

TargetCool

User
Manual

UV5_23



CE 2265

Notice

Thank you for your interest in TargetCool™ (Model: RM-DT02W). CoolHealth strives to provide our customers with the highest quality devices, systems, and services

The TargetCool™ system includes a handheld device (hereinafter “the TargetCool™ device”) that – as part of a system that includes guard, cartridge filter, and cartridge consumables (collectively “TargetCool™ consumables”) – can provide rapid, precise, and controlled cooling to the skin tissue. The TargetCool™ consumables are sold in a kit (hereinafter “the TargetCool™ Consumables Kit”), which is sold separately. Information about how to purchase the TargetCool™ Kit and other TargetCool™ accessories can be found at www.coolhealth.com.

This manual describes how to operate the TargetCool™ system with the main device and the TargetCool™ consumables. Please thoroughly familiarize yourself with this manual to make the most effective use of the device and the consumables.

Observe all cautionary instructions, safety messages, and warnings that appear in this manual.

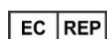
Due to continued technological improvements, this manual may not contain the most updated information and is subject to change without prior notice. You can find the latest version of this manual at www.coolhealth.com.

This document is originally written in English.

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Introduction

This chapter provides an overview of the contents of the TargetCool™ box, the indications for use, and who can use the TargetCool™ system.

The contents of the TargetCool™ box are configured to be used with the TargetCool™ consumables in the TargetCool™ Consumables Kit (sold separately). Information about how to purchase the TargetCool™ Consumables Kit, along with other TargetCool™ accessories, can be found at www.coolhealth.com.

1.1 Inside the TargetCool™ Device Box

The TargetCool™ device box comes with the following:



- ▶ TargetCool™ device and Grip
- ▶ Cooling nozzle
- ▶ Boosting nozzle
- ▶ Freezing nozzle F08
- ▶ Freezing nozzle F15
- ▶ Boosting Guard
- ▶ User Manual
- ▶ Quick Reference Guide

1.1.1 TargetCool™ device and Grip

The TargetCool™ grip is wrapped around the TargetCool™ device, which is a handheld device that – as part of a system that includes the TargetCool™ Consumables kit – can provide rapid, precise, and controlled cooling to the skin tissue.

1.1.2 Nozzle

The outlet of the nozzle is configured to spray cryogen at a controlled, cool temperature to the target area. TargetCool™ is compatible with three nozzle types

- Cooling nozzle: Nozzle used in Cooling mode
- Freezing nozzle: Nozzle used in Freezing mode
- Boosting nozzle: Nozzle used in Boosting mode

1.1.3 Boosting Guard

The Boosting guard is used to connect the Boosting container to the Boosting nozzle. The Boosting guard can only be used when the device is set to Boosting mode.

1.1.4 Charger (USB Type-C) and Power Cord

The charger (PD, USB Type-C) charges the TargetCool™ device when it is not in use.

Recommended Charger Specifications: PD charger (range: DC 5V—3A ~ 20V—1.5A)

The charger (PD, USB Type-C) is not provided separately by the manufacturer.

1.1.5 Cartridge Sleeve

The cartridge sleeve is configured to be wrapped around the cartridge (sold separately).

1.1.6 Quick Reference Guide

The Quick Reference Guide offers an overview of the TargetCool™ device and how to begin using it.

CoolHealth, Inc. assumes no liability for damage to the device, injury to the user, or injury to the patient that may occur when operating the TargetCool™ system without first completely reading the User Guide, and fully adhering to the instructions and warnings contained therein. If you have any

questions whatsoever about how to operate TargetCool™ properly, please contact your sales representative.

1.2 Intended Purpose

The TargetCool is for use when cryotherapy is indicated for the temporary reduction of pain, swelling, inflammation, and hematoma from surgical procedures, sprains or other acute sports injuries, and as an adjunct to rehabilitative treatment (e.g. effects of analgesia, anesthesia and relaxation).

[Intended application]

- To decrease swelling/edema following trauma (injury)
- To treat burns
- To treat Actinic keratosis
- To treat Naevus of Ota
- To treat warts
- To inhibit spasticity
- To reduce muscle spasm
- To reduce acute inflammatory reaction
- To reduce pain
- To reduce limb metabolism (also, it leads a temporary anesthetic effect prior to surgical process)
- To produce reactive hyperemia
- To facilitate muscular contraction for various forms of neurogenic weakness and for muscle reeducation
- To treat restricted knee flexion due to traumatic lower extremity fractures

1.3 Contraindications

- Hypertension (due to secondary vasoconstriction)
- Raynaud's disease
- Rheumatoid arthritis
- Local limb ischemia
- History of vascular impairment, such as frostbite or arteriosclerosis
- Cold allergy (cold urticaria)
- Paroxysmal cold hemoglobinuria
- Cryoglobulinemia or any disease that produces a marked cold pressor response

TargetCool™ Consumables Kit

(Sold Separately)

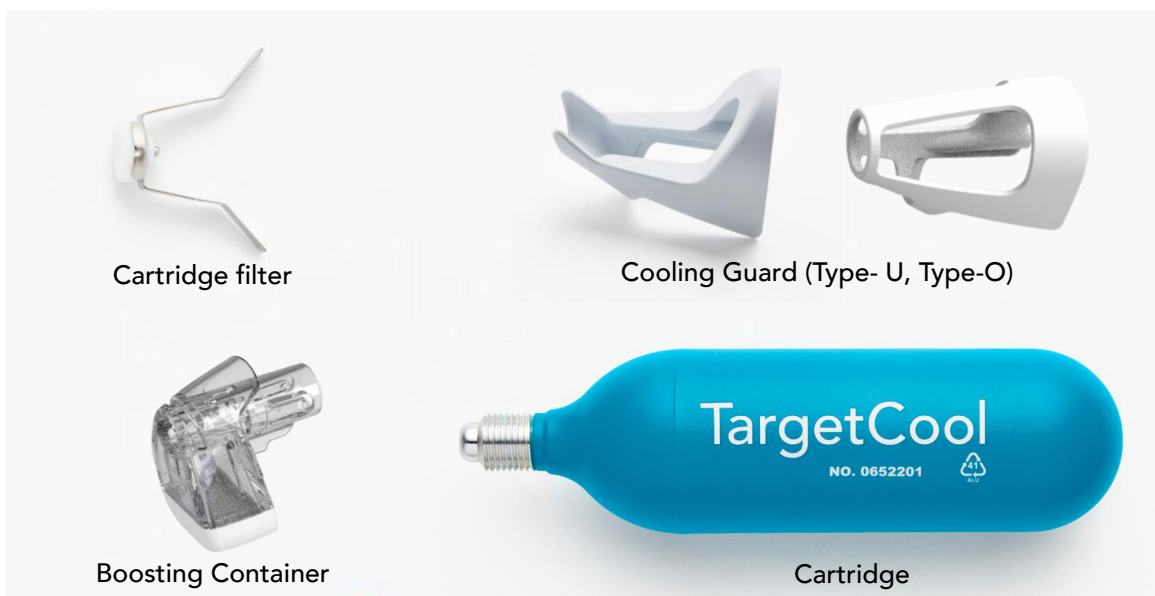
This chapter provides an overview of the TargetCool™ consumables, which can be found in the TargetCool™ Consumables Kit.

The TargetCool™ consumables in the TargetCool™ Consumables Kit are configured to be used with the contents of the TargetCool™ device box. The TargetCool™ Consumables Kit along with other TargetCool™ accessories can be purchased at www.coolhealth.com.

2.1 Inside the TargetCool™ Consumables Kit

(Sold Separately)

The TargetCool™ Consumables Kit comes with the following consumables.



- ▶ **Cartridge filter**
- ▶ **Cooling Guard (Type-U)**
- ▶ **Cooling Guard (Type-O, Optional)**
- ▶ **Boosting Container**
- ▶ **Cartridge**

2.1.1 Cooling Guard

The Cooling guard is configured to attach to the guard dock on the TargetCool™ device. The proximal portion of the guard has three magnets, which are configured to magnetically attach to the guard dock. The distal portion of the guard is configured to contact the target area.

