

CB48

HEATING BLANKETS FOR OPERATING AND RECOVERY ROOM





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Read carefully before use



INTRODUCTION

CB48 blankets are the new generation of Electro Concept heating blankets. They provide a safe and effective patient warming both during and after surgery.

To avoid any interference with monitor, the control unit transforms the 240 volts from the mains into 48 volts direct current.

Each blanket is fitted with 8 independent temperature sensors for a precise use and a maximum safety.

The CB48 blankets are connected to the BCB48 control unit. Of course, any blanket can be connected on any control unit.

BCB48 control unit is fitted with last generation of digital electronic. It offers a temperature setting between 30 and 40 °C, and also numerous active and passive safety devices.

ECM designs and manufactures medical devices (100% made in France): active patient warming systems in neonatal and maternity environments, neonatology and maternity wards, as well as in operating rooms and recovery rooms (SSPI).



IMPORTANT RECOMMANDATIONS

- Lay down **FLAT** the blanket **ABOVE** the patient, on upper sheet or surgical drape.
- Do not use the blanket folded or rucked.
- No matter the side as temperature sensors are spread on each side of the blanket.
- Do not cover the head of the patient.
- Do not put any object on the blanket.
- Periodically check the position of the blanket, and cutaneous aspect of patient



IMPORTANT RECOMMENDATIONS

**BEFORE ANY USE OF THIS DEVICE,
YOU MUST READ AND UNDERSTAND THIS USER'S GUIDE
AND THEREFORE EXACTLY APPLY WHAT IS WRITTEN.**

USE

- Do not place close to a window or any heat source (Heater, Infrared lamp,...).
- Do not use in an explosive area.
- Only use this device as what is described in this manual.
- Wait 12 hours if the device has been stocked at a temperature below 15°C.

CLEANING

Follow instructions given in the relevant topic of this manual.

MAINTENANCE

- As a class IIb medical device, this device must be checked once a year as described in the maintenance book.
- The annual control can only be conducted by technician entitled by Spengler (who has attended a special training).
- Fulfill any requirement regarding periodicity and/or spares to replace.
- A preventative maintenance contract can be contracted with Spengler or a mandated distributor.
- Only use spares pieces from original ECM brand.

RESPONSABILITY

The responsibility of the use of this device is incumbent on the owner or the user if the maintenance or the use are not conducted as described in this manual.

