Guardian Unity™

User Manual

PRESCRIPTION INFORMATION:
Please read the following prescription carefully before using your NMES unit. If you have any questions regarding this information, consult your health care professional before using.

Part#20749 October 2018 Rev. A

RX Only

CAUTION: Federal Law restricts this device to sale by, or on the order of, a practitioner licensed by the state in which he or she practices to use or order the use of the device.

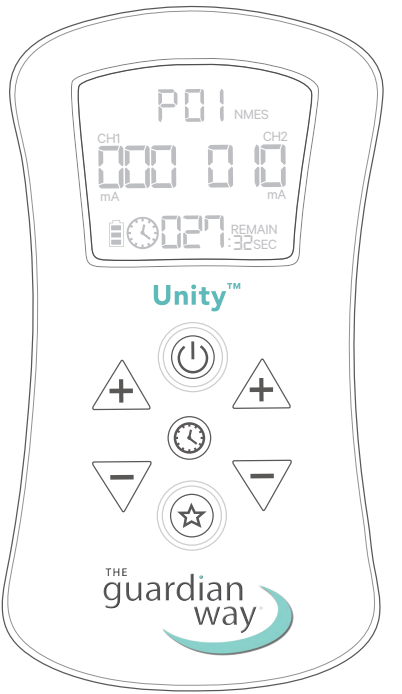


Table of Contents:

The Guardian Unity Instructions For Use (also called IFU) is comprised of instruction guides on varied topics, device features such as getting started, maintaining the device in good working order, or if the need arises, troubleshooting and receiving warranty service.

The instruction guide covers:

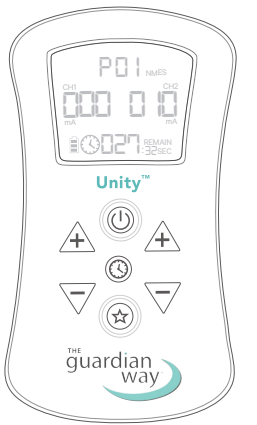
A. Safety First
   - Contraindications
   - Warnings
   - Precautions
   - Adverse Reactions

B. General Information Guide

C. Getting Started

D. Technical Information Guide

E. Device Ownership Guide



Safety First

Important Contraindications, Warnings, Precautions and Adverse Effects

Read carefully and understand fully before using the Guardian Unity device

Contraindications:

1) Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device because this may cause electric shock, burns, electrical interference, or death.

2) Electronic muscle stimulation devices, including this unit, should not be used on patients with any form of cancer.

Adverse Reactions:

- Skin irritation and burns beneath the stimulation electrodes have been reported with the use of powered muscle stimulators.
- Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the face.
- Patients should stop using the device and should consult with their physicians if they experience adverse reactions with the device.
- Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin

Warnings

1. The long-term effects of electrical stimulation are unknown
2. Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias
3. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebi tis, varicose veins, etc.
4. Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use
5. Do not apply stimulation when the patient is in the bath or shower
6. Do not apply stimulation while the patient is sleeping
7. Consult with the patient's physician before using this device because the device may cause lethal rhythm disturbances to the heart in susceptible individuals
8. Apply stimulation only to normal, intact, clean, healthy skin
9. Do not apply stimulation across the patient's chest because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be lethal
10. This unit must be used with the guidance of a health care professional
11. Type BF equipment
12. Do not insert lead wires into a mains power supply
13. Do not immerse unit into water or any other substance
14. Do not use the Neuromuscular Electrical Stimulation (NMES) unit in the presence of a flammable anesthetic gas mixture and air or with Oxygen or Nitrous Oxide
15. If using rechargeable AA Nickel Metal Hydride or Ni - Cad batteries be sure to use a CE approved battery charger
16. Never connect the device directly to a battery charger or any other main powered equipment
17. Patient Electrodes are for single patient use only
18. Keep out of reach of children
19. Do not apply stimulation over, or in proximity to, cancerous lesions
20. Do not apply stimulation while the patient is driving, operating machinery, or during any activity in which electrical stimulation can put the patient at risk of injury

Precautions

1. Precautions should be observed in the presence of the following:
   - When there is a tendency to hemorrhage following acute trauma or fracture
   - Following recent surgical procedures when muscle contractions may disrupt the healing process.
   - Stimulation over the menstruating uterus
   - 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
3. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner
4. Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer
5. Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head
6. Use this device only under the continued supervision of a licensed practitioner
7. Use caution applying stimulation over the patient's neck because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure
8. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex
9. Discontinue and do not increase the intensity level if you feel discomfort during use
10. Stimulation should not be applied trans cerebrally
11. Stimulation should be stopped if discomfort is felt
12. The safety of electrical stimulation during pregnancy has not been established
13. Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians
14. Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians
15. Use caution when the patient has a tendency to bleed internally, such as following and injury or fracture
16. Use caution following recent surgical procedures when stimulation may disrupt the patient's healing process
17. Use caution if stimulation is applied over the menstruating or pregnant uterus
18. Use caution if stimulation is applied over areas of skin that lack normal sensation
19. Keep this device out of reach of children
20. Use this device only with the leads, electrodes, and accessories recommended by the manufacturer

* Long term effects of chronic Electronic Muscle Stimulation are unknown.

