USER MANUAL

MOECK WARMING SYSTEM®

TWINWARM BB

Portable forced air warming device for use with MOECK WARMING SYSTEM® warming blankets/mats

Table of contents

1 The MOECK WARMING SYSTEM®

1.1 General description of products and performance characteristics

MOECK WARMING SYSTEM's comprehensive product solutions provide you with a tool that is effective as it is flexible for optimum temperature control for adult and paediatric patients. It was developed to help provide suitable day-to-day support for work in medical facilities with a particular focus on quality-oriented patient care. The MOECK WARMING SYSTEM® uses convective air transfer and comprises a forced air warming device (TWINWARM range) and various reusable warming blankets and warming mats. The temperature-controlled air generated by the forced air warming device is directed inside the connected warming blankets and warming mats via one or two flexible hoses. The carefully selected materials used for the warming blankets and warming mats ensure even air distribution around the patient. This provides effective patient temperature control according to the settings selected on the forced air warming device. The selection of high-quality components, collaboration with suppliers from Germany and skilled production at our Hamburg site all reflect our commitment to quality.
Improving wellbeing with warming – instead of being taken to an operating room or waking up cold. Patient temperature control with the MOECK WARMING SYSTEM® improves surgical outcomes, for example a lower incidence of wound infection, shorter post-op recovery times and shorter hospital stays.

The MOECK WARMING SYSTEM® TWINWARM BB convective two-hose forced air warming device is a professional medical device for patient temperature control.
Three preselection buttons make using the device quick and convenient, simplifying the clinical routine. With temperature settings to the exact degree between 28°C and 43°C and five selectable airflow output stages, users can take an individual approach to patient temperature control. The TWINWARM BB contains an exceptionally powerful heating element, generating up to 1,500 watts, thus ensuring more stable core body temperatures during patient temperature control. The combination of an optimised air supply and a high-quality radial fan results in low operating noise despite the high air flow. The aluminium handle and silicon components for mechanical protection equip the TWINARM BB for routine hospital use. Thanks to the swivel castors included as standard, the standard rail holding clamp and the trolley receptacle, flexible use in medical facilities is ensured. The hose end receptacle also makes transport and storage easy. The performance of the TWINWARM BB two-hose forced air warming device, used in combination with MOECK WARMING SYSTEM® warming blankets and warming mats, also aims to align the maximum temperature of the surface in contact with the patient – where compatible with the ongoing treatment – with the normothermic patient temperature.

1.2 Intended purpose

Forced air warming device for patient temperature control with reusable convective warming blankets and warming mats.

1.3 Indications

For the treatment of patients in medical facilities who require temperature management.
It is designed to treat both adult and paediatric patients (premature infants from 700 g).

1.4 Contraindications

- Warming of ischaemic limbs
- Warming of body parts distal to an arterial clamp
- Any application where influencing the patient's body temperature is medically contraindicated
- It should be noted that heat therapy can increase the effect or uptake of the patient's medication, which is associated with possible risk to the patient

1.5 Target patient group

- adult patients
- paediatric patients (premature infants from 700 g)

1.6 Intended users

- medically trained specialist personnel

1.7 Compatibility

The TWINWARM BB forced air warming device may only be operated with MOECK WARMING SYSTEM® warming blankets/mats or with other compatible warming blankets. More information is available on our homepage www.moeckundmoeck.de or on request.

1.8 Symbol definitions

	On/Off Switching on from standby Switching off to standby		Temperature (range, display and control)
	Fan speed	°C	Degrees Celsius, unit of measurement of the temperature displayed on the sensor and the default setting
	Increase the temperature or airflow output stage by one degree or one stage at a time		Reduce the temperature or airflow output stage by one degree or one stage at a time
	Baby button for pre-setting a temperature of 40 °C at airflow output stage 3.		Alarm symbol
	Caution		Caution: electrical voltage of 230V!
	Do not operate if a blanket is not connected!		Follow instructions for use
	Equipotential bonding		Alternating voltage (AC)
	Type of applied part (BF type)		Protective conductor
	Manufacturer	SN	7-digit serial number Year (2)/KW (2)/Number (3)
REF	Item number		Mass in kg
	Air humidity, limitation		Temperature limitation
	Top		Protect from moisture
	Fragile packaged goods		
CE 0494	CE-mark with the number of the notified body		Disposal according to the European Directive 2012/19/EU.

1.9 Explanation of signs

 Warning	Safety-related information that warns the user of hazards and provides guidance on how to prevent them. It serves to protect people from **harm**.
 Safety information	Safety-related information collected or grouped according to a rational organised system in a document or section of a document. This information explains safety measures, raises awareness on safety and can be used as a basis for training people on safety. Safety information aims to protect people from **hazards**.
Information	This alerts the user that they need to look at the instructions for use for important safety-related information, such as warnings and precautions, which cannot be affixed to the medical device itself for a variety of reasons.

1.9.1 Warnings

1. There is a risk of electric shock, fire or electromagnetic interference when using endocardial catheters.

2. Do not operate if a blanket is not connected. The hose nozzle MUST be connected to a suitable convective BLANKET, otherwise burns may occur!

3. The connected compatible warming blankets/mats should not come into contact with unhealed wound surfaces. Unhealed wound surfaces must be covered.

4. Additional warming of transdermal medicinal product applications (patches) can increase medication intake and harm the patient!

5. Always secure the patient so they cannot slip/fall off before switching on the device!

6. If you have to restrain the patient, do not attach them with only the warming blanket/mat, as this could lead to injuries.

7. Premature infants and babies absorb the ambient temperature faster!
   The vital signs of young patients must be monitored continuously.
   Warm to a maximum of 40 °C, if necessary, reduce the airflow output stage to 1 - 2.

8. To properly use the blanket, its perforated green side must face the patient. Otherwise there is a risk of thermal injuries.

9. Stop any treatment as soon as you hear or see a (visual or audible) signal and the device switches to standby mode. Follow the instructions in chapter 4 (Alarm system / error messages).
   If necessary, disconnect the device from the mains and contact a qualified service technician! Otherwise there is a risk of thermal injuries.

10. Treatment with warmed air must not be performed in places where transdermal drug therapy is performed! This could lead to increased drug delivery and serious/fatal injury to the patient.

