

GI Genius™ Module

User Manual for Module 100 and Module 200

REF CB1708-HWD-MN01: GI Genius™ Module User Manual Version 1.2 (11th May 2023)



Important Information – Please Read Before Use

If the product is used outside the region, it may not operate as specified in the specifications. Please read this Instructions for Use carefully before using the product to ensure that you use it safely, effectively and for proper maintenance. Please retain this manual for future reference.

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1 Symbols and marking

	Legal Manufacturer		Unique Device Identifier of the medical device
	Consult the instructions for use		The product is a medical device
	Caution		Catalogue code
	CE marking of conformity to Regulation 2017/745/EU		Serial Number of the device
	Date of manufacture		Storage Humidity Range
	Do not throw in trash (WEEE Directive Mark)		Stacking Limit by Number
	Refer to instruction manual/ booklet (Blue)		Storage Temperature range
	Alternating current		Atmospheric Pressure range
	Fuse (2xF5AH250V 5mmx20mm)		Stand-by
	Equipotentiality		Input symbol
	Protective earth		Output symbol
	Dangerous voltage (Yellow)		USB connection symbol
	Keep Dry		LAN connection symbol
	Handle with care		Power ON
	Fragile		Power OFF
	This side up		

2 Introduction

2.1 Safety symbols

This manual and this software use the safety symbols below. The symbols denote critical information. Please read them carefully.

DANGER	Imminent hazardous situation that will result in death or serious injury, if not avoided
WARNING	Potential hazardous situation that could result in death or serious injury, if not avoided
CAUTION	Potential hazardous situation that may result in minor or moderate injury, if not avoided. Can alert about unsafe practices or potential damage

NOTE

Useful information

2.2 Terms and abbreviations

The following table summarizes terms and abbreviations used in this document.

Term	Description
MED	Main Endoscopy Display
SaMD	Third-Part Medical Device Software
WEEE	Waste Electrical & Electronic Equipment
VP	Endoscopy Video Processor

2.3 Document purpose

This document describes the essential information on using the GI Genius™ Module in a safe and effective way. Please carefully read this manual and all the equipment manuals involved in the procedure and use the device as instructed.

WARNING

Failure to follow the instructions in this manual may result in damage to and/or malfunction of the equipment or other equipment involved in its use. Do not use this device for any other purpose than that for which it has been intended.

CAUTION

This document does not contain any information on how to perform endoscopy procedures, please refer to the appropriate manuals for this information.

Keep this and any related document in a safe and accessible location. If you have questions or comments about this manual please contact helpdesk service section 11.

3 Description

3.1 Intended purpose of the device

GI Genius™ Module is intended to be a computing unit for Software as a Medical Device (SaMD) for real-time analysis of endoscopy video streams.

GI Genius™ Module capabilities are:

1. To run compatible SaMDs for real-time analysis of endoscopic videos;
2. To provide SaMDs with input video coming from the Endoscopy Video Processor;
3. To superimpose SaMD generated annotations on said video to be sent to an external display for visualization.

GI Genius™ Module 100 is compatible with endoscopy video processors featuring SDI (SMPTE 259M) or HD-SDI (SMPTE 292M) output ports and displays featuring SDI (SMPTE 259M) or HD-SDI (SMPTE 292M) input ports.

GI Genius™ Module 200 is compatible with VPs featuring HD-SDI (SMPTE 292M), 3G-SDI (SMPTE 259M) or 12G/SDI (SMPTE ST2082) output port and displays featuring HD-SDI (SMPTE 292M), 3G/SDI (SMPTE 259M) or 12G/SDI (SMPTE ST2082) input ports.

WARNING

GI Genius™ Module is not capable of generating and providing medical relevant information, which in turn shall be provided by the third-party medical device software.

WARNING

Any medical application and medical claim of third-party medical software installed in the GI Genius™ Module shall be independently guaranteed by the third-party manufacturer. GI Genius™ Module is not responsible for any medical claim, for performance, or for safety risks related to use and purpose of the third-party medical software.

WARNING

Do not use GI Genius™ Module for any purpose other than its intended use.

3.2 User qualification

Users shall have been properly trained on the GI Genius™ device so that they can use and manage it properly. .

