Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

K093624 (1) of (2)

510(k) Summary of Safety and Effectiveness
Optiscan Confocal Endoscopic Imaging System

Submitter Information:

Optiscan Pty Ltd
15-17 Normanby Rd,
Notting Hill, Victoria, 3168
Australia
Tel: (+61 3) 9538 3333
Fax: (+61 3) 9562 7742

MAR - 5 2010

Area PAK 3/5/10

Date Summary Prepared: 27 January 2010

Name of Device:

Trade Name:	Optiscan CEIS
Classification Name	Endoscope and Accessories (21CFR876.1500)
Product Code	GCJ, KOG

Predicated Device(s) Information:

Model, Description	Manufacturer	PMN #
Pentax Confocal Laser System	Pentax	K042740

Device Description:

The Optiscan Confocal Endoscopic Imaging System (CEIS) is a software controlled device which is intended for use as a required accessory with a legally marketed and compatible video endoscope system that is equipped with confocal imaging module.

The Confocal Endomicroscopy Imaging System (CEIS) consists of three main units.

1. The Control Unit (CEIS-CU) together with its monitor, keyboard, and footswitch, is a computer based unit which performs the instrument control, and image capture and processing functions of the CEIS.
2. The Optical Unit (CEIS-OU) a specialised endomicroscope interface unit which performs the laser illumination and fluorescence detection functions of the CEIS.
3. The Isolation Transformer.

A video endoscope equipped with a confocal imaging module is connected to the CEIS-OU. Under control by the endoscopist, the CEIS-OU transmits visible laser light into the connected endoscope. The endoscope transmits this light to and then subsequently receives return light signals from the subject tissue. The returned light is detected by the CEIS-OU and converted into an electrical signal. The detected signal is sent to the System Computer (CEIS-CU) which processes the confocal image information for display on the system monitor, and allows still images of the tissue to be captured and stored.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

Intended Use:
The Confocal Endoscopic Imaging System (CEIS) is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by legally marketed video endoscopes (equipped with a confocal laser imaging module), during endoscopic medical examination procedures. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

Comparison to Predicated Device(s):
The submission for substantial equivalence included Optiscan Confocal Endoscopic Imaging System (CEIS) literature including intended use and specifications. Comparison tables were provided to illustrate the comparisons to the predicated devices for intended use, technical specifications and materials. The submission for substantial equivalence was not based on an assessment of clinical performance data.

Conclusion:
Because the Optiscan Confocal Endoscopic Imaging System (CEIS) possesses the same or similar intended use, indications, and technological characteristics as the identified predicate device, with no additional questions of safety or effectiveness, the company submits that the device can be found to be substantially equivalent.

Prepared By:

Peter Pavlicek
Quality and Regulatory Affairs Manager

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

MAR - 5 2010

TUV Rheinland of North America, Inc.
% OptiScan Pty. Ltd.
Mr. Peter Pavlicek
15-17 Normanby Road
Notting Hill, Victoria 3168
Australia

Re: K093624
Trade/Device Name: Optiscan CEIS
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: February 19, 2010
Received: February 24, 2010

Dear Ms. Pavlicek:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

K093624

Indications for Use

510(k) Number (if known):

Device Name: Optiscan CEIS

Indications for Use:

The Confocal Endoscopic Imaging System (CEIS) is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by legally marketed video endoscopes (equipped with a confocal laser imaging module), during endoscopic medical examination procedures. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K093624

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MAR - 5 2010

TUV Rheinland of North America, Inc.
% OptiScan Pty. Ltd.
Mr. Peter Pavlicek
15-17 Normanby Road
Notting Hill, Victoria 3168
Australia

Re: K093624
Trade/Device Name: Optiscan CEIS
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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

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Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K093624

Indications for Use

510(k) Number (if known):

Device Name: Optiscan CEIS

Indications for Use:

The Confocal Endoscopic Imaging System (CEIS) is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by legally marketed video endoscopes (equipped with a confocal laser imaging module), during endoscopic medical examination procedures. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K093624

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

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

February 24, 2010

OPTISCAN PTY LTD.
c/o TUV RHEINLAND OF NORTH AMERICA, INC.
12 COMMERCE RD.
NEWTON, CONNECTICUT 06470
UNITED STATES
ATTN: TAMAS BORSAI

510k Number: K093624
Product: OPTISCAN MODEL OPTISCAN CEIS

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

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

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

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

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

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

December 07, 2009

OPTISCAN PTY LTD.
c/o TUV RHEINLAND OF NORTH AMERICA, INC.
12 COMMERCE RD.
NEWTON, CONNECTICUT 06470
UNITED STATES
ATTN: TAMAS BORSAI

510k Number: K093624
Product: OPTISCAN MODEL OPTISCAN CEIS

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

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

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

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

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

Sincerely yours,

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

November 24, 2009

OPTISCAN PTY LTD.
c/o TUV RHEINLAND OF NORTH AMERICA, INC.
12 COMMERCE RD.
NEWTON, CONNECTICUT 06470
UNITED STATES
ATTN: TAMAS BORSAI

510k Number: K093624

Received: 11/23/2009

Product: OPTISCAN MODEL OPTISCAN CEIS

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

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

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

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

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

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

Sincerely,

510(k) Staff

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

K093624

(b)(4) Third Party Information [redacted]

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

FDA CDRH DMC

NOV 23 2009

Received

Subject: 510(k) Notification reviewed by Third Party

K8

Dear Document Control Clerk:

(b)(4) Third Party Information [redacted] as Third Party reviewer is submitting the previewed 510(k) of Optiscan Pty Ltd. for the Optiscan Confocal Endoscopic Imaging System (CEIS), Model: Optiscan CEIS.

The following information is being submitted in accordance with the Third Party Preview Manual.

1. Purpose of Submission:
   New Submission

2. Name and Address of Third Party:
   (b)(4) Third Party Information [redacted]

3. Name and Address of Manufacturer:
   Optiscan Pty Ltd.
   15-17 Normanby Road
   Notting Hill, Victoria 3168
   Australia

4. Trade Name: **Optiscan Confocal Endoscopic Imaging System (CEIS), Model: Optiscan CEIS**
5. Common Name: **Confocal Endoscopic Imaging System**
6. Classification Name: **Endoscope and Accessories**
7. Classification No.: 21 CFR 876.1500 (Code: GCJ & KOG)
8. SE Recommendation:
   (b)(4) Third Party Information [redacted] is recommending that the **Optiscan Confocal Endoscopic Imaging System (CEIS), Model: Optiscan CEIS** is Substantially Equivalent (SE) to the legally marketed device ISC-1000 Pentax Confocal Laser System (K042740).

9. Date documents were received:
   Original Submission: 12-02-2008

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Additional documents (if applicable): 11-10-2009 (Final Response to (b)(4) [redacted] Deficiency Report)

10. Pre-Review documentation
    (See attachment 1)

11. Owner's letter authorizing (b)(4) [redacted] to submit their 510(k) to FDA and discuss its content with FDA
    (See attachment 2)

12. Owner's 510(k) submission as reviewed by (b)(4) [redacted] ((b)(4))
    (See attachment 3)

13. Personnel Qualification and Prevention of Conflict of Interest Criteria Statement: (b)(4) [redacted] will continue to meet the personnel qualification and prevention of conflict of interest criteria as reviewed by FDA.

14. True and accurate statement
    (b)(4) [redacted] certifies that the preview is based on the submitted 510(k), that it is true and accurate to the best of our knowledge, and it is understood that the submission of false information to the government is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q)

Primary Third Party Reviewer:

(b)(6) [redacted]

November 18, 2009
Date

Responsible Third Party Official (or Designee):

(b)(6) [redacted]

Tel: (b)(4) [redacted]
Fax: (b)(4) [redacted]
Email: (b)(4) [redacted]

Title:
Division Manager, Medical Division

(b)(6) [redacted]

(b)(6) [redacted]

Nov 19/2009
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 228

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Submission Cover letter

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- **1.1 Review Memorandum**
- **1.2 Screening Checklist**
- **1.3 510(k) Decision Making Documentation**
- **1.4 Reviewer's Conflict of Interest statement**
- **1.5 Predicate device documentation**
- **1.6 Pre-Review correspondence**
- **1.7 Notes**

Section 2 Owner's Authorization Letter

Section 3 Owner's Submission

Section 4 Other Project Documentation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

(b)(4) [redacted]

FDA 510(k) Review Program

Table of Contents

Section 1

(b)(4) [redacted] Pre-Review Documentation

1.1 Review Memorandum

1.2 Screening Checklist

1.3 510(k) Decision Making Documentation

1.4 Reviewer's Conflict of Interest statement

1.5 Predicate device documentation

1.6 Pre-Review correspondence

1.7 Notes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) [redacted]

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Section 1

(b)(4) [redacted] Pre-Review Documentation

Review Memorandum 1.1

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Review Program
Review Memorandum

(b)(4) Report number: (b)(4)

Review Memorandum for Traditional 510(k) Submission

1.0 Submission / Administrative Information

510(k) Submitter:	**Optiscan Pty Ltd.**			
Common device name:	**Confocal Endoscopic Imaging System**			
Trade name:	**Optiscan Confocal Endoscopic Imaging System (CEIS), Model: Optiscan CEIS**			
Type of Submission:	Traditional			
Reason for the submission:	New Device Submission			
Classification:	21 CFR 876.1500			
Product Code:	GCJ			
Subsequent Product Code:	KOG			
Classification Name:	**Endoscope and Accessories**			
Legally Marketed Device(s):	**ISC-1000 Pentax Confocal laser System**			**K042740**
Truthful and Accuracy Cert:	Section#:	Appendix A	Page#:	1 page
510(k) Summary:	Section#:	Appendix D	Page#:	2 pages
510(k) Statement:	Section#:	N/A	Page#:	N/A
Indication for Use Statement:	Section#:	Appendix F	Page#:	1 page
Form FDA 3654	Section#:	Appendix M	Page#:	10 pages
Form FDA 3674	Section#:	Appendix O	Page#:	3 pages

2.0 Intended Use

Per owner's submission the indication for use statement states, "The Optiscan Confocal Endoscopic Imaging System is intended to be used for confocal endomicroscopy of human tissue. The CEIS, its monitor, and a suitable confocal endomicroscope probe can provide microscopic visualization of the surface and subsurface of various body organs and tissues during endoscopic medical examination procedures".

The device is intended to be used with the Pentax EC-3870CILK Video Endoscope. Also the device is intended to be applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

CEIS is indicated for use as an aid or adjunct to a mode of therapy or diagnosis.

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The Indications for Use Statement is consistent with the labeling in the owner's submission. The labeling sufficiently describe the device, its intended use and directions for its use as required by 21 CFR 807.87(e). There is a warning statement on the User Manual (P/N: 001686, page 8) that states, "Do not use the video images for diagnosis purpose".

The device is intended for prescriptions use per 21 CFR 801.109

3.0 Device Description

CEIS is a software controlled device which is intended for use as a required accessory with a legally marketed and compatible video endoscope system that is equipped with confocal imaging module.

The device consists of three main units:

- **The Control Unit (CEIS-CU):** This is computer based unit which performs the instrument control, image capture and processing functions (Includes Monitor, Keyboard and footswitch). Control unit consists of a number of subsystems and components as detailed:
  1. Personal Computer: is based on the IBM ATX format and utilizes OEM components.
  2. ASC/IAB Card Set: The Card set provides the interface between the PC host computer and the rest of the CEIS system. The card is fitted to one of the computer PCI expansion slots.
  3. ECA Card: It provides a means of converting the internal mechanically unprotected cables to external mechanically protected and flexible cables. The card also contains the system audio amplifier to drive the internal speaker in the CU. It was laso fiited with an EEPROM which holds data specific to the CU to which it is fitted.
  4. ISU Card: This power supply is designed to provide the specific rails required for correct operation of the IAB circuitry. It is mounted on a Sub chassis under the CDROM.
- **The Optical Unit (CEIS-OU):** This is endomicroscope interface unit which performs the laser illumination and fluorescence detection functions. OU interfaces with the endomicroscope optically via a Diamon E2000 through adaptor, electrically via a Pentax supplied EPM connector and mechanically via the Pentax supplied EPM connector and a dowel locating connection. OU interfaces with the CU and the isolation transformer electrically via standard and proprietary cabling. The OU consists of a number of subsystems as detailed:
  1. The OSU: An OSU subassembly supply utilizes power factor corrected AC to isolated DC power which is distributed to other OU subassemblies. It contains 2 separate OEM power supply modules. One power direct to the ISS and the other supplies power to the DU and DUB via the OSB using standard cabling.
  2. The ISS: It provides controlled laser power to the endomicroscope via an optical fiber. It consists of a laser, laser controller, optical attenuation system and associated mechanical mountings. The laser emits a visible output at 488nm.
  3. The DU: Is a light tight enclosure that converts optical image information received from the sample via a multimode patchcord and converts it into an electrical signal. Inside the DU resides the IDA which contains photomultiplier tube that

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CEIS captures and displays endomicroscopy images of surface and subsurface layers of a tissue or organs site. The device transmits light from a variable output laser via an optical fiber and the laser light is focused to a diffraction-limited spot within the tissue. Scanning mechanism in the tip of endomicroscope is used to scan the focused point of laser light across an area of tissue and only the light returning from the focal spot in the tissue is focused back onto the tip of the optical fiber, and it propagated back to the detector.

When an image is captured, the CEIS stores the last complete image. The device uses a Look up Table (LUT) to display an image from the measured data.

Per owner's submission, the CEIS is not labeled or sold as a sterile device and there are no components that have a limited shelf life. Also, there are no components of the CEIS that come into direct or indirect contact with patients.

The device can only be used in the following applications using the compatible Confocal Endomicroscopes as indicated in the table below:

Application	Compatible Confocal Endomicroscopes	Compatible Digital Video Processor
Gastro Intestinal Examination	Pentax EC-3870CILK Pentax EC-3870CIFK Pentax EC-3870CIMK Pentax EC-3770CIK	Pentax EPK-1000

.The CEIS does not have any patient contact components or surface. Also the system is not labeled or sold as a sterile device and there are no components that have a limited shelf life.

CEIS is indicated for use as an aid or adjunct to a mode of therapy or diagnosis.

The video images from the device are not to be used for diagnosis purpose.

4.0 Performance characteristic

4.1 Technology and Hardware Construction:

Light from the laser is launched into an optical fiber which is used for both Illumination and an detection in the Optiscan CEIS.

CEIS can be used in either reflectance or fluorescence mode. The illumination wavelength for CEIS is 488nm (Blue) and the power used is in the order of hundreds of microwatts of optical power and the maximum illumination power used is 1mW. The illumination source is a solid state laser.

Below is the Optical Schematic for CEIS:

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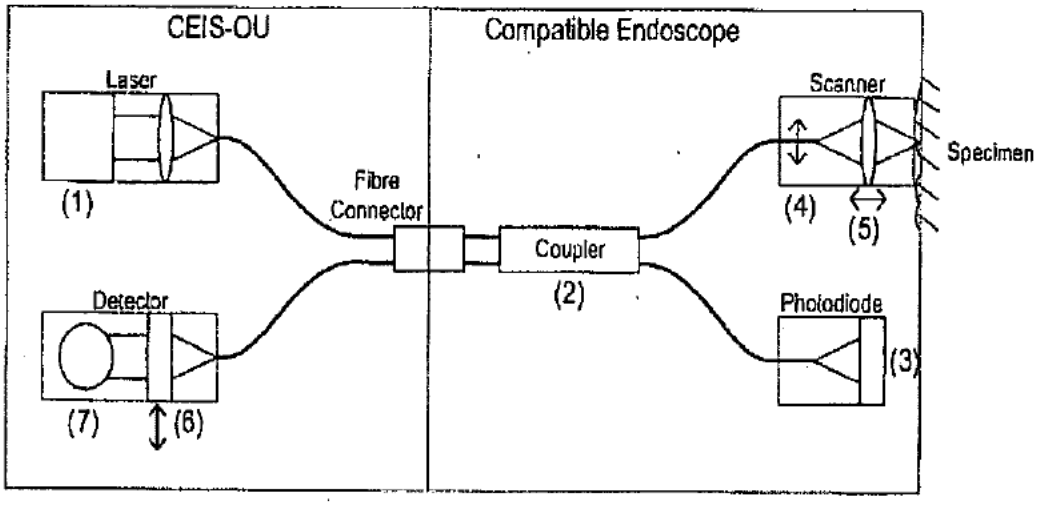

Description of Figure:

1. A laser generates the illumination signal.
2. A fibre optic coupler is used to separate the illumination and detection signals.
3. A photodiode in the endoscope is used to determine the amount of illumination power being emitted by the scanner.
4. The scanning mechanism moves the illumination beam laterally across the specimen.
5. The objective lens in the scanner moves to vary the imaging depth within the specimen.
6. A filter in the detection unit is used to select fluorescence mode or reflectance mode.
7. A photo multiplier tube (PMT) is used to detect the intensity of the optical signal returning from the specimen.

Per sponsor submission, there is no established performance standards for this device classification but the following consensus standards apply to the product:

1. IEC 60825-1, Safety of Laser Products, Part 1 – Equipment Classification, Requirements and user guide.
2. IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety
3. IEC 60601-1-1 Medical Electrical Equipment Part 1-1 – General Requirements for Safety – Safety requirements for medical electrical system.
4. IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety – Electromagnetic Compatibility – Requirements and Test.
5. IEC 60601-2-18 Medical Electrical Equipment Part 2-18: Particular Requirement for the Safety of endoscopic equipment.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4.2 Software Documentation

Software documentation for the CEIS is provided in Section 11 of the sponsor submission. Software related documentation that was provided in the submission is consisted with the intended use of the software device and the level of concern.

The documentation contains all information as required per the guidance documents "Guidance for the Content of Pre-market Submissions for Software contained in Medical Devices, dated May 11, 2005".

The level of concern for the software per owner submission is **"Minor Level".**

CEIS used the same software with Pentax ISC-1000 software (Version 2.3). There is minor changes to configuration files for the Software branding and the regeneration of installation CD's.

The CEIS/ISC-1000 software system consists of Graphical User Interface Applications, Libraries and Firmware. The interface applications are used by various users with various roles throughout the life of the medical device. The main application, clinical, resides on the medical device, and is the main controlling application for the system. Clinical is used during medical procedure to control the device and to capture procedural data. The software libraries provide three main functions: Device Control, Image Handling, and Data Storage. The firmware controls the Imaging System, Laser and Endoscope. ASC firmware implements acquisition and scan control. Laser firmware implements Laser control. ECB firmware implements control mechanisms for the insert in the endoscope.

