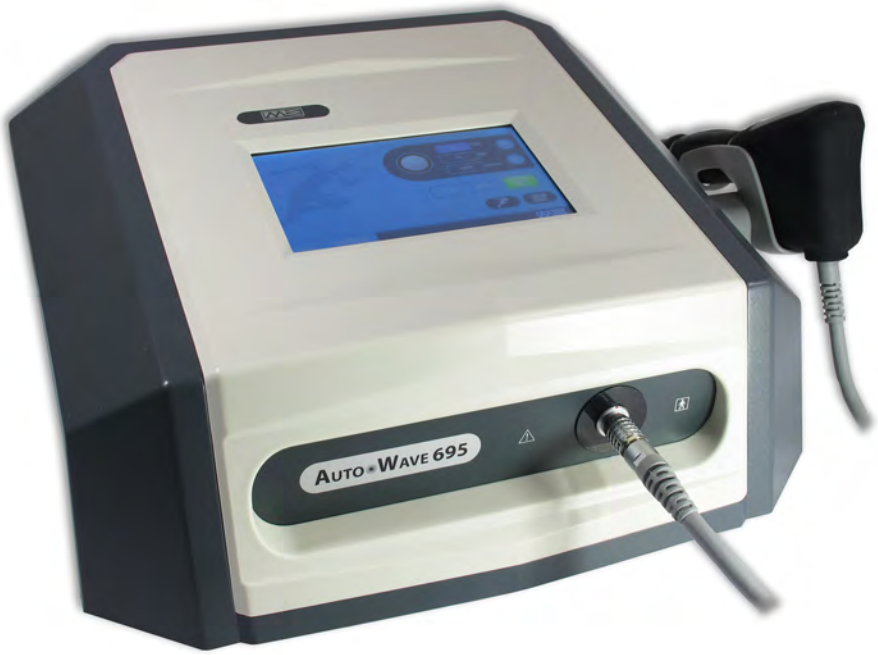
Mettler Electronics Corp.

# Electrical Radial Pressure Pulse Therapy Device

# Auto*Wave 695




**Please read this user manual before starting to use the device.**

Rev.B_022817

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# *Foreword*

*This manual has been written for the owners and operators of the **ME 695**. It contains general information on the instructions for safety, intended use, working principle, operation, maintenance, trouble shooting, and warranty. In order to maximize the use, efficiency, and working life of your unit, please read this manual thoroughly and become familiar with the controls, as well as the accessories, before operating the unit. This manual contains general safety, working principle, operation, protocols guidance, maintenance, and trouble shooting for the owners and operators of the **ME 695**.*

*Specifications put forth in this manual were in effect at the time of publication. However, owing to Mettler Electronics's policy of continual improvement, any changes to these specifications may be made at any time without obligation on the part of Mettler Electronics.*

*Before administering any treatment to a patient, the user of this equipment should read, understand, and follow the information contained in this manual for each mode of treatment available, as well as the indications, contraindications, warnings, and precautions.*

## *Operator Qualifications*

*The **ME 695** is intended exclusively for use by medical specialists and is only allowed to be used by qualified and instructed medical persons in a clinical environment. Specialists must have the basic physical and cognitive prerequisites such as vision, hearing, and literacy. Also, the basic function of the upper extremities is expected.*

## *Operator Training*

*Operators of the **ME 695** must have been adequately trained in using this system safely and efficiently before they operate the unit. A documented, cross-functional review must be performed, as many times as necessary, in order to ensure that instructions can be understood by users. The operator must be instructed in the following points:*

*Instruction in operation and designated use of the instrument with practical exercises;*
*Mode of effect and function of the unit and the applied energies*
*Settings of all components*
*Indications for use of the unit*

*Contraindications and side effects of extracorporeal radial pressure pulse therapy*
*Explanation of the warning notes in all operating status*
*Instructions on how to maintain the unit*

*Further training requirements vary from country to country. It is the operator's responsibility to ensure that the training meets the requirements of all applicable local laws and regulations. Other information about training in the operation of this system can be obtained from Mettler Electronics.*

## *Product Description and Intended Use*

***ME 695** allows for the treatment of indications with radial, pneumatically generated, low energy acoustic waves or pressure pulses.*

***ME 695** is a compressed air operated ballistic Radial Pressure Pulse generator featuring high-precision ballistic components in its applicator for Radial Pressure Pulse generation. The motion and weight of the projectile accelerated by compressed air produce kinetic energy that is converted into sound energy when the projectile strikes an unmoved surface (Radial Pressure Pulse transmitter). This acoustic pulse is transmitted to the target tissue directly.*

*These waves are physically classified as radial pressure pulses. The applied pressure pulse propagates radically within the tissue and has a therapeutic effect on areas of the tissue.*

*It is a class I medical electrical equipment with a type BF applied part. The handpiece is applied part. This device is intended to use in hospitals, rehabilitation centers, clinics and other professional medical places.*

***NOTE:** Medical devices operating on the basis of the above principle are generally referred to as radial pressure pulse systems in modern medical literature.*

*Stay current with the latest clinical developments in the field of extracorporeal radial pressure pulse therapy treatment. Observe all applicable precautionary ensures for treatment. Keep informed on appropriate indications and contraindications for the use of radial pressure pulsed treatment.*

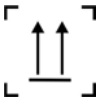
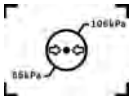
# Safety Instructions

## Symbols

### 1. Symbols on the medical device

| Symbols | Explanation |
|---|---|
|  | *Manufacturer* |
|  | *Date of manufacture* |
|  | *CE certification* |
|  | *Correct Disposal of This Product (Waste Electrical & Electronic Equipment)*<br>*Statement: Contact the local authorities to determine the proper method of disposal of potentially bio-hazardous parts and accessories.* |
|  | *Type BF applied part* |
|  | *Refer to instruction manual/ booklet* |
|  | *Caution* |

## *2. Symbols on the package*

| *Symbols* | *Explanation* |
|---|---|
|  | *This side up*<br>*The transportation package must be vertical and straight up during transportation.* |
|  | *Fragile, handle with care*<br>*The product inside the packaging could be easily damaged if dropped or handled without care and attention.* |
|  | *Keep away from rain*<br>*The product package should keep out of the rain and not to store it in damp conditions.* |
|  | *Temperature limitation*<br>*The product package should be stored at a temperature between -10 and 50 degrees (centigrade).* |
|  | *Upper limit of humidity*<br>*The product package should be stored at a humidity less than 93%.* |
|  | *Atmospheric pressure limitation*<br>*The product package should be stored at an atmospheric pressure between 86kPa and 106kPa.* |

## *Precautionary Definitions*

*The precautionary instructions found in this section and throughout this manual are indicated by specific symbols. Understand these symbols and their definitions before operating this equipment. The definition of these symbols is as follows:*

***CAUTION***

*Text with a "CAUTION" indicator will explain possible safety infractions that could have the potential to cause minor to moderate injury or damage to equipment.*

***WARNING***

*Text with a "WARNING" indicator will explain possible safety infractions that will potentially cause serious injury and equipment damage.*

***DANGER***

*Text with a "DANGER" indicator will explain possible safety infractions that are imminently hazardous situations that would result in death or serious injury.*

***Explosion Hazard***

*Text with an "Explosion Hazard" indicator will explain possible safety infractions if this equipment is used in the presence of flammable anesthetics.*

***Dangerous Voltage***

*Text with a "Dangerous Voltage" indicator serves to inform the user of possible hazards resulting in the electrical charge delivered to the patient or operator in certain treatment configurations.*

***Refer to Instruction Manual/Booklet***

***NOTE:*** *Throughout this manual, "NOTE" may be found. These Notes are helpful information to aid in the particular area or function being described.*

***CAUTION***

*• Read, understand, and practice the precautionary operating instructions. Know the limitations and hazards associated with using any radial pressure pulse therapy device. Observe the precautionary and operational decals placed on the unit.*

*• Before using **ME 695**, make sure you have read and understood all information provided in this manual. Familiarity with the information included in this manual is an essential requirement to ensure efficient and optimal use of the system, to avoid dangers to persons and to the equipment, and to obtain good treatment results.*

*• Knowledge of the content of this manual is an essential prerequisite for operating **ME 695**.*
*• Disregarding any information in this manual is considered to be abnormal usage of the unit.*
*• DO NOT operate **ME 695** in conjunction with any other devices.*
*• DO NOT operate this unit in an environment which other devices are being used that intentionally radiate electromagnetic energy in an unshielded manner. Portable and mobile RF communications equipment can affect medical electrical equipment.*
*No parts of **ME 695** can be serviced or maintained while the machine is in use with the patient.*

