User manual

MMM Group



Steam sterilizer

Selectomat PL CL

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General information

This user manual describes the operation of your steam sterilizer.

If your machine is equipped with an automatic transport system (Cart Logistik), please also read the supplementary user manual for the automatic transport system.

Legend of symbols and hazard warnings

The following hazard warnings and symbols may appear in this user manual:

- ▶ Handling instruction
- List



Ignoring hazard warnings may cause injury!



Ignoring these warnings may cause damage to the machine or the load!



Indicates practical tips or important information about the functioning of the machine.

List of abbreviations

BW	Loading trolley	For transporting goods into a sterilizer with raised loading
TW	Transport trolleys	For transporting loading trolleys
TW HUB	Height-adjustable transport trolley	For transporting loading trolleys
ED	Internal steam	Version with integrated or associated steam generator
FD	External steam	Connection to an on-site steam supply, e.g. domestic steam
StU	Sterilization unit	300 x 300 x 600 mm
DIW	Deionized water	Feed water for the steam generator
SOP	Standard Operating Procedure	Standard operating procedure

Warning signs on the machine

The following warning signs may be present on the machine:



Warning dangerous electrical voltage! Open only by trained personnel.



Warning hot surface! Wear protective gloves.



Warning risk of crushing injury to hands.



Do not sit on the .



Protective ground



Wear protective glasses!



Wear protective gloves!

Device labeling

The specification of this steam sterilizer is indicated by the following device labeling:

This can be explained by way of an example: Selectomat PL 9612 - 2 H R

Machine name	Rated chamber size H W D	Number of doors	Variant	Position of the chamber	
Selectomat PL series	9 6 12	2	H	R	
	The chamber size (9 x 6 x 12) is based on the dimensions for a sterilization unit (1 STU = 3 x 3 x 6 dm). Example: Chamber size 9 6 12 = 12 STU	1-door 2-door	See the table below	R	Chamber right Panel left
				L	Chamber left Panel right

Variant	Version		
	Position of the chamber	Integrated steam generator	Opening direction of the chamber door
H	Right / left	Option	Horizontal
V	Right / left	Option	Vertical
G	Right / left	--------	Horizontal
CL	--------	According to model	Vertical

Chamber specifications: Variant H

Chamber size*	Number of StUs	Volume in liters	Internal chamber clearance in mm (H x W x D)	Loading height
666	4	320	710 x 650 x 690	625 mm
669	6	460	710 x 650 x 990	625 mm
6612	8	622	710 x 650 x 1340	625 mm
966	6	451	1000 x 650 x 690	390 mm
969	9	647	1000 x 650 x 990	390 mm
9612	12	875	1000 x 650 x 1350	390 mm

Chamber size*	Number of StUs	Volume in liters	Internal chamber clearance in mm (H x W x D)	Loading height
9618	18	1267	1000 x 650 x 1940	390 mm

Machines with raised loading (variant H) are loaded and unloaded with a transport trolley and a loading trolley positioned on it.

* Standard chamber sizes only. The dimensions may vary for each project.

Chamber specifications: Variant V

Chamber size*	Number of StUs	Volume in liters	Internal chamber clearance in mm (H x W x D)	Loading height
636	2	160	670 x 350 x 700	850 mm
666	4	314	702 x 652 x 690	850 mm
669	6	453	702 x 652 x 990	850 mm
6612	8	610	702 x 652 x 1340	850 mm

Machines with raised loading (variant V) are loaded and unloaded with a transport trolley and a loading trolley positioned on it.

* Standard chamber sizes only. The dimensions may vary for each project.

Chamber specifications: Variant G

Chamber size*	Number of StUs	Volume in liters	Internal chamber clearance in mm (H x W x D)	Loading height
969	9	1067	1360 x 720 x 1090	Floor level
9612	12	1361	1360 x 720 x 1390	Floor level
9618	18	2095	1360 x 720 x 2140	Floor level

Floor-level, passable machines (variant G) are loaded and unloaded using trolleys.

* Standard chamber sizes only. The dimensions may vary for each project.

Chamber specifications: Variant CL

Chamber size*	Number of StUs	Volume in liters	Internal chamber clearance in mm (H x W x D)	Loading height
636	2	160	670 x 360 x 700	850 mm
559	2	254	508 x 508 x 990	835 mm
666	4	314	702 x 652 x 690	850 mm
669	6	453	702 x 652 x 990	850 mm
6612	8	610	702 x 652 x 1340	850 mm
6618	12	885	702 x 652 x 1940	850 mm

Machines with raised loading (variant CL) are loaded and unloaded with a transport trolley and a loading trolley positioned on it.

* Standard chamber sizes only. The dimensions may vary for each project.

1 Safety

Read this user manual carefully and save it for future reference.



Observe the safety instructions.

Your personal safety and the correct functioning of the machine are at stake.

To be able to operate and maintain this machine safely in a hazard-free and problem-free manner, the user must be familiar with the safety instructions and warnings contained in this user manual and be capable of carrying out the instructions provided correctly.

The machine and accessories must not be modified. This especially applies to the safety mechanisms.

This user manual contains information on the proper use of the machine.

It is directed at the authorized users (see Chapter 1.3, "operators") and the system supervisor (see Chapter 1.3, "operators"), but also at anybody involved in the installation, commissioning, operation or maintenance of the machine.

For reasons of clarify, this user manual only contains the necessary instructions for normal operation and routine maintenance, as well as a description of the essential functions of the machine.

For more information about your machine, please contact the manufacturer.

1.1 Intended use

Intended purpose

The **Selectomat PL** steam sterilizer is suitable for sterilizing medical and non-medical materials.

This machine is intended for use both in the medical sector and outside the medical sector.

Intended use



Applications in the medical sector.

A process validation must be provided for all the types of material to be reprocessed.

The **Selectomat PL** steam sterilizer is used to steam sterilize the following materials using the fractionated vacuum process:

- Solid items made of metal (e.g., instruments, kidney dishes, saline bowls, etc.)
- Heat resistant materials made of rubber or plastic
- Porous materials (e.g., laundry, dressings, swabs, etc.)
- Medical devices that have been used for operations on high-risk tissues (for prion prevention, e.g., cases of suspected CJK/vCJK)



Applications in the non-medical sector.

When equipped with the **Open solutions** equipment package, the **Selectomat PL** steam sterilizer is suitable for sterilizing the following non-medical materials:

- Liquids in open or loosely sealed containers

Limitations of use



The Selectomat PL steam sterilizer is suitable for treating the following materials:

- Flammable and explosive items
- Liquids in open or sealed bottles and containers
  Exception: **Open solutions** equipment package available
- Liquids in tightly sealed bottles and containers
- Infectious hospital waste (e.g., C waste)
- Pathogenic materials

Service life of the machine

If the specified maintenance work is regularly performed, the expected service life of the machine is 10 years (under standard usage conditions, see Directive (EU) 2017/745/EU on medical devices).

During the service life of the product, the properties and performance characteristics are not influenced in a way that could endanger the safety of patients, users and, if applicable, third parties.

If you wish to continue using the machine beyond the above period, please contact the manufacturer or an authorized service company for inspection of the machine to assess the wear, technical status, and the possibility of repair.

1.2 Responsibilities of the operator

This machine is a medical device in accordance with EU Regulation 2017/745 on Medical Devices, and a pressure vessel in accordance with the Pressure Equipment Directive 2014/68/EU.

The operator is responsible for adhering to all regulations and regular inspections under these directives over the entire product life cycle.



Note!

The operator is required to observe the national laws and regulations applicable to the installation site of the machine.

The operator is solely responsible for determining which legal provisions cover the installation and the operation of this machine. These may differ from the information provided in this user manual!



The operator must comply with their reporting obligations to manufacturers and authorities in accordance with EU Regulation 2017/745 on Medical Devices, Article 87.

Before commissioning

The operator must ensure that the following requirements are met:

- The machine has been properly assembled, installed, and set up by an authorized company
- The programs used have been configured for the processes, unused programs have been locked
- The inspection and maintenance plan is available
- The system supervisors and users have been trained
- The operating permit has been issued (if required by national regulations)
- The standard operating procedure is available
- A validation has been performed (if required by national regulations) (see Chapter 1.2.3.1, "Process validation")

Network security

MMM recommends performing a cybersecurity assessment of the network interface, and implementing any necessary measures as part of a risk management process in accordance with the EN 80001 standard.

Interface validation with cycle protocols from outside companies

Cycle protocols that are created and used to release the cycle must contain verified data. If cycle protocols for releasing a cycle are produced by external companies, the operator is responsible for validating the interface or must otherwise ensure the data are verified.

If the machine is being operated in Germany

Observe the German Occupational Safety Act, and the Ordinance on Industrial Safety and Health (BetrSichV). In accordance with BetrSichV, a risk assessment must be performed regarding the operation within the company of an installation subject to monitoring (Chapter 1.2.4, "Operation of pressure equipment").

We recommend documenting the measures resulting from the risk assessment for safe operation and use of the machine (e.g. operating readiness, down times, qualification of operating personnel, etc.) in a standard operating procedure (SOP).

Note

The operator is responsible for performing periodic inspections pursuant to the German Ordinance on Industrial Safety and Health (BetrSichV).

Observe the inspection intervals of BetrSichV.

1.2.1 Commissioning - equipment requirements

The sterilizer must be connected to the supply lines (e.g. drinking water network) and secured to prevent pressure overshoots according to the manufacturer's planning drawing and the dimension drawing, the piping diagram and the local regulations.

Observe the national legal regulations on drinking water protection (e.g. DIN EN 1717).

1.2.1.1 Connection to the electrical power supply

Note!

Make sure that the voltage, current type and frequency specified on the type plate correspond to those at the site.

Observe DIN EN 61010-1, Section 6.10.2, when connecting the machine to the electrical power supply. In particular, it must be ensured that:

- the cable gland is used as strain relief
- the protective conductor is the longest of all individual lines in the connection cable



Turn off the load disconnect switch when working on the machine and secure it with a lock to prevent it from being switched on again unintentionally (Chapter 1.5.5, "Load disconnect switch").

1.2.1.2 Blow off line

For the ED version without the *Blow off line exiting in the bottom tray* option, the machine must be connected to a blow-off line (steam generator safety valve) provided on-site. This line must safely discharge the steam into the open.



Observe the instructions in the installation preparation drawing and technical data sheet.

Blow off line exiting in the bottom tray (option)

When using suitable supplementary equipment (for example a pressure limiter), the blow-off line of the safety valve can exit in the bottom tray of the machine. An on-site blow-off line is then not required.



Risk of contamination!

The operator must inspect and assess the installation location as to whether blow off via the safety valve can safely be implemented!

Observe the instructions in the installation preparation drawing and technical data sheet.

Ensure that the line is unobstructed at all times, and that the steam can be blown off safely.

The blow off line must be adequately dimensioned so that no impermissibly high counter-pressure develops when blowing off the safety valve (see technical connection data).



If the sterilizer is disconnected fully from the power supply (e.g. via an on-site main switch) or in the event of a power failure, the load disconnect switch installed in the assemblies compartment must be switched on again by a specialist before recommissioning the sterilizer.

For daily switching on and off, it is recommended to use the mains switch on the front of the machine.

1.2.1.3 Media

The media, particularly the sterilization steam, must meet the requirements specified in the planning drawing or the technical dimension drawing and the piping diagram (e.g. max. permissible pressure, steam quality etc.) to prevent damage due to excess pressure and corrosion. The media must be regularly checked in this regard.

The steam is supplied either

- via the integrated or assigned steam generator (ED version) or
- via a connection to an external steam supply (FD version).

Requirements for the sterilization steam

The sterilization steam must have the following quality:

- The supply line of an external steam supply must be sufficiently drained.
- The last condensate drain may lie a maximum of 2 m upstream of the sterilizer's connection point.
- Steam pressure fluctuations at the sterilizer's connection point must not exceed the required rated pressure by more than +/-10% as specified by EN 285.
- Pressure reduction stages in the supply lines must not exceed a reduction ratio of 2:1.
- The last pressure reduction must be located a minimum of 5 m upstream from the connection point to the sterilizer.

- The steam velocity in the supply line must not exceed 36 m/s.
- The volume of non-condensible gases in the steam condensate must not exceed 3.5 %.

1.2.2 Installation and operation of the machine

Observe all relevant national regulations when installing and operating the machine.

The following is applicable for machines installed and operated in Germany:

- BetrSichV German Ordinance on Industrial Safety and Health
- TRBS Technical rules for operating safety
- MPBetreibV - German Medical Device Operator Ordinance
- AD 2000 - leaflets and DIN EN 13445
- DIN 58946 T7 Sterilization, steam sterilization
- DIN EN ISO 17665 Sterilization of health care products - Moist heat
- ProdSG German Product Safety Act
- 14. ProdSV Fourteenth ordinance pertaining to the German Product Safety Act
- Accident prevention regulation DGUV Regulation 1

Observe the German Occupational Safety Act, and the Ordinance on Industrial Safety and Health (BetrSichV). In accordance with BetrSichV, a risk assessment must be performed regarding the operation within the company of an installation subject to monitoring (Chapter 1.2.4, "Operation of pressure equipment").

We recommend documenting the measures resulting from the risk assessment for safe operation and use of the machine (e.g. operating readiness, down times, qualification of operating personnel, etc.) in a standard operating procedure (SOP).



Note!

The operator is responsible for performing periodic inspections pursuant to the German Ordinance on Industrial Safety and Health (BetrSichV).

Observe the inspection intervals of BetrSichV.

Noise emission

The average A-weighted emission sound pressure level of the machine during operation measured pursuant to DIN EN 3746 is less than 70 dB(A).

The operator must take the noise emission of the system into account when performing a risk assessment.

Training the users

The machine operator is responsible for adequately training the authorized users and the system supervisor.

The users must be trained for this task by a specialist (see Chapter 1.3, "operators" e.g. MMM customer service) and must be familiar with the user manual by the time the machine is handed over.

The names of all authorized operators of the machine as well as the system supervisor (see Chapter 1.3, "operators") must be recorded in the compulsorily maintained medical products / equipment log. If personnel changes are made, new users must be inducted using this user manual and also recorded in the medical products / equipment log.

The operator is required to prepare a standard operating procedure governing the internal organization for operation of the machine.



Incorrect operation of the system, or non-observance of the warning signs can result in personal injury or damage to equipment.

1.2.3 Maintaining efficiency

The operator is in responsible for ensuring the permanent process efficiency of the device. This is ensured, among other things, by means of the process validation and routine testing.

As part of the validation process, the materials and loading configuration that are to be prepared during the respective process are specified.

A process validation must be provided for all the types of material to be treated. Materials not listed in the validation report must not be treated in the Selectomat PL sterilizer.

1.2.3.1 Process validation

A validation is the proof required of the effectiveness of this process. This involves inspecting and documenting the medical products actually used with the packaging used by the respective operator and the processing conditions. The operator must ensure that the “worst case” load has been inspected during the validation.

The reproducibility of the process must also be documented as part of the validation so that it can be assumed that the desired result will always occur. The inspections and the results must be documented.

The validation process comprises validation of the installation, operation and performance.



The operator is responsible for performing the validation process. National regulations must be observed. The validation must be performed using state-of-the-art technology.

Notes for devices operated in Germany:

Validation requirements are given in e.g. DIN EN ISO 17665 and the recommendations of the Commission for Hospital Hygiene and Infection Prevention (Kommission für Krankenhaushygiene und Infektionsprävention - KRINKO) on the hygiene recommendations when preparing medical products (Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten).

Contact MMM customer service for further information on the inspection and validation of sterilization processes.

1.2.3.2 Routine inspections

The ongoing effectiveness of the processes must be verified by routine checks during the entire service life of the machines.

These include, for example, periodic inspections such as performing the Bowie-Dick test and the vacuum test, planned maintenance activities including checking the measurement and control technology, regular calibration and adjustment of the measurement chain, and requalification.

As a rule, requalification, i.e. repeating the performance validation, is also performed annually.

In the case of changes which affect the process, e.g. changes to packaging, introduction of new, design-critical instruments or after maintenance activities, it is essential to perform a requalification. The content of the inspections depends on the change.

National regulations (in Germany: DIN EN ISO 17665 P. 12 and KRINKO recommendations) must be observed.

1.2.4 Operation of pressure equipment

The sterilizer is a pressure vessel designed in accordance with AD 2000 regulations and DIN EN 13445. Its operation is regulated by European and national legal regulations.

Data on the classification of the pressure vessel can be found on the pressure vessel drawing or the test report according to Annex I of the Pressure Equipment Directive 2014/68/EU.

Before commissioning a test of the status of the machine checking assembly, installation, set-up conditions and safe function must be conducted. The technical safety functions have already been tested during factory testing, which means that the operator is not required to run new tests after installation.

During operation the machine is subject to regular inspections, which are required after a specific period or after the machine has reached a specified number of cycles.

The operator must define the test programme before commissioning based on a technical risk assessment and manufacturer's information (Chapter 7.7, "Periodic inspections of pressure vessels").



Note!

Contact your national regulatory authority, which is responsible for conducting the inspections.

Note for machines that are operated in Germany

The safety-relevant equipment parts of the assembly have been factory tested with regard to their suitability and function as part of the conformity assessment procedure and as part of the final inspection according to 2014/68/EU - Annex I 3.2 and 3.2.3. This is evidenced by the issued declaration of conformity and the CE mark displayed on the machine. Test reports with measurements results are, as a rule, not included with the machine documentation.

The German Ordinance on Industrial Safety and Health (BetrSichV) and the Technical Rules for Operating Safety (TRBS) are applicable. The BetrSichV regulates the intervals for regular tests and the requirements for the testers (qualified person as per TRBS 1203 or accredited inspection body (ZÜS)).

The pre-commissioning inspection and the regular inspections for Category III pressure vessels (Pressure Equipment Directive) must be conducted by an accredited inspection body (ZÜS).

1.2.5 Disposal

The operator is responsible for disposing of the machine, components, packaging and accessories in an environmentally correct and appropriate manner in accordance with the applicable local regulations.

LEGAL NOTES FOR THE OPERATOR:

1. **Disposal of components**

   The local waste disposal regulations must be observed, in particular with regard to used batteries, used rechargeable batteries that are not enclosed within the machine, as well as lamps that can be non-destructively removed from the machine.

2. **Disposal of the machine**

   The machine must not be disposed of with normal domestic waste (“unsorted municipal waste”). The machine must be collected separately, see also “Disposal of components” above.



3. **Return of used machines**

   You have the option to return your used machine to the manufacturer MMM. MMM will dispose of your old machine in the proper manner.



Privacy note

If personal data have been saved on the machine, it is the responsibility of the operator to delete that data before disposal or return of the machine.

If you have any questions about how to dispose of the machine or individual components in an environmentally friendly manner or about returning used machines, please contact MMM customer service:

Customer service hotline +49 1805 - 666 112* | Service@mmmgroup.com

* 14 ct./min. from a German landline, prices for mobiles or calls from outside Germany may vary.

NOTES FOR OPERATORS IN THE EU

- According to the regulations of European Directive 2006/66/EC and the German Batteries Act, used batteries and rechargeable batteries must be returned to a municipal collecting point or to the manufacturer.
- Furthermore, the European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE Directive) and the German Electrical and Electronic Equipment Act (ElektroG) apply. The company MMM GmbH is registered with the EAR Foundation under the WEEE Registration No. DE18670731.
- Personal data are subject to the European General Data Protection Regulation (GDPR, Regulation (EU) 2016/679).

National regulations and provisions or local requirements may, however, necessitate special disposal. Please contact your local waste disposal service.

The disposal method must comply with local and national regulations.

INFORMATION FOR OPERATORS IN GERMANY

The following laws and regulations must be observed when disposing of chemicals and other hazardous substances in Germany:

- Circular Economy Act (KrWG)
- Hazardous Substances Ordinance (GefStoffV)
- Ordinance on the European Waste Catalogue / Waste Catalogue Ordinance (AVV)
- Ordinance on Waste Recovery and Disposal Records (NachWV)
- Chemicals Act (ChemG)

1.3 operators

Operators are divided into the following groups:

- Approved operator
- System supervisor (e.g. building services)
- Specialist (e.g., MMM service technician)



Note!

Only persons with the required training or knowledge and experience are permitted to operate this machine.

Authorized operators and system supervisors must be trained.

Untrained persons are not permitted to operate the machine.

Approved operator

The authorized operators of the machine must be trained how to use the machine correctly by a specialist (e.g. MMM customer service) on the basis of the user manual.



Risk of injury

Using the machine incorrectly or failing to observe the warnings may result in personal injury or damage to property.

System supervisor

The operator must appoint at least one authorized operator to be responsible for the machine. The name of this supervisor must be documented (e.g. in the medical devices / equipment log).

Although maintaining a medical devices / equipment log is voluntary in Germany, we at MMM recommend doing so. Please observe your national regulations.

When the machine is handed over by the manufacturer, the supervisor receives the following documents:

- Technical documentation
- Medical devices / equipment log (depending on the machine type)
- Keys (for the emergency stop switchor program stop button, maintenance hatch, control cabinet depending on the machine type)
- Password for the supervisor (system supervisor) (see Chapter 1.5.10.1, "User permissions")

The system supervisor must confirm receipt of the above with his or her signature.

Specialist

The term **specialist** in this user manual refers to persons who have the required expertise due to their training, experience and recent employment, who perform the assigned work and are capable of independently identifying potential hazards and avoiding dangers.

It refers, in particular, to persons or companies authorized by MMM customer service.

1.4 Rules of Conduct during Operation and Maintenance

To ensure the safety of all persons working with or on the machine, the following guidelines must be observed.

1.4.1 Personal protective equipment

The metal walls of the sterilization chamber and door become so hot during operation that touching them with a bare hand may cause burns.

Internal fittings of the chamber, the material to be sterilized, and loading equipment that have been in the chamber for a longer period of time also become so hot that touching them with a bare hand may cause burns.



Risk of burns!

Wear suitable protective equipment when loading and unloading the chamber!

Steam generator (ED version only)

Work must only be performed on the steam generator when the device is not under pressure and has cooled down. Intervention is only permissible on hot devices in exceptional cases, e.g. to avert hazards.



Risk of burns!

Wear protective gloves.

1.4.2 Starting a program

Before the program is started, it must be ensured that the chamber has been correctly loaded and that all chamber doors and service doors are closed.

1.4.3 Sterilization of liquids (option)

When sterilizing liquids, a flexible measuring sensor with a reference container must always be used to regulate the process temperature.

To prevent boiling retardation and to ensure successful sterilization, the following precautionary measures must be implemented:

- Make sure that adequate reference containers are used. The form, volume and material of the reference containers must correspond to those of the containers to be sterilized.
- Make sure that the reference container is in the correct position. Validating the process with the corresponding material to be sterilized and, whilst doing so, defining the size and location of the reference container, are recommended. If the fluid containers are distributed over several levels, the reference container with the flexible measuring sensor is positioned on the top level.



Note!

The flexible measuring sensor must always be inserted in the container with the largest fluid volume in the load.

