tone

Instructions for use

Z Tone

zimmer

EN

Contents

Contents

These instructions are an integral part of the device. It must be kept with the device to ensure that it can be accessed at any time by the persons responsible for operating the device.

The instructions are valid from April 2022 for the following product ZTone (original trade name Perfect).

If the instructions for use have become illegible, damaged or are not accessible to the user for other reasons, a replacement must be requested from the manufacturer and made available to the user for the safe use of the device. This also includes the information on the labels on the device.

We reserve the right to revise this document or to change described product specifications at any time. There is no obligation to inform the customer about the changes.

1.1 Definitions of symbols

- When there is specific information in the Instructions For Use that needs to be emphasized for safety, the following terms and symbols are indicated. All warnings and precautions shall always be observed.
- The manufacturer or agent of the product is not responsible for any personal/material damage caused by erroneous use, operation for purposes other than its intended objective and negligence of product maintenance.

 Manufacturer	Manufacturer
 Date of manufacture	Date of manufacture
 Serial number	Serial number
 Catalogue number	To identify the manufacturer's catalogue number, for example on a medical device or the corresponding packaging. The catalogue number shall be placed adjacent to the symbol.
 instructions for use	Follow instructions for use.
 Caution	“Caution” symbol is used to indicate that injury or damage can be caused if the caution is disregarded.
 BF Type	Applied part BF type
 Dangerous Voltage	To indicate hazards arising form dangerous voltages.
 Equipotentiality	To identify the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. lacal bonding.
 Alternating current	To indicate on the rating plate that the equipment is suitable for alternating current only to identify relevant terminals.
 “OFF” (Power)	To indicate disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved.
“ON” (Power)	To indicate connection to the mains, at least for mains switches or their positions, and all those cases where safety is involved.
 This way up	To indicate correct upright position of the transport package.

	Fragile	To indicate that the contents of the transport package are fragile and the package shall be handled with care.
	Keep away from rain	To indicate that the transport package shall be kept away from rain and in dry conditions.
	Temperature limitation	To indicate the maximum and minimum temperature limits at which the item shall be stord, transported or used.
	Humidity Limitation	To indicate the acceptable upper and lower limits of relative humidity for transport and storage.
	Atmospheric pressure limitation	To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage.
	WEEE	Indicates that when the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling.
	Recycling	To indicate the location of a recycling bin or container.
	Warning	“Warning” symbol is used to indicate a life-threatening risk to the operator if the warning is disregarded.
	No pushing	To prohibit pushing against an object
	Do not stack	To indicate that the items shall not be vertically stacked, either because of the nature of the transport packaging or because of the nature of the items themselves.

1.2 Requirements for safety

1.2.1 Warning

- The following patients cannot be treated with this equipment and must be approved by the doctor in charge during the procedure.
  - High blood pressure patients
  - Pregnant women and infants
  - Heart disease (especially those with pacemakers)
  - People with acute illness
  - A person who has implanted implants in the body, such as an artificial hip joint
  - Do not use on patients with conductive, ferromagnetic or other magnetically sensitive metals in the vicinity of the head or treatment coil. (e.g. cochlear implants, implanted electrodes/stimulators, aneurysmal clips or coils, stents, deep brain stimulators, vagus nerve stimulators, bullet shards, jewelry or hairpins, etc.)

1.2.2 Notes on targets of use, age or health status, etc., taking into account the characteristics of medical devices

- The following patients must obtain permission from their doctor during the procedure.
  - High fever patients, pregnant women and the elderly
  - Patients with a history or condition of epilepsy or seizure disorder
  - Patients wearing artificial pacemakers, drug injection pumps, and hearing aids
  - People who have implants in the body such as artificial hip joints

- This device should be used for patients who can accurately express and communicate pain during stimulation. (Can be used for men and women aged 13 to 60 years old. Older people over that age can be used according to doctor's prescription)

1.2.3 Precautions for adverse reactions that may occur as a result of the use of medical devices, fatal side effects due to negligence in use, and accidents

- Pain may occur in the application area.
- If any abnormalities other than the intended phenomena are found during use, discontinue use immediately and consult your doctor.
- The device must be used under the supervision of a person with a medical-related professional license or a person who has completed related training.

1.2.4 General precautions

- The device must be used according to the Instructions For Use.
- Equipment installation and reinstallation must be done by professional personnel authorized by the supplier.
- Operators and equipment managers must be familiar with the Instructions For Use, and keep the Instructions For Use in close proximity to the equipment.
- Do not place the ME equipment in a location where it is difficult to remove the power plug or other removable plug.

- For safety accident prevention and proper maintenance, keep safety signs and information provided with the equipment, and regular checklists in a well-visible place around the equipment.
- Keep the area where the equipment is installed free of water, alcohol, and flammable substances.
- For electrical safety, the device must be connected to a safety grounded power source.
- To prevent unintended phenomena, keep the device away from direct sunlight or strong electromagnetic fields.
- When the equipment is in operation, do not use cell phones, walkie-talkies, portable wireless transmitters, and wireless toys in the vicinity.
- Since the main body is equipped with a fan for internal air circulation, remove curtains or other objects that may block airflow from around the machine.
- A strong magnetic field is generated around the magnetic field generator, so when operating the equipment, the operator, assistant, and patient should not carry any belongings that may be affected by the magnetic field.
- No other than the professional personnel authorized by the supplier cannot repair or install the equipment, so it is absolutely forbidden for the user to arbitrarily disassemble and assemble the equipment.
- Equipment in installation and operation must be regularly inspected for safety by qualified personnel authorized by the supplier.
- Check whether the power supply at the installation site meets the input conditions of the device.
- The equipment is only operated indoors where temperature: 5 – 28 ℃, humidity: 30 – 75 % R.H. are maintained.

