Instructions for use



Low temperature hydrogen peroxide sterilizer and cartridge

Hyper LTS with Hyper LTS Cartridge

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CE 0123

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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

StU	Sterilization unit	300 x 300 x 600 mm
SOP	Standard Operating Procedure	Standard operating procedure
H_2O_2	Hydrogen peroxide	Sterilization agent
PPE	Personal protective equipment	Reading of H_2O_2 cartridge information
RFID	Radio frequency identification	Reading of H_2O_2 cartridge information

Warning signs on the machine

The following warning signs may be present on the machine:



Warning dangerous electrical voltage! Open only by trained personnel.



Warning corrosive substances! Wear protective gloves and safety goggles.



Warning hot surface! Wear protective gloves.



Warning risk of crushing injury to hands.



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



Can intensify fires; oxidizing agent



Protective ground



Wear safety goggles!



Wear protective gloves!

Device labeling

The specification of this low temperature hydrogen peroxide sterilizer is indicated by the following device labeling:

Variant	Version			
	Number of doors	Opening direction of the chamber door	Volume in liters	Internal chamber clearance in mm (H x W x D)
Hyper LTS® 150-1	1	Vertical	150	450 x 450 x 760
Hyper LTS® 150-2	2	Vertical	150	450 x 450 x 760

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 General safety notes



Risk of acid burns!

Concentrated hydrogen peroxide can cause burns to the skin, eyes, nose, throat, lungs and the gastrointestinal tract!

Wear chemical-resistant protective gloves made from latex, PVC or nitrile when working on the sterilizer!



Risk of poisoning!

Ingesting hydrogen peroxide can lead to poisoning!

Do not consume hydrogen peroxide in any form! If consumed, contact an emergency physician immediately and following their instructions!



Respiratory distress!

Inhaling hydrogen peroxide can lead to irritation of the airways and respiratory distress!

In the event of a hydrogen peroxide leakage, leave the room immediately!



Danger of fire!

Hydrogen peroxide increases the risk of fires, explosions or container breakage!

Prevent contact of hydrogen peroxide with organic material such as paper, clothing or lubricants! If contact occurs, wash the material thoroughly with water!

Store the hydrogen peroxide in a safe place away from heat or ignition sources to avoid a fire! In the event of a fire, use only water to extinguish the fire!



Injury to the eyes!

Contact with hydrogen peroxide can lead to irreversible tissue damage to the eyes!

If necessary, protect the uninjured eye. Rinse injured eyes with water for at least 15-20 minutes! Remove any contact lenses if possible! Contact a physician immediately!



Injury to the skin by chemicals!

White chemical-containing residues may form inside the sterilization chamber.

Wear chemical-resistant protective gloves made from latex, PVC or nitrile when working on the sterilizer!

Clean the chamber and remove the white residues regularly!



Injury to the skin by chemicals!

Contact of the sterilizing agent with the skin can lead to skin irritation and damage.

Wear chemical-resistant protective gloves made from latex, PVC or nitrile when working on the sterilizer!

Rinse the affected areas of the body with water for at least 20 minutes! Contact a physician immediately!



Risk of burns due to hot surfaces!

Allow the chamber to cool down before working on the machine.



Damage to the materials being sterilized due to incorrect treatment.

Observe the treatment instructions of the instrument manufacturer.

Ensure that all materials being treated are suitable for machine sterilization.



The machine must be serviced regularly by a specialist (e.g. MMM service technician or a person or company authorized by MMM) to avoid material damage and to ensure trouble-free operation of the machine.



Observe the safety data sheets of the H_2O_2 cartridges.



Damage due to weight forces.

Do not place any objects or devices on the sterilizer.

1.2 Intended use

1.2.1 Intended use of Hyper LTS

Intended purpose

The **HYPER LTS** low temperature hydrogen peroxide sterilizer is suitable for sterilizing medical equipment at low temperatures.

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

Intended use

The **HYPER LTS** low temperature hydrogen peroxide sterilizer is intended for sterilizing the following reusable equipment at low temperatures (up to 60 °C):

- Temperature-resistant equipment made of metal, plastic and glass
- Non-temperature resistant equipment

When selecting the equipment for sterilization, take into account the material compatibility for H_2O_2 sterilization.



Note!

Follow the reprocessing instructions of the manufacturer of the material to be treated.

Material compatibility

There are no known material-damaging effects when reprocessing the following materials using the sterilizing agent provided with the Hyper LTS:

Metals
6000 series aluminum 300 series stainless steel Titanium

Non-metals	
■ Acrylonitrile butadiene styrene (ABS) ■ Delrin ■ Ethylene-vinyl acetate (EVA) ■ Fluorinated ethylene propylene (FEP) ■ USP type I borosilicate glass ■ High-density polyethylene ■ Kraton ■ Latex ■ Low-density polyethylene ■ Neoprene rubber (polychloroprene) ■ Nylon ■ Phenolic resin	■ Polycarbonate ■ Polyetherimide ■ Polyethylene terephthalate (PET) ■ Polymethyl methacrylate (PMMA) ■ Poly(phenylene sulfone) ■ Polypropylene ■ Polystyrene ■ Polysulfone ■ Polytetrafluoroethylene (PTFE) ■ Polyurethane ■ Polyvinyl chloride (PVC) ■ Silicone

Limitations of use



The hydrogen peroxide sterilizer is not suitable for treating:

- H_2O_2-absorbing materials (e.g. cellulose, cotton,...)
- Disposable medical products
- Liquids
- Powder
- Oils

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.

1.2.2 Intended use of Hyper LTS Cartridge

Intended purpose

The **Hyper LTS Cartridge** is intended to be used in combination with the **Hyper LTS** low temperature hydrogen peroxide sterilizer.

The **Hyper LTS** sterilizer together with the **Hyper LTS Cartridge** is intended for use in the medical field (e.g. in Reprocessing Units for Medical Devices) for sterilizing medical devices.

Intended use

Hyper LTS Cartridge is a cartridge filled with hydrogen peroxide solution that is used exclusively with the **Hyper LTS** low temperature hydrogen peroxide sterilizer of the company MMM Münchener Medizin Mechanik GmbH.

The **Hyper LTS Cartridge** filled with sterilization medium is intended to be used in the sterilizer. The cartridge and the sterilizer form a functional unit.

When selecting the sterilizers, take into account the material compatibility for H2O2 sterilization (see user manual for the product).

When selecting the items to be sterilized, the material compatibility for H_2O_2 sterilization must be taken into account.

Limitations of use



Limitations of use

The Hyper LTS Cartridge is not suitable for use in the low temperature hydrogen peroxide sterilizers of other manufacturers or for any use other than that described above.

1.3 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.

The operator is responsible for adhering to all regulations and regular inspections under these directives over the entire product life cycle.

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 installed and secured
- 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 1.3.3.1, "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).

1.3.1 Commissioning - equipment requirements

1.3.1.1 Connection to the electrical power supply



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

Consider the following characteristics, in particular, when connecting the machine to the power supply:

- Mains voltage fluctuations: voltage fluctuation +/- 10 %
- Overvoltage category: II
- Degree of contamination: 2
- Rated temperature of the cable: -5 °C to +70 °C



Danger due to electric current!

Pull out the mains plug when working on the machine.

1.3.1.2 Sterilization agent



Use only the original H_2O_2 cartridges from MMM (“Hyper LTS Cartridges”, MMM material no. 010575948) when operating the Hyper LTS machine.

The Hyper LTS Cartridge cartridge contains a 59 % hydrogen peroxide solution (H_2O_2) that is used as a sterilization agent in the Hyper LTS H_2O_2 sterilizer. In the sterilization process, the H_2O_2 solution vaporizes (VH_2O_2) thereby becoming a sterilizing agent.

The cartridge has a limited shelf life because hydrogen peroxide breaks down into water and oxygen over time. The oxygen forming in the cartridge can escape to the surroundings via a membrane. This prevents the pressure from increasing in the cartridge.

The content of one cartridge is sufficient for up to 15 cycles (depending on the program selected).

Usage notes

Cartridges with cracks or other visible damage must not be used in the machine. In this case, contact MMM customer service or persons or companies that have been authorized by MMM.

The cartridge has a shelf life of 40 days from first use in the sterilizer, regardless of whether it is removed from the machine during that time. If an expired cartridge is installed or a cartridge has been in use for longer than 40 days, an alarm (90) is displayed on the machine and program start is prevented.



To purchase new cartridges, please contact MMM customer service or persons or companies that have been authorized by MMM.

Shelf life and storage

Store the cartridge

- in the original container (plastic box)
- away from light, heat and contamination
- without heavy items stored on top of it



Flammable!

Keep cartridge away from heat, hot surfaces, sparks, open flames or other ignition sources. Do not smoke in the storage room.

At temperatures between 5 °C - 30 °C and when stored away from light, the cartridges have a shelf life of one year after filling.



Observe the safety data sheets of the H_2O_2 cartridges.

1.3.2 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
- 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

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).

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 noise emission level of the machine during operation results from the noise emission of the vacuum pump. At full gas ballast, the noise level according to DIN 45635 is: 56 dB(A) (vacuum pump manufacturer’s specification).

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

H_2O_2 concentration in room air

The operator must take the H_2O_2 concentration in the room air at the installation location into account when performing a risk assessment.

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 1.4, "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 1.4, "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.

Installation

The operator is responsible for ensuring an adequate clearance from all sides of the machine. A minimum clearance of 10 cm from the sides and rear, and 100 cm from the doors must be provided.

The machine must also be installed in such a way as to ensure easy access to operate the isolator (unplug the power cable).

The machine is not suitable for outdoor use. It is not designed for use at altitudes greater than 2000 m above. sea level.

1.3.3 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 Hyper LTS sterilizer.

1.3.3.1 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.

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

1.3.3.2 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.

1.3.4 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.

4. **Disposal of cartridges**

   The empty H_2O_2 cartridges can be disposed of with the hospital waste. No special disposal (poisonous waste or the like) is required.

Privacy note

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

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

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

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

NOTES FOR OPERATORS IN THE EU

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

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)

1.4 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.

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
- If applicable: Medical devices / equipment log (depending on the machine type)
- Keys (for the emergency stop switch or program stop switch, maintenance hatch, control cabinet depending on the machine type)
- Password for the supervisor (system supervisor) (see Chapter 2.5, "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.

Only specialists have the level 3 password, which is needed to access the password protected area of the menu-driven controller (e.g., to change parameters) (Chapter 2.5, "User permissions").

1.5 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.

1.5.1 Personal protective equipment

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

Protection from chemical burns

The sterilization chamber, the H_2O_2 compartment and the H_2O_2 cartridges may contain residues of hydrogen peroxide. To avoid hazards to the user, the operator must provide appropriate protective equipment:

- Chemical-resistant protective gloves made from latex, PVC or nitrile
- Safety goggles
- Long-sleeve and closed work clothing

Please consult the safety data sheet for the Hyper LTS Cartridge for more information.

Protection from burns

The metal walls of the sterilization chamber and the locking door may reach high temperatures during operation.

Internal fittings of the chamber, the items 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.

To avoid hazards to the operator, the operator must provide appropriate protective equipment:

- Heat-resistant gloves
- Long-sleeve and closed work clothing

1.5.2 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 and all panels are mounted.

1.6 Maintenance work

Maintenance work see Chapter 7, "Maintenance " may only be performed by qualified personnel (see Chapter 1.4, "Operators").

1.6.1 Working inside the chamber

Only trained personnel (e.g. see Chapter 1.4, "Operators") are permitted to work inside the chamber.



When working inside the chamber (e.g. during cleaning, maintenance), pull out the mains plug.