Adverse Reactions

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

» Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the face.

» Patients should stop using the device and should consult with their physicians if they experience adverse reactions with the device.

» Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin.

General Information Guide

Indicated for use:

Relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, should immediate post surgical stimulation of calf muscles to eliminate venous thrombosis, maintaining or increasing range of motion and stroke rehab by muscle re-education.

IMPORTANT ADVISORY

CAUTION: Federal law restricts this device to sale by or on the order of a licensed physician. This device should be used under medical supervision for adjunctive treatment and for the treatment of medical diseases and conditions.

To download the current version of this guide go to
www.spectramedonline.com

The Guardian Unity is manufactured in the USA*

The Guardian Unity device conforms with the national and international medical device standards and regulations described in the table below.

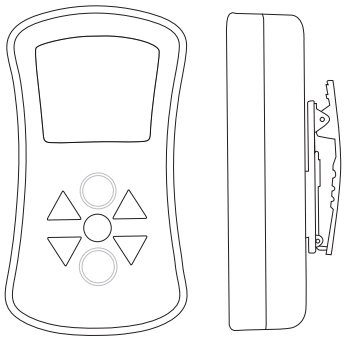
* Made in the USA. FDA 510(k)020637. Designed in California. Assembled and tested in FDA registered facility in the USA. Some parts sourced globally.

STANDARD or REGULATION NO.	NAME	ISSUANCE DATE
IEC 60601-1 3 A1	general requirements	2012/08
IEC 60601-1-2	electromagnetic disturbances	2014/02
IEC 60601-1-6 3.1	usability	2013/10
IEC 60601-1-9	environmentally conscious design	2013/10
IEC 60601-1-11	home healthcare environment	2015/01
IEC 60601-2-10	nerve and muscle stimulators	2016/04
IEC 62304 1.1	software in a medical device	2016/06
ANSI/AAMI 62366	usability engineering	2015/02
ANSI/AAMI NS4:2013	transcutaneous elect. nerve stimulators	2013/03
ISO 14971:2012	risk management	2012/07

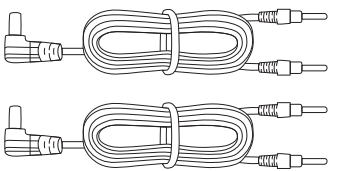
* SAFETY AND ADVISORY NOTICES *			
	Read all instructions, warnings and precautions (including these notices) before using this device in a therapy.		Protect this device from direct exposure to the sun.
STOP	STOP — make sure you are not subject to any of the contraindications before using this device in a therapy.		Protect this device from falling water. Do not use this device in rain or in the shower.
	Do not use this device while under the influence of alcohol or drugs or while intoxicated for any reason.	15 40 °C	The safe operating temperature range for this device is 15C (41F) to 40C (104F).
	This device is ONLY to be used by and for the benefit of the person to whom it was prescribed.	-25 55 °C	The safe storage and transportation temperature range for this device is -25C (-13F) to 55C (131F).
	Keep this device out of the reach of children.	1013 hPa 700 hPa	The safe atmospheric pressure range for this device is 700HPA to 1013HPA or 9882 feet above sea level to sea level.
	Follow your physician's instructions as to which therapy presets to use, electrode placement and suggested amplitude levels.	% 95 5	The safe humidity operating range for this device is 5% to 95% relative humidity.
	Familiarize yourself with the features, benefits and operation of this device before use.	RX Only	CAUTION: Federal Law restricts this device to sale by, or on the order of, a practitioner licensed by the State in which he or she practices to use or order the use of the device
			Dispose of batteries responsibly. Search the Internet for information about the safe disposal of batteries.

Getting Started

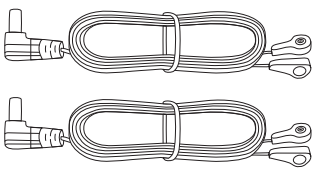
device



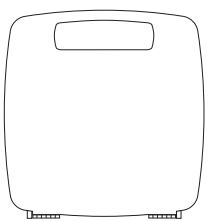
case boot (optional; packaged separately)



pin connect lead wires (2)

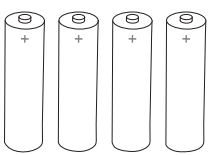


snap connect lead wires (2)



