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ISO 9001 EN ISO 13485

USER MANUAL

CTC-7



This device is a medical device, designed to be used under a doctor's instruction.

This user manual is intended to keep user safety and prevent property damage.

Please keep this manual at a place where a user can find it whenever he/she needs.



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1

Device Information

1-1. CTC-7 Introduction

Thanks for purchasing CTC-7.

DAESUNG MAREF, we pledge to provide the highest quality device with excellent support and service.

This user manual specifies the procedures required for properly using, storing and repairing this device. In addition, this user manual specifies the instructions that must be followed to not only prevent causing property damages to users and other people, but also safely use the purchased device. Since it is important that you learn to control and connect the equipment in order to properly use this device, make sure to read and follow the instructions specified in this user manual prior to safely using this device.

Please always keep this manual with the device.

You must carefully read it before first use and as many times as needed.

 \divideontimes The IFU can be distributed in English / Korean.

If users request, we can provide IFU in the requested language.

1-2. Intended use

The purpose of this system is to treat post-operative injuries and acute injuries to reduce swelling, edema and pain. and It is to treat symptoms requiring medically or surgically local thermal therapy (Cold, Heat, RCT) after post-traumatic or post-operative.

1-3. Target Patient

a) Age: No restrictions

b) Body weight: No restrictionsc) Nationality: Plural (not relevant)d) Intended patient population: 1 person

e) Patient condition : 'Patients who need cooling, heating therapy after acute injury, trauma,

surgery (Not specified)

1-4. Contraindications

* The patient must not use to CTC-7 system if the patient is suspected the following.

Heat Therapy and/or Contrast Therapy

- Vascular dysregulation
- Vascular ischemic disease
- Venous or Arterial Occlusive Disease
- Acute inflammations of the Veins
- Local malignancy
- Acute inflammatory skin disease or infection
- Venous or Lymphatic return is not desirable
- Local or systemic active infection

- Incapacitated patients
- A pregnancy
- Acute unstable fracture
- Cutaneous insensitivity
- Acute trauma
- Bleeding diathesis
- Large scar

Cold therapy and/or **Contrast Therapy**

- Vascular dysregulation
- Vascular ischemic disease
- Venous or Arterial Occlusive Disease
- Acute inflammations of the Veins
- Decompensated Hypertonia
- Cerebral infraction
- Venous or Lymphatic return is not desirable
- Endocarditis
- Atheromatous embolic plaque
- Lymphedema after breast cancer
- Cold urticarial
- Atrial fibrillation
- Cutaneous insensitivity
- * The following patients must use the device for temperature contact therapy under the supervision of a physician.

Thermotherapy (Heat and Cold) and / or Contrast Therapy

- Decompensated Cardiac Insufficiency
- Hypertension, Cardiac failure
- Extreme low pressure

- Diabetes mellitus

- Multiple sclerosis- Spinal cord injuries
- Rheumatoid arthritis
- Poor circulation

- Extremities not sensitive to pain
- Raynaud's Disease
- Hypersensitive to cold
- Children
- Incapacitated patients
- Recent skin graft
- Unstable angina
- Uncontrolled blood pressure

1-5. Side effect

| Heat Therapy | - Burns - Skin discoloration - Increased pain - Increased inflammation | |
|------------------|---|--|
| Cold Therapy | FrostbiteCardiovascular effects (bradycardia)Raynaud's phenomenonCold urticarial | - Nerve and tissue damage - Slowed wound healing |
| Contrast Therapy | - Burns - Frostbite - Cold urticarial - Raynaud's phenomenon | |



Caution for safety

* Make sure that you follow all the specified cautions and warnings prior to using this device.

2-1. Electrical safety cautions

- When this device is not in use, disconnect the power cord.
- When you connect or disconnect the power cord to or from the socket, make sure to grab the plug instead of the line.
- When thunder and lightning cause a sudden blackout, turn off this device and disconnect the power plug.
- (There is a risk of device failure or electric shock.)
- Accurately connect the power cord so that it is rigidly plugged in. (When the power cord is not stably connected, there is a risk of malfunction and fire.)
- Make sure to untie the power cord prior to use.
- (There is a risk of heat generation and fire.)
- When you move this device, use the handle instead of pulling the power cord line.
- (When the power cord is damaged, there is a risk of fire and electric shock.)
- Do not use this device near any equipment that creates electromagnetic waves such as X-ray equipment and MRI equipment. (When influenced by electromagnetic waves, this device may not function properly.)
- (There is a risk of malfunction which may cause injury.)
- When this device is dropped and damaged, do not operate this device.
- When the power cord is damaged, do not operate this device.
- When adding or draining distilled water, make sure to be careful. (There is a risk of fire or electric shock which may cause injury.)
- Operators should not touch the patient while touching the SD card, USB port of the device.



- Use a power cord in compliance with the standard in the involved country. (There is a risk of fire and electric shock.)
- To avoid causing electric shock, use this device by connecting it with a main-power supply unit with a protective ground.

 (There is a risk of fire and electric shock.)
- Do not use a damaged power cord/plug or a loose socket.
 (When the connection is unstable, there is a risk of fire and electric shock which may cause injury.)
- When you smell something abnormal while this device is in use, immediately stop using this device. In this case, immediately turn off the power switch, disconnect the power cord from the socket, and contact the manufacturer or the seller.
- Do not use wet hands or other wet body parts to touch this device, the power cord, plug and socket.

 (There is a risk of electric shock which may cause injury.)
- Do not damage, bend, twist, or heat up the power cord.
 (When the cord is damaged, there is a risk of fire and electric shock.)

2-2. Cautions prior to use

- Do not use this device for any purposes other than the intended use.
- The device cannot be used in home health care environment.
- When the intended user is wearing a life support system, make sure that the intended user consults one's doctor.
 (Ex; heart assist device)
- 1
- When the intended user's skin is sensitive to high or low temperature, make sure
 that the intended user consults one's doctor prior to use.
 (There is a risk of low temperature burn and frostbite (on the spot where this
 device is worn) which may cause injury.)
- When this device is not used for a long time, clean this device and check whether or not this device functions properly prior to use.
- Do not install this system in an environment exposed to heating devices and direct light.
- (There is a risk of deformation and failure which may cause malfunction.)