Users shall be expert clinicians on endoscopy procedure and the training shall be based on the contents of this user manual.

3.3 GI Genius™ Module compatibility

GI Genius™ Module 100 is compatible with VPs featuring SDI (SMPTE 259M) or HD-SDI (SMPTE 292M) output port and displays featuring SDI (SMPTE 259M) or HD-SDI (SMPTE 292M) input ports.	
GI Genius™ Module 200 is compatible with VPs featuring HD-SDI (SMPTE 292M), 3G-SDI (SMPTE 259M) or 12G/SDI (SMPTE ST2082) output port and displays featuring HD-SDI (SMPTE 292M), 3G/SDI (SMPTE 259M) or 12G/SDI (SMPTE ST2082) input ports.	
Any equipment connected to GI Genius™ Module must be compliant with IEC/EN 60601-1 and IEC/EN 60601-1-2.	
DANGER	Using incompatible equipment can result in patient injury or equipment damage and makes it impossible to obtain the expected functionality.

Use of GI Genius™ Module with third-party medical software is possible only if such software does meet the minimum requirements specified in section 5 and the technical specifications in section 3.4.

The GI Genius™ Module can be used in combination with the GI Genius™ software, please refer to the user manual of the latter for further information.

DANGER	Using incompatible apparatus or software can result in patient injury or equipment damage. This makes impossible to obtain the expected functionality.
CAUTION	The usage of OVERSCAN display functionality could result in hiding of medical software graphical information overlaid on the main endoscopy display.

3.4 Technical specifications

In order for a SaMD to run on the GI Genius™ Module, the following technical specifications shall be considered:

- CPU: Intel Core i7-10750H
- RAM: 16 GB DDR4-2933MHz
- GPU: NVIDIA Quadro RTX 3000 with built-in CUDA and cuDNN
- Video I/O: DELTA-12G-elp-key 11 CP with built-in VideoMaster SDK
- OS: Linux Kernel 4.15.0
- Mass storage: 1 TB SSD.

3.5 Cybersecurity measures

GI Genius™ Module does make use of encrypted mass storage.

GI Genius™ Module does not need connections to an IT network to operate.

GI Genius™ Module does not store any data, unless otherwise requested by the third-party medical software.

GI Genius™ Module does not provide user accounts.

GI Genius™ Module does not allow connection and mounting of unrecognized USB drives.

GI Genius™ Module does implement antitampering protection against physical attacks.

Store GI Genius™ Module in areas accessible to authorized personnel only. GI Genius™ Module shall be used by physicians only.

4 Operating the GI Genius™ Module

4.1 Package contents

Check to see if the package contains all of the following items. If any item is missing, contact the distributor you purchased from.

Part #	Description
CB1708-PW-EF-01	GI Genius Type E/F Power Cord (EU) 1.80m/6'
CB1708-PW-G-01	GI Genius Type G Power Cord (UK) 1.80m/6'
CB1708-PW-CA-01	GI Genius Type CA Power Cord (CA) 2.40m/7.8'
CB1708-4KC-01	GI Genius 2x 12G-SDI Cables 2m/6.6'
CB1708-HWD-MN01	GI Genius Module User Manual

WARNING	Use of accessories and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
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NOTE

You should keep all the packaging materials, including the box, in case you need to move or transport this product.

