

SEP 16 2003

K030719

510(K) SUMMARY
substantially equivalent

General Information

Applicant's Name and Address: OCULUS Optikgeräte GmbH
Münchholzhäuser Straße 29
D-35582 Wetzlar

Date of Summary: 04 March 2003

Owner/Operator Number: 8010318
Mr. Joerg Iwanczuk
Product Manager

Device Name

Trade Name: Pentacam Scheimpflug Camera

Class: Class II

Classification Name: Scheimpflug Camera

Product Code: MXK Anterior Eye-Segment Analysis System

Regulation Number: 886.1850

Predicate Devices

The Pentacam Scheimpflug Camera is claimed to be substantially equivalent to the following currently market device:

NIDEK, EAS-1000 Anterior Eye-Segment Analysis System- K991284

Device Description:

The Pentacam Scheimpflug Camera is a non-invasive, diagnostic system created to take photographs of the anterior segment of the eye, table mounted and AC powered. The system is based on the Scheimpflug Principle for Slit Image photography. The device consists of a measurement unit, power supply and a CPU. The measuring system uses blue light (UV-free) given to a slit to illuminate the eye, and a CCD-Camera for photography. The measuring system offers the possibility of automatically rotation to get photographs of every part of the eye. The system calculates from the photos a 3D-modell of the eye.

Product Comparison

	New Device	Anterior Eye-Segment Analysis System
Manufacturer	OCULUS Optikgeräte GmbH	Nidek Inc.
Measuring Principle	Scheimpflug Principle for Slit Image photography	Scheimpflug Principle for Slit Image photography
Optical	Single Aperture	Single Aperture
Viewing Optics	15" Coloured Screen	5.5" Black and White CRT
Observation Illumination	Infrared LED 800nm	Infrared LED for Retro-Illumination 800nm
Flash Output Illumination	Blue LED Light (UV-free) 475nm, max. 2.5Wsec	Xenon Lamp 200Wsec
Photography Camera	CCD-Camera	CCD-Camera
Display	Data digital, displayed on a CPU	Data digital and can be displayed on a CPU
Image resolution	800 x 600 pixels	640 x 400 pixels
Image size	5.6 x 4.5mm	8mm x 6.6mm
Photographic range	Eligible 0 to 180°	Offers Photographic angles from 0 to 180°
Photographic Series	1 to 50 photos	N/A
Slit Length	14mm	2 – 14mm adjustable
Power Consumption	50VA	150 VA
Power requirement	110/220 VAC, 50/60Hz	100VAC, 50/60Hz
Weight	9 kg	25 kg

Basics for Substantial Equivalence

- The systems utilize the same or similar Operating System. They contain:
 - An optical system
 - A source of illumination for observation and photography
 - A CCD-Camera as photographic medium
- Both systems have the same intended use to measure the eye and the anterior eye segment
- Both systems use the same device features like a
 - Head stabilizing device
 - External fixation target
 - Joy stick for control mechanism
- Both systems are considered “Non Invasive” as defined in 21 CFR §812.3(k) and considered not to be a “Significant Risk Device” as defined in 21 CFR §812.3(m)

Indications for Use

Intended Use: The Pentacam is designed to take photos of the anterior segment of the eye, which includes cornea, lens and anterior chamber. To evaluate:

Corneal shape

Analyse condition of the lens

Densitometry, cataract degree and location using the Scheimpflug Image

State of the lens (pre and post intraocular lens implant)

Analyse anterior chamber (size, volume and angle)

Pachymetry (thickness of the cornea)

Scheimpflug Image

Analysing center position of the cornea to iris and lens

Safety

The Pentacam is a non-invasive diagnostic system, which contacts the patient only on his/her chin and forehead. The Pentacam does not present or pose any new or additional effects for risk on the safety prescribed intended uses. The light output is of an eye safe intensity and wavelength. The electrical safety requirements for medical devices are met. The Pentacam is proven effective for its intended uses through internal company and independent clinical studies.



SEP 16 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCULUS Optikgeräte GmbH
c/o Tom Weatherby
18902 NE 150th St.
Woodinville, WA 98072

Re: K030719
Trade/Device Name: Pentacam Scheimpflug Camera
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: MXK
Dated: July 18, 2003
Received: July 21, 2003

Dear Mr. Weatherby:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in cursive script that reads "A. Ralph Rosenthal".

A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic and Ear,

Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



510(k) Number (if known): K030719

Device Name: Pentacam Scheimpflug Camera

Indications For Use:

The Pentacam is designed to take photos of the anterior segment of the eye which includes the cornea, pupil, anterior chamber and lens of the eye. To evaluate:

- corneal shape,
- analyse condition of the lens (opaque crystalline lens),
- analyse the anterior chamber angle,
- analyse anterior chamber depth,
- analyse the volume of the anterior chamber,
- analyse anterior or posterior cortical opacity,
- analyse the location of cataracts (nuclear, subcapsular and or cortical), using cross slit imaging with densitometry,
- corneal thickness.

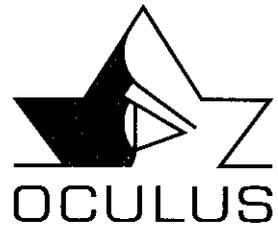
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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

Dan J. Kocum
 (Division Sign-Off)
 Division of Ophthalmic Ear,
 Nose and Throat Devices

510(k) Number K030719

(Optional Format 3-10-98)



K030719/A1

**Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850**

**510(k) Number: K030719
Trade Name: Pentacam Scheimpflug Camera
Owner/Operator No.: 8010318**

REC'D
AUG 15 A 10:51

Dutenhofen, 12-Aug-03

Dear Ladies and Gentlement,

These are the additional information according the 510(k) device

„Pentacam Scheimpflug Camera; k030719.“

Please hand over the documents to

Mr. Everette T. Beers

or

Ms. Daryl Kaufman.

Thank you for co-operation and help.

Yours sincerely

Joerg Iwanczuk

Product Manager

International Sales Department

OCULUS Optikgeraete GmbH

Tel.: ++49-641-2005-272

Fax.: ++49-641.2005-295

J.Iwanczuk@t-online.de

95

SK26



510(k) Number (if known): K030719

Device Name: Pentacam Scheimpflug Camera

Indications For Use:

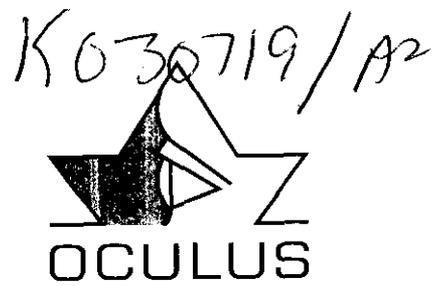
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- analyse anterior chamber depth,
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- analyse anterior or posterior cortical opacity,
- analyse the location of cataracts (nuclear, subcapsular and or cortical), using cross slit imaging with densitometry,
- corneal thickness.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)



**Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850**

**510(k) Number: K030719
Trade Name: Pentacam Scheimpflug Camera**

Owner/Operator No.: 8010318

FDA/CDRH/OC
2003 SEP -8 A 10:08

Dutenhofen, 5-Sep-03

Dear Ladies and Gentlement,

These are the additional information according the 510(k) device

„Pentacam Scheimpflug Camera; k030719.“

Please hand over the documents to

Ms Daryl Kaufman.

Thank you for co-operation and help.

Yours sincerely



Joerg Iwanczuk

Product Manager

International Sales Department

OCULUS Optikgeraete GmbH

Tel.: ++49-641-2005-272

Fax.: ++49-641.2005-295

J.Iwanczuk@t-online.de

21

SKY

3 Description of unit

The OCULUS Pentacam is a rotating Scheimpflug camera. The rotational measuring procedure generates Scheimpflug images in three dimensions, with the dot-matrix fine-meshed in the center due to the rotation. It takes a maximum of 2 seconds to generate a complete image of the anterior eye segment. Any eye movement is detected and corrected for in the process. The Pentacam calculates a 3-dimensional model of the anterior eye segment from as many as 25,000 true elevation points.

The topography and pachymetry of the entire anterior and posterior surface of the cornea from limbus to limbus are calculated and depicted. The analysis of the anterior eye segment includes a calculation of the chamber angle, chamber volume and chamber height and a manual measuring function. In a moveable 3D model, images of the anterior and posterior surface of the cornea, the iris and the lens are generated. The densitometry of the lens is quantified.

The Scheimpflug images taken during the examination are digitalized in the main unit and all Image data are transferred to the PC. When the examination is finished the PC calculates the 3D model of the anterior eye segment, from which all additional information is derived.

The measurements are displayed on the monitor in the form of coloured maps, diagrams and 3D images.

While doing the evaluation of the acquired images, please keep in mind the possibility of the arising of artefacts which are described in chapter **Artefacts**.

The company OCULUS Optikgeräte GmbH emphasises, that the user bears the full responsibility for the correctness of data measured, calculated or displayed using the Pentacam. The manufacture will not accept claims based on erroneous data.

4 Use in accordance with regulations

For the US-Market only: Caution: Federal law restricts this device to sale by or on the order of a physician, or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of this device.

The OCULUS Pentacam is a measuring device used to examine the anterior eye segment and must only be used for the purposes specified in this instruction manual.

Therefore it must only be used by trained personnel capable of using it properly on the basis of their training, expertise and practical experience.

The OCULUS Pentacam is intended for use in clinics and ophthalmologists' practices. It is to be used in connection with the examination station intended for it.

It must only be operated with the original components supplied by us and if in technically good condition.

The special power supply unit (see instrument specification) must be used. Other forms of power supply must not be used.

Observe the safety precautions stated above!

1030719/A^r
DUPLICATE

3 Description of unit

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SEP 16 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCULUS Optikgeräte GmbH
c/o Tom Weatherby
18902 NE 150th St.
Woodinville, WA 98072

Re: K030719
Trade/Device Name: Pentacam Scheimpflug Camera
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: MXK
Dated: July 18, 2003
Received: July 21, 2003

Dear Mr. Weatherby:

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.

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Sincerely yours,



A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic and Ear,

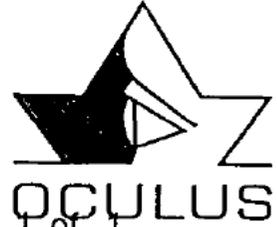
Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



510(k) Number (if known): K030719

Device Name: Pentacam Scheimpflug Camera

Indications For Use:

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- analyse the location of cataracts (nuclear, subcapsular and or cortical), using cross slit imaging with densitometry,
- corneal thickness.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

George K...
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K030719

(Optional Format 3-10-98)

June 16, 2003

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

OCULUS OPTIKGERATE GMBH
C/O OCULUS, INC.
18902 NE 150TH ST.
WOODINVILLE, WA 98072
ATTN: TOM WEATHERBY

510(k) Number: K030719
Product: PENTACAM
SCHEIMPFLUG
CAMERA

Extended Until: 22-AUG-2003

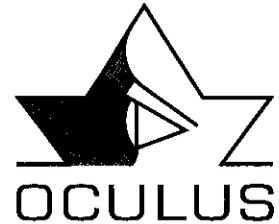
Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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



Oculus Optikgeräte GmbH · Postfach 17 01 52 · D-35549 Wetzlar

OCULUS Optikgeräte GmbH
Dutenhofen
Münchholzhäuser Straße 29
D-35582 Wetzlar

Telefon 06 41 / 2005-0
Telefax 06 41 / 2005-255
e-mail = sales@oculus.de

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

FDA/CDRH/OTC/STC
2003 JUN 16 PM 02:25

Thursday, 12 June 2003

510(k) Device
K030719
Trade Name: Pentacam Scheimpflug Camera

Dear Ms. Daryl L. Kaufman,

We like to request you for a six week extension to July 11 for submission of the additional information.

The reason for the request for a six week extension is:

Completing the Radiation Safety (light hazard) statement

- o do the measurement,
- o complete the calculations,
- o finishing the safety analysis.

Thank you very much for help in advance.

Yours sincerely

Joerg Iwanczuk

OCULUS Optikgeraete GmbH

5532 217

Bankkonten:
Commerzbank Wetzlar
(BLZ 515 400 37) 4 803 268

Sparkasse Wetzlar
(BLZ 515 500 35) 31 001 324

USt.-Id.-Nr.:
DE 112625210

Geschäftsführer:
Dipl.-Ing. Rainer Kirchhübel
Reg.-Gericht Wetzlar B 23

May 23, 2003

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

OCULUS OPTIKGERATE GMBH
C/O OCULUS, INC.
18902 NE 150TH ST.
WOODINVILLE, WA 98072
ATTN: TOM WEATHERBY

510(k) Number: K030719
Product: PENTACAM
SCHEIMPFLUG
CAMERA

Extended Until: 24-JUN-2003

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 is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

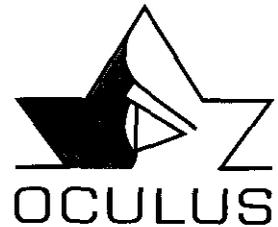
Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

FDA/CDRH/CDE/PMO

Oculus Optikgeräte GmbH · Postfach 17 01 52 · D-35549 Wetzlar

2003 MAY 23 A 9:54

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850



OCULUS Optikgeräte GmbH
Dutenhofen
Münchholzhäuser Straße 29
D-35582 Wetzlar

Telefon 06 41 / 2005-0
Telefax 06 41 / 2005-255
e-mail = sales@oculus.de

Dutenhofen, 21 May 2003

510(k) Device
K030719
Trade Name: Pentacam Scheimpflug Camera

Dear Ms. Daryl L. Kaufman,

Thank you for the detailed letter according our 510(k) device.

We like to request you for a two week extension to June 4 for submission of the additional information.

Thank you very much for help in advance.

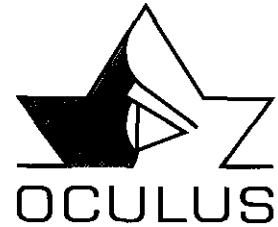
Yours sincerely

Joerg Iwanczuk

OCULUS Optikgeraete GmbH

Sk-4

219



Oculus Optikgeräte GmbH · Postfach 17 01 52 · D-35549 Wetzlar

Food and Drug Administration
Center for Devices and Radiological Health
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9200 Corporate Boulevard
Rockville, Maryland 20850

OCULUS Optikgeräte GmbH
Dutenhofen
Münchholzhäuser Straße 29
D-35582 Wetzlar

Telefon 06 41 / 20 05 - 0
Telefax 06 41 / 20 05 - 255
e-mail = sales@oculus.de

Dutenhofen, 21 May 2003

510(k) Device
K030719
Trade Name: Pentacam Scheimpflug Camera

Dear Ms. Daryl L. Kaufman,

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Thank you very much for help in advance.

Yours sincerely

Joerg Iwanczuk

OCULUS Optikgeraete GmbH

290



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCULUS Optikgeraete GmbH
c/o Mr. Tom Weatherby
18902 NE 150th Street
Woodinville, Washington 98072

APR 24 2003

Re: K030719
Trade Name: Pentacam Scheimpflug Camera
Dated: March 4, 2003
Received: March 7, 2003

Dear Mr. Weatherby:

We have completed an administrative review of your section Premarket Notification (510(k)) application of your intent to market the device referenced above. Our review indicates that your 510(k) is administratively incomplete and we are placing your 510(k) on hold for 30 days pending receipt of the additional information listed in the enclosure. We believe that this basic information is necessary for us to begin our substantive review and to determine whether or not this device is substantially equivalent to devices marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (Act).

Please refer to the FDA website www.fda.gov/cdrh/devadvice for specific information related to the proper submission of a 510(k) application. The following information must be included in your response in order for FDA to complete its review of your submission.

1. A Truthful and Accurate Statement.
2. Proposed labeling for the subject device and predicate device. Please include the material listed on pages 3-4 of the Premarket Notification (510(k)) Manual.
3. A distinct, separate page for your Statement of Indications for Use.
4. A complete description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.
5. Biocompatibility data or justification why you feel this is not required.
6. Sterilization and expiration dating information, if appropriate.

The following additional information is specific to the type of device you intend to market and is required in order for FDA to make a determination of substantial equivalency:

7. Materials (no flammable materials near the light source).
8. Side-by-side comparison with predicate, including a statement, table or chart of similarities and differences with subject device (the chart you did include will need to be expanded to incorporate the additional information).
9. Optical equivalency and radiation safety certification or measurements. Please refer to documentation for the International Organization for Standards (ISO) 10940 and 15004.
10. Electrical safety.
11. Software certification, if applicable.

The additional information should be submitted in duplicate, referencing the 510(k) number above to:

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Please note that since your 510(K) submission has not been substantively reviewed, additional information may be required during the review process and the file may again be placed on hold. You may not market this device until you have provided adequate information as required by 21 CFR 807.87 and you have received a letter from FDA allowing you to do so.

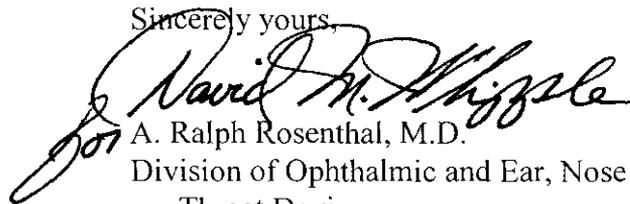
If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations (21 CFR part 812).

If after 30 days the requested information, or a request for an extension of time, is not received, 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); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

Page 3 – Mr. Tom Weatherby

If you have any questions concerning the contents of this letter, please contact Daryl L. Kaufman at (301) 594- 2018. If you have procedural or policy questions, please contact the Division of Small Manufacturers, International and Consumer Assistance at (301) 443-6597 or its toll free number (800) 638-2041, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "David A. Rosenthal". The signature is written in a cursive style with a large, looping initial "D".

A. Ralph Rosenthal, M.D.

Division of Ophthalmic and Ear, Nose and
Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 24 2003

OCULUS Optikgeraete GmbH
 c/o Mr. Tom Weatherby
 18902 NE 150th Street
 Woodinville, Washington 98072

Re: K030719
 Trade Name: Pentacam Scheimpflug Camera
 Dated: March 4, 2003
 Received: March 7, 2003

Dear Mr. Weatherby:

We have completed an administrative review of your section Premarket Notification (510(k)) application of your intent to market the device referenced above. Our review indicates that your 510(k) is administratively incomplete and we are placing your 510(k) on hold for 30 days pending receipt of the additional information listed in the enclosure. We believe that this basic information is necessary for us to begin our substantive review and to determine whether or not this device is substantially equivalent to devices marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (Act).

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4. A complete description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.
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6. Sterilization and expiration dating information, if appropriate.

FILE
 COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HF 2460	Kaufman	4/23/03						
Z460	Boen	4/23/03						
Z460	Diohffle	4/23						

224

The following additional information is specific to the type of device you intend to market and is required in order for FDA to make a determination of substantial equivalency:

7. Materials (no flammable materials near the light source).
8. Side-by-side comparison with predicate, including a statement, table or chart of similarities and differences with subject device (the chart you did include will need to be expanded to incorporate the additional information).
9. Optical equivalency and radiation safety certification or measurements. Please refer to documentation for the International Organization for Standards (ISO) 10940 and 15004.
10. Electrical safety.
11. Software certification, if applicable.

The additional information should be submitted in duplicate, referencing the 510(k) number above to:

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Please note that since your 510(K) submission has not been substantively reviewed, additional information may be required during the review process and the file may again be placed on hold. You may not market this device until you have provided adequate information as required by 21 CFR 807.87 and you have received a letter from FDA allowing you to do so.

If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations (21 CFR part 812).

If after 30 days the requested information, or a request for an extension of time, is not received, 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); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

Page 3 – Mr. Tom Weatherby

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Sincerely yours,

A. Ralph Rosenthal, M.D.
Division of Ophthalmic and Ear, Nose and
Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K030719.RefusettoAccept
Disc:DSDB #12

Draft:4/10/03:Dkaufman
Edited:4/14/03:EBeers
Final:4/23/03:DKaufman

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 07, 2003

OCULUS OPTIKGERATE GMBH
C/O OCULUS, INC.
18902 NE 150TH STREET
WOODINVILLE, WA 98072
ATTN: TOM WEATHERBY

510(k) Number: K030719
Received: 07-MAR-2003
Product: PENTACAM SCHEIMPFLUG
CAMERA

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at <http://www.fda.gov/oc/mdufma>).

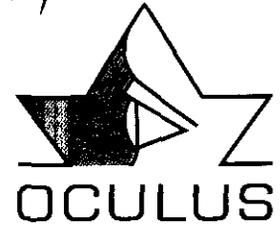
Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, 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 www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

K 030719



Oculus Optikgeräte GmbH · Postfach 17 01 52 · D-35549 Wetzlar

FDA/CDRH – 510(k)
Document Mail Center (HFZ-401)
9200 Corporate Boulevard

Rockville, Maryland 20850-4015

OCULUS Optikgeräte GmbH
Dutenhofen
Münchholzhäuser Straße 29
D-35582 Wetzlar

Telefon 06 41 / 2005-0
Telefax 06 41 / 2005-255
e-mail = sales@oculus.de

Jörg Iwanczuk
Dutenhofen, 04 March 2003

Dear Madam or Sir,
Our company wants to start selling a new product in the United States. So we have to get first the admission and registration of the FDA to do so.

Attached there is the document
510 (k) summary of substantially equivalent

Our company is registered:
Registration No.: 9611269, Owner/Operator No.: 8010318

Our establishment in the USA is registered:
Registration No.: 3033566, Owner/Operator No.: 8010318

Our official Correspondent in the USA has been assigned/designated:
Mr. Tom Weatherby
OCULUS Optikgeraete GmbH
18902 NE 150th Street
Woodinville, WA 98072
Phone 425-867-1800

Our US Agent has been assigned/designated:
No name given
OCULUS, Inc.
18902 NE 150th Street
Woodinville, WA 98072
Phone: 425-867-1800
Fax: 425-867-1881
e-mail: sales@oculususa.com

2003 MAR 11
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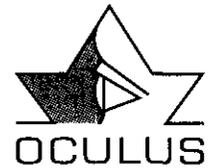
SFA

Bankkonten:
Commerzbank Wetzlar
(BLZ 515 400 37) 4 803 268

Sparkasse Wetzlar
(BLZ 515 500 35) 31 001 324

USt.-Id.-Nr.:
DE 112625210

Geschäftsführer:
Dipl.-Ing. Rainer Kirchhübel
Reg.-Gericht Wetzlar B 23



page -2-

We hope that we give you all the informations and documents you need.
If there are further questions please contact our USAgent or our company directly.

Yours faithfully

A handwritten signature in black ink, appearing to read "J. Iwanczuk".

Jörg Iwanczuk

Product Manager
International Sales Department
OCULUS Optikgeräte GmbH
D-35582 Wetzlar
Tel.: ++49-641-2005-272
Fax: ++49-641-2005-295
J.Iwanczuk@oculus.de

510(K) SUMMARY

substantially equivalent

General Information

Applicant's Name and Address: OCULUS Optikgeräte GmbH
Münchholzhäuser Straße 29
D-35582 Wetzlar

Date of Summary: 04 March 2003

Owner/Operator Number: 8010318
Mr. Joerg Iwanczuk
Product Manager

Device Name

Trade Name: Pentacam Scheimpflug Camera

Class: Class II

Classification Name: Scheimpflug Camera

Product Code: MXK Anterior Eye-Segment Analysis System

Regulation Number: 886.1850

Predicate Devices

The Pentacam Scheimpflug Camera is claimed to be substantially equivalent to the following currently market device:

NIDEK, EAS-1000 Anterior Eye-Segment Analysis System- K991284

Device Description:

The Pentacam Scheimpflug Camera is a non-invasive, diagnostic system created to take photographs of the anterior segment of the eye, table mounted and AC powered. The system is based on the Scheimpflug Principle for Slit Image photography. The device consists of a measurement unit, power supply and a CPU. The measuring system uses blue light (UV-free) given to a slit to illuminate the eye, and a CCD-Camera for photography. The measuring system offers the possibility of automatically rotation to get photographs of every part of the eye. The system calculates from the photos a 3D-modell of the eye.

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Product Comparison

	New Device	Anterior Eye-Segment Analysis System
Manufacturer	OCULUS Optikgeräte GmbH	Nidek Inc.
Measuring Principle	Scheimpflug Principle for Slit Image photography	Scheimpflug Principle for Slit Image photography
Optical	Single Aperture	Single Aperture
Viewing Optics	15" Coloured Screen	5.5" Black and White CRT
Observation Illumination	Infrared LED 800nm	Infrared LED for Retro-Illumination 800nm
Flash Output Illumination	Blue LED Light (UV-free) 475nm, max. 2.5Wsec	Xenon Lamp 200Wsec
Photography Camera	CCD-Camera	CCD-Camera
Display	Data digital, displayed on a CPU	Data digital and can be displayed on a CPU
Image resolution	800 x 600 pixels	640 x 400 pixels
Image size	5.6 x 4.5mm	8mm x 6.6mm
Photographic range	Eligible 0 to 180°	Offers Photographic angles from 0 to 180°
Photographic Series	1 to 50 photos	N/A
Slit Length	14mm	2 – 14mm adjustable
Power Consumption	50VA	150 VA
Power requirement	110/220 VAC, 50/60Hz	100VAC, 50/60Hz
Weight	9 kg	25 kg

Basics for Substantial Equivalence

- The systems utilize the same or similar Operating System. They contain:
 - An optical system
 - A source of illumination for observation and photography
 - A CCD-Camera as photographic medium
- Both systems have the same intended use to measure the eye and the anterior eye segment
- Both systems use the same device features like a
 - Head stabilizing device
 - External fixation target
 - Joy stick for control mechanism
- Both systems are considered “Non Invasive” as defined in 21 CFR §812.3(k) and considered not to be a “Significant Risk Device” as defined in 21 CFR §812.3(m)

Indications for Use

Intended Use: The Pentacam is designed to take photos of the anterior segment of the eye, which includes cornea, lens and anterior chamber. To evaluate:

Corneal shape

Analyse condition of the lens

Densitometry, cataract degree and location using the Scheimpflug Image

State of the lens (pre and post intraocular lens implant)

Analyse anterior chamber (size, volume and angle)

Pachymetry (thickness of the cornea)

Scheimpflug Image

Analysing center position of the cornea to iris and lens

Safety

The Pentacam is a non-invasive diagnostic system, which contacts the patient only on his/her chin and forehead. The Pentacam does not present or pose any new or additional effects for risk on the safety prescribed intended uses. The light output is of an eye safe intensity and wavelength. The electrical safety requirements for medical devices are met. The Pentacam is proven effective for its intended uses through internal company and independent clinical studies.

From: Reviewer(s) - Name(s) Daryl J. Kaufman
Subject: 510(k) Number K030719/S'
To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

SE

- Is this device subject to Section 522 Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N/A

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

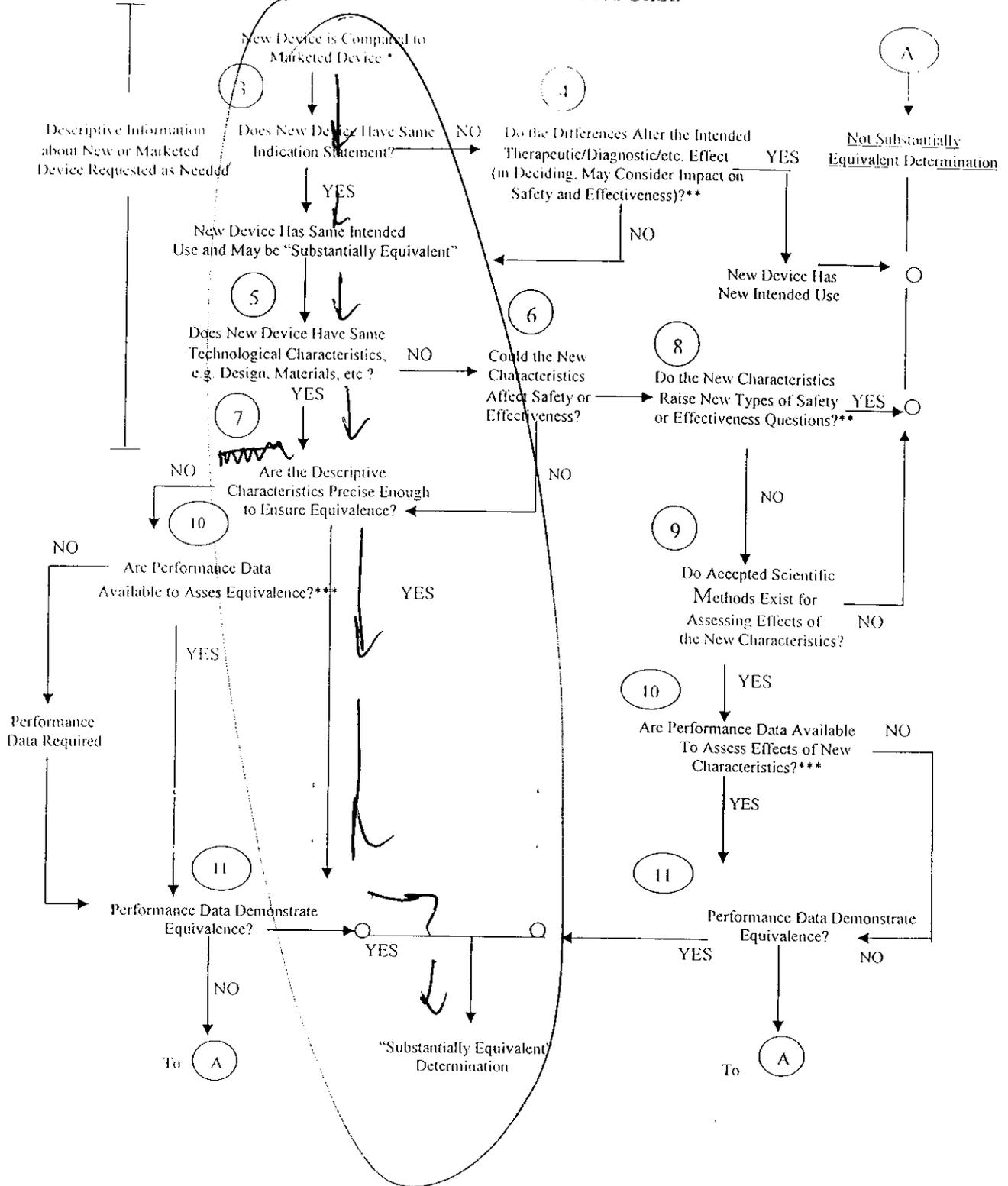
MXK

21 CFR 886.1850

Review: Ernest J. Bean D5DB 9/15/03
(Branch Chief) (Branch Code) (Date)

Final Review: Daryl J. Kaufman for DEED 9/15/03
(Division Director) (Date)

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.

510(k) K030718 –Pentacam Scheimpflug Camera

1. INTENDED USE:

The Pentacam Scheimpflug Camera is designed to take photos of the anterior segment of the eye.

2. DEVICE DESCRIPTION:

	yes	no
a. Is the device life-supporting?	___	<u>X</u>
b. Is the device implanted (short-term or long-term)?	___	<u>X</u>
c. Does the device design use software?	<u>X</u>	___
d. Is the device sterile?	___	<u>X</u>
e. Is the device single use?	___	<u>X</u>
f. Is the device home use?	___	<u>X</u>
g. Is the device for prescription use?	<u>X</u>	___
h. Does the device contain a drug or biological component?	___	<u>X</u>
I. Is the device a kit?	___	<u>X</u>

Provide a summary about the device's design, materials, physical properties and toxicology profile, if important.

3. SUMMARY:

The device is designed to take pictures of the anterior segment of the eye to evaluate and analyze corneal shape; the condition of the lens (opaque crystalline lens); the anterior chamber angle; the anterior chamber depth; the volume of the anterior chamber; the anterior or posterior cortical opacity; the location of cataracts using cross list imaging with densitometry, and corneal thickness.

Device Description and Operation

The Pentacam Scheimpflug Camera is a non-invasive diagnostic system. It is designed to take photos of the anterior segment of the eye and is based on the Scheimpflug principle for slit lamp photography. The system is table mounted and AC powered by an external power supply.

The system is comprised of the following internal components:

Measuring devices:

- an illumination unit with LEDs, 475nm wavelength UV-free to illuminate the anterior segment of the eye;

- two CCD-Cameras, one in the center for the fixation monitoring, and a second one to take the Scheimpflug images;
- an optical lens system to project the slit; and
- two infrared LEDs to illuminate the pupil for fixation monitoring.

Electrical devices:

- a memory board and a CPU which stores and analyses the images taken;
- a power supply board which prepares and controls the electrical condition of the Pentacam Scheimpflug camera;
- an electric motor for rotating; and,
- a communication board for transferring the images to external PCs.

There is no contact between the patient and the Pentacam device; the patient puts his/her chin and forehead to a separate head and chin rest similar to the one used with Nidek slit lamps. Consequently, no sterilization and biocompatibility data are needed.

Measurements can be taken in two different ways depending on what is to be evaluated:

1. Taking photos from one camera position, primarily to get information on the lens.
2. Taking photos from several positions around the eye by a rotating camera which takes up to 50 Scheimpflug images that are digitalized into the system. The images are then transferred to the external PC which calculates a three dimensional mathematical model from which additional information is derived. This method of photo taking can be used to get information about the anterior and posterior surface of the cornea, the thickness of the cornea, and the chamber angle and volume and depth.

The application was received by FDA on March 7, 2003 and was found to be incomplete. A letter requesting additional information was sent to Mr. Tom Weatherby, the company's U.S. representative, on April 23, 2003 listing eleven deficiencies ranging from the completion of a Truth and Accurate Statement and a detailed substantial equivalency table to providing optical equivalency, radiation safety data and software certification. A supplement with this information was received on July 21, 2003. In the interim, communications between Joerg Iwanczuk, Product Manager at the German Oculus site, and Mr. Bob Landry, Physicist, with FDA's Office of Science and Technology, continued because of deficiencies in the optical radiation data Mr. Landry needed to have corrected in order to complete his safety analysis.

The applicant provided a side-by-side substantial equivalency table for this subject device and the Nidek EAS 1000 Anterior Eye-Segment Analysis System (K991284) along with descriptive text of the differences and similarities. The major difference between the two is the ability of the subject device to automatically rotate the Pentacam Scheimpflug Camera via special software. Slit lamp images taken from multiple positions around the eye during a single measurement, rather than from one position (with subsequent manual images taken), allow for a better evaluation of the complete anterior eye segment.

The applicant claimed the level of their software was MINOR. In the initial application, some of the software information required in accordance with recommended FDA guidance was not provided. In a software review completed by Dexiu Shi, Ph.D., on July 16, 2003, she noted that the applicant developed the software under an appropriate development program; however, they did not provide verification and testing of software validation for the device. This information was submitted in a fax dated September 10, 2003 after Dr. Shi had previously spoken with the company engineer in Germany to ensure that the correct data was sent. In her review dated September 10, 2003, which augmented her prior review in July, she stated that the company had carried out an appropriate validation process for their device and from a software perspective, substantial equivalency was recommended.

A review of this supplement was completed by Denis McCarthy, Physicist, on August 4, 2003 evaluating one of the device's indications, pachymetry of the anterior segment of the eye, versus the lack of such a claim for the predicate device (Nidek EAS 1000). He determined and demonstrated with a chapter in a vision science textbook that although such an indication for use was not specified for the

predicate, it had to have been performed because “it represented an advance in the state-of-the-art since the device was designed specifically for Scheimpflug photography.....”. Based on the information submitted in the supplement, he recommended that the subject device be considered substantially equivalent to the Nidek EAS 1000 predicate.

A copy of the Operator’s Manual (Pentacam Instruction Manual) was submitted but without the standard Physician’s warning statement. This team leader sent an email to the applicant with this request after contacting Mr. Tom Weatherby, their U.S. Oculus liaison, by phone on August 5, 2003 at which time two other requests were made: to present the Indications for Use on the correct boilerplate form (emailed to them) and to also provide their verification of their software validation and testing results. The software validation was discussed previously in this review. The corrected Indications for Use Statement was received by the FDA on August 15, 2003 and the revised labeling with the inclusion of the Physician’s warning statement was received on September 8, 2003.

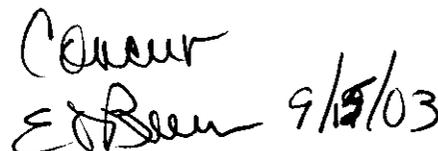
A consultant review from Robert Landry, Office of Science and Technology, for the optical radiation safety for this device was received on August 4, 2003. Based on the intended use of the device, he felt that there was no risk of injury to patients during normal use.

Recommendation:

Based on the information submitted by the applicant and the reviews completed by consulting scientists, it is determined that this device is substantially equivalent to K991284, the Nidek EAS 1000 Anterior Eye-Segment Analysis System.



