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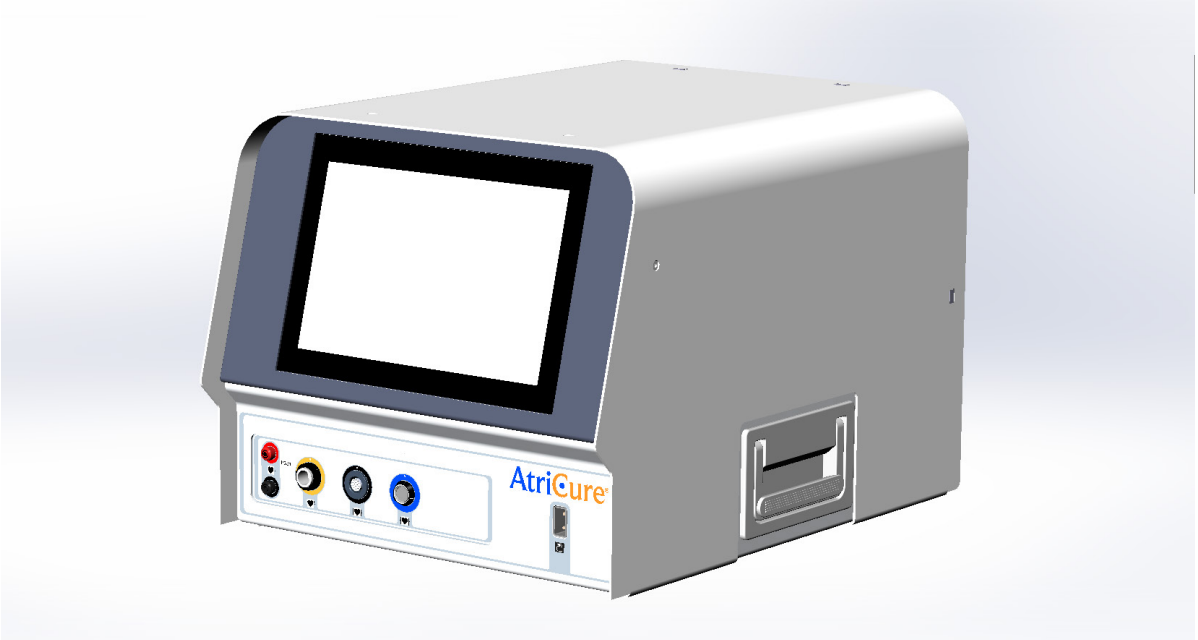
CE 2797

AtriCure®



Multifunctional Ablation Generator (MAG™) Instructions for Use

MAG

REF A001463

Rx ONLY MD

⚠ **Caution: Federal law (US) restricts this device to sale by or on the order of a physician.**

AtriCure Inc.
7555 Innovation Way
Mason, Ohio 45040 USA
+1 866 349 2342
+1 513 755 4100

EC REP European Representative:
AtriCure Europe B.V.
De entree 260
1101 EE Amsterdam
NL
+31 20 7005560
ear@atricure.com

Australian Sponsor Name:
AA-Med Pty. Ltd.
Address:
Suite 10.04, 1 Chandos Street
St Leonards NSW 2065
Australia
Tel: 1300 887 807

BR REP

Commercial Name: Multifunctional Ablation Generator (MAG)
Technical Name: RF Ablation Equipment
Contents:
Unit IFU(s)
01 Unit of the Multifunctional Ablation Generator
01 Unit Footswitch
01 Unit Power Cord

ANVISA Registration n°: 80117581115

Registration Holder: Emergo Brazil Import Importação e Distribuição de Produtos Médicos Hospitalares Ltda. Avenida Francisco Matarazzo, 1.752, Salas 502/503, Agua Branca, São Paulo-SP, CEP – 05001-200 CNPJ: 04.967.408/0001-98

Email: brazilvigilance@ul.com

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FOREWORD

This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. This manual includes the instructions for use for the AtriCure Multifunctional Ablation Generator, also referred to as "MAG" through the manual.

⚠ WARNING ⚠

Read all information carefully. Do not operate the MAG or other devices described in the manual before reading the manual. Failure to properly follow the instructions may lead to serious surgical consequences.

Use only with Handpieces, footswitch, and other products supplied by AtriCure and approved for use with the MAG. The use of any products not approved or supplied by AtriCure may result in increased emissions or decreased immunity of the equipment.

Installation of the MAG, as well as any service needs or repairs, must be performed only by an authorized AtriCure service representative.

Indication For Use

The MAG Generator is indicated to transmit radiofrequency (RF) energy to compatible AtriCure ablation handpieces for treatment of arrhythmias including atrial fibrillation.

Intended Purpose

The MAG Generator is a non-sterile, reusable medical device intended to transmit radiofrequency (RF) energy to compatible AtriCure ablation handpieces for ablation of cardiac tissue.

Intended User

Licensed medical doctors who perform cardiac and/or thoracic surgical procedures using AtriCure instrumentation.

Target Patient Population

Adult patients with arrhythmias including atrial fibrillation.

Clinical Benefit

To achieve the clinical benefit of compatible AtriCure ablation handpieces.

Serious Incident Statement

Any serious incident that has occurred in relation to this device should be reported to AtriCure and the competent authority of the Member State in which the user and/or patient is located.

Summary of Safety and Clinical Performance

A summary of the safety and clinical performance of the device can be found in the European database on medical devices (EUDAMED) at https://ec.europa.eu/tools/eudamed by entering the Basic UDI-DI associated with the device.

Product Code(s)	Basic UDI-DI
MAG	08401439000000000000020ZF

Contraindications

The system is contraindicated for

- Tissue coagulation in any situation where, in the physician's opinion, excessive thermal damage to tissue, or collateral damage to adjacent tissue not intended for coagulation may result.
- Use in the presence of internal or external pacemakers or internal cardioverter / defibrillators (ICDs) and monitoring equipment may require special considerations.

Warnings and Cautions

The safe and effective use of the AtriCure generator, handpieces, and equipment is highly dependent upon factors under the control of the operator. There is no substitute for a properly trained operating room staff. It is important that the operating instructions supplier with the AtriCure MAG Generator be read, understood, and followed before use.

⚠WARNINGS

- To prevent risk of infection, keep the MAG outside of the sterile field.
- Do not use excessive force to connect handpieces, footswitch or power cord as it could prevent RF energy delivery to the handpieces.
- Only use cleaning agents identified within the cleaning section to prevent infection and damage to the MAG.
- Ensure there is sufficient space between the MAG and nearby objects that may damage the screen or connectors preventing use of the unit.
- Do not remove the cover of the MAG as there is a potential for electrical shock. Refer to authorized personnel for service.
- Do not connect products with a wet cable or connector to the generator as this may cause a device malfunction.
- To prevent electrical shock, ensure that the mains power supply is isolated, and that attached equipment is also electrically isolated and does not pose an electrical hazard.
- To prevent electrical shock, connect the MAG Power Cord to a properly grounded receptacle.
- To prevent electrical overload, do not use power adapters or extension cords.
- To correctly operate the MAG, connect the power cord to a power source with the frequency and voltage characteristics that match those on the back panel of the MAG.

