



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (kml)
FOLDER: K100644 - 502 pages
COMPANY: OPTOS PLC (OPTOPLC)
PRODUCT: OPHTHALMOSCOPE,LASER,SCANNING (MYC)
SUMMARY: Product: OPTOS LIMITED PANORAMIC 200CAF

DATE REQUESTED: Mar 15, 2016

DATE PRINTED: Mar 15, 2016

Note: Printed



K100644

510k Summary-Optos Panoramic 200CAF

Name of Device Panoramic 200CAF Ophthalmoscope

Common or Usual Name Scanning laser ophthalmoscope

Classification Name Ophthalmoscope
(per 21 C.F.R. § 866.1570)

JUL 1 5 2010

Product Code MYC

Submitter Optos plc,
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Dunfermline,
Fife,
KY11 8GR
United Kingdom

Phone: 011 44 1383 843300

Facsimile: 011 44 1383 843333

Contact Person: Robert Tweedlie Ph.D.

Date Prepared June 14, 2010

Predicate Device Optos Limited's Panoramic 200 (K983999)

Indications for Use

The Panoramic 200CAF scanning laser ophthalmoscope is intended to be used as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.

Technological Characteristics

The Panoramic 200CAF is a conventional scanning laser ophthalmoscope (SLO), which uses a low power laser beam to scan in two dimensions over the retina. The reflected (or returned) light is detected and used to generate a digital image with a computer or electronic imaging device.

The wavelengths of the lasers residing in the Optos Panoramic 200CAF and the P200 are the same. The generation of the image is performed in the conventional manner using light detectors, the output of which is digitized, and the data collected in a computer for reconstruction, display, and storage. The scanning of the beams on the two axes is done using a conventional rotating polygon for the fast vertical scan and a motor driven mirror for the slower horizontal scan. An alignment pattern helps ensure that the patient's eye is correctly positioned.

The reflected energy from the retinal surface is passed back through the device to an array of two discrete detectors (effectively a red and a green channel). For the Panoramic 200CAF and the P200, in standard imaging mode, the images produced can be viewed either as a composite image (red and green images combined) or separate as a green channel and a red channel image. The Panoramic 200CAF can also generate an alternate red channel image that shows the natural fluorescence (autofluorescence) of the eye. In this imaging mode, the retina is illuminated using the green laser, while the red laser optical path is blocked by a shutter. In this imaging mode, the red channel image now displays the naturally occurring fluorescent material of the retina, such as lipofuscin. The signal strength varies as the laser beam is scanned across the eye, allowing an image to be created and recorded, revealing the variation in its constituent material and structures.

This scanning function is housed in the 'scanhead', which is seated on a table that can move up and down and this affords a height adjustment to achieve correct patient positioning.

The Panoramic 200CAF and P200 capture one image at a time and can present each image as a thumbnail sketch. If more than one image is captured, the Panoramic 200CAF and Panoramic 200 display a series of thumbnail sketches in the order in which they were scanned. The Panoramic 200CAF, like the P200, allows the user to view one or more images of the eye.

Principles of Operation:

Both the P200CAF and the P200 have very similar principles of operation. Both devices use lasers as a light source that is scanned by a deflection system in two axes across the retina to generate an image. The returned light then travels back along the same path to a light detector that converts the light to an electrical signal. This electrical signal is digitized and used to build up an electronic picture in a computer and displayed either on a cathode ray tube or a liquid crystal display.

Both the P200CAF and the P200 use the same red and green lasers. Both devices can generate a composite red/green image. The autofluorescence imaging mode present in the P200CAF can be used by the healthcare professional in conjunction with the standard composite (red/green) and the associated separated red and green channel images to aid in the diagnosing and monitoring of diseases and disorders that manifest themselves in the eye.

The mechanism for autofluorescence is well understood and documented. The green wavelength is primarily reflected by the retinal pigment epithelium (RPE)/photoreceptor interface and the red light is reflected by the choroid. Autofluorescence looks at the distribution of lipofuscin within the RPE. Thus, autofluorescence gives an alternate view of the retinal layers and is complimentary to the red/green composite reflectance image and the separated red and green reflectance images.

Performance Testing:

Compliance to electrical safety (including EMC), light emitting products, programmable devices and biocompatibility standards are met. Each device is tested for electrical safety, laser power output and correct functioning of the laser radiation management system against set criteria and limits. Additionally, performance testing was conducted to demonstrate that

the P200CAF accurately and reproducibly produces images the eye in both standard and autofluorescence imaging modes.

Substantial Equivalence

The Panoramic 200CAF has the same intended use, similar principles of operation, and similar technological characteristics as the predicate device. The minor differences between the Panoramic 200CAF and the predicate device do not raise any new questions of safety and effectiveness. Thus, the Optos Panoramic 200CAF Ophthalmoscope is substantially equivalent to Optos' legally marketed Scanning Laser Ophthalmoscopes (SLO), the P200 (K983999).



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Optos PLC
c/o Mr. Howard M. Holstein
Partner
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004

JUL 15 2010

Re: K100644
Trade Name: Panoramic 200CAF
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulation Class: Class II
Product Code: MYC
Dated: June 15, 2010
Received: June 15, 2010

Dear Mr. Holstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement for Indication for Use

510(k) Number (if known): K100644

Device Name: Optos Panoramic 200CAF Scanning Laser Ophthalmoscope

Indications for Use:

The Panoramic 200CAF scanning laser ophthalmoscope is intended to be used as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.

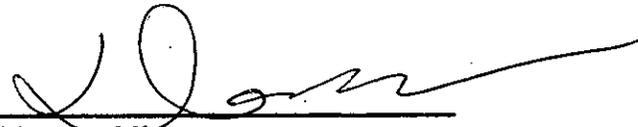
Prescription Use
(Per 21 C.F.R. 801.109)

AND/OR

Over-The-Counter Use

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number _____

K100644

Hogan Lovells US LLP
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July 14, 2010

By Hand Delivery and Electronic Mail

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

K-50
FDA CDRH DMC

JUL 14 2010

Received

Attn: Dexiu Shi, Ph.D. (Room 2246)

Re: Response to FDA's Request for Additional Information Regarding the Optos Limited Panoramic 200CAF (K100644)

Dear Dr. Shi:

As regulatory counsel to Optos Limited ("Optos" or "the company"), Hogan Lovells US LLP (formerly Hogan & Hartson LLP) is filing this response to the Food and Drug Administration's ("FDA" or "the agency") July 13, 2010, e-mail requesting additional information regarding the Panoramic 200CAF (K100644) ("P200CAF" or "the device"). For ease of review, the items from the agency's July 13 e-mail are reproduced in italics below, followed by the company's response to each. We trust that this response provides the information needed for the agency to proceed with the review of the company's 510(k) submission.

- 1. In your response, you state that "the Patient Alignment System (PAS) contains multiple visible LEDs (four red and one green) and a NIR (near infrared) LED source...The company's radiation hazard analysis using ISO15004-2:2007 for the additional LEDs contained in the patient alignment system is provided in **Attachment 6.**"*

However, you only provide the radiation hazard analysis for one green visible LED and the NIR LED. We are unable to locate the hazard analysis for these four visible red LEDs. Please provide this information.

Response: In light of the low light levels involved and the high safety margins with respect to the limits, the original document considered only the green LED, as it has the most stringent weighting factors.

As requested, please find the additional calculations for the red LEDs and the associated tabulation for all LED sources in **Attachment 1**. The tabulated radiation hazard analysis indicates that the system meets the group 1 conditions in all instances.

2. To facilitate our review, please summarize your radiation hazard analysis in the following table:

Light Source/ Wavelength	Measurement (e.g. irradiance and or radiance, etc)	Limit for Group 1 Instrument (based on 15004-2)
Visible Green LED		
Visible Red LED		
NIR (near infrared) LED		

Response: The company has compiled its radiation hazard analysis in the format requested by the agency, below. This table is also provided on page 2 of Attachment 1.

Light Source/ Wavelength	Measurement (e.g. irradiance and or radiance, etc)	Limit for Group 1 Instrument (based on 15004-2)
Visible Green LED – (b) (4)	(b) (4)	EA-R=220µWcm-2 LA-R=2mWcm-2 EVIR-IR=0.7Wcm-2 LVIR-IR=6Wcm-2sr-1
Visible Red LED – (b) (4)	(b) (4)	EA-R=220µWcm-2 LA-R=2mWcm-2 EVIR-IR=0.7Wcm-2 LVIR-IR=6Wcm-2sr-1
NIR (near infrared) LED – (b) (4)	(b) (4)	EVIR-IR=0.7Wcm-2 LVIR-IR=6Wcm-2sr-1
Red and NIR LED's combined [E1/Limit1+E2/Limit2 <1]	(b) (4)	<1 <1
Green and NIR LED's combined [E1/Limit1+E2/Limit2 <1]	(b) (4)	<1 <1

3. Again, pages 8-16 of Attachment 6 are in a poor quality. Please resubmit these pages which should be in a good print quality.

Response: More readable versions of pages 8–16 of Attachment 6 are provided in Attachment 2. These are supplied in PDF format so that the content can be expanded as required.

* * *

The company believes that this response fully addresses the issues raised in the agency's July 13, 2010, e-mail. We trust that the information provided is sufficient for the agency to find the P200CAF substantially equivalent to its predicate devices for the listed indication. If you have any further questions, please contact me at the number below or Danielle Woodlee at 202-637-8853. Upon clearance of the device please forward the substantial equivalence letter to me by facsimile to 202-637-5910.

Sincerely,



Howard M. Holstein

Partner
howard.holstein@hoganlovells.com
D (202) 637-5813

Attachments

cc: Robert Tweedlie, Optos Ltd.
Randy Prebula, Hogan Lovells US LLP
Danielle C. Woodlee, Hogan Lovells US LLP

July 14, 2010

By Hand Delivery and Electronic Mail

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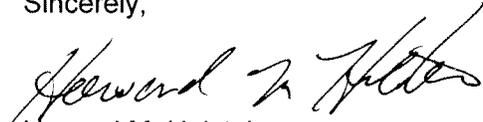
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Sincerely,



Howard M. Holstein

Partner
howard.holstein@hoganlovells.com
D (202) 637-5813

Attachments

cc: Robert Tweedlie, Optos Ltd.
Randy Prebula, Hogan Lovells US LLP
Danielle C. Woodlee, Hogan Lovells US LLP

Attachment 1

Patient Alignment System – Analysis to Requirements and Test Methods – Part 2: Light Hazard Protection (EN ISO 15004-2:2007) – Supplementary Information

The design of the lens system for the Red LEDs is the same as that for the green LED. As a result, the following key parameters are used.

- Geometrical distribution of LED illumination at corneal plane = (b) (4)
- Geometrical distribution of LED illumination at object plane = (b) (4)
- Red LED peak wavelength (b) (4)
- Spectral line half width = (b) (4) used to determine worst case weighting factors
- Red LED power at corneal plane = (b) (4) (measured using Ophir Nova Meter – calibrated 08th March 2010, P/N 1201500, S/N118042- and PD300 photodiode smarthead –calibrated 08th March 2010, P/N1202410, S/N107932)

Following the calculations submitted for the green LED gives:

Spectral Radiance:

(b) (4)

Retinal Spectral Radiance:

(b) (4)

Weighted Retinal Thermal Irradiance:

Weighting factor for (b) (4) = 1, therefore,

(b) (4)

Compared to the group 1 limit of 0.7Wcm^{-2} .

Weighted Retinal Irradiance:

(b) (4)

Compared to the group 1 limit of $220\mu\text{W}\cdot\text{cm}^{-2}$ there is a margin of $>670,000$.

Weighted Retinal Radiance:

(b) (4)

Compared to the group ()

A summary of the radiation hazard analysis is tabulated below and it is concluded that the operation of the system falls within the group 1 limits under all conditions.:-

Light Source/ Wavelength	Measurement (e.g. irradiance and or radiance, etc)	Limit for Group 1 Instrument (based on 15004-2)
Visible Green LED - (b) (4)	(b) (4)	$E_{A-R}=220\mu\text{Wcm}^{-2}$ $L_{A-R}=2\text{mWcm}^{-2}$ $E_{\text{VIR-IR}}=0.7\text{Wcm}^{-2}$ $L_{\text{VIR-IR}}=6\text{Wcm}^{-2}\text{sr}^{-1}$
Visible Red LED - (b) (4)	(b) (4)	$E_{A-R}=220\mu\text{Wcm}^{-2}$ $L_{A-R}=2\text{mWcm}^{-2}$ $E_{\text{VIR-IR}}=0.7\text{Wcm}^{-2}$ $L_{\text{VIR-IR}}=6\text{Wcm}^{-2}\text{sr}^{-1}$
NIR (near infrared) LED - (b) (4)	(b) (4)	$E_{\text{VIR-IR}}=0.7\text{Wcm}^{-2}$ $L_{\text{VIR-IR}}=6\text{Wcm}^{-2}\text{sr}^{-1}$
Red and NIR LED's combined	(b) (4)	<1
Green and NIR LED's combined	(b) (4)	<1

Attachment 2

KPTD-3216SRC-PRV SUPER BRIGHT RED

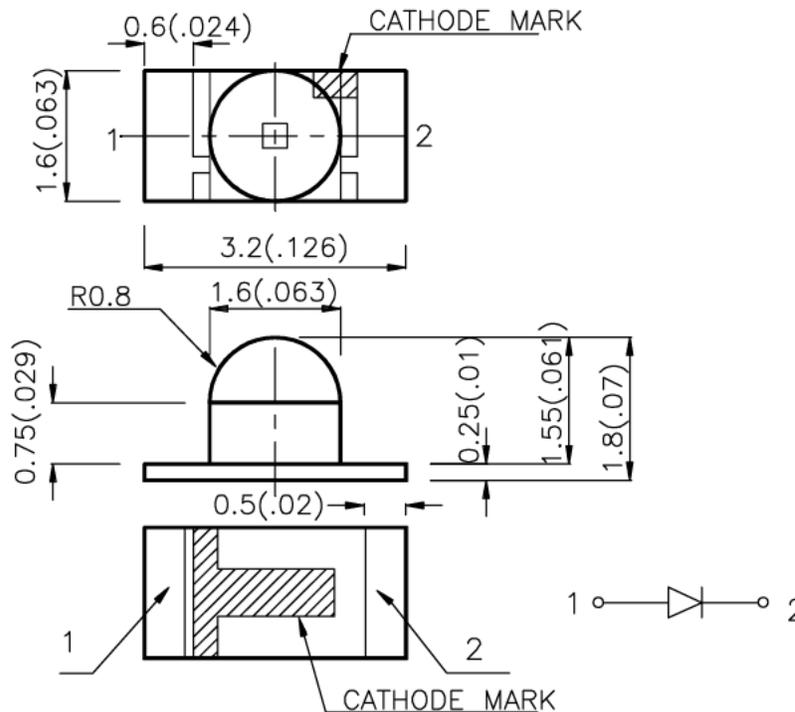
Features

- 3.2mmx1.6mm SMT LED, 1.8mm THICKNESS.
- LOW POWER CONSUMPTION.
- WIDE VIEWING ANGLE.
- IDEAL FOR BACKLIGHT AND INDICATOR.
- PACKAGE : 2000PCS / REEL.

Description

The Super Bright Red source color devices are made with Gallium Aluminum Arsenide Red Light Emitting Diode.

Package Dimensions



Notes:

1. All dimensions are in millimeters (inches).
2. Tolerance is ± 0.2 (0.0079") unless otherwise noted.
3. Specifications are subject to change without notice.

Selection Guide

Part No.	Dice	Lens Type	Iv (mcd) @ 20mA		Viewing Angle
			Min.	Typ.	2θ1/2
KPTD 3216SRC PRV	SUPER BRIGHT RED(GaAlAs)	WATER CLEAR	110	300	50°

Note:

1. θ1/2 is the angle from optical centerline where the luminous intensity is 1/2 the optical centerline value.

Electrical / Optical Characteristics at T_A=25°C

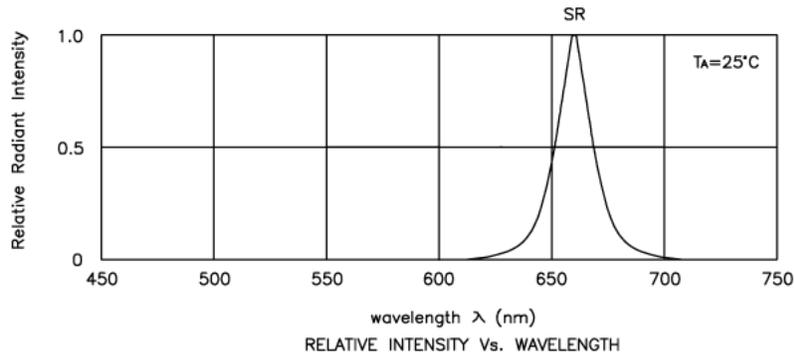
Symbol	Parameter	Device	Typ.	Max.	Units	Test Conditions
λ _{peak}	Peak Wavelength	Super Bright Red	660		nm	I _F =20mA
λ _D	Dominate Wavelength	Super Bright Red	640		nm	I _F =20mA
Δλ _{1/2}	Spectral Line Half width	Super Bright Red	20		nm	I _F =20mA
C	Capacitance	Super Bright Red	45		pF	V _F =0V;f=1MHz
V _F	Forward Voltage	Super Bright Red	1.85	2.5	V	I _F =20mA
I _R	Reverse Current	Super Bright Red		10	μA	V _R = 5V

Absolute Maximum Ratings at T_A=25°C

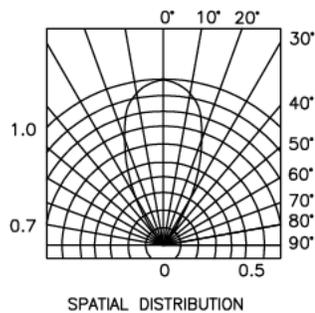
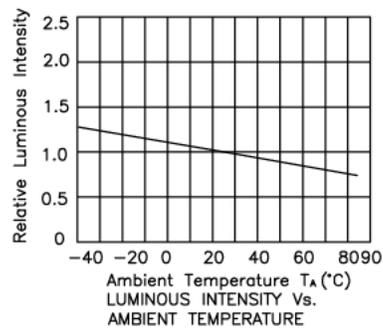
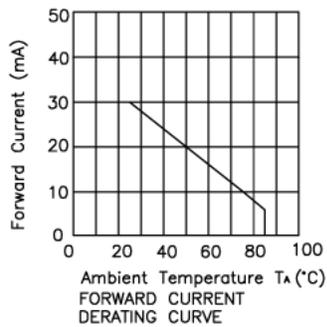
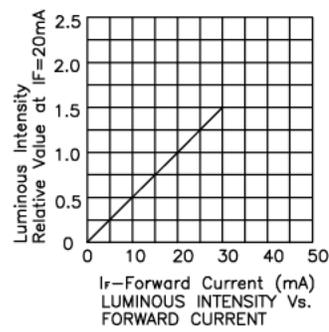
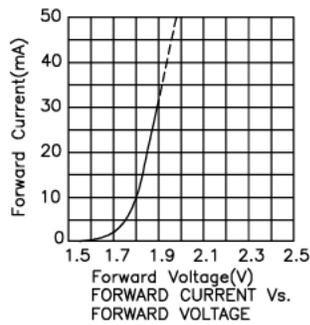
Parameter	Super Bright Red	Units
Power dissipation	100	mW
DC Forward Current	30	mA
Peak Forward Current [1]	155	mA
Reverse Voltage	5	V
Operating/Storage Temperature	40°C To +85°C	

Note:

1. 1/10 Duty Cycle, 0.1ms Pulse Width.

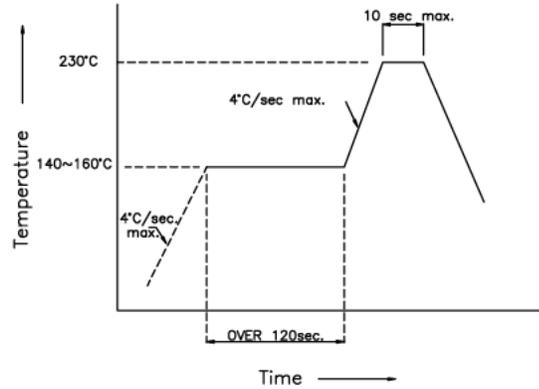


Super Bright Red KPTD-3216SRC-PRV

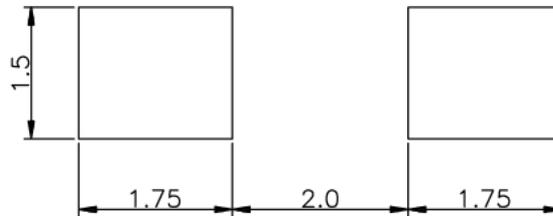


KPTD-3216SRC-PRV SMT Reflow Soldering Instructions

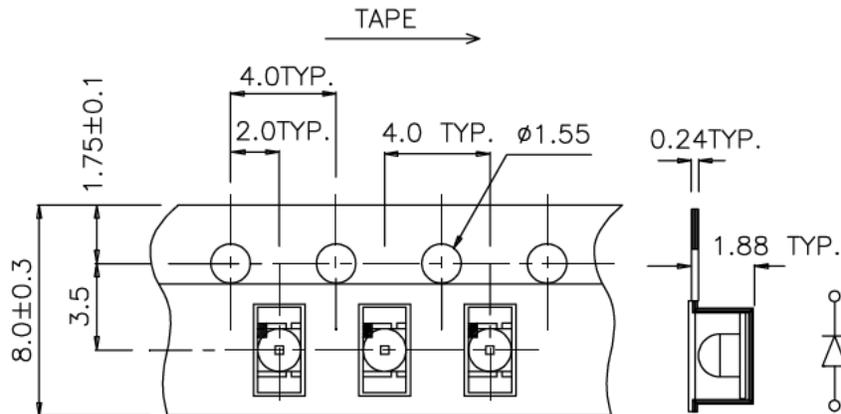
Number of reflow process shall be less than 2 times and cooling process to normal temperature is required between first and second soldering process.



Recommended Soldering Pattern (Units : mm)



Tape Specifications (Units : mm)



KPTD-3216CGCK GREEN

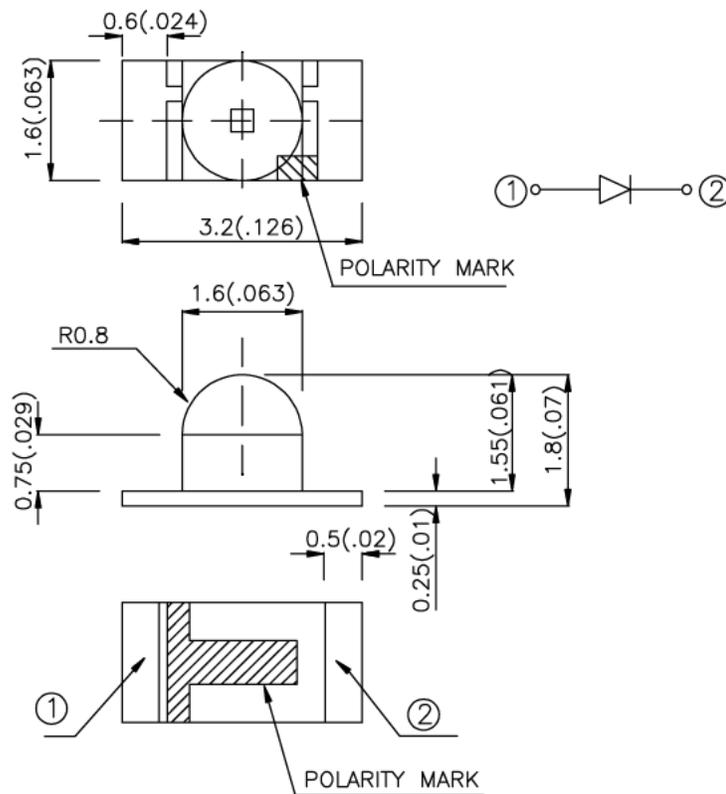
Features

- 3.2mmx1.6mm SMT LED, 1.8mm THICKNESS.
- LOW POWER CONSUMPTION.
- WIDE VIEWING ANGLE.
- IDEAL FOR BACKLIGHT AND INDICATOR.
- PACKAGE : 2000PCS / REEL.

Description

The Green source color devices are made with InGaAlP on GaAs substrate Light Emitting Diode.

Package Dimensions



Notes:

1. All dimensions are in millimeters (inches).
2. Tolerance is ± 0.2 (0.0079") unless otherwise noted.
3. Specifications are subject to change without notice.

Selection Guide

Part No.	Dice	Lens Type	Iv (mcd) @ 20 mA		Viewing Angle
			Min.	Typ.	θ1/2
KPTD-3216CGCK	GREEN (InGaAlP)	WATER CLEAR	70	200	50°

Note:

1. θ1/2 is the angle from optical centerline where the luminous intensity is 1/2 the optical centerline value.

Electrical / Optical Characteristics at T_A=25°C

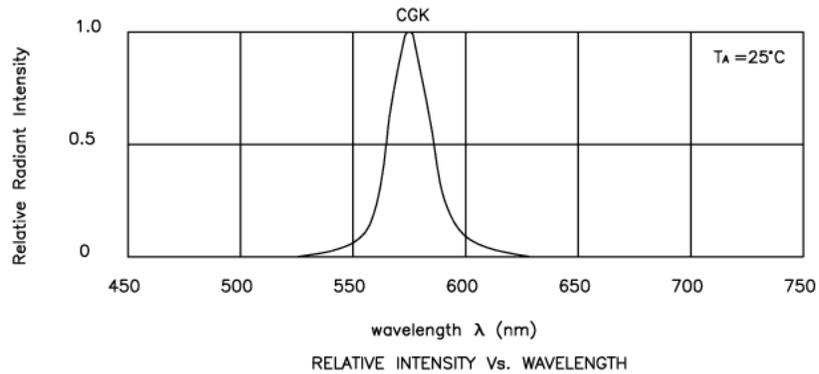
Symbol	Parameter	Device	Typ.	Max.	Units	Test Conditions
λ _{peak}	Peak Wavelength	Green	574		nm	I _F =20mA
λ _D	Dominate Wavelength	Green	570		nm	I _F =20mA
Δλ _{1/2}	Spectral Line Half-width	Green	20		nm	I _F =20mA
C	Capacitance	Green	15		pF	V _F =0V;f=1MHz
V _F	Forward Voltage	Green	2.1	2.5	V	I _F =20mA
I _R	Reverse Current	Green		10	μA	V _R = 5V

Absolute Maximum Ratings at T_A=25°C

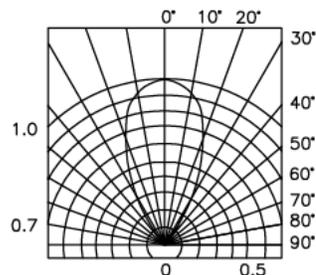
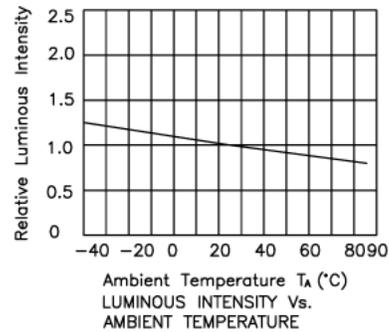
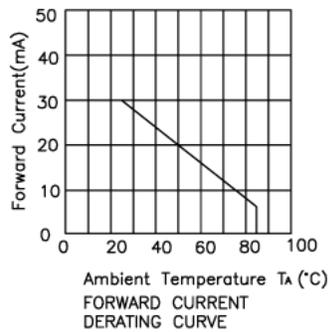
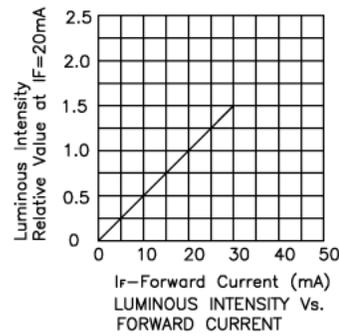
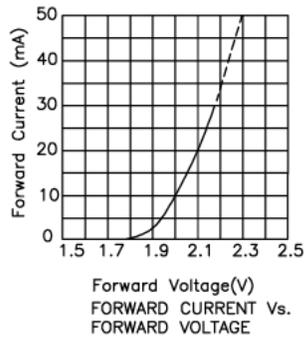
Parameter	Green	Units
Power dissipation	105	mW
DC Forward Current	30	mA
Peak Forward Current [1]	150	mA
Reverse Voltage	5	V
Operating/Storage Temperature	-40°C To +85°C	

Note:

1. 1/10 Duty Cycle, 0.1ms Pulse Width.



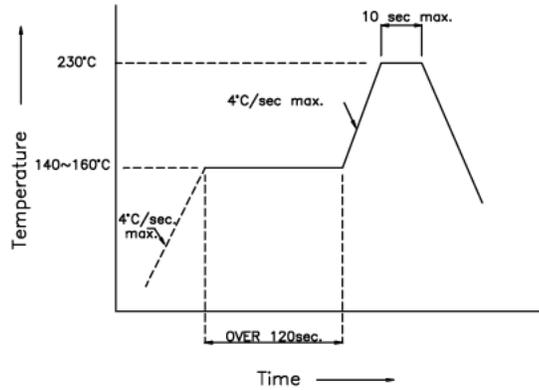
Green KPTD-3216CGCK



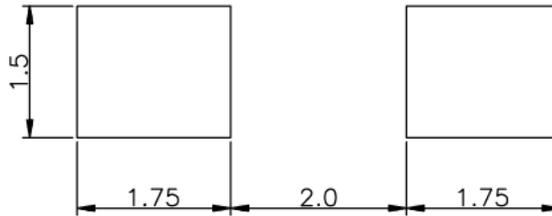
KPTD-3216CGCK

SMT Reflow Soldering Instructions

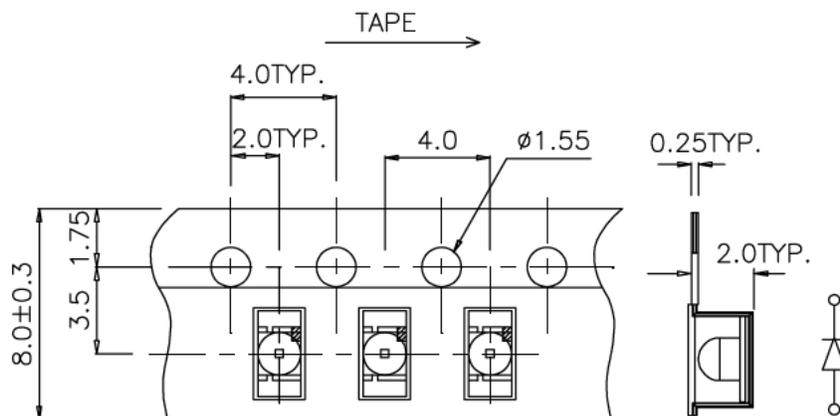
Number of reflow process shall be less than 2 times and cooling process to normal temperature is required between first and second soldering process.



Recommended Soldering Pattern (Units : mm)



Tape Specifications (Units : mm)





Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Optos PLC
c/o Mr. Howard M. Holstein
Partner
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004

JUL 15 2010

Re: K100644
Trade Name: Panoramic 200CAF
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulation Class: Class II
Product Code: MYC
Dated: June 15, 2010
Received: June 15, 2010

Dear Mr. Holstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement for Indication for Use

510(k) Number (if known): K100644

Device Name: Optos Panoramic 200CAF Scanning Laser Ophthalmoscope

Indications for Use:

The Panoramic 200CAF scanning laser ophthalmoscope is intended to be used as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.

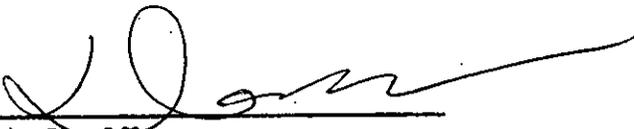
Prescription Use _____
(Per 21 C.F.R. 801.109)

AND/OR

Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K100644



U.S. Food and Drug Administration
Center for Devices and Radiological Health
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10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 16, 2010

OPTOS PLC
C/O HOGAN & HARTSON, LLP
555 THIRTEENTH ST. N.W. COLUMBIA SQUARE
WASHINGTON, DISTRICT OF COLUMBIA 20004-1109
UNITED STATES
ATTN: HOWARD M. HOLSTEIN

510k Number: K100644

Product: OPTOS LIMITED PANORAMIC 200CAF

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

69



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 28, 2010

OPTOS PLC
C/O HOGAN & HARTSON, LLP
555 THIRTEENTH ST. N.W. COLUMBIA SQUARE
WASHINGTON, DISTRICT OF COLUMBIA 20004-1109
UNITED STATES
ATTN: HOWARD M. HOLSTEIN

510k Number: K100644
Product: OPTOS LIMITED PANORAMIC 200CAF

Extended Until: 07/06/2010

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health



Hogan Lovells US LLP
 Columbia Square
 555 Thirteenth Street, NW
 Washington, DC 20004
 T +1 202 637 5600
 F +1 202 637 5910
 www.hoganlovells.com

May 27, 2010

By Hand Delivery

U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Mail Center – WO66-G609
 10903 New Hampshire Avenue
 Silver Springs, MD 20993-0002

FDA CDRH DMC

MAY 27 2010

Received

Attention: Dexiu Shi, Ph.D. (Room 2246)

Re: Request for Extension of Time to Respond to FDA's Request for Additional Information Regarding the 510(k) Premarket Notification for Optos Ltd.'s Panoramic 200CAF (K100644)

Dear Dr. Shi:

The purpose of this letter is to request that the Food and Drug Administration ("FDA" or "the agency") grant a 30-day extension of time for Optos, Ltd. to respond to FDA's May 4, 2010, letter requesting additional information with regard to the 510(k) premarket notification for the Panoramic 200CAF (K100644). The company's response is currently due on June 3, 2010. This extension of the deadline to July 3, 2010, is necessary in order for the company to fully respond to the issues identified in the May 4, 2010, letter.

Please contact me at the below number or Randy Prebula at (202) 637-6548 if you have any questions regarding this request. Thank you in advance for your assistance.

Sincerely,

Howard M. Holstein

Partner
 howard.holstein@hoganlovells.com
 D (202) 637-5813

cc: Robert Tweedlie, Optos, Ltd.
 Randy J. Prebula, Hogan Lovells US LLP
 Danielle C. Woodlee, Hogan Lovells US LLP

KUB



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 Columbia Square
 555 Thirteenth Street, NW
 Washington, DC 20004
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 F +1 202 637 5910
 www.hoganlovells.com

May 27, 2010

By Hand Delivery

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 Center for Devices and Radiological Health
 Document Mail Center – WO66-G609
 10903 New Hampshire Avenue
 Silver Springs, MD 20993-0002

FDA CDRH DMC

MAY 27 2010

Received

Attention: Dexiu Shi, Ph.D. (Room 2246)

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Sincerely,

Howard M. Holstein

Partner
 howard.holstein@hoganlovells.com
 D (202) 637-5813

cc: Robert Tweedlie, Optos, Ltd.
 Randy J. Prebula, Hogan Lovells US LLP
 Danielle C. Woodlee, Hogan Lovells US LLP



Hogan Lovells US LLP
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May 27, 2010

By Hand Delivery

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Springs, MD 20993-0002

FDA CDRH DIV

MAY 27 2010

Received

Attention: Dexiu Shi, Ph.D. (Room 2246)

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Please contact me at the below number or Randy Prebula at (202) 637-6548 if you have any questions regarding this request. Thank you in advance for your assistance.

Sincerely,

Howard M. Holstein

Partner
howard.holstein@hoganlovells.com
D (202) 637-5813

cc: Robert Tweedlie, Optos, Ltd.
Randy J. Prebula, Hogan Lovells US LLP
Danielle C. Woodlee, Hogan Lovells US LLP

Hogan Lovells US LLP is a limited liability partnership registered in the District of Columbia. Hogan Lovells refers to the international legal practice comprising Hogan Lovells US LLP, Hogan Lovells International LLP, Hogan Lovells Worldwide Group (a Swiss Verein), and their affiliated businesses with offices in: Abu Dhabi Alicante Amsterdam Baltimore Beijing Berlin Boulder Brussels Caracas Chicago Colorado Springs Denver Dubai Dusseldorf Frankfurt Hamburg Hanoi Ho Chi Minh City Hong Kong Houston London Los Angeles Madrid Miami Milan Moscow Munich New York Northern Virginia Paris Philadelphia Prague Rome San Francisco Shanghai Silicon Valley Singapore Tokyo Warsaw Washington DC Associated offices: Budapest Jeddah Riyadh Zagreb

73



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May 27, 2010

By Hand Delivery

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 Center for Devices and Radiological Health
 Document Mail Center – WO66-G609
 10903 New Hampshire Avenue
 Silver Springs, MD 20993-0002

FDA CDRH DMC

MAY 27 2010

Received

Attention: Dexiu Shi, Ph.D. (Room 2246)

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Please contact me at the below number or Randy Prebula at (202) 637-6548 if you have any questions regarding this request. Thank you in advance for your assistance.

Sincerely,

Howard M. Holstein

Partner
 howard.holstein@hoganlovells.com
 D (202) 637-5813

cc: Robert Tweedlie, Optos, Ltd.
 Randy J. Prebula, Hogan Lovells US LLP
 Danielle C. Woodlee, Hogan Lovells US LLP

24



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 05, 2010

OPTOS PLC
C/O HOGAN & HARTSON, LLP
555 THIRTEENTH ST. N.W. COLUMBIA SQUARE
WASHINGTON, DISTRICT OF COLUMBIA 20004-1109
UNITED STATES
ATTN: HOWARD M. HOLSTEIN

510k Number: K100644

Product: OPTOS LIMITED PANORAMIC 200CAF

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

A handwritten signature in black ink that reads "Marjorie Shulman". The signature is written in a cursive style with a long horizontal line extending from the end of the name.

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

March 08, 2010

OPTOS PLC
C/O HOGAN & HARTSON, LLP
555 THIRTEENTH ST. N.W. COLUMBIA SQUARE
WASHINGTON, DISTRICT OF COLUMBIA 20004-1109
UNITED STATES
ATTN: HOWARD M. HOLSTEIN

510k Number: K100644

Received: 3/5/2010

Product: OPTOS LIMITED PANORAMIC 200CAF

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

K100644

HOGAN & HARTSON

Hogan & Hartson LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
+1.202.637.5600 Tel
+1.202.637.5910 Fax

www.hhlaw.com

March 5, 2010

K-48

Howard M. Holstein
Partner
+1.202.637.5813
hmholstein@hhlaw.com

Received

BY HAND DELIVERY

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

MAR 05 2010

FDA CDRH DMC

FDA CDRH DMC

MAR 05 2010

Received

Attn: Ophthalmic Lasers, Neuromuscular Stimulators, and Diagnostics Branch

Re: Special 510(k): Device Modification for Optos Limited Panoramic 200CAF

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (“FDC Act”), Optos Limited (“Optos” or the “Company”), by its regulatory counsel, is submitting the attached Special 510(k) premarket notification (“Special 510(k)”) for its Panoramic 200CAF Scanning Laser Ophthalmoscope (“Panoramic 200CAF” or the “device”) for use as a wide field imaging ophthalmoscope for diagnosing and monitoring diseases or disorders that manifest themselves in the posterior pole of the eye. The Panoramic 200CAF is a scanning laser ophthalmoscope. The Panoramic 200CAF is a modification to company’s Panoramic 200 scanning laser ophthalmoscope that has already been cleared by the Food and Drug Administration (“FDA” or the “Agency”) for use as a wide field ophthalmoscope for diagnosing and monitoring diseases or disorders that manifest themselves in the posterior pole of the eye (K983999). The Panoramic 200CAF has the same intended use and fundamental scientific technology as the cleared device. The primary changes are:

- Increased resolution including a zoom mode.
- Directed eye steering to alter the part of the retina being viewed.
- Inclusion of a shutter to permit imaging with either the red or the green laser alone.
- Ability to move optical elements in and out of the return path to optimize the signal strength of different imaging modes. This, combined with closing the red laser

shutter, affords an imaging mode where the natural fluorescence of the eye can be displayed.

- Monitoring of the laser output in both horizontal and vertical scans.
- Modifications to the user interface for ease of use. This includes an integrated monitor and combined capture and table movement controller to improve the device layout.
- Patient Alignment System has an improved visual assist for ease of patient positioning.
- The addition of a head and chin rest for ease of patient positioning.
- The device is powered from the scanhead rather than the table of the device.

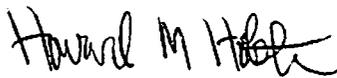
There are associated changes to the software to effect these modifications and these changes were validated in conjunction with the mechanical/physical changes.

The Panoramic 200CAF has the same intended use and similar indications, technological characteristics, and principles of operation as the cleared predicate device. As explained in the attached Special 510(k) notice, the minor differences between the Panoramic 200CAF and the predicate device do not raise any new questions of safety or effectiveness. Thus, we believe that Panoramic 200CAF is substantially equivalent.

In accordance with the Food and Drug Administration Amendments Act of 2007, Optos has submitted the appropriate application fee of \$4,007. A copy of the User Fee Cover Sheet is provided with the attached Special 510(k) notice.

The information contained herein was provided by Optos to Hogan & Hartson for submission to the Agency. We trust that the information provided in the Special 510(k) notice is sufficient for FDA to find the Panoramic 200CAF substantially equivalent to its predicate device for the listed indications. If you have any additional questions regarding the Special 510(k) notice, please contact me at the above number or Randy Prebula at 202- 637-6548. Upon a finding of substantial equivalence, please fax the substantial equivalence letter to me at (202) 637-5910.

Sincerely,



Howard M. Holstein



Attachments

cc: Robert Tweedlie, Ph.D., Optos Limited
Randy Prebula, Hogan & Hartson, LLP
Danielle C. Woodlee, Hogan & Hartson, LLP

HOGAN & HARTSON

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March 5, 2010

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Partner
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hholstein@hhlaw.com

BY HAND DELIVERY

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attn: Ophthalmic Lasers, Neuromuscular Stimulators, and Diagnostics Branch

Re: Special 510(k): Device Modification for Optos Limited Panoramic 200CAF

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (“FDC Act”), Optos Limited (“Optos” or the “Company”), by its regulatory counsel, is submitting the attached Special 510(k) premarket notification (“Special 510(k)”) for its Panoramic 200CAF Scanning Laser Ophthalmoscope (“Panoramic 200CAF” or the “device”) for use as a wide field imaging ophthalmoscope for diagnosing and monitoring diseases or disorders that manifest themselves in the posterior pole of the eye. The Panoramic 200CAF is a scanning laser ophthalmoscope. The Panoramic 200CAF is a modification to company’s Panoramic 200 scanning laser ophthalmoscope that has already been cleared by the Food and Drug Administration (“FDA” or the “Agency”) for use as a wide field ophthalmoscope for diagnosing and monitoring diseases or disorders that manifest themselves in the posterior pole of the eye (K983999). The Panoramic 200CAF has the same intended use and fundamental scientific technology as the cleared device. The primary changes are:

- Increased resolution including a zoom mode.
- Directed eye steering to alter the part of the retina being viewed.
- Inclusion of a shutter to permit imaging with either the red or the green laser alone.
- Ability to move optical elements in and out of the return path to optimize the signal strength of different imaging modes. This, combined with closing the red laser

shutter, affords an imaging mode where the natural fluorescence of the eye can be displayed.

- Monitoring of the laser output in both horizontal and vertical scans.
- Modifications to the user interface for ease of use. This includes an integrated monitor and combined capture and table movement controller to improve the device layout.
- Patient Alignment System has an improved visual assist for ease of patient positioning.
- The addition of a head and chin rest for ease of patient positioning.
- The device is powered from the scanhead rather than the table of the device.

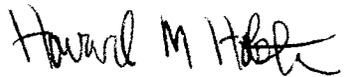
There are associated changes to the software to effect these modifications and these changes were validated in conjunction with the mechanical/physical changes.

The Panoramic 200CAF has the same intended use and similar indications, technological characteristics, and principles of operation as the cleared predicate device. As explained in the attached Special 510(k) notice, the minor differences between the Panoramic 200CAF and the predicate device do not raise any new questions of safety or effectiveness. Thus, we believe that Panoramic 200CAF is substantially equivalent.

In accordance with the Food and Drug Administration Amendments Act of 2007, Optos has submitted the appropriate application fee of \$4,007. A copy of the User Fee Cover Sheet is provided with the attached Special 510(k) notice.

The information contained herein was provided by Optos to Hogan & Hartson for submission to the Agency. We trust that the information provided in the Special 510(k) notice is sufficient for FDA to find the Panoramic 200CAF substantially equivalent to its predicate device for the listed indications. If you have any additional questions regarding the Special 510(k) notice, please contact me at the above number or Randy Prebula at 202- 637-6548. Upon a finding of substantial equivalence, please fax the substantial equivalence letter to me at (202) 637-5910.

Sincerely,



Howard M. Holstein



Attachments

cc: Robert Tweedlie, Ph.D., Optos Limited
Randy Prebula, Hogan & Hartson, LLP
Danielle C. Woodlee, Hogan & Hartson, LLP

Optos plc's

**Panoramic 200CAF
Scanning Laser Ophthalmoscope**

Special 510(k) Premarket Notification

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET	Form Approval OMB No. 9010-0120 Expiration Date: May 31, 2007. See OMB Statement on page 5.
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Date of Submission March 05, 2010	User Fee Payment ID Number (b) (4)	FDA Submission Document Number (if known)
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SECTION A TYPE OF SUBMISSION

PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA &HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Optos PLC	Establishment Registration Number (if known) 9617167		
Division Name (if applicable)	Phone Number (including area code) (01144) 1383 843300		
Street Address Queensferry House Carnegie Business Campus	FAX Number (including area code) (01144) 1383 843333		
City Dumfermline	State / Province Fife	ZIP/Postal Code KY11 8GR	Country GB
Contact Name Robert Tweedlie. Ph.D.			
Contact Title Vice President Global Quality Assurance and Regulatory Affairs		Contact E-mail Address rtweedlie@optos.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name Hogan & Hartson, L.L.P.	Phone Number (including area code) (202) 637-5815		
Division Name (if applicable)	FAX Number (including area code) (202) 637-5910		
Street Address 555 Thirteenth Street, NW	FAX Number (including area code) (202) 637-5910		
City	State / Province	ZIP/Postal Code	Country

Washington	DC	2004	USA
Contact Name Howard M. Holstein			
Contact Title Partner		Contact E-mail Address HMHolstein@hhlaw.com	

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION D2 REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access Request for Removal of Applicant Hold	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
	<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	Manufacturer
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS		
Product Code MYC	C.F.R. Section (if applicable) 21 C.F.R. § 886.1570	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Ophthalmic Devices Panel		
Indications (from labeling) The Panoramic 200CAF scanning laser ophthalmoscope is indicated for use as a wide field ophthalmoscope for diagnosing and monitoring diseases or disorders that manifest themselves in the posterior pole of the eye.		

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number (if known)
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SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 9617617	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Optos PLC		Establishment Registration Number 9035556	
Division Name (if applicable)		Phone Number (including area code) (01144) 1383 843300	
Street Address Queensferry House Carnegie Business Campus		FAX Number (including area code) (01144) 1383 843333	
City Dunfermline	State / Province Fife	ZIP/Postal Code KY11 8GR	Country GB
Contact Name Robert Tweedlie, Ph.D.	Contact Title Vice President Global Quality Assurance and Regulatory Affairs	Contact E-mail Address rtweedlie@optos.com	

SECTION I UTILIZATION OF STANDARDS					
Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.					
1	Standards No.	Standards Organization	Standards Title	Version	Date
	60601-1	IEC	Medical electrical equipment. General requirements for safety	A1:1991 & A2:1995 Corrigendum95	1988 (published date 2005)
2	Standards No.	Standards Organization	Standards Title	Version	Date

	60825-1	IEC	Medical electrical equipment. General requirements for safety.		2007
3	<i>Standards No.</i>	<i>Standards Organization</i>	<i>Standards Title</i>	<i>Version</i>	<i>Date</i>
	60601-1-2	IEC	Medical electrical equipment. General requirements for safety. Collateral standard. Electromagnetic compatibility requirements and tests.	Modified	2007
5	<i>Standards No.</i>	<i>Standards Organization</i>	<i>Standards Title</i>	<i>Version</i>	<i>Date</i>
	60601-1-4	IEC	Medical electrical equipment. General requirements for safety. Collateral standard. General requirements for programmable electrical medical systems.	Edition 1.1	2000-04
6	<i>Standards No.</i>	<i>Standards Organization</i>	<i>Standards Title</i>	<i>Version</i>	<i>Date</i>
	10993-5	ISO	Test for In Vitro Cytotoxicity		1999 & 2009
7	<i>Standards No</i>	<i>Standards Organization</i>	<i>Standards Title</i>	<i>Version</i>	<i>Date</i>
	10993-10	ISO	Tests for Irritation and Delayed-Type Hypersensitivity	Kligman Maximization test	2002 and amendment 2006
8	<i>Standards No.</i>	<i>Standards Organization</i>	<i>Standards Title</i>	<i>Version</i>	<i>Date</i>
	10993-10	ISO	Tests for Irritation and Delayed-Type Hypersensitivity	Intra-cutaneous injection test	2002 and amendment 2006

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

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I. NAME OF DEVICE

Classification Name: Scanning Laser Ophthalmoscope
(21 C.F.R. § 886.1570)

Common Names: Scanning Laser Ophthalmoscope

Trade Name: Panoramic 200CAF

Class: Class II

Classification Panel: Ophthalmic Devices Panel

Product Code: MYC

II. ESTABLISHMENT REGISTRATION NUMBER

Manufacturer: Optos plc
Queensferry House
Carnegie Business Campus
Dunfermline
Fife KY11 8GR
United Kingdom

Phone: 01144 1383 843300
Fax: 01144 1383 843333

Registration Number 9617167; Owner Operator Number 9035556

Distributor: Optos Inc.
67 Forest Street
Marlborough
Massachusetts 01752

Phone: 508 787 1400
Fax: 508 486 9310

Registration Number 1226140; Owner Operator number 9035556

III. DEVICE CLASS

Scanning laser ophthalmoscopes have been classified as class II, product code MYC.

IV. PERFORMANCE STANDARDS

Performance standards for ophthalmoscopes have not been established under 21 C.F.R. § 886.1570.

The Optos Panoramic 200CAF Scanning Laser Ophthalmoscope is a Class 1 laser device. This device complies with 21 C.F.R. Part 1010, “Performance Standards for Electronic Products: General,” and 21 C.F.R. Part 1040, “Performance Standards for Light-Emitting Products.” The Optos Panoramic 200CAF Scanning Laser Ophthalmoscope also complies with 47 C.F.R. Part 15 Sub Part B (2008) (Unintentional Radiators; Conducted and Radiated Emission Limits).

The consensus standards used and a summary data report and summary report are included in **Attachment 11**.

FDA has issued the “Ophthalmoscope Guidance (Direct and Indirect)” (“the guidance document”) that identifies the information that should be provided in a 510(k) notice. For convenience of review, we have identified each of the items required by the guidance document and either briefly provided that information, or indicated where the information appears in this submission.

- A *“No flammable materials may be used near the light source”* - No flammable materials are used near the Panoramic 200CAF’s light sources.
- B *“General Equivalency”* - A comparison of the Panoramic 200CAF and the legally marketed device is provided **Attachment 1a**. A chart summarizing the similarities and differences between the Panoramic 200CAF and the Panoramic P200 (K983999) is provided in **Attachment 1b**.
- B1 *“Intended uses”* - The Panoramic 200CAF and the predicate device are intended to be used to examine the retina of the eye. See Section VIII.
- B2 *“Method of Operation”*- The Panoramic 200CAF and the predicate device are Scanning Laser Ophthalmoscopes (SLO) and both work by the same method. The devices use a laser or lasers as a light source that is scanned by a deflection system in two axes across the retina of the eye. The returned light then travels back along the same path to a light detector that converts the light to an electrical signal. This electrical signal is digitized and used to build up an electronic picture, which is displayed either on a monitor attached to the device or via a Personal Computer (PC). The PC displays on a Cathode Ray Tube (“CRT”) or a Liquid Crystal Display (“LCD”). See Section VII.
- B3 *“Exposure Parameters”*- The Panoramic 200CAF and the predicate device are Class 1 laser devices. See above.
- B4 *“Data collection and/or display systems”*- The Panoramic 200CAF and the predicate device collect the data by a light sensitive device which converts the

- light into an electrical signal. The information is then handled by dedicated electronics and/or by a Personal Computer and displayed on a CRT or an LCD. All of the data collection and display systems are conventional and much of the hardware is standard, off-the-shelf computer devices. See Section VII.
- B5 “*Flammability of materials*”- All of the materials used in the construction of the Optos Panoramic 200CAF are metal or plastic with a UL 94V-0 rating.
- B6 “*Maximum temperature of accessible parts*”- All parts of the Panoramic 200CAF that are accessible by the operator or patient are no more than 10°C above the ambient air temperature.
- B7 “*Brightness Controls*”- Brightness can only be adjusted on the displayed image.
- C “*Optical Equivalence and Radiation Safety*”- Scanning Laser Ophthalmoscopes (SLO) are exempt from this requirement under Section V.C. of this guidance document at page 3, if they are class 1 laser systems. The Optos Panoramic 200CAF, like the predicate device, is a class 1 laser system.
- D “*Electrical Safety*”- The electrical standards with which the Optos Panoramic 200CAF complies are listed in **Attachment 11**.
- E “*Software*”- Optos has developed software under its quality system and has complied with IEC 60601-1-4. See Section X.
- F “*Sterilization*”- No parts of the Optos Panoramic 200CAF require sterilization. Cleaning instructions are given in the operators’ manual. See Section XIII and **Attachment 4**.
- G “*Disinfection*”- Cleaning and disinfection instructions are given in the Introductory Handbook. See **Attachment 4**.
- H1 “*Labeling General*”- The Optos Panoramic 200CAF labeling and introductory handbook are provided in **Attachment 4**.
- H2 “*Specific labeling requirements*”- The specific labeling requirements are provided in **Attachment 4**.
- H2a “*Prescription Device*”- The device is used only on the premises of an Ophthalmologist or Retinal Specialist.
- H2b “*Cleaning and decontamination procedures*”- As defined in **Attachment 4**.
- H2c “*Phototoxicity*”- The brightness of the exposure cannot be adjusted by the user. Additionally, the number of exposures is constrained.

H2d “Lasers”- The device complies to 21 C.F.R. §§ 1040.10–1040.11 and IEC 60825:2007

V. PREDICATE DEVICE INFORMATION

Classification Name: Ophthalmoscope, AC Powered
(21 C.F.R. § 886.1570)

Common Names: Scanning Laser Ophthalmoscope

Trade Name: Panoramic 200 (K983999)

Class: Class II

Classification Panel: Ophthalmic Devices Panel

Product Code: HLI (Note: MYC is an updated product code for a scanning laser ophthalmoscope (21 C.F.R. § 886.1570))

VI. LABELING

The Introductory Handbook and proposed labels for the Panoramic 200CAF are provided in **Attachment 4** of this submission.

The following modifications have been made to the labeling to accommodate the different capture mode for the P200CAF imaging mode:

- The introductory handbook references the autofluorescence imaging mode.
- The addition of a caution not to connect to a DICOM server as this facility is not in place at present.

Associated with the autofluorescence imaging mode, is a change to the graphical user interface that allows an optomap AF (this is the autofluorescence image descriptor) to be selected. A screen shot of this is appended in **Attachment 4**.

In addition, the application software used for review and management of images is the same, and there is commonality in the handbooks for this function. A comparison of the P200 and the P200CAF handbook for this functionality is made in **Attachment 4**. These modifications do not affect the device’s intended use or fundamental scientific technology.

VII. DEVICE DESCRIPTION

A. Introduction

The Optos Panoramic 200CAF is identical to the cleared Panoramic 200 (K983999) in intended use and indications for use.

The Panoramic 200CAF scanning laser ophthalmoscope is indicated for use as a wide field ophthalmoscope for diagnosing and monitoring diseases or disorders that manifest themselves in the posterior pole of the eye.

The Panoramic 200CAF is the same device as the cleared Panoramic 200, except for minor modifications as compared to the cleared Panoramic 200 in the areas of imaging mode and system architecture. Specifically, the following modifications have been made to the device:

- Increased resolution including a zoom mode.
- Directed eye steering to alter the part of the retina being viewed.
- Inclusion of a shutter to permit imaging with either the red or the green laser alone.
- Ability to move optical elements in and out of the return path to optimize the signal strength of different imaging modes. This, combined with closing the red laser shutter, affords an imaging mode where the natural fluorescence of the eye can be displayed.
- Monitoring of the laser output in both horizontal and vertical scans.
- Modifications to the user interface for ease of use. This includes an integrated monitor and combined capture and table movement controller to improve the device layout.
- Patient Alignment System has an improved visual assist for ease of patient positioning.
- The addition of a head and chin rest for ease of patient positioning.
- The device is powered from the scanhead rather than the table of the device.

As described in further detail in Section VII.B and VII.C, below, these modifications do not change the intended use of the device or alter its fundamental scientific technology.

B. Device Description

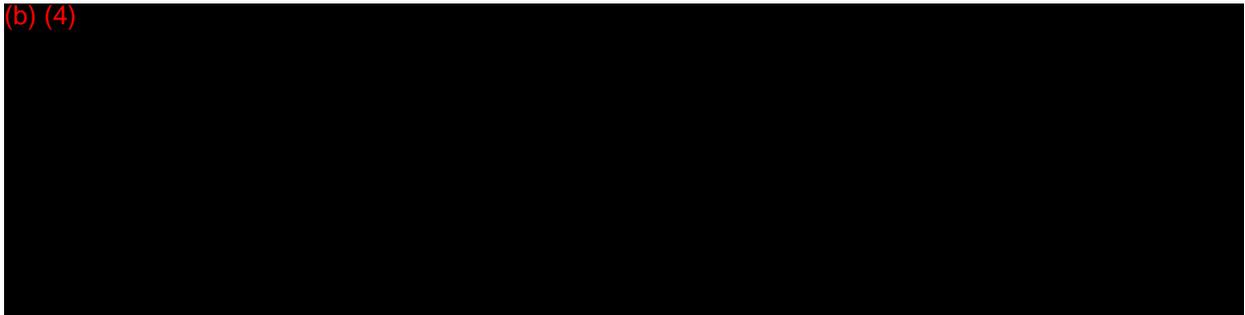
Like its cleared predicate, the Panoramic 200CAF is a conventional scanning laser ophthalmoscope (SLO). A low power laser beam is scanned in two dimensions over the retina and the reflected (or returned) light is detected and used to generate a digital image with a computer or electronic imaging device.

It uses a low power laser beam that scans in two dimensions over the retina. The wavelengths of the lasers residing in the Optos Panoramic 200CAF and the P200 are the same. The generation of the image is performed in the conventional manner using light detectors, the output of which is digitized, and the data collected in a computer for reconstruction, display, and storage. The scanning of the beams on the two axes is done using a conventional rotating polygon for the fast vertical scan and a motor driven mirror for the slower horizontal scan. The device scans [REDACTED] (b) (4) [REDACTED] [REDACTED] 200° when measured from the geometric center of the eye.

The instrument principle relies on the fundamental geometry of a unique ellipsoidal mirror to produce double foci from a bicolor laser beam (which in the case of the P200CAF and the P200 is red/green). The double foci of the form ensures that the light will be passed through the small aperture of the eye regardless of the scan angle, provided that the scan emanates from the small point source coincident with one focus and the eye is correctly positioned at the other. An alignment pattern helps ensure that the patient's eye is correctly positioned.

The geometry of an ellipsoid is such that a ray starting at one focus will be reflected by the surface so that it will cross the other focus. This is a basic geometric property of an ellipsoidal mirror that is true for all angles or beam directions as long as the beam is reflected by the mirror. Hence all rays that pass through one focus and which fall on the mirror are reflected such that they pass the other focus.

(b) (4)



The real scan system is the actual collection of mechanical and optical components that move the beam to generate the two-dimensional scanning light beam. The virtual scanning system is where the scanning system appears to be, *i.e.*, the eye, when viewed in the ellipsoidal mirror. As the virtual scanning system is not a real object it can be made to appear to be in the eye where a real physical scanning system could not be located.

(b) (4)

The Panoramic 200CAF and the predicate Panoramic 200 are capable of creating images [REDACTED] (b) (4) [REDACTED] internal angle of the retina. Given that the Panoramic 200CAF and Panoramic 200 have the same angle of capture, both devices provide practitioners with the same field of view to diagnose and monitor diseases and disorders.

(b) (4)

The eye is not continually exposed to the scanning beam. The patient looks into the instrument in semidarkness so that the eye becomes dark-adapted and the pupil opens. The shutter opens to allow the light to reach the eye to enable the instrument to capture one frame. The shutter then closes. This process has two advantages: (1) the eye does not respond to the light, and thus, the pupil remains wide open; and (2) the eye is exposed to laser light for a greatly reduced time.

