



ADVANTAGE-MR™ EP Recorder/Stimulator System



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DEVICE INFORMATION

Introduction

This manual describes the features and use of Advantage-MR, an EP recorder and stimulator system for capturing and measuring physiological data in the electrophysiology (EP) laboratory. It provides high-fidelity signal acquisition and display of intracardiac electrogram (EGM) and electrocardiogram (ECG) signals on one or two high-resolution monitors. Advantage-MR is designed to work in labs equipped with MR scanning and fluoroscopy imaging equipment. This manual is written for medical professionals.

Device Description

The Advantage-MR EP Recorder/Stimulator System (Advantage-MR) is designed to acquire, amplify, filter, digitize, display, and record electrical signals obtained during electrophysiological studies and related procedures. In addition, Advantage-MR is designed to generate electrical pulses of varying amplitude, pulse width, and frequency for cardiac stimulation.

Advantage-MR is a three-channel system with inputs for Vision-MR ablation and diagnostic catheters and compatible surface ECG monitors. Signals from the catheters and ECG are displayed via the Advantage-MR Host Workstation for the purpose of analyzing cardiac activity. The incorporated cardiac stimulator is used to send electrical pulses to the heart via a catheter. When necessary, ablation therapy from a compatible radiofrequency ablation generator can be delivered through the Advantage-MR ablation catheter port. Advantage-MR also reports and displays the temperature measured at the ablation catheter tip electrode for clinicians to monitor while providing ablation therapy.

The Advantage-MR software contains features for data acquisition, review, interval and amplitude measurement, and annotation. The system can also store and retrieve data. Review, measurement, and annotation of recorded data are provided without interruption of real-time signal waveform display.

The Advantage-MR hardware configuration consists of a Host Workstation, a Digital Amplifier Stimulator (DAS), a Patient Device Interface (PDI), a DAS Power Supply, an ECG Interface Module, and various power, signal, and connection cables.

Advantage-MR does not generate ablation energy, administer drugs, perform any life-supporting or life-sustaining functions, or analyze physiological data or other data acquired during an EP procedure. It does not provide alarms or arrhythmia detection.

Intended Purpose/Intended Use

Advantage-MR EP Recorder/Stimulator System (Advantage-MR) is intended to acquire, amplify, filter, digitize, display, and record electrical signals obtained during electrophysiological studies and related procedures. Signal types acquired include intracardiac electrograms and surface ECG. The system allows the user to monitor, review, store, and retrieve the data, as well as to perform caliper-type measurements of the waveforms.

The system incorporates a stimulator intended for diagnostic cardiac stimulation during electrophysiological evaluation of the human heart.

Advantage-MR can display, and record data received from other medical devices typically used during these procedures, such as a compatible RF generator.

Indications for Use

Advantage-MR is indicated for use in electrophysiology procedures.

User Information

Intended users are cardiologists trained in the management of electrical properties of the heart, often referred to as an electrophysiologist (EP) and who are trained in the use of the Advantage-MR system.

Contraindications

There are no known contraindications.

Clinical Benefits Statement

The Advantage-MR System provides multiple benefits including confirmation of arrhythmia treatment and elimination of exposure to ionizing radiation in successful cases for patients and clinicians. Confirmation of diagnosis and treatment for various arrhythmias is achieved using pacing and sensing techniques within the heart. Additionally, the Advantage-MR System is safe for use in the MR environment. Real-time, MR-guided procedures allow clinicians to leverage superior anatomical imaging of the heart while eliminating exposure to ionizing radiation for patients and clinicians.

Operating Principle

An electrophysiological recording system (EP recording system) is used in diagnostic and therapeutic electrophysiological interventions to diagnose and treat cardiac arrhythmias. Traditional EP recording systems provide the functionality of displaying and recording intracardiac electrogram (EGM) signals and surface electrocardiogram (ECG) signals. These systems typically interface to an external cardiac stimulator system for cardiac pacing and to an external RF ablation generator for delivering ablative therapy.

The Advantage-MR System combines the roles of an EP recording system and external stimulator in one package that is designed to be safe for use not only in a conventional x-ray fluoroscopy lab, but also in a magnetic resonance imaging (MRI) lab. In an MRI lab, the interventional procedure is guided using MRI imaging, rather than x-ray imaging. The Advantage-MR system interfaces to an external RF ablation generator, in a similar fashion to conventional EP recording systems.

The Advantage-MR system was designed to provide a familiar user experience in both functionality and interface, compared to existing systems. The key difference is that the Advantage-MR system was designed with MR compatibility in mind, while existing EP recording and stimulator systems were not. As a result, existing systems are not approved for use in the MR environment.

Warnings

- EP recording systems are used in medical procedures during which intentional or unintentional life-threatening cardiac arrhythmias are likely to occur. To avoid death or injury, Advantage-MR should be used only in an appropriate hospital facility under the direct supervision of a physician trained in electrophysiology and the operation of the Advantage-MR system.
- Do not use Advantage-MR if any component appears damaged or computer appears to start up and/or function abnormally. Contact Imricor Medical Systems if system appears damaged or is functioning improperly.
- Do not modify this equipment without authorization from Imricor Medical Systems as this may void the warranty.
- Comply with Advantage-MR maximum magnetic field strength requirements at all times. Consult the Device Ratings and Specifications section of this document for these requirements.
- The supervising physician must verify all Advantage-MR's settings immediately prior to commencement of pacing.
- Advantage-MR is not a life-support device – operator must have an available external pacemaker.
- Advantage-MR may fail to stimulate or unintentionally stimulate the patient through software, hardware, or human error. To avoid injury to patient from arrhythmias, monitor the function of Advantage-MR and the patient's vital signs continuously while Advantage-MR is connected to the patient.

- In case of repeated recurrence of unexplained life-threatening arrhythmias despite cardioversion/defibrillation during the use of Advantage-MR, disconnect Advantage-MR from the patient by unplugging the ablation and diagnostic cables for the ABL CATH and CATH 2 ports on the front of the PDI in case it has an occult malfunction causing recurrent micro-electrocution and recurrent DC current stimulation.
- The Advantage-MR system should be tested yearly for adequate grounding and patient leakage current. Keep leakage current within acceptable limits when connecting auxiliary equipment to the system.
- Upon installation with compatible equipment, and prior to clinical use, the patient leakage current must be verified to comply with the limits set forth by IEC 60601-1.
- Continuously monitor the tip temperature while ablating. If ablation temperature data appears to be higher or lower than expected, turn off ablation power.
- Discontinue MR scanning if tip temperature rises while not ablating.
- To prevent electrical shock hazards or impaired performance of Advantage-MR from incorrect installation, only representatives of Imricor Medical Systems or its authorized agents may carry out installation of Advantage-MR.
- To avoid the risk of electric shock, only connect Advantage-MR to a supply mains with protective earth. Do not use power strips or extension cords.
- Do not touch accessible contacts of connectors and the patient simultaneously.
- To avoid risk of explosion, do not use in the presence of flammable gases. Also, use only in ventilated areas.
- The Advantage-MR system is not protected against fluid ingress. If fluid of any kind should leak into the system, discontinue use of the equipment and contact Imricor.
- Keep the conductive parts of lead electrodes and associated parts away from other conducting parts, including earth.
- The Advantage-MR system should not be serviced while the system is in use with a patient.
- The Advantage-MR system is not intended to be connected to any network other than a compatible EP Mapping System.
- Interference between other devices may degrade signal quality.
- The dispersive electrode cable has been tested for 100 uses. Inspect the dispersive electrode cable before use and if cracked, damaged or loose, discard according to facility protocol and replace with a new cable.
- When connecting the dispersive electrode cable to the dispersive electrode, ensure the dispersive electrode remains fully adhered and the conductive foil on the tab is not exposed.
- Do not position the Advantage-MR System so that it is difficult to operate the disconnection of device(s) from mains power supply.
- Testing has only been conducted with the compatible equipment identified in this document. Consult the compatible equipment Instructions for Use prior to using the device.

Precautions

- To reduce operator errors, installation, configuration, and customer training should be performed in a manner that allows for optimal use of Advantage-MR by the user.
- Advantage-MR is designed for use with 1.5T MR scanners only.
- If during a procedure the EGM signals are lost or distorted on Advantage-MR, check the location of the Patient Device Interface and move it farther away from the MR scanner, if necessary.
- MR scanning and/or ablation may interfere with the EGM signals. Terminate scanning and ablation prior to performing EGM measurements, if necessary.
- If Advantage-MR components are not used within the MR conditions of use, MR scanner performance may be affected.
- To avoid the creation of noise on the MR scanner, align the catheter and cabling as much as possible with the center of the MR scanner bore – rather than the inside wall of the bore.
- If excessive interference is noted during a procedure, confirm that all cable connections are secure.
- Accessory equipment connected to the analog and digital interfaces must comply with the respective IEC standards (IEC 62368-1 for data processing equipment and IEC 60601-1 for medical equipment). Additional equipment connected to the signal input or output connections comprise a medical system and therefore must comply with the requirements of IEC 60601-1. Failure to comply with this precaution could result in previously unidentified risks to patients, operators, or third parties.
- The Advantage-MR cart is intended for use with Advantage-MR components only. Do not place other equipment on the cart.

- Maximum cart load of 37.7 kg.
- Do not place the Advantage-MR cart on an incline, the cart may slide.

