Instructions for use



Washer-Disinfector

Uniclean PLE

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CE 0123

Uniclean PLE

This **Uniclean PLE** washer-disinfector is available in the following variants:

Machine designation	Capacity [flexible endoscopes]		Number of doors	Heating
	Standard	Extendable to max.		
Uniclean PLE	2	3	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



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

CMS	Channel Monitoring System	Channel monitoring for the endoscope in the machine
SOP	Standard Operating Procedure	Standard work instructions

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!



Protective ground



Functional earth



Wear protective glasses!



Wear protective gloves!

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1 Security

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



Note!

Observe the safety instructions.

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

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

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

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

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

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

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

1.1 Intended use

Intended purpose

The **Uniclean PLE** series of washer-disinfectors is suitable for the automated cleaning, disinfection and drying, as defined in DIN EN ISO 15883-1, of reusable thermolabile endoscopes.

This series is intended for use in the medical field (e.g. in Reprocessing Units for Medical Devices, medical clinics, etc.).

WD-E machines are not to be regarded as storage systems.

Intended use

The **Uniclean PLE** washer-disinfector is suitable for the automated cleaning and disinfection, as defined in DIN EN ISO 15883 –4, of the reusable, flexible thermolabile endoscopes corresponding to the type test groups in Annex H of DIN EN ISO 15883-4.

The following endoscopes are examples from the aforementioned type test groups:

Endoscopes

- Gastroscopes
- Colonoscopes
- Duodenoscopes
- Bronchoscopes
- Ultrasound endoscopes

Note

A) Only flexible, thermolabile endoscopes that have been designated by their manufacturer as suitable for reprocessing in a washer-disinfector can be treated.

B) Only thermolabile and reusable medical devices that have been expressly designated by their manufacturer as suitable for reprocessing in a WD-E can be treated. Always observe the manufacturer's specifications!

C) To store endoscopes in the WD-E overnight after reprocessing, this storage process must first be validated by the operator.

The microbiological risks associated with storing endoscopes in the WD-E overnight must be assessed taking into consideration the maximum duration of this short-term storage. It must be ensured that the endoscopes are microbiologically compliant after storage in the WD-E. This must be verified as part of the process validation (see "Validation", Page 13) by means of a suitable microbiological test.

Limitations of use

Note

Loads not explicitly listed in the Intended Use section must not be treated in the **Uniclean PLE** washer-disinfector.

Examples of loads not permitted to be treated include:

- Rigid endoscopes
- Surgical instruments with a smooth surface
- Instrument basins/trays
- Minimally invasive surgery (MIS) instruments
- Eye instruments
- Robotic instruments
- Dental instruments
- Hollow devices and hoses
- Anesthetic accessories, respiration accessories, anesthetic materials, and respiration materials
- Bowls, basins, receptacles
- Glass items
- Utensils
- Transport containers (e.g. endo trays, sterile goods containers)



Note

The machine is not intended to be used in non-medical applications.

Service life of the machine

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

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

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

1.2 Responsibilities of the operator



Note!

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

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



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

Before commissioning

The operator must ensure that the following requirements are met:

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

Network security

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

Interface validation with cycle protocols from outside companies

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

If the machine is being operated in Germany

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

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

As part of the risk assessment, operators must assess the effect of EM fields on the health and safety of employees and, if necessary, take suitable measures.

Based on the current state of knowledge, it is unlikely for devices with a wireless interface (RFID) to affect medical implants at a distance of 15 cm.

1.2.1 Validation

The operator must ensure that only validated programs are used for medical devices.

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

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 15883-4, DIN EN ISO 15883-5 and in the country-specific guidelines (e.g. DGKH, DGSV and AKI Guideline for the validation of automated cleaning and disinfection processes for reprocessing heat-sensitive endoscopes).

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

As a rule, requalification takes place annually.

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

Guidelines

- DGHK, DGSV and AKI guideline

  For the validation of automated cleaning and disinfection processes for reprocessing heat-sensitive endoscopes
  Guideline compiled by the **D**eutsche **G**esellschaft für **K**ranken**H**aushygiene (German Society for Hospital Hygiene), **D**eutsche **G**esellschaft für **S**terilgut**V**ersorgung (German Society for Sterile Supply) and **A**rbeits**K**reis **I**nstrumentenaufbereitung (Working Group for Instrument Preparation)

- ÖGSV (Austrian Society of Sterile Supply) guideline

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

1.2.2 Medical devices / equipment log

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

Documenting the following in the equipment log is recommended:

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

1.2.3 Training the users

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

The users must be trained for this task by a qualified person (e.g. MMM customer service) and must be familiar with the user manual by the time the machine is handed over.

The names of all persons tasked with operating the machine as well as the supervisor of the system (Chapter 1.3, "operators") must be recorded in the compulsorily maintained medical products / equipment log. When changes in staff occur, new users must be inducted using this user manual and also recorded in the medical products / equipment log.

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



Risk of injury

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

1.2.4 Water quality

Water quality has a significant impact on the cleaning and disinfection results Chapter 6.3.8, "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, see "Maintenance activities ", Page 133



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 Adapter set storage

The adapter set should be stored as follows:

- Suspended
- protected from direct sunlight
- 10 to 90 °C

1.2.8 Disposal

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

LEGAL NOTES FOR THE OPERATOR:

1. **Disposal of components**

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

2. **Disposal of the machine**

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



3. **Return of used machines**

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



Privacy note

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

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

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

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

NOTES FOR OPERATORS IN THE EU

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

1.3 operators

Operators are divided into the following groups:

- Approved operator
- System supervisor (e.g. building services)

- Admin
- Specialist (e.g., MMM service technician)



Note!

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

Authorized operators and system supervisors must be trained.

Untrained persons are not permitted to operate the machine.

Approved operator

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



Risk of injury

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

System supervisor

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

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

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

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

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

Specialist

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

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

1.3.1 Access protection

Operators have different authorizations for operation of the machine depending on their user group see "Operator permissions", Page 93.

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

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

1.4 Rules of conduct for operation

1.4.1 Guidelines for laser class 2

To reduce the risk of mixing up the process chemical canisters, a hand-held barcode scanner is available in the pull-out canister compartment. When using the scanner, the laser beam (laser class 2) is directed at the desired target (barcode) and cannot be seen. An accidental glance into the laser beam, e.g. resulting from reflections from a reflective surface, can produce a strong glare. This will not cause any damage, however, even when using optical aids. Deliberately looking at the beam can cause damage to the retina.



Operators are instructed on the label not to stare into the laser beam, i.e. to perform the active aversion response by moving the head or closing the eyes and by avoiding looking directly into the beam for a longer period of time."



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!

Never deliberately stare into the laser beam!

1.4.2 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



Risk of injury!

The metallic walls and components of the chamber and the trays for the endoscopes become very hot during operation.

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

Service personnel



Risk of injury!

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.

1.4.3 Working inside the chamber

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

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

1.4.4 Working on the assemblies

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

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

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



Risk of injury!

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

Wear personal protective clothing when working on the assemblies!

1.4.5 Working in the electrical control cabinet

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



Danger due to electric current!

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

1.4.6 Maintenance work

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

1.4.7 Power failure or EMERGENCY STOP pressed

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

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

Working on the machine and, in particular, opening a chamber door 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.



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 run is automated and regulated by the controller. The chamber door cannot be opened during the program run.



Risk of injury!

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

Risk of injury due to hot water spray containing chemicals!

If process-related faults occur, only the chamber door on the loading side is activated.

The chamber door can be opened in an emergency see "Emergency opening of the chamber door", Page 109



Risk 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 Master switch

The master switch is located on the lower control cabinet (access to the pull-out canister compartment).

It completely disconnects the machine from the mains.

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



Risk of injury!

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

1.5.3 Cancelling the program

If the program stop button appears on the display after the program has started, it must be pressed in the following cases:

- Irregularities in the program run
- 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.
- Air is blown through the channels
- The chamber is drained.

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



The load 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.

1.5.4 EMERGENCY STOP

The machine 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.

On pressing these switches, all safety-relevant components (hardware-wise all 400 V consumers (heater, circulation pump) as well as the 24 V CMS pump) are switched off. The controller remains active. The message “EMERGENCY STOP pressed” is displayed.

To restart the machine, the emergency stop switch must be unlocked (using the key if present) (Chapter 6.3.7, "EMERGENCY STOP").



Risk of injury!

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

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

1.6 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 operator might fail to detect that the load 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. That is why 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

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



The machine is maintained primarily from the unclean side. Repairs can be performed from both front panels. No maintenance access from the side of the machine is required.

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

Spare and wear parts must be replaced with original parts.
When ordering adapters for the adapter set, take note of the labeling (part number).

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

National regulations must be observed.

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

Note regarding warranty

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

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

1.8 Standards, regulations and directives

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



Notice for EU:

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

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

Applicable EU directives and EU regulations

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



Note

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

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

Applied standards - state of the art

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

Performance and effectiveness

- DIN EN ISO 15883-1 Washer-disinfectors - Part 1: General requirements, terms and definitions and tests
- DIN EN ISO 15883-4 Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
- DIN EN ISO 15883-5 Washer-disinfectors - Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy

Product safety

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

EMC requirements

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

Functional safety

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

Usability

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



Note

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

2 Machine description

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

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

2.1 Type plate

The type plate is located on the control cabinet.

The type plate is located on the upper control cabinet.



Example illustration

Explanation of type plate:

 Manufacturer

 CE mark with identification number (example)

 Medical device

 Disposal (WEEE recycling)

 Type

 Observe the instructions for use

 Serial number

 Fragile, handle with care

 Date of manufacture

 Store in dry place

 Unique Device Identifier

 Lower and upper temperature limit

 Lower and upper air humidity limit

Additional conformity marks apply for the following countries:

 for Ukraine only

 for Serbia only

 for UK only

 for Australia only

2.2 Machine configuration

Cleaning, disinfection and drying

- 2 water inlet valves (cold and demineralized water)
- Automatic chamber tank filling level control (water meter) depending on the loading, to optimize water consumption
- Hygienic demineralized water reprocessing for final rinse
  (1 variant needs to be selected)
  - ⇨ Deionized water final rinse tank, electrically heated, 4 [kW]
  - ⇨ Sterile water filter for UPLE
- Side pull-out canister for the dosing unit and process chemicals
  [H=245 x D=13 x W=220]
  - ⇨ 3 x 10 liters
  - ⇨ 3 x 5 liters
- 2 (process chemical) dosing pumps each with 2 flow meters, suction lance with level switch, dosing inlets made from stainless steel and non-return valves
- Circulation pump 160 [l/min] at 2.0 [bar]
- Reprocessing system with 2 rinsing circuits:
  - ⇨ External with 4 rotary nozzles
  - ⇨ Internal via endoscope adapter kit
- Chamber tank heating, electrical 2 x 4 [kW]
- Drying of the insides of the endoscope channels using medical compressed air

Control and supervision

- Color touch display 10”
- B&R PLC controller
- 25 program slots for cleaning programs, freely programmable
- Three-color LED chamber lighting/panel lighting with alternating colors depending on process status
- 1 Ethernet and 2 USB interfaces
- A_0 value control and monitoring
- Pump pressure monitoring
- Dual PT 100 for monitoring the water and air temperature
- 2 flow meters for dosing and monitoring
- cycle documentation

- Configuration of specific values, e.g., flow for each endoscope
- The respective parameter sets for the endoscopes being reprocessed can be easily transferred to other machines
- Central database for downloading the parameter sets

2.2.1 Chamber design

Fully welded chamber made of CrNi steel, material no. 1.4404 (AISI 316L), hygienic, 2-R grade high-quality surfaces inside (smooth, shiny, reflective). The bottom chamber panel is slanted to allow water droplets to run off better.

Installed on one side inside the chamber are fixation fittings for a maximum of three wire mesh levels on each of which an MMM tray for endoscopes (mat. no. 10621499 MMM endoscope tray). The wire mesh levels can, if necessary, be easily and without tools removed from the fixation fittings.

The chamber tank in the lower section of the chamber has a water capacity of approx. 16 liters. A validation fitting for inserting thermocouples is welded into the chamber ceiling.

In the center of the chamber ceiling there are two temperature measurement probes/double PT100, the position of which is representative of the lowest temperatures in the system and is therefore suitable for controlling the chamber temperature.

The outlet of the chamber tank is fitted with an easily removable sieve.

The water supply to the rotary nozzles and inside the endoscopes is filtered.

For hygienic reasons, the chamber tank does not come with a tap for sampling the rinse water.

Samples for hygiene checks of the last final rinse water can be taken via a function on the display.

2.2.2 Chamber door

Manual, steam-assisted hinged doors with sound and heat insulating glass.

In the open state, the chamber door provides the ability to deposit flexible endoscopes for connecting them to the corresponding rinse adapters in an ergonomic manner. To create a seal between the door and chamber, a wear-resistance door seal extending all the way around the chamber has been fitted.

The loading door is closed manually. On starting a program, the door is then pressed against the wash chamber seal by a closing mechanism.

In the event of a power failure, the door can be opened manually (emergency opening).

Two-door machine, with optional return function for empty MMM endo racks.

The machine also supports single-door operation. This is possible via a setting in the controller, however maintenance access to the rear area of the WD-E should still be ensured.

2.2.3 Control panel

MMM smart HMI

A graphics-capable 10-inch color touch display is integrated into the loading side. The MMM smart HMI (Human Machine Interface) with background lighting has a clearly arranged and user-friendly design, can be operated using buttons with pictograms, and continuously displays all processes, both graphically and in plain text.

Multi-color display of the current operating status. The process and control menu, profile diagrams as well as machine parameters and maintenance aids can also be called up via the screen.

A further 10-inch color touch display can also optionally be installed on the unloading side (with limited functionality).

2.2.4 Controller

Programmable logic controller (PLC) for fully-automated program sequence, with variably adjustable parameters protected via code access, such as e.g. time, temperature, dosing, water volumes, etc., but not outside of pre-defined minimum values. Separate measurement systems for process control and documentation are available.
For processes using chemical disinfection, the program parameters are configured according to the specifications.

For thermal self-disinfection of all water conducting components, the integrated A_0 value calculator determines the actually achieved value. Alternatively, the program sequence can be controlled via a preconfigured A_0 value.

Various interfaces are available for external connections and devices (USB, Ethernet, etc.). An integrated batch memory can be used to store approx. 25,000 batches automatically.

The entire power unit (AC) is installed in a control cabinet underneath the chamber. Above the chamber there is another control cabinet containing the 24 V DC components. Both control cabinets meet the IP 66 protection class and are each clearly laid out and easily accessible for servicing purposes.

2.2.5 Loading the chamber

The endoscope to be reprocessed is manually precleaned at a suitable washing station and then placed in a tray for endoscopes (mat no. 10621499 MMM endoscope tray). The tray is then transported in a commercially available transport trolley or using an additional collection pan (e.g. commercially available endopans) to the machine.

RFID technology is used to record the operator and the endoscope being cleaned.

For easier handling, the connection of the endoscope placed in the tray occurs outside the machine on the opened loading door of the machine. This is done by connecting the corresponding MMM adapter to the respective single channels.

The tray can be loaded directly into the available level in the machine.

Next the adapter set is connected to the counterpiece in the chamber. The machine recognizes which endoscope is connected at which level. This helps reduce operator errors.

In addition, the especially user-friendly “MMM ERGO CONNECT” concept is employed. For ergonomic coupling and decoupling of the adapter set, the swiveling connector arm can be moved in both directions.

2.2.6 Dosing system

For automatic dosing of the process chemicals, two dosing pumps each with two independent flow meters are installed as standard. A further dosing line incl. flow meter is optionally also supported. The dosing inlets are made from stainless steel.

The machine has a pull-out canister compartment for holding and storing chemical containers (up to 3 x 10 l). This enables process chemical canisters to be swapped quickly and in a user-friendly manner. Use of incorrect process chemicals is prevented by reading the barcodes / QR codes on the machine dosing line (suction lance) and process chemical canister using the hand-held scanner on the machine. Optional RFID technology detection is available. The system can be used if the canister has an RFID tag. see "Chemical canister monitoring", Page 38.

A fan unit has been incorporated to prevent a higher concentration of process chemical vapors.

In addition, there is also the possibility of venting the dosing system, e.g. when changing the process chemical canister. This can be conveniently and easily carried out by the user via the controller.

The dosing system is automatically and directly supervised in order to adjust the process and program sequence with regard to the dosed volumes (+/- 5 %) and the timing of dosing.

2.2.7 Cleaning system

A high-performance circulation pump made from chromium-nickel steel (Cr-Ni-Stahl) delivers the preset volume of water from the heated chamber tank through the entire piping system within the machine. The entire piping system is inclined so that residual water can run off freely.

2 water connections for cold water and deionized water are available as standard. These are connected from above.

The cleaning system comprises 2 rinsing circuits:

External cleaning via rotary nozzles inside the chamber

The innovative 4-RN system with a total of 4 rotary nozzles made from CrNi steel fulfill three important functions:

1. Optimal spraying pattern for cleaning and disinfection in the chamber. There is a rotary nozzle on the chamber ceiling and another one on the chamber floor for this purpose. On the side walls opposite the three endoscope connections there are an additional two rotary nozzles between the wire mesh levels.
2. User-friendliness: The rotary nozzles are easily removable (without tools) for cleaning and maintenance work.
3. Resource saving: The use of rotary nozzles also reduces the water and process chemical usage to a minimum, which in turn reduces the use of resources.

For thermal self-disinfection of all water conducting components including the optional boiler and sterile water filter, the process water can be heated to 90°C, e.g. A_0 3000.

