

Service Manual KANMED Operatherm OP3™

Manual no OP3-079/2
2010-02-09



Caution

Incorrect use of heating equipment may cause serious injury.

Read this manual carefully.

Manufactured by:

KANMED AB
Gårdsfogdevägen 18B
SE-168 66 Bromma
Sweden
Tel +46 8 56480630 Fax + 46 8 56480639
E-Mail info@Kanmed.se
Web www.Kanmed.se

This manual is valid for KANMED Operatherm OP3 system serial number 0001-08 and above, with Software version 1.1 (or higher) and Service Software 1.3 (or higher).

Subject to changes.

INDEX

TECHNICAL MANUAL	3
1 INTENDED USE	3
2 EXPLANATION OF SYMBOLS USED	3
3 SAFETY INFORMATION	4
Warnings	4
Caution	4
4 CLEANING, CHECKS BEFORE USE AND MAINTENANCE	5
5 ACCESSORIES AND SPARE PARTS	5
6 TECHNICAL INFORMATION	7
General	7
Detailed system description	7
7 TECHNICAL DATA	9
Classifications	9
8 SERVICE SOFTWARE	10
LOADING SOFTWARE TO THE CU	10
MENU functions	12
Main Menu	12
System Settings	12
Set Time and date	12
Set Identifier	12
Writing Logs to USB	13
Technical Data menu	16
Control Unit Summary	16
Control Unit Calibration Data	16
Heating Pad Data Summary	17
Heating Pad Calibration Data	17
System Measurements	17
Control Unit Calibration Check	18
Log Data Menu	18
Control Unit Log	18
PAD Log	19
Special operation, workshop level only!	20
Control Unit RE-Calibration	20
8 TROUBLE SHOOTING	21
Function Supervision and Alarms	21
Alerts	21
Medium severity alarms	22
High severity alarms	23
9 ANNUAL CHECK OF THE SYSTEM	25
10 REPAIR INSTRUCTIONS OP3 CONTROL UNIT AND PAD	26
CU Disassembling instructions:	26
CU Assembling instructions:	29
PAD Disassembling instructions:	30
11 WARRANTY	31
12 DISPOSAL	31
13 EMC COMPATIBILITY STATEMENT	32
EMC Guidelines for the Operatherm OP3 system	32

Technical 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.

**Only KanMed original parts can be used with this system.
All other use will jeopardise the system function and the safety of the patient.**

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
	Fulfils MDD93/42/ECC. (Notified Body 0413= Intertek Semko AB, Sweden)		

3 SAFETY INFORMATION

Please refer to the safety information found in the User Manual for hazards related to normal operation of the system.

Warnings

- **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 the Operatherm OP3 is suspected to not operating properly, immediately consult a qualified technician for advice.
- **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.
- **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.
- **Always remove mains power when the control unit is opened!**
- **Always perform internal work with the system in an ESD-protected environment.**

Caution

- **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.
- **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 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 the user manual.

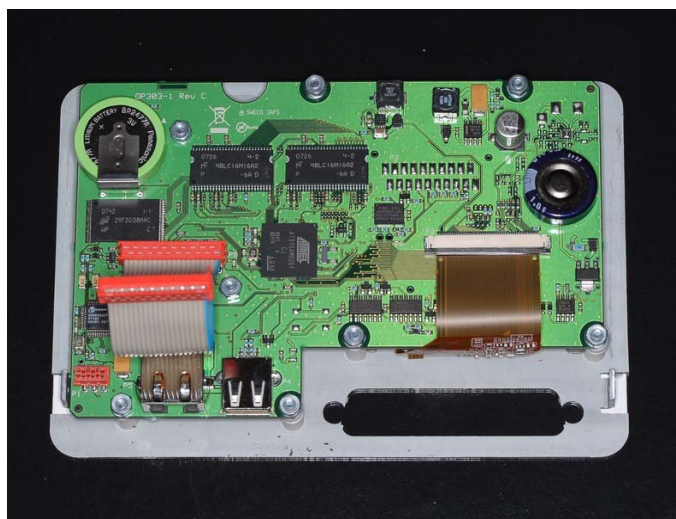
Storage The Heating Pad shall be stored hanging with the Pad Hanger or lying flat. Avoid folding.

5 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. 8 elements, 200W. X-Ray translucent. Standard Heating Pad. Fits most patients. Requires two standard Gel Pads.
OP3-150	150 cm Heating Pad	1500 x 450 mm. 8 elements, 200W. X-Ray translucent. Requires three standard Gel Pads.
OP3-063	63 cm Short Heating Pad	630 x 430 mm. 4 elements, 100W. 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	50 cm Small Heating Pad	500 x 300 mm. 4 elements, 100W. X-Ray translucent. Must always be used with the Gel Pad no GE-305020. 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	320 x 5550 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.
OP3-050	User manual *	English.
OP3-064	Service Manual	English.
OP3-099	Calibration Adapter	For checking the Control Unit calibration.
OP3-100	USB Memory stick	Used for log dumps and for software update.

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.



OP303-1, Display and computer board



OP303-2, Main board



OP303-3, Power board



Cabinet assembly



OP3-099 Calibration Adapter

6 Technical Information

General

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".

Detailed system description.

The Operatherm OP3 system is designed with multiple level of protection against any foreseeable errors that may cause potentially harmful conditions for the patient. The system is computer controlled, with a fail safe (twin state) watch-dog, monitoring the correct operation of the main process and will cause a safety relay to break the power to the pad if a computer error occurs. The computer constantly monitors the running state of all vital parts of the system, and will immediately report an error if any parameter runs outside its stated boundaries.

The calculated temperatures of the eight (or four) heating pad elements are based on individual simultaneous measurement of the voltage and the current to each of the elements by two independent A/D-converters. From these measurements the elements actual resistance is calculated, and compared to the nominal resistance value programmed into the pads PROM memory at calibration. The temperature coefficient of the element is also read from the PROM. Based on this input, the elements current temperature is calculated (average value of the elements area). Several comparative reference measurements are being performed in order to assure both A/D converters integrity. If any discrepancy occurs, the system will break the power to the pad, indicate the error and sound the alarm.

