SoundCare™ Plus INSTRUCTION MANUAL





This manual is valid for the SOUNDCARE™ Plus

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United States Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner

Conformity to safety standards

Compass Health Brands declares that the device complies with following normative documents: IEC60601-1, IEC60601-1-2, IEC60601-2-5, ISO10993-10, ISO10993-1

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1. GENERAL INFORMATION

1.1 General Description

This manual has been written for the SoundCare™ Plus. It contains general information on the operation, precautionary practices, and maintenance information. In order to maximize use, efficiency, and the life of the system, please read this manual thoroughly and become familiar with the controls, as well as the accessories before operating the system.

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The ultrasound therapy SoundCare™ Plus is an apparatus featuring an ultrasound therapy unit. Pain affects the quality and enjoyment of life, especially for those who suffer chronic pain. SoundCare™ Plus is ultrasound therapy device for the treatment of chronic and acute muscular pain.

1.2 Indication For Use

- Application of therapeutic deep heat can be used for the treatment of selected sub-chronic medical conditions such as: Relief of pain, muscle spasms and joint contractures that may be associated with:
- Adhesive capsulitis
- Bursitis with slight calcification
 - Myositis
- Soft tissue injuries
- Shortened tendons due to past injuries and scar tissue
- Relief of sub-chronic and chronic pain and joint contractures resulting from:
- · Capsular tightness
- Capsular scarring
- 3. This device should be operated only by the experienced physician.

2. SAFETY INFORMATION

Read instruction manual before operating. Be sure to comply with all "Contraindications", Warnings", "Cautions" and "Adverse reactions" in the manual. Failure to follow instructions may cause harm to user or device.

2.1 Contraindications

- This device should not be used for symptomatic local pain relief unless etiology is established or unless a pain syndrome has been diagnosed.
- 2. This device should not be used when cancerous lesions are present in the treatment area.
- This device should not be used when open wounds are present in the treatment area.
- This device should not be used on patients suspected of carrying serious infectious disease and or disease where it is advisable, for general medical purposes, to suppress heat or fevers.
- 5. This device should not be used over or near bone growth centers until bone growth is complete.
- 6. This device should not be used over the thoracic area if the patient is using a cardiac pacemaker.
- 7. This device should not be used over a healing fracture.
- 8. This device should not be used over or applied to the eye.
- 9. This device should not be used over a pregnant uterus.
- 10. This device should not be used on 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
- 11. This device should not be used over tumors.

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 are 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.

2.2 Warnings, Cautions and Adverse Reactions

A WARNINGS:

- Care must be taken when operating SoundCare™ Plus the
 equipment around other equipment. Potential electromagnetic
 or other interference could occur to this device or to the other
 equipment. Try to minimize this interference by not using other
 equipment in conjunction with the SoundCare™ Plus.
- 2. The device may not be used in close proximity (i.e. less than 2 meters) to short-wave equipment.
- 3. The device may not be used in so called "wet rooms" (hydrotherapy rooms)
- 4. The user must keep the device out of the reach of children.
- 5. Only use the device for the recommended applications. The device should be used under medical supervision.
- Use of controls or adjustment to, or performance of the SoundCare™ Plus under procedures other than those specified in the instruction manual may result in hazardous exposure to ultrasonic energy.
- 7. Before administering any treatment to a patient you should become acquainted with the operating procedures for each mode of treatment available, as well as the indications, contraindications, warnings, and precautions. Consult other resources for additional information regarding the application of the Ultrasound.

- 8. DO NOT use solvents to clean the device.
- 9. A damaged device must no longer be used.
- The device must only be serviced, repaired and opened by authorized sales center.
- Dispose of the device in accordance with local regulations. Keep the operating instructions with the device.
- 12. Pregnant and nursing women should use the device cautiously.
- 13. Use the device cautiously when using it on immature bones.
- 14. For continuous and effective treatment, the device should not be used more then 30 minutes per day.
- 15. **DO NOT** use cellphone while the device is in operation.
- 16. Use coupling gel for therapeutic ultrasound during treatment.
- 17. Always keep the sound head in constant motion.
- 18. The device complies completely with all parts of 21 CFR 1050. 10 of the performance standard for sonic, infrasonic and ultrasonic radiation-emitting product.
- Cautions- use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.