11. The device's hose must not be under the patient or touch the patient's skin during the heat therapy. Otherwise there is a risk of thermal injuries.

12. If the warming unit, the power cable or any other component of the TWINWARM BB look damaged, do not use the device! In this case contact a qualified service technician!

13. Patients who are unresponsive or unable to communicate, or who have no skin sensitivity, must be checked for possible skin reactions. Furthermore, their temperature must be taken continuously or according to your institution's guidelines. The patient's vital signs must also be checked regularly. If vital signs are unstable, treatment should be discontinued, and a doctor informed immediately. If the treatment goal is achieved, the temperature should be adjusted.

14. Beware of electric shock! Only a qualified service technician may disassemble the temperature management device. If the device is connected to a power source, parts of it are live, even if it is in standby mode.

15. The use of accessories and cables other than those specified or provided by the device's manufacturer may result in increased electromagnetic emissions or reduce the device's electromagnetic immunity and may lead to faulty operation.

1.9.2 Safety information

1. The surface of the forced air warming device must be checked for mechanical damage before each use.

2. Do not use the device if it has mechanical damage or if it is not fixed securely or secured on a hard surface. Otherwise, it may cause injury.

3. Only ever connect the device to a power source that has a protective earth!

4. When using materials with good thermal conductivity, such as water, gel and similar substances, the patient's body temperature can cool down when the warming device is switched off.

5. To reduce the risks associated with dangerous mains voltage and fire:
   - The power cable must be visible and freely accessible at all times. The plug of the power cable serves as a disconnecting device. The wall socket should be as close as possible and freely accessible.
   - Do not use the warming device if the power cable looks like it may be damaged.
   - This device may only be connected to a power supply with a protective conductor.
   - Do not operate the device without filters or with defective ones! There is a risk of fire if the heater comes into contact with dust and lint!

6. Clean and disinfect the device before sending it in for maintenance and before disposing of it. Deliveries of contaminated medical devices should be transported in such a way that these medical devices cannot contaminate anything.

7. The device should only be used by trained medical personnel!

8. The device should only be serviced and repaired by qualified service personnel and according to the manufacturer's instructions.

9. Do not place the device under the operating table's armboard!

10. When the device is connected to a power source, parts of it are live, even if it is in standby mode. Before cleaning/opening the device, unplug it from the mains!

11. The use of accessories and cables other than those specified or provided by the device's manufacturer may result in increased electromagnetic emissions or reduce the device's electromagnetic immunity and may lead to faulty operation.

12. Portable HF communication equipment (radios) should not be used within 30 cm of the cables for the device specified by the manufacturer. Failure to do so may reduce the performance of the device.

13. The device must not be used on several patients at the same time.

1.9.3 Information

1. The patient's body temperature must be taken according to your institution's guidelines and the patient must be checked for any possible skin reactions. The patient's vital signs should be checked regularly.

2. Only clean the forced air warming device according to the method prescribed by the manufacturer and in accordance with the local hygiene guidelines for wipe disinfection of surfaces.

3. This device should not be used directly next to other devices or stacked with other devices, as this could result in faulty operation. If it is still necessary to use it as described above, this device and the other devices should be monitored as they operate to ensure that they are working properly.

4. If an incident occurs that is directly or indirectly related to a MOECK WARMING SYSTEM® product, please immediately inform the manufacturer and the competent authority in your country and that of the patient (if different).

1.10 Proper operation and maintenance

The manufacturer is not responsible if the forced air warming device malfunctions, has performance or safety issues if:

- the device is used for something other than its intended use
- the device is improperly tested, maintained or repaired by persons who do not work for the manufacturer or who have not been commissioned or trained by the manufacturer
- the applicable guidelines for maintenance and repair of medical devices are not observed
- damage is caused by non-compliance with the information in these instructions for use

1.11 Instructions for maintenance and safety inspection (SI)

Maintenance, safety inspections (SI) and repairs of the TWINWARM BB forced air warming device may only be carried out by qualified personnel and in accordance with the service manual BB5304 and local regulatory requirements.

1.12 Warranty

The warranty period is 24 months from the date of sale in Germany and 12 months outside of Germany. It only applies to malfunctions caused by a defect for which the manufacturer is responsible.
There are no warranty claims:

- for wearing parts such as filters (provided there are no manufacturing defects)
- for damage caused by not replacing the filters in time or by operating the device without filters
- for mechanically damaged air hoses

The warranty claim shall be forfeited:

- if there is external damage to the housing
- if any manipulation of the device or in the device (e.g. loosening the cover screws, removing the fan) by unauthorised persons results in the destruction of a security seal. This does not apply if medical personnel remove the base to change the EPA filter unit

