

Ampere™ Generator

INSTRUCTIONS FOR USE INTERNATIONAL EDITION

Software version 1.0


WARNING: The use of this device in conjunction with a radio frequency ablation catheter, as a part of the diagnosis and treatment of cardiac arrhythmias, may pose an increased risk of adverse events such as cardiac perforation, myocardial infarction, air embolism, and hematoma requiring surgical repair and/or blood transfusion.


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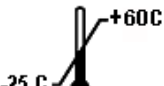
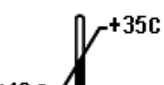

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Symbol	Description
	Do not use if package is damaged.
	Package contains 1 item.
	Defibrillator-proof type CF applied part
	Defibrillator-proof type BF applied part
	Power switch
	AC Power
	Power Plug
	Equipotential jack
	Non sterile
	Do not reuse
	On carton: Transport/storage temperature limitation
	Operating temperature
	Humidity limitation

Symbol	Description
	Weight
	Fragile
	Keep dry
	Manufacturer
	Date of Manufacture
	Use by date
	Lot number
	Catalog number
	Serial number
	Finished Goods number
	Made in U.S.A.
	Not for direct patient contact
	Consult the Instruction for Use
	Dispose of hardware in accordance with local law

Symbol	Description	Symbol	Description
	Warning General Serious injury can occur if care is not taken during use of the system.		Ablate
	Caution		Menu
	Notified body CE Mark		Preset
	Authorized representative in the European community		Up Button
	Input Voltage, Input Frequency and Replacement fuse information		Down Button
	Software		Standby Button
	In Metro Mark - Brazil		Electrogram Cable Connection
	Intertek Safety Agency Certification Mark		Footswitch Connection
	On GenConnect: GenConnect cable connector		USB Connection
	On EnSite™ Velocity™ Cardiac Mapping System Amplifier: Fiber optic cable connector		Monitor Connection
	Dispersive patch cable connector		Pump Connection
	Ablation catheter cable connector		Remote Connection
	Telephone		Remote Control
	Facsimile		Generator Accessories
			Rated Voltage

Symbol	Description
RATED CURRENT	Rated Current
Footswitch	Footswitch
Generator	Generator
	Non-ionizing electromagnetic radiation.
CABLES	Cables
CORDS	Cords
PACKAGE CONTENTS	Package Contents
IP68	Footswitch enclosure is dust tight and protected against submersion in water.
F	Neutral Electrode (Floating Ground)

Introduction

Preface

The use of all components and accessories of the Ampere™ Generator is described in this manual. The ablation catheter description can be found in a separate instruction for use manual available with the catheter. This manual provides a description of the Ampere™ Generator, its controls and displays, and a sequence for its operation. This Ampere™ Generator can operate with/without the Cool Point™ Irrigation pump. Other important information has also been supplied for the user's convenience.

Precaution

DO NOT attempt to operate the Ampere™ Generator before thoroughly reading this Instructions for Use. The Ampere™ Generator Instructions for Use should be read, understood, and followed carefully. For future reference, keep this manual in a convenient, readily accessible place.

Indications For Use

The Ampere™ Generator is intended for use with an EP ablation catheter in creating endocardial lesions during cardiac ablation procedures to treat cardiac arrhythmias.

Contraindications

The use of this device is contraindicated in patients with active systemic infection.

System Description

Overview

The Ampere™ Generator generates radiofrequency (RF) current, at 485 KHz, to be used during RF catheter ablation procedures of the heart. The Ampere™ Generator operates in conjunction with an external Disposable Indifferent Patch (DIP) electrode (such as the 1149C-LP by 3M™ or equivalent) and a compatible ablation catheter with an associated cable. The Ampere™ Generator delivers RF power in a unipolar mode between the ablation catheter's distal electrode and the DIP electrode. For more information regarding the ablation catheter, refer to its instruction manual.

