

User Manual

Vesticam2 Monocular IR video goggles, with fixation light (v2c22021)

Vesticam2 Binocular IR video goggles, with fixation lights (v2c2c22021)



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1.Introduction

1.1 Contact Information

This user manual is valid for Vesticam2 IR video googles, monocular (V2C22021) and binocular (V2C2C22021)



Manufacturer:

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1.2 Intended Use

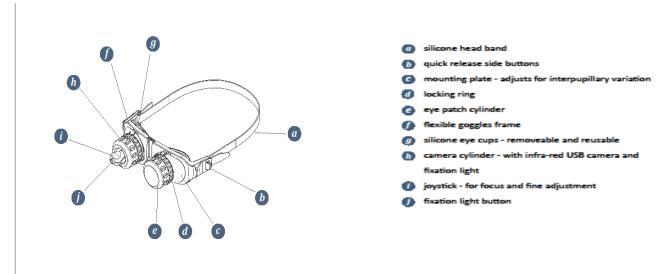
Vesticam2 IR video goggles are a medical device intended to capture eye movements. Viewing and recording eye movement requires a separate device and software.

Vesticam2 IR video goggles are intended to be used by trained health professionals. The health professional remains entirely responsible for their choice of specific bedside tests. The target population is 12+ years of age.

Vesticam2 IR video goggles do not have a measuring function and are not intended by the manufacturer to measure a physiological or anatomical parameter. The device provides no diagnosis or diagnostic recommendations and does not provide specific treatment or treatment suggestions.

1.3 Product Description

(a) System Configuration



Vesticam2 IR video goggles are available as monocular (with one camera unit) or binocular (with two camera units).

A separate device is required for powering the goggles and the viewing or recording of eye movements.

(b) Included Parts

Vesticam2 IR video goggles are supplied with:

- 1. **Goggles flexible face plate and mounting plate**: comfortable, hypo-allergic face frame and quick release buttons.
- 2. Camera cylinder with internal fixation light. Light tight and reversible for use on either eye. Easily adjusted in all planes while in situ to suit most inter-pupillary distances and corneal depths. The camera comes with a light weight, resilient 90mm cable, which can be extended to 2.9 m with supplied extension lead.
- 3. **Eye cover cylinder**. Can be slipped into place without removing goggles to provide light tight seal for tests requiring fixation removed.
- 4. USB adaptors
- 5. 3m extension lead (USB C to C)
- 6. Compact Portable Case
- 7. Spare silicone eye cups and spare headband

Optional:

8. camera unit and dual extension lead (to allow for binocular use)

(c) Minimum IT Requirements for Monocular Viewing

Vesticam2 Monocular can be used with an android smartphone, tablet or a PC/laptop/Mac.

1. Android Phone or Tablet

System requirements:

Android Phone/Tablet	
Application	Monocular / Single camera
Operating System	Android 10+ with OTG
Processor	Octa-core 2.0 GHz or faster
RAM	3GB+
USB Ports	USB Type-C or USB Micro B
Storage	32GB +
Microphone	Built in
Speaker	Built in
External Room Camera	N/A
Internet Connectivity	Not required

2. PC/Laptop/Mac (see 2.2.3)

An extension lead with adaptors (for use as needed) is included in each Vesticam2 case. This allows clinicians to connect directly to PC/Laptop/Mac.

Vesticam2 requires separate standalone software for eye movement viewing or recording on a computer.

Please check with your organization that any software used meets its security requirements.

System requirements:

PC / Laptop / MacBook, Mac Pro	
Application	Monocular / Single camera
Operating System	Windows 10+, macOS Sierra 10.12+
Processor	Core i5, i7, equivalent or higher
Graphics card	A dedicated graphics card (GPU) is not required but is
	recommended
RAM	4GB+
USB Ports	USB Type-C or USB-A
	Use bluetooth compatible mouse to free up a USB port if needed.
Storage	32GB+
Microphone	Built in
Speaker	Built in

External Room Camera	A room camera is optional. The room camera can be added by
	using the laptop's built-in camera or using an external USB
	camera & tripod.
Internet Connectivity	Not required.

(d) Minimum Requirements for Binocular Viewing

Vesticam2 Binocular requires a PC/laptop/Mac.

Hardware requirements for using binocular IR video goggles:

- Two camera units (with fixation light)
- Dual Micro-B extension 2.0m lead
- Adapters connection to PC/Laptop/Mac

Vesticam2 Binocular IR video goggles can be purchased outright as a goggle faceplate, 2X camera units, dual cables adaptors etc. **or** by upgrading an existing Vesticam2 Monocular solution by adding an extra camera unit and dual extension leads.