Appendix L of the sponsor submission contained the Software Release information. The sponsor states that the software for CEIS is identical to the ISC-1000 software release with no change.

The submission included the following for this level of concern for general software guidance for the content of pre-market submissions.

4.201	Level of Concern:	Minor
4.202	Software Description:	Included
4.203	Software Hazards Analysis:	Included
4.204	Software Requirement Specifications:	Included
4.206	Software Dev. Environment Description:	Included
4.207	Verification & Validation:	Included
4.208	Traceability Matrix	Included
4.209	Revision Level History:	Included
4.210	Off-the-Shelf Software	Included

See Attachment 1 for Software Evaluation Review Memorandum.

5.0 Comparison to Legally marketed Devices

The Optiscan Confocal Endoscopic Imaging System (CEIS) is of comparable type and substantially equivalent to ISC-1000 Pentax Confocal Laser System (K042740).

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They have the same intended use, similar device description and device features.

Detailed differences (comparison table) between two systems are documented in Section 4.3 of the sponsor submission.

Per sponsor's submission, Optican is an OEM manufacturer of the Confocal Imaging System (known as ISC-1000) which is the predicate device. The device components and the suppliers that supply those components for ISC-1000 are identical to those that are used within the CEIS. Manufacturing processes and tests that are used to determine conformance of the ISC-1000 are identical to those that are used for CEIS. Also the processing of information collected by the device and the resultant output are identical.

Declaration of equivalence of the CEIS to the ISC-1000 is provided in Appendix G. The sponsor claims that the ISC-1000 and CEIS are essentially identical in performance and construction.

The differences are outline below:

- The labels that are applied to the CEIS product is different in respect to the Manufacturer's Name, European Representatives and the product Names/Model numbers. Labeling for the new device is provided in Appendix J and the example for the predicate device is on Appendix K.
- Software script that provides the logos within the software has been added to the system to provide the Optiscan Logo rather than the ISC-1000 logo.
- Manual supplied to the end user have been modified to be specific to Optiscan. See copies of the 2 CEIS Manuals in Appendix I of the sponsor's submission.
- (b)(4)

(b)(4) . See table below for information on the filter used:

Device	Filter Name	Light Bandwidth
Predicate Device (ISC-1000)	(b)(4)	
Optiscan CEIS		

The differences discussed per sponsor's submission do not raise new issues of safety and effectiveness.

6.0 Deficiencies and Resolution

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Date of Submission

Client response

Date of submission has been added to the cover letter.

(b)(4) Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8148

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

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7.0 Reviewer's Analysis

The complete 510(k) submission follows the pre-market notification information requirement 21 CFR 807.87 and Guidance for Industry and Staff Format for Traditional and Abbreviated 510(k), dated August 12, 2005.

The 510(k) submission fully describes the structural and functional characteristics of the device and its intended use. The descriptions are consistent throughout the submission and are supported by the device labeling.

The indication for Use Statement is consistent with the labeling and sufficient information provided in the labeling regarding directions for its use as required by 21 CFR 807.87(e).

Labeling included in Appendix I and J was reviewed against the FDA Device Labeling Guidance (G91-1) dated March 8, 1991. Appropriate information is provided in the labeling sections.

Declaration of Conformity to Standard was provided in Appendix N of the submission. Sponsor declares that all testing data are on file at Optiscan Pty Ltd.

Appendix G of the sponsor submission contained the "Declaration of Equivalence to the ISC-1000". Optiscan declare that Confocal Endoscopic Imaging System and related accessories is identical with the Product name " Confocal Imaging System" which is listed under Pentax Corporation. Confocal Imaging System is manufactured at the premises of Optiscan Pty Ltd and supplied to Pentax Corporation. The differences are the Labels, Product name and the Model number.

The submitter has compared the device to the legally marketed device and identified significant differences on the Comparison Table.

FDA Form 3654 for all applicable recognized consensus standards was filled out and included in Attachment 19 of the sponsor submission.

Hardcopy of the Certification Form FDA-3674 was included in attachment 20 of the submission, the owner's check box 9A, that claim that no clinical trial was reference by the submission.

The general guidance documents ("Guidance for the Content of Pre-market Submissions for Software Contained in Medical Device", dated May 11, 2005) have been applied in the submission and the device as been classified as **Minor level of concern**. The submission included all required information according to the guidance document.

Labeling review

The following information is included in various attachments of the submission:

- CEIS Owners Manual (Doc. #(b)(4), Rev. (b) Appendix I

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- CEIS Operators Manual (Doc. (b)(4), Rev (b) Appendix I
- Device Labeling Specification (Doc. # (b)(4) Rev. (b: Appendix J
- Predicate Device Labeling Example: Appendix K

8.0 Reviewer's Recommendation

The documents submitted allow for the decision that the Optiscan Confocal Endoscopic Imaging System (CEIS) is substantially equivalent to the legally marketed device, the ISC-1000 Pentax Confocal Laser System (K042740).

Based on my analysis of the Optiscan Pty. Ltd submission, I recommend that the device be determined substantially equivalent to the previously cleared devices.

Primary Third Party Reviewer:

(b)(6)

11/18/2009
Date

Responsible Third Party Official (or Designee):

(b)(6)

Tel: (b)(4)
Fax: (b)(4)
Email (b)(4)

(b)(6)

11/19/2009
Date

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Review Memorandum Attachment 1
Software evaluation

1.0 Administrative Information

510(k) Submitter:	**Optiscan Pty Ltd**
Common device name:	**Confocal Endoscopic Imaging System**
Trade name:	**Optiscan Confocal Endoscopic Imaging System (CEIS), Model: Optiscan CEIS**
Classification:	21 CFR 876.1500
Product Code:	GCJ
Classification Name:	Endoscope and Accessories
Software Release version number:	2.3

2.0 Determining level of concern

Table 1 MAJOR Level of Concern

If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be MAJOR	
1. Does the Software Device qualify as Blood Establishment Computer Software? (Blood Establishment Computer Software is defined as software products intended for use in the manufacture of blood and blood components or for the maintenance of data that blood establishment personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion or further manufacture.)	**No**
2. Is the Software Device intended to be used in combination with a drug or biologic?	**No**
3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?	**No**
4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:	**No**
a. Does the Software Device control a life supporting or life sustaining function?	**No**

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b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?	**No**
c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?	**No**
d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?	**No**
e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	**No**

Table 2 MODERATE Level of Concern

If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be MODERATE.	
1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?	**No**
2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?	**No**
3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	**No**

If the answers to all of the questions in Tables 1 and 2 above are No, the Level of Concern is Minor.

Level of concern determined as: Minor

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3.0 Software-related documents

3.1	Level of concern	Section 11.2
3.2	Software description	Section 11.1
3.3	Software Hazards Analysis	Section 11.3
3.4	Software requirements specification	Section 11.1
3.5	Software Development	Section 11.4
3.6	Software Change Management	Section 11.5
3.7	Verification/Validation documentation	Section 11.6 & Appendix L
3.8	Traceability Matrix	Section 11.7
3.9	Revision level history	Appendix L
3.8	Off-the-Shelf Software	Section 11.1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Screening Checklist 1.2

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Screening Checklist

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

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
X	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)] Manual.	Adequate	
Table of Contents.	Adequate	
Truthful and Accurate Statement.	Adequate	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	Adequate	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	Adequate	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	Adequate	
Statement of Indications for Use that is on a separate page in the premarket submission.	Adequate	
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)] Manual.	Adequate	
510(k) Summary or 510(k) Statement.	Adequate	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	Adequate	
Identification of legally marketed predicate device. *	Adequate	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	Present	
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)] Manual and the Convenience Kits Interim Regulatory Guidance.

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

	Present	Missing or Inadequate
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):		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Screening Checklist

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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	Missing or Inadequate
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.)		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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 <u>and</u> 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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

	Present	Missing or Inadequate
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	N/A	
b) Sterilization and expiration dating information:	N/A	
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	Present	

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: Michael S. Ogunleye
Date: 11/18/2009

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106

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Section 1

(b)(4) [redacted] Pre-Review Documentation

510(k) Decision Making Documentation 1.3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-7106; Rel(b)(4)

510(k) Review Program Decision Making

(b)(4) Report number: (b)(4)

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

Client:	**Optiscan Pty Ltd.**
510(K) Number If Known	
Reviewer:	(b)(6)
Division/Branch:	(b)(4) Third Party Reviewer
Device Name:	**Optiscan Confocal Endoscopic Imaging System (CEIS), Model: Optiscan CEIS**
Product To Which Compared (510(k) Number If Known):	**ISC-1000 Pentax Confocal laser System (K042740)**

	YES	NO	
1. Is Product A Device	X		If **NO** = Stop
2. Is Device Subject To 510(k)?	X		If **NO** = Stop
3. Same Indication Statement?	X		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5. Same Technological Characteristics?	X		If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?	X		If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-7106; Rel

510(k) Review Program Decision Making

(b)(4) Report number: (b)(4)

1. Intended Use:

The Optiscan Confocal Endoscopic Imaging System is intended to be used for confocal endomicroscopy of human tissue. The CEIS, its monitor, and a suitable confocal endomicroscope probe can provide microscopic visualization of the surface and subsurface of various body organs and tissues during endoscopic medical examination procedures

2. Device Description:

See Review Memorandum

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 IF NECESSARY

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-710

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Section 1

(b)(4) [redacted] Pre-Review Documentation

Reviewer's Conflict of Interest statement 1.4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

FDA 510(k) Review Program

(b)(4) [redacted]

Conflict of Interest Statement

(b)(4) [redacted]

CONFLICT OF INTEREST STATEMENT BASED ON THE FDA "STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE EXECUTIVE BRANCH"

(b)(4) [redacted] its employees, contractors, and subcontractors recognize the importance of preventing disclosure of confidential business information, of avoiding, and of reporting any activity that a reasonable person may deem to be an actual or potential conflict of interest. This corporate policy is underscored as it relates to the review of 510(k) submissions for the FDA as an FDA recognized third party. Before you sign this form please make sure you fully understand and acknowledge the content of the "Standards of Ethical Conduct for Employees of the Executive Branch."

In furtherance of this commitment to avoid any conflict of interest, each employee, contractor, and subcontractor of (b)(4) [redacted] assigned to conduct a 510(k) review is to carefully review, and fully adhere to the following:

1. Not to disclose, and to maintain in a secure manner to prevent accidental disclosure, any confidential business information of a (b)(4) [redacted] client of (b)(4) [redacted] to anyone except individuals at (b)(4) [redacted], the client, or FDA that have been identified by (b)(4) [redacted] as authorized to have access to the information.

2. Act impartially and not give preferential treatment to any individual or organization that contracts with (b)(4) [redacted] for a 510(k) review.

3. Employees of (b)(4) [redacted] may not offer to give, or give, or accept a gratuity from a customer, supplier or a representative of either in pursuance of business or in conjunction with negotiating business on behalf of this company. Gratuities are defined as anything of value. Expenses for meals as part of a seminar, convention, or business meeting are not within the definition of gratuities for purposes of this policy. Invitations extended by a customer or supplier to participate in any program or activity, such as a party or football game, should be referred to management for approval on a case-by-case basis.

4. Not engage in financial transactions using nonpublic information or allow the improper use of such information to further any private interest.

5. Not participate in any matter involving specific parties who are likely to or can directly affect the financial interest of a member of their household or a relative with whom they have a close personal relationship.

6. Disqualify his/herself from participating in particular matters involving former employers or companies he/she have been employed by or consulted for, or their representatives, who might present a COI and with whom he/she has worked within the past two (2) years.

7. Disqualify his/herself from conducting any 510(k) review of any medical device for any medical manufacturer or distributor if he/she (and/or spouse, minor children, general partners, etc.)
   a) currently has ownership or other financial interest (stocks, bonds, ownership, etc.) in any medical device, device manufacturer, or distributor
   b) within in the previous two (2) years has had involvement in design, manufacture or distribution;
   c) participated in the preparation of 510(k) submission.

8. Disclose to (b)(4) [redacted] FDA 510 (k) Review Supervisor all financial interests and activities that could cause a reasonable person to question the impartiality and objectively as it relates to any 510(k) review conducted for (b)(4) [redacted].

9. Disclosure of information to document No Conflict of Interest:
   a. Do you or immediate family members have any financial interest (stocks, bonds, ownership, etc.) in any medical device, device manufacturer, or distributor?

   ☐ Yes ☑ No ☐ Not Sure

   If yes or not sure, please provide additional information in an attachment.

   b. In the past two years, have you provided consulting services to any device manufacturer or distributor regarding any specific devices (e.g. preparation of 510(k)s, IDEs, PMAs or quality assurance consultation for the purpose of complying with GMPs)?

   ☐ Yes ☑ No ☐ Not Sure

   If yes or not sure, please provide additional information in an attachment.

Each employee, contractor and subcontractor shall carefully read, fully understand, and agree to abide by the (b)(4) [redacted] Conflict of Interest Statement for FDA 510(k) Reviewer outlined in this document. Violation of this Policy will result in corrective action up to and including termination, as determined by the (b)(4) [redacted] Personnel Policy Handbook, if applicable.

Date: 11/18/2009 Name: (b)(6) [redacted] Signature: (b)(6) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-7106

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Section 1

(b)(4) [redacted] Pre-Review Documentation

Predicate device documentation 1.5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

510(k) Premarket Notification Database

Device Classification Name	Laparoscope, General & Plastic Surgery
510(K) Number	K042740
Device Name	ISC-1000 PENTAX CONFOCAL LASER SYSTEM
Applicant	PENTAX MEDICAL COMPANY 102 Chestnut Ridge Road Montvale, NJ 07645
Contact	Paul Silva
Regulation Number	876.1500
Classification Product Code	GCJ
Subsequent Product Code	KOG
Date Received	10/04/2004
Decision Date	10/19/2004
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	Yes
Expedited Review	No

Database Updated 11/10/2008

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OCT 1 9 2004

K042740

510(k)Summary
Pentax Confocal Laser System

Submitter Information:

Pentax Medical Company
102 Chestnut Ridge Road
Montvale, New Jersey 07645-1856
Tel: (201)-391-0932

Name Of Device:

Trade Name:	Pentax Confocal Laser System
Classification Name:	Endoscope and Accessories (78KOG) {876.1500} [Class II]

Predicated Device(s) Information:

Model, Description	Manufacturer	PMN#
Zeiss Confocal Laser	Carl Zeiss, Inc.	K912581

Device Description:
The Pentax Confocal Laser System (software controlled device) is intended for use as a required accessory with Pentax video endoscope system that are equipped with confocal imaging module. The confocal laser system includes a laser light source, system computer, and display monitor. A video endoscope equipped with a confocal imaging module is connected to a conventional video endoscope system that will present the video endoscopic image. The endoscope is connected to the confocal system laser light source. The endoscope confocal imaging module contains an optical fiber that transmits laser light to, and receives return light from, the subject tissue. The confocal laser system contains a laser light source which produces visible laser light and contains signal detection circuitry to transmit/ receive the light signals through the endoscope confocal imaging module. The detected signal is sent to the system computer. The System Computer processes the confocal image information for display on the system monitor, controls the laser light source, and acts as an image storage device for still frame images.

Intended Use:
The Pentax confocal laser system is a required accessory for legally marketed video endoscopes equipped with a confocal laser imaging module. The system is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by the endoscope. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

Comparison To Predicated Device(s):
The submission for substantial equivalence included Pentax Confocal laser system literature including specifications, the identification of standard set components, and identification of optional accessories, comparison tables were provided to illustrate the comparisons to the predicated devices. The submission for substantial equivalence was not based on an assessment of clinical performance data.

Prepared By:

Paul Silva

Paul Silva, Regulatory Affairs Coordinator

09-09-2004
Date

Control Number: PS-726.ConfocalSys.510KS page 1 of 1

Revision: a

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2004

Pentax Medical Company
c/o Mr. Tamas Borsai
Division Manager, Medical Division, and
Program Manager, Third Party Review Program
TÜV Rheinland of North America
12 Commerce Road
Newtown, Connecticut 06470

Re: K042740
Trade/Device Name: ISC-1000 Confocal Laser System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ, KOG
Dated: September 30, 2004
Received: October 4, 2004

Dear Mr. Borsai:

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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8718

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OptiScan Pty Ltd
ABN 18 060 658 764

22 October 2009

To (b)(6) [redacted],

Please find attached a formal response to the 510(k) Deficiency Report (b)(4) [redacted] reference no. (b)(4) [redacted]. Please note a copy of the deficiency report is included as an annex to this letter for your convenience.

The deficiency report has been addressed in the following manner.

(b)(4) [redacted]

In addition the following other changes have been made to the submission document:

(b)(4) [redacted]

(b)(4) [redacted]

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OptiScan Pty Ltd
ABN 18 060 658 764

The modifications have been made and three (3) new sets of the 510k documentation has been compiled and sent with this letter. I hope that the modifications and responses to the deficiencies are sufficient to allow for the successful completion of the project and the forwarding of the document set to the FDA for clearance.

If you have any further queries please let me know.

Best Regards

Peter Pavlicek
Quality and Regulatory Affairs Manager

Optiscan Pty. Ltd.

(b)(4)

[redacted]

Records processed under FOIA Request # 2015-710

510(k) Deficiency Report

(b)(4) [redacted]

Optiscan Pty Ltd.
Optiscan CEIS

510(k) Submitter:	**Optiscan Pty Ltd.**
Type of Submission:	Traditional
Product:	**Optiscan Confocal Endoscopic Imaging System (CEIS)**
Common Name:	Confocal Endoscopic Imaging System
Classification:	21 CFR 876.1500
Product Code:	GCJ
Subsequent Product Code:	KOG
Classification Name:	Endoscope and Accessories
Legally Marketed Devices:	ISC-1000 Pentax Confocal Laser System (K042740)

(b)(4) [redacted]

Status:	Pending

Dear Mr. Peter Pavlicek,

After reviewing of your above mentioned FDA 510(k) submission response to the first deficiency report, deficiencies were established, therefore the files are not forwarded to FDA for clearance. For the details of these deficiencies please refer to the attached table.

Please perform the necessary modifications in your submission and in order to further processing please provide us three copies of the modified documents for submission.

We hope that you will find the most effective way of performing the necessary changes, and we can successfully finish your project.

