



POLARCAP® SYSTEM



INSTRUCTION FOR USE



WWW.POLARCOOL.SE

Instructions for Use -The PolarCap System

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PART 1 GENERAL INFORMATION

These Instructions for Use - User Manual apply to the SmallCool and the PolarCap HeadCap medical device and contains general safety, operating and maintenance information. When used together the SmallCool device and PolarCap HeadCap device is called the PolarCap System.

System Parts SmallCool

The SmallCool consists of:

- SmallCool - refrigeration and control unit
- IFU Instruction For Use
- Main power cable

PolarCap HeadCap

- PolarCap HeadCap - Silicone based Head/Neck cooler

Accessories

- PC-Coolant
- Stabilization insulation

Labels



Medical Device



Read before use



Consult instructions for use



Manufacturer



”Conformité Européenne”



The symbol indicating separate collection for waste of electrical and electronic equipment (WEEE). Compliance with national regulations regarding waste handling needs to be followed.



Catalogue Number



Serial Number



Body Floating



Single Use



Temperature limitation



Humidity Limitation



Use-by date



Keep away from sunlight



Keep dry



Country of manufacture & Date of Manufacture



Double insulation



ON/OFF



Temperature indicator



Treatment mode Selector



PC-Coolant Fill-Up indicator



Caution + Consult instructions for use





Unique device identifier



International Protection

Symbols

The following safety symbols are used in this manual.

-  (**Warning**) A warning alerts the reader about a situation which, if not avoided, could result in an adverse reaction, injury, or death.
-  (**Caution**) The term caution is used for the statement of a hazard alert that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor injury to the user or patient or damage to the equipment or other property.
- **ATTENTION (Attentions)** are added to give more information.

Intended purpose

The intended purpose of SmallCool is a thermal regulating system indicated for temperature reduction in adult patients where clinically indicated.

The PolarCap HeadCap device is a single use, non-sterile, accessory intended to be connected to the SmallCool for exchange of thermal energy between the PolarCap HeadCap device and head and neck.

Intended medical indication

The intended medical condition is to cool head and neck of adult patients following suspected or diagnosed concussion to reduce exercise induced hyperthermia.

Patient Populations

- Athletes >18 years diagnosed with a concussion.
- The patient is not sedated.
- The patient shall be awake.

Intended Clinical Benefits

The major benefits to the patient provided by the PolarCap System are the possibility of cooling or achieving rapid normalization of brain temperature following concussion. A rapid decrease in brain temperature as early as possible after a concussion may attenuate injury mechanisms and thus improve outcome. This is achieved by improving neuronal function through reducing apoptosis and decreasing metabolic rate and by minimizing the damage stemming from inflammation caused by the response of the body to injury. Therefore, it aims to reduce the metabolic demand in the brain, when a concussion occurs during sports by lowering brain temperature rapidly through controlled cooling.

Contraindications

There are no known contraindications for the use of a thermoregulatory system.

Potential side effects

- Frostnip - PolarCap HeadCap incorrect skin contact, which could lead to minor frostnip on ear.
- Skin-irritation.

Intended users of PolarCap System

The PolarCap System is intended to be used by lay persons. If any presence of red flags (such as seizures, focal neurological deficits, deteriorating level of consciousness, signs of spinal cord injury, other suspicion of serious central nervous system injury) the user should consult healthcare professional.

Applied Part

An applied part refers to the part of the medical device, which comes into physical contact with the patient in order for the device to carry out its intended function. Applied parts also include parts that could come in contact with the patient through an operator.

For the PolarCap System the following items are applied parts:

- PolarCap HeadCap- Silicone based Head/Neck cooler



Warnings

WARNING

The system must be shut off during service and maintenance.

WARNING

- Only manufacturer approved representative or authorized distributor may perform technical maintenance and service, as incorrect handling may greatly endanger the user (electric shock, fire risk).

WARNING

Unauthorized modification of the ME may result in death or injury.

WARNING

Only connect items that are specified as part of the PolarCap System and its accessories to the System.

WARNING

Only directly connect the system to an electrical outlet with correct voltage and frequency.

Only directly connect the system to an electrical outlet that can deliver stated current.

Only use the main power cable delivered with the system.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the PolarCap System including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and other equipment should be observed to verify that they are operating normally.

WARNING

Malfunction or change of the performance of the device can generate not complete treatment.

WARNING

Discard of the PolarCap HeadCap in accordance with applicable regulations for biologically hazardous waste.



Cautions

CAUTION

Only directly connect the system to a permanent electrical outlet.

