

STERIVAP® HP

Large Steam Sterilizer for Health Care











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.

Intended Purpose of Steam Sterilizers STERIVAP® HP

The STERIVAP® HP steam sterilizer is a device intended for use in healthcare for sterilization by moist heat of unpackaged and packaged medical devices, including invasive devices intended by its manufacturers for sterilization by moist heat.

Steam sterilizers line STERIVAP® HP with chamber volume of 148–1490 litres (1–21 STM) finds application in medical material processing in sterilization worksites of various health care facilities and in laboratories.

Meeting the latest standards

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

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 regulation No. 93/42/EEC for health care means
- standard EN ISO 9001 for products

Offer of Services

Besides of traditional supplies of instrumentation we offer further range of services, related to building of central sterilizations and sterilizations by the surgeries.

- consultancy and project elaboration including logistics and capacity calculation
- providing of substitute sterilisation by lending of instruments or mobile sterilization in container
- turn key supply of instrumentation including unified information system



It is at our production plants based in Stadlern, Germany and Brno, Czech Republic that we manufacture the products, which meet the requirements of our clients all over the world. Within both of these plants we ensure a high volume of production and thus meet the highly demanding requirements for quality in the field of medical instruments.

Some programs and functions of the device do not apply to the processing of medical devices. Read the instructions for use carefully.

and together with European regulation 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.

- validation if sterilization instruments by accredited testing laboratory
- consultancy in implementation of quality system ISO 9001 on the sterilization sites



More Than You Can See at First Sight

- the all stainless steel instrument jacket
- divided all stainless steel instrument frame with attractive dimensions and width only 100 cm
- the massive chamber, door and the heating jacket are made of highquality stainless steel AISI 316 L with polished surface with surface roughness of Ra 1,25 μm (50 μinch)
- the outer insulating jacket of the sterilising chamber is made of dip galvanised sheet (optionally of aluminium or stainless steel AISI 304) with high-quality insulation, which reduces substantially the heat losses
- integrated device for supply water saving for suction pump, which saves approx. 15% of operating costs
- unique divided double chamber jacket with new system of steam filling to the sterilising chamber, which

- innovative, colour, large-scale, ergonomically adjustable touchscreen 12"
- double-processor PLC control by two independent systems (Master-Slave) for highest safety
- cycle control by dual independent sensors of absolute pressure and temperature, ensuring operating accuracy, control and independent cycle documentation
- integrated drain due to dampness elimination in the instrument all pipes are led to one common sump
- unique solution of steam distribution for heating and sterilising process – enables accurate meeting of physical requirements standards
- simple mechanical filter on steam and supply water inlet
- the integrated steam generator is equipped as a standard by automatic

STERIVAP® HP



- large, colour, hinged control panel "touch-screen" 12" WITH maximal operation and service comfort
- two-level high-performance suction pump for short times of batches, fast and exact course of cycles
- two-processor control using two independent "Master-Slave" systems for fast and exact course of cycles
- thermal degasification for higher reliability of operation and safety of sterilization
- facing sheets stiffened with split stainless steel frame providing silent operation and extended service life of the device
- ergonomically adjustable position of the touch control panel, located out of the thermally exposed zone
 - it guarantees high-quality readability and easy work of the user regardless the height of his/her stature



reduces the demi-water consumption by approx. 20%

- thermo-degassing of demi-water for the steam generator with minimising of content of the incondensable gasses for higher sterilizing reliability
- high- performance, noiseless, twostage suction pump for higher efficiency and reliability (except of STERIVAP® HP 6612 and higher)
- clarifying device and is made as well as the heating elements of stainless steel AISI 316 Ti, optionally AISI 316 L
- motor driven door of sterilizing chamber with unique spring-loaded mechanism reduces the instrument weight approx. by 50–100 kg
- piping distributions and fittings leading steam to the chamber are as a standard made of stainless steel



New Control Panel with Intuitive Control

- modern technology of "touch-screen" display 12" with ergonomically adjustable panel provides wellorganized and simple using on loading side of the device
- on unloading side (in case of twodoor version) of the device there is the "touch-screen" display 5,7" with the possibility of monitoring the current work phase and pressure in the sterilization chamber
- control panels are located out of the thermally exposed zone
- two built-in microprocessor control systems (Master-Slave) with own sensors for independent assessment, control and documentation of work cycles
- "Emergency push button" the control panel integrated function allows for the device to be put into idle state if necessary
- built-in printer for documentation of sterilization processes
- program selection and start even from the clean side
- the function "Automatic morning switch on" allows for the device to be • switched on in pre-set time without presence of users, automatic preheating of the device and Vacuum test performance
- "History of protocols" the function allows selected of required protocol

from the history (10 recent protocols) and its printing or displaying a record of pressure and temperature on the display (in graphic or numeric form)

- "History of errors" the function allows displaying of recent 50 error messages on the display
- "Additional comments" the devices allows for the user to write additional comments on individual programs, respectively cycles

Broad Range of Operating Programmes Options

The steam sterilizers line STERIVAP® HP can be used for sterilization of solid. porous and plastic materials and solutions in open bottles.

