

VOLUNTARY FIELD CORRECTION NOTICE

May 30, 2016

ATTN: LEGAL, RISK MANAGEMENT AND PATIENT SAFETY 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 of all V-PRO® 1, V-PRO® 1 Plus, and V-PRO® maX Low Temperature Sterilization Systems distributed between January 6, 2014 and May 3, 2016.

Description of the product – The V-PRO® 1, V-PRO® 1 Plus, and V-PRO® maX (V-PRO family) Low Temperature Sterilization Systems are intended for use in the terminal sterilization of properly prepared (thoroughly cleaned, rinsed, and dried) reusable 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 V-PRO® 1, V-PRO® 1 Plus, and V-PRO® maX Sterilizers manufactured after January 1, 2014 may not display the correct date as of February 29, 2016. While the V-PRO units display an incorrect date, the sterilizer functions and cycle operations continue to operate properly. The safety and effectiveness of the V-PRO family sterilizers is not impacted by the incorrect system date.

Users of the affected V-PRO family sterilizers may manually change the system date of their sterilizer using the instructions found in the unit's corresponding operator manual. If users do not manually change the system date of the V-PRO unit, the unit's display and cycle printout will contain an incorrect date.

STERIS Action – STERIS Service Technicians will upgrade each V-PRO® 1, V-PRO® 1 Plus, and V-PRO® maX Low Temperature Sterilization System distributed between January 6, 2014 and May 3, 2016 with updated software which corrects the system date error.

We apologize for any inconvenience this matter may cause you, and as always, STERIS Corporation is dedicated to supporting our products and valued Customers. If you have questions regarding this matter, please contact Sarah Lazzara, Marketing Director, at (440) 392-7375, STERIS Customer Service at 1-800-548-4873, or your local STERIS Representative.

Sincerely,



Kathryn Cadorette
Director, Quality & Regulatory Compliance
STERIS Corporation