Med-Fit® Pro Therapeutic

Rechargeable 1MHz Ultrasound

User Manual and Treatment Guidelines

Please read this User Manual before using your Ultrasound

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Supplied with the following Accessories

- 1x Ultrasound Unit - ULS101
- 1x 250ml Ultrasound Gel - ULS600
- 1x Power Adaptor - ULS800
- 1x Carry Case
- 1x User Manual

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INTRODUCTION

Welcome to the Med-Fit® Pro Ultrasound therapy device, designed and manufactured using advanced digital signal processing. The result is a unit with excellent versatility based on simplicity of operation.
This manual has been written for the owners and operators of the Med-Fit® Pro Ultrasound. It contains general instructions for operation, precautionary instructions and maintenance recommendations. In order to obtain maximum life and efficiency from your Med-Fit® Pro Ultrasound and to assist in the proper operation of the unit, read and understand this manual thoroughly and become familiar with the controls on the panel as well as the accessories that come with the unit before operation of the unit.
The specifications put forth in this manual were in effect at the time of publication.

LIABILITY DISCLAIMER

Before administering any treatment to yourself or a patient please read this user manual and operating instructions within the manual. Please read all precautionary instructions listed below.

Precautionary Instructions

CAUTION: Read, understand and practice the precautionary and operating instructions. Know the limitations and hazards associated with using any ultrasound device. Observe the precautionary and operational decals placed on the unit.
CAUTION: The Ultrasound should be routinely checked before each use to determine that all controls function normally, especially that the intensity settings properly adjust.
WARNING: This device should be kept out of the reach of children.
CAUTION: Meets IEC/EN 60601-1-2 Electromagnetic Compatibility/Interference safety standard. (Care must be taken when operating this equipment around other equipment. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with it.)

WARNING:  Type BF Equipment

CAUTION: This unit should be operated, transported and stored in temperatures between 15˚C -40˚C, with relative humidity ranging from 30%-60%

ATTENTION:  Consult accompanying documents.

IMPORTANT SAFETY PRECAUTIONS AND WARNINGS

It is important that you read all the warning and precautions included in this manual because they are intended to keep your safe, prevent injury and avoid a situation that could result in damage to the device.

SAFETY SYMBOLS USED IN THIS MANUAL	
⚠ DANGER	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
⚠ WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in serious injury and equipment damage.
⚠ CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the device or other property.

⚠ DANGER

- This device must not be used in combination with the following medical devices:
- Internally transplanted electronic medical devices, such as a pacemaker.
- Electronic life support equipment, such as respirators.
- Electronic medical devices attached to the body, such as electrocardiographs. Using this device with other electronic medical devices may cause erroneous operation of those devices.

⚠ WARNING

DO NOT USE THE DEVICE IN THESE CONDITIONS

- If you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.
- Together with a life-supporting medical electronic device such as an artificial heart or lung or respirator.

- In the presence of electronic monitoring equipment (e.g., cardiacmonitors, ECG alarms), which may not operate properly when the device is in use.
- Microwave radiation can disrupt the device. The device should not be used in close proximity of equipment emitting microwave radiation.
- Electromagnetic energy can disrupt the device. The device should not be used in close proximity of equipment emitting electromagnetic energy.
- Equipment emitting RF can disrupt the device. The device should not be used in close proximity of equipment emitting RF waves e.g. mobile phones etc.
- The device should not be used in presence of high frequency devices (shortwave or therapy) systems.
- On open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins);or ontop of,or in proximity to, cancerous lesions.

DO NOT USE ON THESE INDIVIDUALS

- The device is for single paitient use only
- During pregnancy or menses.
- Have allergic dermatitis or hemorrhage.
- Have telangiectasia or disordered liver function caused by long tern uptake of steroid and hormone.
- Over areas of skin that lack normal sensation.
- Children or infants, because the device has not been evaluated for pediatric use.
- Persons incapable of expressing their thoughts or intentions.
- Do not use over eyes, head reproductive organs, head or open wounds.

DO NOT USE ON THESE AREAS

- Do not apply the device over painful areas. If you have painful areas, you should consult with your physician before using this device;
- Do not apply the device over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins);
- Do not apply the device over, or in proximity to, cancerous lesions;

DO NOT USE THIS DEVICE DURING THESE ACTIVITIES

- When in the bath or shower;
- While sleeping;
- While driving, operating machinery, or during any activity in which the device can put you at risk for injury.
- Keep the device out of the reach of young children.
- If you are in the care of a physician, consult with your physician before using this device.