Best regards,

(b)(6) [redacted]

8/6/2009
(Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

510(k) Deficiency Report

(b)(4) [redacted]

Table of Deficiencies

(b)(4) [redacted]

Record of Deficiencies

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2015-7

510(k) Deficiency Report

(b)(4) [redacted]

Optiscan Pty Ltd.
Optiscan CEIS

510(k) Submitter:	**Optiscan Pty Ltd.**
Type of Submission:	Traditional
Product:	**Optiscan Confocal Endoscopic Imaging System (CEIS)**
Common Name:	Confocal Endoscopic Imaging System
Classification:	21 CFR 876.1500
Product Code:	GCJ
Subsequent Product Code:	KOG
Classification Name:	Endoscope and Accessories
Legally Marketed Devices:	ISC-1000 Pentax Confocal Laser System (K042740)
(b)(4) [redacted]	[redacted]
Status:	Pending

Dear Mr. Peter Pavlicek,

After reviewing of your above mentioned FDA 510(k) submission response to the first deficiency report, deficiencies were established, therefore the files are not forwarded to FDA for clearance. For the details of these deficiencies please refer to the attached table.

Please perform the necessary modifications in your submission and in order to further processing please provide us three copies of the modified documents for submission.

We hope that you will find the most effective way of performing the necessary changes, and we can successfully finish your project.

Best regards,

(b)(6) [redacted]

8/6/2009
(Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # (b)(4)

510(k) Deficiency Report

Table of Deficiencies

(b)(4) Report number (b)
Attachment 1a

Record of Deficiencies

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2015-71

510(k) Deficiency Report

(b)(4) [redacted]

Optiscan Pty Ltd.
Optiscan CEIS

510(k) Submitter:	**Optiscan Pty Ltd.**
Type of Submission:	Traditional
Product:	**Optiscan Confocal Endoscopic Imaging System (CEIS)**
Common Name:	Confocal Endoscopic Imaging System
Classification:	21 CFR 876.1500
Product Code:	GCJ
Subsequent Product Code:	KOG
Classification Name:	Endoscope and Accessories
Legally Marketed Devices:	Pentax Confocal Laser System (K042740)
(b)(4) [redacted]:	[redacted]
Status:	Pending

Dear Mr. Peter Pavlicek,

After reviewing of your above mentioned FDA 510(k) submission, deficiencies were established, therefore the files are not forwarded to FDA for clearance. For the details of these deficiencies please refer to the attached table:

Please perform the necessary modifications in your submission and in order to further processing please provide us three copies of the modified documents or the complete submission.

We hope that you will find the most effective way of performing the necessary changes, and we can successfully finish your project.

Best regards,

(b)(6) [redacted]

(Signature)

December 10, 2008
(Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

510(k) Deficiency Report

Table of Deficiencies

(b)(4)

Attachment 1a

Record of Deficiencies

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

510(k) Deficiency Report

Table of Deficiencies

(b)(4) Report number: (b)(4)

Attachment 1a

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

25 May 2009

To (b)(6) [redacted]

Please find attached a formal response to the 510(k) Deficiency Report (b)(4) [redacted], reference no. (b)(4) [redacted]. Please note a copy of the deficiency report is included as an annex to this letter for your convenience.

The deficiency report seven (7) deficiencies which have been addressed in the following manner.

	(b)(4) [redacted]
Deficiency No. 1	
Deficiency No. 2	
Deficiency No. 3	
Deficiency No. 4	
Deficiency No. 5	
Deficiency No. 6	
Deficiency No. 7	

(b)(4) [redacted]

(b)(4) [redacted]

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OptiScan Pty Ltd
ABN 18 080 658 764

(b)(4)

[redacted]

The modifications have been made and three (3) new sets of the 510k documentation has been compiled and sent with this letter. I hope that the modifications and responses to the deficiencies are sufficient to allow for the successful completion of the project and the forwarding of the document set to the FDA for clearance.

If you have any further queries please let me know.

Best Regards

Peter Pavlicek
Quality and Regulatory Affairs Manager

Optiscan Pty. Ltd.

(b)(4)

[redacted]

Records processed under FOIA Request # 2015-7

510(k) Deficiency Report

(b)(4) [redacted]

Optiscan Pty Ltd.
Optiscan CEIS

510(k) Submitter:	**Optiscan Pty Ltd.**
Type of Submission:	Traditional
Product:	**Optiscan Confocal Endoscopic Imaging System (CEIS)**
Common Name:	Confocal Endoscopic Imaging System
Classification:	21 CFR 876.1500
Product Code:	GCJ
Subsequent Product Code:	KOG
Classification Name:	Endoscope and Accessories
Legally Marketed Devices:	Pentax Confocal Laser System (K042740)
(b)(4) [redacted] Report number:	(b)(4) [redacted]
Status:	Pending

Dear Mr. Peter Pavlicek,

After reviewing of your above mentioned FDA 510(k) submission, deficiencies were established, therefore the files are not forwarded to FDA for clearance. For the details of these deficiencies please refer to the attached table.

Please perform the necessary modifications in your submission and in order to further processing please provide us three copies of the modified documents or the complete submission.

We hope that you will find the most effective way of performing the necessary changes, and we can successfully finish your project.

Best regards,

(b)(6) [redacted]

December 10, 2008
(Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

Records processed under FOIA Request # 2015-710
(b)(4) [redacted]

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Section 1

(b)(4) [redacted] Pre-Review Documentation

Notes 1.7

(b)(4) [redacted]

(b)(4) [redacted] sion 4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OptiScan Pty Ltd
ABN 18 080 658 754

22 October 2009

To [redacted]
b

Please find attached a formal response to the 510(k) Deficiency Report (b)(4) reference no. (b)(4) [redacted]. Please note a copy of the deficiency report is included as an annex to this letter for your convenience.

The deficiency report has been addressed in the following manner.

Deficiency No. 1 (b)(4) [redacted]	(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

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Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

The modifications have been made and three (3) new sets of the 510k documentation has been compiled and sent with this letter. I hope that the modifications and responses to the deficiencies are sufficient to allow for the successful completion of the project and the forwarding of the document set to the FDA for clearance.

If you have any further queries please let me know.

Best Regards

Peter Pavlicek
Quality and Regulatory Affairs Manager

Optiscan Pty. Ltd.

(b)(4)

[redacted]

Records processed under FOIA Request # 2015-7

510(k) Deficiency Report

(b)(4) [redacted]

Optiscan Pty Ltd.
Optiscan CEIS

510(k) Submitter:	**Optiscan Pty Ltd.**
Type of Submission:	Traditional
Product:	**Optiscan Confocal Endoscopic Imaging System (CEIS)**
Common Name:	Confocal Endoscopic Imaging System
Classification:	21 CFR 876.1500
Product Code:	GCJ
Subsequent Product Code:	KOG
Classification Name:	Endoscope and Accessories
Legally Marketed Devices:	ISC-1000 Pentax Confocal Laser System (K042740)
[redacted] Report number:	(b)(4) [redacted]
Status:	Pending

Dear Mr. Peter Pavlicek,

After reviewing of your above mentioned FDA 510(k) submission response to the first deficiency report, deficiencies were established, therefore the files are not forwarded to FDA for clearance. For the details of these deficiencies please refer to the attached table.

Please perform the necessary modifications in your submission and in order to further processing please provide us three copies of the modified documents for submission.

We hope that you will find the most effective way of performing the necessary changes, and we can successfully finish your project.

Best regards,

(b)(6) [redacted]

8/6/2009
(Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 201

510(k) Deficiency Report

(b)(4)

Table of Deficiencies

(b)(4)

Attachment 1a

Record of Deficiencies

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2015-

510(k) Deficiency Report

(b)(4) [redacted]

Optiscan Pty Ltd.
Optiscan CEIS

510(k) Submitter:	**Optiscan Pty Ltd.**
Type of Submission:	Traditional
Product:	**Optiscan Confocal Endoscopic Imaging System (CEIS)**
Common Name:	Confocal Endoscopic Imaging System
Classification:	21 CFR 876.1500
Product Code:	GCJ
Subsequent Product Code:	KOG
Classification Name:	Endoscope and Accessories
Legally Marketed Devices:	ISC-1000 Pentax Confocal Laser System (K042740)
(b)(4) Report number:	(b)(4) [redacted]
Status:	Pending

Dear Mr. Peter Pavlicek,

After reviewing of your above mentioned FDA 510(k) submission response to the first deficiency report, deficiencies were established, therefore the files are not forwarded to FDA for clearance. For the details of these deficiencies please refer to the attached table.

Please perform the necessary modifications in your submission and in order to further processing please provide us three copies of the modified documents for submission.

We hope that you will find the most effective way of performing the necessary changes, and we can successfully finish your project.

Best regards,

(b)(6) [redacted]

8/6/2009
(Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7100 [redacted]

510(k) Deficiency Report

(b)(4) [redacted]

Table of Deficiencies

[redacted] Report number (b)(4) [redacted]

Attachment 1a

Record of Deficiencies

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2015-

510(k) Deficiency Report

(b)(4) [redacted]

Optiscan Pty Ltd.
Optiscan CEIS

510(k) Submitter:	**Optiscan Pty Ltd.**
Type of Submission:	Traditional
Product:	**Optiscan Confocal Endoscopic Imaging System (CEIS)**
Common Name:	Confocal Endoscopic Imaging System
Classification:	21 CFR 876.1500
Product Code:	GCJ
Subsequent Product Code:	KOG
Classification Name:	Endoscope and Accessories
Legally Marketed Devices:	Pentax Confocal Laser System (K042740)
[redacted] Report number:	(b)(4) [redacted]
Status:	Pending

Dear Mr. Peter Pavlicek,

After reviewing of your above mentioned FDA 510(k) submission, deficiencies were established, therefore the files are not forwarded to FDA for clearance. For the details of these deficiencies please refer to the attached table.

Please perform the necessary modifications in your submission and in order to further processing please provide us three copies of the modified documents or the complete submission.

We hope that you will find the most effective way of performing the necessary changes, and we can successfully finish your project.

Best regards,

(b)(6) [redacted]

(Signature)

December 10, 2008
(Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

510(k) Deficiency Report

(b)(4)

Table of Deficiencies

(b)(4) Report number (b)(4)

Attachment 1a

Record of Deficiencies

(b)(4)

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-7196; Released by CDRH on 03-01-2016

510(k) Deficiency Report

(b)(4) [redacted]

Table of Deficiencies

(b)(4) [redacted] Report number (b)(4) [redacted]

Attachment 1a

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015

510(k) Deficiency Report

(b)(4) [redacted]

Table of Deficiencies

(b)(4) [redacted] Report number: (b)(4) [redacted]

Attachment 1a

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OptiScan Pty Ltd
ABN 18 080 668 754

25 May 2009

To (b)(6) [redacted]

Please find attached a formal response to the 510(k) Deficiency Report ([redacted] reference no. (b)(4) [redacted]). Please note a copy of the deficiency report is included as an annex to this letter for your convenience.

The deficiency report seven (7) deficiencies which have been addressed in the following manner.

Deficiency No. 1	(b)(4) [redacted]
Deficiency No. 2	
Deficiency No. 3	
Deficiency No. 4	
Deficiency No. 5	
Deficiency No. 6	
Deficiency No. 7	

(b)(4) [redacted]

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OptiScan Pty Ltd
ABN 18 080 658 754

(b)(4)

[redacted]

The modifications have been made and three (3) new sets of the 510k documentation has been compiled and sent with this letter. I hope that the modifications and responses to the deficiencies are sufficient to allow for the successful completion of the project and the forwarding of the document set to the FDA for clearance.

If you have any further queries please let me know.

Best Regards

Peter Pavlicek
Quality and Regulatory Affairs Manager

Optiscan Pty. Ltd.

(b)(4)

[redacted]

Records processed under FOIA Request # 2015-7

510(k) Deficiency Report

(b)(4) [redacted]

Optiscan Pty Ltd.
Optiscan CEIS

510(k) Submitter:	**Optiscan Pty Ltd.**
Type of Submission:	Traditional
Product:	**Optiscan Confocal Endoscopic Imaging System (CEIS)**
Common Name:	Confocal Endoscopic Imaging System
Classification:	21 CFR 876.1500
Product Code:	GCJ
Subsequent Product Code:	KOG
Classification Name:	Endoscope and Accessories
Legally Marketed Devices:	Pentax Confocal Laser System (K042740)
(b)(4) Report number:	(b)(4) [redacted]
Status:	Pending

Dear Mr. Peter Pavlicek,

After reviewing of your above mentioned FDA 510(k) submission, deficiencies were established, therefore the files are not forwarded to FDA for clearance. For the details of these deficiencies please refer to the attached table.

Please perform the necessary modifications in your submission and in order to further processing please provide us three copies of the modified documents or the complete submission.

We hope that you will find the most effective way of performing the necessary changes, and we can successfully finish your project.

Best regards,

(b)(6) [redacted]

December 10, 2008
(Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 03-01-2016

510(k) Deficiency Report

(b)(4) [redacted]

Table of Deficiencies

(b)(4) [redacted] Report number (b)(4) [redacted]
Attachment 1a

Record of Deficiencies

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

(b)(4) Deficiencies

Records processed under FOIA Request # 2015-7106

FDA 510(k) Review Program

(b)(4) [redacted]

Table of Contents

Section 1

(b)(4) [redacted] Pre-Review Documentation

Notes 1.7

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-71(b)(4)

[redacted]

Section 2

Owner's Authorization Letter

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA Third Party 510(k) Review Program
Sponsor's Authorization

(b)(4) [redacted]

To Whom It May Concern:

We at Optiscan Pty. Ltd. _____
(name of sponsor)

hereby authorize (b)(4) [redacted] (b)(4) [redacted] to review and to submit the enclosed 510(k) application to the Food and Drug Administration (FDA) on our behalf, to discuss its contents with the FDA and to function as our Third Party Reviewer.

The enclosed Pre-market Notification 510(k) refers to the

Confocal Endoscopic Imaging System (CEIS)_____
(name of product)

product, manufactured by

Optiscan Pty. Ltd. _____
(name of manufacturer)

We certify that we have not contacted another Third Party Reviewer to perform the review of the 510(k) submission.

Authorization by Officer of the Manufacturer

Peter Pavlicek		8/12/2008
(print name)	*(signature)*	*(date)*

Please return this form to:

(b)(4) [redacted]

347

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

22 October 2009

To whom it may concern,

Please find attached the "510(k) Notification" (21CFR 807.90(e)) for the Optiscan Confocal Endoscopic Imaging System (CEIS) Medical Device.

The submission includes required declarations which are provided in the main submission document. These include:

- Truthful and Accuracy Statement (See Appendix A)
- 510(k) Summary of Safety and Effectiveness (See Appendix D)
- Declaration of Conformity to Standard (See Appendix N)

Summary information about the submission is provided below for convenience.

Submitter Information:

Company Name:	Optiscan Pty Ltd
Address:	15-17 Normanby Road, Notting Hill, Victoria, 3168, AUSTRALIA
Telephone:	(+61 3) 95383333
Fax:	(+61 3) 9562 7742
Contact Person:	Mr Peter Pavlicek
E-Mail Address:	peterp@optiscan.com
FDA Establishment Registration No.:	3003562930
Date of Submission:	22 October, 2009

(b)(4)

[redacted]

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OptiScan Pty Ltd
ABN 15 000 659 764

Administrative Information:

CFR21 Section: 21CFR876.1500 **Product Code:** GCJ, KOG

Classification Panel: General & Plastic Surgery, Gastroenterology/Urology

Device Class: ☐ Class I ☑ Class II

Legally Marketed Comparison Device(s) – at least one legally marketed device must be listed:

1. Pentax Confocal Laser System K #: K042740
2. K #:

Common Device Name: Confocal Endoscopic Imaging System

Trade or Proprietary Device Name: Optiscan CEIS

Submission Type:

☐ Abbreviated

☑ Traditional

☐ Special

☑ Third Party Review

Reviewer: TUV RHEINLAND OF NORTH AMERICA, INC.

Purpose:

☑ New Device

☐ Change in

☐ Technology

☐ Design

☐ Material

☐ Manufacturing Process

☐ Other

(b)(4)

[redacted]

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OptiScan Pty Ltd
ABN 18 003 658 764

Design and Use of the Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)? [A]		✓
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?[A]		✓
Does the device contain components derived from a tissue or other biologic source?		✓
Is the device provided sterile?		✓
Is the device intended for single use?		✓
Is the device a reprocessed single use device?		✓
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		✓
Does the device contain a biologic?		✓
Does the device use software?	✓	
Does the submission include clinical information?		✓
Is the device implanted?		✓

[A] A device may be intended for both prescription and over-the-counter use. If so, the answer to both of these questions is yes.

Peter Pavlicek
Quality and Regulatory Affairs Manager

Optiscan Pty. Ltd.

