

STERIVAP®

Large Steam Sterilizer for Health Care with Excellent Price – High Quality Engineering



MMM Group - Leading **Service Supplier for Health Care**

Since 1954 the MMM Group has been active world-wide as one of the leading system suppliers to the health care sector.

With a complete range of products and services as well as sterilization and disinfection units for hospitals, institutes of science, laboratories and pharmaceutical companies, MMM has established itself as the excellent holder of quality and innovations within the German and international market place.

Economic Use of Utilities Technical Legislative for Reasonable Price

The new STERIVAP® steam sterilizer represents the ideal choice for everyday use in health care.

The steam sterilizer STERIVAP® is a device intended for use in the healthcare for moist heat sterilization of unwrapped and wrapped medical devices including invasive devices intended by their manufacturer for sterilization by moist

A high standard of production, up-to-date electronics and quality materials are the standards that STERIVAP® devices adhere to as a matter of course, recognising the

Standards

The device meets all and any European standards applicable to large steam sterilizers, mainly the standard EN 285+A1.

For this purpose, the company BMT Medical Technology s.r.o. holds certification of the full quality management system according to the following regulations:

- standard EN ISO 13485 and European Directive 2017/745 (MDR) for medical
- standard EN ISO 9001 for products and together with European regulation



In our production plants in Stadlern (Federal Republic of Germany) and Brno (Czech Republic), we manufacture products that meet the requirements of our customers around the world. In both of these production plants, we ensure a high volume of production and at the same time we meet highly demanding quality requirements in the field of medical technology.

MMM Group – perfection of medical instruments

need for an extraordinary level of safety and reliability.

STERIVAP® is designed for the sterilisation • of solid, porous, plastic materials and solutions in open bottles.

The basic version of the device comes with a utilizable volume of 148 - 1490 litres, and together with the offer of optional equipment it will satisfy the interest of those looking to ensure fast, quality sterilization.

No. 2014/68/EU, module H/H 1 for pressure devices.

standard EN ISO 14001, environmental management certificate.

The accredited Testing Laboratory No. 1325 operates at BMT Medical Technology s.r.o.





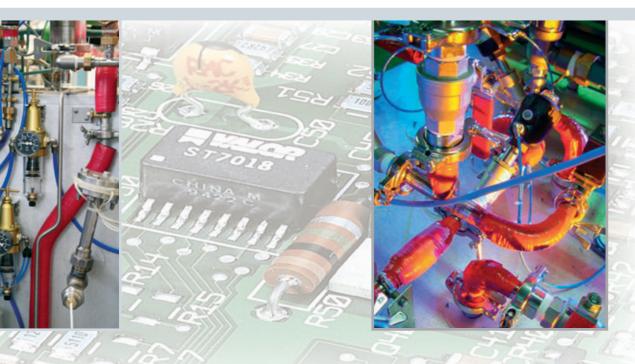
Completely New Design A New Design Version

- massive pressure sterilization chamber with heated jacket, and are made of high-quality stainless steel, applied materials AISI 316 Ti and AISI 316 L
- gradient bottom of sterilization chamber for perfect drying
- ground inner surface of the sterilization chamber, coarseness Ra 1,25 μm (Ra 50 μinch)
- perfect thermal insulation
 of sterilization chamber with
 special insulation layer Rock wool
 in thickness of 125 mm and outer
 insulation jacket made of dip
 galvanized sheet for substantial
 reduction of heat losses and easy
 cleaning and maintenance
- all sterilization chambers are as standard, equipped with two easily accessible inlet connections for validation according to EN 285+A1

- piping distributions conducting steam into the sterilization chamber are made as a standard of stainless steel, valves are made of brass
- all piping distributions are thermally insulated
- high-performance, noiseless suction pump for higher efficiency and reliability (two-stage for types 636 to 669)
- single, mechanical filter on supply water inlet for protection of the valve and suction pump
- bacteriologic filter for vent of the sterilization chamber (0.1 μm)
- integrated drain due to dampness elimination in the device space all pipes are led to one common sump
- single and double door (interleaving) type (type 446 – 6618 vertically and type 9612 – 9621 horizontally sliding doors)