⚠ CAUTION

- If the device is not functioning properly or you feel discomfort, immediately stop using the device.
- Do not use for any other purpose except for what it is intended for.
- Do not use the device while wearing electronic devices such as watches as this may damage the device.
- Dispose of the device, and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.
- You may experience skin irritation or hypersensitivity due to the conductive medium (gel).
- If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician; and
- If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
- You should stop using the device and consult with your physician if you experience adverse reactions from the device.
- Dispose of the device, batteries, and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.
- Use caution if you have a tendency to bleed internally, such as following an injury or fracture;
- Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process;

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DISPOSAL

Used fully discharged batteries must be disposed of in a specially labeled collection container, at toxic waste collection points or through an electrical retailer. You are under legal obligation to dispose of batteries correctly.

Please dispose of the device inaccordance with the legal obligation.

GLOSSARY OF SYMBOLS

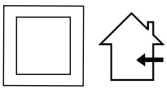
Electrical devices are recycle label material and should not be disposed of with house hold waste after their useful life! Help us to protect the environment and save resources and take this device to the appropriate collection points. Please contact the organization which is responsible for waste disposal in your area if you have any questions.

Type BF equipment

Refer to instruction manual

Do not use with a pace maker

CE certified device



The a AC DC adaptor is for indoor use only and should only be used with this device.

INGRESS PROTECTION (IP) RATING

Note: IP rating mentioned on the datasheet is confirmed by our company in accordance with the following test method defined in the standard. Please check the Sealability in advance under the actual environment and application condition.

IEC (International Electrotechnical Commission) Standard (IEC60529: 2001)

IP-□□

Protection specification code (International Protection)

"First Digit" Protection against solid object

Code	Level of protection	
0		No protection
1		Ingress of solid object diameter 50 mm is protected
2		Ingress of solid object diameter 12.5 mm is protected
3		Ingress of solid object diameter 2.5 mm is totally protected
4		Ingress of solid object diameter 1.0 mm is totally protected
5		Protected against harmful dust
6		Totally protected against dust

Internal standard of oil endurance

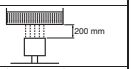
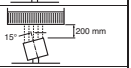
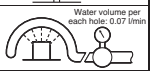
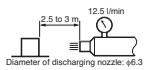
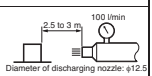
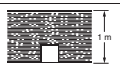
Level of protection	
Prevention	Protected against oil dripping and splashing from all direction
Endurance	Internal part is protected against oil dripping and splashing from all direction

Note: We use standardized oil for the above test. (Equivalent to former JEM standard [Standards of the Japan Electrical Manufacturers' Association])

*1. Our company Test Method
IP67 for proximity sensor:
In addition to the following test, heat shock cycle test (0°C cold water for 1 hour, 70°C hot water for 1 hour) is conducted repeatedly for 5 times, confirming no CR and detection distance problem

*2. Note for our test outline
Proximity sensor E2F term of use: inside water in 10 m depth, in natural condition.
1) sink into 2 atm of water for 1 hour, no water ingress
2) repeat the heatshock cycle for 20 times, confirming no CR and detection distance problem

"Second Digit" Protection against liquid object

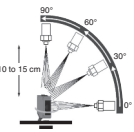
Code	Level of protection		Test method outline (test performed using pure water)
0	No protection	no protection against liquid object	No test
1	Protection against water drop 	No harmful effect of vertical water drip	By using water drip tool vertically dropping water for 10 min 
2	Protection against water drop 	No harmful effect of water drip from vertical direction when the enclosure is tilted at 15° from its normal position	By using water drip tool, move it in angle of 15°, dripping water for 10 min (2.5 min per direction) 
3	Protection against water spray 	No harmful effect of water spray at any angle up to 60° from the vertical direction	By using tool as descripted in right picture, spraying water vertically in angle up to 60° for 10 min 
4	Protection from water splash 	No harmful effect of water spray from all direction	By using tool as descripted in right picture, splashing water from all direction for 10 min 
5	Protection from water jets 	No harmful effect of water splash from all direction	By using tool as descripted in right picture, Jet the water from all direction to the object surface for 1 m^2/min, at least for 3 min in total. 
6	Protection from strong water jets 	No harmful effect of strong water jets from all direction	By using tool as described in right picture, Jet the water from all direction to the object surface for 1 m^2/min, at least for 3 min in total. 
7	Protection from water dip  *1	No harmful effect of water dip in certain level of pressure and length of time	Dip into 1 m depth water for 30 min 
8	Protection from water sink  *2	No harmful effect against water sink which the condition is decided between customer & manufacturer (in severer condition comparing to no.7)	Should be decided between customer and manufacturer

