Dr.MUSIC 3s
(Model: DM-VME03S)

User's Manual

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Manual status: SMD-IFUE-DMV-001 (ver. 0), **Date of preparation:** 16/03/15

About this manual

- Read and understand all instruction in this manual before attempting to use the Device.
- SmartMedicalDevice Co., Ltd. shall not be liable for any incidental, or consequential damages that occurred by not complying with the content of the User's Manual.
- Assist user in the safe and effective operation of the product.
- Explains procedures for the product setup, control and function.
- Keep this manual with the product.
- Content of this manual may be changed or improved.
- All references to standards / regulations and their revisions are valid for the time of publication of this instruction for use.
- The screen graphics and illustrations in this manual are for illustrative purposes only and may be different from what is displayed on the screen or device.

Conventions

Throughout the text in these instructions for use, warnings and other information essential when using this unit, such as cautionary or prohibited items, appear classified as per the following.

Mark	Description
WARNING	Warning indicates a hazardous situation which, if not avoid, may result in death or serious injury.
CAUTION	Caution indicates a hazardous situation which, if not a avoided, may result in minor or moderate injury.

Symbol

Symbol	Description / Function	Reference
	Refer to instruction manual/ booklet.	ISO 7010:2012-M002
	General prohibition sign	ISO 7010:2012-P001
	EU-Warning: This symbol indicates hazard. If not avoided, the hazard can result death or serious injury.	ISO 7010:2012-W001
	EU- Caution: This symbol indicates hazard. Minor personal injury or product damage.	ISO 7000:2014
	No access for people with active implanted cardiac devices.	ISO 7010-P007
IP22	This symbol on the device means: Protected against solid foreign objects of 12,5 mm φand greater and against vertically falling water drops when tilted up to 15 degrees.	IEC60529
	Manufacturer information: This symbol is followed by the name and address of the device manufacturer.	ISO 15223-1:2012
	Manufacture Date: This symbol is followed by the device manufacture date in the form YYYY-MM.	ISO 15223-1:2012
SN	Serial Number: This symbol is followed by the device serial number.	ISO 15223-1:2012
CE	This symbol means: Conforms to EC Directives. CE stands for 'Conformité Européenne'.	-
EC REP	Authorized representative in the European community.	EN ISO 15223-1:2012
	Electrical protection: Insulated patient application(TYPE BF)	IEC 60417-1:2002
	EU-Electronics and Battery Disposal Information: This symbol means that the product and battery should be recycled separately from household waste."	-
	"ON/OFF" (power)	IEC 60417-1:2002

	Direct current	IEC 60417-1:2002
	This symbol means that this device emits non-ionising radiation.	-
	This is the battery symbol. It appears next to the battery indicator.	-
	Bluetooth	-

This device conforms to the following international standards:

- IEC 60601-1:2012 Electrical medical equipment
- IEC 60601-1-2:2014 Electromagnetic compatibility
- IEC 60601-1-6:2013& IEC 62366:2014 Usability safety
- IEC 60601-1-11:2010 Home Healthcare Environment
- IEC 60601-2-10:2012 Nerve and muscle stimulators
- IEC 62304:2006 Software life cycle processes

Contents

Chapter 1.

Safety Information

1. Safety Information

1.1. Contraindications

 Never use this product in combination with following medical electronic device:

- Active implantable medical devices such as pacemakers.
- Electronic life support system such as an artificial heart/lung.
- Portable electronic medical device such as an electrocardiograph.

 Never use person that has problem as below:

- This device is not designed for use on infant or children.
- You are pregnant woman or people with the possibility of pregnancy.
- You have cardiac disorder and cardiac lesion.
- You are physically and mentally debilitating.
- You have a problem for a blood pressure.
- People with high body temperature.
- A person who uses high-frequency medical devices.
- A person who visit the hospital regularly due to venous thrombosis.
- A person with much of menstrual bleed volume.
- If after inserting the (IUD, for example; coils, rings, etc.) within one month contraceptive in the uterus.
- Do not use the site on scar wounds, burns, infected, acne, problems related to blood clots, other vascular (for example; venous varices), or in limited parts of the body.
- People deemed inappropriate by a doctor.

⚠ Patient with problem as below uses carefully and contacts a doctor:

- People with acute disease.
- People with malignant tumors.
- People with a high fever.
- People with problem on the skin of application site.
- People who recently operated on.
- People who are administered the insulin to treat diabetes.
- People who have symptom side effects such as hypersensitivity, Inflammation, skin disorders, etc.
- People with problems in the muscles or joints.
- Within six weeks after the labour.
- People within three months after a caesarean section.
- People who want to use this device as a part of rehabilitation.
- People who received medical treatment by doctor.
- People with serious illnesses what damage has not been mentioned in this document.

1.2. General safety

- Do not modify this product without authorization of SmartMedicalDeivce Co.,Ltd.
- Pregnant women need to consult their healthcare provider before use.
- Use the product only for its intended use as described in this manual.
- Keep the user's manual with the equipment at all times.
- Individuals with any kind of contagious disease or injury must not use or contact with this product.
- Always operate this product within prescribed ranges of temperature, humidity and pressure. Operating in other environments may affect the operation of this product, and may cause

malfunction.

- Be careful not to spill or drop beverages or any other liquid on this product. It may cause serious damage to the electronic components.
- Stop using the device and consult your doctor if you experience adverse reactions from the device.
- Do not use concurrently with other stimulator.
- Strong magnetic line of force or electromagnetic radiation can cause failure or malfunction.
- Keep hands away from where children and pets.
- It may interfere with the normal operation of these devices when used in the presence of electronic monitoring devices (heart monitor, ECG alarms, etc.).
- Patients that are connected to the high frequency surgery equipment is prohibited to use. Skin may cause burns and the device may damage the equipment.
- When used within 1m from a short-wave or microwave medical equipment, Output of the device may become unstable.
- 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 device including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- When used the device in environments such as bathrooms, showers and swimming pools, it may cause a risk of electric shock and burns.

Chapter 2.

Dr.MUSIC 3s Introductions

2. Dr.MUSIC 3s Introduction

2.1. Operating principle

Transcutaneous electrical nerve stimulation (TENS) is a non-invasive pain relief method for which clinical proof exists that it can help relieve pain. TENS treatment passes electrical pulses across the intact surface of the skin to activate the underlying nerves. The device uses a rechargeable battery to generate pulses. These pulses are applied to the skin through self-adhesive hydrogel electrodes. You can choose the stimulation programs with different pulse settings using Mobile App, or Device itself.

2.2. Intended use

DM-VME03S is intended to be used by adults for temporary relief of pain associated with sore/aching muscles in the shoulder, waist, back, neck, upper extremities(arm) and lower extremities(leg) due to strain from exercise or normal household work activities and suitable for home use.

2.2.1. Intended user profile

Considerations	Requirement Description
Education	• Understand the instruction for the product
Knowledge	• Understand Symbols on User's manual and App • Read and understand User's manual.
Language	• The display language depends on the language settings menu of the Mobile phone.
Experience	• Able to use based android or iOS software. • Who read through the user's manual how to use it.
Permissible impairments	• Mild visual impairment. • Average degree of aging-related short term memory impairment.
⚠ **This progress is required to accompany a guardian for the other users**	

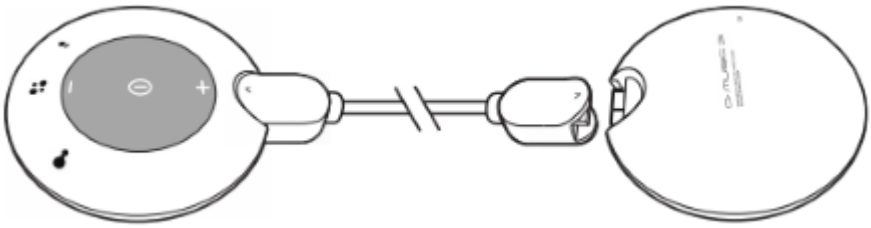
2.2.2. Intended patient population

Considerations	Requirement Description
Age	Adult
Gender	male and female
Health	Do not use patient that operated active implantable medical devices (e.g., Implanted pace-maker). Do not use on infants or patient who cannot properly expresses. Refer to Chapter 1.1 Contraindications in this user's manual.
Nationality	Multiple

