

INTRODUCTION TO SERVICING THE STERRAD[®] NX[™] HYDROGEN PEROXIDE STERILIZATION SYSTEM!



Presented by Neil Blagman Product Engineer Replacement Parts Industries, Inc.

Course Overview



This course will provide an overview of the operation of the Sterrad NX, providing attendees with knowledge of how this machine functions.

The presenter will also provide an introduction to the servicing of the Sterrad NX, including planned maintenance, troubleshooting, and information about key parts and assemblies of the machine.

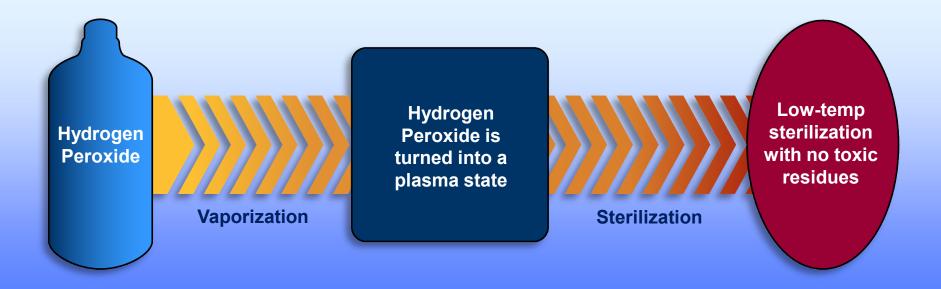


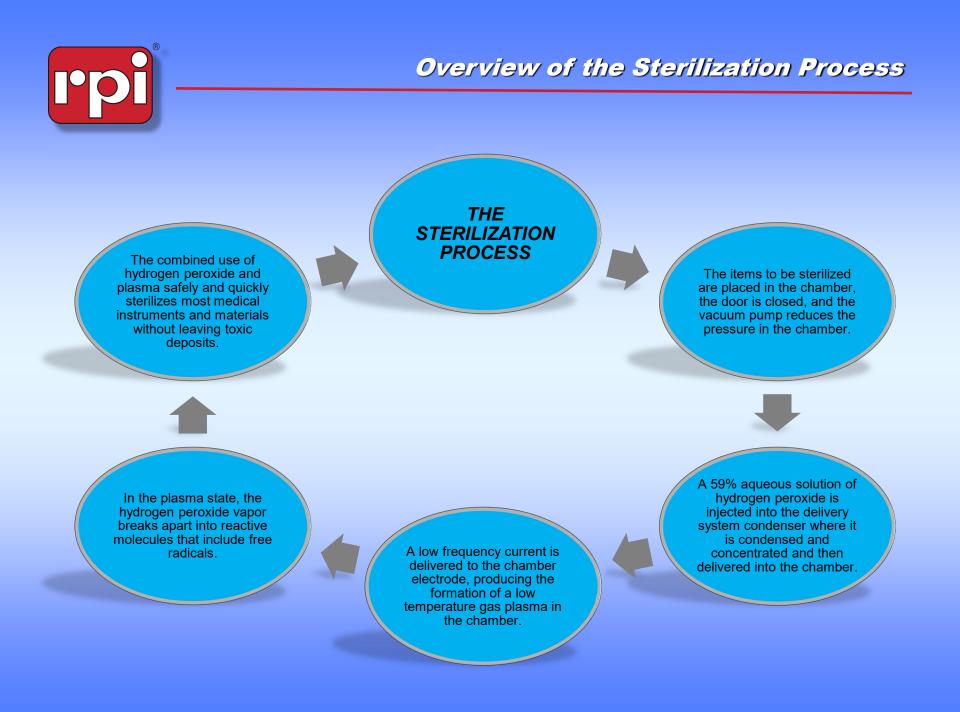


The Sterrad NX sterilizes medical devices by diffusing hydrogen peroxide vapor into a chamber and then electromagnetically exciting the hydrogen peroxide molecules into a low-temperature plasma state.

The combined use of hydrogen peroxide vapor and plasma safely and rapidly sterilizes medical instruments and materials without leaving toxic residues.

All stages of the sterilization cycle operate within a dry environment at a low temperature, so instruments sensitive to heat and moisture are not damaged.