A room camera is optional. The room camera can be added by using your laptop's built in camera or using an external USB camera and tripod.

Binocular Enabling Technology:

System requirements:

PC / Laptop / MacBook, Mac Pro		
Application	Binocular / Dual Camera	
Operating System	Windows 10+, macOS Sierra 10.12+	
Processor	Core i5, i7, equivalent or higher	
Graphics card	A dedicated graphics card (GPU) is not required but is	
	recommended	
RAM	8GB+	
USB Ports	USB Type-C or USB-A	
	Binocular viewing requires two dedicated USB-A and/or USB	
	Type C ports (USB 2.0 or USB 3.0).	
	Use a Bluetooth compatible mouse to free up a USB port if	
	needed.	
Storage	32GB+	
Microphone	Built in	
Speaker	Built in	
External Room Camera	A room camera is optional. The room camera can be added by	
	using the laptop's built-in camera or using an external USB	
	camera & tripod.	
Internet Connectivity	Not required	

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1.4 WARNINGS, PRECAUTIONS, & RECOMMENDATIONS

- Protection against electric shock: Determined by the electric shock protection type of the device connected to the USB
- Mode of operation: Continuous
- Suitable for use in an oxygen rich environment: No

STORAGE AND TRANSPORTATION CONDITIONS

To maximize the life of the Vesticam2 IV video goggles:

- Packaged equipment should be stored in a well-ventilated environment without corrosive gases.
- Handle with care and keep away from rain and electrical shock during transportation.
- For short-distance handling, it is recommended that the goggles are kept in their custom case.
- For long-distance handling, it is recommended to be packaged in a multi-layer corrugated box.

Usage outside of the ranges below 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,	80 kPa - 106 kPa
		Keep Dry.	
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

The manufacturer is not responsible for any damages incurred to the device if these restrictions are not followed.

CONTRAINDICATIONS

Use of Vesticam2 IR video goggles may be contraindicated in patients with recent facial trauma, broken skin, eye surgery, or blindness, and in patients who are infectious.

Persons proposing to use Vesticam2 IR video goggles must rely on their own medical, clinical and legal judgment, and such persons shall be solely responsible for the suitability of Vesticam2 IR video goggles in any situation.

Do not use if the Vesticam2 IR goggle unit is showing any signs of damage. If you are unsure, please contact Vesticam support (support@vesticam.com). See also section 4.1 Care and Maintenance.

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 2.1.1 to confirm that the goggles, computer, and any 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 incompatible components or components not manufactured or supplied by Vesticam Pty Ltd.

CLINICAL SAFETY WARNINGS AND RECOMMENDATIONS

Vesticam2 is to be used by health professionals only.

- 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 head strap on these types of patients.
- Only use Vesticam IR video goggles on intact skin.
- Attend to the position of the cable to avoid patient and clinician entanglement, using the cable clip and adjusting the cable position as needed during position changes or movement.
- Do not leave the patient alone while goggles are in place.
- Always clean the goggles before each patient use, following the recommendations for cleaning in Section 4.1.2.
- Do not allow the electronics components or cables to come into contact with water.

ELECTRICAL SAFETY WARNINGS

- Handle with care. If your Vesticam unit is damaged from being dropped or impacted, contact support@vesticam.com . Do not use if any damage is suspected or if the system is showing visible damage.
- Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components.

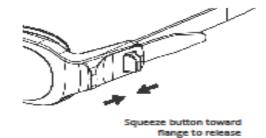
2. Setting Up and Using Vesticam2 Monocular IR Video Goggles

Vesticam IR video goggles are easy to set up and use. See also Quick start manual.

SETTING UP VESTICAM IR GOGGLES ON YOUR PATIENT

- 1. Start with the camera cylinder and eye patch cylinder off...not attached to the goggles
- 2. Follow your normal patient hygiene pathways when applying the goggles. Use effective alcohol/anti-microbial wipes to clean goggles face plate, silicone eye cups and head band before and after each patient. Do not use on patients with infective disorders. (see also 3.1.2 "Cleaning and avoiding contamination" and Appendix 1 full instruction manual)

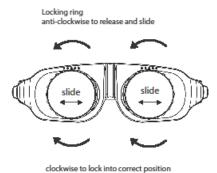
The goggles are comfortable, high quality and flexible enough to fit most face shapes and sizes. Loosen the head strap by squeezing the quick release buttons and the goggles flange together



3. Help your patient to position the goggles for comfort. Most patients can do this themselves, like swimming goggles.

4.

