



VestibularFirst

Insight Infrared Video Goggles
Insight Infrared Video Goggles Pro
Supplemental for USB-C Cable

Thank you for investing in quality care for vestibular patient care and education by adding Insight Infrared Video Goggles to your practice. This user manual will cover contraindications, safety warnings, cautions, recommendations for use, storage, care of the goggles, and contact information for the manufacturer. If you have questions, please reach out to our team:

- Visit us online at **VestibularFirst.com/Support**
- Email us at **Support@VestibularFirst.com**
- Call us at **+1-215-667-8990**

Federal law restricts the sale, distribution or use of the system to, by, or on the order of a licensed medical practitioner.



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1. Introduction

1.1. CONTACT INFORMATION

This supplemental guide is valid for the Insight Infrared Video Goggles & Insight Infrared Video Goggles Pro.

The manufacturer Vestibular First is located at:

**9 Mather Ave
Broomall, PA, 19008
United States**

They can be contacted at:

Online: **VestibularFirst.com/support**

Email : **support@vestibularfirst.com**

Phone: **+1-215-667-8990**

The country of origin is the United States of America.

1.2. INDICATIONS OF USE

The Insight Infrared Video Goggles are intended for viewing and recording eye movements in support of identifying vestibular disorders in patients. The device is intended for use only by a trained healthcare professional in an appropriate healthcare setting. This device provides no diagnoses nor does it provide diagnostic recommendations. The target population is 12+ years of age.

1.3. PRODUCT DESCRIPTION

The system consists of head-mounted goggles made up of modular units including a body unit, removable front cover (camera unit), two infrared video cameras inside the camera unit, a detachable USB-C cable, and an off-the-shelf (OTS) video viewing software application running on a clinician-supplied computer. The Insight Infrared Video goggles are designed to be used by clinicians to visualize and record eye movements with and without fixation. These goggles can be used wherever a clinician may need to examine a patient, including but not limited to hospitals, rehab facilities, outpatient clinics, urgent care centers, and patients' home environments. The goggles are placed on the patient's head with the cameras facing the patient's eyes. The cameras illuminate with infrared light and then transmit a video signal of the eye movements to the computer screen for display. The computer uses an off-the-shelf video software called Open Broadcaster Software (OBS), which allows for viewing and recording.



1.4. SAFETY CLASSIFICATION AND REGULATIONS

SAFETY CLASSIFICATION

- **Protection against electric shock:** Determined by the electric shock protection type of the computer connected to the USB
- **Classification of applied part:** Type BF applied part (cushion)
- **Method(s) of sterilization:** No requirement for sterilization
- **Protection against harmful ingress of water or particulate matter:** IP20
- **Mode of operation:** Continuous
- **Suitable for use in an oxygen rich environment:** No

STANDARDS

The Insight Video Goggles complies with the following standards:

- IEC 60601-1: Medical Electrical Equipment. Part 1: General requirements for safety
- IEC 60601-1-2: Medical Electrical Equipment. Part 2: Electrical Safety
- IEC 62471-1: Photobiological safety of lamps and lamp systems
- ISO 10993-1: Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process. (Biocompatibility)
- ISO 10993-10: Biological evaluation of medical devices - part 10: tests for irritation and skin sensitization
- ISO 10993-5: Biological evaluation of medical devices - part 5: tests for in vitro cytotoxicity

External equipment intended for connection to USB complies with the applicable standards of the IEC 60601 series. In addition, all such combinations of systems comply with the IEC 60601-1 safety requirements for medical electrical systems. Any person who connects external equipment to USB has formed a system and is therefore responsible for the system to comply with the requirements of IEC 60601-1. If in doubt, contact a qualified technician or the manufacturer's representative.



ELECTROMAGNETIC COMPATIBILITY (EMC)

Guidance and manufacturer's declaration - electromagnetic emission - for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer's declaration - electromagnetic emission		
The model Insight Infrared Video Goggles is intended for use in the electromagnetic environment specified below. The customer or the user of the model Insight Infrared Video Goggles should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Model Insight Infrared Video Goggles uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Model Insight Infrared Video Goggles 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.



