IEEE Access
Multidisciplinary | Rapid Review | Open Access Journal

Received March 26, 2021, accepted May 11, 2021, date of publication June 2, 2021, date of current version June 16, 2021.

Digital Object Identifier 10.1109/ACCESS.2021.3085404

A Mobile Tele-Ophthalmology System for Planned and Opportunistic Screening of Diabetic Retinopathy in Primary Care

FRANCISCO NUNES[1], PEDRO MADUREIRA[1], SÍLVIA RÊGO[1], CRISTIANA BRAGA[1], RÚBEN MOUTINHO[1], TIAGO OLIVEIRA[2], AND FILIPE SOARES[1]

[1]Fraunhofer Portugal AICOS, 4200-135 Porto, Portugal
[2]First Solutions, S.A., 4450-102 Matosinhos, Portugal

Corresponding author: Francisco Nunes (francisco.nunes@fraunhofer.pt)

This work was supported by EyeFundusScopeNEO: Demonstration of EyeFundusScope with Non-Expert Ophthalmology Users, cofunded by Portugal 2020, framed under the Operational Program Competitiveness and Internationalization (COMPETE 2020) and European Regional Development Fund from European Union, with operation code POCI-01-0247-FEDER-038400.

This work involved human participants. Approval of all ethical and experimental procedures and protocols was granted by the Ethics Commission of Hospital CUF Infante Santo, and performed in line with the Declaration of Helsinki.

ABSTRACT Diabetic Retinopathy is a complication of diabetes that can cause severe vision impairment or even blindness. The condition is treatable in early stages, but it often progresses asymptomatic and undetected. Once the symptoms become noticeable, damage in the retina might already be permanent, thus many countries have implemented retinal imaging screening programmes for their diabetic population. However, existing screening programmes are not reaching all patients, and Diabetic Retinopathy stands as a leading cause of preventable blindness in the active population. We contend that the existing technological infrastructures and clinical processes may be hindering the coverage of Diabetic Retinopathy screening programmes. This paper presents EyeFundusScopeNEO, a Tele-Ophthalmology system based on a screening information system and a mobile fundus camera, which shall support opportunistic and planned screening in primary care, using cameras that are handheld, non-invasive, avoid drug-induced pupil dilation, are usable by clinicians who are not specialised in Ophthalmology, and that cost a fraction of existing table-top fundus cameras. Preliminary studies indicate the potential of the system to increase the reach of screening programmes and clinical research field trials are under preparation.

INDEX TERMS Diabetic Retinopathy, Diabetic Retinopathy screening, eye fundus camera, mobile, retinal imaging, smartphone, Tele-Ophthalmology, usability.

I. INTRODUCTION

Diabetic Retinopathy is a diabetes complication that affects the retina, leading to blurred vision, dark spots or areas in the vision, double vision, vision loss, and blindness [1], [2]. The condition appears in the eye following long-term exposure to high blood glucose levels, typical in people with diabetes [1]. Diabetic Retinopathy is extremely common: nearly all patients with type 1 and 77% of patients with type 2 diabetes are expected to develop the condition during the first 20 years with diabetes, and the risk increases with time [3]. Despite treatable, Diabetic Retinopathy is a leading cause of preventable vision impairment and blindness in Europe [4]. Since the number of people with diabetes is increasing [5], the condition is considered a major public health issue [3].

To limit the impact of Diabetic Retinopathy, healthcare systems have implemented programmes to screen the eyes of people with diabetes [6]. These programmes are often based on telemedicine and depend on specialised personnel taking retinal images of patients and sending them to ophthalmologists for diagnosis [3], [6]. However, current screening programmes have limited reach due to: the costs of equipment and dedicated personnel [7], [8], the geographic inaccessibility of screening sites [9], the physical inaccessibility of table-top fundus cameras to people with motor disabilities [10], and the high rate of non-attendance to screenings by people with diabetes [7], [11].

Novel Tele-Ophthalmology systems could increase the reach of current screening programmes. If these systems

The associate editor coordinating the review of this manuscript and approving it for publication was Taous Meriem Laleg-Kirati.

support the opportunistic screening of people with diabetes in primary care, by their own care team, most issues of current screening programmes could be minimised, and the reach of the screenings expanded. Thus, in this paper we describe the technological solution we created and initially tested.

The main contribution of this work lies in the novel technological artefact created – the EyeFundusScopeNEO system. Building on a screening information system and a novel mobile eye fundus camera optimised for clinicians without specialisation in Ophthalmology, this work holds the promise to improve Diabetic Retinopathy screening programmes.

This paper is structured in 6 sections. Section II provides background on screening programmes and related technologies. Section III describes the requirements, proposed architecture, and usage scenario of the EyeFundusScopeNEO system. Section IV presents a list of preliminary studies conducted to understand the potential of the system. Section V discusses the results, and Section VI summarises the conclusions and future work.

II. BACKGROUND

A. DIABETIC RETINOPATHY SCREENING PROGRAMMES

The regular screening is essential to diagnose and treat Diabetic Retinopathy. While the condition may be asymptomatic, fundus observation reveals retinal abnormalities early on [1]. The most advanced screening programmes follow clinical recommendations for annual screening [17] and often depend on trained optometrists, eye technicians, or nurses taking retinal images of patients using table-top fundus cameras, and sending images to ophthalmologists for diagnosis [3], [6]. The camera operators undergo days of training (e.g., 2 in [18]) prior to using the camera in the field. Examples of national screening programmes include the EyePACS (United States), the NHS DESP (United Kingdom), SiDRP (Singapore), OPHDIAT (France), and the Rastreio de Retinopatia Diabética (Portugal) [6], [19].

