Instructions for use

MMM Group



Low temperature steam formaldehyde sterilizer

Formomat PL

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CE 0123

MMM. Protecting human health.

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General information

Legend of symbols and hazard warnings

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

- ▶ Handling instruction
- List



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

SOP	Standard Operating Procedure	Standard operating procedure
FO	Formaldehyde	Sterilization agent
LTSF sterilizer	Low temperature steam formaldehyde sterilizer	
PLC	Programmable logic controller	

Warning signs on the machine

The following warning signs may be present on the machine:



Warning dangerous electrical voltage! Open only by trained personnel.



Warning hot surface! Wear protective gloves.



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



Protective ground



Wear safety goggles!



Wear protective gloves!

1.1 Model designation Formomat PL

The specification of this low temperature steam formaldehyde sterilizer is indicated by the following device labeling:

This can be explained by way of an example: Formomat PL 349-1

Machine name	Rated chamber size	Number of doors
Formomat PL	3 4 9	1
	The chamber size (3 x 4 x 9) specification is based on the dimensions of the chamber in dm.	1-door 2-door

Chamber specifications:

Chamber size	Volume in liters	Internal chamber clearance in mm (H x W x D)
349	110	320 x 380 x 900

1 Safety

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



Observe the safety instructions.

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

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

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

This user manual contains information on the proper use 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 **Formomat PL** low temperature sterilizer is suitable for sterilizing medical equipment items at low temperatures.

This machine is intended for use in the medical field (for example in Reprocessing Units for Medical Devices, medical clinics, etc.).

Intended use

The **Formomat PL** low temperature sterilizer is suitable for sterilizing the following reusable equipment items at low temperatures (55 °C, 60 °C and 75 °C):

- Trays and hoses
  - Hoses
  - Sterile PVC containers
  - Instrument containers
- Rigid endoscopes and accessories
  - Laryngoscopes
  - Arthroscopes
  - Laparoscopes
- Flexible endoscopes and accessories
  - Bronchoscopes
  - Hysteroscopes
  - Cystoscopes
  - Ureteroscopes
  - Fibroscopes
  - Optics
  - Fiber optics

When selecting the equipment for sterilization, take into account the material compatibility for sterilization with formaldehyde.



Follow the preparation instructions of the manufacturer of the equipment to be treated.

Limitations of use



The sterilizer is not suitable for treating:

- Highly formaldehyde-absorbing load (e.g. linen made from cotton)
- Liquids in open or sealed bottles and containers
- Flammable and explosive items (e.g. products which create explosive or flammable compounds under the process conditions)
- Disposable medical products

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

This machine is a medical device in accordance with EU Regulation 2017/745 on Medical Devices.

Specific legal regulations apply in Germany to the operation of low temperature sterilizers, for example the Hazardous Substances Ordinance (GefStoffV), which implements the European directives in national legislation.

A low temperature sterilizer can be operated in Germany with less stringent restrictions provided the following special technical requirements are met.

The prerequisites for less restrictive operation are, amongst other things, given in Annex 5 of TRGS 513 (Technical Rules for Hazardous Substances):

- The chamber has a volume < 1 m^3
- The process- and material-specific criterion according to TRGS 513 is met when using our recommended FO solution in shatterproof bottles.

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 inspection and maintenance plan is available
- The system supervisors and users have been trained
- The operating permit has been issued (if required by national regulations)
- The standard operating procedure is available
- A validation has been performed (if required by national regulations) (see Chapter 1.2.3.1, "Process validation")

Network security

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

Interface validation with cycle protocols from outside companies

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

If the machine is being operated in Germany

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

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

1.2.1 Commissioning - equipment requirements

The low temperature sterilizer must be connected to the supply lines (e.g. drinking water network) according to the manufacturer's planning drawing and the dimension drawing, the instrumentation diagram, piping diagram and the local regulations.



Observe the national legal regulations on drinking water protection (e.g. DIN 1988, DIN EN 1717 and TRWI).

1.2.1.1 Connection to the electrical power supply



Note!

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

Observe DIN EN 61010-1, Section 6.10.2, when connecting the machine to the electrical power supply. In particular, it must be ensured that:

- the cable gland is used as strain relief
- the protective conductor is the longest of all individual lines in the connection cable



Danger due to electric current!

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

1.2.1.2 Media

Distilled water

The water must be of distilled water grade.

Formaldehyde sterilization solution

A standard Formaldehyde 2% aqueous solution that is purchased locally is sufficient.

A commercial 2% standard aqueous solution of formaldehyde is adequate.

In Germany, the water and the formaldehyde solution can be purchased from our partner company.

National regulations must be observed. If you have any questions, please contact MMM customer service.

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1.2.2 Installation and operation of the machine

Observe all relevant national regulations when installing and operating the machine.

The machine is intended to be operated in closed rooms in the medical field (e.g., a central sterile goods supply department).

The following is applicable for machines installed and operated in Germany:

- BetrSichV German Ordinance on Industrial Safety and Health
- TRBS Technical rules for operating safety
- MPBetreibV - German Medical Device Operator Ordinance
- DIN 58948, Part 17 - Sterilization - Low temperature sterilizers: Requirements for installation and operation of low temperature steam formaldehyde sterilizers
- DIN EN ISO 25424 Sterilization of medical devices - Low temperature steam and formaldehyde: Requirements for the development, validation and routine control of a sterilization process for medical devices
- DIN EN ISO 11138 - Part 5 Sterilization of health care products - Biological indicators: Biological indicators for steam and formaldehyde sterilization processes
- ProdSG German Product Safety Act
- 14. ProdSV Fourteenth ordinance pertaining to the German Product Safety Act
- Accident prevention regulation DGUV Regulation 1
- GefStoffV - Hazardous Substances Ordinance
- BImSchG - Federal Emissions Control Act
- TA-Luft -Technical Instructions on Air Quality Control
- TRGS 513 - Technical Rules for Hazardous Substances
- BGV - BG rules and regulations

Specific legal regulations apply in Germany to the operation of low temperature sterilizers, for example the Hazardous Substances Ordinance (GefStoffV), which implements the European directives in national legislation.

A low temperature sterilizer can be operated in Germany with less stringent requirements provided the following special technical requirements are met.

The prerequisites for operation with less stringent requirements are, amongst other things, given in Annex 5 of TRGS 513 (Technical Rules for Hazardous Substances):

- The chamber has a volume < 1 m^3
- The process- and material-specific criterion according to TRGS 513 is met when using our recommended formaldehyde solution in shatterproof bottles.

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.



Note!

According to Sect. 20 of the GefStoffV and the TRGS 555, the gas supply manager must produce company-specific operating instructions for all gas sterilization equipment.

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).

Noise emission

The average A-weighted emission sound pressure level of the machine during operation measured pursuant to DIN EN 3746 is less than 70 dB(A).

The operator must take the noise emission of the system into account when performing a risk assessment.

Formaldehyde concentration

The TRGS 900 (version: as published on May 12, 2020) specifies an occupational exposure limit value for formaldehyde of 0.3 ppm, which corresponds to 0.37 mg/m³. The maximum short-term exceedance factor is 2.

The pregnancy group is specified as Y (“Y” indicates materials where there is no risk of teratogenic effects if the MAK value is adhered to).

National regulations may exist regarding the maximum workplace concentration for formaldehyde.

Training the users

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

The users must be trained for this task by a specialist (see Chapter 1.3, "operators" e.g. MMM customer service) and must be familiar with the user manual by the time the machine is handed over.

The names of all authorized operators of the machine as well as the system supervisor (see Chapter 1.3, "operators") must be recorded in the compulsorily maintained medical products / equipment log. If personnel changes are made, new users must be inducted using this user manual and also recorded in the medical products / equipment log.

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



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

1.2.3 Maintaining efficiency

The operator is in responsible for ensuring the permanent process efficiency of the device. This is ensured, among other things, by means of the process validation and routine testing.

As part of the validation process, the materials and loading configuration that are to be prepared during the respective process are specified.

A process validation must be provided for all the types of material to be treated. Materials not listed in the validation report must not be treated in the Formomat PL sterilizer.

1.2.3.1 Process validation

A validation is the proof required of the effectiveness of this process. This involves inspecting and documenting the medical products actually used with the packaging used by the respective operator and the processing conditions. The operator must ensure that the “worst case” load has been inspected during the validation.

The reproducibility of the process must also be documented as part of the validation so that it can be assumed that the desired result will always occur. The inspections and the results must be documented.

The validation process comprises validation of the installation, operation and performance.



The operator is responsible for performing the validation process. National regulations must be observed. The validation must be performed using state-of-the-art technology.

Notes for devices operated in Germany:

Validation requirements are given in e.g. DIN EN ISO 25424 and the recommendations of the Commission for Hospital Hygiene and Infection Prevention (Kommission für Krankenhaushygiene und Infektionsprävention - KRINKO) on the hygiene recommendations when preparing medical products (Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten).

Contact MMM customer service for further information on the inspection and validation of sterilization processes.

1.2.3.2 Routine inspections

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

These include, for example, periodic inspections such as planned maintenance activities including checking the measurement and control technology, regular calibration and adjustment of the measurement chain, and requalification.

As a rule, requalification, i.e. repeating the performance validation, is also performed annually.

In the case of changes which affect the process, or after maintenance activities, it is essential to perform a requalification. The content of the inspections depends on the change.

National regulations (in Germany: DIN EN ISO 25424 and KRINKO recommendations) must be observed.

1.2.4 Outgassing (aeration)

Whether the desorption is adequate for safe use of the medical devices is checked during the process validation.

Notes regarding the limit values for residual formaldehyde on medical devices and their determination can be found in EN 14180 Annex E and Annex D.

In general, the sterilized medical devices can be used on patients immediately after removal.