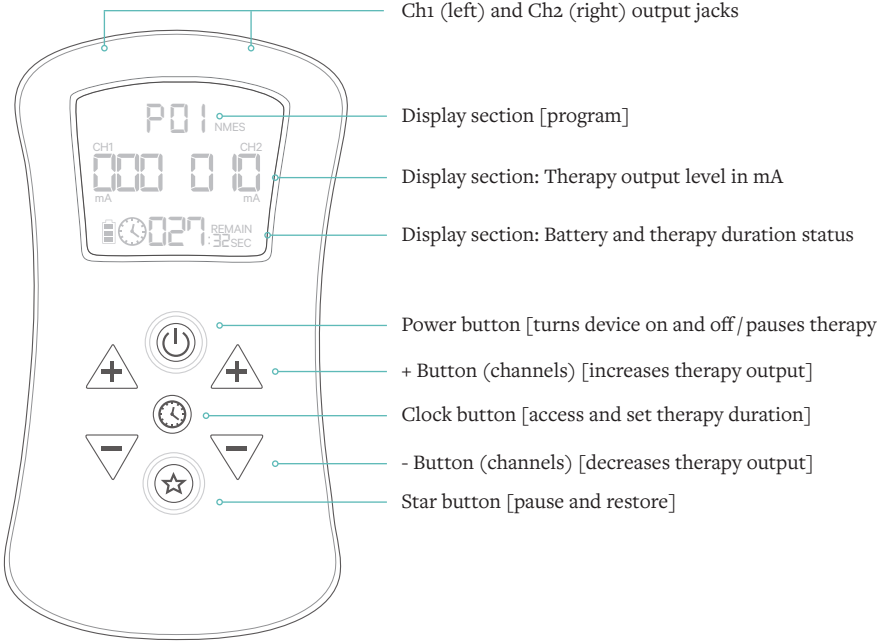
carrying case

device manual



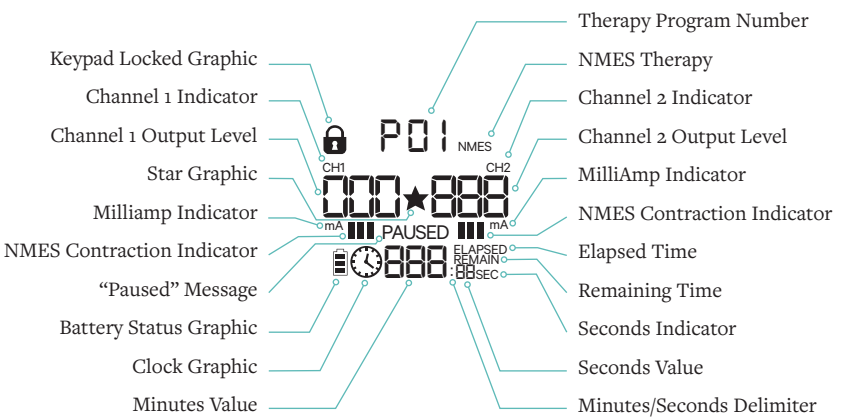
AA batteries (4)

Guardian Unity — Device Legend



Guardian Unity — Display Legend

The LCD is backlight illuminated for user convenience. The backlight only stays illuminated for a few seconds to conserve battery power. During therapy the backlight can be turned on by pressing any button on the keypad with the exception of the power button which will pause the therapy. When the device is off (not in a therapy, not just the display off) the backlight can be turned on by pressing any of the keypad buttons.



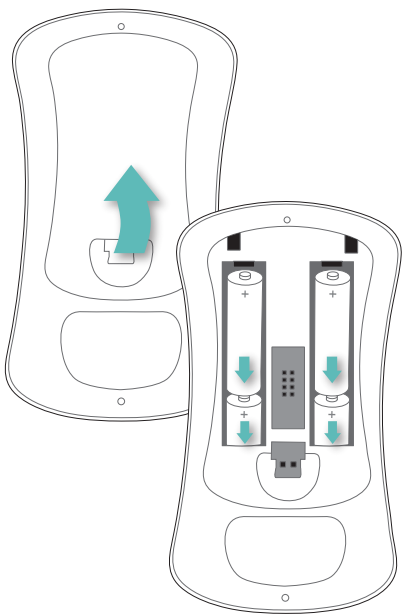
Simple Steps to Starting Your First Therapy

Step 1

Insert Batteries

Remove the battery door and insert (4) AA batteries. Observe the battery's polarity (+) markings and the polarity (+) markings inside the battery compartment.

Re-attach the battery door.

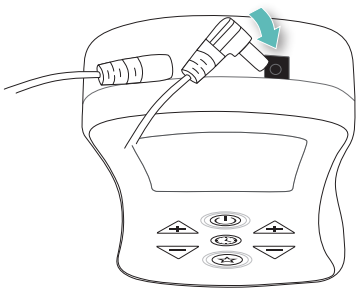


Step 2

Connect Lead Wires to Device

Connect each patient lead wire to the output jacks at the top of the stimulation device. Make sure the connectors are fully inserted.

