



# Steam Sterilizers for Life Science

Pharmaceutical & industry applications

Innovation and product safety  
at the highest level



MMM. Protecting human health.

# Sterilizers from MMM

Individual design, equipment, and process controls

Based on our personal consultations, we develop solutions which are individually adapted to the specific needs of our customers—down to every last detail. The MMM sterilizer concept is highly modular and customizable, while also providing safety, cost-effectiveness, dependability, and sustainability.

## Areas of application

- PHARMACEUTICAL PRODUCTION
- RESEARCH & DEVELOPMENT
- ANIMAL SCIENCES
- INDUSTRIAL APPLICATIONS



## The right process for each individual application

Pharmaceutical and industrial applications primarily use the following processes:

### Saturated steam process

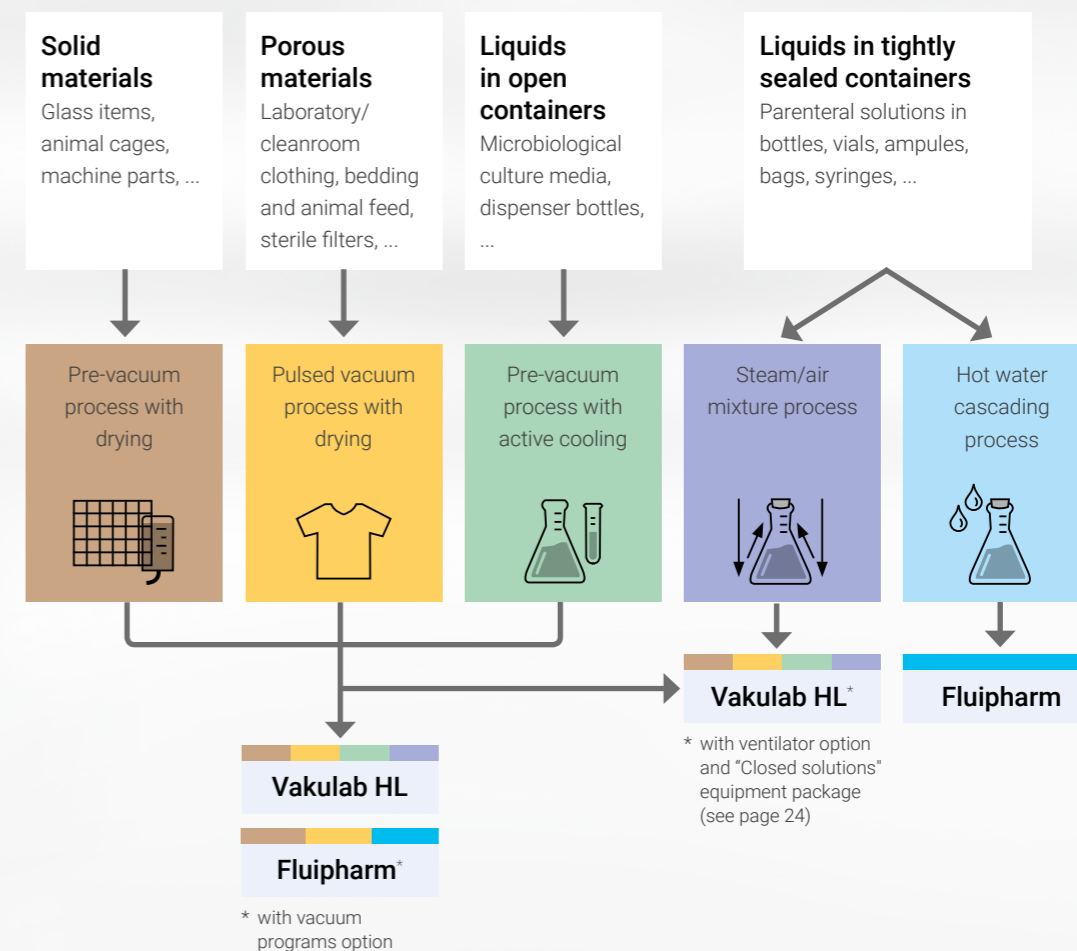
- » Pre-vacuum process with drying (solid materials)
- » Pulsed vacuum process with drying (porous materials)
- » Pre-vacuum process with active cooling (liquids in open or loosely sealed containers)

### Steam/air mixture process with active cooling

(liquids in tightly sealed containers)

### Hot water cascading process

(liquids in tightly sealed containers)



Naturally, MMM sterilizers satisfy all quality-related requirements and are in conformity with the following directives, standards, guidelines, and regulations:

- |                  |                       |               |                               |
|------------------|-----------------------|---------------|-------------------------------|
| • PED 2014/68/EU | • MD 2006/42/EC       | • AD 2000     | • DIN EN 13445                |
| • ASME           | • DIN 58950           | • ISO 12100   | • DIN EN 62304                |
| • GAMP           | • cGMP                | • TRBA 100    | • Biological Agents Ordinance |
| • GenTSV         | • ISPE Baseline Guide | • PDA reports | • CFR21/Part 11               |



Combined with robust, high-quality craftsmanship over a broad vertical range of manufacturing, our sophisticated control systems ensure that even the strictest requirements are met. MMM produces its equipment from top-quality materials on state-of-the-art machinery. Qualified staff and process-oriented quality assurance guarantee consistently high standards.

# Solid and porous materials

# Solutions

### Pre-vacuum process with drying

Solid materials with plain surfaces (e.g., instruments, cages, glass items, etc.) can be sterilized effectively and cost-efficiently using the pre-vacuum process. In this process, the air in the chamber is first removed before saturated steam is continuously introduced until a defined sterilization pressure is achieved. After the sterilization phase, the materials being treated are dried using a vacuum. The temperature range for the sterilization phase can be set between 105 °C and 134 °C.

### Pre-vacuum process with cooling or steam/air mixture cooling

Liquids in open or loosely sealed containers (e.g., culture media, dispenser bottles, etc.) can be sterilized fast and effectively with the simple pre-vacuum process. The temperature range for the sterilization phase can be set between 105 °C and 134 °C. The material is then cooled to a temperature below 80 °C using active jacket cooling. At the same time, a compressed-air cushion prevents the liquid from boiling over.

### Pulsed vacuum process with drying

For materials with porous surfaces (such as laboratory clothing, filters, long hoses or tubes, bedding, animal feed bags, etc.) that are difficult to de-aerate, the pulsed vacuum process is a useful method. This process utilizes repeated vacuum extractions combined with steam pulses for particularly effective removal of any air present. If necessary, the drying phase can also take place across several pulsed rounds. The temperature range for the sterilization phase can be set between 105 °C and 134 °C.

### Steam/air mixture process

The sterilization of liquids in closed containers poses a special challenge for process control, as the inside pressure in tightly sealed containers increases significantly when the liquid expands during the heating phase. To prevent the containers from bursting or deforming, a back pressure equal to the inside pressure in the container is generated in the chamber using compressed air. A mixture of steam and air is used as a heat transfer medium. To improve the transfer of heat and achieve an even temperature distribution, the steam/air mixture is continuously circulated inside the chamber by a fan. The fan is powered via a magnetic coupling, without any seals or gaps.

### Hot water cascading process

As an alternative to the steam/air mixture process, liquids in closed containers can be sterilized using the direct hot water cascading process. This method is mainly used in situations requiring fast and gentle sterilization of large amounts of liquids, primarily those in closed containers (e.g., blood bags, vials, etc.). The sterilization chamber is first filled with water up to a specified level. A circulation pump then pumps the water through a steam-heated heat exchanger, and the water cascades over the material being sterilized at a steadily increasing temperature. Compressed air is used to generate a back pressure, which in turn creates a pressure cushion that prevents the containers from deforming or bursting. In the cooling phase that follows, the sterilization water flows past a water-cooled heat exchanger and, by means of a continuously decreasing temperature, cools the sterilized material to a temperature below 80 °C.



