Instructions for use



Washer-Disinfector

Uniclean ML

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CE 0123

General information

Legend of symbols and hazard warnings

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

- Handling instruction
- List



Ignoring hazard warnings may cause injury!



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



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

List of abbreviations

BW	Loading trolley	For transporting the material to be loaded - all loading trolley types incl. BWI for the Uniclean ML
BWI	Loading trolley for different materials and instruments	For transporting the material to be loaded into the Uniclean ML

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 corrosive substances! Wear protective gloves and glasses.



Warning hot surface! Wear protective gloves.



Warning when working on the machine! Read the user manual!



Protective ground



Wear protective glasses!



Wear protective gloves!

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1 Security

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



Observe the safety instructions.

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

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

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

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

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

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

1.1 Intended use

Intended purpose

The **Uniclean ML** series of washer-disinfectors is suitable for the automated cleaning and disinfection, as defined in DIN EN ISO 15883-1, of medical and non-medical materials.

The Uniclean ML is intended for use in the medical field (for example in Reprocessing Units for Medical Devices).

Intended useRequired equipment for reprocessing invasive medical devices Limitations of use

a) Non-invasive medical devices and other materials

The Uniclean ML washer-disinfector is intended for the automated cleaning and disinfection, as defined in DIN EN ISO 15883-6 / -7, of the following materials:

- Transport trolleys for various uses
- OR shoes
- Kidney basins
- Wash bowls, saline bowls, bowls, basins, receptacles
- Transport containers
  - Sterilization containers
  - Plastic boxes with lids
- OR tabletops
- Other utensils typically used in healthcare facilities

b) Invasive medical devices and other materials

In addition to the aforementioned items, the Uniclean ML washer-disinfector is also suitable for the automated cleaning and disinfection, as defined in DIN EN ISO 15883-2, of the following medical devices:

- Sterilization containers
- Simple standard surgical instruments with a closed surface, including articulated and cutting instruments that do not require direct connection
- Thermostable rigid hollow body instruments*, including those with tube connectors, with a diameter of 3 mm or greater and a maximum length of 300 mm

  * Program acc. to DIN EN ISO 15883: Hollow body device, lumen device

To reprocess invasive medical devices, the **Uniclean ML** washer-disinfector needs to be suitably configured. The configuration comprises:

- suitable load carriers for the material (BWI)
- suitable methods for the material
- the docking system for BWI
- the filter system



Only materials that have been designated by the manufacturer as machine washable and dryable can be treated!

When reprocessing materials in accordance with DIN EN ISO 15883-2, the materials to be treated must also be able to withstand temperatures of at least 80 °C without sustaining any permanent damage.



Materials not explicitly listed in the Intended Use section must not be treated in the Uniclean ML washer-disinfector.

Examples of materials not permitted to be treated include:

- Glassware according to DIN EN ISO 15883-2
- Ophthalmology instruments
- Endoscopes, including rigid endoscopes
- Robotic instruments
- Dental instruments
- Special hollow body instruments with specific reprocessing instructions
- Rigid thermostable hollow body instruments, including those with tube connectors, with a diameter less than 3 mm or length greater than 300 mm
- Anesthetic materials
- Powered devices (motor systems) according to DIN EN ISO 15883-2
- Human waste containers according to DIN EN ISO 15883-3

1.2 Responsibilities of the operator

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

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

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

Before commissioning

The operator must ensure that the following requirements are met:

- The machine has been properly assembled, installed, and set up by an authorized company
- The programs used have been configured for the processes, unused programs have been locked
- The inspection and maintenance plan is available
- The system supervisors and users have been trained
- The operating permit has been issued (if required by national regulations)
- The standard operating procedure is available
- A validation has been performed (if required by national regulations) (see Chapter 1.2.1, "Validation")

Network security

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

Interface validation with cycle protocols from outside companies

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

If the machine is being operated in Germany

Observe the German Occupational Safety Act, and the Ordinance on Industrial Safety and Health (BetrSichV). In accordance with BetrSichV, a risk assessment must be performed regarding the operation within the company of 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 Validation

The operator must ensure that only validated programs are used for medical devices. Non-medical devices cannot be validated.

Medical devices can be reprocessed if the suitability of the selected reprocessing process has been confirmed by a validation.

Only medical devices listed in the validation report must be treated in the Uniclean series washer-disinfector.

The operator is responsible for performing the validation process. The operator must observe and comply with all applicable local authority or national regulations with regard to validation.

Specifications for validation can be found, for example, in DIN EN ISO 15883-1, DIN EN ISO 15883-2, DIN EN ISO 15883-6 and in the country-specific guidelines (e.g. DGKH, DGSV and AKI Guideline for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices and for principles of equipment selection).

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

As a rule, requalification takes place annually.

Requalification is essential in the case of changes that affect the process, e.g. changes to the process chemistry, the water quality, and changes to the load being reprocessed.

Guidelines

- AK-BWA

  German Working Group for Bed Frame and Trolley Decontamination Systems (Arbeitskreis Bettgestell- und Wagendekontaminationsanlagen). This brochure applies to the machine decontamination (cleaning and chemo-thermal disinfection) of various materials to be treated, in particular for the medical sector:

bed frames with bedside tables, transport trolleys, circulation containers, other reusable sterilization containers, surgical tables and furnishings, as well as OR shoes.

- DGHK, DGSV and AKI guideline

  For the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices and for principles of equipment selection
  Guideline compiled by the **D**eutsche **G**esellschaft für **K**ranken**H**aushygiene (German Society for Hospital Hygiene), **D**eutsche **G**esellschaft für **S**terilgut**V**ersorgung (German Society for Sterile Supply) and **A**rbeits**K**reis **I**nstrumentenaufbereitung (Working Group for Instrument Preparation)

- ÖGSV (Austrian Society of Sterile Supply) guideline

  Annex to the guideline for the testing, validation and monitoring of machine washing/disinfection processes for medical devices

1.2.2 Medical devices / equipment log

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

Documenting the following in the equipment log is recommended:

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

1.2.3 Training the users

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

The users must be trained for this task by a qualified person (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 supervisor of the system (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 organisation for operation of the device.



Risk of injury

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

1.2.4 Water quality

Water quality has a significant impact on the cleaning and disinfection results Chapter 6.3.7, "Insufficient water quality". This is why certain requirements apply to the water provided by the operator.

For information on the required water quality, please consult the technical dimensional drawing for the machine as well as the planning drawings that must be observed by the operator. As a process water supply is subject to quality fluctuations during operation, the operator must test the on-site process water supply once a month, Chapter 7.5, "Maintenance activities "



If ultrapure water of conductivity of < 1 µS/cm is used, there will be a correspondingly greater need for maintenance and an increased risk of corrosion!

1.2.5 Noise emission

The average A-weighted emission sound pressure level of the device during operation measured pursuant to DIN EN 61010 is less than 70 dB(A).

1.2.6 Process exhaust air

Exhaust air from the chamber is fed outside via a separate exhaust air duct in the building (in accordance with the MMM specifications in the planning drawings). As, in principle, the exhaust air from a washer-disinfector system may be contaminated, this must be taken into consideration by the internal organisation during any service work. The service technician must be aware of the situation and must, as a minimum, wear the appropriate personal protective equipment that has been provided for such cases in the interest of occupational health and safety.

1.2.7 Special features when heating with steam

Description of the heat exchanger

The heat exchanger integrated into steam-heated machines operates on the counter-flow principle. The water is heated using saturated steam.

The heat exchanger is vertically mounted (upright) with the water flowing from bottom to top. The steam inlet is at the top, the outlet of condensate is at the bottom.

The water side is a tube bundle in a tank surrounded by steam. The tube bundle is rolled into the tank with two tube plates.

The connections for water feed and return are a cover at the top and bottom fitted with bolts, nuts and seals.

The steam and condensate connection is welded to the side of the tank. All connection points for the media are designed as flanges.

The top and bottom cover can be removed for inspecting and cleaning the tube bundle.

CE conformity

The standards and technical specifications (design, manufacture and testing) applied in the heat exchanger conform to the AD 2000 code of practice.

The heat exchanger conforms to the pressure vessel directive and the manufacturer has applied the CE mark.

The conformity evaluation procedure applied by the manufacturer of the pressure vessel conforms to Module A1 (internal manufacturing control with monitoring of acceptance inspection).

Commissioning

The Uniclean ML must be connected to the supply lines and secured to prevent pressure overshoots according to the MMM installation preparation drawing and the technical data sheet, the instrumentation diagram, tube diagram and local regulations.

The operator must install a safety valve in the steam feed line to the machine (see BVZ and Uniclean ML technical data sheet). The operator must check the operation of the safety valve regularly.

The water side of the heat exchanger does not require a safety valve because the design means that the specified pressure cannot be exceeded.

Periodic tests

The pressure-volume product of the vessel means that with the upstream heat exchanger it is a pressure vessel that requires regular inspections.

The operator is responsible for defining the inspection schedule and the type and scope of testing.

Observe the national legal regulations.

If the machine is operated in Germany, the German Ordinance on Industrial Safety and Health (BetrSichV) and the Technical Rules for Operating Safety (TRBS) will apply. The BetrSichV regulates the intervals for regular tests and the responsibility for performing the tests (e.g. accredited inspection body (ZÜS)). The regular tests for pressure vessels must be conducted by a technician in accordance with Module A1 (Pressure Vessel Directive).

Contact the manufacturer if you have any questions.

Technical data of the heat exchanger

Heating area 1.1 m^2

	Steam	**Water**
Max. approved excess pressure [bar]	10	8
Max. approved temperature [°C]	200	200
Volume [l]	9	6.5
Test pressure [bar]	14.6	12.7
Test medium	Water	Water
Fluid group	2	2

Maintenance and faults

The heat exchanger must be replaced if it has a fault (e.g. leak). Contact MMM customer service.

1.2.8 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.



Note

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.



Risk of injury

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

System supervisor

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

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

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

- Technical documentation
- Medical devices / equipment log (depending on the machine type)
- Keys (for the emergency stop switch or program, maintenance hatch, control cabinet depending on the machine type)
- Level 1 access password (e.g., for acknowledging faults).

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.

1.3.1 Access protection

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

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

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

The User Manager (option) can be used to assign specific authorizations to users.

1.3.2 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 30 seconds after log-in (individually adjustable), the *Supervisor* user is automatically logged out and the *Anonymous* user is logged in.

User Manager (option)

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

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

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

Only with second control panel (option):

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

1.4 Rules of conduct for operation

1.4.1 Personal protective equipment

To increase occupational safety for users and service personnel, the machine is equipped with a number of safety-related devices. Nevertheless, users and service personnel may still get injured if it is used in an incorrect or improper manner.

Users



The metallic walls and components of the chamber and loading trolleys become very hot during operation.

Wear gloves and closed long-sleeved work clothing when loading and unloading the chamber.

Service personnel



When servicing the system, also wear safety goggles and gloves that are resistant to the process chemicals.

Additional personal safety measures may be required.

Please consult the safety data sheet of the respective process chemicals for further information. Process chemicals are not supplied by the manufacturer of the washer-disinfector system.

1.4.2 Closing the chamber door, starting a program



There are people in the chamber!

Before closing the doors, the user must ensure that there is no one inside the chamber!

The preparatory measures Chapter 4, "Operation" must be observed before starting a program.

1.4.3 Working inside the chamber

Only trained personnel (e.g. 1.3 "Operators", Page 17) are permitted to work inside the chamber.

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

1.4.4 Working on the assemblies

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.



Risk of injury!

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

Wear personal protective clothing when working on the assemblies!

1.4.5 Working in the electrical control cabinet

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



Danger due to electric current!

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

1.4.6 Maintenance work

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

1.4.7 Power failure or EMERGENCY STOP pressed

If a power failure occurs, all mechanically moving parts are stopped. The machine is de-energized and in a technically safe state. The controller only remains active with the USP (Uninterruptible Power Supply) option. See also "Power failure", Page 88

In case of actuation of the emergency stop switch, all mechanical moving parts are stopped. The machine is de-energized and in a technically safe state. See also "EMERGENCY STOP", Page 89

The program is not completed properly, however. This means that individual parts of the chamber may be contaminated. There may also be water and moist air in the chamber.

When the chamber door is opened, moist air in the chamber that may be contaminated can get into the work area.

Working on the machine and, in particular, opening a chamber door (manually or via the touchscreen) is only permitted after the operator's hygiene officer has decided on the course of action. This decision must be documented in the medical products / equipment log and signed by the system supervisor.



Risk of injury!

Possible leakage of caustic vapors.

Wear personal protective equipment and a surgical mask when opening the chamber door.

1.5 Safety features of the machine

1.5.1 Chamber door interlock

The program sequence is automated and regulated by the controller. The chamber door cannot be opened during the program sequence. Consequently, the chamber door button on the display is inactive.



Do not force open the chamber door while a program is running!

Risk of injury due to hot water spray contaminated with chemicals!

If process-related faults occur, only the chamber door on the loading side is activated. It can be opened by pressing the chamber door button on the touch screen.

The chamber door can be manually pushed open in an emergency.



Danger of contaminating the clean side!

The chamber door may only ever be opened manually from the unclean side and only in an emergency!

1.5.2 Protection against getting crushed in the chamber door

The automatic chamber door drive is fitted with a force limiter that stops door movement as soon as the chamber door encounters an obstacle (e.g. if an object or a person is in the way of the door).

If, during the closing process, this unexpected obstruction lasts a certain amount of time, the machine generates an error and reports it on the display. The chamber door is opened again.

Chamber door movement speed

The electric drive unit and its gear ratio are designed so that chamber door movement is relatively slow (100 mm/s). This allows sufficient time to react in an emergency and to stop the chamber door movement by pressing the chamber door button or the EMERGENCY STOP.

1.5.3 Maintenance hatches

The machine room can be accessed via the maintenance hatches in both of the front panels. This houses the assemblies and the media supply.



The assemblies in the machine compartment (e.g. valves, uninsulated pipework, etc.) are hot.

Wear personal protective clothing when entering the machine compartment (Chapter 1.4.1, "Personal protective equipment").

Never enter the machine compartment while a program is running (Chapter 1.4.4, "Working on the assemblies").

As they move across, the chamber doors encroach on the maintenance hatch area and so anyone who is in the way risks getting crushed. For this reason, the movement of the chamber door is inhibited while the maintenance hatch is open, except when the emergency opening button inside the chamber is pressed.

1.5.4 Master switch

The master switch is located on the control cabinet 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.



Risk of injury!

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

1.5.5 Emergency opening button

There is a red illuminated button in the middle of the chamber for opening the door in an emergency. When this button is pressed, all machine operations are stopped and the door on the loading side opens automatically.

1.5.6 EMERGENCY STOP

The machine is equipped with easily accessible EMERGENCY STOP switches Chapter 3, "Displays and controls". In the event of a hazard (e.g. personal injury or damage to property), immediately press the emergency stop switches marked in red/yellow.

When actuated, the machine is de-energized.

To restart the machine, the emergency stop switch must be unlocked (using the key if present) (Chapter 6.3.6, "EMERGENCY STOP").



Risk of injury!

Unhindered access to the emergency stop switches must be ensured at all times during operation!

Do not park transport trolleys or the like in front of the machine !

1.5.7 Cancelling the program

The “Cancel program” button is shown on the display after the program starts. It must be pressed in the following cases:

- Irregularities in the program sequence
- Incorrect program selection

Pressing the “Cancel program” button puts the machine in a safe state:

- All media valves close, except for the chamber drainage valve.
- The chamber is drained.

The door seals are then released and the chamber door on the loading side can be opened.

If you have the “air permeability reduction” (isolator) option, the door seal on the unloading side remains pressurized by means of compressed air.



The material is not considered properly treated!

Note: If there is a risk of personal injury or damage to property, press EMERGENCY STOP and not the “Cancel program” button.

1.6 Residual risk

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

Nevertheless, they do not eliminate all risks.

Disinfection process

The greatest conceivable residual risk for the disinfection process is that the controller and the user might fail to detect that the treated material has not been properly disinfected when carrying out the subsequent check.

As a result, each cycle must be approved by the user in all circumstances. On completion of each fault-free program, the user must check whether the program was suitable for the material being treated and for the number of loading trolleys. The user must adopt suitable measures to ensure this work process is carried out, organized appropriately and documented.

Process chemicals

Mixing up process chemicals may render the cleaning and disinfection process ineffective and may leave residue on the medical devices. Therefore, the warnings and safety instructions (including the storage and transport conditions) of the process chemical manufacturer must be observed. The operator or user must put suitable measures in place to ensure that process chemicals cannot get mixed up.

Nozzle drive failure

If the lateral nozzle pipes (all or some) no longer pivot, this can cause insufficient disinfection performance during the “chemical disinfection” program.

Causes:

- Interrupted connection between the drive and the drive tube
- Interrupted connection between the drive tube and the driven tubes

Since these scenarios are not detected by the monitoring system within the machine, the operator must observe the movement of the nozzle pipes through the glass door of the chamber, see Chapter 4.9, "Releasing the cycle".