- The flexible measuring sensor must be correctly positioned in the reference container
  (Chapter 4.3.1, "Handling flexible measuring sensors (for Open solutions equipment package)").
- If the same reference container is used in each cycle, the risk is run that the fluid in the reference container does not correspond to the loading temperature. Placing the sensor directly in the load is therefore recommended.



Note!

If a reference container is damaged or breaks during the program sequence, the removed sterilization material to be sterilized must be regarded as unsterile.

The interior of the chamber must be cleaned immediately if the bottle has broken.



Risk of injury!

After bottle breakage, there is a risk of cut injuries from glass splinters.

1.4.4 Working inside the chamber

Only trained personnel (e.g. see Chapter 1.3, "operators") are permitted to work inside the chamber.



Risk of injury!

When working inside the chamber (e.g. during cleaning, maintenance, etc.), turn off the load disconnect switch and lock it out to prevent it from being switched back on unintentionally. Keep the key with you when carrying out work to prevent unintentional unlocking.

1.4.5 Working on the assemblies



Risk of crushing from the door movement!

When working on the assemblies, turn off the load disconnect switch and secure it with a lock to prevent it from being switched back on. Keep the key with you when carrying out work to prevent unintentional unlocking.

Only suitably trained persons (see Chapter 1.3, "operators") are permitted to access the assemblies, e.g. for inspection or maintenance purposes.

Work on the assemblies must only be performed while the machine is switched off.

The means of access to the assemblies is locked. The key is kept by the system supervisor to ensure that only technicians have access to the assemblies.



Risk of burns!

The assemblies (e.g. valves, uninsulated pipework) are hot!

Wear personal protective clothing when working on the assemblies!

1.4.6 Working in the electrical control cabinet

Only qualified personnel are permitted to open the control cabinet (see Chapter 1.3, "operators").



Danger due to electric current!

When working on the electrical equipment (e.g. replacing components), turn off the load disconnect switch.

1.4.7 Maintenance work

Maintenance work see Chapter 7, "Maintenance" may only be performed by qualified personnel (see Chapter 1.3, "operators").

1.4.8 Automatic transport system (option)

For machines with an automatic unloading system, the safety instructions and guidelines in the manufacturer's user manual must be observed.

An acoustic signal sounds twice before the conveying system moves.

The door of the sterilizer is opened automatically before unloading and closed automatically afterwards.



To enable automatic unloading to start, it must be ensured that the conveyor is clear.



Risk of crushing!

There must be no people present in the vicinity of the unloading system during automatic unloading.

Manual intervention in the automatic unloading process is not permitted, except if it is necessary to actuate the emergency stop switch.

1.5 Machine safety devices

The machine is equipped with multiple safety devices, that allow immediate program abort in case of danger.

In the event of a power failure, the machine will be in a safe state. The media valves to the chamber are closed.

1.5.1 Safety strip

The self-closing chamber doors are fitted with a safety strip that stops door movement as soon as the door encounters an obstacle (e.g. if an object or a person is in the way of the door). The door is then opened again.

1.5.2 Automatic program cancellation

In the event of a fault that prevents the program sequence from completing correctly, e.g. faults with the messages *Pressure transducer controls defective or Motor protection switch vacuum pump*, the control system will cancel the program.

In the case of vacuum programs, the program is completed with or without drying depending on the type of fault. If no drying is performed, a safety extraction may be performed depending on the machine configuration. If the program cancellation occurs during the evacuation phase, the chamber is immediately returned to atmospheric pressure by aeration. The door is then released.

In the case of solution programs, the door is only released once the chamber has been evacuated to at least 700 mbar (safety extraction), and if an unpressurized state has then been reached. A re-cooling temperature of 80°C or below must also be reached.



Risk of contamination!

The process is regarded as incorrect.

The material to be sterilized must be regarded as unsterile.

On machines with two doors, only the door on the loading side can be opened.

1.5.3 Program cancellation button

The program cancellation button is visible on the touch screen as soon as a program is started. It must be pressed, for example, if an incorrect program was started and the material could be damaged.

Pressing the “Cancel program” button ends the program as quickly as possible (Chapter 6.1, "Unexpected cancellation of the program sequence").

In the case of vacuum programs, the program is completed with or without drying depending on the type of fault. If no drying is performed, a safety extraction may be performed depending on the machine configuration. If the program cancellation occurs during the evacuation phase, the chamber is immediately returned to atmospheric pressure by aeration. The door is then released.

In the case of solution programs, the door is only released once the chamber has been evacuated to at least 700 mbar (safety extraction), and if an unpressurized state has then been reached. A re-cooling temperature of at least 80°C must also be reached.



Risk of contamination!

The process is regarded as incorrect.

The material to be sterilized must be regarded as unsterile.

On machines with two doors, only the door on the loading side can be opened.

1.5.4 Program stop switch (option)

The program stop switch is located on the control panel and must be used in case of imminent danger, or if irregularities or malfunctions occur during the program.

The program stop switch stops all movement of the machine by hardware, i.e. the door close movement is stopped or prevented (this is also a safety measure for work in an accessible chamber) and a program that has been started is stopped.

When it is actuated the machine is placed in a safe state,
i.e. the media valves are closed.

The program stop switch must be pressed in the following cases:

- Irregularities in the program sequence
- Unusual noises
- Steam emission from the machine room
- Trapping during door movement
- Fire



The process is regarded as incorrect.

The material to be sterilized must be regarded as unsterile.

For machines with two doors, only the door on the loading side can be opened.

To restart the machine, the program stop switch must be unlocked, depending on the machine variant, either by gently pressing and turning it or using the key if present (Chapter 1.3, "operators" and Chapter 6.1, "Unexpected cancellation of the program sequence").

1.5.5 Load disconnect switch

A load disconnect switch must be installed in the on-site power supply. It completely disconnects the machine from the mains.



The load disconnect switch is located in the assemblies compartment of the sterilizer and is only accessible with the appropriate key. The is to be kept by the system supervisor.



Turn off the load disconnect switch when performing work on the machine (e.g. maintenance), and secure it with a lock to prevent it from being switched on again.

1.5.6 Safety valve

The steam sterilizer is optionally fitted with the following safety valves :

- Steam generator (ED version only): Protects the steam generator against an impermissible increase in the internal pressure. The steam is discharged safely via the blow off line (see Chapter 1.2.1.2, "Blow off line").
- Compressed air (option): For certain variants, the compressed air supply line is protected by a safety valve. The safety valve safely discharges the compressed air into the assemblies compartment of the machine in the event the permissible pressure is exceeded.

1.5.7 Safety circuit (ED version only)

In equipment with in integrated steam generator, the device has a safety circuit, which permanently switches off the boiler feed in the event of excess pressure or a insufficient water.

1.5.8 Locking the chamber door and door release

The control system prevents the door from being opened during the program sequence. Consequently, the door buttons are not shown on the display.



Risk of personal injury or damage to property!

Forcibly opening the doors during the program sequence is prohibited.

On completion of the program, the chamber door can only be opened when the following conditions are met:

- The pressure in the chamber is equal to the atmospheric pressure
- The door seal has been released

- The safety extraction was successful
- The temperature in the reference container has fallen to less than 80°C (for solution programs)
- The minimum re-cooling time has elapsed (for solution programs)
- The program is at the *Unloading* process step.

See also see Chapter 4.3.9, "Unloading the chamber ".



Escape of steam possible!

For your personal protection, stand to the side of the chamber when opening the chamber door.

1.5.9 Monitoring the sterilization parameters

The sterilization parameters (temperature, time and pressure) are monitored by the control system. The temperature is measured by means of a reference temperature sensor.

The time measurement is stopped if the temperature falls short of the temperature set for the respective program by maximum 0.5 K. The time measurement continues once the nominal temperature has been reached again.

In the event of a deviation as described below, an automatic program cancellation (Chapter 1.5.2, "Automatic program cancellation") is triggered:

- The temperature falls below the sterilization temperature set for the respective program by less than - 0.5 K; however, the time measurement of the sterilization time is interrupted by more than 90 s. The message “Sterilization temperature too low for too long” appears on the screen.
- The temperature falls below the sterilization temperature set for the respective program by more than - 0.5 K. The message “Temperature has fallen below sterilization temperature” appears on the screen.
- The temperature exceeds the sterilization temperature set for the respective program by more than + 3 K. The message “Sterilization temperature exceeded appears on the screen.

The message is printed on the cycle record.

1.5.10 Access protection

Operators have different authorizations for operation of the machine depending on their user group.

Access to the machine controller is password-protected. This prevents unauthorized access to process parameters and settings relevant to safety.

Preset authorization levels with restricted rights are available for daily operation.

The User Manager (option) can be used to assign specific authorizations to users see "User permissions", Page 34.

1.5.10.1 User permissions

The following users and authorizations are pre-configured:

Level	User name	Users	Authorised for:
1	Anonymous (no password)	Authorised users	e.g. program selection, program start, viewing the audit trail, certain service menu functions
2	Supervisor (name: “s”)	System supervisor	e.g. acknowledging faults, alarm counters, configuration of certain parameters such as auto start, standby mode, cooling circuit, etc.
3	MMM	Specialist, MMM customer service	System administration, access to all parameters

Log-in is not required for normal operation, as the user *Anonymous* is automatically logged in. The user name *Anonymous* is listed in the user bar. There is no automatic logout.

Certain actions can only be performed after user log-in as a supervisor (e.g. confirming fault messages). A user can be logged in and out as a supervisor at any time.

If the screen is not touched for 5 minutes after log-in (individually adjustable), the *Supervisor* user is automatically logged out and the *Anonymous* user is logged in.

User Manager (option)

The *User Manager* option basically allows any user to log in with name and password before performing an action. The permissions of every single user can be assigned regardless of the present authorization levels *Anonymous* and *Supervisor*.

The user will only be able to perform the allowable actions after logging in.

When commissioning the machine, an additional user is created with the User Manager; this additional user has the necessary permissions to add further users or delete them, and to grant specific permissions to the various users (Chapter 5.1, "Configuring the User Manager (option)").

The User Manager can also be used to specify that the names of the users who started a program and who opened the chamber door at the end of the program are recorded in the cycle report.

1.6 Residual risks and measures to prevent them

The machine is fitted with state-of-the-art safety mechanisms.

Furthermore, the parameters relevant to a successful sterilization process are constantly monitored by the control system and comply with the DIN EN 285 standard.

Nevertheless, fault-free completion of a sterilization program is no guarantee of the sterility of the treated material.

Residual risks

The following influencing factors cannot be constantly monitored in all process steps and therefore represent a residual risk for the process effectiveness:

- Poor (in particular fluctuating) steam quality due to an impermissibly high proportion of inert gas in the steam. Inadequate steam penetration due to inert gases is determined periodically by means of the Bowie Dick test, which must be performed daily.
- Poor ventilation of the material due to leaks in the chamber or an operating error (e.g. an incorrect load configuration that hinders ventilation or steam access, reprocessing instructions of the medical device manufacturer not being observed). Leaks are checked for periodically using the vacuum test.
- Incompatibility of the selected program with the materials to be treated. The selected program is not suitable or has not been validated for the materials to be treated (e.g. use of a solid materials program for porous goods).
- An unsuitable or defective reference container (for solution programs option) can lead to insufficient process effectiveness and boiling retardation (risk of injury from spraying fluids when opening the door).
- An incorrectly positioned reference sensor (for solution programs option) can lead to insufficient process effectiveness and boiling retardation (risk of injury from spraying fluids when opening the door).

Measures to prevent the risks listed above and to guarantee successful sterilization:

- Make sure that the steam quality meets the requirements (Chapter 1.2.1.3, "Media") .
- Observe the guidelines in the national regulations on the reprocessing of medical products (Chapter 1.2.3.1, "Process validation").
- The machine may only be operated by trained, authorized operators.

- When using the solution programs option, position the sensor as described in Chapter 4.3.1, "Handling flexible measuring sensors (for Open solutions equipment package)".
- Only trained, authorized operators are permitted to release the cycle on the basis of the cycle record and visual check (e.g.no moisture in the load when using vacuum programs).
- Conduct regular routine tests, such as maintenance and safety inspection, including checking the measurement and control technology, regular calibration and, if necessary, adjustment of the measurement chain.

The following also applies to the reprocessing of medical devices

- Before the sterilization process, thoroughly and properly clean and disinfect the items to be sterilized in accordance with the medical device manufacturer's instructions and the applicable national regulations.



Non-observance of this instruction can have a negative impact on the sterilization results and also the functionality and appearance of the items to be sterilized.

- Use sterilized material barrier systems to protect the sterile goods from recontamination. Only sterile goods packaging must be used which complies with the national EN or DIN standards.
- Perform the routine testing (Chapter 1.2.3.2, "Routine inspections") on daily start-up of the sterilizer.
- Perform the daily vacuum tests (Chapter 2.8.3.1, "Vacuum test") to identify any leaks in the chamber.
- Perform the daily Bowie-Dick tests (Chapter 2.8.3.2) to prevent an impermissibly high fraction of inert gas in the steam. See also Chapter 4.2, "Daily start-up".



Only those goods for which a process validation exists may be reprocessed.

1.7 Maintenance and Safety inspection

Periodic competent inspection, maintenance and calibration offers the best guarantee of trouble-free operation of your machine. We therefore recommend an inspection and maintenance contract.

Maintenance and safety inspections may only be performed by qualified specialists (see Chapter 1.3, "operators"). Similarly, the machine must only be repaired by persons who are authorized to do so by the manufacturer.

Spare and wear parts must be replaced with original parts.

Your attention is expressly drawn to the fact that we accept no responsibility for damage to the machine incl. accessories or personal injuries in connection with the machine if the machine has been repaired or serviced by unauthorized persons.

National regulations must be observed.

Please take into consideration that many factory insurance policies do not provide coverage for loss or damage if maintenance has not been performed.

Note regarding warranty

Warranty and guarantee claims can only be considered if maintenance and safety inspections are performed within the prescribed intervals throughout the warranty and guarantee period.

We refer to our warranty declaration Chapter 9, "Warranty (Liability for defects)", according to which wear-and-tear parts and damage caused by chemical influences are expressly excluded from our warranty.

1.8 Medical devices / equipment log

Keeping an equipment log is recommended by MMM. Observe the legal regulations.

Documenting the following in the equipment log is recommended:

- Parameter settings
- Trained operators
- Program specification
- Specification of the process chemicals
- Work on the machine
- Tests
- Modifications to the machine

1.9 Standards, regulations and directives

The machine has been designed and manufactured in line with applicable standards, directives and statutory provisions.

Notice for EU:

According to the EU declaration of conformity signed by the manufacturer, this machine conforms to the applicable provisions and bears the CE marking.

This machine complies with the following directives, regulations and standards (see also *Declaration of Conformity for Series*):

Applicable EU directives and EU regulations

- Medical Device Regulation 2017/745/EU
- Directive 2014/68/EU on pressure vessels
- Directive 2011/65/EU on restricting the use of certain hazardous substances in electrical and electronic equipment (RoHS)

Note

Application of the directives and regulations listed above also covers the requirements of the following directives:

- Directive 2014/30/EU on electromagnetic compatibility
- Directive 2014/35/EU on electrical equipment (Low Voltage Directive)
- Machinery Directive 2006/42/EC, if more specific than the Medical Device Regulation 2017/745/EU

Applied standards - state of the art

The state of the art is achieved by applying the published standards.

Performance and effectiveness

- DIN EN 285 Sterilization - Steam sterilizers - Large sterilizers

Product safety

- DIN EN 61010-1 Safety requirements for electrical equipment for measurement, control and laboratory use: Part 1 General requirements
- DIN EN 61010-2-040 Safety requirements for electrical equipment for measurement, control and laboratory use
  Part 2-040 Particular requirements for sterilizers and washer-disinfectors used to treat medical materials

EMC requirements

- DIN EN 61326-1 Electrical equipment for measurement, control and laboratory use - EMC requirements, Part 1: General requirements

Functional safety

- DIN EN 62304 Medical device software - software life-cycle processes

Usability

- DIN EN 62366-1 Medical devices - Application of usability engineering to medical devices

Pressure equipment

European Directive 2014/68/EU applies to the product and/or to its components depending on the configuration.

Pressure equipment:

- DIN EN 13445 Unfired pressure vessels

Components of the integrated steam generator:

- DIN EN 13445 Unfired pressure vessels
- DIN EN 60204-1 Safety of machinery
- DIN EN 14222 Stainless steel shell boilers

Other standards

The aforementioned standards reference, amongst other things, the following additional standards. They are also automatically applicable. To make the technical documentation clearer, several of the applied standards that are referenced are listed here.

- DIN EN ISO 17665 Sterilization of health care products – Moist heat: Requirements for the development, validation and routine control of a sterilization process for medical devices

2 Machine description

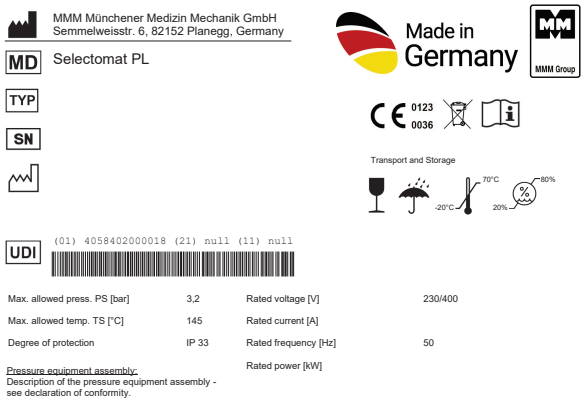
What follows is a general description of the machine and the processes.

For the precise specifications of your machine, please refer to the technical data sheet or the planning drawings as well as the type plate attached to the machine and the machine configuration of the technical documentation.

2.1 Type plate

type plate

The type plate is located on the control cabinet.



Example illustration

Explanation of type plate:

Manufacturer

CE mark with identification number (example)

MD Medical device

Disposal (WEEE recycling)

TYP Type

Observe the instructions for use



Serial number



Fragile, handle with care



Date of manufacture



Store in dry place



Unique Device Identifier



Lower and upper temperature limit



Lower and upper air humidity limit

Additional conformity marks apply for the following countries:



for Ukraine only



for Serbia only



for UK only



for Australia only

2.2 Standard equipment

Pressure container

In accordance with the Pressure Equipment Directive 2014/68/EU , the pressure container has been designed, manufactured and tested for a maximum permissible pressure (PS) of at least 3.2 bar and a vacuum of -1 bar.

Closure

Depending on configuration, the sterilization chamber is equipped with one or two sliding door(s) driven by an electric motor.

The safety devices prevent the doors from opening during the program and the simultaneous opening of the loading and unloading sides (in the case of two-door devices). To prevent jamming, the doors are fitted with a safety strip.

Each sliding door is sealed pressure-tight using a special blow-out seal with steam .

The sliding doors open vertically downward.

Steam supply

The steam is supplied either via the internal steam network (FD) or an assigned or integrated electric steam generator (ED).

Depending on the equipment, it can be manually switched between steam supply from the mains power supply and the higher-level steam generator.

Vacuum facility

The machine is equipped with a vacuum facility which enables air extraction during special programs and program phases, fractionated vacuum drying, safety extraction and door seal release.

The vacuum pump unit comprises a powerful and quiet water ring vacuum pump with an upstream heat exchanger and water circulation container.

The Pt100-regulated supply of cold water ensures optimal water economy.

Electrical equipment

The electrical equipment conforms to DIN EN 61010-1 and 61010-2-040, and also DIN EN 60204-1 when equipped with an integrated steam generator (ED version).

The protection class against penetration of foreign bodies and moisture is IP33 (as per DIN EN 60529).

Control panel

The compact and easy-to-operate 10“ control panel is integrated into the front panel above the sterilizer chamber.

Two-door machines are equipped with an additional 7" panel mounted above the chamber on the unloading side.

The menu system is very user friendly with simple input on a color touch screen and visual display of all user inputs.

Important cycle information, and messages from the safety control system when deviations from setpoints occur are displayed in plain text. Process curves displayed in graphic online mode to show all important information at a glance.

Instrumentation flow diagram

The complete system is also clearly visualized by electronic flow charts that show valve settings and machine states in visual form. Valves and actuators can also be actuated individually from the relevant flow diagram during the *Operational* state.

Instrumentation and control equipment

High-quality industrial controller with no mechanically actuated components.

In accordance with DIN EN 285, the process parameters of temperature and pressure are measured and controlled independently of temperature and pressure curve registration by two Pt100 resistance temperature sensors and two absolute pressure transducers.

The independent safety monitoring system records, evaluates and reports deviations from setpoints, and also monitors the operating states of the machine.

If a fault occurs in the automatic program sequence, the program is cancelled.

High degree of connectivity with Ethernet and USB ports. Cycles saved locally to flash memory. Up to 20,000 cycles can be saved.

2.3 Optional additional features

The equipment and functions described below are available as options.

2.3.1 Hardware components

Mains switch (option)

Mains switch for switching the machine on and off.

In its standard configuration, the sterilizer is equipped with a standby mode that is automatically activated after a longer period of inactivity. When in this state, the integrated steam generator (if present) is switched off. The standby mode is still available if the mains switch option is selected.

Program stop button (option)

Hardware-based mushroom button for stopping the current program.

2.3.2 Optional programs

Further programs can be activated in addition to the standard programs.

To sterilize liquids, the **Open solutions** equipment package is required.

2.3.2.1 Special programs

Prion prevention (option)

Sterilization program for processing medical products that have been used for operations on high-risk tissues.

Special program for countries with high temperatures (option)

Sterilization program for regions with high ambient and cooling water temperatures with high vacuum switching points and additional fractionations.

2.3.2.2 Programs for liquids

Equipment package Open solutions

If the machine is fitted with the required equipment components, it is also possible to treat liquids in open or loosely sealed containers by means of the pre-vacuum process with subsequent cooling (passive cooling).

Safety equipment for the equipment package Open solutions

The additional components include amongst other things, the following safety equipment: a flexible measuring sensor, and various hardware safety components.

These additional components ensure that door movements are only possible if the temperature in the liquid has fallen to below the boiling point at atmospheric pressure.

Passive cooling for the equipment package Open solutions

During the cooling phase, the heat is dissipated via the insulation on the assemblies compartment until a pressure is established within the chamber according to the saturated steam relationship.

The bottle temperature is redundantly monitored by a flexible measuring sensor (double Pt100 for control / recording).

2.3.2.3 APPcycles

APPcycles is a configuration program that can be used to precisely tailor the **aeration, sterilization** and **drying** process phases to the specific characteristics of the items being sterilized and the sterile barrier system used in order to optimize the consumption of media and the cycle times without compromising the effectiveness of the process.

The individual process stages were selected based on DIN EN ISO 17665.

The following characteristics of the medical devices to be processed define the configuration parameters of an APPcycles program: design, material, weight and packaging.



To configure an APPcycles program, please contact MMM customer service.

2.3.3 Additional monitoring equipment

Additional equipment for monitoring further process parameters.

