

PRIMERATM

for Temporary Pain Relief and to Facilitate and Improve Muscle Performance





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Important Notes

The **PRIMERATM** is equipped with a mA LOCKOUT. Forty-five seconds after the stimulator is turned "ON," the intensity setting will lock. To make any adjustment to the level of intensity (mA), you must first press the negative first to increase the mA.

Please carefully read the **Warnings**, **Safety and Indications** sections of this user's manual and be fully aware of the contents of this user's manual before using your **PRIMERA**TM. The device should not be used for any indication other than the intended use!

Indications for use:

Programs 01 to 07, and HAN are to be used for TENS. The device is intended to be used for the temporary relief of pain associated with sore and aching muscles in the lower back, upper extremities (arms) and lower extremities (legs) due to strain from and/or normal non-commercial household work activities.

Programs 08 to 13 are for NMES and are intended to be used to stimulate healthy muscles in order to facilitate and improve muscle performance.

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED HEALTH CARE PROFESSIONAL.

Warnings

- * The **PRIMERA**TM is a Class II Medical device for use by adults only.
- * Keep out of reach of children.
- * Always use this device in accordance with the manual.
- * Do not insert lead wires into a mains power supply.
- * Do not immerse unit into water or any other substance.
- * Do not use the **PRIMERA**TM unit in the presence of a flammable anaesthesia gas mixture and air or with oxygen or nitrous oxide.
- Never connect the PRIMERATM unit directly to a battery charger or any other mains powered equipment.
- Electrodes are for single patient use only do not share electrodes with another person.
- * Operation in close proximity (e.g., one meter, three feet two inches) to a shortwave or microwave therapy equipment may produce instability in the stimulator output.
- * Simultaneous connection to a patient to high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- * No modification of this equipment is allowed!
- * Only use leads, electrodes and accessories provided by the manufacturer.
- * Safety of electrical stimulation during pregnancy has not been established.
- * Think about what you are doing and use common sense.

NEVER DO the following with the PRIMERATM:

- * Never use it in ways other than those recommended by the user's manual.
- * Never operate without full understanding of the user's manual.
- * Never use it while driving or operating machinery.
- * Never use it in a humid/wet atmosphere (e.g., sauna, bathroom, bath, shower or swimming pool).
- * Never use on people with diminished abilities.
- * Never use the unit if it is not functioning properly or you feel discomfort.
- * Stop using the unit if you feel nausea or dizziness.

Warnings:

- * Always place electrodes in accordance with this user's manual.
- Do not place electrodes across the chest or heart as doing so may create rhythmic disturbances to the heart.
- * The **PRIMERA**TM is not effective in treating pain of central origin, including headache.
- * The **PRIMERA**TM provides symptomatic relief only and has no curative value.
- * The PRIMERATM in TENS mode provides symptomatic treatment and as such suppresses the sensation of pain, which would otherwise serve as a protective mechanism.
- * The user must keep the **PRIMERA**TM away from children.
- * Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when PRIMERATM stimulation is in use.

- * The long-term effects of chronic electrical stimulation are unknown. Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- * Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions: *e.g.*, phlebitis, thrombophlebitis, varicose veins, etc.
- * The effects of stimulation on the brain are unknown. Therefore do not apply stimulation to or across the head
- * Stimulation should not be applied to the neck. Spasm of the laryngeal and pharyngeal muscles may occur and cause contractions which may close the airway.
- Stimulation applied to the neck may have adverse effects on heart rhythm and blood flow.
- * Do not remove electrodes while the unit is being used.
- * Do not use on people with diminished capacity or capabilities.
- * Do not use while sleeping.
- * Do not use the unit for any purpose except what it is intended for.
- * Do not place electrodes over the abdominal region during menstruation periods.
- * Do not let electrodes come into contact with metal of any type during the session.
- Do not use the unit for extended periods of time in case muscles become exhausted or painful.

If in doubt about the use of the **PRIMERATM** unit contact your distributor or ask an experienced licensed health care professional for advice.

Contraindications and Precautions

Remember, pain is a signal your body creates as a very important warning function.