The measuring voltage fed to the pad is only 5V DC and one measuring slot is typically 10 ms long (8.3 ms at 60 Hz). A full measuring/heating cycle is 18 pulses long, and 2 of these are always 5V DC measuring pulses, leaving a maximum of 16 (of each 18) pulses available for heating.

The Pad element heating voltage is unregulated rectified 28V AC (typically), generating one hundred pulses per second (one hundred and twenty at 60Hz mains voltage). Eight individual temperature protected semi conductor switches, with built in error supervision, are being used to gate the required number of heating pulses to each of the eight elements. (This regulating method gives the ability to a linear individual control of the heating power to each of the elements from 0.1 to 23.0 W). Maximum power is however only permitted during 10 minutes from start. After this time-out, the system will limit the output to maximum 11 heating pulses in each 18 pulse cycle, (corresponding to max. 16 W/element).

The heating current is fed via a safety relay, and any errors in the system will cause the safety relay to break the current.

Apart from a constant on-line supervision of the systems vital safety functions, the system will automatically turn into a cyclic self test mode for a couple of seconds every 15 min. and perform an full off-line test of the safety circuits, among other thing turning the safety relay on and off, in order to verify its integrity.

The Pad is connected to the control unit using a high grade 37 pin D-sub connector (extra thick gold plating), with a female-female gender changer permanently mounted on the control unit. The major connector-wear will take part in the female side of the connector, giving the ability to periodically change the worn part. In the connector, the outermost 2+2 pins are exclusively used as a safety loop, controlling the safety relay, to guarantee good connection of any intermediate connectors used for the measuring circuits. Feeding voltage is fed on different pins than the measuring circuit, reducing the risk of measurement errors. The common Pad feeding current is fed over eight parallel pins for minimum connector load. All input/output connections are short-circuit proof.

The Pads connector contains a independent micro processor with the dedicated task of monitoring the pad feeding voltage at all time, and will break the safety loop if the heating current to any of the eight elements are more frequent than normally anticipated (>16 of 18 heating pulses) or if the unit is feeding more energy than 22,5 kW over a period of 30 minutes (corresponds to 13,9 W average power output during 30 minutes) to any of the elements. This function will safeguard against any major short circuit in the control unit, (causing uncontrolled power feed to any, or all, of the elements), or a temperature calculating error.

Both the control unit and the pad will automatically log events and running parameters into memory when they are operated, enabling post-analyses to be made of any suspected system malfunction.

7 TECHNICAL DATA

Control Unit		Art. no: OP3-022	
Voltage		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 $\pm 1^{\circ}\text{C}$		
Resolution		1°C (Display resolution 0.1°C)	
Over-temperature alarm level		41.0°C \pm 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 kg	
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		1,4 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

Classifications

The complete KanMed Operatherm OP3 system, International GMDN code: 37329, category 04.

The Control Unit assembly is classified as an Active Therapeutic Class IIb product (since it is designed to be actively heating the body of a patient), according to Rule No. 9 of LVFS:2001:6 Product classification 6§ and appendix 9. International GMDN code: 36955, category 04.

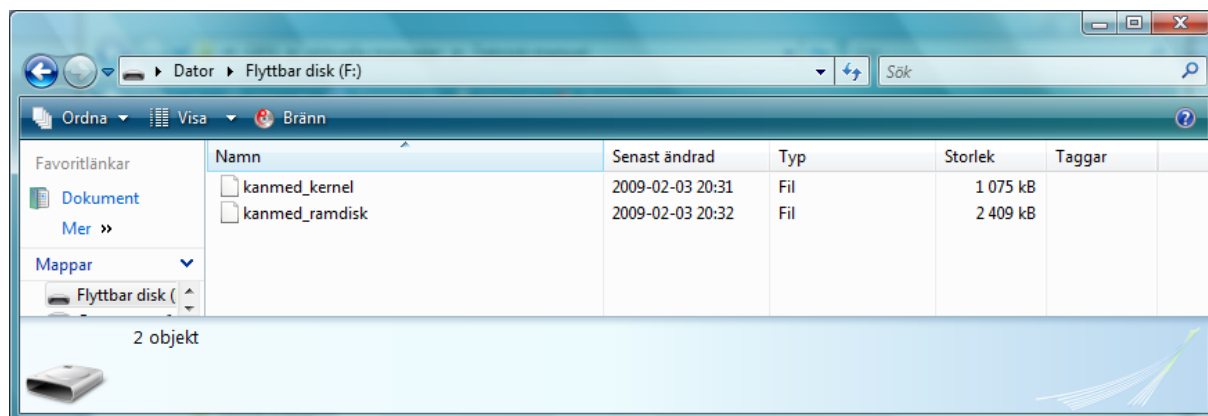
The heating pads are also considered to be Class IIb products according to Rule No. 9 of the same LVFS document. International GMDN code: 11989, category 04.

8 SERVICE SOFTWARE

The Operatherm OP3 can be loaded with different Software versions. The Customer version (with blue bottom bar) is the only version allowed to be used in normal operation. The system function with the Customer version of the software is described in the user manual. There is also a Service SW version available (green bottom bar and the letter S after the version number) with extended functionality. Below is a description of the technical menus and of the additional functions found in the service software. Certain procedures, e.g. calibration check and log dump to USB etc. can also be performed with the customer software version.

LOADING SOFTWARE TO THE CU.

NOTE 1: Before this operation is performed, make sure you have one Kanmed approved USB-memory stick containing the latest version of the Service Software AND one additional Kanmed approved USB-memory stick containing the latest version of the User Software (in order to re-load the user software after the service session has been performed). The USB-memory must have the two files "kanmed_kernel" and "kanmed_ramdisk" in the root level directory. Pls. note that the Service Software and the Customer Software version have exactly the same file names (it is therefore not possible to identify the software type only by the file name).