USERS

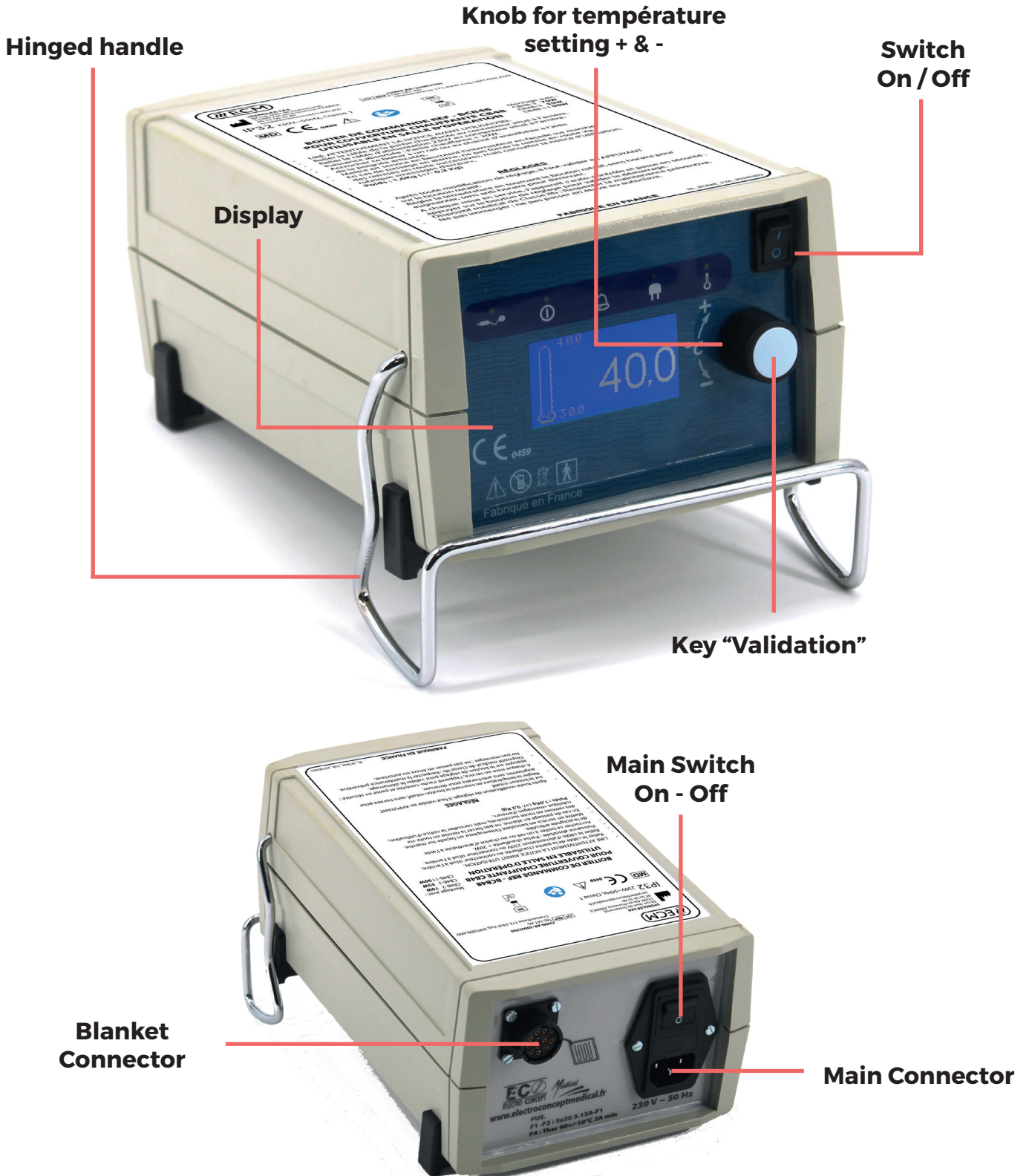
CB48 can only be used by trained staff and under the responsibility of medical staff informed about known risks and advantages of medical patient warming devices.



Do not use mobile phone (GSM) too close of the device !



This chapter gives you a quick overview and introduction to heating blankets.



**Non available
feature**

Light "Alarm"

**Light
"Heating"**

**Light
"Operating"**

**Light
"No power"**



**Requested
Temperature**



The CB48 blanket is designed to warm patients, especially during surgery. *Beware of use in combination with another heat source (e.g. heated mattress).*

User

Heating blankets must only be used by qualified and trained personnel. This appliance may not be used by persons who are not thoroughly familiar with the operating instructions. The user is responsible to all persons in the area where the device is in use.

Application area

The CB48 can be used in:

- Operating room
- Recovery room
- Intensive cares
- Maternity
- Emergency (Not in vehicles)



**Do not use in potentially explosive areas.
Remove the cover when using a defibrillator
or when using radiological equipment.**

Use

Use of this device is strictly limited to patient warming.

Maintenance

The unit must be checked annually to ensure that it is working properly, and all maintenance work must be carried out by specialists trained and authorized by Spengler.

A maintenance contract is strongly recommended, in order to guarantee long-term performance at the lowest possible cost.

Only original Spengler/ECM parts may be used.

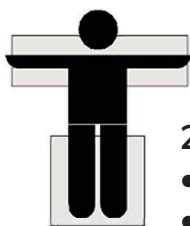
The manufacturer cannot be held liable for any incident or accident caused by faulty installation or maintenance.

