

QuadStar II

Physical Specifications

Power Supply	4 AA Batteries, type LR6
Dimensions	6.30" x 2.75" x 1.25" (160mm x 70mm x 32mm)
Weight	11.4 oz. (323 grams)

Interferential

Output:	4 Square waves centered about device ground (CH1, CH2, CH3, CH4)
Amplitude:	Adjustable from 0-33 volts
Waveform:	Pulsed Sine
CH1/CH3 Frequency:	4000 Hz
CH2/CH4 Frequency:	4001-4150 Hz
Beat Frequency:	1-150 Hz <ul style="list-style-type: none"> •CH1/CH2 are an Interferential Pair •CH1: Fixed Frequency (4000 Hz) •CH2: Adjustable 4001-4150 Hz •CH3/CH4 are an Interferential Pair •CH3: Fixed Frequency (4000 Hz) •CH4: Adjustable 4001-4150 Hz
Modes:	
Constant:	Beat Frequency is adjustable from 1-150 Hz
Sweep 1:	Beat Frequency Modulates from 1-10 Hz and back over 12 seconds (6 second increase, 6 second decrease)
Sweep 2:	Beat Frequency Modulates from 80-150 Hz and back over 16 seconds (8 second increase, 8 second decrease)
Sweep 3:	Beat Frequency Modulates from 1-150 Hz and back over 20 seconds (10 second increase, 10 second decrease)
Premodulated INF (Using one Channel):	A mixed Interferential Beat Frequency will be produced only out of CH 1 and/or CH 3.
Tolerance:	+/- 10%

(Data recorded over a 500 OHM resistance load)

NMS – NeuroMuscular Stimulation

Channels:	4
Waveform:	Symmetrical, biphasic, square Asymmetrical, biphasic, square
Intensity:	Continuously adjustable from 0-120 mA peak
Frequency:	Adjustable 1-120 Hz. A Pulse Rate of less than 60 Hz should be used if repeated muscle contractions are desired. A Pulse Rate of at least 10 Hz should be used if forceful, tetanic muscle contractions are desired.
Impulse Width:	Adjustable 50-400 uS

Ramp On	0-10 seconds
On Time:	0-99 seconds
Ramp Off	0-10 seconds
Off Time	0-99 seconds
Output Voltage	0- 60 V
Intensity	0 - 120 mA
1. Constant:	Use the Constant Mode or a Pulse Rate greater than 60 Hz. for the relaxation of muscle spasms only. Use of continuous stimulation and/or rates above the normal physiological range (e.g., greater than 60 Hz) could lead to rapid onset of muscle fatigue, making the device less effective in producing repeated forceful muscle contractions.
2.Cycled	
3.Reciprocating	

Nine additional preset programs are also offered in the NMS mode of the QuadStar ® II:

Therapy 1	35 Hz, 400µs, Symmetrical Biphasic, CYCLED
Therapy 2	35 Hz, 400µs, Asymmetrical Biphasic, CYCLED
Therapy 3	40 Hz, 400µs, Symmetrical Biphasic, RECIPROCAL
Therapy 4	40 Hz, 400µs, Symmetrical Biphasic, CYCLED
Therapy 5	25 Hz, 400µs, Symmetrical Biphasic, CYCLED
Therapy 6	30 Hz, 400µs, Symmetrical Biphasic, CYCLED
Therapy 7	50 Hz, 180µs, Symmetrical Biphasic, CYCLED
Therapy 8	20 Hz, 250µs, Symmetrical Biphasic, CYCLED
Therapy 9	10 Hz, 50µs, Symmetrical Biphasic, CONSTANT

(Data was recorded across a 500 OHM resistance load)

TENS

Waveform:	Asymmetrical Biphasic Square
Pulse Rate (Hz):	Adjustable 1-120 Hz
Pulse Width (µS):	Adjustable 10-250 µS
Modes:	
Constant	Starting Parameters – 120 Hz, 50 µS. Pulse Rate (Hz) is adjustable from 1-120 Hz and Pulse Width (µS) is adjustable from 10-250 µS
B (Burst):	Starting Parameters 16 Hz, 50 µS. Pulse Width (µS) is adjustable from 10-250 µS
M (Modulation):	120 Hz, 50 µS. Pulse Rate (Hz) is Adjustable from 1-120 Hz and Pulse Width (µS) is adjustable from 10-250 µS and decreases 50% and back to set value over a 10 second cycle.

Graphic Symbol Definitions



CE 0086 We herewith declare that the above mentioned product meets the provisions of the Medical Device Directive

The QuadStar® II is a unique Electrotherapy system incorporating the following:
 • Three modalities- T.E.N.S. (Transcutaneous Electrical Nerve Stimulation), N.M.S. (NeuroMuscular Stimulation), and I.N.F. (Interferential Stimulation)
 • Three waveforms- Symmetrical Biphasic Square Wave, Asymmetrical Biphasic Square Wave, and a Pulsed Sine

Wave.

- Four channels allowing the use of up to eight electrodes at a time
- Pre-programmed and programmable functions
- "Sequential Stimulation" enabling the user to sequence two or more modalities for complete treatment
- Patient Lock/Compliance System: enables the practitioner/physician to lock the parameters for ease of use for the patient, and monitor hours of use.
- Timer - to time treatments
- Comes ready to use, with all accessories, and is powered by 4 AA batteries or Wall Adapter.

This booklet gives the health practitioner/physician an overview of the QuadStar®II device functions. This information is offered in condensed format; should you have further questions, please consult your health practitioner or physical therapist.