The guard is configured to – in connection with the infrared (IR) temperature sensors in the TargetCool™ device – help maintain the appropriate distance between the target area and the outlet of the fastened nozzle while providing visual access to the target area.

There are two types of cooling guards (Type-U, Type-O). The type-U is in contact with the skin in a “U” shape and is used when spraying a flexural treatment area. The type-O is in contact with the skin in an “O” shape and is used to spray over a flat treatment area.

- The Cooling guard is used only when the device is set to Cooling mode.
- The Boosting guard is used in Boosting mode.
- No guard is used in Freezing mode.

2.1.2 Boosting Container

The Boosting container is used in Boosting mode to gently spray cryogen across a wide to target area. The Boosting container is configured to be inserted into the TargetCool™ device after the Boosting nozzle and the Boosting guard are attached.

2.1.3 Cartridge Filter

The cartridge filter is configured to filter any potential impurities from the fastened cartridge and to assist in sealing the fastened cartridge to the TargetCool™ device. The cartridge filter is configured to be inserted into the TargetCool™ device before the cartridge is fastened onto it.

The cartridge filter comprises:

- A circular base that is configured to fit and rest inside the cartridge cavity of the TargetCool™ device; and
- Two wings protruding from the circular base, each

wing configured to fit in a corresponding groove on the edge of the cartridge cavity of the TargetCool™ device; and

- Two white O-rings (one small and one larger) that are attached to the filter. The O-rings must be present and attached to the filter when it is installed and when the cartridge is being installed. The O-rings are configured to help seal the cartridge to the TargetCool™ device and keep gas from escaping. If one or both of the O-rings are not attached to the filter initially, reattach them.

2.1.4 Cartridge

The cartridge is fully sealed and filled with compressed liquefied carbon dioxide. Each cartridge lists the weight of the cartridge and information about the lot that the cartridge was produced.

After the cartridge filter (with O-rings attached) is installed, the narrow portion of the cartridge is configured to fasten into the threads found inside the cartridge cavity of the TargetCool™ device. Rotating the cartridge right will fasten it, while rotating the cartridge left will unfasten it.

The cartridge is made of aluminum and is fully recyclable.

2.2 Who Can Use the Consumables in the TargetCool™ Consumables Kit

The consumables of the TargetCool™ Consumables Kit are intended to be used only by a trained physician or by a physician-designated medical professional.

Safety and Regulations

This chapter provides an overview of the relevant safety signals, color labels, marks, and other symbols used throughout this manual and related TargetCool™ products. This chapter also outlines the safety measures and regulations that should be taken for the safety of the operator and/or patient and for the maintenance of the TargetCool™ device. The operator is responsible for fully understanding the safety measures and properly operating the device.

CoolHealth will not be responsible for any adverse events or issues caused by the operator's failure to comply with the safety measures.

3.1 Safety Signals and Color Labels

The following safety signals and color labels describe important warning and safety information according to the level of risk. Make sure you and any operator fully understand the safety signals, color labels, and accompanying warning and safety information to prevent injury to the operator and/or the patient and to prevent damage to the TargetCool™ device, the TargetCool™ consumables, or the environmental surroundings.



DANGER

Indicates information that should be followed with utmost care. Failure to comply could result in death or severe injury to the patient or operator.



WARNING

Indicates a situation where a potentially hazardous condition exists that could result in death and injury to patient or operator.



CAUTION

Indicates a situation that demands careful action. Failure to comply could result in minor injury to the patient or operator.

IMPORTANT








Indicates a situation or action that could potentially cause problems to the device and/or its operation.

NOTE


Emphasizes important information or provides useful techniques and hints.

3.2 Symbols and Descriptions

The following is a key that explains the different symbols found throughout the User Manual and related TargetCool™ products.


| SYMBOLS | DESCRIPTION |
|--|--|
|  | Date of manufacture |
|  | Addresses where the device was manufactured |
|  | Serial number |
|  | Use-by date |
|  | Catalog number |
|  | Refer to User Manual |
|  | Indicates that electrical and electronic devices must not be disposed of as unsorted municipal waste and instead must be collected separately. |

3.3 Operator's Qualifications

| CAUTION | |
|---|---|
|  | <p>The TargetCool™ system may only be operated by personnel fully trained in its operation. To operate this device, the operator must:</p> <ul style="list-style-type: none"> Be a trained physician or physician-designated medical professional. Have read and understood the User Manual. Be familiar with the fundamental structure and functions of the TargetCool™ device and consumables. Be able to recognize the irregular operation of the TargetCool™ device and consumables and take appropriate measures to address such irregularities. |


3.4 Operator's Obligations

The operator should inspect, clean, and perform general maintenance on the TargetCool™ device as provided in Section 6 (General Maintenance).

| WARNING | |
|---|--|
|  | <p>The TargetCool™ system may be hazardous to patients if proper procedure safety measures and/or operating instructions are not observed. It is important to read this User Manual carefully and strictly abide by all its warnings and instructions.</p> |

3.5 General Safety Management

The operator should inspect, clean, and perform general maintenance on the TargetCool™ device as provided in Section 6 (General Maintenance).



| CAUTION | |
|---|--|
|  | <p>Do not use the TargetCool™ system in an environment that is susceptible to explosion.</p> <p>Operate the device within a temperature range of 15°C to 30°C (59°F to 86°F).</p> <p>Do not place the TargetCool™ device in direct contact with heat, humidity, grease, or dust.</p> <p>Do not expose the TargetCool™ device to liquids, mists, or sprays.</p> <p>Exposing this device to liquids may cause an electric shock or otherwise damage the device.</p> <p>Do not use spray cleaners on the TargetCool™ device as this may be a fire hazard.</p> <p>Do not block the outlet of the nozzle with any foreign objects.</p> <p>Use the TargetCool™ device in a well-ventilated area.</p> <p>If cartridges have been stored in a hot area, keep the cartridges at room temperature for approximately two hours before installation.</p> |

3.6 Operational Safety Management

Check the environmental conditions before operating the TargetCool™ device. Turn off the Power Switch when the TargetCool™ device is not in use. Do not charge the device when in use.

Tampering with the TargetCool™ device in any way is prohibited by law, may negatively impact device performance, will void any warranty, and may cause injury or harm to the patient or operator.

Using non-TargetCool™ consumables or accessories with the TargetCool™ device may negatively impact device performance, will void any warranty, and may cause injury or harm to the patient or operator.


| | |
|---|---|
|  | WARNING |
| | Immediately stop using the TargetCool™ device if an error message appears on the LCD display. |
|  | CAUTION |
| | Do not place the device near flammable materials. In case of physical impact or dropping of the device, please check the device status through the Status Light. |

3.7 Electromagnetic Compatibility (EMC)

Electromagnetic compatibility (EMC) is the ability of electrical equipment and systems to function acceptably in their electromagnetic environment, by limiting the unintentional generation, propagation and reception of electromagnetic energy which may cause unwanted effects such as electromagnetic interference (EMI) or even physical damage to operational equipment.

The TargetCool™ complies with IEC standard 60601-1-2. This medical electrical device is subject to special Electromagnetic Compatibility (EMC) preventive measures. The TargetCool™ device must be installed and operated as specified in EMC information.