If this device is not maintained or repaired by Spengler, or if it is not used in accordance with its intended purpose, its operation is the sole responsibility of the owner or operator.



CHOICE AND USE OF BLANKETS

Visceral surgery



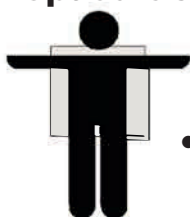
- 2 possible covers :
- 1 CB48-3 on chest and arms
 - 1 CB48-2 on legs

Vascular surgery



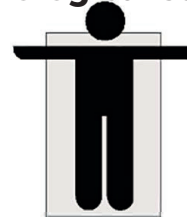
- 1 CB48-3 on chest and arms

Orthopaedic surgery



- 1 CB48-2 on chest

Neurological surgery



- 1 CB48-11 all over the body

Spine surgery



- 1 CB48-2 around the legs

Lay the blanket :

- FLAT, (Do not operate with the blanket folded over the patient)
- directly ON THE TOP DRAP,
- ABOVE the patient.
- DO NOT COVER THE HEAD of the patient.

The blanket must fit the patient as closely as possible.

Do not place the cover in direct contact with the patient's skin!

Check that the blanket is correctly positioned.

Do not cover respiratory assistance tubes.

IMPORTANT : In any case we advise to pre-warm patient before surgery with a whole body CB48-11 blanket. This pre-heating will avoid the loss of 1°C after the induction of the anaesthesia drug. Therefore, maintaining the core temperature of the patient will be much more easier.



FOR A MAXIMUM EFFECTIVENESS, the blanket must “mould” the patient shape : for example, the blanket when on the legs, must be in contact both with outside and inside the legs.



WARNINGS AND CAUTIONS

WARNINGS:

- During cold start-up and until a temperature of 30°C is reached, a message indicates that it is too early to place a patient under the blanket. Wait for this message to disappear before placing the patient (risk of hypothermia).
- Do not use on a patient with severe circulatory deficiencies, or if an artery has been clamped (risk of burns).
- Do not use on patients treated with medicated patches (trans-dermal devices as Fentanyl Zentiva).

CAUTIONS:

- Never operate with the cover folded.
- Regularly check the blanket's if the patient moves.
- Never place heavy objects or objects that could damage the cover on the blanket, especially during operation.
- Do not insulate the blanket.
- Ensure visual monitoring of the skin under the blanket in the event of heating of one or more insensitive limbs (hemi-paraplegia). Ensure visual monitoring of sensitive skin areas (grafts).
- Regularly check the patient's temperature and ensure that the unit is working properly (indicators and display functional).

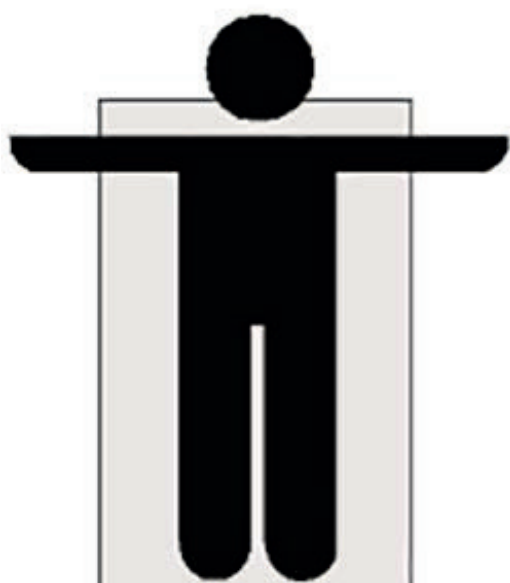




CHECK THE COVER BEFORE GETTING STARTED.



CB48-3 and CB48-2



CB48-11

Note: the heating zone of each product is delimited by the high-frequency welds.



