

KANMED^o WARMCLOUD

User Manual

WC2-070 ver. 7 Eng - 2020-09-14

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User Manual
Kanmed WarmCloud TM
Art no: WC2-070 ver. 7 Eng

2020-09-14



Caution
Incorrect use of WarmCloud
may cause serious injury.
Therefore, please read this
manual carefully.

Manufactured by:
Kanmed AB, Sweden
www.kanmed.se



This manual is valid for Kanmed WarmCloud systems manufactured 2018 or later.
Subject to changes. Latest manual versions are available on www.kanmed.se

Contents

CONTENTS.....	2
WARMCLOUD USER GUIDE - QUICK INSTRUCTION	3
1 INTENDED USE	4
2 EXPLANATION OF SYMBOLS USED	4
REAR SIDE OF THE WARMCLOUD AND REMOTE CONTROL	6
3 SAFETY INFORMATION	7
4 DESCRIPTION KANMED WARMCLOUD AND PARTS.....	8
5 STARTING THE WARMCLOUD AND PRACTICAL ADVICE	10
6 CLEANING, CHECKS BEFORE USE AND MAINTENANCE	13
7 ACCESSORIES AND SPARE PARTS	13
8 TECHNICAL INFORMATION	14
9 TECHNICAL DATA	14
10 ALARMS AND ALARM CODES	15
11 ACTIVATING OR DEACTIVATING THE REMOTE CONTROL	17
12 WARRANTY CONDITIONS.....	18
13 DISPOSAL	18
14 EMC INFORMATION	19

Unpacking the WarmCloud

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. Save the transport material.

Note that Kanmed WarmCloud is delivered from Kanmed AB without the power cable unless otherwise specified.

User Responsibility

This Instructions for Use describe the proper setup, use, maintenance and disposal of the WarmCloud Control System.

The WarmCloud is to be used exclusively by a properly trained user and should not be used if it is damaged, contaminated, or if parts are missing. Instead, please contact the supplier immediately.

The user is solely responsible for the risks to the patient, clinicians, third parties or properties or for a treatment with inadequate performances due to an abusive or improper use, inadequate maintenance, reparation or modifications made by unauthorized individuals.

WarmCloud User Guide - Quick instruction

Warning

Incorrect use of WarmCloud may cause serious injury.
The user manual must be read completely before use.

Caution

The WarmCloud mattress is soft 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).
- Always stand next to the patient when inflating the mattress.
- Check the tension of safety belts and other patient securing tools after inflation of the mattress.


NOTE

Using WarmCloud mattress straps **does not** replace/substitute the need of safety belts and other routines for securing the patient to the OR table.

Preparation

Place the WarmCloud Mattress on the operating table with the air inlets location suitable for the actual surgery. Tie the straps to the side rails 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 around the soft blue part. Connect the power cable to an outlet with protective grounding. Connect medical air. The green lamp and the display will be lit. Connect Remote Control if desired.

Start

Press the  button on the Control Unit or the Remote Control. A self-test will be performed. The Unit will begin to inflate the mattress. Always attend the patient when the mattress is inflating. The unit will inflate the mattress to pressure 4, then increase to pressure 8 and after 10 seconds, reduce back to pressure 4. This is to ensure that the mattress is fully open.

Adjusting the mattress pressure


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 one or two steps. With smaller patients it may be advantageous to reduce the pressure. Ensure that there are no wrinkled materials under the patient.

Adjusting the temperature

40°C is the automatic 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.

STOP procedure for the Control Unit

Reduce the pressure to 0 alternatively press the start/standby button  for 2 seconds on the remote control or on the unit. Always stand by the patient when the mattress is emptying.

Important Safety information

Reduced Blood Flow	Parts of the body that have reduced or no blood flow shall not be warmed. Reduce the temperature setting to 30 (= heating stopped) well ahead of a blood vessel shut off.
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 especially if tilted.
Error Codes	In case of an alarm, error codes are displayed on the Remote Control and the Control Unit. Full information is found in the user manual.

1 Intended Use

The Kanmed WarmCloud is a pressure relieving warm air mattress intended to be used pre, intra and post operatively in a hospital environment by qualified hospital staff. The system is intended to reduce the risk of hypothermia and pressure sores.

The system can be used for patients weighing up to 135kg.

The system must not be set to warming when blood vessels are blocked off; this as warming then could cause serious injury to patient.

Only Kanmed WarmCloud Mattresses can be used with the system. All other uses will risk the function of the system and patient safety.