(b)(4)

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
1/22/2009		

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☑ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☑ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☑ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

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

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Optiscan Pty. Ltd.	Establishment Registration Number *(if known)*: 3003562930
Division Name *(if applicable)*:	Phone Number *(including area code)*: ( ) (+61 3) 95383333
Street Address: 15-17 Normanby Road	FAX Number *(including area code)*: ( ) (+ 61 3) 9538 7742

City	State / Province	ZIP/Postal Code	Country
Notting Hill	Victoria	3168	Australia

Contact Name: Peter Pavlicek	
Contact Title: Quality & Regulatory Affairs Manager	Contact E-mail Address: peterp@optiscan.com

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

Company / Institution Name:	
Division Name *(if applicable)*:	Phone Number *(including area code)*: ( )
Street Address:	FAX Number *(including area code)*: ( )

City	State / Province	ZIP/Postal Code	Country

Contact Name:	
Contact Title:	Contact E-mail Address:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

PSC Graphics: (301) 443-1090 EF

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Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*
- ☐ Response to FDA correspondence:
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing
- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☑ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☐ Other Reason *(specify)*:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GCJ	2	KOG	3		4	
		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K042740	1	ISC-1000 Pentax Confocal Laser	1	Pentax Medical Company
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Endoscope and Accessories (21CFR876.1500)

	Trade or Proprietary or Model Name for This Device		Model Number
1	Optiscan CEIS	1	Optiscan CEIS
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [ ] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
GCJ, KOG	21CFR876.1500	[ ] Class I [x] Class II
Classification Panel: General & Plastic Surgery, Gastroenterology/Urology		[ ] Class III [ ] Unclassified

Indications *(from labeling)*

The Optiscan Confocal Endoscopic Imaging System (CEIS) is intended to be used for confocal endomicroscopy of human tissue. The CEIS, its monitor, and a suitable confocal endomicroscope probe can provide microscopic visualization of the surface and subsurface of various body organs and tissues during endoscopic medical examination procedures. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number	☑ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name Optiscan Pty Ltd		Establishment Registration Number 3003562930		
Division Name *(if applicable)*		Phone Number *(including area code)* ( ) (+61 3) 95383333		
Street Address 15-17 Normanby Road		FAX Number *(including area code)* ( ) (+ 61 3) 9538 7742		
City Notting Hill		State / Province Victoria	ZIP/Postal Code 3168	Country Australia
Contact Name Peter Pavlicek	Contact Title Quality & Regulatory Manager		Contact E-mail Address peterp@optiscan.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60825-1	IEC	Medical electrical equipment Part 1: General Requirements for Safety	1993+A1:1997 +A2:2001	
2	60601-1	IEC	Medical electrical equipment Part 1: General Requirements for Safety	1998+A1:1991 +A2:1995	
3	60601-1-1	IEC	Medical electrical equipment Part 1-1 - General requirements for safety - Safety requirements for medical electrical systems	2000	
4	60601-2-18	IEC	Medical electrical equipment Part 1-2: General Requirements for Safety - Electromagnetic Compatibility - Requirements and Tests	1996+A1:2000	
5	60601-1-2	IEC	Medical electrical equipment Part 1-2: General Requirements for Safety - Electromagnetic Compatibility - Requirements and Tests	2001	
6					
7					

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

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

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

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

510(k) Submission

Optiscan Confocal Endoscopic Imaging System (CEIS)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

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Appendix F: Indications for Use Statement

Appendix G: Declaration of Equivalence to the ISC-1000

Appendix H: Isolation Transformer Specification

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Appendix M: Standards Data Report for 510(k)s

Appendix N: Declaration of Conformity to Standard

Appendix O: Requirements for Clinical Trials (Form 3674)

Appendix P: Manufacturing Flowcharts

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

1 Submitter Information

1.1 Submitter/ Applicant:

Optiscan Pty. Ltd.
15-17 Normanby Road
Notting Hill, Victoria, 3168
Australia
Establishment Registration Number: 3003562930
Owner/Operator Number: 9044050
Phone: (+61 3) 95383333
Fax: (+ 61 3) 9538 7742
Website: http://www.optiscan.com

1.2 Contact Person:

Peter Pavlicek
Quality and Regulatory Affairs Manager
Optiscan Pty. Ltd.
15-17 Normanby Road
Notting Hill, Victoria, 3168
Australia
Phone: (+61 3) 95383348 (Direct)
Fax: (+ 61 3) 9538 7742
Email: peterp@optiscan.com

1.3 US Agent:

Grace Holland
Regulatory Specialists, Inc.
3722 Ave Sausalito
Irvine, CA 92606
United States of America
Phone: 949 262
Fax: 949 552
Email: grace@regulatoryspecialists.com

1.4 Premarket Notification Truthful and Accurate Statement:

The Premarket Notification Truthful and Accurate Statement is provided in Appendix A.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2 Manufacturer Information

2.1 Manufacturer Details

Optiscan Pty. Ltd.
15-17 Normanby Road
Notting Hill, Victoria, 3168
Australia
Establishment Registration Number: 3003562930
Owner/Operator Number: 9044050
Phone: (+61 3) 95383333
Fax: (+ 61 3) 9538 7742
Website: http://www.optiscan.com

2.2 Manufacturer Contact Details

Peter Pavlicek
Quality and Regulatory Affairs Manager
Optiscan Pty. Ltd.
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Notting Hill, Victoria, 3168
Australia
Phone: (+61 3) 95383348 (Direct)
Fax: (+ 61 3) 9538 7742
Email: peterp@optiscan.com

2.3 Manufacturer Quality System Details

Optiscan Pty Ltd is a quality certified company with ISO13485 certification. The current certifications for the company are listed below.

1. EN ISO 13485:2003 Certificate Registration Number SX 60014014 0001. Date of expiry: 1/3/2011, by TUV Rheinland.

This certificate is provided in Appendix B, along with a list of the Standard Operating Procedures of the Quality System.

2.4 Manufacturer Layout

A floor plan of Optiscan Pty Ltd is provided in Appendix C detailing the Production, inspection and despatch areas.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3 Device Registration Information

3.1 510(k) Summary of Safety and Effectiveness:

The 510(k) Summary of Safety and Effectiveness is provided in Appendix D.

3.2 Device Classification

Classification Name:	Endoscope Accessories
Classification Code:	GCJ, KOG
21 CFR Identification:	876.1500 Endoscope and Accessories
Common Name:	Pentax Confocal Laser System
Trade Name:	Optiscan CEIS
Establishment Operations:	Manufacturer

Table 1 –Device Classification details for the CEIS

3.2.1 Current Product Certifications

The CEIS has currently a CE Mark Certification and NRTL certification. The certificate is listed below and copies of the certifications are provided in Appendix E.

1. Annex II 93/42/EEC Certificate Number: HD 60014013 0001 by (b)[redacted] (b)(4)[redacted] with Date of Issue 2/3/2006
2. NRTL License. Certificate Number (b)(4)[redacted] by (b)(4)[redacted]. Date of issue 7/10/2008.

3.3 Identification of Predicated Device(s)

1. Sponsor Name:	Pentax Medical Company
2. Product Description:	ISC-1000 Pentax Confocal Laser System
3. Product Classification Code:	GCJ, Laparoscope, general & plastic surgery KOG, Endoscope and/or accessories
4. Date of Substantial Equivalence:	10-19-2004
5. 510(k) Number:	K042740

Table 2 –Identification Details of the Predicate Device

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3.4 Performance Standard:

To the best of our knowledge, no performance standards have been established for the device classification. The following consensus standards apply to the product:

1. IEC 60825-1, Safety of Laser Products, Part 1- Equipment classification, requirements and user's guide
2. IEC 60601-1 Medical electrical equipment Part 1: General Requirements for Safety
3. IEC 60601-1-1 Medical electrical equipment Part 1-1 - General requirements for safety - Safety requirements for medical electrical systems
4. IEC 60601-1-2 Medical electrical equipment Part 1-2: General Requirements for Safety - Electromagnetic Compatibility - Requirements and Tests
5. IEC 60601-2-18 Medical electrical equipment Part 2-18: Particular Requirements for the safety of endoscopic equipment

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4 Intended Use and Comparisons/ Differences to Predicate(s)

4.1 Intended Use

The Optiscan Confocal Endoscopic Imaging System (CEIS) is intended to be used for confocal endomicroscopy of human tissue. The CEIS, its monitor, and a suitable confocal endomicroscope probe can provide microscopic visualization of the surface and subsurface of various body organs and tissues during endoscopic medical examination procedures. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

4.2 Indications for Use Statement

The Indications for Use Statement is provided in Appendix F.

4.3 Substantial Equivalence Discussion

4.3.1 Criteria for Predicated Device(s) Selection

The Criterion used to demonstrate Substantial Equivalence are listed below.

- Intend Use
- Materials
- Manufacture
- Performance Specifications

4.3.2 Similarities between the Submission and Predicate Device(s)

Optiscan acts as the OEM manufacturer of the Confocal Imaging System (also known as the ISC-1000) which is the Predicate device listed:

- Both devices are intended to allow confocal laser imaging of human tissue during endoscopic medical examination procedures.
- The device components and the suppliers that supply those components for ISC-1000 are identical to those that are used within the CEIS.
- The manufacturing processes and tests that are used to determine conformance of the ISC-1000 are identical to those that are used within the CEIS. An outline of these are provided in Appendix I.
- The processing of information collected by the device and the resultant output are identical.

A declaration of equivalence of the Optiscan Confocal Endoscopic Imaging System (CEIS) to the Confocal Imagng System (also known as the ISC-1000) is provided in Appendix G. The ISC-1000 and the CEIS are essentially identical in performance and construction except for the differences as outlined below in Section 3.2.3

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4.3.3 Differences between the Submission and Predicate Device(s)

Differences between the predicate devices and the submission device are described below:

- the labels that are applied to the above named Products differ only in respect of the Manufacturer's Names, the European Representatives and the Product Names and Model Numbers. The CEIS Device Labeling Specification is provided in Appendix J and, examples of the predicate device labeling are provided in Appendix K.

- A software script that provides the logos within the software has been added to the system to provide the Optiscan Logo rather than the ISC-1000 logo.

- The manuals supplied to the end user have been modified to be specific to Optiscan and the CEIS rather than Pentax and the ISC-1000. Copies of the two CEIS Manuals are provided in Appendix I.

(b)(4)

[redacted]

The Specifications of (b)(4) [redacted] are provided in the Figures 1 & 2 below.

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(b)(4)

[redacted]

A detailed manufacturing Work Instruction describing the differences is on file and held at Optiscan.

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4.4.4 Summary Table of Predicate Device Substantial Equivalence

	Predicate Device (ISC-1000)	Submitted Device (CEIS)
Intended Use	• Is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by the endoscope. • Is intended to be used with the Pentax EC-3870CILK Video Endoscope • Is Intended to be applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations	• Is intended to be used for confocal endomicroscopy of human tissue during endoscopic examination procedures. • Is intended to be used with any suitable confocal endomicroscope probe. This includes the Pentax EC-3870CILK Video Endoscope • The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.
Materials	The materials used to manufacture the ISC-1000 and the CEIS are identical apart from the • device labelling • user instructions • an additional filter	
Manufacture	The Manufacturing of the ISC-1000 and the CEIS utilise the same Work Instructions and In Process test specifications to ensure conformance. All actions are performed at Optiscan Pty Ltd.	
Performance Specifications Confocal Laser Scanning	**ISC-1000 with scope EC-3870CILK**	**CEIS with scope EC-3870CILK**
Wavelength:	488 nm ± 2 nm	488 nm ± 2 nm
Scanner Maximum Optical Output Power:	1 mw @ 488 nm	1 mw @ 488 nm
Transverse modes:	M^2 <1.1, TEMoo	M^2 <1.1, TEMoo
Field of View (minimum):	500 x 500 µm	500 x 500 µm
Depth Range (minimum):	0 – 200 µm	0 – 200 µm
Confocal Axis Response:	8 µm	8 µm
Confocal Lateral Response:	1 µm	1 µm
Scan Modes:	2	2
Scan Mode 1 resolution/ Frame Rate (/sec):	1024 x 1024 / 0.7	1024 x 1024 / 0.7
Scan Mode 2 resolution/ Frame Rate (/sec):	1024 x 512/ 1.2	1024 x 512/ 1.2

Table 4 –Summary Table of Predicate Device Substantial Equivalence

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5 Device Description

5.1 Principle of Operation:

In the Optiscan CEIS, light from a laser is launched into an optical fibre which is used for both illumination and detection. The fibre is attached to a scanning mechanism in the distal end of a compatible endoscope. The scanning mechanism within this endoscope scans a low power focussed point of laser light over the field of view in the translucent specimen. On emerging from fibre tip in the scanning mechanism, the light is focussed to a point within the specimen. Only light returning from the focal plane within the specimen is collected back at the fibre tip to be transmitted back into the Optiscan CEIS system.

In the CEIS system, the returning light is detected by an optical detector in the Optical Unit (CEIS-OU) and converted into an electrical signal. A computer in the Control Unit (CEIS-CU) digitises the signal and position information from the scanner, and then processes and displays the resulting information as a 2 dimensional real time image on the confocal monitor.

Once a suitable image is identified from the real time screen image it may be captured by operating a foot switch or a button displayed on the touch screen of the confocal monitor. Each captured image is stored on the hard disc of the CU1000 for later review. Each image may have information associated with it including patient details and image property information.

The main user interface is via a touch screen on the confocal monitor. Navigation between screens is achieved by operating buttons on the touch screen or by operation of the touch-pad that is located on the keyboard of the CEIS-CU.

The focal plane within the specimen that the image is collected from can be varied by the user by adjusting the position of a lens in the tip of a compatible endoscope. This is done by actuating control buttons on the control body of the endoscope. The maximum depth of optical sectioning depends on the wavelength of light used and the translucency of the object.

The design of the distal end of the endoscope enables immobilisation of the tip in relation to the tissue by wet surface contact (very gentle surface pressure) so that the two move together and thereby allows clear images to be collected.

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The CEIS can be used in either reflectance or fluorescence mode. Reflectance mode uses reflected light when imaging cellular structures and relies on the differences in the reflectivity of structures in order to differentiate between them. In fluorescence mode, fluorescence emitted by the tissue or exogenously applied fluorophores may be detected to provide contrast in the structures being investigated. A specific light source, at the appropriate wavelength, is used to illuminate the tissue structure or fluorophore distribution and the emitted fluorescence signal is measured at a longer wavelength. In the CEIS the illumination wavelength is 488nm (blue). The illumination power used is in the order of hundreds of microwatts of optical power and the maximum illumination power used is 1mW. The illumination source is a solid state laser. The CEIS does not have any patient contact components or surfaces.

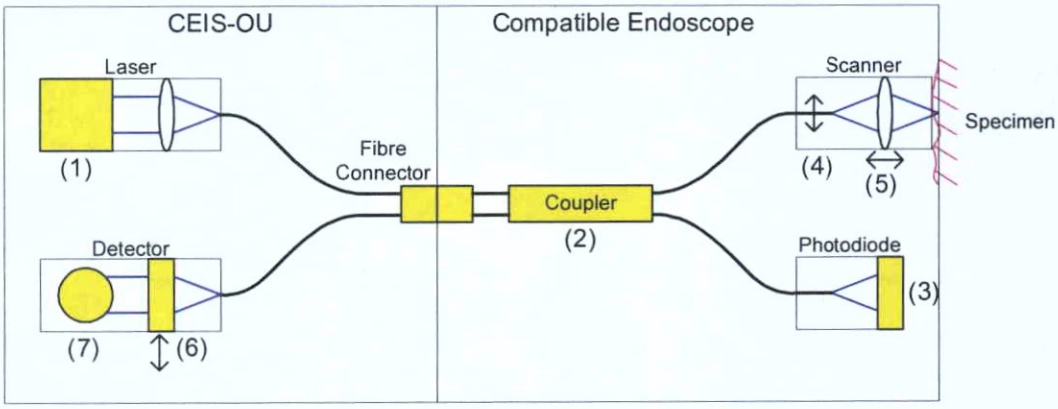

Figure 3 – Optical Schematic

Description of Figure:

1. A laser generates the illumination signal.
2. A fibre optic coupler is used to separate the illumination and detection signals.
3. A photodiode in the endoscope is used to determine the amount of illumination power being emitted by the scanner.
4. The scanning mechanism moves the illumination beam laterally across the specimen.
5. The objective lens in the scanner moves to vary the imaging depth within the specimen.
6. A filter in the detection unit is used to select fluorescence mode or reflectance mode.
7. A photo multiplier tube (PMT) is used to detect the intensity of the optical signal returning from the specimen.

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A typical example of a resultant image is shown below.

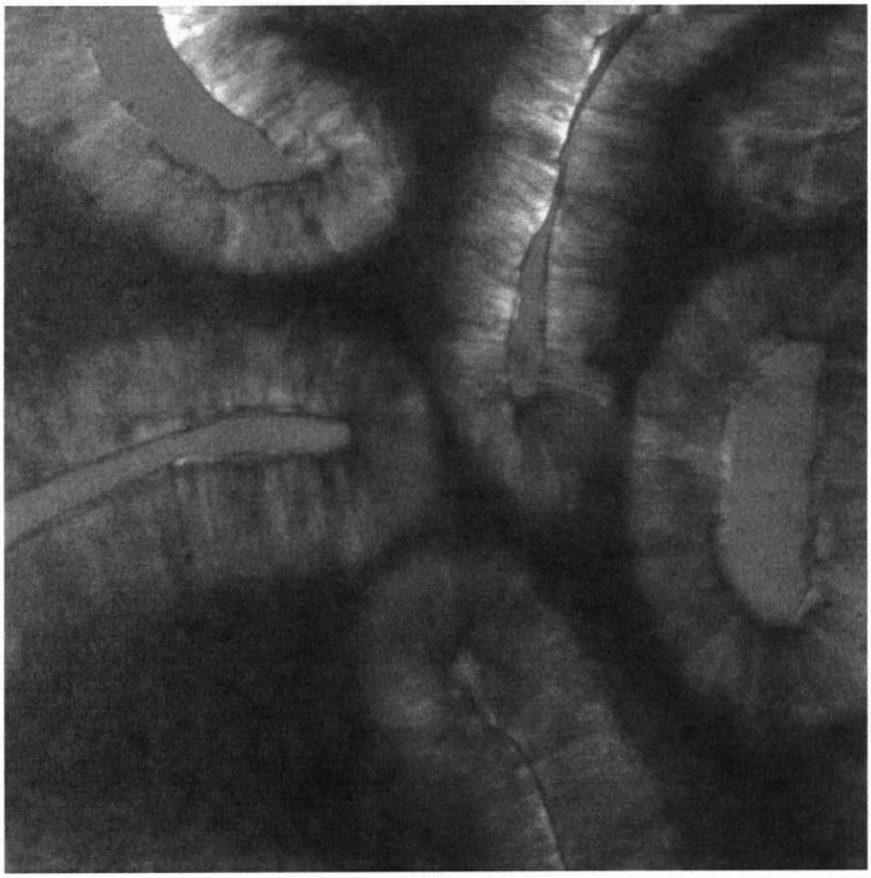

Figure 4 – A Typical Endoscopic Image of a polyp in the colonic mucosa. Image courtesy Professor Finlay Macrae, Cabrini Hospital, Melbourne, Australia.

The CEIS at present can only be used in the following applications using the Compatible Confocal endomicroscopes as indicated in the table below. Where a compatible endomicroscopes also utilises other standard endoscope functions that requires other processing equipment, these have also been indicated.

Application	Compatible Confocal Endomicroscopes	Compatible Digital Video Processor
Gastro Intestinal Examination	EC-3870CILK (PENTAX) EC-3870CIFK (PENTAX) EC-3870CIMK (PENTAX) EG-3770CIK (PENTAX)	EPK-1000 (PENTAX)

Table 5 –List of Compatible Applications and Endoscopes that can be used with the CEIS

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5.2 Components:

The Confocal Endomicroscopy Imaging System (CEIS) consists of three main units.