Hydrogen peroxide residues may be present inside the sterilization chamber.



Risk of acid burns!

Wear chemical-resistant protective gloves made from latex, PVC or nitrile and safety goggles when working on the sterilization chamber.

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

Risk of burns!

Wear gloves when loading and unloading the chamber!

1.6.2 Working on the assemblies

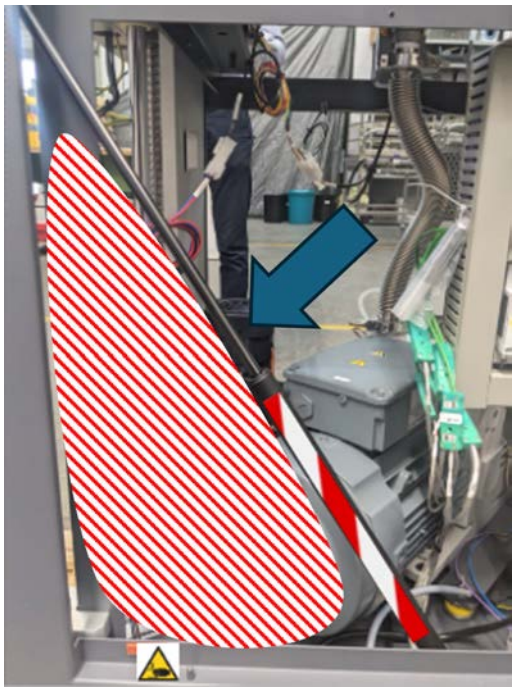
Risk of crushing from the door movement!

Pull out the mains plug when working on the assemblies.

The door is moved by means of a worm drive and there is also a pneumatic spring (blue arrow) located on the door that moves up and down when opening and closing the door.

A significant risk of crushing exists in the red hatched area!

Work on these components must therefore only be performed with the machine switched off.



Only suitably trained specialists (see Chapter 1.4, "Operators") are permitted to access the assemblies, e.g. for inspection or maintenance purposes and access is possible only with the appropriate tool (Phillips head screwdriver).

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



Risk of chemical burns from H_2O_2 residues on the assemblies!

Wear personal protective clothing when working on the assemblies!



Risk of burns!

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

Wear personal protective clothing when working on the assemblies!

1.6.3 Working at the switchboard

Only qualified staff (see Chapter 1.4, "Operators") with the appropriate tool (Phillips head screwdriver) are permitted to access the switchboard.



Danger due to electric current!

Pull out the mains plug when working on the switchboard.

1.7 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.

1.7.1 Safety strip

The self-closing chamber doors are fitted with a safety strip that stops door movement as soon as the door encounters an obstacle (e.g. if an object or a person is in the way of the door). The door is then opened again.

1.7.2 Automatic program cancellation

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



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.

1.7.3 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").



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.

1.7.4 Locking the chamber door and door release

The control system prevents the door from being opened during the program sequence. Consequently, the door buttons are not shown on the display.



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 in the atmospheric pressure range
- The program is at the *Unloading* process step.

See also see Chapter 4.3.7, "Unloading the sterilization chamber".



Escape of H_2O_2 steam possible!

Wear chemical-resistant protective clothing when opening the chamber door.

For your personal protection, stand to the side of the chamber when opening the chamber door.

Do not inhale any escaping vapors when opening the door.

1.7.5 Monitoring the sterilization parameters

The sterilization parameters (temperature, time and pressure) are monitored by the control system. The temperature is measured by means of a temperature sensor.

1.7.6 Access protection

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

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

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

Using the User Manager option, users can be assigned specific authorizations (Chapter 2.5, "User permissions").

1.8 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 ("Intended use of Hyper LTS").
- 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.

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 1.3.3.1, "Process validation").
- Only those products that comply with the intended use of the machine may be sterilized ("Intended use of Hyper LTS").
- 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 and no H_2O_2 residues on the load).
- 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.
- 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 1.3.3.2, "Routine inspections") on daily start-up of the sterilizer.
- Perform the daily vacuum tests to identify any leaks in the chamber.
- Please note that the desorption of hydrogen peroxide from the sterile materials can vary despite the plasma phase. It depends on the type and material of the packaging and the material composition of the sterile items.

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

1.9 Maintenance and Safety inspection

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

Maintenance and safety inspections may only be performed by qualified persons (see Chapter 1.4, "Operators"). Similarly, the machine must only be repaired by persons who are authorized to do so by the manufacturer.

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

National regulations must be observed.

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

Note regarding warranty

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

We refer to our warranty declaration Chapter 9, "Warranty (Liability for defects)", according to which wear-and-tear parts and damage caused by chemical influences are expressly excluded from our warranty.

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

Applicability of standards

The **Hyper LTS Cartridge** is a cartridge that contains the sterilization agent for the **Hyper LTS** low temperature hydrogen peroxide sterilizer of MMM Münchener Medizin Mechanik GmbH. When used as intended, this machine is operated exclusively with this product.

The sterilization agent (see Definition of terms in DIN EN ISO 11139:2017, Term 3.272) is a 59% H_2O_2 solution and is used to produce a sterilizing agent. The sterilizing agent is created by means of a process applied within the Hyper LTS sterilizer.

The cartridge and the sterilizer form a functional unit. No standards were applied intentionally for the **Hyper LTS Cartridge** product. The proof of state of the art applies to the functional unit.

The standards and directives listed below apply to the functional unit:

- **Hyper LTS with Hyper LTS Cartridge**

Applied standards - state of the art

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

Performance and effectiveness

- DIN EN ISO 14937 Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

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

Applicability of standards in regard to the Hyper LTS Cartridge

The **Hyper LTS** low temperature hydrogen peroxide sterilizer uses a cartridge, **Hyper LTS Cartridge**, filled with a hydrogen peroxide solution.

The cartridge filled with sterilization agent (see Definition of terms in DIN EN ISO 11139:2017, Term 3.272) and the sterilizer form a functional unit. No standards were applied intentionally for the **Hyper LTS Cartridge** product. The state of the art applies to the functional unit.

Other regulations and standards

The following other general standards and regulations were applied in part or taken into account:

- DIN EN ISO 15223-1
  Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (Version 2022)
- Technical Rules for Hazardous Substances (TRGS)
- Hazardous Substances Ordinance (GefStoffV)

The hydrogen peroxide solution falls within the scope of application of the regulation:

- REACH, Regulation EC 1907/2006



Note

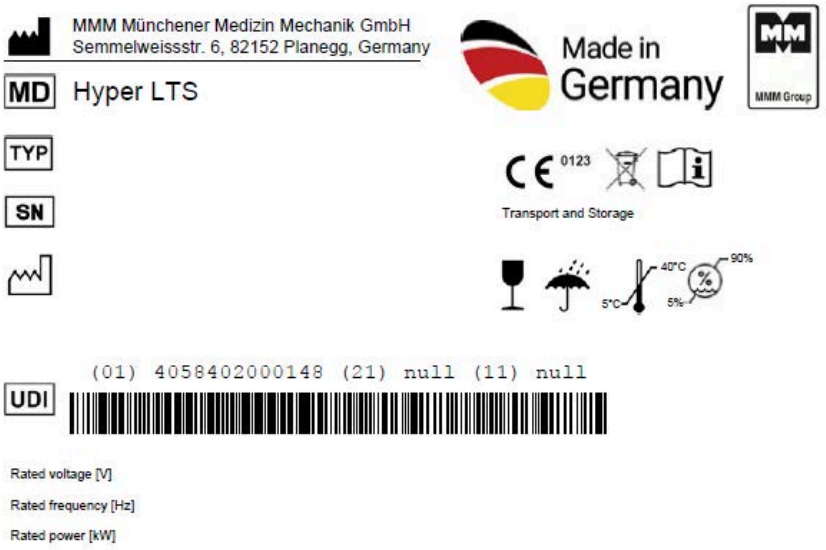
Other standards that are referenced in the aforementioned regulations and may only be applicable in part are not listed separately.

2 Machine description

2.1 Type plate

Hyper LTS type plate

The type plate is located in the left front flap.



Example illustration

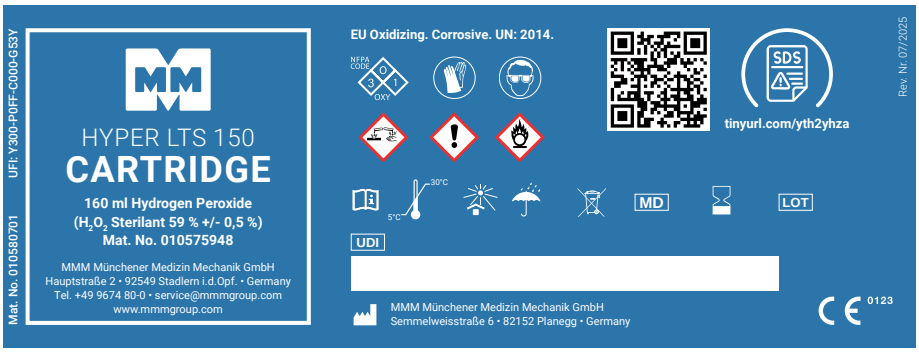
Explanation of type plate:

- 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
- UDI Unique Device Identifier
- Lower and upper temperature limit

Lower and upper air humidity limit

Hyper LTS Cartridge type plate

The labeling is located on the cartridge.



Example illustration

Explanation of the symbols on the label:

National Fire Protection Association Code

Warning corrosive substances! Wear protective gloves and safety goggles.

Wear protective gloves!

Caution

Wear safety goggles!

Can intensify fires; oxidizing agent

Link to safety data sheet of the H_2O_2 cartridge

Observe the instructions for use!

Disposal (WEEE recycling)

Lower and upper temperature limit

Medical device

Keep away from direct sunlight.

Expiration date

Store in dry place.

Batch number

Unique Device Identifier (GS1 Element Strings):

UDI comprises the following elements

(01) GTIN / UDI-DI

(10) Batch or lot number

(17) Expiration date

 Manufacturer

CE mark with identification number (example)

2.2 Standard equipment

Chamber

The sterilization chamber has been designed, manufactured and tested for a maximum permissible pressure (PS) of at least 0.5 bar and a vacuum of 1 bar.

The chamber and door are electrically heated and thermally insulated throughout.

Closure

Depending on configuration, the sterilization chamber is equipped with one or two sliding door(s) driven by an electric motor.

The safety devices prevent the doors from opening during the program and the simultaneous opening of the loading and unloading sides (in the case of two-door devices). To prevent jamming, the doors are fitted with a safety strip.

Each sliding door is sealed pressure-tight mechanically by means of a silicone cord seal.

The sliding doors open vertically downward.

Vacuum facility

The machine is equipped with a vacuum facility which enables air extraction.

The vacuum pump unit comprises a powerful and quiet, oil-sealed rotary vane vacuum pump with attached exhaust air filter and a catalyzer.

Electrical equipment

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

Control panel

The compact and easy-to-operate 7“ control panel is integrated into the front panel above the sterilizer chamber.

Two-door machines are equipped with an additional 7" panel mounted above the chamber on the unloading side.

The menu system is very user friendly with simple input on a color touch screen and visual display of all user inputs.

Important cycle information, and messages from the safety control system when deviations from setpoints occur are displayed in plain text. Process curves displayed in graphic online mode to show all important information at a glance.

Instrumentation flow diagram

The complete system is also clearly visualized by electronic flow charts that show valve settings and machine states in visual form. Valves and actuators can also be actuated individually from the relevant flow diagram during the *Operational* state.

Instrumentation and control equipment

The process parameters of temperature and pressure are measured and controlled by thermocouples and an absolute pressure transducer.