It must be used according to this manual. Latest version of the user manual and other information can be found on www.kanmed.se

2 Explanation of symbols used



Start/stop button.



Lamp over the start /stop button.

Steady light means that the unit has started.

Blinking light means that the unit is in standby or starting.



Read IFU, Instruction For Use.



Alarm control button.



Lamp over the Alarm button.

Steady light means that an alarm is active or has been silenced.

Do not blink.



Safety class BF, Defibrillator safe.



Disposable (single patient use), shall not be reused.



The product meets the requirement in applicable directives such as MDD 93/42/EEC, RoHS and WEEE".



Increase pressure in the mattress.



Decrease pressure in the mattress.



Increase temperature.



Decrease temperature.



Pressure symbol on remote control.



Symbol for temperature.



Remote control connected. Symbol on the display on the Control unit.



Remote control not connected or faulty.



Name of manufacturer.



Date of manufacture.



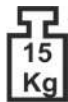
Catalogue number.



Serial number.



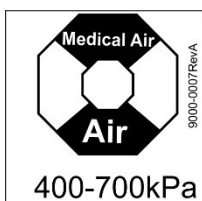
Operating range temperature.



Weight of the complete unit.

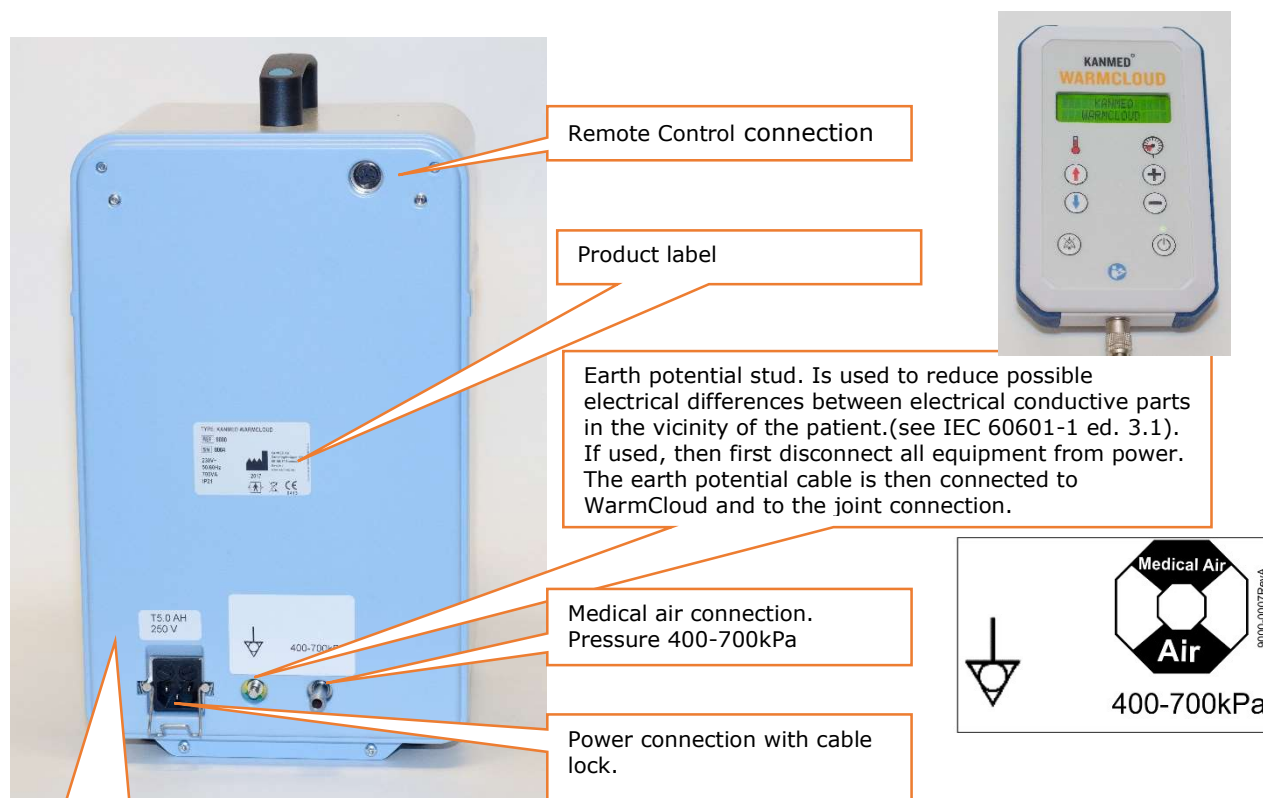


Equipotentiality Connection.



