



VestibularFirst

Insight Infrared Video Goggles
Insight Infrared Video Goggles Pro

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.



Table of Contents

1.	Introduction	3
1.1.	Contact Information	3
1.2.	Indications of Use.....	3
1.3.	Product Description	3
1.4.	Computer Requirements.....	5
1.5.	Safety Classification and Regulations.....	5
1.6.	Transport, Storage, and Use.....	12
1.7.	Contraindications, Warnings, Cautions, and Recommendations	13
1.8.	Markings and Storage	18
1.9.	Packaging inspection and shipping box	20
1.10.	Inspecting for and reporting damage to the goggles.....	20
2.	System Overview	21
2.1.	Modular Goggles.....	21
2.2.	Software	24
3.	Software Installation & Configuration.....	27
3.1.	Installation	27
3.2.	OBS Configuration	29
3.3.	Scene Collection Templates.....	34
4.	Using the Insight Infrared Video Goggles	35
4.1.	Initial Setup & Checks.....	35
4.2.	Cleaning the Goggles.....	38
4.3.	Considerations Prior to a Patient Donning Goggles	40
4.4.	Donning the Goggles.....	41
4.5.	Centering the Eyes.....	44
4.6.	Select Additional Scenes.....	45
4.7.	Starting & Stopping Video Recording	48
4.8.	How to Use the Visual Fixation Light.....	48
4.9.	How to Remove and Attach the Camera Unit.....	49
4.10.	Doffing the Goggles.....	51
4.11.	Accessing and viewing recorded videos	52
4.12.	Accessing and viewing recorded videos	52
4.13.	Cleaning and Storing Your Goggles	52
5.	Troubleshooting, Repair, and Warranty.....	53
5.1.	Goggles Troubleshooting	53
5.2.	Software Troubleshooting	56
5.3.	Warranty and Repairs.....	58
5.4.	Contact Information	58



1. Introduction

1.1. CONTACT INFORMATION

This manual is valid for the Insight Infrared Video Goggles.
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 a 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, cable with two USB connectors, 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 illuminated with infrared light transmits a video signal of the eye movements to the computer screen for display. The computer uses an off-the-shelf video software Open Broadcaster Software (OBS) to allow for viewing and recording.

INCLUDED PARTS

- Insight Infrared Video Goggles
- Travel Case
- Quick-Start Guide

The Insight Pro Infrared Video Goggles additionally include 3 disposable cushions. This manual includes information about the Insight Infrared Video Goggles and the Insight Pro Infrared Video Goggles. All information in this User Manual is applicable to both the Insight Infrared Video Goggles and the Insight Pro except where new information only relevant to the Pro is indicated by this blue box indicator:

PRO

OUR GOGGLES SUPPORT CLINICIANS PERFORMING THE FOLLOWING TESTS:

- Spontaneous Nystagmus
- Gaze-Evoked Nystagmus (Gaze Test)
- Horizontal Head Shake Test
- Vertical Head Shake Test
- Vibration Induced Nystagmus Test
- Hyperventilation Test
- Pressure (Fistula) Test
- Dix Hallpike Positional Test
- Roll Positional Test
- Side Lying Positional Test
- Pupillary Response to Light



1.4. COMPUTER REQUIREMENTS

MINIMUM HARDWARE REQUIREMENTS

- i5 processor or better
- Minimum 8 GB RAM or more
- Hard drive with minimum 64 GB free space
- Two (2) USB 2.0 ports are required or a USB hub can be used in a single USB 2.0 port for the system to perform as intended
- Minimum display of 800x600 (higher resolution recommended)
- Dedicated video card (optional, but strongly recommended)

OPERATING SYSTEM REQUIREMENTS

- **Microsoft** - Windows 10 or later
- **Apple** - MacOS 10.12 Sierra or later

1.5. 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 assure 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	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	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 assure 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	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated RF Immunity IEC 61000-4-3	10 V/m	10 V/m	N/A
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	N/A	N/A
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode line-line	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT (100 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25/30 cycles at 0°	N/A	N/A
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
<i>Note: UT is the a. c. mains voltage prior to application of the test level.</i>			



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 assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz outside ISM bands ^a	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Models Insight Infrared Video Goggles, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80\text{MHz to } 800\text{MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800\text{MHz to } 2.7\text{GHz}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	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 metres(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
<p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			



Guidance and manufacturer's declaration - electromagnetic immunity

a: The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b: The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Insight Infrared Video Goggles is used exceeds the applicable RF compliance level above, the Insight Infrared Video Goggles should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Insight Infrared Video Goggles.

d: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.



Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM

Recommended separation distances between portable and mobile RF communications equipment and the model Insight Infrared Video Goggles

The Model Insight Infrared Video Goggles is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model Insight Infrared Video Goggles can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model Insight Infrared Video Goggles as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}] \sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}] \sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}] \sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.12	0.23
1	1.17	0.35	0.7
10	3.7	1.11	2.22
100	11.7	3.5	7.0

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.


Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



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	Maximum Power W	Distance	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	<p>RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $E = \frac{6}{d} \sqrt{P}$ <p>Where P is the maximum output power rating of the ransmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, 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:</p> 
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					
780	2	0.3	28	28	
870					
930					
1720	2	0.3	28	28	
1845					
1970					
2450	2	0.3	28	28	
5240	0.2	0.3	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!

- 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.

1.6. TRANSPORT, STORAGE, AND USE

STORAGE AND TRANSPORTATION CONDITIONS

We recommend the followings storage and transportation conditions to maximize the life of the Insight Infrared Video Goggles

- Packaged equipment should be stored in a well-ventilated environment without corrosive gases.
- The equipment should be handled with care and kept away from rain and electrical shock during transportation.
- For short-distance handling, it is recommended that the Insight Infrared Video Goggles utilize the included case.
- For long-distance handling, it is recommended to be stored in a solid box with shock absorption and in a padded multi-layer corrugated box.

Below are the required operating conditions for transportation, storage, and use of the Insight Infrared Video Goggles. Usage outside of these ranges is not supported and can cause damage to the device.

	Temperature	Humidity	Atmosphere
Transport	-20° C - 50° C (-4° F - 122° F)	10% - 95% Non-Condensing, Keep Dry	80 kPa - 106 kPa
Storage	0°C - 50° C (32° F - 122° F)	30 - 80%	80 kPa - 106 kPa
Use	16° C - 29° C (60° F - 85° F)	30 - 80%	80 kPa - 106 kPa



1.7. CONTRAINDICATIONS, WARNINGS, CAUTIONS, AND RECOMMENDATIONS

CONTRAINDICATIONS

May be contraindicated in patients who exhibit a broken nose, recent face/head trauma or surgery, or recent eye surgery. Immediately stop using the goggles if the patient shows any signs of allergy to the materials that comprise the goggles. Please consult a specialist in such circumstances before using the mask and strap on these types of patients.

GENERAL WARNINGS

- Inspect goggles upon arrival for any visible damage that may have occurred during shipping. Do NOT use goggles if there is visible damage to the USB connectors, cable, body unit, camera unit shell, or electrical (camera/infrared light bulbs/visible light bulb) components.
- Before using the goggles on a patient, please follow the Initial Setup & Checks in Section 4.1 to confirm that the goggles, computer, and software are functioning properly.
- This device contains camera equipment. Please handle it with care and do not drop the device.
- No modification of this equipment is allowed without manufacturer authorization.
- 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.

CLINICAL SAFETY WARNINGS

- Insight Infrared Video Goggles are to be used by trained personnel only, such as audiologists, ENT doctors, physicians, vestibular rehabilitation specialists, or licensed healthcare personnel with a similar level of qualifications. The device should not be used without the necessary knowledge and training to understand its use and how results should be interpreted.
- Use with caution for patients with blindness, strabismus/amblyopia, active infections, and ptosis. Please consult a specialist in such circumstances before using the goggles and strap on these types of patients.
- Only use the goggles on intact skin.



- Do not use these goggles for tests that are not appropriate to the functionality of the device (example: this version of the device cannot be used to test vHIT).
- Attend to the position of the cable to avoid patient and clinician entanglement, adjusting the cable position as needed during position changes or movement.
- Do not leave the patient alone while goggles are in place.
- Guide the patient verbally, guard closely, and as needed physically assist them with any position changes while they are in the dark environment of the goggles.
- Keep your hands close to the goggles during patient position changes, particularly if the top of the patient's head is toward the ground, to ensure the goggles remain secure.
- Always clean the goggles before each patient use, following the recommendations for cleaning in **Section 4.2**.
- The instrument is not protected against harmful ingress of water or other liquids. If any spillage occurs check the instrument carefully before use and if needed contact the manufacturer for service.
- Please transport, store, and use the Insight Infrared Video Goggles within the temperature and humidity restrictions listed in **Section 1.6** Transport, Storage, and Use. The manufacturer is not responsible for any damages incurred to the device if these restrictions are not followed.

ELECTRICAL SAFETY WARNINGS

- Do not plug the Insight Infrared Video Goggles USB connectors into any ports other than those on a laptop or personal computer.
- Handle the goggles with care. Do not drop the components. Avoid other undue impacts to this device. If the system is damaged from being dropped or impacted, contact the manufacturer for repair. Do not use the system if any damage is suspected or if the system is showing visible damage. Contact the manufacturer immediately to inform them and to arrange for repair or replacement.
- If the camera unit or cable is damaged in such a way that electrical components are exposed, unplug the USB connectors from the computer or laptop. Wait at least 10 minutes before touching any damaged electrical parts. Use protective equipment and do not handle exposed wires, electrical components, camera chips, or light bulbs directly.
- Do not touch the camera chip if it becomes exposed. If it becomes exposed due to damage to the camera unit, disconnect the USB



cables and wait 10 minutes until handling the camera chip. Use protective equipment when handling the camera chip.

