

MAQUET

User's Manual

Heater Unit HU 35








CARDIOPULMONARY



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1. Brief Instructions

1. Connect the unit to the power supply.
2. Attach the oxygenator to the unit via the tubes.
3. Check the unit's water level.
4. Switch on the unit using the power switch (O/I) and observe the automatic performance test.
5. If the temperature setpoint is $> 38^{\circ}\text{C}$ when switching on the unit, the alarm is disabled and the unit is put into operation by pressing the enable key " $>38^{\circ}\text{C}$ ". 
6. Set the temperature using the arrow keys   if necessary.
7. Press the enable key " $>38^{\circ}\text{C}$ "  and the arrow key  simultaneously for temperatures in excess of 38°C .
8. Monitor the patient's body temperature.
9. Monitor the unit's water level and water flow.
10. If the unit is used continuously, carry out the performance test manually by pressing the "Performance Test" key  once daily.
11. **Second priority** acoustic alarms can be disabled by pressing the "Alarm Off" key. 
12. **First priority** alarms can be disabled by switching the unit off.

1. Brief Instructions

Note: re. 12:

If a first priority alarm is sounded, all the unit's functions are automatically shut down. The unit must therefore be switched off in order to switch off the alarm signal. The unit must no longer be used and should be sent to a service technician for inspection and, if required, restoration of operational safety (see Chapter 5 "Alarm Signals" and Chapter 8).



The unit must not be used if:

- the display is not functioning;
- the display is faulty (missing segments of numbers could result in misinterpretation of values);
- the red alarm LED is either continuously lit or does not light up at all (performance test);
- the signal horn either sounds continuously or does not sound at all (performance test);
- the unit fails to react when the keys are actuated;
- the unit does not react as described in the User's Manual when it is switched on or the performance test is carried out.



These brief instructions do not free the user from his obligation to observe the User's Manual and instructions for use for the respective oxygenator!

2. Safety Instructions

- Before putting into operation, the user must ensure that both the unit (power cord, housing, couplings etc.) and the applied part (oxygenator) are in proper working order.
- Fill the tank with tap water only.
- Before opening the water tank's screw cap, the unit must be disconnected from the power supply. The unit must NOT be operated without the screw cap.
- The unit must only be operated in a horizontal position away from heat sources (spotlights, direct sunlight, heating elements, radiant heaters etc.).
- Do not cover the ventilation slots on the bottom and rear of the unit.
- The difference in height between the unit and the oxygenator must not be more than one meter (1 m).
- Observe the automatic performance test when switching on the unit and, if the unit is used continuously, perform the test manually at least once daily.
- When in use, the unit's water flow and water level must be checked regularly.
- The unit must only be operated with a sufficient water level.
- Do not kink the tubes.
- Observe the ambient temperature range (10 - 30°C) and the storage temperature range (10 - 40°C).
- Only operate the unit with the MAQUET PLS oxygenator or other oxygenators and their respective original accessories as part of extracorporeal circuits.
- The unit must not be used in the presence of flammable gases.
- Carry out maintenance work and safety checks in accordance with the User's Manual.

2. Safety Instructions

Dotted lines for writing safety instructions.

