6-Channel Programmable Electroacupuncture

ES-160

OPERATION MANUAL

For Safe and Correct Use

Read the manual carefully and follow the instructions to use the unit safely and correctly

ITO PHYSIOTHERAPY &REHABILITATION

Thank you for purchasing the “ES-160.” This is a 6-channel universal electroacupuncture stimulator equipped with the three functions: Electroacupuncture mode, Ryodoraku Point Measurement mode, and Acupuncture-point Search/Stimulation mode. Please read this manual carefully to ensure proper use of the unit.

Contents

Symbols

- 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 “Waste Electrical and Electronic Equipment (WEEE), Directive”
  * This symbol is valid only in European Union.

- Symbol for “TYPE BF APPLIED PART”

- These marks are to be used to indicate conformity to European Community harmonisation legislations.

- Symbol for “This unit should be used by a licensed medical practitioner”

Main Unit, Standard Accessories, and Specifications

Main Unit and Standard Accessories

	order code
①Main Unit	
②1 x Search/Stimulation Probe【ESE001】*1	011380
③6 x Electrode Cords 【ESC001】	011324 (black) 011325 (brown) 011326 (red) 011327 (green) 011328 (blue) 011329 (gray)
④12 x Exclusive Clips 【ESC002】*2	B060999 (black,6pcs) B061000 (red,6pcs)

※Operation Manual

*1: Applied parts (Applied area dimension: 100 mm²)
*2: Applied parts

Note: Batteries are not included.
Use 4 R14 batteries.

Specifications

Power supply: 4 R14 batteries
Supply voltage: 6 V DC
Rated current consumption: 160 mA
Number of output channels: 6, with the ability to control the outputs independently
Frequency: 0.5, 0.7, 1–500 Hz ± 5%
Pulse shape: Symmetric biphasic rectangular pulse
Phase duration: 50–400 μs
User's programmable memories: 16
Resume memory: One for each mode (5 in total)
Display: LCD x 3
Safety class according to IEC 60601-1: Internally powered equipment, Type BF

For electro-acupuncture

Max. output voltage: 16 V ± 20%

Max. output current: 32 mA (peak) ± 20% (500 Ω load)

Timer: Max. 60 minutes ± 1 min.

Output modes: Constant, Burst, Surge, Fast + Slow, Sweep, and Random program

Acupuncture-point search/stimulation

	Search	Stimulation
Max. output voltage	100 mV ± 20%	24 V ± 20%
Max. output current	0.2 mA ± 20%	48 mA (Peak) ± 20%

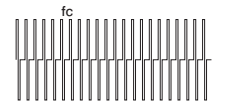
Dimensions: 239(w) x 173.5(d) x 41(h) mm

Weight: Approx. 600 g (batteries not included)

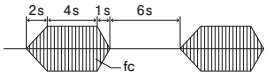
Environmental condition

	Temperature	Humidity	Barometric pressure
In use	10—40℃	30—75%	800—1060 hPa
Storage	-10—60℃	30—95%	700—1060 hPa
Transportation	-10—60℃	30—95%	700—1060 hPa

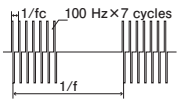
Waveform Specification



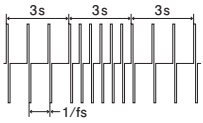
Const fc = 0.5, 0.7, 1–500 Hz



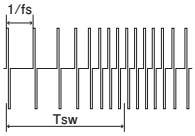
Surge fc = 5–500 Hz



Burst fc = 100 Hz
f = 0.5, 0.7, 1–7 Hz



Fast+Slow Fs (Slow freq.) = Ff (Fast freq.)/3
Fs = 1–166 Hz



Sweep

Fs (Slow freq.) = Ff (Fast freq.)/3
Fs = 1–166 Hz
Tsw = 16 s

ES-160 is a continuous operation equipment.

ES-160 output ports provide an output current exceeding 10 mA rms and 10 V.