See **Attachment 5** for the optical schematics of the Panoramic 200CAF.

The above scanning function is housed in the 'scanhead' (see **Attachment 5**-external schematic). The scanhead is seated on a table that can move up and down and this affords a height adjustment to achieve correct patient positioning.

In terms of the display of the digitized data on a computer screen, the Panoramic 200CAF and P200 capture one image at a time and can present each image as a thumbnail sketch. If more than one image is captured, the Panoramic 200CAF and Panoramic 200 display a series of thumbnail sketches in the order in which they were scanned. The Panoramic 200CAF, like the P200, allows the user to view one or more images of the retina.

C. Modifications

The Panoramic 200CAF incorporates minor modifications as compared to the Panoramic 200 in the areas of imaging mode and system architecture. These modifications do not change the intended use of the device or alter the fundamental scientific technology. **Attachment 1b** provides a chart comparing each change, as well as the similarities, as compared to the cleared Panoramic 200. These modifications have been assessed by Optos for risk, and verification and validation evaluation/testing and results have been performed to certify that any identified risks do not change the intended use or fundamental technology of the device. The modifications are described in detail below.

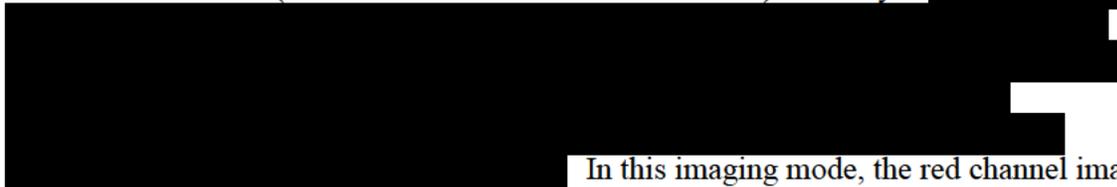
Imaging Modes

The Panoramic 200CAF has the capability of generating a digitized image size of 3K x 3K pixels, as compared to the Panoramic 200's digitized image size of 2K x 2K pixels for the same field of view.

Resolution is related to the digitized image size (expressed as X by Y pixels) and the field of view, which can be expressed as either an internal or external angle. However, Panoramic 200CAF's greater resolution does not change the intended use of the device or alter the fundamental scientific technology. This is because the Panoramic 200CAF and the predicate device display retinal images on a computer screen using the same type of electronics. The Panoramic 200CAF's higher resolution just means that this device's images are potentially clearer.

Additionally, the P200CAF is capable of a zoom mode that generates a close-up (~100° field of view). As above, the greater resolution does not change the intended use of the device and there are no safety issues as the device meets Class 1 at the eye in this imaging mode (as per 21 C.F.R. part 1040 and IEC 60825).

The Panoramic 200CAF can generate an alternate red channel image which shows the natural fluorescence (also referred to as "autofluorescence") of the eye. (b) (4)

 In this imaging mode, the red channel image now displays the naturally occurring fluorescent material of the retina, such as lipofuscin. The characteristics of autofluorescence are well understood, as described in **Attachment 10**.

In the "autofluorescence" imaging mode, the safety of the device is not affected as the light entering the eye is less than a standard red/green image, due to the fact that the red beam is blocked. In addition, the standard red image contains the "autofluorescence" information, but it is swamped by the light reflected by the illumination from the red laser.

The "autofluorescence" image shows the distribution of the naturally occurring fluorescent material by variations in light intensity across the image. This imaging mode can be used by the healthcare professional in conjunction with the standard composite (red/green) and the associated separated red and green channel images to aid in the diagnosing and monitoring of diseases and disorders that manifest themselves in the eye. Therefore, the introduction of the "autofluorescence" imaging mode does not change the intended use of the device or alter the fundamental scientific technology.

Table

When compared to the P200 table, the P200CAF table no longer has the transformer resident to manage the power supply. In the P200CAF, the power is managed through the scan head. This makes the table lighter. As both the P200 and P200CAF are mains powered with the same electrical integrity (as determined by testing to the general safety standard for medical devices) this has no impact on safety or efficacy. The P200CAF also meets the tilt angle criteria for the general safety requirements of medical devices so that no new safety or efficacy issues are raised.

Gaze Angle

The gaze angle permits a different area of the retina to be viewed. This is possible in both the P200 and P200CAF. The additional periphery LED's in the P200CAF assist in eye steering, but confirmation that the correct area has been imaged is made by viewing the image. The device still delivers a 200 field of view but a slightly different area can be imaged as, although wide angle, it is never a complete view of the eye.

The additional LED's, which are included in the laser safety calculations, do not change the intended use of the device or alter the fundamental scientific technology.

User Interface

The user interface in terms of the mouse, monitor, and keyboard are similar for both the P200 and P200CAF. The P200CAF hand control has more buttons as the table position, and exposure button are resident. Button size for the P200 and P200CAF are comparable. Additionally, for the P200CAF hand control, the symbols indicating the key press function/direction are consistent with the Screen User Interface. The software contained with the scanhead communicates within a windows environment in the case of the P200 but the P200CAF operates in a Linux environment. However both the P200 and the P200CAF display their images for review on a screen operating within a windows environment. Therefore these modifications do not change the intended use of the device or alter the fundamental scientific technology.

Laser Radiation Management System (LRM System)

The laser radiation management system resides on two field programmable gate arrays for both the P200 and the P200CAF, thus both units have redundancy in the firmware controlling laser exposure. In both models, the customer has no input or access to the laser radiation management software.

The P200CAF monitors the horizontal and vertical scan, whereas the P200 monitors the vertical scan only.

Both the P200 and the P200CAF have a single exposure shutter, but the P200CAF utilizes additional laser shutters on each wavelength channel.

The P200CAF firmware is different to the P200 firmware as different logic is required for the additional shutters and monitoring. However, the P200CAF assures that the laser classification is 1 at the eye for all permissible conditions (as is the case for P200). Upon detection of a fault condition both the P200 and P200CAF will not permit any exposures to be conducted. Therefore, modifications related to the Laser Radiation Management do not change the intended use of the device or alter the fundamental scientific technology.

Patient Alignment System (PAS), Patient Positioning and Personal Computer

The Panoramic 200CAF's patient places his or her head on a chin rest, his or her head against a head restraint and the side of the face comes into contact with a face pad. Optos' P200 utilizes a face cushion placed around the circumference of the aperture. All materials in contact with the patient meet biocompatibility requirements.

For both the P200CAF and the P200, the device monitor or PC screen provide an assist to the practitioner via a picture of the eye afforded by a camera. The P200CAF gives a visual assist to the practitioner to correctly position the eye whereas the P200 is more dependent on the patient using an eye fixation pattern. With the P200CAF, the operator can adjust the height using the table and effect more finite positioning using the chinrest if the eye is not correctly positioned. With the Panoramic 200, the operator can only adjust the table if the eye is not correctly positioned. Upon correct positioning, for both devices, the hand control can then be pressed, which signals the device to capture the image. For both devices, the operator, who will see the image almost immediately, can then decide whether it is necessary to capture another image. Thus, eye placement for the Panoramic 200CAF does not change the intended use of the device or alter the fundamental scientific technology.

VIII. SUBSTANTIAL EQUIVALENCE

The Optos Panoramic 200CAF is a modification to the company's cleared Panoramic 200 (K983999), Optos' currently marketed Scanning Laser Ophthalmoscope (SLO). A chart of substantial equivalence is provided in **Attachment 1a**. In addition, a chart setting forth the similarities and the differences between the Panoramic 200CAF and the Panoramic 200 is contained in **Attachment 1b**.

As explained in detail below, the Optos Panoramic 200CAF has the same intended use and indications for use, operating principles and similar technological characteristics as the previously cleared predicate. As detailed above, the modifications do not raise new questions of safety or effectiveness. Thus, the Optos Panoramic 200CAF is substantially equivalent to its predicate.

A. Intended Use and Indications

The Panoramic 200CAF has the exact same intended use and indications for use as the cleared Panoramic 200. Both devices are indicated for use as a wide field ophthalmoscope for diagnosing and monitoring diseases or disorders that manifest themselves in the posterior pole of the eye.

Thus, the Panoramic 200CAF satisfies the first criteria for a special 510(k) notice and for substantial equivalence.

B. Technological Characteristics

As described in detail in Section VII, above, the P200CAF has very similar technological characteristics to the cleared P200, to which it is a modification. Each of these modifications has been developed following a robust risk analysis, and validated by the company in accordance with its Design Control and Quality System procedures.

Both the P200 and P200CAF Scanning Laser Ophthalmoscopes have the same mode of operation for imaging the posterior pole of the eye for viewing purposes. Specifically, information on the retina can be derived from (1) the use of a red and a green laser as a source of illumination; (2) a deflection system to scan the laser beam in two orthogonal axes across the eye; (3) the use of the same deflection system to take the reflected light back through the optics to the light detectors; and (4) a computer to reconstruct, display, and store the image.

The light detector used for detecting the relatively weak autofluorescence signal has been changed to optimize the response, but the underlying principle of how the light detector works is unchanged.

The red laser shutter is closed in autofluorescence imaging mode but there is no underlying change to the input path. Similarly, although some optical elements are removed in the return path to optimize the autofluorescence signal, there is no fundamental change to the return path as both the P200CAF and its predicate require light to strike a detector.

3. Conclusion

In summary, the Panoramic 200CAF has the same intended use and indications for use and has very similar principles of operation and technological characteristics to the company's cleared Panoramic 200. The minor differences between the Panoramic 200CAF and its predicate device, as described above, are intended to enhance the functionality of the device, however these differences do not raise any new questions of safety or effectiveness. These modifications have been validated according to the company's Quality System procedures by test methods derived from risk assessments of the modifications. Thus the Panoramic 200CAF is substantially equivalent to the legally marketed Panoramic 200.

IX. SUMMARY OF DESIGN CONTROL ACTIVITIES

The product development lifecycle is defined in the product change work instruction AZ1000 (the software development lifecycle is further defined in work instruction SP1013). The AZ1000 work instruction defines phases, the need for design reviews and also the specific requirements within each phase. A plan, which is specific to each device/project is generated. The change plan template has a comprehensive list of requirements by phase. As part of the Optos change control, all post marketing design changes are subject to the same level of control as exercised for new designs.

The risk analysis method used is based on the methodology defined in BS EN ISO 14971:2007. This is a top down driven approach which "drills down" from the system level. Following the risk management process defined in ISO 14971:2007 assures that risk management is applied throughout the product lifecycle. This includes the initial hazard identification through to a provision in the change plan to review post-production experience.

The quantification of the hazard is defined in **Attachment 6**. The principle of achieving "as low as is reasonably possible" (ALARP) level of risk is applied but overall risk acceptance is based on benefit versus risk. For a device that assists in diagnosis, all identified risks must be scored as "low" or less significant than "low."

A second method applied is failure mode and effect analysis (FMEA). This can be applied at the design or process stage. This is a bottom-up analysis (*i.e.*, looking at elements or modules of the device). The quantification of the Risk Priority Number (RPN) is defined in **Attachment 6**. The principle of achieving "as low as is reasonably

possible” (ALARP) level of risk is applied. In addition, the key criteria for a Design Failure Mode and Effects Analysis (DFMEA) is that for an identified risk with a severity of 9 or 10 (that is a potential hazard to health), the ability for detection during design verification and validation has to be “almost certain” or “very high” (which is a detection rating of 1 or 2 respectively). A DFMEA is in place for the P200CAF.

To look at the impact of the modifications on the device, the specific differences between the P200CAF and P200 tabulated in **Attachment 1b** are used to generate a traceability matrix for the identified risk and the verification and validation activities, the acceptance criteria and the outcome of this testing. This is also shown in **Attachment 1b**.

The declaration of conformity with design controls, which is provided in **Attachment 3**, includes:

1. A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s), and the results demonstrated that the predetermined acceptance criteria were met; and
2. A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 C.F.R. § 820.30 and the records are available for review.

These statements are signed by Alex Warnock, Vice President, Global Research and Development.

X. SOFTWARE

As required by the Quality System Regulation, the software development process at Optos is subject to design control. Software, risk analysis and the development process of this product also conforms to IEC 60601 entitled “Medical Electrical Equipment-Part1: General Requirements for Safety” and its collateral standard IEC 60601-1-4 entitled “Medical Electrical Equipment. General Requirements for safety. Collateral standard. General Requirements for programmable electrical medical systems.” The above activities are defined in Optos’ software development lifecycle work instruction (SP1013) and a brief description is given below.

- The software development lifecycle used by Optos is applied to: Systems developed by Optos for use by external customers and/or key to the functioning of the device.
- Systems developed by Optos for internal customers and related to a key process.
- Third-party systems customized or configured by Optos and related to a key process.

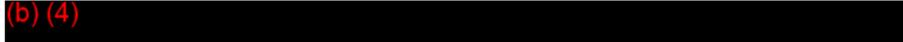
There are 6 software life cycle phases, namely:

1. Feasibility: this focuses on idea and concept development as a precursor to formal design control.
2. Design Planning: this establishes a plan that defines the development activities, the interfaces and the responsibility for implementation.
3. Design Input: In this phase, the requirements for the performance, interface and physical properties are defined.
4. Design Output: In this phase, the implemented design is verified and validated against the requirements. This may include a simulation of end usage and/or a user study under controlled conditions.
5. Design Transfer: In this phase, the replication and deployment method for the software is defined.
6. Launch: in this phase, a released system may be updated in response to a requested change or information post market.

In development, changes to software are identified by software version. Released software uses the last three digits of the part number to indicate the revision.

DESCRIPTION OF SOFTWARE USED IN P200CAF

(b) (4)

A small black rectangular redaction box covering a few lines of text.

(b) (4)

A large black rectangular redaction box covering the majority of the page's content.

The software within the P200CAF was designed with a clear architecture to separate out the laser radiation management function from all other operational functions, as follows:

1. The Image Capture software resides within the system and on an integrated personal computer. This software allows the operator to select the type of image to be captured and controls the image capture process.
2. The Laser Radiation Management firmware resides on two integrated circuits (specifically field-programmable gate arrays). This firmware implements a finite state machine whose sole objective is to monitor exposure levels and automatically prevent an exposure being taken in the event that sensors deviate from tightly defined limits.
3. Application Software

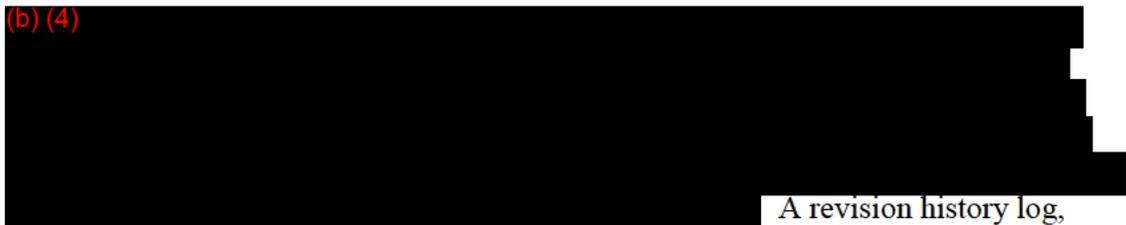
This software operates in a windows environment and allows image storage, archiving and image review functions.

A more detailed listing of this software is given in **Attachment 7(a)**. During verification and validation activities of this software, any anomalies are quantified using assessment criteria defined in **Attachment 7(b)**. All software issues graded 3 or higher are resolved, issues graded less than 3 constitute a 'bug list,' which will drive future enhancements.

The above software is discussed referencing the relevant attachments below:

Panoramic P200CAF Image Capture

(b) (4)

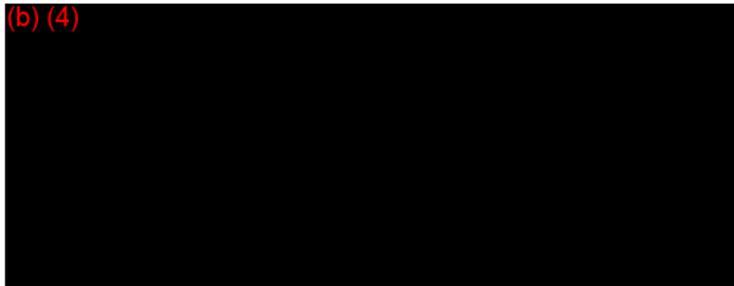


A revision history log, specifications/traceability, and test results are appended in **Attachments 7(c), (d), and (e)** respectively.

Laser Radiation Management Firmware

There is no user input to the firmware. It is a state machine that disables the system if an error is detected. This firmware is designed to detect failures and disable the system (b) (4) The term "disable" means that the lasers are switched off and the shutters closed thereby preventing further exposure. The failure conditions that this system is designed to detect are as follows:

(b) (4)



Although not failure conditions, more than one exposure in (b) (4) is not permitted and, within a given time period, no exposures are available if the maximum number of images has been reached. Furthermore, an exposure is not permitted if the polygon is not at the correct speed of rotation.

(b) (4)

If either of these integrated circuits is in an error status the system will shut down. This duplication reduces the probability of the Laser Radiation Management System itself failing.

A requirements specification [Attachment 7(g)], the outcomes of verification and validation testing [Attachment 7(h)] and revision history log are appended [Attachment 7(f)]. Given that it is a state machine, no known errors or bugs are permissible in this code. Additionally, each device manufactured will have checksum verification of the software loaded and will be tested for correct LRM functionality.

Application Software

This software allows the user to review single images, image sessions via thumbnail overviews, access image libraries, annotation features, 3D representation of the eye for patient education. There is also a scheduling and archiving facility.

This application software is the same for the P200CAF and the P200.

Panoramic P200CAF Software Level of Concern

Optos has evaluated the level of concern for the Panoramic 200CAF software using the decision process outlined in FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005) and determined that the Panoramic 200CAF software presents a minor level of concern.

The process that Optos followed in determining the software level of concern is outlined and summarized below:

If the answer to any <u>one</u> question below is Yes, the level of Concern for the software Device is likely to be Major
<p>1. Does the Software Device qualify as Blood Establishment Computer Software?</p> <p>(Blood Establishment Computer Software is defined as software products intended for use in the manufacture of blood and blood components or for the maintenance of data that blood establishment personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion or further manufacture.)</p> <p>Response: No, the device relates to retinal imaging only.</p>
<p>2. Is the Software Device intended to be used in combination with a drug or biologic?</p> <p>Response: No, there are no drugs or biologics associated with the device.</p>
<p>3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?</p> <p>Response: No, the device is a scanning laser ophthalmoscope and is a class 1 laser at the eye as defined by 21 C.F.R. § 1040.10. A Class 1 laser is considered non-</p>

hazardous.
4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:
<p>a. Does the Software Device control a life supporting or life sustaining function?</p> <p>Response: No, the device is for retinal imaging and is not life sustaining or supporting.</p>
<p>b. Does the Software device control the delivery of potential harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?</p> <p>Response: No, the system delivers Class 1 laser power at the eye as defined by 21 C.F.R. § 1040.10. Additionally, the system is designed to deliver a non-adjustable power level.</p>
<p>c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?</p> <p>Response: No, this is not a therapeutic device.</p>
<p>d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?</p> <p>Response: No, the device supplies diagnostic information as an assist to a practitioner. The device does not interpret images or recommend treatment routes. A practitioner takes responsibility for using a number of information sources prior to forming a diagnosis and determining any associated treatment or therapy.</p>
<p>e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?</p> <p>Response: No.</p>

If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the level of Concern for the software Device is likely to be Moderate.

1. Is the Software Device an Accessory to a medical device that has a Moderate Level of Concern

Response: No, the device is a scanning laser ophthalmoscope and is a Class 1 at the eye as defined by 21 C.F.R. § 1040.10. A Class 1 laser is considered non-hazardous.

2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or a user of the device?

Response: No, the software cannot adjust the level of the laser power delivered to the eye.

3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?

Response: No, the device supplies diagnostic information as an assist to a practitioner. The device does not interpret images or recommend treatment routes. A practitioner takes responsibility for using a number of information sources prior to forming a diagnosis and determining any associated treatment or therapy.

XI. PERFORMANCE TESTING

The Optos Panoramic 200CAF Ophthalmoscope complies with the following six consensus standards.

IEC 60601-1 1988/A1:1991 A2:1995, Corrigendum 95	Medical electrical equipment. General requirements for safety.
IEC 60825-1 Ed.2.0 (2007)	Safety of Laser Products.
IEC 60601-1-2:2007	Medical electrical equipment. General requirements for safety. Collateral standard. Electromagnetic Compatibility requirements and tests.
IEC 60601-1-4 edition 1.1 2000-04	Medical electrical equipment. General requirements for safety. Collateral standard. General Requirements for programmable Electrical medical systems.
ISO 10993-5	Biological evaluation of medical Devices: Tests for In Vitro Cytotoxicity 1999 & 2009.
ISO 10993-10	2002 & amendment 1, 2006.

Standards Data Report Forms and summary report for each listed recognized consensus standard are provided in **Attachment 11**.

XII. BIOCOMPATIBILITY

The same material is used for the cushion in the P200 and the face pad in the P200CAF. As the P200CAF also has a chinrest and head support, two additional materials come into contact with the patient.

Specifically, the chinrest is made of (b) (4)

As per ISO 10993, the contact is skin and for limited duration, requiring that Cytotoxicity, Sensitization, and Irritation or Intracutaneous reactivity is assessed. Both of the additional materials have been assessed for these effects and meet the relevant standards.

XIII. STERILIZATION, CLEANING, DISINFECTION

The Panoramic 200CAF Ophthalmoscope does not require sterilization. Instructions for cleaning the device, including the chin rest and face pad are included in the Introductory Handbook (**Attachment 4**).

XIV. 510(K) SUMMARY

The company's 510(k) Summary for the Optos Panoramic 200CAF is provided in Attachment 2.

XV. CONFIDENTIALITY

Optos considers its intent to market the Panoramic 200CAF as confidential commercial information. The company, therefore requests that FDA not to disclose the existence of this application until such time as final action on the submission is taken.

In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and therefore is not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that you consult with the company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

XVI. SUBMITTER'S NAME AND ADDRESS

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XVII. CONTACT PERSON AND TELEPHONE/FACSIMILE NUMBERS

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XVIII. MEDICAL DEVICE USER FEE

The Company has remitted the Medical Device User Fee of \$4007 concurrent with this submission to the Food and Drug Administration, P.O. Box 956733, St. Louis, MO 63195-6733. The payment identification number is MD6047921-956733

A copy of the Medical Device User Fee Cover Page is provided in **Attachment 12**.

XIX. INDICATIONS FOR USE STATEMENT

The company's Indications for Use Statement is provided in **Attachment 8**.

XX. TRUTHFUL AND ACCURACY STATEMENT

The Company's signed Truthful and Accuracy Statement, as required by 21 C.F.R. § 807.87(j) is provided in **Attachment 9**.

Attachment 1: Chart of Substantial Equivalence

Attachment 1a: Substantial Equivalence

Manufacturer	Optos	Optos
Device	Panoramic 200	Panoramic 200CAF
Common Name	Scanning Laser Ophthalmoscope	Scanning Laser Ophthalmoscope
510k number	K983999	pending
Materials	No flammable materials are used near the light source.	No flammable materials are used near the light source.
Max. Temperature of accessible parts	Does not exceed ambient by more than 10°C.	Does not exceed ambient by more than 10°C.
Intended Use	To examine the retina of the eye	To examine the retina of the eye
Indications for Use	For aiding in diagnosing and monitoring disease and disorders that manifest themselves in the retina of the eye.	For aiding in diagnosing and monitoring disease and disorders that manifest themselves in the retina of the eye.
Method of Operation	Confocal laser scanning system; laser light source; deflection system; scans in two orthogonal axes of the retina; photosensitive device that converts light into image of retina; display system.	Confocal laser scanning system; laser light source; deflection system; scans in two orthogonal axes of the retina; photosensitive device that converts light into image of retina; display system.
Light Source	Laser	
Wavelength and Color of Light	(b) (4)	(b) (4)
Exposure Parameters/laser class	Class 1	Class 1
Number of lasers Used per scan	2	1 or 2
Brightness Controls	Only after image has been taken	Only after image has been taken
Cleaning and disinfection/sterilization	Sterilization not required. Clean/decontaminate contact points	Sterilization not required. Clean/decontaminate contact points
Point of contact	Eye cushion	Facepad, chincup, and headrest
Data collection and/or display system	Light sensitive detector that converts light into electrical signal. Signal digitized and computer or electronic imaging device to convert digital image for display.	Light sensitive detector that converts light into electrical signal. Signal digitized and computer or electronic imaging device to convert digital image for display.
External field of view	(b)	(b) ^o
Internal field of view	200 ^o	200 ^o
Wide Angle Digitized Image Size	2Kx2K pixels	3Kx3K pixels
Pupil Dilation	Normally not	Normally not
Eye Taping	Normally not.	Normally not.
Mains current AC 115/240V	15A/7A	6.3A
Approx. weight	Scan head 70kg; table 100kg	Scan head 70kg; table 50kg

Attachment 1b: Similarities and Differences between the P200 and the P200CAF

Category	Sub - category	P200	P200CAF	Risk Identification	Source of Risk Identification	Verification Activity
Functionality	Imaging Modes	RG imaging, 4M pixels (optomap)	RG imaging, 9M pixels (optomap) 'Zoom' mode available. Directed eye steering	The increase in the number of pixels has the potential for making the image clearer. The image is an aid to diagnosis and it is the practitioner who determines the suitability of the image for diagnosis. Directed eye steering has the potential to look at different wide-angle views of the retina but has no increase in the risk associated with viewing.	Change Request and Risk Assessment no. 684, Image Quality FMEA 69-79	Acceptance criteria: USAF 1951 resolution target used to Confirm 3K image at least as clear as 2K Pass, 3Kx3K displays at least the same number of line pairs Patient Alignment System [PAS] DV Pass
Functionality	Imaging Modes	There is no facility to generate images that display the natural fluorescence of the eye	Has an imaging mode where the red channel image is optimized to display the natural fluorescence of the eye.	The AF mode does not work-unable to acquire image. The translation stage has removed the required optical elements from the input path.	FMEA analysis item 53 FMEA analysis item 100	V&V activity for embedded software checked AF appears on GUI , red laser input path blocked, translation stage is in correct position and image acquisition possible Pass

Category	Sub - category	P200	P200CAF	Risk Identification	Source of Risk Identification	Verification Activity
System Architecture	User Interface	Scan head rests on a supporting table. Solo station PC. Remote review station PC (optional) User interface: - Monitor, keyboard and mouse - Handheld patient capture button - Handheld table up/down button.	Scan head rests on a supporting table. Scan head has integrated monitor. Remote review/storage PC (required). User interface: - Monitor, keyboard and mouse - Operator held patient capture, table up/down movement controller.	. Difficult to use	FMEA item 85	Internal design validation confirmed operation of this layout Pass As an extension to this design validation to confirm that user requirements are met, a Human Factors/Clinical Environment study was conducted. This related to aspects such as patient comfort only. Acceptance Criteria: Subjective assessed using a 1-5 scoring. 1 is least satisfied, 5 is most satisfied. No individual score less than 3 is allowed.: Pass

Category	Sub - category	P200	P200CAF	Risk Identification	Source of Risk	Verification Activity
(b) (4)						
PC's		Embedded processor - Running control and capture s/w on Windows O.S. Viewing PC - Running review s/w on Windows O.S (optional)	Embedded processor - Running control and capture s/w on GNU/Linux OS. Viewing PC/Image Server - Running review s/w on Windows O.S. (required)	Unreliable system	Hazard analysis H69	Software V&V Pass

Category	Sub - category	P200	P200CAF	Risk Identification	Source of Risk Identification	Verification Activity
Table	Table Architecture	Power inlet for 240/120V a.c. and contains isolating transformer to power Scan head.	Power inlet for 240/120V a.c. Provides power to Scan head directly, table is powered by the Scan head. Inlet for Ethernet, which is routed to the Scan head.	The risks associated with mains power is unchanged. Equally safe to locate the power supply/transformer either in the table or the scan head.	Hazard Analysis H66	Meets electrical verification tests: Pass as per IEC 60601-1
	Table Architecture	Table weight is 100kg	Table weight is 50kg	Different weight (which is a combination of scan head and table weight) could change centre of gravity and tilt aspects.	FMEA114 Hazard analysis H13	System tilted to determine toppling angle As per IEC60601-1 Acceptance Criteria: tilt angle must be greater than or equal to 10 degrees before toppling Pass
Patient positioning		Table height adjustment required to position patient correctly for imaging.	Table height adjustment and headrest positions the patient correctly.	Not able to attain correct positioning easily	FMEA 30/31	Image capture included in internal validation tests Pass

Category	Sub - category	P200	P200CAF	Risk Identification	Source of Risk Identification	Verification Activity
	Patient support	Eye cushion	Head rest/Chin support Face pad	Reaction to contact materials	Hazard analysis H33	P200 cushion and P200CAF face pad is the same material. Chincup and headrest material meet ISO10993 Pass certification in place.

Attachment 2: 510k Summary

Special 510k Summary-Optos Panoramic 200CAF

Name of Device Panoramic 200CAF Ophthalmoscope

Common or Usual Name Scanning laser ophthalmoscope

Classification Name Scanning laser ophthalmoscope
(per 21 C.F.R. § 866.1570)

Product Code MYC

Submitter Optos plc,
Queensferry House,
Carnegie Business Campus
Dunfermline,
Fife,
KY11 8GR
United Kingdom

Phone: 011 44 1383 843300

Facsimile: 011 44 1383 843333

Contact Person: Robert Tweedlie Ph.D.

Date Prepared March 05, 2010

Predicate Device

Optos Limited's Panoramic 200 (K983999)

Intended Uses

The Panoramic 200CAF scanning laser ophthalmoscope is indicated for use as a wide field ophthalmoscope for diagnosing and monitoring diseases or disorders that manifest themselves in the posterior pole of the eye.

Principles of Operation and Technological Characteristics

The Optos Panoramic 200CAF is a Scanning Laser Ophthalmoscopes (SLO) that uses lasers as a light source that is scanned by a deflection system in two axes across the retina to generate an image. The returned light then travels back along the same path to a light detector that converts the light to an electrical signal. This electrical signal is digitized and used to build up an electronic picture in a computer and displayed either on a cathode ray tube or a liquid crystal display.

Substantial Equivalence

The Panoramic 200CAF has the same intended use, the same indications and very similar principles of operation and technological characteristics as the predicate device. The minor technological differences between the Panoramic 200CAF and the predicate devices do not raise any new questions of safety and effectiveness. Thus, the Optos Panoramic 200CAF Ophthalmoscope is substantially equivalent to Optos' legally marketed Scanning Laser Ophthalmoscopes (SLO), the P200 (K983999).

Attachment 3: Declarations of Conformity

Declaration of Conformity with Design Controls

Verification Activities:

To the best of my knowledge, the verification and validation activities, as required by the risk analysis, for the modifications to the device were performed by the designated individuals and the results demonstrated that the predetermined acceptance criteria were met.



Alex Warnock, Vice President, Global Research and Development

(Typed Name and Title)

Optos plc
(Company)

16 FEB 2010
(Date)

Manufacturing Facility:

The manufacturing facility, Optos plc, is in conformance with the design control requirements as specified in 21 CFR §820.30 and the records are available for review.



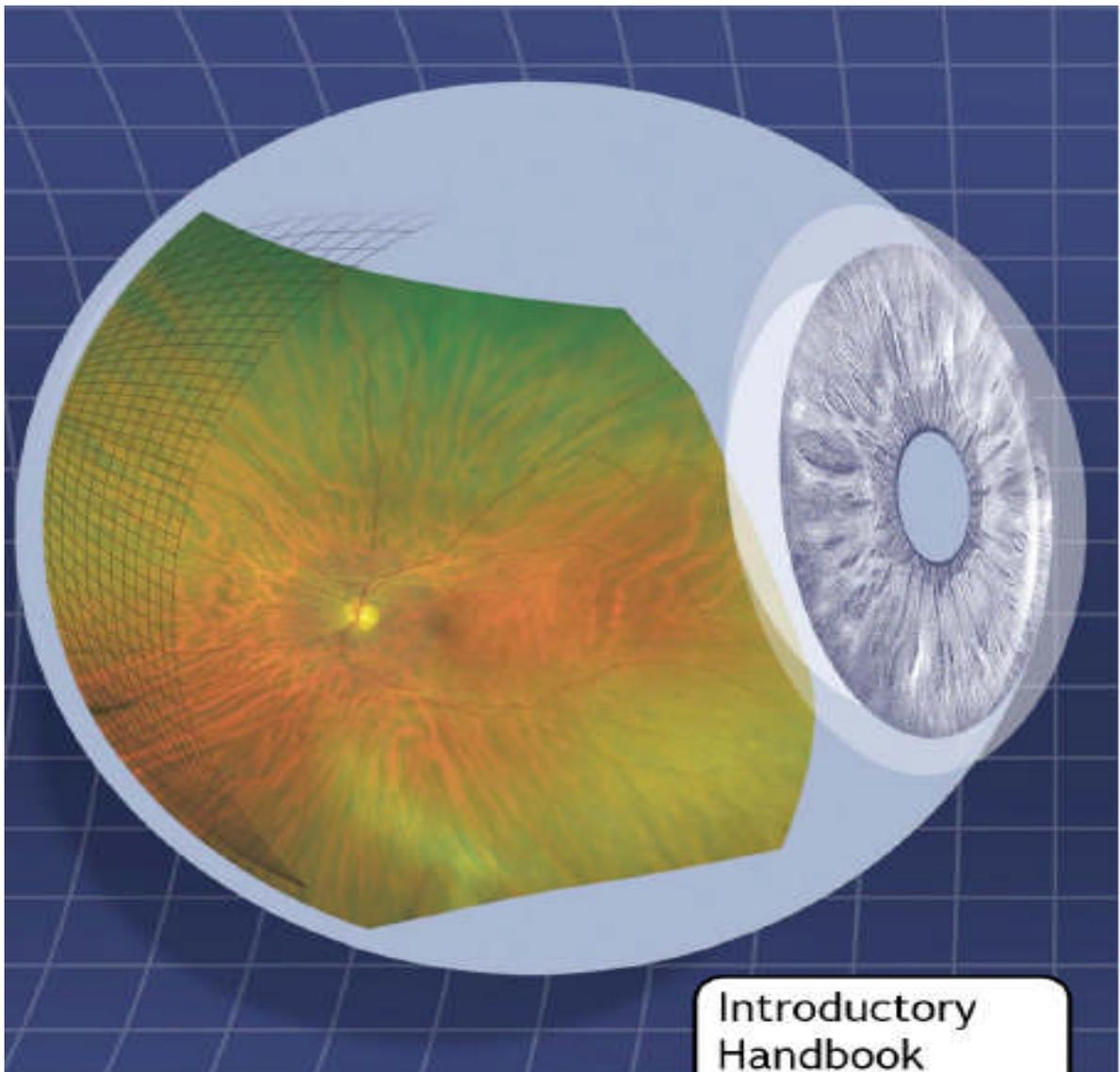
Alex Warnock, Vice President, Global Research and Development

(Typed Name and Title)

Optos plc
(Company)

16 FEB 2010
(Date)

Attachment 4: P200CAF Introductory Handbook



**Introductory
Handbook**

P200MA, P200C
and P200CAF

Introductory Handbook

Manual de introducción - Manuel d'introduction

Copyright 2007-2010, Optos plc. All rights reserved.

The information contained within this document is subject to change without notice. The latest version of this information can be found at www.optos.com.

This document should be used in conjunction with the help files supplied in each application and the Technical Data Specifications supplied with the device. Instructions and service information can be obtained by contacting the Optos Customer Service Department through the contact details given in this handbook.

The device is a prescription device

 Caution	Federal law restricts this device to sale by or on the order of a physician or practitioner. See 21 C.F.R. § 801.109(b)(1) for more information.
---	--

Optos does not provide and the **optomap® plus** guidelines do not constitute advice on making reimbursement claims. Diagnostic tests should be ordered by the treating physician and this physician is responsible for appropriate usage, adequate documentation and proper coding. It is the responsibility of the physician to comply with Medicare regulations, and check with the local insurance carrier for reimbursement information and instructions. Optos does not accept any liability for reimbursement claims made while using **optomap® plus**.

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1 Introduction

This section introduces the device and explains the information contained in this document.

Please read the Safety Guidelines before using your device, see *Safety Guidelines* on page 49.

Your device will be installed by Optos technical personnel. Do not operate the device until Optos technical personnel have completed the installation and training.

About the device

This scanning laser ophthalmoscope is indicated for use as a wide field ophthalmoscope for diagnosing and monitoring diseases or disorders that manifest themselves in the posterior pole of the eye.

Optos' technology is designed to operate through a minimum pupil diameter of 2mm. Although pupil dilation is not required, the decision to dilate is a medical decision to be made by the eye-care professional.

The P200MA uses red, green and blue lasers to produce a digital, high-resolution image, which is displayed on a PC monitor screen. This device can be used to capture angiography images.

The P200C uses red and green lasers to produce a digital, high-resolution image, which is displayed on a PC monitor screen.

The P200CAF use red and green lasers to produce a digital, high-resolution image, which is displayed on a PC monitor screen.

- Red and green lasers are used for digital color imaging. These laser wavelengths penetrate the retinal structures to different depths, each wavelength providing information for interpretation and diagnosis.
- The blue laser is used when capturing angiography images. A series of images is captured as the fluorescein flows through the retinal vessels.
- In autofluorescence mode, the P200CAF uses only the green laser to illuminate the eye. This allows an image of the natural fluorescence of the eye to be captured. No fluorescent dye has to be introduced into the patient.

Images are captured on the scan head and then viewed, magnified, annotated and separated into their color components in the **Review** application see *About the software applications* on page 46.

About this Handbook

This Introductory Handbook explains the information you need to know before you start using the device.

Getting to know the device on page 47 – introduces each part of the device.

Safety Guidelines on page 49 – details the safe operation of the device. You must read this section before operating the device.

Getting Started on page 55 – details how to start and finish using the device each day.

Getting help on page 59 – details how to access the help files and how to contact Optos.

Cleaning on page 62 – details how to clean the user accessible parts of the device.

About the software applications

The **Capture** application runs on the scan head. This application lets you control the device; capturing and checking the quality of images.

V² Vantage DX contains a set of applications that let you review and manage images. These applications are installed on the Image Server PC and Viewing PCs. You can run these applications by double-clicking the relevant icon on the desktop.

<p>V² Vantage DX Admin</p>	<p>Lets you configure your system. You can set password requirements, create new users, modify existing users, and set a variety of system controls.</p> <p>You can also run the Admin application by selecting Start > Programs > OptosV² Vantage DX > Admin.</p>
<p>V² Vantage DX Scheduler</p>	<p>Lets you manage patient records and appointments for the optomap® Retinal Exam.</p> <p>You can also run the Scheduler application by selecting Start > Programs > OptosV² Vantage DX > Scheduler.</p>
<p>V² Vantage DX Review</p>	<p>Lets you review, annotate, and add diagnostic codes to captured images. Also contains exporting, e-mailing and printing tools.</p> <p>You can also run the Review application by selecting Start > Programs > OptosV² Vantage DX > Review.</p>
<p>V² Vantage DX Storage</p>	<p>Lets you archive images and manage the database and image files.</p> <p>You can also run the Storage application by selecting Start > Programs > OptosV² Vantage DX > Storage.</p>

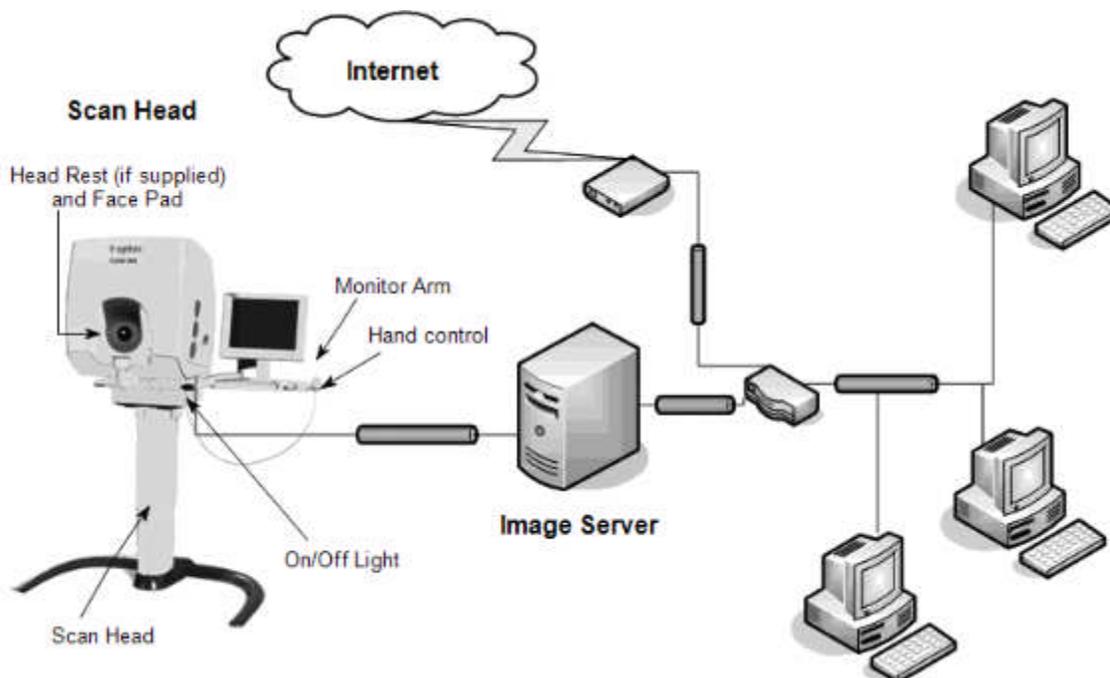
2 Getting to know the device

The device comprises the Scan Head Module, Image Server PC, and Viewing PC. For more information, please refer to the Technical Data Specification supplied with the device.

Images are captured on the scan head. The scan head runs the **Capture** application. The Image Server PC runs the **Storage** application, **Admin** application, and **Scheduler** application. The **Review** application is run on the Viewing PCs. In a typical installation, the images and database will be stored on the Image Server PC. You can review captured images at any Viewing PC that is connected to the Image Server PC across the network.

Understanding the equipment

The device is part of a system of networked PCs.



Scan Head Module

The scan head module runs the **Capture** application. This application lets you select and perform the required patient imaging procedure.

 <p>Caution</p>	<p>The scan head monitor should not be used to review images for diagnostic purposes.</p> <p>The P200CAF should not be connected to a DICOM server.</p>
---	---

The scan head module comprises:

- Scan head – Comprises the lasers and electronics used to capture patient images.
- Scan head table – Supports the adjustment of the scan head height. The table can be raised or lowered using the hand control.
- Face pad – The face pad support the patient's face when the patient is being imaged. The face pad can be removed for cleaning.
- Scan head monitor arm – Links the monitor to the scan head. The keyboard and mouse tray and the hand control hook are part of the monitor arm.
- Scan head monitor – Displays the **Capture** application. The monitor displays alignment feedback and captured images.
- Hand control – Comprises buttons used to raise and lower the scan head table, align the patient, and capture images.
- Head Rest, patient arm support and table wings – Devices used to capture **optomap® fa** images are fitted with a head rest, patient arm support and table wings. They are used to support the patient throughout the imaging process. The head rest and patient arm support can be removed for cleaning. P200C devices are supplied with a head rest.

Viewing PCs

Viewing PCs run the **Review** application. The **Review** application lets you analyze patient images. You can review images in a variety of ways. You can add annotations to highlight areas of interest, add diagnostic codes, add notes, and email images to third parties.

Image Server

The Image Server PC runs the management applications:

- The **Admin** application lets you configure the network and data management environment. You can define security levels, create and modify users, and set a variety of system configuration options.
- The **Storage** application lets you archive and protect database and patient image files. It is essential to archive regularly. For further information refer to the **Storage** application help file.

Depending on your network configuration you may also run the **Review** application and **Scheduler** application from the Image Server. When the **Review** application has been installed on an Image Server, the Image Server may be used as an additional Viewing PC.

The **Scheduler** application lets you schedule patient appointments and manage patient details. The **Scheduler** application may be installed on any PC on the same network as the device.

3 Safety Guidelines

Your system is a medical device and, as such, should be operated within the safety parameters and instructions defined in this Introductory Handbook, the help files and the Technical Data Specification.

To ensure validity of certification, do not replace any part of the device. If the device appears faulty or has non-functioning components, please contact Optos.

If you have any questions regarding the correct use of your device, please contact Optos before attempting to operate the device.

Please read these Safety Guidelines before using your device.

General Safety

 <p>Warning</p>	<p>Only Optos technical personnel are permitted to install and service the device.</p> <p>Your device will be installed by Optos technical personnel. Do not operate the device until Optos technical personnel have completed the installation and training.</p> <p>Do not move the scan head or scan head table.</p> <p>Do not remove the scan head casing. There are no user serviceable or replaceable parts inside.</p> <p>Do not capture images when the face pad is not in place.</p> <p>Do not lean on the head rest, monitor arm, monitor or keyboard tray. Ensure the monitor arm and keyboard tray do not restrict the patient's access to the device.</p> <p>The patient arm support supplied with the P200MA is designed to support the weight of a resting arm. Do not exceed the weight indicated on the patient arm support. When in use, ensure the patient arm support is securely clamped to the table wing, and that it is covered with a piece of absorbent paper.</p> <p>Care should be taken adjusting the head rest or table height when the patient is resting on the head rest.</p>
 <p>Caution</p>	<p>The scan head monitor should not be used to review images for diagnostic purposes.</p> <p>Always wear powder-free gloves when cleaning the device.</p> <p>Do not use lint cloths, tissues, or other materials that may create dust, near the scan head.</p> <p>Do not operate the table motor continuously for a prolonged period of time.</p> <p>Restarting the PC used to store the database and images</p> <p>Ask users to logout of their PCs before you shut down the Image Server PC. Ask Viewing PC users to close any Optos applications before you shut down the Image Server PC.</p>

Medical Safety

 <p>Warning</p>	<p>Laser Safety</p> <p>The device is a Class 1 laser device at the eye, and complies with EN60825-1 and 21 C.F.R.1040.10 and 1040.11. Based on current scientific knowledge, a Class 1 laser device can be considered as safe by engineering design, and safe under reasonably foreseeable conditions of operation.</p> <p>Danger of Laser Injury</p> <p>Do not remove the device cover or attempt to replace the lasers. Only qualified Optos technical personnel are permitted to service the device.</p> <p>The use of this device or any other device which uses light for ocular examination should not be prolonged unnecessarily.</p> <p>While no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, some patients may be less tolerant to an exposure of light. This may be the case for infants, aphakic patients and persons with diseased eyes. Patients who have had any exposure with the same device or with any other ophthalmic device using a visible light source within the previous 24 hours may also be less tolerant to a further exam using light.</p> <p>However, the benefits of an eye exam will almost always outweigh any discomfort associated with the exposure to light.</p> <p>While the scan head covers are fitted the risks are minimized. The following items are monitored by the Laser Radiation Management System:</p> <ul style="list-style-type: none"> • Images may only be captured when the scanning system is within safe operating conditions. • Internal power monitoring prevents excess power at the eye. • An internal shutter and associated controls prevent early or prolonged laser exposure. <p>The Laser Management System maintains a Class 1 accessible emission limit (AEL) at the eye for normal operation and under foreseeable fault conditions.</p>
 <p>Caution</p>	<p>Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.</p>
 <p>Warning</p>	<p>Fluorescence Imaging</p> <p>Optos does not offer any guidance or advice on the use of fluorescein. This is conducted under a separate medical procedure. This procedure should only be conducted by qualified medical staff.</p> <p>The P200MA is indicated for use as a widefield and retinal fluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.</p>
	<p>Use on Patients with Epilepsy</p> <p>The device uses flashes of laser light. Some patients with epilepsy may be sensitive to flashes of light. Caution should be exercised for patients who have a history of reaction to camera flashes or strobe lighting.</p>

<p>Warning</p>	<p>Working in Low Light Conditions</p> <p>The device requires low levels of room light to operate efficiently. Take care to avoid accidents when working under low light conditions.</p> <p>Heat Generated when In Use</p> <p>The face pad may get warm during use.</p> <p>Taking Measurements</p> <p>After you have drawn the points on the image, the software can estimate the relative distance between any two points. The calculated distance is an estimate only and may be used to indicate a need for further review. The measurements of relative distance, however, should not be used as an indication of a specific condition or disease. The size and shape of an image depends on the type of device used to capture it. Images from different types of device should not be compared.</p>
<p> Caution</p>	<p>Optical Elements</p> <p>Do not place any optical elements (with the exception of the patient wearing contact lenses) between the face pad and the patient's eye.</p>

Peripherals

<p> Caution</p>	<p>Only use peripherals supplied with the device. Independently sourced peripherals may not be compatible. Contact Optos for more information on compatible peripherals.</p> <p>Do not connect a printer to the scan head console or power a printer from the scan head.</p> <p>Only power the scan head from the scan head connector. Do not power any other electrical equipment from the scan head table.</p>
--	--

Software on Optos Supplied PCs

<p> Caution</p>	<p>Only load software when supplied and instructed by Optos.</p> <p>Installing New Software</p> <p>If you need to install other software, for example a network printer driver, contact Optos Customer Support to confirm that there are no known compatibility issues.</p> <p>Updating Existing Software</p> <p>Your system administrator should carry out software upgrades using the software and instructions provided by Optos.</p> <p>You can install critical Windows Updates and anti-virus signatures on the Image Server and Viewing PCs by following the instructions given in the Admin Application help file.</p>
---	--

Environmental Safety

 <p>Warning</p>	<p>Do not operate the device in an environment:</p> <ul style="list-style-type: none"> • Where flammable mixtures may be present. • Inside the influence of the magnetic field of a magnetic resonance imaging device.
 <p>Caution</p>	<p>Do not operate the device in an environment:</p> <ul style="list-style-type: none"> • Exceeding the environmental limits described in the Technical Data Specification which accompanies this device. • That blocks the scan head air intake vents . <p>Do not use lint cloths, tissues, or other materials that may create dust, near the scan head.</p> <p>Do not operate mobile phones in the immediate vicinity while operating the device.</p>

Electromagnetic Compatibility (EMC)

 <p>Caution</p>	<p>The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Technical Data Specification which is supplied with the device.</p> <p>Portable and mobile RF communication equipment may affect the device.</p>
--	--

Interference

 <p>Warning</p>	<p>This device has been tested and complies with Part 15 of the FCC (U.S.A.) Rules and the European standard EN60601-1-2. Operation is subject to the following two conditions:</p> <ol style="list-style-type: none"> 1. This device may not cause harmful interference, and 2. This device must accept any interference received, including interference that may cause undesired operation. <p>These limits are designed to provide reasonable protection against harmful interference in a residential environment.</p> <p>There is no guarantee that interference will not occur in a particular installation.</p>
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Electric Shock

 <p>Warning</p>	<p>Do not open the scan head casing. There are no user serviceable or replaceable parts inside.</p> <p>To prevent electric shock:</p> <ul style="list-style-type: none">• Only use cables supplied by Optos. Cables should not be extended or altered.• Mains supply must be earthed.• The device may only be service by Optos technical personnel.• Care must be taken never to touch exposed parts of the device while in physical contact with a patient.• Hospital grade connectors must be used in countries where they are available, for example in the United States of America and Canada.• The mains cable must be regularly inspected.
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Device Failure

 <p>Warning</p>	<p>In the unlikely event you hear a loud noise from the device, see smoke or smell burning, stop imaging and isolate the device by unplugging.</p>
 <p>Caution</p>	<p>If you suspect the device may be faulty check the Frequently Asked Questions section in the application's help file. If in any doubt on how to proceed, contact Optos, see <i>Contact us</i> on page 64.</p>

Cleaning and Biocompatibility

 <p>Warning</p>	<p>If these guidelines are not followed there is the possibility of biocompatibility problems. These risks will be minimized if you clean the face pad and head rest as defined in the Cleaning section, see <i>Cleaning</i> on page 62.</p> <p>Carry out the cleaning procedures regularly. This will ensure a high level of patient interface hygiene and consistently successful images. No other user maintenance is required.</p>
---	--

Symbol and Label Information

	Switch - off position.
	Switch - on position.
	Protected earth connection.
	Danger: high voltage warning.
	Warnings are directions which, if not followed, could cause fatal or serious injury to a user, engineer, patient or any other person.
	Cautions are directions which, if not followed, could cause damage to the equipment described in this manual and/or other equipment or goods and/or could cause environmental pollution.
	Follow the instructions in this order shown.
	Interference may occur in the vicinity of equipment marked with this symbol.
	Laser device present. This symbol is used internally. Only Optos Technical Personnel are permitted to install and service the device. Under normal used, operators should never see this symbol.
	Type B - relates to the allowable maximum current leakage which can flow from the applied part. The limits for this are defined in IEC 60601.
	End of life disposal of this device is subject to the requirements defined in EN 50419. This directive ensures that Waste Electrical and Electronic Equipment (WEEE) is disposed of properly.

4 Getting Started

Please read the **Safety Guidelines** before using your device, see *Safety Guidelines* on page 49.

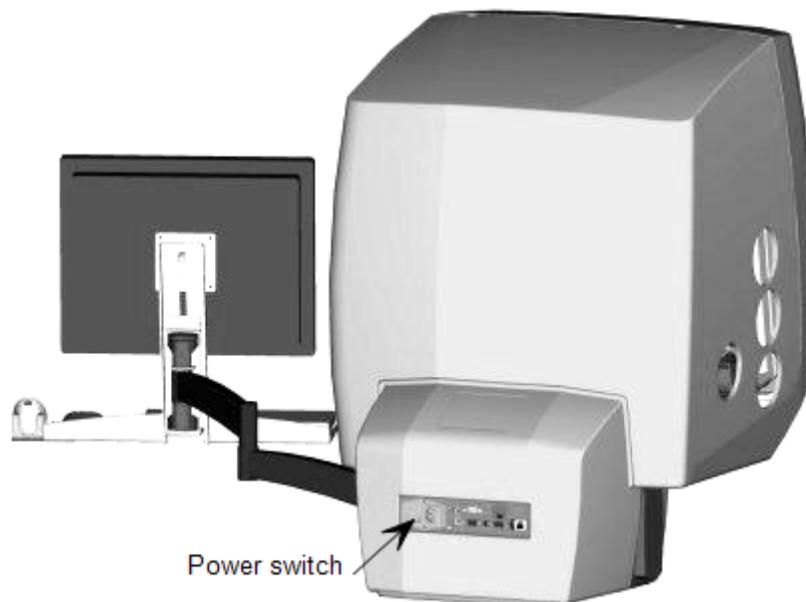
This section explains how to start and finish using the device each day. More detailed instructions can be found in the help files for each application.

Switching on each day

Scan Head Module

You must start and close the device each day.

1. Remove the scan head dust cover.
2. Press the power switch at the rear of the scan head to the **on** (I) position. The green light on the front of the scan head cover will come on.



3. Switch on the scan head monitor. The light will come on to indicate that the monitor is on.
4. The **Welcome dialog box** is displayed when the device has started. Click **LOGIN** and enter your user name and password. (User names and passwords are assigned in the **Admin** application. All passwords are case sensitive).
 - There will be a short delay while the device starts up.

- When switched on from cold, the lasers in the scan head will need time to warm up to the operating temperature required for optimum performance. The imaging procedures will not be available during this time (approximately 10 minutes).
- The images and database are stored on the Image Server PC. The scan head module and Viewing PCs need to communicate with the Image Server PC. A network error will be displayed if the Image Server PC is not available when the scan head tries to communicate with it.
- The scan head will automatically go into stand-by mode when it has not been used for a defined period of time. You can define the period of time in the **Settings Options dialog box**. The device will automatically come out of stand-by mode when in use again.

If there is a network error when starting the device it is likely that there is a temporary problem with the Image Server PC. You can clear any problems by restarting the Image Server PC.

Viewing PC

Captured images are reviewed using the **Review** application running on Viewing PCs. You need to login to the Viewing PCs to access the patient details and images stored on the Image Server PC.

Usually, Viewing PCs will have been logged off at the end of each day. To login to a Viewing PC:

1. Press **[Ctrl]+[Alt]+[Del]** to display the **Unlock Computer dialog box**.
2. Type your user name and password. Click **OK**.
3. Select **Start menu > All Programs > optos V2 Vantage > Review** to run the **Review** application.

Image Server PC

The Image Server PC stores the patient details and image files. You do not need to login to the Image Server PC as the device only needs it to be switched on for the Image Server PC services to be available to the scan head and any Viewing PCs.

If the Image Server PC seems to be switched off, check that the power supply, PC and PC monitor are switched on. Restart the Image Server PC; if the device does not seem to be operating correctly.

Closing the System Each Day

The system must be closed down properly each day by shutting down the scan head and closing the system.

	You should always log off the scan head and switch off the scan head power at the end of each working day.
	You should always log off and shut down each Viewing PC at the end of each working day.
	You should run the Storage application and archive files at least once a week. See the Storage application help files for detailed instructions.

How to shut down the scan head

1. Complete the current session and click **LOGOUT** to close the device.
2. Click **SHUT DOWN** to shut down the device.
3. Wait for the device to display a message indicating that it is safe to switch off the scan head.
4. Switch off the scan head monitor.
5. Switch the power switch at the rear of the scan head to the **off (O)** position.
6. Cover the scan head with the dust cover.

How to close the system

1. Shut down the scan head.
2. Close the Optos applications on all PCs in the system. This is to prevent files being accessed while the archiving task runs.
3. It is important to archive at least once a week. Select **Start > All Programs > Optos V2 Vantage > Storage**. Run any recommended start-up tasks. For more information press [F1] to display the help file when the **Start-up Tasks dialog box** is displayed.
4. Close the **Storage** application after completing the start-up tasks indicated in the previous step.
5. Select **Start button > Log Off** to display the **Log Off Windows dialog box**. Select **Log Off** to log off from the PC. Repeat on each PC.

Notes:

- Logoff the Image Server PC and leave switched on. Do not shut down the Image Server PC.
- Your device communicates with Optos overnight and will need to access the Image Server PC.
- Image files cannot be viewed when the Image Server PC has been shut down.

Attaching and Detaching the Patient Arm Support

Some devices are supplied with a patient arm support and table wings. The patient arm support is fitted with a clamp and can be attached and removed from the table wings.

 <p>Warning</p>	<p>The patient arm support supplied with the P200MA is designed to support the weight of a resting arm. Do not exceed the weight indicated on the patient arm support. When in use, ensure the patient arm support is securely clamped to the table wing, and that it is covered with a piece of absorbent paper.</p>
---	---



Attaching and Detaching the Head Rest

To remove the head rest for cleaning, pull the head rest bolt down and slide the head rest to the left.



5 Getting help

The help files contain detailed information about how to use the device. You can access this information from the application at any time by pressing **[F1]** on your keyboard. In the Review, Storage, Admin and Scheduler Applications you can also access help files from the application's Help menu.

If the help files do not answer your problem, please contact Optos Customer Support.

Additional material may be available on the Partner area of the Optos website. There is a convenient link from the Help menu, see *How to access additional documentation on the web* on page 60.

Accessing Help from the Capture Application

Help is available throughout the application. Press **[F1]** to display information on the current task.

Accessing Help from the applications

There are several ways to access the help files:

Pressing **[F1]** for Help with Your Current Task

The help system can display a help topic that relates to the current application window or dialog box. Press **[F1]** on your keyboard to display information on the current task.

Help from the Help Menu

You can access the application help file from the **Help menu**. Click **Help menu > Optos <application> Help** to display the help file.

How to display the hierarchy of all help topics

1. Click the **Contents tab** to display the help file hierarchy.
2. Click a topic to display it in the right-hand pane. Alternatively, double-click the book icon and select from the list of topics that appears.

How to browse the help index

The help index contains defined keywords and phrases. You can select from the list of keywords and phrases to display a list of related topics.

1. Click **Help menu > Optos <application> Help** to display the help file.
2. Click the **Index tab** to display the alphanumeric list of indexed words and phrases.
3. Select the word or phrase from the list. Alternatively, type the word or phrase in the text box. If you do not find what you were expecting, it may be that the index does not contain the exact word or phrase. Try typing a similar word or phrase. Alternatively, try entering the word or phrase in the **Search tab**.
4. When you have located the topic you want, click **Display** to display the topic in the right-hand pane.

How to search for help

1. Click **Help menu > Optos <application> Help** to display the help file.
2. Click the **Search** tab to display the search pane.
3. Type the words you are looking for. Click **List Topics** to display the search results.
 - Use '?' to replace a single letter, for example 'archive?' to search on 'archived' and 'archives'.
 - Use '*' to replace a group of letters, for example 'archiv*' for 'archive,' 'archived,' 'archives' and 'archiving'.
4. Click a topic to display it in the right-hand pane.

