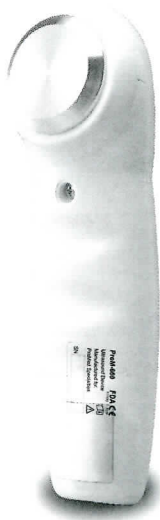


ULTRASOUND THERAPY DEVICE

Personal Beauty / Diathermy / Health Care Product

MODEL NO: ProM-660

USER MANUAL



BEFORE USING THE DEVICE, PLEASE READ OPERATING INSTRUCTION CAREFULLY.

INTENDED FOR USE

The ProM-660 generates deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

CONTRAINDICATIONS

1. Do not use over or near bone growth centers until bone growth is complete.
2. Do not use over a healing fracture.
3. Do not use over the eyes.
4. Do not use for patients with implanted neurostimulation systems because tissue damage can occur at the location of the implanted electrodes resulting in severe injury or death. This can also damage the system components.
5. Do not use to treat malignancies nor in the region with malignant tumors.
6. Do not use for patients with demand type cardiac pacemakers.
7. Do not use on someone who is pregnant.
8. Do not use over ischemic tissues in patients with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and tissue necrosis might result.
9. Do not use over the carotid sinus nerves or arteries, laryngeal or pharyngeal muscles.

PRECAUTIONS

1. Do not use on patients with hemorrhagic diatheses.
2. Do not use over an area of the spinal cord following a laminectomy, i.e., when major covering tissues have been removed.
3. Do not use over anesthetic areas.
4. Avoid bony prominences.
5. When using ultrasound, keep the sound head moving while maintaining contact with skin.
6. If treatment becomes uncomfortable, inform or contact your physician.
7. Do not immerse the Ultrasound device in water or other solvent.
8. Do not use over metallic implants, especially prostheses with a cement-matrix.

EXPLANATION OF ULTRASOUND STIMULATOR EFFECT

Ultrasound equipment generates high frequency sound waves (1MHz) that are transferred to a specific body area via a round-headed probe. The sound waves travel deep into tissue and create gentle heat. As the probe glides over the skin's surface, sound waves penetrate the skin's surface causing soft tissues to creating deep heat. In turn, the heat induces vasodilatation: drawing blood into the target tissues. The generated deep heat is found to help relieve pain and reduce muscle spasms.

SPECIAL FEATURES

1. The precise parts are assembled and tested under strict process.
2. Designed with single chip micro-processor, the quality is assured.
3. Precious alloy round-headed probe creates smooth, nice-touching surface to the skin.
4. Attractive exterior fits to the human body and easy to hold and convenient to use.
5. Micro-computer single button, very user friendly.
6. On/Off button also functions to set output intensity.
7. Three output intensity selections to meet different requirements.

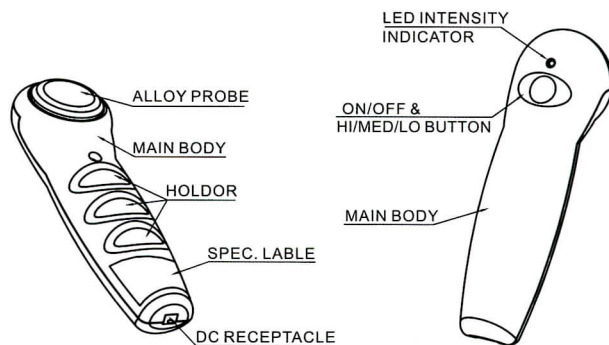
CAUTIONS

- ⚠ **Always use this device under the directions of professional physician.**
- ⚠ **Patients with following diseases or symptoms should not use the device.**
 - Pregnancy or Menses period.
 - Acute disease, Heart disease, Tubercle disease, Facial neuralgia, Pernicious tumor, Hemophilia, High fever, abnormal blood pressure patient, or under abnormally healthy conditions.
 - Patients with Sensitive physical condition, Ringworm, Dermatitis, Infectious disease.
 - Person who can't express themselves clearly such as infants, mental disables, after alcoholic drinking or under extreme fatigues.
 - Don't apply this product on following spots: Gash, Mucous membrane in the mouth, neuralgia spot, surgery area, skin with sun burn problem, sensitive skin irritated by cosmetic, skin implanted with metal, plastic and silicone material.
 - Do not use with other electronic equipments such as ECG machine...etc., even this device conforming to the EMC requirements.
- ⚠ **DO NOT** use on the thoracic region if you are a pacemaker user.
- ⚠ **DO NOT** use on the region with malignant tumors.
- ⚠ **DO NOT** use on the region of blood-lacking tissue, because there is not enough blood supplied to meet the metabolic demand, so that the tissues would result in necrosis.
- ⚠ **For the patient with bleeding physique, DO NOT** use ProM-660.
- ⚠ **DO NOT** use on the anesthesia regions.

*** Warning ***

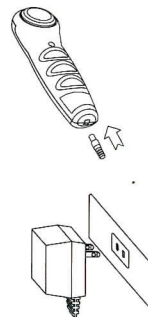
- The device complies completely with all parts of 21 CFR 1050.10 of the performance standard for sonic, infrasonic and ultrasonic radiation-emitting product.
- Cautions- use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.

