

TECHNICAL SPECIFICATIONS FOR ORSAM STEAM STERILIZERS

PRODUCT

ORSAM steam sterilizers are offered with an integrated vacuum pump and a steam generator, in free standing configuration as a fully automatic steam sterilizer. It is possible to choose one of vertical sliding or hinged door and single or double door options. To assure fast & efficient sterilization, steam sterilizers have pre-set programs for textile materials, surgical instruments, dressing tools, rubber materials and liquids in a glass container in healthcare facilities.



APPLICATION

ORSAM steam sterilizers are used in general-purpose steam sterilization in hospitals for surgical instruments, textiles and hospital utensils. ORSAM steam sterilizers can also work for laboratory sterilization and waste disposal purposes with special adapted programs for waste materials or various types of liquid cycles and general-purpose steam sterilized items in laboratories.

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OVERALL

Device is designed without any PVC Lexan printed labels (unless requested) on the panel in order to reduce the risk of contamination. Also, manual controls are omitted from front panel design (except Emergency Stop Button). Water saving design enables savings up to 80% compared to a classical steam sterilizer. Manometers (pressure gauges) are located inside sterilizer for service purposes showing jacket, gasket, chamber and generator pressures. It is optional to have manometers on panels upon request. Device has mobility with 4 castors (Ø 75 mm.) which 2 of them are **swivel**. Firm fixing is done with suspension legs, which also enables leveling in non-flat surfaces.



DIMENSIONS & CAPACITY

Model	Door(s)	Chamber Dimensions (WxDxH mm)	Device Dimensions (WxDxH mm)	Chamber Volume (L)	Capacity (STU)
ORSAM 1S	1	400 x 620 x 400	850 x 1000 x 1600	100	1
	2	400 x 790 x 400	850 x 1150 x 1600	126	1
ORSAM 1M	1	400 x 1020 x 400	850 x 1350 x 1600	163	1,5
	2	400 x 1040 x 400	850 x 1350 x 1600	166	1,5
ORSAM 1L	1	500 x 820 x 500	975 x 1120 x 1750	205	1,5
	2	500 x 840 x 500	975 x 1120 x 1750	210	1,5
ORSAM 1XL	1	500 x 1020 x 500	975 x 1320 x 1750	255	1,5
	2	500 x 1040 x 500	975 x 1320 x 1750	260	1,5
ORSAM 2	1	500 x 1220 x 500	975 x 1520 x 1750	305	2
	2	500 x 1240 x 500	975 x 1520 x 1750	305	2
ORSAM 4	1	670 x 820 x 670	1140 x 1200 x 1900	368	4
	2	670 x 840 x 670	1140 x 1200 x 1900	377	4
ORSAM 6	1	670 x 1020 x 670	1140 x 1400 x 1900	458	6
	2	670 x 1040 x 670	1140 x 1400 x 1900	467	6
ORSAM 8	1	670 x 1220 x 670	1140 x 1600 x 1900	548	8
	2	670 x 1240 x 670	1140 x 1600 x 1900	557	8
ORSAM 10	1	670 x 1520 x 670	1140 x 1900 x 1900	682	10
	2	670 x 1540x 670	1140 x 1900 x 1900	691	10
ORSAM 12	1	670 x 1820 x 670	1140 x 2200 x 1900	817	12
	2	670 x 1840 x 670	1140 x 2200 x 1900	826	12
ORSAM 14	1	670 x 2120 x 670	1140 x 2500 x 1900	952	14
	2	670 x 2140 x 670	1140 x 2500 x 1900	961	14

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Model	Capacity (STU)	Generator Capacity	
		L	KW
ORSAM 1S	1	50	20
ORSAM 1M	1,5	50	30
ORSAM 1L	1,5	50	30
ORSAM 1XL	1,5	50	30
ORSAM 2	2	50	30
ORSAM 4	4	50	30
ORSAM 6	6	50	40
ORSAM 8	8	60	40
ORSAM 10	10	60	50
ORSAM 12	12	70	60
ORSAM 14	14	70	60

* Decimal chamber volumes are rounded up to next integer value.

