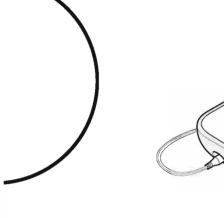
OMRON





Electronic Nerve Stimulator HV-F021

Instruction Manual

All for Healthcare

04/2015 9200746-9B

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Introduction

Thank you for purchasing OMRON Electronic Nerve Stimulator HV-F021.

In order to use the unit safely, read the complete manual carefully before using the unit for the first time.

How does it work?

OMRON Electronic Nerve Stimulator HV-F021 uses Triple Action TENS (Transcutaneous Electrical Nerve Stimulation) technology that helps to:

- block the pain message
- trigger the release of endorphins (natural pain killers)
- improve the blood circulation (as result of repeated muscle contracting and relaxing)

Intended use

Medical purpose

OMRON Electronic Nerve Stimulator HV-F021 is intended for reducing and relieving muscles and joints pain, stiffness and numbness in the back, arms, legs, shoulders and feet by applying electrical nerve stimulation to the surface of the skin near the site of the pain. It should be applied to normal, healthy, dry, and clean skin of adult patients.

Any of the modes can safely be used on body parts or pains described in this manual. Just find one that feels good and is comfortable on your pain. It can be successfully used in conjunction with any other pain treatment or medication.

Since 1970s, pain relief based on Transcutaneous Electrical Nerve Stimulator (TENS) has been widely used by many healthcare professionals, such as physiotherapists and pain specialists.

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It is important that you read all the warnings and precautions included in this instruction manual because they are intended to keep you safe, prevent injury and avoid a situation that could result in damage to the unit.

SAFETY SYMBOLS USED IN THIS INSTRUCTION MANUAL		
△ DANGER	Improper use may cause danger resulting in death or serious injury. These are situations in which the device should not be used.	
△ WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.	
△ CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.	

⚠ DANGER

Do not use this unit with these other devices:

(1) If you have a pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference or death.



- (2) Do not use this device while using another TENS device.
- (3) Together with a life-supporting medical electronic device such as an artificial heart or lung or respirator.
- (4) For Hospitals and Clinics, in the presence of or when attached to the body, electronic monitoring equipment (e.g. cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use
- (5) For Hospitals and Clinics, simultaneous connection of a patient to a high frequency surgical ME equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- (6) For Hospitals and Clinics, operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy ME equipment may produce instability to the stimulator output.

Do not use this unit under these conditions

⚠ Consult with your healthcare professional before using this unit. The unit may cause lethal rhythm disturbances in certain susceptible individuals. If you have had a recent surgical procedure, the stimulation may disrupt the healing process.

Do not use on these individuals

- ⚠ Pregnant women.
- ⚠ Do not use on children or infants because this device has not been evaluated for pediatric use.
- A Keep out of the reach of young children because the electrode cord could cause strangulation.
- ⚠ Persons incapable of expressing their thoughts or intentions.
- A Persons incapable of operating the unit by themselves.
- ↑ Use caution if you have a tendency to bleed internally, such as following an injury or fracture.
- ⚠ If you have suspected or diagnosed heart disease, you should follow precautions recommended by your healthcare professional.
- ⚠ If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your healthcare professional.

▲ Use caution if stimulation is applied over the menstruating uterus.

A NEVER APPLY THE PADS TO THESE BODY AREAS:



The head, the mouth, or any area of the face.



The neck or any area of the throat because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.



Do not use near the heart, or on genital area.



Both sides of the thorax simultaneously (lateral or front and back), or across your chest because the introduction of electrical current may cause rhythm disturbances which could be lethal.



On the calves of both legs at the same time because this may cause cardiac disturbance.



On the bottom of both feet at the same time because this may cause cardiac disturbance.

Open wounds or rashes or over swollen, red, infected or inflamed areas or skin eruptions (such as varicose veins, phlebitis, thrombophlebitis and thrombosis), or on top of or close to cancerous lesions, or over ares of skin that lack normal sensation.

Do not use this unit during these activities

- A When in the bath or shower;
- ⚠ While sleeping;
- ⚠ While driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury.

Pain management warnings

- ⚠ If you have had medical or physical treatment for your pain, consult with your healthcare professional before using this unit.
- ⚠ If your pain does not improve, becomes seriously chronic or severe, or continues for more than 5 days, stop using the unit and consult with your healthcare professional.
- ⚠ The mere existence of pain functions as a very important warning telling us that something is wrong. Therefore, if you suffer from any serious illness, consult your healthcare professional in order to confirm that it is advisable for you to use this OMRON Electronic Nerve Stimulator HV-F021.

Do not alter the unit

- ♠ Do not plug this cord into any other device that is not an OMRON Electronic Nerve Stimulator HV-F021.
- ♠ No modification of this unit is allowed.
- ⚠ Use this unit only with the leads, electrodes, and accessories recommended by the manufacturer to avoid damage to the unit.

Warnings regarding the pads

- ⚠ Apply pads to normal, healthy, dry, and clean skin (of adult patients) because it may otherwise disrupt the healing process.
- ⚠ If you experience any skin irritation or redness after a session, do not continue stimulation in that area of the skin.

Precautions regarding the pads

- ⚠ Do not move the pads to another location while the unit is on.
- ⚠ Therapy won't work with just 1 pad. You must use 2 pads at the same time.
- ▲ Make sure the components are connected well and the pads are fixed on the part of the body you
 wish to treat or the therapy may not be effective.
- ▲ Pads should not touch any metal object, such as a belt buckle, necklace, or other metal worn under clothing.
- ⚠ Do not overlap pads or place pads on top of each other. It may weaken or stop therapy, or the unit may stop working.
 - Gel pads may also stick together and cause gel to be removed when separating.
- ♠ Do not share pads with another person. This may cause a skin irritation or infection. Pads are intended for use by one person.
- ♠ Do not leave pads attached to the skin after treatment.
- ⚠ Do not bend or fold because the gel may get damaged and it won't stick or function properly.
- ⚠ To avoid damage to the adhesive surface of the pads, place the pads only on the skin or on the plastic pad holder provided to avoid damage to the adhesive surface of the pads.
- ▲ Always place clean pads in accordance with illustrations provided (Refer to pages 12-14, Pad Placement).
- ⚠ Do not apply ointment or any solvent to the pads or to your skin because it will disrupt the pads from functioning properly. The self-adhesive pads will adhere to your skin.
- ⚠ Place pads at least 3 cm apart for optimal results.