The Ampere™ Generator features a color LCD screen and easy-to-use controls for setting the desired ablation parameters and for monitoring ablation progress. The generator can be controlled from the front panel of the main unit or by an optional remote control unit connected via fiber optic cables. Additional accessories to the generator include an optional footswitch the operator can use to turn on or off RF delivery. When connected with a compatible St. Jude Medical Cool Point™ irrigation pump, the Ampere™ Generator provides additional pump control options for use with an irrigated ablation catheter. The Ampere™ Generator is designed to be used with ablation catheters having integrated temperature sensors, and can measure temperature from a thermistor or up to 4 thermocouples. The Ampere™ Generator provides for connection to an electrophysiologic recording system and the EnSite™ Velocity™ cardiac mapping system.

User Features

The Ampere™ Generator continuously and automatically monitors electrical impedance between the ablation catheter and DIP electrode at 485 KHz and displays the impedance on the LCD screen. Likewise, temperature from the catheter's temperature sensor is also continuously and automatically monitored and displayed. RF parameters of power output, temperature, duration, and an impedance limit are controlled from the front panel using up/down buttons. Frequently-used RF parameters can be programmed into one of 4 presets also accessible from the front panel. Additional display and ablation control options are accessed through a menu and turn knob control. RF energy can be turned on or off from a single push-button. A standby button is also available for emergency cutoff of RF energy. Displays and controls on the main unit are identical on the optional remote control such that changes made to settings on either the main unit or the remote control are reflected on both.

TempGuard™ Feature

The Ampere™ Generator features a user selectable temperature control algorithm, referred to as the TempGuard™ feature. When the TempGuard™ feature is selected (through the Ablation Parameters menu), the generator operates in temperature control mode, and power output from the generator is automatically modulated so that the temperature measured from the catheter remains at or below the user set temperature. In temperature control mode, additional options are available to control the initial response time of the TempGuard™ feature. Note that if insufficient power is selected while in temperature control mode, the user set temperature may not be achieved.

When the TempGuard™ feature is turned off, the generator operates in power control mode. In this mode, the user set power is output by the generator within a user settable ramp-up time, and then maintains that power. In power control mode, a user set cutoff temperature can be applied such that RF will automatically terminate if the catheter temperature exceeds the user set temperature.

Impedance Control

An impedance limit on the main display can be set using the up/down arrows, where RF will automatically stop if the measured impedance exceeds the limit. Additionally, an optional delta impedance cutoff can be selected. This delta impedance cutoff will automatically stop RF delivery if impedance changes by a user selected amount over a time window of 1 to 10 seconds.

Cool Point™ Irrigation Pump Integration

When used with an irrigated catheter and a Cool Point™ Irrigation Pump, the Ampere™ Generator automatically communicates with the pump and allows changing of pump parameters from the generator (through the Pump Parameters menu). The Ampere™ Generator can also be set to automatically change the irrigation rate during ablation if either the power or temperature reach a user defined level.

Customizable Information Displays

Various additional options are also available to the user from the menu, including statistics on power, temperature, and impedance from previous ablation applications, display of additional information during ablation applications, and language, audio volume, and screen brightness control.

Safety Features

The Ampere™ Generator has many safety features and includes a separate standby button on the front panel to disable RF delivery; automatic RF shutoff if the impedance < 50 ohms or > 300 ohms or greater than the user set impedance limit; and automatic RF shutoff if the catheter temperature > 80 °C or if the catheter temperature exceeds the user set temperature by more than 5 °C for more than 3 seconds.

System Hardware

Components

- Ampere™ Generator
- Footswitch

Cables

- Country-specific power cords
- Equipotential Cable
- 4 Lead EGM Cable
- Serial DB9 Cable
- 1641 Cable - Catheter Extension Cable
- Disposable Indifferent Patch (DIP) (x2)
- GenConnect Cable

Accessories

This accessory is available for use with the Ampere™ Generator:

- Remote Control with power cords, equipotential cable, and fiber optic connecting cables

Warnings, Precautions, and Adverse Reactions

Definitions

- WARNING:** A warning contains instructions for avoiding hazardous situations that could cause significant injury to a patient or operator.
- CAUTION:** A caution contains instructions for avoiding hazards that could adversely affect system components or system performance.
- NOTE:** A note contains specific information relative to the subject at hand.

