

KANMED[®] WARMCLOUD

User Manual

KANMED WarmCloud™

Art no OT-600-070/9

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0413

Caution

Incorrect use of heating equipment
can cause serious injury.
Read this manual carefully.

Manufactured by:
KANMED AB
www.kanmed.se



This manual is valid for KANMED WarmCloud system serial number 200 and above, with main program version 99 1.5 or higher and hand control program version 99 1.4 or higher. Subject to changes.

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Unpacking the system

Is the transport box intact?

If not make sure that the transport company notes this on the delivery receipt. If any damage is found on the equipment then this must be reported immediately to your supplier. Check against your order that everything has been delivered.

Note that KANMED WarmCloud is delivered from KANMED AB without the power cable. Save the transport material.

Be careful not to damage the air hoses when removing the unit from the box.



KANMED WarmCloud User Guide - Quick instruction

Caution! Incorrect use of heating equipment can cause serious injury. The user manual must be read completely before use.

CAUTION

The WarmCloud mattress is soft in order to prevent pressure sores. Consequently the patient stability may be slightly less than normal. Therefore it is important to follow the instructions below.

- Fasten the WarmCloud mattress to the OR table with the straps.
- Always secure the patient to the OR table with belts, hip pads and other means as per your hospital routine.
- Ensure that the mattress is correctly centred under the patient.
- Ensure that the Mattress is flat under the patient before inflating it (alternatively inflate before placing the patient on the Mattress).
- Stand next to the patient when inflating the mattress.
- Check the tension of safety belt and other patient security means after inflation of the mattress.

NOTE


Using a Kanmed WarmCloud mattress *with* straps **does not** replace/substitute the need of safety belts and routines as described above.

Preparation


Place the WarmCloud Air Mattress on the operating table. If the mattress has fastening straps then tie them to the side rail with a reliable knot. Do not tighten down the mattress too hard. The air hoses are connected to the air inlets and the Velcro straps are tightened securely. Connect the Hand Controller to the Main Unit. Connect the power cable to an outlet with protective grounding. Switch on the mains power switch, located at the power intake on the Main Unit. Observe that a self test is performed.

Note: Alarm code **PO LOS** will be received after mains power has been reconnected. This is normal! Press the Alarm button to reset the alarm. The system is now ready for operation.

Start

Press the  button on the Hand Controller to start. Always attend the patient when inflating the mattress.

Correct STOP procedure for the Control Unit

Reduce the pressure to 0 alternatively press the start/standby button  for 2 seconds. Switch of the Control Unit before you pull out the power cable.

Adjusting the temperature

42°C is the recommended start temperature and should be adjusted according to the patient’s needs.

Caution! It is highly recommended to monitor the patient’s actual core temperature with a reliable method.

Adjusting the pressure

Increase after start to about 45 mb. Then reduce to about 30 mb. Make sure that the patient is not “bottoming out”. This will block the airflow and reduce the warming efficiency. Check by inserting your hand between the Mattress and the operating table under the heaviest part of the patient. Very important with heavy patients. If required, increase the pressure by 5 or 10 mb. Ensure that there are no wrinkled materials under the patient.

Important Safety information

| | |
|---------------------------|--|
| Skin Protection | Always place a cushion under the part of the body located at the air inlets to prevent possible local overheating and skin damage. This is especially important when selecting the highest temperature and when using the short mattress. Always use some kind of protection for the heels, especially if they are close to the air inlets. |
| Patient Stability | The Mattress may fill or empty unevenly, therefore you must stand next to the patient when inflating or deflating the Mattress. Always make sure the patient is adequately secured to the OR table, even if you are not planning to tilt the operating table. |
| Weight limits | Please see section 5 for information and advice about patient weight limits. |
| Reduced Blood Flow | Parts of the body that have reduced or no blood flow should not be warmed. Reduce the temperature setting to lowest value well ahead of a blood vessel shut off. |
| Error Codes | Error codes are displayed on the hand controller. Full information is found in the user manual. |

USER MANUAL







1 Intended Use

The KANMED WarmCloud, a pressure relieving warm air Mattress, is designed to be used pre, per and post operatively. It must be used according to this manual. The system is intended to reduce the risk of hypothermia and pressure sores. It is not intended for home use. It may only be used by qualified medical staff that has undergone proper product training according to the hospital routine.

Only KANMED Warm-Air Mattresses can be used with the system. All other uses will risk the function of the system and patient safety.