A CAUTIONS:

- 1. Keep yourself informed of the contraindications.
- 2 Read, understand, and practice the warnings, cautions and operating instructions. Know the limitations and hazards associated with using any device. Observe the precautionary and operational decals placed on the unit.
- DO NOT operate this unit in an environment where other devices used intentionally radiate electromagnetic energy in an unshielded manner
- DO NOT use sharp objects such as a pencil point or ballpoint pen to operate the buttons on the control panel.
- 5. Inspect applicator cables and associated connectors before each use.
- 6. This device should not be used adjacent to or stacked with other equipment. If adjacent to or stacked equipment use is necessary, this device should be observed to verify that it is operating within the normal configuration in which it is to be used.
- Portable and mobile RF communications equipment can affect this
 device. **DO NOT** use a mobile phone or other device that emits
 electromagnetic fields, near the unit. This may result in incorrect
 operation of the device.

- 8. This device has been thoroughly tested and inspected to assure proper performance and operation!
- 9. Patients with an implanted neurostimulation device must not be treated with or be in close proximity to any shortwave diathermy, microwave diathermy, therapeutic ultrasound diathermy, or laser diathermy anywhere on their body. Energy from diathermy (shortwave, microwave, ultrasound, and laser) can be transferred through the implanted neurostimulation system, can cause tissue damage, and can result in severe injury or death. Injury, damage, or death can occur during diathermy therapy even if the implanted neurostimulation system is turned "off."

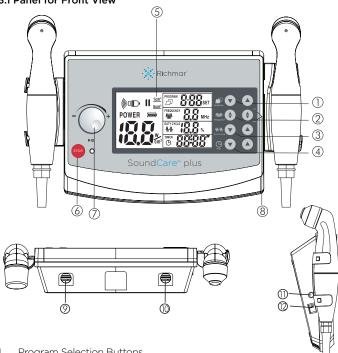
ADVERSE REACTIONS:

- Skin irritation, inflammation, and burns in or around the treatment area are potential adverse reactions. Please consult a physician if any of these occur.
- The clinician should stop using this device and should consult with the patient's attending physician should the patient experience any adverse reactions from treatment used with this device.

Note: Always use devices that are legally marketed and sold in the United States under 510K guidelines.

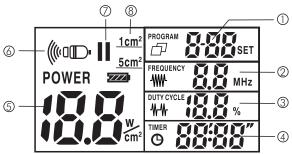
3. PRESENTATION

3.1 Panel for Front View



- Program Selection Buttons 1.
- 2. Frequency Adjustment Button (1MHz and 3MHz)
- 3. Duty cycle adjustment Button
- Treatment Time Adjustment Button 4.
- 5. Liquid Crystal Display
- Stop Button 6.
- 7. Central Controller Dial
- 8. Treatment Head Select Button
- Socket for 5cm² Sound Head 9.
- 10. Socket for 1cm² Sound Head
- 11. Adapter Receptacle
- 12. Power Switch

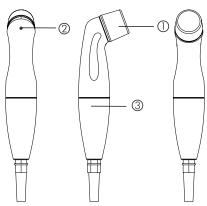
3.2 Liquid Crystal Display



- 1. Program indicator
- 2. Frequency indicator
- 3. Duty cycle indicator
- 4. Timer indicator

- 5. Output intensity/power
- 6. Ultrasound output indicator
 - 7. Pause indicator
- 8. Working Sound Head Size

3.3 Treatment head



- 1. Sound head aperture: Makes contact with patient during treatment.
- Sound head LED Indicator: Indicates if sound head is in working (steady green light) or non working state.
- Sound head handle: Connects to the device and where the clinician holds to administer treatment.

3.4 Symbol Definitions

Below are the definitions for all of the symbols used in the Ultrasound therapy device. Study and learn these symbols before any operation of the system.

