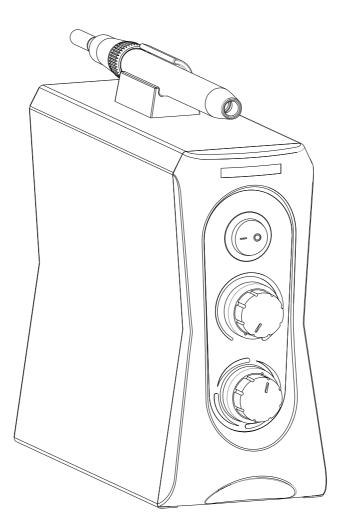
ROLENCE[®] ULTRASONIC SCALER ELITEDENT[®] MS-50 R1 (25K/30K)



ROLENCE ENTERPRISE INC.

No. 18-3, Lane 231, Pu Chung Rd., Chungli, Taoyuan 32083, Taiwan TEL: 886-3-4631999 FAX: 886-3-4631997 www.rolence.com.tw

S-19-01-1232-U0001 V1.5

Table Of Contents

Section	Section Title Page
Number	Description of Contents
1	Precautions
	1.1 Precautions for All Systems
	1.2 Precautions for Ultrasonic Prophylaxis Procedure
2	Introduction4
3	Glossary of Symbols4
4	Indications for Use
5	Specification
6	Contraindications and Warnings5
	6.1 Contraindications
	6.2 Warnings
7	Infection Control
	7.1 Function
	7.2 General Infection Control Recommendations
	7.3 Water Supply Recommendations
8	Installation Instructions7
	8.1 General Information
	8.2 Water Line Requirements
	8.3 Electrical Requirements
	8.4 Unpacking the System
	8.5 System Installation
	8.6 Power Connection
	8.7 Water Supply Line Connection
9	MS-50 R1 Ultrasonic Scaler
	Description
	9.1 Rear Panel
	9.2 System Controls
	9.3 Handpiece Assembly/ Handpiece Sleeve
	9.4 Foot Switch Controls and Operation
10	Accessories9
11	Techniques For Use10
	11.1 Patient Positioning
	11.2 Performing Ultrasonic Scaling Procedures
	11.3 Patient Comfort Considerations
12	System Maintenance And Care11
13	Trouble shooting12
14	Disposable of Unit12

15	Disclaimer	12
16	WARRANTY	13

Section 1: Safety Precautions

Prior to installation and start-up of the ultrasonic scaler, carefully read the instructions provided herein! **1.1 Precautions for All Systems**

Do not place the ultrasonic scaler on or next to a radiator or other heat source. Excessive heat may damage the ultrasonic scaler's electronics. Place the ultrasonic scaler where air is free to circulate on all sides and beneath it. Do not cover vents on rear panel.

 $igtsymbol{\Delta}$ The ultrasonic scaler is portable, but must be handled with care when moving.

Equipment and dental water supply system maintenance are strongly recommended. See Section 12: System Maintenance And Care.

Close the water shut-off valve in the dental water supply system every night before leaving the office.

 Δ The use of an in-line water filter is recommended.

Used for the intended purpose only. The ultrasonic scaler must be used by other than qualified and trained personnel, in medical facilities.

Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked Hospital Only or Hospital Grade.

1.2 Precautions for Ultrasonic Prophylaxis Procedures

- Before first use, clean, disinfect and sterilize new or repaired handpieces and instruments you wish to use with the ultrasonic scaler.
- Always examine the unit and ultrasonic tips before commencing treatment. A damaged ultrasonic scaler or damaged tip must not be used.
- Ultrasonic tips that have been bent, damaged, or reshaped are susceptible to in-use breakage and should be discarded and replaced immediately.

• Retract the lips, cheeks and tongue to prevent contact with the ultrasonic tip whenever it is placed in the patient's mouth.

Section 2: Introduction

ROLENCE ENTERPRISE INC. is an ISO 9001, ISO 13485 certified manufacturer of Ultrasonic Scalers. All the products are FDA registered and compliant with EN standard (CE Marking).

2.1 Conformance to Standards:

The MS-50 R1 Ultrasonic Scaler conforms to IEC60601-1-2:2007 and IEC60601-1-1:2006. The device is CE marked corresponding to European **Medical Device Directive (93/42/EEC)** Contact your local ROLENCE dealer to order supplies or replacement parts. There are no serviceable parts included in this device. Please contact your dealer to acquire all repairing service and technique supports.