1. The Control Unit (CEIS-CU) together with its monitor, keyboard, and footswitch, is a computer based unit which performs the instrument control, and image capture and processing functions of the CEIS.
2. The Optical Unit (CEIS-OU) a specialised endomicroscope interface unit which performs the laser illumination and fluorescence detection functions of the CEIS.
3. The Isolation Transformer.

The overall block diagram of the CEIS is shown in the following figure. The block diagram shown also indicates (b)(4) [redacted].

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Diagram

[redacted]

Figure 5 – Overall Block Diagram of the CEIS

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(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

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(b)(4) Software Information

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(b)(4) Software Information

[redacted]

5.2.3 The Isolation Transformer

The Isolation Transformer is a Non-Proprietary Accessory which is used to provide electrical isolation to IEC 60601-1 safety standard for the CCB1.5 system. It is a Class I, Type B equipment with CE certification (CE003).

Refer to Appendix H for a complete specification as provided by the manufacturer of the Transformer.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6 Device Instructions

Details of the device labelling of the Optiscan Confocal Endoscopic Imaging System (CEIS) is provided in Appendix I.

7 Device Labelling

Details of the device labelling of the Optiscan Confocal Endoscopic Imaging System (CEIS) is provided in Appendix J.

Examples of the predicate device labelling have been provided in Appendix K.

8 Promotional Material

At present there is no promotional material that has been developed for the Optiscan Confocal Endoscopic Imaging System (CEIS).

9 Sterilization and Shelf Life

The Optiscan Confocal Endoscopic Imaging System (CEIS) is NOT labelled or sold as a sterile device and there are no Components that have a limited shelf life.

10 Biocompatibility

There are no Components of the Optiscan Confocal Endoscopic Imaging System (CEIS) that come into direct or indirect contact with patients and as a result no biocompatibility of materials is required.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

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11.2 Software Level of Concern:

In accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for software Contained in Medical device" Dated May 11, 2005,

We believe the level of Concern is **Minor** as any failures or latent design flaws are unlikely to cause any injury to the patient or operator. The Justifications are listed below.

- The function of the software is solely to control the scanning mechanisms of the device, and acquire the resulting scanned images (through interaction with a connected and compatible PENTAX Confocal Endoscope) and present these images (in a raw format absent of any post processing) to the end user via a monitor. The interaction with the connected endoscope is through laser power (of which the software can adjust) which by design cannot deliver an output greater than 3.5mw. This limit is controlled independently of the software, and as a result the software cannot cause any direct injury.

- With regard to potential misdiagnosis or delay of treatment (indirect injury), Optiscan have been explicitly clear that the device is an adjunct only to normal endoscopy (ie) providing additional information to an endoscopist, and is not to be used for diagnostic purposes (Please see the warning under the intended Use section 2.2 of the user manual 001686). A brief explanation of the typical workflow is attached

  The CEIS when attached to a compatible confocal endomicroscope provides confocal imaging capability over and above the normal video endoscope features as called upon in routine endoscopy. The confocal image is provided separately from the primary endoscopic view.

  The primary endoscopic view is used to guide the endoscopy including insertion, anatomical navigation, selection of sites of interest and positioning for biopsy or other minor surgical interventions conducted using accessories introduced via the working channel of the scope. It should be noted that none of these functions are dependent on confocal imaging to be performed as in routine endoscopic procedures where a confocal imaging capability is absent.

  The scope insertion part of the procedure does not usually involve any confocal imaging and certainly does not require it. Once fully inserted, the macroscopic (video) image produced by the endoscope is used for close examination of areas of interest within the anatomical tract. Any site may be selected for biopsy or other intervention based purely on this macroscopic view, and the confocal imaging capability may not be called upon at all.

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Alternatively, areas of interest or randomly placed sites may be interrogated with the confocal imaging capability as an adjunct to the conventional visualisation. This provides high magnification images revealing fine structure not visible with the macroscopic view of the instrument. This has the possibility to unmask additional features of interest for documenting the in vivo microscopic appearance of the tissue (including in the case that biopsies would not be indicated, thereby providing additional information that would be absent from a typical endoscopy record from such a site) or in the case that exceptional structures are noticed at a given site, may give additional cause for suspicion leading to biopsy sampling (if already indicated within the course of the endoscopic procedure and considered safe to do so based on conventional endoscopy considerations) of that specific region. If the confocal capability is not called upon, the other features of the scope are used as per routine endoscopic examination as performed using an endoscope that does not have confocal imaging capability.

In the event that there are technical problems obtaining desirable confocal images (e.g. excessive movement artefacts; difficulty apposing tissue with imaging window; opaque residues/stool/food on surface of tissue; confocal imaging failure) the endoscopy would proceed as with a conventional endoscope not enabled with confocal imaging capability.

This would mean that there has been negligible delay in normal patient care and treatment suggesting there is a that there is a very low risk of indirect injury suggesting that the software should be a minor level of concern. To mitigate against possible malfunction of the device we deliberately included a pre test as per the user manual (document 001686 section 5.3) to check that the instrument is functioning and producing a acceptable image prior to it being used in any clinical procedure.

- The software is not intended to provide any function in the failure of which could result in any foreseeable injury to a patient or end user.

- The device and its software does not qualify as a Blood Establishment Computer Software.

- The device and its software is not intended to be used in combination with a drug or biologic outside the normal prescribed drugs provided in Surgical applications

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- The device and its software is not an accessory to any medical device that has software with a Major or Moderate Level of Concern

- The device and its software does not provide life supporting or life sustaining functions.

- The device provides a radiating laser energy to the soft tissue being scanned, however he inherit design would not allow the laser output at the probe of 3.5mw and in addition the system contains a Laser Safety Shut-off circuit independent of the software that trips at ≈3.5 mW, this is well below the Class 3R maximum power level 5 mW (IEC 60825).

- The device and its software does not provide any control of delivery or treatment

- The device and its software does not provide any diagnostic information that directly drives a decision regarding treatment or therapy

- The device and its software does not provide and monitoring of vital signs or alarms for any potentially life threatening situations where a medical intervention would be required.

- Any latent design flaw within the device that would cause a malfunction during the use of the device cannot cause any minor injury. The failure of the device would result in the device being unable to be used during a procedure and would provide inconvenience to the end user only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8148

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11.3 Software Hazards Analysis:

The hazard analysis to follow is prepared using the following definitions and criteria for Risk Level Assessment:

Table 6 - Probability of Occurrence	
Rating	**Description**
1	Improbable- possible but highly unlikely
2	Remote- possible but not normally expected
3	Occasional- expected as an infrequent occurrence
4	Probable- expected as a normal occurrence
5	Frequent- certain to occur most of the time

Table 7 - Severity of Harm	
Rating	**Description**
1	Negligible- little or no potential for injury
2	Marginal- has the potential to cause minor injury
3	Critical- has the potential to cause serious injury or death

Note: Serious injury = loss of body part, permanent impairment to a body function, or the need for medical intervention to preclude the loss of a body part or permanent impairment to a body function.

Table 8 – Risk Levels	
Level	**Description**
Minor	No other mitigation measures required
Moderate	Mitigation is recommended where it is possible to do so
Major	Mitigation is required to reduce the risk level of concern

Table 9 – Risk Level Calculation	
Probability*Severity	**Risk**
≤5	Minor
6 - 8	Moderate
≥9	Major

Table 10 – Risk Level Lookup			
Probability	**Severity**		
	1 - Negligible	2 - Marginal	3 - Critical
1 – Improbable	Minor	Minor	Minor
2 – Remote	Minor	Minor	Moderate
3 – Occasional	Minor	Moderate	Major
4 - Probable	Minor	Moderate	Major
5 - Frequent	Minor	Major	Major

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11.3.1 System Block Diagram Reviewed under the Hazards Analysis

(b)(4)

[redacted]

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(b)(4) Software Information

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(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Functional Requirements and Traceability Matrix

(b)(4) Software Functional Requirements and Traceability Matrix

(b)(4) Software Functional Requirements and Traceability Matrix

(b)(4) Software Functional Requirements and Traceability Matrix

(b)(4) Software Functional Requirements and Traceability Matrix

(b)(4) Software Functional Requirements and Traceability Matrix

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12 Electromagnetic Compatibility and Electrical Safety

The unit testing was performed in accordance with the requirements as identified in the standards and the results demonstrated that the pre-determined acceptance testing criteria were met. These reports are held on file at Optiscan Pty Ltd.

The CEIS System was tested to the following standards.

- IEC 60601-1:1988+A1:1991 + A2:1995
- IEC 60601-1-1:2000
- IEC 60601-1-2: 2001
- IEC 60601-2-18: 1996 + A1:2000
- IEC 60825-1:1993 + A1:1997 + A2:2001

Standards Data Report forms (FDA 3654) for each of the listed standards above are provided in Appendix M

A Declaration of Conformity to Standard is provided in Appendix N.

Safety Standards

IEC60601-1:1998 +A1 :1991 + A2:1995
IEC 60601-1-1:2000
IEC 60601-2-18:1996 +A1:2000
IEC 60825-1:1993 + A1:1997 + A2:2001

The CEIS system is physically and functionally equivalent to the ISC-1000 system. The ISC-1000 system was tested to the above standard(s) by (b)(4) (b)(4) (b)(4) (b)(4) with the US national deviations.

Test Report for Electrical Safety report Number: (b)(4).

The system complied with the standard without any performance deviations. No alternative test methods were selected during the compliance testing apart from the test methods described within the standard.
The equipment under submission

- is a class 1 equipment with respect toelectrical safety.
- Has one BF applied part
- Not suitable for use in the presence of flammable mixtures.
- Not an AP and APG equipment
- Intended for Continuous Operation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- Not permanently installed equipment
- No medical gas connections
- Does not contain any carrying handles or grips
- Does not contain any patient support or immobilisation system
- Does not contain any external/accessible moving parts
- Does not contain any suspended masses
- Does not contain any pressurized parts or pressure vessels
- Does not contain any other batteries except for the small lithium battery in the control unit.
- Does not contain multiple socket outlet

All the clauses and sub-clauses that are applicable to the device with the above characteristics have been applied and the device was evaluated accordingly against the standard set criteria.

Electromagnetic Compatibility

IEC60601-1-2:2001

The ISC-1000 system was tested for compliance with the above standard with the following classification:

- Group 1 Class B for radiated and conducted emissions (CISPR 11)
- Class A for harmonic emissions (IEC 61000-3-2)

The system was tested by (b)(4) (b)(4) [redacted] for the above standard and found to be compliant. Test Report for Electromagnetic Compatibility report Number: (b)(4) [redacted].

All the clauses and sub-clauses that are applicable to the device with the above characteristics have been applied and the device was evaluated accordingly against the standard set criteria.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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13 Performance Testing - Bench

No Performance Testing (Bench) results have been submitted to support Substantial Equivalence.

14 Performance Testing - Animal

No Performance Testing (Animal) results have been submitted to support Substantial Equivalence.

15 Performance Testing - Clinical

No Performance Testing (Clinical) results have been submitted to support Substantial Equivalence.

A certificate of Compliance for Requirements for Clinical Trials (FDA Form 3674) has been attached and is provided in Appendix O

16 Manufacturing

Detailed manufacturing Work Instructions describing the assembly and testing of the CEIS is on file and held at Optiscan.

Flowcharts of the manufacturing steps in producing the Optiscan Confocal Endoscopic Imaging System (CEIS) are provided in Appendix P.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix A:

Premarket Notification Truthful And Accurate Statement

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Premarket Notification Truthful And Accurate Statement
(As required by 21 CFR 807.87(j))

I certify that, in my capacity as Regulatory Affairs Manager of Optiscan Pty Ltd that I believe to the best of my knowledge, that all data and information submitted in the premarket notification, attached, are truthful and accurate and that no material fact has been omitted.

22/10/2009

Peter Pavlicek
Quality and Regulatory Affairs Manager
Optiscan Pty Ltd.

Date

Device: CEIS, Optiscan Confocal Laser System
510(k) Premarket Notification Number (Assigned by FDA):

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix B:

Quality System Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) [redacted]

Certificate

The Certification Body of

(b)(4) [redacted]

hereby certifies that the organization

Optiscan Pty. Ltd.
15-17 Normanby Road
Notting Hill Victoria 3168
Australia

has established and applies a quality management system for medical devices for the following scope:

Design, Development, Manufacture and Servicing of Rigid and Flexible Confocal Endoscopic Imaging Systems

Proof has been furnished that the requirements specified in

EN ISO 13485:2003

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: (b)(4) [redacted]

An audit was performed. Report No.: (b)(4) [redacted]

This Certificate is valid until: 2011-03-01 (b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Figure - Optiscan ISO13485:2003 Quality System Certificate

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Policies and Standard Operating Procedures

(b)(4) Policies and Standard Operating Procedures

(b)(4) Policies and Standard Operating Procedures

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Appendix C:

Company Layout

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

[redacted]

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Appendix D:

510(k) Summary of Safety and Effectiveness

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Summary of Safety and Effectiveness
Optiscan Confocal Endoscopic Imaging System

Submitter Information:

Optiscan Pty Ltd
15-17 Normanby Rd,
Notting Hill, Victoria, 3168
Australia
Tel: (+61 3) 9538 3333
Fax: (+61 3) 9562 7742

Date Summary Prepared: October 2009

Name of Device:

Trade Name:	Optiscan CEIS
Classification Name	Endoscope and Accessories (21CFR876.1500)
Product Code	GCJ, KOG

Predicated Device(s) Information:

Model, Description	Manufacturer	PMN #
Pentax Confocal Laser System	Pentax	K042740

Device Description:

The Optiscan Confocal Endoscopic Imaging System (CEIS) is a software controlled device which is intended for use as a required accessory with a legally marketed and compatible video endoscope system that is equipped with confocal imaging module.

The Confocal Endomicroscopy Imaging System (CEIS) consists of three main units.

1. The Control Unit (CEIS-CU) together with its monitor, keyboard, and footswitch, is a computer based unit which performs the instrument control, and image capture and processing functions of the CEIS.
2. The Optical Unit (CEIS-OU) a specialised endomicroscope interface unit which performs the laser illumination and fluorescence detection functions of the CEIS.
3. The Isolation Transformer.

A video endoscope equipped with a confocal imaging module is connected to the CEIS-OU. Under control by the endoscopist, the CEIS-OU transmits visible laser light into the connected endoscope. The endoscope transmits this light to and then subsequently receives return light signals from the subject tissue. The returned light is detected by the CEIS-OU and converted into an electrical signal. The detected signal is sent to the System Computer (CEIS-CU) which processes the confocal image information for display on the system monitor, and allows still images of the tissue to be captured and stored.

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Intended Use:
The Optiscan Confocal Endoscopic Imaging System (CEIS) is intended to be used for confocal endomicroscopy of human tissue. The CEIS, its monitor, and a suitable confocal endomicroscope probe can provide microscopic visualization of the surface and subsurface of various body organs and tissues during endoscopic medical examination procedures. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

Comparison to Predicated Device(s):
The submission for substantial equivalence included Optiscan Confocal Endoscopic Imaging System (CEIS) literature including intended use and specifications. Comparison tables were provided to illustrate the comparisons to the predicated devices for intended use, technical specifications and materials. The submission for substantial equivalence was not based on an assessment of clinical performance data.

Conclusion:
Because the Optiscan Confocal Endoscopic Imaging System (CEIS) possesses the same or similar intended use, indications, and technological characteristics as the identified predicate device, with no additional questions of safety or effectiveness, the company submits that the device can be found to be substantially equivalent.

Prepared By:

Peter Pavlicek
Quality and Regulatory Affairs Manager

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix E:

Current CEIS Product Certifications

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

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Appendix F:

Indications for Use Statement

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

510(k) Number (if known):

Device Name: Optiscan CEIS

Indications for Use:

The Optiscan Confocal Endoscopic Imaging System (CEIS) is intended to be used for confocal endomicroscopy of human tissue. The CEIS, its monitor, and a suitable confocal endomicroscope probe can provide microscopic visualization of the surface and subsurface of various body organs and tissues during endoscopic medical examination procedures. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix G:

Declaration of Equivalence to the ISC-1000

The following documents have been attached to the submission in this section:

- 002188 CEIS Declaration of Equivalence to ISC-1000

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Document (b)(4) Rev

DECLARATION

We; Optiscan Pty Ltd
15 to 17 Normanby Rd
Notting Hill
Victoria 3168
AUSTRALIA

Declare that the Product Name:

Confocal Endoscopic Imaging System and related accessories, which is the medical device listed under an Optiscan Pty Ltd Declaration of Conformance, signed 24 January 2007, pursuant to the provisions of Council Directive 93/42/EEC (MDD)

is identical with the Product Name:

Confocal Imagng System, which is the medical device listed under a Pentax Corporation Declaration of Conformity, signed 26 October 2004, pursuant to the provisions of Council Directive 93/42 EEC (MDD)

which is manufactured at the premises of Optiscan Pty Ltd and supplied to Pentax Corporation, with the exception that:

- the labels that are applied to the above named Products differ only in respect of the Manufacturer's Names, the European Representatives and the Prduct Names and Model Numbers.

Signed this day 29th of January 2007

(b)(6)

Regulatory Manager
Optiscan Pty Ltd

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix H:

Isolation Transformer Specification

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) [redacted]

INSTALLATION AND OPERATING INSTRUCTIONS
OF THE INTERNATIONAL ISOBOX SERIES ISOLATION TRANSFORMERS.

Before installing and/or using this product, please check for any visual damage of the enclosure, power cord and plug. If any damage is observed, do not use this product. Contact Toroid Corporation of Maryland or its authorized agent for instructions to return the product for repair or replacement.

The ISOBOX Series Isolation transformers are intended for applications where medical devices require improved electrical isolation and/or reduced leakage current to comply with existing safety standards. With the ISOBOX connected between the device(s) and the wall outlet, the leakage current and the electrical isolation of the installed device will be that of the ISOBOX. (See data on following pages).

DANGER: Risk for explosion exists if used in the presence of flammable anesthetics, or other flammable gases or liquids.

CAUTION: Grounding continuity should be checked periodically

CAUTION: To reduce the risk of electrical shock, do not open enclosure. There are no serviceable parts inside. Refer service to Toroid Corporation of Maryland or its authorized agent only. Do not expose this equipment to rain or moisture.

NOTE: USA and Canada, Grounding reliability can only be achieved when this equipment is connected to a matching receptacle marked "Hospital Only", or, "Hospital Grade".

CAUTION: This product requires convection cooling. Adequate ventilation is therefore required. When installing this product, a minimum clearance of 2" should be provided to all sides, except mounting surface.