01 0	On/Off Switch	P	The Connection Socket of	
0	Stop Treatment		Treatment Treat	
►/II	Start/Pause Button	Ш	Pause	
((()	Ultrasound Intensity	w	Ultrasound Output Power	
□ □ □•	Ultrasound Applicator State	W cm²	Ultrasound Output Intensity	
⊝-⊚-⊕	Polarity of Power Supply	0	Treatment Time	

3.5 Key Function

ON / OFF Switch	· •	With this button the SoundCare™ Plus is turned on or off.
Central		Press to Start/Pause treatment
Controller Dial	- + -/II	Rotate this dial to increase or decrease the output intensity to start/during treatment
STOP button	STOP	Stop treatment
UP and DOWN Arrows	•	Used t increase or decrease parameters on the screen for desired treatment

4. INSTALLATION

4.1 Reception of Equipment and Accessories

Remove the Therapy System and all accessories from shipping cartons. Visually inspect for damage. Report any damages to the company who supplied you the device. Your ultrasound therapy is supplied with case containing:

No.	Part #	Part	Quantity
1	DQ9275	Ultrasound therapy unit	1
2	DQ9275W5	5cm² Ultrasound head	1
3	DQ9275W1	1cm² Ultrasound head	1
4	DQ9276MGC	Medical Grade Adapter	1
5		SoundCare Plus Manual	1

4.2 Connection

Power supply connections must comply with national requirements for medical clinics. This equipment has a safety ground connection and must be connected to another grounded wall socket.

Prior to connecting this device to the wall socket, check that the voltage and frequency stated on the bottom of the device and in this manual correspond with the wall socket.

The device adapter and wall socket are a complete socket on which the device's safety depends on.

A CAUTION:

For safety reasons, if there is a need to replace the adapter, it is recommended to use only the manufacturer supplied adapter or one that meets the requirements listed on the bottom of the device and the requirement standard medical electrical equipment.

! CAUTION:

Only use the sound heads supplied with the device. If a replacement sound is needed, please contact your supplier to get a replacement from the manufacturer. **DO NOT** use any other sound heads with this device.

4.3 Switching On

Turn on the device using the power switch. The device executes a self-test, checking all important functions and enters standby mode about 2-4 seconds later. When an error is found an error code will appear on the display.

4.4 Connecting the Sound Head

Plug the sound head's connection plug corresponding to the correct socket in the back of the device. If connected correctly, LCD will display as should in Figure 1. If there is a connection error, LCD will display as shown in figure 2

Figure 1

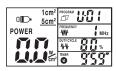
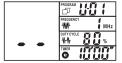


Figure 2



5. OPERATION INSTRUCTIONS

5.1 Therapy System Set Up

The SoundCare™ Plus has 10 default programs available. The programs are fully adjustable to the capabilities of the device for the parameters below:

- Ultrasonic frequency
- The treatment duty cycle
- Treatment time

If changes are made to a program, they will be saved automatically and the device will display the last treatment under that program once the device is turned off and back on again.

Choice / Select Therapy Program

Program Up/Down Selection: Press ♦ button to choose between U01-U10



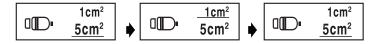
Select the Ultrasound Frequency: 1MHz or 3MHz

Freq Up/Down Selection: Press ♦ button next to FREQUENCY to choose the desired frequency for treatment.



Select Sound Head

Sound head size: Press ♦ next to 1cm² and 5cm² button to choose which sound head will be used for the selected parameters. The selected sound head will display on the LCD as shown below.



A CAUTION:

When only one sound head is connected, the device will automatically detect which one is connect and the sound head that is not plugged in will show as not selectable on the treatment screen.

Select Duty Cycle

Duty Cycle Selection: Press ∇ or \triangle button next to DUTY CYCLE to increase or decrease the duty cycle for desired treatment. 100% duty cycle is continuous. 99% or less is pulsed.



Select Treatment Time

Treatment Time Selection: Press ▼ or ▲ button next to TIME to decrease or increase treatment time for desired treatment time.



5.2 Start Treatment

Place a generous amount of ultrasound gel on the treatment area. Place the ultrasound head on treatment area and move in slow circular motions while rotating the central controller dial to clockwise to slowly increase the intensity to a comfortable level to the patient.

5.3 Ultrasound Intensity

The ultrasound intensity is adjusted with intensity control knob. The ultrasound intensity can only be adjusted during treatment. The ultrasound intensity can be displayed in W or W/cm.

5.4 Check Patient Before Treatment

- Put the patient in a comfortable position. The area to be treated should be properly supported and exposed and perfectly relaxed
- Ensure there are no contraindications to treatment.
- Inspect the skin treatment area for any abrasions, inflammation, surface veins etc.
- Clean the skin treatment area with soap or alcohol (70%).
- Shaving or clipping excessive hair on the skin treatment area can provide optimal treatment.
- · Test the heat sensitivity of the treatment area.