Note

- If you do not get the result you were expecting, it may be that the help file does not contain the exact word or phrase you typed. Try typing a similar word or phrase.
- You can use wildcards to search for parts of words.

How to navigate topics

1. Click **Help menu > Optos <application> Help** to display the help file.
2. Display the topic you require using the **Contents, Index** or **Search** tabs.
3. Repeat for each topic you want to view.
4. Click **Back** and **Forward** to scroll through the topics you have displayed. Only topics you have viewed will be displayed when clicking **Back** and **Forward**. This is particularly useful if you want to go back to a previous topic and you do not want to search for it again.

How to print help topics

1. Click **Help menu > Optos <application> Help** to display the help file.
2. Use the **Contents** tab to display the help section you wish to print.
3. Click **Print** to display the **Print Topic** dialog box.
4. Select to print the current topic or, if applicable, the selected heading and its subtopics. Click **Print**.

You can print the current topic by right-clicking the topic to display the pop-up menu. Select **Print** to display the **Print dialog box** and click **Print**.

Optos on the Web

The Optos web site contains a wide variety of information resources. Simply click the **Partner Login** link at www.optos.com to access the partner login area or to register.

The Partner area of the web site includes:

- Practice Marketing materials.
- Clinical materials.
- Details of the Optos Academy events.
- Software downloads.

How to access additional documentation on the web

1. Select **Help menu > Visit Optos Partner on the web**.
2. Login when prompted.

3. Click your device to display the relevant documentation.

6 Cleaning

While biocompatible materials have been used where the instrument comes into contact with the patient, these need to be cleaned between patients to reduce the risk of contamination or cross-infection.

Cleaning of the external surfaces of the device should be carried out on a regular basis.

The device will be subject to a scheduled inspection and maintenance routine carried out by Optos Technical Personnel.

	<p>Always wear powder-free gloves when cleaning the device. Do not use lint cloths, tissues, or other materials that may create dust, near the scan head.</p>
Caution	

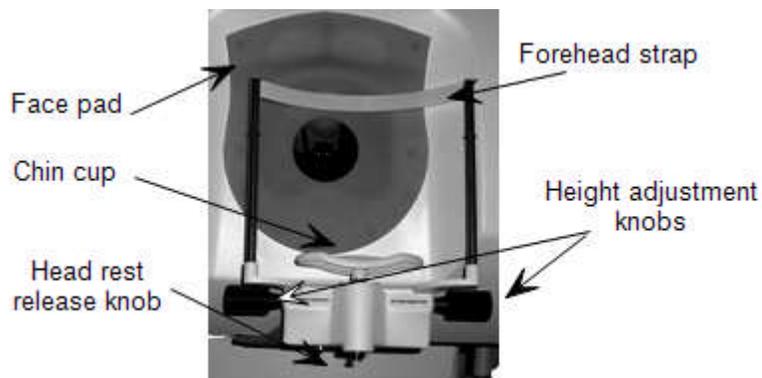
Cleaning Before Each Patient

The areas where the patient comes into contact with the device must be cleaned before each patient is imaged.

How to clean the device before each patient

	<p>Do not capture images when the face pad is not in place.</p>
Warning	

The following cleaning procedures should be carried out between patients:



- The face pad and head rest must be cleaned with an individually sealed, 70% isopropyl alcohol wipe and allowed to air-dry between patients.
- The head rest can be removed for cleaning, see the Introductory Handbook for details on removing the head rest.
- The P200MA is supplied with a patient arm support. This should also be cleaned with an individually sealed, 70% isopropyl alcohol wipe and allowed to air-dry between patients.
- Do not use tissues or other material to dry the areas that have been cleaned as this could create dust. Dust could collect on the scan head mirror and optical components and impair image quality. Always allow cleaned areas to air-dry.
- Do not let the cleaning wipes come into contact with the inside of the instrument.
- The wipes should be checked periodically to ensure that they are within their marked expiration date.

How to clean the head rest and patient arm support before each patient

Some devices are supplied with a head rest and patient arm support. These must be cleaned with an antiseptic cleaning wipe and allowed to air-dry between patients. Do not use tissues or other material to dry the head rest and patient arm support.

General Cleaning

The equipment should be kept clean and dust free.

- Logout, shut down and power off the scan head before cleaning the outer casing of the scan head.
- Use a soft, slightly damp cloth to clean the plastic surfaces.
- Ensure debris does not fall inside the device.
- Use a glass-cleaning agent to clean the PC monitor screen.
- Do not use solvent.

Decontaminating External Surfaces

You should decontaminate external surfaces when they become dirty or contaminated with bodily fluids. Follow your clinic's decontamination procedure when necessary.

Cleaning the Main Mirror

In devices where there is a hatch in the front cover, follow the Main Mirror Cleaning Procedure supplied with the device. In all other systems, where there is no hatch, contact Optos.

7 Contact us

We welcome your questions and comments.

Global Headquarters

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You will need to tell us your site number to allow Optos to access your details. You can find the Site Number on the documentation received from Optos. Alternatively, open the **Admin** application and select **System menu > Set Site Information** to display the **Practice Information dialog box**.

Regional Offices

Please check www.optos.com for the latest information on new regional offices.

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---	--

Switzerland

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Optos Inc 67 Forest Street Mar borough MA 01752 United States of America	Sales and Marketing Toll Free: 866-OPTOMAP Outside continental US & Canada: (508) 787-1400 Fax: (508) 486 9310 Customer Support: 800-854-3039 Website: www.optos.com
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3 About the software applications

V² Vantage DX contains five applications. Each application contains the tools needed to perform specific tasks. Some applications run automatically when the device is switched on. You can run other applications by double-clicking the relevant icon on the desktop.

<p>V² Vantage DX Capture</p>	<p>Lets you control the device; capturing and checking the quality of images.</p> <p>The Capture application runs automatically when the Capture PC is switched on. If the Capture application does not run automatically select Start > Programs > OptosV² Vantage DX > Capture.</p>
<p>V² Vantage DX Admin</p>	<p>Lets you configure your system. You can set password requirements, create new users, modify existing users, and set a variety of system controls.</p> <p>You can also run the Admin application by selecting Start > Programs > OptosV² Vantage DX > Admin.</p>
<p>V² Vantage DX Scheduler</p>	<p>Lets you manage patient records and appointments for the optomap® Retinal Exam.</p> <p>You can also run the Scheduler application by selecting Start > Programs > OptosV² Vantage DX > Scheduler.</p>
<p>V² Vantage DX Review</p>	<p>Lets you review, annotate, and add diagnostic codes to captured images. Also contains exporting, e-mailing and printing tools.</p> <p>You can also run the Review application by selecting Start > Programs > OptosV² Vantage DX > Review.</p>
<p>V² Vantage DX Storage</p>	<p>Lets you archive images and manage the database and image files.</p> <p>You can also run the Storage application by selecting Start > Programs > OptosV² Vantage DX > Storage.</p>

Note: extract from page 9 of the P200 handbook. There is very little change in the handbook and as referenced in section VI, both the P200 and P200CAF run the same application software. This extract compares to page 62 of the handbook for the P200CAF.

Attachment 4 –Labeling

Scan Head Labeling

Panoramic Ophthalmoscope

Model:		Phases:	1
Serial No:	SN	Frequency:	50-60Hz
Date of Manufacture:		Power Input:	500W
		Mode of Operation:	Continuous
		Rated Input Voltage:	100-240Vac
			North America 100-120Vac

CAUTION: CLASS 1 LASER DEVICE. Do not open the instrument casing. No user operable parts inside.
ATTENTION: APPAREIL LASER DE CLASSE 1. Ne pas ouvrir le boîtier de l'appareil. Il ne contient aucune pièce manipulable par l'utilisateur.
VORSICHT: LASERGERÄT DER SCHUTZKLASSE 1. Das Gerätegehäuse nicht öffnen. Das Geräteinnere enthält keine anwenderrelevanten Teile.
PRECAUCION: APARATO LASER DE CLASE 1. No abra la caja del aparato. No contiene piezas que el usuario pueda manipular.
ATTENZIONE: DISPOSITIVO LASER DI CLASSE 1. Non aprire il telaio dello strumento. Non contiene parti manipolabili dall'utente.

注意
クラス1レーザー装置。装置のケーシングを開けないで下さい。内部には使用者が操作できる部品はありません。
小心 1 类激光设备。请勿打开仪器外壳。内部没有用户可以操作的部件。
Laser emissions: Ophthalmoscope complies to EN60825-1 (Class 1) and 21 CFR1040.10 (Class 1) and 1040.11 at date of manufacture. This device complies with part 15 of the FCC rules.

   **optos** 
Queensferry House
Queensferry Road
Dunfermline, Fife
KY11 8UH
UK

M4950001

 ETL LISTED
CONFORMS TO
UL STD 2801-1
3031673
CERTIFIED TO
CAN/CSA STD C22.2 NO. 801.1

Attachment 4- Table Label

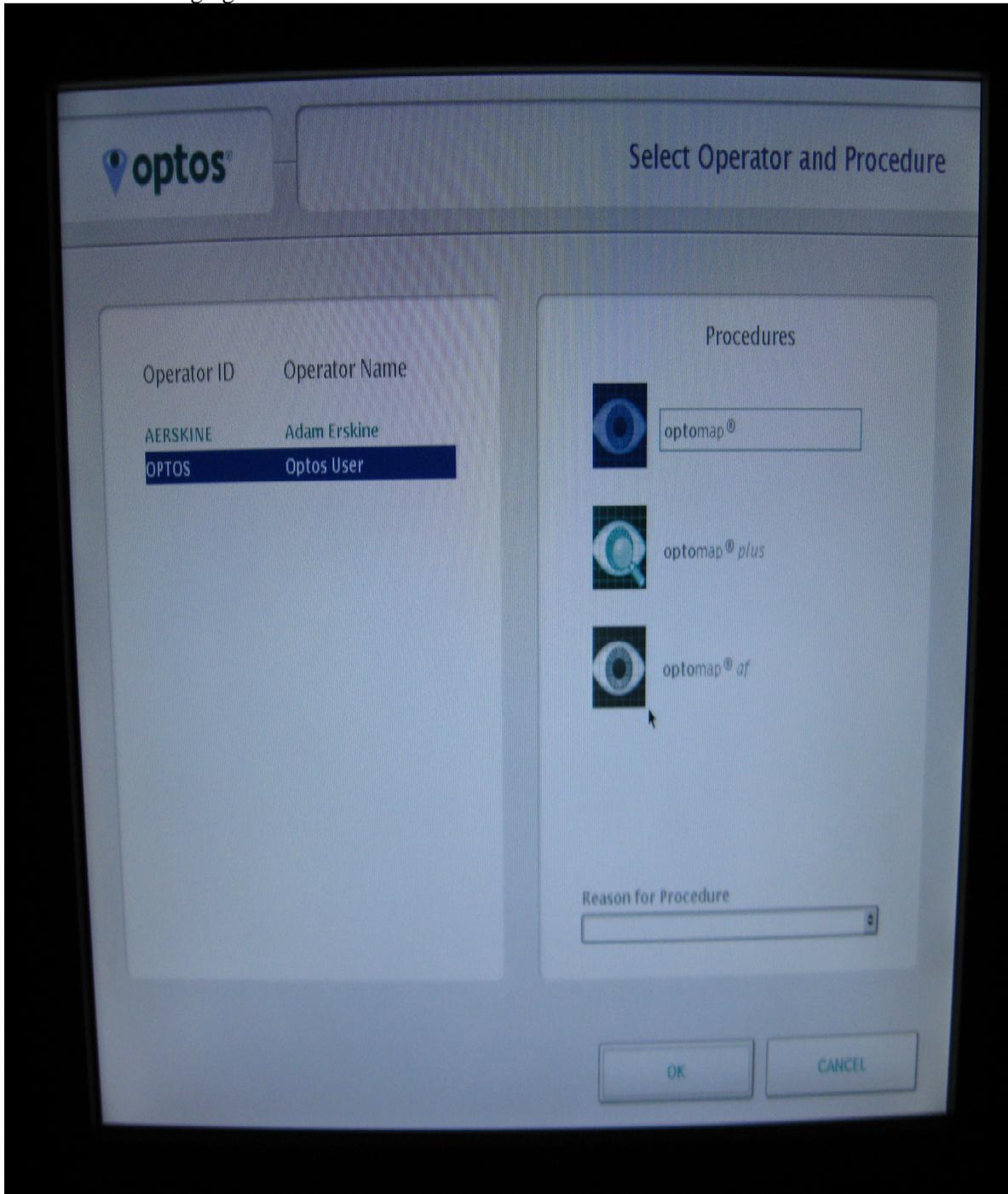


Attachment 4: Laser Labeling

Should be visible before gaining access to lasers. Lasers not accessible to users.

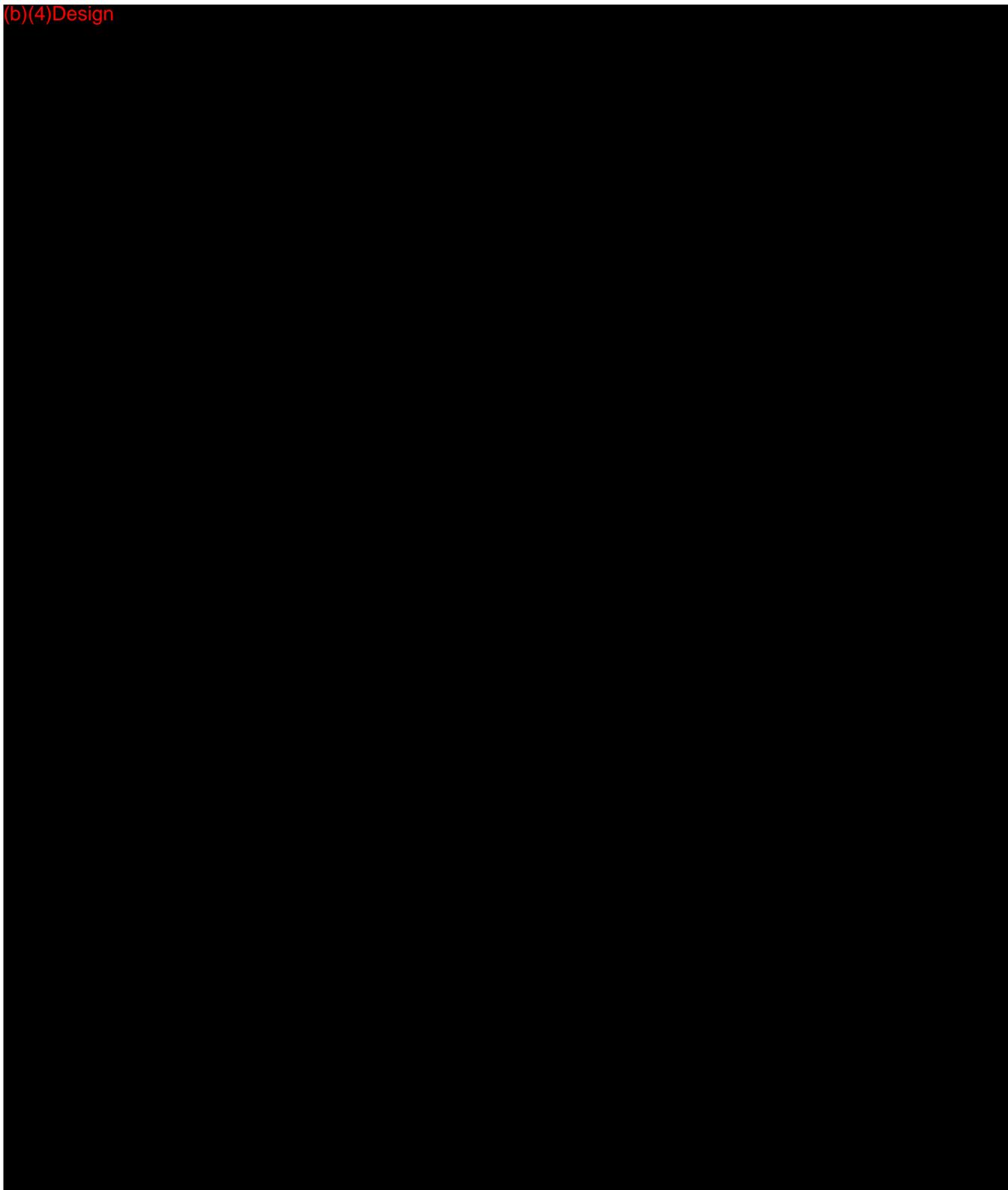


Attachment 4: Imaging Mode Selection for Autofluorescence

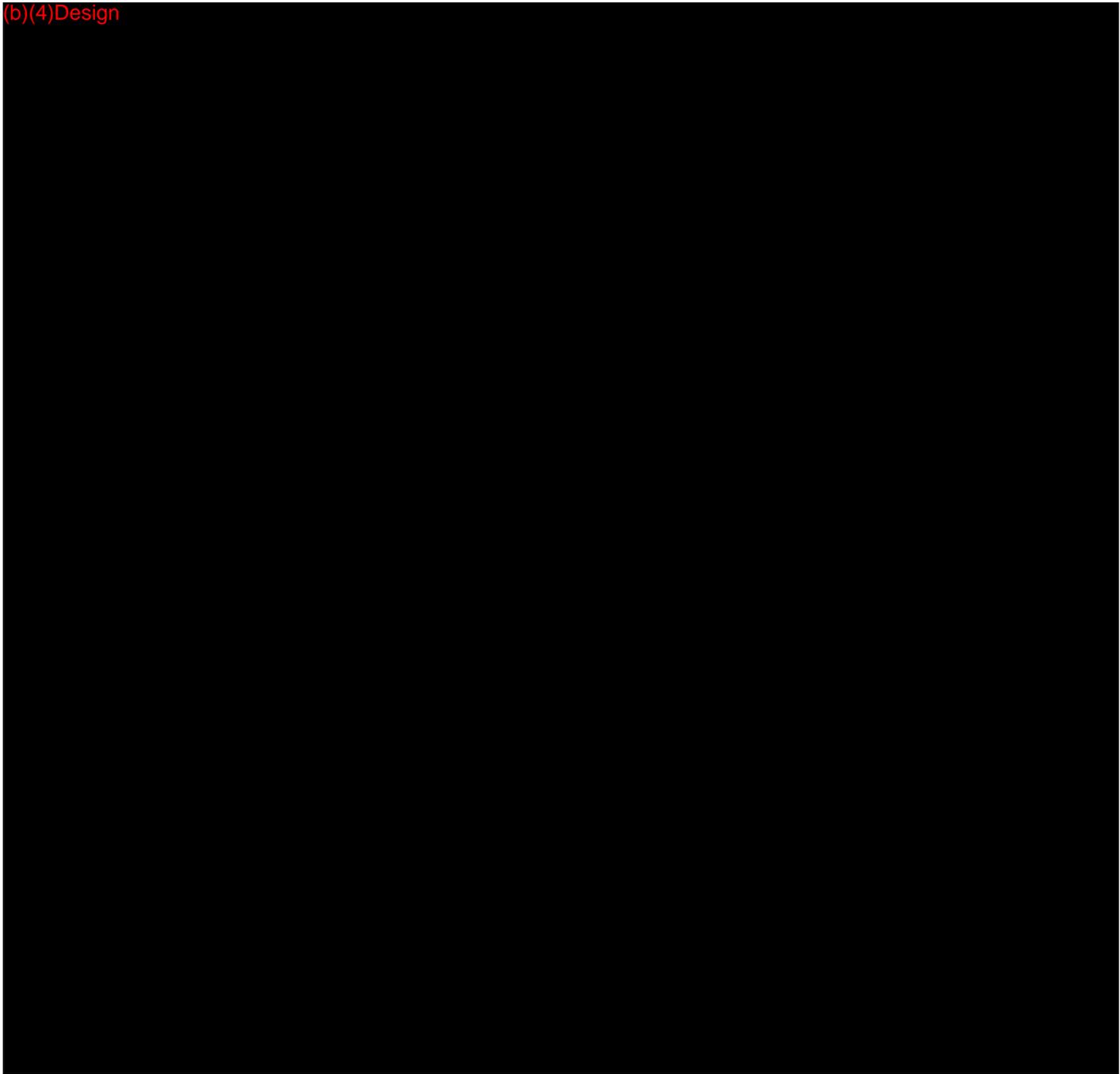


Attachment 5: Device Schematics

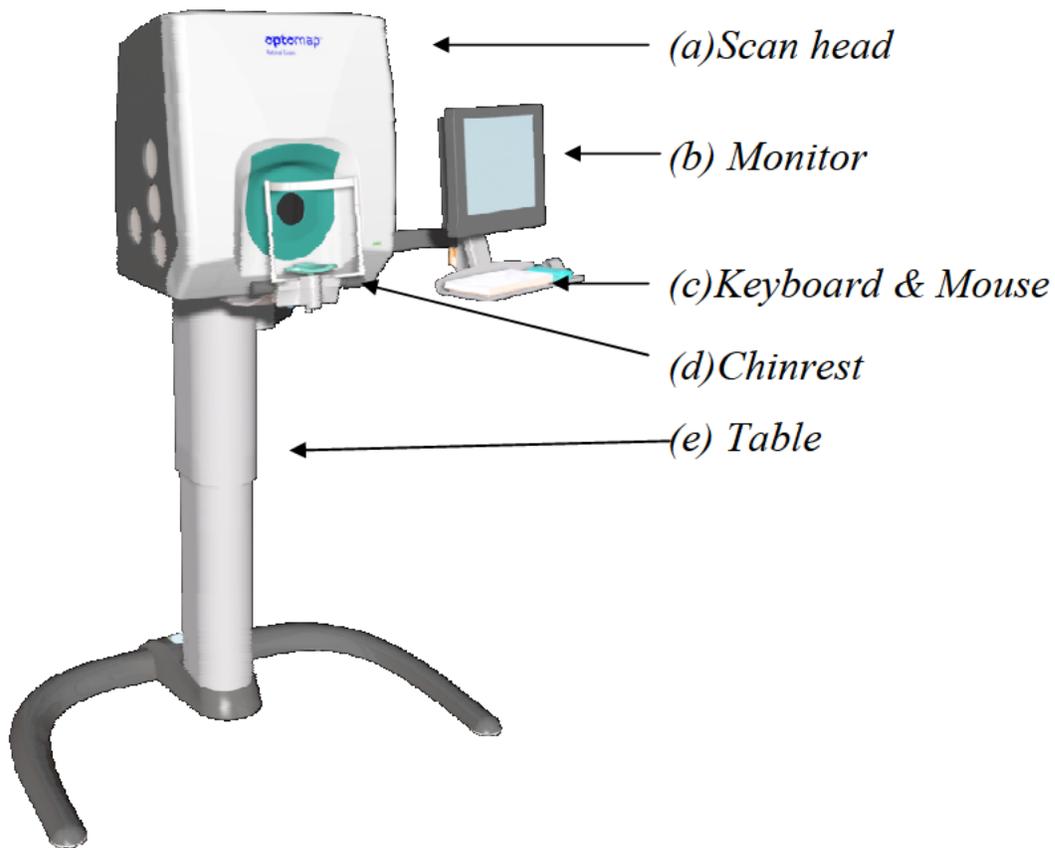
(b)(4)Design



(b)(4)Design



Attachment 5- Panoramic 200CAF External Schematic



Attachment 6: Risk Analysis Quantification Methods

6.1 Use of the Hazard Rating Number in Conjunction with ISO14971(Medical Devices- Application of Risk management to Medical Devices)

A Hazard Rating Number (HRN) will be used to quantify the risk of hazards when applying the risk methodology detailed in BS EN ISO14971:2001.

The HRN is calculated by applying numerical numbers to the likelihood of occurrence (LO), the probability of injury (PI) and the severity of injury (SI).

The Hazard Rating Number (HRN) is:

$$HRN = LO + PI + SI$$

The following table shows the rating numbers used by Optos

Health Hazard Category index:		
Assessment of the likelihood of the occurrence of the potentially hazardous event	Remote	0
	Rare	1
	Occasional	2
	Frequent	3
	Continuously Occurring	4
Probability of injury occurring to the population at risk or exposed	Extremely Unlikely	0
	Unlikely but Possible	1
	Likely	2
	Very Likely	3
	Extremely Likely	4
Severity of the Injury or Adverse Health Outcome	None	0
	Limited	1
	Moderate	2
	Severe	3
	Life Threat	4
Risk Assessment Criteria	None/Negligible	0 – 3
	Low	4 – 6
	Moderate	7 – 9
	High	10 – 12

6.2 Quantification of Design and Process Risks for Failure Mode Effect and Analysis

Risk Priority Number (RPN)

The Risk Priority Number is a product of the Severity (S), Occurrence (O) and Detection (D) ranking :
 $RPN = (S) * (O) * (D)$

This can be applied to design or process.

Detection for design relates to the capability of the verification and validation activities detecting a design issue. Detection for process relates to current manufacturing controls detecting an atypical result or event. The description of detection for design and process are detailed in tables D and C respectively.

Appendix A –Severity Rating Table

Effect	Rating	Severity of effect (design)	Severity of effect (process)
Serious Hazardous Effect	10	Health risk to patient System operable, but potentially unsafe – No indication that fault has occurred. Future patients may be at risk Non compliance with Government regulations	Health risk to patient System operable, but potentially unsafe – No indication that fault has occurred. Future patients may be at risk Non compliance with Government regulations
Hazardous Effect	9	Health risk to patient System operable, but potentially unsafe – Indication that fault has occurred. Current patient may be at risk Non compliance with Government regulations	Health risk to patient System operable, but potentially unsafe – Indication that fault has occurred. Current patient may be at risk Non compliance with Government regulations
Very high	8	System inoperable – severe customer dissatisfaction, Requires Optos engineer to visit. OR . Significant impact on diagnosis capability	System inoperable – severe customer dissatisfaction, Requires Optos engineer to visit. OR . Significant impact on diagnosis capability OR . Major disruption to production line, 100% WIP (Work in progress) reworked.
High	7	System inoperable – customer dissatisfaction, Requires Optos engineer intervention (phone call?) OR . Minor impact on diagnosis capability	System inoperable – customer dissatisfaction, Requires Optos engineer intervention (phone call?) OR . Minor impact on diagnosis capability OR . Major disruption to production line, 100% WIP reworked.
Moderate	6	System performance reduced. No impact on	System performance reduced. No impact on diagnosis capability. Most users will detect.

		diagnosis capability Most users will detect.	OR . Moderate disruption to production line, 50% WIP reworked.
Low	5	System performance reduced. No impact on diagnosis capability Some users will detect.	System performance reduced. No impact on diagnosis capability. Some users will detect. OR . Moderate disruption to production line, 50% WIP reworked.
Very Low	4	System performance reduced. No impact on diagnosis capability. Discriminating users will detect.	System performance reduced. No impact on diagnosis capability. Discriminating users will detect. OR . Minor disruption to production line, 10% WIP reworked.
Minor	3	Defect noticed by most users. System performance not affected	Defect noticed by most users. System performance not affected OR . Minor disruption to production line, 10% WIP reworked.
Very Minor	2	Minor defect noticed by discriminating user. System performance not affected	Minor defect noticed by discriminating user. System performance not affected
No Effect	1	No effect on user, function or performance.	No effect on user, function or performance.

Appendix B –Occurrence Rating Tables

Potential of Failure	Rating	Failure Rates
Very High	10	> 1 in 2
Failure almost inevitable	9	1 in 4
Repeated failure rate	8	1 in 8
	7	1 in 16
Moderate : Occasional Failure	6	1 in 32
	5	1 in 64
	4	1 in 128
Low : Relatively few failures	3	1 in 256
	2	1 in 512
Remote : Failure is unlikely	1	< 1 in 1024

Appendix C: Detection Rating Table

Detection	Rating	Criteria
Almost Impossible	10	Almost impossible potential that current control(s) will detect
Very Remote	9	Remote potential that current control(s) will achieve detect
Remote	8	Very slight potential that current control(s) will detect
Very Low	7	Slight potential that current control(s) will detect
Low	6	Low potential that current control(s) will detect
Moderate	5	Medium potential that current control(s) will achieve detect
Moderately High	4	Moderately high potential that current control(s) will detect
High	3	High potential that current control(s) will detect
Very High	2	Very high potential that current control(s) will detect
Almost Certain	1	Almost certain potential that current control(s) will detect

Appendix D: Design Verification Effectiveness Table

Detection	Rating	Criteria
Absolute Uncertainty	10	Design Verification (DV) will not/ cannot detect a potential cause and subsequent failure mode; or there is no DV.
Very Remote	9	Very remote chance that the DV will detect a potential cause and subsequent failure mode
Remote	8	Remote chance that the DV will detect a potential cause and subsequent failure mode
Very Low	7	Very low chance that the DV will detect a potential cause and subsequent failure mode
Low	6	Low chance that the DV will detect a potential cause and subsequent failure mode
Moderate	5	Moderate chance that the DV will detect a potential cause and subsequent failure mode
Moderately High	4	Moderately High chance that the DV will detect a potential cause and subsequent failure mode
High	3	High chance that the DV will detect a potential cause and subsequent failure mode
Very High	2	Very High chance that the DV will detect a potential cause and subsequent failure mode
Almost Certain	1	Almost Certain that the DV will detect a potential cause and subsequent failure mode

Attachment 7: Software

Attachment 7(a)-P200CAF Image Capture, Management and Review Software

File Versions: as listed

The software components of the system are deployed in three locations:

1. The electronics module (A10014) of the P200CAF scan head (embedded software including user interface software and laser radiation management firmware)
2. The Image Server PC (application software working in a windows environment)
3. The Viewing PC (review functionality of the application software only)

The following tables list the software components and versions

P200CAF Scan Head

Part Number	Name	Version	Description
K100250229	Embedded SW Contains the following:	2.2.9	Top Level Scanhead Embedded Software [S94751 ver 2.2.9]
S90461	Control FPGA SW	2.0.3	Control Card FPGA Software
S90481	Power SW	2.0.6	Power Card Software
S90471	Detector SW	2.0.8	Detector Card Software
S90414	Linux Drivers	1.3.4	Optos Linux Drivers
S90413	Linux Kernel	2.4.27	Linux Kernel
S90416	Linux Processes	2.0.6	Optos Linux Processes
T90416	Test Control	2.0.8	Optos Test Control Process
S90415	UI SW	1.2.0.97	User Interface Software
S90421	COEConfig	1.1.0.1	Common Optical Engine Configuration SW
S99737	en_remote	1.0.0	Enable Remote Access Software
S90411	Linux File System	2.2.9	Linux File System
F11014	Control FPGA	3.0.2	Control Card FPGA
F11017	Power FPGA	2.0.9	Power Card FPGA
F11019	Detector FPGA	2.0.6	Detector Card FPGA
F11016	Config PLD	0.9.0	Configuration PLD
F11055	Control Watchdog PLD	0.4.0	Watchdog PLD
F11056	Power Stepper Mux PLD	0.2.0	Power Card Stepper Multiplexor PLD
F11044	Power LRM 1 PLD	2.0.3	Laser Radiation Management PLD
F11045	Power LRM 2 PLD	2.0.3	Laser Radiation Management PLD
F11036	Power Summit config	1.4.0	Power Card Summit Power Sequencer
F11037	Control Summit Config	1.2.0	Control Card Summit Power Sequencer
F11072	Contro Board Flash	2.2.9	Control Board Flash Programming File
F11073	Detector Board Flash	2.2.9	Detector Card Flash Programming File
F11074	Power Board Flash	2.2.9	Power Card Flash Programming File

Image Server

Part Number	Filename	Version	Description
S90211006	Review.exe	2.4.0.129	Review Application
S90212006	Admin.exe	2.4.0.60	Admin Application
S90213006	Scheduler.exe	2.4.0.39	Scheduler Application
S90214006	Storage.exe	2.4.0.62	Storage Management Application
S90233004	OptosDataGatewayService.exe	2.4.0.34	Data Gateway Service
S90260006	OSCCClient.exe	1.4.0.24	Optos System Communication Client
S90203004*	Installer Package	2.4.0.0010	See below

Viewing PC

Part Number	Filename	Version	Description
S90211006	Review.exe	2.4.0.129	Review Application
S90205004*	Installer Package	2.4.0.0010	See below

*Software components supplied by third parties are installed under the S90203004 and S90205004 Installer Packages.

Attachment 7(b): Assessment Criteria Used for Software

Severity:	Severity Description:
Critical (4)	A problem that stops testing or would render the application unusable to the customer
Major (3)	A problem that stops testing of a whole functional area of an application. Customer usage restricted
Medium (2)	Minor functional omission, usually use of application is not hindered. Customer experience of software may be degraded or limited;
Minor (1)	Trivial problem, unlikely to impact customer ability to utilize software functionality. It may however, present a minor irritation.
Query/Suggestions (0)	Used to report problems that relate to clarification of software function or whether the tester believes improvements to software could be achieved.

Attachment 7(c): Embedded Software Chronology

Product Platform	User Interface/Capture Version	Release Date	COE Top Level Embedded Version	Functionality/changes
COE	1.0.0.36	September 2006	1-0-3	Runs same application software as P200. Different UI/embedded software as COE scanhead is in a linux operating system environment
COE	91.1.0.47	May 2007	2-0-0	Minor bug fixes
COE	1.1.1.71	Oct 2007	2-0-8	Modified to allow red/green only without blue for fluorescein angiography (related product but not applicable to this submission)
COE	1.2.0.96	5 th Jan 2009		Bug fixes for fluorescein angiography (related product but not applicable to this submission)
COE	1.2.0.97	22 nd Jan 2009	2-2-9	Modified to allow autofluorescence user interface.

Attachment 7(d): Specification for the Embedded user interface software and traceability

Document Reference Information

Type D101417
Title P200C-AF Software Traceability

Author: A. McKelvie
Filename (auto field): D101417 CP 684 P200C and AF Software Traceability Matrix.doc

Document Type: Traceability Matrix

Document Title: CP684 P200C-AF

Document No/Rev: D101417 Revision: 1

Filename (auto field): D101417 CP 684 P200C and AF Software Traceability Matrix.doc

Document Reviewers/Approvers:

Job Title:	Name:	For Info Only:	Approver:	Approval Signature:	Date (dd/mmm/yyyy):
Author	(b) (6)				
Design Moderator					
Quality Representative					

Template Reference Information

Title: AZ1000F12 Traceability Matrix
Revision No: 1

Owner:
Change Note No: CAR170

Part No
Page 1 of 6

Document Reference Information

Type: D101417
Title: P200C-AF Software Traceability

Author: (b) (6)
Filename (auto field): D101417 CP 684 P200C and AF Software Traceability Matrix.doc

Contents

1	Revision History	3
2	Introduction	4
3	References	4
4	Requirements Traceability Matrix	5

Template Reference Information
Title: P200C-AF Software Traceability Matrix
Revision No: 1

Doc No: CP 684 P200C and AF
Software Traceability Matrix

Page No: 2 of 6

Document Reference Information

Type D101417
Title P200C-AF Software Traceability

Author: (b) (6)
Filename (auto field): 684 P200C and AF Software Traceability Matrix.doc

1 Revision History

Rev	Amended by	Comment/Amendment	Date	Change & Release Method		
				Concession No.	Change Request No.	Change Plan No.
1	(b) (6)	Initial	19-01-09			684

Template Reference Information

Title P200C-AF Software Traceability Matrix
Revision No. 1

Owner (b) (6)
Change No. (b) (6)
Rev. No.

Page No. 3 of 6

Document Reference Information

Type: D101417
Title: P200C-AF Software Traceability

Author: (b) (6)
Filename (auto field): D101417 CP 684 P200C and AF Software Traceability Matrix.doc

2 Introduction

This document provides the explicit linkage between functional requirements specifications, design details and verification tests and validation tests.

This explicit linkage provides 'at a glance' traceability between these various stages of module (hardware, software, mechanical or optical) production through the AZ3 Design Control SOP.

The project covered by this document is "P200C with AF". The documents covering this project are stored in ProjectLink in the "System Software" project.

3 References

Document type	Author	Title and part number	Revision
Functional Requirements Specification	(b) (6)	D101423 P200CAF Functional Requirements.doc	001
User Interface Requirements	(b) (6)	D95547 S94751 COE User Interface Requirements	006
Design Document	(b) (6)	D101422 CP 684 P200C and AF Software Design.doc	001
Test Plan & Report	(b) (6)	D101421 CP684 P200C and AF Software Test Plan and Report.doc	001

Template Reference Information

Title: AZ1000F-12 Traceability Matrix
Revision: 1
No: 1

Owner: CAS/170
Change Note: No

Part No: Page 4 of 6

Document Reference Information

Type: D101417
 Title: P200C-AF Software Traceability

Author: [REDACTED]
 Filename (auto field): [REDACTED]

CP684, P200C and AF Software Traceability Matrix.doc

4 Requirements Traceability Matrix

D95547 COE User Interface Requirements	Requirement Description	D101422 Design Document Section(s)	D101421 CP684 P200C and AF Software Test Plan and Report Test(s)
3005	The operator will select the required procedure after selecting the patient to image. The set of procedure will depend upon the configuration options for the scan head (see R.10007). The imaging options for procedures will be (b) (4)	3.1 3.2 4	100 200 210 300 310 320 330 400 410 600

Document Reference Information
 Title: ADICWAF-12 Traceability Matrix
 Page: 5 of 6

Author: [REDACTED]
 Filename: [REDACTED]

Page 5 of 6

Document Reference Information

Type: D101417
 Title: P200C-AF Software Traceability

Author: (b) (6)
 Filename (auto field): D101417 CP 684 P200C and AF Software Traceability Matrix.doc

	(b) (4)		3.1	510	
4102			3.1	500	
1007					

Attachment 7(e): Test Results for Embedded Software Version 2-2-9



Test Script

Tested by (Name, title, signature): (b) (4)				
Date: 23/01/09				
Software under test: S94751 2-2-9				
Test Number	Requirement	Action	Expected result	Outcome (Pass/Fail)
100	(b) (4)	Remove front cover so that the state of input and output paths is observable. Start P200CAF, login, and select a patient	Optomap, optomap plus, and optomap af procedures are available in procedure selection window	PASS
200	(b) (4)	Start the procedure Observe state of laser select shutters Observe state of translation stage	Red and green laser select shutters are open Translation stage is in (i.e. optical elements in the return path)	PASS
210	(b) (4)	Capture an image	Composite colour image displayed Composite, red channel and green channel selection buttons are available	PASS
300	(b) (4)	Complete the first step Observe state of laser select shutters Observe state of translation stage	Only green laser select shutter is open Translation stage is out (i.e. optical elements out of the return path)	PASS

SYSTEM	Embedded Software	REVISION	1.0
DOCUMENT:	Test Plan and Reports	AUTHOR:	(b) (4)
REF:	Embedded Software	PAGE:	Page 6 of 18

Tested by (Name, title, signature): (b) (4)				
Date: 23-01-09				
Software under test: S94751 2-2-9				
Test Number	Requirement	Action	Expected result	Outcome (Pass/Fail)
310		Capture a full field image	af image displayed af channel and green channel selection buttons are available (Green Reflectance in green channel, Green Excited Autofluorescence in IR/Red Channel)	PASS
320		Select green channel	Green reflectance image displayed (will have central pole reflex) 3900x3072 pixels	PASS
330		Capture a ResMax image Complete session	af Resmax image displayed. Note: ResMax images are 3072x3072 pixels for all supported image types	PASS
400	(b) (4)	Use V2.4 Review to open optomap af image View "red" channel View "green" channel	Image is initially displayed as composite "Red" channel contains af channel "Green" channel contains green reflectance image	PASS
410		Use V2.4 Review to open	Image is initially displayed as	PASS

SYSTEM:	Embedded Software	REVISION:	1
DOCUMENT:	Test Plan and Reports	AUTHOR:	(b) (4)
REF:	Embedded Software	PAGE:	Page 7 of 18

		optomap of ResMax image View "red" channel View "green" channel	composite "Red" channel contains af channel "Green" channel contains green reflectance image	
500	(b) (4)	Update a P200MA with the software and check that the AF option is not available and that the FA option is available.		PASS
510		Run the scanhead with a V2.4 Dicom image server.		FAIL SEE APPENDIX I FOR MITIGATION
600		Run a self test – 20 cycles to capture images exercising each imaging procedure.	Check file sizes, colour channels against requirement 3005.	PASS

(b) (6)

SYSTEM	Embedded Software	REVISION	1
DOCUMENT:	Test Plan and Reports	AUTHOR:	(b) (6)
REF:	Embedded Software	PAGE:	Page 8 of 18

Attachment 7(f): P200CAF Laser Radiation Management Software

Revision History for Laser Radiation Management Code

Product Platform	Version	Release Date	Functionality/changes
P200	3167001	September 1998	1 st frozen version. Safety logic based on:- Allowable exposure time Allowable laser power Cover in place (interlock) Allowable polygon speed (vertical scan) Exposure shutter in correct predicted state (either open or closed)
P200	3167002	February 2000	Added a maximum number of allowable shots, maximum number (b) incremented every (b)
(b) (4)	(b) (4)	(b) (4)	Maximum number of shots (b) and bucket incremented every (b) (4)
P200 COE [platform for P200CAF]	0.9.0	6 th September, 2005	1 st frozen version. Safety logic based on:- Allowable exposure time Allowable laser power Cover in place (interlock) Allowable polygon speed (vertical scan) Allowable sloscan (horizontal scan) Exposure shutter in correct predicted state (either open or closed) Laser shutters in correct predicted state (either open or closed) Maximum number of shots (b) (4)

	0.10.0	2 nd November,2005	Addition of (b) (4) warm up period and shot bucket top up interval changed from (b) (4) (b) (4)
	0.1.0	14 th December,2005	Over-power condition during arming phase causes LRM trip
P200CAF	2.0.3	26 th January 2007	Current version used in P200CAF Pin Out Reconfigured for new PCB. Removed Un-used IR Laser Functionality

Attachment 7(g)- LRM Requirements Specification



Document Type: Sub-Systems Requirements Specification

Document Title: D95419 Laser Radiation Management Requirements Specification Rev006.1

Filename (auto field): D95419 Laser Radiation Management Requirements Specification Rev6_1.doc

Document Reviewers/Approvers:

Job Title:	Name:	Approval Signature:	Date
Author	(b) (6)		
Global QA/RA			
R&D Manager			

Template Reference Information
Title: Sub-system Requirements Specification
Revision No: 5

Owner: Global Product Director Part No: AZ1000F4
Change Note No: CN04/211 Page 1 of 16

Document Reference Information

Type: Sub-System Requirements Specification
Title: Laser Radiation Management Requirements Specification Rev006.1

Author: Senior Optical Engineer
Filename (auto field): D95419 Laser Radiation Management Requirements Specification Rev6_1.doc

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Template Reference Information
Title: Sub-System Requirements Specification
Revision No: 2

Owner: Technical Director
Change Note No: CN04/211

Part No: AZ1000F4
Page 2 of 16

Document Reference Information

Type: Sub-System Requirements Specification
Title: Laser Radiation Management Requirements Specification Rev006.1

Author: Senior Optical Engineer
Filename (auto field): D95419 Laser Radiation Management Requirements Specification Rev6_1.doc

1 Document Revision History

1.1 Detail of Current Iteration

Revision No: 006.1		ECO No:
Section/Page:	Detail:	
B10	B10 – warm up time requirement deleted. Warmup is implemented in software to ensure image quality is not compromised by premature imaging.	

1.2 Summary of Previous Iteration(s)

Document Revision	ECO No:	Amended by:	Comment/Amendment:	Date
1		DS	Initial Release	Dec '04

Template Reference Information
Title: Sub-System Requirements Specification
Revision No: 2

Owner: Technical Director
Change Note No: CN04/211

Part No: AZ1000F4
Page 3 of 16

Document Reference Information

Type: Sub-System Requirements Specification
 Title: Laser Radiation Management Requirements Specification Rev006.1

Author: Senior Optical Engineer
 Filename (auto field): D95419 Laser Radiation Management Requirements Specification Rev6_1.doc

Document Revision	ECO No:	Amended by:	Comment/Amendment:	Date
002		DS	<ul style="list-style-type: none"> Included IR radiation for interlock and over-ride requirements Included IR radiation in Monitor Shutter Status Requirements Include range over which power monitor signal to be proportional to power at the eye and a tolerance on the level of calibration required. Revised vertical scan speed requirements (b) (4) rpm, min, to (b) (4) min) Revised horizontal scan requirements Interlocks to be used to turn off lasers (revised from removal of DC power). Revised permissible exposure duration Revised laser shutdown time requirements (b) (4) 	03/05
003		DS	<ul style="list-style-type: none"> Addition of production test requirements and interlock requirement amendments 	
004		DS	<ul style="list-style-type: none"> Added requirement for accessible emission limit. Change slow scan pulse period upper limit to (b) Change the top up rate from on every (b) (4) Removed the laser enable supervisory circuit requirements. This is not so much a requirement of the LRM system but a chosen method of implementation. Remove warm-up bypass requirement. 	October 2005
005			<ul style="list-style-type: none"> Added HDL state transition diagrams 	
006			<ul style="list-style-type: none"> Increase maximum exposure time from (b) (4) 	March 2006

Template Reference Information
 Title: Sub-System Requirements Specification
 Revision No: 2

Owner: Technical Director
 Change Note No: CN04/211

Part No: AZ1000F4
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Document Reference Information

Type	Sub-System Requirements Specification	Author:	Senior Optical Engineer
Title:	Laser Radiation Management Requirements Specification Rev006.1	Filename (auto field):	D95419 Laser Radiation Management Requirements Specification Rev6_1.doc

2 Introduction

The laser radiation management scheme comprises of a series of modules that operate together to ensure that that eye-safe, Class I operation is maintained throughout normal use and in the event of foreseeable fault conditions. This is achieved by a combination of system monitors (laser power and scan parameters), digital electronics that determine if the system is safe and exposure control mechanisms.

This document will provide the design input requirements for the Laser Radiation Management sub-system. The level of detail will enable a design solution for the sub-system to be developed that will be integrated with all other sub-systems to provide a system design output that meets the design input of the System Requirements Specification.

Template Reference Information

Title:	Sub-System Requirements Specification	Owner:	Technical Director	Part No:	AZ1000F4
Revision No:	2	Change Note No:	CN04/211	Page	5 of 16

Document Reference Information

Type: Sub-System Requirements Specification
Title: Laser Radiation Management Requirements Specification Rev006.1

Author: Senior Optical Engineer
Filename (auto field): D95419 Laser Radiation Management Requirements Specification Rev6_1.doc

3 Design Input

This section identifies key design input requirements. All requirements in this section will be confirmed during Design Verification.

The following areas are considered;

- A – Sub-system Interface
- B – Features and Attributes – Sub-system
- C – Technical Performance – Sub-system
- D – Safety Controls – Sub-system
- E – Sub-system Schematic

3.1 A - Sub-system Interface.

Characteristic & Verification/Validation Ref #	Requirement
A1. Instrument Covers	(b) (4)
A2. Interlock	(b) (4)
A3. Interlock Override	(b) (4)

Template Reference Information
Title: Sub-System Requirements Specification
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Document Reference Information

Type: Sub-System Requirements Specification
Title: Laser Radiation Management Requirements Specification Rev006.1

Author: Senior Optical Engineer
Filename (auto field): D95419 Laser Radiation Management Requirements Specification Rev6_1.doc

3.2 B - Sub-system Features and Attributes

Characteristic & Verification/Validation Ref #	Requirement
B1. <i>Input Shutter Status</i>	(b) (4)
B2. <i>Monitor Laser Power</i>	(b) (4)

Template Reference Information
Title: Sub-System Requirements Specification
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	(b) (4)
B3. Monitor Vertical Scan Speed	
B4. Monitor Horizontal Scan Status	
B5. Control Exposure Rate	
B6. Monitor exposure shutter status & control	

Template Reference Information
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	(b) (4)
B7. <i>Fault Response</i>	
B8. <i>Fail safe shutters</i>	
B9. <i>LRM Control</i>	

3.3 C - Technical Performance Sub-system

Characteristic & Verification/Validation Ref #	Requirement
C1. <i>Over power response time</i>	(b) (4)
C2. <i>Permitted Exposure Duration</i>	
C3. <i>Laser input shutter close time</i>	
C4. <i>Exposure shutter close time</i>	
C5. <i>Laser Shutdown time</i>	

Template Reference Information
 Title: Sub-System Requirements Specification
 Revision No: 2

Owner: Technical Director
 Change Note No: CN04/211

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Author: Senior Optical Engineer
Filename (auto field): D95419 Laser Radiation Management Requirements Specification Rev6_1.doc

3.4 D - Sub-system Safety Controls

There are no safety controls specific to the Laser Radiation Management system

3.5 E - Sub-system Architecture

Signals from the following functional blocks shall provide the required input to the Laser Management System:

- Laser cover Interlock
- IR laser interlock (if used)
- Laser cover interlock override
- IR laser interlock override (if used)
- Blue laser Power Monitor
- Green Laser Power Monitor
- Red Laser Power Monitor
- IR Laser Power Monitor
- Exposure shutter Power Monitor
- Horizontal Scan Mirror Sensor
- Polygon Speed Sensor

These inputs shall be used to ensure that the features described in this document are achieved with the necessary performance.

Template Reference Information

Title: Sub-System Requirements Specification

Revision No: 2

Owner: Technical Director

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Document Reference Information

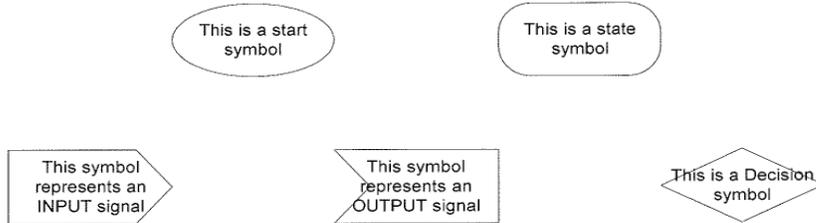
Type Sub-System Requirements Specification
Title: Laser Radiation Management Requirements Specification Rev006.1

Author: Senior Optical Engineer
Filename (auto field): D95419 Laser Radiation Management Requirements Specification Rev6_1.doc

3.5.1 HDL State Transition Diagrams

The following diagrams provide an overview of the state control logic in the LRM HDL. It should partially reflect the structure of the hdl code and obviously will not show all the detail therein.

The legend for the diagrams used is shown in the figure below.



Template Reference Information

Title: Sub-System Requirements Specification
Revision No: 2

Owner: Technical Director
Change Note No: CN04/211

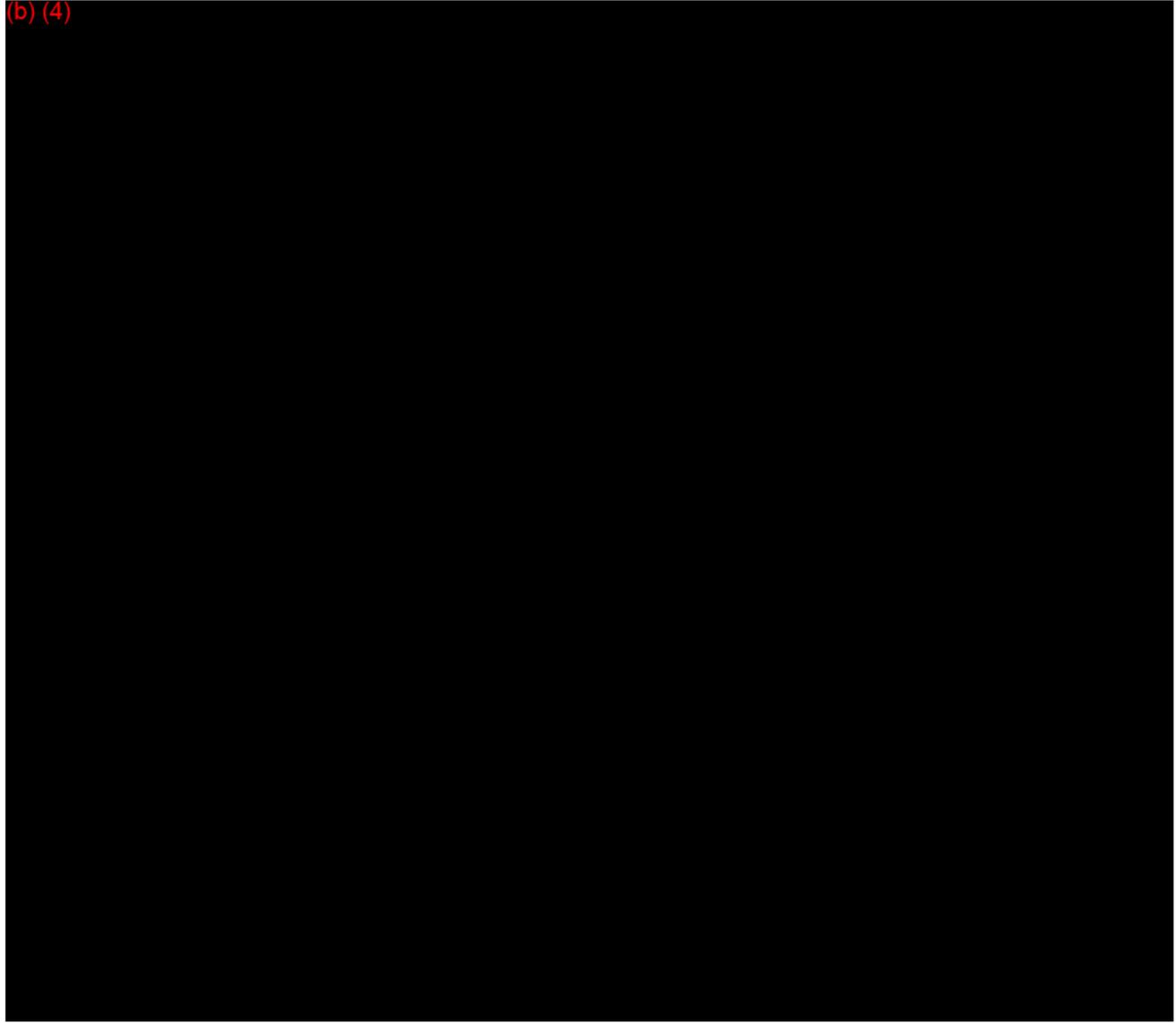
Part No: AZ1000F4
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Document Reference Information

Type: Sub-System Requirements Specification
Title: Laser Radiation Management Requirements Specification Rev006.1

Author: Senior Optical Engineer
Filename (auto field): D95419 Laser Radiation Management Requirements Specification Rev6_1.doc

(b) (4)



Template Reference Information

Title: Sub-System Requirements Specification
Revision No: 2

Owner: Technical Director
Change Note No: CN04/211

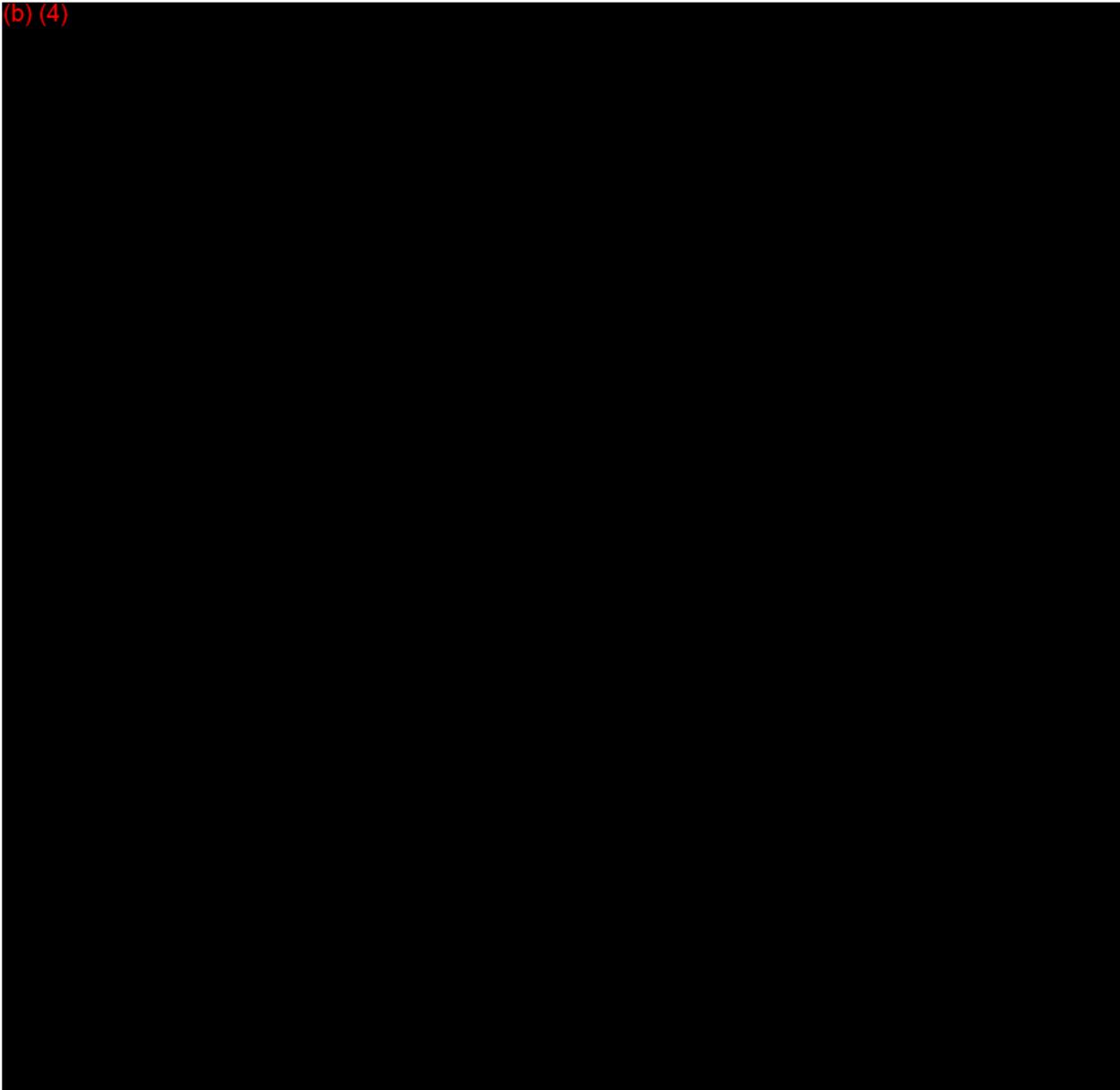
Part No: A21000F4
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Document Reference Information

Type: Sub-System Requirements Specification
Title: Laser Radiation Management Requirements Specification Rev006.1

Author: Senior Optical Engineer
Filename (auto field): D95419 Laser Radiation Management Requirements Specification Rev6_1.doc

(b) (4)



Template Reference Information

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Author: Senior Optical Engineer
Filename (auto field): D95419 Laser Radiation Management Requirements Specification Rev6_1.doc

3.5.1.3 Exposure Control

Template Reference Information

Title: Sub-System Requirements Specification
Revision No: 2

Owner: Technical Director
Change Note No: CN04/211

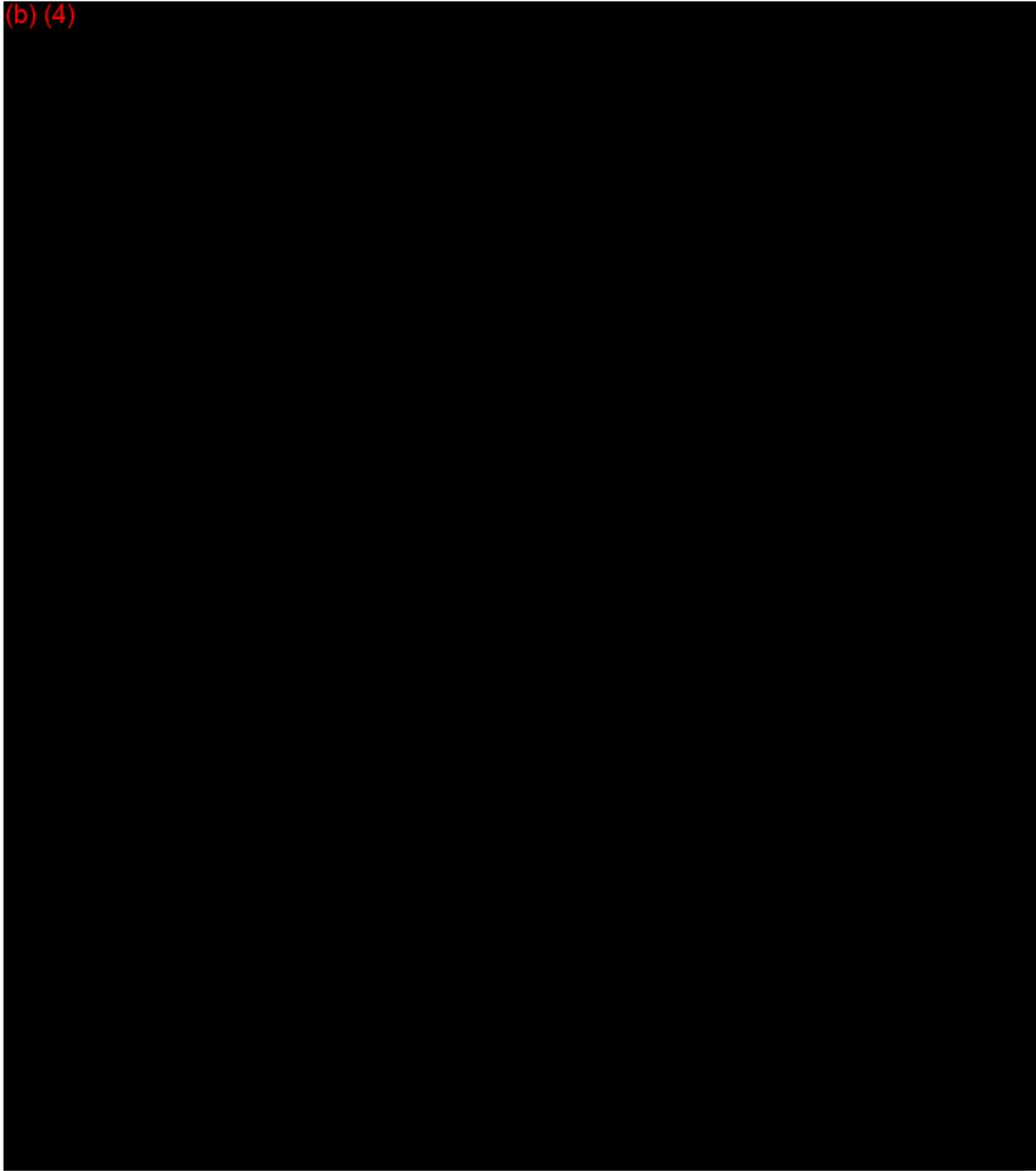
Part No: AZ1000F4
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Document Reference Information

Type: Sub-System Requirements Specification
Title: Laser Radiation Management Requirements Specification Rev006.1

Author: Senior Optical Engineer
Filename (auto field): D95419 Laser Radiation Management Requirements Specification Rev6_1.doc

(b) (4)



Template Reference Information

Title: Sub-System Requirements Specification
Revision No: 2

Owner: Technical Director

Part No: AZ1000F4

Change Note No: CN04/211

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Attachment 7(h): Verification and Validation Activities for LRM Software

Test	Acceptance Criteria	Results	PASS or FAIL?
A1.	<ul style="list-style-type: none"> Covers must be fixed and mechanically secure. Laser emission other than class 1 must not be accessible with covers fitted. Covers shall not be removable without the use of tools. 	<ul style="list-style-type: none"> Covers are secure and can not be removed without tools Laser emission can only be accessed via the front cover aperture. All emission from the front cover aperture is class 1 AEL according to the requirements set out in EN60825-1 and 21CFR1040:10 	PASS
A2.	<ul style="list-style-type: none"> Fault detected – all shutters closed, lasers off and image session not permitted 	<ul style="list-style-type: none"> Fault detected when laser tray cover removed. All shutters closed, lasers off and imaging session not permitted without system restart 	PASS
A3.	<ul style="list-style-type: none"> For platform interlock override: Red, green & blue lasers on, IR laser off. 	<ul style="list-style-type: none"> Red, green and blue lasers on. No IR fitted. 	PASS
B1.	<ul style="list-style-type: none"> An LRM trip shall occur for any manual shutter operation An LRM trip shall occur for any beam block. All combinations in first listed sequence allowed without LRM trip. Any combination in the second listed sequence must cause a LRM trip. 	<ul style="list-style-type: none"> LRM trips if any laser select shutter is manually opened LRM trips if any of the lasers are blocked when the associated laser select shutter is open Red only, green only, blue only and red and green together allowed. Blue can not be opened with any other shutter No IR fitted 	PASS
B2.	<ul style="list-style-type: none"> Percentile change in power monitor signal shall be equivalent to percentile change in power at eye to within (b) (4) over range specified. Each power monitor to be set to (b) (4) for nominal power at the eye on each channel. This must be achievable for any allowed input polarization state. An over power condition must be detected for light levels (b) (4) of the nominal power at the eye for each channel. 	<ul style="list-style-type: none"> Linearity within (b) (4) for all channels. Green channel only tested to (b) (4) See attachment in section 8 (b) (4) set for the following power at eye <ul style="list-style-type: none"> Blue = (b) (4) Green = (b) (4) Red = (b) (4) Tested for both S&P polarization Over power condition detected at (b) (4) on each channel 	PASS

Test	Acceptance Criteria	Results	PASS or FAIL?
		corresponding to (b) (4)	
B3.	<ul style="list-style-type: none"> Set and measured polygon speeds to be in agreement to (b) (4) No images may be acquired at polygon speed (b) (4) 	<ul style="list-style-type: none"> Polygon speed in Optomap: <ul style="list-style-type: none"> set = (b) (4) actual = (b) (4) difference = (b) (4) Polygon speed in Optomap Plus mode: <ul style="list-style-type: none"> set = (b) (4) actual = (b) (4) difference = (b) (4) No images could be taken at polygon speeds (b) (4) 	PASS
B4.	<ul style="list-style-type: none"> Time (b) (4) from last pulse to fault detection. 	<ul style="list-style-type: none"> Fault detected in (b) (4) 	PASS
B5.	<ul style="list-style-type: none"> Exposure period (b) (4) second Counter depleted by one count for every exposure taken Maximum bucket count = (b) (4) Exposure only permitted for counter values (b) (4) Counter refresh rate = (b) (4) 	<ul style="list-style-type: none"> The imaging simulation showed that images could only be taken at (b) (4) second intervals The counter depleted every time an image was taken The maximum number of shots in the bucket before imaging was (b) (4) Exposure was not permitted when the counter value was (b) (4) The counter refreshed by (b) (4) every (b) (4) seconds 	PASS
B6.	<ul style="list-style-type: none"> Status should be OPEN for (b) (4) W (b) (4) at the shutter aperture LRM trip when shutter pulled open Maximum exposure time (b) (4) 	<ul style="list-style-type: none"> The shutter status was OPEN with (b) (4) set at shutter. Imaging sequence was successfully completed LRM trips when shutter is manually opened Maximum exposure time (b) (4) see section 8. 	PASS
B7.	<ul style="list-style-type: none"> All laser select shutters closed Exposure shutter closed All laser output (red, green, blue & IR) off. No further images allowed. 	<ul style="list-style-type: none"> All shutters close and all lasers switch off. No further images allowed without a power cycle 	PASS
B8.	<ul style="list-style-type: none"> All shutters to be closed without electrical power. 	<ul style="list-style-type: none"> Shutters closed by spring mechanism when electrical power 	PASS

Test	Acceptance Criteria	Results	PASS or FAIL?
		removed	
B9.	<ul style="list-style-type: none"> Status conflict results in LRM trip OR function on FPGA inputs and outputs. Lasers off and all shutters closed during FPGA configuration period. 	<ul style="list-style-type: none"> Gated outputs ensure that a status conflict between the two, independent, FPGAs results in an LRM trip. On power up, all lasers are off and all shutters closed until the FPGA is configured. 	PASS
C1.	<ul style="list-style-type: none"> Over power response time (b) (4) 	<ul style="list-style-type: none"> Measured at (b) (4) see section 8. 	PASS
C2.	<ul style="list-style-type: none"> Maximum exposure time (b) (4) 	<ul style="list-style-type: none"> Max exposure time = (b) (4) see B6 	PASS
C3.	<ul style="list-style-type: none"> Laser input shutter close time \leq (b) (4) 	<ul style="list-style-type: none"> Beam stop closes in (b) (4) see section 8 	PASS
C4.	<ul style="list-style-type: none"> Exposure shutter close time \leq (b) (4) 	<ul style="list-style-type: none"> Exposure shutter close time measured at (b) (4) 	PASS
C5.	<ul style="list-style-type: none"> All lasers must fall to (b) (4) of the nominal output power at (b) (4) from activation of interlock. 	<ul style="list-style-type: none"> All lasers off within (b) (4) see section 8. 	PASS

Attachment 8: Indications for Use

Statement for Indication for Use

510(k) Number (if known):

Device Name: Optos Panoramic 200CAF Scanning Laser Ophthalmoscope

Indications for Use:

The Panoramic 200CAF scanning laser ophthalmoscope is indicated for use as a wide field ophthalmoscope for diagnosing and monitoring diseases or disorders that manifest themselves in the posterior pole of the eye.