Even though screening programmes are in place, Diabetic Retinopathy is still a leading cause of preventable blindness [3] which questions the effectiveness of existing programmes [20]. Reviewing the literature we understand that not all patients are covered by screening programmes and that there are high rates of nonattendance [7]. A part of the population is excluded from screening programmes due to their place of residence. Due to the high costs of table-top cameras and personnel [21], devices are placed where they reach higher population density [9], away from the countryside or remote areas. Since transporting cameras is difficult, remote areas often remain excluded [22], [23]. The lack of appropriate public transports also restricts patients from attending screenings in surrounding cities [9]. Moreover, table-top cameras require that patients sit and stay in upright head position during the procedure [24], disabling those who are bedridden or use a wheelchair from participating [10]. Nevertheless, even in areas that are covered by programmes, nonattendance rates reach 40-50% [7]. Studies point that patients are unaware of the consequences of Diabetic Retinopathy and end up missing their screenings [7], [23], [25].

Despite some success, the universal coverage and utilisation of screening programmes is distant and barriers to early diagnosis remain unaddressed. The World Health Organisation [20] recognises the need for new strategies and we believe that the opportunistic screening in routine primary care could be accomplished through the use of the system we developed.

B. TECHNOLOGIES FOR SUPPORTING THE SCREENING OF DIABETIC RETINOPATHY

1) PORTABLE FUNDUS CAMERAS

Recent years have seen the launch of handheld fundus cameras, in an effort to improve access and adherence. Advancements in electronic miniaturisation alongside new optical formulas, 3D printing, and processing power have made it possible to transform traditional table-top fundus cameras into mobile handheld solutions that are potentially effective, highly portable and considerably less expensive [9], [26].

Examples of handheld eye fundus cameras include FOP NM-10 by Remidio [12], Aurora IQ by Optomed [13], Paxos Scope by DigiSight Technologies [14], Eyer by PHELCOM [15], and iC2 by HEINE [16], all of which are characterised in Table 1. These cameras consist of handheld devices that include a set of lenses to focus on the retina, a screen to preview images, and a computing processing unit to support the acquisition. Some solutions use a smartphone as a preview screen and computing processing unit, while others present themselves as one dedicated device. The field of view of the retina captured by each device is distinct, with some cameras reaching 45º (both, horizontal and vertical in the case of Eyer), while others allow a narrower field of view. Image resolution varies between 5 and 12 Megapixels (MP) and the very helpful internal fixation targets are only present in two commercial solutions. For all the models, acquiring images requires approaching the users eye, focusing the macula and/or optic disc, and pressing a button.

Some portable fundus cameras are non-mydriatic [27], [28], which means that they can be used to acquire retinal images without requiring pharmacological dilation of the pupil. This is an important advantage as patients may need to wait for 30 minutes for the dilation drops to work and an equivalent time for it to wear off, before they can drive or perform other activities. Non-mydriatic cameras use near-infrared (NIR) illumination to preview the retina on the device screen and, once the image is aligned and focused, a flash of visible light is applied to capture the moment and generate a coloured representation of the retina.

Handheld fundus cameras were envisioned with high usability requirements, so that they do not require an eye care specialists to operate them [27]–[33]. With minimal training, clinicians can collect images to support the (Tele-Ophthalmology) screening [14], [26], [27], [30], [34]–[36], or their referrals to ophthalmology services [13], [15].

TABLE 1. Examples of handheld fundus cameras and their characteristics.

	Fraunhofer EFS A009	Remidio FOP NM-10 [12]	Optomed Aurora IQ [13]	DigiSight Tech. Paxos Scope [14]	PHELCOM Eyer [15]	HEINE iC2 [16]
Technology	smartphone and lenses	smartphone and lenses	dedicated device	smartphone and lenses	smartphone and lenses	smartphone and lenses
Field of view (vertical)	40º	40º	40º	20º	45º	34º
Resolution	12MP	12MP	5MP	8MP	12MP	12MP
Autofocus	yes	yes	yes	no	yes	no
Non-mydriatic	yes	yes	yes	no	yes	no
Internal fixation targets	yes	no	yes	no	yes	no
User interface	step-by-step	camera-like	camera-like	camera-like	camera-like	camera-like
Telemedicine	yes	yes	no	yes	yes	no

In terms of software, handheld fundus cameras tend to be very specialised. User interfaces usually resemble professional digital cameras, with options to adjust image acquisition (e.g., brightness), but not really supporting the screening workflow. According to our research, the EyeFundusScope (EFS) A009 prototype [37], [38] that is part of the EyeFundusScopeNEO system, is the first to provide a step-by-step user interface that guides clinicians in acquiring and sending images to ophthalmologists.

2) TELEOPHTHALMOLOGY INFRASTRUCTURES

While existing screening programmes often rely on telemedicine, the software architectures in place are very varied, both in terms of technical complexity as well as in the degree of integration with clinical information systems. The most basic approaches store the acquired images on a local hard drive, and ask the technicians to transfer them through FTP to the hospital server, at the end of each screening day [39]. Other solutions comprise a centralised web-based telemedicine system that enables acquisition, storage, and remote analysis [18].

More advanced systems like the open source system EyePACS [40] are able to integrate hospital information systems with the screening process. Operators in screening centres can capture images using table-top cameras and upload patient information and retinal images manually or from their electronic health records (EHR) through the HL7 interface. Ophthalmologists can later analyse the acquired images at the reading centres and, if necessary, arrange appointments through the platform. The screening results and recommendations are communicated to the screening central through PDF reports or through HL7 interface with EHR. Despite the increase in interoperability this system still relies on complex EHR interfaces, and table-top cameras are designed to be operated by technicians hampering the acquisition by non-ophthalmology expert personnel.