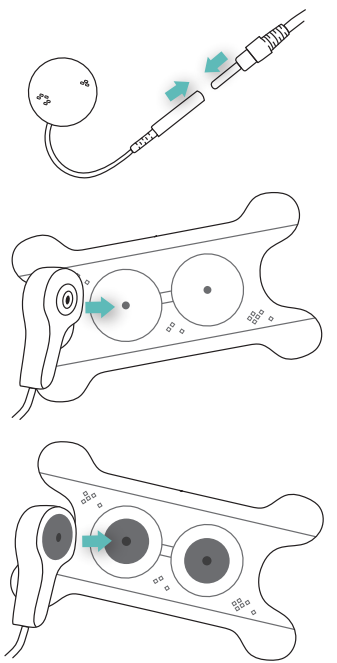
All of the lead wires are interchangeable in the two jacks



Step 3

Connect Lead Wires to Electrodes

Connect the patient lead wires to the electrodes while they are on the electrode liner. Make sure the pin connector is fully inserted into the electrode receptacle.



Step 4

Determine Electrode Placement

Refer to Electrode Placement Section for guidance on the correct arrangement of the electrodes according to the type of therapy. Correct electrode arrangement is vital to receiving a safe and effective therapy.

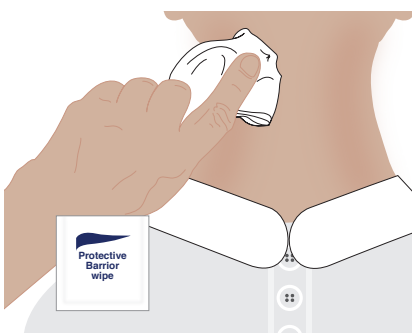
Simple Steps to Starting Your First Therapy

Step 5

Applying the Electrodes

Prior to applying the electrodes, properly clean the skin around the treatment area with soap and water. Dry the skin in the treatment area thoroughly. Gently wipe area with skin protectant barrier wipe. *Do not use alcohol prep pads.*

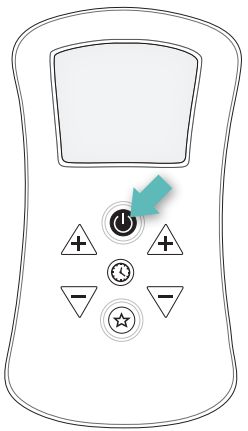
Remove the electrodes from the electrode liner one at a time and apply to the skin in the desired arrangement and location. Press the electrodes to the skin to assure good contact.



Step 6

Power On the Device

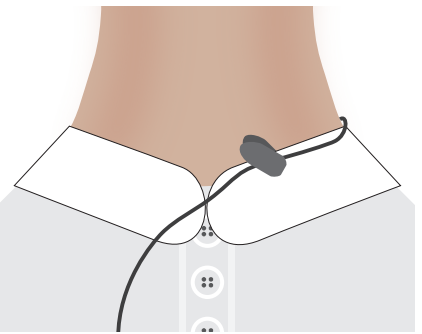
Power on the device by pressing the Power button. The device display and keypad will illuminate.



Step 7

Attach

Attach lead wire clip to patient clothing. Make certain there is enough slack in the lead wire to allow head movement.

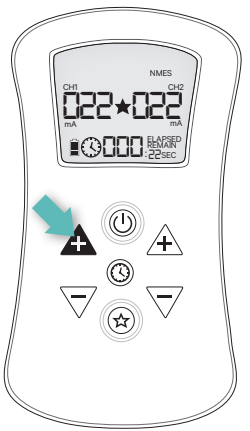


Step 8

Increase Therapy Output

Press either of the “+” buttons to start the therapy. The display will update to include the therapy output indicators and the therapy clock will begin counting down. With each “+” button press you will incrementally increase the therapy output. If you press and hold the “+” button you will increase the therapy output at an increased rate.

Please note: To further increase output after therapy has started, press “-” twice and then press “+” until desired output is reached.