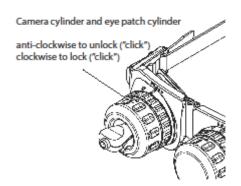
To adjust for interpupillary distance, loosen the locking rings at the front of the mounting plate by turning anti-clockwise. Allow the mounting plates to slide into a comfortable position on your patient's face. Your patient should be able to see out of both viewing holes.



- 5. Pull rubber tags at each side of goggles to tighten gently, and then lock the mounting plates into place by firmly tightening the locking rings in a clockwise direction.
- 6. Hold the camera cylinder so that the lead is exiting the cylinder at "5 o'clock". Insert the camera cylinder into the mounting plate and rotate it clockwise until the camera cylinder "clicks" and locks into place (lead should be at "6 o'clock" when locked).

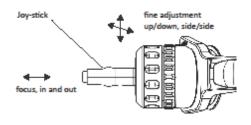
7.

If you cannot see your patient's eye completely on the viewing screen, simply loosen the locking ring, realign the camera, and retighten the locking ring.



8.

TO FOCUS and fine tune eye position use one hand to stabilize the camera cylinder and the other hand to move the camera joystick up / down and side / side until the eye image is central on screen. Firmly pull camera joystick in / out to focus the image of the iris and edge of the pupil. The camera cannot be pushed into the eye as there is an end stop. It is important to focus the eye to ensure that possible torsion is visible



9. To deny vision, slip the eye patch cylinder (e) into the remaining mounting plate. Twist the cylinder clockwise and "click" to lock into place.

TO ALLOW FIXATION:

10. Press the small button (10) at the end of the joystick to activate the fixation light. When the button is IN, the fixation light is ON. When the button is OUT, the fixation light is OFF.

NOTE: the fixation light will only work when the camera is plugged in to a phone, tablet or computer.

Vesticam2 goggles are designed to be light tight. Adjust the goggles on your patient so they are comfortable, secure, light tight, and firm.

If you have questions or concerns, please check www.vesticam.com/support or email support@vesticam.com

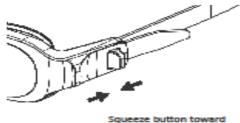
3. Setting up and Using Vesticam2 Binocular IR Video Goggles

The following section is for clinicians wanting to use Vesticam2 for binocular viewing. With a PC/Laptop/Mac that meets the minimum requirements and using separate standalone software and the Vesticam2 Binocular IR video goggles, clinicians can view both of the patient's eyes at the same time.

SETTING UP THE BINOCULAR IR GOGGLES ON YOUR PATIENT

- 1. Start with the camera cylinder and eye patch cylinder off...not attached to the goggles
- 2. Follow your normal patient hygiene pathways when applying the goggles. Use effective alcohol/anti-microbial wipes to clean goggles face plate, silicone eye cups and head band before and after each patient. Do not use on patients with infective disorders. (see also 3.1.2 "Cleaning and avoiding contamination" and Appendix 1 full instruction manual)

The goggles are comfortable, high quality and flexible enough to fit most face shapes and sizes. Loosen the head strap by squeezing the quick release buttons and the goggles flange together

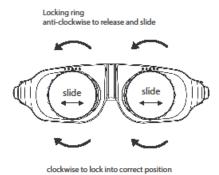


Squeeze button toward flange to release

3. Help your patient to position the goggles for comfort. Most patients can do this themselves, like swimming goggles.

4.

To adjust for interpupillary distance, loosen the locking rings at the front of the mounting plate by turning anti-clockwise. Allow the mounting plates to slide into a comfortable position on your patient's face. Your patient should be able to see out of both viewing holes.



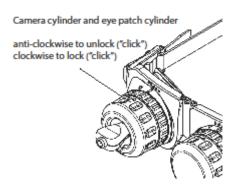
- 5. Pull rubber tags at each side of goggles to tighten gently, and then lock the mounting plates into place by firmly tightening the locking rings in a clockwise direction.
- 6. Hold the camera cylinder so that the lead is exiting the cylinder at "5 o'clock". Insert the camera cylinder into the mounting plate and rotate it clockwise until the camera cylinder "clicks" and locks into place (lead should be at "6 o'clock" when locked).

If you cannot see your patient's eye completely on the viewing screen, simply loosen the locking ring, realign the camera, and retighten the locking ring.

7.

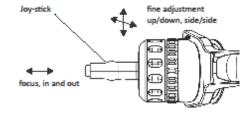
8.

torsion is visible



TO FOCUS and fine tune eye position use one hand to stabilize the camera cylinder and the other hand to move the camera joystick up / down and side / side until the eye image is central on screen. Firmly pull camera joystick in / out to focus the image of the iris and edge of the pupil. The camera cannot be pushed into the eye as there is an end

stop. It is important to focus the eye to ensure that possible



9. To deny vision, slip the eye patch cylinder (e) into the remaining mounting plate. Twist the cylinder clockwise and "click" to lock into place.