CAUTION

Only use the main power cable delivered with the system.

CAUTION

Do not place the PolarCap HeadCap on skin that has signs of ulceration, burns, hives, or rash. Avoid contact with ears.

CAUTION

If the PolarCap HeadCap is incorrectly connected, the System performance can be reduced.

CAUTION

Incorrect placement of the PolarCap HeadCap could lead to insufficient treatment.

CAUTION

Do not kink the hoses on the PolarCap HeadCap.

CAUTION

Other cables and accessories may affect EMC performance.

CAUTION

Sharp objects might penetrate the PolarCap HeadCap and cause a leakage. Replace the PolarCap HeadCap.

CAUTION

The PolarCap HeadCap is intended for single use.

CAUTION

Before using the system, this manual should be carefully studied to ensure safe and efficient usage.

CAUTION

To avoid spillage of coolant, verify that the emptying tap is closed before filling system with coolant.

CAUTION

The PolarCap HeadCap has a shelf life of two years.

CAUTION

The PC Coolant has a shelf life of three years.

CAUTION

PC Coolant is always supplied at the correct concentration. Do not dilute or use any other coolant than PC Coolant for filling the SmallCool's tank.

CAUTION

The system must be shut off during tank fill-up to avoid overfilling.

CAUTION

The intended patient shall be awake during treatment.

CAUTION

The SmallCool is for use only with the PolarCap HeadCap.

CAUTION

When the system is placed at its location, minimize the risk for tripping on the main power cable.

PART 2 PRODUCT INFORMATION

Description of the PolarCap System

The PolarCap System consists of an energy control unit (SmallCool) to which a soft and tight-fitting patient cooling pad covering the scalp and the neck is connected (PolarCap HeadCap).

The SmallCool pushes temperature-controlled PC Coolant through the PolarCap HeadCap. This results in heat exchange between the PolarCap HeadCap and the patient's skin. PC Coolant temperature is controlled by a thermostat and its temperature probe.

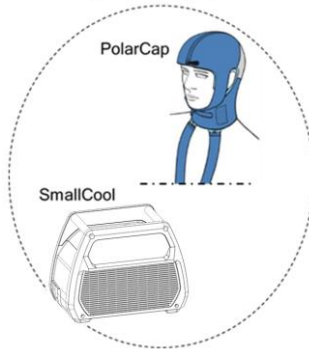
The PolarCap System maintains a controlled PC Coolant temperature during the entire treatment period. Any deviations from the default temperature are automatically adjusted by the system.

System Parts PolarCap System

The PolarCap System consists of:

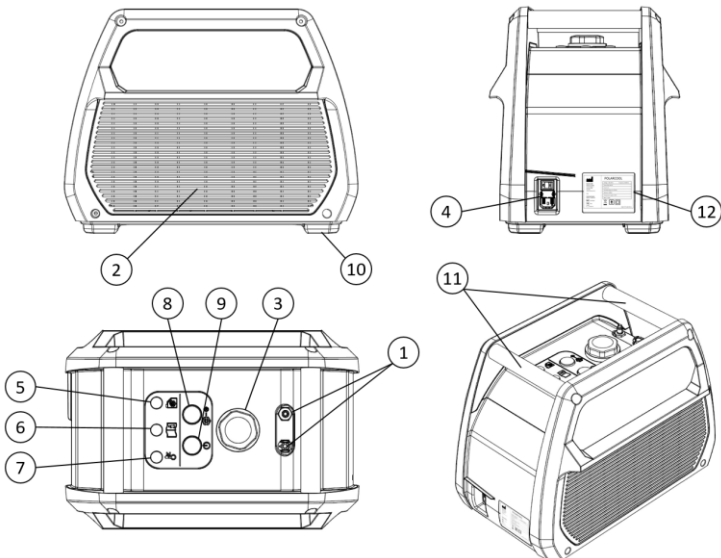
- SmallCool - refrigeration and control unit
- IFU Instruction For Use
- Main power cable
- PolarCap HeadCap- Silicone based Head/Neck cooler
- Stabilization insulation
- PC Coolant - cooling agent

PolarCap System



SmallCool - refrigeration and control unit

SmallCool is a refrigerator unit with an integrated supervisor system.



1. Connections for the PolarCap HeadCap
2. Ventilation holes
3. Tank lid
4. Mains Power switch and inlet
5. Indication light Blue
6. Indication light Yellow
7. Indication light Green
8. Mode selector button
9. ON/OFF
10. Feet (x4)
11. Handle's (x2)
12. Type label



CAUTION

Other cables and accessories may affect EMC performance.



