MMM Group



Instructions for use

Steam disinfection apparatus

Vacudes PL

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General information

Legend of symbols and hazard warnings

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

- ▶ Handling instruction
- ■ List



Danger

Ignoring hazard warnings may cause injury!

NOTICE

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

EW	Loading trolley	For transporting goods into a sterilizer with floor level loading.
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 instructions before entering the chamber.


Protective ground


Wear protective glasses!


Wear protective gloves!

Device labeling

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

This can be explained by way of an example: Vacudes PL 1501 R

Machine name	Effective volume	Position of the chamber	
Vacudes PL	1501	R	
	The machine size is specified as a rounded value in liters. The last digit indicates whether it is a machine with a loading carriage (0) or a machine with floor level loading (1).	R	Chamber right Panel left
		L	Chamber left Panel right

The steam disinfector **Vacudes PL** is available in the following variants:

Machine designation	Effective interior chamber dimensions [1]	Volume [2]	Capacity [3]
1500/1501 R/L	1200 x 850 x 2370	2400	4 BE 6 units
2000/2001 R/L	1350 x 1100 x 2370	3500	7 BE 9 units
3000/3001 R/L	1750 x 110 x 2350	4600	10 BE 12 units

Machine designation	Effective interior chamber dimensions [1]	Volume [2]	Capacity [3]
	[1] Dimensions in mm (H x W x D)	[2] Chamber volume in liters	[3] Capacity in bed equipment of 0.33 m³ each according to DIN 58949, Part 1 (BE) and in mattresses according to DIN 13014 - M 2000 (units).

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Contents

1 Safety

Carefully read this user manual and keep it for later use.

NOTICE

Observe the safety instructions.

They are there to ensure both your own personal safety and the machine's ability to function.

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 how to use the machine as intended.

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

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

Please contact the manufacturer for more detailed information on your machine.

1.1 Intended use

The Vacudes PL steam disinfection apparatus is suitable for treating the following materials:

Applications in the medical sector (medical devices):

- Solid and porous materials
- Mattresses
- Bed equipment
- Solid items such as urine bottles
- Textiles

Applications in the non-medical sector (non-medical devices):

- Infectious hospital waste (C waste) according to RKI-certified process (optional additional equipment required)

- Solid and porous materials
- Bed equipment
- Clothing / laundry



Danger

The steam disinfector is not suitable for handling:

- **Flammable and explosive items**
- **Liquids in open or sealed bottles and containers**

Service life of the steam disinfector

If the specified maintenance work is regularly performed, the expected service life of the machine is 10 years (under standard usage conditions, see 93/42/EEC Annex I, 4).

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 authorised 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 product in accordance with EU Regulation 2017/745 on Medical Devices.

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

NOTICE

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!

NOTICE

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 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.

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 the installation.

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).

1.2.1 Commissioning - equipment requirements

The steam disinfection apparatus 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

NOTICE

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

EN 61010-1, Section 6.10.2 must be observed 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



Danger

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

1.2.1.2 Media

The media, particularly the 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 assigned steam generator (ED version) or
- via a connection to an external steam supply (FD version).

Requirements for the steam

The 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 connection point to the steam disinfection apparatus.
- 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 steam disinfection apparatus.
- 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
- ProdSG German Product Safety Act
- Accident prevention regulation DGUV Regulation 1
- DIN 58949-6 Disinfection - Steam disinfection apparatus

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 the installation .

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).

Sound emissions

The average A-weighted emission sound pressure level of the device 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 qualified person (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 persons tasked with operating the machine as well as the system supervisor (see Chapter 1.3, "Operators") must be recorded in the compulsorily maintained medical products / equipment log. When changes in staff occur, 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 device.



Danger

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

When using the waste disinfection program as specified by RKI in Germany, the following must be observed:

- The waste must be correctly packaged to guarantee successful disinfection Chapter 2.9.3, "Waste disinfection according to RKI (option)"
- The efficiency of the process for the actual load must be confirmed after installation.
- Regular tests must be performed in accordance with DIN 58 949 Disinfection - Steam disinfection apparatus - Part 3: Efficiency testing.

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.

The following applies to the treatment of medical products (Chapter 1.1, "Intended use"): 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 Vacudes PL II steam disinfection apparatus.

The operator is responsible for performing the validation process (Chapter 1.2.3.1, "Process validation") according to national regulations.

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 disinfection 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 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, 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 T1 P. 12 and KRINKO recommendations) must be observed.

1.2.4 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 disposing of or returning 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).

1.3 Operators

The intended users of this product are trained employees of the facility in which the product is operated for its intended purpose.

NOTICE

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

Untrained persons are not permitted to operate the machine .

Approved operator

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



Danger

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 an employee to be responsible for the machine . The name of this supervisor must be documented (e.g. in the medical products / equipment log).

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

- Technical documentation
- Keys (for the EMERGENCY STOP switch or program, maintenance hatch, control cabinet depending on the machine type)
- The supervisor password (see Chapter 2.4, "User permissions")

The 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.

Only specialists have the level 3 password, which is needed to access the password protected area of the menu-driven controller (e.g., to change parameters) (Chapter 2.4, "User permissions").

1.4 Rules of Conduct during Operation

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 chamber and door become so hot during operation that touching them with a bare hand may cause burns.



Danger

Risk of burns!

Wear gloves to protect your hands and long-sleeved, fastened work clothing when loading and unloading the chamber!

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 Maintenance work

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

1.4.3.1 Working inside the chamber

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



Danger

When working in the chamber (e.g. for cleaning, maintenance, etc.), press the program stop switch and store the key (if present) during the work to prevent unintentional unlocking.

The master switch can also be shut off and locked with a padlock to prevent unauthorized reactivation.

1.4.3.2 Working on the assemblies



Danger

Risk of crushing from the door movement!

When working on the assemblies, turn off the master 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 assemblies compartment is locked. The key is kept by the system supervisor to ensure that only technicians have access to the assemblies.



Danger

Risk of injury!

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

Wear personal protective clothing when working on the assemblies!

1.4.3.3 Working in the electrical control cabinet

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



Danger

Danger due to electric current!

When working on the electrical equipment (e.g. replacing components), turn off the main 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 Automatic program cancellation

In the event of faults which prevent a correct program sequence, the control system cancels the program, e.g. faults with the messages *Pressure transducer controls defective* or *Motor protection switch vacuum pump*.



Danger

The process is regarded as incorrect.

The material to be disinfected must be regarded as not disinfected.

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

1.5.2 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").



Danger

The process is regarded as incorrect.

The material to be disinfected must be regarded as not disinfected.

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

1.5.3 Program stop switch

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



Danger

The process is regarded as incorrect.

The material to be disinfected must be regarded as not disinfected.

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").

1.5.4 Master switch

The master switch is located in the assemblies compartment.

It completely disconnects the machine from the mains.

When carrying out any work on the device (e.g., eliminating faults, maintenance, etc.) or in the event of a hazard, turn off the master switch and secure it with a lock to prevent it from being switched back on unintentionally.



Danger

Keep the key with you when carrying out work to prevent unintentional unlocking.

1.5.5 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.



Danger

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 program is at the *Unloading* process step.

See also see Chapter 4.3.7, "Unloading the chamber ".



Danger

Escape of steam possible!
For your personal protection, stand to the side of the chamber when opening the chamber door.

1.5.6 Monitoring the disinfection parameters

The disinfection parameters (temperature, time) 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 1.5.1, "Automatic program cancellation") is triggered:

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

The message is printed on the cycle record.

1.5.7 Access protection

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

Access to specific menu levels of the machine controller is password-protected. This prevents unauthorised access to process parameters and settings relevant to safety.

Preset authorisation levels with restricted rights are available for daily operation. They can be individually changed with the **user administration** option

1.6 Residual risks of the disinfection process

The parameters relevant to a successful process are constantly monitored by the control system.

Nevertheless, fault-free completion of a program is no guarantee the treated material has been sterilized.

The following influences are not registered by the sterilizer during the program sequence and can therefore constitute a residual risk for the process effectiveness:

- Poor steam quality due to an impermissible high proportion of inert gas in the steam.
- Poor ventilation of the material due to leaks in the chamber or an operating error (e.g. loading instructions have not been observed).
- 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 liquids).

