Product Specification

Low Temperature Sterilizer
Getinge Poladus 150

Application

Backed by more than 100 years of experience, Getinge's global reach and extensive installed base, provides us with the knowledge to assist our customers in planning for optimal and efficient workflows. In this way we help you maximize throughput and provide solutions for efficient production. With our equipment, project management, logistics, service and training, you can count on Getinge – right from the start.

Getinge Poladus 150 is a fully automatic low-temperature vaporized hydrogen peroxide sterilizer. It has pre-set programs for the most common sterilization processes for general-purpose hospital use. The program cycles employ mechanical air removal and injection of vaporized hydrogen peroxide for assured sterilization, and aeration via a catalytic converter for the removal of residuals. .

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 continued competitive and successful enterprise.

Intended Use

The low temperature sterilizer 'Getinge Poladus 150', together with 'Getinge Poladus H2O2 Sterilant' are intended for use in terminal sterilization of cleaned, rinsed, and dried, reusable metal and nonmetal medical devices used in healthcare.

Order Information

About this Form

This part of the document is an order form. Mark your selections.

☐ = Standard selection (included in base price)

◯ = Optional selection (not included in base price, additional cost)

Chamber Volume and Size

Getinge Poladus 150 configurations	Door	Inner Dimensions (W x H x D)	Chamber Volume	Usable Space (W x H x D)
Getinge Poladus 150 VH2O2 H1	Single	475 x 421 x 761 mm	152 L	425 x 385 x 761 mm
Getinge Poladus 150 VH2O2 H2	Double	475 x 421 x 769 mm	154 L	425 x 385 x 769 mm

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Installation

Getinge Poladus 150 is designed to cover a wide range of customer requirements concerning installation of the sterilizer.

Number of Doors

☐ Single door

◯ Double door (pass through configuration)

Installation

Wheels for installation
Used to move equipment for servicing in installations in tight spaces, where a pallet truck is not available.

◯ Installation with Cross Contamination Barrier (CCB)

The CCB is an air pressure differential seal designed to prevent cross-contamination between classified zones of the facility and to keep an air differential pressure between zones. The CCB requires both a frame that is mounted onto the sterilizer at production, and a wall connector kit for CCB that is mounted during installation (between the frame of the unit and the wall in the healthcare facility).

Wall connector kit

◯ One wall connector kit for loading or unloading side

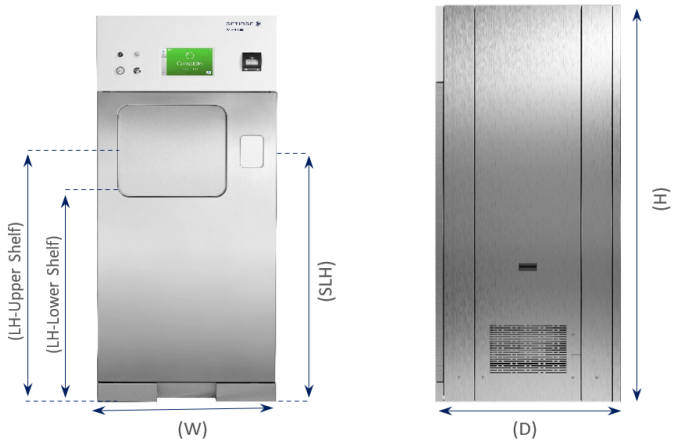
◯ Two wall connector kits for loading and unloading side

Wall connector kit: White aluminium and plastic trimming to cover the gap between the sterilizer and the wall for recessed installations. Pieces for one wall, per kit.

Network connections

Getinge Poladus 150 sterilizers support Ethernet communications on a connection at 100 Mbit/s, half-duplex. It supports standard DHCP and IP addressing technologies. The network supports routing and firewalling: blocking of specific ports and traffic.

Exterior dimensions of device



	Width (W)	Depth (D)	Height (H)	Loading Height (LH)	Sterilant Loading Height (SLH)
			Feet / Wheels	Upper and lower shelf	Feet / Wheels
Getinge Poladus 150 VH2O2 H1	785 mm	920 mm	1791 mm	1198 / 1008 mm	1180 mm
Getinge Poladus 150 VH2O2 H2					

H1: Single Door - H2: Double Door

Service Access

Getinge Poladus 150 is serviced from the front and one of the sides.

Operational Environment

Getinge Poladus 150 is designed for indoor use, with ambient operating temperature 15-35°C, maximum relative humidity 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 40°C, and altitude up to 1000m.

