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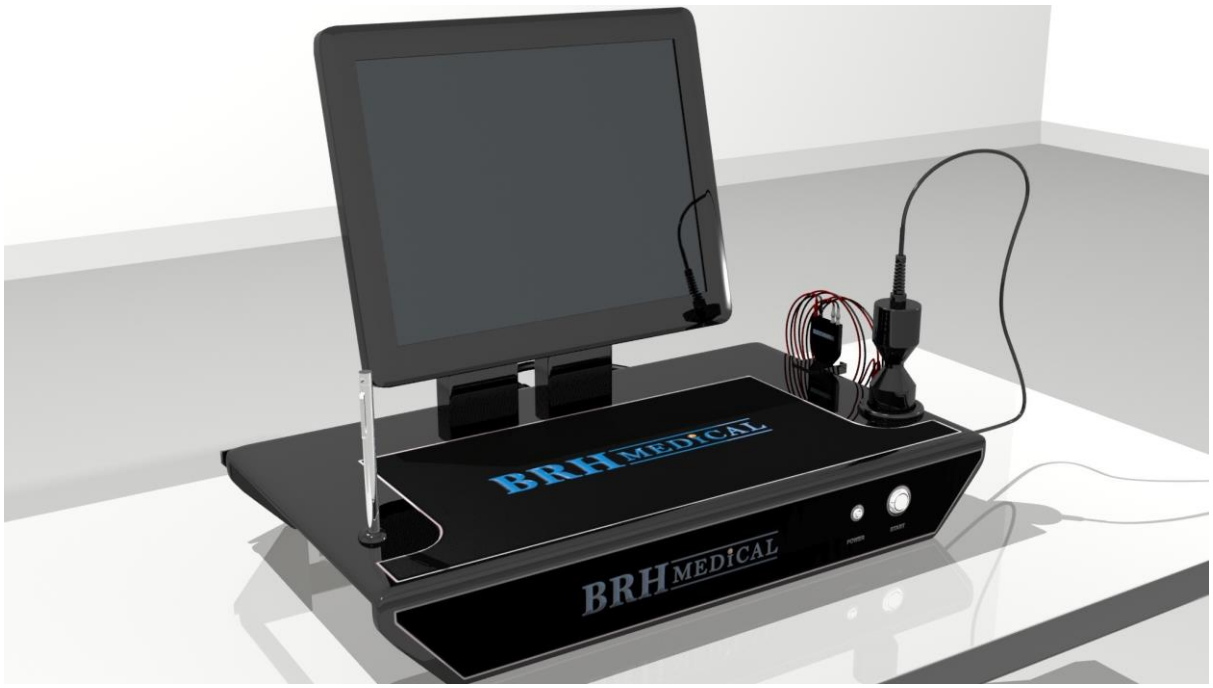

User Manual

BRH-A2

Combined Ultrasound and Electric Field Stimulation (CUSEFS)

BRH Medical Ltd.

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info@brhmedical.com

Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Contact information for equipment manufacturer and technical services:

- **BRH Medical Ltd.**

1. DECLARATION OF EUROPEAN REPRESENTATION CHANGE

BRH medical European representation: Date 04 Jul 2022

ARAZY GROUP [IRELAND] LIMITED

1st Floor, 9 Exchange Place. I.F.S.C.,

Dublin 1, D0l X8h2, Ireland

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Signature _____ Signature _____

FEFERBEG ILAN, CTO Motti Oderberg, CEO

2. GENERAL INFORMATION

This manual provides all the necessary information for installing and operating the BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS).

This manual should be read carefully before using the System.

3. INTENDED USE (clinical benefits of the device)

The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) is intended for ultrasound and neuromuscular stimulation

Therapeutic Ultrasound:

1. Pain relief
2. Reduction of muscle spasm
3. Localized increase of blood flow
4. Increase range of motion of contracted joints using heat and stretch techniques.

Neuromuscular Stimulation

1. Symptomatic relief of chronic intractable pain, acute posttraumatic pain or acute surgical pain
2. Temporary relaxation of muscle spasm
3. Prevention of post-surgical Phlebothrombosis through immediate stimulation of calf muscles
4. Increase of blood flow in the treatment area.
5. Prevention or retardation of disuse atrophy in post-injury type conditions
6. Muscle re-education
7. Maintaining or increasing range of motion

4. SAFETY INSTRUCTIONS

Read this information before using the BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS).

Contraindication – A contraindication indicates a situation in which the device should not be used.

Warning – A warning indicates a situation which, if not avoided, could result in death or serious injury.

Precaution – A precaution indicates a situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment of other property.

WARNING:

To avoid the risk of electrical shock, use only properly grounded equipment. The power cord set must be national safety certified and rated 250VAC for Europe or 125VAC for USA, 10A min. Shock hazards exist if the power supply is not properly grounded. Grounding reliability can only be achieved when equipment is connected to a receptacle marked 'Hospital Only' or 'Hospital Grade' or the equivalent. The grounding wire must not be removed or defected. To disconnect the cord, pull it by holding the plug. Never pull the plug out by the cord. In regions with unexpected power outages use of a Uninterrupted Power Supply (UPS) is recommended.

WARNING:

To avoid the risk of electrical shock and fire hazard, inspect the main power cord, plug and applied parts cables on a regular basis. Ensure they are not damaged.

WARNING:

To avoid the risk of electrical shock or injury, do not open the system enclosures.

WARNING:

Installation, new settings and repairs must be carried out only by the manufacturer or authorized personnel. The electrical installation in the treatment room must comply with the regulations in force;

The unit must be used in accordance with the Operating Instructions;

Only original supplies must be used with the appliance.

WARNING:

Do not use the system if an error message appears on the monitor: Call service personnel.

WARNING:

It is intended that the BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) is only used by qualified professionals trained by BRH Medical Systems.

WARNING:

Electrodes are electrically isolated. Don't let the electrodes come in contact with other conductive parts. See instructions how to connect the electrodes to the patient in this manual.

WARNING:

Application of electrodes near the thorax may increase the risk of cardiac fibrillation.

WARNING:

The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) must be used only with the leads and CE marked electrodes recommended for use by the manufacturer.

WARNING:

Fuse replacement is permitted to be done by BRH Medical qualified personnel only. Fuse type and rating are marked on the BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) label and provided in chapter 8.2 of this User Manual.

CAUTION:

Avoid installing or leaving the system in a location:

- near a heat source such as radiators, air ducts or heaters
- subjected to direct sunlight
- exposed to rain or moisture.

Residual Risks

- The device has no residual risks and/or any undesirable side-effects

Number of allowable re-uses of the device

- The device may be re-used as long as it is possibly can, once it is inactive, contact customer support and it may be re-useable upon repair

Installation of the device

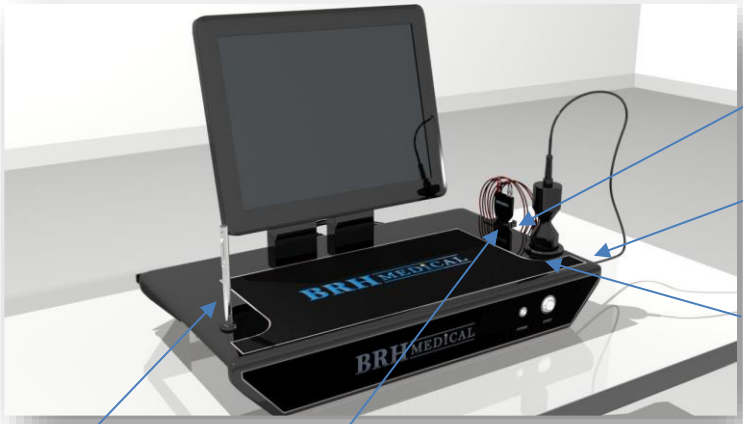
The device arrives packed in a disposable cardboard box

Take out the device from the cardboard box

Place it on a stable treatment trolley

The device is not supplied with a power cord, one is required to be locally purchased

Connect the:



Electric currents cable connects to the right panel rear connector

Ultrasound transducer to the right panel front connector

Ultrasound transducer is to be placed in the top panel right side cup

Electric currents cable tip may be hanged on the top panel right holder

Stylus is to be placed in the stylus cup on the top panel left side

3 Monitor's connectors are to be connected

Power cord should be connected to the rear panel connector

EMC:

The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS). Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to EMC recommendations.

