

KANMED^o OPERATHERM

User Manual KANMED Operatherm OP3™

User manual, art no OP3-070/4

2013 05 17



Caution

Incorrect use of Heating equipment may cause serious injury. Please read this manual thoroughly.



Manufactured by:

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This manual is valid for KANMED Operatherm OP3 system serial number 0001-08 and above, with Software version 1.0 or higher.

Subject to changes.

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KANMED Operatherm OP3 User Guide Quick instruction

Intended Use

The KANMED Operatherm OP3 patient warming system 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. It is not intended for home use. It should only be operated by qualified medical personnel that have undergone proper product training.

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

Preparation

Position the Heating Pad on the operating table. Cover the Heating Pad with pre-warmed Kanmed Gel Pads.

Connect the Heating Pad cable to the front connector on the Control Unit.

Connect the power cable to a mains power outlet with protective grounding. The green LED on the Control unit is lit when mains power has been connected. After mains power has been connected the system program will load and it will take approximately 30 sec before the system is ready to be started (when the stand-by screen is displayed).

Start/Stop

Press the button on the front panel to start. Make sure that the automatic self test is properly performed. When prompted, answer by selecting the "YES" option, confirming that the Heating Pad is covered by Kanmed Gel Pads. If the "No" option is selected, the maximum temperature will be limited to 37°C.

The system is set to stand-by by pressing the start/stop button for five seconds. When in stand-by, the mains power may be removed. (An accidentally triggered power alarm can be reset by pressing the on/off button for two seconds).

Temperature settings

Default temperature setting is 37°C. The average temperature of the Heating Pad can be set between 33°C and 39°C by pressing the [<] or [>] buttons until desired temperature is displayed. 39°C is the recommended setting, suitable for most situations but should be attuned to the patient's requirements.

Note: When temperature settings above 37°C or below 35°C are selected, the unit will alert the operator by prompting for confirmation.

Caution! Always monitor the patient's actual body temperature with a reliable method.

Safety information

User Manual

Read the whole manual carefully before using the equipment.

Reduced Blood Flow

Parts of the body that have reduced or no blood flow should never be warmed. Set the system to stand-by well ahead of a blood vessel shut off.

Error Codes

If an error is detected by the system an acoustic alarm is received and a code is displayed on the Control Unit as "Code XXX". The meaning of the error code is also indicated by an icon. Full information about the error is found in the user manual.

System Malfunction

If the Operatherm OP3 self test does not perform correctly, the function supervision has displayed an alarm or error message or the Control Unit has received mechanical damage, it should then be examined by a qualified technician before being used. If you experience that the Operatherm OP3 is not operating properly, immediately turn the system off and consult a qualified technician for advice.
















User Manual

1 INTENDED USE

The KANMED Operatherm OP3 patient warming system 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. It is not intended for home use. It may only be operated by qualified medical staff that has undergone proper product training according to the hospital routine.

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

2 EXPLANATION OF SYMBOLS USED

	(Green LED) Mains Power indicator		Increase temperature, or change highlighted selection in MENU
	Start/Stop button		Decrease temperature, or change highlighted selection in MENU
	(Red/Orange LED) Error Indicator		Select main MENU, or change highlighted selection in MENU
	Alarm Silence		Select alternative display mode, or change highlighted selection in MENU
	Please read the instruction manual		ENTER, select highlighted item in MENU.
	Risk of explosion in the presence of inflammable gases.		Earth potential equalisation connection point
	Safety class BF, Defibrillator safe		IPX7 Water tight Heating Pad
	Fulfil MDD93/42/ECC. (Notified Body 0413= Intertek Semko AB, Sweden)		

3 SAFETY INFORMATION

Warnings

- **Proper Use.** To ensure optimal performance and to prevent incorrect use, the user manual must be read completely before the system is being used.
- **System Malfunction.** If the Operatherm OP3 self test does not perform correctly or the function supervision has displayed an alarm or error message or the Control Unit has received mechanical damage, it must be examined by a qualified technician before being used. If you suspect that the Operatherm OP3 is not operating properly, immediately consult a qualified technician for advice.
- **Restricted Blood Circulation.** Heat supply to tissue with no, or restricted blood circulation may result in serious tissue damage. Place the Heating Pad where blood circulation is maintained alternatively turn the Operatherm OP3 system off during the period of the restriction.
- **Never use the Operatherm OP3 system without Kanmed GEL Pads!** Ensure that there are no wrinkled materials under the patient. Any collection of fluid under the patient, especially disinfecting agents, can cause skin irritation.
- **Electrical Hazard** The system must always be connected to a mains power outlet with proper protective grounding. Always remove the mains power cable before cleaning the Control Unit. **NOTE:** The OP3 may not be interfaced with any other electrical system. If this is done a new "system" is created per definition, and the safety classification of the OP3 may be effected.
- **Body temperature.** When using the Operatherm OP3 system, the patient's actual body temperature (core temperature) should be constantly monitored by a reliable method.
- **Dropped or otherwise possibly damaged.** If the Operatherm OP3 Control Unit had fallen to the floor or has been subjected to other possible damage it must be examined by a technician before being used.
- Trans dermal medications (patches) can increase drug delivery, resulting in possible harm to patient when used with warming devices.
- **Modifications.** Un-authorized personnel are not allowed to open the Control Unit or the Heating Pad Connector. No modifications of the system, of any kind, are allowed since it will void the safety certification of the system and may seriously endanger patient safety. Only original parts may be used. The Heating Pad cable may not be altered in length or repaired in any way. If damaged, the complete Heating Pad must be replaced.
-

