

August 1, 2022

Medical Device-Field Notification

STERRAD® 100NX Sterilization System
(Parts: 10104, 10104-002, 10104-003, 10104-004)

STERRAD® 100NX Sterilization System with ALLClear® Technology
(Parts: 10104-005, 10104-006, 10104-007, 10104-008)

Advanced Sterilization Products, Inc. (ASP) has determined certain STERRAD 100NX Sterilization Systems may exceed the CISPR 11 Group 1, Class A radiated emissions limits as set forth in international electrotechnical standard, IEC 60601-1-2: *Medical Electrical Equipment – Electromagnetic Compatibility – Requirements and Tests*. Conformance to this international standard is referenced in the STERRAD 100NX Sterilization Systems product labeling. This does not pose a risk to adjacent medical devices or electromechanical equipment and does not pose a safety risk to users including individuals with implantable electronic devices. STERRAD 100NX Sterilization Systems may continue to be used per the product labeling.

During routine internal testing, one STERRAD 100NX Sterilization System exceeded the radiated emissions limit by approximately five (5) decibel-microvolts per meter (dBµV/m) in the 120 to 210 megahertz (MHz) range. Medical device emissions and immunity limits set by the international standard (IEC 60601-1-2) maintain safety margins. The tested STERRAD 100NX Sterilization System was five thousand (5000) times lower than the immunity limits, which, demonstrates a negligible radiated electrical field and will have no impact to other medical devices in normal operating range and no impact to users including individuals with implantable electronic devices.

ASP advises users to continue to take precautions normally exercised for adjacency with other electromechanical equipment and electronic medical devices. Refer to the current user guide *Chapter 2 Safety Information-Guidance and Declaration - Electromagnetic Emissions*.

ASP is currently implementing a correction and will service impacted STERRAD 100NX Sterilization Systems during next service calls starting in October 2022. Users can still operate STERRAD 100NX Sterilization Systems pending the correction.

WHY ARE YOU BEING CONTACTED

ASP records indicate your facility has a STERRAD 100NX Sterilization System that may be impacted by this issue.

CUSTOMER ACTIONS REQUIRED

- Maintain a copy of this notification at your facility and ensure Healthcare Workers have read and understand this notification.
- Complete and return the Customer Reply Form within five (5) business days of receipt of this notification.

ASP is committed to providing safe and effective products around the world. For questions regarding this notification, please contact your ASP representative.

Sincerely,



Chanda Owens
ASP Vice President
Worldwide Quality & Regulatory Compliance