

# CoreControl™

Rapid Thermal Exchange System

## User's Guide

For CoreControl™ Model #570-0001-00



Website: [www.corecontrolcooling.com](http://www.corecontrolcooling.com)

**Caution:** Read all instructions prior to operating the device.

# Table of Contents

<b>Contents</b>	<b>Page</b>
Description and Intended Use	3-4
Instruction for Use	5
1) Device Description	5
2) Priming CoreControl™	6
3) Operation of CoreControl™	7
Shutting Down, Storage, and Cleaning of CoreControl™	9
1) Shut Down	9
2) Storage	9
3) Long Term Storage	9
4) Purging CoreControl™	9
5) Cleaning	10
Accessories and Replacement Parts	10
Trouble Shooting	11
Warranty	13

# CoreControl™

## Rapid Thermal Exchange System

**Congratulations** on your purchase of **CoreControl™**, the only scientifically proven, non-invasive core body temperature cooling device.

### Description

**CoreControl™** is a hand held device that is used to rapidly extract excess heat from an individual. Increased internal body temperature can limit one's ability to perform physical work and impair cognitive function, especially while exercising or working in an extreme environment. In these circumstances, maintaining optimal core temperature enhances physical and mental performance by allowing more blood flow to be used for muscle and brain function and less for cooling the body. **CoreControl™** utilizes the specialized blood vessels that exist in the palms of the hand – the body's radiator – that are designed for thermal exchange. The combined application of a slight vacuum and optimal temperature enhances the natural heat exchange of these radiator structures, cooling a person quickly.

**CoreControl™** consists of a temperature control unit, hand pod assembly, battery charger, cooler, and carrying bag.



## DISCLAIMER

**CoreControl™ is not intended to diagnose, treat, cure or prevent any disease. CoreControl™ is not a medical device. Do not use CoreControl™ for any reason other than to augment natural body cooling processes. CoreControl™ is not to be used for any medical emergency. Normal heat safety precautions should be followed at all times.**

**The statements contained in this User's Guide have not been evaluated by the FDA.**

## WARNINGS:

This device **IS NOT** intended to provide cooling where the internal body core temperature is greater than 104°F. In these cases, get **IMMEDIATE MEDICAL ATTENTION!**

**DO NOT** use when the Temperature Control Unit is plugged into the battery charger.

**DO NOT** use if the Temperature Control Unit is leaking or has been damaged or submerged.

**DO NOT** use if the hand pod is damaged or the wrist seal is punctured or torn. **THE WRIST SEAL IS A CONSUMABLE ITEM AND SHOULD BE REPLACED AS NECESSARY DEPENDING UPON USE. IT IS ADVISABLE TO KEEP SPARE WRIST SEALS TO ENSURE UNINTERRUPTED PERFORMANCE.**

**DO NOT** use with dirty water. Always use clean, fresh tap water or distilled water when filling the Temperature Control Unit.

## Intended Use

**CoreControl™** is designed to non-invasively lower a healthy person's core body temperature when it has become elevated due to exertion. This can occur during exercise, working in a hot environment, or wearing protective clothing.

**CoreControl™** patented technology provides a means to rapidly cool your core body to feel more refreshed and increase one's ability to perform more physical activity. **CoreControl™** augments your body's natural cooling process by returning

your core body temperature to normal. It cannot lower your body beyond normal.