Safety Precautions

Intended Use

Relief of pain of muscles, joints, and other tissues

To Ensure Safe Operation

- Be sure to read this manual first to ensure proper operation.
- Be sure to keep this manual on hand for future reference.
- This unit should be used by a licensed practitioner.
- The instruction manual is necessary for safe use of the unit.
  When loaning or giving the unit to a third party, be sure to provide this manual with the unit.
- Before starting to operate the unit, read these “Safety Precautions” and “Operating Method” carefully to ensure proper use. To prevent operators and patients from injury and the unit from damage, the following pictographic markings are posted in the manual. Before reading other parts of the manual, familiarize yourself with these markings, which indicate the possibility of personal injury and physical damage.

⚠DANGER

Read the manual carefully and follow the instructions to use the device safely and correctly

●Note on Operation Manual

This manual is an integral part of the instrument and components purchased.
It contains important information regarding instrument usage, method of operation, and safety cautions.
Carefully read the manual to fully understand its contents.

●WARNING SYMBOL MARKS

Following warning symbol marks are used in this manual.

⚠DANGER	indicates a danger of death or serious injury of an operator or patient if the operator ignores this symbol and use the ES-160.
⚠WARNING	indicates a possibility of death or serious injury of an operator or patient when the operator ignores this warning and use the ES-160.
⚠CAUTION	indicates a possibility of death or serious injury of an operator or property damage when the operator ignores this caution and use the ES-160.

△	This symbol is intended to draw attention to "Danger, Warning, or Caution."	Sample Indication "Be aware of Electric Shock."	
⊘	This symbol indicates a "Prohibited" action	Sample Indication "Disassembly Prohibited."	
●	This symbol is intended to "Force" an action to be taken.	Sample Indication "Pull out the plug from the wall outlet."	

Contraindications

1) Over or in the region of carotid sinus
2) Thorax of individuals with cardiac disease
3) ES-160 should not be used to people or in conjunction with the devices listed below
   a) Individuals with cardiac pacemakers or other devices implanted
   b) Pump-oxygenators and other electronic devices designed for sustentation
   c) Electrocardiographs and other electronic medical devices used for monitoring patients
4) Over or into abdomen, trunk, pelvis or low back during pregnancy
5) Over or into infected areas
6) Over or into areas of laceration or open wounds
7) Over or into areas of impaired sensory
8) Individuals with active hemorrhage or bleeding disorders such as hemophilia
9) Over the heart
10) Individuals with contagious disease such as tuberculosis
11) Transcranial placement of electrodes (the head in between the electrodes)
12) Electrode placement on the chest where electrical stimulation may be applied to the heart which may result in cardiac fibrillation.

Warnings

1) Excessive stimulation causing muscle contraction should not be applied over the body.
2) Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
3) Stimulation should not be applied transcerebrally.
4) Stimulation should not be applied over swollen, or over skin surface with atrophic contracture, etc.
5) Stimulation should not be applied over, or in proximity to, cancerous lesions.
6) Do not use the device on mentally unstable patients.
7) Do not use over areas of known thrombosis or thrombophlebitis.
8) A warning on the following potential hazards.
9) Simultaneous connection of a PATIENT to a h.f. surgical EQUIPMENT may result in burns at the site of the STIMULATOR electrodes and possible damage to the STIMULATOR.
10) Operation in close proximity (e.g. 1 m) to a shortwave, microwave or any high frequency EQUIPMENT, it may produce instability to the STIMULATOR output.
11) Do not modify the product.

Cautions

1) Caution should be used for patients with suspected or diagnosed heart problems.
2) Caution should be used for patients with suspected or diagnosed epilepsy.
3) Caution should be used in the presence of the following:
   a) Following recent surgical procedures when muscle contraction may disrupt the healing process
   b) Individuals with menstruating
   c) Patient has febrile disease
   d) Patients with abnormal blood pressure or suspected vascular disease
4) Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or needle electrodes.
5) The irritation can usually be reduced by using an alternate needle electrodes, or alternate needle electrodes placement.
6) Needle electrodes placement and stimulation settings should be based on the guidance of the prescribing practitioner.
7) Stimulators should be kept out of the reach of children.
8) Stimulators should be used only with the Electrode Cords and needle electrodes recommended for use by the manufacturer.
9) ES-160 should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user under extreme risk of injury.
10) ES-160 should not be used for other patients determined unsuitable by licensed individuals (EX. acupuncturists etc.). Practitioners using this device should be properly trained for the safe use of this modality.
    Rx ONLY
11) If an allergic reaction to the needle electrodes is noticed, discontinue use.