Caution

- **Gel.** The OP3 Heating Pad must always be completely covered by Kanmed Gel Pads. The Gel increases the contact surface and thereby the amount of energy transferred to the patient. It is important to pre-heat Gel Pads in advance because cold Gel Pads will drain energy from the patient.
- **Temperature setting.** If the OR-table surface is hard, blood pressure is low i.e. bad circulation, old patients, patients with diabetes, etc. 37°C should be the highest temperature setting used. For extraordinarily long operations and for patients sensitive to static pressure (e.g. diabetics), the combination of immobility, skin pressure and warming may prove a bad combination. You may consider not using the Operatherm OP3 system in these cases. Consider Kanmed WarmCloud instead.
- **Temperature reading.** Observe that the indicated temperature is a calculated average temperature value and may differ somewhat from local spot temperature readings of the Heating Pad surface.
- **Children and pre-term babies.** Patients with low body mass, particularly pre-term babies are easily influenced by the surrounding temperature. They get cold fast and may get fever if over-heated. Be particularly careful when temperature settings above 37°C are being selected.
- **Compatibility.** Only KANMED OP3 series Heating Pads can be used with Operatherm OP3 Control Unit. The Operatherm OP3 system is NOT compatible with KANMED OP200 series Heating Pads.
- **EMC.** Operatherm OP3 needs to be installed and put into service according to the EMC information provided. (Detailed EMC information can be downloaded from www.Kanmed.se)
- **DIATHERMY equipment and Defibrillators.** Under normal circumstances the Operatherm OP3 is not disturbed by this type of equipment. However, if the diathermy or defibrillation is set at very high output levels, the Operatherm OP3 might go into alarm state. In such a case, restart the system and observe that the self test is being performed correctly. Note that the Control Unit housing is electrically connected to earth.
- **ECG disturbance.** Under unfavourable conditions there is a risk that interference may occur on ECG traces. This may occur if the ECG electrodes are not being applied strictly to the manufactures instructions or if the Operatherm OP3 Heating Pad is positioned upside down (text side facing down).
- **MRI cameras.** The system is not designed for use with MRI cameras.
- **Heating Pad storage.** The Heating Pad should be stored using the Pad Hanger for wall mount that is included in all control unit deliveries or rolled to a diameter not less than 150mm. Do not bend or fold the Heating Pad in a way that sharp crease arises.
- **Cleaning.** Users should not use cleaning or decontamination methods different from those recommended by Kanmed without first checking with Kanmed that the proposed methods will not damage the equipment.

4 USING THE KANMED OPERATHERM OP3

THE CONTROL UNIT

The Control Unit contains a microprocessor based heating control system that regulates the temperature of each of the elements (heating zones) in the Heating Pad. The temperature is continuously monitored and the calculated average temperature of the Heating Pad is displayed.

Automatic Self Test

Every time the Operatherm is switched on it will perform an automatic self-test of all functions including the internal safety-circuit. If an error is detected, the Operatherm OP3 will not start the heating, the acoustic alarm will sound and the type of error is being indicated by the display.

Warning! Never use the system if the self test does not perform correctly!

Front Panel Layout

1. Display
2. Navigation Pad
3. Heating Pad connector
4. Alarm indication LED
5. Power indication LED
6. Alarm reset button
7. ON/OFF button



Rear Panel Layout



The rear-panel contains information about manufacturer, part number, serial number, voltage, etc. Mains power cord, and optional earth potential equalisation grounding is also connected here.

HEATING PAD

The 104 cm long standard Heating Pad OP3-104 (and the 150 cm Pad OP3-150) consists of eight individual heating zones (elements), and the Heating Pads OP3-063 and OP3-050 of four zones. Each zone is temperature regulated separately. Thanks to this unique feature the heat is supplied to the part of the Pad where it is most needed.

The individual elements are insulated from each other and embedded in a Mylar foil. They are hermetically sealed into the soft hospital grade plastic foil.

The Heating Pad is watertight and easy to clean. Element voltage is only about 30 Volts DC.

The Pad is connected to the front of the Control Unit. The Pad Connector contains a flash memory for calibration parameters of the elements, logged information of the previous sessions and an independent safety circuit.



PREPARATION

The Heating Pad

Place the Heating Pad on the OR-table with the printed side up and make sure it is not folded. Cover the Heating Pad completely with pre-heated Kanmed Gel Pads and a bed-sheet.

Gel Pad	GE-455015	(50 x 45 x 1,3 cm)	Fits the OP3-104 and OP3-150 Heating Pads. Use two Kanmed Gel Pads on OP3-104 and three on OP3-150.
Gel Pad	GE-436315	(63 x 43 x 1,3 cm)	Fits the Heating Pad OP3-063
Gel Pad	GE-305015	(50 x 30 x 1,5 cm)	Fits Heating Pad OP3-050

Connect the Heating Pad to the Control Unit and make sure that the connector engages fully.

Mains Connection

Connect the power cable to a mains power outlet with protective grounding. The green LED on the Control Unit is flashing when mains power has been connected. After mains power has been connected the computer will automatically boot (load the software) and it will take approximately 30 sec before the system is ready to be started (when the stand-by screen is displayed).

Location of the Control Unit

Locate the Control Unit where its display can be easily observed. It can be hung on its handle. Note that the handle and the enclosure are electrically connected to protective earth.

Do not position the Control Unit so it will be difficult to disconnect the mains power cable!

START

Switch the unit on by pressing the start/stop button on the front panel. Observe that a correct self test is executed. Confirm that Kanmed Gel Pads have been properly applied by selecting "✓" (press [>] button and "Enter"). The heating will now start automatically at 37°C. During the first 10 minutes after start, the Operatherm will perform a "power boost" cycle permitting maximum output power to be fed to the Heating Pad. After 10 minutes, the maximum output power will be reduced.

Note 1: If the Operatherm OP3 does not behave as described above it shall not be used and must be examined by a qualified technician.

Note 2: During the first 10 minutes after start, the Operatherm will perform a "power boost" cycle permitting maximum output power (approximately 180 W) to be fed to the Heating Pad. After 10 minutes, maximum output power will be limited. Different types of Pads have different power limits.

STOP

Set the system to stand-by by keeping the start/stop button on the front panel pressed for more than 5 sec. In stand-by mode the mains power may be removed for a complete power down.

Note: The Operatherm OP3 is designed to be left running continuously, so it can keep the Gel Pads heated and be ready for use at any time.

TEMPERATURE SELECTION

The default setting is 37°C. The average temperature of the Heating Pad can be set between 33°C and 39°C by pressing the [←] or [→] buttons until the desired temperature is displayed. 39°C is the normally recommended temperature setting suitable for most situations, but should be attuned to the patient's requirements.

Note: When temperature settings above 37°C or below 35°C are being selected, the unit will alert the operator by prompting for confirmation.

NAVIGATION

During normal operation, two different display screens can be selected. The OP3 will start with the default display screen giving information of the set- and actual temperature, actual power emission and elapsed time since power on.

By pressing the "down arrow" the "Temp and Power" screen is displayed. This screen is useful for monitoring the distribution of power and temperature to the different temperature zones of the Heating Pad, and for information of how much energy has been emitted during the current session. The set temperature can not be changed when this screen is displayed.

If "up arrow" is pressed, the system returns to the default display screen.

GELPADS

Always cover the Heating Pad completely with Kanmed Gel Pads.

Always use Kanmed Gel Pads to get an even heat distribution, a greater contact surface with the body of the patient and reduce the risk of pressure sores.

Always pre heat the Gel Pads. Cold Gel Pads will actually drain energy from the patient during the first 20 - 40 minutes. The Gel Pads should preferably be pre-heated to 42°C (KANMED Warming Cabinets are designed for this purpose).

A thin bed-sheet can be placed over the Gel Pads (under the patient).