Warnings

- WARNING:** Cardiac ablation procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency catheter ablation in a fully-equipped electrophysiology laboratory.
- WARNING:** Catheter ablation procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as an increased risk for somatic and genetic effects to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps have been taken to minimize this exposure. Careful consideration must therefore be given for use of the device in pregnant women. The long-term risk of protracted fluoroscopy has not been established; therefore, careful consideration must be given for the use of the device.
- WARNING:** Pacemakers and implantable cardioverter/defibrillators can adversely be affected by Radiofrequency (RF) signals. It is important to **a)** have temporary external sources of pacing and defibrillation available during ablation, **b)** deactivate ICD's as they could discharge and injure the patient or even damage the ICD's during the ablation procedure, **c)** exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent pacing leads, and **d)** perform complete pacing system analysis on all patients after ablation.
- WARNING:** Ablation within the coronary arterial vasculature has been associated with myocardial infarction and death.
- WARNING:** Patients undergoing left-sided ablation procedures should be closely monitored during the post-ablation period for clinical manifestations of infarction and stroke.
- WARNING:** The long-term risk of lesions created by RF ablation has not been established. In particular, any long-term effects of lesions in proximity to the specialized conduction system or coronary vasculature are unknown.
- WARNING:** When using an EP recording system, the equipment must be front-end isolated or have an isolated patient cable.
- WARNING:** Failure of the Ampere™ Generator could result in an unintended power output increase. In case of system malfunction, attempt to stop RF delivery by a) using the front control panel's Standby button, b) releasing the footswitch, or c) turning the rocker switch on the rear panel to the off position. If none of the previous attempts turns off the power, disconnect the power cord.
- WARNING:** The Ampere™ Generator back panel connectors are NOT isolated. Never connect them directly to a patient. Always plug external devices into an isolation transformer. Do not touch any connectors or equipment affixed to these connectors and the patient at the same time.
- WARNING:** The Ampere™ Generator is not suitable for use within Oxygen Rich Environments or in the presence of flammable gases, including flammable anesthetic mixtures with air or with oxygen or with nitrous oxide.
- WARNING:** Two Dispersive Pad electrodes must be used when power levels exceed 50 Watts to minimize the potential of skin burns.
- WARNING:** To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Precautions

- CAUTION:** While using an irrigated catheter, the temperature displayed on the Ampere™ Generator is the temperature of the cooled electrode at the tip of the catheter—*not the tissue temperature*.
- CAUTION:** Always verify that the tubing and catheter have been properly cleared of air prior to inserting the catheter into the vasculature since entrapped air bubbles may cause emboli. Also, inspect IV tubing for sufficient continuous flow prior to its use as non-continuous flow may lead to coagulation within and around the distal electrode resulting in blockage of irrigation ports.
- CAUTION:** Peri-procedural anticoagulation therapy is recommended for patients undergoing left-sided and transeptal cardiac procedures and should be considered for selected patients undergoing right-sided procedures.
- CAUTION:** The catheter impedance display of the Ampere™ Generator should be continuously monitored during RF power delivery. If a sudden rise in impedance is noted, power delivery should be discontinued. The catheter should be removed, and the distal tip of the catheter should be evaluated and cleaned (if necessary) to eliminate any coagulum.
- CAUTION:** Do not immerse cable connectors in fluids; electrical performance could be adversely affected.
- CAUTION:** Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during radiofrequency power applications. Monitoring systems incorporating high-frequency current-limiting devices are recommended.
- CAUTION:** Desired ablation parameters must be set by the user; otherwise, the default values will be used.
- CAUTION:** Choose the lowest possible output power for the intended purpose.
- CAUTION:** Read and follow the DIP electrode manufacturer's instructions for use.
- CAUTION:** Standard grounding procedures should be followed if electrosurgical instruments are used.
- CAUTION:** The Ampere™ Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the catheter and DIP electrode, particularly when operating the device. During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces. This can be achieved by placing a non-conductive material between the patient and the grounded metal surfaces. DIP electrode attachments are to be as close to the operating field as possible.
- CAUTION:** Position connecting cables in such a manner that contact with patient or other leads is avoided.
- CAUTION:** Accessory equipment connected to the analog and digital interfaces must comply with the respective IEC standards (IEC 60950 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 60601-1-1.
- CAUTION:** Apparent low-power output or failure of the equipment to function correctly at normal settings may indicate faulty application of the DIP electrode or failure of an electrical lead. Do not increase the power before checking for obvious defects or misapplication.
- CAUTION:** Use non-flammable agents for cleaning and disinfecting.
- CAUTION:** Placement must allow adequate airflow around the unit for cooling.
- CAUTION:** Regularly inspect and test reusable cables and accessories.
- CAUTION:** Do not connect items which are not specified as part of system.