Potential Adverse Events

Advantage-MR produces cardiac stimulation and ablation outputs similar to other existing programmable cardiac stimulation and ablation systems. The following is a list of potential adverse events from device malfunction or human error.

- Arrhythmia
- Death
- Myocardial injury
- Electric shock

Refer to above Warnings and Precautions.

NOTICE: Report any serious incident that has occurred in relation to Advantage-MR to Imricor Medical Systems and the Competent Authority of the Member State in which the procedure was performed.

Patient Population

Patients who are eligible for conventional electrophysiological study can be treated with Advantage-MR.

DEVICE RATINGS AND CLASSIFICATION

MR Conditions for Use

Advantage-MR is MR Conditional under the following MR equipment and scanning requirements.



MR system nominal field strength	1.5 T
Maximum gradient slew rate	200 T/m/s

Several Advantage-MR components reside in the MR scanner room; see the Installation section of this document for a complete list of these items and instructions to ensure their proper installation. **The Digital Amplifier Stimulator and DAS Power Supply must reside outside the specified maximum magnetic field strengths listed below.**

Component	Maximum Magnetic Field Strength
DAS Power Supply	100 Gauss
Digital Amplifier Stimulator (DAS)	100 Gauss

CE Mark Compliance

Advantage-MR is compliant with the following regulation:

- Regulation (EU) 2017/745





















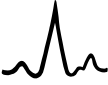

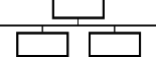




Classification

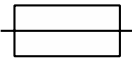







IEC 60601-1 electrical device classification
Class I, IP2X, Type CF


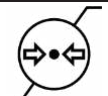
SYMBOLS

The following table displays the symbols used on the system hardware, in the system software, and in the accompanying documentation, including this IFU.

Symbol	Description
	Medical device
	Authorized representative in the European Community
	Authorized representative in Switzerland
	Regulatory importer
	Manufacturer
	Date of manufacture
	Caution
	Consult instructions for use or consult electronic instructions for use
	Catalog number
	Serial number
	Lot number
	Unique Device Identifier
	Fragile, handle with care
	Protect from heat and radioactive sources
	Keep dry
	Separate collection for electrical and electronic equipment

Symbol	Description
	<p>MR Conditional: Use only in 1.5T MRI environment. See MR Conditions for Use section.</p>
	<p>Component must reside outside the 100 Gauss line of the MR system.</p>
<p>ABL CATH</p>	<p>Ablation catheter port</p>
<p>CATH 2</p>	<p>Diagnostic catheter port</p>
	<p>ECG port</p>
	<p>Defibrillation-proof type CF applied part</p>
<p>MAIN POWER</p>	<p>Main power port</p>
<p>ISOLATED POWER</p>	<p>Isolated power ports</p>
	<p>Computer Network</p>
	<p>Serial interface</p>
	<p>HF Isolated Patient Circuit</p>
<p>TEMP</p>	<p>Fiber optic temperature cable port</p>
<p>TRACKING INTERFACE</p>	<p>Tracking module port</p>
<p>RF IN</p>	<p>Radiofrequency generator cable port</p>
	<p>Equipotential</p>
	<p>Cardiac gating output</p>

Symbol	Description
	Fuse
V~	Alternating current
I	Current
 24.5 kg	Mass of cart with components is 24.5kg
CE 0123	Notified body CE mark
HOST	Host Workstation
DAS	Digital Amplifier Stimulator
PDI	Patient Device Interface
DAS PS	Digital Amplifier Stimulator Power Supply
ACCS	Accessories
	Temperature limit
	Monitor
	Cart
	Humidity limitation
	Packaging Unit
IP2X	Protected against solid foreign objects greater than or equal to 12.5 mm diameter
<37.7kg 	Maximum cart load of 37.7 kg

Symbol	Description
	Defibrillation-proof type BF applied part
	Atmospheric pressure limitation

ADVANTAGE-MR CONFIGURATION AND INSTALLATION

System Components

The following are the main components of Advantage-MR system. Do not use accessories or cables other than those specified. For identification information for the DAS Power Supply and PDI, reference the bottom of the component.

Component / Model Number	Description and Function
Digital Amplifier Stimulator (DAS) / AD009	The DAS is an amplifier and stimulator. The amplifier function accepts physiological signals from applied parts; filters, amplifies, and digitizes the signals; and transmits them to the Host Workstation. The stimulator function creates monophasic, bipolar pulses that can be selectively delivered to electrode pairs in the Vision-MR catheters.
DAS Power Supply / AD006	The DAS Power Supply generates the isolated power for the Digital Amplifier Stimulator (DAS). The isolation complies with the safety limits set forth by the IEC 60601-1 standard.
Patient Device Interface (PDI) / AD016	The Patient Device Interface serves as a junction between patient devices (Vision-MR catheters, dispersive electrode) and external compatible systems (MR Scanner, RF generator).
Host Workstation / AD018	Computer and accessories dedicated for use by the Advantage-MR system. The Host Workstation includes the Host, one or more monitors, a DVD drive, a keyboard, and a mouse.
ECG Interface Module / AD010	The ECG Interface Module connects to the gating connector port of an Invivo Patient Monitoring System. The module conditions the ECG gating signal for use in the Advantage-MR system.
ECG Interface Module Cable / CAB012-AD	Cable that connects the external ECG interface module to the DAS.
USB-C to USB-C Display Cable / CAB035-AD	USB-C to USB-C cable to connect the Host to the Host display.
Digital Power Cable / CAB027-AD	Power cable that provides digital power from the DAS Power Supply to the DAS.
Isolated Power Cable / CAB026-AD	Power cable that provides isolated power from the DAS Power Supply to the DAS.
Ablation Catheter Extension Cable / CAB010-AD	Cable that connects ablation catheter signals from the PDI to the DAS.
Diagnostic Catheter Extension Cable / CAB011-AD	Cable that connects diagnostic catheter signals from the PDI to the DAS.
Ablation Line Cable / CAB013-AD	Cable that connects the PDI to the Waveguide Ablation Line Cable.
Waveguide Ablation Line Cable / CAB037-AD	Cable that connects the Ablation Line Cable to the catheter port and dispersive electrode port of the compatible RF generator. Length = 2.5m (with Ablation Line Cable (CAB013-AD), total length = 7m).
Single Dispersive Electrode Cable / CAB030-AD	Cable that connects a compatible dispersive electrode to the PDI when one dispersive electrode pad is used. Cable is plugged into the defibrillation proof Type BF port of the PDI.
Ethernet Cable / CAB025-AD	Ethernet cable that connects the Host computer to a compatible mapping and guidance system.

Component / Model Number	Description and Function
Fiber Optic Cable / CAB036-AD	Fiber optic cable that connects the temperature port of the PDI to the Host.
Fiber Optic Ethernet Cable / CAB021-AD	Fiber optic Ethernet cable that connects the DAS to the Host.
AC Power Cord, Northern EU / CAB018-AD	Power cords that connect mains to the DAS Power Supply, Host, and Host display, Northern EU compatible.
AC Power Cord, UK / CAB020-AD	Power cords that connect mains to the DAS Power Supply, Host, and Host display, UK compatible.
Advantage-MR Cart – MR Compatible / AD002	MR Compatible Cart for use with DAS, DAS Power Supply, PDI, and associated cabling. The DAS and DAS Power Supply are stacked and placed on the middle shelf, the PDI is placed on the top shelf when not in use. The MR Compatible Cart, with components, are located bedside during use and may be transported elsewhere when not in use.
Tracking Interface Cable, Siemens 1.5T / CAB023-AD	Cable that connects the PDI to the Siemens Flex Coil Interface.
Philips Interface, 1.5T / AD017	An adapter module with integrated cable that connects the PDI to a compatible Philips 1.5T scanner to amplify and enable the MR scanner to recognize the signals acquired from Vision-MR device receive coils. The Obelix 8 Channel Shoulder Coil cable provides a connector for the Philips dStream interface.

Compatible External Devices/Equipment

The following devices and/or equipment are used with the Advantage-MR EP Recorder/Stimulator System but sold separately. Consult the manufacturer's instructions for use for the compatible devices and/or equipment.

Device/Equipment Type	Name(s)/Requirements
MR scanners	Siemens 1.5T scanner models (Avanto Fit or newer)
	Philips 1.5T scanner models (Ingenia or newer)
RF generator and associated devices/equipment	Osyпка HAT 500® RF Ablation Generator
	Osyпка HAT 500® Irrigation Pump
Patient monitors	Invivo Precess or Expression Patient Monitoring System
	MiRTLE MRI ECG Monitor
EP mapping system	NorthStar Mapping System (MAP01)
Catheters and cables (type CF applied part)	Vision-MR Ablation Catheter 2.0 (VMRA102) and Vision-MR Ablation Cable Set 2.0 (CABA102)
	Vision-MR Diagnostic Catheter (VMRD102) and Vision-MR Diagnostic Cable 2.0 (CABD102)
Dispersive electrode (type BF applied part)	Vision-MR Dispersive Electrode (VMR300)
Video Monitors	MR Conditional Video Display Monitor with 1920x1080 resolution and DisplayPort interface

Initial Installation

Initial setup and installation of Advantage-MR will be performed by an authorized representative of Imricor Medical Systems to meet the individual needs of each customer's electrophysiology suite. Refer to the Setup Guide if the components of the installed system are disconnected and reconnection is required.

