



GEIS®

General Examination Camera

## USER MANUAL

Connecting patients with doctors  
using quality images





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## STANDARD SYSTEM CONTENTS

GEIS System (System Part Number <b>VFGEISKIT2.04 and UDI 09352527000782</b> ) <u>includes items below:</u>	Part Number UDI	Quantity
GEIS (General Examination Imaging System) General Examination Camera base unit	VFGEISCAM 09352527000775	1
1.5m cable with USB 2.0 Type A connector	VFGEISCABLE1	1
Docking Station (Desk or Wall mounting)	VFGEISDOCK1	1
Derma Hood	VFGEISDRMH1	1
GEIS 20 cm Reference Stick	VFGRS2	1
Tongue Depressor Adapter	VFGEISTDA1	1
Wooden tongue depressors	GETD0001	10
GEIS User Manual	VFGEISMAN1	1
GEIS Derma hood Cap	VFGHC2	10
<b>GEIS Cardboard Flip Box</b>	<b>GELB0007</b>	<b>1</b>

GEIS System (System Part Number <b>VFGEISKIT1.04 and UDI 09352527000799)</b> <u>includes items below:</u>	Part Number UDI	Quantity
GEIS (General Examination System) General Examination Camera base unit	VFGEISCAM 09352527000775	1
1.5m cable with USB 2.0 Type A connector	VFGEISCABLE1	1
Docking Station (Desk or Wall mounting)	VFGEISDOCK1	1
Derma Hood	VFGEISDRMH1	1
GEIS 20 cm Reference Stick	VFGRS2	1
Tongue Depressor Adapter	VFGEISTDA1	1
Wooden tongue depressors	GETD0001	10
GEIS User Manual	VFGEISMAN1	1
GEIS Derma hood Cap	VFGHC2	10

GEIS Aluminium Case	VFGEISCASE1	1
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**OPTIONAL ACCESSORIES:**

Metal Carry Case	VFGEISCASE1
GEIS Cable 4m	VFGEISCABLE2
GEIS Reference Stick Sleeves (50 Pack)	VFGRS-SLV2
Wooden tongue depressors (100 Pack)	GETD0002
GEIS 20 cm Reference Stick (2 Pack)	VFGRS2
GEIS Derma hood Cap (50 Pack)	VFGHC1

The carry case has a custom foam insert for the secure storage of the all the components and elastic straps in the lid section to keep this GEIS User Manual.

**PRODUCT DESCRIPTION**

The GEIS General Exam Camera, is a high quality, high resolution imaging device that can be easily installed and operated from any computer capable of displaying Universal Video Class (UVC) imaging device outputs.

The GEIS General Examination Camera handpiece design is ergonomic and lightweight, enabling single-handed use.

A clever clip-on **tongue depressor adapter**, which holds various size wooden tongue depressors, is included and designed for use in situations where clinicians wish to



take an image of the patient's mouth or throat.

The clip-on **Derma Hood** enables regular skin checks to be performed with ease, giving a repeatable representation of skin colour due to the exclusion of external light and use of the built-in white LED illumination.



The camera may be conveniently placed on the desk or wall mounted docking station which features an automatic standby function, switching off the white LEDs and Video output. This enables the GEIS to be ready in seconds to examine the next patient when lifted.

The GEIS **Derma Hood Cap** is a single use dermatology hood clip-on plastic cap with mm scale, it has been designed to ensure there is no contact between the device and the patient skin. The scale assists the clinician to understand the extent of the affected area.



The GEIS **20 cm Reference Stick** includes a 40 mm scale to help the clinician understand the dimensions of the affected area.



## BASIC SAFETY INSTRUCTIONS

Users must read through these instructions for use and observe the warnings indicated. The device must be operated only in a fault free condition in accordance with its intended use and the instructions for use.

Before each use, check that the device and accessories to be used are free of damage and in full working order.

Storage of the camera and camera accessories in the supplied carry case will protect the parts from accidental damage. Keep the original packaging. Transport the device in its original packaging and use it to return goods if service support is required.

If users detect any faults or malfunctions, Visionflex must be informed immediately.



**WARNING:** Do not make any unauthorised modifications to the device. Risk of serious injury to persons.



**WARNING:** Operating the device in an open condition. Risk of electric shock. Do not open the device. Operate only when closed.



**WARNING:** Risk from the arrangement, setup, combination or properties of connected or surrounding devices or equipment. Follow the instructions for use of the respective devices. Check devices for compliance with IEC 60950-1 electrical safety standard before connecting.



**WARNING:** Improper handling, maintenance and use carries a risk to the patient, user and other persons, or can lead to premature wearing of the device.





