kegelEX Talent®

REMED
Rehabilitation Medical Company

SALUS-TALENT-A-Aes
User Manual

Preface

The user of this device must sufficiently understand its functions and the precautions that must be observed for its safe use and stable performance.

For the safe use and post management of the device, be sure to thoroughly understand the details of the Instructions For Use before using the device. This is essential to guaranteeing the safe use and stable performance of the device.

The Instructions For Use provides a guide to the efficient use of the SALUS-TALENT-A-Aes. For clinical definitions, pathological effects etc., of its functions, refer to the related medical publications.

As the Instructions For Use has been arranged in independent chapters, some of the descriptions have been duplicated.

If you encounter any problems during operation of the equipment, stop its use immediately, and contact the customer service center of REMED (Refer to chapter 12).

This Instructions For Use (IFU-T-Aa) is only valid for Australia.

Contents

List of Figures

List of Tables

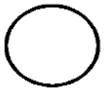
1. Information on safety

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.

	**Warning**	“Warning” symbol is used to indicate a life-threatening risk to the operator if the warning is disregarded.
	**Caution**	“Caution” symbol is used to indicate that injury or damage can be caused if the caution is disregarded.
	**No pushing**	To prohibit pushing against an object
	**No sitting**	To prohibit sitting on a surface
	**BF Type**	Applied part BF type (Transducer, Transducer cable)
	**Instructions for use**	Follow instructions for use
	**Serial number**	Serial number
	**Manufacturer**	Manufacturer
	**Date of manufacture**	Date of manufacture
	**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.

	**Keep away from rain**	To indicate that the transport package shall be kept away from rain and in dry conditions.
	**Fragile**	To indicate that the contents of the transport package are fragile and the package shall be handled with care.
	**This way up**	To indicate correct upright position of the transport package.
	**Recycling**	To indicate the location of a recycling bin or container.
	**“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.
	**Alternating current**	To indicate on the rating plate that the equipment is suitable for alternating current only to identify relevant terminals.
	**WEEE**	Indicates that when the end-user wishes to discard this product it must be sent to separate collection facilities for recovery and recycling.
	**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.
	**Warning Electricity**	To warn of electricity.
	**Operating instructions**	To identify the location where the operator’s manual is stored or to identify information that relates to the operating instructions.

	**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. for local bonding.

1.2 Requirements for safety

1.2.1 Precautions for electrical safety

- ❏ The rated power for this equipment is AC 230 V.
- ❏ Confirm that all the connecting sections (power line or peripheral equipment) are adequately connected to the equipment.
- ❏ Confirm that the equipment is completely grounded.
- ❏ Repair, expansion, and installation of equipment shall not be performed by anyone other than the specialized personnel authorized by the manufacturer. Arbitrary disassembling/assembling of equipment by the user is absolutely prohibited.
- ❏ Before connecting other equipment that is not specified in the Instructions For Use, be sure to inform this company or the agency with authority over product marketing.
- ❏ To avoid electrical noise during use, the equipment shall be installed at a significant distance from any generator, X-ray equipment, broadcasting device, mobile electric wire, and so forth.
- ❏ Needs attention due to potential electromagnetic or other interference between ME EQUIPMENT and other devices.
- ❏ An independent power circuit is essentially required, and sharing of power with other electronic devices is not recommended.
- ❏ Do not place the ME EQUIPMENT in a location where it is difficult to disconnect the power plug or other detachable plug.

1.2.2 Classifications

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

1.3 Precautions during operation

❑ Installation and re-installation of equipment shall always be performed by specialized personnel authorized by the manufacturer.

❑ Installed equipment shall be subject to regular safety inspections from specialized personnel authorized by the manufacturer.

	**Caution**	"PLEASE MAKE SURE THAT PATIENT IS NOT WEARING ANYTHING WITH METALLIC OBJECTS DURING TREATMENT FAILURE TO DO SO MAY RESULT IN SERIOUS SKIN BURN!"

❑ Repair or installation of equipment shall only be performed by the specialized personnel authorized by the manufacturer, and as such, all arbitrary disassembly/assembly of equipment by the user is absolutely prohibited.

❑ For electrical safety, equipment shall always be connected to a safely grounded power supply for operation.

❑ The operator and manager of equipment shall thoroughly understand the Instructions For Use, and it must be kept in the close proximity of the equipment.

❑ To prevent safety accidents and ensure adequate maintenance, place the safety marks, guide phrases and regular inspection table provided with the equipment at an easily visible location near the equipment.

❑ As a fan is installed in the body of the equipment for air circulation, remove curtains or any other objects which can block the flow of air from near the equipment.

❑ From the surroundings of the location where equipment is installed, remove water, alcohol, flammable materials, and so forth.

❑ As a strong magnetic field is generated around the magnetic field generating section, equipment operation technicians, assistants, and patients must not hold any items which can be affected by the magnetic field.

