STERICOOL A Series

Low Temperature H_2O_2 Plasma Sterilizer

Product Specification

Since many components in advanced surgical tools cannot withstand the heat or pressure of traditional steam sterilizers, healthcare providers are growing evermore dependent on low temperature technologies to maintain efficient infection control. Getinge's wide product offering together with an impressive portfolio of low temperature sterilizers provide the right solutions for hospitals embracing new operating techniques, such as Minimal Invasive Surgery (MIS).

The Stericool A series H_2O_2 Plasma Sterilizers are Getinge's technologically advanced and yet affordable solution for Low Temperature sterilization. Stericool sterilizers employ state–of-the-art patented technologies to deliver rapid and safe sterilization for delicate, heat-sensitive, and moisture-sensitive instruments.

Application

Stericool Low Temperature Sterilizers and Stericool Hydrogen Peroxide Sterilant (59±0.5% wt.) are intended for use in terminal sterilization of cleaned, rinsed, and dried, reusable metal and non-metal heat-sensitive medical devices used in healthcare.

Quality Statement

Confidence in the Getinge 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.

Customer

Reference

Chamber Size & Volume

EFFECTIVE USEABLE VOLUME (L)	MODEL	CHAMBER DIMENSIONS (mm)			USABLE CHAMBER DIMENSIONS (mm)		
		W	H	L	W	H	L
□ 110L	A110S A110SF A110D* A110DF*	430	440	739 745*	400	405	710
□ 160L	A160S A160SF A160D* A160DF*	492	532	739 745*	460	500	710

Installation

The Stericool A series is available in many configurations to facilitate the most appropriate integration into your facility

Number of doors
Single Door and Double Door option denoted with ("S" or "D" in Model Type)

□ Single Door

□ Double Door (pass through configuration)

H_2O_2 Sterilant Loading
Front-Loading option denoted with ("F" in Model Type)

□ Front-Loading

□ Side-Loading – *Only available in Turkey, Indonesia, Russia. Please ask your Getinge representative for more information.*

The Front-Loading units feature an easy-to-use automatic loading system supporting 240ml & 29.8 ml H_2O_2 Sterilant Cartridges. The Side-Loading option for 450ml H_2O_2 Sterilant Cartridges, manual replacement, and more cycles.

Service Access
Service access requires a minimum clearance of 2in. (5cm) above the top, and 16 in (40 cm) on each side of the sterilizers. For Single Door units, sterilizers should not be placed closer than 2 in. (5 cm) from the rear wall.

Sterilant

Stericool H_2O_2 (Hydrogen Peroxide) Sterilant
Stericool's High purity 59±0.5% wt H_2O_2 Sterilant cartridges ensure consistently high sterilization efficacy and extends the sterilizer's life cycle while minimizing the service calls. Stericool Sterilant Cartridge Containers are encoded with a traceability system:

H_2O_2 Sterilant Cartridge Containers

	Model	Typical Use(*)	Number of cycles if only Standard/Advanced Program used
ST030**	A110SF/A110DF	2	1
	A160SF/A160DF	2	1
ST240	A110SF/A110DF	24	18
	A160SF/A160DF	20	14
ST450	A110S/A110D	42	32
	A160S/A160D	35	25

(*) Total cycles per cartridge will vary with program selection
(**) Sterilant ST030 has the same form factor of ST240 and shipped via air freight

Shelf life of the cartridges are 12 months for ST240 and ST450; 45 days for ST030 from the date of manufacturing at room temperature. After pairing the cartridge with sterilizer, expiry date will be 7 days for ST030; 30 days for ST240 and 49 days for ST450.
Expired or depleted cartridges will be rejected by the sterilizer.

Process and Instrumentation

Pressure & Temperature Read-out
Chamber pressure and temperature measurement data is available on the facia mounted touchscreen LCD on the Control Side.

H_2O_2 **Concentrator**
Our dual mode injector technology provides users more flexibility of programs to better protect your medical instruments and provide increased sterilization efficiency at the same time.

The presence of water vapor adversely affects the sterilization efficacy of the H_2O_2 sterilization process. Therefore in order to increase the sterilization efficacy and reduce cycle time Stericool has developed and patented an in-situ device concentration technology.