NOTE 2: When re-loading the user software back into the control unit, perform exactly the same procedure as described below.

1. Disconnect the mains power. Turn the control unit up-side down and remove the bottom plate (..mind the earth cable!). See disassembling instruction later in this document.



2. Fit the USB-memory stick containing the Service Software (..or the user software) into the internal USB connector.



3. Connect the mains power, and within 5 seconds, press and hold left AND right arrow buttons pressed simultaneously



4. When the message "Updating SW.." is displayed, the left-and right arrow buttons can be released.



The "Ok" message indicate that the new software has been successfully loaded.

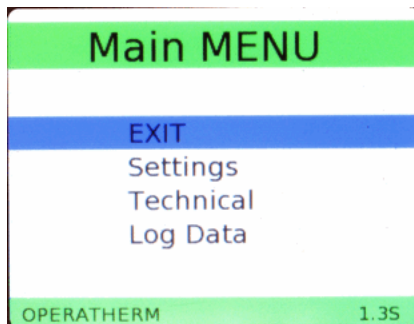


5. When the Stand-by screen is displayed, disconnect the mains power and remove the USB-memory stick from the Control unit. Reconnect the mains power and let the system boot as normal. The new software has now been loaded into the system.

The software type is identified by the version mark in the bottom right corner of the display.

MENU functions

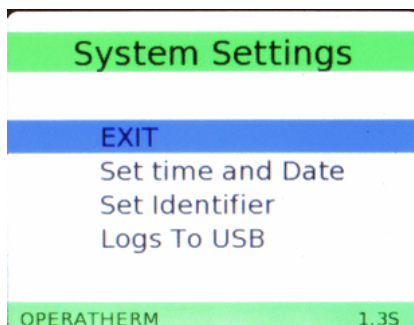
These system functions is accessed if the "Menu" (up arrow) button is pressed when the unit is in stand by mode. This menu or these functions are not available during normal operation of the system. They are exclusively designed for system set-up or technical function control.



Main Menu

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.

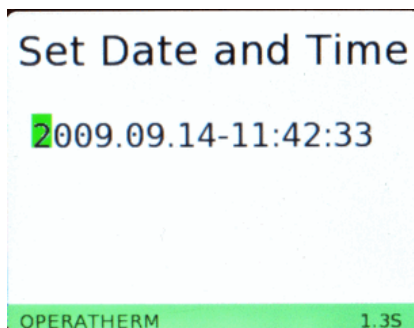
NOTE: "up arrow" (menu) exits the function and returns the system to stand-by mode.



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

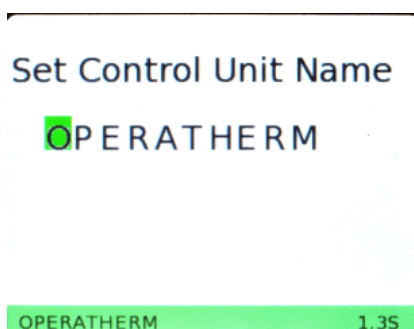
Date will be set on the format YYYY-MM-DD and time on the 24 hour format HH-MM-SS.

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. Also available in the Customer Software version.



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.

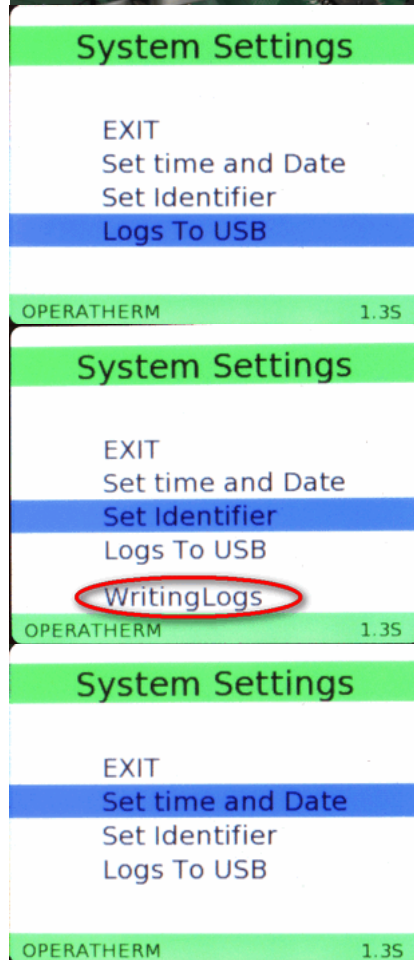
NOTE: "up arrow" (menu) exits the function and returns the system to the System Settings Menu without changing the set name. Also available in the Customer Software version.



Writing Logs to USB.

Note: This operation requires an empty Kanmed approved USB-memory stick (<2 GB, FAT32 formatted). It can also be performed with the Customer Software Version.

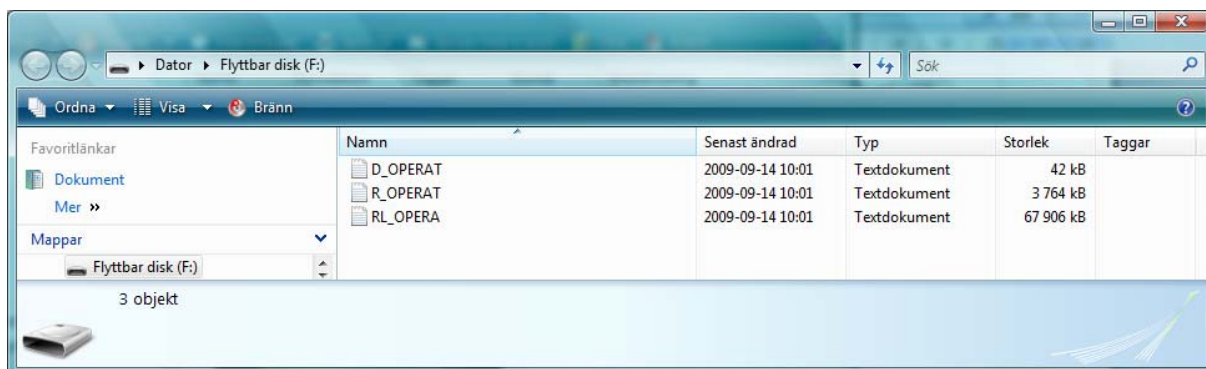
1. Fit the USB-memory stick into the internal USB connector.



