

Table of Contents		
lable of contents		
1 Book of Constitution		
1. Product Specifications		
1.1 Device information		1
1.2 Intended use		2
1.2.1 Transcutaneous nerve stimulation	on	2
1.2.2 Electrical muscle stimulation		2
1.2.3 Impedance plethysmograph		2
1.2.4 Galvanic skin response		2
1.3 Contraindications		3
1.4 Precautions		4
1.5 Device summary description		4
1.6 Signs and symbols		5
1.7 Replacement parts and accessories		6
1.7.1 Electrodes		6
1.7.2 Connection cable		6
1.7.3 Other accessories		6
1.8 Contact information		6
2.General instructions		7
2.1 Buttons		7
2.2 Display		7
2.3 Device appearance		•
2.4 Initial notes on use		8
2.5 Starting applications		8
2.6 Cleaning, storage and disposal		9
3.Functions		9
3.1 TENS/EMS current parameter		10

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Table of Contents	
3.2 TENS/EMS auto (programmed) n	node11
3.3 TENS/EMS manual mode	12
3.4 Body analyzer	12
3.5 Alarms and problem solutions	13
3.6.1 Blue light	1 4
3.6.2 Orange light	1 4
3.6.3 Green light	14
3.6.4 Reset the machine	1 4
4.Warranty and service	15
5. Electromagnetic compatibility info	ormation 16
6.Federal Communications Com	
(FCC) Statement	

## 1.Product Specifications 1.1 Device information

Trade name WeHeal smart transcutaneous electrical nerve stimulation & body analyzer.

TS200 Model

Monophasic or biphasic rectangular pulse Output waveform

Pulse length/ frequency  $40 - 800 \mu s / 1 - 200 Hz$ 

Output voltage/ current Max. 50 V / 90 mA (500 ohm)

Power specification DC 5V=== 0.5A Lithium-ion battery (2100 mAh)

Adjustable from 1 to 60 minutes Treatment time

Adjustable from 1 to 50 Intensity

Bluetooth **BLE 4.0** 

Operating conditions  $10^{\circ}\text{C} - 40^{\circ}\text{C}$  (50°F – 104°F) at a relative humidity of 30 – 85%

Storage/Transport conditions 5°C -40°C (41 °F - 104 °F) at a relative humidity of 10% - 85 %

Use range atmospheric 700 - 1060 hPa / 3000 m pressure/ altitude limit

Galvanic skin response Measuring the skin resistance at 100Hz

BIA (bioelectrical Operating at 50 KHz or 100 KHz impedance analysis)

Software version MCU v3.4/ BLE v2.9

This device complies with standards IEC 60601-2-10 , ANSI/AAMI NS42013 , IEC 60601-1-6 , ISO 14971 , IEC 62304 , IEC 60601-1-6 , IEC 60601-1-11 , IEC 60001-1-8 , EN 301482-17 , EN 301482-17 , EN 300328 , ENIEC 60601-1 and EN IEC 60601-1-2 , and is subject to special recautionary measures with regard to electromagnetic compatibility. Please note that protaids and mobile HF communication systems with interference of the protain and mobile HF communication systems.

The serial number is located on the device. We reserve the right to make changes to improve and develop the product. More details can be requested from the stated Customer Services address on the device. Note: If the device is not used according to the instructions specified, perfect functionality cannot be guaranteed!

# 1.Product Specifications 1.2 Intended use

TENS- transcutaneous nerve stimulation	symptomatic relief of neuro-muscular pain, chronic intractable pain, and post traumatic and post-surgical pain.

Improvement and facilitation of muscle performance, relaxation of muscle spasm, increasing local blood circulation, prevention EMS- electrical muscle or retardation of disuse atrophy, and maintaining or increase stimulation range of motion.

Use bioelectrical impedance analysis (BIA) technology to Impedance determine and estimate body composition, including body fat, plethysmograph body water percentage, body muscle mass, bone mass, and visceral fat rating.

measurement of skin resistance. The device is not intended for Galvanic skin response use in any diagnosis.