- The system must not be used in the presence of explosive or flammable gases.
- Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components.

CAUTIONS

- Proper use of this device depends on careful reading of this manual and all additional instructions and labels.
- Federal law restricts the sale, distribution or use of the system to, by, or on the order of a licensed medical practitioner.
- Allow the system to obtain room temperature before using the equipment. Any components that have been stored previously should be brought to room temperature before usage.
- Patients cannot use corrective eyeglasses when wearing the goggles, although corrective contact lenses can be worn.
- Patients should not wear makeup around the eyes.
- Clean the camera lenses in the camera unit according to the instructions in **Section 4.2**
- Manually adjusting any camera settings should be done under the guidance of the manufacturer. Any camera settings changed can be reset to defaults by disconnecting and then reconnecting the goggles' USB cables to the computer.

CYBERSECURITY RECOMMENDATIONS

Cybersecurity is important to manage when using the Insight Infrared Video Goggles. Keeping your computer updated is as important as keeping the goggles in good working condition. All computers are vulnerable to cyberattacks, and the proper precautions should be taken to ensure that patient privacy is protected—especially when saving videos. The Insight Infrared Video Goggles should not be used if the connected computer is known to be infected or compromised by a virus or malware. Contact our support team as soon as possible to troubleshoot potential security concerns. Please follow the below precautions to minimize your exposure to cybersecurity risks:



HARDWARE

- Keep all hardware on the computer updated and patched with the latest firmware and updates provided by the computer manufacturer
- All storage devices that contain recordings from the goggles should be encrypted in transit and at rest
- Prevent unauthorized physical access to your computer using locked doors, proper security practices, and awareness of your surroundings
- Limit physical access to the machine and if necessary in high traffic areas—do not expose any unnecessary ports
- Only allow authorized USB devices to connect to your computer at the hardware level
- Maintain updated BIOS and motherboard firmware
- Implement a strong BIOS password management system to secure hardware
- Provide physical locks on computers and their ports to minimize tampering
- Block any unknown USB devices from connecting to the computer
- Physically inspect web cameras and their connections to the computer to confirm there are no skimming devices that could intercept the USB signal
- Connect the cameras to only known and trusted USB hubs and/or dongles.
- Keep computers and connected systems secure by implementing NIST-validated procedures and recommendations
- Disconnect any computer known to have any security vulnerability and refresh to factory/organization defaults
- Do not save recordings to unsecured machines
- Do not leave laptops or tablets unattended
- Ensure storage of videos is HIPAA compliant
- Confirm all computers, networks, and servers have their traffic encrypted

SOFTWARE

- Update OBS software only to verified versions listed on the Vestibular First (manufacturer) website and do not use unknown or untested beta versions
- Grant the minimum necessary rights for the shortest duration possible to the logged in user
- Limit access to computer through the authentication of all users



- Setup automatic timed method to lock the system when unused to prevent unauthorized access
- Limit administrative access and elevated privileges to separate administrative accounts to minimize the impact of viruses and malware
- Review communications from the manufacturer regularly to keep updated with any security news
- Utilize unique passwords across multiple systems
- Choose passwords that are difficult for brute force attacks to guess
- Avoid commonly used passwords such as “password” and “1234”
- Use a password manager to maintain unique and strong passwords across all systems

INTERNET

- Utilize an antivirus/anti-malware software and run daily updates
- Do not download applications or templates from unknown websites
- Browse only trusted websites before opening or clicking on any links or opening any files downloaded from the Internet
- Do not click on any links in emails from unknown origins or have suspicious content
- Utilize a firewall and keep it updated to protect against internet attacks
- Do not disable warnings that alert the user when the firewall is turned off or disabled
- Download scene collection templates only from the Vestibular First website

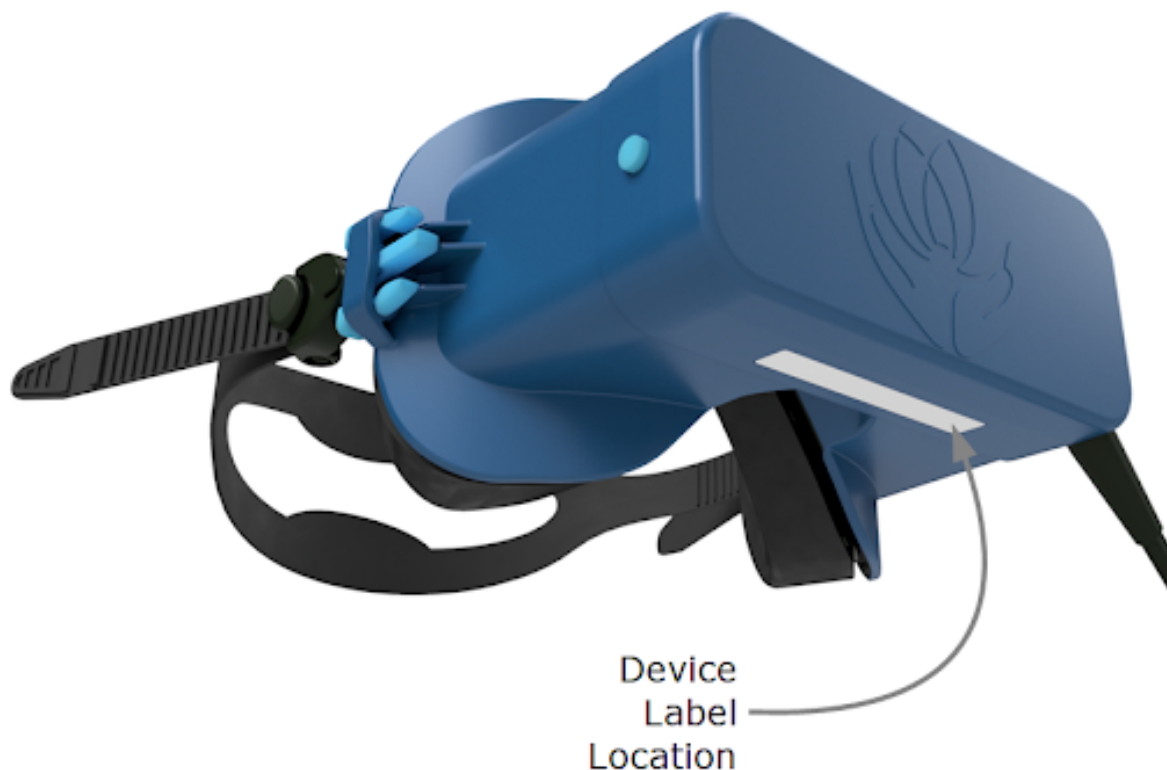
HIPAA RECOMMENDATIONS

Videos or images of the iris are considered Protected Health Information (PHI) and Personally Identifiable Information (PII). If you choose to record the videos to a compatible computer, please follow your organization’s policies and procedures for securing HIPAA-protected data. The Insight Infrared Video Goggles do not store any video or information internally nor does the OBS software have any connection to Vestibular First systems.









1.8. MARKINGS AND STORAGE



The device label is located on the underside of the camera unit.



Sample Device Label







MODEL: Insight Infrared Video Goggles	 Vestibular First Broomall, PA USA VestibularFirst.com		(01) GTIN 00860002280707 (11) DATE 2020-04-30 (21) SERIAL 1234567890
EACH USB INPUT: 5V === 500mA max    IP20	 Refer to Instruction Manual		

PRO

MODEL: Insight Infrared Video Goggles Pro	 Vestibular First Broomall, PA USA VestibularFirst.com		GTIN (01) 00860002280738 DATE (11) 2021-04-30 SERIAL (21) 1234567890
EACH USB INPUT: 5V === 500mA max    IP20	 Refer to Instruction Manual		



Marking Details

Marking	Picture
Power Inputs	EACH USB INPUT: 5V === 500mA max
Data Matrix Barcode	 <p> (01) GTIN 00860002280701 (11) DATE 2020-04-30 (21) SERIAL 1234567890 </p>
Refer to Instruction Manual	
Parts of the product will have patient contact	
Warning against immersion in liquid symbol	
Disposal of electro-medical equipment symbol (WEEE)	
Ingress Protection code IEC standard 60529	IP20
Manufacturer & Location	 Vestibular First Broomall, PA USA VestibularFirst.com



1.9. PACKAGING INSPECTION AND SHIPPING BOX

Packaging inspection and shipping box

- When the Insight Infrared Video Goggles are received, please check the shipping box for rough handling and damage. This information can help with an insurance claim toward the carrier if appropriate, which would be handled by Vestibular First.
- Keep the shipping material for the carrier's inspection and insurance claim if needed.
- Upon arrival the goggles should be checked for proper function as described in **Section 4.1**.
- Please keep the shipping containers as they may be needed for return/exchange shipping purposes.

1.10. INSPECTING FOR AND REPORTING DAMAGE TO THE GOGGLES

Inspecting for damage

- Inspect the Insight Infrared Video Goggles before use, checking all of the components visually for scratches, damage, or missing parts.
- The goggles should be checked for proper function before each session as described in **Section 4.1**.

Reporting damage

- Any missing parts or damage should be reported immediately to Vestibular First along with the order number and a detailed report of the problem.
- Contact Vestibular First by email at **Support@VestibularFirst.com** or by phone at **+1-215-667-8990** (United States) when reporting damage.

Product return for evaluation or repair

- If the manufacturer requests that you return the product for evaluation or repair, pack the product with care and proper padding, preferably in the original shipping container with a Return Material Authorization (RMA) number provided by the manufacturer.
- Contact Vestibular First by email at **Support@VestibularFirst.com** or by phone at **+1-215-667-8990** (United States) with questions about how to safely return products.



