MMM Group




# Instructions for use

Steam-to-steam generator

# Duotherm II

**Manufacturer**

CE 0036

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# 1 Safety

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

NOTICE

**Observe the safety instructions.**

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

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

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

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

It is directed at the authorized users (Chapter 1.4, "operators") and the system supervisor (Chapter 1.4, "operators"), but also at anybody involved in the installation, commissioning, operation or maintenance of the machine.

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

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

## 1.1 Intended use

The Duotherm steam-to-steam generator is used to generate pure steam from deionised water whose condensate contains no impurities in a concentration which could affect the sterilization process or harm the sterilizer or the sterilization material (see EN285 Sub-section 13.3 “Steam supply for the sterilization chamber”). The steam generator must only be operated with deionised water which meets the corresponding requirements Chapter 2.4, "Feed water".

## 1.2 Responsibilities of the operator

NOTICE

**The operator is required to observe national laws and regulations at all times. The operator is solely responsible for determining which legal provisions cover the operation of this device. These may differ from the information provided in this user manual!**

### Before commissioning

The operator must ensure that the following requirements are met:

- The device has been properly assembled and installed
- 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 operator must have given approval
- The standard operating procedure is available

### If this device is operated in Germany

The German Work Safety Act and the German Ordinance on Industrial Safety and Health (BetrSichV) must be observed. BetrSichV requires a risk assessment that regulates the internal organisation for operating the machinea machine requiring monitoring (Chapter 1.2.1, "Operation of pressure equipment").

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

NOTICE

**The operator is responsible for performing periodic inspections pursuant to the German Ordinance on Industrial Safety and Health (BetrSichV).**

**Observe the inspection intervals of BetrSichV.**

## 1.2.1 Operation of pressure equipment

The Duotherm II is a pressure vessel designed in accordance with AD2000 regulations. Its operation is regulated by European and national legal regulations.

Data on the classification of the pressure vessel can be found on the pressure vessel drawing or the test report according to Annex I of the Pressure Equipment Directive.

Before commissioning a test of the status of the machine checking assembly, installation, set-up conditions and safe function must be conducted. The technical safety functions have already been tested during factory testing, which means that the operator is not required to run new tests after installation.

During operation the machine is subject to regular inspections, which are required after a specific period or after the machine has reached a specified number of cycles.

The operator must define the test programme before commissioning based on a technical risk assessment and manufacturer's information (Chapter 6.3, "Periodic inspections of pressure vessels").

NOTICE

**Contact your national regulatory authority, which is responsible for conducting the inspections.**

**Note for machines that are operated in Germany**

The safety-relevant equipment parts of the assembly have been factory tested with regard to their suitability and function as part of the conformity assessment procedure and as part of the final inspection according to 2014/68/EU - Annex I 3.2 and 3.2.3. This is evidenced by the issued declaration of conformity and the CE mark displayed on the machine. Test reports with measurements results are, as a rule, not included with the machine documentation.

The German Ordinance on Industrial Safety and Health (BetrSichV) and the Technical Rules for Operating Safety (TRBS) are applicable. The BetrSichV regulates the intervals for regular tests and the requirements for the testers (qualified person as per TRBS 1203 or accredited inspection body (ZÜS)).

The pre-commissioning inspection and the regular inspections for Category III pressure vessels (Pressure Equipment Directive) must be conducted by an accredited inspection body (ZÜS).

### 1.2.2 Training the users

The machine operator is responsible for adequately training the authorized users and the system supervisor on how to use the system. The users must be trained for this task by a specialist (Chapter 1.4, "operators") and must be familiar with the user manual by the time of machine acceptance.

Recording the names of persons authorised to operate the machine as well as the system supervisor in the equipment log is recommended. In case of personnel changes, new users must be trained on the basis of the user manual and also documented in the equipment log.

### 1.2.3 Disposal

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

## LEGAL NOTES FOR THE OPERATOR:

1. **Disposal of components**

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

2. **Disposal of the machine**

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



3. **Return of used machines**

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



**Privacy note**

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

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

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

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

## NOTES FOR OPERATORS IN THE EU

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

## 1.3 Installation and commissioning

NOTICE

**The machine must be connected to the supply lines according to the planning drawing specified by MMM, the technical dimensioned drawing and the locally applicable regulations. It must be ensured that the voltage and current type specified on the type plate correspond to those at the site.**

### 1.3.1 Load disconnect switch

A load disconnect switch must be installed in the on-site power supply. It completely disconnects the machine from the mains.



