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Model	Theragun halo	Rev	04

# THERAGUN

# **Rev History**

Modification date	Change description	Rev	Modified by
2021-4-12	Update intended use	3	Team
2021-4-12	Updated language and fixed minor errors	4	Team

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## **1** Recommendation of Use

#### **1.1 Contraindications**

It means that the device is unit for use in certain diseases, conditions, or specific populations.

1) Never use this device over any damaged tissue or other type of skin condition can result in delaying the best medical treatment.

2) Do not use if you have had any facial surgery or other surgical procedure – consult your doctor

- 3) Do not use if you have a history of epilepsy or seizures
- 4) Do not use if you are pregnant

5) Never use the device to the patient with Implant Electronic Devices (such as cardiac pacemaker)

6) The device should not be used in the following areas

- Breast area
- Eye area(circular muscle within the orbital rim)
- Mid-line of neck (bone of neck)
- Groin area

7. The ME EQUIPMENT shall not be serviced or maintained while in use with a PATIENT.

## 1.2 Warnings

The patient is an intended operator. The patient can use and maintain the device and its accessories according to this manual

It's used to identify a hazard that may lead to death or serious injury.

Do not apply over the eyeballs in the stimulation mode, otherwise will damage the eyes.

People with a facial trauma are suggested to consult the doctor before using the Halo device.

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People who have had an aesthetic surgery or had Botox injections should consult the doctor before using, otherwise will cause physical damage.

Do not use if you have had any facial surgery or other surgical procedure – consult with your doctor.

Stop using when you have any discomfort.

Use this device only for its intended use as described in this user manual and avoid causing physical damage.

The device should not be used by children and pregnant women and should be kept out of the reach of children (0 to 12 years old).

This product is not waterproof, only clean with a moist washcloth wipe the device .Don't put the device under water.

Do not apply the device near any devices with Electromagnetic Interference (EMI), such as cell phones, Magnetic Resonance Imaging (MRI), computerized axial tomography (CT), diathermy, Radio Frequency Identification (RFID), etc. or MR environment. EMI, RF devices or MR environment may affect the normal function of the device or would cause user injury.

#### The devise is for single patient use.

For device with micro current stimulation mode:

If you are being treated by a physician, consult with your physician before using this device.

Do not apply the electrodes near the thorax; the application of electrodes near the thorax may increase the risk of cardiac fibrillation.

Do not apply Micro current over your neck because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.

Do not apply microcurrent across your chest because the introduction of electrical current into the chest may cause rhythm disturbances to your heart, which could be lethal.

Do not apply stimulation over painful areas. If you have painful areas, you should consult with your physician before using this device.

Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombosis, varicose veins).

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.

Commented [TP1]: Define "children"

**Commented [JS2]:** Deleted for adult use only. Need to discuss

Simultaneous connection of a user to a high frequency surgical ME equipment may result in burns at the site of the simulator electrodes and possible damage to the simulator.

Operation in close proximity (e.g.0. 1 m) to a shortwave or microwave therapy ME equipment may produce instability in the simulator output.

Do not use the device in the shower.

Do not apply stimulation while sleeping.

Do not use the device on children under 12 years of age.

Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury.

Consult with your physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals.

Apply stimulation only to normal, intact, clean, healthy skin.

## Keep clean in use, store in a dry place, do not expose to the sun

## This appliance contains batteries that are non-replaceable

Avoid the LED light irradiate into your eyes when operate the device with LED ring; Otherwise it will cause eyes injury.

During the light irradiation treatment, close your eyes to avoid the light beam get into your eyes.

FCC compliance statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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

This equipment 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. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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-- Reorient or relocate the receiving antenna.

-- Increase the separation between the equipment and receiver.

-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-- Consult the dealer or an experienced radio/TV technician for help.

FCC Radiation Exposure statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

#### **1.3 Precautions**

It's used to identify a hazard that may result in minor or moderate injury to the user or patient or damage to the equipment or other property

Stop immediately if the device shows any sign of failure.