# 1.Product Specifications 1.3 Contraindications

The device is not a substitute for medical consultation and treatment. Consult your doctor first if you are experiencing any pain or are suffering from a chronic illness such as cancer, diabetes, high blood pressure, and blood coagulation/thrombo-embolic diseases. To avoid damage to health, we strongly advise against using the We Heal Smart TENS & body analyzer in the following situations:

- Do not use this device if you have a cardiac pacemaker, known cardiac arrhythmias or heart disorders, the implanted defibrillator, or other implanted metallic or electronic device. Do not place the stimulation electrodes on the front ribcage near to the heart. Such use could cause electric shock, ventricular fibrillation, and induce cardiac arrest or death.
- Do not use this device if you have high temperature (> 38°C), seizure disorder, on the injured or irritated skin, or if you are pregnant.
- Do not use this device in humid environments (e.g. in the bathroom), when bathing or showering, or after consuming alcohol.
- Do not place the electrodes on the neck/carotid artery area, genital area, skeletal skull structure, or around the eyes, mouth, throat or larynx. The stimulation should not be applied across or through the head or the heart.
- Do not use by children or people with restricted physical, sensory (e.g. reduced sensitivity to pain) or mental skills or a lack of experience and/or lack of knowledge, unless they are supervised by a person who is responsible for their safety or are instructed by such a person in how to use the device. Keep the device away from children.
- Do not use the device if the device is damaged. Do not drop or disassemble the device. Do not attempt to open and/ or repair the device yourself. Failure to comply will result in voiding of the warranty. The manufacturer is not liable for damage resulting from improper or careless use. Contact your retailer or the customer services if the device is damaged.

# 1.Product Specifications

## 1.4 Precautions

- Do not expose the device to direct sunlight or high temperatures.
- Keep the device away from sources of heat and do not use it close (approx. 1 m) to shortwave or mobile phones, as doing so can result in unpleasant current peaks.
- Ensure that no metallic objects or high-frequency surgical devices are in contact with the electrodes during stimulation, which could result in electrical burns.
- Do not use the device more than 1 hour, which could result in electrical burns.
- The treatment effect can be affected by the physical, mental and medical conditions of the user
- Do not modify electrodes (e.g. by cutting or change it's shape). This may increase the current intensity, which is potentially hazardous, an effective current intensity beyond 2 mA/cm<sup>2</sup> requires increased awareness.

# 1.5 Device summary description

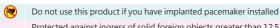
The WeHeal smart TENS & body analyzer is a combination of TENS/EMS unit, galvanic skin response unit, and impedance plethysmograph unit. It is powered by rechargeable lithium-ion battery which is permanently built into the main unit. This device can work independently or receive remote control signals through Bluetooth module. The correspondent App for Android oriOS system can remote control the functions of this device.

The TENS/EMS unit delivers nerve or muscle stimulation by applying an electrical current to electrodes, which are attached on the patient's skin. The output waveform, pulse length/frequency, treatment time, and intensity are adjustable according to the intended treatment of patient. The stimulator has 2 output channels, accessed through jacks at the top of the housing, so that it may stimulate either 2 or 4 electrodes simultaneously.

The galvanic skin response and impedance plethysmograph units measure skin resistance and estimate body composition by bioelectrical impedance analysis (BIA) technology with a low, safe, electrical current.

# 1. Product Specifications

1.6 Signs and symbols



Protected against ingress of solid foreign objects greater than 12.5 mm **TP22** in diameter. Protected against drops of water falling at up to 15° from vertical

SN Serial number

Read the instructions before use

Ϊ́λ Electrodes as the applied part, type BF

Manufacturer

Class II symbol

Disposal in accordance with the Waste Electrical and Electronic Equipment EC Directive – WEEE

# 1.Product Specifications 1.7 Replacement parts and accessories

### 1.7.1 Electrodes:

Adhesive electrodes (small) Ø35mm x 2sets (4pcs); adhesive electrodes (Big)  $97x47mm \times 1set$  (4pcs).

