Ultrasound Bone Growth Stimulator

OSTEOTRON IV

OPERATION MANUAL

CE 0123

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.

ITO PHYSIOTHERAPY &REHABILITATION

Contents

Symbols

- 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 "Waste Electrical and Electronic Equipment (WEEE), Directive 2002/96/EC"
  * This symbol is valid only in European Union.

- Symbol for "TYPE BF APPLIED PART"

- Symbol for "NON-IONIZING ELECTROMAGNETIC RADIATION"

- This mark is to be used for class IIa medical devices. MDD (93/42/EEC)

To Ensure Correct and Safe Use

This unit should be used by a licenced practitioner.

Intended use

OSTEOTRON IV is a low intensity pulsed ultrasound device which is indicated for treatment of fresh fractures, delayed unions and nonunions of bones.

Contraindications

1) Over thoracic area to patients with cardiac pacemakers
2) Abdominal and pelvic regions during pregnancy
3) Patients with serious infection such as tuberculosis
4) Areas with open wound
5) Areas with thrombophlebitis

Precautions

1) The effect for fracture with excessive displacement or gap is unknown.
2) Safety and effectiveness of the treatment using OSTEOTRON IV on patients with cancer is not established.
3) Areas with sensory loss or abnormal sensation.
4) Patients with cardiac pacemakers or other implanted medical devices should be evaluated by a cardiologist or physician before treatment using OSTEOTRON IV and close monitoring is necessary during treatment.

General precautions

1) Have the patient remain in a relaxed, comfortable position during treatment.
2) Avoid using parts or accessories from other devices as replacements.
3) Handle the ultrasound probe carefully. Careless handling may affect its performance.
4) Follow the instructions below when setting up the device.
   a) Set up the device where it will not be exposed to moisture.
   b) Set up the device where it will not be exposed to damaging environmental factors such as excessive pressure, temperature, humidity, wind, sunlight, dust, or airborne salt or sulfur.
   c) Make sure the device is installed in a stable position. Do not place the device on a sloping surface or in locations where it may be subjected to vibrations or impact. These precautions also apply when transporting the device.
   d) Avoid using the device in locations where the ambient atmosphere contains combustible vapors. Examples include locations where flammable anesthetic gas may come into contact with oxygen or with nitrous oxide and air or where flammable antiseptic or cleaning agents are exposed to air.

   e) Do not set up the device in places where chemicals are stored or gas is generated.
   f) Do not set up the device near flames or heat sources. Heat may damage the device and lead to accidents.
   g) Check the frequency, voltage, and allowable current (or power consumption) of the power being supplied to the AC adaptor.
   h) When using the AC adaptor connect it to a dedicated power outlet.
   i) Only use the batteries that are recommended.

Precautions before use

1) Carefully examine the patient's diagnosis results and prescribed course of treatment.
2) Check for the following special precautions or instructions.
   a) Always confirm with a physician when the patient has cardiac pacemakers or other medical devices implanted.
   b) Carefully consider whether use of the OSTEOTRON IV is appropriate when the patient's skin is less sensitive than normal.
3) Ask the patient to indicate when he/she experiences any unusual sensation (e.g. pain, heat, pressure) or notices any equipment malfunction.
4) Proceed with the utmost caution when using the device with individuals to whom or on body regions to which any of the following potential contraindications applies.
   a) Make sure the individual to be treated is free of contagious disease or conditions, since these can be transmitted via the device.
   b) Carefully consider whether use of the device is appropriate with infants or small children (six years of age or younger) or with individuals affected by senile dementia. The patient should be able to communicate effectively to ensure appropriate treatment levels.
   c) If the device is used on children with active bone growth centers (epiphysis) under the approval of a physician, proceed with the utmost caution when treating epiphyseal regions.
5) Check the battery status (e.g. power level, polarity). Use only the specified batteries.
6) Inspect switches and keys to confirm that the device functions properly.
7) Check to confirm all cords are connected correctly and safely.
8) Check to confirm that the ultrasound probe is clean and is free of cracks.
9) Do not pull directly on the coiled ultrasound probe cord. Pulling on the cord with excessive force may result in permanent stretching.