3. General Description

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3. General Description

Figures

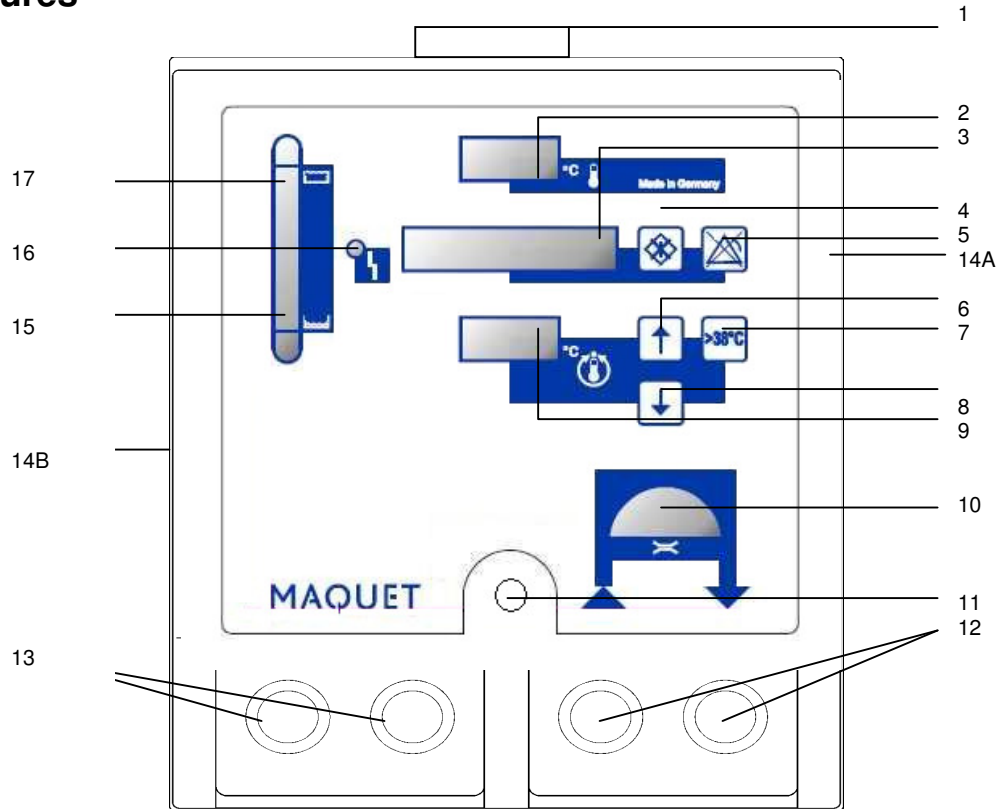


Figure 1: Front

- 1 Water filler neck with screw cap
- 2 Actual temperature display
- 3 Status and error messages display
- 4 "Performance Test" key
- 5 "Alarm Off" key
- 6 "Increase Temperature Setpoint" arrow key
- 7 "Temperature Setpoint greater than 38 °C" enable key
- 8 "Decrease Temperature Setpoint" arrow key
- 9 Temperature setpoint display (33 - 39 °C)
- 10 Water flow display for right coupling pair
- 11 Power switch O/I
- 12 Right coupling pair for connecting the tubes to the oxygenator
- 13 Blind plugs in left coupling pair
- 14 A. Threaded holes (fastening screws on housing) for tubing holder
B. Threaded holes for clamp mounting (accessories)
- 15 Water level display: min. water level
- 16 Fault display lamp
- 17 Water level display: max. water level

3. General Description

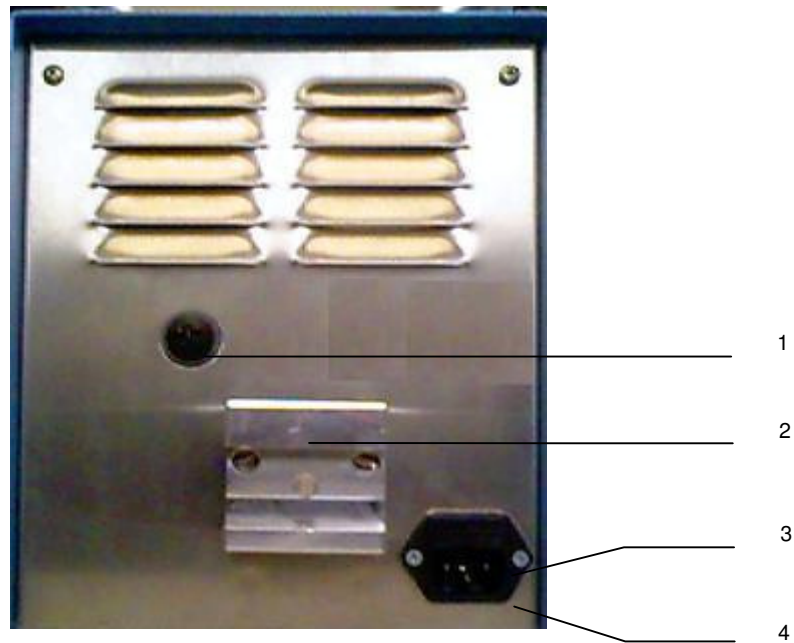


Figure 2: Rear

- 1 Water outflow point with screw cap
- 2 Clamp mounting (accessories)
- 3 Line fuses (2 x T 3.15 A)
- 4 Connector plug for power cord

3. General Description

Product Description

The **Heater Unit HU 35** works on the principle of heat dissipation via a thick membrane to the blood stream with an oxygenator.

A heating element heats up the water in the unit's water tank, this water is electronically controlled and pumped continuously.

The **Heater Unit HU 35** is characterized by its compact design, simple and safe handling and reliability.

The **Heater Unit HU 35**'s main features are its efficient and precise heat transfer and its outstanding operational safety.

The various displays on the front of the unit provide information on the proper functioning of the device at all times. Operation is both simple and intuitive. The temperature on the unit can be set between 33°C and 39°C, which enables body temperature to be maintained.