PARTS OF THE DEVICE



STEPS TO CONNECT THE ADAPTOR

1. Insert the DC plug of the adaptor into the DC receptacle on the main unit. (as the picture)
2. Please hold the main unit tightly, when insert the DC plug into the DC. Insert and pull out the DC plug in correct direction.
3. There are many different adaptors (specification & shape of the plug) used by different countries.
4. Insert the adaptor into the power supply socket. (as the picture)
Be sure the power voltage is appropriate.



— ATTENTION —

Please use the original adaptor. The user can not re-assemble or change the specification of the adaptor. Personal injury or damage to the unit may be caused if you do not follow the above instructions.

FUNCTION TEST OF ULTRASOUND ACTION

Place the probe horizontally, then apply several water drops on the surface of the probe. Turn the device on, you can observe the ultrasound action. The water drops on the probe start to perform one million vibrations per second with slight atomization phenomenon.

Intensity LOW : The water drops vibrate slightly.

MED : The water drops vibrate stronger, and with atomization.

HI : The water drops vibrate very strongly, and with atomization phenomenon.

TROUBLE SHOOTING

The device is manufactured through complete quality assurance system. If there is any performance problem, please check the chart below for problems you can fix. Performance problems often result from little things that you can find and fix at home without tools. This can save you the cost of a service call.

PROBLEM	CHECK POINTS	POSSIBLE SOLUTION
LED does not light on.	<ul style="list-style-type: none">• The plug of adaptor is not inserted into the socket properly.• The DC plug of the adaptor is not inserted into the DC receptacle on the device correctly.• Did not press on the ON / OFF button.	<ul style="list-style-type: none">• Insert the plug of the adaptor into the socket again.• Connect the adaptor with the device again correctly.• Press the ON/OFF button again.
LED is performing normally, but no output function occurs.	<ul style="list-style-type: none">• Output intensity button setting is incorrect.	<ul style="list-style-type: none">• Please make sure and set it again.

For technical documentation or support, please contact your local distributor or the manufacturer as shown on the label.

HOW TO USE THE DEVICE

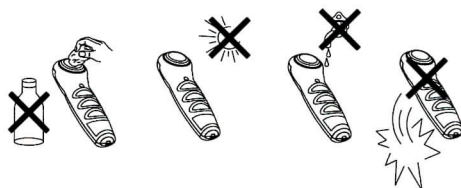
- Connect the adaptor with the main unit.
- Plug the adaptor into DC power supply socket.
- Apply appropriate amount of gel on the probe and on the treated area.
- Press On/Off button to turn on the power, the LED will light up in green.
- To adjust the output intensity, push On/Off button slightly.
When the LED is in green color, the vibrating is in Low lever; press On/Off button again, the LED will turn to orange color, the vibrating is in Medium lever; press On/Off button once again, the LED will turn to red color, the vibrating become in High level.
To return output to low level, just press On/Off button one more time.
- If you need to turn the power off prior to the auto timer shut down: Press the On/Off button and hold it down for just over 3 seconds, the device will then turn off.
- Using gentle upward or circular motions with the probe on treated area.
- Keep the probe gliding over the skin, DO NOT stop the motion at the same place too long.

— CAUTION —

⚠ DO NOT hold the motion at the same place too long.

MAINTENANCE

- Don't put into water, neither fall down or throw to ground from height.
- Do not use volatile solution such as turpentine or gasoline to rub the device.
- Please clean the device housing & alloy probe by wet towel or tissue.
- Do not use coarse or used fabric to rub the surface of the alloy probe.
- Store at room temperature in a dry place.



Prescription Statement

Caution: Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices, according to 21 CFR 801.109.

UNIT SPECIFICATION

1. Power: Switch adaptor
Input: AC100~240V, 50/60Hz
Output: DC 24V
2. Frequency: 1 MHz \pm 10%
3. Type: Non focusing
4. Pulse width: 2 ms \pm 10%
5. Repetition rate: 150 Hz \pm 10%
6. Waveform: Pulse
7. Temporal maximum power: 4W \pm 10%
8. Temporal maximum effective intensity: 1.57W/cm² \pm 10%
9. Effective maximum temporal intensity/
Effective average effective intensity: 1.57/ 0.47=3.34 \pm 10%
10. ERA: 6.16 square centimeter \pm 5%
11. BNR: Max.5.6:1
12. Auto-time setting: 30 minutes \pm 10%
13. Output intensity: Low, Medium, High
14. Size of main unit: 172(L) x 54(W) x 42(H) mm
15. Weight of main unit: 120 grams

STORAGE CONDITIONS

Operating Conditions: 10°C~40°C, 40%~90% r.H.
Conditions for Storage/Transportation: -10°C~60°C, 30%~95% r.H.

PRODUCT POST SALES QUESTIONNAIRE

Product Model: ProM-660 Product Series NO.: _____

Customer's Name: _____

Purchasing Place: _____ Date: _____

1. Does there exit any unclear printing, words not easy to understand, or other confusion in the operation instruction?

☐ No ☐ Yes _____

2. Is there any damaged parts to threaten personal safety?

☐ No ☐ Yes _____

3. Is there any important message to be omitted?

☐ No ☐ Yes _____

4. Does there have any improper action that different from the instruction manual?

☐ No ☐ Yes _____

5. Is there any problem about this product that can't be solved by local distributor?

☐ No ☐ Yes _____

Please send the completed questionnaire to the following address:

1800 Byberry Road, unit 905, Huntingdon Valley, PA. 19006

TEL: 215-9380200

Or drop your suggestion into our E-mail: sales@promedspecialties.com