***CAUTION***

*• Before using the machine, the unit should be routinely checked to determine that all controls function normally (e.g., the STOP button ends treatment, the START button causes the treatment to begin, the trigger button on the handpiece causes the transmitter to pulse, etc.), especially that up and down arrow buttons adjust the number of pulses the transmitter emits.*
*• DO NOT use sharp objects such as a pencil point or ballpoint pen to operate the buttons on the control panel as damage may result.*
*• This unit should be transported and stored in temperatures between -20℃ and 50℃ to prevent damage to the unit or its components.*
*• Handle radial pressure pulse treatment accessories with care. Inappropriate handling of the accessories may adversely affect their characteristics.*
*• Inspect cables, associated connectors, and accessories before each use.*
*• Do not use accessories other than those supplied with the unit, or recommended by Mettler Electronics. The safety of other products has not been established, and their use could result in injury to the patient and degrade minimum safety.*

***CAUTION***

*• Disconnect the power supply cord before removing covers on this equipment. Refer the servicing of this unit to qualified service personnel.*
*• This equipment has an output that is capable of producing a physiological effect.*
*• Medical electrical equipment needs special precautions regarding EMC.*
*• This unit can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this equipment on and off. Try to correct the interference using one or more of the following: reorient or relocate the receiving device, increase the separation between the equipment, connect the equipment to an outlet on a different circuit from that to which the other device(s) are connected, and consult the factory field service technician for help.*
*The mains plug is considered as isolation device from supply mains. Do not to position the equipment to make it difficult to operate this disconnection device.*

## ⚠ CAUTION

*• This equipment is to be used by, and sold to, a trained clinician only under the prescription and supervision of a licensed practitioner.*

*• Only users trained in the use of extracorporeal radial pressure pulse therapy should operate the unit and its applicators.*

*• The Power On/Off button is considered a "soft" switch and does not isolate the unit from mains power when the unit is turned off. Therefore, you must disconnect the male end of the power supply cord from the electrical outlet (mains power supply) in order to isolate it.*

*• The **ME 695** is not intended for the treatment of kidney stones.*

## ⚠ WARNING

*• Improper installation, operation, or maintenance of the radial pressure pulse system may result in malfunctions of this unit or other devices.*

*• In case of display failure or other obvious defects, switch the unit off immediately by means of the power on/off button, disconnect the power cord from the power outlet, and notify a certified service technician.*

*• Adjustments or replacement of components may result in the equipment failing to meet the requirements for interference suppression.*

*• If the unit cannot be installed immediately after delivery, the unit and its external components or accessory elements must be stored in their original packaging in a dry place.*

*• Do not store or operate the unit in a dusty environment.*

*• Keep all line cords away from the unit cables. Do not store or coil line cords where they can come close to the cables on an operating radial pressure pulse unit. Position the power cord in such a way that it does not present a tripping hazard.*

*• This equipment is not designed to prevent the ingress of water or liquids. Ingress of water or liquids could cause malfunction of internal components of the system and therefore create a risk of injury to the patient.*

*• No modification of this equipment is allowed*

## ⚠ WARNING

*• Care must be taken when operating this unit adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the **ME 695** should be observed to verify normal operation in the configuration in which it will be used. Potential electromagnetic or other interference could occur to this or other equipment. Try to minimize this interference by not using other equipment in conjunction with it.*

*• Use only accessories that are specially designed for this unit. Do not use accessories manufactured by other companies on this unit. Mettler Electronics is not responsible for any consequence resulting from using products manufactured by other companies. The use of other accessories or cables (other than those specified) may result in increased emissions or decreased immunity of this unit.*

*• Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to radial pressure pulse energy.*

*• Make certain that the unit is electrically earthed by connecting only to a earthed electrical service receptacle, conforming to the applicable national and local electrical codes.*
*• This device should be kept out of the reach of children.*
*• Do not leave patient unattended during radial pressure pulse therapy.*

***WARNING***

*• Remove the applicator by pulling the connector only. DO NOT remove by pulling the cable.*
*• To remove the applicator from the unit, make certain the power is off. Hold the applicator while removing it to prevent the applicator from dropping to the floor.*
*• Observe the patient at all times during therapy.*
*• Operating the unit at pressures higher than 3 bars without an impact surface can result in damage to the handset.*

***WARNING***

*• Treatment should never be given in the area of metal implants.*
*• Place the unit on a flat surface during treatment and storage to prevent tipping and rolling.*
*• Depress the tabs of the caster locks to prevent the front wheels from moving during treatment and storage.*
*• The temperature of the transmitter may up to 42.8℃ due to continuous pulses. Extended skin contact may cause minor burns. To allow the transmitter cool down, at least 10 minutes interval of the treatment is necessary after a maximum of 3000 pulses.*
*• It is suggested that not applying more than 300 continuous pulses to the same spot.*
*• For continued protection against fire hazard, replace fuses only with ones of the correct type and rating.*

***DANGER***

*• The function of certain implanted devices (e.g., pacemakers) may be adversely affected during treatment with extracorporeal radial pressure pulse therapy. In case of doubt, the advice of a licensed practitioner in charge of the patient should be sought.*
*• Other equipment, including patient connected devices, may be adversely affected when in close proximity to radial pressure pulse equipment.*
*• Patients should not be treated with radial pressure pulse when they have reduced thermal sensitivity over the proposed area of treatment, unless the physician in charge of the patient is notified.*
*• Treatment should not be given through clothing, although it is permissible to administer treatment through a dressing in pulsed modes.*
*• Remove hearing aids prior to treatment.*
*• Before each use, check the condition of the housing and the insulation of the applicator and power supply cable. Also make sure that the cables have been routed correctly.*
*• If the unit is not safe for operation, then it must be repaired by certified service personnel and the operators must be informed of the dangers posed by the unit.*
*• In order to prevent electrical shock, unplug the power plug from the socket before cleaning or disinfecting the unit.*

***DANGER***

*• Under no circumstances may liquid penetrate the openings on the unit (e.g. the connecting sockets of the cables). Therefore, do not use cleaning or disinfectant sprays.*

*• The unit and cables may not be sterilized using steam or gas.*

*• Never clean the unit with abrasives, disinfectants or solvents that could scratch the housing or damage the unit.*

*• The unit's components are under pressure and subject to high voltage. Do not perform unauthorized repairs under any circumstances.*

*• Radial pressure pulses must not be applied to target areas located above air filled tissue (lungs), nor to any regions near large nerves, vessels, the spinal column or head.*

*• The operator should not use radial pressure pulse over the heart in order to prevent theoretical cardiac signal interference.*

*• The unit must be installed so that there is no danger to the patient, the operator, or other persons. Therefore, you must read the safety instruction and contraindications.*

*• Explosion hazard if the **ME 695** is used in the presence of flammable anesthetics mixture with air, oxygen, or nitrous oxide.*

## *Personal Safety*

*In case of improper or unauthorized use of the unit, the operator, the patient or other persons may be subjected to the danger of electric shock due to high voltage produced by the unit, the danger of influence on active implantations by magnetic fields produced by the unit and the danger of being burned due to erroneously positioned handset or false parameters such as the duration of treatment, power output or operating mode.*

*Before operating the unit, please read this instruction manual carefully and observe the information contained therein. Pay special attention to the list of contraindications.*

*Before operating the unit each time, verify that:*

*• the unit has been correctly connected to the Mains Power Supply.*

*• the handset connection cable is connected properly and is not cross-threaded (which may cause capacitive short circuits).*

*• only accessories approved by the manufacturer are connected.*

*• the handset is positioned according to the clinician's instructions (to be checked by the clinician or physiotherapist if applied by assisting personnel).*

*Before using the unit, speak with the patient to verify:*

*• the patient is in a comfortable position during the entire treatment.*

*• that the patient is comfortable before and during treatment.*

*Before using the unit, determine the maximum nominal output power of the respective accessory in order to avoid overheating the tissue.*

*At regular intervals during the treatment, verify:*

*• that the unit is functioning properly*

*• if the patient feels well.*

*After the treatment, ask the patient about the tolerance of the treatment. The treatment environment should be inspected by a licensed practitioner.*

*The affected parts of the body should be unclothed during treatment, since accumulation of moisture on the skin or in folds can cause local overheating of the skin. This is especially important in the event that the patient is wearing clothing made of moisture resistant fabric such as silk or synthetic fibers.*

*The output power must always be set according to the subjective response of the patient. Particular care is to be taken with patients who have a reduced capacity for heat perception.*

## *Protection of the Unit*

***WARNING***

*Improper installation, operation or maintenance of the radial pressure pulse unit may result in malfunctions of this unit or other devices.*

*Before connecting the unit, make sure that:*

*• the voltage rating on the safety label corresponds to the available system voltage.*

*• the frequency rating on the rating plate corresponds to the system frequency.*

*• a grounded socket outlet with ground contact is available for connecting the unit.*

*• the routing of the power cable from the unit to the socket outlet with grounded contact does not pose a danger for personnel or the patient.*

***WARNING***

*Make certain that the unit is electrically earthed by connecting only to an grounded electrical service receptacle, conforming to the applicable national and local electrical codes.*

*Do not connect the unit to the Mains Power Supply until the following requirements have been met:*

*• Before putting the unit into operation, check to make sure that the handset connection cable and the transmitters are undamaged and have been connected correctly to the unit.*

