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# STERIZONE® VP4 Low Temperature Sterilizer

## Product Specification

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**GETINGE**  
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The STERIZONE® VP4 Sterilizer is a dual sterilant, low-temperature sterilization system that uses vaporized hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) and ozone (O<sub>3</sub>). Its single cycle can sterilize a large number and wide range of compatible devices, creating a cost-effective, error-free sterilization process.

### Intended Use

The STERIZONE® VP4 Sterilizer is designed for the terminal sterilization of cleaned, rinsed, and dried moisture sensitive, heat sensitive metal and non-metal reusable medical devices in health care facilities. It can be used for both dedicated and mixed loads. The system has a single preset sterilization cycle for general instruments, single-channel flexible endoscopes, and rigid and semi-rigid channel devices, including single-channel and double-channel rigid endoscopes.

The STERIZONE® VP4 Sterilizer is ideal for use in facilities such as hospitals, central sterile supply departments (CSSD), operating room sterile supply units, outpatient surgery facilities, hospital laboratories, and biomedical research facilities.

### Product Innovations

- First (and only) dual sterilant sterilizer cleared by the FDA for sale in the US.
- First low-temperature sterilizer with a load-sensitive Dynamic Sterilant Delivery System™.
- First documented “wet” cycle with validated micro-condensation sterilant layer.
- First Biological Indicator Test Pack to survive past the first half-cycle.
- First single cycle, low-temperature sterilizer cleared to process a 75-pound load of general instruments, single-channel flexible endoscopes, rigid and semi-rigid channeled devices.



## Key Features

- Unique Dynamic Sterilant Delivery System™ automatically adjusts the quantity of injected sterilant based on the load composition, weight, pressure and temperature.
- Large 75-pound maximum load capacity and short cycle time (cycle time varies between 46 and 70 minutes depending on load size and composition) enhance throughput and lower sterilization costs.
- Produces no toxic residues, reducing risk to workers and potential patient health concerns.
- The software has been developed to monitor the critical performance parameters of the sterilization process and to confirm that the equipment is functioning correctly. Process parameters falling outside the acceptable range will cancel the cycle and provide appropriate information identifying the source of the problem.

## Cycle Description

The single pre-set cycle of the STERIZONE® VP4 Sterilizer uses hydrogen peroxide and ozone. The multiphase process involves the injection of vaporized hydrogen peroxide followed by the injection of ozone, which reacts with residual hydrogen peroxide to form hydroxyl radicals, adding to the overall lethality of the process.

### Pre-Conditioning Step

To prepare the load, the temperature must be between 20° – 26°C (68° – 79°F); do not place in warming/drying cabinet. Eliminate visible moisture droplets; do not leave the load inside the chamber if it's not ready to start.

Upon loading the medical devices into the sterilization chamber and closing the door, the chamber is subjected to a vacuum of 1 Torr.

### Phase 1

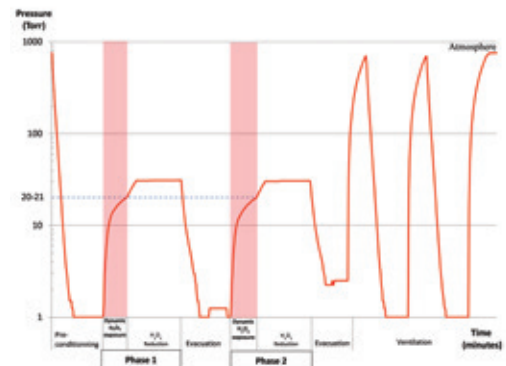
**Step 1: Dynamic H<sub>2</sub>O<sub>2</sub> Exposure:** A 50 weight-percent hydrogen peroxide solution (referred to as a 125 – 280 Solution™) is injected in vapor form into the sterilization chamber through a continuous micro-pulsed injection until a differential pressure set point of 19 Torr is reached (i.e. the actual chamber pressure is 20 Torr, less the initial vacuum of 1 Torr, which is equivalent to a “differential pressure” or “ΔP” of 19 Torr). The total amount of hydrogen peroxide introduced into the sterilization chamber and thus the duration of the injection varies depending on the load's size (e.g., surface area or weight), packaging and material composition, and temperature.