- At distances below 5 cm, the unit primarily stimulates surface structures intensively. Greater distances (>15 cm) between electrodes mean a larger tissue volume is stimulated, but less intensively. Consequently, you must increase the impulse intensity.
- Clean the skin prior to any application; do not use skincare lotions or oils prior to treatment.
- To ensure that the adhesive electrodes remain adhesive for as long as possible, clean them carefully with a damp, lint-free cloth or clean the underside of the electrodes under lukewarm, running water and pat dry with a lint-free cloth.
- Replace the electrodes if they still do not adhere securely after cleaning the electrodes. You can obtain the replacement electrodes directly from customer services.
- Electrodes item numbers: GMP 001357
- 1.7.2Connection cable: The black head of the connection cable is the negative pole of the wire, and the white head is the positive pole of the wire.
- 1.7.3Other accessories : USB charging cord x 1; soft shell package x 1.
- 1.7.4Recommended adaptor:

1.8 Contact information

Manufacturer: We Heal Biotechnology Co.

Address: 9F., No. 205, Minsheng 2nd Rd., Chyan Jin Dist.,
Kaohsiung City 801, Taiwan (R.O.C.)
Phone: +88672216313
Website: www.weheal.com
Email: service@weheal.com.tw

# 2.General instructions

### 2.1 Buttons



ON/OFF button: Press 1 sec to turn on and 3 secs to turn off

ENTER button: START/PAUSE button

**BACK** button

Shift button: switch the display of treatment setting

Setting button: choose left or right, increasing or decreasing the frequency, impulse width, and working time

## 2.2 Display



- 1. Electrode positioning indicator
- 2. Impulse waveform
- 3. Number display
- Display for impedance and resistance (KΩ), frequency (Hz), pulse width (%) and timer
- 5. Impulse intensity
- 6. Battery level display
- 7. Auto (programmed) mode
- 8. Manual mode
- 9. Body analyzer

## 2.General instructions 2.3 Device appearance



### warning light

Dimensions: 121 x 60 x 28 mm Weight: 134.2a Color: Black or pink



### The socket for the connection cables.

The socket for the USB charging cord.

## 2.4 Initial notes on use

- Connect the connection cables with the electrodes.
- Guide the connection cable plugs into the socket on the top of the device. Do not pull, twist or make sharp bends in the cables.
- If the battery level is low, charge this device with the USB charging cord and the corresponding adaptors
  - (HPU15-102-P88D101, Input Voltage:100 240 Vac, 47-63 Hz, 0.2-0.4A; Output Voltage: 5Vdc/2.4A (max), 12W. Make sure the voltage of the power source is correct before connecting the equipment to the power outlet.
- When this device is charging, the blue light is on and this device cannot be used for any applications. When charging is finished, unplug the charging cord and adaptor to disconnect the device from Mains supply.
- Do not charge the device on the place where it is difficult to disconnect the device!

# 2.General instructions

# 2.5 Starting applications



Step 1 Pressure the ON/OFF button to switch on the device.



Step 2 Use the >/< button to navigate through the @/ 63 / R modes and press the ENTER button to confirm your selection.



### Cleaning the device

Please turn off the device while cleaning the device. Clean the device after use with a soft, slightly damp cloth. If it is very dirty, you can also moisten the cloth with a mild soapy solution. Ensure that no water enters the device. Do not use any chemical or abrasive cleaning agents.

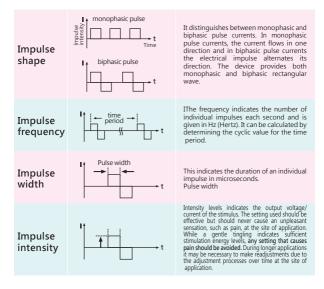
### Storage

Do not make sharp bends in the connection cables and electrodes. Disconnect the connection cables from the electrodes. Reapply the electrodes to the carrier foil after use. Store the device and accessories in a cool, well-ventilated space, Never place any heavy objects on the device.

### Disposal

For environmental reasons, do not dispose of the device in the household waste at the end of its useful life. Dispose of the unit at a suitable local collection or recycling point. Dispose of the device in accordance with EC Directive - WEEE (Waste Electrical and Electronic Equipment). If you have any questions, please contact the local authorities responsible for waste disposal.

# 3.1 TENS/EMS current parameter



## 3.2 TENS/EMS auto (programmed) mode 3 Functions

Step 1 The digital EMS/TENS unit features a total of 15 programs. Use the >/< setting buttons to select the program number you want and press the ENTER button to confirm your selection.