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.

Cycles saved locally to flash memory. Up to 20,000 cycles can be saved.

Fan

The machine is equipped with a fan that speeds up the process of uniformly heating the sterilization chamber and the material to be sterilized.

Foot sensor

A foot sensor enables the chamber doors to be opened without pressing the Open Door button. This makes it easier to load and unload the sterilization chamber.

H_2O_2 dosing system

Hydrogen peroxide is dispensed into the sterilization chamber by means of a H_2O_2 dosing system. The dosing is performed automatically at every half cycle. An optical fill level sensor monitors for correct dosing of the liquid H_2O_2.

H_2O_2 cartridge



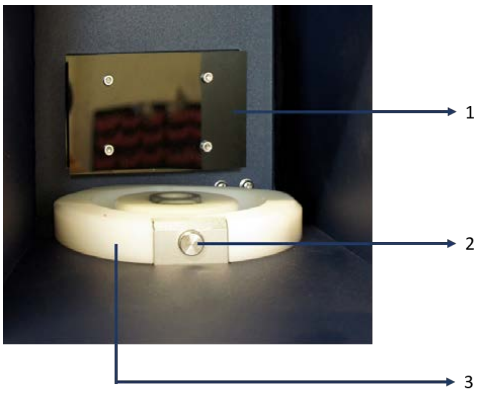
The cartridge is made from H_2O_2-resistant plastic. An aeration system ensures that oxygen (a breakdown product of H_2O_2) can escape.

A self-sealing opening is located on the bottom of the cartridge. This opens automatically when the cartridge is plugged into the Hyper LTS machine and closes again when it is removed.

The operator does not come into contact with H_2O_2 at any time.

H_2O_2 compartment

The H_2O_2 cartridge is installed in the H_2O_2 compartment of the sterilizer. The compartment is located behind a flap at the top right on the front side of the machine. "Installing / replacing the H_2O_2 cartridge"



1. RFID reader
2. Unloading button
3. Docking mechanism for the H_2O_2 cartridge

An RFID reader at the rear of the compartment reads the data stored on the cartridge (shelf life, batch, etc.). This data can be accessed by the operator in the menu of the Hyper LTS.

MMM sensor manager

The sensor manager can be used to configure the recording of additional sensors for specific programs. The sensors which are mandatory for the relevant program are pre-selected and cannot be deselected. The sensor data can then be viewed and analyzed using Rumed360 Cycles.

LED status display

An LED strip indicates the current status of the machine as a color-coded display (see Chapter 3.2, "Colored status displays").

2.2.1 Sterilization agent



Use only the original H_2O_2 cartridges from MMM (“Hyper LTS Cartridges”, MMM material no. 010575948) when operating the Hyper LTS machine.

The Hyper LTS Cartridge cartridge contains a 59 % hydrogen peroxide solution (H_2O_2) that is used as a sterilization agent in the Hyper LTS H_2O_2 sterilizer. In the sterilization process, the H_2O_2 solution vaporizes (VH_2O_2) thereby becoming a sterilizing agent.

The cartridge has a limited shelf life because hydrogen peroxide breaks down into water and oxygen over time. The oxygen forming in the cartridge can escape to the surroundings via a membrane. This prevents the pressure from increasing in the cartridge.

The content of one cartridge is sufficient for up to 15 cycles (depending on the program selected).

Usage notes

Cartridges with cracks or other visible damage must not be used in the machine. In this case, contact MMM customer service or persons or companies that have been authorized by MMM.

The cartridge has a shelf life of 40 days from first use in the sterilizer, regardless of whether it is removed from the machine during that time. If an expired cartridge is installed or a cartridge has been in use for longer than 40 days, an alarm (90) is displayed on the machine and program start is prevented.



To purchase new cartridges, please contact MMM customer service or persons or companies that have been authorized by MMM.

Shelf life and storage

Store the cartridge

- in the original container (plastic box)
- away from light, heat and contamination
- without heavy items stored on top of it



Flammable!

Keep cartridge away from heat, hot surfaces, sparks, open flames or other ignition sources. Do not smoke in the storage room.

At temperatures between 5 °C - 30 °C and when stored away from light, the cartridges have a shelf life of one year after filling.



Observe the safety data sheets of the H_2O_2 cartridges.

2.3 Optional additional features

The equipment and functions described below are available as options.

2.3.1 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 5.5, "Activating standby mode "). The heating elements of the machine are switched off when standby mode is activated.

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.

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.

2.3.2 Uninterruptible power supply (UPS) (option)

Uninterruptible power supply for the control system. In the event of a power failure, the control system remains active and cycle information is saved. Process-relevant valves are closed during the power failure.

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 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, viewing the audit trail, certain service menu functions

Level	User name	Users	Authorised for:
2	Supervisor (name: “s”)	System supervisor	e.g. acknowledging faults, alarm counters, configuration of certain parameters such as auto start, standby mode etc.
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). A user can be logged in and out as a supervisor at any time.

If the screen is not touched for 5 minutes after log-in (individually adjustable), the *Supervisor* user is automatically logged out and the *Anonymous* user is logged in.

User Manager (option)

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

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

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

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

2.6 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:

- Software version of the machine
- Selected program
- Number of cycles already run
- Date of last vacuum test
- Cycle step with time (format hour/minute/second) and pressure (to one decimal place):

Product heating	The material is being conditioned for sterilization.
Vacuum pump (VP) heating	The VP is being prepared.
Vacuum 1	Specifies the start pressure of the process step. Evacuation of the chamber and preparation for injection.
Injection	If the required temperature for vaporizing the hydrogen peroxide is not reached, the program is canceled. Indication of pressure during injection.
Diffusion/Aeration	The pressure increase after injection is measured. If the increase is insufficient, the program is canceled.
Sterilization	Target pressure in the chamber at min. ambient pressure of -50 mbar.
Vacuum 2	Specifies the start pressure of the process step. Preparation for the plasma phase.
Plasma 1	The remaining hydrogen peroxide is broken down at low pressure.
Vacuum 3/Plasma 2	Second half cycle, analogous to the first half cycle.
Aeration	The chamber pressure is equalized to the ambient pressure

- Details of the cartridge used
- Any fault messages that arose including a brief description

- Cycle passed or failed

  The cycle is considered passed if all monitored parameters were within the tolerances during the cycle.

The cycle document that is saved in the machine can be printed out at the end of the cycle Chapter 5.2, "Configuring the cycle print and save option" 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 20 cycles stored in the machine can be shown on the display and reprinted.

2.7 Process Description

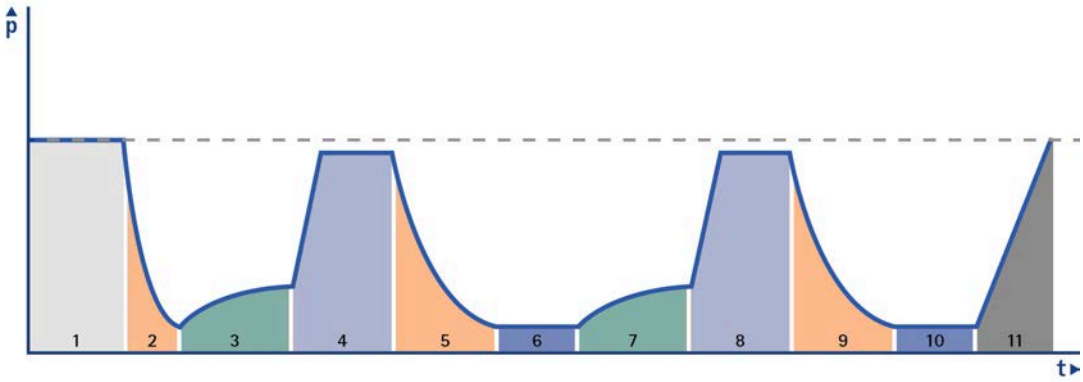
The sterilizer is factory-equipped with the sterilization processes described as examples below.

Three standard programs are available for selection:

- Easy
- Classic
- Complex

Process phases

The process is temperature-monitored, pressure-regulated and time-controlled. The sequence comprises two half cycles (1st half cycle: process steps 2-6, 2nd half cycle: half cycle: process steps 7-10) and is characterized by the following process steps:



1. Conditioning with ventilator
2. Evacuation of the chamber with heating phase and residual drying of the material to be sterilized.
3. Injection and vaporization of hydrogen peroxide in the chamber.
4. Start of the sterilization phase. The vaporized hydrogen peroxide penetrates the loading packaging to reach the surfaces of the materials to be sterilized (diffusion phase).
5. Evacuation of the chamber.
6. Generation of plasma. Hydrogen peroxide decomposes into water and oxygen.
7. Reinjection and vaporization of hydrogen peroxide in the chamber.
8. Start of a new sterilization phase. The vaporized hydrogen peroxide penetrates the loading packaging to reach the surfaces of the materials to be sterilized (repeated diffusion phase).
9. Evacuation of the chamber.
10. Generation of plasma. Hydrogen peroxide decomposes into water and oxygen.
11. Chamber aeration to atmospheric pressure and subsequent release of the door.

Program selection:

Easy program

- Sterilizer temperature: max. 60 °C
- Program time: 40 min

Typical sterilization materials

- Rechargeable batteries
- Telescopes
- Laryngoscope spatula

Classic program

- Sterilizer temperature: max. 60 °C
- Program time: 50 min

Typical sterilization materials

- Cameras
- Illumination equipment (lamps, cables)
- Probes (laser probes, Doppler, flow sensors)
- Flexible and rigid endoscopes with the following lumen properties:

Rigid lumen:

- Diameter: 1 - 3 mm
- Length: max. 500 mm
- Loading quantity: max. 15

Flexible lumen:

- Diameter: min. 1 mm
- Length: max. 1000 mm
- Loading quantity: max. 15



Observe the maximum loading quantity for instruments with lumen. To not load any further sterilization items into the sterilizer.

Complex program

- Sterilizer temperature: max. 60 °C
- Program time: 60 min

Typical sterilization materials

- Flexible and rigid endoscopes with the following lumen properties:

Rigid lumen:

- Diameter: 1 - 3 mm
- Length: max. 600 mm
- Loading quantity: max. 15

Flexible lumen:

- Diameter: min. 1 mm
- Length: max. 2000 mm
- Loading quantity: max. 15

Observe the maximum loading quantity for instruments with lumen. To not load any further sterilization items into the sterilizer.

The load configuration, ambient temperature, among other things, can affect the program run time.

2.7.1 Self-test (vacuum test)

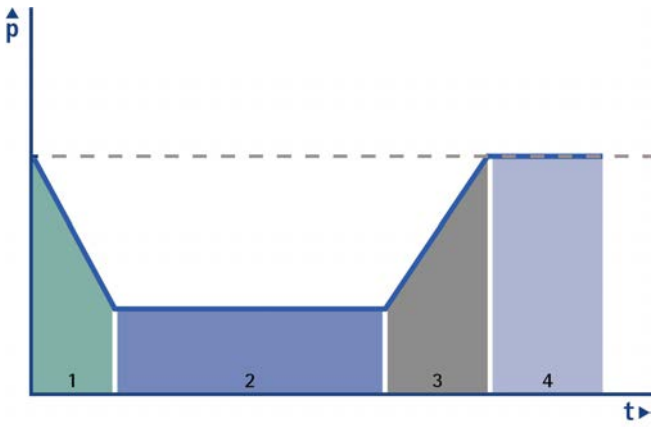
No sterilization program!

Test program with for automatically testing the chamber for leaks and for checking the functioning of the vacuum pump. The vacuum test detects any leaks that exist within the device.