To Ensure Correct and Safe Use

Precautions during use

1) Make sure the treatment duration and output level are suitable for the purpose of treatment.
2) Continuously monitor the device and patient to confirm no abnormalities occur. In the event of abnormalities, confirm that conditions are safe for the patient, then immediately stop using the device. Contact your dealer or the manufacturer/distributor.
3) Make sure the patient does not touch or move the device without being instructed to do so by the physician. Failure to observe this precaution may lead to accidents.
4) If the metal section of the ultrasound probe or ultrasound gel and gel pads results in any abnormal reactions on the patient's body such as rashes, reddening, or itching, immediately stop using the device and take appropriate measures.
5) Position the ultrasound probe correctly on the treatment area. The device may not provide the intended effects if positioned incorrectly.
6) Avoid operating OSTEOTRON IV adjacent to and simultaneously with any shortwave or microwave device.

Precautions after use

1) Do not leave the probe connected to a device with the output left on. This may cause the ultrasound probe to heat excessively and lead to abnormal wear of the device or ultrasound probe.
2) At the end of treatment turn off the power and wipe off the ultrasound gel or take off the Solid Gel Pad from the ultrasound probe.
3) Before disconnecting the AC adaptor from the power outlet, check to make sure the main unit is turned off. Grasp the plug directly when unplugging it from the power outlet. Avoid applying excessive force or pulling directly on the cords, when disconnecting the cords.
4) After use, lightly wash the ultrasound probe in lukewarm water and wipe dry. Make sure the ultrasound head is clean before storing.
5) Clean the main unit and accessories to prevent problems during subsequent use. Store in a safe location.
6) After washing the retainer belt, hang to dry in a shaded area. Do not dry it in a drying machine or under the sun; heat and light may damage the fabric.

Storage and Period of service

1. Storage

1) Observe the following precautions when storing the device. Failure to observe these precautions may result in malfunctions.
① Store the device in locations where it will not be exposed to moisture.
② Store the device in locations where it will not be exposed to damaging environmental factors such as pressure, temperature, humidity, wind, sunlight, dust, or airborne salt or sulfur.
③ Make sure the device is stored in a stable position. Do not store the device on a sloping surface or in locations where it may be subject to vibrations or impact. These precautions also apply when transporting the device.
④ Do not store the device in places where chemicals are stored or gas is generated.
2) Remove the batteries from the device and disconnect the AC adaptor from the power outlet if the device will not be used for extended periods.

2. Period of service

Service life of main unit: Five years (in-house verification) based on the manufacturer's data. Service life of ultrasound probes: 500 hours or two years.

To Ensure Correct and Safe Use

Precautions on Handling

1) Never operate the device with wet hands.
2) Keep the device from knocking against or striking other devices or from tipping over. Avoid dropping the device. Protect against strong vibrations or impact. Even if the device appears to be unaffected by impact, internal damage may lead to malfunctions or accidents.
3) To minimize environmental impact when disposing consumables, residual materials, or end-of-life devices or accessories; abide by all local regulations.

Maintenance and Checkup

1. Precautions

1) If the device malfunctions, post a sign or notice indicating that the device is out of order and contact a specialist to perform repairs.
2) Never attempt to modify the device.
3) Never open the device.
4) When cleaning the main unit and accessories, avoid using volatile oils (e.g. thinner, gasoline, kerosene), polishing powders, hot water, or chemicals. These materials may result in discoloration or component degradation. To clean the main unit and accessories, apply alcohol, cold/lukewarm water, or a mild detergent to a cloth, wring thoroughly, then wipe it off.
5) The probe head features waterproof construction. Never attempt to disassemble the probe head; doing so may damage the waterproofing and affect oscillator performance or result in accidents.

2. Maintenance and checkup by the user

1) Inspect the main unit and accessories before use on a daily basis to confirm that the device functions normally.
2) If you discover any abnormalities (damaged insulation in wire connecting accessories, including scratches or cracks on cord sheath, signs of broken wires, and faulty connector contacts) while inspecting the device before use or during regular inspections, contact your dealer or the manufacturer/distributor.
3) When using the device after an extended period of storage or nonuse, confirm that the device functions properly and safely before performing actual treatment.

3. Maintenance and checkup by a contractor

1) To maintain device performance and ensure safety, ask your dealer or manufacturer/distributor to perform periodic inspections (generally, once a year).
2) Replace consumables (including accessories) periodically to prevent possible hazards when using accessories or the main unit.

4. Maintenance and check items

To ensure safety, perform the following inspections at regular intervals.
If you have any questions, contact your dealer or the manufacturer/distributor.