This equipment has been certified to be protected from emissions and immunity in accordance with the MDR/2017/745 EN 60601-1-2:2007/AC:2010 3rd edition as follows:

Description	Applicable Standard	Requirement	Achieved	Results
Radiated emission in frequencies range of 30MHz – 2.5GHz	EN55011:	Class B	**Class B** The minimum passing margin was 7.72dB at 327.24 MHz.	**PASS**
Conducted emission main terminal frequencies range of 150KHz to 30MHz.	EN55011:	Class B	**Class B** The minimum passing margin was 1.05dB at 6.72 MHz.	**PASS**
Harmonic emission	IEC61000-3-2:	Class A	Class A	**PASS**
Flicker Emission	IEC61000-3-3:	Class D	Class D	**PASS**
ESD Immunity	IEC61000-4-2:	Air Discharge ±2kV, ±4kV, ±8kV; Contact Discharge ±2kV, ±4kV; ±6kV	Air Discharge. ±8kV Contact Discharge ±6kV	**PASS** **PASS**
Immunity to **Radiated Electromagnetic Field**	IEC61000 -4-3:	Field Strength 3 V/m, in frequency range 80MHz- 2500MHz AM 1kHz 80%	10 V/m 80MHz-2500MHz Modulation AM 1kHz 80%	**PASS**
Immunity to **EFT/Burst** Power Lines	IEC61000-4-4:	±1kV ±2kV	±1kV ±2kV	**PASS**
Immunity to **Surge**	IEC61000-4-5:	±1KV (D.M) ±2KV (C.M)	±1KV (D.M) ±2KV (C.M)	**PASS**
Conducted Disturbances Current injection immunity test on the input **power cord**	IEC61000-4-6:	0.15-80MHz 3Vrms Modulation 80% AM (1KHz).	0.15-80MHz 10Vrms Modulation 80% AM (1KHz).	**PASS**
Magnetic Fields Immunity	IEC61000-4-8:	50 Hz; 3 A/m	50 Hz; 3 A/m	**PASS**
Voltage dips immunity	IEC61000-4-11:	Reduction of >95%/ dip 0.5 cycle 60%/dip 5 cycles. 30%/dip 25 cycles. >95%/ dip 5sec.	Reduction of >95%/ dip 0.5 cycle 60%/dip 5 cycles. 30%/dip 25 cycles. >95%/ dip 5sec.	**PASS**

Guidance and manufacturer's declaration - electromagnetic emissions		
The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) is intended for use in the electromagnetic environment specified below. The customer or the user of the BRH-A2 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment guidance**
RF emissions CISPR 11	Group 2	The BRH-A2 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Radiated Emission Class B The minimum passing margin was 1.09 dB at 114.97 MHz. Conducted Emission Class B The minimum passing margin was 1.51dB at 13.53 MHz	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class D	The BRH-A2 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration - electromagnetic immunity			
The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS). is intended for use in the electromagnetic environment specified below. The customer or the user of the BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601-1-2 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	± 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 line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	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	<5 % 230Vac (>95 % dip in U_T) for 0,5 cycle 40 % 230Vac (60 % dip in U_T) for 5 cycles 70 % 230Vac (30 % dip in U_T) for 25 cycles <5 % 230Vac (>95 % dip in U_T) for 5 s	<5 % 230Vac (>95 % dip in U_T) for 0,5 cycle 40 % 230Vac (60 % dip in U_T) for 5 cycles 70 % 230Vac (30 % dip in U_T) for 25 cycles <5 % 230Vac (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME EQUIPMENT or ME SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [ME EQUIPMENT or ME SYSTEM] be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	10 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS). is intended for use in the electromagnetic environment specified below. The customer or the user of the BRH-A2 should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the BRH-A2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d=(3.5/10)*√480=7.69m
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	10 V/m	d=(12/10)*√480=26.29m 80 MHz to 800 MHz d=(7/10)*√480=15.34m 800 MHz to 2,5 GHz

Recommended separation distances between Portable and mobile RF communications equipment and the BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS).

The BRH-A2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BRH-A2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BRH-A2 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**			
	150kHz – 80MHz Outside ISM bands	**150kHz – 80MHz In ISM bands**	**80MHz – 800MHz**	**800MHz – 2.5GHz**
8	3.3	11.31	11.31	21.68

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined 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 The ISM (industrial, scientific and medical) bands between 150 kHz and 80MHz are 6.765MHz to 6.795MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz.

NOTE 3 An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption andreflection from structures, objects and people.

The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) is a 8w max power transmitter

- To avoid risks and effects of exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electro- magnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, the BTH-A2 should be placed at least 15m away from other equipment discharging magnetic fields, external electrical and electro- magnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures .
- To avoid risks and effects posed by the reasonably foreseeable presence of the BRH-A2 device during therapeutic treatment such as electromagnetic interference emitted by the BRH-A2 device affecting other equipment, the BTH-A2 should be placed at least 15m away from other equipment.

The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) software is not network accessible, containing no WIFI communication components and no hardware connection component that enables access to the software code and no ability to remotely handle or change it or affect its ability to run as intended.

5. DISPOSAL OF USED MATERIALS

Disposal of used materials must be done in accordance with local, state, and federal laws and regulations.

Once a client is no longer interested in operating the system, or in case the system malfunctions and the client is not interested in repairing the system:

the system may be sent to an electronic waste collection center that specializes in handling electronic waste or if they do not have access of such collection center, they may send the system to the manufacturer.

Once the system is received in manufacturer's location, the manufacturer is responsible for sending the system to an electronic waste collection center that specializes in handling electronic waste or to refurbish the system and reuse it.

10 year Life Cycle calculation:

Worst case: The system will work for an approximate maximum of 10 hours a day and an approximate maximum of 28 days a month. Therefore, each calendar month the system will operate for an approximate maximum of 280 hours, and each year the system will work an approximate 3,360 hours. In 10 years, the system will work for an approximate maximum of 33,600 hours.

6. OPERATOR

End Users (Operators) are defined as qualified professionals trained by the BRH's training personnel, and holding original BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS). Therapist certification.

7. TARGET POPULATION

ADULT PATIENTS.

8. PRODUCT MAINTENANCE

The System is prepared on receipt of a customer's order.

Once prepared, it undergoes operational testing, for any malfunction or incorrect output.

Once testing has been successfully completed, the system is configured for the customer's local voltage needs and then sent for packing and labeling.

The System is sent to the customer. On arrival, only a trained local distributor may unpack, install the device and perform initial operational testing.

Performance testing carried at the customer's facility is identical to that done at the manufacturer's facility.

Training by the distributor's training personnel is carried out. The Company's training personnel have been certified to treat patients and train operators.

A practical examination has to be successfully passed.

Only a trainee that has passed the practical exam is certified and may operate the system.

The System's Ultrasound Transducer needs recalibration every six months. Thirty days before the end of each 6-month period, the System alerts the Operator. The customer contacts BRH Medical Systems, and an Ultrasound transducer is sent to the clinic.

A replacement Ultrasound transducer should be sent back to the manufacturer.

Any software upgrades will be performed by an authorized BRH technician.

9. CONTRAINDICATION AND PRECAUTIONS

a. Contraindications for Neuromuscular Stimulation treatment

- The BRH-A2 system should not be used in cases of **acute sepsis**
- The BRH-A2 system should not be applied on **tumors**
- The BRH-A2 system should not be used on patients with **cardiac conditions**
- The BRH-A2 system should not be used on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.
- The BRH-A2 system should not be used on patients with **hypersensitivity or fear of electrical treatments**
- The BRH-A2 system should not be used on any patient who cannot understand the nature of the treatment, for example young children, very old or senile patients who cannot report back adequately or understand the potential dangers. This may apply equally to persons who do not speak the same language as the therapist.
- The BRH-A2 system should not be used on patients with **severe hypotension/ hypertension**.
- The BRH-A2 system should not be applied in the region of the lower cervical spine. If in doubt the patient's physician should be consulted.
- The BRH-A2 system should not be used on patients whose pain syndromes are undiagnosed.
- The BRH-A2 should not be used on patients under the age of 16
- The BRH-A2 system should not be applied over pregnant uterus
- Arthroplasties—the effect on bony ingrowth arthroplasties is not well defined; for this reason, the most prudent course is avoiding ultrasonic therapy over these areas
- Over or near bone growth centers until bone growth is complete

- In an area of the body where infectious disease is present
- Blood vessels in poor condition should not be treated
- Patients suffering from cardiac disease should not receive treatment over the cervical ganglia, the stellate ganglion, the thorax in the region of the heart, or the vagus nerve, as a reflex coronary vasospasm might result. Only low intensities and short treatment times should be used if these patients are treated in other areas since the stimulation of practically any afferent autonomic nerve (especially the vagus nerve) in the body may cause a change in cardiac rate
- Patients with thrombophlebitis or other potentially thromboembolic diseases should not be treated since a partially disintegrated clot could result in an obstruction of the arterial supply to the brain, heart or lungs
- The BRH-A2 should not be used over a healing fracture
- The BRH-A2 should not be used over the eye
- The BRH-A2 should not be used over ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand
- The BRH-A2 should not be used over areas of recent bleeding or hemorrhage
- The BRH-A2 should not be used over areas of active tuberculosis

b. Contraindications for ultrasound treatment

- The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) should not be applied on **tumors.**
- The BRH-A2 system should not be used with implanted devices such as cardiac pacemakers

- The BRH-A2 system should not be applied on patients with total hip arthroplasties with methyl methacrylate or high-density polyethylene
- The BRH-A2 system should not be applied over or near bone growth centers until bone growth is complete
- The BRH-A2 system should not be applied over an area of the body where infectious disease is present

  The BRH-A2 system should not be applied over blood vessels in poor condition
- The BRH-A2 system should not be applied on patients suffering from cardiac disease
- The BRH-A2 system should not be applied on patients who are not conscious

- The BRH-A2 should not be used over the cervical ganglia, the stellate ganglion, the thorax in the region of the heart, or the vagus nerve
- Patients with thrombophlebitis or other potentially thromboembolic diseases should not be treated
- The BRH-A2 system should not be applied over a healing fracture
- The BRH-A2 should not be applied over the eye
- The BRH-A2 system should not be applied over the pregnant uterus
- The BRH-A2 system should not be applied over ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand
- The BRH-A2 system should not be applied over areas of recent bleeding or hemorrhage
- The BRH-A2 system should not be applied over areas of active tuberculosis
- The BRH-A2 system should not be used with patients with an implanted deep brain stimulation system
- The BRH-A2 system should not be applied near or over reproductive organs
- The BRH-A2 system should not be applied near the ears
- The BRH-A2 system should not be used on patients under the age of 16
- Patients with thrombophlebitis or other potentially thromboembolic diseases should not be treated
- Patients with metal allergy

c. Warnings for Neuromuscular Stimulation treatment

- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves
- Stimulation should not be applied over the neck or mouth.
- Stimulation should not be applied transthoracically
- Stimulation should not be applied transcerebrally.
- Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- Do not apply electrodes across the patient's chest,
- Do not apply electrodes on genitalia, breast, eye, open wound, ears, rashes, swollen, red, infected, inflamed areas, skin eruptions
- Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms).
- Do not apply stimulation when the patient is in the bath or shower;

- Do not apply stimulation while the patient is sleeping;
- Do not apply stimulation while the patient is driving, operating machinery, or during any activity in which electrical stimulation can put the patient at risk of injury;
- Do not apply stimulation when the leads are open circuited (e.g. when the electrodes are held in the user's hand);
- Do not remove electrodes when stimulation is being applied
- Consult with the patient's physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals;
- Apply electrodes only on normal, intact, clean, healthy skin.
- The treatment head should be moved continuously during treatment to avoid discomfort and burns.
- An appropriate coupling medium should be employed to ensure energy transmission to the tissue.
- Do not use electrodes that are smaller than 5cm round.
  To reduce chance of skin irritation or thermal burns, limit treatment intensity to 40 mA (40V) or less while using 5cm round electrodes. (Warning label can be found under "system label" section of this manual)

d. Warnings for ultrasound treatment

- The treatment head should be moved continuously during treatment.
- An appropriate coupling medium should be employed in order to ensure energy transmission to the tissue.

e. Precautions for Neuromuscular Stimulation treatment

- Safety of powered muscle stimulators for use during pregnancy has not been established.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- Powered muscle stimulators should be kept out of the reach of children.
- Powered muscle stimulators should be used only with the leads and CE marked electrodes recommended for use by the manufacturer.

