

Instructions for use

Washer-Disinfector

Uniclean PL II

Uniclean PL II 15
Uniclean PL II 30

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CE 0123

010483704 | REV13.2 | 2024-08

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 chamber doors	Heating	Position of the chamber	
15 30	1 2	EL - Electric FD - External steam EL/FD - switchable	R - right	Chamber on right, control panel on left
			not specified	Chamber on left, control panel on right

Example: Uniclean PL II 15-2-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
TW HV	Transport trolleys Height-adjustable	For transporting racks

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 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!

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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 15** and **30**washer-disinfector 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 15** and **30** is intended for use in the medical field, for example in Reprocessing Units for Medical Devices. The **Uniclean PL II 15** and **30** is also suitable for use in non-medical applications, e.g., laboratory wash-up facilities.

Intended use

a) Medical devices

The **Uniclean PL II 15** and **30** 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
- Robotic instruments
- Dental 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 (e.g. sterilization containers)
- Other utensils typically used in healthcare facilities

b) Other products in the medical sector

In addition to the aforementioned items, the **Uniclean PL II 15** and **30** 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

c) Other products in non-medical applications

The **Uniclean PL II 15** and **30** series of washer-disinfectors is intended for the automated cleaning and disinfection of non-medical materials in industrial wash-up facilities and laboratories, e.g. non-infectious laboratory items.

- Laboratory glassware
- Other laboratory goods typically used in laboratory facilities.

NOTICE

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

Limitations of use



Danger

Caution
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:

- 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 EU Regulation 2017/745 on Medical Devices, Article 87.

Before commissioning

The operator must ensure that the following requirements are met:

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

Network security

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

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

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

As a rule, requalification takes place annually.

Requalification is essential in the case of changes 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 automated cleaning and thermal disinfection processes for medical devices and for principles of equipment selection
  Guideline compiled by the **D**eutsche **G**esellschaft für **K**ranken**H**aushygiene (German Society for Hospital Hygiene), **D**eutsche **G**esellschaft für **S**terilgut**V**ersorgung (German Society for Sterile Supply) and **A**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
- Tests
- 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 6.4.8, "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 7.10, "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 stop switch depending on the machine type, maintenance hatch and pull-out canister compartment, control cabinet)
- 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 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.

Using the User Manager option, users can be assigned specific authorizations.

1.3.2 User permissions

The following users and authorizations are pre-configured:

Level	User name	Users	Authorised for:
1	Anonymous (no password)	Authorised users	e.g. program selection, program start
2	Supervisor (name: “s”)	System supervisor	e.g. acknowledging faults, alarm counters, configuration of certain parameters
3	MMM	Specialist, MMM customer service	System administration, access to all parameters

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

Certain actions can only be performed after user log-in as a supervisor (e.g. confirming fault messages).

If the screen is not touched for 30 seconds after log-in (individually adjustable), the *Supervisor* user is automatically logged out and the *Anonymous* user is logged in.

User Manager (option)

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

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

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

Only with second control panel (option):

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

1.4 Rules of conduct for operation

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 can 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 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 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 Uniclean PL II 30 with the C-Shuttle System

Operators are informed of the possible hazards associated with improper use when inducted by the machine owner.

Operators may only carry out tasks described in the Instructions for Use of the C-Shuttle System and which the machine owner has expressly assigned to them.



Warning

Observe the Instructions for Use of the C-Shuttle System!

1.4.3 Closing the chamber door, starting a program



Danger

There are people in the chamber!

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

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

1.4.4 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.

1.4.5 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 chamber door lock secured!

1.4.6 Working in the electrical control cabinet

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



Danger

Danger due to electric current!

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

1.4.7 Maintenance work

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

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

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



Danger

Possible leakage of caustic vapors.

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

1.5 Safety features of the machine

1.5.1 Chamber door interlock

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



Danger

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

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

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

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



Danger

Danger of contaminating the clean side!

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

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

- As soon as the cladding door is opened or the cover plates underneath the chamber door are removed, the chamber door must be secured using the mechanical door locking device.

1.5.3 Protection against getting crushed in the chamber door

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

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

Chamber door movement speed

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

1.5.4 Master switch

Uniclean PL II 15	**Uniclean PL II 30:**	
The master switch is located behind the control panel on the loading side.	**Electric heating:**	The master switch is located behind the control panel on the unloading side.
	Heating of external steam:	The master switch is located behind the control panel on the loading side.

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

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 6.4.7, "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 or the roller conveyor!

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.

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

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



The material is not considered properly treated!

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

1.5.7 Crushing protection, built-in fan

Zur Verbesserung der Trocknungsleistung befindet sich in der Kammer ein Lüfterrad (zwei Lüfterräder - bei der Uniclean PL II 30). Vor dem jeweiligen Lüfterrad befindet sich ein Gitter zum Schutz gegen Quetschungen und hineinragendes Behandlungsgut.



Danger

Risk of crushing when the fan wheel is running!

Risk of burns when heating elements are active!

The machine may only be operated with the safety guard in place.

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 (including the storage and transport conditions) of the process chemical manufacturer must be observed. The operator or user must put suitable measures in place to ensure that process chemicals cannot get mixed up.

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 Directive (EU) 2017/745/EU on medical devices).

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

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

Standards, regulations and directives

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

NOTICE

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

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

Applicable EU directives and EU regulations

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

NOTICE

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

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

Applied standards - state of the art

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

Performance and effectiveness

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

Product safety

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

EMC requirements

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

Functional safety

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

Usability

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

NOTICE

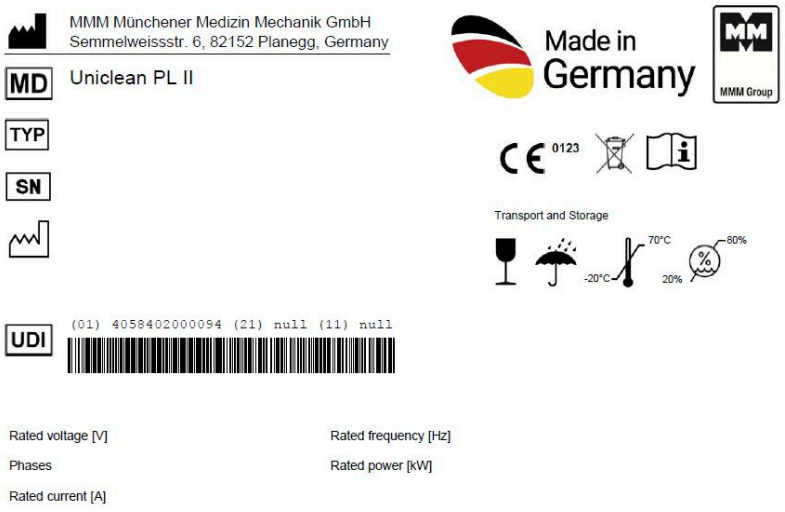
Note
Other standards that are referenced in the aforementioned regulations and may only be applicable in parts are not specifically listed.

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



Example illustration

Explanation of type plate:

 Manufacturer

 CE mark with identification number (example)

 Medical device

 Disposal (WEEE recycling)

 Type

 Observe the instructions for use

 Serial number

 Fragile, handle with care

 Date of manufacture

 Store in dry place

 Unique Device Identifier

 Lower and upper temperature limit

 Lower and upper air humidity limit

Additional conformity marks apply for the following countries:

 for Ukraine only

 for Serbia only

 for UK only

 for Australia only

2.2 Machine configuration

2.2.1 Chamber

- 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, or 110 liters for the Uniclean PL II 30.
- 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 chamber door to the chamber is sealed with a blow-out door seal that goes all the way around the chamber.

In the case of a **two-door machine**, both chamber doors are interlocked so the two chamber doors can never be opened at the same time (rack hatch function). The chamber door on the unloading side can only be opened after a program has run completely and successfully. The loading side can be opened (automatically or manually) once the treated materials have been removed and the chamber door on the unloading side has been closed. Once the loading side has been opened, the unloading side can no longer be opened. The unloading side can be opened again at any time if the loading side has not yet been opened.

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

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

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.

Cycle counter

A cycle counter is integrated into the controller. During the program sequence, the current cycle number is displayed in the Program sequence menu. Alternatively, the cycle number can be retrieved using the “Information” button. Various interfaces are available for transmitting cycle-related data, as well as for external connections and devices (USB, Ethernet, etc.). Cycle storage capacity: at least 25 000 cycles, see "Cycle documentation", Page 40.

Color touch display

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

curve diagrams, machine parameters and maintenance aids via the control menu.

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
- Activation in the drying and disinfection phase, e.g. if on-site exhaust air fan, exhaust air cooling provided

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 floor. 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.

There is a docking support for the water supply of the different racks on each of the lateral chamber walls. In the case of the Uniclean PL II 30, there are two docking supports, one on each of the lateral chamber walls. The docking supports on both sides are 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 installation preparation drawings or in the technical data sheets of the machines.

The method by which the process water in the chamber sump is heated depends on the machine variant.

- **EL** (electric) variant: via two electrical heating elements
- **FD** (external steam) variant: a heat exchanger (on-site supply of saturated steam)
- **EL**/**FD** variant: an electrical heating element and a heat exchanger (on-site supply of saturated steam)

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, a dosing pump with two independent flow meters is installed as standard. Additional dosing lines (max. 4 pcs) are optionally available. The machine has a pull-out canister compartment for holding and storing chemical canisters (up to 10 l) (suction lances are optionally available for an additional charge).

Suction lance for 5 – 10 L containers

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

Additional dosing line (option)

Additional dosing pump including dosing monitoring (by two independent flow meters) for additional process chemical used in the machine.

Dosing line > pH10 UPLII 15/30 (option)

Additional dosing pump including dosing monitoring (by two independent flow meters) 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 including dosing monitoring (by 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 15 for small quantities (option)

Additional dosing pump including dosing monitoring (by two independent flow meters) for automatic dosing of small quantities of a highly alkaline (pH value > 10) process chemical (e.g. rinse aid, cleaning chemical concen-

trates) in a UPL II 15/30 machine, including suitable non-return valve, TYGON dosing pump tubing and TYGON transfer tubing.

2.2.6 Drying

2-step H-Flow

The integrated H-Flow 2-step drying system ensures a turbulent horizontal airflow inside the chamber.

- The fresh air is heated by a heating element integrated into the pipe and routed directly into the loading rack and hollow instruments via the two chamber docking supports. At the same time, a heating element built into the chamber ensures that the material to be treated is dried on the outside.
- A stainless steel axial fan is installed at the side of the chamber to optimise the drying process and achieve short drying times. This is built into a specially installed conical segment of the chamber. As a result, horizontal air turbulence is generated for optimum distribution of the air and temperature inside the chamber and the load.

2.2.7 Supply and exhaust air

HEPA filter

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

The Uniclean PL II 30 has two HEPA filters (H14) installed.

Monitoring the HEPA filter (option)

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

ECONOMIZER exhaust air system with condensate discharge (option)

Maintenance-free exhaust air condenser made entirely of CrNi steel, working in the air/air process. During the drying phase, the warm and moist exhaust air is brought into contact with the incoming cold fresh air by a 2-way heat exchanger. The exhaust air vapours condense and the moisture content drops. The condensate that forms in the heat exchanger during this process is automatically fed into the drain via an internal pipeline.

Exhaust air draft interrupter

Exhaust air draft interrupters integrated directly into the chamber exhaust air pipeline with infiltration air intake from the machine assemblies compartment, including connection nozzle for the building exhaust air pipe and condensate discharge inside the machine.

2.2.8 Rotating arm monitoring (option)

The rotating arm monitoring function is a technical facility for automatically monitoring the movement of the rotating arms in the chamber and on the racks.

The activation of the “rotating arm monitoring” function in the machine software can be program-specific.

The rotation of all rotating arms located in the chamber is detected by means of vertically arranged sensor strips on the chamber wall, analyzed by an evaluation module, and reported to the machine software.

Appropriate reflectors, that serve as signal generators, have been applied to the rotating arms for this purpose.

If the rotating arm monitoring function is activated, movement of the rotating arm below a defined threshold value is detected, a message can optionally be written to the cycle report, or cancellation of the cycle initiated.

The message in the cycle report requests the user of the machine to check the movement of the rotating arms in the chamber, or on the relevant rack after the process.

If the cycle is canceled, the user must take suitable measures to eliminate the cause of the fault and then restart the reprocessing in the WD.



Suitable racks with reflectors fitted to the rotating arms must be used!

2.2.9 Tanks (option)

Tank system

The tank system consists of two optional tanks that can be used individually or together.

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 to 10 minutes.

Deionized water recovery tank

- To save energy, water and time, the deionized water is fed into the recovery tank after the thermal disinfection process and is reused during the next program sequence for intermediate rinsing.

Heating the pre-heating tank

The process water is heated by installed heat exchangers. Depending on the device version, these use the on-site supply of heating steam or electric heating elements.