#### (For micro current stimulation treatment mode)

The long-term effects of electrical stimulation are unknown.

Since the effects of stimulation of the brain are unknown, stimulation should not be applied across your head, and electrodes should not be placed on opposite sides of your head.

The safety of electrical stimulation during pregnancy has not been established.

You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).

If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.

If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.

Use caution if you have a tendency to bleed internally, such as following an injury or fracture.

Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.

Use caution if stimulation is applied over areas of skin that lack normal sensation.

Keep this device out of the reach of children

Use this device only with the accessories recommended by the manufacturer.

This product is not waterproof, only clean with a moist washcloth wipe the device .Don't put device in water, otherwise the device will be damaged.

## **1.4 Adverse Reactions**

1) You may experience headache and other painful sensations during or following the application of electrical stimulation near your eyes and to your head and face.

2) You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin.

## 1.5 Label & Symbols

The following labels and symbols appear on Theragun halo

No.	Symbols	Description
1	CE	CE mark
2	ROHS	the Restriction of Hazardous Substances
3	X	"WEEE (Waste Electrical and Electronic Equipment)". The waste products should be handled legally.
4	IP22	IP Classification: The first number 2: Protected against access to hazardous parts with a finger, and the jointed test finger of 12 mm $\Phi$ , 80 mm length, shall have adequate clearance from hazardous parts, and protected against solid foreign objects of 12.5 mm $\Phi$ and greater.
5		Please read the user manual before use
6	Ŕ	Type BF apply part.
	UK CA	UKCA Mark

## 2.0 Intended Use & Indications for Use

The device provided with 5 operating modes with its individual intended use as below:

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- 1) The EMS mode is indicated for facial stimulation;
- 2) The red light is intended for the treatment of periorbital wrinkles
- 3) The blue light is intended for the treatment of the mild to moderate inflammatory acne
- 4) Red+ IR : Indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.
- 5) Vibration : the mode is intended used for to relax facial muscles

And it is only used for adults.

Target treatment area:

1) Facial stimulation: Both sides of cheek



2) Periorbital wrinkles treatment: Periorbital region



3) Treatment of mild to moderate acne: Both sides of cheek



## **3.0 Device Description**

The Device provided multiple function modes: Vibration, Micro current stimulation mode, LEDs phototherapy mode (Red light, Blue light ,Red +IR). There are Micro current electrodes, Red LEDs, Blue LEDs,Red +IR LEDs. They can be selected by key button of mode.

#### Vibration Feature

Select which vibration attachment you would like and attach. Once attached to the Theragun Halo main device , turn on the vibration feature by short pressing the vibration button once.

To toggle between the 3 speed options (1750, 2100 and 2400 rpm), press the vibration button again.

To stop the vibration, press the vibration button a third times.

#### For Micro current stimulation mode:

The device has two pairs of electrode contacts for facial stimulation by applying an electrical micro current to electrodes, which are attached to the user's facial skin. The output waveform is regulated Voltage of Pulsed Biphasic and provided with 3 steps of output intensity, which can be adjusted by the user.

In this operating mode, the device allows the user to adjust setting output intensity from level 1 to

level 3. You can adjust the intensity according to your feeling and response intensity to muscle contracting.

User can buy the conductive gel individually which are legally sold, to reduce the impedance between the skin and the stimulating device

#### For LEDs photo-therapy function:

The device also can provide specific photon spectrum by LED lamps for Red light irradiation mode and Blue light irradiation mode. There are Red LED lamps and Blue LED lamps assembled in the treatment head. The red light wavelength is 633±10nm and it is intended for the treatment of periorbital wrinkles. The blue light wavelength is 415±10nm and is used for the treatment of acne.

The output wavelength of Red+IR:633  $\pm$  10nm/830nm $\pm$ 10nm is intended for use in the treatment of facial wrinkles

In Red light irradiation mode, the device utilizes Light Emitting Diodes to provide red LED light to the body. The red-light output is a visible light source of high spectral purity. They provide uniform or "hot-

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spot" free illumination. The output is pre-tuned to one wavelength with a narrow spectral bandwidth. The output wavelength of Red is 633±10 at 73 +/-5mW. During the treatment, the user holds the device and place treatment head to the periorbital area.