Caution while using the unit

Main unit

- ⚠ If the unit is not functioning properly or you feel discomfort, immediately stop using the unit.
- ♠ Do not use for any other purpose except for what it is intended for.
- ⚠ Do not place in a room with high humidity, such as a bathroom. This will damage the unit. Ideal temperature for using +10 +40 °C, 30 80 % relative humidity.
- ↑ Do not use the unit without proper lighting. You may not be able to operate the unit successfully.

Cord

- ↑ Do not insert the electrode plug into any place other than the jack on the unit.
- ⚠ Do not pull on the electrode cord during treatment. Do not bend or pull the end of the cord.
- ⚠ When pulling out the cord from the unit, hold the plug and pull.
- ⚠ Replace the cord when broken or damaged.

Battery

- ⚠ Do not throw the batteries into a fire. The batteries may explode.
- ⚠ Dispose of the unit, batteries, and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.
- ⚠ Do not mix alkaline and manganese batteries as this will shorten the battery life.
- ⚠ During therapy, do not remove the battery cover and do not touch the battery terminals.

Pads

⚠ Detach the pads before replacing the batteries.

General precautions

- ⚠ The long-term effects of electrical stimulation are unknown.
- ⚠ Apply stimulation to only normal, intact, clean, dry, and healthy skin.
- ↑ TENS is not effective in treating the original source or cause of the pain, including headache.
- ▲ TENS is not a substitute for pain medications and other pain management therapies.
- ⚠ TENS devices do not cure disease or injuries.
- ▲ TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
- ⚠ You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
- ▲ Keep the unit away from young children. The unit contains small pieces that may be swallowed. Immediately contact your healthcare professional.

Possible adverse reactions

- ▲ You should stop using the unit and consult with your healthcare professional if you experience
 adverse reactions from the unit.
- ⚠ You may experience skin irritation beneath the stimulation electrodes applied to your skin.
- ▲ Do not use to treat one region for extended periods of time (more than 2 × 15 minutes a session, up to 3 times/day) or muscles in that region may become exhausted and sore.

Know your unit

Package contents

Main unit



Pad holder







Long Life Pads



Batteries for trial use



Belt clip



Soft pouch



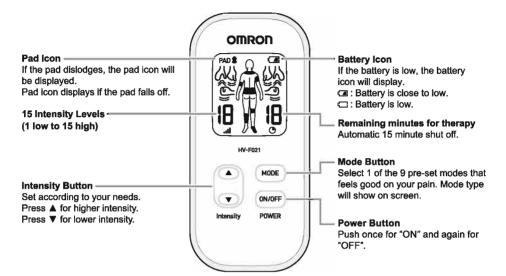
Instruction manual



Optional accessories

• Long Life Pads

Buttons and their functions



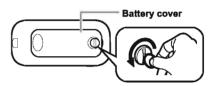
Assembly steps

Before using, check these points to make sure everything is working properly.

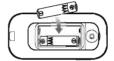
- 1. The cord is not broken.
- 2. The pad adhesive sticks and is not damaged.
- 3. The electrode cord connection is not broken.
- 4. The unit is intact and in working order.
- 5. There is no battery leakage.

STEP 1 - Insert batteries

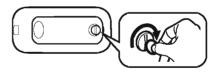
1. Remove the battery cover on the back using a coin.



2. Insert batteries. Make sure the \oplus \ominus signs correspond when inserting batteries.



3. Reinstall the battery cover. Tighten with a coin.



STEP 2 - Attach the electrode cord to the main unit

Attach the electrode cord plug to the bottom of the main unit.



STEP 3 - Snap either electrode cord to each of the pads

During the first use, take the pads out of the sealed package.

 Δ You must use both pads or stimulation will not work.



STEP 4 – Remove and discard plastic film from pads (in case of new pads)

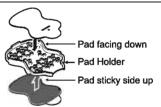
Remove the clear plastic film from the back of the pad.

Discard the plastic film backing as well as the clear packaging.



STORING PADS ON PAD HOLDER

After use place sticky side of pads on either side of the pad holder.



STEP 5 (Optional) - Attach the unit to the belt clip







 $\underline{\Lambda}$ The clip may fall off if attached to soft or thin clothing.

Get started with your therapy

(Use for a maximum of 2 x 15 minutes per session)

STEP 1 - Pad placement

For optimal therapy:

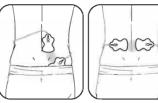
- ⚠ Place pads on either side of the pain, not directly on the pain.
- ⚠ Place 2 pads at least 3 cm apart.
- ⚠ Do not overlap pads or place on top of each other.
- \triangle Do not add spray, lotions or creams to skin or pads.
- ⚠ Do not share pads.

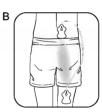
Before starting your therapy, rate your pain from 1 low to 15 high. This mental check gives you a basis you can compare to once the session is completed.

Examples of pads application

LOWER BACK







- A. Attach both pads on the lower back according to your pain.
 Place pads on muscle of the back, not on spine, for optimal therapy.
- B. Attach both pads at same side, one above and one below the region in pain.

<u>ARM</u>

Attach both pads on either side of the area with pain.



Get started with your therapy

JOINT (ELBOW)

Attach both pads on either side of the joint with pain.



JOINT (KNEE)

Attach both pads above the knee or above and below the joint with pain.





LEG (HIP & THIGH)

Attach both pads on either side of the area with pain.



LEG (CALF)

Attach both pads on the calf with pain.

 $\ensuremath{\Delta}$ Pads should not be placed simultaneously on the calves of both legs.







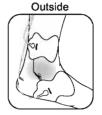
(continued)

STEP 1 - Pad placement (continued)

FOOT (ANKLE)

Attach the pads on the left for pain on the outside of your ankle/foot. Attach the pads on the right for pain on the inside of your ankle/foot.