To prevent the risks listed above, the following measures must be considered:

- Make sure that the steam quality meets the requirements(Chapter 1.2.1.2, "Media") .
- Observe the instructions regarding daily use, in particular those for performing the vacuum test and for testing the door seal.
- Observe the guidelines in the national regulations on the treatment of medical products (Chapter 1.2.3.1, "Process validation").
- Only those products that comply with the intended use of the device may be disinfected .
- The machine may only be operated by trained, authorised operators.
- Only trained, authorized operators are permitted to release the cycle on the basis of the cycle record and visual check (no moistness permitted in the load volume).
- 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 effectiveness of the disinfection programs for the load actually used by the user can also be verified by tests with indicators or by a process validation.

1.7 Maintenance and Safety inspection

Regular competent inspection and maintenance 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 persons (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 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 Equipment log

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

Documenting the following in the equipment log is recommended:

- Program specification
- Process parameters
- Amended parameters
- Name of trained operating personnel
- Name of the system supervisor
- Faults
- Maintenance
- Subsequent modifications to the device
- Tests
- Reported incidents

1.9 Standards, regulations and directives

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

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:

Applicable EU directives and EU regulations

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



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 58949-2 Disinfection - Steam disinfection apparatus: Part 2 Requirements
- DIN 58949-3 Disinfection - Steam disinfection apparatus: Part 3 Efficiency testing
- DIN 58949-6 Disinfection - Steam disinfection apparatus: Part 6 Operation of steam disinfection apparatus, their requirements for the installation and their supply sources

Electrical 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.

Safety valve component:

- AD2000 fact sheet, Design and sizing of safety valves

NOTICE

Other standards that are referenced in the aforementioned regulations and may only be applicable in parts are not specifically listed.

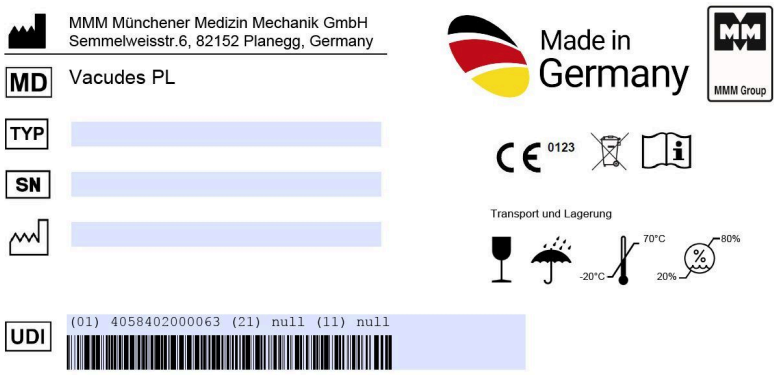
2 Machine description

What follows is a general description of the machine.

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

The type plate is located on the electrical 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
SN Serial number	Fragile, handle with care

 Date of manufacture

 Store in dry place

UDI 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

2.2 Standard equipment

Chamber

The chamber has been calculated, manufactured and tested for a maximum permissible pressure (PS) of at least 0.5 bar and a vacuum of -1 bar and therefore does not fall within the scope of application of the Pressure Equipment Directive.

Closure

Depending on the configuration, the chamber is equipped with one or two sliding door(s) driven by an electric motor. Each sliding door is sealed pressure-tight using a special blow-out seal with compressed air.

The sliding doors open horizontally (H).

Vacuum facility

The machine is equipped with a vacuum facility which enables air extraction during the preliminary phase and vacuum drying.

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.

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

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.

2.3 Optional additional features

The equipment and functions described below are available as options.

2.3.1 Reducing the consumption of media

Standby mode (option)

Standby mode is used to minimise 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.

2.3.2 Optional additional equipment for infectious materials according to RKI

To treat infectious materials, the **Condensate sterilization** software parameter must be enabled and the machine equipped with an additional facility for treating condensate as well as exhaust air

Waste disinfection according to RKI program package (option)

When disinfecting materials that have come into contact with specific, notifiable diseases (e.g. inhalational anthrax, pneumonic plague, pulmonary tuberculosis), the exhaust air and condensate must be post-treated. This is preset in the program parameters of the corresponding program and cannot be changed.

The exhaust air and condensate are also always treated when disinfecting infected waste. This function is preset in the program parameters of the waste disinfection program and cannot be changed.

Condensate treatment ensures that the condensate accumulating in the chamber is disinfected. The condensate is only removed from the chamber after the disinfection process during depressurization.

The exhaust air filter (see exhaust air filter) is also disinfected by steam at process temperature during every RKI process.

Observe Chapter 1.2, "Responsibilities of the operator" and Chapter 2.9.3, "Waste disinfection according to RKI (option)".

2.3.2.1 Exhaust air treatment

Exhaust air filter (option)

Validated sterile filter with an absolute retention rate of 0.2 µm in liquids or 0.003 µm in air/dry gases for filtering the exhaust air from the chamber during the process sequence. Automatic in-line disinfection of the filter during each process cycle through the action of steam at process temperature. Diaphragm filter cartridge of hydrophobic, steam-resistant PTFE.

Vacuum- and pressure-resistant filter housing made of CrNiMo steel, material 1.4404. Removable housing upper part for simple filter exchange.

Combined safety valve/rupture disc (option)

2.3.3 Optional services

Auto start (option)

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) 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 (Option)

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 (option)

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 (option)

Barcodes are used to identify the treated 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.

User identification (option)

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 (option)

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.

2.3.4 Uninterruptible power supply (UPS) (option)

Uninterruptible power supply for the control system. In the event of a power failure, the control system remains active and cycle information is saved. Process-relevant valves are closed during the power failure.

2.4 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
2	Supervisor (name: “s”)	System supervisor	e.g. acknowledging faults, alarm counters, configuration of certain parameters
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).

If the screen is not touched for 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, "Configuration 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 door at the end of the program are recorded in the cycle and are printed on the cycle record .

2.5 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 disinfection
- Course of the pressure and temperature curves over time
- 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.

2.6 Audit trail

Changes to parameters and specific faults are recorded in the audit trail. The audit trail can be viewed via the context menu.

The messages are sorted by date and can be scrolled through with the arrow keys.

Tap a message to view a more detailed description in the comment section at the bottom of the screen.



	Zeit	Prozess	ID
17	Wed Jul 31 14:10:33 2013	guipnmgr	[0,1]
16	Wed Jul 31 14:07:47 2013	guipnmgr	[0,1]
15	Wed Jul 31 13:21:17 2013	bddistri	[42,1]
14	Wed Jul 31 13:21:17 2013	bdcreatr	[43,2]
13	Wed Jul 31 13:00:56 2013	bdcreatr	[43,1]
12	Wed Jul 31 11:57:29 2013	param	[3,4]
11	Wed Jul 31 11:57:25 2013	guipnmgr	[0,1]
10	Wed Jul 31 11:53:48 2013	bddistri	[42,1]
9	Wed Jul 31 11:53:48 2013	bdcreatr	[43,2]
8	Wed Jul 31 11:34:10 2013	bdcreatr	[43,1]

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.

NOTICE

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 disinfection time and temperature has been assigned.

NOTICE

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 temperatures, the lowest temperature is selected.
- A newly scanned barcode is checked to see whether a program with the same temperature but different holding time has already been scanned. If this is the case, the new barcode is rejected. This means that all programs with the same temperature have to have the same holding 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 disinfection times are scanned, the program with the longest disinfection time is selected. However, all of the scanned barcodes must have the same disinfection temperature.

2.8 Disinfection process

According to the state of the art, the “pulsed vacuum process” is the most reliable method for disinfecting porous materials.

Crucial for successful disinfection and thus ensuring that all germs are killed, is the complete extraction of air from the disinfection chamber and especially from the disinfection material, as the presence of non-condensible gases will significantly impede the disinfection effect.

The most economical use of the disinfector and the best prerequisite for successful disinfection is to fully load the chamber. Any partial load should fill at least 15% of the chamber volume.



Danger

If the chamber is not loaded as described, this may endanger the patient and/or the operating personnel. For example, if unsuitable materials are loaded into the chamber (e.g. containers holding larger volumes of liquids), this may cause boiling retardation within the chamber.

2.9 Process description

The steam disinfection apparatus is factory-configured with the processes described as examples in the following.

The programs defined and set with the operator on commissioning are displayed in the program selection menu. A maximum of 13 programs can be activated simultaneously.

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").

NOTICE

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

Field of action

The A, B and C fields of action specified in the following correspond to the definition according to DIN 58949 or the “list of disinfectants and disinfection procedures tested and approved by the Robert Koch Institute”.

Field of action A: for killing vegetative bacterial micro-organisms, including mycobacteria, fungi and fungal spores.