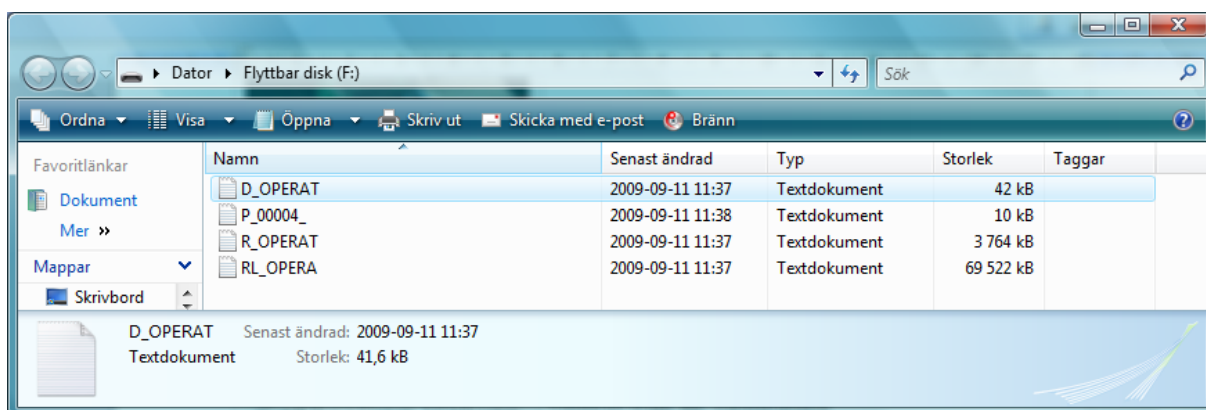
2. Select Menu/Settings/Logs to USB. Press "Enter"

3. The message "WritingLogs" are displayed as long as the writing process continues. Leave the system, it will normally take a few minutes.

4. When the writing process is completed, the "WritingLogs" message disappears. The USB stick can now be safely removed.



If no PAD is connected, three log files will be generated (above). Four if a PAD is connected (below).



The log files are in txt format and can be opened with a text editor, e.g. WordPad or similar. The log files are mainly intended for factory level post analyze of any "un-explainable" errors in the CU or the PAD.

Data example from the CU-session log file D-OPERAT:

```
Log: 0
Start time: Fri Jul 11 14:26:03 2008
End Time:   Fri Jul 11 14:26:16 2008
Time: 13
Total Time: 13          Sessions: 1
Pad: , Mode: 0
Energy: 0, Max Temp: 26.06, Min Temp: 24.78
Alarm: 55, Fri Jul 11 14:26:16 2008

Log: 1
Start time: Fri Jul 11 14:27:56 2008
End Time:   Fri Jul 11 14:28:52 2008
Time: 56
Total Time: 69          Sessions: 2
Pad: , Mode: 0
Energy: 2, Max Temp: 29.60, Min Temp: 26.94
Alarm: 60, Fri Jul 11 14:28:52 2008

Etc.
```

Data example from the PAD log file P-"PAD S/N":

```
Log: 0
time: Tue Sep  8 14:34:40 2009
```

Max Temp: 38.31, Temp: 37.22
 Log: 1
 time: Tue Sep 8 14:33:40 2009
 Max Temp: 34.66, Temp: 33.65
 Log: 2
 time: Tue Sep 8 14:32:39 2009
 Max Temp: 30.40, Temp: 29.68
 Log: 3
 time: Mon Nov 24 14:55:28 2008
 Max Temp: 41.85, Temp: 39.01
 Log: 4
 time: Mon Nov 24 14:54:28 2008
 Max Temp: 41.85, Temp: 38.96

Etc.

Data example from the CU log file R-OPERAT:

Log: 0
 Time: Tue Sep 8 14:35:21 2009
 Pad: 00004
 Desired Temp: 39, Temp: 39.39, Avg Temp: 32.65, Max Temp: 40.72

Log: 1
 Time: Tue Sep 8 14:35:11 2009
 Pad: 00004
 Desired Temp: 39, Temp: 38.86, Avg Temp: 32.35, Max Temp: 40.31

Log: 2
 Time: Tue Sep 8 14:35:01 2009
 Pad: 00004
 Desired Temp: 39, Temp: 38.32, Avg Temp: 32.04, Max Temp: 39.63

Log: 3
 Time: Tue Sep 8 14:34:51 2009
 Pad: 00004
 Desired Temp: 39, Temp: 37.74, Avg Temp: 31.72, Max Temp: 39.02

Etc.

Data example from the file RL-OPERA (Note: normally a very large file!)

Log: 0
 Time: Tue Sep 8 14:35:21 2009
 Pad: 00004
 Desired Temp: 39, Temp: 39.39, Avg Temp: 32.65, Max Temp: 40.72
 DebugLog:

Pad: 2	CurTemp: 40.3127	R: 31.67	Po: 96
Pad: 3	CurTemp: 37.7483	R: 31.46	Po: 96
Pad: 4	CurTemp: 39.7063	R: 31.80	Po: 96
Pad: 5	CurTemp: 38.2161	R: 31.53	Po: 96
Pad: 6	CurTemp: 40.2193	R: 31.76	Po: 96
Pad: 7	CurTemp: 38.1843	R: 31.63	Po: 96
Pad: 0	CurTemp: 40.0399	R: 31.59	Po: 96
Pad: 1	CurTemp: 37.5327	R: 31.22	Po: 96
Pad: 2	CurTemp: 40.4759	R: 31.69	Po: 96
Pad: 3	CurTemp: 37.9906	R: 31.49	Po: 96
Pad: 4	CurTemp: 40.3586	R: 31.87	Po: 96
Pad: 5	CurTemp: 38.3338	R: 31.55	Po: 96
Pad: 6	CurTemp: 40.2193	R: 31.76	Po: 96
Pad: 7	CurTemp: 38.3397	R: 31.64	Po: 96

