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## INTRODUCTION

Thank you for purchasing the Avail™ Wireless Dual Channel TENS Model PM601.
Avail™ is a wireless, independent dual channel electrotherapy device. This deivce delivers TENS (Transcutaneous Electrical Nerve Stumulation) therapy and microcurrent therapy through the simple, convenient control of the Omron TENS iOS or Android app. It is designed to reduce and relieve muscle and joint pain, stiffness and numbness in the back, arms ,legs, shoulder and foot.

Notes:
- Keep this instruction manual in a convenient place or store with the device for future reference.
- Register your product online at www.register-omron.com. You can also register your product via the Omron app.
- Keep your purchase receipt as proof of purchase for warranty coverage.
- The illustrations used in this manual are images.

## SAFETY INSTRUCTIONS

This instruction manual provides you with important information about this device. To ensure the safe and proper use of this device, READ and UNDERSTAND all of the safety and operating instructions. **If you do not understand these instructions or have any questions, contact 1-800-634-4350 before attempting to use this device.**

## INTENDED USE

The Avail™ Wireless Dual Channel TENS is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, legs, shoulders or feet due to strain from exercise or normal household work activities.
When used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis, choose Tap, Shoulder, Arm or Leg mode.
Environment of Use: Clinic, hospital and home environments.
Patient Population: Adult

# INTRODUCTION

## CONTRAINDICATION

Do not use this device if you have a cardiac pacemaker, implanted defibrillator or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference or death.

## RECEIVING AND INSPECTION

**Remove this device from the packaging and inspect all package contents for damage. If there is any damage, DO NOT USE and contact Omron Healthcare Customer Service at 1-800-634-4350.**

# SAVE THESE INSTRUCTIONS

## DEFINITIONS AND SYMBOLS

| | |
|---|---|
| ⚠ **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. |
|  | Type BF applied part. |
|  | Class II equipment. |
| REF | Catalogue number. |
|  | Consult instructions for use. |
|  | This product should not be used by persons with medical implants, e.g. heart pacemakers, artificial heart, lung or other electronic life support systems. |
| **IP21** | 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 vertically falling water drops which may cause issues during a normal operation. |
| **IP22** | 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. |
|  | FCC mark |

## IMPORTANT SAFETY INFORMATION

### WARNINGS

⚠ Keep this device and the pads out of the reach of infants, toddlers and children.

⚠ Consult with your physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals.

⚠ If you have had medical or physical treatment for your pain, consult with your physician before using this device.

⚠ If you are in the care of a physician, consult with your physician before using this device.

⚠ If your pain does not improve, becomes more than mild, or continues for more than five days, stop using the device and consult with your physician.

⚠ Do not place this device across your chest or near your heart because the introduction of electrical current into the chest may cause rhythm disturbances to your heart, which could be lethal.

⚠ Do not place the pads near or on skin with poor circulation, cancerous lesions, sensitive or diseased skin, open wounds, rashes, swollen, red, infected or inflamed areas or skin eruptions such as phlebitis, thrombophlebitis and varicose veins.

⚠ Do not place the pads over your neck because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.

⚠ Do not place the pads on or near the head, mouth, face, heart or genitals.

⚠ Do not use this device when bathing, showering, sleeping, during exercise, while sweating or in high humidity.

⚠ Do not use this device on patients with paresthesia (abnormal sensation) or peripheral neuropathy (damage to your peripheral nerves that causes weakness, numbness, and pain).

⚠ Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury.

## IMPORTANT SAFETY INFORMATION

⚠ Do not use this device on infants, toddlers, children, pregnant women, persons incapable of expressing their thoughts or on persons unable to operate the device by themselves.

⚠ Do not use this device while using another TENS device.

⚠ Do not apply stimulation in the presence of electric monitoring equipment such as cardiac monitors and ECG alarms because the equipment may not operate properly when the device is in use.

⚠ Never bend or fold the pads.

⚠ If you have any serious illness, consult with your physician before using this device.

⚠ Apply the pads only to normal, intact, clean, healthy skin of adult patients.

⚠ 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.

⚠ For Hospitals and Clinics: Simultaneous connection of a patient to high frequency surgical equipment and this device may result in bums at the site of the stimulator electrodes and possible damage to the stimulator.

**Data Transmission/Remote Control**

⚠ This product emits radio frequencies (RF) in the 2.4 GHz band. DO NOT use this product in locations where RF is restricted, such as on an aircraft or in hospitals. For further information on potential restrictions refer to documentation on the Bluetooth usage by the FCC.