1.2.5 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 disposal or return of 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).

National regulations and provisions or local requirements may, however, necessitate special disposal. Please contact your local waste disposal service.

The disposal method must comply with local and national regulations.

INFORMATION FOR OPERATORS IN GERMANY

The following laws and regulations must be observed when disposing of chemicals and other hazardous substances in Germany:

- Circular Economy Act (KrWG)
- Hazardous Substances Ordinance (GefStoffV)
- Ordinance on the European Waste Catalogue / Waste Catalogue Ordinance (AVV)
- Ordinance on Waste Recovery and Disposal Records (NachWV)
- Chemicals Act (ChemG)

1.3 operators

Operators are divided into the following groups:

- Approved operator
- System supervisor (e.g. building services)
- 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 (or program stop button maintenance hatch, control cabinet depending on the machine type)
- Password for the supervisor (system supervisor) (see Chapter 1.9, "User permissions")

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.

1.4 Rules of Conduct during Operation and Maintenance

To ensure the safety of all persons working with or on the machine, the following guidelines must be observed.

1.4.1 Personal protective equipment

The metal walls of the sterilization chamber and door become so hot during operation that touching them with a bare hand may cause burns.

Internal fittings of the chamber, the material to be sterilized, and loading equipment that have been in the chamber for a longer period of time also become so hot that touching them with a bare hand may cause burns.



Risk of burns!

Wear suitable protective equipment when loading and unloading the chamber!

1.4.2 Starting a program

Before the program is started, it must be ensured that the chamber has been correctly loaded and that all chamber doors are closed.

1.5 Maintenance work

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

1.5.1 Working inside the chamber

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



Risk of injury!

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.

1.5.2 Working on the assemblies



When working on the assemblies, turn off the master switch and secure it with a lock to prevent it from being switched back on. Keep the key with you when carrying out work to prevent unintentional unlocking.

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

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



Risk of burns!

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

Wear personal protective clothing when working on the assemblies!

1.5.3 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 .

1.6 Machine safety devices

The machine is equipped with multiple safety devices, that allow immediate program abort in case of danger.

In the event of a power failure, the machine will be in a safe state.

1.6.1 Operating conditions

The following safety functions were specifically taken into consideration when designing the machine:

- The entire operating sequence is performed in the vacuum range. This prevents any sterilization gas from escaping.
- The operating sequence can only be run fully automatically. This prevents incorrect manual interventions.
- The sterilization program will only run after pressing START if
  - the chamber door(s) is (are) properly closed,
  - the chamber has been adequately preheated,
  - the engaged program stop switch has been unlocked,
  - there is an adequate quantity of water in the evaporative heat exchanger.

1.6.2 Program stop switch

The program stop switch is located on the front side of the machine and must be used in case of imminent danger, or if irregularities or malfunctions occur during the program.

When it is actuated the machine is placed in a safe state,
i.e. the media valves are closed.

The program stop switch must be pressed in the following cases:

- Irregularities in the program sequence
- Unusual noises
- Steam emission from the machine room
- Fire



The process is regarded as incorrect.

The material to be sterilized must be regarded as unsterile.

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

To restart the machine, the program stop switch must be unlocked, depending on the machine variant, either by gently pressing and turning it or using the key if present (Chapter 1.3, "operators" and Chapter 6.1, "Unexpected cancellation of the program sequence").

1.6.3 Automatic program cancellation

In the event of a fault that prevents the program sequence from completing correctly, the control system will cancel the program.



Risk of contamination!

The process is regarded as incorrect.

The material to be sterilized must be regarded as unsterile.

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

1.6.4 Program cancellation button

The program cancellation button is visible on the touch screen as soon as a program is started. It must be pressed, for example, if an incorrect program was started and the material could be damaged.

Pressing the “Cancel program” button ends the program as quickly as possible (Chapter 6.1, "Unexpected cancellation of the program sequence").



Risk of contamination!

The process is regarded as incorrect.

The material to be sterilized must be regarded as unsterile.

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

1.6.5 Locking the chamber door and door release

The control system prevents the door from being opened during the program sequence.



Risk of personal injury or damage to property!

Forcibly opening the doors during the program sequence is prohibited.

On completion of the program, the chamber door can only be opened when the following conditions are met:

- The pressure in the chamber is equal to the atmospheric pressure
- The program is at the *Unloading* process step.

1.6.6 Pressure transducer monitoring

In the operational setting, the measured value of the pressure transducer is compared with the fixed setpoints. If the pressure transducer signal is outside the aforementioned tolerance range, the message *Chamber pressure outside tolerance* appears on the display and the machine cannot be started.

In the sterilization process step, the measured values of the control and measurement pressure transducers are continuously compared with one another. If the discrepancy between them is too large, the error message *Difference in P10/ P11too high during sterilization* is displayed on the screen and a program stop is initiated.

1.6.7 Process time monitoring

The process time duration is monitored during all phases of a program. If the duration of a process step is longer than allowed, a program stop is initiated and a corresponding message appears on the display.

1.6.8 Vacuum pump motor protection switch

The thermoelectric safety switch monitors the operation of the vacuum pump during all phases of the program sequence in which the vacuum pump is operated. If this safety switch is triggered, e.g. as a result of a too high switch temperature or a too high current consumption, the power supply to the vacuum pump is interrupted. At the same time, *Vacuum pump motor protection* appears on the display.

Have the fault eliminated by your technical personnel or MMM customer service.

1.7 Residual risks and measures to prevent them

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

Furthermore, the parameters relevant to a successful sterilization process are constantly monitored by the control system standard.

Nevertheless, fault-free completion of a sterilization program is no guarantee of the sterility of the treated material.

Residual risks

The following influencing factors cannot be constantly monitored in all process steps and therefore represent a residual risk for the process effectiveness:

- Incompatibility of the selected program with the materials to be treated. The selected program is not suitable or has not been validated for the materials to be treated.
- Sterilization of products that do not comply with the intended use of the machine.
- Inadequate preparation of the materials to be sterilized. The materials have not been sufficiently cleaned and dried.
- Poor ventilation of the material due to incorrect packaging and loading.
- Unknown initial contamination (type and count) for non-validated cleaning process.
- Steam wash not sufficient for desorption

Measures to prevent the risks listed above and to guarantee successful sterilization:

- Observe the instructions regarding daily use, in particular those for performing the vacuum test and for testing the door seal.
- Observe the guidelines in the national regulations on the reprocessing of medical products (Chapter 1.2.3.1, "Process validation").
- Only those products that comply with the intended use of the machine may be sterilized.
- The machine may only be operated by trained, authorized operators.
- Only trained, authorized operators are permitted to release the cycle on the basis of the cycle record and visual check (e.g. no residual moisture).
- Conduct regular routine tests, such as maintenance and safety inspection, including checking the measurement and control technology and, if applicable, calibration and adjustment of the measurement chain.
- The effectiveness of the sterilization programs for the load actually used by the user can also be verified by tests with indicators or by a process validation.
  If a process validation has been performed, a requalification is required in particular if any process influencing changes (e.g. changes in the load configuration) have occurred.
- Whether the desorption is adequate for safe use of the medical devices is checked during the process validation.
- Observe the instructions regarding preparation of the materials to be sterilized (see Chapter 4.3.1, "Preparing the items to be sterilized").

The following also applies to the reprocessing of medical devices

- Before the sterilization process, thoroughly and properly clean and disinfect the items to be sterilized in accordance with the medical device manufacturer's instructions and the applicable national regulations.

Non-observance of this instruction can have a negative impact on the sterilization results and also the functionality and appearance of the items to be sterilized.

- Use sterilized material barrier systems to protect the sterile goods from recontamination. Only sterile goods packaging must be used which complies with the national EN or DIN standards.
- Perform the routine testing (Chapter 1.2.3.2, "Routine inspections") on daily start-up of the sterilizer.
- Perform the daily vacuum tests to identify any leaks in the chamber.

Only those goods for which a process validation exists may be reprocessed.

1.8 Maintenance and Safety inspection

Maintenance and safety inspections must be carried out in accordance with TRGS 513.

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

Maintenance and safety inspections may only be performed by qualified 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.

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.

1.9 User permissions

The following users and authorizations are pre-configured:

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

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

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

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

User Manager (option)

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

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

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

1.10 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

1.11 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 14180 Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing

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

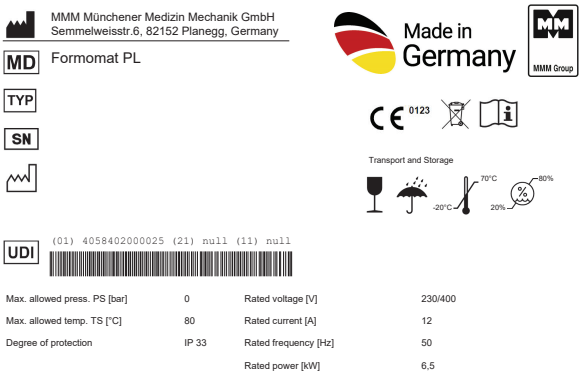
What follows is a general description of the machine and process.

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

type plate

The type plate is located on the control cabinet.



Example illustration

Explanation of type plate:

Manufacturer

CE mark with identification number (example)

MD Medical device

Disposal (WEEE recycling)

TYP Type

Observe the instructions for use

SN Serial number

Fragile, handle with care

 Date of manufacture

 Store in dry place

 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 Standard equipment

Chamber

The chamber has been designed, manufactured and tested for an operating pressure of 0 - 1 bar absolute in accordance with the applicable technical rules.

The chamber is electrically heated and thermally insulated.

Closure

The chamber is closed by means of one (two) sideways swinging hinged door(s) with quick-action locking. The chamber cannot be opened during the program sequence. The safety lock mechanism remains effective even in the event of a total loss of medium.