**Step 2: H<sub>2</sub>O<sub>2</sub> Reduction:** A set dose concentration of ozone (2 mg/L) is injected into the chamber and reacts with residual hydrogen peroxide to form hydroxyl radicals. The ozone additionally serves to break down and scrub residual hydrogen peroxide from the contents, packaging and chamber.

### Phase 2

During the second cycle phase, the same sequence is repeated, including the Dynamic H<sub>2</sub>O<sub>2</sub> Exposure and H<sub>2</sub>O<sub>2</sub> Reduction steps. The full cycle is then completed with an evacuation and ventilation, through catalytic converter to the atmosphere, at which point the chamber door can be safely opened.

Processed medical instruments are ready to use immediately after the cycle ends; no aeration is required.



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## Cycle Performance Documentation

All critical process parameters are monitored during the cycle and the sterilizer provides cycle printouts for verification. Users can enter a load and an identification number prior to starting the cycle.

During the cycle, the status of the cycle step is shown on the screen at the end of each step, and the step parameters are printed. At the end of the overall cycle, the screen indicates "Cycle Completed" and produces a paper printout. During the sterilization cycle, if one of the critical process parameters is not reached, the cycle will abort and the reason for the interruption will be displayed on the screen and on the printout. Spaces are provided for the user's initials or signature at the bottom of the printout.

For optimal performance, the user must ensure the materials, instruments, and devices to be sterilized are thoroughly cleaned and dried, that the instrument manufacturer's instructions are followed, and that the sterilization process is monitored with biological and chemical sterilization process indicators in accordance with the recommendations provided in the STERIZONE® VP4 User Manual.

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## Design Features

### Control System

The control system receives, processes and uses operating data during the sterilization process, and manages all input and output data for the sterilizer's operations. The sterilizer is also equipped with a touch screen that interfaces between the user and the sterilizer, enabling the user to start and stop the sterilizer, as well as monitor the sterilization phases. A printer provides a variety of information on the progress of the sterilization process. After each sterilization cycle, the printer generates a printout for the user. All of the components mentioned above are located either behind the control panel or inside the sterilizer upper front panel.

### Sterilization Chamber

The sterilization chamber construction and features are designed to be airtight so that a vacuum can be generated and maintained to contain the vapor and gases which are generated during the sterilization cycle.

### Instrumentation

A pressure transducer provides information on the pressure inside the sterilization chamber. The heating elements maintain the chamber walls at the optimal temperature for sterilization. The temperature sensors, which are RTDs (resistance temperature detectors), measure the temperature of the ozone generator cooling system, sterilization chamber and H<sub>2</sub>O<sub>2</sub> supply and vaporization systems. The ozone monitor measures the ozone concentration produced by the ozone generation unit and sends the results to the PLC (Programmable Logic Controller). The PLC sends a feedback signal to the ozone generation unit to control generator power and regulate the ozone concentration. All information is sent as analog signals to the A/D converter, which then processes and converts them into digital format to be transmitted to the PLC by a serial link called DeviceNet™. The electrical distribution system is located at the front of the sterilizer. It can be accessed via the upper front panel of the sterilizer.

### Panels

The sterilizer rear and side panels are powder-paint coated steel. The front covers are made of polymer. Four front panels provide access to the following parts of the STERIZONE® VP4 Sterilizer:

- The upper front panel provides access to the control panel (PLC, electrical and controls) as well as the printer and touch screen.
- The middle front left panel provides access to the chamber.
- The middle front right panel provides access to the hydrogen peroxide compartment.
- The lower front panel provides access to the compressed air and cooling systems.

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## Design Features (cont.)

