

Trio*Stim

Instruction Manual

Please read this manual carefully before using the Trio*Stim. This manual is comprised as an essential part of the Trio*Stim. Save this manual in a designated place for your reference whenever required.

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

■ Warning Symbol Marks:

Following warning symbol marks are used in this manual.

! Danger

Indicates a danger of death or serious injury to an operator or patient if the operator ignores this symbol and uses the Trio*Stim.

! Warning

Indicates a possibility of death or serious injury to an operator or patient when the operator ignores this warning and uses the Trio*Stim.

! Caution

Indicates a possibility of death or serious injury to an operator or property damage when the operator ignores this caution and uses the Trio*Stim.

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! Cleaning Instructions

! Cautions for checking and maintenance

! Indications, Contraindications, Warnings, Precautions, Adverse reactions for TENS

! Indications, Contraindications, Warnings, Precautions, Adverse reactions for EMS

■ Specifications

■ General description of the product:

1. Description of the product

The product is a dual-channel electric stimulator for active treatment application, which is equipped with a liquid crystal display indicating operation modes and output as well as an 8-bit microcomputer for controlling the system.

The select key allows you to choose among the four treatment modes: TNS (TENS), EMS, MCR and PRG. PRG runs 5 preset programs and user-specific programs.

2. Intended uses of the Trio*Stim are as follows:

The unit has 3 different modes: TNS, EMS and MCR.

The intended uses of each mode are shown below.

TNS: Symptomatic relief of chronic intractable pain.

EMS: Relaxation of muscle spasm, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, prevention of venous thrombosis, maintaining or increasing range of motion.

MCR: Symptomatic relief of chronic intractable pain.

■ Accessories:

■ Standard accessories:

1. 1 x 2" square V Trode self-adhesive electrodes, 4 /pkg. (ME 2705)
2. 1 x blue lead wire (ME 2152)
3. 1 x white lead wire (ME 2153)
4. 1 x belt clip (ME 2155)
5. 1 x battery (ME 2157)
6. 1 x carrying case (ME 2154)

■ Optional accessories

7. AC adapter (ME 2150, ME 2151) Please specify voltage when ordering.*
8. 2" V round Trode self-adhesive electrodes, 4/pkg. (ME 2702)
9. 2.75"V round Trode self-adhesive electrodes, 4/pkg. (ME 2703)
10. 2"x 4"oval V Trode self-adhesive electrodes, 4/pkg. (ME 2704)

*■ Input: AC120V (ME 2150) or AC230 (ME 2151)
50Hz/60Hz

■ Output: DC9V

☐ Double Insulation

! Caution: Use only designated accessories. Use only with adapters noted in the operation manual.

■ Description of components and functions

Upper View, Front View,

1. AC adapter jack (with cover; AC adapter is optional).
2. Channel 1 output (CH-1).
3. Channel 2 output (CH-2).
4. Battery case.
5. Battery cover retainer (refer to “battery replacement” on page 5).
6. Battery cover (refer to “battery replacement” on page 5).
7. LCD display: Indicates mode, parameter, message, etc.
8. Power key: turns the power on and off.
9. Set key:
 - a. Sets a selected mode.
 - b. Returns to the initial window from the parameter setting mode.
 - c. Terminates output and interrupts therapy.
 - d. Shows the contents of a program in sequence when in reference mode.
10. Up key (▲): Changes the value of a parameter.
11. Down key (▼): Changes the value of a parameter.
12. Keyboard lock key: Locks or unlocks all keys except the power key.
13. Select key: For the selection of mode, parameter, and program number. (Shown as SLT in the message box).
14. Belt clip.

■ Battery replacement

1. To open the battery case, pull the battery cover retainer (5) in the direction illustrated.
2. Open the battery cover (6) by pulling in the direction illustrated.
3. Place an alkali battery in the direction illustrated at the bottom of the battery case (4)
4. Close the battery cover (6) and return the battery cover retainer (5) to its original closed position. The battery may need to be replaced when the low battery mark on the LCD panel lights up.

<p>! Cautions: Remove battery when the unit is not used for a long time. Disposal of battery should be done according to local law.</p>

Diagram

OPEN

CLOSE

■ Layout of the LCD display

Diagram

Group 1: Output mode initial window

Group 2: Output mode for TNS

Group 3: Program mode

Group 4: Parameters

This display indicates whether the parameters displayed are for Channel 1 or 2 on “TNS 1≠2” mode

Hold Time, Rest Time and Message display box

Keyboard lock indicator, Low battery indicator, Error indicator

■ Functions of keys

1. SELECT key

Chooses items from Group 1 (output mode), Group 2 (output mode for TNS), Group 3 (program mode) and Group 4 (parameters). Each time the SELECT key is pressed a frame indicating the item available for selection moves up or down in each group on the LCD window, from Group 1 to 4. The choice available is framed on the display. Selection is made by pressing the SET key. Only the selected item remains displayed, and the control automatically shifts to the next group or the parameter setting.

