Multi-Frequency Ultrasound Unit

US-751

OPERATION MANUAL

To ensure correct use, please read this manual carefully before operating the unit. After reading, store the manual in a safe place for future reference.

CE 0123

* This unit should be used by a licensed medical practitioner.

ITO PHYSIOTHERAPY &REHABILITATION

Contents

Symbols

- Symbol for “WARNING” 
- Symbol for “CAUTION” 
- Symbol for “CONSULT INSTRUCTIONS FOR USE” 
- Symbol for “SERIAL NUMBER” 

- Symbol for “CATALOGUE NUMBER” 

- Symbol for “AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY” 

- Symbol for “MANUFACTURER” 
- Symbol for “DATE OF MANUFACTURE” 
- Symbol for “TEMPERATURE LIMIT” 
- Symbol for “HUMIDITY LIMITATION” 
- Symbol for “ATMOSPHERIC PRESSURE LIMITATION” 
- Symbol for “Ultrasound radiation warning sign” by Canadian ultrasound therapy devices standard 
- Symbol for “Waste Electrical and Electronic Equipment (WEEE), Directive”
  * This symbol is only valid in European Union. 
- Symbol for “TYPE BF APPLIED PART” 
- Symbol for “NON-IONIZING ELECTROMAGNETIC RADIATION” 
- Symbol for “ELECTROSTATIC SENSITIVE DEVICES” 
- These marks are to be used to indicate conformity to European Community harmonisation legislations. 

- Symbol for “POWER ON” (Power switch)
- Symbol for “POWER OFF” (Power switch) 
- Symbol for “STOP” (Stop switch) 
- Symbol for “Probe output port” 
- Symbol for “Combination & EST Cable port” 

To Ensure Correct and Safe Use

The US-751 is a therapeutic ultrasound unit which is equipped with 2 connectable channels each allowing therapy with both a small (S) probe and large (L) probe heads applicable with both frequency settings (1 MHz, 3 MHz).

Intended use

Indications for therapeutic ultrasound can be achieved through thermal and non-thermal effects.

1) Relief of pain
2) Reduction of muscle spasms
3) Localized increase in blood flow
4) Decrease of joint contractures
5) Stimulation of tissue repair

Contraindications

1) Over the uterus during pregnancy
2) Over thoracic area to patients with cardiac pacemakers
3) Over the site of any implanted electronic devices
4) To eyes
5) Over the heart
6) Area of diagnosed or suspected malignancy
7) To reproductive organs such as testes
8) Regions with thrombophlebitis, deep vein thrombosis, or embolism
9) Over tissues recently treated by deep X-ray or other radiation
10) Over stellate ganglions
11) Over area with impaired circulation
12) Over area with impaired sensation especially when using continuous thermal ultrasound
13) Bone growth centers (active epiphysis) in children until bone growth is complete
14) Patients with cognition or communication impairments not being able to give accurate and timely feedback during treatment
15) Over open wounds
16) Over implants that contain plastic or cement
17) Patients with serious infection such as tuberculosis
18) Over acute inflamed tissue especially when using continuous thermal ultrasound
19) Over active bleeding tissue or patients with untreated hemorrhagic disorders
20) Areas near myositis ossificans
21) Over anterior neck or carotid sinus

To Ensure Correct and Safe Use

Precautions

1) Patients with hemorrhagic diatheses or bleeding disorders
2) Use moving technique of the ultrasound probe
3) Heating of joint capsules in acute or subacute arthritis should be avoided
4) Electric treatment tables or whirpools which may come in contact with the patient should be adequately grounded.
5) Over healing fracture
   Therapeutic ultrasound may delay or prevent callous formation in a healing fracture
6) Spinal cord after laminectomy
7) Superficial peripheral nerves
8) Burns may occur in following application of therapeutic ultrasound
   ① High intensity
   ② Stationary technique
   ③ Moving ultrasound probe too slowly
   ④ Treating area with sensory nerve damage
   ⑤ Desensitized areas for example in patients with diabetes, neural damage, and etc.
   ⑥ Bony prominences are especially vulnerable

Precautions on use

1. General precautions

1) Do not use component parts from any other therapeutic devices with this device.
2) Handle the ultrasound probe with great care. Mishandling may affect performance characteristics.
3) Follow the instructions given below when installing the device.
   ① Install the device in a location not subjected to atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, salinity, air containing sulfur or other chemicals.
   ② Avoid flammable atmospheres, including flammable anesthetic gas mixed with oxygen, nitrous oxide and air, or flammable disinfectant or cleanser mixed with air.
   ③ Avoid locations where chemicals are stored or where vapors may be present.
   ④ Avoid installing the device near flames. Doing so may result in accidents due to damage or deformation of the device.
   ⑤ Note the frequency, voltage and allowable current (or power consumption) of the power supply.

4) Do not use gels that are not provided with this device.
5) Do not use this device near any high frequency devices such as shortwave or microwave therapy equipment.