Daryl L. Kaufman
Biologist/Team Leader



Disc DSDB #14
K030719
8/06/03:DKaufman
final:9/15/03:DKaufman

*EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON
PAGE 1 AS NEEDED:*

1. *Explain why not a device: N/A*
2. *Explain why not subject to 510(k): N/A*
3. *How does the new indication differ from the predicate device's indication: N/A*
4. *Explain why there is or is not a new effect or safety or effectiveness issue:
Additional information was needed to demonstrate optical radiation safety
which showed that the device was safe.*
5. *Describe the new technological characteristics:
The ability of the subject device to automatically rotate the Pentacam
Scheimpflug Camera via special software.*
6. *Explain how new characteristics could or could not affect safety or effectiveness:
N/A*
7. *Explain how descriptive characteristics are not precise enough:
The supplement and amendments received by FDA between July 21, 2003
and September 8, 2003 provided the details and documentation lacking in the
initial submission.*
8. *Explain new types of safety or effectiveness questions raised or why the questions
are not new: N/A*
9. *Explain why existing scientific methods can not be used: N/A*
10. *Explain what performance data is needed: N/A*
11. *Explain how performance data demonstrates the device is or is not substantially
equivalent:
N/A*

Memorandum

DATE: September 10, 2003
FROM: Dexiu Shi 
TO: Daryl Kaufman, Team Leader
RE: **510(k) -K030719**
Device: Pentacam Scheimpflug Camera
Manufacturer: OCULUS Optikgeräte GmbH
SUBJECT: Software Review (additional information for software validation)

SUMMARY

The Pentacam Scheimpflug Camera takes images from several positions around the eye, put them together and presents the results. The role of the software in the Pentacam Scheimpflug Camera is, to lead the doctor through the different features and show the results. The software makes no decision for any operation, only the presentation of results in colored maps and values. The software gives no suggestion or recommendation of any parameters for a treatment or therapy.

I have asked the sponsor provided the following additional information for software validation (see my review of July 16, 2003):

You have only provided an appropriate software validation plan/protocol for your software validation. Please provide the testing report/results and verification for the software validation of your device.

In response, the sponsor sent the following information of the testing report/results and verification (via fax dated 9/10/03) for Pentacam Software:

Version Number: 1.03
Test Date: 07/07/03
Device Serial Number 0101-3040
Test Person: Steinmüller

1. Function test: Passed
2. General measurements: Acceptable
3. Evaluation: The calculated mean value and standard deviation are within limit.
4. Results: Test passed
5. Problem appearing after releasing this version: None

CONCUSION/RECOMMENDATION: SE

The sponsor has provided documentation required as outlined in the ODE Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," issued May 19, 1998. Their documentation demonstrated that they have developed the software for this device under an appropriate software development program: that they have performed a hazard analysis, and addressed those hazards; and carried out an appropriate validation process for their device. It is recommended that from a software standpoint this submission to be approvable.



Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
To: Mr. Mrs. Daryl Kaufman
9200 Corporate Boulevard

Rockville, Maryland 20850

USA

Fax: 001-301-480-4201

Sept. 10, 2003
R. Kirchhübel/uw

Case No. K030719
Oculus Pentacam software test protocol - validation

Dear Mrs. Kaufman,

Mr. Iwanczuk, who directly corresponded with you, is out of the office. That is why we got a little delay in sending the test protocol of the software validation which you will find with this fax as annex.

Parallel we will send you this information by FedEx as hard copy.

If you have further questions do not hesitate to contact us.

Best regards

Rainer Kirchhübel
General Manager
OCULUS Optikgeräte GmbH

Enclosure

CC: JI, TW

OCULUS Optikgeräte GmbH

Münchholzhäuser Straße 29 - D-35582 Wetzlar - Tel ++49-641-20 05-0 - Fax ++49-641-20 05-155 - E-Mail sales@oculus.de
Geschäftsführer/Managing Director: Dipl.-Ing. Rainer Kirchhübel - Reg.-Gericht Wetzlar B 23 - USt.-Id.-Nr.: DE 112625210

Pentacam Software Test Protocol

Version number: 1.03

Date: 07-07-03

Test person: Steinmüller

Device serial number 0101-3040

1 Functional test

Pos	Test	Remarks:	OK ?:
101	Test of software installation Insert CD, and install software		OK
102	Start Software (using Test Patient). Start "Scan Menu", Check motor positioning movement		OK
103	Check Slit light normal and maximum		OK
104	Grab Scheimpflug image (1 Picture)		OK
105	Grab Scheimpflug image (5 Picture)		OK
106	Grab Scheimpflug image (10 Picture)		OK
107	Grab Scheimpflug image (15 Picture)		OK
108	Proceed Scan (12 Picture)		OK
109	Proceed Scan (25 Picture)		OK
110	Proceed Scan (50 Picture)		OK
111	Menu "Maps Large" Check all display modes		OK
112	Menu "Image Large" Check functionality		OK
113	Menu "Overview" Check all color maps		OK
114	Menu "3D-Model Large" Check functionality		OK

2 Generate Measurements

Proceed 5 measurements (3D-Scan 25 Picture). Note the results, store the examination data and reload it. Note the results again.

Pos:	Test				OK ?
201	Real Value:	Rh: 8,26	Rv: 7,98	Thickness: 528	OK
202	Measurement 1	Rh: 8,29	Rv: 8,01	Thickness: 526	OK
203	Measurement 2	Rh: 8,31	Rv: 8,04	Thickness: 530	OK
204	Measurement 3	Rh: 8,27	Rv: 8,01	Thickness: 522	OK
205	Measurement 4	Rh: 8,22	Rv: 7,99	Thickness: 521	OK
206	Measurement 5	Rh: 8,31	Rv: 7,97	Thickness: 527	OK
207	Store measurements and reload it				OK
208	Reloaded 1	Rh: 8,29	Rv: 8,01	Thickness: 526	OK
209	Reloaded 2	Rh: 8,31	Rv: 8,04	Thickness: 530	OK
210	Reloaded 3	Rh: 8,29	Rv: 8,01	Thickness: 522	OK
211	Reloaded 4	Rh: 8,22	Rv: 7,99	Thickness: 521	OK
212	Reloaded 5	Rh: 8,31	Rv: 7,97	Thickness: 527	OK
213	Compare Measurements with Reloaded values				OK

3 Evaluation

Calculate mean value and standard deviation.

Pos	Measured value:	Limit:	OK?
301	Mean value of measurement 1-5: 525,2	0 to 1000	OK
302	Deviation from real value -2,8	-5 to +5	OK
303	Deviation: 3,7	0 to +5	OK

4 Result:

401	Test passed: <i>by 07-07-03</i>	Test not passed:
-----	---------------------------------	------------------

5 Problems, appearing after releasing this version

Num:	Problem:	Customer:
501		
502		
503		
504		
505		
506		
507		
508		
509		
510		
511		
512		
513		
514		
515		
516		

August 4, 2003

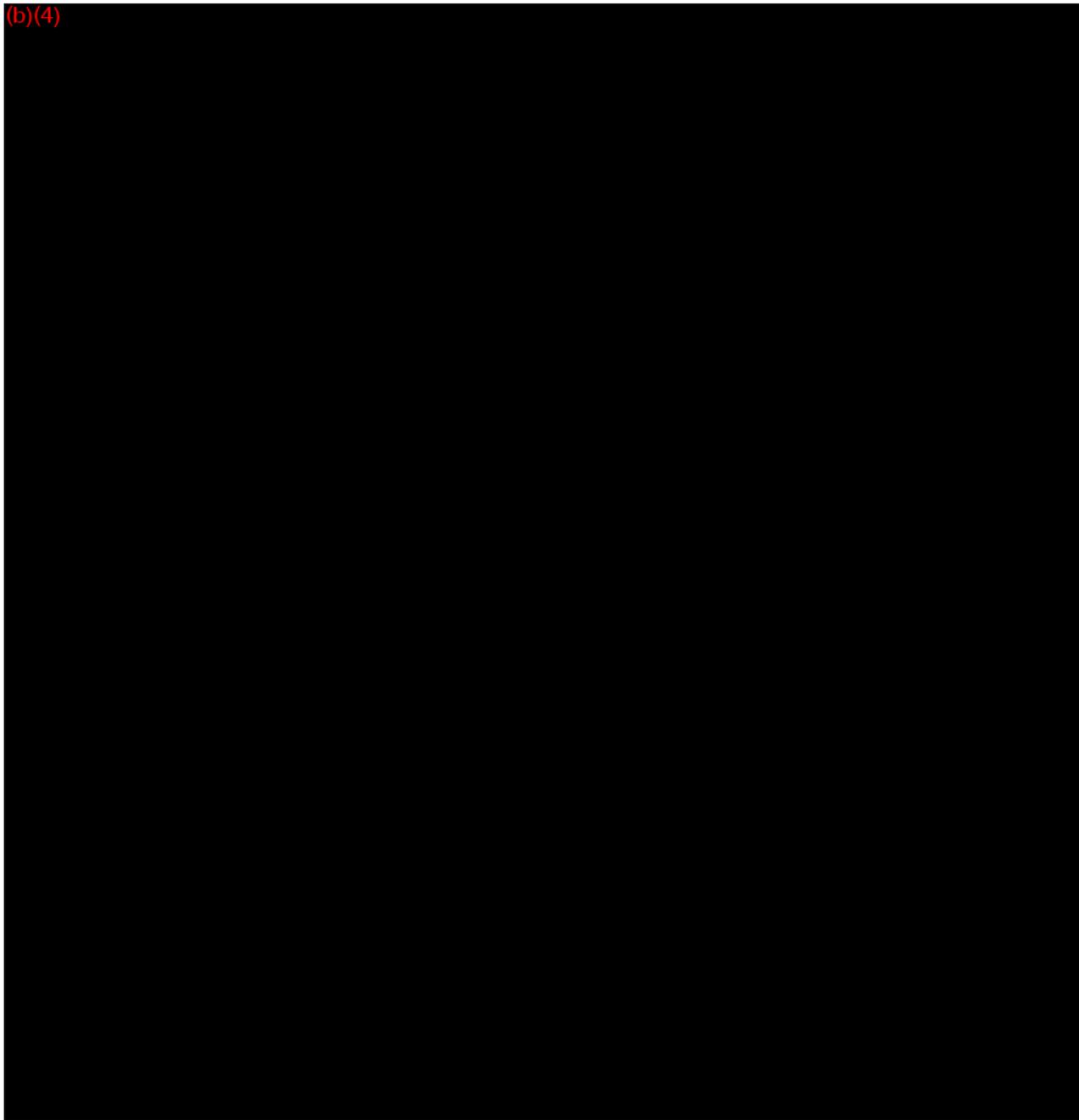
TO: Ms. Daryl Kaufman

SUBJECT: Consultant Review of optical radiation safety for 510K K 030719

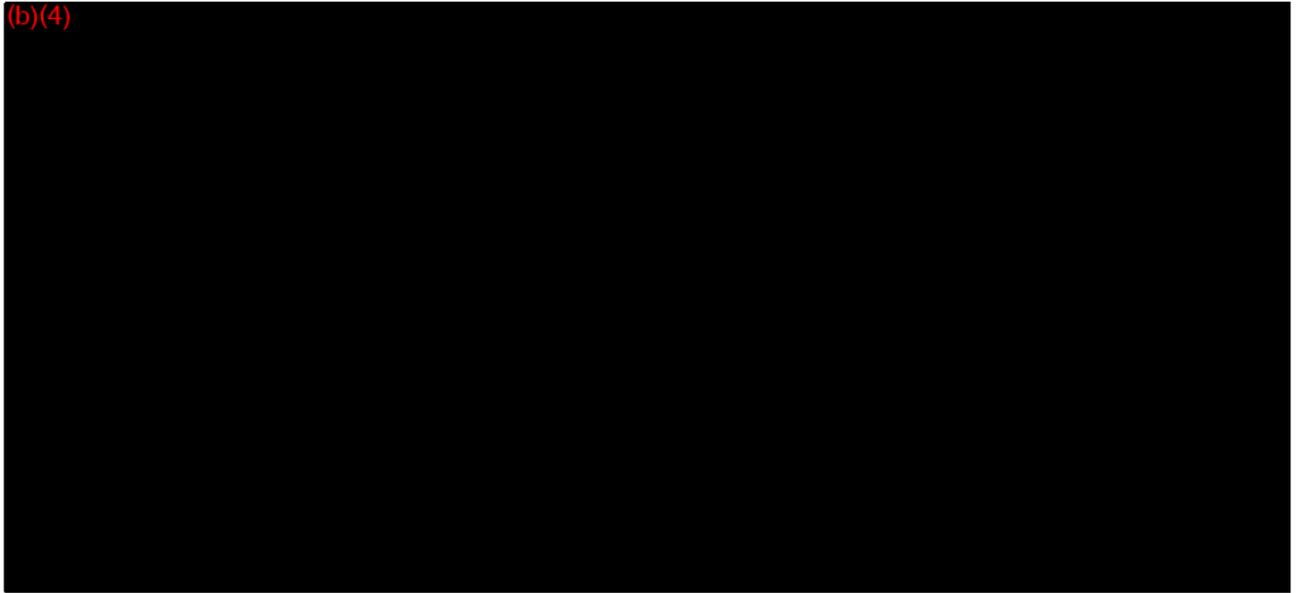
From: Robert J. Landry

I have reviewed the subject 510K submission for phototoxicity as requested. The results of this review are summarized in the following paragraphs.

(b)(4)

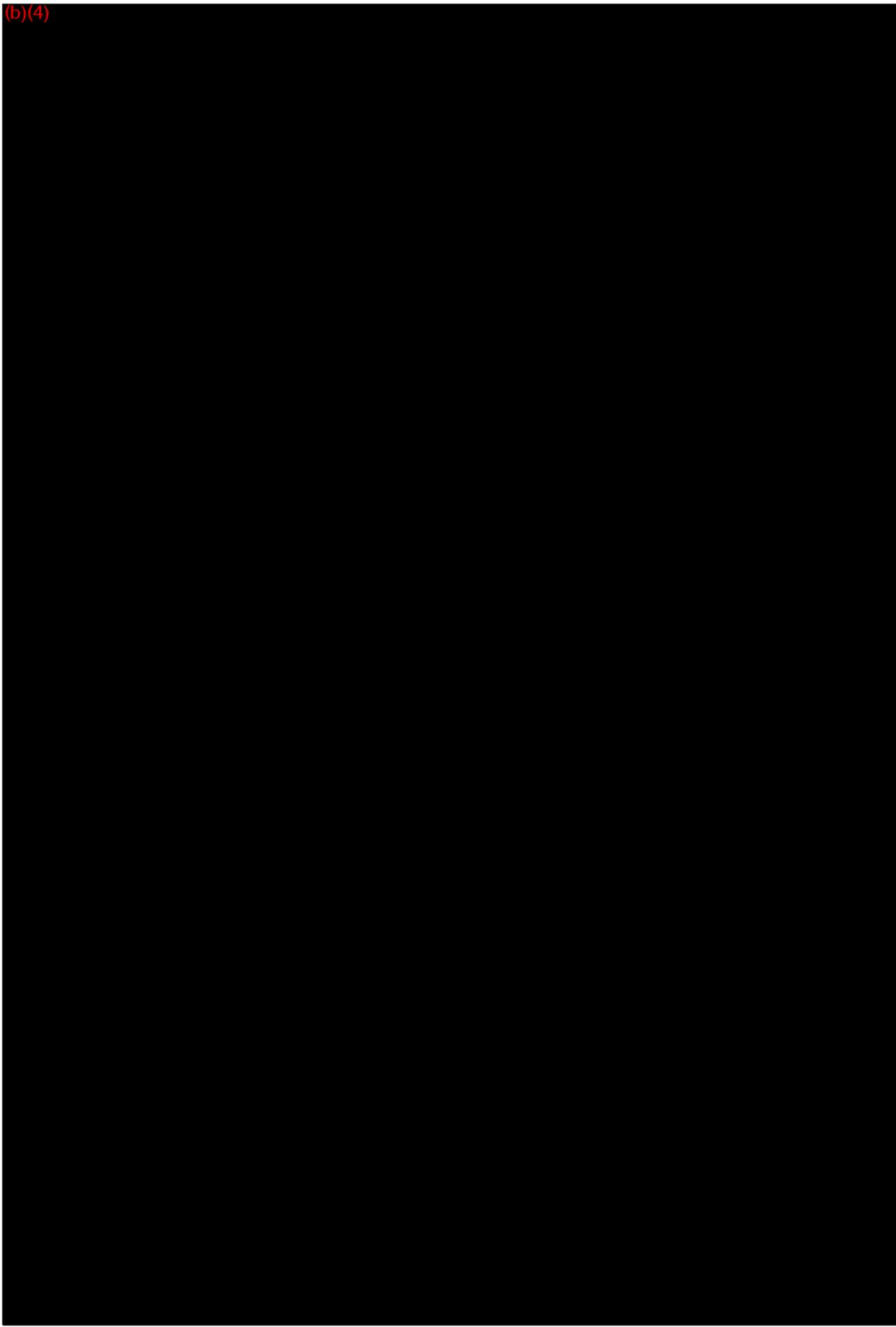


(b)(4)



Robert J. Landry

(b)(4)



August 4, 2003

To: RECORD, K030719/S1, Optikgerate GmBH

From: Physicist – Optics

Subject: Review of Supplement #1

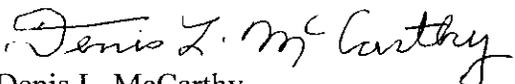
Supplement #1 is a response by the manufacturer to a request for additional information in respect to one of the intended uses of the OCCULUS device, pachymetry of the anterior segment of the eye. Apparently, there is some concern that this function was not claimed in the 510k for the Nidek EAS 1000 which is named as the predicate for this application.

Analysis by the reviewer of the initial submission indicated that both the OCCULUS and Nidek EAS 1000 have as the principle of operation Scheimpflug photography. In addition the design and intended uses of both devices are similar (though not identical). The regulatory question posed seems to be whether or not the intended use of the OCCULUS for anterior segment pachymetry would invalidate a recommendation of substantial equivalence.

First it should be noted that if the 510k for the Nidek EAS 1000 did not specifically indicate that it would be used for anterior segment pachymetry (they may have stated the usage as analysis of the anterior segment) it certainly could have and probable was used in such applications in view of the literature's description of such usage. The attachment, Chapter 16 of "Non Invasive Diagnostic Techniques in Ophthalmology" (published in 1990), page 290 figure 16.16 clearly indicates that prior to 1990 modified slit lamps were converted for Scheimpflug photography of the anterior segment and were used for pachymetric applications. As noted from the figure, the region of pachymetry was highly centralized due to the paucity of available data points at increasing distance from the central zone. The figure clearly illustrates that the ocular cross section pachymetry was one of the intended uses of Scheimpflug photography. For this reason it is fair to assume that the Nidek EAS 1000 was used for this purpose because it represented an advance in the state-of-the-art since the device was designed specifically for Scheimpflug photography and provided many more elevation data points for evaluation and pachymetric reconstruction of patient anterior segment cross sections.

The OCCULUS does have a number of technological advantages with respect to the Nidek EAS 1000. For example, the Nidek EAS 1000 is limited to one photograph at a given location within a 180 degree meridional angle per each patient use whereas the OCCULUS can take up to 50 pictures at given positions within a 360 degree meridional angle. Every OCCULUS Scheimpflug picture contains 500 true elevation points within the anterior segment and can therefore produce up to 25000 true elevation points for analysis of the anterior segment; the Nidek EAS 1000 cannot duplicate this performance.

Supplement #1 clearly delineates the operation, design, functions and intended uses of the OCCULUS in comparison to the Nidek EAS 1000 device. Based on a review of the information provided it is recommended that the OCCULUS device be ruled as substantially equivalent to the Nidek EAS 1000 device.


Denis L. McCarthy

Memorandum

DATE: July 16, 2003
 FROM: Dexiu Shi *Dexiu Shi 7/17/2003*
 TO: Daryl Kaufman, Team Leader
 RE: **510(k) -K030719/51**
 Device: Pentacam Scheimpflug Camera
 Manufacturer: OCULUS Optikgeräte GmbH
 SUBJECT: Software Review

SUMMARY

The Pentacam Scheimpflug Camera takes Images from several positions around the eye, put them together and presents the results.

The role of the software in the Pentacam Scheimpflug Camera is, to lead the doctor through the different features and show the results. The software makes no decision for any operation, only the presentation of results in coloured maps and values. The software gives no suggestion or recommendation of any parameters for a treatment or therapy.

The software is written in the language GFA Basic and a Compiler translates it. So no user can do any changes in the software. The sponsor determined that Level of Concern of software for this device is Minor. Sponsor submitted the additional for software information in a file of *Penta_FDA_New_Test* dated July 11, 2003.

Checklist for Required Software Document for Minor Concern Level

SOFTWARE DOCUMENTATION	Yes	No	PAGE #	COMMENT
Level of Concern	<input checked="" type="checkbox"/>	<input type="checkbox"/>	19	Minor Concern
Software Description	<input checked="" type="checkbox"/>	<input type="checkbox"/>	20	The role of the software is to lead the doctor through the different features and show the results:
Device Hazard Analysis	<input checked="" type="checkbox"/>	<input type="checkbox"/>	26-27	Analysis of safety risks and hazardous events were provided
Software Requirements Specification (SRS)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	21	Limited information were provided
Architecture Design Chart	<input checked="" type="checkbox"/>	<input type="checkbox"/>	28	A chart depicting the partitioning of the software system into functional subsystems was provided
Design Specification				N/A
Traceability Analysis				N/A
Development				N/A
Validation, Verification and Testing (VV&T)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	22-26	Software validation procedure was provided , but no test report and results
Revision Level History				N/A
Unresolved anomalies (bugs)				N/A
Release Version Number	<input checked="" type="checkbox"/>	<input type="checkbox"/>	22	Version 1.02, dated July 1, 2003

CONCLUSION/RECOMMENDATION

The sponsor has provided documentation required as outlined in the ODE Document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,” issued May 19, 1998. Their documentation demonstrating that they have developed the software for this device under an appropriate software development program: that they have performed a hazard analysis, and addressed those hazards; and carried out an appropriate validation process. However, the sponsor failed to provide the verification and testing results of software validation for their device. It is recommended that from a software standpoint this submission to be approvable upon receiving verification and testing results of software validation for current device.

Please convey the following question to sponsor:

You have only provided an appropriate software validation plan/protocol for your software validation. Please provide the testing report/results and verification for the software validation of your device.



OP

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCULUS Optikgeraete GmbH
c/o Mr. Tom Weatherby
18902 NE 150th Street
Woodinville, Washington 98072

APR 24 2003

Re: K030719
Trade Name: Pentacam Scheimpflug Camera
Dated: March 4, 2003
Received: March 7, 2003

Dear Mr. Weatherby:

We have completed an administrative review of your section Premarket Notification (510(k)) application of your intent to market the device referenced above. Our review indicates that your 510(k) is administratively incomplete and we are placing your 510(k) on hold for 30 days pending receipt of the additional information listed in the enclosure. We believe that this basic information is necessary for us to begin our substantive review and to determine whether or not this device is substantially equivalent to devices marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (Act).

Please refer to the FDA website www.fda.gov/cdrh/devadvice for specific information related to the proper submission of a 510(k) application. The following information must be included in your response in order for FDA to complete its review of your submission.

1. A Truthful and Accurate Statement.
2. Proposed labeling for the subject device and predicate device. Please include the material listed on pages 3-4 of the Premarket Notification (510(k)) Manual.
3. A distinct, separate page for your Statement of Indications for Use.
4. A complete description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.
5. Biocompatibility data or justification why you feel this is not required.
6. Sterilization and expiration dating information, if appropriate.

The following additional information is specific to the type of device you intend to market and is required in order for FDA to make a determination of substantial equivalency:

7. Materials (no flammable materials near the light source).
8. Side-by-side comparison with predicate, including a statement, table or chart of similarities and differences with subject device (the chart you did include will need to be expanded to incorporate the additional information).
9. Optical equivalency and radiation safety certification or measurements. Please refer to documentation for the International Organization for Standards (ISO) 10940 and 15004.
10. Electrical safety.
11. Software certification, if applicable.

The additional information should be submitted in duplicate, referencing the 510(k) number above to:

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Please note that since your 510(K) submission has not been substantively reviewed, additional information may be required during the review process and the file may again be placed on hold. You may not market this device until you have provided adequate information as required by 21 CFR 807.87 and you have received a letter from FDA allowing you to do so.

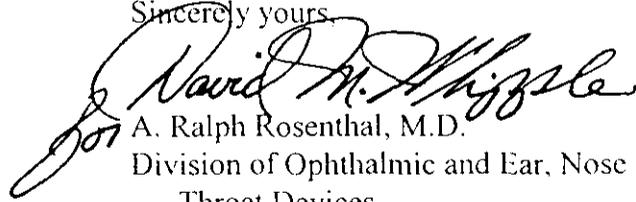
If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations (21 CFR part 812).

If after 30 days the requested information, or a request for an extension of time, is not received, 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); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

Page 3 – Mr. Tom Weatherby

If you have any questions concerning the contents of this letter, please contact Daryl L. Kaufman at (301) 594- 2018. If you have procedural or policy questions, please contact the Division of Small Manufacturers, International and Consumer Assistance at (301) 443-6597 or its toll free number (800) 638-2041, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script that reads "David M. Whipple". The signature is written in black ink and is positioned above the printed name and title.

A. Ralph Rosenthal, M.D.
Division of Ophthalmic and Ear, Nose and
Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

**Part 3 Combination Product Algorithm
(Revised March 12, 2003)**

Quick Reference Table¹ -- Part 3 Combination Product Categories

Category Number	Type of Part 3 Combination Product
N	Not a Part 3 Combination Product
1	Convenience Kit or Co-Package
2	Prefilled Drug Delivery Device/System (syringe, patch, etc.)
3	Prefilled Biologic Delivery Device/System (syringe, patch, etc.)
4	Device Coated/Impregnated/Otherwise Combined with Drug
5	Device Coated or Otherwise Combined with Biologic
6	Drug/Biologic Combination
7	Separate Products Requiring Cross Labeling
8	Possible Combination Based on Cross Labeling of Separate Products (Temporary Code)
9	Other Type of Part 3 Combination Product (e.g., Drug/Device/Biologic Product)

Note: The above categories are intended to be mutually exclusive. If a product meets the definition of more than one category, select the category that you believe best describes the regulatory issues associated with the combination product.

Overview: A 21 CFR Part 3 combination product is a product comprised of components usually regulated under different authorities. It may be a drug combined with a device, a biologic combined with a device, or a drug combined with a biologic. Cells or tissues that are not eligible for regulation solely as cells or tissues because they are combined with a drug or a device (except for a sterilizing, preserving, or storage agent) may also be combination products. Discuss with your Center's product jurisdiction officer.

Combination products include those where the components are²:

- Physically or chemically combined OR
- Separate but provided/packaged as a unit OR

¹ Category descriptions and examples follow.

² See 21 CFR § 3.2(e) for complete definition. [will link to definition on OCP website]

Memorandum

From: Reviewer(s) - Name(s) Janet L. Kuehn

Subject: 510(k) Number 1C030719

To: The Record - It is my recommendation that the subject 510(k) Notification:

AI

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

- De Novo Classification Candidate? YES NO
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)
- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Animal Tissue Source YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 da

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

MKK 21 CFR 886.1850

Review: Evelyn Beer DSDB 4/23/03
(Branch Chief) (Branch Code) (Date)

Final Review: Janet Kuehn for DOD 4/23/03
(Division Director) (Date)

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K 030219

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510(k)] Manual.		✓
Table of Contents.		✓
Truthful and Accurate Statement.		✓
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510(k)] Manual.		✓
Statement of Indications for Use that is on a separate page in the premarket submission.		not on separate page
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510(k)] Manual.	Table but w/o all criteria	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		✓
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	N/A	
Class III Certification and Summary. **	N/A	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	N/A	
510(k) Kit Certification ***	N/A	

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510(k)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which		

is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		✓
b) Sterilization and expiration dating information:		✓
i) sterilization process		}
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		✓

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening Yes No
Reviewer: Dan L Kaufman
Concurrence by Review Branch:

Date: _____

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 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/cdrh/modact/leastburdensome.html>

REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

R 030719

Reviewer: Dan Kaufman

Division/Branch: DOED / D5DB

Device Name: Pentacam Scheimpflug Camera

Product To Which Compared (510(K) Number If Known): K991284

	YES	NO	
1. Is Product A Device	<input checked="" type="checkbox"/>		If NO = Stop
2. Is Device Subject To 510(k)?	<input checked="" type="checkbox"/>		If NO = Stop
3. Same Indication Statement?	<input checked="" type="checkbox"/>		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	If YES = Stop NE <i>don't know</i>
5. Same Technological Characteristics?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If YES = Go To 7 <i>data complete</i>
6. Could The New Characteristics Affect Safety Or Effectiveness?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	If YES = Stop NE
9. Accepted Scientific Methods Exist?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	If NO = Stop NE
10. Performance Data Available?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	If NO = Request Data
11. Data Demonstrate Equivalence?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Final Decision: <i>Need additional information</i>

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

July 22, 2003

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
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OCULUS OPTIKGERATE GMBH
C/O OCULUS, INC.
18902 NE 150TH ST.
WOODINVILLE, WA 98072
ATTN: TOM WEATHERBY

510(k) Number: K030719
Product: PENTACAM
SCHEIMPFLUG
CAMERA

The additional information you have submitted has been received.

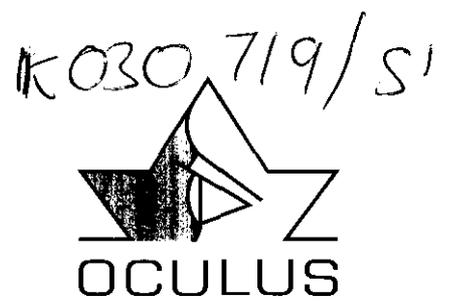
We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any 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 www.fda.gov/cdrh/ode/a02-01.html.

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 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.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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



**Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850**

**510(k) Number: K030719
Trade Name: Pentacam Scheimpflug Camera**

Owner/Operator No.: 8010318

FDA/CDRH/ODE/PMO
2003 JUL 21 A 11:43

Dutenhofen, 18 Juli 2003

Dear Ladies and Gentlement,

These are the additional information according the 510(k) device

„Pentacam Scheimpflug Camera; k030719.“

Please hand over the documents to

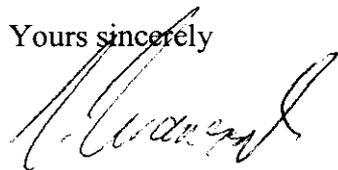
Mr. A. Ralph Rosenthal, MD

or

Mr. Everette T. Beers

Thank you for co-operation and help.

Yours sincerely



Joerg Iwanczuk

Product Manager

International Sales Department

OCULUS Optikgeraete GmbH

Tel.: ++49-641-2005-272

Fax.: ++49-641.2005-295

J.Iwanczuk@t-online.de

34

SK34

**Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850**

FDA/CDRH/ODE/PMO
2003 JUL 21 A 11:45

**510(k) Number: K030719
Trade Name: Pentacam Scheimpflug Camera**

Owner/Operator No.: 8010318

Dutenhofen, 18 July 2003

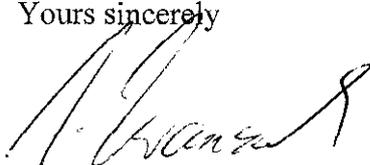
Dear Mr. A. Ralph Rosenthal, M.D.

Thank you for your detailed letter according our 510(k) device.

We try to give you the information you are asking for in the following pages.

Thank you for co-operation and help.

Yours sincerely



Joerg Iwanczuk

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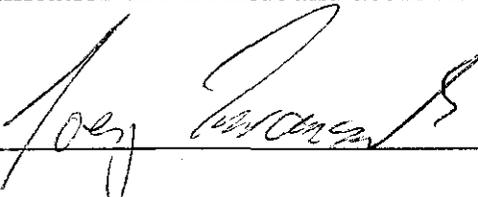
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1. Truthful and Accurate Statement

TRUTHFUL AND ACCURATE STATEMENT

[As required by 21 CFR 807.87(k)]

I certify that, in my capacity as Product Manager of OCULUS Optikgeräte GmbH, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Joerg Iwanczuk

Dutenhofen, AP 1071 2003

K 030719

2. Device description

The Pentacam Scheimpflug Camera is based on the Scheimpflug principle for slit lamp photography. The system is table mounted and AC powered by an external power supply.

The system contains

measuring devices including:

- o illumination unit with LED's, 475nm wavelength UV-free to illuminate the anterior segment of the eye,
- o a CCD-Camera unit to take the Scheimpflug Images,
- o a CCD-Camera unit in the center for the fixation monitoring and internal correction,
- o a optical lens system to project the slit,
- o two infrared LED's to illuminate the pupil for fixation monitoring.

electrical devices, including:

- o a memory board and a CPU and which stores and analyses the taken images.
- o a power supply board which prepares and controls the electrical conditions of the Pentacam Scheimpflug system
- o an electric motor for rotating
- o a communication board for transferring the images to external standard high speed PC's

All the mentioned parts are mounted internal the system and the housing around separates this parts from any external illegal operation.

The measurement can be done in two different ways, depending of what you like to evaluate:

1. Taking photos from one Camera position:

The Camera takes pictures from one fixed position as it is already well known from the common Scheimpflug Cameras. The use is to get information of the condition of the lens.

2. Taking photos from several positions:

The Camera rotates around the eye and takes up to 50 Scheimpflug Images from several positions. Every single picture has 500 measured true elevation points. So in the summary we get 25.000 measured true elevation points. The Scheimpflug Images taken during the examination are digitalized in the system. All Image Data are transferred to the external PC. When the examination is finished, the PC calculates a three dimensional mathematical model from which all additional information is derived.

The use is to get information about

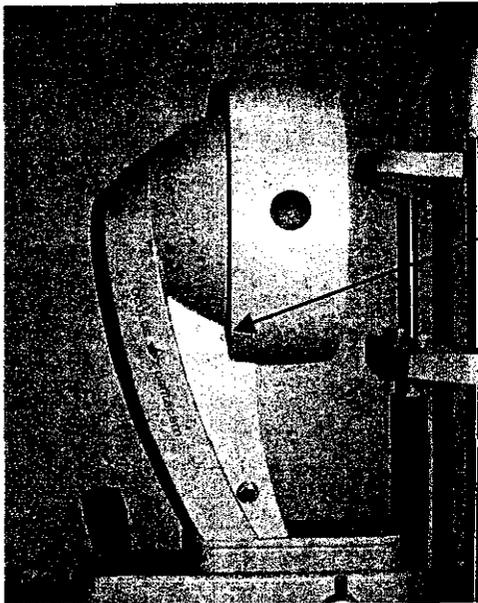
- o anterior and posterior surface of the cornea,
- o thickness of the cornea,
- o chamber angle, volume and depth.

Other systems which are already on the market and has an FDA admission like the Orbscan II™ Keratometer, measures at the beginning about 9.000 true elevation points and now about 18.000 measurement points at all. This instrument calculates the pachymetry and the posterior surface using the measured points too.

So the Pentacam Scheimpflug Camera measures much more true elevation points and we think, we have better conditions for following mathematical calculations.

3. Labelling

The picture below shows the labelling of the Pentacam. The type plate is shown in a bigger format next to Pentacam image.



Please find more information in the operators manual, specially on pages 5 to 8.

The instrument has to be installed by an authorized technician and not by the customer himself. So no package label is mentioned.

The labeling on the CD ROM which includes the software is:

Pentacam,

Ver. (1.02),

OCULUS Optikgeräte GmbH,

Münchholzhäuser Str. 29,

35582 Wetzlar

www.oculus.de

The labeling on the CD ROM which includes the calibration Data is:

Pentacam

Calibration data

Serialnumber: 70700 (6101 3050)

OCULUS Optikgeräte GmbH,

Münchholzhäuser Str. 29,

35582 Wetzlar

www.oculus.de

4. Statement of indication for use

Intended use:

The Pentacam is designed to take photos of the anterior segment of the eye which includes the cornea, pupil, anterior chamber and lens of the eye. To evaluate:

- o corneal shape,
- o analyse condition of the lens (opaque crystalline lens),
- o analyse the anterior chamber angle,
- o analyse anterior chamber depth,
- o analyse the volume of the anterior chamber,
- o analyse anterior or posterior cortical opacity,
- o analyse the location of cataracts (nuclear, subcapsular and or cortical), using cross slit imaging with densitometry,
- o corneal thickness.

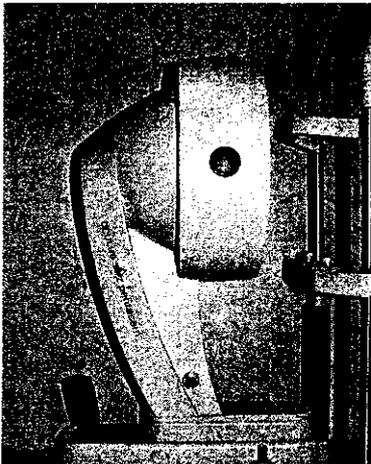
5. Biocompatibility and Sterilisation

The Pentacam Scheimpflug Camera is a non invasive diagnostic system. It is designed to take photos of the eye, specially of the anterior segment.