Some of the cameras we analysed above have their telemedicine systems for supporting screenings. Avenue Sync by Optomed [41] connects with Optomed Aurora IQ [13] and allows integration with Hospital Information Systems and Picture Archiving and Communication Systems (PACS). Optomed's system enables users to create a work list with a number of patients to enable a planned screening session. The images are stored in DICOM format, and Avenue Sync provides interfaces for Ophthalmologist to classify images remotely. The PHELCOM Eyer [15] also has its own proprietary cloud backend system, the EyerCloud. The acquisition device implements a store and forward process, communicating directly with the cloud system for image storing and management.

EyePACS, Avenue Sync and EyerCloud are examples of technological infrastructures that can integrate with healthcare information system. However, these infrastructures were designed to support planned screenings performed by qualified technical personnel, and thus are not optimised to support clinicians in opportunistically acquiring images from patients.

III. THE EyeFundusScopeNEO SYSTEM

A. REQUIREMENTS

The EyeFundusScopeNEO system was designed with the following eight requirements in mind:

- *Be mobile* – Clinician operators should be able to screen individuals with diabetes at home, to be able to reach, for example, people who are bedridden. People that use wheelchairs should be able to be screened, as well;
- *Support opportunistic screening* – Clinician operators should be able to screen individuals with diabetes who visit the clinic for a purpose other than screening (e.g., diabetes appointments, family planning, annual checkups);
- *Impact patients minimally* – Patients should not spend much more time in the healthcare unit than they would if they had not been screened. Pharmacological drops in the eye for pupil dilation should be avoided to enable a non-invasive process without further delays;
- *Enable peripheral imaging without eye movement* – Clinician operators should be able to capture several quadrants of the retina – critical for Diabetic Retinopathy diagnosis – while the patient fixates the eye on internal targets;
- *Impact clinical practice minimally* – The screening process should fit well with existing care practices, and clinician operators should be able to acquire and

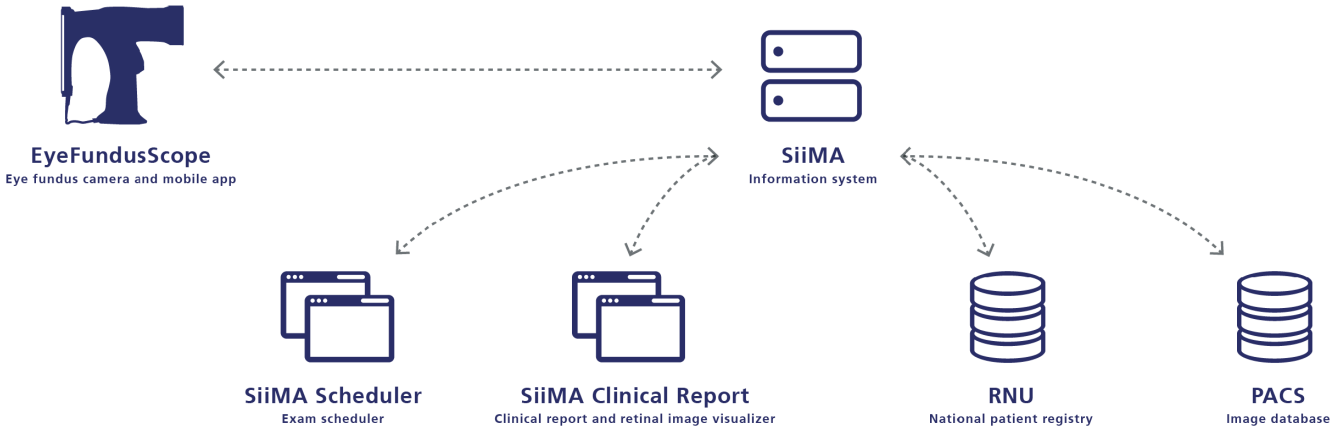


FIGURE 1. Architecture of the EyeFundusScopeNEO system.

send images of both eyes of the patient in less than 10 minutes, to minimise impacts on productivity;
- *Be usable after reduced training* – Clinician operators, such as doctors or nurses without specialisation in Ophthalmology, should be able to learn how to use the system quickly, even if they lack retinal observation training;
- *Be accessible to primary care units* – The expansion of the Diabetic Retinopathy screening is also tied with the cost of the eye fundus cameras, thus the system should cost a fraction of table-top retinographs;
- *Be scalable* – The technological infrastructure should fit existing standards and be prepared to handle a greater load from expanding the screening programme's reach.

B. PROPOSED ARCHITECTURE

The EyeFundusScopeNEO is composed of six main modules or components (see Figure 1), namely: (1) EFS, a fundus camera that clinicians use to scan patients' retinas (2) SiiMA, a clinical management system that connects all other modules and supports the clinical screening process; (3) SiiMA Scheduler, the platform for selecting and inviting patients to programmed screenings; (4) SiiMA Clinical Reports, the platform where ophthalmologists diagnose images; (5) PACS, the place where images are stored; and (6) Registo Nacional de Utentes (RNU), the service that identifies patients in the Portuguese national healthcare system.

1) EFS FUNDUS CAMERA

is a handheld, low-cost, and non-mydriatic fundus camera developed by Fraunhofer Portugal AICOS (current version A009). The device was designed for clinicians non-experts in ophthalmology to acquire retinal images in primary care. The EFS requires minimal training to be operated and the image acquisition takes a few minutes. The device consists of a smartphone running a mobile application, optics and electronic components in a 3D printed body (see Figure 2).

FIGURE 2. EyeFundusScope (EFS) A009 device.

From a regulatory point of view, EyeFundusScope is a non-CE marked device for clinical investigation, with potential Class IIa medical device classification.

