

EUROSTEAM Steam sterilizer series 1-2-4 VSD Medical device





Series: 1, 2 and 4 with



Series 1.80 VSD Series 1.100 VSD

Series 2.150 VSD



Series 2.200 VSD Series 2.250 VSD

Compact dimensions

Technology

The MDSTM Eurosteam line is a series of new generation steam sterilisers, result of the most advanced design by Schlumbohm & Angelantoni Life Science, Leader in the world of Infection Control.

German technology combined with Italian creativity and design, together with the Corporate Know-how matured over decades of activity in the sector, has supported the development of equipment based on the concept of "total quality", able to satisfy the needs of an Elite market requiring total safety assurance, absolute reliability and sterilisation processes that can be repeated in time, without burdening operators with the risk of assessment.

Total quality to produce medical devices with high construction standards, advanced techniques and innovative solutions.

Total quality for an environmentally-friendly project with almost zero impact on the environment of water consumption and extremely low for electricity and heat dissipation

Synergy
Know-how
Experience
Ability
Customer
support

vertical sliding doors.







Series 4.450 VSD Series 4.450 VSD Series 4.600 VSD Series 4.700 VSD

Series 4.900 VSD

versatility and rapidity

Service life

The MDSTM Eurosteam line equipment is designed to last in time.

The generous sizing, the redundant safety factors, the innovative architecture of resistant structures allow to obtain high performances in terms of duration, so as to double those currently offered on the market.

Since the components used also are supplied by world-wide Leading Companies, they are guaranteed over time as well as their interchangeability with future versions.

All this in contrast with the current market setting, where the idea of very quick obsolescence prevails, with evident negative environmental impact.

Savings

The constant research for greater productivity and efficiency distinguishes and accompanies us on a design journey aimed at "Safety", "Total quality" and "Savings".

"Savings" is one of the aims that we set ourselves in the design phase; savings in operating consumption and maintenance with devices, solutions and components of high quality and reliability and long service life.





+ AIC-SCHLUMBOHM

SERIE MDSTM.4 - Rel.1.0 ID1309001 - 01/09/2013

Operatore numero 10 LOTTO: 12345-678-90 CICLO: STRUMENTARIO STER.: 134°C 300 sec.

PULS.: 5

RISC. : Elettrico

INIZIO: 09/09/2013 17:05

NUMERO: 00002345

PULSAZIONE N.1 10,0 kPa 17:06 50,6°C 9,6 kPa PULSAZIONE N.1 180,0 kPa 17:08 115,0°C 187,1 kPa PULSAZIONE N.2 10,0 kPa 17:11 53,4°C 9,6 kPa PULSAZIONE N.2 180,0 kPa 17:13 116,7°C 186,8 kPa PULSAZIONE N.3 10,0 kPa 54,6°C 9,6 kPa 17:16 PULSAZIONE N.3 180,0 kPa 17:18 116,9°C 187,1 kPa PULSAZIONE N.4 10,0 kPa 58,9°C 9,6 kPa 17:20 PULSAZIONE N.4 180,0 kPa 17:22 116,8°C 187,2 kPa PULSAZIONE N.5 10,0 kPa 17:25 47,4°C 9,5 kPa $^{\circ}\mathrm{C}$ RISCALDAMENTO 134,0 17:29 135,0°C 318,6 kPa STERILIZZAZIONE 300 sec 17:29 135,1°C 319,3 kPa 17:30 135,1°C 319,3 kPa 17:30 135,2°C 320,5 kPa 17:31 135,0°C 321,2 kPa 17:31 135,2°C 320,3 kPa 17:32 135,2°C 321,1 kPa 17:32 135,1°C 319,6 kPa 17:33 135,2°C 321,0 kPa 17:33 135,1°C 319,5 kPa 17:34 135,2°C 320,7 kPa 25,0 kPa ASCIUGATURA 17:36 70,3°C 24,4 kPa 600 sec ASCIUGATURA 43,3°C 17:46 4,4 kPa AERAZIONE 100,0 kPa 59,5°C 101,3 kPa 17:47