Medical Air connection. Pressure 400-700kPa.

Rear side of the WarmCloud and remote control



T5.0 A L
250 V
9000-0005RevB

Product label WarmCloud, 230V

TYPE: WARMCLOUD

REF 9000

SN XXXX

230V~
50/60Hz
700VA
IP21



KANMED AB
Gårdsfogdevägen 18B
SE-168 67 Bromma
Sweden
www.kanmed.se



0413

Kanmed/AB 9000-0001RevB

Product label WarmCloud, 120V

Fuse label, 120V models

T8.0 A L
250 V
9000-0006RevB

TYPE: WARMCLOUD

REF 9000-120

SN XXXX

120V~
50/60Hz
950VA
IP21



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0413

Kanmed/AB 9000-0002RevB

3 Safety information

Warnings

- To ensure optimal performance and to prevent accidental misuse please read the user manual completely.
- **Single Patient Use Mattress:** Reuse will cause leakage because of weakening of the plastic material and increase infection risk and void product liability. It may also burst during surgery.
- **Mattress Fixation straps.** The fastening straps must be tightened to the side rails of the OR table with a reliable knot.
- **Operating table Safety Straps:** The patient is secured by the safety straps/belts or other means to the OR table. Check their 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.
- **Sudden drop of pressure:** A sudden drop of pressure will result in the patient's body coming down about 3-5 cm. If that could present a danger for the patient, then WarmCloud should not be used. For example, brain surgery or robot surgery.
- **Bedsheets between the patient and the WarmCloud mattress.** Ensure that the combination is not slippery meaning low friction between the materials.
- **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. All material under the patient must be free of wrinkles..
- **Reduced Blood Flow:** *Parts of the body having reduced or no blood flow must not be warmed.* Reduce the temperature setting to 30°C well ahead of a blood shut off.
- **Compatibility:** Only Kanmed WarmCloud Mattresses may be used with Kanmed Control Unit
- **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).
- **Risk of Fire:** The device should not be used in an oxygen enriched environment.
- **MRI cameras:** The system is not designed or tested for use with MRI cameras.
- **Patient weight** Recommended upper weight limit is 135 kg. Recommended lowest weight is about 2kg. 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.
- **Gas connection.** Never connect WarmCloud to Oxygen or nitrous oxide
- **Gas connection:** Always disconnect the gas connection when the unit is switched of.
- **Fluid collection under the patient:** Do not wash the patient excessively with skin disinfectants so that they pool under the patient which may cause skin maceration.
- **Damaged or dropped unit:** Must be checked by technical competent person.

Cautions

- Be careful not to puncture the Mattress.
- Ensure that the straps are correctly tightened to the OR table.
- If very high patient stability is vital for the surgery, carefully evaluate the risk/benefit involved in using the system also with respect to the risk of accidental deflation of the mattress.
- Always stand next to the patient when inflating or deflating the mattress. When the patient is securely fastened to the OR table then there is no further need to be next to the patient when using WarmCloud.
- Remember to adjust the height of the arm/leg supports and belts over the patient after inflating or deflating the mattress.
- If the unit alarms or it has received mechanical damage, it must be examined by a technician.
- 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.).
- Ensure that the right gas connection is used, medical or apparatus air
- Place the control unit so that the power cable can be easily disconnected. Note that the only way to fully isolate the WarmCloud from mains power is to pull out the cable.
- **Labels Integrity and Readability** In case labels are degraded, the information may be found in this document. Contact the supplier to get new labels.

4 Description Kanmed WarmCloud and parts

Description of the WarmCloud system

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

Because the mattress is under the patient the warming and pressure support can begin immediately and follow the patient into the OR room and into the post-operative area.

The WarmCloud system consists of a soft warm air under body Mattress, and a Main Unit. Optional hand-held wire connected Remote Control is also available. The Main Unit can be placed at the head or foot end. The Main Unit's air hoses are connected to the disposable Mattress. Once the Mattress is pressurised, warm air will circulate under the patient in a closed system. To ensure an even heat distribution the circulating air will change direction every 30 seconds.

WarmCloud unit with patient.

The mattress is carefully tied to the rails of the OR-table.

Note that no belts and or side supports have been attached in this illustrative picture.