Latest version of the user manual and information about accessories can be found on www.KANMED.se

2 Explanation of symbols used

| | |
|---|---|
|  | Start/stop button on Hand Controller |
| I | ON (Main Unit power on switch) |
| O | OFF (Main Unit power off switch) |
|  | Alarm Silence |
|  | Please read the instruction manual |
|  | Risk of explosion in the presence of inflammable gases. |
|  | Safety class BF, Defibrillator safe |
|  | Disposable (single patient use), shall not be reused. |
| CE 0413 | Fulfils MDD93/42 ECC and EMC directive 89/336/EEC |
| + | Increase temperature / Increase pressure |
| - | Decrease temperature/ Decrease pressure |

3 Safety information

Warnings

- To ensure optimal performance and to prevent accidental misuse the user manual must be read completely.
- If you feel that the KANMED WarmCloud is not operating properly, then you must ask a qualified technician for advice.
- **Single Patient Use Mattress:** Reuse will cause leakage because of weakening of the plastic material and increase infection risk and void product liability.
- **Mattress Fixation straps.** If the mattress has fastening straps then they must be tightened to the side rails of the OR table with a reliable knot.
- **Operating table Safety Straps:** When the patient is secured by the safety straps/belts or other means (recommended standard procedure), check the tension after Mattress inflation.
- **Patient Stability:** The Mattress may fill or empty unevenly, therefore you must stand next to the patient when you are inflating or deflating the Mattress. Be extra careful, and always make sure the patient is adequately secured whenever tilting the operating table out of horizontal position. If the mattress is rolled in under the patient after the patient has been placed on the operating table, be extra cautious during inflation!
- **Skin Protection.** *Always place a cushion under the part of the body located at the air inlets to prevent possible local overheating and skin damage. This is especially important when selecting the highest temperature and when using the short mattress.*
Always use some kind of protection for the heels, especially if they are close to the air inlets.
- **Compatibility:** Only use KANMED air Mattress with KANMED Main Unit to assure performance and safety.
- **Reduced Blood Flow:** **Parts of the body having reduced or no blood flow must not be warmed.** Reduce the temperature setting to lowest value well ahead of a blood vessel shut off.
- **Risk of Fire.** Protect the Mattress from laser, electrosurgical active knives and naked flame. Be particularly cautious after use of flammable disinfectants (e.g. alcohol).
- **Skin damage.** Ensure that there are no wrinkled materials under the patient.
- **MRI cameras:** The system is not designed or tested for use with MRI cameras.
- The system must always be connected to a mains outlet with proper protective grounding.
- **Patient weight**
Recommended upper weight limit 130 kg
Read section 5 for more information
- Trans dermal medications (patches) can increase drug delivery, resulting in possible harm to patient when used with warming devices.
-

Cautions

- Be careful not to puncture the Mattress.
- If for instance the patients head is mechanically fixated to the operating table then extra attention must be paid. The patient's body will drop about 5 cm if the mattress is deflated.
- If patient stability is vital for the operation, carefully evaluate the risk/benefit involved in using the system, with respect to the risk of involuntary deflation of the mattress.
- Remember to adjust the height of the arm supports after inflating the mattress.
- If the unit alarms or it has received mechanical damage, it should be examined by a technician. See section Trouble Shooting and Error Codes for advice.
- The KANMED WarmCloud is a powerful heating device! Always monitor the patient's actual body temperature with a reliable method. Be particularly observant on patients with low body mass (small children, elderly etc.), and use lower temperature settings on this patient category.
- Observe that the set temperature is an average air-temperature value and may differ somewhat from the actual mattress temperature, especially if the patient is covered with blankets.
- EMC. MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC, and needs to be installed and put into service according to the EMC information which is provided on the KANMED home page under downloads.

4 Using the KANMED WARMCLOUD

Description of system

KANMED WarmCloud, a pressure relieving closed warm air patient warming system, is designed to be used pre, per and post operatively. It is a highly efficient patient warming system and is particularly suitable for long surgical cases where the risk of hypothermia and pressure sores is high.

KANMED WarmCloud is an under body warming system and thereby provides full access to the patient. It loses very little heat to the surroundings which increases the comfort of the staff working close to the patient.

The risk of pressure sores is very low because of the softness of the Mattress which creates an even pressure distribution under the patient.

Mattress types

Other mattresses may be available. Please contact your local supplier or check on internet www.kanmed.se

NOTE

Using a Kanmed WarmCloud mattress *with straps* **does not** replace/substitute the need of safety belts and routines to secure the patient to the OR table.

Always secure the patient to the OR table with belts, hip pads and other means as per your hospital routine.

Always stand next to the patient when inflating or deflating the mattress.

Full length Mattress OT-600-222 and Reusable Mattress OT-600-222RM

Length 200 cm. Width about 55cm

Suitable for most patients in supine position but may also be used in lateral or prone position.

Always fasten the mattress to the OR table with the fixating straps.

See section about weight limits.