- To avoid electrical shock, do not touch the MAG and the patient at the same time.
- To avoid shock, do not allow patients to contact earthed metal parts of the MAG.
- When the MAG is activated, the conducted and radiated electrical fields may interfere with other electrical medical equipment, such as monitors and imaging equipment causing equipment malfunction.
- To ensure that this device meets specifications, no modification of this equipment is allowed. Do not install any other software on the MAG.
- Use only with products supplied by AtriCure and compatible for use with the MAG. The use of any products not compatible or supplied by AtriCure may result in increased emissions or decreased immunity of the equipment.
- Do not perform procedures if flammable or explosive media are present.
- When multiple footswitches are present in the operating space, verify proper footswitch is selected prior to activating MAG. Inadvertent activation of RF could lead to user burn or unintentional ablation.
- Inspect the MAG, instruments and cables for damage prior to each use. Insulation failures may result in burns or other injuries to the patient or operator.
- Stop delivering RF energy if neuromuscular stimulation is observed.
- Do not use in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.
- When more than one handpiece is being used in a procedure, isolate the inactive handpiece(s) from the patient to prevent injury or inadvertent ablation.
- Do not activate RF energy to the Handpiece when not in contact with target tissue, as this may cause injuries due to capacitive coupling with other surgical equipment.
- To avoid burns, do not touch the active electrode.
- To avoid alternate site burns, prevent skin to skin contact by placing dry gauze between areas of contact.
- To prevent patient burn at the neutral electrode site only use an adult Patient Return Electrode with Contact Quality Monitoring (CQM) or Return Electrode Monitoring (REM).
- Do not operate the MAG before thoroughly reading this manual. The safe and effective use of RF energy is highly dependent upon factors under the control of the operator.
- Do not use the MAG unless properly trained to use it in the specific procedure being undertaken. This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed.
- When transporting or handling the MAG, use caution and care to avoid product damage.
- Use gloves when setting up and operating the MAG.
- While using the MAG touchscreen for RF activation, avoid touching the screen in two locations simultaneously to prevent unintended ablation of tissue.
- When used with products that require fluid cooling, set up the MAG so that it is not in proximity to the fluid cooling subsystem to protect the generator from any ingress of fluid.
- Make sure there are no obstructions underneath or the rear of the MAG to provide sufficient air flow for cooling.
- Only use as marked fuses to ensure the MAG is protected and functioning as intended.
- To ensure correct operation, the MAG should not be used adjacent or stacked with other equipment, except for intended stacking with AtriCure's equipment in accordance with the instructions. The MAG normal use configuration should be observed to verify normal operation.

⚠CAUTION

- Inspect all products and packaging before use. If any breach in the packaging or damage to the product is found, the product should not be used.
- To prevent device malfunction, do not install any other software on the MAG.
- To avoid interference, place monitoring electrodes as far as possible from surgical electrodes when High Frequency (HF) surgical and physiological monitoring equipment used simultaneously on the same patient. Needle monitoring electrodes should not be used under any circumstances. Position patient leads in such a way that contact with the patient or other leads is avoided. Use monitoring systems incorporating HF current-limiting devices.
- The audible tone and indicator are important safety features. Do not obstruct the audible indicator. Ensure that the audible tone can be heard by personnel in the operating room prior to use. The audible tone alerts personnel when the Handpiece is active; refer to Table 5. Do not disable the audible tone.
- Standard care should be used to reduce the risk of tripping on the Footswitch cable.
- The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated.

Manual Conventions

"MAG" and "generator" are used to refer to the AtriCure Multifunctional Ablation Generator.

"Handpiece" refers to devices manufactured or for by AtriCure that are used with the MAG, including Isolator Pens, Synergy Clamps, and EPi-Sense devices.

Meaning of Symbols on MAG Generator

	Defibrillator-proof Type CF Applied Part	F	F-Type Applied part	IPX 1	Protected against water drop falling vertically
	Caution		Follow Instructions for Use	LATEX	Does Not Contain Latex
	Non-ionizing radiation		Waste Electrical and Electronic Equipment (WEEE)	2x 6.3A 250V	Fuse Rating
UDI	Unique Device Identifer	#	Model Number	PHT	Does Not Contain Phthalates
NON STERILE	Non-Sterile	REF	Catalog Number	3	Maximum Stack Quantity
	Manufacturer information	US	Date and Country of Manufacture	Rx ONLY	Caution: Federal law (US) restricts this device to sale by or on the order of a physician.
SN	Serial Number		Indifferent, Dispersive Electrode	MD	Medical Device
CE 2797	Conforms to the requirements of the European Directives and Regulations	EC REP	Authorized Representative in the European Community	85% % 30%	Transit Humidity Range
140°F (60°C) -20°F (-29°C)	Transit Temperature Range				

Symbols Specific to Brazil

Segurança Compulsório INMETRO INMETRO	National Institute of Metrology Standardization and Industrial Quality	BR REP	Authorized representative in the Brazilian Community
85%rH % 30% Limite de umidade de transporte: Umidade: 30% a 85% Transit Humidity Range	140°F (60°C) -20°F (-29°C) CONDIÇÕES DE ARMAZENAMENTO: Temperatura: -29°C a 60°C Transit Temperature Range		Instruções de Uso Advertências e Precauções: Vide Instruções de Uso Follow Instructions for Use

Safety Mark Information

MEDICAL — GENERAL MEDICAL EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012), C1:2009/(R)2012 and A2:2010/(R)2012

CAN/CSA C22.2 No. 60601-1 (2014)

IEC 60601-1:2005, AMD1:2012

IEC 60601-1:2012 / MDFS No. 2020-12, Annex 1

SYSTEM DESCRIPTION

Multifunctional Ablation Generator (MAG)

The MAG is an electro-mechanical ablation system that utilizes both monopolar and bipolar radio frequency (RF) energy to ablate biological tissue. The MAG can be used with a variety of AtriCure Handpieces to perform cardiac ablations.

The MAG is a portable, reusable device that produces and delivers RF monopolar and bipolar energy at 460kHz. It includes a touchscreen display with controls that can be operated with a surgical gloved hand.

RF ablation can be activated (or stopped) by the RF ON button on the touchscreen or by a footswitch. Upon reaching a predetermined threshold (voltage and/or current relationship), the MAG provides visual and audible indications to signal the end of the ablation cycle.

Only the components and products listed below are compatible for use with the MAG.

Components provided with the MAG™

A001463 includes	Part Number	Quantity
MAG	A001463-D	1
Footswitch, FSW2	A001356	1
Cable, Packaged, PSS Interface	A001467	2
Power Cord - Euro, Straight 3.5M, 10A, 250V	C002090	1
Vacuum Adapter	A001091	1

Country-specific component addition (if required)

Country Code	Part Number
EU	A001427
GBR	A001428
ITA	A001429
DNK	A001430
CHE	A001431
BRA	A001511
AUS	A001512

Auxiliary devices compatible for use with the MAG

- Any AtriCure Isolator™ Handpieces
- Any AtriCure Transpolar™ Pens
- Any AtriCure Coolrail™ linear pen
- Any AtriCure EPi-Sense® Coagulation Devices

*Not all products are approved for use in all regions

Display Screen

The MAG uses a touchscreen display for operation. See Figure 1. MAG Front Panel.

The HDMI Connection at the rear of the MAG can be used to provide a remote display of the display content. See "Figure 2.MAG Back Panel." It is required that a ferrite shielded HDMI cable be used for display screen output and connection to the remote display.

The MAG was tested using an HDMI cable (Tripp Lite PN: P569-020-CL2) with two ferrite cores (Laird-Signal Integrity Products PN: 28A087-0A2) placed on the outside of the cable.

⚠ WARNING ⚠

Use of a different HDMI cable than specified can result in interference potentially resulting in medical device equipment malfunction.

Front Panel

The MAG front panel and its connection ports are shown below.