2. System Overview

2.1. MODULAR GOGGLES

The **patented** Insight Infrared Video Goggles are composed of 4 modular sections. The overall size of the goggles and especially the cushion were designed to fit adolescents 12+ and adults.

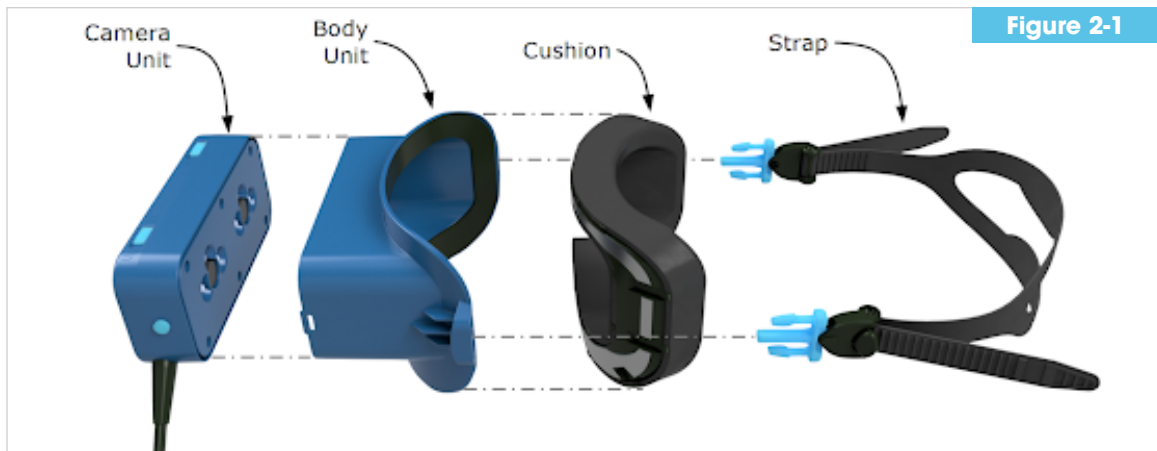


Figure 2-1 - Sectional view of modular goggles components

PRO

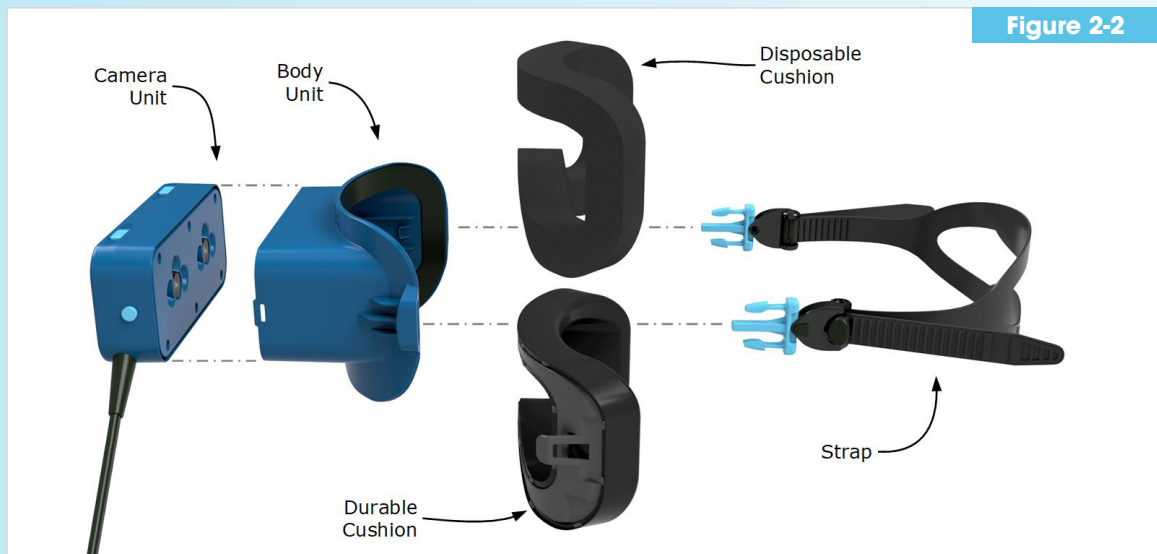


Figure 2-2 - Sectional view of Pro modular goggles components



The **Camera Unit** as seen in **Figure 2-3** 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 two 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.

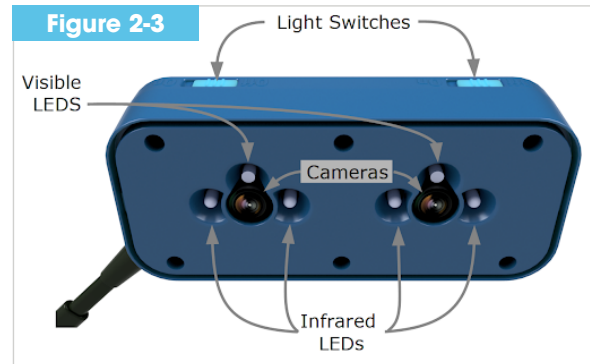
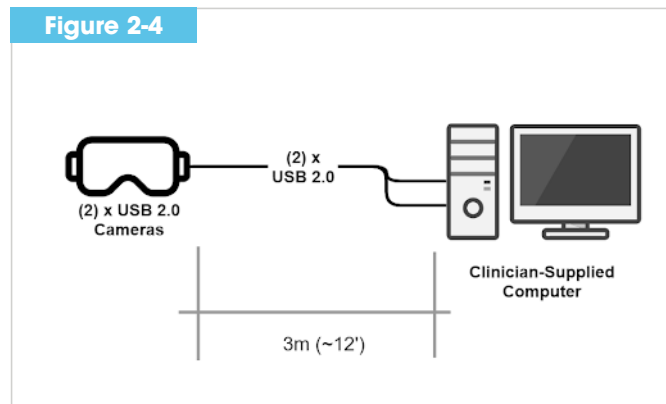
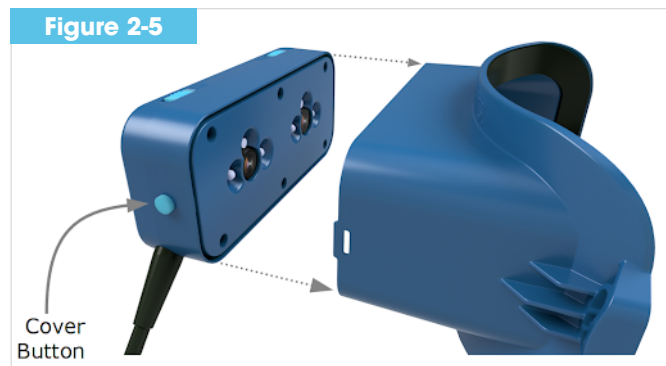


Figure 2-4 The cable that exits the camera unit is over 12 feet long, and at the distal end splits into a Y with two separate USB connectors, one labelled Left and the other labelled Right. The clinician uses these to connect the goggles to a computer via standard USB 2.0 ports so that video data can be sent from the cameras to the computer.



The cover buttons as seen in **Figure 2-5** 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 **Body Unit** connects all of the modular sections together through snap-fit, hook & loop, and spring-activated hook connections as demonstrated in **Figures 2-1 and 2-2**. The body unit provides a secure connection point from the straps all the way to the camera unit to assure a secure fit. It has hook adhesive strips (velcro) along the internal surface of the body unit to connect to the cushion. Additionally, the body unit has connection points to which the strap and camera unit can secure.

The Cushion in Figure 2-6 provides a comfortable and light-proof seal around the eyes with a continuous surface that wraps around the forehead and on the bridge of the nose. The cushion connects to the hook surface of the body unit with embedded strips of loop material. The cushion is the primary surface that contacts the patient's body.

PRO

The Insight Pro has an updated Body Unit to fit with the updated durable cushion. The updated Body Unit has rigid tabs with guide rails which are located on the lateral inside surfaces (one tab/guide rail on each side for a total of two on the Body Unit). The Insight Pro also has an updated (durable) cushion which has two cantilever snaps designed to fit into the guide rails of the rigid tabs on the Body Unit. The rigid tabs with guide rails and cantilever snaps replace the hook and loop attachment method used as the way of attaching the durable cushion to the Body Unit in the original Insight Infrared Video Goggles.

The **Strap** has two strap connectors that snap into a receiving section on the body unit. The connector can be released by pinching it with two fingers to allow for quick removal of the goggles if needed. **Figures 2-1 and 2-2** shows the strap has strap adjusters on each side to allow for tightening and loosening of the goggles during donning and doffing. The section of the strap that connects with the back of the patient's head is designed to improve the security of the strap with a split opening in the middle.



2.2. SOFTWARE

The software recommended for clinicians to use with the Insight Infrared Video Goggles is called Open Broadcaster Software (OBS). OBS allows clinicians to easily connect the cameras in the goggles and the optional external webcam to their computer and then arrange these camera views in multiple configurations using scene collection templates provided by Vestibular First. OBS allows clinicians to view and record eye movements viewed by the infrared video cameras when a patient is wearing the goggles. Clinicians find additional functionality in the software by utilizing keyboard shortcuts within the OBS settings.



The main interface of OBS can be broken down into four main sections: Image Area, Scenes, Recording, and Settings.