In the case of the Uniclean PL II 15, the steam heating can optionally also be combined with electric heating. If the steam supply fails, it is possible to manually switch to an electric heater (1 x 9 kW) (Chapter 6.4.10, "Steam supply failure").

2.2.10 Media supply

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

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 90 °C must not be exceeded.

Pure steam supply for chamber or tank (option)

The chamber heating and the deionized water pre-heating tank have been designed for operation with on-site pure steam. The machine is supplied with “Pure steam” grade steam.

Due to the aggressive nature of this grade of steam, the entire steam and condensate line including fittings is made of stainless steel.

Media shut-off valves (option)

Piston shut-off valves for cold water, deionized water, hot water and steam. During machine operation, the relevant piston shut-off valve remains open. If the machine is switched off or the emergency stop activated, the valve closes, thereby disconnecting the machine from the on-site media supply. When combined with bottom tray fill level monitoring (option), the media shut-off valves also close.

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 (available for Uniclean PL II-15 and Uniclean UPL II-30). 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.

2.2.11 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.

2.2.12 Air permeability reduction (optional)

A technical facility on the loading side (clean side) of a two-door Uniclean PL II machine to reduce the air permeability between the clean and unclean side of a reprocessing unit for medical devices (RUMED).

It essentially comprises two additional stainless steel covering panels with frame and circumferential seal that is applied to the actual machine enclosure.



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

2.2.13 Loading and unloading

Semi-automatic loading and unloading

Uniclean PL II-30	Uniclean PL II-15-1	Uniclean PL II-15-2
yes	option	option

The automatically driven rollers in the chamber are provided for semi-automatic loading and unloading of the racks. After being gently pushed by hand, the rack is transported fully-automatically into the chamber and positioned. On unloading, the rack is automatically transported onto the docked transport trolley. The user then only has to pull the rack a few centimeters onto the transport trolley.

Automatic loading and unloading

Uniclean PL II-30	Uniclean PL II-15-1	Uniclean PL II-15-2
yes	option	option

Electric rack loading and unloading from or onto a roller conveyor. During loading, the rack is pushed manually onto the loading roller conveyor until it is detected by the track rollers and automatically transported further inside. During unloading, the rack is automatically pushed onto the unloading roller conveyor on the unloading side by the motor-driven rollers. Loading and unloading of the two racks occurs automatically for the Uniclean PL II 30. If a TW is docked correctly after a program has completed properly, a rack is pushed onto the TW.

The transport trolley must be correctly docked and locked to the roller conveyor/chamber before activating the rollers. This is ensured mechanically by a manually activated locking pin and electrically by a magnet switch.

If the machine is operated correctly, canting of the rack is not possible and it cannot fall.

If required, the rack can be transported back in the opposite direction by pressing the “Return rack” button on the control panel. For safety reasons, this function is designed so that this button must held down continuously during the transport movement.

For an exact description, see 4 "Operation".

2.2.14 Barcode (option)

UPL II data matrix reading system

Barcode detection system or Datamatrix and QR code reading system for the device, featuring a hand-held scanner for contactless reading of material barcodes. Once read in, the barcodes are shown on the machine display. The system features intelligent barcode management to avoid duplicate barcode entries. The barcodes for the next program can be read in while the current program is still running. Once read, the barcodes are printed on the batch record. They can be read out by documentation systems using the MMM library.

UPL II barcode reading system (cable or wireless)

Barcode detection system for the machine featuring a hand-held scanner so that material barcodes can be read in contactlessly.

Once read in, the barcodes are shown on the machine display. The system features intelligent barcode management to avoid duplicate barcode entries.

The barcodes for the next program can be read in while the current program is still running.

Once read, the barcodes are printed on the batch record. They can be read out by documentation systems using the MMM library.

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 or automatically fed 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.

2.2.15 Cycle documentation

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

The cycle document contains the following information:

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

The cycle document that is saved in the machine can be printed out at the end of the cycle and, depending on the machine configuration, transferred to an external server, e.g. using the MMM RUMED360 Cycles middleware (option)see "Setting cycle report print and save options", Page 94.

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

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

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

2.2.15.1 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)

2.2.16 Energy manager (option)

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

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

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

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

2.2.17 Control room (option)

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

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

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

2.2.18 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 sealed 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 tanks).

- Depending on the respective process step, process chemicals is dosed into the water.
- The water is sucked out of the chamber, heated, and sprayed onto the material to be treated by means of the 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 drying capacity is also improved by the circulation system with integrated heating system located in the chamber.
- The door seals are released and the chamber door on the unloading side can be opened.
  If you have the “air permeability reduction” (isolator) option, the door seal on the loading side remains pressurized.

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 cleaning system.

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

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

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 process chemicals

PL II	Type	Manu-facturer	Product
15/30	Mildly alkaline cleaning agent	Dr. Weigert	neodisher MediClean forte

PL II	Type	Manu-facturer	Product
15/30	Enzymatic cleaning component	Dr. Weigert	neodisher SystemAct
15/30	Mildly alkaline cleaning component	Dr. Weigert	neodisher SystemClean
15/30	Highly alkaline cleaning component with prion inactivation (< pH 10)	Dr. Weigert	neodisher SeptoClean
15/30	Neutralizer	Dr. Weigert	neodisher Z
15/30	Neutralizer	Dr. Weigert	neodisher N
15/30	Mildly alkaline solid cleaning agent	ECOLAB	MetalClean Plus
15/30	Mildly alkaline cleaning agent	Schülke & Mayr	thermosept X tra
15/30	Mildly alkaline 2-component cleaning system	Borer	deconex TWIN PH10 TWIN ZYME

Current as at 04/2024



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

2.3.3 Cleaning and disinfection process

The individual 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.



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.

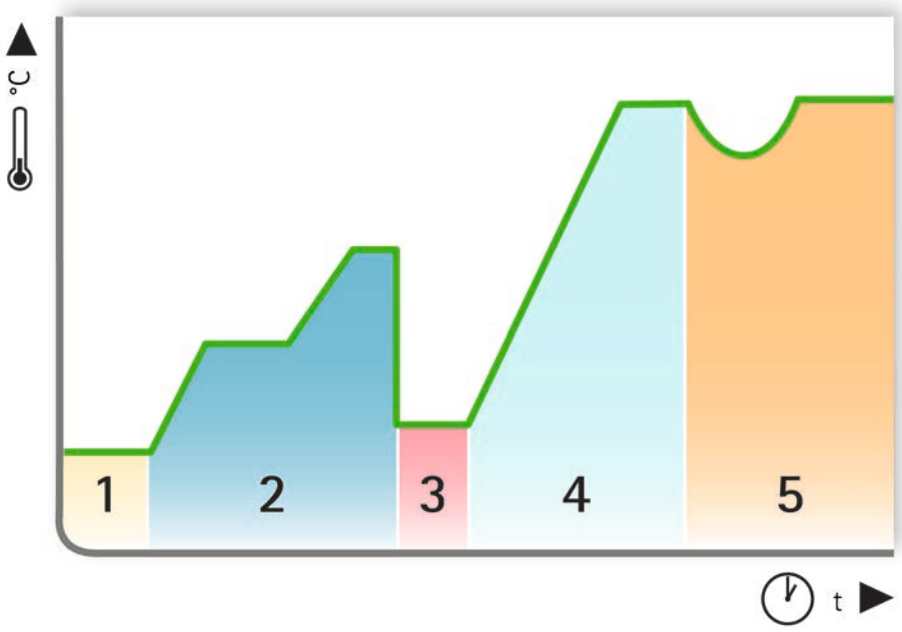
The disinfection effect of the machine is also achieved by spraying water onto the material to be treated.

- 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 process sequence

An example process sequence is shown below. The example may vary from the process sequence that you use.

Example of cleaning with thermal disinfection (for thermostable materials)



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

2.4 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 15 and PL II 30 transport trolley for racks

The transport trolley is used for loading, unloading and transporting an MMM Uniclean PL II 15 and PL II 30 machine series rack.

The transport trolley is available in two designs:

- Transport trolley (TW) with a loading height of 810 mm and a maximum loading weight of 170 kg.
- Height-adjustable transport trolley (TW HV) with a maximum loading weight of 130 kg.
  The buttons for moving the platform are located on the handles. The left button moves the platform upwards, the right button moves the platform downwards. The middle button between the handles moves the platform to a preset height.
  The TW HV is configured on site for the required loading height.



Danger

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



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

Observe the safety instructions.

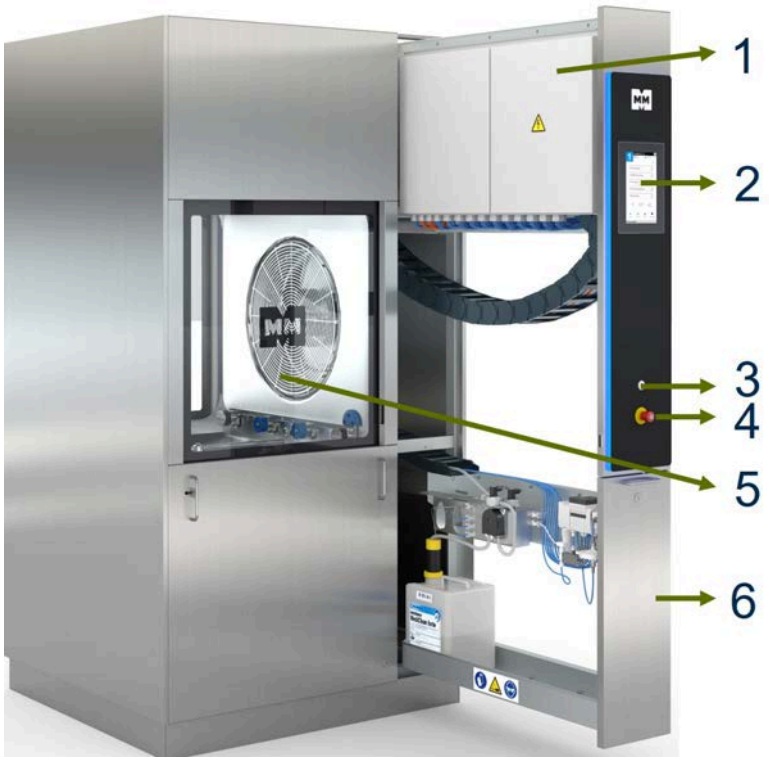
Your personal safety and the correct functioning of the machine are at stake.



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

3 Displays and controls

3.1 Loading side



1 Control cabinet
2 Color touch display*
3 On/off button
4 EMERGENCY STOP
5 Chamber door
6 Pull-out canister compartment

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

In the case of a single-door machine, the loading side is also the unloading 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 the machine off

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

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

NOTICE

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

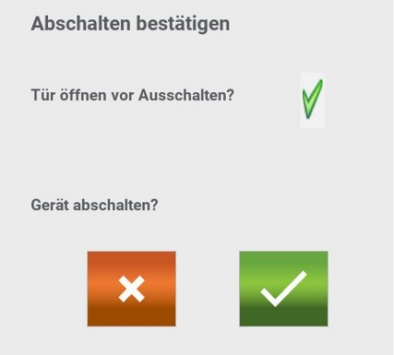
To switch off the machine:

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

By default, after switching off the machine the chamber 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 chamber door on the loading side to open or remain closed after switching off the machine.

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



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

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

3.1.2 EMERGENCY STOP



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

Example

3.1.3 Color touch display

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

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

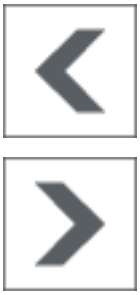
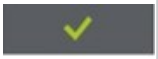
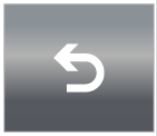
Only those buttons that can be activated in the respective operating state are shown as active on the display. For example, the chamber door button is deactivated during the program sequence, as opening the chamber door during the process is not permitted.

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

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

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

Button	Description	Function
	Log in user	User log in. Every action requires a user to be logged-in. If no user is logged in, the user “Anonymous” is logged in.
 Example	Log out user and display “Current user”	User log out. If a user actively logs out, the user “Anonymous” is automatically logged in. If the user does not actively log out, the user is automatically logged out after a specific period during which no buttons on the display are pressed.
	Start	Starts the selected program.
	Cancel program	Cancels the program, e.g. if the incorrect program was accidentally selected.
	Open/close chamber door	Opens and closes the chamber door on the loading side.
	Extended program selection/Switch screens between various types of program information	This button has two functions: 1. Additional programs are displayed on the program selection screen when more than five programs are pre-configured. 2. During the program sequence, this button switches between the program information screens.
	Information	Displays machine information such as the software and hardware configuration, including the cycle counter and maintenance counter.