	**Note**	Items such as wristwatches, mobile phones may be damaged by magnetic fields, so please be careful and keep them separately.

❑ When equipment is operated, do not use any mobile phones, radio sets, mobile radio transmitters, wireless toys, etc. in the proximity of the equipment.

❑ During the operation of the equipment, the patient shall not take drinks, water, etc. which can influence the equipment.

1.4 Do and Don't

❏ 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

1.5 Abnormal reaction

❏ During the operation of the equipment, if the patient experiences any abnormal symptoms, the operator must stop the treatment immediately, and contact the doctor in charge.

1.6 General warnings

❏ Be sure to use the equipment in accordance with the Instructions For Use.

❏ In the Instructions For Use, the method for the correct use of the equipment is described. Read the Instructions For Use carefully.

❏ The equipment shall be operated under the supervision of a person who has completed specialized medical education.

❏ This company is not responsible for any disadvantages / damages related to the operation of equipment by a person without a medical education.

❏ This equipment shall not be altered, remodeled, or used for any purpose other than the intended objective.

1.7 Safety label

❑ Labels attached to devices provide information and safety information.

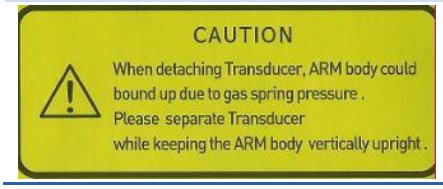
Label	Attachment position	Safety contents
	Upper side surface of transducer arm	Warning mark related to transducer arm

Table 1. Safety label

2. High intensity pulsed electromagnetic field

2.1 Mechanism

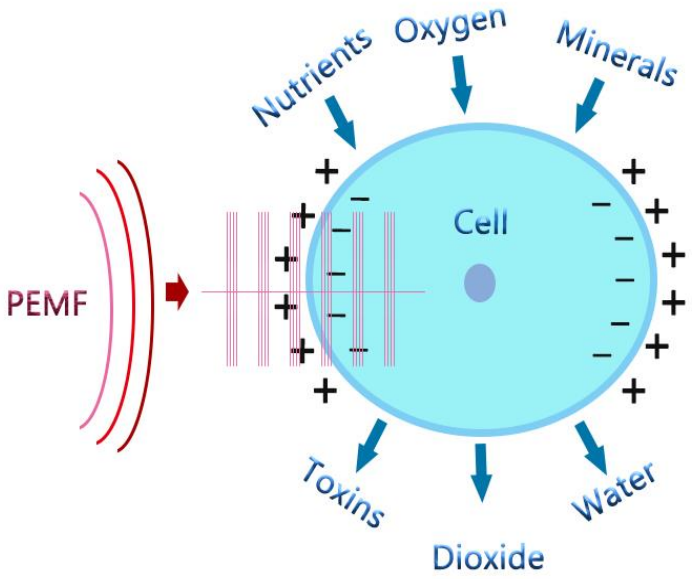


Figure 1. Cells and electromagnetic field

Every tissue in the body is made up of cells, and all the functions are based on the activity of the cells. Each cell is surrounded by a cell membrane and protected. Since ions in a cell have a charge, the cell membrane also has charge, which supplies oxygen or nutrients and removes unnecessary things in the cell. Membrane charge of healthy cells is higher than that of diseased or aged cells, including bacteria, viruses, and cancer cells. For example, cancer cells have a membrane charge of about 15 mV lower than healthy cells. When the cell membrane charge is low, the cell has too little energy to perform its normal function. So, the cell needs energy, and electromagnetic field stimulation is known to increase the energy of the cell and optimize the function of the cell. Electromagnetic fields can pass through cells, tissues, organs and bones without any deformation or loss, activate the electrochemistry of tissues, and improve cell and cell membrane function. PEMF procedures can be used for the following purposes:

(1) Inflammation

The electromagnetic field reduces inflammation by recharging the cell surface. This recharge prevents the chain of inflammation inside the cell, reducing pain and swelling associated with inflammation. In addition, it supplies blood and oxygen to the wound area, and it is said to help the quick recovery.

(2) Bone and Cartilage

The PEMF applied to the fractured area maximizes the electric polarity. This naturally helps to heal fractured parts and promotes fracture recovery. Healthy bones maintain

a dynamic balance of positive and negative charges, while broken or fractured bones show equilibrium breakdown and negative electrical environment. At this time, the body's natural healing begins at the fracture site, and many studies have shown that PEMF affects this natural healing.

(3) Pain

PEMF has been used to treat pain since the late 20th century. PEMF is known to enhance the metabolism of fibroblasts, chondrocytes, osteoblasts, and the effects of hormones and neurotransmitters on the receptors of various cells. A number of studies have shown that patients who have not had an effect on surgery, medication, or physical therapy are less likely to have PEMF treatment. PEMF is used for the treatment of various pain such as back pain, neck pain, shoulder disease, knee osteoarthritis, postherpetic neuralgia, pelvic pain, multiple sclerosis, neuropathic pain.