- Check whether or not the tubing is damaged.
 (When the tubing is damaged, there is a risk of oil leak and water leak which may cause fire and electric shock.)
- Prior to use, check the status of this device as well as the status of the accessories.
 (When this device or the exterior of the accessories is/are damaged, contact the seller or the service center. When you intend to use the damaged device and accessories, there is a risk of electric shock or current leakage which may cause fire and injury.)
- Do not install this device on a desk or a table to which vibration or impact is frequently applied.
- (There is a risk of fall caused by vibration or impact which may cause failure and injury.)
- Make sure to install this device in a place where the power plug can be connected and disconnected without any interfering obstacles and where the power plug can be removed without any interfering obstacles.
- Do not use a separate coolant for this device.
- When installing this device, make sure that the vent is not blocked.
- The SD card and USB cable can only be used as a firmware update.
- Prior to use, make sure that the water tank cover is locked.
- Do not paint this device or attach stickers and other foreign substances to this device.
- (When any foreign substance is inserted into the air socket or the connection port, there is a risk of malfunction.)
- (Depending on the physical constitution of the intended user, there is a risk that the paint or the stickers may cause allergy and eczema. In this case, stop using this device consult your doctor.)
- Do not cover the power cord with a carpet or other objects.
 (As you walk, your feet may be caught in the power cord, making this device fall.)
- (There is a risk of fall which may cause failure and injury.)
- Make sure to install this device on a flat and stable surface.
 (When this device is installed on a tilted or unstable surface, there is a risk of noise, fall, failure and malfunction.)
- Use the wrap with wearing thin cloths.
 (It can cause an allergy to a person with sensitive skin.)



- Do not remodel, disassemble, or repair this device at your own discretion.
 (When this device is remodeled, disassembled, or repaired at your own discretion, you will not be able to receive our free repair service. Make sure to submit a request to our service center to repair this device.)
- Do not install this device on a foldable, portable, or lightweight table.
 (When the weight leans towards one side, there is a risk of table fall which may cause failure and injury.)
- When installing this device, make sure that no liquid or foreign substance is inserted into any part of this device other than the inlet of the water container. (When any foreign substance is inserted into any part of this device, there is a risk of failure, fire and malfunction which may cause injury.)



- When this device is transferred at a temperature below 0°C, make sure to completely dry this device at room temperature for approximately 1~2hours until the dew condensation disappears.
- (Any moisture and liquid ingredients may damage the parts and circuits of this device.)
- The wrap is intended to be connected with the device manufactured by DAESUNG MAREF only. Do not connect the wrap with other devices manufactured by other companies.
- The accessories and parts to be used in CTC-7 must be of those provided or approved by DAESUNG MAREF.
 (When any accessories and parts not approved by DAESUNG MAREF are used, there is a risk of malfunction which may not guarantee user safety.)

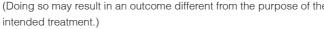
2-3. Cautions during use

- When it comes to determining how the temperature, mode and time of this device should be set, follow the instructions given by your doctor.
- Use this device indoor where the temperature is above 10°C and below 25°C. (When the service environment conditions are not satisfied, there is a risk that the cooling/heating performance of this produce may be degraded.)



- CTC-7 Warp is not sterilized. Make sure that no wounded site is directly touching the cooling/heating pad.
- Do not apply extreme impact by dropping this device.
- Do not use this device while it is inside the recovery bag.
 (When this device is used while the vent is blocked, the device may not function properly.)

- Do not operate this device while the tubing is facing your eyes, nose and lips. (The water and air released from the tubing may cause injury.)
- Make sure that no heat is applied to the gonad and developing embryo. (If you are a pregnant woman, be aware when you wear the back wrap.)
- When this device is used in the Cold, Heat, or RCT mode, do not use this
 device with other heat sources.
 (Doing so may result in an outcome different from the purpose of the



- Do not insert your finger into the water container or the vent.
- Make sure that the front, side, or rear vent of this device is not blocked while this device is in operation.
- Make sure not to touch the side vent of this device while this device is in use or immediately after this device is used.
- When connecting the tubing, make sure not to bend it.
- When moving this device, make sure to turn off this device prior to moving it. (While this device is in operation, do not move this device.)
- Do not use a safety pin on the wrap to fix it.
 (The wrap may be torn by the sharp part of a safety pin.)
- Prior to wearing the wrap, remove all accessories from the part of your body where the wrap will be worn.
- * When accessories are worn, there is a risk that the wrap may be damaged or that the part of your body where the wrap is worn may be injured.
- * When the wrap is to be worn on your leg: your belongings within trouser pockets, ankle bracelet, etc.
- * When the wrap is to be worn on your waist: your waist belt, belongings within trouser pockets, key chain, mobile phone, etc.
- * When the wrap is to be worn on your arm and hand: your watch, bracelet, ring, etc...



2-4. Cautions after use

- When disconnecting the power cord from the device, disconnect the power cord from the socket prior to removing it from this device.
- Check whether or not this device is damaged and whether or not this device functions properly at least once per year.
 - (When this device is used without conducting maintenance, there is a risk of malfunction and injury.)
- Prior to cleaning this device, disconnect the power cord from the socket, and then disconnect the power cord from this device.
 (When you get caught in the power cord line as you clean this device, there is a risk of fall injury, damage and electric shock.)
- Make sure that no liquid is inserted into the socket, AC inlet and vent located on the side of this device.
- (When any liquid is inserted, the influenced internal parts may cause malfunction, electric shock and fire.)
- Do not directly apply the liquid detergent to this device or use benzene, thinner, or alcohol to clean this device. Make sure to apply the liquid detergent to a cloth to be used for cleaning this device.

 (There is a risk of discoloration, damage, electric shock and fire.)
- After operating this device, always wait until this device reaches room temperature prior to storage.
- When the case of this device is damaged, immediately submit a request for repair to the supplier or the customer center.
- Store this device and the accessories in a dry place free from water and moisture.
- (Moisture and liquid ingredients may damage the parts and circuits of this device.)



Do not store this device in a dirty place full of dust.
 (Dust and foreign materials may result in failure, fire, or electric shock which may cause injury.)



- When this device and the accessories are to be stored for a long time, make sure to completely remove the distilled water inside this systems.
 (Unless the distilled water inside this device is completely drained, there is a risk of contamination(microorganism inside this device) which may cause failure.)
- The adequate temperature range for storing this device is from 1°C to 50°C. Make sure that the temperature is within that range while this device is stored.



