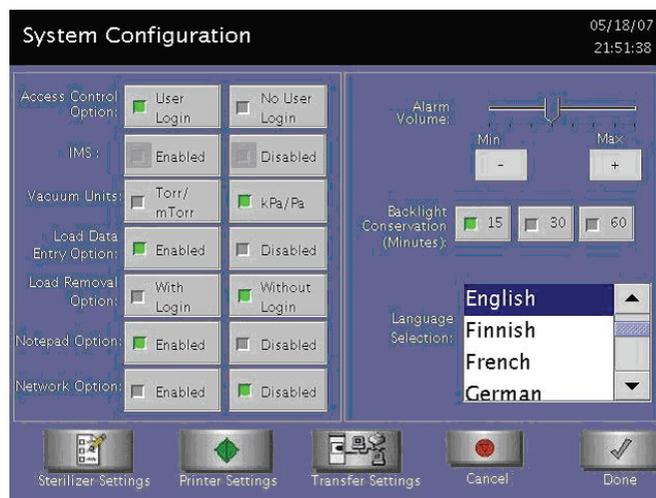


Figure 5. System Configuration.

### 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).

# 3 Functional Description

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

## Backlight Conservation (Minutes)

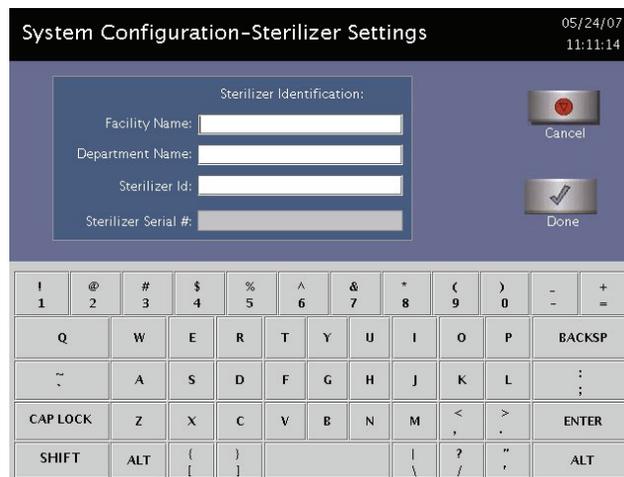
Touch the number of minutes; 15, 30, or 60, to indicate how long the splash screen remains visible in the idle state before starting screen saver mode.

### 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.



**Figure 6. Sterilizer Settings.**

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

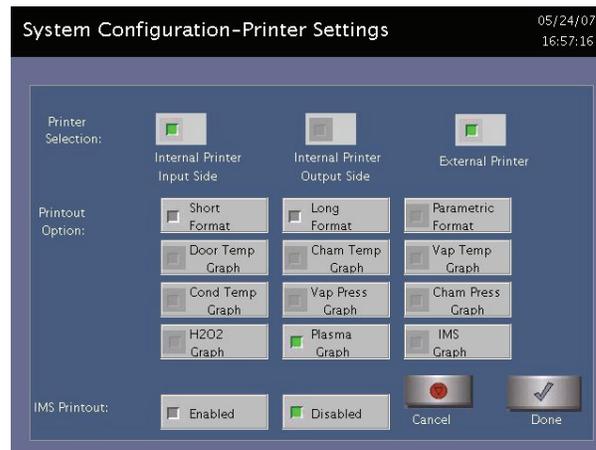
**Department Name** – Enter the name of the department you wish to use as an identifier for the sterilizer.

**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 7. 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.

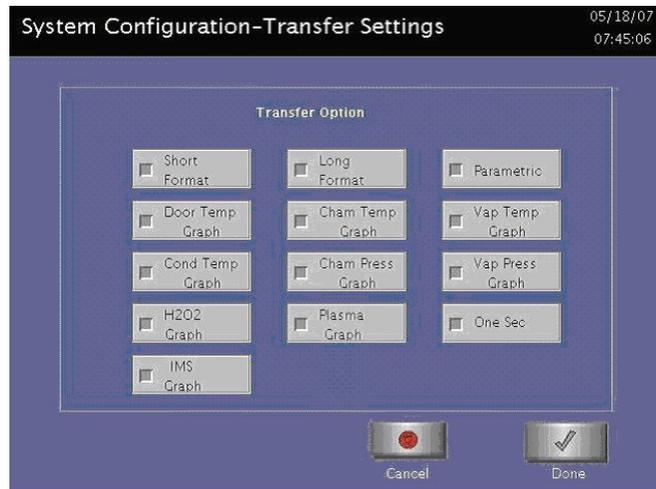


Figure 8. Transfer Settings.

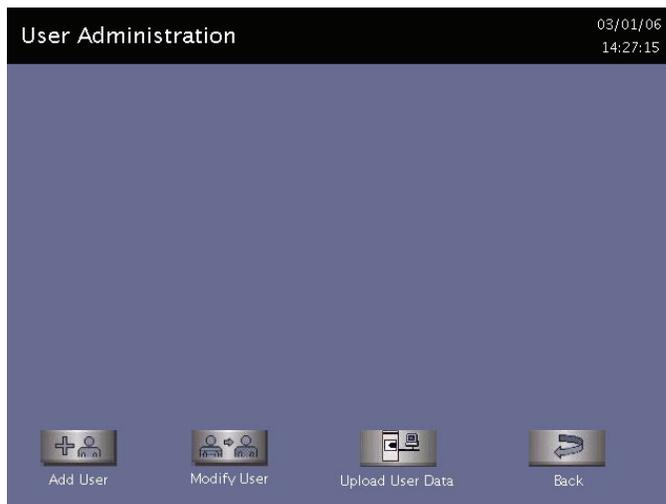
### Cancel/Done

To cancel system configuration, touch **Cancel**. When the system configuration settings are correct, touch **Done**.

## User Administration

Use the User Administration screen to add, modify, or delete user names, passwords, and access levels. A button on this screen allows you to upload user information over 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 9. 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 remote host over the network. (This function does not work if your sterilizer is not configured for a network connection.)

**Back** returns you to the Additional Utilities Menu.

## Add User

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



**Figure 10. Add User.**

1. Enter the user’s operator “identification” in the **Operator** field. The entry must be alphanumeric, 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 alphanumeric, no more than 10 characters.
3. Scroll through the **Access Level** selections and select an appropriate access level. You may choose “Service,” “Operator” or “Supervisor.”
4. Touch **Cancel** to exit this screen and return to the User Administration screen.
5. Touch **Done** when you have finished entering information for a new user.

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## Modify User

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



Figure 11. 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.

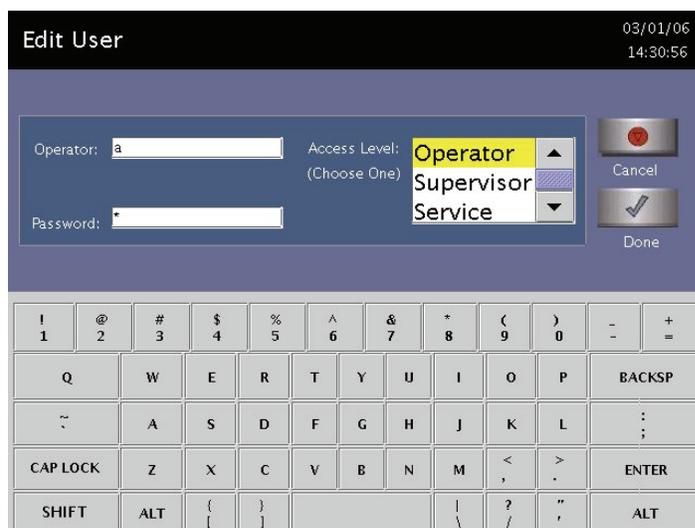


Figure 12. Edit User.

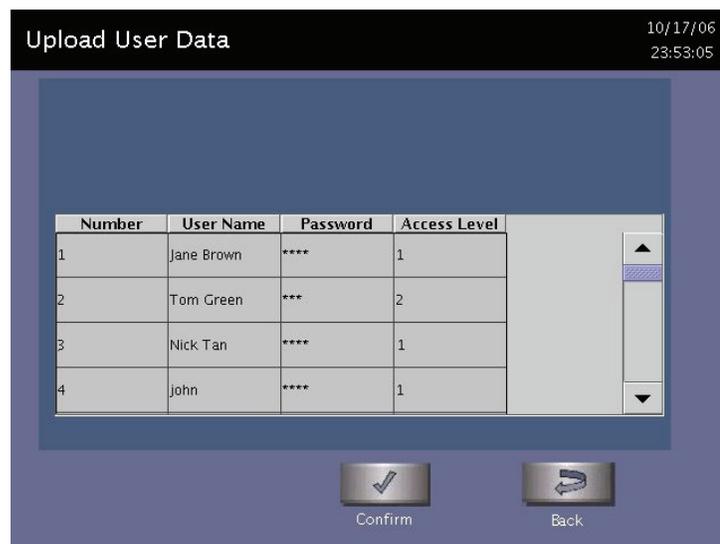
- To modify the selected user’s information, touch **Edit User**.
  - To change the user’s operator name, make changes in the **Operator** field.
  - To change the user’s password, make changes in the **Password** field.
  - To change the user’s access level, select the desired **Access Level**. You may choose “Service,” “Operator” or “Supervisor.”
5. Touch **Cancel** to exit this screen and return to the Modify User screen.
  6. Touch **Done** 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 **Upload User Data** is touched, the Upload User Data screen is displayed.



**Figure 13. 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" dropdown 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).
1. Copy users.rec file to a USB memory stick and insert the memory stick into the sterilizer's port located on the lower right side of the sterilizer.
  2. On the sterilizer, touch **Upload User Data**. 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.
  3. Touch **Confirm** to accept the displayed data, logout the current user and return to the prior screen.

## Dispose Cassette



**WARNING! HYDROGEN PEROXIDE MAY BE PRESENT. WEAR CHEMICAL RESISTANT PVC (VINYL), OR NITRILE GLOVES WHENEVER HANDLING A LOAD AFTER A CYCLE CANCELLATION OR WHEN DISPOSING OF A CASSETTE. HYDROGEN PEROXIDE LIQUID MAY BE PRESENT ON THE CASSETTE, THE LOAD OR IN THE CHAMBER.**

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

Touch **Dispose Cassette** to move the cassette into the cassette disposal box. The full cassette box should be discarded as directed by your facility's procedures.

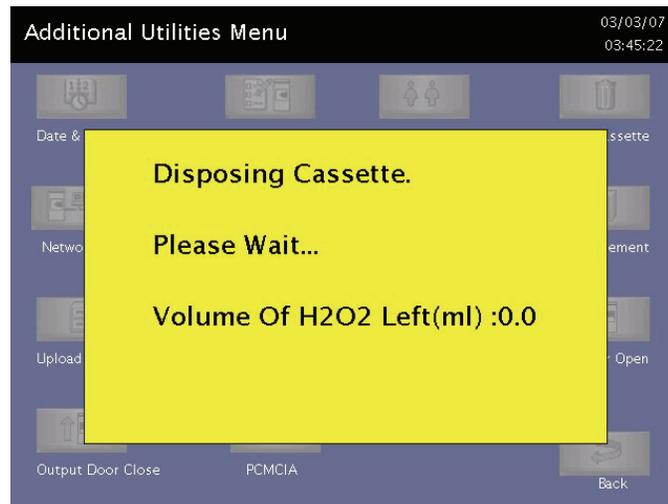


Figure 14. Touch Dispose Cassette to Move the Cassette Into the Cassette Disposal Box.

## Peroxide Clearance Cycle



**WARNING! HYDROGEN PEROXIDE MAY BE PRESENT. WEAR CHEMICAL RESISTANT PVC (VINYL), OR NITRILE GLOVES WHENEVER HANDLING A LOAD AFTER A CYCLE CANCELLATION OR AFTER RUNNING THE PEROXIDE CLEARANCE CYCLE. HYDROGEN PEROXIDE LIQUID MAY BE PRESENT ON THE LOAD OR IN THE CHAMBER.**

This feature is used to dispose of the peroxide remaining in the DUO delivery module when the peroxide has expired (after 10 days in the system), or before servicing. The DUO delivery module holds peroxide in a reservoir to optimize sterilization. If this peroxide expires, or before servicing any part of the DUO delivery module, the Peroxide Clearance cycle must be performed. Two errors specific to DUO cycle functions are:

- "Please Call ASP" indicates that an error is detected in the DUO delivery module.
- If peroxide remains in the DUO delivery module longer than 150 days without running a Peroxide Clearance cycle, the DUO cycle start button will be grayed out and when the Peroxide Clearance button is selected, "Mandatory Service Call Is Required For This Feature. Please Call ASP" is displayed.

See the section "Running a Peroxide Clearance Cycle" in the Troubleshooting chapter of this guide.

Touch **Peroxide Clearance** to start the Peroxide Clearance cycle.

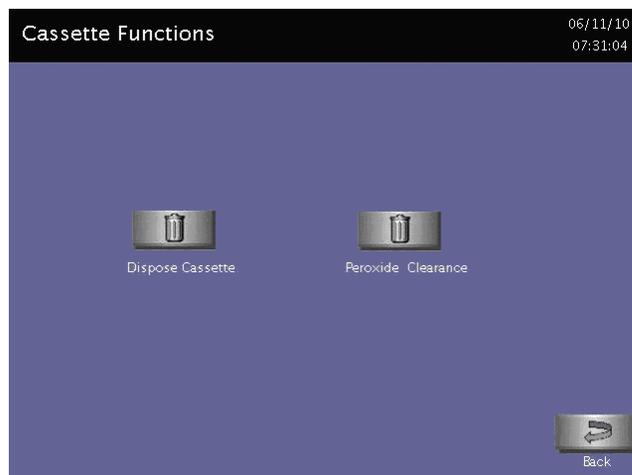


Figure 15. Touch Peroxide Clearance to start the Peroxide Clearance cycle.

## Network

These STERRAD® 100NX® Sterilizer has a networking feature that must be configured by an ASP Field Service Engineer working in conjunction with the customer's network administrator. Call ASP for current information on setting up the network.

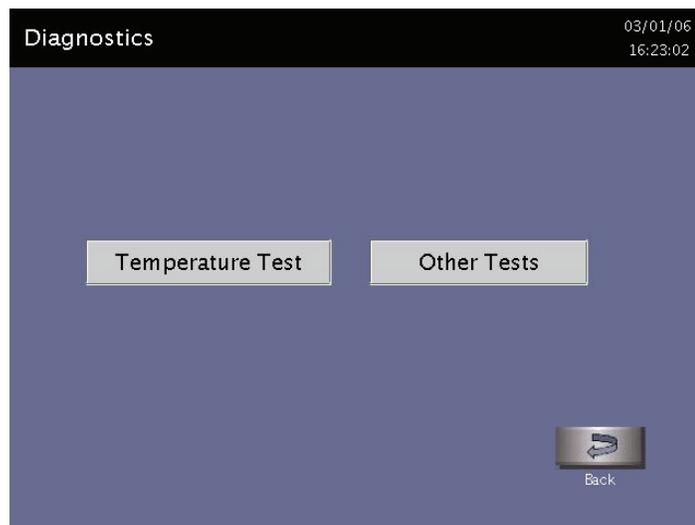
## Diagnostics

The diagnostics function prompts you to select one of two types of tests (either *Temperature* or *Other Tests*). If *Other Tests* is selected, the sterilizer runs ten operator-assisted tests of the sterilizer subsystems. You may skip one or more tests in the automatic sequence by touching **Cancel** 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 **Diagnostics** to start automatic diagnostic testing of the sterilizer.

*Note: The duration of the Temperature Test is 15-60 minutes depending on system temperature.*



**Figure 16. Touch Diagnostics to Run a Series of Tests to Help You Resolve System Messages.**

# 3 Functional Description

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## Diagnostic Tests

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

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

The ten tests take approximately 13 minutes and 30 seconds to complete. When the series of tests is complete, the sterilizer creates and stores a diagnostics file and prints a report. When printing is complete, the Additional Utilities menu is displayed.

## Service Functions

**Service Functions** 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.

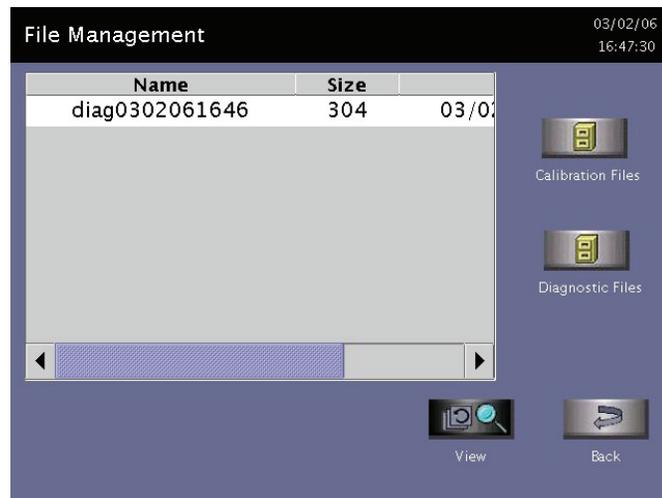


Figure 17. File Management.

### Calibration Files

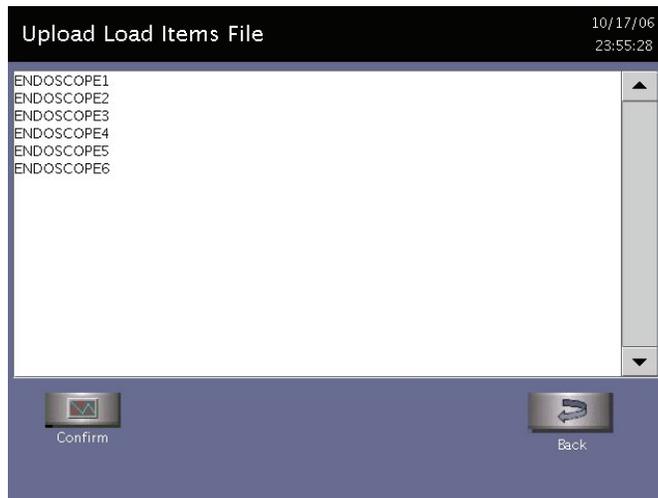
Touch **Calibration Files** to display a list of calibration files created during a sterilizer calibration. Scroll through the list and touch the file name you wish to view. Touch **View** to display the selected calibration file. Touch **Back** to return to the Additional Utilities menu.

### Diagnostic Files

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

## Upload File

This screen allows you to upload item information to the sterilizer using the USB memory port.



**Figure 18. Upload Items Screen.**

1. Using Microsoft “Notepad,” create a list of load items similar to the example shown in the figure. To obtain the above vertical display list; i.e., enter the data on the same line separated by commas. Example: ENDOSCOPE1, ENDOSCOPE2, ENDOSCOPE3, etc. After the last entry, press **Enter**. Up to 1000 load items can be defined.
2. Save the file with the file name “loaditems.txt” and use the “encoding” drop down in Notepad to save the file encoded as UTF-8.
3. Insert the USB memory stick with the file loaditems.txt resident on the stick into the sterilizer’s USB port located on the lower right side of the front panel.
4. Follow the instructions on the display to upload the file.

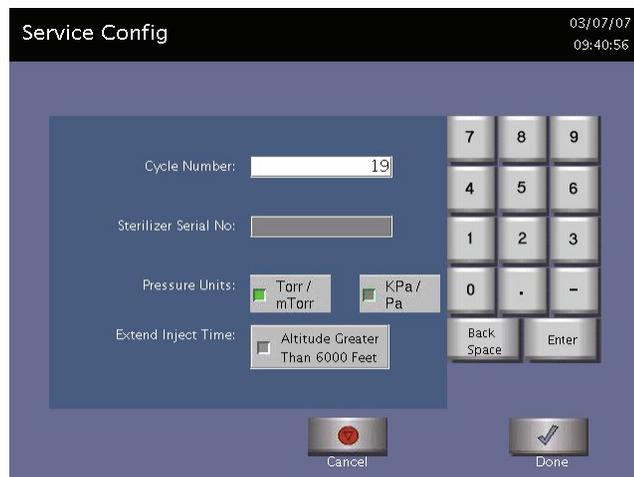
## Input/Output Doors

The doors can be opened or closed via the footpad that you tap with your toe or by touching **Input Door** or **Output Door**. If the system has only one door, only **Input Close Door** and **Input Open Door** are available for use.

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

**Output Open Door** and **Output Close Door** 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.

## Service Configuration



**Figure 19. Service Configuration.**

The Service Configuration display is accessed from the Additional Utilities Menu. On this screen you can set the Cycle Number, Sterilizer Serial Number, Pressure Units and indicate that the sterilizer is being used at an altitude greater than 6,000 ft (1,829 meters). There is a number key pad to enable you to enter the numbers for the cycle and the serial number. This information is set at system installation. Touch **Done** to save the information and exit this screen.

- The cycle number range is 0 to 9999. The default cycle is 0.
- The sterilizer serial number can be up to 11 digits. The default for this field is blank.
- The pressure units are torr/mtorr or kPa/Pa. The default is torr/mtorr.

## Cycle Statistics

Completion Code	No. Of Occurrences	%
Cycle Canceled By Operator	9	45
Cycle Completed Successfully	6	30
Unknown Reason	3	15
H2O2 Curve Area Too Low	1	5
Chamber Center Temperature Too High	1	5
Pressure Out Of Range (High)	0	0
Pressure Out Of Range (Low)	0	0
Input Door Temperature Too Low	0	0
Input Door Temperature Too High	0	0
Output Door Temperature Too Low	0	0
Output Door Temperature Too High	0	0
Chamber Front Temperature Too Low	0	0
Chamber Front Temperature Too High	0	0
Chamber Center Temperature Too Low	0	0
Power Fail Cancellation	0	0
Chamber Rear Temperature Too Low	0	0
Chamber Rear Temperature Too High	0	0
Vaporizer Temperature Too Low	0	0
Vaporizer Temperature Too High	0	0
Condenser Temperature Too Low	0	0
Condenser Temperature Too High	0	0

**Figure 20. Cycle Statistics.**

This screen displays the Completion Code, Number of Occurrences and Percentage (%). The completion code column displays the error conditions that resulted in a canceled cycle. The percentage column indicates the percentage of the total errors that resulted in that code being generated.

The “Number of Occurrences” column displays how many times the particular error condition occurred.

# User Log

Number	User ID	Login/Logout	Date
1	92618	Login	03/07/07
2	92618	Login	03/06/07
3	92618	Logout	03/06/07
4	92618	Login	03/06/07
5	92618	Logout	03/06/07
6	92618	Login	03/06/07
7	92618	Login	03/06/07
8	92618	Login	03/07/07

The screenshot shows a window titled "User Log" with a date and time display (03/07/07, 09:48:18). Below the title bar is a table with four columns: "Number", "User ID", "Login/Logout", and "Date". The table contains eight rows of data. The most recent entry (Number 1) is at the top, showing a login for user ID 92618 on 03/07/07. The interface includes a scroll bar on the right and a "Back" button at the bottom right.

**Figure 21. User Log.**

The User Log displays a listing of every login and logout event, including date, time, user name, and either login or logout. The most recent log entry is displayed first. A total of 100 entries can be displayed.

## Software Error Log



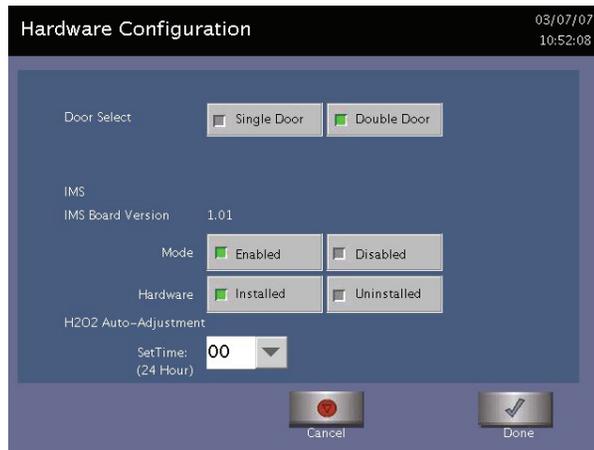
**Figure 22. Software Error Log.**

The Software Error log displays the following details:

- Date
- Time
- Module Name
- Error Type

The most recent error messages are displayed in the bottom of the list. A maximum of 100 logs can be displayed.

# Hardware Configuration



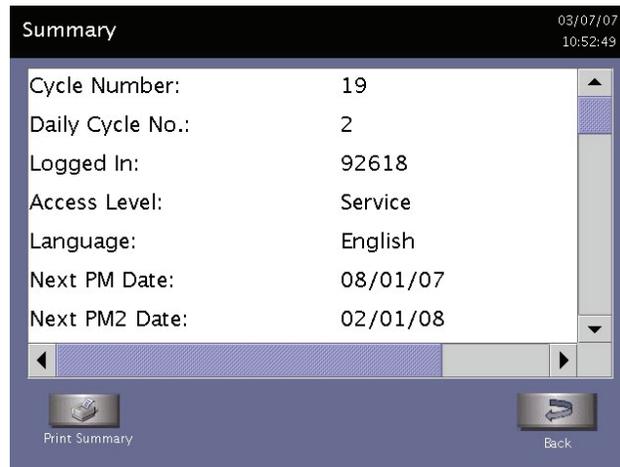
**Figure 23. Hardware Configuration.**

The Hardware Configuration screen allows you to make various choices regarding the sterilizer hardware use. Touch **Done** to save your setting and exit the display. If you changed the IMS selections, the system needs to be rebooted for those selections to be implemented.

The following are displayed or are selectable:

- **Door Select:** Single Door, Double Door allows you to select to use a single door or double-door sterilizer. The default is Single Door. If Single Door is selected on a double-door unit, the second or output door will not be usable.
- **IMS Board Version:** Displays the version of the IMS board if installed.
- **IMS mode:** Enabled or Disabled. If IMS mode Enabled, the IMS software requirement is implemented when the system is rebooted. If the IMS mode is set to Disabled, all the IMS features are removed from the software.
- **IMS Hardware:** Installed or Uninstalled. If Uninstalled is selected, the system sets the IMS mode to IMS Disabled and the system is configured based on the selection.
- **H<sub>2</sub>O<sub>2</sub> Auto-Adjustment:** Set Time. Set a time for the system to perform an automatic adjustment on the H<sub>2</sub>O<sub>2</sub> Monitor. The time appears in 24 hour format: 00 = midnight; 12 = noon; 23 = 1 hour before midnight or 11:00 pm.

## Summary



**Figure 24. Cycle and System Summary.**

The summary screen displays complete details of all the parameters and actions associated with the cycle. These include: Cycle Number, login information, language selected, PM information, cassette information, customer information, etc. Touch **Print** to obtain a paper copy of this information.

# Service Log



**Figure 25. Service Log.**

The Service Log screen allows you to enter information pertaining to a specific service call or event. The sterilizer automatically time-stamps the information with the time, date, and service details. Touch **Save** to save the information you enter. Touch **View All** to see all the logs entered; up to 25. The most recent entry is displayed first.

