

marketing authorization holder

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FUJI MEDICAL
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Menstrual Pain Relief Device Serafina F



MF-01

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About Products

This product offers drug free relief from period pain. If you are unsure of the cause of the pain, then you should seek medical advice to establish the cause and identify the correct treatment.

This product is a non - invasive small and convenient unit that can be worn all day under clothing to provide safe, continuous, drug free period pain relief whilst maintaining a normal, active lifestyle.

The device is indicated for the treatment of primary menstrual pain dysmenorrhoea. It also helps to relieve the pain of secondary menstrual pain due to conditions such as endometriosis, fibroids or pelvic inflammatory disease. Do not use the device for any purpose other than this intended use.



Question

Q

How does the product work? Are there any side effects?

A

Although it provides better pain relief than other treatments for dysmenorrhea, most people start to feel less pain after about 3 minutes of use, and generally get relief after about 20 minutes of use. The relief lasts 3 ~ 4 hours. This product is chosen by physical therapists in Europe and America because it uses the principle of TENS to reduce pain and has no side effects or damage to the human body.

Q

Why does it hurt again when I stop it even though it doesn't hurt during use?

A

The usage time is too short. The usual duration of use is 1 hour, and the pain is reduced. The duration of pain relief varies from person to person. You can use it continuously as many times as you like, so please find the usage time that suits you.

Q

How long does the battery last?it doesn't hurt during use?

A

On a normal full charge, the battery can be used for more than 15 hours continuously, but it must be adjusted to a higher intensity by the individual, and as the usage intensity increases, the usage time decreases accordingly. It is recommended that you charge the machine before and after use to ensure proper operation.

Q

Why does the pain remain after use?

A

The adhesive electrode sheet may not be properly installed. Check if adhesive electrode sheets are placed on both sides of the pain and current is flowing throughout the area of pain. Very good results can be obtained if the distance between the adhesive electrode sheets exceeds 3 cm and at the same time the output strength is increased appropriately. For some people, this product stimulates the production of endorphins and is not sufficient to reduce pain due to constitutional reasons. For best results, extend the duration of use (preferably at least 1 hour).

Q

How long can I use the adhesive electrode sheet?

A

It is related to the frequency of use, but it can be used 30 times in normal use, and it is within six months at most. If the viscosity of the adhesive electrode sheet decreases, you can restore it by spraying water. If the viscosity does not recover after spraying with water, the adhesive electrode sheet must be replaced.

Q

Why does the power automatically turn off when the power is turned on?

A

When the battery is low, the battery indicator flashes on the screen and the machine automatically shuts down to protect the battery, at which point the machine needs to be charged.

It is recommended that you recharge the machine if it is not used for more than four weeks to prevent excessive self-discharge over a long period of time and to ensure that the battery is ready for use.

Content In The Pack



Body
(With Cover)



electrode wire



Adhesive electrode
sheet



dedicated charging cable



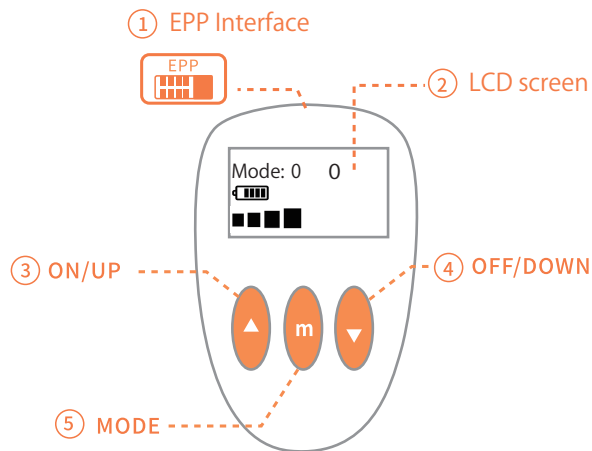
storage pouch



instruction manual

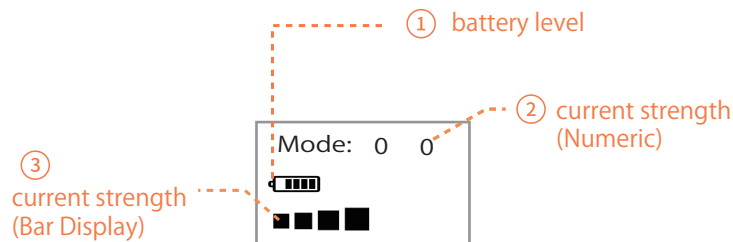
There is no AC adapter. Please prepare it yourself.