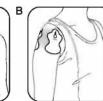
 \triangle Do not attach the pads on the bottom of both feet at the same time.





SHOULDER









- A. Attach both pads on the shoulder according to your pain.
- B. Attach 1 pad on the front and on the back of your shoulder.
- ♠ Do not use near the heart, on both sides of the thorax or across your chest because the introduction of electrical current may cause rhythm disturbances which could be lethal.







STEP 2 - Select 1 of 9 modes

- Push "ON/OFF".
- Select ONLY 1 out of the 9 modes. (Modes cannot be combined.)

Select Massage-like-mode OR Select Pain Mode

1. Tapping

Kneading
 Rubbing

4. Arm

5. Lower Back

6. Leg

7. Foot

8. Joint (Knee/elbow)

9. Shoulder



Push "MODE" Push "ON"

How to switch modes

The unit automatically defaults to the last mode selected. Each time you push the mode button, it switches to the next mode at the lowest intensity. You can only use ONE MODE at a time.

How to select the right mode

Any of the modes can be used on body parts or pains described in this manual. Select the mode that feels right for your unique pain.

Arm





Leg



Foot



Therapies designed for	Arm	Lower back	Leg	Foot
Potential conditions	Swelling, stiffness, sore or achy, muscle or nerve pain.	Stiffness, soreness, muscle or nerve pain.	Swelling, fatigue, stiffness, muscle or nerve pain.	Swelling, fatigue, chilly feeling, sore or achy.
Sensation	Series of low to medium rate tapping, tingling and pulsing sensations.	Series of high rate to low tingling sensations, followed by tapping. With higher intensity, you may feel kneading or massage-like sensations.	Series of low to medium tapping and rubbing sensations.	Series of low rate tapping, pulsing sensations.

(continued)

STEP 2 - Select 1 of 9 modes (continued)

Joint









Rub



Therapies designed for	Joint	Shoulder	Тар	Knead	Rub
Potential conditions	Swelling, stiffness, sore or achy.	Stiffness, sore or achy, tight feeling.	Stiffness, soreness, tight feeling.	Stiffness, sore or achy, knotty muscles, tight feeling.	Stiffness, sore or achy, knotty muscles, tight feeling.
Sensation	Series of medium to high rate tapping, pulsing sensations.	Series of low to high rate tapping, pulsing, kneading and massage-like sensations.	Series of low rate tapping sensations.	Series of medium rate pulsing sensations to mimic massage.	Series of high rate pulsing sensations to mimic hands rubbing.

STEP 3 – Select the correct intensity level (1 low – 15 high)

Start at the lowest intensity level and slowly increase it by pushing the " \triangle (Up)" arrow button. You should feel a gentle pulsing sensation.

How do I pick the right intensity level for my pain?

Each time you push "▲(Up)" or "▼(Down)" arrow, it moves to another level. If the stimulation sensation becomes weaker or disappears, increase the intensity until it is restored. But, if the sensation is at all uncomfortable, press the down arrow to decrease the intensity.

- Press \blacktriangle for higher intensity.
- Press ▼ for lower intensity.

How long is the therapy?

The unit will operate automatically for 15 minutes before it shuts off. We recommend a total of 2 × 15 minutes therapy in one sitting, up to 3 times/day. The screen shows you how many minutes are remaining.



How to manage and reduce your pain

When should I start therapy?

When you feel pain on body area, start with 1 session (the unit automatically turns off at 15 minutes). Turn off with pads still on and rate your pain again.

How long should you use it?

Start with one 15 minute session. Always turn the unit off with pads still on. Rate your pain to check your progress. Stop therapy session if pain has reduced or stopped. Press "ON/OFF" button to continue therapy for another 15 minute session. Each therapy session should not exceed 30 minutes. And maximum 3 sessions of 30 minutes therapy per day.

1 session	Max minutes/session	Max times/day
15 minute	2 x 15 minutes	3 times per day
automatic shut-off		

⚠ See warnings on page 7. Long-time treatment and strong stimulation may cause muscular fatigue and may generate adverse effects.

When to stop using the unit?

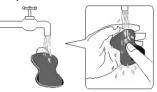
- 1. If you experienced an adverse reaction (skin irritation/redness/burns, headache or other painful sensation, or if you feel any unusual discomfort).
- If your pain does not improve, becomes seriously chronic and severe, or continues for more than 5 days.

Cleaning and storage

The unit is designed for repeated use over time. The pads will last up to 150 uses, or 5 months (based on use 1/day). Here are important cleaning and storage instructions:

Cleaning the pads

- 1. Turn the power off and remove the electrode cord from the pads.
- 2. Wash the pads when the adhesive surface becomes dirty and/or the pads are difficult to attach.
 - Wash the pad softly with your fingertips under slow running cold water for several seconds (do not use a sponge/cloth/ sharp object like a nail on the adhesive side, do not use detergents, chemicals or soap).



- 3. Pads can be washed after 15 uses, approximately 10 times for up to 150 uses. Do not wash the pads too long or too frequently. If the adhesive surface becomes sticky or the pad peels off, leave the pad in the refrigerator (do not freeze) overnight. The adhesion may be restored.
- Dry the pads and let the adhesive surface air-dry completely. Do not wipe with a tissue paper or cloth.
- 5. Pads are replaceable and can be purchased.

The life of the pads may vary by how often you wash the pads, the skin condition, and how you store the pads.

When should you replace your pads?

If the pad no longer sticks to your skin or if more than 25 % of the pad's surface is not in contact with your skin.

Cleaning the unit

- 1. Turn the unit off and disconnect the electrode cord from the pads.
- Clean with a cloth lightly moistened or soaked in a neutral (mild) cleaning solution and wipe gently.
 - · Do not use chemicals (like thinner, benzene).
 - · Do not let water get into the internal area.

Cleaning and storage

Storing the pads

- 1. Turn the unit off and remove the cord from the bottom of the unit.
- 2. Remove the pads from your body.
- 3. Leave the electrode cord connected to the pads.

Place the pads on the pad holder, 1 pad on each side with the sticky side of each pad on the pad holder.

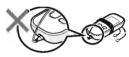
4. Wrap the electrode cord around the pad holder.