### Hydrogen Peroxide Delivery System

The hydrogen peroxide delivery system is used to deliver and vaporize the 125-280 Solution™ into the sterilization chamber during the dynamic exposure portion of the cycle prior to the ozone injection. It can be divided into two subsystems: the delivery system and the vaporization system. The delivery system includes all components related to the retention of the 125-280 Solution™ bottle and the solution delivery under vacuum up to the dual-valve vaporization system. Also included is a bar code reader to verify the solution origin and that the solution date and initial date used is within acceptable expiration time period. The vaporization system includes all components related to the vaporization and injection of a specific volume of solution into the sterilization chamber.

### Ozone Generator

The ozone generation unit is used to generate ozone on site at the flow and concentration required for sterilization. The ozone is produced using medical-quality oxygen (USP grade). Oxygen enters the generator, where it is partially converted into ozone by an electrical discharge. The gas exiting the ozone generation unit is a mixed gas containing oxygen and ozone. The ozone generator is cooled down by circulating glycol in the body of the ozone generator.

### Cooling System

The cooling system is used to maintain the ozone generator cells at operating temperature to ensure optimal performance. It cools the ozone generator down to 4°C – 6°C (39.2°F – 42.8°F) and then maintains it within this temperature range.

### Catalytic Converter

The catalytic converter receives the flow out from the chamber and is used to break down ozone and hydrogen peroxide into water vapor and oxygen.

### Vacuum System

The oil-free vacuum pump is used to create a vacuum required as a sterilization cycle parameter. The pump also runs continuously for a short period of time during and at the end of the cycle in order to evaporate all traces of water condensation in the catalytic converter.

### Compressed Air System

The compressed air system consists of a self-contained and self-controlled stand-alone unit operating under 230 V. It compresses ambient air up to 90 psi and stores it in a one-liter tank. There is safety valve with a set point of 145 psi. This tank feeds compressed air regulated to 70 psi, into the H<sub>2</sub>O<sub>2</sub> delivery system and valves in the vacuum system via pilot valves.

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## Standard Safety Features

A Fault Tree Analysis and Mitigation (FTA-MIT) and a Failure Mode Effects and Criticality Analysis (FMECA) have been conducted on the entire system of the STERIZONE® VP4 Sterilizer to ensure safety features and control redundancies have been implemented in the design and will be maintained during the manufacturing, installation, maintenance and servicing of the sterilizers.

The toxicity of hydrogen peroxide and ozone are well documented in scientific literature, with relevant standards having been established by the United States Occupational Safety and Health Administration (OSHA). Both hydrogen peroxide and ozone decompose with the formation of water (H<sub>2</sub>O) and oxygen gas (O<sub>2</sub>). The STERIZONE® VP4 Sterilizer is equipped with a catalytic converter to decompose the residual hydrogen peroxide and ozone to oxygen and water vapor before they are returned to the room.

The airborne concentration of residual hydrogen peroxide and ozone levels remaining in the breathing zone of the operator immediately after sterilization of different loads of medical instruments satisfies all current regulatory standards.

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## Quality Statement

Confidence in the Getinge Group is the most important quality criteria. This is the hallmark of all our external and internal commitments, activities, and products. Products and services supplied by Getinge conform to the agreed terms and expectations. The achievement of these quality goals is the basis for a continued competitive and successful enterprise.

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## Standards and Codes

The STERIZONE® VP4 Sterilizer has been designed to comply with or meet the requirements of:

- Canadian Standard Association (CSA) Standard C22.2 No 61010-1: 2004
  - Underwriters Laboratory Standard UL 61010-1: 2004
  - Federal Communications Commission (FCC) Part 18/EN 55011
  - International Electrotechnical Commission (IEC) Standard IED 61326: 2012
  - International Electrotechnical Commission (IEC) Standard 61010-1: 2001, 61010-2-040: 2005
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## Documentation

The following documentation will be sent out together with the product:

- MA-200-044 Quality Assurance Certificate for STERIZONE® VP4 Sterilizer (English).  
(Declaration of Conformity (paper)).
  - MA-200-033 STERIZONE® VP4 Sterilizer User Manual (English).
  - MA-200-043 Packaging Item.
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## Disclaimer

Do not use this product specification for installation of equipment.  
Subject to change without notice.