Name of each part



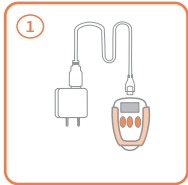
- ① EPP Interface This section connects the dedicated charging cable or electrode wires.
- ② LCD screen Indicates battery level, output strength, etc.
- ③ ON/UP Press and hold the button for 3 seconds to turn on the power. Press this button when you want to raise the current after selecting the mode.
- ④ OFF/DOWN Press and hold the button for 2 seconds to turn off the power. Press this button to lower the current after selecting the mode.
- ⑤ MODE There are 0~5 modes.

LCD display

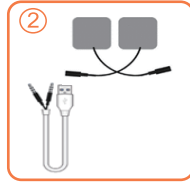


- ① battery level When the battery runs out,  is displayed. When the battery runs out, use the supplied cable to charge the battery.
- ② current strength (Numeric) The strength of the output current is indicated by the number 1~60.
- ③ current strength (Bar Display) The output current strength is indicated by a bar.

How to Assemble Your Unit



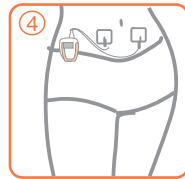
Connect the unit, the dedicated cable, and the AC adapter, and plug the AC adapter into a power outlet. (Charging time is 1.5 to 2.5 hours. It can be used for about 5 hours on a single charge.)



Check the electrode wire and adhesive electrode sheet, and make a connection.



Connect the charged device to the electrode wire.



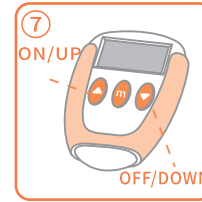
Peel the adhesive electrode sheet from the plastic sheet and place the sheet on the affected area.



Press the ON button for 3 seconds to turn on the power.



Select the Mode button in 0~5. (For information about modes, see About Modes.)



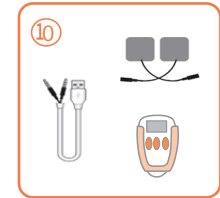
Adjust the output level according to the experience. If you want to increase the output level, press the "▲" Current UP button.



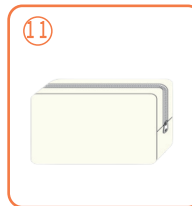
To lower the current, press the "▼" Current DOWN button.



Press and hold the power OFF button on the device for 2 seconds. After making sure that the power is turned off, remove the adhesive electrode sheet from the affected area and return it to the plastic sheet.

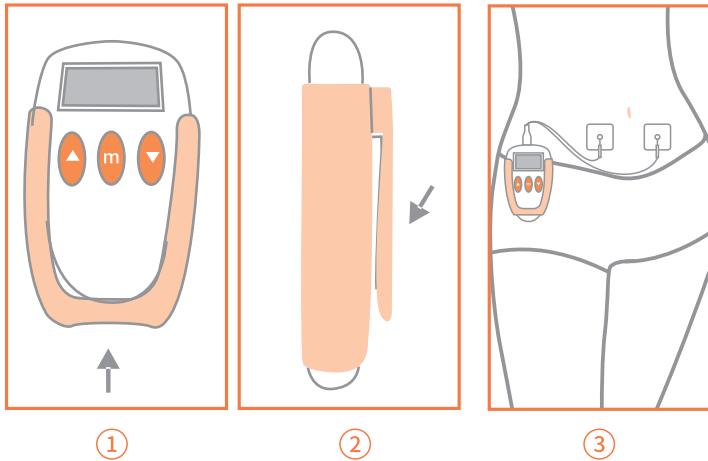


Remove all adhesive electrode sheets, electrode wires, and equipment body.



Place the device body and adhesive electrode sheet in the storage pouch.