CAUTION: This equipment generates, uses, and 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. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to devices—which can be determined by turning the equipment off and on—the user is encouraged to correct the interference by one or more of the following measures:

1. Reorient or relocate the receiving device.
2. Increase the separation between the equipment.
3. Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
4. Consult the manufacturer for help.

CAUTION: Follow the system installation to achieve optimal use.

CAUTION: When used in conjunction with Cool Point™ Irrigation Pump:

1. Refer to the Cool Point™ Irrigation Pump operator manual to troubleshoot the Cool Point™ Irrigation Pump.
2. The Cool Point™ Irrigation Pump tubing set is required for use.
3. If the communication cable used between the Cool Point™ Irrigation Pump and the Ampere™ Generator becomes loose or disconnected, cease ablating until the cables are reconnected and secured.
4. Sterile extension IV tubing may be used with the Cool Point™ Irrigation Pump tubing set.

NOTE: This device and accessories should be recycled according to local and national laws after useful life.

NOTE: This equipment 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.

Display, Controls, and Connections

Front Panel Controls



Figure 1. Front Panel Controls

Callout	Name	Description
1	RF energy delivery Button	<ul style="list-style-type: none"> Press to begin delivery of RF energy. Press again to stop RF energy delivery.
2	Menu Button	<ul style="list-style-type: none"> Displays/hides the Menu.
3	Menu Knob	<ul style="list-style-type: none"> Rotate the knob to navigate through the menu options. Press the knob to select a menu option.
4	Preset Button	<ul style="list-style-type: none"> Displays the Preset menu (4 assignable presets and default settings).
5	Standby Button	<ul style="list-style-type: none"> Red light is on while in standby (Standby message displays on-screen). Press to toggle On/Off Standby. Both the main and Remote unit Standby buttons must be Off to disengage Standby.
6	EGM Connector	<ul style="list-style-type: none"> For connecting to an EP recording system to display the intracardiac signal.
7	Indifferent Electrode Connectors (2)	<ul style="list-style-type: none"> For connecting the Ampere™ Generator to the Disposable Indifferent Patches.
8	Catheter Extension Connector	<ul style="list-style-type: none"> For connecting the catheter to the Generator.
9	Arrow Buttons	<ul style="list-style-type: none"> Press up (increase) or down (decrease) arrows to adjust parameter settings: Power (Watts), Temperature (°C), Impedance (Ω), Time (Seconds)

Display Panel

Therapy data display, parameter adjustments, and generator setup are made through the display panel.