Symbols on the front panel and the remote control



Increase pressure in the mattress



Decrease pressure



Increase temperature



Decrease temperature



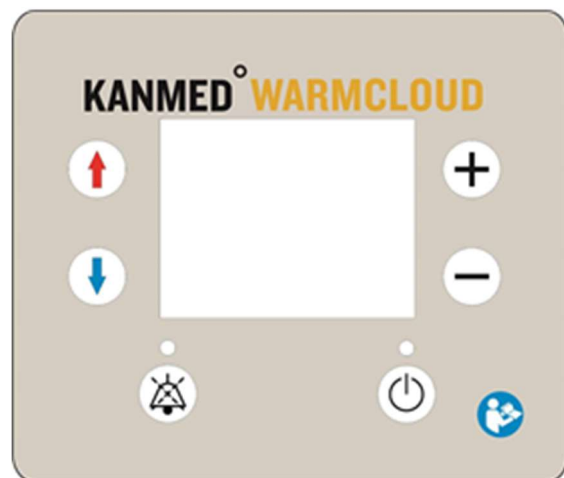
Silence alarm



Start /stop button



No button. Symbol means "Please read user manual"



Remote control



Temperature symbol



Pressure symbol



Mattress types

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

Full length Mattress. Art. no OT-600-222

Length 200 cm. Width inflated about 55 cm.

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

Always secure the mattress to the table with the straps.

Max recommended patient weight 135 kg.

Short Mattress. Art no OT-600-211

Length 110 cm. Width inflated about 55 cm.

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

Always secure the mattress to the table with the straps. Heavy patients and patients where the legs are not fully supported may block the air circulation. This is solved by increasing the mattress pressure. Max recommended patient weight 135 kg.

Preparations before start

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.

Pull hard. There is no left or right.

If you hear that the inflation valve opens often, then there is an air leakage. The leakage is most probably to be found at the Mattress connection. Tighten the Velcro a bit extra and take care that the hose does not disconnect accidentally.



Placing the Mattress on the OR table

The full-length Mattress can be placed so that the air inlets are at the patient's feet or head. The Short Mattress usually has the air inlets at the head end unless used as a whole-body mattress for small patients.

Always secure the mattress with the side straps.

The mattresses are usually not inflated before the patient is placed on the op-table.

The Mattress is relatively strong and can be used to pull a patient via a slide board to their bed or trolley. This allows the user to continue warming postoperatively with the same mattress.

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

Caution

The WarmCloud mattress is soft 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 side 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.

If the patient is correctly secured to the OR table there is no further need to be next to the patient when using WarmCloud.

Connecting the Control Unit to compressed air

Connect the Control Unit to a medical air outlet or apparatus air outlet. Listen for leakages.

WARNING: Do not connect to oxygen or nitrous oxide.



Position of the Main Unit

The Main Unit is most often placed under the operating table. It may also be hung in its handle. The cable of the remote control is generally long enough (about 3m) to reach the anaesthesia work place. The air hoses are 1.5m which will allow you to tilt the Operating table. Place the unit so that you can disconnect the mains power cord easily.

Note: Route the mains cable and the compressed air tube so that they do not risk causing trip hazard or get run over by other equipment.

Note: If the or-table is to be tilted make sure that it does not hit the WarmCloud unit.

5 Starting the WarmCloud and Practical advice

Before first use with patient

Before you start using Kanmed WarmCloud with a patient it is advisable to simulate an operation where both anaesthesia and surgical staff are present. You can then test the best position of the Main Unit, its power cable and gas connection in relation to other operating theatre equipment. Check that arm support, safety straps and retainers still fit because the inflated Mattress increases the height of the patient by about 3-5cm.

Medical air connection

Connect the WarmCloud to a medical air outlet. Arrange the tube to eliminate trip risk.

Connect the remote control if available.

The WarmCloud must be pre-programmed to work with or without a remote control. If this has not been done you can find information about this at the end of this manual.

If WarmCloud is not programmed for the remote control and a remote is connected then the remote will show "NOT ACTIVE".

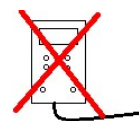
If it is programmed for the remote control but the remote is missing or damaged the unit will display this symbol:

WarmCloud alerts you about this with a short beep.

It will then continue to work as if no remote is connected.

A WarmCloud remote control can be used on any new WarmCloud unit.

Activating and deactivation of the remote is done on the main unit.



Power connection

Connect the power cable to the unit. Arrange the cable to eliminate trip risk.

A beep will be heard, and a green light will blink over the symbol. Display will show "Kanmed WarmCloud".

Power failure

If the power supply is interrupted the unit will alarm. When power is restored it will automatically restart including the self-test. It re-starts with the values set before the power failure.


Connect a mattress

Connect a mattress as described above.

Hose cover

A disposable plastic hose cover is available to help keeping the hoses clean.