* Device dimensions are partially subject to re-engineering to fit in narrow areas or low ceiling spaces.

DOOR FORMATION

Both single and double door formations are available for all models.

DOOR CONFIGURATION

- Vertical Automatic Sliding Door – Available for all models.
 - Hinged Door – Available in all models.
 - Vertical Manual Sliding Door – Only available for ORSAM 1S & ORSAM 1M.
 - Floor Loading – Only available for ORSAM 6 or higher capacities.
- Standard / Available on all models ○ Optional / Available on request / Available on certain models

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SERVICE ACCESS

A distance of minimum 60 cm is required for effective maintenance & service.

- Both Sides Service – Standard in all models.
- Right Aligned Service – Applicable to all models on request.
- Left Aligned Service – Applicable to all models on request.



ELECTRICAL COMPONENTS

Terminals, contactors and similar components are placed inside an electrostatic painted panel box with labeling for easy recognition at panel cover. Other components like switches are mounted at necessary areas in sterilizer.

- Sideway clearance needed in double door configurations. (Distance Min.: 60 cm.)
- Backwards clearance needed in single door configurations.
- Sideway clearance is optional in single door configurations. (Distance Min.: 60 cm.)

VOLTAGE SUPPLY

- 380 VAC $\pm 10\%$ - 50 Hz – 3 Phase
- 380 VAC $\pm 10\%$ - 60 Hz – 3 Phase
- 220 VAC $\pm 10\%$ - 50 Hz – 3 Phase
- 220 VAC $\pm 10\%$ - 60 Hz – 3 Phase

DISPLAY LANGUAGES & DOCUMENTATION

ORSAM steam sterilizers have 5 options for display language:

- Turkish
- English
- French
- Spanish
- German
- Other (Translations to be made!)

Documentation can be presented in 2 languages:

- Turkish
- English

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QUALITY AND CERTIFICATION

ORSAM steam sterilizers are manufactured according to Medical Devices Directive 93/42/EEC as amended by directive 2007/47/EC. ORSAM steam sterilizers are Class IIb device according to MDD 93/42/EEC 2007/47/EC (Annex IX). Electrical tests according to low voltage directive (LVD) EN 60601-1 and electromagnetic compatibility (EMC) EN 60601-1-2. Software complies with EN 62304 (Medical Device Software Cycle Process). Pressure vessels inside device are according to Pressure Equipment Directive (PED) 97/23/EC - EN 13445-1, -2, -3, -4, -5 (Pressure Vessels). ORSAM steam sterilizers are manufactured according to device standard EN 285.

CONSTRUCTION

- Chamber: AISI 316 L/Ti stainless steel.
- Jacket: AISI 316 L/Ti stainless steel.
- Generator: AISI 316 L stainless steel.
- Door(s): AISI 304/316 L stainless steel.
- Panels: AISI 304 stainless steel.
- Frame: AISI 304 stainless steel.

Areas with heat contact are insulated with 30 - 80 mm. CFC free glass wool depending on the impact. Chamber & Jacket and generator are covered with AISI 304 stainless steel plate for a clear view. Backside of the device is covered with a panel made of AISI 304 stainless steel in single door configurations. Side panels are equipped with handgrips for fast and easy service.

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CHAMBER & JACKET DESIGN

The sterilizer chamber is in rectangular shape. STU compatible design is used in according for easy procedures in CSSD and TSSU. Chamber and jacket block are mounted on an AISI 304 stainless steel section of the main frame. Internal surfaces of chamber are glass blasted and then electro-polished ($< 10 \text{ Ra}$) in order to offer a clean, durable and good-looking surface. Chamber is provided with 1" connection for test sensor according to EN 285. Jacket is formed around chamber in continuous "O" shaped forms. These forms increase stability of temperature distribution while also providing a support for chamber in vacuum and pressurized conditions.