EXPLANATION OF GRAPHICS SYMBOLS

The exclamation point with an equilateral triangle is intended to alert the users to the presence of important operating and maintenance (servicing) instructions in the literature accompanying the product.

This apparatus is a Type B equipment.

(b)(4) [redacted]

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(b)(4)

[redacted]

TRANSPORT CONDITIONS:
Do not expose to temperatures below -30 Degr.C (-22F) or above 70 Degr.C (158F).
Do not expose this apparatus to relative humidity in excess of 95% RH (non-condensing).

MOUNTING INSTRUCTIONS:
For high traffic areas, carts and unstable surfaces, it is recommended to use the provided mounting brackets. For wall mounting, use appropriate wall anchors unless fastened into wall stud(s) or other forms of reinforcement available to support the weight of the enclosure. Appropriate air clearance for ventilation of ISOBOX is required (see CAUTION paragraph on previous page).

OPERATING INSTRUCTIONS:
This isolation transformer has eight (8) voltage combinations. To achieve the desired voltage in and out, please refer to this table

Input voltage provided (VAC 50/60Hz)	Power entry module setting	Output desired (VAC)	Output voltage selector setting
100	100	115-125	115
115-120	120	115-125	115
220	220	115-125	115
230-240	240	115-125	115
100	100	230-240	230
115-120	120	230-240	230
220	220	230-240	230
230-240	240	230-240	230

The correct fuse value must be used with the selected input voltage.
SERIOUS DAMAGE AND INJURY MAY RESULT IF INCORRECT INPUT AND/OR OUTPUT VOLTAGES ARE SELECTED. VERIFY ISOBOX SELECTED INPUT AND OUTPUT VOLTAGES, AS WELL AS, WALL OUTLET SUPPLIED AND EQUIPMENT VOLTAGES.

Recommended initial installation procedure:
1. Verify power switch on the ISOBOX is in the OFF (0) position.
2. In Canada and USA, when connecting the ISOBOX to the wall outlet, plug only into a Hospital Grade Wall Outlet to ensure reliable grounding. Connect ISOBOX to Wall outlet.
3. Verify equipment to be connected to the ISOBOX is turned OFF (0).
4. Connect the devices to the receptacles of the ISOBOX.
5. Turn ON (1) the power switch of the ISOBOX.
6. The devices connected to the ISOBOX are now ready to be turned ON (1) and operated.

Note power cord requirements on next page.

The total power consumption equals the sum of all devices connected to the ISOBOX. The total power consumption must not exceed the maximum power rating of the ISOBOX, as shown on the product rating label or table below.

To reduce inrush currents, the M series employs a thermistor. After turning off the IsoBox unit it is recommended to let the ISO-BOX "cool down" for approximately 1 minute. There may otherwise be a risk of blowing a fuse in the power entry module or possibly tripping the wall outlet circuit breaker.

For power cord retention clip and clamp installation, please refer to separate instruction sheet.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8148

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(b)(4)

[redacted]

ISOBOX SPECIFICATIONS.

All ISOBOX models listed in this document are intended for 100 or 115-120 or 220 or 230-240 VAC and 50/60Hz input frequency. DO NOT USE OTHER VOLTAGES OR FREQUENCIES. See previous paragraph for voltage selector settings on the ISOBOX and Datasheets mechanical data.

Model No.	Output voltage (Vac. 50/60 Hz)	Output current (Amps)	Output Power * (VA)	Leakage current 132V Nom/Max **	Leakage current 264V Nom/Max **	Regulation % ***
ISB-030M	115-120/230-240	2.50/1.25	300	50/100	50/100	6.8
ISB-060M	115-120/230-240	5.00/2.50	600	50/100	50/100	5.0
ISB-100M	115-120/230-240	8.33/4.17	1000	50/100	50/100	3.2

* Maximum total output power of the ISOBOX, whether one or more outlets are used.

** Nominal leakage current is measured at normal use and in no fault condition. Maximum leakage current is measured as Non-Patient connected, with reversed polarity and under single fault condition.

This transformer is a Class I, Type B equipment.

POWER CORD REQUIREMENTS:

Input: All power cords must be appropriately approved by testing agency for the country where the ISOBOX is installed, such as UL/CSA/VDE/SEMKO/<HAR> etc. For the US and Canadian Market, a HOSPITAL GRADE Plug is required.

The cord must have one end suitable for the wall receptacle and the other end must be of appliance type, IEC-320 female plug. All power cords must have grounding contacts.

	Minimum wire Diameter	Length Recommended
ISB-030M	AWG 18 (0.75mm^2)	12 ft or less
ISB-060M	AWG 18 (0.75mm^2)	12 ft or less.
ISB-100M	AWG 16 (1.00mm^2)	12 ft or less

FUSE REQUIREMENTS:

These ISOBOX transformers have been tested, approved and deemed to be safe under certain conditions. The fuse in the power entry module is protecting the ISOBOX from overloads and short circuits. If the incorrect fuse is used, there may be danger to operator(s) or patient(s), or damage to equipment. Fuses must be UL and CSA approved and marked for North American use and VDE/EN approved and marked for European use. Use only SLOW BLOW type (T-type) fuse rated 250V. We also recommend the fuses to be ceramic bodied.

Model	Input Setting:	100V	120V	220V	240V
ISB-030M	Fuse rating:	4.0AT	3.15 AT	1.6 AT	1.6 AT
ISB-060M		8.0AT	6.3 AT	3.15 AT	3.15 AT
ISB-100M		12.5AT	10.0 AT	5.0 AT	5.0 AT

DO NOT USE FUSES WITH HIGHER AMP RATING THAN THOSE LISTED ABOVE.

(b)(4)

[redacted]

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(b)(4)

[redacted]

TROUBLE SHOOTING:
DO NOT ATTEMPT TO REPAIR. WARRANTY WILL BE VOID IF UN-AUTHORIZED REPAIR WORK HAS BEEN CARRIED OUT.

No output power:

1. Verify that the ISOBOX is connected and that the power switch is ON (I).
2. Verify fuses in power entry module (disconnect ISOBOX from Power first)
3. Use another wall outlet.
4. Check wall outlet circuit breaker.
5. If you have any other problems with the ISOBOX, please call Toroid Corporation of Maryland, from US/CAN: 800-274-5793 other: 410-860-0300.

If you need to return the ISOBOX for any reason, call the factory for return instructions.

If you notice any Mechanical Damage: Call Toroid Corporation of Maryland for instructions.

LIMITED WARRANTY:
The ISOBOX series enclosed isolation transformers are backed by Toroid Corporation of Maryland's 36 month warranty. For complete information, please refer to the warranty card enclosed with this package.

SAFETY AGENCY LISTINGS:

Lister	Cert./Rep.No's	Standards	Markings
ITS Report No:	3021409_US/CAN	UL2601-1	ETL
	3021409_US/CAN	CSA C22.2 No. 601.1	cETL
SEMKO Certificate:	TDB	EN60601.1	S
CB Certificate No:	US/920/ITS	EN60601.1	-
CE mark Self Declared	CE003	Low Voltage Directive	CE

MECHANICAL DATA:
See Individual Data Sheets.

(b)(4)

[redacted]

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Appendix I:

Device User Instructions/Manuals

The following documents have been attached to the submission in this section:

- 001686 CEIS Owners Manual
- 001685 CEIS Operators Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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User Instructions
CEIS Owners Manual

Document Number: (b)(4) [redacted]
Revision: [redacted]
Release Date: 20/05/2009
Created from Template: Standard.Dotx

This is a **CONTROLLED DOCUMENT**. The current approved revision is available in electronic form. If it is necessary to print this document or send a copy of it electronically, it is the responsibility of the person printing or sending to ensure it is the current approved version. Printed or electronic copies are considered uncontrolled documents.

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Document Approval:

Signature: (b)(6) [redacted] Date: 20/5/2009
Reviewer (Applications Group)

Signature: (b)(6) [redacted] Date: 20/5/2009
Approval (R&[redacted])

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Revision History:

Revision	Modified	Release	Description
(b)(4)	(b)(6)	19/12/2005	Converted from 000421
		24/1/2007	CEIS Owner's manual Updated to reference to the ISC-1000 Owners Manual which includes a number of changes requested from Pentax
		15/1/2008	Update to correspond with the ISC-1000 Owners Manual 000421 revision 19. All references to the ISC-1000 specific references have been changed to their CEIS equivalents.
		17/11/2008	Amendment to Intended Use statement to remove the word prototype Fixed up some Mistaken references of ISC-1000 and CCB1.5 to CEIS Amended Section 3.2.2 to add NRTL Compliance Label
		2/3/2009	Converted to new template and added New Manual Cover Art. Added additional safety warnings in section "safety precautions" including connection of equipment non 60601 equipment and network connections. Change the Attention conventions to be consistent with the Operators Manual 001685. Moved the Intended Use Section to a more prominent position (See Section 2.2) and added additional warning and Contraindication and intended user section. Moved warnings, cautions and notes in section 3 from various tables into the text as per the attention conventions. Added warning in section 4.1.2 regarding connection of only approved endomicroscopes. Inclusion of a tables of Figures and Tables in the contents section. Inclusion of Document reference and revision on all pages.
		20/5/2009	Added symbols to section 1.2 Remove Declaration of Conformity from Last Page Updated the Technical Specifications with more detail Table 8 All Standards quoted have had the release date removed. Included where relevant standards citing both IEC and EN where applicable. Removed Section 4.1.2 as this was contradictory to other warnings within the manual. Added label to Footswitch Section 3.5 with IP explanation Added DIMDI Code to European Representative (Last page)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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OptiScan|CEIS

Confocal Endoscopic Imaging System

Owners Manual

Fluorescence In Vivo Endomicroscopy

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SB 1

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0197

このCEマーキングはEC指令への適合宣言マークです。

The CE marking assures that this product complies with the requirements of the EC directive for safety.

Das CE Zeichen garantiert, daß dieses Produkt die in der EU eforderlichen Sicherheitsbestimmungen efüllt.

Le logo CE certifie que ce produit est conforme aux normes de sécurité prévues par la Commuunatuté Européenne.

Il marchio CE assicura che questo prodotto è conforme alle direttive CE alla sicurezza.

La marca CE asegura que este producto cumple todas las directivas de seguridad de la cE.

CE 标志意味着保证该类产品遵从欧洲共同体安全法规.

IMPORTANT

Read this manual before operating and retain this book for future reference.

This manual describes the recommended procedures for inspecting and preparing the CEIS system prior to its use and the care and maintenance after its use. It does not describe how to use the equipment or operate the software loaded on the system, nor does it attempt to teach the beginner proper techniques or any medical aspects regarding the use of the equipment. Do not use this equipment for any purpose other than that for which it has been designed.

If you have any questions regarding any information in this manual or concerns pertaining to the safety and/or use of this equipment, please contact your Optiscan representative.

CAUTION:

Federal (USA) law restricts this device to sale by, or on the order of, a physician or other appropriately licensed medical professional.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1 SAFETY PRECAUTIONS

The CEIS is **MEDICAL ELECTRICAL EQUIPMENT** as defined in IEC/EN 60601-1.

We would like to provide you with information about safety aspects which must be observed when handling this device, to ensure safety to all involved parties including patients and operators. This chapter contains a summary of the most important information concerning matters relevant to instrument safety.

Important safety information has been incorporated in this manual and is marked with a warning triangle accordingly. Please give this information your special attention. Attention conventions for this manual are provided below in Figure 1-1.

The correct use of the system is absolutely vital for safe operation. Please make yourself totally familiar with the contents of this manual prior to startup of the instrument. Please also observe the user manuals of any additional equipment. Further information is available from our service department or from authorized representatives.

- Please observe all applicable accident prevention regulations.

1.1 Attention Conventions

The following conventions have been established in the text of this manual to aid in the identification of important information.

Warning!
The **warning triangle** indicates potential sources of danger which may constitute a risk of injury for the user or a health hazard.

Caution:
The **square** indicates situations which may lead to malfunction, defects, collision or damage of the instrument.

Note:
The **hand** indicates hints on the use of the instrument or other tips for the user.

Figure 1-1 Attention Conventions

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1.2 Symbols and Markings

The following Symbols and Markings have been established in the text of this manual and also on the labelling provided with the device to aid in the identification of important information.

~	Alternating current
	This product emits laser radiation.
	Type BF applied part (Safety degree specified in IEC 60601-1)
	ON-OFF Power switch or indicator
	Attention
	Protective earth (ground)
	Equipotentiality
	Waste in Electrical and Electronic Equipment
EC REP	Authorised Representative in the European Community
	Manufacturer of the Device
	Manufacturing Date of the Device
SN	Device Serial Number

Figure 1-2 Symbols and Markings

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1.3 Laser Safety

The CEIS is a **CLASS 3R LASER PRODUCT** as defined in IEC/EN 68025-1

Warning!
LASER RADIATION is emitted from any connected endomicroscope.
- **DO NOT** stare into the beam or view directly with optical instruments.

Warning!
LASER RADIATION is generated inside the CEIS-OU.
- **DO NOT** operate the CEIS-OU with the cover removed.
- **DO NOT** operate the CEIS-OU with any optical fibres disconnected.
- **DO NOT** bypass or otherwise make inoperative the CEIS-OU Optical Connector interlock switch

Laser energy is coupled outside the CEIS-OU to the endomicroscope via the Optical Connector. The cover for the Optical Connector on the CEIS-OU is labelled with the labels shown in Figure 1-3

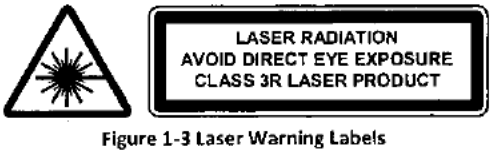

Figure 1-3 Laser Warning Labels

Laser operation and operating energy levels are controlled by the CEIS software applications. Procedures for using the software are covered in the Operator's Manual.

Warning!
Use of controls or adjustments or performance of procedures other than those specified in the Operator's Manual may result in hazardous radiation exposure.

1.4 Electrical & General Safety

The CEIS is **MEDICAL ELECTRICAL EQUIPMENT** as defined in IEC/EN 60601-1.
According to the degree of protection against electric shock as defined in IEC/EN 60601-1, the CEIS is Class One equipment. The CEIS has a fully isolated connection allowing the endomicroscope to be classified as a Type BF Applied Part. The CEIS is designed for continuous operation.

All parts of the CEIS system are suitable for use in the Patient Environment.
The CEIS is classified as IPX0 equipment in regard to the level of protection against the ingress of water. The CEIS Footswitch is rated at IP68.

Warning!
The CEIS is **NOT SUITABLE** for use in the presence of FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.
- **DO NOT** use in potentially flammable surroundings
- **DO NOT** splash or spray equipment with any liquid
- **DO NOT** expose equipment to dusty environments
- **DO NOT** operate the CEIS in an environment outside its operating limits as described in Table 8-1.

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There are no special sterilisation or disinfection requirements for the CEIS. See Section 6.2 of this manual for general equipment cleaning instructions.

Correct connection of the power for the CEIS system and accessories is very important for the safety of the patient and the operator.

Warning!
Connect the CEIS mains inlet power cord directly to a medical grade outlet ONLY.

- **DO NOT** connect the CEIS mains inlet power cord to a portable multiple socket outlet.
- **DO NOT** connect a portable multiple socket outlet or any extension cord to the CEIS Isolation Transformer.

Warning!
DO NOT connect the power cord for any component of the CEIS to any power outlet other than the CEIS Isolation Transformer as shown in Figure 4-1. ***Failure to comply with this instruction bypasses the electrical safety isolation provided by the Isolation Transformer causing seriously compromised electrical safety for the patient and the operator.***

Warning!
DO NOT connect any other external equipment to the CEIS system other than the approved equipment specified in this manual.

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1.5 Electromagnetic Compatibility

The CEIS is **MEDICAL ELECTRICAL EQUIPMENT** as defined in IEC/EN 60601-1. Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility (EMC).

Warning!
Install and operate this equipment in strict accordance with the instructions contained in this Owner's Manual.
DO NOT take any actions that could compromise the EMC shielding of the equipment or the interconnecting cables.
DO NOT replace any supplied cable with any cable that is not a genuine replacement cable supplied by Optiscan. Use of non-genuine cables may result in increased emission levels and/or a decreased immunity to radiated fields

- Separate cables supplied for the CEIS by Optiscan are:
  - One interconnecting Control Data cable one metre long.
  - One interconnecting Control Signal cable one metre long.
  - One interconnecting Optical Signal cable one metre long.
  - Two interconnecting IEC C13 to C14 power cords with EMI suppression two metres long.
  - One interconnecting IEC C13 to C14 power cords without EMI suppression two metres long. Additional cables may be required based upon endoscope used.
  - One incoming mains supply plug to IEC C13 power cord two to three metres long.

Warning!
Mobile phones and other portable or mobile RF equipment can interfere with the operation of the equipment. **DO NOT** operate mobile phones and other portable or mobile RF equipment in close proximity to the equipment.

Warning!
The CEIS must not be operated stacked with or adjacent to any foreign equipment. **DO NOT** operate the CEIS stacked with or adjacent to equipment other than specified in Table 8-2

Guidance and Manufacturer's declaration – electromagnetic emissions		
The CEIS is intended for use in the electromagnetic environment specified below. The customer or the user of the CEIS should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The CEIS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The CEIS is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 1-1 Guidance and Manufacturer's declaration – electromagnetic emissions

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Guidance and Manufacturer's declaration – electromagnetic immunity

The CEIS is intended for use in the electromagnetic environment specified below. The customer or the user of the CEIS should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95% dip in UT) for 0,5 cycle 40 % UT (60% dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles <5 % UT (>95% dip in UT) for 5 seconds	Complies Complies Complies Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CEIS requires continued operation during power mains interruptions, it is recommended that the CEIS be powered from an uninterruptible power supply or battery.
Power Frequency (50-60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
			Portable and mobile RF communications equipment should be used no closer to any part of the CEIS system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 kHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 Mhz to 800 MHz
			$d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 U_T is the a.c. mains voltage prior to application of the test level

NOTE 2 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 3 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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a	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CEIS system is used exceeds the applicable RF compliance level above, the CEIS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CEIS.
b	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 1-2 Guidance and Manufacturer's declaration – electromagnetic immunity

Recommended separation distances between portable and mobile RF communications equipment and the CEIS

The CEIS is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CEIS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CEIS as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0,01	0,12 m	0,12 m	0,23 m
0,1	0,38 m	0,38 m	0,73 m
1	1,2 m	1,2 m	2,3 m
10	3,8 m	3,8 m	7,3 m
100	12 m	12 m	23 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 1-3 Recommended separation distances

1.6 Protective Measures for IT Systems and Networks

The user (or IT officer) is responsible for ensuring that no viruses are transferred to the CEIS system via the network connection. It is the user's responsibility to ensure that the media used for data communication (CD, USB stick) are free from viruses.