Field of action B: for the inactivation of viruses

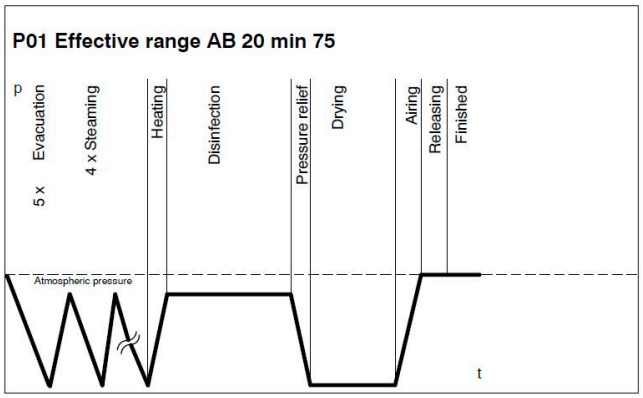
Field of action C: for killing anthrax pathogen.

2.9.1 Disinfection programs with effective range A, B and C

P01 Effective range AB 20 min 75

Disinfection program with effective range of action AB (excluding hepatitis) for temperature-resistant bed equipment according to the pulsed steam disinfection program.

- Disinfection temperature: 75°C
- Disinfection time: 20 min



- Pulsed evacuation of the chamber (5x) with interim steam surges (4x) for air removal and steam penetration
- Heating phase up to disinfection setpoint pressure
- Disinfection for a specific time at a specific temperature.

- Chamber pressure relief
- Drying of the material through evacuation of the chamber for a specific time.
- Chamber aeration to atmospheric pressure
- Release of the door seal

P02 Effective range AB + HEPA 105

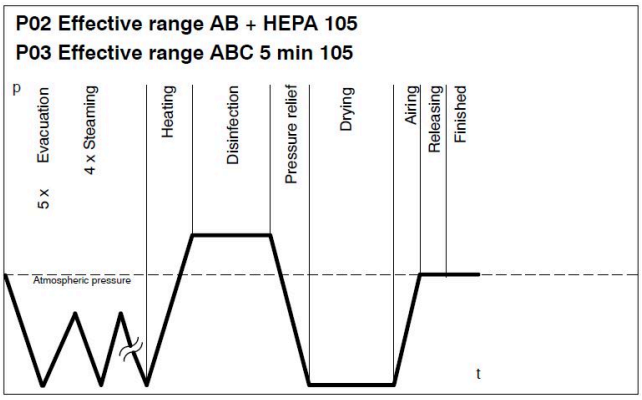
Disinfection program with effective range of action AB (including hepatitis) for temperature-resistant bed equipment according to the pulsed steam disinfection process.

- Disinfection temperature: 105°C
- Disinfection time: 1 min

P03 Effective range ABC 5 min 105

Disinfection program with effective range of action ABC* for temperature-resistant bed equipment according to the pulsed steam disinfection process.

- Disinfection temperature: 105°C
- Disinfection time: 5 min



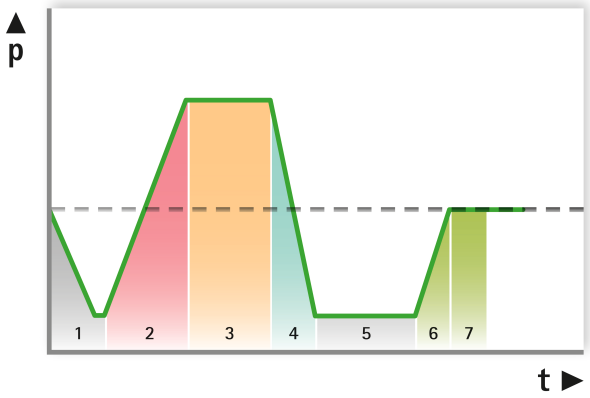
- Pulsed evacuation of the chamber (5x) with interim steam surges (4x) for air removal and steam penetration
- Heating phase up to disinfection setpoint pressure
- Disinfection for a specific time at a specific temperature.
- Chamber pressure relief
- Drying of the material through evacuation of the chamber for a specific time.
- Chamber aeration to atmospheric pressure
- Release of the door seal

2.9.2 Solid materials

P04 Solid good 1 min 105

Disinfection program with field of action AB (including hepatitis) for solid materials such as bed pans, urine bottles, etc. according to the pre-vacuum steam disinfection process.

- Disinfection temperature: 105°C
- Disinfection time: 5 min: 1 min



2.9.3 Waste disinfection according to RKI (option)

P05 Waste RKI

NOTICE

If the machine is located in a bedding department and is additionally used for treating C waste, take note of the specific circumstances and risks.
The operator must define corresponding written instructions in a standard operating procedure (SOP) for handling waste.

Steam disinfection program set as default according to the pulsed vacuum process with additional steaming prior to evacuation to open the packaging. An exhaust air filter (option) must be installed to use the RKI waste disinfection program.

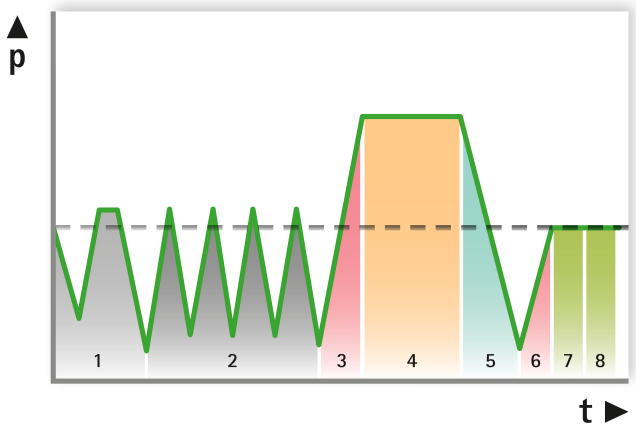
Program run time: 50 - 60 min

Exposure time: 30 min

Exposure temperature: 105°C

The program sequence is carried out as in the steam disinfection process tested and approved by the Robert Koch Institute (RKI) for ABC use (including hepatitis) (see list of disinfectants and disinfection processes tested and approved by the RKI) for infectious hospital waste (C waste).

To avoid possible odor pollution due to the material, the sterilization chamber is blown through for two minutes in the end program phase after pressing the “Open door” button. The door then opens automatically.



1. Evacuation and flow
2. Evacuation and steaming
3. Heating
4. Disinfection
5. Pressure relief
6. Aeration
7. Pressure equalization
8. Release of the door seal

Once the waste disinfection program is complete, only the door on the loading side can be opened.

Handling of waste for disinfection

Steam access to the material to be treated must be guaranteed for successful disinfection. This applied for all microbially contaminated cavities in the objects to be disinfected (e.g. bottles).

The relevant regulations must be observed when collecting and transporting the waste prior to disinfection.

What must not be placed in the disposal containers / sacks (examples):

- Toxic substances, medications, aerosol cans
- Large quantities of residual fluids which are no longer absorbed by the other contents

NOTICE

The total volume of liquid per container or bottle must not exceed 0.5 liters. If this quantity of liquid is located within just one container, that container must have a volume of at least 1 liter.

- Flammable liquids, acids, lyes, unknown liquids
- Empty, sealed bottles
- Full bottles
- In sacks, pointed or sharp objects without protective sleeve

Danger

The process is not suitable for wet waste.

Periodic tests

When using the waste steam disinfection as specified by the RKI, periodic testing in accordance with DIN 58949-3 must be performed Chapter 7.6, "Periodic inspections of RKI waste program").

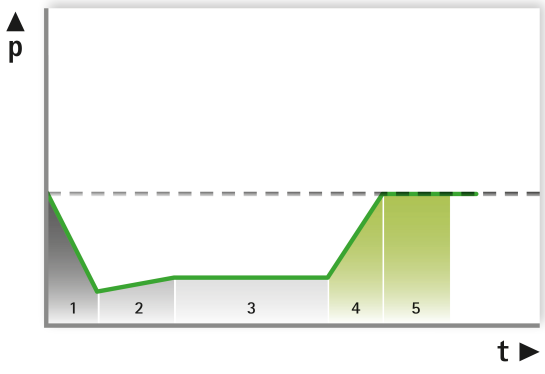
2.9.4 Vacuum test

No disinfection 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 disinfection 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.

Prior to further use, the machine must be checked by a qualified person (preferably MMM customer service) and repaired if necessary. The vacuum test must then be repeated.

2.9.5 Rack hatch

P09 Pass through

Additional program for two-door devices.