1.2.5 Interaction

- Do not use in combination with other electronic medical devices.

1.2.6 Use for pregnant women, lactating women, women of childbearing potential, newborns, infants, children and the elderly

- Pregnant, nursing, pregnant women, newborns, infants, and children are prohibited.

1.2.7 Application Notes

- Use care so that magnetic stimulation does not penetrate the heart area.
- You should review your current or past drug resistance level.
- Before using the device, check the connection status of the wires and connectors connected to the device, damage status, and surface status of accessories to confirm that there is no problem before use. If damage occurs, you should contact the service center.
- A strong magnetic field is generated around the magnetic field, so equipment operators, surgeons, assistants, and patients should not all carry any belongings that may be affected by the magnetic field. In particular, if a patient has metallic accessories (EX: necklaces, earrings, watches, rings,

metallic belts, belt buckles, metallic buttons, etc.) on the human body, it may cause burns, so be sure to remove them before proceeding.
- Wristwatches, cell phones, etc., if affected by magnetic fields, may cause malfunctions, so be careful and store them separately.
- Do not use cell phones, walkie-talkies, portable radio transmitters, and wireless toys in the vicinity while the device is in operation.
- You must inform them of the dangers of long-term use of the device.

1.2.8 Matters necessary for prevention of safety accidents
- As the equipment cannot be repaired except by specialized personnel authorized by the manufacturer, it is absolutely forbidden to disassemble or assemble the equipment by the user.
- The supplied equipment and accessories should not be used for any other purpose as it may cause a risk of electric shock if used for any purpose other than the intended use of this equipment.
- This device must not be operated by children.
- If the equipment does not operate normally during equipment operation, immediately turn the main power switch 'OFF' and contact a designated service company.
- This device is a medical device for hospital use and should only be handled by trained personnel in the hospital under the guidance of a physician.

1.3 Safety device

- When a magnetic field is output, a buzzer sounds periodically to notify you that the magnetic field is being output.
- When the mode is changed or the power is turned on, the output always starts from “0”.

1.4 Indications

- Stimulation of muscular tissue
- Nerve regeneration
- General pain control
- Fracture healing
- Improvement blood circulation
- Urinary incontinence

1.5 Contraindications

- Do not use the equipment in parallel with other electronic medical equipment.
- Be careful to ensure that magnetic stimulation does not penetrate the heart region.
- In general, patients in the following categories cannot be treated with this equipment. Prior to any treatment with this equipment, permission of the doctor in charge must be obtained.
    - Patient with high fever, pregnant women and the elderly and children
    - Patient with a history or status of epilepsy or seizure disability
    - Patient with suspected status of epilepsy on the basis of electroencephalography

- Patient with evidence of external wound at brain and neck
- Patient with cardiac pacemakers, drug injecting pumps or hearing aids
- Patient with cranial implants

1.6 Side Effects

There are no side effects reported. However, if the patient experiences any abnormal symptoms the operator must stop the treatment immediately and contact the doctor in charge.

High intensity pulsed electromagnetic field

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2.1 Principle

The transducer which is used to magnetic stimulation makes electrical fields by pulse current flowing from a capacitor according to the principle of Faraday's Law. Whenever the capacitor bank is discharged by the action of the control system, a pulse of current flows through the stimulating coil. The magnetic stimulation creates intense, rapidly changing magnetic electrical fields that are able to penetrate soft tissue and bone, to reach deep nervous structures. This magnetic electrical fields is used to the treatment.

This device directly generates (induces) electric current in muscles, nerve tissues, etc. affected by a high induction magnetic field and electrically stimulates it to relieve pain and suppress dysuria such as urinary incontinence.

2.2 Intended Use

The Z*Tone* is an electrically powered device intended for medical purposes that repeatedly contracts muscle tissue by passing electrical currents through electrodes non-contacting the affected body area. In addition, the device is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of urinary incontinence in humans.

2.3 Device description

Z*Tone* is a device for relieving muscle pain and treating urinary incontinence with magnetic stimulation function. This Z*Tone* consists of the Main body, Transducer for magnetic stimulation. The main body of Z*Tone* is used to control the both functions. The function of magnetic stimulation is operated with parameters such as Area mode setting, output channel, output level, intensity, operation time, Synchronize. These parameters can be controlled by user on LCD touch screen.

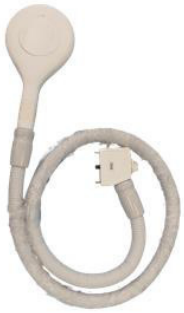
Installation

3

3.1 Components

- Main body with transducer

- Transducer



- Power cable

- Instructions For Use

3.2 Electrical installation condition

- Input power : 220-240 V~, 50/60 Hz
- Power consumption : 3.6 kVA

3.3 Environmental condition

3.3.1 Operation environment

- Temperature : 5 – 28 ℃ (41 - 82.4 ℉)
- Humidity : 30 – 75 % R.H.
- Pressure : 80 - 106 kPa

3.3.2 Transport and Storage environment

- Temperature : -10 – 60 ℃ (14 – 140 ℉)
- Humidity : 0 – 85 % R.H.
- Pressure : 70 - 106 kPa

3.4 Installation method

3.4.1 Precautions during installation

- Install the equipment on a flat surface.
- Install the equipment in a location with appropriate ambient temperature and humidity, and do not install in a location where it will be exposed to dust or flammable materials.
- Be careful not to damage the equipment by excessive shock.
- Do not place the ME device in a place where it is difficult to operate the power plug disconnection means.

