Low temperature sterilizer
Getinge STERIZONE® VP4

GETINGE GROUP

This document is intended to provide information to an international audience outside of the US.
The STERIZONE VP4 sterilizer is a low temperature (41°C) sterilizing system that utilizes dual-sterilants, vaporized hydrogen peroxide ($\text{H}_2\text{O}_2$) and ozone ($\text{O}_3$), to achieve terminal sterilization of heat and moisture sensitive medical devices.

**Dynamic sterilant delivery system reduces operating costs and waste:** STERIZONE VP4 is the first sterilizer to adjust the amount of sterilant used thanks to its dynamic sterilant delivery system which automatically adjusts the quantity of injected sterilant based on the load composition, weight and temperature. With its large 34 kg capacity and short cycle time (46-60 minutes) the STERIZONE VP4 sterilizer enhance throughput and lower sterilization costs.

**Dual sterilant efficacy:** After the pressure set point is achieved, a small dose of ozone ($\text{O}_3$) is injected into the chamber, scrubbing residual hydrogen peroxide from load contents. Additionally, a chemical reaction forms hydroxyl radicals, adding to the lethality of the sterilization process.

**STERIZONE VP4 Test Pack:** The specially designed diffusion-restricted container that holds the proprietary biological indicator has an equivalent or greater resistance than worst case devices and loads in any configuration. The test pack is more resistant than the full half cycle of the STERIZONE VP4 sterilizer, providing advanced monitoring of process lethality for each day the sterilizer is used.

**125-280 mL solution:** The system uses a specially designed 280 mL bottle containing 50 weight-percent $\text{H}_2\text{O}_2$ solution. The sterilizer reads the barcoded bottle prior to initiating a cycle and will not operate if the date of the bottle exceeds the 24 month shelf life or 30 days once punctured, preventing accidental use of expired sterilant.
Intelligently simple
One automated programmed cycle for all loads

Improve processes and engineering controls

The STERIZONE VP4 sterilizer uses a single pre-programmed cycle removing the guesswork and potential human error. There is no need to sort instruments and choose the appropriate cycles as with other machines.

Mixed load capability delivers productivity
STERIZONE VP4 is the only low temperature sterilizer that can process a mixed load of up to 34 kg consisting of general instruments, single or double channel flexible endoscopes, and single or double channel rigid endoscopes, in the same cycle. This ability to run mixed loads significantly reduces labor costs by minimizing the amount of instrument sorting required, while maximizing the device turns.

Sterilize long and complex endoscopes
The STERIZONE VP4 sterilizer is also the only H₂O₂ system validated for the sterilization of multi-channel flexible endoscopes of up to four channels and 3.5 meters in length. The multichannel scope has been cleared to be sterilized with no additional load.

Virtually eliminate aborted cycles and downtime
Cycle aborts can be an issue with other hydrogen peroxide sterilizers if there is an inability to achieve very low chamber vacuum. This can occur when trace amounts of residual moisture are present on instruments at the start of the process, requiring the use of a warming cabinet to achieve complete drying prior to sterilizing. With the STERIZONE VP4 sterilizer there is no need to achieve “bone dry condition” eliminating this extra preparation step and additional time required (to heat and cool down) when cabinet drying instruments. This benefit further enhances a facility’s productivity and load throughput with the STERIZONE VP4 sterilizer.

Increase staff productivity and safety
A single fully automated cycle for all loads simplifies staff training and operation by removing the need for determining correct cycle selection, reducing the potential for error if the wrong cycle is accidentally selected. The STERIZONE VP4 sterilizer and O₃ process yields no toxic residues (only water vapor and oxygen). Processed instruments are ready for immediate use (no aeration time is required).
Intuitive backlit color touch screen user control that is easy to read and operate
- Single START button
- Provides cycle status
- Concise error messages

Easy paper change thermal printer provides documented evidence and shows performance details of each phase along with any errors or malfunctions that may have occurred

Large 125 liter chamber with a full mixed load capacity of 34 kg (exclusive of rack) that accommodates the adjustable 3 shelves loading rack

Sterilant bottle loading area and barcode reader to ensure the use of 125-280 solution and prevent the accidental use of expired sterilant. The specially designed 280 mL bottle contains 50% weight H₂O₂ solution that’s barcoded with an ID and date
Sterilization technology that is tested and proven

The STERIZONE VP4 sterilizer has been thoroughly tested in a variety of environments, and real-world performance data confirms that it:

- Reproducibly and repeatedly sterilizes challenging medical instruments under worst-case simulated-use conditions.
- Can sterilize a wide range of materials, including materials commonly used to manufacture reusable medical devices, according to half cycle and simulated-use test performance on inoculated material samples and medical devices.
- Cycle tested and validated with 9 different loads, varying in device composition and overall weight.

The STERIZONE VP4 sterilizer performance can be conveniently and precisely monitored using the:

- STERIZONE BI+ self-contained biological indicator (G. stearothermophilus)
- STERIZONE CI+ chemical indicator
- STERIZONE VP4 test pack – BI and CI are assembled in the special test pack which is more resistant than the most resistant item in the worst case load conditions.

Specifications

External dimensions
Dimensions, single door, (WxDxH) mm: 775 x 1235 x 1918
Dimensions, double door, (WxDxH) mm: 775 x 1130 x 1930

Internal dimensions
Chamber volume: 125 L

Overall weight
Single door: 565 kg
Double door: 625 kg

Components
STERIZONE VP4 sterilizer – single or double door
STERIZONE loading rack
125 -280 Solution
STERIZONE BI+ self-contained biological indicator
STERIZONE CI+ chemical indicator
STERIZONE VP4 test pack
Sterility assurance
The unique design of the STERIZONE VP4 test pack uses the STERIZONE biological indicator and chemical indicator combined with a diffusion restriction element. The result is a sterility monitoring device that provides equivalent or greater challenge than worst case devices and loads.

Getinge qualified field service provider
An expansive network of professional field service technicians offer a full range of installation, preventative maintenance, and repair service support for the STERIZONE VP4 sterilizer. They will assist with ensuring that the unit delivers the highest level of quality, safety and maximum uptime.

STERIZONE load cart
The stainless steel loading cart provides ease of movement and is designed for the ergonomic and efficient transfer of the loading rack into the unit. Four lockable swivel wheels allow the cart to be maneuvered around tight corners. Lower shelving provides additional storage space for supplies.

STERIZONE load rack
The specially designed loading rack is equipped with three perforated shelves, two of which are height adjustable, allowing the operator to configure the rack to accommodate all types of mixed loads. The configurable rack is a key system component in achieving high productivity and load throughput. The STERIZONE load rack and cart used in combination provides a “zero gravity” solution for the user eliminating the need to lift heavy loads for introducing into the chamber.

Accessories
Getinge Group is a leading global provider of innovative solutions for operating rooms, intensive-care units, hospital wards, sterilization departments, elderly care and for life science companies and institutions. With a genuine passion for life we build quality and safety into every system. Our unique value proposition mirrors the continuum of care, enhancing efficiency throughout the clinical pathway. Based on our first-hand experience and close partnerships, we are able to exceed expectations from customers – improving the every-day life for people, today and tomorrow.