5.5 During the Treatment

- The sound head must be moved in slow circular motions, constantly during treatment.
- Ask the patient regularly about his/her experiences. If necessary, the treatment can be adjusted. By using the central controller dial, the output can be reduced or increased to a comfortable level
- In case of indications of poor transmission of ultrasound energy, it
 is advised to add the contact-gel or reposition the ultrasound-head.
- If the LED light blinks green or is not producing output, reposition
 the sound head and continue to move in a slow circular motion
 and/or more ultrasound gel may be needed.
- If the LED light is solid green, there is good contact and the ultrasonic energy is being emitted.
- If the treatment is paused or the sound head is not connected properly, there will be no green LED light on the top of the sound head.

A CAUTION:

The movement performed with the sound head should be applied with regular movement, not too slow to avoid inducing heat, nor too fast to prevent a bad contact which would reduce the effectiveness of the treatment.

A WARNING:

If replacing the sound head is necessary, the device must be switch off before disconnecting and replacing the sound head.

5.6 After the Treatment

- Clean the treatment area well before treatment as well as the treatment head by using a towel or a tissue.
- The treatment head should be cleaned with a 70% alcohol solution.
- Check if there are any signs of improvement (e.g. pain, circulation and mobility).
- When entering the next treatment session, the patient is instructed to report any possible reaction.

5.7 Pause

Press the central controller dial to pause the treatment. Press the dial again to continue the treatment.

5.8 Emergency stop

Press to stop treatment immediately.

5.9 The Treatment head

A treatment head is a precision instrument. Great care is taken in the development and production in order to obtain the best possible beam characteristics. Rough treatment (jarring or dropping) can adversely affect these characteristics, and must therefore be avoided

5.10 The Contact Medium

In order to ensure efficient transfer of energy, a contact medium is required between the sound head and the body. Air causes virtually total reflection of the ultrasound energy. The best medium for the transfer of ultrasound energy is ultrasound/conductive gel.

- Liberally apply ultrasound/conductive gel to the treatment area on the patient.
- Move the treatment head during therapy session in a circular motion. The area treated should be two times the diameter of the treatment head.z
- If the body surface is very irregular, making it difficult to obtain good contact between the treatment head and the body, or if direct contact must be avoided (e.g. due to pain), the affected area may be treated under water (subaqual method). The water should be degassed (by previous boiling) in order to prevent air bubbles arising on the treatment head and body.
- Sound head should not be submerged in water further than the aluminum portion of the sound head. If submerged further, the sound head is not sealed past this point and will damage the sound head and render it defective for use. DO NOT let liquid enter into unsealed areas of the sound head.

A CAUTION:

NEVER apply the gel to the treatment head. The treatment head will register this as contact and may emit ultrasound energy, which could damage the treatment head. Always use gel with the requirements for medical use, such as with CE mark, or are legally marketed in the US.

5.11 Disconnecting from the Wall Socket Power Supply

Switch the button on the side of the device to the OFF position first. There should not be anything displayed on the LCD screen to indicate it was turned off. Disconnect the adapter from the wall socket.

6. MAINTENANCE

6.1 Cleaning the Device

Switch off the device and disconnect it from the mains supply. The device can be cleaned with a damp cloth. Use lukewarm water and a non-abrasive liquid household cleaner (no abrasive, no alcohol content solution). If a more sterile cleaning is needed, use a cloth moistened with an antimicrobial cleaner.

⚠ CAUTION:

DO NOT submerse the device in liquids. Should the device accidentally become submersed, contact the dealer or Authorized Service center immediately. **DO NOT** attempt to use the system that has been immersed in liquid until inspected and tested by a Service Technician Certified by an Authorized Service center. **DO NOT** allow liquids to enter the ventilation holes in the optional modules. This could permanently damage the modules.

6.2 Cleaning Treatment Heads

The treatment heads and cables should be regularly inspected for damage, e.g. hairline cracks, which could allow penetration by liquids. Clean the contact surface immediately after each treatment. Make sure that no ultrasound gel remains on the treatment head. We further recommend cleaning the head and cable daily, using lukewarm water. The treatment heads can be disinfected using a cloth moistened with 70% alcohol.