INSTALLATION: The cover must always be placed over the patient. over the patient, **NEVER USE UNDER THE PATIENT**



GETTING STARTED

- Before any use, please check the cover of the blanket, the cables and the control unit. Should be something abnormal, do not use the device and contact after sales service.
- Blanket: Place the blanket flat on the top sheet or surgical drape ABOVE the patient.
- Check that the connector base (the part attached to the housing) does not turn on itself.
- Connect the connecting cable to the housing: find the polarizer by turning the connector cover at the edge of the housing connector base; when this key is reached, the connector cover presses into the base. Simply lock (without forcing) this connector by turning the ring clockwise.
- Check that the connecting cable cannot become trapped in the structure of the operating table or bed.
- Hang the BCB48 on a support (rail) or cart. DO NOT COVER THE BOX (risk of overheating).
- Connect the power cord of the BCB48 control box to a 2-pole + earth socket (3 x 1² - max. length 3m).

hou-



WARNING : To avoid the risk of electric shock, this appliance must be connected only to a mains supply fitted with a protective earth conductor. The mains plug must not be connected to an inverter (risk of interference from E.C.G. monitors).

- Toggle the switch on the rear of the back of BCB48.
- Toggle switch on the front of the box.

The control unit's electronics then automatically switch to safety mode: all lights are on and the audible alarm sounds.



Then a message on the screen shows. The message indicates the name of the device and reference of used software. If no failure is detected by the electronic circuit, after two seconds, the device goes in normal mode; the heating blankets is on (with the last valid setting of temperature).



→ PRESS THE «Turn and Push» BUTTON. If no problem is detected, the unit switches to normal mode; the heating blanket operates (using the previous temperature setting).



Set by turning the button in the direction “+” and “-” the temperature chosen by the doctor between 30 and 40°C.



→ Press on button “Valid” (if not the setting will go automatically to the previous one in few seconds).

- When the desired temperature is reached, yellow lamp will flash. As long as a temperature of 30 °C is not reached, a message “Cold” will show on the screen.
- Control regularly (every 20 minutes) the patient temperature, If needed, adjust the temperature of the blanket.



WARNING! In the event of interruption of blood circulation, due to «clamping», stop the blanket.



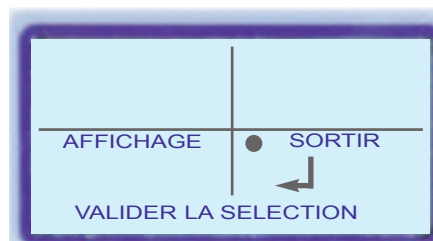
GETTING STARTED

ACCESS TO SETTINGS MENU (FOR MAINTENANCE OPERATIONS)



In MENU mode, heating of the BCB48 is disabled!

- Press the rotary knob for 2 seconds: a menu appears on the screen.
The various choices are :
- Display (displays all probe values)
 - Exit



Select the desired parameter with the knob by turning in + or - direction, so that the black dot appears in front of the parameter concerned.

- Press the Enter button. The chosen menu appears on its own, in a larger font size.
- Turn in + or - direction to set parameter value.
- Press the enter button to confirm.
- Turn in the + or - direction to select the exit line.
- Press the Enter button.
- The display returns to normal mode, with the new parameters active.

The next time you start the BCB48, your settings will be retained.