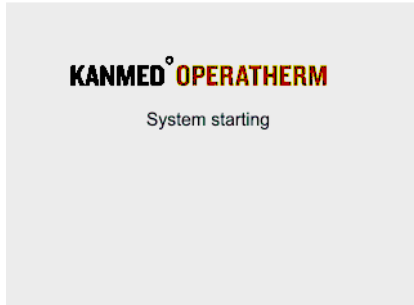
The most efficient pre-heating method is the Kanmed Warming Cabinet. An alternative, is to roll the Gel Pads together with the Heating Pad and leave the system running on maximum temperature setting for more than 2 hours.

EXPLANATION OF THE DISPLAY SCREENS

The system has a screen saver function, causing the display to dim the back light 30 minutes after pressing any button. This function is common for all display screens. In order to “wake” the system up from screen saving mode, just press any button.

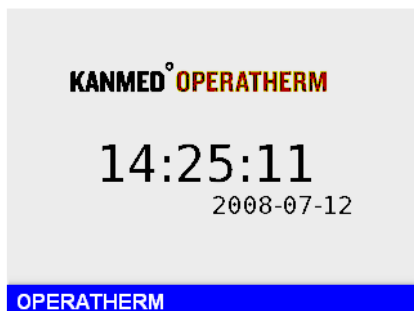
Start Up

Shown when the mains power has been connected.



Start Up screen

This screen is displayed shortly after the unit has been connected to mains power, and is displayed during the time the computer is booting (about 20 sec.), followed by a blank screen during 10 sec. After the blank screen the system will go to standby.



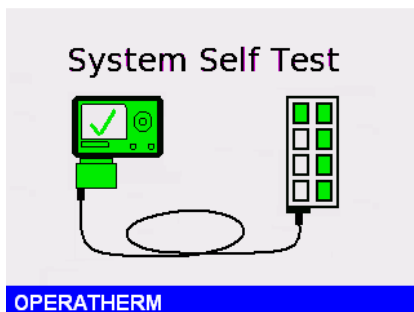
Stand by screen

This screen is displayed when system is in standby, and is ready to be switched on (by pressing the on/off button), or to access the technical menu by pressing “menu”.

To shut down the system completely, the mains power cord must be removed. This is only doable when the system is in stand-by, (otherwise the power loss alarm will be triggered).

Normal Operation

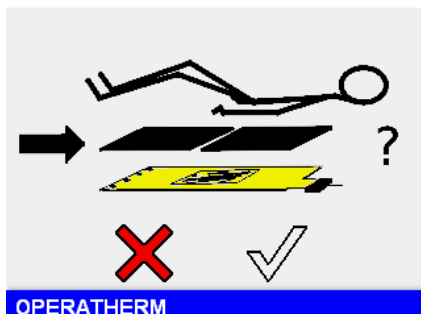
Functions accessed after pressing the on/off button when in standby mode.



Self test screen

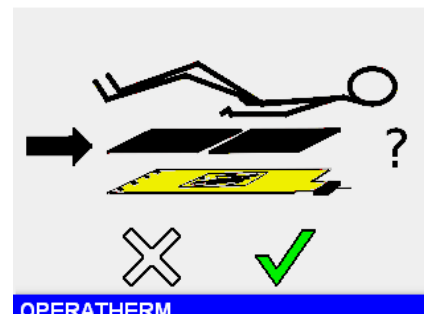
The self test will start automatically when the on/off button is pressed. Information of diagnostic tests being performed is displayed (checked parts turning green if found OK). If an error is detected, an error message will be displayed (see chapter trouble shooting).

The alarm LED will flash orange/red rapidly during the Heating Pad test. A short acoustic alarm signal will sound when the self test is completed.



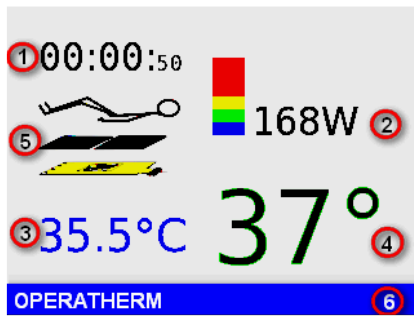
GEL confirmation screen

Prompting the operator to confirm that the Kanmed Gel Pads are properly applied. Positive response enables the use of temperature settings above 37°C.



NOTE: When positively confirmed by moving the highlighted selection to the green “√” (using the [<] or [>] buttons) and pressing “Enter”, the Default screen will be viewed and the system will start operating at the default temperature setting of 37°C. Higher temperature settings are permitted.

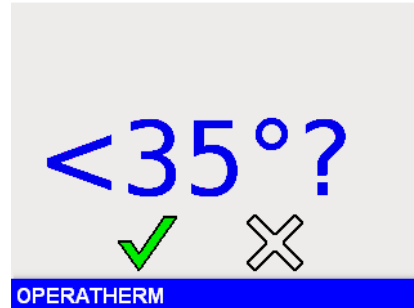
If “X” is selected, the system will start operating at the default temperature setting of 37°C. Temperature setting will now be limited to max 37°C.



Default display

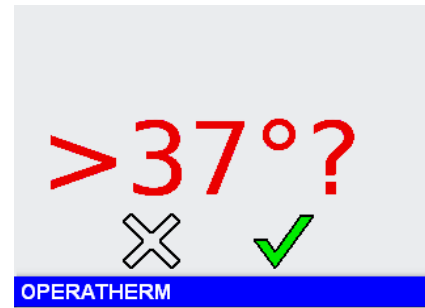
Information about:

1. Elapsed time since start-up
2. Heating Pad power
3. Heating Pad temperature
4. Set (desired) Heating Pad temperature
5. Gel indicator (icon present if positively confirmed)
6. Status bar

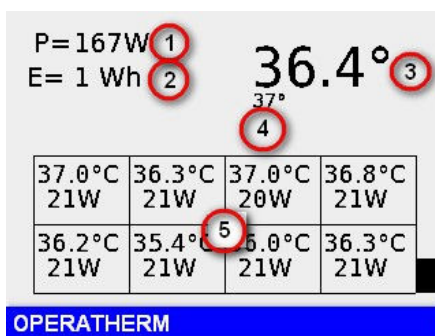


Temperature settings

When temperature settings below 35°C or above 37°C are being selected, the unit will alert the operator by prompting for confirmation (operator to press "Enter")



TIPS: An extra press on the [<] button also acts as "enter" when low temp setting is selected and [>] button when high temp setting is selected.



Power and energy display

By pressing the "down arrow", the system displays information about:

1. P = Current Heating Pad power.
2. E = Energy output from start-up
3. Heating Pad temperature (average value).
4. Set temperature
5. Individual temp and power information of each of the 8 Heating elements in the Pad.

A new press on the "down arrow" or the "up arrow" returns the system to the default operating screen.