System Setup Guidelines

- **WARNING:** Do not modify this equipment without authorization from Imricor Medical Systems.

- The Advantage-MR system must be installed by authorized Imricor representatives.
- The system may be used only after it has been fully tested and approved according to standard Imricor Medical Systems procedures.
- The Host Workstation is intended to serve as a dedicated computer for the Advantage-MR system. The Host Workstation should not be used for any other purposes, nor should unauthorized software be installed on the system. Doing so may make the Advantage-MR system software unstable.
- Authorized Imricor representatives must approve all changes to the installation setup of the Advantage-MR system.
- An equipotential ground connector is provided on the back of DAS Power Supply to allow for connection of the Advantage-MR system to the hospital equalization connection point.

Typical Setup

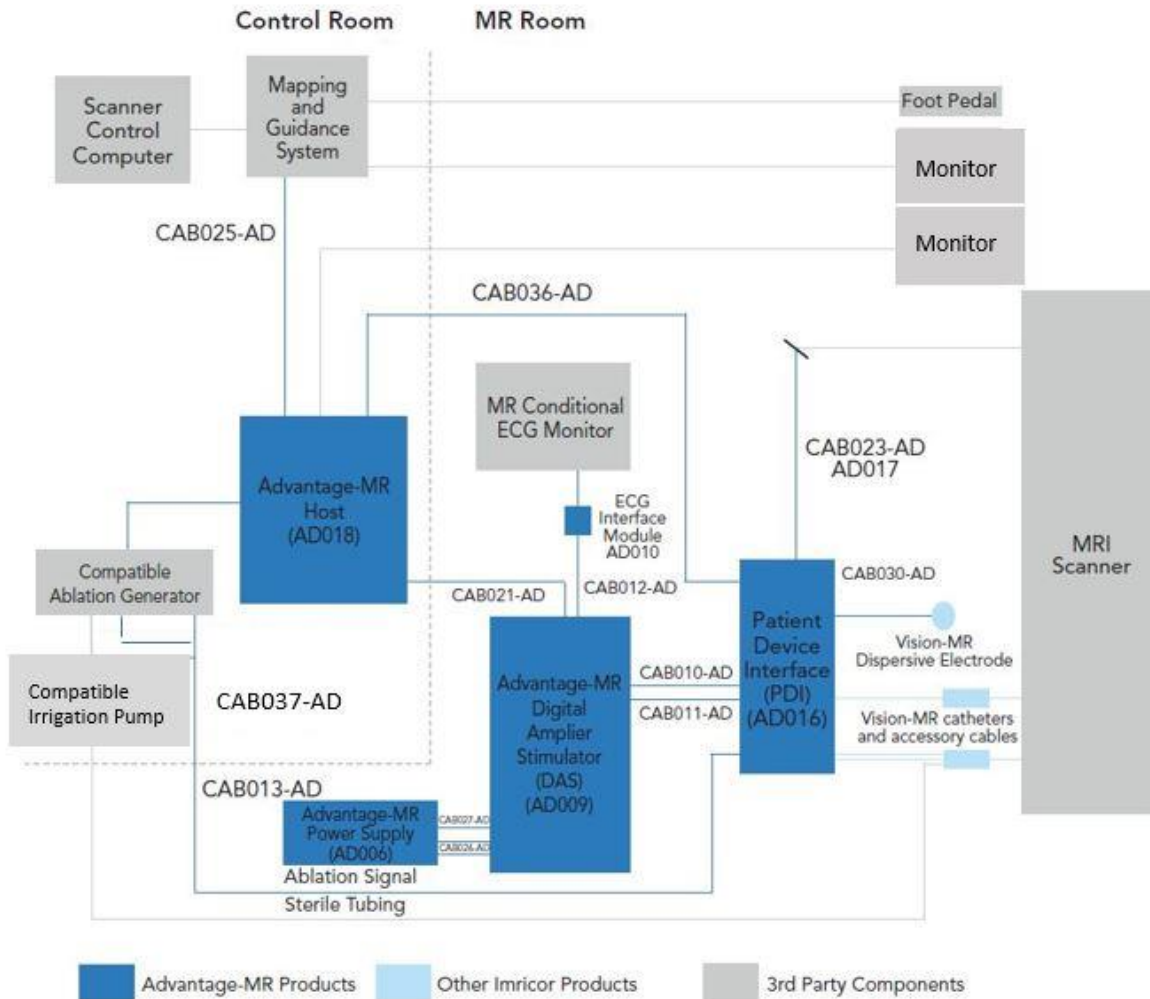
Only the following Advantage-MR components may reside in the MR scanner room.



- DAS Power Supply – maximum magnetic field strength = 100 Gauss
- Digital Amplifier Stimulator – maximum magnetic field strength = 100 Gauss
- Patient Device Interface
- Power Supply Cables
- Ablation Line Cable
- Catheter Extension Cable
- ECG Interface Module and Cables
- Ethernet Fiber Optic Cable
- Temperature Interrogator Fiber Optic Cable
- Dispersive Electrode Cable
- Philips Interface, 1.5T
- Tracking Interface Cable, Siemens 1.5T

The maximum magnetic field strength conditions for the Digital Amplifier Stimulator and DAS Power Supply must be observed at all times for the safety of patients and operators. These specifications can be found in the Device Ratings and Classifications section of this manual.

In a standard system configuration, the Host Workstation is located in the MR control room. In the MR scanner room, the DAS is located on top of the DAS Power Supply on the middle shelf of the cart. The PDI is placed on the foot end of the patient table while in use and is placed on the top shelf of the cart when not in use. The cart is located next to the patient table outside the 100 Gauss line of the MR scanner room. Lock the cart using the caster locks when the cart is in use. In addition to the Host Workstation monitor(s) in the control room, optional MR Conditional slave monitor(s) may be located next to the patient table so that the attending physician can view what is being displayed on the Host Workstation monitor(s). The following figure provides a detailed system block diagram of Advantage--MR.



Training

Upon initial installation and assembly of the Advantage-MR system, Imricor will provide an authorized representative to train physicians and qualified technicians in proper handling and usage of Advantage-MR. In addition, users must read through the Instructions for Use manual in its entirety prior to utilizing the system to maximize patient and user safety and prevent possible damage to equipment. **To avoid death or injury, Advantage-MR should be used only in an appropriate hospital facility under the direct supervision of a physician trained in electrophysiology, MR safety, and the operation of the Advantage-MR system.**

System Operation Verification

Once Advantage-MR has been powered on as indicated in the Starting Advantage-MR section, users should verify the following system indicators.

- Power switch on back of the DAS Power Supply is green.
- Green power (PWR) indicator on back of DAS is lit.
- Green power indicator on front of Host is lit.

Once the user has begun a study and is on the Main Display screen, the waveforms should be updating in the Real-Time Waveform panel.

STARTING ADVANTAGE-MR

To start the Advantage-MR system, power on the following system components.

- DAS Power Supply
 - Turn power switch to the ON position. Switch is located on the back of the DAS Power Supply. Switch will turn green when on.
- Host Configuration
 - Turn the power switch to the ON position. Switch is located on the rear of the Advantage-MR Host enclosure. Switch will turn green when on.
 - Press the power button on the front of the Advantage-MR Host enclosure. Host LED indicator will turn green when Host computer is on.
- Monitor
 - Press the power button located on the lower right corner of the monitor. Power symbol will light up when power is on.

After powering on the Host Workstation, the user must enter the username and password supplied by Imricor. Once this information has been entered, the Advantage-MR application will automatically launch. The Start screen will appear. Select the appropriate language and click the Start button.



USER INTERFACE

The user interface of Advantage-MR consists of the Advantage-MR system software, monitor(s), keyboard, mouse, and external DVD drive. The following section details the basic operations of these components. It is assumed that users have basic personal computer knowledge and are familiar with standard computer equipment.

Advantage-MR Software

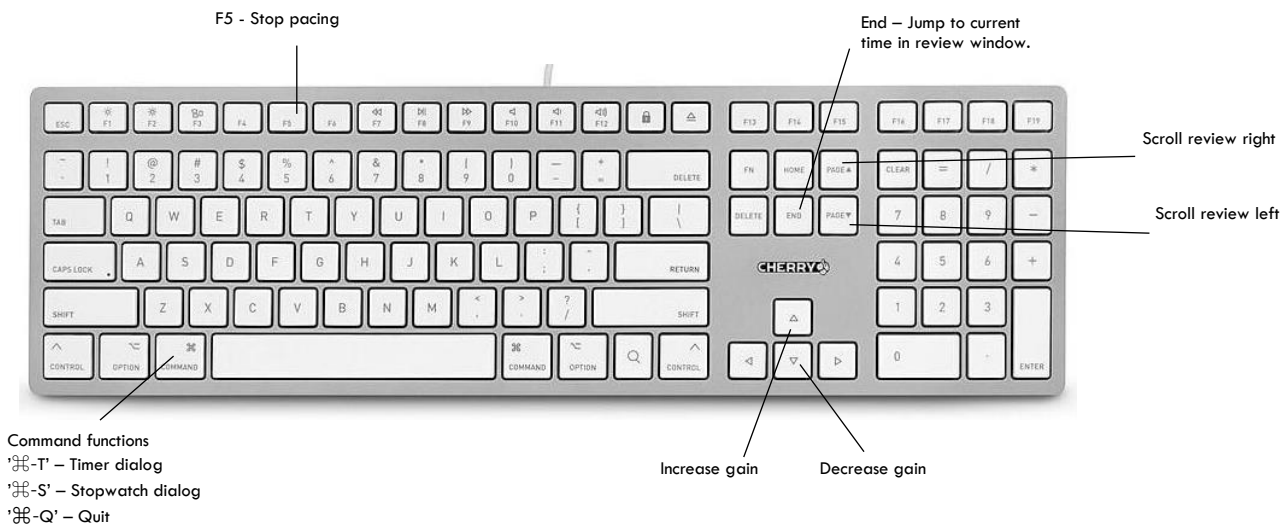
The system software is installed by the manufacturer on the Advantage-MR Host Computer. Software is fully operational after installation. See the System Operation section of this manual for details regarding the use and function of Advantage-MR.

