

EQUIPMENT SPECIFICATIONS

FUNDUS CAMERA FOR DIABETIC RETINOPATHY SCREENING | NON MYDRIATIC

Produced in collaboration between the IAPB Standard List, the IAPB Diabetic Retinopathy Working Group, and international diabetic retinopathy experts
OCTOBER 2019

Minimum Standards

This document specifies the minimum standards for a non-mydriatic digital fundus (retinal) camera unit. It is based on the English National Screening Programme for diabetic retinopathy 2003-2016,

The unit can be a fixed or portable fundus camera.

Portable units include hand-held cameras. Handheld cameras are an order of magnitude cheaper than desktop ones, yet produce images of an acceptable quality if used on a desktop and with the patient in a chinrest. Further, these are inexpensive, portable, and easy-to-operate. These new cameras have revolutionized retinal screening programs and are thus an appealing choice especially in low- and middle-income countries.¹

DEFINITION OF “THE UNIT”

The unit means:

- i. the fundus camera and anything contained within it;
- ii. the digital camera body and anything contained within it (if this is separate from the fundus camera);
- iii. any incorporated computer hardware, firmware, and software;
- iv. any collar or adapter required to attach the fundus camera to the digital camera body;
- v. the data transfer lead used to connect the camera to an external computer; and
- vi. any other power supply, cable, or other such equipment as is necessary to capture a digital image of the retina and transfer it to an external computer.



Core Requirements

The following features are necessary to meet the essential requirements for the unit to be effective in the screening for diabetic retinopathy.²

THE UNIT MEETS RELEVANT QUALITY CRITERIA AND STANDARDS

The quality of the unit must be such as to comply with standards and legislation:

- ISO 10940 (2009) “Ophthalmic instruments – Fundus cameras” and/or individual country standards, except as specified in this document;
- BS EN60601-1 “Medical Electrical Equipment and Medical Electrical Systems” and/or individual country standards and all relevant electrical, mechanical safety legislation;
- quality international and/or individual country certification mark(s) may be indicated on the unit.

THE CONSTRUCTION OF THE UNIT

The construction of the unit must be such as to ensure:

- a clearly visible image – e.g. 200mm screen size (may be via a host computer);
- it is sufficiently robust and portable to enable regular transport between screening locations – e.g. lighter weight, smaller sized, an all-in-one built-in camera and computer;
- leads, cables, and attachments can be securely attached to the unit, providing tidy storage when the camera in use;
- up to 80,000 images per annum without degradation in performance or structure;
- a life expectancy of at least 5-7 years;
- storage between –10°C and +45°C.

The unit must be sufficiently flexible to enable it to accommodate:

- patients of different heights and mobility, providing secure and comfortable access;
- a range of refractive errors – i.e. +/- 15 D;
- appropriate accessories – e.g. a trolley capable of moving the unit;³
- preferably, hand-held cameras should be used on a desktop, with a chin rest for the patient;
- alternative power sources – e.g. mains electricity, rechargeable batteries, generator.

THE OPERATION OF THE UNIT TEXT

The operation of the unit must include the capability to:

- function over a range of room temperatures – i.e. +10°C to +45°C and relative humidity levels of 30% to 90% (non-condensing);
- capture gradable images in a darkened environment or, for mydriated patients, in normal ambient lighting (500 lux);
- be simple to operate, after suitable training, by either technical staff with no medical or optometric background, or by nursing staff with no technical background;⁴
- be efficiently used in a working screening clinic – i.e. capture in no more than one minute per image, a gradable retinal image for a reasonably compliant patient.⁵

The unit must facilitate the ease and rate of capturing quality images via the:

- capability to disable automatic focus (if present) for standard manual focus operation;
- incorporating a user display (may be provided via the host computer) to facilitate the alignment and focus of the eye before capture;
- internal and external fixation aids to facilitate rapid positioning of the eye;
- capability to position the eye via an internal and external fixation aid to capture the “fields of regard”.

FIELD OF REGARD

The field of regard must make it relatively straightforward³ to capture images:

- i. centred on the foveal area;
- ii. centred on the optic disc;
- iii. as per local screening protocol in the macular and nasal fields (EURODIAB Protocol);⁶
- iv. temporal to macula, superior temporal, inferior temporal, superior nasal, inferior nasal (fields 3-7 of ETDRS).⁷

THE OUTPUT OF THE UNIT

The unit must facilitate the capture of images via:

- an image capture unit that is TWAIN or customized API integrated, to allow the use of software not provided by the supplier for the capture of images;
- the integration of the image capture process supported by the unit into a complete diabetic retinal screening framework/system; to achieve this, units must be capable of interfacing directly to all capture and management software in use in local screening programs.