Storing the unit and pads

- Store the unit with the belt clip on.
 Store the pads with the electrode cord on the pad holder and put into the pouch.
- Do not keep in areas subject to direct sunlight, high or low temperatures, humid area, near to fire, vibration, or shock.
- · Do not keep at places that can be easily reached by children.
- When not in use for a long period, remove the batteries before storage, to avoid liquid discharge from batteries.
- Do not wrap the electrode cord around the unit because it may damage the cord.





Troubleshooting

If this happens	Possible causes	Try this solution
The intensity is not felt.	Are you using only 1 pad?	Place the other pad on your skin. You must use both pads for therapy to work.
Very weak intensity level.	Have you removed the transparent film from the pads?	Peel off the film on the adhesive surface of pads.
	Are the pads stacked together or do pads overlap?	Check placement of pads. Refer to pages 12-14, Pad Placement.
	Is the cord properly connected to the unit?	Connect the cord plug correctly into the jack at the bottom of this unit.
	Is the intensity setting too low?	Press the ▲ up button.
	Is the gel damaged?	Replace the pads.
	Are the batteries weak?	Replace both batteries.
The skin turns red or feels irritated.	Is the adhesive surface of pads dirty or dry?	Wash the adhesive surface of pads softly with your fingertips for about 3 seconds under slow and cold running water.
	Is therapy time too long?	Shorten your therapy to less than 15 minutes.
	Are the 2 pads attached properly to the body?	Refer to pages 12-14, Pad Placement and attach correctly.
	Is the pad surface worn out?	Replace both pads at the same time.
No power source.	Are the polarities of battery (+ and -) aligned in the wrong direction? Are the batteries depleted?	Check the batteries for correct alignment. Replace the batteries.
Power cut off	Are the batteries weak?	Replace both batteries at the same time.
during use.	Is the cord broken?	Replace the cord.
Battery icon is empty or close to empty.	Are the batteries weak?	Replace both batteries at the same time.
Pad gel does not stick to skin.	Is the adhesive surface of pads dirty or dry?	Wash the adhesive surface of pads softly with your fingertips for about 3 seconds under slow and cold running water.
	Have you removed the transparent film from the pads?	Peel off the film on the adhesive surface of pads.
	Is the pads wet? or Is your skin too wet?	Air dry the pads. Or dry the skin.
	The pad gel may be damaged.	Replace the pads.
	Are you using the pads during perspiring?	Dry the pad placement area.
	Have the pads been washed too long and/ or too frequently?	Leave the pads in refrigerator (do not freeze) for overnight.
	Were the pads stored under high temperature, high humidity, or direct sunshine?	Replace the both pads.

If this happens	Possible causes	Try this solution
Pad icon is displayed.	Only 1 pad is attached, or both pads are not attached.	Re-attach dislocated pad(s) onto the skin firmly. Power off-on after correction.
PAD \$	Have you removed the transparent film from the pad?	Peel off the film on the adhesive surface of pads. Power off-on after correction.
	Is the cord properly connected to the main unit?	Connect the cord plug correctly into the jack at the bottom of the main unit. Power off-on after correction.
	Is the adhesive surface of pads dirty or dry?	Wash the adhesive surface of pads softly with your fingertips for about 3 seconds under cold slow running water. Power off-on after correction.

Technical data

Product Description	Electronic Nerve Stimulator
Model (code)	HV-F021
Power Source	DC3 V (2 AAA alkaline batteries or 2 AAA manganese batteries)
Battery Life	New batteries (2 AAA alkaline batteries) will last for approx. 4 months (when used for 15 minutes a day, Lower Back Mode, max. intensity).
Frequency	Approx. 1 to 238 Hz
PULSE Duration	150 µsec
Maximum Output Voltage	70 V (during 500 Ω load)
Power Control	15 intensity levels
Operating Temperature and Humidity	+10 to +40 °C / 30 to 80 % RH
Storage and Transportation Temperature, Humidity, Air Pressure	-20 to +60 °C / 10 to 95 % RH / 700 to 1060 hPa
Weight	Approx. 100 g (incl. batteries)
Outer Dimensions	52 (W) × 112 (H) × 25 (D) mm
Package Contents	Main unit, Electrode cord, Pad holder, Long Life Pads, Batteries for trial use, Belt clip, Soft pouch, Instruction manual
Classifications	Internally powered (Protection against electric shock) Type BF (Applied part) IP22 (Ingress Protection)

This OMRON product is produced under the strict quality system of OMRON HEALTHCARE Co. Ltd., Japan.

Designed for a minimum of 5 years life expectancy.

IP classification is degrees of protection provided by enclosures in accordance with IEC 60529. This device is protected against solid foreign objects of diameter 12 mm such as a finger and greater, and against oblique falling water drops which gives trouble to normal operation.



= Type BF applied part





This product should not be used by persons with medical implants, e.g. heart pacemakers, artificial heart, lung or other electronic life support systems.

C E 0197 The device fulfils the provisions of the EC directive 93/42/EEC (Medical Device Directive).

NOTE: These specifications are subject to change without notice.

Important information regarding Electro Magnetic Compatibility (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation.

Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the EN60601-1-2:2007 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

This medical device manufactured by OMRON HEALTHCARE conforms to this EN60601-1-2:2007 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

Do not use mobile (cellular) telephones and other devices, which generate strong electrical or
electromagnetic fields, near the medical device. This may result in incorrect operation of the unit
and create a potentially unsafe situation.

Recommendation is to keep a minimum distance of 7 m. Verify correct operation of the device in case the distance is shorter

Further documentation in accordance with EN60601-1-2:2007 is available at OMRON HEALTHCARE SINGAPORE PTE LTD. at the address mentioned in this instruction manual. Documentation is also available at www.omron-healthcare.com.



Correct Disposal of This Product (Waste Electrical & Electronic Equipment)

This marking shown on the product or its literature, indicates that it should not be disposed of, with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this product from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.

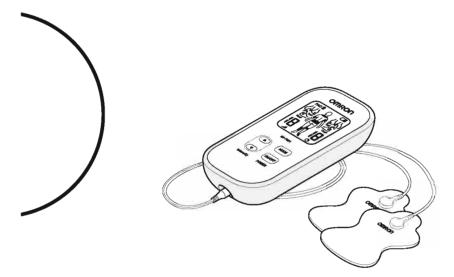
Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can return this item for environmentally safe recycling.

Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial wastes for disposal.

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Made in China

OMRON



低频治疗器 HV-F021 使用说明书

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简介

感谢您购买OMRON低频治疗器 HV-F021。

为了您能够安全地使用本产品,第一次使用前请仔细阅读本使用说明书。

产品功效

OMRON 低频治疗器 HV-F021 采用三重功效 TENS(经皮神经电刺激)技术,可以帮助:

- 缓解疼痛
- 触发内啡肽(天然止痛药)的释放
- 改善血液循环 (通过肌肉反复收缩和放松)

用途

医疗用途

OMRON 低频治疗器 HV-F021通过对疼痛部位附近的表皮进行神经电刺激,从而减缓肌肉和关节的疼痛,以及背部、上臂、腿、肩部和脚的僵硬和麻痹。本设备应在正常、健康、干燥和清洁的成年患者皮肤上使用。

只要按照本说明书所述进行操作,任何一种模式均可安全地应用于身体各部位或疼痛部位。只需选择一种感觉良好且对疼痛有舒缓作用的模式即可。同时还可以与任何其它疼痛治疗或药物治疗结合使用。

自1970年以来,TENS止痛术已被许多医疗保健专业人士广泛采用,如物理疗师和疼痛治疗专家。

重要的安全注意事项和警告信息

▶ 为确保您的安全,防止受伤和损坏本产品,必须仔细阅读本说明书中的所有警告和注意事项。

本说明书中使用的安全标记	
♪ 危险	表示错误使用时会带来导致人员伤亡或者重伤的危险。在此情形下不得使用本仪器。
▲ 警告	表示潜在的危险情况,若不加以预防,可能导致人员伤亡或者重伤的危险。
△ 注意	表示潜在的危险情况,若不加以预防,可能对患者造成轻微或中等伤害、或损坏设备或其 他物品的危险。

▲ 危险

请绝对不要与以下的医用电子器械一起使用:

- (1)心脏起搏器、植入型除颤器或其它植入型金属或电子器械。若同时使用,可能导致电击、烫伤、电子干扰或者死亡的危险。
- (2) 请勿在使用本器械的同时使用其它 TENS 器械。
- (3) 人工心肺等用于维持生命的医用电子器械。
- (4) 医院或诊所中的电子监控设备(如心电监护仪、心电图警报器)使用时,或连接病患身体时,可能会因为同时使用了本产品而导致运行不正常。
- (5) 对于医院和诊所,如果患者在身上同时使用高频手术设备和治疗仪时,在治疗仪电极片位置可能引起烧伤,也可能 损坏治疗仪。
- (6) 对于医院和诊所,如果在短波或微波治疗设备附近使用(1M)治疗仪时,本治疗仪的输出可能不稳定。

请勿在下列情形使用本产品

▲使用前,请先向医生咨询。该仪器可能对某些易感个体造成致命的心率紊乱。如果您近期做过外科手术,进行刺激可能会干扰您的康复过程。

请勿对以下群体使用本产品

∧孕妇

▲由于本产品尚未经过儿科应用评估,请勿在婴幼儿身上使用本产品。

▲由于导线可能导致窒息、故请将本产品置于儿童触摸不到的地方。

▲无表达意识能力的人使用。

⚠无法独立操作本仪器的人。

▲如果有内部出血倾向(如在受伤或骨折后)请慎用。

★如果您疑似或确诊患有心脏病,请向医生咨询后使用。

♠如果您疑似或确诊患有癫痫症. 请向医生咨询后使用。

▲如果是经期对子宫进行刺激,请慎用。
▲请勿对以下身体部位使用电极片:



头部、嘴或者脸部的任何部位。



颈部或喉咙的任何部位,因为这可能 会引起严重的肌肉痉挛,进而导致呼 吸道闭合、呼吸困难或对心率或血压 造成不良影响。



请勿对心脏或生殖器附近的部位使 用。



同时贴于喉咙的两侧(横向、正面和背面),或者交叉贴于胸前。因为产生的电流可能会导致心律失常,这将有可能致命。



同时用于左右腿上,可能会导致心脏障碍。



同时用于双脚脚底,可能会导致心 脏障碍。

创面、皮疹、浮肿、发红、感染、发炎部位或皮疹(如静脉曲张、静脉炎、血栓性静脉炎或血栓症)上,或癌变部位及周边部位,或缺乏正常感觉的皮肤。

请勿在以下活动过程中使用本产品

▲泡澡或淋浴时;

▲睡觉时;

↑驾驶和操作机器时,或在电刺激可能造成您有受伤风险的任何活动中。

疼痛控制警告信息

▲如果您因为疼痛做过药物治疗或物理治疗,使用本产品前请咨询您的医生。

▲如果疼痛没有好转、变成慢性病或加重,或持续超过 5 天,请停止使用本仪器,并咨询您的医生。

▲ 水疾痛本身就是一个非常重要的警告,预示着存在问题。因此,如您患有任何严重病症,请咨询医生,以确认可否使用本 OMRON 低频治疗器 HV-F021。

重要的安全注意事项和警告信息

请勿试图改造本体。

- ▲请勿将电极插入 OMRON 低频治疗器 HV-F021 以外的任何器械。
- ▲请勿对该仪器做任何改造。
- ▲本产品仅使用厂商推荐的导线、电极和附件,以免损坏设备。