Prescription Use _____
(Per 21 C.F.R. 801.109)

AND/OR

Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) _____

Attachment 9: Truthful and Accuracy Statement

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

I certify that, in my capacity as Vice President Global Quality Assurance and Regulatory Affairs, I believe to the best of my knowledge that all data and information submitted in this premarket notification for the Optos Panoramic 200CAF (P200CAF) Ophthalmoscope are truthful and accurate and that no material fact has been omitted

Robert Tweedlie

Robert Tweedlie, Vice President Global Quality Assurance and Regulatory Affairs

(Typed name and Title)

Optos plc

(Company)

16th February, 2010

(Date)

Attachment 10: Autofluorescence Literature Review

Autofluorescence imaging of the retina involves capturing a response from molecules in the retinal pigment epithelium (RPE). The most significant naturally occurring fluorophore is lipofuscin¹.

Light is used to stimulate an emission from lipofuscin. This emission (autofluorescence) is at a longer wavelength than the wavelength of the excitation light. The autofluorescence light is captured by a photo-detector which converts light into an electrical signal. This, in turn, is translated into an image displayed on a monitor.

Autofluorescence imaging is well documented both in terms of journals and reference books such as Atlas of Fundus Autofluorescence Imaging by F.G.Holz, S.Schmitz-Valckenberg, R.F.Spaide and A.C.Bird.

Excitation of lipofuscin has been examined at 364, 488, 568, and 633 nm. It was concluded that RPE lipofuscin had strong autofluorescent emissions that were excited at all the above wavelengths².

Lipofuscin has a broad emission band ranging from about 500nm to 750nm.

Autofluorescence can be effected by either the use of a scanning laser ophthalmoscope or a fundus camera with the required autofluorescence filters.

- a) **Scanning laser ophthalmoscopes (SLO)** generate autofluorescence images using a laser of a specific wavelength and a barrier filter of about 500nm. The barrier filter blocks reflected light and allows the autofluorescence light to pass (³).
- b) **Fundus cameras** generate autofluorescence images using an excitation filter as the light is non coherent and a barrier filter. Typically, a fundus camera uses non coherent light in the range of 500-610nm (using an excitation filter) and a barrier filter in the range of 675 to 715nm(⁴).

It is concluded that autofluorescence is extensively used as an imaging mode for retinal imaging by a number of devices with differing light sources.

¹ *In vivo fluorescence of the ocular fundus exhibits retinal pigment epithelium lipofuscin characteristics*
FC Delori, CK Dorey, G Staurengi, O Arend, DG Goger and JJ Weiter
Macular Degeneration Research Center, Schepens Eye Research Institute, Boston, MA 02114.
(Investigative Ophthalmology & Visual Science, Vol 36, 718-729, Copyright)

² *Spectral Profiling of Autofluorescence Associated with Lipofuscin, Bruch's Membrane, and Sub-RPE Deposits in Normal and AMD Eyes* -Alan D. Marmorstein, Lihua Y. Marmorstein, Hirokazu Sakaguchi and Joe G. Hollyfield
From the Department of Ophthalmic Research, Cole Eye Institute, The Cleveland Clinic Foundation, Cleveland, Ohio. (Investigative Ophthalmology and Visual Science. 2002;43:2435-2441.)

³ *Fundus autofluorescence imaging compared with different confocal scanning laser ophthalmoscopes*
C Bellmann, G S Rubin, S A Kabanarou, A C Bird, and F W Fitzke
(Br J Ophthalmol. 2003 November; 87(11): 1381-1386)

4 *Fundus autofluorescence and age-related macular degeneration.*
RF Spaide (Ophthalmology 2003;110:392-399)

(b) (4)

(b) (4)

(b) (4)	
(b) (4)	

Attachment 11: Standards Data Report and Summary

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s <i>(To be filled in by applicant)</i>		
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).		
TYPE OF 510(K) SUBMISSION <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ IEC 60601-1, Medical Electrical Equipment-Part 1:General Requirements for Safety:2005		
<i>Please answer the following questions</i>		Yes No
Is this standard recognized by FDA ² ?		<input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number ³ # 5-4		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Title of guidance:		
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority [21 U.S.C. 360d]. www.fda.gov/cdrh/stdsprog.html</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or</p> </div> <div style="width: 45%;"> <p>certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.</p> <p>⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html</p> </div> </div>		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE IEC 60601-1, Medical Electrical Equipment-Part 1:General Requirements for Safety:2005		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER clause 10.1	SECTION TITLE Declared transport and Storage Conditions	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Transport excluded from test		
DESCRIPTION Packaging tests-conducted based on ISTA 3A & 3E (2008)		
JUSTIFICATION Air and truck simulation conducted by PIRA International-packaging remains intact. Device is also installed by Optos Personnel.		
SECTION NUMBER 36,48,52.1	SECTION TITLE EMC, Biocompatibility,PEMS	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Conformance confirmed by separate certification.		
DESCRIPTION		
JUSTIFICATION Conformance to these clauses is declared under separate certification.		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.		
* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		
Paperwork Reduction Act Statement		
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:		
Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850		
<i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i>		

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s <i>(To be filled in by applicant)</i>		
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).		
TYPE OF 510(K) SUBMISSION <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ IEC 60825-1, Safety of laser products:2007		
Please answer the following questions		
	Yes	No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number ³	# 12-168	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510(k)?	<input type="checkbox"/>	<input type="checkbox"/>
Title of guidance:		
<div style="display: flex; justify-content: space-between; font-size: small;"> <div style="width: 45%;"> <p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority [21 U.S.C. 360d]. www.fda.gov/cdrh/stdsprog.html</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or</p> </div> <div style="width: 45%;"> <p>certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.</p> <p>⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html</p> </div> </div>		

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s <i>(To be filled in by applicant)</i>		
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).		
TYPE OF 510(K) SUBMISSION <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ IEC 60601-1-2: Medical Electrical Equipment:Electromagnetic Compatibility-Requirements and tests:2007		
Please answer the following questions		
Is this standard recognized by FDA ² ?	Yes	No
.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
FDA Recognition number ³	#	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input type="checkbox"/>
Title of guidance:		
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or	certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html	

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE 60601-1-2:Medical Electrical Equipment:Electromagnetic Compatibility-Requirements and tests:2007		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
The 2001 version of this standard is on the recognition list. The device fully meets the 2007 version of this standard.		
DESCRIPTION Tested to EN60601-1-2:2007 which is equivalent to IEC60601-1-2:2007(modified).		
JUSTIFICATION Newer revision of standard-device meets immunity and emission criteria. Device also meets 47CFR:2002 Part 15, Sub Part B		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>† Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement		
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Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

IEC 60601-1-4 ,Medical Electrical equipment:General requirements for safety:Programmable electrical medical systems:2000

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 5-41

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s (To be filled in by applicant)	
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TYPE OF 510(K) SUBMISSION <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated	
STANDARD TITLE ¹ ISO 10993-5, Biological Evaluation of medical devices, Tests for In Vitro Cytotoxicity:1999	
Please answer the following questions	
Is this standard recognized by FDA ² ?	Yes No <input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number ³	# 2-64
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input checked="" type="checkbox"/> <input type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	<input type="checkbox"/> <input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510(k)?	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Title of guidance: _____	
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or	certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993-5, Biological Evaluation of medical devices, Tests for In Vitro Cytotoxicity:1999		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Part 5	SECTION TITLE In Vitro Cytotoxicity	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * L929 MEM elution test		
DESCRIPTION Used to test Eastar Copolyester MN006		
JUSTIFICATION one of the prescribed tests for (b) (4)		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement		
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Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s <i>(To be filled in by applicant)</i>	
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TYPE OF 510(K) SUBMISSION <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated	
STANDARD TITLE ¹ ISO 10993-10, Biological Evaluation of medical devices, Tests for Irritation and Delayed-Type Hypersensitivity:2002	
Please answer the following questions	
	Yes No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number ³	# 2-87
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input checked="" type="checkbox"/> <input type="checkbox"/>
If no, complete a summary report table.	
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/> <input type="checkbox"/>
If no, include the results of testing in the 510(k).	
Does this standard include more than one option or selection of tests?	<input checked="" type="checkbox"/> <input type="checkbox"/>
If yes, report options selected in the summary report table.	
Were there any deviations or adaptations made in the use of the standard?	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/> <input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.	
Were there any exclusions from the standard?	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.	
Is there an FDA guidance ⁶ that is associated with this standard?	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/> <input type="checkbox"/>
Title of guidance: _____	
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or	certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993-10, Biological Evaluation of medical devices, Tests for Irritation and Delayed-Type Hypersensitivity:2002		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Part 10	SECTION TITLE Test for Irritation and Delayed-Type hypersensitivity	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Kligman maximisation test and intracutaneous injection test		
DESCRIPTION Used to test (b) (4)		
JUSTIFICATION prescribed tests for skin contact of limited duration		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p align="center">Paperwork Reduction Act Statement</p> <p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:</p> <p align="center">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p align="center"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>		

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s <i>(To be filled in by applicant)</i>	
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).	
TYPE OF 510(K) SUBMISSION <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated	
STANDARD TITLE ¹ ISO 10993-5, Biological Evaluation of medical devices, Test for In Vitro Cytotoxicity:2009.	
Please answer the following questions	
	Yes No
Is this standard recognized by FDA ² ?	<input type="checkbox"/> <input checked="" type="checkbox"/>
FDA Recognition number ³	# _____
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input checked="" type="checkbox"/> <input type="checkbox"/>
If no, complete a summary report table.	
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/> <input type="checkbox"/>
If no, include the results of testing in the 510(k).	
Does this standard include more than one option or selection of tests?	<input checked="" type="checkbox"/> <input type="checkbox"/>
If yes, report options selected in the summary report table.	
Were there any deviations or adaptations made in the use of the standard?	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/> <input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.	
Were there any exclusions from the standard?	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.	
Is there an FDA guidance ⁶ that is associated with this standard?	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/> <input type="checkbox"/>
Title of guidance: _____	
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or	certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993-5, Biological Evaluation of medical devices, Test for In Vitro Cytotoxicity:2009.		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Part 5	SECTION TITLE In Vitro Cytotoxicity	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
L929 MITT Cytotoxicity		
DESCRIPTION Used to test (b) (4)		
JUSTIFICATION one of the prescribed tests. 1999 version is listed, this is the latest version of this standard		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850 <i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i>		

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s <i>(To be filled in by applicant)</i>		
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).		
TYPE OF 510(K) SUBMISSION <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ ISO 10993-10, Biological Evaluation of medical devices, Test for Irritation and Delayed-Type Hypersensitivity and 2006:2009		
Please answer the following questions		
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
FDA Recognition number ³	# <u>2-152</u>	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Title of guidance:		
<small> ¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/sldsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html </small>		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993-10, Biological Evaluation of medical devices, Test for Irritation and Delayed-Type Hypersensitivity and 2006:2009		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Part 10	SECTION TITLE Test for Irritation and Delayed-Type Hypersensitivity	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Kligman maximisation test and intracutaneous injection test		
DESCRIPTION Used to test (b) (4)		
JUSTIFICATION prescribed tests for skin contact of limited duration		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.		
* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		
Paperwork Reduction Act Statement		
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:		
Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850		
<i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i>		

Summary

Standard	Exclusions/ Options	Justification	Test House/Outcome
IEC 60601-1 1988/A1:1991 Medical electrical equipment. A2:1995, Corrigendum 95 General requirements for safety.	Clause 10.1 declared transport and storage conditions Clause 36-EMC to IEC 60601-1-2 Clause 48- Biocompatibility to ISO10993-1 Clause 52.1 PEMS to IEC 60601-1-4	Tested by (b) (4) [REDACTED] Device installed by Optos personnel to assure correct operation Separate certification Separate Certification Separate Certification	(b) (4) [REDACTED] Certificate of compliance issued
IEC 60825-1 Ed.2.0 (2007) Safety of Laser Products	N/A		(b) (4) [REDACTED] Report declaring meets requirements for class 1 laser
IEC 60601-1-2:2007 Medical electrical equipment. General requirements for safety. Collateral standard. Electromagnetic Compatibility requirements and tests	N/A		(b) (4) [REDACTED] Certificate stating compliant to this specification
IEC 60601-1-4 edition 1.1 2000-04 Medical electrical equipment. General requirements for safety. Collateral standard. General Requirements for programmable Electrical medical systems.	N/A		(b) (4) [REDACTED] Certificate of compliance issued

<p>ISO 10993-5 Biological evaluation of medical Devices: Tests for In Vitro Cytotoxicity 1999 & 2009</p>	<p>versions of standard relates to the test date for the 2 materials. One material tested to 1999 standard and used L929 MEM elution test. Other material tested to 2009 standard and used L929 MTT Cytotoxicity test</p>		<p>(b) (4)</p>
<p>ISO 10993-10 Biological Evaluation of Medical Devices: Tests for Irritation and Delayed-Type Hypersensitivity, 2002 & amd. 2006</p>	<p>Version dates as above. Kligman Maximisation and Intracutaneous injection used for both materials</p>		<p>(b) (4)</p>

Attachment 12: Medical Device User fee Cover Sheet

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Status

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) OPTOS PLC Queensferry House Carnegie Business Campus Dunfermline Fife KY11 8GR GB 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2. CONTACT NAME Robert Tweedlie 2.1 E-MAIL ADDRESS rtweedlie@optos.com 2.2 TELEPHONE NUMBER (include Area code) 01144-1383843300 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 01144-1383843333	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma)		
Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.		
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (if so, the application is subject to the fee that applies for an original premarket approval application (PMA)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b) (4)		

16-Feb-2010

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet



COVER SHEET MEMORANDUM

From: Reviewer Name Dexiu Shi
Subject: 510(k) Number K100644/S1
To: The Record

Please list CTS decision code:

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/O_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.). **SE**

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
510(k) Summary 510(k) Statement Summary	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III? If yes, does firm include Class III Summary?	Must be present for a Final Decision		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category <u> N </u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/O_413b/CO-MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			X
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			X
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age <=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		X
Nanotechnology		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	X

Regulation Number: 886.1570

Class: II

Product Code: MYC

Review: *Brad Long* ONDB 7/15/10
 (Branch Chief) (Branch Code) (Date)

Final Review: *Kesia Alexander* 7/15/10
 (Division Director) (Date)

.PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):	YES	NO
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)		✓
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?		✓
3. Does this device type require a PMA by regulation? (Please see management.)		✓
Questions 4-8 are intended to help you start your review:	YES	NO
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%20%2007.doc)		✓
5. a. Did the firm request expedited review? (See management.)		✓
b. Was expedited review granted? (See <i>Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions</i> , http://www.fda.gov/cdrh/mdufma/guidance/108.html)		
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:	✓
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:	✓
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see <i>Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission</i> http://www.fda.gov/cdrh/mdufma/guidance/1215.html)		✓

Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

**Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s**
<http://www.fda.gov/cdrh/ode/guidance/1567.html>

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html	✓		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf	✓		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/cdrh/ode/guidance/1567.html	✓		
Indications for Use Statement	Device Advice " Content of a 510(k)" Section D www.fda.gov/cdrh/devadvice/314312.html#link_6	✓		
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E www.fda.gov/cdrh/devadvice/314312.html#link_7	✓		
Truthful and Accuracy Statement	Device Advice " Content of a 510(k)" Section G www.fda.gov/cdrh/devadvice/314312.html#link_9	✓		
Class III Summary and Certification	Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html			✓
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html			✓
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations www.fda.gov/cdrh/ode/guidance/1131.html . FDA Standards program www.fda.gov/cdrh/stdsprog.html . Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard www.fda.gov/cdrh/ode/regrecstand.html			✓

Title	Related Information	Present	Inadequate	N/A
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm	✓ K983999		
Proposed Labeling	Device Advice " Content of a 510(k)" Section H www.fda.gov/cdrh/devadvice/314312.html#link_10	✓		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) www.fda.gov/cdrh/ode/guidance/361.html For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices www.fda.gov/cdrh/ode/guidance/1216.html	Not sterile Cleaning instruction provided		
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" www.fda.gov/cdrh/g951.html	✓ Test report is provided		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices www.fda.gov/cdrh/ode/software.html	✓		
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program www.fda.gov/cdrh/emc See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)	✓		
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓		
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			✓

Title	Related Information	Present	Inadequate	N/A
Performance Testing – Clinical	See section 20 in Chapter II of “Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s” updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf			✓
FORM FDA 3654, Standards Data Report for 510(k)s - http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf	Standards Data Report Form – Form 3654 1: No standard used - No Standards Form Required 2: Declaration of Conformity – Yes Standards Form Required 3: Standard but no declaration – Yes Standards Form Required	✓ FDA 3645 are provided in Attach 11 of original submission.		
Kit Certification	Device Advice http://www.fda.gov/cdrh/ode/odecl874.html			✓

Last Updated: 9/3/08 – Brandi Stuart

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K100644/S1

Date: **July 14, 2010**

To: **The Record**

From: **Dexiu Shi, Ph.D.**

Office: **ODE**

Division: **DONED**

Branch: **ONDB**

Device Name: Optos Limited Panoramic 200CAF

510(k) Holder: Optos PLC

Dated: June 15, 2010

Received: June 15, 2010

Applicant: Optos PLC
Queensferry House
Carnegie Business Campus
Dunfermline,
Fife,
KY11 8GR
United Kingdom
Phone: 011 44 1383 843300
Facsimile: 011 44 1383 843333
Contact Person: Robert Tweedlie Ph.D.

Contact: Howard M. Holstein
Partner
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
Tel (202) 637-5813, Fax (202) 637-5910
howard.holstein@hoganlovells.com

Summary/Recommendation: SE

With this supplement, the sponsor has adequately addressed all deficiencies cited in our letter May 4, 2010. The subject device Panoramic 200CAF (P200CAF) is found to be substantially equivalent to the predicate device (P200 under K0983999). A SE is recommended.

REVIEW SUMMARY

Converting Special 510(k) to Traditional 510(k)

This 510(k) was submitted as special. It has been converted to traditional based on the following reasons:

On page 45/140, Attachment 4, the sponsor states that the P200CAF use red and green lasers to produce a digital, high-resolution image, which is displayed on a PC monitor screen.

1. Red and green lasers are used for digital color imaging. These laser wavelengths retinal structures to different depths, each wavelength providing information for interpretation and diagnosis.
2. The blue laser is used when capturing angiography images. A series of images is captured as the fluorescein flows through the retinal vessels.
3. In autofluorescence mode, the P200CAF uses only the green laser to illuminate the eye. This allows an image of the natural fluorescence of the eye to be captured. No fluorescent dye has to be introduced into the patient.

The predicate device only provides the capabilities of capturing and displaying the color image of the retina. Number 2 and 3, above, are new capacities/features. We believe the new scientific technologies of capturing angiography images and autofluorescence mode are the labeling changes that affect the intended use of the device.

In addition, the new device is intended to be used for diagnosing and monitoring diseases or disorders that manifest in the posterior pole of the eye. In order to test the validity of the angiography image and autofluorescence mode, clinical performance testing may be required.

Based on the above changes and related concerns, we do not believe this submission qualifies for review as a special 510(k). After having 510(k) staff concurrence, this 510(k) was converted to a traditional 510(k) accordingly.

Sponsor's Clarification

On 4/13/2010, Mr. Randy Prebula, Director of Regulatory Sciences of Hogan Lovells US LLP provided (by email) the following clarification about the P200CAF device and the company's previously cleared scanning laser ophthalmoscopes ("SLOs"):

Please note that the P200CAF device that is described in the 510(k) Notice does not include a blue laser and is not capable of generating fluorescein angiograph images. Rather, it is the company's Optos P200a device, which was cleared by FDA under 510(k) submission K042001 that contains both the blue laser and the ability to obtain fluorescein angiography images. With the addition of new internal circuitry, the P200MA was cleared under a Special 510k (K060424), using the cleared P200A model as the predicate.

Page 45/150 of the handbook submitted in K100644 describes the Optos family of scanning laser ophthalmoscopes (SLO's). The device referenced on page 45 as containing a blue laser and capable of fluorescein angiography is the P200MA and not the P200CAF.

Rather, the P200CAF device, like several other members of the company's cleared SLO family of products (including the FDA cleared P200 device, K983999) contains only red and green lasers, and allows users to generate images that can be viewed either as a composite image (that is red and green combined) or as separate red channel and green channel images. Optos described the P200CAF device in the current submission as a modification of the cleared P200 device (resulting from new internal circuitry and incorporation of an additional filter). As such, the company reiterated that both the cleared P200 predicate device and the current P200CAF device utilize the same red and green lasers. To clarify the relationship between the various device versions and features, please see the following table:

Version	P200	P200a	P200ma	P200CAF
510(k) Number	K983999	K042001	K060424	K100644
Status	Cleared	Cleared	Cleared	Pending
Lasers	red, green	red, green, blue	red, green, blue	red, green
Image Type				
Red	yes	yes	yes	yes
Green	yes	yes	yes	yes
Blue	no	yes	yes	no
Composite	yes	yes	yes	yes
Fluorescein Angiography	no	yes	yes	no
Electronics Assembly	Version A	Version A	Version B	Version B
Key Differences	Base model	Added blue laser and fluorescein angiography capability	Added new electronics assembly	Provides ability to capture red and green laser images, and display autofluorescence images, using original lasers and updated electronics assembly

Based on sponsor's clarification that feature of number 2 - capturing angiography images is not included in new P200CAF. The key modification in model of P200CAF is an additional capacity of displaying autofluorescence imaging using original lasers and updated electronics assembly.

Resubmitted Traditional 510 (k)

Per FDA request, the sponsor resubmitted a traditional 510(k) for this subject device. FDA review team identified deficiencies in IFU, Performance Testing – Bench, 510(k) Summary and labeling from this submission. On May 4, 2010, the sponsor was informed, by email, that this submission is being placed on telephone hold (TH), additional information is required.

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Supplement 1

With this submission, the sponsor adequately addressed all deficiencies cited in our telephone hold memo of May 4, 2010. SE is recommended.

I. Purpose and Submission Summary

Purpose: The 510(k) holder requests clearance to commercially introduce Optos Limited Panoramic 200CAF to US market.

Administrative Requirements:

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	✓ Prescription		
Truthful and Accuracy Statement	✓		
510(k) Summary or 510(k) Statement	✓ Summary		
Standards Data Report Form – Form 3654 1: No standard used - No Standards Form Required 2: Declaration of Conformity - Yes Standards Form Required: 3: Standard but no declaration - Yes Standards Form Required	2. Yes		

III. Device Description:

	Yes	No	N/A
Is the device life-supporting or life sustaining?		✓	
Is the device an implant (implanted longer than 30 days)?		✓	
Does the device design use software?	✓		
Is the device sterile?		✓	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	✓ ✓		

Note: Most of the below device description is derived from the sponsor's submission (Section H)

General Description

The sponsor states that like the Panoramic 200CAF is a conventional scanning laser ophthalmoscope (SLO). A low power laser beam is scanned in two dimensions over the retina and the reflected (or returned) light is detected and used to generate a digital image with a computer or electronic imaging device.

It uses a low power laser beam that scans in two dimensions over the retina. The wavelengths of the lasers residing in the P200CAF and the P200 are the same. The generation of the image is

performed in the conventional manner using light detectors, the output of which is digitized, and the data collected in a computer for reconstruction, display, and storage. The scanning of the beams on the two axes is done using a conventional rotating polygon for the fast vertical scan and a motor driven mirror for the slower horizontal scan. The device scans an (b) (4) [REDACTED] 200° when measured from the geometric center of the eye.

(b) (4) [REDACTED]

The geometry of an ellipsoid is such that a ray starting at one focus will be reflected by the surface so that it will cross the other focus. This is a basic geometric property of an ellipsoidal mirror that is true for all angles or beam directions as long as the beam is reflected by the mirror. Hence all rays that pass through one focus and which fall on the mirror are reflected such that they pass the other focus.

(b) (4) [REDACTED]

The real scan system is the actual collection of mechanical and optical components that move the beam to generate the two-dimensional scanning light beam. The virtual scanning system is where the scanning system appears to be, *i.e.*, the eye, when viewed in the ellipsoidal mirror. As the virtual scanning system is not a real object it can be made to appear to be in the eye where a real physical scanning system could not be located. The use of the elliptical mirror and the movement of the scanning system away from the eye makes it possible to scan a larger angle of the retina.

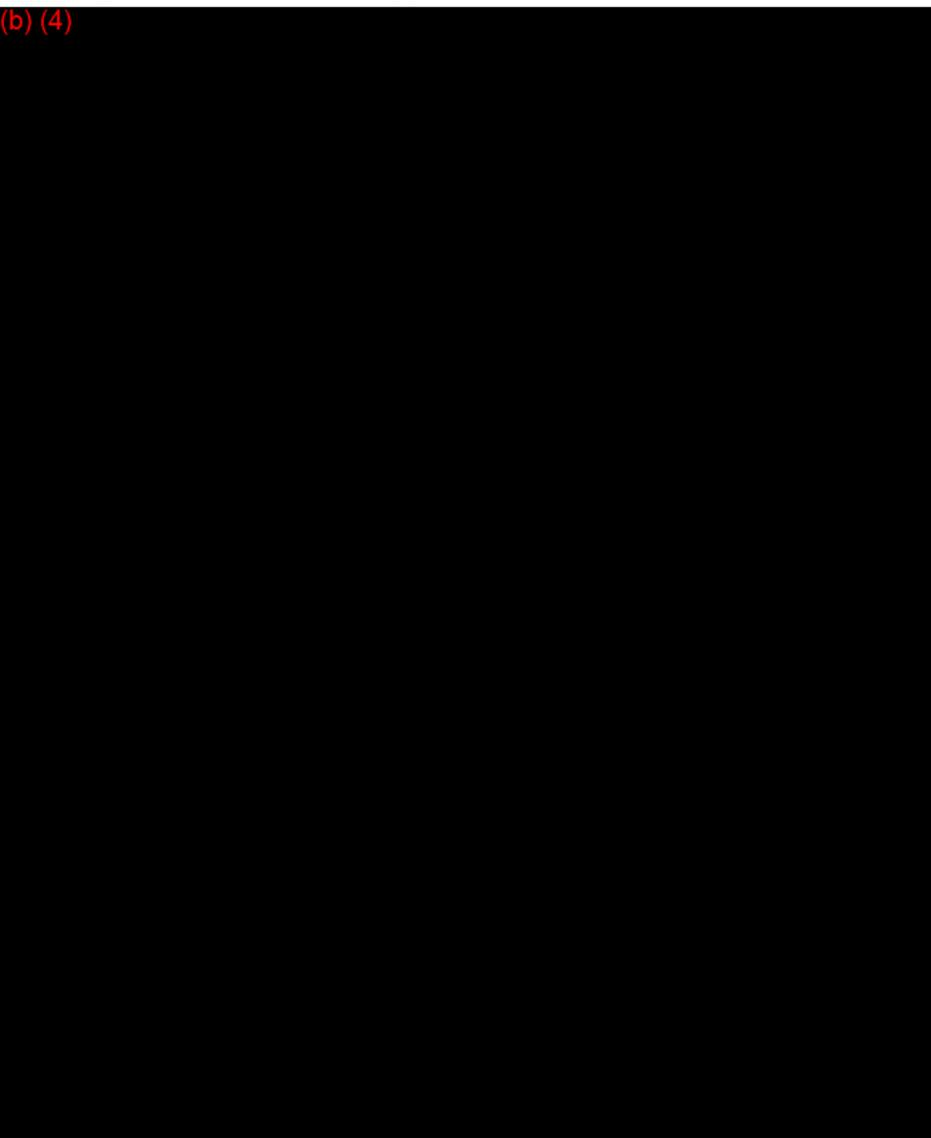
The Panoramic 200CAF and the predicate Panoramic 200 are capable of creating images up to a (b) (4) [REDACTED] 200° internal angle of the retina. Given that the Panoramic 200CAF and Panoramic 200 have the same angle of capture, both devices provide practitioners with the same field of view to diagnose and monitor diseases and disorders. The reflected energy from the retinal surface is passed back through the same system to an array of two (2) discrete detectors (effectively a red and a green channel). For the Panoramic 200CAF and the P200, in standard imaging mode, the images produced can be viewed either as a composite image (red and green images combined) or separate as a green channel and a red channel image. The signal strength varies as the laser beam is scanned across the retina, allowing an image to be created and recorded, revealing the variation in its constituent material and structures.

The eye is not continually exposed to the scanning beam. The patient looks into the instrument in semidarkness so that the eye becomes dark-adapted and the pupil opens. The shutter opens to allow the light to reach the eye to enable the instrument to capture one frame. The shutter then closes. This process has two advantages: (1) the eye does not respond to the light, and thus, the pupil remains wide open; and (2) the eye is exposed to laser light for a greatly reduced time.

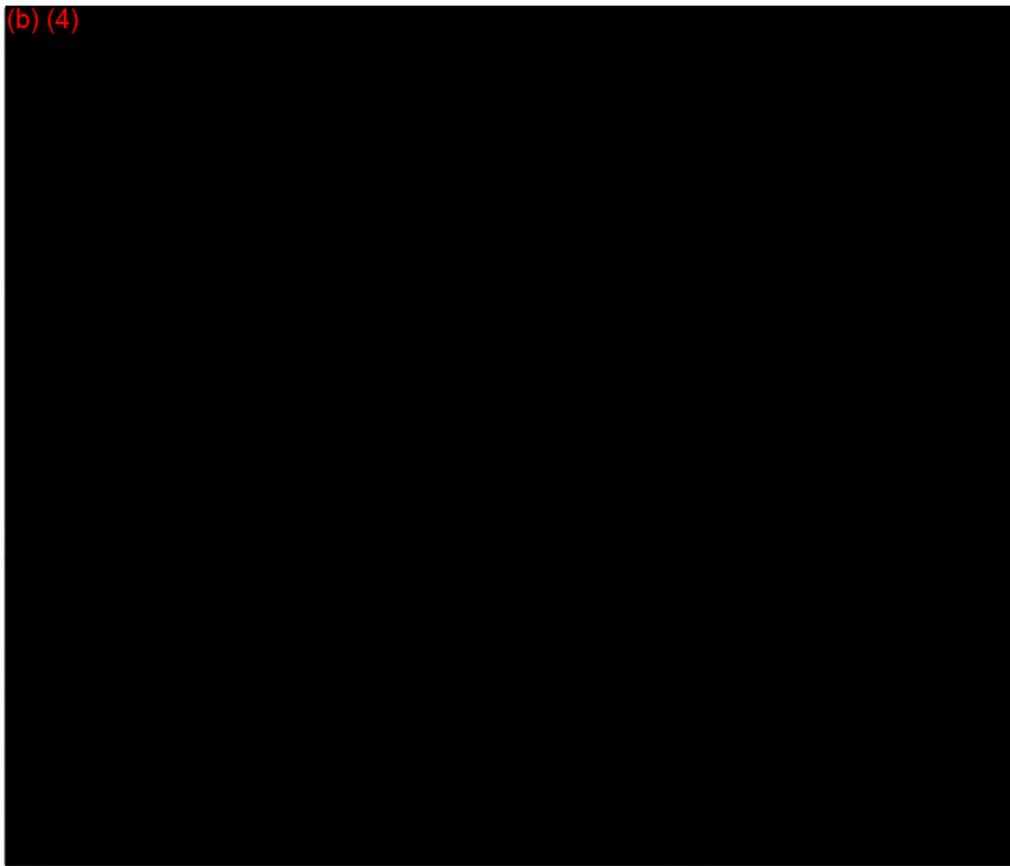
See **Attachment 5** for the optical schematics of the Panoramic 200CAF.

(b) (4)

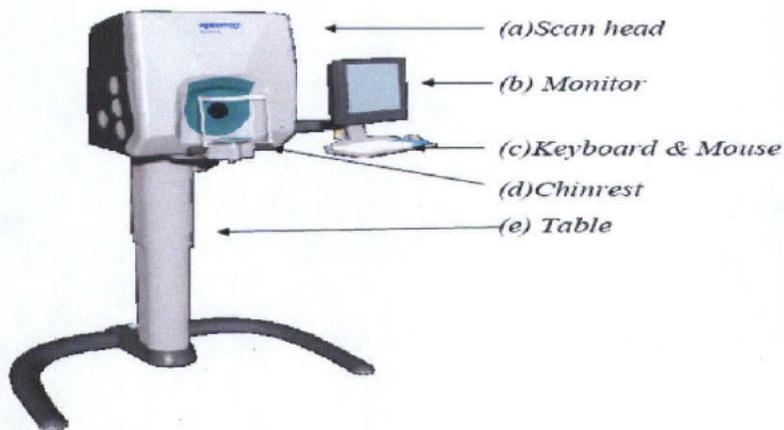
(b) (4)



(b) (4)



The above scanning function is housed in the 'scanhead' (see external schematic below). The scanhead is seated on a table that can move up and down and this affords a height adjustment to achieve correct patient positioning.



In terms of the display of the digitized data on a computer screen, the Panoramic 200CAF and P200 capture one image at a time and can present each image as a thumbnail sketch. If more than one image is captured, the Panoramic 200CAF and Panoramic 200 display a series of thumbnail sketches in the order in which they were scanned. The Panoramic 200CAF, like the P200, allows the user to view one or more images of the retina.

IV. Indications for Use (IFU): Acceptable

Per FDA recommendation, the sponsor has provided a revised IFU:

“The Panoramic 200CAF scanning laser ophthalmoscope is indicated for use as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest themselves in the retina.”

The wording of revised IFU implies that the device has new function of retinal autofluorescence imaging and does not provide a diagnosis and is not intended as the sole source of diagnostic information for any ophthalmic condition.

IFU for predicate Panoramic 200 (K983999):

“The Panoramic 200CAF scanning laser ophthalmoscope is indicated for use as a wide field ophthalmoscope for diagnosing and monitoring diseases or disorders that manifest themselves in the posterior pole of the eye.”

V. Predicate Device Comparison: Acceptable

Predicates: P200 (K0983999)

The handbook submitted in K100644 describes the Optos family of scanning laser ophthalmoscopes (SLO’s). Sponsor also provides (by email through Hogan & Hartson LLP) more detailed comparison information for Optos 200 series SLOs:

The P200CAF device, like several other members of the company’s cleared SLO family of products (including the FDA cleared P200 device, K983999) contains only red and green lasers, and allows users to generate images that can be viewed either as a composite image (that is red and green combined) or as separate red channel and green channel images. Optos described the P200CAF device in the current submission as a modification of the cleared P200 device (resulting from new internal circuitry and incorporation of an additional filter). As such, the company reiterated that both the cleared P200 predicate device and the current P200CAF device utilize the same red and green lasers. To clarify the relationship between the various device versions and features, please see the following table:

Version	P200	P200a	P200ma	P200CAF
510(k) Number	K983999	K042001	K060424	K100644
Status	Cleared	Cleared	Cleared	Pending
Lasers	red, green	red, green, blue	red, green, blue	red, green
Image Type				

Red	yes	yes	yes	yes
Green	yes	yes	yes	yes
Blue	no	yes	yes	no
Composite	yes	yes	yes	yes
Fluorescein Angiography	no	yes	yes	no
Electronics Assembly	Version A	Version A	Version B	Version B
Key Differences	Base model	Added blue laser and fluorescein angiography capability	Added new electronics assembly	Provides ability to capture red and green laser images, and display autofluorescence images, using original lasers and updated electronics assembly

Seminaries:

The sponsor states that both the P200 and P200CAF Scanning Laser Ophthalmoscopes have the same mode of operation for imaging the posterior pole of the eye for viewing purposes. Specifically, information on the retina can be derived from:

1. the use of a red and a green laser as a source of illumination;
2. a deflection system to scan the laser beam in two orthogonal axes across the eye;
3. the use of the same deflection system to take the reflected light back through the optics to the light detectors; and
4. a computer to reconstruct, display, and store the image.

The light detector used for detecting the relatively weak autofluorescence signal has been changed to optimize the response, but the underlying principle of how the light detector works is unchanged.

The side-by-side comparison is listed in Attachment 1a.

Attachment 1a: Substantial Equivalence

Manufacturer	Optos	Optos
Device	Panoramic 200	Panoramic 200CAF
Common Name	Scanning Laser Ophthalmoscope	Scanning Laser Ophthalmoscope
510k number	K983999	pending
Materials	No flammable materials are used near the light source.	No flammable materials are used near the light source.
Max. Temperature of accessible parts	Does not exceed ambient by more than 10°C.	Does not exceed ambient by more than 10°C.
Intended Use	To examine the retina of the eye	To examine the retina of the eye
Indications for Use	For aiding in diagnosing and monitoring disease and disorders that manifest themselves in the retina of the eye.	For aiding in diagnosing and monitoring disease and disorders that manifest themselves in the retina of the eye.
Method of Operation	Confocal laser scanning system; laser light source; deflection system; scans in two orthogonal axes of the retina; photosensitive device that converts light into image of retina; display system.	Confocal laser scanning system; laser light source; deflection system; scans in two orthogonal axes of the retina; photosensitive device that converts light into image of retina; display system.
Light Source	Laser	Laser
Wavelength and Color of Light	(b) (4)	(b) (4)
Exposure Parameters/laser class	Class 1	Class 1
Number of lasers Used per scan	2	1 or 2
Brightness Controls	Only after image has been taken	Only after image has been taken
Cleaning and disinfection/sterilization	Sterilization not required. Clean/decontaminate contact points	Sterilization not required. Clean/decontaminate contact points
Point of contact	Eye cushion	Facepad, chincup, and headrest
Data collection and/or display system	Light sensitive detector that converts light into electrical signal. Signal digitized and computer or electronic imaging device to convert digital image for display.	Light sensitive detector that converts light into electrical signal. Signal digitized and computer or electronic imaging device to convert digital image for display.
External field of view	(b) (4)	(b) (4)
Internal field of view	200°	200°
Wide Angle Digitized Image Size	2Kx2K pixels	3Kx3K pixels
Pupil Dilation	Normally not	Normally not
Eye Taping	Normally not.	Normally not.
Mains current AC 115/240V	15A/7A	6.3A
Approx. weight	Scan head 70kg; table 100kg	Scan head 70kg; table 50kg

Differences:

The sponsor states:

The Panoramic 200CAF incorporates minor modifications as compared to the Panoramic 200 in the areas of imaging mode and system architecture. These modifications do not change the intended use of the device or alter the fundamental scientific technology. **Attachment 1b** provides a chart comparing each change, as well as the similarities, as compared to the cleared Panoramic 200. These modifications have been assessed by Optos for risk, and verification and validation evaluation/testing and results have been performed to certify that any identified risks do not change the intended use or fundamental technology of the device. The modifications are described in detail below.

Imaging Modes

- The Panoramic 200CAF has the capability of generating a digitized image size of 3K x 3K pixels, as compared to the Panoramic 200's digitized image size of 2K x 2K pixels for

the same field of view.

- Panoramic 200CAF's greater resolution does not change the intended use of the device or alter the fundamental scientific technology. This is because the Panoramic 200CAF and the predicate device display retinal images on a computer screen using the same type of electronics. The Panoramic 200CAF's higher resolution just means that this device's images are potentially clearer.
- Additionally, the P200CAF is capable of a zoom mode that generates a close-up (~100x field of view). As above, the greater resolution does not change the intended use of the device and there are no safety issues as the device meets Class 1 at the eye in this imaging mode (as per 21 C.F.R. part 1040 and IEC 60825).
- The Panoramic 200CAF can generate an alternate red channel image which shows the natural fluorescence (also referred to as "autofluorescence") of the eye. In this imaging mode, the retina is illuminated using the green laser only without the red laser. This is achieved by blocking the red laser optical path by means of a shutter. Additionally, the light reflected from the retina is strengthened by the removal of a polariser and waveplate. This is effected by the use of a translation stage which can introduce or remove these elements from the return path. In this imaging mode, the red channel image now displays the naturally occurring fluorescent material of the retina, such as lipofuscin. The characteristics of autofluorescence are well understood, as described in published article (Attachement10)

In the "autofluorescence" imaging mode, the safety of the device is not affected as the light entering the eye is less than a standard red/green image, due to the fact that the red beam is blocked. In addition, the standard red image contains the "autofluorescence" information, but it is swamped by the light reflected by the illumination from the red laser.

The "autofluorescence" image shows the distribution of the naturally occurring fluorescent material by variations in light intensity across the image. This imaging mode can be used by the healthcare professional in conjunction with the standard composite (red/green) and the associated separated red and green channel images to aid in the diagnosing and monitoring of diseases and disorders that manifest themselves in the eye. Therefore, the introduction of the "autofluorescence" imaging mode does not change the intended use of the device or alter the fundamental scientific technology.

Comment: The 200CAF has a new function of displaying retinal autofluorescence imaging. Therefore, the validation test for autofluorescence imaging function is required. In order to support the substantial equivalence, the sponsor performed validation testing, and provided the test reports in Supplement 1. The testing result demonstrates that the autofluorescence mode offers additional information to the area of interest but none of the information derived from the red/green mode is lost. In autofluorescence mode, there is less light entering the eye than in standard red/green imaging. Therefore, the P200CAF is as safe and effective as the predicate, the P200. Please see detailed testing information in sponsor's response to Deficiency 2.

Table

When compared to the P200 table, the P200CAF table no longer has the transformer resident to manage the power supply. In the P200CAF, the power is managed through the scan head. This makes the table lighter.

Gaze Angle

The gaze angle permits a different area of the retina to be viewed. This is possible in both the P200 and P200CAF. The additional periphery LEDs in the P200CAF assist in eye steering, but confirmation that the correct area has been imaged is made by viewing the image. The device still delivers a 200° field of view but a slightly different area can be imaged as, although wide angle, it is never a complete view of the eye.

The additional LEDs, which are included in the laser safety calculations, do not change the intended use of the device or alter the fundamental scientific technology.

Comment: The sponsor provides an acceptable radiation hazard analysis.

User Interface

The user interface in terms of the mouse, monitor, and keyboard are similar for both the P200 and P200CAF. The P200CAF hand control has more buttons as the table position, and exposure button are resident. Button size for the P200 and P200CAF are comparable. Additionally, for the P200CAF hand control, the symbols indicating the key press function/direction are consistent with the Screen User Interface. The software contained with the scan head communicates within a windows environment in the case of the P200 but the P200CAF operates in a Linux environment. However both the P200 and the P200CAF display their images for review on a screen operating within a windows environment. Therefore these modifications do not change the intended use of the device or alter the fundamental scientific technology.

Laser Radiation Management System (LRM system)

The laser radiation management system resides on two field programmable gate arrays for both the P200 and the P200CAF, thus both units have redundancy in the firmware controlling laser exposure. In both models, the customer has no input or access to the laser radiation management software.

The P200CAF monitors the horizontal and vertical scan, whereas the P200 monitors the vertical scan only.

Both the P200 and the P200CAF have a single exposure shutter, but the P200CAF utilizes additional laser shutters on each wavelength channel.

The P200CAF firmware is different to the P200 firmware as different logic is required for the additional shutters and monitoring. However, the P200CAF assures that the laser classification is 1 at the eye for all permissible conditions (as is the case for P200). Upon detection of a fault condition both the P200 and P200CAF will not permit any exposures to be conducted. Therefore, modifications related to the Laser Radiation Management do not change the intended use of the device or alter the fundamental scientific technology.

Patient Alignment System (PAS), Patient Positioning and Personal Computer

The Panoramic 200CAF's patient places his or her head on a chin rest, his or her head against a head restraint and the side of the face comes into contact with a face pad. Optos' P200 utilizes a face cushion placed around the circumference of the aperture. All materials in contact with the patient meet biocompatibility requirements.

For both P200CAF and the P200, the device monitor or PC screen provide an assist to the practitioner via a picture of the eye afforded by a camera. The P200CAF gives a visual assist to the practitioner to correctly position the eye whereas the P200 is more dependent on the patient using an eye fixation pattern. With the P200CAF, the operator can adjust the height using the table and effect more finite positioning using the chinrest if the eye is not correctly positioned. With the Panoramic 200, the operator can only adjust the table if the eye is not correctly positioned. Upon correct positioning, for both devices, the hand control can then be pressed, which signals the device to capture the image. For both devices, the operator, who will see the image almost immediately, can then decide whether it is necessary to capture another image. Thus, eye placement for the Panoramic 200CAF does not change the intended use of the device or alter the fundamental scientific technology.

The side-by side comparison is listed in Attachment 1a of original submission.

Attachment 1b: Similarities and Differences between the P200 and the P200CAF

Category	Sub - category	P200	P200CAF	Risk Identification	Source of Risk Identification	Verification Activity
Functionality	Imaging Modes	RG imaging, 4M pixels (optomap)	RG imaging, 9M pixels (optomap) 'Zoom' mode available. Directed eye steering	The increase in the number of pixels has the potential for making the image clearer. The image is an aid to diagnosis and it is the practitioner who determines the suitability of the image for diagnosis. Directed eye steering has the potential to look at different wide-angle views of the retina but has no increase in the risk associated with viewing.	Change Request and Risk Assessment no. 684, Image Quality FMEA 69-79	Acceptance criteria: USAF 1951 resolution target used to Confirm 3K image at least as clear as 2K Pass, 3Kx3K displays at least the same number of line pairs. Patient Alignment System (PAS) DV Pass
Functionality	Imaging Modes	There is no facility to generate images that display the natural fluorescence of the eye	Has an imaging mode where the red channel image is optimized to display the natural fluorescence of the eye.	The AF mode does not work-unable to acquire image. The translation stage has removed the required optical elements from the input path.	FMEA analysis item 53 FMEA analysis item 100	V&V activity for embedded software checked AF appears on GUI, red laser input path blocked, translation stage is in correct position and image acquisition possible Pass

Comment:

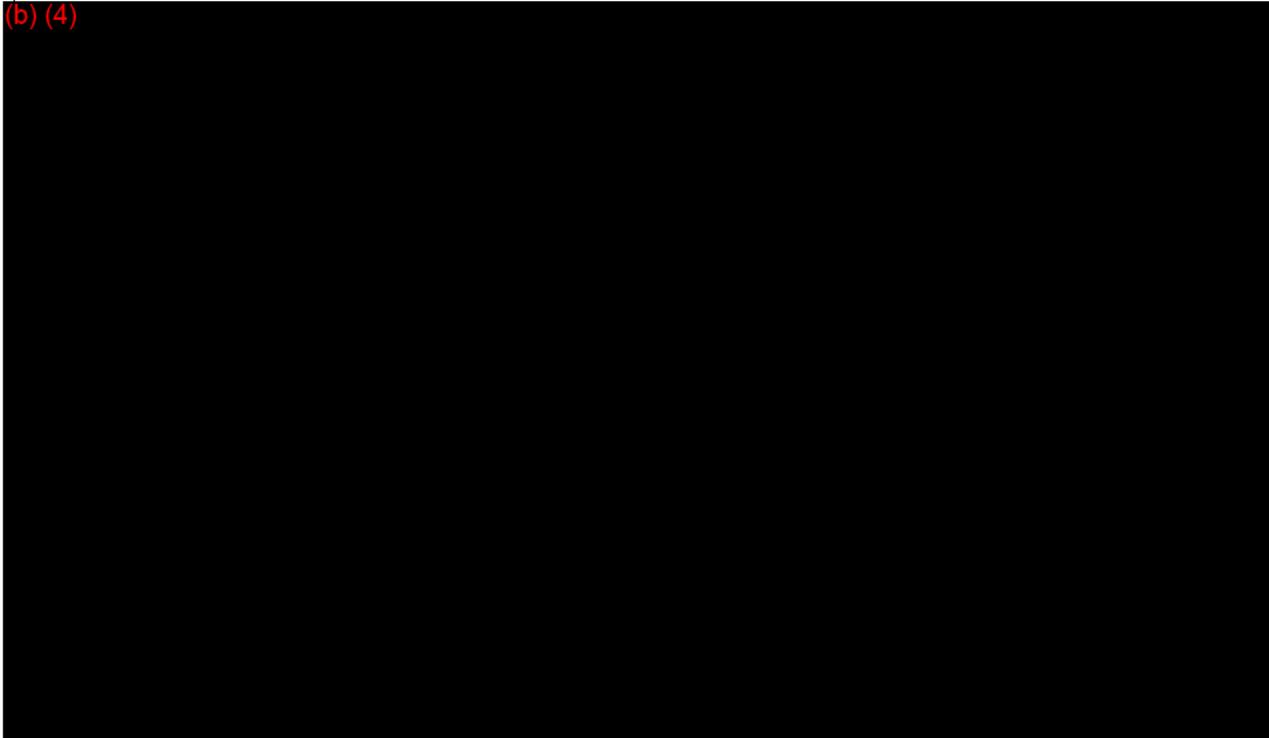
The Panoramic 200CAF incorporates several modifications as compared to the Panoramic 200 in the areas of imaging mode and system architecture. These modifications do not change the intended use of the device or alter the fundamental scientific technology. These modifications have been assessed by Optos for risk, and verification and validation evaluation/testing and results have been performed to certify that the identified risks do not change the intended use or fundamental technology of the device.

Since additional periphery LEDs have been used in the P200CAF assisting in eye steering, the sponsor has provided radiation hazard analysis using ISO15004-2:2007 for the additional LEDs contained in the patient alignment system. The sponsor states that the Patient Alignment System (PAS) is an embedded optical module within the Optos Scanning Laser Ophthalmoscope, containing multiple visible LEDs (four red and one green) and a NIR (near infrared) LED source. The visible LEDs are used as patient fixation targets to ensure that the patient gaze angle is correct for retinal imaging. In normal operation, only one of the visible LEDs is illuminated at any given time, with the green LED projecting along the central axis and the four red LEDs projecting along the nasal, temporal, superior and inferior projections, respectively. The NIR

LED is used to provide flood fill illumination of the patient to provide the operator with a patient view, via imaging cameras embedded in the PAS, and is illuminated during a patient session except during active image acquisition.

The test results are provided in below table:

(b) (4)



Evaluation of the system to the conditions for group 1 instrument demonstrates that the operation of the system falls within the group 1 limits and does not, therefore, present an optical hazard.

V. Labeling: Acceptable

The Introductory Handbook and proposed labels for the Panoramic 200CAF are provided in **Attachment 4** of original submission, and a revised Introductory Handbook is provided in **Attachment** of Supplement 1. The following modifications have been made to the labeling to accommodate the different capture mode for the P200CAF imaging mode:

- The introductory handbook references the autofluorescence imaging mode.
- The addition of a caution not to connect to a DICOM server as this facility is not in place at present.

Comment: The company uses one Introductory Handbook for three models of P200MA (060624), P200C and P200CAF (K100644). We found no 510(k) or other records for model of P200C. In response to our deficiency that whether the P200C is an FDA-cleared device, the sponsor states:

"The P200C is marketed based on a (internal) memorandum to file (MTF) documenting the company's decision *not to file a 510(k) notice for this device*. This decision was based on the fact that the P200C is indicated for a subset of the indications for use for the P200MA (K060624). The company's memorandum documenting its decision not to file a 510(k) notice for this device is provided."

Based on the information provided, it seems that P200C has not a significant change and does not require a 510(k). P200C is indicated for a subset of the indications for use for the P200MA (i.e., the statement "this includes imaging the fluoresced ocular vasculature" has been removed from the indications for use).

The only differences between the P200MA and the P200C are:

- (1) removal of the blue laser;
- (2) removal of the motorized translation stage; and
- (3) removal of an arm rest.

Lead reviewer has consulted with 510(k) staff, Ms. Marjorie Shulman on whether it is appropriate to include the model of P200C in the labeling (use manual). Mr. Shulman said it is okay to accept this user manual.

VI. Sterilization/Shelf Life/Reuse: Acceptable

The Panoramic 200CAF Ophthalmoscope does not require sterilization. Instructions for cleaning the device, including the chin rest and face pad are included in the Introductory Handbook (**Attachment 4**).

VII. Biocompatibility: Acceptable

The sponsor states:

"The same material is used for the cushion in the P200 and the face pad in the P200CAF. As the P200CAF also has a chinrest and head support, two additional materials come into contact with the patient.

Specifically, the chincup is made of (b) (4)

As per ISO 10993, the contact is skin and for limited duration, requiring that Cytotoxicity, Sensitization, and Irritation or Intracutaneous reactivity is assessed. Both of the additional materials have been assessed for these effects and meet the relevant standards."

Comment: The sponsor has provided biocompatibility test reports for the (b) (4) provided biocompatibility review. She commented that none of the test results showed any evidence of

toxicity, and from a biocompatibility perspective, this submission can be found substantially equivalent (SE). Her review is attached.