In Blue light irradiation mode, the device utilizes Light Emitting Diodes to provide blue LED light to the face. The blue light output is a visible light source of high spectral purity. They provide uniform or "hot-spot" free illumination to face skin. The output is pre-tuned to one wavelength with a narrow spectral bandwidth. The output wavelength of blue is 415  $\pm$ 10nm at 50+-5 mW. During the treatment, the user holds the device and place treatment head to the target treatment area with mild or moderate acne.

In Red+Near-infrared mode is intended for use in the treatment of facial wrinkles , The output wavelength of Red+IR:633  $\pm$  10nm/830nm $\pm$ 10nm at 73+/-5 and 55+/-5. During the treatment, Indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

# 3.1 Detachable component List

Detachable component	QTY	Materials	Figure
LED Ring	1	Polycarbonate	
Micro current	1	Polycarbonate+ Steel	

**Commented [TP3]:** Conductive gel was mentioned above. Should be included in the accessory list.

Commented [4R3]: Revised: User can buy the conductive gel individually which are legally sold, to reduce the impedance between the skin and the stimulating device

**Commented [JS5R3]:** Confirm that we can include the MC ring but not the MC gel?



Apply parts are LED Ring, micro current head and vibration massage head.

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# **3.2 Function Introduction**

#### Vibration Mode:

This mode with 3 vibration levels (1750, 2100 and 2400 rpm) are intended used for to relax facial muscles

### LED photo-therapy Mode:

Red light and blue light functional ,and Red +IR mode:

The red light wavelength is 633±10nm and it is intended for the treatment of periorbital wrinkles.

The blue light wavelength is 415±10nm and is for the treatment of mild to moderate acne.

Red +IR wavelength is 633 ± 10nm /830nm±10nm

Choose the red or blue light irradiation or red +IR mode

#### Micro Current stimulation mode:

There are 3 steps of micro current output intensity, intended for facial stimulation and is indicated for over-the-counter aesthetic use.

For the facial stimulation model, the output intensity is gradually increased from the minimum output intensity to obtain a most suitable output intensity.

The user can choose the suitable treatment parameters according to their symptom severity.

# 3.3 How to Operate the Theragun halo

# Using the Theragun halo

Start by washing your face completely and rinse twice to remove all residue. Allow skin to dry completely before starting treatment.

# 3.3.1 Main device with attachment

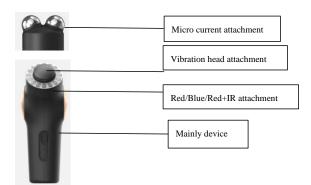


Figure 3-1. Main Device with attachment

# 3.3.2 How to use attach

All attachment was magnetic connection to the device and can be removed by pulling, Use alignment indicator to connect the attachment into the main device

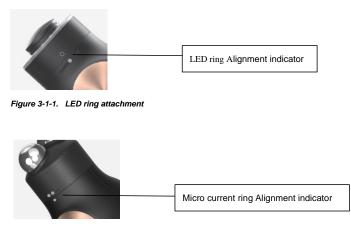


Figure 3-1-2. Micro attachment

	TT 1		
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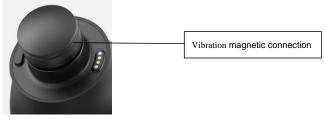


Figure 3-1-3. Vibration attachment

# 3.3.3 Keyboard

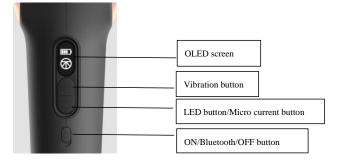


Figure 3-2-1. Control Buttons of Main Device

# 3.3.4 Buttons icon

0	Power slider button
	Vibration button
	Control Button for LED / or control button for Micro current

OLED display
Vibration button level 1
Vibration button level 2
Vibration button level 3
MC button Level 1
MC button Level 2
MC button Level 3
LED Red mode
LED Blue mode
LED Red+IR mode
Battery capacity 100%
Battery capacity 75%

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	Battery capacity 50%
	Battery capacity 25%
*	Bluetooth

Figure 3-3-1. Buttons icon

# 3.3.5 Using Instructions

Haptic feedback = vibration motors stops and moves twice in the period of 1sec to let the user know he/she is supposed to change to a different face region.