Step 2 You can set the impulse intensity of both channels in all programs.

### Program table:

No.	Mode	Area of application, indications
1	TENS	Pain relief in shoulder, back and ankle
2	EMS	Strengthening abdomen and back muscles
3	MASSAGE	Tapping massage
No.	Mode	Area of application, indications
4	TENS	Chronic pain in low back
5	TENS	Pain in back, buttock, thigh
6	TENS	Pain relief
7	TENS	Pain relief
8	EMS	Shaping the muscle
9	EMS	Tightening the muscle
10	MASSAGE	Tapping massage
11	TENS	Pain relief
12	TENS	Pain relief
13	MASSAGE	Relaxing massage
14	TENS	Pain relief
15	TENS	Pain relief

You can apply the program on the discomfort position except the contraindicated area (section 1.4

## 3.Functions 3.3 TENS/EMS manual mode

Step 1	Place the electrodes on the desired area for treatment. Choose the waveform.
Step I	indee the electrodes on the desired area for treatment, enouge the waveform.

- Step 2 Set the impulse frequency between 1 to 200 Hz.
- Step 3 Set the impulse width between 1%-20% (40-800 µs).
- Step 4 Set the timer. Adjust the impulse intensity.

# 3.4 Body analyzer (galvanic skin response and BIA)

Program No.	Indications
1	Measure skin conductance (galvanic response)
2	Estimate body fat, body water percentage by bioelectrical impedance analysis
3	Estimate body muscle mass, bone mass, and visceral fat rating by bioelectrical impedance analysis

# 3.Functions 3.5 Positioning of electrodes



## 3.Functions

- App instruction
   Visit www.weheal.com for further additional information and instruction.
- 3.6.1 Blue light It represents that this device is charging.
- 3.6.2 Orange light It represents that at least one of the electrodes are not adhered to the body. Please adhere the electrodes to the body.
- 3.6.3 Green light It represents the device is in connection with correspondent Apps.
- 3.6.4 (Reset the machine) If the device is not work, press > and (11) simultaneously for 5 secs, the device will return to default status.

  Contact customer service if you cannot reset the machine.

# 4. Warranty and service

In case of a claim under the warranty please contact your local dealer or the local representation. In case of returning the unit please add a copy of your receipt and a short report of the defect.

The following warranty terms shall apply:

- The warranty period for this product is 3 years warranty period from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
- This product does not need regular verification. Repairs (complete unit or parts of the unit) do not extend the warranty period.
- The warranty shall not be valid for damages because of the following reasons:
  - (1) improper use, e.g. not follow the user instructions
  - (2) repairs or tampering by the customer or unauthorized third parties
  - (3) transport from the manufacturer to the consumer or during transport to the service center.
  - (4) The warranty shall not be valid for accessories which are subject to normal wear and tear
  - (5) Liability for direct or indirect consequential losses caused by the unit are excluded even if the damage to the unit is accepted as a warranty claim.

Local dealer/ retailer			
	Purchase Date:	 	

# 5.Electromagnetic compatibility information

## ${\it Table 1. Guidance and manufacturer' s declaration-electromagnetic emissions}$

The TS200 is intended for use in the electromagnetic environment specified below. The customer or the user of the TS200 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance		
RF emissions CISPR 11	Group 1	The TS200 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 emissions CISPR 11	Class B	The TS200 is suitable for use in all		
Harmonic emissions IEC 61000-3-2	Class A	establishments, including domestic establishments and those directly connected to the public low-voltage		
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	power supply network that supplies buildings used for domestic purposes.		