This ensures that almost all scenarios are detected and corrective actions can be undertaken. There is a very small residual risk of the highly unlikely case occurring whereby the outermost nozzle pipes obviously rotate (only these pipes are visible through the door), but the nozzle pipes somewhere in the middle do not.

This will be identified at the latest during maintenance by the service technician, and rectified. Even if this relatively unlikely scenario should occur, the chemical disinfection performance can be ensured because the other pipes rotate and support the disinfection performance. This is because, due to its over-dimensioned nozzle strength, the overall system is capable of balancing itself out.

This residual risk is not applicable to programs with thermal disinfection because they always work, even when the nozzle pipes do not rotate.

Instruments (option)



Clogged filter systems can lead to the material not being properly treated.

Two filter systems are integrated into the machine to separate particles and foreign substances. Both filter systems prevent the machine from getting damaged or clogged. The main role of the filter systems is to protect the material to be treated against foreign particles. One filter system is located in the chamber (chamber filter). The second (referred to below as the “flow-through filter”) is located in the circulation pipeline directly before the jet system that sprays the material to be treated with process water.



Without a flow-through filter, foreign particles may get onto the material to be treated. This must be avoided at all costs. Therefore, when cleaning the flow-through filter, always ensure that its casing is never closed without the filter. There are warning stickers on the casing.

The flow-through filter is integrated into a casing. It must be cleaned regularly and always BEFORE every instrument program. A cover must be removed to access the filter. Under no circumstances may this cover be screwed back onto the casing without the filter being inserted, see Chapter 7.12.

1.7 Maintenance and Safety inspection

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

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

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

National regulations must be observed.

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

Note regarding warranty

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

We refer to our warranty declaration Chapter 8, "Warranty (Liability for defects)", according to which wear-and-tear parts and damage caused by chemical influences are expressly excluded from our warranty.

Service life of the machine

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

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

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

1.8 Standards, regulations and directives

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



Notice for EU:

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

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

Applicable EU directives and EU regulations

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



Note

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

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

Applied standards - state of the art

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

Performance and effectiveness

- DIN EN ISO 15883-1 Washer-disinfectors - Part 1: General requirements, terms and definitions and tests
- DIN EN ISO 15883-2 Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anesthetic materials, bowls, dishes, receivers, utensils, glassware, etc.
- DIN EN ISO 15883-5 Washer-disinfectors - Part 5: Test soils and methods for demonstrating cleaning efficacy
- DIN EN ISO 15883-6 Washer-disinfectors - Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment
- DIN EN ISO 15883-7 Washer-disinfectors - Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical medical devices and healthcare equipment

Product safety

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

EMC requirements

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

Functional safety

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

Usability

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



Note

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

1.9 Commissioning instrument loading trolleys (BWI)

Before loading and using an BWI, the BWI concerned must always undergo a standard wash program while it is still unloaded in order to remove any contamination left over from the transportation process.

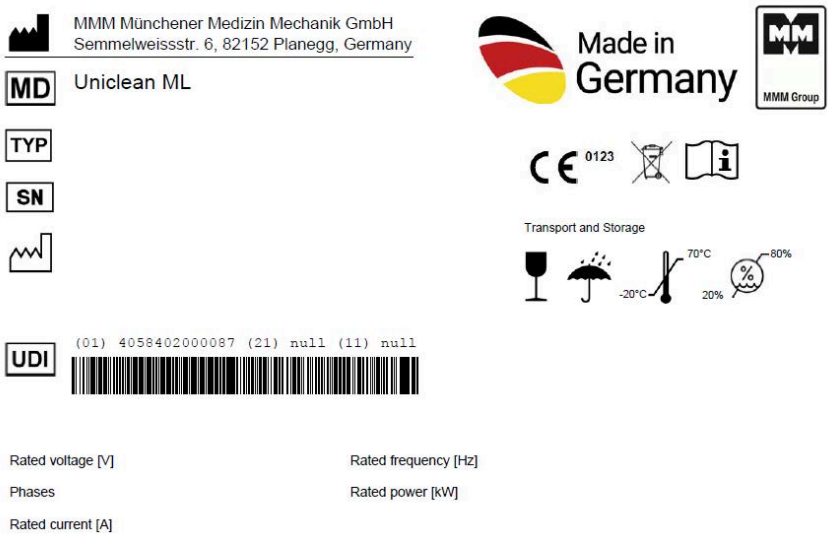
2 Machine description

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

For the precise specifications of your machine, please refer to the technical dimensioned drawing, the planning drawings and the type plate attached to the machine.

2.1 Type plate

The type plate is located on the control cabinet.



Example illustration

Explanation of type plate:

 Manufacturer

 CE mark with identification number (example)

 Medical device

 Disposal (WEEE recycling)

 Type

 Observe the instructions for use

 Serial number

 Fragile, handle with care

 Date of manufacture

 Store in dry place

 Unique Device Identifier

 Lower and upper temperature limit

 Lower and upper air humidity limit

Additional conformity marks apply for the following countries:

 for Ukraine only

 for Serbia only

 for UK only

 for Australia only

2.2 Machine configuration

2.2.1 Chamber

- Chamber made from high-quality CrNi steel with hygienic, high-quality polished inner surfaces.
- Sloped chamber ceiling and floor so water drains away quickly without leaving any residue
- Load surface tiltable depending on the program so water can more easily flow away from the material to be treated, thereby increasing the drying performance
- Easily adjustable positioning aids for transport and instrument loading trolleys on loading surface
- Easily removable dirt filters in the chamber for fast cleaning.
- Tread surface parts can be easily folded away for the self-cleaning program. This ensures that even areas underneath that are difficult to access are hygienically clean.
- Illuminated emergency door release button inside chamber in case of an emergency.
- Chamber overflow prevents chamber from being filled with water in an accident or emergency, and directs water into the gully
- Chamber lighting making the operating status clearly visible from the outside
- For the instrument reprocessing option, the machine has one or two docking couplings on the chamber ceiling for loading trolleys for instruments

Chamber doors

- Horizontally running sliding doors made from safety glass with slow moving chamber doors for safety reasons
- Hardware safety mechanism to prevent opening while program is running
- Safety mechanism on the door sealing edge: If the chamber door encounters resistance in its path, it stops and moves back again after a certain amount of time. Door movement can be stopped manually.
- The chamber door seals inflate when the doors are closed and the program is started. They are pressed onto the chamber doors using compressed air so that the chamber is airtight.

In the case of a **two-door machine**, both chamber doors are interlocked so the two chamber doors can never be opened at the same time (rack hatch function). The chamber door on the unloading side can only be opened after a program has run completely and successfully. The loading side can be opened (automatically or

manually) once the treated materials have been removed and the chamber door on the unloading side has been closed. Once the loading side has been opened, the unloading side can no longer be opened. The unloading side can be opened again at any time if the loading side has not yet been opened.

If you have the “air permeability reduction” (isolator) option, the doors seals on both sides are pressurized by means of compressed air, and the two door seals are never released at the same time.

In the case of a **single-door** machine, the loading side is also the unloading side. The chamber door can only be opened after a program has run completely and successfully.

2.2.2 Electrical equipment and control system

Electrical equipment

The electrical equipment conforms to DIN EN 61010-1 and DIN EN 61010-2-040.

Control system

The programmable logic controller (PLC) fully automatically regulates the process sequence and handles process documentation and interaction with the user. If a fault occurs in the automatic program sequence or the process-related program parameters are not adhered to, the program is canceled.

Cycle counter

A cycle counter is integrated into the controller. During the program sequence, the current cycle number is displayed in the Program sequence menu. Alternatively, the cycle number can be retrieved using the “Information” button. Various interfaces are available for transmitting cycle-related data, as well as for external connections and devices (USB, Ethernet, etc.). Cycle storage capacity: at least 25 000 cycles, see "Cycle documentation", Page 36.

Color touch display

A graphics-capable color touch display is integrated into the loading side (optionally also the unloading side). The MMM smart HMI (Human Machine Interface) with background lighting has a clearly arranged and user-friendly design, and can be operated using buttons with pictograms. The process steps and the current state of the machine are continuously displayed in a graphical format. The color touch display also provides access to process curve diagrams, machine parameters and maintenance aids via the control menu.

2.2.3 Dosing system

- A membrane dosing pump ensures fast dosing of the process chemicals and reduces the cycle time
- The membrane pump is designed in such a way that it can reliably deliver both the larger volumes required for the standard process chemicals as well as the smaller volumes of highly concentrated process chemicals.
- For each process chemical, there are two precise flow meters to ensure a consistently high level of dosing accuracy (max. ± 5%) and redundant monitoring
- Dosing system suitable for canister dosing applications or for connection to a central dosing unit

2.2.4 Drying

Hot air drying

- Fan made entirely from stainless steel ensures a high level of air turbulence inside the chamber for effective drying
- Insulated air injection into chamber
- Air temperature regulated with Pt100 via analogue input, can be adjusted according to how sensitive the material is to temperature
- Pneumatically operated air flap makes it possible to alternate between fresh air drying and circulating air drying
- Heat recovery thanks to circulating air drying. This feature reuses the hot chamber air generated during the washing and drying process.

2.2.5 Supply and exhaust air

HEPA filter

The intake filter takes the form of a HEPA filter (H14). The air entering the chamber passes through the HEPA filter to prevent contamination of the material being treated. (HEPA = High Efficiency Particulate Air filter)

Monitoring the HEPA filter (option)

The HEPA filter contamination level is monitored by means of an analog pressure sensor. If the filter is contaminated, the controller displays a corresponding message which is also documented on the cycle report. The drying process continues nevertheless.

2.2.6 Tanks (option)

Preparation and recovery tank system

The tank system for all machine types always consists of two tanks with exactly the same configuration. The heating type is dependent on the heating system of the basic machine but must be identical in both cases.

The tanks perform two functions:

1. Preparation
   - Supplying water, temporarily storing water
   - Dosing
   - Heating
   In each of the respective tanks, the water is prepared or temporarily stored for the next program or program step. This involves heating the required volume of water and adding the correct dose of the relevant process chemical.
   Advantage: Time saving for the process step and thus the program.
2. Recovery
   In some process steps, the circulating water can be recovered without having to discard it. On completion of the process step, the water is pumped out of the chamber and into the relevant tank by sending it through the relevant pipes and switching the valves accordingly. This process is handled by the drainage pump that has to be installed anyway.
   Advantage:
   - Less water consumption
   - Less heat energy used
   - Less consumption of process chemicals

2.2.7 Media supply

Depending on the machine configuration, it is possible to connect one, two or three different types of water. An additional steam and condensate connection is provided for steam heated machines.

With one water connection, it is preferable to connect deionised water.

With two water connections, it is preferable to connect soft cold water and deionised water.

With three water connections, hot water may be connected as well.

Deionised water is required for the final rinsing of medical devices. The use of hard water is prohibited.

2.2.8 Barcode (option)

ML barcode reading system (cable)

Hand-held scanner system for identifying the loading trolley type and for automatically identifying and selecting the program.

Every loading trolley has 2 barcodes (option) attached to it. When a barcode is scanned, the loading trolley is identified and the correct program selected.

2.2.9 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
- Course of the pressure and temperature curves over time
- Messages in plain text
- Servicing

The cycle document that is saved in the machine can be printed out at the end of the cycle and, depending on the machine configuration, transferred to an external server, e.g. using the MMM RUMED360 Cycles middleware (option) see "Setting cycle report print and save options", Page 82.

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 50 cycles stored in the machine can be shown on the display and reprinted.

2.2.10 Energy manager (option)

Additional device that regulates media consumption from the supply network if multiple machines (max. 9) are connected to the same media supply. The energy manager coordinates the program sequence timings so that the media (steam, water, electricity) of the individual machines are not taken from the shared supply network at the same time.

The connected machines are networked and request whether the media are available in sufficient quantities before starting the program. Depending on the result of this request, each individual machine signals whether it is ready to start.

Using the energy manager does not reduce the overall media consumption but significantly decreases peak demand. The energy manager does not affect the process sequences or the reproducibility of the processes.

You can activate and deactivate the energy manager under Tools menu – Configuration menu – Settings.

2.2.11 ISA (option)

ISA stands for “Intelligent Service Advisor”. This is a JAVA-based program for receiving information from the connected devices.

The ISA server runs on a Windows computer on the Ethernet network.

It can either be started as a program with a user interface or as a Windows service.

Depending on what type of notification is set, the data is converted into an e-mail or SMS and then sent. E-mails are sent via an SMTP server. SMS messages are sent via an Internet HTTP SMS gateway.

Information included in e-mails to MMM customer service

E-mails can be sent via the “Service” menu.

When an e-mail is sent to MMM customer service or a company/person authorised by MMM, it contains the following information:

- Information on the machine
- Information on the current program
- Alarms currently shown on the display
- Information on recent program cancellations
- Information on upcoming service work to be carried out on the machine

- Information on the service work last carried out on the machine
- Current alarm counter values

2.3 Operation and process description

2.3.1 Functioning of the machine

After the chamber doors have been closed and the program started, the door seal is pressurized by means of compressed air. The selected program runs automatically and independently until it has been successfully completed:

- If there is water in the chamber before the program starts, the chamber is drained.
- The chamber is filled with water (either directly from the on-site water supply or via the optional tanks).
- Depending on the respective process step, process chemicals is dosed into the water.
- The water is sucked out of the chamber, heated, and sprayed onto the material to be treated by means of the nozzle system and the rotating arms (option).
- The water that drips off is collected in the base of the chamber and the cycle starts from the beginning.
- This water circulation phase continues until all the parameters set for the selected program have been reached.
- A number of different water recirculation phases follow one another (process steps).
- The material to be treated is then dried with heated, sterile-filtered air.
- The door seals are released and the chamber door on the unloading side can be opened.
  If you have the “air permeability reduction” (isolator) option, the door seal on the loading side remains pressurized.

Depending on the selected program and the accessories used, the trolley is tilted during the process. Firstly to enable the water to run off better during the individual program steps, and secondly to improving the cleaning performance.

To prevent damage, the loading trolleys for reprocessing instruments (option) are never tilted. The machine has a system for identifying BWIs. If a loading trolley for instruments (BWI) is detected, only the appropriate programs can be started.

The entire process is monitored and controlled by an automated control system and by means of temperature and pressure sensors. The door on the unloading side can only be opened after a program has run completely and successfully (i.e. all the configured limit values have been adhered to).

The process water and air in the machine are heated by means of electric or steam-driven heat exchangers. The on-site process water supply is subject to a number of quality requirements, which, like all other supply media required for operating the machine, are defined in detail in the respective planning drawings.

2.3.2 Process chemicals

The process chemicals are an integral part of the washer-disinfector system.

Products made by Dr. Weigert were used when type testing this washer-disinfector. The products listed below have been tested by the machine manufacturer and their basic suitability has been determined.

The use of alternative process chemicals is only allowed after consulting the manufacturer of the washer-disinfector. Observe **Chapter 4.12, "Handling chemicals"** when changing the process chemicals.



Ensure that only hose grades suitable for the approved process chemicals are used (long-term durability).



The suitability of the process chemicals used in conjunction with the program and load must be established by means of validation (see **Chapter 1.2, "Responsibilities of the operator"**). This applies to medical devices only. For non-medical devices, a process check with the process chemicals, program, and load used is adequate.

Type-tested and approved process chemicals

The following products were used when type testing this washer-disinfector. The products listed below have been tested by the machine manufacturer and their basic suitability has been determined.

For all programs including instrument program

Type	Manufacturer	Product
Mildly alkaline cleaning agent	Dr. Weigert	neodisher MediClean forte
Rinse aid	Dr. Weigert	neodisher mediklar
Decontamination agent	Dr. Weigert	neodisher Dekonta

Current as at 02/2019. Please ask the manufacturer of the device for the current list.

Process chemicals successfully used in practice and validated

For all programs **except** instrument program

Type	Manufacturer	Product
Mildly alkaline cleaning agent	BODE	Dismoclean 23 alka zyme
Mildly alkaline cleaning agent	Schülke	Thermosept X tra
Enzymatic cleaning agent	ANIOS	ANIOSYME DLM Maxi
Rinse aid	ANIOS	RHW
Rinse aid	Borer	deconex 64 Neutrady

Current as at 02/2019. Please ask the manufacturer of the device for the current list.

An updated list and a list of approved process chemicals can be requested from the manufacturer of the machine.

2.3.3 Cleaning and disinfection process

The individual program steps can be adjusted to the operator's requirements during commissioning on site. Individual physical parameters (e.g. temperature, time, concentration, etc.) can also be modified as required. The relevant process parameters are determined as part of validation and documented in the validation report and in the equipment log.

Parameters are only to be changed by specialists (Chapter 1.3, "Operators").

Access is password protected. If process-related settings are changed, the program must undergo another recertification.

The cleaning effect of the machine is achieved by spraying water onto the material to be treated. If necessary, the water can be heated or supplemented with process chemicals.

The disinfection effect of the machine is also achieved by spraying water onto the material to be treated.