Starting WarmCloud and self-test

Press  for about 2 seconds and ensure that the self-test is starting (includes a test of the over temperature protection). When successfully completed the unit will begin to inflate the mattress. It will increase the pressure to 8 to ensure full airflow in the mattress. After 10 seconds air will be let out and the pressure will be adjusted to 4. Once the pressure 4 is reached the fans and warming will start. Now you can set the pressure to desired value.

The unit will automatically start at 40°C. It is possible to change temperature as soon as the self-test is over.

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

Setting temperature

The temperature settings can be changed from 31°C to 42°C by pressing temperature arrow buttons.

Temperature value colours on the display:

40

Lower than set value

40

Set value achieved

40

Warmer than set value *)

*) Normally seen if the temperature has been lowered.

Stop the warming but keep the pressure

Reduce temperature to 30°C and the display will show "NO WARMING".

This setting is for situations with clamping of blood vessels and shall be done well ahead.

Adjusting the temperature.

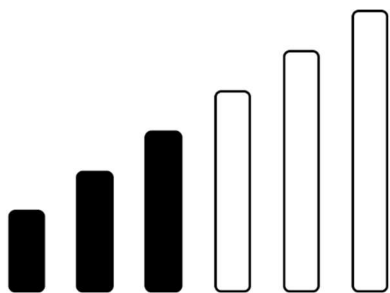
After some time at 40 - 42°C, you may need to reduce the temperature when your patient reaches desired body temperature.

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

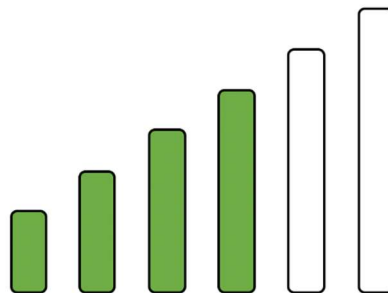
Pressure selection and adjustment

Pressure can be selected from 1 to 9. Start value is 4. Change pressure with the plus and minus buttons. Set pressure is shown with a number over the bars.

Pressure value colours on the display:



Black = pressure is being adjusted




Green = Set pressure is reached

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 heaviest area of your patient; you will feel if there is enough clearance. If required, increase the pressure by one or two steps.

Important: Selecting too high mattress pressure may reduce the pressure relieving properties of the mattress and could cause skin damage.

Stop WarmCloud / Deflating the Mattress


WarmCloud can be stopped in two ways.

1 Press  for more than one second. Mattress stays inflated and the unit will go to stand by. You will manually empty the mattress by carefully opening the Velcro straps.

2 Reduce pressure to 0. Mattress is slowly emptied, and the unit will automatically go to stand by.

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

Disconnecting power and Gas connection

Turn the system off by pressing the start / stop button  for approximately two seconds. Power loss alarm will sound, and the unit will stop if the mains cable is accidentally disconnected during use.

Always disconnect the gas connection when the unit is switched off.

X-Ray

The Kanmed WarmCloud Mattress is fully x-ray translucent.

Cardiac arrest / massage / CPR

The mattress should be emptied of air. 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. Most common reason for air leakage is because the mattress straps at the hose connection are not tightened hard enough.

Recommended weight limits

The recommended upper limit is 135 kg for all mattresses.

Note: 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.

Warming seems inefficient

This is in most cases caused by too low pressure in the mattress and with heavy patients. That the mattress at the air inlet is not warm is an indication of low air flow. Increase the pressure to max and then lower it to a suitable value. Remember that straps over the patient may become too tight at max pressure.

Moving WarmCloud between rooms with a patient on the mattress.

When warming is started in the pre-operative room (recommended) and you want to move the patient to the OR room you just stop WarmCloud with the stop button. It will keep the pressure in the mattress. After disconnecting air and power you can hang the control unit on a hook on the OR table or carry it into the OR room where it is immediately reconnected to continue warming. If you want to continue warming after the surgery, you can easily pull the patient into the bed using the mattress. The control unit is then hung on the bed to be reconnected as soon as possible.

Storing the main unit

Place the hoses around the unit and attach the hose outlets onto the acrylic pegs on the trolley. Note! Disconnect the pressurised air hose from the hospital air outlet.



6 Cleaning, Checks before use and Maintenance

General information

The WarmCloud control unit, hoses and remote control should be carefully cleaned between each patient.

Follow the routines set forth by the person responsible for cleaning and disinfection in your hospital and department and according to the instructions below.

Inspect all parts for wear and damages before and after cleaning.

