Ophthal – AI for the Ophthalmology

An innovative software medical device empowered with AI technologies that helps clinicians to evaluate the health conditions of patients affected by diabetic macular edema and healthy ones

What is Ophthal?

Ophthal is a stand-alone application that distinguishes itself for its unedited efficiency, use easiness and execution speed. Taking advantage of its innovative AI, you can get the segmentation of retinal OCT images and extract all these data:

➢ Hyperreflective Foci count

➢ Hard Exudates area

➢ Intra-Retinal Fluids area and volume

➢ Sub-Retinal Fluids area and volume

➢ ELM and EZ interruptions

➢ Tracking of all retinal layers

In this way, clinicians will have less fatigue and time to spend diagnosing and monitoring retinal pathologies. They are also simplified in evaluating the clinical evolution of pathologic patients' conditions and their therapy-effectiveness.
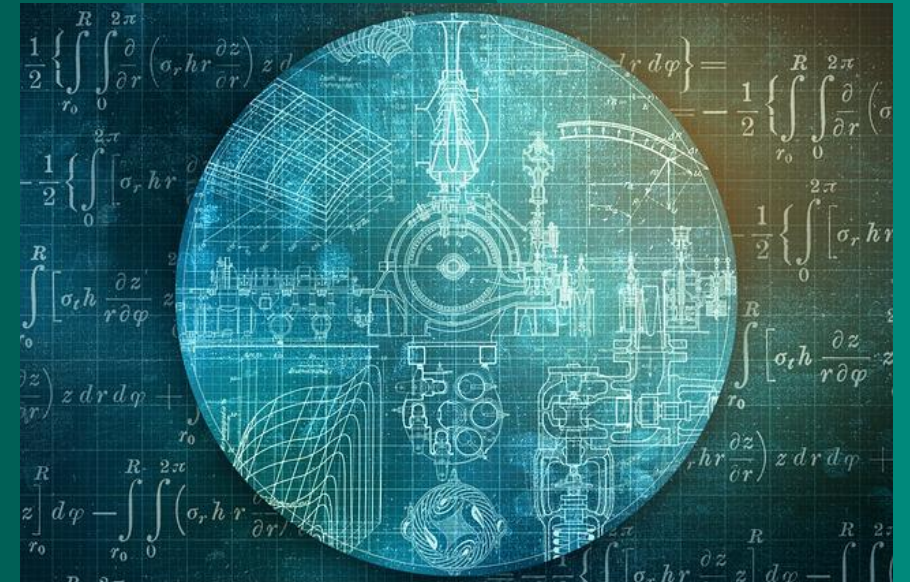
Ophthal works on workstation computers equipped with Windows 10 or 11 and at least 4 GB of free memory space and a RAM of 8 GB.

How it works

Ophthal is a software developed through Artificial Intelligence technologies; it is empowered by our innovative deep convolutional neural network which permits us to automatically reproduce the OCT image manual labelling activity.

After the installation, it is possible with a few clicks to load OCT exams, organize them by progression and get the automatic segmentation of all their scans. Once the automatic elaboration is performed, numerical and graphical data extracted from the segmentation are saved in a specific folder of the pc, and you can also download a PDF report resuming them.

Ophthal can be used to elaborate scans taken from OCT exams of patients affected by diabetic macular edema and healthy.

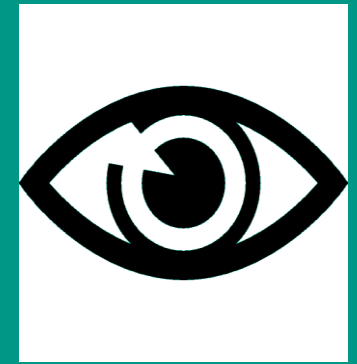# Advantages in using Ophthal software medical device

Ophthal works easily on your pc without the need for an Internet connection

In a few time, you'll get the automatic elaboration of your OCT exams, linear and volumetric

Keep it Simple

After a very fast period of formation, you can simply use this device on images taken with any OCT device

Ophthal is performant and reliable with its >90% accuracy*. It allows you to save time and costs

*Ophthal is clinically tested on more than 200 OCT exams of healthy and affected by DME patients by expert clinicians of the University Hospital of Perugia. The accuracy has been evaluated at over 90% for all the objectives
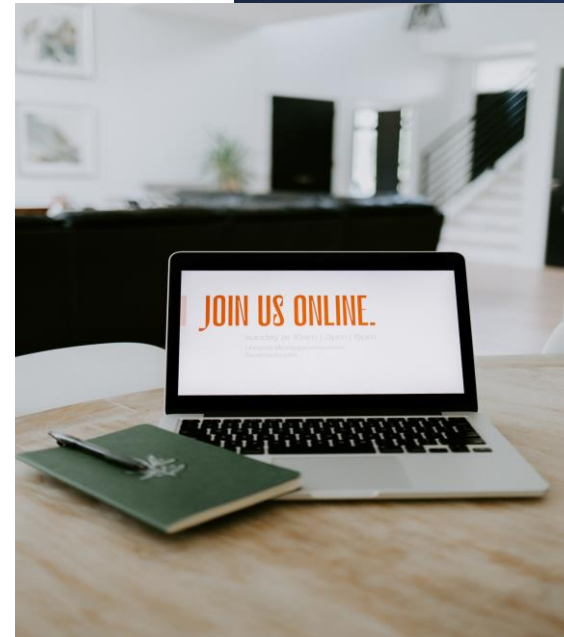
User Manual

It is fundamental that the user will carefully read the user manual before the utilization of the medical device.

The user manual is offered in the electronic modality in PDF format, together with the software, on the Mr. Doc website (prior registration) and after the license purchasing on the personal products page of the website.

When a new version of the user manual is released, the members who have acquired a license will receive an email notification containing the link to download it.

On request, the user who has acquired a license can receive a paper version of the user manual of interest within seven workdays from the request. The request can be sent during the license validity period to Mr. Doc through the ophthal-help@mrdoc.ai email address or the dedicated form on the Mr. Doc website.

Assistance

Once you have acquired the use license, you will receive a rapid and easy formation in the telematic modality for the correct software utilization. You will also have the warranty of continuous software updates for the entire license validity period.

Moreover, you will be guaranteed on-site interventions, support activities and even further formation on request according to what is established in the contract.

In case of doubts concerning the software utilization, you can communicate to Mr. Doc through the ophthal-help@mrdoc.ai email address.

For malfunctions or problems with Ophthal, contact Mr. Doc through the ophthal-segnalazioni@mrdoc.ai email address, providing all the concerning information.

Product Label

Product Name	**Ophthal**
Manufacturer	Mr. Doc s.r.l, Via Enrico Fermi 43, 00146 Rome (RM), Italy
SRN	Not available yet
Product Type	Software Medical Device SaMD
Medical Device Risk Class	IIa
Software Risk Class	A
European Nomenclature	Code Z
MDA Code	0315
Basic UDI-DI code	805361075OPHJW assigned by GS1 Italy
User Manual	Electronic, attached to the software and available prior registration on the website https://www.mrdoc.ai

Compliance with the regulations

Ophthal is safe for clinicians and patients: it's compliant with the European regulation (UE) 2017/745 and it has received the CE marking by the participation of the Notifying body TÜV Rheinland Italia.