*• Never operate the unit with open outputs (i.e. without handset).*

*• Clean and disinfect the unit only when the Mains Power Supply is deactivated (power switch off, power plug disconnected).*

*• Clean and disinfect the unit only by means of disinfection by wiping. Disinfecting by spraying can damage the unit due to penetrating moisture.*

*• Never clean the unit with abrasives, disinfectants, or solvents that could scratch the housing or damage the unit.*

*• Never perform unauthorized service work. All service work must be performed only by service technicians who have been authorized by the manufacturer.*

# *EMC Guidance*

*This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.*

***CAUTION***

*• Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.*

*•This unit has been thoroughly tested and inspected to assure proper performance and operation!*

*• This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.*

| Guidance and manufacture's declaration – electromagnetic emission | | |
|---|---|---|
| The 2500S is intended for use in the electromagnetic environment specified below. The customer of the user of the 2500S should assure that it is used in such an environment. | | |
| **Emission test** | **Compliance** | **Electromagnetic environment – guidance** |
| RF emissions<br>CISPR 11 | Group 1 | The 2500S use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emission<br>CISPR 11 | Class A | The 2500S 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<br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions<br>IEC 61000-3-3 | Complies | |

| Guidance and manufacture's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The 2500S is intended for use in the electromagnetic environment specified below. The customer or the user of 2500S should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact<br>±8 kV air | ±6 kV contact<br>±8 kV air | Floors should be wood, concrete or ceramic tile. If floor 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<br>±1 kV for input/output lines | ±2kV 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)<br>± 2 kV line(s) to earth | ±1 kV differential mode<br>±2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5% $U_T$ (>95% dip in $U_T$) for 0.5 cycle<br><br>40% $U_T$ (60% dip in $U_T$) for 5 cycles<br><br>70% $U_T$ (30% dip in $U_T$) for 25 cycles<br><br><5% $U_T$ (>95% dip in $U_T$) for 5 sec | <5% $U_T$ (>95% dip in $U_T$) for 0.5 cycle<br><br>40% $U_T$ (60% dip in $U_T$) for 5 cycles<br><br>70% $U_T$ (30% dip in $U_T$) for 25 cycles<br><br><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 2500S requires continued operation during power mains interruptions, it is recommended that the 2500S be powered from an uninterruptible power supply or a battery. |
| Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE $U_T$ is the a.c. mains voltage prior to application of the test level. | | | |

| Guidance and manufacture's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The 2500S is intended for use in the electromagnetic environment specified below. The customer or the user of the 2500S should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | 3 Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the 2500S, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>**Recommended separation distance**<br>$d = 1{,}2\sqrt{P}$ |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.5 GHz | 3 V/m | $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz<br>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 metres (m).<br>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]<br>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 field strength in the location in which the 2500S is used exceeds the applicable RF compliance level above, the 2500S should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the 2500S.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

## Recommended separation distances between portable and mobile RF communications equipment and the 2500S .

The 2500S is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 2500S can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 2500S as recommended below, according to the maximum output power of the communications equipment.

| **Rated maximum output power of transmitter (W)** | **Separation distance according to frequency of transmitter (m)** | | |
|---|---|---|---|
| | **150 KHz to 80 MHz** | **80 MHz to 800 MHz** | **800 MHz to 2.5 GHz** |
| 0.01 | **0.12** | **0.12** | **0.23** |
| 0.1 | **0.38** | **0.38** | **0.73** |
| 1 | **1.2** | **1.2** | **2.3** |
| 10 | **3.8** | **3.8** | **7.3** |
| 100 | **12** | **12** | **23** |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

# Clinical Instructions

## Indications

### GENERAL

*Before a treatment with radial pressure pulses, a correct examination and diagnosis should be performed.*

*Please stay current with the latest developments and medical publications on extracorporeal radial pressure pulse therapy for details on contraindications and side effects not known at the time of manufacturing.*

*Extracorporeal radial pressure pulse therapy is indicated for the following:*

***Myofascial Trigger Points***

*Localizing and Deactivating Trigger Points*

*Triggers are localized at the low energy level (approximately 2 bars) by passing the transmitter over the muscle region being treated (increased sensitivity to pain) and then deactivated using a higher energy level (approximately 3 bars).*

***Activation of Muscle and Connective Tissue***

*Increasing Circulation*

*Promote blood flow through the tissue and boosting metabolism.*

***Disorder of Tendon Insertions***

1. *Plantar Fasciitis, Heel Pain, or Heel Spur*
   *Plantar Fasciitis is an inflammatory condition of the foot caused by excessive wear to the plantar fascia that supports the arch.*
2. *Tendinosis Calcarea / Supraspinatus-Tendon*
   *Shoulder calcifications and chronic shoulder pain*
3. *Radial and Ulnar Humeral Epicondylitis*
   *Tennis elbow, inflammation of tendon attachments on cubital or radial part of elbow joint (humeral)*
4. *Achillodynia*
   *Pain due to inflammation of the Achilles tendon or the bursa associated with it.*
5. *Retropatellar Pain Syndrome*
   *Pain in the front of, behind, and around the kneecap.*
6. *Tibial Edge Syndrome*
   *Pain located along or just behind the medial edge of the tibia*
7. *Proximal Iliotibial Band Friction Syndrome / Trochanteric Insertion Tendonitis*
   *Pain or aching on the outer side of the knee or hip*

## *Contraindications*

### *GENERAL*

*Before a treatment with radial pressure pulses, a correct examination and diagnosis should be performed. Stay current with the latest developments and medical publications on extracorporeal radial pressure pulse therapy for details on contraindications and side effects not known at the time of manufacturing. The* ***ME 695*** *is contraindicated for the following:*

1) *Pregnant women (abdomen, pelvis, waist area)*
2) *Post operation (wound, exudation)*
3) *Osteoporosis*
4) *Growing children*
5) *Coagulation defects*
6) *Bleeding tendency*
7) *Patient with pacemaker*
8) *Neoplasms*
9) *Cutaneous infections*
10) *Lung area*
11) *Spine (cervical vertebra, thoracic vertebra, lumbar vertebra)*
12) *Cortisone therapy up to 6 weeks before first treatment*
13) *Mental disorder (unable to express or have difficulty in communication)*

## *Possible Side Effects*

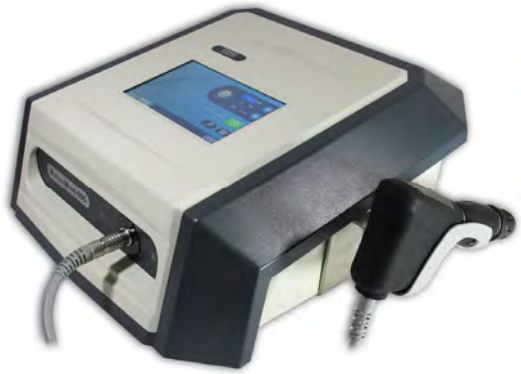
*Side effects could occur after a treatment with extracorporeal radial pressure pulse therapy. The majority will appear after 1-2 days.*

*Do not repeat a treatment until the previous side effects have diminished. Common side effects include:*

- *Reddening*
- *Swelling*
- *Pain*
- *Hematoma*
- *Petechiae, red spots*
- *Skin lesions after previous cortisone therapy*

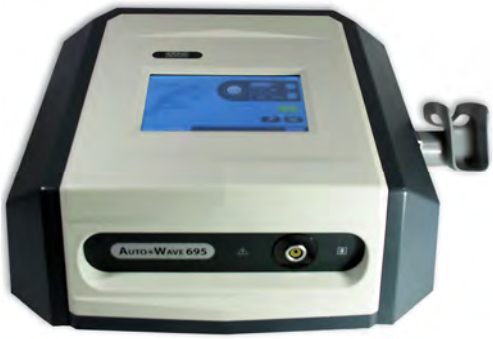
*These side effects generally abate after 5 to 10 days.*