The locking door is also electrically heated. A fan integrated in the door also helps to quickly and evenly distribute the temperature and sterilizing media in the chamber.

Medium supply compartment

Compartment for the supply containers above the sterilization chamber in the front cover with easy to operate plug-in connections.

Vacuum facility

Water ring vacuum pump with three-phase motor and gas separator for ventilation and gas removal.

Electrical equipment

The electrical equipment conforms to the applicable DIN / VDE (German Association for Electrical, Electronic and Information Technologies) regulations.

Instrumentation and control equipment

High-quality industrial controller with no mechanically actuated components.

The process parameters of temperature and pressure are measured and controlled as per DIN EN 14180 by two Pt100 resistance temperature probes and two absolute pressure transducers.

The independent safety monitoring system records, evaluates and reports deviations from setpoints, and also monitors the operating states of the machine.

If a fault occurs in the automatic program sequence, the program is cancelled.

High degree of connectivity with Ethernet and USB ports. Cycles saved locally to flash memory. Up to 20,000 cycles can be saved.

Increased sterilization reliability due to barometrically-compensated pressure measurement and regulation by means of absolute pressure transducer, 0-1000 mbar, class 0.5.

Pt 100 resistance temperature sensor for controlling the process temperatures, 1 x Pt 100 in the chamber for regulating the chamber temperature, 1 x Pt 100 in the chamber for registration of the chamber temperature.

Cycle time monitoring for temporal control of the program sequence within the provided time, including detection of program sequence faults and termination of the program in a safe operational state.

Reference measurement point

The reference measurement point of the Formomat PL is located at the tip of the Pt100 sensor screwed into the side of the chamber wall.

2.3 Optional additional features

The equipment and functions described below are available as options.

2.3.1 Hardware components

Fixed deionized water connection (option)

Permanently installed deionized water connection for steam wash. There is therefore no cycle-related supply of distilled water in the canister. The supplied deionized water must be of a quality in accordance with DIN EN 285 Table B.1 Contaminants in the feed water.

2.3.2 Optional services

Standby mode

If the machine is not operated for a long time (no program active, screen is not touched), it switches to standby mode after an adjustable time. Standby mode is activated automatically after the set time has elapsed (see Chapter 5.4, "Activating standby mode ").

Standby mode switches off as soon as the touch screen is touched.

Barcode administration

Barcodes are used to identify the sterilization material. They are located on the goods to be treated and are scanned individually with a handscanner for each cycle.

A maximum of 100 barcodes can be entered per cycle. The barcode information is transferred to the cycle log.

Central control room

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

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

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

Remote maintenance system

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

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

Uninterruptible power supply (UPS)

Uninterruptible power supply for the control system. In the event of a power failure for up to 2 minutes, the controller remains active and relevant cycle information continues to be saved.

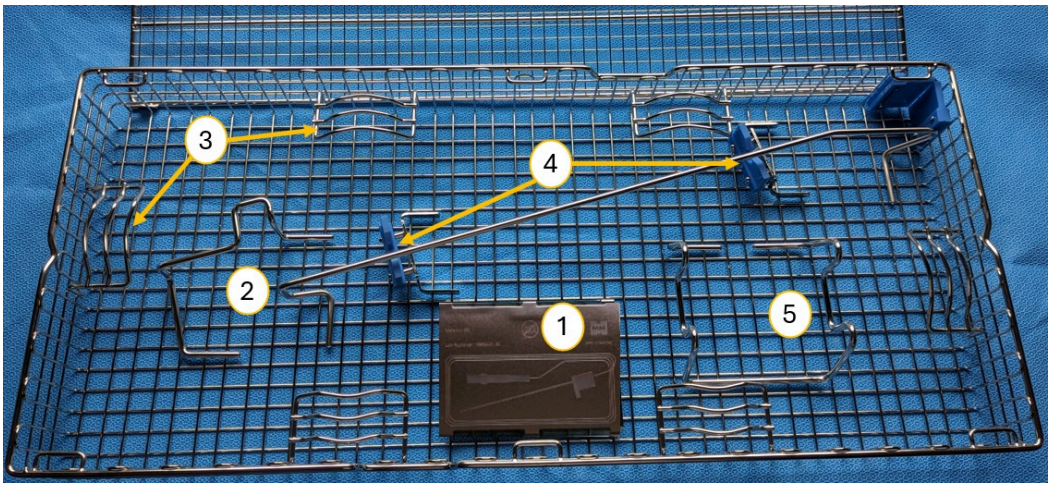
Larger electrical consumers (e.g. pumps) are switched off during power failures and the relevant process valves closed. When the power goes back on, the current program is continued.

Process-relevant media valves are closed during the power failure.

An alarm message appears on the display and, if required, is printed in the cycle report.

2.3.3 Accessories: LT Optic Tray

Rack



1. Engraved plate with the following information
   - Manufacturing number
   - Version number
   - Lot number
   - Info sign “Not autoclavable”
   - Brief description of rack load
2. Rest for the head of the endoscope
3. Guides for the cable of the endoscope
4. Silicone sheets to protect the metal parts of the endoscope
5. Rest for the connection piece of the endoscope

Lid



6. Engraved plate with the following information
   - Manufacturing number
   - Version number
   - Lot number
   - Info sign “Not autoclavable”
7. Closed with metal catch

2.4 Audit trail

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

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

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

2.5 Cycle documentation

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

The cycle document contains the following information:

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

- Messages in plain text
- All barcode numbers on labels read by the barcode scanner

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

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

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

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

2.6 Process Description

Low temperature steam formaldehyde programs

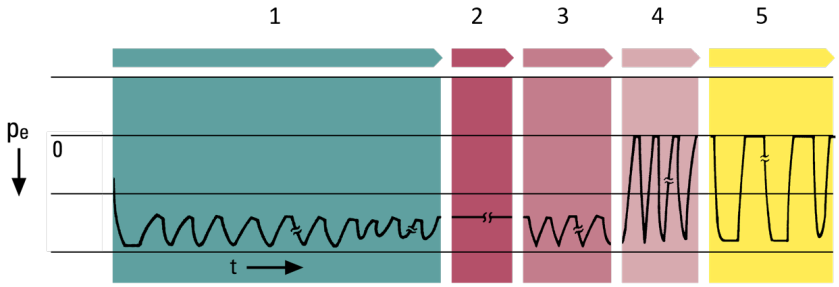
The sterilizer is factory-equipped with the sterilization processes described as examples below.

Three standard programs are available for selection:

- Gentle
- Classic
- Max

Process phases

The process is temperature-monitored, pressure-regulated and time-controlled. The sequence is characterized by the following process steps:



1. Ventilation with FO: Multiple dosing of the formaldehyde steam mixture into the chamber up to a defined pressure alternating with evacuation of the chamber to ensure transport of the sterilization gas in particular into narrow lumens of the items to be sterilized. (fractionation with formaldehyde steam mixture)
2. Sterilization phase: The programmed sterilization time is executed.
3. Steam wash: Multiple fractionation with steam alternating with evaluation of the chamber to remove formaldehyde.
4. Forced degassing: Multiple fractionation with air alternating with evaluation of the chamber. The aeration phase is used to dry the sterile goods and to further remove any formaldehyde residues from the goods.

   This program sequence is repeated until a programmed minimum degassing time of 1 hour has expired and is intended to protect the operators.
5. Degassing: A dialog appears that the chamber is being degassed. The degassing program can be ended by confirming the dialog.
6. End: When the degassing dialog is confirmed, the sterilization chamber is evacuated and re-aerated. After pressure equalization, the degassing program is finished and the door remains locked for 5 min.

Program selection:

Gentle program

- Sterilization temperature: 55 °C
- Sterilization time: 120 min

Typical sterilization materials

- For heat sensitive items with a comparatively high temperature sensitivity (max. 55 °C)

Classic program

- Sterilization temperature: 60 °C
- Sterilization time: 60 min

Typical sterilization materials

- For heat sensitive items with a comparatively low temperature sensitivity (max. 60 °C) and high frequency of reuse

Max program

- Sterilization temperature: 75 °C
- Sterilization time: 30 min

Typical sterilization materials

- For heat sensitive items with a comparatively low temperature sensitivity (max. 75 °C) and high frequency of reuse

2.6.1 Vacuum test program

The prerequisite for successful sterilization is the removal of the air from the sterilization chamber and, in particular, from the sterilization goods. The air otherwise forms “air pockets” within the items being sterilized. These air pockets prevent entry of the steam, which is required to warm up and moisten the items. When the gas acts on inadequately moistened (conditioned) items, safe sterilization of the items cannot be guaranteed.

Optimal removal of the air is achieved through repeated evacuation and inflow of steam. This requires the sterilization system to be vacuum-tight in operation.

To verify the vacuum tightness, the program controller performs a vacuum test. whereby the sterilization chamber including the connected pipes are subjected to a leak test.

Test passed

If the pressure does not increase more than the allowed value during both test phases, the test is considered passed.

Test failed

If the pressure increases more than the allowed value during either of the test phases, the test is considered failed. This is indicated by the Vacuum test failed message and by the red signal lamp.