Danger

**Turn off the load disconnect switch immediately in the event of faults, injury to persons, or damage to equipment.**



Danger

**Turn off the load disconnect switch when performing work on the machine (e.g. maintenance), and secure it with a lock to prevent it from being switched on again.**

### 1.3.2 Blow off line

Without the *Blow off line exiting in the bottom tray* option, the machine must be connected to a blow-off line (steam generator safety valve) provided on-site. This line must safely discharge the steam into the open.

NOTICE

**Observe the instructions in the installation preparation drawing and technical data sheet.**

#### Blow off line exiting in the bottom tray (option)

When using suitable supplementary equipment (for example a pressure limiter), the blow-off line of the safety valve can exit in the bottom tray of the machine. An on-site blow-off line is then not required.



Danger

**The operator must inspect and assess the installation location as to whether blow off via the safety valve can safely be implemented!**

**Observe the instructions in the installation preparation drawing and technical data sheet.**

Ensure that the line is unobstructed at all times, and that the steam can be blown off safely.

The blow off line must be adequately dimensioned so that no impermissibly high counter-pressure develops when blowing off the safety valve (see technical connection data).

## 1.4 operators

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

NOTICE

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

**Untrained persons are not permitted to operate the machine.**

### Approved operator

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



**Danger**

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

### System supervisor

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

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

- Technical documentation
- Keys (for the emergency stop switch or program stop switch depending on the machine type, maintenance hatch, control cabinet)

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

**Specialist**

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

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

## 1.5 Personal protective equipment

Personal protective equipment is only required when working on the machine.

Fault rectification and maintenance work (e.g. tightening bolts) must only be performed when the device is not under pressure and has cooled down.

Intervention when the device is hot is also permissible in exceptional cases, e.g. to eliminate damage in order to avert hazards.



**Danger**

**Risk of burns!**

**Wear protective gloves!**

## 1.6 Rules of conduct for operation

### 1.6.1 Working

Only qualified personnel are permitted to open the control cabinet (see Chapter 1.4, "operators").

### 1.6.2 Maintenance work

Maintenance work see Chapter 6, "Maintenance" may only be performed by qualified personnel (see Chapter 1.4, "operators").

## 1.7 Safety features of the machine

### 1.7.1 Safety valve

The steam generator is fitted with a safety valve.

The safety valve activates in the event of an impermissible increase in the internal pressure and safely discharges the steam via the blow off line.

## 1.8 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.

The device must be inspected after 2000 hours of operation (Chapter 6.1, "Operating hour and maintenance counters") or 12 months.

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.

The relevant monitoring authority must be notified of major repair work and repair welding (Chapter 1.2.1, "Operation of pressure equipment").

Only a boiler scale solvent approved by the regulatory authority must be used to clean the boiler.

Observe the schedule and regulations for the periodic inspection of pressure devices (Chapter 6.3, "Periodic inspections of pressure vessels").

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

National regulations must be observed.

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

**Note regarding warranty**

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

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

## 1.9 Standards and directives

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

According to the EC 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:

**Directives:**

| | Description |
|---|---|
| Directive 2014/68/EU | Pressure Equipment Directive |
| Directive 2011/65/EU | Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) |

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

- Directive 2014/30/EU on electromagnetic compatibility

**Regulations and standards:**

| Standard | Description |
|---|---|
| DIN EN 764-7 | Safety systems for unfired pressure equipment |
| DIN EN 60204 | Safety of machinery |
| AD 2000 regulations | AD 2000 leaflets |

BetrSichV (German Ordinance on Industrial Safety and Health) and, if applicable, the AD 2000 leaflets must be observed when installing and operating the machine.