Internal cleaning of the endoscope channels using an adapter set and up to 3 lateral connections in the chamber

A suitable number of connections are available to cater for different endoscope types:

- 7 channel connections for cleaning and disinfection
- 1 connection monitoring between the endoscope connected to the adapter set and the RD-E
- 1 leak testing channel

A prefilter protects the endoscope against contaminants during reprocessing.

2.2.8 Single channel monitoring

All active channels (up to 7) of the connected endoscope are supervised. This occurs using flowmeters. The target flow values for the active channels are stored in the machine parameters and need to be 10 % of the maximum permissible restriction of the flow per channel. Otherwise the automated control system generates an error message.

Single channel supervision enables blockages or partial blockages in the individual channels of the affected endoscope or the unintended detachment of a single adapter to be detected. This guarantees a reproducible process quality.

The leak test of the endoscope occurs after the endoscope has been connected. The program can only be started after the test has run successfully. A leak test at a reduced applied pressure is performed during the wash cycle to prevent the ingress of liquid into a defective endoscope. The pressure for the leak test can be adjusted according to the relevant manufacturer's instructions.

2.2.9 Drying

The insides of the individual endoscope channels are dried using medical compressed air.



Note

An active external drying is optionally available.

2.2.10 Draining

The water with the process chemicals in the chamber is drained by means of a valve.



Note!

A drainage pump is optionally available (mat.no. 010576900) if no floor drain is present.

2.3 Mandatory options

Boiler

Electrically heated water tank for thermal reprocessing of the sterile water. Boiler manufactured completely from CrNi steel, insulated and equipped with all necessary components. The water in the boiler is thermally disinfected in-process (A_0 = 3000).

The boiler is equipped with a heat exchanger. The thermal energy from the thermally disinfected hot water (approx. 90 °C) is used for the heating steps. At the end, the water reaches a suitable temperature (approx. 50 °C) for the final rinse step. This prevents thermal damage to the flexible endoscopes and ensures that energy is used efficiently.

Note!

Suitable only for process chemicals based on glutaraldehyde.

Sterile water filter

The sterile water filter is used for mechanically reprocessing the sterile water.

The filter cartridge is 10 inch in size and comes with a sterile membrane (0.2 µm). The design of the filter unit allows a needs-based automatic disinfection using hot water (90°C).

Note!

Suitable only for process chemicals based on peracetic acid or glutaraldehyde. Temperature monitoring of the peracetic acid-based process chemicals is possible.

2.4 Optional extras

To be ordered with the unit. Retrofitting is not possible.

Only those options that are important to the operation and maintenance of the machine are listed!

2.4.1 Active external drying

The drying system ensures a uniform airflow inside the chamber. The maximum drying temperature is 60 °C to ensure the flexible endoscopes are dried in a material-friendly manner.
The drying parameters (time / temperature) are freely configurable.

Air is supplied into the chamber via a side channel blower with fresh air intake and a replaceable sterile filter element (H14). To suction infiltrated air out of the assemblies compartment of the machine, a draft diverter including connector for the on-site waste air duct has been installed directly into the outgoing air line of the chamber.

2.4.2 Unloading side control panel

Graphics-capable 10-inch color touch display for displaying the process sequence and the remaining time for the currently running cycle as well as for operator log in/log off.

2.4.3 Energy manager

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 for the individual machines so the media (steam, water, electricity) are not taken from the shared supply network at the same time.

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

Using the energy manager does not reduce overall media consumption but significantly decreases the peak demand.

The energy manager does not affect the process sequences or the reproducibility of the processes.



Note

Please refer also to the options of the RUMED360® Energy Balancing System (EBS) (see RUMED360® technical description).

2.4.4 Drainage pump

Drainage pump, if no floor drain is present on site.

2.4.5 Endo module extension

Extension of the Uniclean PLE with a third endo level including wire mesh level and corresponding extension for single channel monitoring.

2.4.6 Direct hot water connection

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

Note

Only in conjunction with the Sterile water filter option (mat.no. 010576899).

2.4.7 Dosing

2.4.7.1 Additional dosing line

An additional dosing pump with dosing monitoring when using “2-component chemical” in the disinfection step.

Note

Peracetic acid Schülke +: thermosept PAC (two-component PAA, base + additive)

2.4.7.2 Chemical canister monitoring

When using process chemicals, the process chemical used is monitored via RFID detection.

The following characteristic is checked or monitored:

- chemical approved for the process
- the expiry date (incl. monitoring)
- the lot number
- position detection (RFID) of a canister (incl. monitoring)

2.4.7.3 Peracetic acid temperature monitoring

Temperature monitoring by means of a contact thermometer on the chemical canister base.

Recommended when using peracetic acids.

2.4.7.4 Tilting device for canister

Stainless steel plate manufactured completely from CrNi steel for tilting a 5 or 10 l chemical canister.

Used to optimize the emptying of a chemical canister in conjunction with or without a suction lance.

2.4.8 Conductivity measurement system

Test equipment for automatically monitoring the conductivity in the process water of the WD-E. Conductive measurement device including temperature probe for conductivity compensation.

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 rinse phase and, depending on the preconfigured parameters, one or more other rinse steps are repeated automatically.

The maximum possible number of rinses is preconfigured by the controller.

2.4.9 Media shut-off valves

Piston shut-off valves for cold and deionized water or for hot water.

During machine operation, the piston shut-off valves for cold and deionized water or for hot water are opened.

If the machine is switched off, the valves close, thereby disconnecting the machine from the on-site cold water and deionized water or warm water supplies.

2.4.10 Media monitoring

2.4.10.1 Monitoring of cold/DI water pressure

Pressure switch incl. connectors for monitoring the connection pressure of the on-site cold water and deionized water supply to the machine. If the set minimum media pressure (on-site) is not reached, a fault message is sent to the machine and the cycle is prevented from starting.

2.4.10.2 Hot water pressure monitor

Pressure switch incl. connectors for monitoring the connection pressure of the on-site hot water supply to the machine. If the set minimum media pressure (on-site) is not reached, a fault message is sent to the machine and the cycle is prevented from starting.

2.4.10.3 Bottom tray fill level monitoring

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

This is installed in the lower area of the bottom vat and, when a specified water level in the bottom vat is exceeded, stops the draining process and closes the optional media shut-off valves. No further water will then be drained or pumped off.

2.4.11 Monitoring of on-site connections

Fault polling for the following external connections:

- central dosing
- on-site exhaust air system
- waste water collection container

2.4.12 Potential-free contacts

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

- Machine “on/off”
- On-site exhaust air fan activated for drying phase
- Group fault message for central control technology

2.4.13 Air permeability reduction

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

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

Note

The required on-site air pressure difference between the clean and unclean side must also be maintained when the air reduction panels are removed, e.g. for maintenance purposes.

2.4.14 Return flow preventer

Return flow preventer for cold water according to DIN EN 1717, if the WD-E is connected directly to the drinking water network.

2.4.15 HEPA filter monitoring

The HEPA filter contamination level is supervised by means of an analog pressure transducer.

If the filter is contaminated, the controller displays an informational message which is also documented in the cycle protocol. The drying process continues.

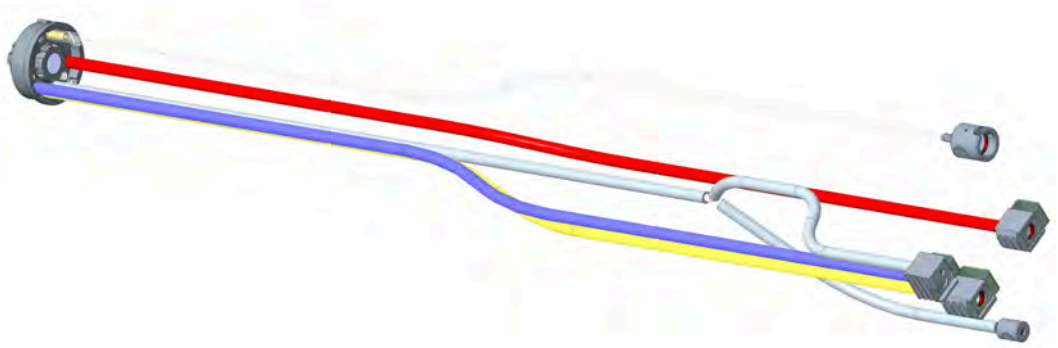
Only in conjunction with the Active external drying option (mat.no. 010592163)

2.5 Adapter set description

The adapter set comprises a 10-fold connector and colored hoses with single adapters. The unique color coding of the hoses always corresponds to a specific channel of the endoscope, which means that the same color is always assigned to a channel, e.g., red for the biopsy channel. The 10-fold connector is connected to the machine. The single adapters are connected to the endoscope. The color of the hoses indicates the channels to which the adapter and endoscope are to be connected.

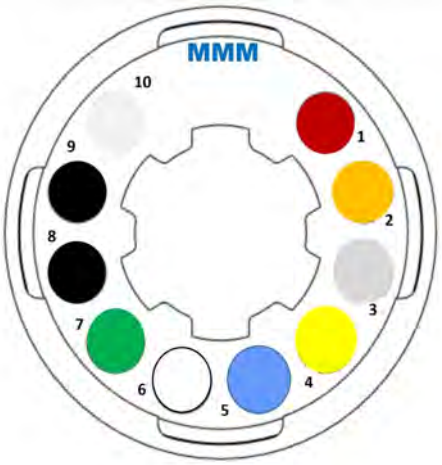
Each adapter set type has a sticker with a unique ID, e.g. O-14 and material number 0106xxxx.

Example adapter set



2.5.1 10-fold connector

Assignment to 10-fold connector

	Channe		Channel	
Leak test channel	10		1	Biopsy channel 1
Not used	9		2	Biopsy channel 2
Not used	8		3	Air channel
Extra rinse, balloon, Albaran and jet channel	7		4	Suction channel
Extra rinse, balloon and jet channel	6		5	Water channel

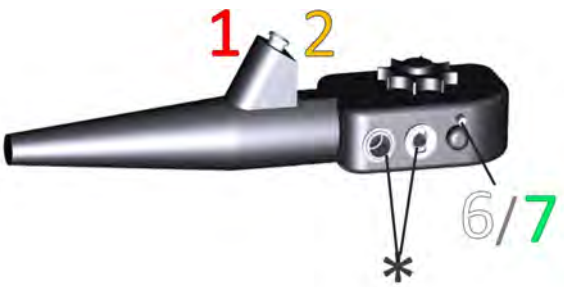
Overview of the channel connections for endoscope adapters

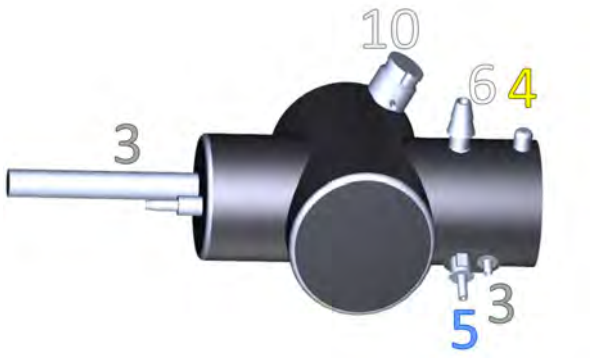
Observe the user manual of the endoscope manufacturer!

The described positions of the channel connections are examples only!

For the exact position of the channel connections of the endoscope, see the user manual of the respective endoscope!

Example images only





1	Biopsy channel 1	6	Extra rinse, balloonand jet channel
2	Biopsy channel 2	7	Extra rinse, balloon, Albaran and jet channel
3	Air channel	10	Leak test channel
4	Suction channel		
5	Water channel	*	Connection for channel separator

2.5.2 Example endoscope adapters

Adapter with spring connection



- Attach and detach the adapter by squeezing the spring.
- Check that the adapter is attached securely and correctly. It should not be possible to pull off the adapter.

Adapter with plug-and-twist connection (bayonet connection)



- Attach the adapter using a push/twist movement.
- Check that the adapter is attached securely and correctly. It should not be possible to pull off the adapter.

Adapter with clamp connection



- To attach and detach the adapter, squeeze it at the top.
- Push on the adapter until the lower jaws enclose the connector.
- Check that the adapter is attached securely and correctly. It should not be possible to pull off the adapter.

Adapter with screw connection



- Attach by screwing tight.
- Check that the adapter is attached securely and correctly. It should not be possible to pull off the adapter.

Adapter to plug in



- Push on the adapter as far as it will go.

Adapter with mark



- Insert the adapter.



Note!

Reduced cleaning performance!

Ensure that the mark on the adapter (green arrow) lines up with the white mark on the endoscope!

The adapter is otherwise not connected correctly!

- Check that the adapter is attached securely and correctly.

2.6 Operation and process description

2.6.1 Functioning of the machine

After connecting the endoscopes, closing and sealing the hinged door, and starting the program, the selected program runs automatically and independently until it has been successfully completed:

- The rinse chamber is filled with a defined volume of water.
- Depending on the particular program step, process chemicals are dosed into the water.
- The water (with the process chemicals) is heated, drawn out of the rinse chamber and applied to the endoscope via the rotary nozzle system, and the endoscope is also rinsed out with water (with the process chemicals) with the single channel system.
- The water (with the process chemicals) that drips off is collected in the base of the chamber and the cycle starts from the beginning.
- This circulation phase is repeated until all the parameters set for the selected program have been reached.
- A number of different circulation phases follow one another (program steps).
- The medical device is then dried with warm, sterile-filtered air.
- The door latch is released and the door on the unloading side can be opened. The door on the loading side remains closed. In single-door operation, the door latch on the loading side is released. The door can be opened.

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

2.6.2 Process chemicals

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



Note!

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

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

The use of alternative process chemicals is only allowed after consulting the manufacturer of the washer-disinfector. Observe Chapter 4.8, "Handling chemicals" when changing the process chemicals.

Note!

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").

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

Combinations of cleaner and disinfectant:

To clean and disinfect endoscopes in the Uniclean PLE, we recommend using one of the process chemicals approved by MMM.

Note

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

Note

Only hose grades suitable for the approved process chemicals are permitted to be used (long-term durability).

Boiler 010576898 option can only be used with glutaraldehyde-based disinfectants.

Process chemical from Dr. Weigert

Glutaraldehyde-based disinfectant

Chemical type	Product	Dosing line
Cleaning agent	neodisher endo® CLEAN	1 (Standard)
Cleaning agent	neodisher® MediClean forte	1 (Standard)
Cleaning agent	neodisher® MediClean advanced	1 (Standard)
Disinfectant	neodisher endo® SEPT GA	3 (Standard)

Peracetic acid-based disinfectant

Chemical type	Product	Dosing line
Cleaning agent	neodisher endo® CLEAN	1 (Standard)
Cleaning agent	neodisher® MediClean forte	1 (Standard)
Cleaning agent	neodisher® MediClean advanced	1 (Standard)
Disinfectant	neodisher endo® SEPT PAC	3 (Standard)

Current as at 05/2025 Please ask the manufacturer of the machine for the current list.

Process chemical from Schülke+

Glutaraldehyde-based disinfectant

Chemical type	Product	Dosing line
Cleaning agent	thermosept® X·tra enzymatic cleaner	1 (Standard)
Disinfectant	thermosept® ED	3 (Standard)

Peracetic acid-based disinfectant

Chemical type	Product	Dosing line
Cleaning agent	thermosept® X·tra enzymatic cleaner	1 (Standard)
2-component disinfectant	thermosept® PAA base	2 (Additional dosing line option)
2-component disinfectant	thermosept® PAA additive	3 (Standard)

Current as at 05/2025 Please ask the manufacturer of the machine for the current list.

2.6.3 Cleaning and disinfection process

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



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

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

Cleaning and disinfection

Temperatures and program steps are shown in the following program run.

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

Cleaning and chemical disinfection for thermolabile endoscopes with glutaraldehyde-based disinfectant



In every program step, the endoscope is rinsed on the outside and inside. At the end, medical compressed air is blown through the channels of the endoscope to avoid entrainment of process chemicals.

1. **Pre-cleaning** with cold water and without process chemicals
2. **Cleaning** with 50 °C deionized water to which detergent has been added.
3. **Intermediate rinse** with cold, clear water to remove the residual detergent.
4. **Chemical disinfection** with deionized water to which disinfectant has been added at 55 °C.
5. **Final rinse** with hygienically safe deionized water approx. 50 °C.
6. **Active external drying (option)** of the endoscope with a uniform air flow up to max. 60 °C

Cleaning and chemical disinfection for thermolabile endoscopes with peracetic acid-based disinfectant



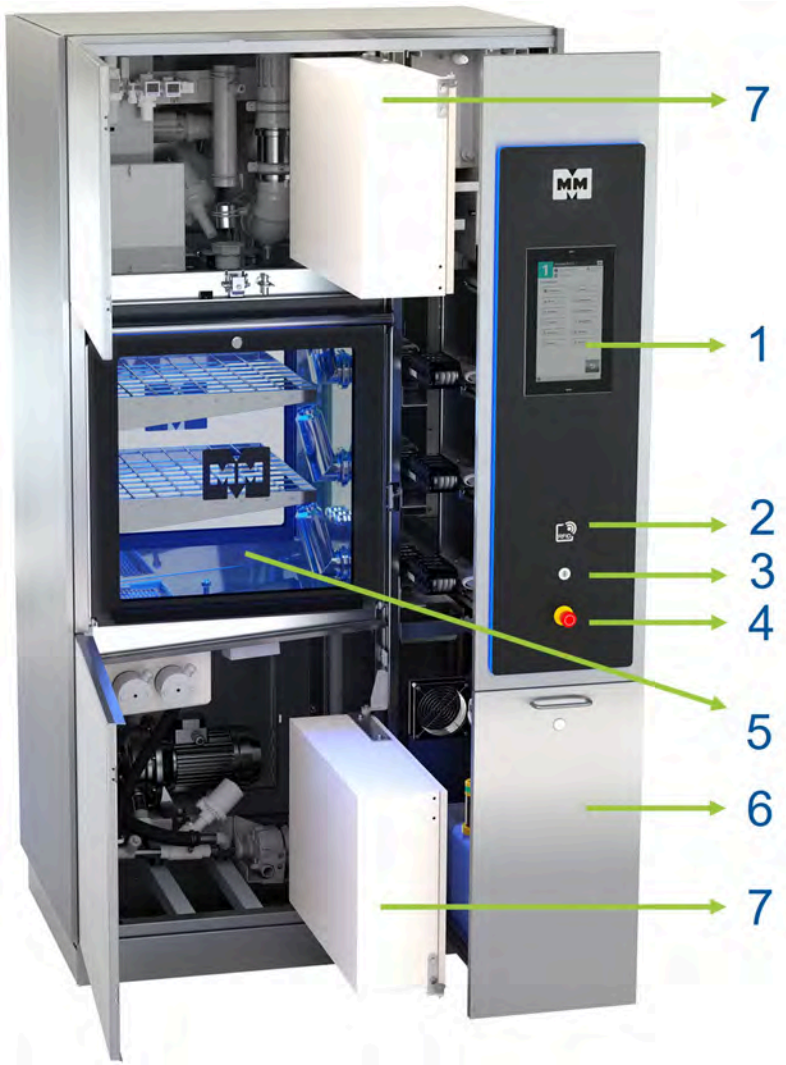
In every program step, the endoscope is rinsed on the outside and inside. At the end, medical compressed air is blown through the channels of the endoscope to avoid entrainment of process chemicals.