Do not play any objects on this device.
 (When this device is operated or moved while any liquid container(vase, water bottle, cup, cosmetic device and chemical), volatile substance, chemical, or sharp object(scissor and knife) is placed on this device, there is a risk of fall which may cause fire and injury.)



Do not disassemble or remodel this device at your own discretion for repair.
 This device can only be disassembled and repaired by the approved personnel.
 (When you disassemble and repair this device at your own discretion, there is a risk of malfunction and injury.)

2-5. Cleaning

2-5-1. Device cleaning

- When any foreign substance(ex: filth, dust, blood) is attached to this device, turn off this device, apply a bit of water or neutral detergent to a cloth, and use the cloth to gently remove the foreign substance.

(There is a risk of discoloration, damage and malfunction.)
(When this device is cleaned, make sure to dry this device completely prior to use.)

- Please be careful to prevent any liquid from going into the air socket or AC inlet on the back of device. If liquid does get in operation errors, electric shock, and fire could occur due to do an affect of internal parts.
- Do not wipe the device with benzene, thinner, alcohol, etc or spray water directly on the device

(It may cause discoloration, damage, electric shock or fire.)

* Use neutral detergent or the alkalescence for cleaning.

Dilute in water if it is Alkali undiluted state.

Drug use: be careful not to enter into the skin or eyes.

2-5-2. Wrap cleaning

- When necessary apply a bit of neutral/mild detergent or water to a soft cloth, use the cloth to clean the wrap, and completely dry the wrap prior to use.
- Close the tubing hole at the bottom with a rubber stopper before cleaning.

 (If you do not close the tubing hole with a rubber stopper, there is a risk of contamination which may cause failure.)
- * Do not use a dryer to dry the wrap.

2-6. Operating / Storage conditions

2-6-1. Operating condition

| Temperature (°C) | Relative Humidity (%) | Atmospheric Pressure(hPa) |
|------------------|-----------------------|---------------------------|
| 10° <u>C</u> | 0% | 700hPa |

2-6-2. Storage condition

| Temperature (°C) | Relative Humidity (%) | Atmospheric Pressure(hPa) |
|------------------|-----------------------|---------------------------|
| 1°C | 90% | 1060hPa |

2-7. WEEE



This symbol indicating separate collection for EEE is based on DIRECTIVE 2012/19/EU.

The purpose of this Directive is to contribute to sustainable production and consumption by, as a first priority, the prevention of WEEE and, in addition, by the re-use, recycling and other forms of recovery of such wastes so as to reduce the disposal of waste and to contribute to the efficient use of resources and the retrieval of valuable secondary raw materials.

This Directive cover all EEE used by consumers and EEE intended for professional use.

Consumers have to actively contribute to the success of such collection and should be encouraged to return WEEE.

The Producer have to provide the information of re-usable, recyclable and recoverable rate. 75% shall be recovered, and 55% shall be prepared for re-use and recycled within category 5 (Small equipment) in DIRECTIVE 2012/19/EU ANNEX III.

CTC-7 is a recoverability rate of 74.4% and a recyclability rate of 81.8%.

Information for treatment facilities shall be made available to centres which prepare for re-use and treatment and recycling facilities by producers of EEE.

DAESUNG MAREF, whenever, is prepared to provide.

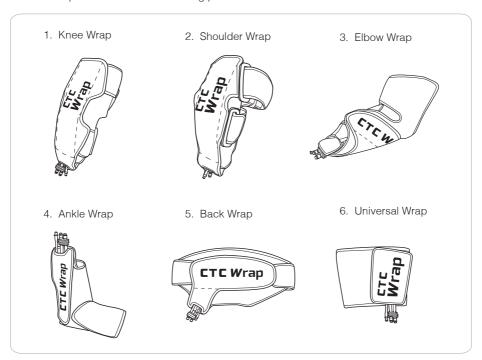
3 Device Composition

3-1. Basic set



3-2. Accessories

- The wrap is a consumable device.
- The wrap is defined as the mounting part in IEC 60601-1.



| NO | Name | Size | Ref.No (Reusable Wrap) | Ref.No (Disposable Wrap) |
|------------------|---------------|---------|------------------------|--------------------------|
| 1 | Knee Wrap | Free | CTCKF00 | CTCKFD0 |
| 2 | Shoulder Wrap | М | CTCSM00 | CTCSMD0 |
| 3 | Elbow Wrap | Free | CTCEF00 | CTCEFD0 |
| 4 | Ankle Wrap | Free | CTCAF00 | CTCAFD0 |
| 5 | Back Wrap | Free | CTCBF00 | CTCBFD0 |
| 6 Universal Wrap | М | CTCUM00 | CTCUMD0 | |
| | L | CTCUL00 | CTCULD0 | |



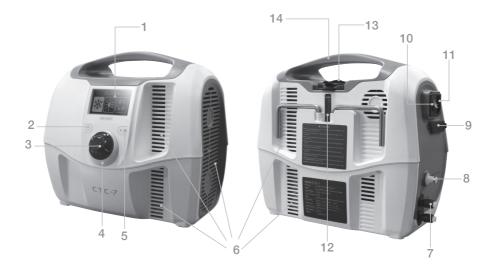
Device Description

4-1. Device specifications/Characteristics

| Device name | Circulating-fluid thermal/compression therapy system control unit | | |
|----------------------------|---|---------------------------|--|
| Model | CTC-7 | | |
| Dimension | 272(W) x 180(D) x 239(H) mm | | |
| AA7. *. I. I | 3.7kg (empty water container) | | |
| Weight | 3.9kg (full water container) | | |
| Power source | AC 100 – 240V, 50/60Hz | | |
| Power consumption | 270VA | | |
| Mode | Cold Therapy, Heat Therapy, RCT Therap | у | |
| Therapy Temperature | Cold Therapy : 6 - 15°C ± 3°C (43 - 59°F : | ±5.4°F) | |
| Range | Heat Therapy: 35 - 45°C ± 3°C (95 - 113° | F ±5.4°F) | |
| | Manual (Cold Therapy) : 5 - 60 min | | |
| Time Range | Manual (Heat Therapy): 5 - 30 min | | |
| | PRESET (Run/Rest) : 20/20, 20/40, 30/30, 30/60 min | | |
| | Cold Therapy: 0 - 4 Level / Heat The | rapy : 0 - 1 Level | |
| | 0 Level : 0mmHg | | |
| Pressure Range | 1 Level : 15mmHg ±5mmHg | | |
| riessule halige | 2 Level : 30mmHg ±5mmHg | | |
| | 3 Level : 50mmHg ±5mmHg | | |
| | 4 Level : 75mmHg ±5mmHg | Βv | |
| Coolant | Distilled water | ONLY | |
| Refrigerant | None | * Setting value | |
| Fluid Capacity | 250mL | should be operated | |
| Ambient Operating Range | 10 – 25°C | under doctor's | |
| Type of protection IP | IPX0 | instructions. | |
| Class / type of protection | on Class I | | |