2 Detailed description

2.1 The forced air warming device

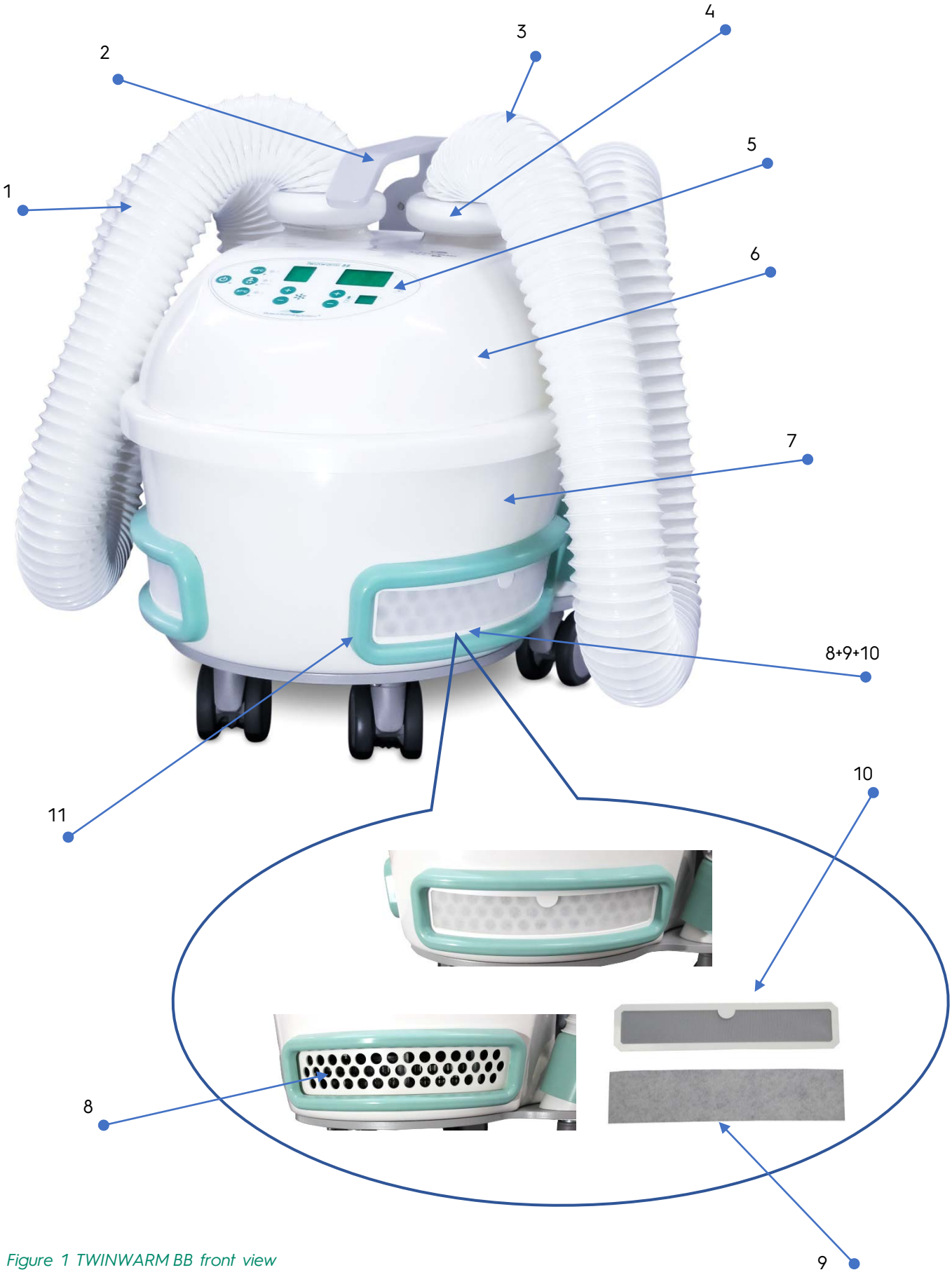
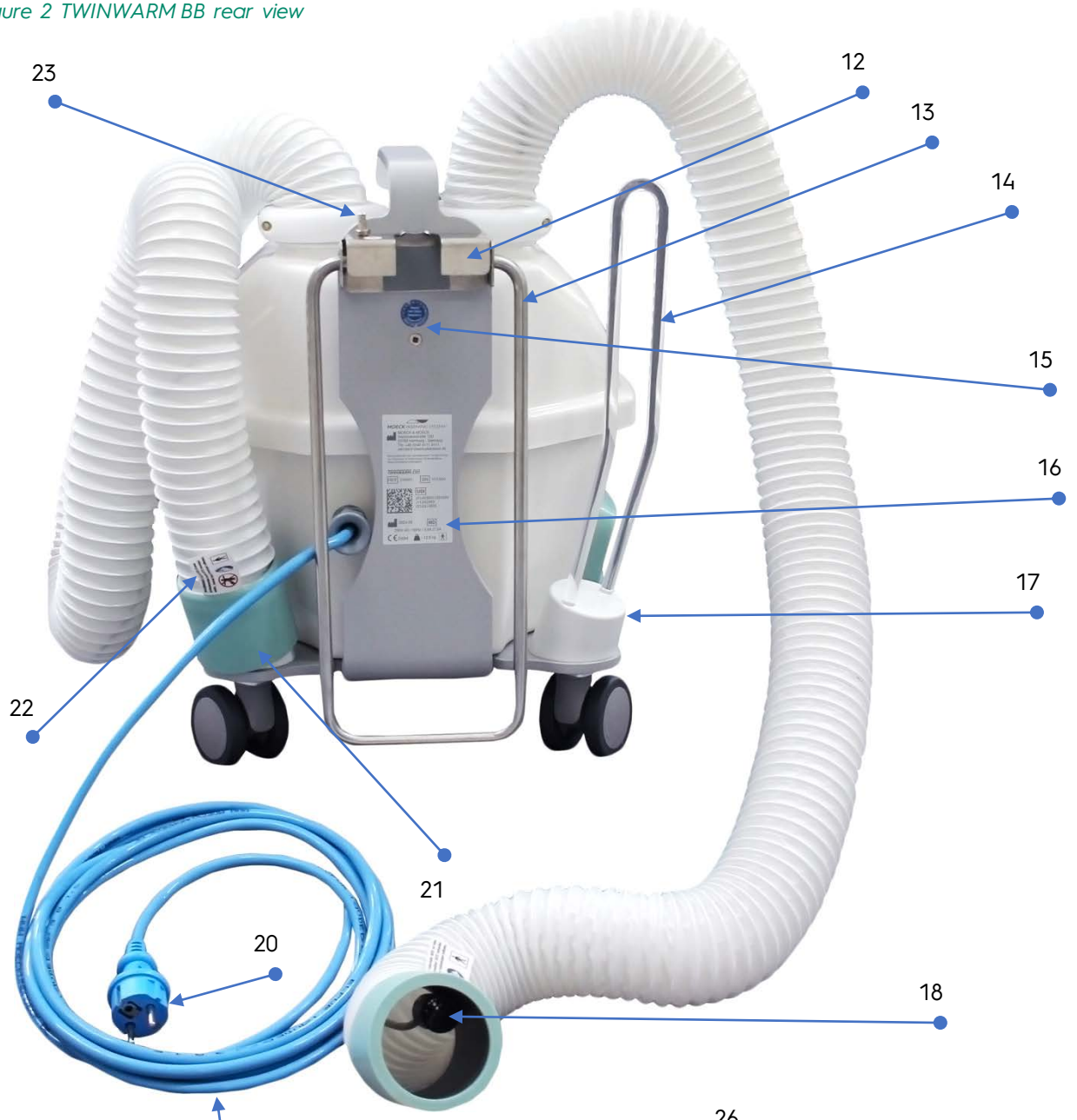