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## Technical Data

### REQUIREMENTS

- Oxygen (94% pure and greater) via tanks
- Electrical supply of 208 V, 240 V
- 125-280 Solution™ containing 50% hydrogen peroxide by weight

### OPERATING CONDITIONS

- The load to be processed should be maintained between 20°C to 26°C (68°F to 78°F).
- The vaporizer temperature is 120°C; the chamber wall temperature is 41 ± 3°C.

### CHAMBER VOLUME

- 4.4 Cu.-Ft. (125L)

### WEIGHT

- Weight: 1,245 lb (565 kg)

### EXTERIOR DIMENSIONS

- H: 75.5 in. (191.8 cm)
- W: 30.5 in. (77.5 cm)
- D: 48.6 in. (123.5 cm)

### COMPONENTS

- STERIZONE® VP4 Sterilizer
- STERIZONE® Loading Rack
- 125-280 Solution™
- STERIZONE® BI+ Self-contained Biological Indicator
- STERIZONE® CI+ Chemical Indicator
- STERIZONE® VP4 Test Pack

### SINGLE DOOR MOUNTING

- Recessed or freestanding
- No exhaust gas ventilation duct is required as long as the room is adequately ventilated

### ACCESSORIES & OPTIONS

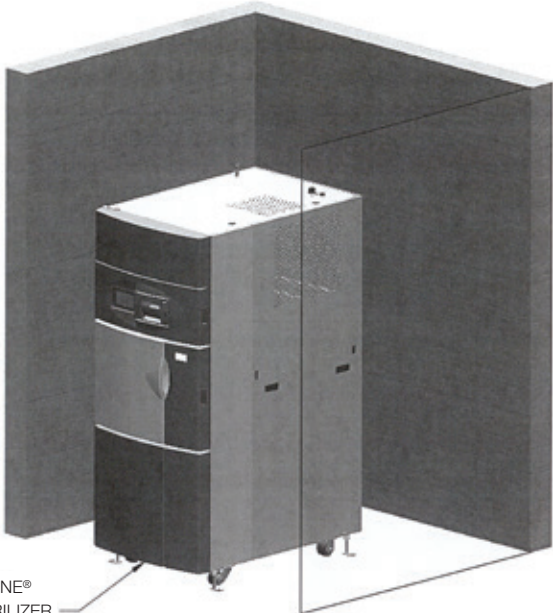
- STERIZONE® BI+ Self-contained Biological Indicator
- STERIZONE® CI+ Chemical Indicator
- Test Pack

**STERIZONE® VP4 Sterilization System Dimensional Information.**  
**For additional details, please refer to installation manual. Documents required for installation:**  
**AA-200-002 : STERIZONE® VP4 + Arrangement Drawing**  
**MA-200-046: Site Preparation Guide for the STERIZONE® VP4 Sterilizer**

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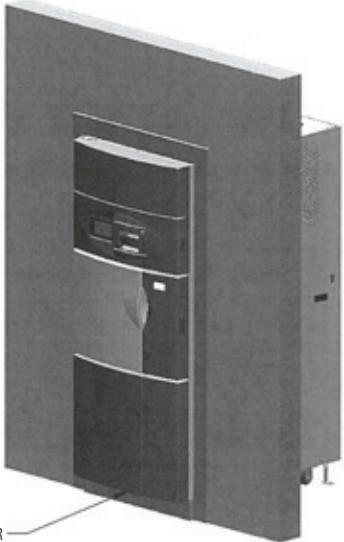
  