4.2 Parts and functions

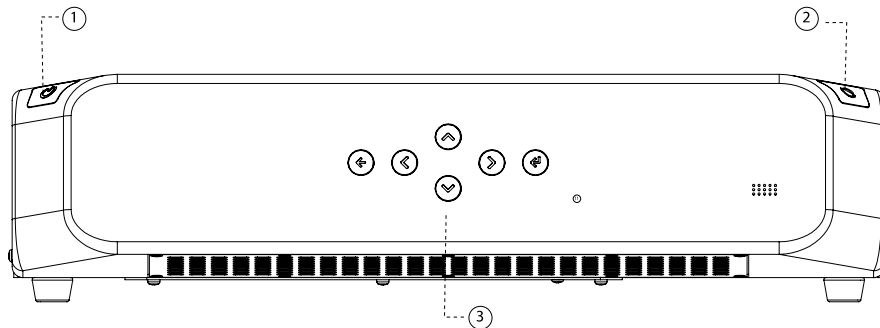


Figure 1: GI Genius™ Module front panel

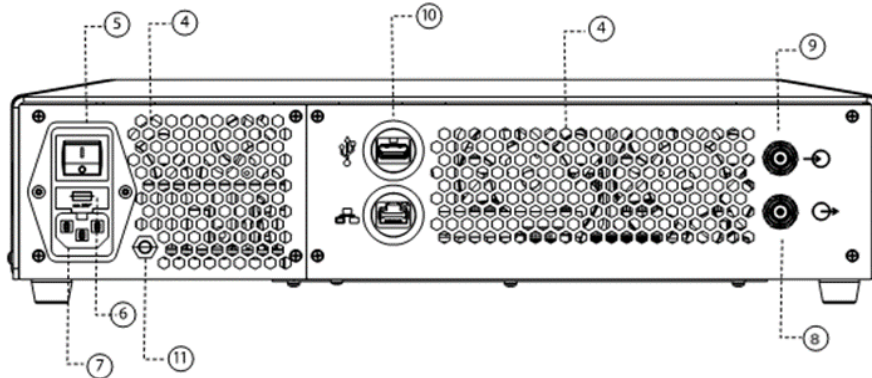


Figure 2: GI Genius™ Module back panel

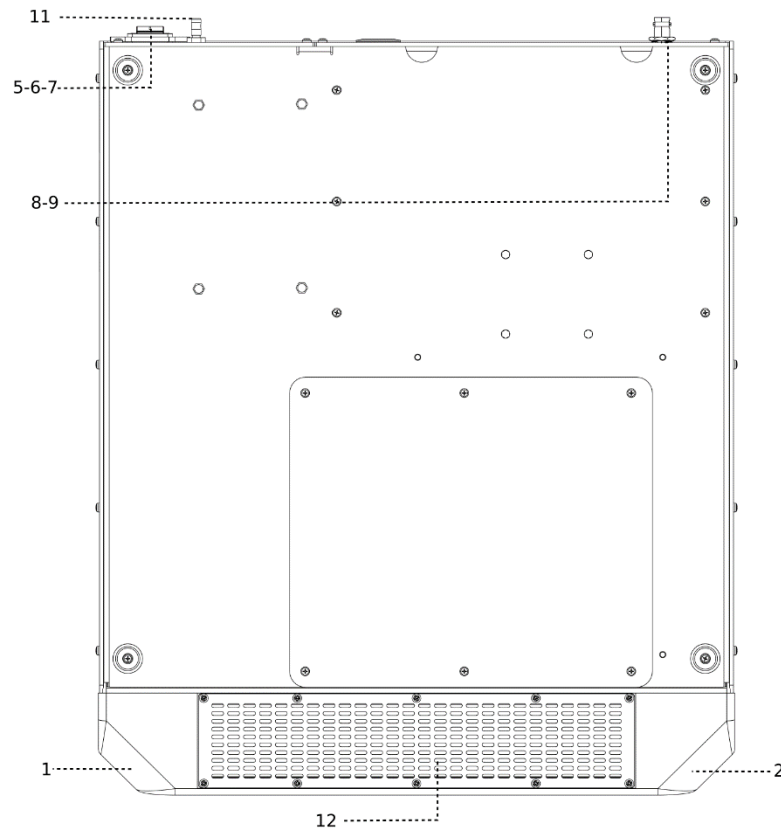
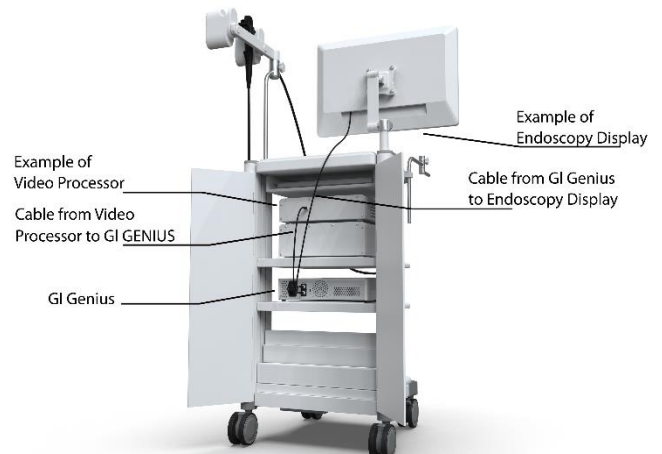
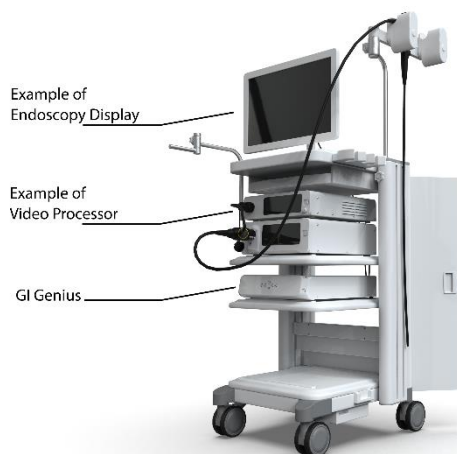