6.3 Maintenance

- Maintenance and repairs should only be performed by an authorized or certified service technician. The manufacturer will not be held responsible for the results of maintenance or repairs completed by unauthorized persons.
- The service and or maintenance must be carried out by conforming to the procedure described in the manual of the device.
- Opening of the device by unauthorized agencies is not allowed and will terminate any claim to warranty.
- The ultrasound performance of device should be adjusted and safety tested once each year.

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7. DIAGNOSTICS

7.1 Displays Fail to Light up

Check to see if the main adapter is connected to the device and the main supply.

7.2 Error

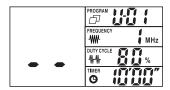
The device has discovered a fault during or after the self-test. The error displays the following figure 3. Remove any applicators or cables from the output sockets and switch the device off and on again. If the code re-appears, contact your supplier. The device is probably defective.

Figure 3

7.3 The Contact Control Fails to Operate

Check the connected plug of ultrasound applicator.

Figure 4



8. SPECIFICATIONS

8.1 Technical Specifications:

Acoustic Frequency	1MHz±10%,3MHz±10%
Output Power	0.5W-10.0W±20%, when duty factor≥80% for 5cm² 0.5W-15.0W±20%, when duty factor≤70% for 5cm² 0.1W-2.0W±20%, when duty factor≥80% for 5cm² 0.1W-3.0W±20%, when duty factor≤70% for 5cm²
Pulse repetition rate	100Hz±10%
Duty factor	10%-100%, Stepping 10%
Timer	Max. 30 minutes
Effective radiating area (AER)	5.0cm² ±20%; 1.0cm² ±20%
Effective intensity (max.)	3.0W/cm²±20% (1MHz) 3.0W/cm²±20% (3MHz)
R _{BN} (Max.)	5.0
Beam type	Collimated
Material of Sound head	Aluminum
Classification of protection against electric shock	Class I medical equipment
Classification of applied part	Type BF
Waterproof grade	IPX7 Only for treatment head

Technical data of power supply		
Adapter supply voltage	AC 100V-240V, 50/60 Hz, 1.5A Max	
Adapter output	15V3A	
Dimensions	4.9" (L) x 2.0" (W) x 1.3" (H)	

Environmental conditions for use		
Environment temperature	50 °F - 104 °F (10°C - 40°C)	
Relative humidity	30%-85%	
Atmospheric pressure	800-1060hPa	

Environmental conditions for storage		
Environment temperature 14°F - 131 °F (-10°C - 55°C)		
Relative humidity	10%-90%	
Atmospheric pressure	700-1060hPa	

8.2 Program List Table

Program	Frequency (MHz)	Duty Cycle (%)	Treatment Time (minutes)	Suggested Intensity (W/cm²)
U-01	1	80	10	1.0
U-02	1	50	10	1.0
U-03	1	50	20	1.5
U-04	1	50	15	1.0
				1.5
				2.0
U-05	3	80	15	1.0
U-06	1	30	15	1.5
U-07	1	80	15	1.0
				1.5
U-08	1	80	8	1.5
U-09	1	50	12	1.5
U-10	3	80	10	1.0

9. SKIN CARE TIPS

Follow these suggestions to avoid skin irritation, especially if you have sensitive skin:

- Wash the area of skin you will be using the device with soap. Rinse thoroughly and dry the area completely before and after placing device.
- Excess hair may be clipped with scissors; DO NOT shave treatment area.
- 3. Wipe the area with the skin preparation your clinician has recommended. Let this dry.

10. STORAGE

- For prolonged pauses in treatment, store the device with the adapter in a cool dry room and protect it against heat, sunshine and moisture.
- 2. Store the device in a cool, well-ventilated place.
- 3. **NEVER** place any heavy objects on the device.

11. DISPOSAL

Please dispose of the device in accordance with the directive 2012/19/EU WEEE (Waste Electrical and Electronic Equipment). Please dispose of the device in accordance with the laws in your area.



12. ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

IMPORTANT INFORMATION REGARDING ELECTROMAGNETIC COMPATIBILITY (EMC)

Guidance and manufacturer's declaration - electromagnetic emissions

The DQ9275 device is intended for use in the electromagnetic environment specified below. The customer or the user of the DQ9275 should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The DQ9275 device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The DQ9275 device is suitable for use in all establishments including domestic and
Harmonic emissions IEC 61000-3-2	Class A	those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Conforms	purposes.