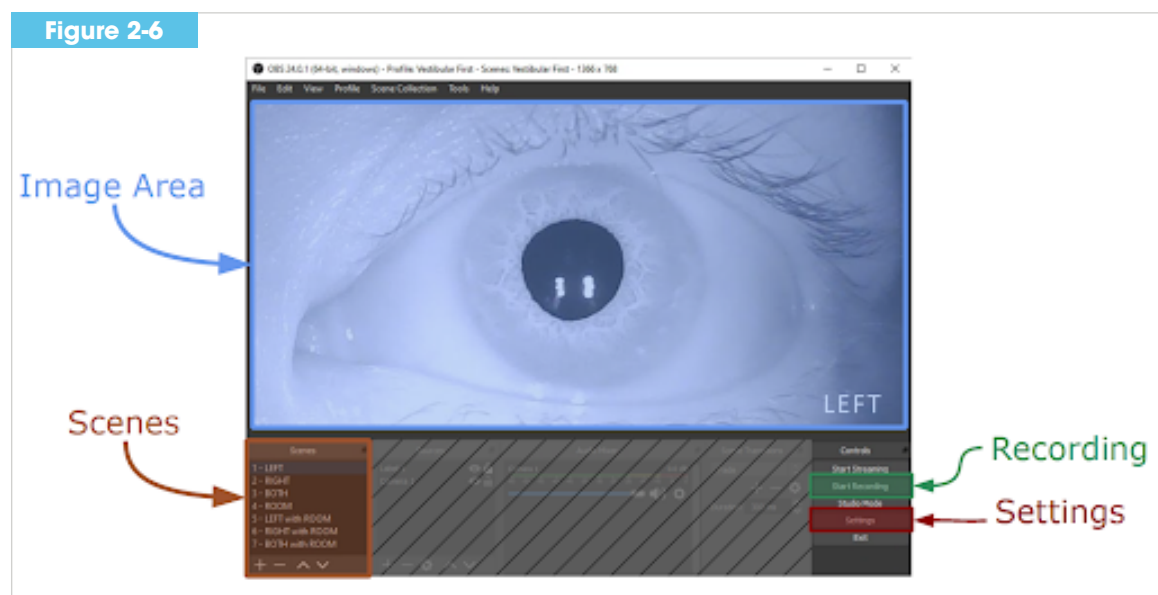


Figure 2-6 - Overview of OBS User Interface








The **Image Area** is where the video from the cameras is displayed. If the clinician chooses to record the patient session, the image area is what is recorded to the file. Lastly, the image area is used to center the area of interest of the eye into the middle of the screen by clicking and dragging in the image area.

The **Scenes** area of OBS is used to select a layout of the video sources and labels. Vestibular First provides pre-built groups of scenes called scene collection templates. The scene collections are used to improve user experience and reduce setup time by



setting up the most commonly requested layouts. Additionally, each scene is associated with a keyboard shortcut to help the clinician navigate the scene options more easily. Table 10-1 shows the available options provided in the scene collection template.

Table 2-1 - Scenes provided in scene collection templates

Table 2-1					
Shortcut	Scene Name	Left Eye	Right Eye	Room	Sample
1	LEFT				
2	RIGHT				
3	BOTH				
4	ROOM				
5	LEFT w/ROOM				
6	RIGHT w/ROOM				
7	BOTH w/ ROOM				



A common action used during a patient session is **Recording**. The “Start Recording” button allows a clinician to start and stop a recording. Once clicked, this button converts to “Stop Recording” and can be selected to stop a recording. The recordings are saved as video files with the user-defined specifications set in Figure X.

In **Settings**, the clinician can control important aspects of software use. This includes the recording path or selection of the file/folder where video recordings will be stored.

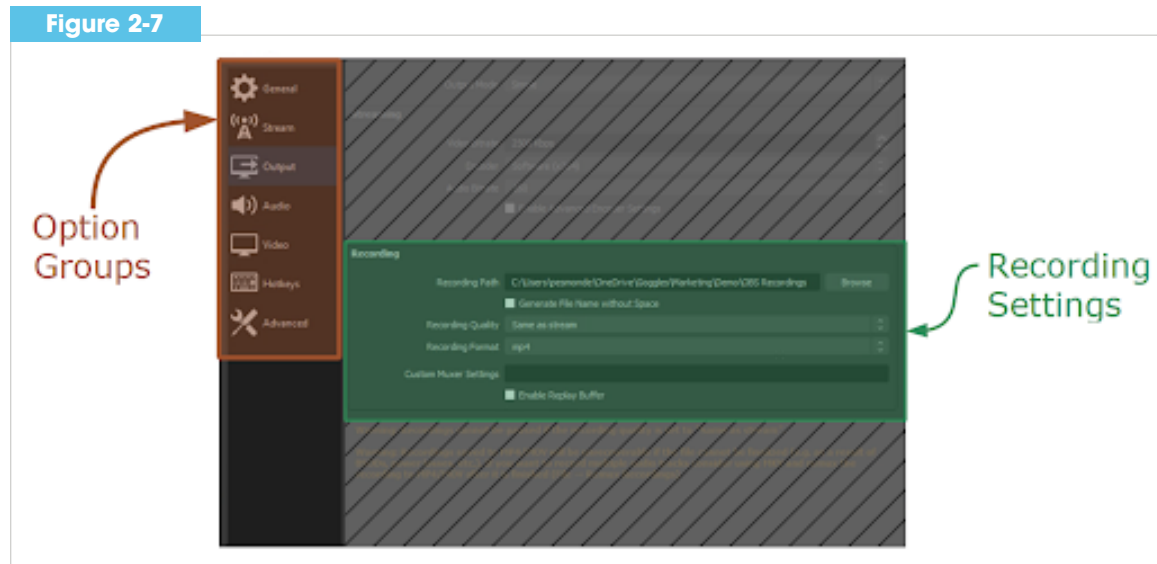


Figure 2-7 - Overview of OBS User Interface

In the “Output” section of the Option Groups, the clinician can select the options to ensure a file type/size that is appropriate for their setting.



3. Software Installation & Configuration

Vestibular First supports the use of Open Broadcaster Software (OBS) for its robust features, strong community support, and that it is freely available. Please note that Vestibular First is not the developer of OBS and does not control its features. Please follow the below instructions on how to install and configure OBS on your computer.



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

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

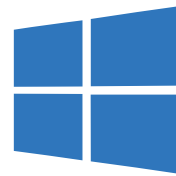
Note: *It is recommended to install the newest hardware and software drivers for your computer. For older computers, bios updates may be needed before use of the goggles. These updates should be available through the support page of your computers manufacturer website.*

3.1. INSTALLATION

A. DOWNLOAD OBS FROM THE FOLLOWING WEBSITE.

<https://obsproject.com>

Insight Infrared Video Goggles are supported only for the use with Windows 10 and MacOS >=10.12



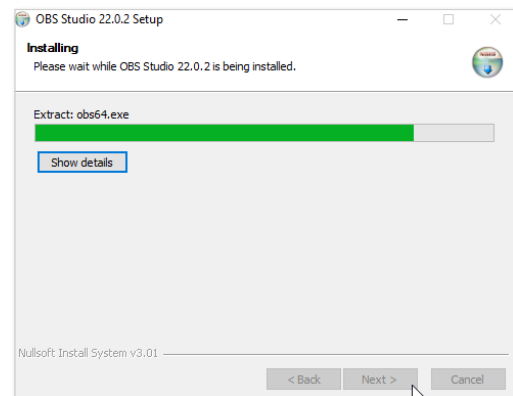
Windows



Apple

B. INSTALL OBS

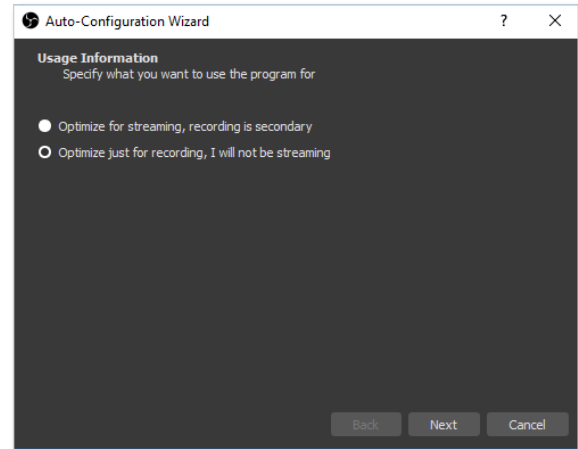
Make sure you're an administrator on your computer (or know someone who is) and then click "next" through all the default settings.



C. OBS AUTO CONFIG WIZARD

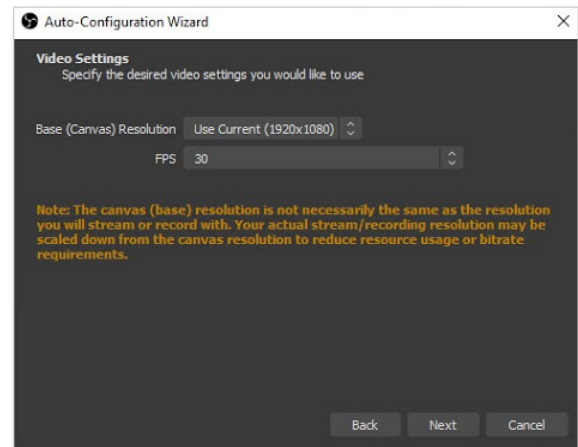
When launching OBS for the first time, the Auto Configuration Wizard will start.

You may also launch the Auto Configuration Wizard via menu bar by selecting Tools, Auto Configuration Wizard.