Guidance and manufacturer's declaration - electromagnetic immunity - for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration - electromagnetic immunity			
The Model Insight Infrared Video Goggles are intended for use in the electromagnetic environment specified below. The customer or the user of the Model Insight Infrared Video Goggles should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 2 kV, ± 4 kV, ± 6 kV ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 2 kV, ± 4 kV, ± 6 kV ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Environmental conditions: Temperature: 23°C (Range: 15 °C to 35 °C) Humidity: 57% (Range: 30 % to 60 %) Atmospheric pressure: 101 kPa (Range: 86 kPa to 106 kPa)
Radiated RF Immunity IEC 61000-4-3	10V/m at 80 – 1000 MHz & 1.0 – 2.7 GHz, both H&V Polarization	10V/m at 80 – 1000 MHz & 1.0 – 2.7 GHz, both H&V Polarization	
Electrostatic transient / burst IEC 61000-4-4	100 kHz repetition frequency ± 1 kV for input/output lines	100 kHz repetition frequency ± 1 kV for input/output lines	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz 30 A/m, 50/60Hz at X,Y,Z axis	30 A/m, 50/60Hz 30 A/m, 50/60Hz at X,Y,Z axis	



Guidance and MANUFACTURER'S declaration - electromagnetic IMMUNITY

Guidance and manufacturer's declaration - electromagnetic immunity			
The Insight Infrared Video Goggles is intended for use in the electromagnetic environment specified below. The customer or the user of the Insight Infrared Video Goggles should ensure that it is used in such an environment.			
Immunity test	IEC 61000 Test Level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms outside ISM bands (150 kHz to 80 MHz)	3 Vrms outside ISM bands (150 kHz to 80 MHz)	Temperature: 24C (Range: 15 °C to 35 °C) Humidity: 55% (Range: 30 % to 60 %) Atmospheric pressure: 101 kPa (Range: 86 kPa to 106 kPa)
	6 Vrms 150 kHz to 80 MHz	6 Vrms 150 kHz to 80 MHz	
<i>Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.</i>			
<i>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</i>			



Recommended separation distances between RF wireless communications equipment

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.

Frequency MHz	Modulation	Distance (m)	Test Level: IEC 61000-4-3:2006 +A1:2007 +A2:2010	Compliance Level	Electromagnetic Environment - Guidance
385	Pulse Modulation: 18 Hz	3	27	27	Temperature: 24C (Range: 15 °C to 35 °C) Humidity: 55% (Range: 30 % to 60 %) Atmospheric pressure: 101 kPa (Range: 86 kPa to 106 kPa)
450	FM + 5 Hz deviation: 1 kHz sine	3	28	28	
710	Pulse Modulation: 217 Hz	3	9	9	
745					
780					
780	Pulse Modulation: 18 Hz	3	28	28	
870					
930					
1720	Pulse Modulation: 217 Hz	3	28	28	
1845					
1970					
2450		3	28	28	
5240		3	9	9	
5500					
5785					

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



WARNINGS!

- The system components should not be used or interchanged with components from infrared video goggles that are not manufactured by Vestibular First, nor should the components be interchanged with versions of goggles that are not made to be compatible with the Insight Infrared Video Goggles.
- This device should not be used in the vicinity or on the top of other electronic equipment such as cell phone, transceiver or radio control products. If you have to do so, the device should be observed to verify normal operation.
- The use of accessories and power cord other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.



2. System Overview - Camera Unit

The **Camera Unit** as seen in **Figure 2-1**

has a primary role of securing two USB 2.0 cameras and connecting them to a computer. The camera unit shell is made of protective and durable PC + ABS plastic and includes two switches and three spring-activated buttons. The light switches turn on and off the visible light LEDs (one on the left, the other on the right) that are a part of each camera. The clinician can turn on each visible light switch to introduce light, which can assist the clinician in observing any differences in eye movements or appearance of the eye/pupil as compared to when each light is off.

