

Instructions for use

Washer-Disinfector

Uniclean PL II

Uniclean PL II 10

CE 0123

MMM Münchener Medizin Mechanik GmbH
Semmelweisstraße 6
D-82152 Planegg

010535053 | REV7.2 | 2022 - 08

Model designations for Uniclean PL II

The various models of the Uniclean PL II are identified as follows:

Chamber size/ number of trays	Number of doors	Heating
10	1 2	EL - Electric

Example: Uniclean PL II 10-2-EL

General information

Legend of symbols and hazard warnings

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

- Handling instruction
- List



Danger

Ignoring hazard warnings may cause injury!



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

TW	Transport trolleys	For transporting racks
SOP	Standard Operating Procedure	Standard operating procedure

Warning signs on the machine

The following warning signs may be present on the machine:



Warning dangerous electrical voltage! Open only by trained personnel.



Warning corrosive substances! Wear protective gloves and glasses.



Warning hot surface! Wear protective gloves.



Warning risk of crushing injury to hands.



Warning laser class 2!
Do not look into the laser beam!



Do not sit on the loading or unloading conveyor.



Protective ground



Wear protective glasses!



Wear protective gloves!

Contents

1	**Safety**	**9**
1.1	Intended use	9
1.2	Responsibilities of the operator	11
1.2.1	Validation	12
1.2.2	Equipment log	13
1.2.3	Training the users	13
1.2.4	Water quality	14
1.2.5	Noise emission	14
1.2.6	Process exhaust air	14
1.2.7	Disposal	15
1.3	Operators	16
1.3.1	Access protection	17
1.3.2	User permissions	17
1.4	Rules of conduct for operation	19
1.4.1	Personal protective equipment	19
1.4.2	Closing the chamber door, starting a program	20
1.4.3	Working inside the chamber	20
1.4.4	Working on the assemblies	20
1.4.5	Working in the electrical control cabinet	21
1.4.6	Maintenance work	21
1.4.7	Power failure or EMERGENCY STOP pressed	21
1.5	Machine safety devices	22
1.5.1	Chamber door interlock	22
1.5.2	Securing the chamber door	22
1.5.3	Protection against getting crushed in the door	22
1.5.4	Master switch	23
1.5.5	EMERGENCY STOP	23
1.5.6	Cancelling the program	23
1.6	Residual risk	24
1.7	Maintenance and Safety inspection	24
1.8	Standards, regulations and directives	25
2	**Machine description**	**29**
2.1	Type plate	29
2.2	Machine configuration	30
2.2.1	Chamber	30
2.2.2	Electrical equipment and control system	31
2.2.3	Washing system	32
2.2.4	Process water	32
2.2.5	Dosing system	33
2.2.6	Drying	34
2.2.7	Supply and exhaust air	34
2.2.8	Tanks (option)	34
2.2.9	Media supply	34
2.2.10	Noise insulation (option)	35

2.2.11 Barcode (option)....35
2.2.12 Batch documentation....35
2.2.12.1 Printer (option)....36
2.2.13 Energy manager (option)....37
2.2.14 ISA (option)....37
2.2.15 Remote maintenance system (option)....38
2.3 Operation and process description....38
2.3.1 Functioning of the machine....38
2.3.2 Process chemicals....39
2.3.3 Cleaning and disinfection process....40
2.3.4 Example of process sequence....40
2.4 Accessories....41
2.4.1 UPL II transport trolley for racks....41

3 Display and control elements....43

3.1 Loading side....43
3.1.1 On/off button....43
3.1.2 EMERGENCY STOP....44
3.1.3 Colour touch display....45
3.1.3.1 Function buttons on the color touch display....45
3.1.3.2 Menu overview on the loading side....47
3.1.3.3 "Tools" menu on the loading side....48
3.2 Unloading side (two-door machines only)....49
3.2.1 Door button....50
3.2.2 Rack redelivery button (option)....51
3.2.3 EMERGENCY STOP....51

4 Operation....53

4.1 Logging users in and out....53
4.2 Programs....54
4.3 Auto start (configurable)....55
4.4 Principles for machine cleaning and disinfection....55
4.5 Loading instructions....56
4.5.1 Notes on the transport trolley....56
4.5.2 Checking the chamber....56
4.5.3 Checking the racks, modules and inserts....57
4.6 Loading the chamber and starting the program....59
4.6.1 Manually loading with and without a barcode....59
4.7 Activating and deactivating rack redelivery (option)....60
4.8 Cancelling the program....60
4.9 Unloading the chamber....61
4.9.1 Manual unloading....61
4.10 Approving the batch....62
4.11 Standby....65
4.12 Last program run (configurable for two-door machine)....65
4.13 Handling chemicals....65
4.13.1 Safety instructions for changing process chemicals....65

4.13.2 Changing the process chemical brand or type..... 66
4.13.3 Replenish process chemicals..... 67
4.13.4 Exchange the canister..... 67
4.14 Shift change..... 68
4.14.1 Cleaning the dirt filter.....68
4.15 Sending messages to customer service via ISA (option).....69

5 Machine configuration.....71

5.1 Configuration User Manager (option).....71
5.2 Setting batch print and save options..... 72
5.3 Auto start (configurable).....72

6 Operating safety and faults..... 75

6.1 Fault messages.....75
6.2 Responding to faults..... 76
6.3 Responding to specific faults..... 77
6.3.1 Power failure..... 77
6.3.2 Opening the door in an emergency..... 77
6.3.3 Fallen parts, jammed moving machine parts..... 78
6.3.4 Process chemicals not being supplied directly..... 78
6.3.5 Process chemicals not being supplied from the central dosing system..... 79
6.3.6 EMERGENCY STOP..... 79
6.3.7 Insufficient water quality.....79
6.3.8 Network outage..... 80
6.4 Status and alarm list..... 80
6.5 Tips for dealing with inadequate cleaning results..... 93
6.6 Thermal printer paper exchange (option)..... 94
6.7 Removing air from the dosing tube.....95

7 Maintenance.....99

7.1 Safety..... 99
7.2 Planning service work.....99
7.3 Servicing contract.....100
7.4 Routine inspections of the technical functions.....101
7.5 Cleaning the control elements..... 101
7.6 Cleaning and servicing the rotating arms..... 101
7.7 Cleaning the racks..... 103
7.8 Cleaning the TW..... 105
7.9 Maintenance activities.....106

8 Warranty (Liability for defects).....113

9 Software Licence Agreement.....115

10 Index..... 121

Contents

1 Safety

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

NOTICE

Observe the safety instructions.

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

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

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

This user manual contains information on how to use the machine as intended.

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

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

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

1.1 Intended use

Intended purpose

The **Uniclean PL II** 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 PL II** is intended for use in the medical field, for example in Reprocessing Units for Medical Devices, medical clinics, etc.

Intended use

a) Medical devices

The Uniclean PL II washer-disinfector is suitable for the automated cleaning and disinfection, as defined in DIN EN ISO 15883-2, of the following materials:

- Surgical instruments with a smooth surface
- Minimally invasive surgery (MIS) instruments
- Eye instruments
- Hollow devices and hoses
- Rigid endoscopes
- Anesthetic accessories, respiration accessories, anesthetic materials, and respiration materials
- Instrument basins and trays
- Bowls, basins, receptacles
- Glass items
- Transport containers
  - Sterilization containers
  - Endo trays
- Other utensils typically used in healthcare facilities

b) Other products in the medical sector

In addition to the aforementioned items, the **Uniclean PL II** washer-disinfector is also suitable for the automated cleaning and disinfection, as defined in DIN EN ISO 15883-6, of the following reusable products:

- Non-invasive medical devices
- OR shoes
- Other utensils typically used in healthcare facilities

NOTICE

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

Limitations of use

Danger

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

Examples of materials not permitted to be treated include:

- Powered devices (motor systems) according to DIN EN ISO 15883-2
- Human waste containers according to DIN EN ISO 15883-3
- Thermolabile endoscopes according to DIN EN ISO 15883-4
- Transport trolleys as well as bed frames, wheelchairs, technical aids for persons with disability according to DIN EN ISO 15883-6
- Thermolabile medical devices and accessories according to DIN EN ISO 15883-7

1.2 Responsibilities of the operator

NOTICE

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

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

NOTICE

The operator must comply with their reporting obligations to manufacturers and authorities in accordance with the European Directive 93/42/EEC, Article 10, or in accordance with European Directive 2017/745/EU, 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.

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 materials to be treated must be designated by the manufacturer as machine washable and dryable.

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

Medical devices must only be treated if a validation has been provided for them.

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 EN ISO 15883-1 and 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 mechanical 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 which affect the process, e.g. changes to the process chemistry, the water quality, the load, or changes to the materials being processed.

Guidelines

- DGHK, DGSV and AKI guideline

  For the validation and routine monitoring of mechanical 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**rbeitsK**r**eis **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 Equipment log

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

Documenting the following in the equipment log is recommended:

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

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.



Danger

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 7.9, "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 Disposal

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

LEGAL NOTES FOR THE OPERATOR:

1. **Disposal of components**

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

2. **Disposal of the machine**

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



3. **Return of used machines**

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



Privacy note

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

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

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

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

NOTES FOR OPERATORS IN THE EU

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

1.3 Operators

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

NOTICE

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

Untrained persons are not permitted to operate the machine.

Approved operator

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



Danger

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

System supervisor

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

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)
- E1 access password (e.g., for confirming 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 specific menu levels of the machine controller is password-protected. This prevents unauthorized access to process parameters and settings relevant to safety.

Preset authorization levels with restricted rights are available for daily operation. These can be individually changed using the **User administration** .

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, "Configuration 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 door at the end of the program are recorded in the batch and are printed on the batch record.

1.4 Rules of conduct for operation

Information on laser class 2



A laser (laser class 2) has been installed on the edge of the chamber to scan the barcode on the racks. An accidental glance directly into the laser beam will produce a strong glare but not cause any damage, even when using optical aids. Deliberately looking at the beam can cause damage to the retina.

Warning

Risk of injury from the class 2 laser!

Retinal damage will occur if you deliberately look into the laser of the barcode scanner (option) for a prolonged period!

Never deliberately look into the laser beam!

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



Danger

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

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

Service personnel



Danger

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

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 16) 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.

Place the transport cover over the rack docking fixture in the chamber so that no small parts can fall into the docking fixture!

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.

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



Danger

Risk of injury!

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

Wear personal protective clothing when working on the assemblies!



Danger

Risk of crushing!

Work in the lower section may only be carried out with the door lock secured!

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

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

In case of a power failure or if the emergency stop switch is pressed, all mechanical moving parts are stopped. The machine is in a technically safe state.

The process 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 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 docu-

mented in the medical products / equipment log and signed by the system supervisor.



Danger

Possible leakage of caustic vapors.

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

1.5 Machine safety devices

1.5.1 Chamber door interlock

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



Danger

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

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

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

The door can be opened in an emergency see "Opening the door in an emergency", Page 77



Danger

Danger of contaminating the clean side!

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

1.5.2 Securing the chamber door

The chamber door can be secured with a mechanical door locking device. This is especially important when performing maintenance work underneath the chamber.

The door locking lever is located on the right or left underneath the door.

- As soon as the cladding door is opened, the chamber door must be secured using the mechanical door locking device.

1.5.3 Protection against getting crushed in the door

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

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 door is opened again.

Door movement speed

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

1.5.4 Master switch

Der Hauptschalter befindet sich am Schaltschrank oberhalb der Kammer.

It completely disconnects the machine from the mains.

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



Danger

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

1.5.5 EMERGENCY STOP

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

Pressing them switches off all safety-relevant components except for the controller. The message "EMERGENCY STOP pressed" is displayed.

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



Danger

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 !