The process is pressure-regulated and time-controlled.

The “Vacuum test” program class does not involve a sterilization program.

The sequence is characterized by the following elements:



1. Evacuation of the chamber
2. Test time 5 minutes
3. Chamber aeration to atmospheric pressure
4. Waiting for door opening

During the evacuation phase, the attainment of three process-relevant vacuum switching points at specific times is checked.

On failure of the vacuum test, the message *Last vacuum test not passed* is shown and the red LED strip lights.

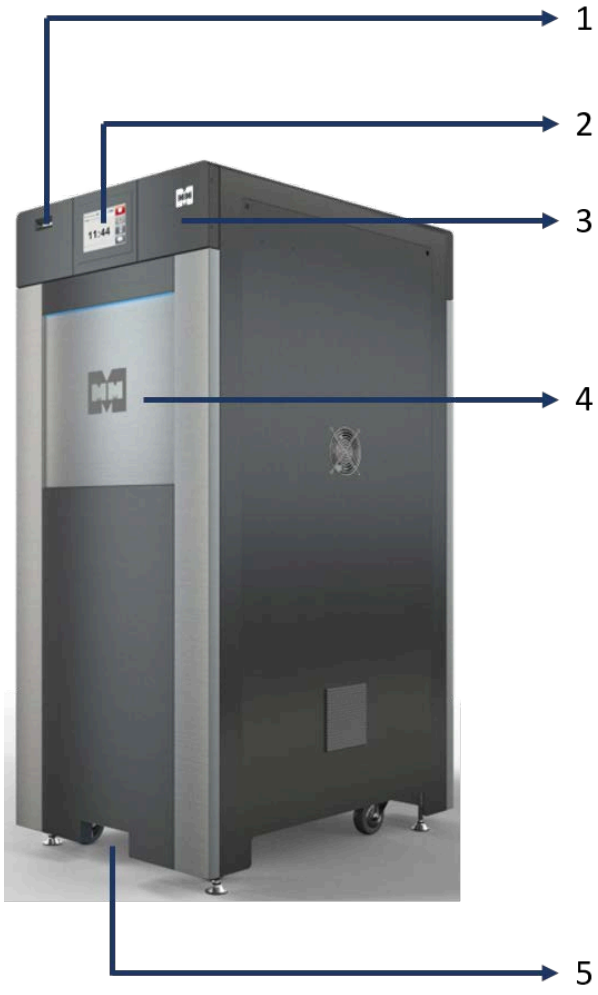
If the cycle is repeatedly not passed, the machine must be checked by a qualified person (preferably MMM customer service) and repaired if necessary. The vacuum test must then be run again.



MMM recommends performing the self-test daily before the first sterilization run/ cycle.

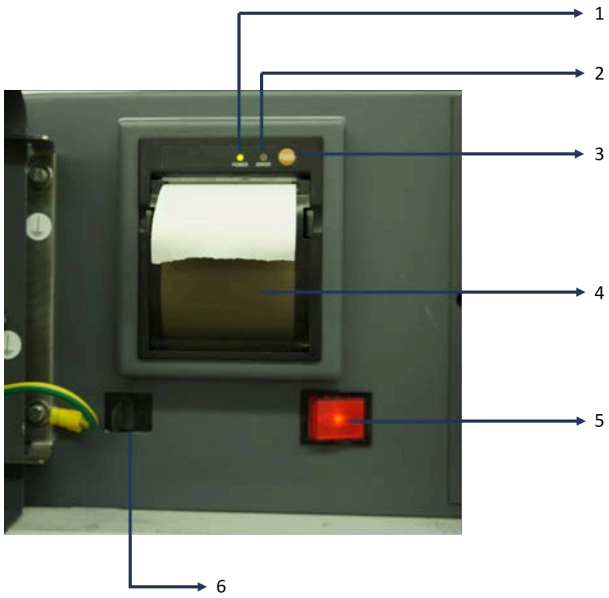
3 Display and control elements

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



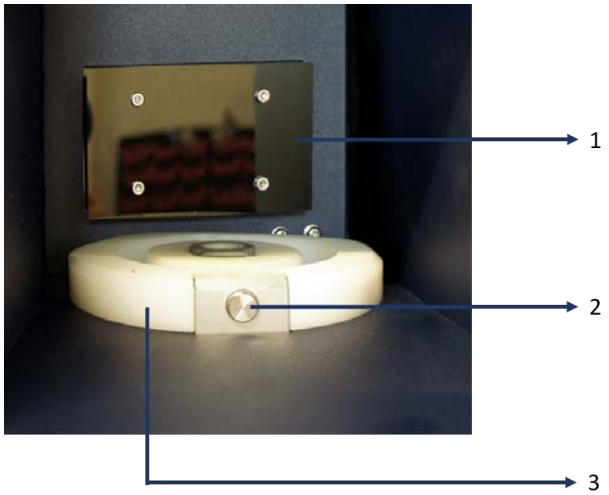
1. Thermal plotter compartment
2. Touch screen
3. H_2O_2 compartment
4. Chamber
5. Door opening sensor

Thermal plotter compartment



1. Power supply indicator
2. Error notification indicator
3. Advance button
4. Thermal paper compartment
5. Sterilizer mains switch
6. USB slot

H_2O_2 compartment

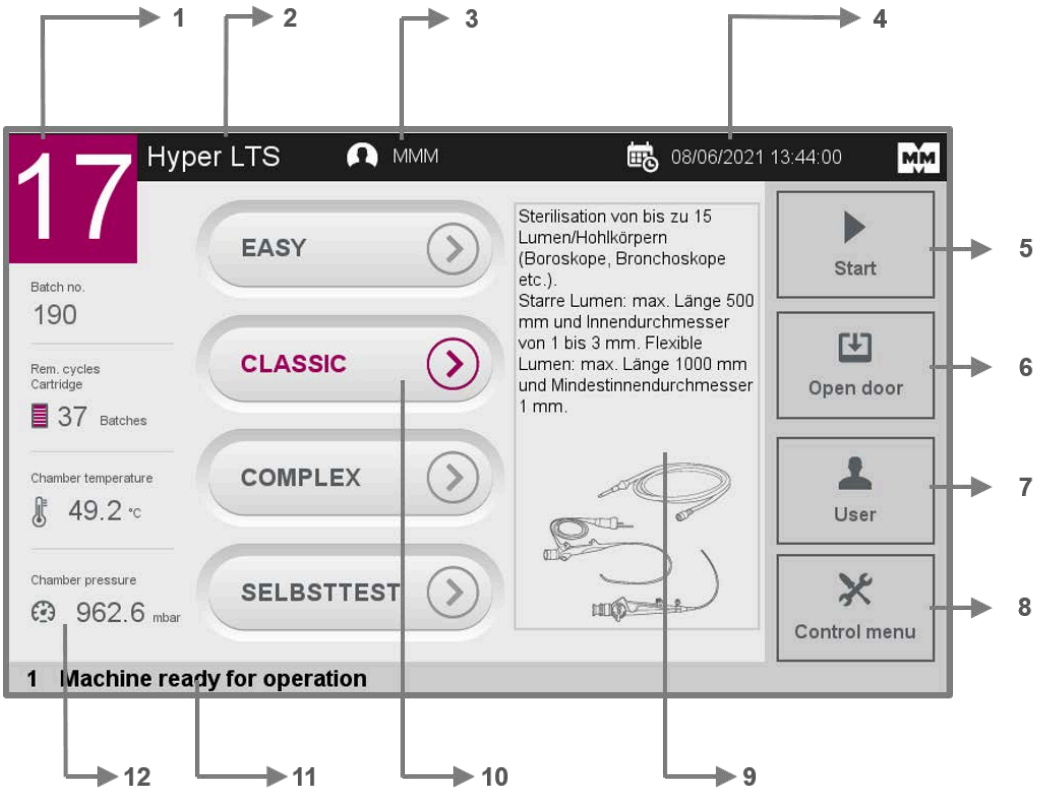


1. RFID reader
2. Unloading button
3. Docking mechanism for the H_2O_2 cartridge

3.1 Color touch screen

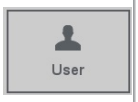
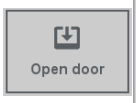
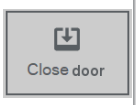
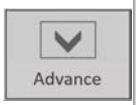
The machine is equipped with a color touch screen. Pressing the buttons and screen buttons executes the stored functions. The touch screen can be operated with gloves or a corresponding tool.

Function overview



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

Function buttons on 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.
6		Opening the door	Opens the chamber door.
		Close the door	Closes the chamber door.
8		Control menu	Opens the Control menu.
		Cancel program	Cancels the current program.
		Acknowledgment button	Acknowledges all messages.
		Advance cycle	Advance cycle to the next program step.
		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 Colored status displays

The colors of the LED strip on the chamber have the following meaning:

Overview of status indicator functions

Color	Designa-tion	On	Off	Flashing
Blue	Ready for operation	Machine is ready for operation	Machine is not ready for operation	Program completed successfully
White	In opera-tion	Program running	No program running	
Red	Fault	Fault	No fault	

4 Operation

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

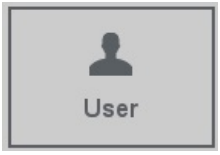
All activities described below must only be carried out by suitably trained persons.

4.1 Logging users in and out

Log-in is not required for normal operation.

If the **User Manager** (Chapter 2.5, "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.

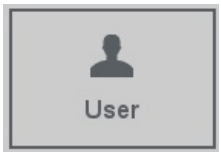
After log-in, the corresponding user name (e.g. “S”) appears in the title bar.

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

Proceed as follows when starting up the low temperature hydrogen peroxide steriliser each day:

- Perform the prescribed maintenance tasks.
- Press the mains switch

⇒ The machine starts with a warm-up program that runs for at least 5 minutes. No operator actions can be performed during the warm-up phase. The required temperature for the chamber and doors is maintained until the machine is switch off.

⇒ After the warm-up phase, the machine is ready for operation. The program selection menu appears with the message *Device is ready for operation*.

To avoid the chamber cooling down, the chamber door must be kept closed whenever the machine is not being loaded or unloaded.

MMM recommends performing the self-test daily.

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 to prevent the formation of hydrogen peroxide residues after low temperature sterilization.

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.

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. 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.



When moving the racks, makes sure they are not dragged or pushed across shelves or the like.

To avoid damaging the packaging, always lift the racks when moving them.



Use packaging that is suitable for hydrogen peroxide sterilization (e.g. Tyvec).

Observe the instructions of the packaging manufacturer and the intended use of the sterilizer.

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.
- Biological indicators: Biological indicators can be enclosed with the sterilization goods before sterilization. These indicate the lethality of the sterilization process. We recommend checking the sterilization process at least once a week using biological indicators. If the number of cycles is high (e.g. several loads per day), we recommend performing this check on a daily basis or, when sterilizing implants, every cycle. Implants should only be used after a negative test result.

Use multiple indicators to identify false positive or false negative results.

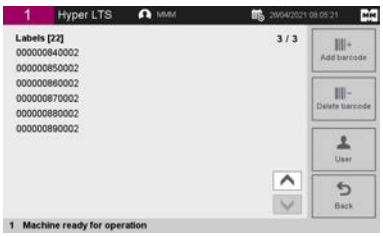
National regulations/guidelines must be observed for the use of indicators.

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 on the title bar.

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 **Control menu** button.



- Press the **Barcodes** button.



- Press the **Add barcode** button.
- Enter the barcode details.
- Confirm the entry with the green tick.

Barcode transfer failure

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

Deleting barcodes

Individual or multiple barcodes that have already been scanned can be deleted.