- The long-term effects of electrical stimulation are unknown; Since the effects of stimulation of the brain are unknown.
- Stimulation should not be applied across the head, and electrodes should not be applied on opposite sides of the head;
- Use caution when the patient has a tendency to bleed internally, such as following an injury or fracture;
- Use caution following recent surgical procedures when stimulation may disrupt the patient's healing process;
- Use caution if stimulation is applied over areas of skin that lack normal sensation
- Use caution over anesthetized areas
- Use caution on patients with hemorrhagic diatheses
- Use caution over areas where there is sensory impairment or sensory loss
- Use caution over acute skin conditions such as eczema, dermatitis, etc.
- Use caution over the anterior aspect of the neck
- Use caution on patients who are febrile

f. Precautions for ultrasound treatment

If a patient complains of pain during ultrasound treatment, intensity should be reduced to a comfortable level. If even at a low intensity patients are still uncomfortable, Ultrasound treatment should be moved further from the affected area until a non-painful location can be found.

- Use caution over anesthetized areas
- Use caution on patients with hemorrhagic diatheses
- Use caution over areas where there is sensory impairment or sensory loss
- Use caution over acute skin conditions such as eczema, dermatitis, etc
- Use caution over the anterior aspect of the neck
- Use caution on patients who are febrile

10. SYSTEM DESIGN AND SPECIFICATION

The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) is assembled in a specially designed cart. The cart encloses Neuromuscular Stimulation and ultrasound therapy medical devices, computerized controls, and an operator's interface including a touch screen. The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) is powered by a standard single phase 120 or 230 V power supply.

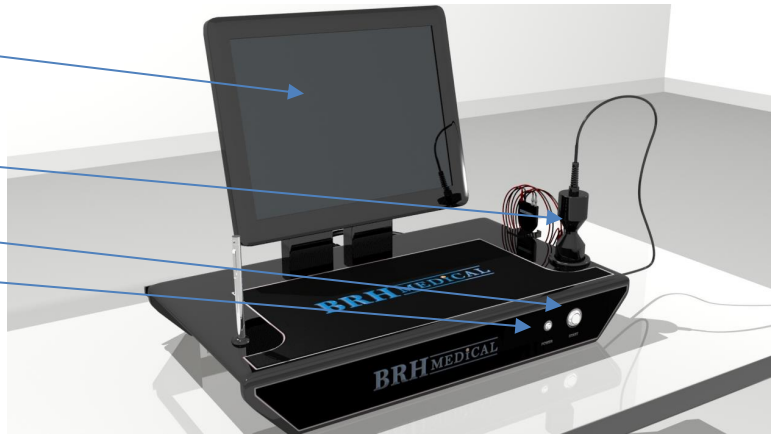
a. BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) General View

Touch screen

Ultrasound transducer receptacle

Power button

Power indication light



Power entry module (rear)

b. General system specifications

The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) meets the requirements of the following standards:

ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	"Medical electrical equipment. Part 1:General requirements for safety and essential performance"
IEC 60601-2-5:2009	"Medical electrical equipment. Part 2-5: Particular requirements for the safety of ultrasonic-physiotherapy equipment"
IEC 60601-2-10:2016	"Medical electrical equipment. Part 2-10 Particular requirements for the safety of nerve and muscle stimulators.
EN ISO 14971:2012	"Medical devices – Application of risk management to medical devices"- including residual risks evaluation.
IEC 60601-1-6:2010	"Medical electrical equipment. Part 1-6: General requirements for safety – Collateral Standard: Usability"
IEC 60601-1-8:2006	"Medical electrical equipment. Part 1-8: General requirements for basic safety and essential performance– Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems"
IEC 60601-1-2: 2007 /AC:2010	"Medical electrical equipment. Part 1-2: Electromagnetic compatibility – Requirements and tests"
ISO 62304: 2015	"Medical Device Software Development"
MDR/2017/745	European Medical Device Regulation Annex IX
ISO 13485:2016	

c. General

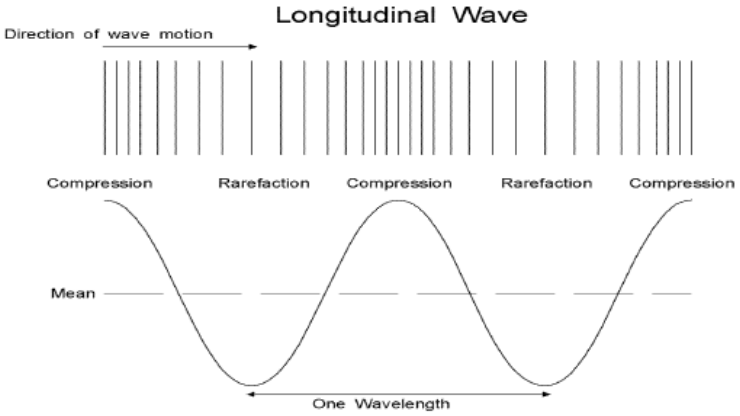
Power Input	Option 1 (for Europe): 230 V~; 50/60 Hz; 2 A Option 2 (for US/Canada): 120 V~; 60 Hz; 4 A
Classification (IEC60601-1:2010)	Class 1, Type BF applied parts
Mains Fuses	For Europe - (5 x 20 mm): 2x (T4AH250V) For US/Canada - (5 x 20 mm): 2x (T8AH250V)
Size(height x width x depth)	56 x 42 x 31 cm
Weight	10 kg

d. Environmental Conditions for Transport and Storage

Temperature	In use:	From 10°C to 40°C
	When not in use:	From 4°C to 75°C
Humidity	In use:	From 30% to 75% RH (not condensed)
	When not in use:	From 20% to 80% RH (not condensed)
Pressure	In use:	From 700 hPa to 1060 hPa
	When not in use:	From 700 hPa to 1060 hPa
Ultrasound System		
Ultrasound frequencies		1 MHz ±5% to 3 MHz ±5%
Maximum Output Power		8 W with at 4 cm^2 transducer
Maximum Intensity		2.0 W/cm^2
Automatic Shut Off		Yes
Treatment Timer		0 to 30 minutes
Contact Monitor		Light on transducer
Transducer's Part Number		Ma-11cb
Neuromuscular Stimulation System		
Waveform		4 Pole Interferential mode
Max Output Current (mA)		0-65±10% mA RMS, max 1 kohm load
Max output Voltage (V)		0-65±10% volts RMS, 1 kohm load
Maximum Current Density (5 cm/dia)		3.2 mA/Cm2
Treatment Timer		0 to 30 minutes

e. Ultrasound system output

Sound is mechanical vibration. The human ear responds to these vibrations in the range of 20 Hz to 20 kHz. Sound above 20 kHz is called ultrasound. Therapeutic ultrasound is sound in the range of



500 kHz to 5 MHz. Sound waves are produced by some disturbance in a material medium causing the particles or molecules of the medium to vibrate. For this reason sound will not pass through a vacuum. If the vibration is continuous and regular, a constant tone or frequency is produced. The vibration or sound wave propagates through the medium, as particles in the medium pass on their vibration to neighboring particles and a series of compressions and rarefactions are produced in the direction of the wave's travel. Therefore, sound waves are longitudinal waves.

The above diagram shows a sound wave traveling from left to right. The vertical bars represent thin slices of the medium which are displaced to form areas of compression and rarefaction. The sine wave represents their displacement relative to their mean position. The distance over which the vibration repeats itself is called the wavelength. The number of complete vibrations in one second is called the frequency of the sound wave. The velocity of sound in the medium is given by:

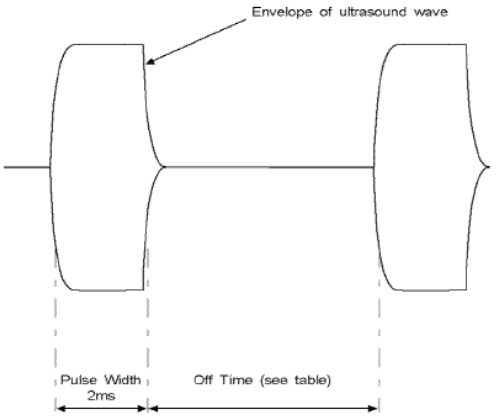
```
Velocity = frequency x wavelength
```

Sound will travel faster through media where the molecules are closer together and so the velocity is higher in solids than in liquids, and higher in liquids than in gases. For example, the velocity of sound in stainless steel is approximately 5800 m/s, in water 1500 m/s and in air only 330 m/s. As the sound wave passes through the medium, causing molecules to vibrate, some of the energy in the wave is converted from kinetic energy to heat. For a collimated sonic beam the intensity, power per unit area, therefore, decreases exponentially with the distance traveled.

