

URGENT DEVICE FIELD CORRECTION

October 24, 2017

ATTN: MATERIALS MANAGEMENT OR STERILE PROCESSING DEPARTMENT

RE: V-PRO® 60 Low Temperature Sterilization System

Dear Valued Customer:

STERIS Corporation is voluntarily implementing a field correction to update the software in all V-PRO 60 Low Temperature Sterilization Systems distributed between July 31, 2014, and August 17, 2017.

Description of the product – The V-PRO 60 Low Temperature Sterilization System (V-PRO 60) with VAPROX® HC Sterilant (VAPROX Sterilant) is a vaporized hydrogen peroxide Sterilizer intended for use in the terminal Sterilization of properly cleaned, rinsed and dried reusable metal and nonmetal medical devices used in Healthcare Facilities.

Description of the problem – STERIS has become aware that the V-PRO 60 software verifies expiration date of the VAPROX Sterilant upon completion of the sterilization cycle rather than prior to cycle initiation. Verification of the VAPROX expiration date at the end of the sterilization cycle will allow for the completion of one cycle with expired VAPROX Sterilant. STERIS has not received any reports of adverse events related to the issue described above.

Our VAPROX Sterilant microbial efficacy studies support a safety margin for use of the product for three (3) days after the indicated expiry date. In addition, the V-PRO 60 cycle printout indicates the expiration date of the VAPROX Sterilant upon the completion of each cycle. Instruments processed in a cycle with VAPROX Sterilant more than three days beyond its expiry date are not considered properly sterilized and should be reprocessed with a new cup of VAPROX Sterilant before use. If users identify that instruments were released following processing with expired sterilant, follow the facility's protocol for addressing a sterilization failure.

STERIS Action – The V-PRO 60 system software has been updated to ensure the VAPROX Sterilant expiration date is verified prior to the initiation of each sterilization cycle. STERIS Service Technicians will be contacting your facility to update your V-PRO 60 Sterilizer(s) with the revised system software.

User Action – Users should continue to review their V-PRO 60 cycle printouts upon completion of each cycle to verify the VAPROX Sterilant was not expired. The VAPROX Sterilant expiration date is identified near the top of each cycle printout following all sterilization cycles as notated in the following illustration:

```
=====
===== STERIS =====
=====
===== L U M E N =====
=====
CYCLE START:  10:28:24A
              03/24/15
CYCLE NUMBER: 580
STERILIZER:   8
SERIAL NO:   0321214-01
VHP LOT NO:  HC2884W3
VHP EXP:     04/06/15
OPERATOR:
LOAD TO:
```

← Sterilant Expiration Date

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 Sarah Lazzara, Marketing Director, at (440) 392-7375, STERIS Customer Service at 1-800-548-4873, or your local STERIS Representative.

URGENT DEVICE FIELD CORRECTION

October 24, 2017

ATTN: MATERIALS MANAGEMENT OR STERILE PROCESSING DEPARTMENT

RE: V-PRO® 60 Low Temperature Sterilization System

Dear Valued STERIS Distributor:

STERIS Corporation is voluntarily implementing a field correction to update the software in all V-PRO 60 Low Temperature Sterilization Systems distributed between July 31, 2014, and August 17, 2017.

Description of the product – The V-PRO 60 Low Temperature Sterilization System (V-PRO 60) with VAPROX® HC Sterilant (VAPROX Sterilant) is a vaporized hydrogen peroxide Sterilizer intended for use in the terminal Sterilization of properly cleaned, rinsed and dried reusable metal and nonmetal medical devices used in Healthcare Facilities.

Description of the problem – STERIS has become aware that the V-PRO 60 software verifies expiration date of the VAPROX Sterilant upon completion of the sterilization cycle rather than prior to cycle initiation. Verification of the VAPROX expiration date at the end of the sterilization cycle will allow for the completion of one cycle with expired VAPROX Sterilant. STERIS has not received any reports of adverse events related to the issue described above.

Our VAPROX Sterilant microbial efficacy studies support a safety margin for use of the product for three (3) days after the indicated in-use expiry date. In addition, the V-PRO 60 cycle printout indicates the expiration date of the VAPROX Sterilant upon the completion of each cycle. Instruments processed in a cycle with VAPROX Sterilant more than three days beyond its expiry date are not considered properly sterilized and should be reprocessed with a new cup of VAPROX Sterilant before use. If users identify that instruments were released following processing with expired sterilant, follow the facility's protocol for addressing a sterilization failure.

STERIS Action – The V-PRO 60 system software has been updated to eliminate the potential of initiating a sterilization cycle past the VAPROX HC Sterilant cup's expiration date. STERIS will provide you with the software, and service instructions required to upgrade each V-PRO 60 Low Temperature Sterilization System.

User Action – If you have further distributed these products, please identify your Customers, notify them of this field correction and perform the upgrade of the system software on each affected unit. Users should continue to review their V-PRO 60 cycle printouts upon completion of each cycle to verify the VAPROX Sterilant was not expired. The VAPROX Sterilant expiration date is identified near the top of each cycle printout following all sterilization cycles as notated in the following illustration:

===== STERIS =====	
===== L U M E N =====	
CYCLE START:	10:28:24A
	03/24/15
CYCLE NUMBER:	580
STERILIZER:	8
SERIAL NO:	0321214-01
VHP LOT NO:	HC2884W3
VHP EXP:	04/06/15
OPERATOR:	
LOAD TR:	

← Sterilant Expiration Date

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 your local STERIS Representative.

Sincerely,



STERIS Corporation