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

Button	Description	Function	
	Barcodes	Opens the “Barcodes” menu for selecting rack code or material barcode	
	Archive of cycle sequences	Opens the “Cycle selection” menu for viewing or reprinting cycles that have already been completed.	
	Return transport	Transports the rack back onto the transport trolley (for example).	The button must be held down constantly during the transport process.
	Printer	Prints the cycle report for the selected cycle at the connected printer.	
	Last program run	Once a program has been run through properly, the machine is automatically switched off or switches to standby after removing the materials. Standby mode can also be activated via the quick access menu.	
	Rack code entry	Allows you to view, edit and delete rack barcodes.	

3.1.4 Menu overview on the loading side

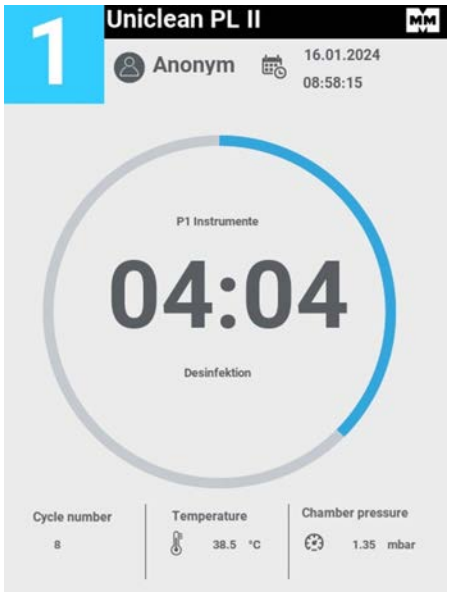
Home page

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



- Logging users in and out, see "Logging users in and out", Page 61
- Program name and number
- Start button, chamber door button open/close, button to "Quick user access"and button to "Initial menu"
- The status bar is located along the bottom edge of the screen and displays information in plain text, e.g. an alarm message.

After starting a program, the remaining time display appears.



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



Remaining time

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



Program information

- Information on the current program

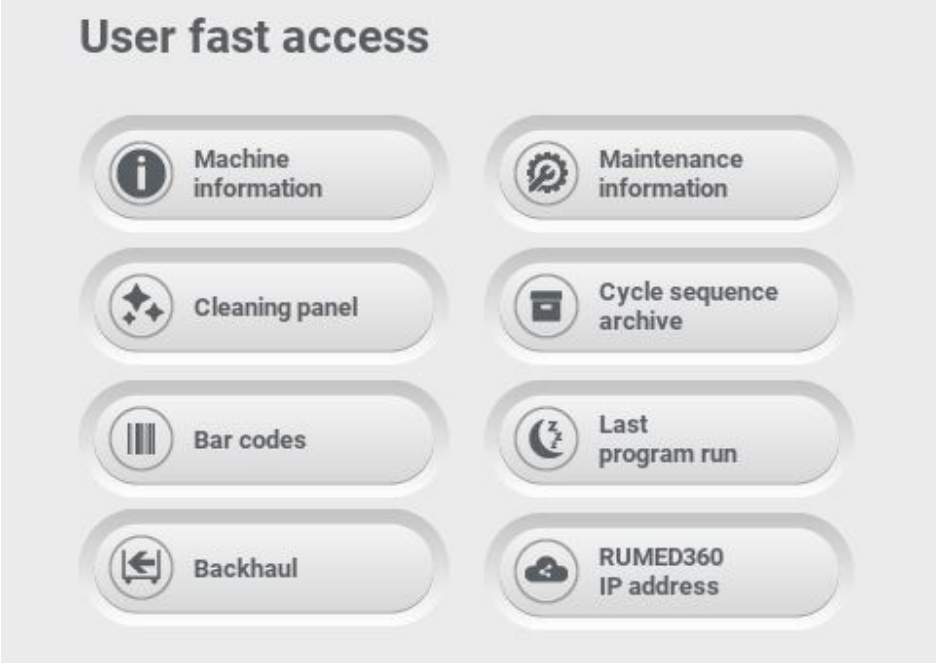


Cycle sequence

- Curve representation of the process-related active sensors.

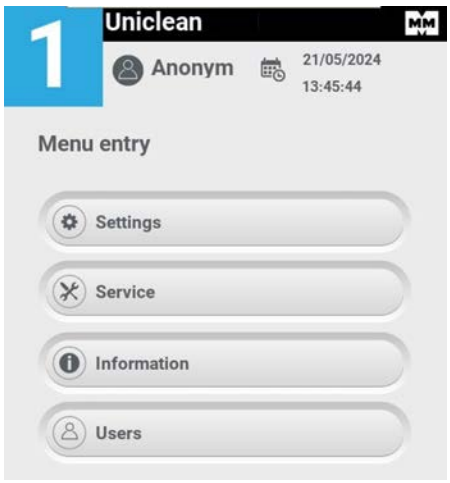
The Open chamber door button is only activated if the chamber door can be opened.

Quick user access



- Machine information (MMM Service Hotline info, software version, model, serial number, cycle counter and next maintenance)
- Screen cleaning, see "Cleaning the control elements", Page 129
- Barcodes
- Return rack, see "Return transport ", Page 75
-
- Maintenance information, see "Planning service work", Page 128
- Archive of cycle sequences, see "Releasing the cycle", Page 84
- Last program run, see "Last program run ", Page 87
- RUMED360 IP address, see "Network outage", Page 101

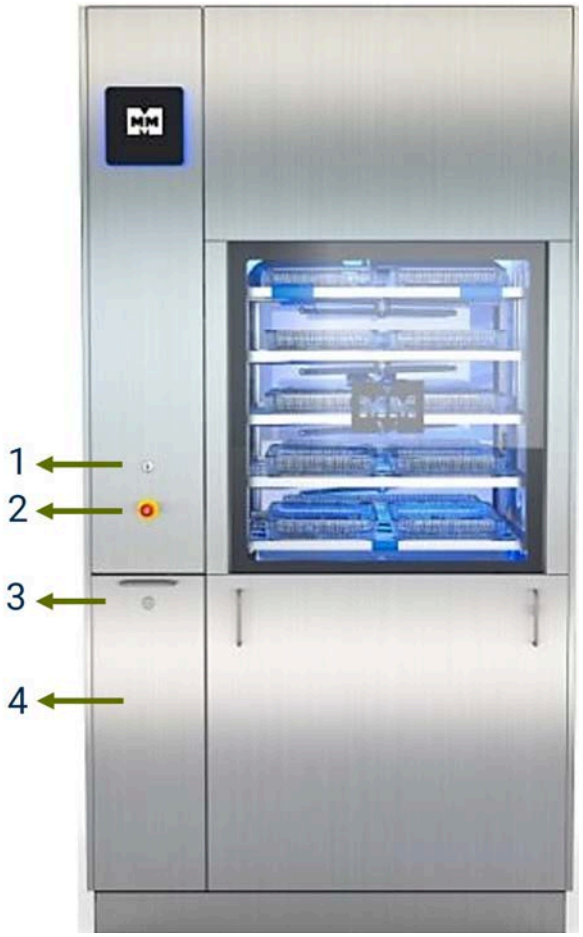
Initial menu



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

3.2 Unloading side (two-door machines only)

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



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

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

3.2.1 Chamber door button



Chamber door button for opening and closing the chamber door.

The chamber door button is only active and illuminated when operating the chamber door is permitted. Pressing this button during the program

sequence or when the chamber door on the loading side is open does not trigger door activity.

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

NOTICE

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

3.2.2 EMERGENCY STOP



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

Example

3.2.3 Menu overview on the unloading side (option)

Home page

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



The screen has no function while no program is running.

After starting a program, the remaining time display appears.

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

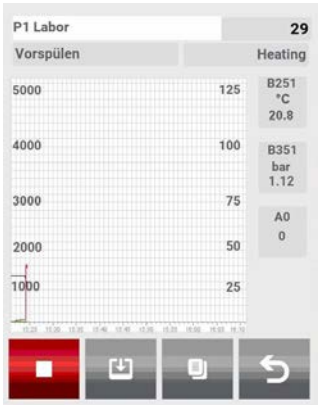
The “Change screen” button (see circle) allows you to switch between the “Remaining time”, “Program information” and “Cycle process” menus.



Remaining time



Program information



Cycle sequence

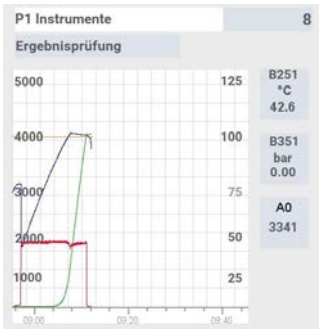
For information on the screens, see Chapter 3.1.4, "Menu overview on the loading side"

Checking the results on completion of the cycle

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



Cycle sequence information



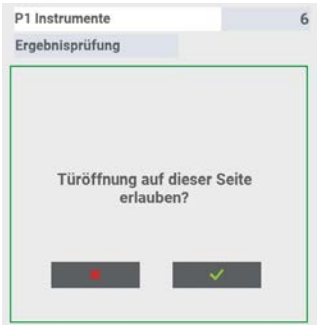
Cycle sequence

- Curve representation of the process-related active sensors.



Program information

- Information on the current program



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



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



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

4 Operation

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

NOTICE

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

4.1 Logging users in and out

Log-in is not required for normal operation.

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

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

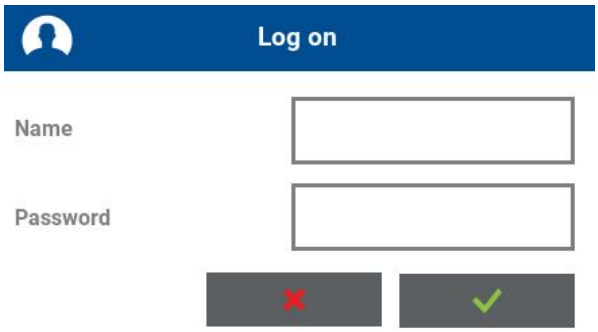
If the **User Manager** (Chapter 1.3.2, "User permissions") option is used, operator log-in can be configured so that each operator has to log in with his name and password.

Operator log-in

Anonym

- Press the button.

The log-in window appears.



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

- Confirm the entry.
- Press the tick button.

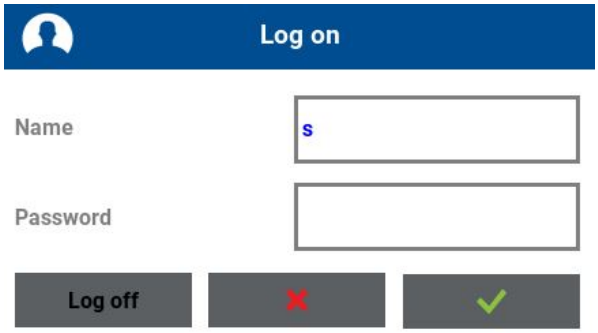
After log-in, the corresponding user name (e.g. “S”) appears in the title bar.

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

Log out actively to prevent misuse of rights!

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

User log-out



- Press the **Log out** button.

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

4.2 Programs

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	Surgical 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

Number	Program name	Disinfection method
P9	OR shoes	Thermal at 70 °C
P10	Robotic instruments	Thermal with A_0 value of 3000
P11	Eye instruments	Thermal with A_0 value of 3000
P12	Dental instruments	Thermal with A_0 value of 3000
P13	-	-
P14	Anesthetic/instruments	Thermal with A_0 value of 3000
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
P18	Unisonic for robotic instruments	Thermal with A_0 value of 3000
P21	Glass items	

4.3 Principles for machine cleaning and disinfection

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

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



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).

4.4 Information on loading



Danger

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

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

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

4.4.1 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 or missing safety pin!

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

Regularly check the function of the transport trolley!



Regularly charge the batteries of the height-adjustable transport trolley.

For more detailed information, refer to the enclosed original user manual for the height-adjustable transport trolley.



A system-specific transport trolley is used in conjunction with a C-Shuttle System. The only difference between the system-specific transport trolley and other transport trolleys is that it has a longer load surface.

4.4.2 Chamber

- The chamber must be clean see "Maintenance activities ", Page 138.
- Check the dirt filter and, if necessary, clean it Chapter 7.7, "Cleaning the dirt filter".
- Prior to each program sequence, check whether the rotating arms in the chamber can move freely.
- After the program has started, check in the chamber whether the upper rotating arm is rotating counterclockwise and the lower rotating arm is rotating clockwise as viewed when standing in front of the loading door.



Danger

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

4.4.3 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!

Flex rack

- Check that all levels are securely seated in both mounts and have been locked using the locking screws.
- Check that all connectors on the levels without a load are closed with caps.

MIS rack with strip

- Check that the MIS strip is seated securely.

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!

MIS module, dental instruments and Modules for eye instruments

- Clean the fine filter and check the fine filter for damage after every use.



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.
- 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!