(4) Osteoporosis

PEMF promotes the formation of bone and helps to treat osteoporosis. Previously published studies have shown that the bone mineral density of 20 osteoporotic patients treated with PEMF increased by an average of 5.6% after 6 weeks of treatment.

(5) Fibromyalgia, Arthritis, Chronic Fatigue

PEMF is known to have immediate pain relief in treating pain in patients with fibromyalgia, arthritis, and chronic fatigue. PEMF also affects the delivery of calcium ions, promotes the uptake of calcium in the bone, and helps in the synthesis of cartilage cells.

2.2 Intended use

An electromagnetic stimulator is an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes non-contacting the affected body area. And, in addition, the electromagnetic stimulator 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 human.

3. Installation

3.1 Components

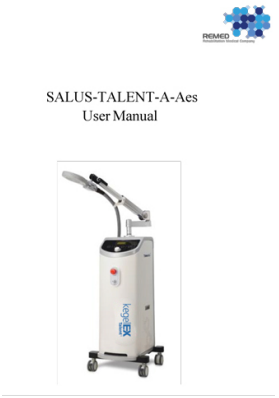
Main body with transducer	Power cable	Instructions For Use
		

Figure 2. Main components

3.2 Electrical installation condition

- ❏ Input power : 230 V~, 50 Hz
- ❏ Power consumption : Max. 1.9 kVA

3.3 Environmental condition

3.3.1 Operation environment

- ❏ Temperature : 10 – 30 ℃ (50 – 86 ℉)
- ❏ Humidity : 30 – 80 % RH

3.3.2 Transport and Storage environment

- ❏ Temperature : -10 – 50 ℃ (14 – 122 ℉)
- ❏ Humidity : 90 % RH max

3.4 Installation method

3.4.1 Precautions during installation

- ❏ Install the equipment on a flat surface.
- ❏ Confirm that the power is connected.
- ❏ 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 EQUIPMENT in a location where it is difficult to disconnect the power plug or other detachable plug.

3.4.2 Connection of power

- ❏ Confirm that power socket and power cable are grounded before operating the machine.
- ❏ Connect the power cable to the back power terminal of SALUS-TALENT-A-Aes, as shown in [Figure 3] below and connect the remaining one to ground.
- ❏ Make sure that the power socket and power cables are grounded.
- ❏ Confirm that the power cable is properly connected to the power terminal and power socket. If the connection is incorrect, unexpected problems can occur.
- ❏ Grap the plug point when you unplug the power cable.
- ❏ Do not connect several devices to one power outlet.
- ❏ In particular, do not use a power cable that generates connection noise.

Figure 3. Power cable connection

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

⚠	**Caution**	Please do not connect the power cable without any power switch off, as this may cause a fault.

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 at the lower section 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.

Figure 4. Transporting wheel in 'Loose' (Left) and in 'Locked' (right)

3.4.4 Transducer

- ❏ The SALUS-TALENT-A-Aes 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.

❑ When separating the transducer from the transducer arm supporter, the pressure of the gas spring may cause the arm to jump up and the transducer may fall off. Be sure to hold the transducer with one hand while holding the arm supporter vertically. When replacing the transducer, be sure to mount the arm support vertically as well.

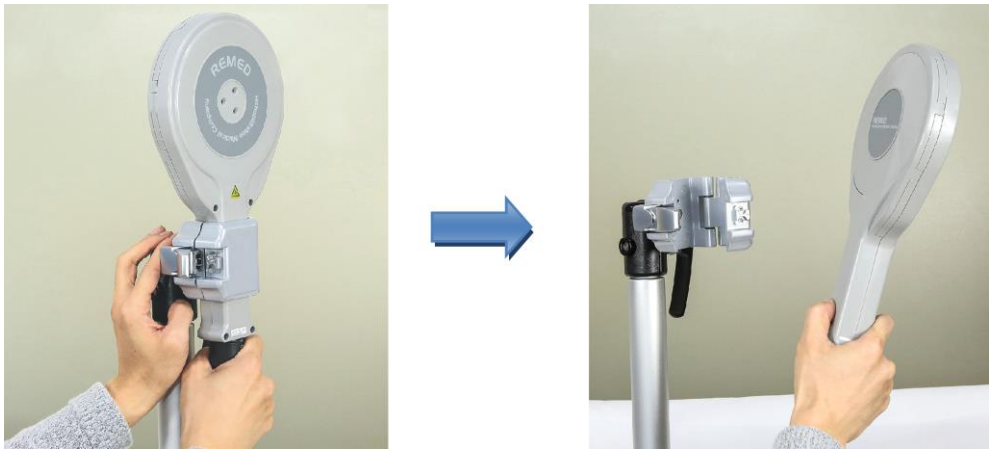


Figure 5. Separating the transducer from the transducer arm supporter

⚠	**Warning**	When separating the transducer from the transducer arm supporter, the pressure of the gas spring may cause the arm to jump up and the transducer may fall off. Be sure to hold the transducer with one hand while holding the arm supporter vertically. When replacing the transducer, be sure to mount the arm support vertically as well.