Monitor

An installation consists of either one or two monitors in the control room. In a single monitor installation, a High Definition monitor displays the main window of the system software from which all operations of Advantage-MR can be controlled by the keyboard and mouse. In a dual monitor installation, a primary monitor displays the live real-time waveforms, and a secondary monitor displays the review waveforms and controls for the stimulation and measurement functions.

Keyboard

Advantage-MR can be operated by keyboard alphanumeric hot keys and function keys as depicted in the following diagram.



Mouse

A two-button mouse is supplied with Advantage-MR.

SYSTEM OPERATION

After the Start button is clicked on the Start screen, the Study/Patient window will appear that allows users to begin a new study or load an existing study. To begin a new study, enter the patient's first and last name and patient ID under the New Patient tab at the top of the page. Optional patient data (middle name, date of birth, gender, height, and weight) can be entered in the Study/Patient window as well. To begin a new study using patient information from a previous study, click the Existing Patient tab and select the desired existing patient information.

Once the correct patient information has been entered or selected, click the Create button at the bottom right of the page.



If a study is interrupted before it is closed by the user, it can be loaded from the Continue Study button in the Study/Patient window. To continue the interrupted study, click on the Continue Study button on the left side of the screen. This will load the information from the most recent, unsaved study and take the user to the Main Display screen. Only the most recent, unsaved study can be accessed via the Continue Study button. To review past, saved studies, refer to the Data Management section of this document.

Advantage-MR can be configured as a single monitor system or a dual monitor system at the time of installation. The functionality of both configurations is the same, however, the screen layout is different.

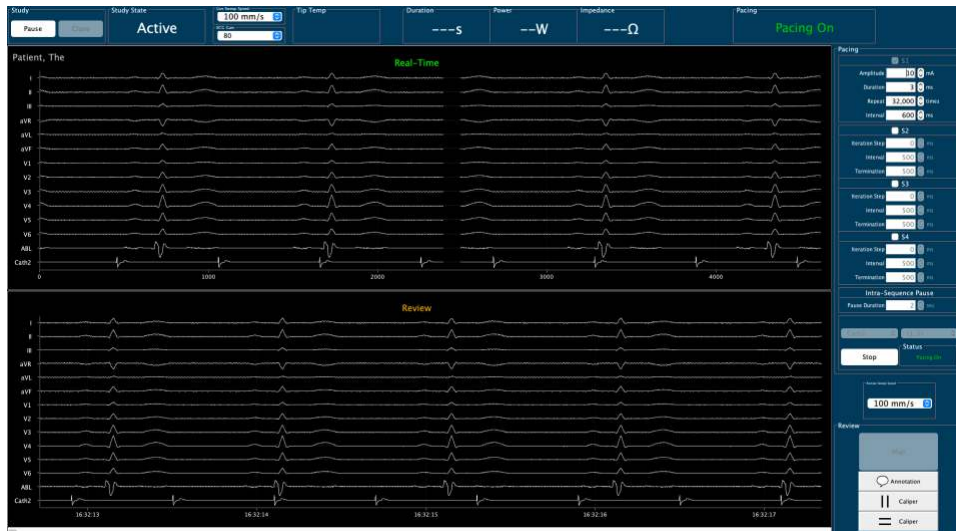
Main Display Screen (Single Monitor System)

From the Main Display screen, all operations of the Advantage-MR system are available, including electrogram real-time display and review, delay and voltage measurements, cardiac pacing and programmed stimulation, display of current ablation settings, and temperature monitoring.

Invivo (4-Lead)



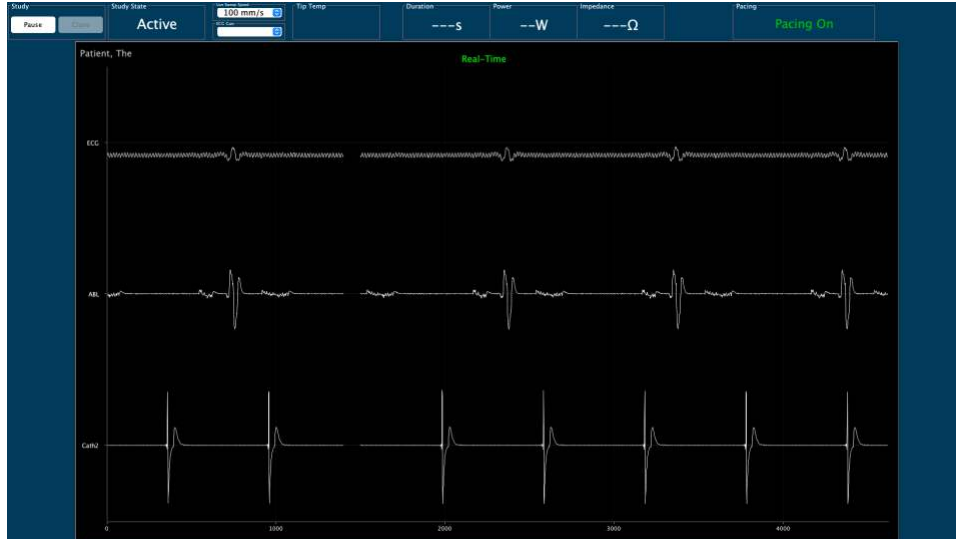
MiRACLE (12-Lead)



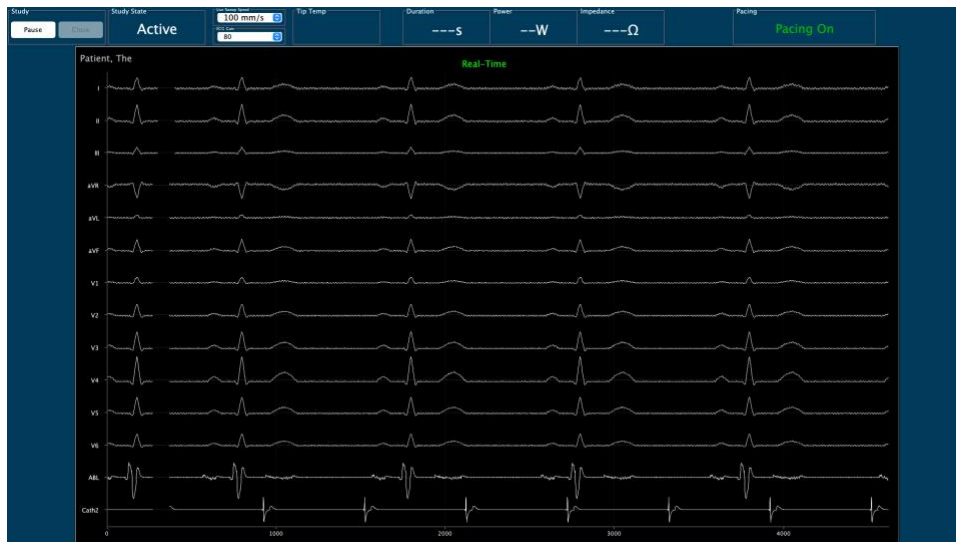
Primary Display Screen (Dual Monitor System)

Display of real-time electrograms, pacing status indicator, and temperature display are located on the primary monitor with the Real-Time Waveform panel.

Invivo (4-Lead)



MiRTLE (12-Lead)



Secondary Display Screen (Dual Monitor System)

Electrogram review and delay as well as voltage measurement calipers and pacing controls are located on the secondary monitor with the Review Waveform panel.

Invivo (4-Lead)



MiRTLE (12-Lead)



To begin the study, click on the Start button in the top left corner of the screen.

Once **Start** has been selected, the Review Waveform panel will appear below the Real-Time Waveform panel. All of the features of the Advantage-MR system are now operational, and the study may begin.

Using the Advantage-MR Software

Main Menu Bar

The Main Menu bar consists of drop-down menus that provide access to several features of the Advantage-MR system.

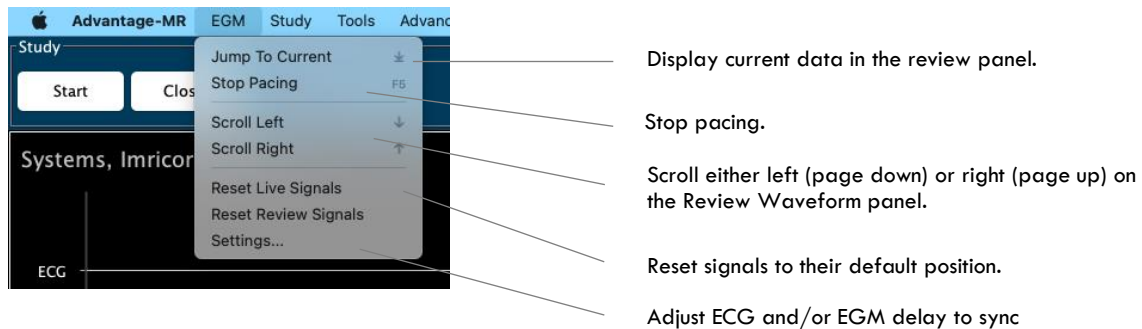


Advantage-MR

The Advantage-MR menu provides information regarding the software of the system. Users can quit the Advantage-MR program by clicking on *Quit* at the bottom of this menu.