Intended Purpose / Indications

The **Heater Unit HU 35** acts as a heat supply in order to maintain the patient's body temperature via a MAQUET PLS oxygenator or other oxygenators as part of extracorporeal circuits.

Side Effects / Contraindications

There are no side effects and no known contraindications when the Heater Unit HU 35 is used for the intended purpose.

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4. Putting into Operation

Setting up the Unit



Figure 3

a) Table top unit

The **Heater Unit HU 35** hyperthermia system unit is designed for use on table tops, i.e., it can be placed on all types of flat, horizontal, hard and load-bearing surfaces. For safety reasons, the unit must not be operated on the floor.

b) Mobile floor-mounted unit

Together with the SPRINTER Cart as an optional accessory and the respective clamp mounting, the unit can be used as a mobile floor-mounted appliance.



Figure 4

The clamp mounting for the SPRINTER Cart is secured on the left side of the unit (see Figure 3) using two screws. The unit is secured to the slide rail of the SPRINTER Cart using the star screw on the clamp mounting.

c) Wall mounting on slide rails

The unit can be attached to the standard slide rails (25 x 10 mm) found in hospitals. To this end, the clamp mounting, which is available as an accessory, is ideally secured to the rear of the unit using two screws. The unit is secured to the rail using the star screw on the clamp mounting (see Figure 4).



Figure 5

d) Tubing holder

If necessary, the tubing holder, which is available as an accessory, can be attached to the right-hand side of the unit using the knurled screws located there (see Figure 5).

4. Putting into Operation

The following must be observed when setting up the unit:



When setting up the unit it must be ensured that the ventilation slots on the bottom and rear of the unit are not covered.



When in operation, the unit must be in a horizontal position (max. incline of 2°) as otherwise the water level display on the front of the unit displays an incorrect value.



Furthermore, it is also recommended that the unit is positioned level or slightly higher than the oxygenator (max. height difference 1 m) due to the water pressure conditions in the circulation system. Moreover, when opening the water filler neck when the unit is switched off, water from the tubes and oxygenator can flow back into the unit causing the water tank to overflow.

Language

The language in the display (Fig. 1 point 3) on the front of the unit, which provides information on the status and error messages, can be changed by the user. The following languages are available: *German, English, French, Spanish, Italian.*

The language is set, with the unit switched on, as follows:

- 1.) Keep the “Alarm Off” key (Fig. 1 point 5) depressed (4 seconds) until the language appears in the display.
- 2.) Pressing the “Increase Setpoint” key (Fig. 1 point 6) serves to display and activate the languages in the following order: *German, English, French, Spanish, Italian, German etc..*
- 3.) The selection option automatically ends 10 seconds after the last entry.

4. Putting into Operation

Water Level

a) Checking

Before switching the unit on and connecting the tube to the oxygenator, the water level must be checked. The water level display is located on the front of the unit, the display has a minimum (Fig. 1 point 15) and maximum (Fig. 1 point 17) permissible value. The water level must be between these two values, whereby the maximum value should be aimed for. The difference between the two values is 0.7 liters.

Water must be refilled under the following conditions:

- the water level is below the minimum value;
- the display shows “WATER LEVEL!?”;
- empty tubes and an oxygenator are connected and the water level is below the maximum value.

b) Filling / Refilling

The water tank is filled with tap water. The unit is filled after it has been switched off and disconnected from the power supply. To pour in water, the screw cap (Fig. 1 point 1) of the water filler neck is removed (e.g., using a coin). After being filled, the water level should be slightly below the max. value on the display. Once the water has been poured in, the screw cap should be screwed on lightly.



Operators should not use any cleaning or decontamination methods other than those recommended by the manufacturer without checking with the manufacturer beforehand whether the suggested methods could cause damage to the unit.



If, when filling, water flows over the unit, this must be dried thoroughly. The unit must not be used again until it is completely dry.

c) Changing the water

The water must be changed every two weeks (see also Chapter 7 “Maintenance and Safety Checks”)

Oxygenator

An oxygenator can be attached either before or after the unit is switched on.

The tube couplings are simply connected to the right-hand coupling pair on the unit (Fig. 1 point 12). The couplings are correctly attached to each other when the lock on the tube coupling clicks into place in the unit's coupling nipple and the connection can no longer accidentally become undone.

On the oxygenator side, the tube is connected to the oxygenator via an adapter on a Hansen coupling. The used Hansen couplings can be connected with all current oxygenators. The connection is correct if the water flow display above the coupling pair on the unit rotates when the unit is switched on.

