ELECTRICAL STIMULATOR

ES-320

Operation Manual

Please read this manual carefully before using the ES-320. This manual is comprised as an essential part in the ES-320. Save this manual at a designated place for your reference whenever required.

Caution : Federal law restricts this device to sale by or on the order of a practitioner licenced by the law of the State in which he/she practices.

ITO PHYSIOTHERAPY &REHABILITATION

The ES-320 has features beneficial to both therapist and patient.

1. The ES-320 monitors the number of treatment sessions, measures the time of the treatment, and keeps a record of these operations (PAT.P). This data may be used to ascertain whether the patient has conducted the treatment as prescribed, or to evaluate to what degree the prescribed parameters were effective.
2. The parameters, after the therapist has prescribed them, are stored in the memory and protected from modification by subsequent operations.
3. The ES-320 is designed to maintain the desired constant intensity regardless of the battery power level (PAT.P).
4. Stored data are maintained in the memory even when the battery is replaced or when the power is off.

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Indications for TENS

TENS devices are used for symptomatic relief of intractable pain. They are indicated also as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain problems.

⚠ Contraindications for TENS

1. Any electrode placement that applies current to the carotid sinus (neck) region.
2. Any use of TENS on patients who have a demand-type cardiac pacemaker.
3. Any electrode placement that causes current to flow transcerebrally (through the head).
4. The use of TENS whenever pain syndromes are undiagnosed, until etiology is established.

⚠ Warnings for TENS

1. The safety of TENS devices for use during pregnancy or birth has not been established.
2. TENS is not effective for pain of central origin. (This includes headache.)
3. TENS devices should be used only under the continued supervision of a physician.

4. TENS devices have no curative value.
5. TENS is a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.
6. The user must keep the device out of the reach of children.
7. Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when TENS stimulation is in use.
8. Stimulus delivered by this device may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax because it may cause a cardiac arrhythmia.

⚠ Precautions for TENS

1. Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
2. Effectiveness is highly dependent upon patient selection by a person qualified in the managment of pain patients.

⚠ Adverse reactions for TENS

Skin irritation and electrode burns are potential adverse reactions.

Indications for EMS

1. Relaxation of muscle spasm
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis
6. Maintaining or increasing range of motion

EMS devices should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

⚠ Contraindications for EMS:

1. EMS devices are contraindicated for patients with cardiac demand pacemakers.
2. EMS devices should not be used on cancer patients.

⚠ Warnings for EMS:

1. The long-term effects of chronic electrical stimulation are unknown.
2. Safety has not been established for the use of EMS devices during pregnancy.

3. Adequate precautions should be taken in the case of persons with suspected heart problems.
4. Adequate precautions should be taken in the case of persons with suspected or diagnosed epilepsy.
5. Do not stimulate over the carotid sinus nerves, especially in patients with a known sensitivity to the carotid sinus reflex.
6. Severe spasm of the laryngeal and pharyngeal muscles may occur when the electrodes are positioned over the neck or mouth. The contractions may be strong enough to close the airway or cause difficulty in breathing.
7. EMS devices should not be applied transcerebrally.
8. EMS devices should not be used over swollen, infected, or inflammed areas or skin eruptions, e.g., phlebitis, thrombo phlebitis, varicose veins.
9. Caution should be used in the transthoracic application of EMS devices in that the introduction of electrical current into the heart may cause arrhythmias.
10. EMS devices should be kept out of the reach of children.

⚠ Precautions for EMS:

1. Precautions should be observed in the presence of the following:

a. When there is a tendency to hemorrhage following acute trauma or fracture.

b. Following recent surgical procedures when muscle contraction may disrupt the healing process.
c. Over the menstruating uterus.
d. Where sensory nerve damage is present by a loss of normal skin sensation

2. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by use of an alternate conductive medium, or alternate electrode placement.

⚠ Adverse effects for EMS:

Skin irritation and burns beneath the electrodes have been reported with the use of electrical muscle stimulators.