Figure 1 TWINWARM BB front view

Figure 2 TWINWARM BB rear view



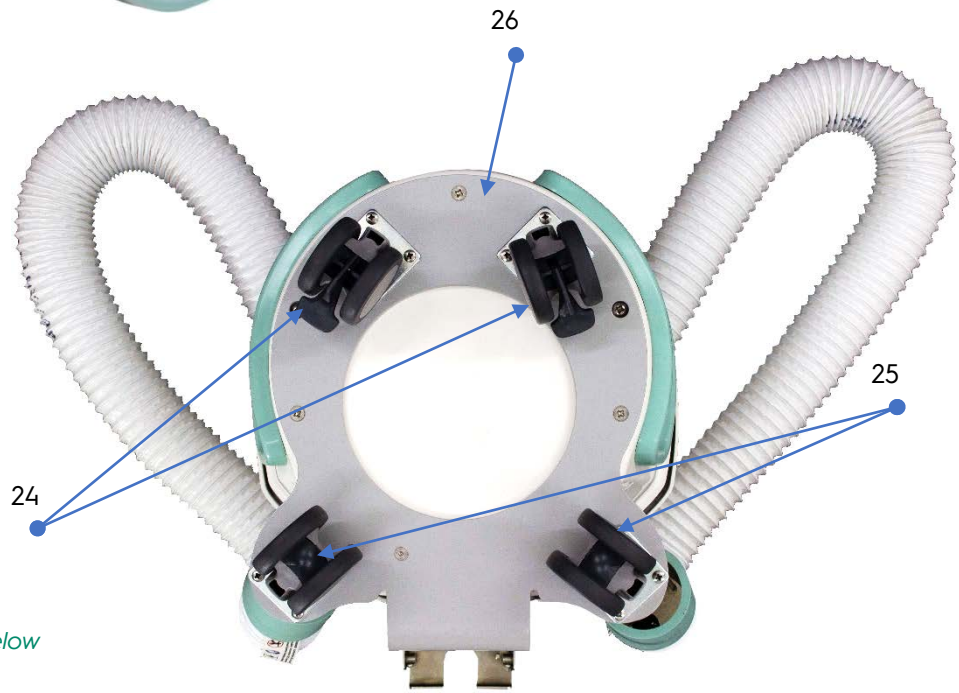


Figure 3 TWINWARM BB from below

2.2 Description of the device

Figure 1 TWINWARM BB front view

1. Warm air hose left
2. Carrying handle
3. Warm air hose right
4. Hose clamp
5. Control panel
6. Top cover of the housing
7. Bottom cover of the housing
8. Air inlet
9. Fleece filter
10. Filter attachment
11. Coarse filter frame

Figure 2 TWINWARM BB rear view

12. Standard rail holding clamp
13. Trolley bracket
14. Hose end receptacle
15. SI inspection sticker
16. Nameplate
17. Hose end cone
18. External temperature sensor in the hose end
19. Power cable
20. Mains plug (country-dependent specifications may differ from the image)
21. Hose end
22. Warning no. 2
23. Protective bonding conductor

Figure 3 TWINWARM BB from below

24. Castors with brakes
25. Castors without brakes
26. Housing bottom

The forced air warming device draws in air at ambient temperature through a three-stage filter system (1. – [9] Fleece filter, 2. – [10] Filter attachment, 3. EPA filter). The filtered air is then warmed to the set temperature by a heating coil. To that end, temperature sensors are located on each of the two hoses. They help to ensure that the air exiting the hose is at the selected temperature. The warmed air passes through the hoses into the connected warming blankets/mats and is supplied to the patient.

The (2) Carrying handle is used to carry the device and an optional (13) Trolley bracket makes it easier to pull the device. When the device is switched off, the (14) Hose end receptacle must be used to hold the hoses (1 + 3); in single-hose operation (see step-by-step operating instructions, no. 3), they are used to create an airtight seal for the unused hose.

The forced air warming device has a (23) Protective bonding conductor, which can be used to establish a direct connection to the electrical installation's equipotential bonding busbar if required. Requirements for the protective bonding conductor can be found in EN 60601-1.