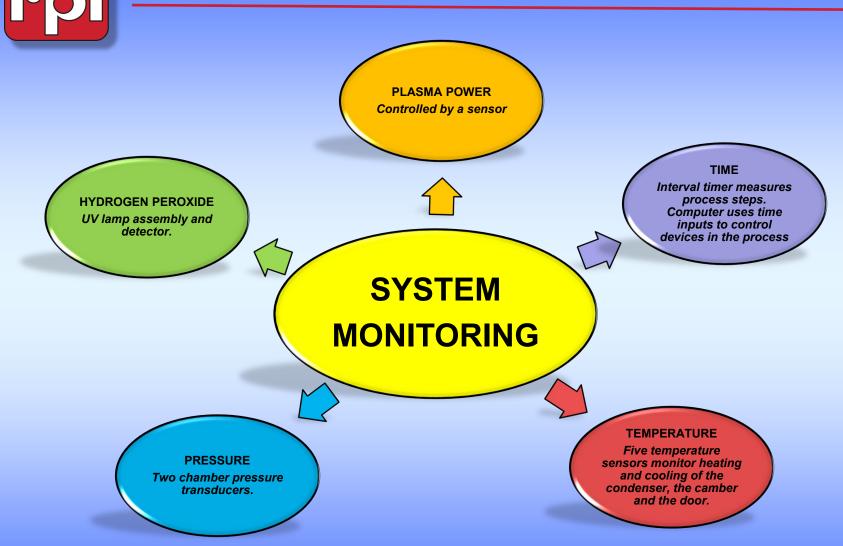


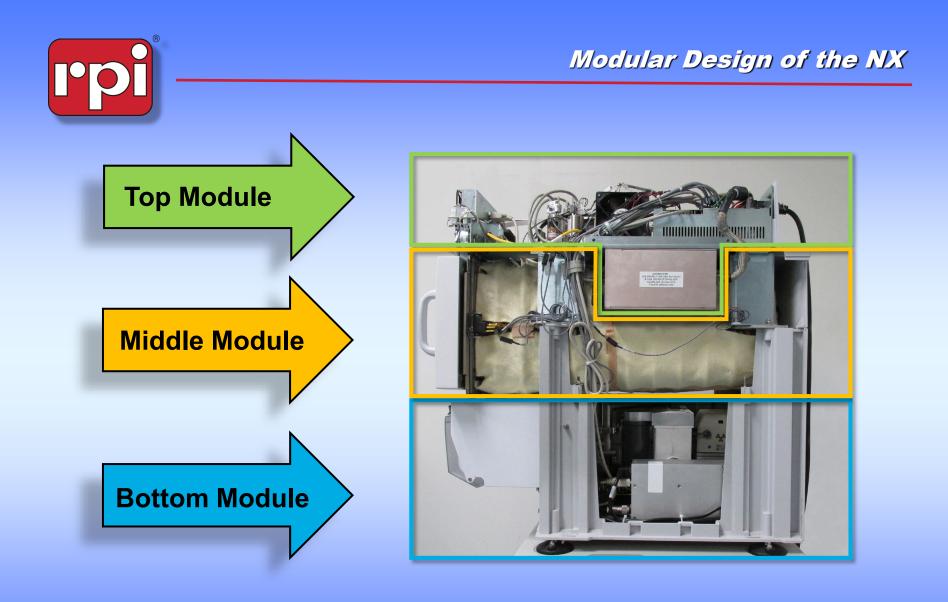


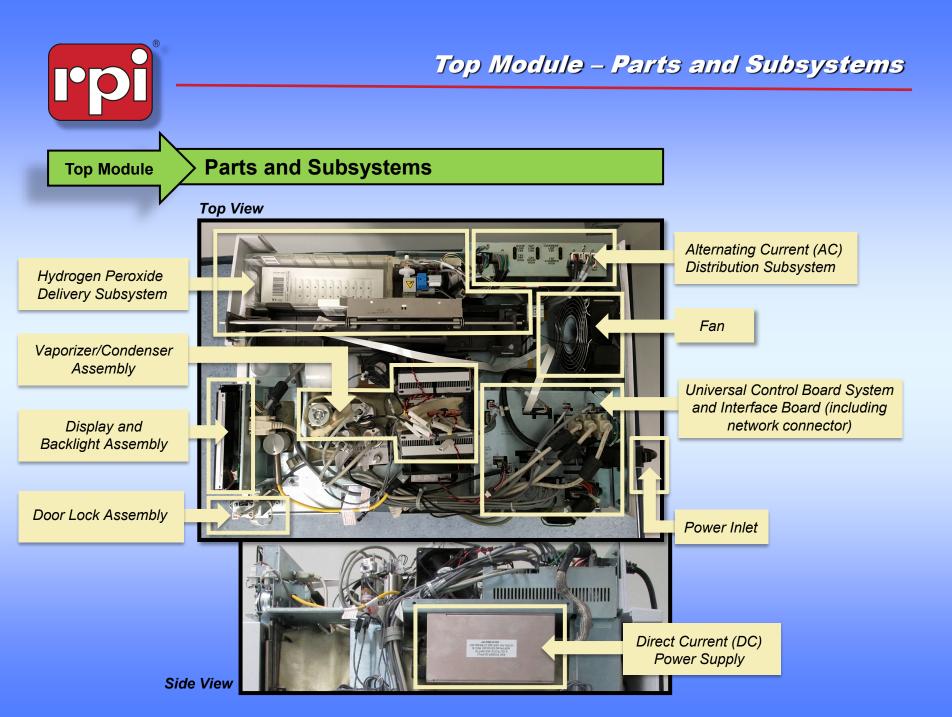


Delivery Step	 Hydrogen peroxide solution is delivered into the vaporizer bowl at atmospheric pressure conditions. Air is removed from the chamber and from the vaporizer/condenser by pulling a vacuum to a controlled pressure in the vaporizer/condenser. At this point, the transfer valve is closed. Water 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 force to remove the water.
Concentration Step	 The flow of water vapor is restricted by an orifice between the condenser and the chamber causing lower chamber pressure. Once the controlled pressure is attained in the condenser, the chamber pressure is reduced even more by closing the orifice with the transition valve.
Transfer Step	• 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.
Diffusion Step	• The diffusion step occurs at atmospheric pressure and is followed by pressure reduction and plasma.