(1) Choosing an output mode from Group 1 (initial window)

TNS : TENS

EMS : Electrical muscle stimulation

MCR : Microcurrent

PRG : Program

(2) Choosing a TNS (TENS) output mode from Group 2.

After choosing TNS (TENS) through the above process (1) and pressing the SET key the control automatically shifts to the item choices available in Group 2.

CST : Constant

BST : Burst

MOD : Modulation

1 ≠ 2 : Dual Freq.

(Channel 1 freq. ≠ Channel 2 freq. in TNS Constant mode)

(3) Choosing an EMS mode or an MCR mode from Group 1.

After choosing EMS or MCR and pressing the SET key, the control automatically shifts to the Parameter setting (Group 4).

(4) Choosing a program mode from Group 3.

Push SET twice after PRG to get Group 3 choices.

RPT : Repeat preset program : This selection is made when using a treatment program already in the memory.

NEW : New (Program): This selection is made when a new program is being created.

REF : Reference : This selection is made to review the contents of the program stored in the memory.

END : End (of Program) : This selection is made when a new program has been created or a program review has been completed.

(5) Choosing parameters from Group 4

The selected item blinks to set or change parameters.

TNS OR Microcurrent Parameters	EMS Parameters
CH-1: sets the intensity of channel 1.	CH-1: Sets the intensity of Channel 1.
CH-2: Sets the intensity of Channel 2	CH-2: Sets the intensity of Channel 2.
FREQ. (Frequency) : Sets the pulse frequency.	FREQ: Sets the pulse frequency
WDTH (Width): Sets the pulse width.	H (Hold Time) : Sets the hold time
(Time) : Sets the treatment time.	R (Reset Time): Sets the rest time
	WDTH: Sets the pulse width.
	(Time) : Sets the treatment time.

Use the Up (▲) or Down (▼) key to set parameters.

Note:

1. Parameters are set automatically without pressing the SET key.
2. Pressing the SET key once stops the parameter from blinking; then use the Up (▲) or Down (▼) key (or the SELECT key) to reset the parameter.
3. Pressing the SET key twice in sequence will automatically return the control to the initial window (i.e. the window for choosing the output mode).
4. In EMS mode, hold time and rest time are indicated in the message box at the top of the display.

2. SET key

Function-1: Finalizes the selected item.

In Output Mode, TNS, EMS, Microcurrent or Program Mode, pressing the SELECT key finalizes the item(s) chosen by pressing the SELECT key, and the control function automatically shifts to the next procedure.

Function-2: Returns the control function from the parameter-setting window to the initial window (i.e. the window for choosing the output mode).

Case (1): Pressing the SET key twice while a parameter item is blinking (during the process of parameter setting), returns the control function to the initial window.

Note: Pressing the SET key once stops the item from blinking.

Case (2): When the parameter item is not blinking (i.e., 30 seconds after the parameter has been set, or when the unit is in the process of treatment) the control function can be returned to the initial window by pressing the SET key once. **Note:** In this case, the parameter selected just before pressing the SET key will be stored in memory.

Function-3: Terminates output and interrupts therapy.

This is the same as in Case (2) of Function-2. By pressing the SET key once, therapy is interrupted and the control function returns to the initial window.

Function-4: Shows the contents of a program in sequence when in reference mode 3.

3. Up (▲) and Down (▼) keys

These keys are for setting or changing parameters. Keeping the key depressed will cause the parameter to increase or decrease in a continuous fashion.

4. Keyboard lock key:

This key locks the keyboard. Pressing this key locks all the keys except for the power key. The keyboard lock is released when the key is pressed for two seconds or longer.

Note: This key is effective only when the control function is on the parameter-setting windows.

5. Power On/Off key

This key turns the power on and off.

General cautions for therapy:

1. Carefully diagnose the patient and check if there should be any special cautions or instructions given to the patient.
2. Explain fully to the patient about therapeutic procedures and have them tell you immediately 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 comfortably.
4. The patient with paralysis tends to overlook the proper level of intensity. As a result, therapy could be conducted with an excessive intensity of stimulation. Repeatedly confirm if the stimulation is comfortable for such a patient during therapy.

Cautions:

1. This equipment generates, uses and can radiate radio frequency energy and if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures.

- Reorient or relocate the receiving devices
- Increase the separation between the equipment
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) is/are connected.
- Consult the manufacturer or field service technician for help.

2. Trio*Stim is a professional use medical device and it should be used under the instructions of a physician, PT or any other practitioner licensed by law of the state in which he or she practices.