Getinge Poladus 150 is suitable for installations in altitudes up to 3000m. For installations above 1000m, additional installation conditions apply, as described in the installation manual.

H_2O_2 Sterilant

Getinge non-reusable H_2O_2 Sterilant bottles containing 59%w/w Hydrogen Peroxide (H_2O_2) are intended for use with Getinge Low Temperature Sterilizers, for the intended purpose of a broad spectrum sterilant in sterilizer's process.

H_2O_2 Sterilant RFID Traceability

H_2O_2 sterilant bottles feature an RFID tag that is used by the sterilizers to confirm that the bottle is within shelf-life, has sufficient remaining volume to conduct a sterilization cycle, and is the correct bottle manufactured by Getinge and validated for use with the sterilizer. Expired or depleted H_2O_2 Sterilant bottles will be rejected by the sterilizer, prompting the user to replace with a new and valid bottle.

H_2O_2 Sterilant Bottle Types

Reference	Packing unit	Cycles / Bottles	Shelf-life	Expiration after Puncture)
6036001701	5 x 29.8 ml	1	3 months	7 days
6036001601	6 x 240 ml	15	12 months	30 days

H_2O_2 Shelf-life and Expiration

The H_2O_2 sterilant will be 59.1 +/- 0.5% w/w when manufactured and filled. The shelf-life testing validates that the peroxide concentration remains above 55% w/w at the end of its maximum shelf-life. Due to the accelerated decomposition of a punctured H_2O_2 sterilant bottle that is placed inside the sterilizer, its expiration date will be reduced after being inserted. The user is prompted to replace the H_2O_2 sterilant bottle via the control panel if the present sterilant bottle is empty or expired. Further, the number of remaining cycles with the bottle, and the expiration date can be viewed on the start screen of the control panel.

Sterilant hatch

The sterilant hatch is fully automatic in operation and is opened and closed by an electric motor. Hatch open and close operation is controlled via push buttons on the control panel. Once a new H2O2 sterilant bottle is inserted, the user is prompted via the control panel to accept pairing. Following confirmation of pairing, a motorized injection needle is lowered to puncture the seal on the H2O2 sterilant bottle. The user cannot remove the bottle without running an H2O2 Empty program (see Section “Programs”) or overriding for manual disposal by a superuser.

Disposal

Getinge Poladus 150 features an H2O2 Empty program (see Section “Programs”) that reduces the remaining sterilant from the bottle. A small volume left at the bottom of the bottle requires disposal as per User Manual. A super user is permitted to override the H2O2 Empty program in order remove the bottle for manual disposal.

Ordering

H2O2 Sterilant bottles can be ordered via Getinge European Distribution Center (EDC) for all countries within Europe. Countries outside Europe please order directly via Quadralene.

Mechanical

Chamber

Surfaces in contact with the sterilization process on the chamber (4mm thickness) and the door is made from AISI 316L/1.4404 stainless steel. Internal surfaces are highly polished. The internal corners have a radius (also to aid cleaning). A stainless steel mesh strainer protects the drain port from blockage by debris.

The sterilizer chamber is completely insulated and mounted on a painted carbon steel framework with adjustable feet.

Loading Shelves

The chamber contains two shelves with raised walls at the sides to facilitate diagonal positioning of goods packaged in Tyvek, and open front and back to facilitate insertion of square profile goods (such as containers and/or wrapped trays).

The loading shelves can be partially retracted. The shelves can be removed for servicing needs with the aid of a tool.

Loading shelves have dimensions 160 x 420 x 715 mm (H x W x D). Please see section on process.

Validation Connection

The chamber is provided with an ISO 2861, DN16 KF connection that can be used for a vacuum/pressure gauge.

Automatic, Vertically Sliding Door(s)

The door is fully automatic in operation and is raised and lowered by a linear motor. The door is sealed with a silicon rubber 'O' ring. Door operation is controlled via push buttons on the control panel and a foot operated switch (as standard).

A line beam safety sensor stops the door if it is obstructed while closing, thus protecting the operator or loading equipment.

