Release additional Maintenance Procedures to minimize H_2O_2 Adjustment Failure for STERRAD® 100NX Systems.

TB-118784 Revision A

May 24, 2022

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Technical Bulletin Category:

- ☐ Mandatory
- ☒ Mandatory, Next Call
- ☐ Mandatory, Next Planned Maintenance
- ☐ Mandatory, Next Corrective Maintenance
- ☐ Informational Only
- ☐ As Required
- ☐ Scope Database
- ☐ Field Action: QRB/CAPA#
- ☒ QRB/CAPA# (Non-Field Action) 010032

Activity Generation	☐ FSE	☐ System Generated	☒ N/A
Terminal Sterilization	☐ NX Legacy (10033) ☐ NX ALLClear (10033)	☒ 100NX Legacy (10104) ☒ 100NX ALLClear (10104)	☐ 100S (10101)
High Level Disinfection	☐ EvoTech (50004)	☐ Endoclens (27000)	☐ AEROFLEX™ (28000)
Ecosystem	☐ ACCESS (53001)	☐ Velocity (43220)	

Part Numbers: **N/A**
Serial Number Breakpoint: **N/A**
CO Releasing TB: **CO-P-0002252**
This TB Replaces: **N/A**
Other CO Reference: **N/A**

Distribution Group(s):

☒ Asia Pacific	☒ Canada	☒ EMEA	☒ Latin America
☒ FSEs	☐ EVOTECH Affiliates	☐ AEROFLEX™ Affiliates	☐ ENDOCLENS Affiliates
☒ Biomed	☒ 3rd Party	☐ Other Distribution: **N/A**	

Important: U.S. based Field Service Engineers (FSEs) must complete online training prior to performing the actions described in this bulletin.

FSEs and Affiliates that are based outside the U.S. should complete their region's training guidelines for technical bulletins prior to performing the actions described in this bulletin.

Part Disposition ☐ Use-As-Is ☐ Scrap ☐ Rework ☒ N/A

Scope

This Technical Bulletin releases additional maintenance procedures for STERRAD®100NX Legacy and ALLClear Systems to perform during PM intervals and CM calls to minimize the H_2O_2 Adjustment failure in the field per CAPA-010032 recommendations.

- Clean and remove debris on the UV Lamp lens and O-ring
- Clean and remove contaminant buildup on the inner walls of the adapter tube for the H_2O_2 Monitor Lamp assembly
- Verify the orientation of the H_2O_2 Monitor Lamp assembly parallels with the chamber door to maximize the H_2O_2 Monitor voltage.

Tools Required

N/A

Instructions

Caution: Ensure to wear safety glasses and Nitrile gloves before performing the procedures below. Be careful handling the H_2O_2 Monitor assembly to prevent mercury exposure from a broken UV lamp.

Cleaning the UV Lamp lens, O-ring and Adapter Tube

1. Power off the system.
2. Remove the H_2O_2 Monitor Lamp assembly from the Chamber Ultra Torr fitting.
3. Unscrew the adapter tube and remove the O-ring and UV Lamp lens.
4. Clean the lens and O-ring with isopropyl alcohol and lint-free cloth. If debris is hard to remove from the lens surface, use deionized water and a non-abrasive scrub pad to remove the debris or replace the lens as needed.
5. Remove the orange contaminant buildup on the inner walls of the adapter tube using deionized water and a non-abrasive scrub pad.

Verify the H_2O_2 Monitor Lamp assembly orientation

1. Close the chamber door.
2. Perform an H_2O_2 100mV reset.
3. Power off the system.
4. Rotate the UV lamp housing so that the UV lamp is parallel to the door as shown in figure 1.

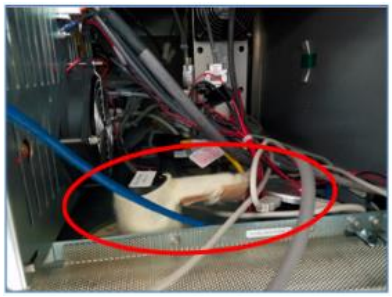

Figure 1. UV Lamp Housing Adjusted Position

5. Power on the system.
6. Wait until the system is warmed up and H_2O_2 Calibration is complete.
7. Verify the H_2O_2 Monitor voltage improves after adjustment.