Item	Description	Method
Appearance and indications	Check the exterior for damage. Confirm that the LCD screen is not deformed and that the LCD screen does not flicker. Make sure the ultrasound probes are clean.	Inspect visually.
Operation	Turn on the POWER switch and confirm that the device functions properly and without issues.	Check by operating the device.
Output	Place a few drops of water on the probe head, turn on output, and make sure the water drops vibrate.	Check by operating the device.
Probe check	Make sure the probe head and cable connecting section are free of cracks or defects that may allow water or treatment gel to enter the probe head.	Inspect visually.
	Make sure the cable and connector are free of poor connections.	Inspect visually and by operating the device.
Safety device	Make sure that disconnecting the probe from the main unit during treatment results in an error display and halts output.	Check by operating the device.

Listed below are replacement accessories and consumables for the OSTEOTRON IV.
To order replacement accessories or consumables, contact your dealer or the manufacturer/distributor.

① 012096 Ultrasound Probe 1.5 MHz
② 012097 Probe Retainer with 700 mm Belt, for use with Cast
③ 012098 Probe Retainer with 450 mm Belt, for use with Cast
④ 012099 Probe Retainer with 470 mm Belt, for use without Cast
⑤ 012100 AC Adaptor
⑥ 012057 Power Cable for AC Adaptor (for EU)
⑦ 120612 Ultrasound Gel
⑧ 260700 Carrying Bag

The equipment, disposal, waste and residue should be scrapped and recycled in accordance with local law.

To Ensure Correct and Safe Use

Rechargeable batteries

1. Do not recharge batteries in any of the following locations

1) Locations where ambient temperatures are below 0°C or above 40°C (The batteries may not recharge if ambient temperatures are too high or too low.)
2) Locations with excessive humidity, dust concentrations, or vibrations (These conditions can affect battery charging.)

2. Be sure to use batteries and battery charger of the specified type.

Specifications: Battery charger : NC-TGR03 or NC-MR58(SANYO ELECTRONICS CO.,LTD)
Rechargeable size-AA nickel hydride battery, 1.2 VDC, min. 1900 m/Ah (HR-3UTGA(SANYO ELECTRONICS CO.,LTD))
To obtain batteries, contact your dealer or the manufacturer/distributor.

3. About recharging

1) Batteries are consumables. If the batteries power down rapidly even after recharging for many hours, replace with new batteries.
2) Batteries self-discharge even when not used. New batteries may be partially charged or completely exhausted when used for the first time. This does indicate a defect.
3) Extended charging times will not damage the batteries.

4. Handling of batteries

Do not attempt to disassemble the batteries.

5. Recycle disused batteries

1) The device uses rechargeable nickel hydride batteries.
2) Rechargeable nickel hydride batteries are recyclable. Do not dispose rechargeable nickel hydride batteries as ordinary waste. Take to a store or facility that collects rechargeable batteries for recycling.
3) Do not discard used rechargeable batteries as ordinary waste.
4) To minimize environmental impact, observe all applicable local regulations when processing rechargeable batteries for disposal.

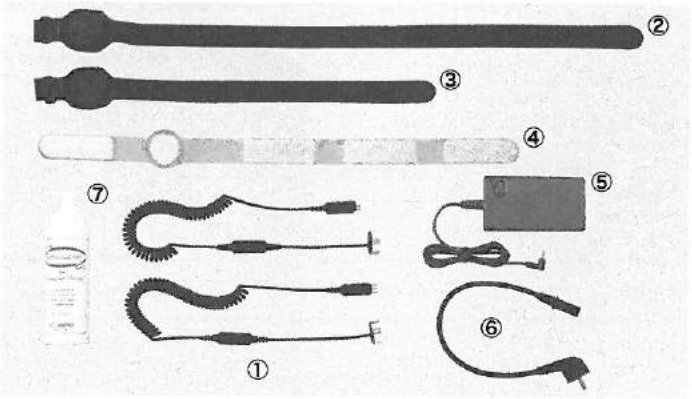
6. Note regarding battery recycling

Take appropriate steps to prevent short-circuiting of rechargeable batteries. Failure to do so may result in a fire or electric shock.

Device Configuration

Main unit and Standard accessories

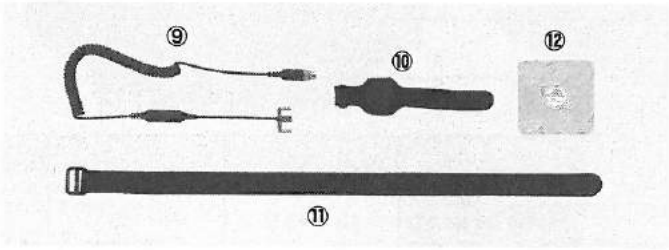
Main unit



① 012096 Ultrasound Probe 1.5 MHz, 2 ×
② 012097 Probe Retainer with 700 mm Belt, for use with Cast
③ 012098 Probe Retainer with 450 mm Belt, for use with Cast
④ 012099 Probe Retainer with 470 mm Belt, for use without Cast
⑤ 012100 AC Adaptor (MPU30-102(SINPRO ELECTRONICS CO.,LTD))
⑥ 012057 Power Cable for AC Adaptor (for EU)
⑦ 120612 Ultrasound Gel
⑧ 260700 Carrying Bag

Note: Batteries and a battery charger are not attached to the standard kit. Purchase them locally.