The amplitude, pulse rate, pulse width and the mode selectors operate independently of each other, but interact to achieve the desired result. As individual syndromes differ, the controls are adjusted to a setting which gives optimal comfort and pain relief.

Amplitude: The amplitude controls the intensity and the depth of the pulse. The higher the amplitude, the higher the pulse peak and the stronger the pulse. If the electrodes are placed over scar or over adipose tissue, care should be taken that the amplitude is set at a level that is both effective for the patient's treatment and does not cause the patient any discomfort. Set the QuadStar® II amplitude to the appropriate level according to patient comfort. There is no benefit to painful stimulation.

Pulse Width: The pulse width governs the width of the pulse. A comfortable sensation covering the injured area is the main purpose of the pulse width. The pulse width has been fixed (preset) in the QuadStar® II Interferential Modality.

Pulse Rate: The pulse rate controls the number of pulses emitted through the electrode to the skin. The pulse rate is also referred to as:

1. Frequency
2. Cycles per second (c.p.s.)
3. Pulses per second (p.p.s.)

A Hertz (Hz) is a unit of frequency equal to one pulse per second, e.g. 50 Hertz = 50 p.p.s

INTERFERENTIAL OPERATING INSTRUCTIONS:

Turn on the device by pressing the power key (12). If it is the first time you have turned the device on, the "Menu" Screen appears and INF is blinking. If the "Menu" screen does not appear, press the "Left Arrow Key" (6) to access it. To choose the INF (Interferential) Modality press the Enter Key (7) to select it.

To select another modality press the down key (9) to scroll until the desired modality blinks and press the Enter Key (7) to select it. (Refer to section on desired modality for further instruction).

When INF is selected a sub menu appears displaying "CONST" and "SW"

CONST = Constant Stimulation
 SW= a pre programmed Sweep mode. There are three pre programmed sweeps in the INF mode. Press the down key (9) to scroll through them. Press the Enter Key (7) when the desired mode blinks.

INTERFERENTIAL OPTIONS:

Frequency or "Hz": 1-150. This is the desired "beat frequency"

Two or Four Channels:

If two channels are chosen, each channel works independently and the beat frequency is mixed inside the unit. This is also known as "pre modulated" stimulation. The user can choose to utilize only one channel by choosing pre modulated stimulation and turning up the amplitude on the channel(s) (1 or 3).

If four channels are chosen, channels 1 & 2 and channels 3 & 4 work together as a pair, and the beat frequency is created when the two waveforms mix inside of the body. The user can choose to use only one interferential pair by turning up the amplitude only on channels 1 & 2 only or 3 & 4 only.

Timer: If timed treatment is desired, press the Timer Key (11) and use the Up and Down Arrows (5 & 7) to set the desired time from 1-99 minutes. The unit will automatically shut off when the timer hits "0 min"

CONST: If Constant stimulation is chosen, the value for "Hz" is blinking. Use the Up and Down Keys (5) and (9) to set the desired amount and then press the Enter Key (7).

Next, the device prompts the user to choose 2 or 4 channels. Use the Up and Down Keys (5 & 7) to change the graphic to represent the desired amount of electrodes to be used. Press the timer key (11) and "0" min blinks. Press the Up/Down arrows (5) and (9) to set the desired amount of minutes 1-99.

Use the amplitude keys (1-4) to turn up the amplitude and begin stimulation, turn up the amplitude one at a time. The unit will not turn up if you press two or more keys at the same time.

SW1: If Sweep 1 is chosen, the value for "Hz" is blinking 1-10 to demonstrate the beat frequency will sweep between 1-10. Sweep 1 is used for edema reduction. This is a preset sweep and cannot be changed.

Next, the device prompts the user to choose 2 or 4 channels. Use the Up and Down Keys (5 & 7) to change the graphic to represent the desired amount of electrodes to be used. Press the timer key (11) and "0" min blinks. Press the Up/Down arrows (5) and (9) to set the desired amount of minutes 1-99.

Use the amplitude keys (1-4) to turn up the amplitude and begin stimulation, turn up the amplitude one at a time. The unit will not turn up if you press two or more keys at the same time.

SW2: If Sweep 2 is chosen, the value for "Hz" is blinking 80-150 to demonstrate the beat frequency will sweep between 80-150. Sweep 2 is used for pain relief. This is a preset sweep and cannot be changed.

Next, the device prompts the user to choose 2 or 4 channels. Use the Up and Down Keys (5 & 7) to change the graphic to represent the desired amount of electrodes to be used.

Press the timer key (11) and "0" min blinks. Press the Up/Down arrows (5) and (9) to set the desired amount of minutes 1-99.

Use the amplitude keys (1-4) to turn up the amplitude and begin stimulation, turn up the amplitude one at a time. The unit will not turn up if you press two or more keys at the same time.

SW3: If Sweep 3 is chosen, the value for "Hz" is blinking 1-150 to demonstrate the beat frequency will sweep between 1-150. Sweep 3 is used for edema reduction and pain relief. This is a preset sweep and cannot be changed.

Next, the device prompts the user to choose 2 or 4 channels. Use the Up and Down Keys (5 & 7) to change the graphic to represent the desired amount of electrodes to be used.

Press the timer key (11) and "0" min blinks. Press the Up/Down arrows (5) and (9) to set the desired amount of minutes 1-99.

Use the amplitude keys (1-4) to turn up the amplitude and begin stimulation, turn up the amplitude one at a time. The unit will not turn up if you press two or more keys at the same time.