CAUTION: EQUIPMENT NOT SUITABLE FOR USE IN THE PRESENCE OF FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR WITH NITROUS OXIDE.

CAUTION: U.S FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A DENTAL PROFESSIONAL.

2.2 Supplies and Replacement Parts

Section 3: Glossary of Symbols

Ĩ	Attention, Consult accompanying Documents
\sim	Alternating Current
0	Power off
I	Power on
	Manufacturer
~~	Date of manufacture
REF	Catalogue number
	Type BF Applied Part; Type BF Equipment - Protection against electric shock
	Equipment class: Class II (IEC601-1) - double insulated

С Є	CE The equipment complies with the requirements in the Medical
1434	Device Directive 93/42 EEC.
X	Icon to identify electric and electronic devices. The unit must be collected and disposed of separately.

Section 4: Indications for Use

Ultrasonic procedure

All general supra and subgingival scaling applications.
Periodontal debridement for all types of periodontal diseases.
Endodontic procedures.

Section 5: Specification

MS-50 R1 Ultrasonic Scaler Voltage input:

100V, 110V, 230V, 240V

5.1 Electric Voltage:		5.2 Dimension:	
VOLTAGE:	CURRENT	HEIGHT :	19.5 CM
100VAC 50/60Hz	0.8 A (MAX)	WIDTH :	8.5 CM
110VAC 50/60Hz	0.72 A (MAX)	DEPTH :	21.0 CM
230VAC 50/60Hz	0.35 A (MAX)	WEIGHT :	2500g
WATTAGE:	MAX. 80 W		
WATER PRESSURE:	20-40 psi		
Tip vibration frequency:	25/30 k +/- 3KHz		
Half-excursion force:	<1N		

5.3 Operation Environment:

AMBIENT TEMPERATURE	$:+10^{\circ}C \sim +40^{\circ}C$
RELATIVE HUMIDITY	:30%~75%
ATOMOSPHERIC PRESSURE	:700 hPa~1060hPa

5.4 Transportation And Storage Environment:

•	5
AMBIENT TEMPERATURE	: −10°C~+70°C
RELATIVE HUMIDITY	: 10%~90%
ATOMOSPHERIC PRESSURE	: 500 hPa \sim 1060hPa

Section 6: Contraindications and Warnings

6.1 Contraindications

- Ultrasonic Systems should not be used for restorative dental procedures involving the condensation of amalgam.
- This device is designed to work with all Cavitron[®] (remark) 25Khz and 30Khz frequency inserts. For optimum performance please use only qualified inserts supplied by Cavitron[®] or ROLENCE.
- Do not use this device if the patient or operator is wearing a pacemaker.

Remark: Cavitron[®] is a registered trademark of Dentsply[®] International, Inc

6.2 Warnings

· Persons who are fitted with cardiac pacemakers,

defibrillators and other active implanted medical devices, have been cautioned that some types of electronic equipment might interfere with the operation of the device. We recommend that the MS Handpiece Cable Set be kept at least 6 to 9 inches (15 to 23 cm) away from any device and

Section 7: Infection Control

7.1 Function:

The MS-50 R1 Ultrasonic Scaler is designed for use in prophylaxis treatments periodontia, and other areas of operative dentistry.

When used in prophylaxis treatment, the unit operates with a fine water spray, requiring little of the physical exertion necessary with hand instruments. It easily and effectively removes stubborn calculus and stains both supragingivally and subgingivally, leaving crown and root surfaces clean and smooth.

7.2 General Infection Control Recommendations

- As with all dental procedures, the use of standard personal protection equipment (i.e., wearing a face mask, eyewear, or face shield, gloves and protective gown) is recommended.
- For maximal operator and patient safety, carefully follow section 12 system maintenance and care information detailed in the operating instruction.
- As with high speed handpieces, and other dental devices, the combination of water and ultrasonic vibration from your MS-50 R1 Ultrasonic Scaler will create aerosols. With proper technique, much of the aerosol dispersion can be effectively controlled and minimized. Please carefully follow the procedural guide lines in this manual regarding the use of your ultrasonic scaler.

their leads during use.

