OMRON

E4 Tens

E4 Tens Massager Low-Frequency Electronic Pulse Massager



Instruction manual Gebrauchsanweisung Gebruiksaanwijzing page 01 Seite 17 pagina 33 Mode d'emploi Manuale de instructone Manual de instrucciones page 49 pagina 65

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INTENDED USE

Medical Purpose

This Electronic Nerve Stimulator is intended to be used as a massager to relieve (muscle) pain, stiffness and fatigue. The massaging effect is achieved by electronic stimulation of the nerves through electrode pads placed on the skin. Various massage regions and treatment programs can be selected.

Suitable Users

Please read "Notes on safety" before using the unit. (This unit should not be used by people prohibited from doing so in "Notes on safety".)

Environment

This unit is intended for home use only.

Effectiveness

Massager: relieve of (muscle) pain, stiffness and fatigue

Precautions for use

Please read "Notes on safety" before using the unit.



1. Notes on safety

- The icons and warning signs are indicated here for your safety and correct usage of the product as well as to prevent injuries and/or damage to properties.
- The icons and meanings are as follows:

Examples of Icons



The ⊗ icon indicates prohibitions (must not do).

Matters involving certain prohibitions are indicated by text or pictures in or near ⊗. The icon to the left means "Prohibitions to Disassemble".



The ● icon indicates something that is compulsory (must be observed).

Matters involving certain compulsory actions are indicated by text or pictures in or near ●. The icon to the left refers to "General compulsory action".

⚠ DANGER

This unit must not be used in combination with the following medical devices:

- (1) Internally transplanted electronic medical devices, e.g. pacemakers
- (2) Electronic life support equipment, such as respirators
- (3) Electronic medical devices attached to the body, such as electrocardiographs
 Using this unit with other electronic medical devices may cause erroneous operation of those devices.



△ WARNING

Persons with the following conditions must consult the doctor before using this unit:

- 1) acute disease
- 2) malignant tumor
- 3) infectious disease
- 4) pregnancy
- 5) cardiac dysfunction
- 6) high fever
- 7) abnormal blood pressure
- 8) skin sensory disorders or skin problems
- receiving medical treatment, especially those feeling discomfort May cause an accident or ill health.

Do not use this unit near the heart, above the neck, on the head, around the mouth or on diseased skin.

May cause an accident or ill health.

 Application of electrodes near the thorax may increase the risk of cardiac fibrillation.



Do not use this unit simultaneously with other therapeutic device or in combination with ointments including spraytype ointments.

May cause discomfort or ill health.

- Simultaneous connection of a PATIENT to a h.f. surgical EQUIPMENT may result in burns at the site of the STIMULATOR electrodes and possible damage to the STIMULATOR.
- Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy
 EQUIPMENT may produce instability in the STIMULATOR output.



Do not use this unit for purposes other than treatment indicated in this manual. May lead to accident, problems, or failure of the unit.

Do not insert the electrode cord plug into any place other than the electrode cord lack of the main unit.

May cause an electric shock or accident.

Do not disassemble or remodel this unit. May cause fire, trouble, or accident.



△ CAUTION

If the unit is not functioning properly or you feel discomfort, immediately stop using the unit.

If you feel any problems with your body or skin, consult the doctor and follow his/her instructions.

If you want to move the Electrode Pad to another region or your body during treatment, be sure to turn off the power. If not, you may receive a strong electrical shock.



Do not try to attach the Pads to any other person during the treatment.

You may receive strong electrical shock.

Do not start treatment while wearing an electronic device.

The settings and timings of the device may be affected.

Do not use this unit on infants or people not capable of expressing their intentions.

May cause an accident or ill health.

Do not use this unit in places with high humidity such as bathrooms or while taking a bath or shower.

You will receive a strong electrical shock.



Do not use this unit while sleeping.

The main unit may develop trouble, or the pad may move to an unexpected region and cause ill health.

Do not use this unit while driving.