Precautions on Maintenance and Checks

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.
   (1) In the undue humidity, temperature, dust, air containing salt or sulfur, or places exposed to direct sunbeam.
   (2) In the inflammable environment containing oxygen, nitrous oxide, anesthetic gas, or inflammable disinfectant mixed with the air.
3. Store the unit
   (1) At a place free from a splash of water.
   (2) At a stable place free from inclination, vibration or shock.
4. Before using a unit that has been out of use for an extended period, confirm that it operates normally and safely.
5. 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.
6. Check the accessories regularly and replace any that are irregular, in order to prevent danger.

Maintenance and Check Items

To ensure safety, contact your dealer or the manufacturer if you have any questions.

ITEM	DESCRIPTION	METHOD
Appearance and markings	(1)Check for a broken or damaged part. (2)Check the indications on the LCD screens to confirm that they are legible.	Visual inspection
Operation	(1)Check the indication on the LCD to confirm that they are all on when the unit is turned on. (2)Confirm that the unit functions as indicated in the operation manual.	Actual inspection
Accessories	(1)Check breakage or damaged parts. (2)Check the cords for any broken or damaged.	Visual inspection

Disposal of the unit

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.

⚠ General cautions for therapy

1. Carefully diagnose the patient and check there should be any special cautions or instructions given to the patient.
2. Explain fully to the patient about therapeutic procedures and the need of immediate appealing if a severe pain or pressure is felt during treatment.
3. Adjust the output intensity to the level at which the patient feels the stimulation comfortable.
4. The patient with paralysis tends to overlook the proper level of intensity. As a result, therapy may be conducted with an excessive intensity of stimulation. Repeatedly confirm if the stimulatlion is comfortable for such a patient during therapy.

⚠ Cautions:

ES-320 should be used under the instructions by physician or PT.

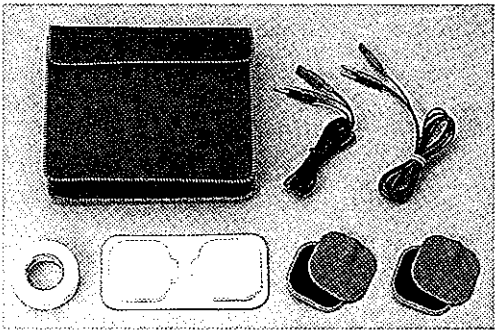
⚠ Warnings:

Do not use with other therapeutic devices. It may cause mal-function and may lead to danger.

Do not use the unit adjacent to microwave or shortwave diathermy unit. It may cause electric burn.

Accessories & Specifications

Standard accessories:



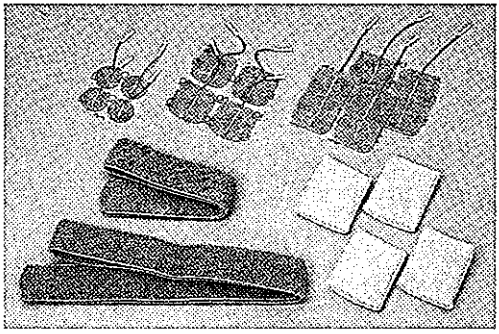
4 x RA-002 Rubber electrode , 4 x HD-001 Gel pad ,
2 x ZL- 350 Electrode cable , 1 x Adhesive tape ,
1 x Carrying bag

NOTE : Batteries are not included. Use three (3) LR6(AA) alkaline batteries.

Specifications:

Power source :	DC4.5V 3 x LR6 (AA) alkaline battery (not included)
Output channels :	2, independently controlled
Pulse shape :	Symmetric, bi-phase rectangular pulse
Amplitude/Voltage :	90mA / 45V (peak) at 500Ω load
Phase duration :	50-200μs ± 10μs
Frequency :	1-100Hz±5%
Output mode :	Constant, Burst, Surge*, Sweep, Random *Selectable Co-Contraction or Alternate Contraction (in Surge mode only)
On/Off time :	1-30sec. / on time x 2,3, or 5
Timer :	1-60minutes
Display :	LCD (46 x 31mm)
Free program :	4 memories , one program per output mode except Random
Safety features :	Self-test , Zero-start for output , Overcurrent protection, Function of detecting and preventing software runaway, Function of warning low battery, Keyboard lock, Auto power Off