# 2 Machine description

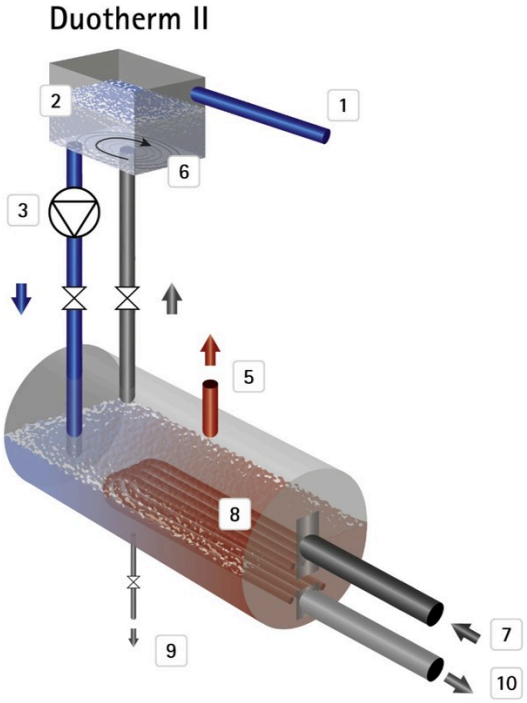
The machine is used to generate pure steam. To do this, the boiler is filled with deionised water, which has first been thermally degassed in the feed water tank, using a feed pump.

In the boiler, the water is heated to boiling temperature via the heating coil's heat exchanger pipes and evaporates. The heat source which is used is the heating steam, which is conducted into the heating coil and condenses due to heat output.

A connection to a return line is provided for the condensate to reuse it in the heating steam system.

For fully automated operation, the machine is equipped with a controller. This regulates the heating steam and feed water feed, feed water degassing and boiler water blow-down. The controller monitors the machine's operation and reports any faults.

### Equipment features




1. Deionised water
2. Feed water tank
3. Feed pump
4. not available
5. Steam removal
6. Degassing
7. not available
8. not available
9. Blow-down
10. not available
11. not available

### Optional equipment

- Conductance-controlled blow-down facility
- Auto start / stop
- Switching on externally

## 2.1 Installation situation

The steam generator can be installed as follows:

- **ON THE TOP:**The machine is on the sterilizer. It can be operated with the sterilizer controls.
- **ALONGSIDE:** The machine is alongside the sterilizer. It can be operated with the sterilizer controls directly on the machine. It is not necessary to install the machine immediately next to the sterilizer; it can also be installed further away.

## 2.2 Heating steam pressure

The steam-to-steam generator is designed for a maximum heating steam pressure of 8 bar. On machines for a heating steam supply pressure of between 8 and 13 bar, the pressure is reduced inside the machine so that the heating coil are pressurised to less than 8 bar. Due to safety reasons, the pipe bundle is designed for a permissible excess operating pressure of 13bar.

NOTICE

**On connection to a protected heating steam line in the building, observe the data concerning protection in the planning drawing or in the technical data sheet.**

## 2.3 Pressure control and limitation

### Pressure control

The pressure in the boiler is registered using a pressure sensor. The controller activates the heating steam supply valves according to the measured pressure.

### Pressure limitation

An impermissible pressure increase can be detected by the pressure sensor, the pressure limiter in the boiler and the pressure switch on the heating steam side. If the pressure is exceeded, the heating steam valves and the boiler feed pump are shut off permanently.

### Safety valve

If the pressure still continues to increase, steam is blown off via the boiler's safety valve.

## 2.4 Feed water

### 2.4.1 Feed water

The level in the feed water tank is continuously monitored by a level sensor. If the level falls below the minimum, deionised water is supplied to the tank through the feed valve.

The feed water is fed to the boiler by the feed pump.

### 2.4.2 Conductivity limit value

The machine must be operated using deionized water only.

The limit value for the conductivity is shown in Table 1, Chapter 2.4.3, "Requirements on the feed water".

The conductivity can be continuously monitored directly on the treatment device using a separate measurement device.

Adherence to this limit value also serves to avoid impurities and coatings on the material to be treated and to minimise blow-down losses.



If ultra-pure water with a conductivity of < 1 µS/cm is used, an increased need for maintenance and possibly an increased risk of corrosion must be anticipated!

### 2.4.3 Requirements on the feed water

We recommend having the quality of the feed water tested regularly.

The conductivity of the feed water must be checked each day. Automatic monitoring is therefore recommended.

Feed water whose properties fail to achieve the values specified in Table 1 can shorten the life of the machine and invalidate the manufacturer's warranty.