The attenuation of the beam is also dependent upon the frequency of the sound. In solids the attenuation is proportional to the frequency; whereas in liquids, the attenuation is proportional to the square of the frequency. The usual method of specifying the degree of attenuation of ultrasound in different media is by the half depth. The half depth is the distance the ultrasound must travel through the medium for its intensity to be reduced to one half of its original value. Many attempts have been made to measure the attenuation in various types of tissue with varying results. It is perhaps more important to remember which types of tissue have the highest absorption and which the lowest. With the lowest absorption first the order is, fat, muscle, skin, tendon, cartilage and bone. For soft tissue the half depth is around 50 mm at 1 MHz and 15 mm at 3 MHz.

It is also important to remember that where there is a change in medium or tissue type, there will be both reflection and refraction of the ultrasound beam. In particular, there is almost 100% reflection at the interface of a solid or liquid to air at therapeutic ultrasound frequencies. Any air bubbles in coupling medium will therefore reduce the effective intensity of the ultrasound. Also, bone reflects a high percentage of incident ultrasound. It is important therefore, when applying ultrasound, to keep the transducer orthogonal to the surface of the treatment area, to keep the ultrasound transducer moving and to use a good coupling medium to avoid unwanted reflections and locally high intensities.

The ultrasound output signal has the following waveform:

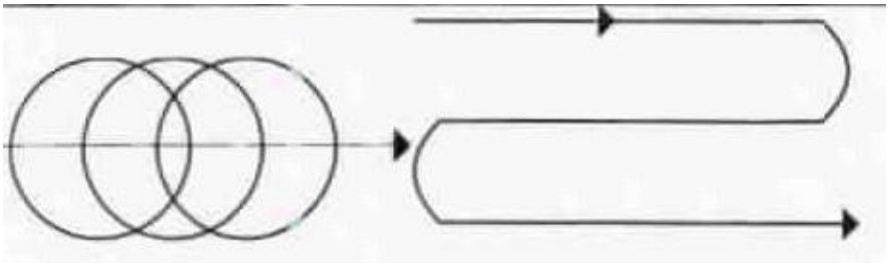


Pulse Off Duty Temporal peak

Mode	Frequency	Time	Cycle	to average ratio
1:1	100 Hz	2 ms	50%	2:1

Ultra sound waves need a medium for their transmission and that is accomplished by using a proper coupling agent**.** Between the transducer and body surface will assist in the propagation of the mechanical vibrations and prevent loss of transmission.

Once the coupling agent is applied to the body surface, the transducer placed in contact, and desired output selected in total watts, or watts per square centimeter, the technique of application is by means of circular or stroking movement. In the circular method, the sound head of the transducer is moved in slow and circular overlapping movements. In the stroking, or 'paintbrush' method, slow back and forth strokes are used, again with slight overlapping. Motions with either technique should be slow enough to ensure proper energy absorption, yet fast enough to eliminate excessive amounts of absorption that could produce periosteal pain. Some references recommend that the treatment area covered by this moving technique, be 2-3 times the effective radiating area of the transducer for every five minutes of exposure.



f. Muscle Stimulator System output

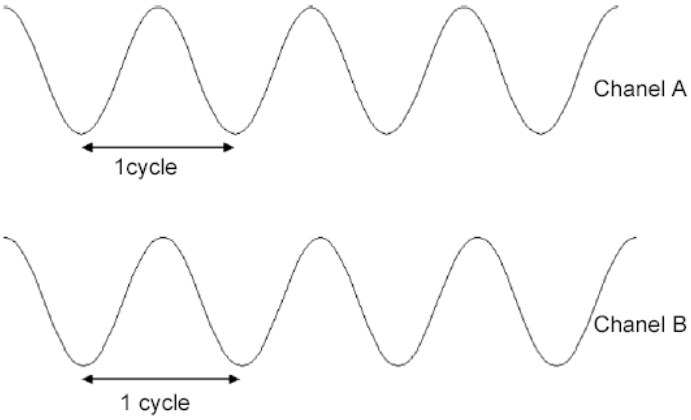
The Muscle Stimulator part in the BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) generates medium frequency currents used in 4-pole interferential current Therapy.

Prior to the introduction of Muscle Stimulator Therapy in the mid 1950s, low frequency stimulation was used for pain relief, muscle re-education etc. These currents however, have the disadvantage that normal human skin has relatively high impedance at such frequencies. In order to overcome the skin's impedance, a larger voltage has to be used to achieve the desired current, resulting in a more uncomfortable treatment for the patient. In addition, the penetration depth of these currents is poor and is, in part, limited by the discomfort to the patient.

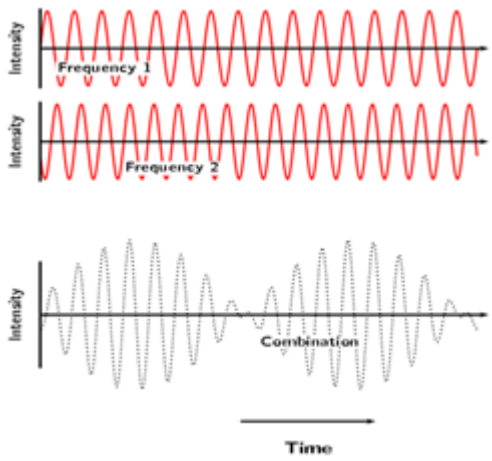
Muscle Stimulator Therapy overcomes the problem of skin impedance. At 50 Hz (faradic current) the impedance for a 100 cm^2 of skin is approximately 3000 ohms. At 4000 Hz (medium frequency) the skin impedance of the same area is around 50 ohms. This means that a much lower voltage signal can be used to produce the desired current, resulting in less skin sensation and a more comfortable treatment. This medium frequency is however, well outside the normal biological frequency range (0.1 to 250 Hz). In order to produce the 4-pole interferential current Therapy, two medium frequencies are used. A constant frequency of, say, 4000 Hz is applied to one pair of electrodes and a slightly different frequency of, say, 3900 Hz is applied to the other pair. These two frequencies 'interfere' to produce amplitude modulated medium frequency (beat frequency) in the tissue. The tissue responds to the cyclic rise and fall in the current intensity. It is the amplitude modulation

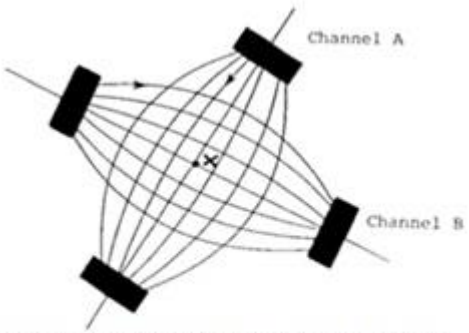
frequency (AMF) that is within the normal biological frequency range and not the medium frequency (carrier).

The 4-pole interferential current therapy output signal has the following waveform:



For signal output parameters see chapter 4.1.





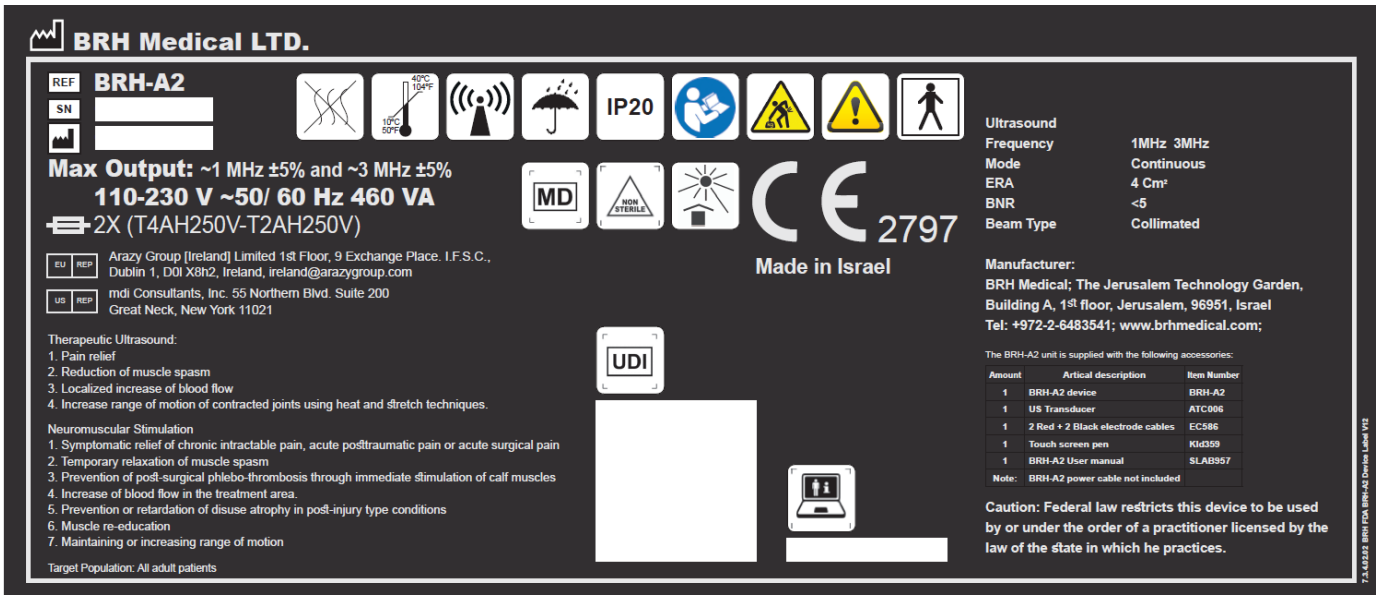
The 4-pole interferential current therapy

11. CONTROLS AND MARKINGS

a. General marking and controls

All information on the model, serial number, and month/year of manufacture is located on the rear panel label.

b. System label



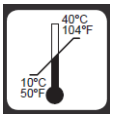
The following warning is displayed on the treatment screen prior to treatment initiation so that the user can't miss it:

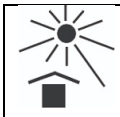
Do not use electrodes pads that are smaller than 5cm round.