Optional Accessories



⑨ 012101 Ultrasound Probe 750 KHz
⑩ 012102 Probe Retainer with 250 mm Belt, for use with Cast
⑪ 012103 Extension Belt, 600 mm
⑫ 012104 Solid Gel Pad , 8pcs/sheet

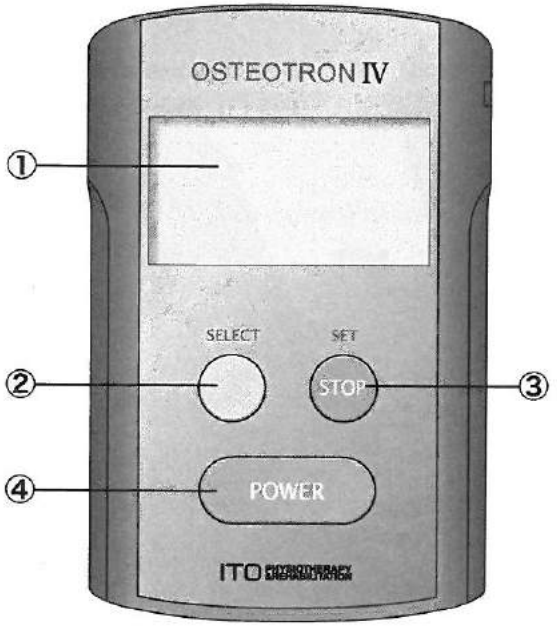
Specifications

Power supply		DC 4.8 V, 4 × Nickel metal hydride rechargeable battery DC 5 V, AC Adaptor AC Adaptor: 100 – 240 VAC, 50/60 Hz		
Power consumption		8.0 VA		
Ultrasound frequency		Ultrasound probe 1.5 MHz	Ultrasound probe 750 KHz	
		1.5 MHz ± 10%	750 KHz ± 10%	
Output		30 mW/cm² ± 20%, 45 mW/cm² ± 20%, 60 mW/cm² ± 20% (SATA)		
Duty		20%		
Pulse frequency		100 Hz or 1000 Hz (switchable)		
Timer		20 min. or 30 min. (switchable)		
Ultrasound probe		1.5 MHz	750 KHz	
ERA	IEC	3.9 cm² ± 20%	3.5 cm² ± 20%	
	FDA	4.6 cm² ± 20%	4.3 cm² ± 20%	
BNR	IEC	3.5 ± 30%	3.0 ± 30%	
	FDA	2.7 ± 30%	4.5 ± 30%	
Classification		Class I / Internally powered equipment Type BF, Class IIa / MDD		
Dimensions		98 (W) × 40 (D) × 145 (H) mm		
Weight		240 g (without batteries)		
Operating Conditions		Operation Environment	Storage Environment	Transportation Conditions
	Ambient Temperature	10 – 40 ℃	-10 – 60 ℃	-10 – 60 ℃
	Relative Humidity	30 – 75 %	30 – 95 %	30 – 95 %
	Atmospheric Pressure	700 – 1060 hPa	700 – 1060 hPa	700 – 1060 hPa

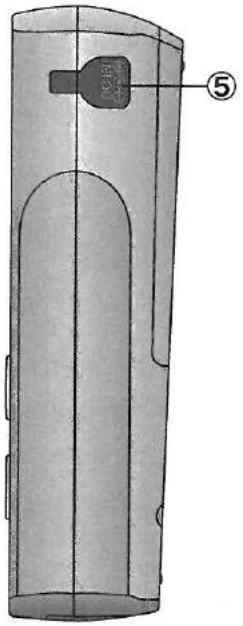
Name of Parts of Main Unit

■Exterior

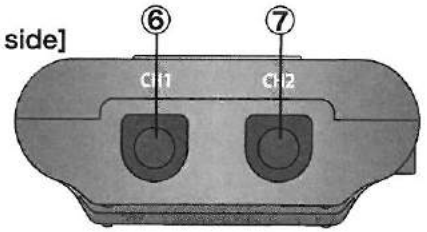
[Front side]