1. **Pre-cleaning** with cold water and without process chemicals
2. **Cleaning** with 50 °C deionized water to which detergent has been added.
3. **Intermediate rinse** with cold, clear water to remove the residual detergent.
4. **Chemical disinfection** with deionized water to which disinfectant has been added at 35 °C.
5. **Final rinse** with hygienically safe cold deionized water

3 Displays and controls

3.1 Loading side and unloading side

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



	Loading side	**Unloading side** (not shown)
1	Color touch display	Color touch display (option) or MMM logo
2	RFID reader	RFID reader
3	On/off button	Return hatch button
4	Emergency stop switch	Emergency stop switch
5	Chamber door	Chamber door
6	Pull-out canister compartment	-
7	Control cabinet	-

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

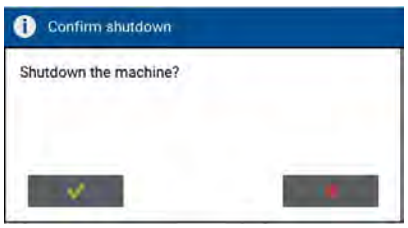
The machine is switched off using the on/off button.

Note!

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

To switch off the system:

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



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

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

3.1.2 EMERGENCY STOP



The emergency stop (see "EMERGENCY STOP", Page 23) must only to be pressed in an emergency, e.g. when there is a risk of personal injury or a risk of damaging the material to be treated or elements of the machine.

Example

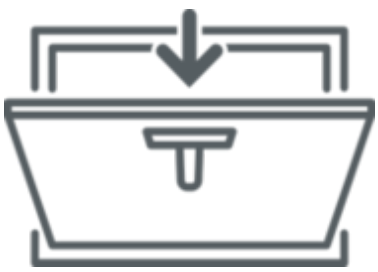
3.2 Color touch display

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

3.2.1 Function buttons

Interaction area

This is where you obtain information or you can switch to the relevant menu by tapping.

	Log in operator via RFID or tap to open the login window.
	Information: Door needs to be opened.

	Information: Door needs to be closed.
	Information: Endoscope can be scanned via RFID.
	Information: Endoscope can be removed
	Information: Program was successful, door can be opened to remove the endoscope.
	Information: Program failed, door can only be opened on the loading side.

	Information: Program was successful.
	Acknowledge alarms - one or more alarm messages can be acknowledged -> switches to “Alarms” menu
	Canister empty -> switches to the "Operating materials" menu

Buttons

	Log operator in or out	Every action requires an operator to be logged in. If no operator is logged in, “Nobody” is displayed.
		Log in operator via RFID
	Manual program selection / program indicator	
	Manually select endoscope	A list of all endoscopes that can be reprocessed in the machine is displayed.
	Menu overview	

	Confirm the selected function	
	Cancel entry	
 	Arrow buttons	For changing the screen within the pages of an individual menu
	Switch view	
	Save	
	Back	Returns to the previous menu.
	Start	Starts the selected program.
	Cancel	Program canceled
	Skip program step	Jump to next program step (for a service technician with MMM access rights only)

	Pre-cleaning white - deactivated blue - activated	Selecting “Pre-cleaning” activates an additional rinsing step before the cleaning rinsing step.
	Additional drying (option) white - deactivated blue - activated	Selecting “Additional drying” increases the defined drying time. Additional drying is only possible with the “Active external drying” option.
	Last cycle white - deactivated blue - activated	Selecting “Last cycle” activates that the next or currently active program is the last program for the day. The machine is then switched off. For machines with a boiler, automatic refilling of the boiler is prevented
	Water sample (microbiological quality) at the start of the final rinse white - deactivated blue - activated	The program option prevents circulation of the water and allows a water sample to be taken before the last final rinse step, see "Taking a water sample", Page 77.
	Water sample (entrainment) at the end of the final rinse white - deactivated blue - activated	The program option prevents pumping out of the water at the end of the last final rinse step, see "Taking a water sample", Page 77.

 	Autostart white - deactivated blue - activated	The program option is only displayed when the self-disinfection program is selected. It allows the program to start automatically, see see "Settings for autostart", Page 101



Function buttons are only active if an action is allowed.

Info

	Date and time
	No adapter set is connected
	A leak test is being performed on the endoscope
	Adapter set is not recognized or the leak test of the endoscope failed
 blue	The adapter set is connected correctly and the connected endoscope can be cleaned.
 Green	The endoscope was successfully reprocessed.

 Red	Program not error-free

3.2.2 Menu overview

Start



1. Logs in the operator by clicking via the menu, or with an RFID tag at the appropriate location.
2. Displays the date and time
3. Displays the selected program

Grayed out functions are not available without operator login!

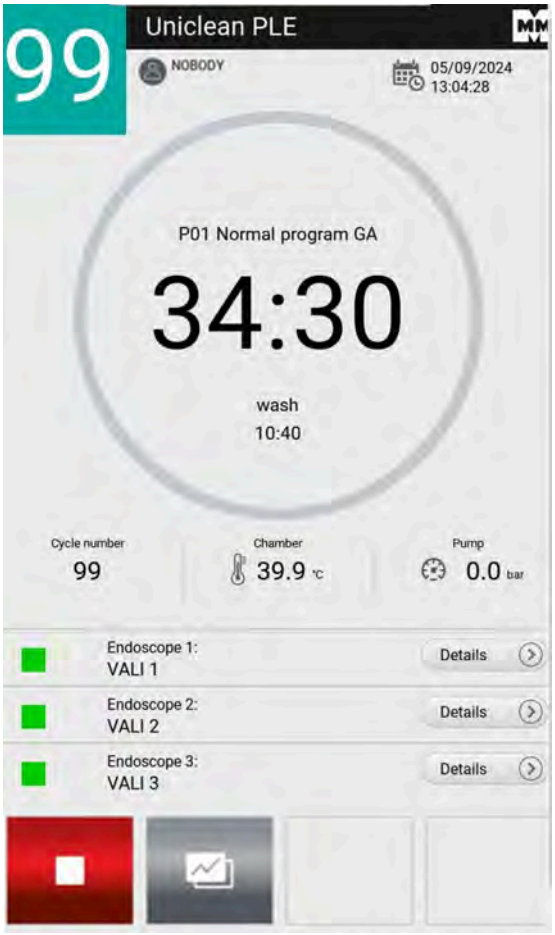
Program start and program run



1. Pre-cleaning (deactivated)
2. Additional drying (deactivated)
3. Last cycle (deactivated)
4. Water sample for microbiological quality (deactivated)
5. Water sample for entrainment (deactivated)
6. Endoscope/blind connectors connected



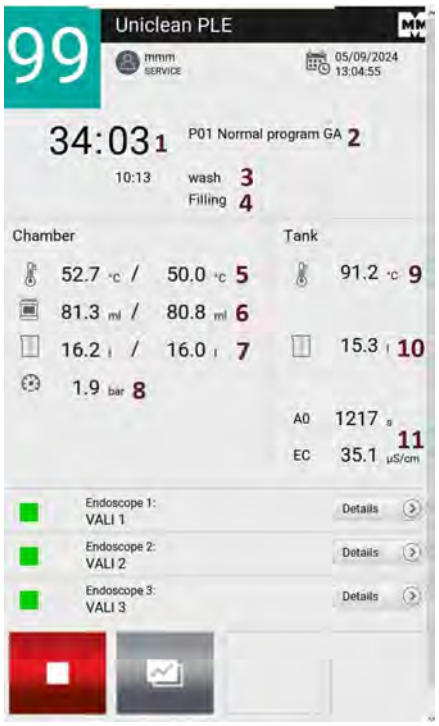
Program ready to start



1. Cycle number
2. Chamber temperature
3. Pump pressure
4. Connected endoscopes



Switch view



1 Program remaining time display
2 Selected program, e.g. P1 normal program
3 Current program step, e.g. cleaning
4 Phase in program step, e.g. holding phase temperature

Chamber:

5 Actual/target temperature [°C]
6 Actual/target process chemical quantity [ml]
7 Actual/target water volume [l]
8 Circulation pump pressure [bar]

Tank:

9 Temperature [°C]
10 Water volume [l]
11 A_0 value [s] and conductivity [µS/cm]

Menu overview

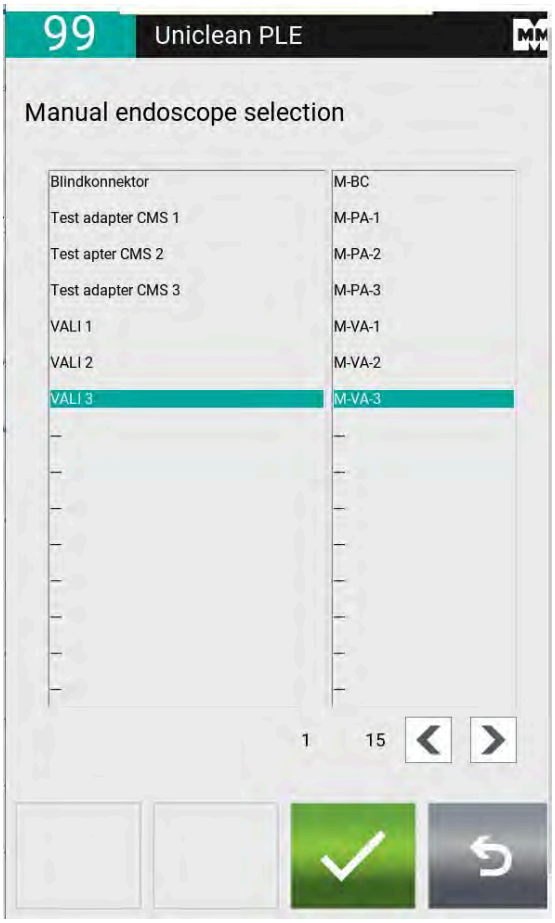
Program overview (example)



Example



Select endoscope manually :





Menu overview :



Access level
1 USER
2 SUPERVISOR
3 ADMIN
4 MMM Service

Grayed out functions are currently not available!

Menus for the user



Information, e.g. software version, service work due see "Planning service work", Page 132



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.



see "Fault messages", Page 104



see "Exchanging the canister", Page 84

see "Deaeration of dosing hoses", Page 143

Menus for the supervisor



Manage endoscopes see "Creating endoscopes and editing or deleting endoscopes", Page 94



Send failed cycle protocols and select alternative IP address see "Network outage", Page 108



"Fault messages"



"Exchanging the canister"

"Deaeration of dosing hoses"

3.3 Machine status indicator

Indirect, three-color LED lighting in the chamber for better visual monitoring and control of the cycle sequence. The operator is also shown the current operating status of the machine by means of a circumferential LED illumination on the operator panel and the MMM logo.

Color	Meaning of the LED illumination
Blue	Machine ready for loading
Blue, flashing	Machine ready for unloading
White	Machine in operation, program running
White, flashing	Rack redelivery
Red	Fault

The following colors also briefly light up on the control panel:

Color	Log in/out
Green	RFID signal, barcode or QR code was recognized, e.g. logging in of operator or registration of endoscope, scanning of chemical canister.
Yellow	RFID signal, barcode or QR code was not recognized. Eliminate the cause and execution the action again.

If at the end of the program not all endoscopes were successfully reprocessed, the following colors light up on the operating panel or alternating with the MMM logo until the door is opened. The color sequence corresponds to the levels with the connected endoscopes from top to bottom. The chamber flashes blue with the same rhythm.

Regarding the removal of the endoscopes and cycle control, observe 4.6 "Unloading the chamber", Page 78.

Color	Program end
Green	Cycle sequence completed properly
Red	Cycle sequence failed!
blue	No endoscope connected (blind connector)

4 Operation

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

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

4.1 Principles for machine cleaning and disinfection

For successful machine cleaning and disinfection, the endoscope to be reprocessed must be pre-cleaned at a suitable washing station and, if necessary, disassembled.

The pre-cleaned endoscope is then placed in a tray for endoscopes.



Observe the pre-treatment instructions of the endoscope manufacturer.

Observe the KRINKO recommendations for Germany or national regulations.

The endoscope must always be suitable for machine cleaning.

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

The use of demineralized water is recommended, especially for the final rinse, as this prevents spots, discoloration and corrosion.

The cleaning performance can only be ensured if the program is all suitable for the endoscope being cleaned.

In accordance with DIN EN ISO 15883-4, heat-resistant endoscopy accessories should be thermally reprocessed in a suitable machine (e.g. Uniclean PL II or Uniclean ML).

4.1.1 Notes regarding the chamber

After 24 hours of non-use, e.g. after a weekend, we recommend running a self-disinfection before the cleaning program for endoscopes, see "Machine disinfection", Page 142.

- The chamber must be clean see "Maintenance activities ", Page 133.

- Check the dirt filter incl. handle and, if necessary, clean it Chapter 7.6, "Cleaning the dirt filter".
- Prior to each program, check whether the rotating nozzles in the chamber can move freely.

Inadequate cleaning and disinfection performance!

Please note the points named above.

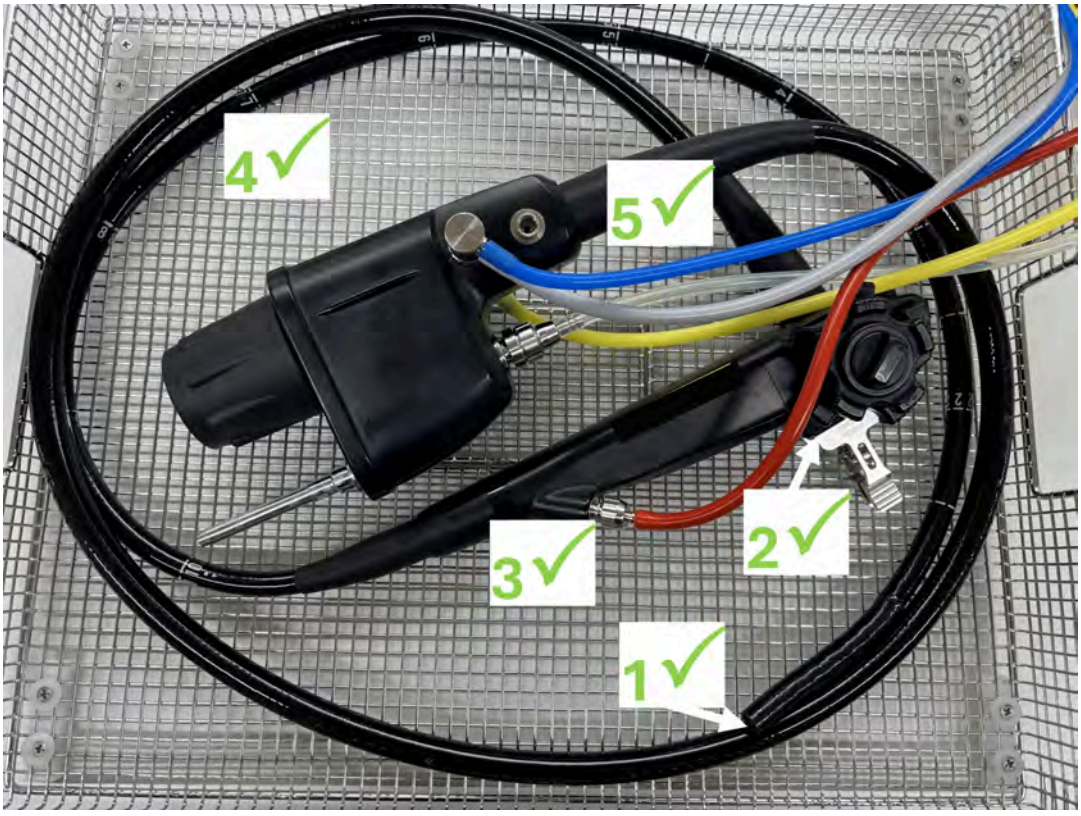
4.1.2 Checking the adapter set

Observe the following points for a valid and reproducible result!

The endoscopes must be suitable for machine cleaning and disinfection. Observe the reprocessing instructions of the endoscope manufacturer.

Make sure that the endoscope is connected to the appropriate adapter set and the program selection is consistent with that used for validation (see “Validation”).