Receiving sudden strong stimulation may lead to traffic accident or trouble.

Do not leave the Electrode Pad attached to the skin after treatment.

Prolonged attachment may cause skin irritation or infection.

Be careful not to allow any metal object, such as a belt buckle or necklace to come into contact with the Electrode Pad during treatment.

You may receive a strong electrical shock.

Do not use cellular phones or other electronic devices near this unit.

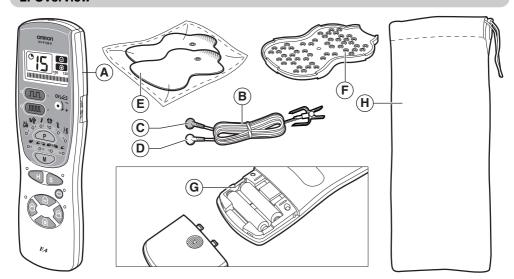
Do not use this unit to treat one region for a long time (more than 30 minutes). The muscles of the region under treatment may be exhausted and may cause poor

Put the Long Life pads only on skin or on the Long Life pads holder to avoid damage of the adhesive surfaces of the pads.



2. Overview

physical condition.

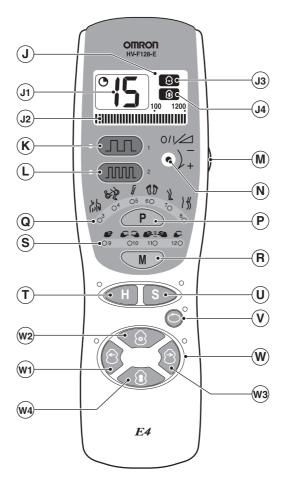


- A Main unit
- B Electrode cord with safety plug
- C Red connector
- **D** White connector

- E Long Life pads
- F Long Life pads holder
- **G** Battery compartment
- **H** Soft fabric storage case



2.1 Control functions



- J Display:
 - J1 Minutes to go during treatment,
 - J2 Blinking bar shows frequency,
 - J3 Indication Point,
 - J4 Indication Wide.
- K Low frequency button: to select treatment for stiff muscles.
- L High frequency button: to select treatment for acute pain.
- **M** On/Off and Adjustment Dial Switch: to turn on/off the power and to adjust the intensity.
- N Display shows on/off, intensity 0 to 10.
- **P** Part of the body button: to select region.
- **Q** Indication Part of the body button (shoulder, joint, arm, sole, leg, back).

- **R** Massage button: to select favourite massage method.
- S Indication massage method (tap, knead, push and rub).
- T Hyper button: to select gradual increase of intensity.
- **U** Soft button: to select soft stimulation.
- **V** Repeat button: to repeat favourite stimulation.
- W Point/Wide:
 - W1 Left (red) Long Life pad,
 - W2 Pulse is applied on one point,
 - W3 Right (white) Long Life pad,
 - W4 Pulse is applied on a wider surface.



3. How to obtain a correctt treatment

Medical Purpose

This Electronic Nerve Stimulator is intended to be used as a massager to relieve (muscle) pain, stiffness and fatigue. The massaging effect is achieved by electronic stimulation of the nerves through electrode pads placed on the skin. Various massage regions and treatment programs can be selected.

3.1 Program

To obtain a correct treatment you have available twelve treatment programs (see table below). A treatment program runs during 15 minutes.