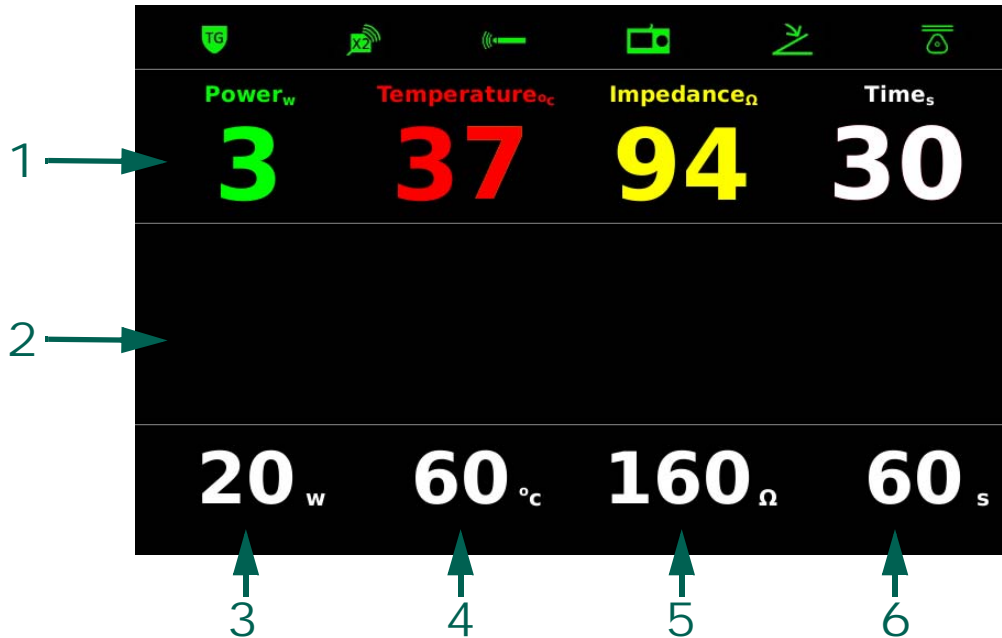


Figure 2. Display Panel

Callout	Name	Description
1	Real-time Display	<ul style="list-style-type: none"> Displays Power, Temperature, Impedance, and Time values as therapy is being delivered. Displays Temperature and Impedance when RF energy is not being delivered.
2	Display	<ul style="list-style-type: none"> Menu display area and therapy feedback.
3	User Set Power	<ul style="list-style-type: none"> Watts of power to be delivered to the catheter location. Arrows increase/decrease power threshold in 1 Watt increments.
4	User Set Temperature	<ul style="list-style-type: none"> Temperature to be reached at the catheter sensor location. Arrows increase/decrease temperature threshold in 1°C increments.
5	User Set Impedance	<ul style="list-style-type: none"> Impedance between the ablation electrode and the DIP electrode(s). If impedance goes above set limit, RF energy delivery stops. Arrows increase/decrease impedance threshold in 1Ω increments.
6	User Set Time	<ul style="list-style-type: none"> Time elapsed from when the RF energy delivery button was pressed -- RF energy delivery stops when the set time is reached. Arrows increase/decrease time duration in 1 second increments.

Connection Icons

The Connection Icons indicate the state of connected accessories:



Figure 3. Connection Icons

Icon	Name	State	Description
	TempGuard™ Feature	Gray	• The TempGuard™ feature is not enabled.
		White	• The TempGuard™ feature is enabled and ready.
		Green	• The TempGuard™ feature is active.
	DIP X2	Gray	• Programmed RF energy delivery power is ≤ 50 Watts — only one Disposable Indifferent Patch is required.
		Yellow	• Programmed RF energy delivery power is > 50 Watts — two Disposable Indifferent Patches are required.
	Catheter	Gray	• Catheter is not connected.
		Green	• Catheter is connected.
	Remote Control	Gray	• Remote control is not connected.
		Green	• Remote control is connected and communicating with the Ampere™ Generator.
	Footswitch	Gray	• Footswitch is not connected.
		Green	• Footswitch is connected and communicating with the Ampere™ Generator.
	Pump	Gray	• Pump is not connected.
		White	• Pump is connected and ready.
		Green	• Pump is running.

Rear Panel Connections



Figure 4. Rear Panel Connections

Callout	Name	Description
1	Foot Switch Connector	Connects to the foot switch.
2	Equipotential Ground Connector	Connects the Amperex™ Generator to the hospital equalization connection point.
3	Main Power Switch	“I” position is on. “O” position is off.
4	Power Cord Connector	AC power cord plug in.
5	Fiber Optic Connector	Single Fiber Optic port to connect to the (optional) Remote Control.
6	Dual Fiber Optic Connector	Dual fiber optic port to connect to the (optional) Remote Control.
7	Fiber Optic Transceiver Connector	Fiber optic port for future use.
8	USB Port	USB memory stick connection.
9	DB 15 Serial Port (female)	Connection for Cool Point™ Irrigation Pump interface
10	DB9 Serial Port (female)	Connection for EP recording system interface
11	GenConnect	Connects the ablation catheter to the EnSite™ Velocity™ Cardiac Mapping System Amplifier for isolation of the location signal.