### Cautions

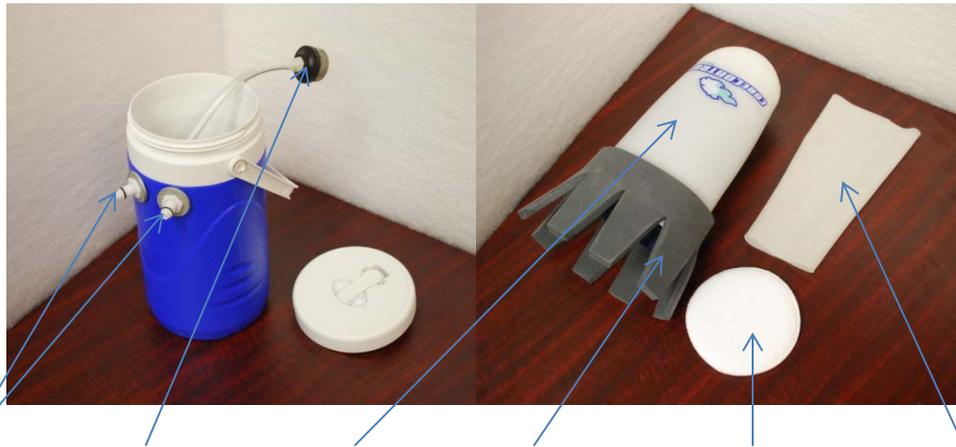
- **CoreControl™** is designed to operate in environmental temperatures of 35°F - 120°F (2°C - 49°C).
- Kinking of the hose to the hand pod can cause **CoreControl™** to cease functioning effectively.
- Use only clean water sources to reduce risk of contamination of internal components.
- Do Not carry or hang **CoreControl™** by the umbilical tubing, this may damage the tubing or internal components.
- Do Not store **CoreControl™** in direct sunlight. **CoreControl™** should be stored in a clean well-ventilated area at room temperature.
- Do Not allow **CoreControl™** to freeze. If freezing is a possibility, follow the purge instructions to remove as much internal water as possible.
- Do Not store **CoreControl™** for extended periods with water in the system; follow the purge instruction to remove water.
- Do Not store wrist seal with small end of the opening pulled back over the hand pod, this will shorten the life of the seal.

### Instructions for Use

Prior to operating CoreControl™ fully charge the internal battery using the provided battery charger. Plug the battery charger in a properly grounded 15 amp (110-120 AC) outlet and the charging plug into the top of the control unit marked "Charging Port". The battery charger will display a red light while the battery is charging. A steady green light will display once the battery is fully charged. Charging of the battery may take up to 3 hours. For extended storage, do not store with battery fully charged.

### Device Description

Use the following illustrations to become familiar with your CoreControl™ unit.



## Priming CoreControl™

Your CoreControl™ unit will require priming prior to providing cooling capabilities. Priming of the system is required to remove the air from the tubing and the pad inside of the hand pod. Priming will be required during initial use and after purging of the system. **NOTE:** clean water is to be used during priming – **Do Not Use ice water for priming.**

- Open the CoreControl™ carrying case and detach the connectors to the cooler by pressing the button on each connector. Gently pull the tubes off and remove the cooler from the bag.
- Open the lid of the cooler and fill ½ with clean water. Verify the cooler

tube and bulb are submerged beneath the water level. **NOTE: DO NOT Use** ice water for priming, the system will not properly prime if ice water is used.

- Tighten the lid back onto the cooler and place inside of bag.
- Attach the connectors to the cooler by pushing them onto the mating connector on the cooler. An audible click will be heard once they are fully engaged. Gently pull on each connector to verify they are engaged.
- Attach the hand pod to the end of the umbilical tubing. An audible click will be heard once the connectors are fully engaged. The two similar connectors on the hand pod are interchangeable can be connected in either manner.
- Once all connections are made and clean water is in the cooler, turn on the device by pressing the power switch.
- Depress the red “Prime-Purge” button on the top of the controller. This button over-rides the temperature controller to allow for water to be continually syphoned from the cooler.
- Continue to hold the button down until few air bubbles are seen in the clear water lines of the tubing. It is recommended that you move the hand pod around during this procedure to help move trapped air out of the hand pod perfusion pad. This may take 30-60 seconds to complete. Note: the **Yellow LED** light may illuminate during priming, this is normal and indicates that the water is too warm to provide sufficient cooling. The yellow LED will go off once iced water is added to the cooler.
- Once all air is removed, turn the unit off.
- **NOTE** – during priming if the yellow LED light begins to flash, the water used to prime the system is too cold (below 55°F (12°C)). Go to trouble shooting for directions to further prime the system.

