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

Presented by
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Replacement Parts Industries, Inc.
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.
Overview of the Sterilization Process

The items to be sterilized are placed in the chamber, the door is closed, and the vacuum pump reduces the pressure in the chamber.

A 59% aqueous solution of hydrogen peroxide is injected into the delivery system condenser where it is condensed and concentrated and then delivered into the chamber.

A low frequency current is delivered to the chamber electrode, producing the formation of a low temperature gas plasma in the chamber.

In the plasma state, the hydrogen peroxide vapor breaks apart into reactive molecules that include free radicals.

The combined use of hydrogen peroxide and plasma safely and quickly sterilizes most medical instruments and materials without leaving toxic deposits.
Hydrogen Peroxide Concentration and Delivery

**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

- **Plasma Power**: Controlled by a sensor.
- **Time**: Interval timer measures process steps. Computer uses time inputs to control devices in the process.
- **Temperature**: Five temperature sensors monitor heating and cooling of the condenser, the camber and the door.
- **Pressure**: Two chamber pressure transducers.
- **Hydrogen Peroxide**: UV lamp assembly and detector.
Modular Design of the NX

Top Module

Middle Module

Bottom Module
Top Module – Parts and Subsystems

- **Top Module Parts and Subsystems**

  **Hydrogen Peroxide Delivery Subsystem**
  - **Vaporizer/Condenser Assembly**
  - **Display and Backlight Assembly**
  - **Door Lock Assembly**

  **Alternating Current (AC) Distribution Subsystem**
  - **Fan**
  - **Universal Control Board System and Interface Board (including network connector)**
  - **Power Inlet**

  **Direct Current (DC) Power Supply**
The delivery process includes accepting a valid cassette from the operator then positioning the cells in the hydrogen peroxide extractor assembly then moving hydrogen peroxide solution from a cell to the vaporizer then isolating the vaporizer from the atmosphere, and disposing of the used cassette.
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.
Middle Module – Parts and Subsystems

Front View

- Door Assembly (including Heaters, Temperature Sensors, and Insulation)
- Feedthrough
- Vacuum Fittings
- Door Latch and Open/Closed Sensor
- Chamber (including heaters, Temperature Sensors, and Insulation) plus the Electrode and Shelves
- Hydrogen Peroxide Monitor Detector (located behind the printer)
- Pressure Sensors
- Hydrogen Peroxide Monitor Lamp Assembly

Top View
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 following components:

- The LFPS II
- 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
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.
Bottom Module – Parts and Subsystems

Bottom Module → Parts and Subsystems

- Vacuum Subsystem
- Printer Subsystem
- Low Frequency Plasma System (LPS II) Power Supply

Side View
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.
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 (43º C advanced, 52º C standard; ±2º 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° C).
- Transfer and transition valves open allowing concentrated vaporized peroxide to enter the chamber.
- Transfer timeout:
  - 3.6 minutes Standard Cycle (maximum allowable, typical is 3 minutes).
  - 7 minutes Advanced Cycle.
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:
  - 382 mg-s/l Standard Cycle.
  - 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:
  - Standard Cycle – 52º C (47º - 57º C).
  - Advanced Cycle – 43º C (38º - 48º 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 the 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

<table>
<thead>
<tr>
<th>Order</th>
<th>Test Name</th>
<th>What is tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Power Supply Test</td>
<td>High- and low-voltage power supplies and sensors.</td>
</tr>
<tr>
<td>2</td>
<td>Vacuum Test</td>
<td>Vacuum pump and pressure sensors.</td>
</tr>
<tr>
<td>3</td>
<td>Plasma Test</td>
<td>Plasma electrical subsystem. Electrode integrity.</td>
</tr>
<tr>
<td>4</td>
<td>Cassette Test</td>
<td>Cassette mechanical subsystem. Barcode reader.</td>
</tr>
<tr>
<td>5</td>
<td>Door Test</td>
<td>Electric door lock.</td>
</tr>
<tr>
<td>6</td>
<td>H₂O₂ Sensor Test</td>
<td>Ultraviolet lamp and detector.</td>
</tr>
<tr>
<td>7</td>
<td>Display Test</td>
<td>Touch screen calibration and function.</td>
</tr>
<tr>
<td>8</td>
<td>Printer Test</td>
<td>Printer function.</td>
</tr>
<tr>
<td>9</td>
<td>Fan Test</td>
<td>Fan speed and function.</td>
</tr>
<tr>
<td>10</td>
<td>Sound Test</td>
<td>Speaker function and volume.</td>
</tr>
</tbody>
</table>

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.
This error generally occurs when the cassette is inserted improperly or when the load shifts during the cycle, blocking the path of the H₂O₂ 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.
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.
RPI also offers PM Kits to fit STERRAD® 100NX™ and 100S™

**Annual PM Kit**
- to fit 100NX
  - **PM-1 Kit** (RPI Part #SDK058)
  - **PM-2 Kit** (RPI Part #SDK059)

**Biannual PM Kit**
- to fit 100NX
  - **PM-1 Kit** (RPI Part #SDK020)
  - **PM-2 Kit** (RPI Part #SDK058)

**Annual PM Kit**
- to fit 100S
  - **PM-1 Kit** (RPI Part #SDK060)

**Biannual PM Kit**
- to fit 100S
  - **PM-2 Kit** (RPI Part #SDK061)
### Planned Maintenance (PM) items to be checked and/or replaced

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inlet Filter</strong></td>
<td>Installed in the delivery system assembly, this filter keeps dust and bacteria from entering the condenser/vaporizer assembly along with the peroxide delivery.</td>
</tr>
<tr>
<td><strong>Air Compressor Seal Tubes</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Oil Mist Filter</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Vacuum Pump Oil</strong></td>
<td>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.</td>
</tr>
<tr>
<td>Planned Maintenance (PM) items to be checked and/or replaced – (continued)</td>
<td></td>
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<tr>
<td>---------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Catalytic Converter</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Vent Valve HEPA Filter</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Door Seal O-ring</strong></td>
<td>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.</td>
</tr>
<tr>
<td>Item</td>
<td>Maintenance Details</td>
</tr>
<tr>
<td>----------------------</td>
<td>--------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Chamber Rail</td>
<td>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.</td>
</tr>
<tr>
<td>UV Lamp Assembly</td>
<td>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 aligned with the line on the lamp holder.</td>
</tr>
<tr>
<td>Lamp Housing and Optical Window O-ring</td>
<td>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.</td>
</tr>
</tbody>
</table>
### Planned Maintenance (PM) items to be checked and/or replaced – (continued)

<table>
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<tr>
<td><strong>Detector Optical Window</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Thermal Print Head</strong></td>
<td>Clean the Thermal Print Head. Tip: alcohol on a cotton swab works well.</td>
</tr>
<tr>
<td><strong>Five Thermistors</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Air Filter</strong> <em>(in base of machine)</em></td>
<td>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.</td>
</tr>
</tbody>
</table>
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 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
Replacement Parts Industries, Inc. (RPI) has been the leader in replacement parts since 1972.

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  - Available via Phone, Fax, and Email
    (Monday – Friday, 8:00 am – 4:30 pm, Pacific Time)

• Mobile Site – Now Available!
  - Go to www.rpiparts.com/mobile.html

• RPI Website – Technical Assistance Center with new “eLibrary” and more!
  - “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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