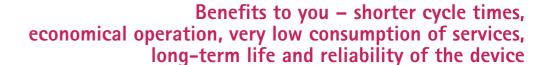
Intelligent System for Saving Media

- special divided double chamber jacket of sterilization chamber for better and more accurate course of sterilization chamber with an independent and stable chamber pre-heating lowering consumption of demi-water ca 20%
- integrated device for supply water saving, lowering consumptieon of operating cost by up to 15%
- steam generator with microprocessor automatic control and unique design of steam generator with big capacity and automatic desalination ensures short times of sterilization cycles and permanently high steam quality





- stainless steel frame able to be divided making it possible for the sterilizer to pass through a door, minimum of 1 000 mm wide
- motor driven doors of sterilization chamber with spring-loaded mechanism, with double safety door protection (safety strip and clutch)
- integrated steam generator is made with heating elements as a standard of stainless steel
- stainless steel cover sheets are reinforced by a frame ensuring an extended working life in comparison with other usual designs
- easy access to the device is ensured by door lockable panels
- reinforced stainless cover sheets for quiet operation





New Control Panel with Intuitive Control

- PLC consisting from two built-in microprocessor control systems (Master-Slave) with own sensors for independent evaluation, control and documentation of operational
- ergonomic positioned control panel at eye level, away from thermally exposed zone
- technology of touch-screen display 8.4" ensures transparent and easy operating on the loading side
- on unloading side (in case of two door type) of the device the LED display with a possibility of monitoring of actual working phase and pressure in the sterilization chamber
- "emergency stop" function integrated into the control panel
- built-in printer for documentation of sterilization processes
- system of chip cards
- possibility of language selection for communication with the device
- transparent digital description of steam pressure in the jacket of sterilization chamber and in steam generator, pressure and temperature in sterilization chamber (reference
- clock indicator of the remaining time of the program and the real time indicator

- protocol history optional SD memory card allows storage of up to tens of thousands of protocols (display in graphical or numerical form)
- error history this function allows the last 50 error messages to be shown on the display
- additional comment the device allows the operator to write to individual programs, respectively cycles, an additional comment (e.g. product name, batch number, series number, etc.), which will be included in the printer record
- logging access rights enabling the setting of user rights for the use of the device - the mode "Free Use" and "Individual Access Rights"
- visual and acoustic signalling of statuses and processes
- standard batch counter and other optional batch counter

Within the Basic **Software Facility We** Offer Up to 20 Standard **Programs**

The sterilizer is standardly equipped with "Preheating program" (134°C/1 min).

Standard programs:

- Unwrapped tools 134°C/4 min
- Wrapped materials 134°C/7 min
- Wrapped materials with intensive subsequent drying 134°C/7 min
- Wrapped products of glass, rubber and plastics 121°C/20 min

Special programs with parameters according to the customer's specifications:

Seven free programs adjustable at the producer for individual software facility according to specific needs of a consumer e.g.:

- Prions 134°C/60 min
- Disinfection 105°C/20min
- Solutions in open bottles -121°C/20 min, spontaneous cooling
- Arnold 100°C, 75°C
- Laparoscopy, alloplasts, plastic materials, optics, ...

Programs according to specific requirements must be validated at the customer's!

Top safety in solution sterilization apart from standard working and safety procedures and processes is sterilization of solutions controlled as well as by three independent systems –temperature and pressure check in sterilization chamber, temperature check in reference bottle and minimal necessary time of sterilization cycle. Only when meeting all the cycles mentioned-above will the program declare itself to be complete. The system will then allow the chamber door to be opened.

Standard testing programs for routine testing:

- Vacuum test test of the chamber airtightness, duration of equalizing phase is 5 min, test duration of 10 min
- Bowie&Dick test 134 test of steam penetration, 134 °C/3.5 min

Equipment for Service

Automatics PLC control is equipped with a wide choice of software for easy check, maintenance and testing (interactive piping connection chart, testing programs enabling the testing of safety elements of the device, calibration adjustment etc.). Software facility can be extended and modified by means of chip cards system and special service software.