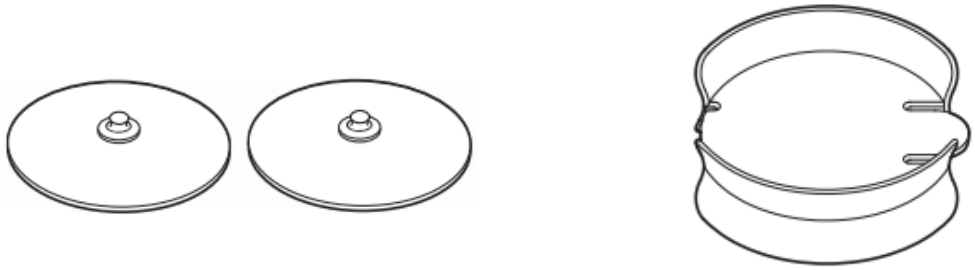
2.3. Product Components

The Dr.MUSIC 3s consists of the following components.

Main Unit



Control part Battery part

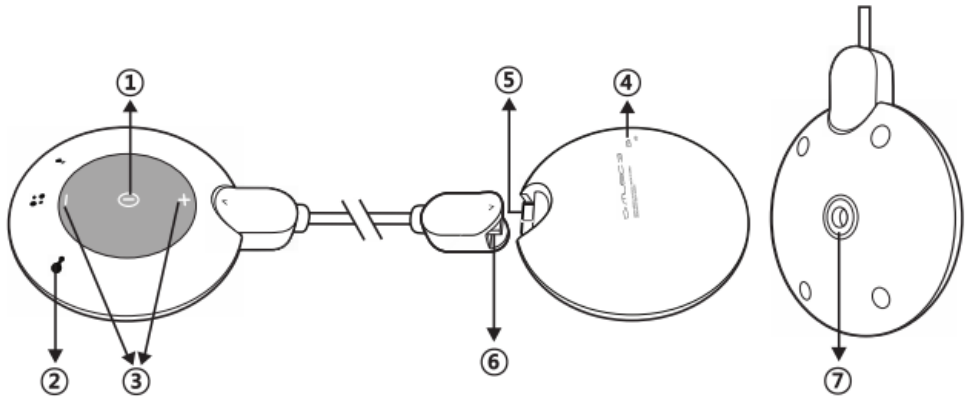


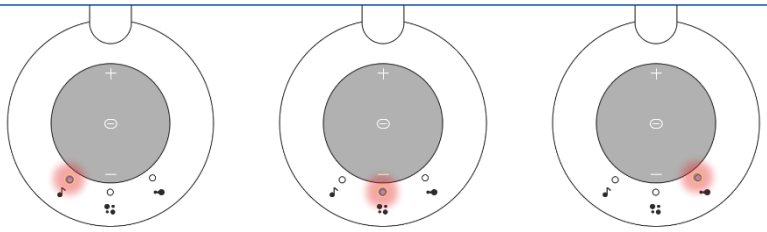
Electrode Holder

- Please inspect defects of each component prior to installation.

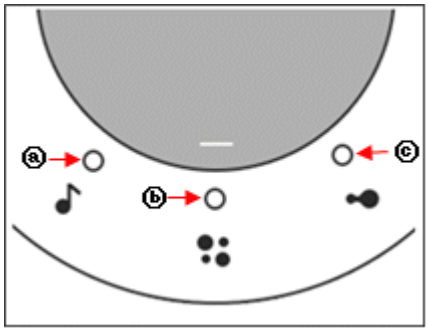
2.4. Exterior and Function

- Main Unit



No.	Name	Description
①	Power/Mode Button	Power ON/OFF, Change of Operating Mode.
②	Mode/Status indicator	Display mode and level, Battery status. - Mode/Level/Output : Orange LED - Battery: Blue LED
③	Intensity Button	Control of the level.  0 to 11 grades　12 to 23 grades　24 to 35 grades
④	Battery Indicator	Indicated the Status of the battery charging. (Charging: Orange LED, Fully Charged: Green LED)
⑤	Micro-USB socket	Socket for the battery charging.
⑥	Detachable Connector	Connector for the cable of Micro USB adaptor.
⑦	Electrode connector	Connected output socket with electrode for Low frequency stimulus.

- Mode/Status Display LED



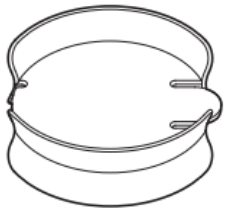
Name	Description
Mode indicator	Indicated each Status. (ⓐ Music sync, ⓑ Tapping, ⓒ Massaging)
Intensity indicator	When adjusting the higher intensity, the LED is lighting from left to right gradually.
output indicator	Each of LED is flashing during output. (ⓐ Music sync, ⓑ Tapping, ⓒ Massaging)
Low battery indicator	When battery is low, ⓑ LED is flashing.

- Component

(1) Electrodes

Description
Electrodes are delivered low frequency pulse to body by attaching on the skin.

(2) Holder



Description
It is used to store the electrodes by attaching.

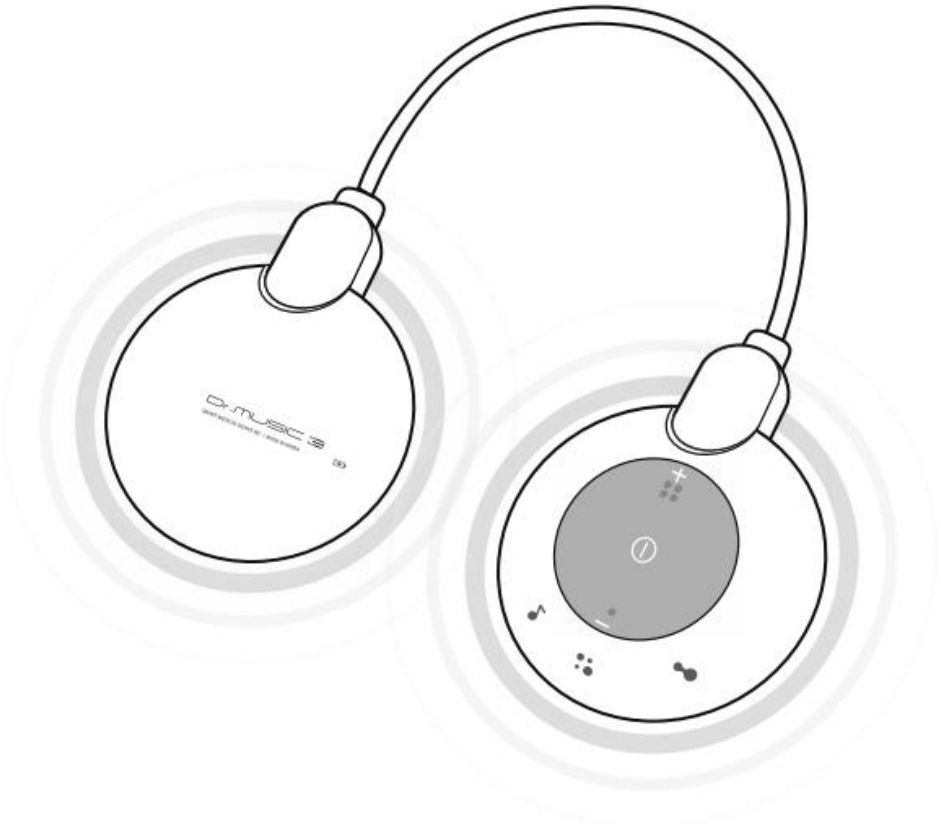
2.5. Layout of Dr.MUSIC 3s APP

<Connection standby> <Main screen after connecting>

No.	Name	Description
①	Status Display	Display the title and status icons.
②	Connect control	Control the connection to the device.
③	Output intensity control	Control and display the output intensity of the stimulation.
④	Contents area	- Change the operation mode. - Display the using time, low frequency wave form and etc.
⑤	Operation control	Control the operation and choice the low frequency wave form.