1.5.6 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.
- Exhaust air is discharged into the on-site ventilation system.

The door latch is then released and the chamber door on the loading side can be opened.



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.

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 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.

1.7 Maintenance and Safety inspection

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

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

Spare and wear parts must be replaced with original parts.

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

National regulations must be observed.

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

Note regarding warranty

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

We refer to our warranty declaration Chapter 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 93/42/EEC Annex I, 4).

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

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

1.8 Standards, regulations and directives

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

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

This machine complies with the following directives, regulations and standards:

Applicable EU directives and EU regulations

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



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

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

Applied standards - state of the art

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

Performance and effectiveness

- DIN 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

Electrical safety

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

EMC requirements

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

Functional safety

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

Usability

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

NOTICE

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

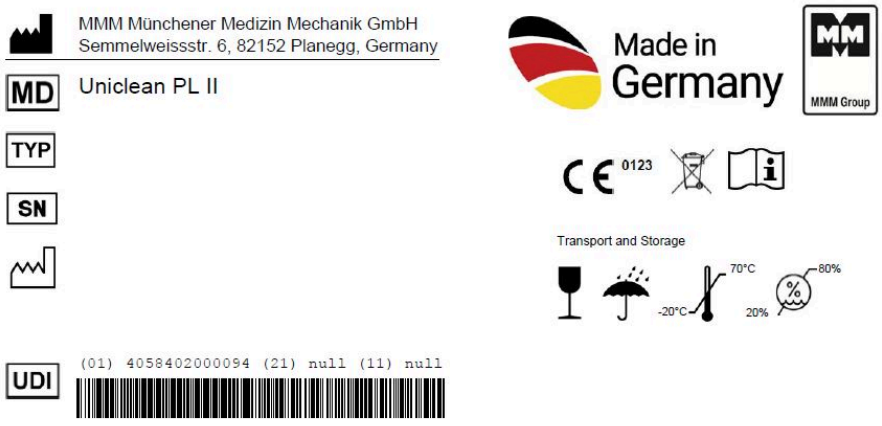
2 Machine description

What follows is a general description of the machine 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 electrical control cabinet.



Example illustration

Explanation of type plate:

- Manufacturer
- MD Medical device
- TYP Type
- SN Serial number
- Date of manufacture
- UDI Unique Device Identifier
- CE mark with identification number (example)
- Disposal (WEEE recycling)
- Observe the instructions for use
- Fragile, handle with care
- Store in dry place
- Lower and upper temperature limit
- Lower and upper air humidity limit

The following countries have additional conformity marks:



Serbia Ukraine

2.2 Machine configuration

2.2.1 Chamber

- Fully welded chamber, made of CrNi steel – material no. 1.4404 – and featuring hygienic, top-quality polished insides made of 3D sheets
- Upper roof panel is slanted to allow water droplets to run off better
- Chamber corners are chamfered not welded
- Chamber contains guide rollers and track rollers for the various loading racks
- The heated tank in the lower section of the chamber has a maximum water capacity of approx. 60 liters.
- Water is supplied and respective process chemicals are dosed directly into the chamber
- The water volume is measured by a flowmeter directly within the water supply line.
- Chamber lit by LED lamps, the color of which indicates the operating state of the machine.

Chamber door

- Automatic vertical sliding door design with heat-insulating and sound-damping double glazing, downward opening
- Driven by cable pull electric motor with crush guard and counterweight balancing
- During operation the door to the chamber is sealed with a door seal that goes all the way around the chamber. The door is mechanically pressed against the static door seal.

In the case of a **two-door machine**, both doors are interlocked so that they can never be opened at the same time (rack hatch function). The 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 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.

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

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
White, flashing	Rack redelivery
Red	Fault

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.

Batch counter

A batch counter is integrated into the controller. During the program sequence, the current batch number is displayed in the Program sequence menu. Alternatively, the batch number can be retrieved using the “Information” button. Various interfaces are available for transmitting batch-related data, as well as for external connections and devices (USB, Ethernet, etc.). Batch storage capacity: at least 25,000 batches, see "Batch documentation", Page 35.

Color touch panel

A graphics-capable color touch panel 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 panel also provides access to process curve diagrams, machine parameters and maintenance aids via the control menu. The unloading side is equipped as standard with a remaining time display and a door operation switch.

Potential-free contacts (option)

Controller can be equipped with potential-free contacts for the following messages:

- Machine "on/off"
- Collective fault message for central process control
- Machine in drying phase, e.g. on-site exhaust air blower activated (for drying phase)

2.2.3 Washing system

A high-performance CrNi steel circulation pump carries the volume of water from the heated tank through the entire device piping system. The entire piping system is inclined so that residual water can run off and no residual water contamination occurs

Rotating arms made from round CrNi steel pipes are located on the chamber ceiling and loading racks. These are mounted on a centrally arranged bearing bush. This ensures an optimized spray pattern for cleaning and disinfection. The rotating arms are easy to remove and have caps on the end that are removable for easy cleaning.

A centrally positioned docking support is located on the chamber floor to evenly supply water to the different loading racks. This centered docking support is positioned so that it does not matter which side of the rack goes in first.

2.2.4 Process water

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.

Process water is heated in the chamber sump by means of two electric heating elements.

Conductance value measuring system (option)

- Measuring device with temperature probe for automatically monitoring the conductivity in the process water.
- Independent measuring system with fully automated evaluation and comparison by the software using the preconfigured setpoint values

If the conductivity is too high, the water is completely drained at the end of the final rinsing and, depending on the preconfigured parameters, one or more rinse steps are repeated automatically. The max. possible number of rinses is preconfigured by the controller.

2.2.5 Dosing system

For automatic dosing of the process chemicals, two dosing pumps, each with a flow meter, are installed as standard. Additional dosing lines (max. 4 pcs) are optionally available.

The machine has space for accommodating and storing chemical containers (up to 3 x 5 l).

Suction lance for 5 – 10 L containers

Suction lance and respective hoses for 5-10 L process chemical containers within the machine. Minimum level control is monitored by the controller.

Additional dosing line (option)

Additional dosing pump including dosing monitoring with a flow meter for additional process chemical used in the machine.

Dosing line > pH10 UPLII 10 (option)

Additional dosing pump including dosing monitoring (by a flow meter) for automatic dosing of a highly alkaline process chemical (pH value > 10), including suitable non-return valve, TYGON dosing pump tubing and TYGON transfer tubing.

Dosing line for small quantities (option)

Additional dosing pump with two independent flow meters incl. non-return valve for automatic dosing of small quantities of process chemicals (e.g. rinse aid, cleaning chemical concentrates).

Dosing line >pH10 UPLII 10 for small quantities (option)

Additional dosing pump including dosing monitoring by a flow meter for automatic dosing of small quantities of a highly alkaline (pH value > 10) process chemical (e.g. rinse aid, cleaning chemical concentrates), including suitable non-return valve, TYGON dosing pump tubing and TYGON transfer tubing.

Dosing verification (option)

Additional dosing pump flow meter for independent verification of process chemical dosing.

Dosing verification for small quantities (option)

Additional flow meter for dosing pump for independent verification of dosing of small quantities of process chemicals. This option must be selected individually for each dosing pump.

2.2.6 Drying

The integrated drying system ensures an efficient and even distribution of the hot drying air in the chamber. Air is supplied into the chamber via a medium-pressure fan with fresh air intake and a replaceable sterile filter element.

For optimized drying and short drying times, heated drying air is simultaneously blown into the upper area of the chamber, directly into the loading rack (hereinafter referred to just as rack), onto the rotating arms, and into any connected cavity instruments.

2.2.7 Supply and exhaust air

HEPA filter

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

Exhaust air draft interrupter

Exhaust air draft interrupter integrated directly into the exhaust air pipeline of the chamber with infiltration air intake from the machine compartment housing the assemblies, including connection nozzle for the on-site exhaust air pipe and condensate discharge inside the machine.

2.2.8 Tanks (option)

Deionized water pre-heating tank

In the deionized water pre-heating tank, water for thermal disinfection is heated before it enters the washing tank. This reduces the overall batch time by approx. 7 minutes.

Heating the pre-heating tank

The process water is heated by an electric heating element.

2.2.9 Media supply

Depending on the machine configuration, it is possible to connect two or three different types of 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.

Direct hot water connection (option)

Hot water connection for filling the chamber directly. The maximum media temperature of 60 °C must not be exceeded.

Electrical media shut-off valve

Suitable for cold, water, deionised water or warm water at max. 65 °C. If the machine is switched off, the valve closes, thereby disconnecting the machine from the on-site media supply.

Bottom tray fill level monitoring (option)

Fill level monitoring of the bottom tray by means of a level switch.

The level switch is installed in the lower area of the bottom tray of each machine and, when a specified water level in the bottom tray is exceeded, stops the draining process and closes the optional media shut-off valves. No further water will then be drained.

We recommend combining the fill level monitoring of the bottom tray with the optional media shut-off valves to create a redundant safety system.

2.2.10 Noise insulation (option)

To reduce the sound pressure level, noise insulation can be installed in the front panel and/or the side panel, see "Noise emission", Page 14.

2.2.11 Barcode (option)

Barcode reading system

Barcode reader integrated into the front panel of the machine for automatic, contactless reading of rack labels when loading racks are manually pushed into the chamber. This enables the program for the particular material to be cleaned to be selected automatically, and the rack number to be saved and documented. This rack number is used to document which material was cleaned in a suitable external sterile goods documentation system.

2.2.12 Batch documentation

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

The batch record contains the following information:

- General data about the operator, user, device
- General data about the program and batch, e.g. selected program, program start
- Course of the pressure and temperature curves over time
- Measurement record in plain text
- Servicing

The batch documentation that is saved in the machine can be printed out at the end of the batch and, depending on the machine configuration, transferred to an external server, e.g. using the MMM RUMED middleware (option)see "Setting batch print and save options", Page 72.

The transferred batch documents can be permanently archived there (e.g. on a separate storage device). The operator is responsible for monitoring that the transmission and saving of the batch record is successful. 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 batch in question discarded.

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

2.2.12.1 Printer (option)

Depending on the model, the following options for printing the data of the batch record will be available.

- Print-out to integrated thermal printer
- Direct printing to an installed DIN A4 printer (Ethernet interface). One printer per machine is required when operating multiple machines.
- MMM RUMED middleware (option) for transferring batch data to a printer installed on the network. The data are written to a specified directory on an external PC where they can be further processed by another application, e.g. saved and printed. Only one PC and one printer are required when operating multiple machines.

The MMM batch documentation system with report printer provides a user-friendly means of documenting batches and easily reviewing the reports. The color printout of process curves along with the measured values presents all the details at a glance.

The following data are printed out:

- Date, institution and department name, selected program
- Machine number

- Batch number, next service, program number, software version
- Batch start / door seal pressurized
- Program phases with start of water intake, water quantity, start and end time, min. and max. temperature values during the diffusion phases, process chemical and concentration if applicable.
- Drying program phase (start time and max. temperature)
- Door seal release / unloading / end of batch
- Target A_0 value, recorded A_0, disinfection start and end, batch result
- Release / signature
- Barcode read (option)

2.2.13 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 (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.

2.2.14 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

2.2.15 Remote maintenance system (option)

Remote maintenance via a remote maintenance access such as “TeamViewer” to analyze the machine status. The remote maintenance software is installed on a PC (server) with Internet access. It may already be available on an existing network (e.g. for SimServ).

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

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

2.3 Operation and process description

2.3.1 Functioning of the machine

After the chamber door (single-door machine) or chamber doors (two-door machine) have been closed and pressed tight and the program started, 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 tank).
- Depending on the specific process step, process chemicals are added to the water.
- The water is sucked out of the chamber, heated, and sprayed onto the material to be treated by means of the rotating arms.
- 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 fresh, heated and sterile-filtered air.
- The door latch is released and the door on the unloading side can be opened. The door on the loading side remains closed.