VIII. Software: Acceptable

The sponsor states that:

Optos is subject to design control. Software, risk analysis and the development process of this product also conforms to IEC 60601 entitled "Medical Electrical Equipment- Part1: General Requirements for Safety" and its collateral standard IEC 60601-1-4 entitled "Medical Electrical Equipment. General Requirements for safety. Collateral standard. General Requirements for programmable electrical medical systems." The above activities are defined in Optos' software development lifecycle work instruction (SP1013) and a brief description is given below.

- The software development lifecycle used by Optos is applied to systems developed by Optos for use by external customers and/or key to the functioning of the device.
- Systems developed by Optos for internal customers and related to a key process.
- Third-party systems customized or configured by Optos and related to a key process.

The software within the P200CAF was designed with a clear architecture to separate out the laser radiation management function from all other operational functions, as follows:

1. The Image Capture software resides within the system and on an integrated personal computer. This software allows the operator to select the type of image to be captured and controls the image capture process.
2. The Laser Radiation Management firmware resides on two integrated circuits (specifically field-programmable gate arrays). This firmware implements a finite state machine whose sole objective is to monitor exposure levels and automatically prevent an exposure being taken in the event that sensors deviate from tightly defined limits.

The sponsor states that the system delivers Class1 laser power at yes as defined by 21 CFR 1040.10. Additionally, the system is designed to deliver a non-adjustable power level.

3. Application Software

This software allows the user to review single images, image sessions via thumbnail overviews, access image libraries, annotation features, 3D representation of the eye for patient education. There is also a scheduling and archiving facility.

This application software is the same for the P200CAF and the P200.

Optos has evaluated the level of concern for the Panoramic 200CAF software using the

decision process outlined in FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005) and determined that the Panoramic 200CAF software presents a minor level of concern.

Version: Imaging capture and management software:2.2.9 Laser radiation management software: 0.9.0		
Level of Concern: Minor		
	Yes	No
Software description:	✓	
Device Hazard Analysis:	✓	
Software Requirements Specifications:	✓	
Architecture Design Chart:	✓	
Design Specifications:	✓	
Traceability Analysis/Matrix:	✓	n/a
Development:		n/a
Verification & Validation Testing:	✓	
Revision level history:	✓	
Unresolved anomalies:		n/a

Comment:

The software is configured as three modules, including image capture, laser radiation management firmware and application. The sponsor states that all three modules are evaluated to be at a minor level of concern, but are designed and documented according to requirements for moderate level of concern. The development procedures, validation procedures and documentation appear satisfactory.

- Image software - a minor level of concern is appropriate.
- Application software - This application software is the same for the P200CAF and the P200 (predicate). No further review is needed.
- The laser radiation management scheme comprises of a series of modules that operate together to ensure that that eye-safe, Class I operation is maintained throughout normal use and in the event of foreseeable fault conditions. This is achieved by a combination of system monitors (laser power and scan parameters), digital electronics that determine if the system is safe and exposure control mechanisms.

For laser safety, if any fault condition is detected, the following safety systems shall be enabled:

- Laser switch-off.
- Closure of all laser input shutters

- Closure of exposure shutter

No further exposure shall be permitted after a fault event has been detected without system power cycling. The sponsor also states that the system delivers Class1 laser power at yes as defined by 21 CFR 1040.10. Additionally, the system is designed to deliver a non-adjustable power level.

Based on above reason, a minor level of concern for laser radiation management firmware seems to be acceptable.

Since no automatic diagnostic capabilities are included in the software, i.e., all diagnostic decisions must be made by a practitioner, with the SLO data serving as one of potentially many pieces of diagnostic information. Therefore, the Indications for Use Statement should be clearly indicated that the device does not provide a diagnosis and is not intended as the sole source of diagnostic information for any ophthalmic condition. The following wording is suggested:

“The Panoramic 200CAF scanning laser ophthalmoscope is indicated for use (IFU) as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest themselves in the retina.”

This concern has been addressed in the revised IFU statement.

Software Document information:

Version: 2.2.9		
Level of Concern: Minor		
	Yes	No
Software description:	✓	
Device Hazard Analysis:	✓	
Software Requirements Specifications:	✓	
Architecture Design Chart:	✓	
Design Specifications:	✓	
Traceability Analysis/Matrix:	✓	n/a
Development:		n/a
Verification & Validation Testing:	✓	
Revision level history:	✓	
Unresolved anomalies:		n/a

IX. Performance Testing – Bench: Acceptable.

The sponsor claims the following bench testings have been performed:

Electrical Safety and Electromagnetic Compatibility:

The sponsor states:

The sponsor states that the Optos Panoramic 200CAF Ophthalmoscope complies with the following six consensus standards.

- IEC 60601-1 1988/A1:1991 Medical electrical equipment.A2:1995, Corrigendum 95 General requirements for safety.
- IEC 60825-1 Ed.2.0 (2007) Safety of Laser Products.
- IEC 60601-1-2:2007 Medical electrical equipment. General requirements for safety. Collateral standard. Electromagnetic Compatibility requirements and tests.
- IEC 60601-1-4 edition 1.1 2000-04 Medical electrical equipment. General requirements for safety. Collateral standard. General Requirements for programmable Electrical medical systems.
- ISO 10993-5 Biological evaluation of medical Devices: Tests for In Vitro Cytotoxicity 1999 & 2009.
- ISO 10993-10 2002 & Amendment 1, 2006.

Standards Data Report Forms and summary report for each listed recognized consensus standard are provided in Attachment 11 of original submission.

Comment:

- Certificates of Compliance with IEC 60601-1 (electrical safety) and IEC 60601-1-2 (EMC) are provided. The EMC test report is also provided. Testing and test results according to IEC 60601-2 appear to be adequate.
- The sponsor provided radiation hazard analysis using ISO15004-2:2007 for the additional LEDs contained in the patient alignment system. The sponsor states that the Patient Alignment System (PAS) is an embedded optical module within the Optos Scanning Laser Ophthalmoscope, containing multiple visible LEDs (four red and one green) and a NIR (near infrared) LED source. The visible LEDs are used as patient fixation targets to ensure that the patient gaze angle is correct for retinal imaging. In normal operation, only one of the visible LEDs is illuminated at any given time, with the green LED projecting along the central axis and the four red LEDs projecting along the nasal, temporal, superior and inferior projections, respectively. The NIR LED is used to provide flood fill illumination of the patient to provide the operator with a patient view, via imaging cameras embedded in the PAS, and is illuminated during a patient session except during active image acquisition.

Evaluation of the system to the conditions for group 1 instrument demonstrates that the operation of the system falls within the group 1 limits and does not, therefore, present an optical hazard.

- The sponsor has provided biocompatibility test reports for the (b) (4) [redacted], provided biocompatibility review. She commented that none of the test results showed any evidence of toxicity, and from a biocompatibility perspective, this submission can be found substantially equivalent (SE). Her review is attached.

X. Performance Testing – Animal:

Animal testing was not conducted for this application, as it is not needed to support substantial equivalence to the predicate device.

XI. Performance Testing – Clinical:

Clinical testing was not conducted for this application, as it is not needed to support substantial equivalence to the predicate device.

XII. Substantial Equivalence Discussion: SE

	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?		X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?			If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		X	If YES = Stop NSE
7. Accepted Scientific Methods Exist?	X		If NO = Stop NSE
8. Performance Data Available?	X		If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision: SE

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

- Explain how the new indication differs from the predicate device's indication:

The sponsor proposed the identical Indications for Use (IFU) to that from predicate device. Per FDA recommendation, the sponsor has provided a revised IFU:

3

“The Panoramic 200CAF scanning laser ophthalmoscope is indicated for use as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest themselves in the retina.”

The revised IFU implies that the device has new function of retinal autofluorescence imaging and does not provide a diagnosis and is not intended as the sole source of diagnostic information for any ophthalmic condition. We believe the revised IFU is more appropriate, and the intended for use has not been changed.

IFU for predicate Panoramic P200 (K983999):

“The Panoramic P200 scanning laser ophthalmoscope is indicated for use as a wide field ophthalmoscope for diagnosing and monitoring diseases or disorders that manifest themselves in the posterior pole of the eye.”

2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:

The subject device (P200AF) has new function of retinal autofluorescence imaging. In autofluorescence mode, the P200CAF uses only the green laser to illuminate the eye. This allows an image of the natural fluorescence of the eye to be captured. No fluorescent dye has to be introduced into the patient.

4. Explain how new characteristics could or could not affect safety or effectiveness:

The key modification in model of P200CAF is an additional capacity of displaying autofluorescence imaging using original lasers and updated electronics assembly. Since the subject uses original lasers and updated electronics assembly, there are electrical safety and EMC concerns.

5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

The effectiveness of imaging function is not a new type issue. It is common issue for ophthalmic image devices. The electrical safety and EMC concerns are also common for medical devices

7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

The performance validation demonstrates that the autofluorescence mode offers additional information to the area of interest but none of the information derived from the red/green mode is lost. In autofluorescence mode, there is less light entering the eye than in standard red/green imaging. Therefore, the subject device is as safe and effective as the predicate device.

XIII. Deficiencies

With this supplement the sponsor has adequately addressed all deficiencies cited in our letter May 4, 2010. Each deficiency is copied below and is followed by the sponsor's response and Lead Reviewer's comments.

Indications for Use (IFU)

1. You proposed the following Indication for Use:

"The Panoramic 200CAF scanning laser ophthalmoscope is indicated for use as a wide field ophthalmoscope for diagnosing and monitoring diseases or disorders that manifest themselves in the posterior pole of the eye."

However, it does not appear that your device has any automatic diagnostic capabilities. As such, all diagnostic decisions must be made by a practitioner, with the scanning laser ophthalmoscope (SLO) data serving as one of potentially many pieces of diagnostic information. Therefore, your IFU should be revised to indicate that the device does not provide a diagnosis and is not intended as the sole source of diagnostic information for any ophthalmic condition. Furthermore, the 200CAF has a new function of displaying retinal autofluorescence imaging, which should be added into IFU. Please modify your IFU accordingly. We recommend you modify your IFU similar to the following:

"The Panoramic 200CAF scanning laser ophthalmoscope is intended to be used as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina."

Please provide your revised IFU statement on the appropriate IFU form, and modify your 510(k) Summary and labeling accordingly.

Response: *After careful consideration of FDA's concerns outlined above, the company has modified the indications for use for the P200CAF to reflect the fact that the device does not have any diagnostic capabilities and to reference the autofluorescence imaging mode. The revised indications for use are as follows:*

The Panoramic 200CAF scanning laser ophthalmoscope is intended to be used as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.

The company's revised Indications for Use Statement is provided in Attachment 1.

Comment: This response is satisfactory. Revised IFU is acceptable.

Substantial Equivalence

2. You claim that the P200CAF has the capability of displaying retinal autofluorescence imaging. In order to support a decision regarding substantial equivalence, performance validation is required for this additional feature. This validation should demonstrate that the new feature is effective and could not affect safety of the device as indicated relative to the predicate device. Therefore, please provide validation testing for the autofluorescence imaging function or provide rationale for not doing so.

Response: To thoroughly address the agency's concerns outlined above, the company is providing the following rationale and validation testing to demonstrate that the device's ability to capture images using the autofluorescence mode has no effect on the safety and efficacy of the device.

Performance Validation

The autofluorescence mode does not affect the safety of the P200CAF as compared to the predicate device. Both the P200CAF and the P200 use the same red and green lasers, and both devices are capable of generating composite red/green images. In autofluorescence mode

(this mode only being available in the P200CAF and not the P200 predicate), the red laser is blocked causing less light to enter the eye. In standard red/green imaging mode, both the P200 and the P200CAF have the autofluorescence information contained in the red channel but this signal is swamped by the red reflectance signal. In the P200CAF autofluorescence mode, the red laser is blocked and some optical elements are removed in the return path to optimize the autofluorescence signal. Because less light enters the eye in autofluorescence mode, with the only other change being in the return path, the use of this mode does not affect the safety of the device.

In addition to meeting consensus standard requirements defined in item 3, below, the P200CAF underwent release performance testing. An example of this testing is contained within the attached certificate of release (file is included). This testing includes electrical safety testing, confirmation that the laser radiation management software prohibits disallowed states (such as shutter remaining open), red and green laser power measurements and eye images (both composite red/green and autofluorescence) as a simulation of end use. The composite red/green image quality of the P200CAF and its predicate, the P200, were assessed against comparable acceptance criteria.

The effectiveness of the autofluorescence image is determined by the following rationale and associated images:

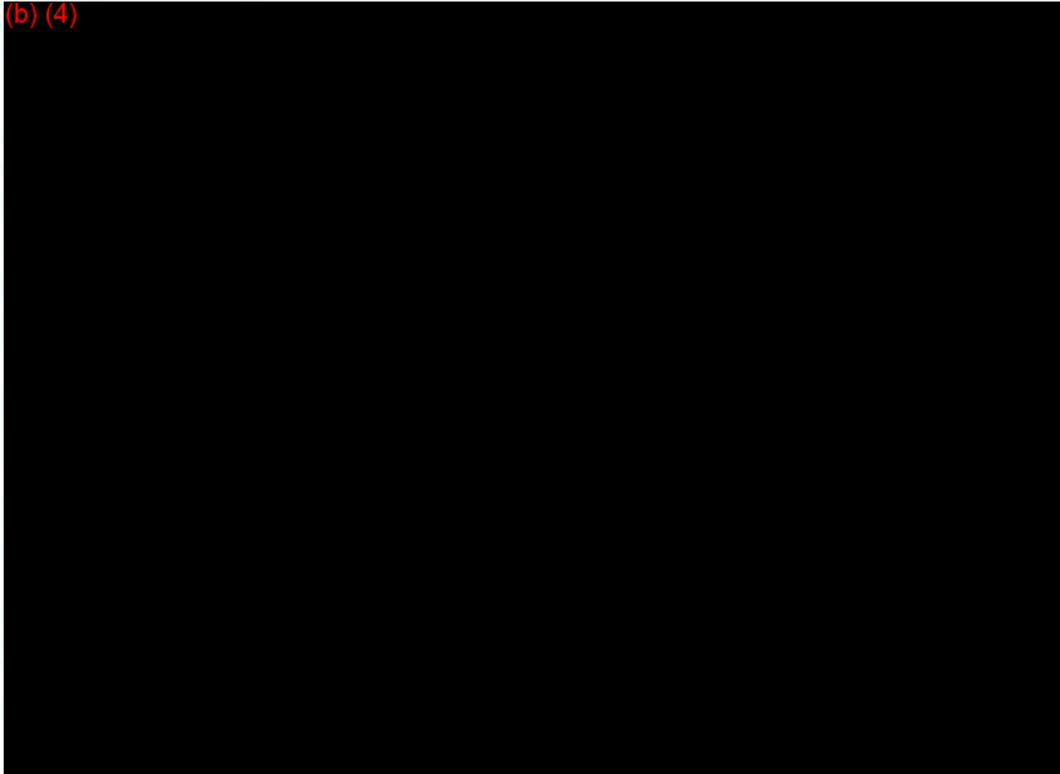
The mechanism, excitation and emission wavelengths that cause autofluorescence are well understood. Specifically, autofluorescence imaging of the retina involves capturing a response from molecules in the retinal pigment epithelium (RPE). The most significant naturally occurring fluorophore is lipofuscin.

The excitation wavelengths of lipofuscin range from approximately (b) (4) nm, with emissions ranging from (b) (4) nm. The P200CAF's configuration includes a green

wavelength of (b) nm with a barrier filter of (b) nm for the return path, and is within the specified operating window.

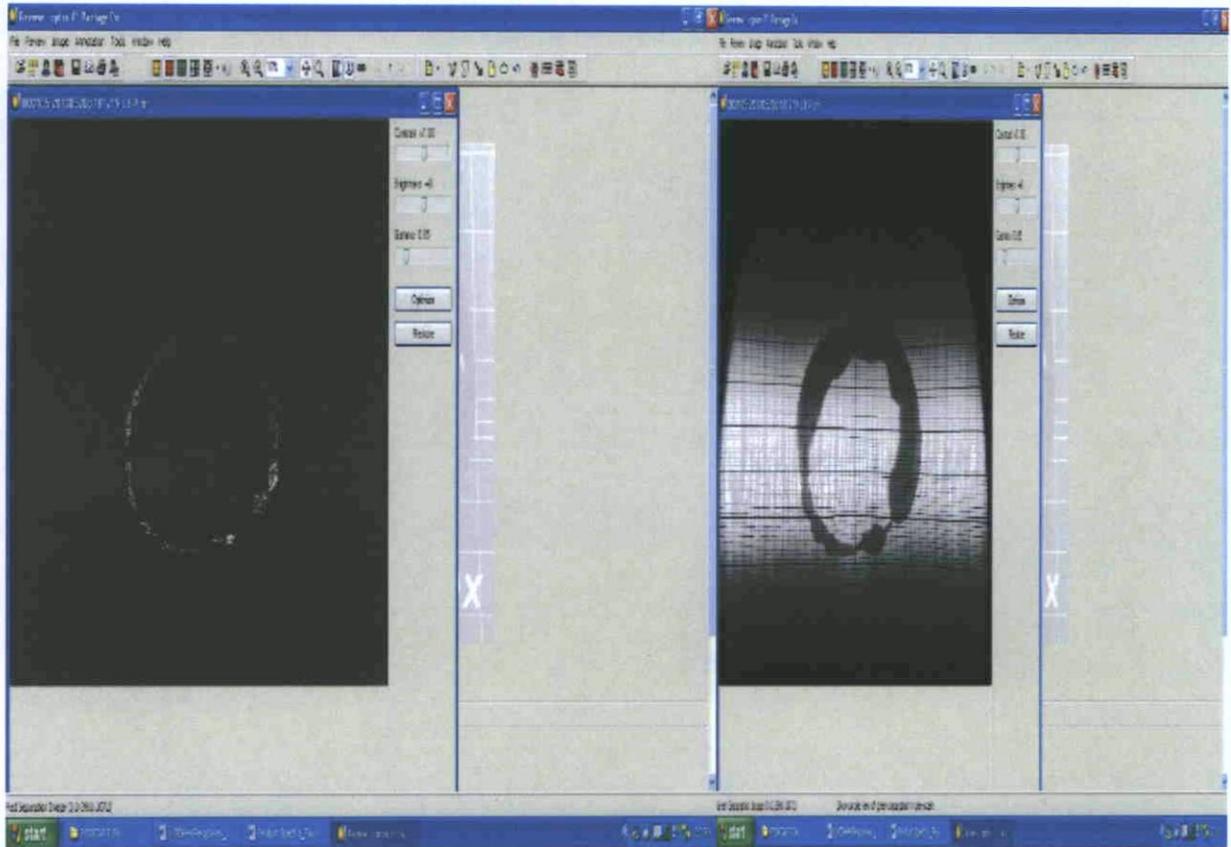
The above mechanism of operation can be verified using red fluorescent microspheres that support excitation at (b) nm and emit in the red spectrum. These 'fluospheres' have the following spectral characteristics and are a close match to the excitation and emission characteristics of lipofuscin:

(b) (4)



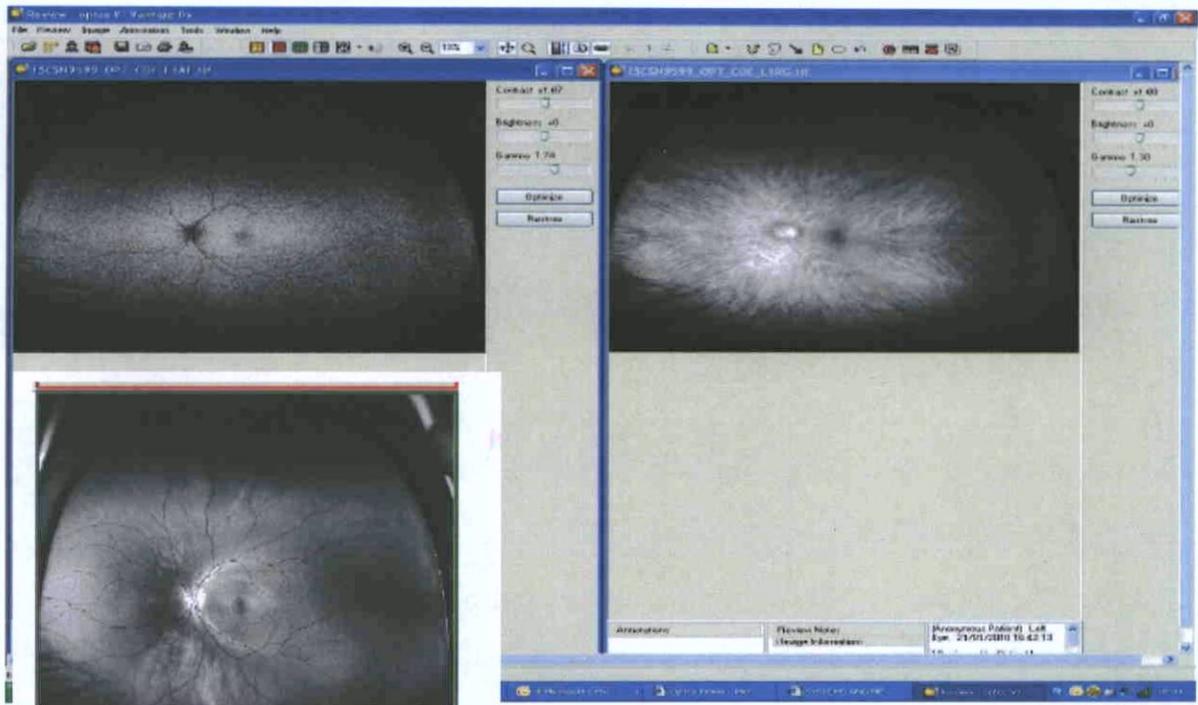
Fluorescence excitation and emission spectra of FluoSpheres red fluorescent microspheres in H₂O.

Applying these fluospheres in a circle on graph paper and immediately examining the red channel in autofluorescence imaging mode verifies that the red fluorescence of these spheres is visible (with the grid less so), whereas in the green channel, full reflectance is seen including the water mark and the grid where the spheres were applied (left and right pictures respectively). Because these fluorophores are excited by laser light and emit fluorescence at the same range of wavelengths as the lipofuscin present in the human retina, these images provide an ex vivo method of assessing the reproducibility of the P200CAF scanning laser ophthalmoscope in obtaining reproducible autofluorescent images.



*Additionally, once the graph paper had dried, thirty such images were generated over 3 days indicating that the excitation and emission of fluospheres, which simulate lipofuscin spectral characteristics, can be captured in a reproducible manner. These images show little difference in appearance although it should be noted the fluospheres deteriorate over time (see **Attachment 2**).*

In terms of the human eye, the figure below illustrates the difference in images generated in autofluorescence mode (top left), which is seen in the red channel, a red reflectance image (top right), which is also seen in the red channel when the red laser is not blocked, and the green reflectance image (bottom left), which is the green reflectance seen in the green channel. These images confirm that the P200CAF device is capable of detecting in vivo autofluorescence as effectively as has been shown in the ex vivo testing described above.



*Reproducibility of image generation for a human eye in autofluorescence mode can be demonstrated by eleven images of an operator's left eye. These images are exhibited in chronological order with the time period from the first to last image being approximately 6 weeks. Again, the differences in these images are small (see **Attachment 3**).*

*The operator's eye has no areas of interest in that the autofluorescence image has a relatively uniform distribution of lipofuscin. For eyes that have areas of interest in terms of atypical distribution of lipofuscin, fifty examples have been selected from clinics that show the autofluorescence red channel, the corresponding red channel from a standard red/green image, and the green channel from a standard red/green image (see **Attachment 4**).*

The green wavelength is primarily reflected by the retinal pigment epithelium (RPE)/photoreceptor interface and the red light is reflected by the choroid. Autofluorescence looks at the distribution of lipofuscin within the RPE. Thus, autofluorescence gives an alternate view of the retinal layers looking at the distribution of lipofuscin and is complimentary to the red/green composite reflectance image and the separated red and green reflectance images.

This complimentary nature is evident in most of these images as the area of interest is highlighted in the autofluorescence image but is less visible in the red and/or green channels of the standard image.

The autofluorescence imaging mode can be used by the healthcare professional, in conjunction with the standard composite (red/green) and the associated separated red and green channel images, to aid in the diagnosis and monitoring of diseases and disorders that manifest in the eye.

As demonstrated in these eleven images obtained over time from the same individual (as described above) and the 50 images obtained from patients with previously identified pathologies, autofluorescence images are reproducibly obtained with the P200CAF device and provide image information that users may view as an aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.

Comment: This response is acceptable. The performance validation demonstrates that the autofluorescence mode offers additional information to the area of interest but none of the information derived from the red/green mode is lost. In autofluorescence mode, there is less light entering the eye than in standard red/green imaging. Therefore, the P200CAF is as safe and effective as the predicate, the P200.

Performance Testing – Bench

3. On page 27/140, you state that “The Optos Panoramic 200CAF Ophthalmoscope complies with the following six consensus standards”:
- IEC 60601-1 1988/A1:1991 Medical electrical equipment.A2:1995, Corrigendum 95 General requirements for safety;
 - IEC 60825-1 Ed.2.0 (2007) Safety of Laser Products;
 - IEC 60601-1-2:2007 Medical electrical equipment. General requirements for safety. Collateral standard, Electromagnetic Compatibility requirements and tests;
 - IEC 60601-1-4 edition 1.1 2000-04 Medical electrical equipment. General requirements for safety. Collateral standard. General Requirements for programmable Electrical medical systems;
 - ISO 10993-5 Biological evaluation of medical Devices: Tests for In Vitro Cytotoxicity 1999 & 2009; and
 - ISO 10993-10 2002 & Amendment 1, 2006.

However, you do not provide any test report. This information is important in evaluating your device performance. Please provide the following information:

- a. Please provide the report of electrical safety and electromagnetic compatibility testing or certificates. The testing results should demonstrate your device complies with IEC 6060-1 and IEC 60601-1-2, as indicated in your submission.

Response: *The company's electrical safety testing to IEC 60601-1 and IEC 60601-1-2 are provided in Attachment 5.*

Comment: Certificates of Compliance with IEC 60601-1 (electrical safety) and IEC 60601-1-2 (EMC) are provided. The EMC test report is also provided. Testing and test results according to IEC 60601-2 appear to be adequate.

- b. On page 16/140, you state that the additional periphery light emitting diodes (LEDs) have been used in the P200CAF assisting in eye steering, and the additional LEDs, which are included in the laser safety calculations, do not change the intended use of the device or alter the fundamental scientific technology. However, you do not provide such laser calculations in your submission. This information is very important in assessing the safety of use of your device. Please provide your radiation hazard analysis for the additional LEDs.

Please be advised that in the updated version of IEC 60825-1:2007, LEDs has been removed from the scope of Part 1. Please be advised that the optical radiation safety of LEDs, in general, may be appropriately addressed by lamp safety standards (e.g., ANSI RP-27.1-05 –Photobiological Safety for Lamps and Lamp Systems-General Requirements) and/or 15004-2:2007, ISO 15004-2:2007 – Ophthalmic instruments – Fundamental requirements and test methods – Part 2: Light hazard protection.

Response: The company's radiation hazard analysis using ISO15004-2:2007 for the additional LEDs contained in the patient alignment system is provided in Attachment 6.

Comment: The sponsor provides radiation hazard analysis using ISO15004-2:2007 for the additional LEDs contained in the patient alignment system. The sponsor states that the Patient Alignment System (PAS) is an embedded optical module within the Optos Scanning Laser Ophthalmoscope, containing multiple visible LEDs (four red and one green) and (b) (4) LED source. The visible LEDs are used as patient fixation targets to ensure that the patient gaze angle is correct for retinal imaging. In normal operation, only one of the visible LEDs is illuminated at any given time, with the green LED projecting along the central axis and the four red LEDs projecting along the nasal, temporal, superior and inferior projections, respectively. (b) (4)

Evaluation of the system to the conditions for group 1 instrument demonstrates that the operation of the system falls within the group 1 limits and does not, therefore, present an optical hazard.

- c. In Section XII (Biocompatibility), you state that “The same material is used for the cushion in the P200 and the face pad in the P200CAF. As the P200CAF also has a chinrest and head support, two additional materials come into contact with the patient. Specifically, the chinrest is made of (b) (4) As per ISO 10993, the contact is skin and for limited duration, requiring that Cytotoxicity, Sensitization, and Irritation or Intracutaneous reactivity is assessed. Both of the additional materials have been assessed for these effects and meet

the relevant standards.” However, you do not provide the biocompatibility testing report of the additional materials. Please provide your testing report. The testing should demonstrate your device complies with cited standards.

Response: The requested biocompatibility testing for the (b) (4) [REDACTED] Attachment 7.

Comment: The sponsor has provided biocompatibility test reports for the (b) (4) [REDACTED] provided biocompatibility review. She commented that none of the test results showed any evidence of toxicity, and from a biocompatibility perspective, this submission can be found substantially equivalent (SE).

The response to biocompatibility issue is satisfactory.

510(k) Summary

4. On page 38/140, you provide a single page 510(k) Summary. The information you provide is not sufficient as you only include the information of device modifications. However you should revise your 510(k) Summary to include a summary of how the technological characteristics of your device are different comparing to the predicate device. Please revise your 510k summary accordingly. We recommend that you use the following in drafting a new 510(k) Summary:

Sec. 807.92 Content and format of a 510(k) summary, at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=807.92>

Response: The 510(k) Summary has been revised for content and format. The company's revised 510(k) Summary is provided in Attachment 8.

Comment: The revised 510(k) Summary is acceptable. This response is satisfactory.

Labeling

5. You use one Introductory Handbook for three models of P200MA (060624), P200C and P200CAF (K100644), and provide an intended use statement. Please address the following related concerns:
 - a. Please clarify whether the P200C is an FDA-cleared device. If so, please provide the 510(k) number under which it was cleared.

Response: The P200C is marketed based on a memorandum to file (MTF) documenting the company's decision not to file a 510(k) notice for this device. This decision was based on the fact that the P200C is indicated for a subset of the indications for use for the

P200MA (K060624). The company's memorandum documenting its decision not to file a 510(k) notice for this device is provided in Attachment 9.

Comment: Based on the response, it seems that P200C has not a significant change and does not require a 510(k). P200C is indicated for a subset of the indications for use for the P200MA (i.e., the statement "this includes imaging the fluoresced ocular vasculature" has been removed from the indications for use).

The only differences between the P200MA and the P200C are:

- (1) removal of the blue laser;
- (2) removal of the motorized translation stage; and
- (3) removal of an arm rest.

I have consulted with 510(k) staff, Ms. Marjorie Shulman on whether it is appropriate to include the model of P200C in the labeling (use manual). Mr. Shulman said it is okay to accept this user manual.

This response is acceptable.

- b. We note that the intended use for P200MA and P200CAF are slightly different. We recommend you provide the intended use for each mode separately. We also recommend you make the intended use a separate section with a title of Intended Use for clarity. Please revise your labeling accordingly.

Response: *The company has revised the handbook to include a section entitled "Indications for Use." A redlined version of the revised handbook is provided in Attachment 10.*

Comment: The sponsor has listed IFU for three models of Panoramic scanning laser ophthalmoscope, respectively:

Indications for Use (IFU)

The Panoramic P200C scanning laser ophthalmoscope is intended to be used as a wide field and retinal imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.

The Panoramic P200MA scanning laser ophthalmoscope is intended to be used as a wide field and retinal fluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina. (K060624).

The Panoramic P200CAF scanning laser ophthalmoscope is intended to be used as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.(K100644)

The indication of "retinal fluorescence imaging" is removed from P200C that is consistent with sponsor's response to deficiency 5.a.

- c. Please revise your labeling for P200CAF to reflect the modification to Indications for Use and include the radiation hazard from the additional LEDs, if any.

Response: As indicated above, the handbook has been revised to include the modified indications for use. However, analysis of the LEDs according to ISO15004-2:2007 concludes that the device meets the requirements of group 1, and no change to the primary or secondary device labeling is required.

Comment: Response is acceptable.

Contact History

On April, the sponsor was contacted by email (through Hogan & Hartson LLP) that we do not believe this submission qualifies for review as a Special 510(k) and will be converted to a Traditional 510(k) accordingly (see attached email).

On 4/13/2010, Mr. Randy Prebula, Director of Regulatory Sciences of Hogan & Hartson LLP provided (by email) the following clarification about the P200CAF device and the company's previously cleared scanning laser ophthalmoscopes ("SLOs") (see attache email information).

On May 4, 2010, the sponsor was informed, by email, that this submission is being placed on telephone hold (TH), additional information is required.

On July 9, 2010, the sponsor responded (by email) to lead reviewer's request to provide an good print quality copy of the "Certificate of Release" regarding the performance testing of the Panoramic 200CAF, in reference to the June 15, 2010, letter to FDA concerning K100644-S1.

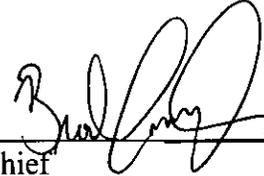
On July 14, 2010, the sponsor responded (by email) to lead reviewer's request to provide additional information on radiation hazard analysis using ISO15004-2:2007 for the Patient Alignment System (PAS) which contains multiple visible LEDs. Their response is adequately addressed FDA concerns. See attached submission.

Recommendation: SE

The subject device Optos Limited Panoramic 200CAF is substantially equivalent to predicate device (Panoramic 200CAF) classed as follows:

Trade Name: Panoramic 200CAF
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulation Class: Class II
Product Code: MYC

Dexiu Shi  07/14/2010
Reviewer Date

 7/15/10
Branch Chief Date

Shi, Dexiu

From: Woodlee, Danielle C. [danielle.woodlee@hoganlovells.com]
Sent: Friday, July 09, 2010 10:16 AM
To: Shi, Dexiu
Cc: Holstein, Howard M.; Woodlee, Danielle C.
Subject: K100644 - Panoramic 200CAF
Attachments: 9618A10090B CofR.pdf

Dear Dr. Shi,

In response to your July 6, 2010, e-mail to Howard Holstein (below), we are writing to provide you with a new copy of Optos Ltd.'s "Certificate of Release" for the company's performance testing of the Panoramic 200 CAF (K100644). The company believes that this copy is of better quality and will be easier to read. Please note, although this certificate has a slightly different lay-out, this change was made to improve readability and does not alter the substance of the document.

Should you have any questions or concerns, please do not hesitate to contact me.

Best Regards,
 Danielle Woodlee

Danielle Woodlee
 Attorney at Law

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 Direct: +1 202 637 8853
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 www.hoganlovells.com

Please consider the environment before printing this e-mail.

From: Shi, Dexiu [mailto:Dexiu.Shi@fda.hhs.gov]
Sent: Tuesday, July 06, 2010 7:12 PM
To: Holstein, Howard M.
Cc: Shi, Dexiu
Subject: K100644-S1 - Panoramic 200CAF

Dear Mr. Holstein:

In your response to FDA deficiency 2 dated June 15, 2010, you provided a certificate of release for your performance testing. However, the page of certificate is in a poor quality, we can not read out. Please resubmit (by email or fax) this certificate. FDA requires, at least, a font 8 should be used.

Regards,

Dexiu Shi, Ph.D., Physicist and Biomedical Engineer

7/14/2010

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Ophthalmic Lasers, Neurostimulators,

and Diagnostics Devices Branch

FDA/CDRH/ODE
10903 New Hampshire Ave.
Building 66, Rm 2246
Silver Spring, MD 20993-0002
Phone: 301-796-6470
Fax: 301-847-8127
dexiu.shi@fda.hhs.gov

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed. This e-mail message is intended for the exclusive use of the recipient named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at dexiu.shi@fda.hhs.gov or call (310) 796-6470.

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7/14/2010

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From: Woodlee, Danielle C. [mailto:danielle.woodlee@hoganlovells.com]
Sent: Wednesday, July 14, 2010 1:49 PM
To: Shi, Dexiu; Holstein, Howard M.; Payne, Kelliann H.
Subject: RE: K100644 - Panoramic 200CAF - more questions

Dear Dr. Shi,

On behalf of our client, Optos Ltd., we are writing to respond to your July 13, 2010, e-mail requesting additional information regarding the Panoramic 200CAF (K100644). Please note, an official copy of this response is also being filed with the Document Mail Center today.

Please do not hesitate to contact us with any additional questions or concerns.

Regards,
Danielle Woodlee

From: Shi, Dexiu [mailto:Dexiu.Shi@fda.hhs.gov]
Sent: Tuesday, July 13, 2010 6:13 PM
To: Holstein, Howard M.; Woodlee, Danielle C.; DelaNoche, Laura D.
Cc: Shi, Dexiu
Subject: RE: K100644 - Panoramic 200CAF - more questions

Dear Mr. Holstein:

I have the following questions on the sponsor's response to our deficiency 3.b. regarding the radiation hazard analysis:

1. In your response, you state that (b) (4) [REDACTED]. The company's radiation hazard analysis using ISO15004-2:2007 for the additional LEDs contained in the patient alignment system is provided in **Attachment 6**."

However, you only provide the radiation hazard analysis for (b) (4) [REDACTED]. We are unable to locate the hazard analysis for these four visible red LEDs. Please provide this information.

2. To facilitate your review, please summarize your radiation hazard analysis in the following table:

Light Source/ Wavelength	Measurement (e.g. irradiance and or radiance, etc)	Limit for Group 1 Instrument (based on 15004-2)
(b) (4)		

3. Again, pages 8- 16 of Attachment 6 are in a poor quality. Please resubmit these pages which should be in a good print quality.

Please provide me your response by COB July 14.

Thanks,

Dexiu Shi

From: Woodlee, Danielle C. [mailto:danielle.woodlee@hoganlovells.com]
Sent: Friday, July 09, 2010 10:16 AM
To: Shi, Dexiu
Cc: Holstein, Howard M.; Woodlee, Danielle C.
Subject: K100644 - Panoramic 200CAF

Dear Dr. Shi,

In response to your July 6, 2010, e-mail to Howard Holstein (below), we are writing to provide you with a new copy of Optos Ltd.'s "Certificate of Release" for the company's performance testing of the Panoramic 200 CAF (K100644). The company believes that this copy is of better quality and will be easier to read. Please note, although this certificate has a slightly different lay-out, this change was made to improve readability and does not alter the substance of the document.

Should you have any questions or concerns, please do not hesitate to contact me.

Best Regards,
Danielle Woodlee

Danielle Woodlee
Attorney at Law

Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004

Tel: +1 202 637 5600
Direct: +1 202 637 8853
Fax: +1 202 637 5910
Email: danielle.woodlee@hoganlovells.com
www.hoganlovells.com

Please consider the environment before printing this e-mail.

From: Shi, Dexiu [<mailto:Dexiu.Shi@fda.hhs.gov>]
Sent: Tuesday, July 06, 2010 7:12 PM
To: Holstein, Howard M.
Cc: Shi, Dexiu
Subject: K100644-S1 - Panoramic 200CAF

Dear Mr. Holstein:

In your response to FDA deficiency 2 dated June 15, 2010, you provided a certificate of release for your performance testing. However, the page of certificate is in a poor quality, we can not read out. Please resubmit (by email or fax) this certificate. FDA requires, at least, a font 8 should be used.

Regards,

Dexiu Shi, Ph.D., Physicist and Biomedical Engineer
Ophthalmic Lasers, Neurostimulators, and Diagnostics Devices Branch
FDA/CDRH/ODE
10903 New Hampshire Ave.
Building 66, Rm 2246
Silver Spring, MD 20993-0002
Phone: 301-796-6470
Fax: 301-847-8127
dexiu.shi@fda.hhs.gov

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed. This e-mail message is intended for the exclusive use of the recipient named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at dexiu.shi@fda.hhs.gov or call (310) 796-6470.

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July 14, 2010

By Hand Delivery and Electronic Mail

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Attn: Dexiu Shi, Ph.D. (Room 2246)

Re: Response to FDA's Request for Additional Information Regarding the Optos Limited Panoramic 200CAF (K100644)

Dear Dr. Shi:

As regulatory counsel to Optos Limited ("Optos" or "the company"), Hogan Lovells US LLP (formerly Hogan & Hartson LLP) is filing this response to the Food and Drug Administration's ("FDA" or "the agency") July 13, 2010, e-mail requesting additional information regarding the Panoramic 200CAF (K100644) ("P200CAF" or "the device"). For ease of review, the items from the agency's July 13 e-mail are reproduced in italics below, followed by the company's response to each. We trust that this response provides the information needed for the agency to proceed with the review of the company's 510(k) submission.

- 1. In your response, you state that "the Patient Alignment System (PAS) contains (b) (4) [redacted] The company's radiation hazard analysis using ISO15004-2:2007 (b) (4) [redacted] the patient alignment system is provided in Attachment 6."*

However, you only provide the radiation hazard analysis for (b) (4) [redacted]. We are unable to locate the hazard analysis for (b) (4) [redacted] provide this information.

Response: In light of the low light levels involved and the high safety margins with respect to the limits, the original document considered only the green LED, as it has the most stringent weighting factors.

As requested, please find the additional calculations for the red LEDs and the associated tabulation for all LED sources in **Attachment 1**. The tabulated radiation hazard analysis indicates that the system meets the group 1 conditions in all instances.

2. To facilitate our review, please summarize your radiation hazard analysis in the following table:

Light Source/ Wavelength	Measurement (e.g. irradiance and or radiance, etc)	Limit for Group 1 Instrument (based on 15004-2)
(b) (4)		

Response: The company has compiled its radiation hazard analysis in the format requested by the (b) (4) 1.

(b) (4)



3. Again, pages 8-16 of Attachment 6 are in a poor quality. Please resubmit these pages which should be in a good print quality.

Response: More readable versions of pages 8-16 of Attachment 6 are provided in Attachment 2. These are supplied in PDF format so that the content can be expanded as required.

* * *

The company believes that this response fully addresses the issues raised in the agency's July 13, 2010, e-mail. We trust that the information provided is sufficient for the agency to find the P200CAF substantially equivalent to its predicate devices for the listed indication. If you have any further questions, please contact me at the number below or Danielle Woodlee at 202-637-8853. Upon clearance of the device please forward the substantial equivalence letter to me by facsimile to 202-637-5910.

Sincerely,



Howard M. Holstein

Partner
howard.holstein@hoganlovells.com
D (202) 637-5813

Attachments

cc: Robert Tweedlie, Optos Ltd.
Randy Prebula, Hogan Lovells US LLP
Danielle C. Woodlee, Hogan Lovells US LLP

Attachment 1

Patient Alignment System – Analysis to Requirements and Test Methods – Part 2: Light Hazard Protection (EN ISO 15004-2:2007) – Supplementary Information

The design of the lens system for the Red LEDs is the same as that for the green LED. As a result, the following key parameters are used.

- Geometrical distribution of LED illumination at corneal plane = (b) (4)
- Geometrical distribution of LED illumination at object plane = (b) (4)
- Red LED peak wavelength = (b) (4)
- Spectral line half width (b) (4) used to determine worst case weighting factors
- Red LED power at corneal plane = (b) (4) W (measured using Ophir Nova Meter – calibrated 08th March 2010, P/N 1201500, S/N118042- and PD300 photodiode smarthead –calibrated 08th March 2010, P/N1202410, S/N107932)

Following the calculations submitted for the green LED gives:

Spectral Radiance:

(b) (4)

Retinal Spectral Radiance:

(b) (4)

Weighted Retinal Thermal Irradiance:

Weighting factor for (b) (4) therefore,

(b) (4)

Compared to the group (b) (4)

Weighted Retinal Irradiance:

(b) (4)

Compared to the group 1 limit of [redacted] (there is a margin of >670,000.

Weighted Retinal Radiance:

(b) (4)

Compared to the group 1 limit of (b) (4) there is a margin of 34.

A summary of the radiation hazard analysis is tabulated below and it is concluded that the operation of the system falls within the group 1 limits under all conditions.:-

Light Source/ Wavelength	Measurement (e.g. irradiance and or radiance, etc)	Limit for Group 1 Instrument (based on 15004-2)
Visible Green LED - (b) (4)	(b) (4)	$E_{A-R}=220\mu Wcm^{-2}$ $L_{A-R}=2mWcm^{-2}$ $E_{VIR-IR}=0.7Wcm^{-2}$ $L_{VIR-IR}=6Wcm^{-2}sr^{-1}$
Visible Red LED - (b) (4)	(b) (4)	$E_{A-R}=220\mu Wcm^{-2}$ $L_{A-R}=2mWcm^{-2}$ $E_{VIR-IR}=0.7Wcm^{-2}$ $L_{VIR-IR}=6Wcm^{-2}sr^{-1}$
NIR (near infrared) LED - (b) (4)	(b) (4)	$E_{VIR-IR}=0.7Wcm^{-2}$ $L_{VIR-IR}=6Wcm^{-2}sr^{-1}$
Red and NIR LED's combined	(b) (4)	<1
Green and NIR LED's combined	(b) (4)	<1

Attachment 2



Memorandum

Date: July 8, 2010

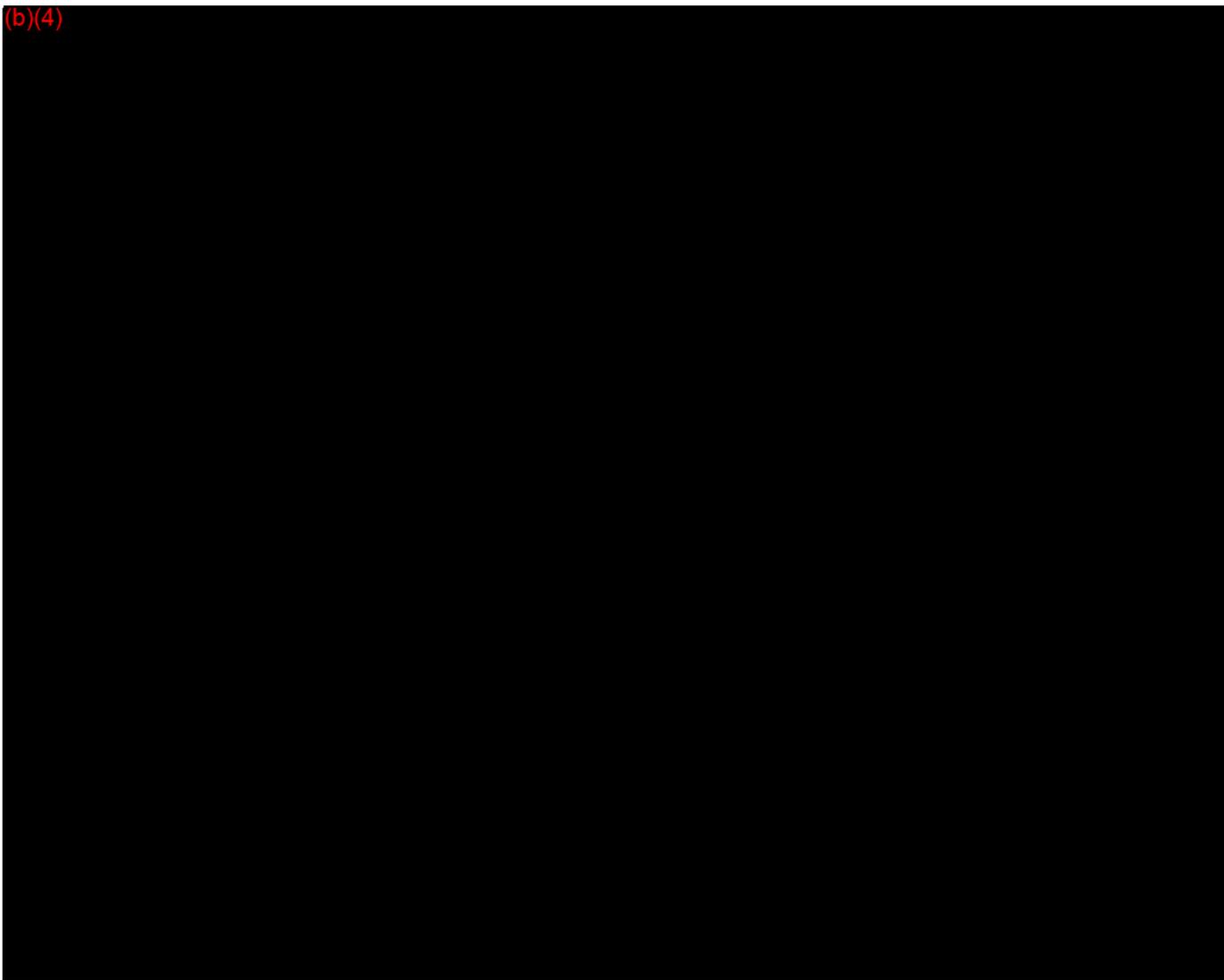
From: Susanna Jones, Toxicologist, ODE/DONED/ICNB, WO66-2468

Subject: Biocompatibility Review of K100644/S1 *Susanna Jones*
Optos PLC
Optos Limited Panoramic 200 CAF

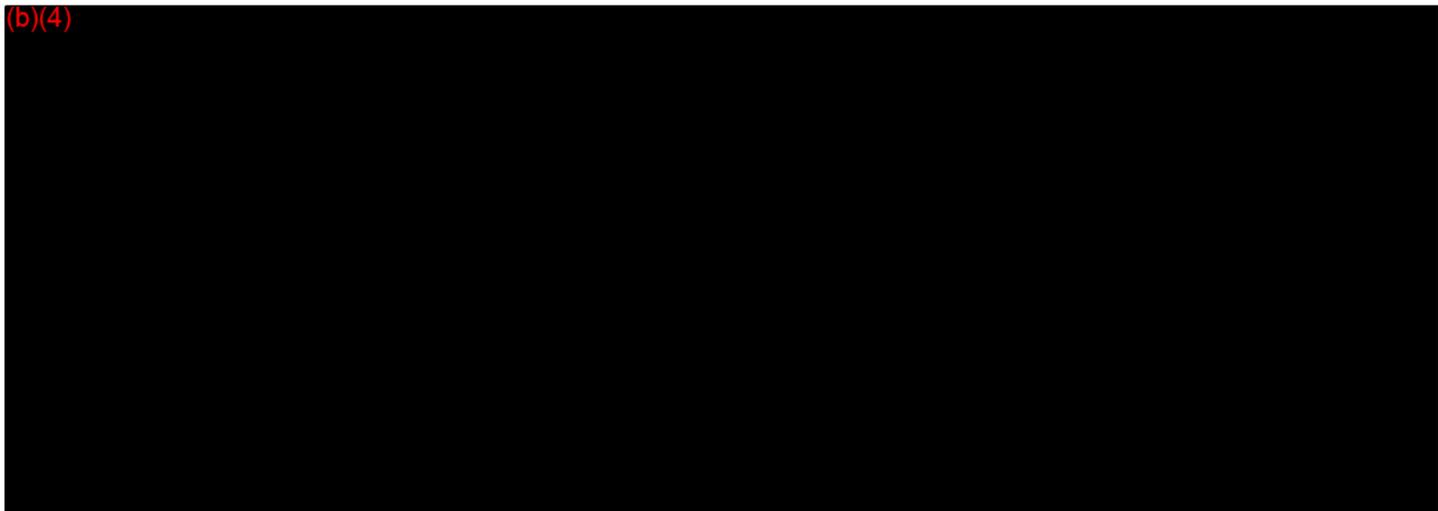
To: Record, K100644/S1

Submitted: This submission is a response to FDA's 05/04/10 memo to the sponsor that lists additional information needed to make a determination of substantial equivalence. (b)(4)

(b)(4)



(b)(4)



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COVER SHEET MEMORANDUM

From: Reviewer Name DEXIN SHI
 Subject: 510(k) Number K900644
 To: The Record

Please list CTS decision code TH

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold). TH
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age <=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days - < 2 years old)			
Child (2 years - < 12 years old)			
Adolescent (12 years - < 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K100644

Date: **May 3, 2010**
To: **The Record**
From: **Dexiu Shi, Ph.D.**

Office: **ODE**
Division: **DONED**
Branch: **ONDB**

Device Name: Optos Limited Panoramic 200CAF
510(k) Holder: Optos PLC
Dated: March 5, 2010
Received: March 5, 2010

Applicant: Optos PLC
Queensferry House
Carnegie Business Campus
Dunfermline,
Fife,
KY11 8GR
United Kingdom
Phone: 011 44 1383 843300
Facsimile: 011 44 1383 843333
Contact Person: Robert Tweedlie Ph.D.

Contact: Randy Prebula
Director of Regulatory Sciences
Hogan & Hartson LLP
Columbia Square,
555 Thirteenth Street, NW,
Washington, DC 20004
Direct +1.202.637.6548, Tel +1.202.637.5600, Fax +1.202.637.5910
Rjprebula@Hhllaw.Com | [Http://Www.Hhllaw.Com](http://Www.Hhllaw.Com)

Summary/Recommendation: **TH**

There are deficiencies in IFU, Performance Testing – Bench, 510(k) Summary and labeling. Telephone hold (TH) is recommended and additional information is requested.

REVIEW SUMMARY

Converting Special 510(k) to Traditional 510(k)

This 510(k) was submitted as special. It has been converted to traditional based on the following reasons:

On page 45/140, Attachment 4, the sponsor states that the P200CAF use red and green lasers to produce a digital, high-resolution image, which is displayed on a PC monitor screen.

1. Red and green lasers are used for digital color imaging. These laser wavelengths retinal structures to different depths, each wavelength providing information for interpretation and diagnosis.
2. The blue laser is used when capturing angiography images. A series of images is captured as the fluorescein flows through the retinal vessels.
3. In autofluorescence mode, the P200CAF uses only the green laser to illuminate the eye. This allows an image of the natural fluorescence of the eye to be captured. No fluorescent dye has to be introduced into the patient.

The predicate device only provides the capabilities of capturing and displaying the color image of the retina. Number 2 and 3, above, are new capacities/features. We believe the new scientific technologies of capturing angiography images and autofluorescence mode are the labeling changes that affect the intended use of the device.

In addition, the new device is intended to be used for diagnosing and monitoring diseases or disorders that manifest in the posterior pole of the eye. In order to test the validity of the angiography image and autofluorescence mode, clinical performance testing may be required.

Based on the above changes and related concerns, we do not believe this submission qualifies for review as a special 510(k). After having 510(k) staff concurrence, this 510(k) was converted to a traditional 510(k) accordingly.

Sponsor's Clarification

On 4/13/2010, Mr. Randy Prebula, Director of Regulatory Sciences of Hogan & Hartson LLP provided (by email) the following clarification about the P200CAF device and the company's previously cleared scanning laser ophthalmoscopes ("SLOs"):

Please note that the P200CAF device that is described in the 510(k) Notice does not include a blue laser and is not capable of generating fluorescein angiograph images. Rather, it is the company's Optos P200a device, which was cleared by FDA under 510(k) submission K042001 that contains both the blue laser and the ability to obtain fluorescein angiography images. With the addition of new internal circuitry, the P200MA was cleared under a Special 510k (K060424), using the cleared P200a model as the predicate.

Page 45/150 of the handbook submitted in K100644 describes the Optos family of scanning laser ophthalmoscopes (SLO's). The device referenced on page 45 as containing a blue laser and capable of fluorescein angiography is the P200MA and not the P200CAF.

Rather, the P200CAF device, like several other members of the company's cleared SLO family of products (including the FDA cleared P200 device, K983999) contains only red and green lasers, and allows users to generate images that can be viewed either as a composite image (that is red and green combined) or as separate red channel and green channel images. Optos described the P200CAF device in the current submission as a modification of the cleared P200 device (resulting from new internal circuitry and incorporation of an additional filter). As such, the company reiterated that both the cleared P200 predicate device and the current P200CAF device utilize the same red and green lasers. To clarify the relationship between the various device versions and features, please see the following table:

Version	P200	P200a	P200ma	P200CAF
510(k) Number	K983999	K042001	K060424	K100644
Status	Cleared	Cleared	Cleared	Pending
Lasers	red, green	red, green, blue	red, green, blue	red, green
Image Type				
Red	yes	yes	yes	yes
Green	yes	yes	yes	yes
Blue	no	yes	yes	no
Composite	yes	yes	yes	yes
Fluorescein Angiography	no	yes	yes	no
Electronics Assembly	Version A	Version A	Version B	Version B
Key Differences	Base model	Added blue laser and fluorescein angiography capability	Added new electronics assembly	Provides ability to capture red and green laser images, and display autofluorescence images, using original lasers and updated electronics assembly

Lead reviewer comment:

Based on sponsor's clarification that feature of number 2 - capturing angiography images is not included in new P200CAF. The key modification in model of P200AF is an additional capacity of displaying autofluorescence imaging using original lasers and updated electronics assembly.

I. Purpose and Submission Summary

Purpose: The 510(k) holder requests clearance to commercially introduce Optos Limited Panoramic 200CAF to US market.

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Administrative Requirements:

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	✓ Prescription		
Truthful and Accuracy Statement	✓		
510(k) Summary or 510(k) Statement	✓ Summary		
Standards Data Report Form – Form 3654 1: No standard used - No Standards Form Required 2: Declaration of Conformity - Yes Standards Form Required: 3: Standard but no declaration - Yes Standards Form Required	2. Yes		

III. Device Description:

	Yes	No	N/A
Is the device life-supporting or life sustaining?		✓	
Is the device an implant (implanted longer than 30 days)?		✓	
Does the device design use software?	✓		
Is the device sterile?		✓	
Is the device reusable (not reprocessed single use)?	✓		
Are "cleaning" instructions included for the end user?	✓		

Note: Most of the below device description is derived from the sponsor's submission (Section H)

General Description

Like its cleared predicate, the Panoramic 200CAF is a conventional scanning laser ophthalmoscope (SLO). A low power laser beam is scanned in two dimensions over the retina and the reflected (or returned) light is detected and used to generate a digital image with a computer or electronic imaging device.

It uses a low power laser beam that scans in two dimensions over the retina. The wavelengths of the lasers residing in the Optos Panoramic 200CAF and the P200 are the same. The generation of the image is performed in the conventional manner using light detectors, the output of which is digitized, and the data collected in a computer for reconstruction, display, and storage. The scanning of the beams on the two axes is done using a conventional rotating polygon for the fast vertical scan and a motor driven mirror for the slower horizontal scan. The device scans **(b)** [REDACTED] 200° when measured ⁽⁴⁾ from the geometric center of the eye.

The instrument principle relies on the fundamental geometry of a unique ellipsoidal mirror to produce double foci from a bicolor laser beam (which in the case of the P200CAF and the P200 is red/green). The double foci of the form ensures that the light will be passed through the small

aperture of the eye regardless of the scan angle, provided that the scan emanates from the small point source coincident with one focus and the eye is correctly positioned at the other. An alignment pattern helps ensure that the patient's eye is correctly positioned.

(b) (4)

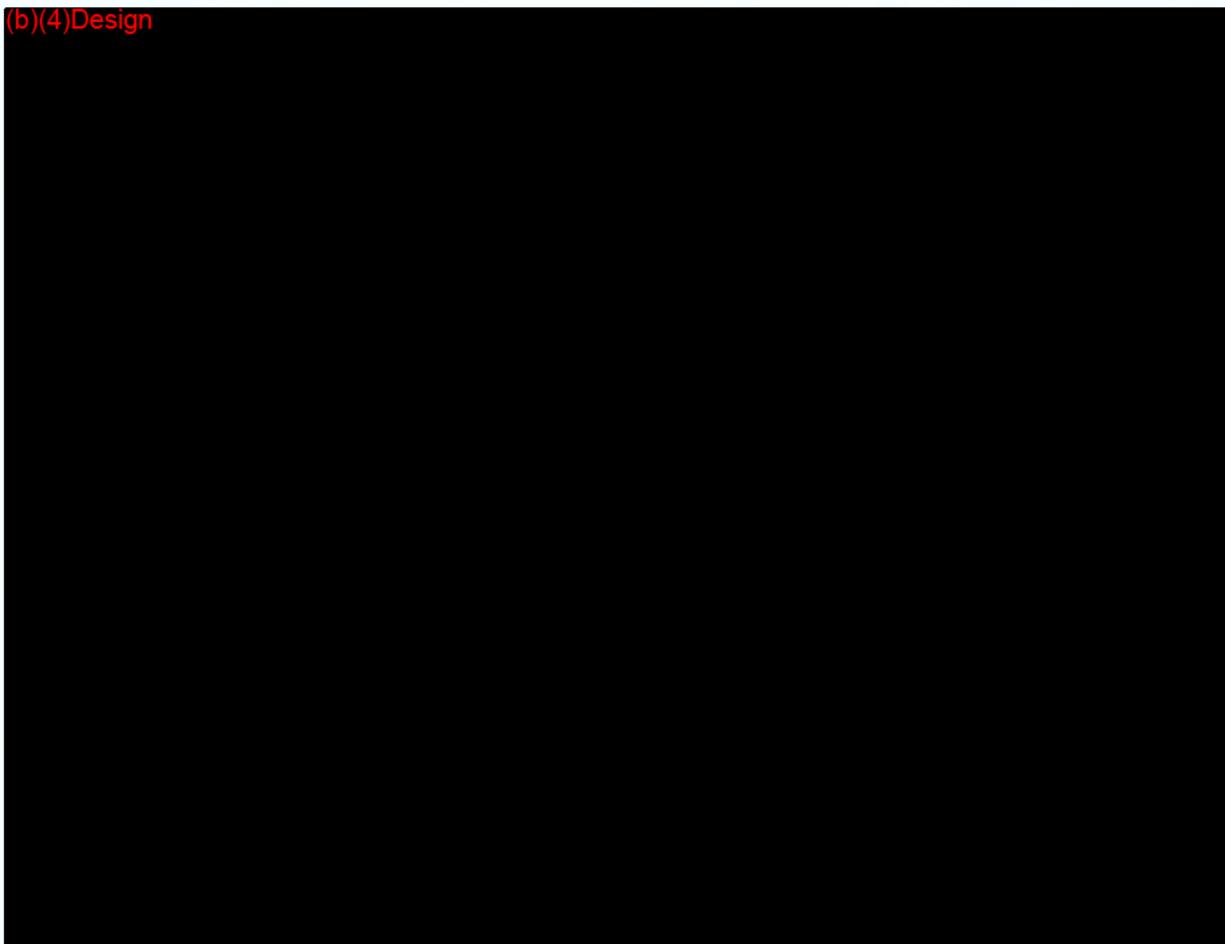
The Panoramic 200CAF and the predicate Panoramic 200 are capable of creating images (b) (4) 200° internal angle of the retina. Given that the Panoramic 200CAF and Panoramic 200 have the same angle of capture, both devices provide practitioners with the same field of view to diagnose and monitor diseases and disorders. (b) (4)

The signal strength varies as the laser beam is scanned across the retina, allowing an image to be created and recorded, revealing the variation in its constituent material and structures.