**STERIZONE®  
VP4 + STERILIZER**

**FREESTANDING INSTALLATION**  
Refer to page 9

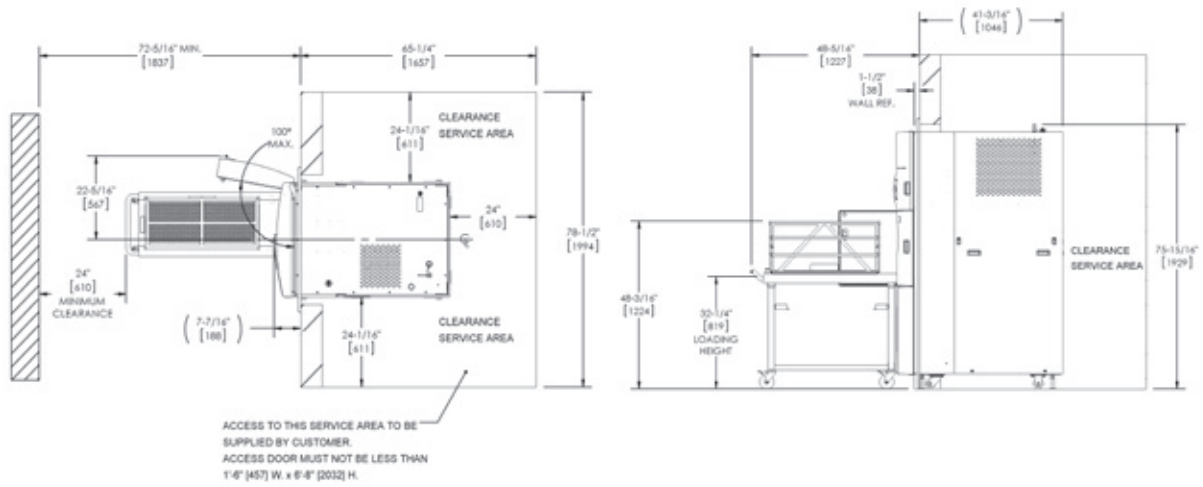


**STERIZONE®  
VP4 + STERILIZER**

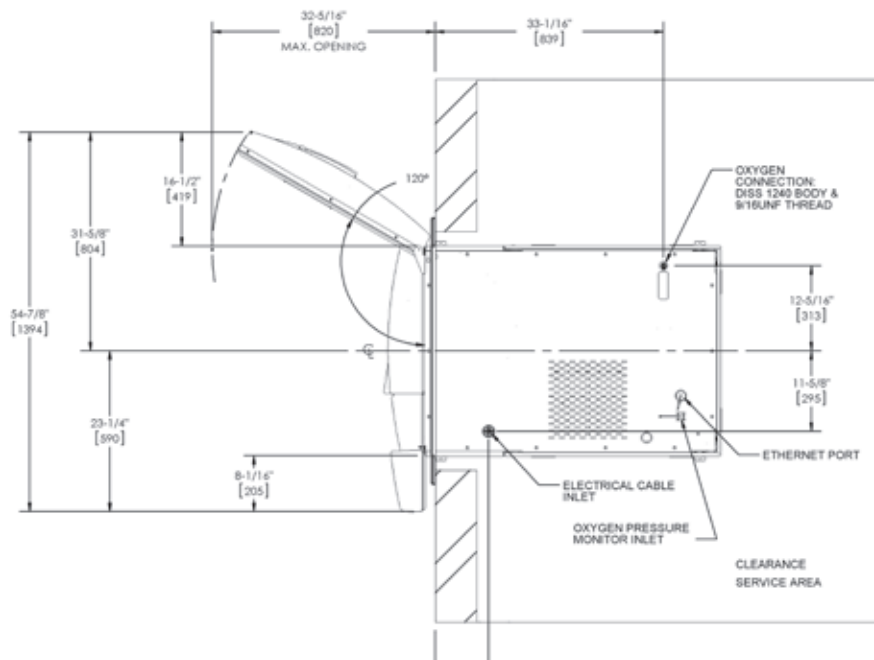
**RECESSED INSTALLATION**  
Refer to page 8

**STERIZONE® VP4 Sterilization System Outer Dimensions.**  
**For additional details, please refer to installation manual.**