The coupling is released by pressing on the small metal plate on the tube coupling. The couplings can be released when the unit is switched on. It must be ensured, however, that the adapter on the oxygenator side is decoupled as otherwise water will leak out. The system has been designed so that, after release, the coupling drips briefly; this is not a sign of a leakage or fault.

Tip

- The black sealing rings on the couplings can become dry, brittle and stiff as a result of ageing. This can be remedied by applying a thin film of silicone grease, Vaseline or similar to the sealing ring.



- The unit must only be operated with the MAQUET PLS oxygenator or other oxygenators as part of extracorporeal circuits.
- The used oxygenators need to resist a pressure of a maximum of 0.34 Bar and to allow a maximum temperature of 40 °C (independent safety shutdown).
- For further information, please refer to the oxygenator's instructions for use.
- An oxygenator must not be connected when performing disinfection (also see Chapter 6 "Cleaning and Disinfection").

4. Putting into Operation

Putting into Operation

The unit can be connected to the power supply using the power plug, taking into account points “Setting up the Unit” – “Oxygenator”.

Switching on (O/I)

The power switch is designed as a push switch with the symbols O/I and is located on the front of the unit (Fig. 1 point 11). The unit is switched on when the power switch button is depressed into the recess and off when the button is flush with the front of the unit.

Performance Test

A short acoustic alarm sounds when the unit is switched off and on. This signals that the power failure alarm is ready. Shortly after switching the unit on, a performance test checks the independent safety device and the result is shown in the display. Furthermore, all the segments (88.8) of the temperature displays, the fault display lamp and the acoustic alarm are activated at the same time. This performance test takes just a few seconds, during this time the user must observe the activation of the above-named displays.

Warm-up Phase

- Once the performance test has been completed, the temperature control mode starts automatically if the temperature is set between 33 and 38 °C.
- **If the set value is greater than 38 °C, an acoustic alarm sounds and the following messages are displayed “SET VALUE >38 °C”, “ENABLE KEY - >”. The temperature control mode is started by pressing the enable key “>38 °C” (Fig. 1 point 7).**

4. Putting into Operation

Once the setpoint temperature has been reached, heat dissipation in watts (W) is shown in the display (also see Chapter 5 “Heat Dissipation”).



The unit must be taken out of use in the following examples and inspected by the authorized customer service organization:

- the short acoustic power failure alarm cannot be heard when switching the unit on and off;
- the automatic performance test identifies a defect in the independent safety device and automatically switches the unit off;
- the user notes a defect in the displays.



The unit is not designed for continuous use without an oxygenator. If the unit is operated for an extended period (> 1h) without an oxygenator, various alarm messages may be given due to the lack of heat dissipation, in this case such messages do not point to a defect, but rather signal the proper functioning of the safety devices. The unit can be used again after a cooling down period.



When used with an oxygenator, the patient's body temperature should be monitored.

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5. Instruction for Use

Setting the Temperature

The desired setpoint temperature can be set at any time between 33 and 39°C in increments of 0.1 °C using the two arrow keys (Fig. 1 points 6 and 8). The temperature display (Fig. 1 point 9) on the left of the keys shows the temperature setpoint.

For temperature setpoints above 38°C the arrow key (Fig. 1 point 6) and the enable key “>38°C” (Fig.1 point 7) must be actuated at the same time for safety reasons.

Note

The unit does not actively regulate the temperature to a setpoint which is below the actual temperature. Cooling is a passive process.

Heat Dissipation

The unit's display shows the actual heat dissipated when in operation, i.e., the heat in watts (W) which is output to the environment (air etc.) and the oxygenator. The percentage of the displayed heat dissipation to the oxygenator is always less than 100%. The more efficient the heat transfer of the oxygenator, the greater the percentage transferred to the patient.

Note

Heat dissipation from the oxygenator to the patient can only occur if the temperature of the water in the oxygenator is greater than the temperature of the patient's blood. In terms of physics, potential heat dissipation is directly proportional to the difference between the temperature of the blood and the temperature of the water in the oxygenator.

Performance and Safety Checks

Visual Inspection prior to Use

Prior to using the **Heater Unit HU 35**, the unit, tubes and oxygenator are to be inspected for damage (see also Chapter 2).

Furthermore, the water level must be checked each time before using the unit. This is done before and after switching the unit on, when the oxygenator is connected, by checking the water level display. The water level must be between the minimum value (Fig. 1 point 15) and the maximum value (Fig. 1 point 17).



The unit must only be operated with a sufficient water level.