DOOR DESIGN

Door is powered by a pneumatic piston in automatic sliding door versions. Door operations can be controlled from touch screen. It is also possible to have manual control buttons on panel to control door movements.



GASKET CHANNEL

Single piece gasket channel manufactured completely with machinery and without any welding is used in door system for placing gaskets. Single piece design increases stability and enables life-long use while non-welding design eliminates risk of leaks in steam sterilizer. Single piece design also prevents mechanical damages which gaskets may bear while being replaced in maintenance or being operated in standard cycles of operations.



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GASKET

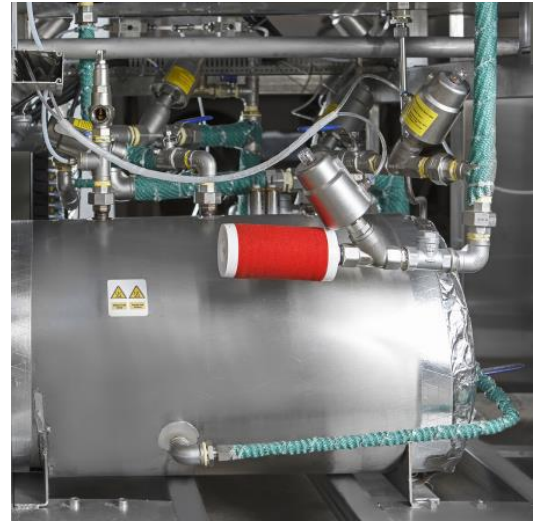
Gasket is silicone rubber in “O” shape. Connection point of gasket is marked with a white stripe in order to provide ease in service and maintenance. It is possible to have oil free gasket as an option. Gasket is pressed from single piece gasket channel with pressurized air after closing door(s) at the beginning of cycle and retracted by vacuum before opening door(s) at the end of the cycle



STEAM SUPPLY

- Integrated electrical steam generator
- Central steam supply
- Dual selection connection (Central steam supply + integrated steam generator)

In standard configurations, an automatic, integrated steam generator with enough capacity and electrical heating power depending on the chamber capacity is mounted below chamber to the frame. All heating elements are made of stainless steel. Steam generator is made of stainless steel and covered with a stainless-steel plate also. Insulation is made by CFC free glass wool. Temperature and pressure inside generator are monitored in real time with necessary sensors.



AIR FILTER

An H14 class HEPA filter is used to filter air entering the chamber for equalizing pressure.

VACUUM PUMP

An integrated liquid ring vacuum pump with 60 mbar capacity and 2,2 KW power is placed on vibration isolators for water saving purposes. Vacuum pump removes air from chamber during necessary parts of a cycle.



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PIPES & VALVES

All pipes are made of AISI 304 stainless steel. Air connection hoses are made of Teflon®. All active pipes are heat insulated. It is also possible to request heat insulation to non-active pipes also. Bending points and connections of pipes are made of stainless materials also.

Pneumatic valves, which require less maintenance and longer service life, are used in ORSAM steam sterilizers. All valves used are made of AISI 304 stainless steel. To increase service life, check valves from AISI 316 stainless steel are adapted to system. Additional safety system provides a barrier between valves and critical parts like vacuum & water pump, hence extending lifetime.

PRESSURE, TEMPERATURE & AIR MONITORING

3 pressure transducers are in chamber (1), generator (1) and jacket (1). In addition to a pressure switch also monitors and controls the pressure inside the steam source (generator).

Controlling a steam sterilizer through temperature may risk operator life or equipment, as a failure may lead to reach the set temperature value under a higher pressure. In order to ensure safety, an advanced software which uses steam-enthalpy chart, controls & monitors temperature through pressure in all pressure vessels. The temperature inside chamber should be dual checked in order to ensure sterilization, so it is cross-checked by a PT 100 (DIN Class A) temperature sensor as well.

DOCUMENTATION

Documentation can be established through computer or integrated thermal printer. Thermal printer has ability to print 40 characters. It is possible to replace thermal printer with an integrated ink printer or a chart recorder.