2.3 The control panel

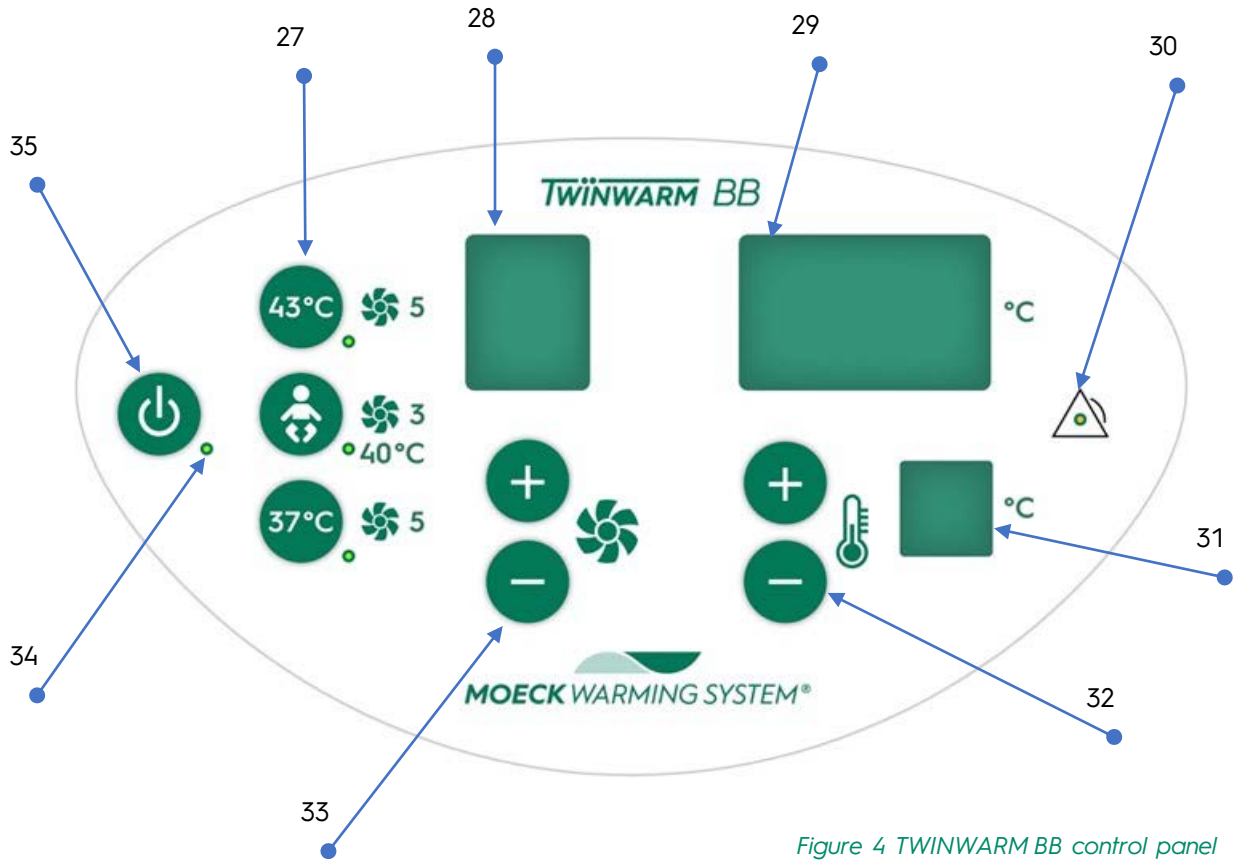


Figure 4 TWINWARM BB control panel

Figure 4 TWINWARM BB control panel

27. Preset buttons (incl. flashing LEDs)
28. Display: Airflow output stage
29. Display: Actual temperature
30. Alarm light
31. Display: Desired temperature
32. Temperature setting buttons
33. Airflow output stage setting buttons
34. Standby light
35. On/Off button

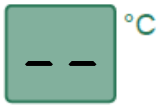
The device is in standby mode when it is connected to a properly earthed power source. The (34) Standby light lights up green and the software version is briefly displayed.

To switch on the device, press the (35) On/Off button and then select the default settings using the three (27) Preset buttons (incl. flashing LEDs). The forced air warming device has three preselection buttons:

43°C 5	43 °C and airflow output stage 5
3 40°C	40 °C and airflow output stage 3 (baby button)
37°C 5	37 °C and airflow output stage 5

After you press the button, the corresponding green LED lights up and the forced air warming device automatically starts a self-test to check that it is functioning properly. The self-test ends with three beeps and the default settings are ready.

During operation, you can set the temperature between **28°C** and **43°C**, to the exact degree if required ([32] Temperature setting buttons). It is also possible to operate the device at **ambient temperature (--)**.

		
temperature control at ambient temperature	desired temperature example (lowest temperature setting)	desired temperature example (highest temperature setting)

The selected temperature appears in the (31)Display: Desired temperature, the temperature currently measured at the (21)Hose end in the large (29) Display: Actual temperature.

There are five different **airflow output stages**. They can be changed by pressing the (33) Airflow output stage setting buttons button and the current stage appears in the (28) Display: Airflow output stage.

The (30) Alarm light lights up or flashes in the event of an error, accompanied by an alarm sound and an error code that appears on the control panel's display fields (28) + (29). Chapter 4 (Alarm system / error messages) describes the meaning of the error codes.

If the power supply is interrupted during operation, the forced air warming device goes back into standby mode again and must be restarted.

3 Step-by-step operating instructions

Warning

Do not operate if a blanket is not connected. The hose nozzle MUST be connected to a suitable convective BLANKET, otherwise burns may occur!

3.1 Preparing the device

Check the device for visible defects and damage.

Ste Make sure that the (9) Fleece filter and (10) Filter attachment are inserted and the opening of the (8) Air inlet is completely covered. (See Figure 6 and Figure 6)

—> Repair any visible damage before powering the device.

Figure 6 Correct

Figure 6 Incorrect

3.2 Setting up the device

Position the device upright on the floor. The device can also be hung on a standard rail or bed frame using the standard rail holding clamp on the back. Make sure that the device cannot fall down.

Check that the (8) Air inlet is not covered (e.g. with a surgical drape) so that the air can flow freely. Otherwise, the device's air supply will be blocked.

Lock the (24) Castors with the brakes to secure the device against unintentional movement.

3.3 Connecting the device to a MOECK WARMING SYSTEM® warming blanket/mat

Insert the hose into one of the warming blanket/mat's Velcro openings. The hose end must be pushed up behind the Velcro in the blanket inlet.

Tighten the blanket inlet's Velcro around the end of the hose so that the rest of the opening is closed, the hose is fixed and cannot slip back. (See Figure 7)

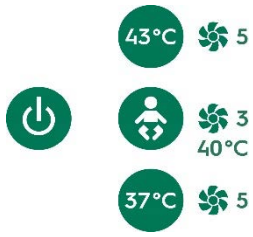
Make sure that airflow is not obstructed by a kinked hose!

Figure 7 Connection to the warming blanket/mat

If you are not using the second air hose, it must be pushed into the (14) Hose end receptacle and closed with an airtight seal by the (17) Hose end cone on the bottom of the housing. The warm air thus only reaches the warming blanket/mat through the other hose. (See Figure 8)

Figure 8

3.4 Connecting the device to the power source and switching it on

Connect the device to a properly grounded power source using the (19) Power cable. IMPORTANT NOTE: The (20) Mains plug serves as a disconnecting device from the mains supply. The (20) Mains plug must therefore be easy to reach and unplug from the socket. Place your device so that it can be disconnected from the power supply at any time. The mains socket should always be near your device and easily accessible. The device automatically switches to standby mode and the green (34) Standby light lights up.	
Switch on the device with the (35) On/Off button and select the desired setting with the (27) preset buttons. The device will then perform a self-test. It will emit three short beeps after a successful self-test. Make sure that this is done correctly. (If you don't hear anything, see chapter 4 (Alarm system / error messages) The device will now start operating with the default settings.	
The airflow speed can be changed at any time. It can be set from level 1 (very low) and level 5 (very high) by pressing the (33) Airflow output stage setting buttons. If small MOECK WARMING SYSTEM® blankets are used, such as the baby/toddler or toddler and cardio blanket, we recommend selecting the default baby button setting (airflow output stage 3) and reducing it if necessary.	
You can set the airflow temperature to the exact degree between 28 °C and 43 °C. You can also operate it at ambient temperature (--).	
In the ambient temperature setting (--), the warming is off. No over- or under-temperature alarm can be triggered in this state!	
The "Lo" or "Hi" information signal lights up during the warming phase and if there are major changes in temperature selection. This means that the device is still in the warm-up or cool-down phase and that the desired temperature has not yet been reached. It is not an indication of a possible malfunction. The "Lo" or "Hi" information signals turn off as soon as the temperature is near the preset value (+/-2 °C).	
The patient's body temperature must be taken according to your institution's guidelines and the patient must be checked for any possible skin reactions. The patient's vital signs should be checked regularly.	