NOTE: The set temperature can not be changed when this screen is displayed. Pls. return the system to the default display by pressing the "down arrow" if set temperature is to be changed.

5 CLEANING, CHECKS BEFORE USE AND MAINTENANCE

Cleaning / Disinfecting

Always unplug mains power cord before any maintenance procedure. Wipe off the Control Unit with a moist cloth and if necessary use normal hospital cleaning agent. Clean the watertight Heating Pad with soap or your usual cleaning agent. Disinfect the Pad with alcohol or any other commonly used disinfectant.

NOTE: Do not autoclave the Pad. Do not submerge the connector in any liquid.

Checks before use

Check that all parts are clean and in good condition. Check that the unit performs a correct self test at start. If error codes appear and can not be eliminated with the suggestions given in the trouble shooting section of this document, then it should be notified to Technical staff. Note: If any part of the system has received mechanical damage, it should always be checked and correct system function verified by technical staff.

Maintenance

Kanmed Operatherm OP3 does not require any special maintenance apart from what is described in the technical section of this manual.

Storage The Heating Pad shall be stored hanging with the Pad Hanger or lying flat. Avoid folding.

6 ACCESSORIES

Article no.	Product	Comment
OP3-022	Control Unit	Includes Pad Hanger, mains cord and instruction manual. Factory set to 220-240V AC , 50/60 Hz
OP3-115	Control Unit	As above, but set to 100-120 AC , 50/60 Hz
OP3-100	Control Unit	As above, but set to 100V AC , 50/60 Hz
OP3-104	104 cm Heating Pad	1040 x 450 mm. X-Ray translucent. Standard Heating Pad. Fits most patients. Requires two standard Kanmed Gel Pads.
OP3-150	150 cm Heating Pad	1500 x 450 mm. X-Ray translucent. Requires three standard Kanmed Gel Pads.
OP3-063	Short Heating Pad	630 x 430 mm. X-Ray translucent. Must always be used with the Gel Pad no GE-436315. For small children during surgery, post operative warming, under radiant heaters, on resuscitation tables.
OP3-050	Small Heating Pad	500 x 300 mm. X-Ray translucent. Must always be used with the Gel Pad no GE-305015. For small children during surgery, post operative warming, under radiant heaters, on resuscitation tables and in baby cribs.
GE-455015	Gel Pad	500 x 450 x 13 mm. Standard Gel Pad.
GE-305015	Gel Pad	300 x 500 x 15 mm. Fits perfectly over Heating Pad OP3-050. Equipped with a pocket for the Heating Pad
GE-436315	Gel Pad	630 x 430 x 13 mm. Fits perfectly over Heating Pad OP3-063.
OP3-005	Pad Hanger	Wall mounted hanger for the Heating Pads.
OP3-070	User manual *	English.
OP3-079	Service Manual	English.
OP3-099	Calibration Adapter	For checking the Control Unit calibration.

SPARE PARTS

Article no.	Product	Comment
700-0751	Rubber Frame	NOTE: Two pcs per unit is required.
700-0766	Rear label	
700-0748	PAD Connector casing	Plastic pad-connector housing (top/bottom) incl. screws.
700-0765	CU Front label	
300-001	CPU unit incl front	(OP303-1 Display and Computer board)
300-002	Main board	(Op303-2)
300-003	Power board	(OP303-3)
300-004	Power transformer	(the large power transformer, 2 x 28,6 V 300 VA)
300-005	Power transformer	(electronics power supply transformer, 10,3 V 9 VA)
300-006	Mains power intake	With RF filter
300-007	Connector Saver	37 pin F/F
300-008	CU Rear panel	excl. label
300-011	Cable kit	Internal control unit cable kit
300-012	CU Handle	
300-013	CU Bottom plate	
300-014	CU Cabinet	(naked cabinet)
700-0255	Elastosil A07, 90ml	Silicon based adhesive for fixing the rubber frames.

* Latest version of the manual can be downloaded from www.Kanmed.se
 For the latest information about accessories, please visit www.Kanmed.se or contact your local dealer.

7 TECHNICAL INFORMATION

The Control Unit contains a microprocessor based heating control system that regulates the temperature of each of the 8 elements (heating zones) of the Heating Pad. The temperature is continuously monitored and the calculated average temperature of the Heating Pad is displayed.

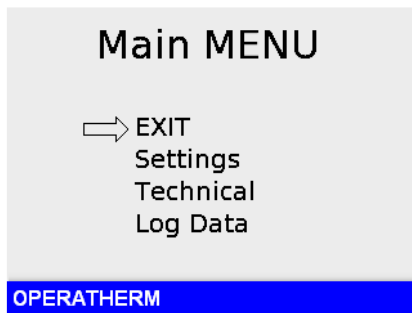
The safety system in the Control Unit is continuously monitoring the main power, internal voltages, running parameters, the Pad condition and the behaviour of each element.

Two autonomous safety circuits, totally independent of the microprocessor based operating system, can at any time stop the warming, should conditions occur that can cause over temperature.

If a fault is detected, the Control Unit will alarm visually and acoustically and switch off the heating. The type of error is indicated on the alarm display. A description of the error codes are found under the chapter "Trouble Shooting".

"MENU"

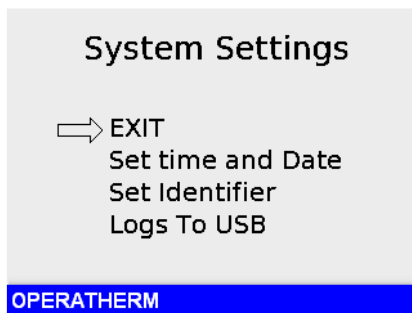
This function is accessed if the "Menu" (up arrow) button is pressed when the unit is in stand by mode. This menu or these functions are not available during normal operation of the system. They are exclusively designed for system set-up or technical function control.



Main Menu screen

Top menu. Navigate by pressing the "up arrow" or "down arrow" to highlight the desired action and press "enter". EXIT returns the system to stand-by mode.

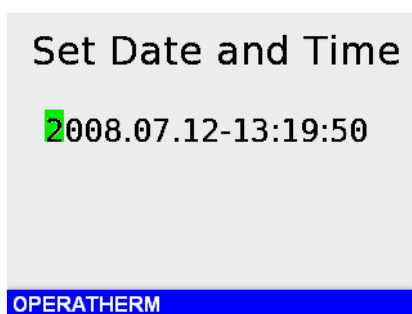
NOTE: "up arrow" (menu) exits the function and returns the system to stand-by mode.



System Settings

Navigate by pressing the "up arrow" or "down arrow" to highlight the desired action and press "enter". EXIT returns the system to the Main Menu.