# System Data

Channel Number	Analog Name	Voltage(mV)	Engr Value	Set Point
1	Chamber Pressure	10000	>30 Torr	798 mTorr
2	Chamber High Pressure	10000	>200 Torr	798 mTorr
3	Reference Pressure	0	0 mTorr	798 mTorr
4	Chamber Center Temperature	1074	50.4 °C	50.0 °C
5	Vaporizer Pressure	10000	>30 Torr	798 mTorr
6	Plasma Delivered Power	0	0 W	XXXXX
7	H2O2 Monitor	3941	0.000 mg/l	XXXXX

**Figure 26. System Data.**

This screen displays analog channel information.

## Displayed Reports

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

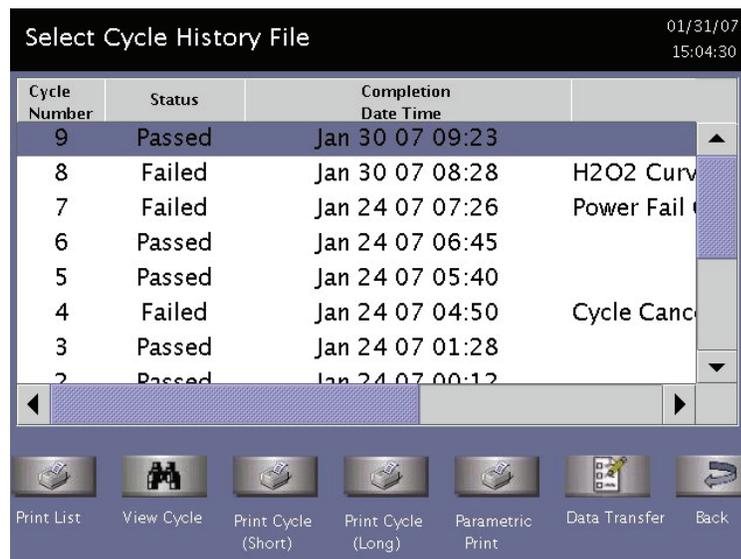
All displayed files can be printed by touching **Print** on the file display screen.

### 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 51<sup>st</sup> 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 **View Cycle History** on any screen where it 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.



The screenshot shows a screen titled "Select Cycle History File" with a date and time display (01/31/07, 15:04:30). Below the title is a table with the following columns: Cycle Number, Status, Completion Date Time, and a fourth column for reasons. The table contains 9 rows of data. Below the table is a scroll bar and a bottom menu with icons and labels for various actions.

Cycle Number	Status	Completion Date Time	
9	Passed	Jan 30 07 09:23	
8	Failed	Jan 30 07 08:28	H2O2 Curv
7	Failed	Jan 24 07 07:26	Power Fail
6	Passed	Jan 24 07 06:45	
5	Passed	Jan 24 07 05:40	
4	Failed	Jan 24 07 04:50	Cycle Canc
3	Passed	Jan 24 07 01:28	
2	Passed	Jan 24 07 00:12	

Bottom menu options: Print List, View Cycle, Print Cycle (Short), Print Cycle (Long), Parametric Print, Data Transfer, Back.

Figure 27. 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.

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

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

**Data Transfer** transfers history files via a network or USB memory stick.

## 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, parametric report, or a long-format report. Each report extracts data from the cycle history record created by the cycle. The short-format report indicates the cycle status (Passed or Failed), date, time, operator and load information. The parametric report contains much more detail than the short report, but is less extensive than the long-format report. The long-format report includes all of the data in the short report plus detailed information about each stage of the sterilization cycle.

### Short Report

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

### Parametric Report

The parametric report shows single-point values for a certain number of parameters. It is a more confined report than the long printout.

# 3

## Functional Description

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### Long Report

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

## Chapter 4.

# Operation

## Before You Start

Each time you use the STERRAD® 100NX® Sterilizer, follow the instructions provided in the chapter on load preparation. It is your responsibility to be familiar with the load preparation and safety information provided in this service guide.

## Start and Warm-up

1. Turn on the main power switch—it is located at lower left side of the input panel.
2. The sterilizer begins by warming up. The warm-up can take up to 1 hour.

*Note:* The sterilizer should not be turned off.

3. “Touch Screen to Start” appears on the display.

## Preparing the Load

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

### Biological Indicators

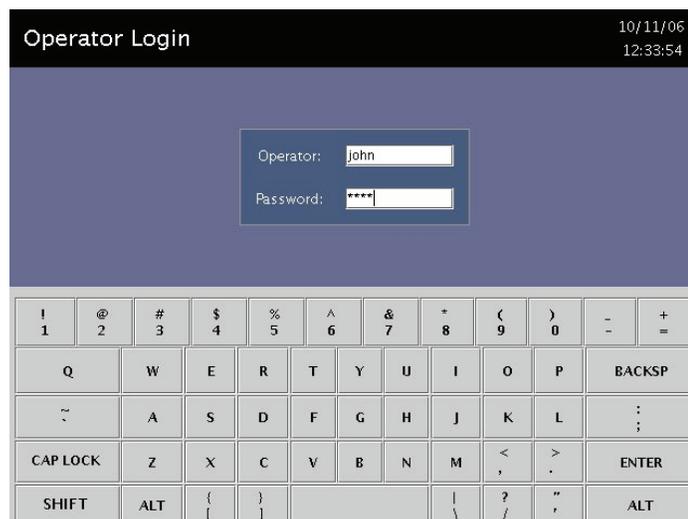
Confirming that sterilizing conditions were achieved during a cycle is an important part of the sterilization process. Biological indicators are one way to ensure that your sterilizer is operating correctly. ASP recommends using the STERRAD® CYCLESURE® Biological Indicator. Contact your ASP Representative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

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

## Login

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

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



**Figure 28. 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. You can also touch the password field.
4. Type your password. The screen displays a series of “\*” characters in place of the characters you type. This is done to keep others from reading your password.
5. When you have finished entering your password, touch the **Enter** key.

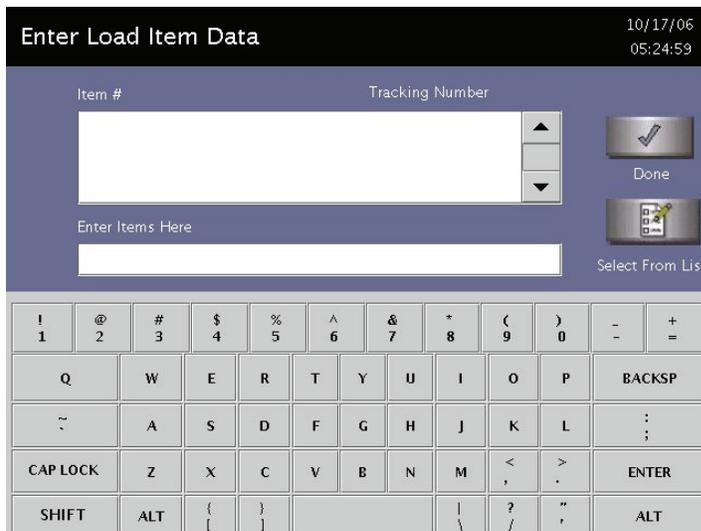
## Entering Load Information

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

### Enter Load Item Data

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

The Load Item Data screen allows you to type items into the screen or select from a predefined list of items in your load. This information is stored by the sterilizer and is printed on a cycle report (and can be transferred to a host computer over the network connection).



**Figure 29. 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.
2. Repeat for additional items always touching **Enter** after each item. Touch **Done** when the list is complete.

An optional barcode scanner can also be used to enter load item data instead of directly entering information using the keyboard. You may use this feature if your sterilizer is equipped with this option.

### Select From List

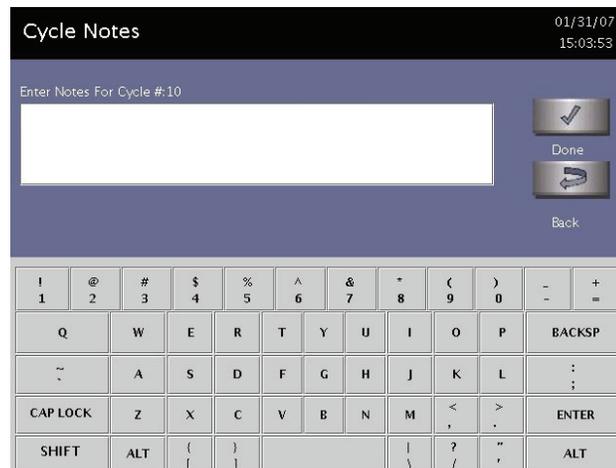
If a database has been established containing frequently used load information, you can select that information using the following steps:

1. Touch **Select from List**.
2. Scroll up or down the load item menu list to the desired item. Touch the items you wish to add to your current list and touch **Select**.
3. Touch **Done** to complete the list.
4. 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. Skip to the subsection titled "Loading the Chamber."*

The Cycle Notes screen can be used to record information about biological indicators used in the cycle or any other information that should be stored in the cycle history file. This information is printed on the cycle report and can be transferred over the network connection.



**Figure 30. Cycle Notes.**

1. Touch the **Enter Notes for Cycle** field. The cursor appears in the field. Use the on-screen keyboard to type your notes. Touch **Done**.
2. If conditions exist which prevent a sterilization cycle from starting; e.g., no cassette, hydrogen peroxide monitor blocked, a message is displayed on the screen.
3. The program displays the System Ready screen. Touch **Back** to return to the previous screen.

## Loading the Chamber

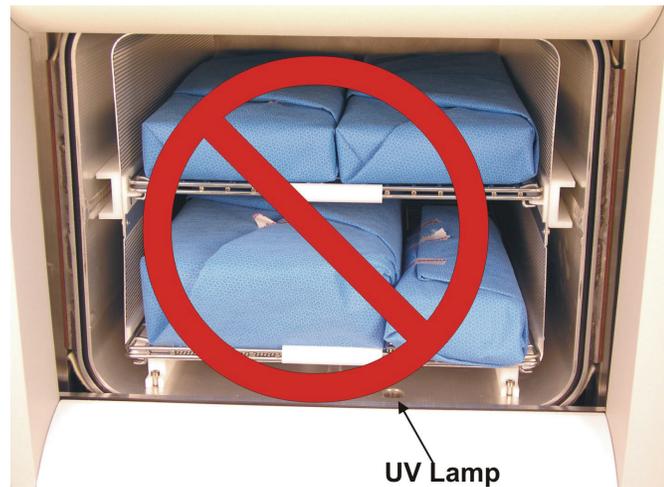
*Note: The doors are equipped with safety mechanisms that prevent them from closing if an obstruction is encountered. If this occurs, the door stops immediately. You must touch Open or Close Door to move the door.*

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 31. Touch the Toe 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 32. Do Not Block the UV Lamp.**

2. When placing the load on the shelves, make certain that you do not block the beam of the ultraviolet lamp in the front right side of the chamber. Make sure the load is centered on the shelves and that the shelves are centered in the chamber. Do not stack trays on top of each other. Trays must be far enough apart to allow proper diffusion of the hydrogen peroxide.



**Figure 33. 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.

## 4 Operation

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**Figure 34. Do NOT Stack Trays.**



**Figure 35. Load Correctly Placed.**

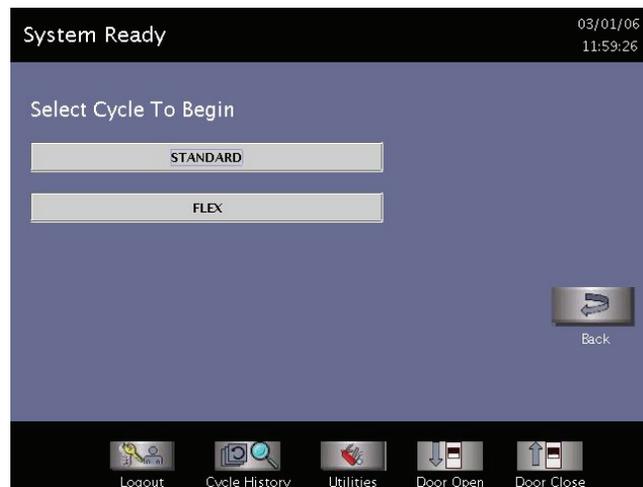
5. When you are finished loading the chamber, close the door by tapping the foot pad or touching **Close Door**.
6. If the message “Please Close Door” is displayed, the door is not securely closed. Make certain that nothing is caught in the door seal.

## Selecting and Starting a Cycle

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

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

If the sterilizer is loaded with an unexpired cassette, touch your cycle choice, either Standard or Flex and the cycle starts.



**Figure 36. Touch the Screen to Start Your Cycle.**

## System Ready Screen

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

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

## Inserting a Cassette

1. Take a new STERRAD<sup>®</sup> 100NX<sup>®</sup> Cassette out of its shipping carton.
2. Look at the package carefully before opening it. The indicator strip should be white. **If the indicator strip is red, do not open the package**—it is possible that hydrogen peroxide has leaked inside the package. Refer to the cassette *Instructions for Use* for proper handling instructions.
3. If the indicator strip is 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 as shown in the following figure. **Do not use force** to push the cassette into the machine.



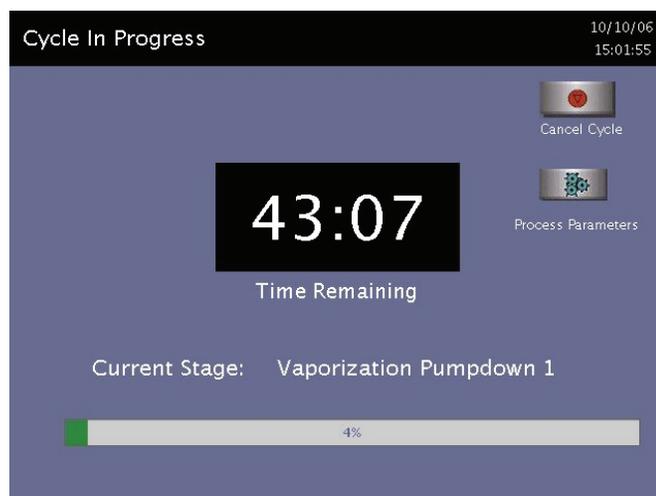
**Figure 37. Inserting the Cassette into the Slot.**

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

*Note: If the cassette is not accepted by the system, e.g., expired, used, invalid, etc, it is ejected into the cassette disposal box. You must insert a new cassette to continue.*

## Cycle in Progress

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



**Figure 38. Cycle In Progress. The Countdown Clock is Displayed.**

## 4 Operation

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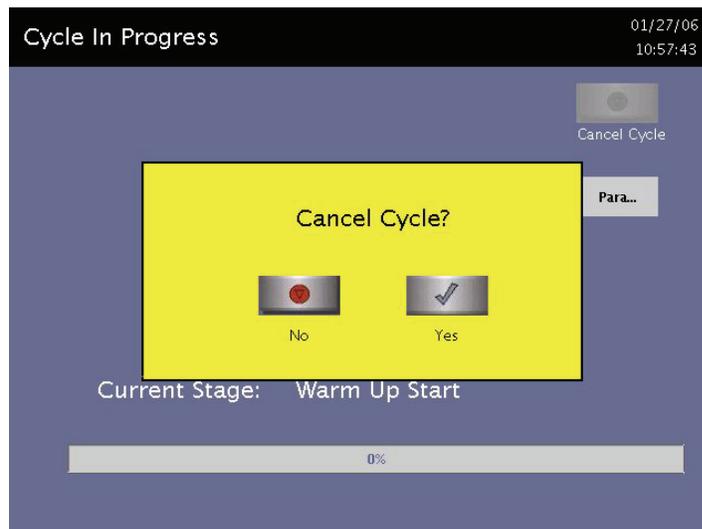
The clock displays the estimated number of minutes and seconds remaining before the cycle is finished. The “Time Remaining” field updates as the sterilization cycle progresses. As each sterilization cycle stage runs, the screen displays the name of the stage. A moving bar graph also displays the percent of the cycle that is complete. For details about the current stage information, refer to the Long Report printout in the “Reports and Files” section.

### Canceling a Cycle

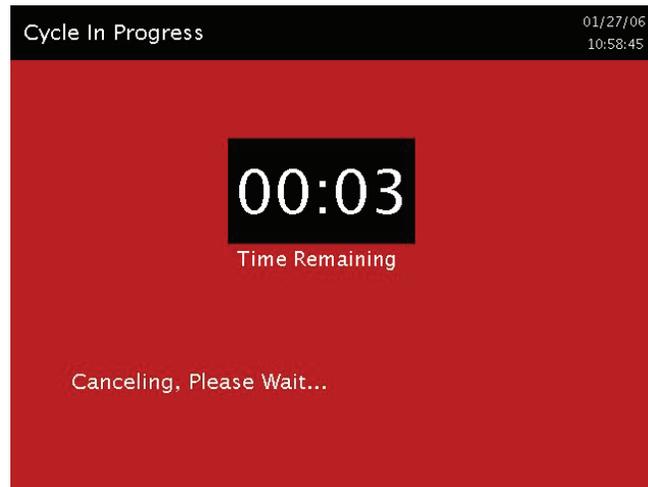
There may be occasions when it is necessary to cancel a cycle before it is completed.

To cancel a cycle, do the following:

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



**Figure 39. Cancel Cycle Confirmation. Touch Yes or No.**



**Figure 40. Cycle Cancellation In Progress. Cancellation Has Been Confirmed.**

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.

Loads from canceled cycles should be rewrapped using new packaging materials, STERRAD<sup>®</sup> Chemical Indicator Strips, and STERRAD<sup>®</sup> SEALSURE<sup>®</sup> 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 PVC (VINYL), OR NITRILE GLOVES WHILE REMOVING THE ITEMS FROM THE CHAMBER, AND WHILE WIPING OFF THE ITEMS WITH A DAMP CLOTH.**

## Process Parameters

During a cycle, you may touch **Process Parameters** to display and verify critical setting used in the cycle process.

Touch **Done** (or **Back**) to return to the Cycle in Progress display.

## 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 41. Cycle Completed.**

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

## Processing a Sterilized Load

When you touch **Done**, the sterilizer's response 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 in the printout acknowledging the completion of the cycle.
- If no login is required for load removal, the door opens and the load can be removed.
- Refer to the cycle completion flowchart on the next page for additional information.

## **Inspecting Chemical Indicators**

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

## **Processing Biological Indicators**

Remove the biological indicator from the load and process it per its *Instructions for Use*. Refer to the biological indicator section in the STERRAD<sup>®</sup> 100NX<sup>®</sup> User's Guide for more information.



Chapter 5.

# Diagnostic Tests and Troubleshooting

## Diagnostic Files

Diagnostic files are created by the diagnostics tests. The files contain details about the tests and the outcomes (Passed or Failed) of each. An example of a Diagnostic file is shown in the figure following the table.

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

## Diagnostics

*Note: The temperature tests run automatically for about 15-60 minutes depending on sterilizer temperature. These tests should only be used if there is a suspected temperature problem.*

Touch **Diagnostics** to start automatic diagnostic testing of the sterilizer. When started, the diagnostics function prompts you to select one of two types of tests (either “Temperature Test” or “Other Tests”). If “Other Tests” is selected, the sterilizer runs a number of operator-assisted tests of the sterilizer subsystems. You may skip one or more tests in the automatic sequence by touching **Cancel** when a test begins. The program advances to the next test in the sequence.

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

# 5 Diagnostic Tests and Troubleshooting

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## Diagnostic Tests

Order	Test Name	What is tested	Minimum Time to Run*
1	Power Supply Test	DC voltage power supplies and sensors.	30 sec.
2	Vacuum Test	Vacuum pump and pressure sensors.	2 min. 20 sec.
3	Plasma Test	Plasma electrical subsystem. Electrode integrity.	3 min. 40 sec.
4	Cassette Test	Cassette mechanical subsystem.	5 min.
5	Door Test	Door motor and sensor.	20 sec.
6	H <sub>2</sub> O <sub>2</sub> Sensor Test	Ultraviolet lamp and detector.	20 sec.
7	Display Test	Touch screen calibration and function.	20 sec.
8	Printer Test	Printer function.	10 sec.
9	Fan Test	Fan speed and function.	10 sec.
10	Sound Test	Loudspeaker function and volume.	40 sec.

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

The ten tests take approximately 13 minutes and 30 seconds to complete. When the series of tests is complete, the sterilizer creates and stores a diagnostics file and prints a report. When printing is complete, the Additional Utilities menu is displayed.

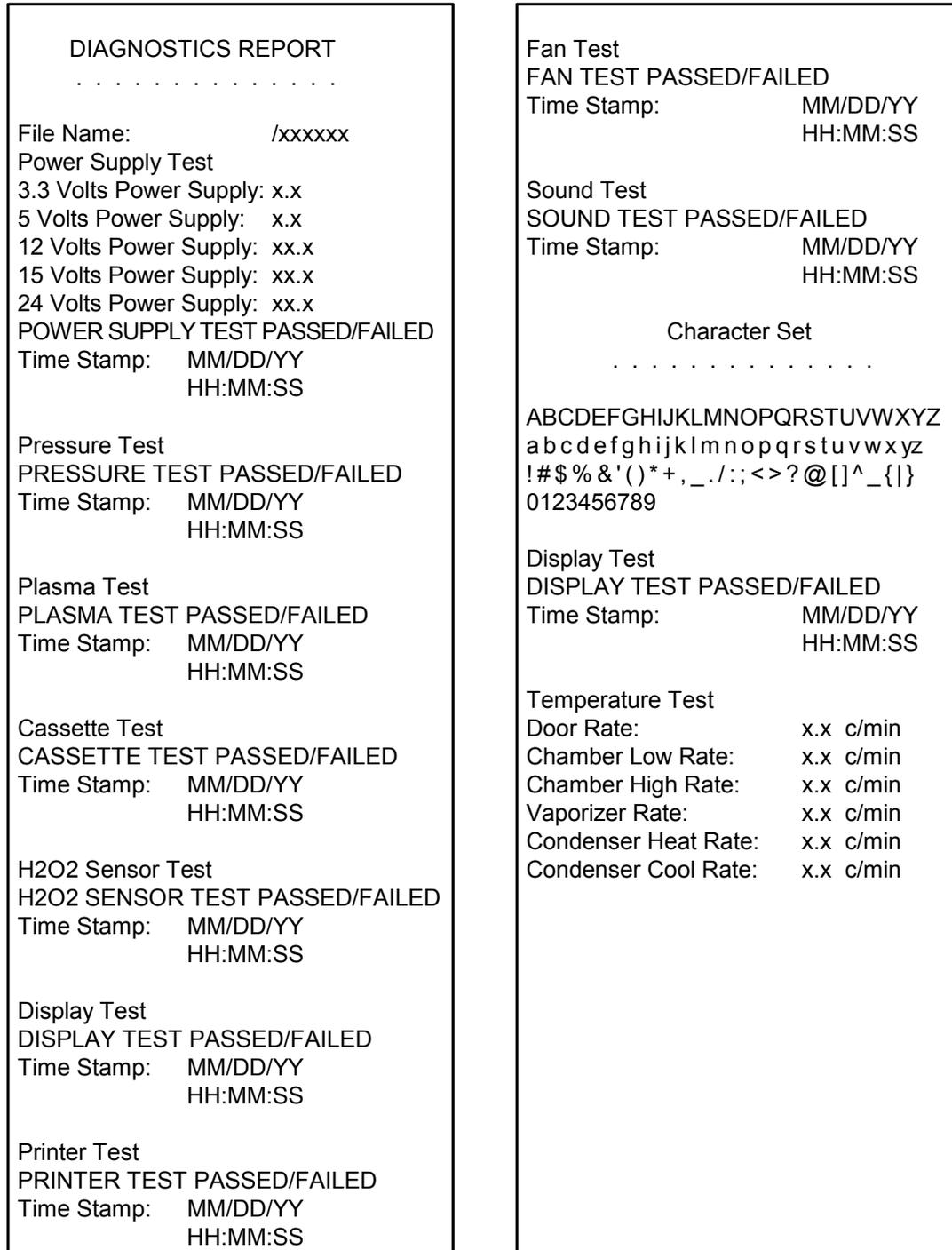


Figure 42. Diagnostic File Example.

## Troubleshooting

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

<b>Error Message</b>	<b>Probable Cause</b>	<b>Suggested Remedy</b>
12 VOLT SUPPLY OUT OF RANGE	12 VDC supply is out of tolerance.	Run the diagnostics. If the diagnostics fail, replace the ATXDC power supply.
15 VOLT SUPPLY OUT OF RANGE	15 VDC supply is out of tolerance.	Run the diagnostics. If the diagnostics fail, replace the ATXDC power supply.
24 VOLT SUPPLY OUT OF RANGE	24 VDC supply is out of tolerance.	Run the diagnostics. If the diagnostics fail, replace the 24 VDC power supply.
3.3 VOLT SUPPLY OUT OF RANGE	3.3 VDC supply is out of tolerance.	Run the diagnostics. If the diagnostics fail, replace the ATXDC power supply.
5 VOLT SUPPLY OUT OF RANGE	5 VDC supply is out of tolerance.	Run the diagnostics. If the diagnostics fail, replace the ATXDC power supply.
AUTO ADJUSTMENT FAILED	A fault was detected during the hydrogen peroxide auto-adjustment.	Check UV lamp and monitor functionality. Verify operation using H <sub>2</sub> O <sub>2</sub> test.
CANNOT DISPOSE CASSETTE, RUN DIAGNOSTICS	The sterilizer cannot move the cassette into the disposal box.	Never put your hand inside the machine to move a cassette. Select "Dispose Cassette" again. If the problem persists, run diagnostics. If diagnostics fail, adjust or replace the delivery subsystem.
CANNOT EJECT CASSETTE, RUN DIAGNOSTICS	The sterilizer cannot eject the cassette.	Run diagnostics. If diagnostics fail, adjust or replace the delivery subsystem.
CANNOT LIGHT PLASMA	The sterilizer cannot light plasma. The load may be touching the electrode or a sensor may have failed.	Try to isolate the problem to the load. If the problem persists, run diagnostics. If diagnostics fail, troubleshoot or replace the LFPS II power supply.