Below is a list of cleaning and disinfection agents recommended by Kanmed. Using other agents and/or exaggerated cleaning may reduce the lifetime of some or all parts. Contact Kanmed with the product specification if in doubt.

Do not use bleach and solvents.

Kanmed recommends using the Kanmed Tube Protection Art no 700-0882

Cleaning: Use soap water in a moist cloth.

Disinfection: The WarmCloud, Remote control with cable and hose set withstands most common surface disinfectants used in hospitals. Kanmed recommends DAX surface disinfectant which is alcohol based. Do not use alcohol based solutions stronger than 70%

If in doubt, try on a small surface or contact your distributor or Kanmed.

Hose protection

Kanmed Disposable Tube Protection Art no 700-0882 is available to facilitate keeping the hoses clean.

WarmCloud Mattresses

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

Checks before use

Check that all parts are clean and in good condition. Check that the hoses are properly connected to the unit by pulling gently. 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 you shall not use the unit.

Note: If the Main Unit or hose set 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 annual check according to the service manual.

7 Accessories and Spare Parts

Article no	Product	Comment
9000	Kanmed WarmCloud	Complete system with standard accessories. 230V
9000-120	Kanmed WarmCloud	Complete system with standard accessories. 120V
OT-600-222	Warm-Air Mattress, Wide	Single-Use Mattress with ties, Length 200 cm, Width 55 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 110 cm, Width 50 cm. Delivered in box of 10 pcs
700-0882	Tube protection	Disposable thin plastic tube
9300	Remote control	
OT-600-705	Remote control cable	
9131	Wheel base	Wheel base with tube storage.
9010	Hose set complete	Kit with two tubes
WC2-070	Manual	English Manual.
9079	Manual	Service manual English.
9000-0014	Test box	For service checks only

Other mattress sizes and accessories may be available 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 and symbol will appear on the display. A code will appear on the Remote Control. Full description of Alarm functions and codes are found in section 10.

Full description of the safety systems and functions are found in the service manual.


9 Technical Data

Voltage art no 9000	220 - 240 VAC 50/60 Hz
Voltage art no 9000-120	100-130 VAC 50/60 Hz
Power consumption	230V:150 VA (Average under normal conditions), 700 VA (Peak value) 120V:150 VA (Average under normal conditions), 950 VA (Peak value)
Fuses	See service manual.
Inflation time	About 90s with OT-600-222 Mattress depending on inlet pressure.
Warming up time	About 10 minutes from room temperature (18-22°C) to 42°C.
Sound level alarm	65 dBA
Measurements	Main Unit: 310 x 295 x 370 mm. Length of Air Hoses: 1500 mm. Remote control cable length: 2900 mm.
Gas Connection	Medical air or apparatus air. 400.700kPa.
Weight Main Unit	15 kg incl. wheelbase and tubing's.
Temperature selection	31°C - 42°C, step of 1°C. Precision +- 2°C.
Max contact temperature	45°C on the mattress.
Pressure selection	0 - 50 mbar indicated as steps 1 to 9. One step is about 5 mbar. Precision +- 5mb. Mechanical overpressure valve release at 75 mbar.
Patient applied part	Mattress.
Function supervision	Audio and visual alert. Error codes displayed on the control unit and Remote Control.
Mattresses material	EVA plastic with non-woven cover.
Control unit and mattresses. Environmental data Use	+15°C to +35°C during operation, less than 90% Relative Humidity 700 to 1060 hPa (equivalent to a max height of about 3000m.)
Control Unit Environmental data Storing	0°C to +40°C non-condensing. Air pressure not relevant.
Control Unit Environmental data Transport	- 40°C to +40°C, non-condensing. Air pressure not relevant.
Mattresses Storing and transport	-40°C to +30°C. Air pressure not relevant.
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.
EU Classification	Control unit: 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 maintained and serviced according to the user and or service manual and that the unit has not been modified, damaged or changed in any way or for any reason.

10 Alarms and alarm codes

Alarm overview

When an alarm is generated, something is wrong with the device or the handling. The alarm consists of a sound and a symbol together with an error-code and/or symbol on the display. Only the error code will be displayed on the remote control.

When an alarm sounds, it can be acknowledged by pressing the alarm button .

Depending on what group the alarm belongs to the consequences of acknowledging the alarm will differ.

Temperature related alarms (too high or too low)

When a temperature related alarm is acknowledged the acoustic signal is muted for 10 minutes. During this time there is no heating, but the pressure will be maintained by WarmCloud. A symbol will be shown on the display on the unit indicating that a temperature alarm is active. On the remote control a number 4 (too high temperature) or 5 (too low temperature) will show. After 10 minutes the alarm comes back to remind the user that no heating is on. The user can acknowledge the alarm once more for a new "mute-cycle" if continuous use of the device without heating is desired.