- Check that all instruments with cavities are connected to the appropriate nozzles.
- Check that the dental instruments (straight and contra-angle handpieces, turbines) are attached to the appropriate adapters.
- Observe the max. loading height of the levels.
- If four MIS modules are used, the MIS rack with 2 module levels cannot accommodate any more than two short MIS modules, otherwise pressure may be lost and cleaning performance reduced!
- 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:

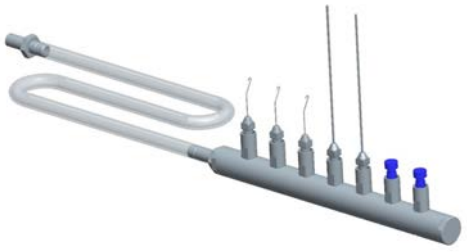


Danger

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.

Da Vinci module:

- Clean the fine filter and check the fine filter for damage after every use.
- Ensure the distal functional end of the instrument is open and free from visible contamination.
- Check that all unused connectors are sealed off with connector adapters.

- Ensure the hoses of the connector adapter are not twisted or kinked.
- Check the holder valves for damage. Damaged holder valves must be replaced!
- Check that the modules are fully docked on the module fittings in the rack.



Danger

Inadequate cleaning!

Blockage of the filter!

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

4.5 Loading the chamber and starting the program

NOTICE

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

The chamber can be loaded as follows depending on the machine configuration:

Uniclean	PL II-30	PL II-15-1	PL II-15-2
Manual loading	no	yes	yes
Semi-automatic loading	yes	option	option
Automatic loading	option	Option	option

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.

Loading of the chamber can occur either from a transport trolley or via a loading roller conveyor.

In the case of the manual variant, the rack must be pushed into the chamber.

In the case of the semi-automatic variant, the rack must be pushed a small distance into the chamber until it is detected by the sensor after which it is automatically pulled into the chamber.

If you have the automatic variant, the chamber is loaded via an automatic loading roller conveyor, the barcode on the rack (option) is read,

and opening and closing of the chamber door, loading and unloading, and selecting and starting the program all occur automatically.

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.

4.5.1 Manually loading with and without a barcode

Uniclean PL II 15 only!

- Open the chamber door on the loading side.
- Check the lock pin on the front panel for correct function!
- Set the TW HV (option) to the loading height.
- Move the TW/TW HV to the machine.

Danger

Risk of injury!

TW HV can be caught! The rack can fall from the TW HV or the machine can be damaged!

No height adjustment when the TW HV is docked and locked!

- Scan the barcodes of the materials (option).
- Dock the TW/TW HV correctly on the loading side and activate the locking lever.

  The TW/TW HV is correctly docked once the locking pins of the TW/TW HV have engaged on the machine and the transport route of the rack between the TW/TW HV and the chamber is also clear.
- 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 chamber door on the loading side.

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

  Provided the start command has not yet been issued, the chamber 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.

4.5.2 Semi-automatic loading with and without a barcode

Uniclean	PL II-30	PL II-15-1	PL II-15-2
Semi-automatic loading	yes	option	option

If the machine is equipped with the semi-automatic loading feature, the rack is transported into the chamber automatically. As the rack is being loaded into the chamber, the barcode reader (option) scans the program and selects it. If the barcode is missing or damaged, a message is output and the program must be selected manually.



- Open the chamber door on the loading side.
- Check the lock pin on the front panel for correct function!
- Set the TW HV (option) to the loading height.
- Move the TW/TW HV to the roller conveyor or to the machine.



Danger

Risk of injury!

TW HV can be caught! The rack can fall from the TW HV or the machine can be damaged!

No height adjustment when the TW HV is docked and locked!

- Scan the material barcodes (option).
- Dock the TW/TW HV correctly on the loading side/loading roller conveyor and activate the locking lever.

  The TW/TW HV is correctly docked once the locking pins of the TW/TW HV have engaged on the machine and the transport route of the rack between the TW/TW HV and the chamber is also clear.

- Push the rack into the chamber/onto the loading roller conveyor until it is detected by the sensor and the transport motor pulls it into the chamber.

If you have the Uniclean PL II 30, repeat the above steps. The program can only be started once the machine has been loaded with two racks.

The racks can be loaded with different materials. The loading configuration must be checked and approved as part of the validation or requalification. Factory-approved configurations see Page 73



- Close the chamber door on the loading side.

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

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



- Select the program.

  If you have the optional barcode reading system, the chamber door closes and the program starts automatically.



- Press the start button.



The “Start” button changes into the “Cancel program” button.

4.5.3 Automatic loading

Uniclean	PL II-30	PL II-15-1	PL II-15-2
Automatic loading	yes	option	option

If the machine is equipped with an automatic loading roller conveyor, the rack is transported into the chamber automatically. In the case of the Uniclean PL II 30, both racks are transported into the chamber. As the rack is being loaded into the chamber, the barcode reader scans the program. Once this step is complete, the machine starts automatically. If the barcode is missing or damaged, a message is output and the program must be selected manually.

- Set the TW HV (option) to the loading height.
- Move the TW or TW HV to the roller conveyor.



Danger

Risk of injury!

TW HV can be caught! The rack can fall from the TW HV or the machine can be damaged!

No height adjustment when the TW HV is docked and locked!

- Scan the material barcodes (option).
- Dock the TW / TW HV correctly on the loading side/loading roller conveyor and activate the locking lever.

  The TW / TW HV is correctly docked once the locking pins of the TW / TW HV have engaged on the machine and the transport route of the rack between the TW / TW HV and the chamber is also clear.

- Push the rack onto the loading roller conveyor until it is detected by the sensor and the transport motor pulls it into the chamber.



If you have the Uniclean PL II 30, repeat the above steps. The program can only be started once the machine has been loaded with two racks.

The racks can be loaded with different materials. The loading configuration must be checked and approved as part of the validation or requalification. Factory-approved configurations see Page 73



- Close the chamber door, select the program, then press the start button.

  If you have the optional barcode reading system, the chamber door will close automatically and the program will be selected and started automatically.



The “Start” button changes into the “Cancel program” button.

Mixed loads for PL II 30

Mixed loads for Uniclean PL II 30

NOTICE

No mixed loads for:

- **Anesthesia items (longer drying time)**
- **Containers (lower cleaning temperatures and pulsed drying for containers)**
- **Endo trays (low cleaning temperatures and pulsed drying for containers)**
- **Glassware (longer drying time)**
- **6-level racks (specific program)**
- **Shoes (low cleaning and drying temperatures)**
- **Shoe soles (low cleaning and drying temperatures)**

Overview of mixed loads

Mixed loads		Note
Instruments (any 1- to 5-level racks, Flex rack)	yes	**Exception**: 6-level rack!
Instruments and MIS	yes	select a longer program!
MIS and MIS	yes/ no	**yes**: 2 x MIS rack*, 2 x MIS rack with 2 module levels **no**: MIS rack and MIS rack with 2 module levels
Instruments and eye/dental	yes	select a longer program!

* also 3- and 4-level rack with MIS strip

Approved loading configurations for the Uniclean PL II 30

Loaded items	Rack		Note
Instruments and instruments	Multi-level racks (1- to 5-level rack) Flex rack	Yes	
Instruments and utensils	Multi-level racks (1- to 5-level rack) Flex rack	Yes	Select a longer program
Utensils and utensils	Multi-level racks (1- to 5-level rack) Flex rack	Yes	
Instruments and MIS instruments	Multi-level racks (1- to 5-level rack) Flex rack and MIS racks (3- or 4-level rack with MIS strip, MIS rack, MIS rack with module levels)	Yes	Select a longer program
MIS instruments and MIS instruments	2 x MIS rack	Yes	
	MIS rack and 3- or 4-level rack with MIS strip	Yes	
	MIS rack and MIS rack with module levels	No	The required rinsing pressure in the racks cannot be achieved
	2 x 3- or 4-level rack with MIS strip	Yes	
	3- or 4-level rack with MIS strip and MIS rack with module levels	Yes	
	2 x MIS rack with 2 module levels	Yes	

Loaded items	Rack		Note
Instruments and eye/ dental	Multi-level racks (1- to 5-level rack) Flex rack and MIS/eye rack with 2 module levels Dental racks	Yes	Select a longer program (eye/ dental instruments should preferably be processed in the PL II 15)
MIS instruments and eye/dental	MIS racks (3- or 4-level rack with MIS strip, MIS rack, MIS rack with module levels) and MIS/eye rack with 2 module levels Dental racks	Yes	Select a longer program (eye/ dental instruments should preferably be processed in the PL II 15)

4.5.4 Automatic loading by the C-Shuttle System

Uniclean	PL II-30	PL II-15-1	PL II-15-2
C-Shuttle System	Option	no	Option

If the machine is loaded using the C-Shuttle System, the rack is transported into the chamber automatically. In the case of the Uniclean PL II 30, both racks are transported into the chamber. As the rack is being loaded into the chamber, the barcode reader scans the program. Once this step is complete, the machine starts automatically.



Please observe the Instructions for Use of the C-Shuttle System!

4.6 Return transport

If necessary, the transport rollers can be operated in reverse in order to move the rack back to its starting position.

Possible reasons for returning the rack include:

- Rack has become canted
- Rack is in an undefined position after the emergency stop was pressed (Chapter 6.4.9, "Rack is not being transported")

To return the rack, proceed as follows:

▶ If the rack is to be unloaded onto a transport trolley, make sure that the transport trolley is correctly docked on the machine.



▶ Press the “Quick user access” button.



- Press the “Return rack” button until the rack is in a defined location or in its starting position. The button must be held down constantly during the transport process.



- Once the rack has been returned, press the confirmation button to resume automatic transport in the original direction.



If you have the Uniclean PL II 30, you can now repeat the above steps for the second rack.



Danger

Risk of crushing injuries or injuries from falling rack!

The transport trolley must be correctly locked in place so that it does not roll away during the rack return process.

Make sure that the transport route of the rack is clear. Do not reach into the path of the rack.

4.7 Activating and deactivating rack redelivery (option)

Uniclean	PL II 30	PL II 15-1	PL II 15-2	PL II with C-Shuttle System
Rack redelivery	yes	no	yes	no

The rack redelivery function provides an easy way of feeding back empty, cleaned and disinfected racks from the unloading side to the loading side.

In the case of semi-automatic loading and unloading (Uniclean PL II-15 option), available racks are transported from the unloading side into the chamber. Once they have been fed back, the racks can be removed on the loading side using a TW docked directly on the machine or an automatic loading roller conveyor.

If in the case of the Uniclean PL II-15 the chamber is always loaded manually, the rack must be pushed through the chamber using both hands.



Shuttle operation is possible for Uniclean PL II-30 machines equipped with an automatic loading and unloading conveyor. Two racks can be transported back and forth for continuous operation.

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

Activating rack redelivery - manual loading

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

Activating rack redelivery - semi-automatic without automatic loading and unloading conveyor

- If necessary, dock the TW/TW HV.
- Press the button on the unloading side.

  Chamber door opens automatically.
- Use both hands to push the rack a little way into the chamber until the rack is pulled in by the transport rollers.

  Chamber door closes automatically.

  Chamber door on the loading side opens automatically.
- Dock the TW/TW HV.
-  Push the button until the rack is almost completely on the transport trolley. Then pull the rack completely onto the TW using both hands!

Activating rack redelivery with automatic loading and unloading conveyor

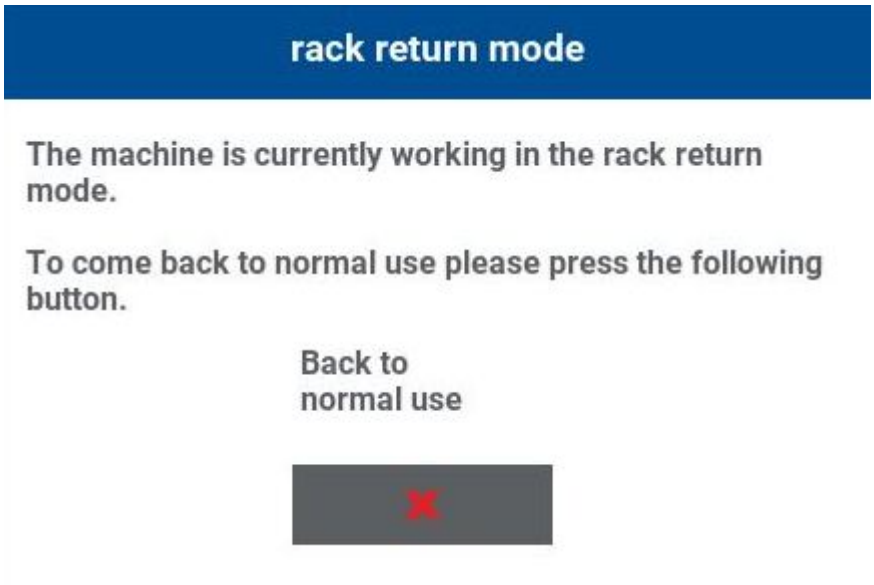
- Make sure that the chamber is empty!
- Press the button on the unloading roller conveyor (option).

  The rack is transported into the chamber by the transport rollers.
- Chamber door closes automatically.