3.4.2 Connection of power

- Do not connect power until equipment installation has not been completed.
- Plug the power cable into the power terminal on the back of the Z*Tone* and connect the other end to a grounded power socket.
- Make sure that the power socket and power cable are grounded before use.
- Check that the power cable is properly connected to the machine's power terminal and power socket. Incorrect connections can cause problems.
- When disconnecting the power cable, hold the plug when disconnecting.
- Do not connect multiple devices to a single power outlet.
- Connect the power cable to the power terminal of Z*Tone* as shown below and connect the other end to a grounded power socket.

Power cable connection

Warning To prevent the danger of electrical shock, connection shall be made to a protected and grounded power supply.

3.4.3 Moving and fixing of equipment

- Before moving the equipment, remove the connected power cable and the connection cables for peripheral equipment.
- When moving the equipment, place the transporting wheel as shown in below in the “loose” position.
- When the movement is completed, prevent the equipment from shaking by placing the transporting wheel in the “locked” position.
- If the equipment is moved while the wheel is in the “locked” position, it will damage the wheel, so please be careful.

Transporting wheel in 'Loose' (Left) and in 'Locked' (right)

3.4.4 Connection of Transducer

- The transducer is detachable from the main body. Before using the product, turn the lever to connect the transducer and the body.

Transducer connection

3.4.5 Transducer

- The Z*Tone* is equipment that generates a magnetic field by applying a strong current to a transducer. As heat is generated from the transducer due to the strong current used to create the magnetic field, cooling is performed by circulating the cooling oil inside the transducer. If the transducer is used while in a tilted position, the cooling oil will not reach all sections of the transducer, and injury or stoppage of operation due to overheating of the transducer can result. For this reason, it is recommended to place the transducer in a horizontal position as much as possible.

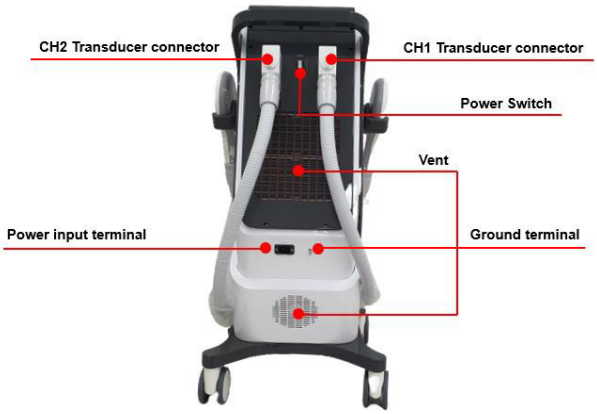
Caution Maintaining the transducer in a horizontal position is recommended.

4.1 External view

4.1.1 Front view

Name	Function
Control Panel (Touch Screen)	A display unit that operates the device using touch or displays the device's operating status
CH1 Transducer	Magnetic field output transducer
CH2 Transducer	Magnetic field output transducer
Wheels	Wheels for transporting and moving the device

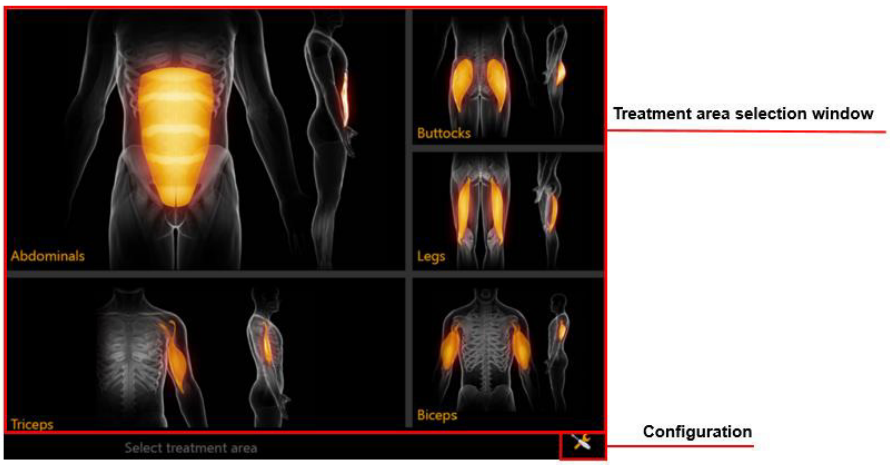
4.1.2 Rear view



Name	Function
CH2 Transducer connector	CH2 Transducer cable connector
CH1 Transducer connector	CH1 Transducer cable connector
Power Switch	Power ON/OFF switch
Vent	Vents for air circulation
Power input terminal	AC power inlet
Ground terminal	Equal power ground connection