NOTE: "up arrow" (menu) exits the function and returns the system to the Main Menu.



Set Time and date

Date will be set on the format YYYY-MM-DD and time on the 24 hour format HH-MM-SS.

Navigate by pressing the [<] or [>] buttons to highlight the desired digit to be changed and press "down arrow" to alter the value of the digit.

"Enter" saves the new setting and returns the system to the System Settings menu.

"Menu" (up arrow) ignores any change and returns the system to the System Settings menu.

NOTE: "up arrow" (menu) exits the function and returns the system to the System Settings menu without changing the time or date.



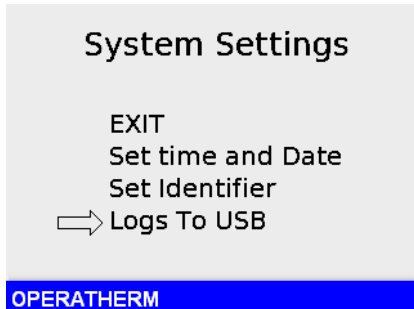
Set Identifier

A name of up to 10 characters can be given the unit (and will be displayed in the bottom left corner of the screen). Navigate by pressing the [<] or [>] buttons to highlight the desired position to be changed and press "down arrow" to alter the character (A to Z _ 0 to 9)

"Enter" saves the new setting and returns the system to the System Settings menu.

"Menu" (up arrow) ignores any change and returns the system to the System Settings menu.

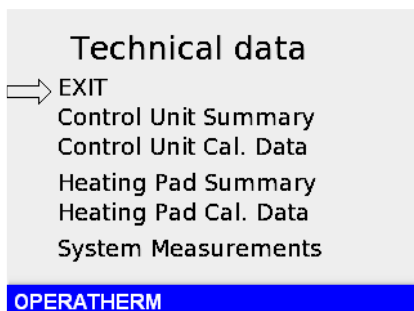
NOTE: "up arrow" (menu) exits the function and returns the system to the System Settings Menu without changing the set name.



Write logs to USB (technical function)

System log files can be written to a USB memory stick for off-line analyzes. Connect a USB memory stick to the internal USB connector, highlight this function and press "Enter". Wait until the text "Writing Data" has disappeared before exiting the function. The Control Unit will now have written a copy of its internal log files to the connected USB memory.

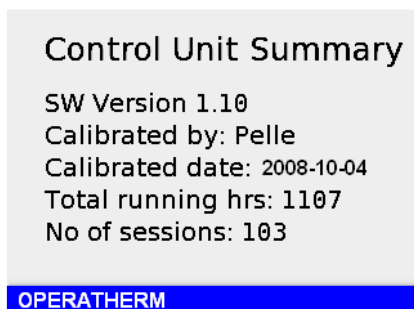
NOTE: The Control Unit must be opened to access the USB connector. This is an operation that only shall be performed by trained technical staff.



Technical Data

Several system functions can be monitored and controlled, e.g. SW version data, calibration data etc. These functions are exclusively designed for technical staff and maintenance personnel.

NOTE: This is functions that only should be used by trained technical staff.



Control Unit Summary

Information of SW version, Calibration information, Running hours and No of system starts (operating sessions)

"Menu" (up arrow) returns the system to the Technical data menu.

NOTE: This is functions that only should be used by trained technical staff.

Calibrated Values

No 8 9214	No 6 9214	No 4 9214	No 2 9212
No 7 9239	No 5 9239	No 3 9242	No 1 9241

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Control Unit Calibration Data

Factory set Calibration values for each of the 8 channels.

“Menu” (up arrow) returns the system to the Technical data menu.

NOTE: This is functions that only should be used by trained technical staff.

Pad Data Summary

PAD Nr: 23750
 PAD type: OP3-104
 PAD SW: 0.1
 Calibrated by: Pelle
 Calibrated date: 2008-10-05
 Total running hrs: 728
 No of sessions: 43

OPERATHERM

Heating Pad Data Summary

Information about the connected Pad.
 SW version, Calibration information, Running hours and No of starts (operating sessions).

“Menu” (up arrow) returns the system to the Technical data menu.

NOTE: This is functions that only should be used by trained technical staff.

PAD Calibrated Values

PAD Nr: 23750

No 8 29.09	No 6 29.11	No 4 29.06	No 2 28.88
No 7 28.90	No 5 29.15	No 3 28.96	No 1 28.95

OPERATHERM

Heating Pad Calibration Data

Information about the connected Pad.
 Factory set Calibration values for each of the 8 elements.

“Menu” (up arrow) returns the system to the Technical data menu.

NOTE: This is functions that only should be used by trained technical staff.

System Measurements

PAD Number: 23750
 CH: 2 U: 5.429 VDC
 I: 169.438 mA
 Calculated R: 29.61 Ohm
 Calculated T: 27.95°C

OPERATHERM

System Measurements

This function measures each of the eight channels separately for deep analyze of the system measurement accuracy and the condition of each of the elements in the connected HeatingPad.

Press the [<] or [>] buttons to change the channel to study.
 “Menu” (up arrow) returns the system to the Technical data menu.

NOTE: This is functions that only should be used by trained technical staff.

CU Unit Log: 46

Start: 2008-10-09 08:37
 End: 2008-10-09 08:38
 Time: 1m 13s
 Mode: No Gel Energy: 2 Wh
 Alarm: 60 at: 2008-10-09 08:38

OPERATHERM

Log Data

Information about the latest session.

Press the [<] or [>] buttons to change the log to study.
 “Menu” (up arrow) returns the system to the Main menu.

8 TECHNICAL DATA

Control Unit

Voltage	Art. no: OP3-022 Internally selectable; 100 V AC, 110-120 V AC, 220-240 V AC
Frequency	50/60 Hz
Power consumption	285 VA (max)
Temperature range	33°C to 39°C in steps of 1°C
Temperature accuracy	Better than ±1°C
Resolution	1°C (Display resolution 0.1°C)
Over-temperature alarm level	41.0°C ± 0.5°C
Dimensions	L 255 mm, W 150 mm, H 120 mm.
Weight	6 kg
Mode of operation	Continuous

Common for all Heating Pads

Voltage	30 V DC
Length of cable	2900 mm
Water protection	Watertight, <u>except for connector</u>
Surface, electrical properties	Not electrical conductive

Heating Pad Standard (104cm)

Art. no:	OP3-104
No. of elements:	8
Max Power	200 W (8 x 25 W)
Dimension	L 1040 mm, W 450mm, H 3 mm
Weight	2 kg

Heating Pad Long (150cm) Art. no: OP3-150

No. of elements:	8
Power	200 Watt (8 x 25W)
Dimension	L 1500 mm, W 450 mm, H 3 mm
Weight	2,6kg