SAFETY FEATURES

ORSAM steam sterilizers provide safety for operator and cycle with various precautions:

- Protection for operator from electrical current leaks.
- Short circuit protection.

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- 5 level password protection.
- Safety valves in chamber, jacket and generator.
- H14 HEPA filter for air filtration.
- Water level control with electrodes in generator.
- Steam traps for precise exhausting.
- Adjustable load sensors against obstructions on the doors pathway to prevent closing.
- Pressure relief system before opening door(s).
- Unable to open both doors at the same time in double door (Septic-Aseptic) models.
- Emergency stop button.
- Fascia temperature below 55 °C.

TESTING PRESSURE VESSELS

Chamber has been tested at 7 Bar (Abs.) at 148°C. It works at 134°C under 3,2 Bar (Abs.) in standard operations. Generator has been tested at 7 Bar (Abs.) at 159°C. It works at 145°C under 4,2 Bar (Abs.) in standard operations.

INSTALLATION REQUIREMENTS

- Power: As per “Voltage Supply” section.
- Steam Supply: 97% Saturated steam with pressure is applied from side (lateral) with a distribution panel for better distribution of steam inside chamber, through integrated steam generator or external steam generator or central steam supply of hospital.
- Water: As per “Water Quality” section.
- Drain: Heat resistant PU or metal pipes with single drain per device if possible.

WATER QUALITY

RO treated water for high performance is required for best performance Water requirements must be according to Annex B of EN 286:2006 standard. Minimum water quality requirement for water hardness is ≤ 0.02 mmol / L; water conductivity is ≤ 5 μ S/cm.

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If RO treated water supply is not enough to supply both vacuum pump and steam generator, please use RO treated water for steam generator and softened water for supplying vacuum pump.

CONTROL SYSTEM & SCREEN

All electrical components are chosen from worldwide famous brands like Siemens & Panasonic. Control system with a microprocessor-controlled PLC unit on clean side. Control system has RS 232, RS 485, USB and Ethernet or GSM connection ports available. Control system can be connected to a computer through USB port for service and operational purposes. It is possible to integrate device to a hospital system.



Single door models have:

- 7" LCD color TFT LCD touch screen
- 10" LCD color TFT LCD touch screen

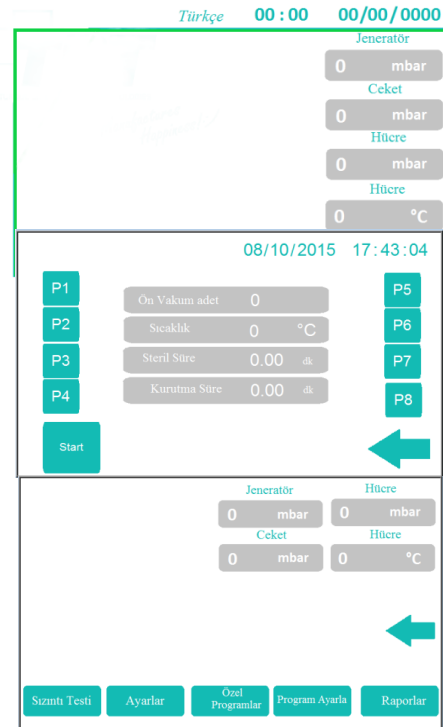
Double door models have a screen on sterile side for monitoring purposes & basic control functions:

- 7" LCD color TFT LCD touch screen
- 10" LCD color TFT LCD touch screen

SOFTWARE

Controlling software is user friendly and consists of an easy to use menu-tree. Pushing 3 buttons on screen is enough to start a cycle. All major functions like cycle selection, setting new cycles, calibrations, reaching other functions, service and maintenance are possible by control software.

Software has a 5-level password protection system in passive mode. Even when password protection is in passive mode, in order to prevent service problems and misuse, service and maintenance areas can be only reached through a service password, provided only to authorized staff.



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Software can be controlled via responsible staff with programmer password and necessary connection programs.