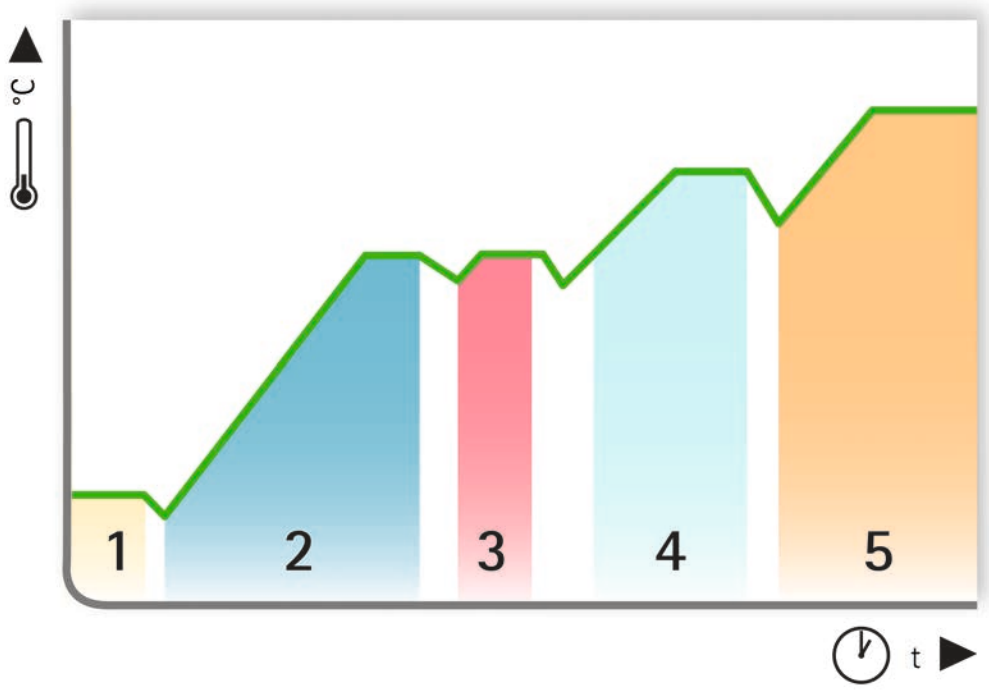
- Thermal disinfection for thermostable materials: The sprayed water is heated to between 65 °C and max. 95 °C and is applied to the material to be treated for a certain amount of time. The higher the water temperature and the longer the application time, the greater the germ-killing effect. This principle is reflected in the A_0 value concept (see EN ISO 15883-1 for more detailed information).
- Chemical disinfection for thermostable materials: The sprayed water is heated to a lower temperature that is compatible with the material to be treated, and corresponding process chemicals are added to achieve the disinfection effect.

Both disinfection processes are used depending on the system configuration

2.3.4 Example process sequence

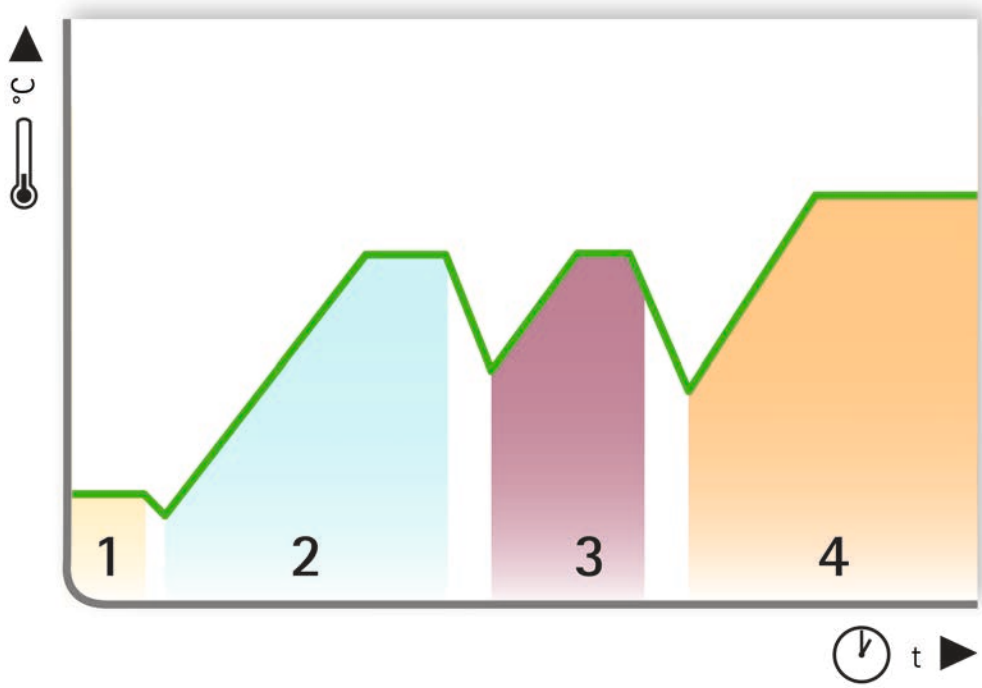
Examples of the process sequence are shown below. They may vary from the process sequence that you use.

Example of cleaning with thermal disinfection (for thermostable materials)



1. **Pre-cleaning**: Cold water is sprayed onto the material to be treated.
2. **Cleaning**: Hot water (between 25 °C and 65 °C) with added process chemicals is sprayed onto the material to be treated.
3. **Intermediate rinsing**: Water is sprayed onto the material to be treated. This removes the residual process chemicals.
4. **Thermal disinfection**: Hot water (between 65 °C and 95 °C), if necessary with added rinse aid, is sprayed onto the material to be treated.
5. **Hot air drying**: Hot, sterile-filtered air is blown onto the material to be treated. Moist chamber air is discharged into the on-site exhaust air system.

Example of cleaning with chemical disinfection (for thermostable materials)



1. **Cold pre-cleaning**: Cold water with no process chemicals added is sprayed onto the material to be treated.
2. **Decontamination**: Hot water (between 55 °C and 65 °C) with an added disinfectant is sprayed onto the material to be treated. This agent combines the cleaning and disinfection steps into one.
3. **Rinsing**: Hot water (between 55 °C and 80 °C), if necessary with added rinse aid, is sprayed onto the material to be treated.
4. **Hot air drying**: Hot air is blown onto the material to be treated. Moist chamber air is discharged into the on-site exhaust air system.

3 Displays and controls

3.1 Loading side



1 Color touch display*
2 On/off button
3 EMERGENCY STOP
4 Chamber door

*(an additional external color touch display may optionally be present)

3.1.1 On/off button



The on/off button switches the machine on and off.

Switching the machine on

To switch on the machine using the on/off button, the master switch in the control cabinet must be switched on. It is not necessary to turn the master switch on and off on a daily basis in the context of normal, intended use.

When the machine is switched on using the on/off button, the controller starts up automatically and the machine enters the ready state.

Switching the machine off

When the machine is switched off using the on/off button, a shut-down procedure runs as follows:

- Automatic closing of the chamber door (single-door machine) or chamber doors (two-door machine).
- Automatic engagement of the door seal(s)
- automatic draining of the chamber and the tanks (if installed)
- The moist air from the chamber is automatically discharged into the on-site exhaust air system.
- Automatic release of the door seal(s)
  If you have the “air permeability reduction” (isolator) option, the door seal on the unloading side remains engaged.
- Depending on the configuration, automatic opening of the chamber door on the loading side, or the chamber door on the loading side remains closed.



The on/off button is deactivated during a program sequence.

To switch off the machine:

- Touch and hold the on/off button for at least 2 seconds.



- Confirm the green tick for “Switch off machine”.

As soon as these internal machine processes are finished, the machine is switched off. The master switch does not need to be pressed.

3.1.2 EMERGENCY STOP



The emergency stop (see "EMERGENCY STOP", Page 24) must only to be pressed in an emergency, e.g. when there is a risk of personal injury or a risk of damaging the material to be treated or elements of the machine.

Example

3.1.3 Color touch display

The color touch display is used to navigate the menus for operating the machine. Touching the corresponding buttons executes the highlighted functions.

Ongoing processes are shown on the display in plain text, along with the current, actual and target parameter values (if available).

Only those buttons that can be activated in the respective operating state are shown as active on the display. For example, the chamber door button is deactivated during the program sequence, as opening the chamber door during the process is not permitted.

- Buttons with a coloured or dark grey background are active and trigger an action when pressed.
- Buttons with a light grey background are deactivated and not functional.

Navigating the submenus and screens does not affect the program that is currently running.

For safety reasons, certain button functions require logging in with appropriate rights and password request.

Function buttons on the color touch display

The touchscreen buttons have the following functions:

Button	Description	Function
	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.
 Example	Log out user and display “Current user”	User log out. If a user actively logs out, 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.
	Start	Starts the selected program.
	Cancel program	Cancels the program, e.g. if the incorrect program was accidentally selected.
	Open/close chamber door	Opens and closes the chamber door on the loading side.
	Extended program selection/Switch screens between various types of program information	This button has two functions: 1. Additional programs are displayed on the program selection screen when more than five programs are pre-configured. 2. During the program sequence, this button switches between the program information screens.
	Information	Displays machine information such as the software and hardware configuration, including the cycle counter and maintenance counter.
	Service	Icon for Service menu

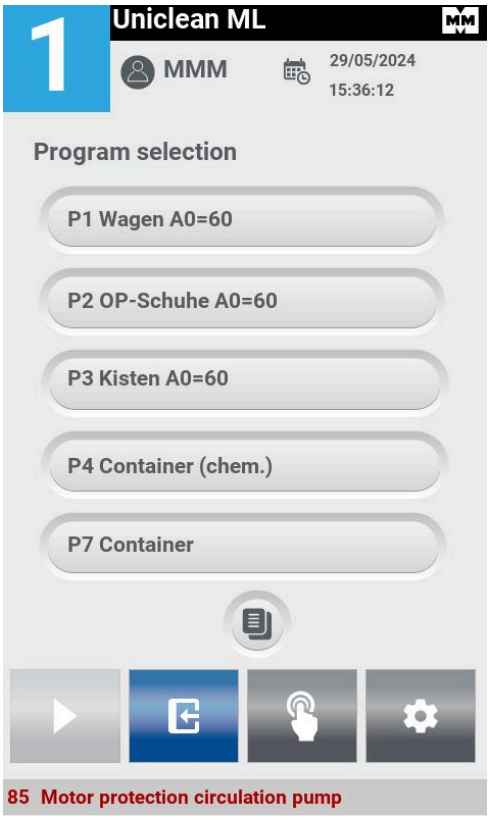
Button	Description	Function
	ISA	Icon for ISA menu
	Quick user access	Opens the “Quick user access” submenu that contains the following buttons: “Process archive” and “Tank cleaning”.
	“Configuration" menu	Password required. Provides access to the following submenu items: “Settings (parameters)”, “Service” and “Information”
	Scroll	For finding and selecting a certain cycle. The selected cycle is highlighted in color.
	Arrow buttons	For changing the screen within the pages of an individual menu
	Confirm	Confirms the selection.
	Confirm/acknowledge	Confirm the selected function or acknowledge one or more alarm messages.
	Cancel entry	
	Back	Returns to the previous menu.
	Save	

Button	Description	Function	
	Screen cleaning	Deactivates the touch function so you can clean the color touch display. The color touch display can be wiped for 30 seconds without executing a function.	
	Barcodes	Opens the “Barcodes” menu for selecting rack code or material barcode	
	Archive of cycle sequences	Opens the “Cycle selection” menu for viewing or reprinting cycles that have already been completed.	
	Return transport	Transports the rack back onto the transport trolley (for example).	The button must be held down constantly during the transport process.
	Docking	Cancels the process for docking instrument loading trolleys (option) and withdraws the ILTs again	
	Printer	Prints the cycle report for the selected cycle at the connected printer.	
	PC	Menu: Process archive – Cycle selection Sends the cycle report for the selected cycle to the cycle documentation system.	
	Email (Option)	Menu: Service – ISA (Option) Contacts MMM customer service or a company/person authorized by MMM by sending them an email.	
	Cleaning the tanks	Opens the drainage valves so that the splash water can run off easily when flushing the tanks.	
	Material barcodes	Allows you to view, edit and delete barcodes of DIN trays, etc.	

3.1.3.1 Menu overview on the loading side

Home page

The “Start” button is only activated when the machine is ready to start and the program selection screen appears.



Example

- Logging users in and out, see "Logging users in and out", Page 60
- Program name and number
- Start button, chamber door button open/close, button to "Quick user access"and button to "Initial menu"
- The status bar is located along the bottom edge of the screen and displays information in plain text, e.g. an alarm message.

After starting a program, the remaining time display appears.



The “Change screen” button allows you to switch between the “Remaining time”, “Program information” and “Cycle process” menus.



Remaining time

- Program name and number
- Current cycle number
- Current program step
- Action during program step
- Remaining program time



Program information

- Information on the current program



Cycle sequence

- Curve representation of the process-related active sensors.

The Open chamber door button is only activated if the chamber door can be opened.

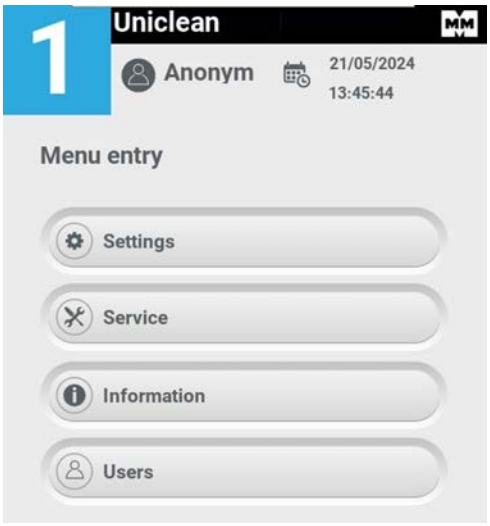
As soon as an instrument loading trolley (option) is inserted into the chamber, the machine detects it. Only the programs configured for BWIs can be selected. Programs are available for handling one or two BWIs. The operator must select the program according to whether there are one or two BWIs.

Quick user access



- Machine information (MMM Service Hotline info, software version, model, serial number, cycle counter and next maintenance)
- Screen cleaning, see "Cleaning the control elements", Page 130
- Barcodes
- Stop docking system
- Cleaning the tanks
- Maintenance information, see "Planning service work", Page 117
- Archive of cycle sequences, see "Releasing the cycle", Page 73
- Last program run, see "Last program run ", Page 77
- RUMED360 IP address, see "Network outage", Page 88

Initial menu



- **Settings** for the supervisor and specialist only
- **Service menu**: Printing a test page and other settings for the supervisor and specialist
- **Information** for the supervisor
- **Users**: The User Manager option can be used to create operators with different permissions

3.2 Unloading side (two-door machines only)

The machine also supports single-door operation. In this case, the unloading side is deactivated.



1 Chamber door button
2 EMERGENCY STOP
3 Thermal plotter (option), not shown

The unloading side can be fitted with a color touch display as an optional extra (Chapter 3.1.3, "Color touch display"). The color touch display replaces the chamber door button.

3.2.1 Chamber door button



Chamber door button for opening and closing the chamber door.

The chamber door button is only active and illuminated when operating the chamber door is permitted. Pressing this button during the program sequence or when the chamber door on the loading side is open does not trigger door activity.

The chamber door on the unloading side can be opened and closed as often as required provided that the chamber door on the loading side is not open. Once the chamber door on the loading side has been opened, the chamber door on the unloading side can only be opened again once the program sequence has run successfully.

According to the chamber door logic, the chamber door on the unloading side must be completely closed again after it has been fully opened in order for the chamber door on the loading side to be released and the chamber door button on the loading side to become visible.

3.2.2 EMERGENCY STOP



The emergency stop (see "EMERGENCY STOP", Page 24) must only to be pressed in an emergency, e.g. when there is a risk of personal injury or a risk of damaging the material to be treated or elements of the machine.

Example

3.2.3 Emergency opening button



The red illuminated emergency opening button is located inside the chamber. If persons inside the chamber find themselves in danger, they can press this button. This stops all running processes immediately and opens the door on the loading side.

Pressing the emergency opening button still opens the chamber door even if the maintenance hatch is open.

3.2.4 Menu overview on the unloading side (option)

Home page

The operator can only log in or out on the unloading side and open the chamber doors during a regular cycle sequence.



The screen has no function while no program is running.

After starting a program, the remaining time display appears.

The Open chamber door button is only activated if the chamber door can be opened.

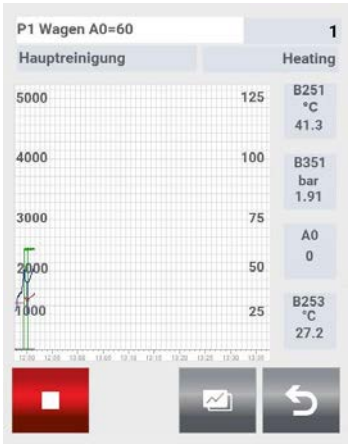
The “Change screen” button (see circle) allows you to switch between the “Remaining time”, “Program information” and “Cycle process” menus.