General information



1. The distal end must not be obscured or covered by other items!
2. Single adapters on the endoscope, e.g. channel separators must not be obstructed and must not be slightly opened due to their position or parts resting on them!
3. Single adapters must be securely and correctly connected!
4. Place the insertion tube in the tray so that no overlapping occurs (avoidance of spray shadows)!
5. Tubes must not be twisted or kinked!

- Check whether the endoscope has undergone pre-cleaning. Observe the reprocessing instructions of the endoscope manufacturer.
- Make sure that the endoscope is connected to the appropriate adapter set.
- Check the endoscope and adapter set for damage. Damaged adapter sets must not be used.
- Check whether a channel separator is required and, if yes, whether the channel separator is connected correctly and securely.
- Check the leak test connection, if present. The leak test channel is connected to a transparent hose.

  The following points must be ensured each time before connecting the endoscope:
  - the leak test connection on the endoscope must be dry;
  - the leak test adapter must be dry, in particular the mating area;
  - the associated connecting hose must be dry.

  Any residual moisture on the endoscope or adapter can be removed using a clean, lint-free cloth. Medical compressed air can be used to remove any residual moisture in the hose.



Water penetrating into the leak test connection can damage the endoscope!

4.1.3 PLE programs

Cleaning programs

The selected program is highlighted in color.



Example:

Number	Program name
P01	Endo Normal
P03	Endo Intensive
P04	Drying
P05	Diagnosis

Further customer-specific programs are freely programmable. Up to 10 programs can be saved.

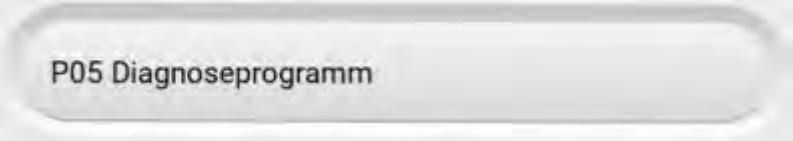
The actual program selected is configured according to the operator's requirements during commissioning. The names of the individual programs can be customized by the operator. The operator must ensure that every program used has been validated with a suitable load.

Machine disinfection



In the thermal machine disinfection method, all water-conducting parts in the machine are thermally disinfected (A_0 = 3000). This program prevents microorganisms and biofilm layers from forming.

Program for diagnosis



Allows the operator to run an internal check of the channel system.

The program for diagnosis can be run if repeated channel errors arise. All 10-fold connectors in the machine must be sealed off with a 10-fold test connector.

The program for diagnosis is started like a normal program. After the program has finished, the cycle protocol can be used to check whether the cycle was completed properly or failed, and which warnings or alarms arose.

Only the door on the loading side can be opened!

4.2 Logging users in and out

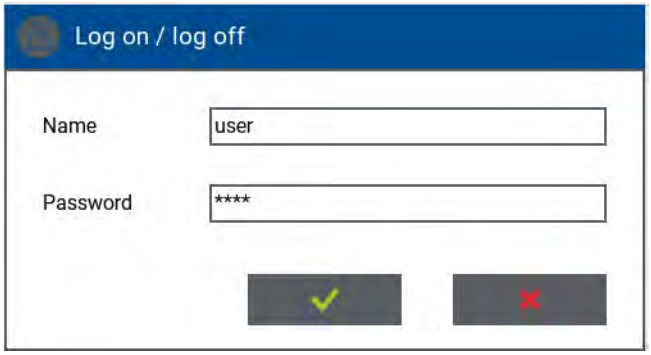
Log-in is always required for normal operation.

Operator log-in using RFID

- Hold the RFID tag against the RFID reader.

You are now logged in and can perform any action for which you are authorized.

Operator log-in manual



Pay attention to capitalization when entering the “Name” and “Password”! The password must be at least 3 characters long.

- Touch the “Name” entry field. The alphanumerical input block appears.
- Enter the relevant operator name.
- 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 appears in the title bar.

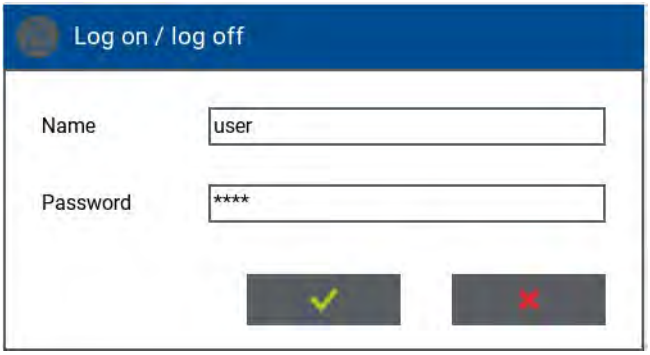
The user can carry out any action for which he is authorised.

Log out actively to prevent misuse of rights!

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

The automatic log-in can be individually configured for each operator in the “Permissions” menu.

User log-out



- Press the **Log out** button.

4.3 Loading the chamber and starting the program

Note!

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

Risk of crushing!

The fingers or hand can be trapped between the chamber and chamber door!

Always open and close the chamber door with both hands on the handle!

Pre-cleaning

- Clean the endoscope as specified by the manufacturer or as per the instructions of the operator, and according to the national regulations.
- Transport the endoscope to the machine.
- Open the door.
- Check that the rotary nozzles in the chamber can move freely.

Note!

The door is made of glass!

Place the trays carefully on the door to avoid breaking the glass!

- Place the tray with the endoscope carefully on the door.

Connecting the endoscope and starting the program

- Select the appropriate adapter set see "Adapter set description", Page 41

Inadequate cleaning and disinfection performance!

Ensure that the adapter set is compatible with the endoscope.

Check the adapter set for damage. Damaged adapter sets must not be used.

- Connect the individual adapters to the endoscope.

Inadequate cleaning and disinfection performance

Check whether a channel separator is required.

Ensure that all adapters and the channel separator are connected to the endoscope securely and correctly.

- Place the tray with the endoscope on a level in the machine.
- Log in to the machine.
- Scan in the endoscope using the RFID tag.
  The endoscope can also be selected manually. see "Manually selecting the endoscope", Page 76



- Check whether the adapter set is compatible with the endoscope, see example above.
- Check whether the locking mechanism of the 10-fold connector on the adapter is positioned at “open”.
- Connect the 10-fold connector of the adapter to the 10-fold connector of the machine and lock the connector of the adapter.
  For easier attachment, you can rotate the swivel arm in the machine in the desired direction. You have 30 seconds to do this, after that the endoscope needs to be scanned in again.
- Set the locking mechanism of the 10-fold adapter to “close”.

A leak test is performed if the endoscope is equipped with a leak test channel.

- Repeat the procedure for all levels.

All 10-fold connectors in the machine must be connected to an adapter set and endoscope or sealed off with a 10-fold blind connector (mat. no. 10606568). This is indicated by a blue tick on the display.



The adapter has been connected correctly.

The confirmation “Endoscope XY connected correctly” appears at the bottom of the display and the program page.

Only the programs that have been approved for the endoscope are now displayed in the program list.

- Check the program selection at the top of the display.
  If desired, you can change the program via the manual program selection. Only programs that have been approved for the endoscope are offered.
- If desired, select the additional “Prewash” and/or “Additional drying” program and/or “Last cycle” via the manual program selection.





- Close the door.

- Click on “Water sample” if you want to take a water sample after the program run.



Note!

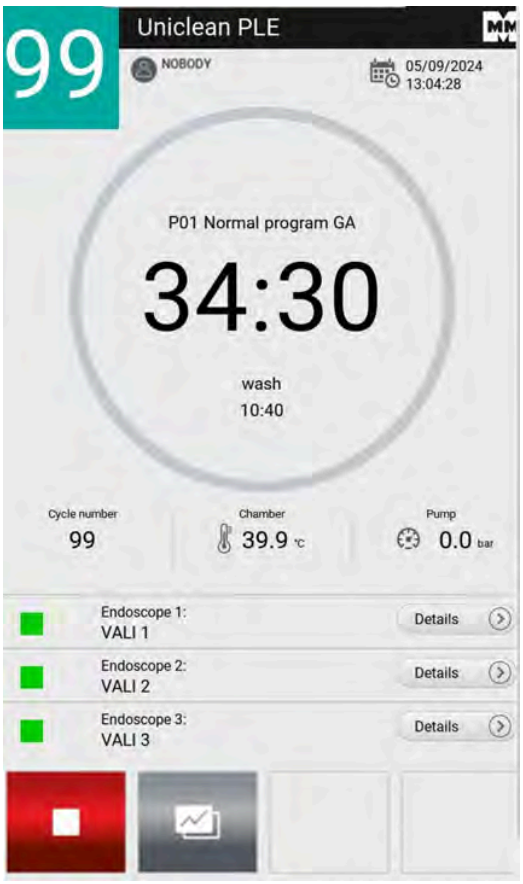
Cycle sequence failed

If the water sample option is selected, the cycle cannot be released.

see Page 77

- Acknowledge all alarm messages from the previous cycle. Unacknowledged alarm messages appear on the cycle protocol.
- Start the program.

The program sequence page appears.



Manually selecting the endoscope

- Press the “Manual endoscope selection” button.



- Select the relevant endoscope.
- Press the confirmation button.



The endoscope is displayed.

4.4 Canceling the program

If a program has been accidentally started that must not be used for the load, the “Cancel program” should be pressed to prevent any damage to the endoscope 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:

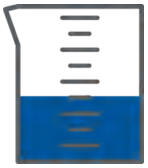
- on-site medical compressed air is blown through the endoscope
- the chamber drains,
- the chamber light turns red,
- an alarm message is shown on the display.

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

4.5 Taking a water sample

If the “Water sample for microbiological quality” or “Water sample for entrainment” option was selected before starting the program, an alarm message “Prg. water sample” appears. The “Microbiological quality” option prevents the water from being circulated during the last rinse step after filling the chamber. The “Entrainment” option prevents the water in the chamber from being pumped off during the last rinse step. The program is ended as a failed cycle.

The chamber lighting is red.



- Acknowledge the alarm message “Prg. water sample”

The chamber door on the loading side is unlocked.

- Take a water sample.
- Close the chamber door.

The door seal is engaged.

The cycle failed.

Restart the program.

4.6 Unloading the chamber

The controller regulates and monitors the cycle 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 with the exception of the channel evaluation at the end of the program.

If, for example, only 2 of the 3 endoscopes pass the channel evaluation, an operator with Supervisor or higher permissions can remove the endoscopes that passed. The endoscope that failed is disconnected and remains in the chamber and is returned to the manual precleaning reprocessing process step. Whether a cycle completed successfully or failed is indicated by means of symbols on the display for each respective endoscope and via a flashing LED illumination on the operator panel (unloading side option). The LED illumination around the MMM logo is decisive for releasing a cycle if no display is installed on the unloading side.

Cycle sequence failed for all endoscopes

If the cycle sequence has not completed properly for all endoscopes, an error message appears on the display and the illumination is red.

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.

Cycle sequence not completed properly for all endoscopes

If the cycle sequence has not completed properly for all endoscopes, a success or fail symbol appears on the display for each respective endoscope. The LED illumination around the operator panel or MMM logo flashes rhythmically in a sequence of different colors, see "Machine status indicator", Page 65.

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.

Example: blue - pause - red - green - blue - pause [1 - 1 - 0.5 - 0.5 - 0.5 - 1 seconds] means:

Blue - pause: this is followed by the color sequence for the endoscope levels

Top level (red): Cycle sequence failed for the endoscope

Middle level (green): Cycle sequence completed properly for the endoscope

Lower level (blue): no endoscope connected.

Cycle sequence completed properly for all endoscopes

If the cycle sequence has completed properly, the chamber door is unlocked. After operator login, the chamber door can be opened.

Proceed as follows to fully unload the machine:

4.6.1 Removing the endoscope and cycle control

The chamber lighting flashes blue.

- Log in.

The cycle protocol is created and the door can be opened.

Checking the cycle protocol

- Open the door.
- Check the cycle protocol.

  The following requirements must be met:

- The program that was run was suitable for the endoscope.
- The adapter sets were compatible with the endoscopes.
- The data in the cycle protocol must be identical to the data determined during validation.



Reduced cleaning performance!

Cycle sequence failed! Red chamber lighting!

If the cycle was not released, the reprocessing of the endoscope must be repeated!



If a program was started even though a machine disinfection is overdue, “Cycle sequence completed properly” appears in the cycle protocol and the warning “Disinfection program required”.



Note!

The “Cycle sequence completed properly” message is not sufficient, however, for releasing the cycle!

The cycle release also requires that a visual inspection be performed after removing the endoscope.

Removing the endoscope



Risk of injury!

The tray can be very warm after treatment.

Wear gloves to protect your hands when removing the tray.

Using both hands, pull the tray out of the chamber.

- ▶ Ensure no adapter has come loose.
- ▶ Disconnect the adapter set from the 10-fold connector in the machine.



Note!

The door is made of glass!

Place the trays carefully on the door to avoid breaking the glass!

- ▶ Place the tray with the endoscope carefully on the door.
- ▶ Perform a visual inspection.

  The following requirements must be met:

- The load must not have changed, i.e. all adapters of the adapter set are still connected to the endoscope.
- No contamination, e.g. caking or deposits, must be visible on any parts of the endoscope.
- Ensure that all rotary nozzles can be rotated freely.

If the endoscopes will next be dried in the MMM EDScab 8H drying cabinet, the adapters can remain on the endoscope!

▶ Detach the adapters from the endoscope if no MMM EDScab H8 drying cabinet will next be used.

Releasing the cycle

Note!

Cycle release requires:

- successful check of the cycle protocol
- successful visual inspection

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 released, the user must ensure that the cycle protocol 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 protocol has not been added to the electronic archive, either the corresponding printout must be retained or the cycle in question discarded.

- Remove the endoscope.
- Close the chamber door.

Note!

Observe the DGKH recommendation

Periodic hygienic microbiological checks of flexible endoscopes after their reprocessing must be performed.

This applies to Germany; observe national regulations!

4.7 Activating rack redelivery

The rack redelivery function provides an easy way of feeding back trays, endoscopes and accessories from the unloading side to the loading side. The chamber lighting flashes white.

Before pressing the “Return hatch” button, check whether the chamber is empty.

Activating rack redelivery

- Log in to the machine.
- Press the button on the unloading side.
- Open the door on the unloading side.
- Using both hands, lay the endoscope(s) and accessories in the tray then place the tray in the chamber on the wire mesh level.
- Close the door.
- Open the door on the loading side.
- Take the tray, endoscope(s) and accessories out of the chamber.

4.8 Handling chemicals

Risk of injury!

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

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

4.8.1 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.

Note!

The operator must take 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 (option)
Blue	Dosing line 3

Risk of process chemical interchange!

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

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

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

4.8.2 Changing the process chemical brand or type

Note!

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

If there is a change in the types of chemicals used compared with commissioning (see Chapter 2.6.2, "Process chemicals"), the program must undergo qualification again. The operator must inform the following people:

- The manufacturer of the washer-disinfector system
- The supplier of the chemicals
- The manufacturer of the load

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.



Risk of injury!

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 load or machine parts, impaired effect, and so on.

4.8.3 Exchanging the canister



Note!

No program must be started on the machine!



Canister exchange must only be performed by a trained person!



Risk of injury!

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

- Click on the display on the symbol with the orange canister.

  You are taken to the Operating materials - Dosing line menu. This menu indicates which process chemicals were used. You **must** also vent the dosing hoses afterwards. The warning is automatically hidden only after the dosing hoses have been vented.

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.

Exchange canister

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

The suction lances and canisters are marked with an optical code, which can be a barcode, QR code, or data matrix.

- Scan the code on the suction lance using the hand-held scanner.
- Now scan the code (e.g., barcode with at least 14 digits) or QR code (with UDI marking) on the full canister with the corresponding process chemicals.

The system automatically determines whether it is the correct canister. In addition, the batch number and expiration date of the canisters can be automatically adopted. This does not work for all canisters.

Note!

If it is an incorrect canister, a message is shown on the display.

- Check the process chemical information in the menu and, if necessary, add any data that was not automatically imported, such as the expiration date.



Risk of process chemical interchange!

Cleaning process and/or disinfection process is ineffective!

Check whether the new canister contains the same process chemicals!

Check batch number and expiration date.

When the expiration date of the process chemicals has passed, a warning message appears on the display.



If the barcode cannot be automatically read, e.g. for technical reasons:

- Note the details of the process chemicals: Canister batch number and expiration date. You need to enter the details in the menu after replacing the canister. The cycle protocol indicates that the data was entered manually.

- Open the full canister.
- Take the suction lance from the empty canister and insert it into the full canister.



Note!

Deviations in the dosage due to contamination

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

- Place the full canister into the pull-out canister compartment.
- Carefully push in the pull-out canister compartment until it is closed and lock it.



Note!

Air in the dosing hoses!

Vent the dosing hoses.

Please note the chapter on dosing hose venting.

If you exit the Operating materials menu before venting the dosing hose, the process chemical data will not be saved.

- Vent the dosing hoses see "Deaeration of dosing hoses", Page 143.

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

4.8.4 Changing the canister with RFID monitoring



This option is not available for all chemical manufacturers.

With the chemical canister monitoring option, the following properties are read, checked, or monitored:

When using process chemicals, the process chemical used is monitored via RFID detection.