Specification of IP69K

IP69K is a protection provision of high temperatured and pressured water which prescribed by Germany standard DIN 40050 PART9.

The test specifies a spray nozzle that is fed with 80°C water at 80 to 100 bar and a flow rate of 14 to 16 L/min. The nozzle is held 10 to 15 cm from the tested device at angles of 0°, 40°, 60° and 90° for 30 s each. The test device sits on a turntable that rotates.

Note: Connected part doesn't satisfy the Degree of protection mentioned in the Ratings/Characteristics in case that the wiring is not normally done, connector does not have the protection performance or e-CON connector is used.



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TROUBLESHOOTING

NOTE: If the following measures fail to alleviate the problem, please call your authorized agency or supplier.

Problem	Possible causes	Possible solution	Display
Charging fail	Poor contact between the socket and the plug	Reinsert the plug into the socket, make sure good contact between them.	Battery indicator Not flashing whilst on Charge
	Circuit fault	Contact authorised agency or supplier	LCD display shows blank screen
No output or output instability	Battery exhausted Circuit fault	Recharge the battery. Contact authorised agency or supplier	Blank display Start/Pause button no operation
Liquid get into the detector	Poor sealed	Contact service agent for repair	NA
The device gets hot during charging	Circuit fault	Contact service agent for repair	NA

CLEANING AND STORAGE

These generalised cleaning instructions are indicated for use with Med-Fit Pro Ultrasound. Cleaning is defined as the removal of all visible soil or contaminants from the transducer. All transducers must be cleaned after every use.

1) Turn unit off.
2) Use a moistened soft cloth or wipe to remove any remaining contaminates that remain on the transducer or cable, do not re-use cloths or wipes. Soap detergents or enzymatic cleaners should be used in accordance with the manufactures instruction. NOTE: The sound head must be cleaned between each therapy session.
3) To clean the accessories, use only soap and water. Alcohol may be used to disinfect the aluminum surface, but avoid the plastic area. The Med-Fit Pro Ultrasound case may be cleaned by wiping with a damp cloth or mild cleaning solution. Avoid abrasive cleansers. Note: This device and accessories does not require sterilization.

Storing the unit - Place the unit, adapter and manual back in the case. Store the case in a cool, dry place, 20~55; 10% ~90% relative humidity.

SPECIFICATIONS

General Information

Power supply:	DC 3.7V
Adaptor:	Input: 100 to 240 Volts AC,50/60Hz Output:DC5V,1A
Safety class:	Class, type BF applied part (according to IEC60601-1)
Weight of unit body:	220g
Dimensions:	170mm*46 mm* 50mm(W*H*D)

The Essential Performance of the device is free from the production of unwanted or excessive ultrasound energy output.

Environment conditions for transport and storage

Environment temperature:	-20° till +55° C
Relative humidity:	10 till 90 % (not condensing)
Atmospheric pressure:	700 till 1060 hPa

Environments conditions for normal use

Environment temperature:	5° till 40° C
Relative humidity:	10 till 90 %

Technical data of Ultrasonic

Acoustic Frequency:	1MHz ± 10%
Output Intensity:	0.75W/ cm^2(Max.)
Ptm:	1.5W
Pulse repetition rate:	145Hz 170Hz 200Hz
Duty factor:	18% 21% 25%
Effective radiating area (AER):	4cm^2± 10%
BNR (Max.):	8.0
Beam type:	Convergent
Waveform:	pulsed
Treatment time:	10min
Material of treatment head:	Stainless steel

Shenzhen Goodwind Technology Development CO., LTD. Declares that the device complies with following normative documents:

IEC60601-1, IEC60601-1-2, I EC60601-2-5, IEC61689, IEC62366, IEC60601-1-11, ISO10993-5, ISO10993-10, ISO10993-1,ISO15223

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INDICATIONS

Ultrasound for use in applying deep heat can be used for treatment of selected medical conditions such as minor aches and pains, it can help the reduction of pain and improvement of blood flow in the indications listed below. Those conditions may be associated with adhesive capsulitis, bursitis with slight calcification, myositis and soft tissue injuries.