Remaining time



Program information

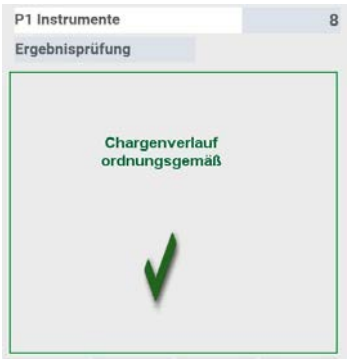


Cycle sequence

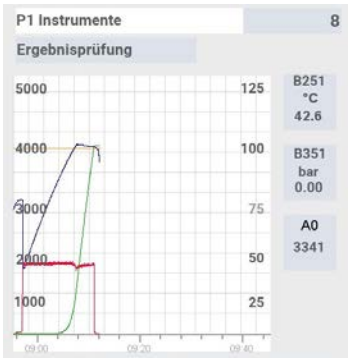
For information on the screens, see Chapter 3.1.3.1, "Menu overview on the loading side"

Checking the results on completion of the cycle (option)

The “Change screen” button allows you to switch to the subsequent screens to check the results.



Cycle sequence information



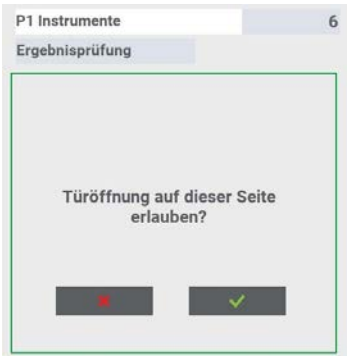
Cycle sequence

- Curve representation of the process-related active sensors.



Program information

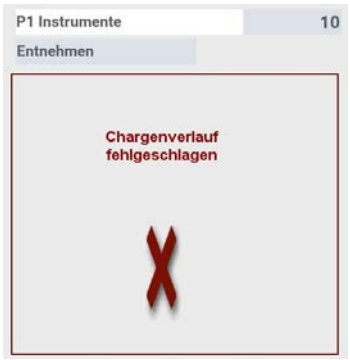
- Information on the current program



If the cycle sequence completed properly, the opening of the chamber doors can be allowed or denied on the unloading side.



Opening of the chamber door on the unloading side was confirmed with “Yes”. Depending on the setting, the chamber door button can be confirmed, or the chamber doors can open automatically.



Opening of the chamber door on the unloading side was rejected with “No”.

Chamber lighting

LED lamps light up inside the chamber of the machine. The color of the lighting changes depending on the operating state of the machine. The chamber lighting is clearly visible from the outside through the glass door.

Colour	Meaning
Blue	Machine ready for loading
Blue, flashing	Machine ready for unloading
White	Machine in operation, program running
Red	Fault

4 Operation

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

Note

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.

It is only possible to log in on the start screen.

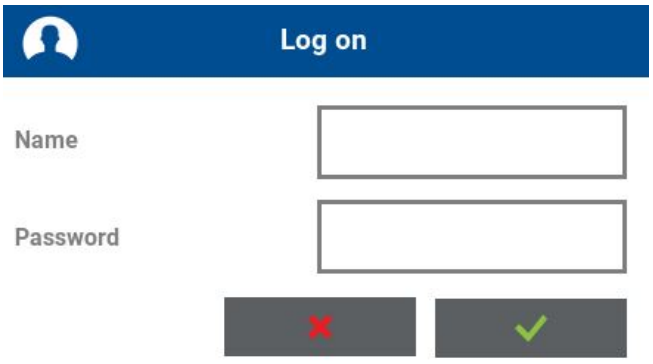
If no user is logged in, the user "Anonymous” appears in the user bar.

If the **User Manager** (Chapter 1.3.2, "User permissions") option is used, operator log-in can be configured so that each operator has to log in with his name and password.

Operator log-in

Anonym ▶ Press the log-in button.

The log-in window appears.



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

- Enter the corresponding password.
- Confirm the entry.
- Press the OK button.

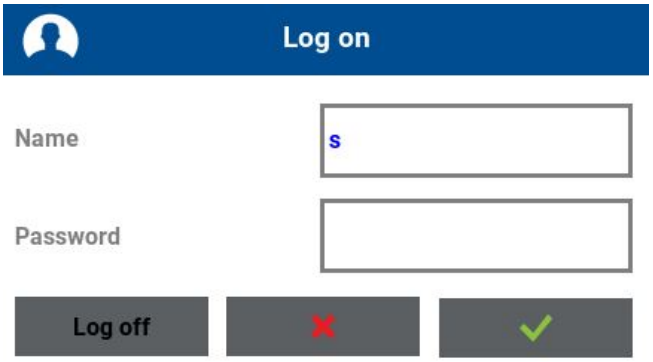
After log-in, the corresponding user name (e.g. “S”) appears in the title bar.

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

Log out actively to prevent misuse of rights!

The user is only logged out automatically once the specified log-out time on the program selection screen and the program sequence screen!

User log-out



- Press the **Log out** button.

The user name “Nobody” appears in the user bar.

4.2 Programs

The actual program selected is configured according to the operator’s requirements during commissioning. The names of the individual programs can be customized by the operator. The operator must ensure that every program used has been validated with a suitable load.

4.3 Principles for machine cleaning and disinfection

Successful machine cleaning and disinfection requires access to all internal and external surfaces of the material to be treated. It may be necessary to take the materials apart and/or pre-clean them.

The operator is responsible for ensuring the materials undergo proper pre-treatment.



Observe pre-treatment instructions of the instrument manufacturer.

Material to be treated must always be suitable for machine cleaning.

Correctly loading the material to be treated so that it can be properly washed is essential for effective machine treatment.

The temperature of the water that first flows into the chamber must not exceed 40°C, as protein coagulates at higher temperatures. This can lead to major cleaning problems.

Using deionised water, especially for the final rinse, prevents spots, discolouration and corrosion.

Instrument program option

- When using rinsing devices, use inserts that are geared towards the instruments.
- Clean and handle instruments in accordance with the manufacturer's instructions. For example, do not use metal brushes or metal scouring pads for manual cleaning and make sure that any instruments that have become worn, corroded, deformed, porous or damaged in any other way are separated out.
- Always treat articulated instruments with a paraffin-based maintenance product (this does not apply to flexible endoscopes and accessories).

4.4 Information on loading



It is imperative that you observe the safety instructions and warnings in the instructions for use of the loading trolley!

The cleaning performance can only be ensured if the loading trolley, load, and program are all suitable for the material being cleaned.

If this is not adhered to, the cleaning performance could be impaired. Check the cleaning results. If the cleaning performance is insufficient, the cleaning and disinfection processes must be repeated.

4.4.1 Chamber

- The chamber must be clean see "Maintenance activities ", Page 119.



The machine must be cleaned before each instrument program!



If only chemical disinfection programs are used during a shift, a self-disinfection program must be run at the end of the shift.

4.4.2 Loading trolleys and inserts



Observe the following points for a valid and reproducible result!

All materials to be treated must be suitable for machine cleaning and disinfection. Follow the reprocessing instructions of the manufacturer of the material to be treated!

Ensure the loading configuration and choice of program correspond to the validation (see "Validation", Page 11)!

General information

- The loading trolley must be loaded correctly.
- Materials must not project from the loading trolley!



Observe the separate instructions for the loading trolleys and insert modules. For exact details, see the instructions for use of the relevant loading trolley and insert module!

BW Flex Container

- Only load similar materials!
- For mixed loads, a program suitable for the higher priority materials must be selected. Refer to the priority of materials overview in the instructions for use of the BW Flex Container.

BWI

- Ensure the DIN trays are not overloaded.
  The maximum load weight is 10 kg!
- The rotating arms in the BWI must move freely.
- Only load similar materials!
- For mixed loads, a program suitable for the higher priority materials must be selected. Refer to the priority of materials overview in the instructions for use of the BWI.
- Before loading the MIS supply strip with hollow body instruments, ensure that both the MIS supply strip and the instruments are not obstructed, see "Before each cycle:", Page 119.

4.4.3 Transport trolley

When treating transport trolleys with double doors, please observe the following points:

- Open the doors of the transport trolley and lock them in place before pushing the trolley inside, as unsecured doors can damage machine components during the program sequence.
- Remove all loose parts that are located on or inside the transport trolley.
- Push the transport trolley into the chamber with the open side of the transport trolley pointing in the direction of the machine compartment. This is because the transport trolley will be tilted inside the chamber during the process so that the water can drain away.

4.4.4 Check during the cycle

For a cycle process to be successful, the materials being treated must be cleaned uniformly. It is necessary to check the function of the lateral nozzle pipes so the cycle can be released after the program has completed.

Inspecting the lateral nozzle pipes

- Ensure the lateral nozzle pipes swivel around their own axes during the spraying phase. This can be identified by the spray pattern also swiveling.
- During a cycle process and during a spraying phase, briefly observe the following through the glass door of the chamber:
  - The movement of the nozzle pipes on the loading side (left- and right-hand spray pattern)
  - The movement of the nozzle pipes on the unloading side (left- and right-hand spray pattern).

The changes in the spray pattern must be readily apparent during the observation phase. This can be identified by the jet of water spraying alternately on the chamber door and then disappearing -> the nozzle system is functioning correctly!

If the jet of water is spraying constantly on the door or at a single location, the nozzle pipes are NOT moving! -> the nozzle system must be repaired.

In this case, the cycle must be regarded as faulty!

4.5 Loading and starting the program (standard)

Opening the door

In order for the machine to be ready, there must not be any pending faults and the chamber doors must be closed. The “Machine ready for use” message must appear.



- Press the door button to open the chamber door.

Scanning barcodes (option)

- Scan the barcode of the loading trolley.

Loading the chamber

- Take the loading trolley that has been prepared according to the loading instructions (Chapter 4.4, "Information on loading") and push it into the chamber as far as it will go so that it is positioned correctly and properly secured.



- Press the door button to close the chamber door.

The symbol on the door button changes to “Open door”.

Provided the start command has not yet been issued, the door can still be opened again.



Before closing the chamber door and before starting the program, make sure that there is no one inside the chamber. If there is, you must not close the door!

Selecting a program

- Select a program. The selected program is highlighted in color.

  If you have the barcode on loading trolleys option, the program will be selected automatically.



Make sure that the selected program is suitable for the materials to be processed!

If necessary, select a program that is suitable for high priority materials.



Before pressing the “Start” button, make sure that there is no one inside the chamber. If there is, you must not issue the start command!



- Press the start button.

In order for a program to be started, there must not be any pending faults and the chamber doors must be closed.

When you press the “Start” button, the “Cancel program” button appears. You have the option to cancel a program while it is running.

4.6 Loading and starting the program with BWI (option)



Risk of injury!

The fully loaded BWI is very heavy!

When using ramps, a BWI that has started rolling off cannot be controlled and must therefore be guided by 2 persons.

Opening the door

In order for the machine to be ready, there must not be any pending faults and the chamber doors must be closed. The “Machine ready for use” message must appear.



- Press the door button to open the chamber door.

Preparatory steps when using the instrument program

The following cleaning tasks must be performed before using an instrument program:

- Clean the chamber (see "Cleaning the chamber", Page 135).
- Clean the flow-through filter (see "Cleaning the flow-through filter (option)", Page 137).
- Clean the tanks (7.9 "Cleaning the tanks", Page 133) as described in the relevant sections.
- The successfully performed cleaning process must be documented. This is to be suitably organized by the operator.

Scanning barcodes (option)

- Scan the barcode of the BWI.

Loading the chamber



Reduced cleaning performance!

Blockage of the filter!

OR shoes and OR shoe soles must not be processed together with instruments!

The loading instructions for the BWI must be observed (see "Information on loading", Page 62)!

- Prior to each program sequence, ensure the rotating arms on the BWI are moving freely.
- Push the first of two BWIs (depending on the model) into the chamber.

- Push the BWI into the chamber as far as it will go so that it is positioned correctly and properly secured.

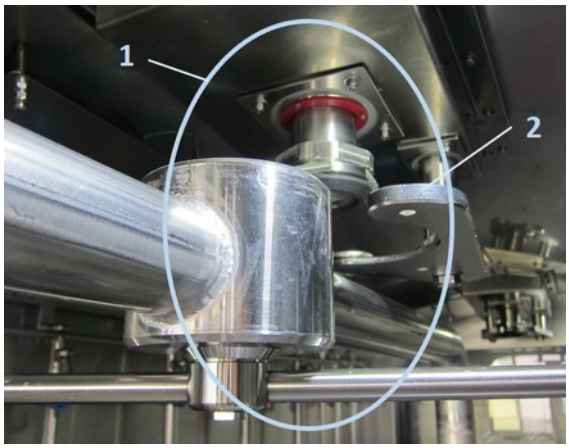
When pushing in the BWI, keep it as perpendicular as possible to the chamber door!



The guide rollers must remain in position on the guiding rails!



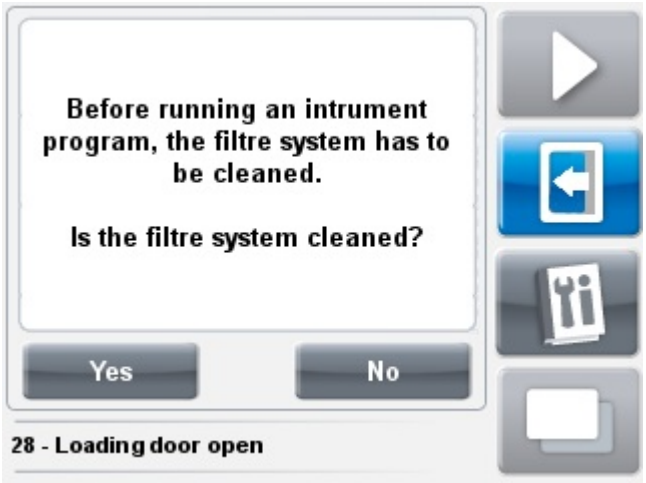
- The coupler moves down and opens.
- Push the BWI as far as the coupler stop (1) on the chamber unloading side and until the retaining claw (2) grasps the BWI.



- The BWI is secured by the retaining claw and can no longer be pulled out.
- If applicable, push the second BWI into the chamber as described above and until the retaining claw grasps the BWI. The BWI is secured by the retaining claw and can no longer be pulled out.

The machine can also be operated with just one BWI!

- A prompt appears on the display asking if the filter system has been cleaned.



▶ Confirm the prompt with 

, but only if you have carried out the cleaning steps described above!

If you select No, the retaining claw moves up again and releases the BWI for removal.

Clean the trays!

Before closing the chamber door, make sure that there is no one inside the chamber. If there is, you must not close the door!



▶ Press the door button to close the chamber door.

As soon as the door is no longer fully open, the symbol on the door button changes to “Open door”.

Provided the start command has not yet been issued, the door can still be opened again.

Starting the program

Only the programs configured for the BWI appear.

- Select a program.

Different programs are available depending on whether one or two BWIs are loaded into the machine.

For mixed loads, a program suitable for the higher priority materials must be selected.

If you no longer want to process an instrument cycle after pushing the BWI inside, you must use the display to reverse the docking process, open the door, and pull the BWI out of the chamber again.



- Open Quick user access.



- Press the “Dock” button to stop the process.

Before pressing the “Start” button, make sure that there is no one inside the chamber. If there is, you must not issue the start command!



- Press the start button.

In order for a program to be started, there must not be any pending faults and the chamber doors must be closed.

When you press the “Start” button, the “Cancel program” button appears. You have the option to cancel a program while it is running.

Watch all the rotating arms on the BWI through the glass panels in the doors on the loading and unloading sides.

During the spray phase that involves the rotating arms, the rotating arms must rotate.

If any of the rotating arms are not rotating, the cycle must be regarded as faulty.

The treatment process must be repeated.

4.7 Canceling 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 machine automatically goes into a safe state and:

- the chamber is drained completely, and moist air from the chamber is discharged into the on-site exhaust air system,
- the chamber light turns red,
- an alarm message is shown on the display.

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

4.8 Unloading the chamber

Program sequence completed correctly

Once the program has been successfully completed, the door button on the unloading side is activated. Depending on the setting, the door on the unloading side either opens automatically or you have to open it manually.



The material is very hot after treatment.

Wear gloves to protect your hands from heat when removing the loading trolley.



Risk of injury!

The fully loaded BWI is very heavy!

When using ramps, one person will not be sufficient to control the rolling BWI!

The BWI must be guided by 2 people!

- Press the door button on the unloading side to open the door.
- Make sure that the maintenance hatch is closed.
- Remove the loading trolley.

- Press the door button on the unloading side to close the door.
  The door on the loading side is only enabled for opening once the door on the unloading side has been closed. Until the door on the loading side is actually opened, the door on the unloading side can still be reopened.
- As soon as the door on the loading side is opened, the door button on the unloading side is deactivated and it is no longer possible to open this door.

Program sequence not completed properly

If a program does not run correctly, “Process failed” is shown on the display on the loading side.

The door on the unloading side cannot be opened. Instead, the door on the loading side is activated.

The cause is described on the display status bar using plain text and a fault number (Chapter 6, "Operating safety and faults"). The operator must take appropriate corrective measures.

4.9 Releasing the cycle

The controller regulates and monitors the program sequence and compares the measured process data with the set values. If the process-related program parameters are not adhered to, the program is canceled

If the values fall within their permissible parameter limits, the message “Cycle process O.K.” appears on the cycle report.



