

COMPEX. | MINI
VERSION 1.0

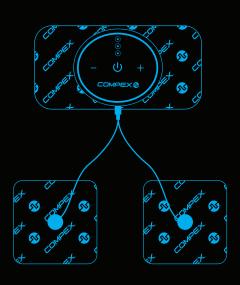


TABLE OF CONTENTS

Introduction	4
Indications for Use	
Safety Warning	4
Contraindications	5
Warnings	5
Precautions	6
Adverse Reactions	8
Symbol and Title	8
Environmental Condition for Transport and Storage	10
How the Device Works	14
Setup	15
Operating Instruction	16
Performance Specifications	20
Electrode Maintenance	20
Trouble Shooting	21
Recommended Use Positions	22
Contact Information	25

INTRODUCTION

Compex* Mini delivers electric pulses generated to the user's skin through the electrodes. The portable and compact device has 6 modes of different pulse frequencies, covering Electrical Muscle Stimulation (EMS) and Transcutaneous Electrical Nerve Stimulation (TENS). It includes operating elements of ON/OFF button, intensity increase, intensity decrease, mode selection button, and can be attached and detached to the electrode through the connector and lead wire. One end of the lead wire is connected to the device and the other end of the lead wire is connected to the electrode pad.

INDICATIONS FOR USF

FMS:

To stimulate healthy muscles in order to help improve and facilitate muscle performance. To be used to help improve muscle tone and firmness, and to aid in strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

It is also intended to help temporarily increase local blood circulation in the healthy muscles of lower extremities

TENS / RELIEF:

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, and leg, due to strain from exercise or normal household and work activities.

It is also intended to aid in symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

CONSULT ACCOMPANYING DOCUMENTS

CONTRAINDICATIONS

- » Do not use this device on persons who have a cardiac pacemaker, implanted defibrillator, or otherimplanted metallic or electronic devices because this may cause electric shock, burns, electrical interference, or death.
- » Do not use this device on patients whose pain syndromes are undiagnosed.

WARNINGS

- » WARNING: Use carefully. May cause serious burns. Do not use over sensitive skin areas or areas with poor circulation. The unattended use of this device by children or incapacitated persons may be dangerous. To reduce the risk of buns, electric shock, and fire, this device must be used in accordance with the instructions.
- » Do not crush the device and its electrodes, and avoid sharp folds.
- » Carefully examine the device and its electrodes, and do not use if they show any sign of deterioration.
- » Do not tamper with this device and its electrodes in any way. There are no user serviceable parts. If for any reason they do not function satisfactorily, return to the authorized service center at address given.
- » The long-term effects of chronic electrical stimulation are unknown.
- » Stimulation should not be applied over the carotid sinus nerves, particularly in persons with a known sensitivity to the carotid sinus reflex. Carotid sinus is located on both sides of the neck.
- » Stimulation should not be applied over the front neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing. Stimulation over the neck can also cause adverse effects on heart rhythm or blood pressure.
- » Do not apply stimulation across the patient's chest contralaterally, because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be lethal.

- » 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 head.
- » Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- » Stimulation should not be applied over, or in proximity to, cancerous lesions.

PRECAUTIONS

- » Caution should be used for persons with suspected or diagnosed heart problems.
- » Caution should be used for persons with suspected or diagnosed epilepsy.
- » Caution should be used if you have any of the following:
 - if you have a tendency to bleed internally following an injury;
 - if you recently had surgery, or have ever had surgery on your back;
 - if areas of skin lack normal sensations, such as skin that is numb.
- » Consult with your physician before use over the menstrual uterus.
- » You 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 alternate electrode placement.
- » Do not use this device while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
- » Keep this device out of reach of children.
- » Do not use this device in high humidity areas such as a bathroom.
- » Stop using this device at once if you feel discomfort, dizziness or nausea, and consult your physician.
- » Do not attempt to move the electrodes while the device is operating.