EFS has a dedicated optical system which includes spherical and aspherical lenses, polarizers, and beam splitters. This optical system enables the acquisition of 12MP images with 40° of Field of View, for pupils $\geq$4mm, at a working distance (distance between lens closest to the eye and smartphone) of 30 to 40mm. The optical system is secured in place by a 3D printed casing of Polylactic acid (PLA), that was chosen due to its rigidity and biocompatibility. To facilitate image acquisition, the EFS A009 includes a silicone eyecup that touches the patient's face and is discarded every 10 sessions.

When approaching the handheld device to the patient's eye, a NIR spectrum Light-Emitting Diode (LED) is used to avoid causing photosensitivity, and thus enable the operator to efficiently align the device with the eye pupil. In the EFS A009, five internal fixation targets are used to enable imaging several retinal quadrants, in which the eye structures of the patient are almost static, even in rooms that are not completely dark. The fixation targets and the aid of an eyecup allows the autofocus feature to run, enabling the correction of

refractive errors that may be present in the eye [42], caused by myopia or hyperopia. While the EFS optical formula was designed to cope with distinct levels of dioptres [43], it is essential to achieve a well-focused image of the retina without having to manually change the distance between optical elements, a feature that often requires additional operator training.

After trying to obtain a correctly focused retina of a given eye, the image acquisition triggers white LED light to illuminate the patient's retina for a few milliseconds, thus maximising user comfort and the quality of image captured.

The mobile application running in the smartphone of the device collects patient information, enables the photography, and forwards images for classification regarding diabetic retinopathy presence and severity by ophthalmologists. The electrical energy is provided by the smartphone battery. The EFS A009 is currently compatible with the Samsung Galaxy S8, whose camera was adapted to be sensitive to the infrared spectrum. The device uses a proprietary mobile application jointly developed by First Solutions SA and Fraunhofer Portugal AICOS. The acquisition module that accesses the smartphone camera and device PCB is implemented using Java for Android and Kotlin. The remaining functionalities are implemented in React native, as the system may become multi-platform in the future.

2) SiiMA

is a commercial clinical management system that was designed to manage different clinical areas. Developed by First Solutions SA, SiiMA is the backbone that connects every module of the EyeFundusScopeNEO system and supports the clinical screening process. All activities of the screening, from patient selection to diagnosis and follow-up are recorded in SiiMA and specifically-built interfaces (e.g., SiiMA Scheduler or SiiMA Clinical Reports) allow different professionals to participate in the screening. In EyeFundusScopeNEO, SiiMA attributes IDs to acquisitions, encrypts communication, retrieves information from the RNU, converts images to DICOM format, and stores images in PACS using DICOM Store. EyeFundusScopeNEO was embedded in SiiMA and could be used for both opportunistic and planned screenings of Diabetic Retinopathy. SiiMA is able to connect operators taking retinal images, administrative personnel scheduling exams, ophthalmologists providing Diabetic Retinopathy screening results, and physicians following up on their patients. SiiMA was developed in Angular (some legacy modules were developed in Adobe Flex), Java Enterprise Edition (Java EE), and Oracle databases.

3) SiiMA SCHEDULER

is a web app for supporting patient selection and invitation to a programmed screening. Having received a list of patients to screen and screening schedules, SiiMA scheduler allocates patients to screening sessions and generates invitation letters to be sent by mail. If patients are not available, administrative personnel can change their screening booking to a later time using SiiMA scheduler. Moreover, SiiMA Scheduler can generate screening sessions with some degree of overbooking to reduce the impact of patients not showing up to sessions. The SiiMA Scheduler is an optional module of the EyeFundusScopeNEO system, because exams can also happen opportunistically, when patients, for example, attend diabetes follow up appointments.

4) SiiMA CLINICAL REPORTS

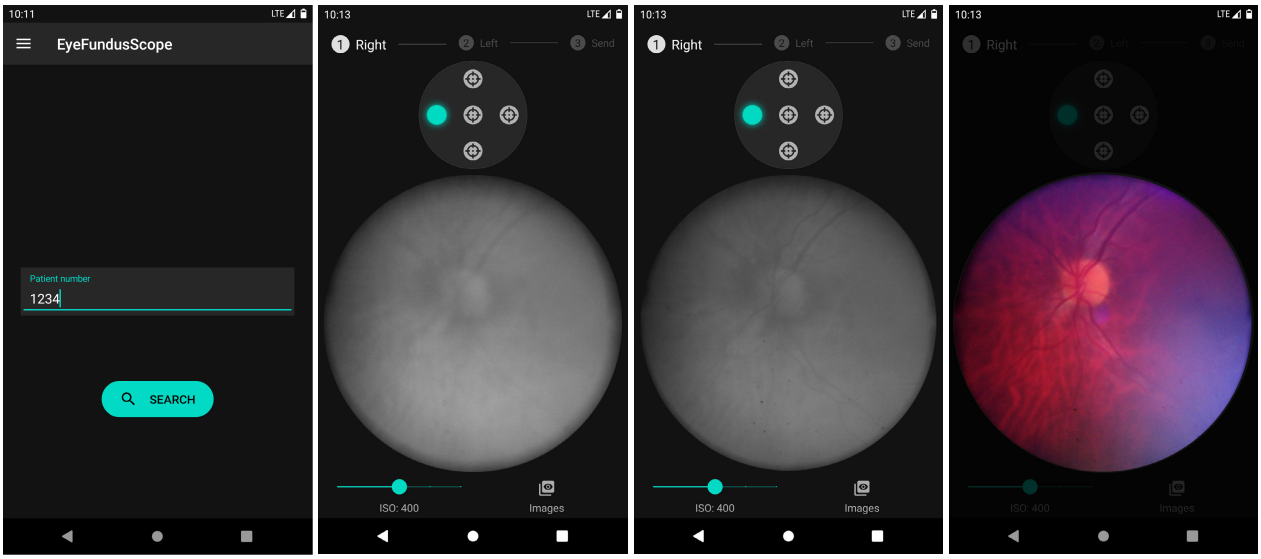
is the web app where ophthalmologists classify retinal images for the presence of Diabetic Retinopathy. Ophthalmologists are provided with a list of images from each patient and they grade the presence and severity of Diabetic Retinopathy, from not present to proliferative state. SiiMA Clinical Reports also provides structured fields for reporting the presence of other common eye conditions, such as Glaucoma or Age-related Macular Degeneration, and there is a free-text field for documenting additional issues observable in the retina. SiiMA Clinical Reports is compatible with central reading centres, where a team of ophthalmologists provide Diabetic Retinopathy screening results for all retinal images, or with distributed reading centres, where ophthalmologists from a certain hospital or region diagnose the clinical cases from their area of influence.