Contraindications:

- * Never use your PRIMERATM on:
 - atrophied muscles.
 - muscles with spasms.
 - muscles associated with an impaired joint or limb.
 - muscles with undiagnosed pain.
- Never use the PRIMERATM when pregnant or if you think you are pregnant.
- * Do not use your PRIMERATM:
 - with demand-type cardiac pacemakers, defibrillators, or other implanted metallic or electronic devices.
 - over the carotid sinus (neck) region.
 - over the neck or mouth.
 - over the carotid sinus nerves.
 - trans cerebrally (over the head).
 - over the eyes.
 - over the heart or chest.
 - when there is a tendency to haemorrhage following acute trauma or fracture.
 - following surgical procedures when muscle contraction may disrupt the healing process.
 - over areas of skin which lack normal sensation.

- over swollen, infected, or inflamed areas or skin eruptions: *e.g.*, phlebitis, thrombophlebitis, varicose veins, etc.
- * Do not use your PRIMERATM if you have one or more of the following medical conditions:
 - epilepsy.
 - cancerous lesions.
 - abdominal or inguinal hernia.
 - critical ischemia of lower limbs.
 - blood flow deficiencies/venous thrombosis.
 - heart problems/condition.

Precautions:

- * Isolated cases of skin irritation may occur at the site of the electrode placement following long-term application. Consult your physician if skin irritation develops.
- * The effectiveness of **PRIMERA**TM in TENS mode is highly dependent upon program selection and electrode placement determined by user response. If in doubt, consult a person qualified in pain management.
- * Caution should be used for patients with suspected or diagnosed heart problems.
- * Caution should be used for patients with suspected or diagnosed epilepsy.
- * Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium or an alternate electrode placement.

- * Electrode placement and stimulation settings should be in accord with the instructions in this manual or based on the advice of an experienced licensed health care professional.
- * Powered muscle stimulators should be kept out of the reach of children.
- * Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
- * Powered muscle stimulators 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.
- * Do not immerse the unit in water or any other liquid.
 - Before using the **PRIMERATM** please consult your physician if you are experiencing or have any of the following conditions:
 - an acute disease.
 - malignant tumor.
 - infectious disease.
 - heart disease.
 - high fever.
 - abnormal blood pressure.
 - skin sensory disorders or skin problems.
 - hernia (abdominal or inguinal).
 - any serious illness.
 - prone to impulsive, foolish or stupid decisions.

Electrode Guidelines

Please note that the correct selection of the skin electrodes for a TENS device is a significant concern. The electrodes for this TENS device are FDA cleared 2 inch skin electrodes from Chattanooga. To ensure you obtain the proper type of skin electrode please re-order from Chattanooga, DJO Global or your **PRIMERA**TM authorized dealer.

Never Apply Electrodes to:

- the head or any area of the face.
- the neck.
- the chest.
- across the heart.
- on both sides of the thorax simultaneously (laterally or front and back).

Caution with Electrodes:

- Always turn the power to the **PRIMERA**TM off when applying or moving electrodes.
- Ensure the entire surface of the electrode is stuck to the skin.
- If skin irritation occurs, move the electrodes to a different position.
- Do not apply solvents or cleaning agents to electrodes.
- Electrodes are for *single patient use only* do not share electrodes with another person.
- Users should discontinue use immediately if there is any dermal discomfort.

Adverse Reactions:

* Please note that this equipment is capable of delivering current densities for any electrodes exceeding 2mA r.m.s/cm². Skin irritation and electrode burns are potential adverse reactions. Users should discontinue use immediately if there is any dermal discomfort.

A Few Good Tips (Self-Adhesive Electrodes):

- * If you find the electrodes will not stick due to oily skin, cleanse the skin with soap and water, then rinse and dry the area around the electrode site. If this does not work, try cleansing the skin with a swab impregnated with alcohol.
- * Clip away hair on skin using scissors; don't use a razor to remove hairs.
- * The electrode's conductive material is water-based. If it becomes saturated (e.g., from perspiration), it will lose its adhesive qualities. After use, leave the electrodes face up overnight to dry out (replace on plastic film in the morning).
- * At some point the electrodes will become dry. Moisten the adhesive surface with a few drops of water, and apply onto the plastic film overnight. This procedure will give you a few more days of electrode life.