The “Cycle process O.K.” message is not sufficient, however, for approving the cycle!

The cycle is released based on the following visual inspection and the cycle report.

Checking the cycle report

The following requirements must be met:

- The program that was run was suitable for the unloaded material in the relevant loading trolley.
- If an instrument program (option) has been run, the number of processed BWIs tallies with the program performed. For mixed loads, a program suitable for the higher priority materials must have been run.
- The data on the cycle report must be identical to the data determined during validation.

Visually inspecting the treatment results

After removing the material to be treated from the chamber, the user must verify the treatment results by carrying out a visual inspection. The following requirements must be met:

- The load must not have changed.
- All connections of hollow-body instruments to the MIS supply strip (option) must still be connected.
- Cleaning result: there are no residues on the item.
- Drying result: the item is dry.

Checking the MIS supply strip

After every cycle using an MIS supply strip, the MIS supply strip needs to be checked for blockages: see "Maintenance activities ", Page 119

Checking the rotating arms (BWI option)

The following requirements must be met:

- All rotating arms can be rotated easily by hand.
- All end caps on all rotating arms are correctly attached.
- There is no mechanical damage to the rotating arms.

Cycle approval requires:

- Successful check of the MIS supply strip (option) before and after starting the program.
- Successful check of the lateral nozzle pipes while the program is running.
- Successful inspection of the rotating arms (option)
- Successful visual inspection of the treatment results
- Successful inspection of the filter if modules for eye instruments have been used
- Successful check of the cycle report
- Successful check that the material to be treated matched the program.

Release 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.

After the cycle is approved, the user must ensure that the cycle report is added to the external archive. The operator is responsible for monitoring the electronic archive. In particular, possible disruptions to the network connection must be considered within this context. If a report has not been added to the electronic archive, either the corresponding printout must be retained or the cycle in question discarded.

Displaying and reprinting past cycles

The last 50 cycles stored on the machine can be shown on the display and reprinted.

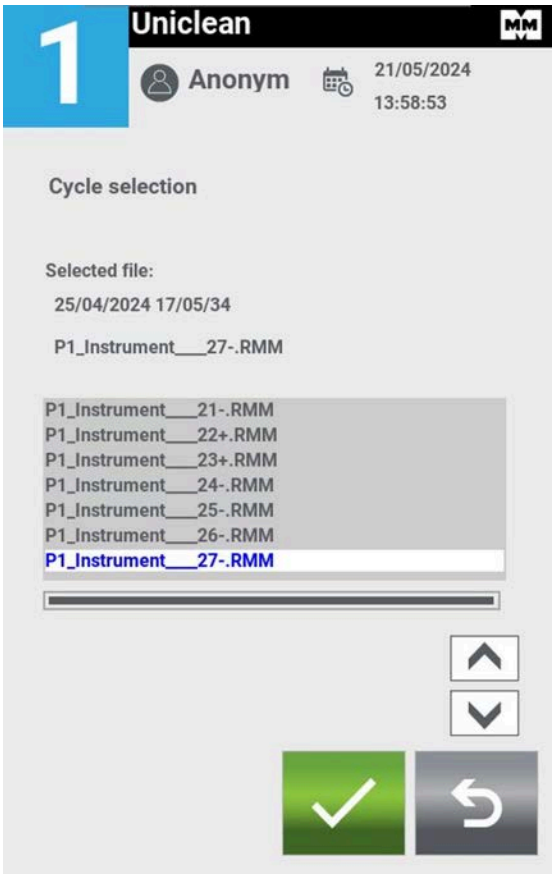
Proceed as follows:



▶ Open Quick user access



- Open Archive of cycle sequences.





- Use the scroll buttons to scroll up or down.



- Select the desired cycle and confirm with the confirmation button.





- Press the “Printer” button.

The cycle data is printed.



- Press the “PC” button.

The cycle data is sent to the cycle documentation system again.

Any irregularities must be reported to the system supervisor and appropriate measures must be taken.

4.10 Standby

If the machine is not operated for some time, the controller goes into standby mode. “Standby mode active” is shown on the black display.

After touching the display, it jumps back to the previous screen.

4.11 Last program run

The last program run function can only be set for two-door machines.



A 'Last program run' button is available in Quick user access 2 / 2.

The function can be selected if you want the machine to switch automatically to standby or off mode after processing and removing the materials.

The function must be activated before or during a running program by pressing the button. The function can be deactivated again by pressing the button again.

Once a program has run through properly, the materials have been unloaded and the chamber door on the unloading side has been closed, the machine automatically drains the tanks and the chamber. The machine switches off automatically. If auto start is activated, the machine switches to standby.

We recommend automatic tank cleaning (option) as the last program run!

4.12 Handling chemicals



The machine, when used as intended, requires the use of chemicals.

Observe the instructions in the respective safety data sheet of the process chemicals supplier (including the transport and storage requirements). This applies not only to the handling of the chemical containers and the equipment that comes into contact with chemicals but also to the personal protective equipment.

4.12.1 Safety instructions for changing the process chemicals

When changing process chemicals, take care not to mix up any of the connections or cannisters! The connecting lines running to the machine must be put back just as they were during validation.



The operator must implement organizational measures to ensure that the connecting lines between the machine and the chemical connection points are always hooked up correctly.

To avoid any errors, each dosing system component on the machine is labeled and color coded.

Color	Dosing system
Green	Dosing line 1
Red	Dosing line 2
Blue	Dosing line 3
Yellow	Dosing line 4



Mixing up process chemicals can render the cleaning and disinfection process ineffective and may leave residue on the medical devices.

Therefore, the warnings and safety instructions of the process chemical manufacturer must be observed.

The operator or user must put suitable measures in place to ensure that process chemicals cannot get mixed up.

4.12.2 Changing the process chemical brand or type



Before using other process chemicals, this should be discussed in advance with the local contact person from MMM to confirm whether alternative process chemicals can be used.

If there is a change in the types of chemicals used compared with commissioning (see Chapter 2.3.2, "Process chemicals"), the program must undergo qualification again. The operator must inform the following people:

- The manufacturer of the washer-disinfector system
- The supplier of the chemicals
- The manufacturer of the material to be treated

Together, they must draw up a concept that takes account of these new conditions.

The machine is not to be operated until it has undergone another requalification.

Under certain circumstances, a change of process chemical may mean that entire system components have to be replaced, e.g. various elastomer components (tubes, seals, etc.).

Before changing the process chemical, the dosing system must always be flushed completely with sufficient quantities of fresh water.

Compatibility of the process chemicals

In consultation with the supplier of the process chemicals, the operator must ensure that the process chemicals can be safely used together and are compatible.

Process chemicals for treating instruments (option):

The following process chemicals were used in the type testing:

- Cleaning: Dr. Weigert, neodisher mediclean forte
- Rinsing: Dr. Weigert, neodisher mediklar



Process chemicals may only be used if they can be safely combined with one another. Otherwise, there is a risk of an uncontrollable chemical reaction occurring, e.g. an explosion, damage to the material being treated or machine parts, impaired effect, and so on.

4.13 End of workday/change of shift

The machine and tanks (if installed) must be drained and cleaned at the end of each shift, see "Maintenance activities ", Page 119

4.14 Sending messages to customer service via ISA (option)

With the ISA (Intelligent Service Advisor) option, MMM customer service or a company/person authorized by MMM can be informed of the need for service via e-mail. This option must be activated via a USB stick.

S ▶ Log in as the supervisor.



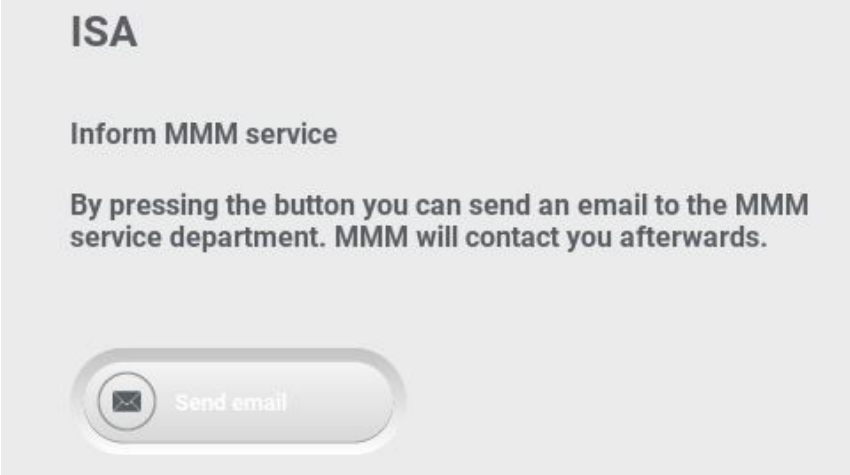
- Open the “Menu overview”.



- Open the “Service” menu.



- Open the “ISA” menu.



- Send an e-mail

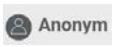
5 Machine configuration

5.1 Configuring the User Manager (option)

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

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

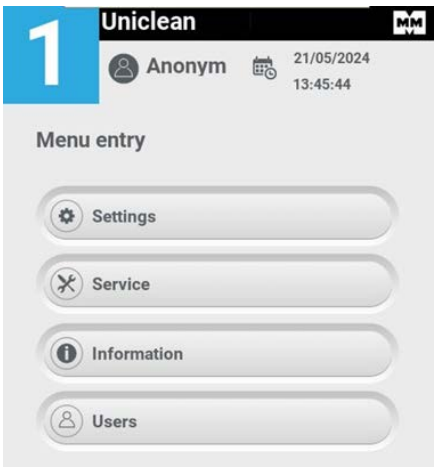
The various user passwords enable access to the corresponding menu levels.



- Log in as a user with the authorization to administer users.



- Open the “Configuration” menu.



- Press the **User** button.

  The button is only activated if the option has been enabled.





- 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. The user is only logged out automatically on the “Program selection” and “Program sequence” screens!



- Save the entry. The menu will close simultaneously.



Users can also be deleted



and passwords changed on this menu screen.

5.2 Setting cycle report print and save options

Depending on which printer is being used, you can adjust the following settings.

Printing the cycle report

The following options can be enabled in the “Settings” - “Printer” menu:



- Direct printing to a printer
- Direct printing on an integrated thermal printer

Direct printer

- Activate **”Direct printing”** by setting the green tick.
- Enter the IP address of the direct printer.

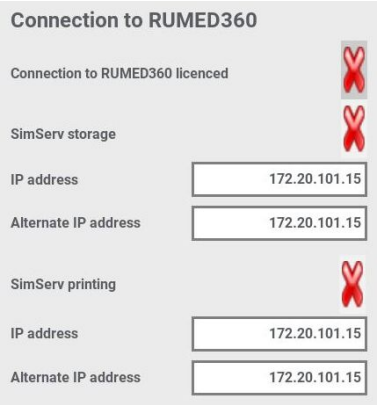
Thermal printer

- Activate **“Thermal printer”** by setting the green tick.

Saving the cycle data and Printing via network (option)

RUMED360 Cycles needs to be licensed by a specialist via a USB stick. The IP address of the network computer can be changed here.

The following options must be enabled in the “Settings” - “RUMED360 IP address” menu:



- Information on whether the RUMED360 connection is licensed (green tick).
- Save cycle data in SimServ
- Cycle report printing on a network printer (option)

1. Enable the cycle data saving function (set the green tick).
2. Enter the IP address and an alternative IP address of the network computer on which SimServ is installed.
3. Enable Cycle report printing on a network printer (set the green tick).
4. Enter the IP address and an alternative IP address of the network computer on which SimServ is installed.

6 Operating safety and faults

Safety-related equipment

The machine is equipped with safety and monitoring equipment to enable safe operation (Chapter 1.1, "Intended use ") when used as intended.

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

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



Observe the instructions in see Chapter 1, "Security"

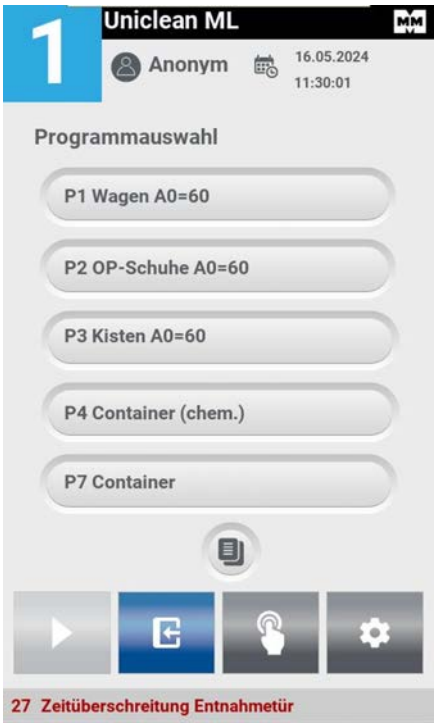
If the fault cannot be eliminated by a qualified person, contact the MMM customer service or a person or company authorized by MMM.

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 Fault messages

If a fault occurs during operation, the respective fault message is shown on the display.



Faults with automatic program cancellation

Most fault messages automatically cancel the program. The chamber is drained, i.e. the chamber drainage valve is opened, the discharge pump operates and moist air from the chamber is blown into the on-site exhaust air system.

Faults without automatic program cancellation

Some faults only show an error message and do not automatically cancel the program. However, the fault must be eliminated once the program sequence is complete and before a new program can be started.

One example is the message: *Dosage 1 empty.*

In this case, the message is displayed if the remaining quantity of process chemicals is sufficient to complete the current cycle successfully. However, the process chemicals must be topped up before a new cycle can be run.

6.2 Responding to faults

If a fault occurs, carry out the following steps:

1. Analyze the fault and, if possible, eliminate it.
2. Report the fault to the system supervisor without making any machine modifications.

3. Analyze the fault and have the cause eliminated by a specialist.
4. Depending on the type of fault, notify MMM customer service, remembering to quote the plain text message and the fault number, if applicable via ISA (option).



Document the fault and its consequences in the medical devices log / equipment log (including the fault number and precise wording of the fault message).

Confirming alarm messages



Alarm messages can only be confirmed after the cause has been eliminated.

- Click the red fault message bar on the display on the loading side.

  A page with all the status and alarm messages appears.





Press the door button to confirm the alarm message.

This confirms all alarm messages!

The alarm message has now been confirmed and the machine is ready for a new program sequence.



If the operator is not logged in or not authorized to confirm alarm messages, the log in dialog appears, "Logging users in and out".

6.3 Responding to specific faults

6.3.1 Power failure

There is no need to intervene in the machine when it is idle, as all media valves are closed in standby mode. The material to be treated remains in the chamber until the compressed air or electricity supply is restored.

- In the event of a power failure, the machine must be switched back on.
- Confirm the fault.

The program must be restarted after the fault has been confirmed and the chamber door opened.

6.3.2 Fallen parts, jammed moving machine parts

If machine parts have jammed, e.g. due to fallen parts in the chamber, the system supervisor must be notified!



Risk of injury or crushing!

The user must not attempt to rectify the problem independently and alone.

6.3.3 Network outage

If a contingency plan is included, the cycle print can be redirected to a direct printer.

It is possible to switch to an alternative IP address. The alternative IP address was specified in RUMED360 connection under Settings.



- Go to Quick user access.



- Press the “RUMED360 IP address” button.



The button lights up blue, the alternative IP address is active.

The alternative IP address remains active until the button is pressed again.

6.3.4 Process chemicals not being supplied directly

- Pull the suction lance out of the empty container.
- Replace the empty chemical container with a full one.
- Insert the suction lance into the new chemical container.



A particular dosage pump, a specific suction lance and two flow meters (along with the corresponding connecting tubes) are assigned to each process chemical supply.

Ensure that the suction lance is inserted into the correct container. All connecting tubes on the suction side are labelled with text and colour coded.

6.3.5 Process chemicals not being supplied from the central dosing system

If a central dosing system is used, the operator is responsible for appointing a trained person to replace the chemical containers and for laying down the procedure in internal work instructions.



The operator is in charge of training the person responsible for replacing the containers.

6.3.6 EMERGENCY STOP

If the EMERGENCY STOP has been pressed, proceed as follows:

- Notify the system supervisor.
- Explain the reasons for pressing the EMERGENCY STOP.
- Clarify the cause and document the incident in the equipment log.
- Eliminate the cause.
- Unlock the emergency stop switch.
  In the case of an emergency stop with key, the key must be kept by the system supervisor and never left at the machine itself.

- Turn on the master switch in the control cabinet.

If the EMEGERNCY STOP has been pressed while the loading door was open and the electric control cabinet is not accessible, proceed as follows:

- Open the panelling.
- Release the toothed belt between door and door driving motor.
- Close the door manually.
- Re-fit the toothed belt.
- Close the panelling.
- Switch on the master switch on the electric control cabinet.

- Switch on the machine at the loading side.
- Confirm the fault message (user right required).

6.3.7 Insufficient water quality

Water quality has a significant impact on the cleaning and disinfection results.