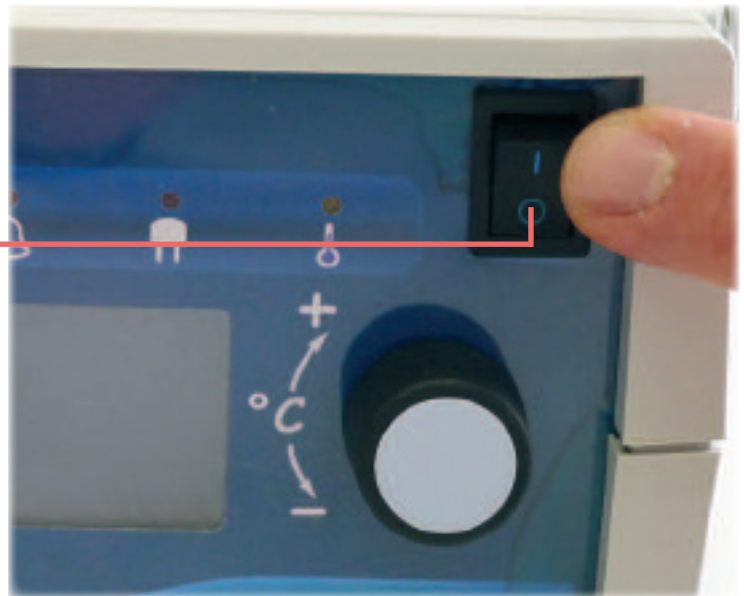


If the settings are not validated, the BCB48 exits the «settings» menu after approx. 40 seconds, without saving the unvalidated parameters.



Do not disconnect the power cable until the cover has been switched off: the mains failure alarm will be activated until the capacitor is completely discharged.

To switch off the unit, turn the small switch on the front panel to off (0).



The device is switched off. To disconnect the device from the mains, turn the switch on the rear panel to off (0).



Disconnect the cable from the wall socket if you are not going to use it for a long time.



CLEANING / DISINFECTION

Disassembly / Reassembly :

- For cleaning, the cover is waterproof and easy to clean.
- Reassembly is as described in «Installation» on page 9.

Frequency

To disinfect and clean:

- **WEEKLY**
- **EVERY NEW PATIENT**

- Surface cleaning with neutral detergent
 - Cover
 - Housing
 - Connecting cable
- Remove dirt with a soft cloth soaked in a neutral, non-aggressive cleaning neutral, non-aggressive cleaning product (e.g. soapy water)
- Disinfect the surface of all components with a CE-marked (quaternary ammonium).

- **Do not put in autoclave nor washing machine.**

- **Do not immerse.**

- **Clean the blanket with a soapy sponge and water.**

- **Disinfect the blanket with a CE marked surface disinfectant. Check the user's guide of the disinfectant solution to ensure it is P.V.C. compliant.**

- **Wait until the blanket is totally dry before use.**

- **When not in use the blanket can be stored folded in four parts.**

- **Never put any object on the blanket when in use.**



EVERY DAY

- Before any use, please check the cover of the blanket, the cables and the control unit. Should be something abnormal, do not use the device and contact after sales service.
- During each new start, the control unit runs into auto-test: all lights are on and sound alarm works + message with name of device (BCB48) and software version (eg 1.02). If different, please do not use the device, and contact after sales service

ONCE A YEAR

Check both blanket and control unit as described in the relevant “annual preventative maintenance book for CB48 type blankets” .

VERY IMPORTANT: The preventative maintenance can only be carried out by technicians who have had a special training given by Spengler.

EVERY 5 YEARS

The heating part (blanket) must be replaced by a new one, in order to avoid any risk of electric arc due to a worn out cable.

NOTA: The two first figures of the serial number indicate the year of manufacturing of the device.

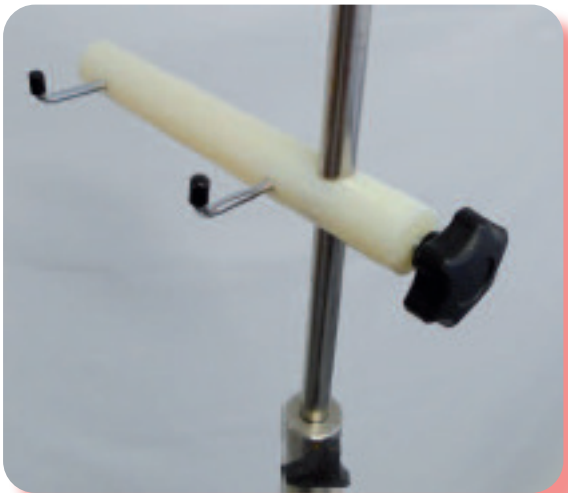
EVERY 15 YEARS

The CONTROL UNIT must be replaced by a new one, as components have reached their end of life.