❑ When using the SALUS-TALENT-A-Aes for a long time, the transducer arm support may be struck down or up. In this case, the position of the transducer arm support can be changed by adjusting the gas spring pressure. To lower the arm support, turn the hexagonal wrench bolt in the (–) direction as shown in Figure 6, and turn it in the (+) direction to lift it upwards.

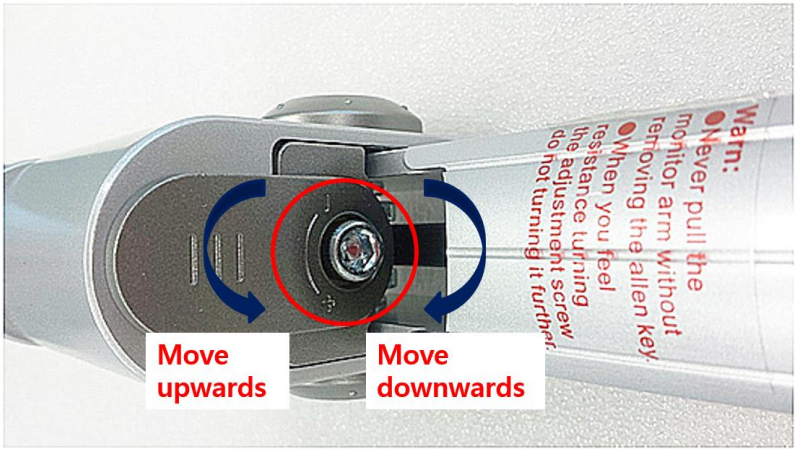


Figure 6. Adjusting height of the transducer arm support

4. Product description

4.1 External view

4.1.1 Front view

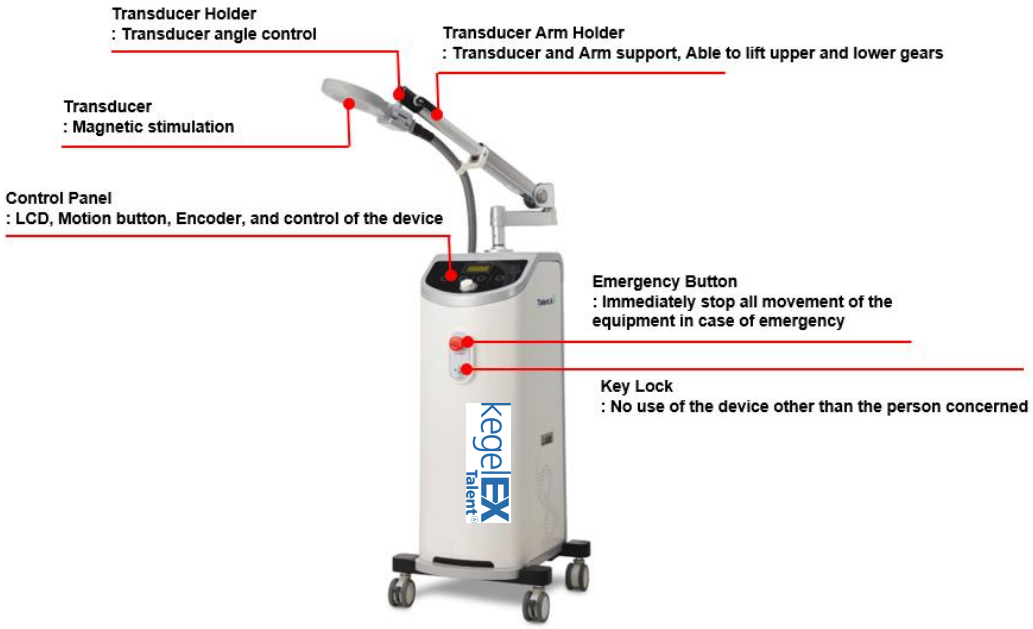


Figure 7. Front view

4.1.2 Rear view

Figure 8. Rear view

4.2 Transducer

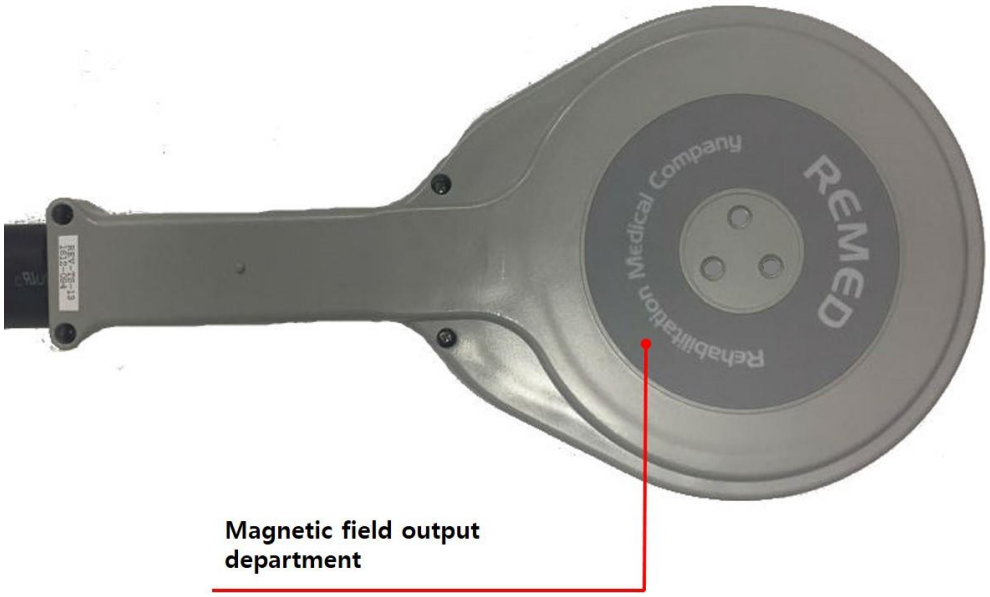


Figure 9. Transducer

4.3 Control

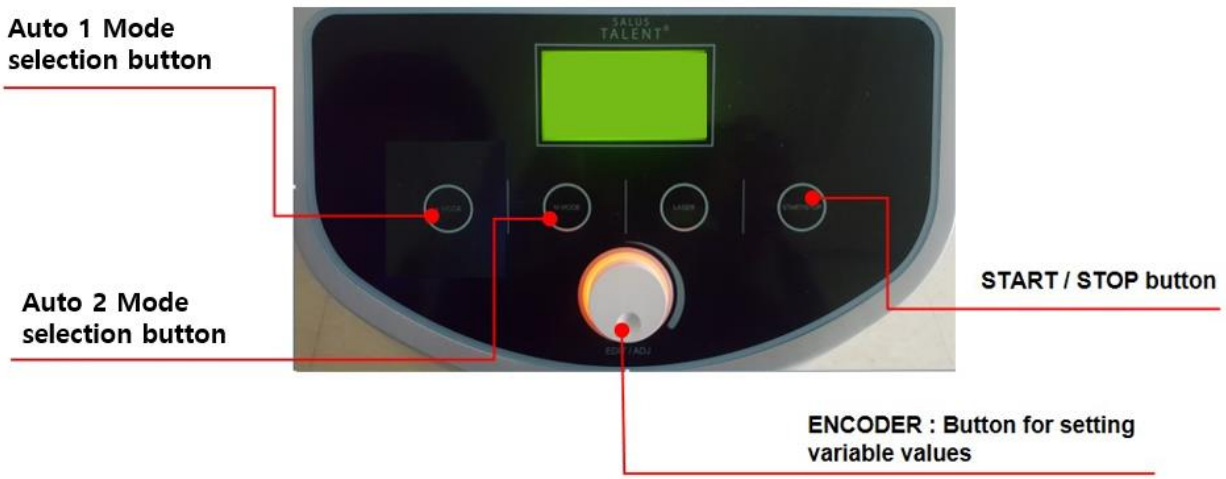


Figure 10. Control

5. Preparations for operation

5.1 Moving and fixing 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 at the lower section 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.

5.2 Power connection

❏ Confirm that power socket and power cable are grounded before operating the machine.

❏ Plug the power cable into the power terminal of the SALUS-TALENT-A-Aes, and connect the other end to a grounded power socket.

❏ Confirm that the power cable is properly connected to the power terminal and power socket. If the connection is incorrect, unexpected problems can occur.

❏ Do not connect several devices to one power outlet.

❏ In particular, do not use a power cable that generates connection noise.

6. Operation instructions

6.1 Transducer placement

❑ You can adjust the position and angle of the transducer according to the patient and the stimulation area. The transducer arm supports can be moved up and down and left and right, and the angle of the transducer can be adjusted using the transducer holder. The height of the transducer arm is adjusted by the weight of the transducer using gas spring pressure. Refer to Figure 6 to adjust the height. To adjust the angle of the transducer, hold the transducer holder in the unlocked position and adjust the angle. The holder must be locked after adjustment is complete. Please refer to Figure 11 below.

Figure 11. Changing the angle of the transducer

❑ If the transducer hose is deflected as shown in Figure 12, the hose may break or be damaged. When positioning the transducer, make sure that the hose is not bent.

Figure 12. Deflected transducer

	**Warning**	Do not use the transducer if the transducer hose is bent.

6.2 Applications

The SALUS-TALENT-A-Aes can be used at different sites of the body depending on the pain. Figure 13 shows the use of the most common applications (Please note that there are some variations in the design of the transducer arm depending on the time of release.).