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

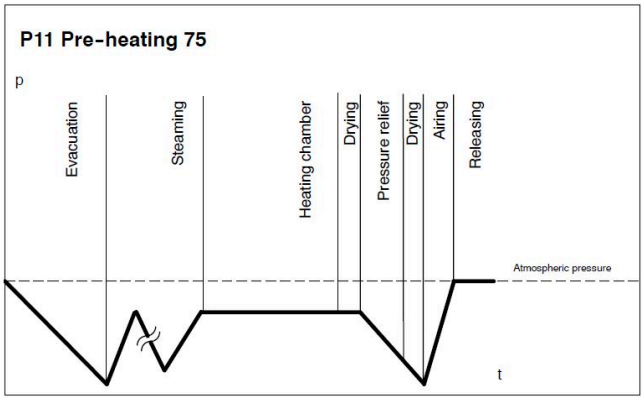
This program can also be used for service purposes (e.g. for cleaning the chamber).

2.9.6 Heating programs

P11 Heating 75

Program for pre-heating the chamber to 75°C.

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

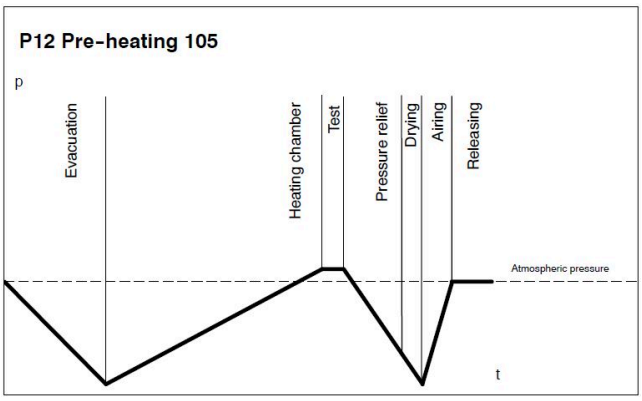


- Evacuation
- Steam through
- Heating the chamber
- Drying
- Release
- Drying
- Aeration
- Release

P12 Heating 105

Program for pre-heating the chamber to 105°C.

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



- Evacuation
- Heating the chamber
- Test
- Depressurise
- Drying
- Aeration
- Release

2.9.7 RKI programs

P13 Effective range AB RKI 75 (option)

Disinfection program for decontamination as per Section 18 IfSG with effective range of action AB for temperature-resistant bed equipment according to the pulsed steam disinfection method.

- Disinfection temperature: 75°C
- Disinfection time: 20 min

P14 Effective range AB + HEPA RKI 105 (option)

Disinfection program for decontamination as per Section 18 IfSG with effective range of action AB (including HEPA) for temperature-resistant bed equipment according to the pulsed steam disinfection method.

- Disinfection temperature: 105°C
- Disinfection time: 1 min

P15 Effective range ABC RKI 105 (option)

Disinfection program for decontamination as per Section 18 IfSG with effective range of action AB for temperature-resistant bed equipment according to the pulsed steam disinfection method.

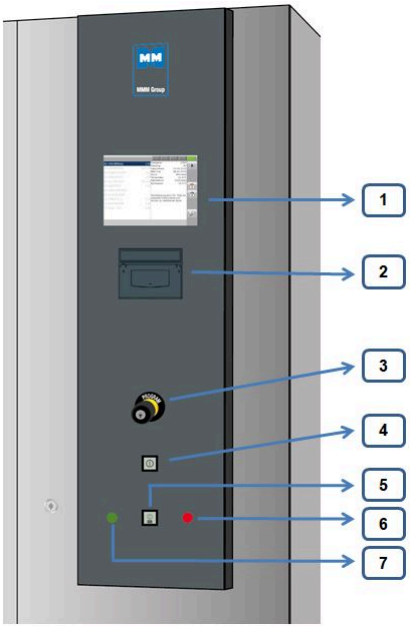
- Disinfection temperature: 105°C
- Disinfection time: 5 min

3 Display and control elements

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

Loading side



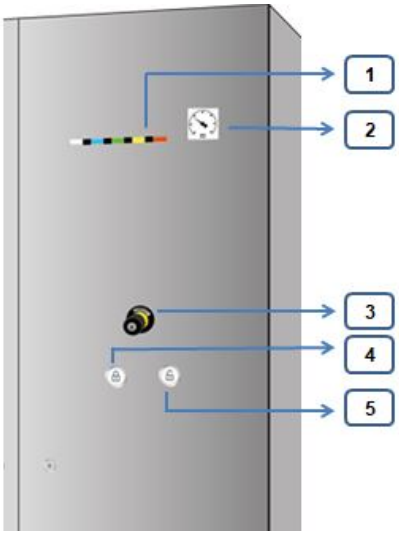


1. Color touch display
2. Thermal plotter (option)
3. Program stop switch
4. Steam disinfection apparatus mains switch
5. Electric steam generator mains switch (option)
6. Red indicator lamp *Steam generator fault* (option)
7. Green indicator lamp *Steam generator in operation* (option)

Unloading side

Control element on the unloading side of two-door machines



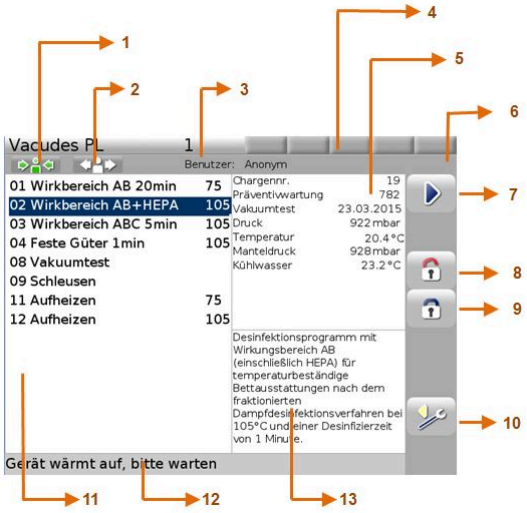


1. Indicator lamps
2. Chamber pressure measurement device
3. Program stop
4. Door open
5. Door closed

3.1 Color touch screen

The machine is equipped with a color touch screen. Pressing the buttons and screen 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. 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 on 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 50
7		Start	Starts the selected program.
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
		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.

3.2 Acknowledgement button



The acknowledgment buttonsmust be pressed within a certain time after the close door button has been pressed.

They are located on the other side of the chamber door in relation to the control panel. Before closing the chamber door, the user is therefore compelled to look into the chamber and ensure that there is no one inside the chamber.

The two acknowledgement buttons, which are located one above the other, must be pressed with both hands during the entire door-closure process (two-hand principle) to prevent crushing.

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	-

3.4 Pressure gauge display

The steam disinfection apparatus is fitted with the following pressure measurement equipment:

- Steam supply: the pressure gauge displays the steam pressure in the steam supply line.
- Jacket: the pressure gauge displays the steam pressure in the annular duct jacket.
- Chamber: the pressure gauge is located on the unloading side and displays the pressure in the chamber.
- Pneumatic system compressed air: the pressure gauges are located on the air pressure reducers in the assemblies compartment and display the air pressure in the line to the control cabinet.

4 Operation

Observe the safety instructions in Chapter 1, “Safety”.

NOTICE

All activities described below must only be carried out by suitably trained persons.

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 Administration** (Chapter 2.4, "User permissions") option is used, operator log-in can be configured so that each operator has to log in with his name and password.

User log-in



- Press the log-in button.

The log-in window appears.

- Touch the “Name” entry field. The alphanumerical input block appears.
- Enter the corresponding user name (e.g. “S” for supervisor).
- Confirm the entry with the tick button.
- Touch the “Password” entry field. The alphanumerical or numerical input block appears.
- Enter the corresponding password.
- Confirm the entry with the tick button.
- 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 a user does not log out actively, this occurs automatically within the set time limit if no button on the touch screen 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 steam disinfection apparatus each day:

- Perform the prescribed maintenance tasks (Chapter 7, "Maintenance").
- Press the mains switch

Once the device has been switched on, the program selection menu will appear with the message *Device is ready for operation*.

If equipped with an associated steam generator:

- Press the electric steam generator mains switch

NOTICE

Observe the steam generator user manual.

When using vacuum programs :

- Start the vacuum test
- Start the heating program

The device is now ready for operation.

When using the autostart:

If the **autostart** function is activated Chapter 5.5, "Activating auto start (option)", the steam disinfection apparatus 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.

4.2.1 Vacuum test

The vacuum test is 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 equipment log .

4.2.2 Heating program

The chamber and jacket must be heated before a disinfection program can be started.