5) PACS

or Picture Archiving and Communication System is the module that stores patients' retinal images. The PACS is an industry standard that became common in the '80s to help hospitals centralise medical images from different devices and machines, and provide access to multiple workstations or clients [44]. At its core, a PACS instance is a data management system in which medical devices and machines can store medical images. In recent years, PACS vendors started including visualisation tools for clinicians, but not all instances of PACS possess these capabilities. The images in PACS are stored in DICOM (Digital Imaging and Communications in Medicine), which is the standard file format in medical imaging (ISO 12052:2017). Integrating a PACS in the EyeFundusScopeNEO system supports modularity and compatibility as these systems are ubiquitous in hospitals and other healthcare institutions. EyeFundusScopeNEO also benefits in terms of scalability because it is possible to ''piggyback'' on existing processes of redundancy, backup, and security for healthcare data centres. The PACS of EyeFundusScopeNEO can be located in the cloud, but complying with privacy regulations and best practices may advise its location in a hospital or a national/regional healthcare system data centre.

6) RNU

is the national patient registry of the Portuguese Ministry of Health [45]. The registry stores demographic information for each patient in the national healthcare system, to ensure that patient information is updated across different health software databases. The RNU is accessible through a web



(a) (b) (c) (d)

FIGURE 3. Screens of the dedicated EyeFundusScope A009 mobile application.

service that is restricted to authorised software running under specific conditions. EyeFundusScopeNEO uses the RNU to ensure that the images collected are correctly identified. After entering the number of the patient in the mobile application, SiiMA connects to the RNU and fetches the name and date of birth of the patient, enabling the clinician to confirm this information with the patient in front of them.

C. USAGE SCENARIO

The system can be used for both planned and opportunistic retinal imaging. Planned screening sessions start by making a list of patients to invite to the screening, which can be provided by clinicians or be made automatically using algorithms that analyse electronic health records. With these lists, administrative personnel can book screening session events and ask SiiMA Scheduler to allocate patients to screening sessions. The software will then generate invitation letters that will be sent using mail to patients. When the screening is opportunistic, clinicians will ask their patients to perform the examination before or after their yearly checkup, family planning, or other appointment, or will conduct the exam as part of a diabetes followup appointment [46].

When ready to acquire images, doctors or nurses working in primary care will turn on the smartphone and start the app on the EyeFundusScope device. The first step in the app is to identify the patient. Clinicians enter the patient's number on the app (Figure 3 a) or select a patient from the day's work list (planned sessions). In either case, the following screen will display the name and age of the patient for confirmation. Clinician operators then select between using 2 or 5 fixation points, giving them a choice to perform a faster acquisition (2 targets) or a more comprehensive image capture of the retina.

The image acquisition follows. Infrared LEDs are turned on to illuminate the retina and allow the operator to approach the device to the patient's eye. A preview of the image is shown at the centre of the smartphone's screen, allowing the operator to see when the retina is focused (Figure 3 b). Once the clinician operator is ready to acquire an image, they press a dedicated button on the device handle, which is recognised by a Printed Circuit Board and communicated via USB to the smartphone. The smartphone will adjust focus, to ensure the relevant eye structures are visible in the image (Figure 3 b). Some milliseconds later, white LEDs light up for few milliseconds to illuminate the patient's retina. After the acquisition, the captured image is shown on the screen for a few seconds for the operator to assess its quality and see if they need to repeat the acquisition (Figure 3 c). Operators can also acquire images using voice commands, such as "Photo" or "Go". The operator then changes to another fixation point in the app and repeats the process. When all images have been acquired, the operator can enter some observations which will be sent together with the images.

The retinal images will appear on the worklist of ophthalmologists when they open SiiMA Clinical Reports. After selecting a patient, ophthalmologists will be able to analyse all their images and grade Diabetic Retinopathy, diagnose additional conditions (e.g., glaucoma), and add free-text notes. If an image is inconclusive, ophthalmologists will have an option to ask for a re-screening. If an image is conclusive, they will conclude the process, triggering notifications to patients and their clinicians.

IV. PRELIMINARY EVALUATION STUDIES

The potential of EyeFundusScopeNEO needs to be assessed in clinical field trials. However, before conducting them, it was important to validate the safety, usability, and flexibility

TABLE 2. External laboratory test results.

