

Low Temperature Sterilization Systems



V-PRO™ Series

WELCOME!

Mongolia
14_15/09/2016
Anno von Lenthe


We Make a Difference




Low Temperature Sterilization

EO	Sterilization
FA	Sterilization
H2O2	Sterilization

Low-temperature sterilization processes
Pros and cons as reported over two decades in *Central Service*®
M. Borneff-Lipp¹, D. Worlitzsch², M. Chwolla³, M. Dürr⁴
Central Service 4/2014



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Vaporized Hydrogen Peroxide

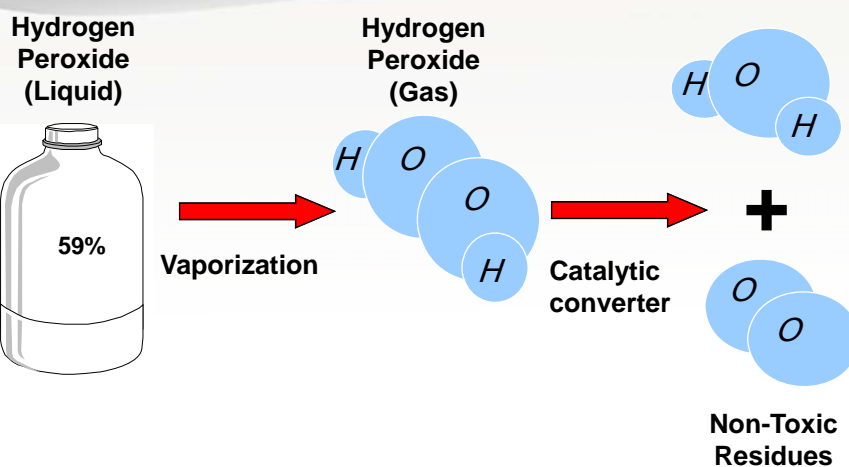
- VHP patented technology by STERIS
- Dry process, pure vapor of H_2O_2
- In use in the pharmaceutical and laboratory field for over 25 years



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VHP - Dry Sterilization Process



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V-PRO Sterilizer Advantages

- ✓ Ease of Use
- ✓ Productivity
- ✓ Material Compatibility
- ✓ Total Cost of Ownership




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Answering Users' needs

Unanimous feedback from Users

- EASE OF USE *how many aborted cycles?*
- RELIABLE *how do you process heat sensitive instruments?*
- GENTLE *Are your instruments validated to be processed in your sterilizer?*
- COST EFFECTIVE *Difficult to operate?
Difficult to load?*

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RELIABLE



- Virucidal, bactericidal, fungicidal, mycobactericidal, fungicidal, cysticidal and sporicidal activity
- Effective sterilization process, including **prion inactivation** for maximized patient safety

bsi. Assessment Report.

Introduction.

This report has been compiled by William Essex and relates to the assessment activity detailed below:

Client Name/Type/Division	Certificate/Standard	Site Address
ED44953 Technical Visit by FS 25/02/2014 J. Duffin No. Employees: 1115	CE 01230 Healthcare ISO 13485:2008 Annex D, Sec. 3.2 (2007/47) Sharnita Duffin	STERIS Corporation 1940 Ramsey Road Flushing Ohio 44130 USA

Client management system version(s):
ISO 13485:2008 revised 11/06/2012

To conduct a certification assessment to review the effectiveness of the product in question to reduce/prevent prion contamination.

Management Summary.

Overall Conclusion:
The objectives of this assessment have been achieved. Based on the objective evidence detailed within this report, the areas assessed during the course of the visit were found to be effective.
No non-conformities were identified during the assessment. Further detail relating to the overall assessment findings is contained within subsequent sections of the report.


Areas Assessed & Findings.

General Requirements:
General Operation & Audit Information:
As this was a desk review, this section does not apply.

Audit Issues:
This assessment was limited to the prion reduction/prevention aspects of the V-Pro process.


Scope of Certification:
The design and manufacture of sterile processing equipment, infection prevention systems and sterilant and disinfectant chemical products for use with equipment for the sterilization and/or high level disinfection of medical devices.

Report Author: William Essex Page 2 of 5 ...making excellence a habit™
Visit Start Date: 15/02/2014


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GENTLE


- Dry process
- Low temperature
- Prolongs the lifespan of devices
- **Safety:**
 - For the users
 - For the instruments
 - For the environment
 - For the patients



No toxic residuals at the end of the cycle
only water and oxygen

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Materials, devices, accessories must be compatible with Hydrogen Peroxide Gas.