**RECESSED INSTALLATION**



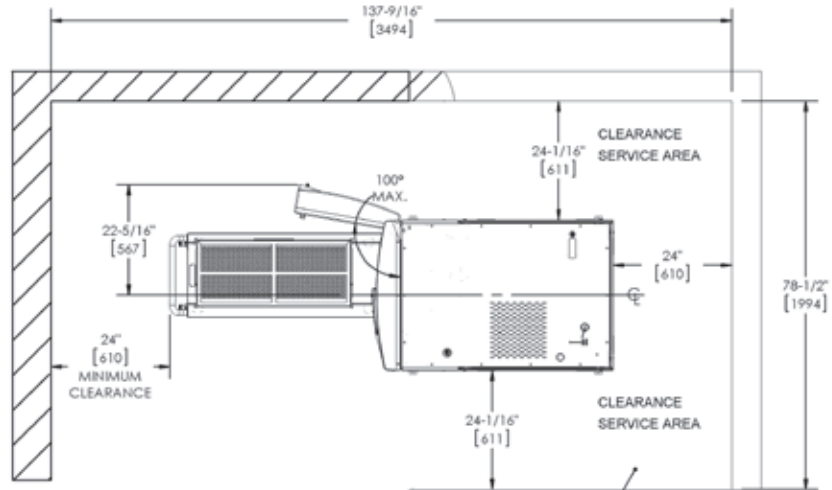
**OXYGEN AND ELECTRIC SUPPLY LOCATION**



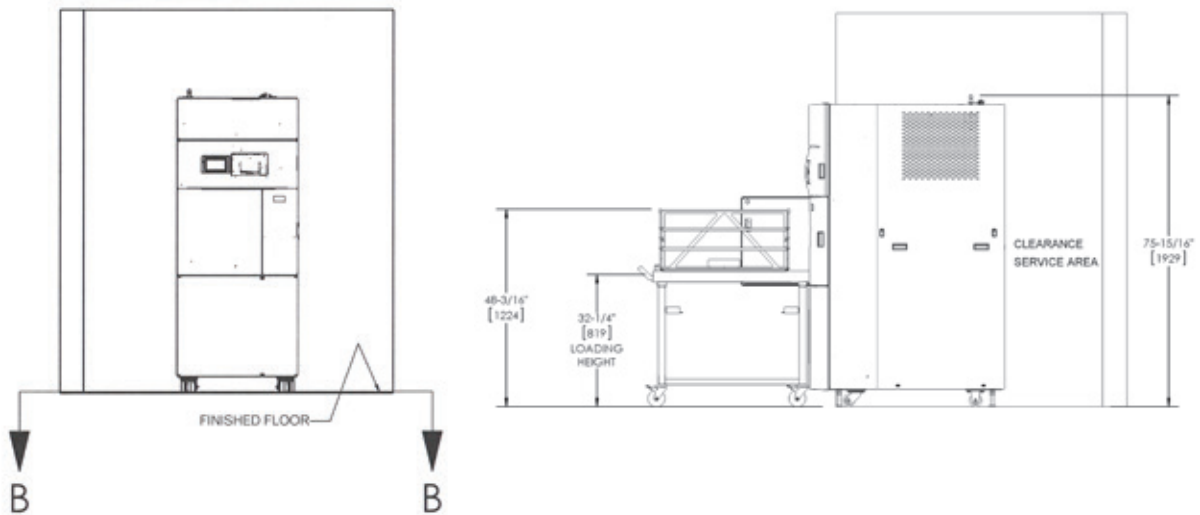


**STERIZONE® VP4 Sterilization System Outer Dimensions.**  
**For additional details, please refer to installation manual.**