# Overview of the Main Unit

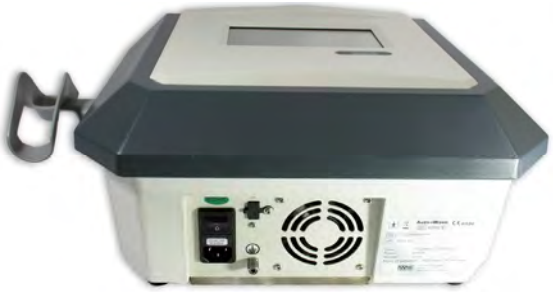


***Front View (right)***

***Front View (left)***

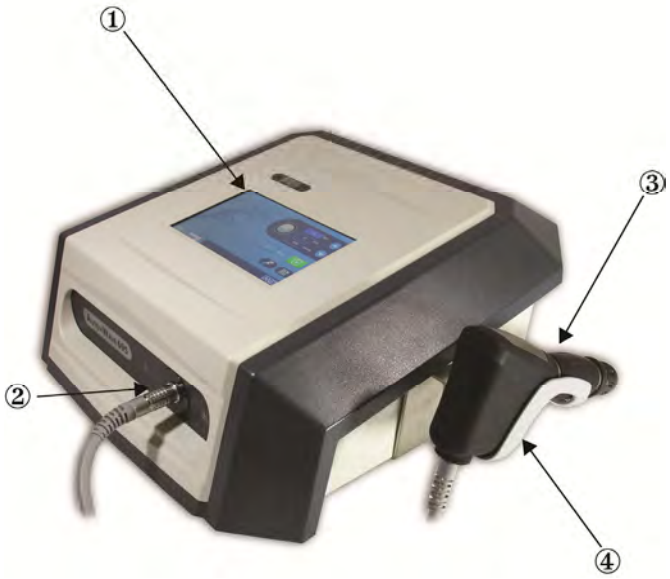



***Front View***

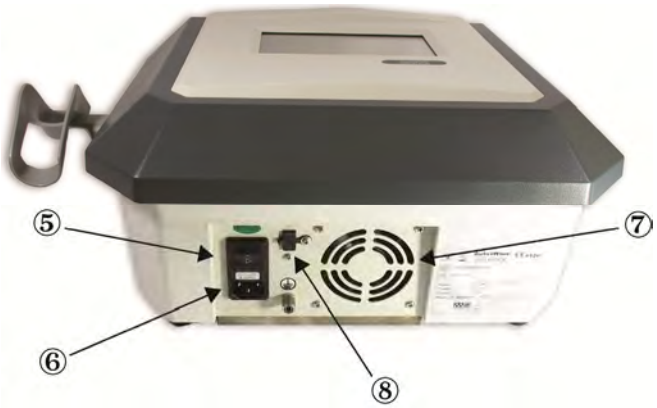


***Back view***

## *Nomenclature*




① *LCD touch screen*
② *Output socket*
③ *Handpiece applicator*
④ *Handpiece holder*




⑤ *ON / OFF button*
⑥ *Switch socket*
⑦ *Cooling fan*
⑧ *USB socket*

## *Handpiece*


1. Main part of the handpiece
2. Cable
3. Trigger
4. Transmitter
5. Rear cap
6. Shaft

## *Transmitter*

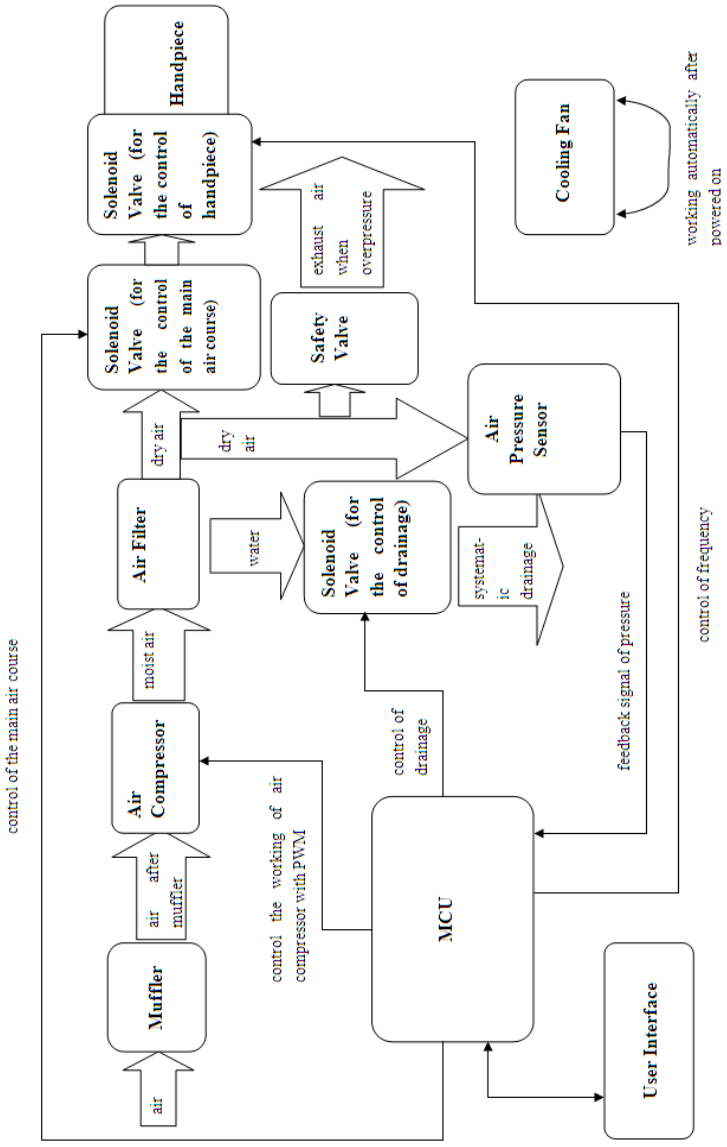
### *1) The standard transmitter*

| Ordering number | Item name |
|---|---|
| 69503 | 15mm Radial transmitter |
| 69502 | 20mm Radial transmitter |

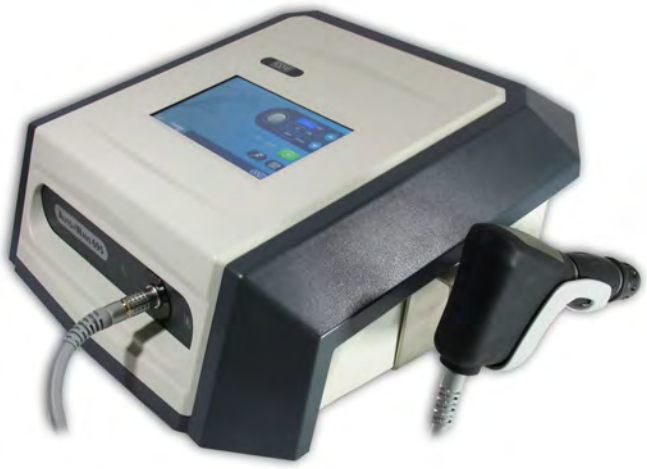
### *2) The optional transmitter*

| Ordering number | Item name |
|---|---|
| 69504 | 15mm Focus transmitter |
| 69505 | 15mm Deep transmitter |
| 69506 | 6mm Acupuncture transmitter |
| 69508 | 36mm Radial transmitter |

## Working Principle



## *Technical Specifications*



Width ……..……..……390 mm, (15.4")
Length……..……..…395 mm, (15.6")
Height ……...194 mm, (7.6")
Standard weight……...10.0 kg, (22 lb.)
Power Consumption……250 VA
Input voltage…….AC 100-240 V, 50/60 Hz
Working pressure ……..……1.0-4.0 bar (adjustable by 0.1 bar)
Working frequency……1-17 Hz (adjustable by 1 Hz)
Shocks ……...……1-3000 (step by 100 shocks)

Max pressure output ……..……..350N in condition of 4.0 bar
Fuses (Mains part)……..……..……F3.15AL250V
Fuse (secondary, pump control board)……..……F10AL250V
Fuse (secondary, main board)……..……F3.15AL250V
Non-continuous operation……..……3000 times / 10min stop

Environmental conditions of operation:

- Temperature: 5 to 30ºC, (41 to 86ºF)
- Rel. humidity: ≤80%
- Atmosphere Pressure: 86 to 106 kpa

Environmental conditions of transport and storage:

- Temperature: -20 to 50ºC, (-4 to 122ºF)
- Rel. humidity: ≤93%
- Atmosphere Pressure: 86 to 106 kpa

# *Preparation before the Treatment*

## *Unpacking the Unit*

*The unit is generally delivered with the packaging material supplied by the manufacturer. Proceed as follows:*

- *Position the transport packaging so that the arrows are pointing upward.*
- *Remove the transport packaging upward.*
- *Remove the remaining foam material.*