Technical Information Guide

Guardian Unity Device — Specifications

SPECIFICATIONS	
Therapy Channels	2
Therapy Output Mode	Neuromuscular Electrical Stimulation (NMES)
Preset Therapy Programs	7 (see chart to the right)
Waveform Characteristics	Square, Symmetrical, Bi-Phasic
Output Voltage Range All values are VAC P2P	0-50 VAC P2P
Output Current Range All values are mA P2P	0-90mA P2P @ 500 Ohm load Program 1-6 0-50mA P2P @ 500 Ohm load Program 7 Each channel employs isolated intensity potentiometers. Constant current control.
Internal Power Supply	(4) AA Cells (1.5V) DO NOT USE LITHIUM CELLS>1.6V
Dimensions inches (mm)	2.6" x 5" x 1.1" (67 x 127 x 28)
Weight (grams) W/O battery	7.5 oz. (212)
Operating Conditions	Temp 41F - 104F, Atmos. Press 700hPa - 1013hPa, Hum. 15% - 95%
Storage & Transport Conditions	Temp -6F - 131F, Atmos. Press. 700hPa - 1013hPa, Hum. 5% - 95%

PRESET THERAPY PROGRAMS								
Program	Frequency	Pulse Duration	Contraction	Relaxation	Ramp Up	Ramp Down	Total Time	Max Power Output
P01	50	200	4 sec.	12 sec.	2 sec.	0 sec.	30 min.	90mA
P02	50	450	4 sec.	12 sec.	2 sec.	0 sec.	30 min.	90mA
P03	50	150	4 sec.	12 sec.	2 sec.	0 sec.	30 min.	90mA
P04	35	250	10 sec.	10 sec.	2 sec.	0 sec.	30 min.	90mA
P05	35	200	10 sec.	10 sec.	2 sec.	0 sec.	30 min.	90mA
P06	50	200	4 sec.	16 sec.	2 sec.	0 sec.	30 min.	90mA
P07*	80	300	58	1 sec.	0.5 sec.	0.5 sec.	60 min.	50mA

*NOTE: In program 7 it should be noted that the output of 50 milliamps peak to peak is the equivalent of representing 25mA (half of the peak to peak measurement).

Guardian Unity Device — Batteries

Battery Size and Voltage

The battery size is AA (also known internationally as LR6). The voltage varies depending on the battery chemistry type but the typical voltage range for individual cells is 1.2 VDC to 1.5VDC.

Battery Type

Battery type for the device is alkaline or rechargeable Nickel Metal Hydride (NiMH). Lithium Manganese Dioxide batteries with a voltage of 1.5VDC are an excellent choice but they are expensive.

NOTE: NiCad rechargeable batteries are not recommended due to their low capacity and diminished performance with repeated charge cycles. So-called "Super Heavy Duty" ("SHD") batteries are not recommended. The chemistry in SHD batteries is zinc chloride and they have an attractive up-front low-cost but their extremely limited capacity and premature exhaustion makes them one of the most expensive choices to power the Device. Avoid Lithium Iron Phosphate (also known as LiPo) batteries with a voltage range of 3.0VDC to 3.7VDC. The use of (4) LiPo batteries will supply too high a voltage and permanently damage the Device and void the warranty.

Battery Disposal

Alkaline batteries are safe to dispose of along with household trash. In Oregon, USA, the cells must be taken to a recycling center. Use the Internet to research Oregon's battery disposal laws. NiMH rechargeable cells must be disposed of according to State law in the United States. Your State, Province, County or Country may have different laws. Search the Internet for battery disposal laws in your area.

Battery Polarity

Observe polarity markings inside the battery compartment when inserting batteries into the Device. Additionally the guide includes an illustration of the correct polarity to observe.

Battery Service Life

There are many variables to consider when estimating battery service life such as the battery type, the freshness of the batteries when placed into service, the quality and capacity of the batteries, the output levels of your therapies, the length of your therapy durations and the variables it is impossible to estimate battery service life.

Device Service Life

The Device Service Life is unlimited. The Device Service Life is not the same as the device Warranty. For Warranty information please see the Device Ownership Guide.

Device Shelf Life

The Device Shelf Life is unlimited. The shelf life of electrodes and batteries are not associated with the Device shelf life.

Device Disposal

At the end of its service life the Device is small enough to be disposed of with household trash.

Guardian Unity Device — Miscellaneous

Size and Type of Electrodes

Premium hydrogel cutaneous electrodes such as the The Guardian Unity brand are recommended for use with the Device. Low quality or "value" electrodes should be avoided due to their low quality materials, poor therapeutic performance and short service life.

There are many shapes and sizes of electrodes available on the market. For safety reasons do not use electrodes smaller than .5 Sq. In. (3.24 CM2) with NMES.

Guardian Unity Device — EMC Information

EMC - Electromagnetic Compatibility

This is the aggregate term for characteristics of an electrical device that determine its ability to function in an environment (such as clinical, hospital, home health, outdoors, airplanes etc.) with other electrical devices without the Guardian Unity Device interfering with their operation or without the device being interfered with by other devices. There are international standards that apply to Electromagnetic Compatibility and devices under test must meet or exceed the test standards. The international standard is IEC 60601-02-2016.

Electromagnetic Interference

The Guardian Unity has been tested in the USA by a National Laboratory to determine the electromagnetic radiation for the device. Testing has confirmed that the Guardian Unity does not emit any harmful electromagnetic radiations.