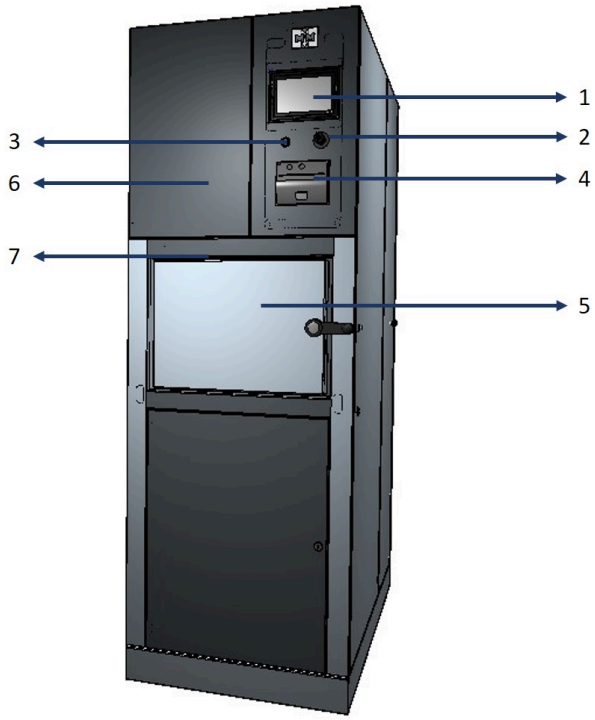
The sterilization chamber is evacuated and re-aerated once. After a brief holding time, the door on the operator's side can be opened.

If the negative leak test was not due to a real leak but instead resulted from residual moisture in the sterilization chamber from the preceding sterilization, rub the interior of the chamber dry with a cloth and leave the door open for some time with the system heating on.

3 Display and control elements

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

Loading side



1. Color touch display
2. Program stop switch
3. Mains switch
4. Thermoplotter
5. Chamber
6. Medium supply compartment
7. LED status display

Unloading side

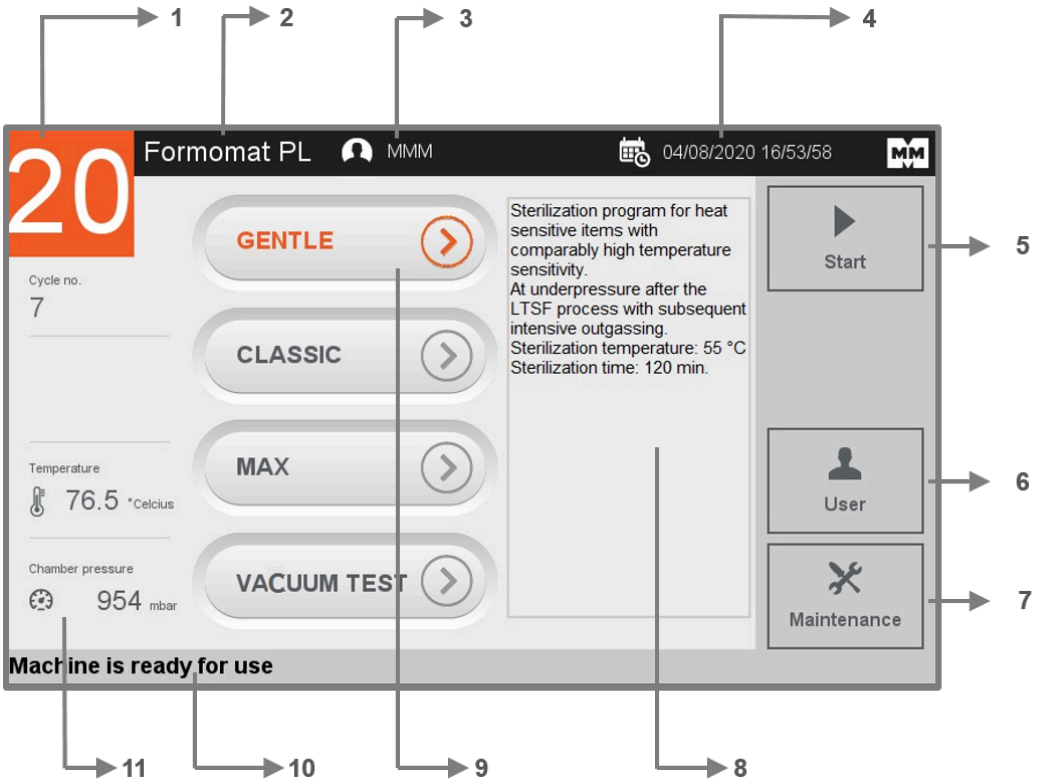


1. Color touch display
2. Program stop switch
3. Chamber
4. LED status display

3.1 Color touch screen

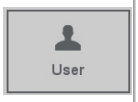
The machine is equipped with a color touch screen. Pressing the buttons executes the stored functions. The touch screen can be operated with gloves or a corresponding tool.

Function overview



1. Machine number
2. Machine designation
3. Logged-in user
4. Date and time
5. Program start
6. Log user in/out
7. Control menu
8. Program information text
9. Selected program
10. Information messages
11. Status information

Function buttons of the color touch display

	Button	Description	Function
7		Log user in/out	Log user in/out. If no user is logged in, the user “Anonymous” is logged in. If the “S” user actively logs out, the user “Anonymous” is automatically logged in. If the user does not actively log out, the user is automatically logged out after a specific period during which no buttons on the display are pressed.
5		Start	Starts the selected program.
8		Control menu	Opens the Control menu.
		Cancel program	Cancels the current program.
		Acknowledgment button	Acknowledges all messages.
		Back	Back the next menu level up.
		Scroll button	If a menu level covers more than one screen, use this button to scroll through the screens.
		Scroll back button	If a menu level covers more than one screen, use this button to scroll back through the screens.

3.2 Colour status displays

The colors of the LED strip on the chamber or on the info bar (if present) have the following meaning:

Overview of status indicator functions

Color	Designation	On	Off
Blue	Ready for operation	Door released for opening	Door not released for opening
White	In operation	Program running	No program running
Red	Fault	Fault	No fault

4 Operation

Observe the safety instructions in Chapter 1 “Safety”.

Note!

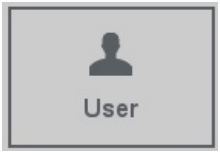
All activities described below may only be carried out by authorized operators.

4.1 Logging users in and out

Log-in is not required for normal operation.

If the **User Manager** (Chapter 1.9, "User permissions") option is used, operator log-in can be configured so that each operator has to log in with his name and password.

Operator log-in



- Press the **User** button.

The log-in window appears.



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

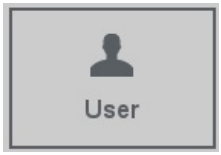
After log-in, the corresponding user name (e.g. “S”) appears in the title bar.

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

Log out actively to prevent misuse of rights!

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

User log-out



- Press the **User** button.



- Press the **Log out** button.

The user name “Anonymous” appears in the user bar.

4.2 Daily start-up

- Perform specified maintenance work
- Press the mains switch

With the chamber doors closed, evacuate and re-aerate the chamber. This evacuates any traces of formaldehyde that may be present in the empty sterilization chamber from a preceding sterilization before the machine is opened for the first time.

- Inspect the attachment device for the medium bottle
  Ensure the needles are well sharpened otherwise a needle could get blocked by rubber residues.

- Check the rubber stoppers
  The needles can get blocked by aged or porous rubber stoppers.



Rubber stoppers must not be reused.

This can lead to leaks and liquid running out.

4.3 Sterilization mode

4.3.1 Preparing the items to be sterilized

Each item to be sterilized must be cleaned, disinfected, rinsed and dried before being reprocessed in the sterilizer. The item to be sterilized is then packaged and loaded in the sterilizer.

Cleaning

Foreign materials (organic or inorganic) on the surface of the item to be sterilized hinder the sterilization process because they present a barrier to the sterilization agent. The item to be sterilized must therefore first be cleaned. Several microorganisms are already removed while doing so.

After cleaning, the item to be sterilized must be dried.



Observe the pre-treatment instructions of the instrument manufacturer (cleaning and drying).

Observe, in particular, the instructions regarding cleaning agents and manual cleaning.



After each cleaning, check the item to be sterilized for contamination, moisture, and damage.

If necessary, repeat the cleaning process and properly dispose of damaged instruments.

Packaging

The cleaned and dried items to be sterilized must be packaged or placed in suitable containers before sterilization. The packages or containers are then stored in suitable racks.

Packaging according to DIN EN 868-6 must be used. To avoid strong absorption of the sterilization gases into the packaging material, do not use cotton or linen packaging.

Unless otherwise specified by the manufacturer, hinged instruments and items with removable parts should be disassembled. Complex instruments should be prepared and sterilized according to the manufacturer's instructions. Items with concave surfaces must be placed in such a way that any water created during the sterilization process can run off. Heavy items must be positioned in such a way that they cannot damage delicate items.

Ensure that the materials to be sterilized are arranged in such a way that the sterilization agent can penetrate every surface. Perforated trays should be placed so the trays are parallel to the shelf. Non-perforated containers should be placed on their edge in a vertical orientation. Small items should be placed loosely in the wire baskets provided. Peel packs should be placed in the perforated or mesh bottom racks or baskets provided.

The material from which the racks are made can affect the sterilization. If, for example, metal racks are replaced with plastic racks, a revalidation is required.

Indicators

- Chemical indicators: Chemical indicators can be applied to the outside of the sterilization goods packages before sterilization. These indicate that the objects were subjected to a sterilization process, but not whether the sterilization was successful. Chemical indicators can also be placed inside the packaging in order to verify the penetration of the sterilization agent.

4.3.1.1 LT Optic Tray / Endoscope sterilization

Sterilization of endoscopes must only be performed using the MMM LT Optic Tray.



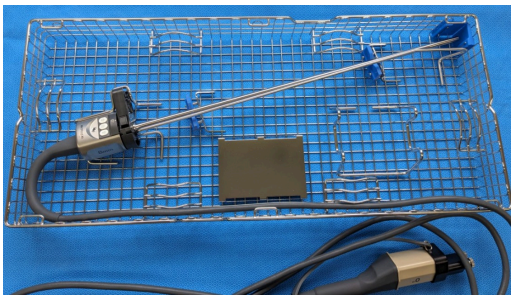
Risk of contamination!