- Depending on the temperature of the subsequent program, select the **Heating 75 °C** program or **Heating 105°C**



- Press the start button.



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

The program selection menu then appears.

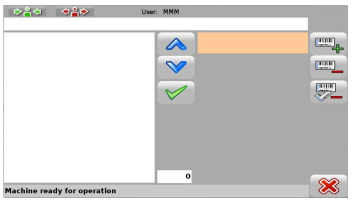
4.3 Disinfection mode

4.3.1 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

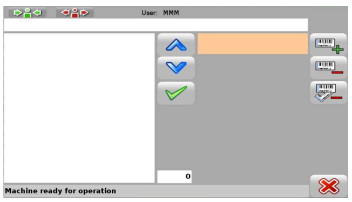
If scanning with the handscanner fails and the barcode does not appear in the list (e.g. because the barcode is dirty), the barcodes can be entered manually).



- 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

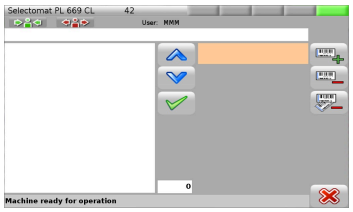
Individual or multiple barcodes that have already been scanned can be deleted.



- 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.

4.3.2 Loading instructions

This machine has, depending on the size of the chamber, capacity for 4, 7 or 10 pieces of bed equipment (see “Machine information”).

According to DIN 58949-1, bed equipment (Bettausstattung - BA) consists of a mattress, a pillow and a duvet.

The capacity is defined in DIN 58949-2 (Annex A). The capacity is calculated by dividing the usable volume (m³) of the chamber (see “Machine information”) by 0.33 (m³).

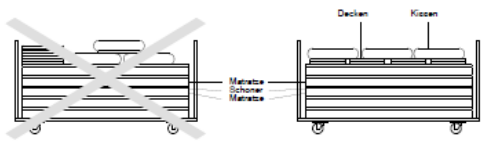
Observe the following instructions

Mattresses, blankets, pillows and covers can be stacked on top of one another, but piles of blankets must be avoided.

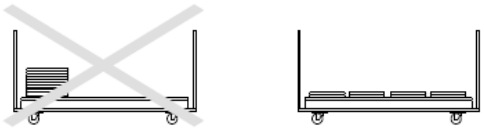
If no covers are available, mattresses covered with a sheet may be stacked on top of one another without an intermediate layer. Polyether foam mattresses that are not covered with a sheet may be stacked on top of one another without an intermediate layer. Steam penetration is hindered.

Correct and incorrect loading of the loading trolley

(Examples for machine sizes 2001 and above)



Full load



Partial load

4.3.3 Loading the chamber

Floor-level, passable machines are loaded and unloaded using trolleys.

To ensure successful disinfection, we recommend loading the chamber with the loading configuration defined during process validation.



- Open the door on the loading side

- Push the loading trolley into the chamber.



- Press the door-closure button on the loading side

The yellow indicator lamp flashes.



- Press both acknowledge keys at the same time (two-hand principle) and continue holding them pressed in during the door-closure process.

Waiting times

A program with a lower temperature must not be used immediately on completion of another program, as the chamber would be too hot for this program sequence.

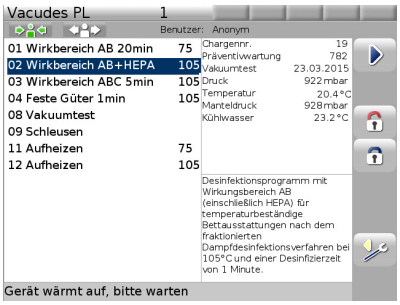
After selecting a corresponding program, the following waiting times therefore apply to cooling because of this (reference values with the chamber door open):

- 105°C → 75°C: 30 minutes

Appropriately, the operating sequence must be structured accordingly.

4.3.4 Program selection and program start

Program selection



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

Danger

Note the information displayed about the program.

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

Program start

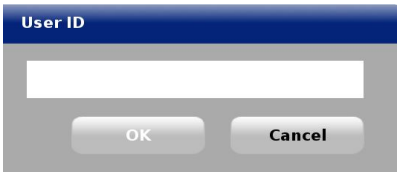


- Press the start button and if necessary enter the user ID (see below).

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.



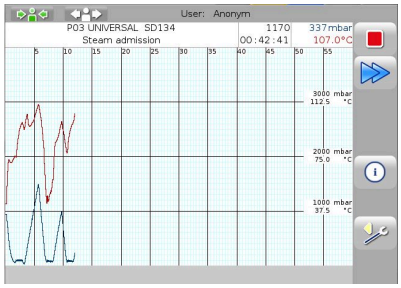
- Touch the entry field so that the alphanumerical input block appears.
- Enter your user ID manually and confirm it with the tick.
- Confirm the process with OK.

The program then starts.

Program sequence

During the program sequence, the on-line process flow chart appears. The pressure and temperature 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.

4.3.5 Cancelling the program

If a program has been accidentally started that must not be used for the material to be treated, the “Cancel program” should be pressed to prevent any damage to the material 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 door on the loading side can be opened.

4.3.6 Program end

On two-door machines, once a disinfection program has completed successfully, 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 closed again.

Once the programs **Vacuum test** and **Heating** have completed and after the **waste disinfection program** or a failed program have finished, only the door on the loading side can be opened on completion of the program.

4.3.7 Unloading the chamber

The disinfection chamber is unloaded manually.



- Open the door on the unloading side.



Danger

Escape of steam possible!

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



Danger

Risk of burns!

Wear suitable protective equipment when unloading the chamber.

- Pull the loading trolley out of the chamber.



- 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)



Danger

If it is necessary to enter the chamber, first press the program stop button and keep the key (if present) with you.

4.3.8 Passing through

The delivery program for redelivering empty loading trolleys 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.

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

- Check that the program selection corresponds to the prepared goods.
- 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.

NOTICE

Identify released goods so that they can be differentiated from goods that have not been released, or ensure a clear differentiation by organisational 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.

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.



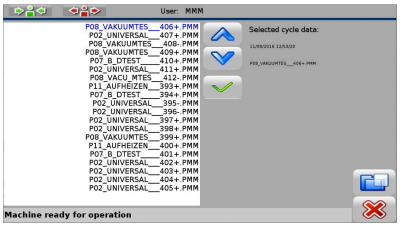
- Press the *Tool selection* button.



- 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.

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.



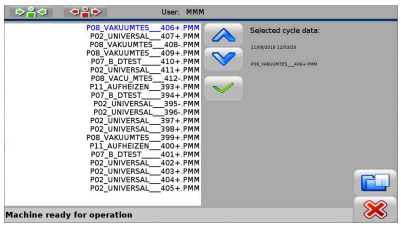
- Log in as the supervisor.



- 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

The device is switched off using the mains switch. In normal operation, the master switch remains switched on.

- Press the mains switch

NOTICE

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.

5.1 Configuration User Manager (option)

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

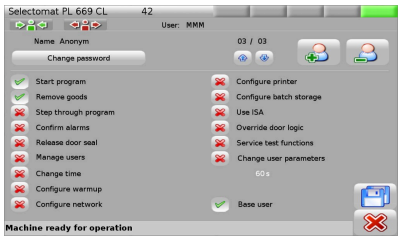
The User Manager needs to be activated by a specialist via a USB stick.

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.

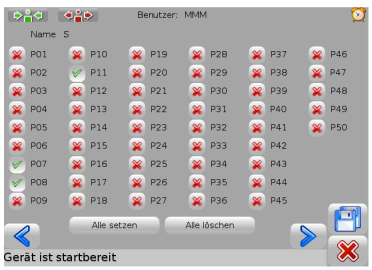
The program selection per user is defined as follows:



- 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

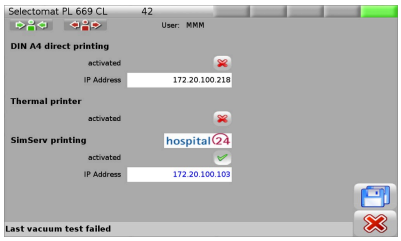
Depending on the model, one or more of the following options for printing and saving the data of the cycle record will be available.

- 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.

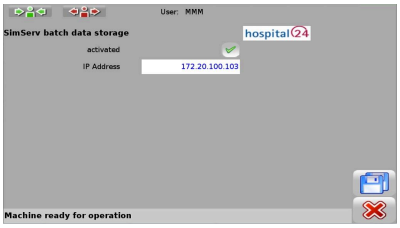
Printing via PC

- *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.