<b>Error Message</b>	<b>Probable Cause</b>	<b>Suggested Remedy</b>
CASSETTE DID NOT INDEX	System could not communicate with delivery subsystem while attempting to index the cassette.	Run diagnostics. If diagnostics fail, adjust or replace the delivery subsystem.
CASSETTE EXPIRED, DISPOSING CASSETTE	The cassette has expired or has been in the sterilizer for more than 10 days. The sterilizer will dispose the cassette.	Load a new cassette. If message persists, run diagnostics. If diagnostics fail, adjust or replace the delivery subsystem.
CASSETTE OUT OF DATE, DISPOSING CASSETTE	The cassette has expired and cannot be used. The sterilizer will dispose the cassette.	Load a new cassette. If problem persists, run diagnostics. If diagnostics fail, adjust or replace the delivery subsystem.
CASSETTE SYSTEM TIMEOUT ON INDEXING	System could not communicate with delivery subsystem while attempting to index the cassette.	Run diagnostics. If diagnostics fail, adjust or replace the delivery subsystem.
CASSETTE SYSTEM TIMEOUT WHEN PIERCING	System could not communicate with delivery subsystem while attempting to pierce the cassette.	Run diagnostics. If diagnostics fail, adjust or replace the delivery subsystem.
CASSETTE USED, DISPOSING	Cassette does not have enough cells to run a complete cycle.	Load a new cassette. If problem persists, run diagnostics. If diagnostics fail, adjust or replace the delivery subsystem.
CCF PARSING ERROR	A corrupted data file was detected.	Reboot the system. If problem persists, replace the software.
CHAMBER 1 TEMPERATURE HAS NOT RISEN	The chamber front temperature did not reach the process temperature during a cycle.	Run diagnostics. Troubleshoot or replace chamber front temperature sensor.
CHAMBER 1 TEMPERATURE TOO HIGH	The chamber front temperature was higher than expected. A sensor or heater may have failed.	Run diagnostics. Troubleshoot or replace chamber front temperature sensor.
CHAMBER 1 TEMPERATURE TOO LOW	The chamber front temperature was lower than expected. A sensor or heater may have failed.	Run diagnostics. Replace failed component.

# 5 Diagnostic Tests and Troubleshooting

<b>Error Message</b>	<b>Probable Cause</b>	<b>Suggested Remedy</b>
CHAMBER 2 TEMPERATURE DRIFTED HIGHER	The chamber center temperature difference was larger than expected. A sensor or heater may have failed.	Run diagnostics. Replace failed component.
CHAMBER 2 TEMPERATURE DRIFTED LOW	The chamber center temperature difference was larger than expected. A sensor or heater may have failed.	Run diagnostics. Replace failed component.
CHAMBER 2 TEMPERATURE HAS NOT RISEN	The chamber center temperature did not reach the process temperature during a cycle.	Run diagnostics. Troubleshoot or replace chamber center temperature sensor.
CHAMBER 2 TEMPERATURE TOO HIGH	The chamber center temperature was higher than expected. A sensor or heater may have failed.	Run diagnostics. Troubleshoot or replace chamber center temperature sensor.
CHAMBER 2 TEMPERATURE TOO LOW	The chamber center temperature was lower than expected. A sensor or heater may have failed.	Run diagnostics. Replace failed component.
COLLECTION BOX FULL, PLEASE CHANGE BOX	There are 2 empty cassettes in the collection box or the collection box is not present.	Empty the collection box or insert collection box. If problem persists, troubleshoot or replace the collection box switch.
CONDENSER TEMPERATURE HAS NOT RISEN	The condenser temperature did not reach the process temperature during a cycle.	Run diagnostics. Adjust or replace the vaporizer/condenser assembly.
CONDENSER TEMPERATURE TOO HIGH	The condenser temperature was higher than expected. A sensor or heater may have failed.	Run diagnostics. Adjust or replace the vaporizer/condenser assembly.
CONDENSER TEMPERATURE TOO LOW	The condenser temperature was lower than expected. A sensor or heater may have failed.	Run diagnostics. Adjust or replace the vaporizer/condenser assembly.
DELIVERY SYSTEM NOT READY	System could not communicate with delivery subsystem.	Run diagnostics. Replace the failed component.

<b>Error Message</b>	<b>Probable Cause</b>	<b>Suggested Remedy</b>
DOOR SENSOR FAULT	A fault was detected during operation.	Run diagnostics. Troubleshoot or replace the door sensor.
DOOR TEMPERATURE HAS NOT RISEN	The door temperature did not reach the process temperature during a cycle.	Run diagnostics. Troubleshoot or replace failed component.
DOOR TEMPERATURE TOO HIGH	The door temperature was higher than expected. A sensor or heater may have failed.	Run diagnostics. Troubleshoot or replace failed component.
DOOR TEMPERATURE TOO LOW	The door temperature was lower than expected. A sensor or heater may have failed.	Run diagnostics. Troubleshoot or replace failed component.
H2O2 BULB/DETECTOR FAULT	The hydrogen peroxide sensor is out of the expected range.	Inspect operation of UV lamp; replace lamp if failed. Clean the optical windows of the lamp and detector. Run diagnostics. Replace failed component.
H2O2 CURVE AREA TOO LOW	The load absorbed too much hydrogen peroxide. Other possible causes are: improperly inserted H2O2 cassette, clogged or bent pierce needles on the H2O2 delivery system, malfunctioning delivery valve, clogged or occluded extractor manifold, and/or obstructed delivery tubes.	Isolate the problem and run diagnostics. Replace failed component.
H2O2 MONITORING FAILURE	The hydrogen peroxide sensor is out of the expected range.	Inspect operation of UV lamp; replace lamp if failed. Clean the optical windows of the lamp and detector. Run diagnostics. Replace failed component.
H2O2 SENSOR FAULT	The hydrogen peroxide sensor is out of the expected range.	Clean the lamp and detector optical windows. Run diagnostics. Verify operation of the UV lamp. Replace any failed components.
HIGH PLASMA POWER	Plasma power out of specification.	Run diagnostics. If the diagnostics fail, replace the LFPS II power supply.

# 5 Diagnostic Tests and Troubleshooting

<b>Error Message</b>	<b>Probable Cause</b>	<b>Suggested Remedy</b>
INCORRECT CASSETTE TYPE, EJECTING	The cassette inserted is not a STERRAD® 100NX® cassette.	Insert a cassette. If the problem persists, run diagnostics. Adjust or replace the delivery subsystem.
IPC FAILURE CANCELLATION	Generic system error.	Power sterilizer down and turn on again. If problem persists, run diagnostics. Replace failed component.
LESS NUMBER OF CELLS AVAILABLE	The number of available cells on the cassette is fewer than the number of cells required for the cycle.	Existing cassette is disposed. Insert a new cassette. If the problem persists, run diagnostics. Adjust or replace the delivery subsystem.
LOW PLASMA POWER	Plasma power out of specification.	Run diagnostics. If the diagnostics fail, replace the LFPS II power supply.
MAIN FAN FAULT	The main fans are not on.	Inspect the fans. Replace if needed.
MANDATORY SERVICE CALL IS REQUIRED FOR THIS FEATURE. PLEASE CALL ASP.	Peroxide has remained in the DUO delivery module longer than 150 days	See the Peroxide Clearance Cycle section in this chapter for instructions.
NO CELLS FOUND DURING START CYCLE	The number of available cells on the cassette is fewer than the number of cells required for the cycle.	Existing cassette is disposed. Insert a new cassette. If problem persists, run diagnostics. Adjust or replace the delivery subsystem.
PLEASE CALL ASP	An error occurred in the DUO delivery module during the start of a DUO cycle or during Peroxide Clearance.	See the Peroxide Clearance Cycle section in this chapter for instructions.
PLEASE REMOVE CASSETTE AND VERIFY CASSETTE ORIENTATION	The cassette may have been inserted backwards.	Inspect the cassette. Orient the cassette and insert it. If problem persists, insert a new cassette. If problem persists, run diagnostics. Adjust or replace the delivery subsystem.

<b>Error Message</b>	<b>Probable Cause</b>	<b>Suggested Remedy</b>
PLEASE REMOVE CASSETTE AND VERIFY CASSETTE TYPE	The sterilizer cannot identify the proper cassette type. The wrong type of cassette may have been inserted.	Inspect the cassette. Make sure it is the correct type for the sterilizer. Insert cassette again. Try a new cassette. If problem persists, run diagnostics. Adjust or replace the delivery sub-system.
PRESSURE OUT OF RANGE [HIGH]	Pressure could not be maintained during vacuum. Excessive load outgassing or wet load.	Try to isolate the problem to the load. Start a new cycle. If the problem persists, run diagnostics. Replace failed component.
PRESSURE OUT OF RANGE [LOW]	Pressure could not be maintained during vacuum.	Try to isolate the problem to the load. If the problem persists, run diagnostics. Replace failed component.
PRESSURE SENSOR BELOW ATMOSPHERE, RUN DIAGNOSTICS	A sensor has detected a fault during operation.	Run diagnostics. Replace failed component.
PRINTER IS OUT OF PAPER. PLEASE LOAD A NEW ROLL	Printer is out of paper.	Insert a new roll of paper. If problem persists, replace printer assembly.
TEMPERATURE HAS NOT RISEN	The temperatures have not reached the operating temperatures during warm-up. The door is open or a heater or sensor may have failed.	If the sterilizer door is open, close the door and wait 30 minutes. If the problem persists, run diagnostics. Replace failed component.
UNKNOWN REASON	Generic system error.	Start cycle again. If problem persists, run diagnostics. Troubleshoot as indicated.

# 5 Diagnostic Tests and Troubleshooting

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<b>Error Message</b>	<b>Probable Cause</b>	<b>Suggested Remedy</b>
UV PATH IS BLOCKED, OPEN DOOR AND CLEAR PATHWAY	An object is blocking the UV lamp and monitor pathway.	Try to isolate the problem to the load. Inspect operation of UV lamp; replace lamp if failed. Clean the optical windows of the lamp and detector. Run diagnostics. Replace failed component.
VACUUM DETECTED, RUN DIAGNOSTICS	A sensor has detected a fault during operation.	Run diagnostics. Replace failed component.
VAPORIZER TEMPERATURE HAS NOT RISEN	The vaporizer temperature did not reach the process temperature during a cycle.	Run diagnostics. Troubleshoot or replace failed component.
VAPORIZER TEMPERATURE TOO HIGH	The vaporizer temperature was higher than expected. A sensor or heater may have failed.	Run diagnostics. Troubleshoot or replace failed component.
VAPORIZER TEMPERATURE TOO LOW	The vaporizer temperature was lower than expected. A sensor or heater may have failed.	Run diagnostics. Troubleshoot or replace failed component.
VENT TIMEOUT	Time to vent the chamber is excessive.	Run diagnostics. Troubleshoot or replace failed component.
VENT TIMEOUT IN VACUUM	Time to vent the chamber is excessive.	Run diagnostics. Troubleshoot or replace failed component.

## Diagnostic Messages

Diagnostic messages are displayed and printed when the diagnostic tests are run.

<b>Error Message</b>	<b>Probable Cause</b>	<b>Suggested Remedy</b>
12 VOLT SUPPLY HIGH	12 volt DC supply > 14.4 volts.	Replace DC power supply.
12 VOLT SUPPLY LOW	12 volt DC supply < 9.6 volts.	Replace DC power supply.
15 VOLT SUPPLY HIGH	15 volt DC supply > 18 volts.	Replace DC power supply.
15 VOLT SUPPLY LOW	15 volt DC supply < 12 volts.	Replace DC power supply.
24 VOLT SUPPLY HIGH	24 volt DC supply > 28.8 volts.	Replace DC power supply.
24 VOLT SUPPLY LOW	24 volt DC supply < 19.2 volts.	Replace DC power supply.
3.3 VOLT SUPPLY HIGH	3.3 volt DC supply > 3.96 volts.	Replace DC power supply.
3.3 VOLT SUPPLY LOW	3.3 volt DC supply < 2.64 volts.	Replace DC power supply.
5 VOLT SUPPLY HIGH	5 volt DC supply > 6 volts.	Replace DC power supply.
5 VOLT SUPPLY LOW	5 volt DC supply < 4 volts.	Replace DC power supply.
ALARMS NOT HEARD	Alarms not functioning.	Verify that the speaker connections are functional. If the connections are correct, place the control enclosure.
ATM SWITCH STUCK AT ATMOSPHERE	Atmospheric switch failure.	Inspect the sensor wiring and connector. Replace the atmospheric pressure sensor if it has failed.
ATM SWITCH STUCK AT VACUUM	Atmospheric switch failure.	Inspect the sensor wiring and connector. Replace the atmospheric pressure sensor if it has failed.
BAD MONITOR	UV monitor not functional.	Replace the UV lamp if it has failed. Clean the optical windows of the lamp and detector. Replace the detector if has failed.

# 5 Diagnostic Tests and Troubleshooting

<b>Error Message</b>	<b>Probable Cause</b>	<b>Suggested Remedy</b>
CANNOT TURN PLASMA OFF	Plasma power out of specification.	Replace LFPS II power supply.
CARRIAGE SENSOR READ FAILURE	Carriage sensor not functional.	Replace delivery system assembly.
CASSETTE MOTOR FAILURE	Cassette motor not functional.	Replace delivery system assembly.
CASSETTE SYSTEM TIMEOUT	System could not communicate with delivery subsystem.	Replace delivery system assembly.
CHAMBER DELTA TOO BIG	The chamber temperature difference was larger than expected. A sensor or heater may have failed.	Inspect sensor wiring and connectors. Replace temperature sensors if failed.
CHAMBER LOW/HIGH SELECT FAILURE	Chamber heater not functioning within specification.	Inspect chamber heater wiring and connector. Replace heater if failed.
CHAMBER PRESSURE RAILED HIGH	Chamber pressure always reads 30 torr.	Replace pressure sensor.
CHAMBER PRESSURE RAILED LOW	Chamber pressure always reads 0 torr.	Inspect sensor wiring and connectors. Replace pressure sensor if failed.
CHAMBER1 TEMPERATURE DID NOT DROP	Chamber heater stuck on.	Replace chamber heater.
CHAMBER1 TEMPERATURE DID NOT RISE	Chamber heater/sensor not functioning within specification.	Inspect sensor and heater wiring and connectors. Replace failed component.
CHAMBER 1 TEMPERATURE RAILED HIGH	Thermistor circuit failure.	Replace temperature sensor 1.
CHAMBER 1 TEMPERATURE RAILED LOW	Thermistor disconnected.	Inspect sensor wiring and connector. Replace temperature sensor 1 if failed.
CHAMBER2 TEMPERATURE DID NOT DROP	Chamber heater stuck on.	Replace chamber heater.
CHAMBER2 TEMPERATURE DID NOT RISE	Chamber heater/sensor not functioning within specification.	Inspect sensor and heater wiring and connectors. Replace failed component.

<b>Error Message</b>	<b>Probable Cause</b>	<b>Suggested Remedy</b>
CHAMBER 2 TEMPERATURE RAILED HIGH	Thermistor circuit failure.	Replace temperature sensor 3.
CHAMBER 2 TEMPERATURE RAILED LOW	Thermistor disconnected.	Inspect sensor wiring and connector. Replace temperature sensor 3 if failed.
CHAMBER 3 TEMPERATURE DID NOT DROP	Chamber heater stuck on.	Replace chamber heater.
CHAMBER 3 TEMPERATURE DID NOT RISE	Chamber heater/sensor not functioning within specification.	Inspect sensor and heater wiring and connectors. Replace failed component.
CHAMBER 3 TEMPERATURE RAILED HIGH	Thermistor circuit failure.	Replace temperature sensor 3.
CHAMBER 3 TEMPERATURE RAILED LOW	Thermistor disconnected.	Inspect sensor wiring and connector. Replace temperature sensor 3 if failed.
CONDENSER FAN NOT OFF	Condenser fan electrical failure.	Inspect wiring and connectors. Replace vaporizer/ condenser assembly if failed.
CONDENSER FAN NOT ON	Condenser fan not functioning.	Inspect wiring and connectors. Replace vaporizer/ condenser assembly if failed.
CONDENSER TEMPERATURE DID NOT DROP	Condenser heater stuck on.	Inspect wiring and connectors. Replace vaporizer/ condenser assembly if failed.
CONDENSER TEMPERATURE DID NOT RISE	Condenser heater/sensor not functioning within specification.	Inspect wiring and connectors. Replace vaporizer/ condenser assembly if failed.
CONDENSER TEMPERATURE TOO HIGH	The condenser temperature was higher than expected. A sensor or heater may have failed.	Inspect wiring and connectors. Replace vaporizer/ condenser assembly if failed.
CONDENSER TEMPERATURE TOO LOW	The condenser temperature was lower than expected. A sensor or heater may have failed.	Inspect wiring and connectors. Replace vaporizer/ condenser assembly if failed.

# 5 Diagnostic Tests and Troubleshooting

<b>Error Message</b>	<b>Probable Cause</b>	<b>Suggested Remedy</b>
CONDENSER TEMPERATURE RAILED HIGH	Thermistor circuit failure.	Inspect wiring and connect-ors. Replace vaporizer/ condenser assembly if failed.
CONDENSER TEMPERATURE RAILED LOW	Thermistor disconnected.	Inspect the wiring and connectors. Replace the vaporizer/ condenser assembly if it has failed.
DELIVERY VALVE SENSOR READ CLOSED	Delivery valve mechanical failure.	Inspect the wiring and connectors. Replace the delivery system if it has failed.
DELIVERY VALVE SENSOR READ OPEN	Delivery valve mechanical failure.	Inspect wiring and connect-ors. Replace the delivery system if it has failed.
DISPLAY TEST FAILURE	Touch panel not functioning.	Replace display assembly.
DISPOSE FAILURE	Collection box not present.	Wear gloves and open the cassette box access panel and free any jammed cassettes. Install a new collection box. If problem persists, troubleshoot or replace collection box switch.
DOOR SENSOR STUCK CLOSED	Door sensor electrical failure.	Inspect the wiring and connectors. Replace door sensor if failed.
DOOR SENSOR STUCK OPEN	Door sensor electrical failure.	Inspect wiring and connectors. Replace door sensor if failed.
DOOR TEMPERATURE DID NOT DROP	Door heater stuck on.	Replace door heater.
DOOR TEMPERATURE DID NOT RISE	Door heater/sensor not functioning within specification.	Inspect sensor and heater wiring and connectors. Replace failed component.
DOOR TEMPERATURE RAILED HIGH	Thermistor circuit failure.	Replace door temperature sensor.
DOOR TEMPERATURE RAILED LOW	Thermistor disconnected.	Inspect sensor wiring and connectors. Replace failed component.

<b>Error Message</b>	<b>Probable Cause</b>	<b>Suggested Remedy</b>
EJECT FAILURE	Cassette did not eject.	Wear gloves and open the cassette box access panel and free up any jammed cassettes. If problem persists, troubleshoot or replace collection box switch.
FAILED TO EXTEND NEEDLE	Needle motor not functional.	Replace delivery system.
FAILED TO RETRACT NEEDLE	Needle motor not functional.	Replace delivery system.
HIGH PLASMA POWER	Plasma power out of specification.	Replace LFPS II power supply.
INLET COMMAND ALWAYS CLOSED	Inlet valve electrical failure.	Inspect valve wiring and connectors. Replace failed component.
INLET COMMAND ALWAYS OPEN	Inlet valve electrical failure.	Inspect valve wiring and connectors. Replace failed component.
LOW PLASMA POWER	Plasma power out of specification.	Replace LFPS II power supply.
MAIN FANS STUCK OFF	Main fans not functioning.	Inspect fans. Replace if failed.
NO PLASMA POWER	Plasma power out of specification.	Replace LFPS II power supply.
OIL RETURN VALVE STUCK CLOSED	Oil return valve mechanical failure.	Replace oil return valve.
OIL RETURN VALVE STUCK OPEN	Oil return valve mechanical failure.	Replace oil return valve.
PRINTER TEST FAILURE	Printer not printing.	Replace printer assembly.
PUMP ALWAYS OFF	Vacuum pump electrical failure.	Inspect pump wiring and connectors. Replace vacuum pump assembly.
PUMP ALWAYS ON	Vacuum pump electrical failure.	Inspect pump wiring and connectors. Replace vacuum pump assembly.

# 5 Diagnostic Tests and Troubleshooting

<b>Error Message</b>	<b>Probable Cause</b>	<b>Suggested Remedy</b>
UV LIGHT IS BAD	UV lamp not functional.	Replace UV lamp.
VACUUM COMMAND ALWAYS CLOSED	Vacuum valve electrical failure.	Inspect valve wiring and connectors. Replace vacuum valve if failed.
VACUUM COMMAND ALWAYS OPEN	Vacuum valve mechanical failure.	Inspect valve wiring and connectors. Replace vacuum valve if failed.
VACUUM CONTROL VALVE STUCK CLOSED	Vacuum control valve mechanical failure.	Replace vacuum control valve.
VACUUM CONTROL VALVE STUCK OPEN	Vacuum control valve mechanical failure.	Replace vacuum control valve.
VACUUM INSUFFICIENT FOR PLASMA	Leak in chamber or wet load in chamber.	Troubleshoot for vacuum leaks. Inspect door seal and replace if worn or damaged. Inspect and retighten Ultratorr fittings.
VACUUM SENSOR STUCK CLOSED	Vacuum valve sensor failure.	Inspect vacuum valve wiring and connectors. Replace vacuum valve if failed.
VACUUM SENSOR STUCK OPEN	Vacuum valve sensor failure.	Inspect vacuum valve wiring and connectors. Replace vacuum valve if failed.
VAPORIZER PRESSURE RAILED HIGH	Vaporizer pressure always reads 200 torr.	Inspect wiring and connect-ors. Replace failed component.
VAPORIZER PRESSURE RAILED LOW	Vaporizer pressure always reads 0 torr.	Replace vaporizer/condenser assembly.
VAPORIZER TEMPERATURE DID NOT DROP	Vaporizer heater stuck on.	Replace vaporizer/condenser assembly.
VAPORIZER TEMPERATURE DID NOT RISE	Vaporizer heater/sensor not functioning within specification.	Inspect wiring and connect-ors. Replace vaporizer/ condenser assembly if failed.
VAPORIZER TEMPERATURE RAILED HIGH	Thermistor circuit failure.	Replace vaporizer/condenser assembly.

<b>Error Message</b>	<b>Probable Cause</b>	<b>Suggested Remedy</b>
VAPORIZER TEMPERATURE RAILED LOW	Thermistor disconnected.	Inspect wiring and connect-ors. Replace vaporizer/ condenser assembly if failed.
VENT SENSOR STUCK CLOSED	Vent valve sensor failure.	Inspect vent valve wiring and connectors. Replace vent valve if failed.
VENT SENSOR STUCK OPEN	Vent valve sensor failure.	Inspect vent valve wiring and connectors. Replace vent valve if failed.
VENT VALVE COMMAND ALWAYS CLOSED	Vent valve electrical failure.	Inspect valve wiring and connectors. Replace vent valve if failed.
VENT VALVE COMMAND ALWAYS OPEN	Vent valve electrical failure.	Inspect valve wiring and connectors. Replace vent valve if failed.
VENT VALVE PARTIALLY OCCLUDED	Filter on vent valve needs cleaning or replacement.	Replace vent valve filter. If problem persists, replace vent valve.
VENT VALVE STUCK CLOSED	Vent valve mechanical failure.	Replace vent valve.
VENT VALVE STUCK OPEN	Vent valve mechanical failure.	Replace vent valve.

## Running the Peroxide Clearance Cycle



**WARNING! HYDROGEN PEROXIDE MAY BE PRESENT. WEAR CHEMICAL RESISTANT PVC (VINYL), OR NITRILE GLOVES WHENEVER HANDLING A LOAD AFTER A CYCLE CANCELLATION OR AFTER RUNNING THE PEROXIDE CLEARANCE CYCLE. HYDROGEN PEROXIDE LIQUID MAY BE PRESENT ON THE LOAD OR IN THE CHAMBER.**

If an error is detected in the DUO delivery module, "Please Call ASP" is displayed. To clear this message, do the following:

1. Reset the DUO software by navigating to Utilities, Service Functions, Cassette Functions, Metering Test. Select "Reset DUO Cycle" button.
2. Run a successful Peroxide Clearance cycle

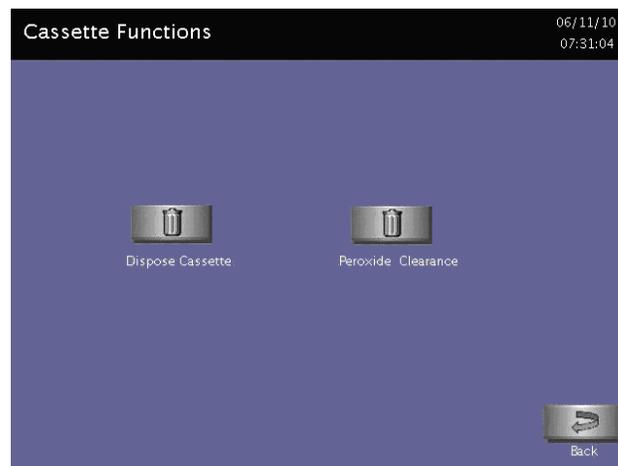
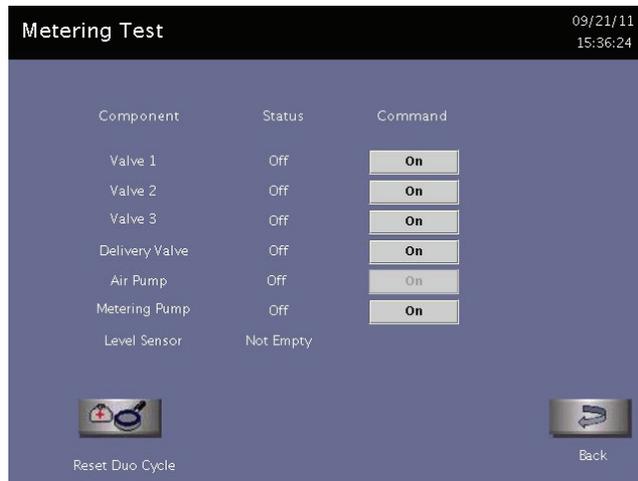


Figure 43. Touch Peroxide Clearance to start the Peroxide Clearance cycle.

3. Run an empty DUO cycle.

If peroxide remains in the DUO delivery module longer than 150 days without running a Peroxide Clearance cycle, “Mandatory Service Call Is Required For This Feature. Please Call ASP” is displayed. To correct this message do the following:

1. Reset the DUO software by navigating to Utilities, Service Functions, Cassette Functions, Metering Test; select the “Reset DUO Cycle button.



**Figure 44. Press Reset DUO Cycle (lower left corner).**

2. Run a successful Peroxide Clearance cycle.
3. Start a DUO Cycle and cancel after Plasma Pumpdown 0 stage.
4. Run another successful Peroxide Clearance cycle.
5. Run a successful empty DUO cycle.
6. Repeat this procedure if installing or replacing the DUO module.



Chapter 6.

# Subassembly Removal and Replacement

## Access to Sterilizer Interior

Service access to the interior of the sterilizer is primarily obtained by using a hex wrench to open the front panel. The side and top panels can be removed if needed.