2. Precautions before use

1) Carefully review the patient's diagnosis and prescription for contraindications, precautions, and instructions.
2) Use caution when using the device for the following patients or areas of the body.
   ① Carefully select the output level and duration when treating facial areas.
   ② When using the device on a child according to a physician's prescription, take great care when treating bony regions that no irritations occur.
   ③ If the individual has had radiation therapy in recent days, be careful in determining whether the treatment is appropriate for the individual. The inactivated tissue may be activated by the treatment.
   ④ Make sure the individual to be treated is free of contagious disease or conditions, since these can be transmitted to other individuals via the device.
   ⑤ Determining treatment intensity can be problematic with babies or infants (aged 6 or under), patients with senile dementia, or other patients who for any other reason are unable to express their preferences. Proceed carefully before deciding whether to use this device on such patients.
3) Check switches and keys to confirm that the device is working properly.
4) Make sure the cables are correctly connected and safely configured.
5) Make sure that the ultrasound probe is clean and free of any cracks.
6) The current density must not exceed 2 mA rms/cm^2 during combination therapy. The current density of the Ultrasound Probe (S) [Electrode size: 16 mm] may exceed 2 mA rms/cm^2. Adjust output and avoid any use that may increase current density. Please note that the difference between a setting at low output (4 mA or less) and the actual level is more than 30%.
7) When the ultrasound probe is not in use, return and set the probe on the probe holder.

3. Precautions during use

1) Make sure the patient gives the operator adequate and timely feedbacks when he or she has unusual sensations (e.g., pain, heat sensation or pressure) or the device doesn' t work properly during treatment with this device. When accurate feedback from the patient is not given, treatment effect from this device may not be gained.

2) If the patient reports abnormal pain or heat, stop treatment and determine whether the sensations goes away. A problem may have occurred or heat may have built up in the patient's body. If so, burns may result if treatment is continued even at reduced output.
3) With any complaint of periosteal pain from the patient, intensity should be reduced.
4) Make sure the treatment time and intensity do not exceed the suitable range for treatment purpose.
5) Monitor the device and the patient constantly to ensure no problems arise. In the event of any problem, take appropriate measures (e.g., shutting down the device in a manner safe for the patient) and contact the dealer or manufacturer or distributor.
6) To prevent accidents, make sure the patient does not operate or touch the device.
7) Make sure the ultrasound probe is positioned correctly on the treatment area. Incorrect positioning can affect effectiveness and results.
8) Do not leave the device with the output turned on. Buildup of heat may damage the device.
9) If the metal of the ultrasound probe or the gel causes any rash, areas of redness, itching, or other such symptoms, or if the patient feels any abnormality, immediately stop using the device and take adequate measures.
10) Avoid operating this device adjacent to and simultaneously with any shortwave or microwave devices.
11) Do not touch the EST Cable port and the Ultrasound Probe ports, when the device is in use.

4. Precautions after use

1) Turn off power, and disconnect the power cable from the outlet according to the steps specified.
2) When disconnecting the power cable from the outlet, make sure the power of the device is off and grasp the cable by the plug.
3) Rinse the ultrasound probe with lukewarm water lightly and thoroughly wipe dry. Take adequate measures to ensure it remains clean in storage.
4) Keep the device and accessories clean to avoid inconvenience for the next therapy session and store in a safe place.

Storage and period of service

1) Follow the instructions given below when storing the device to avoid malfunctions.
   ① Avoid locations where the device will be subject to splashing water.
   ② Avoid locations where the device may be unduly affected by atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, or airborne salt or sulfur or any other adverse factors.
   ③ Make sure the device is kept in a stable position. Avoid tilting the device. Avoid vibrations and shock. These warnings also apply during transportation.
   ④ Avoid locations where chemicals are stored or where gas may be generated.
2) If the device will not be used for an extended period of time, disconnect the power cable from the outlet.

Precautions on handling

1) Do not operate the device with wet hands except for the ultrasound probe. Electrical shock may occur.
2) Do not hit the device against another object, allow it to topple, drop, impose intensive vibration or impact to it. Even though the device may not exhibit abnormality at the time, damage may advance inside, eventually leading to an accident or malfunction.
3) To dispose consumables and residual materials, as well as the device and accessories which end of service life has been reached, follow the rules and regulations in force of the area where the device is installed, in order to minimize impact on the environment.

To Ensure Correct and Safe Use

Maintenance and checkup

1. Precautions

1) In the event of a malfunction, do not attempt to repair the device yourself. Attach an out-of-order notice to the device and contact the dealer, manufacturer or distributor to obtain repair services.
2) Do not attempt to modify the device.
3) Never open the device.
4) When maintaining the Main Unit and accessories, do not clean them with volatile solvents, such as paint thinner, gasoline, kerosene, or polishing powder, boiling water or chemicals. Such agents could cause discoloration or deterioration. Clean using a cloth impregnated with alcohol, water, lukewarm water or neutral detergent and wrung tightly.
   Do not wipe the LCD panel with alcohol. Doing so may cloud the LCD.
5) The ultrasound probe is waterproof. Never attempt to disassemble the probe; doing so may affect the waterproof properties or transducer characteristics, resulting in malfunctions. (IPX7)

2. Maintenance and checkup by the user

1) Check the device and accessories on a daily basis to make sure they work properly.
2) If any problem (deteriorated insulation of accessories, damage to the cord coverings, cracks, early signs of wire breakage, poor connection of connectors, etc.) is detected in the preparatory checkup, be sure you contact your dealer or the manufacturer or distributor.
3) When using the device after an extended period of disuse, check to ensure beforehand that the device works properly and safely.
4) The operator can not exchange parts. Contact manufacturer when exchange of parts are necessary.