Personnel Safety Features

Getinge Poladus 150 is equipped with several safety features, as described below:

- Door beam: Prevents hitting an obstruction when closing the chamber door.
- Door power limiting: Prevents crushing obstruction 150N if door beam were to fail.
- H_2O_2 Containment: During a power failure all channels to exterior are blocked in order to prevent H_2O_2 leak outside of the chamber. Once power is recovered, equipment will finalize the cycle cancellation eliminating all H_2O_2 residuals for the chamber.
- Error Alarms: Designed to alert and abort in the case the process is out of specification.
- Emissions test – compliant to occupational health standards.
- Bottle empty program: H_2O_2 in the bottle is reduced by the sterilizer limiting contact with chemical.
- Automated bottle hatch: Prevents access to H_2O_2 bottle until emptied.
- Thermostats on all heated surfaces: Prevent over-heating of components in case of electrical/electronic fault.
- Electrical Safety: this machine is compliant with the relevant electrical safety standards.
- No sharp edges: The sterilizer is designed to prevent interacting with sharp edges on the access points that a user can reach.

Mechanical Vacuum Pump

Due to deep vacuum requirements, Getinge Poladus 150 features a high-performance, dual-stage rotary vane pump with a pumping speed up to 65m3/h, and a high water vapour capacity up to 1400g/h. The vacuum pump is mounted on vibration isolators for quiet operation. The pump exhaust is protected with an oil-mist filter.

Catalytic Converter

All the vacuum flow from the chamber to the inflow on the vacuum pump passes through a custom designed catalytic converter. The catalytic converter controls emissions by breaking down any peroxide residue into water vapour and oxygen. As a result, it ensures that there are no H2O2 residuals escape to the environment from the exhaust during the vacuum process and increases MTBF by protecting the vacuum pump from the accumulation of H2O2.

Air Filters

Disposable air filters are provided, for filtering of the atmospheric air, entering the chamber. The air is used to equalize the chamber pressure at various stages of the sterilization cycle. The filter separation efficiency is 99,995% for particle size 0,1-0,3 µm (H14 HEPA).

Valves and Components

All process valves are electrically operated solenoid valves and peristaltic pumps.

Use of chemically resistant stainless steel valves provide longer service life and less maintenance when exposed to H2O2. All standard components are non-proprietary and easily sourced.

Fine control of H2O2 extraction/preparation and injection is controlled via precise peristaltic micro-dosing pumps. The dosing pumps operate without direct contact with H2O2, and therefore provide longer service life and less maintenance when exposed to H2O2. The pumps use specialized PharMed BPT pipes, with high compatibility and 30x greater life span than conventional silicone.

Pipes and Valves

All valves are made of stainless steel, all piping is made of stainless steel or polymer hose.

Electrical

Power Rating

Getinge Poladus 150 has a single power supply designed to cover all regions with at least one option of 1Ph or 3Ph and the supply is rated for:

- 200-240VAC 50/60Hz* (Ph+N or 2Ph)

Note! The sterilizer can be connected Phase + Neutral or 2-Phases in order to achieve the rated voltage of 200-240VAC, depending on the facilities mains supply.

Check your facilities power supply capacity towards required electrical requirements above. Getinge Poladus 150 can be installed into sites that provide the following conditions:

Installation Site Conditions

1P 50/60 Hz*	**3P 50/60 Hz***	
220V	200V	2Ph + Gnd
230V	208V	2Ph + Gnd
240V	220V	2Ph + Gnd
	230V	2Ph + Gnd
	240V	2Ph + Gnd
	380V	Ph + N + Gnd
	400V	Ph + N + Gnd
	415V	Ph + N + Gnd
*16A		

Mains supply can be routed from the top or the right side (when facing the loading side) of the sterilizer. Mains supply cable is not supplied with the sterilizer.

Room ventilation status signal and optional Ethernet cables can only be routed from the top of the sterilizer.

On installation, the service technician will need to have materials to connect to the X0 and X3 terminal blocks.

Language

The user interface is available in 30 languages and can be set on-site.
The user interface and the process report print out will be in the same language.

Tick your selections for user manual and user guide in the check boxes below, English is default. Additional languages will be available gradually. The installation manual and service manual are available in English only.

User manual	1-page user guide	Installation manual	Service manual
◯ English	◯ English	◯ English	◯ English
◯ Swedish	◯ Swedish		
◯ German	◯ German		
◯ French	◯ French		
◯ Spanish	◯ Spanish		
◯ Italian	◯ Italian		

Process and Instrumentation

H_2O_2 Injection System

The H_2O_2 sterilant is extracted from the bottle and measured in the injection system to ensure control of the quantity of sterilant to be injected into the chamber. The injection system utilizes micro-dosing measurement and level sensors for increased accuracy and control of H_2O_2 quantity. The injection system features a robust single block design and therefore provides longer service life and less maintenance.