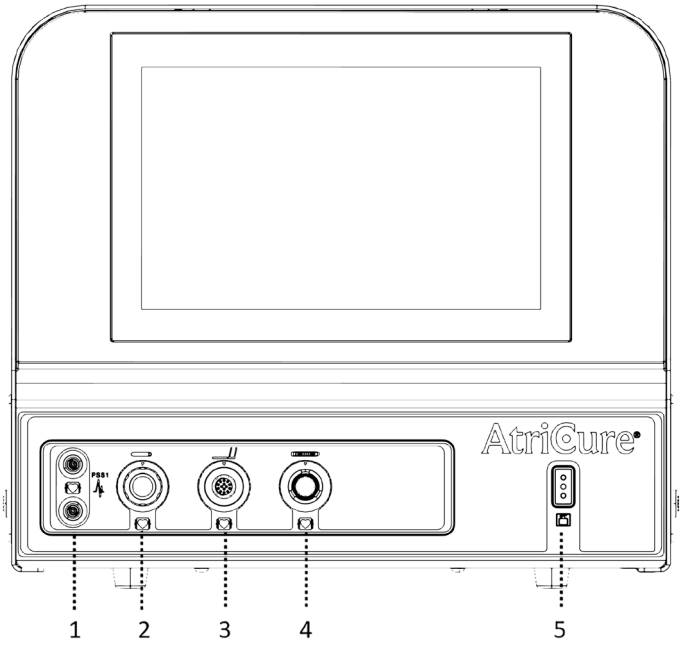
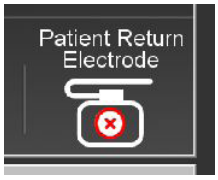


Figure 1. MAG Front Panel

1. Sense-Pace Input (MLP)
2. Pens Receptacle
3. Clamp Receptacle
4. EPi-Sense Receptacle
5. Return Electrode Receptacle

Parts of the Touchscreen Display

	**Clamp Handpiece icon.** During ablation, the graph shows Tissue Conductance on the y-axis and Time on the x-axis (Bipolar ablation).		**EPi-Sense® Handpiece icon.** During ablation, the graph shows Impedance and Power on the y-axis and Time on the x-axis (Monopolar ablation).
	**Pen Handpiece icon.** During ablation, the graph shows Power on the y-axis and Time on the x-axis. MAX1, MAX3, and MAX5		**Pen Handpiece icon.** During ablation, the graph shows Power on the y-axis and Time on the x-axis. MLP1
	**Pen Handpiece icon.** During ablation, the graph shows Power on the y-axis and Time on the x-axis. MCR1		**Patient Return Electrode icon.** This icon is active when a Patient Return Electrode is connected (split ground pad). A green checkmark indicates good connection.
	**Patient Return Electrode icon.** This icon is active when a Patient Return Electrode is connected (split ground pad). A red X indicates a bad connection or an invalid pad.		**Patient Return Electrode icon.** This icon is active when a Patient Return Electrode is connected (split ground pad). NR text indicates "Not Required".
	**Ablate** – When active the MAG is in Ablate mode.		**Sense / Pace** – When active the MAG is in Sense / Pace mode.

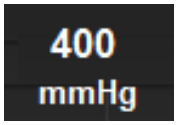
	**Sense** – When active the MAG is in Sense mode.		**Settings menu** — Use this menu to view and adjust the date/time, brightness of the screen, volume of the audio tones, software version, power down (off) function and device-specific settings.
	**Help Menu** – Use this button to view instructions for the active handpiece.		**RF ON button.** If Footswitch is not connected, press and hold (Pens, Clamps), or press and release (EPi-Sense) this button to start RF energy (to perform ablations). To stop RF energy, release (or press and release) this button again.
	Vacuum Pressure **(if using)**: Displays vacuum readings for EPi-Sense devices.		**Footswitch (if using)**: To start RF energy (to perform ablations), press and hold the Footswitch (Pens and Clamp Handpieces) or press and release the Footswitch (EPi-Sense Handpieces). To stop RF energy, release the Footswitch (Pens and Clamps) or press and release the Footswitch (EPi-Sense).

Table 1. Parts of the MAG Touchscreen

Back Panel

The MAG back panel connections are shown below.

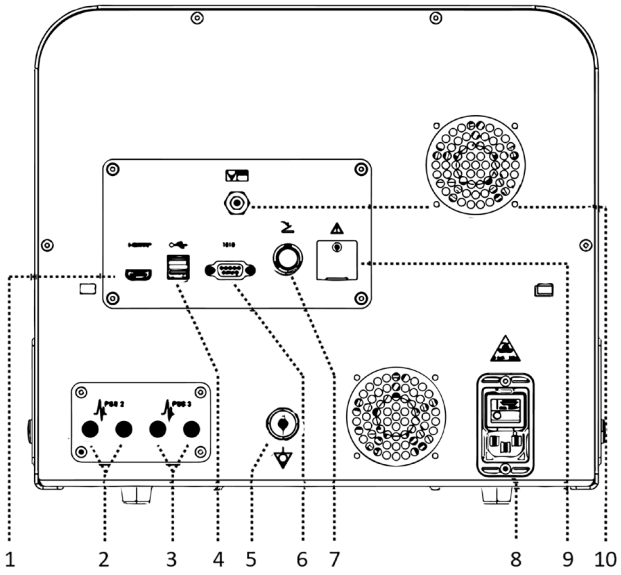


Figure 2. MAG Back Panel

1		HDMI port	Connection for HDMI Compatible monitor for remote display of Operator Screen (must be approved to IEC60950) and appropriate EMC standards.
2		Pen Sense / Pace pass-through	Connection for compatible electrophysiology equipment (must be approved to IEC60601-1), for Sense / Pace pass-through.
3		EPi-Sense Distal-Sense pass-through	
4		USB port	Connection for USB 2.0 or equivalent device only (e.g., USB Memory device), for storing data.
5		Equipotential Connector	Provides a means of securely linking the earth grounds of the MAG to other grounded equipment. For use only by authorized AtriCure service representatives.
6		Serial port	For future use.

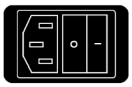
7		Footswitch	Connection for footswitch--use with AtriCure footswitch only.
8		Power Switch	This module contains both the ON/OFF switch and the fuses.
9		Service port	For use only by authorized AtriCure service representatives.
10		Vacuum port	Connection for -500mmHg vacuum source, used with AtriCure EPi-Sense Handpieces.

Table 2. MAG Back Panel Connections

The MAG operates in five modes: STANDBY, READY, RF ON, ERROR and FAULT.

MAG Operating Mode	Function
STANDBY Mode	STANDBY Mode is active after the MAG has been powered ON and successfully passed the self-tests. In STANDBY Mode, the footswitch and the Handpiece may be connected. After the Handpiece has been connected, the MAG will switch to the READY Mode.
READY Mode	READY Mode is active after at least one Handpiece has been connected in the STANDBY Mode, or from the RF ON Mode after RF has been stopped. **Note:** EPi-Sense devices deliver a pulse of RF every 3 seconds to measure impedance. If the MAG detects that a Handpiece has been disconnected, the MAG will switch back to STANDBY Mode if no Handpieces are connected.
RF ON Mode	⚠**Caution:** Ensure that the Handpiece is positioned on patient tissue before pressing RF ON. To activate RF energy, use the touchscreen display, OR the footswitch. When the RF Activation is stopped, the RF output timer will be reset in preparation for the next ablation cycle—and the MAG will return to READY Mode. If the MAG detects that no Handpieces are connected, the MAG will switch back to STANDBY Mode.
ERROR Mode	The MAG will enter the ERROR Mode if it detects any recoverable error conditions during any Mode except for the FAULT Mode (described below). The MAG displays the corresponding error message. If the selected Handpiece is disconnected, the MAG will transition from Error Mode to STANDBY Mode or READY Mode if another Handpiece is connected.
FAULT Mode	The MAG will enter the FAULT Mode if a non-recoverable error condition is detected during any operating mode or as a result of failing a non-recoverable self-test. The MAG is inoperable (and RF energy is disabled) in the FAULT mode. To clear the FAULT Mode, turn the MAG power OFF and then ON again.