3. Maintenance and checkup by a contractor

1) To maintain the performance and ensure safe use, request a periodic check from your dealer or the manufacturer or distributor (once a year as a rule of thumb).
2) Replace consumable parts (including accessories) periodically to prevent problems occurring in the accessories or device during use.

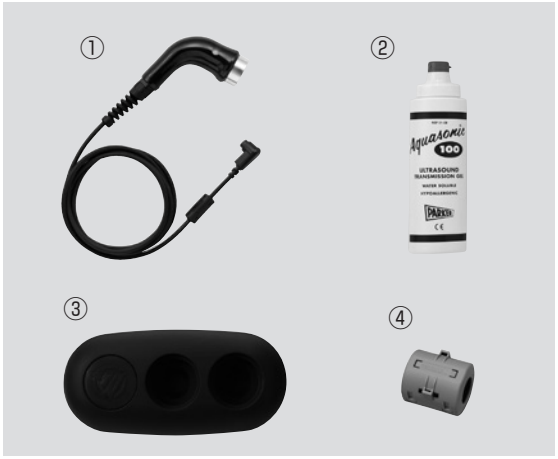
Maintenance and check items

Item	Description	Method
Appearance and indications	Check visible areas for signs of damage. Check for distortions in the LCD panel and for flickering indications. Make sure the ultrasound probe is clean.	Inspect visually.
Operation	Turn on the Power switch and check to confirm that the device operates normally and exhibits no problems.	Inspect by operating.
Output	Place water on the probe head and turn the output on to confirm whether the water vibrates.	Inspect by operating.
Ultrasound probe	Check for cracks in the probe head or problems with the cable connection that may permit water or ultrasound gel to enter the head.	Inspect visually.
	Make sure the cable and the connector are connected firmly.	Inspect visually and by operating.
Safety mechanism	• Check to confirm that an error display appears and output shuts off when the ultrasound probe is disconnected during use. • Check to confirm that the output shuts off automatically if no therapy is performed for more than 3 minutes after setting the output level.	Inspect by operating.

Device Configuration

Main Unit

Standard accessories



① 012297 Ultrasound Probe (L)【USP014】or
012330 Ultrasound Probe (L)
(Canada version)【USP014】

② 120612 Ultrasound Gel (250 ml)

③ 012298 Probe Holder

④ 080611 Core Filter

— 180672 Power Supply Cord
(220–240 V, Type F) or

— 180676 Power Supply Cord
(110–120 V, Type A) or

— 180673 Power Supply Cord
(110–120 V, only North America, Type B)

Optional accessories

⑤ 012296 Ultrasound Probe (S)【USP015】or
012329 Ultrasound Probe (S)
(Canada version)【USP015】

* Use only the specified accessories.

Specifications

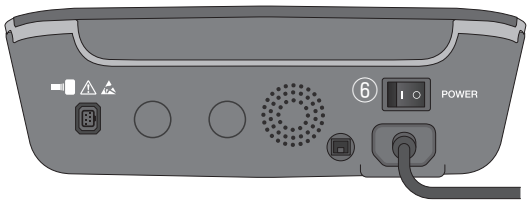
Power supply	AC 100–240 V, 50/60 Hz	
Power consumption	85 VA + within 10%	
Ultrasound frequency	1.0 MHz, 3.0 MHz ± 10%	
Intensity	Maximum effective intensity: 2.0 W/cm² ± 20% (continuous) Peak intensity: 3.0 W/cm² ± 20% (pulsed)	
Pulse frequency	16 Hz, 48 Hz, 100 Hz ± 5%	
Duty	5%, 10%, 20%, 30%, 40%, 50%, 100% ±5%	
Timer	30 min ± 1 min at maximum	
ERA	Ultrasound Probe (L)	1 MHz: 5.0 cm² ± 20% (IEC), 5.5 cm² ± 20% (FDA) 3 MHz: 5.0 cm² ± 20% (IEC), 6.0 cm² ± 20% (FDA)
	Ultrasound Probe (S)	1 MHz: 0.7 cm² ± 20% (IEC), 0.9 cm² ± 20% (FDA) 3 MHz: 0.5 cm² ± 20% (IEC), 0.9 cm² ± 20% (FDA)
BNR	Ultrasound Probe (L)	1 MHz: 3.0 ± 30% (IEC), 2.9 ± 30% (FDA) 3 MHz: 2.4 ± 30% (IEC), 2.9 ± 30% (FDA)
	Ultrasound Probe (S)	1 MHz: 2.9 ± 30% (IEC), 2.9 ± 30% (FDA) 3 MHz: 2.4 ± 30% (IEC), 2.9 ± 30% (FDA)
Output stability	± 20%	
Safety class according to IEC 60601-1	Class Ⅰ, Type BF	
Degree of protection against harmful ingress of water	Main Unit: IPX0 Ultrasound Probe: IPX7	
Dimensions	290 (W) × 233 (D) × 96 (H) mm	
Weight	Approx. 3.0 kg	