The unit must have the capability to capture digital retinal images:

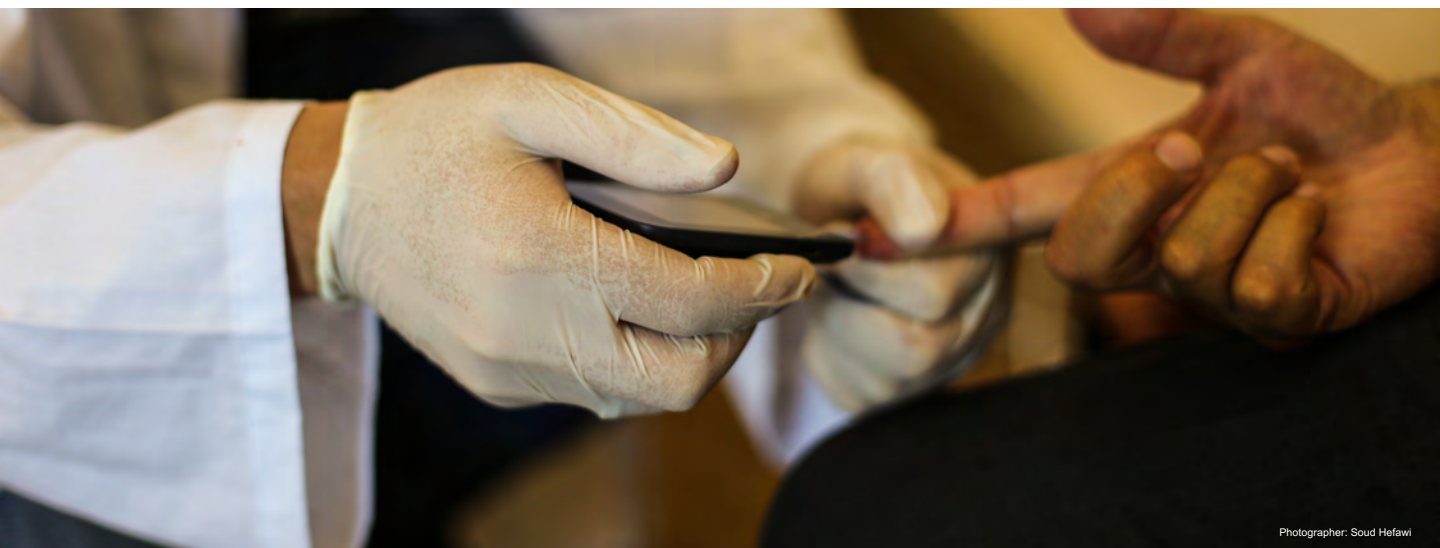
- with a minimum field of view of 45° horizontally and 35° vertically at the specified resolution (at least 30 pixels per degree); systems that build up images by smaller or greater fields of view can be considered but must be capable of producing a single image subtending a minimum of 45° horizontally and 35° vertically;
- that retain the orientation that would be observed should a direct view be possible;
- that automatically identify the eye from which the image was captured (left or right); this should be achieved with a physical identifying mark, which appears by convention in the top right-hand corner of the image;
- with a resolution at all field points and orientations as captured of at least 30 (true colour) pixels per degree, excluding borders, where true colour is defined as the colour that would be seen if direct view was possible;⁸
- compatible with and conforming to DICOM standards.⁹

The unit must have the capability to save and transfer images:

- with a file size that allows fast transfer from the unit to an external PC, fast transfer for subsequent grading and quality assurance, and affordable mass storage (each image is expected to fall within the 500KB - 2MB range);
- to a specified folder and with a specified filename on the same or connected PC/peripheral device;
- supported by direct and immediate image transfer from the image capture device in the unit to the external computer without the need for any manual export process and this must take place in a way that allows the identification of multiple images acquired from any patient;
- via a standard USB;
- linked to Hospital Information Systems to store and via the internet to view images at other locations.

The unit must have the capability to manage/manipulate images:

- without the loss of any clinically significant data, regardless of any down-sampling or compression applied;
- where the raw image is compressed with a 'lossy' compression algorithm such as JPEG, the unit must not apply further 'lossy' compression, for example to apply a software image mask;
- derive from the output any image parameters necessary to display, transfer, or manipulate the image such as height, width, resolution, colour depth and file size (these parameters should be readily available in a form that is easily transferred to text or other files).



PROCUREMENT CONSIDERATIONS ¹⁰

A comprehensive description of what is contained in the unit supplied, including a description of unit components, cover, and post sale support to be used in agreement(s), where relevant:

- warranty – minimum of 12 months;
- availability of parts – minimum of five years beyond the warranty period of each unit;
- availability of spare power cables;
- ease of availability of manuals;
- local support for installation, set-up of equipment, training, regular (annual) preventative check-up, and repairs by a distributor or local presence.