Responsibilities for data protection and information security

The user (or IT officer) must ensure that the national laws and regulations relating to data protection are complied with.

The operators of IT systems and IT networks are responsible for the definition of the safety standards required, i.e. for the creation of the necessary technical and organizational framework.

Definition of terms

- Personal data means any information concerning the personal or material circumstances of an identified or identifiable individual. All data directly attributable to a person (employee, customer, supplier), e.g. marital status, type of employment, religion, income, etc., must be protected.
- Data processing means the storage (entry, recording or preservation), transfer (transmission to third parties outside the organization), modification (alteration of the substance, including anonymization and aliasing), erasure (deletion) and blocking (labelling so as to restrict further processing or use) of data.
- Use means any utilization of data (e.g. in-house transmission).
- Recipient means any person or body receiving data. Third party means any person or body other than the controller (legal entity). The transmission of data to third parties is deemed to constitute data transfer.

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2 CONFOCAL ENDOSCOPIC IMAGING SYSTEM

2.1 Introduction

The instrument described in this manual is designed for use by trained personnel only. This manual should be read thoroughly before using the CEIS.
Failure to read this manual thoroughly and understand the contents of the manual may result in injury to the patient and/or user. It is essential to follow the instructions in this and other manuals which pertain to any equipment or accessories used in conjunction with the CEIS. Failure to follow these instructions may also result in damage to and/or malfunction of the CEIS.
There are no user serviceable parts inside the CEIS. Adjustment, maintenance and repair of the CEIS should only be conducted by qualified and authorised personnel.

2.2 Intended Use

The Optiscan Confocal Endoscopic Imaging System (CEIS) is intended to be used for confocal endomicroscopy of human tissue. The CEIS, its monitor, and a suitable confocal endomicroscope probe can provide microscopic visualization of the surface and subsurface of various body organs and tissues during endoscopic medical examination procedures. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

The CEIS is indicated for use as an aid or adjunct to a mode of therapy or diagnosis.

Warning!
DO NOT use the video images for diagnostic purposes, as the resulting images and the monitor have not been calibrated. The visualized images may therefore include deviations in shape, contrast and colour.

2.2.1 Contraindications

None Known.

2.2.2 Intended User(s)

The system must only be operated by physicians, nurses and other medically trained OR staff who have received appropriate briefing and observe the instructions of the user's manual. The installation conditions and the use of the system must meet surgical requirements:

- low vibration
- dust-free environment
- level, horizontal positioning
- avoidance of extreme mechanical stress.

Caution:
Federal (USA) law restricts this device to sale by, or on the order of, a physician or other appropriately licensed medical professional.

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2.3 System Overview

The Confocal Endomicroscopy Imaging System (CEIS) consists of three main units.

1. The Control Unit (CEIS-CU) incorporating a monitor, keyboard and footswitch.
2. The Optical Unit (CEIS-OU).
3. The Isolation Transformer.

The CEIS is always installed and operated in conjunction with a Confocal Endomicroscope and Video Processor. The full equipment set may be installed on an optional Trolley system. Refer to Table 8-2 for approved and compatible devices.

The Confocal Endomicroscope connects into the CEIS-OU, and contains a fully integrated fluorescence confocal microscope. This microscope provides high magnification, sub-cellular resolution images at and below the surface in living tissue.

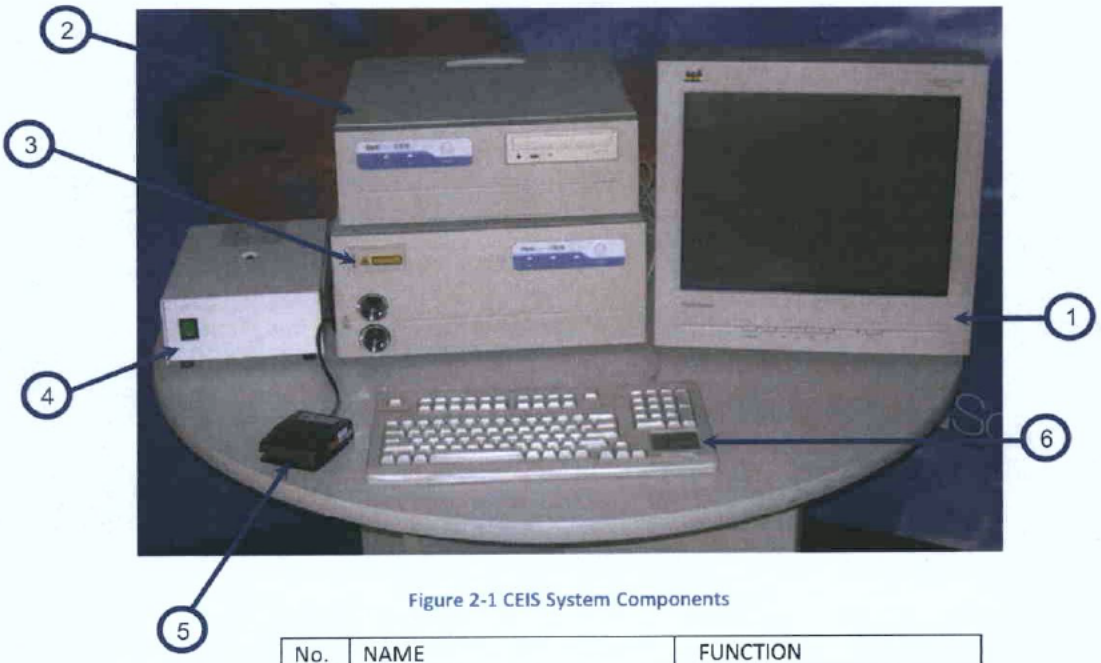

Figure 2-1 CEIS System Components

No.	NAME	FUNCTION
1.	CEIS Monitor	Refer to Section 3.3
2.	CEIS-CU	Refer to Section 3.1
3.	CEIS-OU	Refer to Section 3.2
4.	Isolation Transformer	Refer to Section 3.6
5.	Footswitch Control	Refer to Section 3.5
6.	Keyboard	Refer to Section 3.4

2.3.1 Control Unit (CEIS-CU)

The Control Unit (CEIS-CU) together with its monitor, keyboard, and footswitch, is a computer based unit which performs the instrument control, and image capture and processing functions of the CEIS.

2.3.2 Optical Unit (CEIS-OU)

The Optical Unit (CEIS-OU) is a specialised endomicroscope interface unit which performs the laser illumination and fluorescence detection functions of the CEIS.

2.3.3 Isolation Transformer

The Isolation Transformer is a mandatory safety component of the CEIS System which supplies power to all components of the CEIS System.

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Warning!
ALL components of the CEIS and approved accessories associated equipment electrically connected to the Endomicroscope, **MUST** be supplied from this Isolation Transformer.

2.4 Shipping Containers

Note:
It is recommended that you keep the instrument's shipping containers and packing materials. If you need to transport the instrument at a later time and have not retained the original packaging, you may be required to purchase replacement shipping containers.

2.4.1 Contents

The shipping components of the CEIS consists of 3 boxes containing the following items:

Box 1 – Control Unit (CEIS-CU), keyboard and cover, footswitch, manuals, cables, Operating System CD and licence.
Box 2 – Optical Unit (CEIS-OU)
Box 3 – Monitor, Isolation Transformer

2.4.2 Unpacking

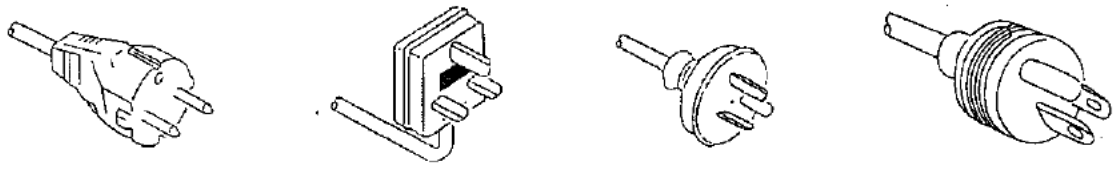
When unpacking the contents of the shipping containers each container should be checked to ensure that all items are present and that there is no obvious physical damage to any item. If any shortage or damage is detected contact your Optiscan representative as soon as possible.

Warning!
DO NOT connect or operate any damaged equipment.

Caution:
The following precautions should be observed when unpacking the equipment.

1. Ensure the equipment is never dropped or jarred when unpacking or setting up.
2. Ensure the screen of the monitor is never facing downward.
3. Check that the Isolation Transformer is set to the correct input and output voltages Figure 3-9 shows the location of the Input Voltage Selector. Figure 3-10 shows the location of the Output Voltage Selector. The voltage settings can be readily seen on both of these selectors without removing any covers. Ensure the enclosed mains input cord is the correct type.
4. Check the standard power plug configurations. that are used in your country. If the appropriate power cord is not included in your product, notify your local Optiscan distributor.

Figure 2-2 shows the power plug types supplied for each country or region.



Continental Europe (Use a SEV approved plug for Switzerland) | U.K | Australia and New Zealand | U.S.A. and Canada (Hospital Grade)

Figure 2-2 Power Cord Plug Types

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3 NOMENCLATURE, CONTROLS AND FUNCTIONS

3.1 Control Unit

3.1.1 Front Panel

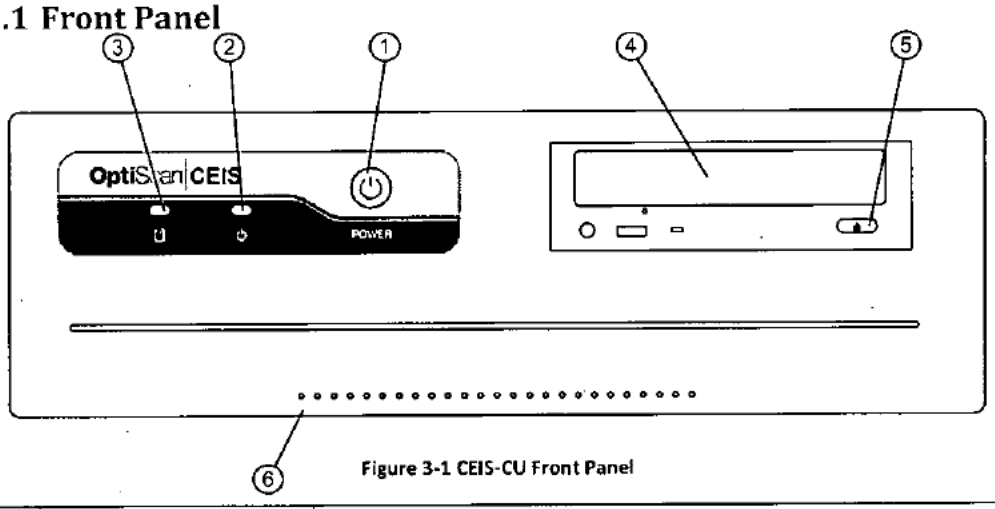

Figure 3-1 CEIS-CU Front Panel

No.	NAME	FUNCTION
1.	ON/OFF Button	Controls the power for both the CEIS-CU and the CEIS-OU. Press to turn on and press to turn off.
2.	ON/OFF Indicator	Indicates with a green light when power is on. The indicator lights when the power is turned on.
3.	Disk Indicator	Indicates with a green light when the disk is active. The indicator lights when the disk is active.
4.	CD/RW Drive	Drive unit for the reading and writing of Compact Disks.
5.	CD/RW Open/Shut Button	Opens and closes the CD/RW Drive. Press to open and press to close.
6.	Ventilation Holes	Allows adequate ventilation and cooling for the CEIS-CU.

<u>Note:</u>
For normal operation, press the ON/OFF Button to turn on. When turning the equipment off, use the "shutdown" control from the Start menu in the CEIS-CU. The ON/OFF Button should only be used to turn the equipment off in the case of a system malfunction or emergency. The Button should be operated with a finger and should not be hit or operated with any hard or sharp object.

Caution:
DO NOT block any of the Ventilation Holes.

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3.1.2 Rear Panel

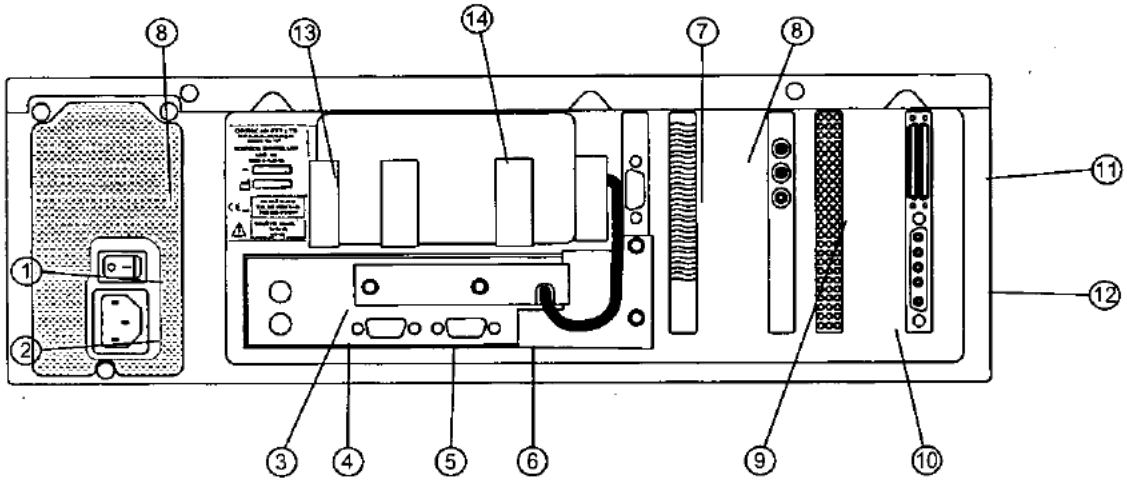

Figure 3-2 CEIS-CU Rear Panel

No.	NAME	FUNCTION
1.	Power Switch	Power isolating switch for the CEIS-CU. **I** is ON and **O** is OFF. This switch must be ON before the ON/OFF Button on the front panel will operate correctly.
2.	Power Cord Inlet	Receptacle for the power inlet cord from the Isolation Transformer.
3.	Mouse Socket	Socket for the Green Mouse Plug from the Keyboard.
4.	Keyboard Socket	Socket for the Purple Keyboard Plug from the Keyboard.
5.	Touch screen Connector	Socket for the Monitor Touch screen connector from the Monitor.
6.	Footswitch Connector	Socket for the Footswitch connector.
7.	Monitor Connector	Socket for Monitor connector.
8.	Ventilation Fan Grilles	Allows exit of forced ventilation and cooling for the CEIS-CU.
9.	Optical Signal Connector	Connector for the Optical Signal cable from the CEIS-OU.
10.	Ventilation Grille	Allows adequate ventilation and cooling of the CEIS-CU.
11.	Control Data Connector	Connector for the Control Data cable from the CEIS-OU.
12.	Control Signal Connector	Connector for the Control Signal cable from the CEIS-OU.
13.	Rating Plate	Displays unit model number, serial number and power requirements.
14.	Network Isolator	Network Isolation device with socket for 10/100 UTP network connection.

Warning!
The Power inlet cord **MUST** be connected to the Isolation Transformer **ONLY**.

Caution:
DO NOT obstruct the flow of air from any of the Ventilation grilles.

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3.2 Optical Unit

3.2.1 Front Panel

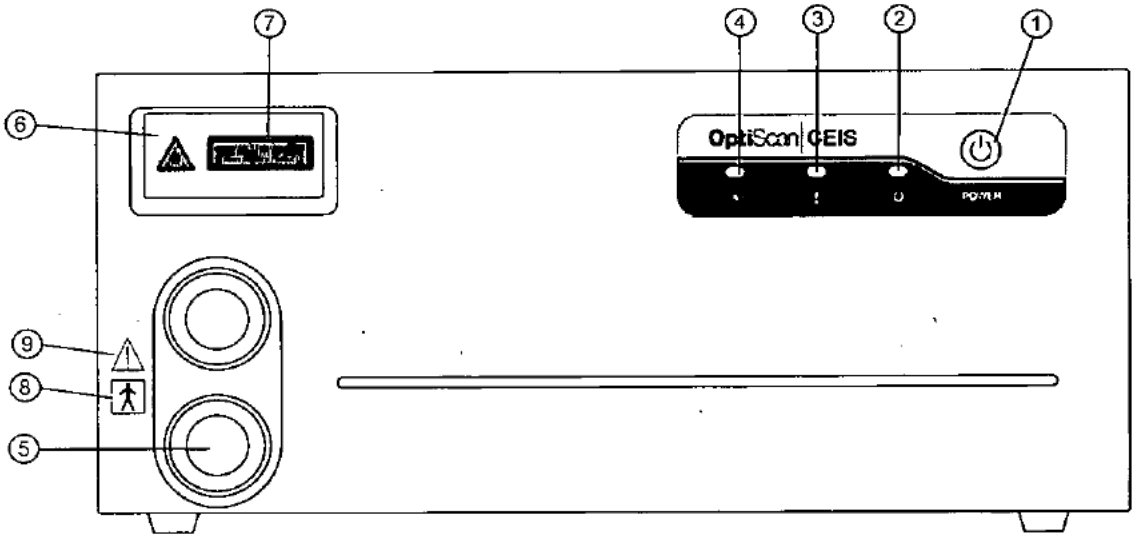

Figure 3-3 CEIS-OU Front Panel

No.	NAME	FUNCTION
1.	ON/OFF Button	Controls the power for both the CEIS-CU and the CEIS-OU. Press to turn on and press to turn off.
2.	ON/OFF Indicator	Indicates with a green light when power is on. The indicator lights when the power is turned on.
3.	Warning Indicator	Indicates with a yellow light when a problem exists. The indicator lights when a problem exists.
4.	Laser ON Indicator	Indicates with a blue light when the laser is on. The indicator lights when the laser is on.
5.	Endomicroscope Electrical Connector	Accepts the electrical connector from the Endomicroscope.
6.	Endomicroscope Optical Connector	Accepts the optical connector from the Endomicroscope. Open the cover door to access the connector.
7.	Laser Radiation Label	Label identifying that the product emits laser radiation and is a Class 3R laser product.
8.	Type BF Applied Part Label	Label identifying classification: Type BF applied part (Safety degree specified in IEC 60601-1)
9.	Warning Label	Label identifying: Attention, Consult owner's manual

<u>Note:</u>
For normal operation, press ON/OFF Button to turn on. When turning the equipment off, use the "shutdown" control from the Start menu in the CEIS-CU. The ON/OFF Button should only be used to turn the equipment off in the case of a system malfunction or emergency. The Button should be operated with a finger and should not be hit or operated with any hard or sharp object.