Shut-off feature = attachment rings turns off. The device also creates a double haptic feedback to let the user know the treatment is finished.

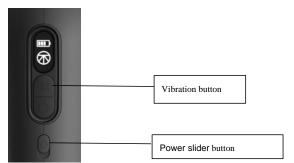
# 1) Vibration mode

1.Connect the vibration head into main device



Figure 3-4-1-1. Vibration attachment

#### 2. How to use vibration attachment



#### Figure 3-4-1-2. control panel

Push the Power slider button up, device power ON, Bluetooth broadcasting

Short press the vibration button one time vibration working on Level I , screen display

Short press vibration button one time, vibration working on Level II , screen display

Short press vibration button one time, vibration working on Level III , screen display

Short press vibration button one time ,vibration stop working , screen display back to main screen

Freestyle mode-no Haptic Feedback or shut off

1 min per face quadrant

4 min per session.

# 2) LED mode (Red/Blue/IR+Red mode)

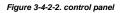
1.Connect the LED ring head into main device



Figure 3-4-2-1. LED ring attachment

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	LED button
0-	Power slider button



Push the Power slider button up, device power ON, Bluetooth broadcasting

Short press LED ring button one time, LED ring working on RED LED mode , screen display

Short press LED ring button again,LED ring working on BLUE LED mode , screen display , and LED ring light up in blue dimly means LED ring ready , LED light up in blue when LED ring touch face skin during working.

Short press LED ring button again, LED ring working on RED+IR , screen display , and LED ring light up in purple dimly , means LED ring ready , LED light Red+IR light up red when LED ring touch face skin during working.

Short press LED ring button once again , LED ring stop working , screen display back to main screen

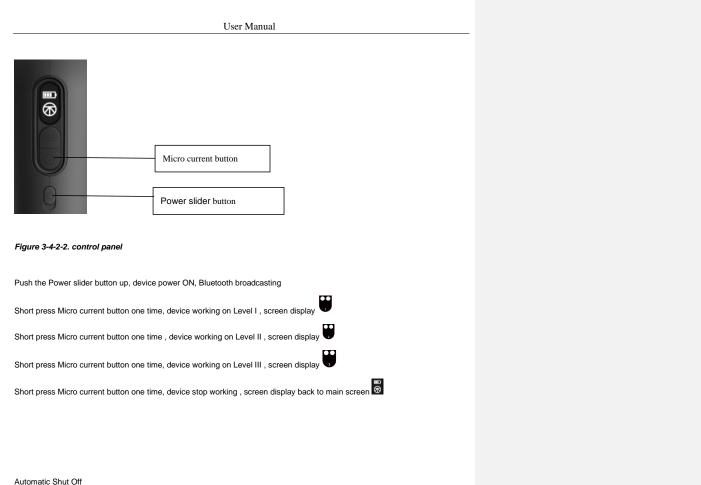
LED Treat time 2 min per face quadrant 8 min per session 2 times per week for 6 weeks Haptic feedback every 2 min, shut of at 8 min

# 3) Micro current mode

1.Connect the micro current into main device



Figure 3-4-2-1. micro current attachment



the device will automatically shut off after using 8 minutes.

Commented [16]: add

# 3.3.6 APP instructions (ISO/Android)

The App must be open on your phone in order to establish a connection with the device Bluetooth  ${\rm I\!R}$  must be turned ON on your smart phone

# **1Permission setting**

After the app is installed, you need to set the permissions manually when you start the app for the first time. (skip this step if it is not started for the first time).