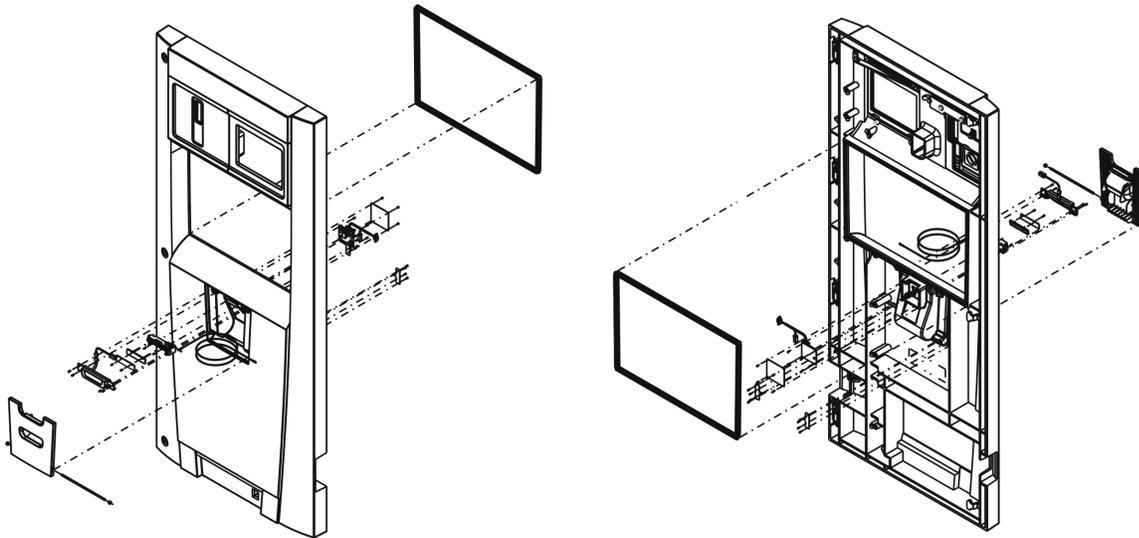


***WARNING! RISK OF ELECTRIC SHOCK AND BURNS!  
THE INTERIOR OF THE STERILIZER CONTAINS  
ELECTRICAL COMPONENTS THAT MAY BE HOT AND MAY  
CAUSE AN ELECTRIC SHOCK. TURN OFF THE STERILIZER  
BEFORE REMOVING THE PANELS. PERFORM  
LOCKOUT/TAG OUT PROCEDURES IF NEEDED.***

# 6 Subassembly Removal and Replacement

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## Front Panel



*Note:* The front panel does not need to be removed unless it is being replaced. The panel swings open allowing you to gain access to the inside of the system.

**Required Tools:** 10 mm hex wrench.

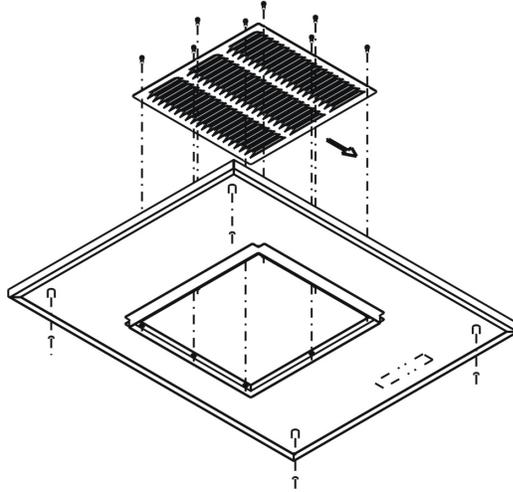
**Opening:**

1. Insert the hex wrench into the locks and turn the top two counter-clockwise and the bottom one clockwise to unlock.
2. Swing open the panel and it will lock in the open position.

**Closing:**

1. As you begin to close the panel, lift the panel brace lever, located at the top of the panel.
2. Push the front panel it seats completely onto the frame.
3. Rotate the hex locks clockwise (top 2) and counterclockwise (bottom) to lock the panel in place.

## Top Panel



**Figure 45. Top Panel Showing Pan Screen.**

**Required Tools:** 3 mm hex wrench.

**Removal:**

1. Remove the 4 screws and washers.
2. Lift the panel to remove. It may be necessary to open the front panel to ease removal.

**Replacement:** Replacement is the reverse of the removal steps.

# 6 Subassembly Removal and Replacement

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## Side Panels

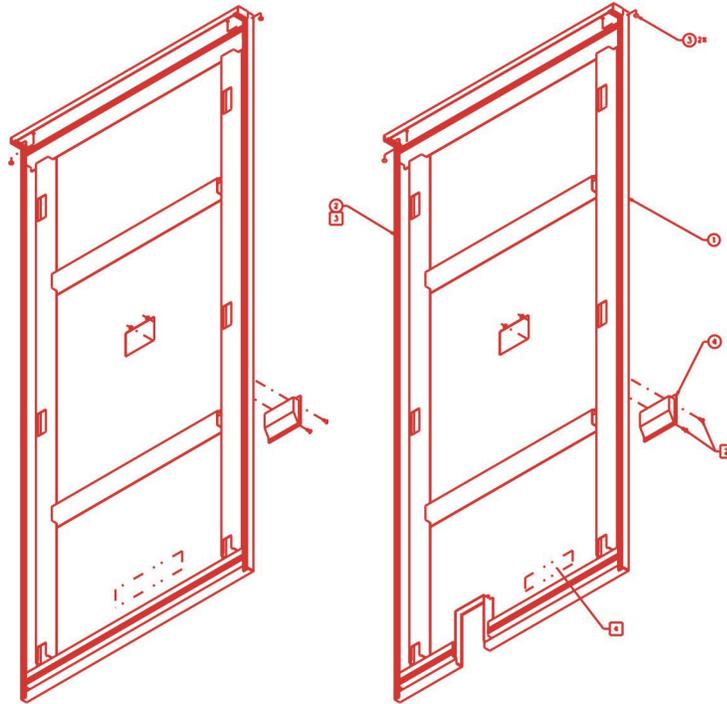


Figure 46. Side Panels.

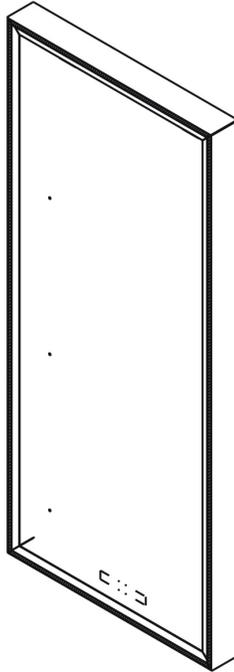
**Required Tools:** 3 mm hex wrench.

- Removal:**
1. Remove the 2 screws and washers at the top of each panel.
  2. Using the handle provided in the panel, lift the panel up and out.

*Note:* Some force may be required to break the panel seal.

**Replacement:** Replacement is the reverse of the removal steps. Ensure that the panel rests over all hooks on the frame before securing.

## Rear Panel



**Figure 47. Rear Panel.**

*Note:* This panel is on one- door units only.

**Required Tools:** 3 mm hex wrench.

**Removal:**

1. Remove the 8 screws and washers.
2. Lift the panel up and out to remove.

**Replacement:** Replacement is the reverse of the removal steps. Ensure that the panel hooks latch onto the support brackets.

## Component Replacement

The following replacement procedures detail removing and replacing various components and subassemblies. Make sure you follow all safety procedures detailed in Chapter 2 for servicing the sterilizer.

### Delivery System Assembly (02-52302)

The delivery system assembly includes the following components:

- Cassette guide sensor.
- Delivery solenoid valve.
- Inlet filter.
- Needles.
- Piercing stepper motor.
- Cassette guide stepper motor.

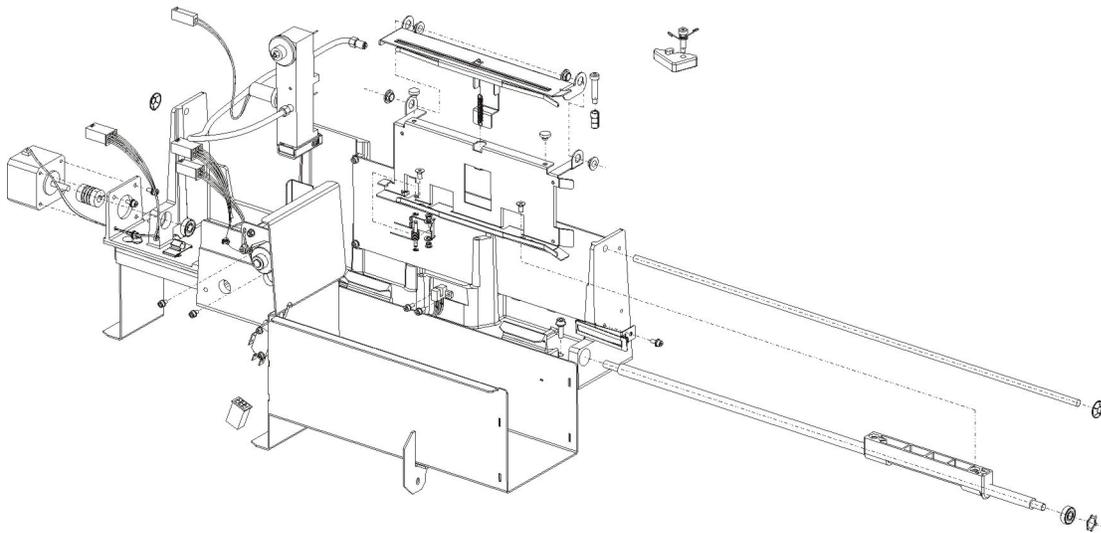


Figure 48. Delivery System.



**WARNING! RISK OF HYDROGEN PEROXIDE EXPOSURE. TRAPPED CASSETTES, NEEDLES, AND DELIVERY SYSTEM TUBING MAY CONTAIN HYDROGEN PEROXIDE. USE APPROVED PERSONAL PROTECTION EQUIPMENT (PPE) INCLUDING EYE PROTECTION AND GLOVES WHEN HANDLING THESE COMPONENTS.**

**WARNING! THE INJECTION NEEDLES ARE VERY SHARP. MAKE SURE YOU KNOW WHERE YOU ARE PLACING YOUR HANDS AT ALL TIMES.**

**Required Tools:**

3 mm hex wrench.

**Preparation:**

1. If a cassette is loaded in the delivery system, use the menu commands to dispose of the cassette.
2. If a cassette is trapped in the delivery system and cannot be disposed of automatically, put on approved PPE (chemical resistant gloves and eye protection) before proceeding.
3. Open the cassette box access door and remove the box of disposed cassettes if present.

**Removal:**

1. If a cassette is trapped in the carriage, slowly turn the lead screw and/or piercing mechanism by hand until the cassette is released. Handle and discard the cassette safely.
2. Slide the carriage on its lead screw toward the rear of the sterilizer to cover the piercing needles.
3. Unscrew and disconnect the tube that connects the bottom needle to the vaporizer.
4. Unplug five cables: P138, P129, P130, P131, and P132.
5. Unplug the cable from the RFID PWA.
6. Remove the 2 screws that attach the delivery system assembly to the frame.
7. Slide the assembly forward to remove.

**Replacement:**

Replacement is the reverse of the removal steps.

# 6 Subassembly Removal and Replacement

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## Needle Replacement

This is a PM procedure.



***WARNING! THE NEEDLES ARE VERY SHARP. USE CAUTION WHEN REMOVING THEM.***

### Removal/ Replacement

1. Locate the needles and unscrew them counter clockwise.
2. Insert the new needles and screw them in clockwise. Finger tighten only.

## Delivery Valve (28-53786) (PM Kit Item)

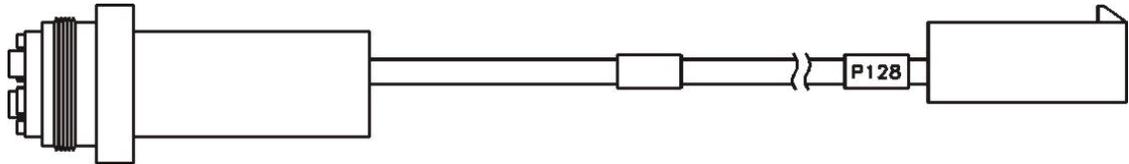


Figure 49. Delivery Valve.

**Required Tools:** Small pick

**Preparation:**

1. Turn the sterilizer OFF and unplug it.
2. Remove the left side panel.

**Removal:**

1. Unscrew and disconnect P128 from the delivery valve.
2. Using the small pick, remove the 2 gaskets from the inside of the fitting.

**Replacement:** Replacement is the reverse of the removal steps. Note that new gaskets come with the valve.

## Delivery Subsystem Inlet Filter (PM kit part 25-50703)

This is a PM procedure.

**Preparation:**

1. Open the front panel
2. If needed, remove the box of disposed cassettes.

**Removal:**

1. Slide the carriage on its lead screw toward the rear of the sterilizer to cover the piercing needles.
2. Unscrew and disconnect the inlet filter cartridge.
3. Connect a new inlet filter to the inlet fitting.

**Replacement:** Replacement is the reverse of the removal steps.

## Vaporizer/Condenser Assembly (02-52303)

The vaporizer/condenser assembly includes the following components:

- Pressure transducer
- Transition valve
- Inlet valve
- Thermoelectric modules (2)
- Thermoelectric fans (2)
- Thermostat
- Thermistor sensor

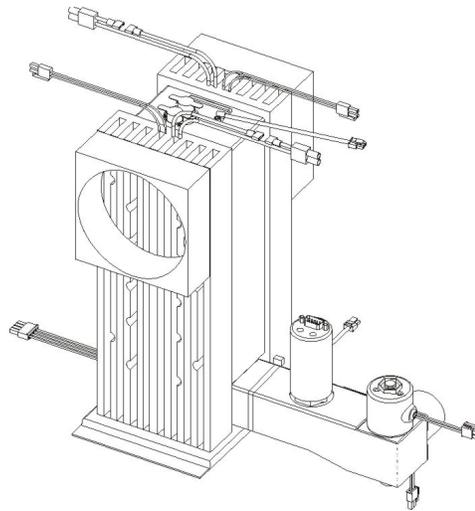


Figure 50. Vaporizer/Condenser Assembly.



**WARNING! RISK OF HYDROGEN PEROXIDE EXPOSURE. THE VAPORIZER/CONDENSER SYSTEM MAY CONTAIN HYDROGEN PEROXIDE. USE APPROVED PERSONAL PROTECTION EQUIPMENT (PPE) INCLUDING EYE PROTECTION AND GLOVES WHEN HANDLING THESE COMPONENTS.**

**Required Tools:** 3 mm hex wrench.  
Soft-jaw pliers.

**Preparation:**

1. Turn the sterilizer OFF and unplug it.
2. Open the front panel and/or remove the right side panel.

**Removal:**

1. Disconnect the delivery tube connecting the vaporizer to the vaporizer/condenser. Retain the small O-ring for later use.
2. Remove all cables from the assembly.
3. Use the soft-jaw pliers to unscrew the collar to the Ultratorr fitting.
4. Remove the two screws that attach the vaporizer/condenser assembly to the frame. Rotate the assembly to the front.
5. Lift the vaporizer/condenser assembly up to remove.
6. Remove the spacer and the O-ring from inside the Ultratorr fitting.

**Replacement:**

1. Clean the inside of the Ultratorr fitting.
2. Lightly coat a new O-ring with approved vacuum grease and place the O-ring in the Ultratorr fitting.
3. Reinstall the spacer in the Ultratorr fitting and replace the threaded collar, but do not tighten.
4. Insert the tube into the Ultratorr fitting. Press down until it is seated firmly.
5. Rotate the assembly toward the back of the sterilizer to engage the sheet metal hold-down tabs.
6. Use soft-jaw pliers to lightly tighten the collar. Do not over tighten.
7. Replace and/or tighten the two screws that attach the assembly to the frame.
8. Reconnect the cables to the assembly.
9. Reconnect the tube from the delivery system to the vaporizer/condenser. Ensure that the small O-ring, previously retained, is replaced between the delivery tube connector and the vaporizer assembly.

**Transfer and Transition Valve Replacement**

This is a PM procedure.

**Removal**

1. Turn off the unit. Allow it to cool down if needed.
2. Unplug the valve cables.
3. Unscrew the valves completely. The entire valve unit should come away from the housing.

**Replacement**

1. Replacement is the reverse of the removal procedure.

## Vent Valve Assembly (02-52424)

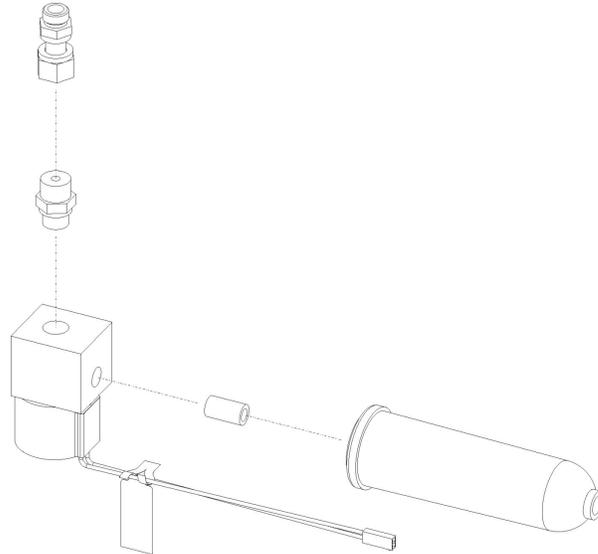


Figure 51. Vent Valve.

**Required Tools:** 1 inch open end wrench and soft-jaw pliers.

**Preparation:**

1. Turn the sterilizer OFF and unplug it.
2. Open the front panel.
3. Engage the door safety stop located on the bottom front edge of the chamber.

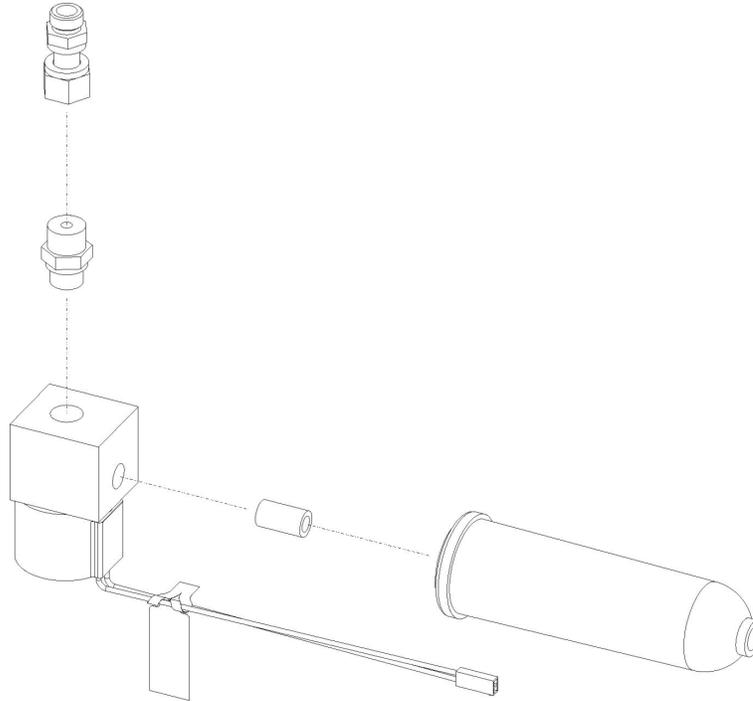
**Removal:**

1. Unplug cable P116.
2. Unscrew the valve from the adapter fitting using two wrenches.
3. Drop the valve down to remove.

**Replacement:**

1. Clean the inside of the fittings.
2. Lightly coat a new O-ring with approved vacuum grease and place the O-ring in the adapter fitting.
3. Fasten the valve to the adapter fitting.
4. Use the pliers to tighten the fittings ensuring that the filter does not interfere with any moving part.
5. Reconnect cable P116.

## Vent Valve HEPA Filter (25-00473)



**Figure 52. Vent Valve showing HEPA Filter.**

**Required Tools:** Teflon<sup>®</sup> tape.

**Preparation:**

1. Turn the sterilizer OFF and unplug it.
2. Open the front panel.

**Removal:** Unscrew the HEPA filter from the valve body.

**Replacement:**

1. Wrap the threaded nipple on the valve body with new Teflon<sup>®</sup> tape.
2. Screw the HEPA filter onto the threaded nipple. The filter should be hand-tightened only.

## Chamber Pressure Control Assembly (02-52387)

The chamber pressure control assembly contains the following components:

- Pressure transducers
  - » Low vacuum transducer (0-30 torr)
  - » High vacuum transducer (0-200 torr)
- Atmospheric pressure switch

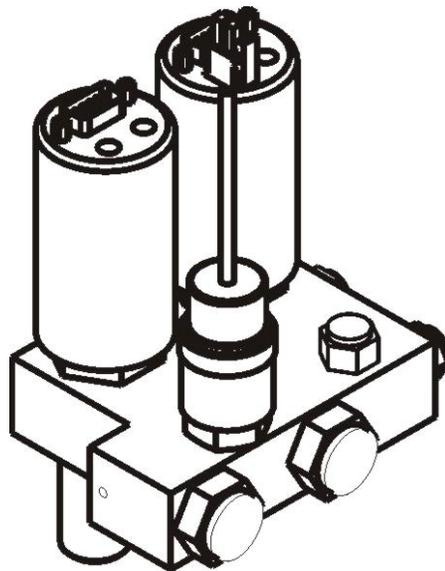


Figure 53. Chamber Pressure Control Assembly.

**Required Tools:**

Soft-jaw pliers.  
Crow foot wrench

**Preparation:**

1. Turn the sterilizer OFF and unplug it.
2. Open the front top panel.

**Removal:**

1. Unplug 3 cables: P7, P11, and P17.
2. Use soft-jaw pliers to unscrew the collar connecting the manifold to the Ultratorr fitting.
3. Pull the manifold up to remove.
4. Remove the spacer and the O-ring from inside the Ultratorr fitting.
5. Use the crowfoot wrench to separately remove the pressure transducers and switch.

**Replacement:**

1. Clean the inside of the Ultratorr fitting.
2. Lightly coat a new O-ring with approved vacuum grease and place the O-ring in the Ultratorr fitting.
3. Reinstall the spacer in the Ultratorr fitting and replace the threaded collar. Do not tighten.
4. Insert the manifold tube into the Ultratorr fitting. Press down until it is seated firmly.
5. Use soft-jaw pliers to tighten the collar. Do not over tighten.
6. Reconnect 3 cables: P7, P11, and P17.
7. If the pressure transducers have been separately removed, replace them making sure the cables are correctly attached. Make sure the O-rings are not damaged or dirty. Clean or replace if necessary. Use the crow foot wrench to tighten.
8. Perform a vacuum calibration.

## System Control Enclosure Assembly (02-53248)

The System Control Enclosure contains the ETX and interface boards. The entire enclosure is replaced if a failure occurs. The test points are located on the interface board behind a removable enclosure panel.

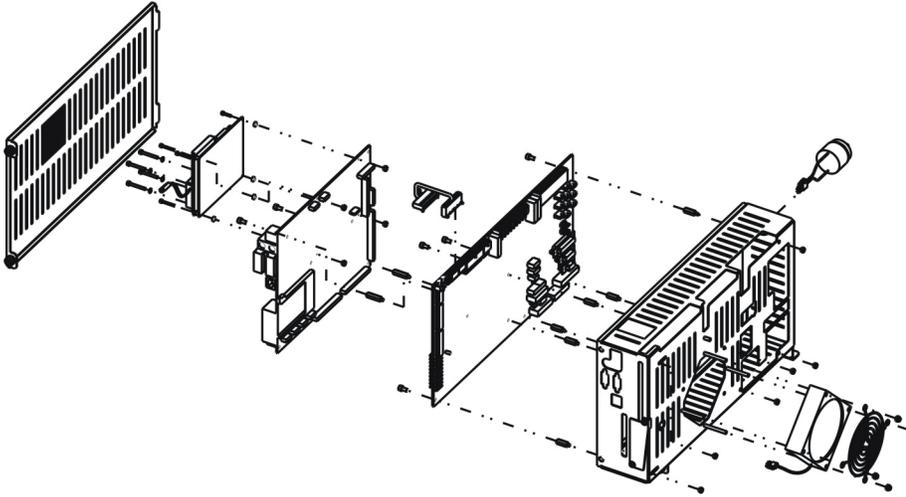


Figure 54. System Control Enclosure.



**CAUTION: ESD-sensitive parts. The circuit boards may be damaged by electrostatic discharge. Avoid touching components on the circuit boards. Attach and use an approved ESD grounding wristband when handling circuit boards.**

**Required Tools:** Flat-blade screwdriver

**Preparation:**

1. Turn the sterilizer OFF and unplug it.
2. Open the front panel.
3. Loosen the 2 screws securing the control enclosure to the frame.

**Removal:**

1. Unplug all cables from control enclosure.
2. Remove the control enclosure through the front of the machine.

**Replacement:** Replacement is the reverse of the removal steps.

## IDE Software Replacement



**CAUTION: ESD-sensitive parts. The circuit boards may be damaged by electrostatic discharge. Avoid touching components on the circuit boards. Attach and use an approved ESD grounding wristband when handling circuit boards.**

### **Removal:**

1. Turn the sterilizer OFF and unplug it.
2. Open the front panel.
3. Loosen the 2 screws below the control enclosure.
4. Slide the control enclosure to the right. Make sure you do not damage the H<sub>2</sub>O<sub>2</sub> lamp.
5. Loosen the 2 screws securing the cover.
6. Remove the cover.
7. Remove the IDE flash card.

### **Replacement:**

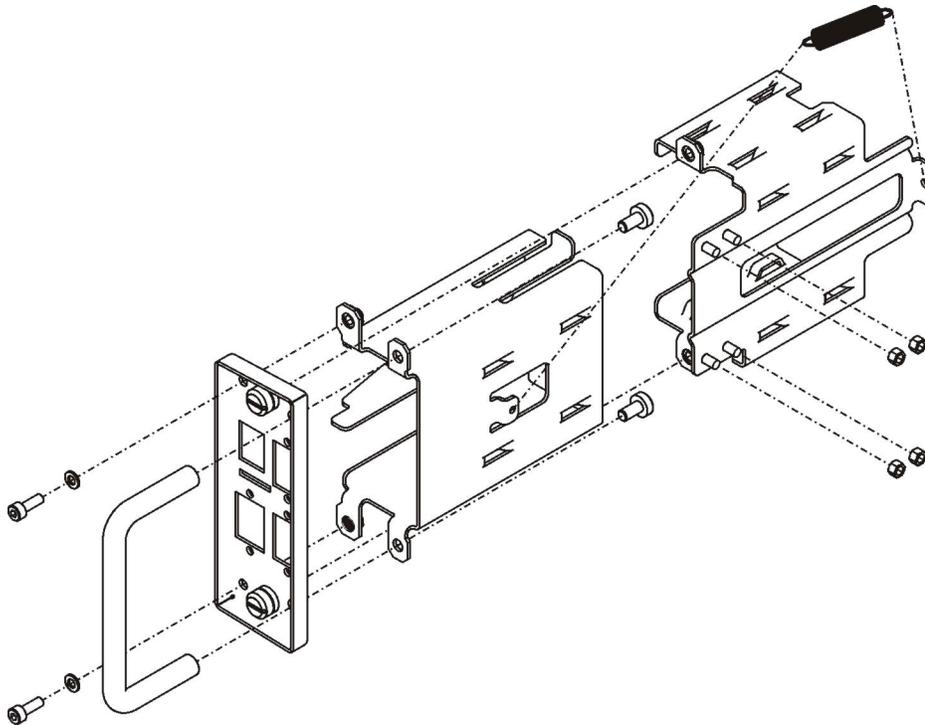
Replacement is the reverse of the removal steps.