Flow Rate Inspection

The flow of water in the water circuit (tube and oxygenator) must be checked before use and at regular intervals during operation using the flow display on the unit (Fig. 1 point 10). Water circulation is sufficient if, due to rotation, the individual indicators in the flow display cannot be made out.

Performance Test

If the unit is used for an extended period, the independent safety device must be manually checked at least once daily. To perform this test, the “Performance Test” key (Fig. 1 point 4) must be actuated when the unit is in use. For a few seconds all the displays are activated, the acoustic signal sounds and the safety electronics are tested. The temperature displays show “88.8”, the red fault display lamp lights up and “FUNCTION. TEST” appears in the display. If the independent safety device is functioning properly, the message “FUNCTION.TEST OK” subsequently appears.



Should this not be the case, the unit must be checked by the customer service organization.

5. Instruction for Use

Alarm Signals

(also see Chapter 8)

Alarm signals always trigger a visual and acoustic signal and thus increase the system's operational safety. The reason for the alarm (error) is shown in the display (except with the power failure alarm).

With **second priority** alarms the acoustic alarm can be disabled for a period of time by pressing the key "Alarm Off", however the visual alarm signal (fault display lamp + display) remains activated until the cause of the alarm is remedied.

First priority alarms can only be disabled by switching the unit off with the power switch. If a first priority alarm is triggered, all the unit's functions are shut down automatically. The unit must no longer be used and should be sent to a service technician for inspection and, if required, restoration of operational safety (see Chapter 8).

The following alarm signals are possible:

Second Priority Alarms:

TEMP <= 32 °C

If a water temperature of 32 °C is measured during operation, the alarm message "TEMP <= 32 °C" is displayed together with the red fault display lamp and the acoustic signal. The acoustic signal can be disabled for 10 minutes using the "Alarm Off" key.

TEMP.DIFF >1 °C

If the actual temperature deviates from the temperature setpoint during operation by more than 1 °C, the alarm message "TEMP.DIFF. > 1 °C" is shown in the display together with the red fault display lamp and the acoustic signal. The acoustic signal can be disabled for 10 minutes using the "Alarm Off" key.

The coupling and decoupling of the connected tubes when the oxygenator is connected and the unit is switched on can result in a temperature difference, which triggers an alarm signal. This is not notification of a fault.

When the tubes and oxygenator are connected, temperature differences in excess of 1 °C are not permitted for any length of time. In such cases, the unit must be checked.

5. Instruction for Use

After the unit is switched on and there has been a change to the temperature setpoint, the alarm function “TEMP.DIFF. >1 °C” is automatically disabled for a specified period of time.

WATER LEVEL!?

If the water level falls below the minimum value on the water level display, the alarm message “WATER LEVEL!?” appears in the display together with the red fault display lamp and the acoustic signal. The acoustic signal can be disabled for 10 minutes using the “Alarm Off” key.



If the unit is operated with too little water this can cause water circulation problems, in the long term this may damage the components and cause the unit to fail. The unit must be immediately filled with water (see Chapter 4 “Setting up the Unit”), otherwise the “Lack of Water” alarm appears (see “First Priority Alarms”).

First Priority Alarms:

TEMP >= 40 °C

If a water temperature of 40 °C is reached during operation, the alarm message “TEMP >= 40 °C” is displayed together with the red fault display lamp and the acoustic signal. At the same time, the heater and pump are automatically switched off. The alarm cannot be disabled and the unit must therefore be switched off using the power switch.

If, after a period of approx. 0.5 hours and subsequent refilling of the water (see Chapter 4 “Setting up the Unit”), an alarm signal recurs on switching on the unit, the unit must be checked by the customer service organization.

ALARM TEST FAIL

->CALL SERVICE

If, during the automatic or manual performance test, the unit detects an error or the independent safety device fails to react, the alarm message “ALARM TEST FAIL” and “->CALL SERVICE” appears in the display together with the red fault display lamp and the acoustic signal. The alarm cannot be disabled and the unit must therefore be switched off using the power switch.

If, after an extended period of time (1 – 2 hours), the alarm signal recurs on switching on the unit, the unit must be checked by the customer service organization.

5. Instruction for Use

TEMP <= 32 °C
CHECK UNIT

If the temperature of the water tank falls below the measuring range (approx. 7 °C), the alarm message “TEMP <= 32 °C” and “CHECK UNIT” appears in the display together with the red fault display lamp and the temperature display “-- --”. The alarm cannot be disabled and the unit must therefore be switched off using the power switch.



The storage and ambient temperature must be observed in order to prevent damage to the unit and ensure maximum possible operational safety.