Support for installation and set-up of equipment should include consideration of safety and comfort of staff and patients, also optimal functioning and protection of the unit:¹¹

- assessment of the various types of power supply available – e.g. electricity supply/mains, battery, and generator;¹²
- advice about and/or installation of appropriate devices to protect equipment from faulty and unreliable power supply;¹³
- assessment of environmental conditions/context of operation and accompanying advice – e.g. ideally maintain an optimum relative humidity (40-60%) both for the comfort of staff and patients, and to minimise the impact of bacteria and respiratory infections:
 - higher humidity and heat is conducive to the proliferation of fungi and mould on lenses, especially if precautions are not followed;¹⁴
 - lower humidity <35%: electrostatic discharge can cause equipment malfunction and damage;
- install software and provide updates as these become available.

Support for training should include the availability of training packages

- with topics relevant to staff who:
 - operate the unit – e.g. use of the unit, including relevant aspects of the capture / management software, care and routine maintenance of the unit
 - maintain and repair the unit – e.g. maintenance and repair of the unit, to enable repairs to be done locally if possible
- to be used by suppliers to provide initial training for a reasonable number of staff, free of charge, at a time and place mutually agreed between project and supplier;
- for both initial training refresher training (ideally annual) should be available, face to face or in real time via the internet.
- training materials such as user manuals and videos should be available online

Support, should equipment become dysfunctional, to include:

- access to information about contacting the supplier, the location of supplier;
- ease of contacting the manufacturer, if needed;
- easy availability of spare parts and comprehensive manuals;
- assistance with local repairs;
- provision of loan units if local repairs are not possible.

References

1. Zhang W, Nicholas P, Schuman SG, Allingham MJ, Faridi A, Suthar T, Cousins SW, Prakalapakorn SG. Screening for diabetic retinopathy using a portable, noncontact, nonmydriatic handheld retinal camera. *J Diabetes Sci Technol*. 2017; 11(1):128-134
 2. Panwar N, Huang P, Lee J, Keane PA, Chuan TS, Richhariya A, Teoh S, Lim TH, Agrawal R. Fundus photography in the 21st century: A review of recent technological advances and their implications for worldwide healthcare. *Telemed J E Health*. 2016; 22(3):198-208.
 - Fenner BJ, Wong RLM, Lam WC, Tan GSW, Cheung GCM. Advances in retinal imaging and applications in diabetic retinopathy screening: A review. *Ophthalmol Ther*. 2016; 7(2):333-346
 - Scanlon PH. Update on Screening for Sight-Threatening Diabetic Retinopathy. *Ophthalmic Res* 2019. 27:1-7
 3. Included as part of the unit or available for separate purchase
 4. Assuming a suitably trained and competent user and a patient without complications
 5. A maximum time of two minutes does not include time for mydriasis or other clinical or administrative tasks, but does include any time required for calibration, pre or post alignment or other routine test or procedure. The total time and the frequency of any such additional activity must also be provided.
 6. Aldington SJ1, Kohner EM, Meuer S, Klein R, Sjølie AK. Methodology for retinal photography and assessment of diabetic retinopathy: The EURODIAB IDDM Complications Study'. *Diabetologia* 1995; 38(4):437-444
 7. Moss SE, Meuer SM, Klein R, Hubbard LD, Brothers RJ, Klein BE. Are seven standard photographic fields necessary for classification of diabetic retinopathy? *Invest Ophthalmol Vis Sci*. 1989;30(5):823-828
 8. Colour retinal images representative of what the operator would see by direct view given that image grading is usually carried out by visual inspection of a colour image
 9. Digital Imaging and Communications in Medicine — is the international standard for medical images and related information. It defines the formats for medical images that can be exchanged with the data and quality necessary for clinical use.
 10. Poore S, Foster A, Zondervan M, Blanchet K. Planning and developing services for diabetic retinopathy in Sub-Saharan Africa. *Int J Health Policy Manag*. 2015 4(1):19-28.
- Ismael Cordero authored the following publications:
11. Electrical safety in the clinical environment – good habits to maintain
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 14. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3864060/> Fungus: how to prevent growth and remove it from optical components

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David Faulmann, Dr Fabrizio D’Esposito, and Rashin Choudhry – The Fred Hollows Foundation. Also their colleagues from Country Offices and their collaborators at St John Eye Hospital in Jerusalem, Palestine and at the Tilganga Institute of Ophthalmology in Kathmandu, Nepal who provided consolidated feedback from the perspective of a program implementer.