Chapter 3.

Operating the Dr.MUSIC 3s



3. Operating the Dr.MUSIC 3s

3.1. Precautions before using

- Read and understand all instruction in this manual before attempting to use.
- It may be occurred incidental, or consequential damages by not complying with the content of the User's Manual.
- Maintain the distance within 5m between the Dr.MUSIC 3s and connected Mobile phone.
- Recommended usage time is three times a day by each region. (one time: less than 30 minutes) It may cause burns to the skin when used beyond the recommended usage time. If you don't use this device for a long time, check the operation before using.
- Large movement makes electrodes separated from the skin.
- Make sure that skin you want to place the electrodes on looks healthy and is free from wounds or rashes.
- The skin you want to place the electrodes on must be dry, clean and free from cream or lotion.
- Dirt, grease or particles left on the skin may lodge themselves in the hydrogel of the electrodes.
- The shelf life of electrodes is 2 years. Check the packaging for the use-by date prior to use. Do not electrodes whose use-by date has expired.
- Regardless of shelf-life, replace the electrodes if;
  - Electrodes are damaged or torn.
  - If electrodes are not attached to skin.
  - If the clothes are attached to skin along with electrode.
  - Stimulation feels less strong.
  - When stimulation is uncomfortable.

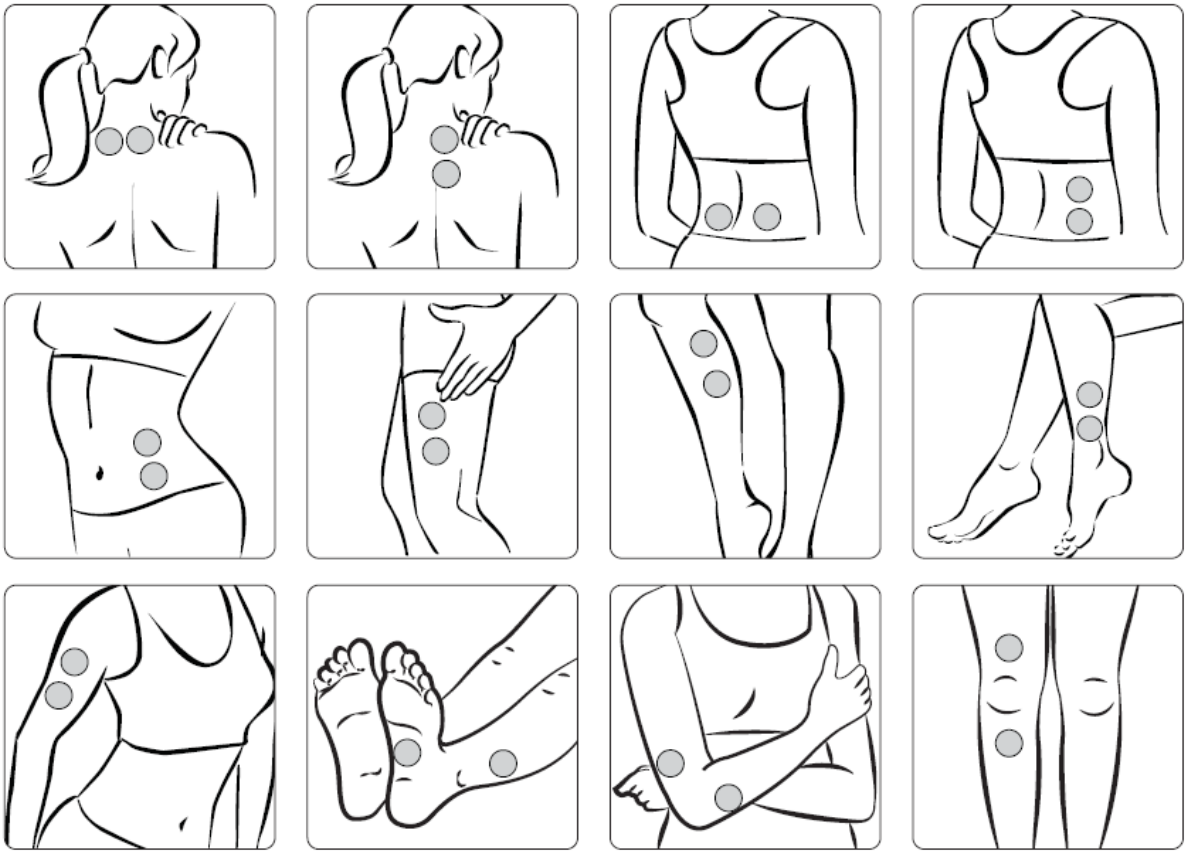
    (i.e. you should replace the electrodes, If you feel irritation or tingling in the sting away.)

    ※ Always replace the electrodes with electrodes recommended for this device by the manufacturer.

※ Available to purchase on the website (http://www.smd21.com/). Or contact a customer service center.

- The effects of loosened electrodes
  - If the electrodes are not properly attached to the skin, it may not be able to operate the device.
  - If the electrodes are not properly attached to the skin, current flow is concentrated can cause burns.
- If there is a change in performance, stop using the device immediately and please contact us by visiting the website (http://www.smd21.com/).
- Electrodes placement guide

※ This is only a recommendation.



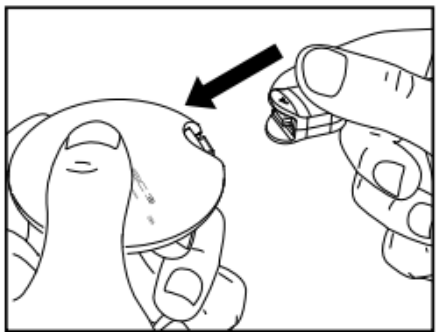
CAUTION

- Individuals with active implantable medical devices such as pacemakers, or essential support devices such as patientmonitoring systems, must not use this equipment.
- Yon can get an electric shock when water intrusion into the product.
- You can be the cause of the product failure when water intrusion into the product.
- Do not measure in a wet state.
- If you feel the problem or feel discomfort during use, please stop using it immediately.
- Do not use in high temperature or the bathrooms during bathing.
- You should not give another electrode to another person during use. Depending on the intensity can cause strong electrical shock to the body.
- To move the electrode during use in other parts of the body, you must first turn off the power of the product. Depending on the strength, It will be may result in a strong electric shock to the body.
- If electrodes lost their adhesive strength, never attach on the skin by using tape.
- When using an electrode near the chest, there is a risk of ventricular fibrillation can be increased.
- Do not stimulate through the head or the eyes directly or chest or the front of the neck (especially the carotid arteries) or do not cross stimulation on the heart.
- Do not stimulate while you cover the mouth.

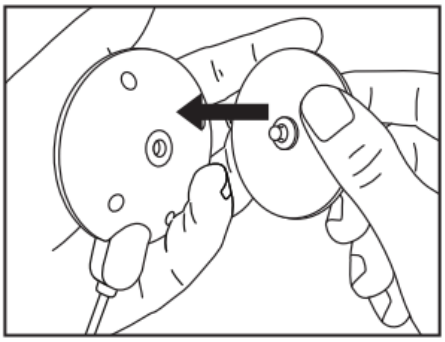
WARNING

- Please check for any physical damage of the exterior, including cracks and foreign materials before using the product.
- You have to remove the electrodes from the skin after using. If you attach a long time, it can cause skin problems.