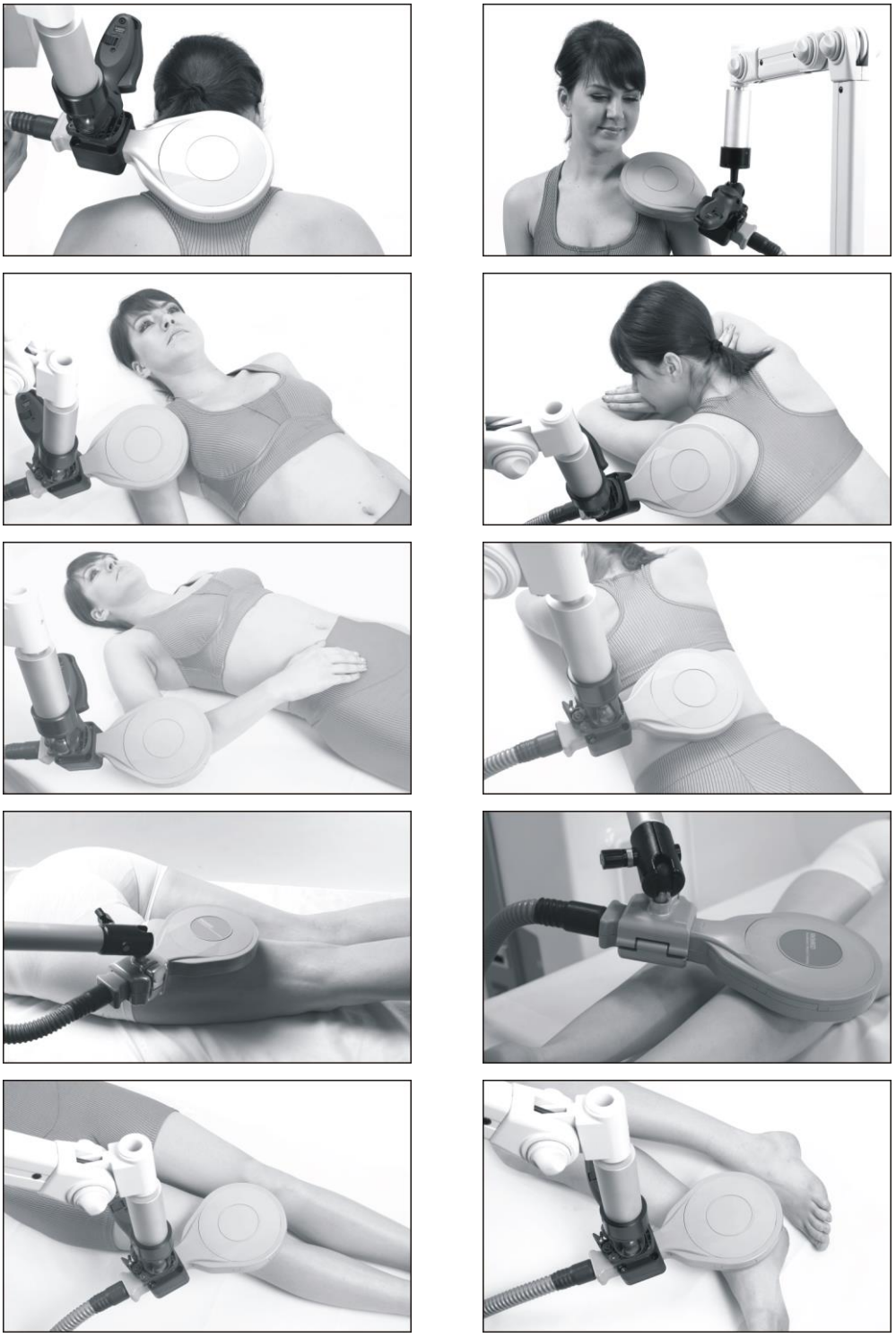


Figure 13. Application of the SALUS-TALENT-A-Aes

6.3 Operating mode

Turn on the power switch located on the back of the equipment. When the power is turned on, the screen of the control panel is turned on as shown below, the screen below appears in the order of the screen:

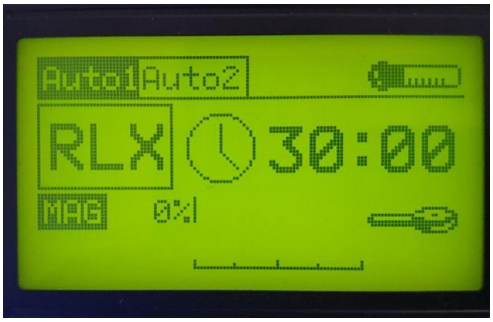


Figure 14. Main Screen

The main screen consists of as follows:

Figure 15. Main Screen Components

The SALUS-TALENT-A-Aes has Auto1 and Auto2 modes. Parameters of the Auto1, 2 mode is pre-fixed. Select the mode you wish to run using the A Mode, M mode button.