The eye is not continually exposed to the scanning beam. The patient looks into the instrument in semidarkness so that the eye becomes dark-adapted and the pupil opens. The shutter opens to allow the light to reach the eye to enable the instrument to capture one frame. The shutter then closes. This process has two advantages: (1) the eye does not respond to the light, and thus, the pupil remains wide open; and (2) the eye is exposed to laser light for a greatly reduced time.

See **Attachment 5** for the optical schematics of the Panoramic 200CAF.

(b)(4)Design [redacted] [redacted]



The above scanning function is housed in the 'scanhead' (see external schematic below). The scanhead is seated on a table that can move up and down and this affords a height adjustment to achieve correct patient positioning.



In terms of the display of the digitized data on a computer screen, the Panoramic 200CAF and P200 capture one image at a time and can present each image as a thumbnail sketch. If more than one image is captured, the Panoramic 200CAF and Panoramic 200 display a series of thumbnail sketches in the order in which they were scanned. The Panoramic 200CAF, like the P200, allows the user to view one or more images of the retina.

IV. Indications for Use (IFU): Deficient

Sponsor states that “the Optos Panoramic 200CAF is identical to the cleared Panoramic 200 (K983999) in intended use and indications for use”:

The Panoramic 200CAF scanning laser ophthalmoscope is indicated for use as a wide field ophthalmoscope for diagnosing and monitoring diseases or disorders that manifest themselves in the posterior pole of the eye.

Lead reviewer comment: The Indications for Use Statement should be revised to make clear that the device does not provide a diagnosis and is not intended as the sole source of diagnostic information for any ophthalmic condition. The following wording is suggested:

“The Panoramic 200CAF scanning laser ophthalmoscope is indicated for use as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest themselves in the retina.”

V. Predicate Device Comparison:

Predicates: P200 (K0983999)

Page 45/150 of the handbook submitted in K100644 describes the Optos family of scanning laser ophthalmoscopes (SLO's). Sponsor also provides (by email through Hogan & Hartson LLP) more detailed comparison information for Optos 200 series SLOs:

The P200CAF device, like several other members of the company's cleared SLO family of products (including the FDA cleared P200 device, K983999) contains only red and green lasers, and allows users to generate images that can be viewed either as a composite image (that is red and green combined) or as separate red channel and green channel images. Optos described the P200CAF device in the current submission as a modification of the cleared P200 device (resulting from new internal circuitry and incorporation of an additional filter). As such, the company reiterated that both the cleared P200 predicate device and the current P200CAF device utilize the same red and green lasers. To clarify the relationship between the various device versions and features, please see the following table:

Version	P200	P200a	P200ma	P200CAF
510(k) Number	K983999	K042001	K060424	K100644
Status	Cleared	Cleared	Cleared	Pending
Lasers	red, green	red, green, blue	red, green, blue	red, green
Image Type				
Red	yes	yes	yes	yes
Green	yes	yes	yes	yes
Blue	no	yes	yes	no
Composite	yes	yes	yes	yes
Fluorescein Angiography	no	yes	yes	no
Electronics Assembly	Version A	Version A	Version B	Version B
Key Differences	Base model	Added blue laser and fluorescein angiography capability	Added new electronics assembly	Provides ability to capture red and green laser images, and display autofluorescence images, using original lasers and updated electronics assembly

Seminaries:

The sponsor states that both the P200 and P200CAF Scanning Laser Ophthalmoscopes have the same mode of operation for imaging the posterior pole of the eye for viewing purposes. Specifically, information on the retina can be derived from:

1. the use of a red and a green laser as a source of illumination;
2. a deflection system to scan the laser beam in two orthogonal axes across the eye;
3. the use of the same deflection system to take the reflected light back through the optics to the light detectors; and
4. a computer to reconstruct, display, and store the image.

The light detector used for detecting the relatively weak autofluorescence signal has been changed to optimize the response, but the underlying principle of how the light detector works is unchanged.

The side-by side comparison is listed in Attachment 1a.

Attachment 1a: Substantial Equivalence

Manufacturer	Optos	Optos
Device	Panoramic 200	Panoramic 200CAF
Common Name	Scanning Laser Ophthalmoscope	Scanning Laser Ophthalmoscope
510k number	K983999	pending
Materials	No flammable materials are used near the light source.	No flammable materials are used near the light source.
Max. Temperature of accessible parts	Does not exceed ambient by more than 10°C.	Does not exceed ambient by more than 10°C.
Intended Use	To examine the retina of the eye	To examine the retina of the eye
Indications for Use	For aiding in diagnosing and monitoring disease and disorders that manifest themselves in the retina of the eye.	For aiding in diagnosing and monitoring disease and disorders that manifest themselves in the retina of the eye.
Method of Operation	Confocal laser scanning system; laser light source; deflection system; scans in two orthogonal axes of the retina; photosensitive device that converts light into image of retina; display system.	Confocal laser scanning system; laser light source; deflection system; scans in two orthogonal axes of the retina; photosensitive device that converts light into image of retina; display system.
Light Source	Laser	Laser
Wavelength and Color of Light	(b) (4)	(b) (4)
Exposure Parameters/laser class	Class 1	Class 1
Number of lasers Used per scan	2	1 or 2
Brightness Controls	Only after image has been taken	Only after image has been taken
Cleaning and disinfection/sterilization	Sterilization not required. Clean/ decontaminate contact points	Sterilization not required. Clean/ decontaminate contact points
Point of contact	Eye cushion	Facepad, chincup, and headrest
Data collection and/or display system	Light sensitive detector that converts light into electrical signal. Signal digitized and computer or electronic imaging device to convert digital image for display.	Light sensitive detector that converts light into electrical signal. Signal digitized and computer or electronic imaging device to convert digital image for display.
External field of view	(b) (4)	(b) (4)
Internal field of view	200°	200°
Wide Angle Digitized Image Size	2Kx2K pixels	3Kx3K pixels
Pupil Dilation	Normally not	Normally not
Eye Taping	Normally not	Normally not.
Mains current AC 115/240V	15A/7A	6.3A
Approx. weight	Scan head 70kg; table 100kg	Scan head 70kg; table 50kg

Differences:

The sponsor states:

The Panoramic 200CAF incorporates minor modifications as compared to the Panoramic 200 in the areas of imaging mode and system architecture. These modifications do not change the intended use of the device or alter the fundamental scientific technology. **Attachment 1b** provides a chart comparing each change, as well as the similarities, as compared to the cleared Panoramic 200. These modifications have been assessed by Optos for risk, and verification and validation evaluation/testing and results have been performed to certify that any identified risks do not change the intended use or fundamental technology of the device. The modifications are described in detail below.

Imaging Modes

- The Panoramic 200CAF has the capability of generating a digitized image size of 3K x 3K pixels, as compared to the Panoramic 200's digitized image size of 2K x 2K pixels for

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the same field of view.

- Panoramic 200CAF's greater resolution does not change the intended use of the device or alter the fundamental scientific technology. This is because the Panoramic 200CAF and the predicate device display retinal images on a computer screen using the same type of electronics. The Panoramic 200CAF's higher resolution just means that this device's images are potentially clearer.
- Additionally, the P200CAF is capable of a zoom mode that generates a close-up (~100% field of view). As above, the greater resolution does not change the intended use of the device and there are no safety issues as the device meets Class I at the eye in this imaging mode (as per 21 C.F.R. part 1040 and IEC 60825).
- The Panoramic 200CAF can generate an alternate red channel image which shows the natural fluorescence (also referred to as "autofluorescence") of the eye. (b) (4)

In this imaging mode, the red channel image now displays the naturally occurring fluorescent material of the retina, such as lipofuscin. The characteristics of autofluorescence are well understood, as described in published article (Attachement10)

In the "autofluorescence" imaging mode, the safety of the device is not affected as the light entering the eye is less than a standard red/green image, due to the fact that the red beam is blocked. In addition, the standard red image contains the "autofluorescence" information, but it is swamped by the light reflected by the illumination from the red laser.

The "autofluorescence" image shows the distribution of the naturally occurring fluorescent material by variations in light intensity across the image. This imaging mode can be used by the healthcare professional in conjunction with the standard composite (red/green) and the associated separated red and green channel images to aid in the diagnosing and monitoring of diseases and disorders that manifest themselves in the eye. Therefore, the introduction of the "autofluorescence" imaging mode does not change the intended use of the device or alter the fundamental scientific technology.

Lead reviewer comment: In order to support the substantial equivalence, the performance validation is required for any additional function. The 200CAF has a new function of displaying retinal autofluorescence imaging. Therefore, the validation test for autofluorescence imaging function is required. This concern is addressed in following deficiency:

Substantial Equivalence

You claim that the 200CAF has the capability of displaying retinal autofluorescence imaging. In order to support a decision regarding substantial equivalence, performance validation is required for this additional feature. This validation should demonstrate that the new feature

is effective and could not affect safety of the device as indicated relative to the predicate device. Therefore, please provide validation testing for the autofluorescence imaging function or provide rationale for not doing so.

Table

When compared to the P200 table, the P200CAF table no longer has the transformer resident to manage the power supply. In the P200CAF, the power is managed through the scan head. This makes the table lighter.

Gaze Angle

The gaze angle permits a different area of the retina to be viewed. This is possible in both the P200 and P200CAF. The additional periphery LEDs in the P200CAF assist in eye steering, but confirmation that the correct area has been imaged is made by viewing the image. The device still delivers a 200° field of view but a slightly different area can be imaged as, although wide angle, it is never a complete view of the eye.

The additional LEDs, which are included in the laser safety calculations, do not change the intended use of the device or alter the fundamental scientific technology.

User Interface

The user interface in terms of the mouse, monitor, and keyboard are similar for both the P200 and P200CAF. The P200CAF hand control has more buttons as the table position, and exposure button are resident. Button size for the P200 and P200CAF are comparable. Additionally, for the P200CAF hand control, the symbols indicating the key press function/direction are consistent with the Screen User Interface. The software contained with the scan head communicates within a windows environment in the case of the P200 but the P200CAF operates in a Linux environment. However both the P200 and the P200CAF display their images for review on a screen operating within a windows environment. Therefore these modifications do not change the intended use of the device or alter the fundamental scientific technology.

Laser Radiation Management System (LRM system)

The laser radiation management system resides on two field programmable gate arrays for both the P200 and the P200CAF, thus both units have redundancy in the firmware controlling laser exposure. In both models, the customer has no input or access to the laser radiation management software.

The P200CAF monitors the horizontal and vertical scan, whereas the P200 monitors the vertical scan only.

Both the P200 and the P200CAF have a single exposure shutter, but the P200CAF utilizes additional laser shutters on each wavelength channel.

The P200CAF firmware is different to the P200 firmware as different logic is required for the additional shutters and monitoring. However, the P200CAF assures that the laser classification is 1 at the eye for all permissible conditions (as is the case for P200). Upon detection of a fault condition both the P200 and P200CAF will not permit any exposures to be conducted. Therefore, modifications related to the Laser Radiation Management do not change the intended use of the device or alter the fundamental scientific technology.

Patient Alignment System (PAS), Patient Positioning and Personal Computer

The Panoramic 200CAF's patient places his or her head on a chin rest, his or her head against a head restraint and the side of the face comes into contact with a face pad. Optos' P200 utilizes a face cushion placed around the circumference of the aperture. All materials in contact with the patient meet biocompatibility requirements.

For both P200CAF and the P200, the device monitor or PC screen provide an assist to the practitioner via a picture of the eye afforded by a camera. The P200CAF gives a visual assist to the practitioner to correctly position the eye whereas the P200 is more dependent on the patient using an eye fixation pattern. With the P200CAF, the operator can adjust the height using the table and effect more finite positioning using the chinrest if the eye is not correctly positioned. With the Panoramic 200, the operator can only adjust the table if the eye is not correctly positioned. Upon correct positioning, for both devices, the hand control can then be pressed, which signals the device to capture the image. For both devices, the operator, who will see the image almost immediately, can then decide whether it is necessary to capture another image. Thus, eye placement for the Panoramic 200CAF does not change the intended use of the device or alter the fundamental scientific technology.

The side-by side comparison is listed in Attachment 1a.

Attachment 1b: Similarities and Differences between the P200 and the P200CAF

Category	Sub - category	P200	P200CAF	Risk Identification	Source of Risk Identification	Verification Activity
Functionality	Imaging Modes	RG imaging, 4M pixels (optomap)	RG imaging, 9M pixels (optomap) 'Zoom' mode available. Directed eye steering	The increase in the number of pixels has the potential for making the image clearer. The image is an aid to diagnosis and it is the practitioner who determines the suitability of the image for diagnosis. Directed eye steering has the potential to look at different wide-angle views of the retina but has no increase in the risk associated with viewing.	Change Request and Risk Assessment no. 684, Image Quality FMEA 69-79	Acceptance criteria: USAF 1951 resolution target used to Confirm 3K image at least as clear as 2K Pass, 3Kx3K displays at least the same number of line pairs Patient Alignment System [PAS] DV Pass
Functionality	Imaging Modes	There is no facility to generate images that display the natural fluorescence of the eye	Has an imaging mode where the red channel image is optimized to display the natural fluorescence of the eye.	The AF mode does not work-unable to acquire image. The translation stage has removed the required optical elements from the input path.	FMEA analysis item 53 FMEA analysis item 100	V&V activity for embedded software checked AF appears on GUI, red laser input path blocked, translation stage is in correct position and image acquisition possible Pass

Lead review comment:

The Panoramic 200CAF incorporates several modifications as compared to the Panoramic 200 in the areas of imaging mode and system architecture. These modifications do not change the intended use of the device or alter the fundamental scientific technology. These modifications have been assessed by Optos for risk, and verification and validation evaluation/testing and results have been performed to certify that the identified risks do not change the intended use or fundamental technology of the device.

We notice that the additional periphery LEDs have been used in the P200CAF assisting in eye steering. The sponsor states “the additional LEDs, which are included in the laser safety calculations, do not change the intended use of the device or alter the fundamental scientific technology. However, they do not provide the mentioned laser calculation in their submission. The sponsor should provide this information. This concern has been addressed in a deficiency of Performance testing – bench

V. Labeling: Deficient

The Introductory Handbook and proposed labels for the Panoramic 200CAF are provided in **Attachment 4** of this submission. The following modifications have been made to the labeling to accommodate the different capture mode for the P200CAF imaging mode:

- The introductory handbook references the autofluorescence imaging mode.
- The addition of a caution not to connect to a DICOM server as this facility is not in place at present.

Associated with the autofluorescence imaging mode, is a change to the graphical user interface that allows an optomap AF (this is the autofluorescence image descriptor) to be selected. A screen shot of this is appended in **Attachment 4**.

In addition, the application software used for review and management of images is the same, and there is commonality in the handbooks for this function. A comparison of the P200 and the P200CAF handbook for this functionality is made in **Attachment 4**. These modifications do not affect the device's intended use or fundamental scientific technology.

Lead Reviewer Comment: The labeling should be revised reflecting the modified IFU.

VI. Sterilization/Shelf Life/Reuse: Acceptable

The Panoramic 200CAF Ophthalmoscope does not require sterilization. Instructions for cleaning the device, including the chin rest and face pad are included in the Introductory Handbook (**Attachment 4**).

VII. Biocompatibility: Deficient

The sponsor states:

“The same material is used for the cushion in the P200 and the face pad in the P200CAF. As the P200CAF also has a chinrest and head support, two additional materials come into contact with the patient.

Specifically, the chincup is made of (b) (4) and the headrest of (b) (4)

As per ISO 10993, the contact is skin and for limited duration, requiring that Cytotoxicity, Sensitization, and Irritation or Intracutaneous reactivity is assessed. Both of the additional materials have been assessed for these effects and meet the relevant standards.”

Leader reviewer comment: The sponsor needs to provide the biocompatibility testing report of the additional materials. The testing should demonstrate your device complies with cited standards.

VIII. Software:

Optos is subject to design control. Software, risk analysis and the development process of this product also conforms to IEC 60601 entitled "Medical Electrical Equipment-Part1: General Requirements for Safety" and its collateral standard IEC 60601-1-4 entitled "Medical Electrical Equipment. General Requirements for safety. Collateral standard. General Requirements for programmable electrical medical systems." The above activities are defined in Optos' software development lifecycle work instruction (SP1013) and a brief description is given below.

- The software development lifecycle used by Optos is applied to systems developed by Optos for use by external customers and/or key to the functioning of the device.
- Systems developed by Optos for internal customers and related to a key process.
- Third-party systems customized or configured by Optos and related to a key process.

The software within the P200CAF was designed with a clear architecture to separate out the laser radiation management function from all other operational functions, as follows:

1. The Image Capture software resides within the system and on an integrated personal computer. This software allows the operator to select the type of image to be captured and controls the image capture process.
2. The Laser Radiation Management firmware resides on two integrated circuits (specifically field-programmable gate arrays). This firmware implements a finite state machine whose sole objective is to monitor exposure levels and automatically prevent an exposure being taken in the event that sensors deviate from tightly defined limits.
3. Application Software

This software allows the user to review single images, image sessions via thumbnail overviews, access image libraries, annotation features, 3D representation of the eye for patient education. There is also a scheduling and archiving facility.

This application software is the same for the P200CAF and the P200.

Optos has evaluated the level of concern for the Panoramic 200CAF software using the decision process outlined in FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005) and determined that the Panoramic 200CAF software presents a minor level of concern.

Lead reviewer comment:

The software is configured as three modules, including image capture, laser radiation management firmware and application. All three modules are evaluated to be at a minor level of concern, but are designed and documented according to requirements for moderate level of

concern. The development procedures, validation procedures and documentation appear satisfactory.

The laser radiation management scheme comprises of a series of modules that operate together to ensure that that eye-safe, Class I operation is maintained throughout normal use and in the event of foreseeable fault conditions. This is achieved by a combination of system monitors (laser power and scan parameters), digital electronics that determine if the system is safe and exposure control mechanisms.

Of particular note, an exhaustive analysis is provided of failure modes that could possibly expose the retina to excessive laser radiation and how these hazards have been mitigated. For laser safety, if any fault condition is detected, the following safety systems shall be enabled:

- Laser switch-off.
- Closure of all laser input shutters
- Closure of exposure shutter

No further exposure shall be permitted after a fault event has been detected without system power cycling.

No automatic diagnostic capabilities are included in the software, i.e., all diagnostic decisions must be made by a practitioner, with the SLO data serving as one of potentially many pieces of diagnostic information. Therefore, the Indications for Use Statement should be revised to make clear that the device does not provide a diagnosis and is not intended as the sole source of diagnostic information for any ophthalmic condition. The following wording is suggested:

“The Panoramic 200CAF scanning laser ophthalmoscope is indicated for use (IFU) as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest themselves in the retina.”

This concern has been included in an IFU deficiency.

IX. Performance Testing – Bench: Deficient

The sponsor claims the following bench testings have been performed:

Electrical Safety and Electromagnetic Compatibility:

The sponsor states:

The sponsor states that the Optos Panoramic 200CAF Ophthalmoscope complies with the following six consensus standards.

- IEC 60601-1 1988/A1:1991 Medical electrical equipment.A2:1995, Corrigendum 95 General requirements for safety.
- IEC 60825-1 Ed.2.0 (2007) Safety of Laser Products.
- IEC 60601-1-2:2007 Medical electrical equipment. General requirements for safety.

- Collateral standard. Electromagnetic Compatibility requirements and tests.
- IEC 60601-1-4 edition 1.1 2000-04 Medical electrical equipment. General requirements for safety. Collateral standard. General Requirements for programmable Electrical medical systems.
 - ISO 10993-5 Biological evaluation of medical Devices: Tests for In Vitro Cytotoxicity 1999 & 2009.
 - ISO 10993-10 2002 & Amendment 1, 2006.

Standards Data Report Forms and summary report for each listed recognized consensus standard are provided in Attachment 11.

Lead reviewer comment:

The sponsor does not provide any test report. The following information is requested:

- Please provide the report of electrical safety and electromagnetic compatibility testing or certificates. The testing results should demonstrate your device complies with IEC 6060-1 and IEC 60601-1-2.
- On page 16/140, you state that the additional periphery LEDs have been used in the P200CAF assisting in eye steering... and the additional LEDs, which are included in the laser safety calculations, do not change the intended use of the device or alter the fundamental scientific technology.

However, you do not provide such laser calculations (LEDs are included) in your submission. This information is very important in assessing the safety of use of your device. Please provide your radiation hazard analysis for the additional LEDs.

Please be advised that in the updated version of IEC 60825-1:2007, the LEDs has been removed from the scope of this Part 1. The optical radiation safety of LEDs in general can be more appropriately addressed by lamp safety standards (e.g., ANSI RP-27.1-05 – Photobiological Safety for Lamps and Lamp Systems-General Requirements) and/or 15004-2:2007, ISO 15004-2:2007 – Ophthalmic instruments – Fundamental requirements and test methods – Part 2: Light hazard protection. We recommend you perform the optical radiation hazard analysis for these additional LEDs by following the guidelines of test methods and light hazard protection requirements given in ISO15004- 2:2007.

- In Section XII- Biocompatible, you state that:

“The same material is used for the cushion in the P200 and the face pad in the P200CAF. As the P200CAF also has a chinrest and head support, two additional materials come into contact with the patient. Specifically, the chincup is made of (b) (4) [REDACTED]. As per ISO 10993, the contact is skin and for limited duration, requiring that Cytotoxicity, Sensitization, and Irritation or Intracutaneous reactivity is assessed. Both of the additional materials have been assessed for these effects and meet the relevant standards.”

However, you do not provide the biocompatibility testing report of the additional materials. Please provide your testing report. The testing should demonstrate your device complies with the cited standards.

X. Performance Testing – Animal:

Animal testing was not conducted for this application, as it is not needed to support substantial equivalence to the predicate device.

XI. Performance Testing – Clinical:

Clinical testing was not conducted for this application, as it is not needed to support substantial equivalence to the predicate device.

XII. Substantial Equivalence Discussion: TH

	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	X		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?		X	If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication: N/A
2. Explain why there is or is not a new effect or safety or effectiveness issue: N/A
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:

The software is configured as two modules, including image capture and management software and laser radiation management firmware. Both modules are evaluated to be at a minor level of concern, but are designed and documented according to requirements for moderate level of concern. The development procedures, validation procedures and documentation appear satisfactory. Of particular note, an exhaustive analysis is provided of failure modes that could possibly expose the retina to excessive laser radiation and how these hazards have been mitigated. No automatic diagnostic capabilities are included in the software, i.e., all diagnostic decisions must be made by a practitioner, with the SLO data serving as one of potentially many pieces of diagnostic information.

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:

The Indications for Use Statement should be revised to make clear that the device does not provide a diagnosis and is not intended as the sole source of diagnostic information for any ophthalmic condition. The labeling should be revised

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XIII. Deficiencies

The Following deficiencies have sent (by email) to the sponsor:

Indications for Use (IFU)

1. You proposed the following Indication for Use:

“The Panoramic 200CAF scanning laser ophthalmoscope is indicated for use as a wide field ophthalmoscope for diagnosing and monitoring diseases or disorders that manifest themselves in the posterior pole of the eye.”

However, it does not appear that your device has any automatic diagnostic capabilities. As such, all diagnostic decisions must be made by a practitioner, with the scanning laser ophthalmoscope (SLO) data serving as one of potentially many pieces of diagnostic information. Therefore, your IFU should be revised to indicate that the device does not provide a diagnosis and is not intended as the sole source of diagnostic information for any ophthalmic condition. Furthermore, the 200CAF has a new function of displaying retinal autofluorescence imaging, which should be added into IFU. Please modify your IFU accordingly. We recommend you modify your IFU similar to he following:

“The Panoramic 200CAF scanning laser ophthalmoscope is intended to be used as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.”

Please provide your revised IFU statement on the appropriate IFU form, and modify your 510(k) Summary and labeling accordingly.

Substantial Equivalence

2. You claim that the 200CAF has the capability of displaying retinal autofluorescence imaging. In order to support a decision regarding substantial equivalence, performance validation is required for this additional feature. This validation should demonstrate that the new feature is effective and could not affect safety of the device as indicated relative to the predicate device. Therefore, please provide validation testing for the autofluorescence imaging function or provide rationale for not doing so.

Performance Testing – Bench

3. On page 27/140, you state that “The Optos Panoramic 200CAF Ophthalmoscope complies with the following six consensus standards”:
 - IEC 60601-1 1988/A1:1991 Medical electrical equipment.A2:1995, Corrigendum 95 General requirements for safety;
 - IEC 60825-1 Ed.2.0 (2007) Safety of Laser Products;
 - IEC 60601-1-2:2007 Medical electrical equipment. General requirements for safety. Collateral standard. Electromagnetic Compatibility requirements and tests;
 - IEC 60601-1-4 edition 1.1 2000-04 Medical electrical equipment. General requirements for safety. Collateral standard. General Requirements for programmable Electrical medical systems;
 - ISO 10993-5 Biological evaluation of medical Devices: Tests for In Vitro Cytotoxicity 1999 & 2009; and
 - ISO 10993-10 2002 & Amendment 1, 2006.

However, you do not provide any test report. This information is important in evaluating your device performance. Please provide the following information:

- a. Please provide the report of electrical safety and electromagnetic compatibility testing or certificates. The testing results should demonstrate your device complies with IEC 60601-1 and IEC 60601-1-2, as indicated in your submission.
- b. On page 16/140, you state that the additional periphery light emitting diodes (LEDs) have been used in the P200CAF assisting in eye steering, and the additional LEDs, which are included in the laser safety calculations, do not change the intended use of the device or alter the fundamental scientific technology. However, you do not provide such laser calculations in your submission. This information is very important in assessing the

safety of use of your device. Please provide your radiation hazard analysis for the additional LEDs.

Please be advised that in the updated version of IEC 60825-1:2007, LEDs has been removed from the scope of Part 1. Please be advised that the optical radiation safety of LEDs, in general, may be appropriately addressed by lamp safety standards (e.g., ANSI RP-27.1-05 –Photobiological Safety for Lamps and Lamp Systems-General Requirements) and/or 15004-2:2007, ISO 15004-2:2007 – Ophthalmic instruments – Fundamental requirements and test methods – Part 2: Light hazard protection.

- c. In Section XII (Biocompatibility), you state that “The same material is used for the cushion in the P200 and the face pad in the P200CAF. As the P200CAF also has a chinrest and head support, two additional materials come into contact with the patient. Specifically, the chincup is made of Eastar Copolyester MN006 and the headrest of Dyneon 1620 PTFE. As per ISO 10993, the contact is skin and for limited duration, requiring that Cytotoxicity, Sensitization, and Irritation or Intracutaneous reactivity is assessed. Both of the additional materials have been assessed for these effects and meet the relevant standards.” However, you do not provide the biocompatibility testing report of the additional materials. Please provide your testing report. The testing should demonstrate your device complies with the cited standards.

510(k) Summary

- 4. On page 38/140, you provide a single page 510(k) Summary. The information you provide is not sufficient as you only include the information of device modifications. However you should revise your 510(k) Summary to include a summary of how the technological characteristics of your device are different comparing to the predicate device. Please revise your 510k summary accordingly. We recommend that you use the following in drafting a new 510(k) Summary:

Sec. 807.92 Content and format of a 510(k) summary, at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=807.92>

For reference, we recommend you prepare your 510(k) Summary by using the following checklist.

510(k) SUMMARY REQUIREMENTS CHECKLIST 21 CFR 807.92				
		Y	N	N/A
All 510(k) summaries shall contain the following information:				
1	The submitter's name, address, telephone number, a contact person, and the date the summary was prepared			
2	The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name			

3	An identification of the legally marketed device(s) to which the submitter claims equivalence.			
4	A description of the device that is the subject of the 510(k), including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device (e.g., device design, material used, and physical properties)			
5	A statement of the indications for use of the device that is the subject of the 510(k), including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is indicated. Or, if the indication statements are different from those of the legally marketed device(s) identified in paragraph (3) of this section, an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, surgical or other use of the device, and why the differences do not affect the safety and effectiveness of the device when used as indicated.			
6	If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source, etc.) as the predicate device(s) identified in paragraph(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified in paragraph (3) of this section.			
510(k) summaries for those 510(k)s in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information				
7	A brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence			
8	A summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. (There can not be any patient identifier information in the summary.)			
9	The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs at least as safely and effectively as the legally marketed device identified in paragraph(3) of this section.			

Labeling

5. You use one Introductory Handbook for three models of P200MA (060624), P200C and P200CAF (K100644), and provide an intended use statement. Please address the following related concerns:
 - a. Please clarify whether the P200C is an FDA-cleared device. If so, please provide the 510(k) number under which it was cleared.

- b. We note that the intended use for P200MA and P200CAF are slightly different, We recommend you provide the intended use for each mode separately. We also recommend you make the intended use a separate section with a title of Intended Use for clarity. Please revise your labeling accordingly.
- c. Please revise your labeling for P200CAF to reflect the modification to Indications for Use and include the radiation hazard from the additional LEDs, if any.

Please provide a red-lined copy of labeling, clearly denoting any changes as requested above, so the changes to the labeling can be identified and reviewed more easily.

Contact History

On April 1, the sponsor was contacted by email (through Hogan & Hartson LLP) that we do not believe this submission qualifies for review as a Special 510(k) and will be converted to a Traditional 510(k) accordingly (see attached email).

On 4/13/2010, Mr. Randy Prebula, Director of Regulatory Sciences of Hogan & Hartson LLP provided (by email) the following clarification about the P200CAF device and the company's previously cleared scanning laser ophthalmoscopes ("SLOs") (see attache email information).

On May 4, 2010, the sponsor was informed, by email, that this submission is being placed on telephone hold (TH), additional information is required.

Recommendation: TH

Trade Name: Panoramic 200CAF
 Regulation Number: 21 CFR 886.1570
 Regulation Name: Scanning Laser Ophthalmoscope
 Regulation Class: Class II
 Product Code: MYC

Dexiu Shi		05/04/2010
Reviewer		Date
		05/04/2010
Branch Chief		Date

Shi, Dexiu

From: Shi, Dexiu
Sent: Tuesday, May 04, 2010 3:33 PM
To: Rjprebula@Hhlaw.Com; 'hnholstein@hhlaw.com'
Cc: Cunningham, Bradley; Shi, Dexiu
Subject: K100644- Optos Limited Panoramic 200CAF
Attachments: K100644 - FDA TH Memo.pdf

Dear Mr. Prebula:

Thank you for your submission regarding the above 510(k). We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided (including the information in your email of 04/15/2010). To complete the review of your submission, we require additional information. The submission is being placed on hold. Please refer to the attached PDF file for the required additional information. Please provide your acknowledge receipt of this memo.

If you have any questions, please contact me at (301) 796-6620 or at dexiu.shi@fda.hhs.gov.

Regards,

Dexiu Shi, Ph.D., Physicist and Biomedical Engineer
Ophthalmic Lasers, Neurostimulators,
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This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed. This e-mail message is intended for the exclusive use of the recipient named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at dexiu.shi@fda.hhs.gov or call (310) 796-6470.

5/4/2010

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: May 4, 2010

From: Dexiu Shi, Ph. D.
Lead Reviewer
Ophthalmic Lasers, Neurostimulators & Diagnostic Devices Branch
Division of Ophthalmic, Neurological and ENT Devices
Center for Devices and Radiological Health

To: Randy Prebula
c/o Optos PLC
Director of Regulatory Sciences
Hogan & Hartson LLP
555 Thirteenth Street, NW
Washington, DC 20004
Rjprebula@Hhlaw.Com

Re: K100644
Device Name: Optos Limited Panoramic 200CAF
Dated: March 5, 2010
Received: March 5, 2010

Dear Mr. Prebula:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. This submission is being placed on hold. To complete the review of your submission, we require the following additional information:

Indications for Use (IFU)

1. You proposed the following Indication for Use:

“The Panoramic 200CAF scanning laser ophthalmoscope is indicated for use as a wide field ophthalmoscope for diagnosing and monitoring diseases or disorders that manifest themselves in the posterior pole of the eye.”

However, it does not appear that your device has any automatic diagnostic capabilities. As such, all diagnostic decisions must be made by a practitioner, with the scanning laser

ophthalmoscope (SLO) data serving as one of potentially many pieces of diagnostic information. Therefore, your IFU should be revised to indicate that the device does not provide a diagnosis and is not intended as the sole source of diagnostic information for any ophthalmic condition. Furthermore, the 200CAF has a new function of displaying retinal autofluorescence imaging, which should be added into IFU. Please modify your IFU accordingly. We recommend you modify your IFU similar to the following:

“The Panoramic 200CAF scanning laser ophthalmoscope is intended to be used as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.”

Please provide your revised IFU statement on the appropriate IFU form, and modify your 510(k) Summary and labeling accordingly.

Substantial Equivalence

2. You claim that the 200CAF has the capability of displaying retinal autofluorescence imaging. In order to support a decision regarding substantial equivalence, performance validation is required for this additional feature. This validation should demonstrate that the new feature is effective and could not affect safety of the device as indicated relative to the predicate device. Therefore, please provide validation testing for the autofluorescence imaging function or provide rationale for not doing so.

Performance Testing – Bench

3. On page 27/140, you state that “The Optos Panoramic 200CAF Ophthalmoscope complies with the following six consensus standards”:
 - IEC 60601-1 1988/A1:1991 Medical electrical equipment.A2:1995, Corrigendum 95 General requirements for safety;
 - IEC 60825-1 Ed.2.0 (2007) Safety of Laser Products;
 - IEC 60601-1-2:2007 Medical electrical equipment. General requirements for safety. Collateral standard. Electromagnetic Compatibility requirements and tests;
 - IEC 60601-1-4 edition 1.1 2000-04 Medical electrical equipment. General requirements for safety. Collateral standard. General Requirements for programmable Electrical medical systems;
 - ISO 10993-5 Biological evaluation of medical Devices: Tests for In Vitro Cytotoxicity 1999 & 2009; and
 - ISO 10993-10 2002 & Amendment 1, 2006.

However, you do not provide any test report. This information is important in evaluating your device performance. Please provide the following information:

- a. Please provide the report of electrical safety and electromagnetic compatibility testing or certificates. The testing results should demonstrate your device complies with IEC 6060-1 and IEC 60601-1-2, as indicated in your submission.
- b. On page 16/140, you state that the additional periphery light emitting diodes (LEDs) have been used in the P200CAF assisting in eye steering, and the additional LEDs, which are included in the laser safety calculations, do not change the intended use of the device or alter the fundamental scientific technology. However, you do not provide such laser calculations in your submission. This information is very important in assessing the safety of use of your device. Please provide your radiation hazard analysis for the additional LEDs.

Please be advised that in the updated version of IEC 60825-1:2007, LEDs has been removed from the scope of Part 1. Please be advised that the optical radiation safety of LEDs, in general, may be appropriately addressed by lamp safety standards (e.g., ANSI RP-27.1-05 –Photobiological Safety for Lamps and Lamp Systems-General Requirements) and/or 15004-2:2007, ISO 15004-2:2007 – Ophthalmic instruments – Fundamental requirements and test methods – Part 2: Light hazard protection.

- c. In Section XII (Biocompatibility), you state that “The same material is used for the cushion in the P200 and the face pad in the P200CAF. As the P200CAF also has a chinrest and head support, two additional materials come into contact with the patient. Specifically, the chinrest is made of (b) (4) and the headrest of (b) (4). As per ISO 10993, the contact is skin and for limited duration, requiring that Cytotoxicity, Sensitization, and Irritation or Intracutaneous reactivity is assessed. Both of the additional materials have been assessed for these effects and meet the relevant standards.” However, you do not provide the biocompatibility testing report of the additional materials. Please provide your testing report. The testing should demonstrate your device complies with cited standards.

510(k) Summary

4. On page 38/140, you provide a single page 510(k) Summary. The information you provide is not sufficient as you only include the information of device modifications. However you should revise your 510(k) Summary to include a summary of how the technological characteristics of your device are different comparing to the predicate device. Please revise your 510k summary accordingly. We recommend that you use the following in drafting a new 510(k) Summary:

Sec. 807.92 Content and format of a 510(k) summary, at
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=807.92>

For reference, we recommend you prepare your 510(k) Summary by using the following checklist.

510(k) SUMMARY REQUIREMENTS CHECKLIST 21 CFR 807.92				
		Y	N	N/A
All 510(k) summaries shall contain the following information:				
1	The submitter's name, address, telephone number, a contact person, and the date the summary was prepared			
2	The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name			
3	An identification of the legally marketed device(s) to which the submitter claims equivalence.			
4	A description of the device that is the subject of the 510(k), including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device (e.g., device design, material used, and physical properties)			
5	A statement of the indications for use of the device that is the subject of the 510(k), including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is indicated. Or, if the indication statements are different from those of the legally marketed device(s) identified in paragraph (3) of this section, an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, surgical or other use of the device, and why the differences do not affect the safety and effectiveness of the device when used as indicated.			
6	If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source, etc.) as the predicate device(s) identified in paragraph(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified in paragraph (3) of this section.			
510(k) summaries for those 510(k)s in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information				
7	A brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence			
8	A summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. (There can not be any patient identifier information in the summary.)			
9	The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs at least as safely and effectively as the legally marketed device identified in paragraph(3) of this section.			

Labeling

5. You use one Introductory Handbook for three models of P200MA (060624), P200C and P200CAF (K100644), and provide an intended use statement. Please address the following related concerns:
 - a. Please clarify whether the P200C is an FDA-cleared device. If so, please provide the 510(k) number under which it was cleared.
 - b. We note that the intended use for P200MA and P200CAF are slightly different, We recommend you provide the intended use for each mode separately. We also recommend you make the intended use a separate section with a title of Intended Use for clarity. Please revise your labeling accordingly.
 - c. Please revise your labeling for P200CAF to reflect the modification to Indications for Use and include the radiation hazard from the additional LEDs, if any.

Please provide a red-lined copy of labeling, clearly denoting any changes as requested above, so the changes to the labeling can be identified and reviewed more easily.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "Guidance for Industry and FDA Staff: FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>.

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

Page 6 – Mr. Randy Prebula

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Dexiu Shi, Ph. D at (301) 796-6470.

From: Prebula, Randy J. [RJPrebula@HHLAW.com]
Sent: Tuesday, April 13, 2010 8:09 AM
To: Shi, Dexiu; Holstein, Howard M.
Cc: Cunningham, Bradley; Robert Tweedlie
Subject: RE: K100644 - Optos Limited Panoramic 200CAF
Dear Dr. Shi,

Thank you for contacting Hogan & Hartson regarding the above-referenced 510(k) submission (K100644) for Optos, Ltd.'s P200CAF device. We understand from your electronic mail message that the Food and Drug Administration ("FDA" or the "Agency") has converted the submission from a Special 510(k) notice to a Traditional 510(k) Notice based, primarily, on the Agency's belief that the modified P200CAF device includes "new scientific technologies of capturing angiography images and autofluorescence" images as modifications that "affect the intended use of the device." FDA also noted that the use of the P200CAF for collection of angiography images and the use of the autofluorescence mode could require additional data.

Based on these statements, Optos has requested that we contact you to provide some clarification about the P200CAF device and the company's previously cleared scanning laser ophthalmoscopes ("SLOs"). Specifically, please note that the P200CAF device that is described in the 510(k) Notice does not include a blue laser and is not capable of generating fluorescein angiograph images. Rather, it is the company's Optos P200a device, which was cleared by FDA under 510(k) submission K042001, that contains both the blue laser and the ability to obtain fluorescein angiography images. With the addition of new internal circuitry, the P200MA was cleared under a Special 510k (K060424), using the cleared P200a model as the predicate.

Page 45/150 of the handbook submitted in K100644 describes the Optos family of scanning laser ophthalmoscopes (SLO's). The device referenced on page 45 as containing a blue laser and capable of fluorescein angiography is the P200MA and not the P200CAF.

Rather, the P200CAF device, like several other members of the company's cleared SLO family of products (including the FDA cleared P200 device, K983999) contains only red and green lasers, and allows users to generate images that can be viewed either as a composite image (that is red and green combined) or as separate red channel and green channel images. Optos described the P200CAF device in the current submission as a modification of the cleared P200 device (resulting from new internal circuitry and incorporation of an additional filter),. As such, the company reiterated that both the cleared P200 predicate device and the current P200CAF device utilize the same red and green lasers. To clarify the relationship between the various device versions and features, please see the following table:

Version	P200	P200a	P200ma	P200CAF
510(k) Number	K983999	K042001	K060424	K100644
Status	Cleared	Cleared	Cleared	Pending
Lasers	red, green	red, green, blue	red, green, blue	red, green
Image Type				
Red	yes	yes	yes	yes
Green	yes	yes	yes	yes
Blue	no	yes	yes	no
Composite	yes	yes	yes	yes
Fluorescein Angiography	no	yes	yes	no
Electronics Assembly	Version A	Version A	Version B	Version B
Key Differences	Base model	Added blue laser and fluorescein angiography	Added new electronics assembly	Provides ability to capture red and green laser images, and display autofluorescence images, using original lasers and

capability

updated electronics
assembly

Please let us know if this additional information is helpful in addressing your questions and whether, with the clarification, the 510(k) submission could be reviewed under the originally requested Special 510(k) pathway. We also look forward to addressing any questions you may have regarding the P200CAF submission.

Sincerely,

Randy Prebula

RANDY PREBULA, DIRECTOR OF REGULATORY SCIENCES
HOGAN & HARTSON LLP
Columbia Square, 555 Thirteenth Street, NW, Washington, DC 20004
direct +1.202.637.6548 | tel +1.202.637.5600 | fax +1.202.637.5910
rjprebula@hhlaw.com | <http://www.hhlaw.com>

Please consider the environment before printing this e-mail.

From: Shi, Dexiu [mailto:Dexiu.Shi@fda.hhs.gov]
Sent: Thursday, April 01, 2010 3:25 PM
To: Holstein, Howard M.; Prebula, Randy J.
Cc: Cunningham, Bradley; Shi, Dexiu
Subject: K100644 - Optos Limited Panoramic 200CAF

Dear Mr. Holstein:

We have completed a preliminary review of your Section 510(k) premarket notification. You make a number of device modifications, which you state "...do not change the intended use of the device or alter its fundamental scientific technology." However, we have identified changes in the labeling:

On page 45/140, Attachment 4, you state that the P200CAF use red and green lasers to produce a digital, high-resolution image, which is displayed on a PC monitor screen.

1. Red and green lasers are used for digital color imaging. These laser wavelengths retinal structures to different depths, each wavelength providing information for interpretation and diagnosis.
2. The blue laser is used when capturing angiography images. A series of images is captured as the fluorescein flows through the retinal vessels.
3. In autofluorescence mode, the P200CAF uses only the green laser to illuminate the eye. This allows an image of the natural fluorescence of the eye to be captured. No fluorescent dye has to be introduced into the patient.

The predicate device only provides the capabilities of capturing and displaying the color image of the retina. Number 2 and 3, above, are new capacities/features. We believe the new scientific technologies of capturing angiography images and autofluorescence mode are the labeling changes that affect the intended use of the device.

In addition, your device is intended to be used for diagnosing and monitoring diseases or disorders that manifest in the posterior pole of the eye. In order to test the validity of the angiography image and autofluorescence mode, clinical performance testing may be required.

Based on the above changes and related concerns, we do not believe your submission quali for review as a Special 510(k) and will be converted to a Traditional 510(k) accordingly. V may require some additional information after having the in-depth review. If you have any questions, please contact me.

Regards,

Dexiu Shi

Dexiu Shi, Ph.D., Physicist and Biomedical Engineer
Ophthalmic Lasers, Neurostimulators,
and Diagnostics Devices Branch
FDA/CDRH/ODE
10903 New Hampshire Ave.
Building 66, Rm 2246
Silver Spring, MD 20993-0002
Phone: 301-796-6470
Fax: 301-847-8127
dexiu.shi@fda.hhs.gov

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed. This e-mail message is intended for the exclusive use of the recipient named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at dexiu.shi@fda.hhs.gov or call (310) 796-6470.

This electronic message transmission contains information from this law firm which may be confidential or privileged. The information is intended to be for the use of the individual or entity named above. If you are not the intended recipient, be aware that any disclosure, copying, distribution or use of the contents of this information is prohibited.

If you have received this electronic transmission in error, please notify us by telephone (+1-202-637-5600) or by electronic mail (PostMaster@HHLAW.COM) immediately.

Shi, Dexiu

From: Shi, Dexiu
Sent: Thursday, April 01, 2010 3:25 PM
To: hmholstein@hhlaw.com; Prebula, Randy J.
Cc: Cunningham, Bradley; Shi, Dexiu
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Based on the above changes and related concerns, we do not believe your submission qualifies for review as a Special 510(k) and will be converted to a Traditional 510(k) accordingly. We may require some additional information after having the in-depth review. If you have any questions, please contact me.

Regards,

Dexiu Shi

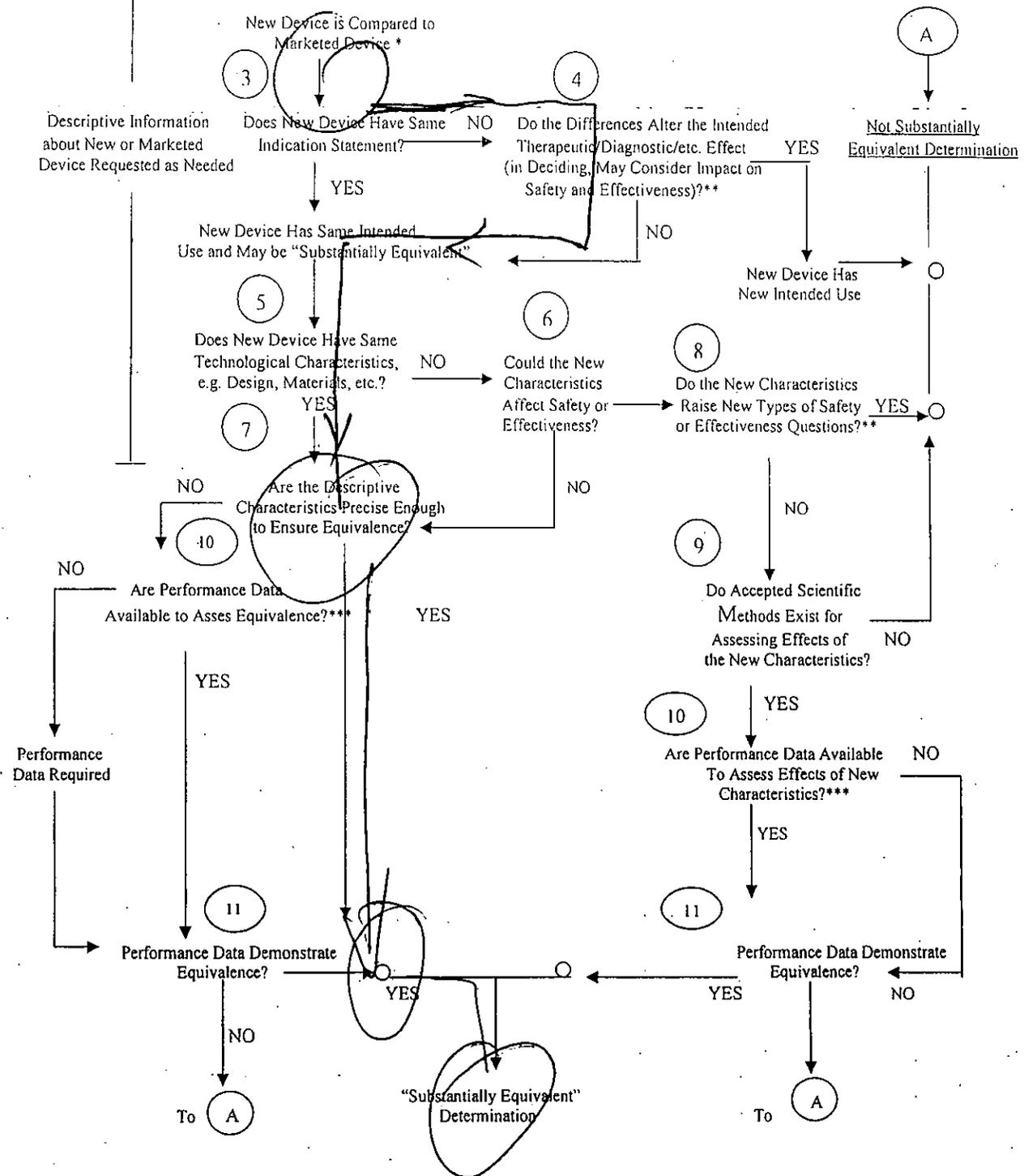
5/3/2010

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Dexiu Shi, Ph.D., Physicist and Biomedical Engineer
Ophthalmic Lasers, Neurostimulators,
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Silver Spring, MD 20993-0002
Phone: 301-796-6470
Fax: 301-847-8127
dexiu.shi@fda.hhs.gov

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed. This e-mail message is intended for the exclusive use of the recipient named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at dexiu.shi@fda.hhs.gov or call (310) 796-6470.

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- ❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- ❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

June 15, 2010

By Hand Delivery and Electronic Mail

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

FDA CDRH DMC

JUN 15 2010

Received

Attn: Dexiu Shi, Ph.D. (Room 2246)

Re: Response to FDA's Request for Additional Information Regarding the Optos Limited Panoramic 200CAF (K100644)

Dear Dr. Shi:

As regulatory counsel to Optos Limited ("Optos" or "the company"), Hogan Lovells US LLP (formerly Hogan & Hartson LLP) is filing this response to the Food and Drug Administration's ("FDA" or "the agency") May 4, 2010, e-mail requesting additional information regarding the Panoramic 200CAF (K100644) ("P200CAF" or "the device"). For ease of review, the items from the agency's May 4, 2010, e-mail are reproduced in italics below, followed by the company's response to each. We trust that this response provides the information needed for the agency to proceed with the review of the company's 510(k) submission.

Indications for Use (IFU)

1. You proposed the following Indication for Use:

"The Panoramic 200CAF scanning laser ophthalmoscope is indicated for use as a wide field ophthalmoscope for diagnosing and monitoring diseases or disorders that manifest themselves in the posterior pole of the eye."

However, it does not appear that your device has any automatic diagnostic capabilities. As such, all diagnostic decisions must be made by a practitioner, with the scanning laser ophthalmoscope (SLO) data serving as one of potentially many pieces of diagnostic information. Therefore, your IFU should be revised to indicate that the device does not provide a diagnosis and is not intended as the sole source of diagnostic information for any ophthalmic condition. Furthermore, the 200CAF has a new function of displaying retinal autofluorescence imaging, which should be added into IFU. Please modify your IFU accordingly. We recommend you modify your IFU similar to the following:

"The Panoramic 200CAF scanning laser ophthalmoscope is intended to be used as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina."

Please provide your revised IFU statement on the appropriate IFU form, and modify your 510(k) Summary and labeling accordingly.

meets the requirements of group 1, and no change to the primary or secondary device labeling is required.

* * *

The company believes that this response fully addresses the issues raised in the agency's May 4, 2010, e-mail. We trust that the information provided is sufficient for the agency to find the P200CAF substantially equivalent to its predicate devices for the listed indication. If you have any further questions, please contact me at the number below or Randy Prebula at 202-637-6548. Upon clearance of the device please forward the substantial equivalence letter to me by facsimile to 202-637-5910.

Sincerely,

Handwritten signature in blue ink that reads "Howard M. Holstein" followed by a stylized initial "HCU".

Howard M. Holstein

Partner

howard.holstein@hoganlovells.com

D (202) 637-5813

Attachments

cc: Robert Tweedlie, Optos Ltd.
Randy Prebula, Hogan Lovells US LLP
Danielle C. Woodlee, Hogan Lovells US LLP

June 15, 2010

By Hand Delivery and Electronic Mail

U.S. Food and Drug Administration
Center for Devices and Radiological Health
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1. *You proposed the following Indication for Use:*

"The Panoramic 200CAF scanning laser ophthalmoscope is indicated for use as a wide field ophthalmoscope for diagnosing and monitoring diseases or disorders that manifest themselves in the posterior pole of the eye."

However, it does not appear that your device has any automatic diagnostic capabilities. As such, all diagnostic decisions must be made by a practitioner, with the scanning laser ophthalmoscope (SLO) data serving as one of potentially many pieces of diagnostic information. Therefore, your IFU should be revised to indicate that the device does not provide a diagnosis and is not intended as the sole source of diagnostic information for any ophthalmic condition. Furthermore, the 200CAF has a new function of displaying retinal autofluorescence imaging, which should be added into IFU. Please modify your IFU accordingly. We recommend you modify your IFU similar to the following:

"The Panoramic 200CAF scanning laser ophthalmoscope is intended to be used as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina."

Please provide your revised IFU statement on the appropriate IFU form, and modify your 510(k) Summary and labeling accordingly.

Response: After careful consideration of FDA's concerns outlined above, the company has modified the indications for use for the P200CAF to reflect the fact that the device does not have any diagnostic capabilities and to reference the autofluorescence imaging mode. The revised indications for use are as follows:

The Panoramic 200CAF scanning laser ophthalmoscope is intended to be used as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.

The company's revised Indications for Use Statement is provided in **Attachment 1**.

Substantial Equivalence

2. You claim that the 200CAF has the capability of displaying retinal autofluorescence imaging. In order to support a decision regarding substantial equivalence, performance validation is required for this additional feature. This validation should demonstrate that the new feature is effective and could not affect safety of the device as indicated relative to the predicate device. Therefore, please provide validation testing for the autofluorescence imaging function or provide rationale for not doing so.

Response: To thoroughly address the agency's concerns outlined above, the company is providing the following rationale and validation testing to demonstrate that the device's ability to capture images using the autofluorescence mode has no affect on the safety and efficacy of the device.

Performance Validation

The autofluorescence mode does not affect the safety of the P200CAF as compared to the predicate device. Both the P200CAF and the P200 use the same red and green lasers, and both devices are capable of generating composite red/green images. In autofluorescence mode (this mode only being available in the P200CAF and not the P200 predicate), the red laser is blocked causing less light to enter the eye. In standard red/green imaging mode, both the P200 and the P200CAF have the autofluorescence information contained in the red channel but this signal is swamped by the red reflectance signal. In the P200CAF autofluorescence mode, the red laser is blocked and some optical elements are removed in the return path to optimize the autofluorescence signal. Because less light enters the eye in autofluorescence mode, with the only other change being in the return path, the use of this mode does not affect the safety of the device.

In addition to meeting consensus standard requirements defined in item 3, below, the P200CAF underwent release performance testing. An example of this testing is contained within the attached certificate of release (see next page). This testing includes electrical safety testing, confirmation that the laser radiation management software prohibits disallowed states (such as shutter remaining open), red and green laser power measurements and eye images (both composite red/green and autofluorescence) as a simulation of end use. The composite red/green image quality of the P200CAF and its predicate, the P200, were assessed against comparable acceptance criteria.

The effectiveness of the autofluorescence image is determined by the following rationale and associated images:

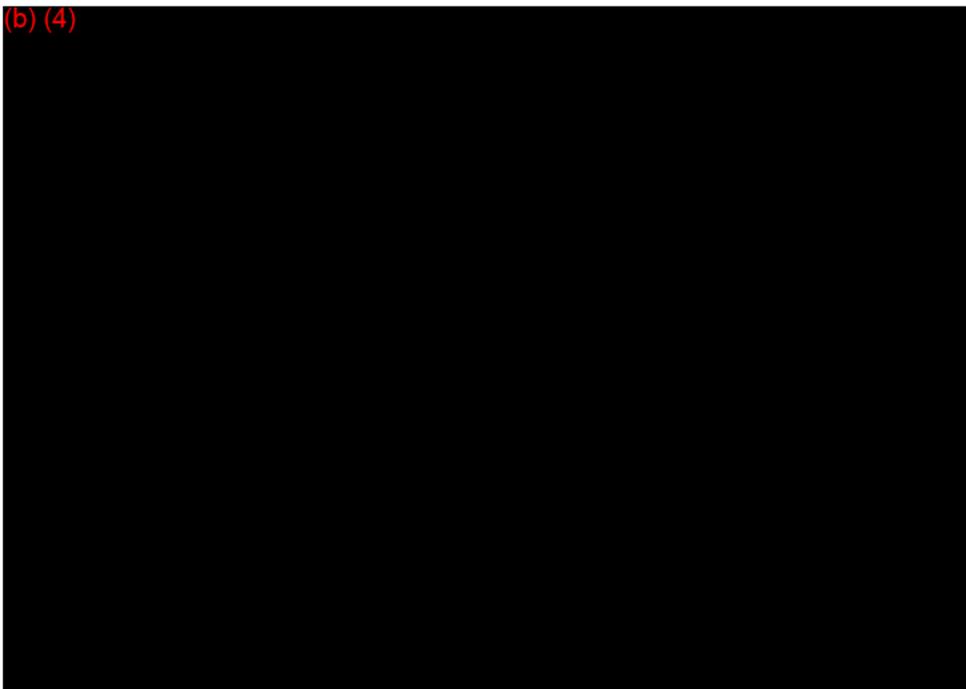
The mechanism, excitation and emission wavelengths that cause autofluorescence are well understood. Specifically, autofluorescence imaging of the retina involves capturing a response from molecules in the retinal pigment epithelium (RPE). The most significant naturally occurring fluorophore is lipofuscin.

The excitation wavelengths of lipofuscin range from approximately (b) (4) nm, with emissions ranging from (b) (4) nm. The P200CAF's configuration includes a green wavelength of (b) nm with a barrier filter of (b) nm for the return path, and is within the specified operating window.

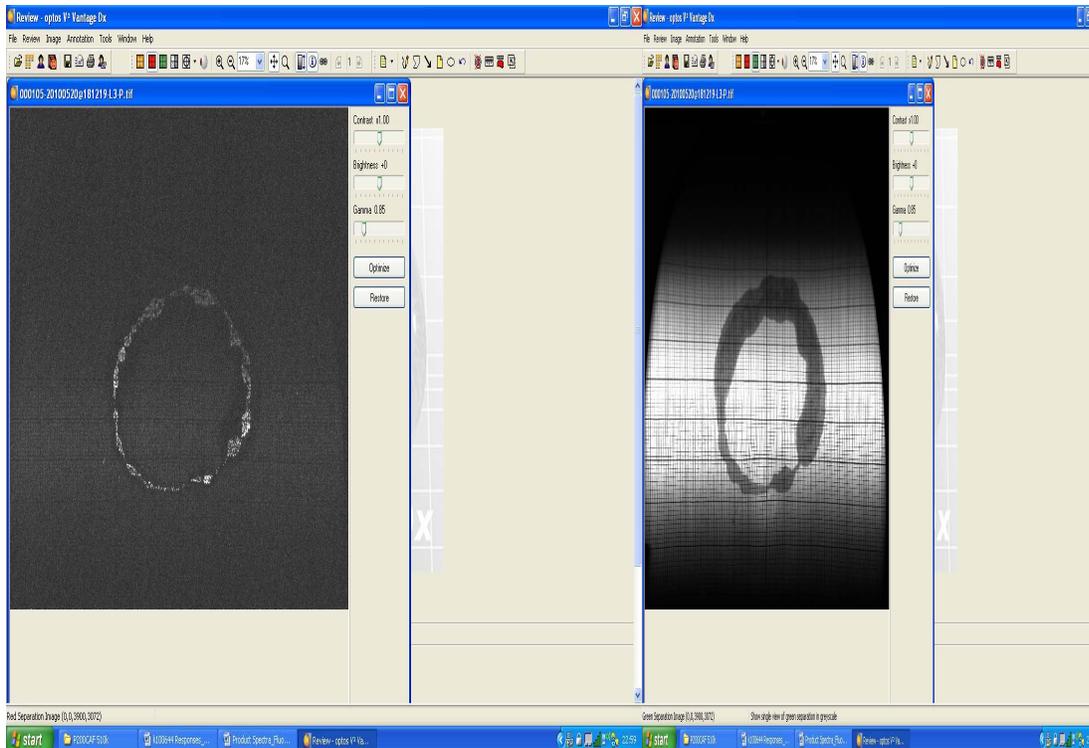
The above mechanism of operation can be verified using red fluorescent microspheres that support excitation at (b) nm and emit in the red spectrum. These 'fluospheres' have the following spectral characteristics and are a close match to the excitation and emission characteristics of lipofuscin:

Product Spectra - FluoSpheres red fluorescent microspheres/H₂O.

