

Record ID:	IU181019-01
Product:	AOS Anterior

Intended use description

1. Medical purpose

a) General

AOS Anterior is a software system 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 typically 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 system 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 system 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) visible on the anterior of the eye. Major medical conditions where the system is potentially used include, but is not limited to:

- Conjunctivitis
- Dry eye
- Contact lenses inflammation and staining
- Age-related Macular Degeneration (AMD)
- Other conditions for which the displayed information may inform the care pathway.

2. Patient population

The system 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.

The intended Users are:-

- The Patients subject to the image analysis
- The individual who is taking the image, e.g, the photo-imaging department in a hospital
- The clinician who interprets the image and data and uses that to determine the care pathway
- Other clinical 'experts' who may be required to interpret the image to aid the clinical User
- The developers/distributers of other devices that want to collaborate, interface with the system to enhance their own offering through access to the system

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

This part is not applicable. It does not drive a device.

4. Intended USER (education, knowledge, experience)

AOS Anterior 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

b) The system is intended to be customisable to the intended environment, use, application and interfaces. This will be achieved by allowing the system to be:-

- White-labelled, i.e. the 'branding', aesthetic look/feel, colour scheme etc. can be customised without impacting on the functionality
- Customisable, in that certain features can be turned on, off, or modified without impacting on the functionality
- Multi-interfaced, in that the data captured can be presented in a variety of forms and transferred to third-party systems and devices as necessary for the care pathway to be realised by the clinical user base

c) Environment (home/ professional use; indoor/outdoor; ambient temperature and humidity)

The system can be installed on any compatible computer or mobile device. These Devices can be home base, hospital base, clinical use, private clinical practises. 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 system and image analysis is applied almost immediately simply by selecting the areas of the eye to be analysed.

d) 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. Subsequently the system 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)

1. 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.

2. Quantify the 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.

3. 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.

4. 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.
5. Quantify the percentage loss of the Meibomian glands.
6. Red-free, Green-free and Wratten filters for image enhancement on any loaded image.

7. Disclaimer

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. It is the clinician's responsibility to ensure the selected mode is relevant to the image loaded for analysis. The app uses standard Windows opening and browsing techniques to find and load the images of interest.

8. Clinical Champion – Dr. Byki Huntjens

Name

Dr. Byki Huntjens

Speciality & place of work

Senior lecturer at City, University of London specialising in contact lenses. Board member of BCLA (British Contact Lens Association).

Biography

<https://www.city.ac.uk/people/academics/byki-huntjens>

I am an optometrist, senior lecturer and Lead of our dry eye clinic and the contact lens department at City, University of London, where I manage and teach undergraduate and postgraduate contact lens modules. I have experience in (dry eye and contact lens related) research, regularly supervise undergraduate and postgraduate projects, and present at (inter-) national conferences. In 2017, I co-organised a two-day workshop event for eye care practitioners, to enhance their clinical abilities in dry eye management and specialised contact lenses. As an active member of the British Contact Lens Association (BCLA) and British and Irish Universities and Colleges Contact Lens Educators (BUCCLE), I have broad knowledge of contact lens education in the UK. I am a fellow of the International Association of Contact Lens Educators (IACLE), BCLA, and Higher Education Academy. In addition, I am the Lead for Teaching Excellence within our optometry division, and a representative for optometry at several School and University committees.

Publications

Huntjens, B., Mulder, J.A. and van Tilborg, M.M., 2018. Comparison between subjective fluorescein breakup time and automated tear breakup time measurements using the E300 corneal topographer. Contact Lens and Anterior Eye, 41, p.S85. [https://www.contactlensjournal.com/article/S1367-0484\(18\)30547-2/abstract](https://www.contactlensjournal.com/article/S1367-0484(18)30547-2/abstract)

Mulder, J.A., van Tilborg, M.M. and Huntjens, B., 2018. The effect of fluorescein sodium volume on anterior eye surface measurements using the Medmont corneal topographer. *Contact Lens and Anterior Eye*, 41, p.S90. [https://www.contactlensjournal.com/article/S1367-0484\(18\)30565-4/abstract](https://www.contactlensjournal.com/article/S1367-0484(18)30565-4/abstract)

