



UNISTERI[®] HP

"medium" steam sterilizer for health service
- powerful, intelligent, exceptional



protecting human health

MMM Group – Leading Supplier of Services For Health Service

Since its establishment in 1921, the company BMT Medical Technology s.r.o., a traditional manufacturer of medical technologies, has been gradually transformed from a small region-oriented company "Chirana" to an international BMT company. In 1992, it became a member of the European MMM Group which has been operating on the world markets since 1954 as an important supplier of systems for the health care industry, science and research.

Intended Purpose of UNISTERI® HP Steam Sterilizers

The UNISTERI® 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. Some programs and functions of the device do not concern the processing of medical devices. Read the instructions for use carefully.

- and any necessary materials: tools, glass, textile, rubber articles,...
- surgical workplaces of hospitals that are far from the central sterilization department, especially to optimize the reuse of the necessary instruments
 - medical clinics and first aid centres where rapid sterilization of medical supplies is needed
 - dental practice, where table models of sterilizers cannot accommodate the necessary volume of material
 - microbiological workplaces of

Top quality production, modern electronics and high quality materials of the device UNISTERI® HP are as natural as user features or exceptional level of safety and reliability. Steam sterilizer UNISTERI® HP – safe, fast, ergonomic design, easily controllable, with the possibility of individual adjustments and multi-purpose use.

General and Actively Provable Quality

The UNISTERI® HP steam sterilizer is designed for healthcare to sterilize medical devices. The device complies with all the European standards for steam sterilizers, in particular EN 285.

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

- EN ISO 13485 standard and European Directive 2017/745 (MDR) for medical devices
 - EN ISO 9001 standard for products and together with the European Directive No. 2014/68 / EU, module H for pressure equipment
 - EN ISO 14001 standard, Environmental Management Certificate
- The company BMT Medical Technology Ltd. also operates the Accredited Testing Laboratory No. 1325.



With its comprehensive offer of products and services, sterilization and disinfection devices for hospitals, scientific institutes, laboratories and pharmaceutical industry, the MMM Group has established itself as an outstanding quality and innovations producer on the global markets.

Individually Built Sterilization Technology

The newest modular line of steam sterilizers UNISTERI® HP is the ideal option for everyday use in health service.

The UNISTERI® HP device is the right choice for smaller medical workplaces as well as for all central sterilization workplaces that emphasize the advantageous value for money ratio.

UNISTERI® HP is designed for rapid sterilization in medical facilities:

- one-day surgical clinics and surgeries of polyclinics for sterilization of all

medical facilities for sterilization of solutions in semi-closed bottles, cultivation media,...

The UNISTERI® HP steam sterilizer is designed for sterilization of solid, porous and plastic materials and solutions in open bottles.

The basic versions of the devices with usable volume of 73, 160 and 254 litres, together with the optional equipment offer, will satisfy the customer in order to ensure fast and high-quality sterilization.

... hospitals
clinics
consultation rooms
laboratories...



MMM Group – perfection in medical technology

New Design, New Construction Version

- 8.4" touch-screen control panel for maximum operator and service convenience
- 5.7" touch-screen display on the unloading side of the device for well organised and easy operation
- automatic closing and sealing system for (manually operated) hinged doors, user-friendly operation
- steam generator with reduced power input (from 7.5 kW)
- powerful water ring vacuum pump for short batch times, fast and accurate course of cycles
- dual-CPU PLC control with two independent systems for reliable, efficient and safe course of cycles
- a special method of controlling the continuous inflow of steam into the steam sterilizer chamber
- the device is made of high quality stainless steel for long life



Modular Layout System

- single-door and double-door (pass-through) version with possibility of building into the stainless steel wall
- optional steam source – own, external, combined
- optional roughness of inner surface of the sterilization chamber
- system for manual insertion of materials and system of transport and charging carriages
- wide range of optional program equipment
- various possibilities of batch documentation processing
- wide range of optional equipment for minimization of operation costs
- possibility of specific additives selection (e.g. possibility of chamber equipment with a flexible sensor PT 100 for safe and precise control of cycles while working with microbiological cultures and solutions, wide range of individual adjustments of programs, ...)
- wide spectrum of services



medicine



laboratories

Powerful and Comfortable

Microprocessor Control

- the highest possible operation safety, double system of sensors for process information collection and assessment and for their continuous comparison and assessment
- two built-in microprocessor control systems for independent assessment, control and documentation of operation cycles
- the system allows users administration and assigning of permissions to individual functions
- storing the logs directly into your device for the whole duration of its life
- unique error protocol for exact and fast diagnostics of errors
- the basic program equipment includes up to 50 standard programs
- easy realization of individual adjustments of programs
- easy import/export of programs using a USB flash disc
- easy and intuitive access for service allows a technician to comfortably set all and any calibrations and configurations and to perform fast diagnostics of the device