Insufficient water quality leads to:

- The formation of spots on the material to be treated
- Pronounced foam formation
- Inadequate cleaning performance

If there are signs of insufficient water quality, proceed as follows:

- Have the water quality tested.
- Clean the machine.

6.4 Status and alarm list

The chamber door is referred to as just door in this section.

No.	Message	Reason	Possible remedy
1	Machine is ready for operation	Ready to start the program. No fault present.	-
3	Confirmation required	There are faults that must be confirmed by the user.	-

No.	Message	Reason	Possible remedy
4	Test program active	The active program has been declared as a test program in the parameters.	-
5	Power failure during program run	A power failure has occurred on the operating panel during a cycle.	– Check on-site power supply – Check that power pack in control cabinet is functioning correctly – Check cable connections between power pack and CPU for loose contacts
6	Program manually advanced	The process has been manually advanced to another process step.	-
7	Program stop performed	The “Stop program” button on the display has been pressed.	– Analyze why the button was pressed
8	EMERGENCY STOP pressed	The EMERGENCY STOP on the machine has been pressed, switch defective.	– Analyze why one of the two EMERGENCY STOP switches was pressed – Check both EMERGENCY STOP switches for damage
9	Standby mode	The machine is in standby mode. No display activity for some time.	– Touch the screen
10	Local cycle storage failed	Process data could not be stored on the CF card. Not enough memory, CF card defective, internal fault.	Contact customer service
11	Save to network failed	Process data could not be transferred to SimServ.	– Check that the IP address of the SimServ computer is correct – Check that SimServ is running – Check that the network addresses are correct
12	Cycle data processing active	Cycle data are being processed. Cycle has just finished, reloading or reprinting cycle report.	-
13	Program run paused	Program has been interrupted. Manual intervention by an authorized person.	-

No.	Message	Reason	Possible remedy
14	Network printing failed	Print job not sent to SimServ.	– Check that the IP address of the SimServ computer is correct – Check that SimServ is running – Check that the network addresses are correct
15	Printing failed	DIN A4 direct printing failed.	– Check printer IP address – Check that printer is switched on – Check paper level in printer – Check that correct printer is connected – Check whether the cycle data contain the correct values
16	Printing active	Direct print job in progress at DIN A4 direct printer. Cycle has just finished, reprinting cycle.	-
17	Thermal printing failed	Printout failed.	– Check that printer is working – Check connection cable – Check whether the cycle data contain the correct values
18	Thermal printing active	Print job in progress. Cycle has just finished, reprinting cycles.	-
19	Integrated printer: No connection	No connection to printer	– Check that printer is connected to power supply – Check connection cable – Check interface card
20	Thermal printer: No paper	Printer reports out of paper.	– Check paper level in printer (Chapter 6.6, "Thermal printer paper exchange (option)") – Inspect printer
21	Door sealing pressure too low	Door seal is actually pressed on but not registered as pressed on.	
22	Door seal pressure too high	Door seal is not actually pressed on but is registered as pressed on.	

No.	Message	Reason	Possible remedy
26	Time exceeded loading door	Door movement on loading side takes longer than expected.	– Check door drive settings on loading side – Check door drive for defects – Check whether an object or person is in the way of the door on loading side (chamber door area or machine compartment)
27	Unloading door time exceeded	Door movement on loading side takes longer than expected.	– Check door drive settings on unloading side – Check door drive for defects – Check whether an object or person is in the way of the door on unloading side (chamber door area or machine compartment)
28	Loading door open	Door on loading side not registered as completely closed.	– Check that door on loading side is closed completely – Check position and setting of end switch for closing the door
29	Unloading door open	Door on unloading side not registered as completely closed.	– Check that door on unloading side is closed completely – Check position and setting of end switch for closing the door
30	Loading door open during cycle	Door on loading side not registered as completely closed during process run.	– Check position and setting of end switch for closing the door
31	Unloading door open during cycle	Door on unloading side not registered as completely closed during process run.	– Check position and setting of end switch for closing the door
32	Service door open on loading side	Service door on loading side registers as open.	– Close service door on loading side – Check end switch of service door on loading side
33	Service door open on unloading side	Service door on unloading side registers as open.	– Close service door on unloading side – Check end switch of service door on unloading side

No.	Message	Reason	Possible remedy
34	Confirmation required to open door	A fault requiring confirmation occurred during the process run. The parameter settings do not allow the door to be opened without first confirming the fault.	– Confirm fault
35	Check loading door	Door switch on loading side is sending incorrect signals.	– Check door end switch
36	Check unloading door	Door switch on unloading side is sending incorrect signals.	– Check door end switch
37	Mode 'Open both doors' active	Both doors have been opened simultaneously in the “Service” menu. Manual intervention by an authorized person.	-
38	Door seal pressure not reached	It is taking too long to press on the door seal(s).	
39	Door seal pressure failed to drop	It is taking too long to release the door seal(s).	– Pneumatic valve defective
40	Door seal press. too low in program	Door seal pressure has dropped during process sequence.	– Check door seals for defects – Check on-site compressed air supply
41	Doorway not free on loading side	It is taking too long to close the door on the loading side. Door opens again.	– Check whether an object or person is in chamber door opening – Check whether door drive system is loose or defective
42	Doorway not free on unloading side	It is taking too long to close the door on the unloading side. Door opens again.	– Check whether an object or person is in chamber door opening – Check whether door drive system is loose or defective
43	Shutdown procedure running	The user has switched off the machine. The machine is being completely drained first.	-
44	Shutdown procedure failed	An error occurred during the shutdown procedure.	– Check whether object or person is in the way of the door – Check compressed air supply – Check chamber level sensor – Check drainage system – Check chamber drainage valve

No.	Message	Reason	Possible remedy
45	A0 value too low	A0 value is relevant to the process result but the required A0 value has not been reached. Program aborted prematurely.	– Check whether correct program was selected – Check and, if necessary, replace sensors
46	Parameters changed during program	Parameters have been changed during a process run.	– Do not change any parameters while a program is running
47	Clock failure	Internal clocks of the control system are too different from one another (RealTimeClock, CPU, cycle time).	– Replace CPU, check for defects
48	Battery replacement required	Battery signals that voltage is too low.	Only for machines with glass control panel – Replace battery – only change the battery during operation! Battery will last for a few days/weeks.
49	Self cleaning - not for goods	The active program has been declared as a self-cleaning program in the parameters.	-
50	Inspection required for dosing line 1	Dosing line 1 is dosing less than expected. Deviation is still small enough.	– Check dosing hose 1 and remove air as required – For peristaltic pump: Replace worn hose in dosing pump – Check connecting hoses for blockages or air bubbles
51	Inspection required for dosing line 2	Dosing line 2 is dosing less than expected. Deviation is still small enough.	– Check dosing hose 2 and remove air as required – For peristaltic pump: Replace worn hose in dosing pump – Check connecting hoses for blockages or air bubbles
52	Inspection required for dosing line 3	Dosing line 3 is dosing less than expected. Deviation is still small enough.	– Check dosing hose 3 and remove air as required – For peristaltic pump: Replace worn hose in dosing pump – Check connecting hoses for blockages or air bubbles

No.	Message	Reason	Possible remedy
53	Inspection required for dosing line 4	Dosing line 4 is dosing less than expected. Deviation is still small enough.	– Check dosing hose 4 and remove air as required – For peristaltic pump: Replace worn hose in dosing pump – Check connecting hoses for blockages or air bubbles
54	Failure dosing line 1	Dosing line 1 is dosing less than expected. Deviation is too high.	– For peristaltic pump: Replace brittle hose in dosing pump – Check connecting tubes for blockages, air bubbles or leaks; remove air from dosing tube 1 as required. – Check flow meter for defects
55	Failure dosing line 2	Dosing line 2 is dosing less than expected. Deviation is too high.	– For peristaltic pump: Replace brittle hose in dosing pump – Check connecting tubes for blockages, air bubbles or leaks; remove air from dosing tube 2 as required. – Check flow meter for defects
56	Failure dosing line 3	Dosing line 3 is dosing less than expected. Deviation is too high.	– For peristaltic pump: Replace brittle hose in dosing pump – Check connecting tubes for blockages, air bubbles or leaks; remove air from dosing tube 3 as required. – Check flow meter for defects
57	Failure dosing line 4	Dosing line 4 is dosing less than expected. Deviation is too high.	– For peristaltic pump: Replace brittle hose in dosing pump – Check connecting tubes for blockages, air bubbles or leaks; remove air from dosing tube 4 as required. – Check flow meter for defects
58	Parameter settings are not valid	Incorrect parameter settings.	– Check logic between machine configuration and parameters set on display See also the audit trail entry.

No.	Message	Reason	Possible remedy
59	Disinfection temp. too low	Water temperature during disinfection is much too low.	– Check on-site steam supply – Check steam valve or electric heating elements for defects – Check condensate line for defective parts, counterpressure
60	Disinfection temp. too low for too long	Water temperature during disinfection slightly too low for too long.	– Check on-site steam supply – Check steam valve or electric heating elements for defects – Check condensate line for defective parts, counterpressure
61	Disinfection temp. too high	Water temperature during disinfection too high.	– Check that steam valve closes completely – Electric heating element contactor is defective
62	Water temperature too high	Water temperature during a washing step exceeds the set maximum temperature.	– Check that parameter settings are correct on display
63	Temp. too low during holding phase	Water temperature too low during a washing step.	– Check on-site steam supply – Check steam valve for defects – Check condensate line for defective parts, counterpressure – Electric heating element contactor is defective
64	Temp. too high during holding phase	Water temperature too high during a washing step.	– Check that steam valve closes completely – Electric heating element contactor is defective
65	Pressure of circulation pump too high	Pump pressure in circulation phase too high.	– Check jets for blockages

No.	Message	Reason	Possible remedy
66	Pressure of circulation pump too low	Pump pressure in circulation phase too low.	– Check jet system for leaks – Check that correct program was selected, as circulation fluid may foam if there is too much contamination – Check parameter settings for chemical dosing and process chemical selection – Check that correct chemical is being used – Check that process chemical is connected correctly
67	No program selected	No program selected on display.	-
68	Temperature probe B251 defective	Temperature probe reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
69	Temperature probe B252 defective	Temperature probe reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
70	Temperature probe B253 defective	Temperature probe reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
71	Temperature probe B254 defective	Temperature probe reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
72	Temperature probe B255 defective	Temperature probe reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
73	Temperature probe B256 defective	Temperature probe reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
74	Pressure transducer B351 defective	Pressure transducer reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
75	Pressure transducer B851 defective	Pressure transducer reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
76	Pressure transducer B852 defective	Pressure transducer reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor

No.	Message	Reason	Possible remedy
77	Pressure transducer B853 defective	Pressure transducer reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
83	Attention: Chamber may not be empty	Program canceled. Machine could not be completely drained.	– Check drainage system for possible blockages – Check pressure transducer of chamber for defects
84	Failure central dosing unit	Central dosing unit signals a fault.	– Eliminate fault in central dosing unit
85*	Motor protection circulation pump	Motor protection switch has been triggered.	*Only for older machines: – Check that motor protection switch in control cabinet is set correctly according to motor data sheet – Check pump for foreign objects and anomalies
86*	Motor protection drain pump	Motor protection switch has been triggered.	*Only for older machines: – Check that motor protection switch in control cabinet is set correctly according to motor data sheet – Check pump for foreign objects and anomalies
87*	Motor protection fan	Motor protection switch/fuse of internal drying fan has been triggered.	*Only for older machines: – Check that motor protection switch in control cabinet is set correctly according to motor data sheet – Check internal drying fan for foreign objects – Check internal drying fan for anomalies

No.	Message	Reason	Possible remedy
88	Motor protection	Motor protection switch has been triggered.	– Check that motor protection switch (circulation pump, discharge pump and drying fan fuse) in the control cabinet is set correctly according to the motor data sheet – Check pump and drying fan for foreign objects and anomalies – Check that motor protection switch of the lateral channel blower in the control cabinet is set correctly according to the motor data sheet
	Motor protection of comp ressor*	Motor protection switch of lateral channel blower has been triggered.*	*Only for older machines: – Check that motor protection switch of lateral channel blower in control cabinet is set correctly according to motor data sheet
89	No trolley inside the chamber	No trolley at specified position inside chamber.	– Check trolley position switch inside chamber – Only push correct trolley inside if machine has docking couplings in the chamber
90	Temperature limiter for chamber heating	– Check water level in chamber, not enough water in system – Check water level in tank 1 and tank 2, not enough water in system – Only check contactor in machines with electric heating systems	
	Temperature limiter for heating 1 *	Temperature limiter for the heater has been triggered.*	*Only for older machines: – Check water level in chamber, not enough water in system – Only check contactor in machines with electric heating systems

No.	Message	Reason	Possible remedy
91*	Temperature limiter for heater 2	Temperature limiter for the heater has been triggered.	*Only for older machines: – Check water level in chamber, not enough water in system – Only check contactor in machines with electric heating systems
92*	Temperature limiter heating tank 1	Temperature limiter for heating has been triggered.	*Only for older machines: – Check water level in tank 1, not enough water in system – Only check contactor in machines with electric heating systems
93*	Temperature limiter for tank 2 heater *	Temperature limiter for the heater has been triggered.	*Only for older machines: – Check water level in tank 2, not enough water in system – Only check contactor in machines with electric heating systems
94	Temperature limiter air heating	Temperature limiter for heating has been triggered.	– Check fan path, no air movement – Only check contactor in machines with electric heating systems
95	Jet pipes not moving	Jet pipes not signaling that they are moving.	– Check chamber jet drive system – Check position of switch for jet drive cylinder position – Check drive jet pipe inside chamber for defective components
96	Compressed air pressure too low	Compressed air supply switch signals that pressure is too low.	– Check on-site compressed air supply – Check that pressure switch is set correctly – Check pressure switch for defects
97	Steam supply pressure too low	Steam supply switch signals that pressure is too low.	– Check on-site steam supply – Check that pressure switch inside steam supply line is set correctly – Check pressure switch inside steam supply line for defects

No.	Message	Reason	Possible remedy
98	Cold water supply pressure too low	Pressure switch signals that water pressure is too low.	– Check on-site water supply – Check that pressure switch inside water supply line is set correctly – Check pressure switch inside water supply line for defects
99	Demi water supply pressure too low	Pressure switch signals that water pressure is too low.	– Check on-site water supply – Check that pressure switch inside water supply line is set correctly – Check pressure switch inside water supply line for defects
100	Hot water supply pressure too low	Pressure switch signals that water pressure is too low.	– Check on-site water supply – Check that pressure switch inside water supply line is set correctly – Check pressure switch inside water supply line for defects
101	Deviation control/ record water temp.	Deviation control/record PT 100 chamber Diff. control/record PT 100 chamber Excessive level of deviation between temperature sensors B251 and B252.	– Check sensor for defects or loose contacts – Replace sensor
102	Deviation control/ record air temp.	Excessive level of deviation between temperature sensors B253 and B254.	– Check sensor for defects or loose contacts – Replace sensor
103	Overfilling of chamber	Water level inside the chamber is rising too fast after closing valve.	– Check that water intake valves are tight – Check whether drainage valves open
104	Overfilling of tank 1	Water level inside tank 1 is rising too fast after closing valve.	– Check that water intake valve is tight
105	Overfilling of tank 2	Water level inside tank 2 is rising too fast after closing valve.	– Check that water intake valve is tight

No.	Message	Reason	Possible remedy
106	Time exceeded filling chamber	Water level inside the chamber is rising too slowly.	– Check on-site water supply – Check if water valve is defective – Check if control valve is defective – Check water supply line for blockages – Check valve between the tank and chamber for defects
107	Time exceeded filling tank 1	Water level in tank 1 is rising too slowly.	– Check on-site water supply – Check if water valve is defective – Check if control valve is defective – Check water supply line for blockages
108	Time exceeded filling tank 2	Water level in tank 2 is rising too slowly.	– Check on-site water supply – Check if water valve is defective – Check if control valve is defective – Check water supply line for blockages
109	Time exceeded heating chamber	Temperature inside the chamber is rising too slowly.	– Check on-site steam supply line – Check steam valve on circulation heat exchanger for defects – Check if condensate discharge is working – Check whether electric heating element is defective
110	Time exceeded heating tank 1	Temperature in tank 1 is rising too slowly.	– Check on-site steam supply line – Check steam valve on tank 1 for defects – Check if condensate discharge is working – Check whether electric heating element is defective

No.	Message	Reason	Possible remedy
111	Time exceeded heating tank 2	Temperature in tank 2 is rising too slowly.	– Check on-site steam supply line – Check steam valve on tank 2 for defects – Check if condensate discharge is working – Check whether electric heating element is defective
112	Time exceeded draining chamber	It is taking too long to drain the chamber.	– Check on-site drainage line for blockages – Check drainage valve for defects – Check drainage pump for defects – Check if chamber level pressure transducer is working
113	Time exceeded draining tank 1	It is taking too long to drain tank 1.	– Check on-site drainage line for blockages – Check drainage valve on tank 1 for defects – Check drainage valve of chamber for defects – Check drainage pump for defects – Check if chamber level pressure transducer is working – Check if tank level pressure transducer is working
114	Time exceeded draining tank 2	It is taking too long to drain tank 2.	– Check on-site drainage line for blockages – Check drainage valve on tank 2 for defects – Check drainage valve of chamber for defects – Check drainage pump for defects – Check if chamber level pressure transducer is working – Check if tank level pressure transducer is working