Mode	Hazard	Result	Compliance
Continuous NIR	$E_{IR\text{-}CL}$	4.54 mW/cm^2	Group 1
	$E_{VIR\text{-}AS}$	6.15 mW/cm^2	Group 1
	$E_{VIR\text{-}R}$	0.48 mW/cm^2	Group 1
Continuous White	$E_{A\text{-}R}$	1.57 mW/cm^2	Group 2
	$E_{VIR\text{-}AS}$	38.38 mW/cm^2	Group 1
	$E_{VIR\text{-}R}$	4.99 mW/cm^2	Group 1
Single Pulse White	$H_{VIR\text{-}R}$	0.47 mJ/cm^2	Group 1
	$H_{VIR\text{-}AS}$	36.461 mJ/cm^2	Group 1

of acquisition of the EyeFundusScope device. SiiMA does not require preliminary validation as it is currently running in clinical practice, averaging 50.000 tabletop retinal images each month.

A. SAFETY STUDIES

1) EYE SAFETY TESTS

As the light spectrum used by EFS could potentially harm the patients, we conducted external laboratory tests to assess the safety of the device. The test methodology described by Melo *et al.* in [47] was based on the requirements of ISO 15004-2 on light hazard protection and ISO 10940 on fundus cameras (including safety), currently accepted and applied to medical devices that treat or diagnose ocular pathologies. The procedure included: (1) Measuring the emission spectrum of each LED with a spectrometer; (2) Measuring the power emitted by each LED through a Power Photodiode; (3) Crossing the two measurements made in the previous steps to obtain the distribution of the power emitted by the wavelength of each LED; and (4) checking the measured values against the standard's limits.

Table 2 presents the measurements performed in external laboratory, for each acquisition mode of operation compared with the Group 1 limits ophthalmic instrument for which no potential light hazard exists. The values were calculated with the LEDs at maximum intensity (100%), considering the exposed retinal area of 1.10 cm^2.

The results showed that the EyeFundusScope device is safe for both patients and operators, being categorised as a Group 2 ophthalmic instrument. Apart from one measurement, all test cases produced results within the safest device class (Group 1). However, when the white LED is turned on at maximum power it exceeds Group 1 limits, which means it could damage the retina in certain circumstances. Nevertheless, the damage to the retina cannot be inflicted considering the direct illumination would have to last for 106 minutes, uninterruptedly, and each image capture only uses the white LED for less than one second. For this reason, the tests confirmed the safety of EFS as an ophthalmic instrument with extremely low risk associated with light emission, and on pair with market devices.

2) BIOSAFETY TESTS

Since the EyeFundusScope touches the face of the patient, it was important to assess its safety to get in contact with the human skin. The body of the device was not an issue because the Ultimaker Polylactic acid (PLA) we used is non-toxic to the human skin according to the manufacturer datasheet. The silicone rubber used in the eyecup is also very common in the industry and safe for the human skin according to the distributor. Nevertheless, we imagined that the silicone could be damaged by the cleaning process with 70% grade ethyl alcohol cleaning solution. For this reason, we decided to test the resistance of the silicone to the cleaning process.

The test was performed according to ASTM D570-98 [48], a standard polymer performance test which determines the relative absorption value of the silicone when immersed and allows to see if the mechanical properties, dimensions and appearance are maintained. During the test, silicone samples were immersed in ethyl alcohol for 24, 72 and 168 hours, and placed in a plastic container, subjected to vacuum conditions and a controlled temperature of 25°C. After these periods, samples were photographed, analysed, and weighted using a digital analytical scale (accuracy of 0.1 mg). The samples were created with the same silicone rubber (HB FLEX 22 Thixo Body, HBQUIMICA Ltd.) and Black Pigment (SLIC PIGTM, SMOOTH-ON, Inc.) used to produce the black eyecups.

Results showed that the silicone did not change. Variations in material density (0.020g at 168 hours) are negligible. The mass of alcohol absorbed increased linearly until the end of the tests, possibly due to internal diffusion. The appearance and shape were intact, without deformations or imperfections, and with constant porosity. Following the standard test, we concluded that ethyl alcohol did not affect the silicone molecular structure and that the material will not be more prone to carrying infections after cleaning (less than 10 uses per piece), ensuring infection risks are kept minimal.

B. USABILITY TESTS WITH CLINICIANS

To assess the usability of EyeFundusScope, we conducted usability tests with clinicians. The current version of EyeFundusScope was under development at the time, so we used the prior one (A008), which is very similar but lacks fixation targets and a silicone eyecup that provides further stability. We started the usability test by explaining the goals of the session and acquiring informed consent. We then played a two-minute tutorial video and instructed participants to acquire images of a volunteer that sat in front of them. Lights were dimmed to simulate the required acquisition conditions. We told participants that we would be able to clarify any doubts, but that they should proceed as they saw fit and to stop acquiring images when they felt they had captured appropriate retinal images. 15 clinicians tested the device: 6 family medicine doctors, 1 intern doctor, 1 resident doctor in nephrology, 1 surgeon, 5 nurses, and 1 physiotherapist. Ages ranged from 24 to 63 years old (AVG = 37, SD = 11), and experience on their domain area ranged from 1 to 37 years (AVG = 11, SD = 11). They had never used fundus cameras, but physicians had previously used an ophthalmoscope.

TABLE 3. Average acquisition time in usability tests.

Tasks	1st acquisition	2nd acquisition
AVG time	3:47	1:50
STD DEV	2:37	1:13
AVG No. photos	9	13
STD DEV	4	11

The clinicians were quick in locating the relevant eye structures and acquiring images (See Table 3). In the first try, clinicians took less than 4 minutes to take the first image, and they usually shot 9 photographs of the retina as they tried to get the best image. The second try was better. Not only clinicians spent less time capturing images as they even acquired more images than on the first take. In terms of the workflow, clinicians made no errors and always selected the most appropriate options in the app.

