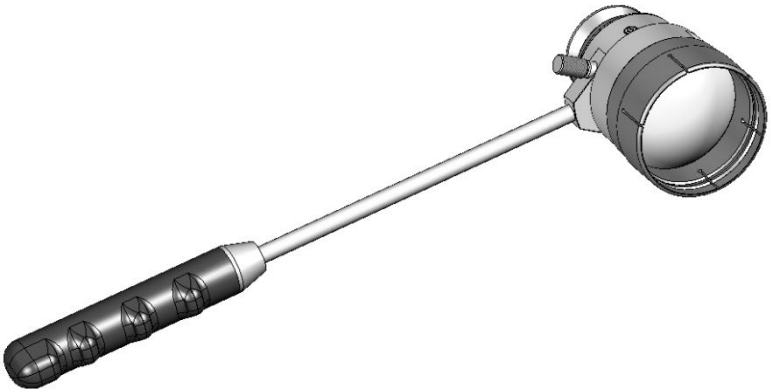
SAMSARA VISION

External Telescope Simulator

User Guide (EN)



MODEL:
2.8X – FF Light

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Important

This User Guide is subject to periodic review, update and revision.
The user of this product has sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, unauthorized service, damage, or alteration by anyone other than authorized Samsara Vision Ltd. service people.
The safety, reliability, and performance of this device can be assured only under the following conditions:

- The device has been used according to the accompanying operating instructions.
- All fittings, extensions, readjustments, changes, or repairs have been carried out by Samsara Vision Ltd.'s authorized representatives.

Throughout these instructions notes, cautions, and warnings are used to provide critical information needed before the device is used.

A **Note** is a statement that alerts the operator to particularly important information

A **Caution** is a statement that alerts the operator to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, and damage to the device or other property. The caution statement includes the precaution that should be taken to avoid the hazard.

A **Warning** is a statement that alerts the operator to the possibility of injury, death, or serious adverse reactions associated with the use or misuse of the device.

Intended purpose

The External Telescope Simulator (ETS) is a handheld magnifier, which provides an Implantable Miniature Telescope (IMT™ by Dr. Isaac Lipshitz) candidate with a visual experience that mimics the implanted device. The ETS serves as a patient selection tool simulating magnification, relative scotoma minimization, field of view, and retinal illumination associated with the telescope prosthesis. Candidates have the opportunity to use the ETS monocularly to better understand what their visual status might be like with the telescope prosthesis, and better align their post-implantation visual expectations.
During the simulation, the practitioner first assesses whether the candidate responds to the magnification provided by the ETS (i.e., improved visual acuity). Next, the practitioner discusses with the candidate the relatively wide field of view, the differences in illumination inherent with telescopes, and the relative scotoma minimization. The practitioner can use the ETS to demonstrate these important factors as a pre-operative assessment tool for visual acuity (VA) improvement.
The ETS is not intended for any other use besides indicated in this paragraph. The device shall be used by certified optometrist.

ETS Package Contents

The ETS package contains the following items (Fig. 1):

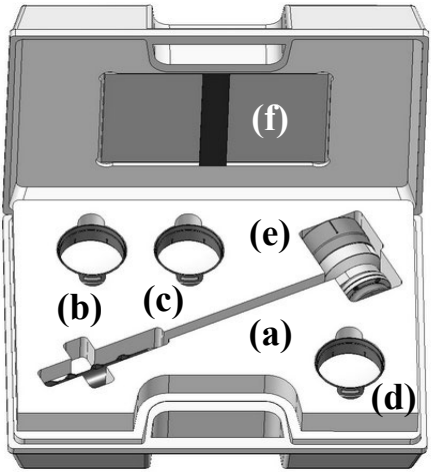
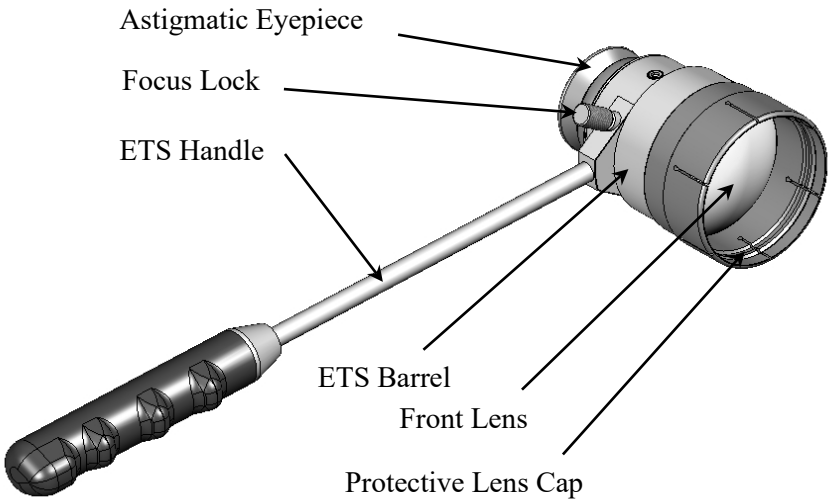


