ELECOM Healthcare

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Eclear refree on Low frequency and heat combined therapy apparatus for household use Heated low frequency therapy apparatus PH01

> Attached Documents Instruction Manual HCM-PH01 Series

For use in Japan only.

This manual has been prepared according to laws pertaining to medical products and equipment in Japan. Customers who purchased the product outside Japan are requested to refer to a manual intended for the country in which the product was purchased.



Thank you very much for purchasing this product.

This Instruction Manual features operating methods, as well as precautions for safe handling of the product.

Be sure to read this Instruction Manual prior to using the product. Store this Instruction Manual for safekeeping once you have finished reading.

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Purpose of use or efficacy

This is a medical device for home use that combines features of a low frequency therapy apparatus and a heat therapy apparatus.

The unit loosens stiff shoulders, prevents atrophy and massages paralyzed muscles as a low frequency therapy apparatus, while it is also intended to provide heating effects using electric heat as a heat therapy apparatus.

The product is intended for use at home.

Notes on low frequency therapy apparatus

Flowing low frequency electric current on human body via skin via electrodes attached on the surface of the skin causes muscles to contract and promotes blood circulation by taking advantage of the pumping action of the muscles, as well as dilation of blood vessels, which loosen stiff muscles. The low frequency electric current is also considered to acts on the nerves and alleviate pain.

Notes on heat therapy apparatus

Applying heat on human body dilates the blood vessels due to the rise in temperature of the skin, which in turn promotes better circulation of blood.

The heating effect is considered to have following benefits:

- Recovery from fatigue
- · Improvement of blood circulation
- Reduction in muscle fatigue
- Loosens stiffness of muscles
- Alleviates nerve and muscle pains.
- Activates gastrointestinal functions

Rough standard on treatment time

Approximately 15 minutes per site is the rough standard. Continuing beyond 15 minutes can cause poor health.

The product incorporates a timer that automatically turns off power when about 15 minutes are elapsed since the start of a treatment.

-<u>∧</u>Caution:

Please thoroughly wipe off any sweat or moisture that is on the skin prior to using the product.

Safety Precautions (please be sure to read this)

Following descriptions are provided to explain matters that must be observed in order to prevent harm to the user as well as other people, along with damages to property.

Extent of harm or damage that are caused when product is used without regard to details indicated in are described according to categories of following indications:

🕂 Danger	Matters described this symbol indicates that there is "high probability of death or serious injury".
🕂 Warning	Matters described with this symbol indicates that there is "high probability of death or serious injury can be anticipated".
▲ Caution	Matters described with this symbol indicates that there is "probability of injury or physical damages only can be anticipated"

This pictorial indicates matters that are "prohibited".

This pictorial indicates matters that are "compulsory" and must be performed.

<u> D</u>anger

Never use the product in combination with such medical devices as those described below.

- Implanted electrical devices such as pace makers.
- Electrical devices for sustaining life such as artificial heart and lung machines.
- Worn electrical devices such as electrocardiograph.

Using the product with in combination with these devices can cause malfunction of medical devices and may cause serious impediment to life.

\mathbb{A}	Warning

	Do not use the product near heart, or on the head, face, inside mouth or genitals, as
S	well as injured or diseases skin sites, tattoos, and the like. Furthermore, do not use the
	product simultaneously on the bottom of the left and right feet or in arrangement that puts
	the heart between two sites of applications when performing the low frequency course or
	the heated low frequency course.

Doing so can cause accidents, injuries and poor physical health.

Do not use the product for purposes other than treatment.

Doing so can cause accidents, problems and malfunctions.

Do not use the product together with any other therapeutic apparatuses.

Doing so can cause poor physical health and can make the user feel unwell.

Do not allow children to use the product and do not allow them to play on or ride the base unit or the gel pad of the apparatus.

Doing so can cause accidents and injuries.