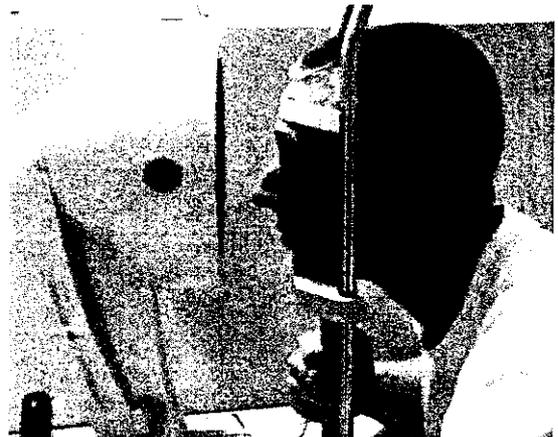
The Pentacam is a non invasive diagnostic device. The patient put his chin and forehead to a separate head and chin rest. There is no contact between the patient and the Pentacam and it is not a vitro diagnostic device and this is the reason why no sterilisation is necessary and no biocompatibility data's are necessary. The head and chin rest is used for example by Nidek slit lamps many years in the US-market.

The examination procedure is similar to the examination using a topographer. Please refer to the pictures below.

Pentacam, including Head-Chin Rest



Pentacam during the measurement

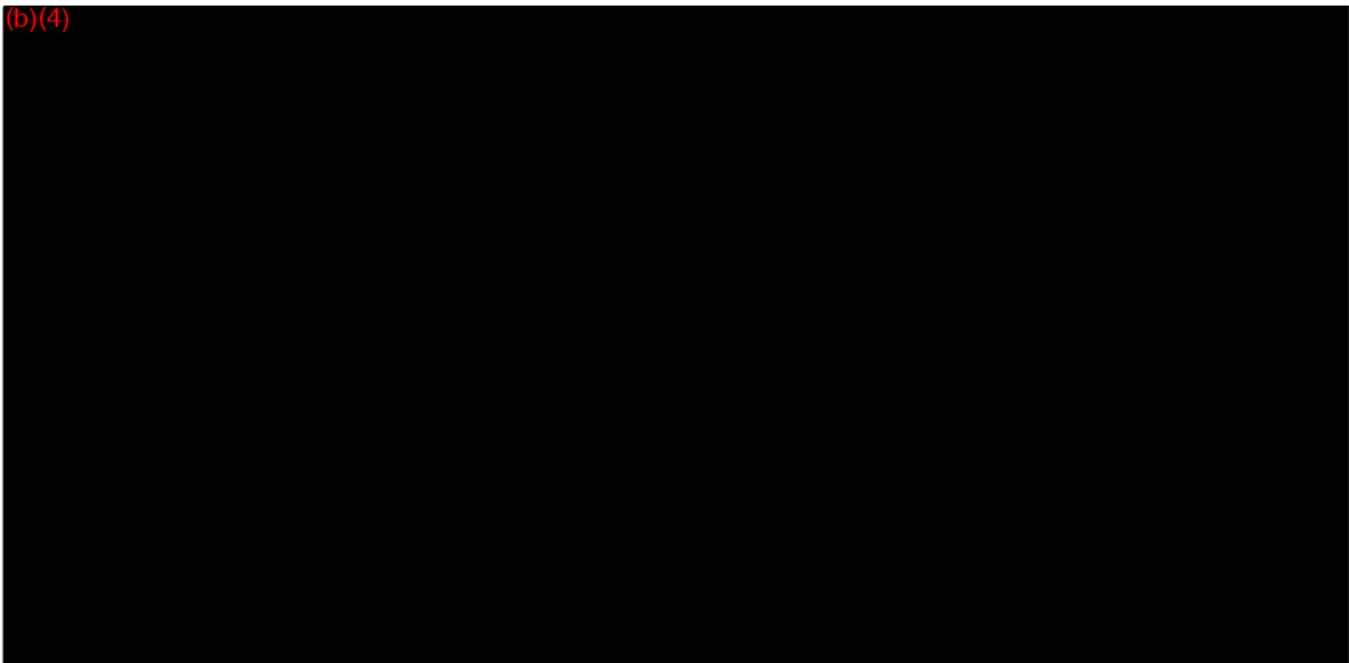


6. Materials

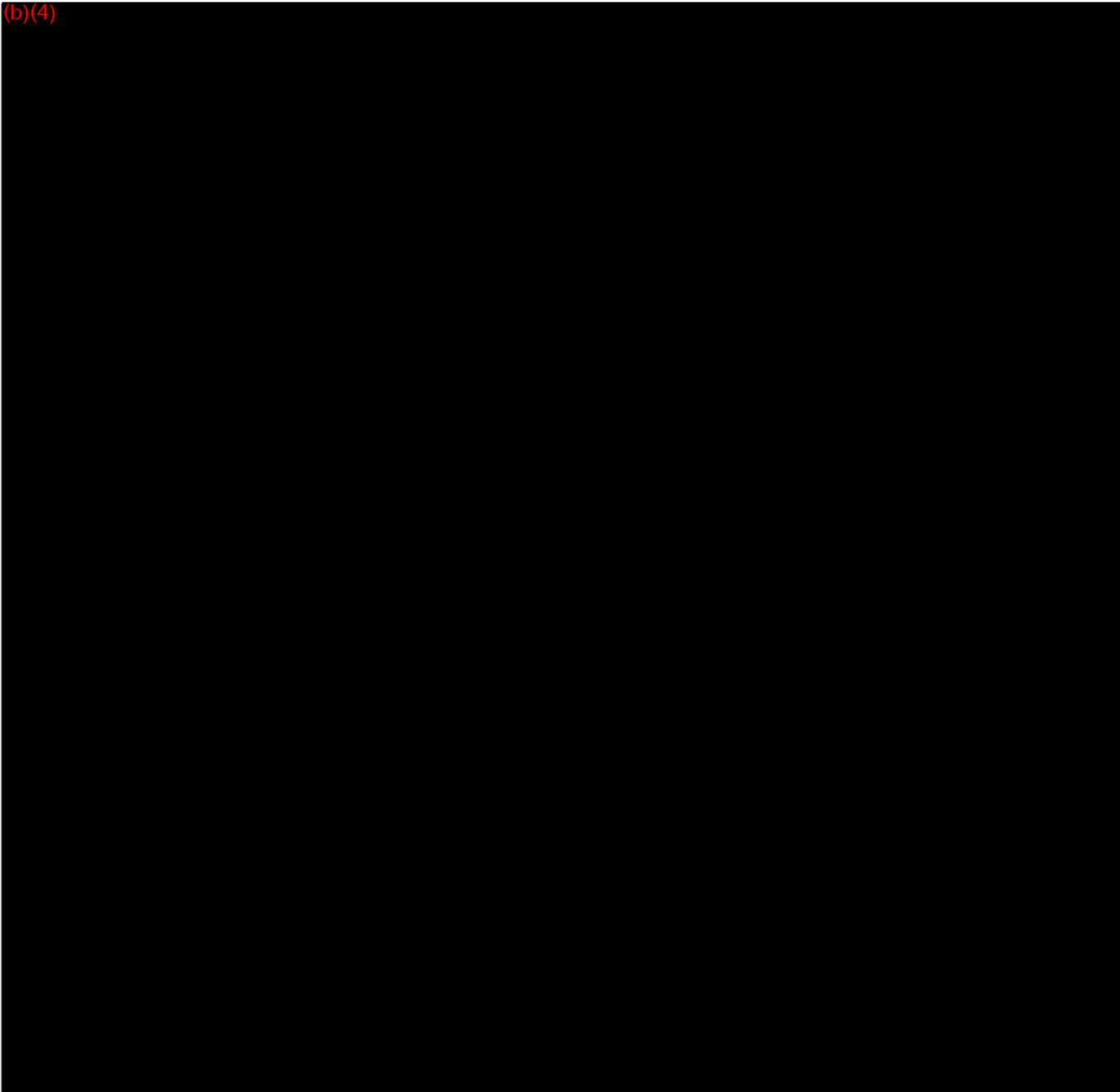
The description is related to the drawing called "Spaltprojektor, montiert" App. 1. So the used values are the values of the drawing.

The drawing includes two units, but only the left one is the valid one. The line separates the two unit which are not mechanical connected. We signed it as "Illumination Unit".

(b)(4)



(b)(4)



7. Substantial Equivalence

a) Side by side comparison

	New Device	Anterior Eye-Segment Analysis System
Manufacturer	OCULUS Optikgeräte GmbH	Nidek Inc.
Measuring Principle	Scheimpflug Principle for Slit Image photography	Scheimpflug Principle for Slit Image photography
Optical	Please refer to the detailed description	
Viewing Optics	15" Coloured Screen	5.5" Black and White CRT
Observation Illumination	Infrared LED 800nm for pupil illumination	Infrared LED for retro-illumination 800nm
Flash Output Illumination	Blue LED Light (UV-free) 475nm, max. 2.5W Power input	Xenon Lamp 200Wsec
Photography Camera	CCD-Camera	CCD-Camera
Display	Data digital, displayed on a CPU	Data digital and can be displayed on a CPU
Image resolution	800 x 600 pixels	640 x 400 pixels
Image size	5.6 x 4.5mm	8mm x 6.6mm
Photographic range	Eligible 0 to 360° automatically	Offers Photographic angles from 0 to 180° manual by hand
Photographic Series	1 to 50 photos	Only 1 photo
Exposure Control	Fixed during calibration, max 2.5Wsec. Power input	4 steps- selectable (50, 100, 150, 200)Wsec
Slit Length	14mm fixed	2 – 14mm adjustable
Where used	Hospital, ambulance	Hospital, ambulance
Intended use	Please refer to the detailed description	
Sterilisation	Please refer to the detailed description	
Materials	housing is made of steel, the back is made of Polyurethane, specially treated, not	The housing is made of steel and not inflammable plastic

	inflammable, App. 5	
Mechanical safety	Please refer to the detailed description	
Power supply	External, 110/220 VAC, 50/60Hz see attached certificate App. 6	implant
Power Consumption	50VA	150 VA
Power requirement	25 VDC 2A / 5 VDC 2A	100VAC, 50/60Hz
Weight	9 kg	25 kg

b) Optical Equivalency

- o In both systems the CCD Cameras for the Scheimpflug Images are mounted under an angle of 45 degrees
- o Both systems use a second CCD-Camera for the fixation and adjustment of the patients eye
- o Both systems use an optical lens system for the small slit projection
 - o Difference:
 - o Nidek uses an adjustable Slit, length from 2 ~ 14mm
 - o Oculus uses a fixed Slit length of 14mm
- o Both systems use LED light (800nm) for the illumination of the eye
 - o Difference:
 - o Nidek use only the LED light (800nm) for illumination and focusing the eye
 - o Oculus
 - o uses LED light (800nm) for the detecting and focusing the pupil, x- and y-direction
 - o uses blue LED's (475nm, UV-free) to get a current Scheimpflug Image during fixation and adjustment of the eye, z-direction focusing
- o Both systems use a Flash Output for image acquisition
 - o Difference:
 - o Nidek uses a Xenon Lamp, intensity selectable in 4 steps.
 - o Oculus uses blue LED light (475nm, UV-free). So we illuminate the eye during focusing and flash to get the Scheimpflug Image with the same source. Intensity is fixed during calibration. No changes by the user is possible.

c) **Intended use and effectiveness**

- Both Systems are Scheimpflug Cameras
- Both systems take Photos from the anterior segment of the eye
 - Difference is the light source
 - Nidek use a flash bulb
 - Oculus use blue LED light
- Both systems analyses condition of the lens (opaque crystalline lens)
- Both systems analyses anterior or posterior cortical opacity
- Both systems analyse the location of cataracts (nuclear, subcapsular and or cortical), using cross slit imaging with densitometry

d) **Sterilisation**

Both systems are non invasive diagnostic system

Both systems do not touch the patient. There is only a contact between the head and chin rest and the patient.

There is no need for any sterilisation on both systems.

e) **Mechanical safety**

Both systems are fixed at a basic system

- Difference
 - Nidek use a basic housing
 - Oculus use a common x-y-z-unit, like it is already use for slit lamps, topographers etc.

Both systems are fixed, so that there is no possibility for accidents like falling down. The Oculus Pentacam is installed only by an authorised and trained person (Operators Manual, chapter 5. Start Up)

Both system are designed, so that no unintentional contact to the patient is possible.

Both systems are designed, so that no unintentional movement of the instrument is possible

Difference

The weight of the Nidek instrument is 25 Kg

The Oculus system is fixed on a table

f) Electrical safety

Both units are checked by the respective laws and standards. The Oculus Pentacam Scheimpflug camera is developed, assembled and tested by the following norms or normative documents

IEC 601 – 1

IEC 601 – 1 – 2

In accordance with the regulations of Directive 93 / 42 / EEC on medical products

g) Differences and Summary:

The Nidek EAS 1000 is only a Scheimpflug Camera and provides Scheimpflug Images. So the whole evaluation of the human lens is generally same.

The biggest difference is the automatically rotation of the Pentacam Scheimpflug Camera and the mathematical calculation, the software.

Using this rotating principle a mathematical calculation of the complete anterior segment is possible. If a system takes slit images from only one position, and manual a second or third one, a mathematical calculation is very complicated at all.

That the reason why we offer some more features as the Nidek EAS 1000 Scheimpflug Camera like topography and pachymetry.

The Pentacam takes automatically images from several positions during one measurement. So the Pentacam know, using the second camera in the center, if the fixation and the rotating axis of each image is same, and if not, the Pentacam recalculates internal to the starting one.

Through the automatically image acquisition the angle between every slit image is fixed and known and one slit image includes information over its entire area.

Summary:

The Nidek Scheimpflug Camera and the Oculus Pentacam has the

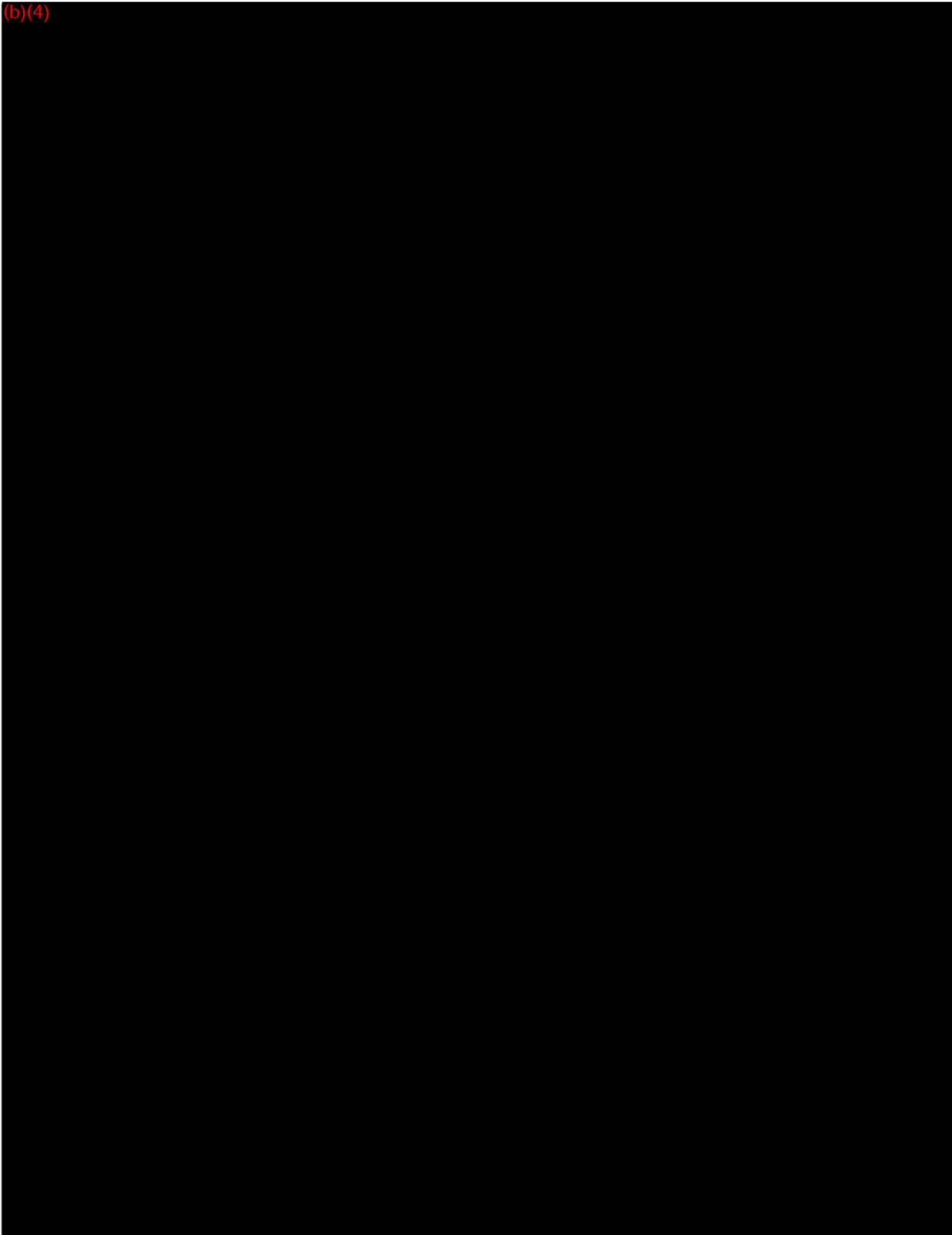
- Same or similar intended use
- Same or similar optical construction
- Same or similar optical principle, Scheimpflug principle
- Same or similar sterilisation, no sterilisation necessary
- Same or similar general construction like described in the side by side comparison
- Same or similar mechanical and electrical assembly
- the basic information, the Scheimpflug Image is the same in both systems.

The improvement or difference is the mathematical evaluation, the software, using the rotating principle based on the taken Scheimpflug Images.

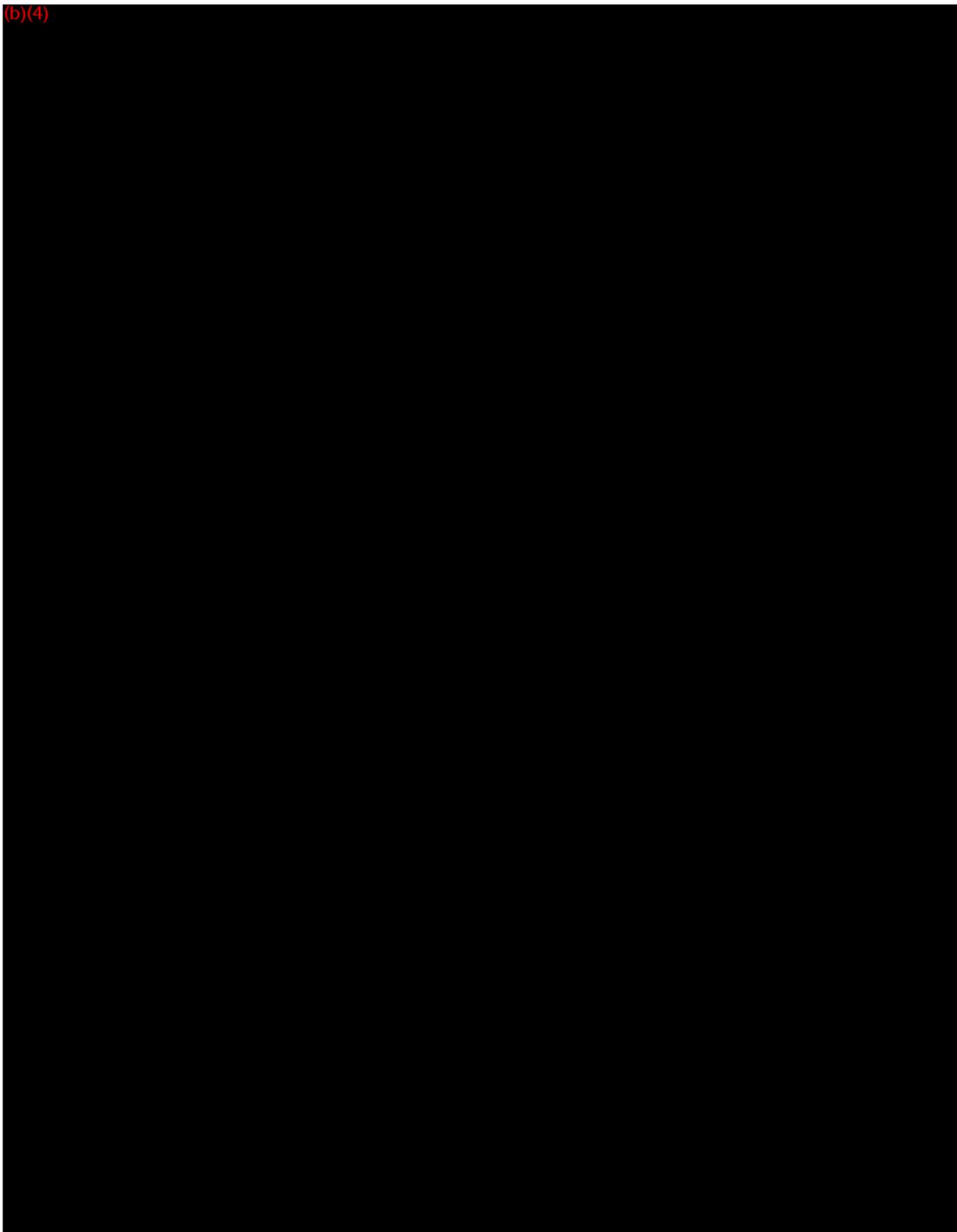
So we think the Nidek EAS 1000 Scheimpflug Camera and the Oculus Pentacam Scheimpflug Camera are substantial equivalence.

Radiation Safety

(b)(4)



(b)(4)



8. Electrical Safety

The Pentacam has an external Power supply, please refer to the certificate of the manufacturer attached App. 6. The power supply is registered for use for medical equipment.

Please refer to the attached Certificate of the electrical test App. 7 for the Pentacam system, which includes the Pentacam main body and the external power supply. We include the original German report and the translated one.

Our company fulfil the provisions of the fundamental requirements of
MDD 93/42/EEC,

IEC 601 – 1,

IEC 601 1 – 2.

Please refer to the declaration of conformity App. 8 attached and in the operators manual

9. Software certification, if applicable

According to the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", issued on May 29, 1998 we explain the software of the Pentacam Scheimpflug Camera.

a) **Level of concern**

We think, the level of our software is **Minor** because: The software

- does not control life supporting or sustaining device
- does not control delivery of harmful energy
- does not control treatment delivery
- does not perform vital signs monitoring.

The software provide diagnostic information. It is the decision of the doctor, if he use this information as a basis for treatment or therapy.

A software failure will never result in death or serious injury or in non-serious injury, because

- the Pentacam Scheimpflug Camera is not the only instrument for a doctor to get any parameters for a therapy or treatment
- many parameters like the examination using a slit lamp and a contact glass, an AutoRefractometer, a Non Contact, an ultra sound pachymeter and the experience of the doctor leads to the result
- to get any parameters for therapy or treatment the doctor will do more than one examination using the mentioned instruments, so he will detect differences between the different examinations
- the doctor know the demographics and the symptoms and the condition of the patient
- there is a logical connection between the examined data's, for example
 - a keratoconus must be visible in the topography and in the pachymetry map and leads anyhow directly to exclusion of corneal refractive injury.
 - a clouding of the human lens is controlled to the doctor using the slit lamp and his contact glass and is classified by his experience. It must be visible in both examinations, combined with the visus of the patient during the refraction using other and different instruments.

The Pentacam Scheimpflug Camera takes Images from several positions around the eye, put them together and presents the results. Every single taken picture can be viewed by the doctor to check its quality. The software do the same and use only the valid pictures. If not enough pictures where taken the system shows an error, and the doctor has to repeat the examination. The software makes no decision for any operation, only the presentation of results in coloured maps and values. The software gives no suggestion or recommendation of any parameters for a treatment or therapy.

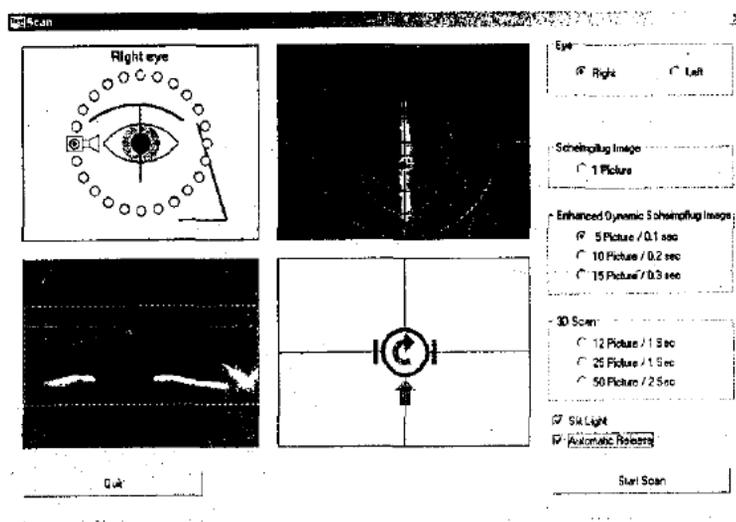
So that's the reason why we think the level of our software is **Minor**.

b) Software description

The software is written in the language GFA Basic and a Compiler translate it. So no user can do any changes in the software.

The role of the software in the Pentacam Scheimpflug Camera is, to lead the doctor through the different features and show the results:

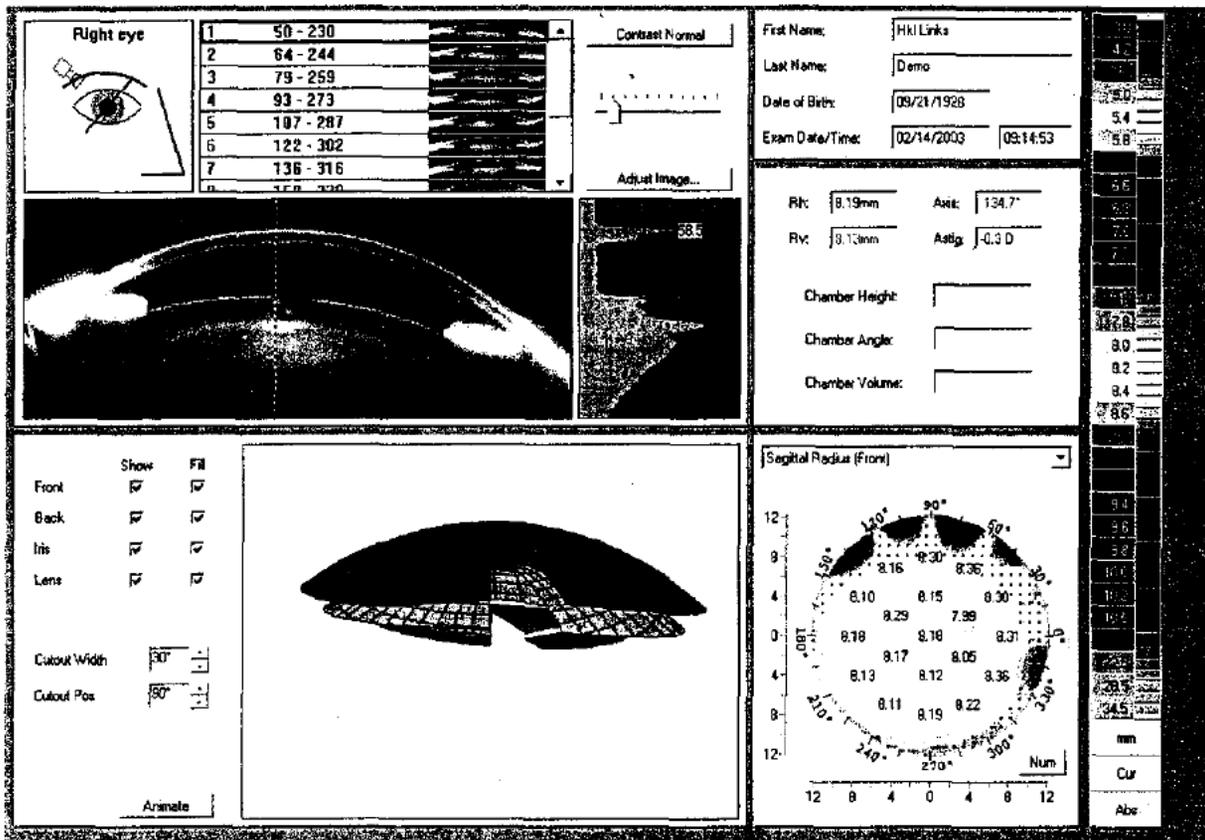
- Examination window



- The doctor chose the image mode, single or 3D-Scan
- The doctor chose automatic (standart) or manual release
- The software shows for a more comfortable allignement the current Scheimpflug Image, lower left and the pupil image, upper center. These images are for a pre adjustment.

- For the fine adjustment the orientation display lead the doctor to the releasing position, independent if automatic or manual release is chosen.

- Overview display



The overview display shows the doctor the examination results.

It is not possible to do any manual editing in the taken images or in the shown maps which may lead to any recalculation by the system.

The single maps and images can be viewed in a bigger size.

In the lower right an example of a map is shown, here the topography of the anterior surface of the cornea. In the same way the other maps for pachymetry or the topography of the posterior surface of the cornea are shown.

c) Software requirements

The Pentacam Scheimpflug Camera operates on a Windows™ based operating system that allows an easy operation and system control. The CPU used with the Pentacam is a standard high speed PC. For the communication between the Pentacam Scheimpflug Camera and the PC we use USB interface of the PC. The printer, monitor, keyboard and mouse are connected to the PC as it is usual for standard PC's.

The software is written in the language GFA Basic and a Compiler translate it. So no user can do any changes in the software. The size of the compiled software is about 5MB. This size does not include the taken images because the size depend on the taken images.

For more detailed description of the software please refer to the device hazard analysis and the architecture design and the validation and verification.

d) Release Version Number

The current release version number is 1.02, dated 1th july 2003.

e) Validation

For software validation a procedure is used to ensure that the software works well for the appropriate use. This procedure is documented in the software test protocol. The test protocol contains the following main items:

1 Functional test

The main important software functions are proceeded. Error Messages or malfunctions will be documented and cancel the positive validation.

2 Generate Measurements

Measurements are proceeded and the results are documented.

3 Evaluation

The measurement results are compared with the expected results. The differences must match the defined accuracy range. A value out of range will cancel a positive validation.

4 Result

Test passed or test not passed.

5 Problems, appearing after releasing this version

Problems of this software version that may appear after releasing this version are documented, to improve the software and the software test protocol.

Pentacam Software Test Protocol

Version number: _____

Date: _____

Test person: _____

Device serial number _____

h) 1 Functional test

Pos.	Test	Remarks:	OK ?:
101	Test of software installation Insert CD, and install software		
102	Start Software (using Test Patient). Start "Scan Menu", Check motor positioning movement		
103	Check Slit light normal and maximum		
104	Grab Scheimpflug image (1 Picture)		
105	Grab Scheimpflug image (5 Picture)		
106	Grab Scheimpflug image (10 Picture)		
107	Grab Scheimpflug image (15 Picture)		
108	Proceed Scan (12 Picture)		
109	Proceed Scan (25 Picture)		
110	Proceed Scan (50 Picture)		
111	Menu "Maps Large" Check all display modes		
112	Menu „Image Large“ Check functionality		
113	Menu „Overview“ Check all colour maps		
114	Menu „3D-Model Large“ Check functionality		

2 Generate Measurements

Proceed 5 measurements (3D-Scan 25 Picture). Note the results, store the examination data and reload it. Note the results again.

Pos.:	Test				OK ?
201	Real Value:	Rh:	Rv:	Thickness:	
202	Measurement 1	Rh:	Rv:	Thickness:	
203	Measurement 2	Rh:	Rv:	Thickness:	
204	Measurement 3	Rh:	Rv:	Thickness:	
205	Measurement 4	Rh:	Rv:	Thickness:	
206	Measurement 5	Rh:	Rv:	Thickness:	
207	Store measurements and reload it				
208	Reloaded 1	Rh:	Rv:	Thickness:	
209	Reloaded 2	Rh:	Rv:	Thickness:	
210	Reloaded 3	Rh:	Rv:	Thickness:	
211	Reloaded 4	Rh:	Rv:	Thickness:	
212	Reloaded 5	Rh:	Rv:	Thickness:	
213	Compare Measurements with Reloaded values				

3 Evaluation

Calculate mean value and standard deviation.

Pos.	Measured value:	Limit:	OK ?
301	Mean value of measurement 1-5:		
302	Deviation from real value		
303	Deviation:		

4 Result:

401	Test passed:	Test not passed:
-----	--------------	------------------

5 Problems, appearing after releasing this version

Num.:	Problem:	Customer:
501		
502		
503		
504		
505		
506		
507		
508		
509		
510		
511		
512		
513		
514		
515		
516		

f) Device Hazard Analysis

1) Safety risks

An software caused hazardous event that leads to a serious injury can not happen with the Pentacam, because the active parts which are controlled by software are not able to treat the patient or doctor seriously.

The active parts of the device that are controlled by the software are:

- blue slit light
- infrared light
- rotation motor

Hazardous Event	Level of concern	probability of occurrence	Remarks
A hardware or software error causes that the slit illumination will be switched on with maximum power.	The patient can be glared by the light	Low	The emitted light intensity is much lower than the limits (refer to measurements of optical radiation).
A hardware or software error causes that the motor will move the inner rotational part of the device	The patient will see a rotational movement	Low	There is no contact between patient and Pentacam, because it is an optical measurement
A hardware error will cause a high voltage on the touchable parts of the device		Impossible	The device is powered with low voltage (24V) by an external power supply

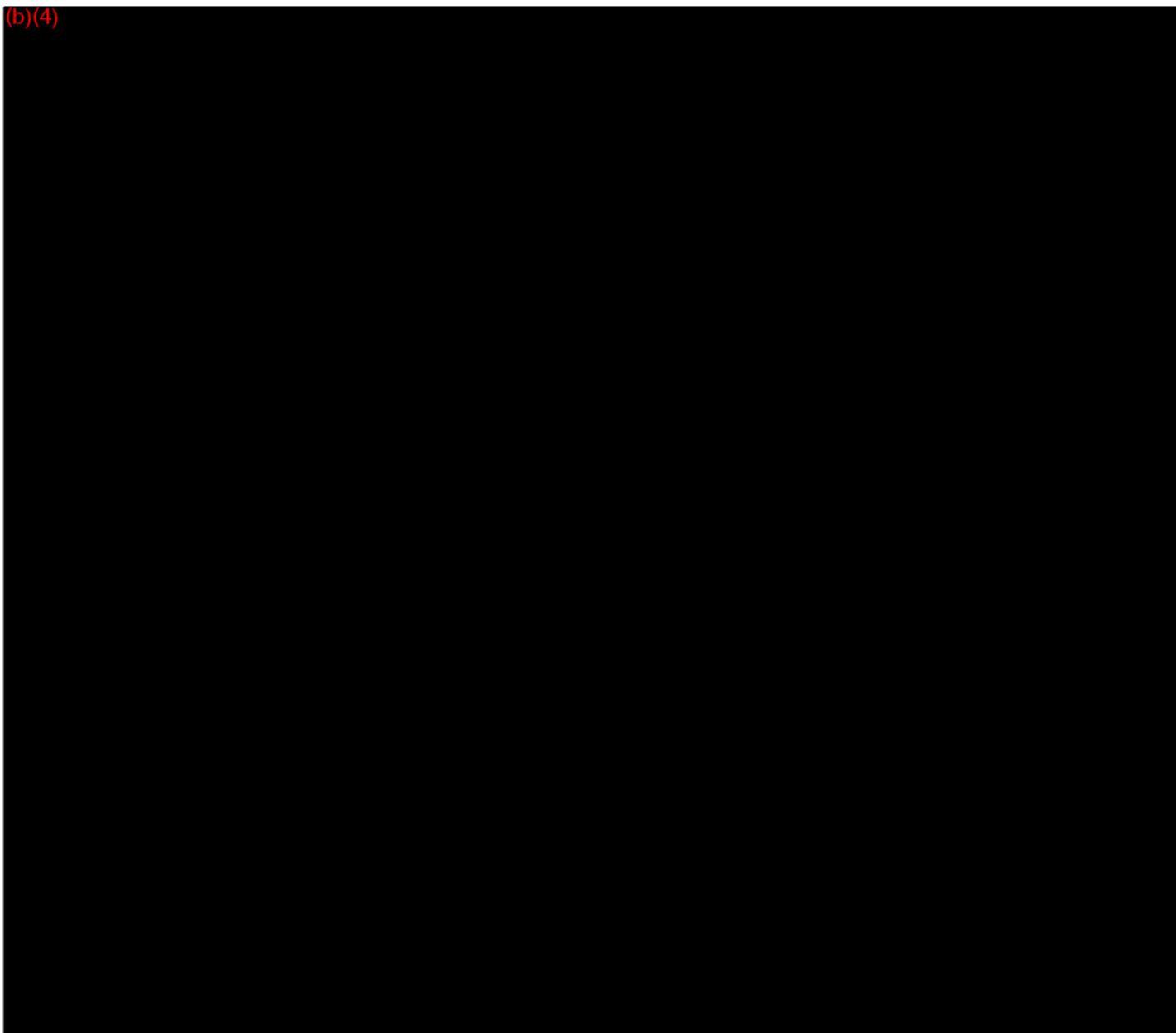
2) Risk of wrong examination results

Hazardous Event	Level of concern	probability of occurrence	Remarks
A hardware or software error causes no measurement result (e.g.: black camera images)	The examination can not be used	Low	
A hardware or software error causes wrong measurement result	The examination results are not accurate	Low	The accuracy and repeatability of the device is tested in normative studies.