Before loading, the endoscopes much be cleaned and disinfected in according with the manufacturer's specifications. Otherwise it is not possible to perform a proper sterilization process.



Note!

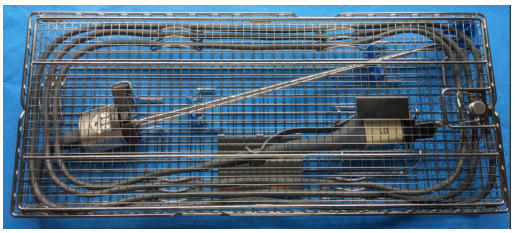
The MMM LT Optic Tray rack is only validated for the sterilization of endoscopic cameras of a robot-assisted surgical system using the Hyper LTS or Formomat PL sterilization machine. Only one endoscope per rack can be sterilized.



- First insert the metal rod of the endoscope between the silicone sheets so that the tip points towards the silicone sheet in the corner of the rack.
- Place the head of the endoscope in the bracket provided.
- Run the cable in a counterclockwise direction along the outside of the rack through the cable guides, beginning with the outermost one.



- Insert the connection piece of the endoscope in the bracket provided.



- Place the rack lid on the rack and lock it with the metal catch.

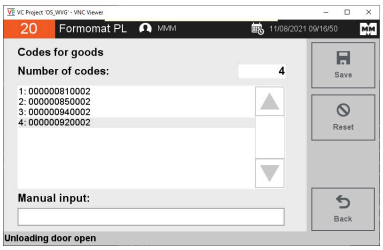
  On which of the two short sides of the rack the metal catch is located does not matter.
- Package the racks in a soft packaging (sterile barrier system).

4.3.2 Reading barcodes

If the device has a barcode management system, barcodes can either be scanned or entered manually.

Reading barcodes with a scanner

- Scan the barcodes at intervals of approx. 15 cm.
  After scanning, the barcode administration window appears. Once the barcode has been scanned, check whether the barcode has been added to the list or not.



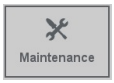
Once read, the barcodes appear in a list. They are assigned to the next program due to start.

The number of scanned barcodes appears in the *Barcodes count* field.

If no further entry is made within 10 s, the barcode administration screen disappears.

Manually inputting barcodes

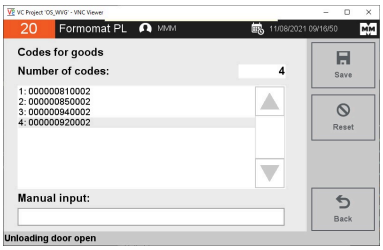
If scanning with the handscanner fails and the barcode does not appear in the list (e.g. because the barcode is dirty), the barcodes can be entered manually).



- Press the **Maintenance** button.



- Press the **Barcodes** button.



- Touch the input window under **Manual input**.

  An input block appears.
- Enter the barcode details.
- Confirm the entry with the green tick.



- Save the entry.

Barcode transfer failure

If a barcode is rejected when scanned or entered manually, (e.g. incorrect barcode length), an explanatory message appears.

Deleting barcodes



- Press the **Reset** button.

4.3.3 Loading the racks

When operating the sterilizer, condensate can form during individual program phases that needs to run off. Items such as trays, containers, etc. should therefore be placed in the loading rack with their opening facing downwards. For this reason, wire baskets open on all sides should also be used for loading. The wire mesh can be relatively coarse because only packaged sterilization goods can be placed in them.

The optimal method of packing the load depends on the objects to be sterilized. Metal-reinforced plastic items, for example, must be placed vertically rather than horizontally in the rack. Hoses should be arranged so that both ends are hanging down to ensure no moisture collects in the bends. The packaged items (packets) should also be loaded in an upright position if at all possible. A small gap should also be maintained between the packets. Nothing must be pressed in. The entire load must be handled “loosely”. For process-technical reasons, the load in the chamber should be limited to 4/5 of the chamber volume. The items must not touch the wall of the chamber.

4.3.3.1 LT Optic Tray



Endoscopes of robot-assisted surgical systems must not be autoclaved as that would damage them.

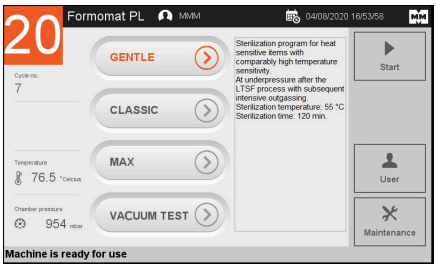
Sterilization must only be performed in a Formomat PL machine using the Max program.

- Place the loaded rack in the sterilization rack of the Formomat. A maximum of two Optic Tray racks can be stacked on top of one another in the sterilization rack.
- Place the sterilization rack in the sterilization chamber.

  Do not place an Optic Tray rack into the chamber without the sterilization rack of the Formomat to ensure the outlet is not blocked.
- Close the chamber door of the sterilizer.
- On the sterilizer start the **Max** program.

4.3.4 Operating the machine

Selecting a program



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



Note the information displayed about the program.

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

Preparations

- Place the plastic bottle with the 2% formaldehyde solution in the supply compartment and connect it.

  2 bottles of formaldehyde solution are required per cycle.

- Place the containers with the distilled water medium in the supply compartment and connect them. This step can be skipped if you have the Fixed deionized water connection option.

  One container of distilled water is required per cycle.

- Wait until the machine has warmed up to the operating temperature.

⇒ The message *Machine is ready for operation* is displayed.

Loading the sterilization chamber

The sterilization chamber is loaded manually.



Wear chemical-resistant protective gloves and safety glasses when working on the sterilization chamber.



Sterilization process compromised!

Make sure the sterilization goods have been cleaned and dried before loading them into the sterilizer.



Ensure that the sterilization goods are only placed in the chamber immediately before the program is intended to be started.

- The chamber is degassed several times while no program is running.

⇒ Once the degassing has completed, the chamber can be unloaded.

- Open the door with clamp lock on the loading side.
- Place the packaged sterilization goods into the chamber.
- Enclose the indicators.
- Close the door with clamp lock on the loading side.

  The door is locked automatically at program start to prevent improper opening.



The program can only be started if the chamber door or chamber doors have been properly closed.

Starting the program



- Press the start button.

The program runs automatically. On completion of the program the machine stops at the *Unload* program step and the door on the unloading side is released.

Program sequence

The dashboard view is displayed while the program is running.

Dashboard view



The dashboard view shows the program name, cycle number of the current cycle, current process step, time remaining to the end of the cycle, chamber pressure (measured) and chamber temperature (measured).

Other views

The **Change view** button in the dashboard view can be used to switch to other views.

The pressure and temperature curves, for example, are displayed on the screen in real time.

To return to the dashboard view, press the **Dashboard** button.

Ending the program

- ▶ The chamber is degassed at the end of the program. Confirm the dialog on the touchscreen by pressing **End now**.
- ⇒ The machine finishes degassing.
- ⇒ The sterilization chamber is aerated. After pressure equalization, *Remove* appears on the display. The door is unlocked for 5 minutes.

If the chamber door is not opened during this period as originally intended, the program returns to the *Degassing* phase. The lockable door(s) is (are) then locked again as required by the program. This process will repeat continuously.



Prerequisite for release from an OH&S perspective according to TRGS 513: Before opening the chamber door, check the cycle documentation to ensure that the desorption phase (forced degassing) has completed properly.

Unloading the sterilization chamber

The sterilization chamber is unloaded manually.



Wear chemical-resistant protective gloves and safety glasses when working on the sterilization chamber.

- Open the door on the unloading side.

  Two-door machine:

  When the door on the unloading side is closed, it is locked and the door on the loading side is unlocked.
- Remove the sterilization goods from the chamber.
- Check the integrity of the sterilization goods and their packaging.
- Check the indicators for a color change.
- After unloading, close the chamber door to reduce the heat loss during non-use and to keep the interior of the chamber clean.
- Remove empty media containers from the medium supply compartment and remove any residual liquid present.



If you are using plastic bottles with formaldehyde solution, wear safety glasses and protective gloves!

4.3.5 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 material to be sterilized or the machine.



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

After confirming the prompt:

- the chamber is completely free of formaldehyde. This may take some time depending on the current process step.
- an alarm message is shown on the display.

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

4.4 Releasing a cycle

Every cycle must be checked, inspected and released.

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

- Check that the program selection is consistent with the materials that were reprocessed.
- Check that the process-related data on the cycle record, e.g. pressure and time, were maintained throughout the entire process and correspond to the data specified in the validation.
- Check the packaging and, if necessary, the seals for integrity (visual inspection).
- Check the results of the process indicators (if present). The operator must document the criteria for evaluating the process indicators in a work instruction.
- Check whether the media containers have been fully emptied.



Label released sterilized materials so they can be differentiated from sterilized materials that have not been released, or ensure a clear differentiation by organizational means.

Cycle documentation

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

Depending on the results of the release inspection, individual packaging items of a cycle may be released and others rejected. If packaging items are rejected, the reason must be documented in the cycle record.

4.4.1 Displaying and printing saved cycle records

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



▶ Press the **Maintenance** button.



▶ Press the **Cycles** button.



▶ Press the **Cycle archive** button.

The last 50 saved cycle files are displayed.

The cycle name is a combination of the date, program number, program name and cycle number.

- ▶ Select the desired cycle using the arrow keys.
- ▶ Confirm the selection with the tick button.

The cycle name and date the selected cycle was saved are shown in the info field (right side of screen).

- ▶ Press the *Load selected cycle* button to view additional information (e.g. program name, cycle times etc.).
- ▶ Press the *Printer* button to print the displayed cycle.

The selected cycle file is printed depending on the setting of the cycle print option (Chapter 5.2, "Configuring the cycle print and save option").