- The exterior and specifications of this device may be changed without notice for performance improvements.
- You can purchase the accessories through the official website of DAESUNG MAREF.
 You must purchase the official parts provided by DAESUNG MAREF. When accessories produced by other companies are used, this device may not function properly. In this case, our free as will not be applicable.
- The time it takes for this device to reach the set temperature may vary depending on the ambient temperature. This device may fail to reach the set temperature depending on the case.

4-2. Parts name/function



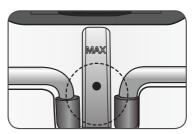
| No | Parts Name | Function |
|----|---------------------|--|
| 1 | LCD display | It is a screen that displays the GUI and operating status of CTC-7 |
| 2 | Back button | When the back button is shortly pressed, the previous screen will appear. |
| 3 | Knob wheel | When the knob wheel is rotated or pressed, the temperature, time and pressure level of this device can be controlled. * While this device is in operation, press the knob wheel to stop this device from operating. |
| 4 | Alarm LED | - Standby status : Green - In operation : Blue and Green flickering - Error : Orange flickering |
| 5 | Start / Stop button | When the button is shortly pressed, this device will operate based on the set values. While this device is in operation, press the button shortly to stop this device from operating. |
| 6 | Air vent | This is a fan-operated air vent, an air-circulated vent that allows internal air to circulate during operation. |
| 7 | Water socket | It is a water socket used to connect the tubing with this device. |
| 8 | Air socket | It is an air socket used to connect the tubing with this device. |

| 9 | Memory card / USB port | It is a port in which the memory card and USB cable can be inserted for device firmware updates. |
|----|---------------------------|--|
| 10 | Power on/off switch | It is a switch used for turning on/off this device. |
| 11 | Power cord socket | It is a socket used for connecting the AC cord with this device. |
| 12 | Water level indicator | It is an indicator used for checking the amount of distilled water contained in the water container. |
| 13 | Water tank cover | It is a cover used for preventing the distilled water contained in the water container of this device from spilling. |
| 14 | Handle | It is a handle used for moving this device. |

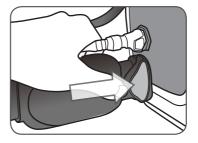
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Installation

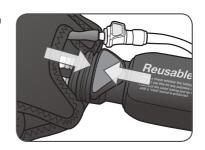
- When you open the package and take out this device, proceed with caution to avoid causing damages. After you take out this device, check whether or not this device and the parts are damaged.
- 2) Install this device on a flat and stable surface.
 - * To avoid the air flow of this device from being interrupted, install this device in a place, where the obstacles are at least 30cm away from the vent of this device.
- Open the water bottle cap located on the rear side of this device, fill the water bottle with distilled water, and rotate the cap until it is completely closed.
 - * When adding distilled water, use a syringe, or a cup with a sharp spout.
 - * Check the water level buoy located on the rearside of this device.
 - * When this device is used without completely closing the cap, the distilled water may spill.
 - * The maximum volume of distilled water is 250mL.



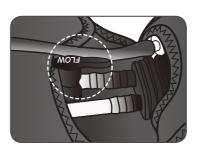
- 4) Check the projected section of the water socket located on the side of this device and connect the water socket to this device by pushing it in the correct direction until you hear a "click" sound.
 - * When this device is used without properly connecting the tubing with this device, there is a risk of water leakage.



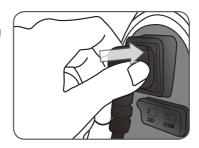
- 5) After you connect the water socket of the tubing with this device, connect the air socket by pushing it until you hear a "click" sound.
 - * When this device is used without properly connecting the tubing with this device, there is a risk of oil leakage.



- 6) Check whether or not the pipe attached to the wrap is rotated.
 - * When the pipe is rotated 90 degrees, the distilled water will spill.
 - * The pipe is only in the reusable wrap.
 (Disposable wrap do not have drain pipes.)



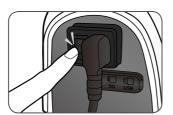
- 7) Check the direction of the power cord socket located on the side of this device, and connect the cord. Then, connect the power cord with the socket.
 - * Install this device in an environment where the power cord can be easily connected and disconnected.

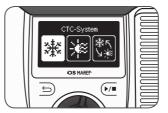


6

How to use

 $\ensuremath{\mathbb{X}}$ Use "Clause 5. Installation" as your reference to install CTC-7 in your intended environment.





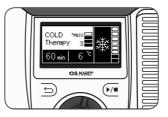
1) When you turn on the power switch located on the side of this device, the mode selection screen will appear.





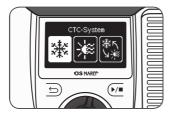
2) On the mode selection screen, rotate the knob wheel counterclockwise or clockwise to select the most to be used. Select the mode to be used and press the knob wheel to move to the standby screen of the selected mode.





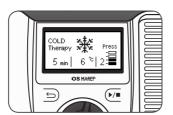
- 3) Finish setting the mode to be used and press the start/stop button to activate the mode based on the settings.
 - * Use "6-1, 6-2 Setting" as your reference to set each mode.
 - * While this device is in operation, the settings cannot be changed. To change the settings, stop this device from operating.
 - * To stop this device from operating, press the start/stop button and press the knob wheel.

6-1. Cold & Heat Therapy setting





 On the mode selection screen, rotate the knob wheel to select Cold or Heat Therapy, and press the knob wheel to move to the standby screen.