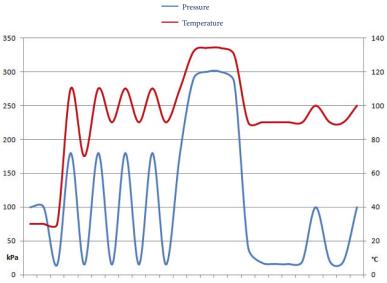
FINE: 09/09/2013 17:47

CICLO REGOLARE

T.MAX 134,5°C T.MIN 134,2°C

Tempo totale :

42 min <



Sterilization cycles

The MDSTM Eurosteam line is configured with the following cycles:

- 1 sterilisation cycle at 134°C for textiles
- 2 sterilisation cycle at 121° for rubber
- 3 sterilisation cycle at 134° for surgical instruments
- 4 sterilisation cycle at 134° for prions
- 5 steam penetration test cycle (Bowie&Dick Test)
- automatic and electronic steam penetration test cycle according to EN 285
- 7 vacuum seal test cycle
- 8 open cycle: possibility of programming 100 new cycles
- 9 flash cycle at 134°C (to validate with the used load)

-25% Total cycle time

Quick cycles

The MDSTM Eurosteam line has a series of features that make the sterilisation cycle faster, compared to the classic steam steriliser.

The care in the details of plants, components and devices affecting and intervening in the sterilisation cycle performance, has allowed phases to be sped up and times to be reduced, thus increasing the production capacity. Particularly:

- **a.** Dry operating vacuum pump with extremely reduced times for achieving vacuum
- **b.** Steam input into the chamber through two opposing inlets, with consequent improvement of steam diffusion and easier air evacuation
- **c.** The generator power and the steam reserve allow pressure and temperature to rise quickly inside the chamber
- **d.** The appropriate size of the vacuum and steam circuit pipes facilitate the passage of the fluids











-40%
Energy consumption

Environmental impact

The MDSTM Eurosteam line has been developed by applying environmentally friendly design with the aim of preserving the environment in which we live as much as possible, adopting innovative technical solutions and high quality components, in order to significantly reduce consumptions and, therefore, pollute less during the entire life cycle.

Basing on the idea of producing sustainable consumption equipment, reducing environmental impact, we have reached significant and measurable objectives that enhance the Eurosteam line in view of the performances it reaches.

Main focused points

- Water consumption
- Energy consumption
- Recycling

Water consumption

85% Water savings compared to similar equipment. The vacuum is generated by an innovative vacuum pump that runs fully dry and is compatible with steam. Water consumption for generating vacuum is zero. The only water consumption relates to the steam production (7.5%) and to outlets cooling (7.5%)

Energy consumption

Energy consumption reduced by 40%. This objective is connected to the reduction in electricity consumption, to the recovery of energy and to the thermal dissipation. In fact, through unique technical solutions and high performing insulating materials, we have obtained excellent results in the thermal insulation of the generator, of the sterilisation chamber, of doors and pipes; results that lead to a reduction of heat emissions up to 30% compared to traditional applications in use. A further recovery is obtained by using the condensate in the cavity for pre-heating the generator water, bringing it to a temperature that supports degassing (elimination of non-condensable gases) and consequent reduction of the temperature variation inside the same generator during input.

A final contribution to reduce the electricity consumption is given by the regulation system of the pre-heated water re-use into the generator, introduced in such quantities to avoid significant temperature variations.

Recycling

80% of the equipment is stainless steel, therefore fully recoverable; the commercial components cover 20%, always recoverable and recyclable according to the procedures provided by the manufacturers.

Chamber & Jacket in stainless steel AISI 316Ti Steam generator & Hydraulic plant in stainless steel AISI 316L





Industrialization

The position of the components, main functional units and the operational phases are designed to facilitate pre-assemblies and general assemblies, to significantly reduce times and costs in the serial production. The reduction of phases and the repetition of assembly operations, together with the optimisation of the semi-finished products, advantage the industrialisation of the production process and guarantee the constant high quality standards of the finished product.

Validation

Validation is one of the most important operations as it allows verifying, after installation, whether design conditions are respected. About the load (which is the subject of validation), has verified that the values for pressure, temperature, time and non-condensable gases are within the correct parametersand therefore the efficiency of the process, in compliance with the Standard UNI EN ISO 17665, is guaranteed.

