	Intended Use
AOS | ADVANCED OPHTHALMIC SYSTEMS	

Record ID:	IU180301-01
Product:	AOS Anterior v2.0

Intended use description

1. Medical purpose

a) *General*

AOS Anterior v2.0 is a standalone software which allows opticians, orthoptists, optometrists and ophthalmologists to analyse images of the anterior part of the eye which include cornea, conjunctiva, vessels and eye lid. Such images of the eye are mainly captured with slit lamps, but can also be captured by other camera devices as tablets and smartphones.

Such analysis allows clinicians to quantify such parameters as the number of vessels over the conjunctiva, the levels of redness of the eye (in particular the conjunctiva and the palpebral conjunctiva) and the level of staining in the corneal and conjunctival regions. Therefore, the software quantifies and stores basic parameters which clinicians can utilise for follow-ups and assess the patient's health.

b) *Condition(s) or disease(s) to be screened, monitored, treated, or diagnosed*

The software doesn't provide or mention any information to the clinician regarding diagnosis or treatments. AOS Anterior v2.0 only quantifies the features displayed in the image (e.g. redness of the eye in a scale from 0 to 4; percentage of vessels in a selected area by the user; lid redness) and quantifies the level of staining (punctuates) which is already visible on the clinician's screen.

Major medical conditions where the software is potentially used involve:

- Conjunctivitis

- Dry eye

- Contact lenses inflammation and staining

- Age-related Macular Degeneration (AMD)

- Etc.

2.	**Patient population**

AOS Anterior v2.0 software can analyse the images of any patient. This includes any age from infants to elderly people who would like to check their eyes conditions with the use of a slit lamp. The software will analyse the images coming from CE and FDA approved slit lamps and devices. The software is not dependent on population characteristics (e.g. age, weight, health, etc.). the software helps clinicians generate values which can be used to assess the patient's health and to be used for comparison on subsequent visits.

3.	**Part of the body or type of tissue applied to or interacted with**

This part is not applicable. It doesn't drive a device.

4.	**Intended USER (education, knowledge, experience)**

AOS Anterior v2.0 is mainly intended for opticians, orthoptists, optometrists and ophthalmologists.
Such software can also be used for education purposes by students in different branches of medicine.

5.	**Application**
a)	*Environment (home/ professional use; indoor/outdoor; ambient temperature and humidity)*

AOS Anterior v2.0 is standalone software which can be installed on any computer which can be home base, hospital base, clinical use, private clinical practises. This also applies to such mobile devices as laptops, tablets and smartphones.

b)	*Frequency of use (how often product is intended to be used)*

A slit lamp is used nearly on every patient who needs a check-up of the anterior part of the eye. The images captured by a slit lamp are uploaded into the AOS Anterior v2.0 software and image analysis is applied almost immediately simply by selecting the areas of the eye to be analysed.

c)	*Mobility (mobile or stationary use)*

The images taken by a slit lamp are stationary images where the patient has to sit still in front of a slit lamp while images of the eye anterior are captured by a camera module. Consequently the AOS Anterior v2.0 software can analyse those images. The camera modules, which captures such images from the Slit Lamp, can be external by attaching a mobile phone on the lenses of the slit lamp; or by using dedicated slit lamp camera modules which plug into a computer.

6.	**Primary operating functions** **(Frequently used and functions related to safety)**

- The first application for the AOS Anterior v2.0 software is to quantify the level of redness in the anterior part of the eye. The software only quantifies with a number what the clinician can already observe during a general medical evaluation of the patient's eyes. Hence, a miscalculation of the eye redness would be clearly visible by the clinician and therefore such miscalculation should be discarded by the clinician.

- The second application for the AOS Anterior v2.0 software is to quantify the amount of vessels in the anterior part of the eye. Miscalculations should be visible to the clinician carrying on the examination as

the software only quantifies what the clinician can already see during the examination.

- The third application is to calculate the lid redness. The software only quantifies with a number what the clinician can already observe during a general medical evaluation of the patient's eyes. Hence, a miscalculation of the eye redness would be clearly visible by the clinician and therefore such miscalculation should be discarded by the clinician.

- The fourth application of the AOS Anterior v2.0 software is to quantify the number of punctuates over the conjunctival and corneal regions. The results provided by these features are also displayed on the original image of interest; thus, clear miscalculations would be visible to the clinician carrying out the eye examination.

- The user has the possibility to crop/snip any image displayed on the screen and import it directly into the AOS Anterior v2.0 app. Alternatively, the user has to upload the image from the location where the user originally saved the patient's image. The user interface is made of basic simple components to allow the user to minimise errors and simplify operations. The software behaves as any other software with windows/mac capabilities as minimising/maximising the windows software, closing the software window, and easily opens the software app by clicking on the AOS Anterior v2.0 software icon which can be set in the display desktop or programs menu. The AOS Anterior v2.0 software doesn't interfere with other programs in the clinicians' computer.

- The software is not responsible if the user selects an image from the wrong location. Users can generally save patient's images wherever is best for them. It's the clinician's responsibility to determine the image analysed comes from correct folder/location.
The app uses standard Windows opening and browses techniques to find and load the images of interest.

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