VH2O2 Concentration

Each sterilization cycle introduces a measured quantity of H_2O_2. As a result, the sterilizer can ensure that vapour injected into the chamber reaches effective concentration. Furthermore, the chamber is heated to a set temperature. The sterilizer can monitor pressure changes to ensure the vapor conditions are maintained at an effective range via rigid tolerance levels.

Vaporizer

The H2O2 sterilant is injected into the chamber as a vapour, via a vaporizer which is designed to flash vaporize the H_2O_2 and hence ensure mobility of H_2O_2 onto the load.

Control System

The G1 controller is dedicated to control Getinge sterilizers. The control system is operated via a very easy-to-use user interface, Centric. The G1 controls all system functions and monitors system operations. G1 both visually and audibly alerts the operator of program malfunctions and provides visual indication of process status. The G1 controller has a built-in battery backup that can support the controller and operator panel for up to 10 seconds in case of power loss.

Operator Panels

Getinge Poladus 150 has operator panels mounted beside the chamber for ergonomic reasons as standard.

Control side:
As standard Getinge supply the G1 Panel. This is a 10.1" touch panel with the Getinge Blue Circle.

Non-control side:
As standard (for double door units) Getinge supply the G1 Panel. This is a 10.1" touch panel.

Independent Monitoring and Records

Getinge Poladus 150 Supervisor is an independent monitoring and documentation system. The Supervisor evaluates the process independently. The system also has an interlock functionality included, preventing doors from opening in unsafe state. Process data from the Supervisor is either printed on a paper or is enabled to be stored on the network. For Getinge Poladus 150, Supervisor is included as standard.

Hands-free operation

For the convenience of hands-free opening and closing of the sterilizer's door, foot operation is standard for Getinge Poladus 150. The foot switch is triggered by a non-contact line beam sensor which detects user's foot when placed into the recess at the bottom of the sterilizer.

RFID

- ○ User authentication via RFID on control side.
  Using a RFID tag to authenticate the user eliminates the need to enter user ID and password when there is a need to secure only authorized personnel performing certain tasks.

USB connection

USB connection on the front panel.

By using the USB connection, the user can download cycle history.

Chamber heating

All surfaces of the chamber and doors are covered in electrical heating jacket segments. The heating jacket contains sensors for optimal control of individual segments, thermostat overheating protection, and is insulated in order to maintain energy efficiency. The operating temperature for instruments inside the chamber is maximum 55°C (131°F).

Alarms

Automatic process checking and failure corrections are provided with the control system. In the event of an anomaly during the sterilization cycle, the process enters an alarm phase which safely will end the process automatically.

Process Reports

Getinge Poladus 150 comes with a "2" Fascia printer" as standard for process reports. For double door units the fascia printer can be relocated to the unloading side by service (e.g. on installation).

Process reports can also be produced in different ways to suite the facility's workflow:

- A4 printer. For printout of process report on a printer directly connected to the sterilizer.
- Enabling network printing for printout of process report. For network printing, Lexmark printers are recommended. One printer per order is needed, please choose A4 printer recommended by Getinge.
- Enabling network storage. Generating a process report in PDF format.
- User authentication via RFID. Using a RFID tag to authenticate the user eliminates the need to enter user ID and password when there is need to secure only authorized personnel performing certain tasks.
- Multilanguage. Enabling possibility to use different language on operator panel and process report. Make your choice in the language section.

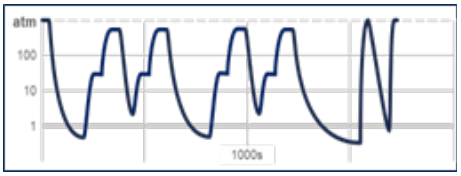
Other features

Hibernate/Wake up timers. As an alternative to manual shut downs and start ups, the sterilizer can be set to automatic hibernation and wake up by timers. The benefit of this is energy saving by reducing stand-by times and still enable the sterilizer to be ready to use when a shift starts.

Sterilization Programs

Getinge Poladus 150 is equipped with a set of pre-programmed cycles. The three (3) included sterilization cycles are for the following applications:

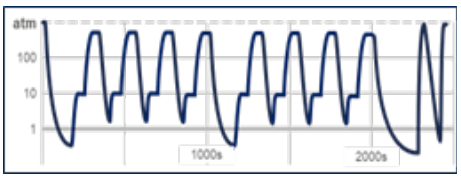
P1. Non-Lumen Program [29 min]: provides fast turnaround for sterilization of medical instruments (forceps, scissors) and non-lumen rigid endoscopes.