Heating Pad Short (63cm)

Art. no:	OP3-063
No. of elements:	4
Power	100 W (4 x 25W)
Dimension	L 630 mm, W 430 mm, H 3 mm
Weight	1,6 kg

Heating Pad small (50cm)

Art. no:	OP3-050
No. of elements:	4
Power	100 W (4 x 25W)
Dimension	L 500 mm, W 300 mm, H 3 mm
Weight	1,1 kg

Heating up time

Elements inside the Heating Pad	about 8-10 minutes from 20°C to 37°C
Heating Pad surface	about 25 minutes from 20°C when tested under conditions of "ADEQUATE HEAT DISCHARGE" in (IEC601-2-35)

Environment

Operating temperature	+15°C to + 40°C
Shipping and storage	- 20°C to + 60°C
Humidity	10% to 85% RH non condensing

Safety Standards

EN60601-1, EN60601-1-2, IEC60601-2-35	
Protection type	BF, Defibrillator safe
Protection class	Class I
MDD classification	Class IIb

Expected lifetimes

Control unit OP3.

Kanmed warrants a safe lifetime for Control unit OP3 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.

Heating Pad.

Heating Pads are consumable products and the expected lifetime is one to two years depending how they are handled and how often they are used.

9 TROUBLE SHOOTING

Function Supervision and Alarms

Apart from a complete self test when the system is turned on, (where all vital parts and safety functions are being tested), the Operatherm OP3 supervises the function of the system during normal operation and will render alarm or alert for any of the following fault conditions:

- Incorrect temperature (e.g. high or low temperature alarm)
- Heating Pad error (defective Heating Pad or too much energy being fed to the Pad)
- Control Unit error (internal error detected).
- Power Failure. (In case of a mains power failure, the Operatherm alarms by flashing the power indication LED and sounding the beeper intermittently. The power failure alarm is kept active for at least 10 min. The power alarm can be silenced by the operator by pressing the on/off button for about 2 seconds).

For added safety against over-temperature due to electrical short circuits, multi fault conditions or similar unforeseen general errors in the Control Unit, each of the OP3 series Heating Pads has its own, completely independent safety circuit located in the Heating Pad connector. This circuit monitors the feeding voltage to each of the eight elements in the Heating Pad at all times and if an error is detected, it will cause the Control Unit to cut the power feed to the Heating Pad (trip the safety relay). Two different conditions will cause the safety circuit to activate:

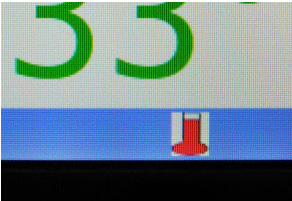
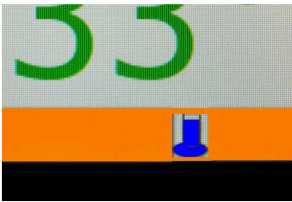
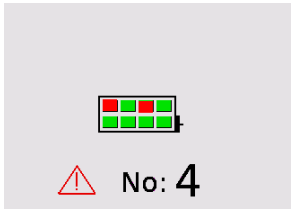
1. If this circuit detects an unregulated voltage being fed to any of the elements (e.g. a major error in the Control Unit causing short circuit output).
2. If the Control Unit is feeding more energy than 25000 Ws over a period of 30 minutes to any of the elements, e.g. error in the temperature regulation – or an abnormally high thermal load.

In case the Operatherm OP3 indicates an alarm, note the error code indicated (see explanation of the codes further down in this section). If there is a logical explanation, try to eliminate the condition that is causing the alarm. Restart the unit and observe a correctly executed self test. In case the alarm comes back without apparent reason, the unit must be fully examined by a qualified technician.

Note: If the mains power is removed before the Control Unit is set to standby, or the on/off button is unintentionally pressed when the main power is not connected, the alarm will start! This "false" alarm is reset by simply pressing the on/off button for about 2 seconds.

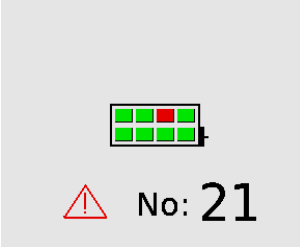
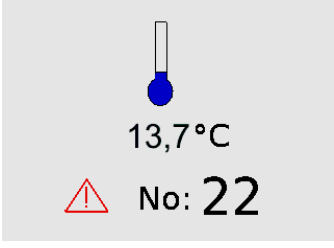
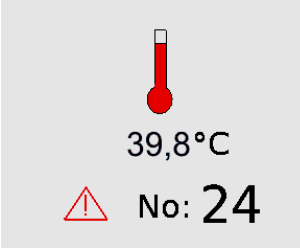
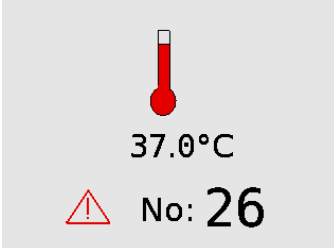

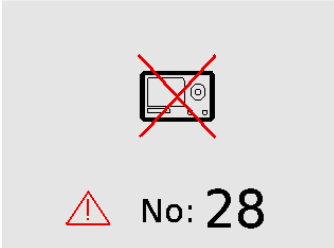
Alerts

Informative system messages only, the system will continue operation.

Alert display and Error Code	Description / Operator actions
	<p>Slow cooling. The Heating Pad has a higher temperature than the Control Units set temperature. The status bar displays a thermometer-icon as long as this condition persists.</p> <p>Action: No action normally required. This alert might occur when the set temperature is reduced from a higher setting.</p>
	<p>Slow heating. One or more of the Pad elements has not reached 2°C less than the set value after 10 minutes.</p> <p>Action: No action normally required. This alert might occur when the unit starts from a cold condition. If the system is re-started, a new 10 minutes power boost period will occur and help the system to faster reach the set temperature.</p>
	<p>Defective elements. A Heating Pad with one or two defective elements has been connected to the Control Unit.</p> <p>Action: Reset the alert. The Pad may be used but should be replaced by a correct Pad at earliest opportunity.</p>









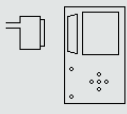







Medium severity alarms

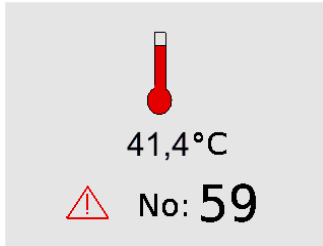
An error in this category turns the heating off but permits resumed operation after the alarm has been reset.