11.07.03 Andreas Steinmueller, OCULUS

g) Software Architecture Design Chart

(b)(4)



11.07.03 Andreas Steinmueller, OCULUS

11. Appendix

- App. 1 Drawing of the Illumination Unit
- App. 2 Product information of the lens of the illumination unit
- App. 3 Certificate of the isolation foil
- App. 4 data sheet of the cooling unit
- App. 5 Certificate for the back housing
- App. 6 CB Test Certificate of the external power supply
 - Test report for Medical Equipment
 - Certificate of the power supply
 - General Description of the power supply
 - Detailed Description of the power supply
- App. 7 Prüfprotokoll of the Oculus Scheimpflug Camera in german
- App. 7a Certificate of the OCULUS Scheimpflug Camera (translation into english)
- App. 8 Declaration of Conformity
- App. 9 3407-01 Calibration Certificate of the Spaltlampenmikroskop, Type Pentacam
- App. 9a Translation of 3407-01 Calibration Certificate of the Spaltlampenmikroskop, Type Pentacam into english
- App. 10 3407-02 Calibration Certificate of the Diodenzeile, Type VU-M 160
- App. 10a Translation of 3407-02 Calibration Certificate of the Diodenzeile, Type VU-M 160 into english
- App. 11 3407-03 Calibration Certificate of the Diodenzeile, Type VU-M 160
- App. 11a Translation of 3407-03 Calibration Certificate of the Diodenzeile, Type VU-M 160 into english
- App. 12 SFH487 Data Sheet GaAIAs, Infrared Emitter
- App. 13 Operators Manual

Properties:

	Unit	Standard	PLEXIGLAS® 7H	PLEXIGLAS® 8H
Mechanical properties				
Tensile modulus (1 mm/min)	MPa	ISO 527	3200	3300
Stress at break (5 mm/min)	MPa	ISO 527	76	78
Strain at break (5 mm/min)	%	ISO 527	5.5	6.5
Charpy impact strength (23°C)	kJ/m ²	ISO 179	20	20
Thermal properties				
Vicat softening temperature (B/50)	°C	ISO 306	103	108
Glass transition temperature	°C	IEC 10006	112	
Temp. of deflection under load (0.45 MPa)	°C	ISO 75	100	
Temp. of deflection under load (1.8 MPa)	°C	ISO 75	95	
Coeff. of linear therm. expansion (0-50°C)	10 ⁻⁵ K ⁻¹	ASTM E831	8	8
Fire rating		DIN 4102	B2	B2
Rheological properties				
Melt volume rate, MVR (230/3.8)	cm ³ /10min	ISO 1133	1.4	0.8
Optical properties				
Transmission factor, τ_{D65}	%	DIN 5036	92	92
Haze	%	ASTM D1003	< 0.5	
Refractive index		ISO 489		1.49
Other properties				
Density	g/cm ³	ISO 1183	1,19	1,19

Product Information

PLEXIGLAS® 7H Molding Compound
PLEXIGLAS® 8H Molding Compound

Product Profile:

PLEXIGLAS® 7H and PLEXIGLAS® 8H are molding compounds based on polymethyl methacrylate (PMMA).

The special properties of these standard PLEXIGLAS® molding compounds are:

- high melt strength
- high mechanical strength, surface hardness and abrasion resistance
- high light transmission
- excellent weather resistance
- free colorability due to crystal clarity

The following properties of PLEXIGLAS® H molding compounds change with increasing grade number:

- improved mechanical properties
- increased heat deflection temperature
- reduced flow

Application:

PLEXIGLAS® molding compounds of the H series are particularly suitable for extruding optical and technical profiles and panels.

Uses of PLEXIGLAS® H molding compounds: panels, tubes, multi-skin sheets, coextrusion of window profiles and similar applications.

Processing:

PLEXIGLAS® 7H and PLEXIGLAS® 8H can be processed on extruders with 3-zone general purpose screws for engineering thermoplastics. Recommended processing conditions:

Predrying temperature:	PLEXIGLAS® 7H	max. 93 °C
	PLEXIGLAS® 8H	max. 98 °C
Predrying time in desiccant-type drier:		2 - 3 h
Processing temperatures:	melt temperature	220 - 260 °C
	barrel temperature	220 - 260 °C
	die temperature	220 - 260 °C

Physical Form/ Packaging:

PLEXIGLAS® molding compounds are supplied as pellets of uniform size, packaged in two-ply, 25 kg polyethylene bags or in 500 kg boxes with PE lining; other packaging on request.

Data sheet

Isola COMPOSITES

Ferrozell® HP HW

Sheets

Kunststoffe Hertrampf GmbH
Am Parir 29
52379 Langerwehe
Tel.: 0 24 23 / 26 03 · Fax: 23 80

Specifications

IEC / DIN EN	60893 / PF CP 201
DIN7735	HP 2081
BS	5102-3
NF C	150 P
NEMA	X / XP
VSM	S-PF-CP 1

App. 3

Properties

FERROZELL® HP HW is a paper laminate bonded with phenolic resin. Standard quality with good mechanical properties for normal electrical stresses. As requested also available up to a thickness of 2 mm as a hot punching quality.

Application

Assembly plates
Drilling templates
Electrical insulation
Electrical insulation at low voltage
Punched parts

Form of delivery

Sheet formats 1150 x 1070 mm
1150 x 2150 mm
Tolerance of length ± 20 mm

Thickness in a range of 0,5 to 120 mm
Thickness tolerances according to DIN EN 60893-3-4

We also deliver cut to size panels and machined parts. Other dimensions and thicknesses on request.

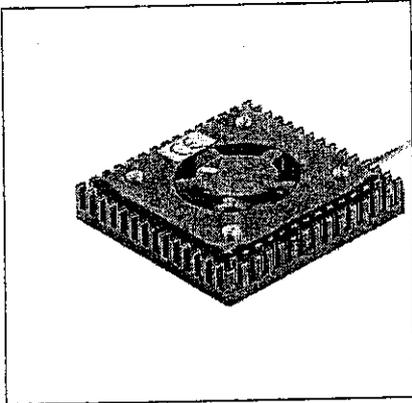
Machining

Machining with carbide tools. As requested hot punchable up to a thickness of 2 mm. Preheating temperature is 80 - 120°C

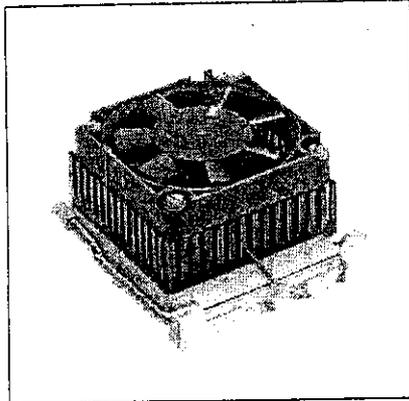
Lüfterkühler für Intel® Pentium® und MMX

Fan Heatsinks for Intel® Pentium® and MMX

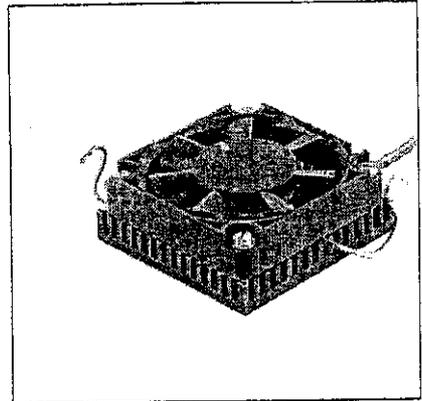
Dissipateurs ventilés pour Intel® Pentium® et MMX



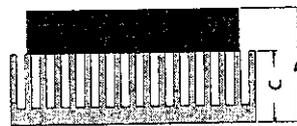
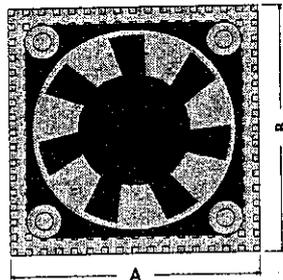
LA ICK PEN 8



LA ICK PEN 16 X



LA ICK PEN 18



App. 4

- einfache Montage auf ZIF Sockel durch Befestigungsklammer

- easy assembly on ZIF socket by fixing clamp

- montage facile sur support ZIF par ressort de fixation

Art.Nr. Art.No. Art.n°	Maße/Dimensions [mm]				R _w [K/W]	bei 85°C for 85°C pour 85°C	besonders geeignet für particularly suited for particulièrement convenable pour
	A	B	C	D			
LA ICK PEN 8...	50,8	50,8	8,0	9,0	2,5		Intel® Pentium®/MMX®/AMD® K 6 und ähnliche/and similar/ et similaires
LA ICK PEN 16...	50,8	50,8	16,51	26,51	1,2		
LA ICK PEN 18...	50,8	50,8	8,0	18,0	1,6		

bitte angeben:

... Befestigungsart:
K = mit Befestigungsklammer
(incl. einseitig anhaftender
Wärmeleitfolie), nicht
geeignet für LA ICK PEN 8
F = mit doppelseitig klebender
Wärmeleitfolie
X W = für Wärmeleitkleber
(bitte gesondert bestellen)
... Betriebsspannung des Lüftermotors:
5 = 5 Volt
X 12 = 12 Volt

please indicate:

... fixing method:
K = with fixing clamp
(incl. one-sided adherent
conductive foil), not
suitable for LA ICK PEN 8
F = with double-sided thermally
conductive adhesive foil
W = for thermally conductive adhesive
(please order separately)
... Circuit voltage of the fan:
5 = 5 Volt
12 = 12 Volt

veuillez indiquer:

... manière de fixation
K = avec ressort de fixation
(feuille thermique adhérente
d'une côté incluse), non
convenable pour LA ICK PEN 8
F = avec feuille thermo-conductrice,
adhésive des deux côtés
W = pour colle thermo-conductrice
(veuillez commander séparément)
... Tension de service du ventilateur
5 = 5 Volt
12 = 12 Volt

nur angeben wenn gewünscht:

... SF = Stromversorgungsstecker
... SM = Molex Anschlußstecker (→ B.33)
... A = Alarmausgang (→ B.32)

only indicate if requested:

... SF = floppy power supply plug
... SM = Molex connection plug (→ B.33)
... A = alarm exit (→ B.32)

indiquer seulement si désiré:

... SF = connecteur pour lecteur
... SM = fiche de connexion Molex (→ B.33)
... A = sortie alarme (→ B.32)

verwendete Lüfter:

LA ICK PEN 8:
5 Volt = Sepa HFB 44 B 05 A
12 Volt = Sepa HFB 44 B 12 A
LA ICK PEN 16/LA ICK PEN 18:
5 Volt = Sepa MFB 50 A 05
X 12 Volt = Sepa MFB 50 A 12
Technische Daten → B.33 - 34

applied fans:

LA ICK PEN 8:
5 Volt = Sepa HFB 44 B 05 A
12 Volt = Sepa HFB 44 B 12 A
LA ICK PEN 16/LA ICK PEN 18:
5 Volt = Sepa MFB 50 A 05
12 Volt = Sepa MFB 50 A 12
Technical Data → B.33 - 34

ventilateurs appliqués:

LA ICK PEN 8:
5 Volt = Sepa HFB 44 B 05 A
12 Volt = Sepa HFB 44 B 12 A
LA ICK PEN 16/LA ICK PEN 18:
5 Volt = Sepa MFB 50 A 05
12 Volt = Sepa MFB 50 A 12
Caractéristiques Techniques → B.33 - 34

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Technische Daten 12 Volt Lüfter

Technical Data 12 Volt Fans

Caractéristiques Techniques Ventilateurs 12 Volt

Fabrikat/ Brand name/ Marque:	Sepa MFB 25 A 12	Sepa MFB 40 D 12 H	Sepa MFB 40 D 12 HA	Sepa MFB 50 A 12	Sepa HFB 44 B 12 A	Popsi 412 F
Betriebsspannung/ Circuit voltage/ Tension de service:	10,2...12,0...13,8 V dc					10...14 V dc
Lagerart/ Bearing type/ Type de pallier:	2-fach kugellagert/ double ball bearing/double à billes			kugellagert/ ball bearing/pallier à billes		2-fach gleitgelagert/ double slide bearing/ double à glissement
Lüftermaße/ Fan dimensions/ Dimensions du ventilateur:	25 x 25 x 10 mm	40 x 40 x 10 mm		50 x 50 x 10 mm	44 x 44 x 6,2 mm	40 x 40 x 10 mm
Betriebsstrom/ Current consumption/ Intensité:	60 mA	80 mA		90 mA	40 mA	60 mA
Max. Anlaufstrom/ Max. initial current/ Intensité initiale max.:	200 mA	140 mA			70 mA	-
Max. Volumenstrom/ Max. volume flow/ Débit max. de ventilation:	38 l/min 2,28 m ³ /h	110 l/min 6,6 m ³ /h		240 l/min 14,4 m ³ /h	50 l/min 3,0 m ³ /h	132 l/min 8 m ³ /h
Max. statischer Druck/ Max. static pressure/ Pression statique max.:	3,2 mmH ₂ O 31,4 Pa	4,8 mmH ₂ O 47 Pa		2,4 mmH ₂ O 23,5 Pa	2,6 mmH ₂ O 25,5 Pa	3,06 mmH ₂ O 30 Pa
Geräusch/ Noise level/ Bruit:	22 dB(A), 1m seitlich/lateral/ latéral	24 dB(A), 1m seitlich/lateral/latéral			28 dB(A), 1m seitlich/lateral/ latéral	26 dB(A), 1m seitlich/lateral/ latéral
Temperaturbereich/ Temperature range/ Gamme de températures:	-10...+60°C					-20...+70°C
Ausfallrate/ Failure rate/ Taux de défaillance:	L ₁₀ = 95.000 h				L ₁₀ = 75.000 h	L ₁₀ = 45.000 h (20°C)
MTBF:	280.000 h (20°C)				210.000 h (60°C)	-
Gewicht/Weight/ Poids:	8 g	20 g		30 g	7 g	17 g
Gehäuse/Casing/ Boîtier:	Kunststoff /Plastic/Plastique PBT (UL E54695)					

Sepa-Lüfter 24 h BURN-IN getestet

Sepa fan 24 h BURN-IN tested

Ventilateur Sepa testé BURN-IN 24 h

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Ferrozell® HP HW

Sheets

Technical values

Kunststoffe Hertrampf GmbH
 Am Parir 29
 52379 Langerwehe
 Tel.: 0 24 23 / 26 03 · Fax: 23 80

Mechanical characteristics	Te	Unit	st	Preparatory treatment	Typical value
Flexural strength		MPa	ISO 178	23°C/50%RH	180
Flexural strength at high temperature		MPa	ISO 178	1h / 150 °C	
Modulus of elasticity		MPa	ISO 178	23°C/50%RH	12900
Notched impact strength		kJ/m²	ISO 179	23°C/50%RH	6
Tensile strength		MPa	ISO 527	23°C/50%RH	130
Compressive strength II/1		MPa	ISO 604	23°C/50%RH	170/340
Bonding strength		MPa	IEC 61212	23°C/50%RH	
Interlaminar bonding strength		N	DIN 53463	23°C/50%RH	2700
Shear strength II		MPa	ISO 60893	23°C/50%RH	

Electrical characteristics

Insulation resistance		Ω	IEC 60167	24h50°C+ 24h23°C water	1,00E+7
Surface resistance		Ω	DIN 53483		
Edgewise breakdown voltage		KV	IEC 60243	90°C oil	25
Flatwise electric strength		KV / mm	IEC 60243	90°C oil	6
Dissipation factor at 1 MHz			IEC 60250	23°C/50%RH	
Relative permittivity at 1 MHz			IEC 60250	23°C/50%RH	5
Comparative tracking index CTI		V	IEC 60112	23°C/50%RH	200
Arc resistance		s	ASTM D 495	23°C/50%RH	

Thermal characteristics

Temperature index		°C	IEC 60216		120
Thermal conductivity		W/m K	DIN 52612	20-100°C	0,2
Coefficient of linear expansion II		10 ⁻⁶ /K	VDE 0304	20-130°C	20

Other characteristics

Density		g/cm³	ISO 1183	23°C/50%RH	1,4
Nom. value for punch. up to 2 mm thickness			DIN 53488	23°C/50%RH	120°C:2
Flammability UL94		Stufe	UL 94	23°C/50%RH	
Color					brown
Water absorption		mg	ISO 62	24h50°C+ 24h23°C water	200
Water absorption		mg/cm³	ISO 62	24h50°C+ 24h23°C water	
Water absorption		%	ISO 62	24h50°C+ 24h23°C water	0,5

Indicated actual values are understood to be the average on on-going fabrication which will fluctuate within a certain tolerance band. The data given in this publication is the best of our knowledge and experience and, therefore, recommend without being binding. Our processes do not relieve the user to his obligation to check our products for suitability in any particular application. User is required to duly observe local legislation, regulation and any third party rights. This data sheet is also available in German. The German version is legally binding.

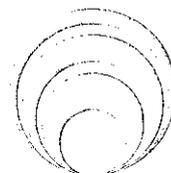
Stand 12.09.2002 Ausdruck 15.07.2003

Isola Composites GmbH, Theodor-Sachs-Str. 1, D-86199 Augsburg
 Tel. +49 (0)8 21 / 9 02 0, Fax +49 (0)8 21 / 9 02 239

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17. Juli 2003

UNNAPUR



KUNSTSTOFFTECHNIK

UNNAPUR - KUNSTSTOFFTECHNIK GMBH
Postfach 1946, D - 59409 Unna, Germany

FORMTEILE
AUS POLYURETHAN
(PUR)

www.unnapur.de

ISO 9001:2000

ISO 14001:1996

OCULUS Optikgeräte GmbH
z. Hd. Herrn Iwanczuk
Postfach 17 01 52



App. 5

35549 Wetzlar

Ihre Nachricht / your reference

zuständig / contact
Wolfgang Milcke

Datum / date
15.07.2003 Mi/sm

Certificate UL 94 V-0 and 5VA

This is to certify that all parts which are manufactured for you out of polyurethane are made exclusively out of the system Baydur 100-FR of Bayer AG, Leverkusen.

From a wall thickness of 3,1 mm onward this material meets the requirements of the flame protection class UL 94 V-0 and 94-5VA.

The corresponding yellow card with the no. E83364 (M) is attached.

With best regards,
UNNAPUR-KUNSTSTOFFTECHNIK GMBH

Enclosure

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ISDN-Fon: + 49 (0)2303 / 2 20 30 u. 31
Telefax : + 49 (0)2303 / 2 20 32
e-mail : unnapur@t-online.de

Geschäftsführer: Dipl.-Ing. Wolfgang Milcke
Registerrichter Unna Nr. HRB 470
Ulzener Weg 27, D - 59425 Unna, Germany

Volksbank Unna Schwerte eG (BLZ 443 600 02) 4 106 100 301
Sparkasse Unna (BLZ 443 600 60) 19 745
Post giro Dortmund (BLZ 440 100 46) 22 108-464

17. Juli 2003

QMFZ2 July 9, 1990
 Component - Plastics

BAYER AG		E83364 (M)								
		(B-cont. from A card)								
Baydur 110 FR	NC	3.10*#	94V-0, 94-5VA	50	50	50	—	—	—	—
Baydur 61FR	NC	5.90- 10.01@	94V-0, 945-VA	50	50	50	—	—	—	—
Baydur 62FR	NC	5.90- 10.01@@	94V-0, 94-5VA	50	50	50	—	—	—	—
Polyurethane (PUR) integral skin rigid foam, furnished in the form of two components.										
6511C/PU1739/ Desmodur 44V10B	NC	9.91- 10.41*	94V-0	50	50	50	—	—	—	—
Polyurethane (PUR), furnished in the form of three liquid components.										
Baydur 6511C/- Exolith 422/- Desmodur 44 P 01	TN	6.20	94V-0, 94-5VA	50	50	50	—	—	—	—

Reports: March 14, 1985; March 14, 1985; March 14, 1985; August 21, 1986; July 17, 1987.

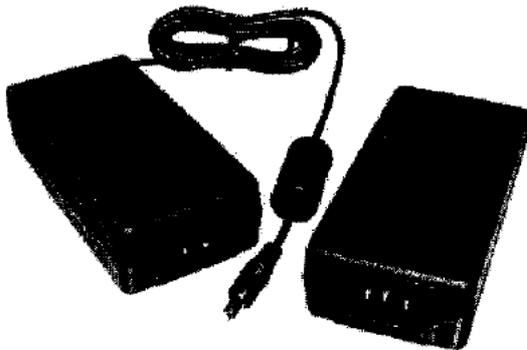
Replaces E83364B dated February 2, 1990. (Cont. on C card)
 223794008 N7047 Underwriters Laboratories Inc.* 011/0097428

App. 6

HiTRON

2000/08/17

**UNIVERSAL INPUT AC TO DC MEDICAL APPLICATION
EXTERNAL ADAPTOR SINGLE OUTPUT 45-50 WATTS
SWITCHING POWER SUPPLIES HES49 SERIES**



FEATURES:

- ACCOMMODATE UNIVERSAL AC SOURCES
- DESKTOP WITH IEC320 2P OR 3P AC RECEPTACLE
- MEET MEDICAL STANDARDS EN60601/UL2601
- EMI MEET EN 55022/ FCC CLASS B
- CE MARKING COMPLIANCE

SPECIFICATION

INPUT SPECIFICATION	OUTPUT SPECIFICATION
Input Voltage: Typ.90-264Vac. Input Connector: IEC320 3P DT7 or 2P DT8 AC input receptacle. Input Frequency: 47-63Hz. Inrush Current: Cold start 32A @230Vac. Input Current: 0.79A@115Vac / 0.37A @230Vac. Dielectric Withstand: Meet IEC601. EMI: Meet EN55022 / FCC Class B. Hold-up Time: 15mS @115Vac./ 78mS @230Vac. Typ. Over Temp. Protection: Optional (NTC ckt.). Earth Leakage: Less than 0.1 mA.	Output Voltage: See Ratings Chart. Output Current: See Ratings Chart. Output Wattage: Typ.48-50Watts. Output Connector & Cord: Optional. Line Regulation: Typ. $\pm 0.1\%$. Load Regulation: Typ. $\pm 3.0\%$ typ. Noise & Ripple: Typ. 1.0% peak to peak. OVP: Built-in Zener diode clamping. Overload Protection: Typ.115-150% of max. power overrange or short circuit, power foldback & self-recovering.

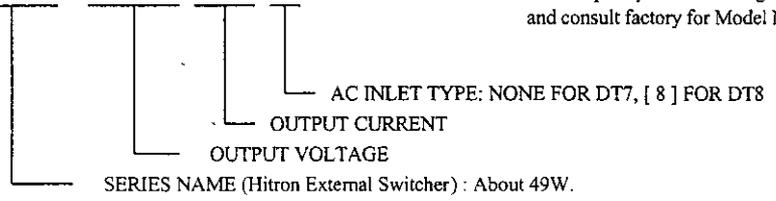
GENERAL SPECIFICATION
Efficiency: Typ.86.8%. Switching Frequency: Typ. 85 ~ 110K Hz. Circuit Topology: Fixed Frequency Flyback circuit. Transient Response: Output voltage returns in less than 3mS following a 25% load change. Safety Standard: IEC601/EN60601/ UL2601. Class I for DT7, or Class II for DT8 type. Power Density: 3.3Watts. / inch ³ . Operating Temperature: 0 ~ 40°C Storage Temperature: -20°C to +85°C. Temperature Coefficient: 0.04% /°C Cooling: Free air convection. Construction: Impact resistant thermo-plastic enclosure case. Desktop Format.

Notes:(1) All measurements are at nominal input, full load, and +25°C unless otherwise specified.
(2) The exact obtainable load regulation depends upon the output cord selected and load current.
Upper data are for 6 ft.(2 meters)cord AWG#18/20 wires with PF or PD type connector.



MODEL NO. DESCRIPTION: HES49 - XXX YY - S

Remark: Please specify the V/A ratings and consult factory for Model No.



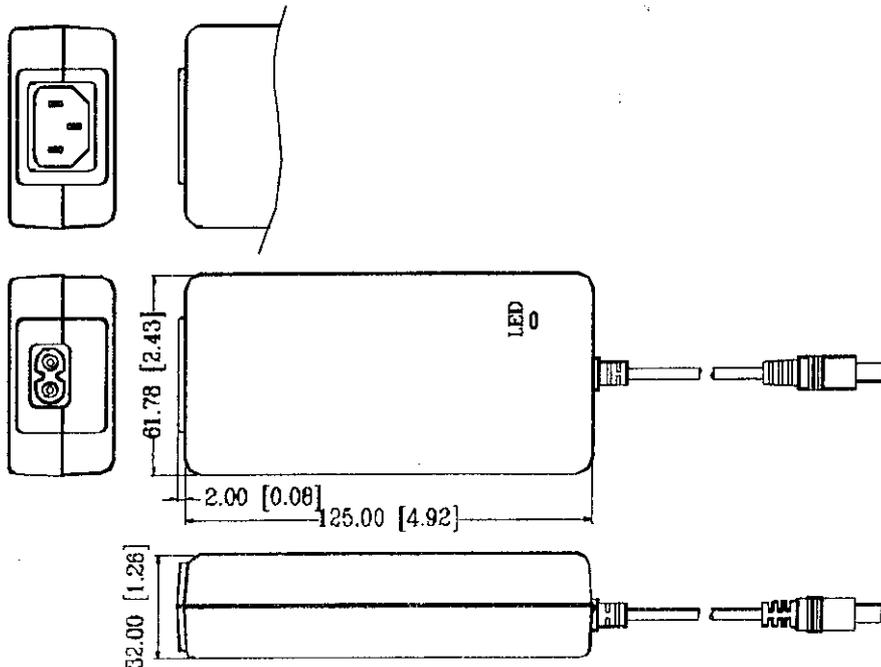
OUTPUT VOLTAGE / CURRENT RATINGS CHART

SINGLE OUTPUT

MODEL NO.	INLET TYPE.	OUTPUT VOLTAGE	OUTPUT CURRENT
HES49-12040	DT7	12.0Vdc.	4.0A
HES49-15033	DT7	15.0Vdc.	3.3A
HES49-24021	DT7	24.0Vdc.	2.1A
HES49-30017	DT7	30.0Vdc.	1.7A
HES49-12040-8	DT8	12.0Vdc.	4.0A
HES49-15033-8	DT8	15.0Vdc.	3.3A
HES49-24021-8	DT8	24.0Vdc.	2.1A
HES49-30017-8	DT8	30.0Vdc	1.7A

MECHANICAL DIMENSIONS: MM [INCHES]

WEIGHT: 373g (13.2 Oz).



App - 6

Ref. Certif. No
NO 8996

IEC SYSTEM FOR CONFORMITY TESTING TO
STANDARDS FOR SAFETY OF ELECTRICAL
EQUIPMENT (IECEE)
CB SCHEME

SYSTEME CEI D'ESSAIS DE CONFORMITE AUX
NORMES DE SECURITE DE L'EQUIPEMENT
ELECTRIQUE (IECEE)
METHODE OC

CB TEST CERTIFICATE CERTIFICATE D'ESSAI OC

Product
Produit

Name and address of the applicant
Nom et adresse du demandeur

Name and address of the manufacturer
Nom et adresse du fabricant

Name and address of the factory
Nom et adresse de l'usine

Rating and principal characteristics
Valeurs nominales et caractéristiques principales

Trade mark (if any)
Marque de fabrication (si elle existe)

Model/type Ref.
Ref. de type

Additional information (if necessary)
Information complémentaire (si nécessaire)

A sample of the product was tested and found
to be in conformity with
Un échantillon de ce produit a été essayé et a été
considéré conforme à la

as shown in the Test Report Ref. No.
which forms part of this certificate
comme indiqué dans le Rapport d'essais numéro
de référence qui constitue une partie de ce certificat

Hes 49 series power supply

Hitron Electronics Corp.,
B4-11, Kaohsiung Export Pros., Zone,
P.O.Box 26-110, Kaohsiung 806,
TAIWAN R.O.C.

Hitron Electronics Corp.,
B4-11, Kaohsiung Export Pros., Zone,
P.O.Box 26-110, Kaohsiung 806,
TAIWAN R.O.C.

Hitron Electronics Corp.,
B4-11, Kaohsiung Export Pros., Zone,
P.O.Box 26-110, Kaohsiung 806,
TAIWAN R.O.C.

100-240V AC 50-60Hz 1.0A max, Output: 12V DC 4A max

HITRON

Hitron Hes 49-12040

SAFETY: IEC 601-1 (2 ed 1988) + Amend. 1 (1991) + Amend. 2
(1995) + Corrigendum (June 1995)

And the Australian, Canadian and US deviation to the above
mentioned standard.

EMC: IEC 60801-1-2:93

SAFETY: 199950197

EMC: 20009208

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme National de Certification



P.O. BOX 73, BLINDERN
N-0314 OSLO, NORWAY

Date 14 April 2000

Signature Arild Hansgård
Principal Engineer

Arild Hansgård



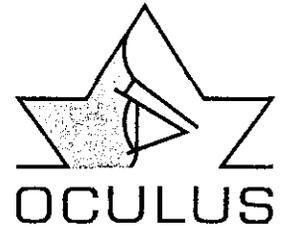
TEST REPORT MEDICAL ELECTRICAL EQUIPMENT

Equipment / Product	Power supplies for medical electric equipment	
Name and address of the applicant	Hiron Electronics Corp. B4-11, Kaoshiung Export Pros. Zone, P.O. Box 266-110, Kaoshiung 806, Taiwan	
Name and address of the manufacturer	Hiron Electronics Corp. B4-11, Kaoshiung Export Pros. Zone, P.O. Box 266-110, Kaoshiung 806, Taiwan	
Name and address of the factory	Hiron Electronics Corp. B4-11, Kaoshiung Export Pros. Zone, P.O. Box 266-110, Kaoshiung 806, Taiwan	
Trade mark		
Model/type	HES49-12040, HES49-15033, HES49-24021.	
Rating and principal characteristics	Input voltage 100-240VAC, 50-60 Hz, 0.9A max	
Serial no	9949 -001, -002, -004	
Tested in the period, dates	February / March 2000	
Tested according to	IEC 601-1 (2 ed. 1988) + Amend. 1 (1991) + Amend. 2 (1995) + Corrigendum (June 1995) MEDICAL ELECTRICAL EQUIPMENT - Part 1: General requirements for safety	P
Result of testing	The equipment complies with the above mentioned standards.	
The test results relate only to the sample(s) tested.		
Name and address of the testing laboratory	 P.O. BOX 73 BLINDERN, N - 0314 OSLO, NORWAY	Telephone (+47) 22 96 01 30 Fax (+47) 22 96 05 50
Tested by	 signature Vegard Andersen	2000-03-02 date
Verified by	 signature Frank Skarpsno	2000-08-02 date
© Nemko AS		

Verdicts are placed in the column to the right: P = Pass, F = Fail, N = Not applicable, — = Considered/Information

Due to Nemko's computerised handling of test reports the layout of this form is modified compared to the original IRE published by UMEDCA, 1992-12-01. The content fully covers the original IRE.

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Oculus Optikgeraete GmbH
 Muenchholzhäuser Str. 29
 D-35582 Wetzlar

15-May-03

App. 7a

Certificate

Manufacturer:	OCULUS	Checking manner:	Quality control
Article No.:	70700	Tester:	Stefan Uhl
Typ:	Scheimpflug-Camera	Date:	14-May-03
Art:	Scheimpflug Camera	Result:	freedom from faults
	System	MPG-Class:	1
Inventar No.:	70700	Protection Class:	1
Serial No.:	70700	Isolation Typ:	B
Norm:	-		

Checking Results

No.	Function	Step	Criterion	Unit	Result	+/-
1	View 01	Housing				
		Is the Instrument all right?	Yes		Yes	+
2	View 01	Is the type plate fixed?				
		Is the instrument all right	Yes		Yes	+
3	Gerb 001	Line / Voltage	216.2 – 243.8	V	226.1	+
4	Gerb 024	Power consumption (3 sec.)	40.0 – 50.0	W	45.2	+
5	Gerb 006	Leakage current NC	< 250.0	µA	66.1	+
6	Gerb 006P	Leakage current NC (P)	< 250.0	µA	65.7	+
7	Gerb 007	Leakage current SFC open Net	< 400.0	µA	123.5	+

Hersteller:	OCULUS	Prüfungsart:	Qualitätskontrolle
Artikel-Nr.:	70700	Prüfer:	Stefan Uhl
Gerätetyp:	Scheimpflug-Kamera	Prüfdatum:	14.05.03
Geräte-Art:	Scheimpflug Kamera system	Ergebnis:	Keine Mängel
Inventar-Nr.:	70700	MPG-Klasse:	I
Serien-Nr.:	70700	Schutzklasse:	SK I
Norm:	-	Isolationstyp:	B

Prüfergebnisse

Nr.	Funktion	Arbeitsschritt	Kriterium	Einheit	Ergebnis	+/-
1	SICHT 01	Sichtkontrolle Gehäuse				
		Ist das Gerät entspr. Memo in Ordnung?	Ja		Ja	+
2	SICHT 01	Typenschild aufgeklebt?				
		Ist das Gerät entspr. Memo in Ordnung?	Ja		Ja	+
3	GERB 001	Netzspannung	216.2 ... 243.8	V	226.1	+
4	GERB 024	Leistungsmessung (3 s)	40.0 ... 50.0	W	45.2	+
5	GERB 006	Erdableitstrom NC	< 250.0	µA	66.1	+
6	GERB 006 P	Erdableitstrom NC (P)	< 250.0	µA	65.7	+
7	GERB 007	Erdableitstrom SFC Netz offen	< 400.0	µA	123.5	+

App. 7

* ORIGINAL *

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DESCRIPTION

PRODUCT COVERED:

USR/CNR: Component - Power Supply, Medical and Dental, Model HES49-12040, Model HES49-15033 and Model HES49-24021.

ELECTRICAL RATINGS:

Model	Input		Output		
	V ac	Hz	V dc	A	VA
HES49-12040	100-240	50/60	+12	4.0	-
HES49-15033	100-240	50/60	+15	3.3	-
HES49-24021	100-240	50/60	+24	2.1	-

MODEL DIFFERENCES:

Model HES49-12040 is similar to Model HES49-15033 and HES49-24021 except for ratings and different ratings of some internal components.

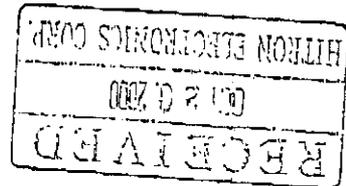
ENGINEERING CONSIDERATIONS (NOT FOR UL REPRESENTATIVE'S USE):

General - The product covered by this Report is a Power Supply component intended for use in/with professional medical and dental equipment.

The product is provided with an appliance inlet, but evaluated without a detachable Power Supply cord. All electrical components are housed within a plastic enclosure.

In addition to UL 2601-1 (1997), the following standards were utilized during the investigation of the subject product:

10/ To: Gventher
19 Im: Alex
Total: 28 pages



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Sec. 3

Page 2

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IEC 60601-1(1988).

IEC 60601-1: Amendment 1 of IEC 60601-1 1991.

IEC 60601-1: Amendment 2 of IEC 60601-1 1995.

CAN/CSA-C22.2 No. 601.1-M90.

Use - For use only in products where the acceptability of the combination is determined by Underwriters Laboratories Inc.

Conditions of Acceptability - When installed in the end-use equipment, the following are among the considerations to be made.

1. This product has been judged on the basis of the required spacing in the 2nd Edition of the Standard for Medical Electrical Equipment, UL 2601-1, CL. 57.10.

2. The Power Supply shall be installed in compliance with the enclosure, mounting, spacing and segregation requirements of the end-use equipment. The enclosure is secured by 2 screws.

3. A Listed detachable Power Supply cord provided with a "Hospital Only" or "Hospital Grade" attachment plugs, shall be use in the end-use application in US. See CL.57.2 and CL. 57.3 of US differences in UL 2601-1. A KAM Certified Power Supply cord shall be used in Europe.

4. The Power Supply was considered as a Class I with no Applied Parts.

5. This product has only been evaluated for non-patient connected circuits.

6. The Temperature Test was conducted on Power Supply with simulated load on an open bench. Temperature Test shall be considered when installed in/with the end-use equipment.

7. Leakage Current Tests (CL.19) shall be considered on the end-use equipment.

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8. This Power Supply was not investigated for ingress of water (IPX0).