Short Mattress OT-600-211 and Reusable Mattress OT-600-211RM

Length 110 cm. Width about 50 cm

Suitable for patients in lithotomic type position (legs supported in the air) or for small children.

Heavy patients and patients where the legs are not fully supported may block the air circulation.

This is solved by increasing the mattress pressure. Always fasten the mattress to the OR table with the fixating straps.

See section about weight limits.



The system consists of a soft warm air under body Mattress, Hand Controller and a Main Unit. The Main Unit can be placed at the head or foot end of the Operating table. The Main Unit's air hoses are connected to the disposable Mattress on which the patient is placed. Once the Mattress is pressurised, warm air will circulate under the patient in a closed system.



The temperature and pressure of the Mattress is displayed on the Hand Controller. The settings can easily be changed by pressing +/- buttons.

The green lamp above each display will glow steadily when the desired setting has been achieved. When temperatures above 38°C or below 35°C are selected, the unit will alert the operator by an audio signal and flashing digits as a reminder that settings that deviate from body temperature are being selected.

Connection of the Mattress

The main Unit is connected by inserting the hoses into the port holes on the Mattress. Tighten securely with the Velcro straps. Either hose connects to either porthole.

If you notice that the compressor is working more than about 10% of the time then the leakage is probably to be found at the Mattress connection. Tighten the Velcro a bit extra and take care that the hose does not dislodge accidentally.




Starting the system

Connect the Hand Controller to the socket on the Main Unit and lock it by turning its ring clockwise. Do not over tighten. The Power cable is connected to the unit and to an outlet with protective ground. When the main switch is turned on the unit will perform a self test. All lamps and displays will light and a short alarm signal is received.


Note: PO LOS alarm is received when unit is first started after the mains power has been connected, or when the hand controller has been reconnected. This is normal! Just press the Alarm button once.

The system is now ready to be started as indicated on the Hand Controller with lines in the displays.

When a Mattress is properly connected the system is started by pressing the start / stop button.  Always stand next to the patient when inflating or deflating the mattress.

Important

Always start and stop the system with the Hand Controller

Power loss alarm will sound and the unit will stop if the unit is switched off at the Main Unit or by accidentally disconnecting the power cable during use. Turn the system off by pressing the start / stop button  for approximately two seconds.

Adjusting the temperature.

Default start temperature is 37°C. The average air temperature of the Mattress can be selected between +20°C (no active heating) and +42°C. By pressing + or - you can select desired temperature. For most patients this is +42°C, which gradually may have to be reduced when your patient reaches desired body temperature. (Note that the actual contact temperature on the mattress may differ some from the set value on the display). When temperatures above 38°C or below 35°C are selected, the unit will alert the operator by an audio signal and flashing digits as a reminder that settings that deviate from body temperature are being selected.

Important: Always monitor the patient’s actual temperature with a reliable method.

Adjusting the pressure / Mattress hardness

Default start value is 30 mb which is suitable for most patients. Increase after start to about 45 mb. Then reduce to about 30 mb. Ensure that the patient is not “bottoming out”. This will block the airflow and reduce warming efficiency. Check this by inserting your hand palm down between the Mattress and the Operating table at the vulnerable area of your patient; you will feel if there is enough clearance. If required, increase the pressure by 5 or 10 mb. The system will automatically reduce temperature when the pressure is increased above certain values. See table below.

Deflating the Mattress

The Mattress is emptied by reducing the set pressure on the Hand Controller to “0”. Alternatively you may stop the system and carefully release the air hose from the Mattress. Always stand next to the patient when inflating or deflating the mattress.

Recommended Mattress pressure

| Patient BMI | Supine (mb) | Lateral (mb) | Prone (mb) |
|-------------|-------------|--------------|------------|
| 20 | 25 | 40 | 30 |
| 25 | 30 | 40 | 30 |
| 30 | 30 | 40 | 30 |
| 35 | 30 | 45 | 30 |
| 40 | 30 | 45 | 40 |
| 45 | 30 | 45 | 40 |

Note: BMI = $\frac{\text{Weight (kg)}}{\text{Length (m)} \times \text{Length (m)}}$

Pressure limitations

| Selected temperature (°C) | Maximum possible Mattress pressure, mb |
|---------------------------|--|
| 42 | 35 |
| 41 | 40 |
| 40 | 45 |
| 39 | 45 |
| 38 | 50 |
| 37 | 55 |
| 20 - 36 | 60 |

Pressure conversion table

| Millibar (mb) | mmHg | kpa | psi |
|---------------|------|-----|------|
| 25 | 19 | 2,5 | 0,36 |
| 30 | 23 | 3 | 0,44 |
| 35 | 26 | 3,5 | 0,51 |
| 40 | 30 | 4 | 0,58 |
| 45 | 34 | 4,5 | 0,65 |
| 50 | 38 | 5 | 0,73 |

5 Practical advice

CAUTION

The WarmCloud mattress is soft in order to prevent pressure sores. Consequently the patient stability may be slightly less than normal. Therefore it is important to follow the instructions below.