Environmental conditions	Temperature	Humidity	Pressure
In use	10–40°C	30–75%	800–1060 hPa
Storage	−10–60°C	30–95%	700–1060 hPa
Transportation	−10–60°C	30–95%	700–1060 hPa

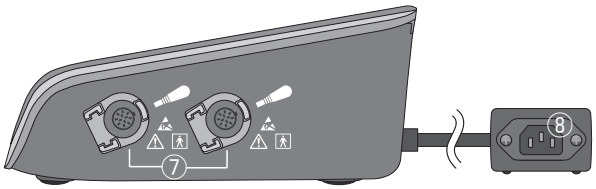
Names of Component Parts

① Touch panel ② Intensity control dial ③ Emergency stop switch ④ Power filter

⑤ LED



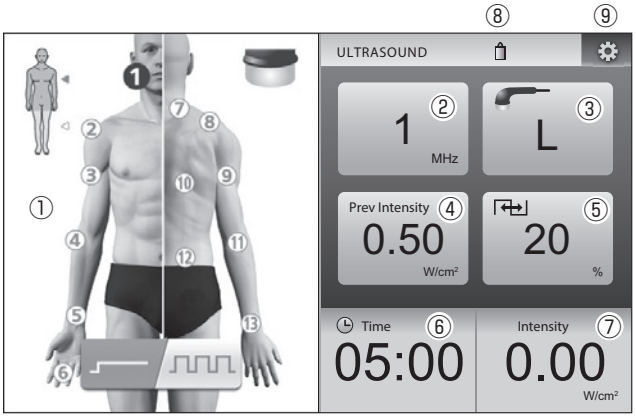
⑥ Power switch



⑦ Ultrasound Probe port ⑧ Power Supply Cord port

Explanation of Displays

Therapy parameter settings screen Set the parameters.



① **Therapy program setting** Select a therapy program.
[Continuous output: 21 programs and Pulsed output: 21 programs]

② **Frequency setting** Select a frequency. [1 MHz or 3 MHz]

③ **Ultrasound Probe setting** Select an Ultrasound Probe. [L or S]
*Probe selection is disabled if only one probe is connected.

④ **Prev Intensity setting** Previous intensity used is shown, and may be changed.
[Duty cycle at 100%: 0.10 W/cm² to 2.00 W/cm²
Duty cycle at 5% to 50%: 0.10 W/cm² to 3.00 W/cm²]

⑤ **DUTY setting** Set the duty cycle. [5%, 10%, 20%, 30%, 40%, 50%, 100%]

⑥ **Time setting** Set the treatment time. [1 min to 30 min]

⑦ **Intensity setting** Set the output level. This is also used to start the output.

⑧ **GEL/OTM indicator** The gel or OTM (ointment) icon selected on the initial settings screen is displayed.

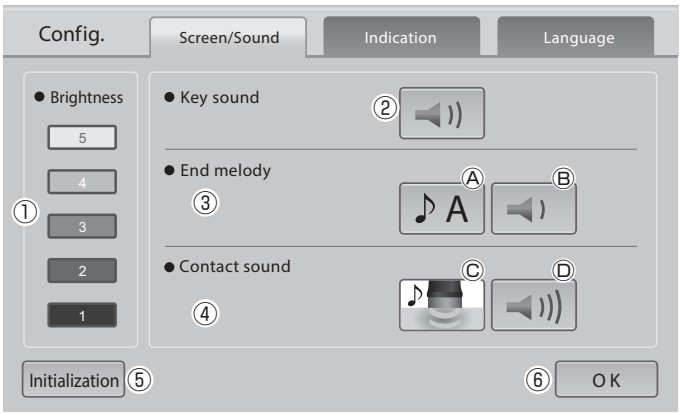
⑨ **Initial settings screen button** Touch this button to go to the initial settings screen.

Explanation of Displays

Initial settings screen

Set Screen/Sound, Indication and Language.
Touch the tab to display the corresponding settings window.

[Screen/Sound]



① **Brightness setting** Set the brightness of the screen.

② **Key sound setting**
Set the volume for the key operation sound. Touch the button to display the volume setting subwindow. Set the volume and press OK.

③ **End melody setting**
Ⓐ Select End Melody (two melodies).
Ⓑ Set the volume for the End Melody. Touch the button to display the volume setting subwindow. Set the volume and press OK.

④ **Contact sound setting**
Ⓒ Set Contact Sound.