Table 3. MAG Operating Modes

TECHNICAL SPECIFICATIONS

RF Output

- Frequency: 460 kHz ±5%, Quasi-sinusoidal
- Accuracy: ±20% from 4W-100W
- Resolution: 1 W increments
- RF Power and Voltage Output:

Handpiece Type	Device Code	Default Maximum Power	Maximum Output Power	Rated Load	Monopolar/ Bipolar	Maximum Output Voltage	Maximum Output Current
Isolator® Pens	B	15W	18W	200Ω	Bipolar	77.5Vrms	0.8A
Isolator® Linear Pen	C	20W	24W	200Ω	Bipolar	77.5Vrms	0.8A
Isolator® Synergy™ Clamp	G	28.5W	34.2W	114Ω	Bipolar	57.0Vrms	0.8A
Isolator® Coolrail® Linear Pen	L	30W	36W	100Ω	Bipolar	77.5Vrms	0.8A
EPi-Sense® 3cm / EPi-Sense ST 3cm	W	30W	72W	100Ω	Monopolar	170Vrms	0.9A

Table 4. RF Output

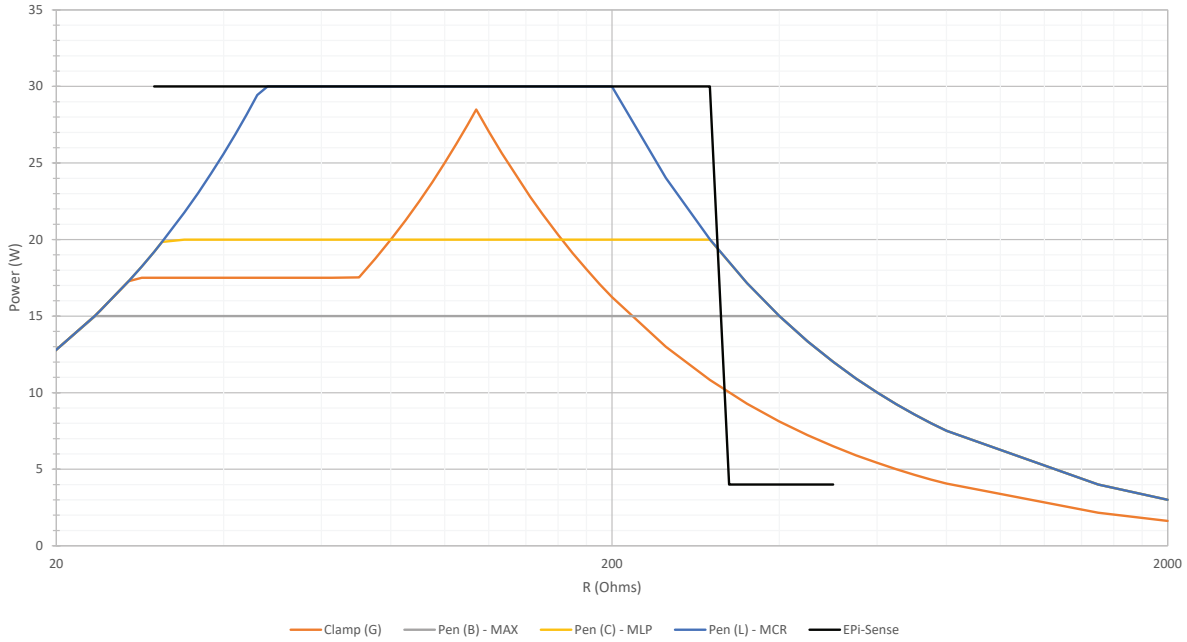


Figure 3. Load Curves for Pens, Clamps and EPi-Sense

Time

- Accuracy: 1 second from 1-150 seconds
- Resolution: 1 second increments

Impedance

- Accuracy: +/-10% from 25-500 Ohms
- Resolution: 1 Ohm increments

Conductance

- Accuracy: +/- 10% from 1-30 milliSiemens
- Resolution: 1 milliSiemen

Pressure

- Accuracy: +/- 10% from 0 to -650 mmHg
- Resolution: 1 mmHg

Environmental Specifications

- Operational temperature: 10° C to 40° C (50° F to 104° F)
- Transit temperature: -29°C (-20° F) to 60° C (140° F)
- Storage temperature: –40° C (-40° F) to +60° C (140° F)
- Operational Humidity: 10% to 90% relative humidity
- Transit Humidity: 30% to 85% relative humidity

Mechanical Specifications

- Size: 15”w x 12”h x 18”d (38cm x 30cm x 46cm)
- Weight: 23lbs (10.4kg)

Electrical Specifications

- 100-240V ~ 50-60 Hz
- 475VA

Software Specifications

- Software Version: 01.02.00

Device Specifications

- Class I Equipment.
- Defibrillation Proof Type CF Applied Part.
- Meets relevant clauses of IEC60601-2-27 for connection to external ECG Equipment.
- Generator meets IPX1 Requirements for protection against fluid ingress.

Fuses

- Replace fuses as marked: Fuse rating is 6.3A/250V Fast Blow, 5 x 20mm, UL Recognized.
- Fuse replacement must be handled only by authorized service representatives.

Footswitch Specifications

- Moisture protection rating: IPX8

PLACING, STORING, TRANSPORTING AND CONNECTING THE MAG

Placement of the MAG

Prior to placing the MAG, inspect both the packaging and the MAG unit for physical damage.There should be no damage to the front panel or enclosure of the unit to ensure it performs as expected. The MAG may be placed on a mounting cart or on any table or platform capable of supporting the weight of the MAG. Carts must have conductive wheels (designed to dissipate static electricity). Refer to hospital procedures or local codes for detailed information.

The MAG is non-sterile and must be placed outside the patient vicinity (outside the sterile field). The MAG console must not contact the patient.

The MAG should not be used adjacent or stacked with other equipment, except for intended stacking with AtriCure’s equipment in accordance with the instructions. See the AtriCure “AtriCure System Cart” instructions for use document.

Storing the MAG

The MAG is capable of being stored at the temperatures listed in the Environmental Specifications section.

If the MAG has been exposed to temperature and humidity levels outside normal limits of hospital operating rooms, allow the generator to stabilize at room temperature prior to use.

Transporting the MAG

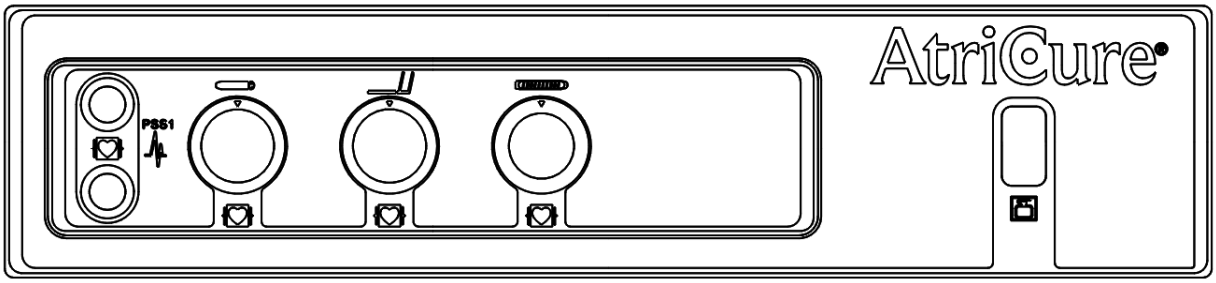
Any time that the MAG is moved, refer to these instructions to ensure that the MAG is secured safely in place.

- The handles may be used to carry the MAG.
- Do not stack packaged MAGs more than three (3) high on a pallet.

Connecting the Handpiece

Refer to the specific Handpiece instructions for use for more detailed information about connecting a Handpiece, cables, and Indifferent, Return Electrode to the MAG in a sterile environment.

Connect the Handpiece to the MAG front panel—see Figure 4. Each receptacle is keyed to aid alignment.



Sense/Pace **Pen** **Clamp** **EPi-Sense** **Return Electrode**

Figure 4. Patient connections—MAG front panel.

⚠**CAUTION:** Do not force connectors into receptacles as this may result in damage to the receptacle or to the connector.

⚠**CAUTION:** Do not connect products with a wet cable or connector to the generator as this may cause a device malfunction.

Typically, the Handpiece is connected to the MAG after the MAG has been powered up and is in STANDBY operating mode (see page 7). However, the Handpiece also can be connected before powering up the MAG.

Disconnecting the Handpiece

To disconnect the Handpiece, pull back on the cable connector body and remove it from the receptacle on the front panel of the MAG. Do not pull on the cable to disconnect the Handpiece, as this may cause damage to the cable, and to the MAG.