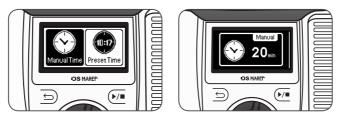
- 2) On the standby screen, press the knob wheel to move to the setting screen.
 - * On the mode setting screen, you can set the time, temperature and pressure level.





- 3) On the setting screen, rotate the knob wheel counterclockwise or clockwise to select from 'Time', 'Temperature' and 'Pressure Level'. Select the item (Time, Temperature, Pressure Level) to be set and press the knob wheel, and a pop-up screen will appear. Rotate the knob wheel counterclockwise or clockwise to adjust the levels. Press the knob wheel to save the settings, and press the back button to return to the standby screen without saving the settings.
 - * On the setting screen, press the start/stop button to activate the mode based on the currently settings.

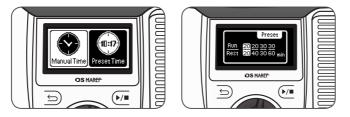
4) On the Time setting screen, rotate the knob wheel to select Manual or Preset.



On the Manual Time setting screen, you can set the run time.

* Manual Time range

Cold Therapy: 5 - 60min / Heat Therapy: 5 - 30min



On the Preset Time setting screen, you can choose the time which is continuously moving for run and rest setting.

* Preset Time range (Run / Rest) : 20/20, 20/40, 30/30, 30/60 min

* Cold Therapy setting range

| Cold Therapy mode | Manual | 5 - 60 min |
|--|------------------------------------|---|
| Time range | Preset | Run/Rest : 20/20, 20/40, 30/30, 30/60 min |
| Cold Therapy mode Temperature range | 6 - 15°C ± 3°C (43 - 59°F ± 5.4°F) | |
| | 0 Level | 0 mmHg |
| Cold Therapy mode Pressure range | 1 Level | 15 mmHg ± 5mmHg |
| | 2 Level | 30 mmHg ± 5mmHg |
| | 3 Level | 50 mmHg ± 5mmHg |
| | 4 Level | 75 mmHg ± 5mmHg |

* Heat Therapy setting range

| Heat Therapy mode | Manual | 5 - 30 min |
|--|--------------------------------------|---|
| Time range | Preset | Run/Rest : 20/20, 20/40, 30/30, 30/60 min |
| Heat Therapy mode Temperature range | 35 - 45°C ± 3°C (95 - 113°F ± 5.4°F) | |
| Heat Therapy mode | 0 Level | 0 mmHg |
| Pressure range | 1 Level | 15 mmHg ± 5mmHg |

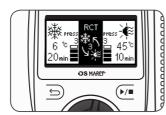
^{*} When the Heat therapy is used at high temperature for a long time, your skin may be damaged. Do not consecutively apply the Heat therapy to the same skin area.

6-2. RCT Therapy setting



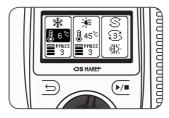


1) On the mode selection screen, rotate the knob wheel to select 'RCT Therapy', and press the knob wheel to move to the RCT therapy standby screen.





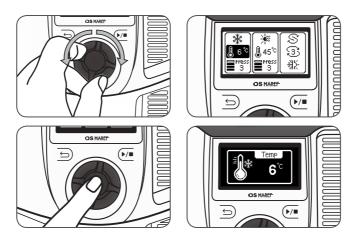
- 2) On the RCT therapy standby screen, press the knob wheel to move to the RCT setting screen.
- * On the RCT setting screen, you can set the temperature, pressure level and treatment cycle for Cold therapy and Heat therapy.
- * In the RCT mode, the time for Cold therapy is fixed to 20 minutes and the time for Heat-therapy is fixed to 10 minutes.



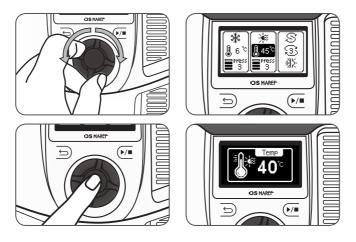




- 3) On the RCT setting screen, rotate the knob wheel counterclockwise or clockwise to select 'Cold', 'Heat', and 'Cycle'. Select the item('Cold', 'Heat', 'Cycle') to be set and press the knob wheel, and a pop-up screen will appear.
 - Press the knob wheel counterclockwise or clockwise to adjust the settings.
 - * On the RCT setting screen, press the start/stop button to activate the mode base on the currently settings.



3-1) On the Cold setting screen, rotate the knob wheel counterclockwise or clockwise to select from 'Temperature' and 'Pressure Level'. Select the item ('Temperature', 'Pressure Level') to be set and press the knob wheel, and a pop-up screen will appear.
Rotate the knob wheel counterclockwise or clockwise to adjust the levels.
Press the knob wheel to save the settings, and press the Back button to return to the RCT therapy standby screen without saving the settings.



3-2) On the Heat setting screen, rotate the knob wheel counterclockwise or clockwise to select from 'Temperature' and 'Pressure Level'. Select the item ('Temperature', 'Pressure Level') to be set and press the knob wheel, and the pop-up screen will appear. Rotate the knob wheel counterclockwise or clockwise to adjust the levels. Press the knob wheel to save the settings, and press the Back button to return to the RCT therapy standby screen without saving the settings.





3-3) On the Cycle setting screen, rotate the knob wheel counterclockwise or clockwise to adjust the levels. Press the knob wheel to save the settings, and press the Back button to return to the RCT therapy standby screen without saving the settings.

* RCT Therapy setting range

| Cold Therapy mode Time range | 20 min | |
|--|--------------------------------------|-----------------|
| Cold Therapy mode Temperature range | 6 - 15°C ± 3°C (43 - 59°F ± 5.4°F) | |
| | 0 Level | 0 mmHg |
| | 1 Level | 15 mmHg ± 5mmHg |
| Cold Therapy mode Pressure range | 2 Level | 30 mmHg ± 5mmHg |
| | 3 Level | 50 mmHg ± 5mmHg |
| | 4 Level | 75 mmHg ± 5mmHg |
| Heat Therapy mode Time range | 10 min | |
| Heat Therapy mode Temperature range | 35 - 45°C ± 3°C (95 - 113°F ± 5.4°F) | |
| Heat Therapy mode | 0 Level | 0 mmHg |
| Pressure range | 1 Level | 15 mmHg ± 5mmHg |
| Cycle range | 1 - 3 cycle | |

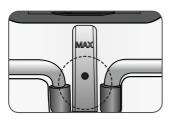
7 Cleaning and Draining

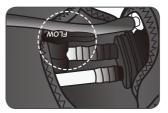




- 1) On the standby screen, press and hold the knob wheel to activate the menu mode.
- 2) On the menu mode selection screen, rotate the knob wheel counterclockwise or clockwise to select from 'Cleaning' and 'Draining', and press and hold the knob wheel to move to the screen of the selected item.

