

1. Introduction

1.1. Safety Symbols

This manual uses the safety symbols below. They denote critical information. Please read them carefully.

DANGER	Imminently hazardous situation that will result in death or serious injury, if not avoided
WARNING	Potentially hazardous situation that could result in death or serious injury, if not avoided
CAUTION	Potentially hazardous situation that may result in minor or moderate injury, if not avoided. Can alert about unsafe practices or potential equipment damage
NOTE	Useful information

1.2. Term and abbreviation

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

Term	Description
MED	Main Endoscopy Display

1.3. Document purpose

This document contains essential information on using the Footswitch in a safe and effective way. Please carefully read this manual and all the equipment manuals involved in the procedure and use the equipment as instructed.

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

This document does not contain any information on how to perform endoscopy procedures, please refer to the related 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 7).

1.4. Intended use

The Footswitch is intended to be used by trained clinicians as an accessory to GI Genius™ for the purpose of enabling and disabling the GI Genius™ overlay over Main Endoscopy display (MED).

1.5. Device description

The Footswitch is made of a pedal with a shield that must be connected to the GI Genius™ hardware via the USB K-switch. (Figure 3);

For each press made by the user foot, the Footswitch sends a switch command to the GI Genius™ hardware through the USB K-switch. The switching command corresponds to the function of the GI Genius™ hardware of switching ON/OFF the software AI of GI Genius™.

This means that the operator can temporarily halt or restore the GI Genius™ software while in the course of a procedure.

The same functionality is already present on the front panel of the GI Genius hardware with a press button, thus the Footswitch offers an alternative means of using the same functionality.



Figure 1 : Footswitch general overview

DANGER	Do not use this Footswitch for any purpose other than its intended use.
DANGER	The Footswitch does not perform any diagnosis.

The Footswitch is compliant with IEC/EN 60601-1 and IEC/EN 60601-1-2 . This allows the device to be placed in the patient area and to be safely connected to the USB K-switch and the GI Genius™ hardware.

1.6. Intended users

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

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

1.7. Symbols and marking

Legal Manufacturer	Humidity limitation
Date of manufacture	Temperature limits
Do not dispose of the product as normal waste. This is product is subject to Directive 2012/19/EU (WEEE). Follow your local regulations on handling of waste electrical and electronic equipment	Atmospheric Pressure limitation
Consult the instruction for use	MD This product is a medical device
CE The product is a class I medical device in compliance with the European Regulation (EU) 2017/745	SN Serial Number of the device
Rx ONLY The device is restricted to professional use only	REF Catalogue number of the device
Keep Dry	Do not use if package is damaged.
Handle with care	Keep away from sunlight
Fragile, handle with care	Caution
UDI Unique Device Identifier	Refer to instruction manual/ booklet (Blue)

2. Information for safe use

2.1. Footswitch compatibility

The Footswitch is intended to be an accessory to GI Genius™ and must be connected for such purpose to the USB K-switch. List of compatible devices.

Part #	Description
GG5100	GI Genius™ System 100
GG5200	GI Genius™ System 200
GGM100	GI Genius™ Module 100
GGM200	GI Genius™ Module 200
UKS01	USB K-switch

DANGER	Using incompatible equipment can result in patient injury or equipment damage. This makes impossible to obtain the expected functionality.
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2.2. Installation

DANGER	This device should NEVER be installed or used in areas where the device 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
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DANGER	This device should NEVER be installed or used in the presence of flammable or explosive gases or chemicals.
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2.3. Repairs and modification

Do not disassemble, modify or attempt to repair the Footswitch. Any attempt at such operations without the guidance and instructions of technical support will void any warranty of the product.

DANGER	Unproper Footswitch disassembly, modification or repair could result in risks for patients and operators.
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2.3.1. Modification of the setup

DANGER	Setup of the endoscopy column requires technical knowledge on safety aspects, like electrical safety, and operability aspects of the devices, like electromagnetic interferences. Do not attempt to change the setup yourself, but contact the technical department of your Organization or personnel qualified by Linkverse, otherwise injury to patient, operator, or equipment could occur.
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2.4. Electrical risks

Following precautions must be strictly observed. Failure to do so may cause danger of electric shock for patient and medical personnel.