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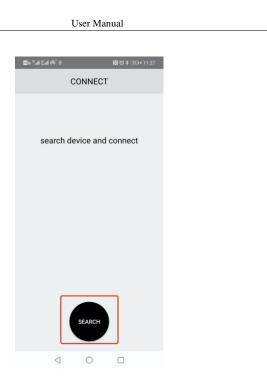
(Bluetooth permission, location permission, storage permission)

CONNECT	CONNECT	
search device and connect	search device and connect	
1 of 2	2 of 2	
Halo requires the Your location permission. Allow access?	Halo requires the Storage permission. Allow access?	Turn on Bluetooth
Never ask again after denying permission	Never ask again after denying permission	Halo is trying to turn on Bluetooth. Allow?
DENY ALLOW	DENY ALLOW	RESTRICT ALLOW

**Commented [JS7]:** Why do we ask for location permissions? Is that in the current app?

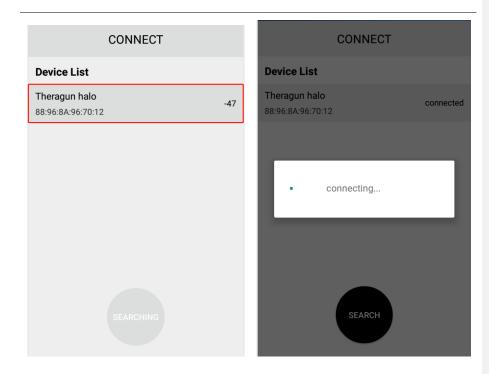
# 2 search and connect Bluetooth devices

1) Open the app and hardware device, and click the search button to scan devices



2) After scanning the device, Click device name (Theragun halo) to connect the device.

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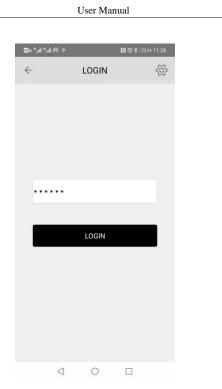


3) After the Bluetooth connection is successful, Will automatically jump to the next page. the device screen shows the following figure.



# 3 pin login

For security, after entering the connection, you need to enter the pin for verification. After the verification is successful, you can enter the device control page (the default pin of the device is **123456**);



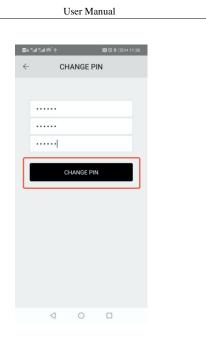
After pin login, enter the device control page. When connecting the device for the first time, the user is strongly required to modify the default pin.

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1 ) click setting in the upper right corner, and then click "**change pin**" to modify the password.

		Word.		ilie	⊚ <sup>1</sup> ∳		₨ぷ% \$35+11:30
				$\leftarrow$		SETTING	
				Change Pin	]		>
$\leftarrow$	Therag	gun halo	ද්වු	Version	,		V1.0.5
Motor Set	LO	Actual Speed	0 RPM				
Battery	19%	Version:	V0.1.7				
SPEED SET							
OFF		L1	L2				
L3							
					$\triangleleft$	0	

2 ) input old & new pin (Pin is a six digit number).



3 ) After the password is successfully modified, you need to enter a new password to continue using app;

÷ <sup>(</sup> @ In. <sup>2</sup> III. <sup>2</sup> a		🕅 10 🗚 💷 + 11:28
$\leftarrow$	LOGIN	\\\\? \\\?
	LOGIN	
$\triangleleft$	0	