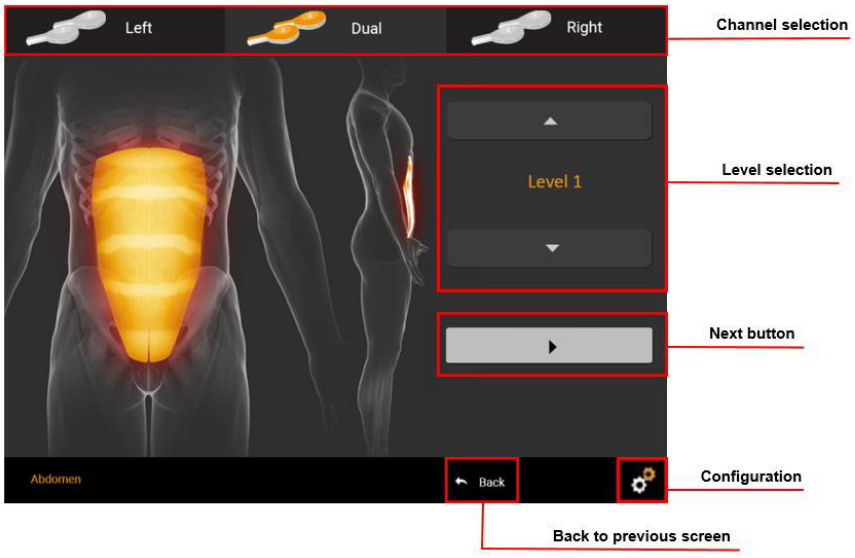
4.2 Controls

Initial screen



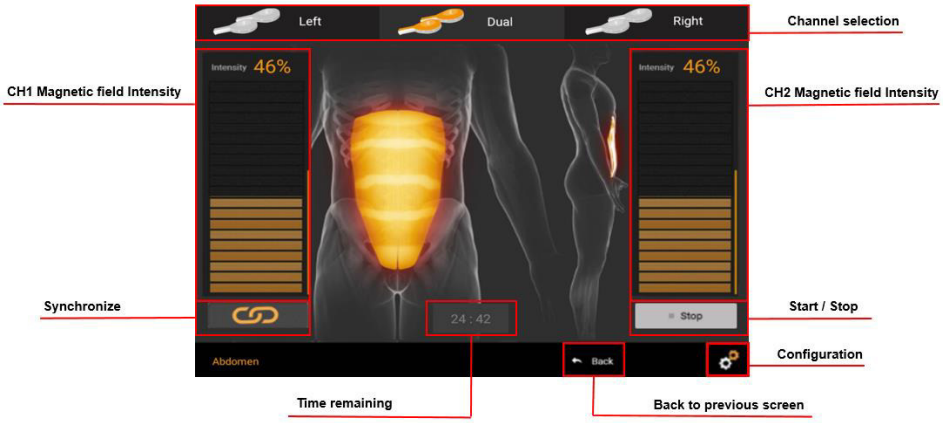
Name	Function
Treatment area selection window	Select the image of the area to be treated
Configuration	Brightness and volume settings

Level selection screen



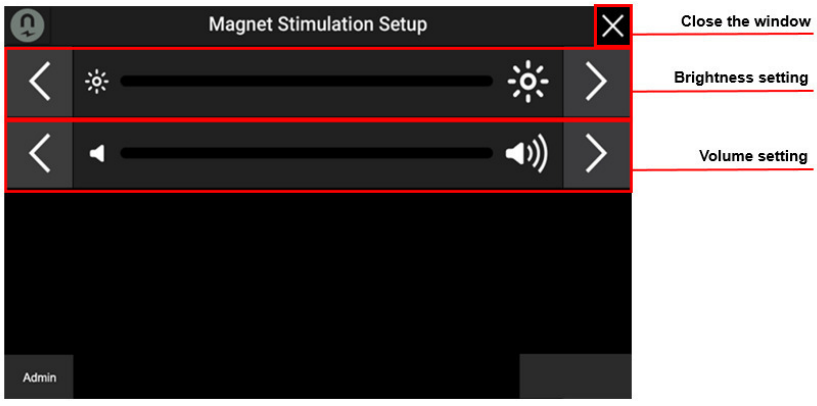
Name	Function
Channel selection	Select the transducer you want to use (Left = CH1, Dual = CH1 and CH2, Right = CH2)
Level selection	Select detail mode
Next button	Change to Intensity setting window
Back to previous screen	Return to treatment area selection window
Configuration	Brightness and volume settings

Intensity setting screen



Name	Function
Channel selection	Select the transducer you want to use (Left = CH1, Dual = CH1 and CH2, Right = CH2)
CH1 Magnetic field Intensity	Magnetic field strength can be set (0%~100%, 1% step)
CH2 Magnetic field Intensity	Magnetic field strength can be set (0%~100%, 1% step)
Synchronize	Simultaneous control of the intensity of CH1 and CH2
Time remaining	Display of remaining operating time
Start / Stop	Start and stop magnetic field output
Back to previous screen	Return to level selection window
Configuration	Brightness and volume settings

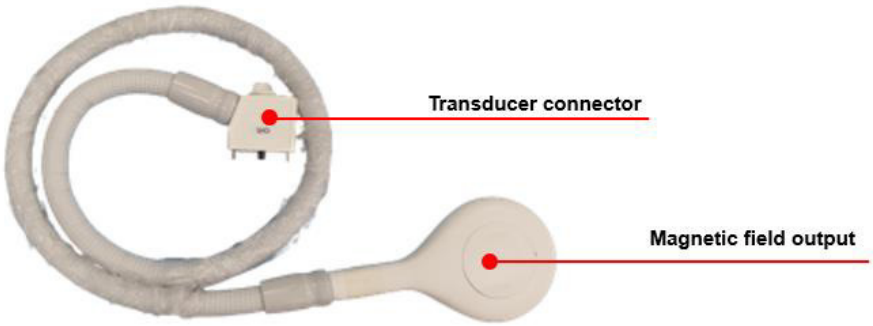
Configuration



Name	Function
Close the window	Return to previous screen
Brightness setting	Adjust the brightness of the screen in 7 steps
Volume setting	Volume control in 7 steps