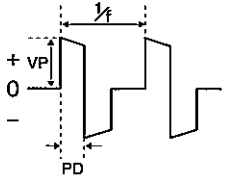
Optional accessories:



VS-30I Electrode sponge (M), 7x7cm, set of 4
AX-002 Self-adhesive electrode, 5x5cm, set of 4
AX-003 Self-adhesive electrode, 5x9cm, set of 4
AX-004 Self-adhesive electrode, 3.2cmø, set of 4
ZS-320S Strap (S), 4.5x60cm
ZS-320L Strap (L), 4.5x120cm

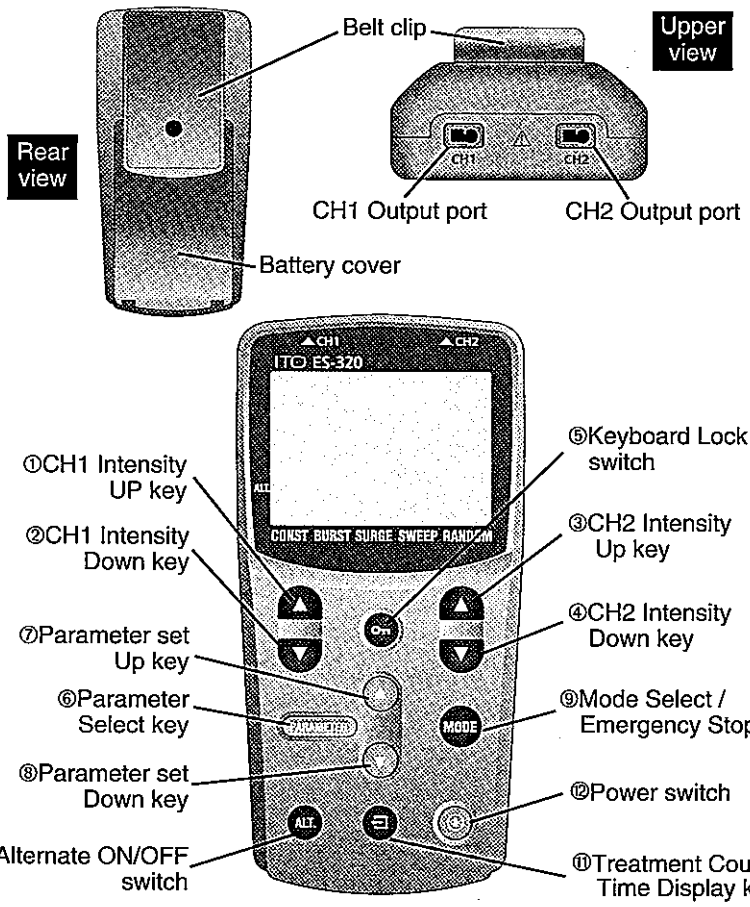
Safety class :	Internally powered equipment Type BF	
Emvironment :	in operation	for storage
Temperature	0°C – 40°C	-40°C – 70°C
Humidity	30% – 85%	10% – 90%
Dimensions :	61 x 122 x 37mm	
Weight :	120g (main unit) (not including batteries)	

Pulse shape :