Observe the following safety rules to ensure EMC.

| | |
|---|---|
|  | WARNING |
| | Do not put electromagnetic wave generators (such as transmitters, wireless toys, etc.) near the place where the device is stored. |

| | |
|--|---|
| | Electromagnetic waves can cause device malfunction. |
|--|---|

| | |
|--|---|
| | If an electromagnetic wave generator is brought into the area near the TargetCool™ device, instruct the user to turn off the generator. |
|--|---|

3.8 Standards and Regulations

3.8.1 Standards

The TargetCool™ system is designed and developed to comply with the following international standards and regulations:

- Medical Device Directive 93/42 EEC revised by 2007/47/EC
- ISO 13485: Medical Device Quality Management System
- ISO 14971: Application of Risk Management to Medical Devices
- IEC 60601-1: Medical Electrical Equipment
- UL 60601-1: Medical Electrical Equipment
- IEC 60601-1-2: Collateral Standard for Electromagnetic Compatibility
- IEC 62304: Medical Device Software
- ISO 10993-1: Biological Evaluation of Medical Device
- IEC 62366: Medical Device Usability Engineering
- ISO 15223-1: Medical Devices-Symbols to be used with medical device labels, labeling and information to be supplied


3.8.2 Classifications (IEC 60601-1 6.1)



Type B Applied Parts





3.9 Labeling

3.9.1 TargetCool™ device Label

Trade Name : TargetCool
 Product Name : Cryosurgical unit
 Model Name : RM-DT02W
 Class type : Internally powered, Type B 
 Rating : (Battery) 7.2 V===, 3350mAh


 2265 

 RecensMedical Inc.
 #507, #908, SK V1 center, 830 Dongtansunhwan-daero,
 Hwaseong-si, Gyeonggi-do, Republic of Korea, 18468
 Tel : +82-31-8043-3064 / Fax : +82-31-630-2092

 CMC Medical Devices & Drugs S.L.
 C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain

SN MADE IN KOREA



3.9.5 Boosting Container pack label

TargetCool 


Model Name : Boosting Container Type 1 pack
 Identifier : AS00000017


QTY 10 ea LOT


 RecensMedical Inc.
 #507, #908, SK V1 center, 830 Dongtansunhwan-daero,
 Hwaseong-si, Gyeonggi-do, Republic of Korea, 18468
 Tel : +82-31-8043-3064 / Fax : +82-31-630-2092


 2265 



3.9.2 TargetCool™ device Packaging Label

TargetCool 

TRADE NAME : TargetCool
 PRODUCT NAME : Cryosurgical unit
 MODEL NAME : RM-DT02W
 CLASS TYPE : Internally powered, Type B 
 DEVICE WEIGHT : 457g
 RATING : Li-ion polymer Battery (7.2 V===, 3350mAh)

 RecensMedical Inc.
 #507, #908, SK V1 center, 830 Dongtansunhwan-daero,
 Hwaseong-si, Gyeonggi-do, Republic of Korea, 18468
 Tel : +82-31-8043-3064 / Fax : +82-31-630-2092

 CMC Medical Devices & Drugs S.L.
 C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain

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MADE IN KOREA

SN Identifier: AS00000011

UDI Label

3.9.3 TargetCool Consumable kit box label

TargetCool 

Model Name : TargetCool Consumable kit
 Identifier : AS00000016

Components :

- Guard (10ea)
- CO₂ Cartridge (10ea)
- Filter (10ea)

QTY 10 SET LOT Exp. date: 

 RecensMedical Inc.
 #507, #908, SK V1 center, 830 Dongtansunhwan-daero,
 Hwaseong-si, Gyeonggi-do, Republic of Korea, 18468
 Tel : +82-31-8043-3064 / Fax : +82-31-630-2092

 2265 

3.9.4 Delivery packaging label

TargetCool 

Identifier: AS00000011

 SN 

   90% 10%  70°C -40°C  1060hPa 500hPa

 RecensMedical Inc.
 #507, #908, SK V1 center, 830 Dongtansunhwan-daero, Hwaseong-si,
 Gyeonggi-do, Republic of Korea, 18468
 Tel : +82-31-8043-3064, Fax : +82-31-630-2092
 e-mail : sales@recensmedical.com

More About the TargetCool™ Device

This chapter provides more information on the TargetCool™ system and more information on specific parts of the TargetCool™ device.

4.1 TargetCool™ device Components

| No. | ELEMENTS |
|-----|-----------------------|
| 1 | Infrared (IR) Sensors |
| 2 | Guard Dock |
| 3 | Status Light |
| 4 | Trigger |
| 5 | LCD Display |
| 6 | Knob |
| 7 | Cartridge Cavity |
| 8 | Power LED Indicator |
| 9 | Charge Port |
| 10 | Power Switch |

4.1.1 Infrared (IR) Sensors

The Infrared (IR) sensors (not shown), which are located near the bolt and the guard dock, are configured to detect the current temperature of the target area.

4.1.2 Guard Dock

The guard dock is configured to have the guard (sold separately) attached, which will magnetically attach to the guard dock.



4.1.3 Status Light

The Status Light is configured to display various light colors and configurations depending on the status of the TargetCool™ device.

A key to the different light colors and configurations is provided below:



| STATUS | STATUS LIGHT |
|---------------|--|
| Power On | Glowing Green |
| SET UP Screen | Solid Green |
| READY Screen | Glowing Blue |
| IN USE Screen | Glowing Blue |
| | Solid Blue (Reach to setting temp.) |
| 1°C or Below | Blinking Light Blue |
| Abnormal | Solid Orange |

4.1.4 Trigger

The trigger is configured to be pressed and held, which engages various functions such as starting the spray of cryogen, stopping the spray of cryogen, or testing the IR temperature sensors.



4.1.5 LCD Display

The LCD Display is configured to provide information about the TargetCool™ device operations and status.

4.1.6 Knob

The knob is configured to be turned, pressed, or held to perform various TargetCool™ device operations.

4.1.7 Cartridge Cavity

The cartridge cavity is where the cartridge filter (sold separately) can be inserted and the cartridge (sold separately) can be fastened.

The cartridge cavity and the two grooves on its edge are configured to receive the cartridge filter's circular base and two wings.

The cartridge cavity is threaded. Rotating the cartridge right will fasten the cartridge into the cartridge cavity. Rotating the cartridge left will unfasten the cartridge from the cartridge cavity.



4.1.8 Power LED Indicator

The Power LED Indicator displays different light colors depending on the battery status of the TargetCool™ device.

A key explaining the different light colors and configurations is provided below. (Reminder: do not operate the device when it is plugged into the charger.)

| STATUS | STATUS LIGHT |
|----------|--------------|
| Charging | Solid Orange |
| Charged | Solid Green |



4.1.9 Charge Port

The charge port, which is located near the Power LED Indicator, is where the charger (USB-C) attaches.

4.1.10 Power Switch

The power switch, which is located near the Power LED Indicator, turns the device ON or OFF.

Using the TargetCool™ Device

This chapter provides instructions on how to use the TargetCool™ system, including instructions on how to install the TargetCool™ consumables onto the TargetCool™ device, instructions on how to operate TargetCool™, and instructions on how to remove consumables from the TargetCool™ device.

IMPORTANT

Before following any of the instructions in this chapter, it is strongly recommended that you familiarize yourself with the entire User Manual, in particular Chapter 1 (Introduction), Chapter 2 (TargetCool™ Consumables), and Chapter 4 (More About the TargetCool™ device).

5.1 Instructions on How to Install the Consumables onto the TargetCool™ Device

To install the TargetCool™ consumables onto the TargetCool™ device, you will need; (1) the TargetCool™ device with the nozzle attached and fully fastened; and (2) a guard, an unused cartridge filter (with two white O-rings attached), and an unused cartridge from the TargetCool™ Consumables Kit (sold separately).

NOTE

Before beginning these steps, ensure that the nozzle is fully fastened to the device. The nozzle is fully fastened when the black O-ring between it and the device is no longer visible.

STEP 1: Select Nozzle and fully fasten it to the TargetCool™

"Based on the mode (Cooling, Freezing, or Boosting) you intend to use, select the corresponding nozzle and attach it to the TargetCool™ device."

- Cooling nozzle
- Boosting nozzle
- Freezing nozzle (F08 & F15)



STEP 2-1: (Only for Cooling nozzle) Attach the guard onto the Guard Dock

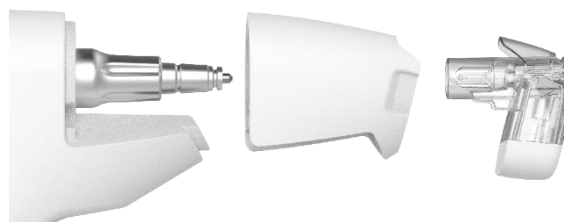
Find the guard and the three magnets on the back of the guard. The magnets are configured to attach

to the guard dock.