- Fasten the WarmCloud mattress to the OR table with the straps.
- Always secure the patient to the OR table with belts, hip pads and other means as per your hospital routine.
- Ensure that the mattress is correctly centred under the patient.
- Ensure that the Mattress is flat under the patient before inflating it (alternatively inflate before placing the patient on the Mattress).
- Stand next to the patient when inflating the mattress.
- Check the tension of safety belt and other patient security means after inflation of the mattress.

NOTE

USING A KANMED WARMCLOUD MATTRESS *WITH STRAPS* **DOES NOT** REPLACE/SUBSTITUTE THE NEED OF SAFETY BELTS AND ROUTINES AS DESCRIBED ABOVE

Preparations

Before you start using KANMED WarmCloud with a patient for the first time it is advisable to simulate an operation where both anaesthesia and surgical staff are present. You can, in a composed manner, test the best position of the Main Unit and Hand Controller in relation to other Operating Theatre equipment.

Check that arm support and retainers still fit because the inflated Mattress increases the height of the patient by about 5cm. (2")



Position of the Main Unit

The Main Unit is most often placed under the operating table. The cable of the Hand Controller is generally long enough (3m) to reach the anaesthesia work place. The air hoses are 1.5m which will allow you to tilt the Operating table.

Placing the Mattress

The Mattress can be placed so that the air inlets are at the patient's feet or head.

Should you have forgotten to place a Mattress under the patient then it can be rolled under the patient in the way you would when changing a sheet. Be extra careful when the mattress is inflated because it may be twisted and can destabilise the patient.

The Mattress is relatively strong and can be used when you transfer a patient via a slide board to their bed or trolley.

For optimal warming the patient should be lying skin to skin against the Mattress. Be sure that there are no wrinkled material between the patient and the Mattress. Keeping the patient well covered whenever possible reduces heat loss further.

X-Ray

The KANMED WarmCloud Mattress is fully x-ray translucent.

Cardiac arrest / massage

The quickest way to empty the Mattress is to pull out an air hose from the Mattress.

Minor air leakage

The Mattress can withstand several needle sticks. If the air leakage becomes excessive, the system will Alarm. A sticky tape can temporarily solve the problem.

Recommended weight limits

The recommended upper limit is 130 kg for all mattresses.

Motivation: KANMED has no reports or data of patients heavier than 130 kg. The WarmCloud Mattress itself can easily carry weights up to 200 kg.

Safety: Heavy patients always present a stability problem and the WarmCloud mattress may make the surface of the OR table less stable. Therefore extra caution must be taken to mechanically stabilise heavier patients. Always use mattresses with straps with heavy patients.

Restarting with a warm mattress

If the mattress is deflated after about 10 minutes of use and is to be started soon again then the pressure must be increased to about 40-50 mb for a few minutes in order to ensure proper inflation. Increasing the temperature will automatically lower the pressure again. The reason is that the mattress is softer after being warmed and may initially not lift the patient as well as a cold mattress.

Warming seems inefficient

This is in most cases caused by too low pressure in the mattress and with heavy patients. If the mattress at the air inlet is not quite warm then this is an indication of low air flow. Increase the pressure to 40 -50 mb and then lower it to a suitable value.

Moving and storing the Main Unit

Place the hoses and the Hand Controller under the elastic strap so that all is clear of the floor. Use the strap to pull the unit.



6 Cleaning, Checks before use and Maintenance

Cleaning

Unplug the power cord before cleaning. Clean the Main Unit and Hand Controller as per the hospital instructions for medical technical equipment.

The Mattress is a disposable item and shall not be reused.

Checks before use

Check that all parts are clean and in good condition. Check that the unit performs a self test at start. If Error Codes appear and cannot be eliminated with the suggestions given in section 10 then they should be notified to Technical staff unless they are of type A (See Trouble Shooting and error codes section 10). **Note:** If the Main Unit or Hand Controller has received mechanical damage, it should always be checked and correct system function verified by technical staff.

Maintenance

KANMED WarmCloud does not require any special maintenance apart from what is described in the technical section of this manual.

The soft part of the air hose Mattress connection needs to be changed if worn. If the air hoses are worn or leaking they must also be changed.