CHECK UNIT
->CALL SERVICE

The alarm message “CHECK UNIT” and “->CALL SERVICE” together with the red fault display lamp and the acoustic signal are triggered following a number of faults. The alarm cannot be disabled and the unit must therefore be switched off using the power switch.

In this case, the unit must be checked by the customer service organization.

Power Failure Alarm

If the power supply fails during operation, this is signaled by the acoustic signal and the red fault display lamp on the unit. None of the other displays function in the event of power failure. The unit’s energy storage system allows the alarm to function for 10 minutes without the power supply.

The alarm can only be disabled by switching off the unit using the power switch. The alarm goes off automatically once the power supply is restored.

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6. Cleaning and Disinfection

Surface of the Unit

Once the unit has been disconnected from the power supply, its surface can be cleaned and disinfected using standard surface disinfectants. The instructions from the manufacturer of the disinfectant regarding handling and material compatibility must be observed.

The unit can only be put back into use once its surface is completely dry.

Water Tank

(see Chapter 7)



Operators should not use any cleaning and decontamination methods other than those recommended by the manufacturer without checking with the manufacturer beforehand whether the suggested methods could cause damage to the unit.

Disposal



This unit must NOT be disposed of as general commercial or domestic waste!

“Separate collection of electric and electronic devices”.



As per product responsibility regulations according to § 22 of the German Recycling and Disposal Act and the German Electrical and Electronic Equipment Act § 2, Para. 1, Fig. 8, this unit **MUST** either be disposed of at a municipal collection point or returned to the manufacturer.

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7. Maintenance and Safety Checks

Maintenance

In order to guarantee maximum operational safety and longevity of the unit, we recommend concluding a maintenance agreement with MAQUET Cardiopulmonary AG.

The water in the water tank must be replaced and the unit, including the tubes, must be disinfected as described below at least every two weeks:

1. Disconnect the unit from the power supply and place a container (bucket, bowl etc.) below the unit or place the unit somewhere where the water can drain away (e.g., sink).
2. Unscrew the screw cap on the filler neck (e.g., with a coin).
3. Unscrew the screw cap on the outflow point (e.g., with a coin) and allow the water to drain out.
4. Close the outflow point.
5. Fill the unit with water as described in Chapter 4 "Water Level" b). The capacity, up to the maximum value on the water level display, is 1.4 liters.
6. Add HU35 disinfectant to the tank as per the instructions for use.
7. Connect the bypass tube (join together the ends of the water tubes using an adapter).
8. Start the pump and occasionally change the water outlet temperature
9. Stop after approx. 30 minutes, allow the water in the tank to drain away (repeat steps 1 to 4) and refill the tank with fresh water (see Chapter 4 "Water Level" b).
10. Repeat every 2 weeks.

A thin film of silicone grease or Vaseline must be applied to the black sealing rings (O-rings) on all the couplings at least every 6 months.

If you have any questions on servicing and maintenance, please contact:

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7. Maintenance and Safety Checks

Safety Checks

Safety checks (SC) must be carried out every 12 months. The operator is responsible for ensuring that the SC is performed correctly. The SC may only be performed by MAQUET Cardiopulmonary AG or an authorized person. The safety checks comprise the following points as a minimum:

1. Inspection of the unit and the applied part for external damage, wear, ageing and legibility of the displays and labels.
2. Measurement of the protective ground resistance and the earth leakage current as per the testing equipment and the manufacturer's instructions.
3. Inspection of all functions as per the User's Manual.
4. Inspection of all safety functions as per the manufacturer's instructions.
5. Calibration of the sensors as per the manufacturer's instructions in the service manual (available to authorized persons from the manufacturer).

