SCOUT MD™

SURGICAL GUIDANCE SYSTEM

EN INSTRUCTIONS FOR USE

MERIT MEDICAL®

English

SCOUT® MD SURGICAL GUIDANCE SYSTEM

INTRODUCTION

Caution

• Read all warnings, cautions, and instructions provided with this SCOUT MD Console before using.
• Read the instructions, warnings, and cautions provided with the SCOUT MD Console, SCOUT MD Multiple-use Guide, SCOUT MD Single-use Handpiece and SCOUT MD Delivery System before using. Specific instructions are not included in this manual.
• Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Device Description

The SCOUT MD Console, SCOUT MD Multiple-use Guides (SCOUT MD Guide, SCOUT MD Access Guide), SCOUT MD Single-use Handpieces (SCOUT MD Single-use Handpiece, SCOUT MD Access Single-use Handpiece) and SCOUT MD Delivery System (including SCOUT MD Reflector) are components of the SCOUT MD Surgical Guidance System. The SCOUT MD Console is a medical device that provides control operations for detecting the presence of the SCOUT MD Reflector within soft tissue during surgery. The SCOUT MD Guides/Handpieces and SCOUT MD Reflectors are available separately.

The SCOUT MD System employs micro-impulse radar and infrared light (IR) technology to determine the location of up to four MD Reflectors, which are placed into the soft tissue during a prior procedure. The Console provides the micro-impulse radar signal to the Guide/Handpiece along with power for the infrared light sources. The Guide/Handpiece delivers the micro-impulse radar signal and infrared light into the soft tissue and in turn receives signals reflected back from up to four Reflectors. The Console processes the reflected radar signals to provide the surgeon with Reflector proximity and location information via audible and visual feedback. The numeric display provides real-time distance between the Guide/Handpiece and Reflectors. The audible feedback produced by the Console increases in cadence as the Guide/Handpiece is placed in closer proximity to the Reflectors. The Console provides a maximum detection range of 60mm from the Guide/Handpiece to the Reflector. Excision of the lesion is then performed using standard surgical technique.

The Console and Multiple-use Guides are provided non-sterile. The Single-use Handpieces and Delivery Systems are provided sterile.

Indications for Use

The SCOUT MD Reflector is intended to be placed percutaneously in soft tissue (>30 days) to mark a biopsy site or a soft tissue site intended for surgical removal. Using imaging guidance (such as ultrasound, MRI, or radiography) or aided by non-imaging guidance (SCOUT MD System) the SCOUT MD Reflector is located and surgically removed with the target tissue. The SCOUT MD System is intended only for the non-imaging detection and localization of the SCOUT MD Reflector that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal.

Contraindications

The SCOUT MD Surgical Guidance System is intended only for use in the location of the SCOUT MD Reflector in soft tissue. The SCOUT MD Surgical Guidance System is contraindicated for use in ocular, cardiac, neurological and spinal clinical applications. The SCOUT MD Reflector should not be placed in a tissue site with clinical evidence of infection.

Clinical Benefits

The intended clinical benefit of the SCOUT MD Surgical Guidance System is accurate marker placement and lesion localization to facilitate target tissue excision.

Compatible Components

The following items are required for the proper use of the SCOUT MD Console. Use of other parts and materials not listed below is contraindicated.
• SCOUT MD Delivery System (SSRXXX-01))
• SCOUT MD Multiple-use Guide (SGMD-01, SGMD-02)
• SCOUT MD Single-use Handpieces (MDHPSU-01, MDHPSU-02)

WARNINGS AND CAUTIONS

It is important that the instructions supplied with this Console be read, understood, and followed.