6.3.1 Auto 1 Mode

Mode		Recommeded application
AUTO1	1	ABDOMEN(ABS)
	2	BUTTOCKS (BTX)
	3	LEGS (LGS)
	4	RELAX (RLX)

This mode has “ABDOMEN”, “BUTTOCKS”, “LEGS”, “RELAX” modes, and the frequency, train duration an, inter train interval are set in advance. The waveform of the selected mode is applied repeatedly during the operation time set by the user. The user is able to set the total operating time and magnetic field strength. The usage of Auto 1 mode is as follows.

(a) Press the A Mode button to select the mode you wish to run. The selected mode appears on the screen.

(b) Turn the encoder to set the operating time. Time can be adjusted from 1 minute to 60 minutes per minute.

(c) Turning the encoders to set the magnetic intensity. The equipment initiates the operation. The magnetic field strength appears in the unit %, and the transducer icon at the bottom right shows the magnetic field output shape.

6.3.2 Auto 2 Mode

Mode		recommeded application
AUTO2	1	ABDOMEN(ABS)
	2	BUTTOCKS (BTX)
	3	LEGS (LGS)
	4	RELAX (RLX)
	5	U.I Mode(U.I)
	6	TEST (TST)

This mode has “ABDOMEN”, “BUTTOCKS”, “LEGS”, “RELAX”, “UI” modes, ″REFERENCE(TEST)” and the frequency, train duration an, inter train interval are set in advance. The waveform of the selected mode is applied repeatedly during the operation time set by the user. The user is able to set the total operating time and magnetic field strength. The usage of Auto 2 mode is as follows.

(d) Press the A Mode button to select the mode you wish to run. The selected mode appears on the screen.

(e) Turn the encoder to set the operating time. Time can be adjusted from 1 minute to 60 minutes per minute.

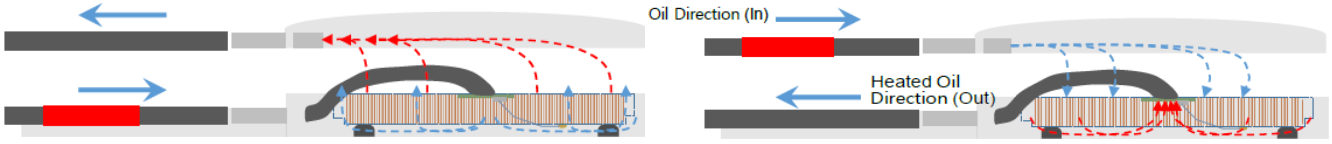
(f) Turning the encoders to set the magnetic intensity. The equipment initiates the operation. The magnetic field strength appears in the unit %, and the transducer icon at the bottom right shows the magnetic field output shape.

6.4 UI (Urinary Incontinence) mode

**UI Chair (Optional)*

The Salus-Talent-A-AES can be used for Urinary Incontinence by changing of In and Out hoses. Depending on whether a device is for UI or for pain treatment, the direction of the hoses is determined for designated use during production.

6.4.1 Difference of In and out Hose Direction



<Pain Treatment or Aesthetics Treatment>

<U.I. Treatment>

6.4.2 Preparations for operation with UI Chair

- Place transducer in the middle of the marked point

7. Messages

7.1 Over Temperature

The SALUS-TALENT-A-Aes 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 as shown in Figure 17 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.

Figure 17. Over temperature message

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

7.2 Cooling Module Life Time

The SALUS-TALENT-A-Aes uses an oil pump for cooling. This is a component with a guarantee of 5,000 hours. Once 5,000 hours is elapsed, the “Cooling Module” message shown in Figure 18 is shown. This is not a failure but a warning to the user for replacing cooling module. The message disappears, when the user presses the message. It is recommended to contact the authorized personnel of our local distributor for replacing the cooling module.

Figure 18. Cooling module life time message

7.3 Transducer Error

The SALUS-TALENT-A-Aes always checks the connection of the transducer cable. If the cable is disconnected or damaged, the message is shown, Figure 19. In this case, equipment cannot be used anymore, and the user must contact authorized personnel of our local distributor maintenance.

