CENTAURI™ Connect

Model GTI-00022-03

User Manual

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List of Symbols

The following is a list of symbols used on the CENTAURI Connect and throughout this user manual.

	Catalogue number		Defibrillator proof type CF applied part
	Serial number		Electric shock hazard
	Follow instructions for use		Foot switch
	Manufacturer		Digital signal cable connection
	Date of manufacture		Do not use if packaging is damaged
	Alternating current		Keep dry during shipping
	Power On (Connect to AC mains)		Humidity limits during transportation
	Power Off (Disconnect from AC mains)		Temperature limits during transportation
	Potential equalization terminal		Atmospheric pressure limits during shipping
	Fuse information	MAPPING	Mapping system connections
	Caution	CATHETER	Catheter connections
	Warning	EGM	Electrogram output connection
	WEEE compliant	MD	Medical device
	CE marking	EC REP	Authorized representative in the European Community
	Importer	CH REP	Swiss Authorized representative

1. Introduction

System Overview

The CENTAURI™ System is an electrosurgical system used in conjunction with cardiac ablation catheters to deliver energy to cardiac tissue. The CENTAURI System is comprised of the CENTAURI Generator (“Generator”), the CENTAURI Connect, and the IVY Cardiac Monitor (“Cardiac Monitor”). This user manual describes the use of the CENTAURI Connect (GTI-00022-03). For full information and instructions on the CENTAURI Generator, see the CENTAURI Generator User Manual.

Application Specification Summary

The CENTAURI System is intended to be used by a healthcare professional within an Electrophysiology (EP) Laboratory to treat patients in need of conventional cardiac ablation procedures. A cardiac ablation catheter is connected to the CENTAURI System and positioned at the target ablation site within the heart. The user presses and holds the foot switch to deliver energy to the target tissue resulting in tissue ablation. The user then repositions the catheter at subsequent target ablation sites and the process is repeated until all targeted tissue is treated.

CENTAURI Connect (GTI-00022-03)

CENTAURI Connect is used to connect a catheter to the CENTAURI Generator (see the CENTAURI Generator User Manual) as well as to an electroanatomic mapping (EAM) system and EP recording system amplifiers. CENTAURI Connect isolates the energy output of the CENTAURI Generator from the EP recording and EAM systems. The Connect is not intended to come in contact with the patient and therefore is not provided sterile.

Interconnect power and instrumentation cables

The CENTAURI Connect is provided with a power cord and instrumentation cables for powering the CENTAURI Connect and for interconnecting various instrumentation signal lines of the System. The interconnect power and instrumentation cables have been specified and tested for use with the CENTAURI System and should not be substituted with any non-Galaxy Medical specified cables.

Other Devices Used with the CENTAURI Connect

WARNING: Do not substitute cables, equipment, or disposables with any cables, equipment, or disposables not provided or specified by Galaxy Medical, Inc. Doing so could potentially damage the system or cause injury.

The CENTAURI Connect is designed to work with the devices listed in the following table.

Device	Manufacturer	Manufacturer Reference
Cardiac Ablation Catheter	Abbott	TactiCath™ Contact Force Ablation Catheter, Sensor Enabled A-TCSE-XX*
Cardiac Ablation Catheter	Biosense Webster	THERMOCOOL SMARTTOUCH™ Catheter D13360X** or D13270X**
Cardiac Ablation Catheter	Boston Scientific	INTELLANAV STABLEPOINT™ Ablation Catheter M004 ERFSDS9620 0 or M004 ERFSDS9620K2 0
Electrophysiology Cable	Abbott (St. Jude Medical)	Electrophysiology Cable 1804-S IBI-85809
Interface Cable	Biosense Webster	CARTO3 System Interface Cable CR3434CT
Interface Cable	Boston Scientific	INTELLANAV STABLEPOINT Catheter Cable M004 RARC03 0
Interface Cable	Galaxy Medical	Compatibility Cable, BW ThermoCool ST GTI-00038

*Applicable Abbott product codes include A-TCSE-D, A-TCSE-F, A-TCSE-J, A-TCSE-DD, A-TCSE-DF, A-TCSE-FF, A-TCSE-FJ, and A-TCSE-JJ.