Other alarms

When other alarm types are generated, acknowledging the alarm by pressing the alarm button will lead to a shutdown of the device. Note that the mattress will not empty itself directly but will "passively" lose pressure.

Pause alarm generation and alarm reset

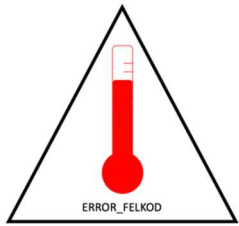
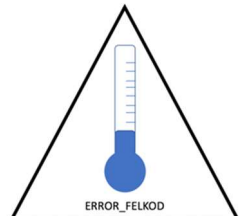
It is possible to pause the acoustic alarm for 10 minutes if the user knows that an action will generate an alarm and does not want the signal to disturb. Just press the alarm button when no alarm is active.

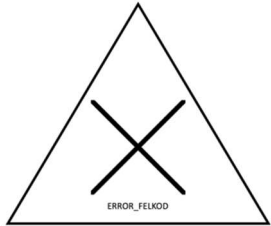
This action does not inhibit the generation of alarm symbol on the display.

To reset the alarm generation back to normal and cancel the acoustic alarm inhibition, press the alarm button for 2 seconds (i.e. *long press*).

Alarm Codes

Below is a table with all error codes, corresponding alarm symbol shown on the display and suggested action to take:

Alarm symbol	Error code	Reason	Possible solution and advice
	Error code 1	Power failure	Power the unit and press the alarm button to acknowledge.
	Error code 13	The unit has been started without a hand control connected. Nothing wrong but just saved in the log.	Connect a hand control or configure the device so that no handset is connected.
	7 TEMP.FAULT. Error code 4	When actual temperature is 4°C higher than set temperature.	Continue to run unit without heating or restart the unit. If alarm returns the unit must be serviced.
	8 TEMP.FAULT. Error code 5	When actual temperature is 4°C lower than set temperature.	Continue to run unit without heating or restart the unit. If alarm returns the unit must be serviced.

Alarm symbol	Error code	Reason	Possible solution and advice
Display blank	POWER FAILURE	Power loss in power outlet, disconnected cable, faulty cable or fuse blown.	Check all cables. Blown fuses. The unit must be checked by a technician because fuses normally don't blow. Fuses must be replaced with same type and rating.
	2 SAFETY RELAY ALARM	Processor Stop, Temp Error.	Restart the unit. If alarm returns the unit must be serviced.
	3 HIGH TEMP. ALARM	Mechanical thermal cut-out has been activated.	Restart the unit. If alarm returns the unit must be serviced.
	4 TEMP.FAULT.1	Internal test error T1, i.e. values outside of reasonable limits.	Restart the unit. If alarm returns the unit must be serviced.
	5 TEMP.FAULT.2	Internal test error T2, i.e. values outside of reasonable limits.	Restart the unit. If alarm returns the unit must be serviced.
	6 TEMP.FAULT.3	Temperature difference between T1 and T2 exceeds 15°C degrees.	Restart the unit. If alarm returns the unit must be serviced.
	9 PRESSURE.FAULT.1	Pressure sensor error i.e. values outside of reasonable limits.	Restart the unit. If alarm returns the unit must be serviced.
	10 PRESSURE.FAULT.2	When actual pressure is 10mb higher than set pressure.	Restart the unit. If alarm returns the unit must be serviced.
	11 PRESSURE.FAULT.3	Leakage. The inlet valve has been opened more than 60% of the last 15 minute period.	Should not be triggering an alarm during inflation period.
	12 INFLAT.FAILURE	Mattress is not inflated after 4 minutes.	Check for leakages. Normally easy to hear. Usually at the tube connection to the mattress. Small holes in the mattress can be temporarily fixed with a sticky tape.
	14 SUDD.DEFLAT	Sudden pressure drop.	Big leakage or someone "jumps" of the mattress.

Alarm delays.

Some alarms will be generated some time after the alarm condition have been detected. A good example is alarm 12 above.

Alarm	Maximum alarm delays*
1, 4, 5, 9, 13 and 14	<1 second
2,3,6,8 and 11	<60 seconds
7 and 10	<600 seconds
12	<240 seconds

Alarm delays consist of alarm conditions delay plus alarm signal generation delay as defined in IEC 60601-1:2006 + A1:2012. The alarm signal generation delay for the alarms used within WarmCloud 2 is insignificant and the alarm delays consist of only alarm conditions delay.