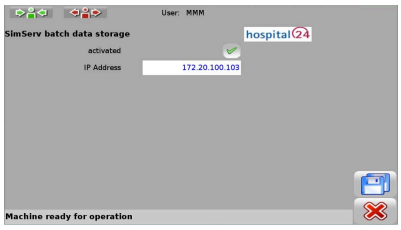
The following results may be displayed:

- *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.

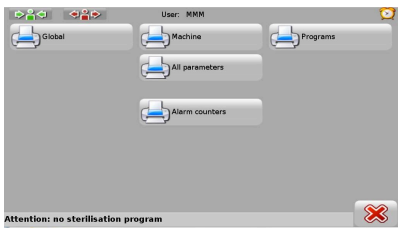


▶ Open the control menu on the loading side.

▶ 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.

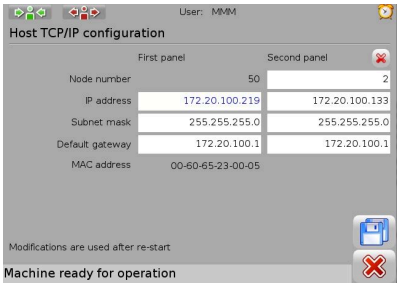
On two-door machines with a control panel on the loading and unloading sides, the first (master) panel and the second (slave) panel communicate with each other over a network. The IP address of the second panel must be input into the first panel to enable communications between the two panels.

NOTICE

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.

NOTICE

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)

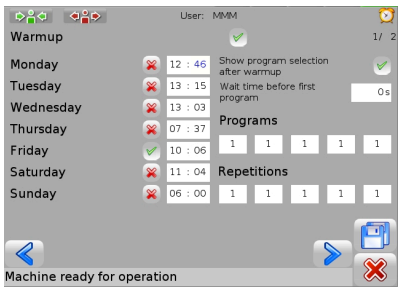
With the **auto start** function, the device starts a configurable sequence of programs automatically. The start time can be individually configured for every day of the week.

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.



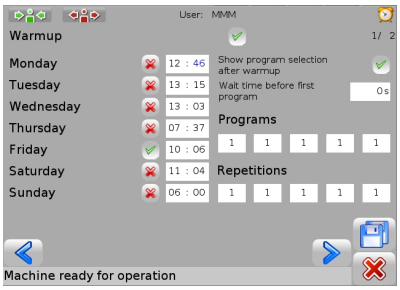
Because the machine must not be shut off if **auto start** is enabled, this function should be combined with the **standby mode** function.

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
- 75°C or 105°C Heating



- 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

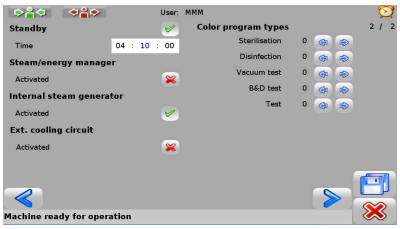
The time after which standby mode is activated can be configured to suit the operating sequence being used.



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



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



- Enable the **Standby mode** parameter.
- Touch 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.



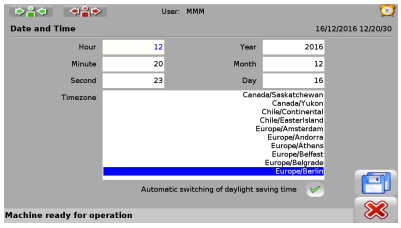
- Save the entry.

5.7 Setting the time

The supervisor can set the time. However, for safety reasons the date cannot be changed.



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



- Enter the current time.
- If this is wanted, set the green tick at **Automatic switch between daylight saving and standard time**.
- Save the entry.

5.8 Calibration screen

Calibration may be necessary if the operation fields 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 (Chapter 1.1, "Intended use").

If a fault occurs, the program is canceled and the machine enters a safe state. 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.

NOTICE

Observe the instructions in see Chapter 1, "Safety"

If the fault cannot be eliminated by a qualified person, contact the MMM customer service or a person or company 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 was pressed

NOTICE

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



Danger

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

The disinfection material must be considered not disinfected.

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

- 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.

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.



Danger

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.

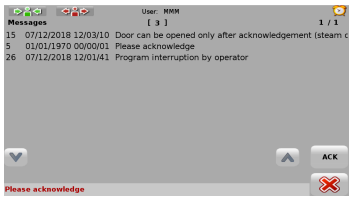
6.2 Acknowledging messages

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:



Danger

Risk of injury!
The chamber doors must not be opened by force!

Door seal not released sufficiently

The release 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 releasedfor a specific, previously set time.



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

If, due to a defect, the door seal repeatedly cannot be released 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.

Door on unloading side not released

In the case of non-disinfection programs or unsuccessful programs, only the loading side is released.

▶ Restart the disinfection program from the loading side.

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 program stop was pressed. The *Program stop actuated* message appears.

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.

6.5 Manual advance

The program can be manually advanced for test purposes.

NOTICE

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").

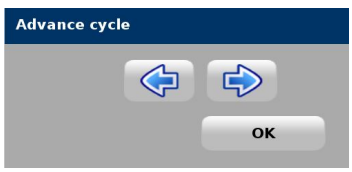
- If necessary, touch the screen to switch to the *On-line process flow chart* view.



- 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.



Danger

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.



Danger

The process is regarded as failed!

The material to be disinfected must be regarded as not disinfected.

NOTICE

Run an empty cycle prior to further operation.

6.6 Fault in the cooling circuit vacuum pump

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:



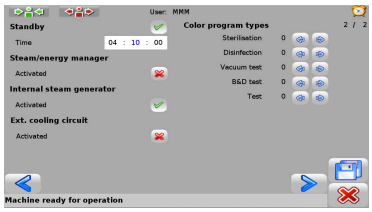
- Open the Control menu.



- Press the **Autostart** button.



- 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
- **To switch to cold water:** Manually move the levers of the three-way ball valves and the lever of the two-way ball valve into the **vertical** position.

  To switch to external cooling circuit: Manually move the levers of the three-way ball valves and the lever of the two-way ball valve 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.

NOTICE

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 "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.

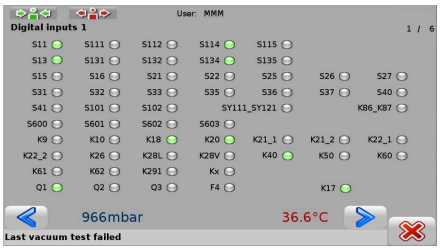


▶ Open the **Control menu**.



▶ Press the **Hardware** button.

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



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.

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 (on the loading side only)
- Cold water valve of the vacuum pump (on the loading side only)



On the loading side:

- Press the **Service** button in the **control menu**.
- Use the blue arrow button to move to screen 2.

Lamps function check



- 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

This function can only be tested on the loading side.



- Press the **Pump** 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.

6.8 Status and alarm messages

All messages are listed in the following with information on the trigger, the machine's reaction and instructions for the user. 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						
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

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
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
16	Press acknowledgement key	The acknowledge key 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
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

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
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
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	Disinfection temperature too high	x	x	x	x	x	x			x	x	Contact customer service
39	Sterilization temperature too low	Disinfection 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 disinfection 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	Disinfection 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	Disinfection 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, disinfection 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, disinfection effect not guaranteed
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

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
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
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 Not relevant for Vacudes
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
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

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
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
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									

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
102	Local storage failed	Saving of cycle to USB stick failed	x	x			x				x	x	Contact customer service
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-disinfection program is active		x									
109	Check loading door	The limit switches of the loading door switch inconsistently	x	x			x					x	Contact customer service
110	Check unloading door	The limit switches of the unloading door switch inconsistently	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	
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

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
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
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

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
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
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	
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	

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
162	Waiting for start of H_2O_2 generator	Waiting for start of gassing		x									
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
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

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
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 uninterruptible power supply (UPS) is active	x	x	x	x	x				x	x	
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

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
193	Preventive maintenance overdue	Preventive maintenance is overdue	x	x	x								Arrange appointment for preventative maintenance with customer service
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.
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	

No.	Message	Trigger	RL	A	T	Z	SV	P mT	P oT	K dm	AT	Q	Note for operators
221	Rupture disc defective	Rupture disc actuated	x	x			x				x		Contact MMM customer service!
222	Chamber cleaning not ready	The chamber cleaning hardware is being used by another machine		x			x	x					Check the mixing tank or canister, if necessary replace the canister
223	Dosing of cleaning chemical unsuccessful	Mixing tank full, canister empty, or maximum dosing time exceeded	x	x			x				x		Check the mixing tank or canister, if necessary replace the canister
224	Filing of mixing tank unsuccessful	Mixing tank was not filled	x	x			x				x		Check deionized water supply
225	Fault during circulation (cleaning)	Fault during circulation	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		Check pressure switch, circulation pump, and connected hardware. Contact customer service!
227	Chamber cannot be rinsed	Fault during circulation	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		Check the mixing tank outlet Contact customer service!
229	Chamber cleaning canceled	Fault during the program	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
231	Cleaning canister empty, please replace canister	An empty cleaning canister has been detected via the suction lance.	x	x			x	x			x	x	Exchange canister
232	Cleaning canister empty, please replace canister	Cleaning cycle counter has decreased to 0		x							x		Exchange canister
233	Cleaning dose incomplete	The cleaning canister became empty during dosing		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	

7 Maintenance

NOTICE

Observe the safety instructions in Chapter 1!

