

VOLUNTARY DEVICE FIELD CORRECTION

July 25, 2018

ATTN: MATERIALS MANAGEMENT OR STERILE PROCESSING DEPARTMENT

RE: V-PRO 1, V-PRO 1 Plus, and V-PRO maX Low Temperature Sterilization Systems

Dear Valued Customer:

STERIS Corporation is voluntarily implementing a field correction to update the software in all V-PRO 1, V-PRO 1 Plus, and V-PRO maX Low Temperature Sterilization Systems distributed between October 31, 2007 and June 27, 2018.

Description of the product – The V-PRO 1, V-PRO 1 Plus, and V-PRO maX Low Temperature Sterilization Systems, using VAPROX HC Sterilant, are intended for use in the terminal sterilization of properly prepared (cleaned, rinsed and dried) metal and nonmetal medical devices in healthcare facilities. The sterilization cycles operate at low pressure and temperature, suitable for processing medical devices sensitive to heat and moisture.

Description of the problem – STERIS has identified that in the unlikely scenario where a punctured cup of VAPROX HC Sterilant expires while the V-PRO unit (1, 1 Plus, or maX) is powered down, upon power-up the V-PRO unit will not detect the expired cup of sterilant; allowing for subsequent cycles to be run. STERIS has not received any reports of adverse events related to the issue described above.

STERIS's VAPROX HC Sterilant microbial efficacy studies support a safety margin for use of the product for three (3) days after the indicated in-use expiry date. If users identify that instruments were released following processing with expired sterilant, the facility's protocol for addressing a sterilization failure should be followed.

STERIS Action – The system software for V-PRO 1, V-PRO 1 Plus, and V-PRO maX will be updated to ensure the VAPROX HC Sterilant expiration date is detected regardless of whether the unit is powered on or off. STERIS Service Technicians will contact all affected Customers and update the system software in the affected V-PRO Sterilization Systems.

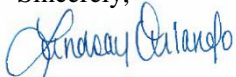
User Action – In the interim of the software update, as is normal practice, V-PRO 1, V-PRO 1 Plus, and V-PRO maX operators should place the unit into "Standby" mode when not in use in lieu of fully powering down the unit. As is stated in the Operator Manual, the unit should only be shut down during unit service activities as required:

Control Power Disconnect Switch — Located behind Operating End (OE) lower access door. This switch is used to disconnect power to Sterilization Unit. Under normal operation, this switch remains in ON position at all times and is only accessed during sterilization unit servicing. This switch is designed to enable lock-out for maintenance purposes.

In addition, users should continue to review their cycle printouts upon completion of each cycle to verify the VAPROX Sterilant was not expired.

We apologize for any inconvenience this matter may cause, and as always, STERIS Corporation is dedicated to supporting our products and valued Customers. If you have questions regarding this matter, please contact STERIS Customer Service at 1-800-548-4873, or your local STERIS Representative.

Sincerely,



Lindsay Orlando
Lead Quality & Regulatory Compliance Specialist
STERIS Corporation