Fluorescence excitation and emission spectra of FluoSpheres red fluorescent microspheres in H₂O.

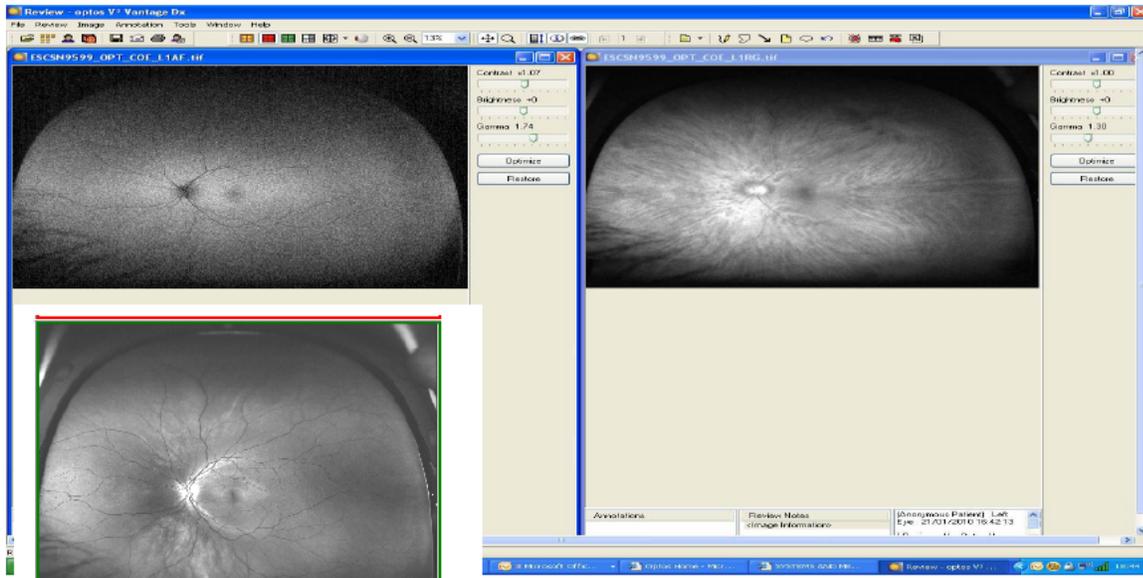


Applying these fluospheres in a circle on graph paper and immediately examining the red channel in autofluorescence imaging mode verifies that the red fluorescence of these spheres is visible (with the grid less so), whereas in the green channel, full reflectance is seen including the water mark and the grid where the spheres were applied (left and right pictures respectively). Because these fluorophores are excited by laser light and emit fluorescence at the same range of wavelengths as the lipofuscin present in the human retina, these images provide an *ex vivo* method of assessing the reproducibility of the P200CAF scanning laser ophthalmoscope in obtaining reproducible autofluorescent images.



Additionally, once the graph paper had dried, thirty such images were generated over 3 days indicating that the excitation and emission of fluospheres, which simulate lipofuscin spectral characteristics, can be captured in a reproducible manner. These images show little difference in appearance although it should be noted the fluospheres deteriorate over time (see **Attachment 2**).

In terms of the human eye, the figure below illustrates the difference in images generated in autofluorescence mode (top left), which is seen in the red channel, a red reflectance image (top right), which is also seen in the red channel when the red laser is not blocked, and the green reflectance image (bottom left), which is the green reflectance seen in the green channel. These images confirm that the P200CAF device is capable of detecting *in vivo* autofluorescence as effectively as has been shown in the *ex vivo* testing described above.



Reproducibility of image generation for a human eye in autofluorescence mode can be demonstrated by eleven images of an operator's left eye. These images are exhibited in chronological order with the time period from the first to last image being approximately 6 weeks. Again, the differences in these images are small (see **Attachment 3**).

The operator's eye has no areas of interest in that the autofluorescence image has a relatively uniform distribution of lipofuscin.

For eyes that have areas of interest in terms of atypical distribution of lipofuscin, fifty examples have been selected from clinics that show the autofluorescence red channel, the corresponding red channel from a standard red/green image, and the green channel from a standard red/green image (see **Attachment 4**).

The green wavelength is primarily reflected by the retinal pigment epithelium (RPE)/photoreceptor interface and the red light is reflected by the choroid. Autofluorescence looks at the distribution of lipofuscin within the RPE. Thus, autofluorescence gives an alternate view of the retinal layers looking at the distribution of lipofuscin and is complimentary to the red/green composite reflectance image and the separated red and green reflectance images.

This complimentary nature is evident in most of these images as the area of interest is highlighted in the autofluorescence image but is less visible in the red and/or green channels of the standard image.

The autofluorescence imaging mode can be used by the healthcare professional, in conjunction with the standard composite (red/green) and the associated separated red and green channel images, to aid in the diagnosis and monitoring of diseases and disorders that manifest in the eye.

As demonstrated in these eleven images obtained over time from the same individual (as described above) and the 50 images obtained from patients with previously identified pathologies, autofluorescence images are reproducibly obtained with the P200CAF device and provide image information that users may view as an aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.

Summary:

The autofluorescence mode offers additional information to the healthcare professional, but none of the information derived from the red/green mode is lost. In autofluorescence mode, there is less light entering the eye than in standard red/green imaging.

Therefore, the P200CAF is as safe and effective as the predicate, the P200.

Performance Testing – Bench

3. On page 27/140, you state that “The Optos Panoramic 200CAF Ophthalmoscope complies with the following six consensus standards”:

- IEC 60601-1 1988/A1:1991 Medical electrical equipment.A2:1995, Corrigendum 95 General requirements for safety;
- IEC 60825-1 Ed.2.0 (2007) Safety of Laser Products;
- IEC 60601-1-2:2007 Medical electrical equipment. General requirements for safety. Collateral standard. Electromagnetic Compatibility requirements and tests;
- IEC 60601-1-4 edition 1.1 2000-04 Medical electrical equipment. General requirements for safety. Collateral standard. General Requirements for programmable Electrical medical systems;
- ISO 10993-5 Biological evaluation of medical Devices: Tests for In Vitro Cytotoxicity 1999 & 2009; and
- ISO 10993-10 2002 & Amendment 1, 2006.

However, you do not provide any test report. This information is important in evaluating your device performance. Please provide the following information:

- a. Please provide the report of electrical safety and electromagnetic compatibility testing or certificates. The testing results should demonstrate your device complies with IEC 6060-1 and IEC 60601-1-2, as indicated in your submission.

Response: The company’s electrical safety testing to IEC 60601-1 and IEC 60601-1-2 are provided in **Attachment 5**.

- b. On page16/140, you state that the additional periphery light emitting diodes (LEDs) have been used in the P200CAF assisting in eye steering, and the additional LEDs, which are included in the laser safety calculations, do not change the intended use of the device or alter the fundamental scientific technology. However, you do not provide such laser calculations in your submission. This information is very important in assessing the safety of use of your device. Please provide your radiation hazard analysis for the additional LEDs. Please be advised that in the updated version of IEC 60825-1:2007, LEDs has been removed from the scope of Part 1. Please be advised that the optical radiation safety of LEDs, in general, may be appropriately addressed by lamp safety standards (e.g., ANSI RP-27.1-05 –Photobiological Safety for Lamps and Lamp Systems-General Requirements) and/or 15004-2:2007, ISO 15004-2:2007 – Ophthalmic instruments – Fundamental requirements and test methods – Part 2: Light hazard protection.

Response: The company’s radiation hazard analysis using ISO15004-2:2007 for the additional LEDs contained in the patient alignment system is provided in **Attachment 6**.

- c. In Section XII (Biocompatibility), you state that “The same material is used for the cushion in the P200 and the face pad in the P200CAF. As the P200CAF also has a chinrest and head

support, two additional materials come into contact with the patient. Specifically, the chincup is made of (b) (4) and the headrest of (b) (4). As per ISO 10993, the contact is skin and for limited duration, requiring that Cytotoxicity, Sensitization, and Irritation or Intracutaneous reactivity is assessed. Both of the additional materials have been assessed for these effects and meet the relevant standards.” However, you do not provide the biocompatibility testing report of the additional materials. Please provide your testing report. The testing should demonstrate your device complies with cited standards.

Response: The requested biocompatibility testing for the (b) (4) is provided in **Attachment 7**.

510(k) Summary

4. On page 38/140, you provide a single page 510(k) Summary. The information you provide is not sufficient as you only include the information of device modifications. However you should revise your 510(k) Summary to include a summary of how the technological characteristics of your device are different comparing to the predicate device. Please revise your 510k summary accordingly. We recommend that you use the following in drafting a new 510(k) Summary:

Sec. 807.92 Content and format of a 510(k) summary, at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=807.92Labeling>

Response: The 510(k) Summary has been revised for content and format. The company’s revised 510(k) Summary is provided in **Attachment 8**.

5. You use one Introductory Handbook for three models of P200MA (060624), P200C and P200CAF (K100644), and provide an intended use statement. Please address the following related concerns:

- a. Please clarify whether the P200C is an FDA-cleared device. If so, please provide the 510(k) number under which it was cleared.

Response: The P200C is marketed based on a memorandum to file (MTF) documenting the company’s decision not to file a 510(k) notice for this device. This decision was based on the fact that the P200C is indicated for a subset of the indications for use for the P200MA (K060624). The company’s memorandum documenting its decision not to file a 510(k) notice for this device is provided in **Attachment 9**.

- b. We note that the intended use for P200MA and P200CAF are slightly different, We recommend you provide the intended use for each mode separately. We also recommend you make the intended use a separate section with a title of Intended Use for clarity. Please revise your labeling accordingly.

Response: The company has revised the handbook to include a section entitled “Indications for Use.” A redlined version of the revised handbook is provided in **Attachment 10**.

- c. Please revise your labeling for P200CAF to reflect the modification to Indications for Use and include the radiation hazard from the additional LEDs, if any. Please provide a red-lined copy of labeling, clearly denoting any changes as requested above, so the changes to the labeling can be identified and reviewed more easily.

Response: As indicated above, the handbook has been revised to include the modified indications for use. However, analysis of the LEDs according to ISO15004-2:2007 concludes that the device

meets the requirements of group 1, and no change to the primary or secondary device labeling is required.

* * *

The company believes that this response fully addresses the issues raised in the agency's May 4, 2010, e-mail. We trust that the information provided is sufficient for the agency to find the P200CAF substantially equivalent to its predicate devices for the listed indication. If you have any further questions, please contact me at the number below or Randy Prebula at 202-637-6548. Upon clearance of the device please forward the substantial equivalence letter to me by facsimile to 202-637-5910.

Sincerely,

Handwritten signature of Howard M. Holstein in blue ink, with a stylized flourish at the end.

Howard M. Holstein

Partner
howard.holstein@hoganlovells.com
D (202) 637-5813

Attachments

cc: Robert Tweedlie, Optos Ltd.
Randy Prebula, Hogan Lovells US LLP
Danielle C. Woodlee, Hogan Lovells US LLP

Attachment 1

Statement for Indication for Use

510(k) Number (if known): K100644

Device Name: Optos Panoramic 200CAF Scanning Laser Ophthalmoscope

Indications for Use:

The Panoramic 200CAF scanning laser ophthalmoscope is intended to be used as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.

Prescription Use
(Per 21 C.F.R. 801.109)

AND/OR

Over-The-Counter Use

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF
NEEDED)

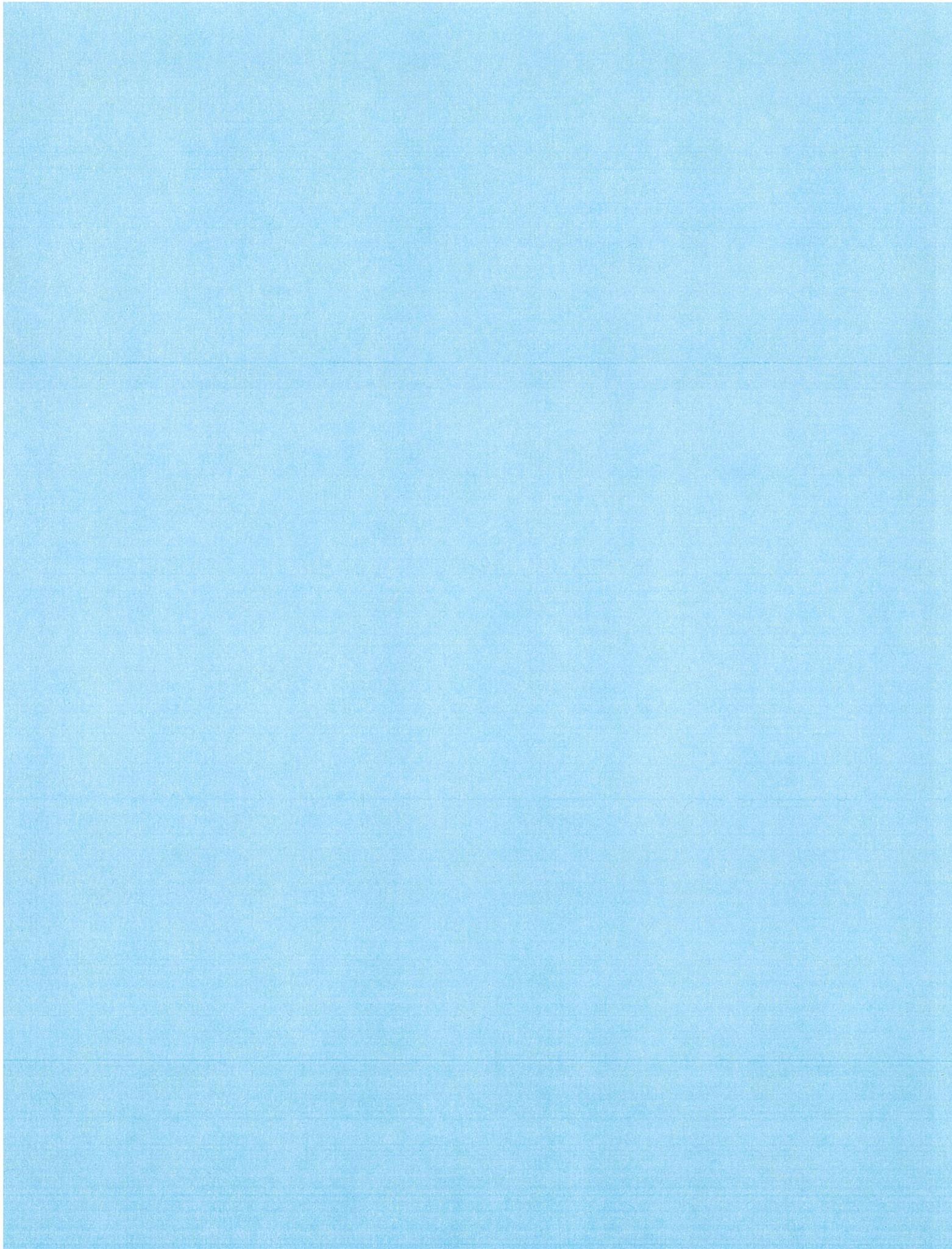
Concurrence of CDRH, Office of Device Evaluation (ODE)

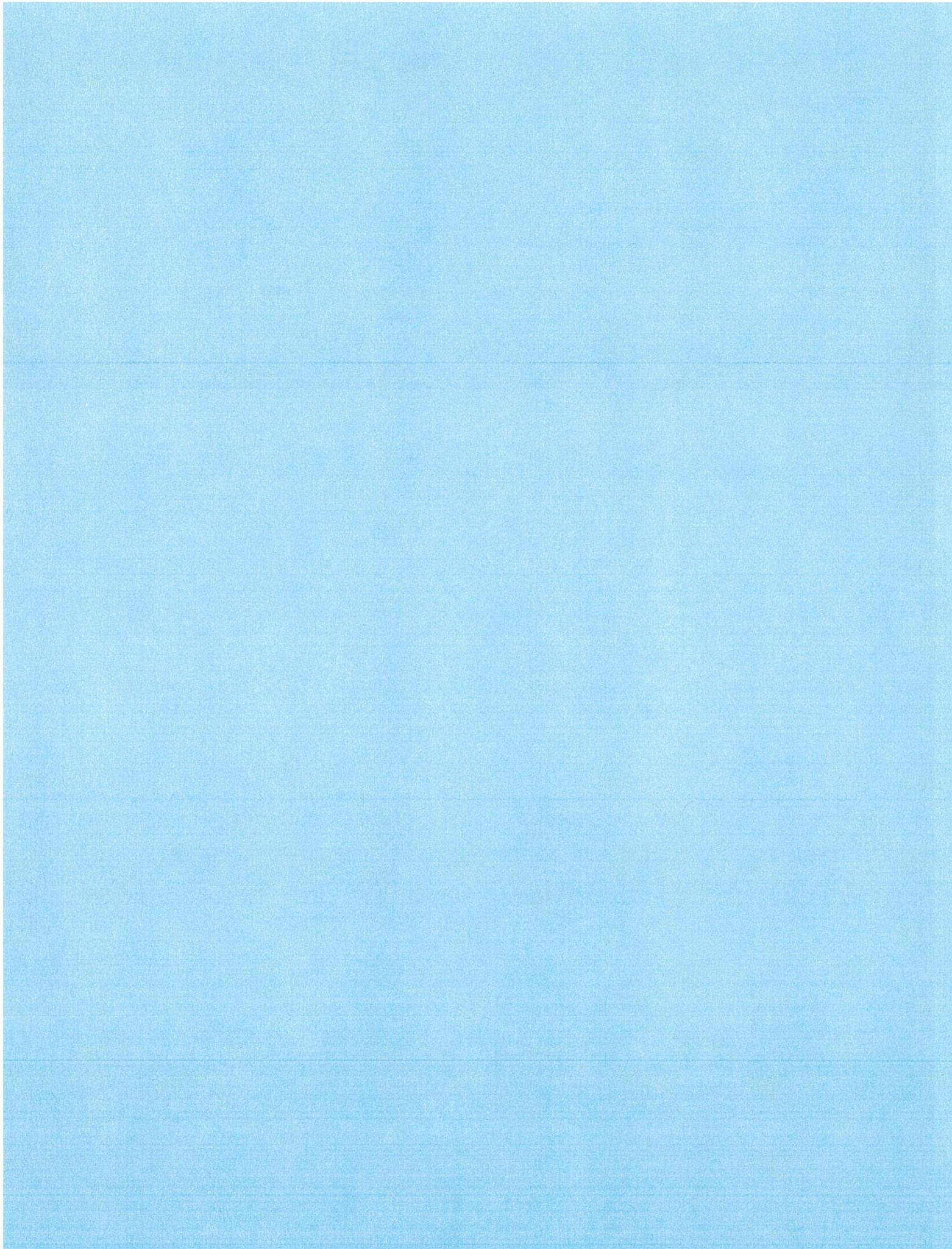
Attachment 2

Attachment 3

Attachment 4

Attachment 5





Attachment 6



Patient Alignment System

Analysis to Requirements and Test Methods - Part 2: Light Hazard Protection(EN ISO 15004-2:2007)

Author: (b) (6)

Signed: (b) (6)

Date: (b) (6)

Reviewer: (b) (6)

Signed: (b) (6)

Date:

Regulatory: (b) (6)

Signed: (b) (6)

Date:

1 Introduction:

This paper gives the outlines the light hazard protection analysis for the embedded patient alignment system according to the treatment, requirements and methods given in the standard EN ISO 15004-2:1997.

The Patient Alignment System (PAS) is an embedded optical module within the Optos Scanning Laser Ophthalmoscope, containing multiple visible LEDs (four red and one green) and a NIR LED source. The visible LEDs are used as patient fixation targets to ensure that the patient gaze angle is correct for retinal imaging. In normal operation, only one of the visible LEDs is illuminated at any given time, with the green LED projecting along the central axis and the four red LEDs projecting along the nasal, temporal, superior and inferior projections, respectively. The NIR LED is used to provide flood fill illumination of the patient to provide the operator with a patient view, via imaging cameras embedded in the PAS, and is illuminated during a patient session except during active image acquisition.

It should be noted that the LED sources on the PAS are not intended as retinal imaging devices and, as such, operate at very low levels of radiance. Evaluation of the system to the conditions for group 1 instruments demonstrate that the operation of the system falls within the group 1 limits and does not, therefore, present an optical hazard.

2 Key Parameters and Data

For treatment of the visible sources, the green LED is considered as it has the most stringent weighting factors.

The NIR source is treated according the measurement method given in Annex D of the standard.

- Green LED at (b) (4) dominant wavelength with FWHM of (b) (4)
 - Weighting factors determined at worst case value of (b) (4)
- Measured power at corneal plane, P_e , using (b) (4) active area broadband detector = (b) (4)
- Geometrical distribution of central LED illumination at corneal plane = (b) (4)
- Geometrical distribution of central LED illumination at object plane = (b) (4)
- The diagrams showing visible and (b) (4) through the optical system to the eye position are given in Appendix 1.
- The PAS drawing is given in Appendix 2.
- The LED product data sheets are given in Appendix 3.

¹ Acquired using Ophir Nova Meter (calibrated 08th March 2010, P/N 1201500, S/N 118042) and PD300 photodiode smart head (calibrated 08th March 2010, P/N 1202410, S/N 107932). Wavelength measurement range 350-1100nm, $\pm 3\%$ accuracy at visible to NIR wavelengths.

3 Weighted Retinal Irradiance

Normal operation, green fixation LED only, brightest setting.

The power of the central fixation target LED was measured at (b) (4) the brightest setting at the corneal plane. For a geometrical distribution diameter (b) (4) is gives the radiated emission through area, (b) (4) at the corneal plane of:

(b) (4)

Effective solid angle, Ω_e , is given by

(b) (4)

Where A_{exit} is the exit aperture area (area on the corneal surface) and D_p is the distance from the source to the cornea.

The limiting aperture on the cornea has a diameter of (b) (4) giving an aperture area of (b) (4). The viewing distance from virtual source to cornea is (b) (4) giving an effective solid angle of

(b) (4)

Spectral radiance is then given as

(b) (4)

The geometrical distribution of radiated emission at the corneal plane has a diameter of (b) (4). Therefore, the effective pupil aperture is limited to this value for consideration of the retinal irradiance (no increase in irradiance for pupil (b) (4))

The effective pupil area is then (b) (4)

The retinal spectral radiance is then given by

(b) (4)

The weighted retinal spectral radiance is then given by

(b) (4)

Where $A(\lambda)$ for (b) (4) resulting in a weighted retinal spectral radiance of

(b) (4)

This is a factor of 181, 818 less than the group 1 limits.

4 Weighted Retinal Radiance

Normal operation, green fixation LED only, brightest setting.

The weighted retinal radiance, L_{A-R} , is given by

(b) (4)

L_{λ} was previously determined to be (b) (4)

The weighting factor used is $A(\lambda_{550nm})$ (b) (4)

Giving a weighted Retinal Radiance value of

(b) (4)

Resulting in a factor of (b) (4) less than the quoted retinal irradiance limit (b) (4) for group 1 instruments.^b

5 Weighted Retinal Thermal Irradiance and Radiance Values.

Normal operation, green fixation LED & NIR flood fill, brightest setting.

(b) (4)

There are two sources to consider: the IR flood illumination and the visible fixation LED.

E_{λ} for the visible fixation LED was previously determined to be (b) (4). The thermal hazard weighting function $R(\lambda)$ at (b) (4). The visible component therefore remains (b) (4) (compared to limit (b) (4) for group 1 instruments).

The IR source was treated as per the method given in Annex 5 of ISO EN 15004-2:2007.

A 2mm aperture was placed in the beam in front of the measurement device. The measurement device active area was placed at the corneal plane, with an effective aperture greater than the illumination distribution (i.e. captured all radiation at corneal surface).

An aperture diameter (b) (4) was used, being placed (b) (4) mm from the corneal plane with a measurement aperture of A_m (b) (4).

The power at the corneal plane, P_c , was measured as (b) (4), giving a radiant exposure of

(b) (4)

The spectral radiant exposure is then.

(b) (4)

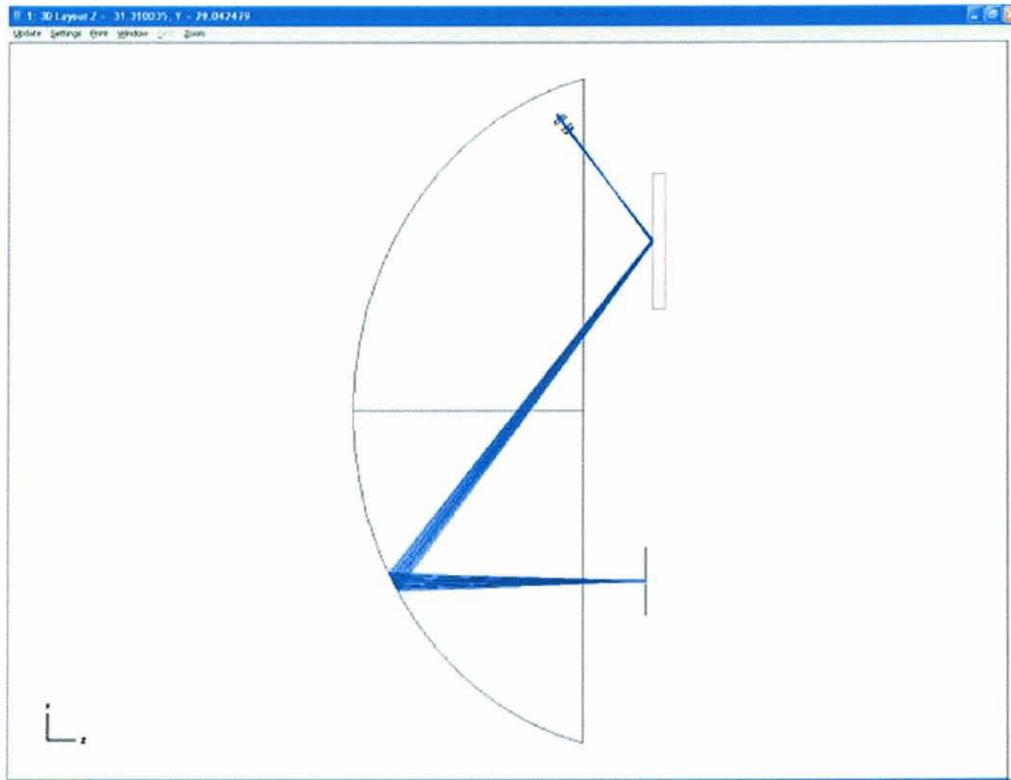
Since the thermal weighting function is $R(\lambda) < (b) (4)$ then the IR component satisfies the criteria for group 1 devices in terms of weighted retinal thermal irradiance and weighted thermal radiance.

For the unweighted corneal and lenticular infrared radiation irradiance, E_{IR-CL} , the measured power through a 1mm aperture at the corneal plane is (b) (4) satisfying the condition for group 1 devices.

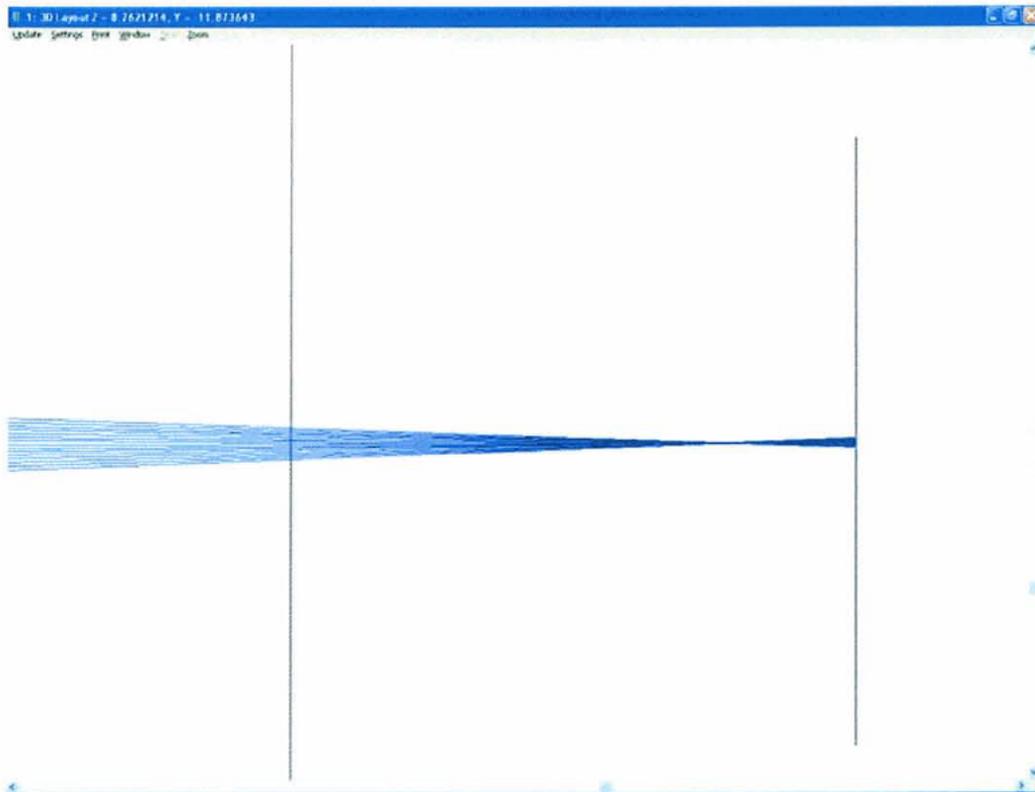
6 Conclusion

Evaluation of weighted retinal irradiance, weighted retinal radiance, weighted retinal thermal irradiance, weighted retinal thermal radiance and unweighted corneal and lenticular infrared radiation irradiance to the Group 1 limit values for continuous wave instruments, presented in table 2 of standard EN ISO 15004-2:2007 demonstrate that the PAS may be considered a group 1 ophthalmic device. As such, no potential hazard exists.

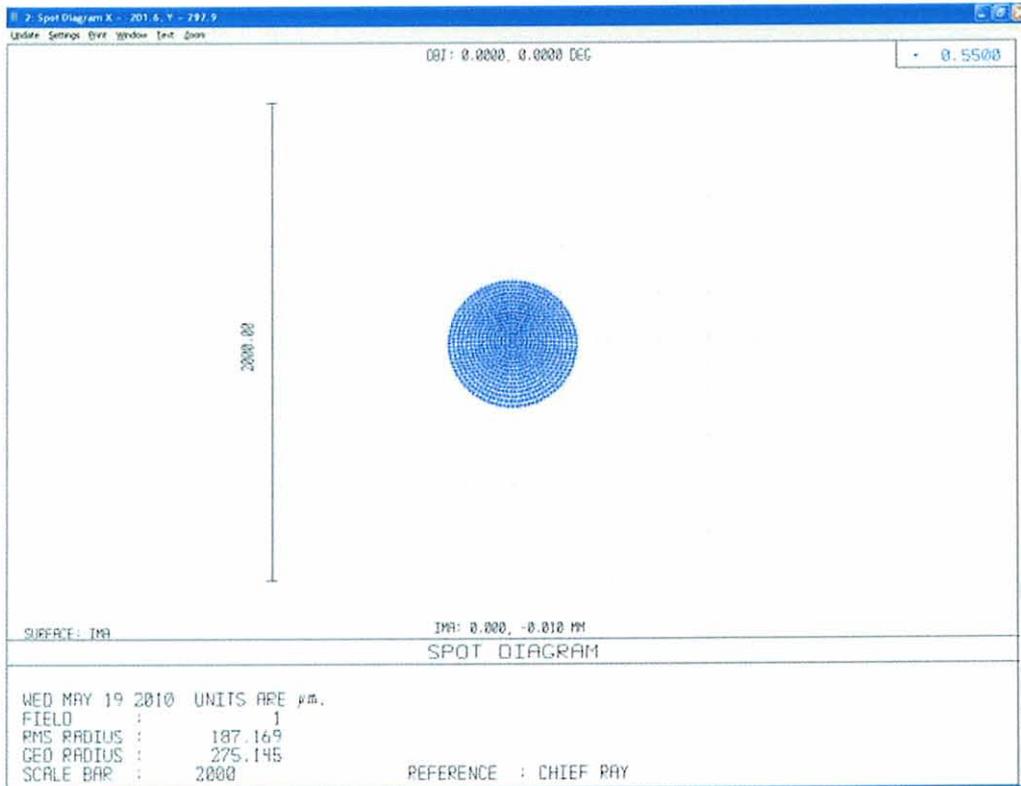
7 Appendix 1. Optical propagation models



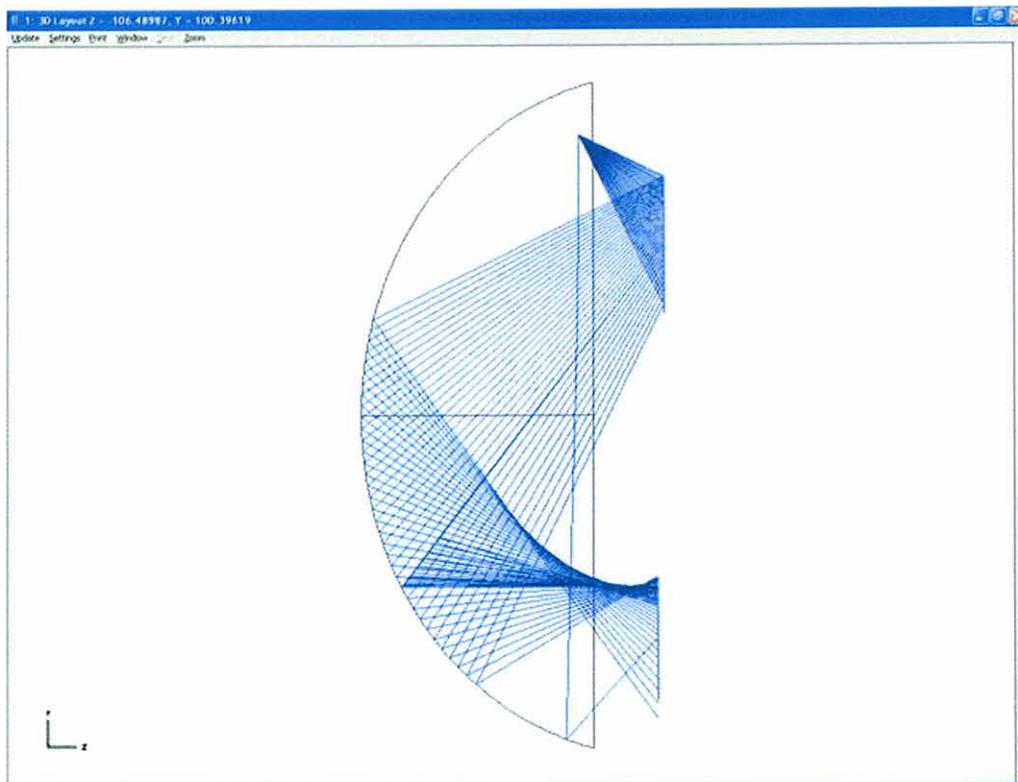
Propagation of green LED through system to corneal plane (illumination is divergent at corneal plane).



Zoomed propagation of green fixation LED from main mirror edge to corneal plane, showing divergence at cornea.

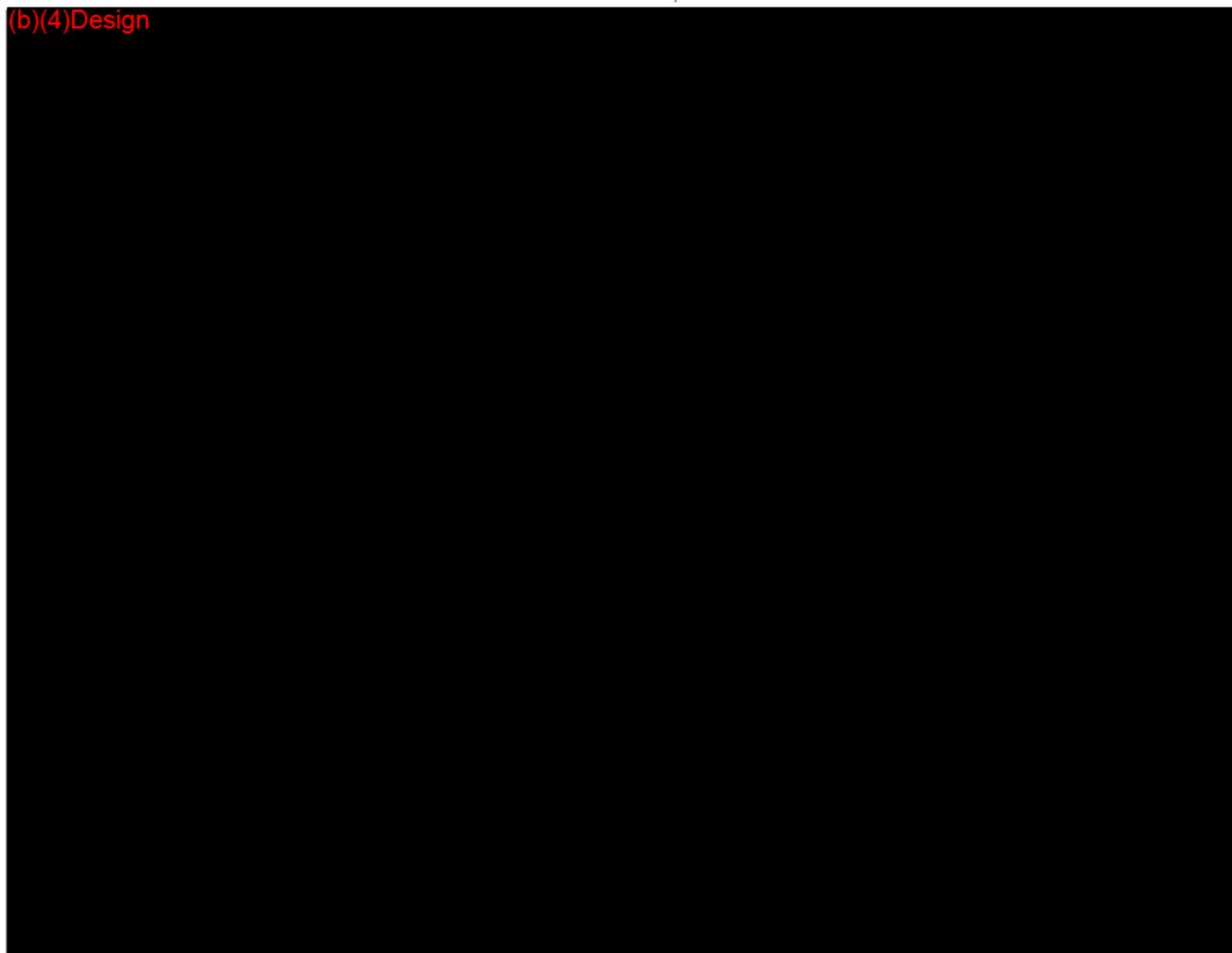


Spot diagram of geometrical distribution of green fixation target at corneal plane



Propagation path of IR flood fill LED.

(b)(4)Design



High-Performance IR Emitter and IR PIN Photodiode in Subminiature SMT Package

Technical Data

**HSDL-44XX IR Emitter
Series**
**HSDL-54XX IR Detector
Series**

Features

- **Subminiature Flat Top and Dome Package**
Size – 2x2 mm
- **IR Emitter**
875 nm TS AlGaAs
Intensity – 17 mW/sr
Speed – 40 ns
- **Wide Range of Drive Currents**
500 μ A to 500 mA
- **IR Detector**
PIN Photodiode
High Sensitivity
Speed – 7.5 ns
- **Flexible Lead Configurations**
Surface Mount or
Through Hole

Applications

- Short Distance IR Links
- IrDA Compatible
- Small Handheld Devices
Pagers
Industrial Handhelds
- Diffuse LANs
- Wireless Audio

Description

Flat Top Package

The HSDL-4400 Series of flat top IR emitters use an untinted, nondiffused, truncated lens to provide a wide radiation pattern that is useful for short distance communication where alignment of the emitter and detector is not critical. The HSDL-5400 Series of flat top IR detectors uses the same truncated lens design as the HSDL-4400 Series of IR emitters with the added feature of a black tint that acts as an optical filter to reduce the effects of ambient light, such as sun, incandescent and fluorescent light from interfering with the IR signal.

Dome Package

The HSDL-4420 Series of dome IR emitters uses an untinted, nondiffused lens to provide a 24 degree viewing angle with high on-axis intensity. The HSDL-5420 Series of IR detectors uses the same lens design as the HSDL-4420 IR emitter and optical filter used in the HSDL-5400 IR detector.



Lead Configuration

All of these devices are made by encapsulating LED and PIN photodiode chips on axial lead frames to form molded epoxy subminiature packages. A variety of lead configurations is available and includes: surface mount gull wing, yoke lead, or Z-bend and through hole lead bends at 2.54 mm (0.100 inch) center spacing.

Technology

The subminiature solid state emitters utilize a highly optimized LED material, transparent substrate aluminum gallium arsenide, TS AlGaAs. This material has a very high radiant efficiency, capable of producing high light output over a wide range of drive currents and temperature.

HSDL-44XX Optical Characteristics at $T_A = 25^\circ\text{C}$

Parameter	Symbol	Min.	Typ.	Max.	Unit	Condition	Ref.
Radiant Optical Power							
HSDL-4400	P_O		16 30		mW	$I_{FDC} = 50\text{ mA}$ $I_{FDC} = 100\text{ mA}$	
HSDL-4420	P_O		16 30		mW	$I_{FDC} = 50\text{ mA}$ $I_{FDC} = 100\text{ mA}$	
Radiant On-Axis Intensity							
HSDL-4400	I_E	1	3 6 15	8	mW/sr	$I_{FDC} = 50\text{ mA}$ $I_{FDC} = 100\text{ mA}$ $I_{FPK} = 250\text{ mA}$	Fig. 4, 5
HSDL-4420	I_E	9	17 32 85	30	mW/sr	$I_{FDC} = 50\text{ mA}$ $I_{FDC} = 100\text{ mA}$ $I_{FPK} = 250\text{ mA}$	Fig. 4, 5
Radiant On-Axis Intensity Temperature Coefficient	$\Delta I_E/\Delta T$		-0.35 -0.35		%/ $^\circ\text{C}$	$I_{FDC} = 50\text{ mA}$ $I_{FDC} = 100\text{ mA}$	
Viewing Angle							
HSDL-4400	$2\theta_{1/2}$		110		deg	$I_{FDC} = 50\text{ mA}$	Fig. 9
HSDL-4420	$2\theta_{1/2}$		24		deg	$I_{FDC} = 50\text{ mA}$	Fig. 10
Peak Wavelength	λ_{PK}	860	875	895	nm	$I_{FDC} = 50\text{ mA}$	Fig. 1
Peak Wavelength Temperature Coefficient	$\Delta\lambda/\Delta T$		0.25		nm/ $^\circ\text{C}$	$I_{FDC} = 50\text{ mA}$	
Spectral Width at FWHM	$\Delta\lambda$		37		nm	$I_{FDC} = 50\text{ mA}$	Fig. 1
Optical Rise and Fall Times, 10%-90%	t_r/t_f		40		ns	$I_{FPK} = 50\text{ mA}$	
Bandwidth	f_c		9		MHz	$I_{FDC} = 50\text{ mA}$ $\pm 10\text{ mA}$	Fig. 11

HSDL-44XX Absolute Maximum Ratings

Parameter	Symbol	Min.	Max.	Unit	Ref.
Peak Forward Current (Duty Factor = 20%, Pulse Width = 100 μs)	I_{FPK}		500	mA	Fig. 7, 8
DC Forward Current	I_{FDC}		100	mA	Fig. 6
Power Dissipation	P_{DISS}		180	mW	
Reverse Voltage ($I_R = 100\text{ }\mu\text{A}$)	V_R	5		V	
Transient Forward Current (10 μs Pulse)	I_{FTR}		1.0	A	[1]
Operating Temperature	T_O	-40	85	$^\circ\text{C}$	
Storage Temperature	T_S	-55	100	$^\circ\text{C}$	
Junction Temperature	T_J		110	$^\circ\text{C}$	
Lead Solder Temperature [1.6 mm (0.063 in.) from body]			260/5 s	$^\circ\text{C}$	
Reflow Soldering Temperatures					
Convection IR			235/90 s	$^\circ\text{C}$	
Vapor Phase			215/180 s	$^\circ\text{C}$	

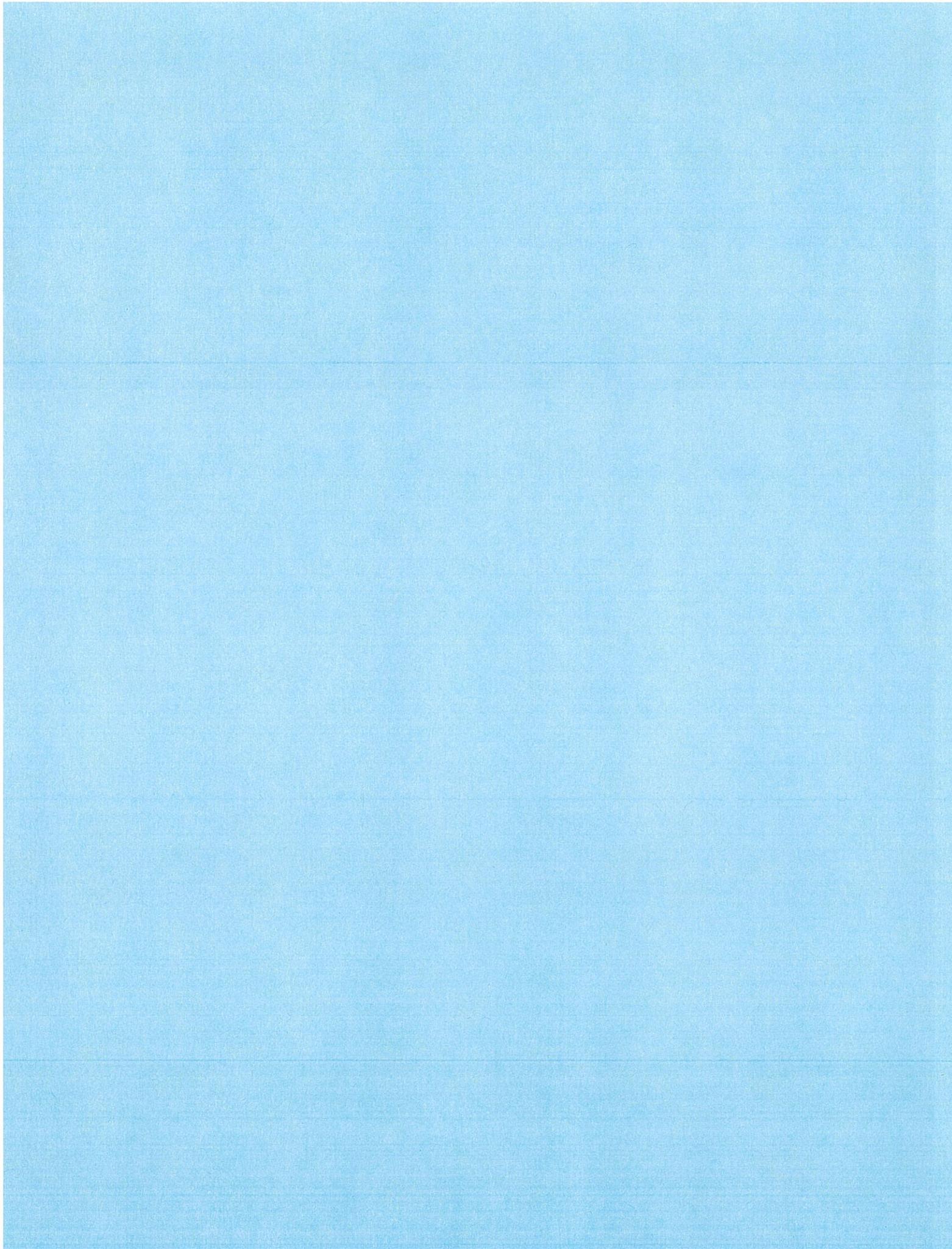
Notes:

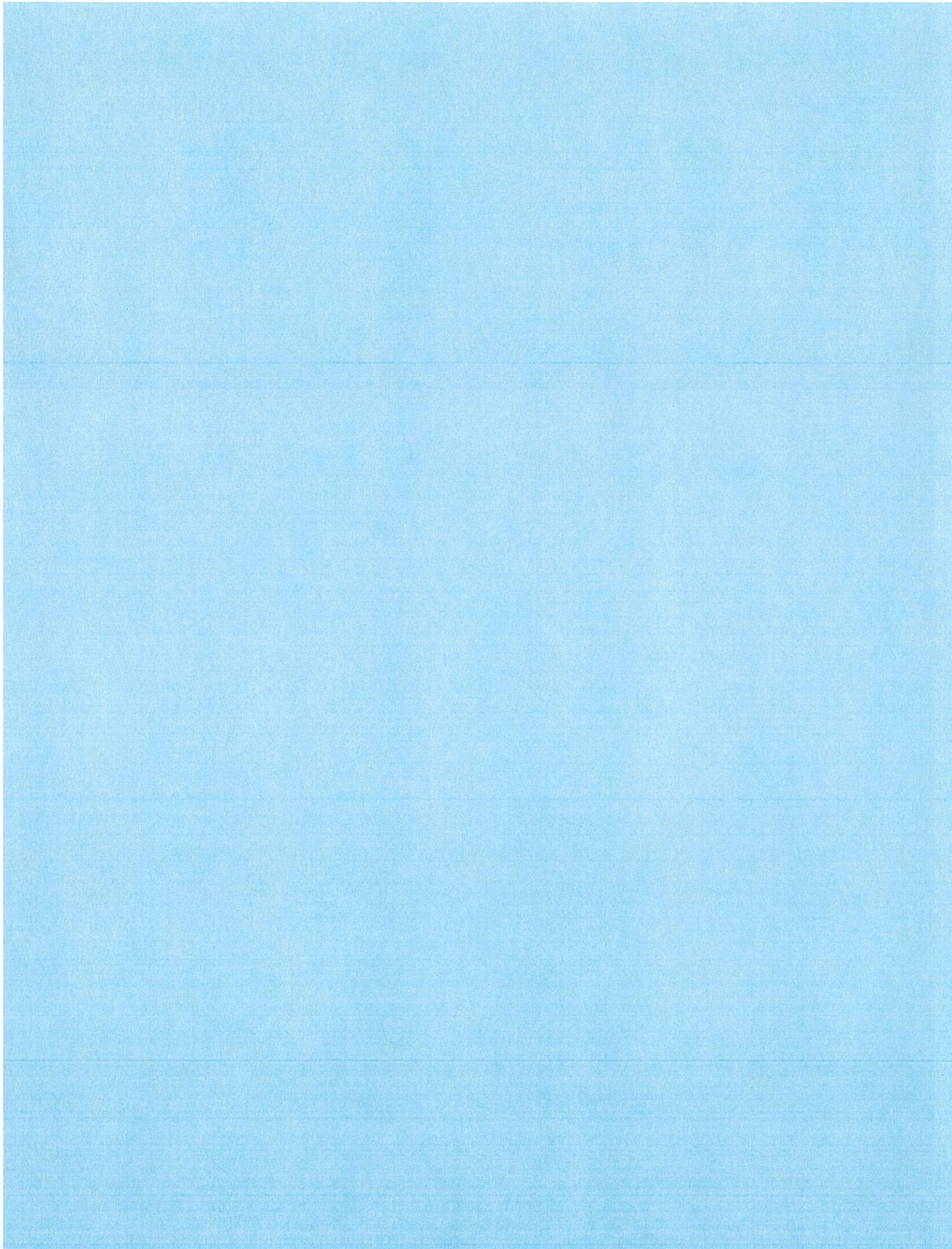
- The transient peak current in the maximum nonrecurring peak current the device can withstand without damaging the LED die and the wire bonds.

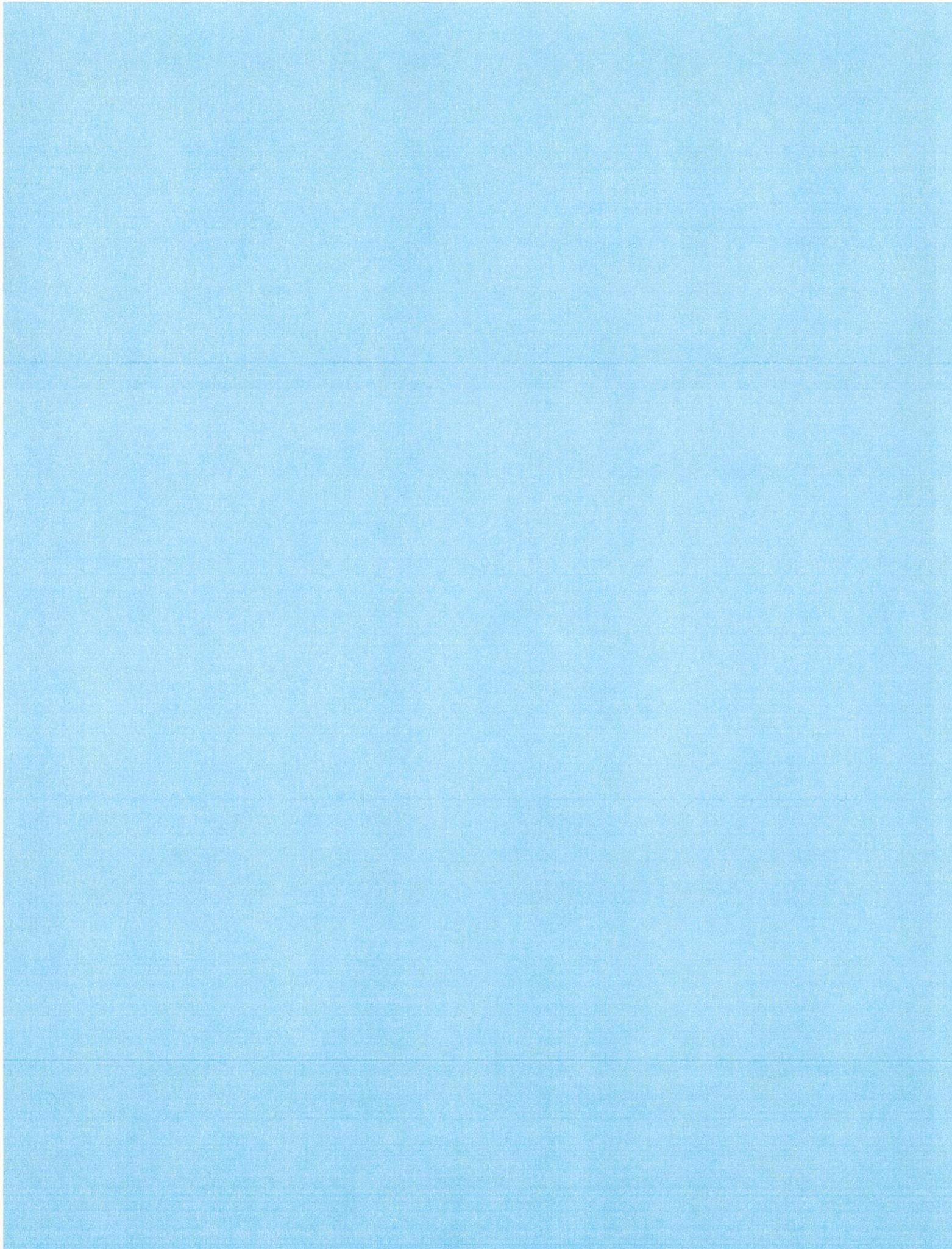
HSDL-44XX Electrical Characteristics at $T_A = 25^\circ\text{C}$

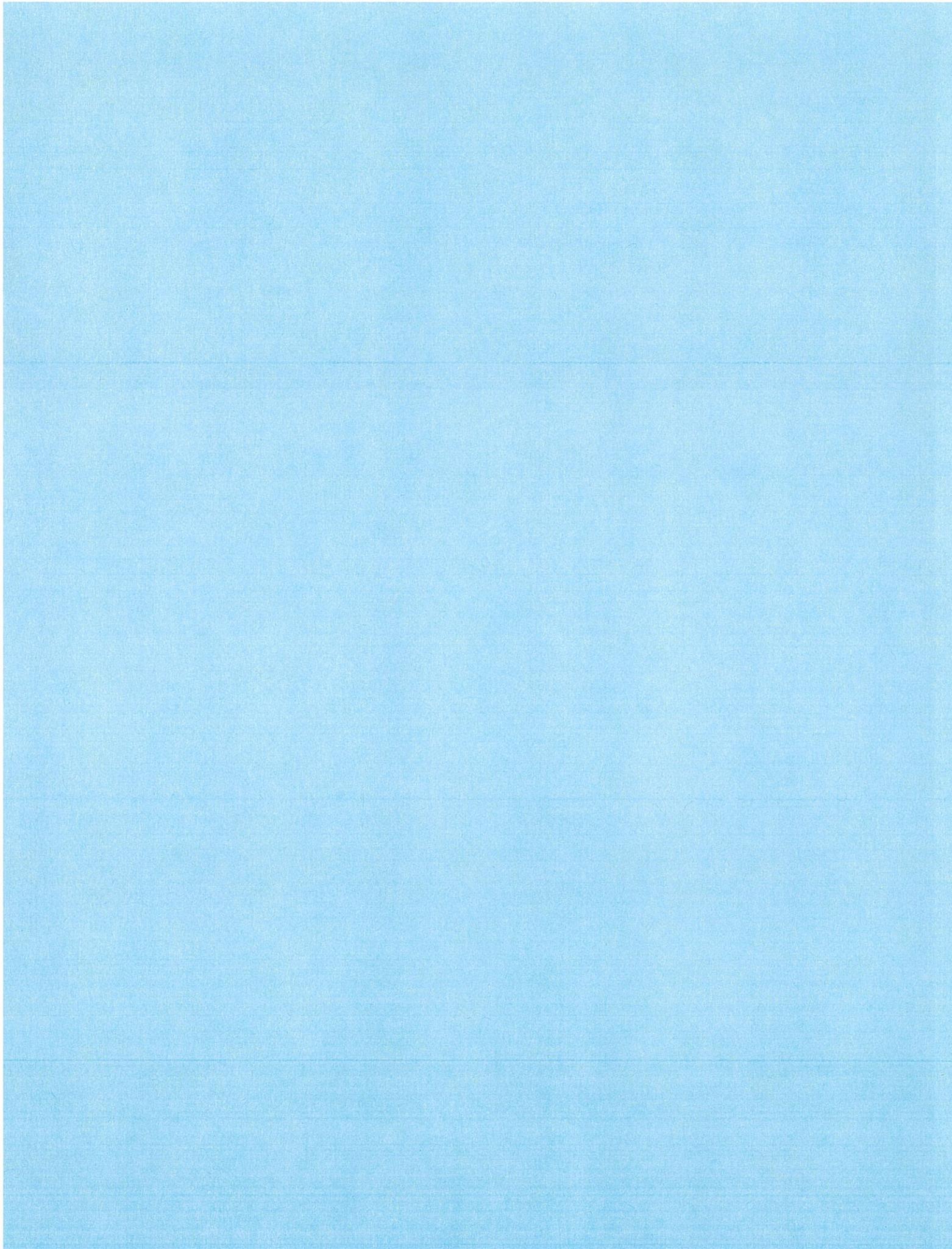
Parameter	Symbol	Min.	Typ.	Max.	Unit	Condition	Ref.
Forward Voltage	V_F	1.30 1.40	1.50 1.67 2.15	1.70 1.85	V	$I_{FDC} = 50\text{ mA}$ $I_{FDC} = 100\text{ mA}$ $I_{FPK} = 250\text{ mA}$	Fig. 2
Forward Voltage Temperature Coefficient	$\Delta V_F/\Delta T$		-2.1 -2.1		mV/ $^\circ\text{C}$	$I_{FDC} = 50\text{ mA}$ $I_{FDC} = 100\text{ mA}$	Fig. 3
Series Resistance	R_S		2.8		Ω	$I_{FDC} = 100\text{ mA}$	
Diode Capacitance	C_O		40		pF	0 V, 1 MHz	
Reverse Voltage	V_R	5	20		V	$I_R = 100\text{ }\mu\text{A}$	
Thermal Resistance, Junction to Pin	$R\theta_{JP}$		170		$^\circ\text{C}/\text{W}$		

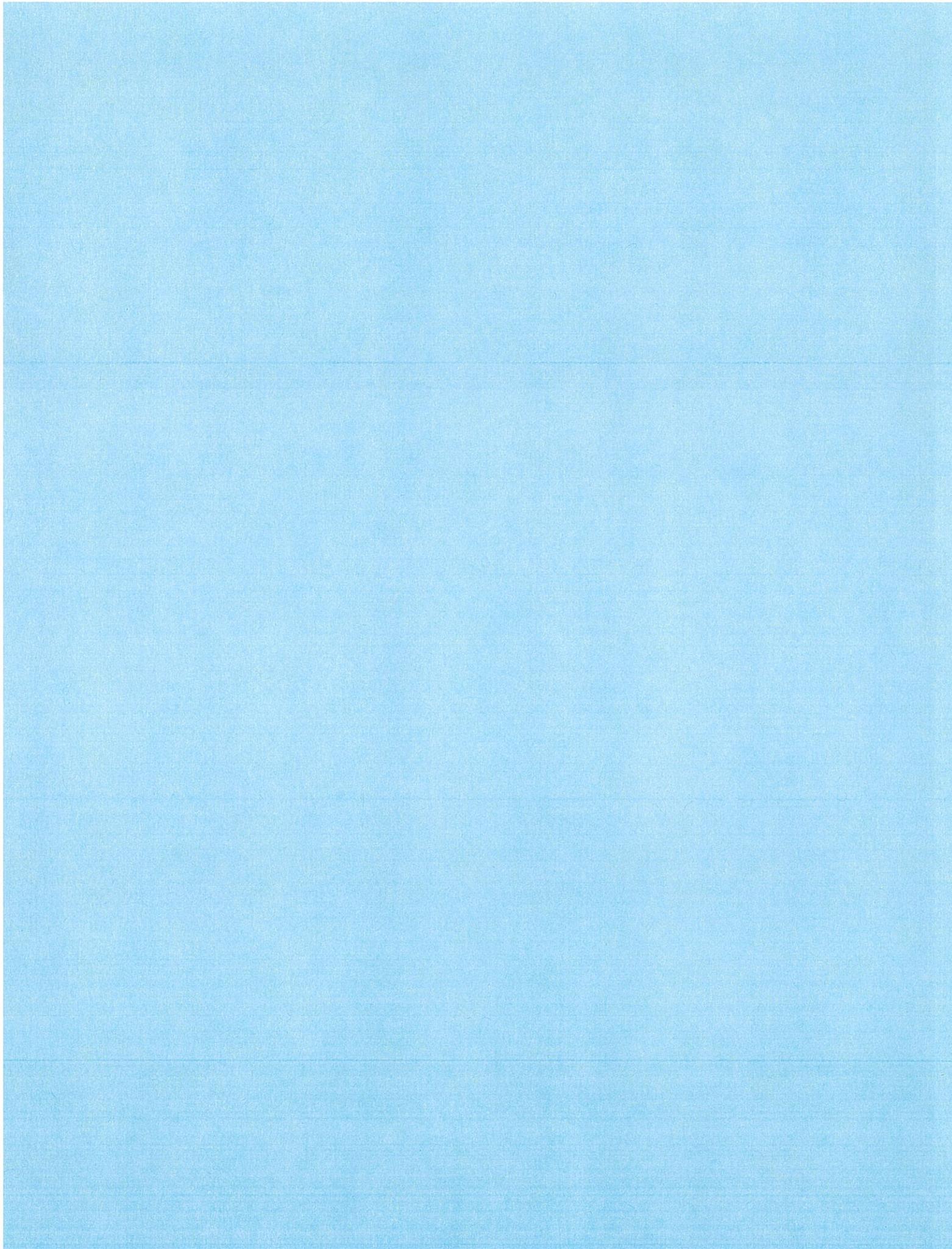
Attachment 7











Attachment 8

Special 510k Summary-Optos Panoramic 200CAF

Name of Device	Panoramic 200CAF Ophthalmoscope
Common or Usual Name	Scanning laser ophthalmoscope
Classification Name	Scanning laser ophthalmoscope (per 21 C.F.R. § 866.1570)
Product Code	MYC
Submitter	Optos plc, Queensferry House, Carnegie Business Campus Dunfermline, Fife, KY11 8GR United Kingdom Phone: 011 44 1383 843300 Facsimile: 011 44 1383 843333
Contact Person:	Robert Tweedlie Ph.D.
Date Prepared	June 14, 2010
Predicate Device	Optos Limited's Panoramic 200 (K983999)

Indications for Use

The Panoramic 200CAF scanning laser ophthalmoscope is intended to be used as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.

