STERIS
Life Sciences

STERIS VHP® LTS-V
LOW TEMPERATURE STERILIZER

APPLICATION

STERIS VHP® LTS-V Low Temperature Sterilizer is designed for on-site low temperature surface sterilization[1] of temperature sensitive biological drug packages and drug delivery devices. This sterilizer utilizes time proven STERIS Vaprox® Hydrogen Peroxide Sterilant (EPA No. 1043-123) vapor in controlled environment and vacuum conditions for maximum sterilization[2] efficacy in low temperature conditions within typical range of 28-40°C (82-104°F), depending on product requirements. Maximum sterilization temperature is 50 °C (122 °F).

[1] Not for use in the terminal sterilization or reprocessing of critical or semi-critical medical devices.

[2] Sterility assurance level SAL 10^{-6}

DESCRIPTION

STERIS VHP® LTS-V Low Temperature Sterilizer provides the solution for cGMP and cGAMP compliant in-house terminal surface sterilization of packaged temperature or radiation sensitive drug products as follows:

- Automated controlled process environment
- Short cycle times (typically two to four hours)
- No toxic process by-products
- Excellent material compatibility
- Maximized throughput in pre-designed high quality stainless-steel chamber
- Fully tested STERIS process that includes feasibility testing and full load Factory Acceptance Test (FAT) Cycle development tests with Customer product loads
- Complete IQ/OQ testing of equipment at factory testing area prior to shipment
- Standard configurations as well as customized arrangements to meet Customer needs

Following on-site installation, STERIS application specialists also provide on-site acceptance testing and validation support services ensuring easy and time-saving procedures for validation of the process and equipment for the application environment and requirements.

(Typical - details may vary.)

STANDARDS

STERIS VHP® LTS-V Low Temperature Sterilizer and products are designed and manufactured to meet CE mark and applicable sections of the following European Union directives:

- **Machinery Directive 2006/42/EC**
- **Low Voltage Directive 2014/35/EU**
- **Electromagnetic Compatibility (EMC) 2014/30/EU**
- **Pressure Equipment Directive 2014/68/EU**

Common standards used during the design, manufacturing and testing of the low temperature sterilizer is as follows:

- **Canadian Standards Association (CSA) Standard C22.2 No. 125**
- **EN60204-1**
- **IEC 60204-1**
- **UL508**

STERIS quality system has been certified to meet the standard **ISO 9001:2008 Quality Management Systems**.

STERIS follows the **GAMP 5, A Risk-Based Approach to Compliant GxP Computerized Systems**.

The Selections Checked Below Apply To This Equipment

CHAMBER/UNIT SIZES*
- ❑ 6912 (0.85 m^3)
- ❑ 91515 (2 m^3)
- ❑ 151818 (4 m^3)
- ❑ 182124 (9 m^3)

MOUNTING CONFIGURATION
- ❑ Floor
- ❑ Pit

CONTROL SYSTEM
- ❑ Siemens PLC Control

* Double Door Standard

OPTIONS
- ❑ Two-Part Construction (Split Crating)
- ❑ Trim Panel Set (Each Side)
- ❑ Laser Printer
- ❑ Sterilant Room Monitor
- ❑ Mirror Construction, Chamber Right Side
- ❑ Air Differential Seal
  - ❑ Sterile Side ❑ Non-Sterile Side
- ❑ Seismic Anchorage Restraints and Calculations
- ❑ Enclosure Side Panels
  - ❑ Right ❑ Left
- ❑ Loading Cart System and Chamber Tracks
- ❑ Transfer Trolley (6912, 91515)
- ❑ Chamber Surface Finish Inspection Report

OPTIONS (Cont'd)
- ❑ FAT Procedures and Results
- ❑ Extended Control System Validation Documentation
- ❑ Installation Kit
- ❑ Spare Parts Kit
- ❑ Manufacturing Procedures Documentation
- ❑ Extended Chamber and Piping Documentation
- ❑ Product Feasibility Testing Services
- ❑ Load Cycle Development Services
- ❑ Validation Support Services

Item _____

Location(s)_____

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STERIS develops, documents and enforces policies and procedures ensuring the security of electronic records and signatures according to **21 CFR Part 11**. Together with our Customers, STERIS helps implement and enforce **Part 11-compliant solutions involving validation, audit trails and security of our computer systems**. The base system includes electronic records, electronic signatures, electronic batch reports and audit trails. STERIS provides more details as requested.