# 6 Subassembly Removal and Replacement

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## I/O Panel Assembly (03-53151)

There is an I/O Panel Assembly on the lower right front of the sterilizer. Connection ports for an external printer and the network are located in the panel. The panel assembly moves in and out to clear the door when it is opened.



### Preparation:

1. Turn the sterilizer OFF and unplug it.
2. Open the front panel.

*Note:* You may need to remove the right side panel to gain access to the mounting hardware.

### Removal:

1. Unplug all external cables from the panel.
2. Remove all internal cables from the panel.
3. Remove the 4 locknuts, ground cable and washers from the frame and pull the panel assembly forward to remove.

### Replacement:

Replacement is the reverse of the removal steps. Ensure that the ground cable is secured to one of the mounting studs.

## Alternating Current (AC) Distribution Assembly (40-52312)

The AC distribution assembly is a closed system which requires no servicing. The unit is certified as electrically safe and is sealed and should not be opened. If the unit requires configuration between high and low voltage (the unit is shipped with the low voltage configuration), use the procedure that follows this section to change the voltage configuration.

Various verification procedures are performed using the LEDs and breakers on the unit.

Should the unit need to be replaced, use the following procedure to completely remove the unit and install a new one.

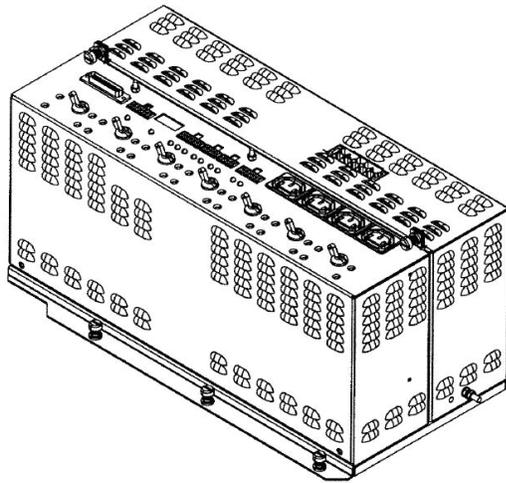


Figure 55. AC Distribution Assembly.



**WARNING! ELECTRIC SHOCK HAZARD. HAZARDOUS VOLTAGES ARE PRESENT INSIDE THE AC DISTRIBUTION ASSEMBLY. TURN THE STERILIZER OFF AND UNPLUG IT BEFORE HANDLING OR OPENING THE AC DISTRIBUTION ASSEMBLY.**

**Required Tools:**

1. Flat-blade screwdriver.

**Preparation:**

2. Turn the sterilizer OFF and unplug it.
3. Open the front panel.
4. Remove the left panel.

*Note:* You may have to loosen or remove the plastic bezel surrounding the main power cord to remove and install the left panel.

# 6

## Subassembly Removal and Replacement

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### Removal:

1. Unplug the cables on top of the AC unit.
2. Loosen the 3 thumbscrews holding the AC unit in place on the frame.
3. Slide the unit to the side, and then pull it forward.
4. At the same time, feed the main power cord through the left side panel and/or frame while removing the AC unit.

### Replacement:

Replacement is the reverse of the removal steps.

### AC Distribution Assembly Voltage Configuration

*Note:* The AC enclosure is shipped with low voltage operation as the default configuration. Use the following procedure only if you need to change the voltage configuration.



**WARNING! RISK OF ELECTRIC SHOCK! THE INTERIOR OF THE STERILIZER CONTAINS ELECTRICAL COMPONENTS THAT MAY CAUSE AN ELECTRIC SHOCK. TURN OFF THE STERILIZER BEFORE SERVICING.**



**CAUTION:** The voltage configuration must match the voltage level existing at the installation site. If the wrong voltage configuration is used, the equipment may be damaged or not perform as designed.

### Required Tools:

Flat-blade screwdriver

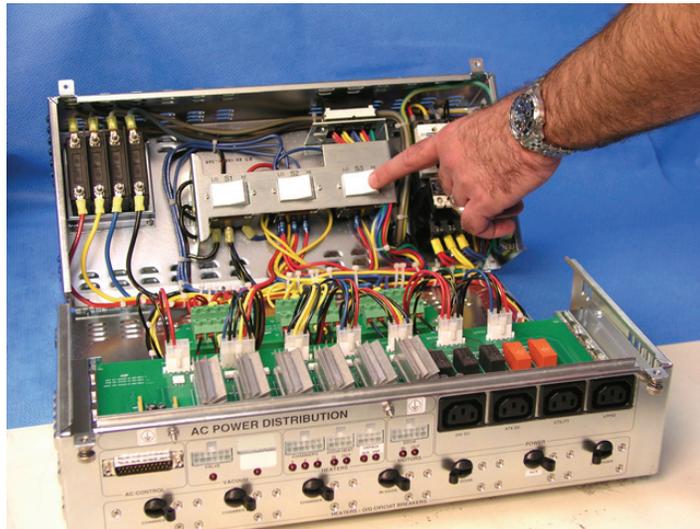
### Preparation:

1. Turn the sterilizer OFF and unplug it.
2. Open the front panel.
3. Remove the existing AC enclosure from the sterilizer using the removal instructions in this section.

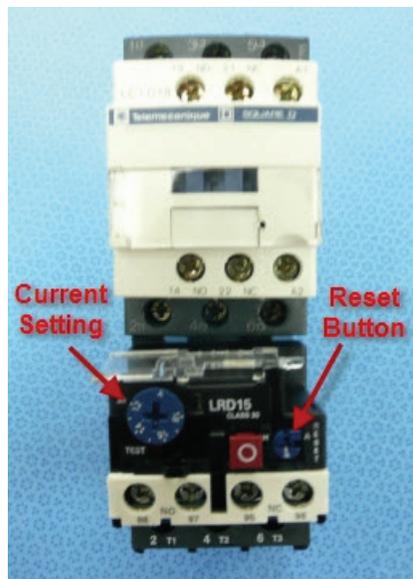
### Configuration:

1. Set the AC unit on the floor or on a stable table if needed.
2. Loosen the 2 captive screws on top of the unit. Swing open both sides of the unit and lay them flat.
3. Locate the voltage configuration switches. They are near the main cord entry point. Change 3 voltage configuration switches to the desired voltage setting (HI or LO). The switches must *not* be in the center position, but moved completely to the HI or LO position. All the switches must have the same voltage. See the following figure.
4. On the motor starter, verify that the current setting is set to 12 Amps. If not, rotate the dial using a screwdriver until the correct setting lines up with the indicator. Press the motor starter reset

- button to ensure that the breaker has not tripped.
5. Close the enclosure sides and tighten the screws.
6. Return the enclosure to the sterilizer using the replacement procedures.



**Figure 56. AC Distribution Assembly.**



**Figure 57. Motor Starter Current Setting and Reset Button.**

## Direct Current (DC) Power Supplies (40-53112 24 VDC, 40-52313 ATX DC)

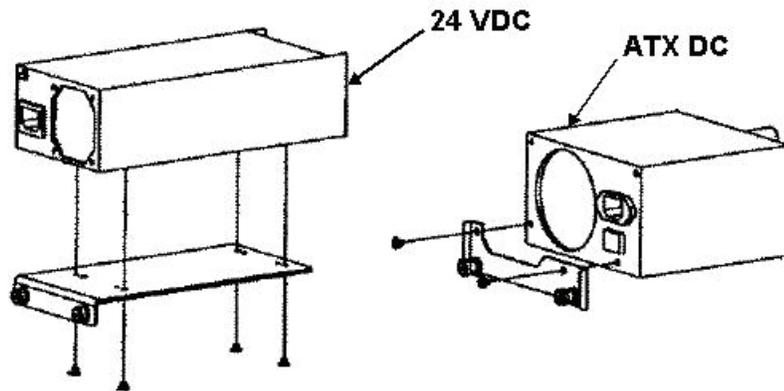


Figure 58. DC Power Supplies.



**WARNING! ELECTRIC SHOCK HAZARD. HAZARDOUS VOLTAGES ARE PRESENT INSIDE THE DC POWER SUPPLY. TURN THE STERILIZER OFF AND UNPLUG IT BEFORE HANDLING THE DC POWER SUPPLY.**

**Required Tools:**

Flat-blade screwdriver

**Preparation:**

1. Turn the sterilizer OFF and unplug it.
2. Open the front panel.

**Removal:**

1. Unplug 2 cables from the interface PWA: P49 and P52.
2. Feed the cables through the mounting brackets.
3. Loosen the captive screws attaching each DC power supply to the frame.
4. Pull the DC power supplies forward to remove.
5. For the 24 VDC power supply, remove 4 screws securing the mounting bracket to the power supply. Note the proper orientation.  
For the ATX DC power supply, remove 2 screws securing the mounting bracket to the power supply. Note the proper orientation.

**Replacement:**

Replacement is the reverse of the removal steps.

## Display Assembly (40-52308)

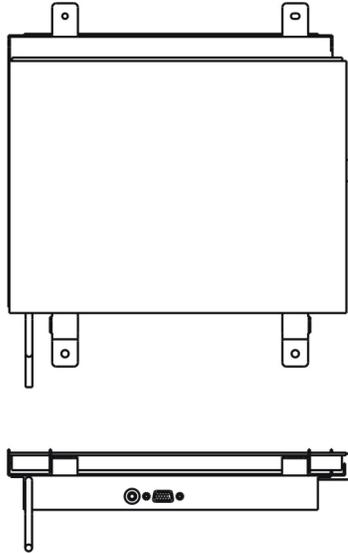


Figure 59. Display Assembly.



**WARNING! ELECTRIC SHOCK HAZARD. HAZARDOUS VOLTAGES ARE PRESENT INSIDE THE DISPLAY BACKLIGHT. TURN THE STERILIZER OFF AND UNPLUG IT BEFORE HANDLING THE DISPLAY ASSEMBLY.**

**Required Tools:**

3 mm hex wrench.

**Preparation:**

1. Turn the sterilizer OFF and unplug it.
2. Open the front panel.

**Removal:**

1. Unplug 3 cables: (input or output) PWR, VGA, USB.
2. Remove 4 screws and 8 washers attaching the display assembly to the panel.
3. Lift the display assembly forward to remove.

**Replacement:**

1. Ensure that the display gasket is undamaged and on the panel before re-installing. Replace the gasket if needed.
2. Replacement is the reverse of the removal steps.

## Fan Assembly (40-53551)

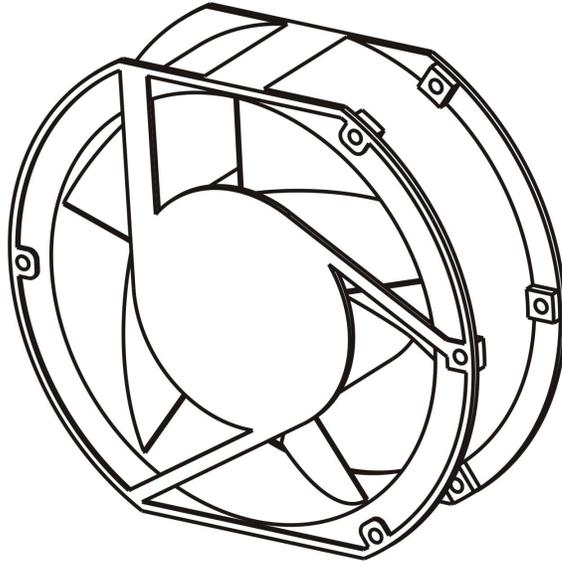


Figure 60. Fan Assembly.

There are 4 fans on the sterilizer. They are inspected as part of PM1 procedures.

**Required Tools:** 4 mm hex wrench.

**Preparation:**

1. Turn the sterilizer OFF and unplug it.
2. Open the front panel, remove the top and left side panels.

**Removal:**

1. Unplug the fan cable.
2. Remove the screws holding the inner grille to the fan.
3. Pull the inner grille straight off the studs to remove.
4. Remove the screws securing the fan to the frame.
5. Remove the fan.

**Replacement:**

1. Clean the inside and the outside of the protective grill.
2. Each fan comes with an arrow on the outer housing indicating the airflow direction. Install the fan so that the airflow is directed out the top of the sterilizer.
3. Replacement is the reverse of the removal steps.

## Ultraviolet Lamp Power Supply (40-51449)

The ultraviolet lamp is part of the hydrogen peroxide monitor system. The power supply is located in the top section of the frame.

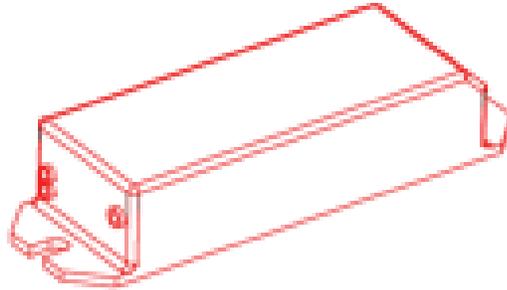


Figure 61. UV Lamp Power Supply.



**WARNING! ELECTRIC SHOCK HAZARD. HAZARDOUS VOLTAGES ARE PRESENT INSIDE THE UV LAMP POWER SUPPLY. TURN OFF THE LAMP USING THE TEST SCREEN. THEN TURN THE STERILIZER OFF AND UNPLUG IT BEFORE HANDLING THE POWER SUPPLY.**

**Required Tools:**

3 mm hex wrench.

**Preparation:**

1. Navigate to the test screen.
2. Turn the lamp OFF.
3. Turn the sterilizer OFF and unplug it.
4. Open the front panel.

**Removal:**

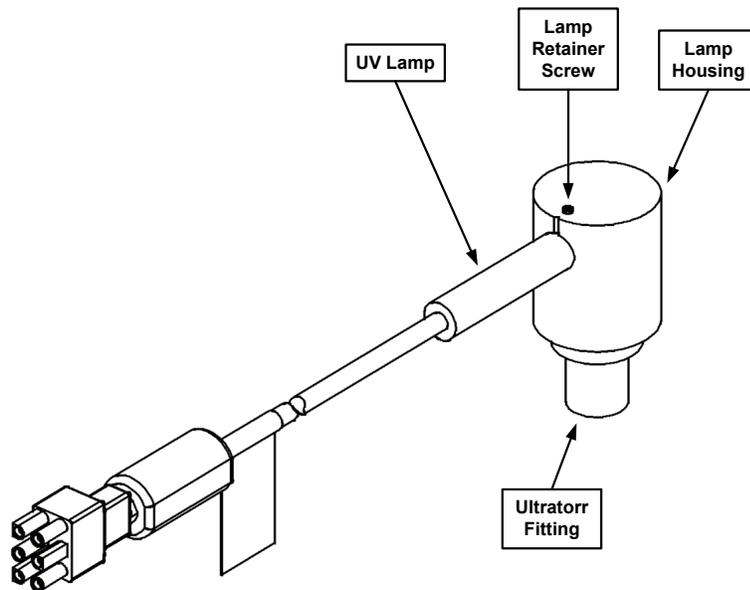
1. Unplug cables: UV lamp and J24.
2. Remove the two screws that attach the power supply to the frame.
3. Lift the power supply to remove.

**Replacement:**

Replacement is the reverse of the removal steps.

## Hydrogen Peroxide Monitor Lamp Assembly (04-50544)

The hydrogen peroxide monitor lamp assembly includes the monitor lamp optical window.



This is a PM procedure.



**WARNING! ULTRAVIOLET LIGHT EXPOSURE!**  
**ULTRAVIOLET LIGHT CAN HARM UNPROTECTED EYES AND SKIN. DO NOT LOOK DIRECTLY AT AN ENERGIZED UV LAMP.**

**HOT SURFACES! THE ULTRAVIOLET LAMP AND ITS HOUSING ARE HOT WHEN ENERGIZED. CONTACT WITH THESE PARTS MAY CAUSE BURNS OR OTHER INJURIES. DO NOT TOUCH THE MONITOR LAMP ASSEMBLY WHEN IT IS ENERGIZED.**

**CAUTION: Safe parts handling. Do not touch the surface of the ultraviolet lamp or the optical window with your bare hands. Oil and contaminants from your skin will damage these parts and cause premature failure.**

### Required Tools:

1 mm hex wrench, soft-jaw pliers, clean nitrile or white cotton gloves.

### Preparation:

1. Turn off the lamp.
2. Open the front panel.

### Removal:

1. Unplug the cable labeled UV lamp.

2. Use soft-jaw pliers to unscrew the collar to the Ultratorr fitting.
3. Lift the lamp housing up to remove.
4. Remove the spacer and the O-ring from inside the Ultratorr fitting.
5. Insert a 1 mm hex wrench through the hole in the top of the lamp housing to loosen the lamp retaining screw.
6. Gently pull the UV lamp and socket assembly out of the lamp housing. **Do not touch the surface of the lamp with your bare hands.**
7. Put on clean gloves. Unscrew the base of the lamp housing and remove the O-ring and the optical window. **Do not touch the optical window with your bare hands.**

### **Replacement:**

1. Put on clean gloves. Install a new ultraviolet lamp in the lamp housing. **Do not touch the lamp with your bare hands.**
2. Install a new optical window and O-ring in the lamp housing (if necessary). **Do not touch the optical window with your bare hands.**
3. Remove your gloves. Clean the inside of the Ultratorr fitting.
4. Lightly coat a new O-ring with approved vacuum grease and place the O-ring in the Ultratorr fitting.
5. Reinstall the spacer in the Ultratorr fitting and reinstall the collar. Do not tighten.
6. Insert the lamp housing tube into the Ultratorr fitting. Press down until it is seated firmly.
7. Orient the lamp housing so that there is no interference with the lamp cable. Use soft-jaw pliers to tighten the collar. Do not over tighten.
8. Reconnect the UV lamp cable.

## Electrode Assembly (02-52391)

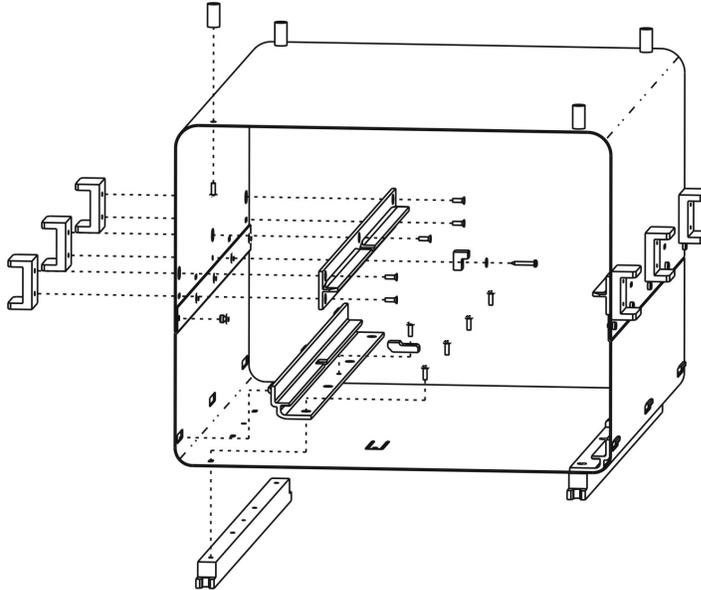


Figure 62. Electrode Assembly.

**Required Tools:** 2.5 mm and 3 mm hex wrenches, #2 Phillips screwdriver and manual door crank.

**Preparation:**

1. Open the front panel.
2. Move the door down to the service position using the manual crank.
3. Remove the shelves from the chamber.

**Removal:**

1. Remove 2 shoulder screws attaching the electrode to the front of the chamber.
2. Remove the screw and star washer near the bottom center of the electrode connecting the electrode to the feedthrough.
3. Gently pull the electrode assembly straight out of the chamber to remove.
4. Remove the spacers and shelf support stops.
5. Clean the electrode if performing a PM procedure. Replace if needed.

### **Replacement:**

1. Replace the spaces and shelf support.
2. Orient the electrode assembly so that the feedthrough lines up with the feedthrough mounting tab on the bottom electrode element.
3. Slide the electrode assembly into the chamber.

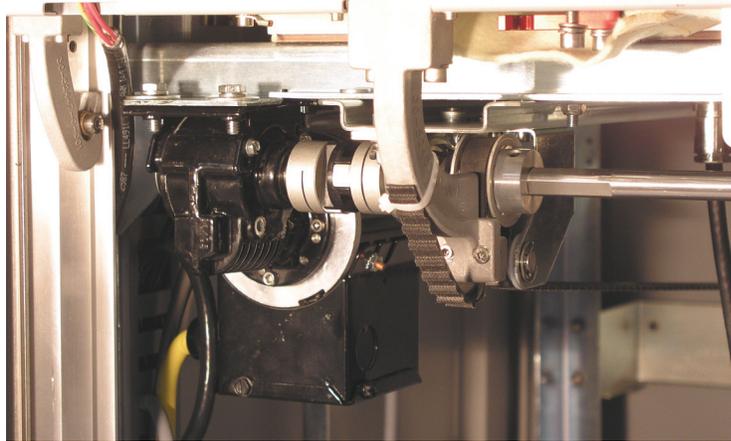
***Note:** Ensure that the electrode bottom spacers engage the remaining 2 shoulder screws located at the far end of the chamber.*

4. Line up the feedthrough with the feedthrough mounting tab and fasten the tab to the feedthrough using the star washer and M3 screw.
5. Fasten the electrode assembly to the chamber using the 2 shoulder screws.
6. Reinstall the shelves. The shelves must be positioned so that they are not pushed back against the rear door/wall.

***Note:** The shelves do not have a specific front or back.*

7. Manually return the door to its normal position.

## Door Drive and Belt



**Figure 63. Door Drive and Belt.**

**Required Tools:** 2.5 and 5 mm hex key, 7/64" hex key, 7/16" or 11 mm wrench

**Preparation:**

1. Close all doors.
2. Open the input or output panel to access the motor needing replacement.
3. Remove the left side panel.
4. Enable the door safety lock by loosening 2 M6 screws (one on the chamber; the other on the door), rotating it from the bottom of the chamber to the door, and securing the hardware.
5. Turn the sterilizer OFF and unplug it.

**Removal:**

1. Disconnect the door harness IDM or ODM.
2. Using a 7/64 inch hex key, loosen only the motor shaft coupling screw closest to the motor.
3. Remove 4 hex-head screws and washers securing the motor to the frame.
4. Drop the motor while sliding the metal coupling collar off the motor shaft.

**Note:** *The coupling has three pieces. A metal collar attached to the motor shaft, a plastic center piece that floats freely on the coupling, and another metal collar attached to the pulley shaft. Retain the motor-side collar and center piece for re-installation.*

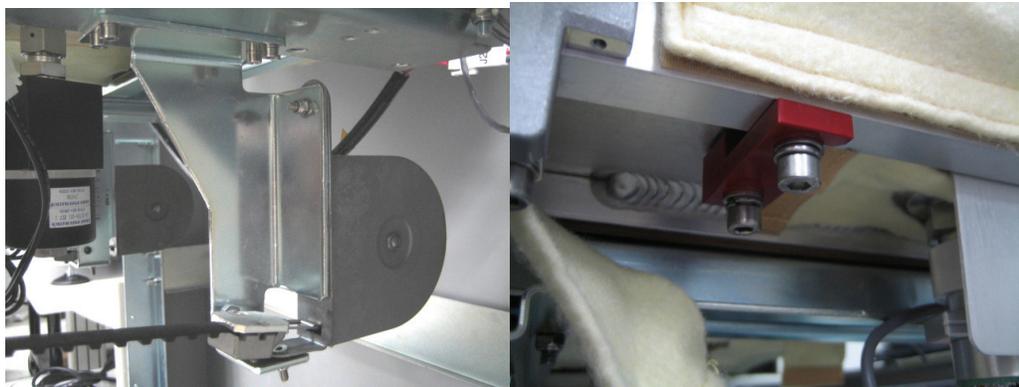
**Replacement:**

1. Slide the metal coupling collar over the motor shaft with the set screw closest to the motor.
2. Set the motor in place onto the frame and loosely install one screw farthest away from the coupling.
3. Install the plastic coupling center piece between both coupling pieces. Rotate the collar to properly engage both sides of the center piece.
4. Install and tighten the remaining screws to secure the motor onto the frame.
5. Ensure that the shaft coupling pieces are all compressed together. Tighten the collar set screw to the motor shaft.

*Note: Shaft misalignment is acceptable, and the coupling is designed to tolerate the maximum amount possible in the sterilizer design.*

6. Reconnect door harness IDM or ODM.
7. Disable the door safety lock.

## Counterbalance



**Figure 64. Door Counterbalance and Safety Lock.**

**Required Tools:**

- 2.5, 3 mm hex key, M7 nut driver or wrench

**Preparation:**

1. Close all doors.
2. Open the input or output panel to access the counterbalance needing replacement.
3. Remove the left or right side panel, as necessary.
4. Enable the door safety lock by loosening 2 M6 screws (one on the chamber; the other on the door), rotating it from the bottom of the chamber to the door, and securing the hardware.
5. Turn the sterilizer OFF and unplug it.

# 6 Subassembly Removal and Replacement

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**CAUTION: Do not bend, nick, or damage the counterbalance metal tape in any way. Do not use any tool to clamp it to another part. If the tape is damaged, it will bind in the housing slit, further damage the part, and disrupt the door motion.**

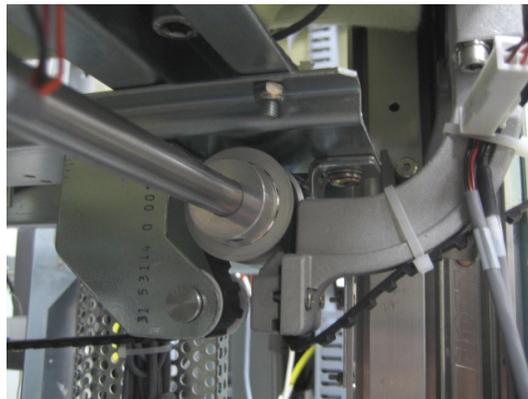
## Removal:

1. Disconnect the timing belt from the counterbalance by loosening two flathead screws securing the belt clamp to the belt holder. The counterbalance hook can then slide out from the belt clamp hook. Leave the timing belt in place in the belt holder if possible.
2. Remove 4 screws securing the counterbalance sheet metal mounting bracket to the drive mechanism mounting plate.
3. Remove 2 screws and hardware securing the counterbalance to its mounting bracket.