## Pharmaceutical industry & beyond

When manufacturing sterile products, especially those in the pharmaceutical industry, every batch is vital. Sensitive products require both reliable sterilization and gentle handling. MMM offers additional equipment components that provide exactly what is needed.

## Programs

Application	Temperature	Description
<b>Programs for solid and porous materials</b>		
Solid materials	134 °C	Program for solid, temperature-resistant sterilization materials with plain surfaces.
Solid materials	121 °C	Program for solid sterilization materials with plain surfaces and low temperature resistance.
Porous materials	134 °C	Program for solid and porous materials with high temperature resistance
Porous materials	121 °C	Program for solid and porous materials with low temperature resistance.
Filters	121 °C	Program for pressure-sensitive membrane filters (e.g., made of cellulose acetate, polyamide or other similar materials), incl. assembled units.
Heating		Program for heating the sterilization chamber and piping.
Bowie-Dick test	134 °C	Steam penetration test
Vacuum test		Feature used to automatically test the chamber for leaks.
<b>Programs for liquids</b>		
Cold solutions	121 °C	Program for cold liquids, preparatory sterilization: culture media and suspensions. Disposal sterilization: cultures, contaminated lab utensils requiring processing.
Hot solutions	121 °C	Program for liquids introduced at higher temperatures (preparatory or disposal sterilization).
<b>Programs for enclosed liquids</b>		
Liquids in closed receptacles	121 °C	Program based on the hot water cascading process
Liquids in closed receptacles	121 °C	Program based on the steam/air mixture process



### Sterile-filtered compressed air

**Sterile-filtered compressed air is used to sterilize liquids.**

- » In-line sterilization of the compressed air filter
- » Highly reliable sterilization: Contamination of compressed air is not possible
- » Available connections for filter integrity tests
- » Temperature monitoring for in-line sterilization of the compressed air filter

### F<sub>0</sub> value calculation and control

**Minimizing the thermal load is a critical factor in the production of sterile solutions.**

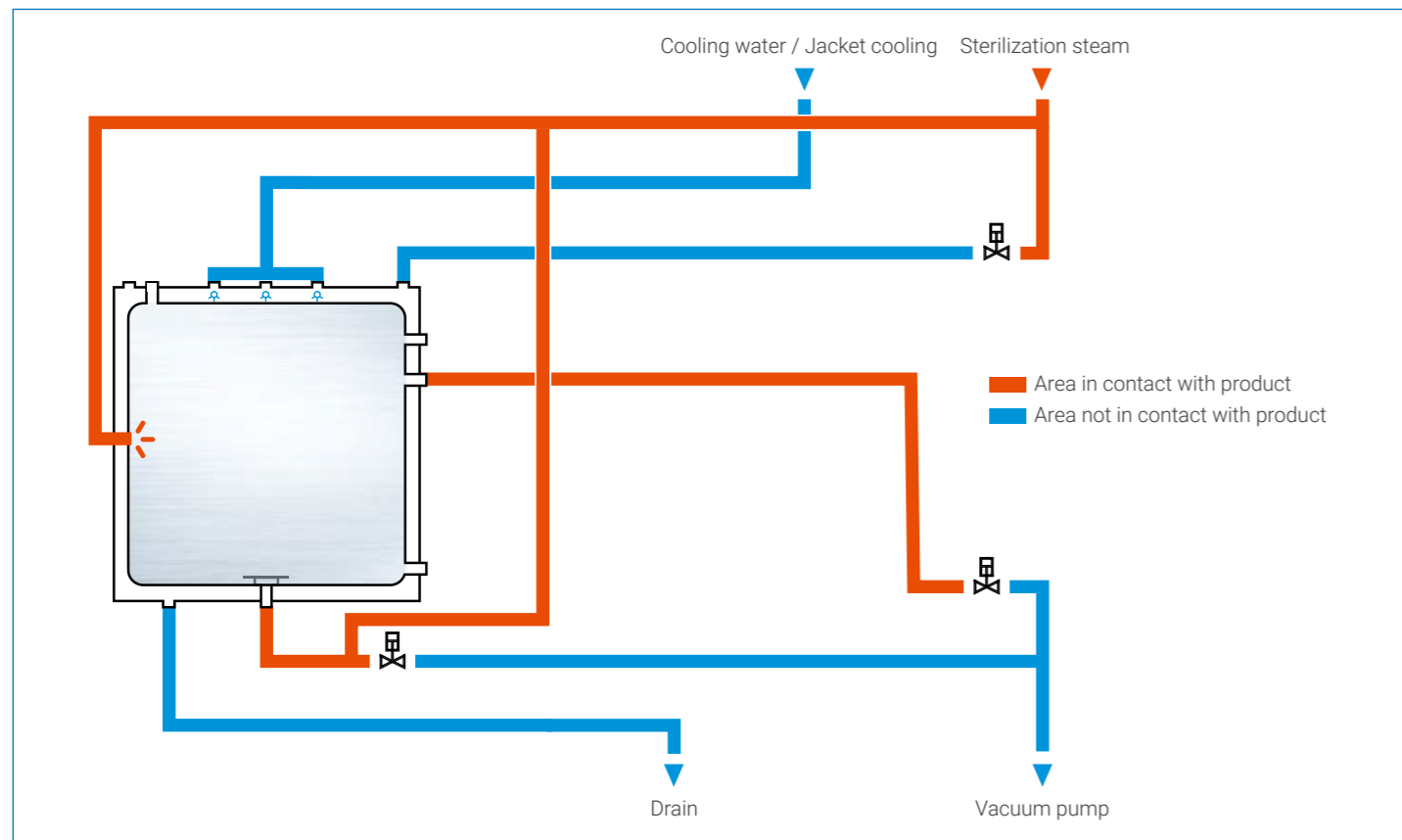
- » Online display of the current F<sub>0</sub> value during the program sequence
- » Documentation of the F<sub>0</sub> value attained
- » F<sub>0</sub> value control of the program sequence

### Typically treated materials

- » Liquids in open or loosely sealed containers
- » Filters
- » Glass items
- » Textiles
- » Tubing and hoses
- » Culture media

# A systematic approach to piping

The more valuable and sensitive the material being treated, the more important the finished quality of the components that come into contact with the sterilizing medium, and by extension, the product. To meet this challenge, we offer piping systems in various quality levels based on our customers' specific needs. The different quality classes defined by MMM make it easier to find the right combination of materials, surface quality, and process connectors.



- » Piping with slope for guaranteed drainage
- » Quality in line with customer needs
- » Pipe insulation to prevent heat loss
- » 3D/6D rule
- » Variable process connections
- » Sensors with diaphragm seals
- » Orbital welding technology

## Sample piping classes for area in contact with product

MMM piping classes	H10	H14	H20
<b>Piping</b>			
Material	1.4571 / 1.4404	1.4404	1.4404 / 1.4435
Interior surface	Bare metal	Bare metal	Ra < 0.8 µm (polished)
<b>Material certification</b>			
	/	/	3.1 EN 10204
<b>Ports/Connections</b>			
	Welding end / ISO 1127	Welding end / ISO 1127	Welding end / ISO 1127
	O-ring threaded connections	Clamp connection DIN 32676 / ISO 1127	Clamp connection DIN 32676 / ISO 1127
<b>Seals</b>			
	Viton	FDA-compliant EPDM	FDA-compliant EPDM

Custom modifications are also possible.