10. Repeat the instructions above (7 -9) to position the second (left) camera.

- 11. If you wish to use "room view", position the room camera (optional extra) or computer external camera to view your patient.
 - 12. TO ALLOW FIXATION press the small button (10) at the end of the joystick to activate the fixation light. When the button is IN, the fixation light is ON. When the button is OUT, the fixation light is OFF. NOTE: the fixation light will only work when the camera is plugged in to the phone, tablet or computer.

Vesticam2 goggles are designed to be light tight. Adjust the goggles on your patient so they are comfortable, secure, light tight, and firm.

If you have questions or concerns, please check www.vesticam.com/support or email support@vesticam.com

4. Maintenance/General Information

4.1 How to care for your Vesticam Unit

4.1.1 General care

(see also 1.3 WARNINGS, PRECAUTIONS, & RECOMMENDATIONS)

- Avoid dropping your Vesticam unit
- Always keep the camera dry
- Usage outside of the ranges below 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,	80 kPa - 106 kPa
		Keep Dry.	
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

- As Vesticam2 IR goggle units are not therapeutic or diagnostic tools and do not provide a measurement or trace, they do not require regular calibration.
- For Vesticam2 repair contact<u>support@vesticam.com</u>
- Check your Vesticam unit before each use. Do not use the Vesticam IR goggle unit if it is showing any signs of damage. If you are unsure, please contact Vesticam support (support@vesticam.com)
- Take care when connecting and disconnecting the camera or any adaptors to your phone/tablet/laptop. The USB ports can be damaged if not used correctly
- Please follow your normal service and maintenance pathways of the charging attachments and USB 240v wall socket charger supplied with your phone/tablet/laptop.

4.1.2 Cleaning and Avoiding Contamination

Vesticam2 is listed as a medical device which can be used in contact with intact skin (like stethoscopes, BP cuffs, and head and chin rests as used by optometrists).

These guidelines are aimed at providing information to assist Vesticam IR video goggle users in minimising the risk of transmission of infection. Persons proposing to use Vesticam IR video goggles for medical purposes must rely on their own medical and legal judgment. Vesticam IR video goggle users are solely responsible for implementing and following standard cleaning and infection control pathways as recommended by their association and/or workplace. Use of PPE and general environmental cleaning is not included in this manual and is the responsibility of the user.

- Follow your normal patient infection control pathways when applying Vesticam goggles
- Use of PPE and general environmental cleaning is the responsibility of the user
- Use of Vesticam IR video goggles may be contraindicated in patients who are infectious or have broken skin
- Remove the camera cylinder prior to cleaning
- Do not autoclave. Do not use hard or pointed objects to clean any part of the Vesticam unit
- Do not allow liquid to enter any part of the goggle camera unit.

4.1.3 Routine Clean and Check (Before Each Use)

Clean and Disinfect:

- 1. Wash hands before and after handling any parts of the goggles.
- 2. Use antimicrobial or alcohol wipes to clean the silicone eye cups, goggles mounting plate, headband, and any exposed surfaces before and after each patient. Allow 60 seconds to dry air.
 - Note: In case of infection, silicone eye cups can be removed, washed, air-dried, and reattached.
 Extra eye cups are supplied and available for purchase.

Check:

- 1. Inspect goggles for visible damage, especially USB connectors, cable, body unit, and camera shell.
- 2. Check eye cups are even. Ensure they are correctly in place by gently pulling on each one.
- 3. Verify the headband tightens and releases easily.
- 4. Eye cylinders should loosen, slide, and lock again easily.
- 5. Camera cylinders should click into place and remain stable. Swap sides and check again.
- 6. The eye cover (patch without a camera) should click in place but may wobble without affecting function.
- 7. The joystick should move in all directions with firm pressure and not shift when the cable is wobbled gently.
- 8. Press the joystick button to check the fixation light.

4.1.4 Full Clean and Maintenance Check

Cleaning:

Important: Remove the camera unit with the cylinder before cleaning. The camera must not be washed or submerged in water.

• Immerse the goggles mounting plate, eye patch, headband, and eye cups in a gentle cleaning detergent. Rinse and air-dry thoroughly.