8. Troubleshooting

Error	Possible causes	Possible remedies
No or insufficient water circulation	<ol style="list-style-type: none"> 1. Tubes are kinked 2. Couplings are not clicked into place 3. Unit is positioned well below the oxygenator 4. Pump is worn out/defective 	<ol style="list-style-type: none"> 1. Ensure that the tubes are laid and positioned correctly 2. Push the couplings together firmly 3. Position the unit at the same height or higher 4. Customer service organization*
Stiff couplings	<ol style="list-style-type: none"> 1. Sealing ring is dry and brittle 	<ol style="list-style-type: none"> 1. Apply Vaseline, silicone grease or a similar product to the sealing ring
Coupling connection drips continuously	<ol style="list-style-type: none"> 1. Outer, visible sealing ring is damaged or missing 	<ol style="list-style-type: none"> 1. Replace the sealing ring*
Coupling valve of the coupling which is not connected drips continuously	<ol style="list-style-type: none"> 1. Inner sealing ring is damaged 2. Inner sealing ring is soiled 	<ol style="list-style-type: none"> 1. Customer service organization* 2. Connect and disconnect the coupling several times – contact the customer service organization if necessary
Heat dissipation value not shown Display message “HEAT EMISS. 0 W” or “WARMING-UP TIME”	<ol style="list-style-type: none"> 1. Temperature difference (setpoint/actual value) 	<ol style="list-style-type: none"> 1. Heat dissipation is only shown if the setpoint and actual temperature are the same
Alarm + display message: “ALARM TEST FAIL” “->CALL SERVICE”	<ol style="list-style-type: none"> 1. Independent safety device is defective 2. Pump has an electrical defect 	<ol style="list-style-type: none"> 1. Customer service organization* 2. Customer service organization*
Alarm + display message (once): “TEMP.DIFF. >1 °C”	<ol style="list-style-type: none"> 1. Coupling or decoupling of the oxygenator during operation 	<ol style="list-style-type: none"> 1. Acknowledge the alarm with the “Alarm Off” key during operation
Alarm + display message (every 10 minutes): “TEMP.DIFF. >1 °C”	<ol style="list-style-type: none"> 1. Heating cartridge or pump defective 2. Bypass is interrupted 3. Insufficient heat dissipation 	<ol style="list-style-type: none"> 1. Customer service organization* 2. Customer service organization* 3. Do not operate the unit continuously (>1h) without the tubes and oxygenator*
Alarm + display message: “WATER LEVEL!?” Can be acknowledged with the “Alarm Off” key for 10 minutes.	<ol style="list-style-type: none"> 1. Water level is too low 2. Unit is not positioned horizontally 3. Sensor error 	<ol style="list-style-type: none"> 1. Refill with water 2. Position the unit horizontally 3. Customer service organization*

8. Troubleshooting

Error	Possible causes	Possible remedies
Alarm + display message: "TEMP >= 40°C" Can not be acknowledged with the "Alarm Off" key	<ol style="list-style-type: none"> 1. Water tank is empty 2. Insufficient heat dissipation 3. Ambient temperature is too high 4. Sensor short circuit T2 	<ol style="list-style-type: none"> 1. Refill with water* 2. Do not operate the unit continuously (>1h) without the tubes and oxygenator* 3. Allow to cool and observe the max. ambient temperature* 4. Customer service organization*
Alarm + display message: "CHECK UNIT" "->CALL SERVICE"	<ol style="list-style-type: none"> 1. Various defects 2. Water tank is empty 3. Sensor failure/short circuit T1 	<ol style="list-style-type: none"> 1. Customer service organization* 2. Refill with water* 3. Customer service organization*
Alarm + display message: "TEMP <= 32°C" "CHECK UNIT"	<ol style="list-style-type: none"> 1. Unit is too cold ($\leq 32^{\circ}\text{C}$) 2. Sensor short circuit T2 	<ol style="list-style-type: none"> 1. Allow the unit to heat up for some time at room temperature* 2. Customer service organization*
The unit's functions and acoustic alarm fail	<ol style="list-style-type: none"> 1. Power failure 2. Power plug not connected 3. Fuse is defective 4. Unit is defective 	<ol style="list-style-type: none"> 1. Switch off the unit until the power returns 2. Check that the power plug is properly inserted into the unit and socket 3. Customer service organization* 4. Customer service organization

* Switch off the unit immediately



Opening the unit voids the guarantee!

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9. Technical Data and Accessories

Technical Data

Heater Unit HU 35

Article No. (REF):	1033557
Rated voltage:	230 VAC, 50 Hz
Power consumption:	530 W
Current consumption:	2.3 A
Measuring range:	approx. 7 - 50 °C
Measurement error 1:	< + 0.1 °C (display – water temperature)
Measurement error 2:	< + 0.5 °C (display – contact surface temperature)
Correction value:	0.5 °C (water temperature – temperature display)
Sensor element:	2 x NTC 5K
Setpoint range:	33 - 39 °C
Safety shutdown:	40 °C (independent safety shutdown)
Tank contents:	approx. 0.7/1.4 l (MIN/MAX)
Pump capacity:	10 W (max. 3-5 l/min., max. 0.34 bar)
Heating capacity:	500 W
Warm-up period:	approx. 5 - 10 min.
Fuse rating:	2 x T 3.15 A
Protection class/type:	I, B
Degree of protection:	IP X1 (protected against dripping water)
Risk class (93/42/EEC):	II b
Ambient temperature:	10 - 30 °C
Storage temperature:	10 - 40 °C
Permitted height difference:	max. 1 m (unit/oxygenator)
Dimensions W x H x D:	approx. 200 x 290 x 330 mm
Weight:	approx. 9 Kg (full)
Noise level:	approx. 35 dB(A) (1 m)
Alarm level:	> 65 dB(A) (3 m)
Applied Standards:	IEC/EN 60601-1, IEC/EN 60601-1-2
UMDNS code:	17-648

Subject to technical changes



The degree of electrical protection with the applied part complies with TYPE B.