**Applicable Biosense Webster product codes include D133601, D133602, D133603, D132701, D132702, D132703, D132704, D132705.

Compatible Mapping Systems

The CENTAURI Connect is designed for use with the cardiac mapping systems listed in the following table.

System	Manufacturer
CARTO® 3 System	Biosense Webster
EnSite Cardiac Mapping System	Abbott
RHYTHMIA HDx™ Mapping System	Boston Scientific

While the foot switch is depressed, ablation catheter visualization and contact force measurement will be unavailable. In addition, the cardiac mapping system may display warnings (e.g., connection to the ablation catheter is lost). If warnings on the cardiac mapping system do not resolve when the foot switch is released, refer to the user manual of the respective mapping system.

When the CENTAURI System is used with a mapping system, an increase to contact force measurement may be observed within published manufacturer tolerances.

2. Intended Purpose and Training

Intended Purpose

The CENTAURI System is intended for use in intracardiac ablation procedures with commercially available compatible ablation catheters for the treatment of atrial fibrillation. Refer to the CENTAURI Generator User Manual and the instructions for use (IFU) supplied with the cardiac ablation catheter to be used with the CENTAURI System.

Training

The setup of the CENTAURI System shall be performed by qualified Galaxy Medical personnel. The CENTAURI System may be used only by medical personnel trained and experienced in the techniques of electrophysiology. Before using the CENTAURI System, review this User Manual thoroughly and completely. For further information, please contact Galaxy Medical, Inc.

3. Warnings and Precautions

Warnings and Precautions

THIS USER MANUAL SHOULD BE READ IN CONJUNCTION WITH THE IFU OF A COMPATIBLE CATHETER AND THE CENTAURI GENERATOR USER MANUAL BEFORE USING THE CENTAURI SYSTEM. FAILURE TO FOLLOW INSTRUCTIONS OR FAILURE TO HEED WARNINGS OR PRECAUTIONS MAY RESULT IN HARM TO THE PATIENT.

1. Hazardous electrical output. The CENTAURI System is for use only by qualified medical personnel trained in the use of this equipment.
2. Do not use the CENTAURI System if there are any signs of damage to any of its components. Visually inspect all accessories and verify cables are not damaged.
3. Do not substitute cables, equipment, or disposables with any cables, equipment, or disposables not provided or specified by Galaxy Medical, Inc. Doing so could potentially damage the system or cause injury.
4. Do NOT connect the catheter to the front panel of the CENTAURI Connect when powering on the CENTAURI Generator and preparing it for use. If the catheter is connected to the CENTAURI Connect while preparing the device for use, injury to the operator or the patient could happen.
5. Do not use sharp towel clips or metal instruments to attach cables to drapes. Sharp metal clips can damage electrical cables or provide an unwanted point of contact with the patient's skin. Overlapping electrical wire around a metal clip creates an electrical transformer that can cause a hazard and may ignite drapes.
6. Cables should never be wrapped around metal instruments, as the current running through them can pass into the metal instrument and may result in harm to the patient and/or operator.
7. Do not use steam or heat sterilization to clean any system component. Do not soak any component in disinfectants or fluids. Do not allow liquid to enter into any of the electrical connections or the interior of any component.
8. To avoid the risk of electric shock, the CENTAURI System must only be connected directly to AC supply mains with protective earth.
9. Do not disassemble the system. Modification of this equipment is not permitted as serious injury to the operator or damage to the unit may result.
10. Electric shock hazard. Do not remove the cover of any equipment or any components from the equipment. Refer servicing to qualified personnel. There are no user-serviceable parts inside the CENTAURI Connect or any of the components of the CENTAURI Connect.
11. Position the connection cables of the ablation catheter in such a way that they do not touch either the patient or other cables. Keep active electrodes that are temporarily not in use at a safe distance from the patient.

12. Interference produced by the operation of the CENTAURI System may adversely influence the operation of other electronic equipment. For patients with cardiac pacemakers or other active implants, interference with the action of the active implant may occur, or the active implant may be damaged. In case of doubt, consult the manufacturer of the device. See the **Technical Specifications** section for Warnings related to Electromagnetic Compatibility.