## Replacement:

1. Replacement is the reverse of the removal steps.
2. The belt clamp screws require Loctite®.
3. Disable the door safety lock.

## Timing Belt



**Figure 65. Timing Belt Routing.**

## Required Tools:

2.5, 3 mm hex key, 1/8" hex key, wire cutters, cable ties, manual door crank

## Preparation:

1. Close all doors.
2. Open the input or output panel to access the timing belt needing replacement.
3. Remove the left or right side panel, as necessary.
4. Enable the door safety lock by loosening 2 M6 screws (one on the chamber; the other on the door), rotating it from the bottom of the chamber to the door, and securing the hardware.
5. Turn the sterilizer OFF and unplug it.

**Removal:**

1. Disconnect the timing belt from the counterbalance by removing two flathead screws securing the belt clamp to the belt holder.
2. Disconnect the timing belt from the door arm lifter by removing two screws securing the belt holder to the door arm lifter.
3. Remove any cable ties securing the timing belt to the door arm lifter. Notice the orientation of the cables.
4. Remove the timing belt.

**Replacement:**

1. Place one end of the timing belt into the belt holder used next to the counterbalance. Three teeth should engage the holder.
2. Loosely secure the belt clamp over the belt holder using two flathead screws and Loctite<sup>®</sup>.
3. Connect the belt clamp to the counterbalance. The belt teeth should face the vacuum pump.
4. Tighten the two flathead screws.
5. Route the timing belt around the tensioner and timing pulley.

*Note:* The timing pulley may need to be loosened using a 1/8" hex key and rotated to get the timing belt through. The manual door crank can be used to rotate the shaft slightly to gain access to the set screws. Note that the door safety lock may need to be loosened, but not removed.

6. Pull the timing belt tight to take up slack, but not too tight as to pull the counterbalance out. Use the other timing belt for reference.
7. If necessary, ensure the timing pulley set screws line up with both shaft flats and center the pulley with the door arm lifter and tighten the screws.
8. Install the other belt holder to the door arm lifter and tighten the screws.
9. Secure the door cables to the door arm lifter with new cable ties.
10. Disable the door safety lock.

## Door Rollers

The procedure for adjusting the door rollers is in the product verification section. The door rollers should only be adjusted if the chamber is unable to hold a vacuum.

# 6 Subassembly Removal and Replacement

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## Door Seal O-Ring

**Required Tools:** Small, plastic, flat-blade screwdriver, and manual door crank.

**Preparation:**

1. Open the front panel.
2. Open the chamber door and manually place in the service position using the door crank.

**Removal:**

1. Insert the small screwdriver in the groove near the center of the bottom of the door seal O-ring channel.



**CAUTION: Do not pinch the O-ring or scratch the O-ring surface.**

2. Pry the O-ring up and out of the channel. Pull the O-ring out of the entire circumference of the channel.

**Replacement:**

1. Thoroughly clean the door seal O-ring channel and the back side of the door.



**CAUTION: Do not scratch the O-ring channel surface.**

2. Lubricate the new O-ring with a light coating of approved vacuum grease.
3. Insert the new O-ring into the channel and press it into the channel until it is seated. Avoid stretching or twisting the O-ring. Make sure the parting line cannot be seen. The parting line can cause leaks if placed against the vacuum seal surface of the channel.
4. Test the fit of the seal by closing the door.
5. Test the integrity of the seal by performing a vacuum diagnostic test.

## Hydrogen Peroxide Detector Assembly (04-52108)

The hydrogen peroxide detector assembly includes the detector optical window.

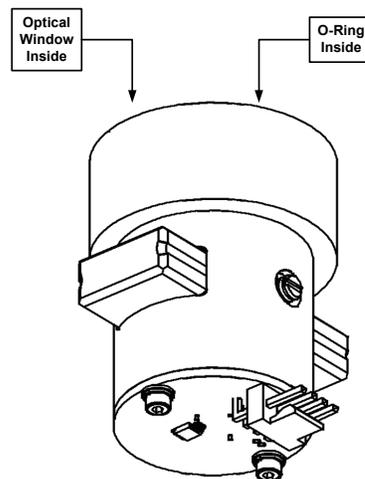


Figure 66. Detector Assembly.



**CAUTION: Safe parts handling. Do not touch the surface of the optical window with your bare hands. Oil and contaminants from your skin will damage the window and cause premature failure.**

**ESD-sensitive parts. The circuit boards may be damaged by electrostatic discharge. Attach and use an approved ESD grounding wristband when handling circuit boards. Avoid touching components on the circuit boards.**

**Required Tools:**

1.5 mm and 3 mm hex wrench, Clean nitrile or white cotton gloves.

**Preparation:**

- Turn the sterilizer OFF unplug it.
- Open the front panel.

**Removal:**

1. Unscrew the 2 screws holding the detector shield bracket to the chamber.
2. Remove the detector shield bracket.
3. Unplug cable P1.
4. Unscrew the detector assembly from the chamber fitting.
5. Put on clean gloves. Remove the O-ring and the optical window. Do not touch the optical window with your bare hands.

## 6 Subassembly Removal and Replacement

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### Replacement:

1. Put on clean gloves. Install a new optical window and O-ring in the detector (if necessary). Do not touch the optical window with your bare hands.
2. Remove the gloves. Clean the inside of the chamber fitting.
3. Lightly coat a new O-ring with approved vacuum grease and place the O-ring in the chamber fitting.
4. Screw the detector onto the fitting and hand-tighten.

*Note:* Ensure that the connector faces the back so that the door does not damage the connector. If the connector on the PC board faces the front of the unit, you need to remove the board so that the connector faces the back of the unit. Remove the two screws to rotate the board. Be careful you do not lose the hardware.

5. Reconnect cable P1.
6. Reinstall the detector shield bracket. Ensure that the front surface is flush with or behind the chamber face.

## Vacuum Pump Assembly

The vacuum pump assembly (02-52301) contains the following components:

- Vacuum pump and tray assembly
- Catalytic converter
- Oil mist filter
- Oil return valve
- Vacuum control valve

*Note:* You may need to remove the vacuum control valve to provide enough clearance to remove the vacuum pump.



**Figure 67. Vacuum Pump Assembly Shown Removed from the System.**

# 6 Subassembly Removal and Replacement

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**Required Tools:** 5 mm hex wrench, flat-blade screwdriver, 10 mm nut driver

- Preparation:**
1. Turn the sterilizer OFF and unplug it.
  2. Open the front panel.
  3. Remove the I/O panel assembly from the frame using the removal instructions shown previously in this chapter.
  4. Prior to turning the system off, drain the oil from the oil mist filter as shown in the following steps.

- Drain the Oil**
1. Navigate to the Vacuum/Plasma screen.
  2. Open the Vacuum Valve.
  3. Open the Oil Return Valve.
  4. Turn on the vacuum pump for 10 seconds, then turn it off.
  5. Open the vent valve until the system reaches atmosphere and then close it.
  6. Repeat the steps 4 and 5 until there is very little oil in the oil return tube.

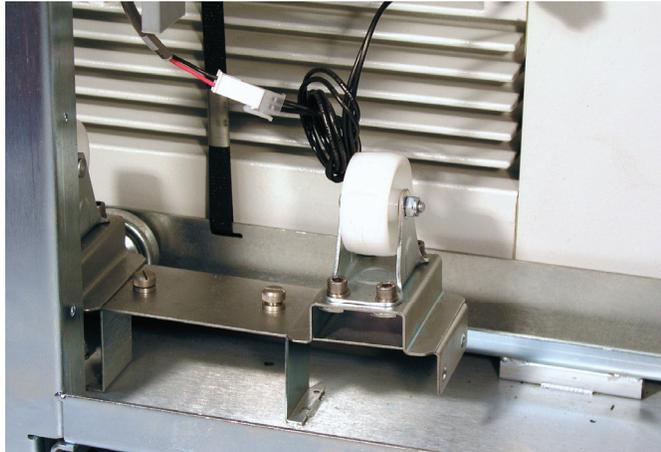
- Removal:**
1. Unplug all cables and harnesses from the pump assembly.
  2. Remove the KF-40 clamp connecting the bellows to the vacuum control valve. Save the centering ring and clamp.
  3. Remove the 2 screws attaching the vacuum pump tray and assembly to the frame.



**WARNING! THE PUMP IS VERY HEAVY (90.7 KG). USE CARE WHEN REMOVING IT FROM THE STERILIZER.**

*Note:* Ensure that no cables, harness, or tubing is caught, pinched, or damaged while removing the pump.

4. Grasp the handle of the vacuum pump tray and pull the vacuum pump assembly straight out. It will slide forward on wheels and stop against a safety plunger.
5. Remove the 4 nuts and washers from the sides of the tray.
6. Loosen the 2 captive screws and remove the tray caster assembly from the lower right side of the frame (it is just to the right of the pump).



7. Slide the castor assembly under the tray and over the M6 studs.

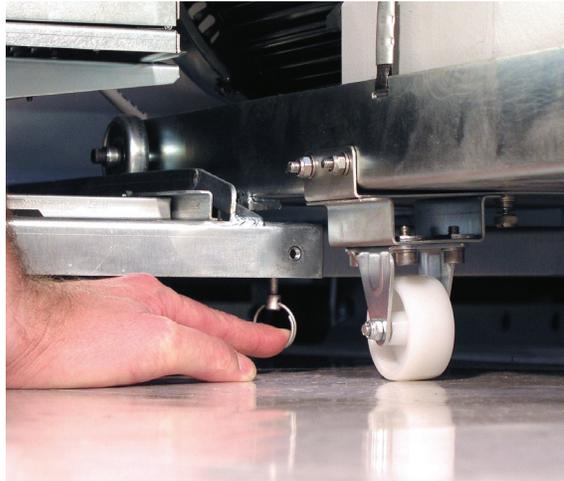


*Note: The castor assembly can only fit one way on the tray. Ensure proper orientation.*

8. Install 4 nuts and washers to secure the castor assembly to the tray.
9. Locate the safety plunger. It is underneath the frame just to the left of the pump assembly. Pull down on the ring of the safety plunger, and hold it while pulling the pump assembly from the frame.

## 6 Subassembly Removal and Replacement

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*Note: The plunger can be released after about 1-2 inches of travel.*

10. Fully remove the pump assembly from the frame.

**Replacement:**

Replacement is the reverse of the removal steps.

## Catalytic Converter (25-05611)

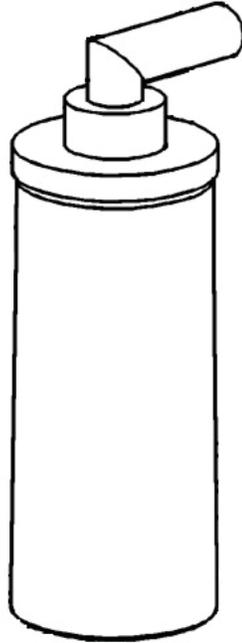


Figure 68. Catalytic Converter.

This is a PM procedure.

**Preparation:**

1. Turn the sterilizer OFF and unplug it.
2. Open the front panel.

**Removal:**

1. Unscrew the catalytic converter.

*Note:* The plastic adapter will probably unscrew from the oil mist filter. Remove the adapter from the catalytic converter. A tool may be needed.

2. Remove the depleted catalytic converter element.

**Replacement:**

1. Install a new catalytic converter onto the plastic adapter.
2. Carefully screw the catalytic converter assembly into the oil mist filter and hand-tighten. Ensure that the adapter threads are not cross-threaded or damaged.

## Oil Mist Filter (Alcatel 25-53795, Solberg 25-54623)



**Figure 69. Solberg Oil Mist Filter.**

This is a PM procedure.

**Required Tools:** 4 mm hex wrench, 6 mm hex wrench.

**Preparation:**

1. Oil may be present in the oil mist filter. Navigate to the Vacuum/Plasma utility screen and run the vacuum pump with the oil return valve ON for 30 seconds to drain oil from the filter.
2. Turn the sterilizer OFF and unplug it.
3. Open the front panel.

**Removal:**

1. Remove the oil return valve tubing from the filter by pressing the colored tubing-fitting collar in towards the filter while pulling the tubing out.
2. Remove the KF-40 clamp and then remove the oil mist filter and catalytic converter from the vacuum pump. Retain the clamp and centering ring.
3. For the Alcatel filter, remove 4 screws and pull the bottom housing off the top housing.
4. Remove the filter from the bottom housing.
5. Remove the bypass valve assembly from the top of the filter element.
6. Discard the filter O-rings and the filter element per local regulation.

*Note: The pump oil is hydrocarbon mineral oil.*

7. For the Solberg filter, remove the clamp. Note the orientation.
8. Remove the thumb-screw securing the filter element to the housing.
9. Remove and discard the filter element according to local regulations.

### **Replacement**

#### **For the Alcatel filter:**

1. Place a new O-ring (filter comes with 2 O-rings) into one end of the filter. Install the bypass valve assembly completely.
2. Place a new O-ring into the other end of the filter element. Install the element onto the bottom housing and ensure that the large housing O-ring is in its groove.
3. Insert the valve-end of the element into the top housing and ensure that the oil drain port is rotated 90 degrees clockwise from the filter outlet port.
4. Secure the housings with the retained hardware.

#### **For the Solberg filter:**

1. Place a new filter element over the inner valve column. Place a new O-ring on the thumbscrew. Tighten the thumbscrew to secure the element.
2. Place the top housing over the bottom housing and ensure that the large housing O-ring is in place between the housings. Ensure that the oil drain port is rotated 90 degrees clockwise from the filter outlet port and secure the clamp around the housings.
3. Ensure that the door cables are routed around behind the oil mist filter and between the filter and catalytic converter.

## 6 Subassembly Removal and Replacement

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### Vacuum Control Valve (28-52422)

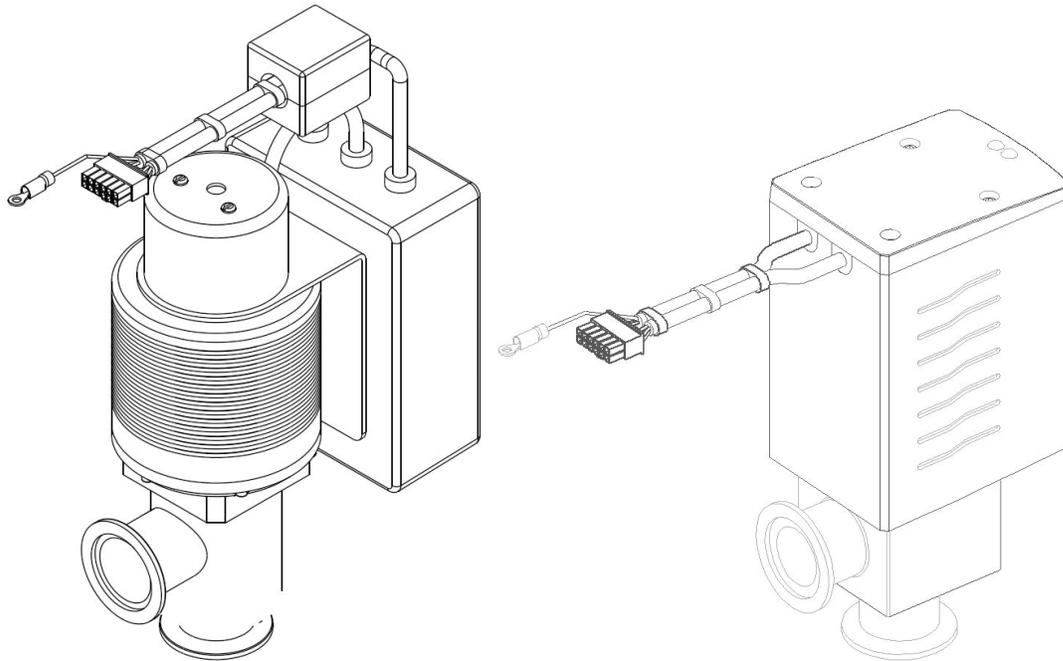


Figure 70. Vacuum Control Valves. MKS (left) Leybold (right).

**Preparation:**

1. Open the front panel.

**Removal:**

1. Disconnect the KF-40 clamps attaching the vacuum control valve to the bellows and the vacuum pump.
2. Unplug cable P118.
3. Remove the vacuum control valve.

**Replacement:**

Replacement is the reverse of the removal steps.

## Oil Return Valve (28-51498)

**Required Tools:** 18 mm open end wrench

**Preparation:**

1. Open the front panel.
2. The vacuum pump may be pulled from the frame to the safety stop to make servicing easier.

**Removal:**

1. Disconnect the oil tube from the valve body by pressing the colored tubing fitting collar in toward the valve while pulling the tubing out.
2. Unplug cable P115.
3. Unscrew the valve from the fitting on the pump.

**Replacement:** Replacement is the reverse of the removal steps.

## Low Frequency Plasma System (LFPS II) (40-52321)

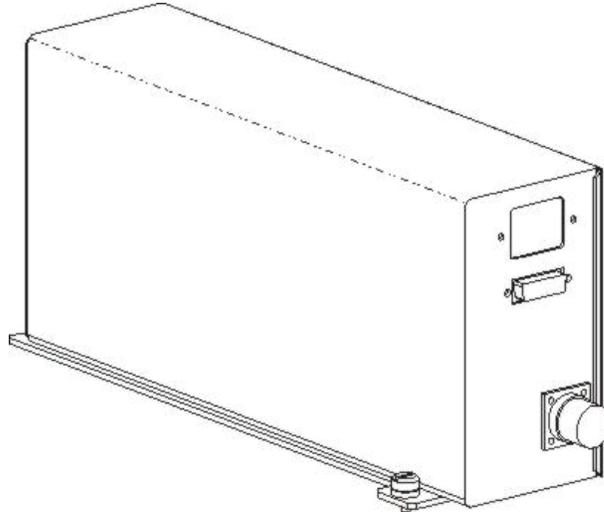


Figure 71. LFPS II.



***WARNING! ELECTRIC SHOCK HAZARD. HAZARDOUS VOLTAGES ARE PRESENT INSIDE THE LFPS II. TURN THE STERILIZER OFF AND UNPLUG IT BEFORE HANDLING THE LFPS 2.***

**Required Tools:**

Flat-blade screwdriver

**Preparation:**

1. Open the front panel.

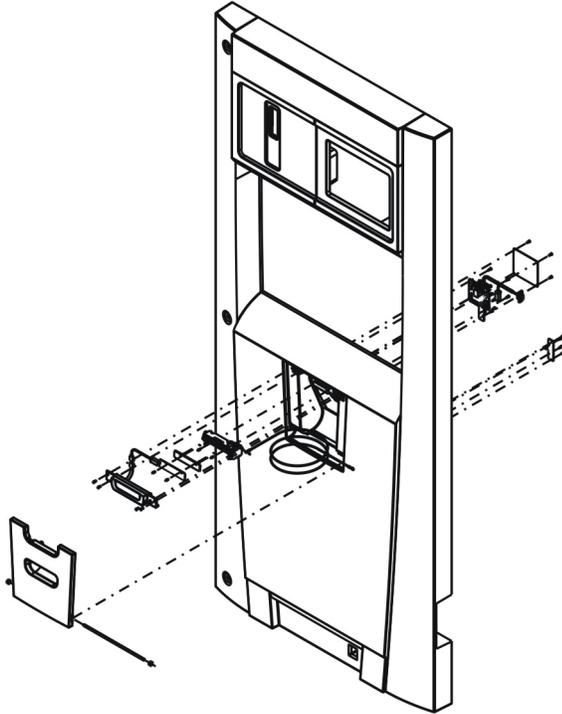
**Removal:**

1. Unplug cables PWR, Communications.
2. Unscrew the Twinax connector on the cable to the feedthrough.
3. Loosen 2 captive screws attaching the LFPS II to the frame.
4. Slide the LFPS II forward and lift up to remove.

**Replacement:**

Replacement is the reverse of the removal steps.

## Printer Assembly



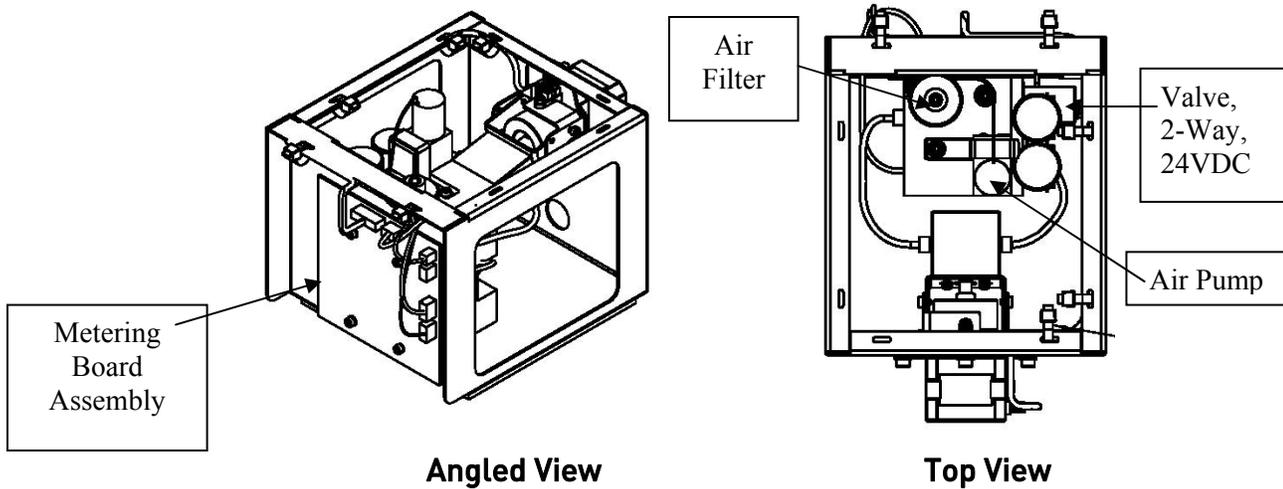
**Figure 72. Printer Assembly.**

The printer assembly is mounted in the front panel.

- Required Tools:** 3 mm hex wrench (long shaft).
- Preparation:**
1. Turn the sterilizer OFF and unplug it.
  2. Open the front panel.
- Removal:**
1. Unplug cable P17.
  2. Remove the 4 screws attaching the printer module to the panel. Support the printer module as the last screw is removed.
- Replacement:** Replacement is the reverse of the removal steps.

## Optional Hardware

### DUO Delivery Module (103329-XX)



The DUO delivery module assembly includes the following replaceable components:

- Metering Board Assembly
- Valve, 2-Way, 24 VDC
- Air Pump
- Air Filter



**CAUTION:** When replacing the 2-way valve, air pump or delivery tubing, ensure the work environment and all tooling that will contact the gaskets or other wetted surfaces is dust and grease free. Wear new powder-free nitrile gloves during the handling of the valves, gaskets and the air pump sleeve to minimize the risk of contamination of the wetted surfaces.



**WARNING! RISK OF HYDROGEN PEROXIDE EXPOSURE. ACCUMULATORS, VALVES AND DELIVERY SYSTEM TUBING MAY CONTAIN HYDROGEN PEROXIDE. USE APPROVED PERSONAL PROTECTION EQUIPMENT (PPE) INCLUDING EYE PROTECTION AND NEW, POWDER-FREE NITRILE GLOVES WHEN HANDLING THESE COMPONENTS.**

- Required Tools:** None.
- Preparation:**
1. Run the Peroxide Clearance cycle prior to removing the DUO delivery module or any of its components.
  2. Turn the sterilizer off and unplug it.
  3. Remove the left side panel.
  4. Clean and remove debris from the DUO delivery module and the surrounding area prior to removal.
- Removal:**
1. Unscrew and disconnect the tube that connects the cassette delivery assembly.
  2. Unscrew and disconnect both tubes that connect to the vaporizer.
  3. Unplug the three cables from the metering board assembly.
  4. Lift up on the assembly until it detaches from the frame.
  5. Remove the assembly from the sterilizer.
- Replacement:** Replacement is the reverse of the removal steps.

### **Metering Board Assembly (103410-XX)**

- Required Tools:** Snap-On® QDRIVER2 torque wrench or equivalent, and a 2.5 mm hex bit.
- Preparation:**
1. Run the Peroxide Clearance cycle prior to removing the DUO delivery module or any of its components.
  2. Turn the sterilizer off and unplug it.
  3. Remove the left side panel.
- Removal:**
1. Disconnect all of the electrical connections to the board.
  2. Remove the four screws.
  3. Pull the board away from the manifold.
- Replacement:**
1. Replacement is the reverse of the removal steps.
  2. Use Loctite® 425 on all screws, but use a minimal amount to minimize the risk of contamination. Torque screws down to 24 in/oz.

# 6 Subassembly Removal and Replacement

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## Valve, 2-Way, 24 VDC (103442-XX)

*Note:* You may need to loosen the 4 screws holding the metering board assembly to the manifold to gain access to the valve.

**Required Tools:** None. (Snap-On® QDRIVER2 torque wrench or equivalent, and a 2.5 mm hex bit.)

**Preparation:**

1. Run the Peroxide Clearance cycle prior to removing the DUO delivery module or any of its components.
2. Turn the sterilizer off and unplug it.
3. Remove the left side panel.

**Removal:**

1. Disconnect the electrical connection to the board.
2. Remove the valve with your hand by turning it counterclockwise to unscrew it from the manifold.
3. Remove the gasket.

**Replacement:**

1. Replacement is the reverse of the removal steps.
2. Hand-tighten the nut of the valve to minimize the risk of damaging the manifold.

## Air Pump (20-50831-004)

**Required Tools:** Snap-On® QDRIVER2 torque wrench or equivalent, and a 2.5 mm hex bit.

**Preparation:**

1. Run the Peroxide Clearance cycle prior to removing the DUO delivery module or any of its components.
2. Turn the sterilizer off and unplug it.
3. Remove the left side panel.

**Removal:**

1. Disconnect the electrical connection to the board.
2. Remove the screw holding the air pump bracket to the manifold.
3. Pull up on the air pump to remove.
4. Remove the silicone tube from the inlet port.

**Replacement:**

1. Replacement is the reverse of the removal steps.
2. Use Loctite® 425 on all screws, but use a minimal amount to minimize the risk of contamination. Torque screws down to 24 in/oz.

# 6

## Subassembly Removal and Replacement

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### **Air Filter 0.2 PTFE, 25mm & Luer MALE 1/4-28UNF (25-50703-001 & 74-50773-001 (PM2 kit parts))**

This is a PM2 procedure.

- Required Tools:** None.
- Preparation:**
1. Remove the left side panel.
- Removal:**
1. Unscrew and disconnect the inlet filter cartridge along with the male Luer fitting.
- Replacement:** Replacement is the reverse of the removal steps.



**CAUTION:** If for some reason the DUO delivery module needs to be returned to ASP, run the peroxide clearance cycle prior to removing the module from the sterilizer. In the event the peroxide clearance cycle did not run or complete, using approved PPE remove the accumulator as follows:

1. Remove the three 2.5 mm hex screws securing the top of the accumulator.
2. Remove the top of the accumulator.
3. While running the water, carefully pour the remaining H<sub>2</sub>O<sub>2</sub> into a facility sink.
4. Reinstall the accumulator top and screws and package the DUO delivery module for shipping.