## Operating CoreControl™

If the CoreControl™ unit does not have water in the system, follow the priming procedure to first prime the system prior to use.

- Remove the cooler from the bag by depressing the connectors release button and disconnecting the tubes.
- Remove the lid and fill cooler with ice and water to just below the connector inputs. Verify the tubing and bulb are below the water. Very little water is needed for the system once primed, the cooler can be filled

to just below the connector inputs with ice, and then add water to the same level.

- Turn the power of the unit on.
- Insert your hand into the hand pod with palm facing toward the umbilical side of the hand pod. Be sure your hand is inside of the perfusion pad with the pad wrapping around the entire hand. Gently rest your hand on the hand pod perfusion pad. The hand support pad creates a bump in the pad to achieve good contact with the hand pod perfusion pad and your palm. Full contact with the palm is necessary for maximum heat transfer.
- Pull wrist support and wrist seal over arm. Wrist seal must be in contact with the skin of the arm to seal, remove clothing or wraps between wrist seal and arm. **Caution:** the wrist seal and hand pod pad can be torn by bulky rings, bracelets, and other sharp objects. Remove jewelry/objects from hand and wrist prior to inserting your hand into the hand pod.



- Keep hand in hand pod during required cooling. A vacuum will be felt on the hand during the operation of the unit. It is normal for the vacuum pressure to increase and decrease during use. If vacuum is not achieved on hand, see trouble shooting tips to rectify.
- Once desired cooling effect is achieved turn unit off and remove hand from hand pod. For additional cooling, turn unit back on and insert hand back into hand pod. Note: power of the unit can be left on while your hand is not in the hand pod without causing damage. This will shorten the duration of time the unit can operate between required battery charges. It is recommended that the unit be powered off if not being used. The **Red LED** light will illuminate once the battery charge is low.
- When the water within the cooler is no longer cold enough to provide sufficient cooling the **Yellow LED** light will illuminate. Replace the water with iced water.

# Shutting Down, Storage, and Cleaning of CoreControl™

## Shut Down

After use of the device, turn off power to unit. Open the bag and remove the cooler from the connectors and dump water from the cooler. Place the cooler back into the bag.

## Storage

After use, clean the device as described in Cleaning of CoreControl™. Store unit in a well-ventilated area, at room temperature to prevent mildew formation. CoreControl™ should not be stored in an environment that could reach temperatures above 120°F (49°C) or temperatures below 32°F (0°C).

## Long Term Storage

To prevent mildew during storage, half fill cooler with a 5% isopropyl alcohol and water mixture and “prime” the unit as described in “Priming CoreControl™”. Circulate the alcohol/water mixture through the system, depressing the prime-purge button for a minimum of 1 minute. Once complete, purge the system and described below prior to storage.

## Purging CoreControl™

Prior to long term storage, the CoreControl™ unit should be purged to remove the water in the internal system.

- Connect all connectors on the hand pod and cooler.
- Pull the bulb up out of the cooler so that it will not pull in water.
- Turn the power on to the unit.
- Depress the “prime-purge” button on the control unit.
- The internal water will be pumped from the system into the cooler. Continue holding the button until all water is removed from the system. It is recommended that the hand pod be moved around during purging to remove the trapped water.
- Once all water is removed and no longer seen in the water line to the hand pod, stop depressing the prime-purge button and turn the unit off.
- Remove the cooler and empty the water.

## Cleaning

The wrist seal, wrist support, and hand support pad can be removed and hand washed using standard detergent (do not use products containing bleach). Do not dry in heated dryer. Allow to air dry.

**DO NOT REMOVE PERFUSION PAD WHEN CLEANING THE INSIDE OF THE HAND POD.** To clean the hand pod, fill with water and detergent (do not use products containing bleach). Wash inside and outside of pod and gently pat dry with a towel and allow to air dry prior to storage.