Recommendation

Use the acupuncture needle electrodes with the CE marking.
Use only the needle electrodes as a minimum diameter of 0.20 mm.

Current density

The maximum output of this device is 14 mA RMS.
L(low)output must be used for Electroacupuncture mode. Keep in mind that if the output current exceeds 2 mA/cm^2, it may burn the patient at the point where the needle electrodes are inserted under certain circumstances.

Cautions for Installation

⚠CAUTION

1) Install the unit at a place free from a splash of water.
2) Avoid installing the unit in the environment susceptible to undue humidity, temperature, dust, air containing salt or sulfur, or places exposed to direct sunbeam.
3) Install the unit at a flat stable place free from inclination, vibration or shock.
4) Do not use the unit in the inflammable environment containing oxygen, nitrous oxide, anesthetic gas, or inflammable disinfectant mixed with the air
5) Do not install the unit at storage places of chemicals and pharmaceuticals, or at places subject to inflammable gas generation.
6) Check the contact and polarities of the switches and the settings of the dials, to ensure that the unit operates normally.
7) Do not place the unit under extreme heat environment. This may deform the unit or interfere with its operation.
8) Connect the Electrode Cords correctly and safely.
9) Use the dedicated accessories. It may cause malfunction.
10) Double-check the associated parts that come into direct contact with the patient.
11) Avoid using the unit in conjunction with surgical instruments, as such use is likely to cause burns where the stimulation needle electrodes are located and damage to the stimulator.
12) Connect the Electrode Cords correctly and safely.

Precautions before the Treatment

For treatment, have the patient sit in a relaxed, comfortable posture or lie on a bed.

⚠WARNING

1) Combined use of the unit with other treatment equipment may result in incorrect diagnoses or other dangerous situations. When such combined use is necessary, pay particular attention to the patient.

2) Designate an administrator responsible for the unit, and do not allow anyone other than trained personnel to operate the unit.
3) Obtain a full understanding of the patient's diagnosis and prescriptions, and determine whether there are any special notes or instructions to be taken into account.
4) Explain the “Treatment Procedure” to the patient and instruct him or her to “inform you immediately if the patient feels any acute pain or pressure due to massage or stimulation.”
5) Set the output of the unit to an intensity such that the patient can be treated comfortably.
6) Some patients under anesthetic are unable to fully comprehend the indicated amount of treatment. Consequently, the operator of the unit may set an inappropriate treatment current, with excessive stimulation sometimes applied as a result. Therefore, ask the patient how he or she feels not only immediately after the treatment, but during it as well.
7) In addition, instruct the patient to inform you if he or she feels anything unusual in the stimulation received during the treatment. If anything unusual is felt, suspend the treatment or take other appropriate action.
8) Continuously monitor both the patient and the unit for any signs of abnormality. Should an abnormality occur, turn the unit off, check the status of the patient and take whatever action is necessary.
9) Caution the patient against operating the unit.
10) Never operate the unit with wet hands to avoid an electric shock.
11) Never insert metallic foreign substance into any output ports. This may cause on electric shock or malfunction of the unit.
12) Avoid operating the unit for more than 60 consecutive minutes or in any manner other than that specified in the Operation Manual. Otherwise, an accident may result.

Precautions after the Treatment

1) After using the unit, put the operation switches and dials back in their original positions in accordance with the prescribed procedure, turn off the power, and store the unit in an appropriate location.
2) Before unplugging the Electrode Cords from the output ports of the unit, be sure to first set the output dials back to “0.”
3) Always keep the unit clean.
4) Never clean the unit and accessories using a cloth moistened with thinner, gasoline, polishing powder, hot water, or chemical agents. Only use a cloth moistened with lukewarm water or a neutral detergent and sufficiently wrung out.

Precautions on Maintenance and Checks

⚠CAUTION

1) When the unit is not to be used for a prolonged period, remove all the batteries.
2) Do not store the unit in environment as follows.
   a) At a place where water may splash.
   b) In the undue humidity, temperature, dust, air containing salt or sulfur, or places exposed to direct sunbeam.
   c) At an unstable place with inclination, vibration or shock.
   d) In the inflammable environment containing oxygen, nitrous oxide, anesthetic gas, or inflammable disinfectant mixed with the air.
3) Before using a unit that has been out of use for an extended period, confirm that it operates normally and safely.
4) Maintain the unit and its accessories daily, in addition to periodic checks, to preserve the performance of the Main Unit and search for deterioration or wear and tear in the accessories.
5) Check the accessories regularly and replace any that are irregular, in order to prevent danger.