	🕂 Warning	
\bigcirc	Do not use the product while the gel pad is in contact with any metal objects, such as a watch or necklace or the like. Doing so can cause accidents and injuries.	
\bigcirc	Do not use the product when the surface of the gel pad is missing or deteriorating. Doing so can cause accidents, problems and malfunctions.	
0	Always make sure that the power has been shut down prior to connecting or removing the gel pad from the base unit or when pasting, replacing or peeling the gel pad to the body.	
	 Be sure to observe following matters when performing heat therapy. Do not cover the gel pad with a towel or use it under a blanket and other such conditions in which heat can become confined. Do not use the product while the body part to which a gel pad has been attached is pressed. If there is no sensation of warmth five minutes after the heat therapy starts, stop using the product immediately. If the gel pad feels hot, remove it. Failure to do so may cause accidents, burns, low temperature burns and poor physical health. 	
\bigcirc	 Individuals who fall under any of the following categories must not use the product: People who are unable to freely manipulate their body and infants People who have taken sleeping pills or have had alcoholic beverages Failure to do so may cause accidents, burns, low temperature burns and poor physical health. 	

	🗥 Warning
	Individuals who fall under any of the following categories must consult a physician:
	• People who are receiving medical treatment, particularly when they are aware of any
	physical anomalies
	 People who have a malignant tumor
	 People who are experiencing heart or cranial nerve disorders
	 People who are confirmed to have lost temperature sensations
	 People who are pregnant and people who have just given birth
	People with body temperature of 38C or higher (in fever stage) (* Example 1: Period with pronounced acute onset of symptoms (such as fatigue, chills, blood pressure
	variation, and the like.); * Example 2: Debilitated).
	People who have contracted an infectious disease
	People who have esthesiodermia or anomalies with skin
	 People who have acute (algetic) ailments such as broken bones, sprains, pulled muscles or the like
	People who require rest
	 People who are taking medications
	 People who have abnormal blood pressure
	People who have paralyzed limbs
	People who are unable to express their will on their own
	• People who have perceptual dysfunctions arising from a high degree of peripheral
	circulatory failure due to diabetes or the like
	People have low temperature conditions
	People who have blood circulation disorders
	People who have experienced low temperature burns Deeple for upon product provides no effect offer upon for some time
	People for whom product provides no effect after use for some time People with align types that are unsuitable for the gel ped
	People with skin types that are unsuitable for the gel pad Failure to do so more accidente, burge, low temporature burge, and poor physical
	Failure to do so may cause accidents, burns, low temperature burns and poor physical health.
\sim	Do not connect the product to any devices other than dedicated gel pads or USB
\bigcirc	cables. Furthermore, do not use any of the accessories with other products either.
	Doing so can potentially lead to burns, as well as heating or short circuiting that can
	cause accidents, fire, other problems and malfunctions.
	This product is intended for use by one person.
	Do not use the product with multiple people.
	Doing so can cause electric shocks and accidents.
	Do not disassemble, repair or modify the product.
Disassembly	Doing so can cause fire and electric shock.

	<u> </u>
\bigcirc	Do not use or store the product in locations described below.
S	 Locations that are exposed to direct sun light.
	Locations near heating devices, electric blankets, heated carpets, inside kotatsu space
	heater and other locations where the temperature is high.
	 Bathrooms and other such locations where humidity is high.
	Locations near moisture.
	Locations with a lot of dust.
	Locations subject to frequent vibration.
_	Doing so can cause fire, electric shocks and malfunctions.
\bigcirc	Do not use the product when going to bed.
•	Doing so can cause accidents, burns, low temperature burns and poor physical health.
\bigcirc	Do not use the product immediately before or during operation of a car, motorcycle,
\mathbf{O}	bicycle and the like.
	Doing so can cause accidents and problems.
\bigcirc	Do not leave the gel pads attached on the skin for long hours.
S	Doing so can cause inflammation of the skin.
\bigcirc	Do not use the product when the gel pad is wet.
S	Doing so can cause electric shocks.
\bigcirc	Do not use the product for more than 15 minutes per location (this includes
S	alternating treatments between low frequency and heating).
	Using the product for long hours can cause accidents, burns, low temperature burns
	and poor physical health.
\bigcirc	Do not use the product when two gel pads are overlapped.
S	Doing so can cause electric shocks and accidents.
	Be sure to avoid cords becoming entangled on the neck when applying gel pads.
•	Doing so can cause accidents and injuries.
0	Use the base unit and gel pads after verifying that they are properly connected.
0	Use the product after verifying that individual operation buttons operate normally.
	Verify that the product operates normally and safely before use according to the
	operations described by the Instruction Manual when using the product for the first
	time or if the device has not been used for long hours.
0	Stop using the product and consult a physician if the use of the product causes strong irritation, or rash,
•	reddening, itch or other anomalies with the skin.