Verification of the alarm functions

Verification of the alarm functions can be done at the annual check. A description of the procedure is found in the service manual.

11 Activating or deactivating the remote control

Enter the menu selections by pressing the blue down arrow presses and simultaneously press the minus button.

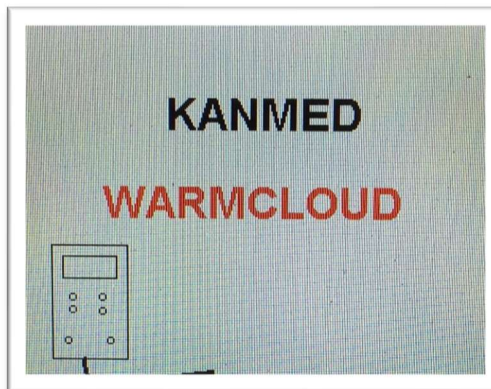
Leave the menus by pressing the alarm button.

Activating and deactivating of the remote control can only be mane on the control unit.

Can only be done in standby mode.

Stand by screen

Picture shows activate remote control.

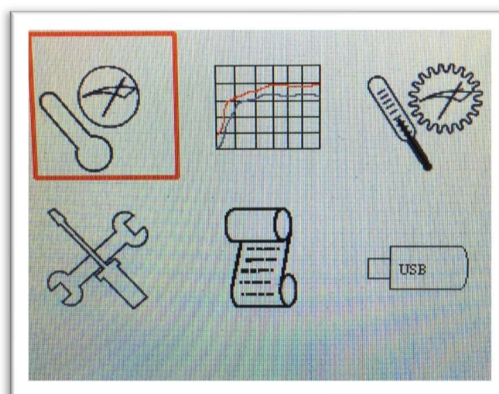


Moving the red marker

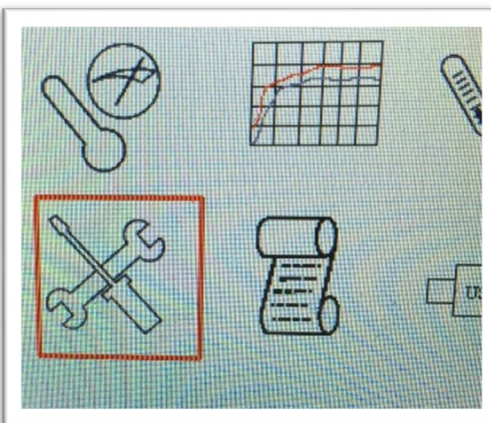
Move with the plus button.

The Red rectangle in the picture shows entry to status screen.

To go back to stand by, press the alarm button.



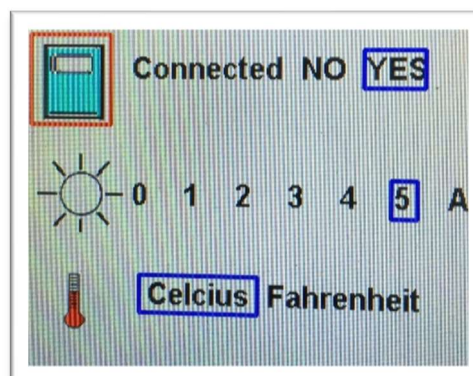
Move the red marker with the + button to the Settings menu and press start button.



First row: Remote connected or not. Change value with + or – button. Exit by pressing the alarm button. Other options.

Second row: Background illumination. The unit will dim the display if not touched for a while. "A" means that background illumination is always on at max.

Third row: Selection of temperature units.



12 Warranty conditions

Kanmed warrants the WarmCloud Main Unit and remote control for a period of 12 months from purchase date. Consumables like hoses and cables 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 have been used for other purposes than 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 shall be disposed for recycling or be returned to the distributor for recycling in accordance with the EU 2002/96/EC (WEEE) directive if applicable.

14 EMC Information

The WarmCloud fulfils the applicable requirements of IEC 60601-1-2:2014 Electromagnetic compatibility (EMC).

The Warmcloud shall be used in a hospital environment, but not in the same room as MRI equipment.

HF surgical equipment should when activated be kept at a distance of at least 50cm from the Warmcloud control unit, cables, and hand control.

The Warmcloud mattress can be used close to the HF surgical instruments.

WARNING: Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (e.g. mobile phones, radio transmitters, antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the WarmCloud 2, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

For further information about EMC compliance with the specified emissions and immunity standard, test levels, etc. please contact Kanmed.

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