Table 1: According to Tab. B1, DIN EN 285

| Contents and properties | Recommended value |
|---|---|
| Evaporation residue | ≤ 10 mg/l |
| Silicate | ≤ 1 mg/l |
| Iron | ≤ 0.2 mg/l |
| Cadmium | ≤ 0.005 mg/l |
| Lead | ≤ 0.05 mg/l |
| Heavy metals except iron, cadmium, lead | ≤ 0.1 mg/l |

| Contents and properties | Recommended value |
|---|---|
| Chloride | ≤ 0.5 mg/l |
| Phosphate | ≤ 0.5 mg/l |
| Conductance (at 20°C) | ≤ 5 µS/cm |
| pH (at 20°C) | 5 - 7.5 |
| Appearance | Colourless, clear without residues |
| Hardness | ≤ 0.02 mmol/l |

Note: Compliance with these values can be verified using recognized analytical methods.

### 2.4.4 Feed water degassing

The water in the feed water tank is heated using steam. Gases dissolved in the water are released due to heating.

The temperature is registered using a resistance temperature sensor in the feed water tank. Depending on the set temperature values, the control activates the valve for feeding steam to the feed water.

## 2.5 Boiler water

### 2.5.1 Water level control in the boiler

Three fill level sensors, which are used to determine the water level in the boiler, are located in the front panel.

LED display:

- Green light: Power supply connected and ready for operation
- Yellow light: Water level OK
- Red light: Fault

If the standard water level is undershot, water is replenished by the feed pump.

If the minimum or maximum water level is undershot or exceeded for a long time, a fault message is output.

### 2.5.2 Boiler water

The following requirements are made on the boiler water of steam generators manufactured from CrNiMo steel:

Table 2: Requirements for the boiler water

| Contents and properties | Recommended value |
|---|---|
| Appearance | ----> Colourless, clear without sediment |
| pH value | 5 - 7 (10) |
| Total alkaline earths (hardness) | < 0.02 mmol/l |
| Phosphates | < 5 mg/l PO4 |
| Chlorides | < 50 mg/l |
| Conductivity | < 100 µS/cm at 25°C water temperature |
| Silica | < 10 mg/l SiO2 |

### 2.5.3 Blow-Down

During operation, the salt concentration in the boiler water increases due to water evaporation. Regular blow-down prevents impermissibly high salt enrichment in the boiler water and ensures pure steam and trouble-free operation. This additionally protects the CrNi steel equipment and extends the machine's service life.

#### 2.5.3.1 Conductance-dependent blow-down - time-controlled

In order not to exceed the max. limit value of approx. 100 µS/cm (with reference to 25°C) in the boiler water, part of the water is continuously drained off via the blow-down valve. The blow-down valve cycle is adjusted to the feed water quality via the controller's parameters.

The salt concentration in the boiler water is reduced through the subsequent infeed of fresh water.

Depending on feed water quality, desalination can be configured customer-specifically to avoid unnecessary energy and water losses.

NOTICE

**Parameter changes are permitted only in consultation with MMM customer service.**

#### 2.5.3.2 Conductance-controlled blow-down (option)

In conductance-controlled blow-down, the blow-down procedure additionally takes place depending on the salt concentration measured via the conductivity. An electrode and a conductance switch are used to monitor the boiler water's conductivity. At a set limit value of approx. 100 µS/cm (with reference to 25°C), part of the water is then drained off via the blow-down valve and the salt concentration is reduced through the subsequent replenishment of feed water.

The LED of the conductance evaluation device in the control cabinet indicates the condition of the boiler water.

| LED | Conductivity | Bolw down procedure |
|---|---|---|
| Red | **Over** limit value | Is performed |
| Green | **Under** limit value | Is not performed |