Alarm display and Error Code	Description / Operator actions	Alarm display and Error Code	Description / Operator actions
 <p>No: 21</p>	<p>Pad element resistance outside of nominal limits. The Pad resistance deviates more than 20% from the anticipated value. This may occur when a Heating Pad is beginning to go defective.</p>	 <p>13,7°C No: 22</p>	<p>Low initial Pad temperature. The Control Unit has calculated the Heating Pad temperature to a value lower than 15°C.</p>
<p>Action: Reset the alarm. If the alarm re-occurs, the Heating Pad should be analyzed and/or replaced</p>		<p>Action: If there is a logical explanation (a cold start when the Pad is chilled), just reset the alarm and the system will operate as usual. If the Heating Pad actually is warm, or the alarm re-occurs, the Heating Pad or the Control Unit should be analyzed and/or replaced.</p>	
 <p>39,8°C No: 24</p>	<p>Hot-spot warning. One or several of the Pad elements has had a calculated temperature higher than the set value, during 10 minutes.</p>	 <p>37.0°C No: 26</p>	<p>Slow cooling. The average temperature of the Pad has had a calculated temperature higher than the set value, during 5 minutes.</p>
<p>Action: If there is a logical explanation (something has accumulated the heat), just reset the alarm and the system will operate as usual. If there is no apparent unusual operating condition, or the alarm re-occurs, the Heating Pad or the Control Unit should be analyzed and/or replaced.</p>		<p>Action: If there is a logical explanation (a lowered temperature setting with a heavy body on the Pad that has accumulated excessive heat), just reset the alarm and the system will operate as usual. If there is no apparent unusual operating condition, or the alarm re-occurs, the Heating Pad or the Control Unit should be analyzed and/or replaced.</p>	
 <p>No: 27</p>	<p>The Control Unit's log-file is very large (time for service of the unit).</p>	 <p>No: 28</p>	<p>Abnormal temperature variation detected. A change in the Pad temperature faster than 5°C in 3 sec has been detected.</p>
<p>Action: The alarm can be reset and the system will operate as usual. Before the unit is used next time, the Control Unit should be serviced by an authorized technician.</p>		<p>Action: The alarm can be reset and the system will operate as usual. If there is no apparent unusual operating condition, or the alarm re-occurs, the Heating Pad or the Control Unit should be analyzed and/or replaced.</p>	

High severity alarms

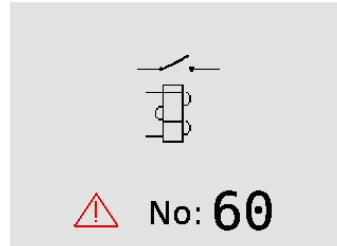
An error in this category turns the Heating off. After the alarm has been reset the system goes to standby. The unit needs to be re-started and an automatic self test carried out.

Alarm display and Error Code	Description / Operator actions	Alarm display and Error Code	Description / Operator actions
  No: 51	<p>Error in the measuring circuitry, no acceptable data received during 20 sec. Probably caused by defective components.</p>	  No: 52	<p>Internal communication error. Probably caused by defective components, faulty memory circuits or software error.</p>
<p>Action: The Control Unit should be analyzed by an authorised technician.</p>		<p>Action: The Control Unit should be analyzed by an authorised technician.</p>	
  No: 53	<p>The Control Unit has corrupted software. Probably caused by defective components, faulty memory circuits or software error.</p>	  No: 54	<p>The Heating Pad has corrupted software. Probably caused by defective components, faulty memory circuits or software error</p>
<p>Action: The Control Unit should be analyzed by an authorised technician.</p>		<p>Action: The Heating Pad should be analyzed by an authorised technician.</p>	
  No: 55	<p>The Heating Pad connector is not properly fitted, or damaged.</p>	  No: 56	<p>The Heating Pad is not correctly calibrated.</p>
<p>Action: Try to re-fit the Pad connector and restart the unit. If the error persists, the Pad and the Control Unit's connector saver should be analyzed by an authorised technician.</p>		<p>Action: The Heating Pad should be returned to KANMED for analysis.</p>	
  No: 57	<p>The Heating Pad is not correctly validated after calibration.</p>	  No: 58	<p>The Pad has too many defective elements to be used (three of eight, or two of four) to be used.</p>
<p>Action: The Heating Pad should be returned to KANMED for analysis.</p>		<p>Action: The Heating Pad must be replaced.</p>	



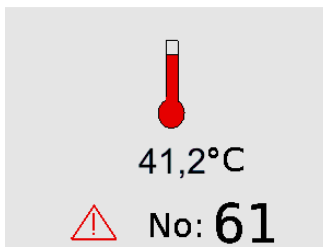
Average temperature has exceeded 41°C for more than 30 sec.

Action: Reset the alarm and restart the unit. Observe the temperature behaviour on the display. If there is no apparent unusual operating condition, or the alarm re-occurs, the Heating Pad or the Control Unit should be analyzed and/or replaced.



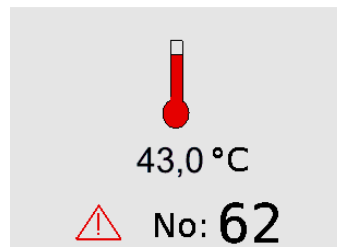
The safety circuit has been activated.

Action: Reset the alarm. If there is a logical explanation e.g. a massive cold object is draining more than normally anticipated amount of heat from the Pad, **disconnect the Heating Pad connector and re-connect it** (in order to reset the internal safety relay). Restart the unit and observe the temperature behaviour on the display. If there is no apparent unusual operating condition, or the alarm re-occurs, the Heating Pad or the Control Unit should be analyzed and/or replaced.



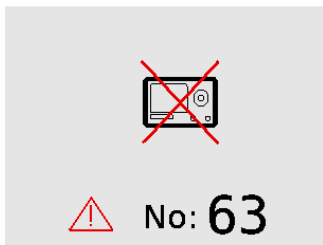
Serious hot-spot warning 1. One or several of the Heating Pad elements has had a calculated temperature higher than 41°C for 3 minutes.

Action: Reset the alarm and restart the unit. Check the actual temperature under the patient. If there is no apparent unusual operating condition (e.g. the Pad being heated by another external device), the Heating Pad and the Control Unit should be analyzed and/or replaced.



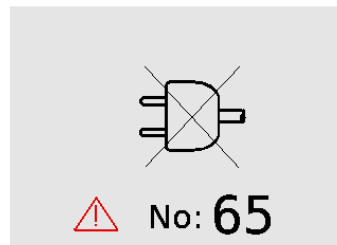
Serious hot-spot warning 2. One or several of the Heating Pad elements has reached a calculated temperature higher than 43°C.

Action: Reset the alarm and restart the unit. Check the actual temperature under the patient. If there is no apparent unusual operating condition (e.g. the Pad being heated by another external device), the Heating Pad and the Control Unit should be analyzed and/or replaced.



The A/D converter (used to calculate Pad temperature) reports inconsistency.