Fig. 1

- External Telescope Simulator: ETS model 2.8X – FF Light (a)
- Three Reading caps: +1.5D and +5.0D optical power lenses (b and c), and a 60% absorption (40% transmission) dark filter (d)
- Protective lens cap (attached to the front of the ETS barrel) (e)
- External Telescope Simulator User Guide (f)



Technical Specifications

Model	ETS 2.8X – FF Light
Device type	Handheld telescope magnifier
Magnification	2.7× ± 10%
Field of view (nominal)	20 degrees
Optimal focusing distance	3m
Depth of field	1.7m – Inf
Interchangeable Reading caps with lenses	+1.5D and +5.0D
Reading cap simulating the retinal illumination associated with the implantable telescope	60% absorption (40% transmission) filter
Objective lens diameter	60mm
Ocular lens diameter	30mm
Overall length	371mm with handle
Weight (±10%) Not including reading cap	308g

Handling and Viewing Instructions

Handling the ETS

Handle the ETS with care. The ETS is a glass optical device. To avoid scratching or dirtying the optical surface, do not lay the telescope down on its lens and avoid touching the lens. Clean the lens gently using a soft, fiber-free, cloth. If necessary, use a 70% isopropyl alcohol solution to remove fingerprints.

Patients should not wear corrective glasses while using the ETS. Focusing the ETS accounts for myopia and hyperopia limited by the indication for use. If the patient has a high astigmatism, then use of the astigmatism-correcting trial lens held in the ETS eyepiece is recommended. Note that the further away the ETS is from the eye, the smaller the field of view becomes.

The clear aperture of the telescope prosthesis is fixed at 3.2mm. When using the ETS, if the patient's pupil diameter appears to be dilated wider than 3.2mm, the image the patient sees through the ETS may be brighter than what the telescope prosthesis may achieve. Using the lens cap with the tinted filter - 60% absorption (40% transmission) can help to demonstrate lower image brightness to the patient.

The telescope prosthesis does not allow for peripheral vision in the implanted eye. The ETS flexible rubber eye guard helps block out any peripheral light, which allows the patient to reach a realistic image.

Fig. 2

Guide the patient to hold the ETS as described in the ***Patient Use*** section of this User Guide to avoid inadvertent dropping of the ETS or banging of the orbit. The ETS is held close to the eye (Fig. 2).

Instruct the patient to carefully press the flexible rubber eye guard to the orbit to securely block out any peripheral light.

Clean the rubber eye guard with a 70% isopropyl alcohol solution before and after use on every patient.

Focusing

Prior to focusing the ETS, confirm that the Focus Lock screw is released.

To focus the ETS, rotate the front lens until the desired focus is achieved (Fig. 3). Clockwise rotation focuses the telescope on targets that are closer to the patient; counterclockwise rotation focuses the device on targets further away. Once the desired focus has been achieved, re-lock the telescope by tightening the Focus Lock screw. Simply release the Focus Lock screw to unlock the focus.

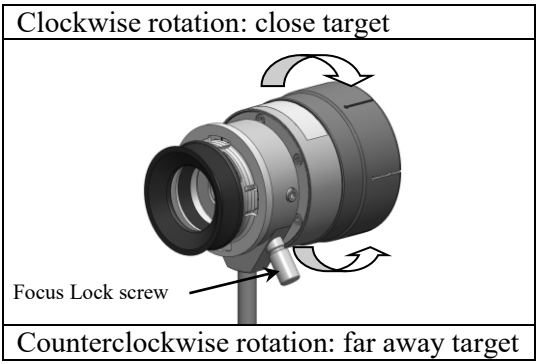


Fig. 3

Reading Cap and Lenses

Lens caps are provided for visual activities to be performed at 1.5 meter or less. Four caps are supplied with the ETS: +1.5D and +5.0D optical power lenses (reading caps) and a dark 60% absorption (40% transmission) filter (tinted filter cap) and protective cap (without lens, used when there is no other cap on the telescope). Slide the cap with the appropriate lens for the viewing distance over the front barrel of the ETS. Clean the lenses with a soft, fiber-free, cloth. If necessary, use a 70% isopropyl alcohol solution to remove fingerprints.