Maintenance and Check Items

To ensure safety, conduct checks on a periodic basis. If you have any questions, contact your dealer or the manufacturer.

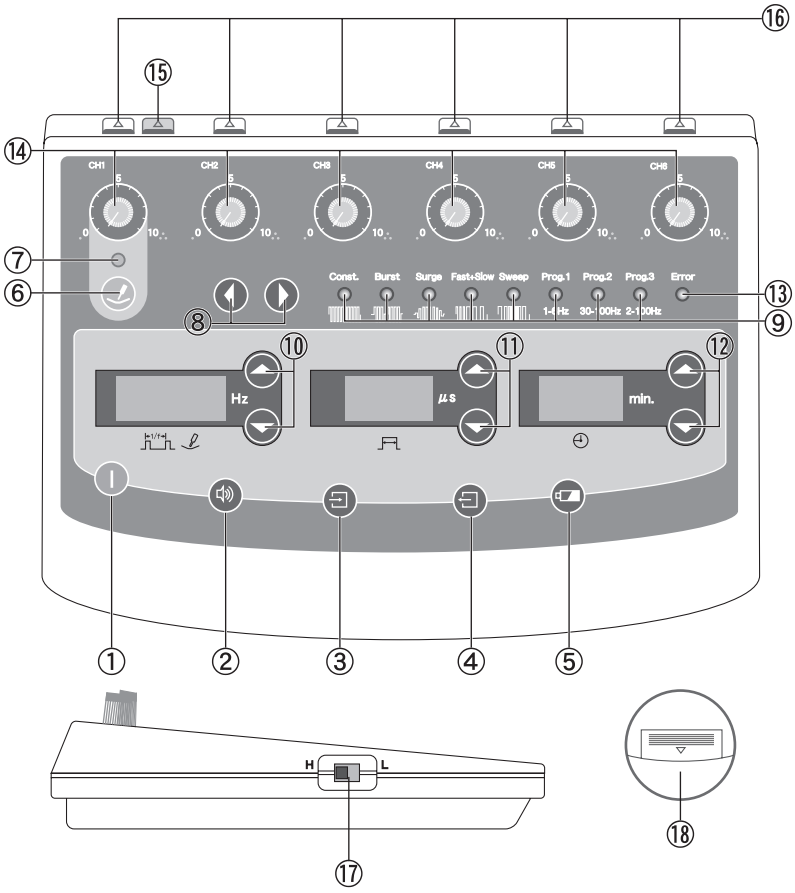
ITEM	DESCRIPTION	METHOD
Appearance and markings	①Check for a broken or damaged part. ②Check the indications on the LCD screens to confirm that they are legible.	Visual inspection
Operation	①Confirm that the LEDs come on when the unit is turned on. ②Confirm that the buzzer sounds. (If the buzzer is currently disabled, it will not beep, except to issue the zero-start warning.) ③Confirm that the unit functions as indicated in the operation manual.	Actual operation
Accessories	①Check breakage or damaged parts. ②Check the electrode cords for any damage.	Visual Inspection
Safety devices	①Confirm that the zero-start function operates normally. ②Confirm that the unit issues an error and cuts off the output if the output mode is changed while the unit is outputting.	Actual operation

Disposal of the Unit

⚠CAUTION

To dispose of the unit, its accessories, or their containers and packing materials, take appropriate actions in accordance with the rules and regulations in force in your area to prevent adverse ecological effects.