The Stericool's concentrator-injector enhances the efficacy of the H_2O_2 Sterilant via concentration to achieve an EN ISO 14937 compliant SAL 10^{-6} reduction in a given half program cycle. Further with reduction of water vapor in the sterilization chamber Stericool ensures repeatable lumen cycle performance.

The Concentrator-Injector unit uses Stericool patented concentration process to increase the the 59±0.5wt concentration of the standard Stericool Sterilant to a predetermined level (82-92%wt concentration depending on the lumen and cycle type) prior to injection. The fast cycle uses non-concentrated Sterilant.

In-Chamber Plasma
Stericool's state of the art patented plasma technology further enhances the sterilization efficacy of the process by ensuring pre-cycle conditioning and post-cycle decomposing of the , H_2O_2 Sterilant.

Pre-cycle conditioning: prior to injection of H_2O_2 Sterilant, plasma application generates controllable homogenous heating up to 55°C at low pressure vacuum for the preconditioning of the instruments and moisture removal.

Post-cycle decomposition: during the cleansing phase of the sterilization cycle, plasma application is used to decompose the H2O2 Sterilant (to water vapor and oxygen) and to contribute to the sterilization via the UV and free radicals generated.

Stericool's plasma generator features dynamic load matching and a unique gentle power control to protect sensitive medical instruments and thus enabling prolonged utilization.

The plasma power is homogenously distributed in-chamber via a 316L stainless steel antenna. Sterilizers that do not offer plasma inside the chamber cannot guarantee the removal of residuals on instruments without heavy reliance on vacuum aeration (via any available catalytic converter) that may reduce the life-time of the vacuum pump.

Sterilization Cycles

The sterilizer is equipped with a set of preprogrammed cycles. The three (3) included cycles are for the following applications:

- **Fast Program:**

Fast program provides fast turnaround for instruments which need surface sterilization such as telescopes and rechargeable batteries for use in laparoscopic, orthopedic or ophthalmology procedures.
  - Duration: 31min
  - H2O2 Sterilant: Non-Concentrated H2O2

  Loading: Max load 5kg for 110 Lt (top tray only), Max load 6 kg 160 Lt (top tray only)
- **Standard Program**

Standard program is designed to sterilize general surgical instruments with flexible lumens (1x850mm and below*) and rigid lumens (1x400mm double sided*). Standard Program is designed to handle Single Channel Flexible Lumens/Endoscopes (maximum 6 lumens per load).
  - Duration: 48min
  - H2O2 Sterilant: Concentrated H2O2
  - Loading: Max load 5.0kg top tray and 5.0 kg for bottom tray(for 160Lt; 6.0kg tray and 6.0

kg for bottom tray)

- **Advanced Program**

Advanced Program is designed to sterilize general surgical instruments which has long rigid lumens (1x500mm double sided, and maximum 6 lumens per load*).

Duration: 57min

- H2O2 Sterilant: Concentrated H2O2
- Loading: Max load 5.0kg top tray and 5.0 kg for bottom tray(for 160Lt; 6.0kg tray and 6.0 kg for bottom tray)

**For full lumen guide, please see Sterilizer's User Manual.*

Routine monitoring

Routine Process Monitoring ensures that the sterilizer is continuously operating at its peak performance. The sterilization process integrity is routinely monitored by use of challenge devices (Getinge Stericool Process Challenge Kit - VH2O2, and Getinge Assured Helix Test - VH2O2) to expose any divergence of critical parameters from their validated boundaries. Further, Stericool provides EN ISO 14937 spec. half cycle tests during installation.

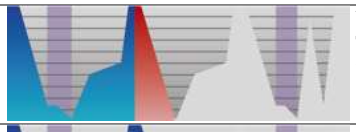
Process Flow

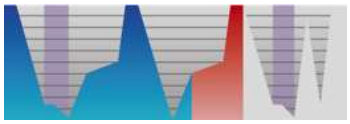
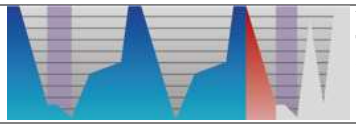
Loading is conducted from the Control Side (Loading) only. In order to satisfy pass-through requirements of CSSDs, double-door units enable unloading from the Non-Control Side (Unloading), and restricted unloading from Control Side (Loading) via a warning notification and authorization on the HMI (after each cycle)..