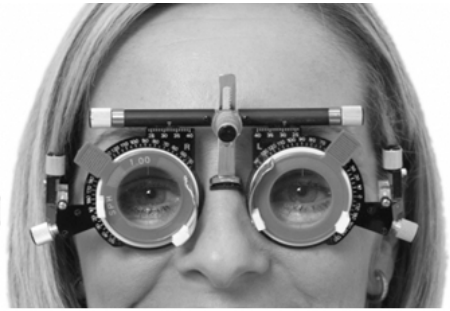
Eyepiece that holds the Astigmatic Correcting Trial Lens

The ETS eyepiece is used for holding the astigmatism-correcting trial lens for examination of patients that have astigmatism (Fig. 4).

Fig. 4

Remove the eyepiece. Insert the astigmatism-correcting trial lens into the slot in the internal edge of the eyepiece (See Fig.5). Then attach the eyepiece to the back lens holder and press it gently until a click indicates that the eyepiece has locked in place. The scale seen through the small window on the eyepiece outside flange indicates the angular position of the horizontal axis of the correcting lens. Rotating the eyepiece allows fine adjustment to the angular position of the lens required for correcting astigmatism.

Fig. 5



Right eye

Step #1: measure the astigmatic values

Step #2:
Place "AS IS" the trial lens into the ETS to correct the astigmatism of the patient's <u>right eye</u>

Left eye

Step #1: measure the astigmatic values

Step #2: replace with equivalent lens, same value but with right eye handling tab

Step #3:
Place lens into the ETS to correct the astigmatism of the patient's <u>left eye</u>

In all cases keep lens facing optometrist
Note: Do not use lenses that rotate in their frame

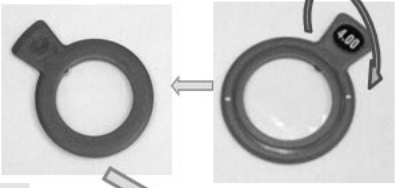
Right eye

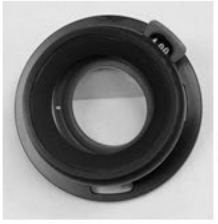
Step #1: measure the astigmatic values

Step #2:
Place "AS IS" the trial lens into the ETS to correct the astigmatism of the patient's right eye keep lens facing optometrist

Left eye

Step #1: measure the astigmatic values





Step #2:
Flip the left trial lens and place it into the ETS keeping the lens facing the patient to correct the astigmatism of the patient's left eye
Note: Do not use lenses that rotate in their frame

Viewing Instructions

Viewing through the ETS should be performed without corrective glasses.

Field of view simulation should always be performed without corrective glasses. Hold the ETS as close to the eye as convenient for maximum accuracy.

Distance Viewing

For all distance viewing tasks remove the Protective Lens Cap using a pull and twist motion and slide the cap with the 60% absorption filter all the way down the ETS barrel. Verify the ETS lens surface is clean. Turn the front lens (entire telescope barrel) counterclockwise until it stops. Slowly rotate the barrel until the image is in focus.

Intermediate Viewing

Ensure that the lens surfaces are clean. For distances of 0.5 – 1.5 meter, it is recommended to use the reading cap of +1.50. Slide this reading cap all the way down the ETS barrel. Preset the front lens by turning it counterclockwise until it stops. Looking through the ETS, slowly rotate the barrel until the image is in focus. If the object is further away than 1.5 meter, remove the reading cap and follow the same focusing instructions.

Near Viewing

Ensure that the lens surfaces are clean. Choose an appropriate reading cap lens and slide the reading cap all the way down the ETS. Preset the front lens by turning it counterclockwise until it stops. Confirm that the viewable target is approximately 35 centimeters away and then turn the front lens slowly clockwise until the image is in focus.

Do not attempt to focus the ETS for near viewing without attaching the reading cap with the +1.50 or +5.00 reading lens.