Position the guard and its magnets onto the guard dock of the TargetCool™ device. Ensure when handling the guard to avoid contacting the front portion of the guard, which is configured to contact the target area.

STEP 2-2: (Only for Boosting nozzle) Attach the Boosting container to the Boosting guard

After fastening the Boosting nozzle to the device and attaching the Boosting guard to the guard dock, insert the Boosting container into the Boosting nozzle.



**STEP 2-3: (Only for Freezing nozzle F08)
Inspect the Guard Dock**

No guard is used with Freezing nozzle F08. So, inspect the Guard Dock once again to make sure nothing is attached.



**STEP 2-4: (Only for Freezing nozzle F15)
Inspect the Guard Dock**

Find the guard and the three magnets on the back of the guard. The magnets are configured to attach to the guard dock.



STEP 3: Inspect the Cartridge Cavity

Find the cartridge cavity of the TargetCool™ device. Inspect the cartridge cavity and its grooves and ensure that the area is clear of any blockage (e.g., remnants of previously used cartridge filters).

STEP 4: Insert the Cartridge Filter into the Cartridge Cavity

Find the cartridge filter and the cartridge cavity. Pick up the cartridge filter by its wings. Insert the cartridge filter by its base first inside the cartridge cavity.

NOTE

Make sure that both white plastic O-rings are attached to the center of the filter. Hold the filter by its wings and insert it fully into the cartridge cavity. It is not uncommon for the smaller O-ring to have become detached from the filter during shipping or storage. If it is not present on the filter, make sure to reattach it.

Position the cartridge filter so that the wings line up and rest inside the corresponding two grooves on the edge of the cartridge cavity. Push the cartridge filter by the wings so that the base of the cartridge filter rests firmly inside the cartridge cavity. Ensure that the circular base of the cartridge filter is fully inserted into the cartridge cavity.

STEP 5: Fasten a Cartridge into the Cartridge Cavity

Find the cartridge and the cartridge cavity, which should already have the cartridge filter fully inserted per Step 5. Hold the TargetCool™ and position the cartridge so that it is being inserted *vertically from below* into the cartridge cavity. Insert the narrow, threaded portion of the cartridge into the cartridge cavity.

IMPORTANT

Throughout the cartridge fastening process, ensure that the cartridge filter remains flush inside the cartridge cavity. This may be difficult to do when the device is pointing up. This can be addressed by positioning a thumb under one of the wings of the filter to maintain the cartridge filter in the flush position while the device is pointing upwards.

Begin fastening the cartridge into the cartridge cavity by rotating the cartridge right and continuing to rotate it until the cartridge is fully fastened. The cartridge is fully fastened when you are no longer able to comfortably rotate the cartridge.

IMPORTANT

As you fasten the cartridge into the cartridge cavity, you may hear some gas noise coming from the cartridge. Continue fastening the cartridge and turning it to the right into the cartridge cavity and the gas noise should stop. If you hear gas noise coming out of the cartridge cavity area even after the cartridge is fully fastened, please refer to the FAQ (Section 7 FAQ 8). If problems persist, contact CoolHealth.

The consumables are all now installed on the TargetCool™ device and the device is now ready to operate. Please proceed to Section 5.2 for instructions on how to operate the device.



CAUTION

During installation, do not remove and store any cartridge that has come into contact with the filter. Contact with the filter may cause a scratch or small hole in the cartridge inlet, leading to gas leakage. Therefore, all cartridges must be properly installed and disposed of. Follow the instructions 5.5 on How to Remove and Dispose of Used Consumables.

IMPORTANT

If the TargetCool™ device does not turn on, it may be that there is not enough charge in the TargetCool™ device. Please turn off the device, connect the USB-C charger to the charge port and charge the device for at least half an hour before attempting to turn the device on again. If the device continues to not function, please toggle the power switch OFF and contact CoolHealth.

5.2 Instructions on How to Operate the TargetCool™ Device (Cooling Mode)

IMPORTANT

Before proceeding with this section:

- Ensure that the TargetCool™ device is unplugged.
- Ensure that you have properly completed all the steps in sections 5.1 and 5.2.
- Ensure that your environment conditions are within a temperature range of 15°C to 30°C (59°F to 86°F).
- Ensure that you are in a well-ventilated space.



STEP 1: Turn On the TargetCool™ Device

Find the power switch near the bottom of the TargetCool™ device and toggle it to turn it ON. The Status Light will show a flashing or “breathing” green color.

STEP 2: Inspect the LCD Display



Find the LCD Display and confirm it is showing the screen in the above image. This is the SET UP SCREEN and the Status Light will show a solid green color.

STEP 3: Aim the TargetCool™ Device at a Fixed Surface

Hold and aim the TargetCool™ device so that the distal portion of the guard is towards a fixed surface. The fixed surface should be flat, non-metallic, and have a fixed temperature.

STEP 4: Press and Hold the Trigger Until You Hear Two Beeps

Find the trigger. While aiming the TargetCool™ device to the appropriate surface, press and hold the trigger. After several seconds of holding the trigger, the device should beep twice, which signals that the IR temperature sensors are properly functioning.

NOTE

If the Error screen appears, it may be that TargetCool™ is not being aimed at an appropriate surface. Turn off the device and repeat the previous start-up steps, ensuring that the guard of the TargetCool™ device is resting lightly on a flat surface. If the problem persists, contact CoolHealth.

STEP 5: Inspect the LCD Display



Find the LCD Display and confirm it is showing the above screen. The LCD Display will be showing "Target Temp.", which means the desired temperature that you want the target area to reach, and below that "Time at Target Temp.", which means the desired duration for which you want the target area to remain cooled at the Target Temp.

STEP 6: Turn the Knob to Set Up the Target Temp.

Find the knob. Turn the knob right to increase the desired Target Temp. and left to lower the desired Target Temp. Each click of the knob will allow you to adjust the Target Temp. by 1° increment anywhere between -10°C to 5°C (or 14°F to 41°F).

STEP 7: Press the Knob to Toggle to Time at Target Temp.

Once you have settled on the desired target temp., press the knob to toggle from adjusting the Target Temp. to adjusting the Time at Target Temp. You will see that you have successfully toggled to the Time at Target Temp. setting when the two arrows adjacent to the Target Temp. number disappear and instead appear adjacent to the Time at Target Temp. number.

STEP 8: Turn the Knob to the Desired Time at Target Temp.

Find the knob. Turn the knob right to increase the desired Time at Target Temp. and left to lower the desired Time at Target Temp. by a 1-sec increment anywhere between 1 to 60 seconds or select the desired modes (PL, Continuous). Each click of the knob will allow you to adjust the Target Temp.

- ▶ **PL mode™** – PL will provide a preset time
- ▶ **Continuous mode** – Continuous will spray coolant without any time limitation



NOTE

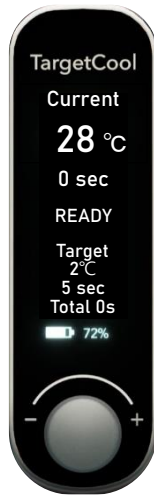
If you do not want the TargetCool to automatically stop spraying, set the desired Time at Target Temp. to Continuous. The device will spray until you re-press the trigger.

OPTIONAL: If you want to go back and adjust the Target Temp., you can do so by pressing the knob to toggle back. You will see that you have successfully toggled back to the Target Temp. setting when seeing the two arrows adjacent to the Time at Target Temp. number disappear and appear adjacent to the Target Temp. number. You can toggle back and forth between the two different settings by pressing the knob button.

STEP 9: Press and Hold the Knob Until You Hear Two Beeps

Find the knob. Once you have settled on the desired Target Temp. and Time at Target Temp., press and hold the knob. After several seconds of holding the knob, the device will beep twice, which signals that the Target Temp. and the Time at Target Temp. are set and the operator is ready to move to the READY screen.

STEP 10: Inspect the LCD Display



Find the LCD Display and confirm that it is showing the above screen. The LCD Display will show at the top the current temperature of the target area, followed by the number of seconds the cryogen has been emitted (0 sec to start), and below that the desired set temperature and time duration. During this step, the Status Light will show a glowing or “breathing” blue light.