Warnings:

1. Operation in close proximity (e.g. 1 m) to shortwave or microwave therapy EQUIPMENT may produce instability in the STIMULATOR output.
2. Simultaneous connection of a PATIENT to h.f. surgical EQUIPMENT may result in burns at the site of the STIMULATOR electrodes and possible damage to the STIMULATOR.
3. Do not use with other therapeutic devices. It may cause a malfunction and may lead to danger.
4. Do not use the unit adjacent to a microwave or shortwave diathermy unit. It may cause an electric burn.
5. The maximum output of this device is 23 mA RMS. Avoid current densities exceeding 2 mA/cm² when using this device. If an electrode smaller than the 2" square V Trode is necessary for treatment, use extreme caution to reduce the chance of thermal burns due to high current density.
6. You may experience electric shock under the following conditions:
 - (1) When a connecting wire is broken.
 - (2) When the contact between a connecting wire and electrode or between a connecting wire and the main unit is poor. Replace the connecting wire and electrode and try again at low intensity. (Consult the distributor if you still feel an electric shock).
 - (3) When electrode contact with the skin is poor. (Ensure contact between the electrodes and skin is correct.)
 - (4) When the electrode is dry or worn. (Replace with a new electrode).

■ OPERATION

1. Power on
2. Preparation for treatment
3. Choosing a mode and beginning treatment
 - 3-1 Choosing TNS (TENS) mode
 - 3-1-1 Choosing TNS CST (TENS Constant)
 - 3-1-2 Choosing TNS BST (TENS Burst)

3-1-3 Choosing TNS MOD (TENS Modulation)

3-1-4 Choosing TNS 1 \neq 2 (TENS Constant, Channel 1 frequency \neq Channel 2 frequency)

3-2 Choosing EMS: Electrical Muscle Stimulation mode

3-3 Choosing MCR: Microcurrent mode

3-4 Choosing PRG: Program mode

3-4-1 Choosing a program number

3-4-2 Choosing a program mode

- (a) Choosing Repeat Preset Program (RPT): Therapy using an existing program
- (b) Choosing New Program (NEW) :Creating a new program
- (c) Choosing Reference (REF) : Referring to the contents of an existing program.

4. End of therapy.

1. Power on

Fig. 1: Initial Check Window

When the power on/off key is turned to the On position, all the indicators in the window (Fig. 1) flash three times to perform an initial equipment check. Then, “OK” is indicated in the message box on the LCD panel, and the control function shifts to the next window (Fig 2 or Fig 2').

2. Preparation for treatment: Placing electrodes prior to stimulation.

- (1) Connect the electrodes to the electrode cable. Connect two electrodes when using one channel, or four electrodes when using two channels.
- (2) Firmly insert the other end of the electrode cable into the output port of the main unit (CH-1, CH-2).
- (3) Place the self-adhesive electrodes on the stimulation point.

Cautions:

If output is set without connecting the electrode cable to the main unit or placing the electrodes on the stimulation point, an “Open Error” will occur and the unit will not function (unless Microcurrent is being used). In this case, turn off the power, place the electrodes correctly, and turn on the power again and

then set intensity. Inspect accessories before every use. Replace with new ones if any damage is found.

For hygienic reasons, use electrodes only on one patient. Electrodes may be used multiple times on the same patient.

3. Choosing a mode and beginning treatment.

Fig 2: Initial window for choosing the output mode.

(1) Figure 2: The figure illustrates the window that appears when the power is turned on for the first time. Each time the SELECT key is pressed the frame shifts to a new mode selection. The mode currently available for selection is framed.

TNS → EMS → MCR → PRG

The message box alternately displays:

SELECT MODE / SLT. OR SET ? (SLT. = Select)

Press SET key to choose the selected item.

(2) Figure 2': Except for case (1) above, i.e., turning the power on for the first time, the parameter setting window of the previously selected output mode is shown. (Figure 2' is an example)

Fig. 2': Window for parameter setting mode

(a) When using the previously selected output for parameter setting mode: Begin treatment by simply setting the intensity of CH-1 and CH-2.

(b) When changing the value of a parameter while using the previously selected output mode: Choose a desired parameter item by the SELECT key. The selected item blinks. Then change the value of the parameter by the Up (▲) or Down (▼) key. The value of the parameter can be changed at any time without interrupting therapy.

(c) When changing output mode:

Case 1: When the parameter item is blinking (i.e., when the parameter is available for setting): Pressing the SET key twice will interrupt therapy and return the control function to the initial window (i.e., the window for choosing the output mode).

Note: A single press of the SET key stops the item from blinking.

Case 2: When the parameter item is not blinking (either during treatment or after 30 seconds have elapsed since the parameter was set): Press the

SET key once, therapy is interrupted, and the control function will return to the initial window.

Note: In this case, the parameter value set immediately before the SET key is pressed is stored in memory. When the initial window is displayed, select the desired output mode.

3-1 Choosing TNS (TENS) Mode:

Fig. 3: Window for choosing TNS (TENS)

The window illustrated in figure 3 appears when choosing TNS (TENS). TNS is selected in the Figure 2 window. The message box alternately indicates the following messages: SELECT MODE / SLT. OR SET? (SLT. = Select)

Four output modes are available for TNS (TENS). Each time the SELECT key is pressed, a frame moves in the following sequence: CST → BST → MOD → 1 ≠ 2

Press the SET key to choose the selected item.