**WARNING: This device is not sterile.** This camera and the camera cable are not autoclavable



**WARNING:** Not intended for optical examinations. Do not directly or indirectly point light source towards the eye.



**WARNING:** This device is IP54 rated. Never dip the device into liquids.

**WARNING:** This device is not for use in oxygen enriched atmospheres. Do not use near flammable substances.



**CAUTION:** Handle the device with appropriate care. Do not kink, crush or sharply bend the camera cable. If the device is dropped or subject to high mechanical stress, stop using it and send it to the manufacturer for inspection.



**CAUTION:** Place the camera in its docking station when not in use to activate standby mode and prevent the device from becoming warm.



**CAUTION:** For connection to non-medical devices, check devices for compliance with electrical safety standard IEC 60950-1 before connecting.



**CAUTION:** For connection to electrical medical devices, check compliance with electrical safety standard IEC 60601-1 before connecting.



**CAUTION:** Incorrect fitting of the tongue depressor adapter may render it a choking hazard. Ensure tongue depressor adapter is fitted correctly.

## INTENDED USE AND INDICATIONS FOR USE

The GEIS General Examination Camera is a non-invasive medical grade camera for the general visualisation of the patient, including skin colour and the oral cavity.

### Note:

The GEIS General Examination Camera is intended for general external examination use and not intended for internal use or for optical examinations.

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## 1.1 INTENDED USERS

These instructions for use are intended for physicians and medical assistants who are entrusted with the installation and operation of the device. The user should be familiar with computer-based equipment.

## INSTALLATION AND OPERATION

Users must ensure familiarity with all cautions and warnings prior to installation and operation of the GEIS General Examination Camera.

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## 1.2 CONNECTION OF THE USB CABLE

Using the supplied USB cable, proceed as follows:

- Remove the cable from the metal carry case. Connect the round 10-pin connector to the rear of the GEIS General Examination Camera (Note: there is a locating key-way at the top of the plug to match the socket on the rear of the camera body)
- Ensure that the black USB plug is securely connected to a suitable PC or Medical device USB 2.0 compatible socket and that the same PC or medical device is correctly connected to its electrical power source. Start the image/video capture program (not supplied with GEIS system). Select the camera identified as: VF GEIS HD from the list of devices and continue with the video streaming or picture capture process.
- It is assumed that any device that this GEIS General Examination Camera is connected to complies with local/international electrical standards for IT devices.
- Always consider the USB cable as a potential trip-hazard. Ensure that this cable is carefully routed to reduce risk.



**(1) Image capture button.** Press and release to capture the image in view. An image can be captured approximately every 2 seconds. To disable vibration, hold it down for approximately 5 seconds until you feel a double vibration (the GEIS will capture an image and beep but continue to hold until you feel the double vibrate alert). This will then disable the vibrate feature until the same procedure is done or you disconnect the USB connector (or press and hold the two brightness (4) and (5) buttons to force a camera re-start).

**(2) and (3) Manual focus control,** which deactivates auto-focus mode. Press and hold button 2 or 3 until there is a “beep” and a vibration to enable “focus-to-end” feature. The camera will then automatically focus approximately 10 steps to either the closest or furthest end-points. This can be useful for focusing quickly to either limit in manual mode.

**(4) and (5) Brightness control.** The GEIS has four levels of LED image illumination: High, Medium, Low & Off. To activate auto-focus when manual mode is enabled, hold (4) and (5) simultaneously for about 2 seconds.

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## 1.4 CAPTURING STILL IMAGES, STREAMING AND RECORDING LIVE VIDEO

To capture still images and record video:

***Images:*** Press the image capture button on the GEIS keypad to capture a still image (if your software permits). Otherwise use the photo/image capture or “still feature” in your software using the on-screen controls.

***Recording:*** As the GEIS General Examination Camera outputs a live video stream in HD (1080p) and provided that your video software supports this feature, you may start/stop recording the live stream at any time. In many cases, your software will permit you to record this video stream into your device for later use.

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## 1.5 USING THE DOCKING STATION

It is recommended that the GEIS General Examination Camera is used for short periods (less than 15 minutes continuously) and placed in the docking station when not in use.

The docking station may be wall-mounted.

When the GEIS General Examination Camera is not in use, clip it into the docking station to switch-off the front white LED illumination, video output and put the device into standby mode to save power.



To remove the GEIS from the docking station, move it in a forward and upward direction.



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## 1.6 CONNECTING THE DERMA HOOD



Using the supplied derma-hood, proceed as follows:

- Hold the GEIS General Examination Camera body in your hand
- Clip the derma-hood onto the front white section of the GEIS – it will click into position (removal is achieved by gentle pulling)
- Hold the front surface of the derma-hood on the patient's skin blocking out external light (this provides a repeatable light source colour/brightness to give consistent images). Continue with video streaming/image capture

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## 1.7 CONNECTING THE TONGUE DEPRESSOR ADAPTER



Use the tongue depressor adapter & standard wooden tongue depressor as supplied.  
Proceed as follows:

- Take the supplied standard disposable wooden tongue depressor and fit it to the slot provided underneath the grey tongue depressor adaptor. Hold the GEIS General Examination Camera body in your hand.
- Clip the grey tongue depressor adaptor onto the front white section of the GEIS – it will easily click into position. Continue and examine the patient.