Figure 3: GI Genius™ Module bottom view

1		Stand-by/ power light indicator	Press it to go into GI Genius™ Module stand-by mode or to end the GI Genius™ Module stand-by mode. NOTE When the stand-by mode is off the green indicator light is solid.
2		Overlay activation/deactivation	Please refer to the software user manual for information about the function activated with this button. NOTE When the indicator light is blinking contact the support (see section 11).
3		Keyboard	To allow user navigation into the menu.
		Arrow keys up and down	To allow user to move up/down in the menu.
		Arrow keys right and left	To allow user to move left and right in the menu.
		Confirm button	To allow user to open the menu and confirm actions
		Back button	To allow user to close the menu
4		Ventilation output grid	Ventilation grid for the cooling fan.

			NOTE Install the device in a location where the ventilation grid will not be blocked. NOTE Do not place any objects on the ventilation grid.
5		Power Supply Switch I/O	Press it to enable or disable the power grid connection.
6		Fuse Box	This fuse box contains two fuses.
7		Power Input Socket	Connect the AC power cord.
8		OUT -SDI/HD-SDI output	To be connected to the MED.
9		IN - SDI/HD-SDI input	To be connected to VP.
10		USB 3.0 socket	Socket to be used to connect external devices (future extensions).
11		Potential Equalization Terminal	This terminal is used with a potential equalization busbar to equalize the potential of other equipment connected to the device.
12		Ventilation input grid and filter	Ventilation grid for the cooling fan. NOTE Install the device in a location where the ventilation grid will not be blocked. NOTE Do not place any objects on the ventilation grid.

4.3 Configuration



4.4 Installation requirements

1. This device should **NEVER** be installed or used in areas where the unit could get wet or be exposed to any environmental conditions such as high temperature, humidity, direct sunlight, dust, salt, etc., which could adversely affect the equipment.
2. This equipment should **NEVER** be installed or used in the presence of flammable or explosive gases or chemicals.
3. This equipment should **NEVER** be installed, used or transported in an inclined position nor it should be subjected to impact or vibration.
4. Ensure that all power requirements are met and conform to those specified on the rear panel.
5. Do not block the air intake vent of this equipment.
6. Do not allow the power cord and the video cable to become twisted, crushed or pulled taut.

4.5 Installing the Module in the cart

Install GI Genius™ Module in a cart while referring to the installation examples in figures above. Make sure the cart is on a stable and level surface.

CAUTION	Do not install GI Genius™ Module in any of the following locations: • Where the device is likely to be exposed to water. • Where flammable or explosive gas is present. • In hot and humid locations. Install the device in a location where the ventilation grids will not be blocked. Install the GI Genius™ Module in a location where dust will not enter inside. Wipe off any dust on the device. Excessive amounts of dust accumulating inside the unit may cause the device to malfunction, emit smoke, or catch fire.
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4.6 Connecting the Module

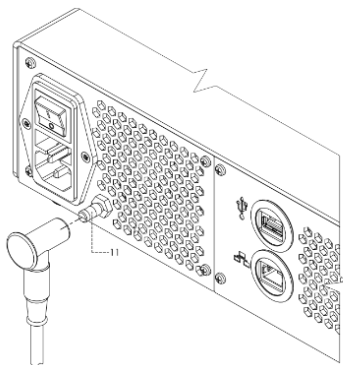


Figure 4: Connection of the Potential Equalization Terminal Cable to GI Genius™ Module

Connect to the Potential Equalization Terminal (optional) – IEC EN 60601-1 section 8.6.7

Connect the Potential Equalization Terminal Cable pushing the cable connector on the GI Genius™ Module Potential Equalization Terminal connector. For the connection use a Potential Equalization Terminal Cable with a connector of 6 mm diameter. Please refer to Figure 4.