No.	Message	Reason	Possible remedy
115	Time exceeded repumping to tank	It is taking too long to pump water back into the tank.	– Check if pressure transducer in tank is working – Check if return valve to tank is working – Check return pump – Check line for foreign objects: blockages
116	Temp. inside controller too high	Temperature inside the PowerPanel is too high.	– Check on-site machine compartment air conditioning, because ambient temperature is too high.
117	Not enough memory space	Not enough free memory in PowerPanel.	– Restart machine – Controller fault - replace controller
118	Cleaning of water filter required	The specified number of programs that clog the filter has been carried out.	– Clean chamber filter, as enough cycles have been carried out to block it
119	Draining program - not for goods	The active program has been declared as a draining program in the parameters.	-
120	Temperature rising chamber	The temperature in the chamber is rising but the heating is not activated.	– Check that steam valve on circulation heat exchanger closes completely – Check whether contactor for electric heating element is defective
121	Temperature rising tank 1	The temperature in the tank is rising but the heating is not activated.	– Check that steam valve on tank 1 closes completely – Check whether contactor for electric heating element is defective
122	Temperature rising tank 2	The temperature in the tank is rising but the heating is not activated.	– Check that steam valve on tank 2 closes completely – Check whether contactor for electric heating element is defective
123	Washing step repeated	At least one washing step was repeated during the process run.	– Check the entire washing system, as there is contamination and carry-over in the machine – Check limit value settings in parameter lists on display

No.	Message	Reason	Possible remedy
124	Dosage 1 empty	Suction lance of dosing line 1 signals that the container is empty.	– Check dosing hose 1 and remove air as required – Replenish process chemicals – Broken cable in suction lance line
125	Dosage 2 empty	Suction lance of dosing line 2 signals that the container is empty.	– Check dosing hose 2 and remove air as required – Replenish process chemicals – Broken cable in suction lance line
126	Dosage 3 empty	Suction lance of dosing line 3 signals that the container is empty.	– Check dosing hose 3 and remove air as required – Replenish process chemicals – Broken cable in suction lance line
127	Dosage 4 empty	Suction lance of dosing line 4 signals that the container is empty.	– Check dosing hose 4 and remove air as required – Replenish process chemicals – Broken cable in suction lance line
128	CF card is full	CF card memory space is below 256 kByte or card was removed from the panel. Card has been removed. Too much data stored on CF card	-
129	Waiting for end of tank cleaning	Tank cleaning is running and is not yet complete. Drainage time has not yet expired.	-
130	Ventilation flap: Position not reached	Fresh air flap is not reaching correct position.	– Fresh air flap has been unhinged – Fresh air flap is stiff, defective.
131	Error exhaust air system	On-site exhaust air system signals a fault.	-
132	No rack coding	Rack scanning is active but no code has been read yet.	– Check barcode on rack – Check scanner – Check the anti-reflection feature (black insulating tape) on the panel

No.	Message	Reason	Possible remedy
133	Wrong rack coding	Rack code barcode was wrong or could not be identified correctly.	– Check barcode on rack – Check scanner – Check the anti-reflection feature (black insulating tape) on the panel
134	Length of rack ID incorrect	The rack code barcode that has been read is not the right length.	– Barcode defective or illegible – Check the anti-reflection feature (black insulating tape) on the panel
135	Loading system time exceeded	The loading procedure has taken too long. Rack could not be loaded.	– Check door – Check sensor
136	Time exceeded unloading system	The unloading procedure has taken too long. Rack could not be unloaded.	– Check sensor
137	Conductivity sensor B551 defective	Conductivity probe reporting incorrect input values. Conductance measurement/measuring transducer reporting invalid values Poor water quality. Too much cleaning agent.	– Check the contacts on sensor B551 – Check the contacts on transducer B991 – Replace with an identical sensor or measuring transducer
138	Conductivity not achieved	Conductivity value in the final rinse too high. Poor water quality. Too much cleaning agent.	– Check water quality – Check dosing
139	Conductivity sensor B552 defective	Conductivity probe reporting incorrect input values.	– Check the contacts on sensor B552 – Check the contacts on transducer B992 – Replace with an identical sensor
140	Pressure transducer B353 defective	Sensor reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
141	Sterile filter change required	A slight vacuum is generated during drying when the fan is activated. HEPA filter is clogged.	– Change HEPA filter. Call service technician
142	Unloading: Wait for free place	Unloading system is waiting for free space.	– Unloading roller conveyor is not clear

No.	Message	Reason	Possible remedy
143	Refilling without success	Too many refilling processes have been performed without managing to supply the chamber with sufficient water.	▪ Doorseal not airtight ▪ defective level switch (Liquiphant) chamber B811 or B812
144	Loading: Fault	Loading system has identified an error. Times exceeded	– Doors not as expected
145	Unloading: Fault	Unloading system has identified an error. Times exceeded	– Doors not as expected
146	No connection to USB device	Required USB connection could not be established or has been interrupted. Scanner unplugged.	– Check cable connection
147	Service mode	The machine is in service mode.	– Technician has pressed a button in the “Service” menu.
148	Transport: Reset required	Repumping mode has been triggered. Transport must be enabled for automatic movement.	-
149	Foaming	Large pump pressure fluctuations in the first cleaning step (step 1). Despite multiple attempts, it was still not possible to achieve a constant pump pressure.	– High levels of contamination – Large amount of blood inside chamber
150	Failure dosage tank	Machine tank dosing failed while preparing for an upcoming program. Dosage hoses are worn or defective	– Check dosage hoses – Check or change cleaning agent
151	Preventive maintenance due shortly	Preventive maintenance due very soon.	– Preventive maintenance due
152	Preventive maintenance overdue	Preventive maintenance is overdue.	– Preventative maintenance was not carried out on time
153	Interval-based maint./inspection due shortly	Interval-based maintenance/inspection due very soon.	– Interval-based maintenance/inspection due
154	Interval-based maintenance/inspection overdue.	Interval-based maintenance/inspection is overdue. Interval-based maintenance/inspection was not carried out on time.	– Carry out interval-based maintenance/inspection
155	Calibration/adjustment due soon	Calibration/adjustment will be due shortly.	– Calibration/adjustment due

No.	Message	Reason	Possible remedy
156	Calibration/adjustment overdue.	Calibration/adjustment is overdue. Calibration/adjustment was not carried out on time.	– Carry out calibration/adjustment
157	Requalification due shortly	Requalification is due very soon.	– Requalification is due.
158	Requalification overdue	Requalification is overdue. Requalification was not carried out on time.	– Perform requalification
159	Wire error energy manager	Wire check during machine start-up failed. Configuration does not match the connected energy manager wires.	– Check configuration
160	Energy supply blocked	No free power wire when configuring start-up prevention. All power wires are already in use.	-
161	Waiting for energy release	No free power wire when configuring automatic program start. All power wires are already in use.	-
162	Time exceeded energy	No free wire for too long. All power wires are already in use.	-
163	Failure docking system	Faults in the BWI docking system. Required positions not reached on time.	-
164	Docking: Acknowledgment required	The user has not yet confirmed 'Chamber empty'. Fault during docking or user has canceled and not yet confirmed.	– Check docking system – Confirm cancellation
165	No serial number	No serial number recorded.	– Enter serial number
166	Reading error scanner	No barcode detected.	– Scanner defective – Check cable – Scanner incorrectly configured – Check the anti-reflection feature (black insulating tape) on the panel

No.	Message	Reason	Possible remedy
167	No code for goods	No barcode has been scanned yet but is required for the program to start. Read error due to defective barcodes on rack or no barcode on rack. Barcode must be replaced or attached.	– Check barcode on rack – Replace or reattach barcode – Check the anti-reflection feature (black insulating tape) on the panel
168	Rise of filling volume	Fill volume measured at the end of the circulation phase much higher than at the start of the circulation phase.	– Check filling valves.
169	Rack redelivery mode active	Customer has started rack redelivery mode by pressing the “Rack redelivery” button.	-
170	Rack redelivery failure	An error occurred in rack redelivery mode.	– Door is blocked and cannot be closed properly – Rack is not correctly positioned inside chamber or on roller conveyors
171	No user logged in	No user logged in	Log in user
172	Missing user action	Menu prompt for automatic tank cleaning “Are all tank covers correctly closed?” has not been confirmed.	Confirm menu prompt “Are all tank covers correctly closed?”
173	Drain full	Waste water drainage to external tank and not to drain. External tank full. Waste water cannot be drained.	Drain external tank
174	Empty cycle required	An empty cycle was not run after venting the dosing line.	Start a program without materials to make sure there is no process chemicals in the machine.
175	Cancel for cleaning check	Program cancellation after cleaning for validation	For service technicians only
176	Door opening rejected	2. operating terminal - door opening on the unloading side was rejected	Determine the cause of why door opening on the unloading side was rejected, and run the cycle again.
177	Waiting for user action	2. operating terminal - waiting for decision, door opening on unloading side no/yes	Check result “Permit door opening on this side?” Press yes or no button.

No.	Message	Reason	Possible remedy
178	Motor protection (general)	Motor overload	Inform service technician
179	-	-	not applicable to Uniclean ML
180	Pressure transducer B354 defective	Pressure transducer reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
181	Auto start active	Auto start is activated	-
182	Last program function active	Last program function is activated	-
183	Machine draining active	Last program function is activated. Once the materials have been unloaded and the unloading door has been closed, the chamber and tanks are automatically drained.	-
184	Machine draining failed	Last program function is activated. Once the materials has been unloaded and the unloading door had been closed, the chamber and tanks were not drained.	– Check on-site drainage line for blockages – Check drainage valve on tank for defects – Check drainage valve of chamber for defects – Check drainage pump for defects – Check if chamber level pressure transducer is working – Check if tank level pressure transducer is working
185	Drainage valve T1 leaky	Water level in the tank is too low	– Check drainage valve T1 on the tank for defects
186	Drainage valve T2 leaky	Water level in the tank is too low	– Check drainage valve T2 on the tank for defects
187	Auto start failed	Faults are preventing auto start	– e.g. media supply not working – e.g. close the door
188	Check cable	RPM of the rotating arms incorrect. Cycle sequence still progressing properly.	not applicable to Uniclean ML
189	Rotating arm fault	RPM of the rotating arms incorrect. Program canceled	not applicable to Uniclean ML

No.	Message	Reason	Possible remedy
190	K19: Wrong position	Correct position of K19 not yet reached.	Inform building services or service technician – Check valve function – Check feedback contact function
191	Drain full for too long	Chamber cannot be emptied for more than 5 min - program canceled If no water is discharged during safety draining either, this error message is displayed in alternation with error message 83 “Caution: Chamber may not be empty”	– Check drainage system for possible blockages – Check pressure transducer of chamber for defects
192	Flow meter error dosing	Flow meter is counting even though the dosing pump is not activated.	Inform building services or service technician – Check non-return valve – Check flow meter
193	Flow meter error water	Flow meter is counting even though the water valve is not activated.	Inform building services or service technician – Water valve leaking – Check flow meter
194	Heating temperature limiter	The temperature limiter for heating or the tank has been triggered.	Inform building services or service technician – Check water level in chamber, not enough water in system – Check water level in the tank (1 or 2), not enough water in system – Check heater circuit breaker
195	Drying temperature too high	Set target temperature was exceeded	Inform building services or service technician – Check heater circuit breaker
196	Too much circulation in tank 1	Level in the tank not static, the water level in the tank is fluctuating due to too much inflowing air and the heater needs to reheat the water too often. The heater contactor is switching too often.	not applicable to Uniclean ML

No.	Message	Reason	Possible remedy
197	Too much circulation in tank 2	Level in the tank not static, the water level in the tank is fluctuating due to too much inflowing air and the heater needs to reheat the water too often. The heater contactor is switching too often.	not applicable to Uniclean ML
198	Emergency open button pressed	The emergency open button in the chamber was pressed. Emergency open button is defective.	Inform building services or service technician
199	-	-	not applicable to Uniclean ML
200	Not a cleaning program acc. to EN 15883	Special program was selected.	-
201	Note regarding overflow of tank into the overflow	Incoming counter pulses when fill valves not activated.	– Check fill valves
202	Fault in pumping system	On-site pumping system signals a fault.	Inform building services

6.5 Tips for dealing with inadequate cleaning results

Practical tips

The following points should be observed if the cleaning results are inadequate:

- Have any necessary pre-cleaning procedures been carried out correctly?
- Has the loading trolley provided been used in accordance with its intended use?
- Was the loading trolley loaded correctly? Machine must not be overloaded and material must not overlap!
- Have all unused threaded connectors been sealed off with caps (option)?
- Have all the filters been cleaned?
- Has the appropriate cleaning program been selected?
- Are the rotating arms able to move freely?
- Are the rotating arms/jets free from contamination?
- Are all rotating arms rotating in the correct direction during the cleaning program?

  The rotating arms in the BW must be rotating clockwise.

- Have all process-related steps according to the validation see "Validation", Page 11 and the reprocessing instructions of the instrument manufacturer (option) been adhered to?



It is imperative that you observe the safety instructions and warnings in the user manual for the accessory!

The cleaning performance can only be ensured if the correct / loading trolley is used for the type of material being cleaned and if it is loaded correctly.

If this is not adhered to, the cleaning performance could be impaired. Check the cleaning results. If the cleaning results are inadequate, the cleaning and disinfection processes must be repeated.

6.6 Thermal printer paper exchange (option)



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

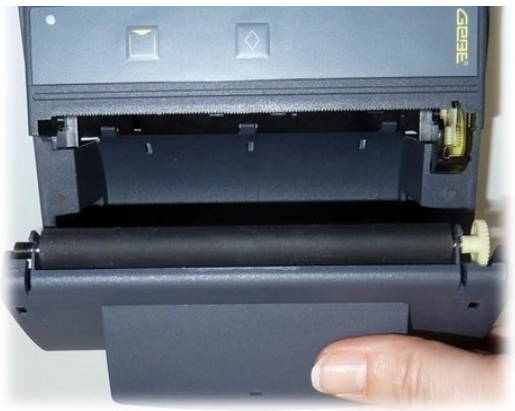
For unproblematic printing, we recommend ordering the paper from MMM.

- 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.



- Press the flap closed.



Example images only

7 Maintenance

Observe the safety instructions in Chapter 1!

Observe the instructions in Chapter 1.2.7, "Special features when heating with steam"!

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.

A preventative inspection and maintenance (preventative maintenance) should be performed after twelve months or after 2500 cycles .

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

The cycle counter continuously counts the cycles performed.

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

If you have the “air permeability reduction” option, reduced air permeability can no longer be guaranteed if the air isolation parts have been dismantled!

The on-site ventilation unit must be designed in such a way that the air pressure difference between the clean and unclean side can be maintained during servicing or maintenance work, or when dismantling the air isolation panels.

7.1 Safety

For all work on the machine, observe Chapter 1, "Security"

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.

Different colors are used to indicate the urgency of the work.

Color	Service work
Green	No action required
Yellow	Arrange appointment for service work
Red	Due shortly
Dark red	Overdue



Indication of when service work is due

In “Quick user access” under “Information”, it is possible to check when maintenance, calibration/adjustment and requalification are due.



- Open Quick user access.



- Press the Maintenance information button.

7.3 Servicing contract

We recommend concluding a servicing contract.

The routine tasks described below are also checked during servicing. If machine malfunctions are detected, the defects are detailed in writing.

Repairs are not covered by the MMM servicing contract. Where required, these are only performed in consultation with the operator.

7.4 Routine monitoring of the technical function

For the routine inspections of technical functions, we recommend the “DGKH, DGSV and AKI guideline for the validation and routine monitoring of mechanical cleaning and thermal disinfection processes for medical devices”, see checklist 10: "Matrix for creation of a checklist for routine monitoring of the technical function [5th Edition 2017]

The washer-disinfector is equipped in such a way that item a) applies to all points of the checklist referred to above. This means that the longest inspection intervals can be chosen in each case.

It is particularly important to ensure the following:

The rotating arms of the instrument loading trolley (BWI) must be cleaned every week in the case of regular operation and at sensible intervals if the instrument program is not used regularly.

The cleaning must be documented.

The maintenance instructions must be followed at all times.

7.5 Maintenance activities

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

The chamber door is referred to as just door in this section.

Before each cycle:

What	How	Remark
Checking the MIS supply strip	▶ Remove the MIS supply strip by pressing against the connection in the supply line and pulling the MIS supply strip out of the bracket. ▶ Hold the open end of the MIS supply strip under flowing water. ▶ Check that the water runs through all connections. ▶ Clean the MIS supply strip if necessary; see the BWI instructions for use.	