**Battery Handling and Usage**

⚠ To prevent the risk of overheating, fire or explosion:
- Do not puncture, crush, disassemble or modify the device.
- Do not throw the device into fire.
- Do not recharge, use, or leave the device in any high temperature environment such as in a location near a fire or in direct sunlight.

⚠ The device contains a built-in rechargeable Lithium-Ion battery which must be disposed of properly. **Dispose of the device according to applicable local government regulations.**

⚠ If disassembling the device is required to dispose of it, call XXXXXXXXXX or visit XXXXXXXXXXXXXXXXX to request the disposal. Do not disassemble the device by yourself.

# IMPORTANT SAFETY INFORMATION

## CAUTIONS

⚠ TENS is not effective for pain of central origin, including headache.

⚠ TENS is not a substitute for pain medications and other pain management therapies.

⚠ TENS devices have no curative value.

⚠ TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.

⚠ Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.

⚠ Do not use this device to treat one region for extended periods of time. The long-term effects of electrical stimulation are unknown.

⚠ If you experience any skin irritation or redness after a session, do not continue stimulation in that area of the skin.

⚠ If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.

⚠ If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.

⚠ Use caution if you have a tendency to bleed internally, such as following an injury or fracture.

⚠ Consult with your physician prior to using the device after a recent surgical procedure because stimulation may disrupt the healing process.

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

⚠ Use caution if stimulation is applied over areas of skin that lack normal sensation.

⚠ Use this device only with components provided in the Avail™ Wireless Dual Channel TENS packaging and accessories recommended by the manufacturer. (Refer to page 11 and 37)

⚠ Place the pads at least 1 inch apart. Do not place the adhesive surface of the pads on the spine.

⚠ Do not apply the pads with wet hands, and do not apply the pads that are wet.

⚠ Pads are for Single Patient Use Only. Never share the pads with another person.

## IMPORTANT SAFETY INFORMATION

⚠ Do not overlap or put the pads on top of each other because therapy may weaken or stop.

⚠ Do not leave the pads placed on the skin after treatment.

⚠ Do not apply any lotion, cream or ointment to the pads.

⚠ Never attempt to modify the device.

⚠ The pads should not touch any metal object such as a belt buckle or necklace.

⚠ To avoid damage to the adhesive surface of the pads, only put the pads on the skin or the plastic pad holder.

⚠ Always place clean pads in accordance with illustrations provided (Refer to pages 20 - 24, Pad Placement).

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

⚠ Before use, inspect the cord for open wires or any damage. If damaged, do not use and replace immediately.

⚠ Clean and dry affected area so it is free of all lotions, oils and sweat.

⚠ Clean or change the pad when it loses adhesion.

⚠ Do not put any metal object, such as coin, clip or other metal on the charger.

**Data Transmission/Remote Control**

⚠ Do not place integrated circuit cards, magnets, metal objects, or other devices that emit electromagnetic fields near this monitor while your reading is being transferred to your smartphone or while the device is controlled remotely. This may result in the incorrect operation of your device and smartphone.

## IMPORTANT SAFETY INFORMATION

### ADVERSE REACTIONS

- You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin.
- You may experience headache and other painful sensations during or following the application of electrical stimulation near your eyes and to your head and face.
- You should stop using the device and should consult with your physician if you experience adverse reactions from the device.

## HOW THE DEVICE WORKS

TENS has been used for over 30 years by medical professionals such as physical thrapists and chiropractors.
TENS therapy suggests that electrical stimulation therapy may work in several ways:

1. Gentle electrical pulses move through the skin to nearby nerves to block or shut out the pain message from reaching the brain from the source of the pain.
2. Gentle electrical pulses increase the production of the body's natural pain killer, such as endorphins.
3. Furthermore, it is thought that electrical stimulation improves blood circulation.

**About Microcurrent Therapy**
Microcurrent is a therapy that applies extremely small (less than 1 microampere) electrical currents to the nerves using electrodes placed on the skin.
Microcurrent technologies of this product were developed by the technological collaboration with ITO Co., LTD.

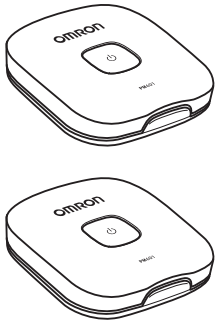
**Recommended Session Time**

| | Recommended 1 session | Max minutes per session | Max times per day |
|---|---|---|---|
| **TENS** | **30 minutes** | **60 minutes** | **3 times per day** |
| **MICROCURRENT** | **30 minutes** | **180 minutes** | **-** |