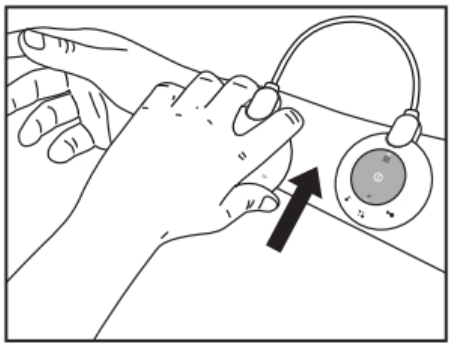
3.2. Using the device alone



(1) Plug the Detachable Connector from the micro-USB socket.

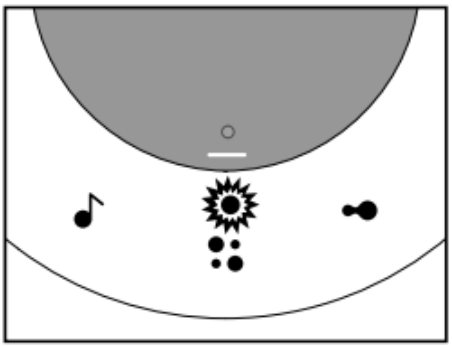


(2) Connect the electrodes with electrode connector

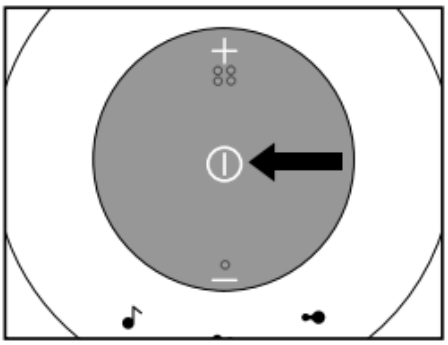


(3) Place the electrodes on the part at the place you want to treat such as shoulder, leg, arm etc.

(4) Long press the Power/Mode Button(⏻) to power on the device.



※ When device turn on, the middle LED is blinking as White.



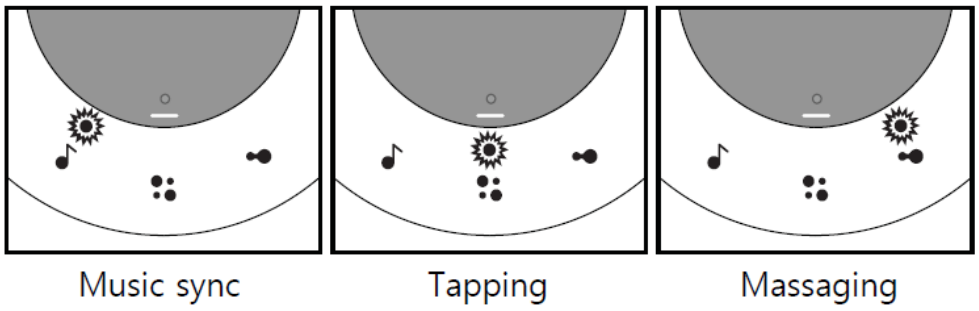
(5) Press lightly the Power/Mode Button(⏻) to select mode.

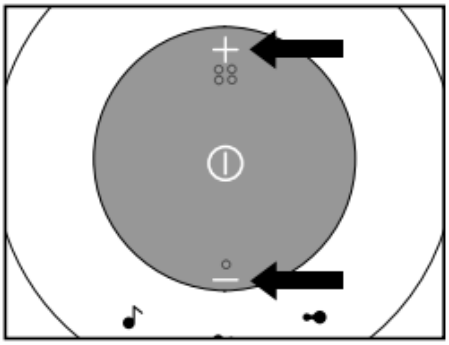
(a) There are three modes; ♪ (Music sync), ⁘ (Tapping), ⬬ (Massaging)

(b) Order of changing mode are as follows;

♪ (Music sync)→ ⁘ (Tapping) → ⬬ (Massaging)

※ The orange LED is lighting at each position of selected mode.



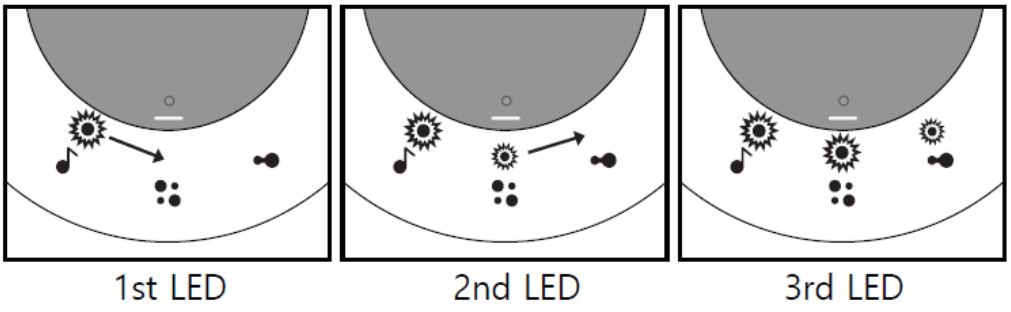


(6) After selecting mode, use by adjusting the intensity of low frequency stimulus using intensity button(⊕ ⊖).

(a) The operation time is 20 minutes.

(b) There run the basic program that is built in each modes.

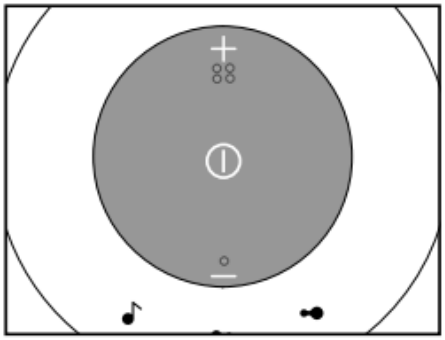
※ When adjusting the higher intensity, the LED is lighting from left to right gradually.



1st LED(♪) is lit : 0 to 11 grades

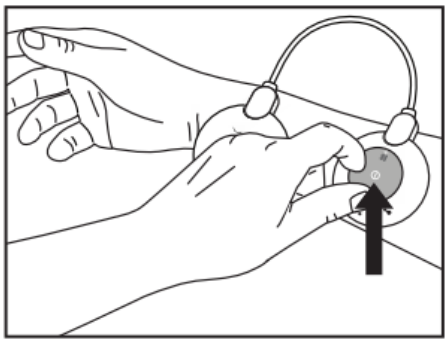
2nd LED(⁘) is lit: 12 to 23 grades

3rd LED(⬬) is lit: 24 to 35 grade



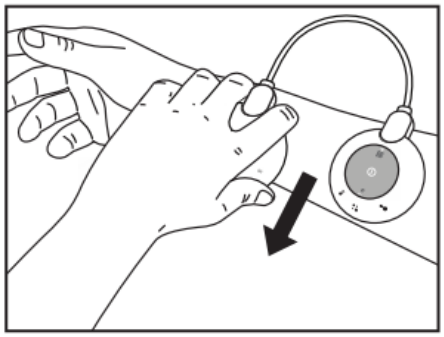
(7) When press the Power/Mode Button(⏻), operation is stop.

Press the Intensity button(⊕ ⊖), operation is started from the beginning.

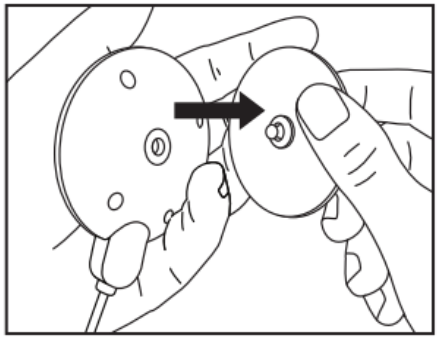


(8) Long press the Power/Mode Button(⏻) of device.

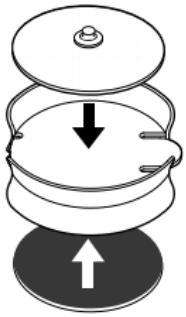
* If you do not operate within 5minutes, the device switches off automatically.



(9) Pull the electrodes to detach from skin.



(10) Separate the electrodes from device.