To reduce the chance of skin irritation or thermal burns due to high current density

(Larger than 2 mA/cm^2), limit treatment intensity to 40 mA (40V) or less while using 5cm round electrodes

The meaning of symbols located in this label as well as in other places is as follows:	
	Warning: read the user manual before using the system
	BF type applied part
CE 2797	The CE marking symbol indicates that the product has been designed and manufactured in conformity with the essential requirements of all relevant directives, and submitted to the relevant conformity assessment procedure

	Warning: While in transport, system is unstable, avoid operation of the system while in transport
	Refer to instruction manual/booklet
	Touch by fingers (>12.5mm), no protection from liquids
	Equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment
	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Indicates the date when the medical device was manufactured.
	Indicates the medical device manufacturer.
	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Non pyrogenic
	Upper temp limits
	Keep dry
	EC-REP Next to name of EU representative
	US-REP Next to name of US FDA representative

	Avoid exposure to direct sunlight
	MD symbol
	None sterile
	Website instructions
	UDI symbol

The following components are located

on the rear panel lower part:

Main Switch

Appliance inlet

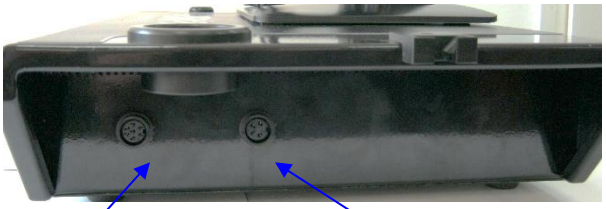
Main fuse

The **Main Switch** is a two-position rocker switch: up for on, down for off.

| On – Connected to the power Tab D1 Symbol 16, IEC 60601-1:2010 3rd edition

O Off – disconnected from the power supply Tab D1 Symbol 15, IEC 60601-1:2001 3rd edition

c. System connector panel

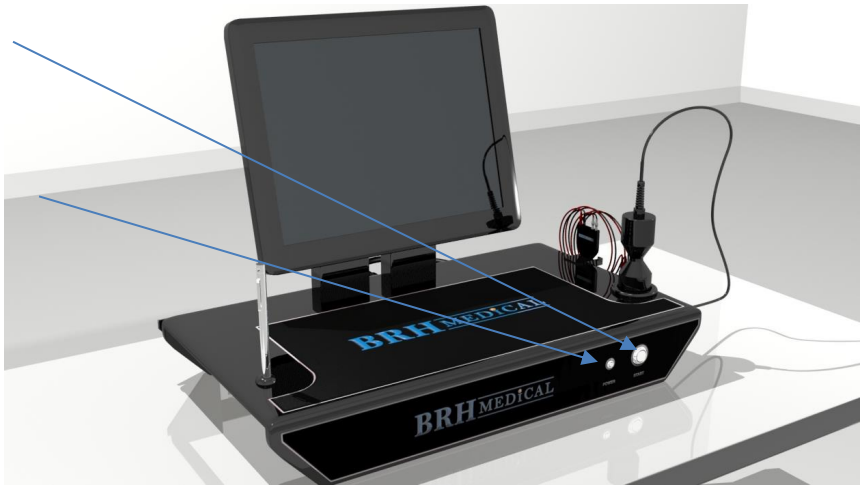


Ultrasound output socket **Neuromuscular Stimulation output socket**

d. Button and indicator lights on the front panel under touch screen

1 - Operational indicator - When the power button is ON the indicator around the button will light.

2 - Power indicator – The LED light is on when the system is ready to be turned on.



12. RECEIPT AND ACCEPTANCE OF SYSTEM

CAUTION:

Upon receipt, check for any visible damage which may have occurred in transit. If any signs of damage are found, then retain all packing material and inform the carrier and the Company or its agent from whom the unit was purchased.

The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) is designed to operate from a single-phase supply 230V, 50Hz, 2A max (For Europe); 120V, 60Hz, 4A max (For US/Canada). Connection is via an IEC socket at the rear of the unit. For power connection use only national safety certified power cord with GND pin, rated 250VAC, 10A.

Before using the unit, be sure that the operating voltage of your unit is identical to that of your local power supply.

WARNING:

If the integrity of the earth connection is in doubt, do not connect the unit to the mains supply. The System must be plugged only into a grounded power outlet.

WARNING:

The first operation of the device must be performed by authorized personnel only.

Connect the mains cable to the IEC socket on the rear of the unit and to a suitable power outlet.

Connect the ultrasound transducer's head to the output connector placed on the side panel of the unit. Connect the electrode's cable to the output connector located on the side panel of the unit.

When inserting the plug make sure that it is correctly aligned with the socket. Make sure that the number of pins in the cable's plug are match the number of holes in the unit's socket.

WARNING:

The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) should not be stacked with other equipment including any other BRH-A2 system.

WARNING:

Use of other cables and supplies than the BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) original ones may negatively affect EMC performance and may result in non-compliance.

13. OPERATING INSTRUCTIONS

Therapy with the Neuromuscular Stimulation system and the Ultrasound system are operated separately.

The length of the treatment can be programmed from 1-30 minutes.

Before beginning any treatment, remove any dressings and/or lotions from the treatment area, and clean the treatment area thoroughly with an alcohol wipe or gauze/antiseptic solution.

In any case of system emergency stop, shut off all systems and reload all intensity and time defaults to the system.

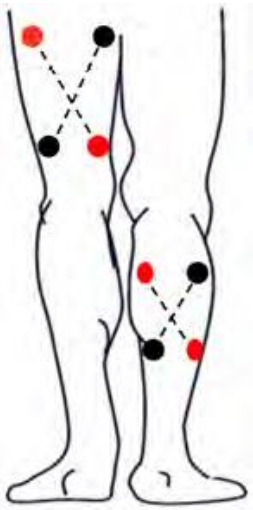
a. Neuromuscular Stimulation System

After applying the electrode pads as per the figures below, the Operator presses Start on the Neuromuscular Stimulation System (1 in the figure below) and begins to adjust the intensity. Immediately following this, the operator presses start on the Ultrasound System menu as well. (See 11.2 for details)

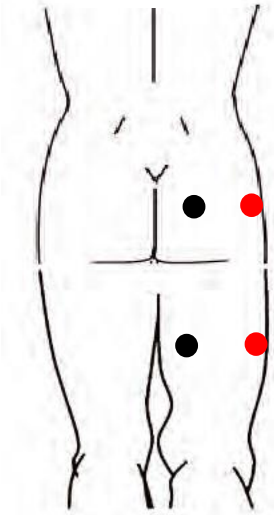
A. Anatomic location of electrode pads

Apply electrode pads in order to surround the affected area according to training video or any of the following:

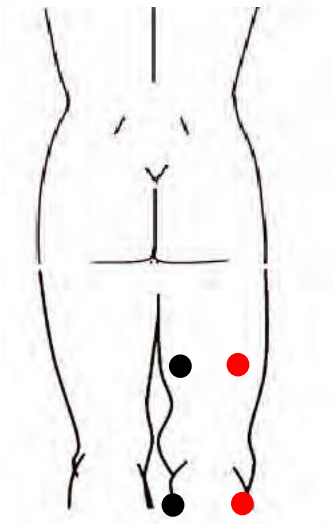
Thigh and Calf



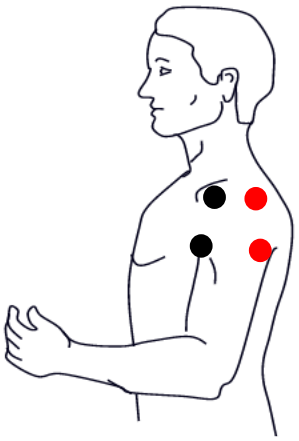
Hip



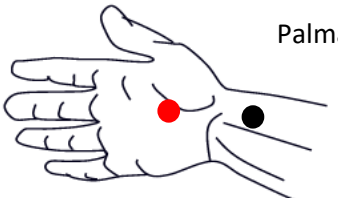
Lateral Knee

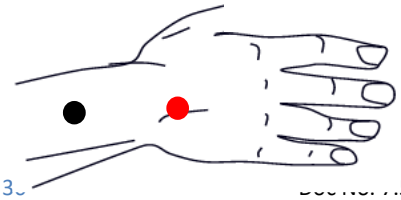


Shoulder

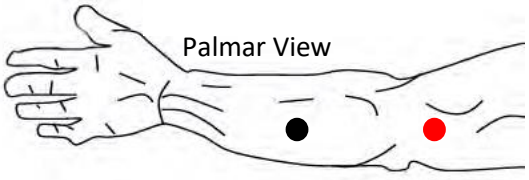


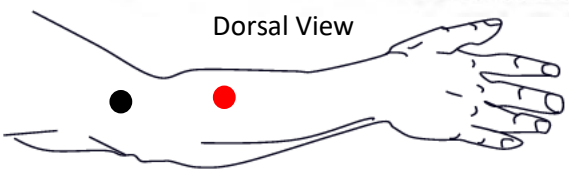
Wrist

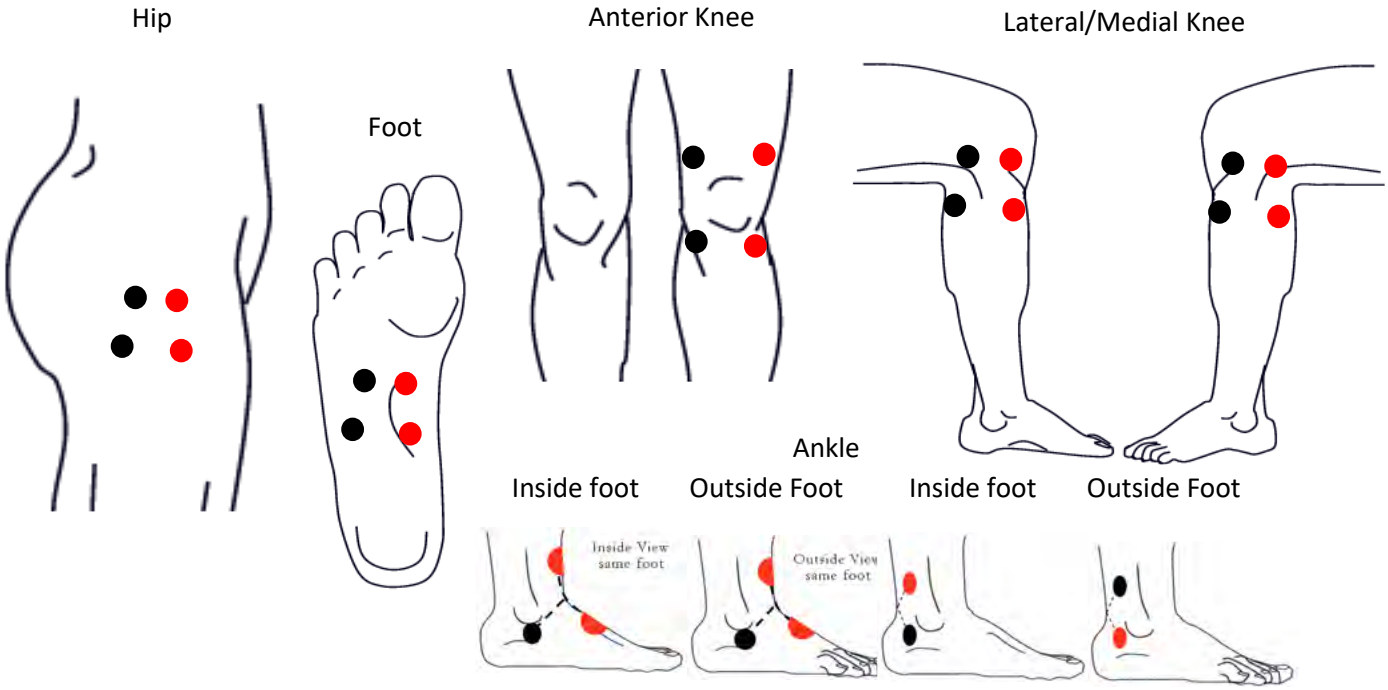




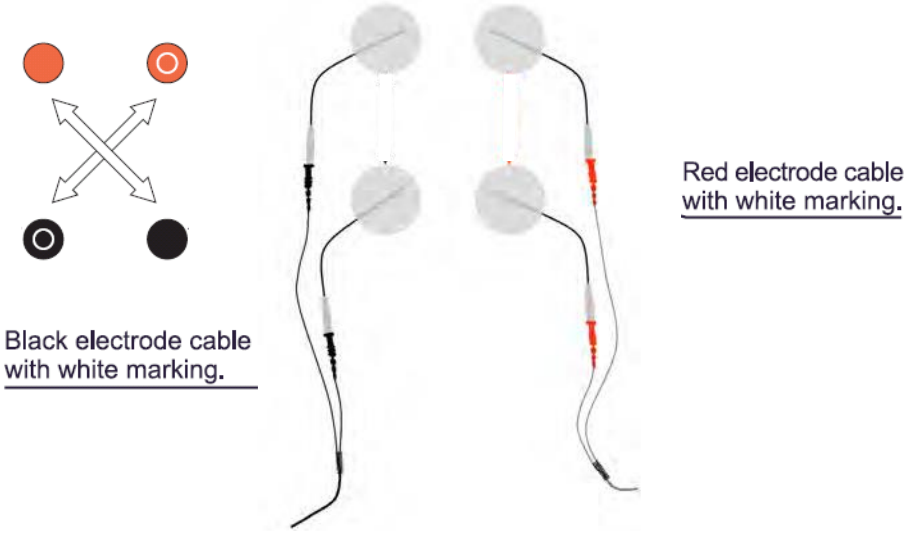
Elbow







1. Connect the electrode pads to the electrode cables.

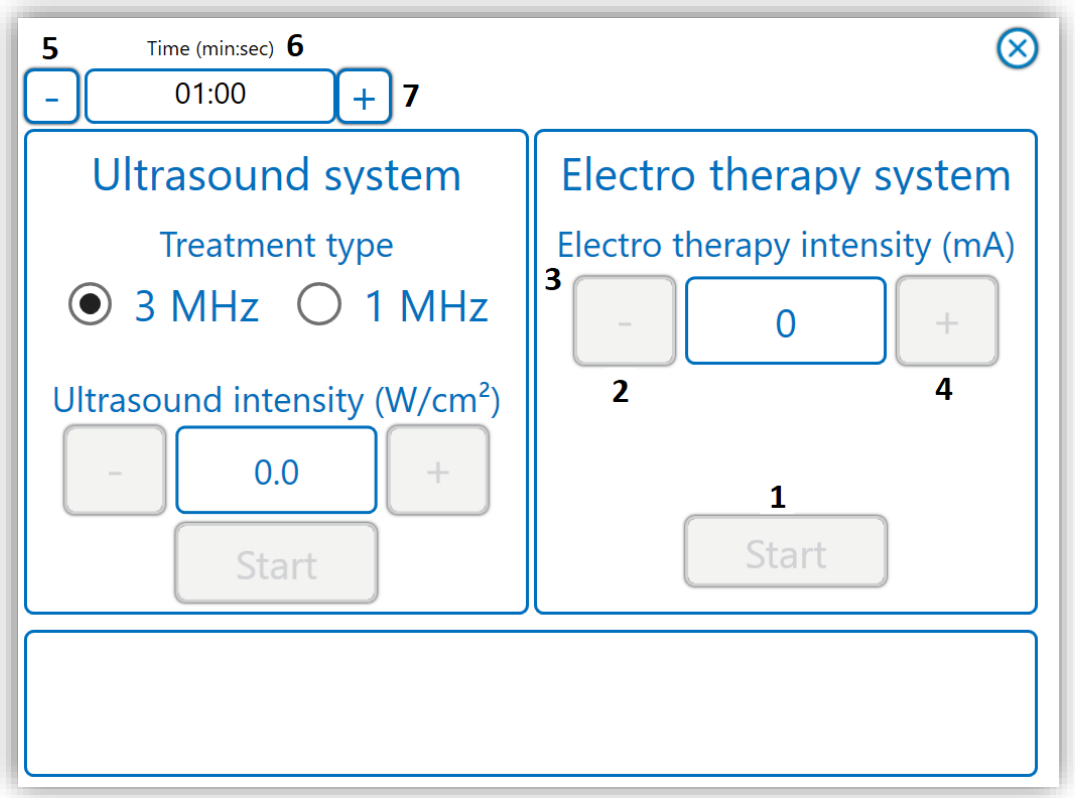


2. Connect electrodes pads to electrodes cables

   Electrodes need to be surrounding the affected area

   If the area is impossible to surround by the 4 electrode pads perform the Neuromuscular Stimulation on the nearest location possible.

The following will be displayed on the screen:



B. Operating the Neuromuscular Stimulation system

WARNING:

The electrodes must never be applied so that the stimulating current crosses the chest or passes near the heart.

WARNING:

If the unit detects that the Ultrasound transducer is disconnected, it will give an alarm “Transducer disconnected” on the status bar, and will stop its activity immediately.

WARNING:

Do not use electrodes that are smaller than 5cm round.

To reduce chance of skin irritation or thermal burns due to high current density (Larger than 2 mA/cm2), limit treatment intensity to 40 mA (40V) or less while using 5cm round electrodes.

(Warning label can be found under "system label" section of this manual)

1. Explain to the patient what is being done and what is going to happen.

2. Tap the **START** button on the left touch screen to begin the Neuromuscular Stimulation system. The timer will start to count down. (Refer to the screen on the previous page)
3. Slowly increase the Neuromuscular Stimulation system intensity up to 12 or until the patient feels the effect of the applied current.

Default setting is 15 minutes

Screen Functions

(1) Start and stop – start allows to begin the treatment and stop the treatment – deactivates the emission

(2) & (4) Intensity down and up button keys – the treatment intensity may be set in 1mA using the up and down keys situated besides the treatment intensity display. The up key increases the treatment intensity in 1mA by each time it is pressed and the down key decreases the treatment intensity in 1mA by each time it is pressed

(3) Output display – indicates the intensity in mA

(5) & (7) treatment time keys situated besides the treatment time display (6). The up and down keys - the treatment time may be set in 1 minute using the up and down keys situated besides the treatment time display. The up key increases the treatment time in 1 minute by each time it is pressed and the down key decreases the treatment time in 1 minute by each time it is pressed

(6) Treatment time displays the time remaining for the treatment by minutes and seconds.

WARNING:

If the unit detects cut off between the BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS)front panel to one of the cables or between one of the electrodes to the cables the unit will give an alarm" Electrodes disconnected" on the status bar, and the Neuromuscular Stimulation system intensity is decreased to 0 mA immediately.