***Note**: Any serious incident that occurs in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.*

4. System Connections and Receptacles

CENTAURI Connect

Front

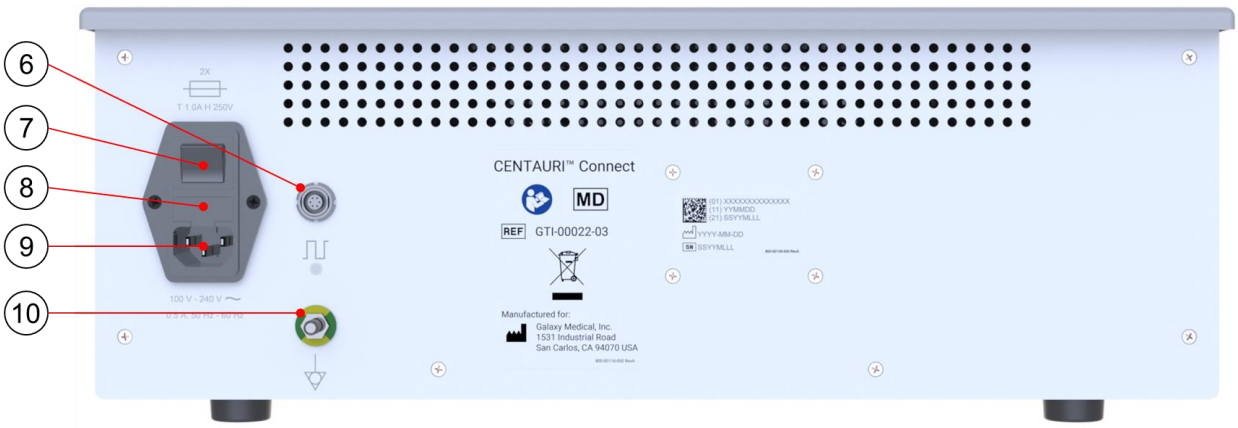
1. **MAPPING**: Receptacle for connecting the CENTAURI Connect to the compatible mapping system equipment.

2. **EGM**: Receptacle for electrophysiology cable to provide electrogram (EGM) signals to the mapping and EP recording systems

3. **CATHETER (Type CF Applied Part)**: Connection for compatible catheters.

4. **INPUT**: Connection to PEF output of the CENTAURI Generator

5. **Foot Switch**: Receptacle for connecting the foot switch, which is used to activate and deactivate energy delivery.



Rear

6. **Digital Signal Connection**: Receptacle for connecting the digital signal cable between the Generator and CENTAURI Connect.
7. **Power Switch**: Switch for turning the CENTAURI Connect on and off
8. **Fuse Access Panel**: Provides access to replaceable fuses
9. **Power Cable**: Receptacle to connect the Generator to an AC mains power outlet
10. **Potential Equalization Terminal**: Connection that provides a common electrical ground for other electronic devices used during the procedure

CENTAURI Generator

Refer to the user manual provided with the CENTAURI Generator for a description of receptacles and connections.

Cardiac Monitor

Refer to the user manual provided with the Cardiac Monitor for a description of receptacles and connections.