4.5 Storage of sterile goods

Sterile goods must **not** be stored in the sterilizer when it is in the *Ready for operation* state or when the machine is switched off.

The packaging material can adsorb the formaldehyde which is then released into the room air. Appropriate ventilation measures must be implemented to ensure the MAK value in the storeroom or the sterile goods store is not exceeded. In accordance with the national regulations in Germany as stipulated in TRGS 513, MMM recommends a fresh air flow rate (quantity of supplied fresh air) of at least 100 m^3/h.

Storage duration of gas sterilized goods in packaging

The acceptable storage duration largely depends on the storage conditions. According to DIN 58 953 Part 7, the following applies:

<table>
<tr><th>Sterile goods packaging</th><th>Packaging type</th><th colspan="2">Storage period</th></tr>
<tr><td rowspan="3">Paper bags as per E DIN EN 868-4 and hot and self-sealing transparent bags and hoses made of paper and plastic composite foil as per E DIN EN 868-5 or other equivalent packaging</td><td rowspan="2">Sterile goods storage packaging unopened or opened and resealed.</td><td>Unprotected storage (as per 4.3a in DIN 58953-8)</td><td>Protected storage (as per 4.3b in DIN 58953-8)</td></tr>
<tr><td>As a supply for immediate use. This storage type should be avoided.</td><td>6 months [1)]</td></tr>
<tr><td>Sterile goods storage packaging unopened or opened and resealed.</td><td colspan="2">5 years,
if the manufacturer has not specified a different expiry date.</td></tr>
<tr><td colspan="4">[1)] Exceeding the storage duration for this packaging type has proven to be inadvisable for practical and economic reasons.</td></tr>
</table>

4.6 Installing the media

On the left-hand side above the sterilization chamber there is a supply compartment for accommodating the containers/bottles filled with the distilled water and formaldehyde solution media (DIN 58 948/15 Section 5). The content is sufficient for one cycle.

- Open the door of the medium supply compartment.
- Connect the hose on the medium canister to the connector provided in the medium supply compartment. If you have the Fixed deionized water connection option, install an empty canister for the distilled water medium.
- Turn the plug-in bottles sealed with a rubber stopper and a crimped aluminum cap upside down, position them on the needles, then push them down.



If there is an aluminum tab present in the needle insertion area to protect the rubber stopper, remove it before plugging in the bottle.

- Close the door of the medium supply compartment.

4.7 Shut-off

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

- Press the mains switch



Keep the chamber doors closed to reduce heat output and prevent chamber interior soiling when the machine is not in use.



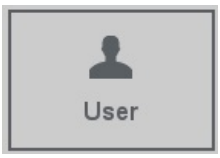
Do not switch off the machine when a program is running!

5 Machine configuration

The machine configuration described below can be performed by the system supervisor via the control menu.

Process-related changes can only be carried out by persons who have the master passport (e.g. MMM customer service).

Opening the control menu:

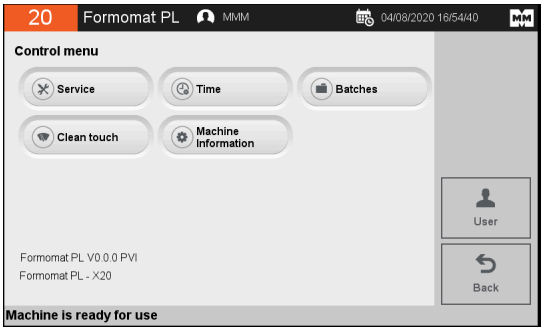


- Log in as the supervisor.



- Press the **Maintenance** button.

The control menu appears.



5.1 Configuring the User Manager (option)

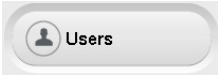
If the machine has the **User Manager** option, users can be created with name, password and specific authorizations.

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

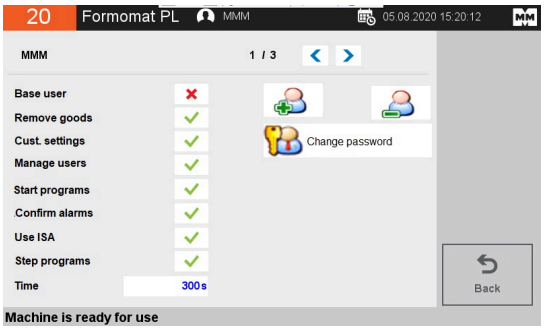
The various user passwords enable access to the corresponding menu levels.



- Press the **Service** button on the loading side.



▶ Press the **User** button.





▶ Press the **Create user** button.

- ▶ Enter the name and password of the new user.
- ▶ Assign the required authorizations to every new user.
- ▶ Enter the required log-out time after which the user will be automatically logged out.
- ▶ Confirm every entry with OK.

On exiting the user administration function, the created users are saved.

Users can also be deleted and passwords changed on this menu screen.

Program start authorizations

Authorizations for programs can be assigned individually to every user, who can then start the specified programs. In the default setting, every user can start all activated programs.

The program selection per user is defined as follows:



▶ Press the **User** button.

▶ Select the desired user and scroll to the page.

▶ Activate the programs that the user is permitted to start.

Programs that the currently logged-in user is not permitted to start are grayed-out in the program selection menu and the user cannot start the programs.

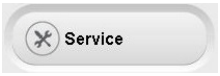
5.2 Configuring the cycle print and save option

Cycle print

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

- Thermal printer: Print-out to integrated thermal printer.
- DIN A4 direct printing option: Direct printing to a connected DIN A4 printer. One printer per sterilizer is required for multiple sterilizers.
- RUMED360 Cycles option: Transfer of cycle data to a PC installed in the network. Data can be saved and printed here. This requires the RUMED360 CycleServ program to be installed on the PC. Only one PC with RUMED360 CycleServ and a printer are required for multiple machines.

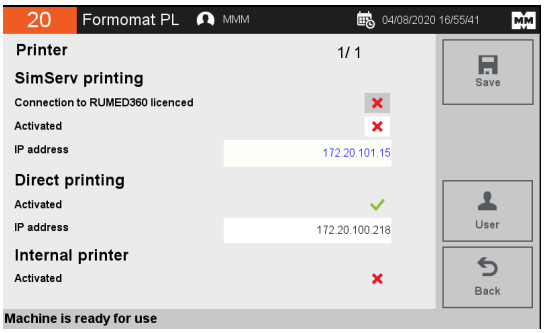
Proceed as follows when set up one of the options:



▶ Press the **Service** button on the loading side.



▶ Press the **Printer** button.



▶ Activate the desired print options. All options can be activated at the same time.



▶ Save the entry.

DIN A4 direct printer

- ▶ Activate this printer by placing a green tick in the *DIN A4 Direct printing* section.
- ▶ Enter the IP address of the printer.

Thermal printer

- Activate this printer by placing a green tick in the *Thermal printer* section.

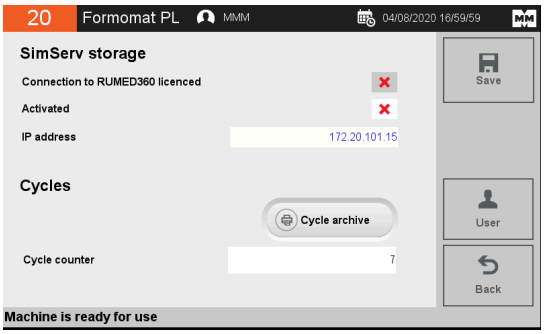
Printing via PC

- *RUMED360 Connect Cycles* is activated by a specialist.
- Activate this printer by placing a green tick in the *External cycle printing* section.
- Enter the IP address of the network computer on which *RUMED360 CycleServ* is installed.

Saving cycle data



- Press the **Cycles** button in the control menu.



- Activate the cycle saving function.
- Enter the IP address of the network computer on which RUMED360 Cycles is installed.



- Save the entry.

5.3 Setting the network addresses of the control panel

TCP/IP configuration

The network settings must be input for every control panel.

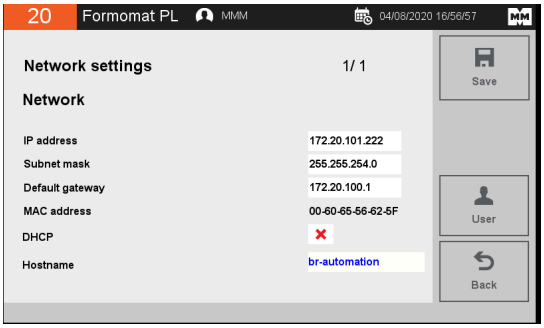
Consult the network administrator of your IT department for the IP addresses.



- Press the **Service** button on the loading side.



▶ Press the **Network** button.



▶ Enter the node number, the IP address, the subnet mask and the default gateway of the two panels.

▶ Touch the respective number field to open the number pad.



▶ Save the entry.

All fields must always be correctly populated.

If there is no default gateway, a valid IP address is still required.

This screen shows the MAC address, which will be required with service questions.

5.4 Activating standby mode

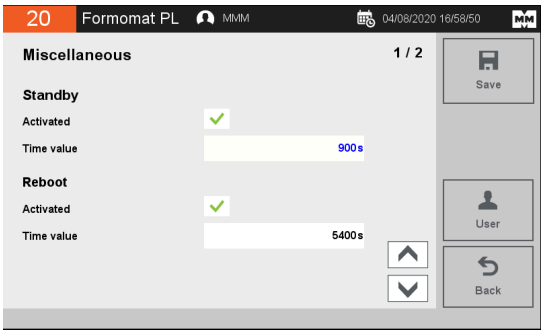
The time after which standby mode is activated can be configured to suit the operating sequence being used.



▶ Press the **Service** button on the loading side.



▶ Press the **Global** button.



▶ Enable the **Standby mode** parameter.