INTRODUCTION TO MUSCLE STIMULATION (NMS)

Electrical Muscle Stimulation (EMS) or Neuromuscular Stimulation (NMS) is the use of electrical stimulation on muscle groups to contract and reeducate muscles. Some of the uses of EMS are as follows:

1. The Prevention or Retardation of Muscle Disuse Atrophy: Muscle disuse atrophy is a reduction in muscle contraction and size due to disuse/lack of use resulting from prolonged impairment or joint immobility from surgery, injury.

2. Relaxation of Muscle Spasms:

Muscle spasms often occur in areas of localized pain and tenderness. Stimulation is used to fatigue the spasmodic muscle.

3. Increasing Local Blood Circulation

Rhythmic muscle contraction helps improve local blood circulation.

4. Immediate Postsurgical Stimulation of Calf Muscles to Prevent Venous Thrombosis.

The use of NMS or EMS to increase local blood circulation assists in the prevention of venous thrombosis.

Button Definitions

(1-4): (Intensity Keys) Use these keys to set the desired Intensity

(5) or (9): (up and down arrow keys) Increase or decrease the values of blinking numeric selections, or scroll through vertical menu selections.

(6): (The left arrow key) Retrace key; goes back to last selection made when in CONST; CYCLED or RECIPROCATING modes.

(7): (Enter key) Accepts a blinking selection.

(8): (The right arrow key) Accesses MODE MENU when nothing on screen is flashing.

(10): (PR/PW/Waveform Key) Change adjustable parameters for Pulse Rate, Pulse Width and Waveform.

(11): (Timer Key) Sets the Timer

(12): (On/Off key) Turns the device on and off.

The menu consists of modes and preset therapies. CONST (Constant Stimulation) CYCLED (Cycled Stimulation) RECIP (Reciprocating Stimulation) and nine preset therapies: THERAPY 1, THERAPY 2, THERAPY 3, THERAPY 4, THERAPY 5, THERAPY 6, THERAPY 7, THERAPY 8 and THERAPY 9

BASIC OPERATING PROCEDURES:

- Attach lead wires to Channel 1/2 (CH1/2) and if needed to Channel 3/4 (CH3/4). (A,B,C,D)

- Attach electrodes to lead wires following instructions on electrode packaging.

- Attach electrodes to body.

- The device defaults to last setting programmed

- If the last setting used is the desired setting, set the timer, if applicable (See Setting the Patient Timer section)

- Press the "+/- oval keys" (1,2,3 & 4) under the corresponding channels to begin stimulation.

Defining and Changing Parameters

- To change the parameters of the current setting; press the "PR/PW Key" (10) and the number next to "Hz" will begin to blink. Hz is the abbreviation for "Hertz" also known as "Pulse Rate" or "PR"

- To change PR (Hz) press the "up and or down arrow keys" (5 & 9) until the desired number is displayed. To accept the value press the "enter key" (7)

- The device automatically progresses to the next parameter; and it flashes. Again, to change the value press the "up and down arrow keys" until desired value is reached and press the "enter key" (7) to accept. The process repeats to the next flashing selection.

- The "µs" symbol stands for "microseconds" which is also

referred to as "Pulse width" or "Pulse Duration"

- The symbol appearing at in the top center of the screen is a waveform symbol. You may change the waveform from symmetrical biphasic to asymmetrical biphasic and vice versa when flashing by pressing the "up or down arrow keys" (5 or 9), the symbol will change accordingly.

- When all flashing ceases; the parameters have been set. Set the timer if desired; and stimulation may begin using the "+/- oval keys (1,2,3 & 4).

Instructions; Changing Modes

- Before a mode can be changed, no values can be flashing. If values are flashing in the current state press the "enter key" (7) repeatedly to accept all values or use the "on/off key" (10) to turn the device off, and then on, and flashing will cease.

- Press the "right arrow key" (8) and the "Mode Menu" will appear.

- The current mode flashes; use the "up and down arrow keys" (5&9) to scroll through the menu.

- When the "down arrow key" (9) is pressed when "Therapy" is blinking; the device scrolls through preset therapy choices 1-9.

- Constant; Cycled; and Reciprocal are PROGRAMMABLE modes. Therapies 1-9 are PRESET modes, and therefore cannot be altered

Instructions; CONSTANT Stimulation

- Attach lead wires to Channel 1/2 (CH1/2) and if needed to Channel 3/4 (CH3/4). (A,B,C,D)

- Attach electrodes to lead wires following instructions on electrode packaging.

- Attach electrodes to body.

- Turn the device on using the "on/off key" (12)

- Press the "right arrow key" (8) to access the "Mode Menu" and the "up and down arrow keys (5&9) to select CONSTANT, press the "enter key" (7) to accept it.

- See "Defining and Changing Parameters" to change the preset values for Hz, µs and waveform or press the "enter key" (7) to accept the last values used.

- See "Setting the Patient Timer" to time the therapy.

- To increase the intensity, and begin stimulation press the "+/- oval keys" (1,2,3,4) under the corresponding channels in an upward direction.

Setting the Patient Timer

- To set the Patient Timer, press (11) and the +(5) or - (9) to increase or decrease the minutes. Once you have selected the value press the "enter key" (7)

- Increase the Intensity Buttons "+/- oval keys" (1,2,3,4) to begin therapy.

- The device will automatically shut off when the timer runs to "0".