Pad: 0 CurTemp: 40.1874 R: 31.61 Po: 96
 Pad: 1 CurTemp: 37.8276 R: 31.26 Po: 96
 Pad: 2 CurTemp: 40.5861 R: 31.70 Po: 96
 Pad: 3 CurTemp: 38.1380 R: 31.51 Po: 96
 Pad: 4 CurTemp: 40.3586 R: 31.87 Po: 96
 Pad: 5 CurTemp: 38.5347 R: 31.57 Po: 96
 Pad: 6 CurTemp: 40.4362 R: 31.79 Po: 96
 Pad: 7 CurTemp: 38.4923 R: 31.66 Po: 96
 Pad: 0 CurTemp: 40.2962 R: 31.62 Po: 96
 Pad: 1 CurTemp: 37.9403 R: 31.27 Po: 96
 Pad: 2 CurTemp: 40.7181 R: 31.72 Po: 96
 Pad: 3 CurTemp: 38.3190 R: 31.53 Po: 96

Etc.

Technical data

⇒ EXIT

Control Unit Summary
 Control Unit Cal. Data
 Heating Pad Summary
 Heating Pad Cal. Data
 System Measurements

OPERATHERM 1.3S

Technical Data menu

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.

Control Unit Summary

SW Version 1.3S
 Calibrated by: 080001
 Calibrated date: 2008-08-25
 Total running hrs: 2118
 No of sessions: 198

OPERATHERM 1.3S

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.

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

OPERATHERM 1.3S

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: The displayed values are proprietary system unique values. They can not be re-calculated to corresponding resistance or similar values. This function is also available in the Customer Software version.

Pad Data Summary

PAD Nr: 23750
 PAD type: OP3-104
 PAD SW: 1.2
 Calibrated by: PKS
 Calibrated date: 2008-10-05
 Total running hrs: 728
 No of sessions: 43

Heating Pad Data Summary

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

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

OPERATHERM 1.3S

NOTE: Also available in the Customer Software version.

PAD Calibrated Values

PAD Nr: 23750

No 8 31.784 39.50	No 6 31.670 39.35	No 4 31.614 39.00	No 2 31.408 39.10
No 7 31.700 39.70	No 5 31.772 39.50	No 3 31.556 39.35	No 1 31.540 39.60

OPERATHERM 1.3S

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: The top value corresponds to the resistance measured for each individual element, at the calibration temperature displayed as the bottom figure. This function is also available in the Customer Software version.

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 1.3S

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 heating pad.

Press the [<] or [>] buttons to change the channel to study. [v] (down arrow) changes to a screen where all 8 channels are shown simultaneously.

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

Measure All Elements

No 8 31.336 35.76	No 6 31.232 35.70	No 4 31.151 35.14	No 2 30.862 34.55
No 7 31.397 37.17	No 5 31.452 36.83	No 3 31.293 37.16	No 1 31.203 36.79

OPERATHERM 1.3S

NOTE: This is a function that is intended to analyze a Control unit's ability to measure correctly on each of the separate channels. If a Calibration Adapter is connected it shall measure the reference resistance to a value better than 0,03 Ohm. It can also be used to measure the Heating Pad resistance on each of the separate heating elements. This function is also available in the Customer Software version.

Calibration Values			
Ref Res:31.888			
No 8	No 6	No 4	No 2
0.0061	0.0047	0.0059	0.0036
31.894	0.0019	0.0037	31.892
31.894	31.893	31.894	31.892
No 7	No 5	No 3	No 1
0.0043	0.0054	0.0046	0.0041
31.892	0.0043	0.0043	31.892
31.892	31.893	31.893	31.892
OPERATHERM 1.3S			

Control Unit Calibration Check

Note: This operation requires the use of a Calibration Adapter (part No. OP3-099).

Connect the calibration adapter (part No: OP3-099) to the control unit and press on/off. The unit will automatically enter Calibration Check mode.

The unit will display the measured resistance for each of the 8 channels. Channel 3 – 6 will display two sets of figures. The reason for this is that channel 1 – 6 is measured with A/D - converter 1, and channel 3 – 8 with A/D-converter 2. Channel 3-6 will therefore show the readings from both converters.

Calibration Values			
Ref Res:31.888			
No 8	No 6	No 4	No 2
0.0201	0.0149	0.0120	0.0171
31.908	0.0004	0.0023	31.905
31.908	31.903	31.900	31.905
No 7	No 5	No 3	No 1
0.0168	0.0148	0.0168	0.0168
31.905	0.0037	0.0001	31.905
31.905	31.903	31.905	31.905
OPERATHERM 1.3S			

After the unit has returned steady and reliable values (after 2-5 min), the readings (the measured resistance for each channel) should correspond to the adapters reference resistance (displayed on top of the screen) within 0,03 ohm. If the error is larger than this, it will display a red marking over the reading, otherwise a green.

Press MENU to exit.

NOTE: If one or several of the readings exceeds 0.03 ohm, leave the unit running for at least 10-15 minutes and check again. If one (or several) of the reading is still just outside limits, pls. restart the control unit and perform the test once more. If the error is consistent, the control unit might need a re-calibration. This function is also available in the Customer Software version.

Log Data Menu	
EXIT	
Control Unit Log	
PAD Log	
OPERATHERM 1.3S	

Log Data Menu

Select Main MENU/Log Data

NOTE: This function is also available in the Customer Software version.