9. Requirement of CL.600.1 of the U.S. Differences shall be considered in the end-use application.

Function of Equipment - The Power Supplies is intended for use in/with professional medical and dental equipment.

Engineering References - Following are provided for engineering references:

- ILL. 1 - Insulation Diagram of the Equipment.
- ILL. 2 - Marking plates.
- ILL. 3 - Mains Transformers Construction Diagram and Cross Section Diagram.
- ILL. 4 - Electronic diagram of Model HES49-12040.
- ILL. 5 - Electronic diagram of Model HES49-15033.
- ILL. 6 - Electronic diagram of Model HES49-24021.

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CONSTRUCTION DETAILS:

Except for items specifically addressed in this Section, all Sec. Gen. requirements apply.

Markings - The following IEC Symbols shown in Sec. Gen. (Ills. 1 and 2) are provided:

Table DI: Nos. 1, 4 and 14.

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MODEL HES49-12040, HES49-15033 AND
HES49-24021, OVERALL VIEW

FIG. 1 (D00-00491)

1. Enclosure - R/C (QMF22), GE Plastics Americas, Designated "Noryl", type SE100(f1)(b), rated 94V-1. Overall 125 by 61.5 by 32.5 mm, min. 2.3 mm thick. Top enclosure overlaps bottom enclosure, secured by 2 screws.
2. Appliance Inlet - R/C (AXUT2), KAM, Supercom Wire & Cable Co Ltd, Type SC-8, rated 250 V ac, 10 A.
3. Output Cord - R/C (AVLV2), KAM, Copartner Wire & Cable Mfg Corp., Type AWM, VW-1, rated 300 V, 80°C. Located in secondary circuit. Provided with plug or connector.

Alternative Output Cord - R/C (AVLV2), KAM, Formal Electric Wire & Cable Co. Ltd., Type AWM, VW-1, rated 300 V, 80°C. Located in secondary circuit. Provided with plug or connector.
4. Indicator Lamp - Color: Green (ON). (Explanation of function described in the accompanying documents).
5. Label Material and Marking plate - R/C (PGDQ2), Sen Kai Printing Co. Ltd., Pressure-sensitive system, Type "SK-1", ABS plastic. Marking plate provided with manufacture name, type designation, ratings, symbol No. 1, 4 and 14 of Table DI.

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MODEL HES49-12040, INTERNAL VIEW -

FIG. 2 (D00-00492)

General - See ILL. 3.

1. Printed Wiring Board - See Section General.
2. Fuse (F1, F2) - R/C (JDYX2), KAM, Wickmann-Werke GmbH, rated 3.15 A, 250 V ac, marked T 1A250.
3. Capacitor (C1, C4) - (Line-to-Line). R/C (FOWX2), KAM, rated 250 V ac, 330 nF. Marked with "X1" (Complies w/ IEC60384-14 2.ed. and UL 1414).
4. EMI Filter (L5) - Hitron Electronics Corp., Type S2-09619. (Rated 150 uH). Open type construction. Core: Ferrite, overall 12.0 by 6.0 mm, Coil: polyester enamel copper magnet wire. Sec. Winding R/C (OCDT2), Triple Insulated Winding Wire (Complies w/ UL 1950, Annex U for reinforced insulation).
5. EMI Filter (L1) - Hitron Electronics Corp., Type S2-09614. (Rated 7 mH). Open type construction. Core: Ferrite, overall 16.0 by 10 mm, Coil: polyurethane enamel copper magnet wire.
6. Inductor (L2) - Hitron Electronics Corp., Type S2-09021. (Rated 60 uH). Open type construction. Core: Ferrite, overall 16.0 by 10 mm or 12 by 9 mm, Coil: polyester enamel copper magnet wire. Provided with Extruded Tubing R/C (YDFU2).
7. Capacitor (C2, C44) - (Line-to-Ground). R/C (FOKY2), KAM, rated: 250 V ac, 1000 pF. Marked with "Y2". (Complies w/IEC60384-14 2.ed. and UL 1414).
8. Capacitor (C7) - (Line-to-Ground). R/C (FOKY2), KAM, rated 250 V ac, 220 pF. Marked with "Y2". (Complies w/IEC60384-14 2.ed. and UL 1414).
9. Capacitor (C8) - (Line-to-Ground). R/C (FOKY2), KAM, rated 250 V ac, 470 pF. Marked with "Y2". (Complies w/IEC60384-14 2.ed. and UL 1414).
10. Optical Isolator (IC2, IC6) - R/C (FPQU2), SHARP CORP., Type PC 123, (rated isolation 5000 V ac). (Meets reinforced insulation requirements). IC2 and IC6 are connected over primary to secondary circuits. Clearance distance on PWB measures minimum 5.0 mm. Creepage distance on PWB measures minimum of 8.0 mm.

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11. Transformer (T1) - Hitron Electronics Corp., P/N E9S49001-6. Overall dimensions 33.5 by 26 by 16 mm. Provided with Insulation System R/C (OBJY2), Hitron Electronics Corp., Type R120E, rated Class B, 600 V. See ILL. 3 for further Construction Details.
12. Varistor (MOV1) - (Line-to-Line). R/C (XUHT2), KAM, Div, Type 471K. Rated 470 V ac.
13. Thermistor (TH1) - NTC. R/C (XGPU2), Thinking Electronics Industries Co. Ltd., Type SCK 102, Rated 240 V ac, 10 Ω at 25°C (Maximum Working Current 2 A). (Tested for 100,000 cycle endurance).
14. Heat sink - Copper, 2 provided. Overall 100 by 48 mm, 1 mm thick.
15. Diode Bridge (DB1) - Rated 4 A, 800 V ac.
16. Electrolytic Capacitor (C6) - Rated 400 V ac, 10 μ F, 105 C.
17. Electrolytic Capacitor (C9) - Rated 400 V ac, 100 μ F, 105 C.
18. Capacitor (C37, C38, C41, C42) - SMD (Surface Mounted Device), rated 500 V ac, 2200 pF.
19. Diode - Type 1N4148.
20. IC1 - Type KA3882D.
21. Switching Transistor (Q1) - Type 2SK2564. Rated 600 V ac, 6 A.
22. Transistor (Q2) - SMD, Type HMBT6517.
23. Transistor (Q3, Q5, Q6) - Type BC817-25.
24. Transistor (Q9) - Type BC807.
25. Resistor (R1, R2) - SMD, Rated 330 k Ω , 1/4 W.
26. Resistor (R4, R5, R6) - SMD, rated 270 k Ω , 1/4 W.
27. Resistor (R3, R7) - SMD, Rated 120 k Ω , 1/4 W.

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28. Resistor (R54, R26) - SMD. Rated 3.3 k Ω , 1/8 W.
29. Resistor (R57, R58, R59) - SMD. Rated 5 Ω , 1/4 W.
30. Resistor (R60, R61) - SMD. Rated 47 k Ω , 1/8 W.
31. Resistor (R21, R22, R42, R49) - SMD. Rated 1.2 M Ω , 1/4 W.
32. Resistor (R19, R44, R45, R55) - SMD. Rated 4.7 k Ω , 1/8 W.
33. Resistor (R12, R13, R14) - SMD. Rated 1.5 Ω , 1/4 W.
34. Resistor (R11) - SMD. Rated 180 Ω , 1/8 W.
35. Resistor (R16) - SMD. Rated 22 k Ω , 1/8 W.
36. Resistor (R9) - SMD. Rated 27 Ω , 1/4 W.
37. Resistor (R10) - SMD. Rated 15 Ω , 1/8 W.
38. Resistor (R17) - SMD. Rated 24 k Ω , 1/8 W.
39. Resistor (R15) - SMD. Rated 24.9 k Ω , 1/8 W.
40. Resistor (R18) - SMD. Rated 12.7 k Ω , 1/8 W.
41. Resistor (R20) - SMD. Rated 1 k Ω , 1/4 W.
42. Resistor (R50) - SMD. Rated 5.62 k Ω , 1/8 W.
43. Resistor (R64, R65) - SMD. Rated 10 Ω , 1/4 W.
44. Electrolytic Capacitor (C23, C24, C25, C29) - Rated 16 V ac, 330 μ F, 105°C.
45. Electrolytic Capacitor (C27) - Rated 16 V ac, 330 μ F, 105°C.

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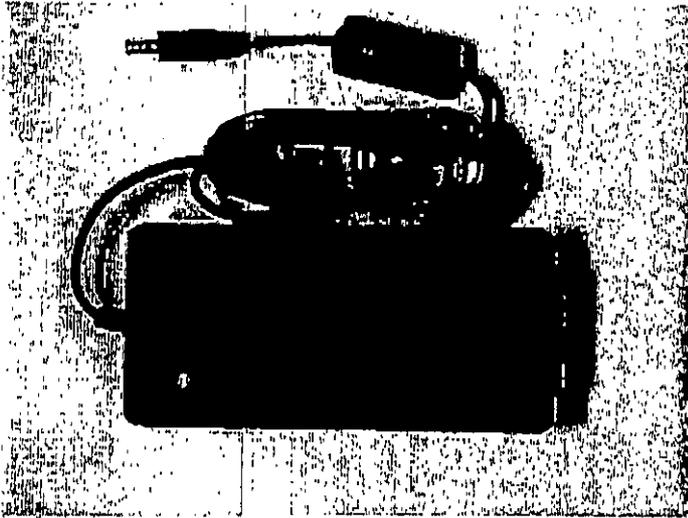
- 46. Diode Bridge (D12, D15) - Rated 10 A, 60 V ac.
- 47. Thermistor (TH2) - TTC, Type TTC-502.
- 48. Operation amplifier (IC3) - SMD. Type LM358.
- 49. Resistor (R46) - SMD. Rated 100 k Ω , 1/8 W.
- 50. Resistor (R29) - SMD. Rated 4.7 k Ω , 1/8 W.
- 51. Resistor (R27) - SMD. Rated 220 k Ω , 1/8 W.

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Sec. 3

Fig-1



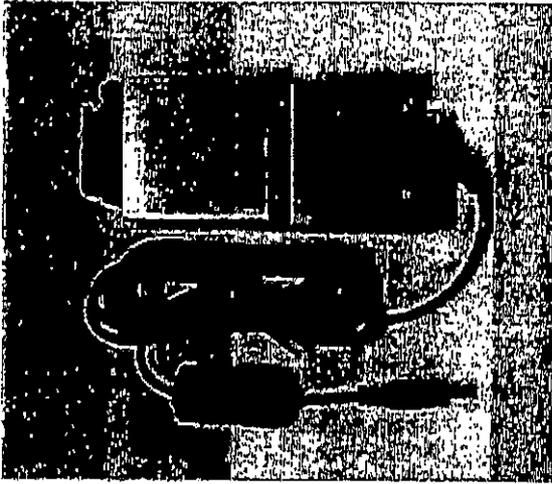
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Flg-2



D0000492.P00

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MODEL HES49-15033, INTERNAL VIEW

FIG. 3 (D00-00493)

General - See Ill. 4. Same as Model HES49-15033, Fig. 2, except for following items.

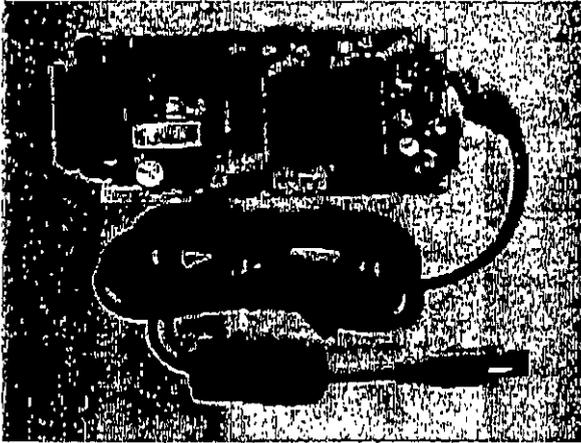
1. Transformer (T1) - HITRON ELECTRONICS CORP., P/N E9S49002-6. Overall dimensions 33.5 by 26 by 16 mm. Provided with Insulation System R/C (OBJY2), HITRON ELECTRONICS CORP., Type R120E, rated Class B, 600 V. See Ill. 3 for further Construction Details.
2. Resistors (R4, R5, R6) - SMD, Rated 390 k Ω , 1/4 W.
3. Resistor (R12) - SMD. Rated 3.3 Ω , 1/4 W. Resistor (R13, R14) - SMD. rated 1 Ω , 1/4 W.
4. Resistor (R18) - SMD. Rated 19.6 k Ω , 1/8 W.
5. Electrolytic Capacitor (C23, C24, C25, C29) - Rated 25 V ac, 330 μ F, 105°C.
6. Electrolytic Capacitor (C27) - Rated 25 V ac, 220 μ F, 105°C.
7. Diode Bridge (D12, D15) - Rated 10 A, 90 V ac.
8. Resistor (R29) - SMD. Rated 3.6 k Ω , 1/8 W.
9. Resistor (R27) - SMD. Rated 30 k Ω , 1/8 W.

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Sec. 3

Fig-3



D0000493.P00

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MODEL HES49-24021, INTERNAL VIEW

FIG. 4 (D00-00494)

General - See Ill. 5. Same as Model HES49-15033, Fig. 2, except for following items.

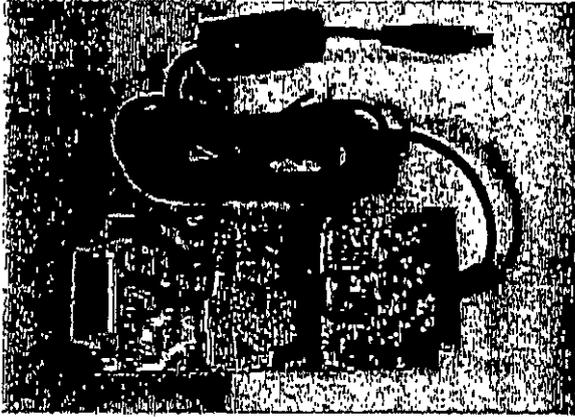
1. Transformer (T1) - Hitron Electronics Corp., P/N E9S49003-6. Overall dimensions 33.5 by 26 by 16 mm. Provided with Insulation System R/C (OBJY2), Hitron Electronics Corp., type R120E, rated Class B, 600 V. See Ill. 3 for further Construction Details.
2. Resistors (R4, R5, R6) - SMD, Rated 330 k Ω , 1/4 W.
3. Resistor (R57, R58, R59) - SMD. Rated 47 Ω , 1/4 W.
4. Resistor (R18) - SMD. Rated 15 k Ω , 1/8 W.
5. Resistor (R64, R65) - SMD. Rated 22 Ω , 1/4 W.
6. Electrolytic Capacitor (C23, C25, C29) - Rated 35 V ac, 220 μ F, 105°C. Electrolytic Capacitor (C23) not used.
7. Electrolytic Capacitor (C27) - Rated 35 V ac, 220 μ F, 105°C.
8. Diode Bridge (D12, D15) - Rated 10 A, 200 V ac.
9. Resistor (R29) - SMD. Rated 2.55 k Ω , 1/8 W.
10. Resistor (R27) - SMD. Rated 23.2 k Ω , 1/8 W.

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Sec. 3

Fig-4



D0000494.P00

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ILL-1

INSULATION DIAGRAM					
Protection against electric shock - Block diagram of system		Refer to table below.			
Drawing					
TABLE TO INSULATION DIAGRAM ABOVE					
Distance (Foot Refer to 20.1 + 20.2)	Insulation type Basic/Supplement./ Double/Reinforced Insulation	Maximum allowable voltage	Required distances (mm)		Dielectric strength test voltage Refer to 20.3
			Clearence	Coverage	
A-a ₁	Basic	203 VAC	2.5 mm	4.0 mm	1500 VAC
A-a ₂	Double/Reinforc.	203 VAC	5.0 mm	6.0 mm	4000 VAC
A-a ₃	Double/Reinforc.	203 VAC	3.0 mm	3.0 mm	4000 VAC
A-1	Basic	<250 VAC	1.0 mm	3.0 mm	1500 VAC
Comments	Note to Table V in A2 used for the calculation of working voltage.				

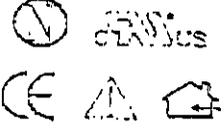
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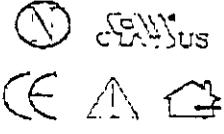
File E164433

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Sec. 3

ILL-2

 HITRON electronics corporation		
Power Supply for Medical use MODEL: HES49-12040		
AC INPUT 100-240V~ 1.0A 60/50Hz	DC OUTPUT 12V === 4.0A	SN WK
MADE IN TAIWAN SK		

 HiTRON electronics corporation		
Power Supply for Medical use MODEL: HES49-15033		
AC INPUT 100-240V~ 1.0A 60/60Hz	DC OUTPUT 15V === 3.3A	SN WK
MADE IN TAIWAN SK		

 HITRON electronics corporation		
Power Supply for Medical use MODEL: HES49-24021		
AC INPUT 100-240V~ 1.0A 60/50Hz	DC OUTPUT 24V === 2.1A	SN WK
MADE IN TAIWAN SK		

D0040388.100

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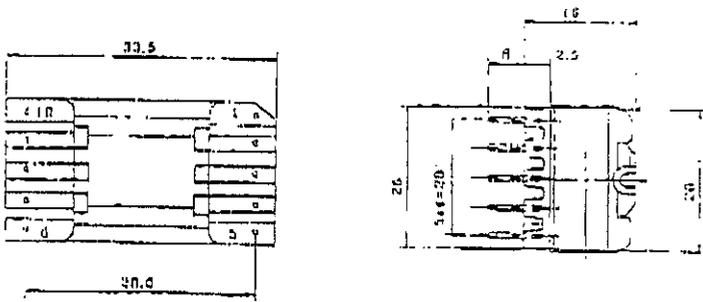
ILL-3 (Page 1)

鴻昌電子股份有限公司
HITRON electronics corporation

FM-3000-12, REV.0-052009

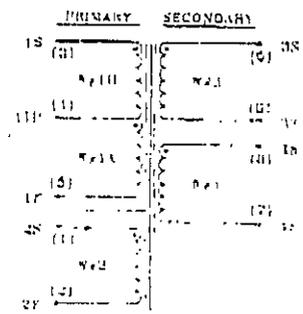
文件/規格名稱	POWER TRANSFORMER T1 FOR HES43-1000YY Series	文件/規格號碼	版本 01 04, 2000
TITLE	FOR HES43-1000YY Series	DOC./SPEC.NO.	ISSUE NO. 'a'

1. PHYSICAL DIMENSIONS (IN MILLI-METERS)



2. ELECTRICAL CHARACTERISTICS.

- 2.1 INDUCTANCE OF WINDING (j) SHOULD BE 0.100mH TO 0.445mH AT 1KHz
- 2.2 TURNS RATIO AND RELATIVE POLARITY OF WINDINGS SHOULD BE MAINTAINED.
- 2.3 LEAKAGE INDUCTANCE SHOULD BE LESS THAN 0.01 AT 1KHz
- 2.4 DIELECTRIC WITHSTAND STRENGTH
PRIMARY - SECONDARY: 3000V FOR 1 MINUTE.



2.5 ELECTRICAL VALUES

UNIT	PRIMARY	SECONDARY
VOLTAGE/VA	100-240VAC	500
CURRENT A	0.33-3.22A	
OUTPUT VA	33-800VA	

TRANSIT

D0040389.I00

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Sec. 3

ILL-3 (Page 2)

HITRON electronics corporation

FW-1000-12/REV.0-042000

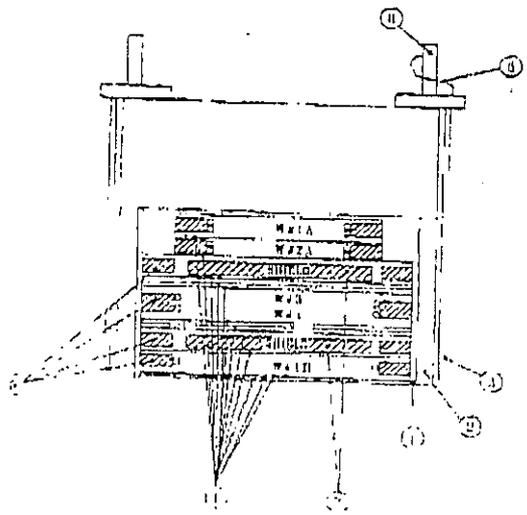
3 页之 3

文件 规格名称 POWER TRANSFORMER T1
 TITLE FOR RES49-1000Y Series
 文件 规格代码
 DOC./SPEC NO.
 版本 01. 04. 2000
 ISSUE NO. "5"

3) NUMBER OF TURNS, WIRES AND WINDING RESISTANCE: (SHOWN RESISTANCE VALUES $\pm 10\%$)

MODEL NO.	WINDING NO.	WIRES	NUMBER OF TURNS & RESISTANCE
RES49-12040 (P/N E0510001-6)	W#1A	2 STRANDS OF $\phi 0.25mm$	21T (0.110 ohm)
	W#1B	2 STRANDS OF $\phi 0.25mm$	21T (0.151 ohm)
	W#2	1 STRAND OF $\phi 0.15mm$	4T (0.232 ohm)
	W#3	2 STRANDS OF $\phi 0.55mm$	4T (0.000 ohm)
RES49-13013 (P/N E0510002-0)	W#1A	2 STRANDS OF $\phi 0.25mm$	20T (0.106 ohm)
	W#1B	4 STRANDS OF $\phi 0.25mm$	20T (0.153 ohm)
	W#2	1 STRAND OF $\phi 0.15mm$	4T (0.232 ohm)
	W#3	2 STRANDS OF $\phi 0.55mm$	4T (0.010 ohm)
49-24021 (P/N E0510003-6)	W#1A	2 STRANDS OF $\phi 0.25mm$	21T (0.110 ohm)
	W#1B	2 STRANDS OF $\phi 0.25mm$	21T (0.150 ohm)
	W#2	1 STRAND OF $\phi 0.15mm$	4T (0.232 ohm)
	W#3	1 STRAND OF $\phi 0.55mm$	4T (0.000 ohm)

4) CONSTRUCTION:
 4.1 INSULATION THICKNESS BETWEEN PRIMARY & SECONDARY:
 3 LAYERS $\times 0.025 mm/m$ TAPE = $0.075 mm/m$ (MINIMUM)



- (1) ROBIN
- (2) CORE
- (3) TAPE FOR OUTER WIND
- (4) INSULATION TAPE
- (5) CORE TAPE TAPE
- (6) PRIMARY (1A) QWT
- (7) OUTER SHEET
- (8) TERMINAL

D0040389.I00

HITRON electronics corporation

PM-0000-12, REV.B-062001

文件 规格名称 POWER TRANSFORMER T1 文件 规格代码
TITLE FOR HES49-XXXX Series DOC./SPEC.NO.
版本 01.04.2000
ISSUE NO. "a"

ITEM	COMPONENT	DESCRIPTION	MANUFACTURER
1	HOHRIN	LP-3213 (3W-3213H) CHANG CHUN PLASTICS CO., LTD. PHENOLIC, PM 13754, FLAMMABILITY CLASSIFICATION: 04V-0, GUIDE BANZU, LL FILE NO. E22491(S)	SMAREN
2	CORE	LP-3213, MATERIAL HC40 FQK2002-T-11 MATERIAL 2400HJ	TOR TORIN
3/1	TAPE FOR OL/ER WRAP INSULATION TAPE	FLAME RETARDANT POLYESTER FILM INSULATING TAPE, SCOTCH BRAND NO.1320, THICKNESS 0.080mm, TEMPERATURE CLASS 130°C, GUIDE BANZU, LL FILE NO. E17305(S)	MINNESOTA MINING & MFG CO. ELECTRICAL SPECIALTIES DIV
		POLYESTER FILM (PETP) TAPE, CAT. 30.033H-C1, THICKNESS 0.025mm, DIELECTRIC STRENGTH 2KV/mm / 1 LAYER, TEMPERATURE CLASS 130°C, GUIDE BANZU, LL FILE NO. K50030(S)	NICHIBAN CO., LTD.
		POLYESTER FILM, FLAME RETARDANT, INSULATING TAPE, SCOTCH BRAND NO.91, THICKNESS 0.084mm, TEMPERATURE CLASS 130°C, GUIDE BANZU, LL FILE NO. H17805(S)	MINNESOTA MINING & MFG CO. ELECTRICAL SPECIALTIES DIV
		POLYESTER WSH INSULATING TAPE, SCOTCH BRAND NO.10, THICKNESS 0.14mm, TEMPERATURE CLASS 130°C, GUIDE BANZU, LL FILE NO. E17305(N)	MINNESOTA MINING & MFG CO. ELECTRICAL SPECIALTIES DIV
5	CREPAGE TAPE	POLYESTER FILM INSULATING TAPE WITH ACRYLIC ADHESIVE, CAT. NO.33661 (P/S MY1), MY20, WIDTH 20mm, THICKNESS 0.15mm(MIN.), TEMPERATURE CLASS 130°C, GUIDE BANZU, LL FILE NO. E50202(S)	FOUR PILLARS ENTERPRISE CO., LTD
		POLYESTER FILM INSULATING TAPE WITH ACRYLIC ADHESIVE, CAT. NO.33661 (P/S MY1), MY20, WIDTH 10mm, THICKNESS 0.15mm(MIN.), TEMPERATURE CLASS 130°C, GUIDE BANZU, LL FILE NO. E50202(S)	FOUR PILLARS ENTERPRISE CO. LTD
6	PRIMARY & SECONDARY LEAD OR TERMINAL WIRE	TENNALE POLYESTER ENAMELED WIRE SS TE, TEMPERATURE CLASS 155°C	PAULI ELECTRIC WIRE & CABLE CO., LTD
		POLYESTER BARE ENAMELED COPPER WIRE 25W SW, TEMPERATURE CLASS 155°C-180°C	J. S. SHING WIRE CO. LTD
7	COPPER SHEET	PAPER SHEET THICKNESS 0.05mm, 0.063mm	
8	TERMINA	SEE ABOVE INSULATING TAPE	

THANONG

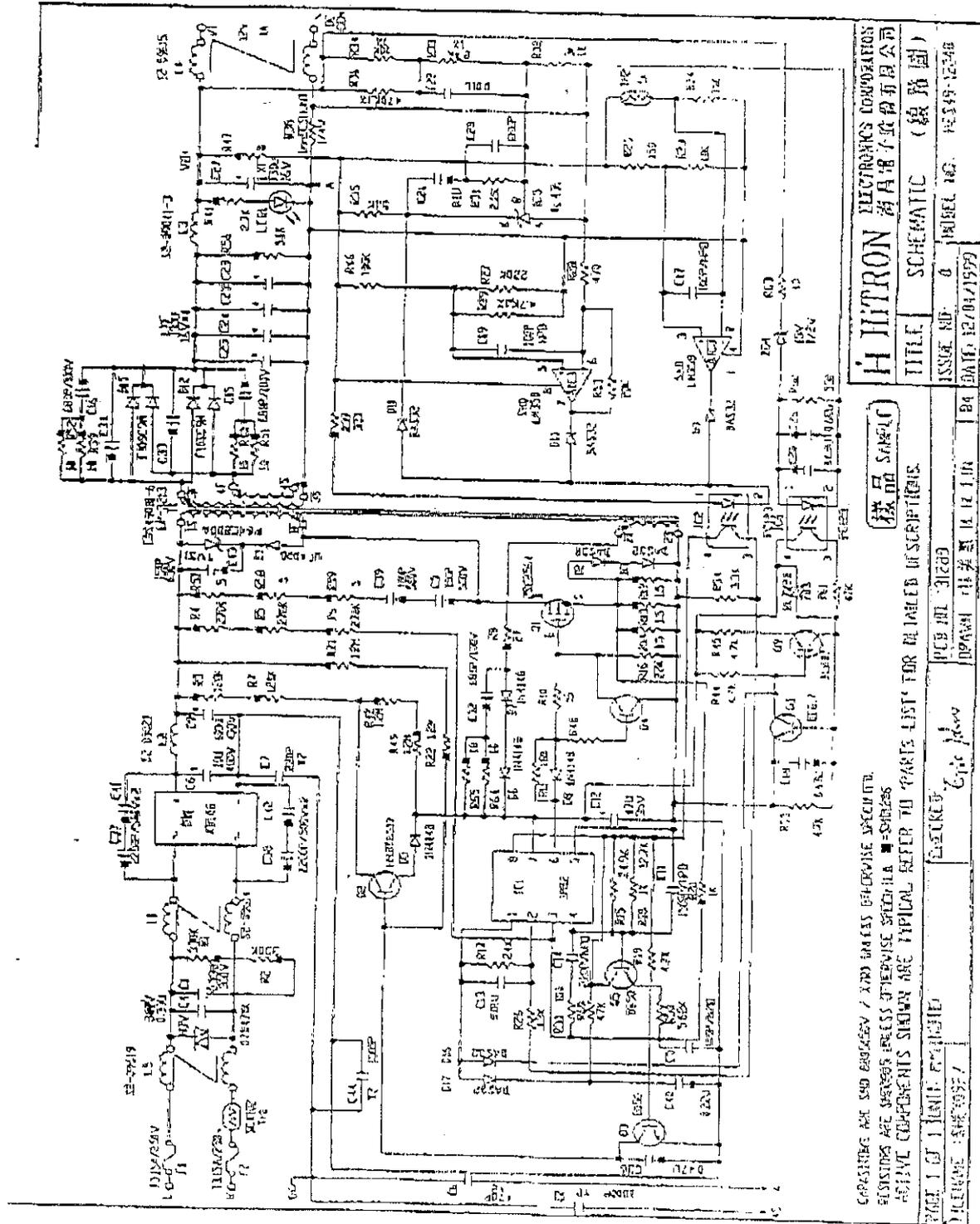
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Vol. 1 and Report

Sec. 3

ILL-4



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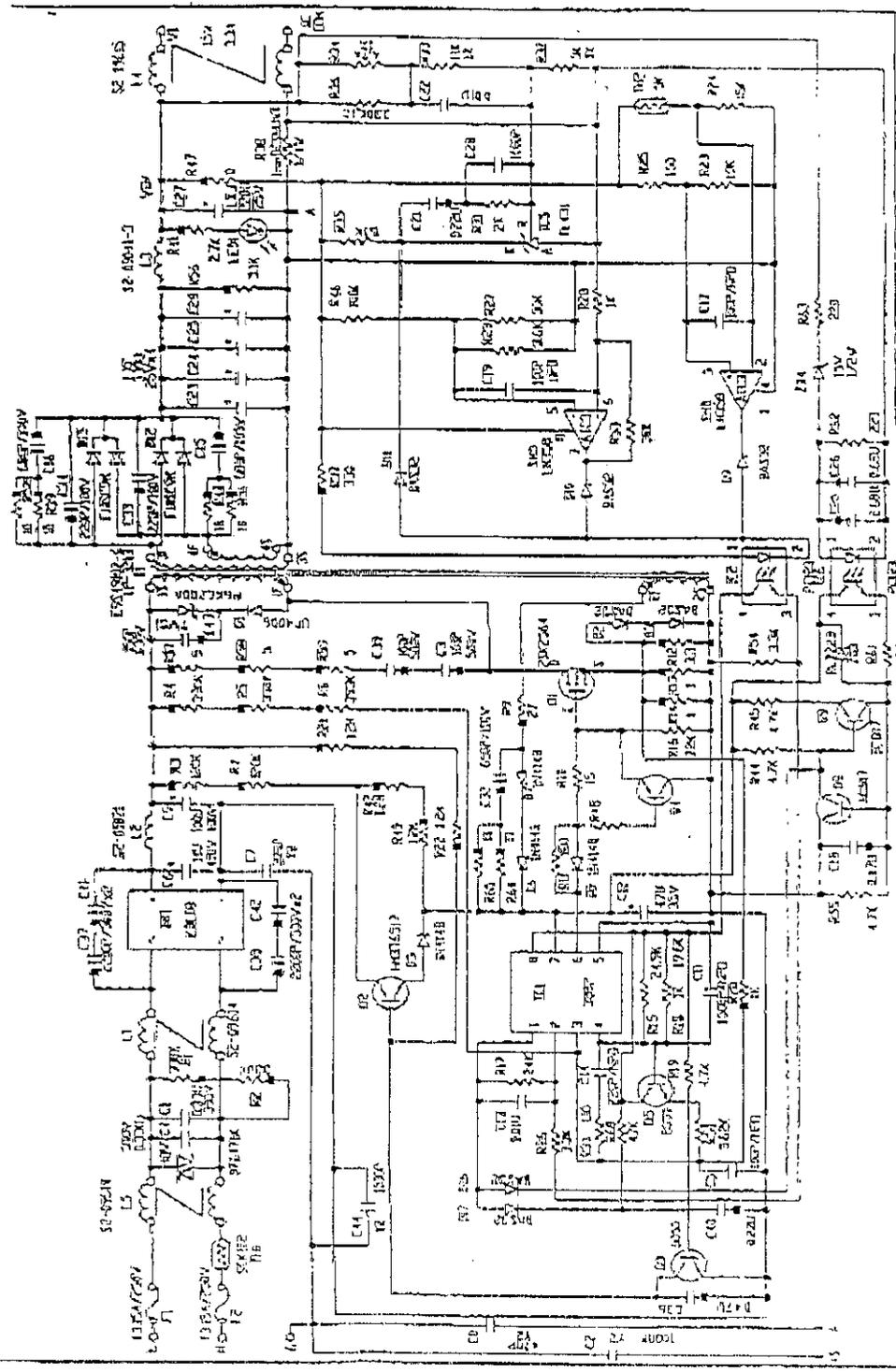
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Vol. 1

Sec. 3

ILL-5

and Report



HITRON ELECTRONICS CORPORATION
 海自電子股份有限公司
 TITLE SCHEMATIC (線路圖)
 ISSUE NO. C
 MOBILE NO. 819-15973
 DATE 11/24/1999

FOR SAMPLE
 (樣品圖)
 FOR PARTS LIST FOR DC UNIT DESCRIPTIONS.

DESIGNED BY: [Name]
 DRAWN BY: [Name]

EXPLANATIONS ARE SHOWN UNLESS OTHERWISE SPECIFIED
 RESISTORS ARE SHOWN UNLESS OTHERWISE SPECIFIED. # = SURFACE
 ACTIVE COMPONENTS SHOWN ARE TYPICAL REFER TO PARTS LIST
 PAGE 1 OF 1
 FILE NO. 164433
 DRAWING NO. 164433

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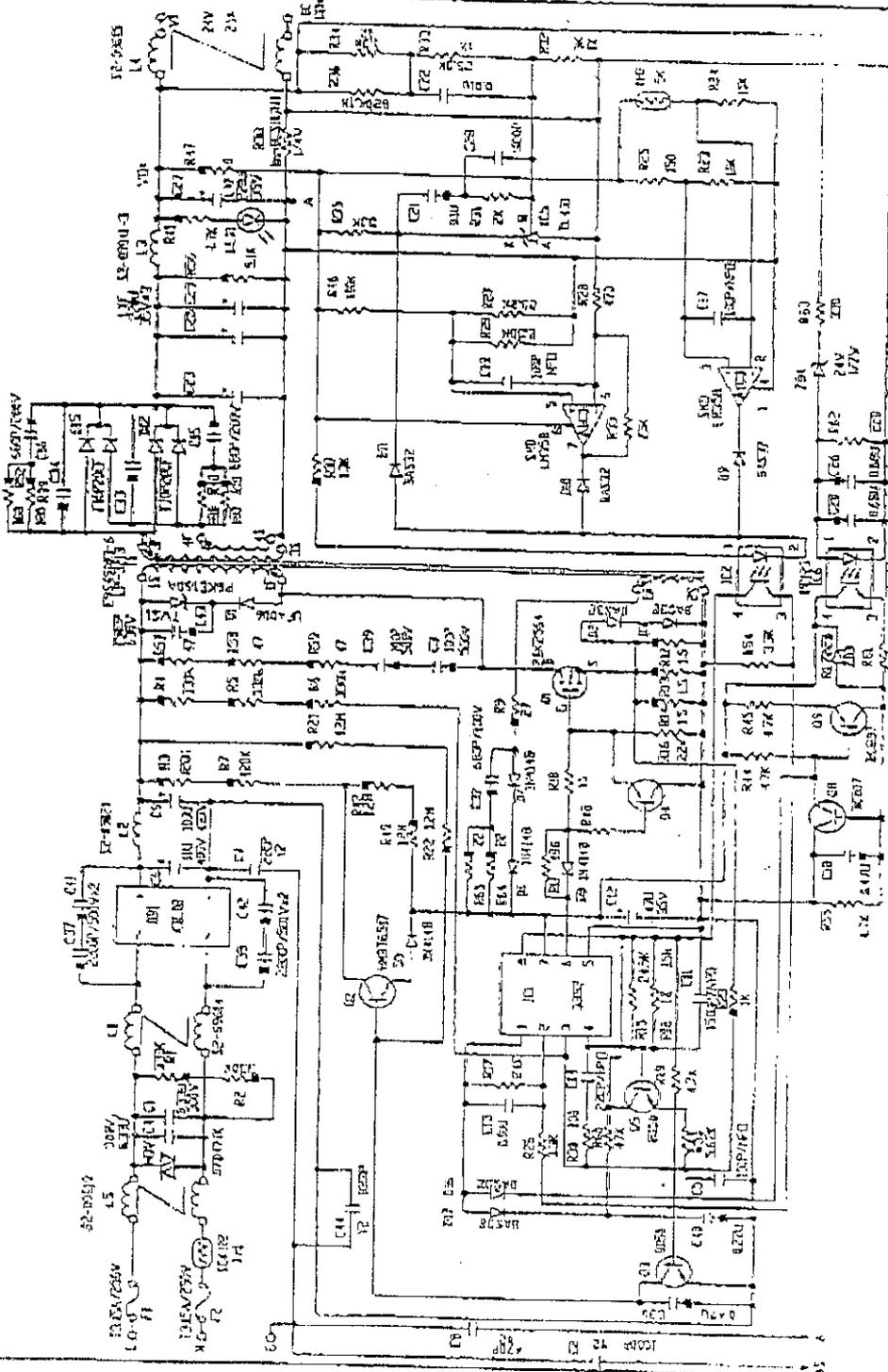
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Vol. 1

Sec. 3

ILL-6

and Report



HITRON ELECTRONICS CORPORATION
 鴻昌電子股份有限公司
TITLE SCHEMATIC (線路圖)
 ISSUE NO. 9 PART NO. HES49-2482
 DATE 12/04/1999
 PCB NO. 131280
 DRAWN 許文進 H. L. H.
 CHECKED 許文進 H. L. H.
 FILED 131280

CAPACITORS ARE 50V UNLESS OTHERWISE SPECIFIED.
 RESISTORS ARE 1/4W UNLESS OTHERWISE SPECIFIED. 1% TOLERANCE.
 ACTIVE COMPONENTS SHOWN ARE TYPICAL. REFER TO PARTS LIST FOR DETAILED DESCRIPTIONS.