Batch Documentation

• independent documentation of working cycles with pressure and temperature recording, allowing the storage of the last 10 records in the sterilizer memory (up to tens of thousands optionally - SD card);

- connection to a PC and storing the records in the computer memory by means of the "PrinterArchive" software;
- connection of the sterilizer to a computer network (LAN) together with the software application Ecosoft and DP 3.5;
- integrated printer allowing to select one of two graphic outputs









Modular System

- system for manual loading of material a) shelf supports
 - b) perforated shelf
- 2 system of transport and loading carts automatic starting of warm
 - a) frame for the loading cart
 - b) loading cart
 - 1) universal
 - 2) special
 - 3) for solutions
 - c) transport and loading cart
 - d) dripping water for solutions
 - e) hook for unloading of the loading
- 3 stainless panel sheets of the device
- 4 possibility of building-in into stainless steel walls, double sided design of the device enabling to join two service rooms into one
- print of graphic record of pressure and by means of build-in printer for documentation of sterilization cycle

Optional Equipment

- 6 optional steam source FD – steam of central source ED – own integrated steam generator FDED - combined supply of medicinal/ technical steam
- 7 thermo-degassing of supply demi-water for the steam generator to minimize the content of incondensable gases
- possibility of installation for the device for after-cooling of condensate
- g stainless steel valves
- 10 "Air detector" for continual presence of air and incondensable gases in sterilization chamber in the course of each sterilization program for maximum safety of sterilization as compared to routine testing programs (Vacuum and Bowie & Dick test) performed only once a day before the start of a routine operation (HTM 2010)
- 11 special programs in chip cards (up to 20 programs on one chip card)
- 12 additional mechanical manometers a) on loading side b) on unloading side
- 13 ground inner surface of the sterilization chamber, coarseness Ra 0.8 μm (Ra 32 μinch), Ra 0.125 μm (Ra 5 µinch)
- tropical version for countries with high temperature of cooling water
- regulation of the device operation control of energy maximum take-off in case of connection of more devices into electric network

- continual control of parameters of input media (pressure air, demi- and cooling water)
- up cycle is one of a series of energy saving features which will save your working time. The device is switched on according to the pre-set time without the presence of the operator. The equipment is pre-heated and a vacuum test is performed.
- 14 automatic sterilizer door opening during a power failure





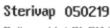
32 GB memory card for the sterilization cycles recording (up to 100,000 hours of record).

"Audit trail" – system events recording on the memory card (conforms to 21CFR part 11)

Chamber Utilization

- 15 sterilization basket
- 16 variability in the use of a series of containers
- 17 sterilization of solutions - reference bottle with temperature probe PT 100





P1 Unwrapped fast 134, 134.0 °C, 4.0 min Start 10:16:12 09:04:2013 T = 94.5 °C: p = 100.3 kPa

Charge 000003

Evecuation (1) 10:18:18 09:04:2013 T = 94.4 °C; p = 9.0 kPe

Heating 10:19:58 09:04:2013 T = 105:0 °C: p = 130:1 kPa

Start Of Stermsation 10:23:44 09:04:2013 T = 134.6 °C: p = 311.3 kPa

End Of Sterilisation 10:27:44 09.04.2013 T = 135.3 °C; p = 312.0 kPa

Orylog (1) 10:28:52 09:04:2013 T = 108:0 °C; p = 89:4 kPa T = 82:9 °C; p = 2.7 kPa

End 10:35:51 09.04.2013

Faultfree



Offer of Clients Services Validation

In addition to the device supplies, we offer other range of services related to the development of central and operating room sterilizations:

- counselling and project drawing including the logistics and capacity calculation;
- turnkey device deliveries including the individual information systems;

Service and maintenance are ensured fully by a worldwide network of BMT Medical Technology s.r.o. contractual organizations.