Electromagnetic Immunity

The Guardian Unity has been tested in the USA by a National Laboratory while in normal operation, in the standard therapy program and connected to a representative load. While in operation many different electromagnetic radiations bombarded the test device and in all instances the device operated normally.

Static Charge Immunity

The Guardian Unity has been tested in the USA by a National Laboratory while in normal operation and exposed to static electricity according to the International Standards. In all Static Charge tests there was no interruption to the device's operation and no damage to the device.

Magnetic Immunity

This final test is directed at the very rare chance that the device would operate in an environment of high magnetic fields. The device passed all Magnetic Field Immunity tests.

Device Ownership Guide

Care and Handling of Your Device, Troubleshooting and Device Warranty

Cleaning Your Device

- Clean the device, as needed, by wiping gently with a damp cloth and mild soap.
- Do not use abrasive cleaners or cleaners containing solvents.
- Do not immerse the device in water or other liquids. Do not splash water or other liquids on the device.

Storage and Transportation

- Remove the batteries and place the device and all accessories in the provided carrying case or storage box.
- Refer to the General Information Guide for the suggested range of storage and transportation conditions.
- Protect the device from exposure to water during storage and transportation.
- The device can safely be transported in the passenger cabin or luggage compartment of modern aircraft.

Customer Service

Contact the party you purchased the device from or the organization that dispensed the device to you. For questions related to operating your device refer to the Instructional Guide supplied with the device. If the guides do not answer your questions please go online to www.spectramedonline.com where you will find articles that provide additional information for many of the topics related to the device operation.

Troubleshooting

Review the table on the next page for the most common device complaints. As an added troubleshooting resource visit www.spectramedonline.com

COMPLAINT	POTENTIAL CAUSE / POTENTIAL SOLUTION
Device does not power on	1. Remove and reinsert batteries carefully observing battery polarity. 2. Insert fresh batteries.
Stimulation is not felt	1. Confirm patient lead wires are fully inserted into the device output jacks. 2. Confirm stimulation output levels are high enough to feel stimulation. 3. Inspect patient lead wires for damage.
Uncomfortable stimulation	1. Decrease output level. 2. Old electrodes / use fresh electrodes.
"NO CON" message appears when a therapy is begun and the amplitude is increased	1. "NO CON" message is intended to alert the user that a lead wire(s) is not connected to the device or to the electrode. 2. The lead wire could be damaged. Contact your dealer or supplier and request a replacement lead wire.
Battery life is short	1. Use fresh alkaline or NiMH rechargeable batteries. 2. Confirm the batteries are not "Super Heavy Duty" or NiCad type. 3. Review the user guide battery life section to determine if your battery life is consistent with expected battery life.
Electrodes do not adhere well	This is not a device issue. Electrodes are a consumable accessory and subject to wearing out. Do not undergo a therapy with electrodes that do not adhere to your skin well. Use fresh electrodes to ensure a safe and effective therapy and minimize adverse events.
Display illumination is dim	Insert fresh batteries. If problems persist file a warranty claim with Warrantor.
Output is intermittent	Test lead wires with integrated lead wire tester (see Special Features Guide). If lead wire tester determines there is a short in the lead wire, request a replacement lead wire from your dealer or supplier.

Device Ownership Guide

Care and Handling of Your Device, Troubleshooting and Device Warranty

COMPLAINT	POTENTIAL CAUSE / POTENTIAL SOLUTION
Output stops abruptly and prematurely	1. Batteries are exhausted. 2. Lead wires have become disconnected from device or electrodes. 3. Device may be in PAUSE state.
Device is powered off, but stimulation is felt	Try to duplicate the problem. If the problem persists file a warranty claim.
After unpausing output is zero	Cycle the device on and off. If the problem persists file a warranty claim.
Display does not stay illuminated	This is normal. To conserve battery power the display illumination ends after five seconds of keypad inactivity.
Some of the display characters are not fully formed	Cycle the device on and off. If the problem persists file a warranty claim.

Guardian Unity Device — Warranty

Spectramed, LLC, (Warrantor) warrants its Electrotherapy Device(s) against any defect in materials and/ or workmanship for a period of one year from the date the Device is dispensed to the user/patient or 15 months from the date of original sale whichever is longer (Warranty Period) and promises to repair or replace, at its sole discretion, any of its Devices that fail due to defects in materials and/or workmanship. The serial number of the Device is automatically registered at the time of initial sale for establishing the Warranty Period start date and no additional warranty registration is required.

This Warranty does not cover a Device that has been damaged by accident, shipment, dropping, exposure to water, misuse, abuse, neglect, improper servicing, or from any cause not arising out of defect in original materials and/or workmanship. This Warranty does not cover devices that have been damaged by the use of Lithium 3.7 volt AA batteries. This Warranty does not cover a Device that has been altered in any way or repaired by any personnel or entity other than the original manufacturer. This Warranty does not cover Devices that have been entered into rental service. This Warranty does not cover accessories such as batteries, lead wires, electrodes, belt clips or carrying case.