## *Inspections*

*Immediately upon unpacking the unit, perform the following steps:*

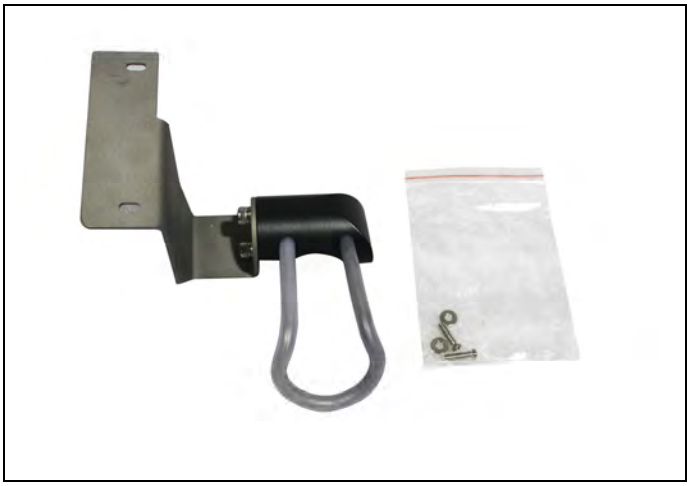
1. *Verify the delivery documents to make sure that the delivery is complete.*
2. *Check the LCD touch screen of the unit when unpack the packaging and make sure it is in good condition. Any scratch on the surface during use will be not covered in the warranty;*
3. *Check the external components and accessories for possible damage due to transport.*
4. *Verify that the packaging contains the following*

| ***Ordering Number*** | ***Item Name*** | ***Amounts*** | ***Unit*** |
|---|---|---|---|
| ME 695 | Auto*Wave 695 Main unit | 1 | piece |
| 69509 | Power cord | 1 | piece |
| 69515 | Fuses 3.15A | 4 | pieces |
| | Certificate of quality | 1 | piece |
| | Instruction manual | 1 | piece |
| 69501 | Handpiece applicator<br>(black cover; 1 pc bullet and metal pipe inside; with 1 piece of 15mm Radial transmitter and installed) | 1 | piece |
| 69507 | Reversion Kit (details as below) | 1 | suit |
| | 25001101 Bullet | 1 | piece |
| | 25001102 Metal pipe | 1 | piece |
| 69502 | 20mm Radial transmitter | 1 | piece |
| 69511 | Spare Seal Ring (color: black; diameter: 11 mm) | 6 | pieces |
| 69516 | Spare Seal Ring (color: black; diameter: 16.5 mm) | 3 | pieces |

| | | | |
|---|---|---|---|
| 69510 | Spare spacer (color: yellow) | 2 | pieces |
| 69514 | Spare spacer ring | 1 | piece |
| 69512 | Screwdriver (Φ3 × 75mm) | 1 | piece |
| 69513 | Cleaning brush | 1 | piece |

## *Install the Handpiece Holder*

*Take out of the handpiece holder and install it to the main unit.*



## *Connect the Handpiece*

*Step 1: Hang the handpiece cable on the holder first and then connect the handpiece.*

*Step 2: Connect the handpiece connector into the output sockets.*
*(PS: Please pay attention to the RED point indicator as following picture)*


## *Connect the Power Cord*

1. *Connect the male end of the power supply cord to an appropriate electrical outlet.*
2. *Connect the female end of the power supply cord into the socket on the backside of the unit.*
3. *Press the ON/OFF button at the back side of the machine to start the unit.*

# Operation

## Preparing the Unit for Therapy

*The unit has been completely assembled in the factory and is ready for use except for connection of the handpiece and the power cord.*

*Proceed as follows in order to prepare the unit for operation:*

- *Make sure that the voltage rating on the serial decal conforms to the system voltage of the building.*
- *Install the required transmitter (insert) into the handpiece.*
- *Check the condition of the housing and the insulation of the handpiece, handpiece connection cable, and the power supply cable. Also make sure that the cables have been routed correctly.*

***DANGER***

*The unit and the handpiece must be positioned so that there is no danger of personal injury. Therefore, you must read and observe the safety instructions and the list of contraindications before putting the unit into operation.*

***WARNING***

*Make certain that the unit is electrically earthed by connecting only to an earthed electrical service receptacle, conforming to the applicable national and local electrical codes.*

***WARNING***

*Check the transmitter before starting the treatment, make sure the transmitter is in good condition and without any damage, and make sure the transmitter is well installed in the handpiece. Falling off of the transmitter from handpiece may injure the patient. Damage of the transmitter may injure the patient.*

***WARNING***

*The temperature of the transmitter may up to 42.8º due to continuous pulses. Extended skin contact may cause minor burns. To allow the transmitter cool down, at least 10 minutes interval of the treatment is necessary after a maximum of 3000 pulses.*

***WARNING***

*Check the shaft (a part of the handpiece, see the structure of handpiece) before starting the treatment. Make sure*

*the shaft is well screwed down in the main part of the handpiece. If not, the handpiece will not work normally and will not generate radial pressure pulses; also this could make damage to the handpiece (mainly bullet and metal pipe).*

## *Preparing the Patient for Therapy*

*Before applying **ME 695** to the patient, you need to do the following step to maximize the treatment effect and minimize the risk of skin irritation that may cause:*

1. *Thoroughly wash the skin on which you intend to administer therapy with mild soap and water or alcohol wipe;*
2. *Dry the skin thoroughly;*
3. *Locate the target area;*
4. *Apply the coupling gel generously to the target area on the patient.*

## *Starting the Treatment*

### *Icons*


**Preset Protocols**


**User-defined Protocols**

**Selection of Transmitter**


**Stop**

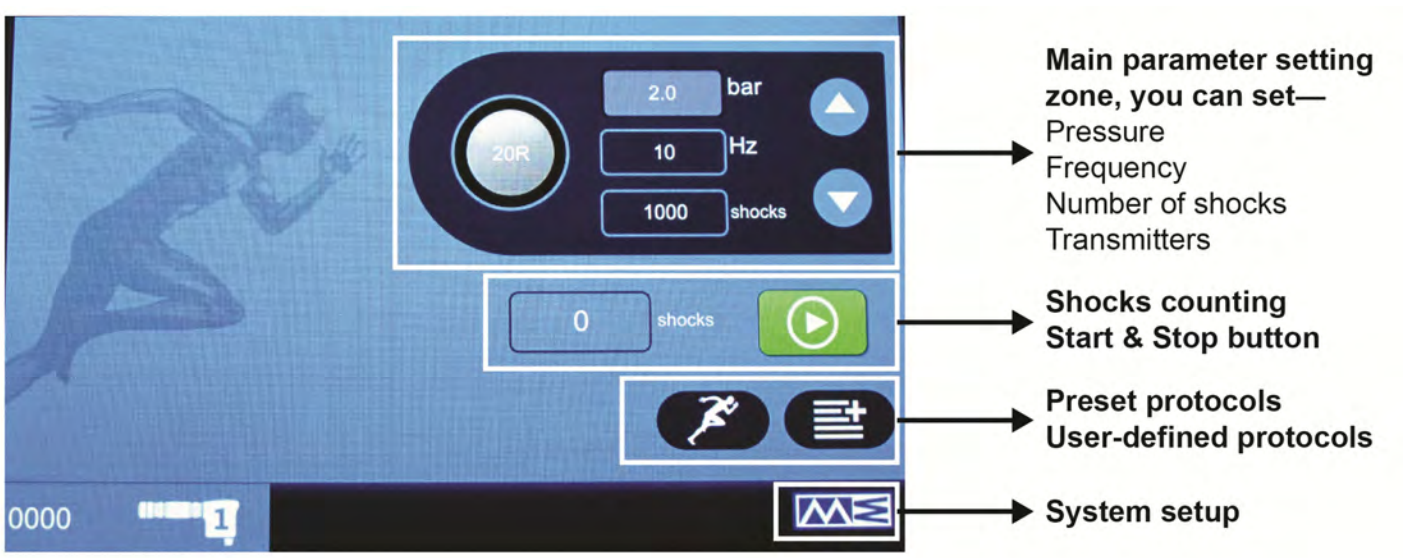

**Up**


**Down**


**Start**

*Turn on the ON / OFF button at the back side of the machine, around 30 seconds later, main interface appears on, the treatment parameters can be reset here.*

## Explanation of the Main Interface



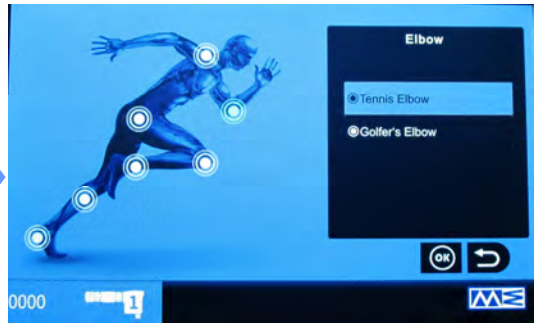

## Parameter Setting

| *ME 695* | *Default Setting* | *Adjustable Range* | *Step* |
|---|---|---|---|
| *Pressure* | *2.0 bar* | *1.0 - 4.0 bar* | *0.1 bar* |
| *Frequency* | *10 Hz* | *1 - 17 Hz* | *1 Hz* |
| *Number of Shocks* | *1000 shocks* | *1 - 3000 shocks* | *100 shocks* |

## *Preset Protocols*

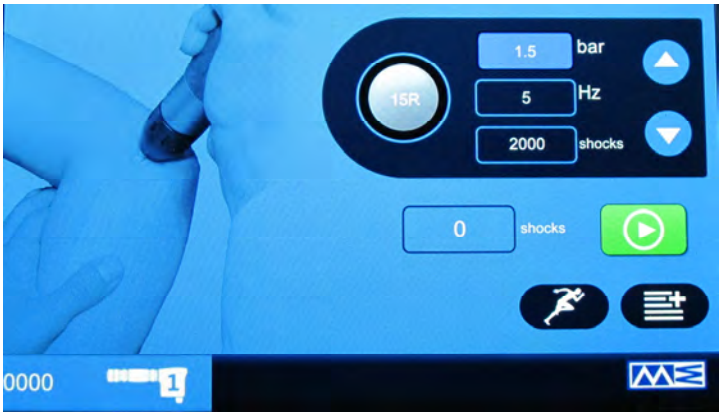
***ME 695** has been programmed more than 10 types of protocols for most popular musculoskeletal diseases use. Please follow the guidance below.*

