SCOUT® SURGICAL GUIDANCE SYSTEM

EN INSTRUCTIONS FOR USE

MERITMEDICAL®

SURGICAL GUIDANCE SYSTEM
INTRODUCTION

Caution

• Read all warnings, cautions, and instructions provided with this Console before using.

• Read the instructions, warnings, and cautions provided with the SCOUT Guide, SCOUT Handpiece, and SCOUT Reflector 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® Console, SCOUT Guide, SCOUT Handpiece, and SCOUT Reflector are components of the SCOUT Surgical Guidance System. The SCOUT Console is a medical device that provides control operations for detecting the presence of the SCOUT Reflector within soft tissue during surgery. The SCOUT Handpiece and SCOUT Reflector are available separately.

The SCOUT® System employs micro-impulse radar and infrared light (IR) technology to determine the location of the Reflector, which is placed into the soft tissue during a prior procedure. The Console provides the micro-impulse radar signal to the Handpiece along with power for the infrared light sources. The Handpiece delivers the micro-impulse radar signal and infrared light into the soft tissue and in turn receives signals reflected back from the Reflector. 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 Handpiece and Reflector. The audible feedback produced by the Console increases in cadence as Handpiece is placed in closer proximity to the Reflector. The Console provides a maximum detection range of 60mm from the Handpiece to the Reflector. Excision of the lesion is then performed using standard surgical technique.

The Console and Guide are provided non-sterile. The Handpiece and Reflector (available separately) are provided sterile.

INDICATIONS FOR USE

The SCOUT 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 System) the SCOUT Reflector is located and surgically removed with the target tissue. The SCOUT System is intended only for the non-imaging detection and localization of the SCOUT Reflector that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal.

Contraindications

• The SCOUT System is intended for use in the location of the SCOUT Reflector in soft tissue or biopsy site. The SCOUT System is contraindicated for use in ocular, cardiac, neurological and spinal clinical applications.

Compatible Components

The following items are required for the proper use of the SCOUT Console. Use of other parts and materials not listed below is contraindicated.

• SCOUT Reflector
• SCOUT Handpiece (Disposable Handpiece)
• SCOUT Guide (Multi-Use Handpiece)

WARNINGS AND CAUTIONS

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

Warnings

• 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 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 system. The micro-impulse radar signal may interfere with the intended function of the cardiac implant.

Cautions

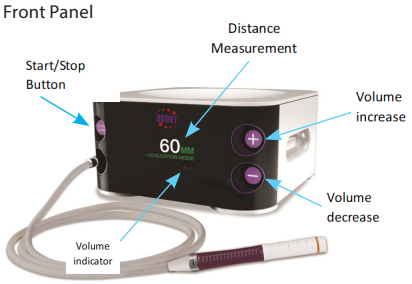
• Read all warnings, cautions, and instructions provided with this Console before using.
• Read the instructions, warnings, and cautions provided with the Handpiece and Reflector before using. Specific instructions are not included in this manual.
• Federal law restricts this device to sale by or on 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 within 10 meters of another Console.
• 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, Handpiece/Cable Assembly, and the Delivery System of the SCOUT System are MR Unsafe and should not be used in the MR environment
• The implanted SCOUT Reflector 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.

CONTROLS, INDICATORS AND RECEPTACLES

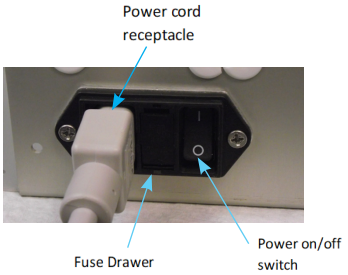
Instrument Description

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 Handpiece's signal.

Front Panel



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 Handpiece and Reflector before using.