	<u> </u>
\oslash	Be sure to prevent hands, fingers or any other parts of the body from coming into contact with a USB connector receptacle. Doing so can cause electric shocks and accidents.
\bigcirc	Do not insert any metal object into a USB connector receptacle. Doing so can cause heating and ignite fire.
\bigcirc	Do not pull, bend or place a heavy object on top of a cable. Doing so can cause damages, cable disconnection, fire and electric shock.
\bigcirc	Do not use a dedicated USB cable when it is damaged, or when the USB connector insertion receptacle is loose. Doing so can cause ignition of fire and electric shocks.
\bigcirc	Do not charge the product using a transformer, such as a travel converter. Doing so can cause heating and ignite fire.
\bigcirc	Do not charge the product in a car using a cigar socket or the like. Doing so can cause ignition of fire, heat and electric shocks.
Wet Hands Prohibited	Do not touch a dedicated USB cable or a gel pad with wet hands. Doing so can cause electric shocks and accidents.
\bigcirc	Do not use a dedicated cable for purposes other than charging the base unit. A dedicated USB cable must not be used for communication purposes or for charging of other devices.
0	Securely insert the dedicated USB cable to the root when charging. Charging with improper insertion can cause ignition of fire or electric shocks.
	Be sure to charge the product at least once in three month. Leaving the product completely discharged may render it incapable of charging.
•	Stop using the product immediately and shut off power when a malfunction with the device occurs or when there are damages or cable disconnection of gel pads. Contact a retailer or our information center.
0	Do not pull on the electrode cord but instead hold the plug when removing a gel pad from the base unit. Doing so can cause electric shocks, accidents and malfunctions.
\oslash	Do not place or store the product in locations that are accessible to infants. Doing so can cause accidents. Consult a physician immediately in the event an infant swallows the base unit.
\bigcirc	Do not pour water or liquid in the base unit or wet the base unit. Doing so can cause heating, explosions or ignite fire.
\oslash	Do not connect the product to any devices other than dedicated gel pads or USB cables. Furthermore, do not use any of the accessories with other products either. Doing so can potentially lead to burns, as well as heating or short circuiting that can cause accidents, fire, other problems and malfunctions.
0	Follow guidance of local municipal government where you live when disposing of the product.
0	Remove contamination and store the device and accessories after use in a place with little humidity.

Verification of package contents

Verify the package to ensure all contents are present prior to using the product. Every effort has been made to ensure proper packaging, however in the event any shortage or damage is discovered, contact the retailer where the product was purchased.



Attached Documents and Instruction Manual (with Warranty) - This document

Retailer

Inquire the retailer for details on separately sold accessories.

Following separately sold accessories are available:

Brand name: Gel Pad PH01

Medical Instrument Notification Number: 27B2X00293000002



- Attached documents and Instruction Manual x1
- Protective plate x1

Names of individual components

Base Unit



Preparation for Use

Be sure to charge the product until it is fully charged prior to using the product (immediately after purchasing the product or when the product has not been used for long hours) or when the charge is depleted from use.







Example of gel pad attachment

Low frequency, heat or heat and low frequency therapy course

Attach the gel pads on locations of the body where pain or stiffness is felt.

Shoulder: Trapezius muscle



Back and hips: Erector spine muscle

Upper arm: Brachial muscles

Buttocks: Gluteus maximus muscle









Calf: Triceps surae muscle



Thighs: Hamstring muscle



- A Caution:

 Do not use the product simultaneously on the bottom of the left and right feet or in arrangement that puts the heart between two sites of applications when performing the low frequency course or the heated low frequency course.
 Do not use the product when two sel pads are overlapped. Attach the gel pads to sandwich the joint with pain.