3-1-1 Choosing TNS Constant (TNS CST) Mode

Fig. 4 Window for choosing TNS Constant.

When CST (Constant) is selected from the window shown in figure 3 and the SET key is pressed, the window changes to the one shown in Figure 4. At the same time, "CH-1 0.0 mA" blinks.

The message box alternately shows the following message: PUSH ▲ KEY / SET CH1 LEV. (LEV. = intensity level)

- Initial parameters set at the time of shipment are as follows:

Frequency 70 Hz

Pulse width 100 μs

Time 10 min.

- Parameters other than the above:

The parameters set at the time of the previous treatment are shown.

(A) When using the same parameters again:

(1) Use the Up (▲) key to set the intensity of Channel 1. When the Up (▲) key is pressed once, output is generated, the timer starts and the following messages appear in sequence:

PUSH ▲/▼ KEY / SET CH1 LEV. (LEV. = intensity level)

(2) Choose CH-2 by pressing the SELECT key, and set the intensity of CH-2 by pressing the Up (▲) key. Peak values of the effective electric currents of CH-1 and CH-2 are shown on the LCD panel.

(B) When changing the parameters for treatment:

The selected item blinks. The item that is blinking shifts each time the SELECT key is pressed. To change the value of the parameter, press the Up (▲) or Down (▼) key.

Note: The value of any parameter item can be changed without interrupting treatment including FREQ, WDTN, time and intensity. (The selected item blinks for 30 seconds. Press the SET key once to stop the blinking. When the key is pressed twice, the control returns to the initial window (i.e., the window for selecting the output mode, main menu)).

● Parameter setting range of TENS Constant Mode

Item	Range	Steps
Frequency	1-200 Hz	1 Hz for 1-10 Hz, 10 Hz for 1-100 Hz 25 Hz for 100-200 Hz
Pulse	50-250 μ s	10 μ s
Output Current	0-80 mA (peak)	1 mA
Time	1-30 min.	1 min.

Note:

When the value of a particular parameter is at its lowest, the message box displays “Push ▲ key”, and when a parameter value is at its highest, the message box displays “Push ▼ key”. Either operation will show the range of the parameter.

Cautions: During treatment, always lock the keyboard by pressing the keyboard lock key.

3-1-2 Choosing TENS Burst (TNS BST) Mode

Fig. 5 Window for choosing TENS Burst

The window in Fig. 5 appears when BST (Burst) is selected by pressing the SELECT key and then the SET key on the window illustrated in Fig. 3 at the same time, “CH-1 0.0mA” blinks.

- Message box display: PUSH ▲ KEY / SET CH 1 LEV.

(LEV. = intensity level)

- Initial parameters set at shipment:

Frequency 2 bursts/sec. (shown as “2 Hz” on LCD)

Pulse width 150 μ s

Time 10 min.

- Parameter setting range of TENS Burst mode

Subsequent operations are identical to those of TENS Constant 3-1-1 (a) and (b). Refer to page 15 and 16.

Item	Range	Steps
Frequency	1-5 bursts/sec	1 burst
Pulse Width	50-250 μ s	10 μ s
Output Current	0-80 mA (peak)	1 mA
Time	1-30 min.	1 min.

3-1-3 Choosing TENS Modulation (TNS MOD) Mode

Fig. 6 Window for choosing TENS Modulation

The window shown in Fig. 6 appears when MOD (Modulation) is selected by pressing the SELECT key and then the SET key on the window illustrated in Fig. 3 at the same time, “CH-1 0.0 mA”

- Message box display: PUSH ▲ KEY / SET CH-1 LEV.

(LEV. = intensity level)

- Initial parameters set at the time of shipment:

Frequency 15 Surge/min. (shown as “15 Hz” on LCD)

Pulse Width 70 μ s

Time 10 min.

- Parameter setting range of TENS Modulation Mode

Item	Range	Steps
Frequency*	1-6, 8, 10, 12, 15, 20, 25, 30, 50 surges/min.	hold time is .6-20 sec., almost equal to rest

		time
Pulse	50-250 μ s	10 μ s
Output Current	0-80 mA (peak)	1 mA
Time	1-30 min.	1 min.

*Frequency in the case of Modulation Mode means the number of surges per minute, i.e., FREQ. 5 Hz = five surges per minute.

The speed of contraction is increased by pressing the Freq. Up (\blacktriangle) key; it is decreased by pressing the Freq. Down (\blacktriangledown) key.

- Subsequent operations are identical to those of TENS constant 3-1-1 (A) and (B). Refer to pages 16 and 17.

Note: During ramp down or rest phase, the intensity Up (\blacktriangle) key will not function, and the LCD indicates “ \blacktriangle KEY INVALID”. It is not possible to increase intensity by pressing the Up (\blacktriangle) key during these phases.