- During using the unit, make sure that water is flowing continuously. If the handpiece overheats please check the water supply, and stop using the unit for a while.
- Always flush your MS-50 R1 Ultrasonic Scaler at least 20 seconds with highest flow after each treatment. Refer to more information in section 12.
- Clean and disinfect the handpiece sleeve between patients. The handpiece sleeve can be autoclaved up to 135° C for at least 10 minutes.

Sterilizing:

- 1. Autoclave: compliant with standard EN 13060.
- Place sterilizable sleeve of handpiece and pouched ultrasonic insert into a steam autoclave.
 After warm-up is completed, operate at a sterilizing temperature and pressure of 273° F/31 psi (134°C/216 kPa) for 18 minutes, followed by a 20-30 minute drying time.
- 3. To maintain sterility, the insert should remain in the sealed pouch until it is ready for use.

DO NOT USE Cold sterilization solution.

7.2 Water Supply Recommendations

 It is highly recommended that all dental water supply systems should conform to applicable CDC (Centers for Disease Control and Prevention) and ADA (American Dental Association) standards, and that all recommendations be followed in terms of flushing, chemical flushing, and general infection control procedures. See sections 7.2 and 12.

8.1 General Information

If the installation of your MS-50 R1 ultrasonic scaler is performed by someone other than trained ROLENCE distributor personnel, care should be taken to observe the following requirements and recommendations.

8.2 Water Line Requirements

- The system's public water supply tube is factory provided. Do not discard it from the ultrasonic scaler kit.
- Incoming water supply line pressure to the ultrasonic scaler must be 20 psi (138 kPa minimum) to 40 psi (276 kPa) maximum. If your dental water system's supply line pressure is above 40 psi, install a water pressure regulator on the water supply line to your ultrasonic scaler.
- A manual shut-off valve on the dental water system supply line should be used so that the water can be completely shut-off when the office is unoccupied.
- A filter in the dental water system supply line is recommended so that any particles in the water supply will be trapped before reaching the ultrasonic scaler.
- After the above installations are completed on the dental water supply system, the dental office water line should be thoroughly flushed prior to connection to the System.
- After flushing system verify there are no leaks.

8.3 Electrical Requirements

Refer to Section 3: Specifications.

8.4 Unpacking the System

Carefully unpack your MS-50 R1 ultrasonic scaler and verify that all components and accessories are included:

- 1. MS-50 R1 Ultrasonic scaler main unit with Sterilizable Sleeve of Handpiece
- 2. External power supply (AC-AC)
- 3. MS Handpiece Cable Set
- 4. Foot Pedal.
- 5. User Manual.

8.5 System Installation

- Place the MS-50 R1 on a level surface.
- Be sure unit is stable and resting on four feet.
- Placing unit in direct sunlight may discolor plastic housing.

8.6 Power Connection

- The ON/OFF Control Switch and power indicator is located on the Rear Panel of the MS-50 R1 Ultrasonic Scaler. (See Section 9.1)
- Verify the ON/OFF Control Switch located on the rear panel of the MS-50 R1 ultrasonic scaler is in the OFF position before proceeding.
- Plug the detachable AC Cord into the back of the ultrasonic scaler and into an approved outlet.

8.7 Water Supply Line Connection

Connect the free end of the ultrasonic scaler's water supply line to the dental water supply line. Inspect all connections to make certain there are no leaks.

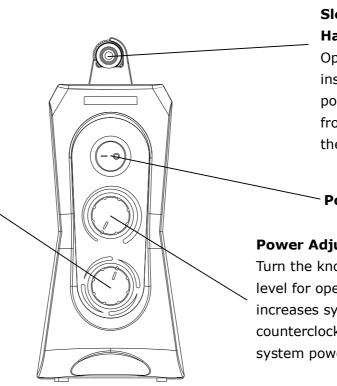
Section 9: MS-50 R1 Ultrasonic Scaler Description

9.1 Rear Panel

Water flow Adjustment

Turn the knob to select water flow level during system operation. Clockwise decreases flow at insert tip, counterclockwise increases the flow.

The rate of flow through the Hand piece determines the temperature of the water flow. Lower flow rates produce warmer temperature; higher flow rates produce cooler temperature.