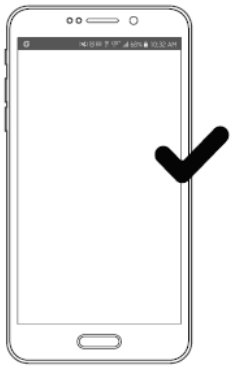
(11) Stored electrodes by attaching on the holder to keep water of gel.

* Do not place the electrodes on top of each other or so close to each other that they touch each other.

3.3. Using the device with Mobile APP

3.3.1. APP Download

– Install the Android APP

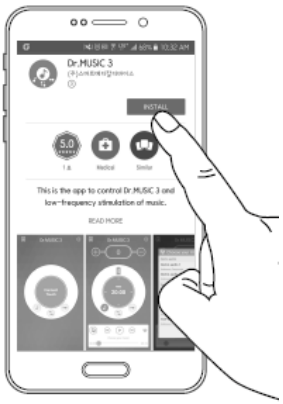


(1) Check whether supported device or not. (≥ Android 4.3)

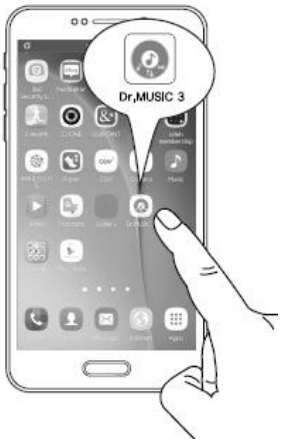
(2) Run the APP store.

(3) Press the search.

(4) Type the 'Dr.MUSIC3' in search.

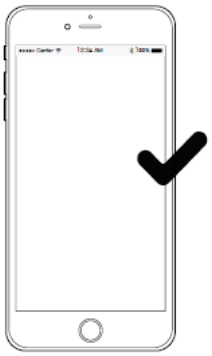


(5) Install the APP.



(6) Run the APP 'Dr.MUSIC3'.

- Install the iOS APP



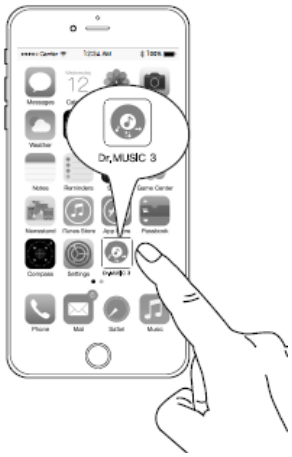
(1) Check whether supported device or not. (≥ iOS 7)

(2) Run the APP store.

(3) Press the search.

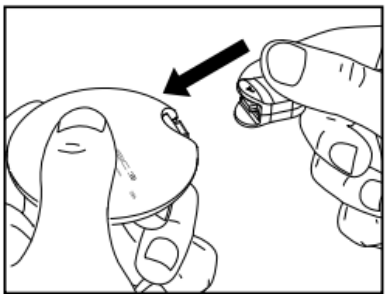
(4) Type the 'Dr.MUSIC3' in search.

(5) Install the APP.

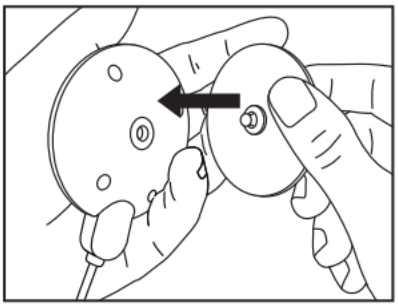


(6) Run the App 'Dr.MUSIC3'

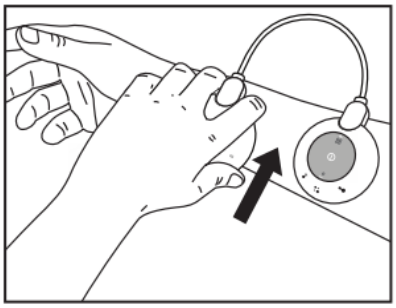
3.3.2. Using the device with Mobile APP



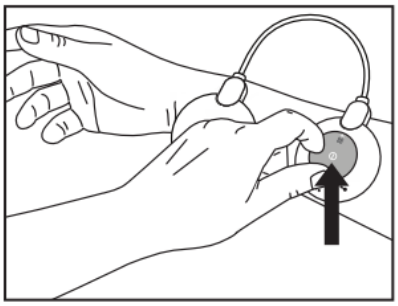
(1) Plug the Detachable Connector from the micro-USB socket.



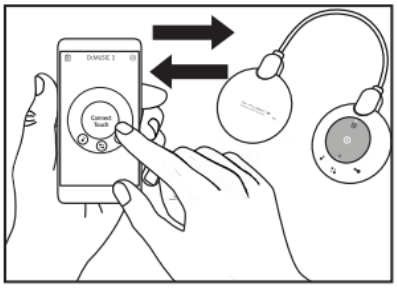
(2) Connect the electrodes with electrode connector.



(3) Place the electrodes on the part at the place you want to treat such as shoulder, leg, arm etc.



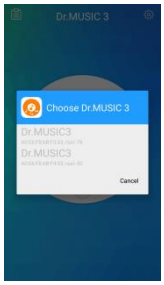
(4) Long press the Power/Mode Button(⏻) to power on the device.



(5) After turn on the Bluetooth of mobile platform, run the Mobile APP.

(6) Pair the device with Mobile APP.

<1st screen after running APP>



<Connection list>

<1st screen after connecting device>

(7) Press the button "Connect Touch".

(8) Touch the "Dr. MUSIC 3s" at list.

(9) Activate the mode.

(You can select the mode among Music Sync Mode, Tapping Mode and Massaging Mode.)

- Music Sync Mode

① Touch the 'Music Sync mode' button ( ).

② After touching the 'Music list button ( )' select music.

③ If you want to start again, you touch the start button ( ).

④ When starting music, adjust the intensity of low frequency stimulus using the Intensity Button ( ).

⑤ If you want to stop or pause, you touch the pause button (⏸).

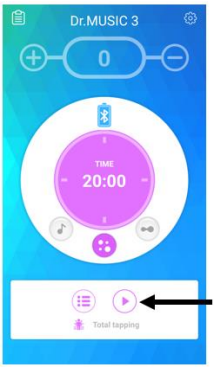
⑥ If you want to start again, you touch the start button (▶).

※ Touch the 'TIME' button to setting the operation time. (Setting time: 5 to 30 min, Basic Setting time: 20 min)

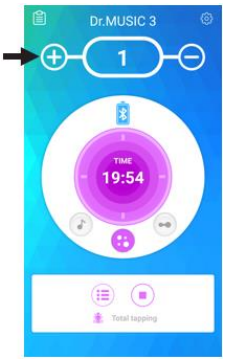
- Tapping Mode

① Touch the 'Tapping mode' button (⁘).

② After touching the 'Tapping list' button (☰), select the program.



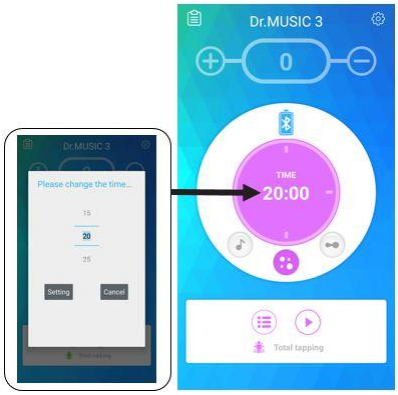
③ Touch the 'Start' button (▶).



④ Adjust the intensity of low frequency stimulus using the Intensity Button (⊕ ⊖).

⑤ If you want to stop or pause, you touch the pause button (■).

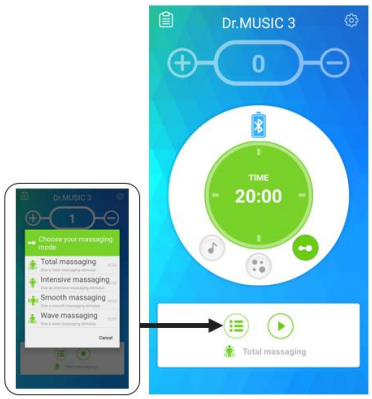
⑥ If you want to start again, you touch the start button (▶).