Pressure Sterilization Chamber

- pressure chamber, steam-heated via heating shell, made of high quality stainless steel 1.4404 (AISI 316 L)
- special way of control of continuous steam intake to the steam sterilizer chamber
- down bottom of the sterilization chamber for perfect drying
- sterilization chamber with ground surface with roughness of Ra 1,25 μm (Ra 50 μinch)
- thanks to high-quality insulation materials Rockwool used (no chlorides), equipped with an Al foil, there are reduced the radiated heat losses and requirements towards air-conditioning

Steam Generator

- the steam generator and the heating bodies are made of high quality stainless steel DIN 1.4571 (AISI 316 Ti)
- high quality insulation Rockwool with AL foil – significant reduction of heat losses
- reduced feed water conductivity requirement of 15 $\mu\text{S} / \text{cm}$ compared to the value recommended by the EN 285 standard provides significant savings in water treatment costs
- unique automatic control of the steam generator including water filling
- thermal degassing of the feeding demi water (optional equipment) and automatic desalination to minimize non-condensable gases and for consistently high steam quality



- as a standard, all the sterilization chambers are equipped for validation with two easily accessible inlet necks according to EN 285
- thanks to the special door hinge, the operator is provided with an extended handling area for comfortable and safe material handling and it allows easy cleaning of the inside of the door
- possibility of setting the pass-through sterilizer so that there does not occur any contamination of any side with material and air from the contaminated side

High Utility Value

New Control Panel

- user friendly, with intuitive control
- two built-in microprocessor control systems with own sensors for independent assessment, control and documentation of operation cycles
- ergonomic position of the touch control panel
- the 8,4" touch screen technology provides well-organised and simple servicing on loading side
- on unloading side of the device (in case of the two-door version) the 5,7" touch screen arranges well-organised and simple service
- the "emergency stop" function integrated to the control panel allows for the device to be put into standby status if needed
- possibility of language selection for communication with the device
- well organised digital displaying of steam pressure in sterilization chamber shell and in the steam generator, pressure and temperature in sterilization chamber (reference bottle)
- clock – an improved estimation of remaining time of the program
- error protocol with recording of all and any parameters at the moment of a fault for the possibility of fast and remote service
- visual and acoustic signalling of statuses and processes
- possibility of building-in a printer for sterilization processes documentation (optional equipment)

The basic program equipment offers up to 50 programs

As a standard, the device is equipped with the "Preheating program" (134°C/1min)

Standard programs:

- "Tools – quick" 134°C/ 4 min, with following short drying, for unpacked tools for immediate consequent use
- "Universal" 134°C/ 7 min, with following short drying
- "Universal containers" 134°C/ 7 min, with intensive drying
- "Packed glass, rubber and plastic products" 121°C/ 20 min, with intensive drying

Standard testing programs for routine checks:

- Vacuum test - chamber air tightness test, settlement phase duration 5 min, test duration 10 min
- Bowie & Dick test 134 - steam penetration test, 134°C / 3.5 min

Equipment according to specific needs of a client

- Prions
- Disinfection 105°C/20 min
- Laparoscopy
- Aoplastics
- Plastics materials
- Optics, ...

Programs according to specific requirements must be validated by the customer!

Special programs with a choice of PT 100 movable sensor for laboratories:

- Solutions in open bottles 121°C / 20 min, self-cooling
- Solutions with forced cooling and air back pressure
- Steaming 100 ° C
- Agar (cultivation media) with self-cooling, ...

Safety in sterilization of solutions

Sterilization of solutions in open and reagent bottles with GL 45 thread, according to DIN 168, part 1, ISO 4796, SIMAX brand, with blue stopper. In addition to standard working and safety procedures and processes, sterilization of solutions is also controlled by three independent systems - temperature and pressure control in the sterilization chamber, temperature in the reference bottle and minimum sterilization cycle time. Only when all the above processes have been completed, the program is declared to be completed and the system will allow the chamber door to be opened.