Action: Reset the alarm and restart the unit. If there is no apparent unusual operating condition, or the alarm re-occurs, the Control Unit should be analyzed and/or replaced.



Power loss has occurred during normal operation.

Action: The power alarm can be silenced by the operator by pressing the on/off button for about 2 seconds. Restart the unit after the power has been restored.

Note: If the mains power is removed before the Control Unit is set to standby, or the on/off button is unintentionally pressed when the main power is not connected, the alarm will start! This "false" alarm is reset by simply pressing the on/off button for about 2 seconds.



Error when Control Unit is writing to the Pad log file.

Action: Reset the alarm and restart the unit. If the alarm re-occurs, the Heating Pad or the Control Unit should be analyzed and/or replaced.




Error when Control Unit is writing to the internal log file.

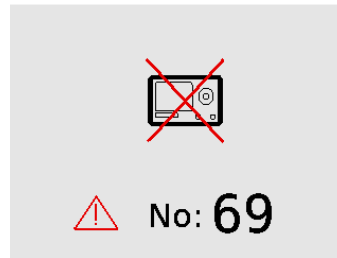
Action: Reset the alarm and restart the unit. If the alarm re-occurs, the Control unit should be analyzed and/or replaced.



No memory space left when Control Unit is writing to its internal log file.

 No: **68**

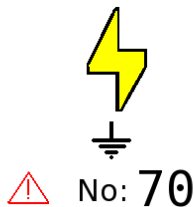
Action: Reset the alarm. The Control Unit needs to be serviced by an authorised technician.




The system measurements temporarily unreliable. May be caused by powerful interference from other equipment or similar.

 No: **69**

Action: Reset the alarm and restart the unit. If the alarm re-occurs, the Control Unit should be analyzed and/or replaced.



Earth current flow is detected in the ground plane of the Heating Pad. This will occur if the Heating Pad has been severely mechanically damaged or penetrated by a sharp object.

 No: **70**

Action: Reset the alarm. The Heating Pad and the Control Unit needs to be serviced by an authorised technician.

10 ANNUAL CHECK OF THE SYSTEM

Maintenance carried out by technical staff.

- Exchange of connector saver.

Annual check of the system

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

- Visual control of the Control Unit and Heating Pad as well as cables.
- Complete electrical safety test (as per hospital regulation).
- Check of the safety functions, as per the list below.

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

a) Check of system calibration. Connect the optional calibration adapter to the Control Unit (to the Pad connector). The system will automatically perform the calibration control by measuring the reference resistance in the calibration adapter and display the result on the screen. Leave the system running for about 5 minutes. If the Control Unit measure the correct resistance within tolerance, the measured value turns green, if the measurement is outside of acceptable tolerance, the value turns red.

b) Check of Mains Failure alarm. Remove the power cord from the Control Unit during normal operation. The alarm should trigger momentarily. Silence the alarm by pressing the on/off button for about 2 seconds.

c) Check of Heating Pad safety circuit. Expose the Heating Pad to an excessive thermal load, by rolling the Heating Pad and inserting it in a bucket with water at room temperature. Run the system at 39°C for approximately 10 minutes. (also note that after 10 minutes the heating output per heating element will drop to about 10 watt). Restart the system and let it run another 10 minutes. Repeat this a third time and observe that the alarm triggers and Error code 60 is received. Total test time about 25 minutes. To reset Error code 60 you have to disconnect the Heating Pad.

d) Check of over temperature alarm. Run the system at 39°C. Warm any point of the Heating Pad with a warm air blower (e.g. a hair dryer) and observe the individual temperature readings on the Power and Energy display. When the element corresponding to the spot being heated reaches 43°C the alarm should trigger and Error code 62 being received.

Technical documentation

The service manual provides information to assist the user's appropriately qualified technical staff to exchange parts of the equipment that are designated by the manufacturer as exchangeable.

NOTE: Only KANMED factory is authorised to perform repairs on the printed circuit boards.

11 WARRANTY

KANMED AB warrants the Operatherm OP3 Control Unit and Heating Pads for a period of 12 month from the purchase date.

In case of a warranty matter KANMED may on its own judgement decide to:

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

This warranty is not valid if:

- The product has been modified, adjusted or repaired without the written consent of KANMED.
- The product has been modified, adjusted or repaired without following the written KANMED guidelines.
- The unit has 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 arising from deviation from the intended use, neglect of safety instructions, neglect of alarms, neglect of annual service etc.

12 DISPOSAL



When the Operatherm OP3 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.

13 EMC COMPATIBILITY STATEMENT

EMC Guidelines for the Operatherm OP3 system

- Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.
- The KANMED Operatherm OP3 system should not be used adjacent to, or stacked with other equipment. If adjacent or stacked use is necessary, the KANMED Operatherm OP3 system should be observed to verify normal operation in the configuration in which it is used.

Guidance and manufacturer's declaration - electromagnetic emissions		
The KANMED Operatherm OP3 system is intended for use in the electromagnetic environment specified below. The customer or the user of the KANMED Operatherm OP3 should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The KANMED Operatherm OP3 system 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.
RF emissions CISPR 11	Class B	
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 KANMED Operatherm OP3 system.

The KANMED Operatherm OP3 system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the KANMED Operatherm OP3 system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the KANMED Operatherm OP3 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.

Guidance and manufacturer's declaration - electromagnetic immunity

The KANMED Operatherm OP3 system is intended for use in the electromagnetic environment specified below. The customer or the user of the KANMED Operatherm OP3 system assures that it is used in such an environment.

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 5 sec	<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 5 sec	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 Operatherm OP3 system be powered from an uninterruptible power supply unit (UPS)
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

Note: U_T is the AC mains voltage prior to application of the test level

Guidance and manufacturer's declaration - electromagnetic immunity			
<p>The KANMED Operatherm OP3 system is intended for use in the electromagnetic environment specified below. The customer or the user of the KANMED Operatherm OP3 system should assure that it is used in such an environment.</p>			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC 61000-4-6</p>	<p>3 Vrms 150 kHz to 80 MHz</p>	<p>3 Vrms</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the KANMED Operatherm OP3 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>Radiated RF IEC 61000-4-3</p>	<p>3 V/m 80 MHz to 2,5 GHz</p>	<p>3 V/m</p>	<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> <div style="text-align: center;">  </div>
<p><i>Note 1:</i> At 80 MHz and 800 MHz, the higher frequency range applies.</p>			
<p><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>			
<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 KANMED Operatherm OP3 system is used exceeds the applicable RF compliance level above, the KANMED Operatherm OP3 system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Operatherm OP3.</p> <p>** Over the frequency range of 150 kHz to 80 MHz, field strength should be less than 3 V/m.</p>			

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