FEATURES

STERIS VHP® LTS-V Low Temperature Sterilizer is designed to meet Customer expectations for on-site surface sterilization of temperature sensitive biological drug packages and drug delivery devices. The system is developed, manufactured and tested with the following features:

Features	Benefits
Dry Vapor Process	STERIS patented process providing consistent Vaporized Hydrogen Peroxide Sterilant for maximum penetration and distribution
Low Temperature	Allows surface sterilization of heat and/or radiation sensitive materials
Non-Toxic Byproducts	Water and oxygen are the only byproducts of the process
Complete Cycle	Surface sterilization and aeration can be completed in one process
Chamber	Manufactured from AISI #316L stainless steel (see CONSTRUCTION Section for more details)
Jacket	Full AISI #304 stainless-steel jacket for temperature control (see CONSTRUCTION Section for more details)
Chamber Sterilant Inlet	Chamber inlet design provides uniform sterilant distribution
Chamber Validation Ports	One dedicated port is provided for sensing and validation purposes
Room Monitoring	Optional sterilant room monitoring sensor(s) provided to detect even minimal hydrogen peroxide sterilant presence in the room.
Vacuum Pump	Vacuum levels to allow for maximum packaging penetration
Leak Test	Customer can ensure chamber is sealed if leak rate is within acceptable limits
PLC Control	Standard, commercially available, PLC control system platform
Operator Interface	Color touch screen with Cycle parameters, alarms and component status
Factory Acceptance Test (FAT)	Fully tested at factory according to FAT procedures.
Sterilant Cartridge Interface	Only accepts Vaprox Hydrogen Peroxide Sterilant Cartridges. Unit control automatically tracks amount of Vaprox Hydrogen Peroxide Sterilant used and Sterilant expiration date. The control prompts the user on the control display when a new Cartridge is needed. The proprietary Cartridge is equipped with a data matrix code to ensure the correct Cartridge is used in the Sterilization Unit and that Cartridge contents are not expired; no Cartridge code (or other information) needs to be entered by the user.
Standard Safety Systems	Redundant door interlock systems, Emergency Stop and pneumatic deactivation key switch are provided to ensure operator safety
Secure Access	User access levels are password protected for secure access to the control

CYCLE DESCRIPTION

STERIS VHP® LTS-V Low Temperature Sterilizer Sterilization Cycle consists of three phases:

1. Pre-Conditioning
2. Sterilant Exposure
3. Post-Conditioning

The Sterilization Cycle is a dry vapor, vacuum process. Cycle uses a deep vacuum for process purposes. Cycle development aims for optimal total Cycle time. Optimization of total Cycle time depends on device and package materials, product sensitivity to vacuum (depth and rate), surrounding atmospheric conditions (room temperature and humidity, product storage temperature) and processing temperature.

PRE-CONDITIONING

This phase is essential for Sterilization Cycle as it controls the environment by removing air and moisture from the chamber and packaging and heating the load to specified temperature. The chamber is evacuated down to a programmed vacuum level for the moisture removal.

Temperature control is supplied for heating at this phase only. Optimal and typical operating temperature range is 28-40 °C (82-104°F). Lower load temperatures may result in longer Cycle times.

STERILANT EXPOSURE

Vaporized Hydrogen Peroxide Sterilant is introduced into the chamber and maintained for a specific time. Vacuum conditions enable penetration of the sterilant through Tyvek®[3] packaging and into the load. Hydrogen peroxide injection depends on load configuration, temperature, materials (packaging, adhesives, plastics, etc.) and chamber size.

[3] Tyvek is a registered trademark of E. I. duPont de Nemours and Company.

POST-CONDITIONING

The load is aerated using a series of vacuum pulses to remove the sterilant from the load and chamber prior to Cycle completion. The sterilant is converted to water and oxygen using a built in catalytic converter system. The chamber is equalized with sterile air.

SAFETY FEATURES

Emergency Stop Button, located on both sterile (ST) and non-sterile (NS) sides of the Unit, returns valves to safe condition and halts Cycle processing when pressed. Once pressed, operator chooses to either abort or continue Cycle operation.

Security Access Codes provide restricted access of unauthorized users to critical operational modes. Three access levels are available:

1. **Operator Level:** Allows operator to select and start Cycle, view Cycle parameters and order control to print limited reports.
2. **Service Level:** Allows operator to select and start Cycle, view Cycle parameters, print reports, calibrate instruments and activate/deactivate inputs and outputs, edit common settings, change date/time and view service diagnostics.
3. **Administrator Level:** Allows operator to select and start Cycle, view Cycle parameters, print reports, calibrate instruments and activate/deactivate inputs and outputs, edit common settings, change date/time, view service diagnostics and edit passwords.