- » Do not apply stimulation of this device in the following conditions:
 - Contralaterally across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart, which could be lethal;
 - over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis. thrombophlebitis. varicose veins):
 - in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms);
 - on children or incapacitated persons.
- » Be aware of the following:
 - consult with your physician before using this device;
 - this device is not effective for pain associated with Central Pain Syndromes, such as headaches;
 - this device is not a substitute for pain medications and other pain management therapies;
 - this device is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism;
 - stop using the device if the device does not provide pain relief;
 - use this device only with the electrodes, and accessories recommended for use by the manufacturer.
- » Store the device away from high-temperature and direct-sunlight. Storage outside of stated storage temperature may result in measurement error or device malfunction.
- » Do not share the use of the electrodes with others; electrodes are intended for single person use.
- » Do not use the device while it's charging.
- » This device contains a lithium battery. If overheating of the device occurred during the charging, stop the charging or operation immediately and contact customer support.
- » Dispose of this battery-containing device according to the local, state, or federal laws.
- » Skin burns may occur, and check the skin under the electrode periodically.

ADVERSE REACTIONS

- » You may experience skin irritation and burns beneath the stimulation electrodes applied to the skin; check skin under electrodes frequently.
- » You should stop using the device and should consult with your physicians if you experience adverse reactions from the device.

SYMBOL AND TITLE

Information essential for proper use shall be indicated by using the corresponding symbols. The following symbols may be seen on the device and labeling.

€	Consult instructions for use
\triangle	Caution, consult accompanying documents
<u> </u>	Use by date
wl	Date of manufacture
LOT	Batch code

REF	Catalogue number
SN	Serial number
	Manufacturer
∦	Temperature limitation
<u></u>	Humidity limitation
STERRE	Non-sterile
MR	MR Unsele - keep away from magnetic resonance imaging (MRI) equipment
Ţ	Fragile, handle with care

*	Keep away from rain
ô	Product packaging is able to be recycled

ENVIRONMENTAL CONDITION FOR TRANSPORT AND STORAGE

- Normal working ambient temperature: 10~40°C
- Normal working ambient humidity: 30~85%
- Store and transport ambient temperature: -10 ~50°C
- Store and transport ambient humidity: 30~90%
- Fragile; handle with care
- Keep away from rain
- Product packaging is able to be recycled
- Non-sterile

ENVIRONMENTAL CONDITION FOR TRANSPORT AND STORAGE

 This product needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile radio frequency (RF) communications equipment.

- 2) Do not use other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
- 3) Caution: This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

This unit has been thoroughly tested and inspected to assure proper performance and operation.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSION			
The device is intended for use in the electromagnetic environment specified below. The customer of the user of the device should assure that it is used in such an environment.			
EMISSION TEST COMPLIANCE ELECTROMAGNETIC ENVIRONMENT – GUIDANCE			
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emission CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public	
Harmonic emissions IEC 61000-3-2	Class A	low-voltage power supply network that supplies buildings used for domestic purposes.	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies		

GUIDANCE AND MANUFACTURE'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The device is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.

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IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE Level	ELECTROMAGNETIC ENVIRONMENT – Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including calles, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ 80 Mer to 80 Mer $d=2.3\sqrt{P}$ 80 Mer to 80 Mer $d=2.3\sqrt{P}$ 80 Mer to 25 Mer $d=2.3\sqrt{P}$ 80 Mer to 25 Mer $d=2.3\sqrt{P}$ For the maximum output power rating of the transmitter in watts (VI) according to the transmitter in watts (VI) according to the transmitter in manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbols: ((v))

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 sits survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocation the device.

B) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device.

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

Rated maximum output power of	Separation distance according to frequency of transmitter (m)		
transmitter (W)	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
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 prower not listed above, the recommended separation distance d in metres (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.

HOW THE DEVICE WORKS

The device has 6 programs, the details of which are listed in the table below.

Program	Contraction Frequency (Hz)	Contraction Time (sec)	Rest Frequency (Hz)	Rest Time (sec)	Work Time (min)	Total Time (min)
Program 1: Pre-Warm Up					25 min 3 sec	
Program 2: Endurance*	18	8	3	3	40	50
Program 3: Resistance*	70	8	9	4	13	23
Program 4: 9 Hz for 2 min, 8 Hz for 2 min, 7 Hz for 2 min, 6 Hz for 3 min, 5 Hz for 3 min, 4 Hz for 3 min, 3 Hz for 3 min, 2 Hz for 3 min, and 1 Hz for 3 min				24 min		
Program 5: Muscle Relaxation	1 Hz			20 min 3 sec		
Program 6: Relief	160	10	0	2	30	30 min

* Note: These three groorams have 10 min of 1 Hz (Muscle Relaxation) at the end. and that is why the total time is 10 min more than the work time.