*STEP 1: Press the preset protocols*  *button in the main interface then you will enter the interface below. Just touch the body part then you can choose the area you want to treat.*

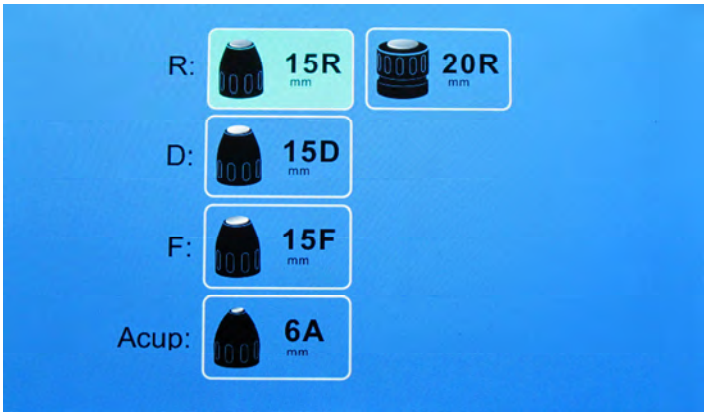

*STEP 2: Choose the indication which you need and press* 

*button, below interface will be showed.*

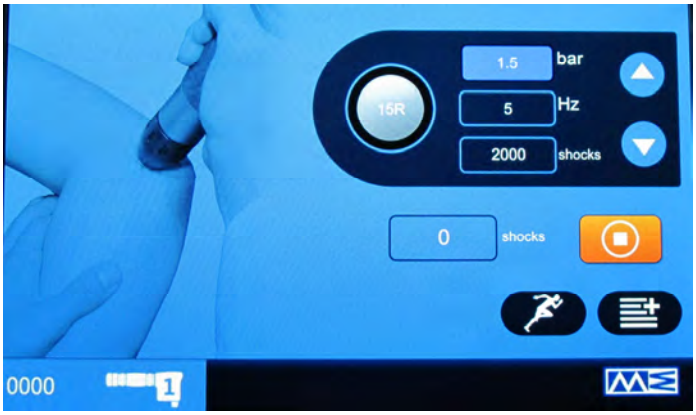



*STEP 3: Press* 

*button for more transmitter options.*




*STEP 4: Press*  *to start the treatment.*




***NOTE:*** *Pressure and Frequency are adjustable during the treatment (Pressure adjustable with 0.1 bars; frequency adjustable with 1 Hz), while number of shocks cannot be adjustable during the treatment.*

*STEP 5: Once the treatment is finished, below interface will come out, press* OK *and you will come back to the main interface. If not, around 3 seconds later, the machine will come back to the main interface automatically.*

## *User-defined Protocols*

***ME 695** allows clinicians to design and save their own treatment parameters according to different patient's conditions. Please follow up the guidance below.*

### *Icons*

**Set up a new protocol**

**Choose a saved protocol and enter the treatment interface**

**Delete a protocol**

**Back**

**See the larger image**

**Up**

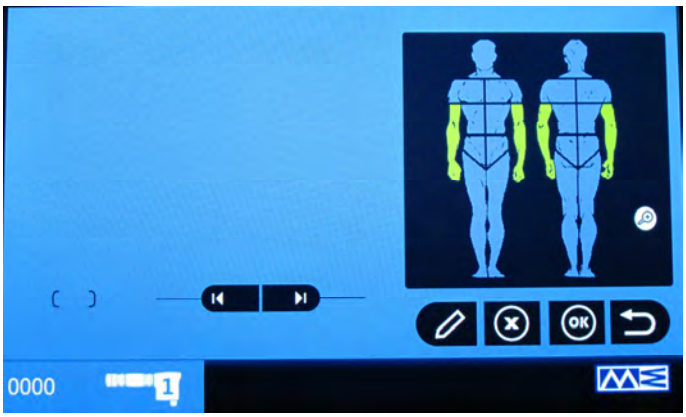
**Previous page**

**Down**

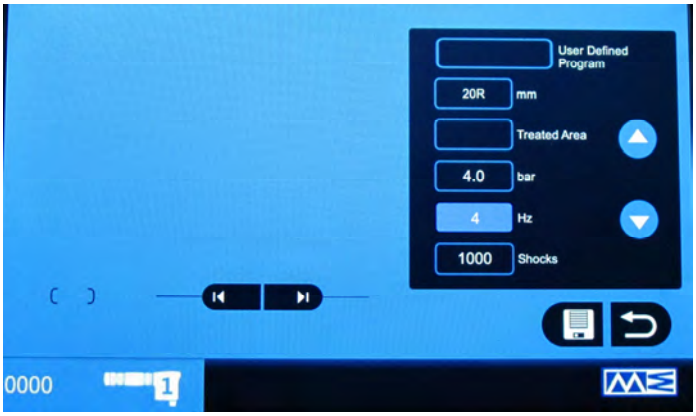
**Next page**

**Save the protocol**

*STEP 1: Press* *button to enter User-defined interface, as below shows.*

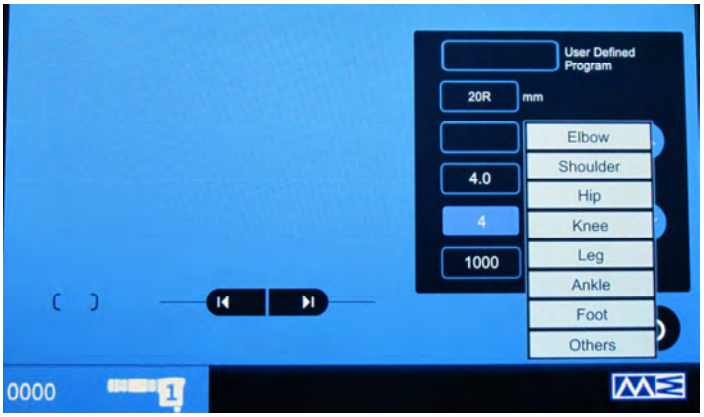



*STEP 2: Press* *button to set up a new protocol and set the treatment parameters you need.*



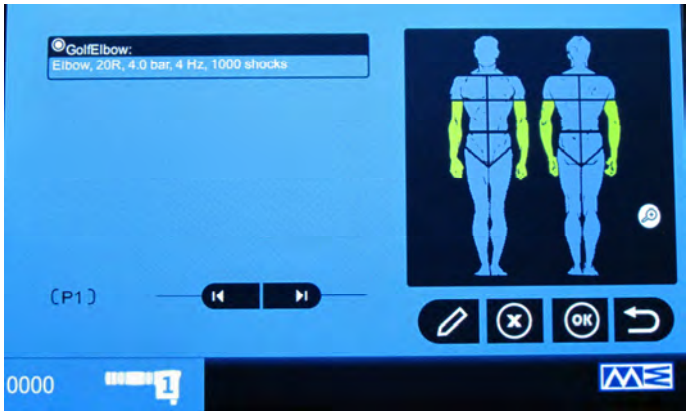

*STEP 3: Touch the blank square in front of* ***User-defined protocol*** *to name your protocol, and then touch* **Enter** *to save it.*


*STEP 4: Touch* **20R mm** *to choose the transmitter.*
*STEP 5: Press the blank square in front of* **Treated Area** *to choose the treatment part.*




*STEP 6: Set treatment parameters: pressure, frequency, and number of shocks. (You can adjust them by touching the* **UP** *and* **DOWN** *button in the right-hand side of it.)*

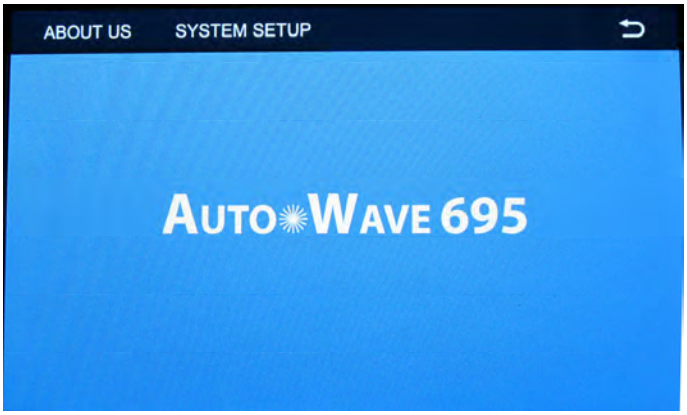
*STEP 7: Press*  *button to save this protocol and below interface will be showed. If you want to start the treatment from this step, please press*  *button and you will enter the treatment interface. Touch* **START** *button to start the treatment.*




***NOTE:*** *If you want to delete protocols, choose the protocols by touching it first and then press the* **DELETE** *button*  .