	Complaint	Program	Effect
1	Stiff muscles, numbness	ЛЛ	Different combinations of vibrations on a low frequency to promote blood circulation. This program is effective over a long period
2	Acute pain	MM.	High frequency vibrations relieve acute pain promptly
3	Stiff shoulders	(1)(1)	Different vibrations promote blood circulation and relieve fatigue
4	Acute elbow or knee pain	8	High frequency vibrations relieve pain promptly
5	Arm fatigue	J	Different vibrations promote blood circulation
6	Swelling and foot fatigue	77	Different vibrations promote circulation of blood and body fluid in the feet
7	Swelling and calf fatigue	75	Different vibrations promote circulation of blood and body fluid in the limbs
8	Back pain or lower back stiffness	<i>\ \(\\</i>	Low frequency vibrations promote circulation of blood and relieve pain (neuralgia)
9		8	
10	Various symptoms	63	Your favourite massage method (tap, knead, push or rub) relieves stiffness, pain and fatigue
11		BES	
12			



3.2 Settings

Several settings can be made to get your favourite treatment. You can compose your favourite treatment at the beginning of the treatment program and you can change it any time.

Hyper mode and Soft mode



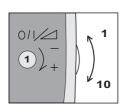
You can select either Hyper mode or Soft mode. Hyper mode increases gradual stimulation during treatment and relieves stiffness effectively. Soft mode stimulates without giving the feeling of irritation and relieves stiffness comfortably.

Treatment surface



The treatment can be applied on a specific point or to a wider surface of the Long Life pads.

Intensity



The intensity level of the massage is adjustable with a dial switch.

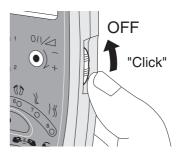
Repeat



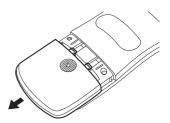
You can repeat your favourite stimulation. If the repeat button is activated the device will repeat the last part of the selected treatment program. The device will continue with the treatment program if the repeat button is deactivated.

4. Preparation

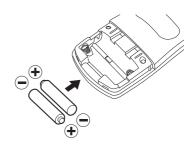
4.1 Insert batteries



1 Turn the On/Off-switch OFF.



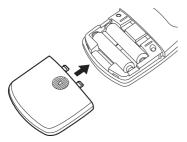
2 Remove the battery cover.



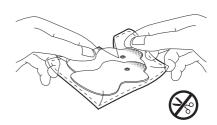
3 Insert two batteries in the battery compartment.
Caution! Use two identical batteries!

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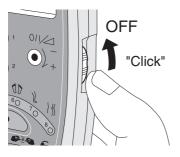


4 Put the battery cover on the battery compartment.

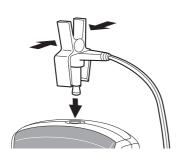


2 Take the Long Life pads out of the sealed package.

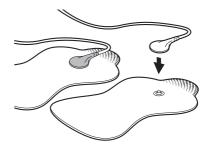
4.2 To use the massager for the first time



Caution! Make sure the device is turned off and that the batteries are inserted correctly!



1 Pinch the safety plug and connect it to the main unit.



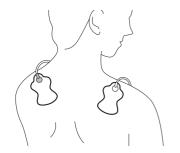
3 Connect the electrode cord to the Long Life pads.

4 Remove the film from the Long Life pads and attach the pads directly onto your skin. Caution! Do not dama the adhesive surfaces of the Long Lands!

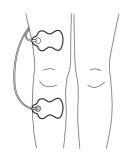
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4.3 Attach Long Life pads

Caution! Always use clean Long Life pads!Caution! Do not fold the Long Life pads!Caution! Avoid the Long Life pads touching any metal object, such as belt buckle or necklace!



 Attach the Long Life pads on both shoulders with the backbone in the centre.





 Attach the Long Life pads on both sides of the joint where you feel pain.



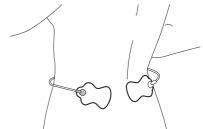
• Attach both Long Life pads on the upper arm where you feel pain.



 Attach one Long Life pad to the sole of the foot that feels cold and the other one on the calf.
 Caution! Do not simultaneously attach the Long Life pads on the soles of both feet!



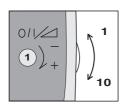
 Attach both Long Life pads on the calf where you feel pain.



 Attach both Long Life pads on the lower back with the backbone in the centre.