Sterilizablew Sleeve of Handpiece

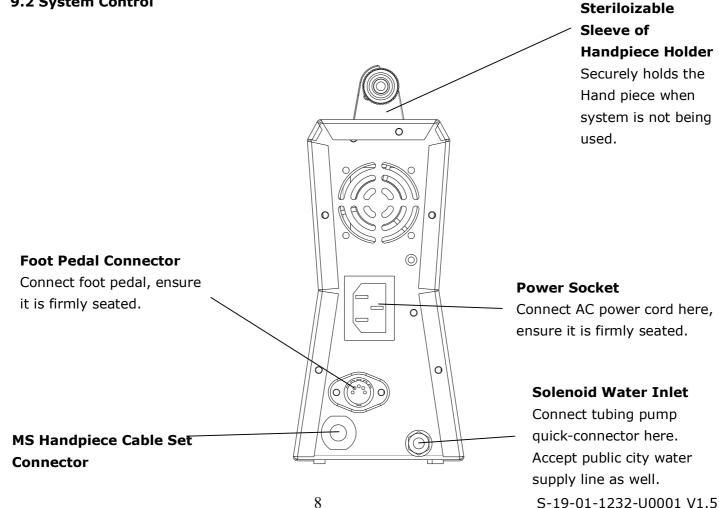
Operates Ultrasonic inserts and transmits power and water flow from the System to the insert.

Power Switch

Power Adjustment

Turn the knob to select power level for operation: clockwise increases system power, counterclockwise decreases system power.

9.2 System Control

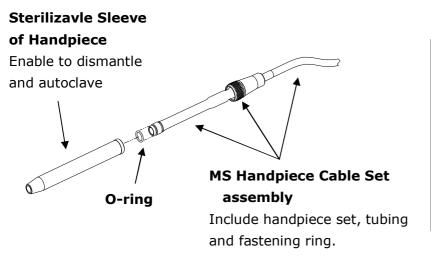


8

9.3 MS Handpiece Cable Set / Sterilizable Sleeve of Handpiece Assembly

The ultrasonic scaler is multi-frequency unit compatible with all Cavitron[®] inserts. The system will automatically detect the insert, no need to switch any button.

For more oral hygiene care, the Sterilizable Sleeve of Handpiece can be dismantled and autoclaved. See below:



Fastening Ring Hold here, rotate Sterilizable sleeve of

Handpiece to release.

To take off the handpiece sleeve, please hold the fastening ring, and rotate the sleeve counterclockwise from MS Handpiece Cable Set assembly. **Note: Avoid rotate or twist the MS Handpiece Cable.**

9.4 Foot Pedal Controls and Operation

The Foot Switch is a two-position momentary switch, which activates both Ultrasonic energy and water flow at insert tip.

Foot Pedal Released	Foot Pedal Depressed Half Way $(1^{st}$	Foot Pedal fully depressed
Both ultrasonic activation and	position)	(2 nd position)
irrigating flow stop.	The ultrasonic insert is activated	This activates the "Turbo" mode
	and irrigating water flow under	increasing extra power.
	normal function.	

Section 10: Accessories

- 1. Ultrasonic insert (optional)
- 2. External Power Supply (AC-AC)

- 4. MS Handpiece Cable Set
- 5. Sterilizable Sleeve of Handpiece

3. Foot pedal

11.1 Patient Positioning

- For optimal access to both the upper and lower arches, the backrest of the chair should be adjusted to a 45° degree angle. This assures patient comfort and Clinician visibility.
- Have the patient turn his/her head to the right or left. Also position chin up or down depending upon the quadrant and surface being treated. Evacuate irrigate using either a saliva ejector or High Volume Evacuator (HVE).

11.2 Performing Ultrasonic Scaling Procedures

- Note: Refer to Section 7 and 12 for general procedures to be followed at the beginning of each day and between patients.
- The edges of ultrasonic inserts are intentionally rounded so there is little danger of tissue laceration with proper ultrasonic scaling technique. Whenever the insert tip is placed in the patient's mouth, the lips, check and tongue should be retracted to prevent accidental prolonged contact with the activated tip.
- Hold the empty sterilizable sleeve of handpiec in an upright position. Activate the Foot Pedal fluid exits.
- Lubricate the rubber O-ring on the insert with water before placing it into the sterilizable sleeve of handpiece. Fully seat insert with a gentle push-twist motion. DO NOT FORCE IT INTO PLACE.
- Activate the System. Hold the sterilizable sleeve of handpiece over a sink or drain. Check spray temperature to verify fluid is reaching the working end of the insert tip. Adjust the water cooler irrigate. Control knob to ensure adequate flow for the selected Power setting. Greater flow settings provide cooler irrigation.

