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EIDON UWF Module

Instructions for Use

DOCUMENT INFORMATION

The information in this document is subject to change without prior notice and it is correct at revision date. The device configuration can change as product improvements are incorporated and this manual may not exactly depict your device: please contact the local distributor if you have any questions about differences.
The original language of this IFU is English. Should a conflict situation arise concerning a translated document, the English language version shall prevail.

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CENTERVUE S.P.A.
Via San Marco 9h, 35129 Padova – ITALY
www.icare-world.com

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1. General Information

Congratulations for choosing EIDON UWF Module.

EIDON UWF Module[1] is an optional medical device accessory of EIDON, EIDON AF and EIDON FA (EIDON Family devices) and it is compatible with all the EIDON Family devices imaging modalities. The intended purpose of the device is to extend the field of view of EIDON, EIDON AF and EIDON FA from 60° to 80°. EIDON UWF Module is indicated to be equipped on EIDON Family devices, to provide ultra-wide field retinal images used for diagnosis and monitoring of several retinal pathologies.

No contraindications and side-effects have been found for fundus photography, whether the devices have a standard or ultra-wide field of view. There are rare and limited discomforts as temporary glare and watery eyes during and after the picture acquisition. The intended end-users are heath care professionals with training in ophthalmology field (or equivalent).The device is to be used in a professional healthcare facility environment: Ophthalmic & Optometrist Offices , Ophthalmology Clinics , Hospitals , Research laboratories , Medical offices, Optical Shops, where a medical office is available. The device is suitable for use in domestic and home healthcare environment. EIDON UWF Module can be used by clinicians on any person able to remain seated, with the forehead placed on the forehead rest, alone or with the aid of another person The intended patient group is the same as the EIDON Family.

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 document to be informed and trained before the use.

[1] *Check that EIDON UWF License (Ref. LFLAWFL001) is active before the first use of the EIDON UWF Module (UWF= Ultra-Widefield)*

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 IFU (same for all the models of the EIDON Family devices)

The device 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 device works with a dedicated EIDON Software feature[3] (software version ≥ 4.0) that allows UWF image acquisition and storage.

[3] *Available under license only. To request the EIDON UWF License, refer to your local distributor.*

2. Content list

Each EIDON UWF Module includes:

- Lens and plastic bag
- transport case
- Lens Cap
- Cleaning solution
- Cleaning tissue
- Instructions for use

Fig. 1 – Contents of the EIDON UWF Module

3. First installation of the EIDON UWF Module

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

Please do not use the EIDON UWF Module if your EIDON device is not upgraded with EIDON software[4] version ≥ 4.0.
Please do not use EIDON UWF Module with more than one model of the EIDON Family devices
Please do not exchange lenses among devices since calibration and performace are loosed.

4. How to mount and remove the EIDON UWF Module

- Remove the lens from its Transport case, by holding it from the lens Cap, which is already mounted on the lens. Use the Cap to cover and protect the glass surface to prevent damage.
- Holding the Cap, place the EIDON UWF Module lens in front of the frontal lens of the EIDON Family device and screw it by rotating clockwise. Always hold the Cap to maintain the lens in the proper position.
- Screw the lens 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 Cap from the EIDON UWF Module lens before starting and exam.
- Refer to section 5 for climatic preconditioning.
- When the EIDON Family device is not in use and the EIDON UWF Module is mounted, re-apply the Cap to protect the lens from damage, dirt, dust, and scratches.
- To remove the lens from the EIDON Family device place the Cap on the Lens and rotate it counterclockwise.
- Place the lens (with the Cap mounted) in its Transport case.

[4] *To request the EIDON UWF Module and for EIDON device upgrading, please refer to your CenterVue local distributor.*

5. Safety Information

The following warnings and precautions[5] are important to use an EIDON Family device with EIDON UWF Module in safety:

1. EIDON UWF Module device is intended to be used in combination with EIDON, EIDON AF, EIDON FA only.
2. The device 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. Manufacturer is not responsible for any dangerous light emissions levels and or injuries caused by improper mechanical coupling.
3. Do not use the device if it is damaged: sharp edges and/or glass splints could result in case of accidentals falls or bad handling. Please check the device condition[6] before mounting it on a EIDON Family device and before performing the exam.
4. Do not force the device mounting if the internal thread is damaged[7].
5. The device needs to be operated and stored under the same environmental conditions of EIDON Family devices: please refer to EIDON Family IFU for further details.
6. 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 establish stable climatic conditions for operation. Preconditioning is achieved by mounting the device on the EIDON Family device and waiting a minimum time of 10 minutes before performing the first exam, to avoid possible moisture condensation.

The following precautions are important to use the device correctly:

[5] *The following warnings and precautions are to be intended in addition to the ones reported in the EIDON IFU.*
[6] *Verify the absence of dirt, dust, and scratches.*
[7] *In this condition the lens can be difficult or impossible to be screwed: please contact to your CenterVue local distributor or CenterVue Authorized Service Center.*

7. EIDON UWF Module is intended for use by eye helathcare professionals only and the clinical interpretation of the images is restricted to licensed eye care practitioners only.
8. Device-specific training is required: it is recommended for the end-user (operator) to carefully read this IFU to be informed and trained before the use.
9. Report any serious incident related to the device, the operator, the patient, or anyone else to Manufacturer and to the Competent Authority of the Country/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 UWF Module.

The use of the EIDON UWF Module does not change the non-mydriatic use of the EIDON Family devices (minimum pupil diameter 2.5 mm). EIDON Family devices used in combination with EIDON UWF Module compensate for a patient's spherical refractive error in the range from -8 to +8 Diopters
The presence of EIDON UWF Module 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 UWF Module lens 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. 3 – Position of 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 it, please refer to EIDON Family IFU 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 IFU for further details and information.

9. Settings

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

Image acquisition: please, refer to EIDON Family IFU 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")
Service life (lifetime):	The service life (lifetime) of the device is five (5) years from the date of manufacturing.

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

11. Cleaning

If needed, for instance due to the presence of a fingerprint, the EIDON UWF Module can be cleaned using the cleaning solution and the tissue provided with the device.

12. Labels and symbols

The serial number of EIDON UWF Module is engraved on each lens 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 Transport case (see Fig. 3)

Fig. 2 – Position of accessory's serial number on an EIDON UWF Module and labelling position inside the transport case

Labelling might be subject to changes depending on local regulatory requirements.
The label QR Code does not contain information for the end-user and it is intended for internal use only.

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

Symbol	Explanation
	Information about the Manufacturer
	Manufacturing Date (yyyymm where mm is 2-digit month and yyyy is 4-digits year)
	Serial number (where nnnnn is 5-digit serial number)
	Catalogue number
	EIDON UWF Module is a MD Accessory
	UDI number
	Refer to the IFU
	CE mark: this accessory complies with the general safety and performance requirements the Regulation (EU) 2017/745 on medical devices
	Caution information

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

Symbol	Explanation
	General Warning, read carefully
	Important Information

13. Disposal

Transport case with all its internal components (see section “Content List” of this IFU) 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 device 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 lens 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 the lens. 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 UWF Module 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 lens 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

14.2.1 ISO 15004-2STO

Please refer to EIDON Family Devices IFU.

14.2.2 ANSI Z80.36

Please refer to EIDON Family Devices IFU.

CENTERVUE S.P.A.

Via San Marco 9h, 35129 Padova – ITALY

Ph.: +39 049 5018399

Fax: +39 049 5018398

info@icare-world.com

www.icare-world.com

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