- Metal and non-metal medical instruments including non-lumen rigid endoscopes.
- Mated surfaces made of stainless steel or titanium.
- Surfaces and instruments having diffusion-restricted spaces, such as the hinged portion of forceps and scissors.

Validation loads consisted of a both shelves loaded with representative instruments with a total weight of 14 kg (30.9 lbs) including the weight of wrapped plastic or metal trays and/or containers, with each shelf having a weight of maximum 7 kg (15.4 lbs).

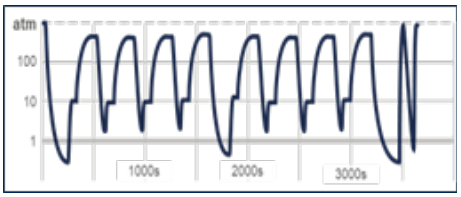
P2. Flexible-Lumen Program [42 min]: is designed to sterilize flexible endoscopes and non-lumen medical instruments (forceps scissors).



- Metal and non-metal non-lumen instruments with diffusion-restricted spaces or mated surfaces such as the hinged portion of forceps and scissors. Mated surfaces are limited to stainless steel, titanium, Ultem®, and Radel®.
- Polytetrafluoroethylene lumen greater than or equal to 1.0 mm internal diameter and less than or equal to 1200 mm length.
- Single channel flexible endoscopes with a lumen greater than or equal to 1.2 mm internal diameter and less than or equal to 1150 mm length.
- Dual channel flexible endoscopes with lumen greater than or equal to 0.8 mm internal diameter and less than or equal to 990 mm length.

Validation loads consisted of loads with (i) a maximum of two flexible endoscopes processed in a single load (one scope per shelf/tray, with no additional load allowed, or (ii) a single flexible endoscope processed in one shelf with up to 7 kg (15.4 lbs) non-lumened load on the other shelf.

P3. Rigid-Lumen Program [60 min]: is designed to sterilize endoscopes with rigid lumen and medical instruments (forceps, scissors).



- Metal and non-metal non-lumen instruments with diffusion-restricted spaces or mated surfaces such as the hinged portion of forceps and scissors. Mated surfaces are limited to stainless steel, titanium, Polyacetal, Ultem®, and Radel®.
- Stainless steel lumen greater than or equal to 0.7 mm internal diameter and less than or equal to 500 mm length.
- Single channel semi-rigid endoscopes with lumen greater than or equal to 1.0 mm internal diameter and less than or equal to 530 mm length.
- Dual channel semi-rigid endoscopes with lumen greater than or equal to 0.8 mm internal diameter and less than or equal to 523 mm length.

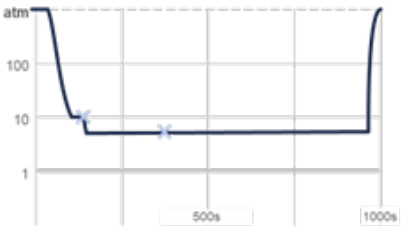
Validation loads consisted of a load of up to 10 kg (22 lbs) including the weight of wrapped plastic or metal trays and/or containers, with each shelf maximum of 5 kg (11 lbs). A maximum of fourteen lumened devices may be processed in a single load, divided equally between the top and bottom shelves.

Other Programs

H2O2 Empty: Is a process intended to safely reduce the amount of remaining H2O2 in the sterilant bottle. The program is intended to be used when the user is prompted to replace the H2O2 sterilant bottle (i.e. if sterilant in the bottle is empty or expired).

The user must run this program before the controller enables the open hatch button to be active. The duration of the process can vary depending on the remaining volume of H2O2 in the sterilant bottle. An information view will be presented to the user when the open hatch is selected to display the estimated time for the process to reduce H2O2 in the bottle and ask for a confirmation. Following confirmation, the user will be prompted to ensure that the chamber is empty. Alternatively, a Super User can override the process for direct extraction of an unemptied bottle for manual disposal. The superuser override is intended to be used only in conditions where there is urgent reprocessing needs.

Leak Test: The sterilization process is sensitive to ingress of air into the chamber. If the chamber is not leak-tight, sterilization efficacy may be impaired. Getinge Poladus 150 is equipped with a leak test to confirm leak tightness of the chamber. Cross-check between the control and supervisor pressure sensor is conducted at the start of the vacuum leak test to ensure integrity of measurement chain.