- It may be necessary to adjust water flow larger under "Turbo" mode (Foot Pedal fully depressed) so adequate fluid will be available to cool tip and tooth interface.
- In general, it is suggested a "feather-light-touch" be used both supra and subgingivally. The motion of the activated tip and acoustic effects of the irrigating fluid, in most cases, is adequate to remove even the most tenacious calculus.
- Periodically check the ultrasonic insert for wear with the Insert Efficiency Indicator.
- The use of a saliva ejector or High Volume Evacuator (HVE) is recommended during all procedures.
- Set the System's Power Adjustment knob to the lowest power setting for the application and the selected insert.
- If water leakage found in sterilizable sleeve of handpiece, replace sleeve or o-ring on MS handpiece cable set to eliminate.

11.3 Patient Comfort Considerations

Reasons for sensitivity

- Incorrect tip placement. Point should be directed away from root surfaces.
- Not keeping tip in motion on tooth. Do not allow the insert to remain in a static position on any one area of the tooth. Change the insert's path of motion.
- Applying pressure. Use extremely light grasp and pressure, especially on exposed cementum.
- If sensitivity persists, decrease power setting and/or move from the sensitive tooth to another and then return.

Daily Maintenance

It is recommended that you perform the following maintenance procedures to help minimize bio-film formation in the water path of your MS-50 R1 ultrasonic scaler which could affect the water flow to the ultrasonic insert, and scaling performance.

Start-Up Procedures at the beginning of the day:

1. Open the manual shut-off valve on the dental office water supply system.

2. Turn the system ON using the power ON/OFF switch. (see illustration on page 7) Verify the Power Indicator Light is on.

3. Set the Power Control knob to minimum setting.

4. Set the Water Control knob to maximum.

5. Hold the Sterilizable Sleeve of Handpiece (without an insert installed) upright over a sink or drain. Activate the Foot Pedal and flush the water line for at least 2 minutes.

6. Place a sterilized insert into the Sterilizable Sleeve of Handpiece and set the water control knob to your preferred operating position.

Between Patients:

- 1. Remove ultrasonic insert and sterilizable sleeve of handpiece used, clean and sterilize.
- 2. Clean and disinfect the surfaces of the cabinet, Power Cord, MS Handpiece cable set Assembly *, control knobs, Foot Pedal and MS Handpiece cable applying set assembly by an approved non-immersion disinfectant solution* type carefully following the instructions provided by the disinfectant solution manufacturer. To clean system, generously spray disinfectant solution on a clean towel and wipe all surfaces. Discard used towel. To disinfect system, generously spray disinfectant on a clean towel and wipe all surfaces. Allow disinfectant solution to air dry. Do not spray disinfectant solution directly on the ultrasonic scaler.
- 3. Place a sterilized sterilizable sleeve of handpiece.

Set power to minimum. Hold the sterilizable sleeve of handpiece over a sink or drain and flush the water line at maximum water flow for 30 seconds.

- 4. When ready, place a sterilized insert into the sterilizable sleeve of handpiece.
- 5. Please consider use a FDA approved sheath to for the cable and entire handpiece or at least to cover the handpiece from the fastening ring to cable when sleeve is sterilized between patients.

Shut-Down Procedures at the end of the day:

- 2. Remove ultrasonic insert and sterilizable sleeve of handpiece used, clean and sterilize.
- 3. Turn the System OFF.
- 4. Clean and disinfect the surfaces of the cabinet, Power Cord, MS Handpiece cable set assembly, control knobs, Foot Pedal MS cable set assembly by applying an approved non-immersion type disinfectant solution* carefully following the instructions provided by the disinfectant solution manufacturer. To clean system, generously spray disinfectant solution on a dean towel and wipe all surfaces. Discard used towel. To disinfect system, generously spray disinfectant on a clean towel and wipe all surfaces. Allow disinfectant solution to air dry. Do not spray disinfectant solution directly on the ultrasonic scaler.
- 5. Close the manual shut-off valve on the dental water supply system.