Vent Step	• The chamber returns to atmospheric pressure. This process occurs twice during a complete sterilization cycle.

System Monitoring







Top Module – Hydrogen Peroxide Delivery Subsystem Top Module Hydrogen Peroxide Delivery Subsystem

Hydrogen Peroxide Delivery Assembly

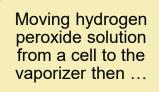


The Hydrogen Peroxide Delivery Assembly moves hydrogen peroxide solution from the Cassette Assembly to the Vaporizer Assembly. Vaporizer Assembly

The delivery process includes accepting a valid cassette from the operator then ...



Positioning the cells in the hydrogen peroxide extractor assembly then ...





Isolating the vaporizer from the atmosphere, and disposing of the used cassette.

Top Module – Vaporization Subsystem

Top Module

Vaporization Subsystem

The vaporizer receives the hydrogen peroxide solution from the delivery system and vaporizes the liquid hydrogen peroxide and water.

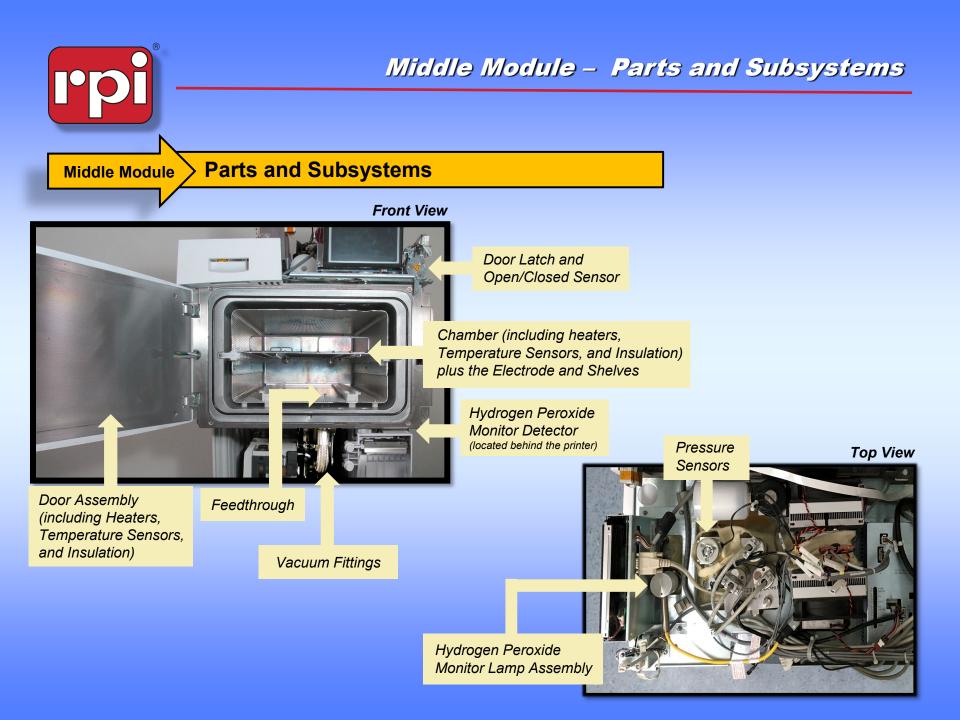
> The condenser condenses the hydrogen peroxide vapor while allowing the water vapor to pass through the chamber.