# 3 Displays and controls

## 3.1 On the steam-to-steam generator

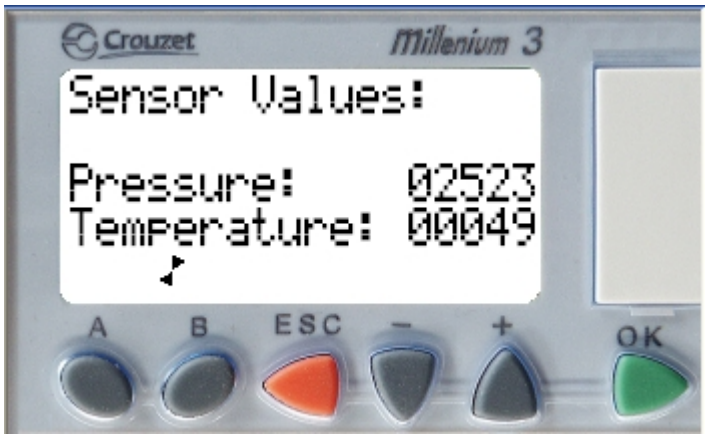
### On the machine

- Pressure gauge for indicating the pure steam pressure
- Pressure gauge for indicating the heating steam pressure

### In the control cabinet

NOTICE

**Not accessible for the user.**




Compact controller with a four-line LCD display for displaying:

- Software version
- Operating hours (since the last SW update) and maintenance counter
- Boiler pressure and feed water temperature
- Status of all inputs and outputs
- Current parameters (configuration option using the buttons on the controller)
- Last alarm
- The last seven alarm statuses

**Buttons on the compact controller**

- Button A: scrolling forwards in the menu
- Button B: scrolling backwards in the menu
- Other buttons: for customer service only

**On installation ALONGSIDE, the following displays and controls are additionally found on the machine:**

- Green lamp: operational
- Red lamp: fault
- Mains switch with lamp for switching the system on and off

## 3.2 On the consumer

**The following displays and controls are found on the front of the consumer**

- Green lamp: operational
- Red lamp: fault
- Mains switch with lamp for switching the system on and off

# 4 Operation

Please observe the safety instructions in Chapter 1.

NOTICE

**All activities described in the following must only be performed by a trained person.**

## 4.1 Commissioning

Before switching on, make sure that the machine is in good condition. In particular, the following preliminary work must be performed:

- Visual inspection of the machine (e.g. for leaks).
- Close the stop valve for draining the boiler.
- Check whether the pure steam line is tight and connected to the consumer.
- Open the stop valves in the following lines:
  - Pure steam line
  - Feed water line
- Slowly and carefully open the valve to the heating steam line. The valve must only be slowly opened completely when the line to the steam-to-steam generator is warm and no conspicuous noises occur.
- Check whether the test valve in the feed line to the pressure gauge is open (boiler feed-through and pressure gauge).
- Make sure feed water supply is OK.
- Make sure compressed air supply is OK.
- Switch the load disconnect switch on.
- Switch the mains switch on.
- Check the error messages (red lamp).

NOTICE

**We recommend monitoring the boiler during the starting process.**

**Pay particular attention to the boiler pressure and any conspicuous noises.**

Once the operating pressure of approx. 2.7 bar is reached, the green lamp lights and the boiler is operational.

Only start assigned consumers when the machine indicates operating readiness, and check it once it has been operating for approx. one hour.

## 4.2 Shutting the machine off

- Switch off the mains switch
- Switch off the load disconnect switch
- Close the stop valves for the feed water and steam lines.
- Close the heating steam stop valve.

**Long system down time**

In the case of a long down time, we recommend completely draining and preserving the boiler.



**Danger**

**Danger of scalding!**

**Hot steam and hot boiler water can escape.**

**Empty only if the steam generator is cold!**

# 5 Operating safety and faults

A fault is indicated by the red fault lamp lighting.

The alarm number is shown on the LCD display in the control cabinet.

The fault is output as long as a fault is present or acknowledged or the machine has not been restarted.



**Danger**

**The load disconnect switch must be switched off immediately in the case of faults on the machine which may cause personal injury or damage to property.**

**The load disconnect switch must also be switched off and secured to prevent it from being switched on again during work (e.g. maintenance) on the machine.**

## 5.1 Responding to faults

If a malfunction occurs (red lamp), the steam generator must be started again.

**User:**

- Switch off the machine at the mains switch.
- Switch on the machine again.

Inform the system supervisor.



**Danger**

**Faults must only be eliminated by a specialist.**

**Specialist**

- Open the control cabinet with the machine switched on; the fault number is shown on the controller's display
- Compare the alarm number with the fault table

  or

- Press and hold button A on the controller until the display shows the "L.Errors" screen. The first five-digit number corresponds to the alarm number of the last fault that occurred (e.g. 01003 corresponds to alarm number 1003).