Checked

Compatible Materials

- Aluminum*
- Brass
- Delrin® acetyl resin (polyacetal)
- Ethyl vinyl acetate (EVA)*
- Glass
- KRATON™ Polymers
- Neoprene
- Noryl (Polyphenylene oxide)
- Non-mated Nylon (polyamide)
- PEEK
- Polymethyl methacrylate (PMMA)*
- Polycarbonate *
- Polyethylene
- Polypropylene
- Polystyrene
- Polyurethane**
- Polyvinyl chloride (PVC)
- Radel® (Polyphenylene sulfone)*
- Silicone
- Stainless Steel
- Teflon® (Polytetrafluoroethylene)
- Titanium
- ULTEM® Polymers (Polyetherimide)*

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Device compatibility

Common Issues

- Copper and brass
- Cellulose and textile
 - i.e. Checklists, wraps
 - i.e. Gauges, linens
- Foam, sponges
- Liquids
- implants

Table A-2. Materials NOT Compatible With VAPROX HC Sterilant

Items made with copper or copper alloys (such as Monel)

Instrument Trays (other than V-PRO Sterilization Trays)

Instrument Positioning Devices (other than the blue V-PRO Instrument Organizers)

Items that are NOT completely dry

Items or materials that absorb liquids

Items made of materials that contain cellulose (e.g., cotton, paper or cardboard, linens, huck towels, gauze sponges or any item containing wood pulp)

Paper instrument count sheets or lot stickers

Liquids and powders

Items with mated Nylon® surfaces

Single use items (manufacturer does not recommend re-sterilization)

Implants where manufacturer has not specifically recommended sterilization in the Amsco V-PRO max Low Temperature Sterilization System


Instruments and devices that cannot withstand a vacuum and are labeled for gravity steam Sterilization methods only

Items whose design permits surfaces to collapse onto each other (unless some method is devised to keep the surfaces separated)

Devices with internal parts (e.g., sealed bearings) that cannot be immersed may present difficulties in cleaning and should not be processed in this Sterilization Unit

*Nylon is a registered trademark of the DuPont Corporation.

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WIDE COMPATIBILITY

- The process is adapted for a wide range of moisture/heat sensitive instruments
- Large amount of validated devices, including:
 - single, dual and triple channel stainless steel rigid scopes
 - Single and dual channel flexible scopes
- Broad OEM endorsements

WE'VE GOT YOU COVERED

The STERIS Device Testing group partners with OEMs to make reprocessing of medical devices safer for you, the patient and the environment.

You can have peace of mind and assurance knowing that our Scientific team with decades of experience and expertise affirm through testing and validation that these devices are compatible with the V-PRO® Sterilizers.

Below is a list of OEMs and device categories that are currently validated for the V-PRO® Low Temperature Sterilization Systems:

Medical Device Manufacturers	Examples of Device Categories
AcuScope	Batteries
Arlco	Baugies
AVIX	Cameras
AXIP Endoscope Products	Cables
BE Medical	Cassettes
Brauer	Decontamination Paddles
Braun	Flexible Endoscopes
Cardinal Health	Forceps
Care West Medical Products	Laryngoscopes
Care Medical	Light Cords
Class Medical	Powered Instruments
Class Medical II	Probes
Compass International	Rigid Containers
COVIDIEN	Rigid Endoscopes
COVIDIEN	Robotic Endoscopes
Dr. Swisher	Semi rigid endoscopes
Endo Optics Inc	Sheaths
Endo	Adapters
Holzer and Payerl	Biopsy
Excel WIP Solutions, Inc	Clampers
Gynec AEM	Transducers
Heraeus	Trays
Hittachi Piatix	Wraps
Hologic	
Innovative Surgical Systems	
Karl Storz Endoscope	
Kimberly Clark	
Koven	
Mars International	
Mobilium	
Mohrwalton	
Myoflex	
Neoflex	
Novostar Technologies	
Ocular Instruments	
Olympus	
Park Medical	
Perlat	
Permacision	
Phelps	
Richard Wolf	
Scand Technology	
Sirona	
Stryker	
Suemed Supply Systems	
Suemed Medical	
Suimed	
Tectico	
Tenax Cardiovascular Systems	
Verathon Inc	

And much more...

New devices are added regularly so don't forget to visit the Device Matrix at: www.steris.com/products/steris/compatibility

Please note that the list on this web page is intended to be used as a general reference guide only. This list should not be used as a final determination for device compatibility with the V-PRO® Low Temperature Sterilization Systems. The user responsibility for the inclusion of devices on this list and their ability to ensure the device is compatible and follows the stated indications for use for the V-PRO® Low Temperature Sterilization System.



V-pro Systems Overview

- Low temperature sterilization systems using hydrogen peroxide sterilant.
- Reusable metal and non-metal medical devices in Health Care Facilities (HCFs).
- The intended application is the terminal sterilization process of properly prepared cleaned, rinsed and dried devices.
- Sterilization cycles operate at low pressure and temperature, suitable for processing medical devices sensitive to heat and moisture.