3.5 Finishing use

When heat therapy is finished, press the (35) On/Off button to switch off the forced air warming device. Unplug the (20) Mains plug and (19) Power cable loosely wind it around the (12) Standard rail holding clamp or (2) Carrying handle. See Figure 9	

Open the Velcro fastener to remove the hose from the warming blanket/mat.

You can now release brakes of the (24) Castors and roll or carry the device, see Figure 9.

Clean the forced air warming device after each use (see chapter 5.1 Cleaning and disinfection).

Figure 9

4 Alarm system / error messages

Precaution

In the ambient temperature setting (--), the warming is off. No over- or under-temperature alarm can be triggered in this state!

The forced air warming device's software detects several operating states which do not pose a danger in themselves, but which trigger a low-priority alarm, e.g. to alert the user of slight over- or under-heating at the (21) Hose end. The associated error messages appear alternately with the (29) Display: Actual temperature during operation. The yellow alarm light lights up and a warning signal sounds. In the event of a persistent error or a technical problem, the device switches itself off and the control panel no longer registers commands (for error acknowledgement see 4.3 Error acknowledgement [ALARM-RESET]).

If several alarms of the same priority level go off, the alarm that occurred first is displayed. If alarms of a different priority level go off, the higher-level alarm has priority.

To observe the alarm, the operator should stand facing the display and preferably less than 4 m away.

Checking the alarm system:

- When the self-test is finished, the forced air warming device plays a sequence of three short beeps. This beep sequence indicates that the speaker is working correctly.

  Make sure that the three beeps are played correctly after a successful self-test each time the device is used!
  If the device does not correctly emit the three beeps, do not operate the device and inform the service department (also see chapter 6 Technical service and orders).

- The procedure for checking that the alarm is functioning correctly is described in the **service manual BB5304**.

4.1 Information signals

Lowest alarm level – no beep, the yellow (30) Alarm light does not light up - only the warning message appears on the display.

Anzeige		Mögliche Ursache	Erklärung/Lösung
	HI	Desired temperature setting up to 40 °C selected: The emitted air temperature is more than 2.5 °C but less than 3 °C higher than the desired temperature. If the emitted air temperature is more than 3 °C higher, a low priority alarm is triggered. Desired temperature setting over 40 °C selected: The emitted air temperature is more than 2.5 °C but less than 5 °C higher than the desired temperature. If the emitted air temperature is more than 5° C higher, a low priority alarm is triggered.	This can occur when you make major changes to the selected temperature. Over time: If the temperature difference persists for more than 3 minutes, a low-priority alarm is triggered.
	Lo	Desired temperature setting up to 40 °C selected: The emitted air temperature is more than 2.5 °C but less than 3 °C under than the desired temperature. If the emitted air temperature is more than 3 °C under the desired temperature, a low priority alarm is triggered. Desired temperature setting over 40 °C selected: The emitted air temperature is more than 2.5 °C but less than 5 °C lower than the desired temperature. If the emitted air temperature is more than 5 °C under the desired temperature, a low priority alarm is triggered.	This is normal when you start up the device or make major changes to the selected temperature. Over time: If the temperature difference persists for more than 3 minutes, a low-priority alarm is triggered.

Note	A non-inflated warming blanket/mat is a sign that the device is malfunctioning!

4.2 Low-priority alarms

Low-priority alarm with beeping and warning message, the yellow (30) Alarm light lights up.

Temperature alarms (beep sequence "c – d")			
Display		**Possible cause**	**Explanation/Solution**
	HI	The emitted air temperature is more than 3 °C(desired ≤ 40 °C) or 5 °C (desired > 40 °C) higher than the desired temperature.	This can occur when you make major changes to the selected temperature. Over time: Alarm goes off immediately after the alarm condition occurs. After 1.5 minutes, the device switches to standby mode with the error display.
	Lo	The emitted air temperature is more than 3 °C (desired ≤ 40 °C) or 5 °C (desired > 40 °C) lower than the desired temperature.	This is normal when you start up the device or make major changes to the selected temperature. Over time: Alarm goes off 45 seconds after the alarm condition occurs. After 1.5 minutes, the device switches to standby mode with the error display.
	F00	Interior temperature too high (> 56 °C)	Temperature inside the device is too high. The device switches to standby mode with the error display.
	F01	Bimetallic switch has been triggered	Temperature inside the device is too high. The device switches to standby mode with the error display.

General alarms (beep sequence "c – c")			
Display		**Possible cause**	**Explanation/Solution**
	F04	Internal power supply	Hardware error. The device switches to standby mode with the error display. The alarm is only deactivated after the error is acknowledged (2×). For further instructions see Error acknowledgement section
	F05	Memory (electronic memory)	
	F06	The airflow is interrupted/blocked	Check that: the air can flow freely through the hoses into the blankets, the filters are not clogged, a compatible MoeckWarmingSystem® warming mat/blanket is being used. Over time: After 3 minutes of the alarm condition, the device switches to standby mode with the error display. **Please note:** Warming is temporarily switched off during this error for safety reasons.

General alarms (beep sequence “c – c”)			
Display		**Possible cause**	**Explanation/Solution**
	F07	Internal transmission path	Hardware error. The device switches to standby mode with the error display. The alarm is only deactivated after the error is acknowledged (2× ). For further instructions see Error acknowledgement section.
	F08	Internal temperature sensor	
	F09	Heating	
	F 10	external temperature sensor — **right**	
	F 11	External temperature sensor — **left**	
	F 12	Control panel	
	F 13	Relay	

Note	Even if the mains plug is unplugged and then plugged back in, the alarm message remains. The alarm message will only disappear when the alarm has been acknowledged (see above).