3-1-4 Choosing TENS Channel-1 freq. \neq Channel-2 freq. (TNS 1 \neq 2)

This mode permits independent setting of the TENS constant mode parameters (frequency, pulse width) on channels 1 and 2 (the timer is commonly used when this is done).

Fig. 7: Window for choosing TENS 1 \neq 2 Mode

The window on Fig. 7 appears when 1 \neq 2 is selected by pressing the SELECT key and then pressing the SET key on the window illustrated in Fig. 3. At the same time, “CH-1 0.0mA” starts blinking.

- Message box display: PUSH \blacktriangle KEY / SET CH-1 LEV.
- Initial parameters set at the time of shipment:

	CH-1	CH-2
Frequency	70 Hz	5 Hz
Pulse width	100 μ s	250 μ s
Time	10 min.	10 min.

- Parameters other than the initial parameters will appear if the settings of the previous treatment have been stored in memory.

- The parameter setting range of TENS 1 ≠ 2 Mode is the same as that of the TENS Constant Mode (refer to page 16)

(A) Using the same parameters for treatment:

(1) Set intensity on CH-1 by using the Up (▲) key. The message box displays “CH-1” indicating that parameters are being set on CH-1

(2) Choose CH-2 by using the SELECT key and set intensity on CH-2. When parameters for CH-2 are being selected the message box shows “CH-2.” The parameter item shifts in the following sequence as the SELECT key is pressed.

CH-1 → FREQ → WIDTH → CH-2 → FREQ → WIDTH → ⌚

Note: The timer is commonly used with CH-1 and CH-2

(A) Changing treatment parameters:

Select the desired parameter by referring to the table in section (A), and change the parameter by pressing the Up (▲) or Down (▼) key.

Note: The selected item will blink for 30 seconds. Pressing the SET key once stops the item from blinking. Two consecutive presses of the SET key will return the control function to the initial window, i.e., the window for selecting output mode, main menu.

- Checking parameter settings on CH-1 or CH-2.

To view the parameter settings for CH-1, press both the SELECT key and the Up (▲) key at the same time. This will cause the parameters on CH-1 to appear.

To view the parameter settings for CH-2 press both the SELECT key and the Down (▼) key at the same time. This will cause the parameters on CH-2 to appear.

3-2 Choosing Electrical Muscle Stimulation (EMS) Mode

Fig. 8 Window for choosing EMS

(1) Choose EMS by pressing the SELECT key on the window shown in Fig 2 (refer to page 14). Then press the SET key. The window shown in Fig. 8 will appear. At the same time, “CH-1 0.0 mA” starts blinking.

- Message box display: PUSH ▲ KEY / SET CH-1 LEV.
Hold Time and Rest Time appear in the message window when the SELECT key is pressed once more after the frequency item.

- Initial parameters set at shipment:

Base frequency	80 Hz
Pulse width	150 μ s
Hold time	3 sec.
Rest time	6 sec.
Time	10 min.

- Parameter setting range of EMS Mode

Item	Range	Steps
Base Frequency	25-100 Hz	5 Hz
Pulse Width	100-300 μ s	10 μ s
Hold time	0.5-30 sec.	0.5-10 sec. in 0.5 sec
Rest time	1-60 sec.	1-20 sec. in 1 sec. 20-60 sec in 10 sec.
Ramp Up/Down	20% of hold time	20% of hold time
Output Current	0-80 mA (peak)	1 mA
Time	1-30 min.	1 min.

- Parameter settings other than the above:

The parameters set at the time of the previous treatment are shown.

(A) When using the same parameters again to stimulate the muscle:

(1) Use the Up (▲) key to set the intensity of Channel 1.

When the Up (▲) key is pressed once, output is generated and timer starts.

Note: The Up (▲) key is invalid during Ramp down or Rest, and the LCD displays “▲ KEY INVALID” During this phase, intensity cannot be increased by pressing the Up (▲) key.

(2) Choose CH-2 pressing the SELECT key and set the intensity of CH-2 by pressing the Up (▲) key. Peak values of the effective electric currents of CH-1 and CH-2 are shown on the LCD panel.

(B) When changing parameters stimulation: The selected item blinks. The blinking item shifts each time the SELECT key is pressed as shown below. To change a parameter of a certain item, choose it and press the Up (▲) or Down (▼) key to change the parameter value. (The selected item blinks for 30 seconds. Press the SET key once to stop the blinking. When the key is pressed twice, the control returns to the initial window (i.e., the window for selecting the output mode)). When setting the Hold Time, the Rest time is automatically set at twice the set Hold Time. To change the Rest Time, press the SELECT key once to blink the Rest Time. Then, use the Up (▲) or Down (▼) key to change the Rest Time. Press the SELECT key twice to skip when not changing the Rest Time.

CH-1 → CH-2 → FREQ → H (Hold Time) → R (Rest Time) → WPTH → ☺

Note: Both Hold Time and Rest Time are shown on the message window.