Compressed Air Back-up for door gaskets.

Door Sensing Device automatically stops door if an obstruction is detected while the door is closing.

Door Interlock allows only one door to be opened at a time, and during processing, prevents either door from being opened until Cycle is complete.

Pressure Relief Device on chamber limits the amount of pressure buildup so rated pressure of vessel is not exceeded.

Pneumatic Key Lock feature for doors provides a safety lock system for disabling all the chamber door functions during service and cleaning operations.

CONSTRUCTION

Chamber/Jacket

Chamber is manufactured from AISI #316L stainless steel with an operating pressure range from full vacuum to 0.34 bar (g) pressure.

Chamber is passivated with a solution that is composed of hydrofluoric acid, nitric acid, and de-ionized water after fabrication. The process (solution concentration, exposure time and temperature, etc.) is controlled by specific Quality Assurance Procedures to ensure proper processing. Chamber is rinsed with de-ionized water and cleaned with pure steam after exposure. A chamber passivation certificate is included.

NOTE: Chamber net size is 300 mm smaller in height compared to the nominal chamber size. For example, 91515 chamber size has 91215 net size and volume.

Jacket material is AISI #304 as a standard.

Chamber and jacket components are designed to monitor and control the Cycle via the PLC and communicate Cycle conditions to the operator. Components are selected to deliver reliable performance while being subjected to the varying pressure conditions of the Sterilization Cycle.

Chamber Doors

The chamber doors are manufactured from AISI #316L stainless steel. Double door is the standard chamber configuration, as it provides a pass-through from NS loading side and opens to ST unloading side after Cycle.

Piping

All piping connections terminate within the confines of the Unit. Pipe connection types, materials and other features include stainless steel, PTFE and Tri-Clamp®[4], threaded or flanged connections as per defined.

[4] Tri-Clamp is a registered trademark of ALFA LAVAL INC.

MOUNTING ARRANGEMENT

Sterilizer is designed for freestanding or recessed mounting through one or two walls. All sterilizer components are integrally mounted within sterilizer footprint (refer to Equipment drawing). Each sterilizer is equipped with adjustable leveling legs.

OPTIONAL FEATURES

Pit-Mounting Installation (floor-mounting is standard) option is designed to enable the frame assembly to be installed in a pit to align the bottom of the chamber with the finished floor. Pit-mounted installation is provided with the following features:

- Unit is designed to be recessed into a 300 mm (12") deep pit.
- AISI #304 stainless-steel exterior fascia panels are extended to the finished floor to provide a clean installation.
- Stainless-steel transition plate is provided for easy rolling of carts to/from the Unit.
- No transfer trolleys are required with this configuration.

Two-Part Construction (Split Crating) design allows separation at the installation site and facilitates rigging into restricted openings or spaces. Typically selected by Customers with entry restrictions that limit the equipment's size. If pit mounted installation is selected with this option, then the unit must be reassembled prior to being set into the pit.

Trim Panel Set (Each Side) are provided with for sealing the gap between the Unit fascia panels and facility wall opening for recessed one or two wall installations. Panels are manufactured of AISI #304 stainless steel. Select this option when other sealing methods such as dry wall installation or on-site sheet metal fabrication are not available. Customer's room layout drawing is required for designing the trim panels.

Stainless-Steel Frame provides enhanced frame material (#304 stainless steel) with an external glass beaded finish.

Laser Printer is remotely mounted on the stainless-steel enclosure to provide paper printout of the Cycle batch reports.

Sterilant Room Monitor is used to detect even very low concentrations of hydrogen peroxide sterilant in the area. The monitor alarms if sterilant levels exceed acceptable limits (> 1 ppm).

Mirror Construction reverses standard positioning of sterilizer chamber and service area. In mirror construction, as viewed from operating end, sterilizer chamber is relocated to right side and service side is relocated to left side. Standard configuration is chamber on left and service on right side (as viewed from operating side).

Air-Differential Seal (Sterile Side) is provided at the sterile end of the Unit to maintain pressure difference between the Unit service area and classified area. The seal is fabricated from AISI 304 stainless steel. Silicone caulking is used to seal the panels within the Unit frame. Adjustable interface panels are provided at the top, bottom and both sides with a silicone gasket to seal the system to the facility structure. Air differential seal on both sides is a special quotation offer.