Clean the cooler inside and outside with standard cleaning detergent. Wipe clean and allow to fully dry prior to placing lid back onto cooler and for storage.

Antiseptic wipes can be used anytime on the hand pod between users or after use.

## Accessories and Replacement Parts

Please visit [www.corecontrolcooling.com](http://www.corecontrolcooling.com) to order accessories and spare parts.

- Wrist seal: 570-0004-05
- Wrist support pad: 570-0004-06
- Hand support pad: 570-0004-07
- Hand Pod Perfusion Pad: 570-0004-08
- Hand Pod assembly (Hand pod shell, wrist seal, wrist support, hand support pad, hand pod perfusion pad): 570-0004-00
- Cooler Assembly: 570-0003-00
- Battery Charger: 570-0007-00
- Carrycase: 570-0005-00
- Li Battery pack: contact customer service

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This product is Made in the U.S.A.

Patents: 6656208, 6602277, 6673099, 6966922, 6974442, 7122047, 7182776, 7862600, 7947068, 8177826, 8277496, 8287581

## Troubleshooting Tips

Problem	Solution
Yellow LED illuminated	Low on Ice, water in cooler too warm. Replace water or add ice to cooler water.
Yellow LED flashes	System was primed with water under 55°F(13°C). The system will not allow priming with cold water as the hand pod pad will be too cold and cause your body to react by constricting blood flow to the hand. This condition may also occur if the red prime/purge button is inadvertently depressed during normal operation. To rectify, remove the cooler water and replace with warm water and attach to unit. Hold down the red prime/purge bottom and turn the power on for 5 seconds and back off. Repeat 3-4 times until the yellow light stops flashing. Continue priming procedure. You may also let the system warm up on its own by placing in warm ambient conditions. Replace ice water with warm water and let sit. Once the internal water warms, the light will stop flashing and the system will operate.
Yellow LED continually flashing (heart beat rhythm)	The temperature control unit has detected a problem. Contact customer service.
Red LED illuminated	The battery voltage is low and needs charged. Plug the battery charger into a grounded 15A, 110-120V AC outlet and charge the battery.
Water will not circulate through system	Verify all connections to the cooler and hand pod are fully engaged.
No vacuum in hand pod	Verify connection to hand pod is fully engaged. Check that wrist seal is fully sealed on arm (no clothing or objects between seal and arm). Verify wrist seal is not damaged or torn. Verify the mounted connectors onto the hand pod shell have not become loose or unscrewed. If so, tighten connectors using a wrench by turning clockwise, do not over tighten.
Wrist seal is torn	Go to <a href="http://corecontrolcooling.com">corecontrolcooling.com</a> to order replacement parts.

There are bubbles in the tube	It is normal to have some bubbles in the tubes when in operation. If a large amount of air is within the system, perform the priming procedure to rid the air within the system. Verify the bulb inside of the cooler is fully submerged under the ice water level.
I don't feel cooler	It is difficult to feel CoreControl™ extracting heat out your body because you do not have temperature sensors deep inside your body. CoreControl™ pulls heat directly out of your core via thermal portals in the hand, while most “cooling” techniques try to cool the body through the general skin surface. While using CoreControl™ you may not “feel” cool, but you will feel more <i>refreshed</i> and be able to perform at a higher level.
Some water is under the cooler	Each time the cooler is disconnected a small amount of water will be released from the connection point. This is normal and can be cleaned with a dry rag to towel.
I spilled water inside the carrying bag	Turn the unit off. Dump all water out of the bag and let dry in a ventilated area at room temperature until the bag and control unit are fully dry. If unit does not operate after drying contact customer service.
Water is accumulating inside the bag	If a significant amount of water is being produced inside the bag, turn the unit off and contact customer service. Some water will drip from cooler connectors when removing cooler, this is normal.
Umbilical tubing damaged	In case of damage to the umbilical and water will not flow, contact customer service.
Water is leaking into Hand Pod	Some condensation may occur in the hand pod, if a significant amount of water is in the hand pod, turn off unit and visit <a href="http://corecontrolcooling.com">corecontrolcooling.com</a> for a replacement hand pod perfusion pad.
System will not purge and continues to circulate water when depressing prime/purge button	Verify the bulb inside of the cooler is above the water lever.