DANGER	Keep fluids away from the Footswitch. If fluids are spilled on or into the Footswitch, immediately stop any operation of the system and contact Support (see section 7).
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	Do not use the Footswitch when not properly closed or if visually damaged. Do not touch electrical contacts inside any component of the Footswitch.
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2.5. Fire or explosion risks

In order to prevent fire and explosion, do not expose the Footswitch where.

DANGER	there is a high concentration of oxygen.
	air contains oxidizing agents (e.g. N ₂ O).
	air contains any flammable gases.
	there are flammable liquids nearby.

2.6. Interferences

WARNING	When connected to the USB K-switch and the GI Genius™ hardware, the Footswitch may interfere with other equipment. Please refer to section 2.1 for further information.
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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 mobile phones. If radio interference should occur, mitigation measures may be necessary, such as reorienting or relocating this instrument or shielding the location. Do not use the Footswitch and its cable closer than 30 cm (12 inches) to the equipment with the following symbol: 
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2.7. Electromagnetic fields

WARNING	Do not use the Footswitch where there is a strong electromagnetic field (e.g. Magnetic Resonance, wireless devices, microwaves emitting devices, etc.).
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2.8. Mechanical forces

CAUTION	While pressing the Footswitch, do not apply excessive force otherwise damage to the equipment will occur.
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2.8.1. Trip risk

CAUTION	Pay attention to the position on the floor of the Footswitch and its cord, you may trip and fall
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2.9. Connection and disconnection

CAUTION	Do not connect/disconnect the Footswitch cable when the GI Genius™ is powered ON, otherwise damage to the equipment will occur.
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2.10. Footswitch package content

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
FS01	Footswitch
FS-MN-01	Footswitch User Manual

WARNING

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

3. Operating the Footswitch

3.1. Installation

The Footswitch is intended to be used connected to the USB K-switch and the GI Genius™ System.

- Connect Footswitch , USB K-switch and GI Genius™ device.
- Connect the USB cable of USB K-switch with the USB port of GI Genius™ (Figure 2).
- Connect the USB K-switch to the Footswitch
- Connect the Footswitch cable with the jack of the USB K-switch (Figure 3).



Figure 2: USB K-Switch with GI Genius

3.2. Functioning test

Once the devices are correctly connected, follow the steps below in order to verify that the system works correctly:

- Verify that the GI Genius™ system is activated and is fully functional: blinking green indicator is shown over the MED;
- Press the Footswitch to disable the GI Genius™ overlay: solid gray strikethrough indicator is shown over the MED;
- Press again the Footswitch to enable again the GI Genius™ overlay: blinking green indicator is shown over the MED;

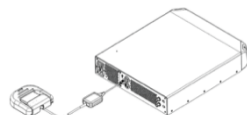


Figure 3: Connection between the Footswitch, the USB K-switch, and the GI Genius™ hardware

4. Technical specifications

Operation environment	The Footswitch shall be operating under the following conditions: +(-10 ÷ 40) °C - (50 ÷ 104) °F +20 ÷ 90% humidity (non-condensing) +75,3 kPa ÷ 101,3 kPa
Storage and transport environment	The Footswitch 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
Power specification	Supply voltages: 25 VAC - 60 VDC

5. Maintenance and disposal

Check periodically by visual inspection if the device shows any sign of damage. A damage could lead to the device malfunctioning.

NOTE	When disposing of this product, follow all applicable national and local regulations on waste of electrical and electronic equipment.
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6. Cleaning

Before cleaning, always ensure that the device is disconnected from the USB K-switch and that the GI Genius™ hardware is switched OFF.


To avoid impaired functionality caused by soiling, including microbial contamination, the Footswitch shall be cleaned after every clinical session. When using cleaning agents, adhere to general safety guidelines according to personal security. Observe the specific safety measures of the cleaning agent manufacturers at all times.

NOTE	When cleaning the Footswitch, use only water and cloth rag dampened with a mild cleanser.
NOTE	Do not use cleaning agents which may damage the plastic surfaces, such as detergents, abrasive cleansers or solvent-based cleansers (such as benzene, stain remover).

Ensure all surfaces are dry before reconnecting to the USB K-switch. Only clean manually.

7. Support

The helpdesk service provided to users of the Footswitch is available at the following references:

Email address	sts@cosmopharma.com
NOTE	In the event that a serious incident has occurred related to the device use, immediately report the event to the manufacturer, competent authorities, and any other regulators as required.
	Linkverse s.r.l., Via Ostiense 131/L, 00154 Rome, Italy