To make a Warranty Claim, contact the Warranty Service Processor (either the party you purchased the Device from or the entity that dispensed the Device to you). DO NOT CONTACT Warrantor. Locate the Device serial number located on the back of the Device. Provide the Device serial number to the Warranty Service Processor so that it can be verified for Warranty coverage. Follow the instructions of the Warranty Service Processor.

The resolution of any Warranty Claim will be at the sole discretion of Spectramed, LLC and is limited to repair or replacement of the Device. Spectramed, LLC assumes no responsibility for incidental, direct, consequential or compensatory loss or damage related to an accepted Warranty Claim. No refunds on the purchase of a Device will be offered by Warrantor. An accepted Warranty Claim whether the Device is repaired or replaced does not extend or alter in any way the original Device's Warranty Period or change the original Device's Warranty terms.

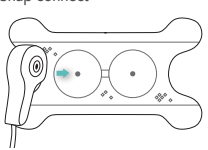
Manufactured in the USA for
Spectramed, LLC.
www.spectramedonline.com

Notes

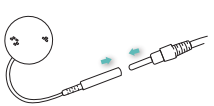
Guardian Unity Device — Part numbers for re-order

PART NUMBER	DESCRIPTION	PART NUMBER	DESCRIPTION
05A150-10	10 pks .6875" mini-snap electrodes w/butterfly	05A156-10	10 pks 1.0" wired electrodes Hydroblue
05A150-30	30 pks .6875" mini-snap electrodes w/butterfly	05A156-30	30 pks 1.0" wired electrodes Hydroblue
05A150-50	50 pks .6875" mini-snap electrodes w/butterfly	05A156-50	50 pks 1.0" wired electrodes Hydroblue
05A150-100	100 pks .6875" mini-snap electrodes w/butterfly	05A156-100	100 pks 1.0" wired electrodes Hydroblue
05A151-10	10 pks .875" mini-snap electrodes w/butterfly	05A158-10	10 pks .875" wired electrodes Hydroblue
05A151-30	30 pks .875" mini-snap electrodes w/butterfly	05A158-30	30 pks .875" wired electrodes Hydroblue
05A151-50	50 pks .875" mini-snap electrodes w/butterfly	05A158-50	50 pks .875" wired electrodes Hydroblue
05A151-100	100 pks .875" mini-snap electrodes w/butterfly	05A158-100	100 pks .875" wired electrodes Hydroblue
05A152-10	10 pks .875" mini-snap electrodes	05A159-10	10 pks 1" x 1.25" wired electrodes Hydroblue
05A152-30	30 pks .875" mini-snap electrodes	05A159-30	30 pks 1" x 1.25" wired electrodes Hydroblue
05A152-50	50 pks .875" mini-snap electrodes	05A159-50	50 pks 1" x 1.25" wired electrodes Hydroblue
05A152-100	100 pks .875" mini-snap electrodes	05A159-100	100 pks 1" x 1.25" wired electrodes Hydroblue
05A154-10	10 pks .875" mini-snap electrodes Hydroblue	05A160-10	10 pks 1.0" wired electrodes
05A154-30	30 pks .875" mini-snap electrodes Hydroblue	05A160-30	30 pks 1.0" wired electrodes
05A154-50	50 pks .875" mini-snap electrodes Hydroblue	05A160-50	50 pks 1.0" wired electrodes
05A154-100	100 pks .875" mini-snap electrodes Hydroblue	05A160-100	100 pks 1.0" wired electrodes