4.3 Component

4.3.1 Transducer



Name	Function
Transducer connector	Transducer connector
Magnetic field output	Output part where the magnetic field of the coil is output

4.3.2 Power cable

Name	Function
Power Cable	The cable that supplies power to the Main Unit

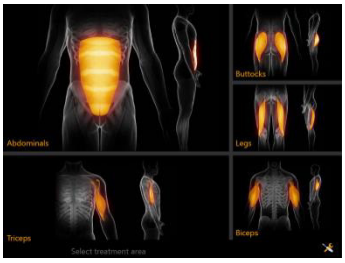
5.1 Patient Preparation

For hygiene reasons, the treatment area of the patient's body and the device are not in direct contact. There is no need to undress when using this device.
Please prepare some fabric towels to be placed on the treatment area of patient body for hygine purpose. We recommend cotton towles or covering materials to be applied before treatment starts.

5.2 How to Use

1. When the power switch on the back of the device is turned "ON", the Z*Tone* logo screen appears momentarily as shown in the figure below and then changes to the Initial screen.

Z*Tone* Logo



Z*Tone* Initial screen

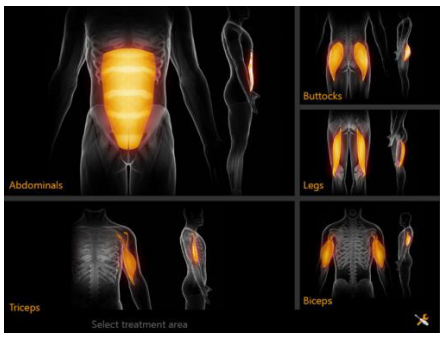
2. Select the image of the area to be treated. Different appropriate protocols are applied for each part of the body.

3. After selecting the desired transducer, select the level according to the frequency.

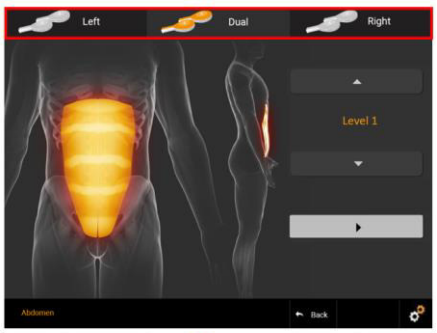
4. Select Intensity and position the transducer near the treatment site.

5.2.1 Method

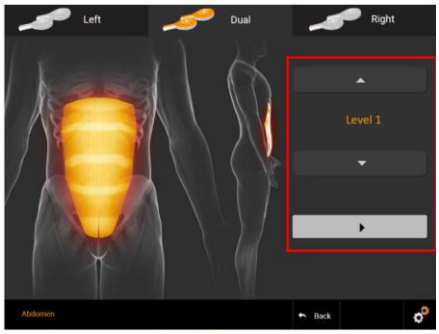
There are 5 modes in which the protocol is applied to suit the body part.
Frequency, on time, off time, strength, repetition are preset.
The selected mode has a fixed operating time.



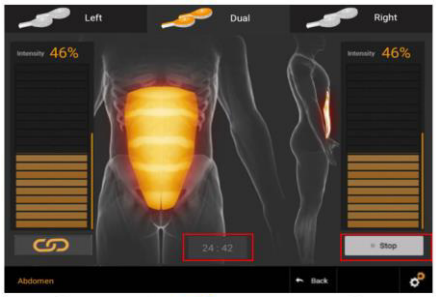
(a) Select the image of the area to be treated using the touch screen.



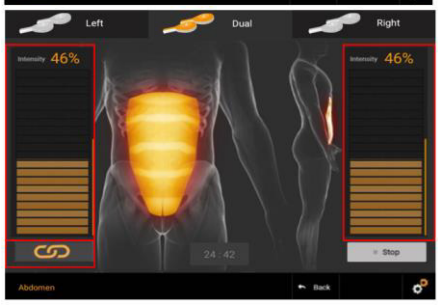
(b) Select the transducer you want to use. (Left = CH1, Dual = CH1 and CH2, Right = CH2)



(c) Select the frequency level of the treatment protocol. After that, click the Next button.



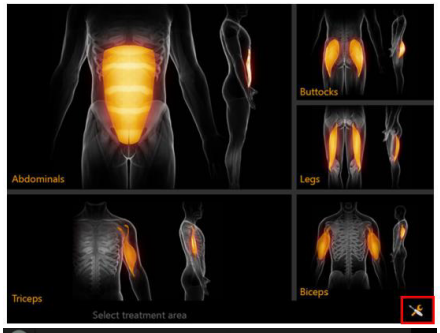
(d) When the start button is pressed, the remaining operating time is displayed.



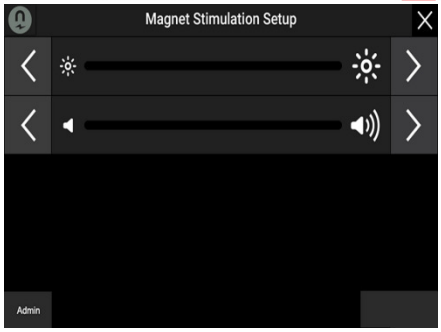
(e) Adjust the Intensity by touch-scrolling. If you touch-scroll after pressing Synchronize, the intensity of CH1 and CH2 is adjusted at the same time. (Synchronize is enabled only in Dual.)