CAUTION

The SmallCool is for use only with the PolarCap HeadCap.

PC Coolant - cooling agent

PC Coolant is a cooling liquid consisting of diluted monopropylene glycol (MPG5). The dilution is made by PolarCool AB to optimally serve the PolarCap System. PC Coolant is delivered with the system.

A summary from the Safety Data Sheet for non-diluted MPG5 is given below.

The product is classified as *non*-hazardous to the environment and health.

The product does *not* require fire or health hazard labeling.

The product is *not* covered by the Transportation of Dangerous Substances Act.



CAUTION

The PC Coolant has a shelf life of three years.

Exposure control

Wash hands with water and soap after contact with the PC Coolant. Provide good ventilation. If clothes have been exposed, remove to avoid further contact.

If the risk of direct contact or splashes is considered high while handling larger quantities, wear a face visor or goggles, protective gloves, and protective clothing.

Firefighting measures

Extinguishing media: CO₂, dry chemical, alcohol-resistant foam, water mist.

Disposal considerations:

PC Coolant must not be flushed into the drain. If PC Coolant is introduced into the drain, alert concerned parties.

Dispose of waste in accordance with applicable local, state, and federal regulations.

Purchasing PC Coolant

PC Coolant can be purchased from PolarCool or from an authorized PolarCool distributor.



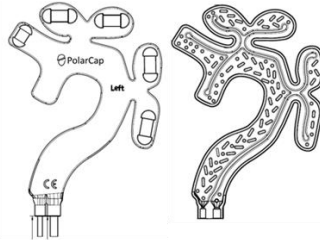
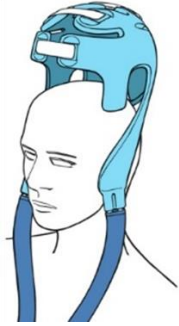
CAUTION

PC Coolant is always supplied at the correct concentration. Do not dilute or use any other coolant than PC Coolant for filling the SmallCool System's tank.

PolarCap HeadCap

The patented silicone based PolarCap HeadCap is molded to ensure the best fit and is available in different sizes. Silicone is a substance that retains its properties even when chilled, and it is adaptable and tolerated by most people with only a small risk of hypersensitivity. PolarCap HeadCap consists of a non-sterile, biocompatible silicone material and contain no latex. The PolarCap HeadCap is delivered pre-filled, and no filling or purging is necessary before or after a treatment. It is designed without any adhesive connection between the silicone and patient skin and can easily be lifted during treatment if the operator needs access to covered body parts.

The PC Coolant in the SmallCool and in the PolarCap HeadCap contains an anti-freeze agent that also minimizes bacterial growth in the fluid pathway. The PolarCap System does not require any rinsing or cleaning of the fluid pathway before or after use.



CAUTION

Sharp objects might penetrate the PolarCap HeadCap and cause a leakage. If damaged, replace the PolarCap HeadCap.



CAUTION

The PolarCap HeadCap is intended for single use.



CAUTION

The PolarCap HeadCap has a shelf life of two years.



WARNING

Discard of the PolarCap HeadCap in accordance with applicable regulations for biologically hazardous waste.

Purchasing PolarCap HeadCap

The Cooling Pads can be purchased from PolarCool or from an authorized PolarCool distributor.



CAUTION

The PolarCap HeadCap is intended for single use.

PART 3 PREPARATION FOR INSTALLATION OF THE SYSTEM

Unpack the SmallCool

Use protective gloves to avoid splinters when handling the wooden pallet on which the system is attached.

The weight of SmallCool is 17 kg and the package including the system weighs approx. 26 kg.

Always start by visually inspecting:

1. Dispatch. Attention to ensure that all components have been included.
2. SmallCool.

If any damage has occurred during transport, or if the delivery does not coincide with the dispatch contact a PolarCool representative or authorized distributor.

Site requirements

The system measures approximately 495(W) x 320(D) x 380(H) mm. To facilitate operation of the system, allow at least 30 cm free space above and at least 20 cm free space around the system for ventilation.

Do not install the system

- Due to the heat dissipation from PolarCap System during operation in a very small space, less than 6m², or in a space with insufficient ventilation.
- In a place where the room temperature and/or the relative humidity is high, e.g. beside a radiator or humidifier or in direct sunlight.
- The location shall be maintained at a hygienic standard and kept free from pets and pests.