Once the examination is complete, pull the wooden disposable part off the GEIS tongue depressor adaptor and dispose of this in accordance with your local regulations/requirements.

## CLEANING AND DISINFECTION



**WARNING:** The GEIS Unit should be disconnected from its power supply during cleaning.

All exterior surfaces of the GEIS can be wiped with:

- Clinell Universal Wipes,
- a soft, lint-free dry cloth,
- a soft cloth moistened with a small amount of ethanol ( $C_2H_6O$ ) or isopropyl alcohol ( $C_3H_8O$ ) when required for infection control.

Do NOT use other cleaners or solvents, they could damage the paint, labels or the GEIS seals/connector. Do not use wet sponges or cloths since this could lead to liquid-ingress and reach the electrical parts which could lead to injury and cause damage to the device.

Only connect the USB cable after all cleaned parts are totally dry.

## MAINTENANCE

The GEIS system has no user replaceable internal serviceable parts. If for any reason the GEIS device fails, please contact Technical Support (see Section 0)

### 1.8 ELECTROMAGNETIC COMPATIBILITY

Medical electrical equipment is subject to stringent electromagnetic compatibility (EMC) requirements.

Despite the devices high interference immunity and low emitted interferences, compliance with EMC related requirements is necessary with regards to installation, installation location and ambient conditions. It is therefore important that users observe the related safety messages in this document.

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### 1.9 COMPATIBILITY WITH OTHER MEDICAL / ELECTRICAL EQUIPMENT

The device can be combined with other manufacturers' devices provided that those devices are compliant with one of the following standards:

- EN IEC 60601-1 (Medical Electrical Equipment)
- EN IEC 60950-1 (Other Electrical Equipment)

It is the user's responsibility to check and ensure that the system is and remains fully operational.

When using devices from different manufacturers and when operating an endoscope and/or endoscopic accessories with electrical medical devices, it must be ensured that the applied part is properly isolated (in accordance with the requirements for BF/CF applied parts defined in IEC 60601-1).

Users can contact Visionflex's service department if they have questions about compatibility with other equipment (see Section 0).

## 1.10 TECHNICAL SPECIFICATIONS

<b>Mechanical Features</b>	
Length of housing (GEIS body only)	136mm
Max. diameter (GEIS body only)	37mm
GEIS General Examination Camera weight (body only)	88g
GEIS weight with cable	150g
Cable length	1.5m
IP rating	IP54
<b>Electrical features</b>	
Supply voltage	DC 5v 500mA, from USB 2.0 compliant source
Max. power consumption	Less than 3W (nominally 2.1W)
Image sensor	1/4" CCIQ III Digital QSXGA CMOS
Pixels	5.0 Mega Pixels, pixel size= 1.4um x 1.4um
Video output resolution	FHD 1920x1080p30
Signal output digital video	Output UVC (Universal Video Class) USB 2.0, format=MJPEG
Illumination output	8 x White LEDs (5700K colour temperature), 4 output levels
<b>Optical features</b>	
Lens	3.87mm / F2.8
Target distance min	5cm
Object distance max	3m approximately
<b>Temperature features</b>	
Unit operating temperature range	+5C to +30C (with internal sensing and auto-cool down)
Unit operating relative humidity range	15 % to 90 %, non-condensing, atmospheric pressure range of 700 hPa to 1060 hPa
Storage temperature range	0 to +60C
Unit storage relative humidity	up to 90 %, non-condensing, atmospheric pressure range of 700 hPa to 1060 hPa
<b>Relevant Standards</b>	
EN ISO 13485:2016/AC:2016	Medical devices – Quality Management System Requirements for Regulatory Purposes



EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance Ed. 3.1 Type BF Applied Part 2 MOPPs
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability Ed 3.1
EN 62366:2008	Medical devices – Part 1: Application of usability engineering to medical devices
EN ISO 15223-1 :2017-04/ 15223-1 :2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied part 1 General Requirements
EN 1041:2008	Information Supplied by the Manufacturer of Medical Devices

## TROUBLESHOOTING

Problem	Possible cause	Solution
No Picture	Chosen software not working or GEIS General Examination Camera not detected	<ul style="list-style-type: none"> <li>*Try disconnecting the GEIS USB cable from the PC/Medical Device. Re-load/restart the chosen compatible software and re-connect the USB cable. Test another camera input device to ensure software works.</li> <li>*Inspect GEIS General Examination Camera body and USB cable for damage.</li> <li>*Call Technical support.</li> </ul>
GEIS buttons are not illuminated with a blue backlight	Cable failure or USB connection on PC/Medical device faulty	<ul style="list-style-type: none"> <li>*Try another USB connection on PC/Medical Device.</li> <li>*Try another PC/Medical Device.</li> <li>*Swap GEIS USB cable.</li> <li>*Call Technical support.</li> </ul>