Instructions; CYCLED Stimulation

- Attach lead wires to Channel 1/2 (CH1/2) and if needed to Channel 3/4 (CH3/4). (A,B,C,D)

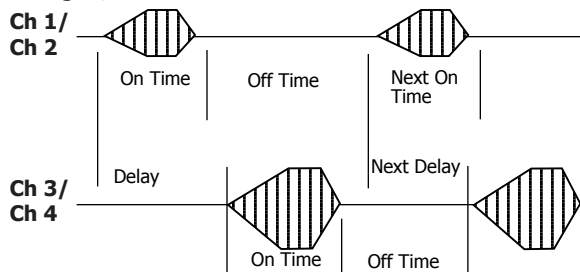
- Attach electrodes to lead wires following instructions on electrode packaging

- Turn on the device press (12)

- Press the "right arrow key" (8) to access the "Mode Menu" and the "up and down arrow keys (5&9) to select CYCLED, press the "enter key" (7) to accept it.

- See "Defining and Changing Parameters" to change the preset values for Hz, µs and waveform or press the "enter key" (7) to accept the last values used.

- CYCLED Stimulation offers more features than the CONSTANT mode. Not only can Hz, µs and waveform be changed, but there are additional TIMING Features.



- The device shows a graphic representation on the screen of how the intensity of the device will react in the determined cycle. The first alterable parameter is called RAMP ON, it is the upward slope of the diagram. It indicates how many seconds it will take for the device to gradually reach maximum intensity in the cycle. This value represents the RAMP ON TIME for all channels 1,2,3 & 4.

- This value can be increased or decreased using the + (5) and - (9) buttons. Once the selected time has been chosen, press "the enter key" (7) to save. Now, RAMP OFF appears on the screen. This value represents the RAMP OFF TIME for Channels 1,2,3 and 4 and indicates how many seconds it will take for the device to gradually lower in intensity until no stimulation occurs in this part of the cycle.

- This value can be increased or decreased using the + (5) and - (9) buttons. Once the selected time has been chosen, press "the enter key" (7) to save.

- Ch 1/2 ON TIME now flashes. The ON TIME is the TOTAL amount of time Channels 1 and 2 will be on. This includes the ramp times, as the diagram suggests.

- To calculate the actual duration of the peak contraction you must subtract the RAMP ON and RAMP OFF times from the ON TIME.

- This value can be increased or decreased using the "up

and down arrow keys" (5&9). Once the selected time has been chosen, press "the enter key" (7) to save.

- CH 1/2 OFF is now displayed. This is the total amount of time CH 1/2 will be off during the cycle. Accept this value by pressing "the enter key" (7) or use the + (4) and -(9) buttons to change the value. Press the "enter key" (7) to save.

- Repeat this process for CH 3/4 ON TIME and OFF TIME.

- CH 3/4 DELAY is now displayed.

The total of Ch1/2 ON TIME and Ch1/2 OFF TIME must be the same values as Ch3/4 ON TIME and CH 3/4 OFF TIME plus DELAY, otherwise an "Err!" symbol will appear.

Channel 3/4 can be delayed 1-99 seconds from the time Channel 1/2 stops stimulation. Accept this value by pressing the "enter key" (7) or use the "up and down arrow keys" (5 & 9) buttons to change the value. Press the "enter key" (7) to save.

- The CYCLED now has been timed and stops flashing. You are now prompted to change or accept the PR, PW and Waveform. Use the up (5) or down (9) arrows to make a change to the setting and E (7) to accept the setting.

- Increase the Intensity Buttons (1,2,3,4) to begin therapy.

Instructions; RECIPROCAL Stimulation

- Attach lead wires to Channel 1/2 (CH 1/2) and if needed to Channel 3/4 (CH 3/4). (A,B,C,D)

- Attach electrodes to lead wires following instructions on electrode packaging.

- Place electrodes to the body

- Turn on the device using "on/off key" (10)

- Press "the right arrow key" (8) and use the "up and down arrow keys" (5/9) until RECIPROCAL begins to blink. Press the "enter key" (7) to accept it. To step through each value and to accept each pre-programmed value press

35 Hz, 300 uS, Symmetrical Biphasic Square Waveform

- The screen shows a graphic representation on the screen of how the intensity of the device will react in the determined cycle. The first alterable parameter is called RAMP ON, it is the upward slope of the diagram. It indicates how many seconds it will take for the device to gradually reach maximum intensity in the cycle. This value represents the RAMP ON TIME for all channels 1,2,3 & 4.

- This value can be increased or decreased using the + (5) and - (9) buttons. Once the selected time has been chosen, press "the enter key" (7) to save. Now, RAMP OFF appears on the screen. This value represents the RAMP OFF TIME for Channels 1,2,3&4 and indicates how many seconds it will take for the device to gradually lower the intensity to "0" for this part of the cycle.

- Ch 1/2 ON TIME now flashes. The ON TIME is the TOTAL amount of time Channels 1/2 will be on. This includes the ramp times, as the diagram suggests.

- To calculate the actual duration of the contraction you must subtract the RAMP ON and RAMP OFF times from the ON TIME.

- This value can be increased or decreased using the "up and down arrow keys" (5&9). Once the selected time has been chosen, press "the enter key" (7) to save.

- CH 1/2 OFF is now displayed. This is the total amount of time CH 1/2 will be off during the cycle. Accept this value by pressing "the enter key" (7) or use the + (4) and -(9) buttons to change the value. Press the "enter key" (7) to save.

- Repeat this process for CH 3/4 ON TIME and OFF TIME.

- The parameters have now been timed and stop flashing.

You are now prompted to change or accept the PR, PW and Waveform. Use the up (5) or down (9) arrows to make a change to the setting and E (7) to accept the setting.

- Increase the Intensity Buttons (1,2,3,4) to begin therapy.