Technical Specifications

Specifications

Power Specifications

Supply Voltage	100-240VAC, 50/60 Hz
Current Rating	2.4 A typical at 115 VAC, full load 1.2 A typical at 230 VAC, full load
Fuse Rating	F1 & F2: 5.2 x 20mm 3A, 250V Medium Acting
Operating Duration	Monitor: Continues until start button or footswitch is activated. NOTE: Pressing the Standby Button (on main unit or Remote Control) enters standby mode, which disables all output until the button is released. Both the main unit's and the Remote Control's Standby button must be released to terminate standby mode. Ablation: Continues from 1-999 seconds
Safety Class	Class I. Type CF according to IEC 60601-1
Operating Frequency	485 kHz
Operating Parameters	Values are digitally displayed on the Ampere™ Generator front panel.

Generator Output Specifications

PARAMETER	Units	Power Up Default	Operating Range	Adjustment Steps	Accuracy
RF Output Power	Watts	30	1-100	1 Watt	± 20% (1-4W) ± 10% (5-100W)
Temperature	°C	Varies (based on catheter)	15-80	1°C	± 3°C
Impedance	Ohms	150	50-300	1 Ω	± 10% @ 100 Ω
Time	Seconds	120	1-999	1 second	+/- 1 second

Physical Characteristics

Operating Modes	Temperature Control Mode
	Power Control Mode
Input/Output	22 pin socket for the catheter
	Socket for the footswitch
	Serial interface (DB9 EP Recording System interface)
	Serial interface (DB15 Pump interface)
	Fiber Optic Connectors (Remote Control Interface)
Dimensions	Generator: 266.7mm H x 360.68mm W x 363.22mm D (10.5" H x 14.2" W x 14.3" D)
	Remote: 121.92mm H x 355.6 W x 208.28 D (4.8" H x 14.0" W x 8.2" D)
Weight	Generator: 22.0 lbs Remote: 6.5 lbs

Environmental Specifications

Storage	Temperature: -25°C to +60°C
	Relative humidity: 20% to 90%, non-condensing
	Altitude range shall be: 0m to 7620m
Operation	Temperature: 10°C to 35°C
	Relative humidity: 20% to 90%, non-condensing
	The operating ambient altitude range shall be: 0m to 3000m (9843')

Electromagnetic Emissions Declaration

The Ampere™ Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the Ampere™ Generator should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The Ampere™ Generator 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 Ampere™ Generator 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	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Electromagnetic Immunity Declaration I


The Ampere™ Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the Ampere™ Generator should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) EN61000-4-2 (IEC 1000-4-2)	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30%.
Electrical fast transient/burst EN61000-4-4 (IEC 1000-4-4)	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN61000-4-5 (IEC 1000-4-5)	±1 kV differential mode ±2 kV common mode	±1 kV ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% U_T >95% dip in U_T for 0.5 cycle 40% U_T 60% dip in U_T for 5 cycles 70% U_T 30% dip in U_T for 25 cycles <5% U_T >95% dip in U_T for 5 sec	>95% dip in VNOM for 0.5 line cycle 60% dip in VNOM for 5 line cycles 30% dip in VNOM for 25 line cycles >95% of VNOM for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Ampere™ Generator requires continued operation during power mains interruptions, it is recommended that the Ampere™ Generator be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note U_T is the a.c. mains voltage prior to application of the test level.

Electromagnetic Immunity Declaration II

The EnSite™ Velocity™ Cardiac Mapping System Amplifier and Workstation are intended for use in the electromagnetic environment specified below. The customer or the user of the EnSite™ Velocity™ Cardiac Mapping System Amplifier / Workstation should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80 MHz	3 Vrms [$V_1 = 3$]	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Ampere™ Generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m [$E_1 = 3$]	$d = 1.2 \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 1.2 \sqrt{P}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \text{ 800 MHz to 2.5 GHz}$ $d = 2.3 \sqrt{P}$ <p>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)</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

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 Cool Point™ Irrigation Pump is used exceeds the applicable RF compliance level above, the Cool Point™ Irrigation Pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Cool Point™ Irrigation Pump.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1]V/m.

Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the Ampere™ Generator

The Ampere™ Generator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Ampere™ Generator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Ampere™ Generator 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 $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	.117	.117	.233
.10	.369	.369	.737
1	1.167	1.167	2.33
10	3.69	3.69	7.37
100	11.67	11.67	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 manufacture.

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.