Attach one on the bottom of a foot and the other on the calf or ankle of the foot. X Do not treat both legs at the same time.

For heat course

Attach gel pads for heat therapy course by referencing following attachment examples aside from attachment examples for low frequency or heated low frequency courses.

Apply on left and right sides of the stomach



Apply on the bottom of both feet



Apply on left and right sides of the hips



Apply on the back of the neck



Usage

Three courses, the "Heat Course", "Low Frequency Course" and "Heated Low Frequency Course" are available with this product. There are five modes that can be selected with the "Low Frequency Course" and the "Heated Low Frequency Course".





Using Low Frequency Course

3

 Turn the Intensity dial clockwise from the "-" condition (standby mode) to start the treatment with low frequency. The Low Frequency lamp flashes.

Select a desirable intensity level from 10 steps.

Turning the Intensity dial back to the "-" position terminates the low frequency course and brings the product to the standby mode.



(2) Modes can be switched while the product is in operation by pressing on the Low Frequency Mode Switch button.

- Start operation with the "System Selected" mode when the power is turned on.
 - The product mode switches in the manner described below, each time the Lowe Frequency Mode Switch button is pressed. The number of buzzer beeps changes, depending on the type of the mode.





Furthermore, pressing the Heat Therapy button terminates the heat course component of the course only and brings the product back to the low frequency course.



- Even when courses are switched during an ongoing treatment, the power is shut off once the total time of 15 minutes elapses.
 - A beep sound is emitted and the product operation is terminated when a gel pad becomes detached from the body or a gel pad is removed from the base unit.

Storing

6

- (1) Peel off the gel pad from the skin. Do not touch the adhesive surface of the gel pad but hold onto the knob to peel it off.
- (2) Remove the plug on gel pads from the base unit and attach it to the protective plate.



③ Wind electrode cords of gel pads onto the protective plate.



4 Place the bundle into the storage pouch provided for storage.

→ Caution: -

Do not place the product in a location with high temperature or humidity or exposed to direct sun light.

Servicing the product

Service the product with gel pads removed from the base unit.

Servicing gel pads

Service gel pads in following cases:

- Gel pad adhesion is weakened
- Stimulation during operation is weakened
- Tingling sensation is felt during operation
- Gel pads are contaminated
- Gel pads do not stick to the protective plate

Replace gel pads when stimulation is weak or tingling sensation is felt even after servicing.

(1) Drip a few drops of water and rub with the ball of a finger to remove lifted contaminants

% Do not drip excessive amount of water. Doing so can cause reduction in adhesive strength or damage to adhesive surface.

X Do not scrape the surface with a nail or a brush.

X Do not use any detergent or the like.

* Prevent dripping water drops on a plug, electrode cord or handle.



(2) Hold on the handle and thoroughly eliminate water and dry naturally with pad surface facing up, ensuring that no water drop drips onto the handle.

st The adhesive strength also weakens from insufficient drying.

st Do not wipe the adhesive surface with a tissue paper or cloth.

* Avoid direct sun light.

Servicing base unit

• Wipe off with dry cloth when the base unit is contaminated.

Be sure to prevent any water from entering into the base unit interiors, as well as the USB connector insertion receptacle.

Storing Method

Store the product in an environment that satisfies following conditions:

Storage temperature: -10° C to 60° C

Storage humidity: 20 to 85% RH

Precautions for servicing and storing

- Do not use any benzene or paint thinner to service the product.
- Do not store the product in locations described below.
 - -Locations that are exposed to direct sun light.
 - Locations with high temperature, high humidity, near water or a lot of dust.
 - -Locations with frequent vibration.
 - -Locations where chemicals are stored or where corrosive gases are generated.
- Place the product at a location that is out of reach of infants.
- Fully charge the product and store it in a location with normal temperature (10 to 30° C) as much as possible when not using the product for many hours.
- Charge the product at least once in three months. Leaving the product completely discharged may render it incapable of charging.