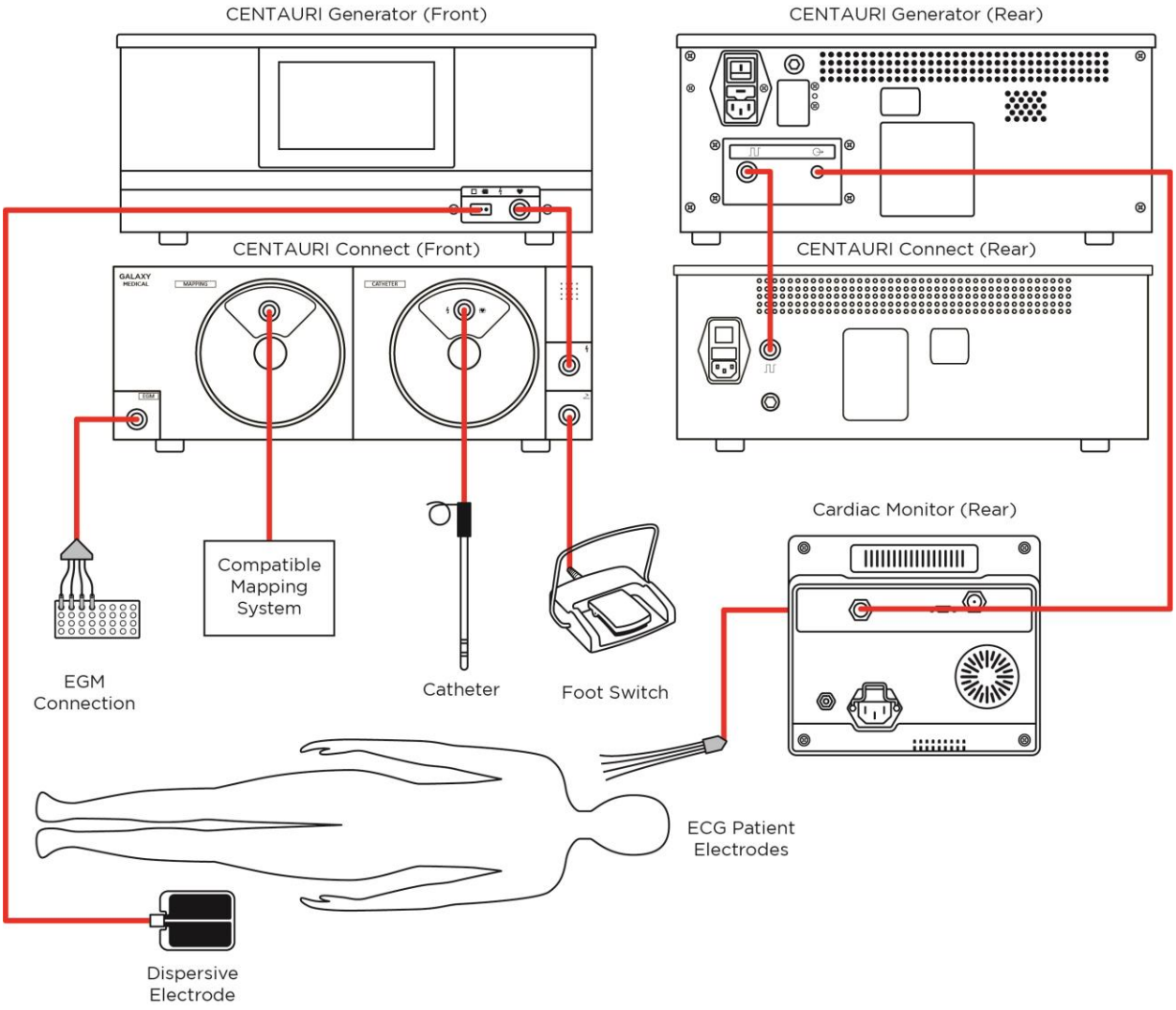
5. System Setup

Prior to initial use of the CENTAURI System, the system should be unpacked and setup by qualified Galaxy Medical personnel according to the typical setup as shown in the System Connection Diagram.

WARNING: Do not use the CENTAURI System if there are any signs of damage to any of its components. Visually inspect all accessories and verify cables are not damaged.

WARNING: Do not substitute cables, equipment, or disposables with any cables, equipment, or disposables not provided or specified by Galaxy Medical, Inc. Doing so could potentially damage the system or cause injury.

System Connection Diagram



System Power-on Self-test

1. Complete the **Pre-Procedure Power-On Sequence** as specified in the **System Operation** section to confirm the system has been set up correctly.

Electrical Safety Inspection

As applicable, follow any site and / or country specific requirements for equipment qualification for use within the facility prior to use. See the **Electrical Safety Inspection** section for recommended guidance and testing specific to on-site electrical safety testing.