Air detector (option)

The sterilizer is equipped with an air detector (air detector) for detection of air leakages.

This monitors compliance with the sterilization conditions, since the effect of sterilization is significantly impaired in the presence of non-condensable gases, which tend to form air pockets in porous materials such as .

A corresponding error message is printed on the cycle documentation for cycles that are canceled as faulty due to an air leak.

Air detector monitoring is only active if the air detector is installed and activated for the current program.

Air detector function test (option)

Additional function for creating a defined leak when performing a test using an air-detection device.

Integrated Bowie-Dick test with SteamSpy (option)

The MMM SteamSpy is an integrated physical B&D test, which has been tested as per ISO11140-4 by an independent test laboratory.

It consists of a tube that is permanently installed in the sterilization chamber that simulates a cavity and a measuring device that is attached to the outer chamber wall.

Its design enables verification of the effectiveness of steam penetration both in the cavities and in porous material.

The temperature, which is measured by a Pt100 sensor, is evaluated by the control unit of the sterilizer and is continuously compared with the target values of the Bowie-Dick test program. The result of the B&D test is defined at the end of the program and it is output in the cycle documentation.

The integration of the electronic B&D test in the *Autostart* option automatically starts the vacuum test, the heating program and the B&D test under program control, which means that the machine is fully ready for operation at the start of the shift.

Integrated cycle control with SteamSpy (option)

If the device has the *SteamSpy* option, the routine cycle control is run via SteamSpy. The sterilization process conditions tested by MMM SteamSpy conform to the test body conditions as per DIN EN 11140-6.

The temperature, which is measured by a Pt100 sensor, is evaluated by the control unit of the sterilizer and is continuously compared with the target values of the respective sterilization program. The result of the cycle control is defined at the end of the program and it is output in the cycle documentation.

Valve for steam sampling (option)

Steam sampling point with needle valve for removing a steam sample between the steam generator and the sterilizer (steam quality test connections as per DIN EN 285).

Compressed air supply monitor (option)

This optional equipment monitors the on-site compressed air supply and is triggered if the supply pressure is too low.

Cold water pressure monitor (option)

This optional equipment monitors the on-site cold water pressure and is triggered if the water pressure of the cold water is too low.

Feed water pressure monitor (option)

This optional equipment monitors the pressure of the on-site deionized water supply and reports if the pressure is too low to supply the jacket.

2.3.4 Reducing the consumption of media

Connection for cooling circuit vacuum pump (option)

To reduce the amount of cold water used to cool the vacuum pump or if the cooling circuit fails, it is possible to connect the machine to an external cooling circuit (see Chapter 6.6, "Fault in the cooling circuit vacuum pump (option)").

Cooling circuit automatic switching (option)

If the machine is connected to an on-site cooling circuit, an automatic switching function can be activated whereby the machine must be switched over to cooling by cold water, from the software side only, if the cooling circuit fails. The switching of the valves then occurs automatically.

Energy manager (option)

Additional machine device that regulates electrical power consumption if multiple sterilizers are connected. When the energy manager is activated, it is only possible to operate four sterilizers at once for technical reasons.

The energy manager coordinates the timing of the programs to ensure that the power consumption of the steam generator is as consistent as possible. The connected machines are networked and request the status of the other machines before starting the program.

Depending on the result of this request, the machine signals whether it is ready to start. The process step from which the next machine is released can be set depending on the performance of the connection. The internal steam generator also operates with significantly reduced heating performance during phases of reduced steam requirement (ready for operation, pressure release, drying, unloading).

Standby mode (option)

Standby mode is used to minimize steam consumption.

If the machine is not operated for a long time (no program active, screen is not touched), it switches to standby mode after an adjustable time. Standby mode is activated automatically after the set time has elapsed (see Chapter 5.6, "Activating standby mode ").

Jacket control is then paused and the machine cools down (energy saving).

Standby mode switches off as soon as the touch screen is touched. As the machine cools down in standby mode, we recommend first running a warm-up program after a long down time.

2.3.5 Optional services

Autostart

When using autostart, the machine automatically starts a configurable sequence of programs. This feature is typically configured to run the routine preparatory programs (vacuum test, heating program, Bowie-Dick test) to ensure that the machine is operational at the start of a shift.

Whether and at what time the auto start should commence can be individually configured for each weekday. For example, a heating program can be set from Monday to Friday, while no automatic program start takes place at the weekend

Sensibly, auto start is combined with standby mode.

Service module

Simplified maintenance planning by indicating on the machine display when service tasks need to be performed. Information about the following service tasks is displayed:

- Preventive maintenance
- Interval-based maintenance & inspection
- Calibration/adjustment
- Requalification

RUMED360® ISA - Intelligent Service Advisor

The machine can send e-mails and/or SMS to the operator or MMM customer service. This provides immediate information on faults and maintenance information (see separate instructions).

Barcode administration

Barcodes are used to identify the sterilization material. They are located on the goods to be treated and are scanned individually with a handscanner for each cycle.

A maximum of 500 barcodes can be entered per cycle. The barcode information is transferred to the cycle log.

The required program can also be stored in the barcodes to enable the program to be selected automatically (see Chapter 2.7, "Automatic program selection using the barcode (option)").

User identification

A user ID that is written to the cycle record can be entered via the touchscreen or the barcode scanner. This makes it possible to establish at a later time who started the program.

Central control room

To simplify plant management, the device data from one or more machines is monitored and displayed online by a centrally located, on-site network-compatible PC.

The following data can be displayed: machine number, cycle number, program start, selected program, next service, current operating status of the machine (position of doors, current processing step, pressure, temperature), online process curve, and the time remaining until the end of the program for the purposes of optimizing the loading and unloading time.

The connection to the VNC server is also activated or deactivated at the machine.

Remote maintenance system

By comprehensively analyzing the machine status remotely, it is possible to locate faulty components and initiate any necessary servicing measures.

Access to the remote maintenance function is via a VNC client. This service can be used to operate the machine, view parameters, check the audit trail, view the IO list, and much more.

Uninterruptible power supply (UPS)

Uninterruptible power supply for the control system. In the event of a power failure for up to 2 minutes, the controller remains active and relevant cycle information continues to be saved.

Larger electrical consumers (e.g. pumps) are switched off during power failures and the relevant process valves closed. When the power goes back on, the current program is continued.

Process-relevant media valves are closed during the power failure.

An alarm message appears on the display and, if required, is printed in the cycle report.

2.3.6 Automatic transport system

Two door machines can be equipped with a system for automatic unloading of the chamber (see the manufacturer's user manual).

The transport system is controlled, and supplied with power and if applicable compressed air, by the associated sterilizer.

An acoustic signal sounds twice before the conveying system moves.



Risk of injury!

To enable automatic unloading to start, it must be ensured that the conveyor is clear.

The door of the sterilizer is opened automatically before unloading and closed automatically afterwards.

Note that wait times can arise at several points when the automatic transport system is running:

- After opening of the door
- After sounding of the acoustic signal
- After changes to the direction of rotation of the motor

2.4 Integrated steam generator (ED version only)

If the steam is supplied via an integrated pure steam generator, this generator has been constructed in accordance with EN 14222.

Pure steam is generated from demineralised boiler feed water with electric immersion heaters by a controlled process with a level-controlled and monitored feed of boiler water and automatic pressure regulation

Feed equipment: Automatic boiler water feed from feed water tank, feed valve and feed pump, automatic monitoring of minimum level.

Pipes and fittings: Complete pipe system with valve for taking water samples and drainage system for manual emptying of the steam generator.

The steam generator is operated and controlled via the sterilizer controller.

Blow-down facility: Automatic blow-down, which can be adjusted depending on the quality of the feed water. Blow-down is initiated depending on the operating state of the steam generator and does not affect its output.

2.4.1 Heating element current supply

Heater circuit breakers

Mechanical circuit breakers are installed for the current supply to the heating elements.

The safety circuit consists of the circuit breakers and an emergency stop safety relay. After switching on the steam generator, the heater circuit breakers are only activated when there is sufficient water in the boiler and no fault preventing heating is present. If faults arise during operation, for example overpressure or insufficient water, the heater circuit breakers are shut off permanently.

2.4.2 Pressure control and limitation

Pressure control

The controller activates the heater circuit breakers according to the boiler pressure registered by the pressure sensor.

Pressure limitation

An impermissible increase in pressure can be detected by the pressure sensor. If the limit value is exceeded, the heater circuit breakers are no longer activated.

Safety valve

The boiler isand the feed module are equipped with a safety valve. If an impermissible pressure increase occurs, steam or water is blown off via the respective safety valve.

2.4.3 Feed mudule

The level in the feed module is continuously monitored by a level sensor. If the level falls below the minimum, feed water is supplied to the tank through the feed valve.

The feed water is fed to the boiler by the feed pump.

2.4.3.1 Conductivity limit value

The machine must be operated using deionized water only.

The limit value for the conductivity is shown in Table 1,
Chapter 2.4.3.2, "Requirements on the feed water".

The conductivity can be continuously monitored directly on the treatment device using a separate measurement device.

Adherence to this limit value also serves to avoid impurities and coatings on the material to be treated and to minimise blow-down losses.



If ultra-pure water with a conductivity of < 1 µS/cm is used, an increased need for maintenance and possibly an increased risk of corrosion must be anticipated!

2.4.3.2 Requirements on the feed water

We recommend having the quality of the feed water tested regularly.

The conductivity of the feed water must be checked each day. Automatic monitoring is therefore recommended.

Feed water whose properties do not meet the values specified in Table 1 may shorten the service life of the machine and invalidate the manufacturer's warranty.

Table 1: According to Tab. B1, DIN EN 285

Ingredients and properties	Recommended value
Evaporation residue	≤ 10 mg/l
Silicate	≤ 1 mg/l
Iron	≤ 0.2 mg/l
Cadmium	≤ 0.005 mg/l
Lead	≤ 0.05 mg/l
Heavy metals except iron, cadmium, lead	≤ 0.1 mg/l
Chloride	≤ 0.5 mg/l
Phosphate	≤ 0.5 mg/l
Conductance (at 20°C)	≤ 5 µS/cm
pH (at 20°C)	5 -7,5
Appearance	Colorless, clear without residue
Hardness	≤ 0.02 mmol/l

Note: Compliance with these values can be verified using recognized analytical methods.

2.4.3.3 Feed water degassing (option)

The water in the feed water tank is heated using steam. Gases dissolved in the water are released due to heating.

The temperature is registered using a resistance temperature sensor in the feed water tank. Depending on the set temperature values, the control activates the valve for feeding steam to the feed water.

2.4.4 Boiler water

The following requirements are made on the boiler water of steam generators manufactured from CrNiMo steel:

Table 2: Requirements for the boiler water

Contents and properties	Recommended value
Appearance	Colorless, clear, without sediment

Contents and properties	Recommended value
pH value	5 - 7 (10)
Total alkaline earths (hardness)	< 0.02 mmol/l
Phosphates	< 5 mg/l PO4
Chlorides	< 50 mg/l
Conductivity	< 100 µS/cm at 25°C water temperature
Silica	< 10 mg/l SiO2

2.4.4.1 Blow-Down

During operation, the salt concentration in the boiler water increases due to water evaporation. Regular blow-down prevents impermissibly high salt enrichment in the boiler water and ensures pure steam and trouble-free operation. This additionally protects the CrNi steel equipment and extends the machine's service life.

Conductance-dependent blow-down - time-controlled

In order not to exceed the max. limit value of approx. 100 µS/cm (with reference to 25°C) in the boiler water, part of the water is continuously drained off via the blow-down valve. The blow-down valve cycle is adjusted to the feed water quality via the controller's parameters.

The salt concentration in the boiler water is reduced through the subsequent infeed of fresh water.

Depending on feed water quality, blow-down can be configured customer-specifically to avoid unnecessary energy and water losses.



Parameter changes are permitted only in consultation with MMM customer service.

2.5 Accessories Transport trolley

The transport trolley is used for loading, unloading, and transporting MMM loading trolleys.

The transport trolley is available in two variants:

- TW – transport trolley with a fixed height corresponding to the loading height of your sterilizer
- TW HUB – transport trolley with a height-adjustable transport platform for loading and unloading machines of different heights

Both variants are available in various sizes to suit the loading trolleys you are using with your sterilizer.

Transport trolley (TW)

Transport trolley (TW) with a fixed loading height of 390 mm, 625 mm or 850 mm.



1. Locking bolt, for securing the BW to the TW.
2. Lever 2 for releasing the BW from the TW.
3. Lever 3 for releasing the TW from the chamber.

Height-adjustable transport trolley (TW HUB)

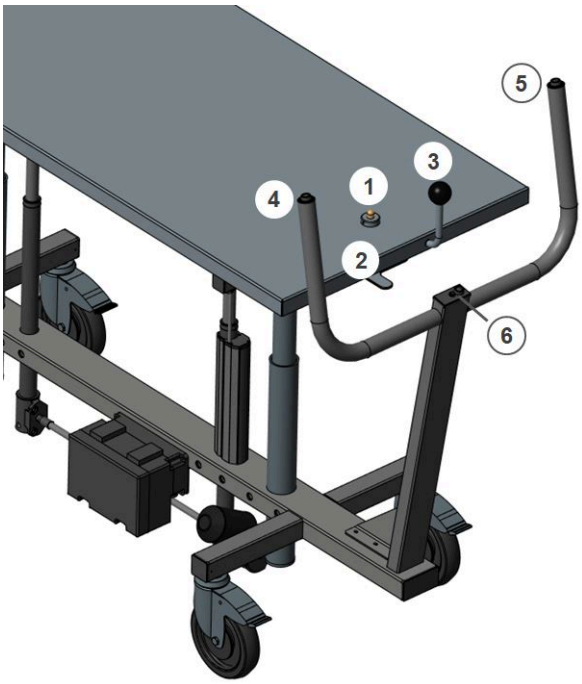
Read the original user manual from the manufacturer of the TW HUB carefully and save it for future reference.

Observe the safety instructions. Your personal safety and the correct functioning of the machine are at stake.

Height-adjustable TW HUB with a maximum loading weight of 120 kg. The TW HUB is equipped with buttons on the handles for moving the platform.

The left button moves the platform upwards, the right button moves the platform downwards. The middle button between the handles moves the platform to a preset height.

The TW HUB is configured on site for the required loading height.



1. Locking bolt, for securing the BW to the TW.
2. Lever 2 for releasing the BW from the TW.
3. Lever 3 for releasing the TW from the chamber.
4. Button for raising the transport platform.
5. Button for lowering the transport platform.
6. Memory button (optional) for setting a preset height.

The transport platform height must **not** be adjusted if the TW HUB is already docked and locked to the sterilizer or conveyor.

Also observe the cleaning and maintenance instructions and the internal work instructions!

2.6 Cycle documentation

At the end of a program, a cycle record with all process-relevant data is created. The user can release or reject the cycles.

The cycle document contains the following information:

- General data about the operator, user, device
- General data about the program and cycle, e.g. selected program, program start, start and end of sterilization
- Course of the pressure and temperature curves over time
- Course of the air detector temperature over time (for **air detector** option only)
- Evaluation of the integrated Bowie&Dick test (for **SteamSpy** option)
- Evaluation of the integrated cycle control (for **SteamSpy** option)
- Messages in plain text

The cycle document that is saved in the machine can be printed out at the end of the cycle Chapter 5.2, "Configuring the cycle print and save option" and, depending on the machine configuration, transferred to an external server, e.g. using the MMM RUMED360 Cycles middleware (option).

The transferred cycle documents can be permanently archived there (e.g. on a separate storage device). The operator is responsible for verifying that the cycle record has been successfully transferred and saved. In particular, possible disruptions to the network connection must be considered within this context.

If a record has not been added to the electronic archive, either the corresponding printout must be retained or the cycle in question discarded.

The last 20 cycles stored in the machine can be shown on the display and reprinted.

2.7 Automatic program selection using the barcode (option)

The barcode entry can be used to automatically preselect the appropriate program for the scanned goods.



It is the responsibility of the operator to create and apply the barcodes for program selection.

Each barcode contains a program number to which a specific sterilization time, sterilization temperature and drying method (e.g. SuperDry) has been assigned.

After scanning, make sure that the correct program for the material to be treated has actually been selected.

The relevant program is automatically highlighted in the program selection menu. Depending on the configuration, it is not possible to select other programs. This prevents the selection of unsuitable programs which may damage the goods to be processed.

The barcode process is configured during commissioning by the customer service team in consultation with the operator.

Two types of processing mode are available: **temperature flexible** and **time flexible**.

Temperature flexible program selection

The compatibility test of the barcode with a suitable program is assessed according to the following process:

- The first barcode to be scanned determines the barcode group. All other scanned barcodes must belong to the same group.
- If barcodes are scanned that are assigned to different sterilization temperatures, the lowest temperature is selected.
- A newly scanned barcode is checked to see whether a program with the same sterilization temperature but different sterilization time has already been scanned. If this is the case, the new barcode is rejected. This means that all programs with the same sterilization temperature have to have the same sterilization time.
- If barcodes are scanned that have been allocated the SuperDry (SD) drying method, the SD program with the lowest previously selected temperature is selected. If there is no SD program with this temperature, the barcode is rejected.
- If barcodes are scanned that have been assigned a program number for a program that has not been activated, the barcode is rejected.

Time flexible program selection

The compatibility test of the barcode with a suitable program is assessed according to the following process:

- If barcodes with different sterilization times are scanned, the program with the longest sterilization time is selected. However, all of the scanned barcodes must have the same sterilization temperature.

2.8 Process description

The sterilizer is factory-configured with the processes described as examples in the following.

On request, the number of available programs can be reduced or increased (authorization level 3 required Chapter 1.3, "operators"). All available programs that can be selected using the touchscreen are displayed in the program selection menu.

It is also possible to set special programs with custom program parameters (authorization level 3 required Chapter 1.3, "operators").



When selecting the program, note the program information text, in which the process and the materials suitable for this program are described.

Special program for countries with high temperatures (option)

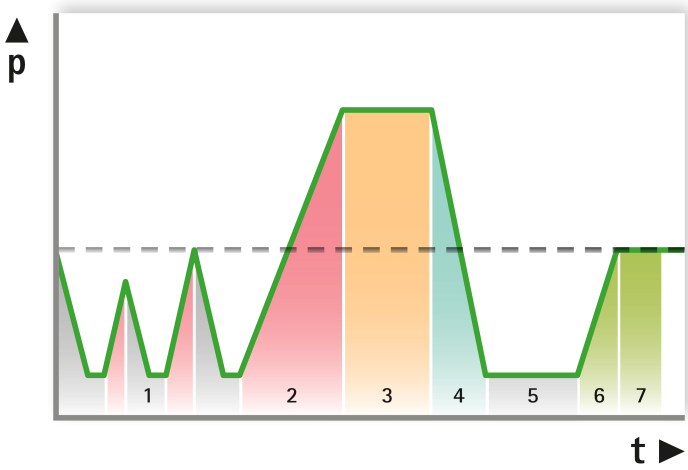
For regions with high ambient and cooling water temperatures, it is possible to activate a special program with raised vacuum switching points and additional pulsing so that the device continues to operate under unfavourable conditions.

Sterilisation temperature: 134°C

Exposure time: 5 min

2.8.1 Sterilization programs

Sterilization program according to the pulsed vacuum process followed by vacuum for drying. The process is pressure-regulated and time-controlled. The sequence is characterized by the following elements:



Example of a process curve.

1. Pulsed evacuation of the chamber with interim steam surges for air removal and steam penetration
2. Heating phase up to the sterilization setpoint pressure
3. Sterilization for a specific time at a specific temperature. The pressure container's design pressure, the installed measurement technology and the media supply allows sterilization temperatures from 105°C to 134°C to be set. Sterilization time variably adjustable.
4. Chamber pressure relief
5. Drying of the material through evacuation of the chamber for a specific time.

6. Chamber aeration to atmospheric pressure
7. Release of the door seal

Program selection:

Universal

Standard program

- Sterilization temperature: 134°C
- Exposure time: 5 min

Typical sterilization materials:

- Laundry
- Packed instruments
- Materials that are difficult to ventilate
- Complex cavity instruments

Universal SD

For goods that are difficult to dry (e.g. excessively heavy packaging), the drying effect is improved by alternating between aeration and evacuation in the *Drying* program phase.

- Sterilization temperature: 134°C
- Exposure time: 5 min

Typical sterilization materials:

- Laundry
- Packed instruments
- Goods that are difficult to dry (e.g. excessively heavy packaging)
- Complex cavity instruments

Plastics

For temperature-sensitive materials.

- Sterilization temperature: 121 °C
- Exposure time: 20 min

Typical sterilization materials

- Materials of rubber
- Steam-resistant plastic

Prion prevention 18 min (option)

For the reprocessing of medical products that have been used for operations on high-risk tissues and for which it was not possible to undergo the appropriate precleaning (see the hygiene recommendations when reprocessing medical products (*Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten*) of the Commission for Hospital Hygiene and Infection Prevention (Kommission für Krankenhaushygiene und Infektionsprävention - KRINKO), 2012).



Observe the KRINKO recommendations to assess how medical products that are probably contaminated with prion protein (e.g. patients with suspected CJK/vCJK) should be classified.

The operator must carry out an appropriate risk assessment that determines the reprocessing method and, if necessary, disposal of the medical product.

The process settings comply with the KRINKO recommendations.

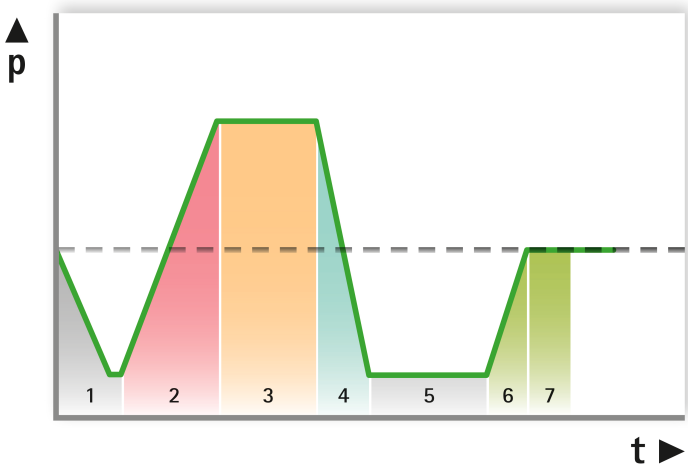
- Sterilization temperature: 134°C
- Exposure time: 18 min

Typical sterilization materials

- Thermostable instruments that have been used for high-risk operations involving prion proteins.

2.8.2 Heating and SteamSpy heating

A program for heating the chamber and the optional **SteamSpy** equipment (option) to the operating temperature.



1. One-off evacuation of the chamber
2. Heating phase to the heating process.
3. Holding at a specific temperature and for a specific time. The pressure container's design pressure, the installed measurement technology and the media supply allows temperatures from 105 °C to 134°C to be set. Variably adjustable holding time.
4. Chamber pressure relief
5. Drying of the chamber by evacuating the chamber for a specific time
6. Chamber aeration to atmospheric pressure
7. Release of the door seal

On machines with two doors, only the door on the loading side can be opened.