EGM

The real-time and review electrogram waveforms can be controlled by clicking on features in the EGM menu. The following figure outlines the functions within this menu.



Study

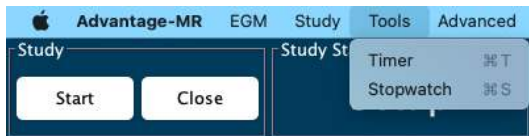
Users can start, pause, or close a study from the Study menu. Click on *Start* to begin a study, *Pause* to place a study on hold, and *Close* to end and record the details of the study. These functions can also be accessed through the Study buttons in the Status bar. See Study Status in the Status bar section of the manual.

Clicking on *Close* will close and finalize the current study and bring the user to the Study/Patient window. ECG source allows choice between Invivo (4-Lead) and MiRTLE (12-Lead). *Details* takes the user to the study details window where users can update patient information, make and record notes about the current study, and view study details. *Events* will display the event log, where the user can view events which occurred during the case. A single-click on an event will display details about the event. A double-click on an event will align the review window with the time the event occurred to display the event.



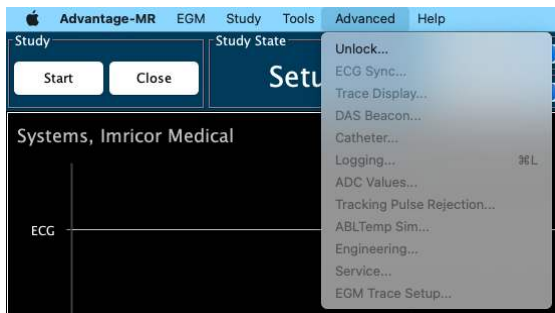
Tools

The Tools menu provides access to two event-timing tools: *Timer* and *Stopwatch*. The *Timer* feature provides countdown functionality, and the *Stopwatch* records elapsed time. Both tools provide readouts in increments of seconds, minutes, and hours. Click on the desired tool from the Tools menu to open the corresponding window.



Advanced

The Advanced menu provides access to the system software in the event of system upgrades or repairs. This menu is for use by authorized Imricor Medical Systems personnel only.



Help

The *About* feature offers basic Advantage-MR information and a link to the Instructions for Use in the language chosen upon starting the system.





Status Bar

The Status bar contains buttons, menus, and labels regarding the following aspects of the study.



Study Status

The Study button and Study State label are located to the far left in the Status bar. The Study buttons allow users to start, pause, and close a study by clicking on the respective button. The Study State label provides information regarding the current status of the study as detailed below.

Study State Label	Meaning
	System is ready to begin study.
	A study is currently underway.
	Current study is paused.
	Study has ended and been recorded.

Live Sweep Speed

The Live Sweep Speed menu provides control over the display speed and event spacing for waveforms in the Real-Time Waveforms panel. The sweep speed can be set to 20, 25, 40, 50, 60, 75, 80, 100, or 200 mm/sec. by clicking on the menu arrow to reveal the drop-down menu and selecting the desired sweep speed.

ECG Gain

The ECG Gain menu provides control over the gain of all ECG signals in the Real-Time and Review Waveforms panel. The gain can be set to 50, 55, 60, 65, 70, 75, 80, 85, 90, 95 or 100 by clicking on the menu arrow to reveal the drop-down menu and selecting the desired gain.

Ablation Labels

The following labels in the Status bar provide information during an ablation procedure. Values in the Duration, Power, and Impedance labels will display while actively ablating. The impedance value is also visible when the RF generator is in set-up mode.

- **Tip Temp**

Once a Vision-MR catheter with temperature sensing capabilities is properly connected to Advantage-MR, the Tip Temp label will display the tip temperature of the catheter. The temperature measurement is monitored via the fiber optic connection to the catheter, is displayed in degrees Celsius, and communicated to the compatible RF generator via a serial communication interface. The tip temperature measurement for each catheter is accurate to within $\pm 2^{\circ}\text{C}$ between 25°C and 60°C . The following table details the possible Tip Temp label displays and provides a description of their indication.

Display	Description
"###°C"	Catheter is properly connected, and Advantage-MR is receiving valid data. '###' represents a temperature value between 0°C and 100°C .
" "	Host Configuration is not properly configured.
"_ °C"	The catheter is not properly connected, or the sterile catheter cable is defective.
"NC"	Catheter is connected but the fiber optic cable is not connected or defective.
"ERROR"	Temperature is less than 0°C or greater than 100°C .

- **Duration**

The Duration label displays the duration of the ablation in seconds.

- **Power**

The Power label displays the power in Watts being delivered by the RF generator.

- **Impedance**

The Impedance label displays the impedance of the ablation procedure in Ohms.

- **Pacing**

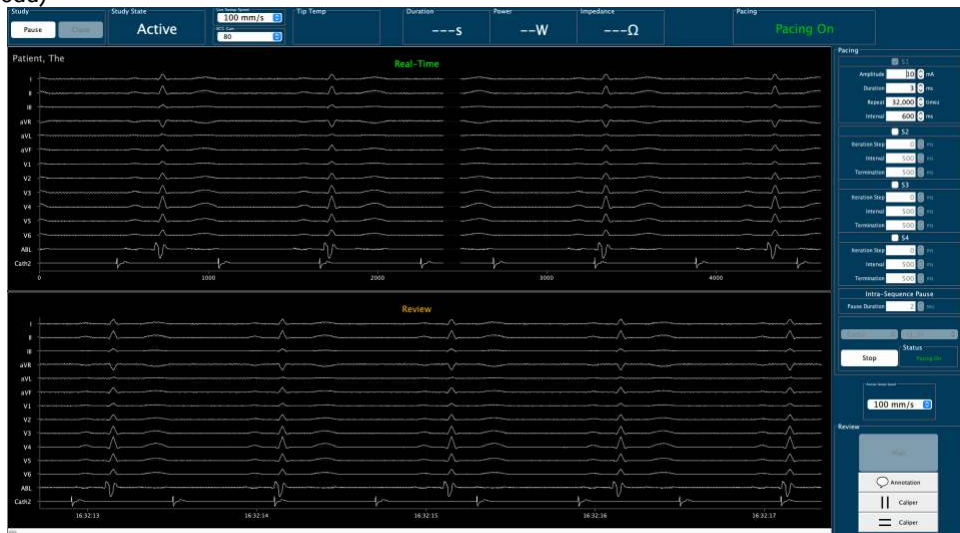
The Pacing label gives the current status of the pacing function.

Real-Time and Review Waveform Panels

Invivo (4-Lead)



MiRTLE (12-Lead)



Real-Time Waveform Panel

The Real-Time Waveform panel allows users to monitor real-time electrograms from the ablation catheter and a second diagnostic catheter. The ECG waveform(s) in the panel shows the electrogram signal from the ECG monitor. The ABL (1,2) displays EGM data from the ablation catheter while EGM data from the second catheter is displayed on the Cath2 (1,2) waveform. Users can rearrange the waveform locations within the panel. To change the location, click and hold the label of a waveform and drag the waveform to the desired location (top, middle, bottom). Users can rename the waveform label by right-clicking on the label and selecting the desired label name from the drop-down menu.

Note: Changes to label names will be saved in the system software. As such, if the name of the ABL (1,2) label is changed to CATH 1 during Patient A's study, when a new study starts for Patient B, the waveform generated by the catheter that is connected to the ABL CATH port will be labeled CATH 1.

The sweep speed of the real-time waveforms can be adjusted from the Real-Time Sweep Speed menu in the Status bar.

Advantage-MR also allows for adjustment of filter settings and selection of trace attributes within the Real-Time Waveform panel. Right-click on the label of the waveform to bring up the Context window for the selected waveform.



From the Context window, users can select the label name, device type, gain setting, and color of the waveform. Users can also apply low pass, high pass, and tracking pulse rejection filters to reduce noise in the trace. In addition, users may select the mains power reduction to filter mains power noise from the electrograms. This will display as either *50Hz Reduction* or *60Hz Reduction*, depending on the mains power frequency at your location. Users can limit the height of the displayed ECG waveforms by changing the clipping settings.

To prevent waveforms from overlapping, clipping can be enabled to limit the maximum waveform size. Clipping can be active continuously, only during pacing, or disabled. If clipping is continuously enabled, a ¢ symbol will appear next to the waveform label. If clipping is enabled only during pacing, a \sim symbol will appear next to the waveform label.