6. System Operation

Pre-Procedure Preparation and Power-On Sequence

Complete the following steps prior to preparing the patient for the cardiac ablation procedure and any time the system is turned off during a procedure.

WARNING: When powering on the CENTAURI Generator and preparing it for use, do NOT connect the catheter to the CENTAURI Connect. If the catheter is connected to the Generator while preparing the device for use, injury to the operator or the patient could happen.

WARNING: Do not use sharp towel clips or metal instruments to attach cables to drapes. Sharp metal clips can damage electrical cables or provide an unwanted point of contact with the patient's skin. Overlapping electrical wire around a metal clip creates an electrical transformer that can cause a hazard and may ignite drapes.

WARNING: Cables should never be wrapped around metal instruments, as the current running through them can pass into the metal instrument and may result in harm to the patient and/or operator.

1. See the CENTAURI Generator User Manual for power on instructions of the Generator.
2. Power on the CENTAURI Connect module by turning the power switch on the rear panel to the On | position. Confirm the status light on the front panel is illuminated.
3. Connect the PEF output of the CENTAURI Generator to the PEF input of the CENTAURI connect.
4. Connect the CENTAURI Connect digital signal output to the CENTAURI Generator.
5. Connect the footswitch to the front panel of the CENTAURI Connect.
6. Connect the cardiac ablation catheter to the CATHETER input of the CENTAURI Connect.
7. Connect the electrophysiology cable from the CENTUARI Connect EGM output to the input of the EP recording system being used.
8. Connect the CENTAURI Connect MAPPING output to the mapping system being used.

Post Procedure

Perform the following steps after the procedure is complete.

1. Disconnect the catheter from the CENTAURI Connect module.
2. Switch the power toggle on the rear of CENTAURI Connect to the Off ◯ position.
3. Refer to the **Cleaning and Maintenance** section for cleaning of the CENTAURI Connect components.

For troubleshooting, see the Troubleshooting section in the CENTAURI Generator User Manual.

7. Cleaning and Maintenance

Cleaning

Clean components of the CENTAURI Connect per the instructions below.

CAUTION: Do not use steam or heat sterilization to clean any system component. Do not soak any component in disinfectants or fluids. Do not allow liquid to enter into any of the electrical connections or the interior of any component.

CENTAURI Connect

1. Disconnect the unit from the wall outlet before cleaning.
2. Wipe the exterior surface of the unit with 70 % to 90 % isopropyl alcohol or an equivalent alcohol-based wipe.
3. Allow all surfaces and connections to dry before reconnecting.

Cables

1. Disconnect all cables from the system components.
2. Wipe down all cables with 70 % to 90 % isopropyl alcohol or an equivalent alcohol-based wipe.
3. Allow cables to dry before reconnecting.

Maintenance

Do not perform maintenance or service when the CENTAURI Connect is in use with a patient.

Routine Maintenance

The CENTAURI Connect does not require routine maintenance or servicing.

Electrical Safety Inspection: EN 62353

Follow test instructions in the appropriate area of the standard. The acceptable limits (normal condition) for the CENTAURI System can be found in Table 1 of Appendix A.

Fuse Replacement

The CENTAURI Connect has two fuses that can be replaced in the field by qualified personnel. Replace the fuses with the same value fuses (see table below). Replacing with incorrect fuse rating could damage the Connect or create a fire hazard. To replace the fuses, open the fuse access panel on the back of the Connect, remove fuse housing with fuses, and replace the fuses. Reinstall the fuse housing and close the fuse access panel.

Component	Replacement Fuses
CENTAURI Connect	T 1.0A H 250V

Service and Returns

Should service or repair be necessary, contact a Galaxy Medical representative.

End of Life Disposition

Do not dispose of CENTAURI System components in the unsorted municipal waste stream. Follow local regulations for proper disposal.

8. Technical Specifications

Input Power	100 V - 240 V ~, 50 Hz - 60 Hz universal power supply, 2 A input power rating. The power cord is used for removing AC mains power from the unit.
Dimensions	CENTAURI Connect: 48.3 cm wide x 17.8 cm high x 45.7 cm deep
Weight	CENTAURI Connect: 7.5 kg
Rear Controls	Line Power On/Off
Connections	AC Line power, foot switch, catheter connector (x3), mapping connector (x3), pulsed field generator input, and electrogram output
Classifications	Class 1, Defibrillator Proof - Type CF, IPX0. Applicable general test and electrical safety requirements for Class 1 protection of ANSI AAMI ES60601-1, EN 60601-1, and CAN/CSA C22.2 No. 60601-1. Safety requirements of high-frequency surgical equipment of ANSI AAMI IEC 60601-2-2 and EN 60601-2-2. Electromagnetic compatibility (EMC) requirements of ANSI AAMI IEC 60601-1-2 and EN 60601-1-2.

Environmental Conditions

	Transport or Storage	**Operating**
Temperature	-29 °C to +60 °C	15 °C to 40 °C
Humidity (non-condensing)	30 % to 85 %	30 % to 70 %
Atm. Pressure	600 hPa to 1060 hPa	700 hPa to 1060 hPa

Replacement Part Numbers

WARNING: Do not substitute cables, equipment, or disposables with other cables, equipment, or disposables not provided by Galaxy Medical, Inc. Doing so could potentially damage the system or cause injury.

Component	Part Number
CENTAURI Connect	GTI-00022-03

Electromagnetic Compatibility (EMC)

The CENTAURI System has been verified to the electromagnetic compatibility requirements of ANSI AAMI IEC 60601-1-2 and EN 60601-1-2.

This equipment uses non-ionizing radiation for treatment. Interference produced by the operation of high-frequency surgical equipment, such as the CENTAURI Generator, may adversely influence the operation of other electronic medical equipment such as monitors and imaging systems and special precautions should be taken. Portable and mobile RF communications equipment (e.g., cellular phones) can affect electronic medical equipment. The CENTAURI System should be setup and put into service according to the EMC information provided in this section.

The CENTAURI System is suitable for use in all establishments other than domestic (i.e., residential) and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

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

If any of the essential performance characteristics are lost or degraded due to electromagnetic disturbances, the user may see any of the following conditions:

- Distortion and / or lock-up of the generator front panel display screen
- Distortion and / or lock-up of the cardiac synchronization monitor

Warnings

- The CENTAURI System is intended for use by healthcare professionals only. This device may cause radio interference and disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the CENTAURI System or shielding the location. Interference with electronic medical equipment such as monitors and imaging systems is usually resolved or minimized by rearranging the cables such that the unit cables do not overlap with the cables from the monitoring equipment.
- Use of the device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to confirm that they are operating properly.
- Use of accessories and cables other than those specified and provided by Galaxy Medical, Inc. could result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the device including cables specified by the manufacturer. Otherwise, degradation of the performance of the device could result.

CENTAURI Connect Cables

Cable	Maximum Length
AC Power Cable	2.5 m
Interconnect Cable, High Voltage	0.2 m
Interconnect Cable, Digital Signal	0.2 m
Contact Force Interconnect Compatibility Cable	1.5 m

Guidance and Manufacturer's declaration – Electromagnetic Emissions

The CENTAURI System is suitable for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11 (EN55011)	Group 1†	When Generator is in the STANDBY state, radio frequency [RF] energy is only used for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment. When Generator is delivering energy, the device must emit electromagnetic energy to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11 (EN55011)	Class A	The CENTAURI System is suitable for use in all establishments other than domestic (i.e., residential) and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations / flicker emissions EN 61000-3-3	Complies	

† Conducted emissions may exceed limits specified in CISPR 11 by up to 14.2 dB when the system is connected to a compatible mapping system.

Guidance and Manufacturer's declaration – Electromagnetic Immunity

The information provided within this section is applicable to the CENTAURI System.

The CENTAURI System has been verified and found to be in compliance with the immunity standards at the test levels specified below. It is suitable for use in the electromagnetic environment specified below. For maintaining the Essential Performance of the device with regards to electromagnetic disturbances, the user must ensure it is used in such an environment.			
Immunity test	**Level Required**	**Level Tested**	**Electromagnetic environment – guidance**
EN 61000-4-2 Electrostatic discharge (ESD)	±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 %.
EN 61000-4-3 Radiated, radio-frequency, electromagnetic field immunity	80 MHz - 2700 MHz, 3 V/m, 80 % 1 kHz AM Various per Table 9 of ANSI AAMI IEC 60601-1-2 and EN 60601-1-2.	80 MHz - 2700 MHz, 3 V/m*, 80 % 1 kHz AM As per Table 9 of ANSI AAMI IEC 60601-1-2 and EN 60601-1-2.	Radio frequency and electromagnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
EN 61000-4-4 Electrical fast Transient/burst	For AC / DC power ports: ±2 kV ±1 kV for signal ports	±2 kV for AC power ports Equipment does not have DC power ports therefore no test. Equipment does not have cables > 3 m connected to signal ports	Mains power quality should be that of a typical commercial or hospital environment.

The CENTAURI System has been verified and found to be in compliance with the immunity standards at the test levels specified below. It is suitable for use in the electromagnetic environment specified below. For maintaining the Essential Performance of the device with regards to electromagnetic disturbances, the user must ensure it is used in such an environment.

Immunity test	Level Required	Level Tested	Electromagnetic environment – guidance
EN 61000-4-5 Surge	For AC / DC power ports: ±1 kV differential mode ±2 kV common mode 1.2/50 µs	For AC power port: ±1 kV differential mode ±2 kV common mode 1.2/50 µs Equipment does not have DC power ports therefore no test.	Mains power quality should be that of a typical commercial or hospital environment.
EN 61000-4-6 Conducted, radio-frequency immunity	For AC / DC power ports, signal ports, and patient ports: 0.15 MHz - 80 MHz, 3 V_{rms}, 80 % 1 kHz AM, 6 V_{rms} in ISM/Amateur bands	For AC power, signal, and patient ports: 0.15 MHz - 80 MHz, 3 V_{rms}*, 80 % 1 kHz AM, 6 V_{rms} in ISM/Amateur bands Equipment does not have DC power ports therefore no test.	Radio frequency and electromagnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
EN 61000-4-8 Power frequency magnetic field	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.
EN 61000-4-11 Voltage dips, short interruptions, and voltage variations on power supply input lines, U_T = AC 230V/50Hz	>95 % dip in U_T for 0.5 cycle 60 % dip in U_T for 5 cycles 30 % dip in U_T for 25 cycles >95 % dip in U_T for 250 cycles	>95 % dip in U_T for 0.5 cycle 60 % dip in U_T for 5 cycles 30 % dip in U_T for 25 cycles >95 % dip in U_T for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CENTAURI System requires continued operation during mains power interruptions, it is recommended that the CENTAURI System is powered from an uninterruptible power supply.
EN 61000-4-39 Radiated fields in close proximity, magnetic field	134.2 kHz, 2.1 kHz pulse mod, 65 A/m 13.56 MHz, 50 kHz pulse mod, 7.5 A/m	134.2 kHz, 2.1 kHz pulse mod, 65 A/m 13.56 MHz, 50 kHz pulse mod, 7.5 A/m	Radiated magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

* The level tested exceeds the test level required by the standard. Testing was performed at a higher severity level to meet the requirements of other tests.

Appendix A

Electrical Safety Tests (Optional)

Only qualified individuals should perform electrical safety testing. Measurements should be made per local electrical safety standards.

Note: *These tests are not required for planned preventative maintenance*

Table 1. Acceptable Safety Test Limits (normal condition) per EN 62353

Measurement	Limit
Protective earth resistance (resistance between Mains Plug protective earth connector and protectively earthed accessible conductive parts)	0.3 ohm
Earth (or Equipment) leakage current (NFPA99/120VAC operation)*	0.3 mA (300 µA)
Earth (or Equipment) leakage current (all other AC operating voltages)**	0.5 mA (500 µA)
Enclosure (or Touch) leakage current	0.1 mA (100 µA)
Patient (or Applied Part) leakage current	0.01 mA (10 µA)

* Applicable only for United States.

** Applicable for all geographies outside of the United States.

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