Warnings

• In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable member state.
• Failure to thoroughly review and adhere to the information contained in this Operation Manual may pose a potential hazard to the patient and/or user.
• Electric Shock Hazard – The Console must be properly grounded to ensure patient safety. Do not connect the included power cord to extension cords or to power plug adapters. To avoid the risk of electrical shock, this equipment must only be connected to supply mains with protective earth.
• Electric Shock Hazard – No modification of this equipment is allowed. Do not remove the cover. Removal of the cover may cause electrical shock. Contact Merit Medical for service.
• Electric Shock Hazard – Do not connect wet accessories to the Console.
• Electric Shock Hazard – Always turn off and unplug the Console before cleaning.
• Fire Hazard – Do not use extension cords.
• Explosion Hazard – This system is not designed for use in an explosive atmosphere.
• Never use any power adapter or cable other than the one specifically supplied with the instrument.
• Check the instrument before use for signs of damage, particularly to cables. If the instrument is damaged or gives unexpected performance or operation, then
cease using the device and ensure that it is serviced or replaced before recommencing use of the device.
• If the patient has an internal or external active cardiac implant, contact the cardiac implant manufacturer for instructions before using the SCOUT MD system. The micro-impulse radar signal may interfere with the intended function of the cardiac implant.

Cautions

• Reflector placement within a hematoma could affect the sensitivity of the system.
• Read all warnings, cautions, and instructions provided with this Console before using.
• Read the instructions, warnings, and cautions provided with the Guide/Handpiece and Reflector before using. Specific instructions are not included in this manual.
• Federal law restricts this device to sale by or on the order of a physician.
• This equipment should only be used by a physician trained in its indicated use, limitations, and possible complications of soft tissue surgery techniques.
• Inspect cords for breaks, cracks, nicks, or other damage before every use. If damaged, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or operator.
• Verify power cord is secure before each use.
• Always switch the instrument off at the mains power outlet, before inserting or removing the power connector from the rear of the instrument. Failure to do so may damage the internal instrument electronics.
• Do not leave the Console in LOCALIZATION Mode when not in use.
• Connect the power cord to a hospital grade wall outlet having the correct voltage or product damage may result.
• Ensure cables are positioned to prevent trip hazards.
• For best results, operate the instrument in a stable (vibration-free) environment, with the Console placed on a level working surface.
• Do not operate Console near electromagnetic radiating sources.
• Do not place Console in contact with other electrical equipment during use.
• The Console is non-sterile. Do not sterilize.
• Care should be taken not to drop the Console, or subject it to any form of rough physical handling, either during normal use or during storage and transportation.
• Never clean the Console using an excessively wet cloth, or by washing it under running water.
• Do not clean the Console with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the unit.
• The Console and Guide/Handpiece/Cable Assembly of the SCOUT MD System are MR Unsafe and should not be used in the MR environment
• The implanted SCOUT MD Reflector is MR Conditional. The SCOUT MD delivery device is MR Conditional.
• The use of Xenon light sources should be used with caution. Xenon light sources may contain wavelengths of light that could affect the sensitivity of the system when the light is illuminating the area of the reflector.
• The device is not intended for use in an aircraft.

Precautions

• The Reflector has been studied in the breast and axilla but use in other anatomical locations has not been well established.

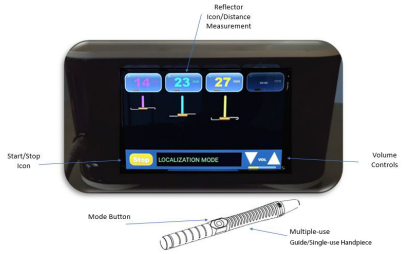
Residual Risks

- Soft tissue injury

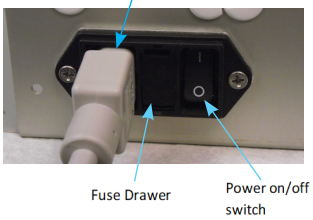
CONTROLS, INDICATORS AND RECEPTACLES

Instrument Description

The Console contains the controls. The controls are located on the front and back of the Console. The Console produces signal outputs in the form of an audible pitch that represent the intensity of the Guide's Guide/Handpiece signal.



Rear Panel



CONSOLE SETUP AND OPERATION

Caution

• Read all warnings, cautions, and instructions provided with this Console before using.
• Read the instructions, warnings, and cautions provided with the Guide/Handpiece and Reflector before using.