For more information, see PART 8 TECHNICAL INFORMATION

Input voltage and current

The electric power supply at the site must:

- Match the voltage and frequency stated on the product label.
- Be able to deliver the power stated on the product label.



Only directly connect the system to an electrical outlet with correct voltage and frequency.
Only directly connect the system to an electrical outlet that can deliver stated current.
Only use the main power cable delivered with the system.

Installation

Before installing the system, the installation site should be prepared according to the site requirements.

1. Place the SmallCool in its desired position.
2. Ensure that ventilation holes on the system are not blocked.
3. Fill the tank with PC Coolant. See PART 4 SYSTEM OPERATION
4. Connect the main power cable to the main inlet. Ensure that the power switch is easy to reach and operate.
5. Turn the main power switch to position "I".



CAUTION

When the system is placed at its location, minimize the risk for tripping on the main power cable.

Transportation of SmallCool

When the SmallCool is transported, make sure that it is secured in an upright position. The systems tank should be emptied from the cooling agent during the transportation.

The position of the system can be changed also when a treatment is running, although it is not advisable to move it for a longer distance than the main power cable allows. Extension cable is not to be used.

Do not start the SmallCool for at least an hour:

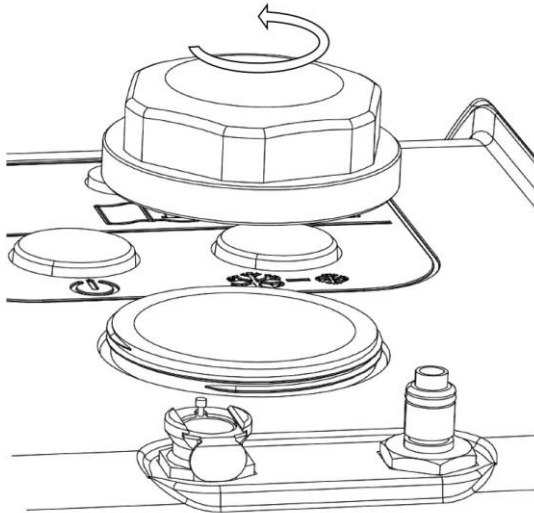
- When it has been moved a considerable distance or if it has been tilted more than 30°.
- If it is taken straight from a cold to a warmer area (to avoid condensation inside the unit).

PART 4 SYSTEM OPERATION

Filling the SmallCool with PC Coolant

Unscrew the tank lid and fill the tank with approximately 0,7l PC coolant before starting the unit.

Fill the tank until you see liquid above the lowest part of the filter mesh. The compressor and the pump will not start until there is a sufficient level of PC Coolant in the tank. PC Coolant is classified as “non-hazardous” to the environment and health. If PC Coolant is spilled on the floor, be aware of slipperiness and clean with water.



CAUTION

PC Coolant is always supplied at the correct concentration. Do not dilute or use any other coolant than PC Coolant for filling the SmallCools tank.



CAUTION

Avoid overfilling.



CAUTION

To avoid spillage of coolant, verify that the emptying tap is closed before filling system with coolant.

**CAUTION**

Before using the system, this manual should be carefully studied to ensure safe and efficient usage.

PART 5 TREATMENT

Introduction

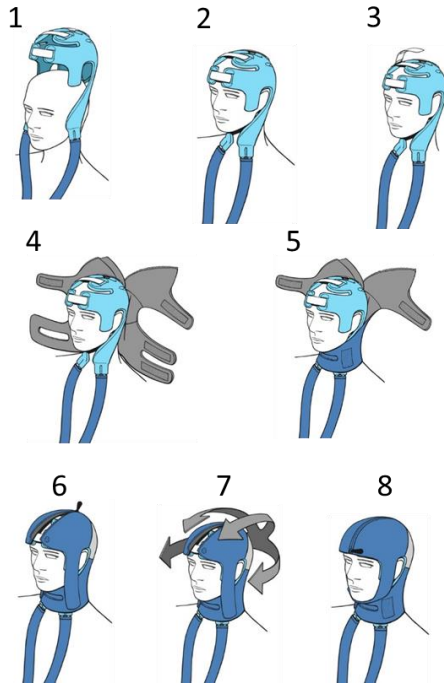
The PolarCap System offers an easy and efficient way of managing cooling. Inspect the patient's skin integrity prior to treating with the PolarCap System. To ensure that coolant is flowing adequately through the PolarCap HeadCap, verify that both hoses are connected properly and are not kinked.