Heating Phase

Heating phase ensures that the sterilization environment satisfies optimal sterilization environment prior to a sterilization cycle. Depending on ambient temperature conditions, cold starting or if the sterilization door is left opened for extended durations between cycles, chamber heating at initialization can take up to 30 minutes.

Typical Sterilization Cycle

1		**Vacuum Conditioning** The Sterilization Process requires a vacuum. The Chamber is held in vacuum to provide an optimal sterilization environment.
2		**Plasma Conditioning** The Chamber is pre-conditioned with plasma in order to (i) remove moisture and (ii) enable homogenous heat distribution.
3		**1st Hydrogen Peroxide Injection** The previously conditioned H_2O_2 Sterilant is injected into the sterilization chamber as a vapor.
4		**1st Diffusion** After injection into the chamber, the H_2O_2 is maintained as a vapor in order to enable homogenous and effective diffusion inside the lumens and cavities of the surgical instruments.
5		**Vacuum Conditioning** The Chamber is evacuated to vacuum in preparation for the 2nd Injection Phase.
6		**2nd Hydrogen Peroxide Injection** Once again: The previously conditioned H_2O_2 Sterilant is injected into the sterilization chamber as a vapor.

7		**2nd Diffusion** Once again: After injection into the chamber, the H_2O_2 is maintained as a vapor in order to enable homogenous and effective diffusion inside the lumens and cavities of the surgical instruments.
8		**Vacuum Conditioning** The Chamber is evacuated to vacuum in preparation for the Plasma Abatement stage.
9		**Plasma Abatement** The plasma at the end of the cycle ensures that all H_2O_2 is decomposed (to water vapor and oxygen) and contributes to the sterilization via the UV and free radicals generated.
10		**Optional Aeration** Sterilization cell is vented with purified dry air to provide further cleansing.
11		**Sterilization Completion** The sterilizer will briefly check all parameters before finalizing the sterilization cycle.

Mechanical

Chamber Design
The sterilizer chamber is made from solid, high quality, type 316L stainless steel. The sterilization chamber is rectangular with radius on internal corners (also to aid cleaning). An RF antenna is located within the sterilization chamber for the homogenous distribution of plasma within the chamber. The sterilizer features two stainless steel instrument loading trays with 10.0kg (22.0lbs) for 110Lt units and 12.0kg (26.45lbs) for 160Lt units (please see Sterilization Cycles section for load specifications per sterilization cycle).

The sterilization heating chamber is completely isolated with armaflex isolation foam and is mounted on a rigid aluminum framework with caster wheels (rubberized feet for stationary sterilizers also included in packaging).

Automatic, Vertically Sliding Door
The door(s) is fully automatic in operation and is raised and lowered by a motor. Door operation is controlled via the user friendly 7" touchscreen LCD (back door in double-door units are controlled via an illuminated push-button on the non-control side). A mechanical safety edge stops the door if it is obstructed while closing, thus protecting the operator and loading equipment. The door is automatically sealed.

In addition to the door safety systems, the chamber is provided with a pressure monitoring system that ensures that all chamber pressure has been relieved prior to allowing the door(s) to open. The fascia temperature never exceeds 55°C.

Pipes, Valves & Components
All piping is made of stainless steel and Teflon. All process valves are electronically operated high quality stainless steel or brass valves. All standard components are non-proprietary and can be easily sourced.

Mechanical Vacuum Pump
Due to deep vacuum requirements, Stericool sterilizers feature an option of highly efficient 2-stage oil-sealed rotary pumps, mounted on vibration isolators for quiet operation. The vacuum pump exhaust is protected with a highly effective oil-mist filter and features an oil-return mechanism to recycle excess clean oil.