7-1. Cleaning





- 1) Fill CTC-7 with distilled water and check whether or not the tubing and wrap are all connected.
 - * Check whether or not the pipe attached to the wrap is rotated. When the pipe is rotated, the water will leak during cleaning.
 - * Disposable wrap do not have drain pipes.





- 2) On the cleaning standby screen, select and press the knob wheel, and the cleaning process will run for approximately 10 minutes.
 - * While the cleaning process is running, press the knob wheel to stop the process and return to the cleaning standby screen.





- 3) After the cleaning process is complete and a pop-up screen appears, press the knob wheel.

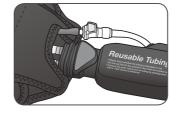
 On the cleaning standby screen, select and press the knob wheel to return to the menu mode.
 - * When this device requires more distilled water, a pop-up screen reading 'ERROR-11' will appear prior to activating the cleaning process.
 - * When a certain temperature is not reached during the cleaning process, a pop-up screen reading 'ERROR-21' will appear.
 - * If impurities or contamination are found when using the device stored for a long time without removing the distilled water, contact the dealer for cleaning method.

7-2. Draining

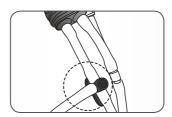
 Check whether or not the cap of the water container located on the rear side of this device is completely closed.



2) Check whether or not the tubing and wraps are connected to CTC-7.



3) Connect the connector tubing supplied with the wrap pipe.



4) When draining, prepare a water container for receiving the drained water.

Set the tubing attached to the wrap in a way that it faces the prepared water container, and open the pipe by rotating it 90 degrees.





5) On the Draining standby screen, rotate the knob wheel to select , and press the knob wheel to drain the water inside this device as well as the water inside the tubing and wrap.





- 6) After the Draining process is complete and a pop-up screen appears, press the knob wheel.

 On the Draining standby screen, select and press the knob wheel to return to the menu mode.
 - * When the water level remains the same during the Draining process, a failure will occur.
 - * When a failure occurs, check whether or not the tubing and wrap are all connected to CTC-7, and check whether or not the pipe is open.

8

Storage

- X To prevent causing problems while moving and storing this device, make sure to use the packaging that this device was initially covered in.
- ※ For long term storage refer to section 7-2 Drain Methods of CTC-7 to remove distilled
 water from the device and accessories.

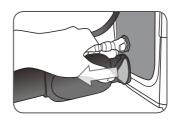


 Check whether or not the cap of the water bottle located on the rear side of this device is completely closed.

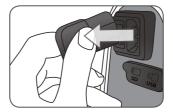


2) Turn off the power switch located on the side of this device.





- 3) Remove the tubing connected with this device and with the wrap.
- 4) Disconnect and remove the power cord connected with this device from the socket.



- 5) Store this device and the tubing and wrap in a safe place.
- * Do not store this device (including the tubing and wrap) in a place exposed to direct light, or in a humid place, or in a place where there is a risk of fall.
- * Make sure to store the tubing in a way that it is not folding.

9 System setting





When this device is in the standby mode, press and hold the 'Back button' and 'knob wheel' at the same time to go to the System set screen.

- * On the system set screen, you can set 5 items : Backlight, Beep sound, RTC initial, Temp unit, and Factory reset.
- * Press the 'Back button' to return to the standby mode after the system setting is complete.
- * You can check the firmware version when you turn on the device the first time.

9-1. How to set the Backlight time





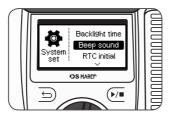
1) On the System set screen, rotate the know wheel, select 'Backlight time', and press the knob wheel to set the time it takes to turn on the LCD screen of this device.





- 2) On the Backlight time set screen, rotate the knob wheel, set the time, and press the know wheel to return to the system set screen.
- * Time setting: 0~60 sec, or all ways

9-2. How to set the Beep sound





 On the System set screen, rotate the knob wheel, select 'Beep sound', and press the knob wheel to turn on/off the beep sound of this device.





2) On the Beep sound set screen, rotate the knob wheel, set the beep sound, and press the knob wheel to return to the system set screen.

9-3. How to set the RTC initial

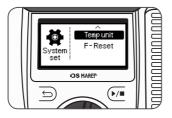




- 1) On the System set screen, rotate the knob wheel, select 'RTC initial', and press the knob wheel to set the date and time of this device.
- 2) On the RTC set screen, rotate the knob wheel, select the item to be set, and press the knob wheel. When the number flickers, rotate the knob wheel to set the preferred date and time, and press the knob wheel to save the setting, and press the Back button to return to the system set screen.



9-4. How to set the Temp unit





- 1) On the System set screen, rotate the knob wheel, select 'Temp unit', and press the knob wheel to change how the temperature is displayed on the device.
- 2) On the Temp unit set screen, rotate the knob wheel, select either (°C) or (°F), and press the knob wheel to return to the system set screen.



9-5. How to set the F-Reset (Factory-Reset)





- 1) On the System set screen, rotate the knob wheel, select 'F-Reset', and press the knob wheel to reset the default setting value of this device.
- By activating 'F-Reset', you can reset, the default 'Backlight time', 'Beep sound', "Temp unit' of this device.



Troubleshooting



The user is encouraged to receive a device quality test from the manufacturer every 1 year.

10-1. Matters to be checked prior to submitting a request for service.

- * When this device does not function properly, make sure to read the user manual and follow the instructions to take adequate actions against the following symptoms prior to contacting the customer center.
- * Refer to the Service Manual for assembly and circuit drawings of the device.

I cannot turn on this device.