INSTRUCTION OF USE; PREPROGRAMMED THERAPY

There are nine pre-programmed therapies to choose from in the QuadStar II these therapies are "fixed" and cannot be altered.

- Turn on the device press (10)

- Press the "right arrow key" (8) to access the "Mode Menu" Press the "down arrow key" when THERAPY is blinking to scroll through the nine preset therapies. Press the "enter key" (7) To accept any of the pre-programmed therapies; increase the Intensity Buttons (1,2,3,4) to begin stimulation. Below are the parameters for each Therapy.

Therapy 1 (Cycled)

35 Hz, 400 µS, Symmetrical Biphasic Waveform

RAMP ON 2.0 sec.

RAMP OFF 2.0 sec.

CH 1/2/3/4 ON 10 sec.

CH 1/2/3/4 OFF 30 sec.

Therapy 2 (Cycled)

35 Hz, 400 µS, Asymmetrical Biphasic Square Waveform

RAMP ON 2.0 sec.

RAMP OFF 2.0 sec.

CH 1/2/3/4 ON 10 sec.

CH 1/2/3/4 OFF 30 sec.

Therapy 3 (Reciprocal)

40 Hz, 400 µS, Symmetrical Biphasic Square Waveform

CH 1/2 and CH 3/4 alternate CH 1/2 will cycle together.

CH 3/4 will cycle together.

RAMP ON 4.0 sec.

RAMP OFF 4.0 sec.

CH 1/2 ON 10 sec.

CH 1/2 OFF 10 sec.

CH 3/4 ON 10 sec.

CH 3/4 OFF 10 sec.

Therapy 4 (Cycled)
 40 Hz, 400 µS, Symmetrical Biphasic Square Waveform
 RAMP ON 4.0 sec.
 RAMP OFF 4.0 sec.
 CH 1/2/3/4 ON 10 sec.
 CH 1/2/3/4 OFF 10 sec.

Therapy 5 (Cycled)
 25 Hz, 400 µS, Symmetrical Biphasic Square Waveform
 RAMP ON 4.0 sec.
 RAMP OFF 4.0 sec.
 CH 1/2/3/4 ON 25 sec.
 CH 1/2/3/4 OFF 10 sec.

Therapy 6 (Cycled)
 30 Hz, 400 µS, Symmetrical Biphasic Square Waveform
 RAMP ON 2.0 sec.
 RAMP OFF 2.0 sec.
 CH 1/2/3/4 ON 15 sec.
 CH 1/2/3/4 OFF 20 sec.

Therapy 7 (Cycled)
 50 Hz, 180 µS, Symmetrical Biphasic Square Waveform
 RAMP ON 2.0 sec.
 RAMP OFF 2.0 sec.
 CH 1/2/3/4 ON 10 sec.
 CH 1/2/3/4 OFF 20 sec.

Therapy 8 (Cycled)
 20 Hz, 250 µS, Symmetrical Biphasic Square Waveform
 RAMP ON 2.0 sec.
 RAMP OFF 2.0 sec.
 CH 1/2/3/4 ON 5.0 sec.
 CH 1/2/3/4 OFF 10 sec.

Therapy 9 (CONSTANT)
 10 Hz, 50 µS, Symmetrical Biphasic Square Waveform
 (No timing in CONSTANT)

INTRODUCTION TO TENS:

Turn on the device by pressing the power key (12). If it is the first time you have turned the device on, the "Menu" Screen appears and INF is blinking. Use the Up/Down arrows (5) & (9) until TENS is blinking press (7) to select it.

To select another modality press the down key (9) to scroll until the desired modality blinks and press the Enter Key (7) to select it. (Refer to section on desired modality for further instruction).

TENS has three modes
 CONST: Constant Stimulation
 B: Burst

M: Pulse Width Modulation
 Scroll through the modes by pressing the UP/Down arrows (5) & (9). When the desired mode blinks press the Enter Key (7) to select.

If CONST is chosen, Hz is blinking. Use the Up/Down arrows 5 & 9 to select the desired value. Press the Enter Key (7) to accept the value. Next PW (Pulse Width) is blinking. Use the Up/Down arrows (5) & (9) to set the desired value. Press the Enter Key (7) to accept the value.

Press the timer key (11) and "0" min. blinks. Press the Up/Down arrows (5) and (9) to set the desired amount of minutes 1-99.

Use the amplitude keys (1-4) to turn up the amplitude and begin stimulation, turn up the amplitude one at a time. (The unit will not turn up if two or more keys are pressed at the same time.)

If Burst is selected, µS is blinking. Use the "Up/Down arrows" (5 & 9) to select the desired value. Press the Enter Key (7) to accept the value. Press the Enter Key (7) to accept the value. (The Hz value is fixed in this mode at 16Hz) Press the timer key (11) and "0" min. blinks. Press the Up/Down arrows (5) and (9) to set the desired amount of minutes 1-99.

Use the amplitude keys (1-4) to turn up the amplitude and begin stimulation, turn up the amplitude one at a time. (The unit will not turn up if two or more keys are pressed at the same time.)

If Modulation is chosen, Hz is blinking. Use the Up/Down arrows 5 & 9 to select the desired value. Press the Enter Key (7) to accept the value. Next PW (Pulse Width) is blinking. Use the Up/Down arrows (5) & (9) to set the desired value. Press the Enter Key (7) to accept the value. Press the timer key (11) and "0" min. blinks. Press the Up/Down arrows (5) and (9) to set the desired amount of minutes 1-99.