4.3 Error acknowledgement [ALARM-RESET]

Only for low priority alarms that cause the device to switch off

1. Acknowledge error message by pressing 2×  (baby button)

2. When the F06 alarm is displayed, if need be, eliminate the cause of the error message (e.g. straightening out a kink in the warm air hose) as described.

3. When the F09 alarm is displayed, resolve the cause of the error message if any (e.g. Device not acclimatised during start-up).

4. Switch the device on again.
   - After a successful self-test, the device works as usual.
   - If the device repeats the error message when restarting after the self-test, return the device for service or repair.

5 Cleaning, disinfection and maintenance

Do not clean, disinfect or service the forced air warming device while it is in operation.
You can find a description of possible repairs in the service manual, which can be obtained from the contact person indicated in the chapter 6 Technical service and orders.

5.1 Cleaning and disinfection

Clean the forced air warming device and the hoses after each use.

Safety information

- When the device is connected to a power source, parts of it are live, even if it is in standby mode. Before cleaning/opening the device, unplug it from the mains!
- Only clean the forced air warming device according to the method prescribed by the manufacturer and in accordance with the local hygiene guidelines for wipe disinfection of surfaces.

Do not clean the device with steam, a water jet or by directly immersing it in water. The parts inside the device can be damaged by direct contact with water.

Resources required

- Cleaning solution
- Soft cleaning cloth
- Soft brush
- Drying cloth
- Suitable disinfectant*

Procedure to be followed

1. Unplug the mains plug before cleaning the device.

2. Check the surface of the forced air warming device for mechanical damage such as cracks or broken housing parts before cleaning. If you find any mechanical damage, inform the service department or send the forced air warming device for repair (also see chapter 6 Technical service and orders).

3. Clean the device with a soft cloth and a cleaning solution containing mild soap. To do this, wring out the cloth you are using thoroughly, so that no excess water drips onto the device. A soft brush can be used if there is significant soiling. Then dry the device with a cloth.

4. The device must be disinfected after each use in accordance with the local hygiene guidelines in place. Efficient wipe disinfection is achieved with a suitable disinfectant*. Refer to the hazard and safety precautions of the disinfectant manufacturer.

   Using a suitable disinfectant*

   4.1 Remove a damp cloth from the disinfectant box and fold once.
   4.2 Wipe the surfaces to be disinfected three times with the moist cloth, so that the whole surface is wetted.
   4.3 As soon as the disinfectant has soaked in, repeat step 4.2 with a second cloth.
   4.4 For optimal disinfection, the application time must not be less than 5 minutes.

   Steps 4.1 to 4.3 should be carried out on all relevant surfaces.

Note	The following surfaces of the Twinwarm BB should be cleaned and disinfected with particular caution: • Warm air hose • Hose clamp • Control panel • Carrying handle • Power cable
Note	The filter frames of the air inlet filters can be cleaned and disinfected in the same way as the outer surfaces of the device. When they are dirty, the fleece filters can be removed and carefully washed with disinfectant liquid. Do not wring them out!
Note	The hoses can be lightly stretched to make cleaning and disinfection easier.
Note	Do not immerse the hoses directly in disinfectant solution.

** **mikrozid® PAA+ wipes** from Schülke & Mayr GmbH*
*The disinfectant **mikrozid® PAA+ wipes** from Schülke & Mayr GmbH has been validated for the TWINWARM BB forced air warming device in accordance with the provisions of the Medical Device Regulation (EU) 2017/745.*

5.2 Changing the coarse filters

The coarse filters can be accessed from the outside ([10] Filter attachment with [9] Fleece filter) should be changed or cleaned when necessary.

Safety information

- Do not operate the air warming device without filters or with defective ones! There is a risk of fire if the heater comes into contact with dust and lint!
- When the device is connected to a power source, parts of it are live, even if it is in standby mode. Before cleaning/opening the device, unplug it from the (20) Mains plug!
- The (7) Bottom cover of the housing of the device may only be opened by qualified service personnel (e.g. for cleaning the inside or changing the EPA filter)
- Any manipulation of the device by unauthorised persons voids the warranty and the declaration of conformity. This does not include changing the coarse filter.

Note	Damaged and missing (10) Filter attachment and (9) Fleece filter must be replaced.

5.3 Procedure to be followed

1 Unplug the (20) Mains plug before changing the filter.

Figure 13

2 Carefully remove the (10) Filter attachment with the (9) Fleece filter from the (11) Coarse filter frame. (See Figure 13 + Figure 12)

The filter attachment can be cleaned by wipe disinfection (see cleaning section). You can also carefully vacuum lint and dust.

Figure 12

3 Insert the new or cleaned (9) Fleece filter into the (11) Coarse filter frame.

Then carefully insert the (10) Filter attachment, pressing the (9) Fleece filter gently if necessary.

Figure 11

Figure 10

Note Make sure that you insert the fleece filter into the coarse filter frame without any gaps! (See Figure 10)

Note Defective coarse filters and significant soiling are signs that the area behind the coarse filters inside the device is contaminated. In which case, this area must be cleaned further. This should only be done by a trained service technician.

Note You can purchase filter attachments and/or fleece filters from the customer service department, as described in chapter 6 Technical service and orders.

5.4 Changing the EPA filter

The EPA filter must be replaced after two years at the latest (e.g. as part of SI testing) or when necessary (e.g. weakened airflow, dirt/contamination inside the device).

Instructions for changing the EPA filter can be found in the **service manual BB5304** or are available on request (for contact information, see technical service and orders). An SI test must always be performed after changing the EPA filter!

6 Technical service and orders

You can request the current spare part and accessory lists as well as information on MOECK WARMING SYSTEM® warming blankets/mats at any time by email or telephone directly from the manufacturer or from the contact person responsible for your account.

For contact details see back of manual.

If further repair work is necessary or if you would like to send the device in for repair, you can request the corresponding descriptions or contact customer service and technical service:

Customer service / technical service:
Email: service@moeckundmoeck.de
Phone: +49 (0)40 4111 4111

Please remember that we need the serial number of the forced air warming device when you call us. This can be found on the nameplate on the back of the device.