ORSAM steam sterilizers have visual, audio and printed warning systems embedded to software. System enables data storage of 1000 last cycles and error logs. If a computer is connected, saved data can be stored in computer too. Software is equipped with an auto warm-up system which activates at a certain time specified. Also auto sleep function enables electricity saving when it is necessary to close the device at a certain time. Stand-by mode is activated when device is not operational in order to save electricity. Sleep, stand-by and auto warm-up features are in passive mode unless other requested. F0 sterilization value can be calculated according to the program upon request.

Software enables self-diagnostic feature showing problems and assuring easy maintenance. In case of an anomaly during sterilization cycle, alarms will safely and automatically end process.

Some of the alarms include below:

- Chamber high pressure
- Low water in generator
- Generator high pressure / temperature
- Chamber temperature sensor error
- Water pump operation time out

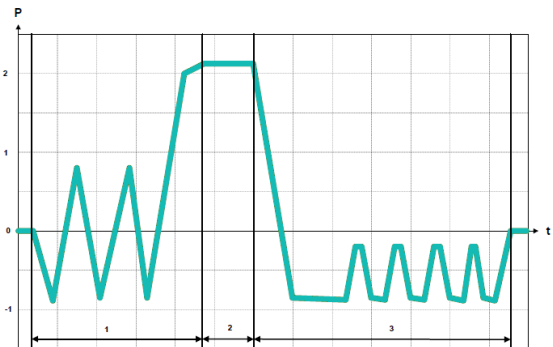
STERILIZATION CYCLES

PLUSTEAM series steam sterilizers have 7 programs in standard for fast use:

- 134°C Surgical Instruments
- 134°C Textile Materials
- 121°C Silicone Implants Cycle
- 134°C Prion Cycle
- 134°C Flash Cycle
- 121°C Rubber Materials Cycle
- 121°C Liquids in a Glass Container, w/o Probe

Number of standard programs can be increased upon request.

ORSAM steam sterilizers have 2 installed test programs:



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- Bowie & Dick Test: For testing air removal and steam penetration.
- Vacuum Leak Test: For testing air tightness.

In addition to these cycles it is possible to have optional cycles to your sterilizers:

- Liquid Cycle with Probe & Fast Cooling
- Liquid Cycle with Probe & Slow Cooling
- Solid Wastes Cycle
- Liquid Wastes in a Container Cycle
- Creutzfeldt Jacob Disease Cycle
- Heavy Load Cycle
- Dental Disinfect Cycle
- Self-Cleaning Cycle

Advanced software enables operators with a decent level of password (for devices with active password mode) may also use free capacity of 8 cycles which may be increased up to 20 cycles (depending on selection and upon request) in order to program new cycles. Also, it is possible to modify already existing cycles.

OPTIONS, ACCESSORIES & SUPPLEMENTARY EQUIPMENT

ORSAM steam sterilizers include wide range of optional features and may be also customized upon request. Below are standard optional features offered for ORSAM steam sterilizers:

- Adding a non-existing language to software
- GSM connection module (excluding local mobile line)
- Computer connection software
- Adding Ethernet connection to device
- 10" color TFT LCD touchscreen
- Drain cooling
- Manometers on panel
- Side panel
- Plinth
- Wall cover frame
- Manual purge in steam generator
- Installing water tank
- Steam line piping and valves from AISI 316 L quality stainless steel
- Manual pressure relief valve in jacket & chamber



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Standard accessories for ORSAM steam sterilizers are as below. Customized accessories are available upon request:

- Fixed height transport trolley (Manually height adjustable 10 cm.)
- Height adjustable transport trolley
- Loading trolley with removable shelves
- Shelf system with rails
- STU basket
- Supplementary equipment's for ORSAM steam sterilizers are listed below. Customized equipment is available upon request:
 - Water softener
 - Silent air compressor
 - RO (Reverse Osmosis) system including tank & motor

PACKING

ORSAM steam sterilizers are foam supported in critical parts like screen(s) at first. Protective foam and device are rounded by a bubble wrap. Finally, it is placed on a pallet and cased with wooden crate in order to stand against possible damages during transport.