# System Setup

*Press*  *button in the right corner of the main interface to enter the* **System Setup** *interface.*

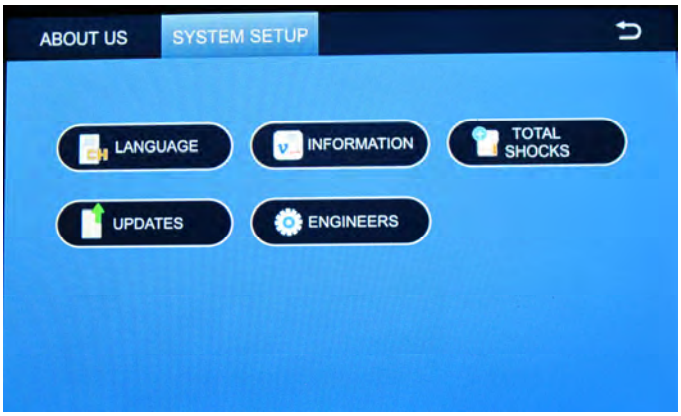



*Press* 

*button and following interface will appear.*


*Press* 

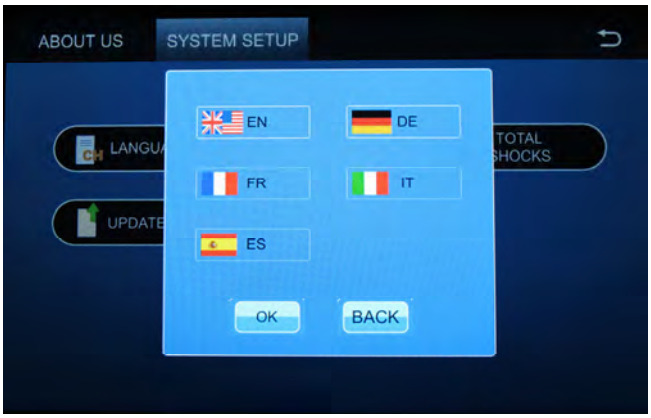
*button following interface appears.*



## *Language*

*Press* 

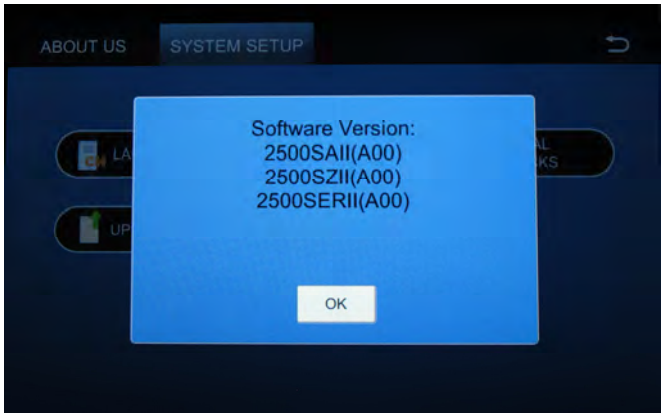
*button to switch the languages. At present available languages are English, German, French, Italian and Spanish. Touch the language and then touch OK button.*




## *System Information*

*Press* 

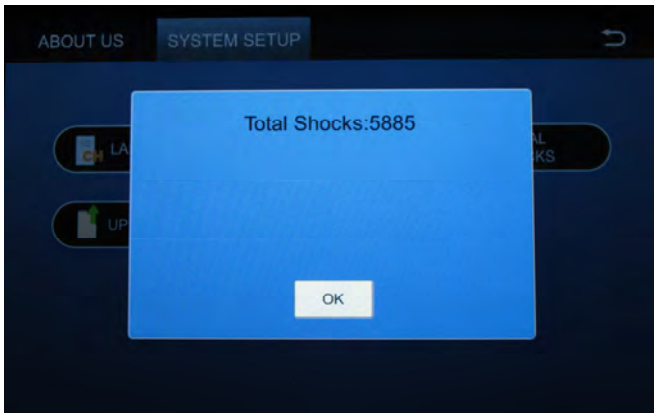
*button to check the basic information of the device.*



## Shocks History

*Touch* 

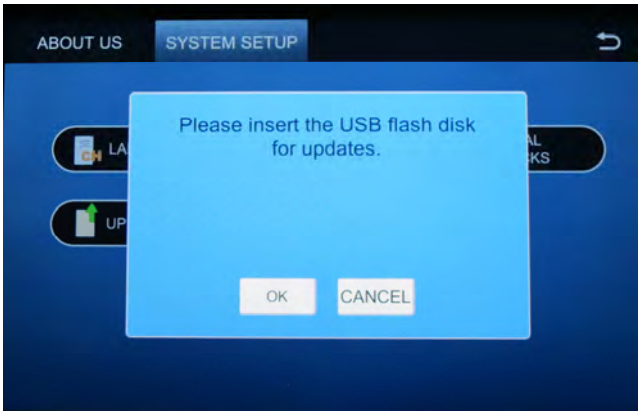
*button, you will be able to check the history shocks of the device.*




## Software Update

*The software of **ME 695** can be updated to the latest version by USB port. (This should be conducted by your local distributor and extra cost might be requested)*

***NOTE:** There is an USB socket at the back side of the main unit, and that is only for software update. For update software, please contact with us or your local distributor.*



# *Cleaning and Disinfection Instructions*

*1. Please turn off and unplug the device before the cleaning and disinfection operation;*
*2. For the main unit cleaning, what recommended are a clean, soft damp cloth for stains, and a clean, soft dry cloth for dust in the surface of the main unit;*
*3. To avoid the risk of cross-infection, transmitter's disinfection is necessary before and after every treatment. Please clean the transmitters with 75% of medicinal alcohol before and after every treatment.*

***NOTE:*** *For transmitter cleaning, you need to disassemble the transmitter because the inner side of the transmitter is also needed to be cleaned. Use a clean cloth to clean the transmitter first and then use 75% of medical alcohol to disinfection it. Thoroughly remove any gel residue from inside the transmitter on a daily basis.*

***WARNING***

*High temperature and high pressure will make damage to the transmitter.*

***CAUTION***

*Do not clean the main unit with organic solvent such as gasoline or diluents, otherwise damage will be happened to the main unit such as deformation and falling off of the paint.*

# Maintenance Instructions

*Read this maintenance instruction thoroughly before doing any maintenance.*

## Maintenance of Handpiece

*To maximize the efficiency of radial pressure pulse handpiece, regular maintenance is necessary.*

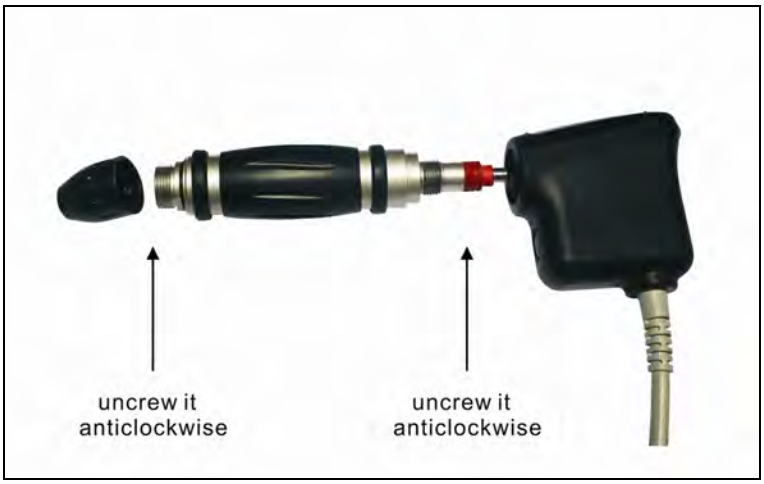
*Maintenance of the handpiece can be done by operator of the device. Follow the instructions strictly. Incorrect operation may cause damage to the patient or machine.*

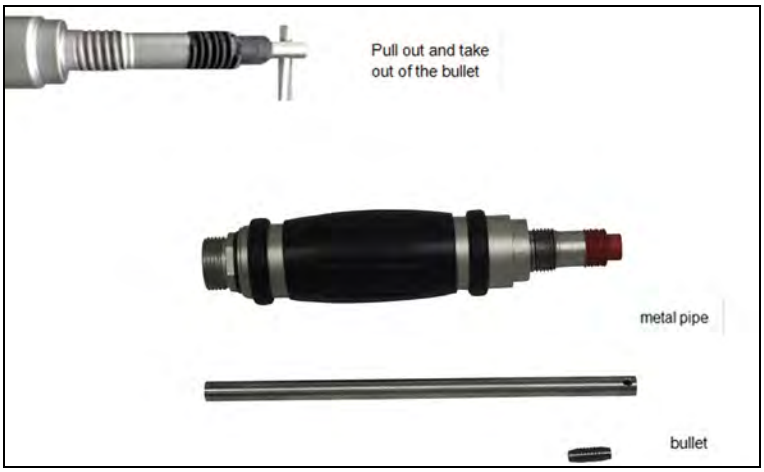
### Type one: Maintenance of the metal pipe and bullet

***Cycle:*** *Recommended cycle is one time every 100,000 to 150,000 shocks. You can look up the amount of history shocks in the system setup interface. After 1 million shocks, reload with a new reversion kit.*