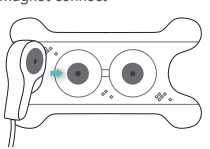
Snap connect



Pin connect

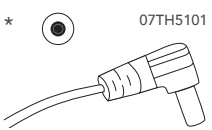


Magnet connect

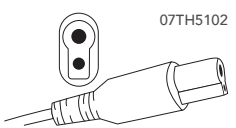


PART NUMBER	DESCRIPTION	PART NUMBER	DESCRIPTION
05A163-30	30 pks .875 wired electrodes	*TH1183BC-10	10 pks .875" Magnetic Connection w/butterfly
05A163-50	50 pks .875 wired electrodes	*TH1183BC-30	30 pks .875" Magnetic Connection w/butterfly
05A163-100	100 pks .875 wired electrodes	*TH1183BC-50	50 pks .875" Magnetic Connection w/butterfly
05A164-10	10 pks 1" mini-snap electrodes	*TH1183BC-100	100 pks .875" Magnetic Connection w/butterfly
05A164-30	30 pks 1" mini-snap electrodes	*TH1183BCS-10	10 pks 1" Magnetic Connection
05A164-50	50 pks 1" mini-snap electrodes	*TH1183BCS-30	30 pks 1" Magnetic Connection
05A164-100	100 pks 1" mini-snap electrodes	*TH1183BCS-50	50 pks 1" Magnetic Connection
05A165-10	10 pks .875" wired butterfly	*TH1183BCS-100	100 pks 1" Magnetic Connection
05A165-30	30 pks .875" wired butterfly	07TH5101	51" Lead connects exclusively with TH1183 series electrodes Lead wire compatible with Guardian Unity and Ampcare devices
05A165-50	50 pks .875" wired butterfly		
05A165-100	100 pks .875" wired butterfly	07TH5102	51" Lead connects exclusively with TH1183 series electrodes Lead wire compatible with VitalStim and eSwallow devices
05A170-10	10 pks .68" x .87" Pediatric wired oval		
05A170-30	30 pks .68" x .87" Pediatric wired oval		
05A170-50	50 pks .68" x .87" Pediatric wired oval	07TH5103	51" Lead connects exclusively with TH1183 series electrodes Lead wire compatible with VitalStim Plus device
05A170-100	100 pks .68" x .87" Pediatric wired oval		

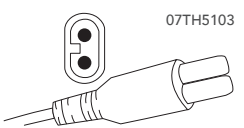
* 07TH5101



07TH5102



07TH5103



Declarations of Conformity

Electromagnetic Compatibility EMC Tables

GUIDANCE AND MANUFACTURER'S DECLARATION — ELECTROMAGNETIC EMISSIONS		
The Guardian Unity electrotherapy system is intended for use in the electromagnetic environment defined below. The customer or the user of the Guardian Unity system should assure that it is used in such an environment.		
EMISSIONS TESTS	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
RF emissions CISPR 11	Group 1	The Guardian Unity electrotherapy system uses RF energy, only, for it internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with near by electronic equipment.
RF emissions CISPR 11	Class B	The Guardian Unity electrotherapy system is suitable for use in all establishments, and those directly connected to the public low voltage power system network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable - battery powered	
Voltage fluctuation IEC 61000-3-3	Not applicable - battery powered	

GUIDANCE AND MANUFACTURER'S DECLARATION — ELECTROMAGNETIC IMMUNITY			
The Guardian Unity electrotherapy system is intended for use in the electromagnetic environment specified below. The customer or the user of the Guardian Unity system should assure that it is used in such an environment.			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Risk Assessment on the Guardian Unity electrotherapy system indicates the compliance levels claimed are acceptable when EDS-precautionary measures are taken.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/ output lines	Not applicable - battery powered Not applicable - signal lines less then 3 meters	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+1kV differential mode (line to line) +2kV common mode (line to ground)	Not applicable - battery powered	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	Not applicable - battery powered	Main power quality should be that of a typical commercial or hospital environment. If the user of the Guardian Unity electrotherapy system requires continued operation during power mains interruptions, it is recommended that the Guardian Unity electrotherapy system be powered from an uninterrupted power supply.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Electromagnetic Compatibility EMC Tables

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE GUARDIAN UNITY ELECTROTHERAPY SYSTEM

The Guardian Unity electrotherapy system is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the Guardian Unity can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Guardian Unity electrotherapy system as recommended below, according to the maximum output power of the communications equipment.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER *P* (**W**)	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER *d* (m)		
	150 kHz to 80 MHz $d=\left[\frac{3,5}{V_1}\right]\sqrt{P}$ (where V_1=3V)	**80 MHz to 800 MHz** $d=\left[\frac{3,5}{E_1}\right]\sqrt{P}$ (where E_1=3V/m)	**800 MHz to 2,5 GHz** $d=\left[\frac{7}{E_1}\right]\sqrt{P}$ (where E_1=3V/m)
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The Guardian Unity electrotherapy system is intended for use in the electromagnetic environment deified below. The customer or the user of this electrotherapy system should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80MHz 3 V/m 80 MHz to 2,5 GHz	[V_1] V, where V_1=3V [E_1] V/m, where E_1=3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Guardian Unity electrotherapy system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=\left[\frac{3,5}{V_1}\right]\sqrt{P}$ $d=\left[\frac{3,5}{E_1}\right]\sqrt{P}$ *80 MHz to 800 MHz* $d=\left[\frac{7}{E_1}\right]\sqrt{P}$ *800MHz to 2,5 GHz* where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Guardian Unity electrotherapy system is used exceeds the applicable RF compliance level above, the Guardian Unity should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Guardian Unity electrotherapy system.

[b] Over the frequency range 150 MHz to 80 MHz, field strengths should be less than [V_1] V/m

1601 Eastgate Pkwy
Columbus, Ohio 43230

1-800-643-1917

www.spectramedonline.com