> > The condenser vaporizes the hydrogen peroxide and delivers the vapor to the chamber.

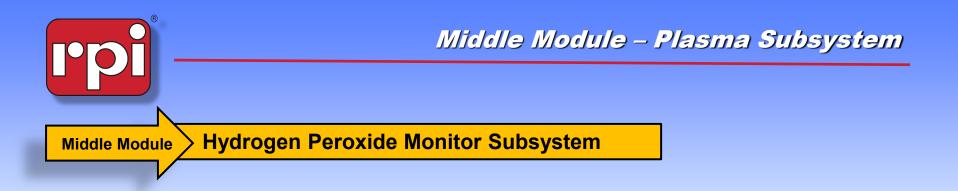
The vaporizer pressure transducer monitors the pressure of the vapor in the vaporizer/condenser housings.

Vaporizer/Condenser Assembly





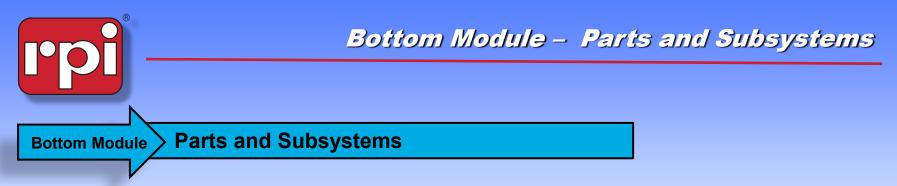
Middle Module – Plasma Subsystem **Plasma Subsystem Middle Module** The Plasma Subsystem consists of the following The plasma subsystem components: generates electrical The LFPS II energy ... An integrated plasma ٠ energy feedthrough The door open/close ٠ sensor functions as a safety switch to Creating a gas plasma in the chamber that reduces residual prevent the LFPS II hydrogen peroxide from the from operating when chamber atmosphere and in the materials of the load. the door is open



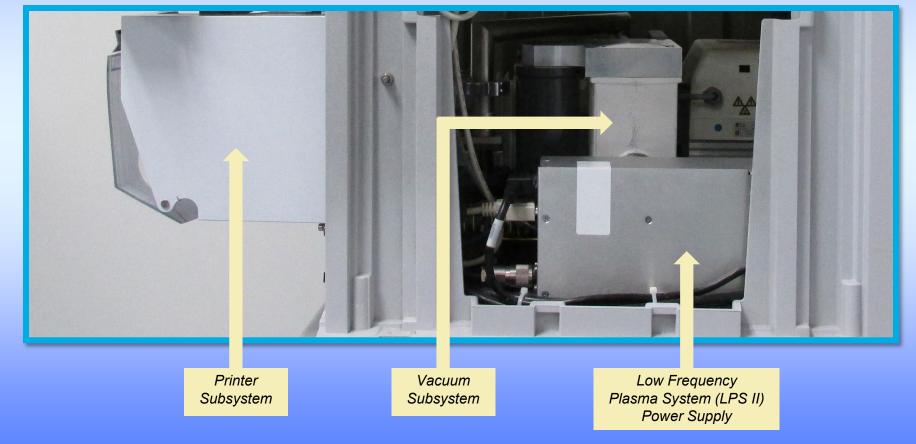
The Hydrogen Peroxide Monitor measures the concentration of hydrogen peroxide vapor in the chamber during the injection and diffusion stages of the sterilization process.

The UV lamp and the lamp manager are located in the top module.

The UV detector assembly is located in the chamber module.



Side View



Bottom Module

Vacuum Subsystems

The vacuum subsystem evacuates the chamber during the vacuum steps of the cycle, controls chamber pressure, and allows filtered air into the chamber during venting. The vacuum subsystem is found in the base module and the top module.