# WARRANTY

AVAcure warrants to the initial purchaser (“purchaser”) that each new CoreControl system (“product”) purchased directly from AVAcure or an authorized AVAcure distributor will be free from defects in materials and workmanship under normal use for a period of one year from the date of its initial shipment to the purchaser notwithstanding the foregoing, the warranty period for the hand pod assembly and the exterior carrying bag is 90 days from the date of shipment. We make no warranty whatsoever in respect to wear items, such as the wrist seal or accessories and parts not supplied by us. Repair or replacement of the CoreControl unit or any part thereof under this warranty does not extend the warranty period. Products that are not new are subject to separate warranties expressly provided in connection with the sale of such products.

The obligations of AVAcure under this warranty shall be limited to repair or replacement (at AVAcure’s option) of any product (or part thereof) under warranty that AVAcure reasonably determines to be covered by this warranty and to be defective in workmanship or materials. AVAcure shall determine whether to repair or replace products and parts covered by this warranty. All products or parts replaced shall become AVAcure’s property. In the course of warranty service, AVAcure may, but shall not be required to, make engineering improvements to the warranted products or parts.

Products shipped by the purchaser under this warranty shall be suitably packaged to protect the product. If the purchaser ships a product to AVAcure in unsuitable packaging, any physical damage in the product upon receipt by AVAcure (and not previously reported) will be presumed to have occurred in transit and will be the responsibility of the purchaser. Risk of loss or damage during shipment under this warranty shall be borne by the party shipping the product.

This warranty shall be invalid if the warranted products (or parts thereof) have been subject to misuse, neglect, or accident; have been damaged by causes external to the warranted product; have been affixed to any nonstandard accessory attachment; have had the serial number removed or made illegible; or have been disassembled, modified, serviced, or reassembled by anyone other than AVAcure, unless authorized by AVAcure.

AVAcure will not be responsible for the effect on safety, reliability, and performance of the product if:

- a) assembly, extensions, readjustments, modifications, or repairs are carried out by anyone other than AVAcure or persons authorized to perform repair service on AVAcure’s behalf; or b) the electrical installation does not comply with the requirements of the applicable national and international standards, including requirements of the IEC; or c) the product is not used in accordance with AVAcure’s instructions for use.

THIS WARRANTY, TOGETHER WITH ANY OTHER EXPRESS WRITTEN WARRANTY THAT MAY BE ISSUED BY AVACORE, IS THE SOLE AND EXCLUSIVE WARRANTY AS TO AVACORE PRODUCTS, AND EXTENDS ONLY TO THE PURCHASER AND IS EXPRESSLY IN LIEU OF ANY ORAL OR IMPLIED WARRANTIES INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. AVACORE SHALL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL, OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE (INCLUDING WITHOUT LIMITATION LOST PROFITS) DIRECTLY OR INDIRECTLY ARISING FROM THE SALE, INABILITY TO SELL, USE, OR LOSS OF USE OF ANY PRODUCT.

## DISCLAIMER OF WARRANTIES

The AVAcure thermal regulation devices are used in extremely variable environments, ancillary equipment connections and physical conditions. The devices may fail to function for a variety of causes, including but not limited to the physical condition of the person or the failure of the device or ancillary equipment by breakage. In addition, despite the exercise of all due care in the design, component selection, manufacture and testing prior to sale, the devices can be damaged, before, during or after use by improper handling or other intervening acts. Consequentially, no warranty is made that failure or cessation of the function of the devices will not occur or that physical complications will not follow the use of the device.