By the end of each test, we asked participants how comfortable they felt using the device and how they envisioned it being used in clinical practice. Participants were comfortable in general, as they felt that it was easy to learn how to use the device. During subsequent interviews [46], participants explained that the device was practical and that it could be used by doctors or nurses in diabetes follow-up appointments. Participants supported the idea of implementing the EyeFundusScope device in primary care because they felt that patients could be screened more frequently, as clinicians could reach people that usually fail to attend the screening sessions. They also felt that diabetes follow up appointments were ideal for performing regular screenings, e.g., every six months.

C. AUTOFOCUS TESTS WITH INTERNAL FIXATION TARGETS

As it is possible to electronically change the focus target distance in the Android smartphone camera, and the EFS A009 optical formula was initially simulated in the range of -5D to $+5$D diopters as refractive errors with a different ophthalmic lens, a preliminary data collection was performed with the device in laboratory. This was done in a set of volunteers with small dioptre ranges (mild to moderate myopia or hyperopia) to verify the real compatibility of the system.

Since EFS A009 uses NIR light and internal fixation points when the camera operator is performing the handheld alignment phase, and the existing focus algorithm of the smartphone manufacturer was not compatible with that, a new smartphone-based approach for automatic focus assessment in NIR fundus images was proposed in [42] to match some of the usability requirements. The acquisition logic developed allows the device to search for the best focus value when the examiner is previewing the retinal image, under NIR illumination, and after locking the focus for a given eye the retinal image should be captured with visible light.

The dataset collected is composed of a total of 853 NIR fundus images obtained from both eyes of 8 humans (32 years-old in average, with brown or blue eyes, 50% female, 5 of them wearing glasses that were removed for the study). Written informed consent was obtained.

TABLE 4. Benchmarks of autofocus feature with an internal fixation target selected to centralise the optic disc.

Metric	Values
Min. time with stable handheld using fixation targets	1120ms
Dioptre range tested with successful focus locking	[-4; 1]
Number of shooting sessions	115
Average number of sessions per eye	7
Min. time with patient (both eyes)	6min
Max. time to perform the full autofocusing logic	2224ms
AUC of focus evaluator on NIR images	0.80

The benchmarks in Table 4 are related to: the minimum time that the camera operator could hold the prototype steady while keeping the fixation of the patient's eye with invisible light; the dioptre range that was successfully tested; the estimated duration of the process; and the Area and the ROC curve (AUC) showing the performance of the focus algorithm.

The results observed show that in the EFS A009 generation it is possible to keep the device steady while aligning the retina, with the help of the internal fixation target and the eyecup touching the patient. This is done in sufficient time so that the autofocus feature can run and obtain the best possible focus distance. We also found that corneal light reflections caused by misalignment of the camera with the pupil may drastically reduce the success rate of the retinal image acquisition.

V. DISCUSSION

This paper described a Tele-Ophthalmology system for screening Diabetic Retinopathy in primary care. The system promises to increase the reach of current screenings by addressing long-standing issues of accessibility [9], [10], cost [7], [8], or lack of patient health literacy [7], [11]. The EyeFundusScopeNEO system can be (a) used to screen people with motor disabilities, (b) transported to remote areas or patient homes, (c) employed by clinicians who are not specialised in Ophthalmology after reduced training, and (d) used opportunistically when people with diabetes visit their care providers, all of which will result in increasing the reach of screening programmes.

The architecture of EyeFundusScopeNEO aligns with best practices of adopting industry standards (e.g., DICOM) and integrating with hospital data management systems (e.g., PACS) [15], [40], [41]. The usage of RNU, the Portuguese national patient registry, could be useful for other solutions that target patients of a region or country instead of a single hospital. However, the most significant innovation is enabling opportunistic screenings through this technological infrastructure.

The EyeFundusScope device is an advancement over existing mobile eye fundus cameras. Unlike prior solutions, EyeFundusScope was specifically designed to fit the needs of

non-Ophthalmology expert clinicians. The device provides a dedicated app that supports the clinical workflow with step-by-step options, advancing existing solutions whose software resembles digital cameras and not clinical support tools. The EyeFundusScope provides an autofocus algorithm to adapt to people with myopia or hyperopia, aligned with the more advanced market solutions. Moreover, the device includes internal fixation targets, a rare feature in the market of smartphone-based devices, that has the potential to support focused and efficient image acquisitions.

Drawing on a reference screening information system in the market, SiiMA, also supports the potential of the EyeFundusScopeNEO system to reach clinical practice. As SiiMA already handles planned screenings with table-top fundus cameras in Portugal, it is straightforward to imagine the replacement of these with mobile eye fundus cameras, or the co-existence of both cameras, all of which while avoiding implementation issues of introducing a novel solution.

Preliminary tests have affirmed the potential of the system. The safety and biocompatibility tests show that the system is safe to use with patients. The quick image acquisitions by clinicians after minutes of training, contrast with existing screening programmes that require operators to undergo two days of training [18]. The autofocus tests show that the system can be used with people with different refraction issues, which is essential for implementation. Moreover, the feedback from clinicians during usability tests and accompanying interview [46], that the system fits well with their practices, that it could be used after or during their appointments, or that the system would increase the Diabetic Retinopathy screening, reaffirms the potential of the EyeFundusScopeNEO.

Having said this, clinical research field trials will be required to confirm the potential of the system. During these studies, we will be able to know if the image quality of EyeFundusScope enables ophthalmologists to provide Diabetic Retinopathy screening results and whether the system integrates appropriately with the practice of clinicians operating the device.