An inspection and safety maintenance (interval-based maintenance & inspection) must be performed at least once a year.

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

Preventative inspection and maintenance (preventative maintenance) must be performed after 600 batches or after at least one year.

The machine is equipped with a cycle- and preventative maintenance counter as standard.The current counter reading 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.



Danger

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.

Vacuum pump

NOTICE

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).

7.2 Planning service work

At regular intervals, 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.

The following service work messages are displayed:

- Preventive maintenance (batch-controlled)
- Interval-based maintenance & inspection (time-controlled)
- Calibration/adjustment (time-controlled)
- Revalidation/requalification (time-controlled).

Additional informational messages are shown on the display and printed on the batch record.

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 button **Service works**

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.

NOTICE

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

Daily:

What	How	Result of check
Check door seals	The seal is automatically tested for vacuum tightness by the vacuum test program.	Beware of steam emissions! In the event of a leak, i.e. when steam escapes from the door area, replace the seal (Chapter 7.4, "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 7.7.1, "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 12 months or 1500 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 1500 cycles. Technical data subject to change without notice.

NOTICE

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
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: Designation of door position switches on the unloading side:	The message: 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	The following valves must close: Switch value: 1.8 bar ±0.2

What	How	Control result / activity
Check pressure monitor for pressure container depressurized message	Door release function check. Door release only if report *Chamber depressurized*. When operational: ▶ Disconnect sensor connector Door movement not possible. **Checking the setpoint:** ▶ Start any program.	The display status of digital inputs changes. When overpressure (0.1 bar) is reached, the digital input indicators turn off.
Check function of the locking relay for vacuum/ solution changeover ■	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.
Check function of the temperature limit value sensor	Limit value sensor : 82 °C ▶ Select solution program ▶ Disconnect sensors	Door movement not possible
Check pilot valves	Check safety shut-off of media valves to the chamber when door end switch reports “Door open”. During the program sequence: ▶ Manually actuate roller lever	The following valves must close: For bulkhead option also
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: When operational: ▶ Open service door	The message, *Maintenance door loading side open* or *Maintenance door unloading side open* appears.

7.3.2 Other function checks and maintenance measures

What	How	Control result / activity
Chamber	Visually inspect the disinfection 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.	

What	How	Control result / activity
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 pressure switch B20 and adjust if necessary.	
Absolute pressure transducer	Check absolute pressure transducer	
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).	
Vacuum pump	Check the vacuum pump power. Check the pipe compensators on the vacuum pump for damage and crack formation.	
Temperature measuring facility	Check temperature measuring facility	
Door drive	Check the door drive(s), toothed belts and motors.	
Check program stop function	When operational: ▶ Press program stop ▶ Press Open door or Close door button	Door movement not possible. Reset with key.
Exhaust air filter between pressure vessel and vacuum pump Replace filter insert (if present)	The filter inserts must be replaced at the latest when the cycle time is consistently 50% longer for the same initial conditions. Unusual disinfection materials, for example dust-forming materials, can cause increased filter soiling or clogging. Replacing the exhaust air filter ■ Switch off the machine ■ Make sure that the chamber is depressurized ■ Release the filter housing clamping ring and remove the housing upper part ■ Replace the filter cartridge ■ Check the O-ring and replace if damaged ■ Place the housing upper part back on the body and tighten the clamping ring ■ Switch on the machine and start the vacuum test program to check for leaks.	 **The filter housing must be depressurized.** To ensure reliable filtration, use only genuine filter inserts.
Filter mats	Replace the filter mats in the aeration filter	
Circulation pump	Check circulation pump function	
Solenoid and automatic valves	Check solenoid and automatic valves for leaks and function, and replace if necessary.	
Steam distributor locking plates	Check the function of the steam distributor locking plate and repair if necessary	

What	How	Control result / activity
Signal column and indicator lamps (if present)	Check the function of the indicator lamps	
Loading trolley Clean rollers	Clean the steering and fixed castors of the loading trolleys, and check they are sufficiently lubricated.	Recommended lubricant: Klübersynth VH1 64-1302 (MMM article no. 0634570)
Cycle counter	Read the number of cycles from the screen and enter the status in the assembly report and equipment log.	

7.4 Replacing the door seal

If the door seal is severely deformed or defective, a new seal must be inserted.

NOTICE

The door seal must only be exchanged by qualified persons (Chapter 1.3, "Operators").

Danger

Switch the machine off and allow it to cool sufficiently, as there is otherwise a risk of burn injuries on the hot seal groove.

- Open the door completely.
- Release the old seal from the compressed air connection and remove it.
- Insert the new seal into the groove.
- Guide the valve for the compressed air into the corresponding hole, and re-establish the connection to the compressed air.

A requalification must then be performed as per DIN EN ISO 17665 T1, P.12.5.

7.5 Thermal printer paper exchange (option)

Use thermal paper 112 x 46 x 12, which can be archived for up to 10 years.

For unproblematic 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.



- 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.

Example images only

7.6 Periodic inspections of RKI waste program

When using of the waste disinfection program as specified by RKI (option) the operator is responsible for ensuring that the periodic inspections are conducted.

DIN 58949-3 (Chapter 7 Scope of testing, Table 2), which defines the nature and scope of tests, applies for devices installed and operated in Germany.

- **Twice a year:**
  Microbiological test with “cavity” test load complete with bioindicators. The check must be performed after maintenance or inspection.
- **Annually:**
  Thermoelectric test

7.7 Cleaning

Regularly cleaning the disinfection chamber, the assemblies compartment and the external surfaces prolongs your steam disinfection apparatus'service life.

7.7.1 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.

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 deionised water and/ or using commercially available stainless steel cleaning agents (observe the manufacturer's instructions for use!). Cleaning can be supported with brushes, textiles, non-woven cloths or abrasive and polishing agents.

NOTICE

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.

NOTICE

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 disinfection chamber and must be analyzed separately.



Danger

Only accordingly trained personnel may treat corrosion.

7.7.2 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.

7.7.3 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.

8 Software Licence Agreement

Please read this licence agreement thoroughly, before using the software.

NOTICE

Please read the terms of this licence agreement (“Licence Agreement”) thoroughly before using the product (as defined in Section 1).

The product includes software which is licensed to you by MMM Münchener Medizin Mechanik GmbH for use only in the manner stipulated below. You must not install or use the software unless you have read and agreed to the contractual terms contained herein. By proceeding with the installation or use of the software or any part thereof, you shall be deemed to have agreed to all the contractual terms of the licence, the warranty, the limitation of liability and the other terms of this Licence Agreement.

You must not use the software if you do not agree to the terms of this Licence Agreement. If that is the case, you must inform MMM Münchener Medizin Mechanik GmbH and return the unused software and the accompanying documentation within ten (10) days of purchase.

Section 1 Definition

“**Patches**” shall mean the removal of program errors (bugs) or faulty functions of the software or of the corresponding software code.

“**Product**” shall refer to (a) one or more machines of this series or other machines that you may have bought for use with the software from MMM Münchener Medizin Mechanik GmbH or (b) the software itself if you have only purchased the software.

“**Purchase Agreement**” shall refer to the purchase order, agreement, or any other document on the basis of which you purchased the product.

“**Software**” shall refer to the software developed by MMM Münchener Medizin Mechanik GmbH and the accompanying documentation (in electronic or paper form), which is either (a) delivered on a data carrier or (b) preloaded on the product (unless the product is the software itself).

“**Specification of Services**” shall refer to the functionality of the software and the auxiliary functions, if any, as described in the product description provided by MMM in either electronic or paper format in connection with the software.