Individual Program Adjustments

The individual programs are downloaded to the device using a USB flash disc and can also be re-loaded onto the USB flash disc. The USB flash disc stores up to 50 new programs developed and tested by the manufacturer upon order. We also offer special MOVEX® software to modify all the sterilization cycle values (evacuation, vacuum depth, exposure, drying) and to set the sterilization cycle temperature and time values. (Verification by the manufacturer required.)

Documentation of Batches

It is possible to arrange well-organized documentation of operation cycles by:

- independent documentation of operation cycles with recording with the possibility of saving recent protocols for the whole service life of the device
- connection to PC and by saving protocols in the computer memory using the "PrinterArchiv" software
- connection of the sterilizer to computer network (LAN) together with software application Ecosoft
- the electronic process documentation, data archiving and Audit Trail together meet

FDA 21 CFR part 11 requirements

- by built-in printer
- possibility of batches export to PDF on the USB flash disc in the A4 format

Equipment for Service

The PLC automatics is equipped with extensive software for easy control, maintenance and testing (interactive schemes of tube connection, testing programs allowing testing of safety elements of the device, calibration settings, etc).



Operation Economy



Intelligent System of Media and Work Time Saving

The low consumption factor affects the models of the future. More and more demanding legislative requirements putting stress on launching safe products in the market and permanently increasing price of input media represent pressure on sterilization engineering operation costs increase. That is why it is the hit and advantage of current era to provide saving and comfortably equipped sterilizers they represent the very new trend in health care industry operations.

Door Mechanism

The comfort and safety of staff's work with the device is automatically arranged by a locking mechanism of the door, including sealing. The two-processor automatic controls the course and multiple check of processes

Easy Maintenance of Sterilization Chamber incl. Door

The construction of the pressure vessel including the door and selection of high-quality of internal surfaces allow perfect, fast and comfortable cleaning of all and any parts of the sterilization space.

Version with "Automatic Morning Switch-On" Function

One of the economic product line elements, saving your time. The function of "Automatic Morning Switch-On" is able to start the device in pre-set time and to perform pre-heating and Vacuum test without the staff presence. In this way, routine testing programs can be performed in a more efficient way.

All for Monitoring You have everything under your control with us!

Equipment arranging documentation and independent archiving

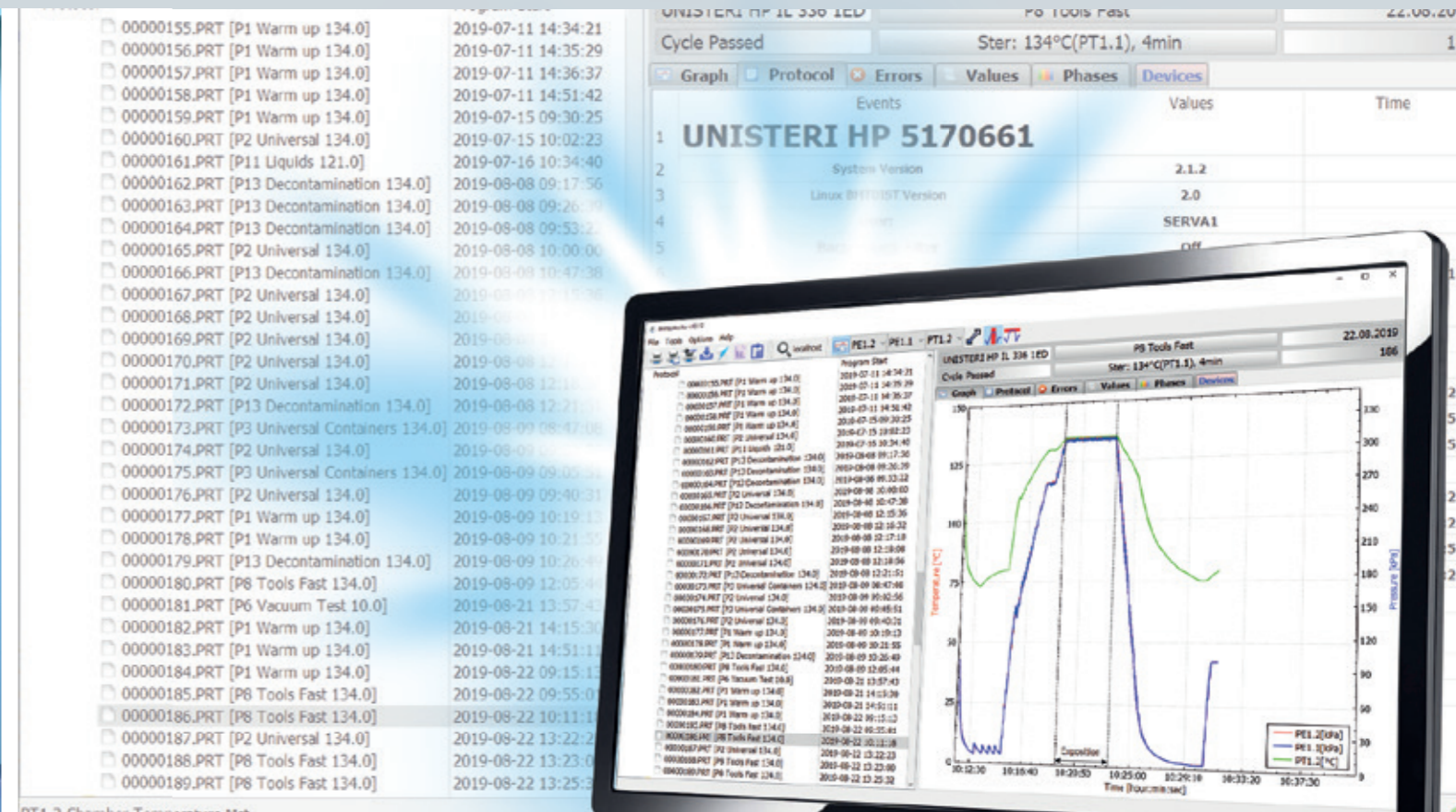
Use our software application "PrinterArchiv", which - together with the device connection at the sterilization work site to the computer network (LAN) - allows documentation of all and any sterilization processes and independent data archiving, protocol printing on A4.