## Chapter 7.

# Maintenance

## Overview

There are two Planned Maintenance (PM) intervals for the STERRAD® 100NX® Sterilizer. PM1 is normally performed after 1500 cycles or 6 months and PM2 is performed at 3000 cycles or after 12 months of operation, whichever occurs first. Planned maintenance consists of replacing sterilizer components that are subject to wear or degradation from use. Maintenance is performed from the input side on a two-door system.

The screenshot displays the 'Planned Maintenance' screen with the following information:

- Title Bar:** Planned Maintenance (left), 03/07/07 (top right), 09:45:47 (bottom right)
- Status:** Date Of Last Planned Maintenance: 02/28/07; Next Maintenance Is Due On: 08/01/07
- Settings:** PM Time Interval: 6 Months; Number Of Cycles: 1500
- Current Status:** Number Of Days Since Last PM Was Performed: 6; Number Of Cycles Since Last PM Was Performed: 19
- Organization Info:** Name Of Maintenance Organization: ASP; Phone Number Of Organization: XXX-XX-XXXXXXX
- Navigation:** Keyboard, Cancel, Done buttons at the bottom.

**Figure 73. Planned Maintenance Display.**

## Maintenance Checks – All Calls

1. Check the door roller alignment, if necessary, by following the procedure shown in the System Verification Chapter.
2. Check the door timing belt pulley and motor shaft coupler set screws to ensure they are properly tightened onto the shaft.
3. Check each door mechanism counterbalance for damage.



**CAUTION: Do not bend, nick, or damage the counterbalance metal tape in any way. Do not use any tool to clamp it to another part. If the tape is damaged, it will bind in the housing slit, further damage the part, and disrupt the door motion.**

## PM1

### Drain the Vacuum Pump Oil

You will need to have at least 3 empty oil bottles for this procedure. You can also use a flat oil drain pan.

1. Run the pump for 5 minutes to warm the oil. Turn off the pump.
2. Make sure you have oil absorbent cloths on the floor.
3. Remove the oil mist filter assembly from the pump.
4. Hold an empty oil bottle up to the drain valve. Lift and turn the drain valve so that the oil flows into the bottle. Before the bottle is completely full, close the drain valve, change to an empty bottle and open the drain valve. Continue until all the oil is drained. Close the drain valve.
5. Pour fresh oil into the pump through the oil mist filter port. You will use about 3 liters of oil. Fill the pump almost to the MAX fill line.
6. Replace the oil mist filter assembly.
7. Clean up any spills and dispose of the used oil and oil absorbent cloths according to the facility's waste disposal policy.

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## Oil Mist Filter Element Replacement

1. Disconnect the oil mist filter tube and remove the oil filter assembly. Leave the connectors attached to the oil filter assembly.
2. Replace the filter element in the oil filter assembly.
3. Reinstall the oil filter on the vacuum pump.

## Air Filter/Fans

1. Locate the filter located on the bottom inside the frame.
2. Press down on the tab and slide the filter out.
3. Install a new filter element. Make sure the tab is in place.
4. Ensure proper filter orientation.
5. Inspect the fans and clean if needed.

## Chamber Plastics

1. Remove the shelves. Remove the plastic handles from the shelves.
2. Remove the screw from the feedthrough.
3. Remove the shoulder screws from the bottom front of the electrode.
4. Remove the electrode assembly from chamber.
5. Remove the screws fastening the rails and stops.
6. Remove the plastic parts from the electrode.
7. Clean the chamber with deionized water and a scrub pad suitable for use on Teflon<sup>®</sup> coated pans. Scrub the electrode using the same method.
8. Attach new plastic parts onto the electrode assembly.
9. Install electrode assembly into the chamber.
10. Install the plastic handles on the shelves.
11. Replace the shelves.

## Additional PM1 Procedure

Remove and replace the transfer and transition valves.

## PM Counter

1. Reset the PM1 counter to 1500.
2. Set the PM1 date to a date 6 months in the future.

## PM2

Perform a PM1 and then proceed to perform the PM2 steps.

### Converter Replacement

1. Grasp the catalytic converter and turn it counter clockwise to unscrew it. The plastic adapter may come off with the converter. Remove and retain the adapter for the new converter. A tool may be needed to remove the adapter.
2. Dispose of the converter according to the facility's waste disposal policy.
3. Replace the converter after you have replaced the oil return filter (PM1).

### HEPA Vent Valve Filter



***WARNING! FOLLOW ALL DOOR SAFETY PROCEDURES BEFORE WORKING BELOW THE DOOR. THE SAFETY STOP MUST BE IN PLACE SO THAT THE DOOR DOES NOT DROP.***

1. Close the door.
2. Unscrew and remove the HEPA filter.
3. Discard the filter according to the facility's waste disposal policy.
4. Install a new filter element and hand-tighten. Make sure the arrow is toward the vent valve.

### H<sub>2</sub>O<sub>2</sub> Monitor Optic Windows

1. Open the input door.
2. Place your finger in the recess and tilt up the optic window.
3. Insert a new optic window making sure it is clean of finger prints and is properly seated.

## Hydrogen Peroxide Monitor Lamp



**WARNING! ULTRAVIOLET LIGHT EXPOSURE!**  
**ULTRAVIOLET LIGHT CAN HARM UNPROTECTED EYES AND SKIN. DO NOT LOOK DIRECTLY AT AN ENERGIZED UV LAMP.**



**HOT SURFACES! THE ULTRAVIOLET LAMP AND ITS HOUSING ARE HOT WHEN ENERGIZED. CONTACT WITH THESE PARTS MAY CAUSE BURNS OR OTHER INJURIES. DO NOT TOUCH THE MONITOR LAMP ASSEMBLY WHEN IT IS ENERGIZED.**

**CAUTION: Safe parts handling. Do not touch the surface of the ultraviolet lamp or the optical window with your bare hands. Oil and contaminants from your skin will damage these parts and cause premature failure.**

1. Turn off the lamp.
2. Open the front panel.
3. Unplug power cable.
4. Use soft-jaw pliers to unscrew the collar to the Ultratorr fitting.
5. Lift the lamp housing up to remove.
6. Remove the spacer and the O-ring from inside the Ultratorr fitting.
7. Insert a 1 mm hex wrench through the hole in the top of the lamp housing to loosen the lamp retaining screw.
8. Gently pull the UV lamp and socket assembly out of the lamp housing.
9. Unscrew the base of the lamp housing and remove the O-ring and the optical window.

To install the new lamp, do the following:



**CAUTION: Safe parts handling. Do not touch the surface of the ultraviolet lamp or the optical window with your bare hands. Oil and contaminants from your skin will damage these parts and cause premature failure.**

1. Install a new ultraviolet lamp in the lamp housing.
2. Install a new optical window and O-ring in the lamp housing (if necessary).
3. Clean the inside of the Ultratorr fitting. Lightly coat a new O-ring with approved vacuum grease and place the O-ring in the Ultratorr fitting. Reinstall the spacer in the Ultratorr fitting.

4. Place the threaded collar around the base of the lamp housing. Insert the lamp housing tube into the Ultratorr fitting. Press down until it is seated firmly.
5. Orient the lamp housing so that there is no interference with the lamp cable. Use soft-jaw pliers to tighten the collar.
6. Reconnect the lamp cable.

## Door Seal O-Ring

1. With the door open, pry out the door seal O-ring.
2. Discard the O-ring according to the facility's waste disposal policy.
3. Lightly lubricate the new O-ring and insert it. Press it in completely all the way around. You may need to stretch it slightly.
4. Repeat for the output side door if necessary.

## Thermistors



***WARNING! FOLLOW ALL DOOR SAFETY PROCEDURES BEFORE WORKING BELOW THE DOOR. THE DOOR SAFETY LOCK MUST BE IN PLACE SO THAT THE DOOR DOES NOT DROP.***

### Doors

1. Open the front panel or open the rear panel.
2. Remove and replace the thermistors.
3. Replace the panels.

### Chamber

1. Close the door.
2. Locate the thermistors fastened to the bottom of the chamber near the front, back and center of the chamber. The thermistors are underneath insulation flaps.
3. Remove the thermistors and discard.
4. Install the new thermistors.

**Vaporizer**

1. Locate the thermistors mounted on the vaporizer manifold.
2. Remove the thermistors and discard.
3. Install the new thermistors.

**Condenser**

You will need to access the top panel, which requires the use of an acceptable ladder or step stool.

1. Locate the thermistor mounted to the top of the condenser housing.
2. Remove the thermistor and discard.
3. Install the new thermistor.

**Additional PM Procedure**

Perform the following removal and replacement procedures during PM2. All these procedures are in the Component Replacement Chapter.

1. Remove and replace the delivery valve. When installing the delivery valve, be careful not to over tighten; finger-tighten only.
2. Remove and replace the delivery tubes. When installing the delivery tubes, be careful not to over tighten; finger-tighten only.
3. Remove and replace the delivery valve air filter
4. Remove and replace the DUO delivery module air filter and Luer, if equipped.
5. Inspect the door counterbalance springs for smooth operation, kinks or cuts when extended. Also check for cuts in the housing. Replace if necessary. There are 2 per door.

**PM Counter**

1. Reset the PM2 counter to 3000.
2. Set the PM2 date to a date 12 months in the future.

## Cassette Disposal

The customer routinely performs the procedures in this section. If the cassette box becomes full during a planned maintenance procedure, it is a good idea to dispose of the empty cassettes and insert a new box in the cassette box opening.

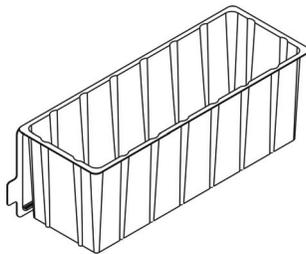
**IMPORTANT!** You **must** use the cassette disposal box to dispose of empty cassettes. Never reuse a cassette disposal box. Once a cassette disposal box has been removed from the unit a new cassette disposal box must be inserted. The following section details cassette disposal:

### 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 in place.

### Removing a Cassette Disposal Box

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



**Figure 74. Open the Access Panel and Remove the Used Cassette Disposal Box by Pulling on the Tab and Sliding the Box Out.**

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



**Figure 75. 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 tab is facing you and the lid is open and not caught in the opening. Make sure the box is flat against the bottom surface.
5. Close the access panel.

## Printer Maintenance

### Replacing Printer Paper

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

1. Open the printer by pushing up on the button in the handle. The printer door drops forward.



**Figure 76. Open the Printer.**

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



**Figure 77. 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 78. Insert a New Paper Roll. Pull the Paper Over the Top of the Door and Align the Paper Between the Guides.**

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 79. 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.

# 7 Maintenance

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**Figure 80. 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 Thermal Printer Head

Inspect the quality of the printed information at the planned maintenance interval. If the quality of the printed information is faint or has blank spots, the thermal printer head needs to be cleaned.



***WARNING! THE PRINT MECHANISM MAY BE HOT IMMEDIATELY AFTER PRINTING. ALLOW IT TO COOL COMPLETELY BEFORE CLEANING.***



**CAUTION: Do not use abrasive materials or sharp objects to clean any printer mechanism.**

To clean the thermal printer head, do the following:

1. Turn the release lever until the platen block separates from the printer mechanism. Lift up the platen block.
2. Clean the heating elements using isopropyl alcohol and a cotton swab. Make sure no fibers from the swab remain on the elements.
3. After the alcohol is completely dry, reinstall the platen block onto the printer mechanism.
4. Load the paper into the printer and close the printer door.



Chapter 8.

# System Calibration

## Overview

The STERRAD<sup>®</sup> 100NX<sup>®</sup> Sterilizer has onboard calibration tools to make it easy to calibrate the various components of the system. As of this publication, calibration is still being researched and the procedures presented here are subject to change. Please contact ASP Technical Service prior to performing any calibration procedure.

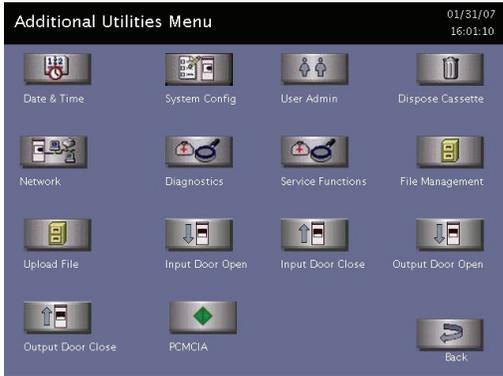
## Temperature Calibration Using a Temperature Bath

Temperature ranges are calibrated or verified in this procedure. If precision resistors are used, see the section containing the precision resistor adjustment procedures.

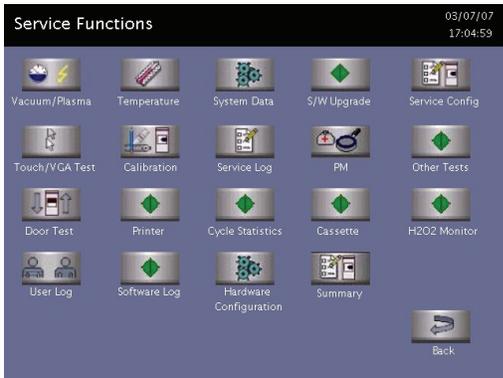
To perform the calibration using the temperature bath, do the following:

1. Login as Service. Navigate to the Temperature Calibration display by touching the buttons in the displays shown in the next page.

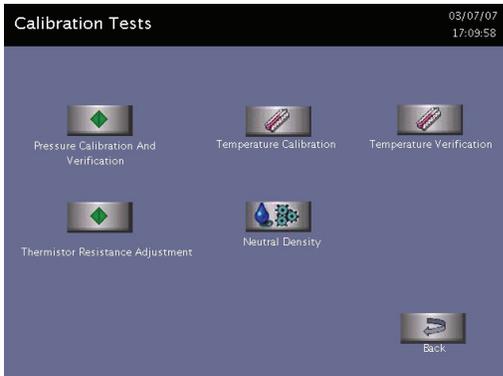
# 8 System Calibration



On Additional Utilities (shown at left) touch **Service Functions**



On Service Functions (shown at left) touch **Calibration**



On Calibration Tests (shown at left) touch **Temperature Calibration.**

“Set the Bath Temperature to 35.0 °C” is displayed.



**Figure 81. Temperature Calibration Showing Virtual Keypad.**

2. Select each heater circuit you wish to calibrate (you can also select ALL). Touch **Start** to turn off the heater and begin the calibration procedure.
3. Set the bath temperature to 35.0° C and place the thermistor in the bath.
4. When all thermistors selected for calibration are within 3° C of the setpoint, the virtual keypad and the Actual Bath Temperature entry fields pop-up to allow entry of the actual temperature of the bath. Touch **Enter** to accept and save the value.
5. “Set Bath Temperature to 50.0° C” is displayed. Set the bath temperature to 50.0° C, entering actual bath temperature when it is stable. Repeat step 4.
6. “Set Bath Temperature to...” 60.0°, 70.0°, and 85.0° C are displayed in turn and the same steps followed until the last temperature in the series has been calibrated.

The 50.0° C and 70.0° C values are used by the system to verify the calibration data. The system independently calculates the calibration coefficients of the Steinhart-Hart equation for each thermistor, using the two extreme points and the center point as inputs to the equation. Calculated coefficients are stored in NVRAM if the data from the 50.0° C and 70.0° C tests are within 0.5° C of the model using the calculated coefficients.

If the calibration is successful and the verification points are inside the acceptable range (<0.5° C) the software does following:

- Opens the file tempcMMDDYYhhmm (path is /ide/tempcal).  
MM=month, DD=day, YY=year, hh=hour, mm=minute.

# 8

## System Calibration

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- Stores the following information in the file: the current timestamp (MM/DD/YY HH:MM), R, A, B, C, both calculated verification points (50.0°C and 70.0°C), last verified dates and status (PASS).
- The software exits the calibration screen and stores the calculated coefficients into NVRAM. The values in NVRAM are used until the next successful calibration.

If the verification points are outside or equal to the acceptable range ( $\geq 0.5^\circ\text{C}$ ) the software does the following:

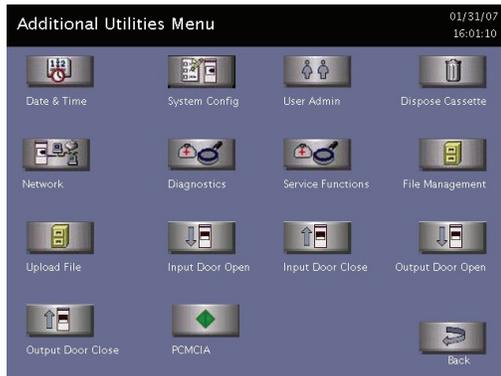
- Opens the file tempcMMDDYYhhmm (path is /ide/tempcal) MM=month, DD=day, YY=year, hh=hour, mm=minute.
- Stores the following information in the file: the current timestamp (MM/DD/YY HH:MM), R, A, B, C, both calculated verification points (50.0°C and 70.0°C), last verified dates and status (FAIL).
- The software exits the calibration screen and returns back to coefficients that existed before the temperature calibration began. The software uses manufacturing defaults if a calibration has never been executed.

Touching BACK during calibration exits the current test. All data from a calibration is then lost and the system reverts to the previous coefficients in use before the calibration was attempted or canceled.

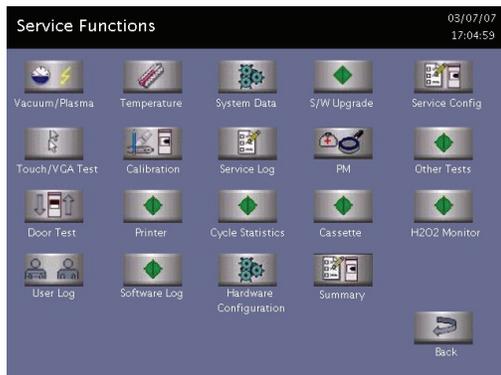
# Temperature Calibration – Thermistor Resistor Adjustment

Electronic temperature circuit ranges are calibrated or verified in this procedure.

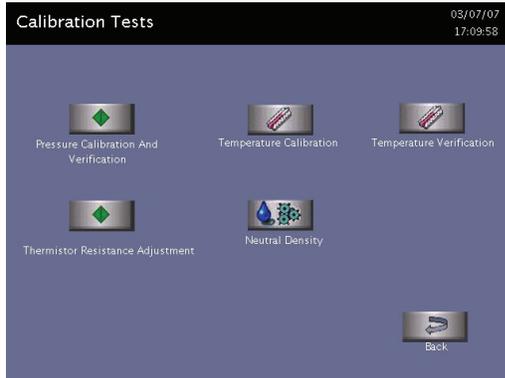
1. Using a Fluke 87 or equivalent digital multimeter, verify that the precision resistor values match the resistor label values  $\pm 1\%$ .
2. Login with Service Access, and then navigate to Additional Utilities/Service Functions/Calibration/Thermistor Resistance Adjustment.



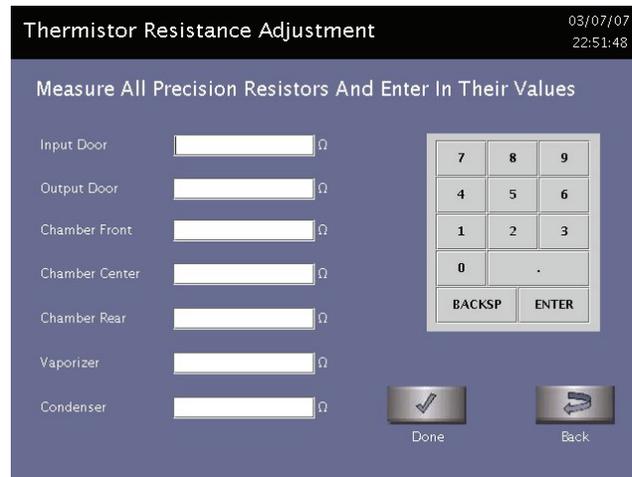
On Additional Utilities (shown at left) touch **Service Functions**.



On Service Functions (shown at left) touch **Calibration**.



On Calibration Tests (shown at left) touch **Thermistor Resistor Adjustment**.

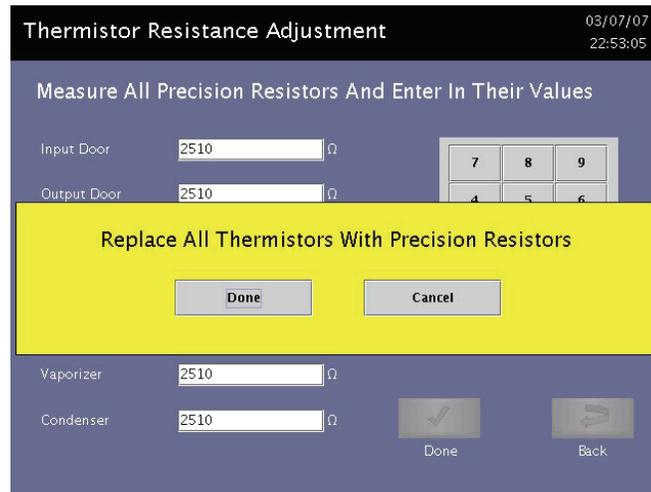


**Figure 82. Thermistor Resistance Adjustment Display.**

3. Touch the entry field for each thermistor to place the cursor in the fields. Using the virtual keypad, enter the Ohm value of each resistor. This value is located on each precision resistor or use the values verified in step 1.

Make sure you input the resistance values in the correct fields; e.g., the value of the precision resistor attached to the door should be entered into the door field.

*Note:* For IMS, make sure to use a duplicate set of resistors.



**Figure 83. Replace the Resistors as Shown in Step 4. Press Done.**

4. Disconnect the thermistors for the circuits to be calibrated and install the appropriate precision resistor to the extension harnesses.
5. Press **DONE**. Press **DONE** again if needed. The results are displayed in a table.

	Rprecision(Ω)	Rmeasured(Ω)	Rgain
Input Door	2510	2513	1.5
Output Door	2510	2497	1.49
Chamber Front	2510	2497	1.49
Chamber Center	2510	2497	1.49
Chamber Rear	2510	2490	1.49
Vaporizer	2510	2497	1.49
Condenser	2510	2497	1.49

**Figure 84. Displayed Results.**

6. Calculate the resistance value in percentages. If the values are acceptable, press **DONE**. If the values are to be saved and applied, press **Yes**. If the values are not  $\pm 5\%$ , press **No** and troubleshoot the system using the procedures in this guide.

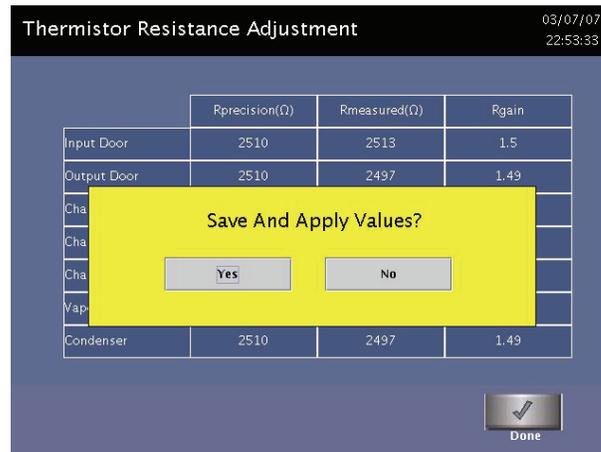


Figure 85. Press Yes to Accept Values.

## Peroxide Calibration With Neutral Density Filters



Figure 86. Neutral Density Filter Calibration Display. Note that Start is Inactive.

1. Open the front panel. All the other panels should be in place.
2. Navigate to the H<sub>2</sub>O<sub>2</sub> Monitor screen. Enter **100** in the bulb intensity voltage field (mV) using the displayed keypad. Touch **Enter** on the keypad. Reboot the sterilizer.
3. Navigate to the Service/Calibration/Neutral Density display. Touch **SET FILTER RANGE** to display the screen.

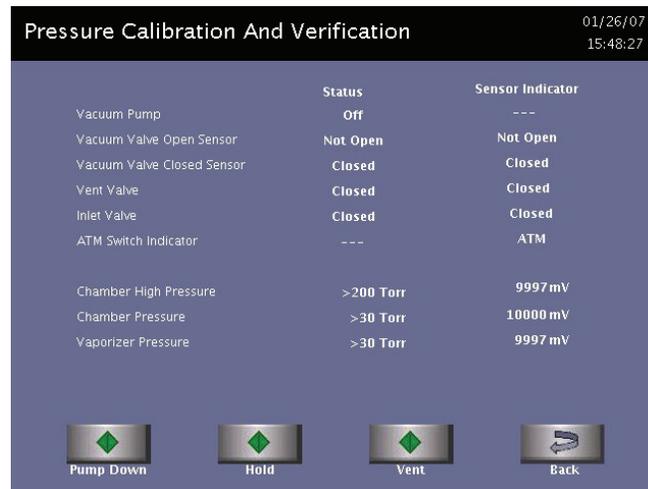
4. Using the displayed keypad, enter the OD values marked on each filter in the order shown on the display. Touch **Enter** after each entry or touch the next field. Touch **Save**. Touch **Back**.
5. This setup may take several minutes. During this time, the system is setting up the sterilizer to support the calibration and is setting the temperature of the condenser to 70° C to ensure no residual peroxide remains in the chamber when the calibration process begins. While the system is performing this setup, **START** is inactive (grayed out). If **START** does not become active, repeat steps 2-4.
6. When the sterilizer is ready, touch **START** to begin the calibration process.
7. Follow the calibration steps on the display. Be sure you touch **OK** after you have completed each step that requires you to provide action. When the calibration is complete, the following is displayed:

#### **Reinstall filter blank**

*Note: If the system does not pass the calibration tests, wait approximately 1 minute after inserting the neutral density filters before touching OK.*

8. A calibration report is automatically printed upon successful completion of the calibration. Review the report, ensure it indicates “H<sub>2</sub>O<sub>2</sub> Monitor: Passed” and tape the report to the Product Verification Form.

## Zero Adjustment Procedure for the Pressure Transducers



**Figure 87. Pressure Calibration and Verification Display.**

This section describes the steps for verifying and adjusting the zero pressure point of the pressure transducers. The zero point of the transducers is verified and adjusted against a traceable reference.

There are 3 pressure transducers in the system. One 30 torr, with 0.25% accuracy, calibrated at 50° C is located on the vaporizer assembly. One 30 torr, with 0.25% accuracy, calibrated at 35 °C and one 200 torr, with 0.25% accuracy, calibrated at 35° C are located on the pressure control manifold.