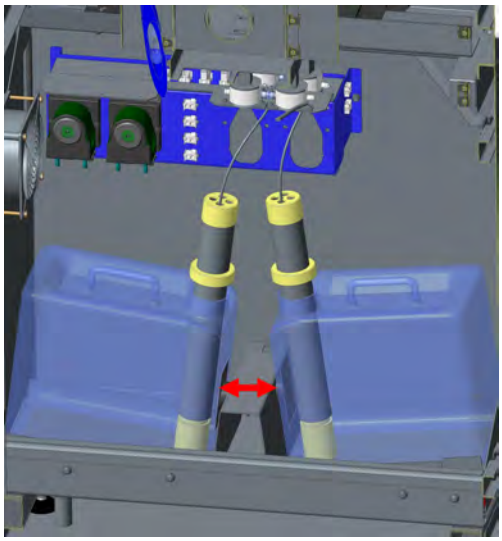
The following characteristic is checked or monitored:

- chemical approved for the process
- the expiry date (incl. monitoring)
- the lot number
- position detection (RFID) of a canister (incl. monitoring)

The canisters have an RFID identification.

The canisters must stand in the pull-out canister compartment as shown in the image.

The RFID identifications must face each other, see arrow.



Note!

No program must be started on the machine!

Canister exchange must only be performed by a trained person!

Risk of injury!

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

- Click on the display on the symbol with the orange canister.

  You are taken to the Operating materials - Dosing line menu. This menu indicates which process chemicals were used. You then must also vent the dosing hoses afterwards. The warning is automatically hidden only after the dosing hoses have been vented.

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.

Exchange canister

- Remove the empty canister with the suction lance and place the canister next to the pull-out canister compartment.

- Place the full canister next to the empty canister.



Risk of process chemical interchange!

Cleaning process is ineffective!

Check whether the new canister contains the same process chemicals!

Check batch number and expiration date.

When the expiration date of the process chemicals has passed, a warning message appears on the display.

- Open the full canister.
- Take the suction lance from the empty canister and insert it into the full canister.



Note!

Deviations in the dosage due to contamination

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

- Place the full canister with the suction lance in the pull-out canister compartment, as shown in the image above.
- Press the “Read RFID tag” button.

  The files in the canister are read.



Note!

If it is an incorrect canister, a message is shown on the display.

- Carefully push in the pull-out canister compartment until it is closed and lock it.

Note!

Air in the dosing hoses!

Vent the dosing hoses.

Please note the chapter on dosing hose venting.

If you exit the Operating materials menu before venting the dosing hose, the process chemical data will not be saved.

- Vent the dosing hoses see "Deaeration of dosing hoses", Page 143
- Return the key to the system supervisor.
- Dispose of the empty canisters as specified by the manufacturer.

4.9 End of workday/change of shift

The machine must be cleaned at the end of each shift "Maintenance activities ".

5 Machine configuration

5.1 Creating users and editing or deleting users

Users must be created with a name and password. There are different access levels,



- Log in as ADMIN or MMM.



- Go to the “Settings” menu

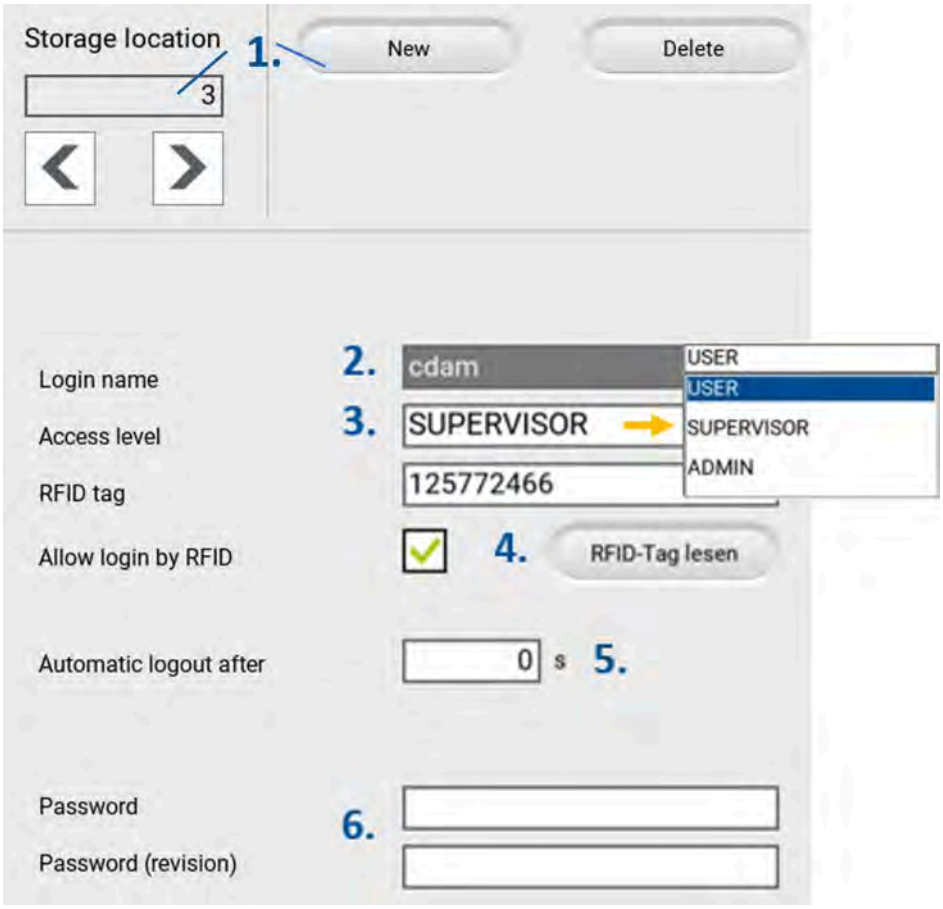


- Select “User access”.



To edit the user details, select the Storage location (1) with the relevant user. Rather than recreating all the details, they can be edited as described below.

- Select “New” (1.) to create a user. A new storage location is created automatically.
- Enter the following data:



2. Login name
3. Select an access level, "Operator permissions".
4. Read the RFID tag of the user card of the new user and allow the RFID log on.
5. Time, in seconds, after which the user should be automatically logged out if the control panel has not been touched.
6. Password and password confirmation for security. The password must contain at least 3 characters.



▶ Save the entry.

You can now create another operator.



The “Delete” button can be used to delete created users.

Operator permissions

It is always necessary to log in. The following operators and authorizations are pre-configured:

Software level	Operator	Function	Authorized to:
1	USER	Approved operators	Personal account with individual login name and individual password - Can start programs - Change process chemicals - Select autostart for self-disinfection program Log on via RFID possible
2	SUPERVISOR	System supervisor	Personal account with individual login name and individual password and additional authorizations - Acknowledge alarms - Replace sterile filter if present in the machine - Create/edit endoscopes - Resend unsent cycle protocols to RUMED - Switch IP address in order to print cycle protocols to a direct printer if the situation requires Log on via RFID possible
3	ADMIN	System supervisor (IT)	Personal account with individual login name and individual password and additional authorizations - Access to network settings - Date/time - User access and display settings Log on via RFID possible

Software level	Operator	Function	Authorized to:
4	MMM	Specialist, MMM Customer Service	Only one account possible, login name “mmm” cannot be changed, monthly password or optional specific password for customer service

The operator is automatically logged out after a certain period (configurable) if the screen is not touched.

5.2 Creating endoscopes and editing or deleting endoscopes

Endoscopes can only be read on the top level (level 1) in the machine.



▶ Log in as the SUPERVISOR.



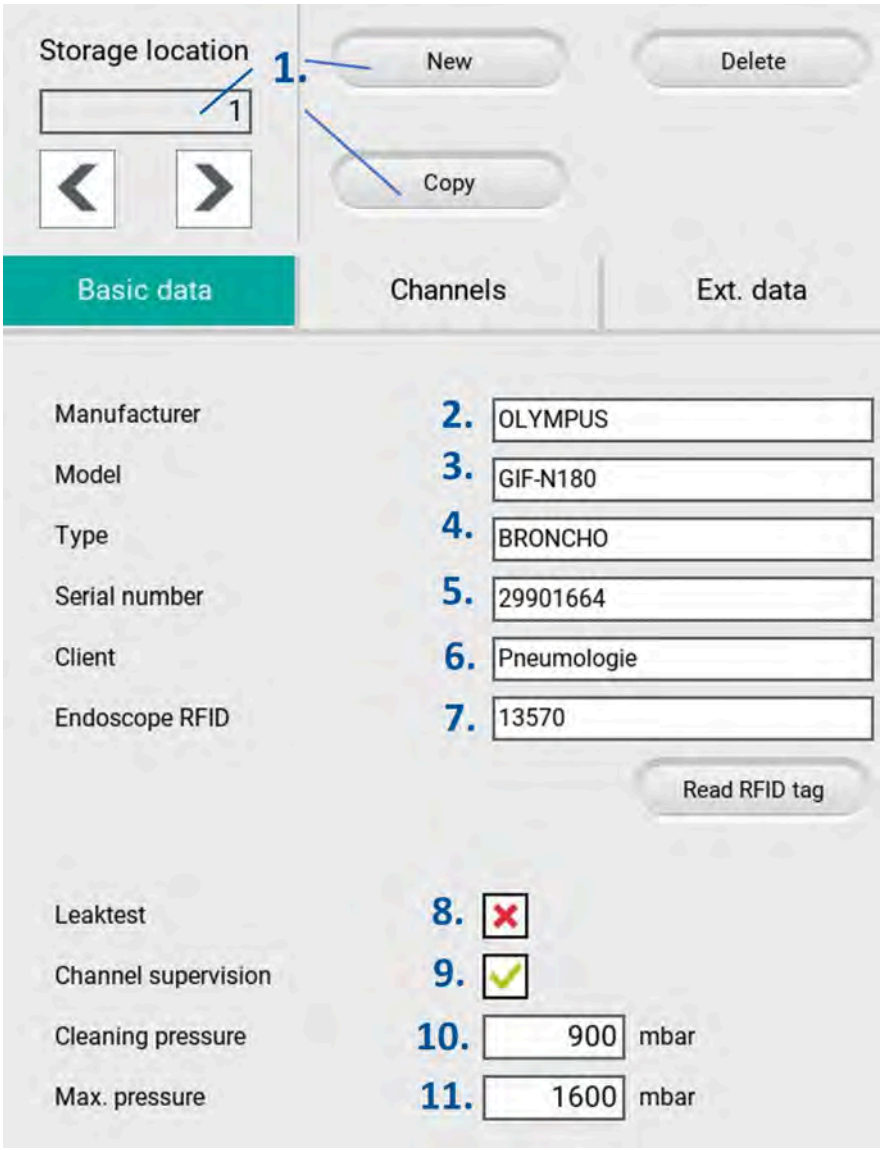
▶ Go to the “Settings” menu.



▶ Select “Endoscopes”.

Creating basic data

- Select “New” (1.) to create an endoscope. A new storage location is created automatically.
- Enter the basic data.



2. Manufacturer – endoscope manufacturer is only displayed in the cycle protocol
3. Model – e.g. GIF-N180, information is only displayed in the cycle protocol
4. Type – e.g. bronchoscope, is displayed for manual endoscope selection
5. Serial number of the endoscope, is displayed for manual endoscope selection and in the cycle protocol
6. Client - e.g. physician name or department, information is only displayed in the cycle protocol
7. Read the RFID tag of the endoscope.
8. Leak test – enable if the endoscope has a leak test channel (displayed in the cycle protocol)
9. Channel monitoring – only if the endoscope has a channel that has to be flushed.
10. Cleaning pressure - setting as per MMM requirements
11. Max. pressure - setting as per manufacturer requirements

- Check the box for the leak test if the endoscope has a leak test connection.
- Check the box for channel monitoring if the endoscope has a channel that has to be rinsed.
- Always enter 1500 mbar for the cleaning pressure and max. pressure values.

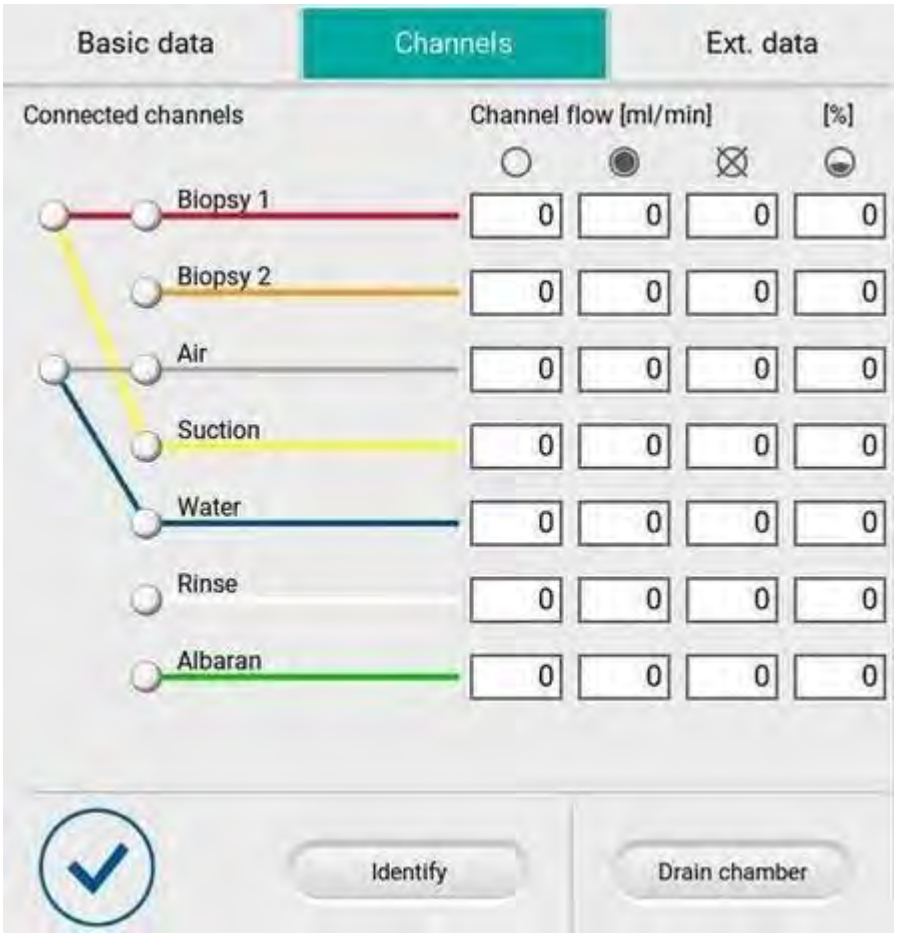
The following values for the cleaning pressure have proven to be optimal:

- Small-caliber endoscopes -> 900 mbar
- Gastroscopes and endoscopes with more than two channels -> 1200 mbar
- Endoscopes with Albarran channel and a channel diameter of less than 1 mm -> 1400 mbar.

The exact values are determined during validation.

- Hold the RFID tag against the RFID marking of the machine.
- Press the “Read RFID tag” button.
- Go to the “Channels” menu.

Channels



1. Connection of two channels, e.g., air and water channel
2. Expected flow rate / measured flow rate – in the channel (target value)
3. Minimum flow – channel blocked (channel clogged)
4. Maximum flow – channel not connected (channel not connected)
5. Partial blockage – expected flow rate minus percentage value equals partial blockage (particles in the channel)

Reading endoscope

When reading the 1st endoscope, the chamber is filled with water. The water remains in the chamber for all other endoscopes. The measurement process then begins, followed by blow-out of the channels.

Determine the maximum values for the flow rate (unconnected channel):

- Select the connected channels (biopsy/extraction or air/water), see the data sheet of the endoscope manufacturer, see 1. in the image above.
- Activate the remaining channels according to the equipment.

- Connect the appropriate adapter set at the top level to determine the maximum flow rate.
- Press the “Read” button and follow the additional instructions.
- Manually transfer the measured values from 2. (read-in data) to 4. (maximum flow rate). The value must be rounded down, e.g., for 799 -> 790, for 85 -> 80
- Disconnect the adapter set.

Endoscope in connected state without connected biopsy channel

Note for endoscopes with biopsy channel

Do not connect the biopsy channel to the endoscope!

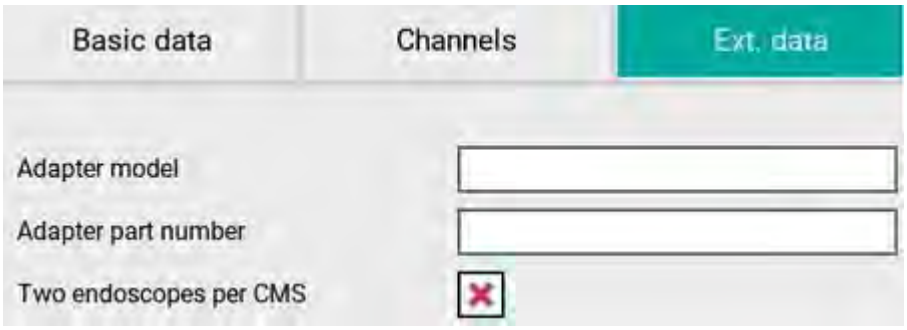
The endoscope with the biopsy channel will be read later.

- Connect the adapter set to the endoscope (without the biopsy channel, if necessary)
- Plug the adapter set connected to the endoscope in at the top level.
- Press the “Read” button and follow the additional instructions.
- Manually transfer the measured values for “biopsy” and “extraction” from 2. (read-in data) to 4. (maximum flow rate). The value must be rounded down, e.g., for 799 -> 790, for 85 -> 80

Endoscope with biopsy channel

- Now also connect the adapter set with the endoscope to the biopsy channel.
- Plug the adapter set connected to the endoscope in at the top level.
- Press the “Read” button and follow the additional instructions.
- Go to the "Extended data” menu.

Entering extended data



- Adapter model -> name of the adapter set e.g. O-12
- Adapter part number -> material number of the adapter set
- Two endoscopes per CMS -> function is not yet implemented. Default setting cannot be changed.

▶ Enter the exact name of the adapter model in the input field provided, e.g., O-12.