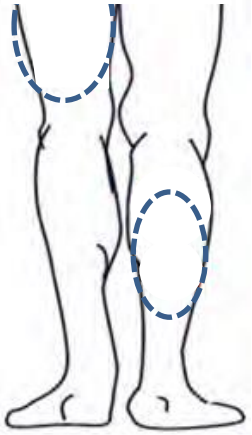
b. Ultrasound System

The Ultrasound System operates automatically once a treatment is begun. The user can control the strength of the ultrasound, and can control the length of the treatment, extend it up to 30 minutes.

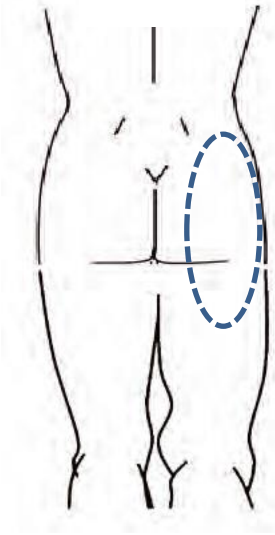
A. Anatomic location of Ultrasound transducer application

i. Apply Ultrasound transducer in the affected area according to any of the following:

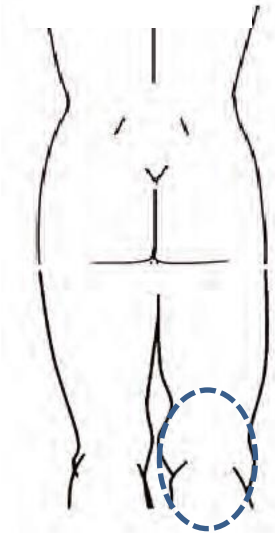
Thigh and Calf



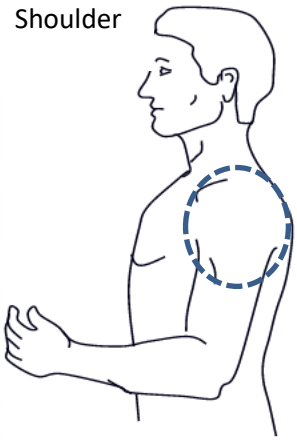
Hip



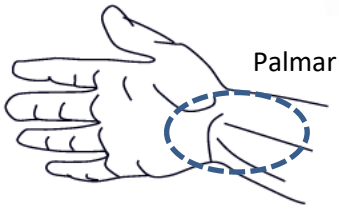
Lateral Knee



Shoulder

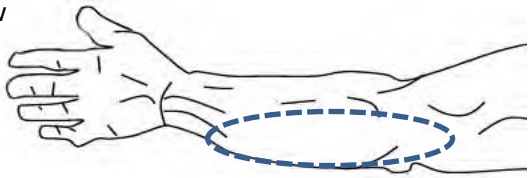


Wrist

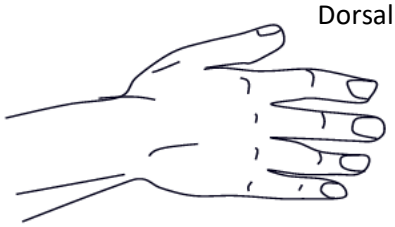


Palmar View

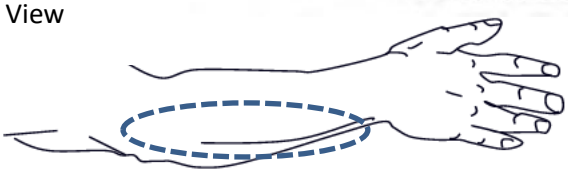
Palmar View



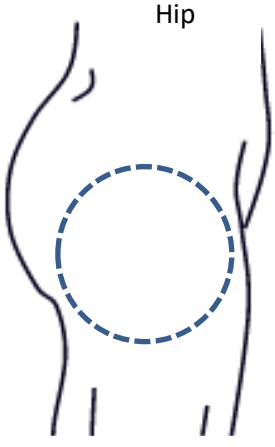
Dorsal View



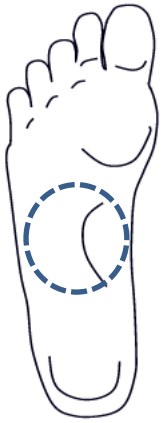
Dorsal View



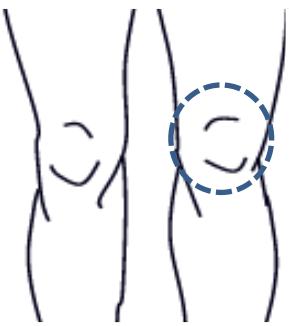
Hip



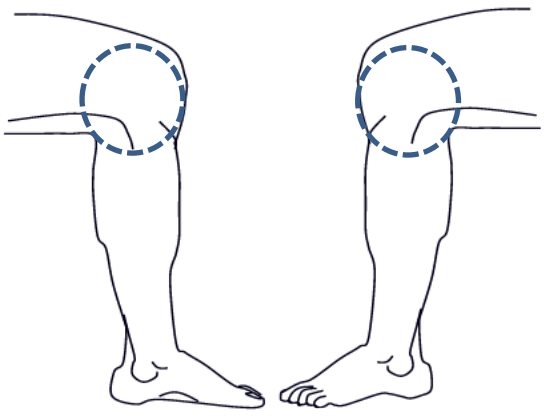
Foot



Anterior Knee

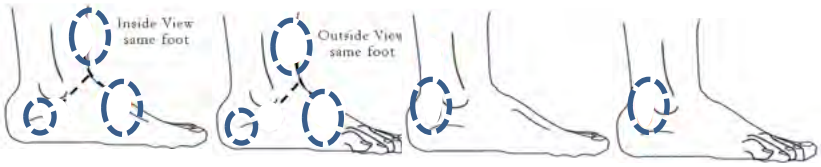


Lateral/Medial Knee



Ankle

Inside Foot Outside Foot Inside Foot Outside Foot

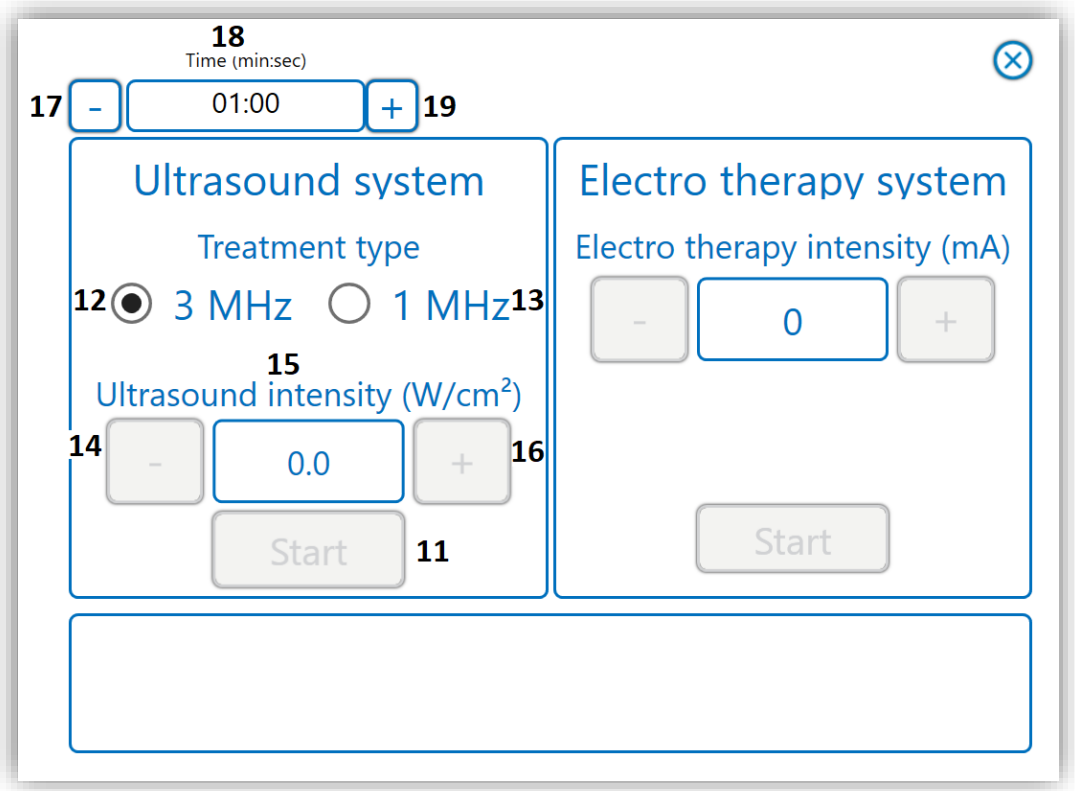


B. Operating the Ultrasound System

1. To activate the Ultrasound system, tap the **START** button on the right of the touch screen. The timer starts to count down and the light on the Ultrasound Transducer turns on. See the screen on next page
2. Select the **Type of the treatment**:
    a. 3 Mhz - Select 3 Mhz
    b. 1Mhz – select 1 Mhz

    Treatment intensity default is set for Low. You should always start with Low and then increase to Medium if patient has no neuropathy, has sensation in the treatment area, and feels mild warmth.
3. If the unit detects the US transducer is disconnected, it will give an alarm “Transducer disconnected” on the status bar, and will stop its activity immediately.

The following will be displayed on the screen:



- Move the transducer over the treatment site in small circular movement
- Always keep the face of the transducer in contact with the treatment area, and always keep the transducer moving to avoid any excessive warmth.
- Be sure that during the treatment there is always a good contact between transducer and skin, at this purpose, pay attention to use a sufficient quantity of gel and to apply the transducer correctly.
- In case ultrasound transducer does not touch the patient body the announcement appears on the screen "transducer out of touch", simultaneously the LED on the transducer will turn off.