**Danger**

**Danger due to electric current!**

**Even when the machine is switched off, voltage is present up to the pump circuit breaker, mains relay and mains switch.**



**Danger**

**Particular caution required when machine is hot!**

**Risk of burns!**

**Wear protective gloves.**

## 5.2 Fault list / Alarm numbers

| No. | Alarm trigger, designation | Possible causes | Further procedure |
|---|---|---|---|
| 1001 | Heating circuit open | Severe fault in hardware safety. | Shut off the machine (load disconnect switch, if fitted).<br>Request MMM customer service. |
| 1002 | Heating steam pressure limiter triggered | Pressure limiter signals that heating steam pressure is too high. | Shut off the machine (load disconnect switch, if fitted).<br>Monitor the machine during cooling.<br>Reduce heating steam pressure.<br>Request MMM customer service. |
| 1003 | Insufficient feed water | B89 reports insufficient feed water in the water tank for too long. | Check feed water supply.<br>Check feed water tank for leaks.<br>Request MMM customer service if necessary. |
| 1004 | Boiler pressure measurement error | Pressure sensor reports boiler pressure values which are too high or too low for too long. | Shut off the machine. (Load disconnect switch, if fitted)<br>Request MMM customer service. |
| 1005 | Standard water level not reached | Level sensor reports insufficient water in the boiler for too long. | Check stop valve between feed water tank and boiler.<br>Request MMM customer service if necessary. |
| | Feed water temperature | Temperature sensor B01 reports invalid feed water temperatures. | Check that the stop valve in the boiler steam line is open.<br>Request MMM customer service. |
| 1007 | Heating circuit defective | Severe fault in hardware safety. | Shut off the machine. (Load disconnect switch, if fitted)<br>Request MMM customer service. |
| 1008 | Boiler water quality | Conductance evaluation has reported excessively high conductance. | Drain boiler and refill.<br>Check feed water quality.<br>Request MMM customer service. |

# 6 Maintenance

NOTICE

**Observe the safety instructions in Chapter 1!**

NOTICE

**Observe the instructions for operation of pressure vessels Chapter 1.2.1, "Operation of pressure equipment" and the regulations for regular inspection of pressure vessels Chapter 6.3, "Periodic inspections of pressure vessels".**

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

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

A preventative inspection and maintenance (preventative maintenance) of the steam generator should be performed after 2000 hours of operation or after one year at the latest.

For economic reasons, it is worthwhile carrying out the maintenance on the steam generator together with the maintenance on the device to be supplied.

## 6.1 Operating hour and maintenance counters

The controller's LCD display in the control cabinet, on which the present faults and operating conditions (boiler pressure, feed water temperature) can also be read, is used to display the operating hours and the maintenance counter.

### Operating hour counter

The operating hours completed so far are shown under “Hour Meter”.

### Maintenance counter

The operating hours since maintenance was last performed are shown under “L.Service”.

## 6.2 Maintenance intervals

When performing maintenance work, please note that the steam generator is hot and pressurized.



**Danger**

**Risk of injury!**

**Maintenance work must only be performed when the device is not under pressure and has cooled down!**

### 6.2.1 Daily

- Perform a visual inspection for leaks.
- Make sure that the boiler supply and heating and also the feed water degassing are connected correctly (green lamp for “Operational” status lights up).
- Check whether error messages are present (red lamp).
- Make sure that the quality of the feed water meets the requirements described in the user manual, and document the measured conductivity value and adherence to the limit value in the equipment log or in the log book of the water treatment plant.



The conductivity of the feed water at the reference temperature of 20 °C must not exceed 5 µS/cm.

### 6.2.2 Quarterly

**Check the descaling function**

Make sure that the device is descaled regularly. When running the descaling function, you will hear valve Y02 opening and a small amount of the boiler water will be discharged through the descaling line into the bottom tray. If necessary, document the descaling interval.



**Danger**

**Danger of scalding!**
**Hot steam and hot boiler water are discharged into the bottom tray during descaling!**
**Use caution and stand back when checking the descaling function!**

Alternatively, the functioning of the descaling feature can be determined by measuring the conductivity of the boiler water.

We also recommend checking the silicic acid content in the boiler water on a regular basis to ensure the medical instruments treated with the pure steam hold their value.

NOTICE

**The boiler must not have been refilled before removing the water sample.**

- Remove water samples at the boiler discharge valve.
- Allow the water sample to cool.

The conductivity at the reference temperature of 25°C should be less than 100 µS/cm and the silica content below 10 mg/l.

- Document the measured values in the equipment log.

**Danger**

**Danger of scalding!**

**Hot steam and hot boiler water can escape.**

**Open the discharge valve carefully and only when the boiler has cooled sufficiently.**

### 6.2.3 Twice a year

**Checking the heating coil for leaks**

- Heat the steam-to-steam generator until the operating pressure is reached.
- Switch off the machine (heating steam and condensate valves must be closed).
- Slowly and carefully open the sample valve at the condensate outlet flange plate. The steam in the heating coil escapes.
- Steam or condensate must stop escaping after a certain period. In the event of a leak, steam or boiler water would enter the heating coil and flow out via the sample valve.

### 6.2.4 After 12 months or 2000 hours of operation

The maintenance interval depends on the operating hours (after 2000 operating hours or after 12 months) or the number of sterilization cycles of the machines being supplied.

NOTICE

**To be done by a specialist only**

**With the machine cold and switched off**

- ▶ Check the non-return valves and flaps, renew if necessary
- ▶ Open the feed water tank, visual inspection of the tank, clean if necessary
- ▶ Completely drain the boiler
- ▶ Check safety valve function

  The safety valve will activate if the pressure in the pressure container of the steam generator overshoots.

  - ▶ To check the function of the valve, remove it and then test it on a suitable test stand or using suitable equipment.

- Water level control function check

  Fill level switch B90

  Steps: ▶ Fill the tank.

  When filling the tank, the yellow LED of the tuning fork switch must light up when the required fill level is reached.

- Check the function of pressure limiting feature

  Steps: ▶ Pull out the plug of the B31 pressure switch.

  The Y15 and Y16 hot steam valves must close.

**With the device at operating temperature**

- Function test of the automatic boiler feed and pressure regulation.
- Check pipe connections for leaks
- Reset the maintenance counter (if present)
- Check the settings of all setpoint sensors and correct if necessary.

## 6.3 Periodic inspections of pressure vessels

Pressure vessels must be inspected regularly. The operator must set up an inspection program defining the type, scope and schedule of inspections (Chapter 1.2.1, "Operation of pressure equipment").

The manufacturer recommends that the following minimum requirements be adhered to.

**Recommended inspection intervals:**

- External inspection : 2 years
- Internal inspection: 5 years
- Strength test: 10 years

Depending on the operating conditions, the number of cycles may require shorter inspection intervals.

NOTICE

**The following tests must be conducted by a qualified specialist.**

**The following national regulations must be observed for technical qualifications.**

**External inspection**: **after 2 years**

| What | How | Control result |
|---|---|---|
| Check external condition | ▶ Visual inspection: Assess relevant system components for external changes, e.g. corrosion, discoloration due to high temperature, mechanical damage, leaks ,etc.<br>▶ Compare local displays and remote displays<br>▶ Function test of closure (if present) | The system parts must be free from external changes. The displays must match. |
| Check safety-relevant components | ▶ Check that they are installed<br>▶ Visual inspection: Check status for visible faults<br>▶ Function test | All safety-relevant components must be installed and in functional condition. |

Visual inspections of the outside of the machine can be replaced with other suitable equivalent procedures if visual inspection is not possible due to the structure of the pressure vessel or the operating conditions. The pressure vessel or system component is not usually shut down for the inspection.

**Internal inspection: after 5 years**

Steam generator:
The objective of the internal test is to determine whether the pressure-resistant walls are in good condition of operation. The operator must define the testing scope and testing depth based on the safety-related evaluation. The internal test is generally performed on the open system section using visual inspection. This may require the use of suitable tools such as viewing devices, or may have to be supplemented by additional testing methods, such as wall thickness measurements or surface crack testing. If the condition cannot be sufficiently determined at inaccessible locations or if there is a suspicion of damage, it may be necessary to remove the parts that are causing the hindrance, such as pipes, installed equipment, walled-in elements and enclosures. Visual inspections of the inside may be replaced with other suitable equivalent procedures if visual inspection is not possible due to the structure of the pressure container or is not useful due to the method of operation. This must result in an equivalent testing conclusion regarding the safety of the equipment.