Connect VP and MED to the GI Genius™ Module.

Make sure the GI Genius™ Module, the VP and MED are turned off beforehand.

Connecting to the VP

Use a BNC video cable (part number: CB1708-4KC-01) to connect the IN (video input) connector to a SDI video output of the VP.

Connecting to the MED

Use a BNC video cable (part number: CB1708-4KC-01) to connect the OUT (video output) connector to a SDI video input of the MED.

Connecting to the mains

Use the power input socket to connect the power cord (part number: CB1708-PW-G-01/ CB1708-PW-EF-01/ CB1708-PW-CA-01) to the wall power socket.

NOTE	After the device has been connected, please be sure that the video stream coming from the endoscopy system is correctly shown in the main endoscopy display without interruption.
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4.7 Turn On/Off the GI Genius™ Module

- Press the power supply Switch (I/O) to enable (I) the power grid connection;
- The device is in stand-by mode;
- Press the stand-by button to turn on the device;
- Press the stand-by button again to turn off the device;

- The device is in stand-by mode;
- Press the power supply switch (I/O) to disable (O) the power grid connection.

CAUTION	After the device has been turned off, wait at least 10 seconds before turning it back on again. A fuse may be blown if you turn the power on and off repeatedly within a short period of time.
	Do not use a sharp object such as the tip of a pen to press the buttons on the operation panel.

4.8 GI Genius™ Module BY-Pass and Emergency Shut Down

If the Module is in stand-by or powered off, a by-pass feature that directly connect video input to video output is automatically activated, so the video directly flows through the device.

If the endoscopic image disappears, the image freezes and cannot be restored or there are interferences in the video signal:

CAUTION	Put the device in stand-by mode with the front switch or shut it down with the back switch (I/O) to disable (O) the power grid connection;
	If the video image still cannot be restored, disconnect the Module from the VP and MED;
	reconnect the Module to the VP and MED;
	If the video image still cannot be restored, follow the procedures described in the endoscopy unit manual.

4.9 Operational environment

GI Genius™ Module shall be operating under the following conditions:

- (10 ÷ 40) °C - (50 ÷ 104) °F
- 20% ÷ 90% humidity (non-condensing)
- 75,3 kPa ÷ 101,3 kPa

4.10 Storage and transport environment

GI Genius™ Module must be stored and transported under the following conditions:

- (-10 ÷ 40) °C - (14 -104) °F
- 20% ÷ 90% humidity (non-condensing)
- 75,3 kPa ÷ 101,3 kPa

5 Third-party medical software

WARNING	Instructions for use and other relevant guidance materials are necessary for the correct use of the medical device software installed in the GI Genius™ Module. Refer to such documentation and information for correct use of the medical software.
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5.1 Safety and performance requirements

The combination of the medical software and the GI Genius™ Module shall be validated for compliance to IEC 60601-1 for basic safety and essential performance.

The combination of the medical software and the GI Genius™ Module shall be validated for compliance to IEC 60601-1-2 for electromagnetic disturbances.

The combination of the medical software and the GI Genius™ Module shall be validated for medical performance and safety according to the medical claims stated by the medical software manufacturer, by also taking into account usability of the final system.

The medical software shall be equipped with built-in functionalities to by-pass or shut down the software overlay on the display in case of problems to the video and images on the display or with other equivalent solutions, as the one in section 4.8.

The GI Genius Module is not intended for use in combination with life-sustaining medical software applications nor for use in the emergency medical services environment.

5.2 Cybersecurity requirements

- Implemented encryption of mass storage
- Restricted user access
- Disabled networking
- Disabled user copying, downloading, and updating of the medical software
- Implemented audit trail of events
- Encryption of data and data backup whenever present
- Self-diagnostics of functionalities and integrity.