5.3 Environment setting

The brightness of screen and volume can be adjusted.



(a) Press environment setting at the right bottom of the screen by using touch screen.



(b) Adjust the brightness of screen and the volume by using the button. After finishing all the settings, close the environment setting screen by pressing a OK button of the screen. (Adjustable to 7 levels in total)

5.4 Frequently used functions

1) Transducer attachment
The transducer must be closered to the affected part and fixed.

2) End operation
An image is displayed on the LCD display that the operation is finished, and the user must check it with the naked eye.

3) Video reading
The user should be able to check that the electromagnetic generator is running through the image displayed on the LCD.

4) Cleaning
After use, the device should be cleaned by lightly rubbing it with alcohol or lukewarm water on a soft cloth.

5) Holding / holding the device
When treating a patient, the user should treat the patient by lightly holding the handle of the Transducer.

6) Remove device
When removing the Transducer, do not pull the cable forcefully.

7) Switch ON
The user must turn on the power switch on the back of the main body to start patient treatment.

8) Switch OFF
The user should turn off the power switch on the back of the main body after using the device.

9) Output adjustment
The output must be controlled by the magnetic field intensity bar from 0% to 100%.

How to store and care for after use

6

How to store and care for after use

- The machine must be stored with the main power switch turned OFF.
- Be sure to remove the power plug from the outlet when not using the machine for a long time.
- To clean the machine, wipe it with a clean, dry cloth.
- Do not allow substances that may cause electric shock or short circuit, such as water or alcohol, to enter the device.
- Used equipment must be stored in a clean, well-ventilated, room temperature environment (temperature: -10 - 60 °C, humidity: 0 - 85 %), away from direct sunlight.
- Do not subject to severe shock or vibration when transporting or storing the equipment.

7.1 Over Temperature

The *ZTone* is an equipment that generates a magnetic field by applying a high current to a transducer. As heat is generated from the transducer using the high current used to create the magnetic field, cooling is performed by circulating the cooling oil inside the transducer. If the transducer is used in a tilted position, the cooling oil will not reach all sections of the transducer, and injury or stoppage of operation can occur. Because of this, it is recommended to place the transducer in a horizontal position. When transducer is overheated, the operation is temporarily suspended and the “Over Temperature” message is displayed. When this message is displayed, put the transducer away from the patient for a while (Do not turn off the equipment) until the message disappears and the equipment returns to a normal state.

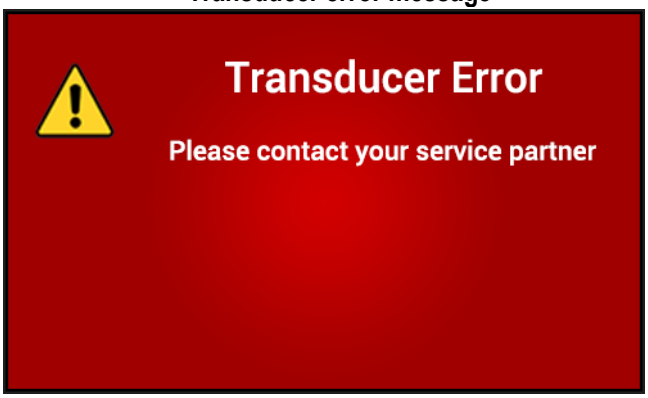
Over temperature message

Caution It is highly recommended to use the transducer in a horizontal position.

7.2 Transducer Error

The *ZTone* always checks the connection of the transducer cable. If the cable is disconnected or damaged, the message is shown. In this case, equipment cannot be used anymore, and the user must contact authorized personnel of our local distributor maintenance.

Transducer error message



Caution The equipment always checks the connection state of the cable connected to the transducer.

7.3 Warning

ZTone measures the temperature of the transducer at regular intervals and, if the temperature is higher than the set temperature, implements a function to notify the user with a warning message and sound.

Warning message

Technical specifications

8

8.1 Size and weight

- Size device: 570 (L) × 700 (W) × 1180 (H) mm
- Weight device: Approximately 81 kg (with transducer, no Safe Working Load)
- Size transducer: 300 (L) × 161 (W) × 36.5 (H) mm
- Weight transducer: 3.5 kg

8.2 Magnetic field strength

- CH1: 3.0 T – pp (±20%)
- CH2: 3.0 T – pp (±20%)

8.3 Protocol provided (electromagnetic field)

- Abdominals
- Triceps
- Buttocks
- Legs
- Biceps

8.4 Stimulation frequency

- 1 ~ 35 Hz (±20%)

8.5 Stimulation Pulse Width

- CH1: 420μs (±20%)
- CH2: 420μs (±20%)

8.6 Classifications

- Protection type and level for electric shock : Class I, BF Type
- Electromagnetic compatibility (EMC) test standard: class A