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).

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 4.13, "Handling chemicals" when changing the process chemicals.

NOTICE

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

Type	Manufac-turer	Product
Mildly alkaline cleaning agent	Dr. Weigert	neodisher MediClean forte
Enzymatic cleaning component	Dr. Weigert	neodisher SystemAct
Mildly alkaline cleaning component	Dr. Weigert	neodisher SystemClean
Highly alkaline cleaning component with prion inactivation (< pH 10)	Dr. Weigert	neodisher SeptoClean
Neutralizer	Dr. Weigert	neodisher Z
Neutralizer	Dr. Weigert	neodisher N
Mildly alkaline solid cleaning agent	ECOLAB	MetalClean Plus

Type	Manufac-turer	Product
Mildly alkaline cleaning agent	Schülke & Mayr	thermosept X tra
Mildly alkaline 2-component cleaning system	Borer	deconex TWIN PH10 TWIN ZYME

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

2.3.3 Cleaning and disinfection process

This machine is a washer-disinfector pursuant to DIN EN ISO 15883-1, DIN EN ISO 15883-2 and DIN EN ISO 15883-6.

The individual process 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.

NOTICE

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

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

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.

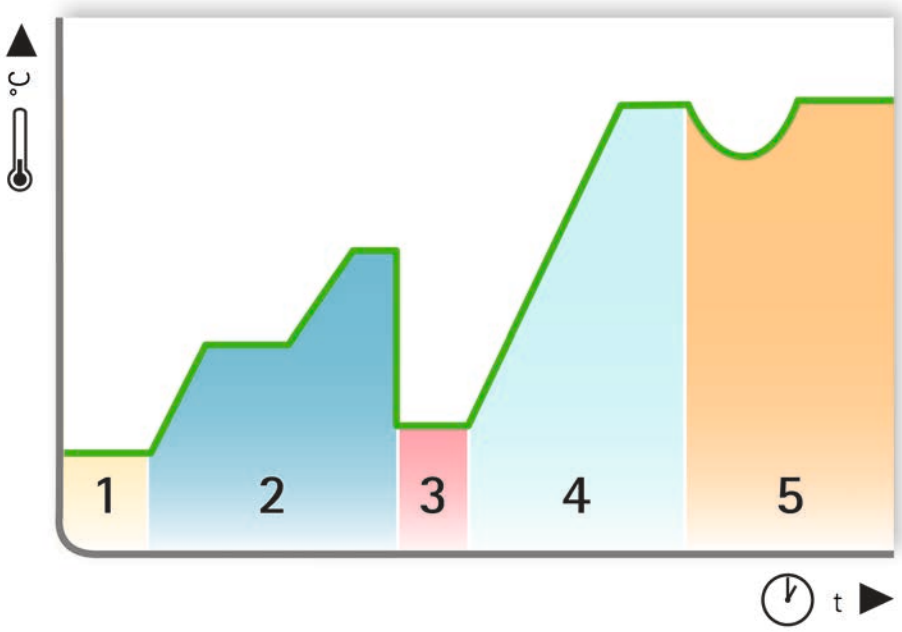
The disinfection effect of the machine is also achieved by spraying water onto the material.

- Thermal disinfection for thermostable materials: The sprayed water is heated to between 65 °C and max. 93 °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).

2.3.4 Example of process sequence

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

Example of cleaning program with thermal disinfection (for thermostable materials)



1. **Pre-cleaning**: Cold water with no process chemicals added is sprayed onto the material to be treated.
2. **Cleaning**: Hot water (between 35°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) with added rinse aid, if necessary, 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.

2.4 Accessories

2.4.1 UPL II transport trolley for racks



Warning

Risk of injury due to tipping of the transport trolley (TW).

The TW must only be used on level surfaces. Do not use the trolley on inclined surfaces.

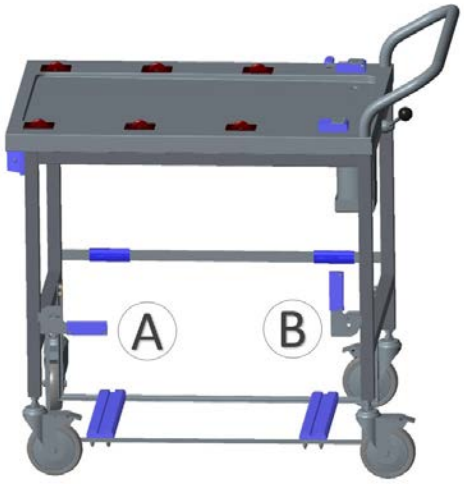
Uniclean PL II-10 transport trolley for racks

The transport trolley is used for loading, unloading, and transporting an MMM Uniclean PL II 10 machine series rack. An **empty** rack can also be stored or transported at the bottom.

The transport trolley (TW) has a loading height of 810 mm and a maximum loading weight of 120 kg; an **empty** rack can also be placed on the bottom.

Please note the following when placing an **empty** rack on the bottom:

- When transporting an empty rack at the bottom of the TW, the cover flaps (A and B) must be closed.
- To close the cover flap (A), fold the cover flap down.
- To open the cover flap (B), slide it upwards and fold it up. The cover flap will automatically drop a small distance and lock in place.



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

3 Display and control elements

3.1 Loading side

Control elements for normal operation on the loading side



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 on 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 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 draining of the chamber and the tank (if installed)

- The moist air from the chamber is automatically discharged into the on-site exhaust air system.
- Depending on the configuration, automatic opening of the door on the loading side, or the door on the loading side remains closed.

NOTICE

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

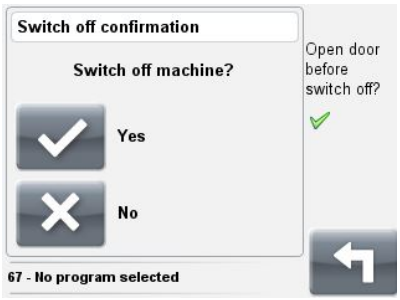
To switch off the machine:

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

By default, after switching off the machine the door on the loading side is opened to allow the water vapor to escape and the chamber to dry more quickly.

- Choose whether you want the door on the loading side to open or remain closed after switching off the machine.

  A green tick means the door on the loading side will be opened, a red cross means the door on the loading side will remain closed. You can change the setting by tapping the green tick or the red cross.



- Confirm the “Switch off machine” prompt with “Yes”.

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 23) 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 Colour touch display

The colour touch display is used to navigate the menus for operating the machine. Pressing 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 door button is deactivated during the program sequence, as opening the 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.

3.1.3.1 Function buttons on the color touch display

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.
	User log out	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.
	User log out inactive	The user "Anonymous" cannot be logged out. The button is then inactive.
	Start	Starts the selected program.
	Open/close door	Opens and closes the door on the loading side.
	Tools	Accesses a submenu that contains the following buttons: "Information", "Quick user access" and "Configuration" menu
	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.

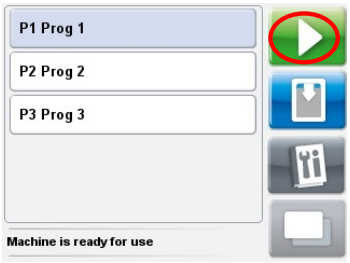
Button	Description	Function	
	Cancel program	Cancels the program, e.g. if the incorrect program was accidentally selected.	
	Information	Displays machine information such as the software and hardware configuration, including the batch counter and maintenance counter.	
	Maintenance information	Displays the "Service work overview" menu. This menu indicates when service work is due.	
	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 batch. The selected batch is highlighted in color.	
 	Arrow buttons	For changing the screen within the pages of an individual menu	
	Confirm	Confirms the selection.	
	Acknowledgment button	Acknowledges one or more alarm messages.	
	Back	Returns to the previous menu.	
	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	
	Batch process archive	Opens the "Batch selection" menu for viewing or reprinting batches 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.

Button	Description	Function
	Printer	Prints the batch record for the selected batch at the connected printer.
	PC	Menu: Process archive – Batch selection Sends the batch record for the selected batch to the batch documentation system.
	Email (Option)	Menu: Service – ISA (Option) Contacts MMM customer service or a company/person authorized by MMM by sending them an email.
	Last program run	Once a program has been run through properly, the machine is automatically switched off or switches to standby after removing the batch. Standby mode can also be activated via the quick access menu.
	Rack code entry	Allows you to view, edit and delete rack barcodes.
	Material barcodes	Allows you to view, edit and delete barcodes of DIN trays, etc.
	Creating users	The administrator can add a new user in the user administration.
	Deleting users	The administrator can delete a user in the user administration.

3.1.3.2 Menu overview on the loading side

Start screen

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



- Program name and number
- The status bar is located on the bottom edge of the screen. This displays information in plain text.
- "Tools" menu Chapter 3.1.3.3, ""Tools" menu on the loading side"

After starting, the remaining time display appears.

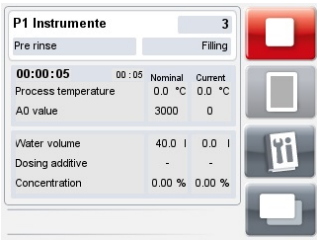
The "Open door" button is only activated if the door can be opened.

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



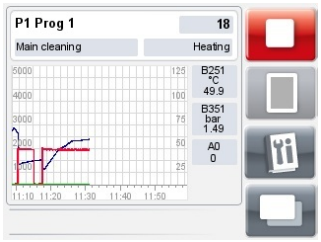
Remaining time

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



Program information

- Information on the current program



Batch process

- Curve representation of the process-related active sensors

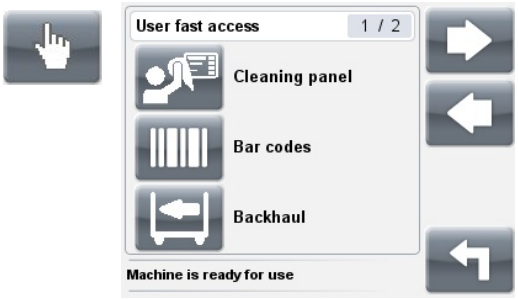
3.1.3.3 "Tools" menu on the loading side

The Tools button opens the Tools submenu.



The following buttons are shown: Information, Quick user access and Configuration menu.

Button	Screen	Function
		Displays detailed information about the hardware and software configuration of your machine Batch (process) and maintenance counters can be read on this screen.



Quick user access / first page:

Selection menu

Screen cleaning

Rack code entry

Return rack

The arrow buttons can be used to scroll between the "Quick user access" screens.



Quick user access / second page:

Batch process archive

Tank cleaning (Uniclean ML only)

Last program run



"Configuration" menu:

Settings

Service

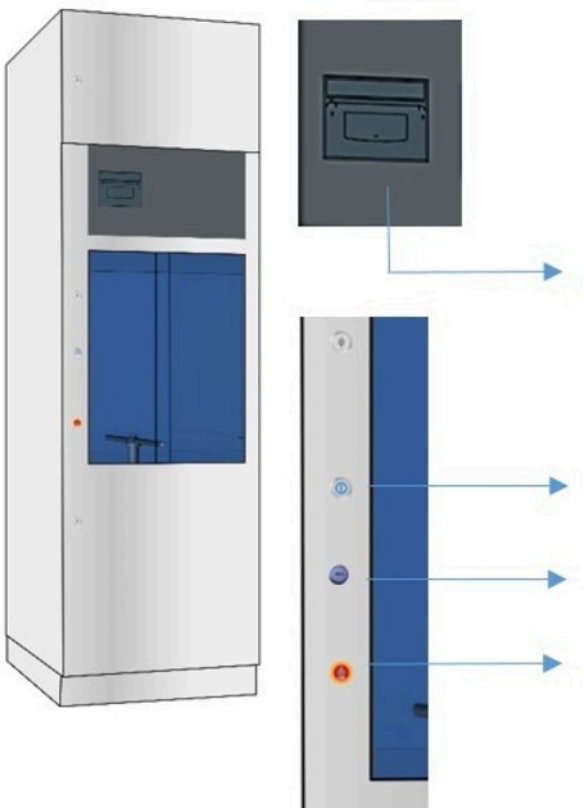
Information

Users

3.2 Unloading side (two-door machines only)

Control elements for normal operation on the unloading side.