Review Waveform Panel

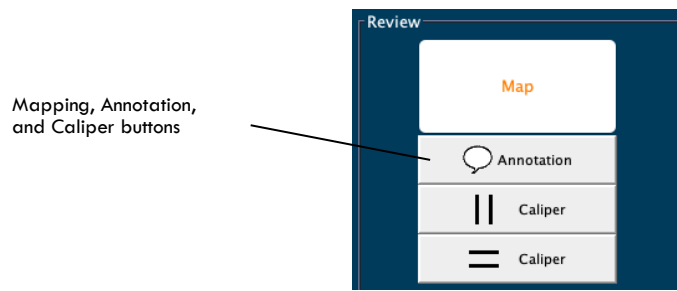
With a format similar to that of the Real-Time Waveform panel, the Review Waveform panel provides users with the ability to record and analyze EGM and ECG data. See the Mapping, Annotation, and Caliper Tools section of this IFU for a detailed description of the features of the Review Waveform panel. Users can also scroll left and right through the Review Waveform panel with the page down and page up keys to view events of the study.

Review Sweep Speed

The Review Sweep Speed menu allows users to select the sweep speed of the review waveform. The review sweep speed can be set to 20, 25, 40, 50, 60, 75, 80, 100, or 200 mm/sec. by clicking on the menu arrow to reveal the drop-down menu and selecting the desired sweep speed.

Mapping, Annotation, and Caliper Tools

Advantage-MR features mapping, annotation, and caliper placement features that allow users to acquire, analyze, and record events throughout the course of a study. Users can quickly access these tools through their corresponding buttons located in the lower right panel of the Main Display screen.



Time Caliper Tool



The Time Caliper tool allows users to measure time intervals between recorded events in the Review Waveform panel. To place calipers, first click on the Time Caliper button. Then, click on the desired location of the first caliper timestamp in either the Real-Time or Review Waveform panel. A vertical caliper will appear to mark the location in the Review Waveform panel. Then, click on the desired location of the second vertical caliper in the Review Waveform panel. The time in milliseconds will appear between the two calipers. This pair of calipers will now be saved in the Review Waveform panel and additional caliper pairs can be created. To delete a caliper pair, select the Time Caliper tool and right click on the measurement label.

Amplitude Caliper Tool



Users can measure amplitude between recorded study events by placing amplitude calipers in the Review Waveform panel. To place an amplitude caliper, click on the Amplitude Caliper button, hover the mouse over the desired trace until the trace changes color, and then click on the desired location of the first horizontal caliper in the Review Waveform panel. Then, move the cursor to the location for the second horizontal caliper and click. The amplitude between the two calipers will appear. This measurement will be recorded on the Review Waveform panel and additional amplitude calipers can be placed. To delete a caliper pair, select the Amplitude Caliper tool and right click on the measurement label.

Map Tool

To send caliper data to a compatible EP mapping system, click on the Map button. This will send the selected caliper measurement and the associated time stamp to the EP mapping system.

Annotation Tool

Advantage-MR provides users with the ability to create annotations in the Review Waveform panel. To create an annotation, click Annotation, and then click on the desired location of the annotation in the Review Waveform panel. A text box will appear for users to type the annotation. Once the annotation is complete, users must press the Return key to save the notation on the Review Waveform panel. To cancel an annotation, press the Escape key or click on a different location in the Review Waveform panel prior to pressing Return.

Annotations can be moved by deselecting the Annotation Tool button, left clicking on the annotation, and then dragging it to the desired location. To delete an annotation, select the Annotation Tool button, left-click the annotation text, and then right-click the text while it is still highlighted (label background will be orange).

Pacing Panel

Advantage-MR can be programmed to deliver non-synchronous, monophasic, bipolar pacing stimuli to any pair of electrodes on any connected Vision-MR catheter. To access the pacing controls and parameters, select the catheter that will receive the pacing stimuli in the lower portion of the Pacing panel.

To begin pacing, click the Start button in the lower portion of the Pacing panel. Users can adjust amplitude, duration, repetition, and intervals of the pacing stimuli at any time, including while pacing. To change pacing parameters for a pacing protocol, select the desired value from the parameters drop down menu or manually enter the value in the parameter text box.

Values entered from the keyboard will appear in italics (e.g. *450*), until they are committed by pressing the 'Return', 'Tab' or 'Enter' key. Out of range values will appear with a strikethrough (e.g. ~~3500~~), and invalid letters or symbols will appear bolded with a strikethrough (e.g. ~~3g9~~).



Parameter	Programmable Range
Pulse Amplitude	0.1 mA to 25 mA
Pulse Duration	0.1 ms to 10 ms
Repeat	1 to 32,767 times
Inter-Stimulus Interval	150 ms to 3,000 ms
Iteration Step	5 ms to 50 ms
Pause Duration	2 sec to 12 sec

Pacing parameters can be changed using the 'Up' or 'Down' buttons next to the parameter. The 'Up' button will increase the parameter value and the 'Down' button will decrease the parameter value. The amount that is incremented or decremented is based on the current parameter value and follows this scheme:

Parameter Value	Increment/Decrement Value
Values less than 1	0.1
Values less than 5 and greater than 1	1
Values greater than 5	5

Pacing can be stopped at any time by pressing the F5 key, selecting 'Stop Pacing' from the EGM menu, or clicking on the Stop button in the Pacing panel.

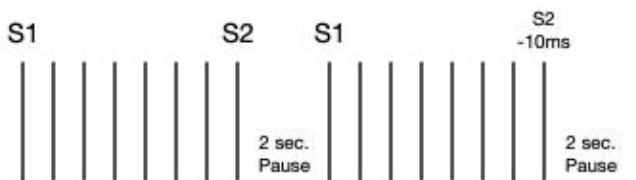
Programmed Stimulation

Advantage-MR can be configured to deliver programmed stimulation pacing protocols to any pair of electrodes on any connected Vision-MR catheter. The S1 stage can be configured to deliver a series of pace pulses with a desired duration, amplitude, interval, and number of repetitions. The S1 amplitude and duration is used for all subsequent stages.

Stages S2 – S4 can be configured with an iteration step, interval, and termination value. When activated, the configured stage delivers a single pacing pulse after the preceding stage and initiates successive pulse trains with the configured stage’s interstimulus interval decremented by the iteration step until the termination value is reached, or pacing is manually terminated.

The delay between successive pulse trains is set using the intra-sequence pause.

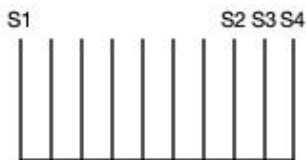
The image below shows two successive S1-S2 pulse trains with seven repetitions of S1, an S2 iteration step of 10ms, and a 2 second intra-sequence pause. Stages S3 and S4 are inactive.



The pulse train can be configured such that no stage is configured to decrement. A single pulse train is delivered consisting of consecutive active stages in numeric order. In this configuration, the S1 stage is delivered as programmed and stages S2 – S4 deliver a single pacing pulse with their programmed intervals.

Stages S2 – S4 can only be configured if all previous stages are activated.

The image below shows an example of a pulse train delivered when S1 – S4 are active, and no stage is configured to decrement.

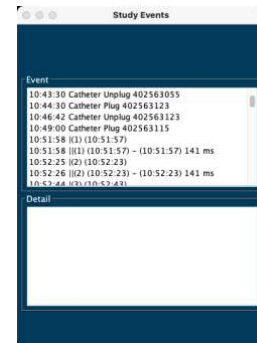


Closing a Study

When a study is finished, click Close in the Study Status label of the Status bar. When Close is clicked, the study will be finalized.

Event Viewer

Events occurring during a study, such as pacing, ablation, and annotation are recorded in the event viewer. The user can browse through the time-stamped list of events. Selecting an event will display details of the event in the lower window of the Event Viewer, if details are available. Double-clicking an event will bring that event in the Review screen for further examination.



Shutting Down Advantage-MR

To shut down the Advantage-MR system, power off the following components:

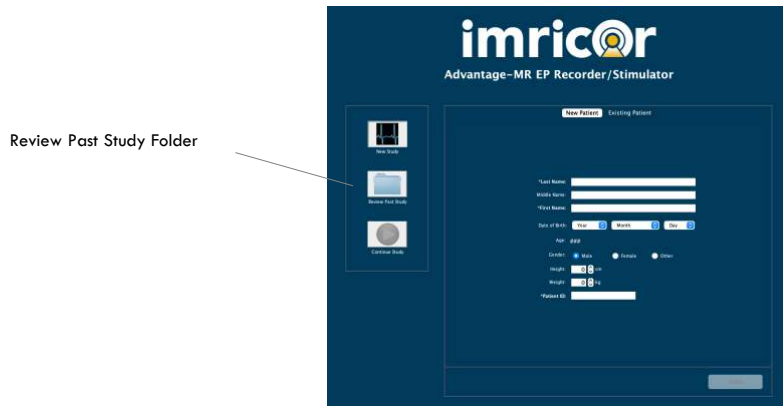
- DAS Power Supply
 - Turn power switch to the OFF position. The switch is located on the back of the DAS Power Supply. The green indicator light on the switch will turn off.
- Host Configuration
 - Close out of the Advantage-MR application by selecting the "Advantage-MR" drop down menu from the top left corner of the Host Display Screen and selecting "Quit Advantage-MR".



- Once the Advantage-MR application has closed, select the Apple icon from the top left corner of the display and select "Shut Down..."
- A pop-up will ask to confirm whether a shutdown was intended. Press the "Shut Down" button on the window or wait 1 minute and the computer will shut down automatically.
- Monitor
 - Press the power button located on the lower right corner of the monitor. Power symbol illumination will turn off.

DATA MANAGEMENT

Initially, all patient studies will be stored on the Host Computer hard drive. All studies on the hard drive are accessible through the Review Past Study folder on the Study/Patient window.