关于电极片的警告信息

▲请在正常、健康、干燥和清洁的成年患者皮肤上使用电极片,否则可能干扰康复过程。

▲如果使用一次后出现皮肤刺激或发红的现象,请勿继续刺激该部位的皮肤。

关于电极片的注意事项

▲仪器处于正常运行状态时,请勿将电极片移到其它部位。

▲请确保各组件连接良好,并把电极片固定在想要治疗的身体部位上,否则治疗无效。

△上中极片不得接触任何金属物体,如皮带扣、项链、或佩戴在衣服底下的其它金属。

▲请勿重叠放置电极片或将电极片至于其他电极片顶上。这可能会削弱疗效或停止治疗,甚至导致仪器停止运行。

凝胶垫片也可能会互相黏连, 试图分开时凝胶可能会脱落。

- ⚠请勿与他人共用电极片。否则可能导致皮肤刺激或感染。电极片仅限同一个患者使用。
- ▲治疗后请勿将电极片留在皮肤上。
- ▲请勿对电极片弯曲或折叠,因为可能会损坏凝胶、导致丧失黏性或运行不正常。
- ▲人为避免损坏电极片的粘合表面,请将电极片放在皮肤或塑料电极片存放板上。
- △按照所提供的说明放置清洁的电极片(请参阅第 12-14 页 "电极片放置")。
- ▲请勿将药膏或任何溶剂涂到电极片或皮肤上,因为它会破坏电极片的正常运行。自粘式电极片会粘到您的皮肤上。
- ▲ 将电极片间隔至少3厘米安放可取得最佳效果。

使用时的注意事项

本体

- ▲如果因本体异常而感到身体不适时,请立即停止使用。
- ▲请勿用于使用说明书中所记载的治疗以外的目的。
- **△请**勿在浴室等湿度高的地方使用。可能会损坏仪器。理想的运行温度为: +10 +40 ℃, 相对湿度为 30 80 %。
- ↑请勿在照明不足的环境中使用本仪器,可能导致无法正常使用。

导线

介请勿将导线插头插入本体导线插孔以外的插孔内。

▲治疗过程中请勿拉拽导线。请勿弯曲或拉导线的末端。

↑从本体上拔下导线时,应握住导线插头拔出。

▲异线破损或损坏时请更换。

电池

▲清勿将电池扔入火中。否则电池可能会爆炸。

办处理废弃的仪器、电池和组件时、必须符合当地适用的法律法规。非法弃置可能会造成环境污染。

△请勿将碱性电池和锰电池混用,否则会缩短电池的使用寿命。

▲ 介治疗过程中,不要取下电池盖,不要触摸电池末端。

电极片

↑更换电池前,请将电极片分开。

一般注意事项

▲电刺激的长期影响未知。

⚠只对正常、完整、清洁、干燥和健康的皮肤进行刺激。

▲TENS 对于治疗疼痛的根源或起因无效,包括头痛。

⚠TENS 并不能代替止痛药和其它镇痛疗法。

♠TENS 设备不能治愈疾病或疗伤。

⚠TENS 是对症治疗,因此,只是作为一种额外的保护机制来抑制痛感。

▲您可能会经历因电刺激或导电性介质(凝胶)引起的皮肤刺激或过敏。

▲ 小由于本产品含有较小零件、易被儿童误吞、请将本产品远离儿童。如发生此类情况、请及时就医。

可能出现的不良反应

▲如果本仪器对您造成任何不良反应,应立即停止使用并咨询您的医生。

▲可能会在您皮肤接触的刺激电极下方产生刺激。

▲请勿在同一部位持续治疗过长时间(每次治疗超过 2 × 15 分钟,每天超过3次),否则该部位肌肉可能会产生劳损会酸痛。

产品构成

包装内含物

本体



电极片存放板







长寿命电极片



试用电池



皮带扣



软袋



使用说明书

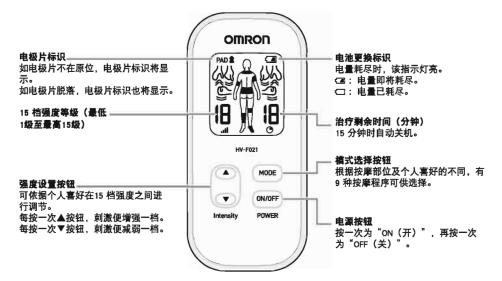


可选配件

(在欧盟医疗器械指令 93/42/EEC 的范围内)

· 长寿命电极片

各部件名称与功能



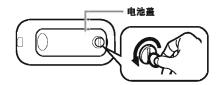
组装步骤

使用前,请检查关键要素,确保产品正常运行。

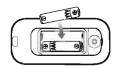
- 1. 导线无损。
- 2. 电极片胶贴无损。
- 3. 导线连接完整。
- 4. 仪器完好无损,处于正常运行状态。
- 5. 电池无漏液。

第 1 步一插入电池

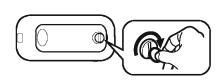
1. 如图旋动硬币打开本体背部的电池盖。



2. 按照正确方向装入电池。确保⊕ ⊝ 标记对应正确。



3. 如图旋动硬币关闭本体背部的电池盖。

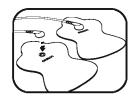


第 2 步一将导线插头插入到本体的导线插孔 将导线插头插入到本体的导线插孔。



第 3 步一将两根导线按扣到两个电极片上

初次使用时, 把电极片从透明袋中取出。



第 4 步一揭下并丢弃电极片上的塑料薄膜(使用新电极片的情况下)

从电极片背面撕下透明的塑料薄膜。

丢弃塑料衬底膜和透明包装。



将电极片储存在电极片存放板上

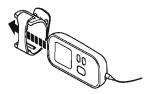
使用后,将电极片有粘性的一面放在电极片存放板的任意一侧。



电极片朝下 电极片存放板

· 电极片有粘性的一 面向上

第 5 步(可选)将仪器连接到皮带扣上。







△加果连接到柔软或薄的衣服上,皮带扣可能会脱落。

进行治疗

(每次治疗最多使用 2 x 15 分钟)

第 1 步一电极片放置

最佳疗效:

△将电极片放在疼痛部位的两侧,而不是直接放在疼痛部位。

▲ 个电极片间至少相隔 3 厘米安放。

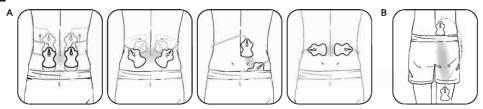
△请勿重叠粘贴,或将某一电极片放在其他顶上。

△请勿对皮肤或电极片喷水、涂乳液或面霜。

治疗前,先将疼痛分级为 1 (低)至 15(高)。这项心理检查在治疗结束后能为你提供一个对比的依据。

电极片应用示例

腰



- A. 根据疼痛情况将两个电极片贴在后腰上。
 - 将电极片放在背部肌肉上而不是脊椎上,以获得最佳疗效。
- B. 将两个电极片贴在同一侧,一片贴在疼痛部位上方,另一片贴在疼痛部位下方。