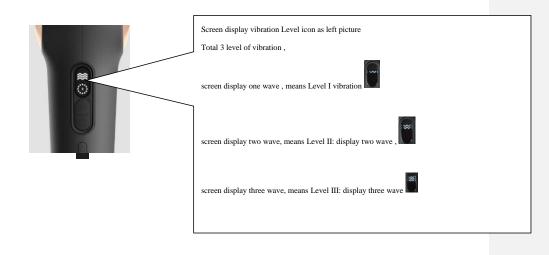
# 4 device control

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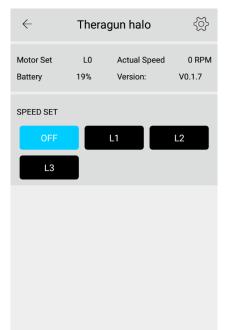
## a Vibration module

1) Click L1 / L2 / L3 to set the vibration level

Motor Set L1 Actual Speed 0 RPM   Battery 19% Version: V0.1.7     SPEED SET     OFF   L1     SPEED SET     SPEED SE	$\leftarrow$	Thera	gun halo	\l] \	$\leftarrow$	Thera	agun halo	<u>ج</u>	$\leftarrow$	The	eragun halo	\l] \
OFF L1 L2 OFF L1 L2 OFF L1 L2												
	OFF		LI C	L2	OFF		1	L2	0	FF	1	L2



# 2) Click "off" to stop the vibration.



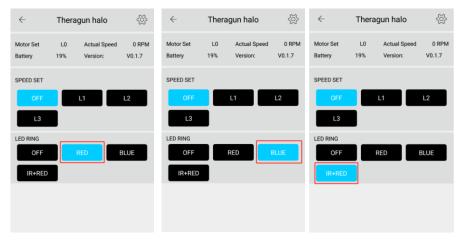
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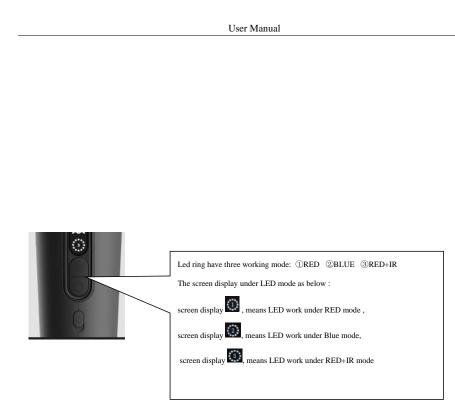
# b. Led beauty lamp module

1) Remove the vibration head and to install the LED ring attachment onto the main device, and the app interface will automatically display the LED lamp control module.



2) Click the corresponding button to set different light color modes, The device screen shows the corresponding gears.





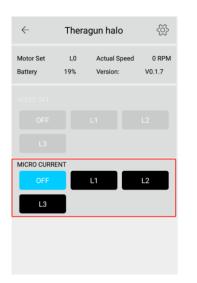
2) click off in the LED module, the LED beauty lamp will be off and stop working;



## C Micro current module

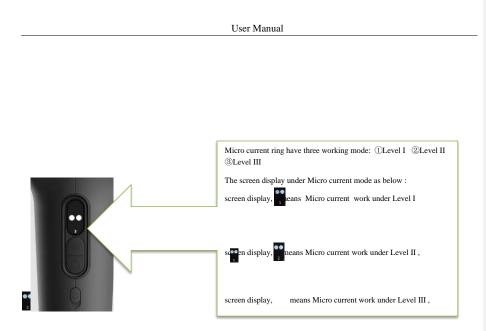
Remove the LEDs attachment and to Install the micro current attachment to the main device, and the app interface will automatically display the micro current control module. (Note: and the motor can not be operated at this time);

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Click L1 / L2 / L3 in the micro current module to set different current gears; The device screen shows the corresponding gears.