What is Pain?

When we feel pain it is the body's process of informing us that something is wrong. To feel pain is important, without this feeling abnormal conditions may go undetected, creating damage or injury to critical parts of the body. Although pain is essential in warning our body of trauma or malfunction, nature may have gone too far in its design. Continued long-term chronic pain has no useful value apart from its importance in diagnosis. Pain only begins when a coded signal travels to the brain where it is decoded, and analysed. The pain message travels from the injured area of the body along small diameter nerves leading to the spinal cord. At this point the message is switched to a different kind of nerve that travels up the spinal cord to the brain area. The brain then analyses the pain message, refers it back and the pain is felt.

What is TENS?

Transcutaneous Electrical Nerve Stimulation (TENS) uses a small battery-operated unit to provide a noninvasive method of controlling acute and principally long-term intractable pain. It can also be used as an adjunctive treatment in the management of post-surgical traumatic pain problems. In TENS mild electrical impulses are transmuted through the skin via surface electrodes to modify the body's pain perception. TENS does not cure problematic physiological conditions; it only helps to control the pain perception. TENS will not work for every user. However, physical therapists and

physicians throughout the world prescribe TENS extensively and it is generally seen to work for the majority of users. There are millions of small nerve fibers throughout the body and it only requires a few impulses to produce chronic pain. In addition to small fibers, which allow the sensation of pain to be felt, the body is also made up of larger diameter nerve fibers. These larger nerve fibers transmit less unpleasant sensations such as touch or warmth, assisting us to form an impression of our environment. Stimulating the larger nerve fibers using TENS may have the effect of inhibiting the transmission of pain along the smaller nerve fibers to the spinal cord [known as the 'Pain Gate Theory'].

What is NMES?

Neuro Muscular Electrical Stimulation has been used for many years to stimulate muscle to treat a number of muscle and nerve related conditions. The **PRIMERATM** is a dual channel device combining several treatment programs into one unit. Neuromuscular Stimulation is increasingly understood by therapists and physicians. There is a better understanding of the mechanisms that exist between nerves and muscles that makes it possible to stimulate the neuromuscular system with precise electrical signals. The **PRIMERATM** offers precision, giving full controls of Pulse Widths, Rates, Rampup Times, Work/Rest cycles as well as alternating or synchronous application if two channels are used.

How to Use the PRIMERATM

In order to use the **PRIMERA**TM effectively, you must consider the following points:

- Planning of stimulation sessions
- Choice of appropriate treatment mode
- Stimulation intensity level
- Electrode placement

Planning:

The **PRIMERATM** is a portable device so no special planning is required for use of temporary pain relief. The unit should not be used while operating a vehicle or machinery.

When using the **PRIMERA**TM to improve muscle performance it is recommended that you only stimulate the muscle groups for sessions of **30 minutes three times per week.**

Appropriate Treatment Mode:

There are five treatment modes available on the **PRIMERA**TM:

- Continuous TENS or Normal: This is the most frequently used mode for pain relief.
 For general TENS use, the most common selection is program 01.
- 2. **Burst Mode:** This mode is comparable to the low rate TENS technique except that each low rate pulse is substituted by a short BURST of 9 pulses [$200 \mu S$] at 150 Hz. It is a combination of conventional and low rate TENS. Use program 06 or 07.

- 3. **Modulation TENS:** This mode was designed to help prevent nerve accommodation that some patients experience. It is achieved by continuously cycling the pulse width and rate. Use program 04 or 05.
- NMES (Neuro Muscular Electrical Stimulation): This mode enables the users to train their muscles. NMES is generally used at higher milliamp levels. Choose the program most suited to your requirements.

Choose the mode/program most suited to your requirements. For pain relief, alternate between the programs 01 to 07 and HAN until you find the most effective program.

There is no clinical basis for selecting one mode over the other for temporary pain relief. There is no output mode or waveform that can be detrimental to one's self. Take care to use the unit only at a comfortable level for the recommended program time limit.