Technical Data Monograph

Amsco® V-PRO® maX
Low Temperature Sterilization System



WIDE COMPATIBILITY

Discover the online compatibility matrix:

[Vpro Device Wizard](#)

V-PRO Device Compatibility Wizard

Enter Model Number

V-PRO Device Compatibility Wizard

Select Manufacturer

- Philips
- Richard Wolf
- Smith & Nephew
- StrenuMed
- Stryker
- Summit Doppler Systems
- Teleflex
- Terumo Cardiovascular Systems
- Trudell Medical International
- Zoll

V-PRO Device Compatibility Wizard

Enter Model Number

V-PRO Device Compatibility Wizard

Manufacturer: Olympus
Part Number: AR-T10SA
Description: Video Adapter

Status: Lumen Non Lumen Flexible

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Questions so far?




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 **Lumen Cycle:** If an instrument with a stainless-steel lumen is present in the load, Lumen Cycle **MUST** be pressed. Non-lumened instruments or instruments with mated surfaces (such as hinged portion of forceps and scissors) may also be processed in this cycle

 **Non Lumen Cycle:** If the load contains only non-lumened instruments or instruments with only stainless-steel mated surfaces, such as the hinged portion of forceps and scissors, it may be processed in the Non Lumen Cycle. Non-lumened flexible endoscopes may be processed in this cycle. Do not choose this cycle if there is a mated surface other than stainless steel in the load.

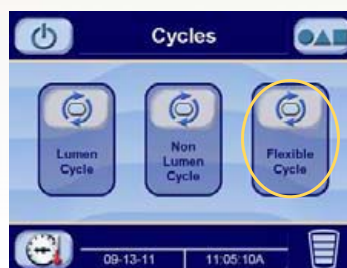
 **Flexible Cycle:** Flexible surgical endoscopes, such as those used in ENT, Urology and Surgical Care, and bronchoscopes with a single or dual flexible lumens may only be processed in the Flexible Cycle. Non-lumened instruments and instruments with mated surfaces may also be placed into a load with one flexible endoscope. Non-lumened flexible endoscopes may also be processed in this cycle.

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FLEXIBLE CYCLE

✓ Process single channel **surgical flexible endoscopes**, such as urethrosopes, bronchoscopes and those used in ENT



✓ Process **dual channel** surgical flexible endoscopes

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Summary: Claims and Productivity Advantages

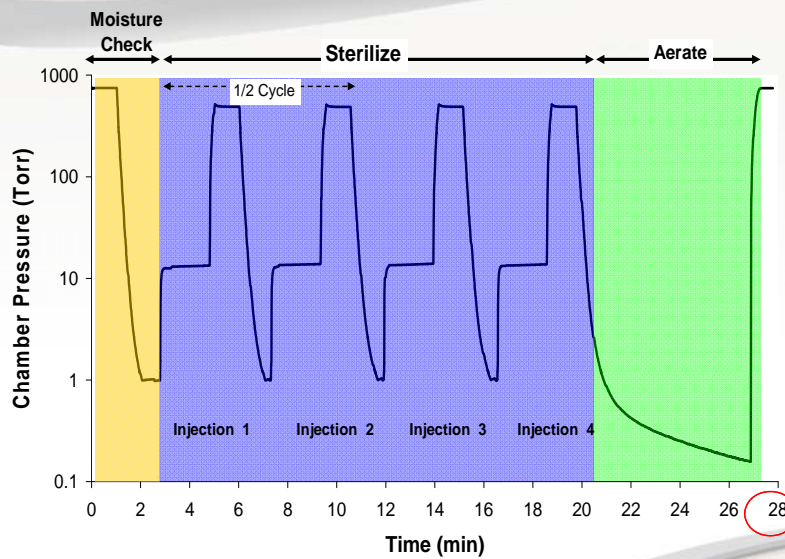
- *Lumen Cycle:*
 - More lumens and weight per cycle for stainless steel lumens
 - Dual and Triple Channel stainless steel lumens
- *Flexible Cycle:*
 - Dual Channel Surgical Flexible Endoscopes
 - Longest single channel Flexible Endoscope claims
 - Process mixed loads
 - Fastest Processing time
 - Greater number of DaVinci Endoscopes
 - Process Olympus Endoscopes
- *Non Lumen Cycle:*
 - Highest weight claims in the shortest amount of time

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Non-Lumen Cycle



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Thank you!

Summary

Safe

- Patients/Users/Environment/Devices

Efficient

- Wide range of applications
 - from hysteroscopy to cystoscopy, non-invasive cardiology cables, shavers, probes, batteries, defib paddles and flex 's
- Quicker processing allows for better inventory control; no need for large stock

Cost Saving

- No complex installation requirements or maintenance costs
- Save costs by reducing device inventory and invest
- Reduced instrument damage and expensive repairs

• **Speed**

- Terminally sterile packaged instruments; when you need them, where you need them
- Increase instrument throughput, availability, more caseloads, improve efficiency, reduce costs

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