Rack is automatically transported through the chamber onto the loading roller conveyor.

Deactivating rack redelivery

- Press the button on the loading side operating panel.



4.8 Canceling the program

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



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

After confirming the prompt, the machine automatically goes into a safe state and:

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

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

4.9 Unloading the chamber

Uniclean	PL II-30	PL II-15-1	PL II-15-2
Manual unloading	no	yes	yes
Semi-automatic unloading	yes	option	option
Automatic unloading	Option	Option	option

Unloading of the chamber occurs, depending on the machine configuration, manually, semi-automatically or automatically.

When unloading two-door machines onto an unloading roller conveyor, the opening and closing of the chamber door and the unloading onto the roller conveyor occur automatically.

Program sequence not completed properly

If the program sequence has not completed properly, an error message appears on the display and the chamber lighting is red.

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

Two-door machine: The chamber door on the unloading side cannot be opened. After confirming the message, the chamber 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 alarm number (Chapter 6, "Operating safety and faults"). The operator must take appropriate corrective measures.

Program sequence completed properly



Danger

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 CoolTouch plastic handles provided.

Single-door machine: Once the program has completed properly, the chamber door button is activated. Depending on the machine configuration, the chamber door opens automatically.

Two-door machine: Once the program has completed properly, the chamber door button is activated on the unloading side. Depending on the machine configuration, the chamber door opens automatically.



If the machine is equipped with an unloading roller conveyor, ensure that the conveyor is clear.

Proceed as follows to fully unload the machine:

Manual unloading see Page 80

Semi-automatic unloading see Page 82

Automatic unloading see Page 82

4.9.1 Manual unloading (Uniclean PL II 15 only)

- Set the TW HV (option) to the loading height.
- Move the transport trolley (TW/TW HV) to the machine.



Danger

Risk of injury!

TW HV can be caught! The rack can fall from the TW HV or the machine can be damaged!

No height adjustment when the TW HV is docked and locked!

- Once the program has completed properly, dock a TW/TW HV on the unloading side and activate the locking lever.

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

4.9.2 Semi-automatic unloading one-door

- Set the TW HV (option) to the loading height.
- Move the transport trolley (TW or TW HV) to the machine.



Danger

Risk of injury!

TW HV can be caught! The rack can fall from the TW HV or the machine can be damaged!

No height adjustment when the TW HV is docked and locked!

- Once the program has completed properly, dock a TW/TW HV on the unloading side and activate the locking lever.

  The TW/TW HV is correctly docked once the locking pins of the TW are locked in place on the machine and the transport route of the rack between the chamber and the TW/TW HV is also clear.
- If the chamber door has not opened automatically, press the chamber door button to open the chamber door.

  The “Return rack” button appears  .
- Press the “Return rack” button until the rack is located fully on the TW/ TW HV.
- Press the “Finished” button to end the process. 



For safety reasons, this function is designed so that the “Rack return” button must be held down continuously during the transport movement.

When the “Return rack” button is released, the “Finished” button appears.

The “Return rack” button can be pressed again until the rack has been fully transported onto the TW/TW HV.

After pressing the “Finished” button, the “Return rack” menu is closed. If the rack has not yet been fully transported out of the chamber, the process can be restarted via the “User quick access” - “Return rack” menu see Page 75.

- Release the TW/TW HV and move the transport trolley away.
- Check the lock pin on the front panel for correct function!

4.9.3 Semi-automatic unloading two-door

- Set the TW HV (option) to the loading height.
- Move the transport trolley (TW or TW HV) to the machine.



Danger

Risk of injury!

TW HV can be caught! The rack can fall from the TW HV or the machine can be damaged!

No height adjustment when the TW HV is docked and locked!

- Once the program has completed properly, dock a TW/TW HV on the unloading side and activate the locking lever.

  The TW/TW HV is correctly docked once the locking pins of the TW are locked in place on the machine and the transport route of the rack between the chamber and the TW/TW HV is also clear.

  The rack is pushed a little onto the TW/TW HV
- Using both hands, grip the rack by the CoolTouch plastic handles and pull it fully onto the TW/TW HV.
- If you have the Uniclean PL II 30, repeat the above steps for the second rack.
- Release the TW/TW HV and move the transport trolley away.
- Check the lock pin on the front panel for correct function!

4.9.4 Automatic unloading

Once the program has completed properly, the rack is transported onto the unloading roller conveyor automatically.

- Move the TW or TW HV to the roller conveyor.
- Set the TW HV to the loading height (option).



Danger

Risk of injury!

TW HV can be caught! The rack can fall from the TW HV or the machine can be damaged!

No height adjustment when the TW HV is docked and locked!

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

  The transport trolley is correctly docked once the locking pins of the transport trolley are locked in place on the machine and the transport route of the rack between the chamber and the transport trolley is also clear.

The rack is pushed onto the TW or TW HV.

- Using both hands, pull the rack the last few cms onto the TW or TW HV.
- If you have the Uniclean PL II 30, repeat the above steps for the second rack.



Danger

Risk of injury due to crushing or the rack falling!

The TW or TW HV must be correctly engaged to ensure it does not roll away during the unloading process.

Only disengage the TW or TW HV once the rack is located fully on the TW or TW HV.

After unloading the single-door chamber

- If necessary, press the door button to close the door.

After unloading the two-door chamber

- Press the door button (option) on the unloading side to close the door.



If door on unloading side closed → Release door on loading side for opening.

If door on loading side has not been opened → Door on unloading side can be opened again.

Once door on loading side has been opened → Door on unloading side can no longer be opened.

Automatic unloading



If the TW or TW HV was not docked properly and the pin is standing out and obstructing the transport route of the rack, the rack will be pushed against the pin by the motorized drive thereby pushing the TW or TW HV a few centimeters away from the machine. When this situation arises, the electrical safety device of the machine deactivates the control of the transport rollers and the unloading stops.



Danger

Press the EMERGENCY STOP switch in case of imminent danger from, for example, the rack tipping over, the transport trolley rolling away, an operator being crushed, etc.

4.9.5 Automatic unloading by the C-Shuttle System

Once the program has completed properly, the rack is transported out of the chamber automatically.



Please observe the Instructions for Use of the C-Shuttle System!

4.10 Releasing the cycle

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

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



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

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

Checking the cycle report

The following requirements must be met:

The program that was run was suitable for the unloaded material in the relevant rack.

- The data on the cycle report must be identical to the data determined during validation.

Visually inspecting the treatment results

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

- The load must not have changed, i.e. all instruments and hoses are still fully connected.
- Cleaning result: there are no residues on the item.
- Drying result: the item is dry.

Checking the rotating arms

The following requirements must be met:

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

Inspecting the filter on modules for eye instruments and da Vinci modules



Danger

The fine filters must be visually inspected for contamination or damage after every cycle 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 cycle 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 cycle can be released.**
- **The fine filter must be cleaned if the filter is contaminated (> 30% of the filter area). The cycle must not be released and must be processed again.**

NOTICE

Cycle approval requires:

- **Successful inspection of the rotating arms (option)**
- **Successful visual inspection of the treatment results**
- **Successful inspection of the filter if modules for eye instruments or da Vinci modules have been used**
- **Successful check of the cycle report**
- **Successful check that the material to be treated matched the program.**

Release documentation

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

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

Displaying and reprinting past cycles

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

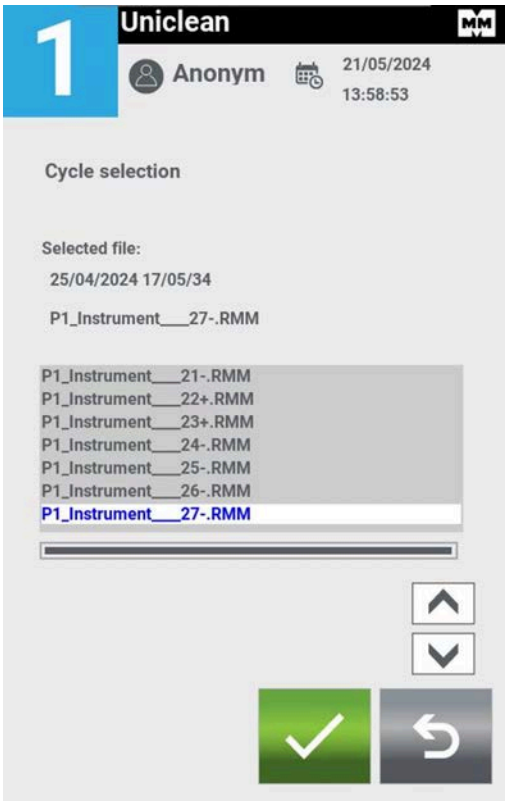
Proceed as follows:



- Open Quick user access



- Open Archive of cycle sequences.





- Use the scroll buttons to scroll up or down.



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





▶ Press the “Printer” button.

The cycle data is printed.



▶ Press the “PC” button.

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

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

4.11 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 control panel is activated, it jumps back to the previous screen.

4.12 Last program run

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



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

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

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

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

With the automatic unloading option, the rack is unloaded, the chamber door on the unloading side is closed, and the tanks and chamber are drained once a program has run through properly. The machine switches off automatically. If auto start is activated, the machine switches to standby.

4.13 Handling chemicals



Danger

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

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

4.13.1 Safety instructions for changing the process chemicals

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

NOTICE

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

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

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



Danger

Using the wrong process chemicals can render the cleaning 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

NOTICE

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

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

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

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

Compatibility of the process chemicals

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



Danger

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

4.13.3 Replacing the canister



No program must be started on the machine!



Canister exchange must only be performed by a trained person!

If the machine is equipped with a roller conveyor, the roller conveyor must be dismantled. If the machine has no roller conveyor see "", Page 90

Loosen roller conveyor connection from the machine

Retaining bolts are located on the left and right at the connection between the roller conveyor and machine.

- ▶ Turn the retaining bolts up and remove them.
- ▶ Disconnect the voltage connection (24 V) from the pull-out canister compartment.

Remove roller conveyor

- Lift the roller conveyor out of the plates fastened to the floor, and pull the roller conveyor away slightly.
- Remove the earth wire from the machine.
- Position the roller conveyor so that the pull-out canister compartment is easily accessible.



Danger

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

Opening the pull-out canister compartment

- Unlock the pull-out canister compartment. The key is administered by the system supervisor.
- Pull out the pull-out canister compartment by the handle.
- Fold over the locking lever. The locking lever is located at the end of the pull-out canister compartment.

Exchange canister

- Remove the empty canister and place the canister next to the pull-out canister compartment.
- Place the full canister next to the empty canister.



Danger

Risk of process chemical interchange!

Cleaning process 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 into the pull-out canister compartment.
- Fold over the locking lever.
- Carefully push in the pull-out canister compartment until it is closed and lock it.
- Return the key to the system supervisor.
- Dispose of the empty canisters as specified by the manufacturer.

- Install the roller conveyor in reverse order.
- Confirm any fault message.

4.14 End of workday/change of shift

The machine and tanks (if installed) must be drained and cleaned at the end of each shift,

5 Machine configuration

5.1 Configuring the User Manager (option)

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

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

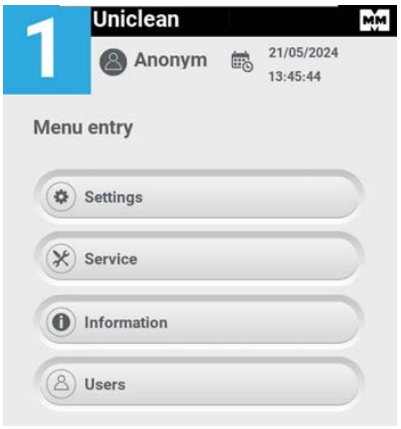
The various user passwords enable access to the corresponding menu levels.



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



▶ Open the “Configuration” menu.



▶ Press the **User** button.

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





▶ Press the **created user** button.

- Enter the name and password of the new user to be created.
- Assign the required authorizations to every new user.
- Enter the required log-out time after which the user will be automatically logged out. The user is only logged out automatically on the “Program selection” and “Program sequence” screens!



- Save the entry. The menu will close simultaneously.



Users can also be deleted



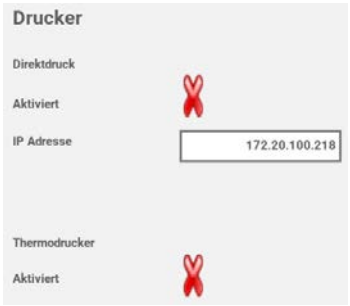
and passwords changed on this menu screen.

5.2 Setting cycle report print and save options

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

Printing the cycle report

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



- Direct printing to a DIN A4 printer (*RUMED360 CyclePrint Direct*)
- Direct printing on an integrated thermal printer

Direct printer

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

Thermal printer

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

Saving the cycle data and Printing via network (option)

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

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



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

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

6 Operating safety and faults

Safety-related equipment

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

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

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

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.