STORAGE

- When not in use, the cover can be folded in 2 or 4 and placed on a flat shelf, or hung up if it has handles or eyelets.
- Never place objects on the cover that could damage the P.V.C. cover.
- The assembly can also be placed on a cover support and housing for a serum stand.



Conditions of use

Recommended ambient temperature	21°C to 26°C
Temperature range	10°C / 40°C
Atmospheric pressure	700 hPa to 1060 hPa
Humidity (non-condensing)	30% to 90%

**Do not use in
an oxygen-rich
environment**

Conditions of storage

Temperature range	-20°C to 50°C
Atmospheric pressure	900 hPa to 1060 hPa
Humidity (non-condensing)	30% to 90%

ELIMINATION

ECM brand heating blankets are medical devices subject to the WEEE directive and their disposal must therefore follow the requirements of this regulation; their end-of-life disposal must be carried out either by a specialist company or by contacting our Technical Support Centre :

- on +33(0)5 55 56 32 40
- or by emailing to sav@electroconceptmedical.fr.

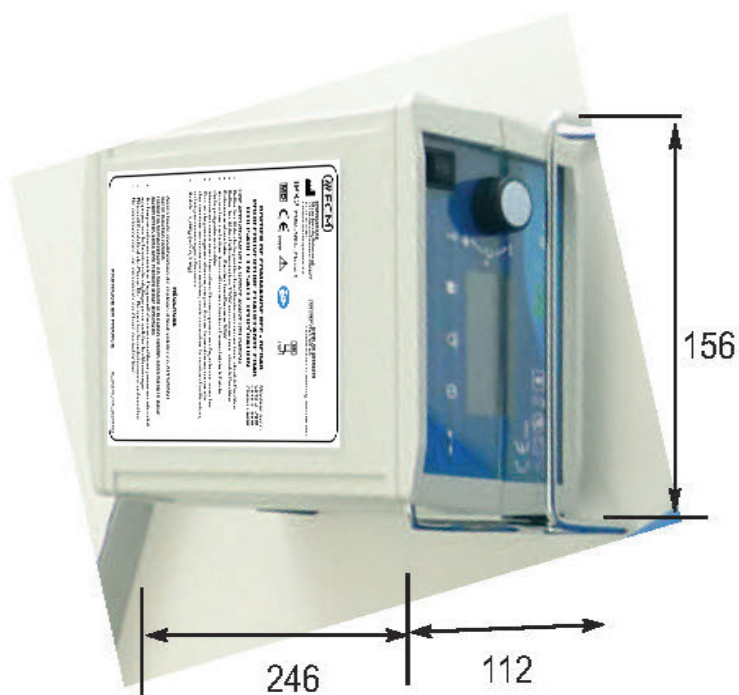


TECHNICAL DATA

TABLE 1

	HEATING BLANKET REFERENCE CB48 :		
	Model CB48-2 Pediatric half-body	Model CB48-3 Adult-Upper body	Model CB48-11 Adult - Full body
DIMENSIONS	80 x 100 cm	50 X 150 cm	100 x 150 cm
WEIGHT (excluding case) +/-0.2 Kg	1,9 Kg	1.7 Kg	2.7 Kg
RATED POWER	70W	55 W	90 W
INPUT VOLTAGE	230 V-50 Hz		
HEATING VOLTAGE	48Vcc		
CLASSIFICATION	Classe 2		
PROTECTION	BF		
WATERPROOFING	IP 35		
COVER	PU		
INSIDE FABRIC	83% acrylic / 17% cotton		
FABRIC HANDLE	0	0	4
CONTROL UNIT BOX	BCB48		
TEMPERATURE SETTING	30 to 40°C		
SKIN PROBE	no		

Control Unit Box
(dimensions in mm)



NOTA : Heating blankets are powered by 48 volts direct current. The medical device's class is IIb.