Front Panel

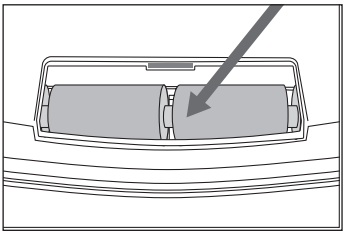

⑯
⑮
⑭
CH1
CH2
CH3
CH4
CH5
CH6
⑦
⑥
⑧
Const.
Burst
Surge
Fast+Slow
Sweep
Prog.1
Prog.2
Prog.3
Error
⑬
⑨
⑩
⑪
⑫
Hz
µs
min.
1-4Hz
30-100Hz
2-10kHz
①
②
③
④
⑤
H
L
⑰
⑱

① Power switch	Turns the power ON/OFF.
② Buzzer key	ON/OFF Turns the buzzer sound ON/OFF.
③ Store key	Saves displayed data and parameters that appear during operation of the unit.
④ Recall key	Recalls stored data.
⑤ Battery check key	Checks the amount of battery power remaining. The unit displays FF, F, L, and LL. When LL is displayed on the right LCD, replace all the batteries.
⑥ Search/Stimulation selector key	The lamp lights up in this mode.
⑦ Search/Stimulation-mode indicator lamp	When CH1 is switched to the search mode, CH2–CH6 cannot be used.
⑧ Output-mode selector key	Chooses from among 8 output modes.
⑨ Output-mode indicator lamp	The selected mode lamp lights up.
⑩ Frequency key	Sets the frequency. Holding down this key for over 0.5 sec varies the frequency continuously.
⑪ Phase duration key	Sets the phase duration. Holding down this key for over 0.5 sec varies the phase duration continuously.
⑫ Timer key	Sets the timer (in 1-minute steps). Holding down this key for over 0.5 sec varies the timer continuously.
⑬ Error lamp	The lamp comes on, when the output intensity knobs are not in “0.”
⑭ Output intensity knob	Controls the output intensity.
⑮ Search/Stimulation probe insertion port	The blue marked cord of the Search/Stimulation probe is inserted here.
⑯ Output ports	The electrode cords are inserted here.
⑰ Output-level selector switch	Switches the output level between High (H) and Low (L)
⑱ Battery case cover	(on the bottom of the unit) 4 alkaline LR 14 batteries are installed under the cover (load them as indicated by the battery marks).

Operating Method

Preparations

1 Open the battery cover on the rear of the unit, and load the batteries as indicated by the battery marks.



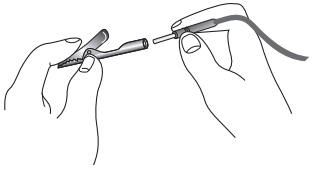
Note:
The unit is supplied without batteries installed.
Use 4 R14 batteries.

2 Confirm that all output intensity knobs are set to “0.”

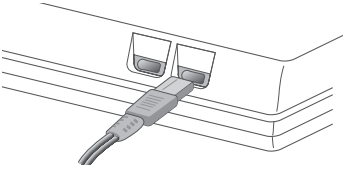
Electroacupuncture Mode

1 Connect the Exclusive Clips to each Electrode Cord.

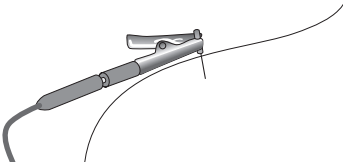
※Connect the same colors to each other (red to red, black to black).



2 Insert the Electrode Cord plug securely into each Output port.



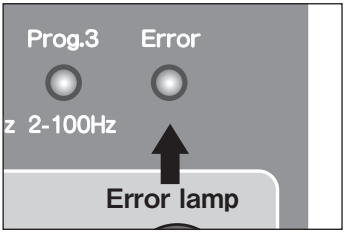
3 Pinch the needle electrodes (handle) firmly with the Exclusive Clip.



4 Turn on the unit.

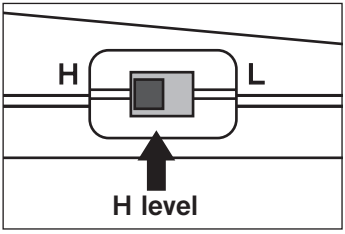
⚠CAUTION

L (low) output level must be used in Electroacupuncture mode



①If all 6 Output intensity knobs are not set to "0," a warning sound will be emitted (4 intermittent beeps) for 15 seconds and the Error lamp will come on when the unit is turned on.

②If the output level is set to H (High), the buzzer will sound (2 intermittent beeps) for 15 seconds. Press the Buzzer key to mute the beeping.