f : frequency
PD : phase duration
VP : output voltage

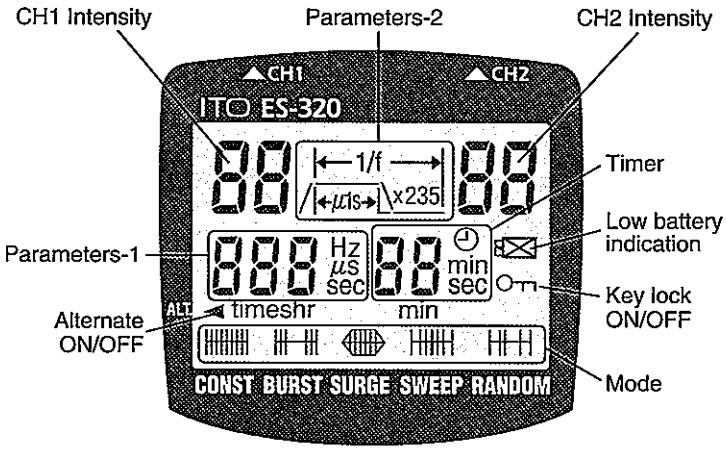
Keys and Switches



* Holding down the keys ①,②,③,④,⑦,and ⑧ will change the values continuously.

LCD Indications and Parameter Setting Range

(all On)



Parameter Setting Range:

Mode	Frequency	Phase Duration	ON/OFF Time	Timer
CONST	1-10Hz : 1Hz unit 10-100Hz : 10Hz unit	50-200µs : 10µs unit		1-30min : 1min unit 30-60min : 5min unit
BURST	1-7Hz : 1Hz unit	50-200µs : 10µs unit		1-30min : 1min unit 30-60min : 5min unit
SURGE (EMS)	20-100Hz : 10Hz unit	50-200µs : 10µs unit	ON time1~30sec : 1sec unit OFF time : ON time x 2,3,5	1-30min : 1min unit 30-60min : 5min unit
SWEEP	3-10Hz : 1Hz unit 10-100Hz : 10Hz unit	50-200µs : 10µs unit		1-30min : 1min unit 30-60min : 5min unit
RANDOM				10-30min : 5min unit

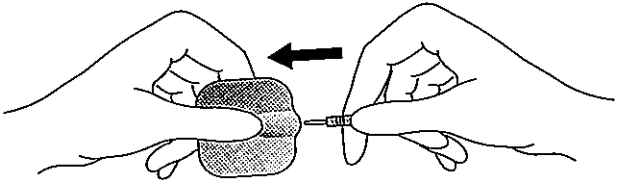
Preparations 1

First of all, install three (3) LR6 (AA) alkaline batteries.

Note: Batteries are not included in the standard kit.

■When using the rubber electrodes and the gel pads (standard acc.)

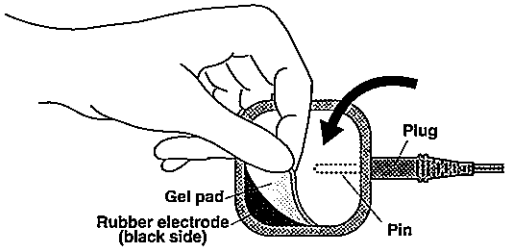
(1) Connect the electrode cable to the rubber electrode.



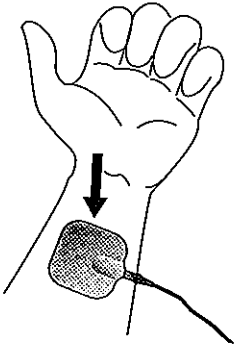
* Connect the cable securely to the electrode such that the metal part of the connector is no longer visible

(2) Place the gel pad over the black side of the rubber electrode.

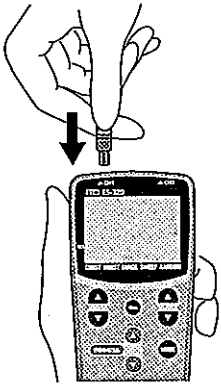
Note: Fix the gel pad after peeling off one of the protective films.



(3) Place the electrodes to the stimulation points, and fix them firmly with the adhensive tape attached, or a similar fixative.



* Connect an electrode cable when using one channel, or two electrode cables when using two channels.



(4) Connect the electrode cable(s) to the main unit.*

Note: Insert the electrode cable correctly so that the arrow mark(▼) does not faces to the front side.

About Electrodes (rubber with gel pad or self-adhensive):

(1) Do not apply the electrode to injured areas of the skin.