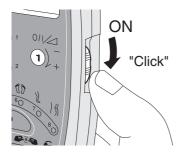
5. Operation

Caution! Make sure that the components are connected well and the Long Life pads are fixed on the part of the body you wish to treat! **Caution!** Do not pull on the electrode cord during treatment!

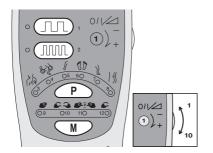


Note: Turn Adjustment Dial-switch for intensity (1-10) if required.

5.1 Treatment program

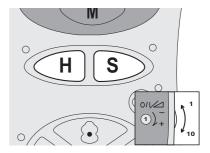


1 Turn On/Off-switch to level 1.

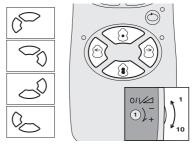


2 Select one of the twelve programs according to your complaint.

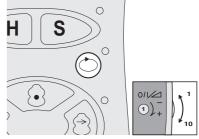
5.2 Setting



1 Select Hyper mode or Soft mode. For selecting Hyper mode press 3 seconds Hyper button.



2 Select point pulse or wide pulse.



3 Press repeat button to have previous treatment program start over.



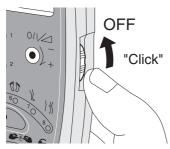
Treatment program runs for 15 minutes.

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6. End of treatment and care



After 15 minutes the massager stops automatically.



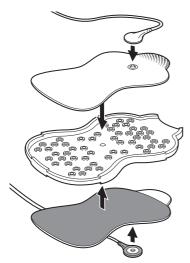
1 Stop program if required.

Caution! Stop treatment when you want to change the treatment program!

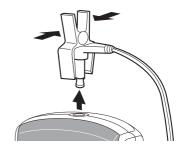
Caution! Stop treatment when you want to move a Long Life pad!

Caution! Stop treatment when you feel discomfort with your body or skin!

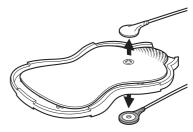
Caution! Stop treatment when the massager is not functioning properly or you feel discomfort!



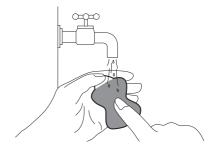
2 Remove the Long Life pads and place the pads on the Long Life pads holder.



3 Pinch the safety plug and remove it from the main unit.



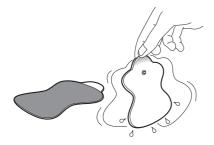
4 Disconnect the electrode cord from the Long Life pads.



5 Wash the pads softly with your fingertips under slow running water for about 3 seconds.

Caution! Do not use hot water!

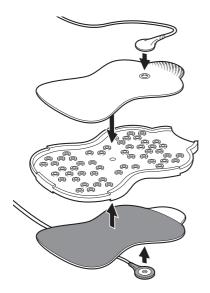
E4 English



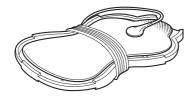
6 Sufficiently dry the Long Life pads.

Caution! Do not wipe the adhesive surfaces! **Caution!** Let the adhesive surfaces of the Long Life pads air-dry!

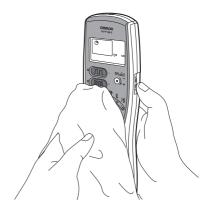
Caution! Adhesive surface sides up during drying!



7 Connect the electrode cord on the Long Life pads and place the pads on the pad holder.



8 Wrap the electrode cord around the pad holder.



9 Use a soft, slightly moistened cloth to clean the main unit.

Caution! Do not wash and do not use petrol, thinners or similar solvents!

7. Storage



- Put the massager and the pad holder in the soft storage case.
- Store the massager on a dry, closed place with a temperature between -20° and 60°C.

Caution! Remove the batteries for a long time storage (more than three months)!