Potential side effects are mostly related to potential discomfort, minor frostnip on ear, skin irritation, mild shivering, increase blood pressure and cross contamination of PolarCap HeadCap lead to risk of infection.

PolarCap HeadCap placement

Place the PolarCap HeadCap on healthy clean skin only. Remove any creams or lotions from the patient's skin before application. The PolarCap HeadCap may be removed and reapplied as necessary. The PolarCap HeadCap surface must be contacting the skin for optimal energy transfer efficiency. Inspect the patient's skin under the PolarCap HeadCap after treatment.

The PolarCap HeadCap is delivered pre-filled, so no filling or purging is necessary before or after treatment. It is designed without any adhesive connection between the silicone and patient skin and can easily be lifted during treatment if the operator needs access to covered body part.



Cooling with the PolarCap System

Cooling with the PolarCap System is initiated with the fitting of the PolarCap HeadCap, a silicone cap, at room temperature, i.e. the cap does not need to be cooled in beforehand. Above an insulating neoprene cap is placed. The cooling commences for a recommended 30-120minutes.

ATTENTION

Inform the patient that the cooling treatment can be interrupted or discontinued at any time if desired. Be aware that this might affect the cooling therapy



CAUTION

Incorrect placement of the PolarCap HeadCap could lead to insufficient treatment



CAUTION

Do not place the PolarCap HeadCap on skin that has signs of ulceration, burns, hives, or rash. Avoid contact with ears.



CAUTION

Do not kink the hoses on the PolarCap HeadCap.



CAUTION

Sharp objects might penetrate the PolarCap HeadCap and cause a leakage. If damaged, replace the PolarCap HeadCap.



CAUTION

The PolarCap HeadCap is intended for single use.



CAUTION

The PolarCap HeadCap has a shelf life of two years.

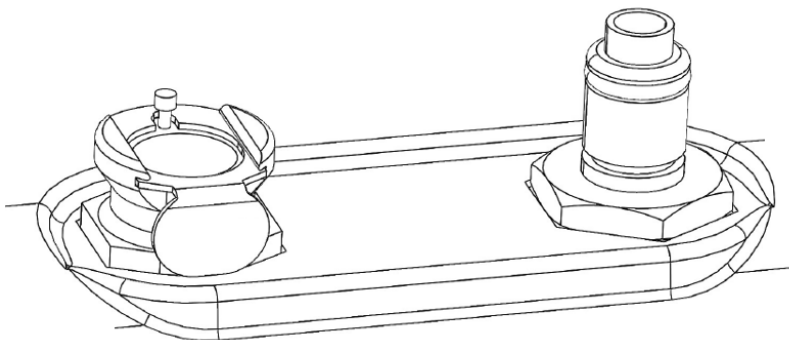


CAUTION

Before using the system, this manual should be carefully studied to ensure safe and efficient usage.

Connecting and disconnecting the PolarCap HeadCap

The PolarCap HeadCap shall be connected to the connectors on top of the SmallCool.

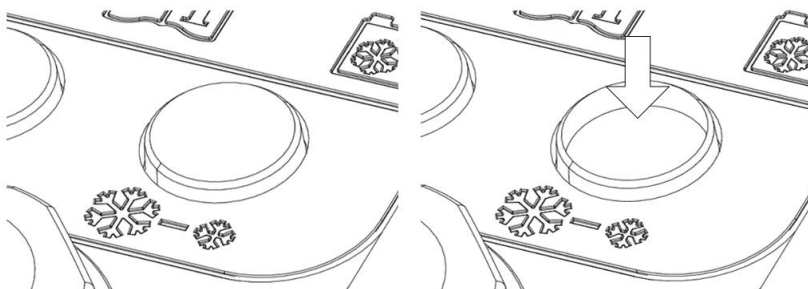


CAUTION

If the PolarCap HeadCap is incorrectly connected, the System performance can be reduced.

Modes of operation

The SmallCool provides two different modes of operation.



1. Treatment mode :

Mode selector button in high/released position - Intended for temperature reduction in adult patients where clinically indicated.

2. Convenient mode :

Mode selector button in pressed down - Comfort cooling.

Starting the treatment mode

Make sure that the ventilation sides are free and that the PolarCap HeadCap is connected.

Turn ON the main power switch on the back of the unit and turn on the system on its top and select treatment mode on the mode selector button by releasing it (—■—). During the cooling down period the indication light will be flashing green. When the system has reached its target temperature the indication light will show a steady green light.