IMPORTANT

The SCOUT Console is intended for use by suitably 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 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 Handpiece as follows:
   - o The white dot on the Handpiece should be toward the top of the connector
   - o Align the Handpiece with the Handpiece receptacle on the console
   - o Push the 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 logo.
   - o After several seconds,the display should show the message SYSTEM READY.
7. Activate the Handpiece by pressing the START/STOP button on the front panel of the Console. Verify that the display shows LOCALIZATION MODE, indicating that the Console is ready to operate.
8. Perform a Handpiece test by placing the distal end of the Handpiece near the self-test card
   - o If the test is successful, an audible indication sounds and display reads millimeter measurement.

o If the test is not successful, an audible indication does not sound. See 'Troubleshooting' section of this manual for appropriate steps.

9. Perform the localization procedure by applying the Handpiece tip to skin or soft tissue. Ensure that no air gaps are present between the Handpiece tip and tissue.
   When the Handpiece detects the Reflector, the Console will emit an audible feedback that increases in cadence as the Handpiece is placed closer to the Reflector. The distance reading will decrease as the handpiece is placed closer to the Reflector.

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

After Surgery

10. Turn off the Console by pressing the power switch off (O).
11. Remove the Handpiece from the front panel
12. 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 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 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 Handpiece is connected and attached properly. • Turn the Console off, then on again. • Replace Handpiece. • If symptom persists, the Console may require service. Contact Merit Medical.
CHECK CONNECTIONS message appears	• Completely detach Handpiece and re-attach to ensure fully connected. • Verify that the Handpiece connections are connected and attached properly. • Turn the Console off, then on again. • Replace 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 Handpiece connections are connected and attached properly. • Turn the Console off, then on again. • Replace Handpiece. • Use self-test card to check for system function. •If symptom persists, the Console may require service. Contact Merit Medical.
REPLACE HANDPIECE message appears (for disposable handpiece only)	• Handpiece has expired and will need to be replaced. • Turn power off, replace handpiece then turn power on.
LOCALIZATION MODE message does not appear	• Press START/STOP button • Turn the Console off, then on again. • If symptom persists, the Console may require service. Contact Merit Medical.
Clicking during nonuse of handpiece	• Press START/STOP button, put system in SYSTEM READY • Ensure console is not stacked on top of, or under, other equipment. • Move handpiece away from other cables e.g. electrocautery system cable • Turn the Console off, then on again.

MAINTENANCE AND SERVICE

The SCOUT 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.

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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.

SYMBOL	DESIGNATION
SN	Serial Number
REF	Catalog Number
	Warning: risk of electric shock. No user serviceable parts inside.
	See instructions for use
	General warning
	Manufacturer of the device
	Identifies a type BF applied part
	Caution: Consult accompanying documents
MD	Medical Device.
	"For European Union (EU) States, this symbol indicates 'Not for general waste.' Dispose of in accordance with the waste electronic & electrical equipment (WEEE) directive."

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	12 inches width 6 inches height 12 inches depth
Weight	6 lbs.
Operating ambient temperature range	10°C to 30°C (50° to 86° F)
Operating relative humidity range	30% to 75%, non-condensing
Storage ambient temperature range	-20° to 60° C (-40° to 104° 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	Buttons
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

Parameter	Specification
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 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 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 System is intended for use in the electromagnetic environment specified below. The customer or user of the SCOUT 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 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.

Guidance and manufacturer's declaration - electromagnetic emissions		
The SCOUT System is intended for use in the electromagnetic environment specified below. The customer or user of the SCOUT System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Class A	The SCOUT 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 System is intended for use in the electromagnetic environment specified below. The customer or user of the SCOUT 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	±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 % 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 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	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The SCOUT System is intended for use in the electromagnetic environment specified below. The customer or the user of the SCOUT System should assure that it is used in such an environment.			
*NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**

Guidance and manufacturer's declaration - electromagnetic immunity			
The SCOUT System is intended for use in the electromagnetic environment specified below. The customer or user of the SCOUT System 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 V*	Portable and mobile RF communication equipment should be used no closer to any part of the SCOUT 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 2.5 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 2.5 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 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. 
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 System is used exceeds the applicable RF compliance level above, the SCOUT 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 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 System			
The SCOUT System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SCOUT System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SCOUT 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.			

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