6 Power specification

SUPPLY VOLTAGES	100 - 240 V AC
	50 - 60 Hz
POWER CONSUMPTION	240W

7 Information for safe use

Repair and modification

Do not disassemble, modify or attempt to repair the Module. Any attempt at such operations without the guidance and instructions of authorized service personnel will void any warranty of the device.

DANGER

Unproper Module disassembly, modification or repair could result in risks for patients and operators.

Risks

GI Genius™ Module is compliant with IEC/EN 60601-1 and IEC/EN 60601-1-2 can be placed in the patient environment and can be safely connected to other IEC/EN 60601-1 equipment.

WARNING

Compliance with IEC/EN 60601-1 and IEC/EN 60601-1-2 in combination with third-party software shall be independently guaranteed by the third-party developer.
Do not use GI Genius™ Module for any purpose other than its intended use.

Electrical risks

Strictly observe the following precautions. Failure to do so may place the patient and medical personnel in danger of electric shock.

DANGER

Keep fluids away from the Module. If fluids are spilled on or into the Module, immediately stop any operation of the Module and contact helpdesk service (section 11).

Do not use the Module when not properly closed. Do not touch electrical contacts inside any component of the Module.

The Module must be connected to a grounded main outlet.

WARNING

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

Fire or explosion risks

In order to prevent fire and explosion, do not expose the Module where:

DANGER

there is a high concentration of oxygen

air contains oxidizing agents (e.g. N₂O).

air contains any flammable gases.

there are flammable liquids nearby.

Interferences and electromagnetic fields

WARNING	Module may interfere with other equipment. Please refer to section 3.3 for further information.
CAUTION	Electromagnetic interference may occur to this instrument when it is placed near equipment marked with the following symbol  or other portable and mobile RF communications equipment such as cellular phones. If radio interference occurs, mitigation measures may be necessary, such as reorienting or relocating this instrument or shielding the location. Do not use GI Genius™ Module and its cables closer than 30 cm (12 inches) to such RF communications equipment.

WARNING	Do not use the device where there is a strong electromagnetic field (e.g. Magnetic Resonance, wireless devices, microwaves emitting devices, etc.).
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This product is intended for use in the electromagnetic environments specified below.
The customer or the user of this product should assure that it is used in such an environment.

Electromagnetic emission compliance information and guidance		
Emission test	Compliance	Electromagnetic environment - Guidance
RF emissions CISPR 11	Group 1	This product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity compliance information and guidance			
This product is intended for use in the electromagnetic environments specified below. The customer or the user of this product should assure that it is used in such an environment.			
Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment — Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV air	Floors should be made of wood, concrete, or ceramic tile that hardly produces static. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1/2kV differential mode	±1/2kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycles <5 % U_T (>95 % dip in U_T) for 1 cycle 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T)	<5 % U_T (>95 % dip in U_T) for 0,5 cycles <5 % U_T (>95 % dip in U_T) for 1 cycle 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>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 this product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or battery.

	for 250 cycles		
Power frequency (50Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Electromagnetic immunity compliance information and guidance			
This product is intended for use in the electromagnetic environments specified below. The customer or the user of this product should assure that it is used in such an environment.			
Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment — Guidance
Conducted RF EN 61000-4-6	6Veff 150kHz to 80MHz	6Veff 150kHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of this product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1,2 x √P 150kHz to 80MHz d = 1,2 x √P 80MHz to 800MHz d = 2,3 x √P 800MHz to 2,7GHz Where “P” is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and “d” is the recommended separation distance in meters (m).
Radiated RF EN 61000-4-3	10Veff 80MHz to 2,7GHz	10Veff 80MHz to 2,7GHz	
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 			

Mechanical forces

CAUTION	While pressing buttons or touching the device, do not use hard or pointed objects or apply excessive force otherwise damage to the equipment will occur.
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Connections and disconnections

CAUTION	Do not connect/disconnect any cable of the device while any component is powered on, otherwise damage to the equipment will occur.
	Disconnect the power cord and cables when moving the unit. Moving the unit with the power cord or cables attached is dangerous and may result in injury.

8 Maintenance and disposal

Periodically this equipment and any applicable accessories should be inspected for operation and safety.