## Impressive design

Getting the machine into the building is often the first challenge faced during installation. At MMM, we're always mindful of the transport and assembly conditions, as well as the workflows required on-site.

- » Delivery into building in stages
- » Small footprint thanks to compact design
- » Ergonomic loading and working height
- » Front-side maintenance access for easier service
- » Single and double-door models
- » Height-adjustable outer frame on machines with floor-level loading



## Doors and quick-action closures

The automatic doors are equipped with a safety system featuring redundant pressure sensors and position switches that prevent the sliding doors (which are powered by electric motor) from being opened while a program is in progress or the chamber is pressurized.

### Safety & quality are the top priority

- » Door safety system: Cannot be opened when chamber is pressurized, cannot be closed if obstacles are present in door path
- » Door interior made of 1.4404 (AISI 316 L)
- » Exterior made of 1.4571 (AISI 316 Ti)
- » Door seal can withstand steam or compressed air
- » Silicon cord seal (FDA-compliant)
- » Contact-sensitive safety strip
- » Door cannot be opened when chamber is fully drained (Fluipharm)



On walk-in chambers, additional safety buttons prevent people from being trapped.

## Dual function for separation

In many cases, the sterilizer separates two areas that have different air-handling requirements. To maintain the difference in pressure between these two areas, the sterilizer is equipped with an air-tight partition in the assemblies compartment.

The control system also prevents both chamber doors from being opened at the same time. Even when the machine is switched off, at least one of the two doors is always pressurized to ensure air-tight separation.



### Leak-tight

- » Air-tight separation in stainless steel 1.4301 (AISI 304)
- » Chamber designed as airlock
- » Not possible for both doors to be open at same time
- » Sound-insulated separation, approx. 40 db (optional)
- » Superior safety: Automatic switching of door sealing medium to maintain separation effect in the event of a pressure drop.
- » Gas-tight design (optional)

Air-tight separation in stainless steel



# CUSTOM STERILIZATION CHAMBER



The centerpiece of every steam sterilizer is the sterilization chamber. Robotic technology combined with high-precision manual craftsmanship results in chambers built with superior quality. Made in Germany.

## Pressure vessel by MMM

- » Certified to the AD 2000-Merkblatt HP 0 and DIN EN ISO 3834-2 standards
- » Designed and manufactured according to the pressure equipment directive 2014/68/EU, AD 2000, and DIN EN 13445, ASME
- » Chamber dimensions based on customer specifications
- » Pressure vessel interior (1.4404 / AISI 316L)
- » Pressure vessel exterior (1.4571 / AISI 316Ti)
- » Design pressure at least 3.2 bar, relative (4.5 bar, e.g. BSL3 optionally available)
- » Surface quality:
  - Blasted
  - Smoothed to  $Ra < 0.8 \mu m$  (optional)
  - Electropolished (optional)

## Chamber & sensors with hygienic design

- » Chamber nozzles with hygienic process connectors (DIN 32676 compliant clamp, optional DIN 11864-3 compliant sterile clamp)
- » Horizontal nozzles sloped towards chamber (self-draining)
- » Sensors in contact with product equipped with highly temperature-resistant diaphragm seals
- » FDA-compliant seals
- » 3D/6D rule (optional)

## Easy-to-service design

We take the machine's entire lifecycle into consideration right from the development phase. Particularly in the case of extremely durable goods like MMM sterilizers, service and maintenance play an important role in terms of cost and time. That's why we arrange our components so that they are easily accessible, and it's also why we choose software that allows easy maintenance.

### Intelligent device layout

- » Front-side maintenance access
- » Front panel can be opened without being disassembled
- » All sensors feature plug connectors (optional)
- » HMI with piping & instrumentation diagram (optional)
- » Clear visualization of device status (actuators, valves, sensors, pumps, etc.)
- » Anti-pinch protection provided by service door switch
- » Easy to clean

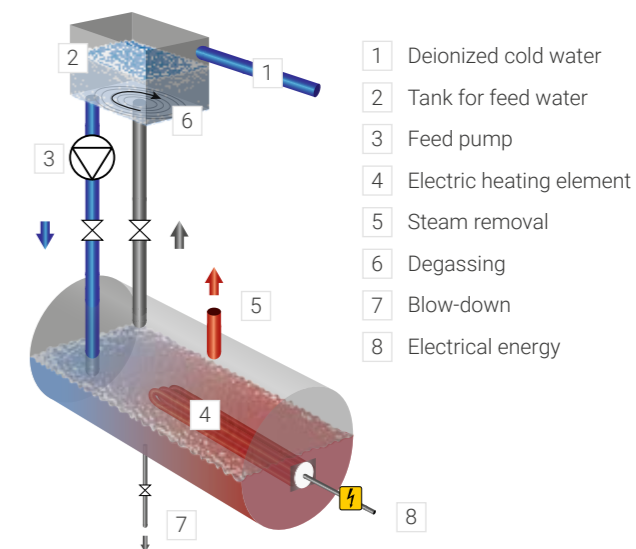


## Pure steam generation

If a supply of pure steam is not available on site, the sterilizer can be operated together with an MMM steam generator in conformity with DIN EN 285. No matter how your facilities are laid out, the steam generator can be integrated into the sterilizer, or can be installed next to, above or away from the steam consumer.

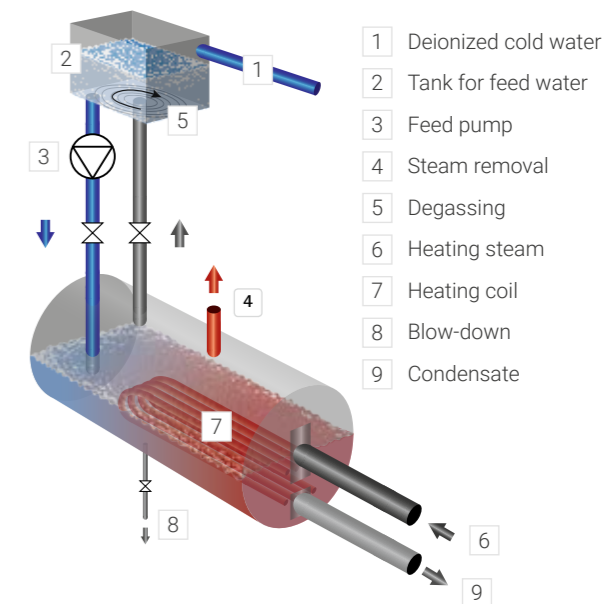
### Unootherm II electric steam generator

The Unootherm II is a low-noise pure steam generator that offers high performance with low energy requirements. It has been specially designed for facilities without a central steam supply. It can also be used for cost-effective steam generation in an emergency or on weekends. The boiler output can be optimized to meet the specific requirements of the connected sterilizer.



### Duootherm II steam-to-steam generator

The Duootherm II also offers the option of converting heating steam to pure steam in facilities with a separate heating steam supply. High performance is guaranteed with optimal sterilization steam, the required steam pressure is reached quickly, and the long service life of the parts means that maintenance costs are kept low. Even if the heating steam pressure is low, the Duootherm II is an ideal steam-to-steam generator: It can be ready for use and supply pure sterilizing steam starting at a heating steam pressure of just 4 bar.



## Ultrapure steam generators

Used to produce sterile, pyrogen-free ultrapure steam for pharmaceutical applications. Ultrapure steam generators are available as special customer-specific solutions.