Connecting and Disconnecting the Footswitch

Prior to using the footswitch, inspect the cable, connector, and the footswitch housing for physical damage.There should be no damage to the unit to ensure it performs as expected. Typically, connect the footswitch after the MAG has been powered up and is in STANDBY mode. However, the footswitch may be connected before the MAG has been powered up.

Connect the footswitch cord to the receptacle at the back of the MAG. The receptacle is keyed to aid alignment. Do not force connectors into receptacles as this may result in damage to the receptacle or to the connector.

See "Figure 2. MAG Back Panel Connections." The MAG display screen has an indicator that shows if the footswitch is connected. If the footswitch does not indicate that it is connected, check that the connector is fully inserted into the receptacle.

Place the footswitch on a flat floor. Keep the area near the footswitch dry to reduce the risk of slippage.

⚠**CAUTION:** Trip Hazard—Take appropriate precautions to ensure that the cable connecting the footswitch to the MAG does not create a hazard in the operating room (for example, do not place the footswitch in an area that it will likely be tripped over).

Use of the footswitch is optional. If the footswitch is connected, it must be used to start and stop RF energy to perform an ablation (the RF button is not available while the footswitch is connected).

INSTRUCTIONS FOR USE

Powering Up the MAG

⚠ WARNING ⚠

Connect products to the MAG only when RF energy is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.

USE GLOVES WHEN OPERATING THE MAG

1. Connect the provided power cord to the back of the MAG. See "Figure 2. MAG Back Panel Connections."
2. Make sure that power cord is fully seated in the receptacle.
3. Plug the MAG into a grounded power outlet.
   - Do not use multiple-outlet sockets, extension cords or three-prong to two-prong adapters. Periodically check the power cord assembly for damaged insulation or connectors.
   - Ensure that access to the power cord outlet is maintained, so that the power cord can be quickly removed in the event of an emergency.
4. If using the footswitch, make sure that it is connected. See "Figure 2. MAG Back Panel Connections."
5. If using an external pacing system for emergency pacing, make sure that it is available and powered up.
6. Check MAG and all connected cables for damage and that proper cleaning has taken place prior to powering on the unit.
7. Turn the power on using the ON/OFF switch located on the back panel. See "Figure 2. MAG Back Panel Connections."

8. After it has been powered up, the MAG performs initialization tasks such as System Self-Tests. The Self-Tests generate two quick beeps at startup.

Figure 5. Touchscreen Display showing System Initializing

9. Verify that the beeps are generated.
10. If all Self-Tests pass, the MAG transitions to the STANDBY mode.
11. If any Self Test fails, the MAG will emit a constant audible tone and will go into the FAULT mode. For more information, see the "FAULT Mode" section.
12. Connect the Handpiece and any needed products.
13. For more information about specific Handpieces, see "Using Handpieces with the MAG."

FAULT Modes

If the MAG fails a self-test after it is powered up or if a non-recoverable error condition is detected at any time, the MAG enters FAULT mode. A Fault code number will be displayed on screen.

The MAG is inoperable in the FAULT mode. RF energy is disabled during the FAULT Mode.

To clear the FAULT Mode, turn the MAG power OFF and then ON again.

Recoverable error messages will stay on the LCD display until RF energy is initiated by the footswitch, or the message is cleared from the screen. Other messages will stay on the LCD display until the error is corrected (e.g. until an expired Handpiece is removed).

System Menu


To select the System menu, press the Symbol in the upper left of the touchscreen.

Use the System menu to view and adjust the date/time, brightness of the screen, volume of the audio tones, software version, and device-specific functions. Software updates are managed by AtriCure.

Figure 6. System Menu

Languages

To change the selected language:

1. Press the Settings button
2. Press the Language button
3. View and select the preferred language
4. Press the Save button to initiate the selection
5. Confirm Language Selection following prompt
6. After 10 seconds, power cycle the generator to display selected language

Available Languages

- Albanian
- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- Estonian
- Finnish
- French
- German
- Greek
- Hungarian
- Icelandic
- Italian
- Latvian
- Lithuanian
- Norwegian
- Polish
- Portuguese
- Romanian
- Russian
- Serbian
- Slovak
- Slovenian
- Spanish
- Swedish
- Turkish
- Japanese
- Chinese
- Korean
- Brazilian Portuguese

Figure 7. Language Selection Screen

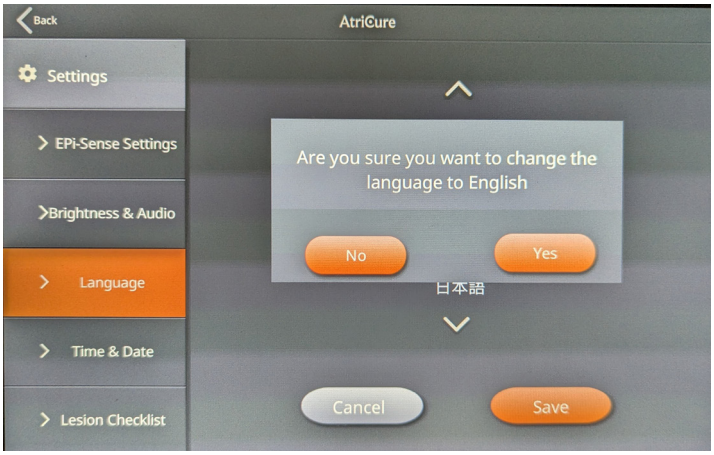


Figure 8. Language Selection Save Screen

Footswitch Actions

When the footswitch is connected, the Footswitch icon will be displayed. When footswitch is attached, it must be used to start and stop RF energy (the RF button is not available while the footswitch is connected).

If the footswitch is continually pressed but RF delivery mode has ended, RF delivery will not be restarted until the footswitch is released.

To provide a continuous RF delivery, the footswitch operation is:

- Clamp: Press and Hold
- Pen: Press and Hold
- EPi-Sense: Press and release

Audible Tones

The MAG uses different audible tones during its operation, as shown below. To control the volume of these tones, use the Volume Control in Settings. See the following table for descriptions of the audio tones.

Audible Tone	Tone Description	Meaning of tone:
Start Tone	Two quick beeps	Generated when the power switch is placed in the ON position.
Error Tone	Constant medium-pitched tone	Occurs while a recoverable error is present.
Fault Tone	Rapid succession of medium-pitched beeps for 2 seconds duration	Occurs upon entering the FAULT mode.
RF ON - Constant	Constant low-pitched tone	Generated when RF energy is being delivered to the Clamp Handpieces. This tone has a higher pitch than the Error tone.
	Varying low-pitched tone	A discrete, decrementing tone in 10 second intervals is generated when RF energy is being delivered to the Pen Handpieces. The starting tone is a higher pitch than the Error tone.
RF ON - Intermittent	Intermittent low-pitched tone	A 0.2 second tone, emitted once per second when RF energy is being delivered to the EPi-Sense Handpiece.
Transmurality Tone	Intermittent low-pitched tone	Generated in the RF ON mode when Transmurality is achieved with a Clamp Handpiece. The Transmurality tone will continue—and RF energy will continue to be applied—until the RF ON button/footswitch is released or until 40 seconds has elapsed.

Table 5. Audible tone descriptions.

USING HANDPIECES WITH THE MAG

Pen Handpieces: Sensing and Pacing

1. This procedure focuses on the operation of the MAG, ensure that the specific Pen Handpiece instructions for use is read and understood.