$\leftarrow$	Thera	agun halo	 	$\leftarrow$	Ther	agun halo	 	$\leftarrow$	Thera	agun halo	<u>ح</u> ک
Motor Set Battery	L0 19%	Actual Speed Version:	0 RPM V0.1.7	Motor Set Battery	L0 19%	Actual Speed Version:	0 RPM V0.1.7	Motor Set Battery	L0 19%	Actual Speed Version:	0 RPM V0.1.7
MICRO CURRE		LI	L2	MICRO CURRE		L1	L2	MICRO CURRE		L1	L2
L3				L3				L3			LZ



# click off in the micro current module to stop the micro current;



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4. Product specification

Basic Unit Character	ristics		
Power Source	Battery operated		
Indicator Light	YES		
Housing Materials	PC		
	Firmware: V0.1.8		
Software vision	App IOS: V1.0.13		
	APP Android: V1.0.9		Commented [18]: Add vision
Battery operation time	180min		
product warrenty	2 years		
Additional Features			
Environment for	Temperature: 5 ~ 33° C		
operation	Relative humidity: <95% RH		
Environment for	Temperature: -10° C ~ 50° C		
storage	Relative humidity: 10~95% RH		
Use atmospheric pressure	70-106Kpa		

For Micro current stimulation mode:

Number of modes	1
Output Intensity Level	3
Indicator Light	Yes,OLED display
Housing Materials	Console: PC plastic
Output Specification	
Waveform	Pulsed Biphasic
Operating voltage	6V~8.4V
Maximum power	24mW
Automatic shut-down	Yes
Maximum Output	

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Voltage(+/- 10%)	1.0V @ 2k Ohm
Maximum Output Current	500 uA @ 2k Ohm
	JOU UA @ 2K OIIII
Pulse Width	On 60ms / Off 60ms
Frequency	8.3Hz
Net Charge	0uC@ 500 Ω
Maximum Current Density	0.2mA/cm <sup>2</sup> @500Ω
Maximum Power Density	23.1uW/cm <sup>2</sup> @500Ω

# For LEDs therapy

(m\///om2)	Red light: 94±5 mW/cm2 Bule light: 65±5 mW/ <mark>cm2</mark> Red/IR: 94±5 / 55±5 mW/cm2	Commented [19]: Updated
SHORT WAVELENGTH	Red light: 645 nm Bule light: 411 nm IR: 815 nm	
the output of the product is checked before each start up for treatment and that the method of checking is	Before using the LED ring, please check it for normal operation. The main device of the product is started up, making it enter the three kinds of light working position. When the LEDs are observed by visual observation, the outputs of light are judged to be norma	

## For Vibration mode:

Vibration	1750, 2100 and 2400 rpm		
Frequency	1750rpm :29.1Hz 2100rpm:35Hz 2400rpm:40Hz		

## 4.1 Switch off the device

Press the ON/OFF Button again to switch the device off and all the indicator lights will be off.

## 5.0 Maintenance

The following maintenance instructions are important to ensure that your device continues to work as it was designed. Failure to follow these instructions may cause your device to stop delivering the required dose or to stop working altogether.

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Note:

This product is for personal use only.Only clean with a moist washcloth wipe the device . Don't put the device in water .

Do not touch any corrosive solution, otherwise it will damage the appearance and function.

- Storage the device in a cool and dry place (Temperature: -10°C  $\sim$  50°C Relative humidity: 10~95% RH) .

The device can work normally immediately after it is taken from the highest or lowest storage environment.

# 5.1 Trouble Shooting

In the event that the device fails to perform as intended, the following notes will help to identify potential problems with the device and its setup.

Problem	Solution	
Device turns off automatically	Maybe reach the set time or low power	
Device cannot turn on	Maybe battery is in low power and you should recharge batteries	
Device shuts off in mid-treatment or only after few treatments	Check and recharge batteries.	
Cannot charge battery	Check if the adapter output connector insert into the charging port in the device firmly	

If the device breaks or quits working, and you cannot fix the problem, please contact us.

# 5.2 Disposal of Electrical and Electronic Equipment Waste (E-waste)

Disposal information for e-waste depends on the city you are in, as all regulations are local, to learn about recycling or disposal programs in your area search "E-waste recycling or disposal" online.

You can also contact your city directly or look into your local electronics store policy.