## High-tech – harnessed intelligently

Combined with MMM's SiSoft control software, the latest generation of Simatic controllers enables intuitive operation, password-protected data management, and parameter-controlled free process programmability that allows all project-specific details to be individually accounted for.

### Precise process control

- » State-of-the-art industrial control
- » Redundant sensors for superior process reliability
- » PPV system: process parameter verification
- » Interfaces for optimal integration

### The software: secure and user-friendly

Software is developed and validated in conformity with the DIN EN 62304 standard for software life cycle processes. The sophisticated parameter structure enables highly flexible machine configuration. User management features ensure excellent access security.

### Custom device configuration

- » Continuous monitoring of all measured values
- » Precision actuator control
- » Barcode reading system with automatic program pre-selection (optional)
- » Autostart for automated program sequences, such as vacuum test, heating (optional)
- » Recipe revision and enabling (optional)
- » Active piping & instrumentation diagram (optional)
- » External communication interfaces (optional)

### Conformity with 21 CFR Part 11

- » User management
- » Data archiving with checksum
- » Audit trail

## HMI: modern & intuitive

The human/machine interface is just one part of MMM's concept for simplifying the work handled by operating personnel. All process-relevant information—such as the device status, process steps, values, and process graphs—is available at a glance on the display.

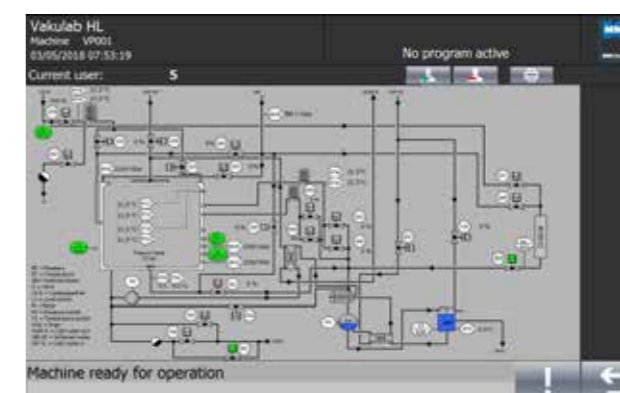
Program	Temperature	Batch number	Maintenance counter
P1	Machine parts 134°C	3	798
P2	Sterile filters 121°C		
P3	Ampules 121°C		
P4	Bottles 250ml 121°C		
P5	Bags 500ml 121°C		
P6	Heating-up 134°C		
P7	Vacuum test		
P8	Bowie Dick Test 134°C		
P9	Pass through		

**Selected program: P1 Machine parts 134°C**  
Vacuum program  
For solid and porous load.

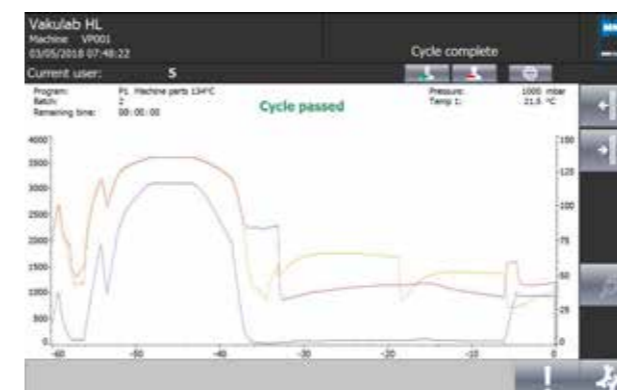
Program selection

### Features

- » Intuitive menu navigation on a color touch-panel display
- » 12" or 15" display (optional)
- » Large display for remaining time
- » Easy to clean
- » Active piping & instrumentation diagram (optional)
- » PDF screenshot function



Active piping & instrumentation diagram



Program sequence

Parameter management (recipe management)



## Resource management

The MMM sustainability concept helps protect the environment in day-to-day operations. Water is the only substance ever used as a sterilizing medium. To conserve this resource, MMM devices can be equipped with energy and media recovery systems.

MMM also has a DIN EN ISO 14001 environmental management system and a DIN EN ISO 50001 certified energy management system covering both our products and our operating processes.

### Water-saving system

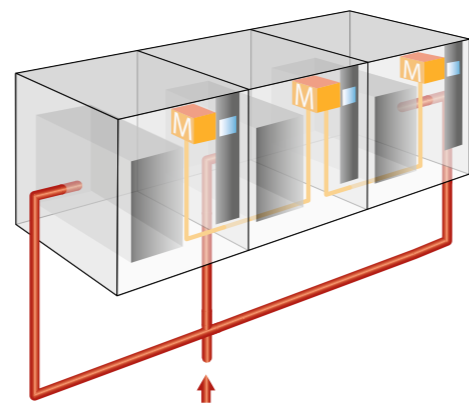
Since it is connected to the on-site cooling circuit, the vacuum pump is cooled using a resource-friendly recirculation method. Fresh water is only added where necessary. The optional media recovery system makes it possible to use up to 95 % less cold water.

### Standby mode & autostart

The control system includes a standby function which activates a power-saving standby mode during longer periods of device inactivity (jacket heating is stopped). It also allows the autostart to be individually programmed for each day, so that the sterilizer can automatically start a defined program sequence (e.g., vacuum test, heating). This provides users with significant time savings.

### Smart steam manager

The optional MMM steam manager controls the chronological program sequence of multiple sterilizers so that the removal of steam from the supply network is distributed as evenly as possible, which in turn prevents peak steam consumption loads. This means that devices can be designed with a lower output and allows investment and media costs to be reduced.



The steam manager can be used with either an external or integrated steam supply.

## Cost-efficient cooling & reduced water usage

For safety reasons, sterilized liquids cannot be removed from the chamber until their temperature falls below 80 °C. Depending on the specific cooling rate requirements, various different methods are available for cooling the liquids.

### Passive cooling – self-cooling

» No cold water used, long cooling times

### Active cooling – jacket cooling

» Temperature-controlled cold water usage, short cooling times

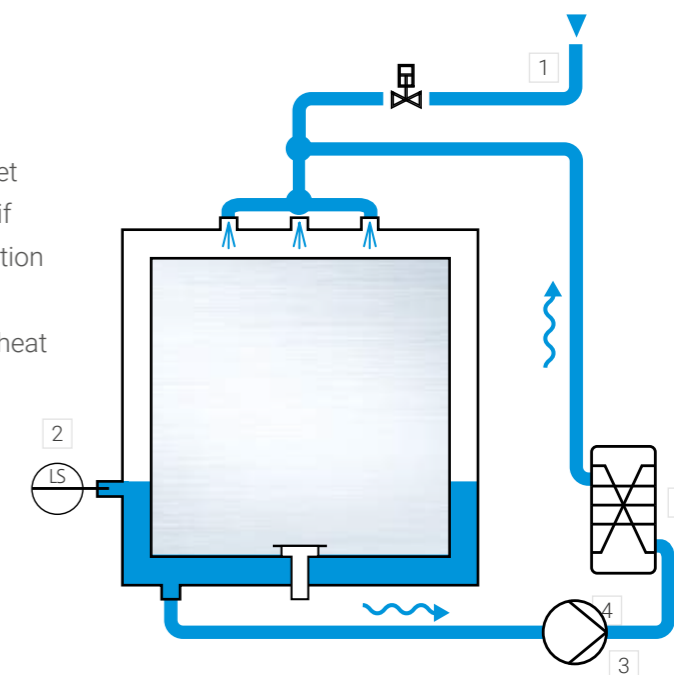
### Recirculation cooling

**90%**  
less water used

**Minimal cooling water usage, short cooling times.**

The amount of water used for jacket cooling can be drastically reduced if the water is re-cooled in a recirculation process. Here, a circulation pump routes used cooling water through a water-cooled heat exchanger, which cools the water again.

- 1 Soft water as cooling medium for jacket
- 2 Level switch
- 3 Circulation pump
- 4 Water-cooled heat exchanger



#### Take advantage of potential savings:

- » **Short batch times:** Active jacket cooling for temperature-sensitive products
- » **Efficient:** Reduce usage of soft water by up to 90 %
- » **Maximum potential savings:** Connect heat exchanger to on-site cooling circuit

### Cooling circuit

You can save even more cold water by connecting both the cooling for the heat exchanger and the condenser cooling for the vacuum device (which is active during the sterilization of solid and porous materials) to an on-site cooling circuit. This will allow you to use up to 95 % less cold water.

**95%**  
less water used

#### Take advantage of potential savings:

- » **Sustainability:** Reduce cold water usage by up to 95 % by connecting to an on-site cooling circuit

# Straightforward process documentation

Batch data is saved in the sterilizer to document the successful completion of a program sequence. The process documentation contains all of the relevant information required for documentation that complies with both standards and customer specifications: the program name, batch number, sterilization temperature, pressure, process start and end times, etc.

## Full data integrity

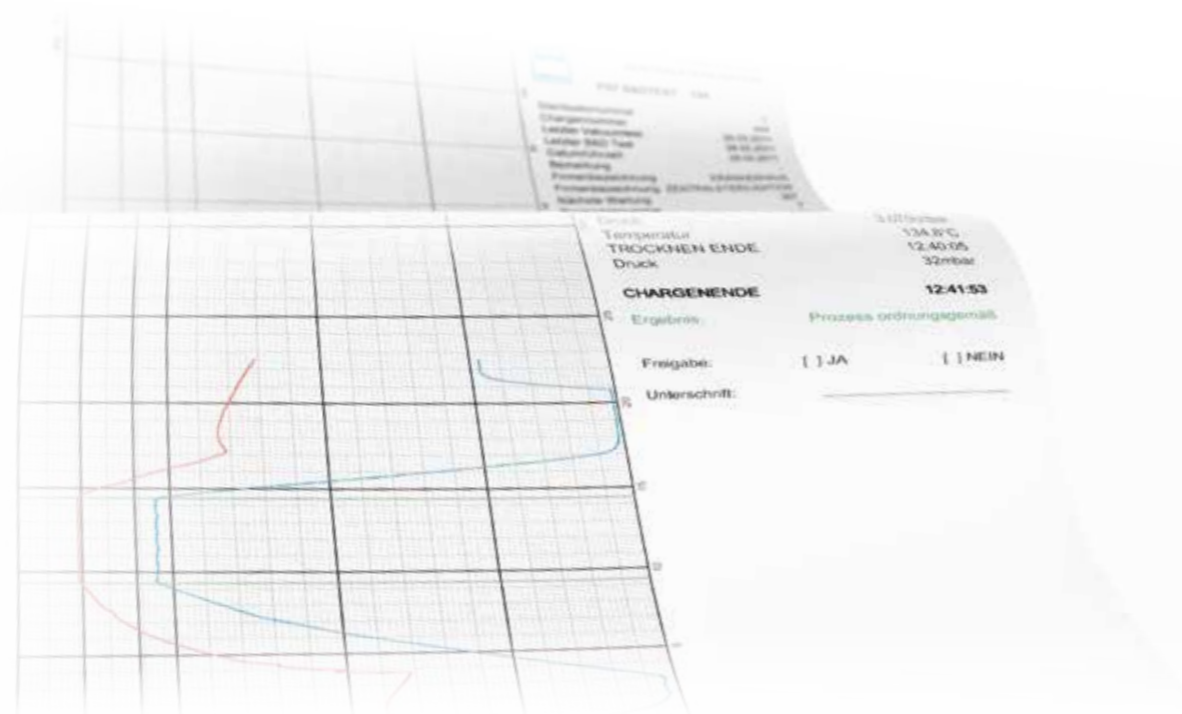
- » Batch and cycle log with plain text and color graph display
- » Nonvolatile data storage in the controller with MMM's SimServ software
- » Printouts on a connected network printer using MMM's Sicon software (optional)
- » Create a PDF file of the batch log on the sterilizer and export it to a server or external PC using MMM's Sicon software (optional)
- » Use MMM's ChargenViewer software to search for, analyze, and print batch data (optional)

## Safety first

We've developed a special software package for further processing of your batch data: SimServ allows batch data to be saved in a file on an external computer. This data can then be used by the ChargenViewer for various different management levels.

## Available at all times

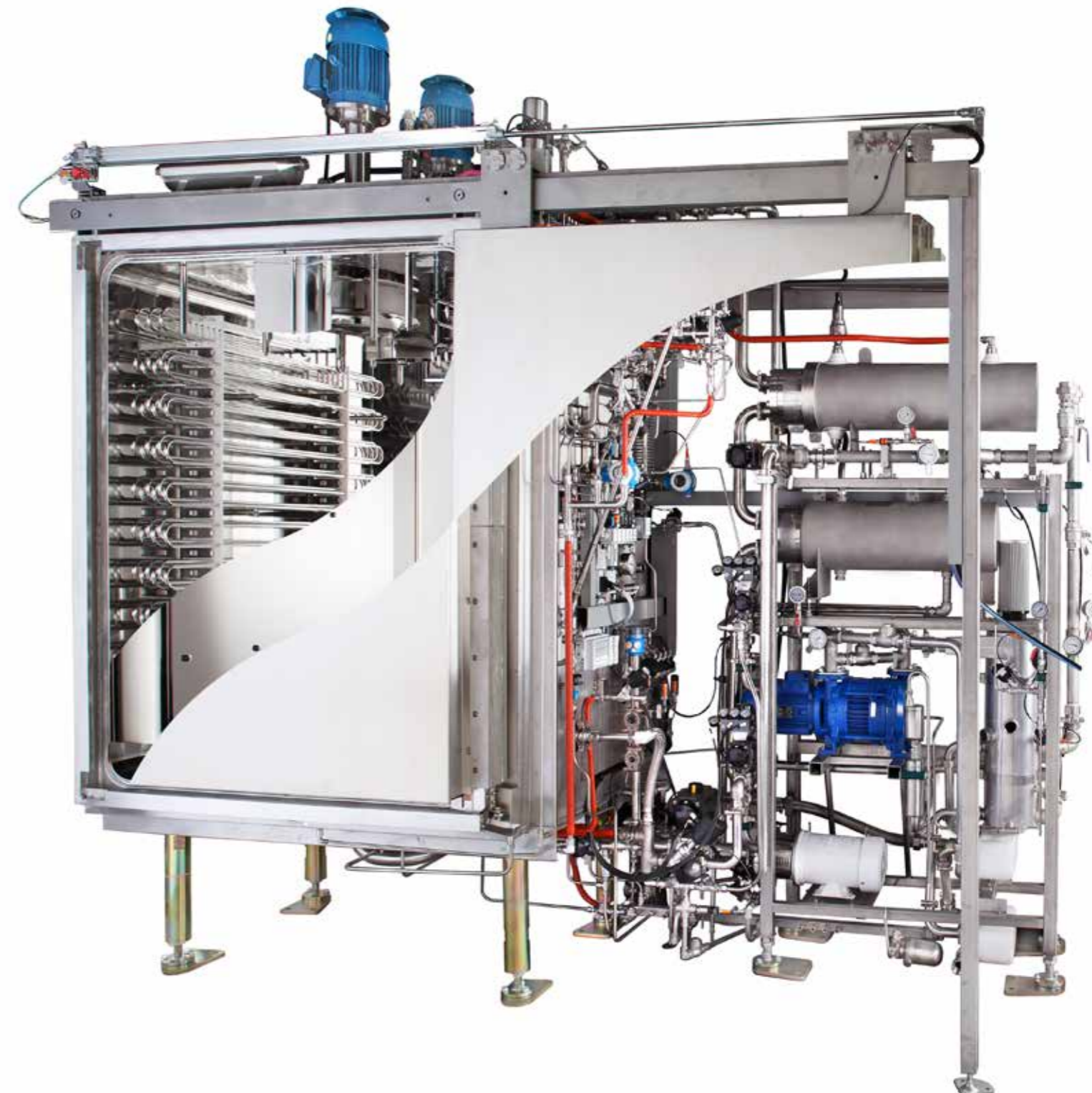
- » Long-term archiving of batch data as files
- » Can be reprinted any number of times
- » Can be viewed and analyzed at a later date
- » Export to Microsoft® Excel
- » Data can be saved as a PDF file if desired



# High-tech customizing

– every sterilizer is one of a kind

Every customer has application-specific requirements, and every installation is different. As a result, each and every MMM sterilizer is a unique machine. The MMM Group specializes in developing and manufacturing sophisticated high-end devices. Our experienced engineering experts work closely with the customer to develop creative and functional solutions at the highest level, tailor-made to deliver exactly what our customers need.



# Communication & automation

It is now rare to find sterilizers being used as full standalone solutions in an industrial setting. In a growing number of applications, sterilizers are being networked with other machines and systems. The communications requirements that go hand-in-hand with this development can be divided up into the groups described below.

## Direct communication with other machines

### Automatic transport systems

The sterilizer operates as a slave and executes commands from a transport system, such as opening or closing the loading door, and selecting or starting a program. Transport can be fully handled by systems from a single manufacturer.

### Connection to an H<sub>2</sub>O<sub>2</sub> generator

The sterilization chamber is used as a gassing chamber by the generator. The sterilizer notifies the generator that the chamber is dry and cold enough for an effective gassing process to take place. Faults are communicated from machine to machine, and appropriate actions are initiated.

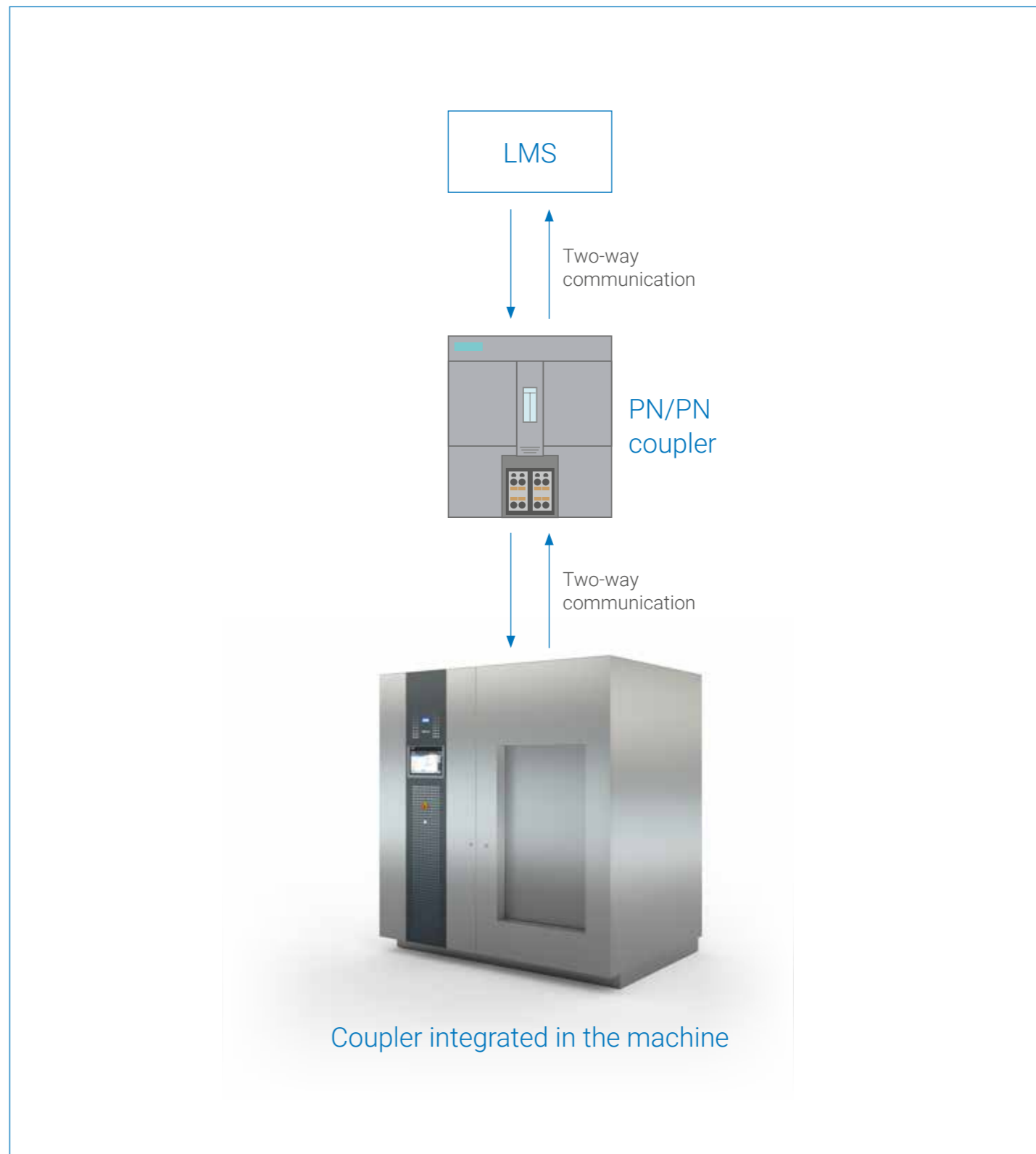
## Data provision for other systems

Defined process data (such as the program name, process step, alarm information, etc.) is provided unidirectionally for use by a building management system or data historian.



## Communication with logistics management systems (LMS)

Two-way communication between the sterilizer and an LMS. The LMS handles the control and monitoring functions for an entire production line made up of multiple individual systems, ranging from the filling equipment and transport systems to the sterilizer itself.







# Vakulab<sup>®</sup> HL / H

Our response to the pharmaceutical industry's strict demands for design and process reliability.

Hygienic design and customer-specific special equipment handle the tough tasks necessary in the production of sterile materials, such as solutions or filled syringes, as well as those encountered in production-related areas where the sterilization of fermenters, machine parts, clean room garments, filters, etc. calls for individual solutions.

- » Hygienic design for the strictest hygiene requirements
- » Flexible equipment options
- » Custom design engineering

## Available processes

-  Steam/air mixture process for liquids in closed containers
-  Pre-vacuum process with drying for solid materials
-  Pulsed vacuum process with drying for porous materials
-  Pre-vacuum process with cooling for liquids in open containers

## Features

- » Siemens controller
- » 12" or 15" display, or customer-specific size
- » Clamp or aseptic threaded connections
- » FDA-compliant sealing materials and lubricants (21 CFR)
- » F<sub>0</sub> value display
- » Filter housing and elements can be sterilized inline
- » Active jacket cooling
- » Recirculation cooling and cooling circuit connection
- » Cooling coil
- » Sterile filtration of compressed air
- » Air detector
- » Air-tight separation
- » Fan for steam/air mixture process
- » "Closed solutions" equipment package

(selection of equipment options)



## Standards

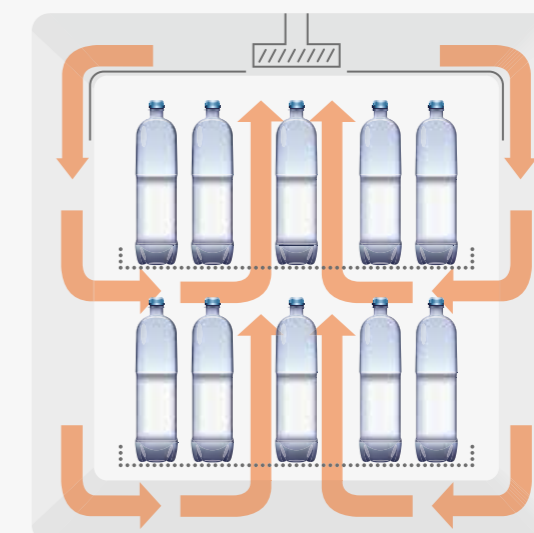
The Vakulab<sup>®</sup> HL / H is a pharmaceutical sterilizer that meets the requirements of DIN 58950-2

## Size chart

The standard chamber sizes listed below are currently available at MMM. Custom sizes are also available based on individual application specifications. All models are available as a single- or double-door design. For double-door models, add an additional 20 mm to the device depth.

Type	Internal chamber clearance in mm (H x W x D)	Volume in L	Dimensions of device exterior in mm (H x W x D)
<b>H models</b>			
669	710 x 650 x 990	460	1918 x 1900 x 1360
969	1000 x 650 x 990	644	1918 x 1900 x 1360

Customer-specific sizes available on request.  
Technical data subject to change without notice.



Steam/air mixture process

## Typically treated materials

- » Filters
- » System equipment
- » Glass items
- » Textiles
- » Tubing and hoses
- » Liquids







# Vakulab<sup>®</sup> HL / G

Demanding requirements for design and process reliability where large-volume materials and trolleys are used.

Hygienic design and customer-specific special equipment handle the tough tasks necessary in the production of sterile materials, such as solutions or filled syringes, as well as those encountered in production-related areas where the sterilization of fermenters, machine parts, clean room garments, filters, etc. calls for individual solutions.

- » Hygienic design for the strictest hygiene requirements
- » Flexible equipment options
- » Floor-level loading

## Available processes

-  Steam/air mixture process for liquids in closed containers
-  Pre-vacuum process with drying for solid materials
-  Pulsed vacuum process with drying for porous materials
-  Pre-vacuum process with cooling for liquids in open containers

## Features

- » Siemens controller
- » 12" or 15" display, or customer-specific size
- » Clamp or aseptic threaded connections
- » FDA-compliant sealing materials and lubricants (21 CFR)
- » F<sub>0</sub> value controlled process sequence
- » Filter housing and elements can be sterilized inline
- » Active jacket cooling
- » Recirculation cooling and cooling circuit connection
- » Cooling coil
- » Sterile filtration of compressed air
- » Air detector
- » Air-tight separation
- » Fan for steam/air mixture process
- » "Closed solutions" equipment package

(selection of equipment options)



## Standards

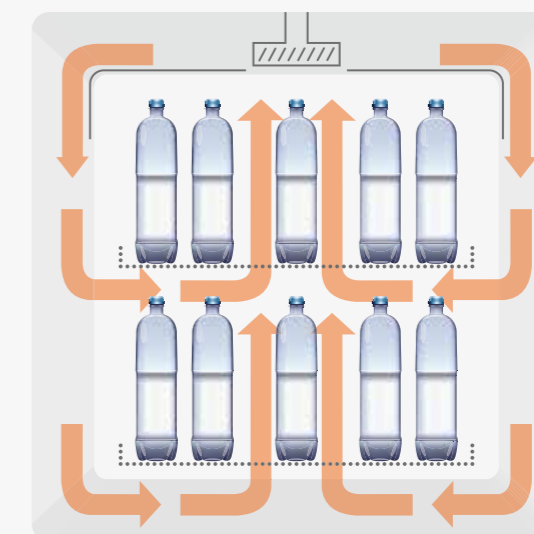
The Vakulab<sup>®</sup> HL / G is a pharmaceutical sterilizer that meets the requirements of DIN 58950-2

## Size chart

The standard chamber sizes listed below are currently available at MMM. Custom sizes are also available based on individual application specifications. All models are available as a single-door design.

Type	Internal chamber clearance in mm (H x W x D)	Volume in L	Dimensions of device exterior in mm (H x W x D)
<b>G models</b>			
181015	2010 x 1100 x 1640	3626	2550 x 3100 x 2210

Customer-specific sizes available on request.  
Technical data subject to change without notice.



Steam/air mixture process

## Typically treated materials

- » Filters
- » System equipment
- » Glass items
- » Textiles
- » Tubing and hoses
- » Liquids






# Fluipharm®

For fast, gentle, and efficient sterilization of liquids in closed containers.

Perfected for the use of the hot water cascading method, the Fluipharm® offers everything necessary for research and development, the production of sterile materials and, last but not least, the treatment of parenteral solutions in hospital pharmacies. After all, fast sterile processing is a key ingredient to the success of any business in the pharmaceutical or biotech industry.

- » Fast and reliable process sequence
- » Individual design and equipment
- » Special programs: vacuum drying, ampule check, wash and rinse program for ampules

## Available processes

-  Hot water cascading process for liquids in closed containers
-  Pre-vacuum process with drying for solid materials
-  Pulsed vacuum process with drying for porous materials

## Features

- » Siemens controller
- » 12" or 15" display, or customer-specific size
- » Clamp or aseptic threaded connections
- » FDA-compliant sealing materials and lubricants (21 CFR)
- » F<sub>0</sub> value controlled process sequence
- » Sterile filtration of compressed air
- » Air-tight separation
- » "Vacuum programs" equipment package
- » Additional programs: "Vacuum drying, ampule check, rinse cycle"
- » Heat exchanger with heating steam
- » Connection to cooling circuit
- » Heat exchanger fully drainable on product side, hygienic process connections

(selection of equipment options)



## Standards

The Fluipharm® is a pharmaceutical sterilizer that meets the requirements of DIN 58950-2

## Size chart

The standard chamber sizes listed below are currently available at MMM. Custom sizes are also available based on individual application specifications. All models are available as a single- or double-door design. For double-door models, add an additional 20 mm to the device depth.

Type	Internal chamber clearance in mm (H x W x D)	Volume in L	Dimensions of device exterior in mm (H x W x D)
<b>H models</b>			
969	1000 x 650 x 990	644	1918 x 1900 x 1290
9612	1000 x 650 x 1340	871	1918 x 1900 x 1590
9618	1000 x 650 x 1940	1267	1918 x 1900 x 2310

Customer-specific sizes available on request.  
Technical data subject to change without notice.