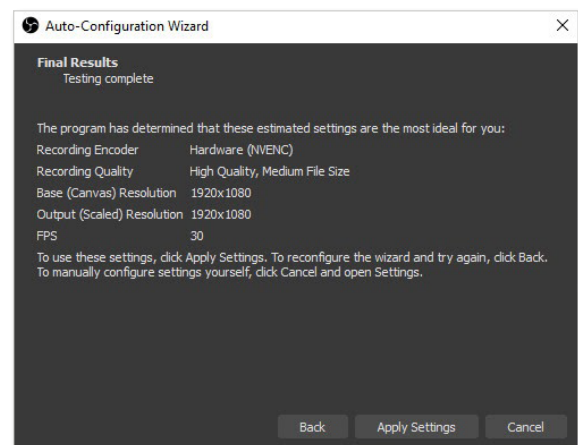
1. Usage Settings

Select **Optimize for Recording, I will not be streaming**, and click next.



2. Video Settings

Select FPS of 30 and click next.



3. Final Results

Click Apply settings.

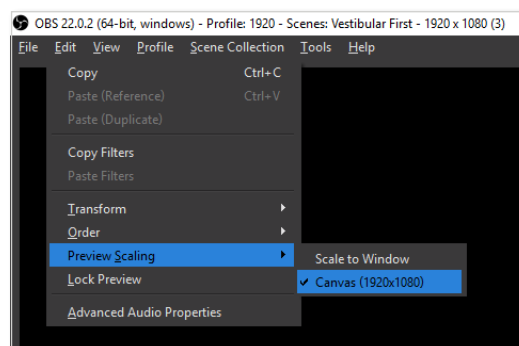


3.2. OBS CONFIGURATION

A. FIND AND DOWNLOAD SCREEN RESOLUTION TEMPLATE

1. Identify your screen resolution.

At the top of the screen. Select the dropdown menu "Edit" Select "Preview Scaling" Note the resolution listed next to Canvas.



2. Download the Vestibular First template.

Navigate with your Internet browser to <https://v1st.co/how-to>

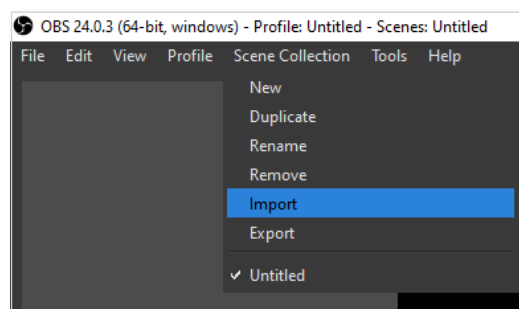
Find your model of goggles and then find the Download Templates link. For the correct screen resolution, click **Download**. Save the file to your computer. Depending on your internet browser, you may be prompted if you want to open or save the file. Select save.

A screenshot of a web browser showing a table of screen resolutions. The table has columns for 'Screen Resolution', 'Windows', and 'Apple'. Each row lists a resolution and has 'Download' links for both Windows and Apple.

Screen Resolution	Windows	Apple
800 x 600	Download	Download
1024 x 768	Download	Download
1152 x 864	Download	Download
1280 x 720	Download	Download
1280 x 768	Download	Download
1280 x 800	Download	Download
1280 x 960	Download	Download
1280 x 1024	Download	Download
1344 x 840	Download	Download
1360 x 768	Download	Download
1366 x 768	Download	Download
1368 x 912	Download	Download
1440 x 900	Download	Download
1500 x 1000	Download	Download

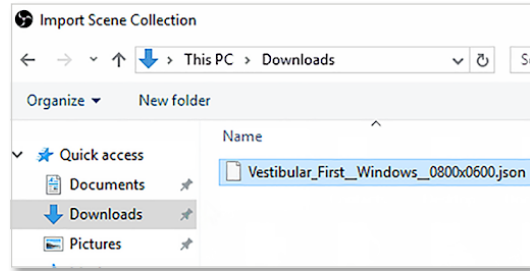
3. Import Template into OBS.

In OBS, select the dropdown menu "Scene Collection", then click on Import Select the file and click Open.



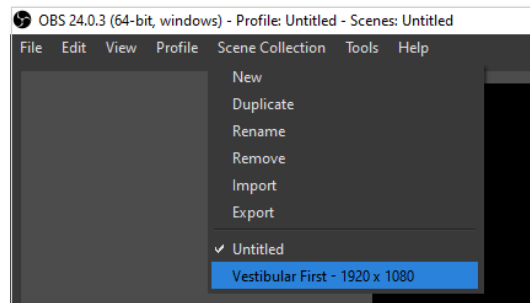
4. Navigate to the location where the file is saved.

Select the file and click Open.



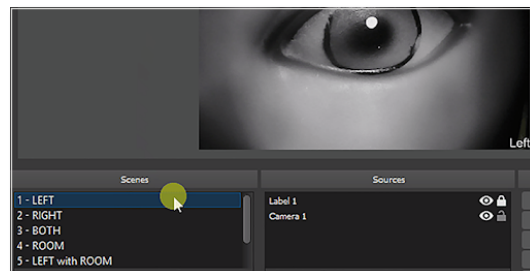
5. Activate the template.

Select the dropdown menu "Scene Collections", then click on the appropriate template resolution.



6. Confirm Imported scenes.

You should now see in the Scenes panel a list of the new scenes available to you for your viewing of the infrared video goggles.



Note: In the event that you are unsure of what screen resolution template you have selected, verify the selected template by opening the Scene Collection tab in the menu. Your selected Screen Resolution template will have a check mark to the left of it.



B. CONFIRM CAMERA SOURCES

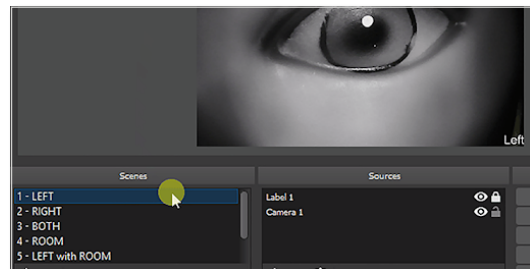
Here we will check to ensure the cameras are mapped correctly and displaying video.

1. Connect All Cameras.
2. Confirm functionality of Left, Right, and Room Scenes.



Did you see the video?

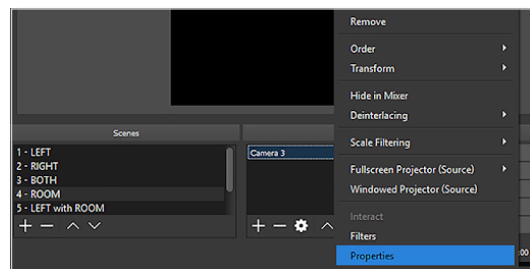
- **Yes** – Great! Check the next scene in the list.
- **No** – Continue to the next step for each scene that does not work.



C. MAPPING CAMERA SOURCES

1. Open Camera Properties.

Right-Click on the Camera shown in the Sources panel and click Properties.



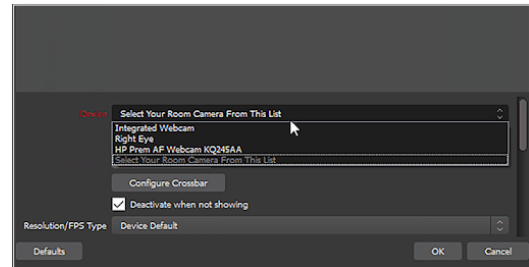
2. Selecting Device

Click the dropdown for Device selection and select the camera name from the list.

Camera 1: Left Eye

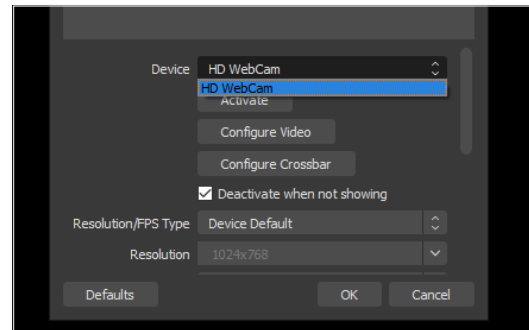
Camera 2: Right Eye

Camera 3: Room Camera
(webcam on computer used or an external webcam supplied by the user/clinician)*:



If the listed devices are not listed in the dropdown menu, please ensure the USB plugs are firmly connected to the computer.

Once you select a camera from the list, a live preview window will appear showing a thumbnail of the video source. Confirm this is the correct camera before clicking OK.



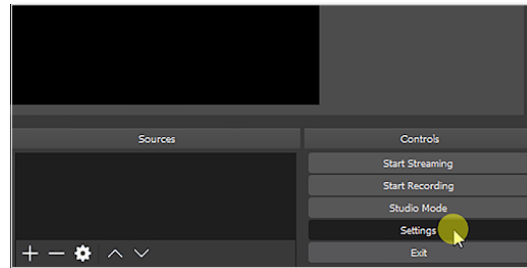
**The Room camera name can vary from computer to computer. Use the preview window to confirm the appropriate camera.*



D. SETUP RECORDING OPTIONS

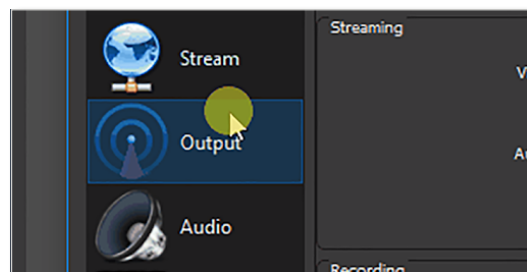
1. Access Settings

Click the Settings button in the lower-right corner to view the viewing and recording preferences.



2. Output Options

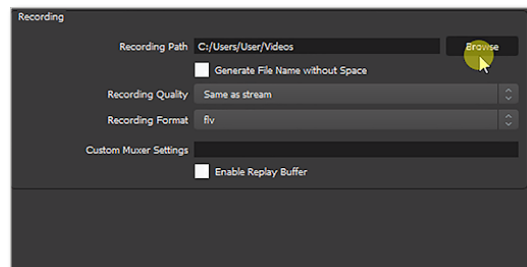
Click the menu on the left labeled Output to view the settings specific to the recording type and location.