Indications for use

1. Soft tissue injuries
2. Chronic connective tissue and joint dysfunction
3. Osteoarthritis
4. Periarthritis
5. Bursitis
6. Tenosynovitis
7. Tendonitis, bursitis, capsulitis
8. Chronic sprains / strains
9. Muscle spasm

Warnings

Always keep the applicator sound head in constant motion.

Always keep the sound head in full contact with the patient's skin when setting intensity.

Use ample conductive gel to ensure good coupling throughout the treatment. If needed, apply when setting intensity. The gel supplied with the unit is ISO10993 certified.

Be sure to read all instructions before treating yourself or patient.

Do not drop the sound head on hard surfaces.

CONTRAINDICATIONS

Ultrasound should not be used over:
An area of the body where a malignancy is known to be present.

- The eyes
- The reproductive organs
- An acute infection or sepsis
- A pregnant uterus
- A deep vein thrombosis
- An arterial disease
- An anesthetized area or condition that causes impairment of sensation, such as chemotherapy.
- Not to be used on any person under the age of 16 without medical supervisions.
- The chest area if the patient is using a cardiac pacemaker.

A healing fracture

Ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase, in metabolic demand and tissue necrosis might result.

Patients with an implanted neurostimulation device must not be treated with or be in close proximity to the ultrasound device..

Precautions

Precautions should be taken when used:

- For acute conditions of inflammation and tendinitis that can be exacerbated by the use of ultrasound.
- Over an area of the spinal cord following a laminectomy.
- On patients with a tendency toward haemorrhaging.

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PREVENTING ADVERSE EFFECTS

Applicator Movement

If movement of the ultrasound applicator is too slow, the patient may feel perosteal pain characterized by a deep ache or pain. If motion is too fast, or if the applicator head does not maintain good contact with the skin, the therapeutic effect of the sound waves will be reduced and the sound head may overheat.

Patient Susceptibility

Some patients are more sensitive to ultrasound output and may experience a reaction similar to a heat rash. Be sure to inspect the treatment area during and following treatment, and discontinue if an adverse reaction does occur.

Output Power

Choose a lower watt setting to reduce output or select a pulsed duty cycle. Higher output levels have a greater potential for patient discomfort.

Coupling

Coupling is described as contact between the sound head and the treatment site and may be accomplished through the use of a coupling agent, such as gel, lotion or Polar Frost gel. Anything used as a coupling agent must be highly conductive. Air is a very poor conductor of ultrasonic waves.

Safety Considerations for the Ultrasound Head

The crystal within the ultrasound head will only perform predictably and safely if it is not mishandled by the operator. If the soundhead is dropped, the manufacturer should be called to determine if the crystal has been damaged (possibly changing its output).

It is also essential that the ultrasound intensity NEVER be turned up before the soundhead is against a medium that will conduct the soundwaves. When the intensity is turned up without a transmission couplant, the soundwaves bounce back into the crystal, heating the head and risking the integrity of the crystal.

TECHNIQUES OF APPLICATION

Treatment area

The skin should be clean and dry before applying the coupling gel. The treatment area should be no more than twice the size of ultrasound transducer head.

Transmission media (couplant)

The higher the water conductive medium, the less the ultrasound energy is absorbed by the medium and the more energy is available to produce thermal effect. Less efficient mediums heat up, resulting in surface warmth to patient. In order of efficiency:

1. Water
2. Aqueous gel (conducts 96% of sound)
3. "Hydro" gel, (brand x), 68% of sound conducted
4. Mineral oil
5. Coupling lotion

Treatment time

Treatment time is generally between 5 and 10 minutes.
Never treat over 15 minutes regardless of treatment area.