8.7 Expected life time

- 2.4 years

EMC emissions and immunity

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A).
If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guidance and Manufacturer's Declaration – Electromagnetic Emission		
COMPACT-II is intended for use in the electromagnetic environment specified below. Customers and users of the COMPACT-II should ensure that the Z*Tone* is used in such an environment.		
Radiation test	**compatibility**	**Electromagnetic Environment - Guidance**
RF Emission CISPR 11	Group 1	The Z*Tone* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emission CISPR 11	Calss A	The Z*Tone* is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This Z*Tone* is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Z*Tone* or shielding the location.
Harmonic Emission IEC 61000-3-2	Class A	
Voltage fluctuation / Flicker IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The COMPACT-II is intended for use in the electromagnetic environment specified below. The customer or the user of the Z*Tone* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Fit level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge 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, ±15kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, a relative humidity of at least 30% is recommended.
Electrical fast transient/burst IEC 61000-4-4	±2 kV (for power Supply lines) ±1 kV (for input /output lines)	±2 kV (for power supply lines) ±1 kV (for input /output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IED 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, Short interruptions, and voltage variations on power-supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5/1 cycles 70% U_T (30% dip in U_T) for 25/30 cyclesa 0% U_T (100% dip in U_T) for 250/300 cycles[a]	0% U_T (100% dip in U_T) for 0.5/1 cycles 70% U_T (30% dip in U_T) for 25/30 cyclesa 0% U_T (100% dip in U_T) for 250/300 cycles[a]	Mains power quality should be that of a typical commercial or hospital environment. If the user of this product requires continued operation during power mains interruptions, it is recommended that this product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

NOTE: U_T is the main voltage (AC) prior to the application of the test level.

[a] For example, 10/12 means 10 cycles at 50 Hz or 12 cycles at 60 Hz.

Guidance and manufacturer's declaration-electromagnetic immunity			
The Z*Tone* is intended for use in the electromagnetic environment specified below. The customer or the user of the Z*Tone* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Fit level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz – 80 MHz Outside ISM Bands[c] amateur radio bands Bands[d] 6 Vrms 150 kHz – 80 MHz In ISM bands[c] amateur radio bands Bands[d]	3 Vrms 6 V/m	Portable and mobile RF communications equipment should not be used closer to any partof the Ultrasound System, including cables, than the recommended separation distance. This is calculated using the equation applicable to the frequency of the transmitter. Recommended Separation Distance d = 1.2√P
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.7 GHz		d=2.0√p 80 MHz to 2.7 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 COMPACT-II is used exceeds the applicable RF compliance level above, the COMPACT-II should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the COMPACT-II

[b] When the frequency range exceeds 150 kHz – 80 MHz, the electric field strength should be not higher than 3 V/m.

[c] The ISM (Industrial, Scientific and Medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz

[d] The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Recommended separation distances between portable and mobile communication equipment and the *ZTone*		
The *ZTone* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *ZTone* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *ZTone* 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]**	
	IEC 60601-1-2:12014	
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 2.7 GHz** $d = 2.0\sqrt{P}$
0.01	0.12	0.20
0.1	0.38	0.63
1	1.2	2.0
10	3.8	6.3
100	12	20

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.
NOTE 1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration-electromagnetic immunity					
The Z*Tone* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Portable RF communications equipment should be used no closer than 30cm (12 inches) to any part of the Z*Tone*. Otherwise, degradation of the performance of this equipment could result.					
Immunity test	**Band [a]**	**Service [a]**	**Modulation**	**IEC60601 test level**	**Compliance Level**
Proximity fields From RF wireless Communications IEC61000-4-3	380 - 390 MHz	TETRA 400	Pulse modulation 18Hz	27 V/m	27 V/m
	430 – 470 MHz	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	28 V/m	28 V/m
	704 – 787 MHz	LTE Band13, 17	Pulse modulation 217 Hz	9 V/m	9 V/m
	800 – 960 MHz	GSM800:900 TETRA 800 iDEN 820 CDMA 850	Pulse modulation 18 Hz	28 V/m	28 V/m
	1700 – 1990 MHz	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,2,4,25 UMTS	Pulse modulation 217 Hz	28 V/m	28 V/m
	2400 – 2570 MHz	Bluetooth WLAN 802.11b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	28 V/m	28 V/m
	5100 – 5800 MHz	WLAN 802.11a/n	Pulse modulation 217 Hz	9 V/m	9 V/m

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

[a] For some services, only the uplink frequencies are included.
[b] The carrier shall be modulated using a 50% duty cycle square wave signal.
[c] 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.

Can it be used for the area of the body with artificial joints or plate pins?	Due to the nature of the magnetic field deep heat will be generated, which may cause deep-seated burns.
Is it the same effect to use on clothes?	One of the characteristics of a magnetic field is that it is permeable with a similar therapeutic effect. Therefore, it can be used on clothes.
Are there any precautions when using on clothes?	If there is a metallic decoration on the clothes, the magnetic field may cause burns on the surface of the skin. (e.g., bra strap rings, underwear metal ornaments, metal-containing fibers).

If you wish to discard the existing product after purchasing a new product from Zimmer MedizinSysteme GmbH, we will deal with it free of charge when the new product is delivered. This device cannot be disposed of with household waste and must be disposed of in accordance with professional disposal procedures. Please proceed according to the disposal procedure of each country. If necessary, please contact our customer service center.

11.1 Cleaning procedure

ZTone and accessories can be kept clean in a number of ways. Use the methods recommended below to avoid damage or contamination of the instrument. Before cleaning the device, be sure to turn off the power of the device. Cleaning the inside of the device is only permitted by persons authorized by us.

- Periodically clean the exterior of the instrument, transducer, and touch screen with a soft cloth moistened with alcohol, and do not use abrasives, lacquers, thinners, ethylene, or oxides. These substances may cause permanent damage to the product.
- Do not immerse any part of the device in liquids or detergents. Also, do not allow any liquids to enter the device or accessories.
- At the end of single patient use, clean the transducer surface with alcohol and a soft cloth.
- If you want to use a method or disinfectant other than those mentioned above, the device may be damaged, so be sure to contact us before using it. Please note that if the device is damaged by using an unauthorized substance, the warranty is not guaranteed even during the warranty period.