Air Differential Seal (Non-Sterile Side) is provided at non-sterile end of Unit to maintain pressure difference between Unit service area and classified area. Seal is fabricated from AISI #304 stainless steel. Silicone caulking is used to seal panels within Unit frame. Adjustable interface panels are provided at top, bottom and both sides with a silicone gasket to seal system to facility structure. Air differential seal on both sides is a special quotation offer.

Seismic Restraints and Calculations provide Unit with seismic anchorage designed to meet seismic zone four requirements. Angle brackets and frame mounting hardware are manufactured from AISI #304 stainless steel and are provided by STERIS. The Hilti type, or equivalent, floor anchors are provided and embedded (not by STERIS) into the concrete floor. Calculations are per latest California UBC as standard and certified by a California registered Engineering Company. Other calculations are available on request and may require additional cost. Seismic calculations are located in the Manufacturing Documentation.

Enclosure Side Panels (stainless steel) are installed on the right and/or left side of Unit framework as specified.

Loading Cart System and Chamber Tracks are custom designed and used to support and convey assorted products in the loading, sterilizing and unloading process. Loading equipment is a critical component for the process and throughput of the Unit. Product details need to be provided to optimize design of the load pattern, size and weight. Some typical features include:

- Stainless-steel frame design
- Cart size (chamber net size) is 300 mm lower in height to nominal size (e.g., 91515 cart and chamber size is 91215)
- Equipped with four fixed wheels (two swivel casters for pit mounted units)
- Multiple carts can be provided depending on chamber size to help facilitate loading and minimize weight. Note standard arrangement is one cart for 91515, two carts for 151818 and four carts for 182121 size chambers. Any different cart arrangement from this standard must be quoted separately as SSQ (special sales quotation).
- Cart(s) are supplied with shelves depending on product load configuration. Materials are typically stainless steel or polymer based and are compatible with sterilant. Shelves are customized for each project and product via the special sales quotation (SSQ) system.
- Tracks in chamber are installed to guide the cart(s) during loading and unloading procedures. Tracks are AISI #316L stainless steel. A transfer trolley is required with this option if the unit is not pit mounted (91515 size chamber only).

Transfer Trolley (6912 and 91515 only) is designed to support and convey the loading cart to and from the chamber and throughout the facility. A mechanical interlock system is provided to lock the transfer trolley to the Unit's chamber while loading/unloading the cart. Another mechanical interlock system is provided to lock the loading cart to the transfer trolley to enable safe movement of the combination. The total weight on the transfer trolley is not to exceed 450 kg (1000 lb). Features:

- Constructed of AISI #304 stainless steel
- Includes two swivel wheels with brakes and two fixed wheels without brakes
- Wheels are constructed of polyamide with an exterior polyurethane coating and stainless-steel mounting hardware

FAT Procedures and Results were developed for the purpose of providing written qualification procedures that can be implemented into a Customer's validation plan for FAT Testing. Procedures and Results Package integrates detailed written procedures and test plans into the FAT report. This material may then be used as a basis for the customer's Standard Operating Procedures (SOPs) used to complement their IQ/OQ requirements during Site Acceptance Test (SAT).

Extended Control System Validation Documentation Package adds the following material to the standard package:

- Hardware Specification
- Software Test Documentation
- PLC Change Control Documentation

NOTE: Validation and customer defined requirements remain the sole responsibility of the customer.

Installation Kit provides a set of counter flanges or clamps and their gaskets and clamp connectors to make Unit connection to utility piping installation easier.

Spare Parts Kit containing selected mechanical and electrical components is provided to fulfill the need for two years normal maintenance and operation of the Unit. Components typically provided are valve rebuild kits, solenoid valve, temperature sensor, pressure sensor, door gaskets and other applicable components. Additional parts may be required for other features.

Extended Chamber and Piping Documentation can be supplied. Vessel codes require manufacturers to maintain material certificates and traceability documentation at factory to provide evidence of proper manufacturing. As standard, STERIS archives these documents at factory for reference purposes. Option is for Customers requiring extended vessel documentation to be on-site. Package also provides detailed piping inspection information, material certificates and weld information for Customer record purposes.

Product Feasibility Testing Services is available for Customers defining the initial process feasibility of their products with low temperature surfaces sterilization (e.g., if considering a new device material, pressure range, temperature, package type or material, etc.). A customized test plan will be drafted and executed at the STERIS factory by a qualified STERIS representative. Feasibility testing time will be quoted per day. Typical procedures with feasibility testing is to run product samples in Sterilization Cycle and study device and package exposure, self-contained biological indicators and/or chemical indicator tests for product integrity. Typical outcome for test deviations from agreed scope of test plan will require additional days.