(2) If the skin becomes irritated or burned during treatment, suspend use immediately. The electrode will not be able to be affixed properly to skin that has not been cleansed of lotion, oils, cosmetics, or the like. Wash the skin with soap and lukewarm water and dry thoroughly before using electrode.

(3) Place the electrode in close contact with the skin. Any gap between the electrode and skin surface could intensify the stimulation and cause the patient to feel pain.

(4) To avoid infection, do not use the electrodes between the patients.

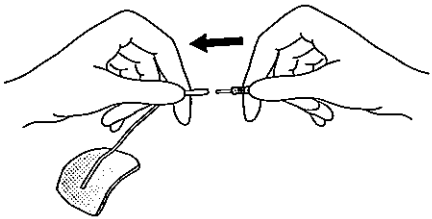
(5) Replace the gel pad or the self-adhesive electrode, if it loses adhesion. It may cause reddening or burn.

Preparations 2

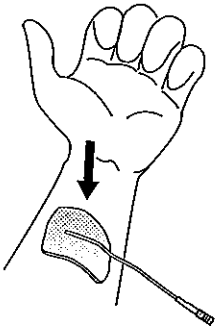
■When using other (optional) electrodes

• How to use self-adhensive electrodes

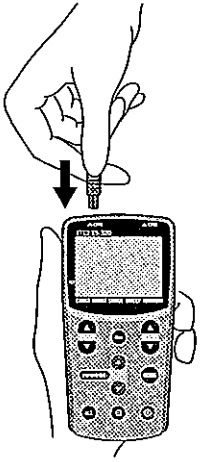
(1) Connect the electrode cable to the self-adhensive electrode.



(2) Place the electrodes to the stimulation points.



(3) Connect the electrode cable(s) to the main unit.*

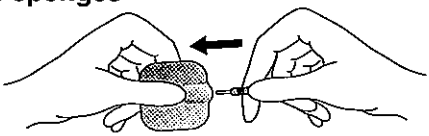


Note: Insert the electrode cable correctly so that the arrow mark(▼) does not faces to the front side.

* Connect an electrode cable when using one channel, or two electrode cables when using two channels.

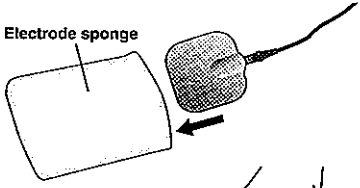
• How to use electrodes sponges

(1) Connect the electrode cable to the rubber electrode.

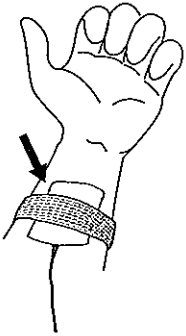


(2) Soak the electrode sponge in water, then squeeze it until water no longer drips from the sponge. Insert the rubber electrode into the sponge as deep as possible.

Note: Black side of the rubber electrode must face to the skin with electrode sponge.

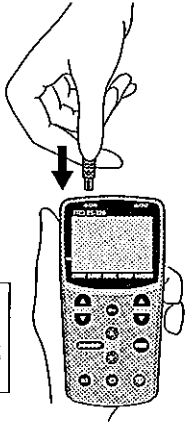


(3) Fasten the electrode with a strap.



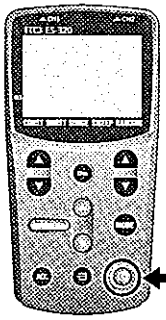
(4) Connect the electrode cable(s) to the main unit.*

Note: Insert the electrode cable correctly so that the arrow mark(▼) does not faces to the front side.



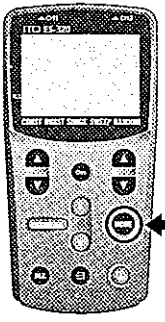
* Connect an electrode cable when using one channel, or two electrode cables when using two channels.

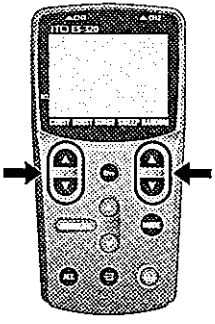
Treatment Using the Default Setting



(1) Turn on power by pressing the power switch for a second or longer.