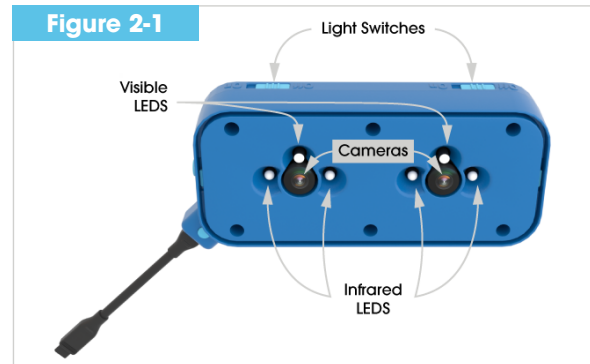
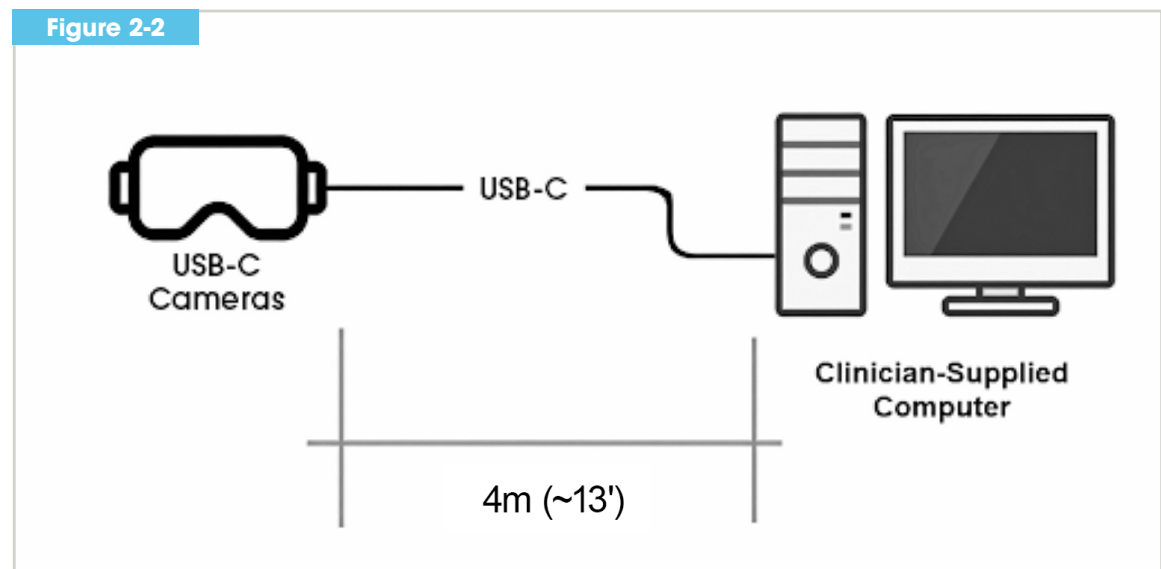


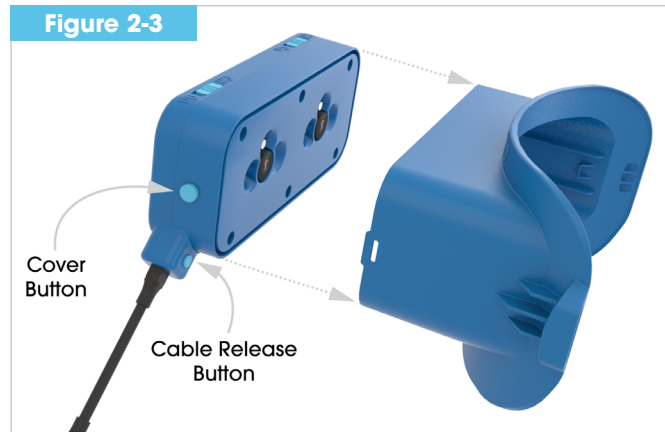
Figure 2-2 The cable that exits the camera unit is over 13 feet long. It is detachable and has a USB-C connector at each end. The clinician uses these to connect the goggles to a computer via a standard USB-C port so that video data can be sent from the cameras to the computer.

For the most current information, please visit our support page at:

<http://v1st.co/how-to>



The cover buttons as seen in **Figure 2-3** on the camera unit must be compressed on both sides in order to allow removal of the camera unit from the body unit. A clinician may want to remove the camera unit so that the patient is no longer in a darkened environment, giving them the opportunity to change positions safely for example. The cable release button on the camera unit is depressed to allow removal of the USB-C cable from the camera unit.



3. Using the Insight Infrared Video Goggles

3.1. INITIAL SETUP & CHECKS

Perform before each use of the goggles.

GOGGLES AND ROOM SAFETY INSPECTION:

1. Confirm the following on the Insight Infrared Video Goggles:
 - a. Goggles assessment – Visually inspect to confirm that there is no visible damage to the cushion, strap, body unit, camera unit, and cable. Do NOT use goggles if there is visible damage to any components. Contact support@vestibularfirst.com for next steps if damage present.
 - b. Cushion is firmly in place on body unit
 - c. There are no loose materials within the body unit
 - d. Plug one side of the USB-C connector into a USB-C port on a computer. Do not plug the Insight Infrared Video Goggles USB-C connector into any ports other than those on a laptop or personal computer.
 - e. Ensure that the other end of the USB-C cable is seated in the receptacle on the camera unit. If not already seated, insert the cable connector into the receptacle until you hear a click.
2. Arrange clinical space with the computer on a secure surface that is close enough to the exam table to avoid strain on the cable when the patient is wearing the goggles.
3. If using a laptop or tablet computer, confirm it is on a stable flat surface placed at a reasonable distance so that the cable will not receive any undue strain.
4. Clinicians should attend to the cable position to avoid catching the cable on objects in the environment, themselves, or the patient.