General specifications

- Housing weight: 1.6 kg (+/- 0.2Kg)
- Heater weight :(See table 1)
- Storage/transport temperature: -20 / 50 °C
- Operating temperature : 10 / 40 °C
- Atmospheric pressure: 900 hPa to 1060 hPa
- Humidity : 30% to 90% non-condensing

Electrical specifications

Operating voltage	230 Vac - 50 Hz
Mains filter	Special medical
Heating voltage	48 Vcc
Card voltage	5 Vcc
Power consumption	Cover (see Table 1) + 20 W
No-load current	0.087 A (RMS)
Electrical classification	CLASSE I (Housing)
Leakage current	<10 µA (EN 60601-1 imposes <500µA)
Fuse	2 x 3.15A FI (dim. 5x20)
Thermal fuse	90°C +/- 10°C 2.A min

**Contact
technical service
if a thermal fuse
has tripped!**

Performance

- Warm-up time: 20 minutes for a rise of 11°C from
 - from 23°C to 37°C in approx. 15 minutes (all sizes except -CM)
 - from 23°C to 37°C in approx. 7 minutes for CB48-1CM
- Core temperature more than 1°C higher (compared to an uneated patient) after patient) after surgery lasting more than 3 hours
- Total loss of performance when :
 - Ambient temperature is greater than 39°C (if ambient temperature is 30°C or above, using the blanket with a temperature setting 1°C below the ambient temperature may trigger an alarm)
 - Mains (230V 50Hz) not present (alarm for 15 minutes)



Control specifications and temperature display

Heating element temperature control	
Measurement principle	CTN
Number of probes	8
Measurement range	20°C à 41°C
Measurement accuracy	+/- 1°C
Setting range	30°C à 40°C / pas de 0.5°C

Classifications

Standards	The device complies with IEC / EN60601-1 IEC / EN60601-2-35 standards
Protection class	I
Electromagnetic compatibility	Tested in accordance with IEC / EN60601-1-2 IEC / EN60601-2-35 (36.202.2.1) 3V/m
Type	BF
Degree of protection	Housing - IP32 Applied part - IP35
CE marking	CE 0459, notified body : G-MED, Classification: IIb



Symboles utilisés



Class BF device



DEEE



Do not use GSM phone



Electrical class 2 device



Warning



CE device (LNE-GMED)



Skin probe



Power on



Alarm



Power alarm



Heating



Read the user guide



Do not use after this date



Manufacturer



Medical device



Swiss representative



Sealing index



Manufacturing Date



Serial number



TROUBLE SHOOTING

- If any incident occurs, the blankets switches automatically into safe mode: sound alarm continuous and red lamp on. The blanket is no more powered.
- Those incidents can result from a loose connection between cable and control unit. In this case, secure the connection, switch off then ON. The device will operate properly.
- If the alarm is still on after this new start, do not use anymore and contact after sales service.
- **IMPORTANT** : The control unit will alarm if the 230 V from the mains is not present. Always switch OFF the control unit before removing the cable from the mains socket (risk of discharge of the internal battery).
NOTA: The internal capacitor cell do not power the blanket, but only the alarm system.



NOTA : Don't forget to press the validation key after the boot sequence and each time you modify a setting.

For further information
or after-sales service, please contact
Tel: (33) 05 55 56 32 40
sav@electroconceptmedical.fr



The BCB48 control unit features a digital electronic which permanently controls the safety devices both internal and those from the blanket.
If a problem is detected, a message will show on the screen.