2.8.3 Test programs

2.8.3.1 Vacuum test

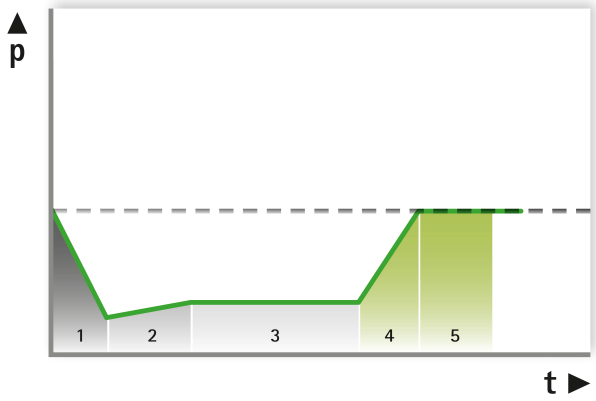
No sterilization program!

Test program in accordance with EN 285 for automatically testing the chamber for leaks. The vacuum test detects any leaks that exist within the device.

The process is pressure-regulated and time-controlled.

The “Vacuum test” program class does not involve a sterilization program.

The sequence is characterized by the following elements:



1. Evacuation of the chamber
2. Waiting time 5 minutes
3. Test time 10 minutes
4. Chamber aeration to atmospheric pressure
5. Release of the door seal

On failure of the vacuum test, the message *Last vacuum test not passed* is shown and the red indicator lamp lights.

If the cycle is repeatedly not passed, the machine must be checked by a qualified person (preferably MMM customer service) and repaired if necessary. The vacuum test must then be run again.

2.8.3.2 Bowie-Dick test

The Bowie-Dick test is a steam penetration test for providing evidence of the successful removal of air in porous sterilization material (laundry) and the subsequent steam penetration.

- Exposure temperature: 134°C
- Exposure time: 3.5 min

Performing the Bowie-Dick test

The test must be performed once daily in accordance with DIN EN ISO 17665 at operating temperature (e.g. following an empty sterilization or a heating program). The following test methods are available:

- Original test package comprising folded cotton cloths. The test is performed and evaluated according to the manufacturer's instructions.
- Alternative Bowie-Dick test in accordance with DIN EN ISO 11140-4, e.g. using chemical indicators or SteamSpy. The test is performed and evaluated according to the manufacturer's instructions.

When using the **Bowie-Dick test with SteamSpy** option, the **SteamSpy Heating** program must be used.

The Bowie-Dick test is not a sterility test.

2.8.3.3 Air detector function test (option)

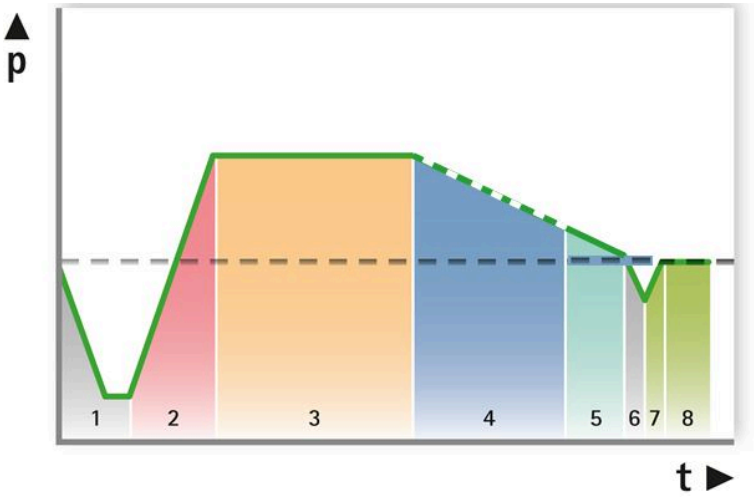
The **air detector function test** enables one or more programs to be set up to test the function of the air detector. During an air detector function test program a defined leak is generated during the entire preliminary phase when the chamber is at underpressure.

If the air detector operates correctly, the process fails.

2.8.4 Special programs

2.8.4.1 Open liquids (option)

Sterilization program according to the pre-vacuum process with subsequent cooling of the material to less than 80°C by means of passive cooling. The process is pressure-regulated and both time- and temperature-controlled. The sequence is characterized by the following elements:



Cold liquids with passive cooling

Process phases

1. One-off evacuation of the chamber
2. Heating phase up to the sterilization setpoint pressure
3. Once the sterilization temperature has been reached in the reference bottle, the sterilization process is continued for a specific time at a specific temperature. Due to the pressure container's design pressure and the installed measurement technology, sterilization temperatures from 105°C to 134°C can be set.
4. Cooling phase until the temperature at the reference sensors is less than the re-cooling temperature (80°C or less).
5. Chamber pressure relief
6. Safety extraction to 700 mbar
7. Chamber aeration to atmospheric pressure
8. Release of the door seal

Typical cold liquid sterilization materials:

- Liquids in open or loosely sealed containers with a temperature less than 35°C

2.8.4.2 Rack hatch

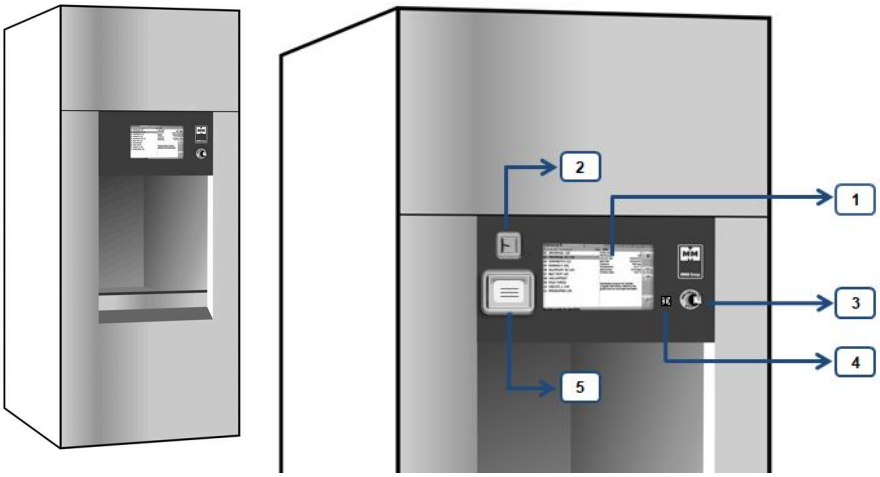
Additional program for two-door devices.

For redelivery of empty loading trolleys from the unloading to the loading side through the machine chamber. Only one door can be opened at one time.

This program can also be used for service purposes (e.g. for cleaning the chamber).

3 Display and control elements

The actual layout of the control elements may differ from this schematic representation.



1. Color touch screen
2. Manometer (optional)
3. Program stop switch (optional)
4. Mains switch (optional)
5. Thermal plotter (optional)

Model with color touchscreen on the unloading side

The loading side and unloading side of the machine are equipped with a color touchscreen.

Model without color touchscreen on the unloading side



The loading side of the machine is equipped with a color touchscreen. The unloading side is equipped with an indicator lamp and *Open door* and *Close door* buttons.

3.1 Pressure gauge display

The sterilizer is fitted with the following pressure measurement equipment:

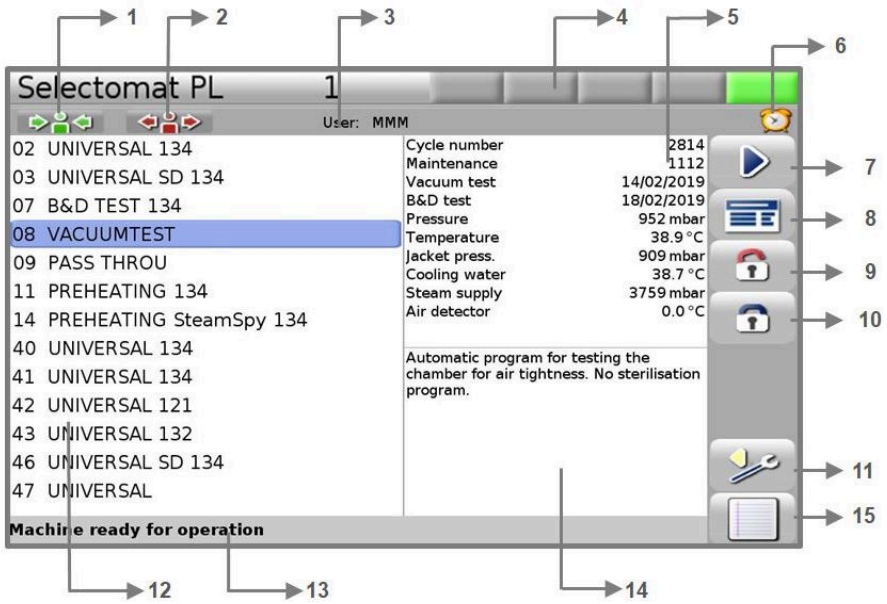
- Jacket: the pressure gauge measures the steam pressure in the annular duct jacket. The value is shown on the display.
- Chamber: the pressure gauge displays the pressure in the chamber. The value is shown on the display. The value can also be displayed on a pressure gauge on the loading side as an optional extra.

- Pneumatic system compressed air: the pressure gauge is located on the air pressure reducer and displays the air pressure in the line to the control cabinet.
- Devices with an integrated steam generator: Pure steam pressure. the pressure gauge is located in the steam generator in the assemblies compartment. The value is shown on the display.

3.2 Color touch screen

The machine is equipped with a color touch screen. Pressing the buttons executes the stored functions. The touch screen can be operated with gloves or a corresponding tool.

Function overview



1. Log in user
2. User log out
3. Logged-in user
4. Indicators
5. Machine status information
6. Autostart activated
7. Program start
8. Switch between vacuum programs and solution programs (optional)
9. Open door
10. Close door
11. Tools selection
12. Selected program
13. Information messages
14. Program information
15. Short instructions

Function overview

1. Log in user
2. User log out
3. Logged-in user
4. Indicators
5. Machine status information
6. Auto start activated
7. Program start
8. Open door
9. Close door
10. Tools selection
11. Selected program
12. Information messages
13. Program information

Function buttons of the color touch display

	Button	Description	Function
1		Log in user	User log in. Every action requires a user to be logged-in. If no user is logged in, the user “Anonymous” is logged in.
2		User log out	User log out. If logs out actively, the user “Anonymous” is automatically logged in. If the user does not actively log out, the user is automatically logged out after a specific period during which no buttons on the display are pressed.
		User log out inactive	The user “Anonymous” cannot be logged out. The button is then inactive.
4		Indicators	see "Colored status displays", Page 76
7		Start	Starts the selected program.

	Button	Description	Function
8		Switch	Switches between the “Vacuum programs” and “Solution programs” program selection screens.
9		Open door	Opens the chamber door.
10		Close door	Closes the chamber door.
11		Tools selection	Accesses a submenu that contains the following buttons: Quick user access, selection of saved cycle records, barcodes and control menu
15		Short instructions	Access to short instructions.
		Loading control	Access to the loading control menu.
		Selection of saved cycle records	Opens the list of the last 20 saved cycle records.
		Quick user access	Access to submenu: Start standby mode immediately, stop or continue loading, view panel configuration
		Barcodes	To administer barcodes
		Tools	Open the control menu.
		Cancel program	Cancels the current program.
		Acknowledgment button	Acknowledges all messages.
		Advance cycle	Advance cycle to the next program step.

	Button	Description	Function
		Save	Saves the current setting.
		Loads the selected cycles.	Opens the selected old cycle.
		Print	Prints the opened old cycle record.
		Cancel / Back	Back the next menu level up.
6		Auto start	If auto start is activated, this icon is shown on the program selection screen.
		Sensor values	Display of all activated sensor values (pressures and temperatures) and the door that is to be opened at the end of the program.
		Scroll button	If a menu level covers more than one screen, use this button to scroll through the screens.
		Scroll back button	If a menu level covers more than one screen, use this button to scroll back through the screens.

3.3 Colored status displays

The colors of the status display on the touch screen have the following meaning:

Overview of status indicator functions

Color	Designation	On	Off	Flashing
Green	Operational	Machine is ready for operation	Machine not ready for use, program running	-
Blue	Door locked	Door seal pressure applied	Door seal pressure not applied	Door seal pressure being built up or reduced
Yellow	In operation	Program running	No program running	During door movement
White	Cycle end	Program end	Program has finished; door has been opened	-
Red	Fault	Fault	No fault	-

4 Operation

Observe the safety instructions in Chapter 1 “Safety”.

Note!

All activities described below may only be carried out by authorized operators.

4.1 Logging users in and out

Log-in is not required for normal operation.



If no user is logged in, the user "Anonymous” appears in the user bar.

If the **User Manager** (Chapter 1.5.10.1, "User permissions") option is used, operator log-in can be configured so that each operator has to log in with his name and password.

Operator log-in



- Press the log-in button.

The log-in window appears.

- Touch the “Name” entry field. The alphanumerical input block appears.
- Enter the relevant user name (e.g. “S” for supervisor).
- Confirm the entry.
- Touch the “Password” entry field. The alphanumerical or numerical input block appears.
- Enter the corresponding password.
- Confirm the entry.
- Press the OK button.

After log-in, the corresponding user name (e.g. “S”) appears in the title bar.

The user can carry out any action for which he is authorised.

Log out actively to prevent misuse of rights!

If an operator does not log out actively, this occurs automatically within the set time limit if no button on the touchscreen display has been pressed within this period of time.

User log-out



- Press the log-out button.

The user name “Anonymous” appears in the user bar.

4.2 Daily start-up

Proceed as follows when commissioning the sterilizer each day:

- Perform the prescribed maintenance tasks (Chapter 7, "Maintenance").
- Touch the screen to stop standby mode.

For machines with an integrated steam generator, the current status is shown on the display while the steam generator is heating up. Once the machine is operational, the following message appears: *Machine is ready for operation*.

When using vacuum programs :

- Start the vacuum test
- Start the heating program
- Run the Bowie-Dick test (Chapter 4.2.3, "Bowie-Dick test").

The device is now ready for sterilization mode.

If the **SteamSpy** or **Airdetector** options are installed, the vacuum test only needs be performed every four weeks.

When using the autostart:

If the **autostart** function is activated Chapter 5.5, "Activating auto start (option)", the sterilizer is ready for operation as soon as the configured program sequence is completed.

If the configured morning autostart cannot be run because the device was switched off on the previous evening, or a door of the device was left open, the autostart can be initiated manually.

The configured autostart programs are then run automatically.



- Press the button: **Tools selection**.



- Press the button: **Quick user access**



- Press the **Start now** button in the **Autostart** field.

  The list of configured programs that are started now is shown below the button.

With option Blow off line exiting in the bottom tray :

For daily start-up, it is recommended to use the mains swich on the front of the sterilizer.

If the sterilizer is fully cut off from power supply (e.g. by an on-site master switch) or in case of a power outage, the load disconnect switch in the assemblies compartment must be re-activated by a specialist before the next start-up of the device.

4.2.1 Vacuum test



Note!

The vacuum test is part of the routine inspections and therefore essential for maintaining effectiveness (see Chapter 1.2.3, "Maintaining efficiency").

The vacuum test is normally performed when the machine is cold.



- Select the **Vacuum test** program



- Press the start button.



- Open the door on the loading side once the program has finished.

  The program selection menu then appears.

- Enter the vacuum test result in the daily record.

4.2.2 Heating program

The chamber and jacket must be warmed up by means of a preheating program before a sterilization program can be started.



- Select the **Heating** program or another program suitable for heating the chamber.



- Press the start button.



- Open the door on the loading side once the program has finished.

The program selection menu then appears.

4.2.3 Bowie-Dick test

The Bowie-Dick test is part of the routine inspections and therefore essential for maintaining effectiveness (see Chapter 1.2.3, "Maintaining efficiency").

The Bowie-Dick test is performed once a day when the machine is warm.



- Open the chamber door on the loading side.

- Insert the test package or test specimen for the Bowie-Dick test (Chapter 2.8.3.2, "Bowie-Dick test ")



- Close the chamber door.



- Select the **B&D test 134** program.



- Press the start button.

The program runs automatically until the end of the program.



- Open the chamber door on the loading side.

- Evaluate the test results and enter the results in the daily record.

Bowie-Dick test with SteamSpy (option)



- Select the **B&D test 134** program



- Press the start button.

The program runs automatically until the end of the program.

The Bowie-Dick test is evaluated automatically. The result is shown on the cycle record.

If the Bowie-Dick test has been passed, the following appears:

- SteamSpy - integrated B&D test passed
- Result: Cycle sequence completed properly

If the Bowie-Dick test has been failed, the following appears:

- SteamSpy - integrated B&D test failed
- Result: Cycle sequence failed

4.3 Sterilization mode

Prior to sterilization, the goods must be thoroughly cleaned and disinfected to reduce the initial germ load. The goods must then be packaged to protect the sterilized goods from recontamination until they are used. Only sterile goods packaging that complies with the respective national standard must be used.

See also Chapter 1.6, "Residual risks and measures to prevent them".

4.3.1 Handling flexible measuring sensors (for Open solutions equipment package)

When sterilizing liquids and treating ampules, the temperature must be measured inside the material or in a reference container equivalent to the sterilized material. The temperature in the reference containers is measured using resistance thermometers Pt100 (flexible measuring sensors) on flexible cables in the sterilizer chamber. The protective tube around the flexible sensors prevents the ingress of moisture and water vapor.

The flexible measuring sensor can be precisely positioned and locked in place in the reference container using a corresponding connection facility.



Note!

Handle the flexible measuring sensor with care.

It is a sensitive measuring instrument.

- The sensor tip must not be subjected to shocks or impacts.
- Do not insert the sensor to the bottom of the bottle (approx. 1 - 3 cm above the bottom).
- Do not throw or drop the sensor into the chamber.
- Do not place tension on or crush the sensor cable.
- Ensure that the cables can move freely when moving the trolley in and out.
- Do not run over cables with the loading trolley.
- Before the trolley is removed, remove the sensors from the reference containers and insert them into the sensor pouch.
- In vacuum programs, insert the sensor into the sensor pouch.



No automatic unloading for solution programs!

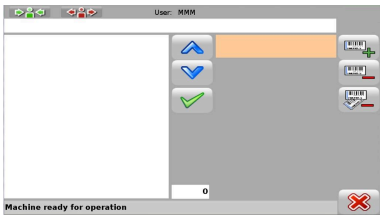
Automatic unloading is not possible for solution programs because the flexible measuring sensor needs to be manually removed from the reference bottle.

4.3.2 Reading barcodes

If the device has a barcode management system, barcodes can either be scanned or entered manually.

Reading barcodes with a scanner

- Scan the barcodes at intervals of approx. 15 cm.
  After scanning, the barcode administration window appears. Once the barcode has been scanned, check whether the barcode has been added to the list or not.



Once read, the barcodes appear in a list. They are assigned to the next program due to start.

The number of scanned barcodes appears at the lower edge of the screen.

If no further entry is made within 10 seconds, the barcode administration screen disappears.

Manually inputting barcodes

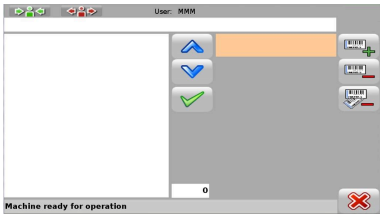
If scanning with the handscanner fails and the barcode does not appear in the list (e.g. because the barcode is dirty), the barcodes can be entered manually).



- Press the **Tool selection** button.



- Press the **Barcodes** button.



- Touch the input window to the right next to the arrow keys.

  An input block appears.
- Enter the barcode information.
- Confirm the entry with the green tick.



- Press the **Barcode Plus** button to save the barcode.
  The barcode appears in the list.

Barcode transfer failure

If a barcode is rejected when scanned or entered manually, (e.g. incorrect barcode length, incompatible program number Chapter 2.7, "Automatic program selection using the barcode (option)" etc.) an explanatory message appears in the upper information line.

Deleting barcodes

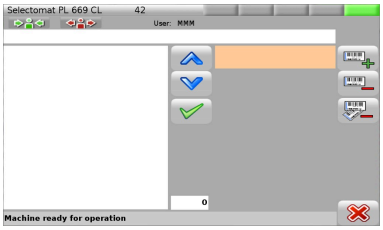
Individual or multiple barcodes that have already been scanned can be deleted.



- Press the **Tool selection** button.



- Press the **Barcodes** button.



- Touch the input window next to the arrow keys.

  An input block appears.
- Use the arrow keys to select the barcode to be deleted
- Confirm the entry with the green tick.



- Press the **Delete barcode** button to deleted the selected barcode.



- Press the **Delete all barcodes** button to deleted all of the entered barcodes.

4.3.3 Loading the loading trolley

Load the chamber according to the process specified in the process validation. This is the only way to guarantee a satisfactory sterilization result.

Place heavy containers at the bottom or with neutral impact on the centre of gravity.

Maximum load per StU**:**

- Instruments: max. 10 kg
- Textile load: max. 7.5 kg

Deviations are possible if they have been tested as part of a validation and authorized.

Minimum load in the chamber:

- For a pure metal load: 50 g
- For a pure textile load: 150 g

- For a pure plastic load: 150 g
- For other materials, composites or mixed loads: 150 g



1. Light or small containers
2. Loading trolley
3. Locking lever
4. Transport trolley
5. Heavy containers



Risk of injury!

Make sure that the loading trolley is firmly locked on the transport trolley.

4.3.4 Waiting times (for vacuum programs)

Before loading the chamber, consider any waiting times that need to be adhered to. A program with a lower temperature must not be used immediately on completion of another vacuum program, as the chamber would be too hot for this program sequence.

After selecting a corresponding program, the following waiting times therefore apply to cooling because of this (reference values with the chamber door open):

- 134°C # 105 °C: 40 minutes
- 121°C # 105 °C: 30 minutes
- 134°C # 121 °C: 10 minutes

These should be taken into consideration when selecting the operational sequence.

Store the sterilization material outside the sterilizer during waiting times, and only transport it into the chamber directly before starting the actual program.

Note!

Hygroscopic loads (for example textiles) must only be transported into the chamber immediately prior to starting the program, as there is otherwise a risk of the sterilization material's overheating.

4.3.5 Loading the sterilization chamber

The sterilization chamber is loaded manually.



- Open the door on the loading side.

Risk of burns!

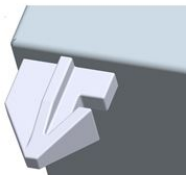
For **Open liquids** option: The flexible measuring sensor and the chamber wall are hot after a previous sterilization.

Wear suitable protective equipment when loading the chamber.

Machines with floor level loading:

- **Push the loading trolley into the chamber.**

Machines with raised loading:



- Dock the transport trolley securely to the sterilizer so that it is locked in place.

  The transport trolley is correctly docked when the two locking guide rails are engaged.

Risk of injury!

Make sure that the loading trolley is firmly locked on the transport trolley.

Do not adjust the height when the TW HUB is docked and locked!

When using solution programs

- **Position the flexible measuring sensor (Chapter 4.3.1, "Handling flexible measuring sensors (for Open solutions equipment package)")**
  - When sterilizing **solid or porous items**: insert the flexible measuring sensor into the sensor pouch on the side chamber wall.
  - When sterilizing **liquids**: insert the flexible measuring sensor into the reference container.

- To load the sterilization material into the chamber, push lever 2 on the transport trolley to release the loading trolley from it.
- Push the loading trolley into the chamber.



Risk of injury!

The loading trolley can fall off while being drawn into the sterilizer.

Ensure that the transport trolley is docked correctly to the sterilizer before the loading trolley is pushed into the chamber.

- **To release the transport trolley from the sterilizer, push lever 3 on the transport trolley.**



Risk of injury!

Ensure that the loading trolley is located fully within the chamber before releasing the transport trolley.



- Close the door on the loading side

4.3.6 Program selection and program start

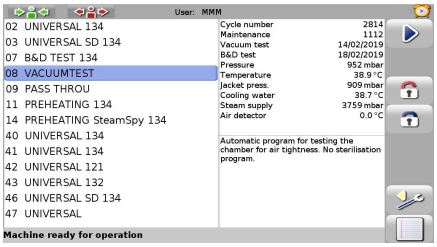
Program preselection

For safety reasons a pre-selection is required between programs for sterilizing solid materials and programs for sterilizing liquids.



- Press the switch button to open the corresponding program selection screen (vacuum programs, solution programs).

Program selection



- Select the desired program by touching the name of the program on the touch screen.

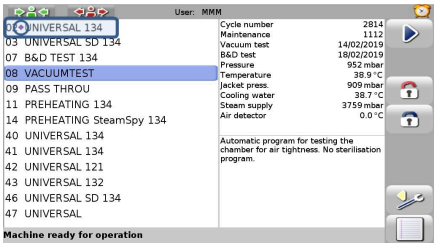


Note the information displayed about the program.

The program must be suitable for the material to be sterilized.

Using APPcycles programs

APPcycles® programs can be recognized by the colored diamond in front of the program name and also in the information displayed about the program.



- Select the desired program by touching the name of the program on the touch screen.
- Insert the associated MMM BMS PCD test with enclosed chemical indicator strip (if used).



The color of the diamond indicates which MMM BMS PCD test needs to be used for the selected program.

Observe the instructions for use included with the PCD test.

Program start

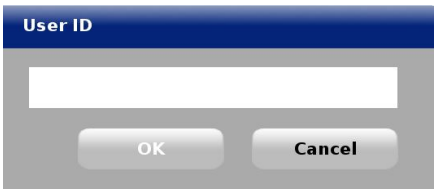


- Press the start button and if necessary enter the user ID (see below).

The program runs automatically. On completion of the program the machine stops at the *Unload* program step and the door on the unloading side is released.

User identification

If the **user identification** function is activated, the user ID is requested after pressing the start button.



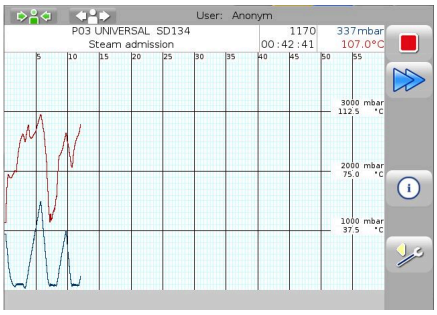
- Touch the entry field so that the alphanumerical input block appears.
- Enter your user ID manually and confirm it with the tick.
- Confirm the process with OK.

The program then starts.

Program sequence

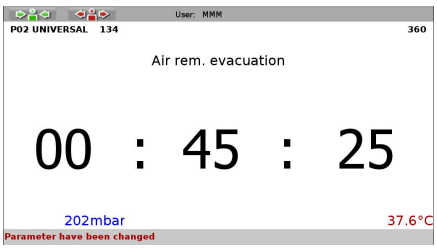
During the program sequence, the on-line process flow chart appears. The pressure, temperature and, if applicable, air detector curves are displayed in real time on the screen.

Online process curve



After a pre-set time, the display automatically switches to the remaining time screen, on which the remaining time is displayed.

Remaining time



The program name, cycle number of the current cycle, current process step, time remaining to the end of the cycle, chamber pressure (registration) and chamber temperature (registration) are also shown on the remaining time display.

The user can switch back to the screen with the online process curve by touching the screen.

4.3.7 Canceling the program

If a program has been accidentally started that must not be used for the load, the “Cancel program” should be pressed to prevent any damage to the material to be sterilized or the machine.



- Press the “Cancel program” button.
- Confirm the security prompt with **Yes**.

After confirming the prompt:

- the current program is ended without drying (Chapter 6.1, "Unexpected cancellation of the program sequence"),
- an alarm message is shown on the display.

After acknowledging the alarm message, the chamber door on the loading side can be opened.

4.3.8 Program end

Once a sterilization program has been properly completed, the message *Remove* appears on the display and the door buttons on the unloading side are activated.

On two-door devices, the door on the unloading side can be opened and closed as many times as desired, until the loading door has been opened once.

The door on the loading side can only be opened once the door on the unloading side has been opened and closed again.

Once the following programs are complete, only the door on the loading side can be opened at the end of the program:

- B&D Test
- Vacuum test
- Heating and SteamSpy heating
- Failed program

4.3.9 Unloading the chamber

The sterilization chamber is unloaded manually.

If your machine has an automatic unloading system, refer to the user manual of the transport system (e.g. MMM Cart Logistik or other manufacturer).

No automatic unloading after an Open liquids program.

Automatic unloading is not possible for solution programs because the flexible measuring sensor needs to be manually removed from the reference bottle.



- Open the door on the unloading side.

Escape of steam possible!

For your personal protection, stand to the side of the chamber when opening the chamber door.

Risk of burns!

For **Open liquids** option: The flexible measuring sensor and the chamber wall are hot after sterilization.

Wear suitable protective equipment when unloading the chamber.

Machines with floor level loading:

- Pull the loading trolley out of the chamber.

Machines with raised loading:



- Dock the transport trolley securely to the sterilizer so that it is locked in place.

  The transport trolley is correctly docked when the two locking guide rails are engaged.



Do not adjust the height when the TW HUB is docked and locked!



- Manually draw the loading trolley onto the transport trolley until it is locked securely onto the transport trolley by the locking bolts.



Risk of injury!

The loading trolley can fall off while being drawn into the transport trolley.

Ensure that the transport trolley is coupled firmly to the sterilizer before the loading cart is pulled out of the chamber.

- Take the flexible measurement sensor out of the reference bottle and insert it into the sensor mount.

- **To release the transport trolley from the sterilizer, push lever 3 on the transport trolley.**



Risk of injury!

Ensure that the loading trolley is located fully on the transport trolley before releasing the transport trolley from the locking mechanism.



- After removing the loading trolley, close the chamber door to reduce the heat loss during non-use and to keep the interior of the chamber clean.



- Press the confirm buttons (if present)

4.3.10 Passing through

The pass through-program for the redelivery of empty loading carts from the unloading side to the loading side is started from the loading side.



- Select the rack hatch program.



- Press the start button.

The message *Door on the unloading side can be opened* is displayed.

The door on the unloading side can now be opened and closed as many times as desired, until the door on the loading side has been opened once.

However, the door on the loading side can only be opened once the door on the unloading side has been shut again.

4.4 Releasing a cycle

Every cycle must be checked, inspected and released before being reused or stored in the sterile goods store.

The cycle is released based on a visual inspection and the cycle record.

- Check that the program selection is consistent with the materials that were reprocessed.
- Check that the process-related data on the cycle record, e.g. pressure and time, were maintained throughout the entire process and correspond to the data specified in the validation.
- Check the packaging and, if necessary, the seals for integrity (visual inspection).
- Check the packaging for condensate residue (visual inspection).
- Check the results of the process indicators (if present). The operator must document the criteria for evaluating the process indicators in a work instruction.
- When using the MMM SteamSpy: Check the results of the cycle control reported in the cycle record.

Label released sterilized materials so they can be differentiated from sterilized materials that have not been released, or ensure a clear differentiation by organizational means.

Cycle documentation

The release results must be documented. The goods must only be released by a person named by the operator. The cycle and the person who released it must be clearly identifiable in the release documentation.

Depending on the results of the release inspection, individual packaging items of a cycle may be released and others rejected. If packaging items are rejected, the reason must be documented in the cycle record.

4.4.1 Displaying and printing saved cycle records

The last 20 cycle files stored on the machine can be shown on the display and reprinted.



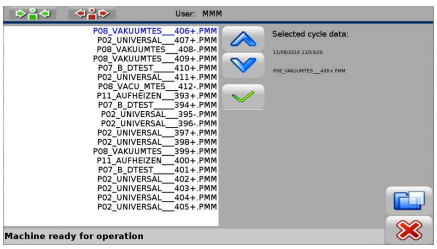
- Press the *Tool selection* button.



- Press the *Select saved records* button.

The list of the last 20 saved cycle files is displayed.

The cycle name is a combination of the date, program number, program name and cycle number.



- Select the desired cycle using the arrow keys.
- Confirm the selection with the tick button.

The cycle name and date the selected cycle was saved are shown in the info field (right side of screen).



- Press the *Load selected cycle* button to view additional information (e.g. program name, cycle times etc.).



- Press the *Printer* button to print the displayed cycle.

- Press the *Load selected cycle* button to view additional information (e.g. program name, cycle times etc.).
- Press the *Printer* button to print the displayed cycle.

The selected cycle file is printed depending on the setting of the cycle print option (Chapter 5.2, "Configuring the cycle print and save option").

4.4.2 External saving of cycle files

The last 20 cycles stored in the machine can be copied to a USB stick.

This function can only be performed if no program is active.



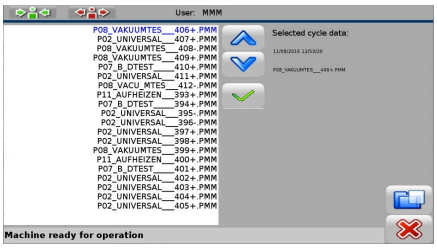
- Log in as the supervisor.



- Press the *Tool selection* button.



- Press the *Cycle viewer* button.



A list of the last 20 saved cycles is displayed.



- Press the *Save* button to copy the last 20 cycle files to the USB stick.

4.5 Standby mode

The **standby mode** is initiated automatically after a configured time has elapsed (Chapter 5.6, "Activating standby mode ").

This function can also be actively initiated.



▶ Press the button: *Tools selection*.



▶ Press the button: *Quick user access*.



▶ Press the button: **Start standby mode**.

The device immediately switches to standby mode. The MMM logo and the following message appears in the display: *Standby mode active.*

The jacket control is paused in standby mode.

4.6 Shut-off

Standby mode is activated to switch off the device each day.

To disconnect all poles of the device from the mains supply, activate the load disconnect switch. This is not necessary for standby mode.

Note!

Do not switch off the machine if the **Autostart** function is activated.

Keep the chamber doors closed to reduce heat output and prevent chamber interior soiling when the machine is not in use.

5 Machine configuration

The machine configuration described below can be performed by the system supervisor via the control menu.

Process-related changes can only be carried out by persons who have the master passport (e.g. MMM customer service).

Opening the control menu on the loading side:



- Log in as the supervisor.



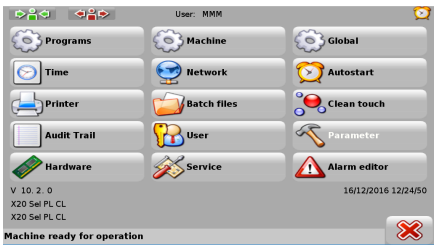
- Press the *Tool selection* button.





- Press the *Tools* button.

The control menu appears.



The number of functions available depends on the authorizations of the logged-in user.

Opening the control menu on the unloading side:

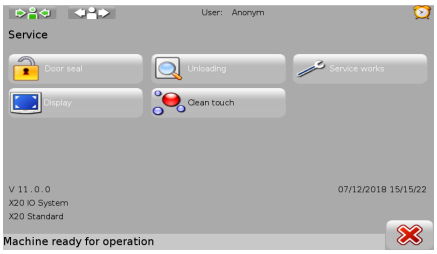


- Log in as the supervisor.



- Press the *Tools* button.

The control menu appears.



5.1 Configuring the User Manager (option)

If the machine has the **User Manager** option, users can be created with name, password and specific authorizations.

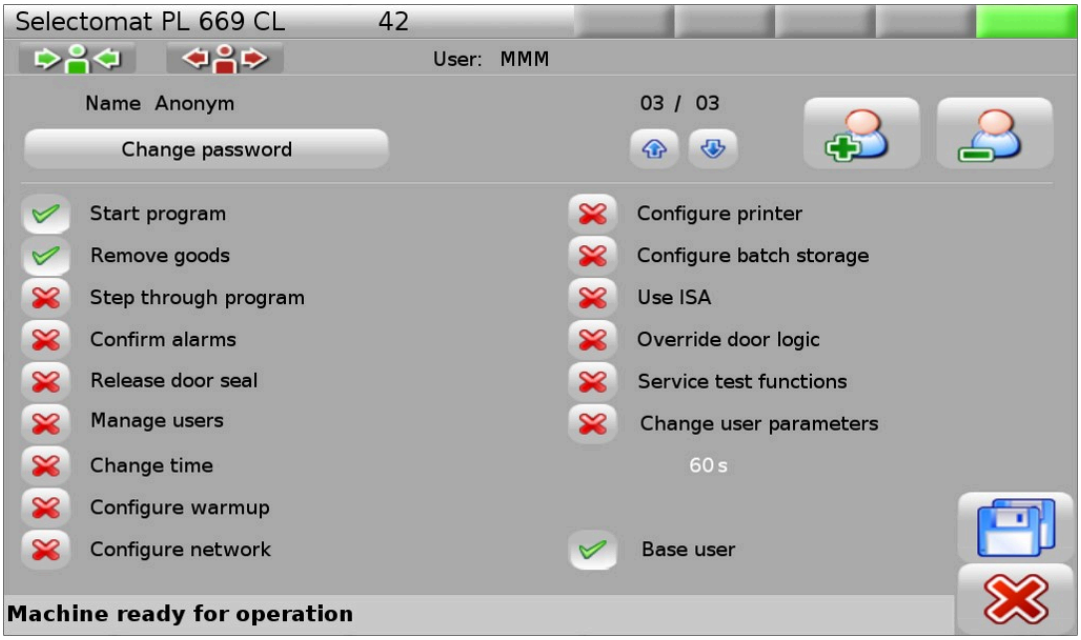
The User Manager needs to be activated by a specialist via a USB stick.

The various user passwords enable access to the corresponding menu levels.

- Open the control menu on the loading side.



- Press the **User** button.





- Press the **created user** button.

- Enter the name and password of the new user to be created.
- Assign the required authorizations to every new user.
- Enter the required log-out time after which the user will be automatically logged out.
- Confirm every entry with OK.



- Save the entry.

Users can also be deleted and passwords changed on this menu screen.

Program start authorizations

Authorizations for programs can be assigned individually to every user, who can then start the specified programs. In the default setting, every user can start all activated programs.

The program selection per user is defined as follows:



- Press the **User** button.



- Select the desired user and scroll to the page.



- Activate the programs that the user is permitted to start.

Programs that the currently logged-in user is not permitted to start are grayed-out in the program selection menu and the user cannot start the programs.

5.2 Configuring the cycle print and save option

Cycle print

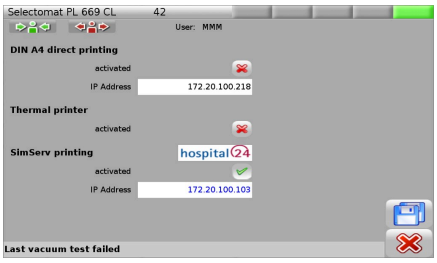
Depending on the model, one or more of the following options for printing and saving the data of the cycle record will be available.

- Thermal printer option: Print-out to integrated thermal printer.
- DIN A4 direct printing option: Direct printing to a connected DIN A4 printer. One printer per sterilizer is required for multiple sterilizers.
- RUMED360 Cycles option: Transfer of cycle data to a PC installed in the network. Data can be saved and printed here. This requires the RUMED360 CycleServ program to be installed on the PC. Only one PC with RUMED360 CycleServ and a printer are required for multiple machines.

Proceed as follows when set up one of the options:



- Open the control menu on the loading side.
- Press the **Printer** button.



- Activate the required print options. All options can be activated simultaneously.



- Save the entry.

DIN A4 direct printer

- Activate this printer by placing a green tick in the *DIN A4 Direct printing* section.
- Enter the IP address of the printer.

Thermal printer

- Activate this printer by placing a green tick in the *Thermal printer* section.

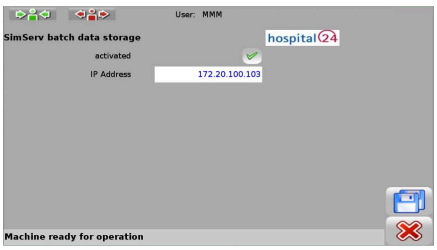
Printing via PC

- *RUMED360 Connect Cycles* is activated by a specialist.
- Activate this printer by placing a green tick in the *External cycle printing* section.
- Enter the IP address of the network computer on which *RUMED360 CycleServ* is installed.

Saving cycle data



- Press the **Cycles** button in the control menu.



- Activate the cycle saving function.
- In the *External cycle printing* section, enter the IP address of the network computer on which *RUMED360® CycleServ* is installed.



- Save the entry.



- The connection to this IP address can be tested by pressing the ping button.

⇒ A ping command is sent to the specified IP address. The result of the ping command is displayed.

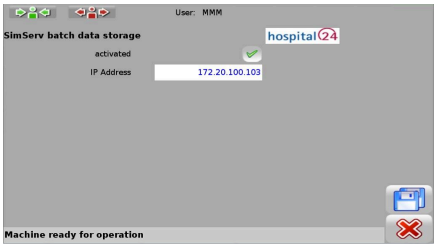
The following results may be displayed:

- *Ping successful.*
  The network connection was successfully tested.
- *No response received.*
  No connection to the specified IP address. Check the cable, network settings, etc.
- *Destination cannot be resolved.*
  Check the network settings.
- *No free socket.*
  All network resources are already allocated. If no program is active, restart the machine and try again.
- *Command blocked by firewall.*
  The configured firewall rules do not allow a ping command. Check the firewall rules in the Service menu.

Saving the cycle data in case of a network outage



▶ Press the **Cycles** button in the control menu.



▶ In the *External cycle saving* section, enter the *IP address in case of a network outage*.



▶ Save the entry.

⇒ You can switch between the standard and alternate connection in the quick access menu.

⇒ The button setting is retained after a restart.



▶ The connection to this IP address can be tested by pressing the ping button.

⇒ A ping command is sent to the specified IP address. The result of the ping command is displayed.

5.3 Print settings

The current settings for global parameters, machine parameters and programs can be output over a directly connected printer. The data of the alarm counter can also be printed. At least one direct printer or a thermal plotter must be activated in the **printing** function.

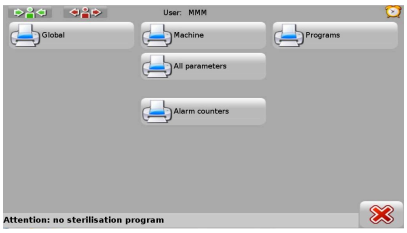
- ▶ Open the control menu on the loading side.



- ▶ Press the **Service** button.



- ▶ Press the **Parameters** button.



- ▶ Press the applicable button.

The selected parameters are printed out to the connected and activated printer.

If a printer is not connected, this button is disabled.

5.4 Setting the network addresses of the control panel

TCP/IP configuration

The network settings must be input for every control panel.

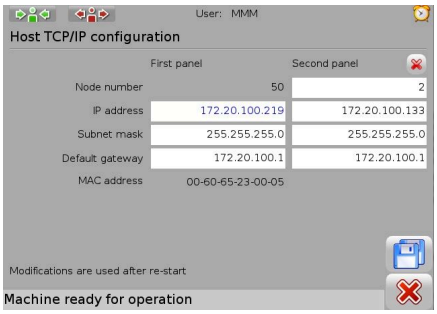
On two-door machines with a control panel on the loading and unloading sides, the first (master) panel and the second (slave) panel communicate with each other over a network. The IP address of the second panel must be input into the first panel to enable communications between the two panels.

Consult the network administrator of your IT department for the IP addresses.

- ▶ Open the control menu on the loading side.



- ▶ Press the **Network** button.



- Enter the node number, the IP address, the subnet mask and the default gateway of the two panels.
- Touch the respective number field to open the numerical block.



- Save the entry.

Each panel has a node number, which is set with the rotary switch on the back of the panel. The node numbers per machine must match. Duplicate node numbers are not permitted in the network.

All fields must always be correctly populated.

If there is no default gateway, a valid IP address is still required.

This screen shows the MAC address, which will be required with service questions.

5.5 Activating auto start (option)

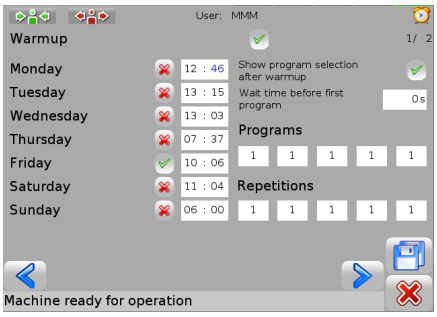
With the **auto start** function, the device starts a configurable sequence of programs automatically. The start time can be individually configured for every day of the week.

Proceed as follows to configure **auto start**:

Configuration of starting time



- Open the control menu on the loading side.
- Press the **Autostart** button.



- Activate the require day of the week with the green tick or disable it with a red cross.
- Touch the time field to enter the starting time. Hours and minutes are entered separately.
- Confirm every single entry with the tick button.



- Save the entry.



If **auto start** is activated, a corresponding icon is shown.



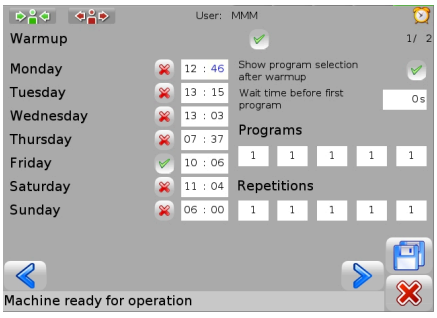
Because the machine must not be shut off if **auto start** is enabled, this function should be combined with the **standby mode** function.

In the energy-saving standby mode, the jacket heating is paused and the machine cools down.

Configuration of program sequence

The following sequence is recommended:

- Vacuum test
- Heating or SteamSpy heating (Option)
- B&D test (only available with the **SteamSpy** option or automatic loading and unloading)



- Touch the number field under **Programs**.
- Enter the program number. If a program is not wanted, enter a zero.
- Touch the number field under **Repetitions**.
- Enter the number of repeats of the respective program.
- Confirm the entry with the tick button.



- Save the entry.

5.6 Activating standby mode

The time after which standby mode is activated can be configured to suit the operating sequence being used.

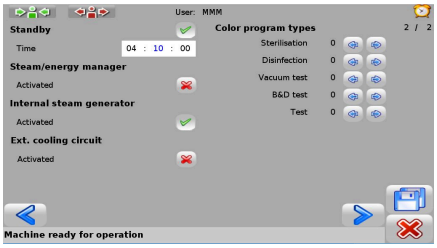
- Open the control menu on the loading side.



- Press the **Autostart** button.



- Navigate to the relevant page.



- Enable the **Standby mode** parameter.
- Tap the time entry field.
- Enter the hours, minutes and seconds after which the machine is to switch to standby mode.
- Confirm the entry with the tick button.



- Save the entry.

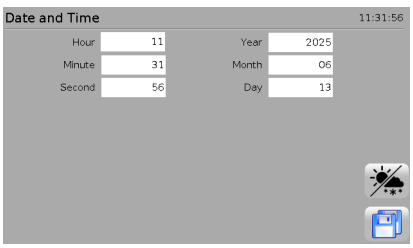
5.7 Setting the time

The supervisor can set the time. The date can only changed, however, by a user with a high authorization level.

- Open the control menu on the loading side.



- Press the **Time** button.



- Enter the current time.
- The **Clock change** button on the right side of the display can be used to configure the changeover from daylight saving (summer) to standard time (winter).
- Save the entry.

5.8 Activating the energy manager (option)

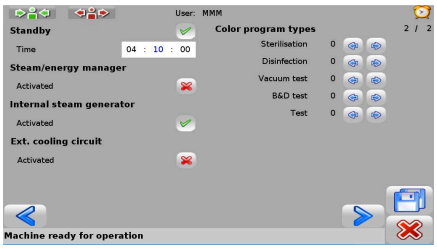
If the device is equipped with a energy manager , the function must be activated in the control menu.



- Open the control menu on the loading side.
- Press the **Autostart** button.



- Use the right arrow button to move to screen 2.



- Enable the **energy manager** parameter.



- Save the entry and restart the machine.

5.9 Activating steam source switching

If the machine has been designed for an external steam supply and is also equipped with an integrated steam generator, the steam source can be switched to the integrated steam generator if the external supply of steam is lost.

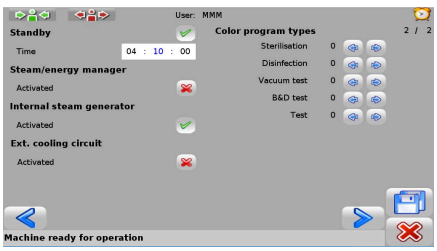
The switching function is located in the control menu.



- Open the control menu on the loading side.
- Press the **Autostart** button.



- Use the right arrow button to move to screen 2.



- Enable the **Internal steam generator** parameter.



- Save the entry and restart the machine.

The steam is then supplied via the internal steam generator.

5.10 Calibrating the screen

A calibration may be necessary if the operator controls on the screen do not respond.

- Open the control menu on the loading side.



- Press the **Service** button.



- Press the **Screen** button.



- Press the **Calibrate** button.

  Several cross-hairs appear in succession.

- Touch them as precisely as possible.

6 Operating safety and faults

Safety-related equipment

The machine is equipped with safety and monitoring equipment to enable safe operation when used as intended.

If a fault occurs, the program is canceled and the machine enters a safe state. This may take several minutes depending on the current process step. The door on the loading side can only be opened after the fault has been confirmed. The door on the unloading side is locked.

An appropriate status or alarm message is displayed. If several messages are generated at the same time, they are displayed one after the other.

After the fault has been eliminated, the interrupted program must be restarted manually.

Note!

Observe the instructions in see Chapter 1, "Safety"

If the cause of the fault cannot be eliminated by an authorized operator, inform MMM customer service or a person or company that has been authorized by MMM.

Customer service hotline +49 1805 - 666 112* | Service@mmmgroup.com

* 14 ct./min. from a German landline, prices for mobiles or calls from outside Germany may vary.

6.1 Unexpected cancellation of the program sequence

The program sequence may be canceled unexpectedly for the following reasons:

- The device initiates an automatic program cancellation (Chapter 1.5, "Machine safety devices")
- The program cancellation button was pressed
- The program stop switch (option) was pressed

Note!

Always inform the system supervisor of the machine, who will analyze and remedy the cause of the fault.

Risk of contamination!

The service and chamber doors must not be opened by force.

The sterilization material must be considered unsterile.

After pressing the program stop button



If the program cancellation button has been pressed, a security prompt appears, asking whether the program is really to be canceled.

- Confirm the security prompt with **Yes**.

  The program is ended without drying and an alarm message is shown on the display.
- Acknowledge the message.

After pressing the program stop switch (option)

- Unlock the switch, depending on the machine variant, either by gently pressing and turning it or using the key if present.
- Wait for the program cancellation to finish, and for the machine to be at the *Remove* program step.
- Acknowledge the message.

After triggering of the pressure switch (option)

If the integrated steam generator is fitted with a pressure limiter, the pressure limiter will activate in the event of an impermissible increase in pressure and switch off the supplementary load disconnect switch.

- Eliminate the cause of the triggering of the pressure switch.
- Switch on the load disconnect switch again.

Unloading the chamber after the program has not completed properly

On machines with two doors, only the door on the loading side can be opened.



Risk of burns!

Steam may escape. Stand to the side of the chamber when opening the door.

Wear gloves to protect your hands when removing the material.

- Unload the chamber manually by pulling the loading trolley out of the chamber on the loading side.

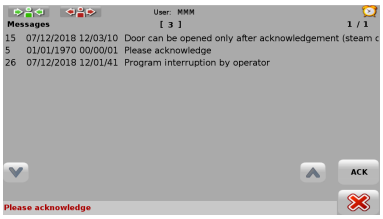
6.2 Acknowledging messages

The information and fault messages appear at the bottom edge of the screen. If a message has to be acknowledged, the following note appears, alternating with the relevant messages: *Please acknowledge.*



- Log in as the supervisor.
- Touch the **information message and faults** field.

The messages overview page appears.



The messages are displayed with alarm number, the time the alarm occurred, and the alarm description.

You can use the arrow buttons to scroll through multiple pages.



- Press the ACK button to acknowledge the alarm.



- Log out again.

6.3 Time taken to switch off the vacuum pump exceeded

If the process time is exceeded with the program process blocked during the program phases pressure relief, venting or release of the door seal, the vacuum pump is switched off.

The *Vacuum pump stopped because time exceeded* fault message appears.

Correct the cause of the problem and start the pump.

- Open the control menu on the loading side.



- Press the **Service** button.



- Press the **Pump** button.

The vacuum pump is switched on and the program is interrupted or continued depending on the process step.

6.4 Faults in door movement

If a fault occurs in the door movement when opening or closing, the causes may be the following:



Risk of injury!

The chamber doors must not be opened by force!

Door seal not sucked back sufficiently

The resuction of the door seal can be repeated manually. To do this, the machine must be set to *Operational* or *Unloading*.



- Log in as the supervisor.



- Open the **Control menu**.



- Press the **Service** button.



- Press the **Door seal** button.

The door seal is suctioned backfor a specific, previously set time.



If the door seal cannot, or cannot be fully suctioned back, automatic movement of the door is not possible.

If, due to a defect, the door seal repeatedly cannot be suctioned back and the door cannot be opened (e.g. if the door seal pressure cannot be reduced), inform MMM customer service or a company/person authorized by MMM.

Service door opened

The service door has been opened. The corresponding message appears: *Service door loading side opened* or *Service door unloading side opened*

- Close the service door.

Program stop pressed

During the preceding program sequence, the was pressed. The *Program stop actuated* message appears.

Chapter 6.1, "Unexpected cancellation of the program sequence".

Chamber door on opposite side opened

According to the door logic, only one door can normally ever be opened. The message *Door BS open* or *Door ES open* appears.

- Close this door.

Program sequence failed

If the program sequence is incorrect, the message *Door can be opened after acknowledgment* (steam discharge) appears.

- Acknowledge the message

Chamber not depressurised

The chamber door cannot be opened whilst the chamber is not recognised as depressurised.

- Inform MMM customer service or a company/person authorized by MMM.

Product temperature too high (for solution programs)

The door remains locked as long as the flexible measuring sensor measures 80 °C or over (Chapter 1.5.8, "Locking the chamber door and door release"). The message *Door release blocked by hardware* appears.

- Wait until the product temperature has fallen below 80°C.

6.5 Manual advance

The program can be manually advanced for test purposes.

Note!

Manual advance assumes detailed knowledge of the functioning and principle of operation of the machine and must therefore only be performed by suitably trained persons (see Chapter 1.3, "operators").

- If necessary, touch the screen to switch to the *On-line process flow chart* view.



- **Log in as the supervisor.**



- Press the *Advance* button.



- **Press the right-hand arrow to scroll to the next process step.**

- Press the OK button to exit the dialog.

This process can be continued up to the *Pressure relief* process step. In the *Pressure relief* process step, the system can only be advanced when the chamber pressure has reached or fallen below the ambient pressure of approx. 1000 mbar.

Advancing from the *Aeration* and *Relief* process steps for the door seal is not generally possible.

The program is ended after releasing the door seal.

In the *Unloading* process step, the messages *Cycle manually advanced* and *Please acknowledge* are displayed.

- Acknowledge the message.



Risk of burns!

Steam may escape.

Stand to the side of the chamber when opening the door.

Wear gloves to protect your hands when removing the material.

- Unload the chamber manually by pulling the the loading trolley out of the chamber on the loading side.



Risk of contamination!

The process is regarded as failed!
The material to be treated must be regarded as not sterilized.



Note!

Run an empty cycle prior to further operation.

6.6 Fault in the cooling circuit vacuum pump (option)

The heat exchanger vacuum pump and the operational water vacuum pump are cooled either with cold water or by connection to an external cooling circuit (option).

In the event of a fault in the cooling system, the switching between operation with cold water and operation with an external cooling circuit can be carried out using manually actuated ball valves or valves and by enabling the corresponding parameter.

To disable/enable the parameter, proceed as follows:



- **Open the Control menu.**



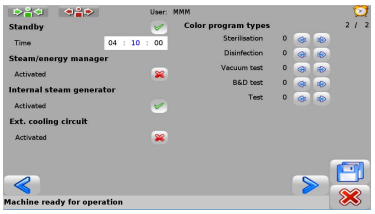
- Press the **Autostart** button.



- **Open the Control menu.**



- Use the right arrow button to move to screen 2.



- In the **Cooling water** section, enable the **External cooling circuit** parameter.



- Save the entry.

Switching between cold water and external cooling circuit:

- Open the inspection opening in the chamber panel on the unloading side of the machine

The key is kept by the system supervisor to ensure that only technicians have access to the assemblies.

- Remove the flap

While the inspection flap is open, safety switch S112 prevents the door of the machine from moving.

- **To switch to cold water:** Manually move the levers of the three-way ball valves (piping diagram item 2) and the lever of the two-way ball valve (piping diagram item 1) into the **vertical** position.

  To switch to external cooling circuit: Manually move the levers of the three-way ball valves (piping diagram item 2) and the lever of the two-way ball valve (piping diagram item 1) into the **horizontal** position.

- When operating with an external cooling circuit: Enable the **External cooling circuit** parameter.
- After switching the ball valves, refasten the inspection flap to the chamber panel.

Note!

Disable the External cooling circuit function if the building cooling circuit is not in service.

Cooling circuit automatic switching (option)

Automatic switching between the cooling circuit and cold water can optionally be configured in the global parameters of the machine (accessible by a specialist only see Chapter 1.3, "operators").

If the cooling circuit of the building signals an error, it is necessary to switch to operation with cold water only in the software in the Service menu. The valves of the machine automatically switch to cooling with cold water.

6.7 Analysis options in the event of faults

Analog and digital inputs and outputs

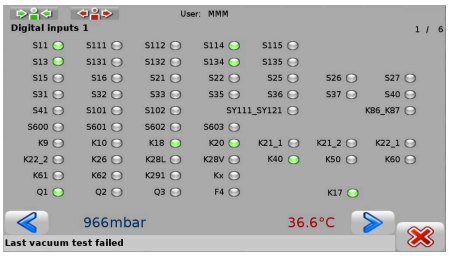
The current switching status of all analog and digital inputs and outputs can be analyzed in the control menu.

- **Open the Control menu.**



- **Press the Hardware button.**

If the green lamp next to the hardware name is lit, the input is active or the output actuated.





▶ **Press the Hardware button.**

You can scroll between the individual pages using the arrow buttons.

The names of the inputs and outputs can be assigned to the corresponding hardware elements based on the electrical plan.

Instrumentation diagram view

To check the function, it is also possible to display the instrumentation diagram on the screen in order to observe the status of the individual machine components.



▶ **Log in as the supervisor.**



▶ Open the Control menu.

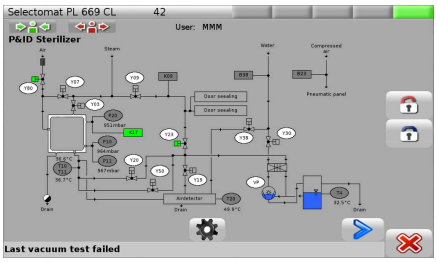


▶ Press the **Service** button.

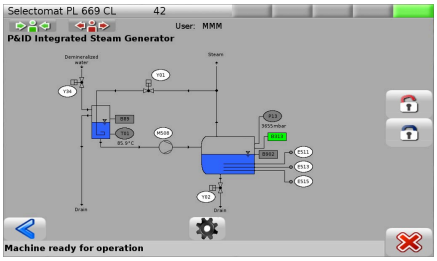


▶ Press the **P&ID** button.

The system instrumentation diagram appears on which it is possible to observe the status of the individual machine components.



Sterilizer instrumentation diagram



Integrated steam generator instrumentation diagram (if present)

Displaying the software licenses



▶ Open the Control menu.



▶ Press the **Service** button.



▶ Press the **Software licenses** button.

The available software licenses for the system appear.

6.7.1 Sending a debug e-mail

If the **ISA - Intelligent Service Advisor** option is activated, the user can send a message with diagnostic information to MMM customer service after a fault.

▶ Open the control menu on the loading side.



▶ Press the **Service** button.



▶ Press the **ISA** button.



▶ Press the button
Send debug email.

The machine automatically sends an e-mail message to the configured recipient.

For configuration of the ISA option observe the **ISA Installation and Configuration Manual**.

6.7.2 Function check for specific components

The following function checks can be performed without having to start a program. The machine must be *ready for operation*.

- Lamps
- Vacuum pump
- Cold water valve of the vacuum pump (on the loading side only)
- Unloading (automatic transport system)



On the loading side:

▶ Press the **Service** button in the **Control menu**.

▶ Use the blue arrow button to switch to screen 2.

Function check of the lamps



- **Press the Lamps button.**

The status display on the screen and the info bar (if installed) switch on and off alternately.

Vacuum pump function check



- **Press the Pumps button.**

The vacuum pump is now switched on for 10 seconds.

Vacuum pump cold water valve function check

This function can only be tested on the loading side.



- Press the **Cooling** button.

The cold water valves are opened and closed several times.

Unloading function check

This function can be tested with the **rack hatch** program.



- **First start the rack hatch program on the loading side.**



- Open the chamber door on the **unloading side**.



- Open the control menu on the unloading side .
- Press the **Unload** button.



▶ **First start the rack hatch program on the loading side.**

Unloading is started.



Risk of injury!

Observe the process and ensure that the movement zone of the transport cylinders remains clear.

6.8 Status and alarm messages

All messages with information on the trigger, the response of the machine, and instructions for the operator are listed below. Depending on the machine's equipment, not all messages are available.

Meaning of the abbreviations used in the following:

RL Red lamp
A Advertisement
T Printed in cycle documentation
Z Message to CCT (central control technology)
SV Start prohibition
PmT Program interruption with drying
PoT Program interruption without drying
Kdm Depressurise chamber
AT Audit trail
Q Confirmation required

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
1	Machine ready for operation	Ready for operation pending		x									
2	Standby active	The machine is in standby mode.		x			x						
3	Machine is warming up. Please wait.	Standby mode has been terminated, the machine is warming up.		x			x						
4	Power failure	Power failure	x	x	x	x	x	x			x	x	
5	Please acknowledge	An alarm requiring acknowledgement has occurred	x	x			x						Clear fault and acknowledge alarm
6	Loading door open	Limit switch of loading door actuated when ready for operation		x			x						

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
7	Unloading door open	Limit switch of unloading door actuated when ready for operation		x			x						
8	Loading door open during cycle run	Limit switch of loading door actuated during program	x	x	x	x	x		x		x	x	Contact customer service
9	Unloading door open during cycle run	Limit switch of unloading door actuated during program	x	x	x	x	x		x		x	x	Contact customer service
10	Time exceeded loading door	Time of loading door open exceeded	x	x		x	x						Clear door fault
11	Time exceeded unloading door	Time of unloading door open exceeded	x	x		x	x						Clear door fault
12	Service door open on loading side	Service door switch open on loading side	x	x			x						Close service door on loading side in standard operation
13	Service door open on unloading side	Service door switch open on unloading side	x	x			x						Close service door on unloading side in standard operation
14	Safety bar on loading or unloading side actuated	Safety bar on loading or unloading side actuated	x	x									Remove obstacle on loading or unloading door
15	Door can be opened only after acknowledgement (steam discharge)	The released machine door can only be opened after acknowledgment if an alarm that must be acknowledged occurs during the cycle.	x	x			x						Acknowledge messages on screen

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
16	Press acknowledgement key	The acknowledge button of the loading door must be actuated to start the closing process.		x									Press acknowledge key of loading door
18	Door seal press too low (chamber in vacuum)	Door sealing pressure switch (K9) reports pressure below 1.8 bar, chamber in underpressure	x	x	x	x	x	x			x	x	Check steam supply
19	Door seal press too low (chamber in overpressure)	Door sealing pressure switch (K9) reports pressure below 1.8 bar, chamber in overpressure	x	x	x	x	x	x			x	x	Check steam supply
20	Door sealing pressure could not be built up	Door sealing pressure could not be built up	x	x	x		x		x		x	x	Check steam supply
21	Door sealing pressure could not be reduced	Door sealing pressure could not be reduced	x	x			x				x	x	Contact customer service
22	Chamber pressure at program start outside tolerance	Chamber pressure at prompt for program start outside tolerance	x	x			x		x			x	Contact customer service
23	Check pressure switches K17 and K17.1	Chamber depressurized switches B17 and B171 do not switch in tolerance range.		x	x		x					x	Contact customer service
24	Compressed air pressure too low	The machine compressed air supply is too low	x	x	x		x				x	x	Check compressed air supply
25	Program STOP	Program stop button pressed	x	x	x		x		x		x	x	If necessary, clear fault and unlock program stop switch

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
26	Program interruption by operator	Program stop actuated by software	x	x	x		x		x		x	x	If necessary clear fault
27	P10, P11, P20 or P30 pressure too high	At least one of the P10, P11, P20 or P30 pressure probes returns a pressure greater than 3999 mbar	x	x	x	x	x			x	x	x	Check steam supply
28	Vacuum pump motor protection switch	Motor protection switch vacuum pump has triggered.	x	x	x	x	x			x	x	x	Contact customer service
29	Temperature probe control defective	Chamber temperature probe controls (T10) defective	x	x	x	x	x	x			x	x	Contact customer service
30	Temperature probe recording defective	Chamber temperature probe recording (T11) defective	x	x	x	x	x	x			x	x	Contact customer service
31	Bottle probe defective	Bottle probe defective	x	x	x	x	x		x		x	x	Contact customer service
32	Temperature probe air detector defective	Temperature probe air detector (T20) defective	x	x	x	x	x				x	x	Contact customer service
33	Cooling water probe defective	Cooling water temperature probe (T4) defective	x	x	x	x	x		x		x	x	Contact customer service
34	Pressure transducer control defective	Chamber pressure transducer controls (P10) defective	x	x	x	x	x		x		x	x	Contact customer service
35	Pressure transducer recording defective	Chamber pressure transducer recording (P11) defective	x	x	x	x	x		x		x	x	Contact customer service

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
36	Pressure transducer jacket defective	Pressure transducer jacket (P20) defective	x	x	x	x	x	x			x	x	Contact customer service
37	Cooling water temperature too high	Cooling water temperature too high (T4)	x	x	x	x	x		x		x	x	Check cold water connection
38	Sterilization temperature exceeded	Sterilization temperature too high	x	x	x	x	x	x			x	x	Contact customer service
39	Sterilization temperature too low	Sterilization temperature too low	x	x	x	x	x	x			x	x	Contact customer service
40	Chamber pressure transducer unacceptable difference (> 200 bar)	P10 and P11 measured values differ by more than 200 mbar and neither of the two probes has completely failed	x	x	x	x	x			x	x	x	Contact customer service
41	Chamber pressure transducer unacceptable difference (> 60 bar)	P10 and P11 measured values differ by more than 60 mbar but less than 200 mbar and neither of the two probes has completely failed	x	x	x	x	x		x		x	x	Contact customer service
42	Chamber temperature probe unacceptable difference (> 5 K)	T10 and T11 (or T12 and T13 for solution programs) measured values at ready for operation differ by more than 5 K and neither of the two probes has completely failed	x	x	x	x	x				x	x	Contact customer service

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
43	Temperature probe difference too high	T10 and T11 (or T12 and T13 for solution programs) measured values have unacceptable difference in sterilization and neither of the two sensors has completely failed	x	x	x	x	x	x			x	x	Contact customer service
44	Cooling time is running, please wait	Sterilization chamber is still too hot at the start of a program (risk of overheating). Start prevention is selected.		x			x						Wait for machine to cool sufficiently
45	Cooling time is running	Sterilization chamber is still too hot at the start of a program (risk of overheating). Start prevention is NOT selected.		x									Wait for machine to cool sufficiently
46	Low pressure jacket	Selectomat only: Low pressure jacket	x	x	x	x	x	x				x	Check steam supply
47	Jacket pressure too low	Jacket target pressure not met		x			x				x		Check steam supply
51	Last vacuum test failed	The last vacuum test was not passed.		x	x								Seal chamber, sterilization effect not guaranteed
52	Pressure increase waiting time too high	Vacuum test not passed, because pressure increase waiting time too high	x	x	x	x	x		x		x	x	Seal chamber, sterilization effect not guaranteed

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
55	Cycle manually advanced	Cycle manually advanced not executed after program start	x	x	x		x				x	x	Program sequence not completed
56	Parameter have been changed	Parameters in menu were changed during program	x	x	x		x					x	Take into account when releasing the cycle
57	Warmup active	The automatic program start is active		x									
58	Warmup configured incorrectly, program not known	Machine is fitted with warmup and a non-activated program is entered in the list of programs for execution		x									Contact customer service
59	Perform preventive maintenance	Preventative maintenance interval reached		x		x					x		Contact customer service to set up a preventative maintenance appointment
62	Change buffer battery	Buffer battery voltage below minimum value	x	x		x					x		Do not switch off machine, data may be lost! Contact customer service
63	Air detector: Temperature too low	Air detector: The temperature is too low at the measuring point. Program interruption by air detector is selected.	x	x	x		x	x			x	x	Inert gas level too high, program is interrupted, if configured appropriately
65	Air detector: measuring point not reached	Air detector: The measuring point was not reached.	x	x	x		x				x	x	Contact customer service

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
66	Air detector: Sterilization temperature too low	Air detector: Air detector temperature has fallen below sterilization temperature during sterilization. Program interruption by air detector is selected.	x	x	x		x	x			x	x	Inert gas level too high, program is interrupted, if configured appropriately
70	Loading: Time exceeded loading cylinder	Time exceeded during movement of loading cylinder during automatic loading	x	x								x	Clear cause of fault and acknowledge message
71	Loading stop	Automatic loading is stopped	x	x								x	
72	Loading: Waiting for second trolley	Loading: waiting for second trolley		x									
73	Unloading: Time exceeded unloading cylinder	Time exceeded during movement of unloading cylinder during automatic unloading	x	x								x	Correct cause of fault
74	Unloading ramp occupied	The unloading ramp is occupied when unloading is required		x									Remove loading trolley from the unloading ramp
75	Unloading stop	Automatic unloading is stopped	x	x								x	
76	Wire error steam manager	At least one connecting line of the steam manager is interrupted	x	x		x							Contact customer service

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
77	Steam supply not yet available	No steam manager line is free		x			x						Wait for steam release (green indicator lamp on)
78	Printing failed	Direct printing at USB printer has failed for various reasons	x	x			x					x	Check printer, if necessary add paper and set it on line, if necessary reprint cycle
81	Cycle data memory not available	Cycle data memory not available (USB stick not inserted).	x	x									Contact customer service
82	Cycle data memory full	Cycle data memory full.	x	x									Contact customer service
83	Unloading: Time exceeded door	Time exceeded during door movement with automatic unloading	x	x			x					x	Clear cause of fault and acknowledge message
84	Unloading: transport trolley removed	During automatic unloading of a loading trolley on a docked transport trolley the transport trolley was removed.	x	x			x					x	
85	Time exceeded: air removal inject	Time exceeded: air removal inject	x	x	x	x	x	x			x	x	Contact customer service
86	Time exceeded: air removal evac.	Time exceeded: air removal evac.	x	x	x	x	x		x		x	x	Contact customer service
87	Time exceeded: air removal flush	Time exceeded: air removal flush 1	x	x	x	x	x	x			x	x	Contact customer service
88	Time exceeded: air removal flush 2	Time exceeded: air removal flush 2	x	x	x	x	x	x			x	x	Contact customer service

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
89	Time exceeded: steam admission	Time exceeded: steam admission	x	x	x	x	x	x			x	x	Contact customer service
91	Time exceeded: pressure adjustment	Time exceeded: pressure adjustment	x	x	x	x	x		x		x	x	Contact customer service
92	Time exceeded: drying	Time exceeded: drying	x	x	x	x	x		x		x	x	Contact customer service
93	Time exceeded: air admission	Time exceeded: air admission	x	x	x	x	x				x	x	Contact customer service
94	Unloading: Door movement during transport process	Door movement unloading side during unloading	x	x			x					x	
95	Unloading active	Unloading is active		x									
96	Loading active	Loading is active		x									
97	Loading: Time exceeded: transport cylinder	Time exceeded: transport cylinder	x	x			x					x	Clear trolley accumulation
98	Loading: Time exceeded door	Time exceeded during door movement with automatic unloading	x	x			x					x	Clear door fault
99	Loading: Door movement during transport	Door movement during automatic loading	x	x			x					x	
100	Loading: Program start failed	Program start failed	x	x			x					x	
101	Loading procedure stopped	User selects program without required loading to machine while loading action has already started		x									
102	Local storage failed	Saving of cycle to USB stick failed	x	x			x				x	x	Contact customer service

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
103	Network batch storage failed	Network batch storage failed	x	x							x	x	Check network connection
104	Network printing failed	Network printing failed	x	x							x	x	Check network connection
106	Check IO module	CAN node EX470 connection interrupted or problem at a connected module											
108	Attention: No sterilization program	A non-steriliza-tion program is active		x									
109	Check loading door	The limit switches of the loading door switch inconsis-tently	x	x			x					x	Contact customer service
110	Check unloading door	The limit switches of the unloading door switch inconsis-tently	x	x			x					x	Contact customer service
111	Plot failed	Printing by thermal printer failed	x	x			x					x	Contact customer service
112	Plot initialization failed	Plot initialization failed	x	x			x					x	Contact customer service
114	Door seal is released	Door seal release		x			x						
115	Vac-Liq switching defect	Relay self-test of switching vacuum/solution programs failed	x	x			x				x		Contact customer service
116	Back pressure not reached	Back pressure could not be built up	x	x	x	x	x				x	x	
117	Back pressure too low	Back pressure in the chamber not reached	x	x	x	x	x				x	x	

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
118	Steam pressure not yet reached	Steam pressure not yet reached		x			x						
119	Steam supply pressure too low	Steam supply pressure too low		x	x		x						Check steam supply pressure
120	No door release	No door release		x									Door movement not released by hardware.
121	Program selection manually changed	Program selection manually changed		x	x								
122	RUMED360® CyclePrint Direct active	RUMED360® CyclePrint Direct active		x			x						Wait for the printing operation to finish
123	Time exceeded unloading	Time exceeded unloading		x									Correct fault in unloading system
124	Unloading system not ready	Unloading system not ready		x									Correct fault in unloading system
125	Steam generator not ready	Steam generator not ready		x			x						
127	T13 defective	T13 defective	x	x	x	x	x	x			x	x	Contact customer service
128	T14 defective	T14 defective	x	x	x	x	x	x			x	x	Contact customer service
129	P30 defective	P30 defective	x	x	x		x		x		x	x	Contact customer service
130	Condenser circulation pump motor protection switch	Motor protection switch of the circulation pump of the condenser has triggered	x	x	x	x	x			x	x	x	Contact customer service
131	Jacket circulation pump motor protection switch	Motor protection switch of the circulation pump of the jacket has triggered	x	x	x	x	x			x	x	x	Contact customer service

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
132	Chamber fan motor protection switch	Motor protection switch of chamber fan has triggered	x	x	x	x	x			x	x	x	Contact customer service
142	Time exceeded safety extraction	Time exceeded safety extraction	x	x	x	x	x		x		x	x	Contact customer service
143	Vacuum pump stopped because time exceeded	Vacuum pump stopped because time exceeded		x	x						x		Correct vacuum pump fault and restart pump from the service menu (pump button)
144	Check liquifant	Liquifant reports jacket full of water at start of cooling		x	x		x				x	x	Contact customer service
145	Air flow	Released door is to be opened and air flows through the chamber to eliminate odors		x									
146	Jacket cooling active	Jacket cooling active before H2O2 program		x			x						
147	Unloading: Check latch	Latch sensor at waste unloading does not report the setpoint position of the latch		x									Contact customer service
148	Unloading: Overload	Force monitored at waste unloading has triggered	x	x		x	x					x	Remove blockage at unloading
149	Unloading: Clear transport area	Transport area for waste unloading has not been reported clear yet		x									Clear the unloading transport area and press the “ramp clear” button

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
150	Unloading: Emergency stop actuated	Program stop on machine or waste unloading was pressed	x	x		x	x					x	
151	Unloading: Please acknowledge	Reset button of waste unloading must be pressed		x		x							
152	Both doors open	The user has activated function opening both doors simultaneously		x			x				x		
153	Parameter incorrect: Air detector function test	Wrong program setting: The air detector function test is activated in at least one program, but the program is not a test program	x	x	x		x						Check parameter settings: If the “Air detector function test” program parameter is set to 'Yes', the “Program type” parameter must be set to 'Test'.
154	Air detector function test	A program for the air detector function test is running		x	x								
155	Back pressure too low	Heating during heating or cooling is too low	x	x	x	x	x		x		x	x	
156	Back pressure too low	Back pressure much too long during cooling	x	x	x	x	x				x	x	

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
157	Machine is warming up. Please wait.	Jacket pressure significantly below setpoint pressure at program start. Wait until the jacket pressure has reached the setpoint and another two minutes for the steam supply pressure to regenerate.		x									
158	RFID reader does not respond	RFID reader does not respond	x	x			x					x	
159	Condensate temperature too low	Chamber condensate temperature monitor with T41 is active and the condensate temperature is too low	x	x	x	x	x	x				x	
160	Condensate temperature too high	Chamber condensate temperature monitor with T41 is active and the condensate temperature is too high										x	
161	Temperature probe condensate defective	Temperature probe condensate (T41) defective	x	x	x	x	x	x				x	
162	Waiting for start of H_2O_2 generator	Waiting for start of gassing		x									

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
163	Departure from H_2O_2 pressure range	Chamber pressure outside the approved tolerance	x	x	x	x	x		x			x	
164	Valve feedback Y11/Y12 defective	Valve feedback of H_2O_2 valves does not match actuation	x	x	x	x	x		x			x	Contact customer service
165	Temperature sensor replaced, check cycle curve	One of the temperature probes (control or recording) has failed. The cycle is completed with the other sensor		x	x	x	x				x	x	Contact customer service
166	Error thermal cooling interlock	Thermal cooling interlock (MMM-UK) present. The feedback of the load size does not match the actuation.	x	x	x	x	x		x			x	Contact customer service
167	Waiting for release from cooling interlock	Thermal cooling interlock (MMM-UK) present. The interlock release is not yet enabled in cooling or removal		x									
168	Motor protection switch exhaust air heating	Motor protection switch exhaust air heating heater group 1 or heater group 2	x	x	x	x	x		x			x	Contact customer service
169	Electric current supervision exhaust air heating	Electric current supervision exhaust air heating heater group 1 or heater group 2	x	x	x	x	x		x			x	Contact customer service

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
170	Temperature too low exhaust air heating	Temperature too low exhaust air heating heater group 1 or heater group 2	x	x	x	x	x		x			x	Contact customer service
171	Temperature too high exhaust air heating	Temperature too high exhaust air heating heater group 1 or heater group 2	x	x	x	x	x		x			x	Contact customer service
172	Exhaust air heating is warming up	Exhaust air heating is warming up		x			x						
173	Check exhaust air heating	Check exhaust air heating		x			x						Contact customer service
174	External monitor failure	For MMM-UK: External monitor failure											
175	Unloading system disarranged	Unloading ramp has slipped.	x	x		x	x						Adjust ramp to correct position
176	Delayed program start	Delayed program start		x									
177	Last B&D test failed	Last B&D test failed		x	x								Test can be repeated. If this persists, contact customer service
180	Integrated B&D test failed	MMM SteamSpy reports that the integrated B&D test failed	x	x	x	x	x	x			x	x	Test can be repeated. If this persists, contact customer service
181	Temperature probe SteamSpy defective	Temperature probe SteamSpy (T21) defective	x	x	x	x	x	x			x	x	Contact customer service
182	UPS active	The uninterrupt-ible power supply (UPS) is active	x	x	x	x	x				x	x	

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
183	Cold water supply pressure too low	The pressure of the cold water supply to the machine is too low	x	x	x		x				x	x	
187	Cycle control failed	MMM SteamSpy reports that the cycle control failed	x	x	x	x	x	x			x	x	If this persists, contact customer service
188	Error reading barcodes	Faulty barcode read		x			x					x	If this alarm is wanted, the actions “Display”, “Red lamp” and “Confirmation” can be set.
189	Preventive maintenance due shortly	Carry out preventive maintenance		x	x								Arrange appointment for preventative maintenance with customer service
190	Interval maintenance & inspection due shortly	Interval maintenance & inspection due shortly		x	x								Arrange appointment for periodic maintenance and inspection with customer service
191	Calibration due shortly	Carry out calibration/adjustment		x	x								Arrange appointment for calibration/alignment with customer service
192	Requalification due shortly	A requalification is due shortly		x	x								Arrange appointment for requalification with customer service
193	Preventive maintenance overdue	Preventive maintenance is overdue	x	x	x								Arrange appointment for preventative maintenance with customer service

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
194	Interval maintenance & inspection overdue	The interval maintenance & inspection is overdue	x	x	x								Arrange appointment for interval-based maintenance and inspection with customer service
195	Calibration/adjustment overdue	Calibration/adjustment is overdue	x	x	x								Arrange appointment for calibration/alignment with customer service
196	Requalification overdue	The requalification is overdue	x	x	x								Arrange an appointment for the requalification with customer service
197	Please insert serial number of the machine	Serial number not input into machine parameters	x	x			x						Enter and save the machine serial number in the machine parameters
198	Flow rate of external cooling circuit too low	Flow rate of external cooling circuit too low	x	x	x		x				x	x	Check external cooling circuit.
199	Pressure external cooling circuit too low	Pressure external cooling circuit too low	x	x	x		x				x	x	Check external cooling circuit.
200	Steam generator: Heating circuit failure	Steam generator: Heating failure	x	x		x	x				x	x	Check the steam generator
201	Steam generator temperature too high	Steam generator temperature too high	x	x		x	x				x	x	Check the steam generator
202	Steam generator: Not enough water	Steam generator: Not enough water	x	x			x				x	x	Check the steam generator
203	Pressure transducer B13 defective	Pressure transducer B13 defective	x	x		x	x				x	x	Check the steam generator
204	Temperature probe T01 defective	Temperature probe T01 defective	x	x		x	x				x	x	Check the steam generator

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
205	Steam generator feed water temperature too high	Steam generator feed water temperature too high	x	x			x				x	x	Check the steam generator
206	Steam generator: Boiler water quality	Steam generator: Poor boiler water quality		x	x						x	x	Check the steam generator
207	Steam generator: Feed water temperature too low	Steam generator: Feed water temperature too low	x	x			x				x	x	Check the steam generator
208	Steam generator: Pressure too high	Steam generator: Pressure too high	x	x		x	x				x	x	Activate main fuse
209	Manual setting of digital outputs active	Manual setting of digital outputs active		x			x						Contact customer service; press load disconnect switch
210	Cycle processing failed	Problem serializing the cycle	x	x		x	x				x	x	Contact customer service
211	Cycle creation failed	Main memory problem in power panel	x	x		x	x		x		x	x	Contact customer service
212	Energy supply not yet available	Energy supply is being used by other machines		x			x						Wait until another machine reaches a stage with a lower energy consumption.
213	Perform air heating maintenance	Perform air heating maintenance		x							x	x	Call customer service for the air heating.
214	General fault with the air heating	General fault with the air heating		x			x				x	x	Call customer service for the air heating.
215	Faults are deactivated on the air heating	Faults are deactivated on the air heating		x							x		Call customer service for the air heating.

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
216	Check SteamSpy temperature probe	Check SteamSpy T21 temperature probe	x	x	x	x	x				x	x	Contact customer service
217	Jacket cooling water pressure too low	Pressure switch B35 signals that the pressure is too low	x	x	x		x				x	x	Check water supply
218	Deionized water pressure too low	Pressure switch B36 signals that the pressure is too low	x	x			x				x		Check water supply
219	Deionized water pressure too low	Pressure switch B36 signals that the pressure is too low	x	x			x				x		Check water supply
220	Loading: Barcode error	No / incorrect barcode read during loading	x	x			x					x	
221	Rupture disc defective	Feedback that one of the rupture discs has triggered.	x	x			x				x		Contact MMM customer service! You can determine which rupture disc has triggered on the digital inputs page in the control menu.
222	Chamber cleaning not ready	The chamber cleaning hard-ware is being used by another machine		x			x						Check the mixing tank or canister, if necessary replace the canister
223	Dosing of cleaning chem-ical unsuc-cessful	Mixing tank full, canister empty, or maximum dosing time exceeded	x	x			x	x			x	x	Check the mixing tank or canister, if necessary replace the canister
224	Filing of mixing tank unsuc-cessful	Mixing tank was not filled	x	x			x	x			x	x	Check deionized water supply

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
225	Fault during circulation (cleaning)	Fault during circulation	x	x			x	x			x	x	Check pressure switch, circulation pump, and connected hardware. Contact customer service!
226	Fault during circulation	Fault during circulation	x	x			x	x			x	x	Check pressure switch, circulation pump, and connected hardware. Contact customer service!
227	Chamber cannot be rinsed	Fault during circulation	x	x			x	x			x	x	Contact customer service! If rinsing is unsuccessful, do not continue to use the sterilizer!
228	Draining of the mixing tank unsuccessful	Fault during draining of the mixing tank	x	x			x	x			x	x	Check the mixing tank outlet Contact customer service!
229	Chamber cleaning canceled	Fault during the program	x	x			x				x	x	Contact customer service!
231	Cleaning canister empty, please replace canister	An empty cleaning canister has been detected via the suction lance.	x	x			x	x				x	Exchange canister
232	Cleaning canister empty, please replace canister	Cleaning cycle counter has decreased to 0		x									Exchange canister

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
233	Cleaning dose incomplete	The cleaning canister became empty during dosing	x	x			x				x	x	Exchange canister
234	Q5 digital input not present	Q5 motor protection switch - chamber cleaning	x	x	x		x	x			x	x	
235	Temperature registered during temperature measurement too high to start the chamber cleaning	Jacket temperature too warm for chamber cleaning	x	x	x		x	x			x	x	Allow the jacket to cool down further. Then restart the program.
236	Time exceeded during a chamber cleaning program step	Chamber cleaning time exceeded	x	x	x		x	x			x	x	
237	Bottom tray full of water	Leak sensor in the bottom tray is triggered and sets the linked digital input to High	x	x			x				x	x	
238	Program selection required	The machine is configured so that an active program selection is required after switching on, after a program has completed, or after a certain time has elapsed.		x			x						Tap a program on the program selection page to actively select it.
239	Machine restart required	The machine configuration was changed in the service menu.		x			x						Switch the machine off/on

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
240	Transport system: Emergency stop triggered	Transport system: Emergency stop of the transport system has been triggered	x	x									Eliminate the cause, unlock the emergency stop and then acknowledge the alarm using the reset button.
241	Transport system: Power supply unit fuse tripped	Transport system: Fuse of the power supply unit of the transport ramp has tripped	x	x									Eliminate the cause and then acknowledge the alarm using the reset button.
242	Transport system: Timeout	Transport system: Timeout during unloading	x	x									Eliminate the cause and then acknowledge the alarm using the reset button.
243	Transport system: Ramp not clear	Transport system: Ramp not clear for unloading		x									Remove all transport trolleys from the ramp. If no transport trolleys are present, have the sensors checked by a technician.
244	Transport system: Door area not clear	Transport system: Sensor in front of the door triggered. Door area is not clear		x									Remove all transport trolleys from the ramp. If no transport trolleys are present, have the sensors checked by a technician.
245	Loading: Timeout motor transport	The movement of the motor transport has taken too long.	x	x			x	x			x	x	Eliminate the cause. Acknowledge message and continue transport with quick access.

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
246	Dosing failed	Filling of the mixing tank in the chamber failed.	x	x			x	x			x	x	The counter-pressure in the chamber is too high. The chamber must first cool down.
247	Chamber cleaning canceled. Chemical in the chamber.	When chamber cleaning is canceled, the chamber is still contaminated with chemical.	x	x			x						The chamber cleaning program must be run again. Other program types cannot be started.

7 Maintenance



Note!

Observe the safety instructions in Chapter 1!



Note!

Observe the instructions for operation of pressure vessels Chapter 1.2.4, "Operation of pressure equipment" and regulations for regular inspection of pressure vessels Chapter 7.7, "Periodic inspections of pressure vessels".

An inspection and safety maintenance (interval-based maintenance & inspection) must be performed at least once a year. The results of the check must be documented. Observe the instructions in Chapter 1.7, "Maintenance and Safety inspection".

However, this inspection and interval-based maintenance does not provide the necessary safety for sustained reproducible operation. Preventative maintenance is thus required.

A preventative inspection and maintenance (preventative maintenance) of the machine should be performed after 800 cycles or after one year at the latest.

A preventative inspection and maintenance (preventative maintenance) of the steam generator should be performed after 2000 hours of operation or after one year at the latest.

It is practical for commercial reasons to carry out the maintenance of the steam generator at the same time as the maintenance of the machine that it is supplying.

The machine is equipped with a cycle/ and preventative maintenance counter as standard. The current counter readings can be read on the screen at any time .

The cycle counter continuously counts the cycles performed.

The preventative maintenance counter displays how many cycles are left until the next preventative maintenance procedure. If the preventative maintenance counter displays zero, the info message *Perform preventative maintenance* appears on the display after each cycle and is printed on the cycle record.

7.1 Preparatory measures

Observe the following points when performing maintenance work.



When working on the machine, turn off the master switch / load disconnect switch and secure it with a lock to prevent it from being switched back on unintentionally.

Working in the door area and assemblies compartment

Work in the area of the door mechanism or closure mechanism must only ever be performed by qualified persons (see Chapter 1.3, "operators") as specified by the manufacturer.

Working on the automatic transport system



Risk of crushing!

When working on the automatic transport system, disconnect the compressed air supply.

Press the **emergency stop switch.**

Vacuum pump



Drain the vacuum pump during extended downtime.

When the machine is idle for long periods (longer than four weeks) or if there is a risk of frost, the vacuum pump and circulation containers must be drained by removing all lock screws at the bottom and preserved with antifreeze (MMM article no. 010495501).

Steam generator (ED model)



Risk of injury!

The steam generator is hot and pressurised.

Maintenance work must only be performed on the steam generator when the device is not under pressure and has cooled down.

7.2 Planning service work

At regular intervals by means of alarm messages and at the bottom edge of the display, the user receives information about service work that is due shortly so that this can be planned early on. The intervals recommended by MMM are entered during commissioning of the machine. Please contact MMM Customer Service to arrange a time for servicing.

Messages are display on the screen for the following service work:

- Preventive maintenance (batch-controlled)
- Interval-based maintenance & inspection (time-controlled)
- Calibration/adjustment (time-controlled)
- Requalification (time-controlled)

Suitable informational messages are also shown on the cycle report.

The exact due dates for all maintenance can be accessed manually at any time.

Indication of when service work is due

To see when the cycle-controlled and time-controlled service work is due:

- Log in as the supervisor.



- Open the Control menu.



Loading side:

- Press the **Service** button.



- Press the **Service work** button.

An overview of upcoming service work is displayed.

7.3 Maintenance activities

a medical products log / equipment log must be maintained; current reports such as cycle documentation, assignment of the temperature and pressure curves (if available) and the tests, checks, maintenance and repairs performed must be entered in this each day.

Note!

The following activities must be performed by a qualified specialist (Chapter 1.3, "operators").