The Contact Sound is issued when the Ultrasound Probe is in contact with the treatment area.

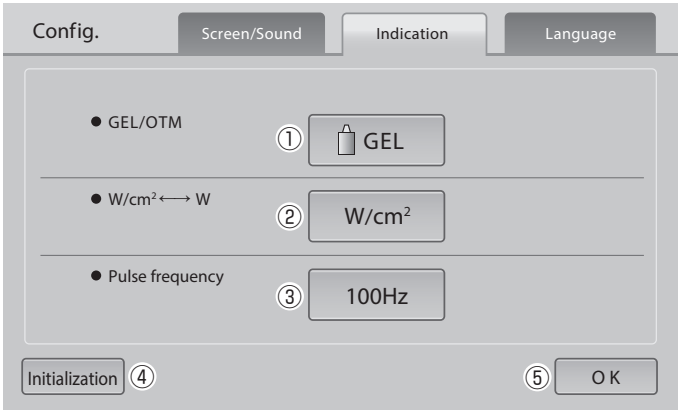

Contact Sound is issued when the Ultrasound Probe is not in contact with the treatment area.

Ⓓ Set the volume for the Contact Sound. Touch the button to display the volume setting subwindow. Set the volume and press OK.

⑤ **Initialization button** This button returns the settings made on the initial and therapy parameter settings screens to their default values.

⑥ **OK button** Press this button to complete the settings and return to the therapy parameter settings screen.

[Indication]



① **GEL/OTM setting** Select gel or ointment.

② **W/cm² ⟷ W setting** Select a unit for intensity. [W/cm² or W]

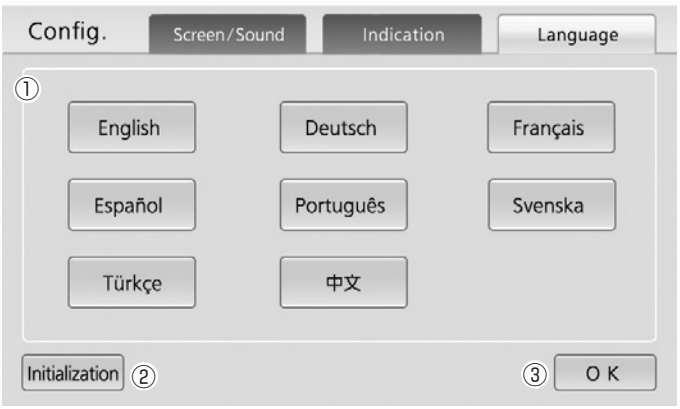
③ **Pulse frequency setting** Select a pulse frequency. [16 Hz, 48 Hz, 100 Hz]

④ **Initialization button** This button returns the initial settings and the therapy parameters to their default values.

⑤ **OK button** Press this button to complete the settings and return to the therapy parameter settings screen.

Explanation of Displays

[Language]



① **Language selection** Select a language. The following eight languages are available. After you make your selection, the language button will turn light blue.
English, German, French, Spanish, Portuguese, Swedish, Turkish, and Chinese

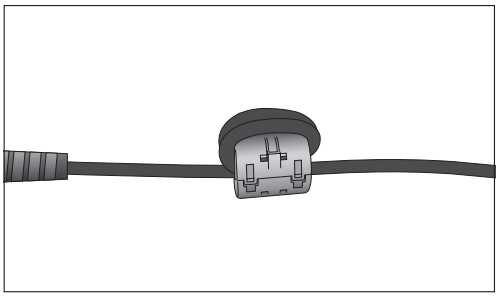
② **Initialization button** This button returns the settings made on the initial and therapy parameter settings screens to their default values.

③ **OK button** Press this button to complete the settings and return to the therapy parameter settings screen.

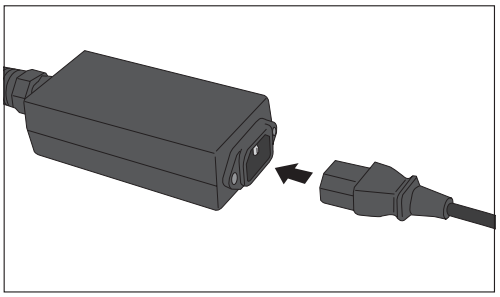
Preparations before Use

1 Make sure that the Power switch is off.

2 Attach a core filter to the power filter.



3 Connect the power filter to the power supply cord, then plug the power supply cord into a wall socket.



⚠ Warning

1. To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
2. MULTIPLE SOCKET-OUTLET or extension cord shall not be connected to the US-751.

⚠ Caution

1. In order to disconnect from a wall socket, pull the plug.
2. Do not position the US-751 where it is difficult to pull out the plug.

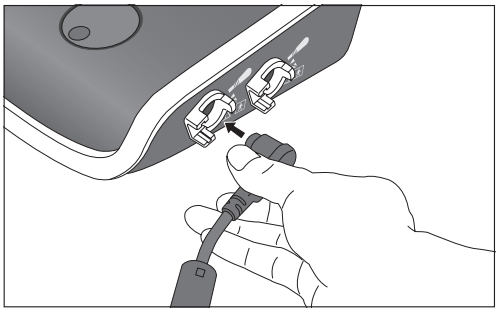
Note:

The operator's intended position is distance reachable by hand (about 60 cm away).