Equipment arranging power maximum monitoring

This is a set of software and hardware adjustments of the sterilizer providing the possibility of individual and mutual regulation of built-in steam generators regulation in such a way so as to arrange monitoring of power maximum of electric power take off and possibility of limiting the dimensioning of electric power distribution in the place of installation.

Equipment with an "Air Detector"

The "Air detector" is a device that continuously monitors and detects leakage and presence of air, respectively non-condensable gases in the sterilization chamber in the course of every sterilization program for packed materials. In case of a device to be equipped with this equipment, it represents a higher guarantee of sterilization compared to hitherto operated routine checks by testing programs (Vacuum test and Bowie & Dick test), being performed only once a day before the ordinary operation run.



The low consumption factor is reflected in models of the future

UNISTERI® HP – Basic Equipment

- 13 steel frame of the device
- 12 inner surface of sterilization chamber – ground surface with roughness Ra 1,25 µm (Ra 50 µinch)
- distribution system leading steam to sterilization chamber and demi-water to built-in steam generator – made of copper, valves of brass
- touch-screen 8,4" control panel on loading side
- 1 5,7" touch screen display on unloading side (in case of the two-door version)
- "Automatic Morning Switch - On" of the device
- 4 optional language version for communication with the device
- 6 castors for easy handling of the device during assemblage, service
- "Audit trail" – recording of system events on the memory card (it conforms with 21CFR part 11)

UNISTERI® HP – Optional Equipment

- one-door or two-door (pass-through) version
- stainless steel lining sheets of the device
- possibility of building into stainless steel partition walls
- mirror version of the device; in case of several devices application it allows connection of two service spaces into one
- 2 optional steam source
 - FD – steam from central source,
 - ED – own built-in gas generator (from 7,5 kW)
 - FDED – combined way of steam feeding from central source or from built-in generator
- 12 inner surface of sterilization chamber – ground surface with roughness Ra 0,8 µm (Ra 32 µinch); Ra 0,125 µm (Ra 5 µinch)
- chamber passivation (staining) – only for ground / polished surface treatment
- stainless steel valves leading steam to sterilization chamber and demi water to built-in steam generator
- 3 control panel on unloading side – touch display 8,4"
- "Air detector" for continuous control of air and non-condensable gases presence in sterilization chamber
- thermal degasification of steam generator degasification for