NOTE

OPTIONAL: If you want to go back to the SET UP screen, you can do so by pressing and holding the knob in the READY screen.

STEP 11: Position Guard and Nozzle Over the Target Area

Find the attached guard and the outlet of the nozzle. Position the guard and nozzle so that the distal portion of the guard is resting on the surface of the target area and the outlet of the nozzle is over the target area. The temperature reading under the “Current” heading on the LCD Display should show the real-time temperature of the target area.

IMPORTANT

Hold the TargetCool™ device so that it is tilted forward (ideally at a 45° angle relative to a flat floor), allowing the cryogen within the cartridge to flow downward. Failure to properly position the device may limit the device’s ability to rapidly or properly cool the target area to the target temperature.

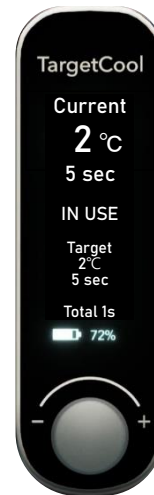
Press the guard *lightly* against the skin, to avoid skin at the target area protruding into the guard, which can cause errors in reading the real-time

temperature at the area immediately in front of the guard.

NOTE

OPTIONAL: It is a good idea to initially test the device on the palm of the hand of the user, in order to determine whether the device is properly reaching the target settings. Position the guard and nozzle over the palm and proceed with Steps 12 and 13 (starting and stopping the spray). If the device is not functioning correctly, repeat the previous set-up steps or consult the FAQs (Section 7).

STEP 12: Press the Trigger to Start the Spray



Find the trigger. Once you have properly placed the guard and nozzle over the target area and are holding the device with the appropriate forward tilt, press the trigger.

After pressing the trigger:

- The LCD Display will change from READY to IN USE.
- The device will begin spraying the temperature-controlled cryogen onto the target area.
- As the target area is being sprayed, the temperature reading under the “Current” heading (“Current Temp.”) should drop from the uncooled temperature of the target area to the Target Temp. set during the SET UP screen (and to the temperature depicted underneath the “Target” heading in the above screen). When the Current Temp. reaches the set Target Temp., the device will beep once (high-pitched). The Status Light will become a solid blue.

IMPORTANT

Each device has an estimated 180 seconds of total cooling spray time. After that, the device will continue to spray residual gas but will not cool the target area. If the target area is no longer being cooled properly, it is because the cooling spray time has elapsed. The cartridge is now spent and must be replaced.

If the device is set to -1°C or below, if the target area reaches that temperature, the device status light will change color to a blinking light blue.

- Once the Current Temp. reaches the set Target Temp., the time under the "Current" heading ("Current Time at Target Temp.") should start counting up. When the Current Time at Target Temp. reaches the set Time at Target Temp. (i.e., the time depicted underneath the "Target" heading on the above screen), the device should beep once (low-pitch).
- The device will continue to spray until the target time at the target temperature has been reached, and will then shut off after some remaining gas has discharged.

STEP 13: Press the Trigger Once to Stop the Spray

IMPORTANT

If the target area is not able to reach the set temperature, the device will beep repeatedly. Please read below for possible solutions.

If the cartridge is spent, it may be time to remove, dispose, and replace the cartridge (along with the other consumables). Please refer to Section 5.5 to find instructions on how to remove used consumables. Please refer to Section 5.1 to find instructions on how to install new consumables.

Pressing the trigger to stop the spray will move the LCD Display back from the IN USE to READY screen.

OPTIONAL STEP: Reposition Guard and Nozzle Over Any Additional To-Be Cooled Target Areas

If the operator wishes to cool any additional target areas while the device is spraying the temperature-controlled cryogen, the operator can reposition the guard and nozzle over the new target area. In doing so:

- The device will continue to spray the temperature-controlled cryogen onto the target area
- As the target area is being sprayed, the temperature reading under the "Current" heading ("Current Temp.") should drop from the uncooled temperature of the target area to the Target Temp. set during the SET UP screen (and to the temperature depicted underneath the "Target" heading in the above screen). When the Current Temp. reaches the set Target Temp., the device should beep once.
- Once the Current Temp. reaches the set Target Temp., the time under the "Current" heading ("Current Time at Target Temp.") should start counting up. When the Current Time at Target Temp. reaches the set Time at Target Temp. (i.e., the time depicted underneath the "Target" heading on the above screen), the device should beep once (low-pitch).

IMPORTANT

Each device has an estimated 180 seconds of total cooling spray time. After that, the device will continue to spray residual gas but will not cool the target area. If the target area is no longer being cooled properly, it is because the cooling spray time has elapsed. The cartridge is now spent and must be replaced.

If the target area is not able to reach the set target temperature, it may be because you are holding the device incorrectly (see Step 11 and instructions about holding the device at preferably a 45° angle). Alternatively, it may be because your cartridge is spent (no longer capable of cooling).

If the cartridge is spent, it may be time to remove, dispose of, and replace the cartridge (along with the other consumables). Please refer to Section 5.5 to find instructions on how to remove used consumables. Please refer to Section 5.1 to find instructions on how to install new consumables.

STEP 14: Turn Off the TargetCool™ Device

When you are finished using the TargetCool™ system, turn the device off. Find the power switch on the bottom of the device. Toggle the power switch to OFF to turn the device off.

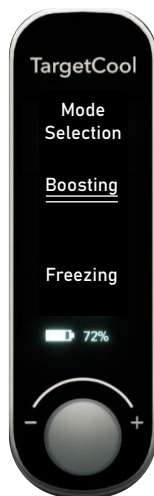
5.3 Instructions on How to Operate the TargetCool™ Device (Boosting Mode)



STEP 1: Turn On the TargetCool™ Device

Find the power switch near the bottom of the TargetCool™ device and toggle it to turn it ON. The Status Light will show a flashing or “breathing” green color.

STEP 2: Inspect the LCD Display



Find the LCD Display and confirm it is showing the screen in the above image. This is the MODE Selection and the Status Light will show a solid green color.

IMPORTANT

If the TargetCool™ device does not turn on, it may be that there is not enough charge in the TargetCool™ device. Please turn off the device, connect the USB-C charger to the charge port and charge the device for at least half an hour before attempting to turn the device on again. If the device continues to not function, please toggle the power switch OFF and contact CoolHealth.

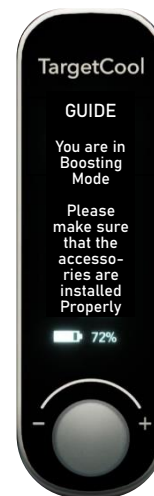
STEP 3: Turn the Knob to Select Boosting Mode

Find the Knob. Turn the knob to cycle through the Freezing and Boosting modes. Turn the Knob to place = mark is under the “Boosting”.

STEP 4: Press and Hold the Knob Until You Hear Two Beeps

Once you have settled on the Boosting mode, press and hold the knob. After several seconds of holding the knob, the device will beep twice.

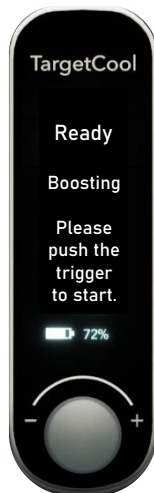
STEP 5: Inspect the LCD Display



Find the LCD Display and confirm that it is showing the above screen. The LCD Display will read “You are in Boosting Mode” and “Please make sure that the accessories are installed properly”. During this step, the Status Light will show a glowing or “breathing” blue light.

STEP 6: Press and Hold the Knob Until You Hear Two Beeps

Find the knob. Press and hold the knob. After several seconds of holding the knob, the device will beep twice, which signals that the Boosting mode is set and the operator is ready to move to the Ready screen.



STEP 7: Position Boosting Container and Boosting Guard Over the Target Area

Find the attached Boosting Container and Boosting guard. Position the Boosting Container and Boosting guard so that the outlet of the Boosting Container is over the target area.

IMPORTANT

Hold the TargetCool™ device so that it is tilted forward (ideally at a 45° angle relative to a flat floor), allowing the cryogen within the cartridge to flow downward. Failure to properly position the device may limit the device's ability to rapidly or properly cool the target area to the target temperature.