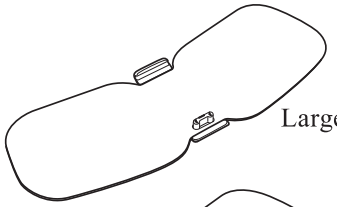
# KNOW YOUR DEVICE

## PACKAGE CONTENTS

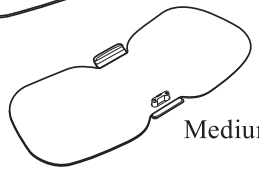
**Devices**



**Pads**

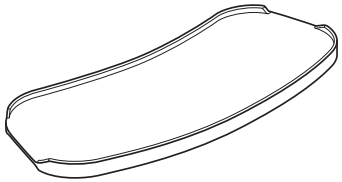


Large Pad = L

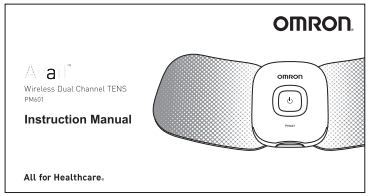


Medium Pad = M

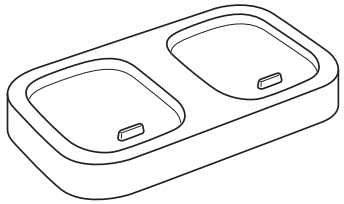
**Storage Case and Pad Holder**



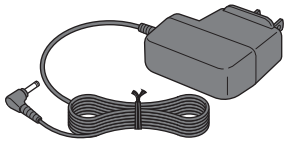
**Instruction Manual**




**Charger**

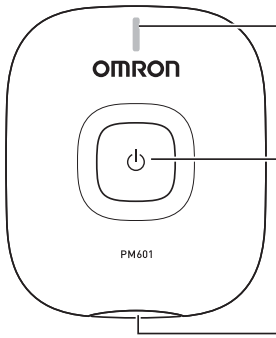


**AC Adapter**



## PART NAMES AND FUNCTIONS ON THE DEVICE

**Front**

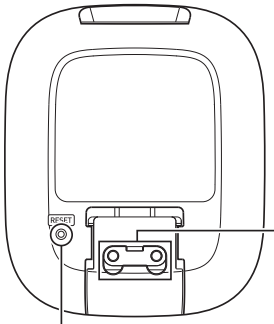



Indicator
Lights green, orange, white, purple and blue.

Power button

Pad release button

**Back**



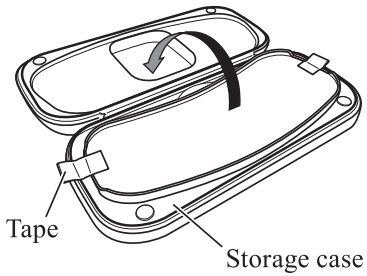

Connection hole
This hole is used for attaching the pad as well as securing the device to the battery charger.

Reset button

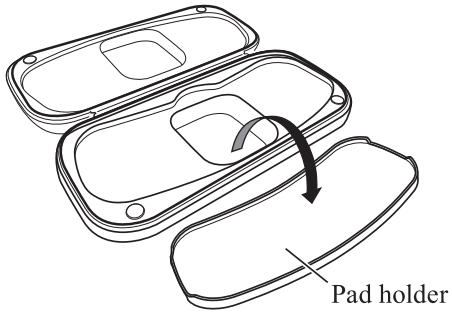
**Display of Indicator Lights**

| Indication | Description |
|---|---|
| Blinks green slowly (every 1 second) | The power is turned on and waiting for pairing or connecting to smartphone. |
| Blinks green quickly (every 0.5 seconds) | Before selecting the therapy setting. |
| Lit green | The device is connected to smartphone. |
| Blinks orange | Battery is being recharged. (When the battery is fully charged, the indicator light will go off.) |
| Lit orange | Battery is depleted. |
| Blinks white | Therapy session is live. |
| Blinks purple | The device is damaged. Refer to page 35 on Troubleshooting. |
| Blinks blue | Software is being updated. While updating, the device cannot be recharged or used. |