CU Unit Log: 201	
Start: 2009-09-08 14:31	
End: 2009-09-08 14:35	
Time: 3m 48s	
Mode: With Gel Energy: 9 Wh	
OPERATHERM 1.3S	

Control Unit Log

Select "Control Unit Log" and press "Enter" to display the CU logs. Press [<] or [>] to step through the different logs. Press "MENU" to exit.

NOTE: This function is also available in the Customer Software version.

PAD Nr: 00004

No	Date	Time	T max	T avg
13	08-11-24	14:29:20	31.95	30.43
14	08-09-03	08:16:37	39.81	38.96
15	08-09-03	08:15:36	39.81	38.95
16	08-09-03	08:14:36	39.81	38.91
17	08-09-03	08:13:36	39.81	38.88
18	08-09-03	08:12:36	39.81	38.97
19	08-09-03	08:11:36	39.81	38.99
20	08-09-03	08:10:36	39.81	38.96
21	08-09-03	08:09:36	39.81	38.90
22	08-09-03	08:08:36	39.81	38.94
23	08-09-03	08:07:36	39.81	38.94
24	08-09-03	08:06:36	39.81	38.89

OPERATHERM 1.35

PAD Log

Select "PAD Log" and press "Enter" to display the logs of the connected PAD. Press [<] or [>] to step through the different log pages. Press "MENU" to exit.

NOTE: The CU must first have been started in normal operation (performed a self test) with the PAD connected in order to read these logs! This function is also available in the Customer Software version.

Special operation, workshop level only!

Calibration Values			
Ref Res: 31.888		U	
No 8	No 6	No 4	No 2
33.763	33.544 33.767	33.532 33.764	33.763
No 7	No 5	No 3	No 1
33.552	33.753 33.548	33.748 33.547	33.545

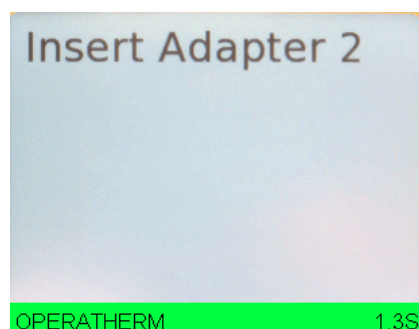
OPERATHERM 1.3S

Control Unit RE-Calibration

Note: This operation requires **two** Calibration Adapters (part No. OP3-099), **and the special service SW-version 1.3S** (or newer).

Connect a calibration adapter (part No: OP3-099) to the control unit and press on/off. The unit will automatically enter Calibration Check mode.

After the unit has returned steady and reliable values (after 2-5 min), indicated by the red or green markings of each of the readings, the unit can be unlocked by pressing the key sequence "left arrow", "down arrow", "right arrow" and "up arrow".



The system will display a "U" after the reference resistance indicating that a calibration update process has been initiated. Let the system measure for approximately 10 - 15 minutes and the system will then automatically prompt for the second calibration adapter to be inserted (**note:** two separate adapters are mandatory for a control unit re-calibration).

Calibration Values			
Ref Res: 31.888			
No 8	No 6	No 4	No 2
0.0017	0.0014	0.0022	0.0019
31.890	31.887	31.886	31.886
No 7	No 5	No 3	No 1
0.0007	0.0023	0.0011	0.0007
31.889	31.886	31.887	31.889

OPERATHERM 1.3S

Approximately 5 minutes after the second adapter has been fitted the verification process is finished, and the system returns steady values (indicated by the red or green markings of each of the readings), the readings (the calculated resistance for each channel) should correspond to the adapters reference resistance within 0,025 ohm.

"Enter" writes the new calibration values to the CU, MENU exits without changing the values.

WARNING: This procedure may only be performed by Kanmed factory or by a Kanmed certified workshop! CU re-calibration should NEVER be performed in field. Furthermore, the cu unit must be in thermal balance before the procedure is performed, i.e. it should be in operating temperature. The calibration adapters must also be room tempered (approx 21 deg C). Failing in this procedure will/might jeopardize the operation of the system and can in worst case result in the overheating of a patient.

8 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:



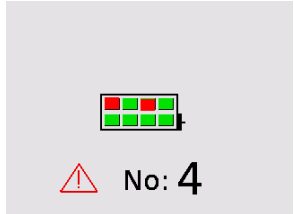
1. If this circuit detects an unregulated voltage being fed to any of the elements (e.g. a major error in the Control Unit causing short circuit output).
2. If the Control Unit is feeding more energy than 25000 Ws over a period of 30 minutes to any of the elements, e.g. error in the temperature regulation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









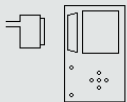











Medium severity alarms

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
  No: 21	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.	 13,7°C  No: 22	Low initial Pad temperature. The Control Unit has calculated the Heating Pad temperature to a value lower than 15°C.
Action: Reset the alarm. If the alarm re-occurs, the Heating Pad should be analyzed and/or replaced		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.	
 39,8°C  No: 24	Hot-spot warning. One or several of the Pad elements has had a calculated temperature higher than the set value, during 10 minutes.	 37.0°C  No: 26	Slow cooling. The average temperature of the Pad has had a calculated temperature higher than the set value, during 5 minutes.
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.		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.	
  No: 27	The Control Unit's log-file is very large (time for service of the unit).	  No: 28	Abnormal temperature variation detected. A change in the Pad temperature faster than 5°C in 3 sec has been detected.
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.		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.	

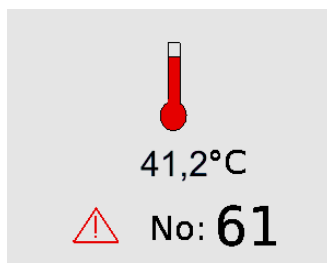
High severity alarms

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	Error in the measuring circuitry, no acceptable data received during 20 sec. Probably caused by defective components.	  No: 52	Internal communication error. Probably caused by defective components, faulty memory circuits or software error.
Action: The Control Unit should be analyzed by an authorised technician.		Action: The Control Unit should be analyzed by an authorised technician.	
  No: 53	The Control Unit has corrupted software. Probably caused by defective components, faulty memory circuits or software error.	  No: 54	The Heating Pad has corrupted software. Probably caused by defective components, faulty memory circuits or software error
Action: The Control Unit should be analyzed by an authorised technician.		Action: The Heating Pad should be analyzed by an authorised technician.	
  No: 55	The Heating Pad connector is not properly fitted, or damaged.	  No: 56	The Heating Pad is not correctly calibrated.
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.		Action: The Heating Pad should be returned to KANMED for analysis.	
  No: 57	The Heating Pad is not correctly validated after calibration.	  No: 58	The Pad has too many defective elements to be used (three of eight, or two of four) to be used.
Action: The Heating Pad should be returned to KANMED for analysis.		Action: The Heating Pad must be replaced.	
 41,4°C  No: 59	Average temperature has exceeded 41°C for more than 30 sec.	  No: 60	The safety circuit has been activated.

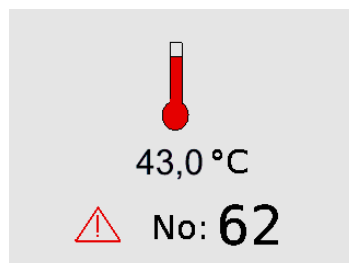
Action: Reset the alarm and restart the unit. Observe the temperature behaviour on the display. If there is no apparent unusual operating condition, or the alarm re-occurs, the Heating Pad or the Control Unit should be analyzed and/or replaced.

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 (the most likely source of error) or the Control Unit should be further 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.



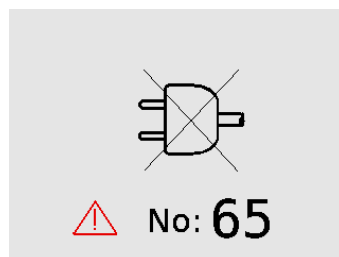
Serious hot-spot warning 2. One or several of the Heating Pad elements has reached a calculated temperature higher than 43°C.

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.

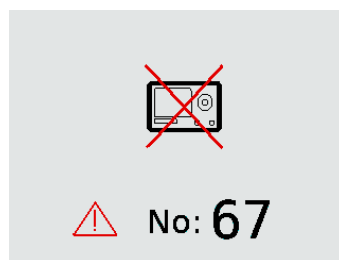
Action: The power alarm can be silenced by the operator by pressing the on/off button for about 2 seconds. Restart the unit after the power has been restored.

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.

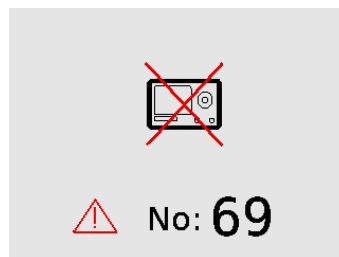


Error when Control Unit is writing to the internal log file.

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



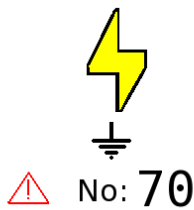
No memory space left when Control Unit is writing to its internal log file.



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

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

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.

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

9 ANNUAL CHECK OF THE SYSTEM

Note: This procedure can be made with the Customer Software Version

Maintenance to be carried out by technical staff

- Exchange the 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.

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 and inserting it in a bucket with room temperature water. Run the system at 39°C for approximately 10 minutes. (pls 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 gently 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.

10 REPAIR INSTRUCTIONS OP3 Control Unit and PAD

Repairs of the OP3 control unit are limited to replacement of circuit boards and sub-units. Only Kanmed factory may perform repairs of the boards itself.

Pre requirements:

- Disconnect the cable from the power inlet and from the control unit.
- Position the control unit up side down.
- Make sure that you have proper **ESD-protection** as you are handling ESD sensitive circuit boards. Always work in an anti-static environment. Use an ESD-protection bracelet attached to the earth pin on the back of the control unit.

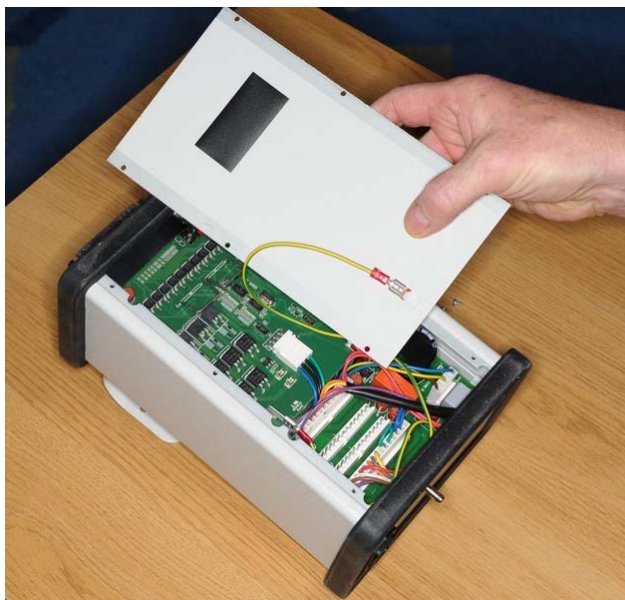
Tools required:



- Torx key, Size T10 (pref. magnetic ^{note})
- Screwdriver, slotted type 6 mm
- Box-cutter knife, and/or a Pair of scissors
- ESD-protection bracelet

note: If no magnetic torx key is available, a standard torx key can be used with a small magnet (e.g. neodymium type) attached to the shaft.

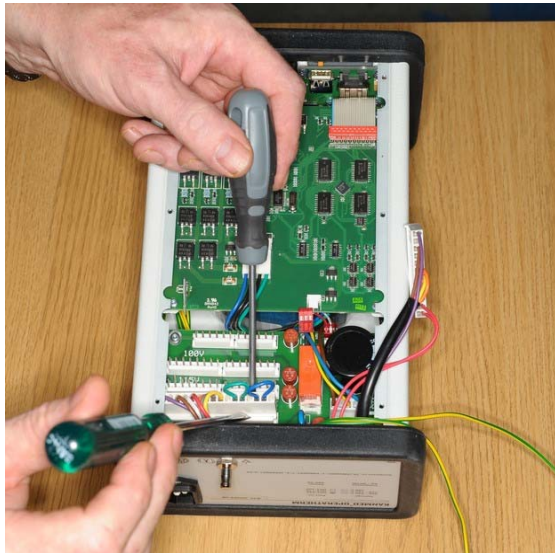
CU Disassembling instructions:



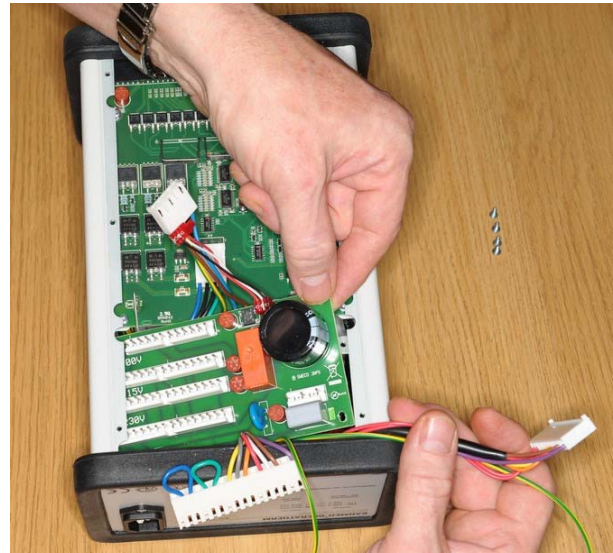
Remove all screws (6 pcs) from the bottom plate of the control unit. Remove the bottom plate and disconnect the earth cable.

NOTE: Isolate the cable connector with some tape so it does not cause any damage to the unit when hanging loose.

With the bottom plate removed, the power board can be removed without removing any of the other boards. In this case, **carefully** disconnect the cables (4 pcs) from the power board and the earth pin for easier removal of the circuit board. Do not pull directly on the cables! Use a screw driver to carefully pry the connector locking device open. Then pull the connectors straight up. Remove the 4 screws that hold the circuit board in place.

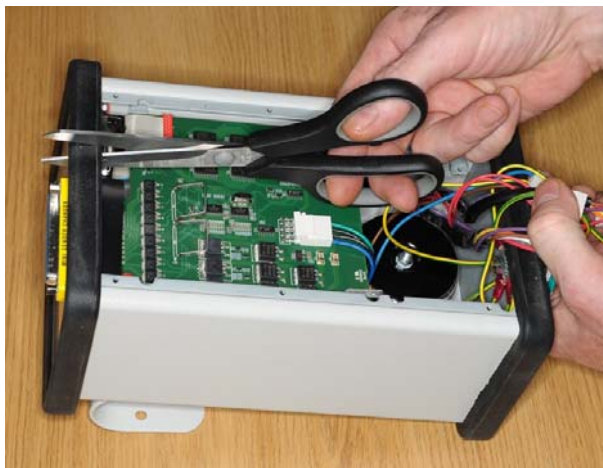


Carefully pry the connector locking device open



Slide the PC board to the side and carefully remove it.

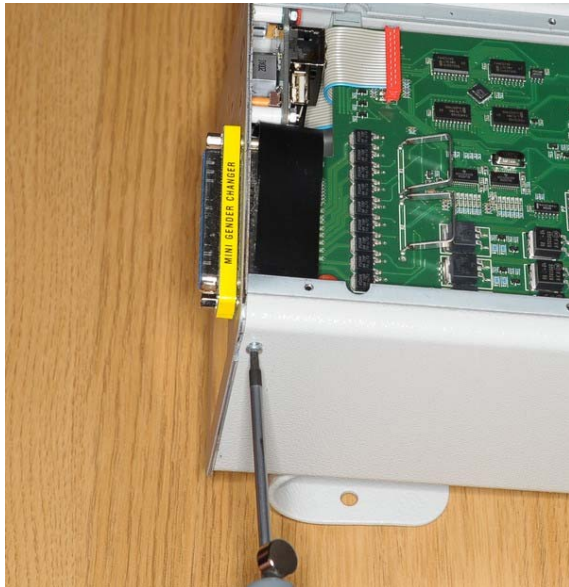
If the Display assembly or the main board needs to be removed, pls proceed as follows.



1. Cut the front rubber open



2. Peel it off.



3. Remove the 4 screws that holds the display assembly



4. Remove the connector saver



5. Carefully loosen the display assembly from the cabinet



6. Remove the flat cable and the earth cable.



7. Loosen the 4 main board screws



8. Remove the main board.

CU Assembling instructions:

Assemble the unit in reverse order as described above. Fit the main board in position but do not tighten the four screws until the display assembly is in place. Take particular caution when fitting the display assembly in order not to damage the components mounted on the flat cable.



1. Slide the display assembly carefully in under the plastic protective sleeve.



2. Mount the display assembly. Fit the connector saver, adjust then the position and tighten the four main board screws.



3. Mount the rubber frame. Be observant to position the cavities over the screw heads. Adjust the frame for a nice close fit. Carefully apply a small amount of *Wacker Elastasil A07* under the frame - close to the corners. Remove any excessive silicone.

PAD Disassembling instructions:

NOTE: No repairs are possible on the PAD connector circuit board. It is not possible to replace the board either since it is factory calibrated with the pad and the connecting cable. Only the casing can be replaced if damaged.



Remove all screws (4 pcs) from the bottom plate of the Connector assembly. Remove the bottom part. Replace the PAD Connector Casing if required and refit the screws. Pls observe to use proper ESD protection!

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			
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.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the 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> <p>$d = 1,17 \sqrt{P}$</p> <p>$d = 1,17 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,33 \sqrt{P}$ 800 MHz to 2,5 GHz</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></div>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	
<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>			