BMT Medical Technology s.r.o. We organize regular training of service technicians and measure their ability before issuing a special certificate showing their ability to carryout service operations. We have an extensive network of recognised worksites connected to a HOT-LINE service, this ensures a quick reaction to client's questions and requirements. In order to ensure a good quality service to the user and the possibility of fast service intervention we have developed a special auto diagnostic program. We offer ON-LINE internet diagnostics and monitoring of sterilization device (RMS), which provides fast and direct communication with instrumentation and ensures a continuous, problem-free operation of the equipment within its installed site. This all guarantees low cost operation and long operational life of the system.

The ability of the sterilization processes to be validated and recorded is one of the conditions for their quality assurance. For these pruposes, the users of STERIVAP® steam sterilizers are also offered a new service - Validation - which allows proving the compliance of the appropriate standards EN 285+A1 and EN ISO 17665 with the device parameters. The technical measurement are performed by own accredited testing laboratory.

Environmental Features

The device meets all present ecologic requirements. It does not burden the working conditions and environment. The outer cover of the insulated jacket of the sterilization chamber is manufactured using galvanized sheet with a quality insulation beneath. This substantially reduces the thermal losses therefore saving electric energy. As standard the equipment has a built-in device which saves up to 15% of the water requirements consumed by the vacuum pump. A uniquely divided double chamber jacket with a steam system allows pressurization of the sterilization chamber, this reduces the demi-water consumption by approximetly 20%.

The steam generator is controlled by an automatic microprocessor system and as a standard it is equipped with a clarifying

In production we monitor the quality of the materials ensuring a long operational life of the device. The equipment is fitted with additional components that cool the waste water to a pre-set temperature before it enters the drainage systems.

The production of the equipment and

its process cycles are all based on environmentally friendly methods. All the substantial parts of the unit and packaging are recycled. The unit is made up of 95% steel, 4% of other materials, 1% electric material and plastics. Ecologic liquidation is performed after the disassembling by the authorized person in accordance with EU regulation, which meets the Regulation WEEE (Waste Electric and Electronic Equipment).

STERIVAP® - Technical Parameters



Model SP HP E	Dimensions (hxwxd) [mm]		Number of steri-	Chamber volume [I]	Weight [kg]		Cca max. input [kW]/ fuses [A]		Cca max. consumption per 1 sterilization cycle				
	Internal dimensions of the chamber	External dimensions of the unit	lization modules	Total	ED	FD	ED	FD	Water [m³]	Demineralized water [m³]**	Steam [kg]	Electric energy [kWh]**	Electric energy [kWh]*
446 – 1	480×450×700	1918×1200×970	1	148	780	750	24,5/63	2/10	0,06	0,006	5	5	0,3
446 – 2	480×450×700	1918×1200×990	1	148	800	770	24,5/63	2/10	0,06	0,006	5	5	0,3
559 – 1	509×509×990	1918×1200×1270	***	254	890	840	24,5/32	2/6	0,07	0,008	7	6	0,3
559 – 2	509×509×990	1918×1200×1290	***	254	930	880	24,5/32	2/6	0,07	0,008	7	6	0,3
636 – 1	670×350×700	1918×1000×970	2	160	690	660	24,5/63	2/10	0,06	0,006	5	5	0,3
636 – 2	670×350×700	1918×1000×990	2	160	830	800	24,5/63	2/10	0,06	0,006	5	5	0,3
666 – 1	700×650×690	1918×1300×970	4	314	910	860	38/63	2/10	0,07	0,008	7	6	0,4
666 – 2	700×650×690	1918×1300×990	4	314	980	930	38/63	2/10	0,07	0,008	7	6	0,4
669 – 1	700×650×990	1918×1300×1270	6	453	970	920	47/80	2/10	0,08	0,009	9	7,5	0,4
669 – 2	700×650×990	1918×1300×1290	6	453	1080	1030	47/80	2/10	0,08	0,009	9	7,5	0,4
6612 – 1	700×650×1340	1918×1300×1620	8	610	1120	1070	48/80	3/10	0,09	0,011	11	9	0,6
6612 – 2	700×650×1340	1918×1300×1640	8	610	1260	1210	48/80	3/10	0,09	0,011	11	9	0,6
6615 – 1	700×650×1640	1918×1300×1920	10	748	1170	1120	57/85	3.2/16	0,16	0,012	13	14	1,1
6615 – 2	700×650×1640	1918×1300×1940	10	748	1310	1260	57/85	3.2/16	0,16	0,012	13	14	1,1
6618 – 1	700×650×1940	1918×1300×2220	12	885	1340	1170	66/100	3.2/16	0,2	0,013	15	15	1,4
6618 – 2	700×650×1940	1918×1300×2240	12	885	1470	1290	66/100	3.2/16	0,2	0,013	15	15	1,4
969 – 1	1000×650×990	1918×1900×1270	9	647	1490	1400	48/80	3.2/16	0,12	0,012	12	11	0,7
969 – 2	1000×650×990	1918×1900×1290	9	647	1750	1660	48/80	3.2/16	0,12	0,012	12	11	0,7
9612 – 1	1000×650×1340	1918×1900×1620	12	868	1830	1650	66/100	3.2/16	0,2	0,013	15	16	1,4
9612 – 2	1000×650×1340	1918×1900×1640	12	868	2040	1860	66/100	3.2/16	0,2	0,013	15	16	1,4
9615 – 1	1000×650×1640	1918×1900×1920	15	1060	1720	1580	76/125	3.2/16	0,25	0,02	20	21	1,6
9615 – 2	1000×650×1640	1918×1900×1940	15	1060	1880	1700	76/125	3.2/16	0,25	0,02	20	21	1,6
9618 – 1	1000×650×1940	1918×1900×2220	18	1260	1870	1690	76/125	4.2/16	0,3	0,025	23	23	1,7
9618 – 2	1000×650×1940	1918×1900×2240	18	1260	2070	1890	76/125	4.2/16	0,3	0,025	23	23	1,7
9621 – 2	1000×650×2300	1918×1900×2600	21	1490	-	2560	-	4.2/16	0,4	-	26	-	2