Stimulation Intensity Level [mA]:

Patients respond differently to the level of intensity due to differences in individual skin resistance, enervation and the type and condition of electrode being used. **Never use high intensity levels for pain relief,** only a slight sensation should be felt for optimal pain relief.

Lower and comfortable intensity levels should be used for temporary pain relief. If using the **PRIMERA**TM for improving muscle performance, select the highest **comfortable**

stimulation level and gradually increase the intensity from session to session to achieve the best results.

How Long Do I Use TENS and NMES?

This depends on the individual patient's condition, accuracy of electrode placement, stimulation and the characteristics selected, but typically the onset of pain relief starts after 20-30 minutes. Generally TENS is used for longer periods, normally 1 hour 30 minutes per session. With some patients it can be much longer. Before electing longer sessions, consult an experienced licensed health care professional.

Electrode Placement:

CAUTION MUST BE EXERCISED AT ALL TIMES TO ENSURE SAFE AND PROPER ELECTRODE PAD PLACEMENT. See warning section for areas on the body where not to apply electrodes.

The placement of electrodes is one of the most important parameters in achieving effective pain relief using TENS. It is always wise to ask your physical therapist or physician to advise as to which location is most appropriate. It is likely that various positions need to be experimented with before the user finds the most effective positioning.

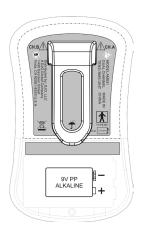
An effective method to help with temporary pain relief associated with aching or sore

muscles is to place electrode pads symmetrically over the pain site (opposite of each other in a straight line going through the muscle).

Garment Belt:

If using the unit for temporary pain relief of back muscles we recommend using the garment belt to allow correct placement of electrodes. Attach the electrodes to the garment belt and remove the plastic backing. Insert the lead wire on the belt into Channel A or B of the unit. Attach the belt to your body with the electrodes placed on the lower back and secure comfortably around your front (see page 25). Turn on the unit and increase the current intensity until you feel the desired sensation.





General Quick Start Instructions

- Check the polarity of the electrodes.
- Be sure the lead wires are securely connected, then position and apply the electrodes.
- Insert lead wires into Channel A and/ or Channel B of the **PRIMERA**TM.
- Insert a 9 Volt alkaline battery into the battery compartment and turn on the PRIMERATM by pressing the ON button (please note: electrodes must be in position before activation).
- Using the PRG button select the program.
- Slowly adjust left and right mA current output with the positive button. This starts the program and you will begin to feel the stimulation. Increase this to tolerance.
 The PRIMERATM is equipped with a mA LOCKOUT. Forty-five seconds after the
- The **PRIMERATM** is equipped with a mA LOCKOUT. Forty-five seconds after the stimulator is turned "ON," the intensity settling will lock. To make any adjustment to the level of intensity, you must first press the negative first to increase the mA.
- You may notice some muscle contraction and this is normal.
- You can track treatment time in the upper right hand corner of the PRIMERATM screen.
- At the end of the program duration remove the electrodes and replace the electrode covers.
- You can treat every day but no more than as advised and never to a point of fatigue or pain.

Programs

	-						
	Prog. No.	Description	Rate (Hz)	Pulse width (μS)	Work time (s)	Rest time (s)	Prog. time
	P01	CON	80	200	n/a	n/a	1 hour
	P02	CON	150	175	n/a	n/a	20 min
	P03	CON	2	175	n/a	n/a	20 min
TENS	P04	BST	150	200	n/a	n/a	1 hour
TE	P05	BST	150	175	n/a	n/a	1 hour
	P06	MOD	100/65	200/100	n/a	n/a	1 hour
	P07	MOD	65/100	200/100	-	-	1 hour
	HAN	HAN	2/70	250/150	-	-	30 min
	P08	NMES	12	200	5	5	15 min
	P09	NMES	35	250	8	8	15 min
NMES	P10	NMES	12	200	5	10	15 min
$\frac{2}{2}$	P11	NMES	35	200	6	12	15 min
	P12	NMES	12	250	5	15	15 min
	P13	NMES	35	200	6	18	15 min

Key to Program Description for above

CON = CONtinuous TENS

BST = BurST TENS MOD = MODulation TENS

HAN = HAN Mode TENS NMES = Neuro Muscular ElectroStimulation

Program Notes:

TENS

Program 1: Temporary relief of dull, constant pain in the back and lower extremities. Multiple applications as needed per day.