We recommend performing at least the following tests:

| What | How | Control result |
|---|---|---|
| Check pressure-bearing walls | ▶ Visual inspection: Visually assess relevant system components. Pressure-bearing walls can be inspected with aids such as mirrors or camera systems.<br>▶ If damage is suspected, suitable non-destructive test methods can be used, such as color penetration tests to detect surface cracks. | The system parts must be free from damage. |
| Check safety-relevant components | ▶ Check that they are installed<br>▶ Visual inspection: Check status for visible faults<br>▶ Function test | All safety-relevant components must be installed and in functional condition. |
| Documents | ▶ Check that the system is installed as specified by the information in the inspection documentation (check the documentation is in order). | Document check inspection results: Documents are available and consistent, e.g. with regard to previous inspections, method of operation or repair work. |



See pressure vessel drawing or acceptance inspection report with reference to the relevant number of cycles.

**Strength test**: **after 10 years**

| What | How | Control result |
|---|---|---|
| Strength test | Strength tests comprise as a minimum static pressure tests to confirm safety under the approved operating pressure $P_B$. | The system must not leak under the test pressure and must not show any deformation that could compromise safety. |

**Note for machines operated in Germany:**

The recurring inspections must be performed as per TRBS 1201 Part 2.

# 7 Software Licence Agreement

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

NOTICE

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

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

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

### Section 1 Definition

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

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

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

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

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

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

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

**Section 2 Scope of the licence**

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

### Obtaining warranty service.

If the Licensee identifies a defect in the Software that may give rise to an obligation under the foregoing warranty, it shall cease using the Software immediately and notify the Licensor in writing of the defect within the defect notification period while also providing sufficient supporting documentation.

The defect notification period is ninety (90) days from delivery of the data carrier (for a defect in the data carrier) and six (6) months from delivery of the software (for a defect in the software). The written supporting documentation providing proof of the defect shall be sufficient if the Licensor is able to reproduce the defect identified by the Licensee. The Licensee shall enclose the relevant purchase receipt so that the Licensor may determine whether the defect notification period has been observed in respect of the defect concerned. The Licensee shall not carry out any modifications or repairs itself or allow modifications or repairs to be carried out by unauthorised third parties. If the Licensor so desires, the Licensee shall support the Licensor in the analysis of the causes and circumstances giving rise to the defect, as well as in the development and testing of correction codes or a work-around solution.

**Exclusivity of warranty.**

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### Section 4 Intellectual property rights

The Licensee shall only hold those rights to the Software that are expressly described in Section 2 of this Licence Agreement. The Licensor shall remain the sole holder of any other rights with regard to the software, including, without limitation, ownership rights and patent, copyright, trademark, trade secret and other intellectual property rights. The Licensee must not remove, obscure or modify any references on the software to copyrights, trademarks or other ownership rights of the Licensor. The Licensee shall take all reasonable steps to prevent any unauthorised use, reproduction, sale or publication of the software or the unauthorised provision of access thereto. The Licensee shall indemnify and hold harmless the Licensor against any loss, damage, claims and expenses (including, without limitation, reasonable legal expenses) relating to any infringement of the rights of the Licensor caused by the Licensee, the Licensee's breach of this Licence Agreement or the Licensee's use of the software in a manner not permitted under this Licence Agreement.

### Section 5 Limitation of liability

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

### Section 6 Contract period and termination

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

In addition to other rights of cancellation according to this licence agreement, each party is allowed to cancel this licence agreement with immediate effect, if the other party essentially infringes a contractual duty,

including but without limitation, delay in payment of the licence fee, provided that the party violating the contract does not correct the infringement within forty-five (45) days upon receipt of a written reminder.

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

### Section 7 Applicable law and jurisdiction

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

MMM Münchener Medizin Mechanik GmbH

# 8 Warranty (Liability for defects)

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

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

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

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

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

# Warranty (Liability for defects)

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