Daily:

What	How	Result of check
Check safety strip	Check the function of the safety strip on both sides. When operational ▶ Close the door ▶ Activate the safety strip	The door must reverse and open again.
Check door seals	The seal is automatically tested for vacuum tightness by the vacuum test program. During subsequent empty sterilization (heating program), check the seal for leak tightness against excess pressure. If the SteamSpy option is installed, the door seal only need be checked for leak-tightness with the vacuum test program every four weeks.	Beware of steam emissions! In the event of a leak, i.e. when steam escapes from the door area, replace the seal (Chapter 7.5, "Replacing the door seal").
Check dirt filter	Check the dirt filter in the chamber floor; remove and clean it if necessary.	

Weekly:

What	How	Result of check
Clean the chamber	Clean the chamber thoroughly. The chamber must be cold. The chamber fittings must first be covered to prevent foreign bodies from entering the pipe system (Chapter 7.8.1, "Chamber interior").	 **Risk of burns!** Allow the chamber to cool sufficiently beforehand.
Door seal and closure	Check the chamber's door seal and closure mechanism for wear and damage.	

After approx. 200 cycles:

To prolong the service life, we recommend cleaning the seal groove regularly.



Note!

The following activities must be performed by a person trained by a specialist.

Clean seal groove	Remove the seal from the groove using a suitable tool. ▶ Clean seal groove. ▶ Grease the sides of the seal groove (with MMM special lubricant, article no. 0613047). ▶ Press the seal into the groove.	Observe the instructions in Chapter 7.5, "Replacing the door seal", to avoid damaging the seal.

After 12 months or 800 cycles:

Due to reasons of operating safety, reliability and economy, the machine must be regularly checked by a specialist (preferably MMM customer service). The result must be entered in the medical products log / equipment log.

Maintenance is required after 12 months or 800 cycles. Technical data subject to change without notice.



Note!

The following activities must be performed by a specialist (preferably MMM customer service, Chapter 1.3, "operators").

7.3.1 Technical check of safety relevant equipment

Function check of safety relevant components including the safety-related measurement & control equipment: Sterilizer

What	How	Control result / activity
Chamber door and locking components	Check the door drive belts or chains, rollers, drive motor, guide rails, door mounting, door brackets (pressure frame), pawls (door supports), spring, friction clutch and threaded joints for wear and tighten as required.	Locking components have been fastened properly and are not worn

What	How	Control result / activity
Check door lock and closing process	Check the adjustment of the chamber door(s) during the closing process. Check that the door position switches and strip sensor (actuator) are seated firmly and functioning correctly. Designation of door position switches on the loading side: ■ S11, S111, S114 Designation of door position switches on the unloading side: ■ S13, S131, S134	The message: *Loading or unloading side door open* disappears once the closed position is reached. The locking door must reliably remain in the end position.
Check pressure monitor for pressure in door seal groove	Check the safety shut-off of media valves to the chamber if the pressure switch reports *Door seal pressure too low*. During the program sequence: ▶ Disconnect the sensor connector ■ B20 (B22 if present)	The following valves must close: ■ Y07 Switch value: 1.8 bar ±0.2
Check pressure monitor for chamber depressurized message	Door release function check. Door release only if B17/B171 (is present) report *Chamber depressurized*. When operational: ▶ Disconnect sensor connector B17/B171 Door movement not possible. **Checking the setpoint.** ▶ Start any program.	The display status of digital inputs B17/B171 (if present) changes. When overpressure (0.1 bar) is reached, the digital input indicators turn off.
Check function of the locking relay for vacuum/solution changeover (for solution program option only) ■ K28	Locking relay for activating the protection against boiling retardation for the solution program option When operational: ▶ Switch between vacuum/solution in the program selection screen	The switch status must change. K28

What	How	Control result / activity
Check function of the temperature limit value sensor B101 (for solution program option only)	Limit value sensor B101 : 82 °C ▶ Select solution program ▶ Disconnect sensors T1 / T13 ▶ Switch the machine off and on again	Door movement not possible
Check valves (CL variant): ■ Valves Y09 / Y07	Check safety shut-off of media valves to the chamber when door end switch S11 or S13 reports “Door open”. During the program sequence: ▶ Manually actuate roller lever S11 (S13)	Valves must close
Check pilot valves ■ Y771 / (Y772 if present)	Check safety shut-off of media valves to the chamber when door end switch S11 / S13 reports “Door open”. During the program sequence: ▶ Manually actuate roller lever ■ S11/S13	The following valves must close: ■ Y771 For bulkhead option also ■ Y772
Check safety valves(s) (if present)	Check function of the safety valves (e.g. chamber, compressed air, others). The function of the valve can be checked by removing it, and then testing it on a suitable test stand or using suitable equipment.	Safety valve functioning properly
Check maintenance switch function	▶ Press the maintenance switch	Drive motors for the doors must stop, movement of the door must only be possible after a reset.
Check service door switch function (if present)	Check service door switch: ■ S112 / S132 When operational: ▶ Open service door	The message, *Maintenance door loading side open* or *Maintenance door unloading side open* appears.

Function check of safety relevant components including the safety-related measurement & control equipment: Electrical steam generator / steam-to-steam generator

What	How	Control result / activity
Check safety valve	With the machine cold and switched off: To check the function of the valve, remove it and then test it on a suitable test stand or using suitable equipment.	Safety valve functioning properly
Fill level switch function check ■ B902, B911 and B912 or ■ B90	With the machine cold: ▶ Shut down the immersion heater (switch off the fuses) ▶ Fill the tank	When filling the tank, the yellow LED of the tuning fork switch must light up when the required fill level is reached.
Low water level safety shut-off function check	With the machine cold: ▶ Drain the water ▶ Alternatively: Pull out the plug of the fill level switch B911 or B912	When the water level falls below the low water limit, the following circuit breakers must open: **Unotherm II:** Heater circuit breakers Q501, Q502, Q503 **Selectomat PL CL and Vakulab PL CL:** Heater circuit breakers Q511, Q513, Q515
Heating energy shut-off in case of overpressure function check	With the machine cold: ▶ Pull out the plug of the B31 pressure limiter	**Unotherm II 36 to 54 kW with the Blow off line exiting in the bottom tray additional feature and** **Unotherm II 63 to 81 kW:** Heater circuit breakers Q501, Q502, Q503 must remain open **Duotherm II:** Hot steam valves Y15 and Y16 must close

7.3.2 Other function checks and maintenance measures

What	How	Control result / activity
Chamber	Visually inspect the sterilization chamber on the inside	
Dirt traps	Open and clean the dirt traps in the supply and disposal lines.	
Non-return valves	Open and clean the non-return valves, renew the seals if necessary.	
Pipes and fittings	Check all pipes and fittings for leaks, and tighten threaded connections if necessary.	
Drain water separators	Drain the water separators on the maintenance unit in the compressed air supply for pneumatic valve.	
Pipe interrupter (if present)	Check pipe interrupter function	
Clean assemblies compartment	Remove dust deposits from assemblies compartment.	
Condensate drain	Open and clean condensate drain, renew insert if necessary.	
Return flow preventer	Open and clean return flow preventer if fitted.	
Threaded connections	Check threaded connections, pipe connections and pneumatic lines for leaks	
Check the pressure switch	Check the setting of the pressure switch for the seal pressure.	
Absolute pressure transducer	Check absolute pressure transducer	
Vacuum pump	Check minimum vacuum of vacuum pump. The setpoint is ≤ 50 mbar	
Check electrical equipment	Check electrical components for visible wear. Particularly check that the protective conductor is fastened properly (note VDE regulations)	
Check thermal water valve	Check setting of thermal water valve and adjust if necessary	
Check valve Y03	Check the valve function by starting a program (except vacuum test).	
Steam pressure reducer (if present) and air pressure reducer	Check setting of steam and air pressure reducers, adjust if necessary	

What	How	Control result / activity
Temperature measuring facility	Check temperature measuring facility	
Check program stop function (if present)	When operational: ▶ Press program stop ▶ Press Open door or Close door button	Door movement not possible. Reset with key.
Function of SteamSpy (if present)	Check the function of SteamSpy using a Bowie-Dick test or cycle control.	The error message “Failed integrated B&D test” or “Failed cycle control” appears.
Signal column and indicator lamps (if present)	Check the function of the indicator lamps	
Transport trolley	Check the function of the locking bolt and parking brake.	
Cycle counter	Read the number of cycles from the screen and enter the status in the assembly report and equipment log.	
Test run	Perform test run and check program sequence for correct time setting. Check pressure and temperature measurement devices and their displays.	

7.4 Maintenance activities for steam generator

For machines with an integrated steam generator, the maintenance work described below must be performed at the specified intervals.



Note!

To be performed by a trained person only.



Risk of burns!

Wear protective gloves! The machine is hot.

Maintenance work, e.g. tightening bolts and threaded connections, must only be carried out when the machine is depressurized and has cooled down.

Intervention while the machine is hot is only permissible in special cases, e.g. to avert hazards.

7.4.1 Daily

- Perform a visual inspection for leaks.
- Make sure that the boiler supply and heating and also the feed water degassing are connected correctly (green lamp for “Operational” status lights up).
- Check whether error messages are present (red lamp).
- Make sure that the quality of the feed water meets the requirements described in Chapter 2.4.3.2, "Requirements on the feed water", and document the measured conductivity value and adherence to the limit value in the equipment log or in the log book of the water treatment plant.



The conductivity of the feed water at the reference temperature of 20 °C must not exceed 5 µS/cm.

7.4.2 Quarterly

Check the descaling function

Make sure that the device is descaled regularly. When running the descaling function, you will hear valve Y02 opening and a small amount of the boiler water will be discharged through the descaling line into the bottom tray. If necessary, document the descaling interval.



Danger of scalding!

Hot steam and hot boiler water are discharged into the bottom tray during descaling!

Use caution and stand back when checking the descaling function!

Alternatively, the functioning of the descaling feature can be determined by measuring the conductivity of the boiler water.

We also recommend checking the silicic acid content in the boiler water on a regular basis to ensure the medical instruments treated with the pure steam hold their value.



The boiler must not have been refilled before removing the water sample.

- Remove water samples at the boiler discharge valve.
- Allow the water sample to cool.



The conductivity at the reference temperature of 25°C should be less than 100 µS/cm and the silica content below 10 mg/l.

- Document the measured values in the equipment log.



Danger of scalding!

Hot steam and hot boiler water can escape.

Open the discharge valve carefully and only when the boiler has cooled sufficiently.

7.4.3 After 12 months or 2000 hours of operation

The maintenance interval depends on the operating hours (after 2000 operating hours or after 12 months) or the number of sterilization cycles of the machines being supplied.



To be done by a specialist only

With the machine cold and switched off

- Check the non-return valves and flaps, renew if necessary
- Open the feed module, carry out a visual inspection of the tank, clean if necessary.
- Completely drain the boiler
- Check safety valve function

  The safety valve will activate if the pressure in the pressure container of the steam generator overshoots.

  - To check the function of the valve, remove it and then test it on a suitable test stand or using suitable equipment.

- Water level control function check:

Fill level switches –B902, –B911 and –B912

Steps: ▶ Switch on the machine.

⇒ The boiler is filled.

▶ When filling the boiler, the yellow LED of the tuning fork switch must light up when the required fill level is reached.

When the machine is switched on:

▶ Check the function of the safety shut-off:

Steps: ▶ Pull out the plug of the fill level switch –B911 or –B912.

The heater circuit breakers –Q511, -Q513 (if present),-Q515 (if present) must open.

▶ Check the function of pressure limiting feature

The pressure limiting feature is included with:

- Selectomat PL CL, ED variant with the Blow off line exiting in the bottom tray additional feature

Steps: ▶ Pull out the plug of the B31 pressure limiter.

The heater circuit breakers –Q511, -Q513 (if present), -Q515 (if present) must remain open.

With the device at operating temperature

▶ Function test of the automatic boiler feed and pressure regulation.

▶ Check the function of the pressure limiting feature:

Increase the boiler pressure using the *Test pressure switch* function until the pressure switches respond. The heater circuit breakers -Q501, -Q502, -Q503 (Unotherm HL 81 kW only) must remain open.

▶ Reset the maintenance counter (if present).

▶ Check the settings of all setpoint sensors and correct if necessary.

7.5 Replacing the door seal

If the door seal is severely deformed or defective, a new seal must be inserted.

Note!

The door seal must only be exchanged by qualified persons (Chapter 1.3, "operators").

Risk of burns on the hot seal groove!

Switch the machine off and allow it to cool sufficiently.

- Open the door completely.
- Remove the old seal from the seal groove.
- Insert the new seal into the groove according to the instructions on the packaging.

A requalification must then be performed as per DIN EN ISO 17665, P.12.5.

7.6 Thermal printer paper exchange (option)

Use 112 x 46 x 12 thermal paper that can be archived for up to 10 years.

For trouble-free printing, we recommend ordering the paper from MMM.



- Open flap.

  On opening the paper repository, the printer roller is automatically guided out of the printing mechanism with the flap.



- Remove the empty paper reel.



Example images only

- Insert a new paper reel as shown in the figure.

  The paper reel is simply inserted into the container. Threading the paper in is not necessary.

7.7 Periodic inspections of pressure vessels

Pressure vessels must be inspected regularly. The operator must set up an inspection program defining the type, scope and schedule of inspections (Chapter 1.2.4, "Operation of pressure equipment").

Steam sterilizers with an integrated steam generator are equipped with pressure vessels of different categories.

The manufacturer recommends that the following minimum requirements be adhered to.

Recommended inspection intervals:

External inspection

- Sterilizer pressure unit: 2 years (incl. quick acting closure)
- Steam generator pressure unit: 1 year (steam generator components at risk of overheating)
- Sterilization chamber pressure container: 2 years
- Steam generator pressure container: 1 year

Internal inspection

- Pressure container (sterilization chamber): 5 years
- Steam generator: 3 years

Strength test

- Pressure container (sterilization chamber): 10 years
- Steam generator: 9 years

Depending on the operating conditions, the number of cycles may require shorter inspection intervals.

A cycle corresponds to one cycle of a standard MMM program.

For further information, see the pressure container drawing or the acceptance test report as per Annex I of the Pressure Equipment Directive.

Note!

The following tests must be conducted by a qualified specialist.

The following national regulations must be observed for technical qualifications.

External inspection:

What	How	Result of check
Check external condition	▶ Visual inspection: Assess relevant system components for external changes, e.g. corrosion, discoloration due to high temperature, mechanical damage, leaks ,etc. ▶ Compare local displays and remote displays ▶ Function test of closure (if present)	The system parts must be free from external changes. The displays must match.
Check safety-relevant components	▶ Check that they are installed ▶ Visual inspection: Check status for visible faults ▶ Function test	All safety-relevant components must be installed and in functional condition.

Visual inspections of the outside of the machine can be replaced with other suitable equivalent procedures if visual inspection is not possible due to the structure of the pressure vessel or the operating conditions. The pressure vessel or system component is not usually shut down for the inspection.

Internal inspection: after

The operator must consult the manufacturer's documentation to determine the parts under the highest stress for inspection (Chapter 1.2.4, "Operation of pressure equipment").

The vessel must be checked for cracks (e.g. surface cracking, ultrasonic tests) as part of the inspection program specified by the operator with reference to the number of cycles during operation.
Depending on the number of cycles, shorter inspection intervals may be required for the pressure container.

What	How	Result of check
Check pressure-bearing walls	▶ Visual inspection: Visually assess relevant system components. Pressure-bearing walls can be inspected with aids such as mirrors or camera systems. ▶ If damage is suspected, suitable non-destructive test methods can be used, such as color penetration tests to detect surface cracks. ▶ Inspection of cracks at locations under high stress. ▶ If visual inspection is not possible, a water pressure test can be substituted in the area around the tubes.	The system parts must be free from damage. Highly stressed locations must not have any cracks.
Check safety-relevant components	▶ Check that they are installed ▶ Visual inspection: Check status for visible faults ▶ Function test	All safety-relevant components must be installed and in functional condition.
Documents	▶ Check that the system is installed as specified by the information in the inspection documentation.	



See pressure vessel drawing or acceptance inspection report with reference to the relevant number of cycles.

Strength test:

What	How	Result of check
Strength test	Strength tests comprise as a minimum static pressure tests to confirm safety under the approved operating pressure P_B.	The system must not leak under the test pressure and must not show any deformation that could compromise safety.

Note for machines operated in Germany:

The recurring inspections must be performed as per TRBS 1201 Part 2.

7.8 Cleaning

Regularly cleaning the sterilization chamber, the assemblies compartment and the external surfaces prolongs your sterilizer'sservice life.

7.8.1 Chamber interior

The inner chamber walls are manufactured from stainless steel, which is corrosion-resistant to many media and environmental conditions. Regular cleaning is recommended to maintain the chamber's corrosion resistance and durability "Maintenance activities ".

Contamination and dirt accumulations must be removed during regular cleaning. Surface discolourations can also be prevented through regular cleaning.

This cleaning can be carried out by washing out with deionized water and/or using commercially available stainless steel cleaning agents (observe the manufacturer's instructions for use!). Cleaning can be supported with brushes, textiles, nonwoven cloths or abrasive and polishing agents.



When using cleaning agents, always make sure they are suitable for stainless steel!

This applies to both chemical cleaning agents and aids such as cloths and brushes, etc.



Normal steel wool or steel brushes, whose abrasion can cause extraneous rust, and cleaning agents containing halogens (chloride and fluoride ions), i.e. hydrochloric or hydrofluoric acid, must not be used under any circumstances.

All traces of cleaning agents must be removed.

Clean chambers with special surfaces (e.g. ground) as gently as possible to avoid impairing the surface quality.

Local corrosive attacks (e.g. pitting) must be removed through mechanical or chemical processing. Depending on characteristics, such corrosive attacks may affect the safety of the pressure container and must be analyzed separately.

Material damage if corrosion treated incorrectly!

Corrosion must only be treated by suitably trained personnel.

7.8.2 Assemblies compartment

Careful cleaning and disinfection of the assemblies compartment prevents the increased accumulation of micro-organisms which can occur with even moderate levels of dust.

Clean the assemblies compartment every three months with an industrial vacuum cleaner, which must be equipped with a disposable dust bag (paper).

All parts of the system must then be disinfected with a commercially available disinfectant.

7.8.3 External care

To care for the stainless steel front cover, we recommend Ultrapur D steel cleaning agent (MMM Art. No.: 0544308-3921). It is sprayed sparingly onto the metal surfaces or a cloth and distributed in the direction of the grinding surface patterns.

The touch screen can be cleaned with a soft cloth and a gentle cleaning agent or a standard disinfectant.

If this is done with the machine switched on, the touch screen's sensitivity to touch must be temporarily deactivated to prevent unintentionally pressing buttons.



- Open the control menu.
- Press the **Clean touch** button.

The touch screen no longer reacts to inputs for 30 seconds. The time remaining for this function is decremented on the screen.

7.8.4 Cleaning the TW and BW

The following cleaning instructions apply to all MMM transport trolleys (incl. TW HUB and TW HV) and loading trolleys.

The transport trolleys are not suitable for automated reprocessing!

If necessary, clean the transport trolley or loading trolley using cleaning agents specifically intended for stainless steel and plastics.

Clean and disinfect the rollers and platform using a cleaning cloth and suitable surface disinfectant.

Removable parts can be reprocessed in a washer-disinfector.

8 Software Licence Agreement

Please read this licence agreement thoroughly, before using the software.

Please read the terms of this licence agreement (“Licence Agreement”) thoroughly before using the product (as defined in Section 1).

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Section 5 Limitation of liability

To the extent permitted under applicable law, the Licensor shall not be liable for any direct, indirect or consequential loss or damage, including, without limitation, loss of profits, unrealised cost reductions, loss of data or increased costs on the part of the Licensee or any other financial losses resulting from or in connection with the purchase, licensing, use, or failure of the software, or disturbances when operating the software. The foregoing limitation of liability shall also apply in the event that the Licensor has been notified in advance of the possibility of such loss or damage being incurred. The Licensor shall only be liable for loss or damage caused by the Licensor's gross negligence or wilful misconduct. This limitation of liability shall apply to all claims for damages irrespective of their legal grounds, including, without limitation, claims based on tort, contract, pre-contract or quasi-contract. This limitation of liability shall also apply to any officers, directors or employees of the Licensor and any representatives or agents of the Licensor that are involved in the development, marketing or delivery of the software. It is the sole obligation of the Licensee to ensure that it and its employees possess the required knowledge to properly install and/or use the software. The Licensor shall not be liable for problems and defects that arise from insufficient knowledge on the part of the users of the software.

Section 6 Contract period and termination

This licence agreement shall become effective on the date, when the licensee accepts and acknowledges the terms of this licence agreement.

In addition to other rights of cancellation according to this licence agreement, each party is allowed to cancel this licence agreement with immediate effect, if the other party essentially infringes a contractual duty, including but without limitation, delay in payment of the licence fee, provided that the party violating the contract does not correct the infringement within forty-five (45) days upon receipt of a written reminder.

On termination of this licence agreement, all righs of the licensee to use this software will cease. Within thirty (30) days on termination of this licence agreement, the licensee must return the software to the licenser or destroy it and all copies or partial copies the licensee has generated, all modified parts of the software or interfaces to other programs or data systems and - if exist - all safety devices (and confirm the destruction in writing to the licenser).

Section 7 Applicable law and jurisdiction

This contract is governed by German law. Place of jurisdiction for any disagreements resulting from this contract are the regular courts at the primary location of MMM Münchener Medizin Mechanik GmbH in Planegg, Germany. The licenser is also entitled to appeal in their sole discretion the courts concerned at the seat or place of business of the licensee.

MMM Münchener Medizin Mechanik GmbH

9 Warranty (Liability for defects)

MMM is liable for the proper delivery and functionality of this product pursuant to the contractual terms of the delivery contract, the contract for work and materials and the development contract. Please refer to the MMM contractual terms and the terms and conditions of delivery.

MMM assumes no liability for defects or other loss or damage resulting from natural wear, chemical or physical influences, excessive strain, incorrect handling and/or inappropriate or improper use, particularly in case of failure to observe the user manual supplied with the machine or instructions for use attached to the machine, improper installation and/or commissioning by the buyer or third parties, loss or damage caused by foreign objects and improper or faulty maintenance.

If maintenance is not performed at certain intervals as prescribed by the manufacturer or is carried out by persons not authorised by the manufacturer, this also constitutes improper or faulty maintenance. The same applies in case of improper or faulty repairs carried out by persons not authorised by the manufacturer to perform this work.

In order for MMM machines to be connected correctly to on-site supply and discharge lines, the specifications in the MMM planning drawings (including the technical specifications for the order) are binding on the contract partner. The MMM warranty shall be rendered null and void if the subsequent operating conditions of these lines are subject to negative deviations, e.g. if the supply pressure is too low or the quality of the supply medium is insufficient and the machine suffers defects or damage as a result.

The beginning and end of the warranty period is defined in the contractual agreements.

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