

STERIS VHP® MD Series Sterilization System

**Low Temperature
Vaporized Hydrogen Peroxide
(VHP) GMP Sterilization for
Medical Devices**



**Ideal for On-Site,
Point-of-Manufacture Use**

STERIS®



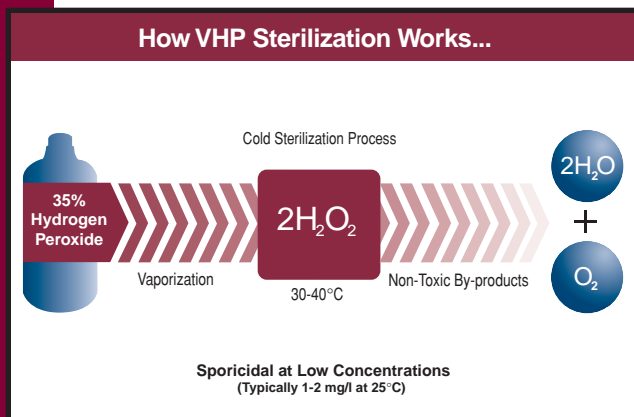
Scientific Division

VHP Sterilization Where You Need It

STERIS VHP MD Series brings efficiency and cost savings to medical device manufacturing by providing rapid just-in-time Vaporized Hydrogen Peroxide (VHP) sterilization. This allows integration with current in-line manufacturing processes. Reduced finished goods inventory and shortened delivery times allow you to reduce costs and ship product to your customer faster!

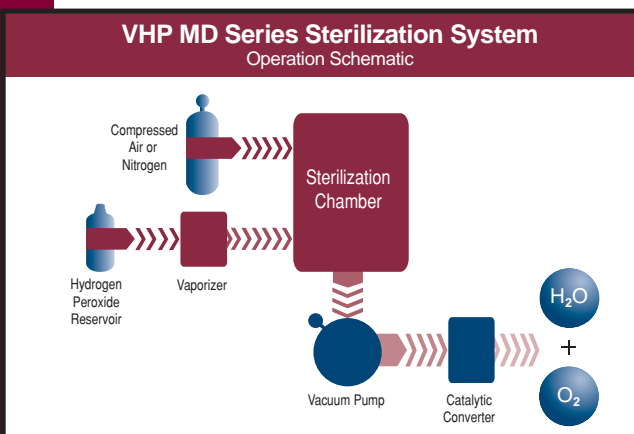
Select the sterilization chamber size that optimizes your production process. The process is fully controlled, repeatable, and easily validated. The process is cost effective, safe and reliable, and offers a wide range of material compatibility.

Capitalize on the VHP process that has been the pharmaceutical industry standard for over ten years. Used in hundreds of validated installations, VHP is the predominant choice for sterilization in pharmaceutical aseptic production and research facilities.



Advantages of VHP Sterilization

- Low temperature
- Proven efficacy
- Rapid sterilization cycle time
- Low operating cost
- No toxic residuals
- Environmentally friendly by-products: water vapor and oxygen
- No post-process aeration
- Compatible with a wide range of materials
- Gas plasma phase not required



Proven Efficacy

The efficacy of the STERIS VHP MD Series Sterilization System is proven with the ability to kill a broad range of organisms including highly resistant spore formers.

VHP MD Series Cycle Description

The VHP cycle consists of four phases:

- Leak test** Vacuum is held to assure leak tight chamber.
- Condition** To remove air from the chamber and packaging, and to equilibrate product temperature, the chamber is evacuated and then recharged with dry, sterile air.

- Sterilization** To enhance penetration, hydrogen peroxide vapor is injected into the chamber via a series of multiple pulses. A gas plasma phase is not required.

- Aeration** After a series of aeration pulses, the chamber is evacuated to remove residual hydrogen peroxide vapor.



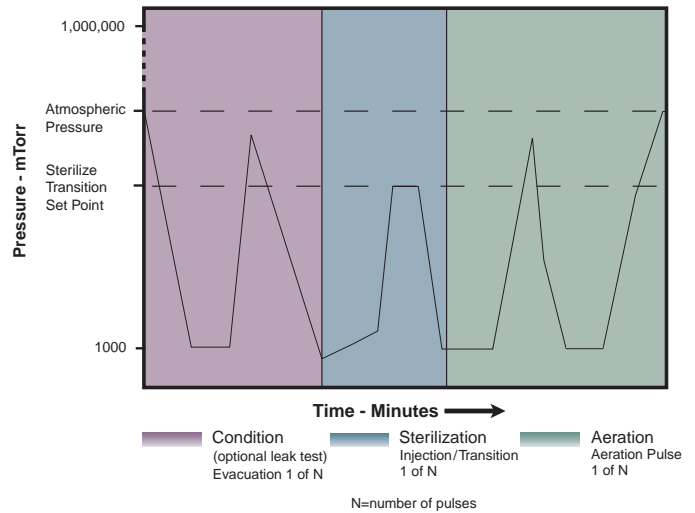
VHP MD2000 Load Side

Product must be in a gas permeable package (e.g. Tyvek®).



VHP MD2000 Unload Side

VHP MD Series Cycle Graph



Cycle times vary with chamber size and product configuration. The process is fully automated. All cycle parameters are monitored and recorded for process validation.