USE THE SAME PCB FOR ALL UNITS.

D0040392.I00

File E164433

Page T1-1 of 2

Issued: 9-30-00

TEST RECORD NO. 1

SAMPLES:

A sample of Hitron Power Supply Model HES49-24021 was subjected to the following test.

GENERAL:

Test results relate only to items tested.

Only the following test was conducted on Model HES49-24021 to verify test data generated by NEMKO A/S, Norway, under CB scheme and contained in a CB Report No. 1999 50197, dated 08.02.2000.

Due to its size and bulk the Report is kept on file at the originating office, DEMKO A/S.

SUMMARY:

- 1 Marking Durability (6.1)
- 2. Working Voltage Measurements (20.3)

The test method and results of the tests indicated above have been reviewed and found in accordance with the requirements in UL 2601-1 and CAN/CSA C22.2 No. 601.1-M90.

MARKING DURABILITY TEST (IEC 60601-1, Sub-Clause 6.1)

METHOD

Each specified marking in Table 6.1 was rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked in methylated spirit at ambient temperature, and then for 15 s with a cloth rag soaked with isopropyl alcohol.

File E164433

Page T1-2 of 2

Issued: 8-30-00

RESULTS

TABLE 6.1: Marking Durability

<u>Marking Tested</u>	<u>Remarks</u>
Marking plate	+, ++

+ The markings did not work loose and did not curl at the edges.

++ The markings were clearly readable.

ADDITIONAL TEST:

METHOD

Test indicated in the table below was conducted in accordance with the provided instructions.

Working Voltage Measurement (20.3) - The reference voltage to which the relevant insulation is subject in normal use and at rated supply voltage was measured. The voltage and measurement points were recorded.

RESULTS

TABLE: Additional Tests

<u>Clause</u>	<u>Test Type and Condition</u>	<u>Remarks and Observed Results</u>	<u>Verdict</u>
20.3	Working Voltage Measurement on primary transformer(T1) under worse-case conditions. Full load was 4.0 A.	The highest stressing Voltage was measured as primary winding W1 + secondary winding W3: Vref(rms) = 181 + 22 = 203 V	P

The results complied with the requirements of the Standard.

File E164433

Page C1

Issued: 8-30-00

CONCLUSION

Samples of the products covered by this Report have been found to comply with the requirements covering the class and the products are judged to be eligible for Component Recognition and Follow-Up Service. Under the Service the manufacturer is authorized to use the Recognized Marking described in the Follow-Up Service Procedure on such products which comply with said Procedure and any other applicable requirements of Underwriters Laboratories Inc. Only those products which properly bear the Recognized Marking are considered as Recognized Components by Underwriters Laboratories Inc.

Report by:

Reviewed by:

Michael J. Jepsen
MICHAEL JESPERSEN
Project Engineer

Mona Helbo Nielsen
MONA HELBO NIELSEN
Project Engineer

Pursuant to the Certification and Registration Agreement, between DEMKO A/S and Underwriters Laboratories Inc. ("UL"), UL hereby accepts and issues this report.



CERTIFICATE

App.6

No. P00100680

Order No. 199950197

Applicant Hitron Electronics Corp.
 B4-11, Kaoshiung Export Pros.
 Zone, P.O.Box 26-110
 Kaoshiung 806
 TAIWAN R.O.C.

Manufacturer Hitron Electronics Corp.
 B4-11 Kaoshiung Export
 Processing Zone, P.O.Box 26-110
 TAIWAN R.O.C.

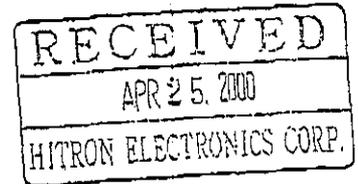
Factory Hitron Electronics Corp.
 B4-11 Kaoshiung Export
 Processing Zone, P.O.Box 26-110
 TAIWAN R.O.C.

Group 63 92000 Build-In power supplies

Model/type Hitron Hes 49-15033

Data 100-240V AC 50-60Hz 1.0A ma

Other specification Output: 15V DC 3.3A max



The above product is certified according to the following standard(s)

Safety std.: EN 60601-1 (1990) + A1 (1993) + A2 (1995) + A12 (1993) + A13 (1996)+ Corrigenda (July 1994)

EMC std.: EN 60601-1-2 (1993)

Validity The certificate is valid until 1. May 2010, provided that all signed certification conditions are complied with, and that possible changes to the product are notified to Nemko for acceptance prior to implementation. The validity time may be reduced in case new standards are made applicable. The certificate also applies as licence for use of Nemko's name and certification mark.

Additional information Additional information on page 2

Variants This Certificate also covers variants with Position No. from 001 to 002
 See next page(s)

Date of issue 14 April 2000

Jon Arild Hansgård
 signature

Arild Hansgård
 Head of section

Vegard Andersen
 signature
 Vegard Andersen

Nemko AS P.O. Box 73, Blindern N-0314 Oslo, Norway	Office address Gaustadalléen 30 Oslo	Telephone +47 22 96 03 30 Enterprise number:	Fax +47 22 96 05 50 NO 974404532
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CERTIFICATE

No. P00100680

Order No. 199950197

Group 63 92000	Build-in power supplies
Position No	001
Model/type	Hitron Hes 49-12040
Data	100-240V AC 50-60Hz 1.0A max
Other specification	Output: 12V DC 4A max

Group 63 92000	Build-In power supplies
Position No	002
Model/type	Hitron Hes 49-24021
Data	100-240V AC 50-60Hz 1.0A max
Other specification	Output: 24V DC 2.1A max

Date of issue 14 April 2000

Jørn Arild Gundersen

signature

Arild Hansgård
Head of section

Vegard Andersen

signature

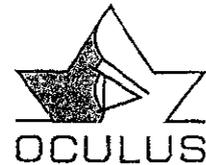
Vegard Andersen

Nemko AS
P.O. Box 73, Blindern
N-0314 Oslo, Norway

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Gaustadalléen 30
Oslo

Telephone
+47 22 96 03 30
Enterprise number:

Fax
+47 22 96 05 50
NO 974404532



App. 8

KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY

Gemäß Richtlinie 93/42/EWG vom 14. Juni 1993 über Medizinprodukte
According to Medical Device Directive 93/42/EEC dated 14. June 1993

Hersteller-Adresse: **OCULUS Optikgeräte GmbH**
Manufacturer Address: **Münchholzhäuser Str. 29, 35582 Wetzlar**

Produkt: **Pentacam, Typ 70700**
Product: **Pentacam, type 70700**

Einstufung: **I (Richtlinie 93/42/EWG, Anhang IX, Regel 1 und 12)**
Classification: **I (MDD 93/42/EEC, annex IX, rule 1 and 12)**

Konformitätsbewertung nach: **Richtlinie 93/42/EWG, Anhang VII**
Conformity according: **MDD 93/42/EEC, annex VII**

OCULUS Optikgeräte GmbH erklärt hiermit unter eigener Verantwortung, daß die obengenannten Produkte die Grundlegenden Anforderungen des Anhangs 1 der Richtlinie 93/42/EWG erfüllen.

OCULUS Optikgeräte GmbH herewith declares under its own responsibility, that the above mentioned products comply with the provisions of the fundamental requirements of MDD 93/42/EEC.

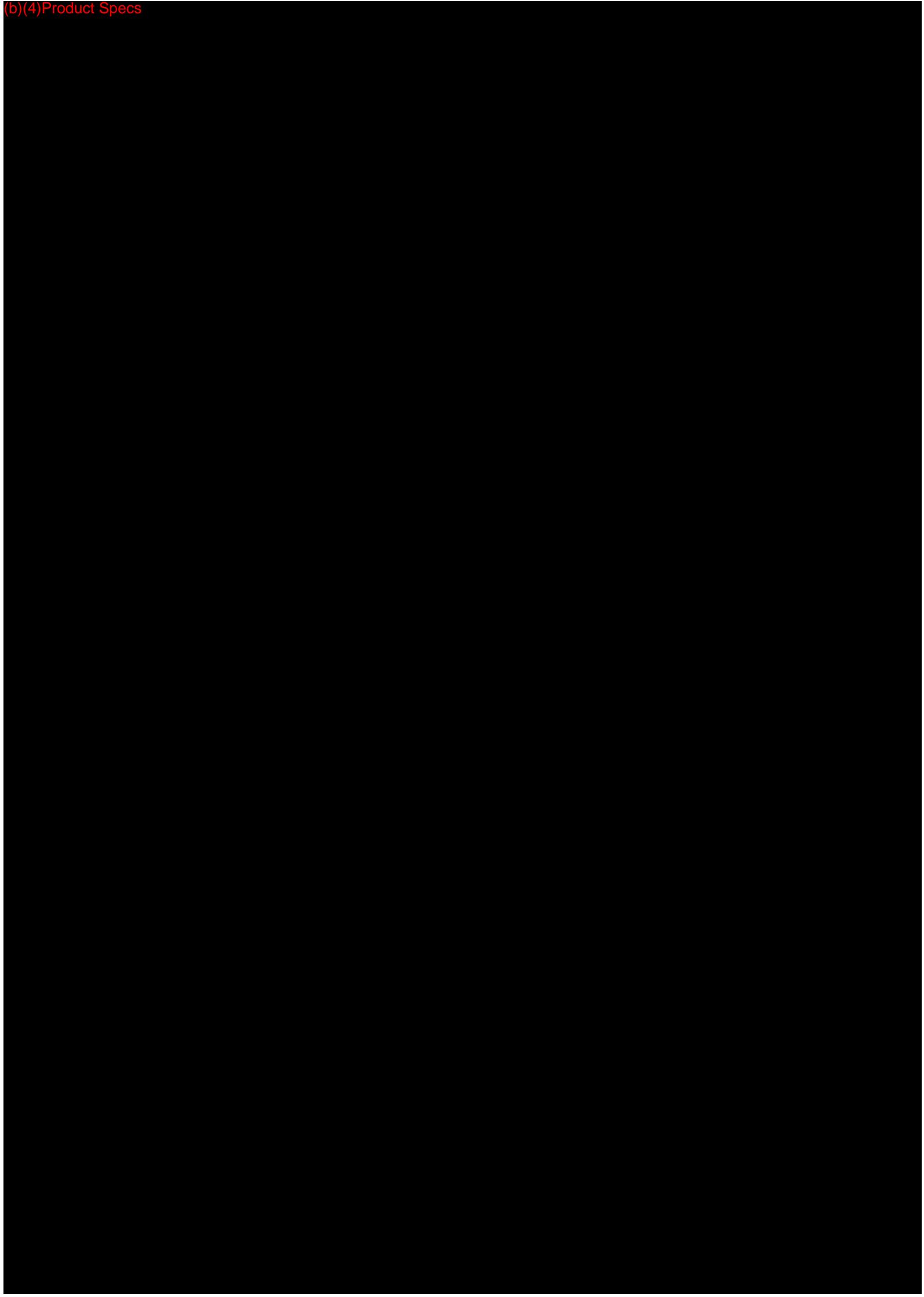
Zur Verifizierung der oben angegebenen Anforderungen wurden folgende harmonisierte Normen herangezogen:
Following harmonized standards were employed to verify the above mentioned requirements:

DIN EN 60601-1 DIN EN 980
DIN EN 60601-1-2 DIN EN 1441
DIN EN ISO 15004

Wetzlar, 13.03.2003

OCULUS Optikgeräte GmbH
Geschäftsführer / Managing Director

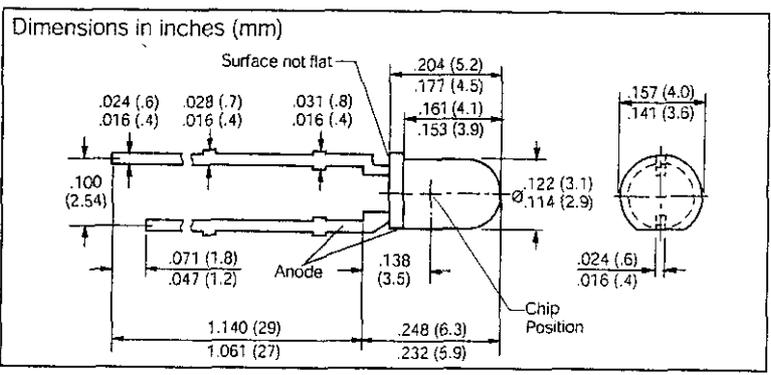
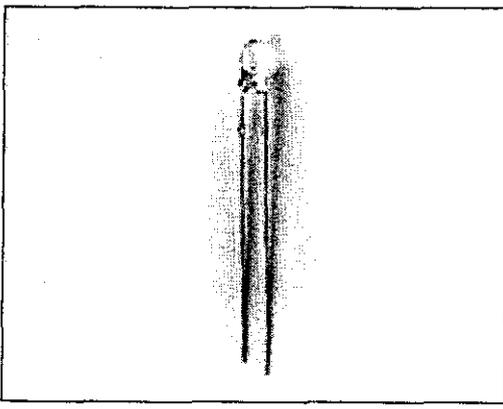
Dipl.-Ing. Rainer Kirchhübel



App 12

SIEMENS

SFH 487
GaAlAs INFRARED EMITTER



FEATURES

- Radiant Intensity Selections
SFH 487-1, 12.5–25 mW/sr
SFH 487-2, ≥20 mW/sr
- T1 (3mm) Package
- Clear Blue Tinted Plastic Lens
- Long Term Stability
- Good Spectral Match with Silicon Photo Detector
- Gallium Aluminum Arsenide Material
- Medium Beam, 40°

DESCRIPTION

SFH 487, an infrared emitting diode, emits radiation in the near infrared range (880 nm peak). The emitted radiation, which can be modulated, is generated by forward flowing current. The device is enclosed in a T1 (3 mm) plastic package. Uses for SFH 487 include: IR remote control for color TVs, smoke detectors, and other applications requiring very high power, such as IR touch screens.

Maximum Ratings

Operating and Storage Temperature Range (T_{OP} , T_{STG}) -55° to +100°C
 Junction Temperature (T_J) 100°C
 Reverse Voltage (V_R) 5 V
 Forward Current (I_F) 100 mA
 Surge Current (I_{FSM}) $t=10 \mu s$ 2.5 A
 Power Dissipation (P_{TOT}) 200 mW
 Thermal Resistance (R_{thJA}) 375 K/W

Characteristics ($T_A=25^\circ C$)

Parameter	Symbol	Value	Unit	Condition	
Peak Wavelength	λ_{PEAK}	880±20	nm	$I_F=100 \text{ mA}$	
Spectral Bandwidth	$\Delta\lambda$	80	nm	$I_F=100 \text{ mA}$	
Half Angle	ϕ	±20	Deg.		
Active Chip Area	A	0.16	mm ²		
Active Chip Area Dimensions	L x W	0.4x0.4	mm		
Distance, Chip Surface to Case Surface	D	2.6	mm		
Switching Times, I_E 10% to 90% and 90% to 10%	t_R, t_F	0.6/0.5	μs	$I_F=100 \text{ mA}$	
Capacitance	C_0	25	pF	$V_R=0 \text{ V}$, $f=1 \text{ MHz}$	
Forward Voltage	V_F	1.5 (≤1.8)	V	$I_F=100 \text{ mA}$, $t_p=20 \mu s$	
	V_F	3.0 (≤3.8)	V	$I_F=1 \text{ A}$, $t_p=100 \mu s$	
Reverse Current	I_R	0.01 (≤1)	μA	$V_R=5 \text{ V}$	
Temperature Coefficient, I_E or Φ_E	TC_I	-0.5	%/K		
Temperature Coefficient, V_F	TC_V	-0.2	mV/K		
Temperature Coefficient, λ	TC_λ	0.25	nm/K		
Parameter	Symbol	SFH 487-1	SFH 487-2	Unit	Condition
Radiant Intensity I_E in Axial Direction at a solid angle of $\Omega=0.01 \text{ sr}$					
Radiant Intensity	I_E	12.5–25	≥20	mW/sr	$I_F=100 \text{ mA}$, $t_p=20 \text{ ms}$
		140	270	mW/sr	$I_F=1 \text{ A}$, $t_p=100 \mu s$
Total Radiant Flux	Φ_E	23	25	mW	$I_F=100 \text{ mA}$, $t_p=20 \text{ ms}$

977

Figure 1. Radiation characteristic $I_{REL}=f(\varphi)$

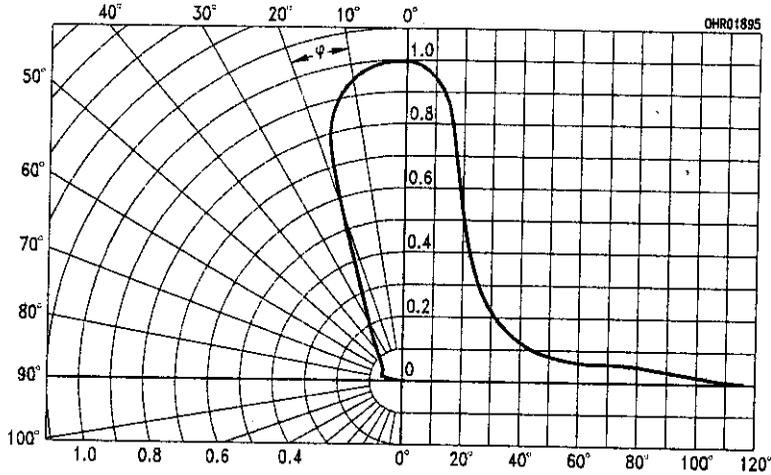


Figure 2. Relative spectral emission $I_{REL}=f(\lambda)$

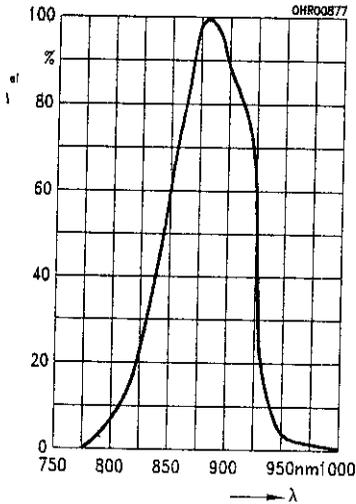


Figure 4. Maximum permissible forward current $I_F=f(T_A)$

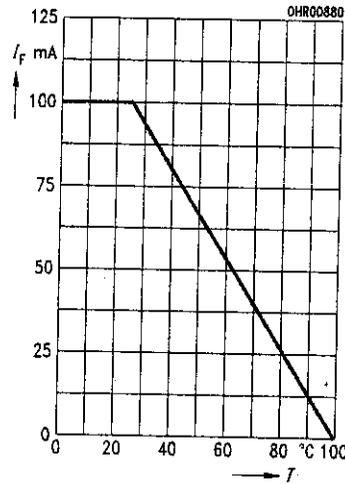


Figure 3. Radiant intensity $I_E/I_E(100mA)=f(I_F)$, Single pulse, $\tau=20 \mu s$

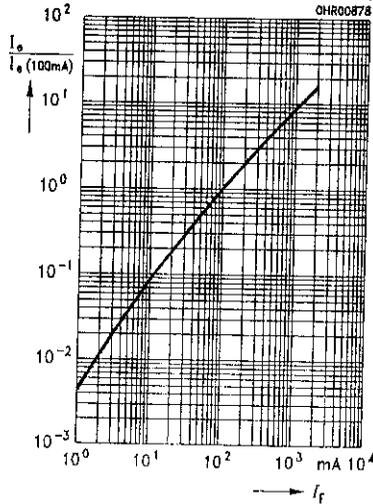


Figure 5. Forward current $I_F=f(V_F)$, Single pulse, $\tau=20 \mu s$

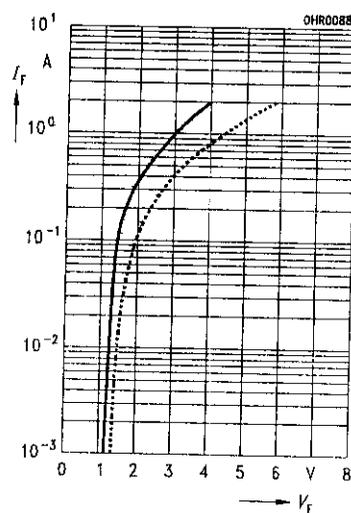


Figure 6. Permissible pulse handling capability $I_F=f(\tau)$, $T_A=25^\circ C$, duty cycle $D=Parameter$

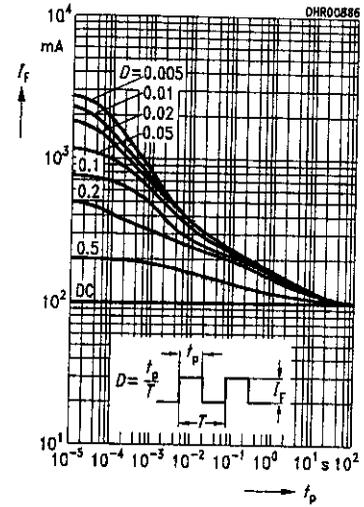
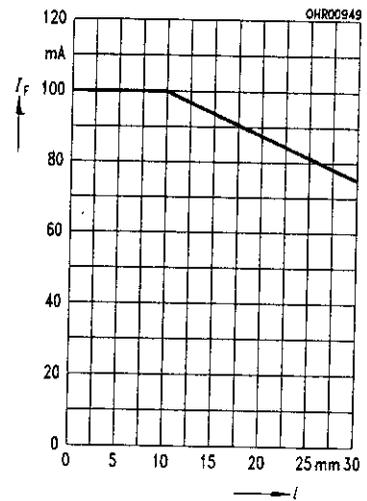
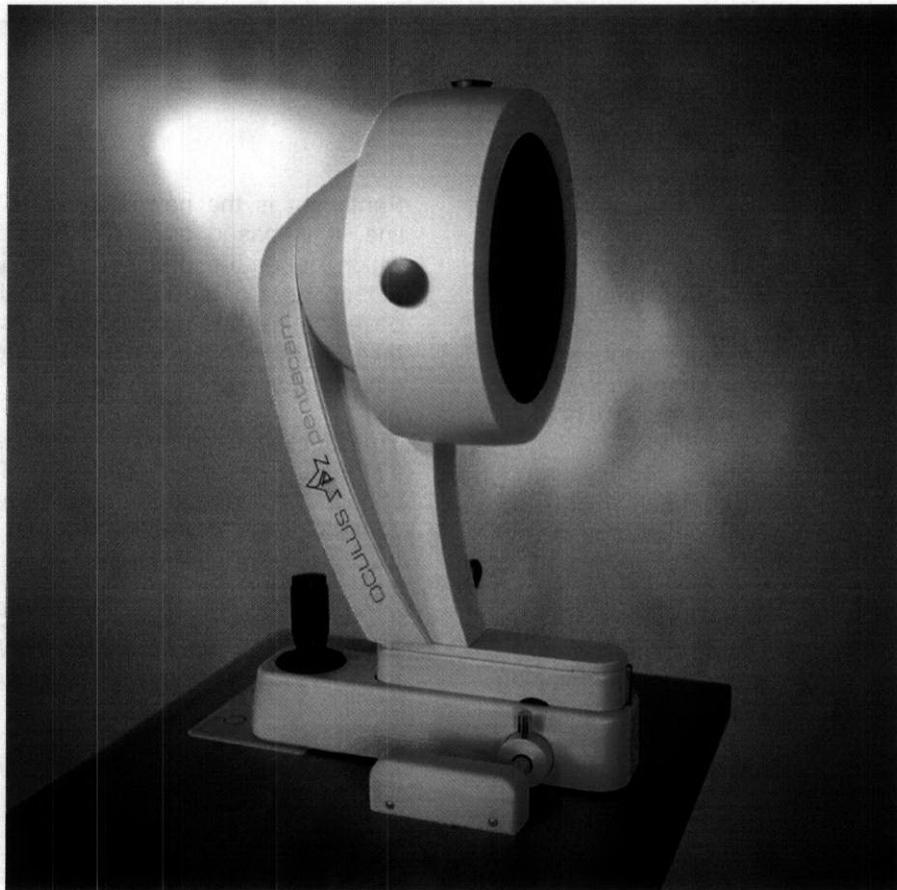


Figure 7. Forward current vs. lead length between package bottom and PC-board $I_F=f(l)$, $T_A=25^\circ C$





Pentacam

Instruction Manual

Measurement and Evaluation System for the Anterior Chamber of the Eye



Copyright by

G/70700/0703/e

0 Foreword

We thank you for the trust you have put in this OCULUS-product. With the purchase of this instrument you have chosen a modern, sophisticated product which was manufactured and tested according to strict quality criteria.

Ongoing research and development are of benefit to you but can result in changes in certain features of the product as well as in extent of supply.

Therefore in individual cases the diagrams shown in this instruction manual might not correspond completely with the features of the product you received.

Our enterprise has been doing business for over 100 years. Today OCULUS is a medium-sized enterprise concentrated completely on helping ophthalmologists and opticians to carry out their responsible work by supplying an optimal range of instruments for examinations and operations on the eye.

Pentacam is the newest product in the Oculus line. It is based on the Scheimpflug principle, which generates precise, sharp images of the anterior eye segment. Our painstaking product development has produced an instrument which takes extremely accurate measurements and is easy to use.

To assure safe operation, it is imperative that the instrument is used properly. Therefore you should become thoroughly familiar with the content of the instruction manual before putting the instrument into operation.

If you have questions or desire further information on this product, call us or send us a fax. Our service team will be glad to help you.

OCULUS Optikgeräte
Managing director and management team

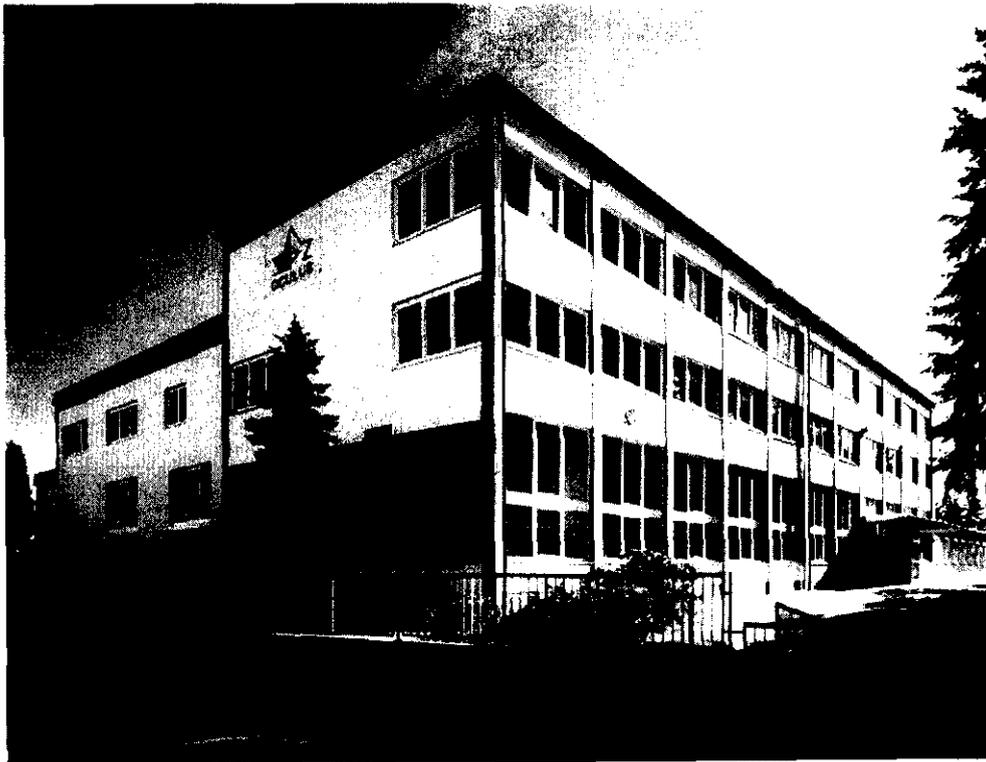


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1. Scope of supplies and optional accessories

Pentacam E:

70700

Including:

- Pentacam mounted on x-y-z moveable base
- Head and chin rest
- Power supply unit input 100-240Volt, output 5V, 1A
- Plate for mounting on refraction unit or table (size 28 x 36cm)
- USB-cable
- Testing protocol for electronic safety
- Instruction Manual
- Dust cover
- Paper for chin rest
- Windows™ Software package and manuals
- Mouse

G / 70700/.../e

60100-5/1

65313

Optional applications:

Software module Pachymetry

70702

Software module Densitometry

70704

Software module 3D chamber analyser

70706

Software module Corneal topography, front and rear surface

70708

Optional:

Color printer

70520

We reserve the right to make changes in extent of supply if called for by technical developments.

2 Safety precautions

The legislator expects the manufacturer to inform the user of safety precaution measures which should be taken when operating this instrument. The following chapter contains a summary of the most important information on technical safety features.

Further safety precautions are incorporated into the text of this instruction manual and are indicated by this symbol:



Please heed these precautions.

Please save this instruction manual and ensure that it is accessible to operating personnel at all times. This instrument must only be used for the "specified use" as laid down in section 4 of this instruction manual and operated by persons who can assure that the instrument is used properly on the basis of their training, expertise or practical experience.

Before using this instrument for the first time, you must be instructed on how to use it by our staff or an authorized dealer.

Only operate the instrument with the original components supplied by us and if the instrument is in technically good condition. Should the instrument be defective, do not operate; contact the supplier.

Please observe the legally binding accident prevention regulations.

The instrument may only be used in medical facilities which comply with VDE regulations 0107.

Before maintaining and cleaning the instrument, always pull out the plug of the Pentacam and all equipment attached to it, for example PC and printer.

Do not connect cables if this proves difficult. If it is impossible to make a connection, check to see whether the plug fits into the socket. In case you ascertain a defect, have it repaired by our service team.

When disconnecting electrical connections, always pull on the plugs, not on the cables.

Supplementary equipment which is connected to the analogue or digital interfaces of the instrument must comply with pertinent EN- / IEC specifications. All configurations must conform consistently to norm IEC 601 -1.

If the Pentacam is coupled with non-medical electrical equipment (for ex. data processing equipment) this must not result in a decrease of patient safety beyond the tolerance levels laid down in IEC 601-1. If the coupling of equipment causes the tolerance levels for leakage current to be exceeded, safety features which include a disconnection device must be provided for.

Do not operate the delivered equipment

- o in areas with risk of explosion,
- o in the presence of flammable anesthetics or volatile solvents such as alcohol, benzine or similar substances.

Do not use or store the instrument in damp rooms. Avoid placing the instrument in the vicinity of dripping, running or spraying water and ensure that no moisture can penetrate the instrument. For this reason, do not place any containers filled with fluids near the instrument. When cleaning the instrument with a damp cloth, be sure that no moisture enters it.

Do not cover up ventilation holes.

Important to note: this instrument is a high-quality technical product. In order to assure faultless and safe operation, we recommend that the instrument be inspected by our service team every two years. If a defect arises which you cannot eliminate yourself, mark the instrument as defective and notify our service department.

3 Description of unit

The OCULUS Pentacam is a rotating Scheimpflug camera. The rotational measuring procedure generates Scheimpflug images in three dimensions, with the dot-matrix fine-meshed in the center due to the rotation. It takes a maximum of 2 seconds to generate a complete image of the anterior eye segment. Any eye movement is detected and corrected for in the process. The Pentacam calculates a 3-dimensional model of the anterior eye segment from as many as 25,000 true elevation points.

The topography and pachymetry of the entire anterior and posterior surface of the cornea from limbus to limbus are calculated and depicted. The analysis of the anterior eye segment includes a calculation of the chamber angle, chamber volume and chamber height. In a moveable 3D model, images of the anterior and posterior surface of the cornea, the iris and the lens are generated. The densitometry of the lens is quantified.

The Scheimpflug images taken during the examination are digitalized in the main unit and all Image data are transferred to the PC.

When the examination is finished the PC calculates the 3D model of the anterior eye segment, from which all additional information is derived.

The measurements are displayed on the monitor in the form of coloured maps, diagrams and 3D images.

While doing the evaluation of the acquired images, please keep in mind the possibility of the arising of artefacts which are described in chapter **6.3.8 Artefacts**.

The company OCULUS Optikgeräte GmbH emphasises, that the user bears the full responsibility for the correctness of data measured, calculated or displayed using the Pentacam. The manufacture will not accept claims based on erroneous data.

4 Use in accordance with regulations

The OCULUS Pentacam is a measuring device used to examine the anterior eye segment and must only be used for the purposes specified in this instruction manual.

Therefore it must only be used by trained personnel capable of using it properly on the basis of their training, expertise and practical experience.

The OCULUS Pentacam is intended for use in clinics and ophthalmologists' practices. It is to be

used in connection with the examination station intended for it.

It must only be operated with the original components supplied by us and if in technically good condition.

The special power supply unit (see instrument specification) must be used. Other forms of power supply must not be used.

Observe the safety precautions stated above!



5 Start-up

5.1 Setting up and installing equipment

Before initial operation, the "OCULUS Pentacam" examination station must be set up and connected by our service department or your authorized dealer.

Please store the CD-ROMs which include the Pentacam Software and the Calibration Data at a safe place.

For the installation to any PC's or Laptop, please contact our service department or your authorized dealer.

The Pentacam must be placed in such a way as to prevent direct light from influencing the measurements. A reflex-free examination must be assured. Therefore the Pentacam should be used in a darkened room.

This is an optical device and should be handled with due care. Do not subject it to vibrations, jolts, contamination or high temperatures.

5.2 Transport and storage

Should you ever transport the instrument to another place, do so with particular care. Avoid placing near heating units or in a damp environment during operation as well as storage.

Check the instrument for defects after any transport. Do not under any circumstances put a defective instrument into operation, but rather contact our service department.

If you store the instrument in a cold room or in a vehicle in cold weather, the optical components of the instrument can become fogged up in the case of an extreme change of temperature from cold to warm.

Give the instrument time to adapt to the new environmental conditions before putting it into operation.

The transport and storage specifications required by IEC 601 - 1 are:

Environmental temperature -40° C to +70° C

Relative humidity including
condensation 10% to 100%

Air pressure 500 hPa to 1060 hPa

These tolerance levels are valid for packaged products for a period of no more than 15 weeks.

6 Operation



First switch on the PC or laptop and then the Pentacam.