Note: Two of the following settings:

(1) Hold Time > Rest Time, and

(2) Rest Time > Hold Time X 5

result in an error and are impossible to be set.

●Guide for setting parameter values (not absolute):

(1) Rest Time \geq Hold Time X 2

(2) Fast (twitch) muscles:

Base frequency: 80-100 Hz

Hold Time: 0.5-5 sec.

Pulse width: 100-150 μ s

(3) Slow (twitch) muscles:

Base frequency: 40-60 Hz

Hold Time: 10-15 sec.

Pulse width: 200 μ s or more

(4) Mixed muscles:

Base frequency: 60-80 Hz

Hold Time: 5-10 sec.

Pulse width: 150-200 μ s

(5) Weak muscles:

Base frequency: 25-40 Hz

Hold time: 15-30 sec.

Pulse width: 250-300 μ s

3-3 Choosing the Microcurrent (MCR) Mode

Fig. 9 Window for choosing MCR

(1) Choose MCR by using the SELECT key on the window shown in Fig. 2 (refer to page 14). Then press the SET key. The window shown in Fig. 9 will appear. At the same time, "CH-1 0.0 mA" starts blinking.

- Message display: PUSH ▲ KEY / SET CH1 LEV.

- Initial parameters set at the time of shipment:

Frequency 100 Hz

Pulse width 4 ms

Time 15 min.

- Parameters other than the initial parameters will appear if settings of the previous treatment have been stored in memory.

- Parameters setting range of Microcurrent Mode

Item	Range	Steps
Frequency	0.3,0.5, 1-400 Hz	0.3 Hz, 0.5 Hz, 1-10-100 Hz, in 10 Hz, 100-400 Hz in 25 Hz
Pulse width	1-250 ms	1-10 ms in 1 ms, 10-100 ms in 10 ms, 100-250 ms in 25ms
Output current	10-750 μ A (peak)	10 μ A
Time	1-30 min.	1 min.

The following procedures are the same as those described under TNS Constant 3-1-1 (A) and (B) (refer to page 16 and 17).

Note: (1) No open error function is provided for Microcurrent Mode.

(2) The maximum duty (pulse width) available for selection on Microcurrent Mode is 50 %. Accordingly, parameter setting is limited for frequency and pulse width. Please observe the display of PUSH ▲ KEY or PUSH ▼ KEY on the message box. The display indicates the limit of the range for the parameter being set.

3-4 Choosing Program (PRG) Mode:

Five programs (10 steps each) are stored in the memory. Programs are easy to recall, and new programs are easy to create. Three programs (Nos. 1-3) are already stored at the time of shipment.

Program No. 1: Fast frequency mode (30-100 Hz, 120-250 μ s)

No. 2: Slow frequency mode (1-8 Hz, 120-250 μ s)

No. 3: Fast + Slow freq. mode (1-125 Hz, 120-250 μ s)

These programs can be modified freely.

3-4-1 Choosing a program number (Nos. 1-5)

Fig. 10 Window for choosing PRG Mode

(1) Choose PRG on the window shown in Fig. 2 and press the SET key. The window shown in Fig. 10 will appear.

(2) Choose a program number by pressing the SELECT key. The display in the message box will change in the following sequence.

PROG 1 ? → PROG 2 ? → PROG 3 ? → PROG 4? → PROG 5? → END?

(3) Press the SET key to select the desired program number. The program will be selected and the window will change to the one illustrated in Fig. 11. **Note:** If no program exists in the selected number, the window shows NEW and END only. When the SET key is pressed on END, program number selection is interrupted, and the initial window (i.e., Fig. 2) appears.

3-4-2 Choosing the program mode

(1) When the SELECT key on the window illustrated in Fig. 11 is pressed, the program mode will change in the following sequence.

RPT → NEW → REF → END

When the desired mode is framed, press the SET key. The control function then moves to the next step of mode selection.

RPT : Repeat preset program. This selection repeats the program already stored in memory.

NEW : New program. This selection is used to create a new program.

REF : Reference. This selection is used to refer to the contents of the program stored in memory.

END : End of program. When a new program has been created or at the end of Reference, press the SET key after choosing END. This will return the control function to the initial window illustrated in Fig. 2 (refer to page 14).

(A) Choosing Repeat Preset Program (RPT)

RPT repeats the treatment program already stored in the memory. From the window illustrated in Fig. 11, choose RPT by pressing the SELECT key, then press the SET key to display the window illustrated in Fig. 12.

Fig. 12

- Message display: "▲ TO START ". Pressing the Up (▲) key generates output from CH-1 to execute the program.

- CMCB..... The steps of the programmed stimulation mode are displayed as illustrated (up to 10 steps).

C.... TNS Constant

B.... TNS Burst

M.... TNS Modulation

U.... Microcurrent

E.... Electrical Muscle Stimulation

*The subsequent procedures are the same as those of TNS Constant (3-1-1) or TNS 1 ≠ 2 (3-1-4 (A) and (B)). Refer to 3-2 (A) and (B) regarding EMS mode.