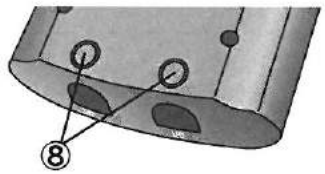
[Right side]



[Bottom side]



[Rear side]

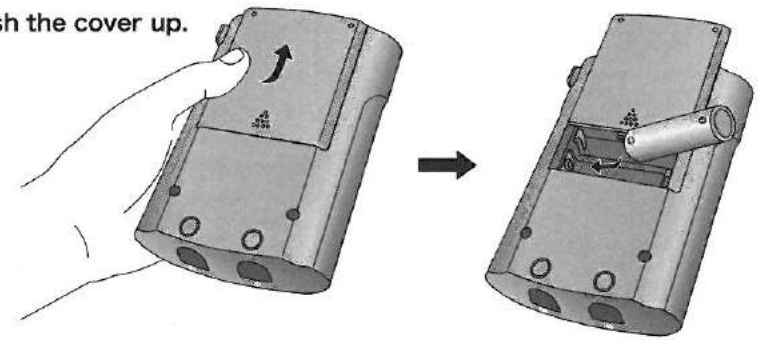


① LCD screen
② SELECT switch
③ SET/STOP switch
④ POWER switch
⑤ AC Adaptor connector
⑥ CH1 output terminal
⑦ CH2 output terminal
⑧ Probe release button

Preparation

Insert the batteries from the rear side of the main unit.

Push the cover up.



* When inserting the batteries, check the indications for the positive ⊕ and negative ⊖ poles to confirm the batteries are correctly oriented.

Note: Batteries and a battery charger are not attached to the standard kit. Purchase them locally.

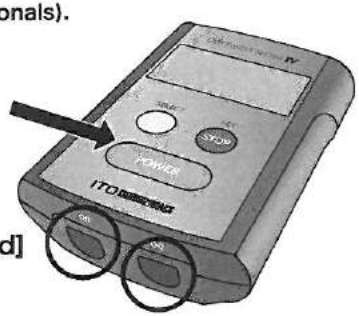
Electrical supply when the AC Adaptor is attached and rechargeable batteries are installed.

When the AC Adaptor is connected to the main unit containing the rechargeable nickel hydride batteries, power will be supplied from the AC Adaptor.* The rechargeable batteries will not charge in this state. Use the battery charger to charge the batteries.

Physician Mode (Mode for Medical Professionals)

If no probe is connected, the device will start up in Physician Mode (Mode for Medical Professionals).

Press and hold the POWER switch (for approx. 1.5 sec).



[With no probe connected]

[Config (setting) screen 1/3]

Config	CH1	CH2	
Power	① 30	② 30	mW/cm²
Freq.	③ 1000	④ 1000	Hz
Time	⑤ 20:00		

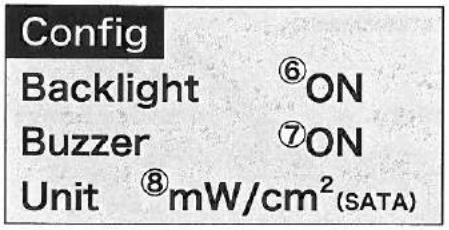
Pressing the SELECT button switches the selection, from ① through ⑨ and back to ① again. Select a parameter and press the SET (STOP) button to change it.

Power	① Ultrasound output from CH1 terminal ② Ultrasound output from CH2 terminal	30 → 45 → 60 mW/cm²
Freq.	③ Pulse frequency of output from CH1 terminal ④ Pulse frequency of output from CH2 terminal	100 → 1000 Hz
Time	⑤ Output duration	20 → 30 min

Continued to the next page →

Physician Mode (Mode for Medical Professionals)

[Config (setting) screen 2/3]



⑥ **Backlight**: Turns the backlight ON/OFF.

ON: Turns light on. → **OFF**: Turns light off.

⑦ **Buzzer**: Changes the sound of buzzer produced during ultrasound output.

* Applies only to the sound of the buzzer produced during ultrasound output.