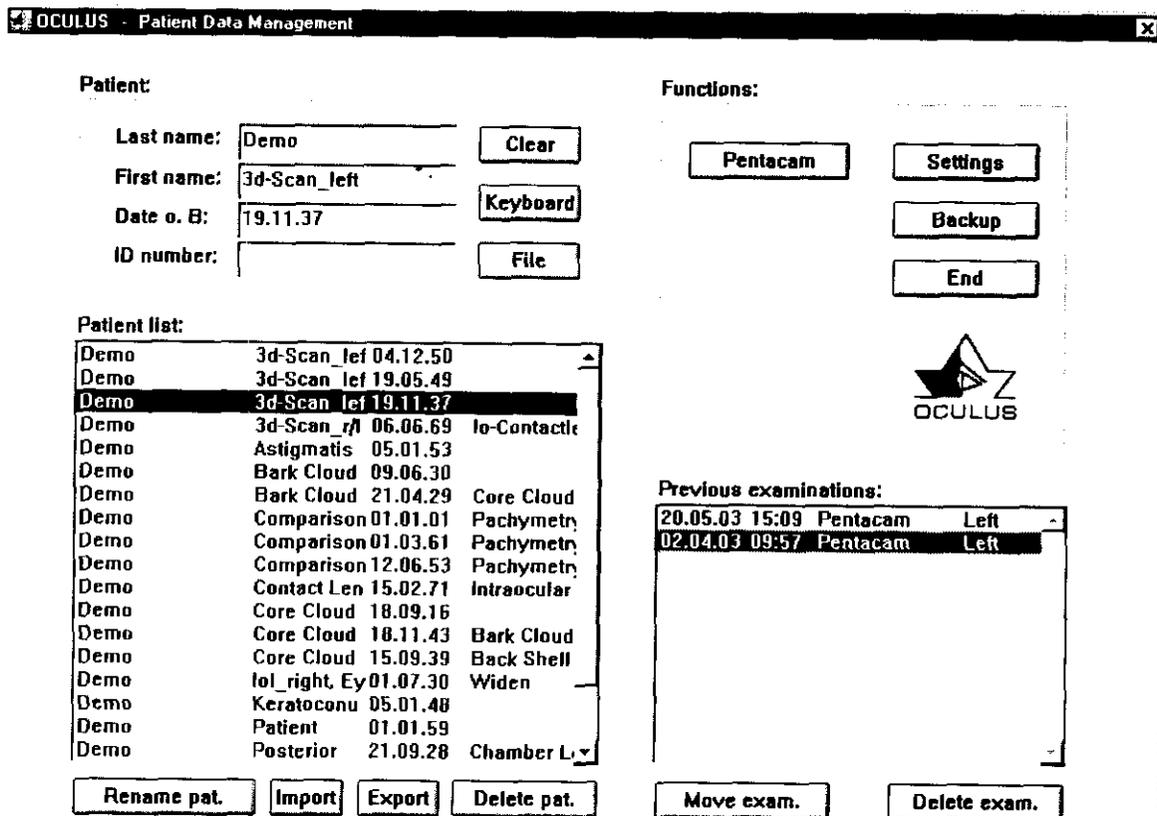
Via mouse click, by pressing down any key or by clicking on the OCULUS icon twice the patient data administration can be started up.

After being switched on, the PC loads the operation system and then displays the OCULUS Logo.

6.1 Patient data administration

In order to access the examination program, either a new patient must be entered in the first

field or a patient must be selected from the directory of already existing patients.



The screenshot shows the 'OCULUS - Patient Data Management' window. It is divided into several sections:

- Patient:** Fields for 'Last name:' (Demo), 'First name:' (3d-Scan_left), 'Date o. B:' (19.11.37), and 'ID number:'. Buttons for 'Clear', 'Keyboard', and 'File' are present.
- Functions:** A vertical stack of buttons: 'Pentacam', 'Settings', 'Backup', and 'End'. The OCULUS logo is displayed below these buttons.
- Patient list:** A list of patients with columns for name, date, and examination type. The entry 'Demo 3d-Scan_left 19.11.37' is highlighted. Below the list are buttons for 'Rename pat.', 'Import', 'Export', and 'Delete pat.'.
- Previous examinations:** A list of past exams with columns for date, time, program, and eye. The entry '02.04.03 09:57 Pentacam Left' is highlighted. Below are buttons for 'Move exam.' and 'Delete exam.'.



6.1.1 Selecting patients

On the left side of the monitor all previously examined patients are listed alphabetically.

If more patients are listed than can be displayed on the monitor, the list can be scrolled up or down with the help of the Windows scroll bar.

In order to find the desired patient in the list quickly it is advisable to enter the name of the patient in the patient field (upper left). After entry

of each new letter the entry in the directory is searched for and displayed.

The patient can also be searched for via his ID number.

If the patient's name has been found in the directory, it is transferred to the patient window by clicking on the entry. At the same time the *already existing* examinations of the patient appear in the examination window (lower right).

6.1.2 Adding new patients

To add a new patient to the patient administration first **[Empty]** should be activated in order to delete the previous patient from the patient window. Then the complete last name, first name and birth date must be entered into the patient window (upper left).

An ID number for the patient can be entered, but this is not obligatory.

When **[Register]** is activated the following message appears:

„No patient data found!“

„Should the patient be registered?“. Via **[Register new patient]** the patient is entered into the list of patients.

6.1.3 Starting examination program

After selecting the patient the examination program (see 6.2, page 17) can be started by activating **[Pentacam]**. If an examination is clicked on in the examination window as well, it is automatically loaded in the examination program.

By double-clicking on the patient's name the examination program is started as well. It is also possible to start the examination program by double-clicking on "previous examination". Then this examination is also automatically loaded in the examination program.

6.1.4 Deleting / reallocating examinations

Underneath the list of examinations you will find two buttons. They can be used to activate functions which always refer to the previously marked examination:

[Delete exam]

This function makes it possible to delete individual examinations from the patient data. After activating the button one will be asked if one really wants to delete the examination.

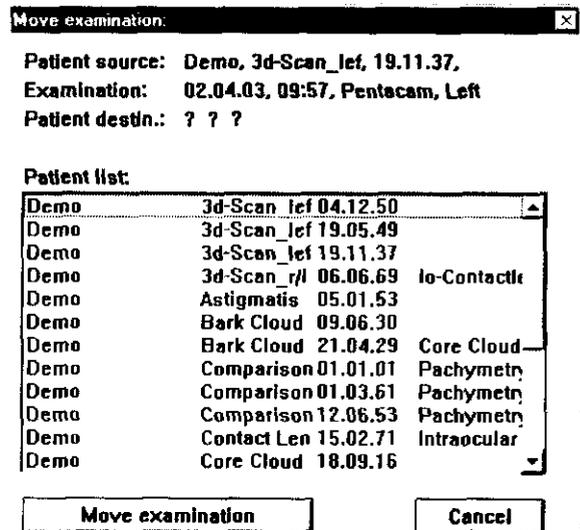
[Move examination]

If the wrong patient's name was inadvertently selected when performing an examination, the results of the examination can be allocated to the proper patient afterwards.

After activating **[Move examination]** in the patient data administration, the patient directory is displayed.

The desired patient can now be selected from this directory (scroll down to correct line and click).

If the correct patient name has been found and selected, the examination data is allocated to the patient by activating **[Move examination]**.





6.1.5 Patient data

6.1.6 Renaming patients

Patient data can be changed later by activating **[Rename patient]** (under the patient directory).

In the window which now appears (on the top right) – **“Change patient data”** – patient data can be corrected.

By activating the **[Update]** the changes are recorded.

6.1.6.1 Deleting patient data

Patient data can be deleted via **[Delete patient]**.

Caution! ⇒ Before data is actually deleted, one must confirm twice that all the examinations performed on the patient as well as all patient data from the patient data administration are to be removed.

6.1.6.2 Exporting patient data

This function makes it possible to transfer patient and examination data from a PC to other types of data carriers (for example floppies).

After activating **[Export]** a window will appear which has two buttons.

The upper field designates the data record which is being exported, and the lower one serves to designate the target data carrier.

In the field “target data carrier” the drive to which the data record is to be transferred (for ex. “A:” in the case of floppies) is entered into the **“Index”** field.

A subdirectory can be created at the same time. (for ex. “D:\Pentacam”).

“Data record”

This field is used to choose whether all examinations of the patient should be exported or only one. Should only one examination be exported, then it is selected from the list of examinations before **[Export]** is activated.

“Only camera images”

It is possible to extract the camera images from a data record, as data without camera images requires less memory space.

“Memory space”

The two memory space specifications show how much memory space is required and how much memory space is available on the target data carrier.

By activating **[Export]** the data record is transferred. **[Cancel]** deactivates the function without transferring data.

6.1.6.3 Importing patient data

(for ex. from a floppy or CD-ROM to the hard disc or to an index on the PC)

[Import] activates this function.

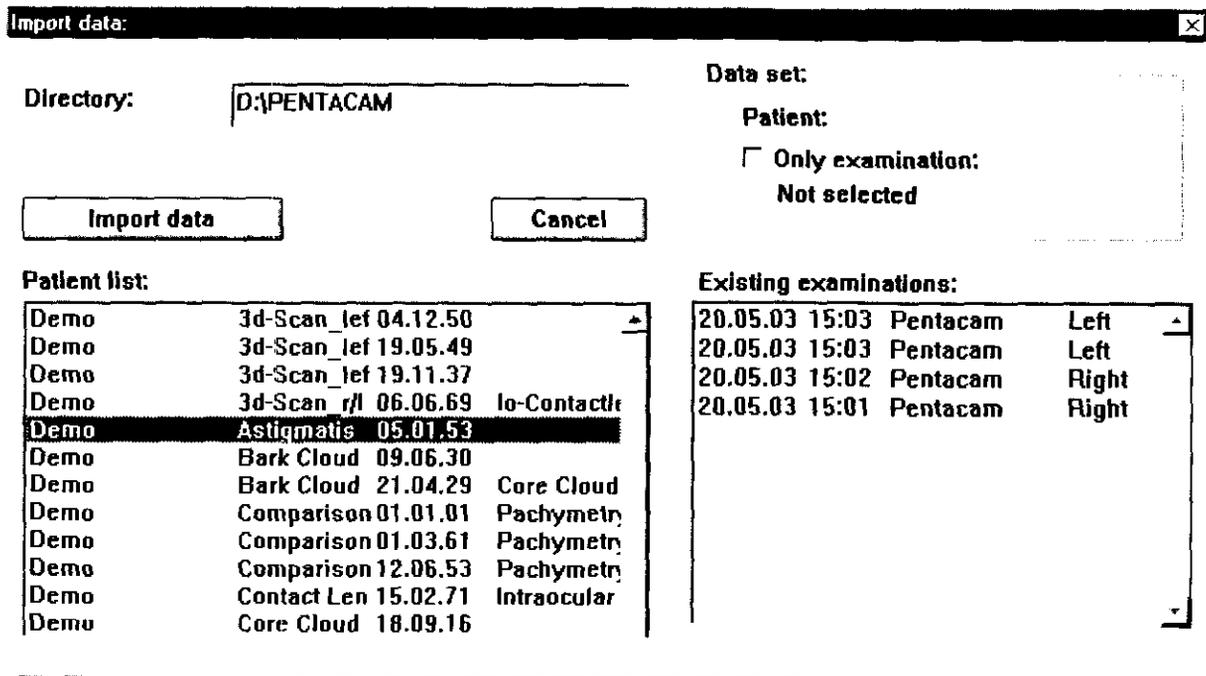
“Directory”

In this field the letter which designates the drive and, if it exists, the subdirectory of the source from which the data is being imported are entered.

A patient directory shows which patients are registered on the data carrier. In the same way the examinations performed on a patient are listed after the patient has been selected.

Should only one examination be imported, click on the appropriate line in the list of examinations.

Importing data is initiated by activating **[Import data]**.



Import data:

Directory:

Data set:

Patient: Only examination: Not selected

Patient list:

Demo	3d-Scan_llef	04.12.50	
Demo	3d-Scan_llef	19.05.49	
Demo	3d-Scan_llef	19.11.37	
Demo	3d-Scan_r/r	06.06.69	Io-Contactl
Demo	Astigmati	05.01.53	
Demo	Bark Cloud	09.06.30	
Demo	Bark Cloud	21.04.29	Core Cloud
Demo	Comparison	01.01.01	Pachymetr
Demo	Comparison	01.03.61	Pachymetr
Demo	Comparison	12.06.53	Pachymetr
Demo	Contact Len	15.02.71	Intraocular
Demo	Core Cloud	18.09.16	

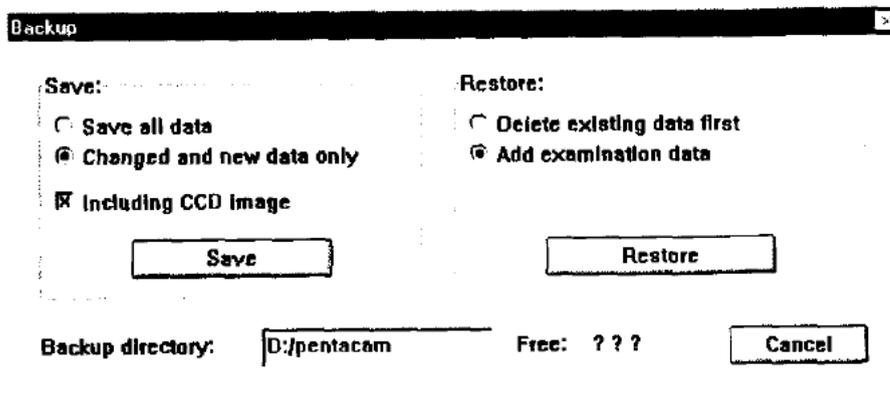
Existing examinations:

20.05.03	15:03	Pentacam	Left
20.05.03	15:03	Pentacam	Left
20.05.03	15:02	Pentacam	Right
20.05.03	15:01	Pentacam	Right



6.1.7 Saving data (backup)

6.1.7.1 Saving data



[Backup] opens up the backup-window. This consists of two fields: **“Save”** and **“Restore”**.

In these fields the index can be marked in which the data is to be saved or from which it is to be loaded, for ex. “F:” for an external drive with exchangeable data carriers (replacement disc).

Saving data can proceed according to various criteria:

- **“Save all data”**
All patient and examination data is saved.

- **“Changed and new data only”**
Only such data is saved which has been changed or added since data was last saved.
- **“Including CCD image”**
This function can be deactivated in order to reduce amount of memory space required. This is useful when saving data on floppies.

Tip ⇒ Saving data can be very time-consuming depending upon the amount of data; therefore you should perform this function when the PC (or the Pentacam) will not be needed for some time.

To initiate data storage, activate **[Save]**.

6.1.7.2 Reconstructing data

The reconstruction of saved data can also be carried out according to various criteria:

- **“Delete existing data first”**
This function deletes all currently saved examination data of the patients before reconstructing the patient data on the data carrier. Thus after data reconstruction only

the examinations are recorded which are also to be found on the backup data carrier.

- **“Add examinations”**
This function adds the examination data of the data carrier to the already existing examination data of the patient.

[Restore] activates the reloading of data from the backup data carrier into the system.

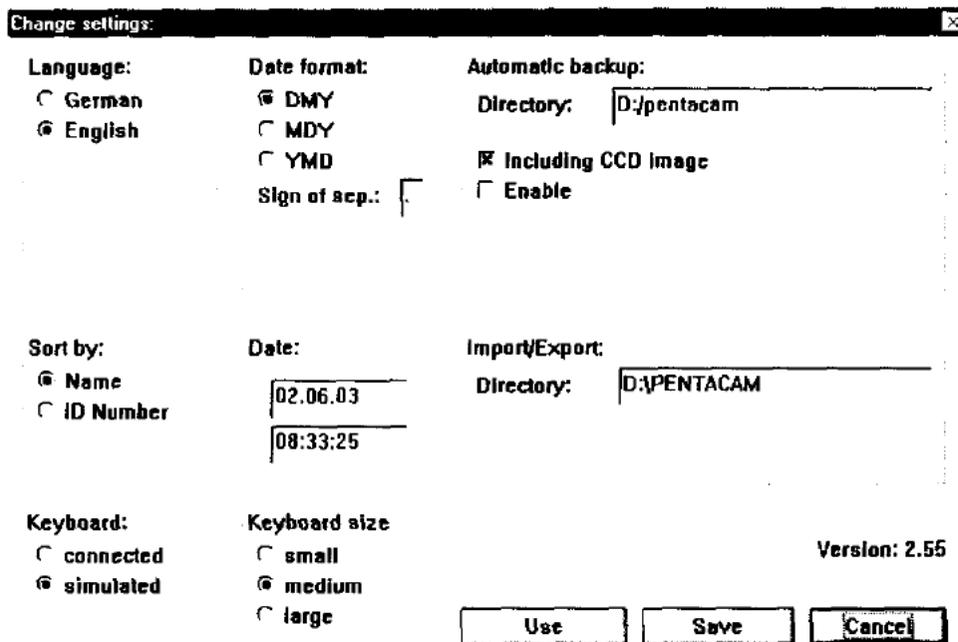
6.1.7.3 Automatic backup

It is also possible to save backup data automatically. When exiting an examination program the new examination data is always saved automatically.

This function is activated in the "Settings" menu.

This function should only be used if an additional drive with replaceable data carriers is available.

6.1.8 Change settings



After [Settings] is activated, the menu "Change settings" appears. Here the patient data administration can be adjusted according to your individual wishes.

- **Language**
To select the language which the program should use (German, English, French, Italian, etc.).
- **Date format**
To choose the order in which date is entered:
Day/Month/Year (DMY),
Month/Day/Year (MDY),
or Year/Month/Day (YMD),
as well as to choose type of punctuation.

- **Automatic backup**
This activates the automatic backup function (click on "Activate").

The backup index in which the data is to be saved has to be entered. This index is also used in the normal backup function as backup index.
It is also possible to designate whether camera images should be saved when data is saved automatically or not.
- **Sort**
The patient directory can be sorted according to the name or ID number of the patient. If the patient's name is used to find the patient, then it is advisable to sort the directory according to name.
- If the patient's data is loaded according to the patient's ID number, then the directory should



be sorted according to ID number.

- **Date**

In this field the system time and date can be changed.

- **Import / Export**

To enter the drive, and if applicable also the subdirectory from which or into which data is to be exported

- **Keyboard**

If "simulate" is clicked on, then **[Keyboard]** appears next to the field where the patient's name is entered. If this is activated a virtual keyboard appears via which the patient's name can be entered.

- **Size of keyboard**

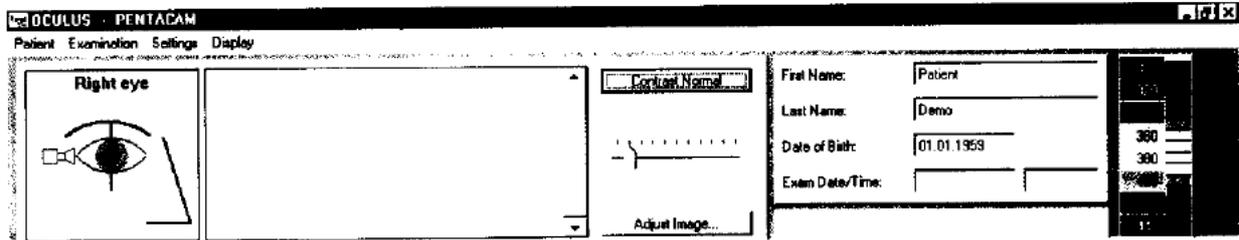
The size of the virtual keyboard can be selected here.

If **[Use]** is activated, the selected setting is used for all further steps of the program. When restarting the program the saved settings will be reloaded, however.

By activating **[Save]** the selected setting can be saved. Then this setting will be loaded every time the program is restarted.

[Cancel] cancels the selected alterations and deactivates the function.

6.2 The examination program



To start the examination program first you select the patient from the patient directory and confirm this via **[Pentacam]**.

After loading the examination program of the "Pentacam" the patient data (top left) as well as the menu bar for operating the program appear. The menu bar consists of the following functions:

which the results of an examination should be displayed.

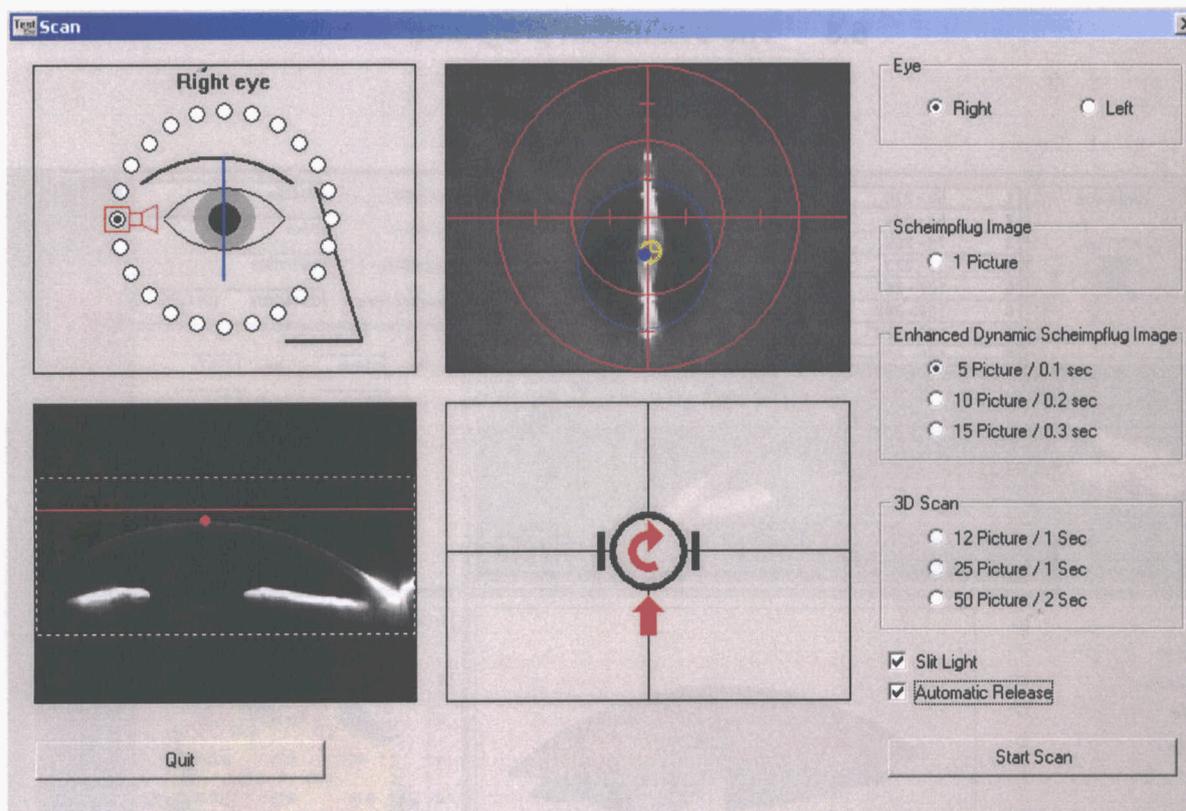
- ✓ Overview
- 3D-Model (large)
- Maps (large)
- Image (large)

- **Patient**
Ends the examination program and returns to patient administration.
 New Patient / End
- **Examination**
Loads previous examinations or performs new ones.
 Load
 Scan
- **Settings**
Here various program settings can be selected.
- **Display**
This function is used to select the form in



6.2.1 Measuring procedure

- Adjust the height of the table so that the head of the patient can be fixated in the head and chin rest comfortably.
- Adjust the head and chin rest so that the eyes of the patient are approximately level with the black ring on the chin-forehead rest.
- Start examination program (see 6.2 page 17) and select “Scan” function in “Examination” menu.
- In “Eye” field the eye which is to be examined must now be selected.
- The left, upper image is called the “Orientation display”. It contains the information on the eye which is to be examined and the current position of the camera.
- If “Scheimpflug image” is selected, then only one Scheimpflug image will be generated. The desired camera position can be selected by clicking on the red rings in the orientation display.
- In the “Enhanced Dynamic Scheimpflug image” field one chooses whether 5, 10 or 15 Scheimpflug images should be taken from a single camera position. The mean value of the individual images is taken and represented as a single image. The camera position can be selected as desired by clicking on the red rings in the orientation display. This kind of imaging is suitable for a purely densitometric assessment of the lens.
- In the “3D Scan” field 12, 25 or 50 images can be selected per Scan. The difference is the number of evaluated measuring points and the length of the examination. This type of examination must be selected to evaluate the pachymetry, the topography and the 3D anterior chamber analysis. One should note that only the image which appears inside the white dotted rectangle is recorded.
- The “Automatic Release” button (lower right) enables or disables the automatically releasing. Please choose this function before starting the alignment.
- The instrument should be set so that the blue slit lamp illuminates the iris of the eye.
- Inform the patient that he/she should constantly fixate the middle of the black ring (in the middle of the blue slit lamp) and open his eye wide.
- Adjust the Pentacam with the help of the cross wires in such a way that the pupil appears in the middle (upper center, pre-adjustment). Then set the distance between the Pentacam and the patient's eye so that the anterior surface of the cornea is aligned with the red line on the live Scheimpflug image (lower left). The for the pre adjustment is, to bring the yellow circle into the center of the red cross in the pupils image.
- The alignment screen (lower center) gives the information for the fine alignment. The arrows shows you the direction in which the instrument has to be moved to reach the point of automatically releasing. If this point is reached a red cross is shown in the center of the alignment screen and the measurement starts.
- If the automatic release is not chosen, the measurement is now taken by activating the foot pedal or the “Scan” button.
- By activating the “Quit” button the measuring procedure is interrupted.
- The “Light” button in the lower center switches the illumination of the eye on and off. It is used for screening purposes in order to get an impression of the condition of the eye's lens without dilating the pupil. The Pentacam is now set in the prescribed way, the light is switched off and in the reticle one can see the patient's eye becoming dilated. Then the measurement is initiated. This function is only useful when generating individual images, however.



The live Scheimpflug image (lower left) describes the orientation of the measuring head in z-direction, i.e. closer or farther away from patient. The image of the pupil (upper center) shows the orientation of the measuring head in vertical or horizontal position. These two representations are for the pre-adjustment. The small blue circle represents the center of the pupil, the big blue circle marks the pupil. The yellow circle marks the apex of the cornea.

The measurement starts automatically if the **"Automatic Release"** button is activated. A black cross in the center of the alignment screen shows the point of automatically releasing. If the automatically releasing is not activated the measurement is initiated by activating the foot pedal or the "Start Scan" button. Before the measurement is initiated, or you come to the point of automatically releasing the patient should be asked to open his eye as far as possible in order to measure as large an area of the anterior eye segment as possible.

After the measurement is initiated the image is transferred to the PC digitally and displayed.

Then the image processing procedure is started automatically.

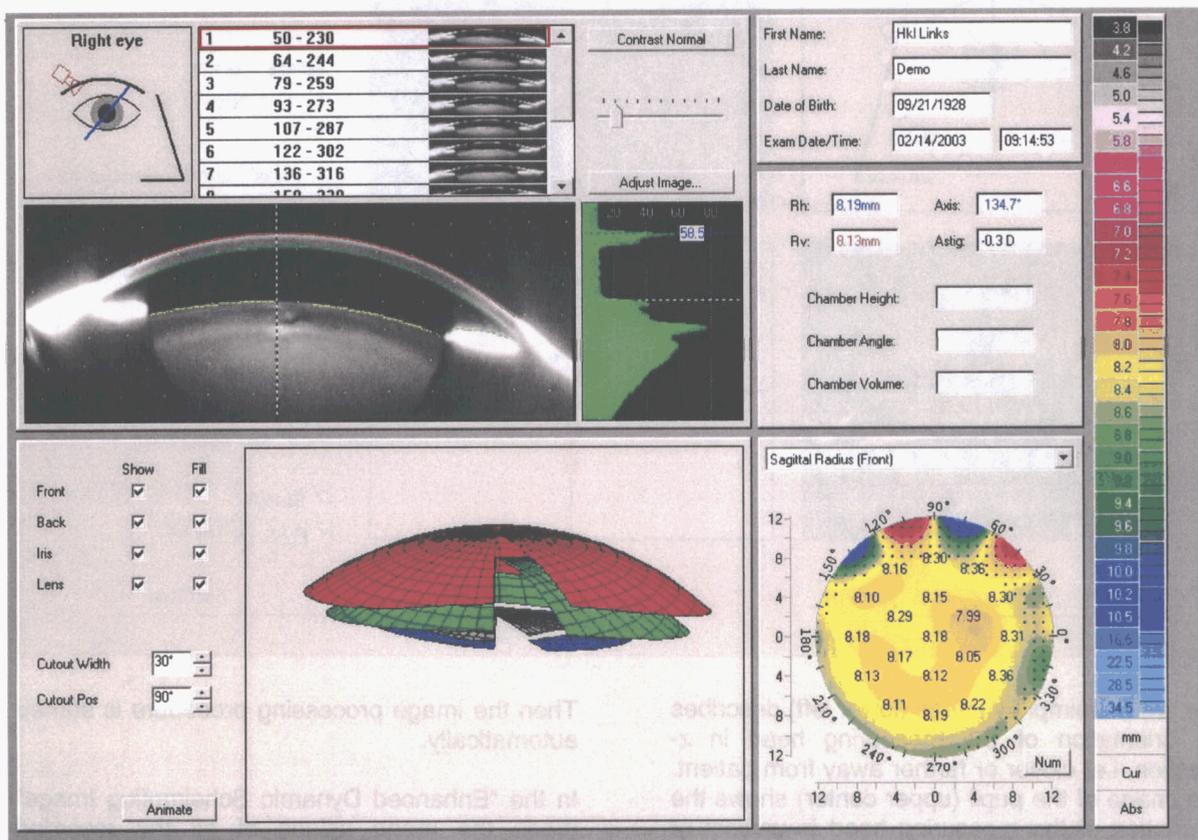
In the "Enhanced Dynamic Scheimpflug Image" mode the mean values of all the recorded images are taken and a Scheimpflug image is displayed on the overview display (Overview). If the 3D-Scan mode was selected, the first Scheimpflug image which was recorded is displayed on the overview display (Overview). All of the following images can be displayed and examined individually.

From the recorded Scheimpflug images the system calculates a 3D-model of the anterior eye segment. From this all further information such as the anterior chamber analysis, the topography and the pachymetry are calculated.

Those areas which are not measured and were darkened in some way (eyebrows or eye lashes), are interpolated and marked with black points or whitened areas on the topographical and the pachymetrical maps.

6.3 The evaluation programs

6.3.1 Overview display



The overview display is a compilation of several evaluation representations which gives a quick overview of the measured anterior eye segment.

It contains the following data fields:

- **Patient data** (upper right)
The patient data is displayed on the upper right.
- **Camera/slit lamp position and individual images**
The display on the upper left shows the position of the camera and the cross-section of the eye as well as the matching Scheimpflug image. All the Scheimpflug images which were generated can be viewed individually by clicking on them. The images are numbered and the cutting angle of the

individual images is displayed. The selected image is displayed below.

- **Scheimpflug image and densitometry**
(left of center) The selected image is displayed. By clicking on any part of the lens with the left mouse key its densitometry is displayed in a green bar on the right. The height of the green graph indicates how hazy the lens is. This entails evaluating the cross section, which is marked with dotted lines. By moving the mouse while holding down the left mouse key, the densitometry of any part of the lens can be evaluated.
By clicking on the Scheimpflug image with the right mouse key an additional window is opened. Here the display of the automatically found lines in the image can be activated. By

activating "Show edge pixel" the anterior surface of the cornea is marked in red, the posterior surface in green and the anterior surface of the lens in yellow. This representation shows the edges found. If one clicks on "Show fitted curve", all the edges found are depicted in the form of a mathematical model and shown in red. The two forms of representation can differ.

- **3D-model**

The 3D-model is in the lower half of the overview display. In this model the anterior and posterior surface of the cornea, iris and lens are depicted as planes. By clicking on the "Show" button on the left they can be activated and deactivated. By clicking on [Fill] the individual surfaces appear in the form of transparent lattices. In control field [Cutout width] the cutout angle is changed via arrow keys. It is immediately possible to look down "deeper" into the model. In the field [Cutout pos.] the model can be turned a certain number of degrees. By clicking on [Animate] the model begins to rotate until the button is activated again. If one clicks on the model with the left mouse key while holding it down, the model can be rotated in the desired direction by moving the mouse.

Chamber analysis (middle right)

In this field the calculated anterior chamber depth, the chamber angle and the chamber volume is depicted. The anterior surface of the cornea is topographically analysed and described in terms of sphere, astigmatism

and axis.

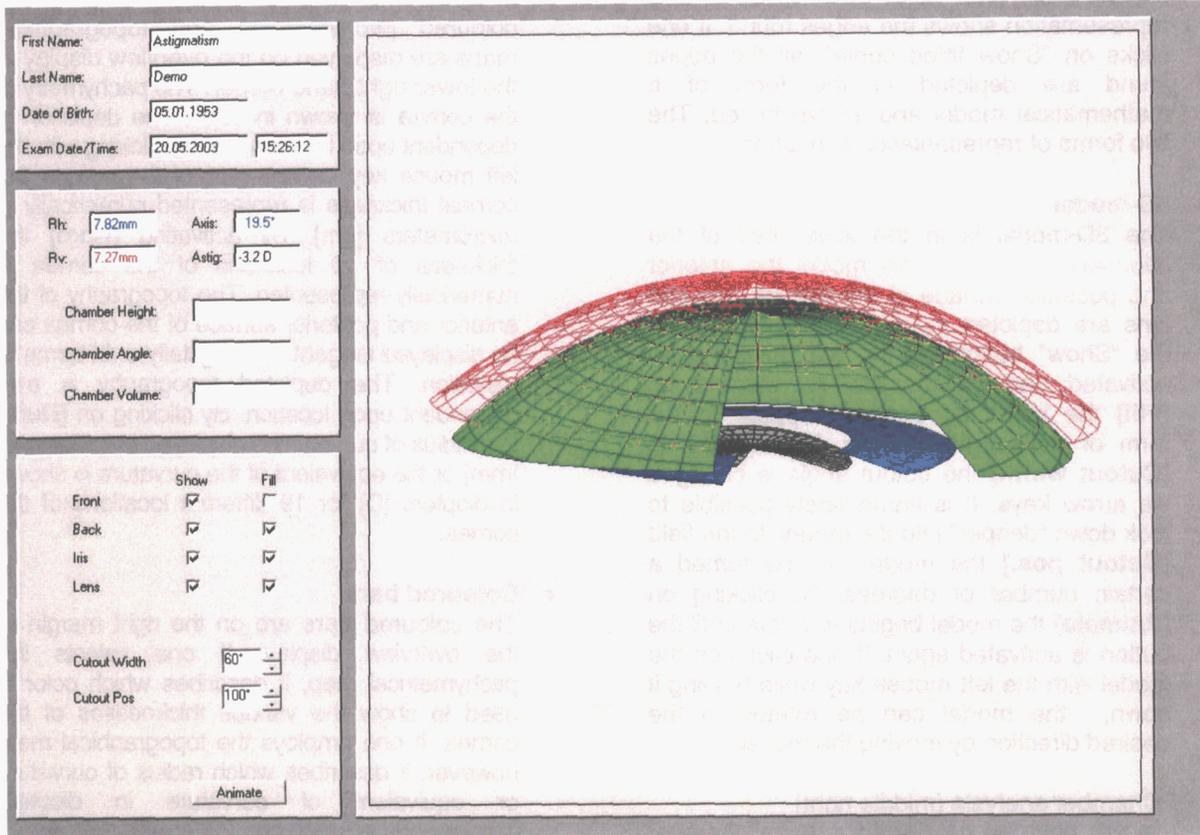
- **Pachymetrical and topographical maps**

In order to gain a first impression, the coloured pachymetrical and topographical maps are displayed on the overview display in the lower right-hand corner. The pachymetry of the cornea is shown in color. The depiction is dependent upon location, i.e. by clicking with the left mouse key on any part of the cornea the corneal thickness is represented numerically in micrometers [μm]. By activating [Num] the thickness of 19 locations of the cornea is numerically represented. The topography of the anterior and posterior surface of the cornea can be displayed tangentially, sagittally or in terms of elevation. The depicted topography is also dependent upon location. By clicking on [Num] the radius of curvature is displayed in millimetres [mm] or the equivalent of the curvature is shown in diopters [D] for 19 different locations of the cornea.

- **Coloured bars**

The coloured bars are on the right margin of the overview display. If one selects the pachymetrical map, it describes which color is used to show the various thicknesses of the cornea. If one employs the topographical map, however, it describes which radius of curvature or equivalent of curvature in diopters corresponds to which bar.