Program 2: Temporary relief of dull, constant pain in the back and lower extremities. Multiple applications as needed per day.

Program 3: Temporary relief of acute or sub-acute pain due to strain from exercise or normal household activities. To be used as needed

Program 4: Temporary relief of pain associated with sore and aching muscles in the lower extremities. Multiple applications as needed per day.

Program 5: Temporary relief of pain associated with sore and aching muscles in the lower extremities. Multiple applications as needed per day.

Program 6: Temporary relief of pain combined with a muscle massage effect for pain associated with sore and aching muscles in upper extremities. Multiple applications as needed per day.

Program 7: Temporary relief of pain combined with a muscle massage effect for pain associated with sore and aching muscles in upper extremities. Multiple applications as needed per day.

Program HAN: A combined frequency custom electrotherapy TENS program for the temporary relief of pain.

NMES

Program 8: Muscle massage to relax muscles. Multiple applications as needed per day. Unless otherwise indicated by an appropriately licensed healthcare professional, do not use on muscle spasms and never on undiagnosed muscle spasms.

Program 9: Brief, intense physical workout of muscles. Up to three applications per day. **Program 10:** Muscle massage and mild warm up/cool down of muscles. Up to three applications per day.

Program 11: Stimulate healthy muscles in order to improve and facilitate muscle performance, mild exercise program to increase muscle strength. Up to three applications per day.

Program 12: Muscle massage and moderate warm up/cool down of muscle. Up to three applications per day.

Program 13: Stimulate healthy muscles in order to improve and facilitate muscle performance. Moderate exercise program to increase muscle strength. Up to three applications per day.

Description of Kit Components

PRIMERATM Unit Complete with Carrying and the Accessories Shown



Electrodes Item # 42182



Battery Item # 200001-001



PRIMERATM Complete Kit Item # 77615



Lead Wires Item # 77619



User's Manual Item # 77617

PRIMERATM TENS/NMES Complete Unit Item # 77615

Contains: Manual, Lead wires (2), Garment Belt, Battery, and

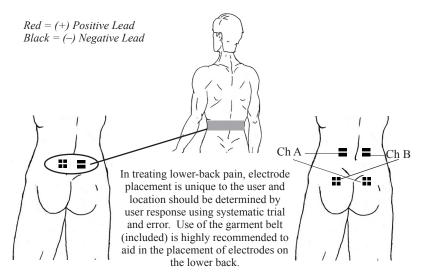
Electrodes in the Plastic Case

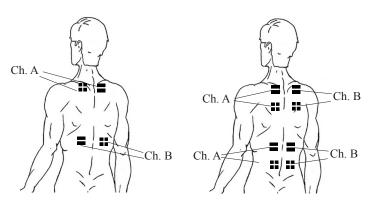
Accessories

You can obtain replacement accessories from your authorized PRIMERATM dealer:

PRIMERATM Unit Sliding Back Cover	Item # 77616
User's Manual	Item # 77617
Plastic Carrying Case	Item # 77618
Leadwire Set - 2 each	Item # 77619
Electrode Positioner Belt for the Back	Item # 77620
Battery, Energizer 9-volt	Item # 200001-001
Dura-Stick+ 2" Round Reorder Electrodes	Item # 42182
(Includes 10 packs of 4 electrodes in each pack)	

Suggested General Electrode Placement

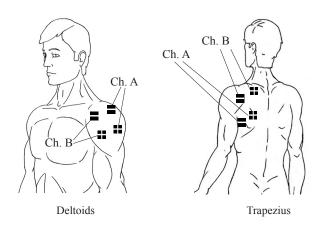




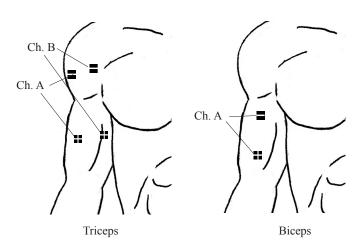
Upper/Mid Back Pain Relief.