(2) Select mode.





(3) Adjust intensity of each channel. (adjustable separately between 1– 45V in 45 steps.) By holding down one of the four intensity UP and Down keys, the intensity will change continuously.

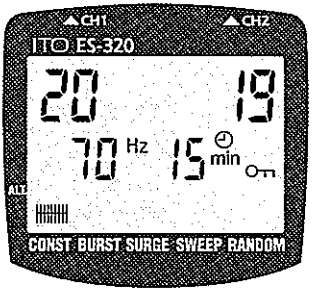
Note: To interrupt or end treatment, press the Mode Select key or Power SW. (The parameters used will be stored in the memory.)

(4) When the set time has elapsed, the output intensity drops to zero.

Default Settings:

Mode	Frequency	Phase Duration	Timer	ON/OFF Time
CONST	70Hz	100μs	20min	—
BURST	2Hz	100μs	20min	—
SURGE	60Hz	200μs	25min	5 /10sec
SWEEP	30-90Hz	100μs	20min	—
RANDOM	—	—	20min	—

About Keyboard Lock



"O⊓" mark appears on LCD

Press ⑤Keyboard lock switch once to enable the keylock. When the keylock is on, any key operation except for ⑫Power switch and ⑤Keyboard lock switch is disabled.

Hold down ⑤Keyboard lock switch for more than two seconds to unlock the system.

About Alternate ON/OFF Switch

" ◀ " mark appears when Alternate switch is on.

When treatment is performed in SURGE mode, if ⑩Alternate ON/OFF switch is pressed once, the output is turned to alternate stimulation (contraction) between channel 1 and channel 2.

Press ⑩Alternate ON/OFF switch again to cancel the alternate output to turn to co-stimulation (contraction) mode.

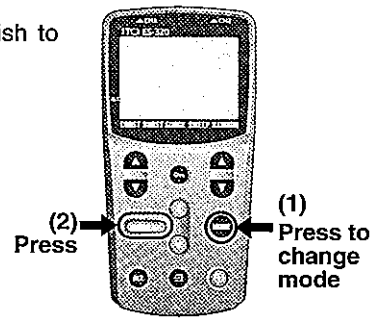
Parameter Setting Mode

Note: You are able to set parameters only when the intensity is zero.

(1) Turn on power.

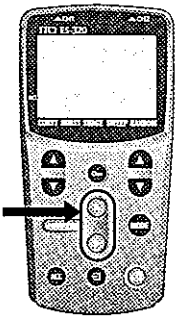
(2) Select the mode in which you wish to set the parameters.

Every time the Mode select key is pressed, the mode is changed as CONST→BURST→SURGE→SWEEP→RANDOM



(3) Select the parameter you wish to set out of Frequency, Phase duration, ON/OFF time* and Treatment time.

* Applicable to SURGE mode only.

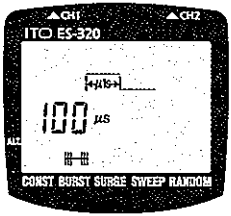


(4) Press Parameter set UP/DOWN key to change parameters.

Note: The parameters and setting ranges vary from mode to mode.

- In SURGE (EMS) mode, set the ON time, and the OFF time to a multiple of the ON time; choose between x2, x3, and x5.
- In SWEEP mode, set only the upper limit of the frequency; the lower limit will be automatically set to 1/3 of the upper limit.
- In RANDOM mode, only the treatment time is to be specified. This mode is a preset program consisting of five phases, combining low-to-high-range frequency and phase duration as well as the other modes described above. If treatment is not succesful in other modes, try this mode.

(5) After setting all the parameters for a mode, press ⑥Parameter select key, and the set parameters will be stored in the memory.



Note : • If you are to change only one or some of the parameters, be sure to complete steps (3) to (5) above: otherwise, the changes will not be stored in the memory.