STEP 8: Press the Trigger to Start the Spray

Find the trigger. Once you have properly placed the guard and nozzle over the target area and are holding the device with the appropriate forward tilt, press the trigger.

After pressing the trigger:

- The LCD Display will change from Ready to Boosting.
- The device will begin spraying the temperature-controlled cryogen onto the target area.



STEP 9: Press the Trigger Once to Stop the Spray

IMPORTANT

If the target area is not able to reach the set temperature, the device will beep repeatedly. Please read below for possible solutions.

If the cartridge is spent, it may be time to remove, dispose, and replace the cartridge (along with the other consumables). Please refer to Section 5.5 to find instructions on how to remove used consumables. Please refer to Section 5.1 to find instructions on how to install new consumables.

Pressing the trigger to stop the spray will move the LCD Display back from the Boosting to Ready screen.

STEP 10: Turn Off the TargetCool™ Device

When you are finished using the TargetCool™ system, turn the device off. Find the power switch on the bottom of the device. Toggle the power switch to OFF to turn the device off.

5.4 Instructions on How to Operate the TargetCool™ Device (Freezing Mode)



(Freezing Nozzle - F08)

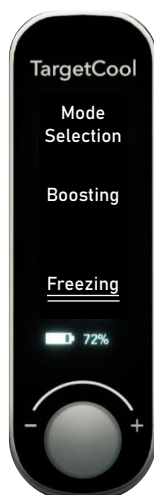


(Freezing Nozzle - F15)

STEP 1: Turn On the TargetCool™ Device

Find the power switch near the bottom of the TargetCool™ device and toggle it to turn it ON. The Status Light will show a flashing or “breathing” green color.

STEP 2: Inspect the LCD Display



Find the LCD Display and confirm it is showing the screen in the above image. This is the Mode Selection and the Status Light will show a solid green color.

IMPORTANT

If the TargetCool™ device does not turn on, it may be that there is not enough charge in the TargetCool™ device. Please turn off the device, connect the USB-C charger to the charge port and charge the device for at least half an hour before attempting to turn the device on again. If the device continues to not function, please toggle the power switch OFF and contact CoolHealth.

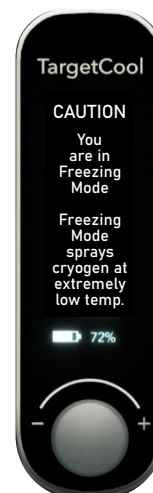
STEP 3: Turn the Knob to Select Freezing mode

Find the knob. Turn the knob to cycle through the Freezing, and Boosting modes. Turn the Knob to place = mark is under the “Freezing”.

STEP 4: Press and Hold the Knob Until You Hear Two Beeps

Once you have settled on the Freezing mode, press and hold the knob. After several seconds of holding the knob, the device will beep twice.

STEP 5: Inspect the LCD Display



Find the LCD Display and confirm that it is showing the above screen. The LCD Display will read that “You are in Freezing Mode” and “Freezing mode sprays cryogen at extremely low temp.”. During this step, the Status Light will show a glowing or “breathing” blue light.

STEP 6: Press and Hold the Knob Until You Hear Two Beeps

Find the knob. Press and hold the knob. After several seconds of holding the knob, the device will beep twice, which signals that the Freezing mode is set and the operator is ready to move to the READY screen.

STEP 7: Position Nozzle Over the Target Area

Find the outlet of the nozzle. Position the nozzle so that the outlet of the nozzle is over the target area.

IMPORTANT

Hold the TargetCool™ device so that it is tilted forward (ideally at a 45° angle relative to a flat floor), allowing the cryogen within the cartridge to flow downward. Failure to properly position the device may limit the device's ability to rapidly or properly cool the target area to the target temperature.

STEP 8: Press and Hold the Trigger to Start the Spray



Find the trigger. Once you have properly placed the nozzle over the target area and are holding the device with the appropriate forward tilt, press the trigger.

- Hold the trigger for continuous application of cryogen.
- The procedure stops when the trigger is released.
- The Freezing time means the time of spraying.
- The Total time means the accumulated injection time when the trigger is sprayed several times.

STEP 9: Turn Off the TargetCool™ Device

When you are finished using the TargetCool™ system, turn the device off. Find the power switch on the bottom of the device. Toggle the power switch to OFF to turn the device off.

5.5 Instructions on How to Remove and Discard Used Consumables

Remove all used consumables by following these steps:

STEP 1: Ensure that the TargetCool™ Device Is Off

Find the power switch on the bottom of the device. Toggle the power switch to OFF to turn the device off.

STEP 2: Put the Cartridge Sleeve over the Cartridge

Find the cartridge and the cartridge sleeve. Put the cartridge sleeve over the cartridge. This will provide insulation should the cartridge become very cold during removal.

STEP 3: Point the Guard Up (So the Cartridge Is Inserted Vertically)

Hold the TargetCool™ device and position the cartridge so that it is being inserted vertically from below into the cartridge cavity.

STEP 4: Slowly Turn the Cartridge Left for a Quarter Rotation

Find the used cartridge fastened to the TargetCool™ device. While holding the device per Step 2, slowly turn the cartridge left for a quarter of a turn. You may hear the sound of any remaining gas in the cartridge coming out. This is normal and will likely last for around 10 seconds. Wait until this sound stops before proceeding to Step 5.

STEP 5: Completely Unfasten and Discard the Cartridge

Find the partially rotated cartridge. After any remaining gas in the cartridge has escaped, continue rotating the cartridge to the left until the cartridge is completely unfastened from the cartridge cavity. Remove the cartridge sleeve. Dispose of the spent cartridge.

IMPORTANT

As any remaining gas in the cartridge is coming out, the surface of the cartridge may get cold. Hence, attach the cartridge sleeve to the cartridge to provide insulation. It is also recommended to wear protective gear over your hands.



WARNING

There may be a risk of electrostatic shock if the device is turned on when the cartridge is removed. Turn off the device power before removing the cartridge.

IMPORTANT

Do not dispose of the cartridge sleeve.



IMPORTANT

Follow relevant ordinances on the disposal of medical waste.

STEP 6: Remove and Discard the Cartridge Filter

Find the used cartridge filter. Grab the used cartridge filter by the cartridge filter wings to remove the cartridge filter from the cartridge cavity. Dispose of the used cartridge filter.



IMPORTANT

Follow relevant ordinances on the disposal of medical waste.

STEP 7: Inspect the Cartridge Cavity to Ensure No Blockage

Inspect the cartridge cavity to ensure that there is no

residue or blockages. If residue remains, use a cotton swab to remove it.

STEP 8: Remove and Clean the Used Guard

Find the used guard attached to the TargetCool™ device. Detach the guard from the device.

General Maintenance


6.1 Cleaning (After Every Patient)

The TargetCool™ system is designed so that maintenance and management of the device is minimized. However, to guarantee the most effective results, the exterior of the TargetCool™ device including the nozzle and the guard should be cleaned thoroughly at all times.

6.1.1 The TargetCool™ Device

First, make sure to remove and dispose of all the consumables per Section 5.5. Then, proceed to remove and set aside (do not discard) the fastened nozzle. Finally, make sure to clean the TargetCool™ device, including inside the cartridge cavity, with alcohol-based cleaning solutions. For optimum cleaning, it is recommended to clean the cartridge cavity surface with an alcohol-soaked cotton swab. Wipe dry with a dry cloth.

Using cleaners other than alcohol swabs can damage device appearance. Do not use spray cleaners or any harsh cleaning solutions to clean the device.

| | |
|---|--|
|  | CAUTION When cleaning the device, first toggle the Power Switch OFF and then disconnect the USB-C charger. |
|---|--|


6.1.2 The Nozzle

Make sure to clean the nozzle with alcohol-based cleaning solutions.

Do not use non-alcohol cleaners, such as spray cleaners or any harsh cleaning solutions, to clean the nozzle.