▶ Please enter the material number of the adapter set.

The name and material number can be found on the label on the connector of the adapter set.



▶ Save the entry.

You can now create another endoscope.

After the last endoscope has been identified, the chamber needs to be drained.

▶ Press the “Drain chamber” button.

The “Copy” button can be used to create a new storage location. The data are copied and can be edited for a new endoscope.

Check that **ALL** fields correspond to the newly created endoscope.

To edit the endoscope data, select the Storage location (1) for the relevant endoscope. Rather than recreating the endoscope data, they can be edited as described below.

The “Delete” button can be used to delete created endoscopes.

5.3 Setting the time

The supervisor can set the time.

The date can only be set by a qualified person.



- In the menu open Date/time



- Select your timezone.
- Enter the current time.
- The green tick can be used to activate the automatic changeover from daylight saving (summer) to standard time (winter).
- Save the entry.

5.4 Settings for autostart



▶ Log in as the SUPERVISOR.



▶ Go to the “Settings” menu.

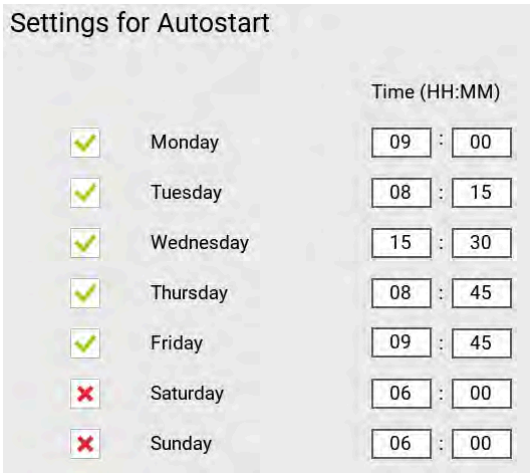


▶ Select “Autostart.”

Setting times



The autostart function is only available for the “Self-disinfection” program.



▶ Check the days of the week for which you want autostart to be activated.

▶ Specify a time at which autostart should begin.

5.5 Display settings



▶ Press Display settings in the Settings menu

The following settings can be configured.

Set language



- Press the **arrow buttons** to change the language.
- Save the setting.

Set brightness

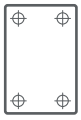


- Press the **arrow buttons** to change the brightness.
- Save the setting.

A screen saver with timeout can also be activated, and whether this should be active during the program run.

Touch calibration

A calibration may be necessary if the operator controls on the color touch display do not respond.

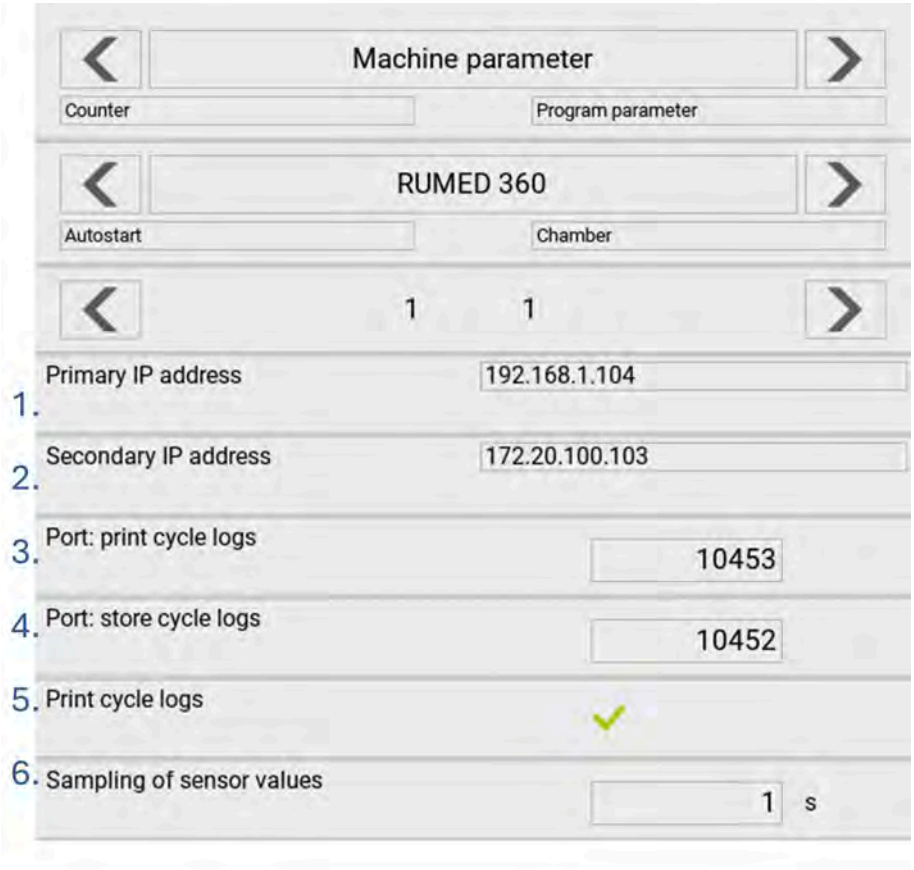


- Click on Touch calibration.

  A crosshair appears on the display.
- Click on each crosshair as it appears.

5.6 Printer settings

- Select “Settings” – “Machine parameter” – “RUMED 360.”



1. Primary IP address: the IP address of the host computer on which the Rumed installation is running.
2. Secondary IP address: alternative IP address as an emergency plan (or for backup/service technicians/paper printouts) to redirect the cycle printout to another host. The alternative IP address can be selected on the machine.
3. Port: print cycle logs -> default values cannot be changed!
4. Port: store cycle logs -> default values cannot be changed!
5. Print cycle logs: additional print command can be activated/deactivated using the green tick, e.g., for printing on paper, etc.
6. Sampling of sensor values for setting the measurement interval -> default value cannot be changed!



- Save the setting.

6 Operating safety and faults

Safety-related equipment

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.

Note!

Observe the instructions in see Chapter 1, "Security"

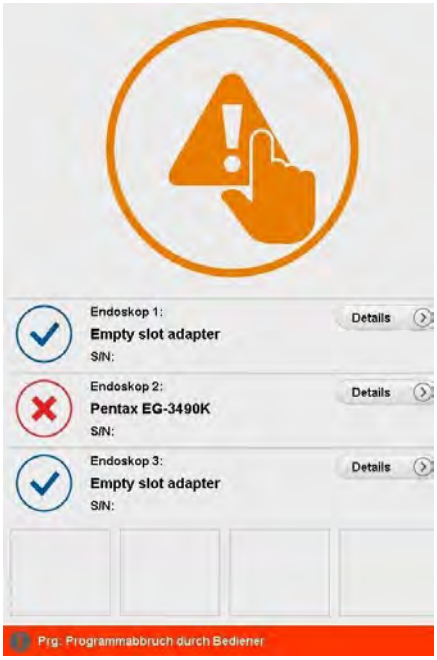
If the cause of the fault cannot be eliminated by an authorized operator, inform MMM customer service or a person or company that has been authorized by MMM.

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

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

6.1 Fault messages

If a fault occurs during operation, the respective fault message is shown on the display and an acoustic signal sounds.



Red faults with automatic program abort

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

Faults without automatic program cancellation

Some faults only show an error message and do not automatically abort the program. The fault must be eliminated, however, once the program run is complete and before a new program can be started.

One example is the message: *DOS1:cleaning agent empty*.

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

6.2 Responding to faults

If a fault occurs, carry out the following steps:

1. Analyze the fault and, if possible, eliminate it.
2. Report the fault to the system supervisor without making any machine modifications.
3. Check the channel system using the diagnostics program.
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



Note!

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.





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.

- Press the button to send the e-mail.



Press the door button to confirm the alarm message.

All alarm messages that are no longer active are confirmed.
Alarms in a yellow circle and with a red exclamation mark are still active, alarms in a gray circle are resolved.

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

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

6.3 Responding to specific faults

6.3.1 Power failure

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

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

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

6.3.2 Network outage

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

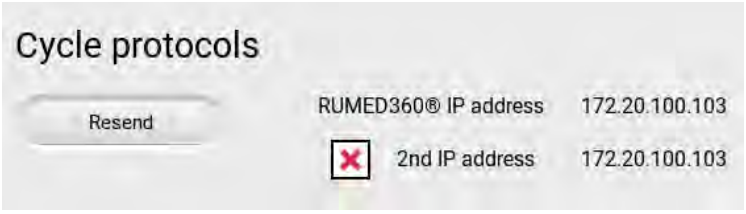
It is possible to switch to an alternative IP address. The alternative IP address was specified in RUMED360 connection under Settings.



- Go to Settings.



- Press the button.



- Set the tick next to IP address 2.

Under cycle reports, cycle reports that have not been sent or printed out are shown (the list is empty in this figure); these can be resent using the “Resend” button and printed out.

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

6.3.3 Temperature limiter active

One of the temperature limiters has tripped and activated alarm 409. The temperature limiter switches (red pin) are located behind the panels, see "Opening and closing the cladding door", Page 143.

- Open the panel
- Push the red pin back in.

⇒ If you hear a click, the temperature limiter has been reactivated.

⇒ If the temperature limiter trips again immediately, look for and eliminate the cause.

- Acknowledge the alarm.

Position of temperature limiters:

F291, F292	Behind the lower panel door on the loading side, to the right of the chamber heating/chamber sump
F294	Behind the technical pull-out compartment on the loading side, in the upper part in front of the boiler
F296	Upper panel door on the loading side: swing the upper control cabinet to the side; the drying module and the switch for the “Active external drying” option (if available) are located to the left of the outgoing air outlet

6.3.4 Emergency opening of the chamber door

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

Note!

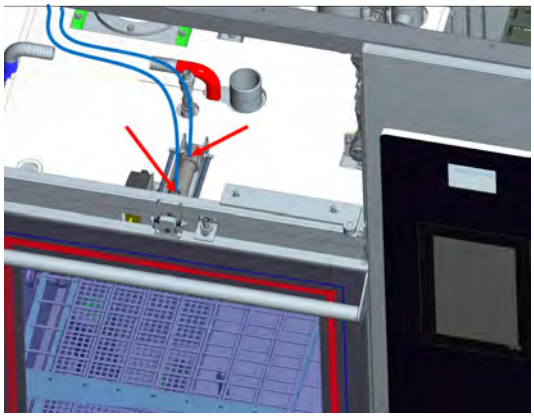
False alarm of the smoke detector!

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.

- Switch off the machine!
- Unlock the pull-out canister compartment see "operators", Page 17.
- Open the pull-out canister compartment.
- Pull out the pull-out canister compartment approx. 30 cm.

- Release the catch and pull out the control panel.
- Open the front panel at the top.
- Release the catch and swivel the control cabinet to the right side.
- Disconnect the compressed air hoses (R75 and R751) from the lift cylinder for the door locking mechanism.





Risk of injury!

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

Wear personal protective equipment see "Personal protective equipment", Page 20!

- Pull the lift cylinder back and open the door.

The loaded items can now be removed.



Risk of injury!

After an emergency opening, the chamber door must be recommissioned by a specialist see "operators", Page 17!

6.3.5 Process chemicals not being supplied directly

- Pull the suction lance out of the empty container.
- Replace the empty chemical container with a full one. see "Exchanging the canister", Page 84
- Insert the suction lance into the new chemical container.



Risk of process chemical interchange!

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 labeled with text and color coded.

6.3.6 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.



Risk of injury!

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

6.3.7 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).

6.3.8 Insufficient water quality

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

Insufficient water quality leads to:

- Formation of spots on the load
- Pronounced foam formation
- Inadequate cleaning and disinfection performance

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

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

6.4 Status and alarm list

Info (green)

No.	Message	Cause	Possible remedy
0	System ready	Ready to start the program. No fault present.	
1	Program started		
2	Program finished		

Warning (yellow)

No.	Message	Cause	Possible remedy
9	Prg: water sample	The “Water sample” option was also selected before starting the program. A hygienic water sample of the final rinse water can be taken.	“Cycle failed” appears in the cycle protocol because it cannot be guaranteed that the endoscope is sterile after taking the water sample on the clean side. The cleaning of the endoscope must be repeated.
10	DOS1: Deviation in dosed quantity	Flow meters B451 and B455 deviate from each other by > 3 %.	Inform building services or customer service hotline - Check non-return valve - Check flow meter
11	DOS2: Deviation in dosed quantity	Flow meters B452 and B456 deviate from each other by > 3 %.	Inform building services or customer service hotline - Check non-return valve - Check flow meter
12	DOS3: Deviation in dosed quantity	Flow meters B453 and B457 deviate from each other by > 3 %.	Inform building services or customer service hotline - Check non-return valve - Check flow meter
404	DOS1: Process chemicals empty	Suction lance of dosing line 1 reports that the container is empty.	- Check dosing hose 1 and vent if necessary Chapter 7.9, "Deaeration of dosing hoses" - Replenish process chemicals - Broken cable in suction lance line

No.	Message	Cause	Possible remedy
405	DOS2: Process chemicals empty	Suction lance of dosing line 2 reports that the container is empty.	▪ Check dosing hose 2 and vent if necessary Chapter 7.9, "Deaeration of dosing hoses" ▪ Replenish process chemicals ▪ Broken cable in suction lance line
406	DOS3: Process chemicals empty	Suction lance of dosing line 3 reports that the container is empty.	▪ Check dosing hose 3 and vent if necessary Chapter 7.9, "Deaeration of dosing hoses" ▪ Replenish process chemicals ▪ Broken cable in suction lance line
408	Drain full	Fill level sensor B891 reports too much water in the drain	▪ Check for signs of leaks and, if necessary, repair ▪ Inform building services or customer service hotline
432	Error at external exhaust system	On-site exhaust air system reports a fault.	▪ Request building services to check for fault/error in the exhaust air system ▪ Eliminate error in on-site exhaust air system
435	Error at external draining system	Draining of machine failed. An external signal is preventing draining.	▪ Signal from the building to the machine reports a fault, e.g. draining system reports that the device cannot be started. ▪ Check on-site drainage line for blockages ▪ Check drainage system for possible blockages ▪ Call building services or customer service hotline
438	Shut off valves closed	The machine cannot be filled.	▪ Request building services to check the process media (compressed air or water) ▪ Inform building services or customer service hotline

No.	Message	Cause	Possible remedy
442	Barcode scanner not connected	No communication between the machine and barcode scanner	▪ Check the USB connection of the barcode scanner ▪ Is the barcode scanner plugged in ▪ Reboot machine
443	DOS1: Expiration date exceeded	The expiration date of the chemical canister for dosing line 1 has passed.	Observe the specifications of the chemical manufacturer.
444	DOS2: Expiration date exceeded	The expiration date of the chemical canister for dosing line 2 has passed.	Observe the specifications of the chemical manufacturer.
445	DOS3: Expiration date exceeded	The expiration date of the chemical canister for dosing line 3 has passed.	Observe the specifications of the chemical manufacturer.
511	Service mode is active	Service mode has been activated	When finished servicing, deactivate service mode again
512	External dosing unit empty	The process chemical storage container for the external dosing unit has not been filled.	▪ Check the central dosing system or fill the external dosing unit ▪ Eliminate fault in central dosing unit
513	Program step skipped	With MMM user authorization, a program step was skipped to check an error.	This function is deactivated again when the MMM user is logged out
514	RFID reader not connected	The RFID reader cannot send a signal to the controller.	▪ Inform building services or customer service hotline When this error is displayed, it is only possible to operate the machine via the manual function (operator/ endoscopes).
515	Connection to Rumed360 failed	The process data could not be transferred to RUMED360	▪ Check that the IP address of the Rumed computer is correct ▪ Check that Rumed is running ▪ Check that the network addresses are correct You can send the cycle protocol to RUMED using *Settings - Cycle protocols - Resend*.