- higher reliability of operation and sterilization safety
- media monitoring – continuous control of input media parameters (water, demi water, pressure air, softened water, steam)
- "Power Maximum Function" – device operation regulation; monitoring of power take-off maximum in case of connection of several devices to the electric network
- 5 built-in device for additional cooling of condensate for reduction of waste water temperature in case of plastic waste piping use

- special software MOVEX® allows modification of individual stages of the sterilization cycle (evacuation, vacuum depth, exposition, drying) and setting the temperature and time values for the sterilization cycle (verification with the manufacturer is a must)
- 14 USB flash disk
- optional electric connection depending on required parameters of the network
- 3F socket
- stainless steel tube below the device
- design in compliance with ASME, AOSIQ
- validation tests according to EN 285 and EN ISO 17665-1
- monitoring start package of indicators
- and more ...

UNISTERI® HP System for Manual Material Loading

- 20 stainless steel wire built-in elements for shelves and trays
- 21 stainless steel wire base for containers and baskets
- 22 stainless steel shelf (max. 4 pcs)
- 23 stainless steel trays (max. 4 pcs)
- 24 dripping tube for solutions to the sterilization chamber
- 25 sterilization basket – 1 STJ, 1/2 STJ

Transport System for Material Loading

- 15 transport cart
- loading cart
- 16 container
- 17 cassette
- 18 solution
- 19 stainless steel base for loading carriage
- handling hook for loading carriages



Modular system of the Device Layout

Unique Solution for Your Individual Requirements



Unisteri HP 5170661
System Version: 2.0.2
Linux BMDIST Version: 2.0
P03 Universal Containers
Ster: 134°C (PT1.1), 7.0min
User1: SERVA1
User2: openuser
Bacteriologic Filter - Off
Start 15:15:12 2019-05-06
T(PT1.2)=51.7°C; p=98.8kPa

15:20 2019-05-06
17:43 2019-05-06
16

UNISTERI HP 5170661
System Version: 2.1.2
Linux BMDIST Version: 2.0
P06 Vacuum Test
Vac: 10kPa , 10.0min
User1: Open User
User2: openuser
Bacteriologic Filter - Off
Start 09:38:58 2019-09-06
T(PT1.2)=72.7°C; p=99.7kPa

Charge 00210
Prevacuum 09:39:50 2019-09-06
T(PT1.2)=59.4°C; p=10.1kPa
Vacuum Test 09:44:49 2019-09-06
T(PT1.2)=61.4°C; p=12.0kPa
End of Vacuum Test 09:54:44 2019-09-06
dp = 0.4kPa
T(PT1.2)=53.2°C; p=12.4kPa

End 09:55:30 2019-09-06
Program Length = 00:16:32

Cycle Passed
User: Open User

Signature:

UNISTERI HP 5170661
System Version: 2.1.2
Linux BMDIST Version: 2.0
P08 Tools Fast
Ster: 134°C (PT1.1), 4.0min
User: SERVA1
Bacteriologic Filter - Off
Start 10:11:18 2019-08-22
T(PT1.2)=103.8°C; p=99.4kPa

Charge 00186
Evacuation (0) 10:11:25 2019-08-22
T(PT1.2)=103.4°C; p=99.5kPa
Preheating (3) 10:15:52 2019-08-22
T(PT1.2)=110.4°C; p=144.3kPa
Heating 10:15:53 2019-08-22
T(PT1.2)=110.1°C; p=148.6kPa
Preparation 10:19:25 2019-08-22
T(PT1.2)=130.3°C; p=275.0kPa
Start of Sterilization 10:19:25 2019-08-22
T(PT1.2)=134.6°C; p=312.8kPa
End of Sterilization 10:23:25 2019-08-22
T(PT1.2)=135.3°C; p=313.7kPa
Aeration 10:30:56 2019-08-22
T(PT1.2)=77.0°C; p=93.2kPa
End 10:31:26 2019-08-22
Program Length = 00:20:08

Cycle Passed
User: Open User

Signature:

Client Service Arrangement

Together with classic supplies of instrumentation, we offer a complete spectrum of services connected with development of central and chart room sterilizations.