After each cycle:

What	How	Remark
Visual inspection of nozzle pipe movement	For the procedure see Chapter 4.9, "Releasing the cycle"	
Checking the MIS supply strip	see "Before each cycle:"	

Before each instrument program (option):

What	How	Remark
Drain and clean the tanks if tanks (option) are installed	Procedure see "Cleaning the chamber", Page 135, "Cleaning the flow-through filter (option)", Page 137, "Draining program", Page 132 "Cleaning the tanks", Page 133	Report extraneous rust to the system supervisor. Cleaning results: must have a metallic and shiny appearance.

After each shift:

What	How	Remark
Self-disinfection	▶ Start the "Self-disinfection" program **when the chamber is empty!**  **The self-disinfection is not a cleaning program for materials!**	If only chemical disinfection programs were run during a shift, a self-disinfection program must be run at the end of the shift. The self-disinfection is a thermal process. The self-disinfection can be configured when the machine is commissioned.

Daily:

What	How	Remark
Drain and clean the tanks if tanks (option) are installed (for instrument program, see above)	For the procedure see Chapter 7.9, "Cleaning the tanks"	To be performed at the end of each workday or at each shift change. Report extraneous rust to the system supervisor. Cleaning results: must have a metallic and shiny appearance.
Emptying and cleaning the chamber: regular maintenance can significantly extend the lifespan of the interior chamber walls if certain precautions are taken. The surfaces must always be metallic and shiny. If the walls are covered in a gray or slightly spotty layer after extended use, this must be removed. A cycle without load must now be run. Rust formation (surface rust, extraneous rust) can destroy the chamber. Spots of this nature must be treated immediately. For chambers with blasted walls (dull surface finish), this is done using a commercially available stainless steel cleaning agent (observe the manufacturer's instructions for use!). A stiff plastic brush is the best tool for cleaning. Thoroughly rinse the chamber walls with water after a treatment of this nature.	For the procedure see Chapter 7.11, "Cleaning the chamber"  Wear protective gloves!	To be performed at the end of each workday or at each shift change. Report extraneous rust to the system supervisor. Cleaning results: must have a metallic and shiny appearance.

What	How	Remark
Visually inspect and clean the door seal	The door seal is sensitive as it is subjected to stress during the washing process. Defective seals disrupt proper system operation. 1. Visually inspect the door seals – on the loading and unloading sides – with the chamber door open. The door seal is located in the groove on the open front end of the chamber. 2. Remove any foreign objects from the seals! 3. If the seals are slightly dirty, wipe with a lint-free cloth. 4. Visually inspect the visible side of the seal for damage.	Report damage to the system supervisor.
Check door operation.	Observe door movement on both sides during opening and closing. If there are any irregularities compared to normal door movement, notify the system supervisor. Possible irregularities are: – Jerking – Moving too slowly or too quickly – Friction noises – Unusual motor noises	Report information to the system supervisor.
Check the door force limiter	Briefly stop the door movement with your hand whilst the door is closing. The door must stop. The door must continue moving when your hand is removed. If the door cannot be stopped, remove your hand and report the incident to the system supervisor. The door continues moving. When performing this test, bring in a second person who is prepared to press the EMERGENCY STOP on the front panel if necessary!  The tester must stand in front of the chamber. Never inside the chamber! When performing this test, bring in a second person who is prepared to press the EMERGENCY STOP on the front panel if necessary!	

What	How	Remark
Cleaning the rotating arms after using the BWI (option)	The rotating arms on the BWI (option) must be dismantled and cleaned. Then reassemble the rotating arms and check that they are able to move freely. Chapter 7.7, "Cleaning and servicing the rotating arms"	
Clean the pit daily (drain system without gully option)	Some residual water always remains in the pit. ▶ Suction out the pit using an industrial vacuum cleaner (e.g. Kärcher). ▶ Wipe out the pit if necessary.	To be performed at the end of each workday or at each shift change
Check the submersible pump (drain system without gully option)	▶ Check whether the submersible pump is plugged into the Schuko socket in the machine compartment.	To be performed at the start of each workday

Weekly:

What	How	Remark
Check the content of the process chemical canisters	1. Open the maintenance hatch on the loading side. 2. Visually inspect the almost transparent canisters from the outside. If the fill level in the canister is more than approximately 5 cm, the process chemicals are sufficient for at least one program run.  Mixing up process chemicals may render the cleaning and disinfection process ineffective and may leave residue on the medical devices. Therefore, the warnings and safety instructions of the process chemical manufacturer must be observed. Suitable measures must be in place to ensure that process chemicals are not mixed up.	During the program sequence, the machine controller automatically monitors the fill level of the process chemicals.
Cleaning the flow-through filter	See Chapter 7.12, "Cleaning the flow-through filter (option)"	

Quarterly

What	How	Remark
Vacuum the machine compartment	Clean the machine compartment with an industrial vacuum cleaner. The vacuum cleaner must have a disposable dust bag. Then disinfect all system components with an approved disinfectant.	

As required:

What	How	Remark
Clean the front panel	Front panel - Wipe the front panel with a lint-free cloth. - Disinfect and clean the stainless steel surfaces using a suitable surface disinfectant or care product. Follow the manufacturer's instructions! Color touch display - Disinfect and clean the color touch display using a suitable cleaning agent or commercially available surface disinfectant. Follow the manufacturer's instructions!  Chemical cleaning agents must not be used on the glass surfaces.  The machine must always be switched off for cleaning.	
Clean the chamber after the OR shoe program	The fine filters must be cleaned after every OR shoe program, as a lot of fluff comes off OR shoes during treatment (see Chapter 7.11, "Cleaning the chamber"). A message prompting this may also be displayed and must be confirmed once the task has been performed.	



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

Weekly:

What	How	Remark
Check the process chemical connections	Visually inspect whether the individual suction lances are located in the correct process chemical canisters. Visually inspect whether the supply lines are connected to the correct dosing devices (lines, containers, pumps, etc.).  Mixing up process chemicals may render the cleaning and disinfection process ineffective and may leave residue on the medical devices. Therefore, the warnings and safety instructions of the process chemical manufacturer must be observed. Suitable measures must be in place to ensure that process chemicals are not mixed up.	
Check the dirt traps.	Open, check and, if necessary, clean the dirt traps in the steam and water supply lines.	

Weekly if the instrument cycles (option) is used regularly:

What	How	Remark
Check and clean all the rotating arms on the instrument trolley	▶ Unscrew the rotating arm from the holder on the trolley ▶ Remove the end caps and loosen the holder ▶ Visually inspect for chips, loose parts and foreign objects ▶ Clean the rotating arms ▶ Assemble ▶ Check that the installed rotating arms can move freely See also Chapter 7.7, "Cleaning and servicing the rotating arms"	

Monthly:

What	How	Remark
Test the water quality.	The water supplied to the machine must be sampled and tested in a laboratory. It must be compared against the water quality when the machine was commissioned. If there are large deviations between the current quality and the quality at the time of commissioning, the impact of this must be clarified with the responsible in-house hygienist. For this purpose, water samples can be taken at the free inlet of the tank intake and tested in a laboratory. Generally, the following types of water must be tested: - Cold water (usually not directly from the drinking water supply but from an upstream softening system) - Hot water (optional) - Deionized water (usually via a reverse osmosis system)	
Check the door force limiter.	Briefly stop the door movement with your hand whilst the door is closing during the program sequence. If it works, the door force limiter is working correctly and you can remove your hand. The door continues moving. If the door cannot be stopped, remove your hand and report the incident to management. The door continues moving.  The tester stands **in front of** the chamber! When performing this test, bring in a second person who is prepared to press the EMERGENCY STOP on the front panel if necessary!	Report information to the system supervisor

Quarterly:

What	How	Remark
Inspect and clean the door seals.	The door seals are sensitive as they are subjected to stress during the washing process. Defective seals disrupt proper system operation. 1. Visually inspect the door seals – on the loading or unloading sides – with the chamber door open. The door seal is located in the groove on the open front end of the chamber. 2. Remove any foreign objects from the seals. 3. If the seals are slightly dirty, wipe with a lint-free cloth. 4. Visually inspect the visible side of the seal for damage.  The door seal is not resistant to every form of grease or oil. It must not be lubricated with grease or oil at any point during its entire service life.	Report damage to the system supervisor.
Check the door movement.	Observe door movement on both sides during opening and closing. If there are any irregularities compared to normal door movement, notify the system supervisor. Possible irregularities are: Jerking Moving too slowly or too quickly Friction noises Unusual motor noises	Report information to the system supervisor
Check that the machine compartment is watertight.	Visually inspect the inside of the machine compartment for water leaks.	
Check the jets for blockages.	Visually inspect all jets openings inside the chamber to make sure they are clear of obstructions. If they are not: Unscrew the jet with a spanner and remove the foreign object. Re-install the jet. Do not apply any sealing compound.	

Every 2 years:

What	How	Remark
Replace the rubber hose used for tank cleaning	Rubber hoses must be replaced regularly or they will become worn. Only materials specified by the manufacturer may be used.	

As required:

What	How	Remark
Update and check the medical devices / equipment log.	All changes and incidents concerning the machine must be recorded in the equipment log included in the scope of delivery. This also applies to all service calls.	

What	How	Remark
Replace the door seal	The door seal must be replaced if it is damaged. When inserting the new door seal, proceed as follows. ▶ Remove the old door seal.  Take care not to cause any damage. ▶ Clean the door seal edge using only alcohol or acetone.  Do not use grease or oil under any circumstances. ▶ Moving upwards from the valve, insert the new door seal up to and beyond the second door seal radius. ▶ Then, moving downloads from the valve, insert the door seal up to and beyond the second radius. ▶ Finally, insert the door seal on the opposite side of the valve. ▶ Correct any possible length problems by stretching or compressing the seal. ▶ Ensure the door seal lies flat in the door seal groove. ▶ Ensure the door seal does not become twisted, especially in the curved areas. Tip: When inserting the door seal, it helps to twist it slightly in the radii to begin with so that the outer door seal radius sits in front of the inner door seal radius on the bottom of the door seal. Then, press the inner door seal radius again and correct it until the door seal sits untwisted in the groove.	

7.6 Cleaning the control elements

The control elements are only to be cleaned after selecting the screen cleaning function Chapter , "". The touch function is disabled and you then have 30 seconds to wipe the control elements without accidentally triggering an unwanted action.

When the machine is switched off, only wipe the on/off button briefly, as extended contact will switch on the machine.

7.7 Cleaning and servicing the rotating arms

The rotating arms of the BWI must be regularly cleaned to ensure their freedom of movement and the performance of the entire cleaning system. Do not mix up the different types of rotating arms, e.g. the rotating arms for the da Vinci rack or the 6-level rack. This is the only way to guarantee a satisfactory cleaning result.

The end caps of the BWI are blue.

Dismantling the rotating arms

- Loosen the lock screw by hand and remove the rotating arm.

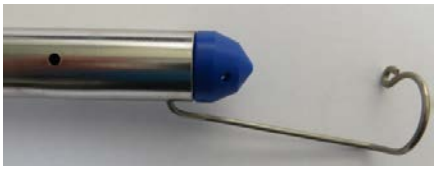


- Remove the distance washer.
- Check whether the spacer is damaged, worn, or highly discolored.

Replace damaged distance washers!

Failing to do so may impair the function of the rotating arms!

Removing the safety catch and end cap



- Open and turn down the safety catch.
- Remove the safety catch.



- Remove the end cap.
  (The end caps of the 6-level rack are blue)

Cleaning the rotating arms

- Clean the end caps.
- Clean the rotating arm with a suitable brush, e.g. an instrument brush.

Assembling the rotating arms



Risk of mixing up the rotating arms!

Reduced cleaning performance or damage to the rotating arms!

Check that the rotating arms are of the right type for the trolley!

Mounting the safety catch and end cap



- Apply the end cap.



- Apply the safety catch.



- Lock the safety catch.

Installing the rotating arms

- Place the distance washer between the rotating arm and the rotating arm bearing.
- Reattach the rotating arms.
- Screw in the lock screw **tightly** by hand.

7.8 Draining program

A draining program should not be run before the automatic tank cleaning (option).

This program is used to empty the machine. This involves sending the water in the tanks (if installed), the jet pipes and the chamber to the drain.

- Select the draining program.
- Press “Start”.

In contrast to other programs, only the door on the loading side is activated at the end of the program. As soon as the program finishes, the machine is drained and the tanks (if installed) and the chamber can be cleaned (Chapter 7, "Maintenance").

7.9 Cleaning the tanks

The tank system (if installed) must be cleaned at the end of each working day by flushing it out.

Exception: The tanks must always be cleaned before every instrument program (option)!

Persons and material for treatment must not be in the chamber!

Manual tank cleaning

- Run the draining program to empty the machine completely (Chapter 7.8, "Draining program").

  So the water used to flush out the tanks and chamber can drain away easily, the drainage valves must be opened.
- Press the following buttons:



Manual tank cleaning

- Confirm the prompt.
- The drainage valves are opened.
- Open the maintenance hatch on the unloading side.

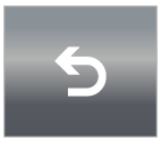
  While the tanks are being flushed, the chamber door on the loading side can be opened or closed as required. At the same time, various cleaning tasks can be performed inside the chamber (e.g. cleaning the fine filter).
- Remove both tank covers. Caution! The tanks and covers may be hot. Wear gloves.
- Visually inspect the inside of the tanks for foreign objects and extraneous rust. Remove any foreign objects.
- Flush the tanks using the hose supplied.

Only spray the inside of the tanks with the hose. Do not wet the machine compartment. Risk of damage to electronic components!

Keep the tank and chamber valves open.

After flushing the tanks

- Replace the two tank covers!
- Confirm



The valves are closed with a time delay; the machine is ready for use again in approx. 2 minutes.

- Close the door.



- Continue cleaning the chamber see "Cleaning the chamber", Page 135.

7.10 Automatic tank cleaning

Do not run a draining program before automatic tank cleaning.

Available energy (hot water) and dosed cleaner can still be used.

There is a program for automatic tank cleaning. Material for treatment must not be in the chamber while the program for automatic tank cleaning is running.

- Check that the tank covers are correctly seated on the tanks.

Water may leak out during the program.

Machine parts may be damaged by hot water with process chemicals.

Check that the tanks are closed.

- Close the maintenance doors to the machine room from the outside.
- Select the tank cleaning program.



- Confirm the prompt that the tank covers are correctly seated on the tanks.
  - The automatic tank cleaning program starts.
  - The machine is drained completely after tank cleaning.
  - The door on the loading side is released and can be opened.
  - Automatic tank cleaning is saved in the cycle documentation system.



- Continue cleaning the chamber see "Cleaning the chamber", Page 135 .

7.11 Cleaning the chamber



Wear protective gloves!

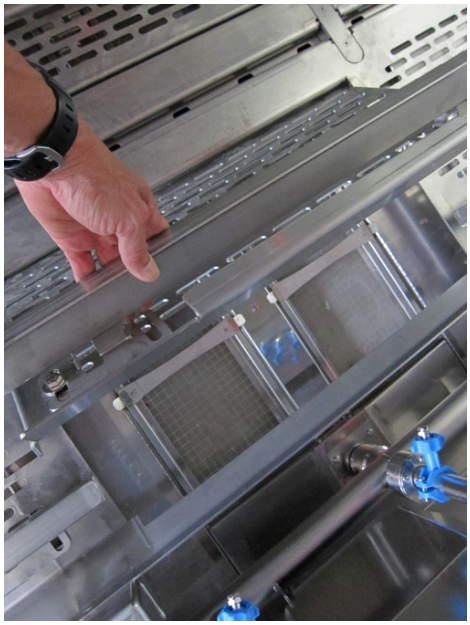
The chamber must be cleaned at least once a day with a standard stainless steel cleaner (follow the directions of the manufacturer) at the same time as the tank cleaning.

A stiff plastic brush is the best tool for cleaning. Thoroughly rinse the chamber walls with water after a treatment of this nature.



Exception: The tanks must always be cleaned before every instrument program (option)!

- Run the draining program. The chamber must be empty.
- Open the loading door of the chamber
- Visually inspect the chamber for foreign objects and extraneous rust.
  Remove any foreign objects.
- Lift up the cover flaps on the entry rail above the fine filters.



- Lift the fine filters out carefully so that no loose pieces fall off.



- Clean the filters outside the chamber.
- Check the drain channel underneath the fine filters for foreign objects and extraneous rust and clean if necessary.
- We recommend that you use a spray head to clean the walls and floor of the chamber.



Damaged filters must be replaced!

- Reinsert the cleaned fine filters.
- Close the walk-on cover flaps over the fine filters.



Make sure they are tightly fitted for a good seal!

7.12 Cleaning the flow-through filter (option)

The flow-though filter (option) must be cleaned before every instrument program. The filter is located inside the machine compartment. Do not start a program before entering the machine compartment (1.4.4 "Working on the assemblies", Page 20).

- Open the clamp closures



- Remove the clips, lid and seal.



- Pull out the filter together with the integrated bayonet slide.



- Clean the filter.
- Insert the filter by following the above steps in reverse order.



The seals must be inserted!

Under no circumstances is the machine to be switched back on unless the closures are sealed shut.

- Use the clamp closures to make sure the openings are securely sealed.



8 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.

9 Software Licence Agreement

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

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

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.

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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

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