No.	Message	Cause	Possible remedy
516	Water filter disconnected	The machine is in “Empty filter” mode	Inform building services or customer service hotline This error is only displayed while replacing the sterile water filter.
517	Disinfection program required	The machine was not operated during the last 24 hours!	Run the machine disinfection program. A cleaning program can be started. The cycle protocol includes a note that a machine disinfection is required.
518	Deviation between clocks	Deviation between system time and calculated cycle time.	Inform customer service hotline
520	DOS1: no canister	Dosing line 1: RFID does not detect a canister	▪ Place a suitable canister in the pull-out canister compartment ▪ Check whether the RFID code on the canister is facing the RFID reader ▪ Check the RFID reader
521	DOS1: wrong canister	Dosing line 1: RFID detects a canister with incorrect process chemical	Place a canister with the appropriate chemical in the pull-out canister compartment
522	DOS3: no canister	Dosing line 3: RFID does not detect a canister	▪ Place a suitable canister in the pull-out canister compartment ▪ Check whether the RFID code on the canister is facing the RFID reader ▪ Check the RFID reader
523	DOS3: wrong canister	Dosing line 3: RFID detects a canister with incorrect process chemical	Place a canister with the appropriate chemical in the pull-out canister compartment
530	Preventive maint. due soon	Preventive maintenance is due very soon.	Schedule preventive maintenance
531	Preventive maint. due	Preventive maintenance is due. Preventative maintenance was not carried out on time	Perform preventive maintenance
532	Interval maint. due soon	Interval maintenance/inspection is due very soon.	Schedule interval maintenance/inspection

No.	Message	Cause	Possible remedy
533	Interval maint. due	Interval maintenance/inspection is due. Interval maintenance/inspection was not carried out on time	Carry out interval maintenance/inspection
534	Adjustment due soon	Calibration/adjustment is due very soon.	Schedule calibration/adjustment
535	Adjustment due	Calibration/adjustment is overdue. Calibration/adjustment was not carried out on time.	Carry out calibration/adjustment
536	Recertifying due soon	Recertification is due very soon.	Requalification is due.
537	Recertifying due	Requalification is due. Requalification was not carried out on time.	Perform requalification

Alarms (red)

No.	Message	Cause	Possible remedy
	Program run alarms		
1	Emergency stop active	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
3	Prg: Program interruption by operator	The “Stop program” button on the display has been pressed.	Analyze why the button was pressed
4	Prg: Idle temperature too low	Water temperature too low during a washing step.	Electric heating element contactor is defective
5	Prg: Conductivity test failed	Conductivity meter/measuring transducer reporting invalid values Conductivity value in the final rinse too high. Poor water quality. Too much cleaning agent.	▪ Check the contacts on sensor B551 or B552 ▪ Check the contacts on sensor B991 or B992 ▪ Replace with an identical sensor or transducer ▪ Check water quality ▪ Check dosage

No.	Message	Cause	Possible remedy
6	Prg: Pre-rinse temperature above 40 °C	The water temperature in the “Pre-rinse” process step is above 40 °C.	Check the temperature of the cold water to avoid possible protein coagulation due to too high temperature
8	Prg: Saving of cycle protocol failed	Saving of the last cycle protocol failed.	▪ Check company network ▪ Inform building services or customer service hotline
9	Prg: water sample	The “Water sample” option was also selected before starting the program. A hygienic water sample of the final rinse water can be taken.	“Cycle failed” appears in the cycle protocol because it cannot be guaranteed that the endoscope is sterile after taking the water sample on the clean side. The cleaning of the endoscope must be repeated.
10	DOS1: emitted volume out of range	Flow meters B451 and B455 deviate from each other by > 5 %.	Inform building services or customer service hotline ▪ Check non-return valve ▪ Check flow meter
11	DOS2: emitted volume out of range	Flow meters B452 and B456 deviate from each other by > 5 %.	Inform building services or customer service hotline ▪ Check non-return valve ▪ Check flow meter
12	DOS3: emitted volume out of range	Flow meters B453 and B457 deviate from each other by > 5 %.	Inform building services or customer service hotline ▪ Check non-return valve ▪ Check flow meter
13	DOS: Time exceeded while dosing	Dosed target quantity not achieved within a specified time or not at all for all dosing lines	Inform building services or customer service hotline ▪ Flow meter defective ▪ Dosing pump defective ▪ Dosing hose or suction lance between canister and flow meter blocked or defective ▪ Check process chemical canister The affected dosing line can be determined via the audit trail.

No.	Message	Cause	Possible remedy
30	Door: Locking time exceeded	Chamber door on the loading side was not closed Door switches B311 on the loading side are reporting incorrect signals. Door on loading side not reported as completely closed during the program.	▪ Check whether there is an object in the door area on the loading side (chamber door area) ▪ Check position and setting of end switch for closing the door
31	Door: Unlocking time exceeded	Door switch B312 on unloading side is sending incorrect signals.	Check position and setting of end switch for closing the door
32	Door open after locking	Door on loading side not reported as completely closed during the program.	Check door switch and, if necessary, replace with identical door switch
34	Error locking	Door on loading side not reported as completely closed during the program.	Check door switch and, if necessary, replace with identical door switch
40	Chamber: Circulation pressure too low	Pump pressure in circulation phase too low.	▪ Pump pressure in circulation phase too low. ▪ Check the fine filter in the chamber sump for possible blockage.
41	Chamber: Circulation pressure too high	Pump pressure in circulation phase too high.	Inform building services or customer service hotline
42	Chamber: Water level too low	Too little water in the chamber in the prescribed time period	▪ Check the inlet water pressure ▪ Check whether any contamination is present in the prefilter
43	Chamber: Temperature too high	Temperature limiter for the heater has been triggered.	▪ Check water level in chamber, not enough water in system ▪ Only check contactor in machines with electric heating systems
44	Chamber: Time exceeded filling	Water level in 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/ sterile water filter ▪ Check chamber for defects

No.	Message	Cause	Possible remedy
45	Chamber: Time exceeded draining	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 (option) ▪ Check sensor B811
46	Chamber: unexpected inflow	Water level inside the chamber is rising too fast after closing valve.	Check that water intake valves are tight
47	Chamber: Error at bottom temp. sensor	No signal at sensor B253/B254	▪ Check sensor B253/B254 ▪ Inform building services or customer service hotline
48	Chamber: Error at top temp. sensor	No signal at sensor B251/B252	▪ Check sensor B251/B252 ▪ Inform building services or customer service hotline
49	Chamber: Time exceeded: steam admission	Temperature in the chamber / chamber tank is rising too slowly.	Check whether electric heating element is defective
50	Filter: Temperature too high	Temperature of the sterile water filter is too high. After the machine disinfection, the machine was started too early for a new program. Water must not flow through the sterile water filter at high temperatures.	▪ Wait approx. 15 min before you restart the machine ▪ Check sensor B256/B257
51	Filter: Error at temperature sensor	A sensor problem has arisen with the sterile water sensor B256/B257	Check sensor B256/B257
60	Tank: Temperature too high	Temperature limiter for the heater has been triggered (boiler option).	▪ Check water level in tank (option), not enough water in system ▪ Check contactor
61	Tank: Time exceeded filling	Water level in boiler (option) 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	Cause	Possible remedy
62	Tank: Time exceeded draining	Conductivity sensor (B552) in the boiler reports too high conductivity, tank (option) is therefore not displayed as empty.	▪ Check drainage valve on tank (option) for defects ▪ Check conductivity sensor (B552) in boiler ▪ Check conductivity of sterile water
63	Tank: unexpected inflow	Water level in tank (option) is rising too fast after closing valve.	Check that water intake valve is tight
64	Tank: Error at temperature sensor	Temperature probe B256/B257 reporting invalid values.	▪ Check contacts on sensor ▪ Replace with an identical sensor
65	Tank: max. water level exceeded	Water level in boiler (option) is rising too fast after closing valve.	Check that water intake valve is tight
66	Tank: Water level too low	Water level in boiler (option) is rising too slowly.	▪ Check water level in boiler, not enough water in system ▪ Check contactor ▪ Check on-site water supply ▪ Check if water valve is defective ▪ Check if control valve is defective ▪ Check water supply line for blockages
67	Tank: Water loss	Drainage valve Q43 leaky	Check drainage valve K43 on the boiler for defects
68	Tank: Conductivity has increased	Heat exchanger in boiler leaking or change in water quality	Inform building services or customer service hotline ▪ Check heat exchanger ▪ Check water conditioning
69	Tank: Time exceeded: steam admission	Temperature in boiler (option) is rising too slowly.	Check whether electric heating element is defective

No.	Message	Cause	Possible remedy
	Adapter alarms		
100 - 199	**see message 200 to 299**	Alarm 100 to 199 corresponds to alarm 200 to 299	
200	Prg: Cancellation due to error at CMS 2	General error in the CMS 2 system 100 corresponds to CMS 1 300 corresponds to CMS 3 (option)	▪ Check the CMS system x ▪ Call building services or customer service hotline
201 - 207	CMS 2 : Channel test for channel y failed	Partial blockage: specified channel flows were not achieved 101 to 107 corresponds to CMS 1 301 to 307 corresponds to CMS 3 (option)	“y” corresponds to channel 1 to 7 The last digit of the alarm message indicates the channel ▪ Check the individual adapters on the endoscope are seated correctly ▪ Check the O-rings on the individual adapters and 10-fold connector ▪ Check the channel separator (if present) ▪ Check for visible contamination ▪ Clean the endoscope again with a cleaning brush as per manufacturer and internal requirements and then reprocess the endoscope again in the machine ▪ if the error occurs repeatedly -> run the program for diagnosis
210	CMS2: Channel check failed	Specified channel flows were not achieved in any channel. Partial blockage: General error when evaluating endoscopes on the levels. This error occurs immediately after the channel check message. 110 corresponds to CMS 1 310 corresponds to CMS 3 (option)	Note the channel check messages, see above.

No.	Message	Cause	Possible remedy
211 - 217	CMS2: Flow in channel y too low	Blockage: specified channel flow rates were not achieved 111 to 117 corresponds to CMS 1 311 to 317 corresponds to CMS 3 (option)	“y” corresponds to channel 1 to 7 The last digit of the alarm message indicates the channel - Check whether any visible contamination is evident. - Clean the endoscope again with a cleaning brush as per manufacturer and internal requirements and then reprocess the endoscope again in the machine - if the error occurs repeatedly -> run the program for diagnosis
221 - 227	CMS2: Flow in channel y too high	Unconnected channel: specified channel flow rates were not achieved 121 to 127 corresponds to CMS 1 321 to 327 corresponds to CMS 3 (option)	“y” corresponds to channel 1 to 7 The last digit of the alarm message indicates the channel - Check the individual adapters on the endoscope are seated correctly - Check the O-rings on the individual adapters - Check the channel separator (if present) - if the error occurs repeatedly -> run the program for diagnosis
230	CMS2: Leak test failed	Prescribed channel flow was not reached 130 corresponds to adapter 1 330 corresponds to adapter 3 (option)	The connected endoscope is: - not connected properly - not airtight or - the pressure test adapter is not airtight - if the error occurs repeatedly -> run the program for diagnosis

No.	Message	Cause	Possible remedy
231	CMS2: Time exceeded leak test	The target pressure of the leak test was not reached 131 corresponds to adapter 1 331 corresponds to adapter 3 (option)	The connected endoscope is: ▪ not connected properly ▪ not airtight or ▪ the pressure test adapter is not airtight ▪ if the error occurs repeatedly -> run the program for diagnosis
232	CMS2: Leak test max. pressure	The target pressure of the leak test was not reached 132 corresponds to adapter 1 332 corresponds to adapter 3 (option)	The connected endoscope is: ▪ not connected properly ▪ not airtight or ▪ the pressure test adapter is not airtight ▪ if the error occurs repeatedly -> run the program for diagnosis
233	CMS2: hull pressure below min.	The target pressure of the leak test was not reached. 133 corresponds to adapter 1 333 corresponds to adapter 3 (option)	The connected endoscope is: ▪ not connected properly ▪ not airtight or or ▪ the pressure test adapter is not airtight ▪ if the error occurs repeatedly -> run the program for diagnosis
240	CMS2: Invalid configuration	Invalid control parameter 140 corresponds to adapter 1 340 corresponds to adapter 3 (option)	▪ Check endoscope parameters for permissible pressures
241	CMS2: Deviation from target pressure	The prescribed values are not appropriate for this endoscope type 141 corresponds to adapter 1 341 corresponds to adapter 3 (option)	▪ Check connection of endoscope ▪ Check the adapters ▪ if the error occurs repeatedly -> run the program for diagnosis

No.	Message	Cause	Possible remedy
242	CMS2: max. pressure exceeded	The connected endoscope may not be connected properly or an adapter is not airtight 142 corresponds to adapter 1 342 corresponds to adapter 3 (option)	▪ Check the adapter set ▪ Inform building services or customer service hotline ▪ if the error occurs repeatedly -> run the program for diagnosis
250	CMS2: Connection to adapter lost	The maximum prepressure of the connected endoscope was exceeded 150 corresponds to adapter 1 350 corresponds to adapter 3 (option)	▪ Check the 10-fold connector in the machine and, if necessary, detach and reattach the adapter set to the 10-fold connector in the machine ▪ Inform building services or customer service hotline ▪ if the error occurs repeatedly -> run the program for diagnosis
301 to 399	**see alarm message 201 to 299**	Alarm 200 to 299 for **adapter 2** corresponds to alarm 300 to 399 for **adapter 3**	

No.	Message	Cause	Possible remedy
	Sensor alarms		
400	Lack of supply: compressed air	Pressure switch for compressed air B317 reports pressure is too low.	▪ Check on-site compressed air supply ▪ Check that pressure switch is set correctly ▪ Check pressure switch for defects
401	Lack of supply: Cold water	Pressure switch for cold water B313 reports 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
402	Lack of supply: Deminleralized water	Pressure switch for demineralzed water B314 reports 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

No.	Message	Cause	Possible remedy
403	Lack of supply: hot water	Pressure switch for hot water B315 reports 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
404	DOS1: Process chemicals empty	Suction lance of dosing line 1 reports that the container is empty.	▪ Check dosing hose 1 and vent if necessary Chapter 7.9, "Deaeration of dosing hoses" ▪ Replenish process chemicals Chapter 4.8.3, "Exchanging the canister" ▪ Broken cable in suction lance line
405	DOS2: Process chemicals empty	Suction lance of dosing line 2 reports that the container is empty.	▪ Check dosing hose 2 and vent if necessary Chapter 7.9, "Deaeration of dosing hoses" ▪ Replenish process chemicals Chapter 4.8.3, "Exchanging the canister" ▪ Broken cable in suction lance line
406	DOS3: process chemicals empty	Suction lance of dosing line 3 reports that the container is empty.	▪ Check dosing hose 3 and vent if necessary Chapter 7.9, "Deaeration of dosing hoses" ▪ Replenish process chemicals Chapter 4.8.3, "Exchanging the canister" ▪ Broken cable in suction lance line
407	Motor protection active	Motor protection (Q10 to Q16) has been triggered. One of the motors is overloaded: Circulation pump, drainage pump, side channel blower,	Inform building services or customer service hotline
408	Drain full	Fill level sensor reports too much water in the drain	▪ Check for signs of leaks and, if necessary, repair ▪ Inform building services or customer service hotline

No.	Message	Cause	Possible remedy
409	Temperature protection active	One of the temperature limiters has been triggered: F291, F292, F294, F296	▪ Check water level in chamber or tank, not enough water in system ▪ Check contactor ▪ Check fan path, no air movement (active external drying option)
410	Air pressure for blowout too high	Set value for the channel blowout was exceeded	Inform building services or customer service hotline
411	Air pressure for blowout too low	Set value for the channel blowout was not reached	Inform building services or customer service hotline
412	Sensor failure B251	PT100 is reporting invalid values - chamber control	▪ Check contacts on sensor ▪ Replace with an identical sensor
413	Sensor failure B252	PT100 is reporting invalid values - chamber measurement	▪ Check contacts on sensor ▪ Replace with an identical sensor
414	Sensor failure B253	PT100 is reporting invalid values - loading temperature protection control	▪ Check contacts on sensor ▪ Replace with an identical sensor
415	Sensor failure B254	PT100 is reporting invalid values - loading temperature protection measurement	▪ Check contacts on sensor ▪ Replace with an identical sensor
416	Sensor failure B256	PT100 is reporting invalid values - boiler control	▪ Check contacts on sensor ▪ Replace with an identical sensor
417	Sensor failure B257	PT100 is reporting invalid values for the boiler	▪ Check contacts on sensor ▪ Replace with an identical sensor
418	Sensor failure B259	PT100 is reporting invalid values - sterile water filter measurement	▪ Check contacts on sensor ▪ Replace with an identical sensor
419	Sensor failure B351	Invalid values - pump pressure	▪ Check contacts on sensor ▪ Replace with an identical sensor
420	Sensor failure B353	Invalid values - HEPA filter pressure transducer	▪ Check contacts on sensor ▪ Replace with an identical sensor
421	Sensor failure B551	Conductivity sensor reporting invalid values.	▪ Check contacts on sensor ▪ Replace with an identical sensor
422	Sensor failure B552	Conductivity sensor in boiler reporting invalid values.	▪ Check contacts on sensor ▪ Replace with an identical sensor

No.	Message	Cause	Possible remedy
423	Sensor failure B355	Invalid pressure values for leak test level 1	▪ Check contacts on sensor ▪ Replace with an identical sensor
424	Sensor failure B356	Invalid pressure values for leak test level 2	▪ Check contacts on sensor ▪ Replace with an identical sensor
425	Sensor failure B357	Invalid pressure values for leak test level 2	▪ Check contacts on sensor ▪ Replace with an identical sensor
426	Sensor failure B391	Invalid pressure values for cleaning level 1 - control	▪ Check contacts on sensor ▪ Replace with an identical sensor
427	Sensor failure B392	Invalid pressure values for cleaning level 2 - control	▪ Check contacts on sensor ▪ Replace with an identical sensor
428	Sensor failure B393	Invalid pressure values for cleaning level 3 - control	▪ Check contacts on sensor ▪ Replace with an identical sensor
429	Sensor failure B394	Invalid pressure values for cleaning level 3 - measurement	▪ Check contacts on sensor ▪ Replace with an identical sensor
430	Sensor failure B395	Invalid pressure values for cleaning level 3 - measurement	▪ Check contacts on sensor ▪ Replace with an identical sensor
431	Sensor failure B396	Invalid pressure values for cleaning level 3 - measurement	▪ Check contacts on sensor ▪ Replace with an identical sensor
432	Error at external exhaust system	On-site exhaust air system reports a fault.	Inform building services or customer service hotline
433	Air filter blocked	HEPA air filter A slight vacuum is generated during drying when the fan is activated. HEPA filter is clogged.	▪ Change HEPA filter. ▪ Call building services or customer service hotline
434	Detergent temperature too high	Temperature supervision in the detergent compartment (option) is too high	▪ Check fans in the pull-out chemicals compartment ▪ Call building services or customer service hotline

No.	Message	Cause	Possible remedy
435	Error at external draining system	Draining of machine failed. An external signal is preventing draining.	▪ Signal from the building to the machine reports a fault, e.g. draining system reports that the device cannot be started. ▪ Check on-site drainage line for blockages ▪ Check drainage system for possible blockages ▪ Call building services or customer service hotline
437	Sys: Reboot required	Manual changing of IOs and parameters	Restart the system to apply the changes
438	Shut off valves closed	The machine cannot be filled (during process)	▪ Request building services to check the process media (compressed air or water) ▪ Inform building services or customer service hotline
440	Sensor calibration invalid	Deviation during sensor calibration > 10 %	▪ Service technician must check the sensor calibration. Additional information is available in the audit trail.
441	SCAN: Wrong type of chemicals	The type of chemical in the scanned canister is not the expected type (stored in the parameters).	▪ Check whether the hose or suction lance (option) is in the correct process chemical container
500	Sys: Loading of configuration failed	An error occurred while starting the machine. The machine cannot load the configuration data. Data access to the internal memory has failed.	Call customer service hotline
501	Sys: Saving of configuration failed	An error occurred while starting the machine. The machine cannot load the configuration data. Data access to the internal memory has failed.	Call customer service hotline
502	Sys: Changing of configuration failed	An error occurred while starting the machine. The machine cannot load the configuration data. Data access to the internal memory has failed.	Call customer service hotline
503	Sys: Applying of configuration failed	An error occurred while starting the machine. The machine cannot load the configuration data. Data access to the internal memory has failed.	Call customer service hotline

No.	Message	Cause	Possible remedy
504	Sys: Initialization failed	An unrecoverable error occurred while starting the machine.	Call customer service hotline
505	Sys: Time exceeded while starting	An unrecoverable error occurred while starting the machine.	Call customer service hotline
506	Sys: invalid configuration	An unrecoverable error occurred while starting the machine.	Call customer service hotline
507	Prg: inconsistent parameters	Parameters do not match or are inconsistent	▪ Please enter correct values in the system ▪ Call customer service hotline

6.5 Tips for dealing with inadequate cleaning results

Practical tips

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

- Have any necessary pre-cleaning procedures been carried out correctly?
- Has pre-cleaning been performed in accordance with the treatment instructions provided by the endoscope manufacturer?
- Has the relevant adapter been used in accordance with its intended use?
- Has the adapter in the chamber and at the connections to the endoscope been connected correctly?
- Are all the tubes securely connected without any kinks?
- Have all the filters been cleaned?
- Has the appropriate cleaning program been selected?
- Are the rotating nozzles able to move freely?