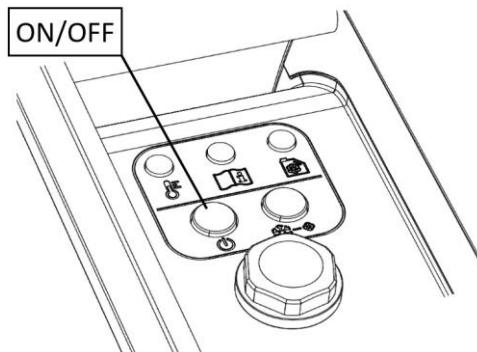
Starting the convenient mode

Make sure that the ventilation sides are free and that the PolarCap HeadCap is connected.

Turn ON the main power switch on the back of the unit and turn on the system on its top and select convenient mode on the mode selector button by pressing it down (—■—). During the cooling down period the indication light will be flashing green. When the system has reached its target temperature the indication light will show a steady green light.

Interrupting the treatment

To interrupt the treatment, push the ON/OFF button.



After treatment

After achieving the overall treatment goal or when terminating a procedure,

1. Press the ON/OFF button and turn off the main power switch on the back of the unit.
2. Slowly and carefully remove the PolarCap HeadCap from the patient's skin, avoiding aggressive removal.
3. Disconnect the PolarCap HeadCap from the SmallCool .

PART 6 TROUBLESHOOTING

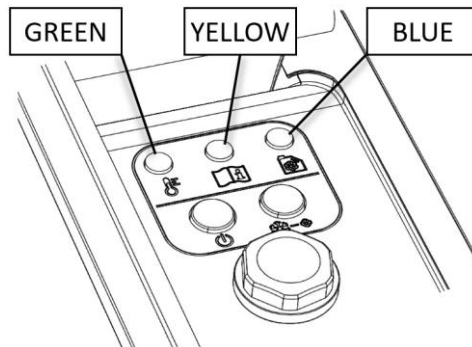
Notifications

The SmallCool is equipped with an independent supervisor system that always monitor system performance. If a problem occurs, the SmallCool generates a notification.

A notification is denoted by visible signals. The notification signal is active while the notification condition continues.

Indication light

During a notification the indication lights will show a steady or flashing light.



Notifications Yellow Light

While there are multiple Yellow notifications in the PolarCap System, there are three main notifications that will place the device into stop mode until the condition is addressed.

1. The supervisor independently monitor coolant flow and the system turns the treatment off if the flow rate becomes too low. A notification is issued.
2. The supervisor independently monitor coolant temperature and the system turns the treatment off if the temperature becomes too low. A notification is issued.
3. The supervisor independently monitor coolant level and the system turns the treatment off if the coolant level becomes too low. A notification is issued.

Notifications Green Light

Green light is the temperature indication light.

1. Green Flashing light, The PolarCap System is working to reach the target temperature.
2. Green steady light, The PolarCap System have reached the target temperature.

Notifications Blue Light

Blue light is PC Coolant level light.

1. Blue light notification is an indication of low level of PC Coolant and the operator is recommended to fill up the PolarCap system with PC Coolant See PART 4 SYSTEM OPERATION.



WARNING

Malfunction or change of the performance of the device can generate not complete treatment.

Troubleshooting schedule SmallCool

SmallCool behaviour	Action
<ul style="list-style-type: none">- Yellow light indication- SmallCool is running	<ol style="list-style-type: none">1. Check if the PolarCap HeadCap is connected correctly2. Make sure that the PolarCap HeadCap hoses are free from kinks and not entangled3. Contact your PolarCool distributor

<ul style="list-style-type: none"> - Blue light indication - SmallCool is running 	<p>Recommended action</p> <ol style="list-style-type: none"> 1. Fill-up the tank with PC Coolant to recommended level ¹ 2. Contact your PolarCool distributor
<ul style="list-style-type: none"> - Yellow light indication - Blue light indication - SmallCool is NOT running 	<p>Necessary action</p> <ol style="list-style-type: none"> 1. Fill-up the tank with PC Coolant to recommended level ¹ 2. Contact your PolarCool distributor
<ul style="list-style-type: none"> - NO light indication - SmallCool is NOT running 	<ol style="list-style-type: none"> 1. Ensure that the main power cable is correctly inserted 2. Check that the main power inlet switch is ON “I” 3. Replace the fuses according to PART 7 CHANGING FUSES ¹ 4. Contact your PolarCool distributor
<ul style="list-style-type: none"> - Other 	<p>Contact your PolarCool distributor</p>
<p>¹ Prior to performing this action, ensure that the SmallCool main power inlet switch is OFF “O”</p> <p>² Green Indication light is not part of the troubleshooting.</p>	

To report unexpected operation or events please contact your PolarCool distribution See last page.