IMPORTANT

The SCOUT MD Console is intended for use by qualified, trained and authorized physicians and/or operating room staff. Merit Medical, Inc. takes no responsibility for the possible misuse or use by inadequately qualified staff.

Setting up the Console

Warning

• To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
• **Electric Shock Hazard** – Do not connect wet Guide/Handpiece cables to the Console.
• **Fire Hazard** – Do not use extension cords.

1. Verify the Console is off by pressing the power switch off (O).
2. Place the Console on a stable flat surface.
3. Plug the Console power cord into the rear panel receptacle.
4. Insert the power cord into a grounded power outlet.
5. Install the Guide/Handpiece as follows:
   o The white dot on the Guide/Handpiece should be toward the top of the connector
   o Align the Guide/Handpiece with the Guide/Handpiece receptacle on the console
   o Push the Guide/Handpiece into the receptacle until fully seated.

NOTE: User must be able to hear the audible feedback provided by the Console for proper operation. Ensure the speaker grill on the rear of Console is clear of obstruction. Ensure that front panel is visible.

Operating the Console

6. Turn on the Console by pressing the power switch on (|). Verify the following:
   o Display on the console lights up, shows the SCOUT MD logo.
   o After several seconds,the display should show the message SYSTEM READY.
7. Activate the Guide/Handpiece by pressing the START/STOP icon on the display screen of the Console. Verify that the display shows LOCALIZATION MODE, indicating that the Console is ready to operate.
8. Perform the localization procedure by applying the Guide/Handpiece tip to skin or soft tissue. Ensure that no air gaps are present between the Guide/Handpiece tip and tissue.

When the Guide/Handpiece detects the Reflector, the Console will emit an audible feedback that increases in cadence as the Guide/Handpiece is placed closer to the Reflector. The distance reading will decrease as the Guide/Handpiece is placed closer to the Reflector.

9. When initially placed into localization mode, the SCOUT MD system is capable of simultaneously detecting up to four uniquely coded reflectors, identified on the display screen by shape as well as the identification letters A, B, C, D. Note: if multiple reflectors of the same code (e.g. A, A) are placed in the tissue, the system will detect the one that is in closest proximity to the Guide/Handpiece.
10. The SCOUT MD system may also detect and display each coded reflector individually by either depressing the labeled reflector icon at the top of the display screen or by depressing the mode button on the Guide/Handpiece. When using the Guide/Handpiece mode button, depress the button repeatedly until the desired reflector is reached. To return to the ALL DETECTION screen, either touch the RETURN icon on the screen or depress the Guide/Handpiece mode button until the ALL DETECTION screen appears. Note: When in individual detection mode, the system will only detect the coded reflector that is currently displayed.
11. Grounding Lug: The grounding lug is provided for additional grounding of the chassis when required.

NOTE: When not in use, place the Console in Standby mode by pressing the Start/Stop icon. The display will show SYSTEM READY. To return to LOCALIZATION MODE, perform Step 7 again.

After Surgery

12. Turn off the Console by pressing the power switch off (O).
13. Remove the Guide/Handpiece from the front panel
14. Unplug the power cord from the wall outlet.

CLEANING

Warning

• **Electric Shock Hazard** – Always turn off and unplug the Console before cleaning.

Notice

• Do not clean the Console with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the console.

1. Turn off the Console, and unplug the power cord from the wall outlet.
2. Thoroughly wipe all surfaces of the Console, including Guide/Handpiece receptacles, and power cord with a mild cleaning solution or disinfectant and a damp cloth.

Follow universal, generally accepted practices when handling components that have come in contact with blood or tissue.

Follow the procedures approved by your institution or use a validated infection control procedure. Do not allow fluids to enter the Console. The Console cannot be sterilized.

TROUBLESHOOTING

General Troubleshooting Guidelines

If the Console malfunctions, check for conditions that may have caused the problem:

• Check the Console for visible signs of physical damage.
• Verify that the power cord is connected to the Console and power outlet.
• Verify that the Guide/Handpiece cable is connected and attached properly.