Faults with automatic program cancellation

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

Faults without automatic program cancellation

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

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

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

6.2 Sending messages to customer service via ISA (option)

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

S ▶ Log in as the supervisor.



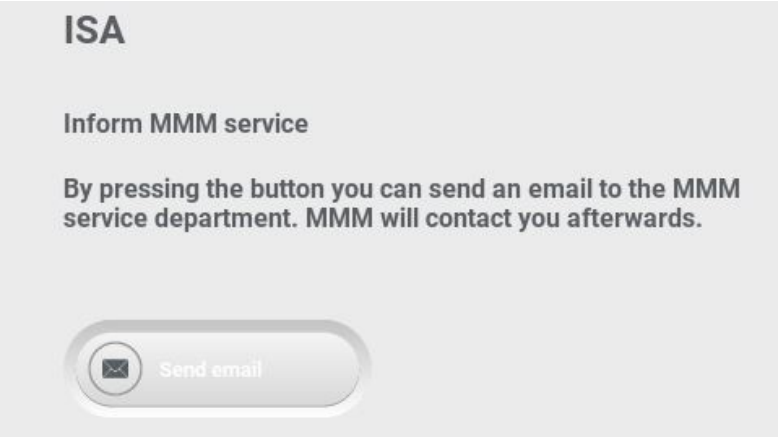
▶ Open the “Menu overview”.



▶ Open the “Service” menu.



▶ Open the “ISA” menu.



▶ Send an e-mail

6.3 Responding to faults

If a fault occurs, carry out the following steps:

1. If necessary, place the rack in a defined position Chapter 6.4.9, "Rack is not being transported".
2. Analyze the fault and, if possible, eliminate it.
3. Report the fault to the system supervisor without making any machine modifications.
4. Analyze the fault and have the cause eliminated by a specialist.
5. Depending on the type of fault, notify MMM customer service, remembering to quote the plain text message and the fault number, if applicable via ISA (option).



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

Confirming alarm messages

NOTICE

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

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

  A page with all the status and alarm messages appears.





Press the door button to confirm the alarm message.

This confirms all alarm messages!

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

If the operator is not authorized to confirm alarm messages, the log in dialog appears, see "Logging users in and out", Page 61.

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

6.4 Responding to specific faults

6.4.1 Power failure, loss of compressed air

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

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

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

6.4.2 Network outage

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

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



- Go to Quick user access.



- Press the “RUMED360 IP address” button.



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

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

6.4.3 Emergency opening of the chamber door

Opening the chamber door during a cycle should only be performed in an emergency, e.g. if there is a power failure and the goods being treated are urgently required!



Danger

Risk of injury!

Hot, chemical-containing and infectious steam may escape when opening the chamber door!

Wear personal protective equipment **see "Personal protective equipment", Page 19** !

NOTICE

False alarm of the smoke detector!

Check whether there is a smoke detector installed in the vicinity of the chamber door.

If necessary, notify the building services department to briefly deactivate the smoke detector!

There are two ways of opening the chamber door.

Opening the chamber door manually:

- Unlock the pull-out canister compartment see "Operators", Page 16.
- Open the pull-out canister compartment.
- Pull out the pull-out canister compartment approx. 30 cm.
- Use one hand to relieve the chamber door counterweight located at the side, then use the other hand to carefully slide the glass pane downwards until it is possible to grasp it along the top edge.
- Grasp the top edge of the glass pane with both hands and slowly slide the glass pane downwards until the chamber door is completely open.

Opening the chamber door using a suction lifter/glass suction cup

- Apply the suction lifter to the upper area of the chamber door.
- Secure the suction lifter.
- Using the suction lifter, carefully pull the chamber door down a little until it is possible to grasp it along the top edge.
- Remove the suction lifter.
- Grasp the top edge of the glass pane with both hands and slowly slide the glass pane downwards until the chamber door is completely open.



Danger

After an emergency opening, the chamber door must be recommissioned by a specialist **see "Operators", Page 16****!**

6.4.4 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.

6.4.5 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.

6.4.6 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.

6.4.7 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 a defined position (Chapter 6.4.9, "Rack is not being transported").

6.4.8 Insufficient water quality

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

Insufficient water quality leads to:

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

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

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

6.4.9 Rack is not being transported

For automatic transport of the rack, the rack must be detected by one of the sensors that are located at defined positions. After pressing the EMERGENCY STOP switch or using the return transport function, it is possible for the rack to be located in a non-defined position and to not be detected by a sensor.

To restart the automatic transport, the rack can be brought into a defined position either manually or using the return transport function (Chapter 4.6, "Return transport ").

Depending on the location of the rack, it can be returned to the following positions:

Loading for two-door machine

- back onto the TW/TW HV
- back to the start of the roller conveyor
- immediately in front of the chamber door

Unloading for two-door machine

- back into the chamber
- immediately behind the chamber door
- to the end of the roller conveyor

Loading and unloading for one-door machine

- back onto the TW/TW HV
- immediately in front of the chamber door



If the rack is not transported out, the TW/TW HV must be removed and redocked.

6.4.10 Steam supply failure

If the electric heating / external steam supply option is installed

If the steam supply fails, the machine can be switched to electric operation with reduced output (9 kW). To do this, you must activate the corresponding parameters in the menu under “Settings”.

- Initial menu
- Settings
- Customer settings

6.5 Status and alarm list

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

No.	Message	Reason	Possible remedy
1	Machine is ready for operation	Ready to start the program. No fault present.	-
3	Confirmation required	There are faults that must be confirmed by the user.	-
4	Test program active	The active program has been declared as a test program in the parameters.	-
5	Power failure during program run	A power failure has occurred on the operating panel during a cycle.	– Check on-site power supply – Check that power pack in control cabinet is functioning correctly – Check cable connections between power pack and CPU for loose contacts
6	Program manually advanced	The process has been manually advanced to another process step.	-
7	Program stop performed	The “Stop program” button on the display has been pressed.	– Analyze why the button was pressed
8	EMERGENCY STOP pressed	The EMERGENCY STOP on the machine has been pressed, switch defective.	– Analyze why one of the two EMERGENCY STOP switches was pressed – Check both EMERGENCY STOP switches for damage
9	Standby mode	The machine is in standby mode. No display activity for some time.	– Touch the screen
10	Local cycle storage failed	Process data could not be stored on the CF card. Not enough memory, CF card defective, internal fault.	Contact customer service
11	Save to network failed	Process data could not be transferred to SimServ.	– Check that the IP address of the SimServ computer is correct – Check that SimServ is running – Check that the network addresses are correct
12	Cycle data processing active	Cycle data are being processed. Cycle has just finished, reloading or reprinting cycle report.	-
13	Program run paused	Program has been interrupted. Manual intervention by an authorized person.	-
14	Network printing failed	Print job not sent to SimServ.	– Check that the IP address of the SimServ computer is correct – Check that SimServ is running – Check that the network addresses are correct
15	Printing failed	DIN A4 direct printing failed.	– Check printer IP address – Check that printer is switched on – Check paper level in printer – Check that correct printer is connected – Check whether the cycle data contain the correct values

No.	Message	Reason	Possible remedy
16	Printing active	Direct print job in progress at DIN A4 direct printer. Cycle has just finished, reprinting cycle.	-
17	Thermal printing failed	Printout failed.	– Check that printer is working – Check connection cable – Check whether the cycle data contain the correct values
18	Thermal printing active	Print job in progress. Cycle has just finished, reprinting cycles.	-
19	Integrated printer: No connection	No connection to printer	– Check that printer is connected to power supply – Check connection cable – Check interface card
20	Thermal printer: No paper	Printer reports out of paper.	– Check paper level in printer (Chapter 6.7, "Thermal printer paper exchange (option)") – Inspect printer
21	Door sealing pressure too low	Door seal is actually pressed on but not registered as pressed on.	– Check on-site compressed air supply – Check machine pressure switch settings – Check pressure switch for defects – Check that adjustable compressed air supply valve is set correctly – Pneumatic hoses are not tight
22	Door seal pressure too high	Door seal is not actually pressed on but is registered as pressed on.	– Check machine pressure switch settings – Check pressure switch for defects
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)
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

No.	Message	Reason	Possible remedy
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 seal(s).	– Check on-site compressed air supply – Check machine maintenance unit settings
39	Door seal pressure failed to drop	It is taking too long to release the door seal(s).	– Pneumatic valve defective
40	Door seal press. too low in program	Door seal pressure has dropped during process sequence.	– Check door seals for defects – Check on-site compressed air supply
41	Doorway not free on loading side	It is taking too long to close the door on the loading side. Door opens again. 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 compressed air supply – 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	Battery replacement required	Battery signals that voltage is too low.	Only for machines with glass control panel – Replace battery – only change the battery during operation! Battery will last for a few days/weeks.
49	Self cleaning - not for goods	The active program has been declared as a self-cleaning program in the parameters.	-
50	Inspection required for dosing line 1	Dosing line 1 is dosing less than expected. Deviation is still small enough.	– Check dosing hose 1 and remove air as required Chapter 6.8, "Venting the dosing hoses" – Replace worn hose in dosing pump – Check connecting hoses for blockages or air bubbles
51	Inspection required for dosing line 2	Dosing line 2 is dosing less than expected. Deviation is still small enough.	– Check dosing hose 2 and remove air as required Chapter 6.8, "Venting the dosing hoses" – Replace worn hose in dosing pump – Check connecting hoses for blockages or air bubbles
52	Inspection required for dosing line 3	Dosing line 3 is dosing less than expected. Deviation is still small enough.	– Check dosing hose 3 and remove air as required Chapter 6.8, "Venting the dosing hoses" – Replace worn hose in dosing pump – Check connecting hoses 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 hose 4 and remove air as required Chapter 6.8, "Venting the dosing hoses" – Replace worn hose in dosing pump – Check connecting hoses for blockages or air bubbles

No.	Message	Reason	Possible remedy
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 6.8, "Venting the dosing hoses" – Check flow meter for defects
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 6.8, "Venting the dosing hoses" – 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 6.8, "Venting the dosing hoses" – 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 6.8, "Venting the dosing hoses" – Check flow meter for defects
58	Parameter settings are not valid	Incorrect parameter settings.	– Check logic between machine configuration and parameters set on display See also the audit trail entry.
59	Disinfection temp. too low	Water temperature during disinfection is much too low.	– Check on-site steam supply – Check steam valve or electric heating elements for defects – Check condensate line for defective parts, counterpressure
60	Disinfection temp. too low for too long	Water temperature during disinfection slightly too low for too long.	– Check on-site steam supply – Check steam valve or electric heating elements for defects – Check condensate line for defective parts, counterpressure
61	Disinfection temp. too high	Water temperature during disinfection too high.	– Check that steam valve closes completely – Electric heating element contactor is defective
62	Water temperature too high	Water temperature during a washing step exceeds the set maximum temperature.	– Check that parameter settings are correct on display

No.	Message	Reason	Possible remedy
63	Temp. too low during holding phase	Water temperature too low during a washing step.	– Check on-site steam supply – Check steam valve for defects – Check condensate line for defective parts, counterpressure – Electric heating element contactor is defective
64	Temp. too high during holding phase	Water temperature too high during a washing step.	– Check that steam valve closes completely – Electric heating element contactor is defective
65	Pressure of circulation pump too high	Pump pressure in circulation phase too high.	– Check jets for blockages
66	Pressure of circulation pump too low	Pump pressure in circulation phase too low.	– Check jet system for leaks – Check that correct program was selected, as circulation fluid may foam if there is too much contamination – Check parameter settings for chemical dosing and process chemical selection – Check that correct chemical is being used – Check that process chemical is connected correctly
67	No program selected	No program selected on display.	-
68	Temperature probe B251 defective	Temperature probe reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
69	Temperature probe B252 defective	Temperature probe reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
70	Temperature probe B253 defective	Temperature probe reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
71	Temperature probe B254 defective	Temperature probe reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
72	Temperature probe B255 defective	Temperature probe reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
73	Temperature probe B256 defective	Temperature probe reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
74	Pressure transducer B351 defective	Pressure transducer reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
75	Pressure transducer B851 defective	Pressure transducer reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
76	Pressure transducer B852 defective	Pressure transducer reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
77	Pressure transducer B853 defective	Pressure transducer reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor

No.	Message	Reason	Possible remedy
83	Attention: Chamber may not be empty	Program canceled. Machine could not be completely drained.	– Check drainage system for possible blockages – Uniclean PL II 15: Check pressure transducer of chamber for defects – Uniclean PL II 30: 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.	*Only for older machines: – Check that motor protection switch in control cabinet is set correctly according to motor data sheet – Check pump for foreign objects and anomalies
86*	Motor protection drain pump	Motor protection switch has been triggered.	*Only for older machines: – Check that motor protection switch in control cabinet is set correctly according to motor data sheet – Check pump for foreign objects and anomalies
87*	Motor protection fan	Motor protection switch/fuse of internal drying fan has been triggered.	*Only for older machines: – Check that motor protection switch in control cabinet is set correctly according to motor data sheet – Check internal drying fan for foreign objects – Check internal drying fan for anomalies
88	Motor protection	Motor protection switch has been triggered.	– Check that motor protection switch (circulation pump, discharge pump and drying fan fuse) in the control cabinet is set correctly according to the motor data sheet – Check pump and drying fan for foreign objects and anomalies – Check that motor protection switch of the lateral channel blower in the control cabinet is set correctly according to the motor data sheet
	Motor protection of comp ressor*	Motor protection switch of lateral channel blower has been triggered.*	*Only for older machines: – Check that motor protection switch of lateral channel blower in control cabinet is set correctly according to motor data sheet
89	No trolley inside the chamber	No rack at specified position inside chamber.	– Check rack position switch inside chamber – Only push correct rack inside if machine has docking couplings in the chamber

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

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

No.	Message	Reason	Possible remedy
109	Time exceeded heating chamber	Temperature inside the chamber is rising too slowly.	– Check on-site steam supply line – Check steam valve on circulation heat exchanger for defects – Check if condensate discharge is working – Check whether electric heating element is defective
110	Time exceeded heating tank 1	Temperature in tank 1 is rising too slowly.	– Check on-site steam supply line – Check steam valve on tank 1 for defects – Check if condensate discharge is working – Check whether electric heating element is defective
111	Time exceeded heating tank 2	Temperature in tank 2 is rising too slowly.	– Check on-site steam supply line – Check steam valve on tank 2 for defects – Check if condensate discharge is working – Check whether electric heating element is defective
112	Time exceeded draining chamber	It is taking too long to drain the chamber.	– Check on-site drainage line for blockages – Check drainage valve for defects – Check drainage pump for defects – Uniclean PL II 15: Check pressure transducer of chamber for defects – Uniclean PL II 30: 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
114	Time exceeded draining tank 2	It is taking too long to drain tank 2.	– Check on-site drainage line for blockages – Check drainage valve on tank 2 for defects – Check drainage valve of chamber for defects – Check drainage pump for defects – Uniclean PL II 15: Check if chamber level pressure transducer is working – Uniclean PL II 30: Check level switch of chamber – Check if tank level pressure transducer is working

No.	Message	Reason	Possible remedy
115	Time exceeded repumping to tank	It is taking too long to pump water back into the tank.	– Check if pressure transducer in tank is working – Check if return valve to tank is working – Check return pump – Check line for foreign objects: blockages
116	Temp. inside controller too high	Temperature inside the PowerPanel is too high.	– Check on-site machine compartment air conditioning, because ambient temperature is too high.
117	Not enough memory space	Not enough free memory in PowerPanel.	– Restart machine – Controller fault - replace controller
118	Cleaning of water filter required	The specified number of programs that clog the filter has been carried out.	– Clean chamber filter, as enough cycles have been carried out to block it
119	Draining program - not for goods	The active program has been declared as a draining program in the parameters.	-
120	Temperature rising chamber	The temperature in the chamber is rising but the heating is not activated.	– Check that steam valve on circulation heat exchanger closes completely – Check whether contactor for electric heating element is defective
121	Temperature rising tank 1	The temperature in the tank is rising but the heating is not activated.	– Check that steam valve on tank 1 closes completely – Check whether contactor for electric heating element is defective
122	Temperature rising tank 2	The temperature in the tank is rising but the heating is not activated.	– Check that steam valve on tank 2 closes completely – Check whether contactor for electric heating element is defective
123	Washing step repeated	At least one washing step was repeated during the process run.	– Check the entire washing system, as there is contamination and 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 hose 1 and remove air as required Chapter 6.8, "Venting the dosing hoses" – Replenish process chemicals – Broken cable in suction lance line
125	Dosage 2 empty	Suction lance of dosing line 2 signals that the container is empty.	– Check dosing hose 2 and remove air as required Chapter 6.8, "Venting the dosing hoses" – Replenish process chemicals – Broken cable in suction lance line
126	Dosage 3 empty	Suction lance of dosing line 3 signals that the container is empty.	– Check dosing hose 3 and remove air as required Chapter 6.8, "Venting the dosing hoses" – 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 hose 4 and remove air as required Chapter 6.8, "Venting the dosing hoses" – Replenish process chemicals – Broken cable in suction lance line
128	CF card is full	CF card memory space is below 256 kByte or card was removed from the panel. Card has been removed. Too much data stored on CF card	-
129	Waiting for end of tank cleaning	Tank cleaning is running and is not yet complete. Drainage time has not yet expired.	-
130	Ventilation flap: Position not reached	Fresh air flap is not reaching correct position.	– Fresh air flap has been unhinged – Fresh air flap is stiff, defective.
131	Error exhaust air system	On-site exhaust air system signals a fault.	-
132	No rack coding	Rack scanning is active but no code has been read yet.	– Check barcode on rack – Check scanner – Check the anti-reflection feature (black insulating tape) on the panel
133	Wrong rack coding	Rack code barcode was wrong or could not be identified correctly.	– Check barcode on rack – Check scanner – Check the anti-reflection feature (black insulating tape) on the panel
134	Length of rack ID incorrect	The rack code barcode that has been read is not the right length.	– Barcode defective or illegible – Check the anti-reflection feature (black insulating tape) on the panel
135	Loading system time exceeded	The loading procedure has taken too long. Rack could not be loaded.	– Check door – Check sensor
136	Time exceeded unloading system	The unloading procedure has taken too long. Rack could not be unloaded.	– Check sensor
137	Conductivity sensor B551 defective	Conductivity probe reporting incorrect input values. Conductance measurement/measuring transducer reporting invalid values Poor water quality. Too much cleaning agent.	– Check the contacts on sensor B551 – Check the contacts on transducer B991 – Replace with an identical sensor or measuring transducer
138	Conductivity not achieved	Conductivity value in the final rinse too high. Poor water quality. Too much cleaning agent.	– Check water quality – Check dosing
139	Conductivity sensor B552 defective	Conductivity probe reporting incorrect input values.	– Check the contacts on sensor B552 – Check the contacts on transducer B992 – Replace with an identical sensor
140	Pressure transducer B353 defective	Sensor reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor

No.	Message	Reason	Possible remedy
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.	Doorseal not airtight
144	Loading: Fault	Loading system has identified an error. Times exceeded	– Doors not as expected
145	Unloading: Fault	Unloading system has identified an error. Times exceeded	– Doors not as expected
146	No connection to USB device	Required USB connection could not be established or has been interrupted. Scanner unplugged.	– Check cable connection
147	Service mode	The machine is in service mode.	– Technician has pressed a button in the “Service” menu.
148	Transport: Reset required	Repumping mode has been triggered. Transport must be enabled for automatic movement.	-
149	Foaming	Large pump pressure fluctuations in the first cleaning step (step 1). Despite multiple attempts, it was still not possible to achieve a constant pump pressure.	– High levels of contamination – Large amount of blood inside chamber
150	Failure dosage tank	Machine tank dosing failed while preparing for an upcoming program. Dosage hoses are worn or defective	– Check dosage hoses – Check or change cleaning agent
151	Preventive maintenance due shortly	Preventive maintenance due very soon.	– Preventive maintenance due
152	Preventive maintenance overdue	Preventive maintenance is overdue.	– Preventative maintenance was not carried out on time
153	Interval-based maint./ inspection due shortly	Interval-based maintenance/inspection due very soon.	– Interval-based maintenance/inspection due
154	Interval-based maintenance/inspection overdue.	Interval-based maintenance/inspection is overdue. Interval-based maintenance/inspection was not carried out on time.	– Carry out interval-based maintenance/inspection
155	Calibration/adjustment due soon	Calibration/adjustment will be due shortly.	– Calibration/adjustment due
156	Calibration/adjustment overdue.	Calibration/adjustment is overdue. Calibration/adjustment was not carried out on time.	– Carry out calibration/adjustment
157	Requalification due shortly	Requalification is due very soon.	– Requalification is due.
158	Requalification overdue	Requalification is overdue. Requalification was not carried out on time.	– Perform requalification
159	Wire error energy manager	Wire check during machine start-up failed. Configuration does not match the connected energy manager wires.	– Check configuration
160	Energy supply blocked	No free power wire when configuring start-up prevention. All power wires are already in use.	-

No.	Message	Reason	Possible remedy
161	Waiting for energy release	No free power wire when configuring automatic program start. All power wires are already in use.	-
162	Time exceeded energy	No free wire for too long. All power wires are already in use.	-
163	Failure docking system	Faults in the BWI docking system. Required positions not reached on time.	-
164	Docking: Acknowledgment required	The user has not yet confirmed 'Chamber empty'. Fault during docking or user has canceled and not yet confirmed.	– Check docking system – Confirm cancellation
165	No serial number	No serial number recorded.	– Enter serial number
166	Reading error scanner	No barcode detected.	– Scanner defective – Check cable – Scanner incorrectly configured – Check the anti-reflection feature (black insulating tape) on the panel
167	No code for goods	No barcode has been scanned yet but is required for the program to start. Read error due to defective barcodes on rack or no barcode on rack. Barcode must be replaced or attached.	– Check barcode on rack – Replace or reattach barcode – Check the anti-reflection feature (black insulating tape) on the panel
168	Rise of filling volume	Fill volume measured at the end of the circulation phase much higher than at the start of the circulation phase.	– Check filling valves.
169	Rack redelivery mode active	Customer has started rack redelivery mode by pressing the “Rack redelivery” button.	-
170	Rack redelivery failure	An error occurred in rack redelivery mode.	– Door is blocked and cannot be closed properly – Rack is not correctly positioned inside chamber or on roller conveyors
171	No user logged in	No user logged in	Log in user
172	Missing user action	Menu prompt for automatic tank cleaning “Are all tank covers correctly closed?” has not been confirmed.	Confirm menu prompt “Are all tank covers correctly closed?”
173	Drain full	Waste water drainage to external tank and not to drain. External tank full. Waste water cannot be drained.	Drain external tank
174	Empty cycle required	An empty cycle was not run after venting the dosing line.	Start a program without materials to make sure there is no process chemicals in the machine.
175	Cancel for cleaning check	Program cancellation after cleaning for validation	For service technicians only
176	Door opening rejected	2. operating terminal - door opening on the unloading side was rejected	Determine the cause of why door opening on the unloading side was rejected, and run the cycle again.
177	Waiting for user action	2. operating terminal - waiting for decision, door opening on unloading side no/yes	Check result “Permit door opening on this side?” Press yes or no button.
178	Motor protection (general)	Motor overload	Inform service technician

No.	Message	Reason	Possible remedy
179	Fault rotating arm monitoring	Speed of the rotating arms incorrect (PL II 30 rack on the loading side). Cycle sequence still progressing properly.	– 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.
180	Pressure transducer B354 defective	Pressure transducer reporting invalid values.	– Check contacts on sensor – Replace with an identical sensor
181	Auto start active	Auto start is activated	-
182	Last program function active	Last program function is activated	-
183	Machine draining active	Last program function is activated. Once the materials have been unloaded and the unloading door has been closed, the chamber and tanks are automatically drained.	-
184	Machine draining failed	Last program function is activated. Once the materials has been unloaded and the unloading door had been closed, the chamber and tanks were not drained.	– Check on-site drainage line for blockages – Check drainage valve on tank for defects – Check drainage valve of chamber for defects – Check drainage pump for defects – Uniclean PL II 15: Check if chamber level pressure transducer is working – Uniclean PL II 30: Check level switch of chamber
185	Drainage valve T1 leaky	Water level in the tank is too low	– Check drainage valve T1 on the tank for defects
186	Drainage valve T2 leaky	Water level in the tank is too low	– Check drainage valve T2 on the tank for defects
187	Auto start failed	Faults are preventing auto start	– e.g. media supply not working – e.g. close the door
188	Check cable	RPM of the rotating arms incorrect. Cycle sequence still progressing properly.	– 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.

No.	Message	Reason	Possible remedy
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 – Uniclean PL II 15: Check pressure transducer of chamber for defects – Uniclean PL II 30: Check level switch of chamber for defects
192	Flow meter error dosing	Flow meter is counting even though the dosing pump is not activated.	Inform building services or service technician – Check non-return valve – Check flow meter
193	Flow meter error water	Flow meter is counting even though the water valve is not activated.	Inform building services or service technician – Water valve leaking – Check flow meter
194	Heating temperature limiter	The temperature limiter for heating or the tank has been triggered.	Inform building services or service technician – Check water level in chamber, not enough water in system – Check water level in the tank (1 or 2), not enough water in system – Check heater circuit breaker
195	Drying temperature too high	Set target temperature was exceeded	Inform building services or service technician – Check heater circuit breaker
196	Too much circulation in tank 1	Level in the tank not static, the water level in the tank is fluctuating due to too much inflowing air and the heater needs to reheat the water too often. The heater contactor is switching too often.	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

No.	Message	Reason	Possible remedy
198	Emergency open button pressed	The emergency open button in the chamber was pressed. Emergency open button is defective.	Inform building services or service technician
199	Check rotary arms 2	Speed of the rotary arms for the rack on the unloading side in the PL II 30 is defective. Cycle sequence still progressing properly.	– 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.
200	Not a cleaning program acc. to EN 15883	Special program was selected.	-
201	Note regarding overflow of tank into the overflow	Incoming counter pulses when fill valves not activated.	– Check fill valves
202	Fault in pumping system	On-site pumping system signals a fault.	Inform building services

6.6 Tips for dealing with inadequate cleaning results

Practical tips

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

- Have any necessary pre-cleaning procedures been carried out correctly?
- Has pre-cleaning been performed in accordance with the treatment instructions provided by the instrument manufacturer?
- Has pre-cleaning been performed in accordance with the treatment instructions provided by the endoscope manufacturer?
- 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?
  Clockwise for the lower rotating arm in the chamber. 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.