Use the amplitude keys (1-4) to turn up the amplitude and begin stimulation, turn up the amplitude one at a time. (The unit will not turn up if two or more keys are pressed at the same time.)

SEQUENTIAL STIMULATION

FIXED SEQUENTIAL PROGRAMS

The QuadStar® II has 9 fixed sequential stimulation patterns. The fixed patterns cannot be altered, each is a preset sequential stimulation pattern (See the following section on programming sequential stimulation.)

To choose a fixed sequential treatment press the "Left Arrow Key" (6) and use the "Up and Down Arrows"(5) and (9) to toggle to "Seq" when "Seq" blinks press the "Enter Key" (7) to choose sequential stimulation. "Fixed Seq. 1" blinks, if you wish to choose this sequence, press the "Enter Key" (7). If another fixed sequence is desired, press the "Down Key" (9) to scroll through the nine fixed sequence, pressing the "Enter Key" (7) when the desired sequence blinks. When the desired sequence is chosen, the

screen will display the first part of the sequence to show the practitioner the settings for the sequence. When the electrodes are placed, the device is ready to begin stimulation. Use the "Intensity Selector Keys" (1-4) to begin stimulation and set the device to the desired intensity.

Once the first modality in the fixed sequence is finished, the device will stop stimulation and the word "Start" will blink at the top of the screen. Once the "Enter Key" (7) is pressed, the device will begin the second part of the sequence. Again use the "Intensity Selector Keys" (1-4) to begin stimulation and set desired intensity for the current modality. Repeat steps for the third modality.

*Each part of the sequence runs for 20 minutes.

PROGRAM 1
 INF: Sweep 1, 1-10 Hz

NMS – Symmetric Cycled
 PR = 45 Hz, PW = 400 uS
 Ramp ON/OFF = 1 sec.
 CH1/2/3/4/ On time = 10 sec.
 CH1/2/3/4/ OF time = 30 sec.

TENS –Burst
 PR – Fixed (8 pulses per burst; 2 bursts per sec)
 PW = 50 uS

PROGRAM 2
 INF - Sweep 2 , 80-150 HZ

NMS – Symmetric Cycled
 PR = 45 Hz, PW = 400 uS
 Ramp ON/OFF = 1 sec.
 CH1/2/3/4/ On time = 10 sec.
 CH1/2/3/4/ OF time = 30 sec.

TENS - Burst
 PR – Fixed (8 pulses per burst; 2 bursts per sec)
 PW = 50 uS

PROGRAM 3
 INF: Sweep 3, 1-150 HZ

NMS – Symmetric Cycled
 PR = 45 Hz, PW = 400 uS
 Ramp ON/OFF = 1 sec.
 CH1/2/3/4/ On time = 10 sec.
 CH1/2/3/4/ OF time = 30 sec.

TENS –Burst
 PR – Fixed (8 pulses per burst; 2 bursts per sec)
 PW = 50 uS

PROGRAM 4
 INF: Sweep 1, 1-10 Hz

NMS – Symmetric Cycled
 PR = 45 Hz, PW = 400 uS
 Ramp ON/OFF = 1 sec.
 CH1/2/3/4/ On time = 10 sec.
 CH1/2/3/4/ OF time = 30 sec.

TENS- Const, PW = 50 uS, PR = 120 Hz.

PROGRAM 5
 INF - Sweep 2, 80-150 Hz

NMS – Symmetric Cycled
 PR = 45 Hz, PW = 400 uS
 Ramp ON/OFF = 1 sec.
 CH1/2/3/4/ On time = 10 sec.
 CH1/2/3/4/ OF time = 30 sec.

TENS- Const
 PW = 50 uS, PR = 120 Hz.

PROGRAM 6
 INF - Sweep 3, 1-150 Hz

NMS – Symmetric Cycled
 PR = 45 Hz, PW = 400 uS
 Ramp ON/OFF = 1 sec.
 CH1/2/3/4/ On time = 10 sec.
 CH1/2/3/4/ OF time = 30 sec.

TENS- Const, PW = 50 uS, PR = 120 Hz.

PROGRAM 7
 INF - Sweep 1, 1-10 Hz

NMS – Symmetric Cycled
 PR = 45 Hz, PW = 400 uS
 Ramp ON/OFF = 1 sec.
 CH1/2/3/4/ On time = 10 sec.
 CH1/2/3/4/ OF time = 30 sec.

TENS- PW modulation, PW = 50 uS, PR = 120 Hz.

PROGRAM 8
 INF - Sweep 2, 80-150 Hz

NMS – Symmetric Cycled
 PR = 45 Hz, PW = 400 uS
 Ramp ON/OFF = 1 sec.

CH1/2/3/4/ On time = 10 sec.
 CH1/2/3/4/ OF time = 30 sec.

TENS- PW modulation, PW = 50 uS, PR = 120 Hz.

PROGRAM 9
 INF - Sweep 3, 1-150 Hz

NMS – Symmetric Cycled
 PR = 45 Hz, PW = 400 uS
 Ramp ON/OFF = 1 sec.
 CH1/2/3/4/ On time = 10 sec.
 CH1/2/3/4/ OF time = 30 sec.

TENS- PW modulation, PW = 50 uS, PR = 120 Hz.