Every six months the dust filters shall be cleaned (please refer to section 9.1).

A monthly physical inspection of the Module shall be performed in order to check:

- the power cord integrity;
- the video cable integrity;
- any obstruction to air vents.

NOTE	When disposing of this equipment or any of its components (such as fuses), follow all applicable national and local regulations and guidelines on waste of electrical and electronic equipment.
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8.1 Fuse replacement

Always use the fuses designated below. To order new fuses, please contact the support (section 11).

NOTE	The fuses replacement shall be performed only from authorized service personnel.
NOTE	Fuses identification: • Quantity: 2 • Type: F5AH250V • Dimensions: 5 mm x 20 mm
WARNING	Never use a fuse other than the fuse model reported above. Otherwise, malfunction or failure of the GI Genius™ Module, may cause a fire or electric shock hazard. Be sure to turn the GI Genius™ Module OFF and unplug the power cord before removing the fuses from the Module. Otherwise, fire or electric shock may result. If the power fails to come on after replacing the fuses, unplug the power cord immediately from mains power inlet and then contact support (section 11). Otherwise, electric shock may result.

Follow the instructions below for the fuses replacement (see Figure 5):

- Turn the GI Genius™ Module OFF and disconnect the power cord;
- Pull the fuse box straight out (step A), then rotate it down (step B);
- Remove the fuses by pulling them upwards (step C) and replace them (step D);
- Rotate the fuse box upwards (step E) and insert it inwards until the end of stroke (step F);
- Plug the power cord and turn the GI Genius™ Module ON and confirm the power output.