Bioseal

The modern concept of sterilisation unit foresees equipment, flows, paths, procedures, checks and traceability that must be installed in order to consider safe the "reprocessing" of the instruments, the production and the preservation of medical devices.

In particular, sterile preservation of medical devices is such a determining aspect that a protected area is set aside for the purpose, with significant access limits and constructive solutions aimed at guaranteeing a "sterile" and non pollutable environment. Hence the need to create a barrier inside the through sterilisers, between clean and sterile, that prevents contact between the areas.

The Eurosteam line is produced in order to fully meet this need through complete separation of the equipment on the sterile side called "Bioseal", that is aligned and sealed with the wall.

Certificates quality and construction standards

The MD.STM Eurosteam line equipment is CE marked with identification number issued by the notified body according to the European Directive 93/42/EEC and 2007/47/EEC as a medical device and the European Directive 97/23/EC pressure equipment (PED) and European directive 2009/125/EEC (ecodesign).

Also to conform the following European directives: 2006/95/EC low-voltage directive, 2004/108/EEC for electromagnetic compatibility and 2006/42/EEC for machinery.

The construction is done in compliance with European Standard of reference UNI EN ISO 285: 2009 (steam sterilizers) and those related to it UNI EN ISO 17665-1 (development, validation, and routine tests), CEI EN ISO 61010-1 (electrical safety), CEI EN ISO 61010-2-041 (electrical safety) CEI EN ISO 61010-2-041 (electrical safety) CEI EN 60204-1 ISO (electrical), UNI EN ISO 15614-1: 2012 (welding procedures), UNI EN ISO 287-1 (welders qualification), UNI CEI EN ISO 17050-1: 2005 (conformity assessment), UNI EN ISO 14971-1: 2000 (risk analysis), EN IEC 62304: 2006 (validation of software) and EN IEC 62366: 2008 (human-machine interface).

All of that within a UNI EN ISO 9001 Quality System (quality certification) and UNI EN ISO 13485 (medical quality certification).

Main technical features

- 1 Frame and panels totally in stainless steel ASI 304.
- 2 Sterilization chamber totally in stainless steel AISI 316ti, thickness 8 mm, easy to clean and fully drainable.
- 3 Collecting chamber bottom and central filtering.
- 4 AISI 316ti stainless steel, 5 mm thick chamber Interstice.
- 5 Interstice with chamber total covering.
- 6 Door totally in stainless steel AISI 304 or superior, thickness 20 mm.
- 7 Scotch-brite finishing for internal chamber and mirror doors, roughness less than 0,2 microns.
- 8 Automatic sliding device for vertical door/s.
- 9 Door closure by dynamic «air chamber» gasket.
- 10 Chamber, steam generator, condensation line and steam line totally isolated with silicon material with internal fibres of Kevlar.
- 11 Bio-seal shield: separation between sterile side and clean side.
- 12 Electrical steam generator totally in stainless steel AISI 304 or superior (E).
- 13 AISI 304 stainless steel or superior (SE) steam thermal exchange generator.
- 14 Direct steam to the chamber (S).
- 15 Electrical direct steam generator (ES).
- 16 -Generator water preheating device.
- 17 Energy recovery system.
- 18 Water generator de-gassing system.
- 19 Steam quality check device.
- 20 Drain temperature control device.
- 21 steam resistant dry vacuum pump.
- 22 Double data process system.
- 23 PLC Siemens Medical Device classification.
- 24 HD Siemens touch screen monitor.
- 25 Built-in alphanumeric printer.
- 26 Remote maintenance control device.
- 27 Ability to operate in accordance with 21 CFR Part 11 FDA.
- 28 B&D Test Electronic / Automatic.