- consultancy and project processing, including logistics and capacity calculations
- instrumentation supply including individual information systems "on turnkey"

Service and support of users are fully arranged by a worldwide network of contractual organisations of the company BMT® Medical Technology s.r.o. We have an extensive network of brand service work sites connected to HOT-LINE service providing fast response to clients' questions and requirements. So as to arrange user comfort and fast and high-quality service intervention we developed a special auto-diagnostic program. We offer internet diagnostics and monitoring of the sterilization device (RMS), providing fast and direct communication with the instrumentation and it arranges fluent and trouble-free operation of a work

Validation

Validation and documentation is one of the conditions for arrangement of sterilization process quality. For this purpose, the steam sterilizer UNISTERI® HP is offered with the service "Validation", allowing proving of the sterilization processes competence with the device parameters according to the EN 285 and EN ISO 17665-1 standards; the technical measuring is performed by our own accredited testing laboratory.

Environmental Awareness

The device meets all and any current environmental requirements. It represents no burden for the work and life environment. A powerful suction pump with built-in device for feeding water saving saves approximately 15% of operation costs. The unique construction of the steam generator with automatic desalting arranges permanently high quality of steam.

High quality materials guaranteeing long service life of the device are used for its manufacture. Optionally, the device can be equipped with an element for additional cooling of waste water, allowing its temperature setting. The device does not produce any harmful waste. Environment - friendly methods are used for its manufacture in the workshop. All the main parts of the device as well as the packages are recyclable. The device consists of 95% of steel, 4% of other materials, 1% of electro material and plastics. Environment-friendly liquidation to be performed after dismantling by an authorised person in compliance with EU regulations, corresponding with the WEEE directive (Waste Electric and Electronic Equipment).

TECHNICAL PARAMETERS

UNISTERI® HP

| Chamber | Dimension (mm) (height x width x depth) | | Number of sterilization modules | Chamber volume (l) Total | Weight (kg) | Cca max. input (kW) / fuses (A) | | Consumption cca max. per ster. cycle | | | | |
|---------|--|----------------------|---------------------------------|-----------------------------|-------------|---------------------------------|--------|--------------------------------------|--------------------------|------------|---------------------|--------------------|
| | Internal of the chamber | External of the unit | | | | ED | FD | Water [m³] | Demineralized water [m³] | Steam [kg] | El. energy ** [kWh] | El. energy * [kWh] |
| 336 - 1 | 320 x 320 x 625 | 1500 x 600 x 805 | 1 | 73 | 260 | 8,5 / 16 | 1 / 16 | 0,06 | 0,003 | 2,7 | 3,0 | 0,2 |
| 336 - 2 | 320 x 320 x 625 | 1500 x 600 x 860 | 1 | 73 | 297 | 8,5 / 16 | 1 / 16 | 0,06 | 0,003 | 2,7 | 3,0 | 0,2 |
| 636 - 1 | 670 x 350 x 700 | 1720 x 690 x 965 | 2 | 160 | 520 | 17 / 25 | 2 / 16 | 0,07 | 0,005 | 5,0 | 5,0 | 0,3 |
| 636 - 2 | 670 x 350 x 700 | 1720 x 690 x 1020 | 2 | 160 | 635 | 17 / 25 | 2 / 16 | 0,07 | 0,005 | 5,0 | 5,0 | 0,3 |
| 559 - 1 | 509 x 509 x 990 | 1720 x 850 x 1255 | *** | 254 | 690 | 24,5 / 40 | 2 / 16 | 0,08 | 0,008 | 8,0 | 8,0 | 0,4 |
| 559 - 2 | 509 x 509 x 990 | 1720 x 850 x 1310 | *** | 254 | 710 | 24,5 / 40 | 2 / 16 | 0,08 | 0,008 | 8,0 | 8,0 | 0,4 |

Chamber xxx-1 single - door
Chamber xxx-2 double - door.
Connecting voltage model 336 and 636 - 3P/PE 400 V, 50/60 Hz
Connecting voltage model 559 - 3P/N/PE 480 V, 60 Hz (for USA)
Noisiness: max. 65 dB

* FD type - without steam generator, to be connected to external steam distribution
** ED type - with 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.



UNISTERI® HP

- equipped with more individuality and comfort



site. All these features guarantee low operation costs and long service life of the device.

**Engineering providing service to humans
- simply, economically and safely**



For more information see
our internet web site

www.bmt.cz

Make acquaintance with our further offers...



VENTICELL® IL depyrogenation cabinets



Steam sterilizers



Laboratory drying devices and incubators



Stainless steel instrumentation



Formaldehyde sterilizer



Exchanger steam/steam



Washer Disinfectors



Cleaning and disinfection agents



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MMM Group



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UNISTERI HP - 01/2024 - EN/PR