Preparations before Use

4 Connect the Ultrasound Probe (L) and/or (S) (optional) to the probe ports.

* The Ultrasound Probes may be connected to either port.
* Do not connect Ultrasound Probes of the same size to the Main Unit simultaneously. A probe error will occur.



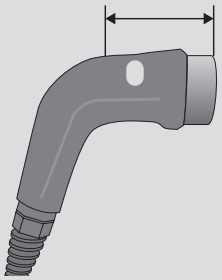
⚠ Warning To prevent electric shock, never touch the device with wet hands (except for the Ultrasound Probes).

⚠ Precautions on Auto Contact function

1. Auto Contact function is designed to reduce output levels to the minimum when the Ultrasound Probe is not in contact with the treatment area (skin). It will not shut off all output. For this reason, do not leave the probe with the power on. Make sure power is off if the probe is not in use. Do not leave gel on the probe; always remove the gel after use.
2. If you have not touched the Ultrasound Probe for more than one minute, check the temperature of the probe head before using it. The head may be hot, resulting in burns.
3. Output will switch off automatically if the Ultrasound Probe is left untouched for more than three minutes.

⚠ Caution

Do not hold the head of the Ultrasound Probe or LED area of the probe for a long period during treatment, due to heating of these locations.



Operating Procedures

1 Turn on the Power switch.

The Main Unit will start up. After the initial check has been complete, the therapy parameter settings screen will appear.

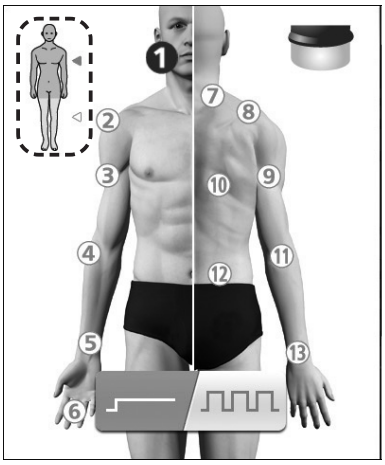
2 Set the Ultrasound Probe.

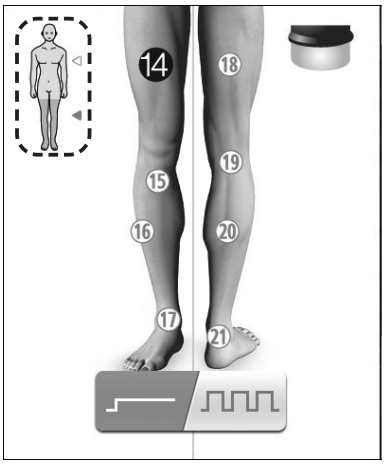
Touch the Ultrasound Probe setting and select L or S.

* This selection is disabled if only one probe is connected.

3 Select a therapy program.

Touch the icon on the top left to switch between the upper body and the lower body.
Touch the number of the area to be treated.





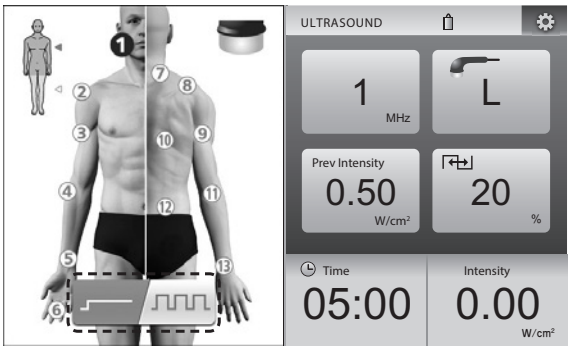
Operating Procedures

4 Select an output mode.

: Continuous output

: Pulsed output

The selected mode is shown in light blue.



Changing the therapy parameters

The therapy parameters may be changed for every treatment area. The revised parameters will overwrite the therapy program selected at the start of therapy.

* Changes in parameter settings are discarded (not saved) if another therapy program is selected or if the device is powered off before therapy is performed.

Any changes made in the parameters during output will be saved at the end of therapy or when the emergency stop switch has been pressed.

* Changes in parameter settings are discarded if power is turned off before therapy is complete.

1) Changing frequency

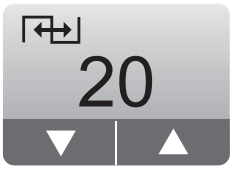
Touch the frequency setting and select 1 MHz or 3 MHz.

2) Changing Prev Intensity (Previous Intensity)

Touch the Prev Intensity setting to displays arrow keys ▼ ▲ . Use these keys to change the Prev Intensity.

3) Changing DUTY

Touch the DUTY setting to display the arrow keys ▼ ▲ . Use these keys to set the duty cycle.