Stericool offers two pump options with varying power. The higher power Trivac Leybold D 40B is standard for 160L units or for installations where lower sterilization duration is critical

- ☐ Trivac Leybold D 40B, 2.2kW – (additional cost) *Mandatory in Europe*
- ☐ Value VRD-M 48, 1.5kW (only available for 110L sterilizers).

Air Filter

Replaceable hydrophobic HEPA filters are provided for the filtering of air introduced into the chamber for pressure control during the cycle. The medical grade HEPA filter, with 99.97% efficiency at 0.3µm, minimizes the effect of relative humidity by ensuring dry air injection.

Catalytic Converter
Stericool utilizes a custom designed catalytic converter in order to ensure that there are no H_2O_2 Sterilant residuals escaping to the environment from the exhaust during the vacuum process, and to protect the vacuum pump from the accumulation of Sterilant.

Our catalytic converter uses a very effective catalytic material to ensure improved environmental safety and lowered MTBF.

Control System

Stericool features a 7" color touchscreen LCD with Master Supervisor and custom built IO Controller Card.

Stericool's intelligent system management software constantly monitors the devices performance and all cycle parameters through multiple sensors (pressure, temperature, vacuum-level, plasma and Sterilant level and concentration) and keeps the user informed about the sterilization cycle progress and system errors. The Sterilizer software has been designed so that only operating cycles with process parameters well within the preset acceptable range are allowed for completion.

In case of an operator error (e.g. loading of moist material) or cycle error (e.g. sensor failure) the active cycle is aborted in an orderly manner with audio alarm and the operator is appropriately informed by displaying the relevant error code on the graphical display.

Operator Panels
The intuitive HMI features a user friendly single-touch design and displays sterilization programs stage, duration, vacuum pressure, in chamber temperature and Sterilant usage data in real-time. Access to other functions such as its resident self-diagnostic programs, setting user defined parameters, sterilizer-settings, cycle-logs and service-technician control is controlled using a pre-defined set of access levels preventing unauthorized changes to the system.

Cycle Documentation
Sterilization cycle data is printed during the cycle and at cycle completion and includes all critical parameters. The printed cycle data includes pressure, temperature, program-stage and total cycle durations, cycle number, and any alarm that occurred during the process. In the case of printer failure during the cycle, printer log data can be printed from the 7-year cycle log archive.

Printer

- □ A 2" thermal printer is standard and mounted into the fascia on the Control Side (Loading) or Non-Control Side (Unloading) Control Side (Loading)
- □ Non-Control Side (Unloading) – *only available for double-door (pass-through) units.*.

External Communication

- □ T-Doc Connectivity (additional cost)

Monitor Sterilizer workflow through network communication with Getinge T-Doc traceability system via NetCOM. Workflow traceability includes monitoring of sterilizer settings, status, printer logs, sterilization cycle progress and performance.

Independent Monitoring System (IMS)
Independent Monitoring System (IMS) is an independent monitoring and documentation
System that supports real-time monitoring of critical data from independent sensors to give users additional verification of process parameters. Process data from IMS is printed on paper report and can be accessed via T-DOC.

- □ Independent Monitoring System (IMS) – (additional cost) *Mandatory in Europe*

Temperature and Pressure Sensors

- Chamber Temperature-1

- Chamber Temperature-2
- Liquid Reference Temperature-1
- Door Temperature-1 (per door)
- Chamber Pressure-1
- Vaporizer Temperature-1
- Plasma Power indicator-1

Alarms
In the event of a critical failure during the sterilization cycle, the process enters an alarm phase which will safely and automatically end the process. The range of alarms includes but is not limited to:

- Excess moisture alarm
- Excess cellulosic material alarm
- Sterilant preparation alarms
- Concentration preparation alarms
- Injector malfunction alarms
- Diffusion pressure alarms
- Sterilization temperature alarms