Remove the 2 devices and accessories from the box. The accessories include electrodes, lead wires and a USB cable. The USB cable should be used to charge both units.



1. There are two devices included. The device marked "1" on its side is the master device, and the device marked "2" is the affiliation device. The master device and the affiliation device are paired as received. Therefore, after turning on the devices, you can use them directly out of the box.

Note: If the devices unpair, you can pair the mother device with the affiliation device manually. Use a pin to press the PAIR (RESET) hole on the back of the devices. Press and release the reset hole of the affiliation device first (beeping twice (0.5s per beeping) and the LED lights keep flashing), meaning the affiliation device is ready for pairing; then press and release the reset hole of the mother device (beeping and flashing none, 0.5s per beeping/flashing) to send the pairing signal to the affiliation device. When the pairing is successful, the affiliation device will beep once (0.5s per beeping) and its LED lights becomes steadily on. Pressing the reset hole for more than 2 seconds could unpair the affiliation device, indicated by the flashing/beeping twice (0.2s per beeping/flashing).



- 2. Intensity levels +/- can only be increased or decreased via puck 1 (master device).
- 3. Alternatively, the phone application can automatically pair with the master device and operate it via Bluetooth. Simultaneously, the master device controls the affiliation device via the radio frequency. If using one device make sure it is the master device which is marked "1" on its side. Nate: Cannat independently use pack #2"

The following Operating Instructions are used to guide the operation. The step-by-step details are listed below:

STEP 1 – Check the battery power of the device	
The devices comes with rechargeable batteries and can be used as received. If the battery icon is flashing when turned on, it means the battery is running out of power. Turn off and charge the device with the enclosed USB cable. The LED light flashes during charging, and becomes solid when the device is charged fully. Note: When the battery is full, the 3 yellow LED lights are on; when the battery is running low, only one yellow LED light is on.	© (- 0 +) Converge Battery charging
STEP 2 - Install the electrode pad onto the device Snap the enclosed rectangular electrode pad onto the device through the snap-on connector, and use the lead wire to connect the device to the two square electrode pads. This should be done prior to applying the device onto the skin of the treatment area.	Electrode pad installation
STEP 3 - Put the electrode pad-installed device on the stimulation-needed body area Place the pad-installed device onto the treatment area (such as the bicep). Press down firmly and ensure a full and firm contact with skin. Note: The skin should be clean and dry before placing the electrode pad-installed device.	Place the device on the body area

STEP 4 - Press the "ON/OFF" to turn on the power		
Press and release the ON/OFF button to turn on the device, indicated by the yellow LED indicators on and beeping once (0.5 second).	(− () +	Ů ON / OFF
STEP 5 - Select one of the stimulation modes		
After the device is on, press and release the ON/OFF button to change the 6 programs: The flashing/beeping times of LED indicator represent the corresponding programs (0.2s per beeping). For example, 3 timers of flashing/beeping mean Program 3; 6 timers of flashing/beeping mean Program 6.		Program change
STEP 6 - Adjust the stimulation intensity		
Press and release the + or - button to increase or decrease the intensity by one level (up to 299 levels), indicated by the LED flashing once and beeping once (0.2s per beeping); holding the + or - button for 1 second could increase or decrease the intensity by 10 levels, indicated by the LED flashing twice and beeping twice (0.2s per beeping). After the above mode, time, and intensity are set up, the stimulation provided by the device will last until the device until the program is completed.	COMPEXS	Intensity change
STEP 7 - Press the "ON/OFF" to turn off the power after done		
Hold the ON/OFF button for 1 second to turn off the device, indicated by the three LED indicators off and beeping twice (0.5s per beeping). Note: When not in use, store the device and accessory in a cool place, out of direct sunlight.	© 0 + COMPEX®	() ON ∕ OFF

Recommended Practice:

- Start from the lowest intensity and gradually adjust the intensity to a comfortable level. Duration for each skin area is based on the preset timer for each program. Frequency is 2 times per day per skin area. Consult with your physician for longer and more frequent uses.
- Good skin care is important for a comfortable use of device. Be sure the treatment site is clean of dirt and body lotion.
- Keeping the electrode on its backing in the storage bag after use will extend its lifespan. The electrode pad is disposable and should be replaced when it loses the adhesiveness. To purchase additional electrodes, please contact the seller.

