

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®

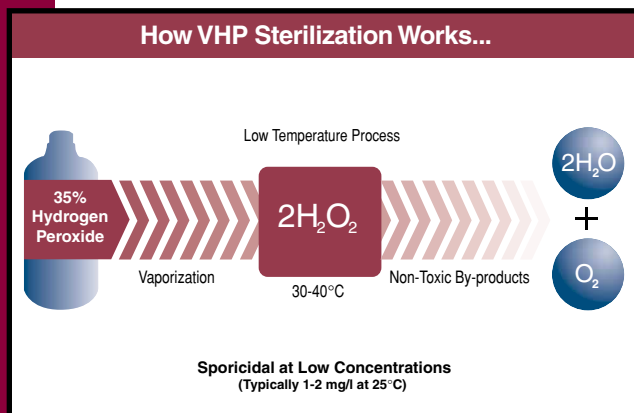


VHP Sterilization Where You Need It

STERIS VHP MD Series Sterilization Systems bring 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!

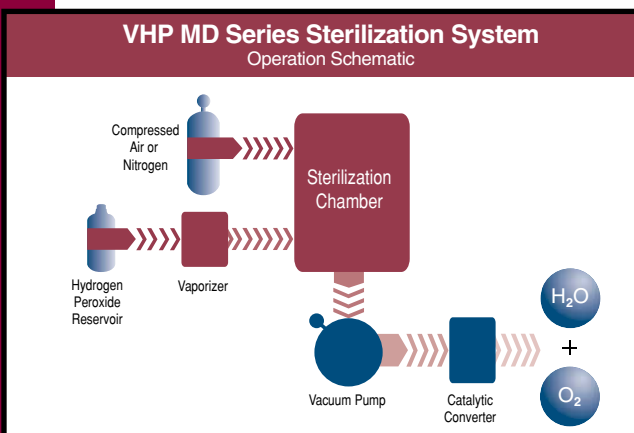
Select the sterilization chamber size that optimizes your production process. The process is fully controlled, repeatable, and easily validated. The process is cost effective, safe and reliable, and offers a wide range of material compatibility.

For over ten years, the STERIS VHP process has been widely used in validated pharmaceutical aseptic production and research applications. Now, the STERIS VHP process is rapidly emerging as the standard for low temperature sterilization in the medical device market.



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

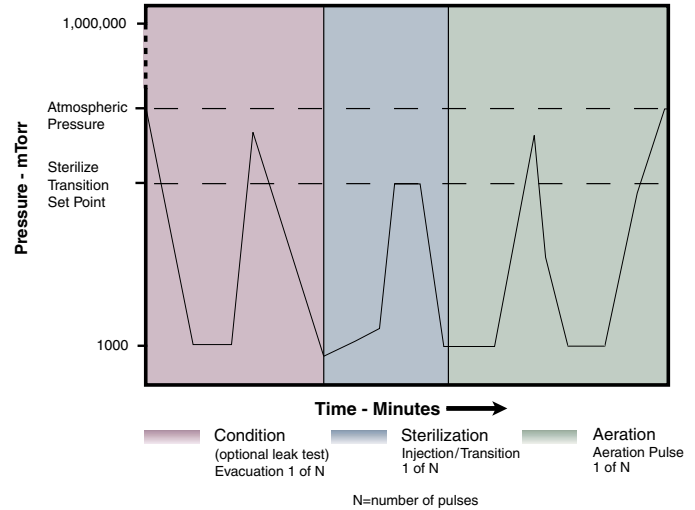
The efficacy of the STERIS VHP MD Series Sterilization System is proven with the ability to kill a broad range of organisms including highly resistant spore formers.

VHP MD Series Cycle Description

The VHP cycle consists of four phases:

- Leak test** Vacuum is held to ensure 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 short aeration pulses, the chamber is evacuated to remove residual hydrogen peroxide vapor.

VHP MD Series Cycle Graph



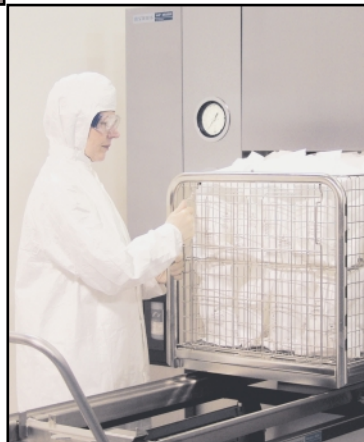
Cycle times vary with chamber size and product configuration. The process is fully automated. All cycle parameters are monitored and recorded for process validation.

	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)
Maximum Outside Dimensions	W - 44" (1118 mm) H - 74.5" (1892 mm) D - 46.75" (1187 mm)	W - 68" (1727 mm) H - 78.5" (1944 mm) D - 67.5" (1715 mm)

*Custom Chamber Sizes Available



Operator friendly touch-screen control permits standard or custom cycles.



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

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



To maximize safety during handling and ensure optimum equipment performance, the system uses specially designed cartridges (available separately) containing approximately 950 ml Vaprox 35% Hydrogen Peroxide (H₂O₂) Sterilant.



Interior Design

- One inch sanitary capped chamber penetration port for up to 2 resistance temperature device (RTD) probes for validation and heat distribution penetration cycles
- Visible chamber and jacket analog pressure gauges
- RTD's for vaporizer and chamber jacket temperature control
- Dual-range chamber pressure transducers with sanitary clamp connections



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

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, or rack and shelves (MD880 only)
- Cross-contamination seal for recessed mounting in a cleanroom
- Additional reference pressure transducers
- Seismic mounting

STERIS®


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 Representatives
- 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, and will bear the CE mark.

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

- Underwriters Laboratories (UL) Standard 6101A-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)

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

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, industrial, and government 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

Control power supply:

- 230 VAC, 1-Phase, 50/60 Hz, 17 A

Unit power supply options:

- 230 VAC, 1-Phase, 50/60 Hz, 17 A
- 200/220/230 VAC, 3-Phase, 50/60 Hz, 13/11/10 A
- 230 VAC, 1-Phase, 60 Hz, 17 A
- 460 VAC, 3-Phase, 60 Hz, 6 A
- 230 V, 1-Phase, 50 Hz, 17 A
- 400 V, 3-Phase, 50 Hz, 5 A

Vacuum pump power supply options:

- 200 V, 3-Phase, 50/60 Hz, 13 A
- 220 V, 3-Phase, 50/60 Hz, 11 A
- 230 V, 3-Phase, 50/60 Hz, 10 A
- 400 V, 3-Phase, 50 Hz, 5 A
- 460 V, 3-Phase, 60 Hz, 6 A

Dry air supply:

60 to 100 psi (4.1 to 6.9 bar), 10 scfm

Nitrogen: (optional)

60 to 100 psi (4.1 to 6.9 bar), 10 scfm

Cold deionized water is required to fill the chamber water jacket



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