Figure 19. Transducer error message

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

8. Technical specifications

8.1 Size and weight

❏ Size : 526 (L) × 460 (W) × 980 (H) mm

❏ Weight : Approx. 50 kg

8.2 Power

❏ Input power : 230 V~, 50 Hz

❏ Power consumption : Max 1.9 kVA

8.3 Magnetic field strength

❏ 3.0 T – pp (±20%)

8.4 Modes

❏ Auto 1 Mode : Freq: 35 Hz / On Time: 5.7 ~ 8 Sec / Off Time: 7 Sec

❏ Auto 2 Mode : Freq: 1, 45 Hz / On Time: 5.4 ~ 7.6 Sec / Off Time: 7 Sec

9. EMC emissions and immunity

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The SALUS-TALENT-A-Aes System is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions EN55011	Group 1	The SALUS-TALENT-A-Aes system is intentionally generated and/or used conductively coupled radio-frequency energy which is necessary for the internal functioning of the equipment itself.
RF emissions EN55011	Class A	The SALUS-TALENT-A-Aes system is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The SALUS-TALENT-A-Aes System is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity Test IEC 60601	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 contact ±15 air	±8 contact ±15 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	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Anti-surge protection needs to be incorporated into the main supply to the equipment if surge protection is to be guaranteed.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) 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 sec	<5 % *U*T (>95 % dip in *U*T) 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 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SALUS-TALENT-A-Aes System requires continued operation during power interruptions, it is recommended that the SALUS-TALENT-A-Aes System be powered from an interruptible power supply.
Power Frequency (50/60Hz) Magnetic Field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical

IEC 61000-4-8			commercial or hospital environment
Radiated RF Immunity EN61000-4-3	80 MHz – 2.5 GHz 2Hz 80% amplitude modulation		Equipment should only be used in the vicinity of other equipment compliant with EN60601-1-2.
Conducted RF Immunity EN61000-4-6	0.15 MHz – 80 MHz 2Hz 80% amplitude modulation		Equipment should only be used in the vicinity of other equipment compliant with EN60601-1-2.
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The SALUS-TALENT-A-Aes System is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that 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 – 80 3 V/m 80 MHz – 2.5	3 V_{rms} 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the SALUS-TALENT-A-Aes System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz – 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz – 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 the 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 filed strength in the location in which the SALUS-TALENT-A-Aes System is used exceeds the applicable RF compliance level above, the SALUS-TALENT-A-Aes System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re- orienting or relocating the SALUS-TALENT-A-Aes System

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

Rated maximum output power of transmitter, W	**Separation distance according to frequency of transmitter**		
	150 kHz - 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ Where V_1 = 3	80 MHz - 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ Where E_1 = 3	800 MHz - 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ Where E_1 = 3
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333

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..

10. FAQ

Q1) Can it be used for the area of the body with artificial joints or plate pins?
A) Due to the nature of the magnetic field deep heat will be generated, which may cause deep-seated burns.

Q2) Is it the same effect to use on clothes?
A) 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.

Q3) Are there any precautions when using on clothes?
A) 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).

11. Maintenance

11.1 Cleaning procedure

❏ Cleanliness of the SALUS-TALENT-A-Aes and accessories can be maintained through various methods. Avoid damage or contamination of the equipment using the following recommended methods.

❏ Periodically clean the equipment's exterior surface, transducer and touch screen with a soft cloth moistened with alcohol. Do not use abrasives, lacquers, thinners, ethylene, or oxides, as these materials may cause permanent damage to the equipment.

❏ Do not submerge any section of equipment into liquid or detergent. In addition, no liquid must be allowed to enter the equipment or accessories.

❏ When the operation for one patient is completed, clean the surface of the transducer with alcohol and smooth cloth.

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.

❏ Wash 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 this company.

❏ 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 company 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 REMED Customer Service Center.

Symptom	What to do	References in the Instructions For Use
Equipment does not turn on.	Check if the power connector of the equipment is properly connected.	• 3.4.2 Figure 3. Power cable connection
	Check if the power switch of equipment is turned on..	• 4.1.2 Figure 8. Rear view
	Confirm if the Key Lock switch ON.	• 4.1.1 Figure 7. Front view
	Confirm if the emergency button on the equipment is pressed. If it is pressed, turn it to the right to release it	• 4.1.1 Figure 7. Front view
Magnetic field is not generated from equipment	Confirm if the LCD displays an ERROR message.	• 7. Messages
	Check if the output strength is set by turning the encoder after pressing the Start button.	• 6.3.1 Auto mode – (c)
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

Symptom	What to do	References in the Instructions For Use
	If the room temperature is too high, disorder can be caused in the cooling. Maintain the room temperature at less than 25℃ as much as possible.	• 3.3 Environment condition
Wheel does not roll when moving the equipment.	Move the equipment by placing the wheel in the ”Loose” position..	• 3.4.3 Figure 4. Transporting wheel in ‘’Loose’ and ‘Locked’.

In the following cases, stop the operation by cutting 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.

Table 2. Self-Troubleshooting

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 company 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 service center.

❑ If a problem with the equipment occurs during the warranty period, prepare the following customer service request to report to our company.

12. Contact information

12. Contact information

Cryomed Aesthetics
Unit 5B / 32 Ralph Street, Alexandria NSW 2015 AU
service@cryomed.com.au

Sales & Enquiries
1300 346 448

Service & Support
02 9538 0874