	H
Benzine	Nail p
	Nail polish remover
Paint thinner	

Loving Care Inspections	Inspect your	heated low frequency therapy a	appa	aratus yo	ou are using for many years!
\bigtriangledown	Do you have any of the following symptoms?	 There are abnormal sounds or vibrations while charging or operating the product The base unit is abnormally hot The base unit is deformed or has burning smell 		When use of product is sus- pended	In order to prevent accidents, turning the power off or remove the dedicated USB cable and make sure to have the product inspected by your retailer.

Request about recycling of lithium ion batteries



A lithium ion battery is built into the product. Lithium ion batteries are precious resources that can be recycled, so we request for your cooperation in recycling. Lithium ion batteries are precious resources that can be recycled, so we request for your cooperation in recycling.

- Furthermore, do not disassemble a battery when disposing of the product.
- Do not dispose of the product as general household waste. Lithium ion batteries that have been disposed of may be shorted by the motion of a garbage truck and can cause ignition of fire or heat.

Removing lithium ion battery

Never disassemble the product except when disposing of the product.

The procedure described below outlines the steps taken to dispose of the <u>product and is not intended for repairs</u>. Disassembling the product yourself can disable the product from sustaining its functions and can lead to malfunction or accident.

ullet Use up the charge in the battery if there is any charge remaining.
Peel off the sticker on the Intensity dial.
(1) Remove the screw that is securing the Intensity dial. (1) f_{1}
(2) Remove the screws that are securing the base unit. 3
(3) Insert a minus screwdriver in the location described in the figure and gradually pry open the entire circumference.
 (4) Insert a minus screwdriver in the location described in the figure and gradually pry open the entire circumference. ※ Take out the battery from the case, still mounted on the substrate.
(5) Cut off the negative black cord from battery, located on the reverse side of the substrate, using a pair of cutting nippers.
6 Remove the battery
7 Remove the battery

igodot Be sure to prevent the removed battery from shorting at terminals + and \ominus and insulate the terminals by attaching a tape.

Circumstance

Symptom	Cause	Responsive action	
Power does not turn on	Insufficient charging of battery or depleted battery	Turn off power and charge the battery. → P.11	
	Battery being charged	Once the battery has been charged, remove the dedicated USB cable before using the product. → P.11	
	Turn off power and charge the battery. If the product still does not operate, there is malfunction inside the product. Stop using the product and contact a retailer or our information center. \rightarrow P.11		
Power turns off soon after it is turned on All three LEDs are flashing	Insufficient charging of battery or depleted battery	Turn off power and charge the battery. ➡ P.11	
Power turns off while product is in use All three LEDs are	Improper connection of the base unit with a gel pad	Turn the power off and securely insert the plug on the gel pads as far as it goes. \Rightarrow P.12	
flashing	A gel pad is not properly sealed onto the skin	Turn the power off and securely seal gel pads on the skin. → P.13	
The battery does not charge	Battery completely discharged after storing product for a long period	The product can no longer be used. Charge the product at least once in about three months to prevent a complete discharge. \Rightarrow P.11	
	Dislodged dedicated USB cable	Connect the dedicated USB cable. \Rightarrow P.11	

Symptom	Cause	Responsive action
Gel pads do not stick to the skin	Transparent protective films have not been removed from the adhesive surface of gel pads	Peel off transparent protective films on the adhesive surface → P.13
	The adhesive surface of a gel pad is contaminated	Drip a few drops of water and rub with the ball of a finger to remove lifted contaminants. → P.21
	Used immediately after being washed	Thoroughly remove moisture and let the adhesive surface dry naturally. → P.21
	The adhesive surface of a gel pad is damaged	Gel pads are consumables. Stop using a gel pad once the adhesive surface becomes damaged and purchase a separately sold replacement. → P.9
The adhesive surface of a gel pad peels off or shifts	Excessive amount of sweat or moisture attached on the adhesive surface of a gel pad	Gel pads are consumables. Stop using a gel pad once the adhesive surface becomes damaged and purchase a separately sold replacement. → P.9
No stimulation felt or stimulation is weak	A gel pad is not properly sealed onto the skin	Apply gel pads on the skin by establishing sealed contact on the skin. \Rightarrow P.13
	Gel pads are overlapped when they are applied	Attach them without overlapping them. \Rightarrow P.14
	The adhesive surface of a gel pad is contaminated	Drip a few drops of water and rub with the ball of a finger to remove lifted contaminants. \Rightarrow P.21
	A gel pad is not properly connected.	Securely insert the plug on the gel pads into the base unit, as far as it goes.
	Intensity adjustment is weakening	Adjust to stronger intensity. ⇒ P.17
	Insufficient charging or depleted battery	Charge the battery. → P.11