Frequency of treatment

Acute conditions may be treated using low intensity ultrasound once or even twice daily for 6 to 8 days until acute symptoms such as pain and swelling subside. In chronic conditions, treatment may be done on alternating days. Ultrasound treatment should continue as long as there is improvement. If no improvement is noted following three or four treatments, ultrasound should be discontinued, or different parameters (i.e., duty cycle, frequency) employed. Typically recommended treatment times are between 5 and 10 minutes.

Ultrasound treatments are similar to exercise session in that each session builds on the previous one. For most conditions and whenever possible, daily ultrasound treatments will provide the most benefits to the patient.

Ultrasound Sensation and Tolerance

It is important to remember that everyone's tolerance to ultrasound is different, and therefore the intensity should always be adjusted to the correct level. **You should not feel warmth during the treatment as ultrasound is absorbed deep inside the tissues and surrounding underlying structures.** If the transducer feels hot at the skin surface, it is likely that the coupling medium is inadequate. If you feel a deep aching sensation during the treatment, stop immediately. Periosteal burns may feel like a deep ache while the ultrasound is still on, and only later in the day will feel intensely painful.

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TECHNIQUES OF APPLICATION

The Med-Fit Pro Home Ultrasound now features the auto-pulsed mode

Low setting ▮ one bar setting, automatically sets a pulsed mode. This is ideal for acute conditions where low intensity is required.

Medium settings ▮▮ two bar setting, automatically sets the pulse mode, this is a longer pulsed mode, ideal for more sub-acute conditions.

High settings ▮▮▮ three bar setting, automatically sets a pulsed mode. Ideal for chronic conditions or treating larger muscle groups for example quadriceps hamstrings and deep-seated muscles with long standing injuries.

Methods of Soundwave Transmission

Direct Contact- When using the direct technique, the ultrasound head is put against the skin with only a thin layer of couplant (gel or lotion) in between. Considerations when using this technique are the amount of soft tissue over the bone in that area.
Treatment time: 5 – 10 minutes Penetration: 4 – 6 cm

1. Apply a generous amount of coupling medium to clean dry skin
2. Move transducer in either a circular or stroking pattern
3. Turn intensity up to treatment level
4. Each circle / stroke should overlap the previous by ½
5. Treatment area limited to 2 times size of transducer
6. Slow and deliberate (moving the soundhead approximately 4 cm per second)
7. Transducer must stay in contact and in motion to avoid overheating of the transducer

FUNCTIONS AND CONTROLS

ULTRASOUND TREATMENT SETTINGS

Pulsed PPR 145Hz	Acute Level 1
Pulsed PPR 170Hz	Sub Acute Level 2
Pulsed PPR 200Hz	Chronic Level 3

Intensity Settings	Acute Level 1
	Sub Acute Level 2
	Chronic Level 3

DISPLAY FUNCTIONS AND FEATURES

A. The ultrasound frequency is displayed once the intensity level is set

B. Intensity level has three settings

Level 1 ▮ (One Bar)

Level 2 ▮▮ (Two Bars)

Level 3 ▮▮▮ (Three Bars)

C. Battery Indicator

One Bar 25% charge

Two Bars 50% charge

Three Bars 100% charge

D. Ultrasound output indicator SONIC

The ultrasound output indicator will flash on and off, when the ultrasound start button is pressed and ultrasound is being transmitted

DISPLAY FUNCTIONS AND FEATURES

E. Countdown timer

The first you switch on the ultrasound the timer display is set at 00:00 pressing the intensity level button automatically sets the timer at 10:00 minutes this is not adjustable and will countdown once the start button is pressed.

You may pause the treatment at any time by pressing the start/pause button. To re-start the treatment simply press the button again.

CHARGING YOUR ULTRASOUND

Your ultrasound is supplied with

1 x charging Adaptor

Plug directly into the probe and connect to any mains outlet

STEP BY STEP GUIDE

STEP 1 Before using the ultrasound device please fully charge the ultrasound as described on pages 19 and 22.

STEP 2 We always recommend that a small amount of ultrasound coupling gel is now placed onto the transducer head before switching on the device. (smear over the complete surface of the transducer head).