- · Check whether or not the power cord is connected with this device.
- · Check whether or not the supplied power satisfies AC100-240V and 50/60Hz.

While operating this device, I got a message saying that there is no water.

- This device needs more water. Add more water to the water container.
- · If this device is tilted, install it on a flat floor.

Water is leaking from this device.

- · Check whether or not the cap of the water tank located on the rear side of this device is completely closed.
- · When dew condensation occurs inside this device, water may be created on the floor.
- · Check whether or not the pipe of the wrap is closed.
- *When water is leaking from a hole created on the wrap, contact the agency or the store from which you purchased this device.

I cannot drain water from this device.

- · Disconnect the tubing and wrap from this device and re-connect the tubing and wrap with this device.
- · Check whether or not the pipe valve attached to the wrap is open.

I cannot apply pressure.

- · Check whether or not the tubing is connected with this device and with the wrap.
- · When air is leaking from the wrap, contact the agency or the store from which you purchased this device.

While using this device, I got a message saying that the temperature of this device is high.

- •Turn off this device and let it cool down for approximately 1 hour prior to turning it back on for use
- •When the ambient temperature is high or this device is continuously used for a long time, take a break from using this device. When you still get a message saying that the temperature of this device is high even after taking a break, contact the service center and the local person in charge.

I feel like the wrap is neither hot nor cold.

- ·When the tubing or the wrap is bent, water will not flow.
- When the ambient temperature is too high or too low, the cooling and heating may not function properly.
- •When the peltier inside this device does not function properly, the cooling and heating will not function properly. In this case contact the service center and the local person in charge.

This device generates too much noise.

- ·Check whether or not there is any foreign substance attached to the fan of the vent hole.
- ·Check whether or not this device is placed on an unstable or tilted floor.

10-2. Error Code Occurrence

* If an error occurs during operation, the device displays the error code on the LCD screen.

| Error Code | Symptom | Solution | |
|---|---|---|--|
| ERROR-01 Temperture error Check the device | Occurs when the internal temperature of this device increases - Turn off and turn of this device Turn off this device and let this device of down for approximately 1 hour prior to till back on. | | |
| ERROR-O2 Temperture error Check the device | Occurs when the temperature of the heat sink increases | When the error occurs when this device is used after it is cooled down, contact the service center and local person in charge. | |
| ERROR—11 Low error Pour the Water | Occurs when the water container lacks water prior to operating this device | This device lacks water. Add more water to the water container. Check whether or not this device is tilted. Install this device on a flat floor. | |
| ERROR—12 Low error Pour the Water | Occurs when the water container lacks water while this device is in operation | This device lacks water. Add more water to the water container. Check whether or not the pipe of the wrap is open. Check whether or not there is any water leakage. | |

| Error Code | Symptom | Solution |
|--|--|--|
| ERROR—21 Check the Peltier | Occurs when the temperature cannot be adjusted due to failure of the cooling system | |
| ERROR-22 Check the Water pump | Occurs when the temperature cannot be adjusted due to failure of the water pump | - Contact the service center and local person in charge. |
| ERROR-51 Check the or Rir pump Sol valve | Occurs when the air sensor has no load while this device is in operation | |
| ERROR—32 Check the Air leak | Occurs when no pressurization is executed due to air leakage in the wrap area | - Check whether the wrap/tubing has any air leakage Disconnect and re-connect the tubing connected to the wrap and main body. When the same error occurs, contact the service center and local person in charge. |
| ERROR—41 Sensor error Check the Sensor | Occurs when the temperature sensor within this device causes an error | |
| ERROR—42 Sensor error Check the Sensor | Occurs when the temperature sensor within the heat sink causes an error | |
| ERROR—4B Sensor error Check the Sensor | Occurs when the water temperature sensor causes an error | - Contact the service center and local person in |
| ERROR—44 Sensor error Check the Sensor | Occurs when the pressure sensor causes an error | charge. |
| ERROR—45 Sensor error Check the Sensor | Occurs when the IR-Sensor causes an error | |
| ERROR—46 System error Check the device | Occurs when the System overload an error | |

11 Labels Information

| No | Label Position | Label Design |
|----|----------------|---|
| 1 | Device Back | ■ Caution Before use the product, please read the manual and follow every precautions and warnings. Please turn off the power when you fill up distilled water in the product. Please be careful not to spill distilled water on the product when you fill it up. Please look the cap by turning it sill the end after fill up distilled water. Please do not use any other liquid or refrigerant except distilled water when use the product. It is 250mL for the optimum amount of distilled water into the product. Please be careful not to block ventilation to prevent overheating when use the product. Please do not use the product with other heat source when use it on GROY, HEAT, or RCT mode. Please remove accessories on the body part before wear a wrap. |
| 2 | Device Back | Model : CTC-7 |
| 3 | Device Top | Bubbles or a small amount of water could be gathered around the water tank cover during or after use of the device, but it does not indicate a malfunction of it. |

Information on EMC

12-1. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The CTC-7 is intended for use in the electromagnetic environment specified below.

The customer or the user of the CTC-7- should assure that it is used in such an environment.

| The customer or the user of the CTC-7- should assure that it is used in such an environment. | | | | |
|--|---|---|--|--|
| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic environment-guidance | |
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the CTC-7, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance | |
| Conducted RF IEC 61000-4-6 | 3 Vrms (150 kHz to 80 MHz) | 3 Vrms | $d = [1.2]\sqrt{P}$ $d = [1.2]\sqrt{P}$ 80 MHz to 800 MHz $d = [2.3]\sqrt{P}$ 800 MHz to 2,50GHz | |
| Radiated RF IEC 61000-4-3 | 3 V/m (80 MHz to 2.5 GHz) | 3 V/m | Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths fixed RD transmitter, as determined by an electromagnetic site surveya, should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol: | |
| Electrostatic Discharge(ESD) IEC 61000-4-2 | ± 8 kV (contact) ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV (air) | ± 8 kV (contact) ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV (air) | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material; the relative humidity should be at least 30%. | |
| Electrical fast transient/burst IEC 61000-4-4 | ± 2 kV, 100 kHz repetition frequency | ± 2 kV, 100 kHz repetition frequency | Mains power quality should be that of a typical commercial or hospital environment. | |
| Surge IEC 61000-4-5 | ± 0.5 kV, ± 1 kV differential mode ± 0.5 kV, ± 1 kV, ± 2 kV Common mode | ± 0.5 kV, ± 1 kV differential mode ± 0.5 kV, ± 1 kV, ± 2 kV Common mode | Mains 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 | $ < 5\% \ U_T \\ (>95\% \ dip \ in \ U_T) \\ for \ 0.5 cycle \\ 40\% \ U_T \\ (60\% \ dip \ in \ U_T) \\ for \ 5 \ cycles \\ 70\% \ U_T \\ (30\% \ dip \ in \ U_T) \\ for \ 25 \ cycles \\ < 5\% \ U_T \\ (>95\% \ dip \ in \ U_T) \\ for \ 5 \ seconds $ | N/A | Mains power quality should be that of a typical commercial or hospital environment. If the user of the CTC-7 requires continued operation during power Mains interruptions, it is recommended that the CTC-7 be powered from an uninterruptible power supply or a battery. | |