PROGRAMMABLE SEQUENCING:

There is also a programmable mode in the QuadStar®II. To utilize the Programmable sequential option, press the "Left Arrow Key" (6) and use the "Up and Down Arrows"(5) and (9) to toggle to "Seq" when "Seq" blinks press the "Enter Key" (7) to choose sequential stimulation. Press the "Down Key" (9) to scroll through the nine fixed sequences until "Programmable is blinking. Press the "Enter Key"(7) to accept. "Programmable 1" blinks when the screen appears. Press the "Enter Key" (7) to accept, as nothing on the first screen is adjustable. "Programmable 2" is now blinking and the Pulse Rate value is also blinking. Change the value by pressing the "Up or Down Arrows" (5 and 9). When the desired value is blinking, press the "Enter Key" (7) to accept. The PW value is now blinking. Change the value by pressing the "Up or Down Arrows" (5 and 9). When the desired value is blinking, press the "Enter Key" (7) to accept. The waveform is now blinking. Toggle between Symmetrical Biphasic and Asymmetrical Biphasic waveforms by pressing the "Up and Down Arrows" (5 and 9), followed by the "Enter Key" (7) to accept. "Programmable 3" is now blinking. Since nothing on this screen is adjustable press the "Enter Key" (7) to accept. The screen toggles back to Programmable 1, prompting the use to set the desired intensity using the "Intensity Keys" (1-4) to begin stimulation when ready.

Program 1:
 INF SW 3; 1-150 HZ,; (FIXED)
 20 minute duration

Program 2:
 NMS Cycled; 20 minute duration
 PW adjustable 50-400 uS
 PR adjustable 1-120 Hz
 Wave shape adjustable; Symmetric / Asymmetric
 Timing Parameters; (Fixed)
 Ramp On: 2 Seconds
 Ramp Off: 2 Seconds
 On Time: 10 seconds
 Off Time: 30 seconds

Program 3:
 TENS: CONST, 50 uS PW, 120 HZ (FIXED);
 20 minute duration

Instruction for use; Patient Compliance Meter/The Patient Lock:

Locks the unit in a mode. The only parameters that can be changed while the unit is locked is the intensity and Timer options.

To turn on the patient lock make sure nothing on the screen is blinking and hold down the "enter key" (7) and the "up arrow" (5) simultaneously for 2 seconds. A small key will appear at the bottom of the screen. The unit is now locked.

To turn off the Patient Lock, hold down the "enter key" (7) and the "down arrow" (9) simultaneously for 2 seconds. The small key will disappear. The unit is now unlocked.

As the unit is unlocked, the amount of time the Patient has used the device while locked is displayed. The number of hours the device has been used will be displayed on the bottom of the screen. The device will store use up to 99 hours, then resets to zero. To delete the stored time, press and hold both (5) "up arrow" and (9) "down arrow" simultaneously.

BATTERIES:

In order to maintain the functional operation of the QuadStar®II the batteries will have to be changed periodically. The device is supplied with 4 AA Alkaline batteries.

When batteries are running low, a battery image will appear and flash on the bottom right hand corner of the display screen (C). When this image appears, the batteries should be changed to ensure maximum performance.

Warning: We do not recommend the use of rechargeable batteries, as they may weaken the performance and/or readout of the device.

To change batteries:

- Before opening the battery compartment, check to make sure that the device is switched off.
- Slide open the battery compartment cover.
- Remove the batteries from the compartment. Gently insert the new batteries by matching the +/– end of each battery with the +/– symbol found inside the battery compartment.
- Slide the battery cover to the closed position.
- Remove the batteries if you do not plan to use the device for long periods of time. Otherwise leakage and

damage to the device can occur.

- Dispose of batteries in a proper manner.

Safety and Technical Checks

Once a year, a maintenance check should be performed on the device as follows:

- Visually check the exterior case of the device for damage.
- Visually check the input and output sockets for damage.
- Visually check the device for clarity of reading instructions and indicator decals.
- Visually check that the symbols of the LCD are operating correctly.
- Visually check the lead wires and electrodes for damage

MALFUNCTIONS:

Should any malfunctions occur while using this device, check:

- Whether the lead wires and electrodes are correctly connected to the device. The lead wires should be inserted firmly into the device sockets.
- For possible damage to the lead wires. Change the lead wires if any damage is detected.

During use the surface of the QuadStar II may get warm. This is normal, due to the high level of therapeutic power being produced. This unit fully complies with the requirement that under normal use the temperature never exceed that allowed by law. If an unusual situation occurs (for example, electrodes touching each other or insufficient air clearance around the unit) the unit will automatically shut down in order to prevent excessive heating. If this should occur, find and correct the reason for the shutdown, allow the unit to cool for a few minutes, and then turn it on in the normal manner. If the unit does not turn on, the unit is not cool enough, and more cooling time will be necessary.

Do not attempt to repair a device yourself!

Opening the device case voids the warranty. Please contact the dealer from whom the device was purchased. If they are unable to assist you, please contact:

In the USA and Canada, BioMedical Life Systems, Inc., (760) 727-5600.

In Europe, BMLS BV, Alkmaar, The Netherlands.

This device MUST only be serviced by the manufacturer.

To reorder any accessories or supplies, contact your dealer.

MAINTENANCE AND CARE:

- The case housing is made of insulated ABS plastic and can be cleaned with isopropyl alcohol.
- Stubborn stains and spots can be removed with a cleaning agent. Do not submerge this device in any liquid or use excessive cleaning liquid when cleaning the surface area

NOTE: Do not smoke or work with an open flame (for example, candles, etc.) When working with flammable liquids!

- Store device and accessories in a cool dry place
- See electrode packaging for instructions on maintenance and care.

CAUTION:

Federal law (USA) restricts this device to sale by or on the order of a physician so licensed by the State which he or she practices. Keep out of reach of children.