LIQUID CYCLES

ORSAM steam sterilizers may be designed in order to proceed liquid cycles. There are three kinds of liquid cycles available:

- Liquids in a Glass Container, w/o Probe
 - Liquid Cycle with Probe & Fast Cooling
 - Liquid Cycle with Probe & Slow Cooling

WARNING: ORSAMTIP recommends liquids cycles with probe only.

WARNING: Hazardous wastes and explosive materials must not be processed with this sterilizer.

WARNING: Liquids must be processed with appropriate liquid programs only.

WARNING: This sterilizer is not designed to process flammable liquids.

WARNING: When sterilizing liquids, please follow below listed procedures:

-It is inappropriate for a health care facility to sterilize liquids for direct patient contact.

-Use proper liquid cycles only.

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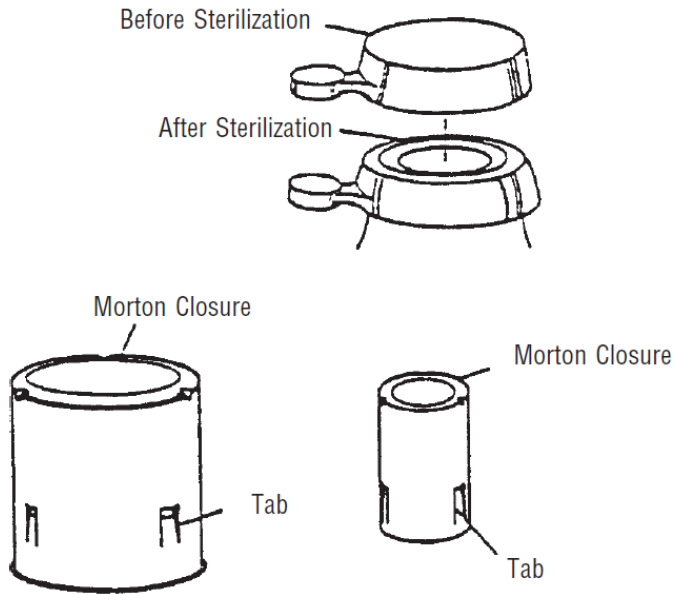
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- Use only vented closures.
- Use only Type I borosilicate glass bottles
- Don't allow hot bottles to be jolted.

WARNING: Sterilization of solutions containing chloride (i.e. saline) can cause corrosion in chamber and hence it is not recommended. Clean chamber after each use if it necessary
Please read below text before using liquid cycle and keep warnings listed in mind.

Due to its superior capability of resisting thermal shock, borosilicate glass is required to use in liquid cycles. Using glass without enough thermal resistance may cause greater potential for bursting.

Vented closures release internal pressure by automatically venting the containers due to their design. Pressure in non-vented closure remains until cooling hence affect sterilization and may cause injuries or loss of material properties. Sterilizing liquids in any other type of container or with non-vented closures requires a specially designed sterilizer.



Place small bottles in a separate basket for minimizing sliding. Use side rails in loading carts to prevent falling off. For extremely large liquid loads, a daily air removal test according to AAMI standard ST-46 should run properly.

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Below table assume using of vented closures or Erlenmeyer flasks. The "minimum sterilization time" includes the time required to bring the solution up to the sterilization temperature plus the time required to achieve sterilization. Load probes and F0 option may allow you to optimize cycle times.

Volume of Liquid in One Container	Minimum Recommended Sterilize Time at 121°C
75 ml	25 min.
250 ml	30 min.
500 ml	40 min.
1000 ml	45 min.
1500 ml	50 min.
2000 ml	55 min.
> 2000 ml	55 + 10 min./L

* Minimum sterilize times are based on obtaining a 10⁻⁶ SAL (Sterility Assurance Level) with standard test loads. Your specific loads may require different sterilize times to achieve this level of sterility, or you may require a different SAL.

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