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



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

3.2.1 Door button



Door button for opening and closing the door

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

The door on the unloading side can be opened and closed as often as required provided that the door on the loading side is not open. Once the door on the loading side has been opened, the door on the unloading side

can only be opened again once the program sequence has run successfully.

NOTICE

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

3.2.2 Rack redelivery button (option)



The rack redelivery function provides an easy way of feeding back racks from the unloading side to the loading side.
Chapter 4.7, "Activating and deactivating rack redelivery (option)"

3.2.3 EMERGENCY STOP



The emergency stop (see "EMERGENCY STOP", Page 23) 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

4 Operation

Please observe the safety instructions in Chapter 1, "Safety".

NOTICE

All activities described in the following must only be performed by trained persons.

4.1 Logging users in and out

Log-in is not required for normal operation.



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



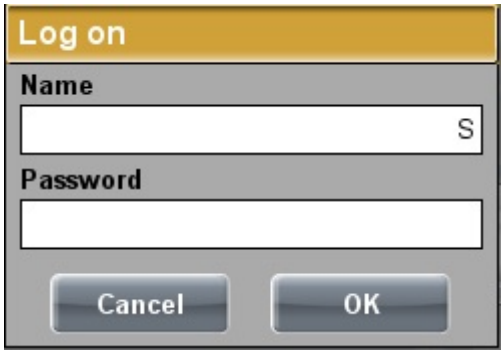
If the **user administration** (Chapter 1.3.2, "User permissions") option is used, operator log-in can be configured so that each operator has to log in with his name and password.

User log-in



- Press the log-in button.

The log-in window appears.



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

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

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

Log out actively to prevent misuse of rights!

The use 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 "Anonymous" appears in the user bar.

4.2 Programs

Typical cleaning and disinfection programs are listed below. 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.

Number	Program name	Disinfection method
P1	Instruments	Thermal with A_0 value of 3000
P2	MIS instruments	Thermal with A_0 value of 3000
P3	Containers	Thermal with A_0 value of 600
P4	Anesthetic materials	Thermal with A_0 value of 3000
P5	Utensils	Thermal with A_0 value of 600
P6	Containers	Thermal with A_0 value of 3000
P7	-	-
P8	Baby bottles	Thermal with A_0 value of 3000
P9	OR shoes	Thermal at 70 °C
P10	-	-
P11	Eye instruments	Thermal with A_0 value of 3000
P12	-	-
P13	-	-
P14	-	-
P15	Instruments > pH 10	Thermal with A_0 value of 3000
P16	Instruments intensive	Thermal with A_0 value of 3000
P17	6-level/instruments	Thermal with A_0 value of 3000

4.3 Auto start (configurable)

In normal operation, the tankis prepared for the selected program after the start button is pressed.

When auto start is activated, the tankis automatically prepared for a preset program after the machine is restarted. Auto start can only ever be activated for one program.

Activating auto start Chapter 5.3, "Auto start (configurable)"

4.4 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.



Danger

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.

Instruments with cavities, such as tubes, anaesthetic materials, MIS instruments, MIS eye instruments or similar instruments, must also be fully rinsed on the inside.

- 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).

4.5 Loading instructions



Danger

It is imperative that you observe the safety instructions and warnings in the enclosed user manuals for the racks and modules!

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

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

4.5.1 Notes on the transport trolley

The transport trolley is also referred to below as just TW.



Danger

Risk of injury!

Do not use a transport trolley with a defective rack locking mechanism or missing safety pin!

Do not use a transport trolley with a defective parking brake!

Regularly check the function of the transport trolley!

4.5.2 Checking the chamber

- Check whether the chamber is clean.
- Check the dirt filter and, if necessary, clean it Chapter 4.14.1, "Cleaning the dirt filter"
- Prior to each program sequence, check whether the rotating arm in the chamber can move freely.
- After the program has started, check whether the upper rotating arm in the chamber is rotating counterclockwise as viewed when standing in front of the loading door.



Danger

If this is not adhered to, the cleaning performance could be impaired!

4.5.3 Checking the racks, modules and inserts



Danger

Observe the following points for a valid and reproducible result!

All instruments and materials to be treated must be suitable for machine cleaning and disinfection. Follow the preparation instructions of the manufacturer of the instruments or materials to be treated!

Ensure the loading configuration and choice of program correspond to the validation (see "Validation", Page 12)!

General

- Check whether the material to be treated has undergone pre-cleaning. Follow the preparation instructions of the instrument manufacturer.
- Ensure the DIN trays are not overloaded.
  The maximum load weight is 10 kg!
- Ensure all articulated instruments are in the open position as per the instrument manufacturer's instructions.
- Check that the rotating arms in the rack can move freely.
- Check that the tube connectors are tight and correctly connected!
- Ensure the hoses are not kinked.
- Check that all unused threaded connections are sealed off with caps.
  Exception: for the rack 1 level, the threaded connections remain open.
- Check that the rack has been correctly loaded (see the instructions for use of the rack).
- After the program has started, check whether the rotating arms in the rack (if present) are rotating counterclockwise as viewed when standing in front of the loading door.



Observe the separate instructions for the racks, modules and insert modules. For exact details, see the instructions for use of the relevant rack!

MIS rack

- Disassemble all MIS instruments that can be taken apart as per the instrument manufacturer's instructions.
- Use only one MIS instrument per rinsing holder. Damaged rinsing holders must be replaced!

Modules for eye instruments

- Clean the fine filter and check it for damage.

Danger

Inadequate cleaning!

Blockage of the filter!

Perform adequate manual precleaning as per the manufacturer's instructions and clean the filter! Check the filter for damage!

- Ensure the filter is inserted without gaps.
- Disassemble all eye instruments that can be taken apart as per the instrument manufacturer's instructions.
- Check that all instruments with cavities are connected to the appropriate nozzles.
- Observe the max. loading height of the levels.
- Check that the modules are fully docked on the module fittings in the rack.

Anesthesia rack

- Make sure to mount the breathing masks in such a way that water cannot pool.
- Check that the hoses are mounted securely on the nozzles, and the end of each hose is elevated.
- Ensure all instruments with cavities have been connected to the appropriate nozzles.

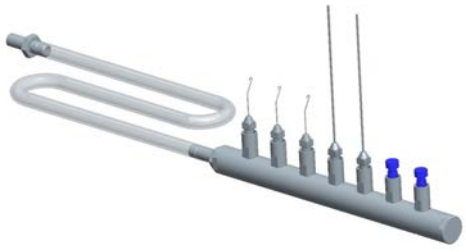
Flush strip:

Danger

Use a syringe to rinse the cannula with water immediately after use on the patient.

The cannula may otherwise become blocked.

The cleaning performance may otherwise be impaired.



- Connect the narrow-lumen cannulas as near as possible to the available threaded connections near the hose.
- Ensure the flush strip is sitting properly in the holder so that the drain hole is located at the lowest point.

4.6 Loading the chamber and starting the program

NOTICE

The machine must be switched on (on/off button on the loading side).

The chamber can only be loaded manually. The rack must be pushed fully into the chamber.

If the machine features a barcode reading system, the barcode reader detects which program is required for the material to be treated while it is being loaded into the chamber and this program is selected automatically. If the barcode is missing or damaged, a message is output and the program must be selected manually.

If you have the optional barcode reading system, the laser is deactivated if no barcode is read within 20 seconds. Press the “Start scanner” button to activate the barcode reading system for another 20 seconds.

A corresponding message is displayed on the screen.

4.6.1 Manually loading with and without a barcode



- Open the door on the loading side.
- Move the TW to the machine.
- Dock the TW correctly on the loading side and activate the locking lever.

  The TW is correctly docked once the locking pins of the TW have engaged. Disengage the locking pins on the TW to release the rack.
- Using both hands, grip the correctly loaded rack by the handles and push it into the chamber as far as it will go.



- Close the door on the loading side.

  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.



- Select the program.

If you have the optional barcode reading system, the program will be selected automatically.



▶ Press the start button.



The "Start" button changes into the "Cancel program" button.

4.7 Activating and deactivating rack redelivery (option)

The rack redelivery function provides an easy way of feeding back racks from the unloading side to the loading side.

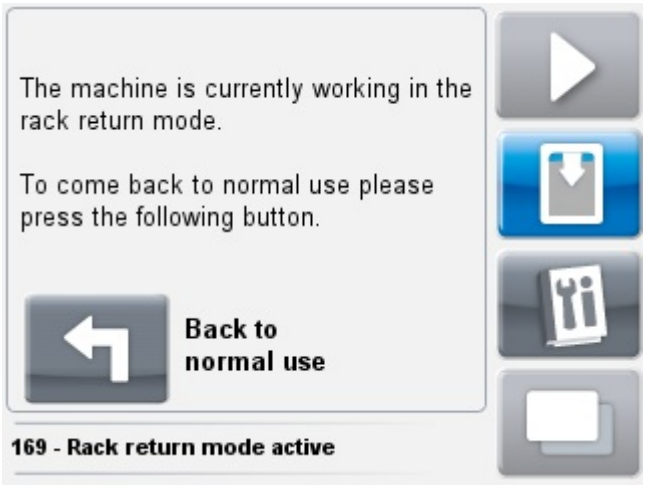
The button (option) for rack redelivery mode is located on the unloading side Chapter 3.2, "Unloading side (two-door machines only)" .

Activating rack redelivery

- ▶ Press the button on the unloading side.
- ▶ Open the door.
- ▶ Dock the TW and use both hands to push the rack into the chamber.
- ▶ Close the door.
- ▶ Dock the TW on the loading side.
- ▶ Open the door on the loading side.
- ▶ Using both hands, pull the rack out of the chamber and onto the TW.

Deactivating rack redelivery

- ▶ Press the button on the loading side operating panel.



4.8 Cancelling the program

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



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

After confirming the prompt, the 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 door on the loading side can be opened.

4.9 Unloading the chamber

Unloading of the chamber occursmanually.

Program sequence not completed properly

If the program sequence has not completed properly, “Process failed” appears on the display and the red chamber lighting is activated.

Single-door machine: The door cannot be opened. After acknowledging the message, the door is released and can be opened.

Two-door machine: The door on the unloading side cannot be opened. After acknowledging the message, the door on the loading side is released and can be opened.

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.

4.9.1 Manual unloading



Danger

Risk of burns
The rack can be very hot after treatment.
Wear gloves to protect your hands from heat when removing the rack.

Using both hands, pull the rack out of the chamber using the Cool Touch plastic handles provided.

- Move the transport trolley to the machine.
- Once the program has completed properly, dock a TW on the unloading side and activate the locking lever.

  The TW is correctly docked once the locking pins of the TW are locked in place on the machine.
- If the chamber door has not opened automatically, press the door button to open the door.
- Using both hands, grip the rack by the CoolTouch plastic handles and pull it fully onto the TW.
- Release the TW and move the transport trolley away.
- Check the lock pin on the front panel for correct function!

4.10 Approving the batch

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 “Batch process O.K.” appears on the batch record.