Clicking on the Review Past Study folder will bring up a window that contains all of the studies that are stored on the hard drive.



From here, users may copy studies to or from a DVD via the external DVD drive, delete studies, delete patients and view saved studies.

Copying Studies to and from a DVD

To copy studies from the hard drive to a DVD, ensure that the external DVD drive is properly connected to the monitor and that a DVD has been inserted into the drive. Select the study to be saved and click the Copy To DVD button at the bottom of the window. Only one study at a time may be selected when using the Copy To DVD function. **Studies are not automatically deleted from the hard drive after they have been copied to DVD.** Studies must be manually deleted. See the Deleting Studies section below for details.

To copy studies from a DVD to the hard drive, insert a DVD with previously saved studies into the DVD drive. A list of the studies from the DVD will be displayed in the window. Select the study or studies to be copied and then click the Copy From DVD button. More than one study may be selected by holding down the Command (⌘) button on the keyboard while selecting multiple entries. The studies will be copied to the Review Past Study folder and can be accessed as an existing study.

When the hard drive lacks sufficient memory to save a new study, old studies must be saved to DVD and deleted before beginning a new study. Advantage-MR will not allow a new study to begin if there is insufficient memory available to save the study. If users attempt to start a new study under these conditions, the error message "Disk Space Full. Studies must be removed before new studies are allowed," will appear requiring the user to delete studies. When enough studies have been deleted from the hard drive, the message "Disk Space Now Available. New study capability is reinstated," will appear and a new study may begin.

Deleting Studies

To delete studies from the Advantage-MR hard drive, select the studies to be deleted from the Study/Patient window and click the Delete button at the bottom of the window. A message will appear asking the user to verify that the studies are to be deleted.

Deleting Patients

To delete a patient from the patient database, switch to the Existing Patient tab, located on the Study/Patient window. This window is only available if there are no open studies. Select the patient from the list, then press the Delete button at the bottom of the window.

Ejecting DVD

To eject the DVD from the DVD drive, click on the Eject DVD button at the bottom of the window.

ERROR MESSAGES

During a study, users may encounter error messages. A list of the error messages that may be encountered and their probable cause and the recommended course of action can be found below.

Error Message	Problem/Cause	Course of Action
Advantage-MR System Unresponsive	Host Computer unable to communicate with DAS	Verify proper setup and power of Advantage-MR System. Call Imricor for assistance.
File Type Not Supported for That Operation	Under normal operation, loading a study with invalid/corrupt files.	Improper file selected for current task. Call Imricor for assistance.
File Access Error	Host account permissions not allowing read/write access to file.	Improper host installation. Call Imricor for assistance.
Error Accessing Database	Host database software improperly installed or non-existent. Required for fully functional system.	Improper host installation. Call Imricor for assistance.
Catheter Card Detection Error	An internal error has been detected by Advantage-MR.	Discontinue use and contact Imricor for assistance.
Review Chart Full	Review chart is full.	Prompt allows study continuation in a new study with same patient information or ending of study.
Disk Space Full Studies must be removed before new studies are allowed.	Too many studies on hard drive.	Copy studies to external DVD and remove studies from hard drive.
Disk Space Now Available New study capability is reinstated.	Hard drive space is now available for new study.	Previous error has been resolved. New studies can now be created.
Advantage-MR Configuration Load Failed	Advantage-MR configuration file corrupted.	Improper host installation. Call Imricor for assistance.
Advantage-MR Configuration Save Failed	Advantage-MR configuration file failed to save properly on shut down	Improper host installation. Call Imricor for assistance.
Advantage-MR Installation Configuration File Missing	Advantage-MR configuration file corrupted.	Improper host installation. Call Imricor for assistance.
Study Configuration Load Failed	Loading a study with invalid/corrupt configuration file.	Archived study is corrupted. Call Imricor for assistance.
Study Configuration Save Failed	Study configuration file failed to save update.	Improper host installation. Call Imricor for assistance.
Mapping Template Load Failed	Advantage-MR mapping configuration file corrupted.	Improper host installation. Call Imricor for assistance.
Mapping Template Save Failed	Advantage-MR mapping configuration file can't be saved.	Improper host installation. Call Imricor for assistance.
Hours: Invalid Entry Minutes: Invalid Entry Seconds: Invalid Entry	Time value is not a valid time. One or more parts are out of range	Correct entry to use a valid time value
Input Field Contains Non-numeric Values	A numeric value was expected, but non-numeric characters or symbols were entered.	Correct the entry and remove any non-numeric characters or symbols

TROUBLESHOOTING

If users experience any irregular or untoward performance from Advantage-MR, consult the troubleshooting table below. If the irregularity in performance is not corrected with the suggested solutions or if the symptom is not addressed, contact Imricor before any further use.

General Troubleshooting

Issue	Action
Unresponsive system components - Step 1	Verify for missing hardware or loose components: Verify that all components listed in the Typical Set-up Section are present and properly connected in the system.
Unresponsive system components - Step 2	Verify all cable connections are secure: Cables can appear to be connected without making a complete connection. Unplug and reconnect all connections to verify the connections are secure.
Unresponsive system components - Step 3	Inspect all cables for kinks or breaks: Inspect cables for kinks and breaks. Pay special attention to the fiber optic cables, which should not have any sharp bends in the cables.
Unresponsive system components - Step 4	Verify all system power switches are in the ON position: There are several power switches in the system. They are listed below: -Host enclosure, rear power inlet -Host Computer, front power button -DAS Power Supply, rear power inlet
Unresponsive system components - Step 5	Verify that the wall outlets used are live: If necessary, use a line analyzer to verify the outlet for both power and ground.
Monitors do not receive video signal	Verify monitor cables between the monitors and the back connection panel of the Host Workstation enclosure are properly connected. Verify that one or both monitors are powered on.
Keyboard and/or mouse is unresponsive	Verify the USB-C connection between the Host Workstation Monitor and the back connection panel of the Host Workstation. Verify the keyboard is plugged into a USB port on the Host Workstation Monitor. Verify the mouse is plugged in to a USB port on the Host Workstation Monitor.
Unable to login to the host computer	Verify that you have the correct username and password for the system. Verify that the CAPS LOCK is not on. Note: that the password is case sensitive.
Advantage-MR host software does not automatically launch	Verify that the Advantage-MR Host Software is listed in the Login Items for the user that is logged in.

Functional Troubleshooting

Issue	Action
No electrograms displayed	<p>Verify that power is applied to the DAS Power Supply in the Magnet Room. Green LED should be illuminated.</p> <p>Verify all power cable connections between the DAS Power Supply and the Digital Amplifier Stimulator (DAS).</p> <p>Verify optical Ethernet cable connections at the DAS and the back of the Host Workstation cabinet. Verify connector is seated all the way in the connector, and that the cable is not kinked or broken. Reference the connection diagram if necessary.</p> <p>Verify the RJ-45 Ethernet cable connection between the Fiber Optic Ethernet Converter inside the Host Workstation cabinet on the shelf, and the Host Workstation Ethernet port. Reference the connection diagram if necessary.</p>
Loss of electrograms for a single catheter	<p>Verify that the sterile cable from the catheter to the Patient Device Interface (PDI) is properly connected.</p> <p>Verify that the cable from the Patient Device Interface (PDI) to the Digital Amplifier Stimulator (DAS) is properly connected.</p> <p>Verify that all power cables between the DAS Power Supply and the DAS are properly connected.</p>
Unable to activate/update Review screen	<p>The Review screen is only active once a Study has been started. If a study has not been started, press the study Start button to begin recording a study.</p>
Signal gain cannot be changed	<p>To change the gain of a signal, you must either hover the mouse over the signal label and press the Up/Down arrow keys or right-click on the signal label and adjust the gain value in the edit box.</p>
Sweep speeds between the Live screen and the Review screen are not the same	<p>Verify the Sync checkbox is checked in the EGM settings menu.</p> <p>Select a sweep speed for the live window to sync both the live and review screens.</p>
Loss of catheter tip temperature	<p>Verify that the optical fiber is plugged in at the catheter and the Patient Device Interface (PDI).</p> <p>Visually verify that the optical fiber is not kinked or broken.</p> <p>Verify that the optical fiber between the PDI and the Host enclosure is properly connected.</p> <p>Straighten the ablation catheter.</p>
Temperature error message displayed	<p>Use the Tip Temp table to determine the potential cause of the error message</p>
RF Generator data is not displayed (no data available)	<p>Verify that the RF Generator is connected to the Advantage-MR system using the supplied cable.</p> <p>Verify that the serial adapter is connected to the serial port on the back panel of the Host enclosure.</p>
Unable to place calipers	<p>To place calipers, you must Start a study.</p> <p>Press one of the caliper button types to enable the caliper tool.</p>
Unable to send caliper measurements to the mapping system	<p>Verify that the RJ-45 Ethernet cable is connected at both the compatible Mapping System and at the back of the Host enclosure.</p> <p>Refer to the Connection diagram to verify that the Ethernet cable is connected to the proper port on the back of the Host enclosure.</p>
Incorrect voltage measurements	<p>Verify that prior to the first caliper being placed, that the intended signal to be measured is highlighted orange. Whichever signal trace the mouse is hovering over is the highlighted trace and it will be the active trace for the voltage caliper measurement.</p> <p>If the desired signal amplitude to be measured is outside of the signal area, a few actions may be performed to achieve an accurate measurement:</p> <p>Decrease the gain for that signal until it can be measured accurately within the active signal area. Or, place calipers within the signal area, and once placed with a voltage measurement displayed, move the calipers to their desired locations.</p>
Unable to remove calipers	<p>Verify that a caliper tool has been selected (either vertical or horizontal). Left click on the caliper measurement you wish to remove. The measurement value should have a grey background if selected. Right-click outside of the caliper to delete the selected caliper.</p>
Noisy electrograms	<p>Place the mouse over the signal label in the Real-time screen and right-click on the label to bring up the properties of the signal trace. Select filter configuration to remove unwanted noise from the signal.</p>
Surface ECG issues	<p>Verify that the surface ECG pads are placed correctly and that none of the pads have become partially or entirely removed from the patient.</p> <p>Verify all cable connections are secure.</p> <p>Verify the gain of the ECG signal traces.</p>