- Press the **Control menu** button.



- Press the **Barcodes** button.



- First select the desired barcode then press the **Delete barcode** button to delete that barcode only.
- To delete all entered barcodes, press the **Delete barcode** button with no barcodes selected.
- Confirm the entry with the green tick.

4.3.3 Loading the sterilization chamber

The sterilization chamber is loaded manually.

Hydrogen peroxide residues may be present inside the sterilization chamber.



Wear chemical-resistant protective gloves made from latex, PVC or nitrile 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.

The process involves surface sterilization. For porous goods and materials with a very large surface (e.g. fabrics), this can have a negative effect on the sterilization result.

Also make sure that the items to be sterilized are made from the materials listed in Chapter 1.2.1, "Intended use of Hyper LTS". If you do not know what material the items are made from, follow the recommendations of the medical device manufacturer regarding what sterilization is suitable.



Items made from cellulose (plant-based or synthetic cellulose), in particular, are not suitable for sterilization with the Hyper LTS.



- Open the door on the loading side using the Open door button or the foot sensor.
- Place the packaged sterilization goods into the chamber.



The total weight of the material to be sterilized per mesh should not exceed 10 kg.



Do not slide or pull the material to be sterilized beyond the lateral edges of the top mesh.

Always carefully lift up and put down the material to be sterilized to avoid damaging the sterile goods packaging.



▶ Close the door on the loading side.

4.3.4 Program selection and program start

Program selection



▶ 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.

Program start



▶ 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 following information is displayed in the dashboard view:

- Program name
- Cycle number of the current cycle
- Current process step
- Time remaining to the end of the cycle
- Remaining time of the current process step
- Remaining cycles for H_2O_2 cartridge
- Chamber pressure (registered)
- Chamber temperature (registered)

Online process curve



The **Change view** button in the dashboard view can be used to switch to the online process curve.

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

If the process takes longer than one hour, the pages of the graphic can be turned by clicking on the left or right half of the screen.

For detailed information about the process run, select the i symbol at the bottom left edge of the screen.

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

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 H_2O_2. This may take several minutes 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.

4.3.6 Program end

Once a sterilization program has been properly completed, the message *Remove* appears on the display and the door buttons on the unloading side are activated.

On two-door devices, the door on the unloading side can be opened and closed as many times as desired, until the loading door has been opened once.

The door on the loading side can only be opened once the door on the unloading side has been opened and closed again.

4.3.7 Unloading the sterilization chamber

The sterilization chamber is unloaded manually.

Hydrogen peroxide residues may be present inside the sterilization chamber.



Wear chemical-resistant protective gloves made from latex, PVC or nitrile and safety glasses when working on the sterilization chamber.



▶ Open the door on the unloading side using the Open door button or the foot sensor.



Escape of H_2O_2 residues!

Wear chemical-resistant protective clothing when opening the chamber door.

For your personal protection, stand to the side of the chamber when opening the chamber door.

Do not inhale any escaping vapors when opening the door.

- Remove the sterilization goods from the chamber.

Do not slide or pull the material to be sterilized beyond the lateral edges of the top mesh.

Always carefully lift up and put down the material to be sterilized to avoid damaging the sterile goods packaging.

- Check the sterilization goods and their packaging for integrity and H_2O_2 residues.
- 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.

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 (for details, see Chapter 2.6, "Cycle documentation").

- 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.



When using the half cycle feature, the cycle report may indicate proper cycle completion.

The medical device should not, however, be regarded as sterile when the half cycle feature is used.

The cycle should not be released in this case.

- 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.



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 20 cycle files stored on the machine can be shown on the display and reprinted.



- Press the **Control menu** button.



- Press the **Cycle archive** button.

The last 20 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).

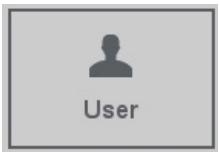
- Press the *Load selected cycle* button to view additional information (e.g. program name, cycle times etc.).
- Press the *Printer* button to print the displayed cycle.

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").

4.4.2 External saving of cycle files

The last 20 cycles stored in the machine can be copied to a USB stick.

This function can only be performed if no program is active.



- Log in as the supervisor.



- Press the **Maintenance** button.



- Press the **Archive Cycles** button.

A list of the last 20 saved cycles is displayed.



- Press the **USB Export** button to copy the last 20 cycle files to the USB stick.

4.5 Installing / replacing the H_2O_2 cartridge

Unpacking the H_2O_2 cartridge



Risk of acid burns!

Do not use the cartridge if the packaging is damaged. Please get in touch with your contact for further clarification.

- First put on your personal protective equipment.

  This includes as a minimum chemical-resistance gloves, closed shoes, and safety goggles. Gauntlets or a long-sleeve laboratory coat can also be worn if required.

- Remove the H_2O_2 cartridge from the blister packaging and check for integrity (e.g. no cracks in the plastic).

Installing a new H_20_2 cartridge



Risk of acid burns!

Concentrated hydrogen peroxide can cause burns to the skin, eyes, nose, throat, lungs and the gastrointestinal tract!

Wear chemical-resistant protective gloves made from latex, PVC or nitrile when working on the sterilizer!

- Check the new cartridge for integrity.



- Open the H_2O_2 compartment. The compartment is located behind a flap at the top right on the front side of the machine.



- Insert the cartridge in the compartment with the notch in the docking mechanism so that the notch at the bottom edge (image) faces towards the operator, and the RFID code of the cartridge faces towards the sterilizer.
- Press down on the cartridge until it engages. A key-lock principle ensures that it cannot be inserted incorrectly

- Close the H_2O_2 compartment.

⇒ You can now start a sterilization program.

One H_2O_2 cartridge is sufficient for 15 cycles. An RFID reader records the number of cycles since the cartridge was installed. This and other information about the H_2O_2 cartridge can be viewed in the controller of the sterilizer.

The cartridge has a shelf life of 40 days from first use in the sterilizer, regardless of whether it is removed from the machine during that time. If an expired cartridge is installed or a cartridge has been in use for longer than 40 days, an alarm (90) is displayed on the sterilizer and program start is prevented.

Replacing the H_2O_2 cartridge

If an empty or expired H_2O_2 cartridge is installed, this is detected via an RFID reader. A message (90) appears on the display of the sterilizer. The cartridges must then be exchanged as follows:



Risk of acid burns!

Concentrated hydrogen peroxide can cause burns to the skin, eyes, nose, throat, lungs and the gastrointestinal tract!

Wear chemical-resistant protective gloves made from latex, PVC or nitrile when working on the sterilizer!

- Open the H_2O_2 compartment.
- Press the unloading button on the docking mechanism at the bottom of the H_2O_2 compartment.

⇒ The H_2O_2 cartridge can now be released from the docking mechanism.

- Remove the empty or expired H_2O_2 cartridge.
- Place the cartridge in a sealable, tearproof plastic bag and dispose of it properly see Chapter , "Disposal".
- Proceed as described under "Installing a new H202 cartridge" .

4.6 Standby mode

The **standby mode** is initiated automatically after a configured time has elapsed (Chapter 5.5, "Activating standby mode ").

This function can also be actively initiated.



- Press the **Maintenance** button.



- Press the **Service** button.



- Press the **Start standby mode** button.

The device immediately switches to standby mode. The MMM logo and the message *Standby mode active* appears in the display.

The heating elements of the machine are switched off.

4.7 Shut-off

The machine is switched off using the mains switch. In normal operation, the mains plug remains plugged in.

- 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.

For the UPS option:

If the machine is equipped with the UPS option, a dialog window “UPS active” appears after pressing the mains switch.

- Confirm the dialog button using the tick button to shut down the machine.

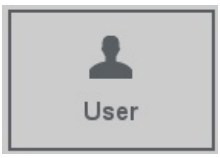
If you confirm the dialog using the cross button, the machine is not shut down.

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 **Control menu** button.

The control menu appears.



5.1 Configuration User Manager (option)

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

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

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



▶ 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.



- Save the entry.

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.

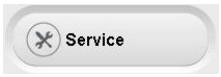
5.2 Configuring the cycle print and save option

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.
- 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.

Thermal printer

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

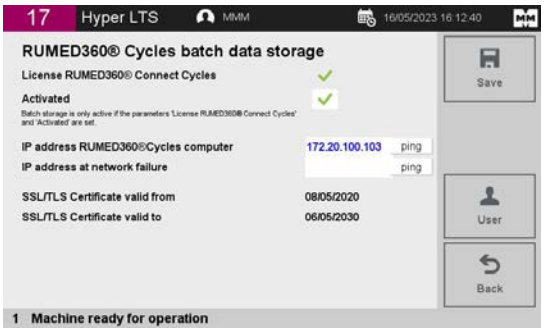
Printing via PC

- *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 **Ext. cycle saving** button in the service menu.



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



- Save the entry.



- The connection to this IP address can be tested by pressing the ping button.

⇒ A ping command is sent to the specified IP address. The result of the ping command is displayed.

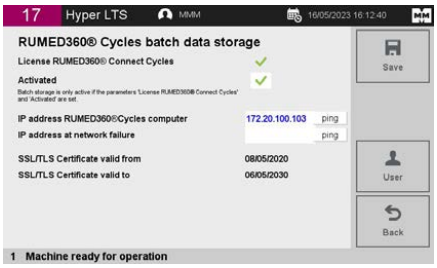
The following results may be displayed:

- *The ping command is executed. Please wait*
  The command is still active. Wait until it has finished.
- *Ping successful.*
  The network connection was successfully tested.
- *No response received.*
  No connection to the specified IP address. Check the cable, network settings, etc.
- *Destination cannot be resolved.*
  Check the network settings.
- *No free socket.*
  All network resources are already allocated. If no program is active, restart the machine and try again.
- *Command blocked by firewall.*
  The configured firewall rules do not allow a ping command. Check the firewall rules in the Service menu.

Saving the cycle data in case of a network outage



▶ Press the **Ext. cycle saving** button in the control menu.



▶ Enter the *IP address in case of a network outage*.



▶ Save the entry.

⇒ You can switch between the standard and alternate connection in the control menu.

⇒ The button setting is retained after a restart.



▶ The connection to this IP address can be tested by pressing the ping button.

⇒ A ping command is sent to the specified IP address. The result of the ping command is displayed.

5.3 Setting the network addresses of the control panel

TCP/IP configuration

The network settings must be input for every control panel.

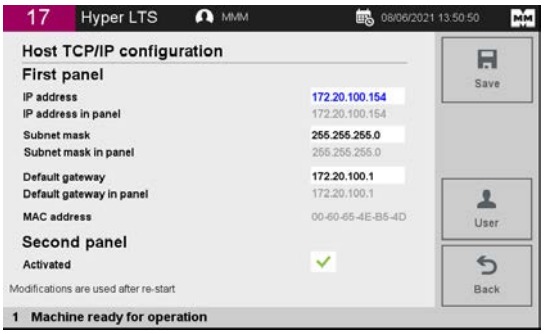
Consult the network administrator of your IT department for the IP addresses.



- 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.



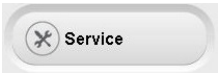
- Save the entry.

All fields must always be correctly populated.

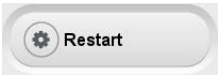
If there is no default gateway, a valid IP address is still required.

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

5.4 Activating automatic restart



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

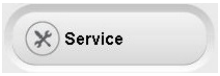


- Press the **Restart** button.
- Confirm the prompt regarding whether to perform a restart.

⇒ The machine is restarted.

5.5 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 **Parameter** 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.



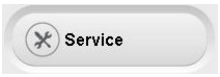
- Save the entry.