H (High)-level output : Max. 32 mA (peak)

L (Low)-level output : Max. 16 mA (peak)

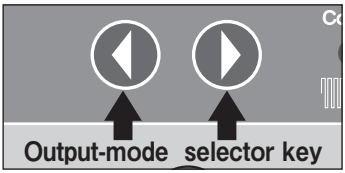
⚠CAUTION

If the output level is switched from the L level to the H level with the unit turned on, a warning sound will be emitted for 15 seconds. the Error lamp will come on, and the output will be cut off. In such a case, put all the Output intensity knobs back in the "0" position. Otherwise, it will not be possible to start the treatment.

Incidentally, when the output is set to the H level, the output-H warning sound (2 intermittent beeps) will be emitted continuously. The warning sound can be muted by pressing any one of the Buzzer key, Battery check key, Output-mode selector key, Frequency key, Phase duration key, and Timer key.

When the unit is turned on with the Output level selector switch set to H, the warning sound will be emitted (2 intermittent beeps).

5 Select the output mode using the Output-mode selector key.



■When a free programmable mode such as Const Burst Surge Fast+Slow Sweep, or the like is selected

① When the unit is turned on for the first time, the initial settings of the unit are as specified below. To change a parameter values, use the Frequency key, Phase duration key, or Timer key, as appropriate.

Setting units and setting ranges for the parameters

The table right lists setting units for frequency and phase duration, and available phase duration for frequency range.

Frequency settings	
Range	Unit
1–10 Hz	1 Hz
10–100 Hz	10 Hz
100–250 Hz	25 Hz
250–500 Hz	50 Hz

Phase duration settings	
Range	Unit
50–100 μs	10 μs
100–200 μs	25 μs
200–400 μs	50 μs

Phase durations for the frequency ranges	
50–400 μs	0.5–90 Hz
50–200 μs	100–200 Hz
50–100 μs	225–350 Hz
50–80 μs	400–500 Hz

Precautions on changing parameter values:

While the Fast+Slow mode or Sweep mode is activated, the unit displays the Fast frequency. When the Fast frequency is set to the desired value, the Slow frequency is automatically set to one-third of the set Fast frequency.

Initial setting

MODE	FREQUENCY	PHASE DURATION	TIMER
Constant	3 Hz	300 μs	15 min
Burst	2 Hz	150 μs	
Surge	10 Hz	150 μs	
Fast+Slow	3 Hz/10 Hz	250 μs	
Sweep	3 Hz/10 Hz	250 μs	

The unit will emit the sound for 10 seconds to indicate the end of treatment, automatically turning off in 5 minutes if no action is taken.

Note:

During the treatment, the display alternates the Fast frequency and Slow frequency.

②As the unit stores the latest data used in each mode for the immediately previous treatment, it is automatically set to that data in subsequent treatment sessions.

※The stored data consists of the output mode used in the previous treatment and the relevant parameter values.

③Upon completion of setting the parameter values, operate the Output intensity knob to increase the output intensity. The treatment will begin.

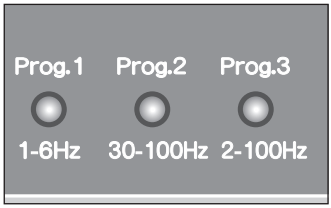
⚠CAUTION Increase output intensity gradually to avoid shock to the patient.

■ When a preset program mode such as Random program 1, 2, 3, etc., is selected

To prevent habituation to stimulation, the unit comes equipped with three preset programs: the Slow-frequency, Fast-frequency and Slow+Fast-frequency programs. These programs have their respective parameters preset as shown below. To change the preset data, use the Frequency key, Phase duration key, or Timer key, as appropriate during the treatment.

Note:

The parameters changed will be canceled when the treatment is terminated except the timer set.