Hot water cascading process

## Typically treated materials

- » Liquids in closed containers
- » Vials
- » Ampules
- » IV bottles / IV bags



# Overview of MMM sterilizers



Technical features	Vakulab® HL	Fluipharm®
<b>Directives, standards, guidelines, and regulations</b>		
PED 2014/68/EU, MD 2006/42/EC, DIN 58950	●	●
<b>Mechanical design</b>		
Chamber inner jacket material (1.4404 / AISI 316L)	●	●
Chamber inner surface blasted	●	●
Chamber inner surface smoothed to Ra < 0.8 µm	○	○
Chamber inner surface electropolished	○	○
Hygienic design – chamber & sensors	○	○
Air-tight separation	○	○
<b>Piping</b>		
MMM piping class H10	●	●
MMM piping class H14	○	○
MMM piping class H20	○	○
Insulation with aluminum-laminated mineral wool	○	○
<b>Cooling</b>		
Self-cooling (passive cooling)	○	/
Jacket cooling (active cooling)	●	/
Recirculation cooling (active cooling)	○	/
Sterilization water cooling (hot water cascading process)	/	●
Cooling circuit connection	○	○
<b>Control &amp; software</b>		
PLC controller	●	●
Simatic touch panel 4", 12", 15" (sizes available as options)	●	●
UPS for SiSoft control system	○	○
Active piping & instrumentation diagram	○	○
<b>Sterilization process &amp; additional programs</b>		
"Closed solutions" equipment package	○	/
"Hot water cascading process" equipment package	/	●
"Vacuum programs" equipment package	●	○
Fan	○	/
Inline compressed air filter sterilization	○	/
Autostart program	○	/
Standby mode program	○	/
F <sub>0</sub> value display and control	○	○
H <sub>2</sub> O <sub>2</sub> connection	○	/
<b>Process technology components</b>		
Internal vacuum equipment	●	○
External vacuum equipment	○	○
Compressed air filter	○	○
Exhaust air filter	○	/
Connection for filter integrity test	○	○
<b>Technical documentation</b>		
Standard device documentation	●	●
Enhanced device documentation	○	○
FDS, HDS, SDS	○	○
Risk analysis based on Machinery Directive	○	○
<b>Factory acceptance test &amp; qualification</b>		
Standard FAT	○	○
Installation / Qualification (IQ) for pharma	○	○
Operation / Qualification (OQ) for pharma	○	○
Performance / Qualification (PQ) for pharma	○	○
<b>Batch documentation</b>		
SimServ – external batch documentation	●	●
Sicon – internal batch documentation	○	○
BatchViewer	○	○

● = standard ○ = optional / = on request (subject to change)



## Customer service: Reliable & effective

Our knowledgeable service organization is here for you around the clock to help ensure continuous, trouble-free operation of your installed systems. With branches and representative offices located for optimal coverage throughout Europe, we're always close by and can quickly arrive on-site in case of an emergency.

The sophisticated and innovative design of our systems and devices allow functional impairments to be resolved in little time in many cases, thanks to remote diagnostics performed by qualified personnel. Based on our professional maintenance planning, we can guarantee you the highest possible availability of your systems.

However, our goal is to prevent any problems from arising in the first place. We won't hand over our systems to you until everything is running flawlessly, until all programs have been tested/validated and accepted in accordance with your individual customer specifications, and until operating personnel have been trained to use our systems.

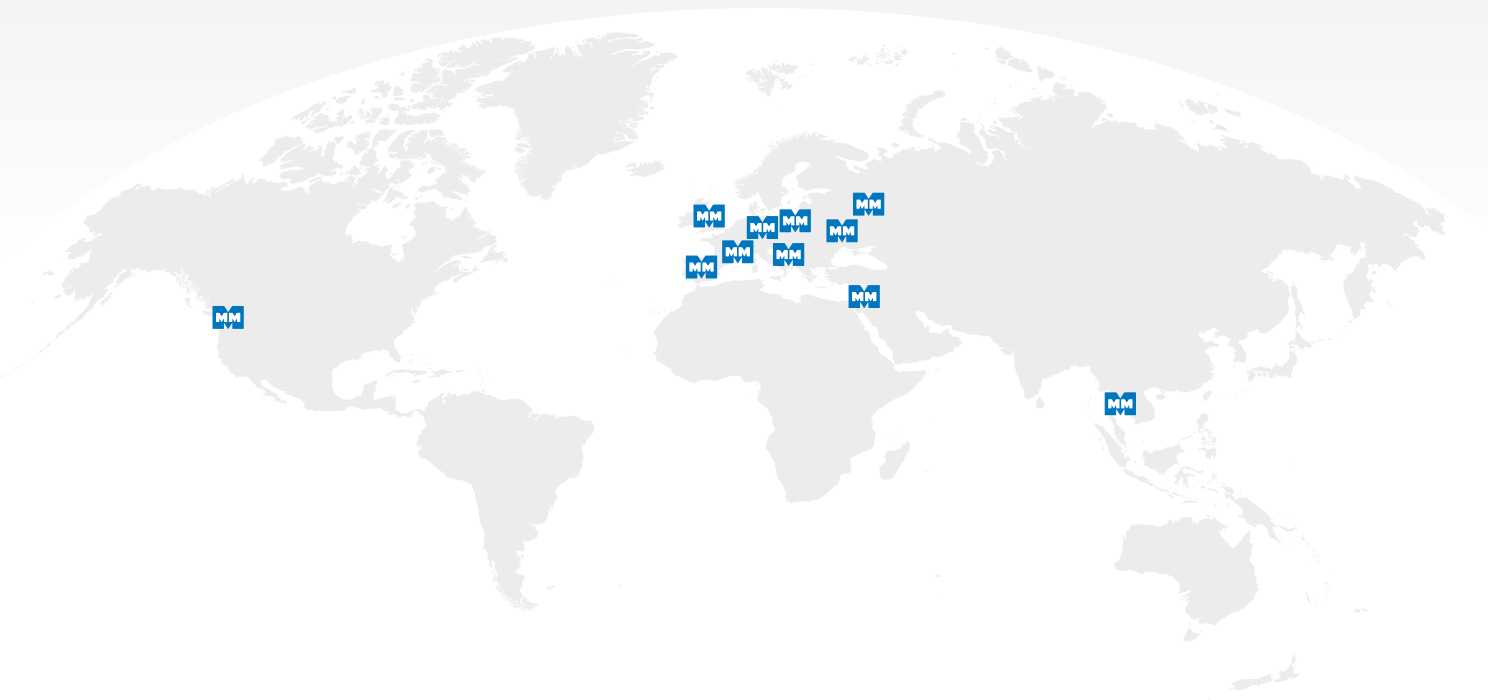
In addition to performing maintenance and repair, we also make sure that the installed systems are up-to-date. Tailor-made solutions for adapting to changing conditions, optimizing the use of consumables, and continuously meeting new individual needs and legal requirements increase the service life and cost-effectiveness of the systems and secure the value of your investment.

### Services

- » Maintenance planning
- » Inspection and service
- » Repair
- » 24-hour hotline
- » Spare parts logistics – 24-hour service
- » Upgrade service
- » Process validation
- » Initial & advanced training



MMM. Subsidiaries worldwide.



Healthcare

Life Science

Customer Service



## MMM Group

MMM has been operating worldwide as one of the leading system providers in service of health since 1954. With a complete range of products and services relating to all aspects of cleaning, disinfection and sterilization systems for the fields of Healthcare and Life Science, MMM has positioned itself as a major driver of quality and innovation in both the German and international markets. Our products are

individually adapted to the requirements of our customers all over the world. The high vertical range of manufacturing in our production plants ensures that we fulfill the most stringent demands for quality in the medical technology industry. More than 1100 employees apply their expertise and dedication to the mission of the MMM Group: **Protecting human health.**



**MMM Münchener Medizin Mechanik GmbH**

Semmelweisstraße 6

82152 Planegg / Munich, Germany

Tel.: +49 89 89918-0

Fax: +49 89 89918-118

[www.mmmgroup.com](http://www.mmmgroup.com)