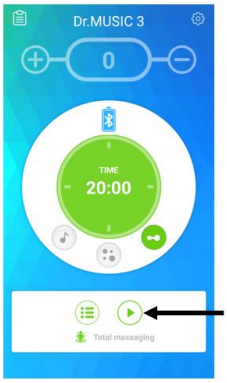
※ Touch the 'TIME' button to setting the operation time. (Setting time: 5 to 30 min, Basic Setting time: 20 min)

- Massaging Mode

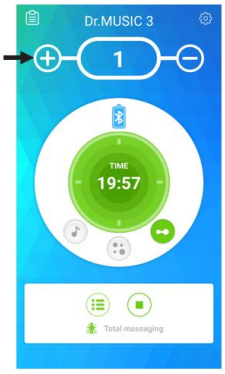
① Touch the 'Massaging mode' button (⚭).



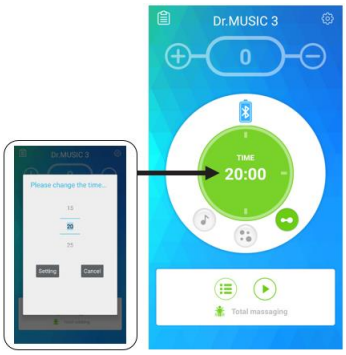
② After touching the 'Massaging list' button (☰), select the program.



③ Touch the 'Start' button (▶).



④ Adjust the intensity of low frequency stimulus using the Intensity Button (⊕ ⊖).



⑤ If you want to stop or pause, you touch the pause button (⏹).

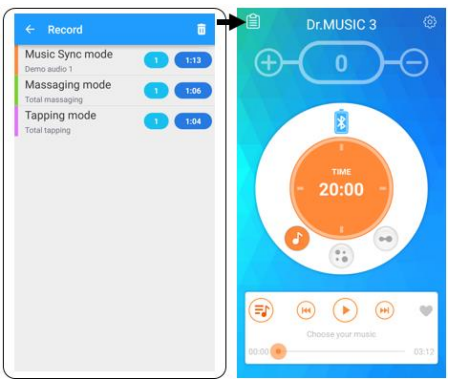
⑥ If you want to start again, you touch the start button (▶).

※ Touch the 'TIME' button to setting the operation time. (Setting time: 5 to 30 min, Basic Setting time: 20 min)

- Mode & Program

Mode & Program Name		Frequency	Pulse Width	Pre-set time
Using the device alone	Music Sync Mode	2Hz, 8Hz	50 μs	20min
	Tapping Mode	2-10Hz	50μs	20min
	Massaging Mode	5-100Hz	50-88μs	20min
Using the device with mobile APP	Total Music Sync	1-100Hz	50-150μs	20min
	Total Tapping	2-10Hz	50μs	20min
	Intensive tapping	2Hz,10Hz	50μs	20min
	Smooth tapping	3Hz,5Hz	50μs	20min
	Wave tapping	2-10Hz	50μs	20min
	Total Massaging	5-100Hz	50-88μs	20min
	Intensive Massaging	100Hz	50μs	20min
	Smooth Massaging	80Hz	80μs	20min
	Wave Massaging	5Hz,100Hz	50-88μs	20min
* When you switch to another program during using, the intensity is automatically reset to 0. This is a safety measure. The intensity level of the previous program may be too high for the new program.				

- Check record

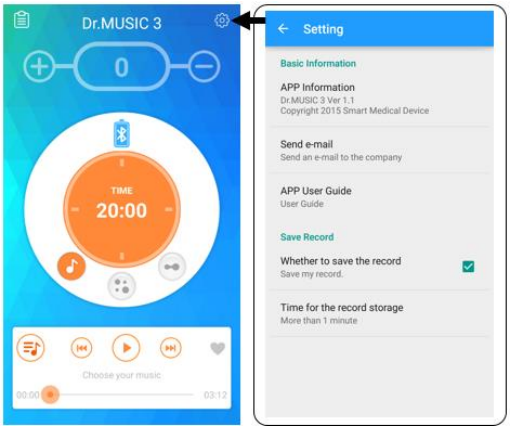


(1) Touch the 'Record' button (📋) at top left.

(2) Check the record.

- Mode
- Program
- Intensity
- Time

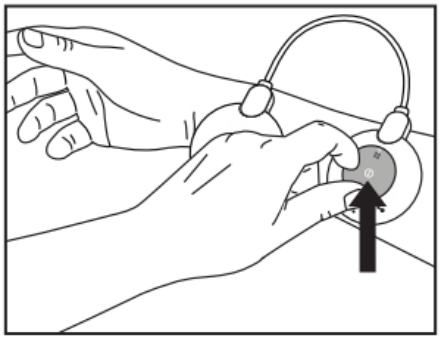
- Setting



(1) Touch the 'Setting' button (⚙) at top right.
(2) Check the Basic information.
- APP Information
- Send e-mail
- User's Guide
(3) Set the save record.
- Record store presence.
- The time range used record stores.

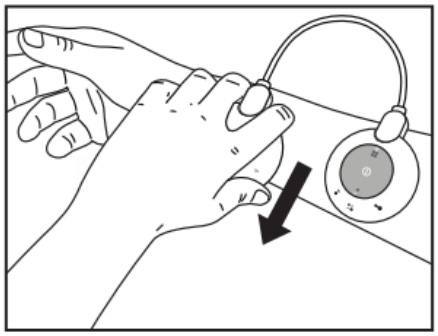
- APP User Guide

- System OFF

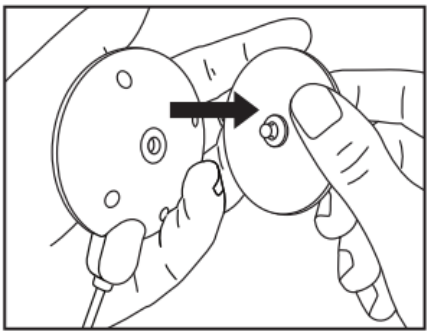


(1) The 'Dr.MUSIC3' APP is terminated depending on how the APP quit at mobile phone.

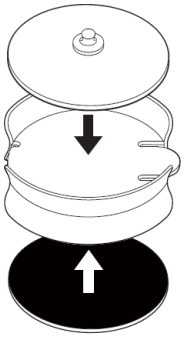
(2) Long press the Power/Mode Button(⏻) of device.



(3) Pull the electrodes to detach from skin.



(4) Separate the electrodes from device.



(5) Stored electrodes by attaching on the holder to keep water of gel.

* Do not place the electrodes on top of each other or so close to each other that they touch each other.

3.4. Charging the device

3.4.1. Precautions for charging the device

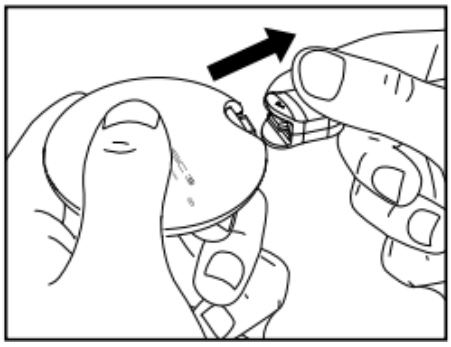
- Treatment is not possible when the device is charging.
- Only use this device with the adapter, cord and accessories recommended by the manufacturer.
- Charge using a compatible Micro 5pin USB cable.
- Micro 5pin USB cable or a charge adapter (DC5V, more than 1A) is products for sold separately. Charge by using the certified products.
- Charging the device takes approx. 3 hours at room temperature.
- When the rechargeable battery is fully charged, it contains sufficient energy for approx.8 hours of continuous use under normal operating conditions.
- When the device is stored during prolonged, Keep state of battery from 40( ) to 60( )% after removing control part.
- Do not store in the car that is exposed to direct sunlight.
- When the battery part of device become inflated or hot during charging, please dispose of it immediately.
- When disposing of the Battery, please dispose completely discharged.
- Years of battery replace (It will replace the battery part of device.): 3 years (Charging time: more than 3 hours, Discharge time: If the device is operated less than 8 hours.)
- Discharge cycles: About 300 times (2400Hours / 8Hours)
- Display the battery level
  - ➢ Using the device alone

    : If the Blue LED is blinking, the remaining time is approximately 5 minutes. Please recharge.
  - ➢ Using the device with Mobile App

    : When less than 5% in accordance with the display the battery level, please recharge.