Caution: The instructions and User's Manual must be observed.

9. Technical Data and Accessories

Accessories

Obligatory:

- The oxygenators to be used are listed in the brochures and price lists. Only original MAQUET PLS oxygenators or other original oxygenators may be used.
- HU35 water tube (approx. 1.5 m or 3 m)
- Double Hansen connectors
- HU35 coupling set on Hansen connectors
- HU35 disinfectant

Optional:

- HU35 clamp mounting for slide rails and HU35 clamp mounting for SPRINTER Cart
- HU35 water tube (approx. 1.5 m or 3 m) and HU35 tube holder

9. Technical Data and Accessories

Guidance and manufacturer's declaration – electromagnetic emissions

Tables for medical electrical equipment – General Requirements: – abridged version

Table 201

Row		
1	Guidance and manufacturer's declaration – electromagnetic emissions	
2	The [equipment or system] is designed for use in the electromagnetic environment specified below. The customer or the user of the [equipment or system] should ensure that it is used in such an environment.	
3	Emissions test	Compliance
4	RF emissions CISPR 11	Group 1
6	RF emissions CISPR 11	Class B
7	Harmonic emissions IEC 61000-3-2	Class A
8	Voltage fluctuations flicker emissions IEC 61000-3-3	Not applicable.
9		[see 6.8.3.201 a) 3) and image 201]

Table 202

Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines
Surges IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for ½ cycle 40% U (60% dip in UT) for 5 cycles 70% UT (60% dip in UT) for 25 cycles	<5% UT (>95% dip in UT) for ½ cycle 40% U (60% dip in UT) for 5 cycles 70% UT (60% dip in UT) for 25 cycles
Power frequency (50Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m

9. Technical Data and Accessories

Table 204: NON life-supporting systems

Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V
Radiated RF IEC 61000-4-3	3 Vrms 80 MHz to 2.5 GHz	3 V/m
Radiated RF IEC 60601-2-35	10 V/m	10 V/m

Table 206: Recommended separation distances between portable and mobile RF communication equipment and the equipment or system

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d=P*\exp0.5*3.5/V1$	80 MHz to 800 MHz $d=P*\exp0.5*3.5/E1$	800 MHz to 2.5 GHz $d=P*\exp0.5*7/E1$
0.01	0.12 m	0.12 m	0.24 m
0.1	0.37 m	0.37 m	0.74 m
1	1.17 m	1.17 m	2.34 m
10	3.69 m	3.69 m	7.38 m
100	11.67 m	11.67 m	23.34 m

10. Warranty and Liability Limitations

Warranty and Liability Limitations

MAQUET Cardiopulmonary AG warrants the conformity of this product with legal requirements, in particular those set forth in the European Medical Device Directive, 93/42/EEC. Therefore, if this device exhibits faults that can be directly attributed to defects in materials or workmanship that occurred during its manufacture or packaging ("faults"), and said faults appeared during the legally binding warranty period, MAQUET Cardiopulmonary AG will, at its discretion,

- a) replace the product with one of identical design, or
- b) replace the product with a comparable product with regard to function, or
- c) repair the product.

All the following conditions must be met in order to make a claim under this warranty:

- a) the product must not have been used outside its specification, or outside its intended use;
- b) the fault was immediately reported to MAQUET Cardiopulmonary AG or its representative.

This warranty in no way limits, but applies in addition to, the regulations governing liability on the part of the seller as well as German product liability law.

Furthermore, this warranty applies only to the extent defined above. Additional claims arising from this warranty are excluded. This warranty as well as the specified statutory rights apply in place of, and to the exclusion of, all other warranties, whether verbal or written, express or implicit, given by MAQUET Cardiopulmonary AG. None of our representatives or employees are authorized to give assurances or reach agreements to the contrary.

Due to numerous factors which lie outside the control of MAQUET Cardiopulmonary AG, such as shipping, storage, and handling on the part of the user, MAQUET Cardiopulmonary AG is not liable, in particular, for damage of any type resulting directly or indirectly from the product or its use unless said damage can be shown to be the result of a failure on the part of the product.

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