Screen Functions

(12) & (13) Type of treatment – shows which operation selected 3Mhz or 1Mhz **(for the difference between 3MHz and 1 MHz treatment types please refer to page 21-22 clause 8.3)**

(14) & (16) Intensity down and up button keys – the treatment intensity may be set in 0.1 W/cm^2 using the up and down keys situated besides the treatment intensity display. The up key increases the treatment intensity in 0.1 W/cm^2 by each time it is pressed and the down key decreases the treatment intensity in 0.1 W/cm^2 by each time it is pressed

(15) Output display – indicates the intensity in W/cm^2

(17) & (19) treatment time keys situated besides the treatment time display (18). The up and down keys - the treatment time may be set in 1 minute using the up and down keys situated besides the treatment time display. The up key increases the treatment time in 1 minute by

each time it is pressed and the down key decreases the treatment time in 1 minute by each time it is pressed

(18) Treatment time displays the time remaining for the treatment by minutes and seconds.

C. Prepare the transducer for operation:

i. Apply Ultrasound gel on Ultrasound transducer's metal face

ii. Apply Ultrasound gel to the treatment area for obtaining good contact between Ultrasound transducer and skin.

WARNING:

Be careful while handling treatment head because rough handling may adversely affect its characteristics

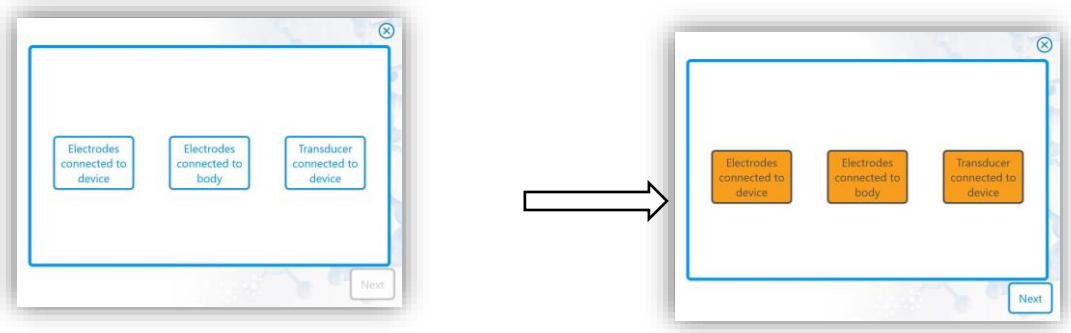
Once the Timers have reached 00:00, the treatment is finished.

Use this device only with the leads CE marked electrodes, and supplies recommended by the manufacturer.

c. Starting a new treatment

Activate the BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) by pressing on the "new treatment" on the touch screen.

Confirm to the system that the electrodes are applied on treatment area (1) connected to the electrodes cables (2) and that you are about to prepare the transducer for treatment (3):



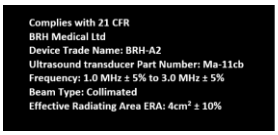
14. DESCRIPTION OF APPLIED PARTS

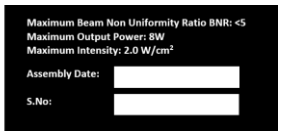
The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) is supplied one applied part: an Ultrasound Transducer. This applied part is a BF-type (floating- no ground for minimal patient leakage currents), as required by IEC 60601-1:2010 3rd edition safety standard.

a. Ultrasound Transducer (Part No ATC006)

The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) is equipped with an Ultrasound Transducer 1.0 MHz ±5% to 3.0 MHz ±5%.

The working frequency is marked on the Transducer's case:





b. Neuromuscular Stimulation electrodes (Part No ET53)

Maximum current density: 3.2 mA/Cm^2 for 65mA, 5cm diameter electrode

BRH Medical recommends using CE marked K160138 Adhesive Electrodes (manufactured by GMDASZ Manufacturing Co, Ltd.- P/N OCWN1005 model) complied with 21 CFR 898

Adhesive Electrodes manufactured by GMDASZ are multi-layer reusable, flexible structures composed of laminated materials commonly used in this application:
First layer: Insulating backing material: Fabric/foam/tan fabric
Second layer: Conductive film: Carbon film/Carbon film coated with silver/Aluminum foil film
Third layer: Biocompatible self-adhesive conductive hydrogel
Protective liner: PET
The electrodes are designed for single-patient/multiple application use. Because of the adhesive nature of the biocompatible conductive hydrogel, no securing materials are required to secure the device to the patient's skin.
The electrode is connected to the electrical stimulator by lead wire, with a standard 2 cm recessed female terminal with insulating outer jacket. By design, the insulated outer jacket prevents the conductive connection to earth or hazardous voltages. Wire assembly is incompliance with FDA performance standard 21 CFR Part 898.

Size: Round 5cm diameter.

WARNING:

For patient safety, use only the electrode connection cables supplied with the BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS).

Do not use electrodes that are smaller than 5cm round.

To reduce chance of skin irritation or thermal burns due to high current density (Larger than 2 mA/cm2), limit treatment intensity to 40 mA (40V) or less while using 5cm round electrodes. (Warning label can be found under "system label" section of this manual)

Electrodes should be used only once.

15. CLEANING – DECONTAMINATION

The device and any of its parts are all not sterile and shouldn't be treated as such (i.e. do not place any of its parts in any sterilization equipment)

Caution:

There are no user serviceable parts inside the unit and it must not be opened.

15.1 Cleaning / decontamination must be carried out by the Operator within the suggested timeframe.

15.2 Regularly inspect the transducer head, cables and connectors for signs of damage. If any damage is detected refer to BRH medical qualified service personnel.

15.3 Before cleaning / decontaminating the BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS), the Mains Switch must be set to OFF and the power cord plug must be removed from the wall socket outlet.

The unit should be cleaned / decontaminated by wiping down with a damp antiseptic cloth. The use of abrasive materials and cleaning solvents should be avoided. It is necessary to clean / decontaminate applied parts (Ultrasound Transducer and Neuromuscular Stimulation cables) after each treatment.

- The Ultrasound transducer hand piece and Neuromuscular Stimulation cables requires cleaning / decontamination on a regular basis.
- Cleaning / decontamination procedure is mandatory after each treatment.
- Cleaning / decontamination of the ultrasound transducer hand piece and Neuromuscular Stimulation cables is important as the treatment procedure may involve contact with mucus membranes, sterile body cavities, intact skin, blood, body fluids and other infectious materials.

Please refer to the next section for detailed Cleaning Instructions

Detailed procedure

- **1st step – cleaning remaining gel on the Ultrasound hand piece**
  Use a paper towel or cloth for cleaning the Ultrasound hand piece from any visible remaining gel on it.
  Wipe off any remaining gel until it is as dry as possible.

- **2nd step - Cleaning**
  Use an antiseptic wipe cloth or put some antiseptic solution/liquid/spray on a paper/cloth and wipe the hand piece/transducer.
  1. **Do not use water or detergents**, since water might damage the hand piece.
  2. **Very important!**
     Each part of the hand piece/transducer needs to be thoroughly wiped with the antiseptic wipe and dried.
     It may be dried by a cloth followed by hot air.
     A wet part might cause damage to the part itself – and in the future, might cause the improper performance of the entire system.

15.4 The Ultrasound Transducer must be disinfected using a 70% v/v aqueous solution of isopropyl alcohol. It is NOT suitable for steam sterilization or for disinfectants containing sodium hypochlorite.

WARNING:

Isopropyl alcohol is flammable and should be kept away from naked flames. Isopropyl alcohol must not be brought into contact with eyes or mouth.

16. COMPONENTS

The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) unit is supplied with the following components:

Quantity	Article Description	Item Number
1	BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS)device	BRH-A2
1	Ultrasound Transducer	ATC006
1	2 Red + 2 Black electrode cables	EC586
1	Touch screen pen	Kld359
1	BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) User manual	SLA8957
Note	**BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS)power cable not included**	

*** User is required to locally purchase a standard desktop PC power cable and water based gel prior to first use of the system**

17. VIGILANCE

Importers , distributor, healthcare professionals, any BRH-A2 user and patient shall immediately (and in any event, no later than eighteen (18) hours after becoming aware) notify BRH Medical Ltd. in writing of serious incident related to the device (see definition below), and also report to the competent authority of the country in which the incident occurred.

'Serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following:

- The death of a patient, user or other person,
- The temporary or permanent serious deterioration of a patient's, user's or other person's state of health.
- A serious public health threat;

In case of one of the aforementioned serious incidents events, the distributor shall suspend marketing and sale of the device immediately and wait for further instructions from the manufacturer.

18. WARRANTY

This BRH medical, (hereinafter called the Company) product is warranted against defects in materials and workmanship for a period of two years from the date of shipment.

The Company will at its option, repair or replace components which prove to be defective during the warranty period, provided that the repairs or replacements are carried out by the Company or its approved agents.

The Company will consider itself responsible for the effects on safety, reliability and performance of the product:

- Only if any assembly operations, re-adjustments, modifications or repairs are carried out by persons authorized by it, only if the product is used in accordance with the instructions for use.
- Only if the electrical installation of the relevant room complies with the appropriate national requirements.

Should the product be returned to the Company for repair, it must be sent inside its original packaging. Contact BRH medical customer service personnel at:

Customer Service

In case of any need for operational support, problems encountered or malfunction please reach out:

Telephone: + 972-2-6483541; 054-6678330; 054-6678331

E-mail: Tal@brhmedical.com

All products being returned for warranty repair shall be shipped prepaid to:

BRH medical

The Jerusalem Technology Garden

Building A, 1st floor

Jerusalem, Israel

BRH medical will prepay the shipment of the repaired or replacement product to customer at BRH medical's expense.

19. REFERENCES

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