STEP 3 Press the On/Off button once (Fig 1)

Fig1

Press level button, to the required intensity settings (Fig 2)

Fig2

For the correct intensity level please refer to page 15-16 (Techniques of application)

STEP 4 Press the start button the word sonic will start to flash and the counter will start to count down. A green light on the back indicates the unit is transmitting correctly (Fig 3)

Fig3

STEP 5 Once you have the desired ultrasound settings, place more ultrasound gel on the transducer head and further gel on to the area of the body to be treated. (Please follow the guidelines laid out in this manual, techniques of application see page 15).

STEP 6 At the end of each treatment session wipe the transducer head clean with a damp soft cloth or tissue.

STEP BY STEP GUIDE

STEP 7

It is recommended that you test the output of your Ultrasound on a regular basis (once a month) to do this place a small amount of water on the transducer head. Turn the intensity level to high and you will notice that the water will vibrate and may also create a break up of the water particles, to crate a cold steam effect. This is created by the 1Mhz transducer vibrating at 1 million cycles per second.

Do not operate the device in this condition for more than 10 seconds as it may result in damage to the device. Please see Fig C.

Fig C

CHARGING INDICATOR GUIDELINES

How do I know my ultrasound is charging ?

The charging of the ultrasound is indicated by the battery symbol which is located in the top right hand corner of the display.

Fig A

The bars in the battery symbol will flash on and off in the charging mode. Once fully charged the battery symbol will stay illuminated with 3 bars see Fig A

The battery takes approximately 2 hours to charge.

Please note

The display switches off after approximately 10 seconds whist in charging mode, pressing the on /off button once illuminates the display for a further 10 seconds.

WARRANTY

Please contact your dealer or the device center in case of a claim under the warranty. If you have to send in the unit, enclose a copy of your receipt and state what the defect is. The following warranty terms apply:

1) The warranty period for device is one year from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
2) Repairs under warranty do not extend the warranty period either for the device or for the replacement parts.
3) The following is excluded under the warranty:

- All damage which has arisen due to improper treatment, e.g. nonobservance of the user instruction.
- All damage which is due to repairs or tampering by the customer or unauthorized third parties.
- Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service center.
- which are subject to normal wear and tear.

4) Liability for direct or indirect consequential losses caused by the unitis excluded even if the damage to the unit is accepted as a warranty claim.

Service and Calibration

Service to these units should be performed only by a Qualified Service Technician Ultrasound requires annual calibration

The Med-Fit Pro Ultrasound Service Manual is available for purchase and can be requested from your dealer. The Service Manual contains safety precautions, nomenclature, specifications, troubleshooting, removal and replacement instructions, general maintenance, calibration instructions, parts lists, schematics, warranty and other information which would assist a certified service technician to repair the unit.

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IMPORTANT INFORMATION REGARDING ELECTRO MAGNETIC COMPATIBILITY (EMC)

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.

1)* 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.

2) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!

3) * Caution: 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。

4) Warning:

The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the DEVICE as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

Guidance and manufacture's declaration – electromagnetic emission		
The DEVICE is intended for use in the electromagnetic environment specified below. The customer of the user of the DEVICE should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The DEVICE 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 CISPR 11	Class B	The DEVICE is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity			
The DEVICE is intended for use in the electromagnetic environment specified below. The customer or the user of DEVICE 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 ±8 kV air	±6 kV contact ±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	±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)	±1 kV differential 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 40% UT (60% dip in UT) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles for 5 sec <5% U_T (>95% dip in U_T) for 0.5 cycle for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles for 5 sec <5% U_T (>95% dip in U_T) for 0.5 cycle for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DEVICE requires continued operation during power mains interruptions, it is recommended that theDEVICE be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital IEC 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 DEVICE is intended for use in the electromagnetic environment specified below. The customer or the user of DEVICE should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the DEVICE, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.167\sqrt{P}$ $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,ashould be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:

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

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

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the DEVICE is used exceeds the applicable RF compliance level above, the DEVICE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the DEVICE.

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

Recommended separation distances between portable and mobile RF communications equipment and the DEVICE .

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

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 KHz to 80 MHz $d = 2.333\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.167\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 1.167\sqrt{P}$
0.01	**0.117**	**0.117**	**0.233**
0.1	**0.369**	**0.369**	**0.738**
1	**1.167**	**1.167**	**2.333**
10	**3.689**	**3.689**	**7.379**
100	**11.667**	**11.667**	**23.333**

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

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

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

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