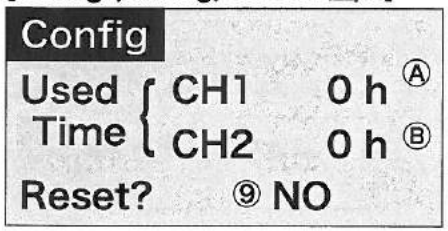
ON → **OFF**

⑧ **Unit**: Changes the unit of output.

mW/cm² (SATA*1) → **W***2 → **W/cm²** (PEAK*3)

*1: Spatial-Average Temporal-Average: time-based average value of sound intensity calculated based on the effective radiating area (ERA)
*2: If the unit of output is set to "W," the ultrasound output value of the channel without probe connection will not be displayed.
*3: Maximum value of average "total output" calculated based on the effective radiating area (ERA)

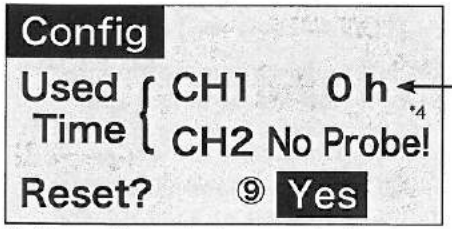
[Config (setting) screen 3/3]



Used Time : Cumulative probe usage hours

ⒶCH1 terminal ⒷCH2 terminal

To display the cumulative usage hours, turn on the device in Physician Mode first, and then connect a probe.



*4: Screen displayed when no probe is connected to the main unit.

⑨Reset? : Resets the cumulative usage hours.

After selecting "Yes," press the SELECT button to reset the cumulative usage hours to "0."

NO → **YES**

Cumulative probe usage hours are reset.

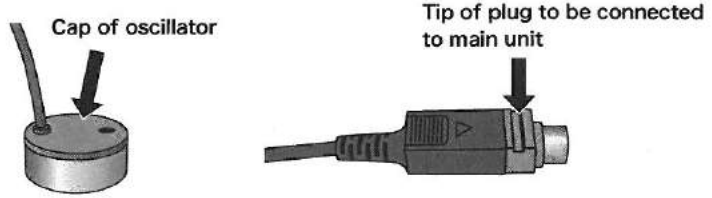
* If the device is not operated for about three minutes, it will automatically turn off.

Change of oscillating frequency

The oscillating frequency is automatically set to 1.5 MHz or 750 KHz based on the ultrasound probe connected. Before starting actual treatment, connect the probe appropriate for the specific treatment.

The oscillating frequency of the ultrasound probe is indicated by the color of the following parts.

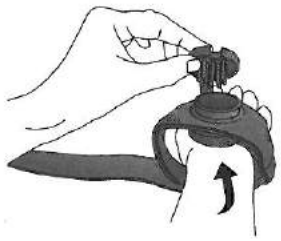
- Ultrasound Probe 1.5 MHz: Black
- Ultrasound Probe 750 KHz: Gray



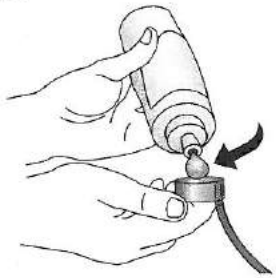
Patient Mode

When using Probe Retainer with 700 and 450 mm Belt, for use with Cast.

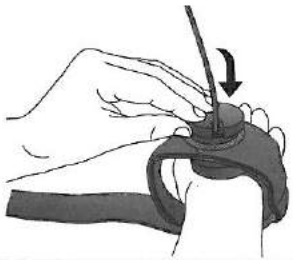
1 Attach the retainer to the treatment area.



2 Apply the Ultrasound Gel to the probe.



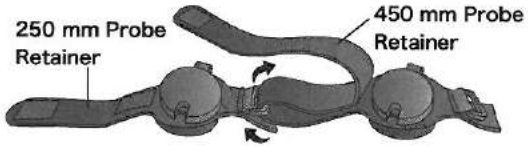
3 Insert the probe and close the cap.



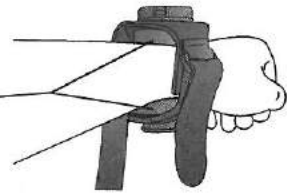
Two-sided treatment

Using two Probe Retainers makes it possible to apply treatment from two sides of the treatment area.

①Attach the 450 mm Probe Retainer to the 250 mm Probe Retainer.



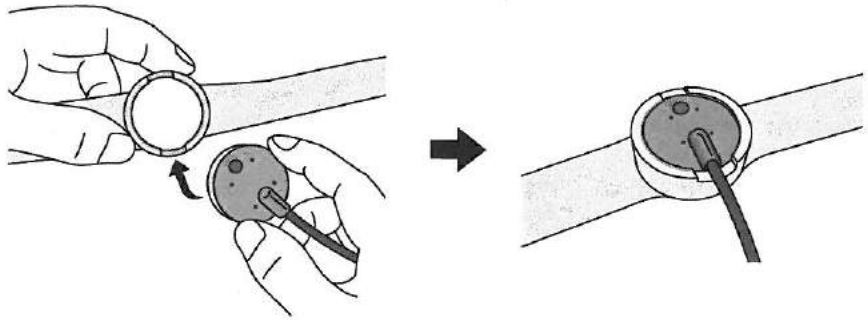
②Wrap the retainers around the arm (treatment area) so that the retainers are positioned over two sides of the treatment area.