Preset Parameters in Random Programs

	STEP	MODE	FREQUENCY (Hz)	PHASE DURATION (μs)	TIMER (min)
Prog1 1–6 Hz	1	Constant	5	300	2
	2	Fast+Slow	2/6	300	4
	3	Burst	3	50	3
	4	Sweep	1–5	150	3
	5	Constant	1	150	3

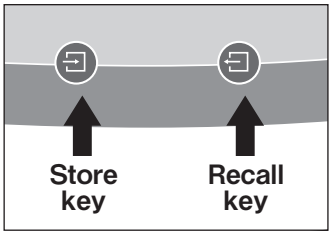
	STEP	MODE	FREQUENCY (Hz)	PHASE DURATION (μs)	TIMER (min)
Prog2 30–100 Hz	1	Constant	80	150	2
	2	Surge	100	150	3
	3	Fast+Slow	30/90	150	4
	4	Sweep	33–100	150	3
	5	Constant	70	150	3

	STEP	MODE	FREQUENCY (Hz)	PHASE DURATION (μs)	TIMER (min)
Prog3 2–100 Hz	1	Constant	20	150	2
	2	Fast+Slow	2/6	400	4
	3	Surge	100	100	3
	4	Sweep	3–10	300	3
	5	Constant	70	100	3

The treatment time can be chosen from among 10, 15, and 20 minutes.
Upon completion of the preparations, operate the Output intensity knob to increase the output intensity. The treatment will begin.

⚠CAUTION Increase output intensity gradually to avoid shock to the patient.

6 Storing and recalling the parameters



①Pressing the Store key allows the parameters currently in use to be stored.

②The parameters are stored each time the Store key is pressed, up to a maximum of 16. Storing the 17th parameter deletes the first one stored (deleted sequentially from older data).

③The stored parameters can be recalled sequentially from among newer data by pressing the Recall key. As the output intensity is increased, the unit starts treatment in the recalled parameters.

7 When the Timer counts down to “0,” the treatment ends. To continue the treatment, first put all Output intensity knobs back in the “0” position, and then restart the unit. If the Output intensity knobs are not put back in the “0” position, no output will be made, the Error lamp will come on, and a warning beep will sound. And the Timer can not be set.

Note:
As the unit automatically stores the parameters of the program used immediately before. It will not be necessary to set new parameters in the next treatment session, if the same parameters as in the previous treatment are to be used.

Acupuncture-Point Search/Stimulation Mode

1 Set the Search/Stimulation Probe.

Note:

※The Search/Stimulation Probe allows the application of current stimulation to a local area.

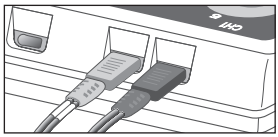
※One end of the Search/Stimulation Probe is made of metal. The probe is used with the other end stuffed with purified cotton soaked in water. Either end can be used. (Wring the water from the soaked cotton before using the probe.) It is recommended to use a cotton cone soaked in water. Keep in mind that when the metallic part of the probe is applied to the skin, that portion of the skin may turn red in some cases.

Prepare a suitable cotton cone soaked in water and wring it enough.

And place it over one end of the probe.

The portion of the cotton cone soaked should be applied to the skin.

2 Insert one plug of the Search/Stimulation Probe cord into the Output port of CH1, and the other plug into the Search/Stimulation Probe insertion port (blue mark).



3 Turn on the unit and press the Search/Stimulation selector key. When the Search/Stimulation mode is selected, the Search/Stimulation mode indicator lamp will light up in green.

⚠CAUTION

Confirm that the Output intensity knob of CH1 is set to “0.” Otherwise, a warning sound will be emitted and the Error lamp will come on.

While the Search/Stimulation mode is activated, CH2 to CH6 cannot be used.

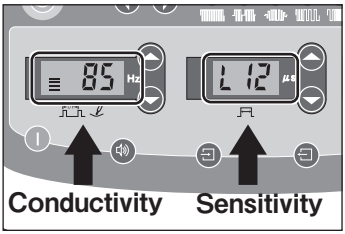
4 Have the patient hold the grounding rod, and apply the tip of the Search/Stimulation Probe to the patient's skin. When the stimulation button of the probe is pressed in an area of the skin at which the resistance is low, the stimulation output will be delivered. Before treatment, the Output intensity knob should be set to the “0” position. Otherwise, the alarm will sound, and the Error lamp will come on.

■Display in the Search Mode

①Pressing the Search/Stimulation selector key, the left LCD displays [0].

②When the search begins, the unit displays the level of sensitivity using bars, a value, and sound.

As the number of displayed bars increases, the value rises, and the buzzer beeping interval becomes shorter, the acupuncture-point can be located. The center LCD indicates the sensitivity level. The LCD displays the sensitivity in three steps, L6 L12, and L21, which are automatically switched over according to the conductivity.