| Power Frequency (50/60Hz) magnetic field IEC 61000-4-8 | 30 A/m 50 Hz or 60 Hz | 30 A/m 50 Hz or 60 Hz | Power frequency magnetic fields should be at levels characteristic of a typical location in a Typical commercial or hospital environment. |
|--|--------------------------|--------------------------|---|
|--|--------------------------|--------------------------|---|

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.

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment, due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CTC-7 is used exceeds the applicable RF compliance level above, the CTC-7 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CTC-7.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

12-2. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The CTC-7 is intended for use in the electromagnetic environment specified below. The customer or the user of the CTC-7- should assure that it is used in such an environment.

| Emission test | Compliance | Electromagnetic environment-guidance |
|--|------------|---|
| RF emissions CISPR 11 | Group 1 | The product does not use RF energy. |
| RF emissions CISPR 11 | Class A | |
| Harmonic emissions IEC 61000-3-2 | Applicable | The CTC-7 is suitable for use in all establishments other than domest and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Applicable | |

13 Symbols Information

| Symbol | Description | Reference |
|----------|--|-------------------------|
| \sim | Manufactured Date | EN ISO 15223-1 5.1.3 |
| | Manufacturer | EN ISO 15223-1 5.1.1 |
| | Symbol that indicates electrical and electronic components which must be collected separately. | EN 50419 |
| SN | Serial Number | EN ISO 15223-1 5.1.7 |
| LOT | Batch code | EN ISO 15223-1 5.1.5 |
| † | Type of applied part | IEC 60878 5333 |
| | Refer to the User Manual | ISO 7010 M002 |
| | Keep dry | ISO 15223-1 5.3.4 |
| | Fragile, handle with care | ISO 15223-1 5.3.1 |
| | Symbol recommending the recycling of polluting components | IEC 60878 1135 |
| ! | General warning, Caution | ISO 7010 W001 |
| | General prohibition sign | ISO 7010 P001 |
| | Do not take to pieces | Custom Symbol |
| <u> </u> | This way up | ISO 7000 0623 |

| Symbol | Description | Reference |
|--|---|-------------------------|
| * | Convenience | ISO 7000 0622 |
| \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\ | Load Limitation | ISO 7000 2403 |
| | "ON" (power) button | IEC 60878 5007 |
| | "OFF" (power) button | IEC 60878 5008 |
| C € 0068 | The official mark of Europe Certificate | CE logo |
| EC REP | European Representative | EN ISO 15223-1 5.1.2 |
| | Temperature limitation (Operating: 10°C~25°C / Storage: 1°C~50°C) | EN ISO 15223-1 5.3.7 |
| | Humidity limitation (Operating: 0%~60% / Storage: 0%~90%) | EN ISO 15223-1 5.3.8 |
| (- | Atmospheric pressure limitation (Operating: 700hPa~1060hPa / Storage: 500hPa~1060hPa) | EN ISO 15223-1 5.3.9 |

| Custom Symbol | Description |
|------------------|---------------------------------|
| * | Cold therapy |
| ₩ ≋ | Heat therapy |
| 業へ | RCT (Rapid Contrast Therapy) |
| | Air compression |
| (++) | Synergy |
| | No moisture |
| | Convenience |
| | Back button |
| ▶/■ | Start/Stop button |
| on card | Memory card port icon |
| | USB port icon |
| B | No leakage |
| ŗ | Manual Time |
| P | Preset Time |



Much appreciated on using our device. We, DAESUNG MAREF are doing our best to improve the quality of our products.

- * We can not be responsible for any defect occured from user's careless use or in case of followings, even though warranty period:
 - 1. Disorder happened by strong impact.
 - 2. In case user repair or reproduce internal part arbitrarily.
 - 3. In case of using the device in prohibited place.
 - 4. In case of against our <How To Use>
 - 5. Wraps are articles of consumption.

| Device name | Circulating-fluid thermal compression therapy system control unit |
|-------------|---|
| Model name | CTC-7 |
| Warranty | Device : 1 year |



RND-R-MUM-501-01-01 (Rev.0) 2019-09

COMPANY HISTORY

o 1990's

1986

- Established DAESUNG Machinery Company

1994

- Conversion to DAESUNG MAREF CO.,LTD.

1999

- Registered DOCTOR LIFE
- Registration of utility model for limb compression circulation therapy machine

o 2000's

2004

- The 34th precious Technique bronze awards
- Vice president award
- Selected World class products

2006

- Innovation management awards
- KGMP registration
- KFDA awards by Prime minister

2007

- Authentication of Merit certificate

2008

 Received a citation from the Chungbu Regional Tax Service Director

2009

- Gunpo-si Mayor's Citation
- Awarded by the Minister of Health and Welfare

o 2010's

2010

 Awarded the Governor's Citation for Day of Commerce and Industry by Gyeonggi province

2011

- President Award
- Gold Listed at the Korea Precision Industry Technology Contest

2012

- Selected an Global Small Giants Company

2013

- A credit guarantee fund star company
- Member of Trade Industry Forum

2014

- Commissioned member of INNO-BIZ
- Korean world-class product award in recognition of DVT prevention system

2015

- The 8th medical devices day president award to industrial company

2017

- Selected as a design innovation company
- Grand prize of service satisfaction selected by consumers

2018

- Official sponsor of Seoul E-Land FC
- A citation from the Ministry of Employment and Labor





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