Side View

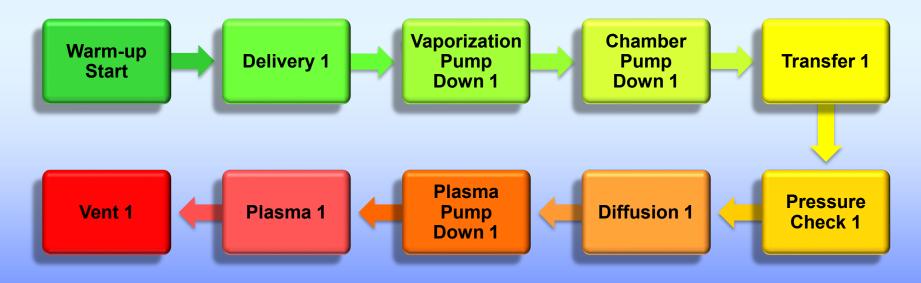






The STERRAD NX Sterilization System process takes 28 to 38 minutes, depending on the cycle, and uses 1.8 ml of 59% hydrogen peroxide. The sterilizer has 2 separate peroxide delivery/plasma stages in the sterilization cycle. The STERRAD NX System concentrates vaporized peroxide at a controlled rate. This process concentrates the 59% hydrogen peroxide to 90% nominal.

The following occurs twice sequentially in a full sterilization cycle:





Warm Up Start

- · Control heaters to achieve desired temperatures.
- Transition valve pulsed open/closed 5 times (cleans opening).

Delivery 1

- · Delivery begins at atmospheric pressure.
- 1.8 ml (nominal) of 59% hydrogen peroxide solution is injected into the vaporizer by piercing a cell.

Vaporization Pump down 1

- Air removal pump down chamber pressure from atmospheric to 140 Torr.
- Transfer Valve (inlet valve) is closed.
- · Water removal.
- Pressure in vaporizer/condenser is reduced to 10 Torr (9.75 10.25) for the advanced cycle or 16.28 Torr (15.86 16.7) for the standard cycle.
- Condenser temperature (43° C advanced, 52° C standard; ±2° C).
- Close transition valve.
- Vacuum control valve is open.



Chamber Pump down 1

- Evacuate chamber, chamber pressure reduced to 300 mtorr, 5 min. max.
- Preparation for transfer.

Transfer 1

- Concentrated hydrogen peroxide enters the chamber. Vacuum valve is closed.
- Condenser is heated to 68° C ($65 72^{\circ}$ C).
- Transfer and transition valves open allowing concentrated vaporized peroxide to enter the chamber.
- Transfer timeout:
 - o 3.6 minutes Standard Cycle (maximum allowable, typical is 3 minutes).
 - o 7 minutes Advanced Cycle.



STERRAD[®] NXTM Sterilization Process

Pressure Check 1

- Chamber pressure is monitored.
- 2.5 18.7 Torr Standard Cycle.
- 3.1 23.7 Torr Advanced Cycle.
- Hydrogen peroxide monitor verifies concentration:
- o 382 mg-s/l Standard Cycle.
- o 795 mg-s/l Advanced Cycle.

Diffusion 1

- Chamber is vented to atmosphere through the HEPA filter and held.
- Venting to atmosphere causes the hydrogen peroxide to compress; driving it into the lumens and hinged areas..

Plasma Pump down 1

- Pressure is reduced from atmosphere to 800 mTorr.
- Pressure is controlled by vacuum control valve.
- Condenser is cooled to set point:
 - \circ Standard Cycle 52° C (47° 57° C).
 - \circ Advanced Cycle 43° C (38° 48° C).



Plasma 1

- Plasma is lit once pressure is reached.
- Plasma must light in 45 seconds.
- Range 600 1500 mTorr (Can peak at 1500 for 30 seconds or less. If it peaks for more than 30 seconds the cycle will cancel.)
- This action enhances decomposition of hydrogen peroxide.
- LFPS Plasma power is 500 Watts ±10%.
- LFPS Frequency is 50 kHz at 25 ohms of impedance.
- Plasma remains on for 4 minutes.

Vent 1

- Plasma is turned off (5 seconds).
- Vent valve opens venting chamber to atmosphere through the HEPA filter.
- Transition valve pulsed open/close 5 times.





WARNING! Hydrogen Peroxide is corrosive to skin, eyes, nose, throat and lungs. Always wear gloves when handling items removed from the sterilizer following a cancelled cycle. If any items appear to be wet concentrated Hydrogen Peroxide may be present. Direct Hydrogen Peroxide contact with skin can cause severe irritation. If Hydrogen Peroxide is inhaled nose, throat and lung irritation may occur – immediately move to fresh air



WARNING! Hydrogen Peroxide is an oxidizer. Avoid allowing Hydrogen Peroxide to contact organic materials including paper, cotton, wood or lubricants. Contact between concentrated Hydrogen Peroxide and organic materials may lead to ignition and fire.