5.6 Activating half cycle mode



The half cycle mode is suitable for testing purposes only.

The material to be sterilized must be regarded as unsterile.



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

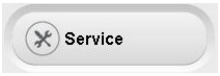


- Press the **Half Cycle Mode** button.

⇒ An informational message appears in the message bar.

5.7 Graphics settings

Setting the line thickness of curves on the graphic display



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



- Press the **Parameters** button.
- Enable the **Thick Lines** parameter.



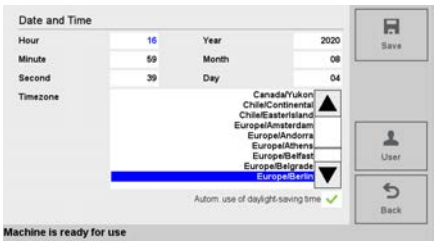
- Save the entry.

5.8 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.

5.9 Calibrating the screen

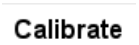
A calibration may be necessary if the operator controls on the screen do not respond.



- Press the **Service** button.



- Press the **Screen** button.



- Press the **Calibrate** button.

  Several cross-hairs appear in succession.
- Touch them as precisely as possible.

6 Operating safety and faults

Safety-related equipment

The machine is equipped with safety and monitoring equipment to enable safe operation when used as intended.

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

An appropriate status or alarm message is displayed. If several messages are generated at the same time, they are displayed one after the other.

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



Note!

Observe the instructions in see Chapter 1, "Safety"

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

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

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

6.1 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 1.7, "Machine safety devices")
- The program cancellation button was pressed
- the power supply was interrupted due to a power failure



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



The 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. *Evacuation, Plasma phase*...) are initiated to bring the machine into a safe state. This may take several minutes. The door on the loading side can be opened during the *Remove* process step.

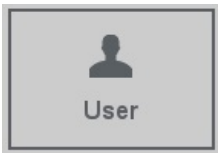
- Acknowledge the message.

After a power failure

The necessary process steps (e.g. *Evacuation, Plasma phase*...) are initiated to bring the machine into a safe state. This may take several minutes. The door on the loading side can be opened during the *Remove* process step.

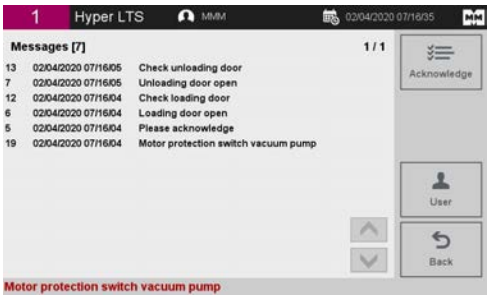
6.2 Acknowledging messages

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.

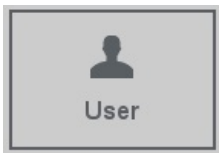


The messages are displayed with alarm number, the time the alarm occurred, and the alarm description.

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



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



- Log out again.

6.3 Faults in door movement

If a fault occurs in the door movement when opening or closing, the causes may be the following:



Risk of injury!

The chamber doors must not be opened by force!

Chamber door on opposite side opened

According to the door logic, only one door can normally ever be opened. The message *Loading door opened* or *Unloading door opened* appears.

- Close this door.

Program sequence failed

If the program sequence is incorrect, the message *Door can be opened after acknowledgment* appears.

- Acknowledge the message

Chamber under vacuum

The chamber door cannot be opened until the chamber has been aerated to atmospheric pressure.

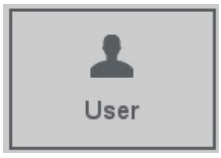
- Inform MMM customer service or a company/person authorized by MMM.

6.4 Manual advance

The program can be manually advanced for test purposes.

Manual advance assumes detailed knowledge of the functioning and principle of operation of the machine and must therefore only be performed by suitably trained persons (see Chapter 1.4, "Operators").

- Switch from the dashboard view to the *On-line process flow chart* view.



- Log in as the supervisor.



- Press the *Advance* button.

- Press the right-hand arrow to scroll to the next process step.
- Press the OK button to exit the dialog.

Advancing is not possible in some process steps.

In the *Unloading* process step, the messages *Cycle manually advanced* and *Please acknowledge* are displayed.

- Acknowledge the message.



The process is regarded as failed!
The material to be treated must be regarded as not sterilized.



Run an empty cycle prior to further operation.

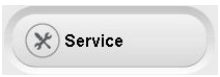
6.5 Analysis options in the event of faults

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.

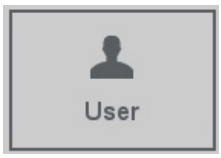
If the green lamp next to the hardware name is lit, the input is active or the output actuated.

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.

Instrumentation diagram view

To check the function, it is also possible to display the instrumentation diagram on the screen in order to observe the status of the individual machine components.



▶ Log in as the supervisor.

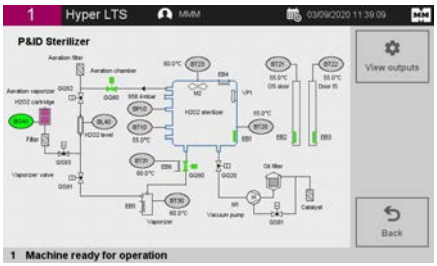


▶ Open the Control menu.



▶ Press the **Instrumentation diagram** button.

The system instrumentation diagram appears on which it is possible to observe the status of the individual machine components.



Sterilizer instrumentation diagram

6.5.1 Viewing the cartridge information of the RFID reader



▶ Press the **Maintenance** button.



- Press the **H_2O_2 cartridge** button.

⇒ An information page about the H_2O_2 cartridge appears with the following contents:

- Date of manufacture and expiry date
- First and last use
- “Usable until” in days
- Country code
- H_2O_2 concentration
- Capacity and remaining capacity
- Model
- Batch ID and serial number
- RFID card serial number

6.5.2 Function check for specific components

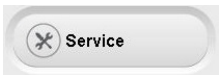
The following function checks can be performed without having to start a program. The machine must be *ready for operation*.

- LED chamber / foot sensor
- Vacuum pump
- Thermoplotter



On the loading side:

▶ Open the **Control menu**.



▶ Press the **Service** button.

Function check of the chamber LED strip



▶ Press the **Chamber LED** button.

The colored status indicators on the chamber switch on and off alternately.

Function check of the foot sensor LED strip



▶ Press the **Foot sensor LED** button.

The foot sensor LED switches on and off alternately.

Vacuum pump function check



▶ Press the **Pumps** button.

The vacuum pump is now switched on for 10 seconds.

Function check of the printer



▶ Press the **Test page** button.

The printer prints out a test page.

6.6 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.

Meaning of the abbreviations used in the following:

RL Red door indicator
A Display
D Printed in cycle documentation
SV Start prohibition
PA Program canceled
AT Audit trail
Q Confirmation required

No.	Message	Trigger	RL	A	D	SV	PA	AT	Q	Note for operators
1	Machine ready for operation	Ready for operation pending.		x						The machine can be used for sterilization.
2	Standby mode active	The standby mode activation time has expired.		x		x				The machine goes into standby mode and the heater (the highest consumer of energy in percentage terms) is switched off.
3	Machine is warming up	Machine is warming up.		x		x				The machine will only switch to ready for operation mode once the required temperature is reached.
4	Power failure	Program active when switched off.	x	x	x	x	x	x	x	The material must be regarded as unsterile.
5	Please acknowledge	At least one alarm requiring confirmation is active.	x	x		x				Acknowledge the alarm on the screen.
6	Loading door open	The BG11 limit switch reports that the loading door is no longer closed. No program is active.		x		x				
7	Unloading door open	The BG13 limit switch reports that the unloading door is no longer closed. No program is active.		x		x				

No.	Message	Trigger	RL	A	D	SV	PA	AT	Q	Note for operators
8	Fault in loading door limit switch during program	The BG11 limit switch reports that the loading door is no longer closed. A program is active.	x	x	x	x	x	x	x	Respiratory distress due to escape of H_2O_2! Inhaling hydrogen peroxide can lead to irritation of the airways and respiratory distress! Leave the room immediately! Contact MMM customer service.
9	Unloading door open during cycle run	The BG13 limit switch reports that the loading door is no longer closed. A program is active.	x	x	x	x	x	x	x	Respiratory distress due to escape of H_2O_2! Inhaling hydrogen peroxide can lead to irritation of the airways and respiratory distress! Leave the room immediately! Contact MMM customer service.
10	Time exceeded loading door	The loading door is moving for too long - The Open door button was pressed and the digital input BG111 was not received within the tolerance time - The Close door button was pressed and the digital input BG11 was not received within the tolerance time	x	x		x		x		Check if there are objects in the door that are blocking it.

No.	Message	Trigger	RL	A	D	SV	PA	AT	Q	Note for operators
11	Time exceeded unloading door	The unloading door is moving for too long - The Open door button was pressed and the digital input BG131 was not received within the tolerance time - The Close door button was pressed and the digital input BG13 was not received within the tolerance time	x	x		x		x		Check if there are objects in the door that are blocking it.
12	Check loading door	The BG11 and BG111 limit switches are activated at the same time.	x	x		x		x		
13	Check unloading door	The BG13 and BG131 limit switches are activated at the same time.	x	x		x		x		
14	Safety strip on the loading side actuated	The loading door is currently closing and the safety strip was actuated.	x	x						
15	Safety strip on the unloading side actuated	The unloading door is currently closing and the safety strip was actuated.	x	x						
16	Door can be opened after acknowledgment	Program end of a failed program. The OS door can only be opened after acknowledging the alarm.		x						The material must be regarded as unsterile.
17	Chamber pressure at program start outside tolerance	The chamber pressure at program start is less than 600 mbar or greater than 1100 mbar.		x		x				
18	Program interruption by operator	An operator pressed the Cancel program button during a program.	x	x	x	x	x	x	x	The material must be regarded as unsterile.

No.	Message	Trigger	RL	A	D	SV	PA	AT	Q	Note for operators
19	Vacuum pump motor protection switch	The vacuum pump motor protection switch has triggered.	x	x	x	x	x	x	x	
20	Pressure transducer BP10 defective	An alarm was activated due to a wire break, a lower limit not being reached, or an upper limit being exceeded.	x	x	x	x	x	x	x	
21	Pressure transducer BP11 defective	An alarm was activated due to a wire break, a lower limit not being reached, or an upper limit being exceeded.	x	x	x	x	x	x	x	
22	Pressure transducer BPRef defective	An alarm was activated due to a wire break, a lower limit not being reached, or an upper limit being exceeded.	x	x	x	x	x	x	x	
23	Temperature probe BT10 defective	An alarm was activated due to a wire break, a lower limit not being reached, or an upper limit being exceeded.	x	x	x	x	x	x	x	
24	Temperature probe BT11 defective	An alarm was activated due to a wire break, a lower limit not being reached, or an upper limit being exceeded.	x	x	x	x	x	x	x	
25	Temperature probe BT20 defective	An alarm was activated due to a wire break, a lower limit not being reached, or an upper limit being exceeded.	x	x	x	x	x	x	x	
26	Temperature probe BT21 defective	An alarm was activated due to a wire break, a lower limit not being reached, or an upper limit being exceeded.	x	x	x	x	x	x	x	

No.	Message	Trigger	RL	A	D	SV	PA	AT	Q	Note for operators
27	Temperature probe BT22 defective	An alarm was activated due to a wire break, a lower limit not being reached, or an upper limit being exceeded.	x	x	x	x	x	x	x	
28	Temperature probe BT23 defective	An alarm was activated due to a wire break, a lower limit not being reached, or an upper limit being exceeded.	x	x	x	x	x	x	x	
29	Temperature probe BT30 defective	An alarm was activated due to a wire break, a lower limit not being reached, or an upper limit being exceeded.	x	x	x	x	x	x	x	
30	Chamber pressure transducer difference too high		x	x	x	x	x	x	x	
31	Temperature probe difference too high		x	x	x	x	x	x	x	
32	Last vacuum test failed	The last vacuum test was not passed.		x	x			x		
33	Position of vacuum valve incorrect	Valve actuation not same as valve feedback	x	x	x	x	x	x	x	Valve actuation not same as valve feedback. The valve setting of GQ20 can, if no program is running, be set manually (yellow lever). You can then check whether the feedback on the display, GQ20O (open) or GQ20C (closed) (hardware) is consistent.
34	Cycle manually advanced	The operator advanced the process to the next step by pressing the Advance button.	x	x	x	x		x	x	The material must be regarded as unsterile.
35	Parameter has been changed	Program, global or machine parameters were changed during a program.		x	x	x		x	x	The material must be regarded as unsterile.