[Setting range] 5%, 10%, 20%, 30%, 40%, 50%, 100%

* This setting is synchronized with the output mode selected in **4** on page 18.

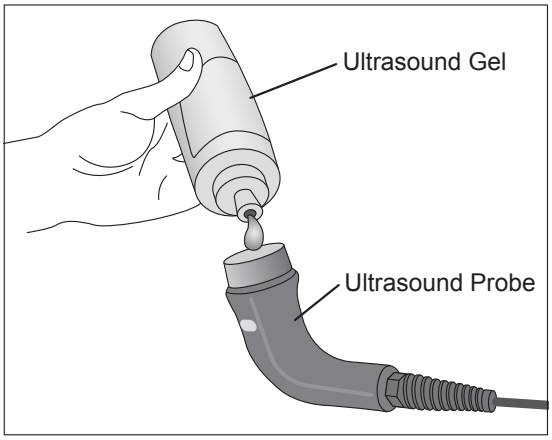
4) Changing timer

Touch the time setting to display the arrow keys ▼ ▲ . Use these keys to set the timer.

[Setting range] 1 min to 30 min

5 Apply ultrasound gel to the probe head.

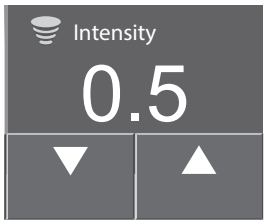
* When using OTM (ointment), select OTM on the initial settings screen, select the Indication tab, then touch the button for GEL/OTM settings. (See page 13.)



Operating Procedures

6 Start output.

Touch the intensity setting on the touch panel or turn the intensity control dial clockwise. The intensity setting will turn light blue. Intensity is automatically set to the level set as Prev Intensity, and output starts.



During output, LEDs on the Main Unit and the Ultrasound Probe will light up.

You can change the intensity and time settings during output.
To change the intensity, touch the intensity setting and change the level using ▼ and ▲, or turn the intensity control dial. Turn the dial counterclockwise to reduce and clockwise to increase output levels.

To change the time, touch the time setting and adjust using ▼ and ▲.

To end the therapy before the set time elapses, set the intensity to “0” or press the emergency stop switch.

* No Contact Sound will be issued if this is muted. (See page 12.)

7 When the timer reaches “00:00,” end melody will sound to indicate that therapy is complete.

Turn off the Power switch.

* Note that the melody will not sound if End Melody is muted. (See page 12.)
* Any changes made in parameters during therapy will overwrite the therapy program selected at the end of therapy or when the emergency stop switch has been pressed.

8 Make sure power is off.

Wipe to remove ultrasound gel from the probe head and disconnect the Ultrasound Probe from the Main Unit.

9 Disconnect the power supply cord from the wall outlet.

* Keep the device and accessories clean to make the next therapy as convenient as possible. Store in a neat and orderly condition.

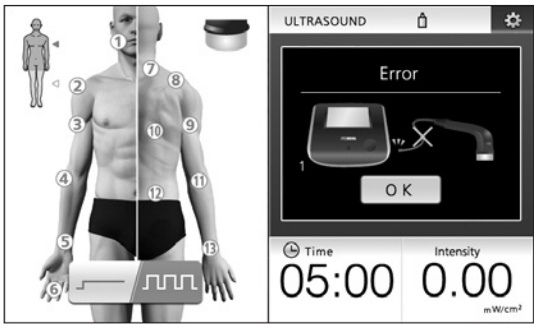
Note:

Basis for the measurement conditions for sound pressure level is determined as the distance able to be reached by hand (about 60 cm away).

Error Display

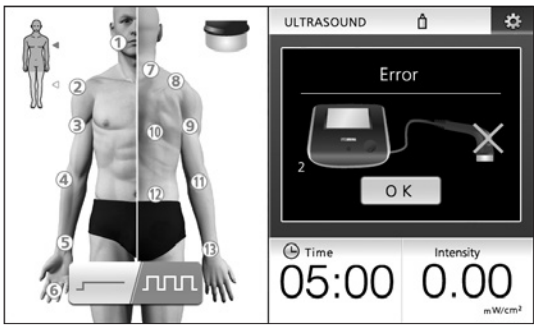
● Open error

This error occurs if the Ultrasound Probe is disconnected from the Main Unit during output.
Make sure the probe is securely connected to the Main Unit.



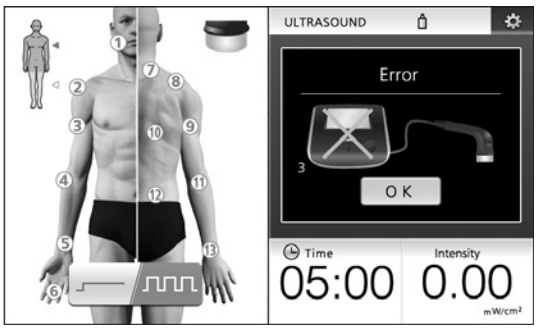
● Probe error

This error occurs if a broken wire in the Ultrasound Probe is detected.
Replace the probe.
When two Ultrasound Probes are connected to the Main Unit, disconnect both probes before resetting the probe error.