VI. CONCLUSION AND FUTURE WORK

This paper described EyeFundusScopeNEO, a Tele-Ophthalmology system that supports opportunistic and planned screening of Diabetic Retinopathy in primary care. The system draws on a market screening information system and a novel mobile eye fundus camera that advances existing solutions by being optimized for clinicians who are not specialised in Ophthalmology. Preliminary tests show the device is safe, that clinicians can acquire images quickly after reduced training, and that the non-mydriatic system focuses appropriately on eyes with different dioptres. The characteristics of the system address long-standing issues of current screening programmes, thus we expect to be able to increase the reach of screenings once the system is implemented.

Once COVID-19 restrictions allow, we will field trial EyeFundusScopeNEO in real-world conditions. The goal will be to assess (a) the clinical effectiveness, (b) image quality and reproducibility, (c) impact, and (d) acceptance of the system to both clinicians and patients.

ACKNOWLEDGMENT

The authors thank David Melo, Elsa Oliveira, Eduardo Pereira, João Monteiro, Cristina Santos for supporting this work. They also acknowledge all the participants from the usability and autofocus tests for their time.

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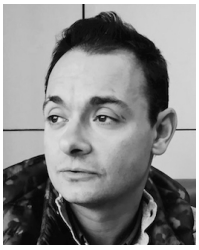
FRANCISCO NUNES received the master's degree in informatics and computer engineering from the University of Porto, in 2010, and the Ph.D. degree in human–computer interaction from TU Wien, in 2017. He is currently a Senior Researcher with the Fraunhofer Portugal AICOS, where he is working on the Human-Centred Design Team. His research is concerned with the user research, design, and evaluation of technologies for healthcare, with a special interest in self-care technologies. He draws on ethnographic methods and participatory design approaches to understand the practices, needs, and issues of patients, carers, and clinicians, with the ultimate goal of better designing for them.

PEDRO MADUREIRA received the M.Sc. degree in electrical and computers engineering from the Engineering Faculty of Porto University (FEUP), in 2012, with a specialization in communication services and networks. His dissertation was entitled Run-time Management of Energy Efficiency on Industrial Scenarios–An Autonomic Computing Approach, which was developed in a partnership with the Fraunhofer Portugal AICOS. Since then, he has been working as a Researcher with the Fraunhofer Portugal AICOS, developing his skills in embedded systems development, data structures, mobile application development, data collection systems, and human–computer interaction. His main research interests include development of embedded systems, mobile applications development, autonomic computing, and remote management.

SÍLVIA RÊGO graduated in nursing from the Escola Superior de Enfermagem do Porto. She received the master's degree in health evidence and decision (MEDS) from the Faculty of Medicine, University of Porto, where she is currently pursuing the Ph.D. degree in clinical and health services research (PDICSS). She is currently a Researcher with the Fraunhofer Portugal AICOS. Her research interests include clinical validation of medical devices and mathematical models for disease prediction.

CRISTIANA BRAGA received the bachelor's degree in information science and the M.Sc. degree in services engineering and management from the University of Porto, in 2016 and 2018, respectively. She is currently a Junior Scientist with the Fraunhofer Portugal AICOS. She is also the part of the Human-Centred Design Department and has experience in performing user research in healthcare settings. Her research is concerned with the needs, wishes, and pains of end users of technological solutions. To do so, she employs exploratory methods, helps to conceptualize and to improve the solutions, iterates, and evaluates them through fieldwork with real users.



RÚBEN MOUTINHO was born in Oporto, Portugal, in 1983. He received the B.S. degree in product design from the University of Aveiro, Aveiro, Portugal, in 2010, and the M.S. degree in product design from the Polytechnic Institute of Viana do Castelo, Viana do Castelo, Portugal, in 2013. Since 2013, he has been involved in some startups and companies-based in Portugal and USA on medical devices, cooking machines, research and development of small appliances, clothes, and cutlery. He was a Researcher with the Instituto de Plasmas e Fusão Nuclear and Instituto Superior Técnico, Lisbon, Portugal. He coordinated the design and integration activities of diagnostics for ITER with emphasis on the development of the ITER Plasma Position Reflectometer, Collective Thomson Scattering, and DEMO plasma position control systems. He is involved in research and development with Eurocrane to develop a new type of crane for the French Navy. He is currently an Industrial Designer with the Fraunhofer Portugal AICOS, where he is also a member of the Human-Centred Design Department, aims to develop different systems which will improve people's lifestyle in future through interactive discoveries.

TIAGO OLIVEIRA received the master's degree in electronics and telecommunications from the University of Aveiro, in 1997. He has more than 20 years of experience in the area of information systems for health. He started his professional career as a Researcher with INESC. He currently has the role of Business Development Manager with First Solutions, with responsibilities on analysis, design, coordination, and integration of new products into the company's offer. At this company, in 2009, he was responsible for the creation of the first information system for Diabetic Retinopathy Screening Management with remote reading, grading, and integration with fundus cameras. Previously, he assumed the direction of the telemedicine area with First Solutions for five years, and participated as a project manager in regional and national projects.

FILIPE SOARES received the Ph.D. degree (Hons.) in computer science and engineering from the University of Beira Interior, Portugal, in 2014. He worked as a Researcher in medical imaging with Siemens Healthcare, in the field of computer-aided detection and diagnosis of breast cancer, in a project for which he received the Siemens Innovation Award, in 2012. He worked as a Software Engineer in telecommunications and embedded systems with Coriant (former Nokia Siemens Networks), in 2013. He is currently a Senior Scientist with the Fraunhofer Portugal Research Center for Assistive Information and Communication Solutions (AICOS), conducting research on computer vision and decision support systems in the field of retail, manufacturing, precision agriculture, and mHealth, in particular in the area of ophthalmology. His main research areas are image processing, computer vision, machine learning, deep learning, decision support systems, embedded and intelligent systems, and software engineering.