6.1.3 Guard Cleaning


1. Disconnect the guard from the device
2. Wipe the entire guard with an alcohol-coated cotton swab. Wipe the outside and inside of the contact area several times thoroughly.
3. Wipe the curved part on the inside of the guard.
4. Dry the cleaned guard completely and connect it back to the device.

| | |
|---|--|
|  | CAUTION The guard should be thoroughly and properly cleaned before applying it to treatment area of a patient. |
|---|--|

6.2 Battery and Charging

When the device is not in use, turn the Power Switch OFF. At this stage, it is recommended to connect the device to the USB-C charger to begin charging the device.

It is recommended that the device be turned ON only when operating the device.

| | |
|---|---|
|  | WARNING The device must not be connected to the USB-C charger while the operator is operating the device. |
|---|---|

| |
|--|
| IMPORTANT |
| If you notice any issues with the battery life, please contact CoolHealth. |

6.3 Storage

6.3.1 The TargetCool™ Device

When not in use, store the TargetCool™ device on a flat surface. Store at a temperature range of -40°C ~ 70°C (-40°F ~ 158°F). Do not store the device in any area near water or any area that is subject to extreme fluctuation of temperature, poor ventilation, direct sunlight, dust, or salt. Please refer to Section 8.1 for specific operation and storage temperatures.

6.3.2 The TargetCool™ Consumables Kit

The TargetCool Consumables Kit states the maximum temperature is 50°C. This is a conservative estimate; please avoid temperatures higher than 50°C if at all possible.

If cartridges have been stored in a hot area, keep the cartridges at room temperature for approximately two hours before installation.

For all used consumables, please dispose of them per Section 5.5.

6.4 Repairs

Only technicians authorized by CoolHealth can perform repairs on the equipment. When facing any technical issues with the device or consumables, first carefully review the User Manual. If the problem persists, please contact CoolHealth.

Do not attempt to tamper with, repair, modify, damage, or open up the TargetCool™ device or equipment. Doing so will void the warranty.

FAQ/Troubleshooting

This chapter provides responses to some of the most frequently asked questions an operator may have in connection with the TargetCool™ device, including the meaning of an error code portrayed on the LCD Display and common challenges the operator may encounter while operating the TargetCool™ device. We strongly recommend you review, become familiar with, and follow the instructions as provided in the User Manual. However, if any issues continue to

1

Q: The LCD Display shows one of the following error codes (E01, E02, E03, E04, E08, E09, and E46). What do they mean and how should I respond?

A: The following chart summarizes all the error codes, what they mean, and how the operator should respond:

| CODE | MEANING | SOLUTION |
|------|--|---|
| E01 | The main infrared (IR) temperature sensor may be malfunctioning, especially if the electrical connection between the IR sensor and the circuit board. | Turn the TargetCool™ device OFF, remove and dispose of any consumables on the TargetCool™ device, and contact CoolHealth. |
| E02 | The sub-infrared (IR) temperature sensor may be malfunctioning. | Turn the TargetCool™ device OFF, remove and dispose of any consumables on the TargetCool™ device, and contact CoolHealth. |
| E03 | Both the main and sub-infrared (IR) temperature sensors may be malfunctioning, with the electrical connection between them and the PCB (Printed Circuit Board) lost. | Turn the TargetCool™ device OFF, remove and dispose of any consumables on the TargetCool™ device, and contact CoolHealth. |

| CODE | MEANING | SOLUTION |
|------|--|---|
| E04 | One or both of the main and sub-infrared (IR) temperature sensors may have issues with temperature detection during the "Aim at the fixed surface" screen. | Turn the TargetCool™ device OFF and back ON. When the screen states "Aim at fixed surface" screen, ensure that the guard is resting on a flat, non-metallic, and temperature-fixed surface before pressing the trigger. If the error code persists, turn the TargetCool™ device OFF, remove and dispose of any consumables on the TargetCool™ device, and contact CoolHealth. |
| E08 | An internal component in the TargetCool™ device regulating temperature control may be malfunctioning. If the TEC cables are not connected to the PCB (Printed Circuit Board) or there is a problem with the TEC, the temperature will not be controlled. | Turn the TargetCool™ device OFF, remove and dispose of any consumables on the TargetCool™ device, and contact CoolHealth. |
| E09 | An internal component in the TargetCool™ device regulating temperature control may be malfunctioning. If the temperature of the regulator is too hot (>60°C) or the sensor is disconnected, an E09 error will pop up. | Turn the TargetCool™ device OFF, remove and dispose of any consumables on the TargetCool™ device, and contact CoolHealth. |

2

Q: Why is the TargetCool™ device not working even when I turn the power switch ON?

A: It may be that there is not enough charge in the TargetCool™ device. Please make sure the device is powered off and then connect the USB-C charger to the device and charge the device for at least half an hour before attempting to turn the device on again.

If the problem persists, keep the TargetCool™ device off, remove and discard any consumables on the TargetCool™ device, and contact CoolHealth.

3

Q: Why does the temperature or time on the LCD Display not adjust properly when I turn the knob?

A: It may be that you are turning the knob too quickly. Please try turning the knob slowly left or right one click at a time, which should resolve the issue.

If the problem persists, keep the TargetCool™ device off, remove and discard any consumables on the TargetCool™ device, and contact CoolHealth.

4

Q: There is a lot of noise from the cartridge when I unfasten it. Are there any ways to mitigate that noise?

A: There are three potential reasons:

1. Try to safely maximize the use of each cartridge before unfastening. The less remaining gas there is in the cartridge at the time it is removed, the less noise there should be.

2. At the outset of unfastening the cartridge, slowly rotate the cartridge and stop when reaching a quarter revolution. Gas should come out, but should come out in a slower and softer manner. Once all the gas has come out, continue rotating the cartridge until it is completely unfastened.

3. When unfastening the cartridge, make sure to position the device and cartridge so that the guard

is pointed up and the cartridge is positioned beneath it. This should also mitigate the noise during the cartridge unfastening.

If the problem persists, please contact CoolHealth.

5

Q: Instead of a smooth spray of cryogen, the spray cryogen is sputtering out of the outlet of the nozzle. What is the reason for this?

A: The issue may be that the nozzle is not sufficiently tightened onto the device. There is a black O-ring where the nozzle attaches to the device, but it should not be visible when the nozzle is fully tightened. When you notice the sputtering, please turn the device off, wait 5 minutes (to give time to let the nozzle return closer to room temperature), remove the guard (remembering to avoid touching the distal portion of the guard), unfasten the nozzle (it is recommended to wear protective gear over your hands), clean any residue that may be around the device and nozzle (using alcohol wipes or other alcohol-based cleaning solutions), and re-fasten the nozzle onto the device (ensuring that the nozzle is fully fastened so that the black O-ring on the device is no longer visible).

If the problem persists, keep the TargetCool™ device off, remove and dispose of any consumables on the TargetCool™ device, and contact CoolHealth.

If the problem persists, please contact CoolHealth

6

Q: Ice pellets are coming out of the outlet of the nozzle. What is the reason for this?

A: The issue may be that the nozzle is not sufficiently tightened onto the device. There is a black O-ring where the nozzle attaches to the device, but it should not be visible when the nozzle is fully tightened. When you notice the ice pellets, please turn the device off, wait 5 minutes (to give time to let the nozzle return closer to room temperature), remove the guard (remembering to avoid touching the distal portion of the guard), unfasten the nozzle (it is recommended to wear

protective gear over your hands), clean any residue that may be around the device and nozzle (using alcohol wipes or other alcohol-based cleaning solutions), and re-fasten the nozzle onto the device (ensuring that this time the nozzle is fully fastened so that the black O-ring on the device is no longer visible).

If the problem persists, keep the TargetCool™ device off, remove and dispose of any consumables on the TargetCool™ device, and contact CoolHealth.

If the problem persists, please contact CoolHealth.

7

Q: I understand the TargetCool™ device is configured to be able to reach the cooled target temperature within 5 seconds. But the device takes much longer to reach that target temperature (or does not even reach that target temperature at all). What is the reason?