	Parameter		Range	Delivered
12	Cross-check Pressure	mbar	10	10
3	Cross-check Stabilizing Time	min	0.5	0.5
4	Test pressure	mbar	0.5	0.5
5	Test Stabilizing Time	min	5	5
6	Test Time	min	10	10
	Leak integrity	mbar	≤2	≤2

Monitoring and Testing Devices

Routine Monitoring

Biological Indicators:

Self-contained biological indicators (BI) are intended for routine monitoring of hydrogen peroxide sterilization cycles. The Biological Indicators contain 10^6 population of spores (Geobacillus Stearothermophilus). Getinge offers the following types of BI for VH_2O_2 monitoring:

- V**H2O2 BI (24h) (item number 6005500025):** produces visible confirmation of conditions to kill bioburden within 24 hours.
- **Superfast BI (item number 6005500507):** produces verifiable confirmation of conditions to kill bioburden within 20 minutes.

The Biological Indicators are to be placed (individually packed) with the load in the first sterilization cycle of its type every day, and recommended to be used with every cycle, and used as permanent record of VH_2O_2 exposure.

Chemical Indicator:

Getinge Assured Indicator VH_2O_2 Type 4 (item number 6005500559): give visible confirmation that the pack has been exposed to hydrogen peroxide and are intended for routine monitoring of VH_2O_2 sterilization cycles. Chemical Indicator provides further assurance by reacting to multiple variables (time, temp, VH_2O_2 concentration).

The Chemical Indicators are to be placed with each pack in the load in every sterilization cycle and used as permanent record of VH_2O_2 exposure.

Monitoring devices can be ordered via Getinge European Distribution Center (EDC).

Periodic Testing

Getinge VH_2O_2 (PCD) Process Challenge Device: is intended for periodic verification of the operational status of Getinge Poladus 150 sterilizers. The PCD test is to be conducted following installation / relocation, after service repairs, and requalification testing by service personnel.

The PCD is to be placed in an empty sterilization chamber and is designed to verify that the operating cycle continues to function correctly, and that the sterilization process remains reproducible. The PCD is not intended for routine monitoring and has been validated only for use in periodic testing of Getinge Poladus 150 sterilizers.

Service and Preventive Maintenance

Getinge Poladus 150 requires preventative maintenance at the following intervals:

- 12 months or 425 cycles: Basic PM including replacement of filters, basic cleaning and diagnostic testing.
- 24 months or 850 cycles: Intensive PM including replacement of filters, additional parts replacement, basic cleaning, sensor calibration and diagnostic testing.

The expected lifetime of Getinge Poladus 150 is 10 years or max. 15000 cycles with prescribed use and maintenance.

Conformity

Getinge Poladus 150 is designed to cover a wide range of customer requirements concerning installation of the sterilizer.

Directives, Standards and Codes (HC)

Getinge sterilizers comply with the applicable requirements such as current versions of directives and standards. Some of the directives and standards are mentioned below:

IEC 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN 61010-2-040	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040 Particular requirements for sterilizers and washer-disinfectors used to treat medical materials
IEC 61010-2-040	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040 Particular requirements for sterilizers and washer-disinfectors used to treat medical materials
UL 61010-2-040	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040 Particular requirements for sterilizers and washer-disinfectors used to treat medical materials
ISO 14971	Medical devices - Application of risk management to medical devices
EN 14937	Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
ISO 14937	Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
ISO 22441	Sterilization of health care products - Low temperature vaporized hydrogen peroxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 62304	Medical device software - Software life cycle processes

Consumption and Emission

Electrical Consumption

Process	Energy (Wh)	Power avg. peak (W)
Non-Lumen, Max load	680	3100
Flex-Lumen, Max load	820	2800
Rigid-Lumen, Max load	1125	2900
Standby (1h)	300	1150
Start-up cold machine*	800	2900
* Until machine is ready for process.		

Sound level

The sound level was tested in laboratory conditions according to ISO 3746:2010.

One measurement was taken at operator's position in normal use and one measurement was taken at a distance of 1m from the enclosure

The following measurements were taken:

Location tested	Measured maximum sound level (dB(A))
Normal use position standby	45
1m distance standby	42
Normal use position working mode	65
1m distance working mode	63

Disclaimer

Do not use this product specification for installation of equipment!

We reserve the right to correct clerical errors and the right to change without notification!

Legal Manufacturer

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