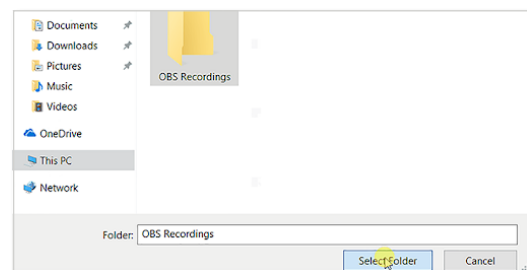
3. Saved Recordings Location

To change the location of where the stored recordings are saved

Click the **Browse** button
Click **Select Folder** when you have decided on the new location.



Note: This is optional and can be adjusted at any point in the future.



4. Recording Format

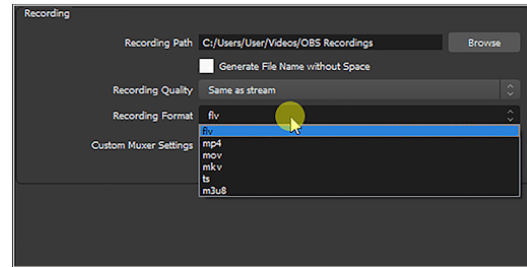
OBS allows an extensive list of output formats like MP4, MOV, etc. and can be changed at any point.

We suggest the following formats based on your Operating System to maximize compatibility:

Recommended Formats

- Windows OS: MP4
- Apple OS: MOV

Click **Recording Format dropdown** and Select the format appropriate to your system. Click the format you require, followed by OK.



3.3. SCENE COLLECTION TEMPLATES

Vestibular First maintains the templates used with OBS software for proper viewing of the inputs from the goggles. The templates were created for use with OBS and the Insight Infrared Video Goggles. Vestibular First is not responsible for any use of templates outside of use with OBS. Vestibular First is also not responsible for any use of the templates if they have been modified by the user/clinician.

Templates may be updated from time to time to improve user experience with the Insight Infrared Video Goggles. The most updated templates are available at this address:

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



4. Using the Insight Infrared Video Goggles

4.1. INITIAL SETUP & CHECKS

Perform before each use of the goggles.

GOGGLES AND ROOM SAFETY INSPECTION:

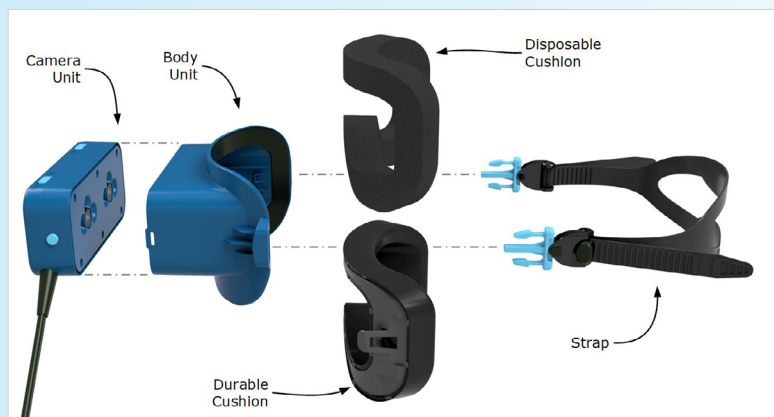
1. Confirm the following on the Insight Infrared Video Goggles:
 - a. Cable and USB connectors are not damaged or frayed
 - b. Cushion is firmly in place on body unit
 - c. There are no loose materials within the body unit
 - d. There is no visible damage to the cushion, strap, body unit, and camera unit.
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 will have the goggles on their head.
3. If using a laptop or tablet computer, confirm it is on a stable flat surface and will not be susceptible to falling if the cable is stretched beyond the range of your movements.
4. Clinicians should attend to the cable position to avoid catching themselves or the patient on it.

PRO

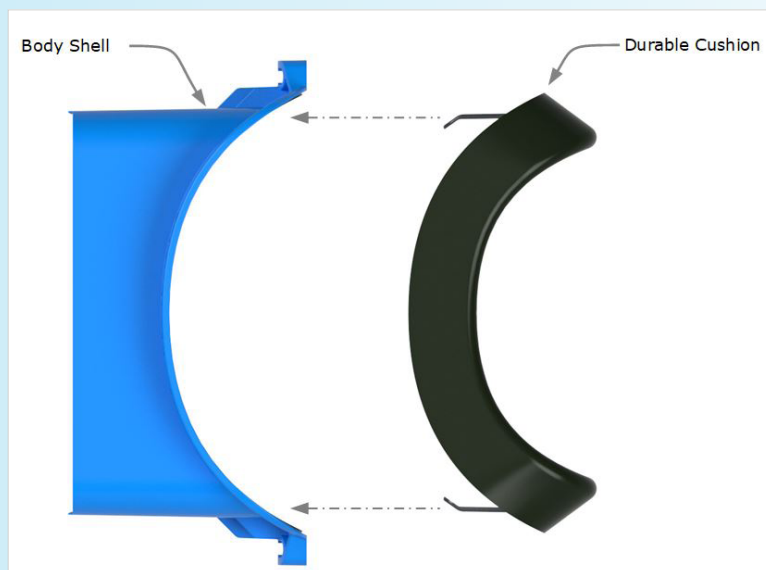
DECIDE WHICH CUSHION YOU WILL BE USING WITH THE INSIGHT PRO.

If using a durable cushion on the Insight Pro:

1. Remove any disposable cushion that is in place
2. Face the durable cushion unit "right side up"



3. Connect the durable cushion unit to the body unit by sliding the cantilever snaps of the durable cushion into the rigid tabs of the body unit
4. Please note that the Insight Pro requires the use of both the updated body unit (with guide rails and rigid tabs) and the updated durable cushion unit (with cantilever snaps). Do not try to place the updated durable cushion unit onto the original Insight body unit which does not have the guide rails and rigid tabs. Likewise, avoid placing the original durable cushion onto the updated body unit since the updated body unit is specifically designed to work with the updated durable cushion unit.



If using a disposable cushion on the Insight Pro:

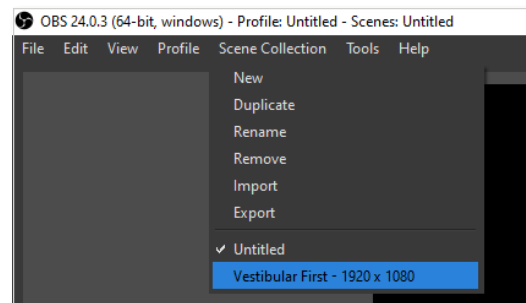
5. Remove the durable cushion unit if currently attached to the updated body unit. When removing the updated durable cushion unit, ensure that the cantilever snaps on the updated durable cushion unit are pulled (toward the center or midline of the goggles) when releasing the snaps so they can then slide through the guide rails and off of the updated body unit.
6. Attach the disposable cushion to the updated body unit, aligning the edges. Press firmly along all of the edges of the cushion to ensure that it firmly adheres to the hook surface of the updated Body Unit.
7. Examine the disposable cushion you intend to use for its integrity. Do not use a torn or damaged disposable cushion.
8. Ensure any cuts or wounds on clinician's hands are properly bandaged so as to avoid contaminating the disposable cushion when handling it.



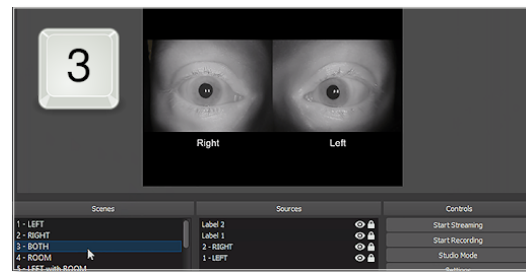
9. When removing the disposable cushion, it may be easiest to start at the widest section which would be either at the top or the lateral portions of the goggles. Pull the disposable cushion gently away from the hook surface of the Body Unit, trying not to tear the foam so that the cushion can be removed in one full piece if possible.
10. Use a new disposable cushion during every individual patient care session.

COMPUTER AND SOFTWARE SAFETY INSPECTION

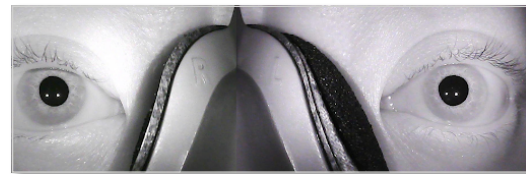
1. Confirm the correct screen resolution template is selected in the Scene Collection menu. If not, repeat the steps in **Section 3.2** to import the correct scene collection.



2. Confirm both cameras are functioning and displaying video in the Both Eyes Scene. The performance in infrared LEDs can dim over time. Be sure to check that both eyes appear illuminated when assessing camera function.



3. Confirm Left and Right eye videos match true Left and Right eyes. The L/R imprinted on the nose bridge of the goggles should match the camera video and be oriented correctly.



4.2. 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 or 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	
Strap	



4.3. CONSIDERATIONS PRIOR TO A PATIENT DONNING GOGGLES

Contraindications: May be contraindicated in patients who exhibit a broken nose, recent face/head trauma or surgery, or recent eye surgery. Immediately stop using the goggles if the patient shows any signs of allergy to the materials that comprise the goggles. Please consult a specialist in such circumstances before using the mask and strap on these types of patients.

PRIOR TO DONNING:

- Only use the goggles on intact skin.
- Explain to the patient the purpose of the goggles and what symptoms the patient may experience during testing while wearing the goggles.
- Reassure the patient that the clinician will remain present for safety throughout the testing and treatment procedures and that the patient can request removal of the goggles at any time.