Circumstance

Symptom	Cause	Responsive action
No stimulation felt or stimulation is weak	The adhesive surface of a gel pad is contaminated or damaged	Gel pads are consumables. Stop using a gel pad once the adhesive surface becomes damaged and purchase a separately sold replacement. → P.9
The skin becomes red or there is tingling irritation of skin	The operating time of the product is too long	Use for up to 15 minutes on any single location, then peel off the gel pad after use. → P.20
	A gel pad is not properly sealed onto the skin	Apply gel pads on the skin by establishing sealed contact on the skin. \Rightarrow P.13
	The adhesive surface of a gel pad is contaminated or dehydrated	Drip a few drops of water and rub with the ball of a finger to remove lifted contaminants. → P.21
	The adhesive surface of a gel pad is damaged	Gel pads are consumables. Stop using a gel pad once the adhesive surface becomes damaged and purchase a separately sold replacement. → P.9
Pads do not warm up even when the product is set to the heat mode	One of the gel pads has come off the skin	Seal both gel pads securely on the skin.
Pads are too hot. Burning smell comes out of a pad	An electrode cord is disconnected or shorted.	Stop using the product immediately and replace the gel pad.
The product does not stop automatically when a gel pad is dislodged	The device may be malfunctioning.	Contact our user support immediately. → P.29

Product specifications

Product name	Heated low frequency therapy apparatus PH01
Series model number	HCM-PH01
Classification	Equipment 78 Electric therapy apparatus for household use
Generic name	Low frequency and heat combined therapy apparatus for household use (Code: 70998000)
Type of medical equipment	Controlled medical equipment
Medical equipment certification number	229AGBZX00103000
Rated input voltage	DC 5V
Built-in battery	Lithium ion battery (2,600 mAh %1, %2)
Service life	Approximately 5 years (according to our measurements) ¥3
Charging time	Approximately 2.5 hours ¥4
Operating time	Approximately 2.5 hours (with full charge) % 5
Maximum output current	10 mA or less
Fundamental frequency	Approximately 60 V
Output pulse width	Approximately 2.7 to 1,200 Hz
Electric Power Consumption	Approximately 45 to 200 $\mu{ m s}$
Electric Power Consumption	Approximately 3.8 W (heating heater) / Approximately 0.3 W (low frequency)
Timer	Approximately 15 minutes
Base unit dimensions	Approximately W 26mm x D 48 mm x H 96.5 mm
Base unit weight	Approximately 100g (not including gel pad)
Operating environment temperature and humidity	0° C to 40° C 20 to 85% RH
Storing environment temperature and humidity	-10° C to 60° C 20 to 85% RH
Manufacturer and seller	Elecom Healthcare Co., Ltd. LA Tower 8F, 4-1-1 Fushimicho, Chuo-ku, Osaka City, Osaka Prefecture
Manufacturer	Zhangzhou Easepal Industrial Corporation
Country of production	China
Accessories	
Dedicated LISB cable length	Approvimately 20 cm

Dedicated USB cable length	Approximately 20 cm
Gel pad electrode cord length	Approximately 110 cm

※1 According to JIS C 8711.

**2 Excessive charging, discharging and excessive voltage protection functions built in.
**3 Rough standard when charged twice weekly.
**4 Rough standard when fully charging depleted battery.
*5 Varies depending on operating details and operating environment.

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