11.2 Routine inspection of equipment

- The covering of power line of equipment, transducer connecting line, etc. shall not be peeled off and internal lines shall not be exposed, and shall not be damaged by impact from outside.
- There shall be no trace of oil leakage from transducer.
- Clean the outside of equipment so that there is no foreign material.
- The button for equipment operation, etc. must not shake.
- The various parts attached to equipment must not shake.
- If any of the above occur, contact customer service for help.

11.3 Safety inspection

- In order to ensure safe use, internal cleaning should be performed once per year by a person authorized by the manufacturer.
- In order to ensure safe use, be sure to check the equipment including internal components and output voltage from the person who has been given authorization from the manufacturer once per year.
- Please clean the transducer before storing it
- When storing the product for a long period of time, be sure to check the product before using it.
- Please note the followings regarding storage conditions.
    - Keep out of water
    - Keep away from direct sunlight
    - Do not store near heaters
    - Avoid locations subject to excessive shock or vibration, exposure to chemicals or explosive gases.

11.4 Troubleshooting

If the equipment does not operate normally during use, please check the items listed in the table below before requesting service. If none of the following problems apply, or if the following remedies do not help, turn off the power to the equipment and contact the Zimmer MedizinSysteme GmbH Customer Service Center.

Symptom	What to do	References in the Instructions For Use
Equipment does not turn on.	Check the power connector of the equipment is properly connected.	• 3.4.2 Connection of power
	Check the power switch of equipment is turned on.	• 4.1.2 Figure 5. Rear view
Magnetic field is not generated from equipment	Check the LCD displays an ERROR message.	• 7. Messages
	Check the output strength is set by magnetic field intensity bar after pressing the Start button.	• 5.2.1 Method – (e)
Over Temperature message is displayed.	If transducer is in an upright position, it is easy for the transducer to overheat. Maintain a horizontal position as much as possible.	• 7. Messages
	If the room temperature is too high, disorder can be caused in the cooling. Maintain the room temperature at less than 25°C as much as possible.	• 3.3 Environmental condition
Wheel does not roll when moving the equipment.	Move the equipment by placing the wheel in the ”Loose” position.	• 3.4.3 Figure 3. Transporting wheel in ‘Loose’ and in ‘Locked’.

In the following cases, stop the operation by off the power to the equipment, and contact the service center.

→ The main power switch spontaneously turns off.
→ The LCD screen of operation panel does not illuminate when power is turned off and then turned on again.
→ When stimulation is not generated by transducer, even after intensity is increased.
→ The temperature icon on the screen blinks and the equipment is not operated.

11.5 Regular inspection for performance maintenance

In order to ensure safe use, be sure to do regular inspection from the person who has been given authorization from the manufacturer once per year.

11.6 Warranty

- This product is manufactured through an intensive quality control and inspection process.
- Compensation for repair and exchange of the product will be in accordance with the “Consumer Injury Compensation Rule” announced by the Economy Planning Board.
- The warranty period for this equipment is 1 year.
- If a failure occurs during the warranty period under normal operating conditions, the equipment will be repaired free of charge by our customer service center.
- If a problem with the equipment occurs during the warranty period, prepare the following customer service request form to report to our company.

Customer Service Request Form

The purpose of this form is to obtain information that will enable us to expeditiously process your service request. Please describe the fault or abnormality in as much detail as possible.

1. User information
- Name of hospital:
- Address of hospital:
- User name/telephone number: (Tel :)

2. Information on the equipment in use (refer to label on the back of product)
- Name of model : Z*Tone*
- Date of purchase :
- Serial number of product :

3. Description of technical problems (Describe as much detail as possible.)

4. User checklist
If you are not able to answer the questions with yes or no, please add information in the remarks column. If you are unsure of the answer, you can leave the item blank.

Number	Inspection item	Evaluation result	Remarks
1	Is the equipment unavailable due to the failure, currently?	Yes/No	
2	When the power switch of the equipment is turned on, do the touch screen and any part of the equipment operate properly?	Yes/No	
3	Is output generated by the equipment?	Yes/No	
4	Is the strength of the output from equipment conspicuously different from when it was first installed? If so, how would you rank the difference in performance, in terms of a percentage?	Yes/No	
5	Can you perceive a change of output if the output strength of equipment is adjusted?	Yes/No	
6	Is there any leakage of liquid from equipment?	Yes/No	
7	Is there any damaged part in the external appearance? Describe this in the remarks column.	Yes/No	

Customer Service Request Form

Customer service

It is essential that you notify technical support / customer service of any problems that occur frequently or cannot be resolved.
Technical support / customer service can be reached via the head office in Neu-Ulm.

Manufacturer

Remed Co.,Ltd. (certified device name „Perfect“)
Member of Zimmer Group
301-303, Migun Techno World II, 187, Techno 2-ro, Yuseong-gu, Daejeon, 34025, Republic of Korea

Service Head office

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Junkersstraße 9
89231 Neu-Ulm
Germany
Tel. +49 731 / 9761-291
Fax +49 731 / 9761-299
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Device Disposal

The device must be returned to the factory.
It must be disposed of by Zimmer MedizinSysteme GmbH.

In (European) foreign countries, please observe the national disposal regulations.
If necessary, contact the distributor.

European Representative

EC REP

Obelis s.a.
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Instructions for use

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