7 Accessories and Spare Parts

| Article nr. | Product | Comment |
|-------------|--------------------------|--|
| OT-600-001 | KANMED WarmCloud | Complete system with standard accessories. |
| OT-600-002 | Hand Controller | With rubber edges and 3m cable |
| OT-600-004 | Accessory strap | Transport band with elastic strap. |
| OT-600-222 | Warm-Air Mattress, Wide | Single-Use Mattress with ties, Length 200 cm, Width 60 cm. Delivered in box of 10 pcs |
| OT-600-211 | Warm-Air Mattress, Small | For "leg-up" positions and for Children Single-Use Mattress with ties, Length 100 cm, Width 50 cm. Delivered in box of 10 pcs |
| OT-600-701 | Hose set complete | Consumable |
| OT-600-702 | Hose seal (2 pcs) | Consumable |
| OT-600-704 | Fuses (2 pcs) | T 6.3 A L 250V, 5x20 mm |
| OT-600-705 | Cable 3 m for Hand Unit | Spare part, complete with connectors |
| OT-600-070 | Manual | English Manual. |
| OT-600-060 | Manual | Service manual English. |

Other mattress sizes and other accessories will be available in the future. Always check with your dealer or www.KANMED.se for the latest information.

8 Technical information

Safety systems

KANMED WarmCloud is equipped with several safety functions to prevent dangerous situations. If a fault is detected an alarm will sound and an error code will appear on the Hand Controller. Depending on the seriousness of the error the system will continue to function normally, enter a safe mode or shut down. See "Error Codes" later in this section.

An alarm of less seriousness will, if still persisting, reappear after 10 minutes.

A serious fault in the warming system will shut down the warming but the pressure regulation of the Mattress will continue to function.

The green lamp over pressure and temperature displays indicates the status of the regulating circuits.

A steady glow indicates that set values have been achieved. A blinking lamp indicates that the unit is working on reaching set values.

Monitoring of the Mattress pressure

The system will alarm if the pressure deviates from set value. If a compressor failure (or big leak) prevents the set pressure from being reached then the fans and heating will not start.

If the electronic pressure control fails to stop the compressor then a mechanical over pressure valve will prevent the pressure from exceeding 75mb. A sudden pressure drop (puncture or loose hose) will create an alarm and stop the system.

Monitoring of the fans

The system uses two high quality silent fans that periodically changes the air direction in order to achieve an even temperature distribution under the patient. In case one fan stops the system will alarm and enter into *safe mode* (See description in the trouble shooting section). Lowering of temperature should be considered since the air is constantly going in the same direction ("hot-spot" hazard).

Monitoring of the temperature regulation

The electronic temperature sensors (one in each hose connection at the Main Unit) will alarm if the air temperature deviates from selected value. Mean air temperature and peak temperature values are monitored. The system is also equipped with 2 capillary thermostats that will cut the heating if the electronics should fail. As a third independent passive patient protection the Mattress is equipped with a temperature sensitive weak point that will puncture the Mattress if the temperature should pass critical values.

9 Technical Data

| | |
|-----------------------|---|
| Voltage | 220 - 240 VAC 50 - 60 Hz |
| Power consumption | 150 VA (Average under normal conditions), 700 VA (Peak value) |
| Inflation time | About 90 sec with 200 cm Mattress. |
| Warming up time | About 4 minutes from room temperature (18-20°C). |
| Measurements | Main Unit: 310 x 295 x 370 mm Length of Air Hoses: 1500 mm Hand Unit: 115 x 145 x 27 mm Length of cable: 3000 mm |
| Weight | Main Unit: About 27 kg incl. wheelbase. Hand Unit about 800 g Transport packing in plywood box: About 34 kg |
| Temperature selection | 20°C - 42°C, step of 1°C Precision +- 1°C |
| Pressure selection | 0 - 60 mb. Step of 5 mb. Precision +- 5mb. Mechanical overpressure valve release at 75 mb |
| Function supervision | Audio and visual alert. Error codes displayed on the hand unit with a |

code key on the back of the hand controller.

| | |
|--------------------|---|
| Environmental data | +15°C to +35°C during operation, less than 90% RH 0°C to +40°C during storage, non-condensing. - 40°C to +50°C (max 56°C/30 min) during transport, non-condensing. |
| Modifications | Any modifications on the control unit, hand unit, hoses and the mattress will void KANMED’s responsibilities totally and are not allowed without the written consent of KANMED. |
| Creating Systems | Any person connecting the WarmCloud to any other systems mains socket may have created a “system” according to IEC 60601-1 section 16, and must be qualified to evaluate any consequences that may harm staff, patient and equipment. |
| Classification | Control unit OT-600-001: MDD Class IIB All Mattresses: MDD Class I |
| Expected Lifetime | Control unit WarmCloud. Kanmed warrants a safe lifetime for the Control unit of 10 years from first day of use. This is under the condition that the unit has been serviced according to the user and or service manual and that the unit has not been modified or changed in any way or for any reason. |