Reporting

Please note that any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the national authority of the country in which the user and/or patient resides.

PART 7 MAINTENANCE AND CLEANING

Cleaning SmallCool

Make sure that the power is switched off and unplug the unit.

- Clean the external surfaces with a cloth dampened with alcohol-based detergent after use.
- Remove any spilled PC Coolant with a cloth dampened with water

Changing the PC Coolant

Refill with coolant when needed.



CAUTION

To avoid spillage of coolant, verify that the emptying tap is closed before filling system with coolant.



CAUTION

The PC Coolant has a shelf life of three years.



CAUTION

Avoid overfilling.



CAUTION

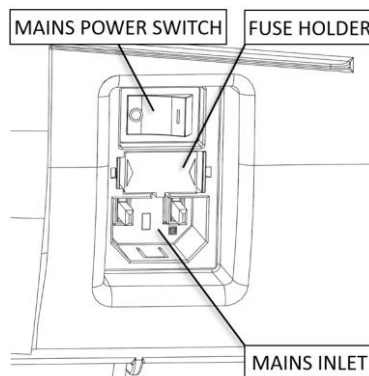
PC Coolant is always supplied at the correct concentration. Do not dilute or use any other coolant than PC Coolant for filling the SmallCool's tank.

Inspection of the SmallCool

1. Check for leaks and defects
2. Check for damages and cracks on the SmallCool enclosure
3. Visual inspection of the main power cable
4. General condition

Changing fuses

Turn off the main power switch at the back side of the SmallCool unit.
Remove the main power cable from the mains power inlet. Remove the fuse holder from the mains power inlet and replace the fuses. Fuse type, see part 8.



Preventive maintenance of the SmallCool

Preventive maintenance should be performed once a year, please contact a sales representative for offers & agreements.

PolarCool AB and authorized distributors offers on-site technical support and service maintenance, fault localization, repair service, product upgrade wherever our clients are located.



WARNING

The system must be shut off during service and maintenance.

Only PolarCool representative or authorized distributor may perform technical maintenance and service, as incorrect handling may greatly endanger the user (electric shock, fire risk).



WARNING

Unauthorized modification of the ME may result in death or injury.

PART 8 TECHNICAL INFORMATION

REF.No.	Article	Description	Class
PC10-003	SmallCool	Refrigeration and control unit	Class IIa
PC10-002	PolarCap HeadCap	PolarCap HeadCap	Class I

Expected service life of the SmallCool is 5 years.



Body Floating

Enclosure safety IP 21

Protected from touch by fingers or solid objects greater than 12,5 millimetres.

Protected from condensation or vertically falling drops of water.

Continuous operation

Equipment is not suitable for use in the presence of flammable mixtures.

Weight:
 17kg (with empty tank)
Dimensions (HxWxD):
 493x318x374 (mm)
Environmental conditions
Operating:
 Temperature: 15 to 30°C
 Humidity range: 10 to 75% RH
 Altitude: ≤3000m
Transport:
 Temperature: 5°C to 65°C
 Humidity range: 10 to 90% RH
 (No Condensation)
 Altitude: ≤3000m
Mains Input
 100/230 VAC, 50/60 Hz, Max 400W
Fuse:
 T 6.3AH 250V

Refrigeration system:
Construction:
 Fully hermetically sealed unit
Refrigerant:
 CFC-free R134a
Coolant system:
Coolant:
 Diluted monopropylene glycol
Reservoir Capacity:
 0.7 liters
Coolant Temperature:
 Maintained at 0°C ±2°C during
 Treatment mode
 Maintained at 8°C ±4°C during
 Convenient mode
Low Coolant Temperature Notification
 -4°C
PolarCap HeadCap:
 Material: Biocompatible Silicone rubber

Guidance and manufacturer's declaration - electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The PolarCap System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The PolarCap System is suitable for use in a home health environment i.e. domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic Distortion	IEC 61000-3-2	230 V, 50 Hz or 60 Hz
Voltage changes, voltage fluctuations and flicker	IEC 61000-3-3	230 V, 50 Hz