WARNING! Hot Surfaces. Components inside the chamber as well as surrounding the chamber may be hot enough to burn skin. Avoid touching any surface labeled with a hot sticker until to sterilizer has been allowed to cool.



CAUTION! Avoid exposure to ultraviolet light. Ultraviolet light can lead to retinal and skin damage



WARNING! Electric shock hazard. High voltages are present inside the sterilizer case. Turn sterilizer off and unplug before performing any service tasks.



Diagnostic Tests Order Test Name		What is tested
1	Power Supply Test	High- and low-voltage power supplies and sensors.
2	Vacuum Test	Vacuum pump and pressure sensors.
3	Plasma Test	Plasma electrical subsystem. Electrode integrity.
4	Cassette Test	Cassette mechanical subsystem. Barcode reader.
5	Door Test	Electric door lock.
6	H ₂ O ₂ Sensor Test	Ultraviolet lamp and detector.
7	Display Test	Touch screen calibration and function.
8	Printer Test	Printer function.
9	Fan Test	Fan speed and function.
10	Sound Test	Speaker function and volume.

The complete set of tests take approximately 13 ½ minutes to complete. When the tests are complete, the sterilizer creates and stores a diagnostics file and prints a report. Once the report is printed, the Additional Utilities menu is displayed.



VACUUM SYSTEM TIMEOUT/UNABLE TO EVACUATE CHAMBER

Only dry items should be loaded into the sterilization chamber. This failure occurs most commonly when there is excessive moisture on the load. If this cancellation occurs, please take the following steps:

- 1. If a cycle cancels and the load appears wet, hydrogen peroxide may be present. Wear chemical-resistant latex, PVC (Vinyl), or nitrile gloves while removing the items from the chamber, and while wiping off the items with a damp cloth. Discard contaminated cloth according to your facility's procedures.
- 2. Once everything is removed from the chamber, run an empty STANDARD Cycle.
- 3. If the cycle completes successfully, this confirms that the cancellation was due to excessive moisture on the load, or that the load did not meet the criteria outlined in the System User's Manual.

H₂O₂ AREA TOO LOW/H₂O₂ DELIVERY FAILURE

This error generally occurs when the cassette is inserted improperly or when the load shifts during the cycle, blocking the path of the H_2O_2 Monitor. Please follow these steps to resolve this issue::

STEP 1

- Check to be sure the load did not shift to block the lens. Pouches, in particular, can shift from pressure changes.
- Ensure the shelves are pushed all the way in.
- Clean any debris off of the H₂O₂ Detector Lens.
- Check the H₂O₂ Detector Lens for scratches or other imperfections.
- If a failure is not indicated through the preceding, continue to Step 2. Otherwise, continue processing.



H₂O₂ AREA TOO LOW/H₂O₂ DELIVERY FAILURE

STEP 2

- Dispose of the cassette in the system (as it was potentially inserted improperly).
- Firmly insert a new cassette. Note: When the cassette is fully inserted you will feel it stop.
- Using appropriate Personal Protective Equipment, remove the load.
- Run an empty cycle and continue processing.



Planned Maintenance (PM) consists of replacing sterilizer components that are subject to wear or degradation from use.

Planned Maintenance for the STERRAD® NX[™] Sterilizer is normally performed after 6 months and 12 months of operation.





RPI offers PM Kits to fit STERRAD® NX™

Biannual PM Kits

- PM-1 Kit (Adixen/Pfeiffer Pump) (RPI Part #SDK004)
- PM-1 Kit (Leybold Pump) (RPI Part #SDK075)

Annual PM Kits

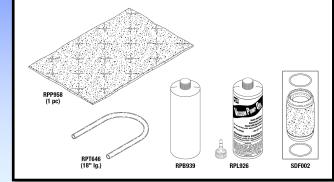
- PM-2 Kit (Adixen/Pfeiffer Pump) (RPI Part #SDK003)
- PM-2 Kit (Leybold Pump) (RPI Part #SDK076)

Note: Shown to the right are the PM Kits to fit Adixen/Pfeiffer Pumps which require (1) bottle of Vacuum Pump Oil. The PM Kits to fit Leybold Pumps include (2) bottles of Vacuum Pump Oil.