▶ Tap the time entry field.

▶ Enter the hours, minutes and seconds after which the machine is to switch to standby mode.

- Confirm the entry with the tick button.



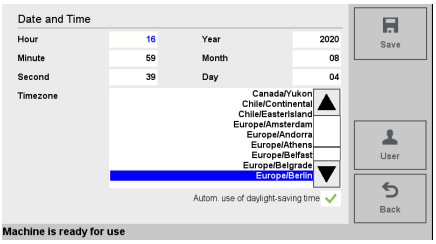
- Save the entry.

5.5 Setting the time

The supervisor can set the time. The date can only changed, however, by a user with a high authorization level.



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



- Enter the current time.
- If this is wanted, set the green tick at **Automatic switch between daylight saving and standard time** (corresponds to time change in Europe).
- Save the entry.

5.6 Calibrating the screen

A calibration may be necessary if the operator controls on the screen do not respond.



- Press the **Service** button.



- Press the **Calibrate screen** button.

Several cross-hairs appear in succession.

- Touch them as precisely as possible.

6 Operational safety and faults

6.1 Unexpected cancellation of the program sequence

The program sequence may be canceled unexpectedly for the following reasons:

- The device initiates an automatic program cancellation (Chapter 1.6, "Machine safety devices")
- The program cancellation button was pressed
- The program stop switch was pressed
- the power supply was interrupted due to a power failure



Note!

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



Risk of contamination!

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

The sterilization material must be considered unsterile.

After pressing the program stop button



If the program cancellation button has been pressed, a security prompt appears, asking whether the program is really to be canceled.

- Confirm the security prompt with **Yes**.

  The necessary process steps (e.g. *Forced degassing*) are initiated to bring the machine into a safe state.
- Acknowledge the message.

  The door on the loading side can be opened during the *Remove* process step.

After a power failure

The necessary process steps (e.g. *Forced degassing*) are initiated to bring the machine into a safe state.

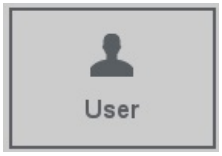
The door on the loading side can be opened during the *Remove* process step.

After pressing the program stop switch

- Unlock the switch, depending on the machine variant, either by gently pressing and turning it or using the key if present.
- Wait for the program cancellation to finish, and for the machine to be at the *Remove* program step.
- Acknowledge the message.

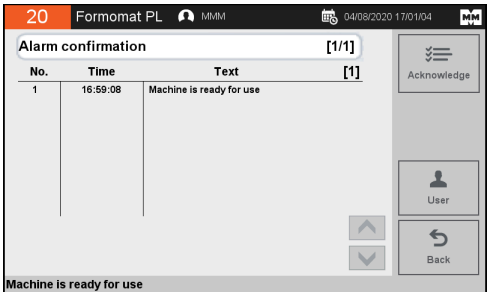
6.2 Acknowledging messages

The information and fault messages appear at the bottom edge of the screen. If a message has to be acknowledged, the following note appears, alternating with the relevant messages: *Please acknowledge.*



- Log in as the supervisor.
- Touch the **information message and faults** field.

The messages overview page appears.

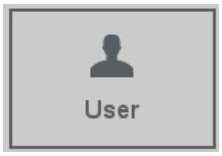


The messages are displayed with alarm number, the time the alarm occurred, and the alarm description.

You can use the arrow buttons to scroll through multiple pages.



- Press the **Acknowledge** button to acknowledge the alarm.



- Log out again.

6.3 Analysis options in the event of faults

Analog and digital inputs and outputs

The current switching status of all analog and digital inputs and outputs can be analyzed in the control menu.



▶ Open the **Control menu**.



▶ **Press the Service button.**



▶ Press the **Hardware** button.

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

You can scroll between the individual pages using the arrow buttons.

The names of the inputs and outputs can be assigned to the corresponding hardware elements based on the electrical plan.

6.3.1 Function check for specific components

The following function checks can be performed without having to start a program. The machine must be *ready for operation*.

- Thermoplotter



On the loading side:

▶ Open the **Control menu**.



▶ Press the **Service** button.

Function check of the printer



▶ Press the **Print test page** button.

The printer prints out a test page.

6.4 Heating pad temperature too low or too high

The chamber of the Formomat PL along with the doors are heated by means of 5 separately controlled heating pads. After switching on the Formomat PL in the cold state, the machine cannot be started until all temperatures of the chamber heating are within the required range. This typically takes approx. 20 - 40 min.

6.5 Status and alarm messages

All messages are listed in the following with information on the trigger, the machine's reaction and instructions for the user. Depending on the machine's equipment, not all messages are available.

No.	Message	Trigger	Note for operators
1	Machine ready for operation	Ready to start the program.	
2	DEBUG ACTIVE	Several monitoring functions are disabled.	The machine must not be operated in this mode.
3	Confirmation required	Operator must acknowledge faults.	
4	Test program active	The active program has been declared as a test program in the parameters.	
5	Power failure during program run	A power failure has occurred on the operating panel during a program run.	
6	Program manually advanced	The process has been manually advanced to another process step.	
7	Program stop performed	The “Stop program” button on the display has been pressed.	
8	Emergency stop pressed	The emergency stop switch on the machine was pressed.	
9	Standby mode	The machine is in standby mode.	
10	Local batch storage failed	Process data could not be stored on the CF card.	
11	Network batch storage failed	Process data could not be transferred to SimServ.	
12	Batch data processing active	Batch data is being processed.	
13	Program run paused	Program has been interrupted.	Not currently used.

No.	Message	Trigger	Note for operators
14	Network printing failed	Print job not sent to SimServ.	
15	Printing failed	DIN A4 direct printing failed.	
16	Printing active	Direct print job in progress at DIN A4 direct printer.	
17	Thermal printing failed	Printing by thermal printer failed.	
18	Thermal printing active	Print job in progress on thermal printer.	
19	Thermal printer: No connection	No connection to thermal printer.	
20	Thermal printer: No paper	Thermal printer signals that it is out of paper.	
21	Pressure increase in waiting time	The measured chamber pressure was too high or the pressure increased too quickly during the waiting time in the vacuum test.	
22	Pressure increase in test time	The measured chamber pressure was too high or the pressure increased too quickly during the test time in the vacuum test.	
23	Pressure increase in holding time	The chamber pressure increased too quickly during a holding time.	
24	Chamber pressure outside tolerance	The chamber pressure is too high or too low for program start.	
25	Fault in door fan	Unexpected signal from the fan controller.	
26	Last vacuum test failed	Last vacuum test failed	
27	H2O used instead of FO	Incorrect parameter settings.	
28	Loading door open	Door on loading side not registered as completely closed.	
29	Unloading door open	Door on unloading side not registered as completely closed.	
30	Loading door open during cycle	Door on loading side not registered as locked during process run.	

No.	Message	Trigger	Note for operators
31	Unloading door open during cycle	Door on unloading side not registered as locked during process run.	
32	Vacuum pump motor protection	The motor protection switch has triggered.	
33	Fault in vaporizer level sensor	There is insufficient water in the vaporizer.	
34	Confirmation required to open door	A fault requiring confirmation occurred during the process run. The parameter settings do not allow the door to be opened without first confirming the fault.	
35	Check loading door	Lock mechanism is not locking the door.	
36	Check unloading door	Lock mechanism is not locking the door.	
37	Mode 'Open both doors' active	Both doors have been opened simultaneously in the “Service” menu.	
38	Discrepancy in pressure sensors	Excessive discrepancy between the P10 and P11 pressure sensor readings.	
39	Discrepancy in temperature sensors	Excessive discrepancy between the T10 and T11 temperature sensor readings.	
40	Vaporizer heating up	Vaporizer still needs to reach the required temperature after having been switched on.	
41	Parameters changed during program	Parameters have been changed during a process run.	
42	Clock failure	Internal clocks of the control system are too different from one another (RealTimeClock, CPU, cycle time).	
43	Heating pads heating up	The temperature of the heating pads was too low when switched on.	Only appears after switch on.
44	Fault in heating pad T20	Heating pad has been activated continuously for too long.	

No.	Message	Trigger	Note for operators
45	Fault in heating pad T21	Heating pad has been activated continuously for too long.	
46	Fault in heating pad T22	Heating pad has been activated continuously for too long.	
47	Fault in heating pad T23	Heating pad has been activated continuously for too long.	
48	Fault in heating pad T24	Heating pad has been activated continuously for too long.	
49	Parameter settings are not valid	Incorrect parameter settings.	See audit trail entry.
50	Sterilization temperature too low	Sterilization temperature too low	
51	Sterilization temperature too high	Sterilization temperature exceeded	
52	Pressure increase during sterilization	The chamber pressure increased too much during sterilization.	
53	No program selected	No program selected on display.	
54	Pressure sensor P10 defective	Sensor reporting invalid values.	
55	Pressure sensor P11 defective	Sensor reporting invalid values.	
56	Pressure sensor P20 defective	Sensor reporting invalid values.	
57	Pressure sensor P30 defective	Sensor reporting invalid values.	
58	Temperature sensor T10 defective	Sensor reporting invalid values.	
59	Temperature sensor T11 defective	Sensor reporting invalid values.	
60	Temperature sensor T20 defective	Sensor reporting invalid values.	
61	Temperature sensor T21 defective	Sensor reporting invalid values.	
62	Temperature sensor T22 defective	Sensor reporting invalid values.	
63	Temperature sensor T23 defective	Sensor reporting invalid values.	
64	Temperature sensor T24 defective	Sensor reporting invalid values.	
65	Temperature sensor T25 defective	Sensor reporting invalid values.	