Wolffsohn, J.S., Naroo, S.A., Christie, C., Morris, J., Conway, R., Maldonado-Codina, C. ... Harknett, T. (2015). Anterior eye health recording. *Contact Lens and Anterior Eye*, 38(4), pp. 266–271. doi:10.1016/j.clae.2015.03.001. <https://www.sciencedirect.com/science/article/pii/S1367048415000399>

Wolffsohn, J.S., Naroo, S.A., Christie, C., Morris, J., Conway, R., Maldonado-Codina, C. ... Harknett, T. (2015). History and symptom taking in contact lens fitting and aftercare. *Contact Lens and Anterior Eye*, 38(4), pp. 258–265. doi:10.1016/j.clae.2015.03.002. <https://www.sciencedirect.com/science/article/pii/S1367048415000405>

9. Clinical Champion – Dr. Sandip Doshi

Name

Dr. Sandip Doshi

Speciality & place of work

- Optometrist @ The Eye Care Centre, Brighton, UK.
- Clinical advisor at Birmingham Optical Group
- Clinical advisor at Optos
- Clinical advisor at Keeler
- Clinical advisor at Bausch & Lomb

Biography

Dr Sandip Doshi is an optometrist who owns a private practice in Hove, East Sussex. He is probably best known for his work in publishing and was the lead editor/ author for the popular series of books: Eye Essentials published by Elsevier Science. Sandip was also the first clinical editor of Optician magazine and previously was responsible for developing and running journal based CET in Optometry Today He has written numerous articles and lectured a variety of subjects within the profession ranging from clinical matters to business development.

He received his PhD from City University for his work in limbal anatomy and biochemistry over 20 years ago. As a result of this work, Sandip has always had a keen interest of the anterior segment of the eye and it was this which sparked his in interest of examination techniques of this area.

Articles & publications

Franklin, A., Franklin, N., Doshi, S and Harvey. 2007. Soft contact lens in presbyopia. DOI: [10.1016/B978-0-7506-8856-7.50010-7](https://doi.org/10.1016/B978-0-7506-8856-7.50010-7)

Franklin, A., Franklin, N., Doshi, S and Harvey. 2007. Spherical lens fitting. DOI: [10.1016/B978-0-7506-8856-7.50008-9](https://doi.org/10.1016/B978-0-7506-8856-7.50008-9)

10. Clinical Champion – Dr. John Gelles

Name

John D. Gelles, OD, FIAO, FCLSA, FSLs

Speciality & place of work

Specialising in the Cornea and Contact Lens, working for The Cornea and Laser Eye Institute – Hersh Vision Group and the CLEI Center for Keratoconus.

Biography

Dr. Gelles is the director of the specialty contact lens division at the Cornea and Laser Eye Institute-Hersh Vision Group and the CLEI Center for Keratoconus in Teaneck, New Jersey. He is a graduate of Pennsylvania College of Optometry and is an adjunct clinical instructor for State University of New York College of Optometry and New England College of Optometry. He is an optometric consultant and serves on the boards of the International Keratoconus Academy of Eye Care Professionals, the Contact Lens Society of America, and the Gas Permeable Lens Institute. Fellow of the International Academy of Orthokeratology, the Contact Lens Society of America, and the Scleral Lens Education Society. His clinical work is dedicated exclusively to specialty contact lenses and surgical co-management for corneal disease, ocular surface disease, and post-surgical corneal conditions.

Articles and Publications:

"Transepithelial corneal crosslinking for keratoconus", Peter S. Hersh, MD, , Michael J. Lai, BS, John D. Gelles, OD, Sebastian P. Lesniak, MD, Journal of Cataract & Refractive Surgery, Volume 44, Issue 3, March 2018, Pages 313–322 "The Times Are-A-Changin': Keratoconus". <https://odsonfb.com/times-changing-keratoconus/>

"Reflect on This: Corneal Topography and Keratoconus". <https://odsonfb.com/reflect-corneal-topography-keratoconus/>

"Spare the Cornea: Keratoplasty and Keratoconus". <https://odsonfb.com/spare-cornea-keratoplasty-keratoconus/>

Academic Positions

- State University of New York College of Optometry
- Adjunct Clinical Instructor: Cornea and Specialty Contact Lenses Site
- New England College of Optometry
- Associate Clinical Professor: Cornea and Specialty Contact Lenses Site

Date: 19.10.2018

Prepared by/Signature:

Dr Eduardo Mangieri /