• While you are you are setting parameters, if you press ⑫Power switch to turn off the power or ⑨Mode select key to move to another mode, the changes you have made will not be stored in the memory.

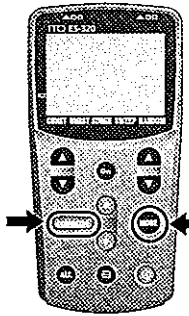
(5) Adjust intensity to start treatment.

Parameters and Setting Ranges for Each Mode:

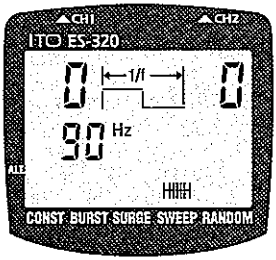
	CONST	BURST	SURGE	SWEEP	RANDOM
Frequency	1~100Hz	1~7Hz	20~100Hz	3~100Hz	—
Phase Duration	50~200μs	50~200μs	50~200μs	50~200μs	—
ON Time	—	—	1~30sec	—	—
OFF Time	—	—	x2, x3, x5	—	—
Timer	1~60min	1~60min	1~60min	1~60min	1~60min

Parameter Protection Mode

(1) When the unit is in the Default mode (p.18) or in the Parameter Setting (p.20) mode and the intensity is zero, press ⑥Parameter select key and ⑨Mode select key simultaneously for more than three seconds and the unit will enter the Parameter Protection mode and the LCD display will blink.



Press the two keys simultaneously to enter the Parameter Protection Mode



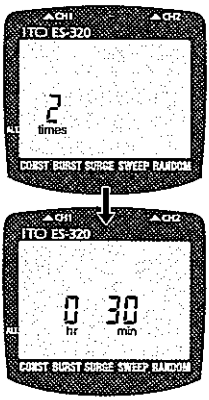
The LCD display blinks.

(2) When the LCD display starts blinking, follow the operation procedures (2)-(5) on pages 20-21 to set parameters.

(3) If ⑥Parameter Select key and ⑨Mode Select key are pressed again simultaneously in the parameter protection mode, the unit will return to the Parameter Setting Mode (see page 20) after storing the set parameters. However if ⑫Power switch is pressed before returning to the Parameter Setting Mode, the parameters will not be stored.

Note : • In the parameter protection mode, you can store a program mapped out for a particular patient. The stored program can be retrieved at any time if ⑥Parameter select key and ⑨Mode select key are pressed simultaneously.
• In the parameter protection mode, you can set parameters while monitoring the output pulses from CH1 and CH2.
• In the parameter protection mode, the power is turned off in 15 minutes, regardless of the timer setting.

Display of Treatment Count / Time



(1) When the unit is in the Parameter Setting or Default mode and the intensity is zero, press ⑪Treatment count/time display key. The number of treatment sessions will be shown.

(2) Press ⑪Treatment count/time display key again, and the total treatment time will be displayed.

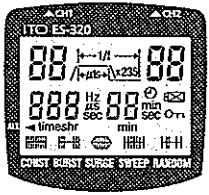
(3) Press ⑪Treatment count/time display key once more, and the unit will return to Parameter Setting mode.

(4) To clear the data of the treatment count and time, hold down ⑪Treatment count/time display key for more than two seconds in the treatment count/time display mode, then the numerical value will start to blink. Hold down again ⑪Treatment count/time display key for more than two seconds and the data will be cleared and the unit will return to Parameter Setting mode.

About Treatment Count/Time :

When the parameters set by the therapists are the same as those used by the patients and five minutes have passed since output from CH1 or CH2 began, the unit considers the treatment to have been performed. The unit measures the time it took to complete the treatment and stores its data as one treatment session (PAT.P).

How to retrieve default settings



Turn on the power.
Press ⑤Keyboard lock switch, ⑩Alternate ON/OFF switch, and ⑪Treatment count/time display key simultaneously and all values will be overwritten by the default settings and the power will be turned off. During the overwriting, all the indicators on the LCD will blink.