A: There are three likely reasons:

1. You may be holding the device incorrectly. For optimum cooling performance, the operator should hold the device at a 45° angle while the device is spraying.
2. The cartridge may not be fully tightened onto the device.
3. If you find that the device is still not able to reach the desired target temperature within 5 seconds, it may be because the cartridge is spent. Each cartridge has approximately 180 seconds of total cooling spray time. If the cooling spray time has elapsed, then the cartridge will continue to spray gas but the target area will not be cooled. Please replace the cartridge.

If the problem persists, keep the TargetCool™ device off, remove and dispose of any consumables on the TargetCool™ device, and contact CoolHealth.

If the problem persists, please contact CoolHealth.

8

Q: There is an issue with CO₂ gas escaping during

use, or cryogen not being emitted properly from the device.

A: It is likely that the filter was not fully inserted into the cartridge cavity. Make sure that the filter (with both white O-rings attached) is fully inserted into the cartridge cavity before threading the cartridge into the cavity.

1. When installing the cartridge, the device should be held in a vertical position, which could loosen the filter. Ensure that the vertical position of the device does not cause the filter to become loose. You may find that fixing the filter in place, by positioning a thumb on one of its wings while installing the cartridge, helps.

2. It is also possible that the smaller white O-ring on the filter has fallen off. Remove the cartridge and check the filter to make sure that both O-rings are attached.

3. The cartridge has not been inserted fully, and therefore the filter is not flush to the cartridge cavity.

Additionally, it is normal for some CO₂ gas to discharge throughout the day. The cartridge is not meant to be left (opened) overnight.

Remove the cartridge and the filter, and ensure that both white O-rings are attached to the filter. Reinsert the filter and make sure that it remains flush to the cartridge cavity while the cartridge is being installed.

If the problem persists, please contact CoolHealth.

9

Q: The knob is not properly toggling settings / temperatures on the LCD Display.

A: The knob may need to be slightly “released” from its current position. Gently pull the knob toward you until you hear a click.

If the problem persists, please contact CoolHealth.

Specification

8.1 Operating & Storage Conditions

| ITEM | DESCRIPTION | |
|---------------------|----------------------|------------------------------|
| Operating Condition | Temperature | 15°C~30°C (59°F to 86°F) |
| | Humidity | 30% ~ 80% |
| | Atmospheric Pressure | 700~ 1060 hPa |
| Storage Condition | Temperature | -40°C ~ 70°C (-40°F ~ 158°F) |
| | Humidity | 10%~90% |
| | Atmospheric Pressure | 500~ 1060 hPa |

8.2 TargetCool™ Device Specifications

| ITEM | PRODUCT NAME |
|-----------------------------|---|
| Product name | Cryosurgical unit |
| Device name | TargetCool |
| Model No. | RM-DT02W |
| Rating | Battery: Li-ion Polymer battery pack 7.2 V, 3350 mAh Charger: PD charger (range: DC 5V—3A ~ 20V—1.5A) |
| Size of device | 5.86 x 9.76 x 1.53 [inch] / 149 x 248 x 39 [mm] |
| Weight of device | 457 g (1.007lb) |
| Target temperature accuracy | ±3°C |
| Product Life-cycle | 5 years |

Appendix A

9.1 Guidance and manufacturer's declaration

9.1.1 Electromagnetic emissions

| ELECTROMAGNETIC EMISSIONS | | |
|---|---|---|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment. | | |
| Immunity test | Compliance | Electromagnetic environment - Guidance |
| RF emissions | Group 1 | The device 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. |
| CISPR 11 | | |
| RF emissions | Class A | The device is suitable for use in all establishments other than domestic and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| CISPR 11 | | |
| Harmonic emissions | N/A | |
| IEC 61000-3-2 | | |
| Voltage fluctuations / flicker emissions | N/A | |
| IEC 61000-3-3 | | |
| Note | Do not use cables or components which are not currently used in the device. The electromagnetic emission performance of the device may be affected. | |

9.1.2 Electromagnetic immunity

| ELECTROMAGNETIC IMMUNITY | | | |
|---|---|--------------------------|--|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601-1-2 Test level | Compliance level | Electromagnetic environment - Guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV Contact ±2,±4,±8,±15 kV/ air | IEC 60601-1-2 Test level | 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 | IEC 60601-1-2 Test level | Main power quality should be that of a typical commercial or hospital environment. |
| Surge IEC61000-4-5 | ±1 kV line(s) to line(s) ±2 kV line(s) to earth | IEC 60601-1-2 Test level | Main power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | 0 % U_T (100% dip) for 0.5cycle 0% U_T (100% dip) for 1 cycle 70% U_T (30% dip) for 25 cycle 0% U_T (100% dip) for 250 cycle | IEC 60601-1-2 Test level | Main power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during main power interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery. |


ELECTROMAGNETIC IMMUNITY

| | | | |
|--|---|-----------------------------|---|
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | IEC 60601-1-2 Test level | 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 A.C. mains voltage prior to the application of the test level. Do not use cables or components which are not currently used in the device. The electromagnetic immunity performance of the device may be affected. | | |

9.1.3 Electromagnetic immunity – For non-life sustaining/supporting device

ELECTROMAGNETIC IMMUNITY

The device is intended for use in the electromagnetic environment specified as below. Customers or users of the TargetCool™ device should assure that it is used in such an environment. The TargetCool™ device is not intended to be life-sustaining or life-supporting.

| Immunity test | IEC 60601-1-2 Test level | Compliance level | Electromagnetic environment - Guidance |
|-------------------------------|--|------------------|--|
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz ~ 80 MHz | 3 Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: 150 kHz ~ 80 MHz: $d = 1.2 \sqrt{P}$ |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz ~ 2.5 GHz | 3 V/m | 80 MHz ~ 800 MHz: $d = 1.2 \sqrt{P}$ 800 MHz ~ 2.5 GHz: $d = 2.3 \sqrt{P}$ 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 meters(m). a) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the b) compliance level in each frequency range. Interference may occur in the vicinity of the equipment marked with the following symbol:  |
| Note 1: | At 80 MHz and 800 MHz, 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. | | |
| Note 3: | Do not use cables or components which are not currently used in the device. The electromagnetic immunity performance of the device may be affected. | | |
| 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 broadcasts, and TV broadcasts 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 where the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. | | |
| b: | Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m. | | |

9.1.4 Recommended separation distances between portable and mobile RF communications equipment and the device – For non-life sustaining/supporting device

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE DEVICE

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

| Rated maximum output power of transmitter (W) | Separation distance according to frequency of transmitter (m) IEC 60601-1-2 | | |
|---|---|--|---|
| | 150 kHz ~ 80 MHz $d = 1.2 \sqrt{P}$ | 80 MHz ~ 800 MHz $d = 1.2 \sqrt{P}$ | 800 MHz ~ 2.5 GHz $d = 2.3 \sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 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. |
| Note 3: | Do not use cables or components which are not currently used in the device. The electromagnetic immunity performance of the device may be affected. |

Product Warranty

Thank you for choosing our product. This product has passed strict quality assurance and testing procedures. CoolHealth, Inc. will take full responsibility and provide technical support for any manufacturing defect or any issue arising as a result of using the TargetCool™ device properly in accordance with the operation manual.

1. Warranty Period

This product has passed strict quality assurance and testing procedures. CoolHealth, Inc. provides free repair service for 12 months from the date of purchase for malfunctions arising as a result of using the product under normal operating conditions.

Please contact the dealer the product was purchased from or the customer service center of our head office for other malfunctions or inquiries.

Make sure you read the operation manual thoroughly before using the product.

2. Exceptions from Warranty

Malfunction or damage due to handling negligence or mistake by the customer.

Malfunction or damage due to a repair or modification by a third party.

Malfunction or damage due to the use of the product with a device not authorized by CoolHealth.

Malfunction or damage due to the use of the product for a purpose other than what it is intended for.

Malfunction or damage caused by natural disaster.

Please contact CoolHealth for other malfunctions or inquiries.

Make sure you read the operation manual thoroughly before using the product.

3. Repair after Warranty Period

Malfunctions that occur after the warranty period can be repaired at your own cost.

Issues that are not addressed in this warranty card are dealt with in accordance with consumer damage compensation rules under the Consumer Protection Act.



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