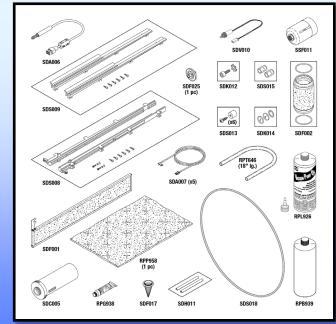
Biannual PM Kit

Annual

PM Kit



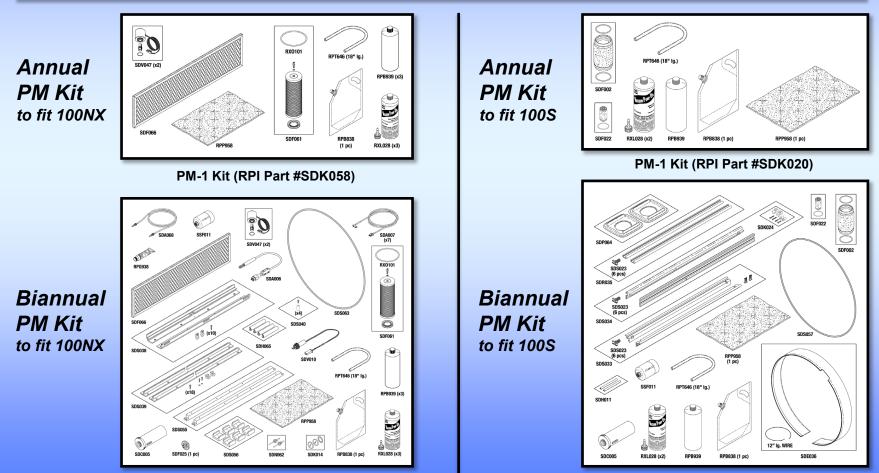
PM-1 Kit (Adixen/Pfeiffer Pump) (RPI Part #SDK004)



PM-2 Kit (Adixen/Pfeiffer Pump) (RPI Part #SDK003)



RPI also offers PM Kits to fit STERRAD® 100NX™ and **100S™**



PM-2 Kit (RPI Part #SDK059)

PM-2 Kit (RPI Part #SDK060)



Planned Maintenance (PM) items to be checked and/or replaced

Inlet Filter	Installed in the delivery system assembly, this filter keeps dust and bacteria from entering the condenser/vaporizer assembly along with the peroxide delivery.	
Air Compressor Seal Tubes	Used to seal around the stems of the air pump, which is part of the delivery system assembly. These gaskets ensure that the air pump only handles filtered air.	
Oil Mist Filter	Installed in the vacuum pump assembly, this filter collects oil out of the air stream exiting the vacuum pump and prevents premature fouling of the catalytic converter with vacuum oil. And while you've got the vacuum pump fittings opened remember to replace the conical screen filter found in the vacuum pump return line.	
Vacuum Pump Oil	Use fill tube and spout for process, catch spills using absorbent pad, dispose of old oil into empty bottle (hazmat) and be aware not all of oil needed for fill.	



Planned Maintenance (PM) items to be checked and/or replaced - (continued)

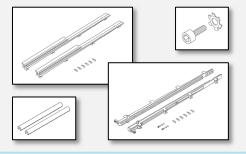
Catalytic Converter	Installed in a confined space next to the vacuum pump be very sure that you do not cross thread this filter into its mounting block – cross threading it will damage the plastic threads and could make the part unusable.	
Vent Valve HEPA Filter	screwed onto a threaded stem at the vent valve assembly. Be sure the Teflon tape on the stem is fresh and that the filter does not cross thread when it is screwed onto the stem.	
Door Seal O-ring	Used a plastic pick or non-marring tool to remove the old door seal from the groove in the chamber. Clean the groove to remove any old vacuum grease. Lightly coat the new door seal with vacuum grease and press the seal into the groove until seated – avoid stretching the door seal when installing it.	



Planned Maintenance (PM) items to be checked and/or replaced - (continued)

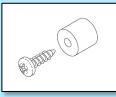
Chamber Rail

To ease the disassembly and reassembly process remove the entire electrode assembly and rails as a unit. To remove the electrode assembly, remove the feed through screw and the two screws at the front ends of the rails.



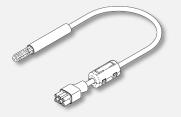
UV Lamp Assembly

Do not remove this bulb from its housing while powered as it is continually on and the UV light from the bulb can damage the retina of your eyes. Do not handle this bulb with ungloved fingers as the oils on your skin can lead to premature blackening and lower light output. Be sure the new bulb is fully seated in the lamp housing and that the line on the bulb is alligned with the line on the lamp holder.