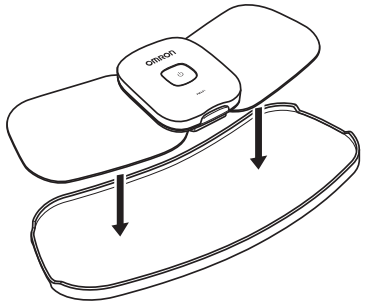
## USAGE OF STORAGE CASE AND PAD HOLDER




1. Open the storage case.
2. Remove the tape from the pad holder.




3. Remove the pad holder from the storage case.



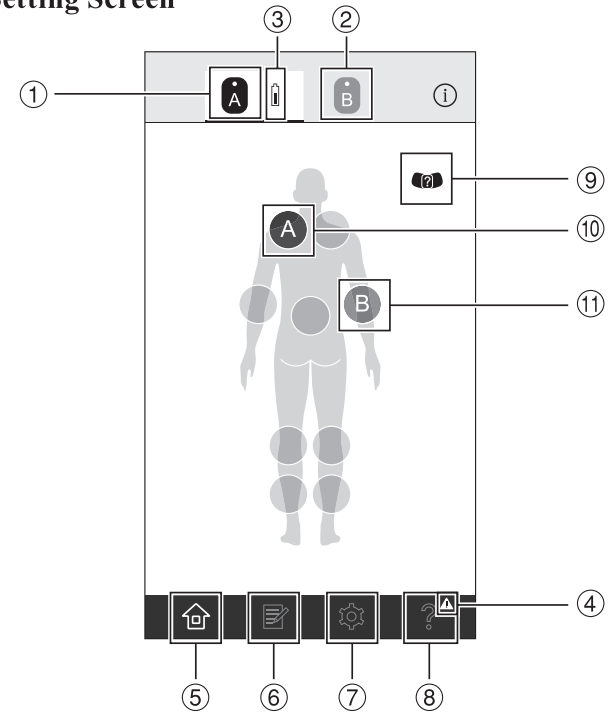

4. Attach the pad to the pad holder.

   For more details, refer to “Storing the Pads on the Pad Holder” on page 30.


5. Place the pad holder back into the storage case.
6. Close the storage case.

## PART NAMES AND FUNCTIONS OF THE OMRON TENS APP

### Therapy Setting Screen

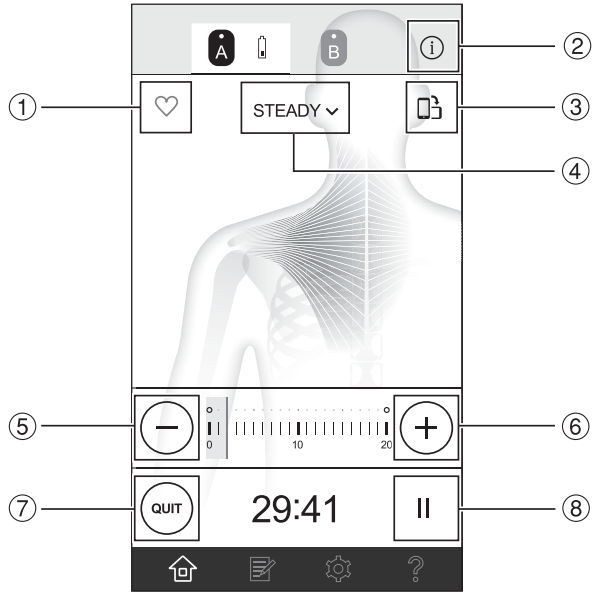



Screen design may be changed. View of the screen may be slightly different depending on the smartphone type.

| | | |
|---|---|---|
| ① | A | Tap to make the first connected device active. You can select a treatment area that the first connected device will be placed. |
| ② | B | Tap to make the second connected device active. You can select a treatment area that the second connected device will be placed. |
| ③ | | Battery charge is full. |
| | | Battery charge is about half full. |
| | | Battery charge is close to low. |
| ④ | | Displayed when there is any notification. |
| ⑤ | | Tap to show the therapy setting screen. |
| ⑥ | | Tap to show the pain diary screen to record your pain level or view your pain history. |
| ⑦ | | Tap to show the settings screen. |
| ⑧ | | Tap to show the help information. |
| ⑨ | | Tap to show the proper pad placement. |
| ⑩ | A | Indicates the area that the first connected device will be placed. |
| ⑪ | B | Indicates the area that the second connected device will be placed. |

## PART NAMES AND FUNCTIONS OF THE OMRON TENS APP

**Session Screen**




| | | |
|---|---|---|
| ① | ♡ | Tap to save your favorite therapy setting.<br>When tapped, it will change to " ♥ ".<br>" ♡ " indicates that this setting is not favorite.<br>" ♥ " indicates that this setting is favorite. |
| ② | ⓘ (For iPhone)<br>*i* (For Android) | Tap to show the caption for app's display.<br>To close caption, tap "ⓧ". |
| ③ | | Tap to switch view orientation. |
| ④ | ⌄ | Tap to change the mode. |
| ⑤ | ⊖ | Tap to decrease intensity. |
| ⑥ | ⊕ | Tap to increase intensity. |
| ⑦ | QUIT | Tap to quit the session. |
| ⑧ | II | Tap to pause the session. To restart, tap " ▶ ". |

Screen design may be changed. View of the screen may be slightly different depending on the smartphone type.