Issue	Action
Unable to start pacing	<p>Verify that there is power to Digital Amplifier Stimulator (DAS). Verify all power cable connections between the DAS Power Supply and the DAS.</p> <p>Verify that the optical Ethernet cable is connected to both the DAS and the Host Workstation. Unplug and re-plug the cable and make sure that the connector is properly seated.</p> <p>Verify that you have selected an Electrode Pair to pace between. If the Catheter selection box says None, select a catheter from the dropdown list.</p>
Unable to stop pacing	<p>Press the function key F5 to stop pacing.</p> <p>Unplug the catheter you are pacing on from the Patient Device Interface (PDI).</p> <p>Disconnect the fiber Ethernet (orange) cable from the Digital Amplifier Stimulator (DAS).</p>
Signals are clipped	<p>Right-click on the signal name that is being clipped, bringing up the signal configuration box. Select Never as the desired clipping effect</p>
Data is missing in the Review screen	<p>You must Start a study for data to be recorded to the Review window.</p> <p>Using the scroll bar, Page Up, or Page Down buttons, scroll past the time where there was no data collected. All data is recorded once a study has been started until it is closed or paused</p>

MAINTENANCE

Maintenance

To disinfect the dispersive electrode cable after each use, wipe with disinfectant such as 10% bleach and water solution, Cidex[®], or Lysol[®]. Do not use organic solvents. After disinfecting, the dispersive electrode cable should be wiped with water and then dried with a clean cloth. **Do not sterilize (e.g., autoclave) the dispersive electrode cable.**

Periodic maintenance is needed to ensure reliable operation. Annually, an authorized representative from Imricor Medical Systems will perform on-site maintenance services according to Imricor standard procedures. Only Imricor personnel or an Imricor authorized representative should perform annual maintenance for the Advantage-MR system.

For weekly preventative care, users should:

- Inspect all cables for damage, such as excessive pinching or crushing. Contact Imricor if damaged cables are discovered.
- Clean system components externally using a cloth dampened with standard hospital equipment cleaning agents such as isopropyl alcohol, Cidex[®], or mild soap and dry with a clean cloth. **Do not spray or pour agents directly onto equipment and do not use acetone solvents. Do not submerge the cables. Use an antistatic screen cleaner to clean the monitors.** Place the cleaner on a cloth and wipe the screen. Do not apply the cleaner directly to the screen and do not use window or glass cleaner on the monitors.

Serviceable Life and Disposal

The dispersive electrode cable has been tested for 100 uses. Inspect condition before use and if cracked, damaged or loose, discard according to facility protocol and replace with a new cable.

The Advantage-MR EP Recorder/Stimulator System has an expected life of three years and will be serviced by Imricor for this period of time. Upon decommissioning the Advantage-MR system, all components and cabling, except the dispersive electrode cable(s), must be returned to Imricor Medical Systems for proper disposal as per the WEEE Directive 2012/19/EU. Contact Imricor for information regarding the proper procedure for returning the system for disposal.

Security

The Advantage-MR System is not designed to connect to a network.

To ensure security and patient privacy (including PHI), follow these recommendations:

- Use strong passwords
- Change passwords regularly
- Ensure that the Advantage-MR System is operated only in a secured hospital environment

SPECIFICATIONS

General Specifications	
Electrical Isolation	
Leakage Current	Conforms to IEC 60601-1.
Dielectric Withstand	Conforms to IEC 60601-1.
Temperature Range	
Operating:	+15 °C to +35 °C, 30% to 85% relative humidity, non-condensing, 80 to 106 kPa
Storage:	-29 °C to +60 °C, 30% to 85% relative humidity, non-condensing, 80 to 106 kPa
Transport	-29 °C to +60 °C, 30% to 85% relative humidity, non-condensing, 80 to 106 kPa
AC Power Input	
Input voltage	100 to 240 VAC (EU)
Input frequency	50/60 Hz

Functional Specifications	
Electrograms	
Amplitude Range	5 μ Vp-p to 100 mVp-p
Amplitude Accuracy	\pm 5 μ V or 10%, whichever is greater
Signal Data Rate	1000 samples/sec
Catheter Tip Temperature	
Temperature Range	25°C to 60°C
Temperature Accuracy	\pm 2°C
Sample Rate	1 s
Pacing	
Current Amplitude Max	25 mA
Voltage Amplitude Max	27 V
Pulse Duration	0.1 ms to 10 ms
Inter-Stimulus Interval	150 ms to 3,000 ms


GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

This product has been tested to EN/IEC60601-1-2:2015 +A1:2021.

EMI/EMC Specifications

- Medical Electrical (ME) equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided below.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- ME equipment or systems should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the ME equipment or system should be observed to verify normal operation in the configuration in which it will be used.
- During interruptions of power or high levels of transient interference, performance of the display monitors, including tip temperature display, may degrade requiring user intervention.
- During interruptions of power, the Host computer may restart requiring the user to launch the application and resume the case. In this situation, tip temperature display will be unavailable.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The Advantage-MR EP Recorder/Stimulator System is intended for use in the electromagnetic environment specified below. The customer or the user of the Advantage-MR system should assure that is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Advantage-MR system uses RF energy only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions - CISPR 11	Class A	The Advantage-MR system is suitable for use in all establishments other than domestic and those connected directly to the public low-voltage power supply network that supplies buildings used for domestic purposes. 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.
Harmonic Emission - IEC 61000 3-2	Not Applicable	
Voltage Fluctuations/ Flicker Emission - IEC 61000 3-3	Not Applicable	
Essential performance function	Remarks	
Tip temperature accuracy has been identified as essential. The tip temperature must either be reported accurately (± 2 °C) or not reported.	Measurement and display of tip temperature are relevant during electrophysiological studies and related procedures and is an indicator for ablation power delivery.	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Advantage-MR system is intended for use in the electromagnetic environment specified below. The customer or the user of the Advantage-MR 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 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. During high levels of interference, displays may not recover to their normal operating mode. See troubleshooting for restoring displays to their normal operating mode.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	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 (NOTE Ut is the AC mains voltage prior to application of the test level.)	<ul style="list-style-type: none"> ● 0% Ut (100% dip in Ut) for 0.5 cycle ● 0% Ut (100% dip in Ut) for 1 cycle ● 70% Ut (30% dip in Ut) for 0.5 sec ● <0% Ut (>100% dip in Ut) for 5 sec 	<ul style="list-style-type: none"> ● <0% Ut (>100% dip in Ut) for 0.5 cycle ● 0% Ut (100% dip in Ut) for 1 cycle ● 70% Ut (30% dip in Ut) for 0.5 sec ● <0% Ut (>100% dip in Ut) for 5 sec 	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Advantage-MR system requires continued operation during power mains interruptions, it is recommended that the Advantage-MR system be powered from an uninterruptible power supply or battery. During interruption in power, displays may not recover to their normal operating mode. See troubleshooting section for restoring displays to their normal operating mode. During interruption in power, the Host computer may restart requiring the user to restore display operation, launch the application, and resume the case.
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 Radiated RF 61000-4-3	<p>3Vrms 150 kHz to 80 MHz</p> <p>3Vrms In ISM bands between 150kHz and 80 MHz 80% AM at 1 kHz</p> <p>3V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz</p>	<p>3Vrms 150 kHz to 80 MHz</p> <p>3Vrms In ISM bands between 150kHz and 80 MHz 80% AM at 1 kHz</p> <p>3V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Advantage-MR system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance: $D = (3.5/\sqrt{V1}) \sqrt{P}$ $D = (3.5/E1) \sqrt{P}$, 80 MHz to 800 MHz $D = (7/E1) \sqrt{P}$, 800 MHz to 2.5 GHz</p> <p>Where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol.</p> 
<p>NOTE 1 At 80 and 2.7 GHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			
<p>^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 Advantage-MR system is used exceeds the applicable RF compliance levels above, the Advantage-MR system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Advantage-MR system.</p> <p>^b Over the frequency range 150kHz to 80 MHz, field strengths should be less than 6 V/m for ISM bands and 3 V/m otherwise.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the Advantage-MR system.			
The Advantage-MR system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Advantage-MR system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Advantage-MR system 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 $d = [3.5/3] \sqrt{P}$	80 MHz to 800 MHz $d = \{3.5/3\} \sqrt{P}$	800 MHz to 2.5 GHz $d = \{7/3\} \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.73
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.70	11.70	23.33
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.			

SERIOUS INCIDENT REPORTING

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



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