CUSHION USE:

- Ensure the cushion used is lined up with the borders of the goggles and does not intrude into the interior of goggles.
- Ensure the hook and loop (Velcro) is firmly attached and no gaps between the cushion used and body unit.

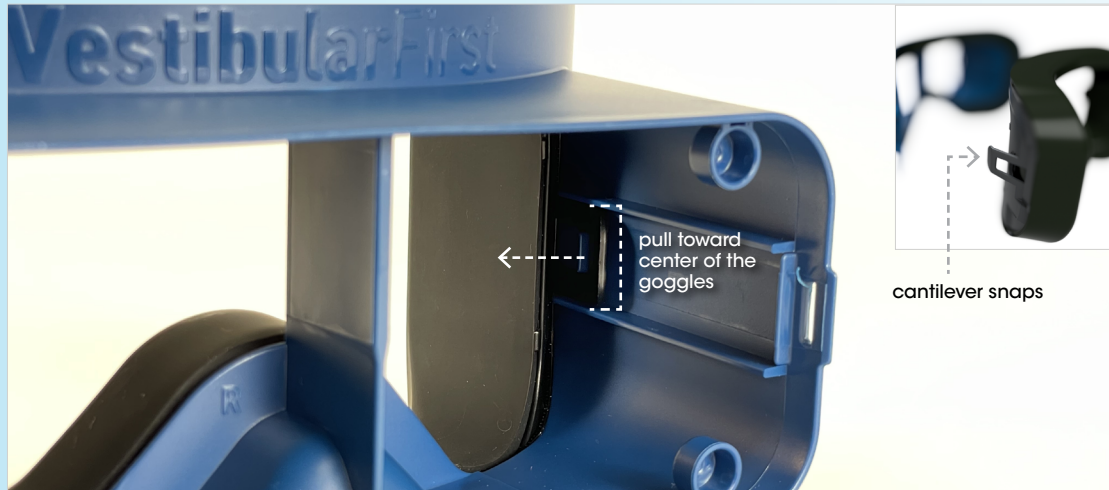
PRO

IF USING THE DURABLE CUSHION ON THE INSIGHT PRO:

- Ensure that the cantilever snaps of the updated durable cushion unit are properly aligned such that they slide smoothly into the guide rails of the rigid tabs of the updated body unit. Do not misalign and then try to force the cantilever snaps onto the updated body unit.
- Please note that the Insight Pro requires the use of both the updated body unit (with guide rails and rigid tabs) and the updated durable cushion unit (with cantilever snaps). Do not try to place the updated durable cushion unit onto the original Insight body unit which does not have the guide rails and rigid tabs. Likewise, avoid placing the original durable cushion onto the updated body unit since the updated body unit is specifically designed to work with the updated durable cushion unit.



- When removing the Pro durable cushion unit, ensure that the cantilever snaps are pulled (toward the center or midline of the goggles) when releasing the snaps so they can then slide through the guide rails and off of the updated body unit.



IF USING A DISPOSABLE CUSHION ON THE INSIGHT PRO, ENSURE THE FOLLOWING:

- Examine the disposable cushion you intend to use for its integrity. Do not use a torn or damaged disposable cushion.
- Ensure any cuts or wounds on clinician's hands are properly bandaged so as to avoid contaminating the disposable cushion when handling it.
- Use a new disposable cushion during every individual patient care session.

4.4. DONNING THE GOGGLES:

SAFETY REMINDERS:

- Always clean the goggles before each patient use, following the cleaning instructions in **Section 4.2**
- Always guard your patient and ensure their safety to avoid cable entanglement and to ensure they are able to move and change position safely while in the dark environment of the goggles.
- Ensure that the visual fixation light is "OFF" for both eyes prior to having the patient don the glasses unless desired "ON" at that time.



1. Ask the patient to remove any glasses.



2. Using the strap adjuster, loosen the straps of the goggles.



3. Place the goggles in front of the patient's eyes, with patient assistance if they are able. Place the strap behind the patient's head.



4. Using the strap adjuster, secure the strap comfortably but firmly enough to keep goggles in place over eyes.



5. To prevent slippage, ensure the silicone strap lies flat on the back of the patient's head and that the split strap opening is separated.



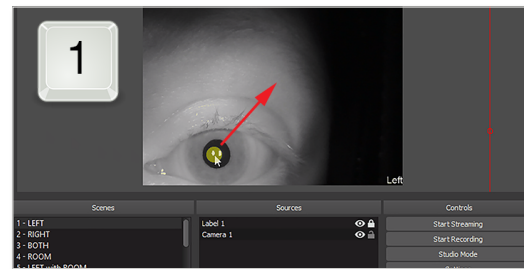
Note: Be sure to communicate with the patient to ensure comfort and appropriate level of tightening of the strap, such that it is secure but that the pressure from the goggles and strap on the patient's head is not considered significantly uncomfortable to the patient.



4.5. CENTERING THE EYES

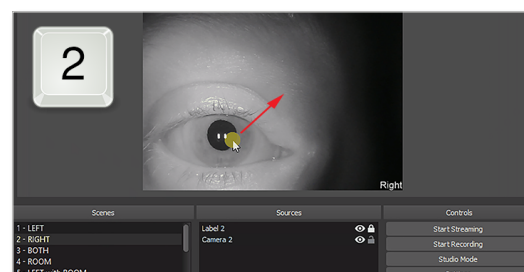
A. CENTER LEFT EYE

- Press the number **1** on your keyboard to switch to the left eye master scene.
- Click and drag pupil of eye into the center of the preview window.



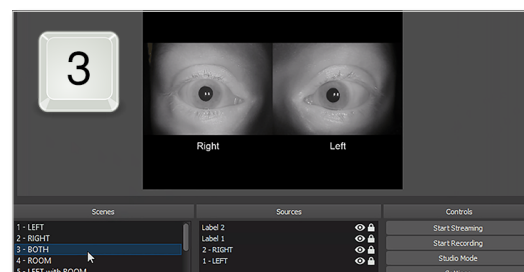
B. CENTER RIGHT EYE

- Press the number **2** on your keyboard to switch to the right eye master scene
- Click and drag pupil of eye into the center of the preview window.



C. CONFIRM BOTH EYES ARE CENTERED

- Press the number **3** on your keyboard to switch to scene with both eyes displayed.
- If you need to modify one or both eyes, return to the master scenes by pressing 1 and/or 2 and update the individual eye positions until they are in the correct position.



Note: You can only adjust the position of the eyes in Scene 1 and Scene 2.



4.6. SELECT ADDITIONAL SCENES

Using your keyboard is fast and efficient during a session. While in OBS, use the following keyboard shortcuts to switch quickly between the views.

Table 4.6.1. Scenes provided in scene collection templates



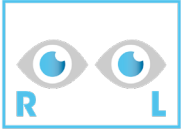




Table 4.6.1					
Shortcut	Scene Name	Left Eye	Right Eye	Room	Sample
1	LEFT				
2	RIGHT				
3	BOTH				
4	ROOM				
5	LEFT w/ROOM				
6	RIGHT w/ROOM				
7	BOTH w/ ROOM				



Table 4.6.2. Scenes details

Table 4.6.2

1 - LEFT

This shows the Left camera and a label. This is a master scene and is used to center the pupil for all other scenes.



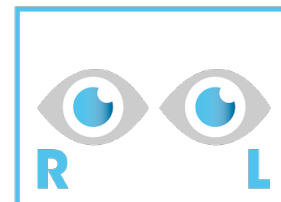
2 - RIGHT

This shows the Right camera and a label. This is a master scene and is used to center the pupil for all other scenes.



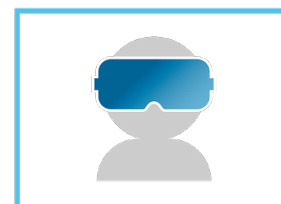
3 - BOTH

This shows the Left and Right camera centered in the display.



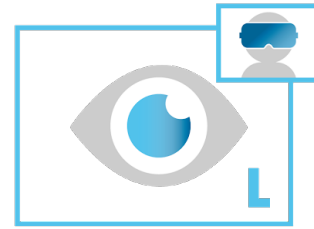
4 - ROOM

This shows the optional Room camera and a label. This is a master scene and is used to center the room for all other scenes.



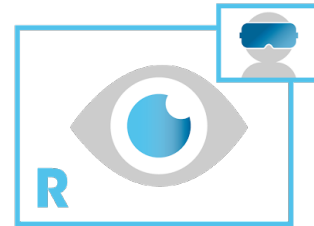
5 - LEFT WITH ROOM

This shows the Left camera with the Room camera as a picture-in-picture in the upper-right.



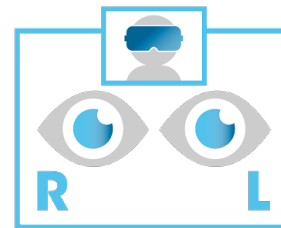
6 - RIGHT WITH ROOM

This shows the Right camera with the Room camera as a picture-in-picture in the upper-right.



7 - BOTH WITH ROOM

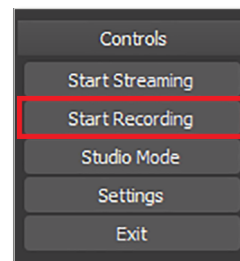
This shows the Left and Right camera with the Room camera as a picture-in-picture in the top center.



4.7. STARTING & STOPPING VIDEO RECORDING

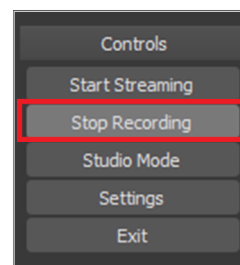
A. CLICK START RECORDING

The button is in the lower right-corner in the Controls section



B. CLICK STOP RECORDING

Click this when you are ready to stop recording.