No.	Message	Trigger	Note for operators
66	Heating pad at chamber center too cold	Pad too cold during program.	
67	Heating pad chamber center too warm	Pad too warm during program.	
68	Heating pad chamber OS too cold	Pad too cold during program.	
69	Heating pad chamber OS too warm	Pad too warm during program.	
70	Heating pad chamber IS too cold	Pad too cold during program.	
71	Heating pad chamber IS too warm	Pad too warm during program.	
72	Heating pad door OS too cold	Pad too cold during program.	
73	Heating pad door OS too warm	Pad too warm during program.	
74	Heating pad door IS too cold	Pad too cold during program.	
75	Heating pad door IS too warm	Pad too warm during program.	
76	Heating pad temperature limiter	Temperature limiter for heating has been triggered.	
77	Vaporizer temperature limiter	Temperature limiter for heating has been triggered.	
78	Discrepancy in pressure sensors during sterilization	Excessive discrepancy between the P10 and P11 pressure sensor readings.	
79	Discrepancy in temperature sensors during sterilization	Excessive discrepancy between the T10 and T11 temperature sensor readings.	
80	Temp. inside controller too high	Temperature inside the Power-Panel is too high.	
81	Not enough memory space	Not enough free memory in PowerPanel.	
82	CF card is full	CF card memory space is below 256 KB or the card has been removed from the panel.	See audit trail entry.
83	No connection to USB device	Required USB connection could not be established or has been interrupted.	
84	Service mode	The machine is in service mode.	

No.	Message	Trigger	Note for operators
85	Preventive maintenance due shortly	Preventive maintenance due very soon	
86	Preventive maintenance overdue	Preventive maintenance is overdue	
87	Routine maintenance/inspection due shortly	Routine maintenance/inspection due very soon	
88	Routine maintenance/inspection overdue	Routine maintenance/inspection is overdue	
89	Calibration/adjustment due shortly	Calibration/adjustment due very soon	
90	Calibration/adjustment overdue	Calibration/adjustment is overdue	
91	Revalidation due shortly	Revalidation/Requalification due very soon	
92	Revalidation overdue	Revalidation/Requalification is overdue	
93	No serial number	No serial number recorded.	
94	Reading error scanner	No barcode detected.	
95	No code for goods	No barcode has been scanned yet but is required for the program to start.	
96	Door opening rejected by operator	When prompted on the IS panel, door release was rejected by the operator.	Only possible if using a second display.
97	Waiting for user action	Machine is waiting for an action that must be performed by the user.	
98	Time exceeded: air removal evac.	Evacuation has taken too long.	
99	Pressurization time exceeded	The required pressure could not be reached in time.	
100	Aeration time exceeded	The required pressure could not be reached in time.	
101	Canister filling failed	The canister could not be filled in the prescribed time.	'Fixed deionized water connection' option only
102	Uninterruptible power supply active	The uninterruptible power supply (UPS) was activated during a non-critical process step.	A running program is continued.

No.	Message	Trigger	Note for operators
103	Supply voltage interrupted	The uninterruptible power supply (UPS) was triggered during a critical process step.	A program abort is initiated.

7 Maintenance



Note!

Observe the safety instructions in Chapter 1!

An inspection and safety maintenance (interval-based maintenance & inspection) according to TRGS 513 must be performed at least once a year or after 400 cycles. The results of the check must be documented. Observe the instructions in Chapter 1.8, "Maintenance and Safety inspection".

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

This is recommended after 400 cycles.

The machine is equipped with a cycle/ and preventative maintenance counter as standard. The current counter readings can be read on the screen at any time (see Chapter 7.2, "Planning service work") .

The cycle counter continuously counts the cycles performed.

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

7.1 Preparatory measures

Observe the following points when performing maintenance work.



Risk of injury!

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

Working in the door area and assemblies compartment

Work in the area of the door mechanism or closure mechanism must only ever be performed by specialists (see Chapter 1.3, "operators") as specified by the manufacturer.

7.2 Planning service work

At regular intervals by means of alarm messages and at the bottom edge of the display, 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.

Messages are display on the screen for the following service work:

- Preventive maintenance (batch-controlled)
- Interval-based maintenance & inspection (time-controlled)
- Calibration/adjustment (time-controlled)
- Requalification (formerly revalidation) (time-controlled)

Suitable informational messages are also shown on the cycle report.

The exact due dates for all maintenance can be accessed manually at any time.

Indication of when service work is due

▶ Open the Control menu.



▶ Press the **Machine information** button.



▶ Press the **Information** button.

An overview of upcoming service work is displayed.



7.3 Maintenance activities

A medical products log / equipment log must be maintained; current reports such as cycle documentation, assignment of the temperature and pressure curves (if available) and the tests, checks, maintenance and repairs performed must be entered in this each day.

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

Daily:

What	How	Result of check
Sterilization chamber	Visual inspection of the sterilization chamber for residual moisture and foreign bodies	The sterilization chamber must be free of moisture and contamination.
Check dirt filter	Check the dirt filter in the chamber floor; remove and clean it if necessary.	

Weekly:

What	How	Result of check
Clean the chamber	Clean the chamber thoroughly. The chamber must be cold. The chamber fittings must first be covered to prevent foreign bodies from entering the pipe system (Chapter 7.6.1, "Chamber interior").	 **Risk of burns!** Allow the chamber to cool sufficiently beforehand.
Door seal and closure	Check the door seal and closure mechanism of the chamber for wear and damage.	

Annually or after 400 cycles:

The following maintenance work is required after 400 cycles or 12 months at the latest. Technical data subject to change without notice.



The following activities must be performed by a specialist (preferably MMM customer service, Chapter 1.3, "operators").



After the maintenance

- the maintenance container on the machine must be reset
- the equipment log must be updated
- the inspection label must be updated.

What	How
Chamber interior	Visual inspection for deposits and, if necessary, cleaning.
Vaporizer	Check water level and, if necessary, fill.
Vacuum pump	Perform vacuum test and check capacity of the pump.
Air filter insert	Replace the air filter insert.
Dirt traps	Clean the dirt traps in the water supply line.
Level sensor	Check the level sensor.
Vacuum valve	Check the vacuum valve.
Thermal printer	Check the thermal printer.
Position switch	Check the position switch of the door(s).
Quick coupling	Replace the quick coupling.
Manometer	Calibrate using a data logger (must be designed for low pressure range).
Door locking	Check solenoids are securely seated as well as reliable door locking and pretensioning of the door.
Door seal	Check the seal on the door(s).
Heating elements	Check door heating and chamber heating.
Fan motor	Check the fan motor.
Circulation pump	Check function of the circulation pump.
Buffer battery (option)	Check the buffer battery.

What	How
Program stop switch	Check function of the program stop switch.
Temperature limiter	Check function of the temperature limiter (setting 105 °C)
Chamber fan	Check function of the chamber fan.
Piping	Check piping, pipe interrupter and screw connections.
Safety valves	Check the safety valves.
Magnetic valves	Check the magnetic valves.
Analog measurement systems	Perform a plausibility check of the analog measurement systems.
Piercing needles for FO bottles	Check piercing needles and correct emptying of the FO bottles.
Flow meter	Check flow meter and clean if necessary.
Gas ejector	Check air orifice of gas ejector and clean if necessary.
Indicator lamps	Check the indicator lamps.
Cycle documentation	Check the cycle documentation.
Hand-held scanner (option)	Check function of the hand-held scanner.

7.4 Replacing the door seal

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



Note!

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



Risk of burns on the hot seal groove!

Switch the machine off and allow it to cool sufficiently.

7.5 Thermal printer paper exchange

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

For trouble-free printing, we recommend ordering the paper from MMM.



- Open flap.

  On opening the paper repository, the printer roller is automatically guided out of the printing mechanism with the flap.



- Remove the empty paper reel.



- Insert a new paper reel as shown in the figure.

  The paper reel is simply inserted into the container. Threading the paper in is not necessary.

Example images only

7.6 Cleaning

Regularly cleaning the sterilization chamber, the assemblies compartment and the external surfaces prolongs the service life of your sterilizer.

7.6.1 Chamber interior

Formaldehyde residues may be present inside the sterilization chamber.

Irritation of the skin by chemicals!

Wear chemical-resistant protective gloves and safety goggles when working on the sterilization chamber.

Regular maintenance can significantly extend the service life and safety of the chamber. Ensure that the metallic sterilization chamber walls and inner surface(s) of the door(s) always appear shiny. If the walls are covered in a gray or slightly discolored and spotty layer after extended use, this layer must be removed using a gentle commercial rinsing agent solution.

Perform a final rinse by wiping the surfaces with additive-free water.

Contamination and dirt accumulations must be removed during regular cleaning. Surface discolourations can also be prevented through regular cleaning.

All traces of cleaning agents must be removed.

7.6.2 Assemblies compartment

Careful cleaning and disinfection of the assemblies compartment prevents the increased accumulation of micro-organisms which can occur with even moderate levels of dust.

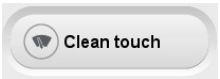
Clean the assemblies compartment every three months with an industrial vacuum cleaner, which must be equipped with a disposable dust bag (paper).

All parts of the system must then be disinfected with a commercially available disinfectant.

7.6.3 External care

The touch screen can be cleaned with a soft cloth and a gentle cleaning agent or a standard disinfectant.

If this is done with the machine switched on, the touch screen's sensitivity to touch must be temporarily deactivated to prevent unintentionally pressing buttons.



- Open the control menu.
- Press the **Clean touch** button.

The touch screen no longer reacts to inputs for 30 seconds. The time remaining for this function is decremented on the screen.

8 Warranty (Liability for defects)

MMM is liable for the proper delivery and functionality of this product pursuant to the contractual terms of the delivery contract, the contract for work and materials and the development contract. Please refer to the MMM contractual terms and the terms and conditions of delivery.

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MMM Münchener Medizin Mechanik GmbH

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