Upper/Mid Back Muscle Improvement.

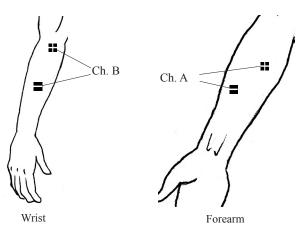
Red = (+) Positive Lead Black = (-) Negative Lead



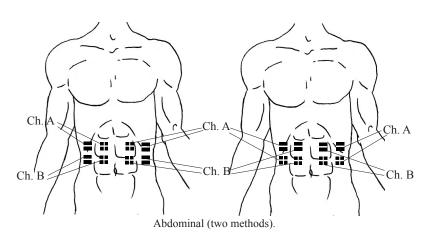
Red = (+) Positive Lead Black = (-) Negative Lead



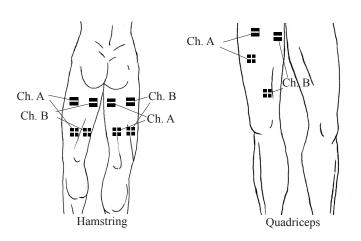
Red = (+) Positive Lead Black = (-) Negative Lead



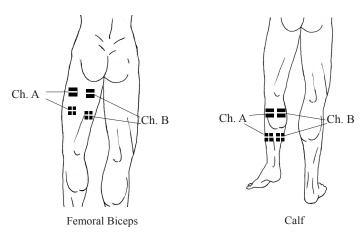
Red = (+) Positive Lead Black = (-) Negative Lead



Red = (+) Positive Lead Black = (-) Negative Lead



Red = (+) Positive Lead Black = (-) Negative Lead



Red = (+) Positive Lead Black = (-) Negative Lead

Commonly Asked Questions

The device should not be used for any indication other than the intended use.

- Q How can I have a better chance of success?
- A Seeking professional advice from your physical therapist or physician on how to best apply TENS is the best answer we can give to this question.
- Q Are there circumstances in which TENS/NMES should not be used?
- A Yes. For undiagnosed pain; when using a cardiac pacemaker; during pregnancy and other instances as fully detailed in this manual on pages 3 to 9.
- Q Can there be any permanent side effects?
- A There are no known permanent side effects caused by using a TENS stimulator.
- Q If I have any medical or product queries how can I get help?
- A Any clinical advice on the PRIMERA™ be provided by your physical therapist or licensed health care provider.

Care and Maintenance

Control Unit:

- * Wipe the surface once a week with a damp cloth or antiseptic wipes.
- * Do not use cleaning sprays or alcohol-based cleaning solutions.
- * Expected service life is five years.

Battery:

- * Check periodically for any visable changes to the battery. Immediately remove and replace the battery if there is any discharge.
- * Remove battery completely from unit if not in use for any extended period of time (typically if placed in storage one month or longer).
- * Low battery indicator of 6.9 Volts shown on LCD display, when flashing, change battery for a new one.
- * Preferably use a Energizer 9-volt battery (reorder instructions are on the back cover).
- * Expected average battery life [of a standard 800 mAh, alkaline battery] is 24 hours.

Lead Wires:

- * The lead wires should be handled carefully and never stretched, as this can cause the stimulation to function below normal standards or not at all.
- * Examine lead wires before each treatment for loose connections or damage.
- * Avoid stretching and twisting the lead wires.
- * Store the lead wires carefully after each use.
- Expected service life is six months.

Self-Adhesive Electrodes:

- * Be sure the short pin connectors are securely/completely attached to the electrode.
- * Replace electrodes onto plastic film after each use/session. If the electrodes drop onto the floor, debris will adhere to conductive gel rendering the electrodes ineffective.
- * Expected service life is a ten day period within two years of the manufacture date.
- * Expiration date is clearly marked on each electrode package.