Range of product EUROSTEAM

Series	Model	Capacity (I)	STU	Chamber dimensions (WxHxD mm)	Overall dimensions (WxHxD mm)
1	MDSTM.1.80 .1/2VSD.E/S/ES/SE	80	1	330x330x700	890 or 1020x1850x850*
1	MDSTM.1.100.1/2VSD.E/S/ES/SE	110	1.5	330x330x1000	890 or 1020x1850x1150*
2	MDSTM.2.150.1/2VSD.E/S/ES/SE	158	2	330x680x700	890 or 1020x1850x850*
2	MDSTM.2.200.1/2VSD.E/S/ES/SE	212	3 ISO	460x460x1000	1020x1850x1150
2	MDSTM.2.250.1/2VSD.E/S/ES/SE	275	4 ISO	460x460x1300	1020x1850x1450
2	MDSTM.2.220.1/2VSD.E/S/ES/SE	218	3 ISO	460x680x700	1020x1850x850
4	MDSTM.4.300.1/2VSD.E/S/ES/SE	315	4	660x680x700	1400x1850x850
4	MDSTM.4.450.1/2VSD.E/S/ES/SE	449	6	660x680x1000	1400x1850x1150
4	MDSTM.4.600.1/2VSD.E/S/ES/SE	584	8	660x680x1300	1400x1850x1450
4	MDSTM.4.700.1/2VSD.E/S/ES/SE	718	10	660x680x1600	1400x1850x1750
4	MDSTM.4.900.1/2VSD.E/S/ES/SE	897	12	660x680x2000	1400x1850x2150

^{*}The overall dimensions change according to the model of pump installed on the device.

Definition of the model code:

Euro Steam Line:

Type of equipment - Steam sterilisers Medical Device - "MD": Hospital Application

Steam - "STM": Sterilization agent

Series - "1/2/4/": load capacity in S.U. (size 300X300 mm)

considering the chamber section

Volume - "from 100 l to 897 l": Chamber capacity in litres

Number of Doors : "1 or 2"

Door Movement - "VSD": vertical sliding door

Heating - "E/S/ES/SE": Internal Electric Steam Generator / Centralised

Steam / Electric-Steam / Steam Exchange

Example. Model MDSTM.4.600.2VSD.ES

Medical Device

Steam

 $\ensuremath{\text{4}}\xspace \text{S.U.}$ according to the section

600 litres

2 Vertical sliding automatic doors

Internal electric steam generator and connection for centralised

steam line



Our skills and basic services for total customer satisfaction:

- Training, either at our premises a the customer's premises
- Testing and quality control
- Process Validations (IQ-OQ-PQ)
- Design for Central of sterilization (CSSD) and central of disinfection (CSDD).
- Management of traceability and remote control of the equipment
- Certificate tools SIT Calibration
- Service contracts "full risk"
- Extended warranties
- Research and development
- Production and Assembly
- Installation and commissioning
- Preventive maintenance
- Market analysis and advice
- Special applications

Angelantoni Life Science

Angelantoni Life Science (ALS) is sub-wholly-owned holding company Angelantoni Industrie, is among the internationally leading supplier of refrigeration equipment and designing technological solutions in the biomedical field, with a constant commitment to innovation and safety, environmental or biological.

Research centres, hospitals, laboratories, universities, industrial companies of chemical and pharmaceutical sectors are the target Customers of ALS, which covers all the requirements of refrigeration, control of infection (Infection Control) and microbiological safety through a wide range of standard and special products.

Angelantoni Life Science is present in more than 40 countries and can be an ideal partner in Science and Technology.

Angelantoni Life Science, with agents and distributors in over 40 countries, is the ideal partner for the health sector and scientific research. Angelantoni Life Science has a long presence in refrigeration applied to biomedical field, both in research and industrial sectors within the cleaning, disinfection and sterilization with a complete range of equipment and services to meet the needs of sterilization (CSSD), disinfection stations (CSDD) and special applications BSL3 laboratories-BSL4 and treating infected waste (Biohazard).

Our strength comes from the expertise of engineers and handed experience that they have acquired in the design, by the professionalism of the technicians in the production and service, from coordinating manager who complete our team.

Each team member brings their enthusiasm and their scientific and industrial knowledge, in a working environment that stimulates innovation and development.

Angelantoni Life Science invests more than 10% of its turnover in research and development, which involved a multidisciplinary team of scientists that provides clients with cutting-edge solutions in terms of quality, reliability and innovation



Angelantoni Life Science srl

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