Model 969, 9612, 9615, 9618, 9621 with horizontally sliding door(s).
Model xxx-1 single-door type, model xxx-2 double-door type.
Model 6618, 969,9612,9615, 9618, 9621 – steam generator is placed above or beside the sterilizer
Connecting voltage 3P/PE 400 V, 50/60 Hz, connecting voltage of the model 559 – 3P/N/PE 480 V, 60Hz (for the U.S.A.)

* Model FD - steam of central source

** Model ED – own integrated steam generator
*** The dimensions are not standardized for the container syster

The values may differ depending on specific charge and media parameters. Changes in the design and make reserved.



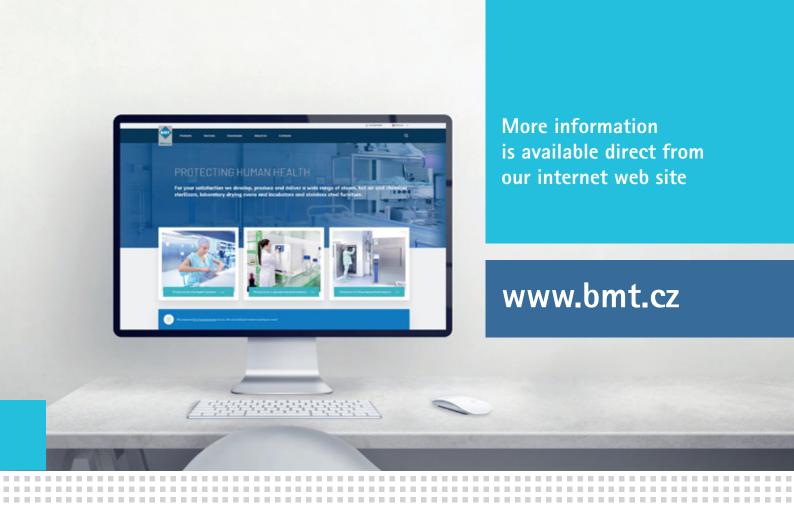
Technology training of service people, simply, economically, safely.

STERIVAP®

- high utility value for reasonable price

STERIVAP® HP

- more individuality and comfort



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