Electrical

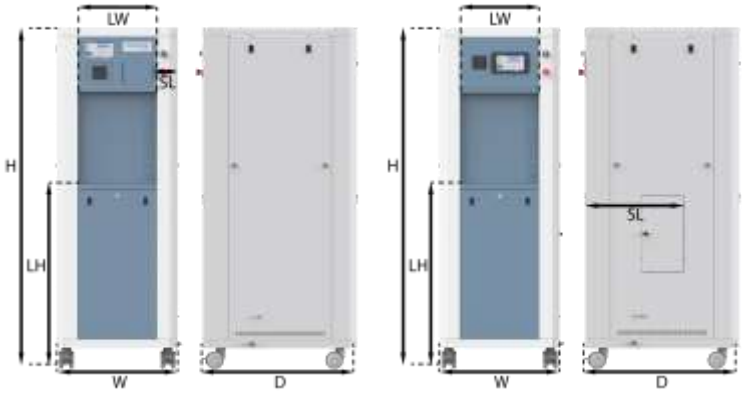
Electrical Power Supply Unit
Power supply is distributed from a housed power supply box to a replaceable power distribution panel. Other electrical components are directly mounted on the sterilizer.

Power Connection
Stericool sterilizers only require a power connection (single phase as standard, with three-phase as an option) to operate in a typical CSSD facility without a need for drainage or airflow.

□ 220-230V_{AC} 1~ 3400W (50-60Hz)

□ 380-400V_{AC} 3~ 3200W (50-60Hz)

Specification of Layout



Model	Width W	Depth D	Height		Loading Width LW	Loading Height LH		Sterilant Load SL
			Rubber feet	Caster Wheels		Rubber feet	Caster Wheels	
A110S	680mm	864mm	1845mm	1910mm	445mm	972mm	1037mm	551mm
A110D								
A110SF								140mm
A110DF								
A160S					495mm	877mm	942mm	551mm
A160D								
A160SF								140mm
A160DF								

Language

Operator displays and printer logs are available in a selection of languages, and can be configured from the user defined parameters menu.

☐ English
☐ Spanish
☐ Portuguese
☐ German
☐ French
☐ Turkish
☐ Italian
☐ Polish
☐ Romanian
☐ Dutch
☐ Swedish
☐ Russian
☐ Slovakian
☐ Slovenian
☐ Czech
☐ Danish
☐ Hungarian

More available by request.

Accessories

Getinge Consumables offer wide range of accessories fully validated for use with Stericool sterilizers; including Tyvek rolls and process monitoring indicators:

Tyvek Pouches & Rolls:
To suit a variety of needs, Getinge offers a wide range of different sizes of high quality Tyvek pouches and rolls.

Chemical and Biological Indicators:
Chemical and Biological are used to independently monitor the sterilization cycle.

- **Getinge Assured Indicator - VH2O2**: contains 250x chemical indicators
- **Getinge Assured Self-Contained Biological Indicator - VH2O2: contains** 100x units of ISO 11138-1:2006 compliant biological indicators.

Routine Monitoring
The following challenge devices (used together) provide the user with EN- ISO 14937:2009 compliant routine assurance that the device is running at its original performance level:

- **Getinge Process Challenge Device (VH2O2):** contains biological challenge device and 100x units of ISO 11138-1:2006 compliant biological indicators.
- **Getinge Helix Device (VH2O2)**: contains chemical challenge device and 100x Getinge Assured Helix Indicators (VH2O2).

Directives, Standards & Codes

Stericool Sterilizer is designed to comply with the following directive's requirements and standards:

- 93/42/EEC Medical Device Directive as amended by 2007/47/EC
- 2014/35/EU Low Voltage Directive (EN 61010-2-040:2015 and EN 61010-1:2010)
- 2014/30/EU EMC Directive (EN 60601-1-2:2015)
- 2006/42/EC Machinery Directive
- 2011/65/ EU RoHS2 Restriction of Hazardous Substances Directive
- 2012/19/EU WEEE2 Waste Electrical and Electronic Equipment Directive
- Quality Management System- Requirements for EN ISO 13485:2012 and EN ISO 9001:2008
- Environmental Management Systems EN ISO 14001:2004

Stericool's sterilization processes are validated to 10-6 SAL (Sterility Assurance Level) by an EN ISO 17025 accredited European laboratory. Stericool provides EN ISO 14937:2009 spec half cycle tests during installation.

Disclaimer

This product specification should not be used for installation of equipment!

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

Legal manufacturer:

Getinge Stericool Medikal Aletler San. Ve Tic. A.Ş., Getinge Group

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