“**Defined Computer System**” shall refer to the electronic data processing (EDP) environment defined in the product description that is required for the software to function correctly.

“**Updates**” shall mean software that corrects faults in an older version of the software or that, without implying any obligation under this contract to do so, enhances the functionality of the software by providing additional functions or any other increases in performance.

Section 2 Scope of the licence

MMM Münchener Medizin Mechanik GmbH, Semmelweisstr. 6, 82152 Planegg, Germany (hereinafter called either “licenser” or “MMM”) herewith grants to user (herinafter called “licensee”) - subject to the settlement of the corresponding licence fee and continuous compliance with the provisions of this agreement - the non-exclusive, non-negotiable and nottransferable right to use one (1) copy of the software in a manner as described below, as far as the purchase agreement does not stipulate otherwise. The use of the software for a purpose other than stipulated in this agreement is not permitted.

The afore-mentioned licence agreement is restricted as follows: (a) the software shall be used in the authorised number of users and in machine-readable form only; (b) the software must be installed, saved and executed as a whole or in parts only on the defined computer system in compliance with the instructions for installation of the licenser; and (c) it is allowed to create one (1) copy of the software for securing and archiving purposes exclusively, provided that this copy is marked with comprehensive copy right annotations including all additional notes to the rights of the licenser of the software and with the indication of the original version. If the software is an update or an additional module for a system, machine or equipment, that is already licenced, the licensee is authorised to make only as many copies as this has been approved by the licenser

Provided that the following restrictions are legally acceptable, the licensee is allowed to use the software only in such a way, as it is allowed according to the licence agreement described above; the licenser is not allowed (a) to modify the software or parts of the software in any way whatsoever (including, but without limitation by modifying, adapting, translating or secSoftware Licence Agreement REV1.0 / 2014-09 45 / 49 ond-hand version), (b) to decompile the software or parts of the software, (c) to reverse engineer or disassemble the software or parts of the software or to transform the software in any other way into a human readable format, (d) to transform the software or parts of the software in another operating system, (e) to pass on or make availabe the software or parts of the software to any third party without written consent of the licenser (f) to use the software or parts of the software without written consent of the licenser on a computer system other than the defined computer system or on more than one work station, in networks, on a client-server system or on additional mobile equipment.

This software licence does not apply to software of any third party and does not include the use of such software. The right of the licensee to use such software is subject to regulations stipulated by such third parties.

Section 3 Warranty

Express warranty. The Licensor warrants to the original Licensee that (a) the data carrier on which the software is stored is free from any manufacturing and material defects when delivered to the Licensee and that (b) the software (but not updates) shall, at a fundamental level, function in compliance with the Specification of Services for a warranty period of one (1) year from the date of purchase, provided that the software is used in accordance with the foregoing licence, on the Defined Computer System and in compliance with the terms stipulated in the product description relating to its installation, use and operation.

The Licensor does not warrant that the software shall be free from defects, run without interruption, meet the expectations of the Licensee or function in combination with third-party hardware or software products, or that all program errors shall be removed. In addition to the foregoing, in order for a defect in the software to be sufficiently material as to violate the warranty set forth in letter (b) above of this paragraph, the defect must cause the software – whilst being used as permitted by the foregoing license – to function in a way so divergent from the Specification of Services that it is unsuitable for the purpose described in the product description. If the required functionality can be achieved by the Licensee indirectly (through a “work-around”), then the applicable impairment shall not constitute a defect giving rise to obligations under the foregoing warranty. The Licensor's sole obligation under the foregoing warranty shall be – at its own discretion and cost – to either (a) replace the data carrier and/or software so that it corresponds, at a fundamental level, to the Specification of Services (including replacement with a newer version or an equivalent piece of software) or (b) repair the software by supplying correction code, work-around solutions and/or updates, including updated documentation and other documents, or (c) to terminate this Licence Agreement and refund the licence fee upon return of the software, if the fee was charged separately when the product was handed over, in accordance with Section 6 below. The foregoing warranty shall apply to any replaced data carriers and software until expiry of the original warranty period. The costs and risk of delivering software to the service point defined by the Licensor shall be borne by the Licensee.

Obtaining warranty service.

If the Licensee identifies a defect in the Software that may give rise to an obligation under the foregoing warranty, it shall cease using the Software immediately and notify the Licensor in writing of the defect within the defect notification period while also providing sufficient supporting documentation.

The defect notification period is ninety (90) days from delivery of the data carrier (for a defect in the data carrier) and six (6) months from delivery of the software (for a defect in the software). The written supporting documentation providing proof of the defect shall be sufficient if the Licensor is able to reproduce the defect identified by the Licensee. The Licensee shall enclose the relevant purchase receipt so that the Licensor may determine whether the defect notification period has been observed in respect of the defect concerned. The Licensee shall not carry out any modifications or repairs itself or allow modifications or repairs to be carried out by unauthorised third parties. If the Licensor so desires, the Licensee shall support the Licensor in the analysis of the causes and circumstances giving rise to the defect, as well as in the development and testing of correction codes or a work-around solution.

Exclusivity of warranty.

The Licensee's sole remedy for software defects is set forth in the foregoing express warranty. The software is licensed with its current features “as is”. Other than the foregoing express warranty, the Licensor provides no other warranty or guarantee whatsoever. Such express warranty is in lieu of all other warranties, express or implied, either in fact or by operation of law, including assurances, terms or conditions of merchantability, fitness for a particular purpose, satisfactory quality and non-infringement, all of which are expressly disclaimed. It shall be the responsibility of the Licensee to select the software that fulfils its requirements. The Licensee shall bear the full risk for the performance of and results achieved by the software and for its suitability for the use that Licensee has planned for it, even if the Licensor has been informed of the planned use of the software in advance. The Licensor shall be relieved of its obligations under the foregoing express warranty insofar as a defect has been caused by circumstances for which it is not responsible, including, without limitation, (a) non-compliance with the conditions of use and operation defined in the product description or the documentation; (b) non-compliance with the terms of this Licence Agreement; (c) unauthorised modifications to or interference with the software by the Licensee or third parties; (d) errors in the operation of the software attributable to the Licensee or third parties; (e) influences from systems or programs that have not been supplied by the Licensor; or (f) use on a computer system other than the Defined Computer System. In the event that the Licensor is not responsible for a defect pursuant to these warranty terms or that the Licensor incurs additional expenses as a result of the failure of the Licensee to comply fully with its obligations under this Section 3 (including, without limitation, its obligation to support and provide documentation to the Licensor), the Licensor shall be entitled to charge the Licensee for the costs that it incurs for the analysis and rectification of the defect on a time and materials basis and in accordance with the applicable rates charged by the Licensor at the time.

Section 4 Intellectual property rights

The Licensee shall only hold those rights to the Software that are expressly described in Section 2 of this Licence Agreement. The Licensor shall remain the sole holder of any other rights with regard to the software, including, without limitation, ownership rights and patent, copyright, trademark, trade secret and other intellectual property rights. The Licensee must not remove, obscure or modify any references on the software to copyrights, trademarks or other ownership rights of the Licensor. The Licensee shall take all reasonable steps to prevent any unauthorised use, reproduction, sale or publication of the software or the unauthorised provision of access thereto. The Licensee shall indemnify and hold harmless the Licensor against any loss, damage, claims and expenses (including, without limitation, reasonable legal expenses) relating to any infringement of the rights of the Licensor caused by the Licensee, the Licensee's breach of this Licence Agreement or the Licensee's use of the software in a manner not permitted under this Licence Agreement.

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.

Revisionsstand und Freigabe

von Dokumenten, die in Smart Media Creator erstellt sind

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Angaben zum Revisionsstand:

Rev.	Datum	Änderung
Rev. 2.5	2023-10	■ Kapitel Gerätekennzeichnung hinzu ■ Kapitel 2.1 Typenschild hinzu ■ Hinweis Barcode-Erstellung hinzu in Kapitel 2.7 automatische Programmvorwahl über Barcode (Option) ■ UK-Regulierungen (nur in EN Version) hinzu in Kapitel ■ Deckblatt (UKCA-Logo) ■ 1.9 Normen un Richtlinien ■ 2.2 Standardaustattung

Freigabe

	Name	Funktion	Datum	Unterschrift
Erstellt:	Amrei Hüßner	TDO		
Geprüft & Freigegeben:	Dr. Martin Bönisch	Leitung F&E		

Revisionsstand und Freigabe

Angaben zur Dokumenterstellung in SMC

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