In basic program design we offer up to 20 standard programmes. The sterilizer is standardly equipped with "Preheating program" (134°C/1 min).

Examples of standard and validated 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

Standard testing programs for routine testing:

- Vacuum test
- Bowie&Dick test

The program equipment can be extended and modified by means of chip cards and special service software UNICONFIG.

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

- Prions 134°C/60 min
- Disinfection 105°C/20 min
- Solutions in open bottles 121°C/20 min
- Arnold 100°C and 75°C
- Automatic starting the instrument at the morning - pre-heating and Vacuum test – without operator

The programs according to specific requirements must be validated at the client! Top safety during sterilization of solutions - together with standard operation and safety procedures and processes, sterilization of solutions is also checked by three independent systems - check of temperature and pressure in the sterilization chamber, check of temperature in the reference bottle and check of minimal necessary time of the sterilization cycle. Only in case of fulfilment of all the above stated processes, the program is declared to be finished and the system allows for the chamber door to be open.

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 UNICONFIG. The program data values may be modified directly from the touch display. The device allows detailed planning of service operations with consequent warning on

Batch Documentation

the display or on printer report.

- 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 "PrinterArchiv" 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



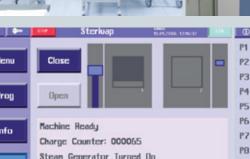
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Modular System **Optional Equipment**

- onedoor and passthrough version, stainless steel lining sheets, possibility of building in into stainless steel partition walls, mirror version of the
- into one 2 optional steam source FD - steam feeding ED – steam feeding from own steam generator

device - in case of installation of

several devices one next to each other

it allows merge of two service areas

FD ED – steam feeding from external source of medicinal steam or steam feeding from own steam generator (original FED).

FDD – steam feeding from own steam/ steam exchanger (the steam/steam exchanger is fed with technical steam) ED FDT – steam feeding from own generator and heating shell feeding with technical steam

- 7 stainless steel safety valve
- 8 gas-tight version of the device "Bio-Seal" with the possibility of independent and permanent sealing of the chamber door with pressure air and with the possibility of independent door control on any side
- 9 special stainless steel sterilizable filters at the sterilization chamber inlet and
 - bacteriological filter at the chamber outlet (de-contamination, including the condensate sterilization)
 - bacteriological air-inlet sterilizable filter with preparation for the integrity test
- 10 temperature sensor PT 100
- 11 chip cards system
- 12 drip tube for solutions into the sterilization chamber
- 13 possibility of building in a device for additional condensate cooling
- 14 "Air detector" for continuous check of presence of air and non-condensable

- 17 large "touchsreen" display 12" on unloading side as well
- 18 bar code reader
- 19 special software PrinterArchiv for documentation of batches in PC
- software for connection of sterilizer to computer network (LAN)
- chamber passivation (staining)
- laboratory software it allows for the users to perform individual adjustments in already programmed programs
- special programs "Sterilization of solutions with independent cooling of shell and supporting air pressure" (it contains even the movable temperature sensor PT 100)
- solutions controlled using the Fo value special software UNICONFIG allows modification of individual phases of the sterilization cycle (evacuation. vacuum depth, exposition, drying) and setting the values of temperature and time of the sterilization cycle

- optional electric connection depending on required mains parameters
- 20 automatic door opening in case of power outage
- 32 GB memory card for sterilization cycles recording (up to 100 000 hours of recording)
- "Audit trail" system events recording on memory card (in conformity with 21CFR part 11)
- Device anchoring for seismically active areas

- 21 transport cart
- 22 loading cart
 - a) solution
 - b) universal
 - c) special
- 23 stainless steel shelf
- 24 stainless steel trav (except for 446 and 636)
- 25 hook for loading carts removal

Additional Equipment

- 26 wide range of laboratory equipment bags and sacks for contaminated material, sterilization baskets, plastic vessels, test tubes, Petri dishes, etc.
- 27 basic documentation IQ, OQ, PQ for validation according to GMP and GLP

- tests and validations according to EN 285 and EN ISO 17665-1
- air compressor including air jet and case (for devices with additional "Solution program with forced cooling of shell and supporting air pressure" it is necessary to use more powerful compressor, e.g. Ekom plus 2 V)
- water processing equipment for demineralised water preparation
- monitoring starting package of indicators
- optional language version for communication with the device...