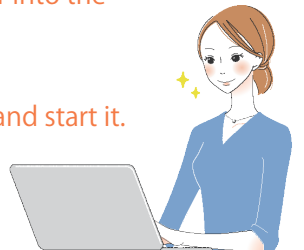
Mounting method



① Insert the body and mounting

② Insert the clip on the holder into the waist of shorts, skirts, etc.

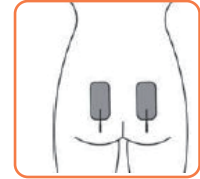
③ Put it on the affected area and start it.



Placement of electrode pads

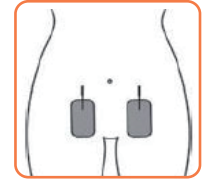
① place at the waist

Place the pads about 10 cm apart so that the bottom of the electrodes is not higher than the top of the buttocks.



② Place in the lower

Place the pads about 10 cm apart near the groin.



- The pain varies from person to person. In the affected area above, use your own mode to find the most painful area and mode.

- If sufficient relief is not obtained after 30 minutes, the position of the pad should be moved.

- Pads are reusable. However, please do not use between multiple people.

Mode of the device

Program	Frequency (Hz)	pulse width (μ s)	Treatment time (min)
0	2.5~120	100~330	30
1	2.5~120	100~330	60
2	60~120	170~330	30
3	60~120	170~330	60
4	2.5~100	100~330	30
5	2.5~100	100~330	60

This mode differs in treatment time and output current (pulse width).

If you are using this mode for the first time, you will need to start with a treatment time of 30 minutes, experiment with each mode and intensity, and look for a mode that relieves your pain.



safety precautions



Warning

Follow your doctor's judgment in the following cases:
[May adversely affect the body]

- (1) Patients who require medical expertise from a specialist
- (2) If the pain is not relieved after using this product for more than 5 days
- (3) If you are a patient diagnosed with a malignant tumor and want to relieve pain

Do not use this medicine in the following places:
[May adversely affect the body]

- (1) Attach to the mouth or neck
- (2) Attach close to the chest and heart
- (3) Attach to joints, spine and cervical spine

Do not use this product with any of the following medical devices.

[This may cause malfunction of the device]

- (1) Proximal operation (e.g., a distance of about 1 m) or direct irradiation with devices that emit strong electromagnetic waves, such as ultrasonic therapeutics, microwave therapeutics, electric scalpels, etc., or devices that emit X-rays may cause malfunction of the device.
- (2) Simultaneous use with electric scalpels may result in burns or damage to the device.



Contraindications

1. This medicine is a low-frequency therapeutic device. Do not use for any other purpose.
2. Do not use for the following patients.

[It can be harmful to the body.]

- (1) Patients with implantable electronic devices (e.g., pacemakers)
- (2) Patients with suspected or probable heart disease
- (3) Pregnant women
- (4) Patients with suspected or diagnosed epilepsy
- (5) Children 12 years of age or younger
- (6) Patients deemed inappropriate by the physician

3. Avoid use in the following areas, areas, or conditions:

[It can be harmful to the body.]

- (1) Areas where the skin is irritable, inflamed, damaged, or diseased
- (2) Areas where vascular disorders such as blood clots or aneurysms may occur
- (3) Areas that remain wet
- (4) Face and head
- (5) Areas of sensory loss

Troubleshooting

At a time like this	possible cause	How to deal with it
The screen does not	1, The battery is not charged. 2, Failure of the device	1. Charge the battery. 2. Contact the retailer where you purchased the card.
Low battery level	Lack of charge	Charge the battery.
The adhesive electrode pad does not stick to the skin.	1. The surface of the adhesive electrode pad is dirty. 2. The skin is dirty.	1. Add a small amount of water to the adhesive electrode pad to restore the adhesiveness. If you add too much water and the pad becomes soft, place it in the refrigerator for several hours to harden the adhesive gel. 2. Do not use lotion or skincare oil on the skin before using the device. If using the device, clean the skin.
No electricity is output from the adhesive electrode pad.	1, Defective contact of electrode part 2, Defective electrode part of equipment 3, Insufficient charge of equipment	1. Make sure that the body, electrode wire and adhesive electrode pad are properly connected. 2. Contact the retailer where you purchased the product. 3. Charge the device.