No.	Message	Trigger	RL	A	D	SV	PA	AT	Q	Note for operators
36	Perform preventive maintenance	The preventive maintenance counter is zero.		x	x			x		Due to reasons of operating safety, reliability and economy, the machine must be regularly maintained.
37	Integrated printer is defective	The integrated printer is currently printing. This message is displayed while printing is active.		x						
38	Integrated printer: Paper has run out	No paper in the integrated printer or the cover of the integrated printer is open.	x	x	x	x		x		see Chapter 7.4, "Thermal printer paper exchange"
39	Printing failed	Direct printing to the network printer has failed.	x	x		x		x	x	
40	DEBUG ACTIVE! Not production software!	The software is a test version that is not intended for production use.		x						
41	Chamber temperature too low		x	x	x	x		x	x	
42	Chamber temperature too high	The chamber temperature measured by BT10 is too high.	x	x	x	x		x	x	
43	Position of injection valve incorrect	Valve actuation not same as valve feedback	x	x	x	x	x	x	x	The valve setting of GQ90 can, if no program is running, be set manually (yellow lever). You can then check whether the feedback on the display, GQ90O (open) or GQ90C (closed) (hardware) is consistent. Please note: GQ90 was installed rotated by 90°, so the details on the valve are incorrect.

No.	Message	Trigger	RL	A	D	SV	PA	AT	Q	Note for operators
44	Local cycle storage failed	Saving of cycle files to the local storage medium in the controller failed.	x	x		x		x	x	
45	Network batch storage failed	Transfer of cycle files to SimServ failed.	x	x				x	x	
46	Network printing failed	Transfer of print job to SimServ failed.	x	x				x	x	
47	Caution: No sterilization program	The currently running program is not a sterilization program.		x						The material must be regarded as unsterile.
48	Integrated printer: Printing failed	Printing of the cycle on the integrated printer has failed.	x	x				x	x	see Chapter 4.4.1, "Displaying and printing saved cycle records"
52	Both doors open	An operator pressed the button for opening both machine doors.		x		x		x		
57	Please insert serial number of the machine	No serial number is recorded in the machine parameters.	x	x		x				
58	Manual setting of digital outputs active	Setting of digital outputs was activated in the Service menu.		x		x				
59	Cycle processing failed	Error serializing the cycle.	x	x		x		x	x	
60	Cycle creation failed	Error creating cycle data.	x	x		x	x	x	x	
62	Vaporizer too cold	The target temperature of the heated element was reached but then dropped below the alarm temperature.	x	x		x		x	x	
63	Loading door too cold	The target temperature of the heated element was reached but then dropped below the alarm temperature.	x	x		x		x	x	

No.	Message	Trigger	RL	A	D	SV	PA	AT	Q	Note for operators
64	Unloading door too cold	The target temperature of the heated element was reached but then dropped below the alarm temperature.	x	x		x		x	x	For single-door machines, the heater on the rear wall of the sterilizer is affected.
65	Chamber too cold	The target temperature of the heated element was reached but then dropped below the alarm temperature.	x	x		x		x	x	
66	Chamber fan too cold	The target temperature of the heated element was reached but then dropped below the alarm temperature.	x	x		x		x	x	
67	Vacuum test evacuation 1 taking too long	The time required to reach the first vacuum switching point during the vacuum test is longer than the configured time plus tolerance time.	x	x	x	x	x	x	x	
68	Vacuum test evacuation 2 taking too long	The time required to reach the second vacuum switching point during the vacuum test is longer than the configured time plus tolerance time.	x	x	x	x	x	x	x	
69	Vacuum test evacuation 3 taking too long	The time required to reach the third vacuum switching point during the vacuum test is longer than the configured time plus tolerance time.	x	x	x	x	x	x	x	
70	Vacuum test pressure increase during test time too high	The pressure increase during the test time for the vacuum test is higher than allowed.	x	x	x	x	x	x	x	

No.	Message	Trigger	RL	A	D	SV	PA	AT	Q	Note for operators
71	Evacuation: First evacuation taking too long	The first evacuation during the Evacuation 1, 2 or 3 step of a H_2O_2 program is taking longer than the configured time plus the tolerance time.	x	x	x	x	x	x	x	
72	Evacuation: Second evacuation taking too long	The second evacuation during the Evacuation 1 or 2 step of a H_2O_2 program is taking longer than the configured time plus the tolerance time.	x	x	x	x	x	x	x	
73	Evacuation: Third evacuation taking too long	The third evacuation during the Evacuation 1 or 2 step of a H_2O_2 program is taking longer than the configured time plus the tolerance time.	x	x	x	x	x	x	x	
74	Evacuation: Pressure increase taking too long	The time required to increase the chamber pressure to the pressure switching point during the Evacuation 1 or 2 step of a H_2O_2 program is longer than the configured time plus the tolerance time.	x	x	x	x	x	x	x	
75	Evacuation: Fill level BL40 has not decreased	The time for the H_2O_2 fill level in the dosing element to decrease during the Evacuation 1 or 2 step of a H_2O_2 program is longer than the configured time plus the tolerance time.	x	x	x	x	x	x	x	

No.	Message	Trigger	RL	A	D	SV	PA	AT	Q	Note for operators
76	Evacuation: Time exceeded for fill level BL40	The time required to reach the H_2O_2 fill level in the dosing element during the Evacuation 1 or 2 step of a H_2O_2 program is longer than the configured time plus the tolerance time.	x	x	x	x	x	x	x	
77	Injection: Pressure increase taking too long	The time required to reach the injection pressure during the Injection 1 or 2 step of a H_2O_2 program is longer than the configured time plus the tolerance time.	x	x	x	x	x	x	x	
78	Aeration/diffusion: Pressure increase taking too long	The time required to reach the diffusion pressure during the Aeration/Diffusion 1 or 2 step of a H_2O_2 program is longer than the configured time plus the tolerance time.	x	x	x	x	x	x	x	
79	Aeration: Pressure increase taking too long	During aeration before the end of the H2O2 program, the time required to reach the ambient pressure minus a pressure difference (global parameter) is longer than the configured time plus the tolerance time.	x	x	x	x		x	x	It is taking too long to reach the ambient pressure at the end of sterilization
81	No H_2O_2 cartridge installed	The H_2O_2 cartridge sensor reports that no cartridge is installed.	x	x	x	x	x	x	x	If there is a cartridge in the machine, remove it and install it again. The sensor may not have been pushed down far enough.
82	Wrong type of H_2O_2 cartridge	The RFID tag on the H_2O_2 cartridge is not of type Mifare Classic 1K.	x	x	x	x	x	x		

No.	Message	Trigger	RL	A	D	SV	PA	AT	Q	Note for operators
83	H_2O_2 cartridge authentication failed	It is not possible to authenticate the data on the RFID tag using the MMM keys.	x	x	x	x	x	x		
84	Cannot read H_2O_2 cartridge	The H2O2 cartridge has no RFID tag or the data on the RFID tag cannot be read.	x	x	x	x	x	x		
85	H_2O_2 cartridge with invalid data version	The MMM data version on the RFID tag of the H_2O_2 cartridge is invalid.	x	x	x	x	x	x		
86	H_2O_2 cartridge with invalid date	A date on the RFID tag of the H_2O_2 cartridge has errors: - Day is 0 or greater than 31 - Month is 0 or greater than 12 - Year is less than 2019 or greater than 2100	x	x	x	x	x	x	x	
87	H_2O_2 cartridge with invalid data	The cartridge capacity value or the remaining cartridge capacity value on the RFID tag of the H_2O_2 cartridge has errors: - Cartridge capacity is less than 3.0 or greater than 50.0 - Remaining capacity is less than the cartridge capacity	x	x	x	x	x	x		
88	Cannot write to H_2O_2 cartridge	An error occurred while writing data to the RFID tag of the H_2O_2 cartridge.	x	x	x	x	x	x		
89	H_2O_2 cartridge has expired	The current date is later than the expiry date of the H_2O_2 cartridge.	x	x	x	x	x	x		

No.	Message	Trigger	RL	A	D	SV	PA	AT	Q	Note for operators
90	H2O2 cartridge has expired	The current date is later than the date of first use of the H2O2 cartridge plus the shelf life (default 40 days).	x	x	x	x	x	x		
91	No connection to cartridge reader	No connection to RFID reader.	x	x	x	x	x	x		
92	H_2O_2 cartridge is empty	The remaining cartridge capacity value stored on the RFID tag of the H_2O_2 cartridge is zero.	x	x	x	x	x	x		
93	H_2O_2 cartridge is being read	The digital input of the cartridge sensor has changed from 'low' to 'high' or a H_2O_2 program has finished or the date has changed.		x		x				
94	Injection valve too cold	The target temperature of the heated element was reached but then dropped below the alarm temperature.	x	x		x		x	x	
95	Half cycle mode active	An operator has pressed the button in the Service menu that activates half cycle mode.		x	x					The material must be regarded as unsterile.
96	Error correction value for pressure transducer	The value at the activated reference points did not increase.	x	x	x	x		x		
97	Error correction value for temperature sensor	The value at the activated reference points did not increase.	x	x	x	x		x		
98	Temperature probe BT31 defective	An alarm was activated due to a wire break, a lower limit not being reached, or an upper limit being exceeded.	x	x	x	x	x	x	x	
99	No connection to integrated printer	The connection to the integrated printer is disrupted or the printer has no power.	x	x		x		x		

No.	Message	Trigger	RL	A	D	SV	PA	AT	Q	Note for operators
100	Free cycle memory less than 20 Mbytes	This alarm is generated if there is less than 20 Mbytes of free space in the controller at the start of the “Unload” step.		x				x	x	
101	Vaporizer too warm	The target temperature of the heated element is above the upper alarm temperature.	x	x	x	x		x	x	
102	Loading door too warm	The target temperature of the heated element is above the upper alarm temperature.	x	x	x	x		x	x	
103	Unloading door too warm	The target temperature of the heated element is above the upper alarm temperature.	x	x	x	x		x	x	
104	Chamber too warm	The target temperature of the heated element is above the upper alarm temperature.	x	x	x	x		x	x	
105	Chamber fan too warm	The target temperature of the heated element is above the upper alarm temperature.	x	x	x	x		x	x	
106	Injection valve too warm	The target temperature of the heated element is above the upper alarm temperature.	x	x	x	x		x	x	
107	Pressure increase during sterilization too large	The increase in chamber pressure during sterilization is too high.	x	x	x	x	x	x	x	
108	Pressure drop during sterilization too large	Sterilization in a H_2O_2 program.	x	x	x	x	x	x	x	

No.	Message	Trigger	RL	A	D	SV	PA	AT	Q	Note for operators
109	Final preheating temperature too low	While actuating the fan during a H_2O_2 program, the chamber temperature did not reach the target temperature of at least 60.0 °C.	x	x	x	x		x	x	
110	Faulty barcode	A faulty barcode was read. Example: wrong length, wrong characters.		x		x			x	
111	Uninterruptible power supply active	The UPS detected a power outage.	x	x	x	x				
112	Supply voltage interrupted	▪ Power outage during a critical step: An alarm is triggered immediately ▪ Power outage during a holding phase: An alarm is triggered after 5 s (configurable)	x	x	x	x	x	x	x	
113	Machine restart required	A hardware configuration was selected in the Service menu.		x	x					

Note!