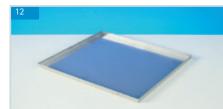






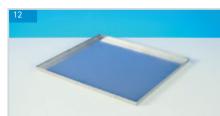




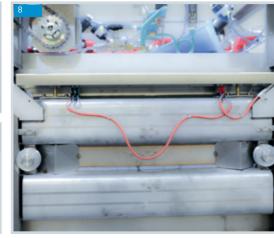












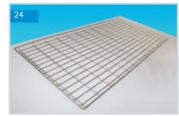
















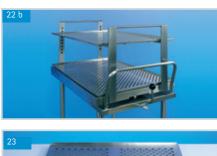


















- FD FDT steam feeding from external source of medicinal steam and heating shell feeding with technical steam
- 3 polishing the inner surface of the sterilization chamber with roughness of Ra 1,25 μm"(Ra 50 μinch); 0,8 μm (Ra 32 μinch); Ra 0,125 μm (Ra 5 μinch)
- 4 system of transport and charging carts - frame for loading cart 5 system for manual insertion of
- materials lead of trays, shelves 6 stainless steel valves with screwed or welded necks of the type "CLAMP"
- gases in the sterilization chamber in the course of each sterilization program for maximal safety of sterilization compared to routine checks using testing programs (Vacuum and Bowie&Dick test) performed only once a day before standard operation start (HTM 2010)
- 15 additional mechanic manometers - on loading side
- on unloading side
- 16 drip tube to be placed below the device

- (verification with the manufacturer needed)
- media monitoring continuous check of input media parameters (pressure air, demineralized and cooling water)
- "Power maximum function" - regulation of the device operation, control of power take off maximum in case of several devices connection into the mains
- tropical version for countries with high cooling water temperature



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.

One of the conditions for arrangement of sterilization processes quality is the possibility of their validation and documentation. For this purpose, the "Validation" service is offered for STERIVAP® HP, allowing for compliance of relevant standards EN 285 and EN ISO 17665-1 to be proved in relation to device parameters; the technical measuring is performed by own accredited testing laboratory.

Environmental Awareness

The device meets all and any current environmental requirements. It does not burden the work and living environment. The powerful air pump with standard built-in device for feeding water economy saves approximately 15% of operation costs. The construction of steam generator with automatic desalination arranges permanently high steam quality. In the course of production there are used high quality materials guaranteeing long service life of the device.

The device can be optionally equipped with a device for additional cooling of drain water, allowing its draining temperature setting.

The device does not produce any harmful

In the course of its workshop manufacture there have been use environment-friendly methods of processing. All the main parts of the device and its packages are

The device consists of 95% of steel, 4% of other materials, 1% of electro material and plastics. The environment-friendly liquidation is performed after dismantling by an authorised person, in compliance with EU regulations, pursuant to WEEE (Waste Electric and Electronic Equipment) regulation.

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

STERIVAP® HP - Technical Parameters



Model SP HP	Dimensions (h \times w \times d) [mm]		Number of sterili-	Chamber volume [I]	Weight [kg]		Cca max. input [kW]/ fuses [A]		Cca max. consumption per 1 sterilization cycle				
	Internal dim of the chamber	External dim. of the unit	zation 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	1190	1130	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 x 650 x 990	1918×1900×1270	9	647	1490	1400	48/80	3.2/16	0,12	0,012	12	11	0,7
969 – 2	1000 x 650 x 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	1000x650x1640	1918×1900×1920	15	1060	1720	1580	76/125	3.2/16	0,25	0,02	20	21	1,6
9615 - 2	1000x650x1640	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
12612 - 2	1360x650x1340	2200x2000x1660	16	1182	2230	2050	85/125	4.2/16	0,3	0,025	23	23	1,7
12622 – 2	1360x650x2300	2200x2000x2620	28	2020	-	3100	-	4.2/16	0,5	-	34	-	2,2

Model 969, 9612, 9615, 9618, 9621, 12612, 12622 with horizontally sliding door(s)

Model xxx-1 single-door type, model xxx-2 double-door type.

Model f618, 969, 9612, 9615, 9618, 9621, 12612 – steam generator is placed above or beside the sterilize nnection voltage 3 PE AC 400/50/60 Hz, Connection voltage model 559-3P / N / PE 480 V

- Steam of central source Own integrated steam generator

The dimensions are not standardized for the container system

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







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