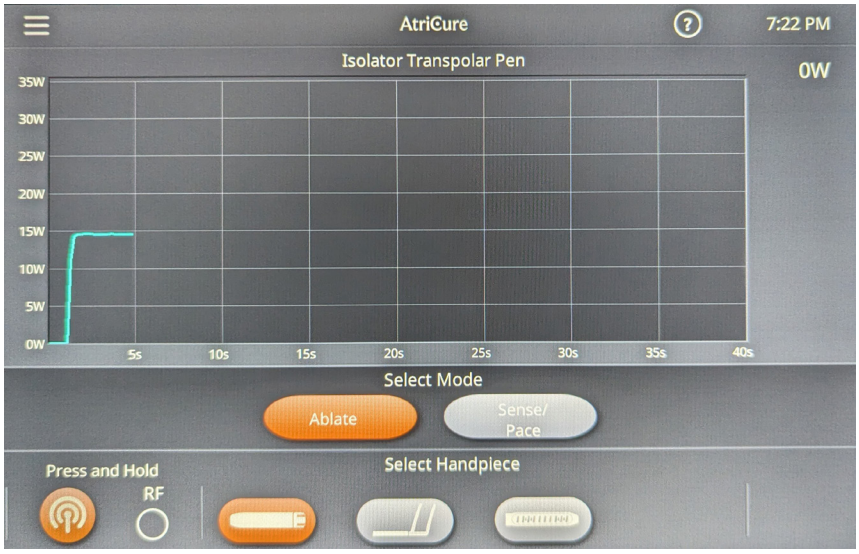


Figure 9. Pen Handpiece Screen.

2. Verify that the MAG has been powered ON and has successfully passed the Self-Tests.
3. Refer to the Pen Instruction for Use for details on how to remove the Pen from its sterile packaging.
4. With the Connector Alignment Arrow symbol in the 12 o'clock position, insert the connector into the receptacle on the MAG front panel. Refer to Figure 1.
5. The MAG will automatically detect that the Pen is connected. The Pen button will be illuminated (orange) and will be in Ablation mode.
6. If applicable connect the Red and Black Pacing Connections to the PSS1 socket. Refer to Figure 1.
7. Press the Sense/Pace mode button on the screen.
8. Connect the PSS Interface Cable to the external ECG monitoring or sense/pace equipment.

Pen Handpieces: Performing Ablation

1. The MAG will automatically detect that the Pen is connected and will illuminate the Pen button on the touchscreen display. The type of Pen device will be shown on the screen
2. Position the Pen electrodes on patient tissue.
3. To start RF energy, press and hold the RF ON button (Figure 7) on the touchscreen OR press and hold the footswitch.
4. The Pen Handpieces will automatically set the appropriate ablation time settings on the MAG. The RF ON button will be illuminated on the display screen. The MAG will emit an audible tone indicating that current is flowing between the ablation electrodes of the Pen through the tissue.
5. Use the display screen to monitor the ablation and listen to the audible tone to monitor the progress of the ablation.
6. Release the RF ON button (Figure 7) on the touchscreen OR release the footswitch to stop RF energy.
7. Operate the Pen per the handpiece IFU.
8. Repeat the ablation process as necessary.
9. To switch between Ablation and Sensing/Pacing Modes use the selection button on the touchscreen.
10. At the end of the procedure, disconnect the Pen from the MAG and discard it. Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

Clamp Handpieces: Performing Ablation

1. The MAG will automatically detect that the Clamp is connected and will illuminate the Clamp button on the touchscreen display. The type of Clamp device will be shown on the screen.

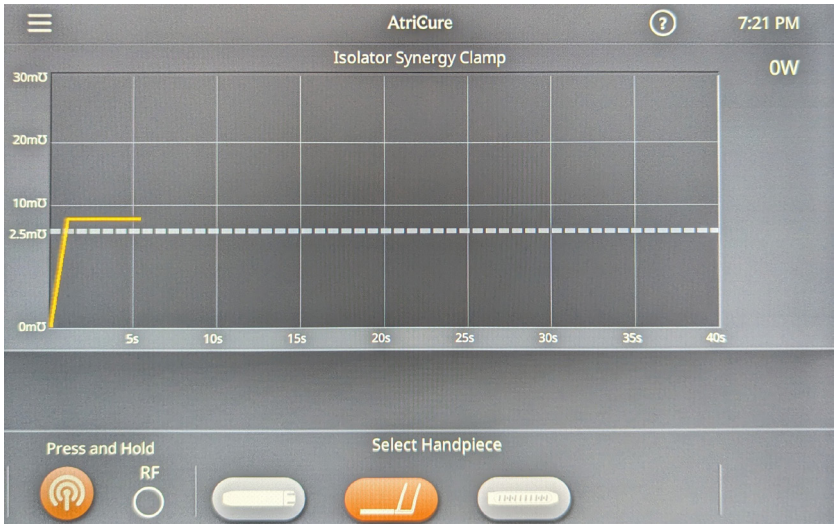


Figure 10. Clamp Handpiece Screen.

2. Position and close Clamp on target tissue.
3. To activate RF energy, press and hold the RF ON button on the touchscreen OR press and hold the footswitch.
4. The RF ON button will be illuminated on the touchscreen. The MAG will emit an audible tone indicating that current is flowing between the jaws of the Clamp.
5. Use the screen to monitor the ablation.
6. When transmurality is achieved, an audible tone will sound. The transmurality tone will continue—and RF energy will continue to be applied—until the RF is stopped or until 40 seconds has elapsed. The lesion times out at 40 seconds and RF energy stops whether or not the footswitch is being pressed at the time.
7. To stop RF before the 40 seconds has elapsed, release the RF button on the touchscreen OR release the footswitch.

Note: The time necessary to create a transmural lesion depends on tissue thickness, composition, and the length of tissue captured between the electrodes.

8. Operate the Clamp per the handpiece IFU.
9. Repeat the ablation process as necessary.
10. At the end of the procedure, disconnect the clamp from the MAG and discard it. Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

EPi-Sense® Handpiece: Performing Ablation

⚠**CAUTION:** EPi-Sense start/stop ablation behavior differs from the other handpieces. Press and Release to Start an ablation for EPi-Sense.

1. The MAG will automatically detect that the EPi-sense device and Patient Return Electrode are connected and will illuminate the EPi-Sense button on the touchscreen display. The Patient Return Electrode will show a green check mark if there is sufficient skin contact.

Figure 11. EPi-Sense Handpiece Screen – Energy

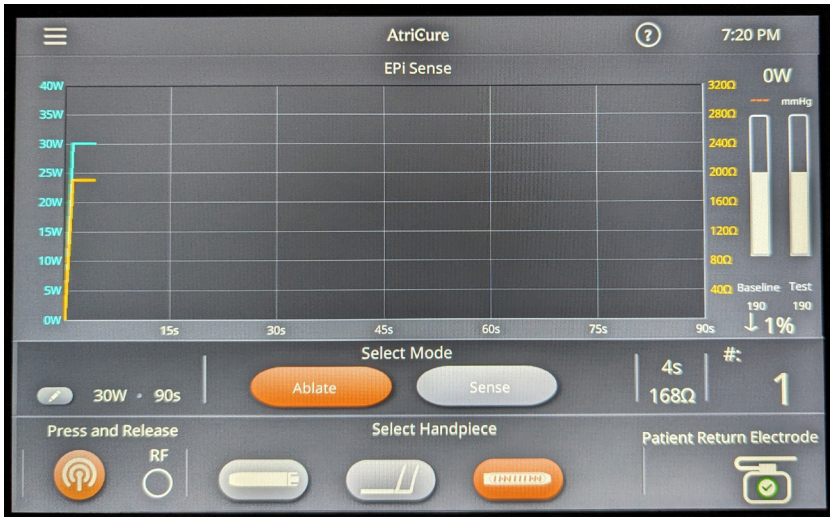


Figure 12. EPi-Sense Handpiece Screen - Impedance

2. Select Energy or Impedance Bar graph preference in Settings -> EPi-Sense.
3. Attach vacuum line from the vacuum canister to the vacuum adapter/connection on the back of the MAG if using this optional feature. Refer to Figure 2.
4. Select Ablation mode.
5. Check the EPi-Sense settings on the touchscreen:
    - Power: Default value = 30 W; Range 4W to 60W.
    - Time: Default value = 90 seconds; Range = 1 – 150 seconds.
6. Prepare and position the EPi-Sense Handpiece on patient tissue.
7. To activate RF energy, press and release the RF ON icon on the touchscreen OR press and release the footswitch.
8. MAG checks the split ground pad contact quality prior to activating RF energy.
9. The RF ON button will be illuminated on the touchscreen. The time will begin counting from zero to the time set point for that EPi-Sense device. This is the therapy time shown on the display. The MAG will emit an audible tone indicating that current is flowing through the Handpiece.
10. To stop RF energy, press and release the RF ON icon OR press and release the footswitch.
11. RF energy also will be terminated at the end of 90 continuous seconds (set time) of energy delivery, or if the impedance rises above 500Ω.
12. Operate the EPi-Sense per the handpiece IFU.
13. Repeat the ablation process as needed.