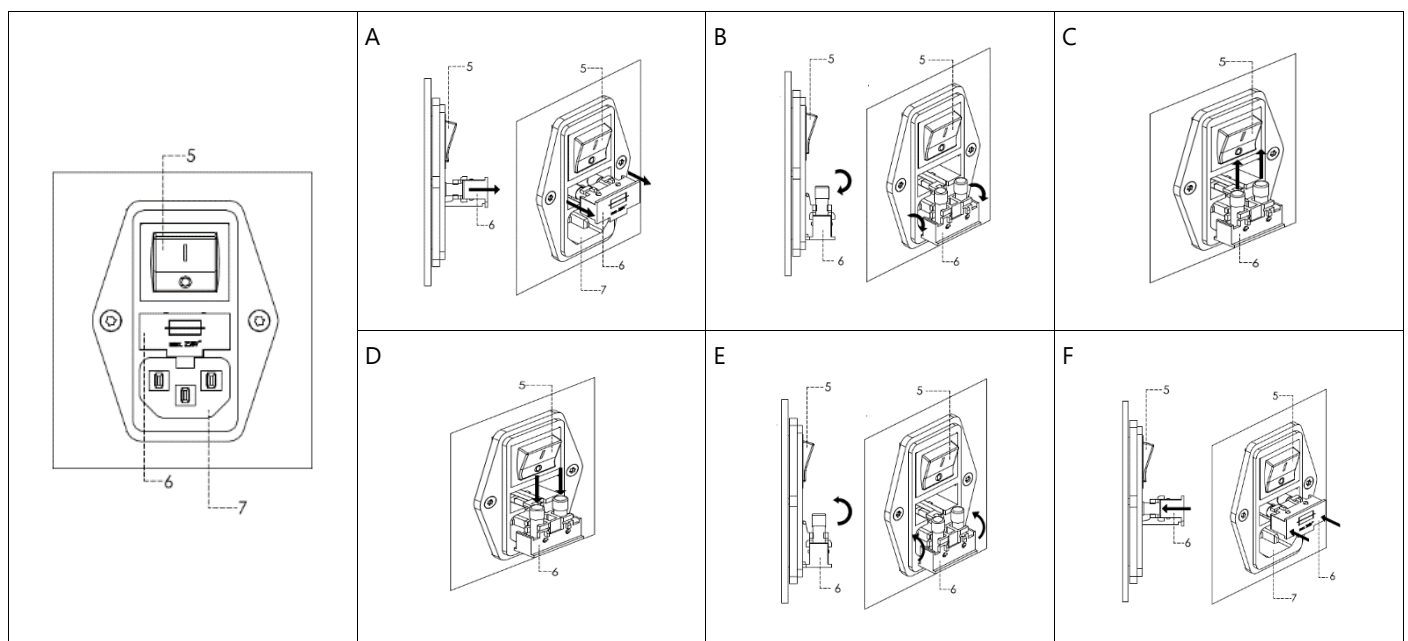


Figure 5: Fuse replacement

9 Cleaning

The device does not require regular cleaning, but may be cleaned if dirt/dust has accumulated on visible panels. Before cleaning, ensure the device is switched off and disconnected from mains power. Wipe clean the front, sides and top of the device with a soft gauze slightly dampened with water and/or a neutral detergent. The power cord and video cable may also be cleaned with a soft gauze slightly dampened with water and/or a neutral detergent. Ensure all surfaces are dry before reconnecting to mains power.

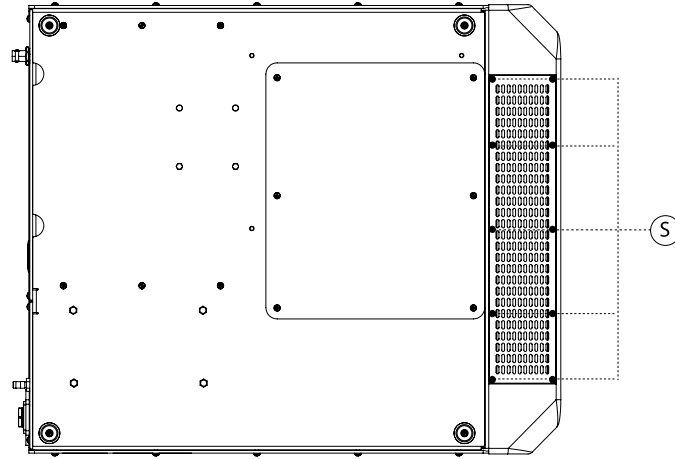


Figure 6: Dust filter screws

9.1 Cleaning of the dust filters

On the bottom side of device there are the dust filters (Figure 3) that shall be cleaned every six months from authorized service personnel (section 11) according the following instruction

1. Turn off the device and unplug the power cable and video cables;
2. Take off the device from the endoscopy cart;
3. Turn the Module upside down;
4. Remove the dust filter support unscrewing the screws S (Figure 6). Repeat this action for all Module dust filters;
5. Remove the filter. Repeat this action for all Module dust filters;
6. Clean the filters using a vacuum set on low power;
7. Place back the dust filter within its filter support screwing the screws S (Figure 6). Repeat this action for all Module dust filters.

10 Troubleshooting

Symptom	Possible Cause	Solution	Reference
Cannot turn on GI Genius™ Module	The power cord is not connected properly.	Securely connect the power cord to the power input.	section 4.5 section 4.6
	Hardware failure	Contact Support	section 11
Output does not appear on MED	A cable is not connected properly.	Connect all cables properly.	section 4.5
	Hardware and/or Software failure	Contact Support	section 11
The screen remains frozen	Hardware and/or Software problem	Immediately power off the GI Genius™ Module.	section 4.7
	A cable is not connected properly.	Connect all cables properly.	section 4.5
Black screen	Hardware and/or Software problem	Immediately power off the GI Genius™ Module.	section 4.6 section 4.7
	Hardware and/or Software failure	Contact Support	section 11

Symptom	Possible Cause	Solution	Reference
	Electromagnetic Disturbances	Reorienting or relocating this hardware or shielding the location.	section 7
Screen flickering	Electromagnetic Disturbances	Reorienting or relocating this hardware or shielding the location.	section 7

WARNING	If you discover any abnormalities (e.g. smoke, abnormal sounds or smell) turn off the power switch immediately, disconnect the power plug, then contact the help desk (section 11). Attempting to use a malfunctioning unit may result in fire, electric shock, or equipment damage.		
NOTE	For any other problem please contact the help desk as provided in section 11.		

11 Support

The helpdesk service provided to the users of the GI Genius™ Module is available at the following references:

Email address

serviceandrepair.uk@medtronic.com

gi-support@medtronic.com

NOTE	In the event that a serious incident has occurred related to device use, immediately report the event to the manufacturer, competent authorities, and any other regulators as required.
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