- Parameters can be changed at any time during therapy.

- Press the SET key or turn off the power to interrupt therapy. (Refer to Function-3 of page 9.)

Note: As a safety feature, intensity automatically returns to zero when the program shifts from one step to another, then resumes gradually to the set level.

- The step blinking in the message box is the one currently being executed. The contents of the step being executed are displayed on the LCD.

(B) Choosing New Program (NEW): Creating a new program.

Choose NEW when programming frequently used modes or creating a program for specific patients. Choose NEW on the window illustrated in Fig. 11 and press the SET key to display the window shown in Fig. 13.

Fig. 13

- **Message display:** SELECT MODE / PROG-4

*-1 in this example, Program No. 4 is selected in the item 3-4-1 (page 26).

- On the window in Fig. 13, each press of the SELECT key shifts the display in the following sequence:

TNS → EMS → MCR → END

Note:

(1) TNS and EMS (Electrical Muscle Stimulation) can be programmed into the same program, but MCR (Microcurrent) cannot be combined with TNS or EMS in a single program.

Accordingly, if the TNS or EMS mode is selected in the first step of the program, the subsequent steps cannot contain MCR.

On the other hand, if MCR is selected in the first program step, all subsequent steps must be for MCR.

(2) PRG in the window remains lighted during programming to ensure that the unit operates in program mode.

Fig. 14

(1) This window is where the creation of a new program begins.

(Program No.4 is used as an explanatory example. In the first step, TNS Constant is assumed to have been chosen.)

The window shown in Fig. 14 will appear when TNS is chosen by pressing the SELECT key and then pressing the SET key.

(2) Choose CST by pressing the SELECT key: then press the SET key to display the parameter setting window, as illustrated in Fig. 15.

(3) This window (Fig. 15) is the one used for setting parameters.

Note: At each step, it is possible to feel the difference in parameters by increasing intensity, provided that the intensity is increased only temporarily and is not stored in the memory.

When setting a parameter while checking the intensity, the electrode cable must be connected to the main unit and the electrodes must be placed on the body. Otherwise, an OPEN ERROR will occur.

The selected parameter item blinks.

Each press of the SELECT key shifts the parameter items in the following sequence:

TENS OR MICROCURRENT:

CH-1 → CH-2 → FREQ. → WIDTH → ⊕

Skip by using the SELECT key when not using a mode of stimulation.

Note:

- (1) Skip the item(s) by using the SELECT key when no change is required.
- (2) When setting the Hold Time, the Rest Time is automatically set as twice the set Hold Time. To change the Rest Time, choose the Rest Time with the SELECT key, and change it by pressing "Up (▲) or Down (▼)" key.
- (3) Two of the following settings:
 - (a) Hold Time > Rest Time, and
 - (b) Rest Time > Hold Time X 5cause an error and are impossible to set.
- (4) For programming while checking intensity, increase intensity of CH-1 or CH-2. To set FREQ., Hold Time, Rest Time, WDTN, and TIME without checking intensity, skip CH-1 and CH-2 by pressing the SELECT key.
- (5) Choose FREQ., Hold Time, Rest Time, WDTN and TIME in sequence by pressing the SELECT key and setting the respective parameters by pressing the Up (▲) and Down (▼) keys.
- (6) When the parameters have been set, press the SET key twice to complete the first step of programming. In the second step, the window shown in Fig. 13 (without MCR) will appear.

The message box will display "PROG-4-2".

- (7) Repeating procedures (1) to (6) enable the output mode (TENS or EMS) and parameters to be set for each programming step.

Note: In the case of Microcurrent Mode, programming must be done in Microcurrent Mode.

Each program has a maximum of 10 steps. When creating a program with fewer than 10 steps, choose END from the window illustrated in Fig. 13 and press the SET key to terminate programming.

(C) Choosing Reference (REF) to review the contents of an existing program.

REF is chosen to review the contents of the program stored in memory. From the window shown in Fig. 11, choose REF by pressing the SELECT key. Then press the SET key to display the window shown in Fig. 16 (an example of a program containing TENS Constant).

Fig. 16

(1) Press the SET key. Each time the SET key is pressed, the programming steps are shown in sequence in the message box. The mode and parameters corresponding to each step are displayed on the LCD.

(2) To terminate, choose END and press the SET key. The window illustrated in Fig. 17 will appear. Press the SET key one more time. Choose END and press the SET key to return to the initial window, as illustrated in Fig. 2.

4. End of therapy

(1) Remove the electrodes when therapy is completed. Return them to their liner and place into their plastic bag for storage.

(2) Remove the electrode cables from the unit and place them in the carrying case.

(3) Turn off the power on the Trio*Stim, Unplug the AC adapter from the wall outlet and the unit. Hold the plug, not the cable when removing the AC adapter.

(4) Store the electrodes and other accessories after cleaning.

Cautions: Stop use of the unit and consult doctor if any allergic reaction occurs on the skin covered by the electrodes.