Patient Use

Demonstrating the ETS

Before allowing the patient to use the ETS, walk through the following steps together:

1. *Demonstrate the ETS*. Make the patient aware of the weight, handle grip, and focus adjustment features. Explain the potential leverage that could cause the device to swing back towards the patient if the barrel is not firmly grasped.

2. *Hold the ETS*. Demonstrate to the patient how to hold the ETS with two hands, one hand on the handle, and the other around the telescope barrel. The hand holding the telescope barrel should coincide with the side of the eye evaluating the device (i.e., if viewing through the right eye, the right hand holds the telescope barrel). When handing the ETS to the patient, the practitioner should hold the handle mid-shaft so the patient can grasp the handle grip with one hand and the telescope barrel with the other (Fig. 6).

Fig. 6

3. *Raise the ETS to the eye.* When viewing with the right eye, instruct the patient to hold the handle with the left hand and place their right hand around the telescope barrel. Slowly bring the ETS close to the right eye. Gently press the flexible rubber eye guard to the orbit to securely block out peripheral light and maximize the field of view (Fig. 7).

Fig. 7

To use the ETS with the left eye, use the above technique, this time holding the handle with the right hand and the telescope barrel with the left hand.

4. *Adjust the focus*. Show the patient the location of the Front Lens barrel and explain how to rotate it for focusing. The ETS is held steady, and the target object is sighted. Explain to the patient that they should preset the front lens by turning it counterclockwise until it stops and then turn the lens clockwise until the viewable image appears in focus.

Patient's Visual Tasks

Distance Visual Tasks
Confirm that the lens cap is fitted with the tinted filter - 60% absorption (40% transmission) and the objects viewed are farther than 10 feet away from the patient.

Seeing Faces or Watching Television
To simulate seeing the faces of people sitting across a table or to simulate watching television, the ETS performs best when focused on an object fewer than 3 meters away. At this focal position, all objects in the range of 1.5 to 10 meter should be in focus. To achieve realistic retinal illumination, use the cap with the 60% absorption filter. Again, adjust the focus ring to achieve optimal results. If a desired object is closer than 1.5 meter, use the +1.50 lens and focus ring to obtain optimal results. There is no need to use the absorption filter for these tasks, but it can be used as desired by the practitioner for demonstration of illumination.

Indoor and Outdoor Visual Tasks
Indoor and outdoor visual tasks may include looking across a room to see a face or object and looking through a window to see a distant object. At these distances, objects will be out of focus with a reading cap in place. Ensure near reading lenses have been removed and the tinted filter cap is on the telescope barrel at this time. Focusing the ETS at a distant object seen through a window, for instance, will optimally focus objects clearly placed at 1.5 to 10 meter and beyond. Adjusting the focus by rotating the telescope barrel at any stage may improve the image. Ensure adequate illumination.

Reading and Near-Vision Tasks
The +5.00 Diopter optical power lens is recommended for reading. When using the reading cap, the ETS should be positioned 19 centimeters away from the target for optimal results. The focus adjustment may also be used to enhance viewing. To view a computer screen with the ETS, consider using the +1.50 or +5.00 reading lenses.

Troubleshooting

a. If focusing is not smooth or the lens is stuck: make sure that the Focus Lock screw is released.
b. If Astigmatism correcting trial lens cylindrical axis is incorrectly aligned vertically as indicated by the zero angle on the scale: remove the correcting lens and reinsert it with the correct orientation.

Reporting

Please report to manufacturer without delay:

Any malfunction or deterioration in the characteristics and/or performance of an ETS device, as well as any customer complaints including quality complaints, adverse events and other medical device related observations.

The report should include the details of the complaint/event, the applied therapy, the product type/model, and the serial number of the device used.

Symbols

Symbol	Meaning
	Catalogue number
	Manufacturer
	Date of manufacture
	Authorized representative in the European Community
	CE Marking
	UK Conformity Assessed
	Serial number
	Medical device
	Consult instructions for use
	Model number
	Unique device identifier

Standards Compliance

EN ISO 13485: 2016
21 CFR Parts 820
MDR 2017/745
EN ISO 14971: 2019 / ISO 14971: 2019
EN ISO 15223-1: 2016 / ISO 15223-1: 2021
UK Medical Device Regulations 2002 (MDR 2002)

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Version control code RM00873-02 Rev.7 Revision Date: June 2022