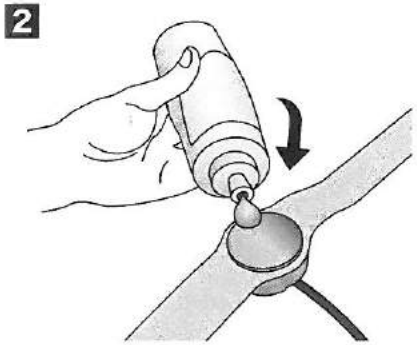
Retainers should be positioned over two sides of treatment area.

When using Probe Retainer with 470 mm Belt, for use without Cast.

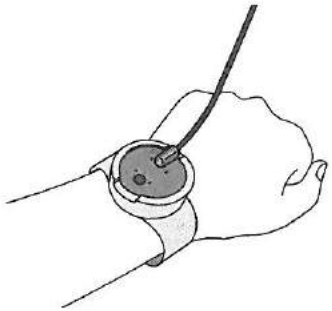
1 Attach the probe to the Probe Retainer.



2



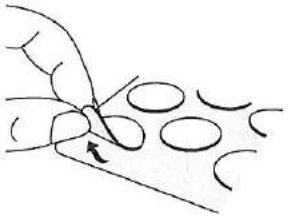
① Apply the Ultrasound Gel to the probe.



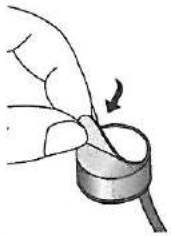
② Attach the retainer to the treatment area.

Patient Mode

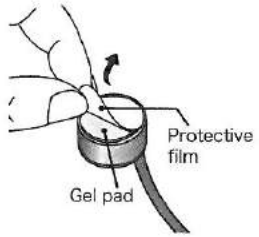
⟨When using Solid Gel Pad (optional accessory)⟩



①Set the retainer on the treatment area. Remove a gel pad together with the protective film from the sheet.



②Clean the probe surface with alcohol, then paste the gel pad to the probe. Make sure no gap or air is between the probe surface and gel pad.



③Remove the protective film from the gel pad. Insert the probe into the retainer and close the cap.

* Do not leave the ultrasound head with gel or gel pad on it.
* Gel pads are consumables. Replace the gel pad when it begins to lose its adhesiveness or generates auto contact errors even when correctly attached.

⚠WARNING About Solid Gel Pad

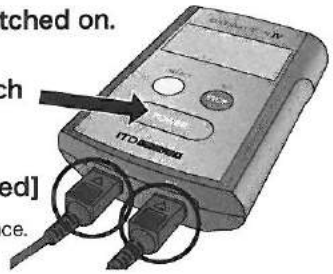
- Proceed carefully and watch for skin reactions if the patient's skin is generally sensitive or sensitive specifically to poultices or adhesive plasters. Gel pads may cause rashes or reddening of the skin.
- Avoid using gel pads on areas of skin with open wounds.
- If use of the gel pad results in rash, reddening, itching, etc., immediately stop using the device. Consult your dealer.
- When using gel pads, make sure it is not placed over or in contact with metals (necklaces, belts, watches, etc.).
- Make sure the gel pad is in firm contact with the skin. If the gel pad is partially lifted from the skin, the resulting stimulation may be excessive and cause pain. In some cases, this may even cause skin problems, including burns.
- The gel pad will not adhere properly to areas of skin with residual lotion, oil, or other skin-care products or areas of skin with excessive perspiration or oil. If so, clean the area by wiping with alcohol. Make sure the skin area is dry, then attach the gel pad.
- Always turn off the POWER switch on the main unit before removing the gel pad.

The device will start up in Patient Mode when a probe is connected and the power is switched on.

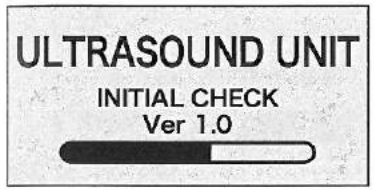
Press and hold the POWER switch (for approx. 1.5 sec).

[With probe connected]

Insert the connector until it clicks into place.