Insert the cable connector into the receptacle until you hear a click



3.2. CLEANING AND DISINFECTING THE GOGGLES

Goggles must be cleaned and disinfected **before** and **after** each patient use. Below are general guidelines and cleaning recommendations:

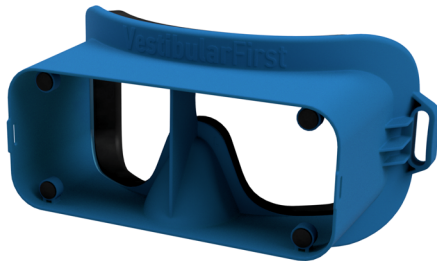
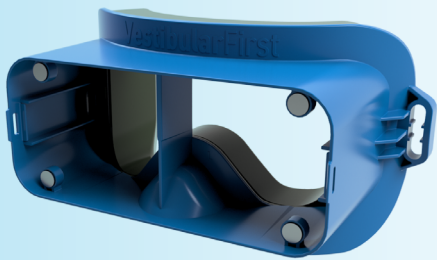
General Guidelines

- Wash your hands before and after handling any parts of the goggles.
- The instrument is not protected against harmful entry of water or other liquids. If any liquid enters the openings on the camera unit, check the instrument carefully before use, and if/when needed, contact the manufacturer for service.

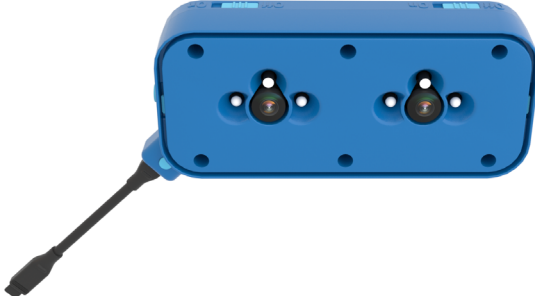
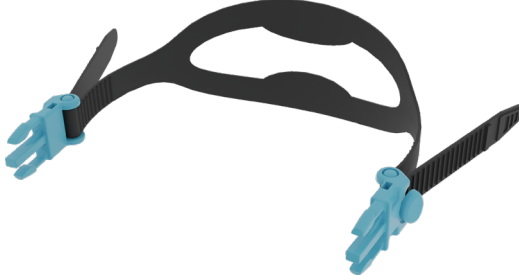
GOGGLES CLEANING AND DISINFECTING STEPS

1. Wipe down all parts of the goggles in Table 4.2.1 with 70% isopropyl alcohol solution (30% purified water). Ensure removal of any debris as well as thorough wiping to disinfect.
2. Ensure a contact/treatment time of 5 minutes, following the recommendation of the cleaning and disinfecting product used.

Table 4.2.1 - Goggles Parts to Clean

Part	Photo
Body Unit	
Pro Body Unit	



Part	Photo
Durable Cushion	
Camera Unit & Cable	
USB-C Cable	
Strap	



4. FREQUENTLY ASKED QUESTIONS & CONTACT INFORMATION

4.1. FREQUENTLY ASKED QUESTIONS

1. What if my computer does not have a USB-C port?

You can purchase a USB-C to USB-A converter (not provided or sold by Vestibular First).

2. Can I use non-Vestibular First USB-C cables that I purchase online or at an electronics store with my Insight goggles?

No, you must use a USB-C cable provided by Vestibular First. Replacement USB-C cables are available – contact support@vestibularfirst.com for any parts needed either under warranty or at reasonable cost if outside of warranty.

Also note that Insight goggles system components including USB-C cables should not be used or interchanged with components from infrared video goggles that are not manufactured by Vestibular First, nor should the components be interchanged with versions of goggles that are not made to be compatible with the USB-C receptacle version of the camera unit.

3. I have a version of the Insight goggles which does not have a removable USB-C cable. How can I get the USB-C version?

Please continue to use your current version of the cable on your Insight goggles as long as it is functioning well. If your current cable is damaged or stops working, contact Vestibular First at support@vestibularfirst.com for next steps on troubleshooting and repair if needed, including potential transition to the USB-C cable version.

4.2. CONTACT INFORMATION

You can contact our team for support through the following channels:

- Online: **VestibularFirst.com/support**
- Email : **Support@VestibularFirst.com**
- Phone: **+1-215-667-8990**