14. To switch between Ablation and Sensing Modes use the selection button on the touchscreen. Refer to Figure 11. EPi-Sense Handpiece Screen – Energy.

EPi-Sense® Handpiece: Sensing

1. Connect the PSS Interface Cables from the PSS Ports to the Stimulus Connection Box on the external monitoring equipment. Refer to Figure 2.
2. Press the Sense mode button on the screen.
3. At the end of the procedure, disconnect the EPi-Sense Handpiece and cable from the MAG and discard them. Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

TROUBLESHOOTING

Use the following sections to help troubleshoot possible problems with the MAG.

Display Problems

- If the active device cannot be selected using the Touch Screen, disconnect all handpieces except the device that is required.At the physician's discretion the lesion may be continued using default settings.
- If RF activation or deactivation is not working via the Touch Screen, use the Footswitch to activate and de-activate RF.
- If the display is not working, connect a Remote display using the HDMI cable.
- If the Remote display (HDMI) is not working, disconnect then re-connect the HDMI cable to ensure that the connector is fully inserted.
- If the Touch Screen or Remote display is not working use the power entry module ON/OFF switch to power off the generator, then power on again.
- The default power settings may display 0W while in Sense Mode, move to Ablate Mode and verify the default settings are correct. If they need to be reset, press the default button in the settings menu.

Handpiece Not Functioning as Expected

Check for the following:

- Ensure that only Handpieces, footswitch, and other products supplied by AtriCure and indicated for use with the MAG are used.
- Check that the Handpiece is plugged into the appropriate receptacle on the MAG. Connectors for AtriCure Handpieces are not interchangeable. For example, a Pen Handpiece connector will not fit into the receptacle for a Clamp Handpiece.
- After the Handpiece has been plugged in, check to see that the corresponding Handpiece is illuminated on the display screen. On some of the display screens, the name of the Handpiece (e.g., "Pen" or "Clamp") is also displayed at the top of the screen.
- If needed, review the Handpiece instructions for use to make sure that the Handpiece capability is consistent with the attempted use. For example, if bipolar electrodes are needed to perform ablation, make sure the Handpiece has this capability.
- Check the Handpiece for any loose wires or damage.
- In the event of an emergency, use the power entry module ON/OFF switch to power down the generator, unplug the handpiece, or remove the power cord from the power outlet.

No RF Power Output

If there is no RF power output, attempt to correct this problem using the checklist below.

Possible Cause	Solution
Power failure from surge or interruption	Check outlet power or use alternative power outlet.
MAG not turned on	Turn power ON
MAG not plugged in	Confirm electrical connections and then turn power ON
Blown fuse	Replace fuses as marked
No Handpiece connected	Connect Handpiece
Wrong Handpiece selected	Check required Handpiece is connected and selected
No Footswitch connected	Connect Footswitch
MAG in FAULT mode	Turn Power OFF and then ON
MAG in STANDBY mode	Ensure that Handpiece and Footswitch are properly connected
Broken Handpiece cable	Replace Handpiece
Fault in Footswitch	Replace Footswitch, or use touchscreen activation
Fault in Handpiece	Replace Handpiece
Internal MAG failure	Contact AtriCure Customer Service
MAG in Sense Mode	Set MAG to Ablate mode with on screen button

Table 6. Troubleshooting when there is no RF power output.

If the lack of MAG RF power output persists, contact AtriCure Customer Service.

No USB Data Download

USB Memory Devices:

- If a USB Memory Device is not working disconnect then re-connect the device to ensure that it is fully inserted.
- Use windows explorer to check that there is sufficient memory available to download data.

Recoverable Error Messages

Message Number	Message Text
1	Power Measurement Problem. Clear error and continue. If problem persists, contact AtriCure Customer Service.
5	High Impedance Problem. Check Handpiece. If problem persists, contact AtriCure Customer Service.
4	Low Impedance Problem. Check Handpiece. For CoolRail devices, possible cooling problem if the LED is illumated. If problem persists, contact AtriCure Customer Service.
6	
8	Cooling Fan Problem. Cycle power off and back on. If problem persists, contact AtriCure Customer Service.
13	Invalid or expired handpiece. Reconnect or replace handpiece. If problem persists, contact AtriCure Customer Service.
14	
15	Relay problem. Clear error and continue. If problem persists, contact AtriCure Customer Service.
16	Active device removed. Reconnect handpiece. If problem persists, contact AtriCure Customer Service.
18	Return electrode current problem. Check return electrode. If problem persists, contact AtriCure Customer Service.
21	
23	Current Measurement Problem. Check Handpiece. For CoolRail devices, possible cooling problem if the LED is illumated. If problem persists, contact AtriCure Customer Service.
24	Return electrode contact problem. Check return electrode. If problem persists, contact AtriCure Customer Service.
25	Power Measurement Problem. Clear error and continue. If problem persists, contact AtriCure Customer Service.
26	
27	Voltage Measurement Problem. Cycle power off and back on. If problem persists, contact AtriCure Customer Service.
29	Footswitch disconnected. Reconnect or replace footswitch. If problem persists, call AtriCure Customer Service.
30	Invalid or expired Handpiece. Reconnect or replace handpiece. If problem persists, call AtriCure Customer Service.
32	Incorrect Return Electrode. Replace solid return electrode with a split return electrode. If problem persists, call AtriCure Customer Service.

Table 7. Recoverable Error Messages

Warning Messages

Message Number	Message Text
1	Handpiece close to expiration. Less than 1 hour remaining.
2	Return electrode detaching from patient. Re-apply or replace the return electrode.
3	Footswitch connected during an ablation. Restart ablation.
4	Ablation attempted while in sense mode. Switch to ablate mode before attempting an ablation.

Table 8. Warning Messages

Non-Recoverable Error Messages

Message Number	Message Displayed
1	Internal RF Problem, Cycle power off and back on. If problem persists, contact AtriCure Customer Service.
2	
3	Internal Temperature Problem. Cycle power off and back on. If problem persists, contact AtriCure Customer Service.
4	
5	24V power problem. Cycle power off and back on. If problem persists, contact AtriCure Customer Service.
6	Footswitch Self-Test problem. Disconnect Footswitch. Cycle power off and back on. If problem persists, contact AtriCure Customer Service.

Message Number	Message Displayed
7	Measurement System Problem. Cycle power off and back on. If problem persists, contact AtriCure Customer Service.
8	High lesion temperature detected. Cycle power off and back on. If problem persists, contact AtriCure Customer Service.
10 -18	Internal communication problem. Cycle power off and back on. If problem persists, contact AtriCure Customer Service.
19	Real Time Clock problem. Cycle power off and back on. If problem persists, contact AtriCure Customer Service.

Table 9. Non-Recoverable Error Messages

ELECTROMAGNETIC OR OTHER INTERFERENCE

The MAG has been tested and found to comply with the limits for medical devices in IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

The MAG generates and can radiate RF energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If the MAG does cause harmful interference to other devices—which can be determined by turning the generator power OFF and then ON again—try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the MAG and the other devices.
- Connect the MAG into an outlet on a circuit different from that to which the other device(s) are connected.
- Contact the AtriCure service representative for help.

Use the following sections to troubleshoot specific types of interference, including monitor (display) interference, neuromuscular stimulation, and pacemaker interference.