10 Trouble Shooting and Error codes

Error levels

- | | |
|--|--|
| A) Warning => <i>Continued operation</i> | B) Serious error => <i>Reduced heating</i> |
| C) Major error => <i>Heater OFF, Pressure ON</i> | D) Fatal error => <i>System OFF</i> |

| Alarm Code and Level | Description / Systems Actions |
|----------------------|--|
| Err 001 C | <p>High reading on temp sensor 1. Too high value detected. Probably sensor error or too warm heating element. Can be caused by blocked air hose or channel in Mattress.</p> <p>System actions: The heating will stop and the Hand Unit shows Err 001. After resetting the alarm the temperature will display “---” and the alarm lamp will blink until the system is stopped. This alarm is not active during the first 60 seconds after start.</p> <p>User action required: Reset the alarm. Examine if the airflow is blocked by the patient bottoming out, a blocked air hose or similar. If there is a natural cause for this alarm, correct the condition and the system may be restarted. Otherwise contact a qualified technician to examine the system.</p> |
| Err 002 C | <p>High reading on temp sensor 2. Too high value detected. Probably sensor error or too warm heating element. Can be caused by blocked air hose or channel in Mattress.</p> <p>System actions: The heating will stop and the Hand Unit shows Err 002. After resetting the alarm the temperature will display “---” and the alarm lamp will blink until the system is stopped. This alarm is not active during the first 60 seconds after start.</p> <p>User action required: Reset the alarm. Examine if the airflow is blocked by the patient bottoming out, a blocked air hose or similar. If there is a natural cause for this alarm, correct condition and the system may be restarted. Otherwise contact a qualified technician to examine the system.</p> |
| Err 003 C | <p>Air temperature exceeds safe value. The measured air temperature exceeds maximum permitted value for more than 65 seconds. Can be caused by a blocked air channel or hose.</p> <p>System actions: The alarm will switch off the warming and the display will show Err 003. The alarm lamp will blink until the system is stopped. This alarm is not active during the first 60 seconds after start.</p> <p>User action required: Reset the alarm. Examine if the airflow is blocked by the patient bottoming out, a blocked air hose or similar. If there is a natural cause for this alarm, correct the condition and the system may be restarted. Otherwise contact a qualified technician to examine the system.</p> |
| Err 004 A | <p>Set temp not reached, slow warming. The selected value has not been reached in 10 minutes. NOTE that this alarm may trigger if the unit is started in cold surroundings.</p> <p>System actions: Err 004 will be displayed. When the alarm is silenced the lamp will stop blinking and the unit will continue. If the alarm condition still exists after 10 minutes the alarm will return.</p> <p>User action required: Reset the alarm. Observe if the error returns, if it does, contact a qualified technician to examine the system.</p> |