Use the table below to help identify and correct specific conditions.

Situation	Recommendation
Display does not light up	• Verify that AC power cord is connected. • Verify that the AC power outlet is live. • Replace power cord. • Replace power fuse (replace with a T 1AL, 250V type fuse).
SYSTEM READY message does not appear	• Verify that the Guide/Handpiece is connected properly. • Turn the Console off, then on again. • Replace Guide/Handpiece. • If symptom persists, the Console may require service. Contact Merit Medical.
CHECK CONNECTIONS message appears	• Completely detach Guide/Handpiece and re-attach to ensure fully connected. • Verify that the Guide/Handpiece is connected properly. connected. • Confirm volume is turned up.• Turn the Console off, then on again. • Replace Guide/Handpiece. • If symptom persists, the Console may require service. Contact Merit Medical.
No sound heard from Console / visual display numbers do not change	• Verify that the console is in LOCALIZATION MODE. • Verify that the Guide/Handpiece is connected properly. • Turn the Console off, then on again. • Replace Guide/Handpiece. •If symptom persists, the Console may require service. Contact Merit Medical.
LOCALIZATION MODE message does not appear	• Press START/STOP icon. • Turn the Console off, then on again. • If symptom persists, the Console may require service. Contact Merit Medical.
Clicking during nonuse of Guide /Handpiece	• Press START/STOP icon, put system in SYSTEM READY • Ensure console is not stacked on top of, or under, other equipment. • Move Guide/Handpiece away from other cables e.g. electrocautery system cable. • Turn the Console off, then on again.
System will not switch between multiple reflectors.	• Press START/STOP icon • Verify that the Guide/Handpiece is connected properly. • Turn the Console off, then on again. • If symptom persists, the Console may require service. Contact Merit Medical.
Distance values flash off and on, shows erratic increase / decrease in values. System shows distance values for reflector shapes that may or may not be present.	Device is experiencing electromagnetic disturbance. Remove any active electromagnetic radiating source such as cell phones, secondary SCOUT MD System, two-way communications device (walkie talkies), RFID devices, or electrocautery devices from the area during the active SCOUT MD localization process. See Recommended separation distances between portable and mobile RF communication equipment and the SCOUT MD System, below.

MAINTENANCE AND SERVICE

The SCOUT MD Console must be serviced by Merit Medical, Inc. To ensure proper performance, the Console should be checked for any signs of damage or wear before each use and storage. This includes the housing, integrity of switches, and power cord. Should abnormalities be discovered by the user, the user should contact Merit Medical, Inc. Do not use a damaged Console.

Preventative maintenance is limited to external cleaning of console, fuse replacement, and confirmation of power up functional diagnostics as described in this manual. The SCOUT console does not require any specific routine service.

The Console contains no user serviceable parts and should not be opened by the user. Please contact Merit Medical for service.

Merit Medical Systems, Inc.
1600 West Parkway Blvd.
South Jordan, UT 84095 USA
www.merit.com

Caution

• If a Console is to be shipped from your institution for repair, then please clean and disinfect the Console as described in this manual before packing for shipment. Indicate on the outside of the shipping container that the Console has been cleaned and disinfected.

Disposal

The SCOUT Console is a reusable device. Should disposal be necessary at the end of its use life, please dispose in accordance with electronic waste procedures.