		ACTION
0	0.x HEATING ELEMENT 0.1 → Blanket heats but no heating request 0.2 → heating request but blanket does not heat	Go back to customer technical support centre Go back to customer technical support centre
2	2.x TEMPERATURE SENSOR TOO COLD 2.0 → Sensor N°0 2.1 → Sensor N°1 2.2 → Sensor N°2 2.3 → Sensor N°3 2.4 → Sensor N°4 2.5 → Sensor N°5 2.6 → Sensor N°6 2.7 → Sensor N°7	Check nothing has been put on the blanket, or check the blanket is properly layed over the patient (no fold)
3	3.x MISCELANEOUS TEMPERATURE SENSOR 3.0 → Over heating on sensor N°0 3.1 → All temperature sensors too hot 3.2 → Temperature sensors disconnected 3.3 → Error : Mass 1 3.4 → Error : Mass 2	Check nothing has been put on the blanket Go back to customer technical support centre Go back to customer technical support centre
4	4.x SETTINGS 4.0 → Potentiometre failure 4.1 → Wrong offset offset temperature	Return to after sales service Return to after sales service
5	5.x TEMPERATURE SENSOR TOO HOT 5.0 → Sensor N°0 5.1 → Sensor N°1 5.2 → Sensor N°2 5.3 → Sensor N°3 5.4 → Sensor N°4 5.5 → Sensor N°5 5.6 → Sensor N°6 5.7 → Sensor N°7	Check nothing has been put on the blanket, or check the blanket is properly layed over the patient (no fold)
6	6.x CONNECTED BLANKET NOT CORRECT 6.1 → Connected blanket not correct	The device connected is not a CB48 blanket.

MAINS POWER FAILURE

Alarm sounds and red lamp "Power failure" is on.

CAUTION ! The internal capacitor powers only the alarms; the heating blanket is not powered.



ELECTROMAGNETIC COMPATIBILITY

The type CB48 cover with BCB48 housing complies with the main electromagnetic compatibility standards. Nevertheless, some useful precautions must be taken to ensure its essential performance and, in particular, its basic safety.

Portable RF communications devices (including peripherals such as antenna cables or peripherals such as antenna cables or antennas) closer than 30 cm from any part of the part of the cover or its housing, including specified cables. Otherwise, the device's performance may be impaired.

Avoid using this device next to or stacked with other devices, as this may result in malfunction. If such use is necessary, observe this and other devices to ensure normal operation.

The use of accessories, transducers and cables other than those specified or supplied by the manufacturer of this device may cause increased electromagnetic emissions or reduced immunity of this device, resulting in inappropriate operation.

The emission characteristics of this device make it suitable for use in industrial and hospital environments. When used in residential environments, this device may not provide adequate protection for radio-frequency communication services. The operator may be required to take corrective action (relocation or reorientation of the device).

POSSIBLE INCIDENTS IN THE EVENT OF ELECTROMAGNETIC DISTURBANCES

- Electronics can be destroyed by repeated strong electrostatic discharges;
- The device may stop and restart instantly (reboot);
- The display may show transient faults (loss of display or artifacts).
- Stealth alarms may be observed;
- Standard alarm (visual and audible) with mandatory restart.

Whatever the incident, and once normal operation has been restored, the patient's temperature and the unit's correct operation should be checked regularly.







COUVERTURES CHAUFFANTES CB48

NU_CB48_1VB_20240705_EN

ECM FRENCH QUALITY

CE MARKING 0459

Warming cots are class IIb medical devices. They comply with current European regulations.

CUSTOMER TECHNICAL SUPPORT CENTRE

GSH provides maintenance and repair services for heating blankets.
Contact our after-sales service on : +33 5 55 56 32 40.

ECM WARRANTY

ECM heating blankets are guaranteed for 12 months (under normal conditions of use). The warranty does not cover maintenance faults made by the user.

SPENGLER SAS

30 rue Jean de Guiramand
13290 Aix en Provence | FRANCE
www.gsh-med.fr

Contact :
+33 (0) 4 42 90 31 31 - info@gsh-med.fr