**Note:** *Prior to conducting this procedure, ensure that the sterilizer has been powered on, and the chamber and vaporizer assembly temperature are regulating at their respective setpoints (50° C on the chamber and 75° C on the vaporizer). Also, the system leak rate must be  $\leq 25$  mtorr per minute. Be sure you record the sterilizer serial number; all pressure transducers serial numbers, and calibration instrumentation information on the calibration data sheet included with the calibration package.*

---

To calibrate the pressure transducers, do the following:

1. Login as Service. Navigate to Additional Utilities/Service Functions/Pressure Calibration.
2. Attach the vacuum gauge (reference meter) to the pressure manifold using the KF-16 to 7/16-20 adapter, KF-16 centering ring adapter, and a KF-16 clamp.
3. Turn on the reference meter.
4. Connect the COM probe of the digital voltmeter to T54 or T56 on the system interface board. Connect the voltage probe to T35, then connect the voltage probe to T40. For reference, T58 is the test point for the chamber 200 torr sensor.
5. Navigate to the Service Function display, then Vacuum/Plasma. In sequence, set Vacuum Valve: Open, Vent Valve: Close, Inlet Valve: Open, Transition Valve: Open, and Vacuum Pump: On.
6. Evacuate the chamber until the reading on the reference meter is less than 100 mtorr. Wait for the readings to stabilize for at least 1 minute. The typical vacuum reading should be between 40-20 mtorr.
7. Close the vacuum control valve and turn off the vacuum pump. Wait for 2 minutes. Open the vacuum control valve; turn on the vacuum pump again. Evacuate the chamber until the reading on the reference meter is less than 100 mtorr. Close the vacuum control valve.
8. Record all 3 system displayed pressure values, 3 voltage readings, and reference meter reading on the data sheet. If the difference between any of the pressure transducers and the reference meter is greater than 100 mtorr, adjust the zero potentiometer on the pressure transducer to match the reading indicated by the reference meter. Record displayed pressure values, voltage readings, and the reference meter reading on the data sheet.
9. Vent to atmosphere and pump down again. Close the vacuum control valve and turn off the pump at (near) 25 torr, 15 torr, 5 torr, 1 torr and 100 mtorr pressure points to hold the pressure. Record all pressure transducers and reference gauge readings on the data sheet.
10. The acceptance criteria of a successful zero adjustment is that the difference between the transducer readings should be less than 100 mtorr. The difference between the reference gauge and system pressure transducers readings when pressure is less than 1 torr, should be less than 50 mtorr.



Chapter 9.

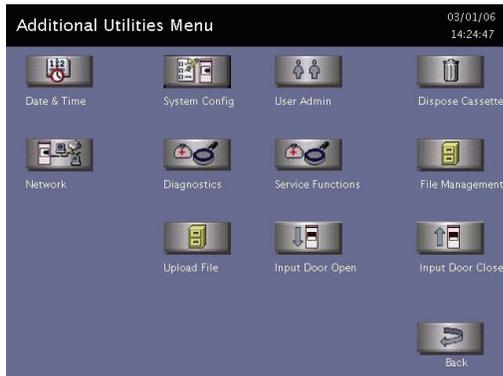
# System Verification

## Overview

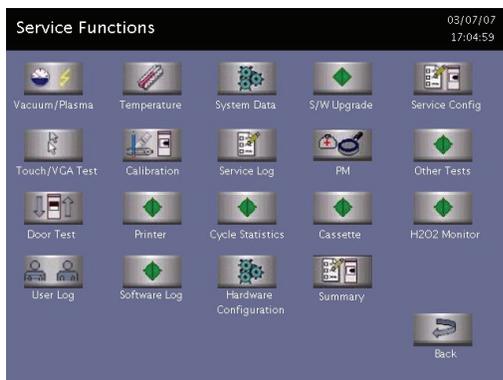
System Verification includes the following activities:

- Check the DC voltages
- Verify the plasma power.
- Zero the pressure transducers.
- Verify Vacuum (leak back)
- Verify user interface
- Verify cassette system
- Run Diagnostics
- Run an empty chamber cycle.
- Verify temperatures:
  - >> chamber front
  - >> chamber middle
  - >> chamber rear
  - >> door 1
  - >> door 2
  - >> vaporizer
  - >> condenser

# 9 System Verification



On Additional Utilities (shown at left) touch **Service Functions**.



On Service Functions (shown at left) touch **Calibration**.

## Service Action Table

Use the system verification procedures to verify sterilizer performance whenever the service actions listed in the following table are completed.

Service Action Performed	System Verification Test Requirements
PM Level 1	Run standard cycle.
PM Level 2	All tests.
All Service	Run standard cycle.
Replace vacuum subsystem components	Leak test, plasma power measurement, and run standard cycle.
Replace plasma subsystem components	Vacuum plasma test, leak test, plasma power measurement, and run standard cycle.
Replace AC enclosure components	Door and chamber temperature. Run standard cycle.
Replace controller or components	Reprogram customer details, cycle information, PM and login. Temperature calibration, and neutral density calibration. Run standard cycle.

Service Action Performed	System Verification Test Requirements
Replace thermistor	Complete temperature verification and run standard cycle.
Replace delivery system components	Leak back test, cassette guide test and run standard cycle.
Adjust door or replace door sensor	Door operation and run standard cycle.
Replace printer	Complete printer test and run standard cycle.

## Check Voltages

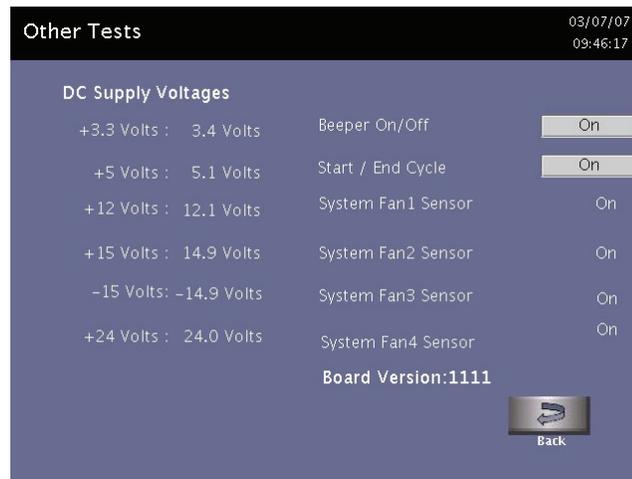
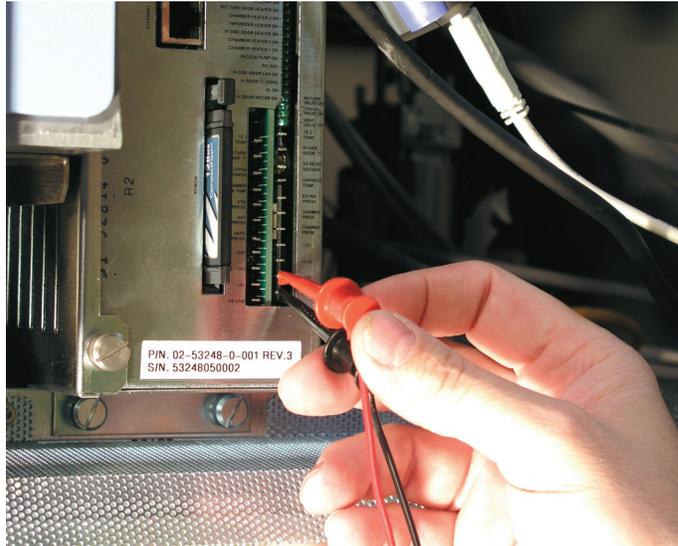


Figure 88. DC Supply Voltages.

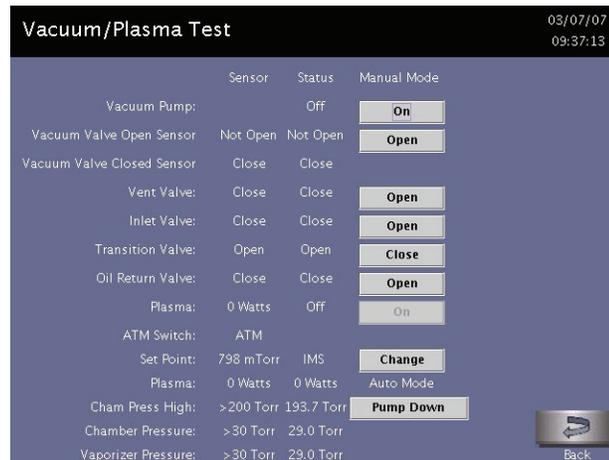
**CAUTION: Do not use probe type leads to measure voltages on the control enclosure. Use of incorrect digital multi-meter leads may short out the power supply and damage the unit. Use spring hook type test leads.**

1. Login as Service. Navigate to Additional Utilities/Service Functions/Other Tests.
2. Verify power supply voltages at the test points accessible on the interface board.
3. Connect the common (-) lead to PSGND, connect the positive (+) to +3.3.
4. Repeat step 3 for test points +5, +12, ±15, +24.



**Figure 89. Connect the leads.**

# Plasma Power Verification



**Figure 90. Vacuum Plasma Test.**

This section describes the steps for verifying the output of the LFPS II against a traceable reference. This procedure requires the use of the LFPS II Power Verification Meter (PVM).

1. Login as Service. Navigate to Additional Utilities/Service Functions/Vacuum Plasma Test.
2. Ensure that plasma is off. Disconnect the LFPS2 power cable.
3. Disconnect the twin-axial cable from the LFPS2 PSM and connect this cable to the LFPS2 PVM.
4. Connect one end of the 1-foot twin-axial cable to the LFPS2 PVM. Connect the other end of the 1-foot twin-axial cable to the LFPS2 PSM.
5. Connect the IEC 320 power cable to the PVM and turn the PVM on. Connect the BNC to dual banana adapter to the PVM. Connect the DVM to the PVM dual banana adapter.
6. Connect the power cable to the LFPS2. Navigate to the vacuum plasma test and run the test at 500 mtorr. (0.5 torr is the setpoint.)
7. Read the output voltage on the DVM. Output should be between 3.82 - 4.79 VDC. If the output is not correct, troubleshoot the system and replace components if needed.
8. Run the plasma test for 4 minutes. Record initial and approximately 4 minute values. The test is complete.
9. Stop the test and exit the vacuum plasma test screen. Remove the LFPS2 PVM and reconnect the twin-axial cable.

10. Read the output voltage on the DVM. Output should be between 3.82 - 4.79 VDC. If the output is correct, the test is complete. If the output is not correct, troubleshoot the system and replace components if needed.

## Zeroing Pressure Transducers



**Figure 91. Pressure Calibration and Verification.**

- Login as Service. Navigate to Additional Utilities/Service Functions/Pressure Calibration.
  - Remove the plug from the pressure control manifold and connect the KF-16-7/16 threaded adaptor.
1. Connect a calibrated vacuum gauge to the KF-16 adaptor using the KF-16 centering ring and clamp.
  2. Navigate to the Additional Utilities/Service Functions/Calibration Tests/Pressure Calibration display. Touch **Start** to pump the system down.
  3. Allow the chamber pressure to stabilize. This should be below 100 mtorr (microns) as indicated on the vacuum gauge.
    - Once the system has stabilized, adjust the zeroing potentiometers on the vaporizer and chamber pressure transducers so that their pressure indications match the pressure displayed on the calibrated vacuum gauge.
  4. When completed, vent the system. Remove the vacuum gauge and adaptor and reinstall the plug removed in step 1.

---

# Chamber and Vaporizer-Concentrator Leak Test

*Note: If the chamber does not evacuate, then check all vacuum seals for tightness. If the chamber still does not evacuate, then the door(s) may need readjustment. See the Door Roller Adjustment section for details.*

1. Using the vacuum plasma test, set the pressure set point to 0.5 torr.
2. Open the vacuum control valve, inlet valve and transition valve.
3. Turn the vacuum pump on and evacuate the chamber to 500 mtorr.
4. Close the vacuum control, inlet, and transition valves, and then turn off the pump.
5. Start a stopwatch and record the initial pressures for the vaporizer/concentrator assembly and also for the chamber assembly.
6. At 5 minutes, record the pressures for the vaporizer/condenser assembly and also for the chamber assembly.
7. Vent the chamber and vaporizer/concentrator assemblies.
8. Calculate the leak rates by subtracting the initial reading from the final reading and dividing the result by 5. Record the leak rates on the Product Verification Form.

## Door Roller Adjustment

This procedure is only performed if the chamber cannot be evacuated (pumped down) for testing.

Tools needed: 3 mm and 5 mm Hex keys, small 10 mm open end wrench, flat-blade screwdriver, and a clean piece of paper (standard 20 lb bond from a copy machine).

For each functional door that needs adjustment, do the following:

1. Open the door.
2. Remove the perforated sheet metal screen attached to the chassis above the door. Retain the hardware.
3. Loosen the jam nut on top of the door adjustment support.

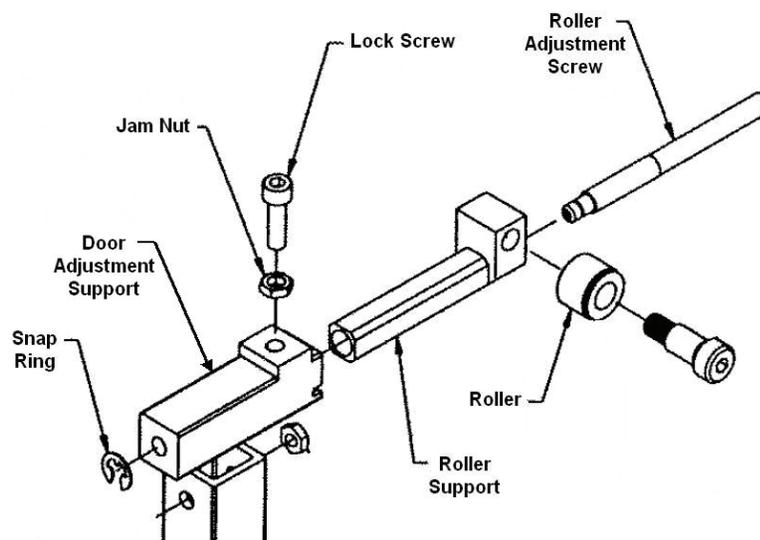


Figure 92, Door Roller.

4. Loosen the lock screw.
5. Close the door.
6. Insert one piece of paper (one sheet thickness) between the chamber O-ring and the door along the top edge of the chamber. Move the paper to the chamber corner next to the roller being adjusted.

7. Using a flat-blade screwdriver, turn the roller adjustment screw until the piece of paper has some slight resistance when pushed/pulled slightly. The paper should be able to be moved. Do not over-tighten the adjustment screw. Do not turn the screw too much in one direction or else the snap ring will come off. Only a small amount of adjustment is necessary. This adjustment causes the roller to push the door closer to the chamber or allows the door to relax away from the chamber.
8. Move the paper to the opposite chamber corner and adjust that roller. Slide the paper along the entire top length of the chamber. The same resistance should be felt along the entire length. Adjust the rollers as necessary. The door is very near parallel with the chamber.
9. Use the flat-blade screwdriver to keep each roller adjustment screw in place while the lock screw is tightened. Ensure that the roller adjustment screw does not move. Tighten the jam nuts.
10. Open and close the door once or twice.
11. Turn on the vacuum pump and verify that the chamber pressure drops. If it does, then perform a system leak check. If the pressure still does not drop, repeat this procedure or troubleshoot other vacuum seal areas.

## Temperature Verification

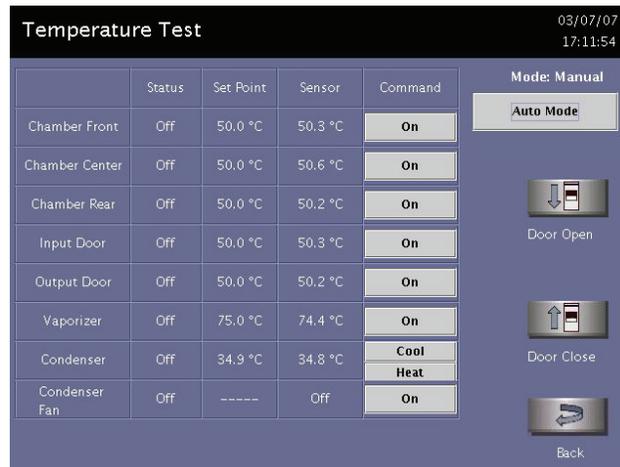


Figure 93. Temperature Test.

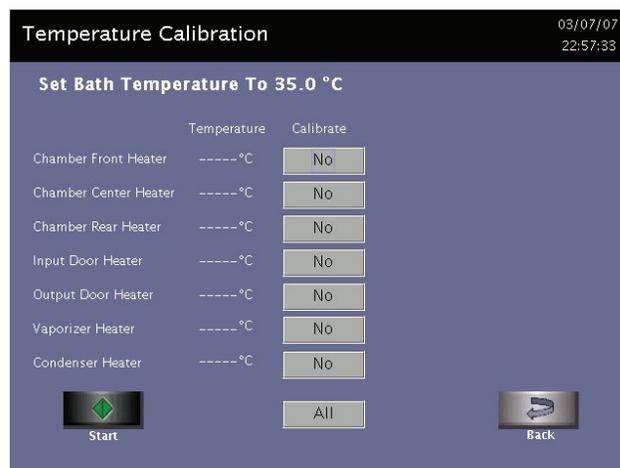


Figure 94. Temperature Calibration.

1. Login as Service. Navigate to Additional Utilities/Service Functions/Temperature Test.
2. Run an empty chamber Standard Cycle until it is completed.
3. Log in as "Service." Navigate to the Service/Temperature display.
4. Using an electronic thermometer, measure the temperature at the chamber front, chamber middle, chamber rear, door 1, door 2, vaporizer, and condenser thermistors. Record the system display and electronic thermometer readings on the Product Verification Form.

# Door Test



**Figure 95. Door Test.**

This display helps you test the functionality of the doors and door sensors.

1. Login as Service. Navigate to Additional Utilities/Service Functions/Door Test.
2. Touch **Open** and observe the sensors and signals as the door functions.
3. Touch **Close** and verify that the sensors are displaying the correct functions.
4. Touch **Manual** repeatedly to open or close the doors in increments.

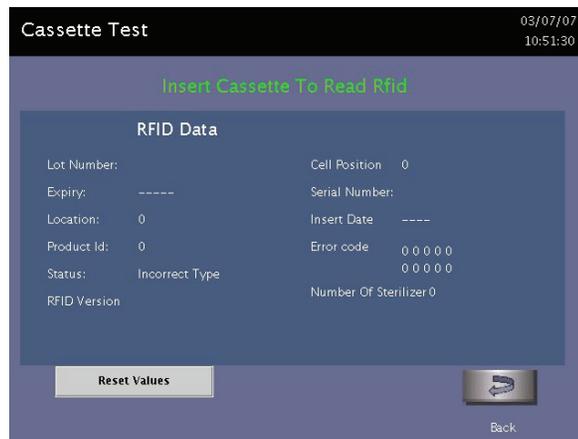
## Cassette Test



Figure 96. Cassette Test.

This display tests the cassette and the cassette system. Follow the instructions on the screen. You will be instructed to insert the cassette at a certain time.

1. Login as Service. Navigate to Additional Utilities/Service Functions/Cassette Test.
2. Touch **Extend** to extend the injector needles.
3. Touch **Retract** to retract the injector needles.
4. Touch **In** or **Out** to verify the cassette guide direction.
5. Touch **Open** to test the delivery valve and carriage sensor.
6. Touch **RFID**. The following screen is displayed.



**Figure 97. Cassette Test (Insert Cassette).**

The display will instruct you as to when to insert the cassette. A used cassette that has a least two usable cells can be used for this test.

1. Examine the cassette label. Insert cassette when instructed to do so.
2. Verify that the information displayed for the cassette matches the label.
3. Touch **Reset** to insert another cassette if needed.

## H<sub>2</sub>O<sub>2</sub> Monitor



**Figure 98. H<sub>2</sub>O<sub>2</sub> Monitor.**

This screen displays information that allows you to verify the function of the H<sub>2</sub>O<sub>2</sub> Monitor.

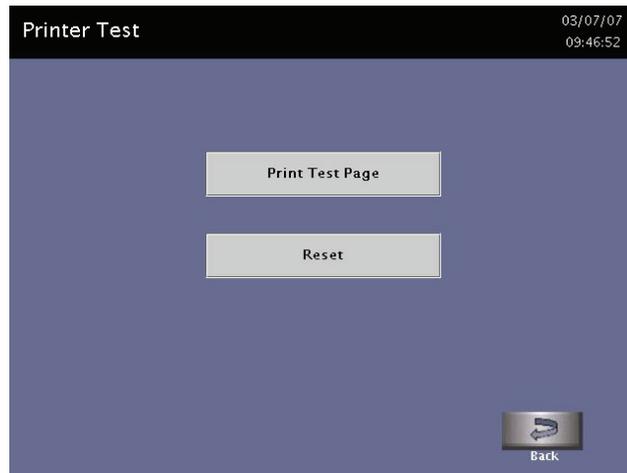
1. Login as Service. Navigate to Additional Utilities/Service Functions/H2O2 Monitor.
2. Enter the bulb intensity voltage.

*Note: "100" is the lowest intensity that can be entered for an accurate reading.*

3. The system displays the appropriate parameters.
4. Touch **On** or **Off** to verify function.

If the H<sub>2</sub>O<sub>2</sub> monitor is out of specification, enter 100 into the voltage intensity field. Touch **Enter**. Then, with the H<sub>2</sub>O<sub>2</sub> Monitor screen still displayed, open the front panel and turn off the ATX. Wait for 15 seconds then turn it on. The system will reboot and auto-adjust the H<sub>2</sub>O<sub>2</sub> parameters.

## Printer Test

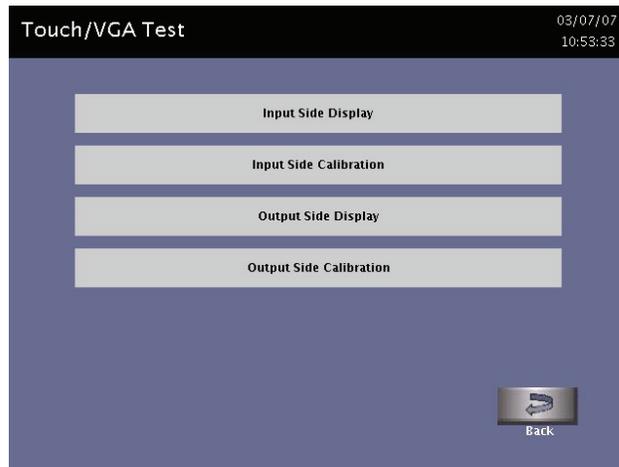


**Figure 99. Printer Test.**

The printer test verifies the function of the printer.

1. Login as Service. Navigate to Additional Utilities/Service Functions/Printer Test.
2. Touch **Print Test Page**. Verify that the test page printed correctly.
3. If the test page is not correct, touch **Reset** to reset the printer and then touch **Print Test Page** again.

## Touch Screen Test



**Figure 100. Touch Screen Test.**

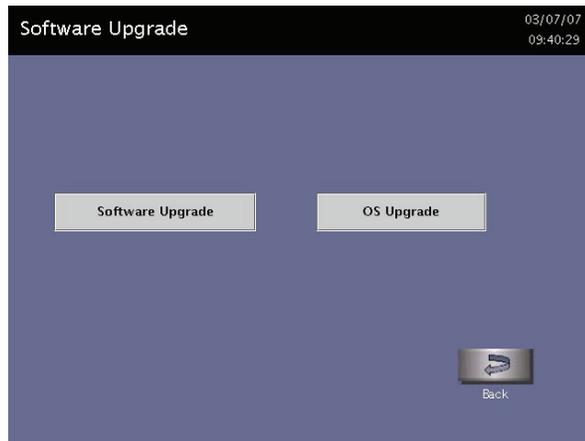
Use this display to calibrate the touch screen.

1. Login as Service. Navigate to Additional Utilities/Service Functions/Touch/VGA Test.
2. Touch Input (or Output) side display to verify that the display is functioning correctly.
3. Touch **Calibration** for the display you wish to calibrate.

*Note: On one-door units, only the Input Side buttons are displayed.*

4. Locate the target (yellow icon) and touch the target for the time shown.
5. Touch **Done**.

## Software Upgrade



**Figure 101. Software Upgrade.**

This display is only used when you are upgrading the software via a compact flash.

1. Login as Service. Navigate to Additional Utilities/Service Functions/Software Upgrade.
2. Touch **Software Upgrade** and follow the displayed instructions:

*Note:* OS Upgrade is not used at this time.



Appendix A.

# Sterilizer Specifications

Power	<p>The phase rotation is adjusted to match the system requirements at installation.</p> <p><b>208V 60 Hz Power:</b> 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><b>380 - 415V 50/60 Hz Power:</b> The sterilizer requires a five-wire grounding outlet attached to a dedicated 30 AMP, 3 phase, (200-240 VAC, 380-415 VAC) <math>\pm 10\%</math>, 50/60 Hz <math>\pm 5\%</math> circuit with separate neutral and ground conductors.</p> <p><b>200V 50-60 Hz Power (Japan):</b> 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	<p>Front: 39.5 in. (100 cm); Back: 39.5 in (100 cm); Top: 39.5 in. (100 cm)</p> <p>Left side: 39.5 in. (100 cm); Right side: 39.5 in. (100 cm).</p>
Weight	<p>1-door 938 lb (426 kg)</p> <p>2-door 1,006 lb (457 kg)</p>
Chamber volume	152 liters. W 20.7 in. (51 cm), H 16.1 in. (41 cm), D 28.93 in. (73.5 cm).
Chamber shelves	<p>Two shelves, W 17 in. (42.5 cm), D 28 in. (70 cm).</p> <p>Shelf capacity: 55 lb. (25 kg) uniformly distributed.</p> <p>Both shelves are removable.</p>

# A Specifications

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Temperature	Operating: 18° C - 35° C (64° F - 95° F). Storage: -29° C - 70° C (-20° F - 158° F)
Humidity	Operating: 10% – 85% up to 30 °C. linearly decreasing from 85% at 30 °C to 70% at 40 °C. Storage: 10% – 100% (rainfall will be permitted).
Altitude/Pressure	Operating altitude up to 3095 m (10,152 ft). Atmospheric pressure 520-775 torr
Sound	<65 dBa
Cycle temperature	47 °C – 56 °C (116.6 °F – 132.8 °F)
Cycle time	47 minutes Standard (depends on load and other conditions) 42 minutes Flex 24 minutes Express 60 minutes DUO
Cycles per cassette	5
Connectors	Network: RJ45; Barcode reader: USB. Printer: USB
Data storage	PCMCIA nonstandard compact flash.
Cordset and plug	12 AWG (4 mm <sup>2</sup> ), 3 m (9.84 feet) long, 5 conductors NEMA L21 - 30P (USA and Canada.) Each country is responsible for installing an appropriate plug according to their facility's power requirements. The plug must match the required phase rotation.
RF Generation	Portable and mobile RF communications equipment can affect medical electrical equipment.