6.3.2 3D model, large

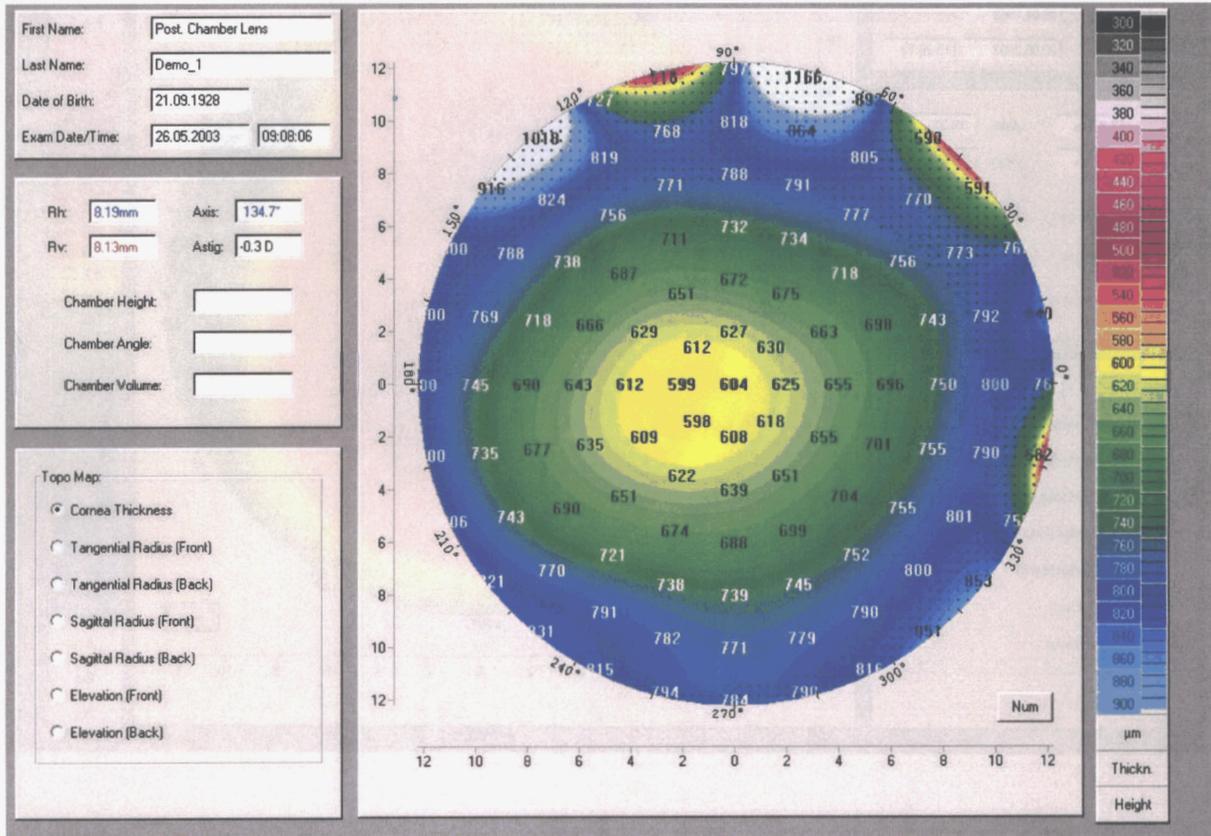


If one clicks on **[Display]** in the upper menu bar and then **[3D-model (large)]**, the mode of representation shown above is displayed. The patient data is displayed on the top to the left. Underneath the refractive data of the anterior surface of the cornea and the results of

the anterior chamber analysis are shown (see chapter 7.2.2.1). The 3D model is depicted in enlarged dimensions. This model is intended for use when consulting with patients. The same functions are available as those found in the overview display.

6.3.3 Coloured map, large

6.3.3.1 Pachymetry



If one clicks on **[Display]** in the upper menu bar and then **[Maps (large)]** then the mode of representation shown above is displayed.

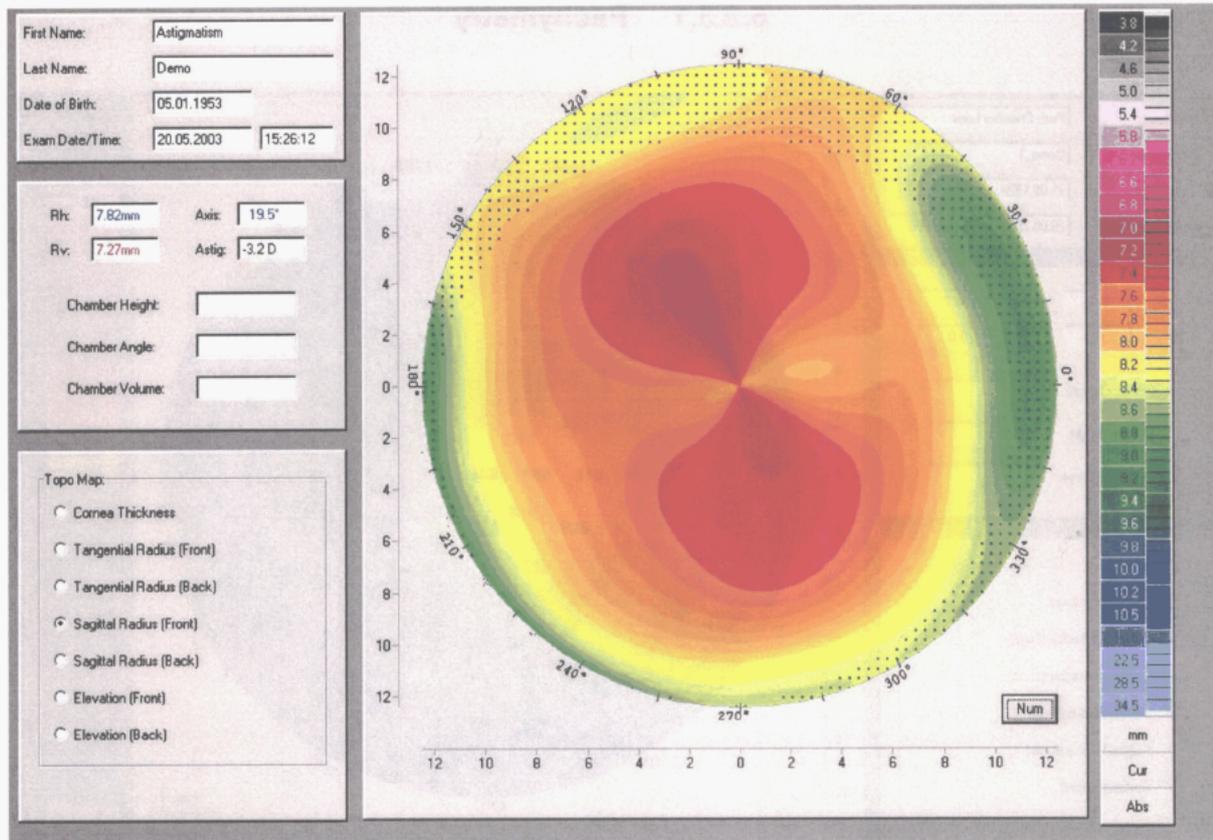
The patient data is shown on the top left-hand side. Underneath the refractive data of the anterior surface of the cornea and the results of the anterior chamber analysis (see chapter 7.2.2.1) are shown.

In the selection field in the lower left-hand corner the various depiction modes of the pachymetry and the topography are shown when clicked on.

The varying thickness of the cornea is depicted in color across its entire surface. Any point can

be selected and evaluated individually by clicking on it with the mouse using the coordinate system. **[Num]** shows the thickness of the cornea in many locations numerically and thus gives a precise impression of the varying thickness of the cornea. The coloured bars on the right show which thickness is represented by the individual colours. The surfaces which were not measured, for ex. because they were covered up by the eye lid or eyelashes, are interpolated. They are represented by black dots.

6.3.3.2 Topography of the anterior surface of the cornea



If one clicks on **[Display]** in the upper menu bar and then **[Maps (large)]**, then the mode of representation shown above is displayed.

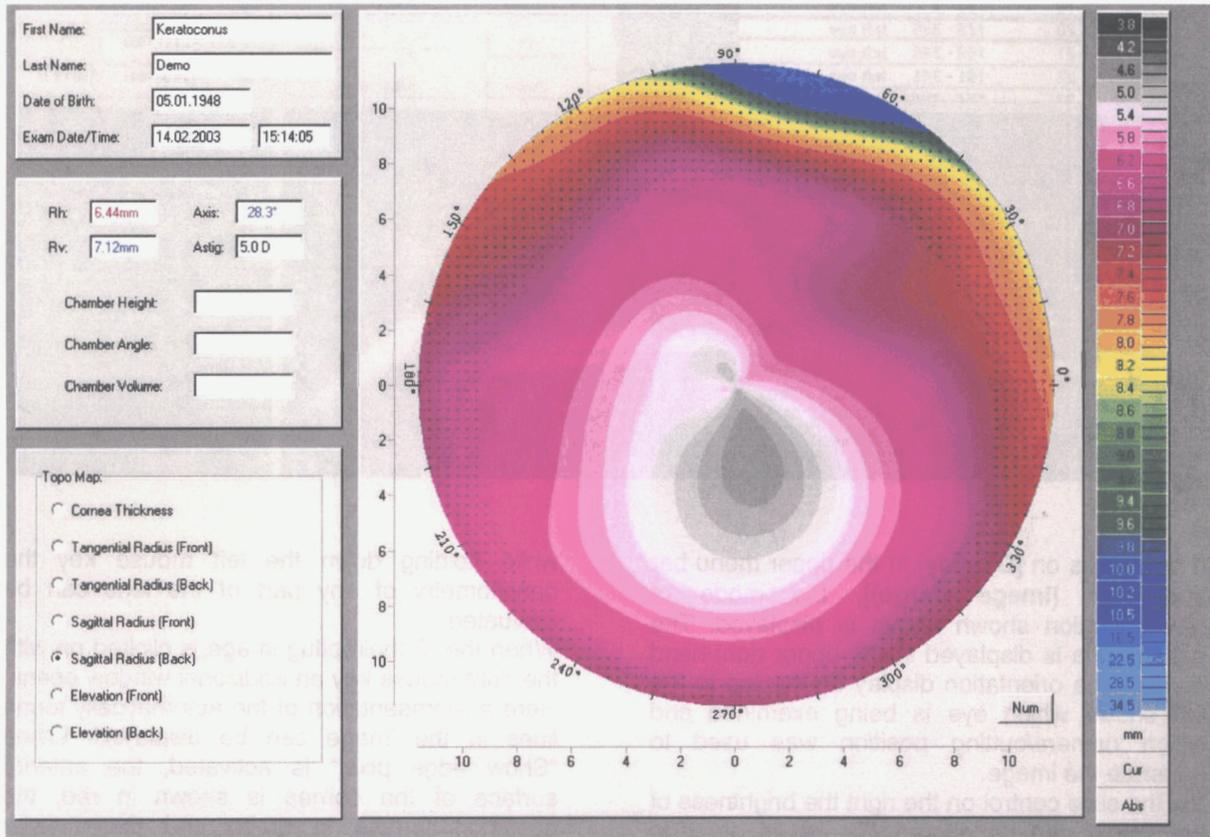
The patient data is shown in the upper left-hand corner. Underneath the refractive data of the anterior surface of the cornea and the results of the anterior chamber analysis are shown.

In the selection field in the lower left-hand corner the various modes of depicting the pachymetry and topography are shown when clicked on. Here the topography of the anterior surface of the cornea was selected, depicted in the form of a sagittal radius map.

The topography of the cornea is shown in color across the entire surface, from limbus to limbus. This depiction gives a good impression of the

varying curvature of the measured cornea. Each individual point can be selected individually by clicking on it with the help of the coordinate system and evaluated in terms of the radius of curvature in millimetres [mm], or equivalent curvature in diopters [D]. By clicking on **[mm]** one can switch back and forth between the two curvature units. A numerical representation of the curvature values can be switched on and off via **[Num]**. This is analogous to the representation of the anterior surface of the cornea shown in the form of a tangential radius map. The surfaces which were not measured, for ex. because they were covered up by the eye lid or eyelashes, are interpolated. They are represented by black dots.

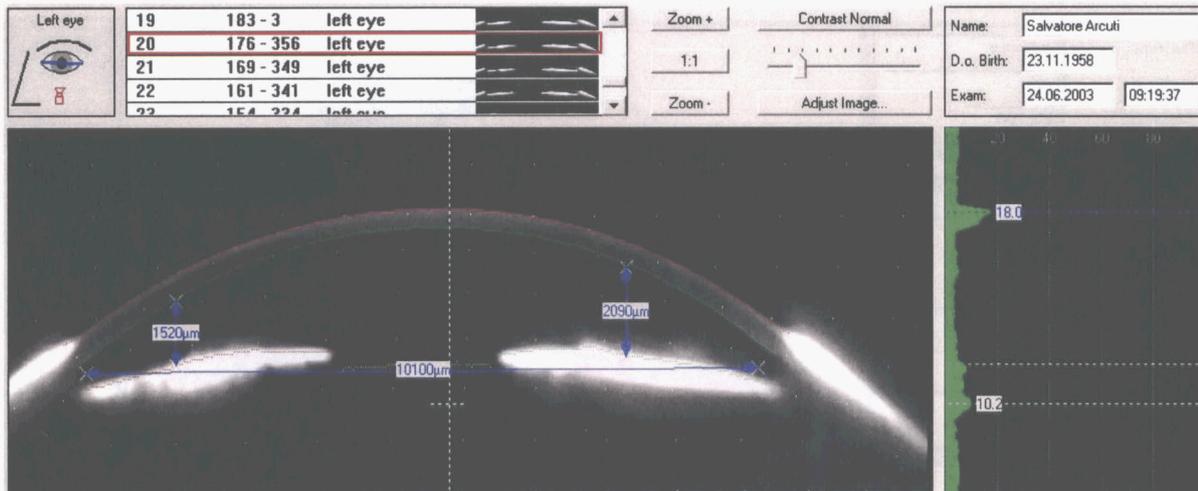
6.3.3.3 Topography of the posterior surface of the cornea



If one clicks on **[Display]** in the upper menu bar and then **[Maps (large)]**, the mode of representation shown above is displayed. The patient data is displayed in the upper left-hand corner. Underneath is the refractive data of the anterior surface of the cornea and the results of the anterior chamber analysis. In the selection field in the lower left-hand corner the various forms of pachymetrical and topographical representation are shown when clicked on. Here the topography of the posterior surface of the cornea was depicted in the form of a sagittal radius map. The entire posterior surface is shown in color in respect to location.

Each individual point can be selected individually by clicking on it with the help of the coordinate system and evaluated in terms of the radius of curvature in millimetres [mm], or equivalent curvature in diopters [D]. By clicking on **[mm]** one can switch back and forth between the two curvature units. A numerical representation of the curvature values can be switched on and off via **[Num]**. This is analogous to the depiction of the anterior surface of the cornea shown in the form of a tangential radius map. The surfaces which were not measured, for ex. because they were covered up by the eye lid or eyelashes, are interpolated. They are represented by black dots.

6.3.3.4 Scheimpflug image of a 3D-Scan, large



If one clicks on **[Display]** in the upper menu bar and then **[Image (large)]**, the mode of representation shown above is displayed. The patient data is displayed in the upper right-hand corner. The orientation display on the top to the left shows which eye is being examined and which camera/cutting position was used to generate the image.

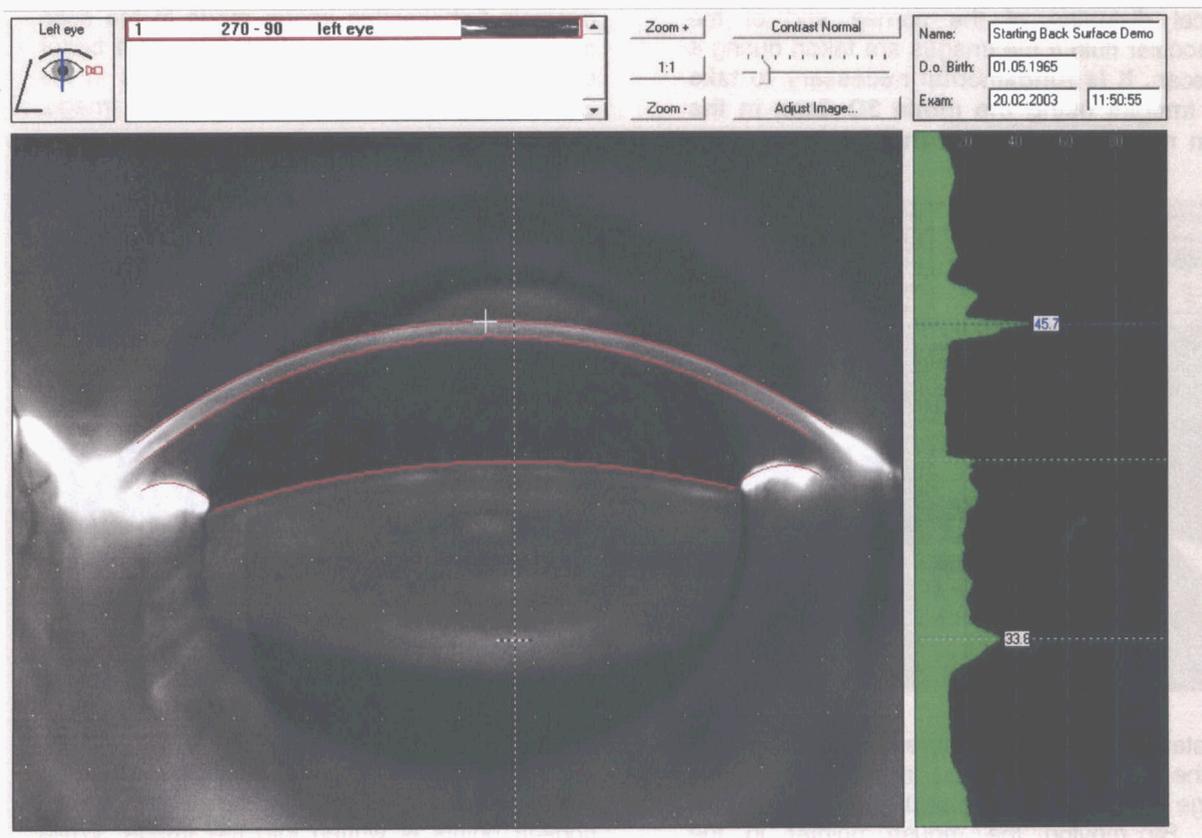
Via the slide control on the right the brightness of the image can be altered, for ex. in order to detect the edges found, which are coloured in.

By clicking on any part of the lens with the left mouse key its densitometry is shown in a green bar next to the image. The height of the green bars gives an indication of how hazy the lens is. The cross-section, which is represented by a dotted line, is evaluated. By moving the mouse

while holding down the left mouse key the densitometry of any part of the lens can be evaluated.

When the Scheimpflug image is clicked on with the right mouse key an additional window opens. Here a representation of the automatically found lines in the image can be displayed. When "Show edge pixel" is activated, the anterior surface of the cornea is shown in red, the posterior surface in green and the anterior surface of the lens in yellow. This depiction shows the discovered edges. If one clicks on "Show fitted curve", however, all the edges found are represented in the form of a mathematical model and shown in red. Thus the two modes of representation can differ.

6.3.3.5 Individual Scheimpflug image, large



If one clicks on **[Display]** in the upper menu bar and then **[Image (large)]**, the mode of representation shown above is displayed. The patient data is displayed in the upper right-hand corner.

The orientation display on the top left shows which eye is being examined and which camera/cutting position was used to generate the image.

With the slide control on the right the brightness of the image can be altered. This is good for detecting artificial lenses, which only produce a small degree of reflection. **[Contrast Normal]** resets the instrument to the original brightness.

[Adjust Image] offers the possibility to alter the image in terms of contrast, brightness and other options. By clicking on **[Set Brightness]** the settings are saved and applied for all images.

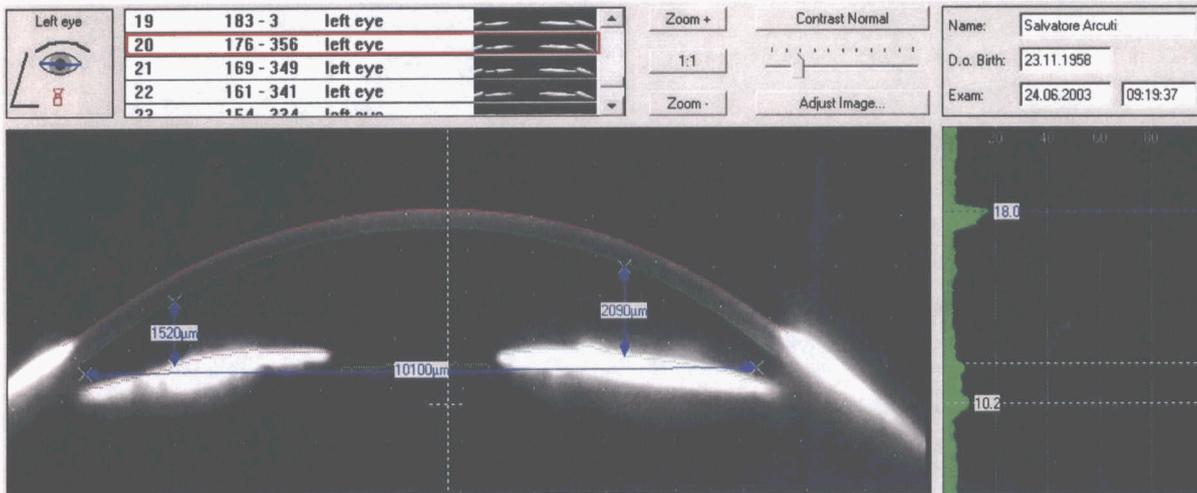
By clicking on any part of the lens with the left mouse key its densitometry is shown in a green bar next to the image. The height of the green bars gives an indication of how hazy the lens is. The cross section in question, which is designated by a dotted line, is evaluated. By moving the mouse while holding down the left mouse key the densitometry of any part of the lens can be evaluated.



6.3.4 Manual measurement function

The Pentacam has an implant manual measurement function which considers the optical distortion of the cornea and of the intraocular fluid if the images are taken during a 3D-scan. **It is fundamental necessary to take the images using the mode 3D Scan in the scan menu to use the manual measurement**

function. The optical distortion is not corrected if the images are taken using the enhanced dynamic Scheimpflug image mode in the scan menu. A mm-raster is implanted to get a better overview and to define reference points in the Scheimpflug Image.



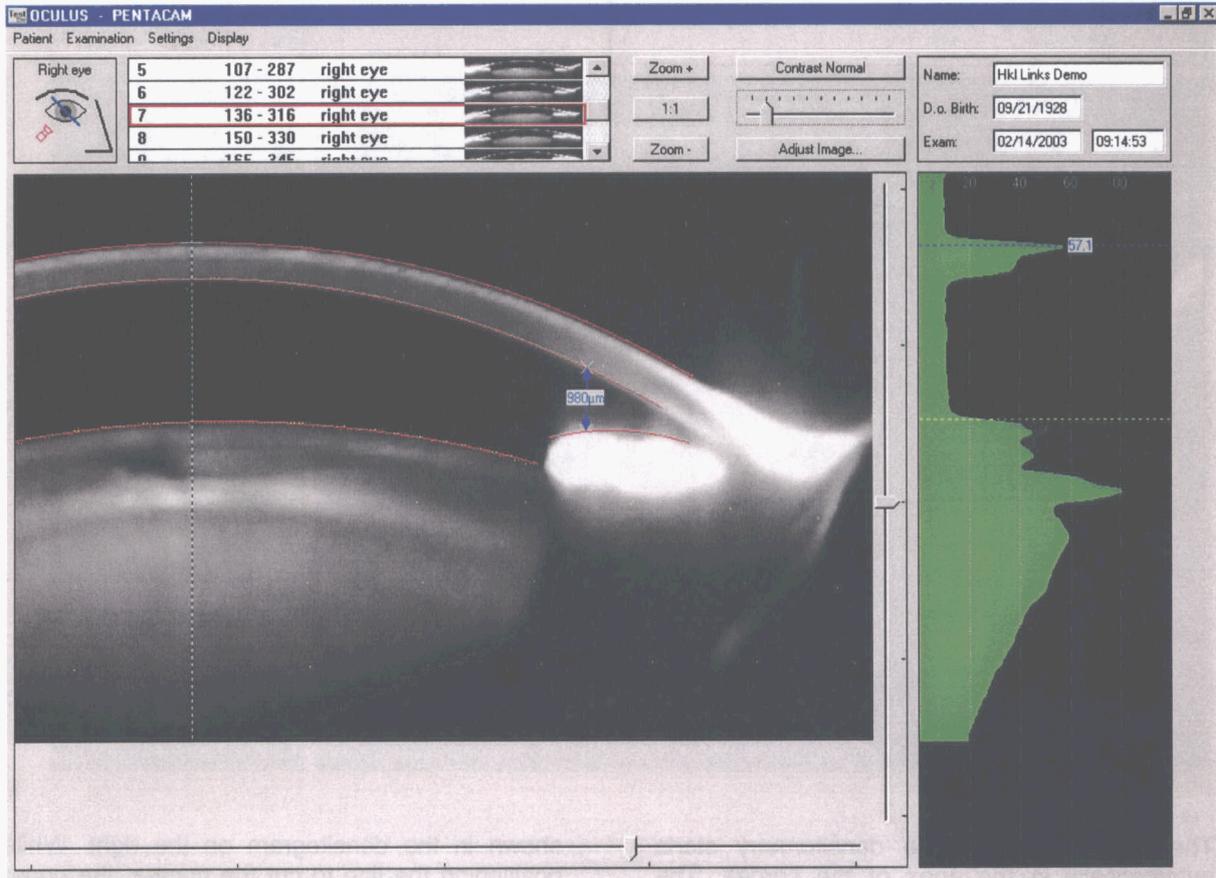
To start the manual measurement function click to the current start point in the Scheimpflug image by the mouse pointer using the left mouse key. By moving the mouse pointer in the Scheimpflug Image the measurement arrow hangs like a rubber band to the mouse pointer.

The current distance is shown in μm . While reaching the target point and press the left mouse button the distance between the two chosen points is written into the Image. While pressing the right mouse button during the measurement the current measurement stops.

6.3.5 Zoomfunction

The Zoomfunction is valid to the chosen Scheimpflug Image. The zoomed parts are

displayed while considering the optical relations to get a better evaluation of the image.

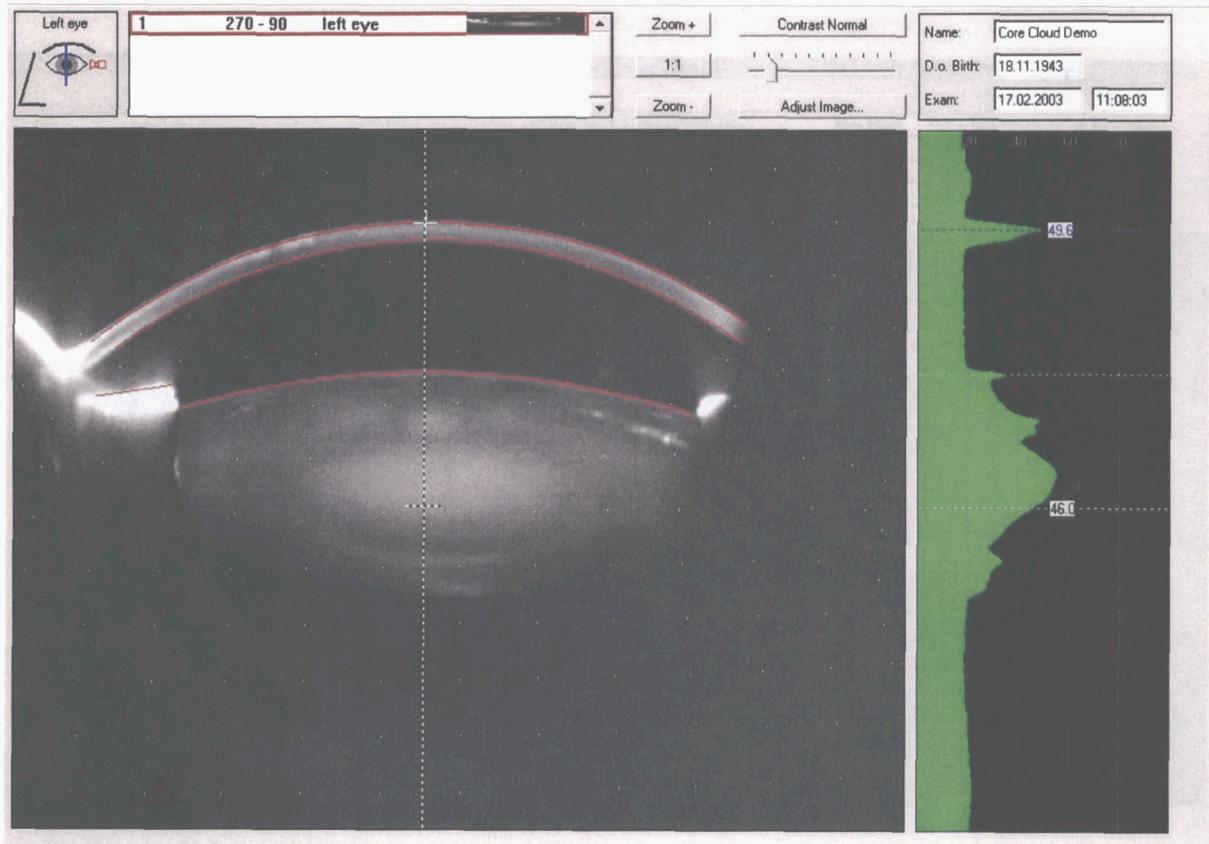


The button „Zoom +“ enlarges, the button „1:1“ bring the picture to the original size and the button „Zoom -“ reduces the current Scheimpflug Image. While enlarging the Scheimpflug Image the image can be scrolled up and down and left and right with the help of the windows slide bar.

As an example in the picture above, the measurement of the distance between iris and posterior surface of the cornea is displayed, related to the mathematically fitted curve. The zoomfunction considers the optical distortion of the cornea and of the intraocular fluid.

6.3.6 Quantification of the Densitometry

The densitometry of the lens becomes quantified and is scaled from 0 to 100. The apex of the cornea in the current Scheimpflug Image is marked by a cross.



The quantification of the densitometry starts automatically in the apex of the cornea. The position is marked by the white line. To move the line in order to evaluate different points and layers of the lens catch the line by the left mouse button. The quantification of the densitometry is

shown in the densitogram on the right. While positioning the line to cut the cornea, the upper value shows the maximum densitometry value of the cornea and is marked by a blue line. The yellow line marks the beginning of the lens in the densitogram.

6.3.7 Additional functions of the examination program

6.3.7.1 Loading previous examinations

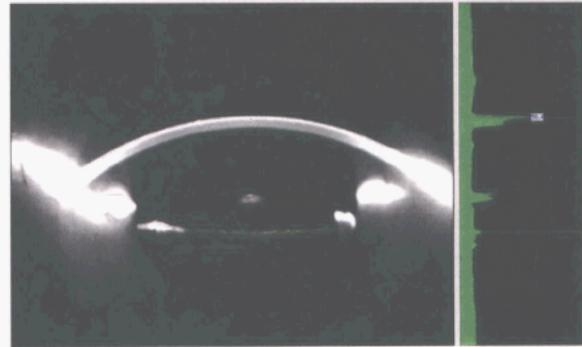
The saved examinations performed on selected patients can be reloaded with the help of the “**Load**” function in the “**Examination**” menu. The selection is made via a displayed list of

examinations. Simply click on desired examination and confirm with **[OK]** (the displayed examination can also be reloaded by double-clicking on it).

6.3.8 Artefacts

When performing a densitometric evaluation of the lens one must note that haze can be caused by reflexes produced by a ceiling lamp or light coming through a window (sunlight), lower left picture. When in doubt the measurement should be retaken. The Pentacam must be set up in such a way so as to prevent incidence of direct light from impairing the examination. Another

artefact appears if the central slit or the lens in front of the camera is soiled, lower right picture. Please clean these parts as it is described in chapter 7.1 **Care and maintenance**. If the artefacts are not eliminated after cleaning the mentioned parts and checking the surrounding light conditions contact the service division.



6.3.9 Other functions

The “**Settings**” menu contains the following service functions:

- **Display units:**
Here one can choose between diopters and radius of curvature in the topographical representation.
- **Foot switch:**
In the control box the connected foot switch must be activated. The matching COM port must be set up for operation.
- **Date format**
The desired date format can be selected. D stands for day, M stands for month and Y for year.
- **Mode:**
When Pentacam is connected, “Online USB” must be selected in order to establish communication between the PC and the camera. The “Demo” field is only intended for demonstrating the software while the Pentacam is disconnected.

7 Maintenance

7.1 Care and maintenance



When cleaning always pull out plug!

Casing

Do not use any aggressive cleansers which contain chlorine, solvents, abrasive or caustic substances!

It is best to clean the surface of the casing with a soft cloth and an anti-static cleansing agent.

Otherwise wipe off outer surfaces with a damp cloth. In case of residue, remove with a mixture of equal parts of spirit and distilled water with a squirt of conventional detergent.

Optical components

The optical components of the slit illumination in the center of the unit and the lens in front of the camera are precision parts and sensitive to pressure. One should prevent the surface from being scratched.

The lens in front of the camera must be cleaned with particular care. Use a lint-free dry cloth. The slit illumination in the center has to be cleaned by using cleaned compressed air only, no clothes or other cleaning detergents.

7.2 Elimination of errors and malfunction

7.2.1 Replacement of fuses



Pull out plug before replacing fuses!

It is not necessary to replace the fuses as the instrument is operated via a power supply unit with integrated automatic overload switch.

7.2.2 Error detection



Do not plug in or pull out any cables while the PC or the Pentacam are switched on!

If an error occurs which you are not able to eliminate on the basis of the following instructions, designate the instrument as defective and notify our service department.

ERROR: After starting the examination software the PC displays the message “No Communication”

- Check to see whether the pilot lamp on the power supply unit is illuminated. If not, plug in the power supply unit.

- Check to see whether the cable is plugged into the Pentacam properly.
- Check to see whether the blue slit lamp of the examination program is illuminated.
- Check to see, if the USB-Connector is plugged into the Laptop or Standard PC properly
- Switch off the Pentacam and restart the PC. As soon as the OCULUS patient data administration is active, switch on the Pentacam. The message “Load bootloader” must appear when the Pentacam software is being started.
- Contact our service department.



8 Conditions of warranty and service

8.1 Conditions of warranty

This OCULUS product is a high-quality instrument. It was manufactured with great care using high-quality materials and modern production technology. It is important for you to read the instruction manual before operation and to observe the safety precautions.

You have a warranty on this instrument in accordance with legal warranty regulations

starting on the day of purchase. This warranty covers all kinds of malfunction caused by faulty material and manufacture. Malfunction caused by improper operation and external influences is not covered. Should you nevertheless have reason for legitimate complaint during the period

of warranty, the malfunction will be eliminated at no cost to you.

These warranty claims can be made if a receipt documenting date of purchase is presented. If the instrument is manipulated by unauthorised persons, all warranty claims become void, for improper alterations and handling can cause considerable damage to the user and patients.

We request that complaints concerning damages which occur during transport or delivery be made to the shipping firm immediately and that the damage be documented on the consignment note so that the claim can be settled properly.

Our terms of trade and delivery are valid as laid down at the time of purchase.

8.2 Liability for function and damages

OCULUS only considers itself responsible for the safety, reliability and proper function of the instrument if it is used in compliance with this instruction manual.

There are no parts attached to or inside the instrument which should be serviced or repaired by the user.

If assembly work, expansions, adjustments, maintenance work, alterations or repairs are carried out by non-authorized personnel or if the unit is maintained or handled improperly, OCULUS is not liable for any damages which might occur.

If the kind of work described above is performed by authorized persons, documentation of the nature and extent of the repair work must be demanded of them, if pertinent with a statement regarding changes made in specifications or application. The document must include date and particulars of services performed as well as name and address of firm and signature.

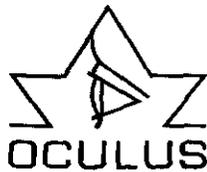
If desired, OCULUS will put wiring diagrams, lists of replacement parts, additional descriptions and instructions for instalment at the disposal of such authorized persons.

In case of maintenance and repairs, only original OCULUS parts may be used.

8.3 Address of manufacturer and service department

You can receive additional information from our service department and authorized dealers.

Address of manufacturer and service department:



www.oculus.de

OCULUS *Optikgeräte GmbH*
Münchholzhäuser Str. 29
35582 Wetzlar
Germany
Tel.: +49 641/2005-0
Fax: +49 641/2005-255
E-Mail: sales@oculus.de

9 Appendix

9.1 Declaration of conformity

We declare that this product complies with the following norms or normative documents:

IEC 601 - 1
IEC 601 - 1 - 2

in accordance with the regulations of Directive 93 / 42 / EEC on medical products.



We take sole responsibility for this declaration.

Dipl'd eng. Rainer Kirchhübel

Managing director of
OCULUS *Optikgeräte GmbH*



9.2 Technical data

Measuring component:

Camera	digital CCD-Camera
Light source	blue LED's (475nm, UV-free)
Velocity	50 images in two seconds with 500 recorded measuring points each
Number of evaluated measuring points	max. 25,000
Dimensions (height, width, depth)	535 x 280 x 360 mm
Weight	9 kg

Power supply unit:

Mains connection	100 - 240 V AC, 50 - 60 Hz
Power input	60 W
Fuses	integrated overflow switch

Classification according to IEC 601 – 1:

Type of protection against electric shock	Protection class 1
Degree of protection against electric shock	Type B
Degree of protection against damaging penetration of water	IP20

Operating conditions:

Temperature	+10° C to +40° C
Humidity	30 % to 75 %
Air pressure	700 hPa to 1060 hPa

Transport and storage conditions: (according to IEC 601-1)

Ambient temperature	40° C to +70° C
Relative humidity	10 % to 100 % Including condensation
Air pressure	500 hPa to 1060 hPa

9.3 Minimum PC-requirements

CPU:	Pentium 500MHz
Operating system:	Windows 98 or higher
Memory:	256 MB Ram
Graphic card:	4 MB graphic card (800*600 Pixel)

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