上臂

请在手臂酸疼处的上下部位粘贴。



关节(手肘)

请在疼痛关节的两侧粘贴。



关节(膝盖)

请在膝盖上方或疼痛的关节上、下方粘贴。





腿(臀部和大腿)

请在疼痛部位的两侧粘贴。



腿(小腿)

请在疼痛的小腿上粘贴。

△请勿将电极片同时贴下于左右小腿上。







(续)

第 1 步—电极片放置(续)

脚(脚踝)

请在疼痛的脚踝关节/脚外侧的左边粘贴。请在疼痛的踝关节/脚内侧的右边粘贴。

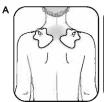
▲请勿对双足同时进行治疗。



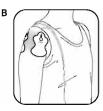




虘











A.根据疼痛情况将两个电极片贴在肩部。

B.将一个电极片贴在肩膀前面,另一个贴到肩膀后面。

▲请勿粘點在心脏附近、喉咙两侧或交叉贴于胸部,因为产生的电流可能会导致心律失常,这将有可能 致命。







第 2 步一在 9 种按摩模式中选择一种

·按"打开/关闭"

· 仅选择 9 种按摩模式中的 1 种。(各种按摩模式不能组合使用。)

选择按摩模式

或 选择疼痛模式

1.敲

4.上臂

2.按 3.揉

5.腰 6.腿

7.脚

8.关节(膝盖/手肘)

9.肩



按 "ON/开"

如何切换模式

设备自动默认为最后一次选择过的模式。每按一次模式选择按钮,模式就会以最低的强度切换到下一个 模式。每次只能选择一种模式。

如何选择正确的模式

任何一种模式都可用于身体的各部位或本说明书中所述的疼痛部位。 选择您感觉适合您的疼痛部位的模式。

腰







腿



治疗目标	上臂	腰	腿	脚
潜在状况	肿胀、僵硬、酸痛 或疼痛,肌肉或神 经痛。	僵硬、酸痛,肌肉或 神经痛。	肿胀、疲劳、僵硬, 肌肉或神经痛。	肿胀、疲劳、痛感、 酸痛或疼痛。
感觉	一系列低速到中速的 敲,有麻剌感和搏 动感。	一系列由强到弱的刺 痛感加上敲。强度较 大时,可能会有按或 按摩似的感觉。	一系列低速到中速敲 和揉的感觉。	一系列低速敲、搏动 的感觉。

第2步一在9种按摩模式中选择一种(续)









	స్థ
$\mathbb{Z}_{\mathbb{Z}}$	

治疗目标	关节	肩	敲	按	揉
潜在状况	肿胀、僵硬、酸 痛或疼痛。	僵硬、酸痛或疼 痛、紧张感。	僵硬、酸痛、紧 张感。	僵硬、酸痛或疼 痛、紧张感。	僵硬、酸痛或疼 痛、紧张感。
感觉	一系列中到高速 的敵、搏动的感 觉。	一系列低速到高 速的敲、搏动、 按和按摩的感 觉。	一系列低速敲的感觉。	一系列中速搏动 的感觉,模拟按 摩。	一系列高速搏动 的感觉,模拟摩 擦。

第 3 步一选择正确的强度(1低 - 15高)

从最低的强度开始、按 "▲(上)"箭头按钮慢慢增加强度。您应该有一种轻轻搏动的感觉。

如何正确选择适合自己疼痛的强度?

每按一次 "▲(上)" 或 "▼(下)"箭头,就会移动到另一个强度。如果刺激感变弱或者消失,可增加强 度,直到刺激感恢复。但是,如果感觉非常不适,可按向下箭头调低强度。

- ·按 ▲ 可提高强度。
- ·按 ▼ 可降低强度。

治疗需要多长时间?

仪器会自动运行 15 分钟,然后自动切断电源。我们建议一次进行 2×15 分钟治疗,每天不超过3次。屏幕上会显示还剩多少分钟。



如何控制和缓解疼痛

应该何时进行治疗?

如果身体某个部位感觉疼痛,即可治疗一次(本机开机15 分钟后自动断电)。关电源时,不取下电极 片,并再次评估疼痛等级。

应该使用多长时间?

开始进行一次 15 分钟治疗。在不取下电极片的情况下关机。评估疼痛等级,检查疼痛改善情况。如果疼痛减轻或消失,则停止本次治疗。按 "ON/OFF(打开/关闭)"按钮继续进行下个 15 分钟治疗。每次治疗不得超过 30 分钟。每天最多可进行 3 次 30 分钟治疗。

一个疗程 15 分钟 自动切断电源	每个疗程时间最长为(分钟) 2 次 15 分钟	每天治疗次数不超过 3次
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△◆阅第7页的警告信息。长时间治疗和强烈刺激可能会引起肌肉疲劳并产生不良反应。

何时停止使用治疗仪?

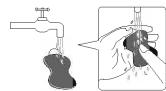
- 1. 发生不良反应(皮肤刺激/发红/灼热、头痛或其它痛感,或者感到非常不舒服)时。
- 2. 疼痛没有好转、变成慢性病或加重,或持续超过 5 天时。

清洗与保管

该仪器可以重复使用。电极片可持续使用 150 次, 或 5 个月(一天使用一次的情况下)。下面是重要的 清洗和保管说明。

清洗申极片

- 1. 关上电源, 将导线从电极片上取下。
- 2. 电极片胶粘表面变脏和/或电极片很难粘贴时、请清洗电极片。
 - · 用指尖在缓慢流动的冷水中轻轻地擦洗电极片几秒钟(请勿使用海绵/布/像钉子之类的锋利物体擦拭粘胶表面,不要使用洗涤剂、化学品或肥皂)。



- 3. 电极片可以在使用 15 次以后进行清洗,使用 150 次大约要清洗 10 次。冲洗电极片时间不要过长或过于频繁。如果胶粘表面黏性变差或电极片剥离,可将电极片放 在冰箱里(不要冷冻)一整夜。粘性可能会恢复。
- 4. 将电极片晾干, 让胶粘表面彻底风干。请勿使用卫生纸或布擦拭。
- 5. 电极片是可更换的, 可以另外购买。

电极片的使用寿命根据您清洗电极片的频率以及保管方法的不同而有所不同。

何时应更换电极片?