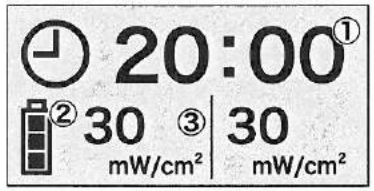


4 [Initial check]



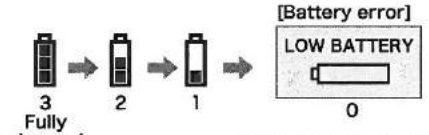
After the initial check is completed, the LCD screen will display the output screen, treatment will begin immediately, and the timer will begin counting down.

5 [Output screen]



① Timer countdown (remaining time)

② Remaining battery level

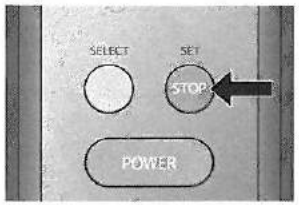


When the remaining battery level drops to a certain level, the battery error screen will appear, and the device will shut down. If this happens, recharge the batteries.

③Ultrasound output level

Patient Mode

6

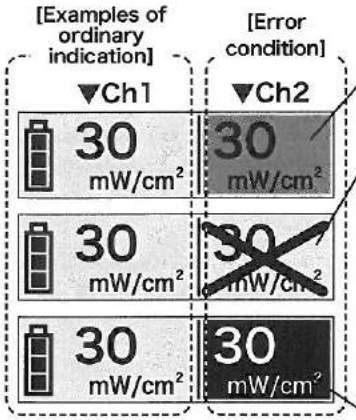


To pause output, press the SET STOP button.

To resume output, press the SET STOP button again.

To stop output completely, press and hold the POWER button (for approx. 3 seconds). This will shut off the device.

[Examples of output indication]



Probe not connected

Probe disconnected

A "X" mark appears over the indication for the CH from which the probe was disconnected. The device halts output.
Turn off the device, connect the probe, then turn the device back on.

*Contact your dealer or manufacturer/distributor if a "X" mark appears immediately after power ON or if the "X" mark continues to appear after the probe is reconnected.

Auto contact error

If the numeric indication appears in white against black background and you hear a warning sound (buzzer), the amount of ultrasound gel applied may be insufficient. Add gel, reattach the retainer, turn off the power and restart the device.

* If no action is taken with a device in "probe disconnected" or "auto contact error" state for about three minutes, the device will shut down automatically.

7 When the treatment time indication reaches "0," the buzzer will sound, and the device will halt output.
(The device will shut down automatically.)

8 Make sure the device is turned off, then remove the probe from the treatment area. Wipe the gel from the probe.

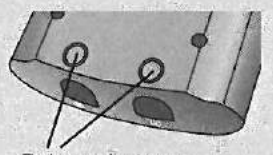
* After use, wipe gel from the probe and turn off power. Leaving the device on with gel on the probe will drain the batteries.

⚠ Caution regarding probe

Disconnect any probe not being used for treatment. Leaving an unused probe connected to the main unit during treatment will drain the batteries.

⚠ Caution regarding disconnecting probes

When disconnecting a probe, hold down the release button and pull out the connector. Pulling on the connector with excessive force may result in damage.



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.
- Portable and mobile RF communications devices may affect medical electronic devices.
- Cable length
  1) Ultrasound Probe: 0.5 m 2) AC Adaptor: 1.22 m
  3) Power Cable for AC Adaptor (for EU): 0.5 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

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

Emissions test	Compliance	Electromagnetic environment — guidance
RF emissions CISPR 11	Group 1	The OSTEOTRON IV use 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	The OSTEOTRON IV 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	

Guidance and manufacturer's declaration — electromagnetic immunity

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

Immunity test	IEC 60601-1-2 test level	Electromagnetic environment — guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 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	Mains power quality should be that of a typical 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 commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the OSTEOTRON IV requires continued operation during power mains interruptions, it is recommended that the OSTEOTRON IV be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

EMC

Guidance and manufacturer's declaration — electromagnetic immunity

The OSTEOTRON IV 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.

Immunity test	IEC60601-1-2 test level	compliance level	Electromagnetic environment — guidance
Conducted RF IEC 61000-4-6	3Vrms 150kHz ~ 80MHz	3Vrms	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 $d = 1.2\sqrt{P}$ 150kHz to 80MHz $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz 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: 
Radiated RF IEC 61000-4-3	3V/m 80MHz ~ 2.5GHz	3V/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 the OSTEOTRON IV should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the OSTEOTRON IV.

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

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

The OSTEOTRON IV is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OSTEOTRON IV can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OSTEOTRON IV 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		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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.

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