| | |
|--------------|--|
| Err 005 A | <p>Over pressure, measured air pressure exceeds selected value with more than 10mb. Probably a fault on the electronic pressure relief valve or electronic error.</p> <p>System actions: Err 005 is displayed. When the alarm is silenced the lamp will stop blinking and the unit will continue. If the alarm situation still exists after 10 minutes the alarm will come back.</p> <p>User action required: Reset the alarm. Observe if the error returns, if it does, contact a qualified technician to examine the system.</p> |
| Err 006 C | <p>Air leakage. The compressor is working continuously for more than 3 minutes. Probably a major air leakage in the Mattress connection, the Mattress or the hoses.</p> <p>System actions: Err 006 is displayed. If the system is in the phase of starting up a new Mattress then it will go to stand by after silencing the alarm. If the situation occurs during normal use the heating will be shut down but the compressor will continue to keep the pressure. If the alarm condition still exists after 10 minutes the alarm will come back.</p> <p>User action required: Reset the alarm. Examine the air hose connection. If there is a natural cause for this alarm, correct the condition and the system may be restarted. Otherwise contact a qualified technician to examine the system.</p> |
| Err 007 A | <p>Low air pressure. The compressor is working more than 50% of the time. Probably an air leakage in the Mattress connection, the Mattress or the hoses.</p> <p>System actions: Err 007 is displayed. When the alarm is silenced the lamp will stop blinking and the unit will continue. The alarm will come back if the error exists during the next alarm period. With a bigger air leak the alarm will come more often.</p> <p>User action required: Reset the alarm. Examine the air hose connections. If there is a natural cause for this alarm, correct the condition and continue using the system. Otherwise contact a qualified technician to examine the system.</p> |
| Err 008 D | <p>Sudden drop of pressure. The Mattress pressure is below 4mb. Probably puncture or a hose has come off.</p> <p>System actions: Err 008 is displayed. The warming stops and the unit stops.</p> <p>User action required: Reset the alarm. Examine the air hose connection. If there is a natural cause for this alarm, correct the condition and the system may be restarted. Otherwise contact a qualified technician to examine the system.</p> |
| Err 011 C | <p>Low reading on temp sensor 1. Too low value detected, probably sensor or electronic error.</p> <p>System actions: The heating will stop and the Hand Unit shows Err 011. After resetting the alarm the temperature will display "---" and the alarm lamp will blink until the system is stopped. This alarm is not active during the first 60 seconds.</p> <p>User action required: Reset the alarm, contact a qualified technician to examine the system.</p> |
| Err 012 C | <p>Low reading on temp sensor 2. Too low value detected, probably sensor electronic error.</p> <p>System actions: The heating will stop and the Hand Controller shows Err 012. After resetting the alarm the temperature will display "---" and the alarm lamp will blink until the system is stopped. This alarm is not active during the first 60 seconds after start.</p> <p>User action required: Reset the alarm, contact a qualified technician to examine the system.</p> |
| Err 014 A | <p>Set temp not reached, slow cooling. The selected value has not been reached in 10 minutes. NOTE this alarm is only activated for temperature settings from 31°C and above.</p> <p>System actions: Err 014 will be displayed. When the alarm is silenced the lamp will stop blinking and the unit will continue. If the alarm situation still exists after 10 minutes the alarm will return.</p> <p>User action required: Reset the alarm. Observe if the error returns, if it does, contact a qualified technician to examine the system.</p> |
| SAFE B | <p>Fan error. One fan is not working.</p> <p>System actions: SAFE is displayed. When the alarm is silenced the unit will continue to operate with only one fan.</p> <p>User action required: Reset the alarm. The system can be temporarily used for the duration of the present procedure. You can still change the pressure and temperature values. Change of temperature must be done after careful consideration of the fact that the air is constantly going in the same direction (risk for "hot spots"). After the present procedure is concluded, contact a qualified technician to examine the system.</p> |
| PO LOS | <p>Power Lost. If mains power is lost during operation, the system will sound an acoustic alarm. When power is restored the display shows PO LOS. The alarm need to be reset and the system restarted.</p> <p>Communication Lost: If the communication with the hand controller is lost during operation, the system will sound an intermittent acoustic alarm. When communication is restored the display shows PO LOS. The alarm need to be reset and the system restarted.</p> |

11 Annual check of the system

The system must be checked annually by a qualified technician. The following shall then be tested:

- Visual control of the Main Unit and Hand Controller as well as all hoses and cables.
- Complete electrical safety test.
- Check that the main unit is "air tight" i.e. the compressor is working less than 10% of the time.
- Check of safety functions as per the list below.

For further service activities we ask you to refer to the service manual.

a) Normal start and running.

Connect a standard Mattress to the unit. Connect power cable and Hand Unit. Switch on the power switch at the Main Unit and note that its green power indicating lamp is lit, that all lamps on the Hand Controller are lit and that an alarm sounds for about 2 seconds. Start the system with the start button on the Hand Controller. The default values are +37°C and 30 mb. Listen and note that the fan starts once the compressor has inflated the Mattress. Listen and note that change of air direction takes place every 30 seconds. Listen for unusual fan noise.

- b)** When the system is running normally disconnect the power by pulling out the power cable. A acoustic power alarm will be received. Reconnect the power. An alarm shall now sound from the Hand Unit, and PO LOS is displayed. Reset the alarm.

c) Hand Controller connection.

Start the system and disconnect the cable to the Hand Controller. An intermittent acoustic alarm will sound and the system shall stop after about 5 seconds. Reconnect the hand controller and the system will alarm and display PO LOS. Reset the alarm.

d) Safe pressure / temperature regulation.

Start the system. Set the temperature to +36°C and the pressure to 60 mb. Step up the temperature to 42°C and note the pressure is stepped down to 35 mb.

e) Control of the air (mattress) temperature

With a mattress connected, start the system with 42°C & 30 mb. Place an accurate thermometer/probe, preferably an FLUKE 52 II, in good contact with the air stream at the centre of the mattress. Place a piece of insulating material on top of the probe to ensure good contact with the mattress surface. Cover the whole mattress with a sheet. The system should operate > 10 min. with the system in thermal balance (the green temperature indicator permanently lit) before any reading is done. The received temperature should read set temperature $\pm 1^\circ\text{C}$

f) Check of error code 008, sudden drop of pressure.

With the system running, disconnect one of the air hoses. Note that Err 008 is shown and that the unit goes to stand by. Reset the alarm.

g) Check of error code 006, Air leakage

Start the system without a Mattress connected. Note that the unit alarms with Err 006 after about 4 minutes and goes to Stand by. Reset the alarm.

h) Correct stop of the system.