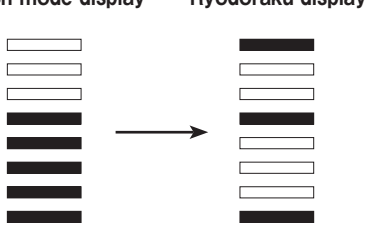


Ryodoraku Point Measurement Mode

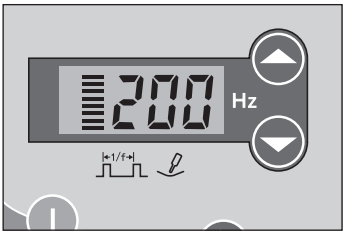
When either ▲ or ▼ (Phase duration key) is pressed on the center LCD, the unit is switched to the Ryodoraku point measurement mode. If ▲ or ▼ is held down, the sensitivity level can be set to any one of L6 (6 V), L12 (12 V), or L21 (21 V). Set the level properly according to the degree of the patient's skin resistance (continuity).

⚠CAUTION

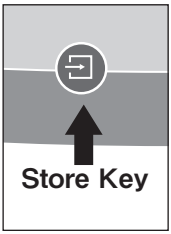
When the mode is switched to the Ryodoraku point measurement mode, the bar indication is changed to the figure at right.



1 While the Ryodoraku point measurement mode is actived, the measurement values can be held. The unit displays 200 as the maximum measurement value. The unit displays a value when the probe is applied to the surface of the skin. This value is retained when the probe is removed from contact with the skin.

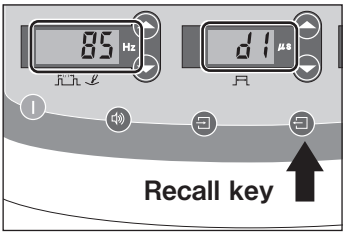


2 A held measurement value can be recorded by pressing the Store key, or the Stimulation button of the probe.
The unit stores 24 values (d1–d24).



Note:
When 24 values have been stored, the unit stops storing.

3 To recall a stored value, press the Recall key. The stored values will be displayed sequentially in order of the measurements (beginning with the oldest value) each time the Recall key is pressed. The left LCD displays the measurement data, while the center LCD indicates memory Nos. from d1 to d24.

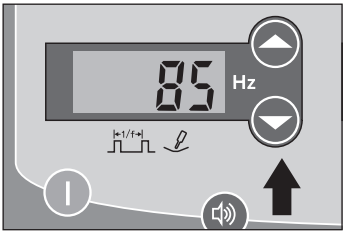


4 If the Recall key is pressed after measurement data has been partially stored using the Store key, the data stored up to that point can be checked. If the Store key is held down, more data can be stored in continuation from the point at which the data storing was suspended.

How to clear the stored data
Press the Search/Stimulation selector key on the Main Unit ⑥ to clear all the stored data, and allow storage once again from d1.

Display of Average Value

The average value of the stored data can be computed and displayed. Press ▼ on the left LCD; the average value of the measured data will be displayed on the LCD at left.



Upon completion of operation, confirm that the LCD screens are off and unplug the probe cords from the unit. If the unit is not to be used for an extended period, store it with the batteries removed.

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 medical electronic device. If it is brought closer than 30 cm, the performance of the medical equipment may deteriorate.
- Electrode Cord length 2 m
- If accessories other than those supplied as spare parts by the manufacturer are used, the emission of this unit may increase and immunity may be reduced.
- Do not place this unit 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 unit 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	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

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 (LED abnormality and output stop 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	Not applicable	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	Not applicable	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	Not applicable	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 U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

This unit is intended for use in the electromagnetic environment specified below.
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It does not harm users and patients within the electromagnetic environment shown below.
However, it is possible to affect the medical equipment (LED abnormality and output stop 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 to 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.
	6 Vrms ISM and amateur radio bands between 150 kHz to 80 MHz	6 Vrms	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).
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz IEC 60601 -1-2: 2014 Table 9	10 V/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: 

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.

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	800 MHz to 2.7 GHz
	$d = 1.2 \sqrt{P}$	$d = 0.58 \sqrt{P}$	$d = 0.35 \sqrt{P}$	$d = 0.7 \sqrt{P}$
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

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