Once Dry, Check:

- 1. Inspect goggles for damage, focusing on electronic parts like USB connectors, cables, and the camera shell.
- 2. Verify that the eye cups are securely in place by gently pulling on each one.
- 3. Confirm the headband tightens and releases easily.
- 4. Eye cylinders should move, slide, and lock without resistance.
- 5. Camera cylinders should click into place and remain stable. Swap sides and check again.
- 6. The eye cover should also click in place and may wobble slightly without impacting function.
- 7. Ensure the joystick moves in all directions with firm pressure and does not move when the cable is wobbled.
- 8. Test the fixation light by pressing the joystick button.
- 9. Check the camera by holding it over a recording screen to ensure all 7X IR LEDs appear as blue dots.
- 10. Hold the camera over white paper to check for lens damage or markings. The lens can be gently cleaned with a spectacle cloth wrapped around an earbud. Avoid rotating the lens, as it may affect focus.
- 11. Open the viewing software and hold the camera 8-10mm over printed material. The image should be clear and smooth without jumpiness during viewing or on playback.

4.2 Features and Specifications

TECHNICAL SPECIFICATIONS: Medica	l Equipment, Vesticam2 IR Video Goggles
	Wired
	USB Type-C, or
	USB-A [2.0+] for PC/Mac/Laptop (via supplied adapter), or
	USB Micro-B for Android with Micro-B (via supplied adapter)
Camera	Lead length = 1.0m + USB Extension lead 2.0m (supplied) = 3.0m
Carriera	Frame Rate: 30fps+
	Resolution: 1080P
	Illumination: IR LED lights x 7
	Fixation Light: LED (Green) x 1
	Focus adjustment: range 14mm
	Material: Nylon P12
Caralan and Balancal and	Interpupillary adjustment range: 90mm – 55mm
Goggles, camera cylinder and eye	Light tight seal: removable Silicon Gaskets (Left/Right)
patch cylinder	Fastening mechanism: Silicon band: Adjustable 230mm – 420mm
	Dimensions: 170mm (Width) x 50mm (Height) x 65mm (Depth)
	Weight: 130g
	USB Extension Lead 2.0m
Accessories (included)	USB OTG Adapters x 2
	Actual size Inner ear model (L)
	Dimensions: 210mm x 290mm x 90mm,
Case	Dual zip release with zipped internal pocket and internal foam
	compartments
For hinacular viewing	+ 2nd Vesticam Camera unit
For binocular viewing (optional extra)	+ Custom Dual USB Extension Lead 2.0m
	+ USB OTG Adapters x 2

4.3 Legal, Safety and Regulatory

Patent

Vesticam has a light and easy-to-use patented adjustment system.

The design of Vesticam2 is registered globally and owned by Vesticam Pty Ltd.

Trademark

The name "Vesticam" and the Vesticam logo are trademarked and owned by Vesticam Pty. Ltd.

Hold Harmless Clause

Persons proposing to use Vesticam2 IR video goggles for any medical purpose must rely on their own medical, clinical and legal judgment, and such persons shall be solely responsible for the suitability of our product for any medically-related applications.

The purchasing party and/or practicing clinician agrees to indemnify, defend, and hold harmless Vesticam Pty Ltd from and against any loss, cost, or damage of any kind, including loss or damage may arise from non-performance or defective performance; damage to real or personal property of purchasing parties or third parties; injuries suffered by employees, sub-contractors or the general public.

Warranty

30 day money back satisfaction guarantee on purchase.

If for any reason you are not satisfied with your Vesticam IR video goggles, simply e-mail support@vesticam.com in the first 30 days from delivery and we will fully refund your money (less shipping costs).

Full 2 year replacement warranty

Vesticam2 IR goggle manufactured parts come with a full two year guarantee, when used according to instructions.

Vesticam2 Pty Ltd will not be held under responsible if any repairs are made on the system components without authorisation by our support team, or if the unit is not used in accordance with the supplied instructions.

Liability is limited to the replacement cost of the relevant components. If you are based in Australia, our turn around on parts and servicing etc is 4 working days (2 days shipping each way).

Vesticam Pty Ltd specify a 3 year lifecycle for Vesticam2 IR video goggles (monocular and binocular).

4.4 Contacting support

Your feedback is valued and helps us to improve the Vesticam2 IR video goggle solution for clinicians.

If you have questions or concerns, please check www.vesticam.com/support or email support@vesticam.com We want your Vesticam2 IR video goggles working well for you!

4.5 Marking Details

Marking	Picture
Medical Device	MD
Serial Number	SN
Refer to Instruction Manual	(i
Manufacturer and Location	
Fragile	<u>.</u>
Keep electronics & cables dry	T
Warning	\triangle
Temperature	
Humidity	%
Atmospheric Pressure	\$• \$