当电极片无法粘到皮肤上或电极片表面 25% 以上都接触不到皮肤时,应进行更换。

清洗仪器

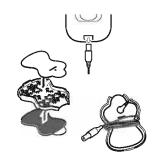
- 1. 关上电源, 将导线与电极片分离。
- 2. 用微湿或醮有中性(温和的)清洗液的布轻轻地擦拭。
 - · 请勿使用化学品(如稀释剂、苯)。
 - · 请勿让水进入本体内部。

保管电极片

- 1. 关上电源, 将导线从仪器底部取出。
- 2. 从皮肤上取下电极片。
- 3. 导线保持与电极片相连。

将电极片放在电极片存放板上,将每个电极片有粘性的那面放 在电极片存放板上。

4. 将导线卷在电极片存放板上。



保管仪器和电极片

- 保管仪器时必须扣上皮带扣。
 保管电极片时保持导线卷在电极片存放板上并装入软袋中。
- 请勿放在阳光直射、低温或高温、潮湿的区域、火附近、有震动或 振荡的地方。
- 请放在儿童触摸不到的地方。
- 长期不使用时,请取出电池后保管,以免电池漏液。
- 请勿将导线卷在仪器上, 因为这样可能会损坏导线。





故障排除

现象	可能原因	解决方案
感觉不到刺激。 刺激很弱。	只使用了 1 个电极片?	请把另一个电极片也粘贴到皮肤上。必须同时 使用两个电极片,治疗才会有效。
	已揭下电极片上的透明薄膜?	揭下电极片胶粘表面上的薄膜。
	电极片被重叠或搭接在一起?	检查电极片的放置情况。 请参阅第 12-14 页的 "电极片放置"。
	导线未正确连接?	请把导线插头正确插入仪器底部的插孔中。
	强度调的太弱?	按 ▲ 向上按钮。
	凝胶失效?	更换电极片。
	电池能量耗尽?	请更换两节电池。
皮肤变红或感觉疼 痛。	电极片粘贴面脏污、干燥?	用指尖在缓慢流动的冷水中轻轻地清洗电极 片 3 秒钟左右。
	治疗时间太长?	将治疗时间缩短至 15 分钟以内。
	两个电极片是否正确粘到身体上?	请参阅第 12-14 页的"电极片放置"正确 粘贴。
	电极片表面磨损?	同时更换两个电极片。
没有电源。	电池的两极(正极和负极)方向弄反? 电池 能量耗尽?	检查电池电极方向是否正确。更换电池。
电源被切断。	电池能量耗尽?	同时更换两节电池。
	导线破损?	更换导线。
电池图标为空或接近 为空。(电池能量耗尽?	同时更换两节电池。
电极片的凝胶无法粘 到皮肤上。	电极片粘贴面脏污、干燥?	用指尖在缓慢流动的冷水中轻轻地清洗电极 片 3 秒钟左右。
	已揭下电极片上的透明薄膜?	揭下电极片胶粘表面上的薄膜。
	电极片湿了?或者皮肤湿的?	风干电极片。或擦干皮肤。
	电极片粘贴面损伤?	更换电极片。
	出汗时使用了?	擦干粘贴电极片的部位。
	长时间或频繁的水洗了?	将电极片放入冰箱(不要冷冻)中一整夜。
	放在高温多湿、阳光直射的地方了?	更换两个电极片。

现象	可能原因	解决方案
显示出电极片图标。 PAD	只粘贴了 1 个电极片,或者两个电极片均未 粘上。	将脱落的电极片重新粘到皮肤上。更正后关 闭和打开电源。
	已揭下电极片上的透明薄膜?	揭下电极片胶粘表面上的薄膜。更正后关闭 和打开电源。
	导线正确连接到本体上?	将导线插头正确插入仪器底部的插孔中。更 正后关闭和打开电源。
	电极片粘贴面脏污、干燥?	用指尖在缓慢流动的冷水中轻轻地清洗电极 片 3 秒钟左右。更正后关闭和打开电源。

规格

产品名称	低频治疗器
型号(代码)	HV-F021
电源电压	DC3 V (2 节 AAA 碱性电池或 2 节 AAA 锰电池)
电池寿命	新电池(2 节 AAA 碱性电池)可使用约 4 个月(每日一次连续使用15 分钟时,腰模式,最大强度)。
輸出頻率	约1Hz ~ 238Hz
脉冲持续时间:	150 微秒。
最大輸出电压	70 V (500 Ω 负载)
电源控制	15 挡强度等级
使用环境温湿度	+ 10° C ~+ 40° C / 30%RH ~ 85%RH
运输和保存温湿度和气压	-20 to +60 ° C / 10 to 95 % RH / 700 to 1060 hPa
本体重量	约100g(含电池)
本体尺寸	约52mm (宽) ×112mm (高) ×25mm (厚)
包装内含物	本体、导线、电极片存放板、长寿命电极片、试用电池、皮带 扣、软袋、使用说明书
分类	内部电源(防止触电) BF型(应用部件) IP22(防护等级)

本 OMRON 产品是严格按照 OMRON HEALTHCARE Co. Ltd., Japan 的质量体系生产的。设计平均使用寿命至少 5 年。

IP分类为根据IEC 60529的规定,由外壳所提供的保护等级。该设备能抵御直径为12mm的坚硬异物,例如:手指,以及更大的外部物体,并能防止斜流水滴,以确保设备的正常运行。

★ = BF 型应用部件 请仔细阅读使用说明书。

本产品不可用于带有医学植入体的人员,如心脏起搏器、人造心脏、肺或其它电子生命 维持系统。

 $C \in 0.197$ 该设备符合欧盟指令 93/42/EEC(医疗器械指令)的相关规定。

注: 规格如有变更, 恕不另行通知, 敬请谅解。

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