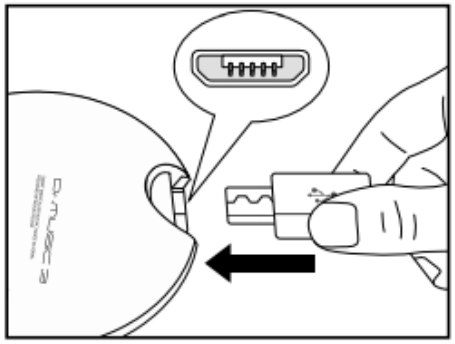
Battery/Bluetooth Indicator						
battery remains	100 %	80 %	60 %	40%	20%	5%

3.4.2. Charging the device

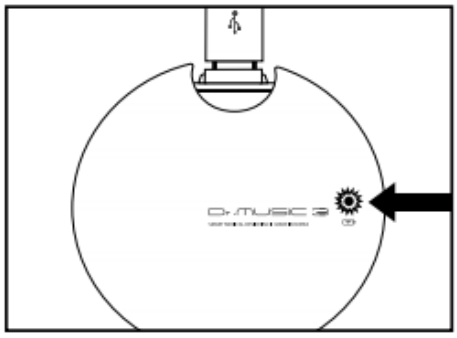


* Micro-USB cable is used for charging only.

(1) Unplug the Detachable Connector from the micro-USB socket.

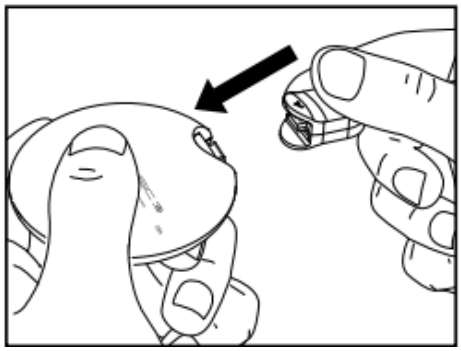


(2) Insert the charging cable into the micro-USB socket of the device.



(3) The battery indicator is solid orange during charging.

(4) When the battery is fully charged, the battery indicator turns solid green.



(5) When complete charging the device, plug the Detachable Connector from the micro-USB socket.

Chapter 4.

Maintenance and Information of Dr.MUSIC 3s

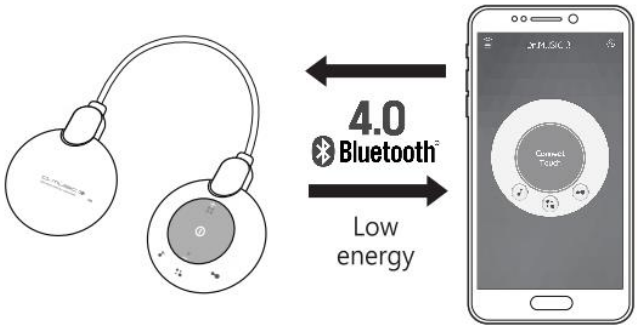
4. Maintenance and Information of Dr.MUSIC 3s

4.1. Specification of Dr.MUSIC 3s

Type of Protection against electric shock	Internally Powered Rating (100 mAh)	
Degree of protection against applied parts	TYPE BF APPLIED PARTS	
Internally Powered Rating	3.7Vd.c.(Li-Polymer), 400 mAh	
Charging Voltage	DC 5V, 1A	
Applied part	Electrode	
Input Device	Power/Mode Button, Intensity Button	
Operation time	Using the device alone :	20min (FIXED)
	Using the device with Mobile APP :	5~30min (Default: 20min)
Output voltage	The output stage is from 0 to 35. Whenever increases the output intensity by one, The output voltage is increased 1Vpk. Starting from 4Vpk at Stage 1, finally maximum output voltage is 38Vpk at 35 stages. * Rated load resistance: 500Ω	
Dimension	56(W)㎜×56(D)㎜×12.8(H)㎜ Length of cable : 200mm Electrode(BWX4500, YXN45AX) : Ø45mm	
Equipment Weight	54.5g	
Transportation and Storage environment	Temperature range	-25 ~ 70℃
	Relative humidity	10~93%R.H. (non-condensing)
	Atmospheric pressure	700 ~ 1060 hPa
Operating environment	Temperature range	5℃ ~ 40℃
	Relative humidity	15~93% R.H. (non-condensing)
	Atmospheric pressure	700 ~ 1060 hPa
Classification	- For continuous operation. - Not suitable for use in the presence of flammable anesthetics. - Not for use in the presence of an oxygen-enriched atmosphere (oxygen tent).	

4.2. Specification of External Device connection

A. Connectable devices



<Dr.MUSIC 3s devices> <Dr.MUSIC 3s APP>

Name	Description
Bluetooth	The data for controlling the device is transmitted to the device from the APP and the data indicating the status of the device is transmitted to the APP from the device

** Here by, SmartMedicalDevice Co.,Ltd. declares that this DM-VME03S is in compliance with the essential requirements and other relevant provisions of directive 1999/5/EC.*

CE 1177

B. The required properties of the Interface and IT- network that combines PEMS

① Main Device/ Mobile APP interface

- Data format: Bluetooth
- Device status information: Read Channel & Notify Channel (0000fff4)
  Device information (Bringing information when connecting to BLE)
  Battery information (Receiving information periodically)
- CMD to Device –Write Channel(0000fff1)
  Mode Change – Music sync/ Tapping/ Massaging
  Operation Control – Start, Pause
  Intensity Control – Level Control
- Data to Device – Data Channel (0000fff3)
  Transmits the music to the energy level (16Level)
- Notify Channel for the transmission from the device to the smart phone
  If the low frequency electrode away from the user's skin while the low-frequency output
  Emergency stop -→ 255(FF) transfer (Pad open, Electrode separation)
  Emergency stop by user while the low-frequency output
  Emergency stop -→ 254(FF) transfer (Stopped by user)

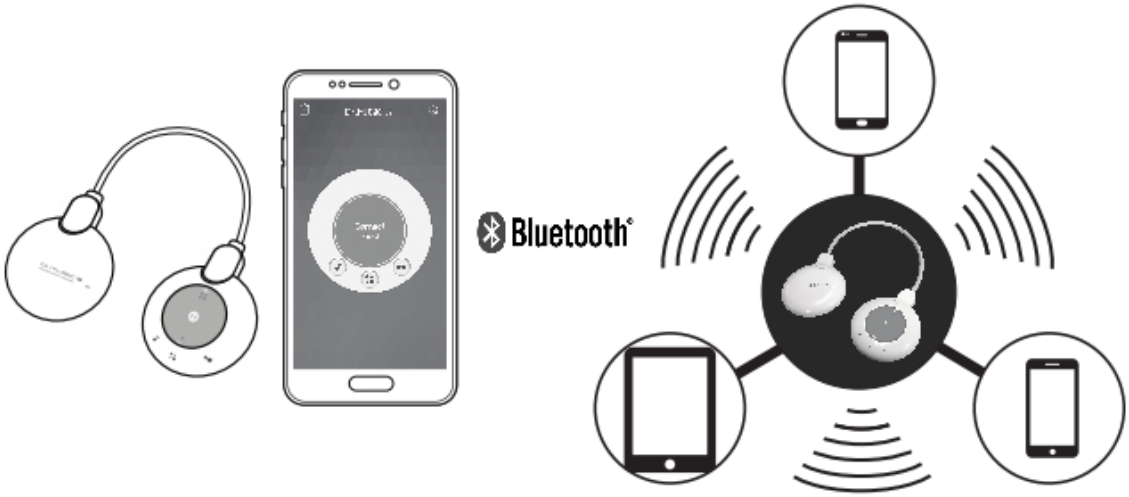
C. Technical specification about network connection of PEMS including security features

① Dr.MUSIC 3s APP program is designed to not-affect by an external virus infiltration. But if infected with virus, Operating System may be a loss of storage data. Therefore, in the case of virus infection it should be operated by an antivirus program.