Garment Belt:

- * Keep the belt clean because use of the garment belt is recommended to aid in the proper placement of electrodes on the lower back and as such may make dermal contact
- * Follow the cleaning instructions delineated in the sewn on care tag.
- Expected service life is approximately one year.

User's Manual:

* Keep the user's manual clean, dry and away from any open flame or heat source.

Caution: Static electricity may damage this product.

Note: Do not perform unauthorized repairs under any circumstances. Should the unit require service, warranty, or repair, please contact the selling dealer or your local DJO customer service.

Specifications

General:

- 1. Dual channel: individually isolated circuits.
- 2. Type: Constant Current. 500 to 1,500 Ohms.
- 3. Waveform: Asymmetrical, rectangular bi-phasic with zero DC current.
- Low Battery Indicator: If the battery goes below 6.9 volts +/- 0.2 Volts the battery symbol will flash on/off once every second.
- 5. If the battery voltage is below 6.6 (+/-0.2) Volts the unit will not turn on.
- Open Electrode Detect: If an open circuit is detected at the output of channel A or B the output current will be reset at zero.

TENS:

- Amplitude: 0-80 mA into 500 Ohms load; indication only. Actual mA will tend to be less than indicated due to electrode impedance: at 1,000 Ohms load (Electrodes in poor condition) the maximum will be limited to 70 mA, at 1500 Ohms load the maximum will be limited to 65 mA.
- 2. Selectable pulse width:175, 200, 200/100, 250/100 or 250/150 μ S (2% accuracy).
- 3. Program pulse rate selection in the continuous mode: 2, 80 or 150Hz (2% accuracy).
- 4. Modes: Continuous, Burst, Modulated and HAN.
- 5. Burst Mode: Bursts of 9 pulses, 150Hz at 200μS, repeating twice every second.
- 6. Modulation Mode: 6-second cycle of concurrent width modulation and pulse repetition rate modulation. Width starting at $200\mu S$, and decreasing exponentially to

 $100\mu S$ in three seconds and then returning back to $200\mu S$ in the next three seconds. Hertz start at 65 or 100Hz, and increasing or decreasing exponentially to 100 or 65Hz in three seconds and then returning back to 65 or 100Hz.

- 7. HAN: $2 \text{ Hz} / 250 \,\mu\text{S} / 3 \text{ Sec. then } 70 \,\text{Hz} / 150 \,\mu\text{S} / 3 \text{ Sec.}$; Repeat
- 8. Time duration of programs: 1 hour or less per session.

NMES:

- Amplitude: 0-80 mA into 500 Ohms load; indication only. Actual mA will tend to be less than indicated due to electrode impedance: at 1,000 Ohms load (Electrodes in poor condition) the maximum will be limited to 70 mA, at 1500 Ohms load the maximum will be limited to 65 mA.
- 2. Program selectable pulse width: $200\mu S$ or $250\mu S$ (2% accuracy).
- 3. Program pulse rate selection: 12 or 35Hz (2% accuracy).
- 4. Time duration of programs: 15 minutes.

Physical and Environmental:

- 1. Physical dimensions: 108 x 62 x 26 mm without clip (32 mm with clip).
- 2. Weight: 0.09 kg. without battery, 0.1 kg. with battery.
- Environmental conditions for storage and transport: -10 to +50 degrees Celsius (14 to 122 degrees Fahrenheit), 0-90% Humidity.
- Environmental conditions for use: 5 to 40 degrees Celsius (41 to 104 degrees Fahrenheit), 15-93% Humidity.

Issues and Solutions

Issue	Possible Cause	Solution
Battery symbol on LED flashing.	The voltage is low.	Replace the batteries.
	Batteries discharged.	Replace batteries.
The display does not come on and there is no	Batteries were incorrectly positioned.	Remove batteries and replace correctly.
signal from the unit.	Battery contacts bent.	Use a tool to push contacts in case forward.

Never tamper with the battery.

Discard the battery if any indication of damage.