Technological Characteristics

The Panoramic 200CAF is a conventional scanning laser ophthalmoscope (SLO), which uses a low power laser beam to scan in two dimensions over the retina. The reflected (or returned) light is detected and used to generate a digital image with a computer or electronic imaging device.

The wavelengths of the lasers residing in the Optos Panoramic 200CAF and the P200 are the same. The generation of the image is performed in the conventional manner using light detectors, the output of which is digitized, and the data collected in a computer for reconstruction, display, and storage. The scanning of the beams on the two axes is done using a conventional rotating polygon for the fast vertical scan and a motor driven mirror for the slower horizontal scan. An alignment pattern helps ensure that the patient's eye is correctly positioned.

The reflected energy from the retinal surface is passed back through the device to an array of two discrete detectors (effectively a red and a green channel). For the Panoramic 200CAF and the P200, in standard imaging mode, the images produced can be viewed either as a composite image (red and green images combined) or separate as a green channel and a red channel image. The Panoramic 200CAF can also generate an alternate red channel image that shows the natural fluorescence (autofluorescence) of the eye. In this imaging mode, the retina is illuminated using the green laser, while the red laser optical path is blocked by a shutter. In this imaging mode, the red channel image now displays the naturally occurring fluorescent material of the retina, such as lipofuscin. The signal strength varies as the laser beam is scanned across the eye, allowing an image to be created and recorded, revealing the variation in its constituent material and structures.

This scanning function is housed in the 'scanhead', which is seated on a table that can move up and down and this affords a height adjustment to achieve correct patient positioning.

The Panoramic 200CAF and P200 capture one image at a time and can present each image as a thumbnail sketch. If more than one image is captured, the Panoramic 200CAF and Panoramic 200 display a series of thumbnail sketches in the order in which they were scanned. The Panoramic 200CAF, like the P200, allows the user to view one or more images of the eye.

Principles of Operation:

Both the P200CAF and the P200 have very similar principles of operation. Both devices use lasers as a light source that is scanned by a deflection system in two axes across the retina to generate an image. The returned light then travels back along the same path to a light detector that converts the light to an electrical signal. This electrical signal is digitized and used to build up an electronic picture in a computer and displayed either on a cathode ray tube or a liquid crystal display.

Both the P200CAF and the P200 use the same red and green lasers. Both devices can generate a composite red/green image. The autofluorescence imaging mode present in the P200CAF can be used by the healthcare professional in conjunction with the standard composite (red/green) and the associated separated red and green channel images to aid in the diagnosing and monitoring of diseases and disorders that manifest themselves in the eye.

The mechanism for autofluorescence is well understood and documented. The green wavelength is primarily reflected by the retinal pigment epithelium (RPE)/photoreceptor interface and the red light is reflected by the choroid. Autofluorescence looks at the distribution of lipofuscin within the RPE. Thus, autofluorescence gives an alternate view of the retinal layers and is complimentary to the red/green composite reflectance image and the separated red and green reflectance images.

Performance Testing:

Compliance to electrical safety (including EMC), light emitting products, programmable devices and biocompatibility standards are met. Each device is tested for electrical safety, laser power output and correct functioning of the laser radiation management system against set criteria and limits. Additionally, performance testing was conducted to demonstrate that

the P200CAF accurately and reproducibly produces images the eye in both standard and autofluorescence imaging modes.

Substantial Equivalence

The Panoramic 200CAF has the same intended use, similar principles of operation, and similar technological characteristics as the predicate device. The minor differences between the Panoramic 200CAF and the predicate device do not raise any new questions of safety and effectiveness. Thus, the Optos Panoramic 200CAF Ophthalmoscope is substantially equivalent to Optos' legally marketed Scanning Laser Ophthalmoscopes (SLO), the P200 (K983999).

Attachment 9

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November 28, 2007

TO: Design History File **Panoramic, Model 200C (“P200C”)**

FROM: Robert Tweedlie, Director of Quality Assurance and Regulatory Affairs
Robert Tweedlie 28TH November, 2007

RE: Assessment to Support Decision Not to Submit a 510(k) for Changes to the Panoramic, Model 200MA (Originally cleared under K060424).

Optos PLC (“Optos” or the “company”) proposes to make the following lesser indication modifications to the cleared Panoramic device, Model 200MA (“P200MA”) by removing the: (1) blue laser; (2) motorized linear translation stage; and (3) an arm rest. The modifications are being made to permit the device to incorporate some, but not all, of its present features. These changes do not have a significant affect on safety and effectiveness as described below. The modified device will be referred to as the Panoramic Model P200C. This memorandum analyzes the proposed lesser indication modifications to the P200MA in accordance with 21 C.F.R. § 807.81 and under the framework set forth in FDA’s guidance document “Deciding When to Submit a 510(k) for a Change to an Existing Device” (January 10, 1997) (the “Device Modification Guidance”). As discussed below, the

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proposed modifications require documentation in a memorandum-to-file and do not require a new 510(k) clearance.

I. DESCRIPTION OF MODIFICATIONS TO DEVICE

The P200MA is a conventional scanning laser ophthalmoscope (SLO) that uses red, green, and blue lasers of defined wavelengths to scan the surface of the retina and create a digital image that may be viewed, stored, and manipulated by a healthcare professional. Technologically, the device is indicated for use as a wide field and retinal fluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest themselves in the retina. In angiographic mode, the blue laser is used to fluoresce a dye (the dye being injected into the patient in a separate clinical procedure) which supplies images relating to the vasculature of the retina and fundus of the eye. The wavelengths used in standard imaging mode are the same as originally cleared for non-angiographic imaging.

Optos proposes to make the following modifications to the P200MA to create the P200C: (1) removal of the blue laser; (2) removal of the motorized linear translation stage; and (3) removal of an arm rest. Table 1 compares the cleared and modified devices:

Table 1: Comparison of the cleared and modified device

	P200MA	P200C
Intended Use	To examine the retina of the eye	To examine the retina of the eye

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	P200MA	P200C
Indications	For aiding in the diagnosing and monitoring disease and disorders that manifest themselves in the retina of the eye. This includes imaging the fluoresced ocular vasculature.	For aiding in the diagnosing and monitoring disease and disorders that manifest themselves in the retina of the eye.
Technological Characteristics		
Imaging Modes	RG* imaging, 4M pixels (optomap) RG imaging, 9M pixels (optomap <i>plus</i>) Automated Angiography, 9M pixels (optomap <i>fa</i>) Single shot Angiography, 9M pixels (optomap <i>fa</i>) RG central field, 9M pixels (zoom) Directed eye steering	RG imaging, 4M pixels (optomap) RG imaging, 9M pixels (optomap <i>plus</i>) RG central field, 9M pixels (zoom) Directed eye steering
Scan Head Architecture	Motorized translation stage in optical return path (switches between RG and blue imaging)	Fixed optical return path

* RG = red/green

	P200MA	P200C
Lasers	Red laser, $\lambda = 633\text{nm} \pm 1\text{nm}$, delivers 0.4-0.55mW to the eye Green laser, $\lambda = 532\text{nm} \pm 1\text{nm}$, delivers 1.4-1.7mW to the eye. Blue laser, $\lambda = 488\text{nm} \pm 2\text{nm}$, delivers 1.8-2.25mW to the eye.	Red laser, $\lambda = 633\text{nm} \pm 1\text{nm}$, delivers 0.4-0.55mW to the eye Green laser, $\lambda = 532\text{nm} \pm 1\text{nm}$, delivers 1.4-1.7mW to the eye.
Patient Support	Chin support Face pad Arm support	Chin support Face pad

II. ASSESSMENT OF CHANGE

Optos followed the Device Modification Guidance to assess the proposed modifications to the P200MA. Based on the Main Flowchart, the proposed modifications require that labeling and three technological changes be considered. The proposed modifications are discussed below based mainly on the corresponding

Device Modification Guidance flowcharts, namely Flowchart A (Labeling Change) and Flowchart B (Technology or Performance Change). Moreover, the proposed changes are not due to a recall or corrective action. The memorandum includes an annotated version of the Main Flowchart and applicable sub-flow charts marked **Attachment 1**.

A. Labeling Change

Optos proposes to make the following labeling limitation for the P200C:

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- Removal of the statement “[t]his includes imaging the fluoresced ocular vasculature” from the indications for use.

Labeling of the device for the P200C is provided in **Attachment 2** and is identical to the original labeling. The labeling change is discussed below. The labeling change does not affect the impact of the intended use of the P200C, or alter a contraindication; however, the labeling change affects the indications for use, but not in a manner that requires a 510(k). As discussed in greater detail below, the Device Modification Guidance leads to the conclusion that the labeling for the P200C requires documentation in a memorandum-to-file and not a 510(k) clearance.

1. Removal of the statement “[t]his includes imaging the fluoresced ocular vasculature” from the indications for use.

First, as listed above, the P200MA is indicated for “aiding in the diagnosing and monitoring disease and disorders that manifest themselves in the retina of the eye. This includes imaging the fluoresced ocular vasculature.” Unlike the P200MA, the P200C will not be used for angiography of any kind, but will be used solely to visualize the fundus (retina and vasculature). The viewed image will be absent of fluorescent dyes or markers.

FDA’s Device Modification Guidance, concerning when modifications to a cleared device will require a 510(k), explicitly excludes instances where the cleared indications are narrowed. FDA has stated: “Any change in the indications for use that limits use within the currently cleared indication may occur without the

submission of a 510(k)." For example, where a device is cleared for three indications but is marketed for only two of the three cleared indications. Consequently, the change in indications for use does not require a premarket notification submission.

Second, the label will not change any warning or precautions. Third, the change neither adds nor deletes a contraindication. Lastly, the labeling is not being revised for clarity to ensure safer or more effective use. Thus, according to the Device Modification Guidance, there is no change to labeling required to market the P200C.

B. Technology or Performance Change

Optos proposes to make the following technology or performance changes:

- removal of the blue laser and associated optical control components;
- removal of the motorized linear translation stage; and
- removal of an arm rest.

Each change is discussed individually below. Per Flowchart B, the following characteristics are addressed: control mechanism, operating principle, energy type, environmental specifications, performance specifications, ergonomics of the patient/user interface, dimensional specifications, software, firmware, packaging and sterilization.

The same validation testing was conducted for the P200C as for P200MA with the exception of the angiographic mode. Validation reports for the P200C are held in the design history file. As stated above, Flowchart B, along with

the guidance document text, leads to the conclusion that all of these changes require documentation in a memorandum-to-file and not a 510(k) clearance.

1. Removal of the blue laser

The first modification to the P200MA is the removal of the blue laser and associated optical control components. While the Device Modification Guidance speaks of changes in energy as the type of modification requiring a 510(k), we interpret the word “change” as not relating to the subtraction of a feature. The examples of technological changes that require a 510(k) are very different from the modifications that are the topic of this memorandum-to-file and support our interpretation of the word “change.” In short, the examples concern actual changes to a device. For example, from the use of an ultrasound to do X to the use of radiofrequencies to do X. In the present case, Optos does not intend to change the energy type. The new model is not a change from laser A to B, but is simply a change from lasers ABC to AB.

2. Removal of the motorized linear translation stage

The second modification to the P200MA is the removal of the motorized linear translation stage, which enables the device to change the response of the optical return path for blue laser imaging and the red/green laser imaging. This is a redundant function after the removal of the blue laser.

The removal of the motorized translation stage does not affect the control mechanism, operating principle, energy type, environmental specifications, performance specifications, ergonomics of the patient/user interface, dimensional specifications, software or firmware, packaging or sterilization.

Again, this is simply the removal of a cleared feature, not the addition of an un-cleared feature. Also, it is not a material mechanism of the device, such as a control mechanism, which might require a 510(k) if significantly modified.

3. Removal of arm rest

The third and final modification of the P200MA is the removal of the arm rest. While ergonomic changes can trigger a 510(k) under the appropriate circumstances, the subtraction of this feature does not qualify. Although it relates to a change in the indications for use, we have already noted above that such a change does not require a 510(k). Therefore, the related loss of the arm support, which is employed only when users intend to inject fluorescein, does not require a 510(k).

Thus, all of the technology changes lead to a conclusion of a memorandum-to-file. A 510(k) clearance is not required because of technology and performance changes.

C. Material Changes

Optos is not proposing to make any material changes, and, thus, Flowchart C is inapplicable to the proposed modifications.

III. CONCLUSION

In summary, the only differences between the P200MA and the P200C are: (1) removal of the blue laser; (2) removal of the motorized translation stage; and (3) removal of an arm rest. The Main Flowchart in FDA's Device Modification Guidance directed Optos to use Flowcharts A and B to assess the proposed changes. The Device Modification Guidance instructions for use, along with Flowcharts A and B, led to the conclusion to document the changes in a memorandum-to-file. The text of the guidance specifically addressed changes in the indications for use that limit the use of a device within the currently cleared indications and stated that such changes do not require the submission of a 510(k). In addition, by parity of reasoning, the technological changes do not require a 510(k). Just as subtracting a



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cleared indication does not call for a 510(k), one can conclude that the subtraction of device functionality related to a lesser indication also does not require a 510(k), absent a significant affect on safety and/or effectiveness.

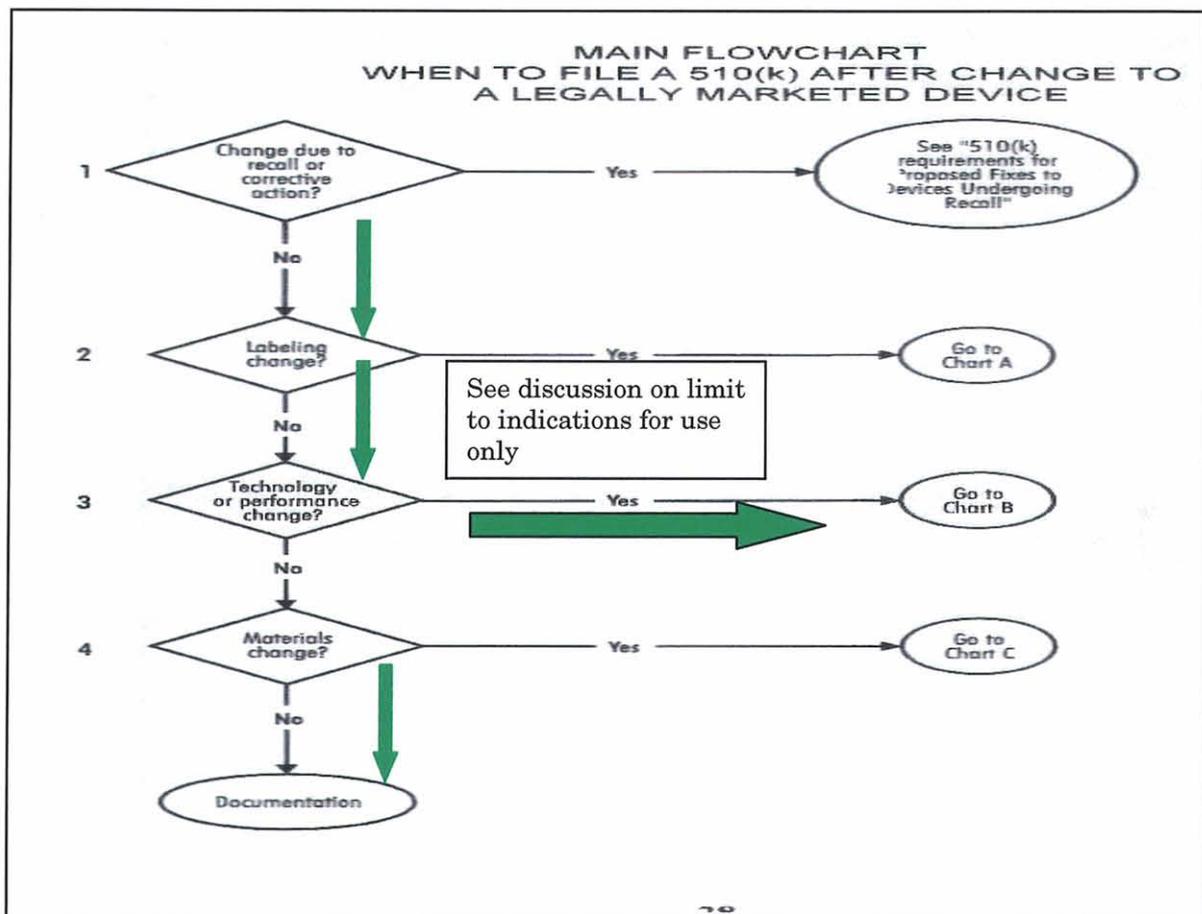
Based on FDA's guidance, Optos has determined that these modifications could not significantly affect the safety or effectiveness of the device or constitute a major modification in the device's intended use. Therefore, a new 510(k) is not required under 21 C.F.R. § 809.81(a)(3). This memorandum-to-file documents the company's determination that a new 510(k) is not required to market the P200C.



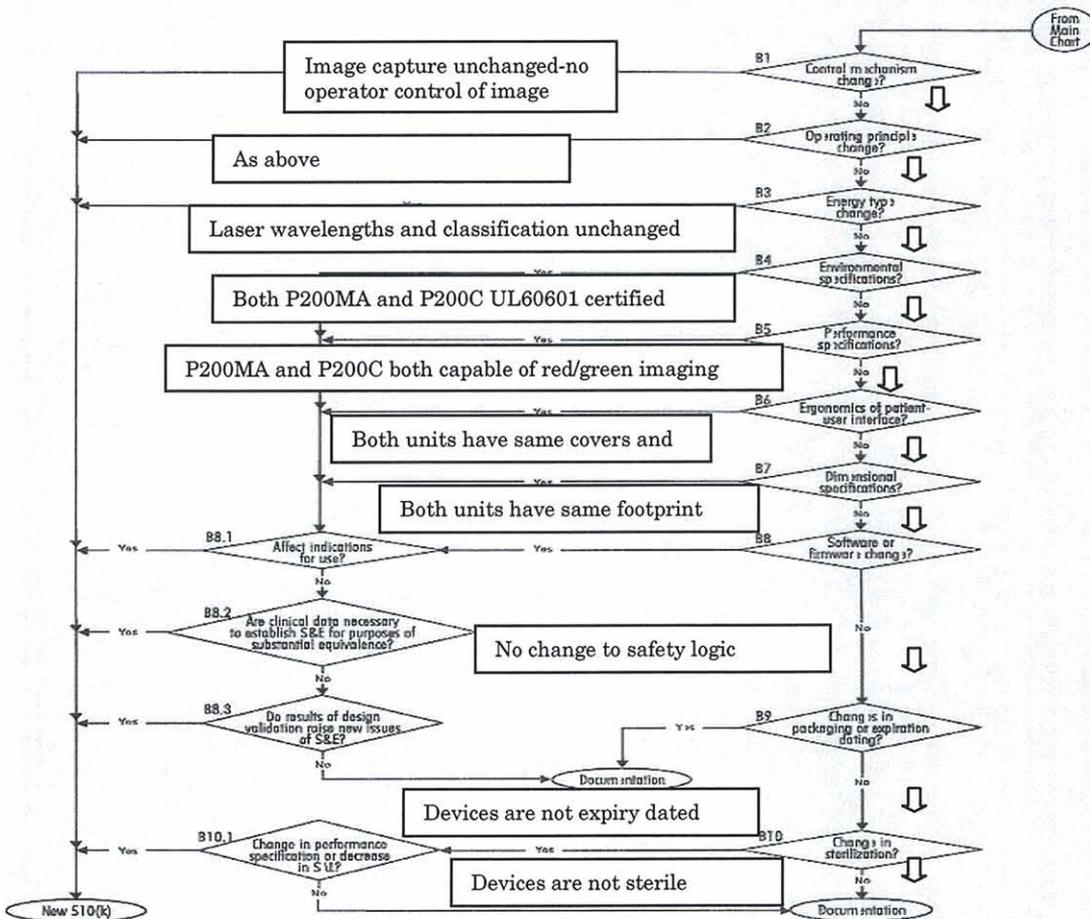
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Attachment 1



FLOWCHART B - IS IT A TECHNOLOGY OR PERFORMANCE CHANGE?



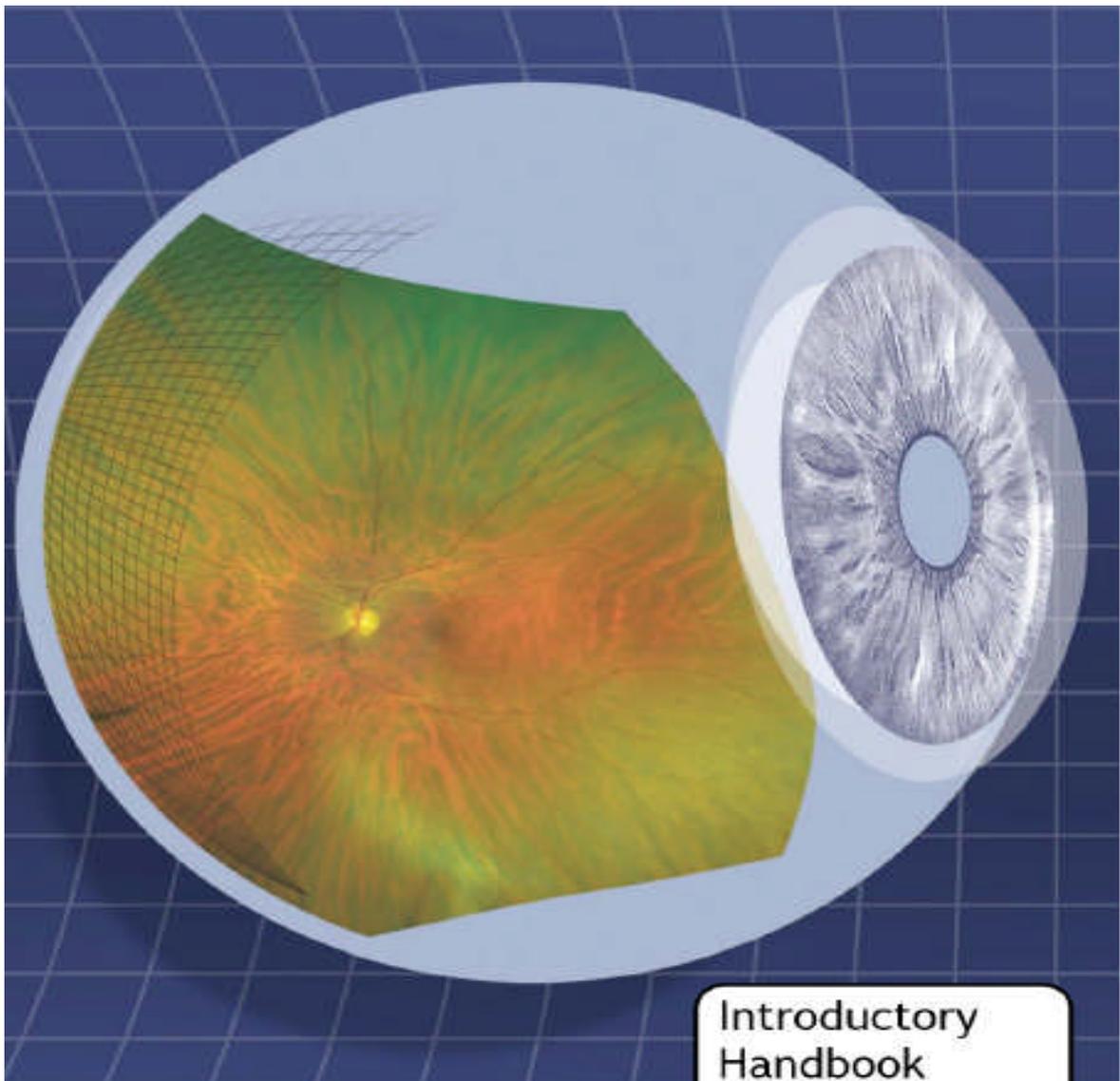
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Attachment2



Attachment 10



**Introductory
Handbook**
P200MA, P200C
and P200CAF



Introductory Handbook

Manual de introducción - Manuel d'introduction

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The information contained within this document is subject to change without notice. The latest version of this information can be found at www.optos.com.

This document should be used in conjunction with the help files supplied in each application and the Technical Data Specifications supplied with the device. Instructions and service information can be obtained by contacting the Optos Customer Service Department through the contact details given in this handbook.

The device is a prescription device

 Caution	Federal law restricts this device to sale by or on the order of a physician or practitioner. See 21 C.F.R. § 801.109(b)(1) for more information.
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Optos does not provide and the **optomap® plus** guidelines do not constitute advice on making reimbursement claims. Diagnostic tests should be ordered by the treating physician and this physician is responsible for appropriate usage, adequate documentation and proper coding. It is the responsibility of the physician to comply with Medicare regulations, and check with the local insurance carrier for reimbursement information and instructions. Optos does not accept any liability for reimbursement claims made while using **optomap® plus**.

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1 Introduction

This section introduces the device and explains the information contained in this document.

Please read the Safety Guidelines before using your device, see *Safety Guidelines* on page 8.

Your device will be installed by Optos technical personnel. Do not operate the device until Optos technical personnel have completed the installation and training.

About the device

The Optos family of scanning laser ophthalmoscopes are widefield digital imaging devices capable of capturing from the far periphery of the retina. The retinal images are captured in an automated, patient friendly way without scleral depression or contact with the cornea.

The Panoramic P200C uses red and green lasers to produce a digital, high resolution image, which is displayed on a PC monitor screen. Red and green lasers are used for digital color imaging. These laser wavelengths penetrate the retinal structures to different depths, each wavelength providing information for interpretation and diagnosis.

The Panoramic P200MA uses red, green and blue lasers to produce a digital, high resolution image, which is displayed on a PC monitor screen. Red and green lasers are used for digital color imaging. These laser wavelengths penetrate the retinal structures to different depths, each wavelength providing information for interpretation and diagnosis. The blue laser is used when capturing angiography images. A series of images is captured as the fluorescein flows through the retinal vessels.

The Panoramic P200CAF uses red and green lasers to produce a digital, high resolution image, which is displayed on a PC monitor screen. Red and green lasers are used for digital color imaging. These laser wavelengths penetrate the retinal structures to different depths, each wavelength providing information for interpretation and diagnosis. In autofluorescence mode, the device uses the green laser to illuminate the eye. This allows an image of the natural fluorescence of the eye to be captured.

Optos' technology is designed to operate through a minimum pupil diameter of 2mm. Although pupil dilation is not required, the decision to dilate is a medical decision to be made by the eye-care professional.

Images are captured on the scan head and then viewed, magnified, annotated and separated into their color components in the *Review* application see *About the software applications* on page 5.

Indications for Use

The Panoramic P200C scanning laser ophthalmoscope is intended to be used as a wide field and retinal imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.

The Panoramic P200MA scanning laser ophthalmoscope is intended to be used as a wide field and retinal fluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.

The Panoramic P200CAF scanning laser ophthalmoscope is intended to be used as a wide field and retinal autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.

About this Handbook

This Introductory Handbook explains the information you need to know before you start using the device.

Getting to know the device on page 6– introduces each part of the device.

Safety Guidelines on page 8– details the safe operation of the device. You must read this section before operating the device.

Getting Started on page 13– details how to start and finish using the device each day.

Getting help on page 16– details how to access the help files and how to contact Optos.

Cleaning on page 18– details how to clean the user accessible parts of the device.

About the software applications

The **Capture** application runs on the scan head. This application lets you control the device; capturing and checking the quality of images.

V² Vantage DX contains a set of applications that let you review and manage images. These applications are installed on the Image Server PC and Viewing PCs. You can run these applications by double-clicking the relevant icon on the desktop.

<p>V² Vantage DX Admin</p>	<p>Lets you configure your system. You can set password requirements, create new users, modify existing users, and set a variety of system controls.</p> <p>You can also run the Admin application by selecting Start > Programs > OptosV² Vantage DX > Admin.</p>
<p>V² Vantage DX Scheduler</p>	<p>Lets you manage patient records and appointments for the optomap® Retinal Exam.</p> <p>You can also run the Scheduler application by selecting Start > Programs > OptosV² Vantage DX > Scheduler.</p>
<p>V² Vantage DX Review</p>	<p>Lets you review, annotate, and add diagnostic codes to captured images. Also contains exporting, e-mailing and printing tools.</p> <p>You can also run the Review application by selecting Start > Programs > OptosV² Vantage DX > Review.</p>
<p>V² Vantage DX Storage</p>	<p>Lets you archive images and manage the database and image files.</p> <p>You can also run the Storage application by selecting Start > Programs > OptosV² Vantage DX > Storage.</p>

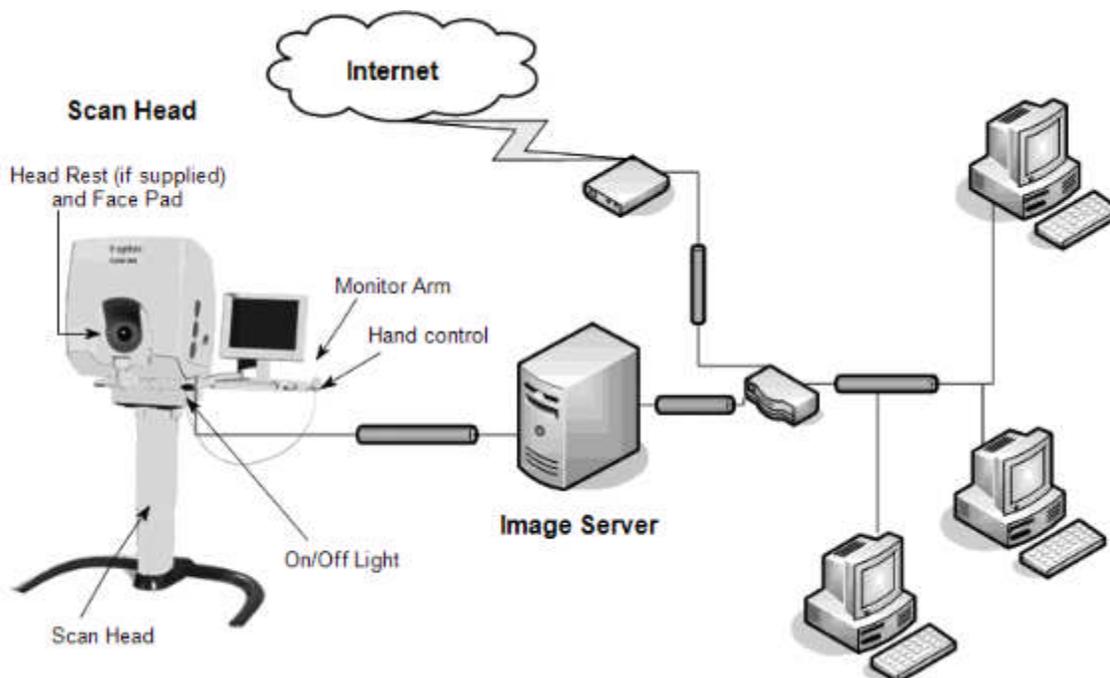
2 Getting to know the device

The device comprises the Scan Head Module, Image Server PC, and Viewing PC. For more information, please refer to the Technical Data Specification supplied with the device.

Images are captured on the scan head. The scan head runs the **Capture** application. The Image Server PC runs the **Storage** application, **Admin** application, and **Scheduler** application. The **Review** application is run on the Viewing PCs. In a typical installation, the images and database will be stored on the Image Server PC. You can review captured images at any Viewing PC that is connected to the Image Server PC across the network.

Understanding the equipment

The device is part of a system of networked PCs.



Scan Head Module

The scan head module runs the **Capture** application. This application lets you select and perform the required patient imaging procedure.

	<p>The scan head monitor should not be used to review images for diagnostic purposes. The P200CAF should not be connected to a DICOM server.</p>
<p>Caution</p>	

The scan head module comprises:

- Scan head – Comprises the lasers and electronics used to capture patient images.
- Scan head table – Supports the adjustment of the scan head height. The table can be raised or lowered using the hand control.
- Face pad – The face pad support the patient's face when the patient is being imaged. The face pad can be removed for cleaning.
- Scan head monitor arm – Links the monitor to the scan head. The keyboard and mouse tray and the hand control hook are part of the monitor arm.
- Scan head monitor – Displays the **Capture** application. The monitor displays alignment feedback and captured images.
- Hand control – Comprises buttons used to raise and lower the scan head table, align the patient, and capture images.
- Head Rest, patient arm support and table wings – Devices used to capture **optomap® fa** images are fitted with a head rest, patient arm support and table wings. They are used to support the patient throughout the imaging process. The head rest and patient arm support can be removed for cleaning. P200C devices are supplied with a head rest.

Viewing PCs

Viewing PCs run the **Review** application. The **Review** application lets you analyze patient images. You can review images in a variety of ways. You can add annotations to highlight areas of interest, add diagnostic codes, add notes, and email images to third parties.

Image Server

The Image Server PC runs the management applications:

- The **Admin** application lets you configure the network and data management environment. You can define security levels, create and modify users, and set a variety of system configuration options.
- The **Storage** application lets you archive and protect database and patient image files. It is essential to archive regularly. For further information refer to the **Storage** application help file.

Depending on your network configuration you may also run the **Review** application and **Scheduler** application from the Image Server. When the **Review** application has been installed on an Image Server, the Image Server may be used as an additional Viewing PC.

The **Scheduler** application lets you schedule patient appointments and manage patient details. The **Scheduler** application may be installed on any PC on the same network as the device.

3 Safety Guidelines

Your system is a medical device and, as such, should be operated within the safety parameters and instructions defined in this Introductory Handbook, the help files and the Technical Data Specification.

To ensure validity of certification, do not replace any part of the device. If the device appears faulty or has non-functioning components, please contact Optos.

If you have any questions regarding the correct use of your device, please contact Optos before attempting to operate the device.

Please read these Safety Guidelines before using your device.

General Safety

 <p>Warning</p>	<p>Only Optos technical personnel are permitted to install and service the device.</p> <p>Your device will be installed by Optos technical personnel. Do not operate the device until Optos technical personnel have completed the installation and training.</p> <p>Do not move the scan head or scan head table.</p> <p>Do not remove the scan head casing. There are no user serviceable or replaceable parts inside.</p> <p>Do not capture images when the face pad is not in place.</p> <p>Do not lean on the head rest, monitor arm, monitor or keyboard tray. Ensure the monitor arm and keyboard tray do not restrict the patient's access to the device.</p> <p>The patient arm support supplied with the P200MA is designed to support the weight of a resting arm. Do not exceed the weight indicated on the patient arm support. When in use, ensure the patient arm support is securely clamped to the table wing, and that it is covered with a piece of absorbent paper.</p> <p>Care should be taken adjusting the head rest or table height when the patient is resting on the head rest.</p>
 <p>Caution</p>	<p>The scan head monitor should not be used to review images for diagnostic purposes.</p> <p>Always wear powder-free gloves when cleaning the device.</p> <p>Do not use lint cloths, tissues, or other materials that may create dust, near the scan head.</p> <p>Do not operate the table motor continuously for a prolonged period of time.</p> <p>Restarting the PC used to store the database and images</p> <p>Ask users to logout of their PCs before you shut down the Image Server PC. Ask Viewing PC users to close any Optos applications before you shut down the Image Server PC.</p>

Medical Safety

	<p>Laser Safety</p> <p>The device is a Class 1 laser device at the eye, and complies with EN60825-1 and 21 C.F.R.1040.10 and 1040.11. Based on current scientific knowledge, a Class 1 laser device can be considered as safe by engineering design, and safe under reasonably foreseeable conditions of operation.</p>
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<p>Warning</p>	<p>Danger of Laser Injury</p> <p>Do not remove the device cover or attempt to replace the lasers. Only qualified Optos technical personnel are permitted to service the device.</p> <p>The use of this device or any other device which uses light for ocular examination should not be prolonged unnecessarily.</p> <p>While no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, some patients may be less tolerant to an exposure of light. This may be the case for infants, aphakic patients and persons with diseased eyes. Patients who have had any exposure with the same device or with any other ophthalmic device using a visible light source within the previous 24 hours may also be less tolerant to a further exam using light.</p> <p>However, the benefits of an eye exam will almost always outweigh any discomfort associated with the exposure to light.</p> <p>While the scan head covers are fitted the risks are minimized. The following items are monitored by the Laser Radiation Management System:</p> <ul style="list-style-type: none"> • Images may only be captured when the scanning system is within safe operating conditions. • Internal power monitoring prevents excess power at the eye. • An internal shutter and associated controls prevent early or prolonged laser exposure. <p>The Laser Management System maintains a Class 1 accessible emission limit (AEL) at the eye for normal operation and under foreseeable fault conditions.</p>
 <p>Caution</p>	<p>Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.</p>
 <p>Warning</p>	<p>Fluorescence Imaging</p> <p>Optos does not offer any guidance or advice on the use of fluorescein. This is conducted under a separate medical procedure. This procedure should only be conducted by qualified medical staff.</p> <p>The P200MA is indicated for use as a widefield and retinal fluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.</p>
 <p>Warning</p>	<p>Use on Patients with Epilepsy</p> <p>The device uses flashes of laser light. Some patients with epilepsy may be sensitive to flashes of light. Caution should be exercised for patients who have a history of reaction to camera flashes or strobe lighting.</p> <p>Working in Low Light Conditions</p> <p>The device requires low levels of room light to operate efficiently. Take care to avoid accidents when working under low light conditions.</p> <p>Heat Generated when In Use</p> <p>The face pad may get warm during use.</p> <p>Taking Measurements</p> <p>After you have drawn the points on the image, the software can estimate the relative distance between any two points. The calculated distance is an estimate only and may be used to indicate a need for further review. The measurements of relative distance, however, should not be used as an indication of a specific condition or disease. The size and shape of an image depends on the type of device used to capture it. Images from different types of device should not be compared.</p>

 <p>Caution</p>	<p>Optical Elements</p> <p>Do not place any optical elements (with the exception of the patient wearing contact lenses) between the face pad and the patient's eye.</p>
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Peripherals

 <p>Caution</p>	<p>Only use peripherals supplied with the device. Independently sourced peripherals may not be compatible. Contact Optos for more information on compatible peripherals.</p> <p>Do not connect a printer to the scan head console or power a printer from the scan head.</p> <p>Only power the scan head from the scan head connector. Do not power any other electrical equipment from the scan head table.</p>
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Software on Optos Supplied PCs

 <p>Caution</p>	<p>Only load software when supplied and instructed by Optos.</p> <p>Installing New Software</p> <p>If you need to install other software, for example a network printer driver, contact Optos Customer Support to confirm that there are no known compatibility issues.</p> <p>Updating Existing Software</p> <p>Your system administrator should carry out software upgrades using the software and instructions provided by Optos.</p> <p>You can install critical Windows Updates and anti-virus signatures on the Image Server and Viewing PCs by following the instructions given in the Admin Application help file.</p>
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Environmental Safety

 <p>Warning</p>	<p>Do not operate the device in an environment:</p> <ul style="list-style-type: none"> • Where flammable mixtures may be present. • Inside the influence of the magnetic field of a magnetic resonance imaging device.
 <p>Caution</p>	<p>Do not operate the device in an environment:</p> <ul style="list-style-type: none"> • Exceeding the environmental limits described in the Technical Data Specification which accompanies this device. • That blocks the scan head air intake vents . <p>Do not use lint cloths, tissues, or other materials that may create dust, near the scan head.</p> <p>Do not operate mobile phones in the immediate vicinity while operating the device.</p>

Electromagnetic Compatibility (EMC)

	<p>The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Technical Data Specification which is supplied with the device.</p>
<p>Caution</p>	<p>Portable and mobile RF communication equipment may affect the device.</p>

Interference

	<p>This device has been tested and complies with Part 15 of the FCC (U.S.A.) Rules and the European standard EN60601-1-2. Operation is subject to the following two conditions:</p> <ol style="list-style-type: none"> 1. This device may not cause harmful interference, and 2. This device must accept any interference received, including interference that may cause undesired operation.
<p>Warning</p>	<p>These limits are designed to provide reasonable protection against harmful interference in a residential environment.</p> <p>There is no guarantee that interference will not occur in a particular installation.</p>

Electric Shock

	<p>Do not open the scan head casing. There are no user serviceable or replaceable parts inside.</p> <p>To prevent electric shock:</p>
<p>Warning</p>	<ul style="list-style-type: none"> • Only use cables supplied by Optos. Cables should not be extended or altered. • Mains supply must be earthed. • The device may only be service by Optos technical personnel. • Care must be taken never to touch exposed parts of the device while in physical contact with a patient. • Hospital grade connectors must be used in countries where they are available, for example in the United States of America and Canada. • The mains cable must be regularly inspected.

Device Failure

	<p>In the unlikely event you hear a loud noise from the device, see smoke or smell burning, stop imaging and isolate the device by unplugging.</p>
	<p>If you suspect the device may be faulty check the Frequently Asked Questions section in the application's help file. If in any doubt on how to proceed, contact Optos, see <i>Contact us</i> on page 20.</p>

Cleaning and Biocompatibility

 <p>Warning</p>	<p>If these guidelines are not followed there is the possibility of biocompatibility problems. These risks will be minimized if you clean the face pad and head rest as defined in the Cleaning section, see <i>Cleaning</i> on page 18.</p> <p>Carry out the cleaning procedures regularly. This will ensure a high level of patient interface hygiene and consistently successful images. No other user maintenance is required.</p>
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Symbol and Label Information

	Switch - off position.
	Switch - on position.
	Protected earth connection.
	Danger: high voltage warning.
	Warnings are directions which, if not followed, could cause fatal or serious injury to a user, engineer, patient or any other person.
	Cautions are directions which, if not followed, could cause damage to the equipment described in this manual and/or other equipment or goods and/or could cause environmental pollution.
	Follow the instructions in this order shown.
	Interference may occur in the vicinity of equipment marked with this symbol.
	Laser device present. This symbol is used internally. Only Optos Technical Personnel are permitted to install and service the device. Under normal used, operators should never see this symbol.
	Type B - relates to the allowable maximum current leakage which can flow from the applied part. The limits for this are defined in IEC 60601.
	End of life disposal of this device is subject to the requirements defined in EN 50419. This directive ensures that Waste Electrical and Electronic Equipment (WEEE) is disposed of properly.

4 Getting Started

Please read the **Safety Guidelines** before using your device, see **Safety Guidelines** on page 8.

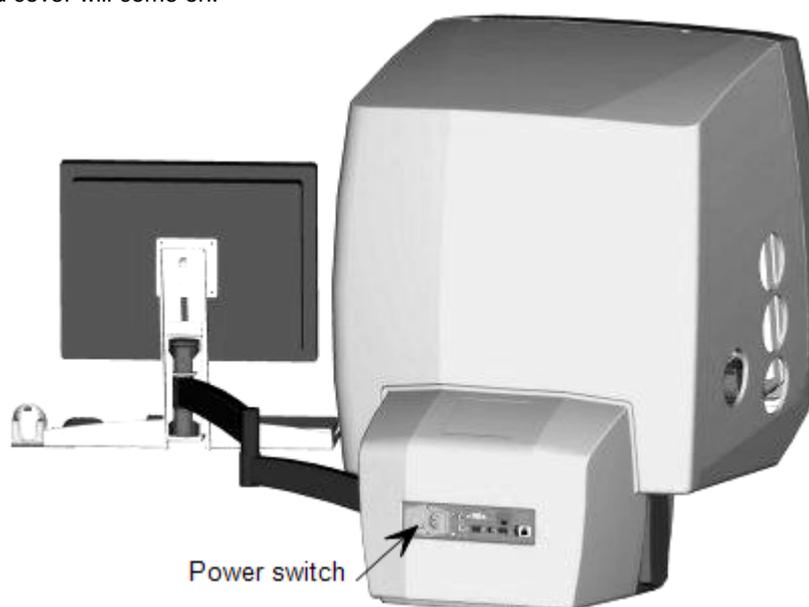
This section explains how to start and finish using the device each day. More detailed instructions can be found in the help files for each application.

Switching on each day

Scan Head Module

You must start and close the device each day.

1. Remove the scan head dust cover.
2. Press the power switch at the rear of the scan head to the **on (I)** position. The green light on the front of the scan head cover will come on.



3. Switch on the scan head monitor. The light will come on to indicate that the monitor is on.
4. The **Welcome dialog box** is displayed when the device has started. Click **LOGIN** and enter your user name and password. (User names and passwords are assigned in the **Admin** application. All passwords are case sensitive).
 - There will be a short delay while the device starts up.
 - When switched on from cold, the lasers in the scan head will need time to warm up to the operating temperature required for optimum performance. The imaging procedures will not be available during this time (approximately 10 minutes).
 - The images and database are stored on the Image Server PC. The scan head module and Viewing PCs need to communicate with the Image Server PC. A network error will be displayed if the Image Server PC is not available when the scan head tries to communicate with it.
 - The scan head will automatically go into stand-by mode when it has not been used for a defined period of time. You can define the period of time in the **Settings Options dialog box**. The device will automatically come out of stand-by mode when in use again.

If there is a network error when starting the device it is likely that there is a temporary problem with the Image Server PC. You can clear any problems by restarting the Image Server PC.

Viewing PC

Captured images are reviewed using the Review application running on Viewing PCs. You need to login to the Viewing PCs to access the patient details and images stored on the Image Server PC.

Usually, Viewing PCs will have been logged off at the end of each day. To login to a Viewing PC:

1. Press [Ctrl]+[Alt]+[Del] to display the Unlock Computer dialog box.
2. Type your user name and password. Click OK.
3. Select Start menu > All Programs > optos V2 Vantage > Review to run the Review application.

Image Server PC

The Image Server PC stores the patient details and image files. You do not need to login to the Image Server PC as the device only needs it to be switched on for the Image Server PC services to be available to the scan head and any Viewing PCs.

If the Image Server PC seems to be switched off, check that the power supply, PC and PC monitor are switched on. Restart the Image Server PC; if the device does not seem to be operating correctly.

Closing the System Each Day

The system must be closed down properly each day by shutting down the scan head and closing the system.

	<p>You should always log off the scan head and switch off the scan head power at the end of each working day.</p> <p>You should always log off and shut down each Viewing PC at the end of each working day.</p> <p>You should run the Storage application and archive files at least once a week. See the Storage application help files for detailed instructions.</p>
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How to shut down the scan head

1. Complete the current session and click LOGOUT to close the device.
2. Click SHUT DOWN to shut down the device.
3. Wait for the device to display a message indicating that it is safe to switch off the scan head.
4. Switch off the scan head monitor.
5. Switch the power switch at the rear of the scan head to the off (O) position.
6. Cover the scan head with the dust cover.

How to close the system

1. Shut down the scan head.
2. Close the Optos applications on all PCs in the system. This is to prevent files being accessed while the archiving task runs.
3. It is important to archive at least once a week. Select Start > All Programs > Optos V2 Vantage > Storage. Run any recommended start-up tasks. For more information press [F1] to display the help file when the Start-up Tasks dialog box is displayed.
4. Close the Storage application after completing the start-up tasks indicated in the previous step.
5. Select Start button > Log Off to display the Log Off Windows dialog box. Select Log Off to log off from the PC. Repeat on each PC.

Notes:

- Logoff the Image Server PC and leave switched on. Do not shut down the Image Server PC.
- Your device communicates with Optos overnight and will need to access the Image Server PC.
- Image files cannot be viewed when the Image Server PC has been shut down.

Attaching and Detaching the Patient Arm Support

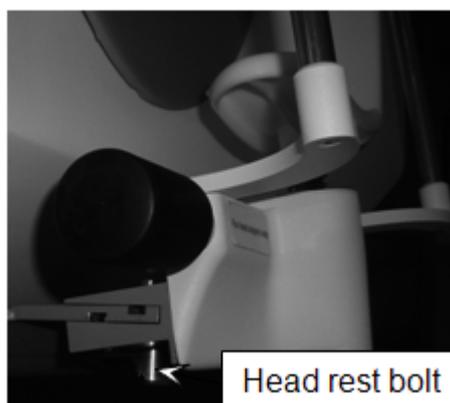
Some devices are supplied with a patient arm support and table wings. The patient arm support is fitted with a clamp and can be attached and removed from the table wings.

	<p>The patient arm support supplied with the P200MA is designed to support the weight of a resting arm. Do not exceed the weight indicated on the patient arm support. When in use, ensure the patient arm support is securely clamped to the table wing, and that it is covered with a piece of absorbent paper.</p>
<p>Warning</p>	



Attaching and Detaching the Head Rest

To remove the head rest for cleaning, pull the head rest bolt down and slide the head rest to the left.



5 Getting help

The help files contain detailed information about how to use the device. You can access this information from the application at any time by pressing **[F1]** on your keyboard. In the Review, Storage, Admin and Scheduler Applications you can also access help files from the application's Help menu.

If the help files do not answer your problem, please contact Optos Customer Support.

Additional material may be available on the Partner area of the Optos website. There is a convenient link from the Help menu, see *How to access additional documentation on the web* on page 17.

Accessing Help from the Capture Application

Help is available throughout the application. Press **[F1]** to display information on the current task.

Accessing Help from the applications

There are several ways to access the help files:

Pressing **[F1]** for Help with Your Current Task

The help system can display a help topic that relates to the current application window or dialog box. Press **[F1]** on your keyboard to display information on the current task.

Help from the Help Menu

You can access the application help file from the **Help menu**. Click **Help menu > Optos <application> Help** to display the help file.

How to display the hierarchy of all help topics

1. Click the **Contents tab** to display the help file hierarchy.
2. Click a topic to display it in the right-hand pane. Alternatively, double-click the book icon and select from the list of topics that appears.

How to browse the help index

The help index contains defined keywords and phrases. You can select from the list of keywords and phrases to display a list of related topics.

1. Click **Help menu > Optos <application> Help** to display the help file.
2. Click the **Index tab** to display the alphanumeric list of indexed words and phrases.
3. Select the word or phrase from the list. Alternatively, type the word or phrase in the text box. If you do not find what you were expecting, it may be that the index does not contain the exact word or phrase. Try typing a similar word or phrase. Alternatively, try entering the word or phrase in the **Search tab**.
4. When you have located the topic you want, click **Display** to display the topic in the right-hand pane.

How to search for help

1. Click **Help menu > Optos <application> Help** to display the help file.
2. Click the **Search tab** to display the search pane.
3. Type the words you are looking for. Click **List Topics** to display the search results.
 - Use **'?'** to replace a single letter, for example **'archive?'** to search on **'archived'** and **'archives.'**
 - Use **'*'** to replace a group of letters, for example **'archiv*'** for **'archive,' 'archived,' 'archives'** and **'archiving'**.
4. Click a topic to display it in the right-hand pane.

Note

- If you do not get the result you were expecting, it may be that the help file does not contain the exact word or phrase you typed. Try typing a similar word or phrase.
- You can use wildcards to search for parts of words.

How to navigate topics

1. Click **Help menu > Optos <application> Help** to display the help file.
2. Display the topic you require using the **Contents, Index or Search** tabs.
3. Repeat for each topic you want to view.
4. Click **Back and Forward** to scroll through the topics you have displayed. Only topics you have viewed will be displayed when clicking **Back and Forward**. This is particularly useful if you want to go back to a previous topic and you do not want to search for it again.

How to print help topics

1. Click **Help menu > Optos <application> Help** to display the help file.
2. Use the **Contents** tab to display the help section you wish to print.
3. Click **Print** to display the **Print Topic** dialog box.
4. Select to print the current topic or, if applicable, the selected heading and its subtopics. Click **Print**.

You can print the current topic by right-clicking the topic to display the pop-up menu. Select **Print** to display the **Print dialog box** and click **Print**.

Optos on the Web

The Optos web site contains a wide variety of information resources. Simply click the **Partner Login** link at www.optos.com to access the partner login area or to register.

The **Partner** area of the web site includes:

- Practice Marketing materials.
- Clinical materials.
- Details of the Optos Academy events.
- Software downloads.

How to access additional documentation on the web

1. Select **Help menu > Visit Optos Partner on the web**.
2. Login when prompted.
3. Click your device to display the relevant documentation.

6 Cleaning

While biocompatible materials have been used where the instrument comes into contact with the patient, these need to be cleaned between patients to reduce the risk of contamination or cross-infection.

Cleaning of the external surfaces of the device should be carried out on a regular basis.

The device will be subject to a scheduled inspection and maintenance routine carried out by Optos Technical Personnel.

 <p>Caution</p>	<p>Always wear powder-free gloves when cleaning the device.</p> <p>Do not use lint cloths, tissues, or other materials that may create dust, near the scan head.</p>
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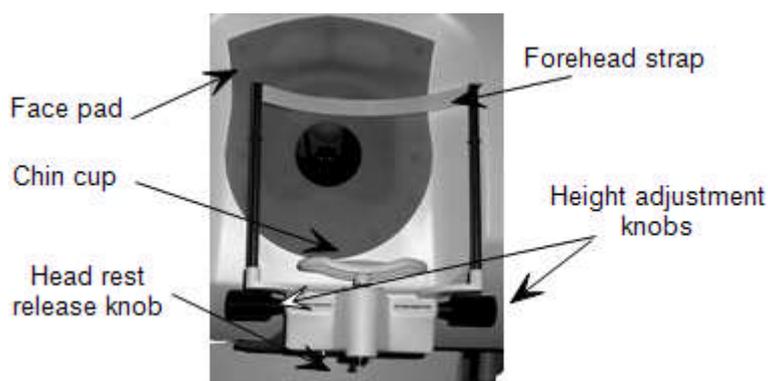
Cleaning Before Each Patient

The areas where the patient comes into contact with the device must be cleaned before each patient is imaged.

How to clean the device before each patient

 <p>Warning</p>	<p>Do not capture images when the face pad is not in place.</p>
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The following cleaning procedures should be carried out between patients:



- The face pad and head rest must be cleaned with an individually sealed, 70% isopropyl alcohol wipe and allowed to air-dry between patients.
- The head rest can be removed for cleaning, see the Introductory Handbook for details on removing the head rest.
- The P200MA is supplied with a patient arm support. This should also be cleaned with an individually sealed, 70% isopropyl alcohol wipe and allowed to air-dry between patients.
- Do not use tissues or other material to dry the areas that have been cleaned as this could create dust. Dust could collect on the scan head mirror and optical components and impair image quality. Always allow cleaned areas to air-dry.

- Do not let the cleaning wipes come into contact with the inside of the instrument.
- The wipes should be checked periodically to ensure that they are within their marked expiration date.

How to clean the head rest and patient arm support before each patient

Some devices are supplied with a head rest and patient arm support. These must be cleaned with an antiseptic cleaning wipe and allowed to air-dry between patients. Do not use tissues or other material to dry the head rest and patient arm support.

General Cleaning

The equipment should be kept clean and dust free.

- Logout, shut down and power off the scan head before cleaning the outer casing of the scan head.
- Use a soft, slightly damp cloth to clean the plastic surfaces.
- Ensure debris does not fall inside the device.
- Use a glass-cleaning agent to clean the PC monitor screen.
- Do not use solvent.

Decontaminating External Surfaces

You should decontaminate external surfaces when they become dirty or contaminated with bodily fluids. Follow your clinic's decontamination procedure when necessary.

Cleaning the Main Mirror

In devices where there is a hatch in the front cover, follow the Main Mirror Cleaning Procedure supplied with the device. In all other systems, where there is no hatch, contact Optos.

7 Contact us

We welcome your questions and comments.

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Scotland, UK	
	All inquiries: UKinfo@optos.com
	Technical Support: UKtechsupport@optos.com
	Web site: www.optos.com

You will need to tell us your site number to allow Optos to access your details. You can find the Site Number on the documentation received from Optos. Alternatively, open the **Admin** application and select **System menu > Set Site Information** to display the **Practice Information dialog box**.

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Please check www.optos.com for the latest information on new regional offices.

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