② Specification of Network connection

Communication protocol: The protocol between the main unit and the mobile app is a BLE central (Mobile) – peripheral (main unit) communications and they communication with security requirements defined in the BLE Protocol Stack.

D. PEMS, the intended flow of information between the IT-Network and other devices combined with the IT-Network. Intended route via the IT-Network



E. When Dr.MUSIC 3s IT-Network connections, recommendations for responsible Organization.

The following recommendations should be carried out under the responsibility of the person/institution for connecting to a network.

1) All cleaning and disinfection procedures perform in accordance with the document.

2) Connection of the Dr.MUSIC 3s to an IT-Network that includes other equipment could result in previously unidentified risks to patient, operator or third parties.

3) The users should identify, analyze, evaluate and control these risks.

4) Subsequent changes to the IT-Network could introduce new risks and shall require additional analysis

* Change to the IT-Network includes:

· Changes in the IT-Network configuration;

· Connection of additional items to the IT-Network.

· Disconnecting items from the IT-Network.

· Update of equipment connected to the IT-Network.

· Upgrade of equipment connected to the IT-Network

4.3. Questions about Equipment

Questions	Answers
Q1) The treatment feels different or less pleasant than usual.	A1) If the intensity is Too high or too low, you will be felt different or less pleasant than usual. You should control the intensity button or change the mode.
	A2) If the electrodes are not properly attached, you will be felt different or less pleasant than usual. Check if the electrodes are attached to the skin properly.
	A3) The electrodes are worn, Replace the electrodes.
Q2) The output level is not changed.	A1) Check if the electrodes are attached to the skin properly.
Q3) During using, stimulus is output but Blue LED is flashing.	A1) The battery is low, Charge the battery.
Q4) The electrodes do not attach to the skin.	A1) The electrodes are worn, Replace the electrodes.

4.4. Maintenance

4.4.1. Cleaning Plan

ITEM	Method	Period
Check	Contamination and damage inspection of the appearance.	Check before use.
Cleaning	Refer to Section 4.4.2 "Cleaning & Storage"	Clean after use.

4.4.2. Cleaning & Storage

- Clean it with a dry towel.
- If the electrodes are dirty, put a drop of water on your finger and gently rub the dirt off the surface.
- Storage the product specified environment cited under chapter 4.1 Specification of Dr.MUSIC 3s.

WARNING

Always operate this product within prescribed ranges of temperature, humidity and pressure. Operating in other environments may affect the operation of this product, and may cause malfunction.

CAUTION

- Do not use abrasive or solvent-based cleaners.
- Do not expose the product to extremely high or low temperature.
- Do not leave the product in direct sunlight for an extended period of time.
- Do not immerse the device in water or rinse it under the tap.
- Do not immerse the electrodes in water.

4.4.3. Replacing the Battery

- If the shelf life of battery is end, contact us and purchase the battery part.
- It provides the other information such as circuit diagrams, parts and description that is needed to repair the product when the service personnel are required.

  Tel: +82-70-7525-2104 E-Mail: sales@smd21.com

  Homepage: http://www.smd21.com

WARNING

- Only the trained service personnel of the manufacturer will carry out the repair service.
- Do not disassemble or modify the equipment including internal parts without written consent from the manufacturer. This may cause electric shock or injury, product malfunction, inaccurate results, and will void the manufacturer's warranty.
- The minimum qualifications for SERVICE PERSONNEL.

  - Service and Installation trained service personnel.

  - Only personnel read the instruction manual or received training to use.

4.4.4. Expected service life

The Dr.MUSIC 3s has an expected service life of 3 years. To maintain the condition of the device have the device maintained regularly according to the schedule recommended by manufacturer.

4.4.5. Disposal

The device described in this manual must be disposed of in compliance with the applicable local waste control regulations at the end of their service life. If you have questions regarding the disposal of the device, please contact the manufacturer or an authorized disposal company.

4.5. EMC(Electro-Magnetic Compatibility)

Guidance and Manufacturer's Declaration - Electromagnetic Emissions – This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions 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 emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity – This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	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	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for supply mains ± 1 kV for input/output lines	Mains power quality should be that of hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV for common mode	Mains power quality should be that of hospital environment.
Voltage dips, short	<5 % U_T (>95 % dip in U_T)	<5 % U_T (>95 % dip in U_T)	Mains power quality should be that of hospital

interruptions and voltage variations on power supply input lines IEC 61000-4-11	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 s	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 s	environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) 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 hospital environment.
NOTE: U_T is the ac. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity – This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure 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 V_{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V_{rms} 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\ \sqrt{P}$ $d = 1.2\ \sqrt{P}$ 80MHz to 800 MHz $d = 2.3\ \sqrt{P}$ 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 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 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 relocating 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 This Device: The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter, W	Separation distance according to frequency of transmitter, M		
	150 kHz to 80 MHz $d = 1.2\ \sqrt{P}$	80 MHz to 800 MHz $d = 1.2\ \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\ \sqrt{P}$
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.

4.6. FCC(Federal Communications Commission)

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 technical for help.

WARNIG: *This equipment may generate or use radio frequency energy. Changes or modifications to this equipment may cause harmful interference unless the modifications are expressly approved in the instruction manual. The user could lose the authority to operate this equipment if an unauthorized change or modification is made.*

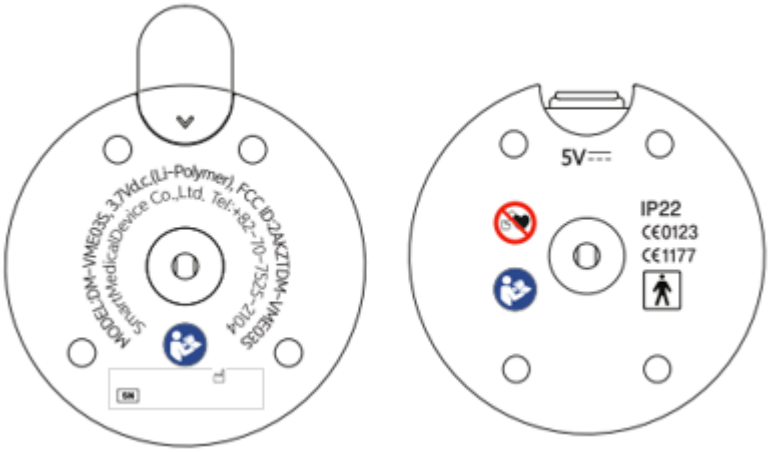
This device complies with Part 15 of the FCC's Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept ant interference received, including interference that may cause undesirable operation.

This device complies with rf exposure requirement.

4.7. Marking plate

- Trademark: Dr.MUSIC 3s
- Model: DM-VME03S
  - Position of label: the back side of Control part
  - Label of device



  - Position of box label: the bottom side of outer box
  - Box label

[Dr.MUSIC 3s]
- Product : Transcutaneous Electrical Nerve Stimulator
- Model : DM-VME03S
- Weight : 54.5g
- Packing Unit : 1set
- Charging Voltage : 5V ⎓
- Internally Powered Rating: 3.7Vd.c.(Li-Polymer)
- Max. Output Voltage : 38Vpk
- FCC ID : 2AKZTDM-VME03S

Follow instructions for use.
Do not use this equipment with active implantable medical devices such as pacemaker.
Do not disassemble or modify the equipment including internal parts without written consent from the manufacturer. This may cause electric shock or injury, product malfunction, and will void the manufacturer warranty.

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