

EIDON UWF Module User Manual

MANUAL INFORMATION

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The information in this manual is correct at the date of issue. The accessory configuration can change as product improvements and this manual may not exactly depict your accessory. Please contact the local distributor if you have any questions about differences. The original language of the EIDON UWF Module User Manual is English: in case of conflict of terms, the English version shall prevail. In case of further information for the EIDON Family devices, refer to the EIDON Family User Manual.

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1. **INTRODUCTION**

Congratulations for choosing EIDON UWF Module.

EIDON UWF Module¹ is an optional accessory to EIDON, EIDON AF and EIDON FA (EIDON Family devices) and it is compatible with all the EIDON Family devices imaging modalities. It is intended for extending the field of view of EIDON, EIDON AF and EIDON FA from 60° to 80° in a single shot (center of the eye convention: from 90° to 120°) and up to 200° with the Mosaic functionality (center of the eye convention).

The key functional element of the EIDON UWF Module is EIDON Ultra-Widefield Lens (EIDON UWFL). It is compatible with all the EIDON Family devices' imaging modalities (color, infrared and autofluorescence imaging and fluorescein angiography).

The clinical interpretation of the images acquired by the EIDON Family devices equipped with EIDON UWF Module is restricted to licensed eye care practitioners: the process of making a diagnosis is the responsibility of the eye care practitioner. It is recommended for the end user to carefully read this User Manual to be informed and trained before the use.



Federal laws (US) restrict this device to sale by or on the order of a physician or a properly licensed practitioner.



For detailed and complete information about the EIDON Software, please refer to the EIDON Family User Manual (same user manual for all the models of the EIDON Family devices)

¹ Check that EIDON UWF License (Ref. LFLAWFL001) is active before the first use of the EIDON UWFL – Ultra-Widefield Lens.

The EIDON UWFL integrates a threaded gear to be easily mounted on the frontal lens of the EIDON Family devices. It is designed to be easily mounted and dismounted by the end user thanks to the cap that allows both to hold the lens and to cover the glass surface preserving it from damage, dirt, dust, and scratches.

The EIDON UWFL works with a dedicated EIDON Software feature² (software version ≥ 4.0) that allows EIDON UWF image acquisition and storage.

2. **CONTENT LIST**

Each EIDON UWFL Transport case includes:

- EIDON UWFL – EIDON Ultra-Widefield Lens
- EIDON UWFL Cap
- Cleaning solution
- Cleaning tissue
- This User Manual



Fig. 1 – Example of main contents of the EIDON UWFL Transport case

² Available under license only. To request the EIDON UWF License, refer to your CenterVue local distributor.

3. FIRST INSTALLATION OF THE EIDON UWF Module

The first installation and first calibration of the EIDON UWF Module shall be done by CenterVue Authorized Service Center only: contact your CenterVue Authorized Service Center or CenterVue Local Distributor to book an installation visit.



Please do not use the EIDON UWF Module if your EIDON device is not upgraded with EIDON software³ version ≥ 4.0 .

It is not possible to use the same EIDON UWF Module with more than one model of the EIDON Family devices.

4. HOW TO MOUNT AND REMOVE THE EIDON UWFL

- Remove the EIDON UWFL from the EIDON UWFL Transport case, by holding it from the EIDON UWFL Cap, which is already mounted on the lens. Use the EIDON UWFL Cap to cover and protect the glass surface to prevent damage.
- Holding the EIDON UWFL Cap, place the EIDON UWFL in front of the frontal lens of the EIDON Family device and screw the EIDON UWFL by rotating clockwise. Always hold the EIDON UWFL Cap to maintain the lens in the proper position.
- Screw the EIDON UWFL carefully until to the end-stroke: once in the proper position the cap will turn freely.
- Remove the external fixation if mounted or take care to avoid collision with EIDON UWF Module.
- Remove the EIDON UWFL Cap from the EIDON UWFL before starting and exam.
- Refer to section 5 for climatic preconditioning.
- When the EIDON Family device is not in use and the EIDON UWFL is mounted, re-apply the EIDON UWFL Cap to protect the EIDON UWFL from damage, dirt, dust, and scratches.