discomfort at the start of treatment	<p>1, Cannot be installed in the correct position.</p> <p>2, Life of the electrode wire</p>	<p>1. Check the installation position referring to the instruction manual to make sure that the machine is installed in the correct position.</p> <p>2. The electrode wire may have failed. If the product is used as it is, it may cause skin roughness. Discontinue use immediately and purchase a new electrode wire at the dealer where you purchased it.</p>
The treated area has red skin.	<p>1, Stimulation-induced blood flow increase</p> <p>2, Allergic reaction to electrode</p>	<p>1. Stop the treatment immediately and see if the red part of the skin disappears. If the red part does not disappear immediately, consult a doctor.</p> <p>2. If there is persistent itching on the skin, consult a doctor.</p>

Usage Notes



Important Basic Notes

- Avoid use while sleeping.
- Avoid use during activities that may cause sudden muscle stretching during operation.
- Discontinue use immediately if symptoms such as rash, redness, or itching occur due to use of this product.
- Adhesive electrode sheets can be reused, but do not use with multiple people.
- Place adhesive electrode sheets at least 3 cm apart.
- Avoid using in areas with water. Failure to observe this precaution may result in equipment failure.

Caution for use with this precaution

- If devices handling faint signals are installed around this product, they may be affected by electromagnetic waves generated from this product. Before using this product, be sure to check the operating status of the peripheral devices. If any problems occur, immediately discontinue use. repairer designated by our company or our company.

Appendix

What is TENS?

TENS is a painless physical therapy developed in the 1970s based on the pain-gate control theory proposed by American scientists Melzack & Wall. When we refer to low-frequency therapy, we generally refer to TENS.

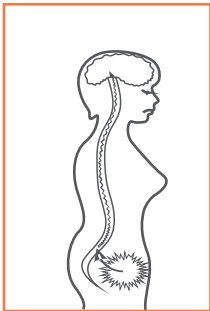
TENS therapeutics are very popular in Western countries because their main function is pain relief and they are safe without side effects, and they are widely used in pain and physical therapy clinics around the world.

Reason for use in menstrual cramps

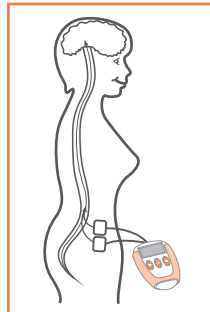
A substance called a prostaglandin is released during the passage of menstrual blood from the uterus. This prostaglandin is transmitted to the brain through the spine.

The product sends low-frequency electron pulses to painful areas of the human body, stimulates sensory nerve resistance fibers under the skin, and helps produce endorphins, which are painkillers.

Before Use



After Use



Tips for Dysmenorrhea

Dysmenorrhea can be caused by a variety of causes.

Western medicine classifies dysmenorrhea as primary dysmenorrhea and secondary dysmenorrhea.

The former is abdominal pain during menstruation without pelvic organ disease, which occurs mainly within 6~12 months after menarche, whereas the latter often occurs within 2 years of menarche due to gynecologic disorders such as endometriosis and pelvic inflammatory disease.

There are many reasons for primary dysmenorrhea, but the condition is mainly related to increased uterine contractions and decreased uterine blood volume.

The prostaglandin (PG) content of menstrual blood has been found to be significantly higher in people with dysmenorrhea than in normal women.

The higher the PG level, the more serious the dysmenorrhea. PG contracts the muscles of the uterus, causing spasms such as contractions during childbirth, and may cause uterine ischemia, hypoxia, worsening pain, and nausea and vomiting.

Symptoms of dysmenorrhea can occur in many gynecologic disorders and are called secondary dysmenorrhea.

Major factors include endometriosis, pelvic inflammatory disease, adhesions of the uterine cavity or cervix, and abnormal growth of the uterus.

In addition to dysmenorrhea, these disorders cause menstrual irregularities and excessive or insufficient menstrual blood.

Therefore, menstrual cycles, menstrual blood volume, color, and regular gynecologic examinations are important.