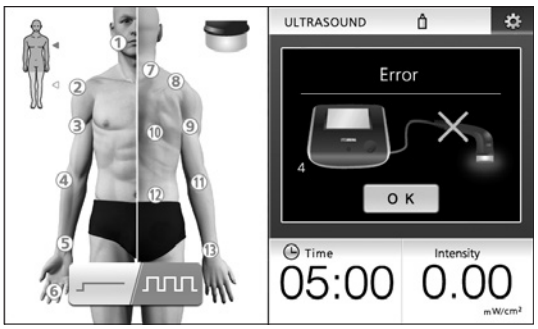
● System error

This error occurs if a problem has occurred with the Main Unit. Turn power off, then back on.



● Ultrasound Probe temperature error

This error is displayed when the probe head becomes extremely hot.
Terminate treatment and restart when the probe head has cooled down.



EMC

- Medical electronic devices are designed to ensure electromagnetic compatibility (EMC). These devices must be installed and used in accordance with the EMC information provided in the attached document.
- Do not use portable and/or mobile RF communication devices closer than 30 cm within the US-751. If it is brought closer than 30 cm, the performance of the medical equipment may deteriorate.
- Cable length
  (1) Ultrasound Probe (L): 2.0 m
  (2) Ultrasound Probe (S): 2.0 m
  (3) Power Supply Cord: 0.5 m
  (4) EST Cable (for combo use with ES-521): 1.5 m
  (5) EST Cable (for combo use with ES-320): 1.5 m
  (6) Power filter: 1.5 m
- If accessories other than those supplied as spare parts by the manufacturer are used, the emission of this instrument may increase and immunity may be reduced.
- Do not place this instrument next to or on top of another device when using it. If it has to be placed next to or on top of another device, check that this instrument and the device function properly before use.

Guidance and manufacturer's declaration — electromagnetic emissions

This unit is intended for use in the electromagnetic environment specified below.
The customer or the user of this unit should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment — guidance
RF emissions CISPR 11	Group 1	This unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	This unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

EMC

Guidance and manufacturer's declaration — electromagnetic immunity

This unit is intended for use in the electromagnetic environment specified below. The customer or the user of this unit should assure that it is used in such an environment.
It does not harm users and patients within the electromagnetic environment shown below.
However, it is possible to affect the medical equipment (display abnormality, error indication etc.). If you suspect any abnormality with the equipment, please suspend use and inspect it.

Immunity test	IEC 60601-1-2 test level	compliance level	Electromagnetic environment — guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air		Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical home, commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth		Mains power quality should be that of a typical home, commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0%U_T: for 0.5 cycle 0%U_T: for 1 cycle 70%U_T: for 25/30 cycles 0%U_T: for 250/300 cycles		Mains power quality should be that of a typical home, commercial or hospital environment. If the user of this unit requires continued operation during power mains interruptions, it is recommended that this unit be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home, commercial or hospital environment.

NOTE 1 U_T is the a.c. mains voltage prior to application of the test level.
NOTE 2 To prevent electrostatic discharge, the operator must remove any static charge from his or her body before connecting or disconnecting the connector near the symbol .

Guidance and manufacturer's declaration — electromagnetic immunity

This unit is intended for use in the electromagnetic environment specified below. The customer or the user of this unit should assure that it is used in such an environment.
It does not harm users and patients within the electromagnetic environment shown below.
However, it is possible to affect the medical equipment (display abnormality, error indication etc.). If you suspect any abnormality with the equipment, please suspend use and inspect it.

Immunity test	IEC 60601-1-2 test level	compliance level	Electromagnetic environment — guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz ~80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of this unit. including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance Conducted RF $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 0.58\sqrt{P}$ 150 kHz to 80 MHz (ISM and amateur radio bands) Radiated RF $d = 0.35\sqrt{P}$ 80 MHz to 800 MHz $d = 0.7\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
	6 Vrms ISM and amateur radio bands between 150 kHz ~80 MHz	6 Vrms	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz ~2.7 GHz IEC 60601 -1-2: 2014 Table 9	10 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this unit is used exceeds the applicable RF compliance level above, this unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this unit.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

EMC

Recommended separation distances between portable and mobile RF communications equipment and this unit

This unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this unit as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz		80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 2.7 GHz $d = 0.7\sqrt{P}$
	$d = 1.2\sqrt{P}$	$d = 0.58\sqrt{P}$		
0.01	0.12	0.06	0.04	0.07
0.1	0.38	0.18	0.11	0.22
1	1.2	0.58	0.35	0.7
10	3.8	1.8	1.1	2.2
100	12	5.8	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

EC REP "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"

CE 0123

Manufacturer
ITO CO.,LTD.
3-1-8 Sakae-cho, Kawaguchi-shi, Saitama 332-0017, Japan
TEL: 81-48-254-1031 FAX: 81-48-254-1033
URL: https://www.itocoltd.com/ E-Mail: itocoltd@itolator.co.jp

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