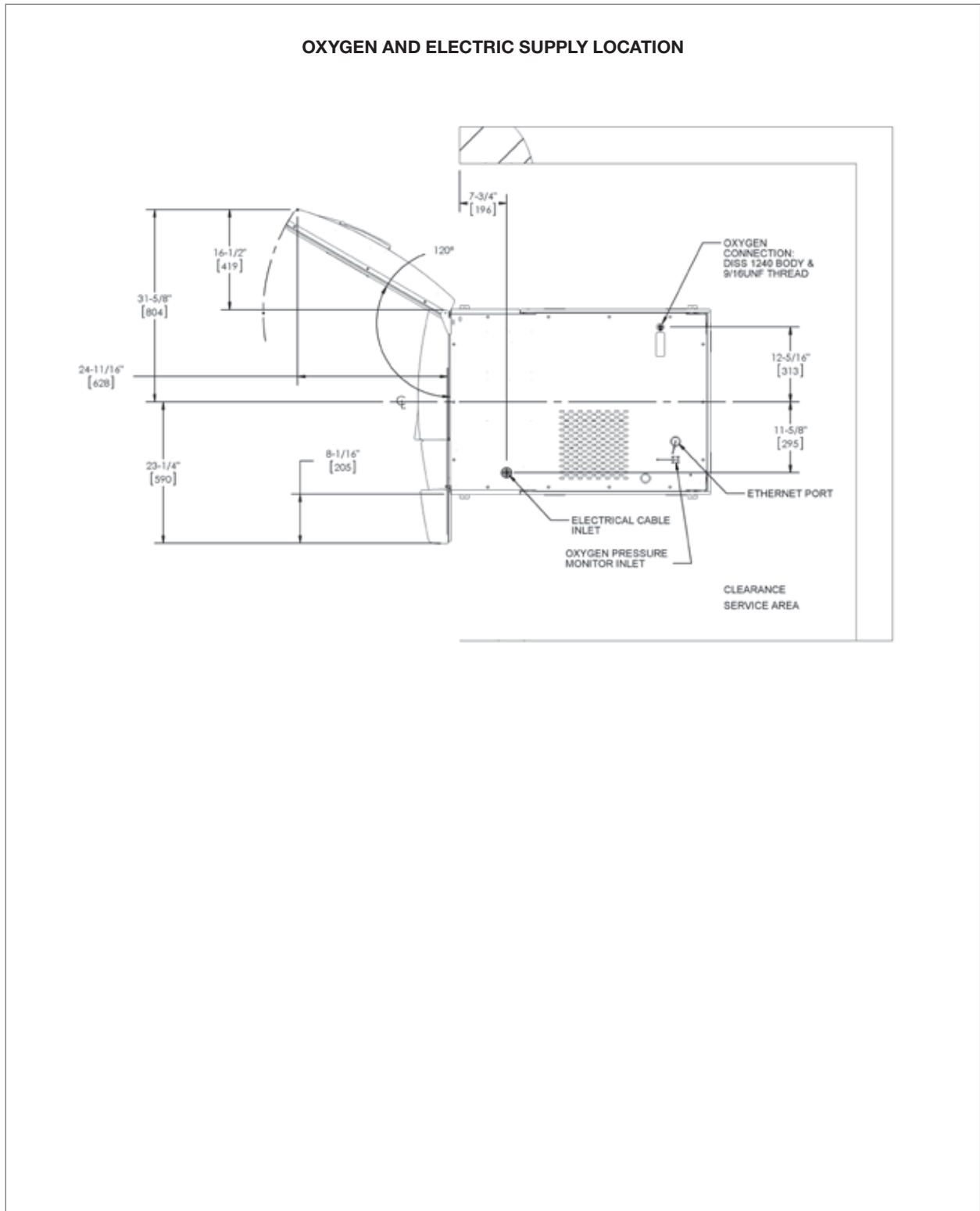
**FREESTANDING INSTALLATION**



ACCESS TO THIS SERVICE AREA TO BE SUPPLIED BY CUSTOMER.  
 ACCESS DOOR MUST NOT BE LESS THAN 1'-6" [457] W. x 6'-8" [2032] H.



**STERIZONE® VP4 Sterilization System Outer Dimensions.**  
For additional details, please refer to installation manual.



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