³ To request the EIDON UWF Module and for EIDON device upgrading, please refer to your CenterVue local distributor.

- To remove the EIDON UWFL from the EIDON Family device place the EIDON UWFL Cap on the Lens and rotate it counterclockwise.
- Place the EIDON UWFL (with the EIDON UWFL Cap mounted) in the EIDON UWFL Transport case.

5. **EIDON UWF Module WARNING AND PRECAUTION**

The following warnings and precautions⁴ are important to use an EIDON Family device with EIDON UWFL in safety:



- EIDON UWF Module is intended for use by eye professional professionals only and the clinical interpretation of the images is restricted to licensed eye care practitioners only.
- EIDON UWF Module is intended to be used in combination with EIDON, EIDON AF, EIDON FA only.
- It is recommended for the end user to carefully read this User Manual and the EIDON Family User Manual to be informed and trained before the use.
- EIDON UWFL cannot be used with other ophthalmic devices or optical products than the EIDON Family devices: any misuse than the EIDON UWF Module intended use exclusively under end user's responsibility. CenterVue is not responsible for any dangerous light emissions levels and or injuries caused by improper mechanical coupling.
- Do not use the EIDON UWFL if it is damaged: sharp edges and/or glass splints could result in case of accidentals falls or bad handling. Please check the EIDON UWFL condition⁵ before mounting it on a EIDON Family device and before performing the exam.
- Do not force EIDON UWFL mounting if the internal threaded is damaged⁶.
- EIDON UWFL needs to be operated and stored under the same environmental conditions of

⁴ The following warnings and precautions are to be intended in addition to the ones reported in the EIDON User Manual.

⁵ Verify the absence of dirt, dust, and scratches.

⁶ In this condition EIDON UWFL lens can be difficult or impossible to be screwed: please contact to your CenterVue local distributor or CenterVue Authorized Service Center.

EIDON Family devices: please refer to EIDON Family User Manual for further details.

- EIDON UWF Module could have a shift in performance if used without preconditioning. In general EIDON UWF Module needs same preconditioning for optical components when moving from storage conditions to operating conditions to establishing stable climatic conditions for operation. Preconditioning is achieved by mounting the EIDON UWFL on the EIDON Family device and waiting a minimum time of 10 minutes before performing the first exam, to avoid possible moisture condensation.
- **Report any serious incident to CenterVue and to the competent authority of the Member State in which the user and / or patient is established.**

6. PREPARING THE PATIENT

This section explains how to prepare the patient for the exam with EIDON UWFL.

The use of the EIDON UWFL does not change the non-mydratic use of the EIDON Family devices (minimum pupil diameter 2.5 mm). EIDON Family devices used in combination with EIDON UWF Lens compensate for a patient's spherical refractive error in the range from -8 to +8 Diopters

The presence of EIDON UWFL reduces the EIDON Family devices working distance from 28mm to 16 mm.



Before starting an exam, please check the following recommendations to assure patient's comfort:

- Patient should sit in a comfortable position, with the forehead and chin in firm contact with the rests and the head looking straight (see Fig. 2 below):
- In case of patient with deep-set or small orbits, the EIDON UWFL holder may get in contact with the eyebrow arches or with the nose: this contact is a normal exam condition for this type of patient. In this case, ask to the patient turning the head to the right when testing the left eye, and to the left when testing the right eye (see Fig. 3 below).



Fig. 2 – Patient position during exam during exam with EIDON UWF Module



Fig. 2 – Position o a patient with deep-set or small orbits during an exam with EIDON UWF Module

7. **PERFORMING THE EXAM**

To perform the exam with EIDON UWF Module as made per standard exam without UWFL, please refer to EIDON Family User Manual for further details and information.

8. **REVIEWING EXAM IMAGES**

Review of retinal images acquired with EIDON UWF Module is made as per standard images review used on EIDON Family devices without the EIDON UWF Module installed: please, refer to EIDON Family User Manual for further details and information.

9. **SETTINGS**

There are no special and/or additional settings related EIDON UWF than the EIDON Family devices' ones: please, refer to EIDON Family User Manual for further details and information.