Guidance and manufacturer's declaration - electromagnetic immunity

The PolarCap System is intended for use in the electromagnetic environment specified below. The customer or the user of the PolarCap System should assure 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	± 8 kV contact ± 2 kV, ± 4kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4kV, ± 8 kV, ± 15 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 Power port	± 2 kV Power port	Mains power quality should be that of a typical commercial environment, hospital environment or mains public network.
Surge IEC 61000-4-5	Line-to-line ± 0.5 kV, ± 1 kV Line-to-ground N/A Class II double insulated	Line-to-line ± 0.5 kV, ± 1 kV Line-to-ground N/A Class II double insulated	Mains power quality should be that of a typical commercial environment, hospital environment or mains public network.
Voltage dips and voltage interruptions IEC 61000-4-11	0% U _T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U _T ; 1 cycle and 70% U _T ; 25/30 cycles Single phase: at 0° 0% U _T ; 250/300 cycles	% U _T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U _T ; 1 cycle and 70% U _T ; 25/30 cycles Single phase: at 0° 0% U _T ; 250/300 cycles	Mains power quality should be that of a typical commercial environment, hospital environment or mains public network.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial environment, hospital environment or mains public network.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the PolarCap System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Conducted RF IEC 61000-4-6	3 Vrms (6 Vrms inside ISM / ASR bands) 150 kHz to 80 MHz	3 Vrms (6 Vrms inside ISM / ASR bands) 150 kHz to 80 MHz	Recommended separation distance $d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3 RF wireless communications equipment IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 27 V/m 380 to 390 MHz 28 V/m 430 to 470 MHz 9 V/m 704 to 787 MHz 28 V/m 800 to 960 MHz 28 V/m 1700 to 1990 MHz 28 V/m 2400 to 2570 MHz 9 V/m 5100 to 5800 MHz	10 V/m 80 MHz to 2.7 GHz 27 V/m 380 to 390 MHz 28 V/m 430 to 470 MHz 9 V/m 704 to 787 MHz 28 V/m 800 to 960 MHz 28 V/m 1700 to 1990 MHz 28 V/m 2400 to 2570 MHz 9 V/m 5100 to 5800 MHz	$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2.7 GHz 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a should be less than the compliance level in each frequency range. ^b Interference might occur in the vicinity of equipment marked with the following symbol. 

NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.

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

^a 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 assess 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 PolarCap System is used exceeds the applicable RF compliance level above, the PolarCap System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PolarCap System.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the PolarCap System

The PolarCap System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PolarCap System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PolarCap 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 $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

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

The SmallCool maintains basic safety and operational performance in the specified electromagnetic environments which is continuous cooling with the PolarCap device within specified coolant temperature.



WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the PolarCap System including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and other equipment should be observed to verify that they are operating normally.

PART 9 ADDITIONAL INFORMATION

Clinical Evaluations

Evaluations have been conducted to evaluate the efficacy and safety of the system.

Warranty

PolarCool AB provides a one-year limited system warranty. PolarCool AB warrants that the system meets the Manufacturer's specifications and is free from manufacturing defects at the time of delivery.

This warranty is contingent upon proper use of the system in the application for which it was intended. The warranty shall not extend or apply to any damage or defect resulting from product misuse, abuse, neglect, modification, alteration, unusual stress or improper storage and handling.

Disposal of the device

SmallCool

The European Directive 2012/19/EU on Waste Electric and Electronic Equipment (WEEE) aims to minimize the impact on the environment by prevention of waste. The SmallCool device has been labelled with the WEEE symbol, and there is a procedure to allow waste collection and recycling of the equipment at the end of its life cycle.



PolarCap HeadCap



WARNING

Discard of the PolarCap HeadCap in accordance with applicable regulations for biologically hazardous waste.

Certifications

PolarCool AB has ISO 13485:2016 certification.

The SmallCool complies with the requirements of active therapeutic products under Medical device Class IIa and EU regulation for Medical device MDR 2017/745.

The

has been tested and complies with the requirements of:

- IEC/EN 60601-1:2005 3rd Edition A1(2012). Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- EN 60601-1-2:2014. Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC/EN 60601-1-6:2010 A1(2013). Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC/EN 60601-1-11:2015. Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.



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The CE-conformity mark indicates that the SmallCool conforms to the requirements in the regulation (EU) 2017/745, concerning medical devices. It also indicates that the Intertek Medical Notified Body AB (, No. 2862) Adress: Torshamnsgatan 43, 164 40 Kista, Sweden has approved the Quality Management System of PolarCool AB.

The PolarCap System complies with the requirements of:

- WEEE 2012/19/EU
- RoHS 2011/65/EU
- REACH 1907/2006
- IPR - Intellectual Property Rights

PART 10 CONTACT INFORMATION

Legal manufacturer



PolarCool AB

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