Lamp Housing and Optical Window O-ring

The lamp needs to be removed before the lamp housing can be unscrewed from the chamber. The lamp housing holds one optical window and an O-ring. Lightly apply vacuum grease to the O-ring before installing it.





Planned Maintenance (PM) items to be checked and/or replaced - (continued)

Detector Optical Window	You may need to remove the printer assembly before you can get enough access to the optical detector assembly to completely unscrew it from its chamber fitting.	and the second s
Thermal Print Head	Clean the Thermal Print Head. Tip: alcohol on a cotton swab works well.	
Five Thermistors	One located on the chamber requires removal of the thermal insulation pad which is held in place with Velcro. Two more are located on the door and require removal of the door cover. The last two are located on the vaporizer/condenser assembly. All thermistor replacements should include removal of any existing thermal compound with an alcohol swab and a liberal amount of new thermal compound especially under the thermal sensor.	E ON MARK
Air Filter (in base of machine)	Held in place with a Nylock locking nut, this filter is hard to locate on the underside of the NX and is removed from the front of the machine.	

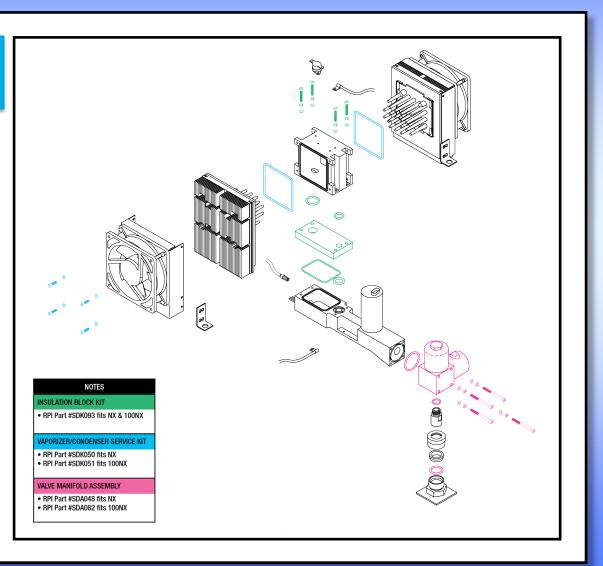


Vaporization/Condenser Assembly

Critical to the function of all Sterrad peroxide sterilizers is the vaporization and transfer of concentrated hydrogen peroxide. This is handled by the Vaporizer/Condenser Assembly.

The maintenance of the Vaporizer/Condenser Assembly in the NX or 100NX requires replacement of the highlighted parts in the exploded view to the right including:

- Insulation Block
- Vaporizer/Condenser
- Valve Manifold Assembly





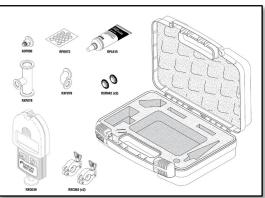
RPI Test Equipment and Tools

RPI is your source for repair parts and PM Kits as well as for test equipment and valuable tools.

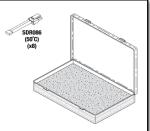
TEST EQUIPMENT

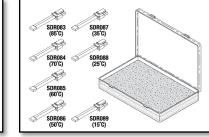
RPI's Vacuum Test Gage Kit

(RPI Part #SDK112) Used to set the vacuum transducers on the NX, 100NX and 100S. Kit contains all the necessary fittings.



RPI's **Calibration Resistor Kits** For use on the NX (RPI Part #SDK069), and the Calibration Resistor Kit for the 100NX (RPI Part #SDK070).





VALUABLE TOOLS

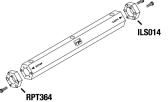
Soft Jaw Pliers (RPI Part# RXT005) For working on Ultra-Torr® fittings



Spanner Wrench (RPI Part #RXT020) For use on the Vent Valves



Spanner Wrench (RPI Part #RPT501) For use on the Transition and Inlet Valves





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 - "Quick Search" feature to help identify parts needed
 - "Create a Parts Listing" feature to identify all parts available for a specific equipment model
 - Troubleshooting Guides, Exploded Views and Installation Instructions
 - Tech Talk and Service Tip Articles
 - At-a-glance Cross References and Quick Reference Guides
- RPI Planned Maintenance Kits and Posters
 - Kits specifically for planned maintenance of a variety of tabletop and bulk sterilizers
 - Informative posters featuring planned maintenance service tips and technical assistance articles

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