If the machine has not been used for more than 40 days, this may cause information such as the date and time to be reset. In this case please contact MMM customer service or persons or companies that have been authorized by MMM.

7 Maintenance

Observe the safety instructions in Chapter 1!

An inspection and safety maintenance (interval-based maintenance & inspection) must be carried out at least once a year. Observe the instructions in Chapter 1.9, "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.

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

The cycle counter continuously counts the cycles performed.

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

7.1 Installation

You can install the Hyper LTS as follows:

- Position the machine at the desired location with the help of the integrated rollers.

  A minimum clearance of 10 cm from the sides and rear, and 100 cm from the doors must be provided.

There must be sufficient space available to allow the side panel to be removed for machine maintenance, or to move the machine to a location with sufficient space using the installed wheels.

- Engage the brakes on the rollers and check to make sure that the rollers are locked.



Risk of injury!

Ensure that the machine is secure and cannot roll away in an uncontrolled manner before adjusting the feet.

- Turn the feet integrated into the housing out of the panel to the desired installation height.



Make sure that the machine is level.

We recommend using a spirit level to check the position.

- Connect the machine to the mains supply.



Install the machine in such a way as to ensure easy access to operate the isolator (unplug the power cable).

7.2 Preparatory measures

Observe the following points when performing maintenance work.



Risk of injury!

Pull out the mains plug when working on the machine.

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 1.4, "Operators") as specified by the manufacturer.

Vacuum pump



Drain the vacuum pump during extended downtimes.

When the machine is idle for long periods (longer than four weeks), the oil in the vacuum pump must be checked for discoloration before first operation.

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 an authorized operator (see Chapter 1.4, "Operators").



For more information on the individual maintenance tasks, refer to the service instructions of the sterilizer, which MMM specialists have access to.

Daily:

What	How	Result of check
Check safety strip	Check the function of the safety strip on both sides. When operational ▶ Close the door ▶ During the closing process, actuate the safety strip	The door must reverse and open again.
Check door seals	The seal is automatically tested for vacuum tightness by the maximum vacuum and leakage test. In case of leakage, check the silicone cord seal in the door and replace if necessary.	Self-test passed

Weekly:

What	How	Result of check
Clean the chamber	Clean the chamber thoroughly. The chamber must be cold. To do so, switch the machine off with the door open so the chamber can cool down. The chamber fittings at the bottom must first be covered to prevent foreign bodies from entering the pipe system (Chapter 7.5.1, "Chamber interior").	 **Risk of burns!** Allow the chamber to cool sufficiently beforehand.

After 6 months or 600 cycles:

Due to reasons of operating safety, reliability and economy, the machine must be regularly checked by a specialist (preferably MMM customer service). The result must be entered in the medical products log / equipment log.

The following maintenance work (Preventive Maintenance 1) is required after 6 months at the latest. Technical data subject to change without notice.

After logging on, the valves can be individually controlled. In the case of the BL40, the signal feedback can also be checked via the Service menu.



The following activities must be performed by a specialist (preferably MMM customer service, see Chapter 1.4, "Operators").

Use the PM1 Maintenance Kit for this maintenance work (MMM part no.: 10574001)

What	How
Catalyzer	Replace the catalyzer for the exhaust air of the vacuum pump.
Vacuum pump	Replace the oil in the vacuum pump . Perform the maximum vacuum and leakage test.  Escape of steam or smoke! Maintain the vacuum pump regularly to avoid malfunction.
Oil mist filter	Replace the oil mist filter.
Level sensor BL40	Check the BL40 level sensor.
Vacuum valve GQ20	Check the GQ20 vacuum valve.
Vaporizer aeration valve GQ92	Check the GQ92 aeration valve.

What	How
Chamber valve GQ90	Check the GQ90 chamber valve.
Chamber aeration valve GQ80	Check the GQ80 chamber aeration valve.
Oil vapor separator	Check the oil vapor separator.
RFID reader	Check the RFID reader.
Silicone tube	Check that the silicone tube of the dosing unit has no leaks and is seated securely.
Thermal printer	Check the thermal printer. Print out a test page see Chapter 6.5.2, "Function check for specific components"
Cable guide chain	Check the cable guide chain. ▶ Remove the front panel (and the rear panel also for two-door machines). ▶ Open and close the door and check the cable chain while doing so.
Door motor	Check the door motor.
Position switch	Check the position switch of the door(s).

After 12 months or 1200 cycles:

Due to reasons of operating safety, reliability and economy, the machine must be regularly checked by a specialist (preferably MMM customer service). The result must be entered in the medical products log / equipment log.

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

After logging on, the heaters can be individually controlled.



The following activities must be performed by a specialist (preferably MMM customer service, see Chapter 1.4, "Operators").

Use the PM2 Maintenance Kit for this maintenance work (MMM part no.: 10574002)

What	How
HEPA filter	Change HEPA filter. This is located above the chamber.
Vacuum seal	Replace the vacuum seal. This is located in the cover plate of the chamber, below the fan motor.
Quick coupling	Replace the quick coupling. It is located inside the cartridge compartment.

What	How
Manometer (see spare parts list no. 10574251)	Calibrate using a data logger (must be designed for low pressure range) .
Chamber heating	Check the chamber heating.  The heaters can be individually controlled for testing purposes.
Fan heater	Check the fan heater.
Heating strip	Check the heating strip.
Door heating	Check the door heating.
Fan motor	▶ Operate the fan motor. ▶ Check the movement.

Vacuum pump

Daily:

What	How	Result of check
Vacuum pump	Operate the vacuum pump with min. 1 h of gas ballast. Fulfilled if a vacuum test and 1 to 2 cycles are run each day.	Condensate is removed from the oil
Oil	Check the oil level and replace the oil if necessary. Visually inspect the oil quality and replace the oil if necessary.	The normal condition is light and transparent; replace oil if increasingly discolored. The oil level should be between 0.6 - 1.4 l.

After 6 months:

What	How	Result of check
Oil	Replace the oil after 100 hours of operation with the pump switched off and warm. Clean the oil sight glass using a cleaning agent and blow with compressed air.	The oil level should be between 0.6 - 1.4 l.

After 12 months:

What	How	Result of check
Oil	Replace the oil after 100 hours of operation with the pump switched off and warm. Clean the oil sight glass using a cleaning agent and blow with compressed air.	The oil level should be between the marks and therefore between 0.6 - 1.4 l.
Pump fan, motor fan and motor cooling fins	Check the pump fan, motor fan and motor cooling fins for contamination and clean if necessary using a brush and industrial vacuum cleaner.	Fan free of dust and contamination

7.4 Thermal printer paper exchange

Use thermal paper that can be archived for up to 10 years.

For trouble-free printing, we recommend ordering the paper from MMM (MMM part no.:010576494).



- Press the thermal printer compartment to open it.



- Press on both sides of the printer cover and pull it downwards.



- Remove the plastic part of the spent 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.



- Slide the printer cover back up until it engages. Make sure that a little paper is sticking out of the paper compartment.

- Press the feed button to check the paper feeding.

7.5 Cleaning

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

7.5.1 Chamber interior

Hydrogen peroxide residues may be present inside the sterilization chamber.



Risk of acid burns!

Concentrated hydrogen peroxide can cause burns to the skin, eyes, nose, throat, lungs and the gastrointestinal tract!

Wear chemical-resistant protective gloves made from latex, PVC or nitrile and safety goggles when working on the sterilization chamber.

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

This cleaning can be performed using a cloth moistened with distilled water. Dry the inner surfaces of the chamber well afterwards using a dry cloth.



The chamber must be clean and dry with no residues before performing a sterilization because residual hydrogen peroxide or residual distilled water can impair the sterilization process.

Local corrosive attacks (e.g. pitting) must be removed through mechanical or chemical processing. Depending on characteristics, such corrosive attacks may affect the safety of the pressure container and must be analyzed separately.



Material damage if corrosion treated incorrectly!

Corrosion must only be treated by suitably trained personnel.

7.5.2 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.

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

7.5.3 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 **Deactivate touchscreen** button.

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

8 Software Licence Agreement

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

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

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

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

Section 1 Definition

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

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

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

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

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

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

“**Updates**” shall mean software that corrects faults in an older version of the software or that, without implying any obligation under this contract to do so, enhances the functionality of the software by providing additional functions or any other increases in performance.

Section 2 Scope of the licence

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

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Section 3 Warranty

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

Obtaining warranty service.

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

of the defect concerned. The Licensee shall not carry out any modifications or repairs itself or allow modifications or repairs to be carried out by unauthorised third parties. If the Licensor so desires, the Licensee shall support the Licensor in the analysis of the causes and circumstances giving rise to the defect, as well as in the development and testing of correction codes or a work-around solution.

Exclusivity of warranty.

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Section 4 Intellectual property rights

The Licensee shall only hold those rights to the Software that are expressly described in Section 2 of this Licence Agreement. The Licensor shall remain the sole holder of any other rights with regard to the software, including, without limitation, ownership rights and patent, copyright, trademark, trade secret and other intellectual property rights. The Licensee must not remove, obscure or modify any references on the software to copyrights, trademarks or other ownership rights of the Licensor. The Licensee shall take all reasonable steps to prevent any unauthorised use, reproduction, sale or publication of the software or the unauthorised

provision of access thereto. The Licensee shall indemnify and hold harmless the Licensor against any loss, damage, claims and expenses (including, without limitation, reasonable legal expenses) relating to any infringement of the rights of the Licensor caused by the Licensee, the Licensee's breach of this Licence Agreement or the Licensee's use of the software in a manner not permitted under this Licence Agreement.

Section 5 Limitation of liability

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

Section 6 Contract period and termination

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

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

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

Section 7 Applicable law and jurisdiction

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

MMM Münchener Medizin Mechanik GmbH

9 Warranty (Liability for defects)

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

MMM assumes no liability for defects or other loss or damage resulting from natural wear, chemical or physical influences, excessive strain, incorrect handling and/or inappropriate or improper use, particularly in case of failure to observe the user manual supplied with the machine or instructions for use attached to the machine, improper installation and/or commissioning by the buyer or third parties, loss or damage caused by foreign objects and improper or faulty maintenance.

If maintenance is not performed at certain intervals as prescribed by the manufacturer or is carried out by persons not authorised by the manufacturer, this also constitutes improper or faulty maintenance. The same applies in case of improper or faulty repairs carried out by persons not authorised by the manufacturer to perform this work.

In order for MMM machines to be connected correctly to on-site supply and discharge lines, the specifications in the MMM planning drawings (including the technical specifications for the order) are binding on the contract partner. The MMM warranty shall be rendered null and void if the subsequent operating conditions of these lines are subject to negative deviations, e.g. if the supply pressure is too low or the quality of the supply medium is insufficient and the machine suffers defects or damage as a result.

The beginning and end of the warranty period is defined in the contractual agreements.

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