Electrodes have a shelf life of 2 years, are intended for single person use, and should be replaced as necessary. If the electrode no longer contacts well with your skin, it is time to replace it. If needed, you can use a damp and clean cloth to wipe electrodes between uses.

Electrode In Use Direction

- Clean skin thoroughly prior to each application of electrodes, which will not contact well if any lotion, make-up, or dirt is left on the skin.
- 2. Ensure the device is off before applying the electrode to it.
- 3. Apply the electrode-installed device firmly to the skin.

Electrode Removal and Storage

- 1. Turn the device off before removing the electrode from the skin.
- 2. Grab the edge of the electrode and remove from the skin, replace to its backing.
- 3. When not in use and/or between each use, store the electrode in the re-sealable bag, out of direct sunlight.

As shown above, the device can be operated independently by pressing its three buttons (ON/OFF button, intensity increase button, and intensity decrease button). Alternatively, the phone application interface provides a secondary operation method to wirelessly realize the functions mentioned above. At any time you can switch to manually operate the device itself by pressing its three buttons to deal with any safety issues that may arise.

PERFORMANCE SPECIFICATIONS

Power Source

Number of Output Modes

Timer Range (minutes)

Dimensions (mm) [L x W x D]

Waveform Shape

Maximum Output Voltage

Maximum Output Current
Maximum Pulse Duration

Maximum Frequency

3.7V Battery

6 preset modes

20-50 66 x 56 x 18 mm

MW 81 X 96 X 99

Biphasic

Rectangular 72V@500Ω

144mA@500Ω

345µSec 184Hz

ELECTRODE MAINTENANCE

The electrodes are disposable. Electrodes have a shelf life of 2 years, are intended for single person use, and should be replaced as necessary. If the electrode no longer contacts well with your skin, it is time to replace it. If needed, you can use a damp and clean cloth to wipe electrodes between uses. Electrodes can be ordered at

www.compex.com

TROUBLE SHOOTING

If your device is not operating properly, please check below for common problems and suggested solutions. If the recommended action does not solve the problem, please contact the seller.

Stimulation is weak or non-existent

- Be sure skin is clean and pads are firmly attached to skin.
- The battery is low and needs to be charged.

Device does not turn on

• Check if battery is low and needs to be charged.

Electrodes are not sticky

The pads will lose adhesiveness over use. Visit www.compex.com for replacements.

Skin turns red

- · Stop use.
- If problem persists, contact your physician.

Wireless control not connected

- · Restart the device and wireless controller to re-connect automatically.
- Switch to operate the device manually.

RECOMMENDED USE POSITIONS

SHOULDERS		ARMS	
BACK	-TT-	LEGS	
BUTTOCKS		FEET	
ABDOMEN		Never a on the sides of the caro are local	pply electrodes threat or both the neck where tid sinus nerves ed.

WARRANTY

This device carries a limited warranty of one year from the date of delivery. The warranty applies to the device only, the accessories are not covered by this warranty.

During the warranty period, defective items will be repaired or replaced at no charge. Any evidence of misuse, abuse, alterations, or externally caused damage the warranty is invalid.

For more information, please contact Compex*.

FCC STATEMENT

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

This device may not cause harmful interference, and

(2) This device must accept any interference received, including interference that may cause undesired operation.

The subject device has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

The product generates, uses, and can radiate radio frequency energy and, if not installed and used accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that the interference will not occur in a particular installation. If the product does cause harmful interference to radio or television reception, which can be determined by turning the product on or off, the user is encouraged to try to correct the interference by one or more of the following measures:

- a) Reorient or relocate the receiving antenna;
- b) Increase the separation between the product and the receiver;
- c) Consult the dealer or an experienced radio / TV technician for help.
- d) Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

FCC STATEMENT

Changes or modifications to this product not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

INDIVIDUAL RESULTS MAY VARY. Neither DJO Global, Inc. nor any of its subsidiaries dispense medical advice. The contents of this document do not constitute medical, legal, or any other type of professional advice. Rather, please consult your healthcare professional for information on the courses of treatment, if any, which may be appropriate for you.

CONTACT INFORMATION

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