# 5. Electromagnetic compatibility information

### Table 2. Guidance and manufacturer's declaration – electromagnetic immunity

The TS200 is intended for use in the electromagnetic environment specified below. The customer or the user of the TS200 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	Contact:±8 kV Air:±2 kV,±4 kV,±8 kV, ±15 kV	Contact:±8 kV Air:±2 kV,±4 kV, ±8 kV,±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	+ 2kV for power supply lines + 1kV for input/output lines		Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	+ 0.5kV, +1kV line(s) to line(s)		Mains power quality should be that of a typical home healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 25/30 cycles Voltage interruptions: 0 % UT; 250/300 cycle	Voltage dips: Not applicable Not applicable Not applicable Voltage interruptions: Not applicable	Mains power quality should be that of a typical home healthcare environment. If the user of the TS200 requires continued operation during power mains interruptions, it is recommended that the TS200 be powered from an uninterruptible power supply or a battery.
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	The TS200 power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

# 5. Electromagnetic compatibility information

### Table 3. Guidance and manufacturer's declaration – electromagnetic immunity

The TS200 is intended for use in the electromagnetic environment specified below. The customer or the user of the TS200 should assure that it is used in such an environment.

### Immunity test IEC 60601 test level IEC 60601 test level Electromagnetic environment – guidance

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
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Radiated RF 10 V/m 80 MHz – 2,7 GHz 15C 61000-4-3 80 % AM at 1 kHz 80 % AM

Portable and mobile RF communications equipment should be used no closer to any part of the TS200, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

### Recommended separation distance:

 $\begin{array}{l} d=1,2\,\sqrt{p}\\ d=1,2\,\sqrt{p} & 80~\text{MHz to }800~\text{MHz}\\ d=2,3\,\sqrt{p} & 800~\text{MHz to }2,7~\text{GHz}\\ \text{where }P\text{is the maximum output power rating of the} \end{array}$ 

transmitter in watts (W) according to the transmitter manufacturer and of is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as

rieio 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: ((2))

### 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.

at 1 kHz

<sup>•</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and Fix radio broadcast and IV 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 TS200 is used be exceeds the applicable RF compliance level above, the TS200 should be observed to verify not provide the TS200 is used to be observed to verify not provide provided to the transmission of the TS200 should be observed to verify not provided to the TS200 should be observed to verify not provided to the TS200 should be observed to verify not provided to the TS200 should be observed to verify not provided to the TS200 should be observed to verify not provided to the TS200 should be observed to verify not provided to the TS200 should be observed to verify not provided to the TS200 should be observed to verify not provided to the TS200 should be observed to verify not provided to the TS200 should be observed to verify not provided to the TS200 should be observed to verify not provided to the TS200 should be observed to verify not provided to the TS200 should be observed to verify not provided to the TS200 should be observed to verify not provided to the TS200 should be applied to the TS200 should be appli

# 5.Electromagnetic compatibility information

### Table 4. Recommended separation distances between portable and mobile RF communications equipment and the TS200

The TS200 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TS200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TS200 as recommended below, according to the maximum output power of the communications equipment.

Dated and an arrival	Separation distance according to frequency of transmitter m				
Rated maximum output power of transmitter W	50 kHz to 80 MHz d = 1,2 √P	80 MHz to 800 MHz d = $1.2\sqrt{P}$	800 MHz to 2,5 GHz d = 2,3√P		
0,01	N/A	0,12	0,23		
0,1	N/A	0,38	0,73		
1	N/A	1,2	2,3		
10	N/A	3,8	7,3		
100	N/A	12	23		

For transmitters rated at a maximum output power 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.

 ${\bf NOTE~1~At~80~MHz}$  and  ${\bf 800~MHz}$ , 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.

# 5.Electromagnetic compatibility information

Manufacturer's declaration-electromagnetic immunity
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment
The TS200 is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the TS200 should assure that it is used in such an environment.

Test frequency (MHz)	Band <sup>a)</sup> (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home healthcare)
385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
1 720 1 845 1 970	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
2 450	2 400 - 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240 5 500 5 785	5 100 - 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EOUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

For some services, only the uplink frequencies are included.
 Fro carrier shall be modulated using a 50 % duty cycle square wave signal.
 As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

# 6.Federal Communications Commission (FCC) Statement

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:

- 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.

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 of the device.
- RF Exposure Warning!

This device contains transmitters and receivers which emit Radio Frequency (RF) energy. The device is designed to comply with the limits for exposure to RF energy set by the Federal Communications Commission (FCC) of the United States, Industry Canada (IC) of Canada, and the regulating entities of other countries.



## Manufacturer: We Heal Biotechnology Co.

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