10. **TECHNICAL SPECIFICATIONS**

Technical specifications below are intended to be in addition to the EIDON Family devices' ones: please, refer to EIDON Family User Manual for further details and information.

Image acquisition: please, refer to EIDON Family User Manual for further details and information.

Field of view for single image:	80°(H) x 75°(V) captured in a single exposure (external eye notation) 120°(H) x 110°(V) captured in a single exposure (center of the eye notation)
Field of view for mosaic:	up to 200° (H) captured with 3 images horizontally (center of the eye notation)
Imaging modalities:	compatible with Color, Red-free, IR reflectance, Autofluorescence (AF) and Fluorescein Angiography (FA)
Working distance:	16 mm
Minimum pupil size:	2.5 mm
Focus adjustment:	-8 D to + 8 D

Other features:

Compatible with:	EIDON, EIDON AF, EIDON FA, with software version 4.0 or higher
Automatic operation:	auto-alignment, auto-focus, auto-exposure, auto-capture
Weight:	34g (0,08 lbs)
Size (W x H x D):	64mm x 64mm x 22mm (2.52" x 2.52" x 0.87")
IP classification:	IPX0

Specifications are subject to change without notice for improvement, as result of ongoing technical development.

11. **CLEANING**

To remove dust particles, the EIDON UWF Lens shall be cleaned using a small hand pump air blower. Only if really needed, for instance due to the presence of a fingerprint, the EIDON UWF Lens can be cleaned using the cleaning solution and the tissue provided with the EIDON UWF Lens.

12. **LABELLING INFORMATION**








Serial number of EIDON UWFL the is engraved in each EIDON UWFL as shown in the Fig.3. Also, you will find the same serial number and the other information (see the table below for the type of the information) in the label fixed on the internal surface of the EIDON UWFL Transport case (see Fig. 3)





Fig. 3 – Position of accessory's serial number on an EIDON UWFL and labelling position inside the EIDON UWF transport case

Labelling might be subject to changes depending on local regulatory requirements.

The meaning of the symbols adopted in the EIDON UWF Module labelling is as follows:

Symbol	Explanation
	Manufacturer Data
	Manufacturing Date (yyyymm where mm is 2-digit month and yyyy is 4-digits year)
	Accessory serial number (where nnnnn is 5-digit serial number)
	Catalogue number
	Refer to the User Manual
	CE mark: this accessory complies with the general safety and performance requirements the Regulation (EU) 2017/74 on medical devices
	Caution information

The meaning of the additional symbols adopted in this User Manual is as follows:

Symbol	Explanation
	General warning, read carefully
	Important information

13. DISPOSAL

EIDON UWFL Transport case with all its internal components (see section “Content List” of this User Manual) is composed by different materials, such as glass, ABS, aluminium, plastics.

In case of disposal, please separate the various materials and follow the laws and regulations regarding disposal or recycling for each material effective in your own Country.

14. INFORMATION ABOUT OPTICAL RADIATION HAZARD

14.1 Use in combination with EIDON and with EIDON AF

The use of the EIDON UWFL in combination with EIDON and with EIDON AF devices does not change their classification in relation to Light Hazard protection. EIDON and EIDON AF used in combination with the EIDON UWFL are in Group 1 according to ISO 15004-2:2007 (Ophthalmic instrument for which no potential light hazard exists).

14.2 Use in combination with EIDON FA

This section provides details on the optical radiation hazards related to the use of EIDON FA with UWFL. To grant the highest degree of protection to the patient, the values reported here are obtained considering the worst-case scenario of use.

The EIDON UWFL is spreading the same amount of energy on a wider surface of the retina; for this reason, the worst-case scenario is the use of the Device without the UWFL mounted.

The values reported below are calculated differently, depending on the applicable standard: for Light Hazard Protection, these standards are:

- for ISO 15004-2 (International), see section 14.3
- for ANSI Z80.36 (USA), see section 14.4

14.3 ISO 15004-2

Please refer to EIDON Family Devices User Manual

14.4 ANSI Z80.36

Please refer to EIDON Family Devices User Manual