7 Disposal

1. DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of July 2012 on waste electrical and electronic equipment
2. German Act Governing the Sale, Return and Environmentally Sound Disposal of Electrical and Electronic Equipment (Electrical and Electronic Equipment Act – ElektroG)

According to European regulations (1) and German law (2), used electrical and electronic equipment may no longer be disposed of with unsorted household waste.

You should return the device either to the manufacturer or to the employee responsible for your account. If you have any questions regarding disposal, please contact us via the contact information on the back of these instructions for use.

Note

- The device must not be taken to public collection points for disposal
- Dispose of the used coarse and EPA filters with hospital waste
- Dispose of exchanged hoses and castors with hospital waste

8 Technical specifications

Classification	
Standards	EN 60601-1 *et seq.*
	EN 80601-2-35
EMC	EN 60601-1-2
Classification according to the Medical Device Directive	Class IIb Type BF

Device characteristics	
Dimensions	46 cm high × 37 cm wide × 46 cm deep
Weight	12.6 kg
Lifespan	10 years
Filter system	Coarse and EPA filters

Ambient condition	
Operating temperature	15 °C – 35 °C
Humidity	10% to 90 % relative humidity
Height above sea level	Max. 2,000 m
Storage/transport conditions	0 °C to 50 °C

Thermal properties	
Adjustable temperature range	Ambient temperature, 28 °C – 43 °C
Temperature deviation at hose outlet	+/- 1 °C
Duration of warming of the contact surface from 23°C to 37°C	165 seconds
Maximum temperature of the contact surface	44 °C

Electrical properties	
Device performance	230 VAC, 50 Hz, 7 A max.
Protection class	Class 1
Power consumption	Max. 7 A (1,725 watts)
	Average: 3.6 A (828 watts)
Power cable	4.6 m (3-pole)
Fuses	2× F10AH/250V

9 Electromagnetic compatibility (EMC)

This medical device is intended for use in hospitals and professional healthcare institutions.

The essential performance characteristics of the device (i.e. warming to the set temperature with a deviation – even in the event of a fault – of no more than +/-3.0 °C, or otherwise generating an over- or under-temperature alarm) are not affected by the EMC conditions established in accordance with EN 60601-1-2.

Medical electrical devices are subject to special EMC-related precautions

Wismar, 2019-10-24

Test Report #418.023.2 Rev.0

EMC tests on the devices/equipment:

Twinwarm BB

Equipment under Test:

Description: Patient warming system
Model: Twinwarm BB

Applicant/ Manufacturer: **Moeck & Moeck GmbH**
Waidmannstraße 21d
D-22769 Hamburg, Germany

Test laboratory: CEcert GmbH.
Alter Holzhafen 19/19a
D-23966 Wismar, Germany

Summary of Test and Certification:

Tests:	Standards:	Result:
Emission:		
Conducted emission	IEC 60601-1-2:2014	**PASS**
Radiated emission	IEC 60601-1-2:2014	**PASS**
Interference immunity:		
Electrostatic discharge	IEC 60601-1-2:2014	**PASS**
Electromagnetic field	IEC 60601-1-2:2014	**PASS**
Electrical Fast Transient (Burst)	IEC 60601-1-2:2014	**PASS**
Surge immunity	IEC 60601-1-2:2014	**PASS**
Conducted disturbances, induced by RF-fields	IEC 60601-1-2:2014	**PASS**
Magnetic field (power-frequency)	IEC 60601-1-2:2014	**PASS**
Power supply drop, short interruptions	IEC 60601-1-2:2014	**PASS**
Low frequency phenomena:		
Harmonic current	IEC 61000-3-2:2014	**N/A**
Flicker in power supply	IEC 61000-3-3:2013	**N/A**

Explanation:
PASS – The EUT meets the test requirements. FAIL – The EUT does not meet the requirements N/A – Test is not applicable.

Evaluation :

The Equipment under Test (EuT) meets the EMC requirements of the IEC 60601-1-2 (group 1, class B equipment for use in professional healthcare facilities) in the above listed specification.

Period of test: 2019-08-28 - 2019-09-04

This test report with appendix consists of **30** pages.

1. General information on the test item(s)

Description: Patient warming system
Model: Twinwarm BB
Serial no.: 194401

Manufacturer/Customer: Moeck & Moeck GmbH
Contact person: Mrs. Weiser
Date of receipt of test items: 2019-08-13

Brief description:
EMC conformity test of a patient heating system for use in medical application. The warming system consists of a ventilating heating unit combined with an air hose and various blankets.
The test scope was defined by the manufacturer.

Steps to EMC, suppressions:
- Ferrite WE 742 715 3 (two turns) on temperature sensor (both sensors)

Participant in the tests: none

Responsible for the technical content of the test report:

	name	signature
Tested by	Sebastian Lupp	S. Lupp
Approved by Dipl. Ing. (FH)	Andreas Schenk	CEcert GmbH EMV EMC + Safety

Note:

The CEcert GmbH assures the applicant that the tests are carried out within the scope of the tests outlined under point 2 and in accordance with the test specifications outlined under point 3. Any exceptions or deviations will be clearly indicated.

The results contained in this test report are relevant exclusively to the item(s) submitted for testing. The CEcert GmbH is not liable for any conclusions and generalizations which may be drawn from the test results and applied to further samples and examples of the type of device represented by the item submitted for testing.

This report may only be reproduced or published in its entirety. Written permission must be obtained from the CEcert GmbH prior to the reproduction or publishing of extracts.

Report history Log:

Ref.	Date of issue	Comment	Approved by
418.023.2 Rev.0	2019-10-24	first certification	A. Schenk

A detailed manufacturer's declaration on electromagnetic emission and immunity can be found in the service manual BB5304 and is available on request (for contact details see technical service and orders).

Notes

CE 0494

MOECK & MOECK

MOECK & MOECK GmbH
Waidmannstraße 12 d · 22769 Hamburg · Germany
Tel. +49 (0)40 4111 4111 · Fax +49 (0)40 4116 7354
info@moeckundmoeck.de · MOECKWARMINGSYSTEM.COM

BB5300en Rev. 8.1 As of 04-2025