- Are the rotating nozzles free from contamination?
- Have all process-related steps according to the validation see "Validation", Page 13 and the reprocessing instructions of the instrument manufacturer been adhered to?



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

The cleaning performance can only be ensured if the correct adapter is used for the endoscope to be cleaned and the adapter is connected 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.

7 Maintenance

Note!

Observe the safety instructions in Chapter 1!

An inspection and safety maintenance (interval-based maintenance & inspection) must be performed at least once a year or after 1000 cycles.

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 1000 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

Note!

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

7.2 Planning service work

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

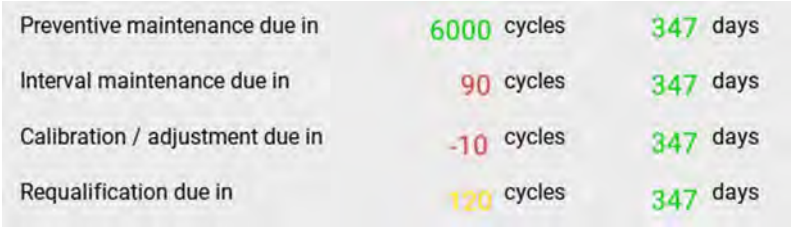
The following service work messages are displayed:

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

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

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

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



Indication of when service work is due



- Open the Menu overview.



- Open Information.

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 Maintenance activities

Note!

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

Daily:

For Germany observe the "Guideline of the DGKH, DGSV and AKI for the validation of automated cleaning and disinfection processes for reprocessing thermolabile endoscopes“, Checklist 9 “Daily routine checks” [Edition 19. Series 3/2011].

What	How	Remark
Check medical compressed air	Operator must ensure a permanent supply of medical grade compressed air. If there are signs of insufficient compressed air quality, proceed as follows: ▶ Have the medical grade compressed air tested. ▶ Clean the machine.	

What	How	Remark
Drain the tank	1. There must be no load left inside the chamber. 2. Shutdown the machine using the on/off button.	To be performed at the end of each workday or at each shift change.
Emptying and cleaning the chamber: Periodic maintenance can significantly extend the service life of the interior chamber walls if certain precautions are taken. The surfaces must always be metallic and shiny. If the walls are covered in a gray or slightly spotty layer after extended use, this must be removed. An empty cycle must now be run. Rust formation (surface rust, extraneous rust) can destroy the chamber. Spots of this nature must be treated immediately.	 **Risk of injury!** Wear protective gloves! 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 7.6, "Cleaning the dirt filter" 4. Install the cleaned filters and the cleaned tray.	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.
Check the rotary nozzles	▪ Visually inspect the rotary nozzles for contamination -> clean if dirty! ▪ Check the function of the rotary nozzles by manually rotating the rotary nozzles -> replace if defective!	
Visually inspect and clean the door seal	The door seal is sensitive as it is subjected to stress during the cleaning/disinfecting process. Defective seals disrupt proper program operation. 1. Visually inspect the door seals – on the loading and unloading sides – with the chamber door open. 2. Remove any foreign objects from the seals! 3. If the seals are slightly dirty, wipe with a lint-free cloth. 4. Visually inspect the visible side of the seal for damage.	Report damage to the system supervisor.

What	How	Remark
Check the content of the process chemical canisters	1. Open the maintenance hatch on the loading side. 2. Open the pull-out canister compartment on the loading side. 3. 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.  **Risk of process chemical interchange!** Mixing up process chemicals may render the cleaning and disinfection process ineffective and may leave residue on the medical devices. Therefore, the warnings and safety instructions of the process chemical manufacturer must be observed. Suitable measures must be in place to ensure that process chemicals are not mixed up. 2. Close the pull-out canister compartment. 3. Close the maintenance hatch.	The machine uses flow meters to supervise whether the process chemicals are available in sufficient quantities. For early detection of depleted process chemicals, suction lances (option) can be used to supervise the fill level.

As required:

What	How	Remark
Last program end was 24 hours ago and note regarding machine disinfection in the cycle protocol	Run machine disinfection	

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! Control panel ■ Disinfect and clean the control panel using a suitable cleaning agent or commercially available surface disinfectant. Follow the manufacturer's instructions!  **Note!** Chemical detergents must not be used on the glass surfaces.  **Risk of injury!** The machine must always be switched off for cleaning.	The control elements may only be cleaned after selecting the screen cleaning function see "Function buttons", Page 52. 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.



Note!

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

Daily:

What	How	Remark
Check demineralized water quality Conductivity measurement	The water sample for entrainment is taken at the end of the last rinse operation in the chamber. ▶ Before starting the program, select the “Water sample” button and follow the instructions. ▶ Have the water quality tested. ▶ Clean the machine See also "Taking a water sample"	Requirements for water quality can be found in DIN EN ISO 15883-1 and in country-specific guidelines, see "", Page 14 and in the technical data sheet or the installation preparation diagram (IPD).

Weekly:

What	How	Remark
Check water quality, total hardness	**Sterile water**: The water sample for microbiological quality is taken at the start of the last rinse operation in the chamber. ▶ Before starting the program, select the “Water sample” button and follow the instructions. ▶ Have the water quality tested. ▶ Clean the machine See also "Taking a water sample" In general, the following water types must be tested: – **Cold water** (usually not directly from the drinking water supply but from an upstream softening system) – **Hot water** (optional)	Requirements for water quality can be found in DIN EN ISO 15883-1 and in country-specific guidelines, see "", Page 14 and in the technical data sheet or the installation preparation diagram (IPD).
Check the dirt traps.	Open, check and, if necessary, clean the dirt traps in the water supply lines.	

Quarterly:

What	How	Remark
Inspect and clean the door seals.	The door seals are sensitive as they are subjected to stress during the cleaning/disinfecting process. Defective seals disrupt proper program operation. 1. Visually inspect the door seals – on the loading or unloading sides – with the chamber door open. 2. If there are any foreign objects on the seals -> remove them! 3. If the seals are slightly dirty, wipe with a lint-free cloth. 4. Visually inspect the visible side of the seal for damage.  **Damage to the door seal!** 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.
Clean the assemblies compartment	Clean assemblies 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.  **Note!** Any leaks in the system, e.g. due to aged door seals etc., must be eliminated immediately!	
Check the jets for blockages.	Visually inspect all rotary nozzles inside the chamber to make sure the nozzle openings are clear of obstructions. If not: remove the release pin on the nozzle and remove the foreign object. Remount the nozzle and secure the release pin again. Do not apply any sealing compound.	

Annually:

What	How	Remark
Replacing the dosing pump hoses (silicon connection tube)	The dosing pump hoses need be changed now or after 1000 cycles by a suitably trained person. Only materials specified by the manufacturer may be used.	
Check water quality Chemical analysis	The water sample is taken from the chamber. ▶ Before starting the program, select the “Microbiological water sample” button. Water can be taken from the chamber at the end of the program. In particular the total hardness, salt content (evaporation residue), chloride content, pH value, and electrical conductivity should be determined (microbiological sample of sterile water). In general, the following water types must be tested: – Cold water (usually not directly from the drinking water supply but from an upstream softening system) – Hot water (optional) – Demineralized water Microbiological properties are described in DIN EN ISO 15883 in Part 4, Section 6.3, and in Annex E the tests for the properties of the water for the final rinse. Accordingly, the water must be free of Legionella, Pseudomonas aeruginosa and mycobacteria and the colony count less than 10 CFU per 100 ml of rinse water sample. It is recommended to perform the tests of the properties of the sterile water during the validation and then at least annually.	Requirements for water quality can be found in DIN EN ISO 15883-1 and in country-specific guidelines, see "", Page 14.
Clean boiler (option)	Clean the boiler using suitable cleaning utensils. ▶ For this, the covers must be removed and reattached once cleaning is complete. ▶ Manual check of the conductivity by the operator or automatically by an optional conductivity measurement system	

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.	
Replace the transfer hoses	The transfer hoses must be replaced regularly by a suitably trained person or they will become worn. Only materials specified by the manufacturer may be used.	

7.5 Maintain the endoscope adapter/10-fold connector

Note!

Leaks in the endoscope adapters!

This can result in incorrect measurements!

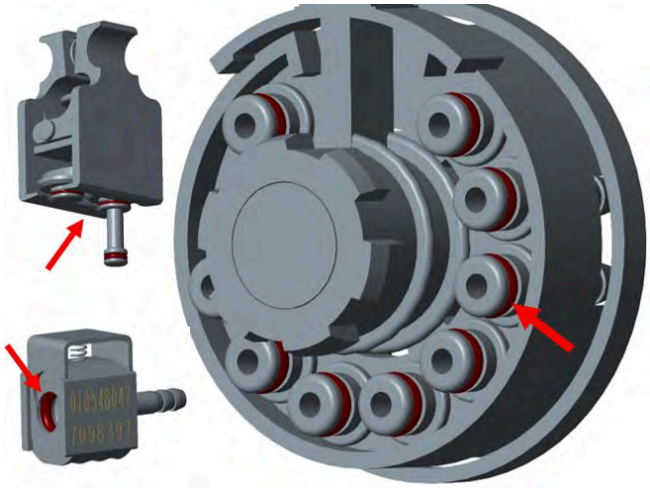
Maintain the O-rings. Dry O-rings will wear significantly faster!

- Check the endoscope adapter and the 10-fold connector for damage before each use.
- Replace damaged or worn O-rings.
  O-rings must only be replaced by a specialist.
- Wet the O-rings with a care product as required (at least 1 x weekly).

  MMM recommends the care product (No. 10631255).

Note!

Do not use silicone sprays; these contain additives that can damage the endoscope adapter!



Example illustration

7.6 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** tray and **no** endo level in the chamber!

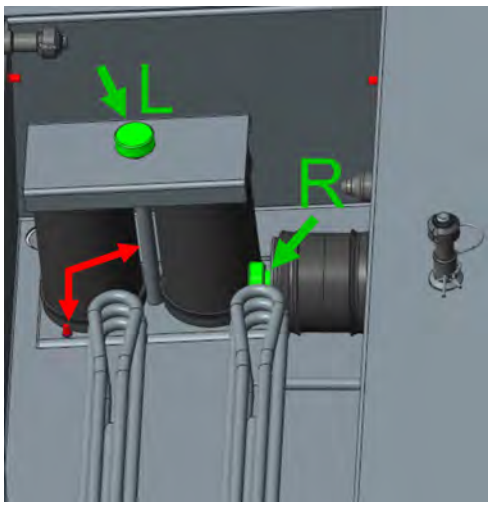
The dirt filter is located at the bottom of the chamber.

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



Example

- Undo the screw L (green).
- Remove the cover.
- Remove both filters.
- Undo the screw R (green).
- Remove the filter.
- Clean the filter with a soft brush and water or using compressed air.



- Reinsert filter R and tighten the screws to secure filter R again.
- Reinsert both filter L.

  The pins (4 pcs) and the central bar are used to center the two filters (red arrow).
- Place the cover on both filters and tighten the screws to secure the two filters again.

Note!

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

- Reinsert the dirt filter, ensuring a snug fit.

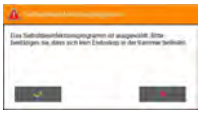
Note!

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

7.7 Machine disinfection

Self-disinfection can only be started if all 10-pin connectors in the device are sealed off with self-disinfection connectors (material no. 010611984). During the program run, the temperature protection is set to a suitably high value. For machines with a sterile water filter, the chamber and the filter are disinfected at the same time. For machines with a boiler, the tank is first disinfected. The chamber and the re-cooling unit are then disinfected with the pre-heated water.

- Plug the self-disinfection connectors into the 10-fold connectors in the machine.



- Confirm that there are no endoscopes inside the chamber.



- Start the self-disinfection program.



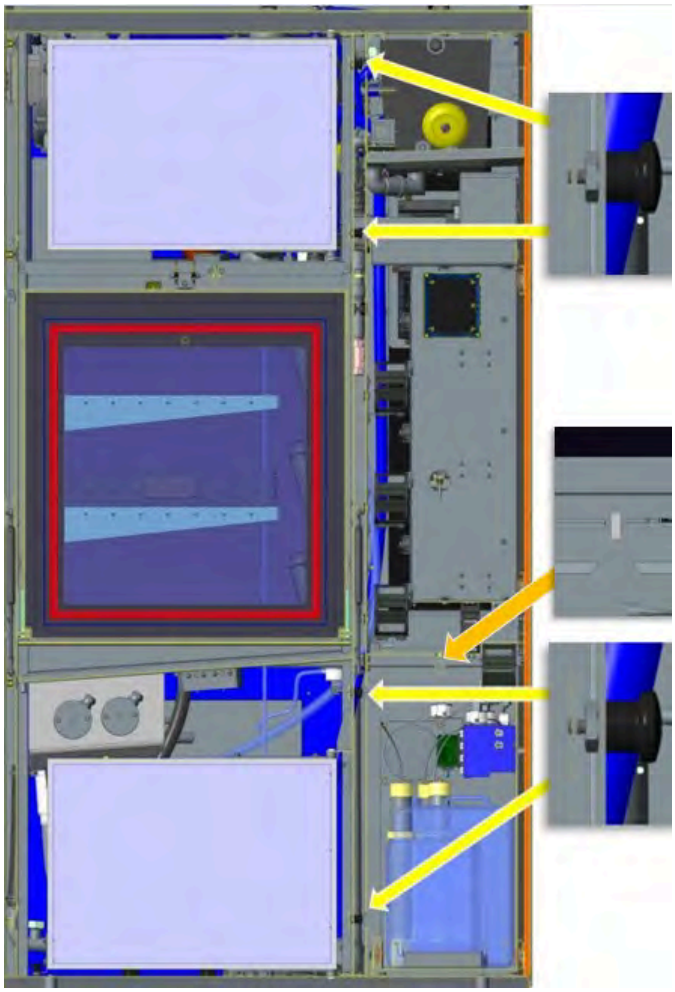
Machine disinfection is running. After the machine disinfection program, only the loading door can be opened.

7.8 Opening and closing the cladding door

- Unlock the pull-out canister compartment with the key and pull it out.
- Unlock the panel cover by rotating the closure mechanism (see center image, orange-colored arrow) and pull it out.
- Open the cladding doors (top and bottom) by pulling and rotating the pins at the side of the door (see image, yellow arrows).

⇒ The cladding doors can now be pivoted to the side.

- Repeat the procedure in reverse order to close the cladding.



7.9 Deaeration of dosing hoses

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

Risk of injury!

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

Note!

You must be trained and have the access right for changing the process chemicals and venting the dosing hoses, i.e. there must be a green tick next to “Use ISA.”

- Log in.

If the Canister button automatically takes you to the Operating materials menu, you can skip the first few steps and continue from the “Place a container (e.g. chemical collection tray UPLE 3, a kidney dish) in the chamber” step.



- Open the Menu overview.



- Click on Operating materials.



- Click on Detergent.
- Place a container (e.g. chemical collection tray UPLE 3, a kidney dish) in the chamber.
- Position the container under the relevant dosing outlet.

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



- Select the relevant dosing line.



- **Keep pressing the button** until **the detergent flows** out of the corresponding dosing outlet.

  The dosing line 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!



Risk of acid burns!

Uncontrolled chemical reaction!

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

- Start a short program with endoscopes.
  Seal off the connections with 10-fold blind connectors.

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MMM Münchener Medizin Mechanik GmbH

10 List of compatible endoscopes

The fundamental suitability for cleaning and disinfection with the Uniclean PLE washer-disinfector has been verified for the majority of endoscopes.

To check the fundamental suitability for your endoscope, please contact customer service. Please observe the local authority or national regulations with regard to validation see "Validation", Page 13.

The Customer Service department will prepare for you a list of compatible endoscopes incl. suitable adapter sets.

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.

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