Guidance and manufacturer's declaration - electromagnetic immunity

The DQ9275 device is intended for use in the electromagnetic environment specified below. The customer or the user of the DQ9275 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	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.

Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) 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 the DEVICE be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic emissions

The DQ9275 device is intended for use in the electromagnetic environment specified below. The customer or the user of the DQ9275 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 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the DQ9275 device, including cables, than the recommended separation distance calculated from
Radiated RF IEC 61000- 4-3	d 10 V/m 10 V/m 80 MHz 80 MHz to	80 MHz to	recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance. d=1.2 \(\text{VP} \) 4-0.35 \(\text{VP} \) 800 \(\text{MHz} \) to 800 \(\text{MHz} \) to 27 \(\text{GHz} \) where \(\text{P} \) is the maximum output power rating of the transmitter in watts \((\text{VV} \) according to the Transmitter manufacturer and \(\text{d} \) is the recommended separation distance in meters \((m) \). Field strengths from fixed RF transmitters, as determined by an electromagnetic site a survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following.

NOTE I At 80 MHz ends 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 du to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the UTIO41 device is used exceeds the applicable RF compliance level above, should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the UTIO41.

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 DQ9275 device

The DQ9275 device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DQ9275 device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DQ9275 as recommended below, according to the maximum output power of the communications equipment.

Rate maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)				
erensimites (11)	150 kHz to 80 MHz d=1.2√P	80 MHz to 800 MHz d=0.35 √ P	800 MHz to 2.7 GHz d=0.7√P		
0.01	0.12	0.04	0.07		
O.1	0.38	O.11	0.22		
1	1.2	0.35	0.7		
10	3.8	1.1	2.2		
100	12	3.5	7.0		

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) accordable to the transmitter manufacturer.

NOTE I 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.

13. GLOSSARY OF SYMBOLS

SN	Serial number
\triangle	Attention: Read the operating instruction before use! Equipment capable of delivering output values in excess of 10mA r.m.s. or 10V r.m.s. averaged over any period of 5s.
A	Electrical devices are recyclable material and should not be disposed of with household 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 Applied Part
(3)	Refer to instruction manual
IPX7	Only for treatment head: Protected against the effects of temporary immersion water.
M	Date of manufacture
LOT	Batch Code
СВ	The electrical safety meet the CB system requirements
	Indoor use only
Ŕ	Risk of electric shock

14. 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. Richmar's sole obligation in the case of any breach of its warranties set forth in the manual shall be, at Richmar's option, to replace the Product with a new or factory certified refurbished product without charge to the purchaser or to refund the purchase price of the Product. If the product is unopened/unused it can be returned minus a 25% restock fee. The warranty period for the SoundCare Plus® device is two years from date of purchase and does not include accessories.
- 2. For defective products, please contact your distributor or Richman directly at 800-376-7263 to speak with Tech Support. If product cannot be remedied over the phone, a prepaid shipping label will be sent to you with the authorized RMA number (if product is within warranty). Any product sent back without an authorized RMA number will be returned to the sender. Richmar will not be responsible for damage due to improper packaging or shipment. If Richmar determines in its sole reasonable discretion that the Product contains defective workmanship or materials, Richmar will replace the product with a new or factory certified refurbished product at Richmar's expense or refund the purchase price to the original purchaser for the price of the defective product (minus shipping costs). If Richmar determines in its sole reasonable discretion that the Product does not contain defective workmanship, materials, or it is observed that product has been mishandled. abused or device has been opened, Richmar will inform the Purchaser and return the product, freight billed to the purchaser.
- Repairs or replacements under warranty DO NOT extend the warranty period either for the device or for the replacement parts. Replacement lead wire, applicators and power cords have a one year warranty from date of original device purchase.

- 4. The following is excluded under the warranty:
 - a. All damage which has arisen due to improper treatment, e.g. nonobservance of the user instruction.
 - b. Any device that has been opened or has a damaged warranty seal, automatically voids the warranty and no refund or warranty replacement will be provided.
 - c. Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service center.
 - d. Accessories which are subject to normal wear and tear.
- Liability for direct or indirect consequential losses caused by the unit is excluded even if the damage to the unit is accepted as a warranty claim.
- 6. Serial number is a sequential and unique identification number that represents date of manufacture.

Manufactured for:

