ECGenius™ System Instructions for Use

R̽ **Only**

CathVision
Titangade 11
2200 Copenhagen N
DK - Denmark
+45 31 47 07 30
www.cathvision.com

	ECGenius™ System Instructions For Use
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[manufacturer symbol]	**CathVision** Titangade 11 2200 Copenhagen N DK-Denmark
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R_X Only	
	This version of the ECGenius™ System Instructions For Use (IFU) applies to ECGenius™ Software V3.0.x.x

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Introduction

This document contains instructions for use of the ECGenius™ electrophysiology recording system. It should be read in full by users of the ECGenius™ System prior to use, and in conjunction with the ECGenius™ System Technical Manual which contains advanced usage information.

In the event of any discrepancy between the electronic version and the printed version of the ECGenius™ System Instructions for Use and ECGenius™ System Technical Manual, the user should rely on the printed version. Additional printed versions of the ECGenius™ System Instructions for Use (this document) and the ECGenius™ System Technical Manual are available from CathVision on request.

Definitions and abbreviations
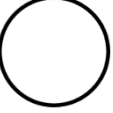
Within this document, the following terminology and abbreviations are used:

ECG	Electrocardiograph or electrocardiogram - in this context, this refers specifically to surface-recorded electrocardiograms
EP	Electrophysiology
IECG	Intracardiac electrocardiograph or electrocardiogram
IFU	Instructions for Use (this document)
PC	Personal Computer

Symbols

The following symbols are used on the ECGenius™ System components, labels, and packaging:

	Manufacturer
LOT	Batch code
REF	Catalogue number
SN	Serial number
	Country of manufacture
	Refer to instruction manual/booklet

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	Do not use if package is damaged and consult instructions for use
	Fragile, handle with care
	Keep dry
	Temperature limit
	Humidity limitation
	Consult instructions for use or consult electronic instructions for use
	Caution – Alerts the reader of a situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.
MD	Medical device
UDI	Unique device identifier
	General warning sign – Alerts the reader about a situation which, if not avoided, could result in death or serious injury, or describes potential serious adverse reactions and safety hazards.
	On (power)
	Off (power)

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	Fuse
	Equipotentiality
	Alternating current
	Defibrillation-proof type CF applied part
	Item must be disposed in accordance with local waste electrical and electronics equipment regulations.
CE xxxx	CE-mark applied on devices marketed within the European Economic Countries
R$_X$ Only	Federal law restricts this device to sale by or on the order of a physician.
TÜV SÜD US	TÜV SÜD logo

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System description

The ECGenius™ System consists of an electrophysiology amplifier (Cube Amplifier), ECGenius™ Software running on a PC, and additional components including cables, monitors, and a printer. Electrophysiological signals (surface ECG, intracardiac ECG, and blood pressure) are filtered, amplified, and digitized in the Cube Amplifier and sent to the ECGenius™ Software on the PC for further processing, visualization, and recording. Impulses from a connected diagnostic stimulator are routed through the Cube Amplifier. Additionally, the Cube Amplifier has connections for input and output of analog signals.

Components

The ECGenius™ System comprises the following components:

Item	Qty	Part number	Type	
Cube Amplifier	1	CVHW-0009	ME equipment	

Fuses (in amplifier)
  Power Module Fuse
  Backplane Fuse
	
	2
	1
		
		CVHW-0065
		CVHW-0066
			n/a	

Equipotential Ground Cable	1	CVHW-0071	non-ME equipment	

Ethernet Cable
  10ft
  25ft
  50ft
  100ft
	1	
		CVHW-0023
		CVHW-0024
		CVHW-0025
		CVHW-0098
			non-ME equipment	

ECGenius™ PC*	1	CVHW-0092	non-ME equipment	
Windows OS	1	installed on the ECGenius™ PC	n/a	
ECGenius™ Software	1			
Microsoft Office 2019	1			
Keyboard Mouse US Black	1	CVHW-0053	non-ME equipment	
Monitors*	4	CVHW-0079	non-ME equipment	

Displayport Cables
  2m
  20m
	4	
		CVHW-0041
		CVHW-0040
			non-ME equipment	

ECGenius™ Laser Printer*	1		non-ME equipment	
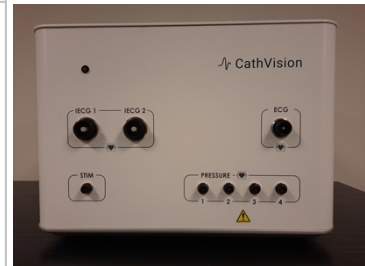
US EU		CVHW-0038 CVHW-0039	
USB Cable	1	CVHW-0099	non-ME equipment
Power Cable (US only)	5	CVHW-0026	detachable power supply cord
Power Cable hospital-grade (US only)	3	CVHW-0027	detachable power supply cord
Power Cable (EU only)	4	CVHW-0028	detachable power supply cord
Power Cable (EU only)	4	CVHW-0032	detachable power supply cord
ECG Trunk Cable	1	CVHW-0072	applied part
ECG Leadwire Grabber Set	1	CVHW-0014	applied part
IECG Pin Box	2	CVHW-0073	applied part

IECG Pin Box Mount	1	CVHW-0078	accessory	
Simple Clamp	1	CVHW-0081	accessory	
Blood Pressure Cable	1	CVHW-0015	ME equipment	
Stimulator Cable	1	CVHW-0016	ME equipment	

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Single Analog Output Cable	1	CVHW-0019	non-ME equipment	
Multi Analog Output Cable	1	CVHW-0021	non-ME equipment	
Analog Input Cable	1	CVHW-0018	non-ME equipment	

Isolation Transformer
  110VAC
  220VAC
	1	CVHW-0075
		CVHW-0076
			non-ME equipment	

ECGenius™ System Instructions For Use (IFU) (this document)	1	CVT-0066	n/a	
ECGenius™ System Technical Manual	1	CVT-0096	n/a	

* Items of the ECGenius™ System that are required to be plugged into an isolation transformer are indicated with an asterisk.

⚠ Items of the ECGenius™ System that are required to be plugged into an isolation transformer must not be connected directly to a mains supply power outlet. Plugging these items directly into the mains supply can cause excessive patient leakage currents.

Refer to IEC 60601-1:2005/A1:2012/A2:2020 for type definitions.

The quantities indicated are for a typical installation and may not match your specific installation. Refer to your purchase agreement with CathVision.
If you think you are missing any items, contact CathVision and do not use the ECGenius™ System.

Typical configuration

The ECGenius™ System will be configured as a part of the installation process. A typical configuration of the

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ECGenius™ System is shown below.

Patient Area   **Control room**

| Monitor | Monitor |

| Monitor | Monitor |

Stimulator

Ablation generator

Localization system

Vital signs monitor

Cube Amplifier

PC with ECGenius Software

Blood Pressure Cable

ECG Trunk Cable
ECG Leadwire Grabber Set

Localization PC

Blood Pressure Transducer

Ablation remote

Stimulator PC

IECG Pin Boxes

Minimally invasive catheters

Body surface electrodes

☐ ECGenius System

▨ 3rd party equipment

Context of use

Use environment

The ECGenius™ System is used in EP laboratories and operating rooms at hospitals. The Cube Amplifier is typically placed in the patient environment, such as on a moving cart, but not within the sterile area. The host computer is typically placed outside the patient environment behind a lead shielded wall (the control room).
The ECGenius™ System is not intended for use with flammable gasses or liquids, no part of it is sterile or sterilizable and the device is protected from ingress of fluids (IPX1).
The ECGenius™ System is intended for use in air-conditioned hospital EP laboratories and operating rooms equipped for advanced cardiac resuscitation.
Refer to the **System description** section for more information about the typical configuration.

Indications for use

The ECGenius™ System is an electrophysiology measurement system and analysis tool used to acquire, filter, digitize, amplify, display, record, and analyze data obtained during electrophysiological studies and related procedures. The system is compatible with a 3rd-party stimulator, intended to be used for diagnostic cardiac stimulation during electrophysiological testing of the heart.

The PVI Analyzer™ feature is a secondary measure of pulmonary vein isolation and should not replace traditional methods of confirming isolation.

Intended users

The users are licensed health practitioners (e.g. electrophysiologists), technicians and nurses in electrophysiology laboratories and operating rooms. Typically, a technician operates the ECGenius™ System and a practitioner interprets the data. The nurses play a secondary role as they assist the practitioner and technician.

Intended patients

The intended patients are patients diagnosed with cardiac arrhythmia, including patients with supra ventricular tachycardia and ventricular tachycardia. Patients include only adult patients.

The PVI Analyzer™ is only indicated for adult patients in sinus rhythm receiving their first PVI treatment.

Clinical benefits

The ECGenius™ System is an electrophysiological recording system which enables acquisition, filtering, digitization, amplification, display, and recording of low-noise high-quality physiological signals, including surface ECG as well as intracardiac ECG, stimulus data, and blood pressure during electrophysiological studies. The data is only displayed, not evaluated to provide diagnostic assistance, and the diagnosis is the responsibility of the user. A high-quality signal is essential for an electrophysiologist to be able to interpret the displayed data. Accordingly, for the electrophysiologist, the indirect benefit of the ECGenius™ System is that high-quality signals allow for interpretation of the data to provide the correct diagnosis of arrhythmia as well as establish the indications for specific treatments. For the patients, the indirect benefit is that a precise diagnosis is the first step of initiating the appropriate treatment and increase the chance of treatment success.

Clinical indications

The ECGenius™ System and its accessories are indicated for measurement and recording of clinical data, including electrocardiograms (ECG), during electrophysiological studies and related procedures in the hospital electrophysiological (EP) laboratory or the hospital operating room. Clinical data includes surface ECG, catheter based intracardiac ECG, invasive blood pressure, stimulus data and other analog signals. Physiological parameters such as diastolic, systolic, mean pressures, heart rate, and R-R interval are derived from the signal data and displayed.
The purpose of the ECGenius™ System is to support the diagnosis of patients (no specific demographic requirements) suffering from arrhythmias. The ECGenius™ System is not a diagnostic system. Data are only displayed, but not evaluated to provide diagnostic assistance. Diagnosis is the responsibility of the user.
The ECGenius™ System is indicated for use under the direct supervision of a licensed health care practitioner.

The ECGenius™ System does not have alarms for vital signs, does not generate energy delivered to the patient, does not administer drugs, and does not perform any life-supporting or life-sustaining functions.

The licensed health practitioners, the technicians and the nurses need to be trained before using the ECGenius™ System.

The Signal Complexity™ module analyzes various properties of the signals from a connected 10-pole catheter and visualizes them on a color map. No clinical claims are made for Signal Complexity™.

The PVI Analyzer™ module aids the user in evaluating the isolation status of a pulmonary vein. The module performs automated real time analysis of electrograms (EGM) from connected 8 or 10 pole circular mapping catheters during a PVI procedure. The result of the analysis (Isolated vs Non-isolated) is presented in a visual plot to the user

Contraindications

The ECGenius™ System is not suitable for continuous monitoring of a patient. For ECG and vital signs monitoring, a dedicated patient ECG monitor including blood pressure should be used.

Safety information

Users of the ECGenius™ System should be aware of the following safety information.

Warnings

⚠ The ECGenius™ System and any other mains-powered equipment connected to it (e.g. stimulator, ablation generator) form a medical electrical system. Refer to IEC 60601-1:2005/A2:2020. The user is responsible for ensuring that appropriate electrical safety tests have been conducted prior to use. These tests should be repeated at regular intervals during the lifetime of the ECGenius™ System, in accordance with local electrical safety policies.

⚠ The ECGenius™ System and its components are 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.

⚠ The use of the ECGenius™ System and components with any other medical electrical equipment or medical electrical system may result in increased electromagnetic emissions or decreased electromagnetic immunity of that equipment/system or of the ECGenius™ System.

⚠ Always measure and confirm the system leakage current and isolation (hi-pot test) after each installation or if the system has been moved. Do not use the ECGenius™ System if any electrical safety test has failed.

⚠ To avoid the risk of electric shock, this equipment must only be connected to a mains supply with protective earth.

⚠ Items of the ECGenius™ System that are required to be plugged into an isolation transformer must not be connected directly to a mains supply power outlet. Plugging these items directly into the mains supply can cause excessive patient leakage currents.

⚠ Interconnecting cables may be subject to damage if laid on the floor. Precautions must be taken to cover cabling to prevent damage.

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

⚠ There should be at least 6 inches of clearance on all sides of the Cube Amplifier. The Cube Amplifier relies on natural convection cooling with intake vents along the underside and an exhaust vent along the top of the rear. These areas should be kept free of obstructions to ensure adequate ventilation.

⚠ To avoid electrical safety hazard, check grounding reliability at least once a year. Do not use the ECGenius™ System if any electrical safety test has failed.

⚠ Do not use the ECGenius™ System in a patient monitoring, critical care or life supporting application as this is outside its intended use. Relying on a device with no alarms may result in death or serious injury.

⚠ Always ensure that rescue equipment, including an external pacemaker is available at all times during the EP procedure, as the ECGenius™ System is not a life-sustaining device.

⚠ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of the ECGenius™ System, including cables. Otherwise, degradation of the performance of this equipment could result.

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⚠ Do not use the ECGenius™ System outside its intended use and outside the indication of use as this may lead to inappropriate patient treatment.

⚠ Use only blood pressure transducers compatible with ANSI/AAMI BP22 standard as the use of non-compatible transducers could limit protection against defibrillation.

⚠ Always check mapping between catheters and channels in the study configuration prior to each procedure to avoid stimulation at the incorrect site(s) which may lead to a serious adverse event.

⚠ Do not apply stimulation signals to the same electrode(s) that are to be used for ablation while ablation is taking place. It is recommended that the ablating electrode(s) are deselected for stimulation before ablation is initiated to further reduce risk of inducing ventricular fibrillation.

⚠ The Cube Amplifier has stimulator bypass output connections that can be used to ensure that external stimulation signals are delivered to the patient, irrespective of the functioning of the ECGenius™ System. In the event of loss of power or ECGenius™ System malfunction, connect the catheters that are to be used for pacing to the stimulator bypass output connections.

⚠ Do not handle electrical cables while in contact with the patient to prevent leakage current to the patient which potentially could cause patient shock.

⚠ Do not use the PVI Analyzer™ outside its intended use, outside the indication for use or with incompatible catheters as this may lead to inappropriate patient treatment.

⚠ Do not use the PVI Analyzer™ output as the only source of information regarding pulmonary vein isolation.

Cautions

⚠ Do not alter the installation of the ECGenius™ System as this may cause the system to malfunction and potentially lead to incorrect measurements.

⚠ Do not connect products that are not compatible/interoperable with the ECGenius™ System as this may degrade the performance of the system or the connected products.

⚠ Do not use the ECGenius™ System outside its operating conditions (temperature, pressure, humidity) as this may degrade the components leading to short circuiting and leakage current that could harm the patient or user.

⚠ Use only CathVision approved accessories, cables, and peripherals, including extension cords and multi socket-outlets. Use of non-approved accessories, cables and peripherals can degrade the system performance and safety or result in loss of compliance with emissions and immunity requirements.

⚠ The conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, should not contact other conductive parts, including earth ground.

⚠ The maximum total output power of the isolation transformer is limited to 1500 VA.

⚠ Do not operate the ECGenius™ System in a manner that is not described in the IFU as this may result in damage to the system or cause the system to malfunction.

⚠ Do not use the ECGenius™ System if a component is damaged as this may cause the system to malfunction, result in damage to other parts of the system or influence the interpretation of the signals.

⚠ Always ensure a full set of ECG electrodes are properly placed on the patient's body and properly connected to the Cube Amplifier.

⚠ Be aware that the use of filters can have an effect on the morphology of the displayed waveforms and hence influence the interpretation of the signals.

⚠ The calculated blood pressure is affected by the waveform morphology. When in doubt, it is recommended to check the values using amplitude calipers.

⚠ The calculated heart rate is affected by the waveform morphology. When in doubt, it is recommended to check the values using time calipers.

⚠ Do not turn the power off while the ECGenius™ Software is running, as this could cause loss of data related to the treatment of the patient.

⚠ An unexpected termination of the ECGenius™ Software due to loss of power or software malfunction may result in the loss of the most recent segment of recorded waveform data. After restarting the application, check the latest recording to make sure that all required information has been captured. Refer to the Troubleshooting section for more information.

⚠ Service and maintenance of the ECGenius™ System should always be performed by an authorized CathVision representative to avoid unauthorized modifications to the system that might impact the performance and security.

⚠ ECG Trunk Cable, ECG Leadwire Grabber Set, and Blood Pressure Cable have an expected service lifetime of 1 year of normal use, due to mechanical wear and tear. These cables should be replaced once a year.

⚠ A blown fuse must only be replaced by one with the correct rating, that has been approved by CathVision. Using an unapproved fuse may cause the ECGenius™ System not to function or damage its electronics.

⚠ Always unplug the cables (including AC power cord) from the ECGenius™ System before cleaning or disinfecting to avoid ingress of fluid that may cause the electrical part of the system to malfunction.

⚠ Always follow the recommendation for cleaning and disinfection as described in the IFU to avoid contamination and possible ingress from cleaning fluids that can cause the system to malfunction.

⚠ Do not use any cleaning products containing abrasives, acetone, ammonia, benzene, or bleach as these could degrade the device surface.

⚠ Do not allow liquid or moisture to enter the ECGenius™ System, as this may cause electrical damage and/or the system to malfunction, which could result in injury to patient or user.

⚠ This device and accessories, cables and peripherals should be recycled according to local and national laws after useful life. Refer to the Disposal section for more information.

⚠ The ECGenius™ System is not a data storage device, and data should be backed up regularly.

⚠ Use only virus checked USB storage devices to avoid infection of the ECGenius™ PC. Infection with virus or malware may impact the performance of the ECGenius™ PC or ultimately stop the ECGenius™

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System from working.

⚠ Do not modify the Windows OS automatic logout setting as this can cause Windows to interrupt a procedure by showing the lock screen.

⚠ Do not connect the ECGenius™ PC to a computer network or the Internet to avoid installation of malware or other unauthorized software that might jeopardize the security of the ECGenius™ PC and performance of the system.

⚠ Do not make changes to the operating system or install software on the ECGenius™ PC. Installing unapproved software or making changes to the operating system may affect system performance and device safety.

⚠ Do not activate automatic update of Windows OS and Microsoft Office as the update may use system resources and thereby impact the overall performance of the ECGenius™ System or interrupt an ongoing procedure.

⚠ Do not activate automatic update of .net Core. Installing unapproved versions of .net core may affect system performance and device safety.

⚠ Do not de-activate the Windows OS automatic logout setting as doing so could allow an unauthorized user to gain access to the ECGenius™ System.

⚠ Always protect your user credentials (username and password) and change the password in case you think that it has been compromised to avoid unauthorized access to the ECGenius™ System.

⚠ Be aware that cardioversion, stimulation, noise, power-line interference, pulmonary vein automaticity, ventricular extra systoles, premature ventricular contractions, and delayed pulmonary vein potentials may affect the PVI Analyzer™ output. Always check electrograms to confirm PVI.

⚠ Be aware that positioning the circular mapping catheter too deep in the vein may lead the PVI Analyzer™ to give an inaccurate output. Always check catheter position and electrograms manually when using the PVI Analyzer™.

⚠ Always make sure that the selected catheter in PVI Analyzer™ corresponds to the one intended for analysis.

⚠ When using the PVI Analyzer™, be aware that the Biosense Webster Lasso® catheter compatibility is limited to only RF ablation procedures.

⚠ Do not use the PVI Analyzer™ as an indicator of isolation progress. It is not intended to convey incremental pulmonary vein isolation status before ablation of each pulmonary vein is considered complete.

⚠ Be aware that the performance of the PVI Analyzer™ has not been validated for PVI procedures on patients with structural heart disease or persistent atrial fibrillation.

⚠ When resuming a study, the Signal Complexity™ and PVI Analyzer™ need to be re-opened and catheters re-selected.

⚠ Be aware that cardioversion, stimulation, and noise may affect the Signal Complexity™ output.

⚠ Always make sure that the selected catheter in Signal Complexity™ corresponds to the one intended

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for analysis.

The following cautions may be shown by the ECGenius™ Software if triggered by an associated event.

⚠ An error has occurred in the Cube Amplifier and the connection has been closed. Power cycle the amplifier and click "Connect" in the Live screen to try again. Contact CathVision support if the error persists. Error: <ERROR CODE>

⚠ Disk space is running low, <XX> GB available (<XX>% of total). The application may stop and data may be lost when the disk is full. Are you sure you want to resume the study?

⚠ The Cube Amplifier is running outside its temperature range. Turn off the Cube Amplifier, let it rest and try again later. Contact CathVision support if the error persists. Error: <ERROR CODE>

The "<ERROR_CODE>" included in some messages is a unique label that can be used by a CathVision technician to analyze the problem but holds no information for the user.

Residual risk

Although it is impossible to fully eliminate all risks that are associated with the use of the ECGenius™ System, CathVision has determined that all identified risks have been reduced to an acceptable level, and the ECGenius™ System is safe and effective when used in accordance with its intended use.

Prior to use

The following information describes how the ECGenius™ System is set up prior to use.

Handling

The Cube Amplifier weighs more than 20 kg and should only be lifted and carried by two or more persons. The Cube Amplifier do not provide handles. Therefore, each person should grab the Cube Amplifier from the bottom with both palms facing up at opposite sides of the amplifier to handle and move it safely. All other components in the ECGenius™ System weighs less than 20 kg and can be lifted and carried by a single person.

Installation

The ECGenius™ System is only to be installed by a suitably qualified CathVision representative. A typical configuration of the ECGenius™ System is described in the **System Description** section, although other configurations are possible.
Do not discard the shipping boxes and inserts. If these are not visibly damaged, they can be used to return a component to CathVision for service if necessary.

⚠️ The ECGenius™ System and any other mains-powered equipment connected to it (e.g. stimulator, ablation generator) form a medical electrical system. Refer to IEC 60601-1:2005/A2:2020. The user is responsible for ensuring that appropriate electrical safety tests have been conducted prior to use. These tests should be repeated at regular intervals during the lifetime of the ECGenius™ System, in accordance with local electrical safety policies.

⚠️ The ECGenius™ System and its components are 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.

⚠️ The use of the ECGenius™ System and components with any other medical electrical equipment or medical electrical system may result in increased electromagnetic emissions or decreased electromagnetic immunity of that equipment/system or of the ECGenius™ System.

⚠️ Always measure and confirm the system leakage current and isolation (hi-pot test) after each installation or if the system has been moved. Do not use the ECGenius™ System if any electrical safety test has failed.

⚠️ To avoid the risk of electric shock, this equipment must only be connected to a mains supply with protective earth.

⚠️ Items of the ECGenius™ System that are required to be plugged into an isolation transformer must not be connected directly to a mains supply power outlet. Plugging these items directly into the mains supply can cause excessive patient leakage currents.

⚠️ Interconnecting cables may be subject to damage if laid on the floor. Precautions must be taken to cover cabling to prevent damage.

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

⚠️ There should be at least 6 inches of clearance on all sides of the Cube Amplifier. The Cube Amplifier relies on natural convection cooling with intake vents along the underside and an exhaust vent along the

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top of the rear. These areas should be kept free of obstructions to ensure adequate ventilation.

⚠️ To avoid electrical safety hazard, check grounding reliability at least once a year. Do not use the ECGenius™ System if any electrical safety test has failed.

⚠️ Do not alter the installation of the ECGenius™ System as this may cause the system to malfunction and potentially lead to incorrect measurements.

⚠️ Do not connect products that are not compatible/interoperable with the ECGenius™ System as this may degrade the performance of the system or the connected products.

⚠️ Do not use the ECGenius™ System outside its operating conditions (temperature, pressure, humidity) as this may degrade the components leading to short circuiting and leakage current that could harm the patient or user.

⚠️ Use only CathVision approved accessories, cables, and peripherals, including extension cords and multi socket-outlets. Use of non-approved accessories, cables and peripherals can degrade the system performance and safety or result in loss of compliance with emissions and immunity requirements.

⚠️ The conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, should not contact other conductive parts, including earth ground.

⚠️ The maximum total output power of the isolation transformer is limited to 1500 VA.

⚠️ The ECGenius™ System is not to be used in a sterile environment. None of the ECGenius™ System components are qualified to be sterilized.

Verify the proper operation of any other device or system used in conjunction with the ECGenius™ System and its components.
The potential equalization conductor can be connected to that of other equipment, when necessary, to make sure that all these devices are connected to the potential equalization bus bar of the electrical installation.
The Cube Amplifier and ECGenius™ PC should use detachable mains power cords that when disconnected provide a means for isolation from the mains power. Adequate rear side clearance should be maintained to ensure the power cords remain accessible and able to be disconnected.

Calibration

The ECGenius™ System is calibrated during manufacturing and does not require any further calibration during its lifetime.

Using the ECGenius™ System

This section describes the basic operation of the ECGenius™ System. Refer to the ECGenius™ Technical Manual for a complete description of all ECGenius™ System functions.

⚠ Do not use the ECGenius™ System in a patient monitoring, critical care or life supporting application as this is outside its intended use. Relying on a device with no alarms may result in death or serious injury.

⚠ Always ensure that rescue equipment, including an external pacemaker is available at all times during the EP procedure, as the ECGenius™ System is not a life-sustaining device.

⚠ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of the ECGenius™ System, including cables. Otherwise, degradation of the performance of this equipment could result.

⚠ Do not use the ECGenius™ System outside its intended use and outside the indication of use as this may lead to inappropriate patient treatment.

Start-up procedure

The start-up procedure for the ECGenius™ System consists of the following sequence:
- Switch on Cube Amplifier
- Switch on ECGenius™ PC
- Launch ECGenius™ Software

Switch on Cube Amplifier
The Cube Amplifier is switched on by flipping the on/off switch on the rear of the unit to the 'On' position.
The Cube Amplifier will emit an audible beep to indicate that power is applied.
After approximately 10 seconds, the Cube Amplifier will emit a second beep to indicate that the boot sequence has completed.
The status LED flashes green until communication with the ECGenius™ PC has been successfully established.

Switch on ECGenius™ PC
The ECGenius™ PC is switched on by pressing the power button on the front of the tower unit. When the ECGenius™ PC has completed the boot-up process, after logging into Windows, the Windows desktop should be visible on the ECGenius™ monitors.

Launch ECGenius™ Software
The ECGenius™ Software is launched by double-clicking the ECGenius™ Software icon on the Windows desktop.

The ECGenius™ Software will attempt communication with the Cube Amplifier. Successful communication between the ECGenius™ Software and the Cube Amplifier is indicated in two ways: the LED on the Cube Amplifier will change from flashing green to steady green, and the ECGenius™ Software will display the word Connected in the top right-hand corner of the Live View screen (refer to the **Frequently used functions** section).
Note: only one instance of ECGenius™ Software can run at any one time. The ECGenius™ Software will close if another user logs onto the PC while the ECGenius™ Software is running.

While connected to the Cube Amplifier the ECGenius™ Software may present these messages if the hardware reports an error.

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⚠ An error has occurred in the Cube Amplifier and the connection has been closed. Power cycle the amplifier and click "Connect" in the Live screen to try again. Contact CathVision support if the error persists. Error: <ERROR CODE>

⚠ The Cube Amplifier is running outside its temperature range. Turn off the Cube Amplifier, let it rest and try again later. Contact CathVision support if the error persists. Error: <ERROR CODE>

The "<ERROR_CODE>" included in the messages is a unique label that can be used by a CathVision technician to analyze the problem but holds no information for the user.

Refer to the **Troubleshooting** guide if the start-up procedure is not successful or if any errors are reported by the ECGenius™ Software.

Connecting to the patient

Refer to the **Specifications** section for information on devices that have been tested for interoperability/compatibility with the ECGenius™ System. Consult CathVision if you intend to use equipment that is not listed here.

⚠ Use only blood pressure transducers compatible with ANSI/AAMI BP22 standard as the use of non-compatible transducers could limit protection against defibrillation.

⚠ Do not apply stimulation signals to the same electrode(s) that are to be used for ablation while ablation is taking place. It is recommended that the ablating electrode(s) are deselected for stimulation before ablation is initiated to further reduce risk of inducing ventricular fibrillation.

⚠ The Cube Amplifier has stimulator bypass output connections that can be used to ensure that external stimulation signals are delivered to the patient, irrespective of the functioning of the ECGenius™ System. In the event of loss of power or ECGenius™ System malfunction, connect the catheters that are to be used for pacing to the stimulator bypass output connections.

⚠ Do not handle electrical cables while in contact with the patient to prevent leakage current to the patient which potentially could cause patient shock.

⚠ Do not operate the ECGenius™ System in a manner that is not described in the IFU as this may result in damage to the system or cause the system to malfunction.

⚠ Do not use the ECGenius™ System if a component is damaged as this may cause the system to malfunction, result in damage to other parts of the system or influence the interpretation of the signals.

⚠ Always ensure a full set of ECG electrodes are properly placed on the patient's body and properly connected to the Cube Amplifier.

The ECGenius™ System does not include any intracardiac catheters, which are the responsibility of the hospital and clinician user.

The ECGenius™ System does not include any surface ECG patch electrodes, which are the responsibility of the hospital and clinician user.

Only high-quality surface ECG electrodes should be used with the equipment. Refer to the Specifications section for compatible electrodes. Electrodes should be applied according to laboratory procedure.

The ECGenius™ System does not include an RF ablation generator, a stimulator or localization/mapping systems which if needed, are the responsibility of the hospital and clinician user.

Frequently used functions

Refer to the ECGenius™ System Technical Manual for full details on how to use the ECGenius™ Software.

The basic structure of ECGenius™ Software is as shown in the figure below.
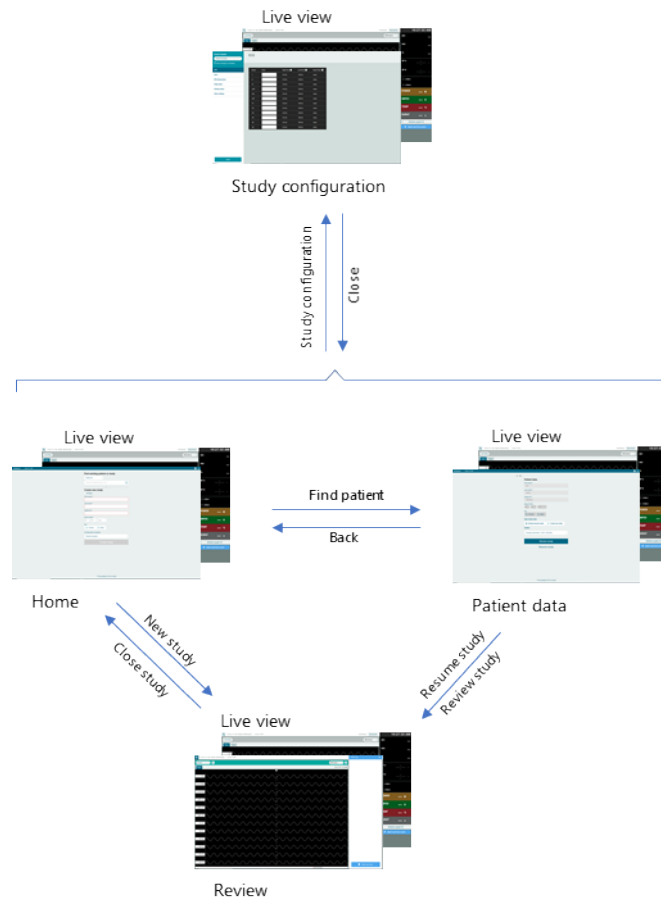
When the ECGenius™ Software is launched (see **Startup procedure** section) the user is presented with the Home screen and the Live View. The Live View screen indicates in the top right-hand corner if the ECGenius™ Software is connected to the Cube Amplifier.
A new study can be initiated using the **Create new study** function.

Alternatively, it is possible to retrieve records of previously conducted studies, by using the **Find existing patient or study** function, which will bring up the Patient Data screen. From here, a previous study can be reviewed or resumed.

From both the Home screen and the Patient Data screen, it is possible to access the **Study configuration** screen. It is also possible to Exit the application from the Home screen or the Patient Data screen.

Find existing patient or study

The **Find existing patient or study** function is used to retrieve a list of studies performed on a specific patient. After selecting a search filter (Patient ID or Patient name) typing in the search box will generate a list of patients (matching the search string). Clicking on one of the listed patients takes the user to the Patient Data screen.
On the Patient Data screen, the patient's personal information is shown. From here, it is possible to review or resume a previous study, or create a new study, using the options/buttons underneath the patient data. Choosing to review allows the user to revisit a previously conducted study. Choosing to Resume additionally enables recording of further data that will be appended to the study.

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If the PC is running low on disk space, the user may be presented with a message when resuming a study:

⚠ Disk space is running low, <XX> GB available (<XX>% of total). The application may stop and data may be lost when the disk is full. Are you sure you want to resume the study?

It is also possible from the Patient data screen to start a new study for the selected patient using the **Create new study** option.

Create study

The **Create study** function is used to begin a new study on a patient.
From the Home screen, the patient's data should be entered (mandatory: first and last name, patient ID; optional: date of birth, gender). From the Patient data screen, the study will be created using the patient data shown.

The configuration template to be used for the study should also be chosen. See **Study Configuration** section for details of how to define a study configuration.

Study configuration

⚠ Always check mapping between catheters and channels in the study configuration prior to each procedure to avoid stimulation at incorrect site(s) which may lead to a serious adverse event.

From the Home screen or the Patient data screen, click on the 'gear' symbol in the top right-hand corner

⚙

and choose Study configuration to enter the Study configuration screen.

From the Review screen, click on the 'hamburger' icon in the top left-hand corner

☰

and choose Study configuration to enter the Study configuration screen.

The Study configuration screen allows the user to adjust the settings for acquiring data. Configurations are saved as named templates and include catheter configuration, filter settings, and display settings (pages, elements, colors, scaling etc.). Refer to the ECGenius™ System Technical Manual for full details.

PVI Analyzer™

The PVI Analyzer™ can be used during a study to perform automated analysis of electrograms (EGM) to aid the user in determining the isolation status of a pulmonary vein.

⚠ Do not use the PVI Analyzer™ output as the only source of information regarding pulmonary vein isolation.

From the Review screen, click on the 'hamburger' icon in the top left-hand corner, choose Open PVI Analyzer™ option to open the PVI panel, and then select the circular mapping catheter (CMC) in use for the procedure. Supported CMC catheters are shown in **Compatibility/Interoperability**.

⚠ Be aware that positioning the circular mapping catheter too deep in the vein may lead the PVI Analyzer™ to give an inaccurate output. Always check catheter position and electrograms manually when using the PVI Analyzer™.

⚠ Always make sure that the selected catheter in PVI Analyzer™ corresponds to the one intended for analysis.

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⚠ When using the PVI Analyzer™, be aware that the Biosense Webster Lasso® catheter compatibility is limited to only RF ablation procedures.

The PVI Analyzer™ Isolation Pane displays an analysis of pulmonary vein isolation status as two 30-second bar graph timelines: an Isolation Status timeline of red and green bars and a Model Confidence timeline of gray bars. In the Isolation Status graph, red bars indicate Non-Isolated status, and green bars indicate Isolated status. In the Model Confidence graph, taller gray bars indicate a higher model confidence in the corresponding isolation status, and shorter gray bars indicate a lower model confidence. No isolation status will be displayed when the model confidence is below 80%. Both the isolation status graph and the model confidence graph show empty black bars when the PVI Analyzer™ is unable to detect a QRS on the ECG leads or IECG leads contain too much noise. The isolation status of the PVI Analyzer™ has been validated to have a sensitivity and specificity of more than 80% respectively.

⚠ Do not use the PVI Analyzer™ as an indicator of isolation progress. It is not intended to convey incremental pulmonary vein isolation status before ablation of each pulmonary vein is considered complete.

The PVI Analyzer™ includes a Signal Viewer that displays the ECG lead II trace and bipolar traces of the CMC catheter, and a Catheter Avatar that displays a representation of the CMC catheter. The Signal Viewer will display a red frame around trace signals to indicate that they are not recent when no QRS is detected for 3 seconds.
PVI Analyzer™ measurements are only valid if the CMC is correctly positioned in the pulmonary vein. The PVI Analyzer™ is only indicated for patients receiving their first PVI treatment. Refer to the ECGenius™ System Technical Manual for full details.

⚠ Do not use the PVI Analyzer™ outside its intended use, outside the indication for use or with incompatible catheters as this may lead to inappropriate patient treatment.

⚠ Be aware that the performance of the PVI Analyzer™ has not been validated for PVI procedures on patients with structural heart disease or persistent atrial fibrillation.

⚠ Be aware that cardioversion, stimulation, noise, power-line interference, pulmonary vein automaticity, ventricular extra systoles, premature ventricular contractions, and delayed pulmonary vein potentials may affect the PVI Analyzer™ output. Always check electrograms to confirm PVI.

⚠ When resuming a study, the Signal Complexity™ and PVI Analyzer™ need to be re-opened and catheters re-selected.

PVI Analyzer™ Machine Learning Algorithm

The PVI Analyzer™ uses a machine learning (ML) algorithm. The algorithm is locked before release and is not adaptive. The data sets for training and testing comprising patients with paroxysmal or persistent atrial fibrillation, undergoing their first PVI treatment. The data consists of EGMs from a (8 or 10 pole) circular mapping catheter placed in the pulmonary vein, recorded at baseline (non-isolated) and isolated states (verified by clinical expert annotation or using pacing maneuvers). The two data sets are independent of each other. The training data set contains EGMs from 137 patients (594 EGMs at baseline and 601 EGMs at isolation). The test data set contains EGMs from 78 patients (264 EGMs at baseline and 268 EGMs at isolation).

The clinical performance of the machine learning algorithm has been validated on data from a clinical multicenter trial, where EGM data from 78 patients measured before and after pulmonary vein isolation, are

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collected. Clinical experts have annotated the EGMs, either by visual inspection or pacing maneuvers, as ground truth baseline or isolated. During clinical validation the machine learning algorithm is applied to the EGMs. The isolation status is demonstrated to have a sensitivity and specificity above 80%.

Training (n=137 patients) – combination of 2015 and 2017 data sets.			**Test** (n=66 patients) – PVISION data set		
Age			**Age**		
Distribution	2015: 58 +/- 8 years 2017: 53 +/- 12 years [mean +/- SD]			N	%
			Above 60 years	41	64
			Below 60 years and Above 22 years	24	36
Sex			**Sex**		
	N	%		N	%
Male	2015: NA 2017: NA	2015: NA 2017: 61	Male	39	61
Female	2015: NA 2017: NA	2015: NA 2017: 39	Female	26	39
AF type			**AF type**		
	N	%		N	%
Paroxysmal	NA	91	Paroxysmal	60	92
Persistent	NA	9	Persistent	5	8
BMI			**BMI**		
	N	%		N	%
Less than 18.5 kg/m^2	NA	NA	Less than 18.5 kg/m^2	0	0
Between 18.5 kg/m^2 and 25 kg/m^2	NA	NA	Between 18.5 kg/m^2 and 25 kg/m^2	27	42
Between 25kg/m^2 and 30 kg/ m^2	NA	NA	Between 25kg/m^2 and 30 kg/ m^2	27	42
Above 30 kg/ m^2	NA	NA	Above 30 kg/ m^2	11	17
NA: Data not available			Note: Patient meta-data was missing for one patient in the PVISION data set		
Procedure type and CMC type			**Procedure type and CMC type**		
	%			N	%
RF (10 pole CMC)	74		RF (10 pole CMC)	32	47
Cryo (8 pole CMC)	26		Cryo (8 pole CMC)	34	53
Number of EGMs			**Number of EGMs**		
	N	%		N	%
Baseline	594	50	Baseline	181	49
Isolated	601	50	Isolation	189	51

Signal Complexity™

The Signal Complexity™ module analyzes various properties of the signals from a connected 10-pole catheter and visualizes them on a color map.
From the Review screen, click on the 'hamburger' icon in the top left-hand corner, choose the Open Signal

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Complexity™ option to open the Signal Complexity™ panel, and then select the desired 10-pole catheter for the procedure. Supported catheters are shown in **Compatibility/Interoperability**.

⚠ Always make sure that the selected catheter in Signal Complexity™ corresponds to the one intended for analysis.

The Signal Complexity™ properties are described in the following table.

Property name	Description	Color coding
Cycle Length	The average cycle length of the local activations on the distal or proximal part of the catheter. *Abbreviations:* CL dist / CL prox *Range:* 125 ms to 1500 ms, *Accuracy* <= 20 ms	Red – low values Blue – high values
Fractionation Index	The average % of the cycle time that deviates from baseline on the distal or proximal part of the catheter. The baseline is defined as a threshold value relative to the activation amplitude. *Abbreviations:* FI dist / FI prox *Range:* 0% to 100%, *Accuracy* <= 20%	Red – high values Blue – low values
Cycle Length Variation	The standard deviation of cycle lengths within the time of an analysis window on the distal or proximal part of the catheter. *Abbreviations:* CLVAR dist / CLVAR prox *Range:* 0 ms to 150 ms, *Accuracy* <= 20 ms	Red – high values Blue – low values
Dominant Frequency	The average peak frequency of the rectified filtered signal in the interval of 3-12 Hz across all bipolar traces. *Abbreviation:* DF *Range:* 3 Hz to 12 Hz, *Accuracy* <=0.5 Hz	Red – high values Blue – low values
Dominant Frequency Gradient	The proportion of dominant frequency for distal electrodes relative to proximal electrodes. *Abbreviation:* DF grad *Range:* -100% to 100%, *Accuracy* <= 10%	Red – near 100% or -100% Blue – near 0%

The Signal Complexity™ module dynamically maps signal property values to a color scale ranging from blue to white to red where and bluer colors indicate lower signal complexity, whiter colors indicate moderate signal complexity, and redder colors indicate higher signal complexity. New signal property values are calculated every 5 seconds from the last 10 seconds of EGM data, and the color mapping is dynamically updated after each measurement to highlight changes in the timeline.

⚠ Be aware that cardioversion, stimulation, and noise may affect the Signal Complexity™ output.

⚠ When resuming a study, the Signal Complexity™ and PVI Analyzer™ need to be re-opened and catheters re-selected.

Close study

From the Review screen, click on the 'hamburger' icon in the top left-hand corner and choose Close study to end the study in progress.

Disconnecting from the patient

After completing a study, ensure that all electrodes, catheters, and cables are disconnected from the patient. The cables in the ECGenius™ System can be re-used. Refer to the **Cleaning and disinfection** section.

Shutdown procedure

⚠ Do not turn the power off while the ECGenius™ Software is running, as this could cause loss of data related to the treatment of the patient.

The shutdown procedure for the ECGenius™ System consists of the following sequence:

- Close down ECGenius™ Software
- Back up data
- Shut down ECGenius™ PC
- Switch off Cube Amplifier

Close down ECGenius™ Software
From the Home screen or the Patient Data screen, click the 'power' symbol in the top right-hand corner of the screen

and select Exit application. The application will close and the ECGenius™ monitors will show the Windows desktop.
Do not leave ECGenius™ Software running when you leave the PC. Only one instance of ECGenius™ Software can run at any one time. Other users will not be able to start the ECGenius™ Software if it is already running under another logged-in Windows user account.

Back up data
It is recommended to perform a data backup after every completed procedure. Refer to the **Data backup** section for details.

Shut down PC
The ECGenius™ PC is shut down by clicking on the Windows symbol to bring up the Windows start menu

and then clicking the 'power' symbol

and subsequently the 'shutdown' symbol.

When shutdown is complete none of the LEDs on the ECGenius™ PC tower unit will be illuminated**.**

Switch off Cube Amplifier
The Cube Amplifier is switched off by flipping the on/off switch on the rear of the unit to the 'Off' position. The status LED will no longer be illuminated.

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Between uses

The following activities should be performed in between recording sessions:

Activity	How often?
Data backup	After each finished procedure
Cleaning and disinfection	When necessary and at least once a week
Inspection	Once a week
Check/adjust PC clock	Once a month
Data security review	Once a month, or as necessary
Electrical safety testing	Once a year, or if the system is relocated
ECG Trunk Cable, ECG Leadwire Grabber Set, and Blood Pressure Cable replacement	Once a year
Fuse replacement	When necessary
Upgrades	When available from CathVision

Data backup

⚠ The ECGenius™ System is not a data storage device, and data should be backed up regularly.

⚠ Use only virus checked USB storage devices to avoid infection of the ECGenius™ PC. Infection with virus or malware may impact the performance of the ECGenius™ PC or ultimately stop the ECGenius™ System from working.

Data should be backed up to an external USB storage device after each finished procedure. From there, data can be transferred to a suitable hospital data repository, as appropriate. It is recommended to use encryption on the USB storage device to protect patient data.
In the event of a failure of the hardware or software, study recordings may become corrupted or unavailable. CathVision accepts no responsibility for any loss of data.

Backing up is the process of creating an additional copy of the ECGenius™ study recording data files, so that data can be recovered if the original files are lost or corrupted.

To backup study recordings:
- Connect the external USB storage device to which the data files will be backed up.
- Open ECGenius™ Software
- Go to Settings from the Home screen
- Click "Browse" to select the backup location
- Select the study recordings that should be backed up (use Ctrl+mouse or Shift+mouse to select multiple studies)
- Click "Backup" and wait for the operation to complete
- Click "Ok" to close the confirmation dialogue
- Safely remove the external USB storage device.
The data files will now exist on the ECGenius™ PC and the USB storage device.

Refer to the **Data restore** section for information on how to recover data files from backups.
Refer to the **Backup security** section for information on how to manage sensitive data.

Cleaning and disinfection

It is recommended to clean and disinfect the ECGenius™ System immediately if it becomes contaminated and at least <u>once a week</u>.

⚠ Always unplug the cables (including AC power cord) from the ECGenius™ System before cleaning or disinfecting to avoid ingress of fluid that may cause the electrical part of the system to malfunction.

⚠ Do not use any cleaning products containing abrasives, acetone, ammonia, benzene, or bleach as these could degrade the device surface.

⚠ Do not allow liquid or moisture to enter the ECGenius™ System, as this may cause electrical damage and/or the system to malfunction, which could result in injury to patient or user.

⚠ The ECGenius™ System is not to be used in a sterile environment. None of the ECGenius™ System components are qualified to be sterilized.

The ECGenius™ System should be shut down, switched off and disconnected from the mains power prior to cleaning (refer to the **Shutdown procedure**).

Remove all visible soiling from the components of the ECGenius™ System using a moist cleaning wipe. Disinfect all surfaces by wiping them with a disinfectant wipe, leaving them to dry naturally.

CathVision recommends the use of CaviWipes™ for cleaning and disinfection.

After cleaning, reconnect the ECGenius™ System to the mains power and check that it starts up correctly (refer to the **Start-up procedure**).

Inspection

It is recommended to inspect the ECGenius™ System components for damage at least <u>once a week</u>.

Inspect all cords and cables for fraying or other damage.
Inspect all plugs and connectors for bent or damaged pins.
Inspect the Cube Amplifier for cracks or other damage.
Inspect all other components for signs of damage.

⚠ Do not use the ECGenius™ System if a component is damaged as this may cause the system to malfunction, result in damage to other parts of the system or influence the interpretation of the signals.

Check/adjust ECGenius™ PC clock

The clock on the ECGenius™ PC will drift over time. In order to ensure that collected data is correctly time-stamped, it is recommended to check the ECGenius™ PC clock, and if necessary, adjust to the correct time <u>once a month</u>. This should be done when the ECGenius™ Software is not running.

⚠ Do not connect the ECGenius™ PC to a computer network or the Internet to avoid installation of malware or other unauthorized software that might jeopardize the security of the ECGenius™ PC and performance of the system.

Data security review

<u>Virus/malware scan</u>
The ECGenius™ PC should be scanned for viruses/malware <u>once a month</u> or more frequently if necessary. This should be done by using an anti-virus/anti-malware application running from an external USB storage

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device, which itself has been scanned for viruses/malware.
Anti-virus/anti-malware software applications should not be installed on the ECGenius™ PC, to prevent unnecessary multitasking which may degrade system performance or interrupt an ongoing procedure.

Windows log review
It is recommended that a Windows administrator perform a review of the Windows log once a month to identify potential data security breaches. Refer to the ECGenius™ System Technical Manual for further details.

Electrical safety testing

⚠️ To avoid electrical safety hazard, check grounding reliability at least once a year. Do not use the ECGenius™ System if any electrical safety test has failed.

Electrical safety testing should be performed at regular intervals during the ECGenius™ System lifetime, in accordance with local policies. It is recommended to perform the following tests once a year, or if the ECGenius™ System is relocated.

Cube Amplifier earth continuity test
Measure the resistance between the earth pin of the Cube Amplifier mains plug and the equipotential stud on the rear of the Cube Amplifier enclosure.
It must be less than 0.1Ω.

Cube Amplifier patient leakage current test
Measure the current that flows through any applied part with the Cube Amplifier connected to the mains power supply.
It must be less than $10\mu A$ under normal conditions.
It must be less than $50\mu A$ under any mains power fault conditions (reversed polarity, open earth or open neutral).

Monitor touch current test
For ECGenius™ monitors in the patient environment, measure the current that flows to earth from any exposed metal part with the monitor connected to the mains power supply.
It must be less than $100\mu A$ under normal conditions.
It must be less than $500\mu A$ under any mains power fault conditions (reversed polarity, open earth or open neutral).

Consult a specialist if you are uncertain about how to perform electrical safety testing.

Cable replacement

The ECG Trunk Cable, ECG Leadwire Grabber Set, and Blood Pressure Cable used in the ECGenius™ System should be replaced once a year. This ensures that the high signal-to-noise ratio provided by the ECGenius™ System is maintained. Contact CathVision to order replacements.

Fuse replacement

The Cube Amplifier is the only component of the ECGenius™ System that contains user-replaceable fuses.

⚠️ A blown fuse must only be replaced by one with the correct rating, that has been approved by CathVision. Using an unapproved fuse may cause the ECGenius™ System not to function or damage its electronics.

The procedure for replacing the fuses is as follows:
- ensure that the Cube Amplifier is disconnected from the mains power supply

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- using a slotted screwdriver, gently press on the top and bottom of the fuse-holder in the power inlet, and pull it out
- replace the burned-out fuse(s) with new ones of the correct type and rating (the fuse types are given in the **Specifications** section and indicated on the enclosure)
- reinsert the fuse-holder in the power inlet

Upgrades

⚠ Do not make changes to the operating system or install software on the ECGenius™ PC. Installing unapproved software or making changes to the operating system may affect system performance and device safety.

Upgrades to the ECGenius™ System, including software/firmware upgrades, may be provided by CathVision during the product lifetime. Firmware upgrades must only be performed by authorized CathVision representatives and may require that the Cube Amplifier is returned to CathVision.
Any product upgrades will be accompanied by an addendum to, or a new revision of the ECGenius™ System Instructions for Use (this document) and ECGenius™ System Technical Manual, where necessary.

In the event that the ECGenius™ PC needs to be sent to CathVision (for repair or upgrade), all patient data should be backed up (see **Data backup**) and then purged, in order to maintain patient confidentiality. The patient data can be restored from the backup when the ECGenius™ PC is returned.

Service

Other than the activities described above, the ECGenius™ System has no service requirements.

⚠ Service and maintenance of the ECGenius™ System should always be performed by an authorized CathVision representative to avoid unauthorized modifications to the system that might impact the performance and security.

Storage

When not in use, the ECGenius™ System should be maintained in accordance with the conditions specified in the **Environmental conditions** section.

Product return

Please contact CathVision prior to returning product. Items should always be cleaned prior to packing and shipping.
When returning items, it is recommended to use the original packing. Please contact CathVision if the packing is not available, damaged or seems to be contaminated.

End of life

The ECGenius™ System has been designed for a service lifetime of at least 7 years. ECG Trunk Cable, ECG Leadwire Grabber Set, and Blood Pressure Cable have during normal use an expected service lifetime of 1 year, due to mechanical wear and tear. These cables should be replaced once a year.

⚠ This device and accessories, cables and peripherals should be recycled according to local and national laws after useful life. Refer to the Disposal section for more information.

Disposal

The ECGenius™ System comprises electrical and electronic equipment that should be recycled/disposed at the end of its lifetime in accordance with locally applicable regulations.
In accordance with the WEEE Directive (European Council Directive 2002/96/EC of 27 January 2003) customers within the European Union should treat the ECGenius™ System as WEEE, meaning that the following is applicable at the end of the product lifetime:
- Do not dispose WEEE as unsorted municipal waste
- Deliver electronic devices to collection facilities for WEEE in your region or return them to CathVision. Contact CathVision for further details.

Data transfer

If the ECGenius™ PC is to be recycled or disposed of, it is recommended to transfer all data from the hard drive to another computer. This can be achieved by backing up the ECGenius™ PC data to an external USB storage device (according to the procedure described in the **Data backup** section) and then performing a data restore to the new computer (according to the procedure described in the **Data restore** section). Follow your local policy for disposal of IT equipment with patient-sensitive data. CathVision recommends that the hard disk is shredded.

Troubleshooting

Serious incident

Notify CathVision immediately if a serious incident occurs whilst the ECGenius™ System is in use. A serious incident is defined as one which resulted (or potentially could have resulted) in the death of a patient/user or a serious deterioration in his/her health or wellbeing.

Problems

⚠️ The Cube Amplifier has stimulator bypass output connections that can be used to ensure that external stimulation signals are delivered to the patient, irrespective of the functioning of the ECGenius™ System. In the event of loss of power or ECGenius™ System malfunction, connect the catheters that are to be used for pacing to the stimulator bypass output connections.

The following table is a list of possible problems that may be encountered, and an explanation of how they may be addressed.

If this happens...	...try this
Cube Amplifier does not start	check the mains power supply to amplifier
	check the power supply cable connection between supply socket and amplifier
	check Cube Amplifier on/off switch is in the 'On' position
	if all the above are correct and the LED on the front of amplifier is not illuminated/flashing, check/replace the fuses (see **Fuse replacement** section)
Cube Amplifier front LED yellow (steady or flashing)	follow instructions in ECGenius™ Software error message (see **ECGenius™ Software messages** section)
Cube Amplifier front LED red	power cycle the Cube Amplifier and re-attempt connection
ECGenius™ PC does not start	check the mains power supply to ECGenius™ PC
	if an isolation transformer is in use, check isolation transformer output
	check the power supply cable connection between supply socket/isolation transformer and ECGenius™ PC
	if the ECGenius™ PC power LED indicator is illuminated, check the display ECGenius™ monitors
Nothing showing on ECGenius™ monitor(s)	check the mains power supply to ECGenius™ monitors
	if an isolation transformer is in use, check isolation transformer output
	check the power supply cable connection between supply socket/isolation transformer and ECGenius™ monitor(s)
Unable to log on	check correct username and password (ensure Caps Lock is not on)
ECGenius™ Software does not connect to Cube Amplifier	check the LED on the front of the amplifier to see if it is functioning
	check Ethernet cable between ECGenius™ PC and Cube Amplifier
Noisy signals	ensure CathVision-approved cables are being used
	check cables for damage/fraying
	replace cables that are over 12 months old
	ensure adequate separation between amplifier/cables and interfering equipment (e.g. other high-frequency electronic devices, RF transmitters, mobile phones, etc.)
No signals	confirm Cube Amplifier indicator LED is illuminated, if not, check power to

If this happens...	...try this
	Cube Amplifier (as above)
	check cable connections to Cube Amplifier
Software error message	follow instructions in message
	switch Cube Amplifier off and back on again
	restart ECGenius™ Software application and resume study
	reboot ECGenius™ PC
ECGenius™ Software freezes	utilize stimulator bypass output connections (see above)
	restart ECGenius™ Software application and resume study
	reboot ECGenius™ PC
	switch Cube Amplifier off and back on again
Loss of power	utilize stimulator bypass output connections (see above)
	check the mains power supply
	if an isolation transformer is in use, check isolation transformer output
	once power is restored, check correct functionality of ECGenius™ System
Corrupted configuration	do not use the system and contact CathVision for assistance
Infection with malware/ransomware	do not use the system and contact CathVision for assistance

If the above troubleshooting does not resolve the problem, contact CathVision for support.
In the event that the ECGenius™ PC needs to be sent to CathVision (for repair or upgrade), all patient data should be backed up (see **Data backup**) and then purged, in order to maintain patient confidentiality. The patient data can be restored from the backup when the ECGenius™ PC is returned.

ECGenius™ Software messages

The ECGenius™ Software may in case of errors display any of the messages from the following table.

Situation	Message	Recommended action
Cube Amplifier related error	An error has occurred in the Cube Amplifier and the connection has been closed. Power cycle the amplifier and click "Connect" in the Live screen to try again. Contact CathVision support if the error persists. Error: <ERROR CODE>

Related <ERROR_CODE>:
  • eAPPL_FAULT_ID_STIMULATOR | Follow instructions in message or contact CathVision support |
| | The Cube Amplifier is running outside its temperature range. Turn off the Cube Amplifier, let it rest and try again later. Contact CathVision support if the error persists. Error: <ERROR CODE>

Related <ERROR_CODE>:
  • eAPPL_FAULT_ID_THERMAL | Follow instructions in message or contact CathVision support |
| | An error was found during power-on self-testing of the Cube Amplifier and the connection has been closed. Power cycle the amplifier and click "Connect" in the Live screen to try again. Contact CathVision support if the error persists. Error: <ERROR CODE>" | Follow instructions in message or contact CathVision support |

Situation	Message	Recommended action
	Related <ERROR_CODE>: • eAPPL_FAULT_ID_POST	
	An error has occurred in the Cube Amplifier and the connection has been closed. Click "Connect" in the Live screen to reestablish the connection. If reconnection is not possible, or if the error persists, power cycle the amplifier and try again. Error: <ERROR CODE> Related <ERROR_CODE>: • eAPPL_FAULT_ID_SYSTEM • eAPPL_FAULT_ID_POWER • eAPPL_FAULT_ID_BRIDGE • eAPPL_FAULT_ID_EEPROM • eAPPL_FAULT_ID_COMM • eAPPL_FAULT_ID_LINK • eAPPL_FAULT_ID_VALIDITY • eAPPL_FAULT_ID_INTEGRITY • eAPPL_FAULT_ID_CONFIGURATION • eAPPL_FAULT_ID_SYNC • eAPPL_FAULT_ID_POWER_MON	Follow instructions in message or contact CathVision support
Communication problem	A communication error between the Cube Amplifier and the ECGenius™ PC has occurred and the connection has been closed. Click "Connect" in the Live screen to reestablish the connection. If reconnection is not possible, or if the error persists, check the network cable, power cycle the amplifier and try again.	Follow instructions in message or contact CathVision support
Incompatible firmware version	The Cube Amplifier firmware version <FW version> is incompatible with software version <SW version>. Contact CathVision support.	Follow instructions in message or contact CathVision support
Configuration mismatch	An error in configuration of the Cube Amplifier has occurred, and the connection has been closed. Click "Connect" in the Live screen to reestablish the connection. If reconnection is not possible, or if the error persists, power cycle the amplifier and try again.	Follow instructions in message or contact CathVision support
Review/resume a study while ECGenius™ Software is connecting / disconnecting from the Cube Amplifier	The study cannot be opened while the connection to the Cube Amplifier is transitioning. Wait a few seconds and try again.	Follow instructions in message or contact CathVision support
Study folder missing while opening a study	The study cannot be opened because the study folder is missing.	Follow instructions in message or contact CathVision support
Cube Amplifier not found	The Cube Amplifier is not found. Check that the amplifier is powered on and that the network cable is properly connected between the ECGenius™ PC and the amplifier. Click "Connect" in the Live screen to retry connection.	Follow instructions in message or contact CathVision support

Situation	Message	Recommended action
Disk space is below 16 GB when resuming a study	Disk space is running low, <XX> GB available (<XX>% of total). The application may stop and data may be lost when the disk is full. Are you sure you want to resume the study?	Follow instructions in message or contact CathVision support
Unhandled application error	A software error has occurred. Restart the application and try again. Contact CathVision support if the error persists	Follow instructions in message or contact CathVision support

Data restore

In the event of data corruption (or if studies are to be transferred from another computer) study recording data can be restored from a backup as follows:

Copying from USB
- Connect the external USB storage device on which the data files have been backed up to the ECGenius™ PC.
- Open ECGenius™ Software
- Go to Settings from the Home screen
- Click "Browse" to select the location from which data should be restored
- Click "Restore all" and wait for the operation to complete
- Click "Ok" to close the confirmation dialogue
- Safely remove the external USB storage device.

ECGenius™ Software About box

The About box shows details about the ECGenius™ Software, such as the version number.

From the Home screen or the Patient Data screen, click on the 'power' symbol in the top right-hand corner and choose About to view the About box.

From the Review screen, click the 'hamburger' icon in the top left-hand corner and choose About to view the About box.

Data security

The ECGenius™ PC is provided with a Windows 10 operating system, together with Microsoft Office 2019 applications.

⚠ Do not connect the ECGenius™ PC to a computer network or the Internet to avoid installation of malware or other unauthorized software that might jeopardize the security of the ECGenius™ PC and performance of the system.

User management

Users on the ECGenius™ PC can upon login with a valid password use the standard Windows functions. Password-controlled access is important for providing protection against malicious modification of ECGenius™ PC and the ECGenius™ Software study configuration. It is recommended to use strong passwords for all user accounts. Refer to the ECGenius™ System Technical Manual for information about the password policy. Users should not disclose or share their credentials and must change password if it is suspected that account security has been compromised.

New users are created and managed through the Windows User Management Application found on the desktop. For users to be granted access to the ECGenius™ Software, they must be members of the `ECGENIUS_USERS` local user group and the `Users` local user group. New users must be manually added to this group to be able to launch the ECGenius™ Software application.

Users that should have administrative privileges must additionally be added as members of both the `ECGENIUS_ADMINS` local user group and the `Administrators` local user group.

Users with administrative privileges can:
- Manage users through the Windows User Management Application (create, modify, or delete users)
- Run a virus scan
- Inspect the ECGenius™ audit log

CathVision recommends limiting the number of users with administration privileges to as few as possible.

Windows has been configured so that, if the ECGenius™ PC is left running unattended, it will automatically logout after 5 hours of inactivity, to prevent unauthorized access. These settings should not be changed. Similarly, the user should lock the ECGenius™ PC when not in use and/or if unauthorized users are present, to prevent disclosure of patient sensitive information.

Windows update

The Windows update service is disabled on the ECGenius™ PC, and should remain so, to avoid any risk of future incompatibility issues. As part of CathVision product updates, the relevant Windows patches will be included when necessary.

⚠ Do not activate automatic update of Windows OS or Microsoft Office as the update may use system resources and thereby impact the overall performance of the ECGenius™ System or interrupt an ongoing procedure.

⚠ Do not activate automatic update of .net Core. Installing unapproved versions of .net core may affect system performance and device safety.

Antivirus

No additional antivirus software is installed on the ECGenius™ PC in order to minimize multitasking by the

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processor which might slow down signal processing. Anti-virus/anti-malware software applications <u>should not be installed on the ECGenius™ PC.</u>

The ECGenius™ PC should be scanned for viruses/malware once a month or more frequently if necessary. Refer to **Data security review**.

Other functions

Avoid using the Windows system for anything that is not strictly needed or related to the use of the ECGenius™ System.

Data backup

It is recommended to perform a data backup after each finished procedure. See **Data backup** section.

Data breaches

It is recommended that a Windows administrator perform a review of the log file once a month to identify potential data security breaches. Refer to the ECGenius™ System Technical Manual for further details.

Specifications

The following sections provide information regarding the specifications of the ECGenius™ System.

Environmental conditions

	In use	Storage/transport
Temperature range (°C)	10 to 30	-15 to 50
Humidity range (% non-condensing)	30 to 75	10 to 95
Altitude	≤ 2000 m	
equivalent to ambient pressure (kPa)	80 to 106	70 to 106

Power supply

	Voltage (V_{AC})	Power (W)
Cube Amplifier	100 to 240 @ 50-60Hz	75
ECGenius™ PC	100 to 240 @ 50-60Hz	950
ECGenius™ Monitor	100 to 240 @ 50/60Hz	186
ECGenius™ Laser Printer (US)	110 to 127 @ 50/60Hz	495
ECGenius™ Laser Printer (EU)	220 to 240 @ 50/60Hz	
Isolation transformer (US)	100 to 120 @ 50/60Hz	Rated up to 1500
Isolation transformer (EU)	200 to 240 @ 50/60Hz	

Product specifications

Cube Amplifier

Dimensions	430 × 430 × 315 mm
Weight	22 kg
Power consumption	0.35A @ 240V_{AC}
	0.7A @ 110V_{AC}
Ingress protection rating	IPx1
IECG	
Electrodes	130 (128 × unipolar, 2 × reference)
Input range	± 1.1V (defibrillation-proof)
Recovery time (after defibrillation)	<1s
Bandwidth	0-500Hz min.
Noise (max.)	10 µV peak-to-peak
Default filters	Low-pass: 100Hz (unipolar traces), 500Hz (bipolar traces) High-pass: 0.5Hz (unipolar traces), 30 Hz (bipolar traces)
ECG	
Electrodes	10 (12-lead)
Input range	± 0.31V (defibrillation-proof)
Recovery time (after defibrillation)	<1s

Bandwidth	0-500Hz min.
Noise (max.)	10 µV peak-to-peak
Default filters	Low-pass: 150Hz High-pass: 0.5Hz
Heart rate / R-R interval calculation	
Averaging method	Rolling 3-period average
Accuracy	±10% or 5bpm (whichever is greater) Note: heart rate calculation may be inaccurate in the presence of pacemaker signals and/or during arrhythmias or defibrillation
Responses to irregular rhythms IEC 60601-2-27 §201.7 b) 4)	A1: 80 bpm A2: 60 bpm A3: 120 bpm A4: 73 or 51 bpm
Response time to change in heart rate IEC 60601-2-27 §201.7 b) 5)	80 to 120 bpm: ≤ 2 seconds 80 to 40 bpm: ≤ 3 seconds
Blood pressure input*	
Channels	4
Excitation voltage	6V
Bandwidth	0-100Hz min.
Accuracy	± 4mmHg
Default filter	Low-pass: 10Hz
Recovery time (after defibrillation)	<1s
*the blood pressure input ports are only defibrillation-proof when used with the CathVision-supplied cable and with an approved transducer (see **Compatibility/Interoperability**).	
Stimulator input	
Channels	2
Input range	≤ 75V
Current (max.)	40mA
Analog input	
Channels	2
Input range	± 5V
Bandwidth	0-250Hz min.
Default filters	Low-pass: 250Hz High-pass: 0.5Hz
Timebase scaling options	6, 13, 25, 50, 100, 200, 400mm/s
Analog single output (ECG Lead II)	
Full-scale range	± 1V
Bandwidth	1-150Hz
Gain	100

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Analog multi output	
Channels	13 (12 × ECG, 1 × IECG)
Full-scale range	± 1V
Bandwidth	1-150Hz (ECG) 1-500Hz (IECG)
Gain	100
Connectivity	Ethernet (RJ45)
Fuses	
Power entry module	2A, 250V$_{AC}$ (5mm × 20mm) LITTELFUSE 0217002.HXP ×2
Backplane (not user-replaceable)	6A, 125V$_{AC}$ (5mm × 20mm) BELFUSE 5TT 6-R ×1

ECGenius™ PC

Dimensions	418 × 177 × 518 mm
Weight	15.4 kg
Power consumption	950 W

ECGenius™ Monitors

Dimensions	531 × 173 × 364 ~ 511 mm (incl. stand)
Weight	6.1 kg with stand and cables
Power consumption (max.)	186 W

ECGenius™ Laser Printer

Dimensions	381 × 357 × 216 mm
Weight	8.2kg
Power consumption (max.)	495W

Isolation transformer

Dimensions	297 × 400 × 89 mm
Weight	18kg
Power rating (max.)	1500VA

Compatibility/interoperability

The following items are compatible with the ECGenius™ System:
- ECG patch electrodes suitable for connection to Conmed DL36-10 leadwires
- IECG catheters with 2mm shrouded plugs
- Blood pressure transducers compatible with ANSI/AAMI BP22 standard with a nominal sensitivity of 5 µV/V/mmHg

The following items have been tested for interoperability with the ECGenius™ System:
- MicroPace Stimulus Generator Unit MP3008 stimulator
  (e.g. as part of StimLab™, StimCor™ or EPS320™ system)
- Utah Medical Deltran® DPT-200 blood pressure transducer

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- Biosense Webster CARTO® 3 mapping system
- Stockert SmartAblate® ablation generator

The Signal Complexity™ module uses the signals from a connected 10-pole catheter.

The PVI Analyzer™ module support the following circular mapping catheters:
- Biosense Webster Lasso® 2515 variable loop, diameter: variable 15 to 25 mm, 10 poles
- Medtronic, Achieve™ (Advance), diameter 20 mm, 8 poles

⚠ When using the PVI Analyzer™, be aware that the Biosense Webster Lasso® catheter compatibility is limited to only RF ablation procedures.

Regulatory information

The ECGenius™ System complies with all applicable clauses of the following standards, with the exceptions/notes indicated:

IEC 60601-1 : 2005/A1:2012/A2:2020
IEC 60601-1-2 : 2014/A1:2020
IEC 60601-2-27 : 2011
- except §208 - the ECGenius™ System is not intended to provide alarms to patient or operator
- note to §201.12.1.101.8 - compliance achieved with high-pass filter set to 0.05Hz, 0.01Hz or None
IEC 60601-2-34 : 2011
- except §208 - the ECGenius™ System is not intended to provide alarms to patient or operator

Essential performance

The essential performance of the ECGenius™ System is as follows:
- The system shall maintain correct ECG, IECG, and blood pressure waveform formation and labeling as specified by the user
- The system shall cause no greater than a 20% amplitude change (error) under a single fault condition, otherwise the system shall fail safe by preventing use.
- The relays shall not change state from the user programmed setting, otherwise they shall default to the fail-safe (all open) position.
- The system shall cause no greater than a 20% time measurement error during a single fault condition, otherwise, the system shall fail by preventing use.
If the essential performance is lost or degraded due to electromagnetic disturbances, the ECGenius™ System may present waveform data that do not accurately represent the source signals. The stimulator output may be directed to a catheter different than that defined by the user in software.

IEC 60601-1 classification

Mode of operation:	Continuous
Protection against electric shock:	Class I
Applied parts:	CF
Ingress protection:	IPx1
Method of sterilization:	The ECGenius™ System is not intended to be sterilized
Oxygen rich environment:	The ECGenius™ System is not intended to be used in an oxygen rich environment

EMC

The ECGenius™ System complies with standard IEC 60601-1-2:2014/A1:2020 (EN 60601-1-2:2015+A1:2021) for electromagnetic compatibility for medical electrical equipment and/or systems. For this compliance, the ECGenius™ System is only to be used in combination with cables and accessories either supplied by CathVision or approved by CathVision in writing.
To prevent adverse events due to electromagnetic disturbances:
- all cables connected to the ECGenius™ System must be engaged and locked (where possible)
- all equipment must be undamaged
- the Cube Amplifier must be plugged into the mains supply and the enclosure must not be open
- all other mains-powered equipment in the ECGenius™ System must be powered via the isolation transformer.

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The following table list the EMC compliance levels:

Method	Description	Test voltage & frequency	Test class / level
CISPR 11	Power line conducted emissions	100VAC 60Hz 240VAC 50Hz	Class A
CISPR 11	Radiated emissions	120VAC 60Hz 230VAC 50Hz	Class A
IEC 61000-3-2	Harmonics emissions	230VAC 50Hz	Class A
IEC 61000-3-3	Flicker emissions	230VAC 50Hz	--
IEC 61000-4-2	Electrostatic discharge	230VAC 50Hz	±8kV contact ±15kV air
IEC 61000-4-3	Radiated field immunity	230VAC 50Hz	3V/m 80MHz - 2.7GHz proximity fields
IEC 61000-4-4	Electrical fast transients	230VAC 50Hz	±2kV - Mains ±1kV - I/O
IEC 61000-4-5	Surge immunity	230VAC 50Hz	±1kV Line-Line ±2kV Line-Ground
IEC 61000-4-6	Conducted RF immunity	230VAC 50Hz	3Vrms 150kHz - 80MHz 6Vrms ISM bands 150kHz - 80MHz
IEC 61000-4-8	Power frequency magnetic field	230VAC 50Hz	30 A/m
IEC 61000-4-11	Voltage dips	100VAC 60Hz 240VAC 50Hz	0% during 0.5 cycles 0% during 1 cycle 70% during 25/30 cycles
IEC 61000-4-11	Short interruptions	100VAC 60Hz 240VAC 50Hz	0% during 250/300 cycles
IEC 61000-4-39	Immunity to Proximity Magnetic Fields from 134.2kHz RFID Readers	230VAC 50Hz	134.2kHz 2.1kHz PM 65 A/m
IEC 61000-4-39	Immunity to Proximity Magnetic Fields from 13.56MHz RFID Readers	230VAC 50Hz	13.56MHz 50kHz PM 7.5 A/m

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.

Contact

Please write to support@cathvision.com for support.

Please write to contact@cathvision.com if you are interested in learning more about CathVision products and services.

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Version History

ECGenius™ System with ECGenius™ Software V3.0	**Version: 3, Revision: 1, EN, US, Effective 2022-09-19** Initial version of the IFU for ECGenius™ System with ECGenius™ Software V3.0. Note this version should only be used for usability studies.
	Version: 3, Revision: 2, EN, US, Effective 2022-11-08 Added more details of the user interface elements to section PVI Analyzer. Added description of PVI Analyzer™ Machine Learning Algorithm. Added table describing calculated Signal Complexity properties to section Signal Complexity.
	Version: 3, Revision: 3, EN, US, Effective 2022-12-06 Added demographics table in section PVI Analyzer™ Machine Learning Algorithm. Added accuracy to Signal Complexity table, and corrected lower limit for Cycle Length and upper limited for Dominant Frequency. Added description of Signal Complexity and PVI Analyzer to Clinical Indications section.
	Version: 3, Revision: 4, EN, US, Effective 2023-06-19 Updated cautions and intended population for the PVI Analyzer. Updated section on PVI Analyzer.
	Version: 3, Revision: 5, EN, US, Effective 2023-08-08 Updated indications for use for PVI Analyzer: "The PVI Analyzer™ feature is a secondary measure of pulmonary vein isolation and should not replace traditional methods of confirming isolation" Added new caution: "When using the PVI Analyzer™, be aware that the Biosense Webster Lasso® catheter compatibility is limited to only RF ablation procedures."
	Version: 3, Revision: 6, EN, US, Effective 2023-08-15 Added section concerning handling the Cube amplifier by two persons. Updated product specification for weight from 18 kg to 22 kg. Updated photo of Stimulator Cable.

Signatures:

Controlled Document Approved:	I hereby state that I have found no errors in the contents of this controlled quality document. The document is ready for release.
Name:	**William Riddell** **cathvision.com\wir**

2023-08-15 09:08:00 (UTC+00:00)

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