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

The batch is released based on the following visual inspection and on the batch record.

Inspecting the batch record

- After unloading the chamber, check whether the completed program was suitable for the unloaded goods in the relevant rack.
- Compare the data on the batch record with 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.

- Check that the load is unchanged, i.e. that all instruments and tubes are still fully connected.
- Cleaning results: Is there any residue on the items?
- Drying results: Is the material wet?

Inspecting the rotating arms

- Can all rotating arms still be rotated easily by hand?
- Are all end caps on all rotating arms still correctly attached?

Inspecting the filter on modules for eye instruments



Danger

The fine filters must be visually inspected for contamination or damage after every batch to ensure the performance of the entire cleaning system. This is the only way to guarantee a satisfactory cleaning result.

The fine filters must be replaced if they show visible damage. The batch must not be released and must be processed again.

- **The fine filter must be cleaned if the filter is contaminated (< 30 % of the filter area). The batch can be released.**
- **The fine filter must be cleaned if the filter is contaminated (> 30 % of the filter area). The batch must not be released and must be processed again.**

NOTICE

Batch approval requires:

- **Successful inspection of the batch record**
- **Successful check to ensure that the material to be treated matched the program**
- **Successful visual inspection of the treatment results**
- **Successful inspection of the filter if modules for eye instruments have been used**
- **Successful inspection of the rotating arms (option)**

Release documentation

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

After the batch is approved, the user must ensure that the batch record 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 record has not been added to the electronic archive, either the corresponding printout must be retained or the batch in question discarded.

Displaying and reprinting past batches

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

Proceed as follows:



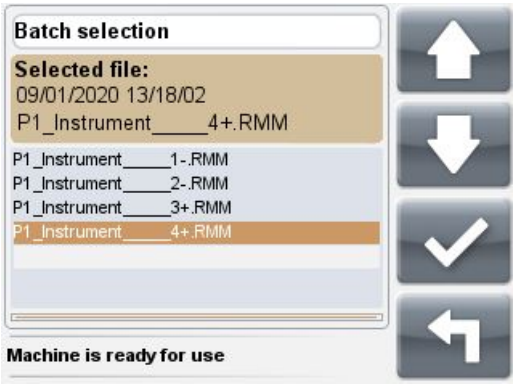
- Open the “Tools” menu



- Open “Quick user access”



- Open ”Process archive”

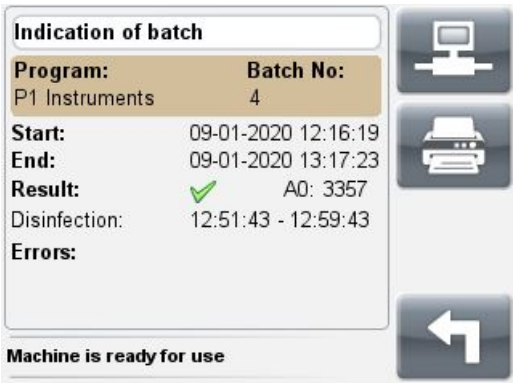




- Use the scroll buttons to scroll up or down.



- Select the required batch and confirm with the confirmation button.





- Press the “Printer” button. The batch data is printed.



- Press the “PC” button. The batch data is sent to the batch documentation system again.

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

4.11 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.

When the colour touch display is activated, it jumps back to the previous screen.

4.12 Last program run (configurable for two-door machine)



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

The function can be selected if the machine is to switch automatically to standby or off mode after the process and removal of the batch.

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 been run through properly, the materials have been unloaded and the unloading door 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.

4.13 Handling chemicals



Danger

Chemical are used in accordance with the intended use.

Observe the instructions in the respective safety data sheet of the process chemicals supplier. This applies when handling the chemical containers and accessories as well as to the use of personal protective equipment.

4.13.1 Safety instructions for changing process chemicals

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



The operator must implement organisational 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 labelled and colour coded.

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



Danger

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.

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

4.13.2 Changing the process chemical brand or type

If there is a change in the types of chemicals used compared with commissioning (see Chapter 2.3.2, "Process chemicals"), the process 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 performance evaluation.

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.



Danger

Only process chemicals that can be safely combined may be used. Otherwise there is a risk of an uncontrollable chemical reaction, such as explosion, damage to the treated material or machine parts and impairment of the effect, etc.

4.13.3 Replenish process chemicals

NOTICE

No program must be started on the machine!

Canister exchange must only be performed by a trained person!

4.13.4 Exchange the canister

Danger

Wear your personal protective equipment, e.g. safety goggles and gloves that are resistant to the process chemicals used.

Exchange canister

- Close the chamber door on the loading side.
- Open the cladding door. The key is administered by the system supervisor.
- Secure the chamber door using the door locking lever see "Securing the chamber door", Page 22.
- Remove the empty canister and place the canister next to the machine.
- Place the full canister next to the empty canister.

Danger

Risk of process chemical interchange!

Cleaning and disinfection processes is ineffective!

Check whether the new canister contains the same process chemicals!

- Open the full canister.
- Insert the hose (optionally, suction lance) from the empty canister into the full canister.

NOTICE

Deviations in the dosing due to contamination

Check the suction lance (option) for contamination. If necessary, wipe the suction lance with a lint-free cloth.

- Place the full canister in the machine.
- Release the locking mechanism (door locking lever).
- Close the cladding door.

- Return the key to the system supervisor.
- Dispose of the empty canisters as specified by the manufacturer.
- Acknowledge any fault message.

4.14 Shift change

The machine and tank must be drained and cleaned at the end of each shift.

4.14.1 Cleaning the dirt filter

The dirt filter must be cleaned at least once a day at the same time as the tanks. There must be **no** rack in the chamber!



Danger

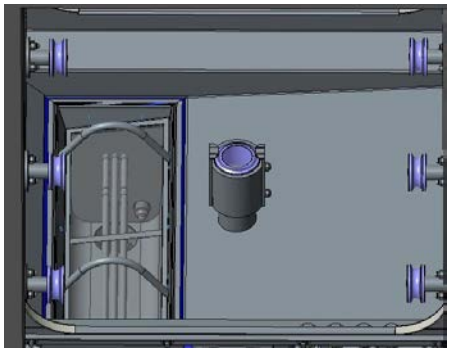
Risk of injury from class 2 laser on the loading side!

Retinal damage will occur if you deliberately look into the laser of the barcode scanner (option) for a prolonged period!

Never deliberately look into the laser beam!

The dirt filter is located at the bottom of the chamber.

- Remove any coarse dirt particles from the chamber and the filter.
- Lift the dirt filter out carefully so that no dirt falls off.
- Clean the edges on which the dirt filter rests.
  Make sure that no dirt falls into the chamber sump!



- Clean the dirt filter outside the chamber.

NOTICE

If the dirt filter is damaged, it must be replaced!

- Reinsert the dirt filter, ensuring a snug fit.

NOTICE

Check that there are no gaps after the dirt filter has been installed!

4.15 Sending messages to customer service via ISA (option)

With the ISA (Intelligent Service Advisor) option, MMM customer service or a company/person authorised by MMM can be informed of the need for service via e-mail. For a precise description, see 2.2.14 "ISA (option)", Page 37

The "ISA" menu is displayed.



▶ Access the "Tools" submenu.



▶ Open the "Configuration" menu.



▶ Open the "Service" menu.



▶ Open "ISA".





▶ Send an e-mail.

5 Machine configuration

5.1 Configuration User Manager (option)

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

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

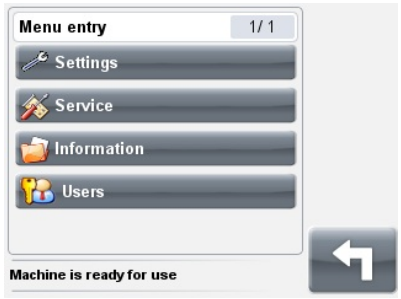
The various user passwords enable access to the corresponding menu levels.



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



- Open the "Configuration" menu.



- Press the **User** button.





- Press the **created user** button.

- Enter the name and password of the new user to be created.
- Assign the required authorizations to every new user.
- Enter the required log-out time after which the user will be automatically logged out. 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 batch print and save options

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

- Direct printing to a DIN A4 printer (*RUMED360® CyclePrint Direct*)
- Transfer of batch data to a network printer (*RUMED360® Cycles*)
- Direct printing on the integrated thermal printer

Batch print on a network printer (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.

- Information on whether the RUMED360® connection is licensed (green tick)
- Activate/deactivate the batch print
- The IP address of the network computer can be entered/changed here.

Direct printing of the batch on a *DIN A4 RUMED360® CyclePrint Direct* (option)

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

Direct printing of the batches using a thermal printer (option)

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

Saving batch data

The following options must be enabled in the “Settings” - “Batches” menu:

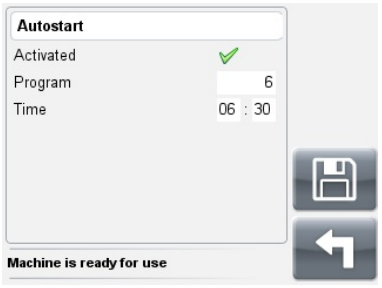
- Enable the batch saving function (set the green tick).
- Enter the IP address of the network computer on which SimServ is installed.

5.3 Auto start (configurable)

Configuration can be used to start a preparation program or a self-cleaning program without a rack automatically at a specific time. The program can be configured by a specialist. Prior to auto start, the machine is completely emptied, unless an emptying program or "Last program run" has been performed beforehand.

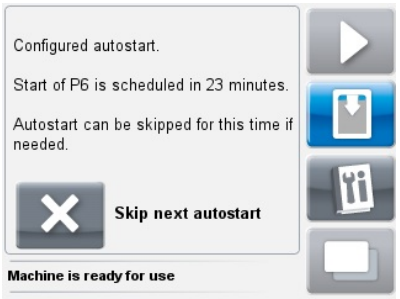
Configuration:

-  "Tools" menu
- Settings
- Customer settings
- Auto start
  - Activate auto start (green tick).
  - Enter program number.
  - Enter desired time.



The operator is shown on the display that auto start is present.

With X, auto start can be skipped once to start a program in an emergency.





If the machine is shut off, auto start is not activated!

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 door on the loading side can only be opened after the fault has been confirmed. The door on the unloading side is locked.

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

NOTICE

Observe the instructions in see Chapter 1, "Safety"

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

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

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

6.1 Fault messages

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



Fault with automatic program cancellation

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

Fault 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 is empty.*

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

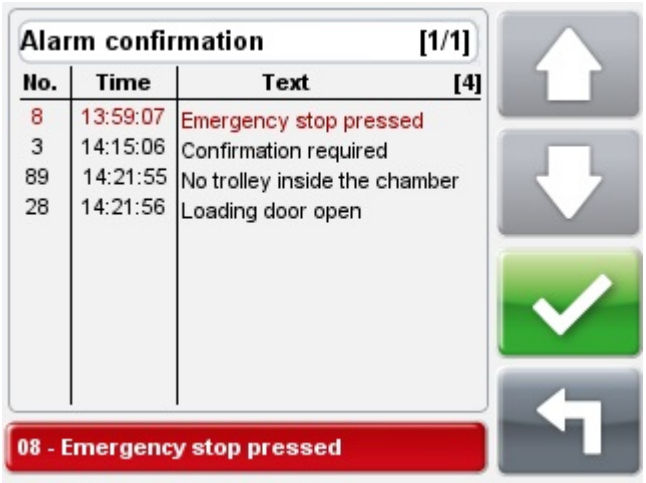
Document the fault and its consequences in the medical devices log / equipment log (including the fault number and precise wording of the fault message).

Confirming fault messages

NOTICE

Faults can only be confirmed after the cause has been eliminated.