6.7 Thermal printer paper exchange (option)



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

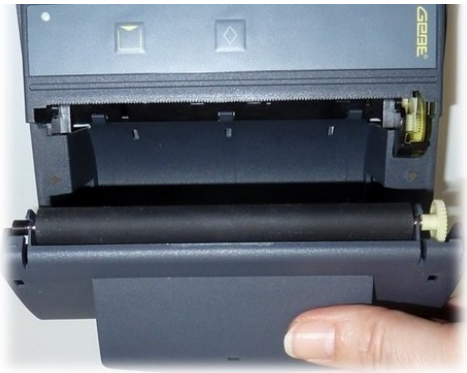
For unproblematic printing, we recommend ordering the paper from MMM.

- 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

6.8 Venting the dosing hoses

If the Canister button automatically takes you to the Operating materials menu, you can skip the first few steps and continue from the “Selecting the dosing line” step.

Once the canister with the process chemicals has been replaced, there may be air in the dosing hoses.

Alarm messages 50 - 57 and 124 - 127 may appear in the display. The dosing hoses can be vented. 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 venting the dosing hoses, i.e. there must be a green tick next to “Use ISA”. **Chapter 5.1, "Configuring the User Manager (option)"**



- Log in.



- Open the Menu overview.



- Open the Service menu.

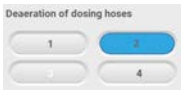


- Open the Deaeration of dosing hoses menu.
- Place a container (e.g. a kidney dish) in the chamber.
- Position the container under the relevant dosing outlet.

  The foremost dosing outlet corresponds to Dosing line 1 (from the loading side). The arrangement of the dosing outlets corresponds to the arrangement of the dosing lines within the machine.



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



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

  The dosing hose has now been vented.

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

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



To vent another dosing hose, a new container must be used! The process chemicals must not be mixed!



Danger

Risk of acid burns!

Uncontrolled chemical reaction!

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



174 - Empty cycle required

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

7 Maintenance

NOTICE

Observe the safety instructions in Chapter 1!

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

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

A preventative inspection and maintenance (preventative maintenance) should be performed after twelve months or after 1250 cycles .

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

The cycle counter continuously counts the cycles performed.

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

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

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

7.1 Safety

NOTICE

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

Danger

Risk of injury!

If the Uniclean PL II is connected to a C-Shuttle System, there is a risk of a collision with the C-Shuttle (lateral moving unit)!

When performing maintenance tasks on the Uniclean PL II, the C-Shuttle System must be switched off and secured against switching on again!

Observe the Instructions for Use of the C-Shuttle System!

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



- Open Quick user access.



- Press the Maintenance information button.

7.3 Servicing contract

We recommend concluding a servicing contract.

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

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

7.4 Routine monitoring of the technical function

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



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

7.5 Cleaning the control elements

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

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

7.6 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. Do not mix up the different types of rotating arms, e.g. the rotating arms for the da Vinci rack or the 6-level rack. This is the only way to guarantee a satisfactory cleaning result.

Dismantling the rotating arms

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



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

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.
- If necessary, remove the reflector (option).



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

Cleaning the rotating arms

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

Assembling the rotating arms



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!

NOTICE

Instructions for older rotating arms!

Observe the installation direction!

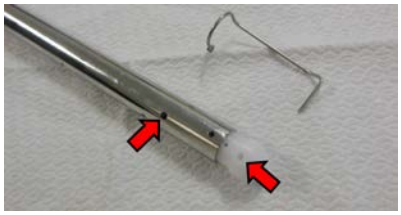
Ensure that the cross-holes on the rotating arm and on the end cap match up (see red arrow).

The rotation of the rotating arms is impaired if the holes are aligned incorrectly.



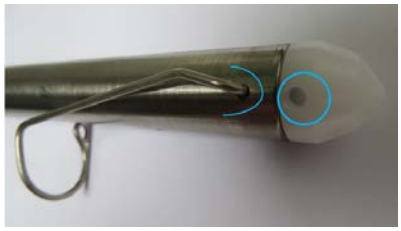
Mounting the safety catch and end cap

Old rotating arm



New rotating arm







- Apply the end cap.
- Apply the safety catch.

If you have the rotating arm monitoring option, also mount the reflector as described below.

- Lock the safety catch.

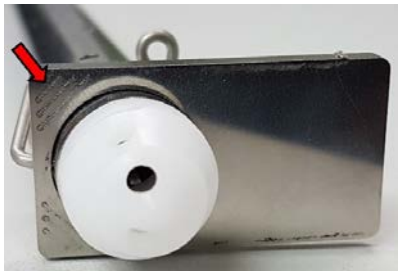
Mounting the reflector for rotating arm monitoring (option) (Uniclean PL II-15 only)



The reflector for rotating arm monitoring is attached to the rotating arm and secured using the safety catch.

There are two types of reflectors: one reflector for the rotating arm on racks and the bottom rotating arm in the chamber, and one angled reflector for the top rotating arm in the chamber.

If necessary, remove the protective film on the replacement parts.



Reflector for **the bottom rotating arm in the chamber** and **the rotating arm on racks**

The hatching on the reflector must face outwards (towards the chamber wall).

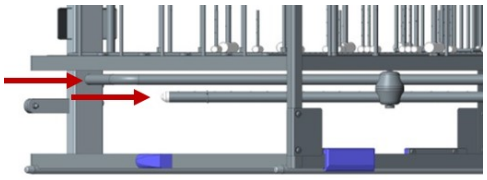


Reflector for **the top rotating arm in the chamber**

The angled section of the reflector must face towards the center of the rotating arm, as shown.

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.



- Ensure that the rotating arms are parallel to the water supply pipes of the rotating arms!
- Make sure that the rotating arms rotate freely!

7.7 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!

The Uniclean PL II 30 comes with two dirt filters. One dirt filter is located on the loading side, the other on the unloading side. For simplicity's sake, the following text will refer to a single dirt filter.

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!

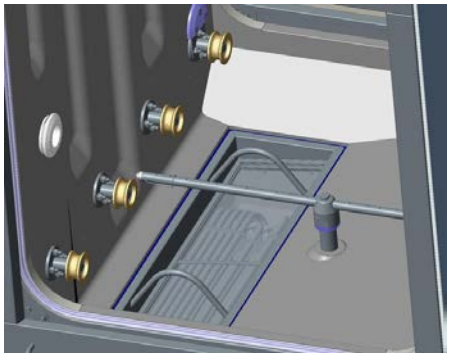
For the Uniclean PL II 30, we recommend keeping one dirt filter as a replacement!

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.

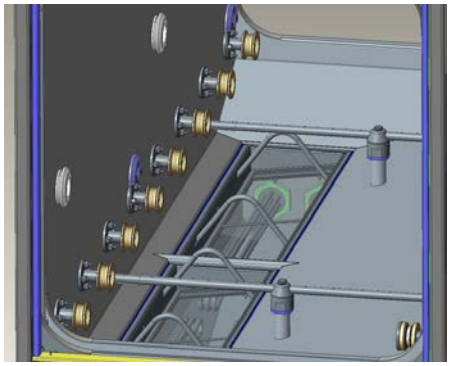
For the Uniclean PL II 30, you can remove the dirt filter on the unloading side and place it next to the dirt filter on the loading side.

If necessary, the door on the removal side can be opened with the "Sieve removal RS" program.



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- Clean the edges on which the dirt filter rests.
  Make sure that no dirt falls into the chamber sump!



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- If necessary, insert a clean replacement dirt filter on the unloading side and ensure a snug fit.
- 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!

7.8 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 cycle	MIS module - short, long, eye instruments and da Vinci rack and module	▶ 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. Replace defective rinsing holders!

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).

Interval	What	How	Remark
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 3 and 4 level with MIS strip	▶ Pull the grid out of the rack. ▶ Remove the MIS strip. ▶ Pull support rails out of the mount. ▶ Unscrew all threaded connections. ▶ Clean the grid and support rails under running water. ▶ Clean the MIS strip 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.	Threaded connections must be remounted securely. Replace defective rinsing holders!
As required	Rack MIS	▶ Pull the grid out of the rack. ▶ Remove the support rails. ▶ Clean the grid and support rails under running water. ▶ Unscrew both of the blind screw caps on the end of the supply pipe. ▶ 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/ anesthetic drum rack	▶ Remove the metal brackets from the drum. ▶ 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.	Check that the screws of all metal brackets have been securely tightened!
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!

7.9 Cleaning of transport trolleys

The following cleaning instructions apply to all MMM transport trolleys (incl. TW HUB and TW HV).

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

NOTICE

Rust can form when using chloride-containing cleaning agents and disinfectants!

Chloride-containing cleaning agents and disinfectants are not suitable for stainless steel surfaces.

What	How	Remark
Removable collection container (transport trolley for racks 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 the fill level of the collection container. When used constantly, the collection container should be rinsed once a day with a suitable disinfectant. Alternatively, reprocessing in the washer-disinfector is also possible.
Rollers and storage table	Cleaning and disinfection according to the work instruction using a cleaning cloth together with a suitable surface disinfectant.	The removable parts can also be reprocessed in the washer-disinfector.

NOTICE

The transport trolleys are not suitable for automated reprocessing!

7.10 Maintenance activities

NOTICE

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

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

Daily:

What	How	Remark
Drain the tanks.	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.

What	How	Remark
Emptying and cleaning the chamber: regular maintenance can significantly extend the lifespan of the interior chamber walls if certain precautions are taken. The surfaces must always be metallic and shiny. If the walls are covered in a gray or slightly spotty layer after extended use, this must be removed. A cycle without load must now be run. Rust formation (surface rust, extraneous rust) can destroy the chamber. Spots of this nature must be treated immediately.	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 7.7, "Cleaning the dirt filter" 4. There is a safety guard in front of the fan wheel in the chamber. This must be removed and cleaned. 5. Check the fan wheel and the integrated heating systems for contamination and, if necessary, clean them. 6. Install the cleaned filters and safety guard.  **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.
Visually inspect and clean the door seal	The door seal is sensitive as it is subjected to stress during the washing process. Defective seals disrupt proper system operation. 1. Visually inspect the door seals – on the loading and unloading sides – with the chamber door open. The door seal is located in the groove on the open front end of the chamber. 2. Remove any foreign objects from the seals! 3. If the seals are slightly dirty, wipe with a lint-free cloth. 4. Visually inspect the visible side of the seal for damage.	Report damage to the system supervisor.
Check door operation.	Observe door movement on both sides during opening and closing. If there are any irregularities compared to normal door movement, notify the system supervisor. Possible irregularities are: – Jerking – Moving too slowly or too quickly – Friction noises – Unusual motor noises	Report information to the system supervisor.
Lock pin in the door panel (for machines with manual or semi-automatic transport only)	Check the function of the lock pin.  **A defective lock pin must be replaced!**	

What	How	Remark
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 pull-out canister compartment on the loading side. 2. Visually inspect the almost transparent canisters from the outside. If the fill level in the canister is more than approximately 5 cm, the process chemicals are sufficient for at least one program run.  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.** 3. Close the pull-out canister compartment.	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!  **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 steam and 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. The door seal is located in the groove on the open front end of the chamber. 2. Remove any foreign objects from the seals. 3. If the seals are slightly dirty, wipe with a lint-free cloth. 4. Visually inspect the visible side of the seal for damage.  **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 tanks (option)	Clean the tanks 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 and TW HV	The parking brake function must be tested carefully with the transport trolley fully loaded.	
Transport trolley TW and TW HV	The smooth action and height of the locking bolt can be checked by switching the locking lever over.	

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. ▶ Moving upwards from the valve, insert the new door seal up to and beyond the second door seal radius. ▶ Then, moving downloads from the valve, insert the door seal up to and beyond the second radius. ▶ Finally, insert the door seal on the opposite side of the valve. ▶ Correct any possible length problems by stretching or compressing the seal. ▶ Ensure the door seal lies flat in the door seal groove.	

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

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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.

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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

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