***Note**: Those Water-based disinfection solutions are preferred, due some alcohol-based disinfectant solutions may be harmful and may discolor plastic materials.

***Note**: The electric wire winding covered by heat shrinkage tube which protected by sterilizable sleeve of handpiece is very sensitive to the disinfectant solution and water. After the disinfection, wipe surface of shrinkage tube with a slightly damp cloth and dry thoroughly before use.

Although service and repair of the MS-50 R1 Ultrasonic Scaler should be performed by ROLENCE dealer personnel, the following are some basic trouble shooting procedures that will help avoid unnecessary service calls. Generally, check all lines and connections to and from the system, a loose plug or connection will often create problems. Check the settings on the system's knobs.

13.1 Troubleshooting Guide

Problem: System will not operate: (Power Indicator Light is not lit.)

- 1. Check that the Power switch is in the ON position, and that the AC Power Cord is fully seated in the receptacle on back of System.
- 2. Check that the System's three-prong plug is fully seated in an appropriate AC receptacle, and that AC current is present.

(Power Indicator Light is lit.)

- 1. Check that the Foot Pedal Connector is fully seated in the Foot Pedal Receptacle on the back of the System.
- 2. Check foot Pedal switch.

System operates: (No water flow to insert tip.)

- 1. Assure that water control is properly adjusted.
- 2. Check that water supply control valve(s) (dental office water supply) are open.

(Insert stops vibrating)

- 1. Deactivate foot control.
- 2. Verify insert is in good condition.
- 3. Depress foot control to try again.

Section 14: Disposal of Unit

- Keep original packaging until the MS-50 R1 Ultrasonic Scaler is to be disposed of permanently. You can use it for shipping or storing your MS-50 R1 Ultrasonic Scaler at any time.
- Dispose of the MS-50 R1 Ultrasonic Scaler in accordance with local and national laws.

Section 15: Disclaimer

ROLENCE considers itself responsible for the effects on safety, reliability and performance of this product only if:

- Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by ROLENCE.
- The electrical installation of the relevant room complies with the requirements.
- The equipment is used in accordance with these instructions for use.

Section 16: Warranty

16.1 Malfunction

ROLENCE hereby warrants that for a period of one year from the delivery date, this device shall be free from defects in material and workmanship. In case the machine is found malfunctioned under normal use, ROLENCE will offer service of free maintenance and parts for replacement.

16.2 Repair

Repairs must be only carried out by an authorized ROLENCE engineer/dealer. If repairs during warranty period are not carried out by an authorized engineer/dealer, warranty will expire immediately.

16.3 Warranty Exception

The warranty stated herein is the sole warranty applicable to ROLENCE products. ROLENCE expressly disclaims the liability for warranty even within warranty period, if

- (1) Damages caused by natural disaster.
- (2) Operator's fault or wrong operation.
- (3) Application use other than curing light-cured material purpose.

(4) A malfunction or damage caused by repair, adjustment, modification which is not carried out by ROLENCE authorized technicians/dealers.

- (5) A malfunction caused by abnormal power source or voltage.
- (6) It is a consumption part.

(This instruction subjects to change without pre-notice.)

The equipment complies with the requirements in the Medical Device Directive 93/42 EEC



1434

Rolence Enterprise Inc.

No. 18-3, Lane 231, Pu Chung Rd., Chungli, Taoyuan 32083 Taiwan

EU authorized representative name and address



CMC Medical Devices & Drugs S.L. C/ Horacio Lengo n18, C.P 29006, Málaga-Spain

REM: Please contact our authorized dealer if users require user manual in other European language.