8. Troubleshooting & Maintenance

Problem	Cause	Rectification
Device will not	Batteries inserted in wrong	Insert batteries in correct direction
turn on	direction	
Power turns off	Long Life pads not attached	Attach Long Life pads correctly to the skin
too soon	correctly to the skin	
Power turns off	Batteries weak/exhausted	Fit two new identical 1.5V alkaline
while using massager		batteries type AAA LR03
	Treatment period of 15	Restart treatment or turn off
	minutes is over and power	the massager
	turns off automatically	
	Electrode cord broken	Replace electrode cord
It is difficult to attach	Transparent film not peeled off	Peel off film on the adhesive
Long Life pad to		surface of Long Life pad
the skin	Long Life pad applied	Sufficiently dry Long Life pad
	immediately after washing	
	Adhesive surface of Long	Replace Long Life pad
	Life pad damaged	
Adhesive surface	Use of Long Life pad	
of Long Life pad	during perspiring	
is sticky	Long Life pad washed too	Leave Long Life pad in
	long and/or too frequently	freezer for overnight
	Long Life pads stored under	
	high temperature, high	
	humidity, direct sunshine	
It is difficult to	Long Life pads not attached	Attach Long Life pad firmly
feel stimulation	correctly to the skin	to the skin
	Long Life pads overlap each other	Reattach Long Life pads with no overlap
	Electrode cord not	Connect electrode cord correctly
	connected correctly	
	Applied intensity too weak	Increase the intensity by turning the dial switch
The skin turns	Adhesive surface of Long	Wash adhesive surface of Long Life pads
red or the skin	Life pads dirty or dry	softly with your fingertips for about 3 seconds
feels irritated		under slow running water
	Adhesive surface of Long	Replace Long Life pads
	Life pads damaged	

8.1 Maintenance and spare parts

 Do not carry out repairs of any kind yourself. If a defect occurs consult the customer service or authorised dealer of Omron. **Attention!** Disposal of used batteries should be carried out in accordance with the national regulations for the disposal of batteries.

8.2 Replace batteries

 Remove the batteries from the battery compartment and insert two new identical batteries.



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 Europe 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 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 take 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.

This product does not contain any hazardous substances.

Disposal of used batteries should be carried out in accordance with the national regulations for the disposal of batteries.

9. Technical Data

Frequency generation

Power consumption

Product Name OMRON E4 TENS massager

Model HV-F128-E

Power supply 3 VDC (2 1.5V alkaline batteries type AAA LR03)

Battery life Approx. 3 months: when used 15 minutes a day continuously

Approx. 2 months: when used 15 minutes a day continuously

under Hyper mode Approx. 1 to 1200 Hz

Approx. 85 mA

Maximum Output Voltage $U \le 90 \text{ V (during 1 k}\Omega \text{ load)}$ Maximum Output Current $I \le 10 \text{ mA (during 1 k}\Omega \text{ load)}$ Operating temperature and humidity 10°C to 40°C. 30 to 85% RH Storage temperature and humidity -20°C to 60°C, 10 to 95% RH

Main unit dimensions 60 (W) x 199 (H) x 21 (D) mm Weight Approx. 155 g (including batteries)

Package Contents Flectrode cord Set of Long Life pads

Batteries for monitor (2 identical 1.5V alkaline batteries type AAA LR03)

Long Life pad holder Soft fabric case Instruction manual

Specifications may be changed without prior notice.

Available accessories / replacement parts:

order no. 4928818-7 1. Electrode Pads (Long Life Pads) with holder 2. Electrode Cord (with safety plug) order no. 3027801-6 3. Flectrode Pad Holder order no. 1614950-5

Type BF **C € 0197**



Read the instructions in this manual carefully.



Disposal of this product and used batteries should be carried out in accordance with the national regulations for the disposal of electronic products.



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

This device fulfils the provisions of the EC directive 93/42/EEC (Medical Device Directive). This OMRON product is produced under the strict quality system of OMRON HEALTHCARE Co., Ltd., Japan.



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Made in China