Indications

Transcutaneous Electrical Nerve Stimulation (TENS)/Interferential devices are used for the symptomatic relief and management of chronic (long-term) intractable pain and as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain problems.

External electrical neuromuscular stimulation using bi-phasic output is indicated as therapeutic adjunct for prevention or retardation of muscle disuse atrophy; relaxation of muscle spasm; muscle reeducation; maintaining and increasing the range of motion; increasing local blood circulation and as an immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

Contraindications

TENS & EMS/NMS devices can adversely affect the operation of demand-type cardiac pacemakers. TENS & EMS/NMS is not recommended for patients with known heart disease without a physician's evaluation of risk. Do not stimulate over the eyes or carotid sinus nerves as severe spasm of the laryngeal and/or pharyngeal muscles may occur when electrodes are placed over the neck or mouth. (These contractions may be strong enough to close the airway or cause difficulty in breathing.) Do not apply TENS & EMS/NMS for un-diagnosed pain syndromes until etiology is established. Do not place electrodes in a manner that causes current to flow trans cerebrally (through the head). TENS & EMS/NMS devices should not be applied to malignant tumors.

Warnings

This device should be used only under the continued supervision of a physician, or outside the USA, by a qualified pain management specialist. TENS/Interferential stimulation is ineffective for pain of central origin (i.e. appendicitis, hepatitis). TENS/Interferential stimulation is of no curative value; it is a symptomatic treatment which suppresses pain sensation which would otherwise serve as a protective mechanism on the outcome of the clinical process. Safety of TENS/Interferential devices for use during pregnancy or delivery has not been established. For external use only. Electronic equipment such as EKG monitors and EKG alarms may not operate properly when TENS/Interferential Stimulation is in use.

This device should not be used over metal implants or sleep apnea monitors.

Adequate precaution should be taken when treating patients with suspected heart problems or epilepsy. Caution should be exercised in the trans thoracic application of EMS devices so that the introduction of electrical current into the heart does not cause arrhythmia. The long-term effects of chronic electrical stimulation are unknown.

Persistent use of stimulation in the presence of skin irritation may be injurious. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc. Simultaneous connection to RF surgery equipment can cause a burn. Operation near (e.g. 1m) short wave or micro wave therapy equipment can change the output values of the stimulator. EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE

PRECAUTIONS:

Skin irritation may occur under electrodes in isolated cases following long-term application. Consult physician if skin irritation develops. The effectiveness of TENS & EMS/NMS/Interferential Stimulation directly depends upon patient selection. Use only for the specific pain problem prescribed by the physician. Do not immerse device in water or other liquids. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner. Turn the stimulator off before applying or removing electrodes. Powered TENS/EMS/NMS/Interferential devices should be used only with leads and electrodes recommended for use by the manufacturer and should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury. The device may be affected by electromagnetic interference. Also other electrical equipment in the close vicinity may be affected by the device. If such effects are suspected, either switch off the affected equipment and that suspected of causing the interference, or shorten connecting leads. Precaution should be exercised when stimulation is used:

- After recent surgical procedure where muscle contraction may disrupt the healing process.
- After an acute trauma or fracture where there is a tendency to hemorrhage;
- Over the menstruating uterus;
- Where the sensory nerve damage has caused the loss of normal skin sensation

Adverse Reactions

Possible allergic reaction to tape or gel. Possible skin irritation or electrode burn under electrode. Be sure to follow the instructions of your health professional. If you do have questions or problems make sure you contact them for assistance.

WARRANTY

LIMITED WARRANTY (USA only, unless otherwise noted)*

BioMedical Life Systems, Inc. Promises to the original consumer-purchaser to repair or, at the option of BioMedical Life Systems, Inc., to replace any Neuromuscular Stimulator which malfunctions or proves defective in materials or workmanship under normal use during the period of the Warranty. During this time, BioMedical Life Systems, Inc. will provide all labor and parts necessary to correct such defects or malfunctions free of charge. If the product is no longer available, BioMedical Life Systems, Inc. reserves the right to substitute a comparable product. The consumer-purchaser is responsible for all shipping charges when returning the device to the manufacturer or designated service facility.

EXCLUSIONS

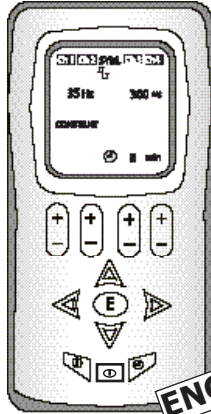
This warranty shall not apply to damage resulting from failure to follow these Instructions, accident, abuse, alteration, or disassembly by unauthorized personnel. This warranty does not extend to accessory items such as rechargeable batteries, electrodes, lead wires, and conductive gel. These items can be provided by your dealer, but costs for repair or replacement will be the responsibility of the consumer-purchaser. BioMedical Life Systems, Inc. shall not be liable for incidental or consequential damages resulting from the sale or use of the device. In the USA, some states do not allow the exclusion or limitation of incidental or consequential damages, or do not allow limits on how long an implied warranty lasts, so the above limitation may not apply to you.

NO OTHER WARRANTIES

This limited warranty is the only express warranty given by BioMedical Life Systems, Inc. Implied warranties, including, but not limited to, warranties of merchantability and fitness for a particular purpose are limited to the warranty period set forth below. This warranty gives you specific legal rights, and you may also have rights which vary from state to state. Warranty Period 3 Years (U.S.A. Only)

If the device case is opened or tampered with in any way, all warranty coverage is void.

BioMedical Life Systems, Inc.
Neuromuscular Stimulator
QuadStar® II



ENGLISH

Instructions

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