NOTE: All cycle development services are quoted on a customized basis for the application. Feasibility testing is carried out at STERIS Finn-Aqua R&D Science Room by dedicated R&D personnel. STERIS Finn-Aqua holds national Finnish Medicinal Manufacturing License that enables easy shipping and handling of Customer's product samples used for feasibility and load cycle development tests.

Load Cycle Development Services and testing is encouraged to be part of the FAT for new applications. This development test is to ensure a Cycle can be run with a full load in the chamber and is a starting point for Cycle optimization or Performance Qualification (PQ) activities. This testing is expected to be conducted over a specified time period and is performed after the FAT document is executed.

Validation Support Services is available for Customers required to validate their equipment. Validation support services time will be quoted per day. Validation support typically includes on-site support in validation test runs at customer site.

Additional Copy of User's Manual or Document File option. An additional hard copy of the complete documentation set is provided, including the user's manual, Factory Acceptance Test documentation, as well as the manufacturing and control system documentation (standard and optional). Manufacturer's booklets and CDs for installation, operation and maintenance for control systems, instrumentation and components are excluded.

Manufacturing Procedures Documentation binder provides the following internal procedures:

- Mechanical Grinding and Polishing Procedure
- Pickling and Passivation Procedure
- Surface Roughness Measuring of Vessels Procedure

Chamber Surface Finish Inspection Report option. As standard, the procedure for inspection of the Chamber surface finish is by random inspection during manufacturing by the quality assurance (QA) department. With this option the instrument documentation and data of the surface finish measurements are provided with the Manufacturing Documentation.

NOTES

1. The VHP options are to be used by trained and certified Applicators who have successfully completed both the STERIS Training and Certification Course for applicators of Vaprox Hydrogen Peroxide Sterilant and the VHP pertinent Sterilization System Operator Course. Certification must be active and in force for all Applicators of Vaprox Hydrogen Peroxide Sterilant.
2. Consult Vaprox Hydrogen Peroxide Sterilant SDS, label and package insert for information regarding storage and handling of Cartridges.
3. Refer to equipment drawings showing all utility and space requirements for actual installation specifications. Clearances shown are minimum required for servicing equipment. Floor surface must be hard and level.

FOOTPRINT

Refer to equipment drawing for installation details and specifications.

EQUIPMENT DIMENSIONS (SI-UNITS - millimeters)

	Equipment				Chamber			
UNIT SIZE	W	H	D	Weight [kg]	LW	LH	LD	VOLUME [L]
6912	2580	1931	1780	1920	650	735	1200	850
91515	2880	2531	2080	3035	950	1330	1500	2000
151818	3780	2831	2380	4085	1550	1635	1800	4000
182124	4380	3118	2980	8800	1850	1835	2400	9000

EQUIPMENT DIMENSIONS (US-UNITS - inches)

	Equipment				Chamber			
UNIT SIZE	W	H	D	Weight [lb]	LW	LH	LD	VOLUME [L]
6912	101 1/2	76	70	4234	25 1/2	29	47	850
91515	113 1/2	99 1/2	82	6692	37 1/2	52 1/2	59	2000
151818	149	111 1/2	93 1/2	9008	61	64 1/2	71	4000
182124	172 1/2	123	117 1/2	19405	73	72	94 1/2	9000

UTILITY REQUIREMENTS

Refer to equipment drawing for installation details and specifications.

Utility	Data
Vaprox Hydrogen Peroxide Sterilant	STERIS patented process providing consistent Vaporized Hydrogen Peroxide Sterilant for maximum penetration and distribution
Softened Water	2-5 bar (29-73 psig) 570-770 L/h (150-203 gph) during cycle (depending on unit size and cycle type)
Instrument Air	5-8 bar (73 - 116 psig)
Drain	Gravity Discharge
Vent	Exhaust
Chamber Safety Relief Device	Release to open air, no back pressure
Unit Electricity	200-600 V 50-60 Hz 3 Phase

CUSTOMER IS RESPONSIBLE FOR COMPLIANCE WITH APPLICABLE LOCAL AND NATIONAL CODES AND REGULATIONS.

The base language of this document is ENGLISH. Any translations must be made from the base language document.

Loading STERIS VHP LTS-V Low Temperature Sterilizer (Typical)

Transfer Trolley (Typical)

For Further Information, contact:

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