	VHP MD880	VHP MD2000
Chamber Size*	8.8 ft ³ (249 L)	19.2 ft ³ (543 L)
Chamber Dimensions	W - 20" (508 mm) H - 20" (508 mm) D - 38" (965 mm)	W - 26" (660 mm) H - 26" (660 mm) D - 49" (1245 mm)
Overall Dimensions	W - 40" (1016 mm) H - 79.5" (2019 mm) D - 42.63" (1083 mm)	W - 56.81" (1443 mm) H - 78.25" (1988 mm) D - 65" (1651 mm)

*Custom Chamber Sizes Available

Product Features

- Select chamber size of 8.8 ft³, 19.2 ft³ or custom
- Select from single-door or double-door pass-through configuration
- Independent monitoring of cycle time, temperature, and pressure
- GMP design
- Polished stainless steel paneling
- Passivated Type 316L stainless steel chamber
- Water jacket maintains uniform chamber temperature
- Vacuum system
- Parametric release capability
- Touch-screen control
- Permanent cycle records
- Sanitary plumbing
- Floor mounted system

STERIS Vaprox® Hydrogen Peroxide Sterilant is specially formulated to maintain optimum equipment performance.



To minimize exposure to the liquid hydrogen peroxide during handling, the system uses specially designed disposable cartridges (available separately) containing approximately 950 ml Vaprox 35% Hydrogen Peroxide (H₂O₂) Sterilant.



STERIS VHP Chemical Indicators and STERIS Spordex® VHP Biological Indicators (Bacillus stearothermophilus) are available for use in hydrogen peroxide vapor distribution studies, efficacy studies, and sterility testing.

Interior Design

- One inch sanitary capped chamber penetration port for up to 2 thermocouple probes for validation and heat distribution penetration cycles
- Visible chamber and jacket analog pressure gauges
- Resistance temperature detectors (RTD) for vaporizer, chamber jacket, and chamber interior temperature control
- Dual-range chamber pressure transducers with sanitary clamp connections

Control Features

- Operator friendly touch-screen control
- 320 x 240 pixel, vacuum fluorescent, 40 character x 30 line display
- Standard cycle or custom cycle parameter selection
- Cycle alarms for all cycle parameters
- Security access code
- Help screen
- Shows sterilizer status and all current cycle parameters
- Service diagnostics mode for calibration, service, etc.
- Language options – English, French, Japanese, German, Spanish
- Impact printer
- RS 232 or RS 485 communication ports for transfer of data to local or remote data acquisition system
- Battery back up protects cycle memory for ten years
- GAMP software documentation package available

Options

- Double-door pass-through
- GAMP software documentation package
- Integrated H₂O₂ sensor
- Chamber load temperature probes
- High-polish chamber finish
- Loading cart, transfer carriage, and racking
- Cross-contamination seal for recessed mounting in a cleanroom
- Additional reference pressure transducers
- Seismic mounting



Partnership Programs

STERIS can provide technical assistance with feasibility studies, efficacy studies, and material and packaging compatibility testing. In addition, assistance with determining cycle parameters, load configuration, and sizing is provided.

Technical Support, Service, and Maintenance

- STERIS Microbiologists, Chemists, and Application Engineers available to assist with product and process evaluations, validation, and on-site training
- Installation services available from local, factory-trained STERIS Service Representative
- STERIS Field Service Engineers available to support IQ/OQ, calibration, start-up, and preventive maintenance
- One-year parts and labor warranty



VHP Sterilization Where You Need It... At Point of Manufacture

Standards

Designed, fabricated, assembled, and tested in accordance with all applicable sections of ASME, UL, CSA, GMP, and ISO 9001.

The unit and control system have been designed to meet the applicable requirements of the following:

- Underwriters Laboratories (UL) Standard 3101-1 as certified by ETL Testing Laboratories, Inc.
- Canadian Standards Association (CSA) Standard C22.2 No. 1010.1-92 as certified by ETL Testing Laboratories, Inc.
- EMC Directive (89/336/EEC)
- Low Voltage Directive (73/23/EEC)
- Machinery Directive (89/392/EEC)
- Pressure Equipment Directive (97/23/EC)



STERIS Corporation is a leading provider of infection prevention, contamination prevention, microbial reduction, and therapy support systems, products, services, and technologies to healthcare, scientific, research, food, and industrial customers throughout the world.

VHP technology is patent protected by U.S. 5,527,508, U.S. 5,445,792, U.S. 5,389,336, U.S. 5,286,448, and other issued and pending U.S. and international patents.

System Requirements

- **Unit power supply:**
United States: 120 VAC, single phase, 50/60 Hz, 15A
Japan: 100 VAC, single phase, 50/60 Hz, 18 A
Europe: 230 VAC, single phase, 50/60 Hz, 8 A
- **Vacuum pump power supply:**
United States: 208/240 VAC, three phase, 60 Hz, 8/6A; 480 VAC, three phase, 60 Hz, 3A
Japan: 200 VAC, three phase, 50/60 Hz, 9A
Europe: 400 VAC, three phase, 50 Hz, 4A
- **Air supply:** 60 psi to 100 psi (4.1 bar to 6.9 bar)
- Cold deionized water is required to fill the chamber water jacket

NOTE: The medical device manufacturer should follow applicable regulations and standards to ensure the efficacy of the sterilization process for a specific medical device and evaluate any effects on its safety and performance.

STERIS®



STERIS Corporation
Scientific Division
5960 Heisley Road
Mentor, OH 44060-1834 ■ USA
440-354-2600 ■ 800-444-9009
www.steris.com

STERIS Offices Worldwide:

Benelux	32 2 523 2488
Canada	800 661 3937
France	33 1 44 882688
Germany	49 2233 69990
Italy	39 02 66 80 53 10
Japan	81 78 321 2271
Latin America	305 442 8202
Nordic	358 9 25851
Singapore	65 68 41 7677
Spain	34 916 585 920
Sweden	46 152 228 30
United Kingdom	44 1276 683300

M2134EN.2002-04, Rev. B
© 2001, 2002 STERIS Corporation.
All rights reserved.
Manufactured exclusively by STERIS Corporation in our Erie, PA facility, which is ISO 9001, EN 46001 and, ISO 13485 certified.