Cleaning instructions:

Clean the main unit and accessories using cloth soaked with lukewarm water after every use.

Do not use thinner, gasoline, kerosene, cleaning powder or chemicals for cleaning the Trio*Stim. They may cause discoloration.

Cautions for checking and maintenance:

1. Do not make any modifications or repairs by yourself.

2. Do not damage the Trio*Stim by hitting, dropping or shaking. This rough handling may cause a malfunction at a later time even though no apparent problem immediately occurs.

3. For storage, please observe following cautions.

(1) Do not get the Trio*Stim wet.

(2) Protect the Trio*Stim from excess humidity, temperature or dust. Do not expose to direct sunlight.

(3) Do not store the Trio*Stim with chemicals, pharmaceuticals or gas.

(4) Confirm that the Trio*Stim functions properly and safely before using after a long time of non-use.

Indications for TENS and Microcurrent

The TENS and Microcurrent modes of the Trio*Stim are indicated for the symptomatic relief of chronic intractable pain. They are also indicated for the treatment of post-traumatic and post-surgical pain.

Contraindications for TENS and Microcurrent

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

Warnings for TENS and Microcurrent

1. The safety of TENS and Microcurrent devices for use during pregnancy or birth has not been established.
2. TENS and Microcurrent are not effective for pain of central origin. (This includes headache.)
3. TENS and Microcurrent devices should be used only under the continued supervision of a physician.
4. TENS and Microcurrent devices have no curative value.
5. TENS and Microcurrent are symptomatic treatments and as such, suppress the sensation of pain that 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 and Microcurrent stimulation are 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 and Microcurrent

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 management of patients in pain.

Adverse reaction for TENS and Microcurrent:

Skin irritation and electrode burns are potential adverse reactions.

Cautions for MCR:

Indications, contraindications, warnings, precautions and adverse reactions for MCR are the same with TENS.

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 post surgical 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 inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis and 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 affects for EMS:

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

Specifications:

Output channel: 2 channels, independently controlled

Pulse Shape: Symmetric, biphasic rectangular pulse.

(1) TENS & EMS

(200 Ω - 1k Ω load)

f: pulse frequency

PW: pulse width

Vp: output voltage

I_p : output current
* I_p : $v_p/500k\ \Omega$

(2) Microcurrent
[f_+]=[f_-]= f (pulse frequency)
[PW_+]=[PW_-]= PW (pulse width)
($500\ \Omega - 50k\ \Omega$ load)
 f =pulse frequency
 PW : pulse width
 V_p : output voltage
 I_p : output current
* I_p : $v_p/50k\ \Omega$

Output current: Constant current, peak value display

Max. 80 mA at 500 Ω load ...TENS, EMS

Max. 750 μ A at 50k Ω load ...Microcurrent

At maximum output setting

	<u>Maximum charge per pulse</u>	<u>Maximum average current</u>
TENS	20 μ Coulomb	4 mA
EMS	24 μ Coulomb	2.4 mA
MCS	187 μ Coulomb	0.3 mA

Pulse width:

50-250 μ s... TNS

100-300 μ s... Muscle Stimulation

1-250 ms... Microcurrent

Pulse rate:

1-200 Hz... TNS Pulse rate and width can be set independently on each channel in Constant mode.

25-100 Hz... Muscle Stimulation

0.3-400 Hz... Microcurrent

Output mode:

(1)TNS: Constant, Burst, Modulation, Dual Frequency.

(2) Muscle Stimulation:

Hold time: 0.5-30 sec.

Rest time: 1-60 sec.

Ramp Up/Down time: 0.6 sec.

(3) Microcurrent Constant only

(4) Program: up to 5 programs

Programming capability:

Number of programs...5

Steps per program...10

Timer: 30-minute digital timer, with accuracy of +/-2%

Display: LCD (46 mm x 37 mm)

Other functions:

Memory of the previous setting parameters and mode, keyboard lock, automatic power off, low battery power detection, abnormal pulse output detection and electronics self-test.

Power source: Dual power source with DC 9 V battery or AC (AC adapter optional)

Classification: Class II / internally powered equipment, TYPE BF

Conformity: CE Marking

UL listed: E203404

Size: 113 mm (H) X 2.7 in (W) X 25 mm (D), (4.4 in (H) X 2.7 in (W) X 1.0 in (D))

Weight: 185 gr. (6.5 oz). Including a battery

Environment for transport and storage:

Temperature: -10°C - 60°C (14°F - 140°F)

Humidity: 30% - 80%

Warning:

Do not attempt to repair or modify the Trio*Stim. Unauthorized repair may result in fire or other hazard to the patient. Turn off the unit and return to either Mettler Electronics Corp. or your distributor

Note: All warranty repairs must be performed by Mettler Electronics Corp. or by a service facility authorized by Mettler Electronics to perform warranty repair work.

Specifications and designs are subject to change without prior notice.

Distributor place label here

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