## 6.0 Service

Operation Instruction of has no parts you can fix. Do not try to repair it. If the requires service, please contact the selling retailer. All returned units to the manufacturer for repair, including Warranty repair and Out-Of-Warranty repair, must include the following:

During Warranty Period with proof of Purchase (store receipt)

RMA Number: Should your product become defective during the warranty period, call our service center or contact your retailer

Package the item securely and return it prepaid/insured – along with proof of purchase to:

Theragun, Inc.

6100 Wilshire Blvd. Suite 200 Los Angeles, CA 90048-5107, USA

To insure prompt repair, provide complete, legible name, address and phone number information, RMA number and a note indicating the nature of the product defect and a copy of the original invoice issued for purchase of the unit. We will Repair or Replace (at our sole discretion) product at no charge. Ship unit to the manufacturer in the original container with all detachable component and information as required above.

## 7.0 Safety, EMC & Bio-compatibility

This device is Class II equipment with type BF applied part. It complies with Medical Electrical Safety Standards (IEC 60601-1).

This device is also complied with Medical EMC Standard (IEC 60601-1-2).

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All the user directly contracting materials for main device housing and output contacts in this device are bio-compatible for its intended use. They are complied with bio compatibility standards ISO 10993-5 (Cytotoxicity) and ISO 10993-10 (Irritation and Sensitization).

The has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical device to IEC 60601-1-2: 2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

## CAUTION:

Do not apply the device near any devices with Electromagnetic Interference (EMI), such as cell phones, Magnetic Resonance Imaging (MRI), computerized axial tomography (CT), diathermy, Radio Frequency Identification (RFID), etc. or MR environment. EMI, RF devices or MR environment may affect the normal function of the device or would cause user injury.

Manufacturer's declaration - electromagnetic immunity

1\* WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally."

2\* WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

3\* WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

## Table 1

declaration - electromagnetic emission		
Emissions test	Compliance	
RF emissions	Group 1	
CISPR 11		
RF emissions	Class B	
CISPR 11		
Harmonic emissions	Not applicable	
IEC 61000-3-2		
Voltage fluctuations/	Not applicable	
flicker emissions		
IEC 61000-3-3		

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		Table 2
	declaration - e	lectromagnetic immunity
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable
Surge IEC 61000-4-5	$\pm$ 0.5kV, $\pm$ 1 kV line(s) to lines $\pm$ 0.5kV, $\pm$ 1 kV, $\pm$ 2 kV line(s) to earth	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: UT is the a	a.c. mains voltage prior to a	pplication of the test level.

	declaration - electromagnetic immunity			
Immunity test	IEC 60601 test level	Compliance level		
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	Not applicable		
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m		

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decla	ration - IMML	JNITY to proxim	ity fields from	RF wireless co	mmunications equipment
Immunity test		IEC60601 1		Compliance level	
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF IEC	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m
61000-4-3	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz	**Pulse	0.2 W	9 V/m	9 V/m
	745 MHz	Modulation: 217Hz			
	780 MHz				
	810 MHz	**Pulse	2 W	28 V/m	28 V/m
9: 17 18 19 24	870 MHz	Modulation: 18Hz			
	930 MHz				
	1720 MHz	**Pulse	2 W	28 V/m	28 V/m
	1845 MHz	Modulation: 217Hz			
	1970 MHz				
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	5240 MHz	**Pulse	0.2 W	9 V/m	9 V/m
	5500 MHz	Modulation: 217Hz			
	5785 MHz				

Note\*\* - The carrier shall be modulated using a 50 % duty cycle square wave signal.

Manufacturer Information

Theragun, Inc.



6100 Wilshire Blvd. Suite 200 Los Angeles, CA 90048-5107,USA

## 8. LIMITED WARRANTY

For full warranty information, please visit www.therabody.com/warranty. To request a copy of the warranty by mail, you may send a request to the following address:

Therabody - Warranty

Attn: Customer Service

3003 W. Olympic Blvd., Suite 106-140

Los Angeles, CA 90006

Please note, this is not a return address or a retail location. No Theragun Products or packages will be accepted at this location.