***Notice:*** *After the first time maintenance, the cycle can be adjusted according to practical situation.*

***Step 1: Disassemble metal pipe and bullet.***

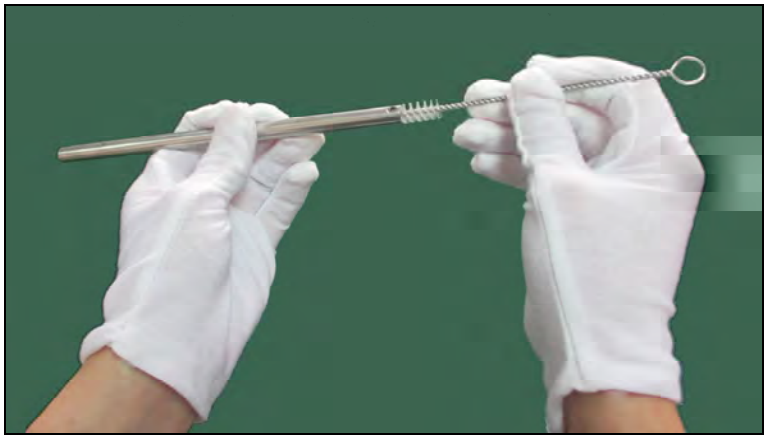





1. *Turn off and unplug the device first, and then unplug the handpiece from the main unit.*
2. *Unscrew the transmitter and the other end of metal pipe from the handpiece body.*
3. *Use a small screwdriver to put through the 2 holes on the metal pipe and then pull the metal pipe out of the shaft gently.*
4. *Take out of the bullet from metal pipe, and then clean the metal pipe and the bullet.*

***Step 2: Clean the metal pipe.***

*Use a cleaning brush to brush the metal pipe back and forth. A better way is to dip the brush into kerosene first, and then do the brush action, which will clean the metal pipe thoroughly.*



***Step 3: Clean the bullet***

*Put the bullet into the kerosene first and then dry it out with a clean, soft cloth.*

***Step 4: Keep the bullet falling down from one end of the metal pipe to the other end of it. Repeat this several times.***

***Step 5: Test the performance.***

*Reload metal pipe and bullet to the handpiece, and test performance. Methods: adjust parameters when the machine is working, and listen to the sound of the handpiece. The sound should be smooth and regular.*

***NOTE:***

*1. When reloading, pay attention to the spacer in the handpiece and make sure it is not dropping or deflection.*

*2. Please adjust the pressure to 1 bar, and frequency to1 Hz, and then start the machine, and then listen to the sound of the handpiece; Secondly, adjust the pressure to 2.5 bar, frequency to10 Hz, and start the machine, and then listen. Try this 2 to 3 times. The sound should be smooth and regular and not any pause.*

***WARNING***

*When you are reloading the metal pipe and bullet, make sure the transmitter is in good condition and without any damage, and make sure the transmitter is well installed in the handpiece. Falling off of the transmitter from handpiece may make harm to the patient during the treatment. Damage of the transmitter may make harm to the patient during the treatment.*

***WARNING***

*Check the shaft (a part of the handpiece, see the structure of handpiece) before starting the treatment. Make sure the shaft is well screwed down in the main part of the handpiece. If not, the handpiece will not work normally and will not generate radial pressure pulses; also this could make damage to the handpiece (mainly bullet and metal pipe).*

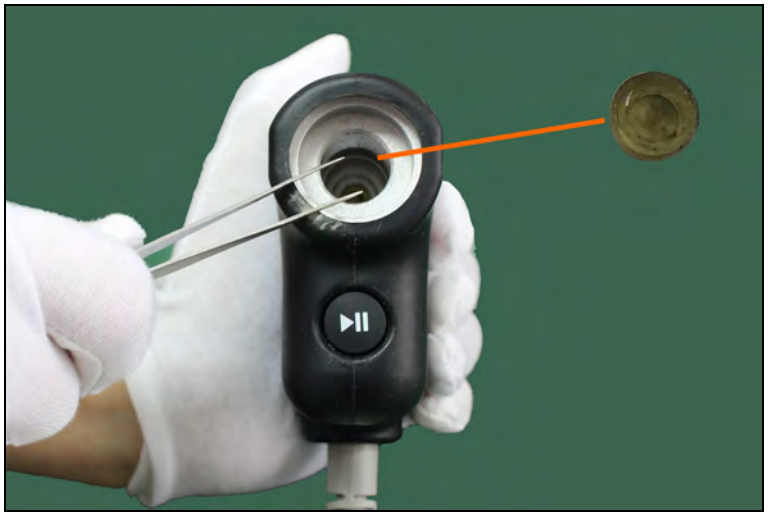
### *Type two: Replacement of the spacer*

***Cycle:*** *There is no regular cycle because the wear and tear of the spacer can be different according to different usage frequency.*

***Method:*** *Observe the spacer when you are doing maintenance to the metal pipe and bullet. If the spacer is worn badly, then you need to replace it with a new one. Usually this will happen between 500,000 to 1 million times of total shocks.*

*Step 1: Turn off and unplug the device first, and then unplug the handpiece from the main unit. Dismantle the tail end of the handpiece anticlockwise.*

*Step 2: Take out of the old spacer with a tweezers.*



*Step 3: Put a new spacer into the handpiece and make some adjustment with a tweezers. Make sure the spacer is*

*settled firmly.*

*Step 4: Reinstall the handpiece and test the performance (start the machine and listening to the sound of the handpiece)*

***WARNING***

*When you are testing the performance, make sure the transmitter is in good condition and without any damage, and make sure the transmitter is well installed in the handpiece. Falling off of the transmitter from handpiece may make harm to the patient during the treatment. Damage of the transmitter may make harm to the patient during the treatment.*

*Make sure all these steps are OK, and then the maintenance procedure is fully finished.*

# *Trouble Shooting*

| *Troubles* | *Possible causes* | *Solutions* |
|---|---|---|
| *1. No response after starting the machine.* | *1. Lack of power;*<br>*2. Fuse might be burned out.* | *1. Check whether the power plug and socket of the instrument are plugged or not;*<br>*2. Replace the burned fuse with a new one (Specifications: F3.15AL250V)* |
| *2. Leaking of air* | *Gas tightness of the solenoid valve and the air pipe is not very well.* | *Check the solenoid valve and air pipe.* |
| *3. Trigger failed* | *1. Trigger button might be damaged;*<br>*2. Incorrect installation on applicators.* | *1.Check if the triggers are right installed;*<br>*2. Replace the old one with a new trigger.* |
| *4. No response after press the trigger* | *1. Connection hoses might be not contact well;*<br>*2. Connection hose might be damaged.* | *1. Check the connection hose and contact distributors;*<br>*2. Replace a new connection hose.* |
| *5. Unusual noise on applicators* | *1. Sound eliminator might be not well installed;*<br>*2. Bullet and pipe might be worn down* | *Re-install the applicator or contact with your local distributor to replace a new applicator kit.* |

# *Assistance and Spare Parts*

*Every intervention on the device must be performed by manufacturer. For any assistance intervention and original spare parts please contact the manufacturer at following address:*

*To preserve product warranty, functionality and product safety we recommend using only original spare parts.*

***MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.***

# *Warranty*

## *ATTENTION*

*Modifications to the instrument or handpiece are not permitted. Any unauthorized opening, repair or modification of the instrument by unauthorized personnel will relieve the manufacturer of its liability and responsibility for safe system operation. This will automatically void the warranty even before the end of the warranty period.*

### *1) Warranty for the main unit*

*• During the two-year warranty period from the date of delivery of the product to the end customer, defects will be remedied at no charge to the customer upon that the defect is due to defects in material or workmanship. The warranty does not extend to wear parts.*

*• To validate the warranty, please complete the Warranty Card.*

### *2) Warranty for the handpiece*

*• Warranty claims will only be accepted if the handpiece is returned in its complete and original state. Cleaned and in the case. Missing components will be replaced subject to charge. Accessories also sent will be checked and, if necessary, replaced after we have assessed them. Shock transmitters and overhaul kits are not covered by the handpiece's warranty.*

*• The warranty period of the handpiece is 12 months (1 year) from the date of delivery of the product to the end customer.*

*• If the main unit and handpiece fail to function during the warranty period due to a defect in material or workmanship, at the Manufacturer's Option, Manufacturer or the authorized dealer will repair this Product without charge. Damages due to non-adherence to the User Manual or wear of parts are excluded from warranty.*

### *3) This Warranty Does Not Cover:*

*• Replacement parts or labor furnished by anyone other than the Manufacturer, the authorized dealer or a certified Company service technician.*

*• Defects or damage caused by labor furnished by someone other than Manufacturer, the authorized dealer or a certified Company service technician.*

*• Any malfunction or failure in the Product caused by product misuse, including, but not limited to, the failure to provide reasonable and necessary maintenance or any use that is inconsistent with the User Manual.*

Mettler Electronics Corp.

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