Start the system and reduce the pressure to 0 mb. Note that the air valve starts releasing the pressure. The display will show "h" + the number of running hours, then the software version of the Main Unit (CP) and last the software version of the Hand Controller (PP)

i) Check of pressure

Connect a pressure measuring device at the mattress connection as well as a mattress-
Check that the measured pressure is within +- 5 mb

Change of air hose

The hose locking device is turned anti clockwise until it comes off. Pull off the old hose. Apply a little grease of some kind on the coil on the main unit. Insert the hose in the locking device and push it onto the stud on the main unit. Turn the locking device clockwise while holding the hose so that it does not turn. Test that the hose is properly fitted by pulling it relatively hard. Both hoses should be changed at the same time.



Change of hose seal



The worn out seal is pulled off and the area is properly cleaned. Fit the new seal carefully.

12 Warranty conditions

KANMED warrants the WarmCloud Main Unit and Hand Controller for a period of 12 months from purchase date. Consumables like hoses are not included in the KANMED warranty. In case of a warranty matter KANMED may in its own judgment decide to:

- Repair the units with new or exchange parts
- Change the equipment
- Take the unit back against a refund

The warranty is not valid if:

- The unit has been modified, adjusted or repaired without the written consent of KANMED.
- The unit has been modified, adjusted or repaired without following the written KANMED guidelines.
- The units has been used for other purposes that the intended use, misused, dropped or in any other way been abused.

Warranty claims must be confirmed in writing.

KANMED is not responsible in any way for any damages of any kind arising from deviation from intended use, neglect of safety instructions, neglect of alarms, neglect of annual service, etc.

13 Disposal



When the WarmCloud have reached end of life, it should be returned to the distributor for recycling in accordance with the EU 2002/96/EC (WEEE) directive if applicable.

14 EMC Information

Guidance and manufacturer's declaration – electromagnetic emissions

The WarmCloud system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.

| Emission test | Compliance | Electromagnetic environment – guidance |
|---|------------|--|
| RF emissions CISPR 11 | Group 1 | The WarmCloud WarmCloud system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The WarmCloud WarmCloud is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class B | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |

Recommended separation distances between portable and mobile RF communications equipment and the WarmCloud WarmCloud system.

The WarmCloud WarmCloud system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the WarmCloud WarmCloud system as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter m | | |
|---|---|--|---|
| | 150 kHz to 80 MHz $d = 1,17 \sqrt{P}$ | 80 MHz to 800 MHz $d = 1,17 \sqrt{P}$ | 800 MHz to 2,5 GHz $d = 2,33 \sqrt{P}$ |
| 0,01 | 0,2 m | 0,2 m | 0,3 m |
| 0,1 | 0,4 m | 0,4 m | 1,6 m |
| 1 | 1,2 m | 1,2 m | 2,3 m |
| 10 | 3,7 m | 3,7 m | 7,4 m |
| 100 | 11,7 m | 11,7 m | 23,3 m |


For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be established using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

| immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
|--|---|---|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact ±8 kV air | ±6 kV contact ±8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% |
| 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 | Mains power quality should be that of a typical commercial or hospital environment |
| Surge 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 the power supply input lines IEC 61000-4-11 | <5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles | <5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles | Mains power quality should be that of a typical commercial or hospital environment. If continued operation during power mains interruptions, it is recommended that the Kanmed WarmCloud system be powered from an uninterruptible power supply unit (UPS) |

| | | | |
|---|--|--|--|
| | <5% U_T (>95% dip in U_T) for 5 sec | <5% U_T (>95% dip in U_T) for 5 sec | |
| Power frequency (50 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment |
| <i>Note:</i> | U_T is the AC mains voltage prior to application of the test level | | |

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
|---|-----------------------------|------------------|--|
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms | <p>Portable and mobile RF communications equipment should be used no closer to any part of the WarmCloud system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1,17 \sqrt{P}$ $d = 1,17 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,33 \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range**</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2,5 GHz | 3 V/m | |
| <i>Note 1:</i> At 80 MHz and 800 MHz, the higher frequency range applies. | | | |
| <i>Note 2:</i> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |
| <p>* Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the WarmCloud is used exceeds the applicable RF compliance level above, the WarmCloud system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the WarmCloud.</p> <p>** Over the frequency range of 150 kHz to 80 MHz, field strength should be less than 3 V/m.</p> | | | |

KANMED[®] WARMCLOUD

KANMED AB
Gårdsfogdevägen 18B
SE-168 66 Bromma
Sweden

Telephone +46 8 56480630
Telefax + 46 8 56480639

E-Mail: info@kanmed.se
Internet: www.kanmed.se

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