Low Battery Indicator:

If the battery's Voltage goes below 6.9 (+/- 0.2) Volts the battery symbol will flash on/off once every second. If the battery voltage is below 6.6 (+/- 0.2) Volts the unit will not turn "ON". Dispose of batteries responsibly and in full compliance with all laws.

continued to next page

Issue	Possible Cause	Solution
The unit turns "ON," but does not carry out commands (e.g., mA intensity increases but then drops to 0mA and readjustment to higher than 10mA level is not possible.).	Open circuit detected: Poor connection between electrode and skin.	Turn unit "OFF." Remove the electrode, lubricate it (see electrode care), reapply the electrode, then turn unit "ON."
	Open circuit detected: Lead wire connections are not secure.	Turn unit "OFF," unplug lead wires at all connection points and then reinsert all points, then turn unit "ON."
	Open circuit detected: Broken lead wires.	Turn unit "OFF," Replace lead wires or electrode unit, then turn unit "ON."

Worn/ broken lead wires, not always visible, are the most common problem.

Never tamper with the electrode or lead wires.

Discard if any indication of damage to either the electrode or wires. Consult your licensed health care professional if the solutions above do not address the issue.

Issue	Possible Cause	Solution
Increasing intensity causes unpleasant sensation.	Dry spots or other factors that could increase	Turn unit "OFF." Remove the electrode, lubricate it (see electrode care), reapply the electrode, then turn unit "ON."
	resistance.	Use new electrodes or use a different brand or style of electrode gel.
	Local muscle fatigue.	Be less aggressive in mA intensity or frequency of use.

PRIMERATM Warranty

DJO, LLC, a DJO Global Company, provides a warranty to the original purchaser that this product will be free from defects in the material, components and workmanship for a period of two (2) years from the date of purchase (invoice date). If DJO, LLC is satisfied that the product/s is/are defective the purchaser may return the unit/s to DJO, LLC or the appointed distributor for repair or replacement with a new unit. All returns must first be authorized by DJO, LLC. The liability of DJO, LLC under this limited product warranty does not extend to any misuse or abuse such as heating, cooling, freezing, tampering with or dismantling the **PRIMERA**TM, commercial use or normal wear and tear. Any evidence of abuse or tampering with the **PRIMERA**TM will nullify this warranty.

This warranty does not cover consumable items; including batteries, lead wires, garment belt and electrodes.

Symbols Appearing on the Back of the Device

\triangle	Caution! (electrical output).
(3)	Follow operating instructions! Failure to do so could place the patient or operator at risk.
®	Neuromuscular Stimulation (NMES/STIM) should not be used by patients fitted with demand style cardiac pacemakers. Please seek advice from your health supervisor.
*	This product should be kept dry. The unit is not protected from ingress of water droplets from a water shower if used outside the carrying case.
LOT	Manufacturer's LOT/Batch number. Present it together with SN number when you report a technical fault or claim a warranty return.
SN	Manufacturer's serial number of the unit. Present it together with LOT number when you report a technical fault or claim a warranty return.

REF	Model number: Present it together with LOT and SN numbers when ordering supplies, report a technical fault or claim a warranty return.
TYPE BF	Patient's shock protection type: BF (Body Floated) Equipment. This equipment is not earthed but contains a battery within an insulated unit.
IP20	IP -indication for protection against ingress of water and particulate matter. IP20 means: protected against solid foreign objects of 12.5mm dia and greater. Not protected against water.
Z	At the end of the product life cycle, do not throw this product into the normal household garbage, but bring it to a collection point for the recycling of electronic components. Incorrect disposal can be harmful to the environment and to human health. Please contact your local authorities if you need more information about collection points in your area.

Special Notes

The **PRIMERATM** is equipped with a mA LOCKOUT. Forty-five seconds after the unit is turned, "ON" the intensity setting will lock. To make any adjustment to the intensity setting, you must first press the negative button to increase the mA.

For reorder of replacement electrodes, replacement batteries, and accessories, please visit our website.

Web: www.DJOglobal.com/chattanooga

Distributed by: DJO, LLC A DJO Global Company 1430 Decision Street Vista, CA 92081-8553 U.S.A.