ANNEX I

Guidance and manufacturer's declaration-electromagnetic emissions

The MS-50 R1 is intended for use in the electromagnetic environment specified below. The customer or the user of the MS-50 R1 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance
RF emissions	Group 1	The MS-50 R1 uses RF energy only for its internal function. Therefore, its
CISPR 11		RF emissions are very low and are not likely to cause any interference in
		nearby electronic equipment.
RF emissions	Class B	The MS-50 R1 is suitable for use in all establishments, including domestic
CISPR 11		establishments and those directly connected to the public low-voltage
Harmonic emissions	Class A	power supply network that supplies buildings used for domestic
IEC 61000-3-2		purposes.
Voltage fluctuations	Compliance	
/flicker emissions		
IEC 61000-3-3		

Guidance and manufacturer's declaration-electromagnetic immunity					
The MS-50 R1 is intend	The MS-50 R1 is intended for use in the electromagnetic environment specified below.				
The customer or the us	ser of the MS-50 R1 sho	ould assure that it is use	ed in such an environment.		
Immunity test	IEC 60601	Compliance level	Electromagnetic		
	test level		environment-guidance		
Electrostatic	+ 6 kV contact	+ 6 kV contact	Floors should be wood, concrete or		
discharge(ESD)	+ 8 kV air	+ 8 kV air	ceramic tile. If floors are covered with		
IEC 61000-4-2			synthetic material, the relative		
			humidity should be at least 30%		
Electrical fast	+ 2kV for power supply	+ 2kV for power supply	Mains power quality should be that of		
transient/burst	lines	lines	a typical commercial or hospital		
IEC 61000-4-4			environment.		
Surge IEC 61000-4-5	0.5~+ 2kV common	0.5~+ 2kV common	Mains power quality should be that of		
	mode	mode	a typical commercial or hospital		
			environment.		
Voltage Dips, short	<5% UT(>95% dip in	<5% UT(>95% dip in	Mains power quality should be that of		
interruptions and	UT) for 0,5 cycle	UT) for 0,5 cycle	a typical commercial or hospital		
voltage	40% UT(60% dip in	40% UT(60% dip in	environment. If the user of the MS-50		
variations on power	UT) for 5 cycles	UT) for 5 cycles	R1 requires continued operation		
supply	70% UT(30% dip in	70% UT(30% dip in	during power mains interruptions, it		
input lines IEC	UT) for 25 cycles	UT) for 25 cycles	is recommended that the RMS-50 R1		
61000-4-11	<5% UT(>95% dip in	<5% UT(>95% dip in	be powered from an uninterruptible		
	UT) for 5 s	UT) for 5 s	power supply or a battery.		
Power frequency(50/60	3 A/m	3 A/m	The MS-50 R1 contains no devices		
Hz) magnetic field IEC			susceptible to magnetic fields.		
61000-4-8					
NOTE UT is the a.c. mains voltage prior to application of the test level.					

Guidance and manufacturer's declaration-electromagnetic immunity					
The MS-50 R1 is intended for use in the electromagnetic environment specified below.					
The customer or the user of the MS-50 R1 should assure that is used in such and environment.					
Immunity test	IEC 60601 test	Compliance	Electromagnetic environment-guidance		
	level	level			
Conducted RF	3 V/m	3 V/m	Portable and mobile RF communications		
IEC 61000-4-6	150 KHz to 80		equipment should be used no closer to any part of		
Radiated RF	MHz	3 V/m	the MS-50 R1 including cables, than the		
IEC 61000-4-3	3 V/m		recommended separation distance calculated		
	80MHz to 2,5		from the equation applicable to the frequency of		
	GHz		the transmitter. Recommended separation		
			distance:		
			d = 1,2 [•] P		
			d = 1,2 P 80MHz to 800 MHz		
			d = 2,3 [•] P 800MHz 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,		
			(a) should be less than the compliance level in		
			each frequency range. (b) Interference may		
			occur in the vicinity of equipment marked with		
			the following symbol:		
			NOTE1		
			$((\cdot,\cdot))$		

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 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 MS-50 R1 should be observed to verify normal operation. If abnormal performance is observed, additional measures my be necessary, such as re-orienting or relocating the MS-50 R1.

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

Recommended separation distance between portable and mobile RF communications equipment and the MS-50 R1

The MS-50 R1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MS-50 R1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MS-50 R1 as recommended below, according to the maximum output power of the communications equipment.

Rated	Separation distance according to frequency of transmitter						
maximum		m					
output	150 kHz to 80 MHz	150 kHz to 80 MHz 80 MHz to 800 MHz 800 MHz to 2,5 GHz					
power of	d =1,2°P	d =1,2°P	d =2,3 P				
transmitter							
W							
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 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.