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





Press the acknowledgment button.

This acknowledges all alarm messages!

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

If the operator is not authorized to acknowledge alarm messages, the log on dialog appears, see "Logging users in and out", Page 53

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 electricity supply is restored.

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

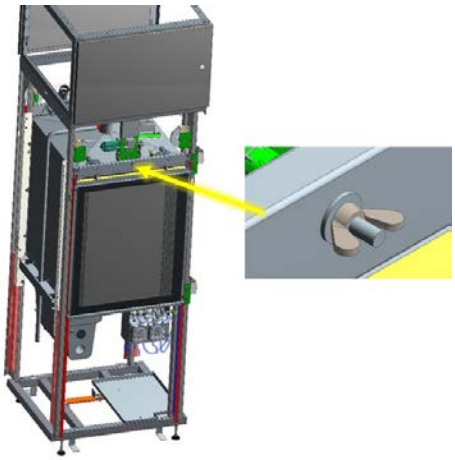
The program must be restarted after the fault has been confirmed and the door opened.

6.3.2 Opening the door in an emergency

The door must ONLY be opened manually if a power outage occurs during a batch!

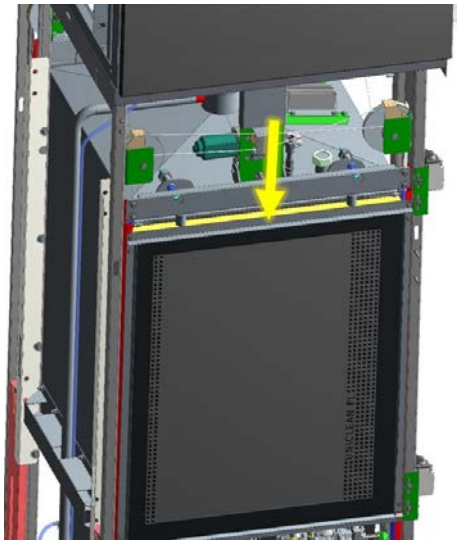
Open the door only if absolutely necessary!

After an emergency opening, the machine must be put into operation again by a specialist!



- Loosen the wingnut until the glass door detaches from the edge seal (top and bottom) and can move freely.

  The inbuilt springs press the closing mechanism in the opening direction.



- Manually press the glass door downwards (see arrow).

The loaded items can now be removed.

- When the electrical supply is available again, the machine must be restored to the proper state by a specialist!

6.3.3 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!



Danger

Risk of injury or crushing!

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

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.



Danger

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.



Danger

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.
- Switch on the machine at the loading side.
- Confirm the fault message (user right required).
- Place the rack in the chamber or onto the trolley.

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

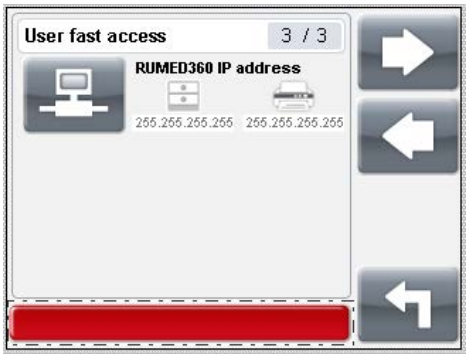
If there are signs of insufficient water quality, proceed as follows:

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

6.3.8 Network outage

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





6.4 Status and alarm list

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.	
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 occurred on the operating panel during the batch.	– 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 batch storage failed	Process data could not be stored. Not enough memory - internal fault.	Contact customer service
11	Network batch storage 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	Batch data processing active	Batch data is being processed. Batch has just finished, reloading or reprinting batch data.	

No.	Message	Reason	Possible remedy
13	Program run paused	Program has been interrupted. Manual intervention by an authorized person.	
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 that batch data contains the correct values
16	Printing active	Direct print job in progress at DIN A4 direct printer. Batch has just finished, reprinting batch data.	
17	Thermal printing failed	Printout failed.	– Check that printer is working – Check connection cable – Check that batch data contains the correct values
18	Thermal printing active	Print job in progress. Batch has just finished, reprinting batch data.	
19	Thermal 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 in but not registered as pressed in.	– Check position switch on machine
22	Door seal pressure too high	Door seal is not actually pressed in but is registered as pressed in.	– Check position switch on machine
26	Time exceeded loading door	Door movement on loading side takes longer than expected. Two racks (Uniclean PL II 30 only) in the machine with incorrectly mounted bumper.	– 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) – Check the bumpers on the racks. The opening on the bumper must face towards the same side for all racks. The opening should be on the left when looking at the bumper.
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)

No.	Message	Reason	Possible remedy
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
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.	– Check position switch on machine
39	Door seal pressure failed to drop	It is taking too long to release the door.	– Lift motor defective
40	Door seal press. too low in program	Door contact pressure has dropped during process sequence.	– Check position switch on machine
41	Doorway not free on loading side	It is taking too long to close the door on the loading side. Door opens again. Two racks (Uniclean PL II 30 only) in the machine with incorrectly mounted bumper.	– Check whether an object or person is in chamber door opening – Check whether door drive system is loose or defective – Check the bumpers on the racks. The opening on the bumper must face towards the same side for all racks. The opening should be on the left when looking at the bumper.
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.	

No.	Message	Reason	Possible remedy
44	Shutdown procedure failed	An error occurred during the shut-down procedure.	– Check whether object or person is in the way of the door – Check chamber level sensor – Check drainage system – Check chamber drainage valve
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	Low battery	Battery signals that voltage is too low.	– 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 tube 1 and remove air as required Chapter 6.7, "Removing air from the dosing tube" – Replace worn hose in dosing pump – Check connecting tubes 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 tube 2 and remove air as required Chapter 6.7, "Removing air from the dosing tube" – Replace worn hose in dosing pump – Check connecting tubes 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 tube 3 and remove air as required Chapter 6.7, "Removing air from the dosing tube" – Replace worn hose in dosing pump – Check connecting tubes for blockages or air bubbles
53	Inspection required for dosing line 4	Dosing line 4 is dosing less than expected. Deviation is still small enough.	– Check dosing tube 4 and remove air as required Chapter 6.7, "Removing air from the dosing tube" – Replace worn hose in dosing pump – Check connecting tubes for blockages or air bubbles
54	Failure dosing line 1	Dosing line 1 is dosing less than expected. Deviation is too high.	– Replace brittle hose in dosing pump – Check connecting tubes for blockages, air bubbles or leaks; remove air from dosing tube 1 as required. Chapter 6.7, "Removing air from the dosing tube" – Check flow meter for defects

No.	Message	Reason	Possible remedy
55	Failure dosing line 2	Dosing line 2 is dosing less than expected. Deviation is too high.	– Replace brittle hose in dosing pump – Check connecting tubes for blockages, air bubbles or leaks; remove air from dosing tube 2 as required. Chapter 6.7, "Removing air from the dosing tube" – Check flow meter for defects
56	Failure dosing line 3	Dosing line 3 is dosing less than expected. Deviation is too high.	– Replace brittle hose in dosing pump – Check connecting tubes for blockages, air bubbles or leaks; remove air from dosing tube 3 as required. Chapter 6.7, "Removing air from the dosing tube" – Check flow meter for defects
57	Failure dosing line 4	Dosing line 4 is dosing less than expected. Deviation is too high.	– Replace brittle hose in dosing pump – Check connecting tubes for blockages, air bubbles or leaks; remove air from dosing tube 4 as required. Chapter 6.7, "Removing air from the dosing tube" – 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 audit trail entry.
59	Disinfection temp. too low	Water temperature during disinfection is much too low.	– Check electric heating elements for defects
60	Disinfection temp. too low for too long	Water temperature during disinfection slightly too low for too long.	– Check electric heating elements for defects
61	Disinfection temp. too high	Water temperature during disinfection too high.	– 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.	– Electric heating element contactor is defective
64	Temp. too high during holding phase	Water temperature too high during a washing step.	– Electric heating element contactor is defective
65	Pressure of circulation pump too high	Pump pressure in circulation phase too high.	– Check jets for blockages
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

No.	Message	Reason	Possible remedy
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
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 level switch 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.	– Check that motor protection switch in control cabinet is set correctly according to motor data sheet – Check pump for foreign objects – Check pump for anomalies
86	Motor protection drain pump	Motor protection switch has been triggered.	– Check that motor protection switch in control cabinet is set correctly according to motor data sheet – Check pump for foreign objects – Check pump for anomalies
87	Motor protection fan	Motor protection switch/fuse of internal drying fan has been triggered.	– 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
88	Motor protection compressor	Motor protection switch of middle pressure fan has been triggered.	– Check that motor protection switch of middle pressure fan in control cabinet is set correctly according to motor data sheet
89	No trolley inside the chamber	No rack at specified position inside chamber.	– Check position switch inside chamber – Only push correct inside if machine has docking couplings in the chamber
90	Temperature limiter heating 1	Temperature limiter for heating has been triggered.	– 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 heating 2	Temperature limiter for heating has been triggered.	– 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.	– Check water level in tank 1, not enough water in system – Only check contactor in machines with electric heating systems
93	Temperature limiter heating tank 2	Temperature limiter for heating has been triggered.	– 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
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	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

No.	Message	Reason	Possible remedy
102	Deviation control/record air	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
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 water supply line for blockages
109	Time exceeded heating chamber	Temperature inside the chamber is rising too slowly.	– 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
111	Time exceeded heating tank 2	Temperature in tank 2 is rising too slowly.	– 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 level switch of chamber
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

No.	Message	Reason	Possible remedy
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 level switch of chamber – Check if tank level pressure transducer is working
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 batches 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 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 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 carryover in the machine – Check limit value settings in parameter lists on display
124	Dosage 1 empty	Suction lance of dosing line 1 signals that the container is empty.	– Check dosing tube 1 and remove air as required Chapter 6.7, "Removing air from the dosing tube" – 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 tube 2 and remove air as required Chapter 6.7, "Removing air from the dosing tube" – 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 tube 3 and remove air as required Chapter 6.7, "Removing air from the dosing tube" – Replenish process chemicals – Broken cable in suction lance line

No.	Message	Reason	Possible remedy
127	Dosage 4 empty	Suction lance of dosing line 4 signals that the container is empty.	– Check dosing tube 4 and remove air as required Chapter 6.7, "Removing air from the dosing tube" – 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 code	Rack scanning is active but no code has been read yet.	– Check barcode on rack – Check scanner
133	Wrong rack code	Rack code barcode was wrong or could not be identified correctly.	– Check barcode on rack – Check scanner
134	Wrong rack code length	The rack code barcode that has been read is not the right length.	– Barcode defective or illegible.
135	Loading system time exceeded	The loading procedure has taken too long. Trolley could not be loaded.	– Check door – Check sensor
136	Time exceeded unloading system	The unloading procedure has taken too long. Trolley could not be unloaded.	– Check sensor
137	Conductivity probe 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 – 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 probe B552 defective	Conductivity probe reporting incorrect input values.	– Check contacts on sensor – 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
143	Refilling without success	Too many refilling processes have been performed without managing to supply the chamber with sufficient water.	Door not airtight

No.	Message	Reason	Possible remedy
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 tubes are worn or defective	– Check dosage tubes – 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
156	Calibration/adjustment overdue.	Calibration/adjustment is overdue. Calibration/adjustment was not carried out on time.	– Carry out calibration/adjustment
157	Revalidation/requalification due shortly	Requalification is due very soon.	– Requalification is due.
158	Revalidation/requalification is 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 trolley docking system. Required positions not reached on time.	

No.	Message	Reason	Possible remedy
164	Docking: Confirmation 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
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
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	No 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 batch required	An empty batch was not run after venting the dosing line.	Run empty batch
175	Cancel for cleaning check	Program cancellation after cleaning for validation	For service technicians only
176	Door opening rejected	2nd 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 batch again.
177	Waiting for user action	2nd 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.
178	Motor protection (general)	Motor overload	Inform service technician
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 the tank are automatically drained.	

No.	Message	Reason	Possible remedy
184	Machine draining failed	Last program function is activated. Once the materials have been unloaded and the unloading door has been closed, the chamber and the tank are automatically drained.	– Check on-site drainage line for blockages – Check drainage valve on tank for defects – Check drainage valve of chamber for defects – Check level switch of chamber – Check level switch of tank
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. Batch process still completed correctly.	– Check the rotating arms are moving freely -> rotating arms are not hindered by protruding parts. – Check rotating arms are moving smoothly, if necessary clean the rotating arms. – Check whether the rotating arms are bent. – Check the spacer – Reflector on the rotating arm is soiled. – Adjust the rotating arm monitoring Inform service technician
189	Rotating arm fault	RPM of the rotating arms incorrect. Program canceled	– Check the rotating arms are moving freely -> rotating arms are not hindered by protruding parts. – Check rotating arms are moving smoothly, if necessary clean the rotating arms. – Check whether the rotating arms are bent. – Check the spacer – Reflector on the rotating arm is mounted incorrectly or soiled. – Adjust the rotating arm monitoring Inform service technician
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 level switch of chamber for defects
192	Flow meter dosing fault	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

No.	Message	Reason	Possible remedy
193	Flow meter water error	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.	Inform building services or service technician – Adjust the circulation in the tank
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.	Inform building services or service technician – Adjust the circulation in the tank
198	Chamber 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	Check cable	RPM of the rotating arms incorrect. Batch process still completed correctly.	– Check the rotating arms are moving freely -> rotating arms are not hindered by protruding parts. – Check rotating arms are moving smoothly, if necessary clean the rotating arms. – Check whether the rotating arms are bent. – Check the spacer – Reflector on the rotating arm is soiled. – Adjust the rotating arm monitoring Inform service technician.

6.5 Tips for dealing with inadequate cleaning results

Practical tips

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

- Has pre-cleaning been performed in accordance with the treatment instructions provided by the instrument manufacturer?
- Have any necessary pre-cleaning procedures been carried out correctly?

- Has the rack/module provided been used in accordance with its intended use?
- Were the racks loaded correctly? Machine must not be overloaded and material must not overlap!
- Are all the tubes securely connected without any kinks?
- Have all unused threaded connectors been sealed off with caps ?
- 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?

  Counterclockwise for the upper rotating arm in the chamber and in the rack (if present) as viewed when standing in front of the loading door.
- Have all process-related steps according to the validation see "Validation", Page 12 and the reprocessing instructions of the instrument manufacturer been adhered to?



Danger

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 rackis 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.

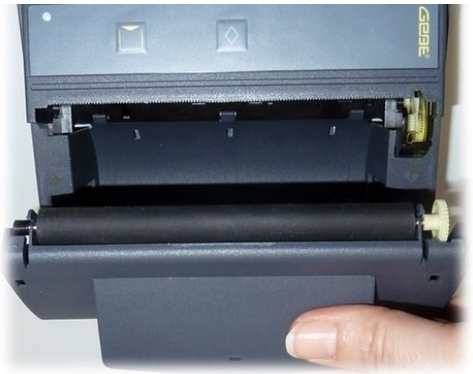
For unproblematic printing, we recommend ordering the paper from MMM.

- 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

6.7 Removing air from the dosing tube

Once the canister with the process chemicals has been replaced, there may be air in the dosing tube. Alarm messages 50 - 57 and 124 - 127 may

appear in the display. Air can be removed from the dosing tube. Follow the instructions.

Danger

Wear safety goggles and gloves that are resistant to the process chemicals. Additional personal safety measures may be required.

NOTICE

You must be trained and have the access right for removing air from the dosing tube, i.e. there must be a green tick next to "Use ISA".
Chapter 5.1, "Configuration User Manager (option)"



- Log in.



- Open the "Configuration" menu.



- Open the "Service" menu.



- Open the menu for removing air from the dosing tube.
- Place a container (e.g. a kidney dish) into the chamber.
- Position the container under the dosing outlet in question.

  The foremost dosing outlet corresponds to Dosing Tube 1 (from the loading side). The arrangement of the dosing outlets corresponds to the arrangement of the dosing pumps within the device.



- Close the door, so that no process chemicals spray out of the chamber.



- Press the button for the dosing line in question and **keep the button pressed for as long as the process chemicals** run out of the corresponding outlet.

  The air has now been removed from the dosing tube.

- Open the door and dispose of the process chemicals in the proper manner.

  Never tip the process chemicals into the device chamber. (Please contact the manufacturer for information about how to dispose of the waste in a proper manner).

A new container must be used to remove the air from another dosing tube! The process chemicals must not be mixed!

Danger

Risk of acid burns!

Uncontrolled chemical reaction!

If process chemicals enter the chamber, an empty batch must be run!



174 - Empty batch required

- Place an empty rack in the chamber and run an empty batch.

7 Maintenance

NOTICE

Observe the safety instructions in Chapter 1!

An inspection and safety maintenance (interval-based maintenance & inspection) must be carried out at least once a year. Observe the instructions in Chapter 1.7, "Maintenance and Safety inspection".

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

After 12 months or 1250 batches a preventative inspection and maintenance (preventative maintenance) must be performed.

The device is equipped with a batch and preventive maintenance counter as standard equipment. The current counter readings can be read on the screen at any time.

The batch 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 batch 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!

7.1 Safety

NOTICE

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

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

Indication of when service work is due

In the "Service work overview" menu, it is possible to check when maintenance, calibration/adjustment and requalification are due.



▶ Open the Tools submenu.



▶ Open the machine information screen.



▶ Open the Service work overview.

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 inspections of the technical functions

For the routine inspections of technical functions, we recommend check-list 11 of the "DGKH, DGSV and AKI guideline for the validation and routine monitoring of mechanical cleaning and thermal disinfection processes for medical devices and for principles of equipment selection".

The washer-disinfector system is equipped in such a way that item a) applies to all points of checklist 11 referred to above. This means that the longest inspection intervals can be chosen in each case.

7.5 Cleaning the control elements

The control elements are only to be cleaned after selecting the screen cleaning function Chapter 3.1.3.1, "Function buttons on the color touch display". 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.

7.6 Cleaning and servicing the rotating arms

The rotating arms of the chamber and of the rack must be regularly cleaned to ensure their freedom of movement and the performance of the entire cleaning system. This is the only way to guarantee a satisfactory cleaning result.

Dismantling the rotating arms

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



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

NOTICE

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.

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

Danger

Risk of mixing up the rotating arms!

Reduced cleaning performance or damage to the rotating arms!

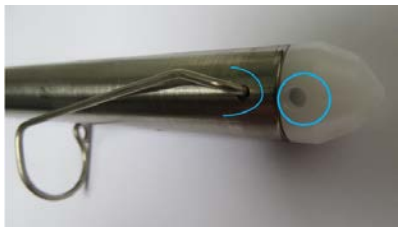
Check that the rotating arms are of the right type for the rack!

- **Rotating arms for Uniclean PL II-10 -> short rotating arms, length 52 cm.**
- **Rotating arms for Uniclean PL II-15 / PL II-30, length 63 cm**
- **Rotating arms for robotics rack -> length 63 cm with only 6 holes on the side**
- **Rotating arms for Uniclean ML -> long rotating arms, length 82 cm and blue caps**

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.

7.7 Cleaning the racks

NOTICE

All of the racks can be cleaned empty in the device.

Certain racks can be dismantled depending on the level of contamination.

Interval	What	How	Remark
After each batch	Ophthalmology instruments	▶ Remove the filter from the module. ▶ Clean the filter under running water, clean carefully with a soft brush if particles adhere. ▶ If further cleaning of the individual elements is necessary, pull both blue fine filters from the frame and clean them under running water. ▶ The fine filter can also be cleaned with compressed air. ▶ Reinstall all parts in reverse order. For a detailed description see the rack and module user manuals.  **Danger** **Damage!** **The fine filter may be damaged. Foreign objects may enter the washing system!** **Do not use sharp-edged brushes!** **The fine filter must not be kinked!** **Damaged fine filters must always be replaced!**	Check that the fine filter is inserted without gaps.
Interval	**What**	**How**	**Remark**
As required	all racks with injection and rinsing nozzles with an internal diameter smaller than 3 mm (nozzles with side holes)	To ensure unobstructed flow, all injection and rinsing nozzles must be cleaned using suitable brushes.	Uses brushes such as those used to clean hollow instruments (MIS).
As required	1/2 rack and 1 StU container with lid	▶ Loosen and remove the lower safety retainer. ▶ Remove the cleaning pipes completely. ▶ Loosen and remove the upper safety retainer. ▶ Flush the individual pipes and, if necessary, clean them with a soft brush. ▶ Reinstall the tubes in reverse order. For a detailed description: see the rack user manual.	When mounting the tubes, the slots in the tubes must always face the open side of the containers. The curvature of the slots must face upward.
As required	Rack MIS	▶ Pull the grid out of the rack. ▶ Remove the support rails. ▶ Clean the grid and support rails under running water. ▶ Wash the empty rack in the machine. ▶ Reinstall all parts in reverse order. For a detailed description: see the rack user manual.	The blind screw cap must be screwed tight again. When replacing rinse nozzles, make sure that the replacement nozzles are the same diameter! The rinse nozzle layout is determined by the load configuration and validation. Replace defective rinsing holders!

Interval	What	How	Remark
As required	Anesthetic rack	▶ Clean the supply pipe under running water and, if necessary, clean it with a soft brush. ▶ Reinstall all parts in reverse order. For a detailed description: see the rack user manual.	
As required	Flush strip, straight and angled	▶ Pull off the hose. ▶ Remove the plugs at both ends. ▶ Unscrew all threaded connections. ▶ Rinse all parts thoroughly under running water and, if necessary, clean them with an instrument brush. ▶ Completely reassemble the flush strip. For a detailed description: see the rack user manual.	Threaded connections must be remounted securely.



Cleaning as required means that the racks should be kept in a clean condition. The cleaning cycle depends on the frequency of use and degree of contamination.



Danger

Pressure loss!

Reduced cleaning performance!

Racks and modules must be remounted correctly!

Observe the separate user manuals for the racks!

7.8 Cleaning the TW

Interval	What	How	Remark
As required	Cleaning the TW	Clean the TW as per the work instruction using cleaning agents that are specifically suitable for stainless steel and plastics.	

Interval	What	How	Remark
	Removable collection container (option)	A collection container is located at the side beneath the storage table. ▶ Raise the collection container slightly. ▶ Push the bracket aside. ▶ Remove the collection container. ▶ Empty the collection container. ▶ Reinstall all parts in reverse order.	Regularly check how full the collection container is. When used constantly, the collection container should be rinsed once a day with a suitable disinfectant. Alternatively, preparation in the washer-disinfector is also possible.
	Rollers and storage table	Cleaning and disinfection according to the work instruction with a cleaning cloth together with a suitable surface disinfectant.	The removable parts can also be prepared in the washer-disinfector.

The transport trolleys are unsuitable for machine preparation!

7.9 Maintenance activities

NOTICE

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

NOTICE

When carrying out maintenance activities, the rack docking element must be sealed off with the supplied blue cover!

Daily:

What	How	Remark
Drain the tank.	1. There must be no material left inside the chamber. 2. Start the draining program or switch off the machine using the on/off button. If auto start is activated, the machine must be switched on again.	To be performed at the end of each workday or at each shift change.
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. An empty batch must now be run. Rust formation (surface rust, extraneous rust) can destroy the chamber. Spots of this nature must be treated immediately.	1. Open the loading door of the chamber 2. Visually inspect the chamber for foreign objects and extraneous rust. Remove any foreign objects. 3. There is a dirt filter in the chamber. This must be removed and cleaned. See Chapter 4.14.1, "Cleaning the dirt filter" 4. Install the cleaned filter. **Danger** **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. 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.
Lock pin in the door panel (for machines with manual or semi-automatic transport only)	Check the function of the lock pin. NOTICE **A defective lock pin must be replaced!**	
Cleaning the rotating arms	The rotating arms in both the chamber and the racks must be dismantled and cleaned. Then reassemble the rotating arms and check that they are able to move freely. Chapter 7.6, "Cleaning and servicing the rotating arms"	
Check the content of the process chemical canisters	1. Open the maintenance hatch on the loading side. **Danger** **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.** 2. Close the maintenance hatch.	The machine uses flow meters to monitor whether the process chemicals are available in sufficient quantities. For early detection of depleted process chemicals, suction lances (option) can be used to monitor the fill level.

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! NOTICE **Chemical cleaning agents must not be used on the glass surfaces.** Danger **The machine must always be switched off for cleaning.**	

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

Daily:

What	How	Remark
Check deionized water quality Conductance measurement	The water sample should be taken at the connection point to the WD. Alternatively, the water can also be taken at the sampling valve of the WD or at the open inlet of the tank (conductivity measurement). The maximum electrical conductivity of 15 µS/cm must not be exceeded.	Specifications for water quality can be found in DIN EN ISO 15883-1 and in the country-specific guidelines (e.g. DGKH, DGSV and AKI guideline for the validation and routine monitoring of mechanical cleaning and thermal disinfection processes for medical devices and for principles of equipment selection).

Weekly:

What	How	Remark
Check water quality Total hardness	The water sample should be taken at the connection point of the WD. Alternatively, the water can also be taken at the sampling valve of the WD or at the open inlet of the tank. The maximum total hardness of 5°dH must not be exceeded. 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)	Specifications for water quality can be found in DIN EN ISO 15883-1 and in the country-specific guidelines (e.g. DGKH, DGSV and AKI guideline for the validation and routine monitoring of mechanical cleaning and thermal disinfection processes for medical devices and for principles of equipment selection).
Check the dirt traps.	Open, check and, if necessary, clean the dirt traps in the water supply lines.	

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. 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.  **Danger** **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
Clean the machine compartment	Clean the machine compartment. Then disinfect all system components with an approved disinfectant.	
Check that the machine compartment is watertight.	Visually inspect the inside of the machine compartment for water leaks.	
Clean the tank (option)	Clean the tank using suitable cleaning utensils. For this, the covers must be removed and reattached once cleaning is complete.	

Twice a year:

What	How	Remark
Transport trolley TW	The parking brake function must be tested carefully with the transport trolley fully loaded.	
Transport trolley TW	Check the functioning of the rack stop.	

Annually:

What	How	Remark
Check water quality Chemical analysis	The water sample should be taken at the connection point to the WD. Alternatively, the water can also be taken at the sampling valve of the WD or at the open inlet of the tank (chemical analysis). In particular the total hardness, salt content (evaporation residue), chloride content, pH value, and electrical conductivity should be determined. 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	Specifications for water quality can be found in DIN EN ISO 15883-1 and in the country-specific guidelines (e.g. DGKH, DGSV and AKI guideline for the validation and routine monitoring of mechanical cleaning and thermal disinfection processes for medical devices and for principles of equipment selection).
Visual inspection of the transport trolley TW HV	Observe the instructions as per the manufacturer's specifications for the TW HV.	

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 dosage tubes	The dosage tubes must be replaced regularly or they will become worn. Only materials specified by the manufacturer may be used.	
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.  **Warning** **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. ▶ Insert the new door seal into the door seal groove. Ensure the vent holes are located on the outside! Position the join of the door seal on the upper edge if possible. ▶ Ensure the door seal lies flat in the door seal groove.	

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.

NOTICE

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

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

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

Section 1 Definition

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

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

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

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

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

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

"**Updates**" shall mean software that corrects faults in an older version of the software or that, without implying any obligation under this contract to do

so, enhances the functionality of the software by providing additional functions or any other increases in performance.

Section 2 Scope of the licence

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

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

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

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

Section 3 Warranty

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

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

Obtaining warranty service.

If the Licensee identifies a defect in the Software that may give rise to an obligation under the foregoing warranty, it shall cease using the Software immediately and notify the Licensor in writing of the defect within the defect notification period while also providing sufficient supporting documentation. The defect notification period is ninety (90) days from delivery of the data carrier (for a defect in the data carrier) and six (6) months from delivery of the software (for a defect in the software). The written supporting documentation providing proof of the defect shall be sufficient if the Licensor is able to reproduce the defect identified by the Licensee. The Licensee shall

enclose the relevant purchase receipt so that the Licensor may determine whether the defect notification period has been observed in respect of the defect concerned. The Licensee shall not carry out any modifications or repairs itself or allow modifications or repairs to be carried out by unauthorised third parties. If the Licensor so desires, the Licensee shall support the Licensor in the analysis of the causes and circumstances giving rise to the defect, as well as in the development and testing of correction codes or a work-around solution.

Exclusivity of warranty.

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

Section 4 Intellectual property rights

The Licensee shall only hold those rights to the Software that are expressly described in Section 2 of this Licence Agreement. The Licensor shall remain the sole holder of any other rights with regard to the software, including, without limitation, ownership rights and patent, copyright, trademark, trade secret and other intellectual property rights. The Licensee must

not remove, obscure or modify any references on the software to copyrights, trademarks or other ownership rights of the Licensor. The Licensee shall take all reasonable steps to prevent any unauthorised use, reproduction, sale or publication of the software or the unauthorised provision of access thereto. The Licensee shall indemnify and hold harmless the Licensor against any loss, damage, claims and expenses (including, without limitation, reasonable legal expenses) relating to any infringement of the rights of the Licensor caused by the Licensee, the Licensee's breach of this Licence Agreement or the Licensee's use of the software in a manner not permitted under this Licence Agreement.

Section 5 Limitation of liability

To the extent permitted under applicable law, the Licensor shall not be liable for any direct, indirect or consequential loss or damage, including, without limitation, loss of profits, unrealised cost reductions, loss of data or increased costs on the part of the Licensee or any other financial losses resulting from or in connection with the purchase, licensing, use, or failure of the software, or disturbances when operating the software. The foregoing limitation of liability shall also apply in the event that the Licensor has been notified in advance of the possibility of such loss or damage being incurred. The Licensor shall only be liable for loss or damage caused by the Licensor's gross negligence or wilful misconduct. This limitation of liability shall apply to all claims for damages irrespective of their legal grounds, including, without limitation, claims based on tort, contract, pre-contract or quasi-contract. This limitation of liability shall also apply to any officers, directors or employees of the Licensor and any representatives or agents of the Licensor that are involved in the development, marketing or delivery of the software. It is the sole obligation of the Licensee to ensure that it and its employees possess the required knowledge to properly install and/or use the software. The Licensor shall not be liable for problems and defects that arise from insufficient knowledge on the part of the users of the software.

Section 6 Contract period and termination

This licence agreement shall become effective on the date, when the licensee accepts and acknowledges the terms of this licence agreement.

In addition to other rights of cancellation according to this licence agreement, each party is allowed to cancel this licence agreement with immediate effect, if the other party essentially infringes a contractual duty, including but without limitation, delay in payment of the licence fee, provided that the party violating the contract does not correct the infringement within forty-five (45) days upon receipt of a written reminder.

On termination of this licence agreement, all righs of the licensee to use this software will cease. Within thirty (30) days on termination of this licence agreement, the licensee must return the software to the licenser or destroy it and all copies or partial copies the licensee has generated, all modified parts of the software or interfaces to other programs or data systems and

- if exist - all safety devices (and confirm the destruction in writing to the licenser).

Section 7 Applicable law and jurisdiction

This contract is governed by German law. Place of jurisdiction for any disagreements resulting from this contract are the regular courts at the primary location of MMM Münchener Medizin Mechanik GmbH in Planegg, Germany. The licenser is also entitled to appeal in their sole discretion the courts concerned at the seat or place of business of the licensee.

MMM Münchener Medizin Mechanik GmbH

10 Index

A

Accessories..... 41
Access protection..... 17
Additional dosing line (option)..... 33
alarm list..... 80
Anesthesia rack..... 58
Approved operator..... 16
Approving the batch..... 62
assemblies..... 20
Auto start..... 55, 72

B

Barcode (option)..... 35
Barcode reading system..... 35
Batch counter..... 31
Batch documentation..... 35
Bottom tray fill level monitoring (option).... 35

C

Chamber..... 30
Chamber door..... 30
Changing the process chemical brand..... 66
Changing the process chemical type..... 66
Checking the racks, modules and inserts.. 57
Cleaning and disinfection process..... 40
Cleaning the racks..... 103
Cleaning the TW..... 105
Closing the chamber door..... 20
Compatibility of the process chemicals..... 66
Conductance value measuring system (option)..... 32
Confirming fault messages..... 76
Control system..... 31
cybersecurity..... 12

D

Direct hot water connection (option)..... 35
Disinfection process..... 24
Displaying and reprinting past batches..... 64
Disposal..... 15
Dosing line > pH10 UPLII 10 (option)..... 33
Dosing line >pH10 UPLII 10 for small quantities (option)..... 33
Dosing line for small quantities (option)..... 33
Dosing system..... 33
Dosing verification (option)..... 33
Dosing verification for small quantities (option)..... 34
Drying..... 34

E

Electrical equipment..... 31
EMERGENCY STOP..... 79
EMERGENCY STOP pressed..... 21
Example of process sequence..... 40
Exchange the canister..... 67
exhaust air..... 34
Exhaust air draft interrupter..... 34

F

Flush strip:..... 58

H

Heating the pre-heating tank..... 34
HEPA filter..... 34

I

Inspecting the batch record..... 62
Inspecting the filter on modules..... 63
Inspecting the rotating arms..... 63
Intended purpose..... 9
Intended use..... 9

L

Last program run..... 65
Liability for defects..... 113
Limitations of use..... 10
Loading instructions..... 56

M

Machine configuration..... 71
Maintenance..... 24, 99
Maintenance activities..... 106
Manual unloading..... 61
Master switch..... 23
Media supply..... 34
MIS rack..... 57
Modules for eye instruments..... 58

N

Network security..... 12
Noise emission..... 14
Noise insulation (option)..... 35
Note regarding warranty..... 25

O

Opening the door in an emergency..... 77

P

Planning service work..... 99
Potential-free contacts (option)..... 32
Power failure..... 21
Printing the batch..... 72
Process chemicals..... 24
Process water..... 32
Programs..... 54

R

Release documentation..... 63
Removing air from the dosing tube..... 95
Replenish process chemicals..... 67
Residual risk..... 24
Responding to faults..... 76
Responsibilities of the operator..... 11
RUMED360..... 72

S

Safety inspection..... 24
Saving batch data..... 72
Service life of the machine..... 25
service work..... 99
Specialist..... 17
starting a program..... 20
Status list..... 80
Suction lance for 5 – 10 L containers..... 33
Supply air..... 34
System supervisor..... 16

T

Tanks..... 34
Thermal disinfection..... 41
Thermal printer paper exchange (option).. 94
Training the users..... 13
Type plate, explanation..... 29

U

Uniclean PL II-10 transport trolley for racks..... 42

User Manager..... 71
User permissions..... 17

V

Visually inspecting the treatment results... 62

W

Warranty..... 113
WEEE Directive..... 16