Monitor (Display) Interference

Continuous Interference

1. Check the Power Cord connections for the MAG.
2. Check all other electrical equipment in the operation room for defective ground conditions.
3. If the electrical equipment is grounded to different objects, rather than a common ground, voltage differences can appear between the two grounded objects. The monitor may respond to these voltages. Some types of input amplifiers can be balanced to achieve optimum common mode rejection and may possibly correct the problem.

Interference Only When MAG is Activated

1. Check all connections to the MAG, and connections to the active handpiece, to look for possible metal-to-metal sparking.
2. If interference continues when the MAG is activated and while the electrode is not in contact with the patient, the monitor is responding to radio frequencies. Some manufacturers offer RF choke filters for use in the monitor leads. These filters reduce interference while a generator is activated. RF filters minimize the potential for an electrosurgical burn at the site of the monitor electrode.
3. Check that the ground wires in the operating room are electrically consistent. All ground wires must go to the same grounded metal with wires that are as short as possible.
4. If the above steps do not remedy the situation, have the MAG checked by qualified service personnel.

PREVENTIVE MAINTENANCE

AtriCure has considered internationally recognized standards and guidances in determining preventive maintenance requirements.

The MAG and compatible reusable components shall be periodically subjected to preventive maintenance, as specified below.

The Preventive Maintenance for MAG and reusable components comprises the following activities:

- Performing Power On Self Test (POST)
- Visual Inspection (for damages, fraying, cracked parts, missing items, etc.)

Please contact your local AtriCure Service representative for more detailed information about Preventive Maintenance programs.

CLEANING

⚠ WARNING ⚠

Always turn OFF and unplug the unit before cleaning to prevent electric shock hazard.

Note: Do not spray or pour liquids directly on the unit.

Note: The unit and/or accessories cannot be sterilized.

⚠**CAUTION:** Ensure Isopropyl Alcohol (IPA) is completely dry before operating the unit to prevent potential equipment malfunction.

⚠**CAUTION:** Avoid caustic or abrasive cleaners to avoid damage to MAG chassis.

Guidelines

The following guidelines are recommended for cleaning the unit. It is the user's responsibility to qualify any deviations from these processing methods.

1. Disconnect the unit or cart from the outlet before cleaning.
2. If the unit and/or accessories are contaminated with blood or other body fluids, they shall be cleaned before the contamination can dry (within two hours of contamination).
3. The outer surfaces of the unit and/or accessories shall be cleaned with a cloth that has been dampened with 70% -90% Isopropyl alcohol (IPA) wipes for a minimum of two minutes. Do not allow fluids to enter the chassis.
4. Pay attention to all areas where fluids or soil may gather, such as under/ around the handles or any tight crevices/ grooves.
5. Dry the unit and/or accessories with a dry, white lint-free cloth.
6. Conduct a final confirmation of the cleaning process by visually inspecting the white cloth for remaining soil.
7. If soil remains on the white cloth, repeat steps 3 through 6.
8. Visually inspect the MAG unit for any signs of degradation.
9. After cleaning is complete, turn the unit ON to perform Power On Self-Test (POST). If any errors are received, contact AtriCure to begin return process.

DISPOSAL

Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

1. Disconnect handpieces and accessories and treat as regulated medical waste requiring decontamination to render safe for further handling and disposal.
2. Follow cleaning and disinfecting steps for the unit as outlined in this IFU.
3. Contact local medical equipment recycling and disposal service.

EXPECTED LIFE TIME

The Expected Life Time is the time-period during which the MAG, Components and Accessories are expected to remain suitable for its intended purpose, assuming the responsible organization will follow AtriCure's Instruction For Use for preventative maintenance.

AtriCure has defined the Expected Life Time of the MAG to be 10 years

ELECTROMAGNETIC REQUIREMENTS

⚠ WARNING ⚠

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Essential Performance: The generator shall not deliver excess energy to the patient. This is related to basic safety as part of IEC 60601-2-2.

The MAG has been tested and found to comply with the limits for medical devices in IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

The MAG can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity.

Portable and mobile RF communications equipment or other strong RF emitter can also affect MAG performance, and care must be taken to minimize such interference. If such interference happens,

- Reorient or relocate the possible emitting device.
- Increase the separation between the MAG and the other devices.
- Connect the MAG into an outlet on a circuit different from that to which the other device(s) are connected.
- Contact the AtriCure service representative for help.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential ENVIRONMENT (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

ELECTROMAGNETIC EMISSIONS

Guidance and manufacturer's declaration – electromagnetic emissions		
The MAG is intended for use in the electromagnetic environment specified below. Make sure that the MAG is used in an environment that complies with these standards.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The MAG 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 A	The MAG is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 10. Electromagnetic emissions.

ELECTROMAGNETIC IMMUNITY

Guidance and manufacturer's declaration – electromagnetic immunity			
The MAG is intended for use in the electromagnetic environment specified below. The customer or the user of the MAG 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	± 8KV contact ± 2KV, ± 4KV, ± 8KV, ± 15KV air	± 8KV contact ± 2KV, ± 4KV, ± 8KV, ± 15KV 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	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5KV, ± 1KV, ± 2KV	± 0.5KV, ±1KV, ± 2KV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MAG requires continued operation during power mains interruptions, it is recommended that the MAG be powered from an uninterruptible power supply or a battery.
Voltage Interrupt IEC 61000-4-11	0 % U_T; 250/300 cycle	0 % U_T; 250/300 cycle	
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			
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.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the MAG, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$

Guidance and manufacturer's declaration – electromagnetic immunity			
The MAG is intended for use in the electromagnetic environment specified below. The customer or the user of the MAG should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	$d = 1.2 \sqrt{P}$ 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). [a] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, 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: 
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See table 13	See table 13	
Proximity magnetic fields IEC 61000-4-39	See table 14	See table 14	
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MAG is used exceeds the applicable RF compliance level above, the MAG should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MAG. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 11. Electromagnetic immunity.

Recommended separation distances between portable and mobile RF communications equipment and the MAG			
The MAG is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MAG can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MAG as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	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.			

Table 12. Recommendation Separation Distance.

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	28
870				
930				
1 720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	28
1 845				
1 970				
2 450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28
5 240	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9
5 500				
5 785				
If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.				
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) As an alternative to FM modulation, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.				

Table 13. IMMUNITY specification to RF wireless communications equipment

Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz [a]	CW	8
134,2 kHz	Pulse modulation [b] 2,1 kHz	65 [c]
13,56 MHz	Pulse modulation [b] 50 kHz	7,5 [c]
a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) r.m.s., before modulation is applied.		

Table 14. IMMUNITY specification to proximity magnetic fields

WARRANTY

Limitation on Liability

This warranty and the rights and obligations hereunder shall be construed under and governed by the laws of the State of Ohio, U.S.A.

AtriCure, Inc. warrants this product to be free from defects in material and workmanship under normal use and preventive maintenance for the respective warranty period shown below. AtriCure's obligation under this warranty is limited to the repair or replacement, at its option, of any product, or part thereof, which has been returned to AtriCure, Inc. or its Distributor within the applicable time period shown below and which examination disclosed, to AtriCure's satisfaction, to be defective. This warranty does not apply to any product, or part thereof, that has been: (1) adversely affected due to use with devices manufactured or distributed by parties not authorized by AtriCure, Inc. (2) repaired or altered outside AtriCure's factory in a way so as to, in AtriCure's judgment, affect its stability or reliability, (3) subjected to improper use, negligence or accident, or (4) used other than in accordance with the design and use parameters, instructions and guidelines for the product or with functional, operational or environmental standards for similar products generally accepted in the industry. **AtriCure has no control over the operation, inspection, maintenance or use of its products after sale, lease or transfer, and has no control of the selection of Customer's patients.**

AtriCure's products are warranted for the following periods after shipment to the original purchaser:

MAG RF Generator	One (1) Year
AtriCure Footswitch	One (1) Year
Grounded Electrical Cord(s)	One (1) Year

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