White LED front illumination dim/off	Brightness level set too low.	Provided you have an image on the PC/Medical Device using your compatible software, adjust the brightness buttons on the GEIS keypad. *Call Technical support.
GEIS General Examination Camera picture out of focus or auto-focus “hunting”	Too close or distant from target or target is moving. Range 5cm to 3m approx.	*Reposition target image within range. *Try the manual focus by pressing the < or > buttons on the GEIS keypad. This will override the auto-focus function until you disconnect the USB plug or force a reset by pressing and holding the two brightness buttons simultaneously. *Inspect GEIS General Examination Camera body and USB cable for damage. *Call Technical support.
GEIS General Examination Camera will not start operating – Blue backlight illumination is ON.	GEIS requires a USB 2.0 compliant connection on a PC/Medical Device. Possible poor output levels from this USB connector.	* Remove GEIS General Examination Camera from Docking Station. *Try another USB connection on PC/Medical Device. * Re-load/restart the chosen compatible software and re-connect the USB cable. *Inspect GEIS General Examination Camera body and USB cable for damage. *Call Technical support.
GEIS keypad Blue backlight illumination flashing	GEIS General Examination Camera body is too warm.	*Place GEIS in docking cradle for 10 minutes or until Blue flashing stops and continue use. *Disconnect USB cable from PC/Medical Device for 5 minutes to cool down.
GEIS General Examination Camera will not switch off video feed and white LED backlight when placed in the docking station.	Damage to GEIS General Examination Camera or metal docking station.	*Inspect GEIS General Examination Camera body and USB cable for damage. *If possible, try another GEIS docking station. *Call Technical support.

## TECHNICAL SUPPORT AND REPAIR

Should you need to arrange technical support or a repair for the device, please visit [www.visionflex.com.au](http://www.visionflex.com.au) or call +61 2 8914 4000 (from outside Australia).

**NOTE:** For a fast processing of your service requests, please return the product with the following information:

**Return authorisation number, model, serial number & detailed description of the problem.**

**NOTE:** the serial number can be found on the GEIS General Examination Camera's underside towards the rear connector.

Guarantee and warranty claims will not be accepted if the user or a non-authorized repair centre effects maintenance or repair on its own.



**WARNING:** For the protection of your staff as well as the staff at the repair centre, thoroughly clean and disinfect the product before shipment. The repair centre can refuse the repair of contaminated product due to safety reasons.

## WARRANTY

Visionflex commits to a 12 month 'Back to Base' (Return to Supplier) warranty on the functionality of the GEIS General Examination Camera . This warranty is restricted to claims presented within the warranty period starting from the invoiced date of purchase of the GEIS General Examination Camera . Details about the fault/repair is required along with the original purchase invoice number.

This guarantee is only applicable to defects that cannot be attributed to normal wear and tear, misuse or incorrect handling, lack of proper care or Acts of God.

## DISPOSAL

When disposing of or recycling the device and its components, you must adhere to the applicable national regulations governing waste disposal and recycling in your region.



Any device carrying this symbol must be disposed of separately through dedicated electrical and electronic devices recycling. Within the EU, such disposal is taken care of by the manufacturer, free of charge.

## INFORMATION ABOUT THIS DOCUMENT

The User Manual applies to the following device:













Description: GEIS General Exam Camera

These instructions for use are an integral component of the device and contain all the information required by users for safe and proper use.

These instructions for use must be stored in a defined logical location so that they may be accessed at all times by the intended users.

In the event of the sale of the device or its relocation, this document must be handed over to the new owner.

## KEY TO SYMBOLS

Symbol	Title
	<b>WARNING:</b> Indicates the need for the user to consult the user manual for important warnings that cannot be presented on the medical device itself.
	<b>CAUTION:</b> Indicates the need for the user to consult the user manual for important cautionary information that cannot be presented on the medical device itself.
	Refer to user manual (this document) Note: On ME Equipment “Follow instructions for use”
	Type BF Applied Part
	Manufacturer
	Date of manufacture
	Authorised Representative
	Item number
	Serial number
	Separate collection for WEEE (waste of electrical and electronic equipment)
	Packaging widely recycled - The universal recycling symbol (U+2672 ♻️ UNIVERSAL RECYCLING SYMBOL in Unicode) is internationally recognized for recycling activity
	Medical Device



CE mark. The device satisfies the requirement of the MDR 2017/745

## Notes:




**MD**

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Equality healthcare

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