SYMBOL	DESIGNATION
SN	Serial Number
REF	Catalog Number
	Warning: risk of electric shock. No user serviceable parts inside.
	Refer to instruction manual
	General warning
	Manufacturer
	Identifies a type BF applied part
	Caution
MD	Medical Device.
	'Not for general waste.'
	Date of Manufacture
UDI	Unique Device Identifier
	Consult Instructions for Use. For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, call U.S.A or E.U. Customer Service
EC REP	Authorized Representative in European Community
SYMBOL	**DESIGNATION**
	Non-Sterile
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Do Not Use if Package is Damaged
	Equipotentiality

SPECIFICATIONS

Parameter	Specification
Operating power	AC Line Power 120/240 VAC (50/60Hz)
Power consumption	26 watts, nominal 38 watts, maximum (at high volume)
Audio volume	70 dB Sound Pressure Level at 1 meter
Sound indicator	Frequency proportional to event rate.
Visual Indicators	LCD display with system messages
Instrument make / model	Merit Medical Inc. / SCOUT Console
Dimensions	Width: 30.48cm (12in) Height: 15.24cm (6in) Depth: 30.48cm (12in)
Weight	2.72kg (6 lbs.)
Operating ambient temperature range	10°C to 30°C (50° to 86° F)
Operating relative humidity range	20% to 75%, non-condensing
Storage ambient temperature range	-20° to 60° C (-4° to 140° F)
Storage relative humidity range	10 percent to 95 percent relative humidity, non-condensing
Shipping temperature:	-40°C to 60°C (-40°F to 140°F) for 3 consecutive days.
Shipping humidity:	10% to 95% RH, non-condensing, for 3 consecutive days.
Storage and transit atmospheric pressure	500hPa to 1060 hPa (7.3 psia to 15.4 psia)
Operating altitude	Maximum of 2000m
System Controls	Touch screen icons
Interconnects	Custom cables
Ingress of Fluids	Not protected against the ingress of fluid. IPX0
Flammability	Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or with nitrous oxide
Electrical Conformity	This medical equipment has passed all required testing for electric shock, fire and mechanical hazards in accordance with UL60601-1, IEC/EN 60601-1
Electrical shock protection - Classification	Class I
Electrical shock protection - Degree	Type BF Equipment
Product Life	The Console is a non-sterile, durable good. The product warranty is for a one-year time period consistent with use described in this manual.
Applied Part	The Guide /Handpiece is the patient applied part
Separation from power mains	Power switch on rear panel provides full separation from power mains

EMC Statement
Important information regarding Electromagnetic Compatibility (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation.

Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC 60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

The SCOUT MD System conforms to this IEC60601-1-2:2014 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

• The use of accessories and cables other than those specified by Merit Medical, may result in increased emission or decreased immunity of the device.
• The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.

Refer to further guidance below regarding the EMC environment in which the device should be used.

Electromagnetic Compliance (EMC) Tables

Guidance and manufacturer's declaration - electromagnetic emissions		
The SCOUT MD System is intended for use in the electromagnetic environment specified below. The customer or user of the SCOUT MD System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The SCOUT MD System uses very low power RF energy for its 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 A	The SCOUT MD System is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **WARNING**: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the SCOUT system or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-2	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The SCOUT MD System is intended for use in the electromagnetic environment specified below. The customer or user of the SCOUT MD System 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	±4 kV contact ±8 kV air	±4 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±1 kV for power supply lines ±0.5 kV for input/ output lines	±1 kV for power supply lines ±0.5 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 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SCOUT MD System requires continued operation during power mains interruptions, it is required that the SCOUT System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) 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 U_T is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V*	Portable and mobile RF communication equipment should be used no closer to any part of the SCOUT MD System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m*	Recommended separation distance $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 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 meters (m). Field strength 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. 

Guidance and manufacturer's declaration - electromagnetic immunity			
The SCOUT MD System is intended for use in the electromagnetic environment specified below. The customer or user of the SCOUT MD System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
NOTE 1: At 80MHz and 800MHz, 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 SCOUT MD System is used exceeds the applicable RF compliance level above, the SCOUT MD System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessarily, such as reorienting or relocating the SCOUT MD System. (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 SCOUT MD System

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

Rated maximum output power of transmitter Watts (W)	**Separation distance according to frequency of transmitter in meters (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

MERITMEDICAL®

www.merit.com

Manufacturer:
Merit Medical Systems, Inc.
6 Journey, Suite 125
Aliso Viejo, CA 92656 USA
Customer Service 1-800-356-3748