4.8. HOW TO USE THE VISUAL FIXATION LIGHT

- Each eye has an independent visual fixation light and switch. Use one or both lights as desired.
- To operate the visual fixation light, locate the sliding switches at the top of the Insight Infrared Video Goggles.

1. To activate the visual fixation light, slide switch toward the ON label and confirm the patient can see the light.
2. To deactivate the visual fixation light, slight the switch toward the OFF label and confirm that the patient no longer sees the light.



4.9. HOW TO REMOVE AND ATTACH THE CAMERA UNIT

The camera unit (which contains the cameras) can be removed to allow the patient to see the room. This is advised at times when:

- The patient is changing position (such as repositioning between testing or treatment maneuvers).
- The patient indicates they need a break from the dark environment of the goggles between testing or treatment procedures.
- The clinician and patient agree that it is not necessary to fully remove the goggles from the patient.

Note: When the camera unit is removed, no viewing or recording of patients' eyes can occur since the cameras are inside of the camera unit.

REMOVING THE CAMERA UNIT

1. Simultaneously press both spring release buttons (there is one button on each side of the goggles).



2. Remove the camera unit by pulling it straight away from the body unit.

Always remember to place the camera unit in a secure location.



ATTACHING CAMERA UNIT

1. Orient the camera unit so that the logo is upright, the cord is coming out of the bottom corner, and the ON/OFF light switches for the visual fixation light are on the top of the camera unit.



2. Press the camera unit onto the body unit with even and firm pressure. Confirm the camera unit is securely attached on both sides by ensuring that the camera unit does not move before proceeding with further use.



4.10. DOFFING THE GOGGLES

1. Loosen the straps by lifting the tab. Slide the goggles off the head of the wearer, with the wearer assisting if able.



2. If you want to remove the goggles more quickly, press both sides of the side release buckle (strap connector) to release the strap from its connection to the goggles on one side.



PRO

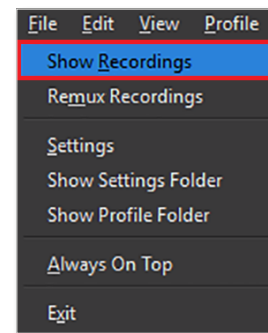
3. Cleaning considerations for the Insight Pro:
 - a. If using the durable cushion on the Insight Pro:
 - i. Clean and disinfect the updated durable cushion unit along with all other parts of the goggles as listed in Section 4.2 of this User Manual.
 - b. If using the disposable cushion on the Insight Pro:
 - i. Properly dispose of used disposable cushion in the standard waste container or in a biohazard container when appropriate



4.11. ACCESSING AND VIEWING RECORDED VIDEOS

Click File... *Show Recordings*

The menu is along the top of the screen. Click to select File and choose Show Recordings in the drop-down menu. Once Show Recordings is selected, a window will open showing you the location of your recordings.



4.12. ACCESSING AND VIEWING RECORDED VIDEOS

Videos can be played by a native video playback application provided with the operating system. Users can utilize additional 3rd party viewers, however Vestibular First does not support any applications for video playback. Please contact your IT professional for assistance in selecting and downloading any playback applications to ensure compatibility with your computer's operating system.

4.13. STORING YOUR GOGGLES

1. Unplug and store the goggles safely between uses. It is not recommended to leave the goggles plugged in continuously.
2. After cleaning the goggles based on the steps in Section 4.2, coil the cable starting at the USB plugs into a circle approximately 150mm (6") in diameter.
3. Place coil into the cutout in case
4. Place goggles into the case, with Vestibular First logo right side up and the part of the cable where it exits the camera unit pointing toward the bottom of the case. The face cushion area of the goggles should rest against the curved portion of the divider wall inside the case, and the goggles should be oriented as indicated by the molded outline in the bottom of the case.
5. Secure the lid of the case by zippering the case closed completely.



5. Troubleshooting, Repair, and Warranty

5.1. GOGGLES TROUBLESHOOTING

For the most up-to-date information and video-based tutorials, please visit:

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



PROBLEM

Light leakage from around the cushion.

SOLUTION

1. Ensure the goggles are positioned firmly on the face of the patient and that the cushion is evenly positioned so that light is not visible leaking in from the edges of the goggles at any point.
2. Ensure there is no damage to the cushion (tears, missing portions, or deformed shape). If the cushion is damaged, contact Vestibular First at **Support@VestibularFirst.com** or **215-667-8990** regarding how to obtain replacement parts.
3. Check the cushion to ensure there is no gapping between the cushion and goggles. If there is gapping, remove and reattach the cushion so that there are no gaps between the cushion and goggles.
4. Ensure the hook and loop is firmly attached to the cushion and the goggles.
 - a. If the hook and loop does not attach well even when firm even pressure is applied, inspect the hook (body unit) and loop (cushion) for debris or dirt that may be caught in the material.
 - b. Clean the cushion and body unit using the cleaning instructions provided in **Section 4.2**. If there is remaining debris stuck on the hook or loop material, remove it manually, then disinfect the surfaces.
 - c. If the hook and loop do not attach properly after these inspection and cleaning steps are completed, please contact the manufacturer for assistance.



If using the updated durable cushion unit:

1. Check that your durable cushion is properly attached to the Body Unit. Make sure that the cantilever snaps on the durable cushion are engaged with the rigid locking tab and within the guide rails on the body unit.

**If using the disposable cushion:**

1. Examine the disposable cushion you intend to use for its integrity. Do not use a torn or damaged disposable cushion.
2. See **Section 4.1** on proper process for attaching the disposable cushion.
3. Ensure the goggles are positioned firmly on the face of the patient with strap effectively secured so that light does not leak in between the cushion and the patient's face.



PROBLEM

"L" and "R" printed on the nose portion of the goggles are upside down.

SOLUTION

Detach and rotate camera unit (part which holds the cameras) 180 degrees. Re-attach camera unit. Confirm that L/R are now oriented upright when viewed on the software.

PROBLEM

Artifacts or static in the camera video.

SOLUTION

Unplug and replug in USB cables and ensure a proper connection.

PROBLEM

Visual fixation light does not light up when the switch is turned to "On."

SOLUTION

Ensure USB plugs are connected firmly so that the lights are getting power from the computer. The computer must be turned on as well.

Ensure there is no debris in the switch preventing it from moving to the "On" position. If there is debris, remove it.



5.2. SOFTWARE TROUBLESHOOTING

For the most up-to-date information and video-based tutorials, please visit:

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



PROBLEM

Video of the eye is colored and/or dim.

SOLUTION

1. Ensure the goggles are positioned firmly on the face of the patient and that the cushion is evenly positioned so that light is not visibly leaking in from the edges of the goggles at any point.
2. Ensure a good connection to the computer. Unplug and replugin USB cables and restart OBS.

PROBLEM

Left and Right eye are reversed (only occurs in Mac OS)*

***Note:** In this case, the right eye is labeled in the software as "Left" and the left eye is labeled in the software as "Right." This can be assessed by having the patient wear the goggles and looking to see if the physical "L" and "R" printed on the inside nose portion of the goggles matches with the video display labels of "Left" and "Right" in the software.

SOLUTION

Perform only those steps necessary to get the desired result of a Right and Left eye nose portion "L" and "R" to match with the software video displays labeled "Left" and "Right" respectively.

1. Unplug and left and right cables. Plug the right cable where the left cable was plugged in and the right cable where the left one was plugged in previously.



2. Restart OBS.
 3. Restart computer, open OBS, and see if video is displaying.
-

PROBLEM

Video of left and right eye are not synchronized or freezing (lost frames)

SOLUTION

1. Check to see if the computer being used with the goggles meets the minimum hardware requirements.
 - a. Processor – i5 or better with 2.0 ghz or higher
 - b. Memory (RAM) – 8GB or more
 - c. Dedicated Video Card – Not necessary, but preferred
2. If the computer does not meet the minimum hardware requirements, please either update that computer to meet the requirements or select a different computer to use with the goggles. If your computer meets the requirements, proceed to following steps.
3. Close any programs other than OBS to reduce the drain on the system's resources.
4. Restart your computer to clear any issues that may have resulted in system resources being drained even after all programs other than OBS are closed.
5. If you have a dedicated video card, there is a way in settings of OBS to transition the encoder from software to hardware, which may eliminate asynchronous or freezing video.



5.3. WARRANTY AND REPAIRS

Vestibular First warrants that the Insight Infrared Video Goggles are free from defects in material and workmanship under normal use and service for a period of 36 months from the date of delivery by Vestibular First. If the Insight Infrared Video Goggles require service during the applicable warranty period, the purchaser should communicate directly with Vestibular First. Warranty is not transferable to another entity and only covers the original purchasing entity.

When Damage is Not Covered by Warranty

If items are damaged by accident or misuse, please visit the following site to view repair costs and contact our team:

<https://v1st.co/v1-repair>

Shipping and Handling Fees for Replacement Parts

- All shipping fees are covered by the manufacturer if under warranty [replacement part(s) needed due to a manufacturing defect].
- Shipping and handling fees will be the responsibility of the customer and appropriate in amount to cover the part(s) shipped plus a standardized handling fee per part, in the case where customer actions/inactions resulted in damage to the original parts.

Timeline for Replacement Parts

- Time until delivery of a replacement part, both in cases of parts under warranty and customer action-related damage, is 3 business days from receipt of request/confirmation that a new part will be shipped to you.
- Potential for faster or overnight shipping may be available for an additional fee, depending on the location of the customer - please contact us for details

5.4. 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**