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3.2.2 Rear Panel

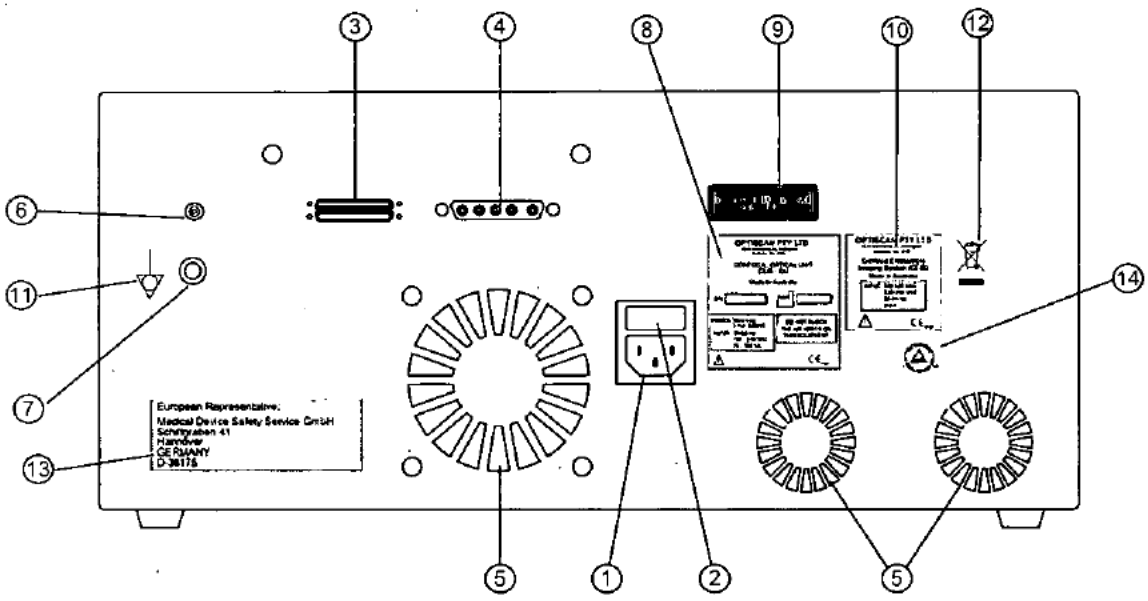

Figure 3-4 CEIS-OU Rear Panel

No.	NAME	FUNCTION
1.	Power Cord Inlet	Receptacle for the power inlet cord from the Isolation Transformer.
2.	Power Fuses	Drawer for the power fuses.
3.	Control Data Connector	Connector for the Control Data cable from the CEIS-CU.
4.	Control Signal Connector	Connector for the Control Signal cable from the CEIS-CU.
5.	Ventilation Fan Grilles	Allows exit of forced ventilation and cooling for the CEIS-OU.
6.	Optical Signal Connector	Connector for the Optical Signal cable from the CEIS-CU.
7.	Equipotential Connector	Connector for equipotentiality.
8.	Rating Plate	Displays unit model number, serial number and power requirements.
9.	Laser Class Label	Displays laser product class and wavelength
10.	System Label	Displays system power requirements.
11.	Equipotential Label	Label denoting a connector for equipotentiality.
12.	WEEE Label	Label denoting Waste in Electrical and Electronic Equipment
13.	European Representative Label	The Contact Name and address of the European Representative of the System (For use by EC Community Member Countries Only)
14.	NRTL Compliance Label	Label denoting Compliance to the Requirements of NRTL

Warning!
The Power inlet cord **MUST** be connected to the Isolation Transformer **ONLY**.

Warning!
Use only the correctly rated power fuses.

Caution:
Do not obstruct the flow of air from any of the Ventilation Fan Grilles.

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3.3 Monitor Display Screen

3.3.1 Front of Monitor

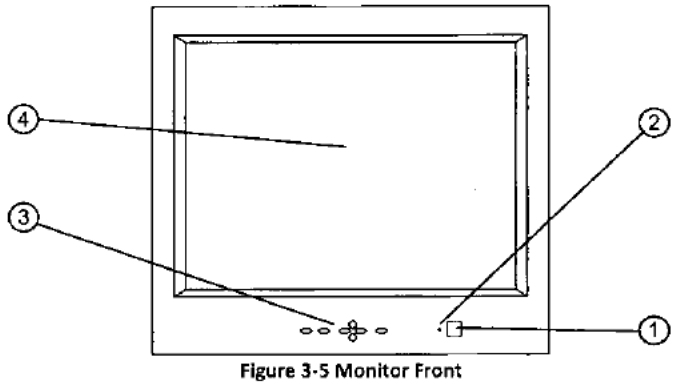

Figure 3-5 Monitor Front

No.	NAME	FUNCTION
1.	ON/OFF Switch	Turns the Monitor ON and OFF. Press for ON and press again for OFF.
2.	Power Indicator	Indicator lights when the power is ON.
3.	Adjustment Controls	Controls to adjust the characteristics of the screen image.
4.	Touch screen	Touch sensitive sensor over the whole screen area.

Caution:
To maintain the clarity of the front surface of the touch screen, keep it free of dirt, dust, fingerprints and other materials that could degrade optical properties. Long term contact with abrasive materials will scratch the front surface, decreasing image quality.
The touch screen may be cleaned or disinfected with non-abrasive agents such as, isopropyl alcohol or ethyl alcohol. We recommend that pre-soaked wipes or towelettes should be used to avoid applying excessive amounts of liquids.

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3.3.2 Rear of Monitor

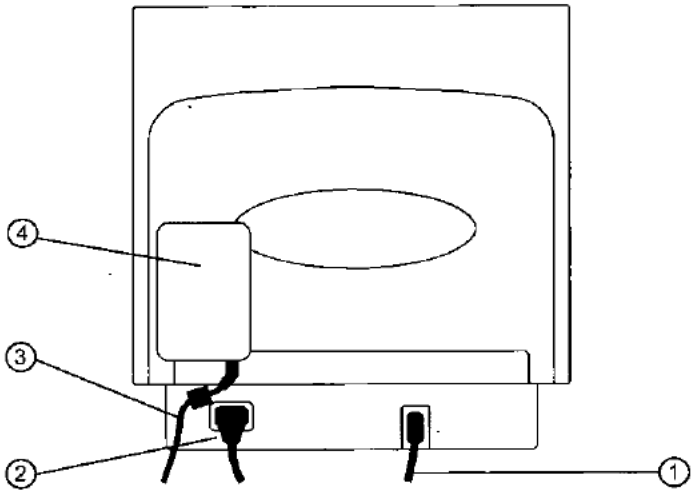

Figure 3-6 Monitor Rear

No.	NAME	FUNCTION
1.	Video Signal Cable	Cable that connects to the CEIS-CU Monitor Connector.
2.	Power Cord and Socket	Receptacle for the power inlet cord from the Isolation Transformer.
3.	Touch screen Cable	Cable that connects to the CEIS-CU Touch screen Connector.
4.	Touch screen Controller	Control unit for the touch screen.

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3.4 Keyboard

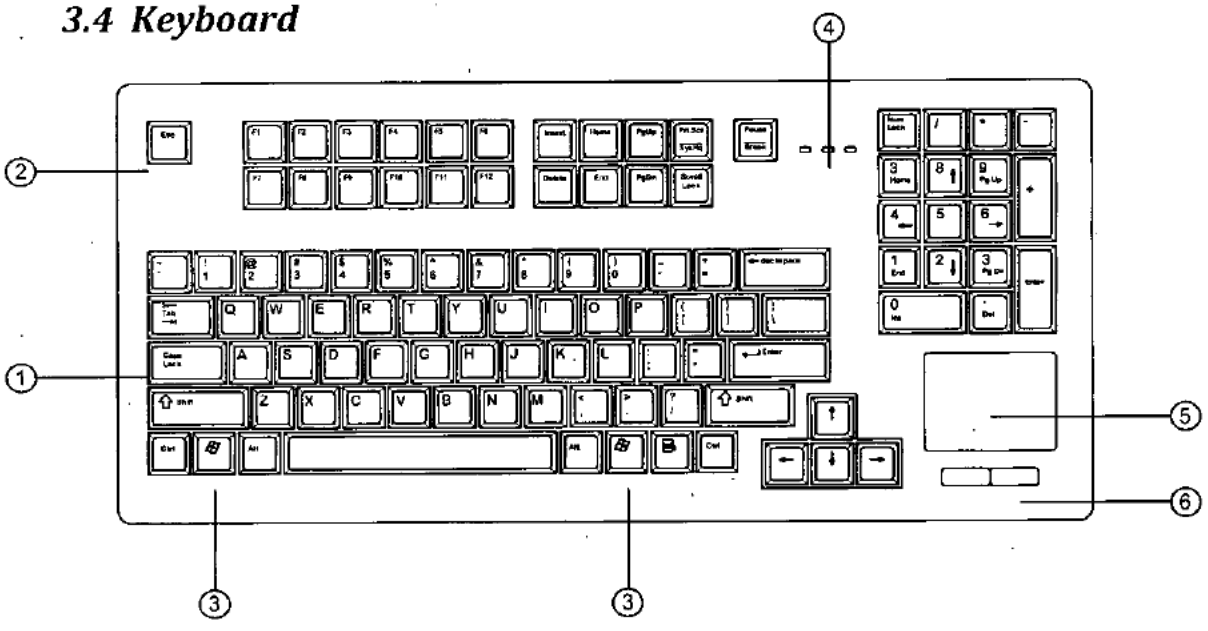

Figure 3-7 Keyboard

No.	NAME	FUNCTION
1.	QWERTY Keyboard	Standard QWERTY Layout Keyboard
2.	Escape key	Escape function key
3.	"Windows" keys	Microsoft Windows function keys
4.	Keyboard Status Indicators	Indicate status of Caps Lock, Num Lock and Scroll Lock functions
5.	Mouse Pad	Pressure sensitive mouse pad pointing device
6.	Mouse Buttons	Left and Right mouse buttons

3.5 Footswitch

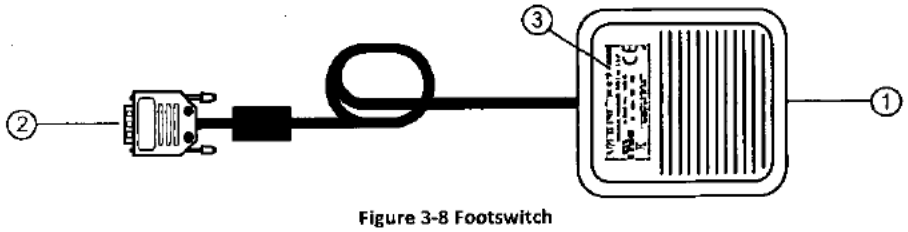

Figure 3-8 Footswitch

No.	NAME	FUNCTION
1.	Footswitch	Footswitch unit used to trigger image capture
2.	Footswitch Connector	Connector for connection to the CEIS-CU
3.	Footswitch Label	Contains the relevant Safety data and Ingress Protection Rating (IP68)

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3.6 Isolation Transformer

3.6.1 Front and Rear Panels

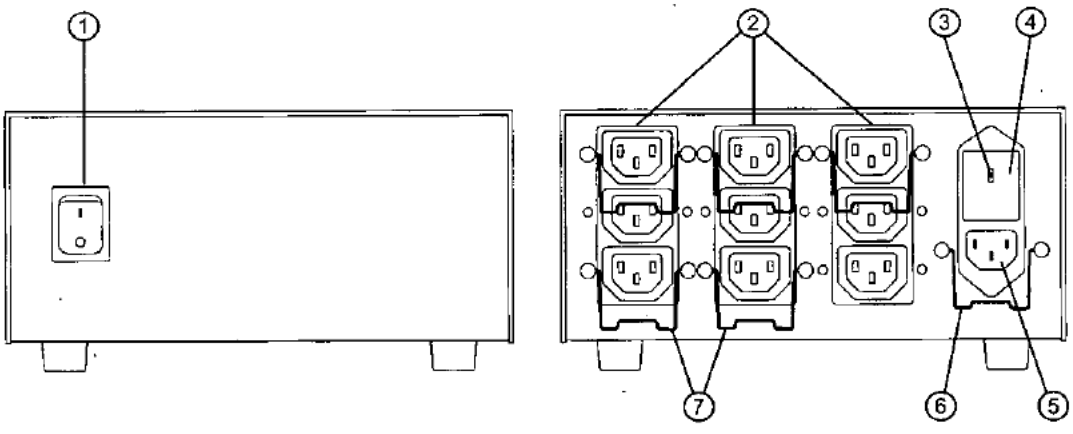

Figure 3-9 Isolation Transformer Front and Rear Panels

No.	NAME	FUNCTION
1.	ON/OFF Switch	Turns the system ON and OFF. Operate **I** for ON and **O** for OFF.
2.	System Cord Connectors	Connectors for power cords to the system equipment.
3.	Input Voltage Selector	Device to select the Isolation Transformer input (primary) voltage.
4.	Fuse and Selector Drawer	Drawer that contains the input fuses and the mains (input) voltage selector.
5.	Mains Cord Connector	Connector for the incoming mains cord.
6.	Mains Cord Clip	Clip to retain the incoming mains cord against accidental removal.
7.	System Cords Clips	Clips to retain the system equipment power cords against accidental removal.

Warning!
Use only the correctly rated fuses.

Warning!
All Power cords **MUST** be clipped.

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3.6.2 Base

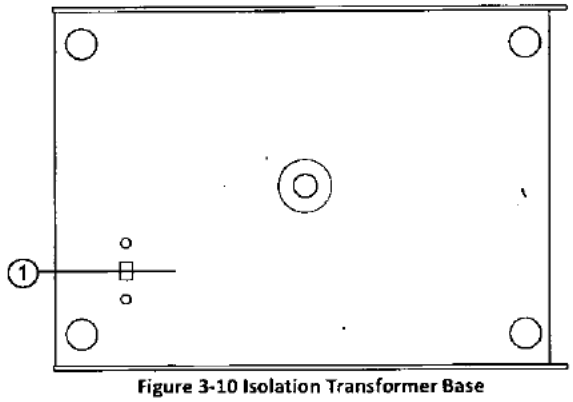

Figure 3-10 Isolation Transformer Base

No.	NAME	FUNCTION
1.	Output Voltage Selector	Switch to select the Isolation Transformer output (secondary) voltage.

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4 PREPARATION AND SAFETY CHECK

Warning!
The CEIS Control Unit and Optical Unit are medical electrical equipment incorporating delicate components and sophisticated circuitry that should not be subjected to harsh conditions, including strong vibrations or impact.

If the equipment is mishandled or dropped, **DO NOT** use it. Contact your Optiscan representative to arrange inspection.

4.1.1 Setting up the System

Note:
TO THE INSTALLER: The CEIS should be installed as described in this section to enable the user to achieve optimal use of the system.

Note:
If the CEIS and the associated Endomicroscope are to be used in a portable or moveable configuration then it is recommended that the components be installed onto a trolley system, so that the components can be securely mounted and transported without hindering the proper operation of the system. Refer to Table 8-2 for recommended trolley systems.

1. Place all equipment on a stable and level surface.
2. Place equipment in locations and positions that are suitable for convenient and safe operation.

Caution:

- **DO NOT** locate the CEIS Monitor and the Isolation Transformer directly adjacent to each other.
- **DO NOT** locate the Isolation Transformer on top of any other equipment.
- **DO NOT** install or use this equipment in areas where the unit could get wet or be exposed to adverse environmental conditions such as high temperature, humidity, direct sunlight, dust, salt, etc.
- **DO NOT** install or use this equipment in the presence of flammable or explosive gases of chemicals

3. Ensure all ventilation grilles are clear of obstructions.
4. Connect power cords from each piece of equipment to the Isolation Transformer as shown in Figure 4-1. The two EMI suppression cords supplied must be used for the CEIS-CU and the CEIS-OU. Use the supplied clips to secure the cords into the Isolation Transformer sockets.
5. Connect any power cords for peripheral equipment used with the CEIS to the Isolation Transformer.
6. Connect the mains power cord to the Isolation Transformer. Use the supplied clip to secure the cord into the Isolation Transformer socket. **DO NOT** plug the mains cord into the wall socket until instructed.

Warning!

- This equipment **MUST** be properly grounded. In the U.S.A. and Canada this equipment MUST be connected to a three (3) prong hospital grade outlet.
- Only power cords supplied with the CEIS equipment may be used for the CEIS equipment.
- Connect the power cords from all components of the CEIS System and accessories into the Isolation Transformer **ONLY**.
- Connect any peripheral equipment into the Isolation Transformer **ONLY**.

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(Refer to Table 8-2 for approved equipment)

Warning!

- When additional peripheral equipment is connected to the Isolation Transformer, check that the total power consumption of all connected equipment does not exceed 1000VA.
- **DO NOT** allow power cords or other cables to become twisted, crushed or pulled taut.

7. Connect the interconnecting Control Data, Control Signal and Optical Signal cables between the CEIS-CU and the CEIS-OU as shown in Figure 4-1. Ensure all interconnecting cables are not stretched tight and that all connectors are properly inserted. Ensure all the retaining screws are tightened.
8. Connect the Monitor Signal and Touch screen cables to the CEIS-CU as shown in Figure 4-1. Ensure all the retaining screws are tightened.
9. Connect the Keyboard cables to the CEIS-CU as shown in Figure 4-1.
10. Connect the Footswitch cable to the CEIS-CU as shown in Figure 4-1. Ensure the retaining screws are tightened.

Warning!

Ensure all interconnecting cabling is secured off the floor and away from trafficked areas to remove potential trip risks. Ensure the mains cord is routed away from trafficked areas to reduce the trip risk.

11. Ensure the Isolation Transformer is turned OFF.
12. Plug the mains cord into the wall socket and turn the wall socket ON.

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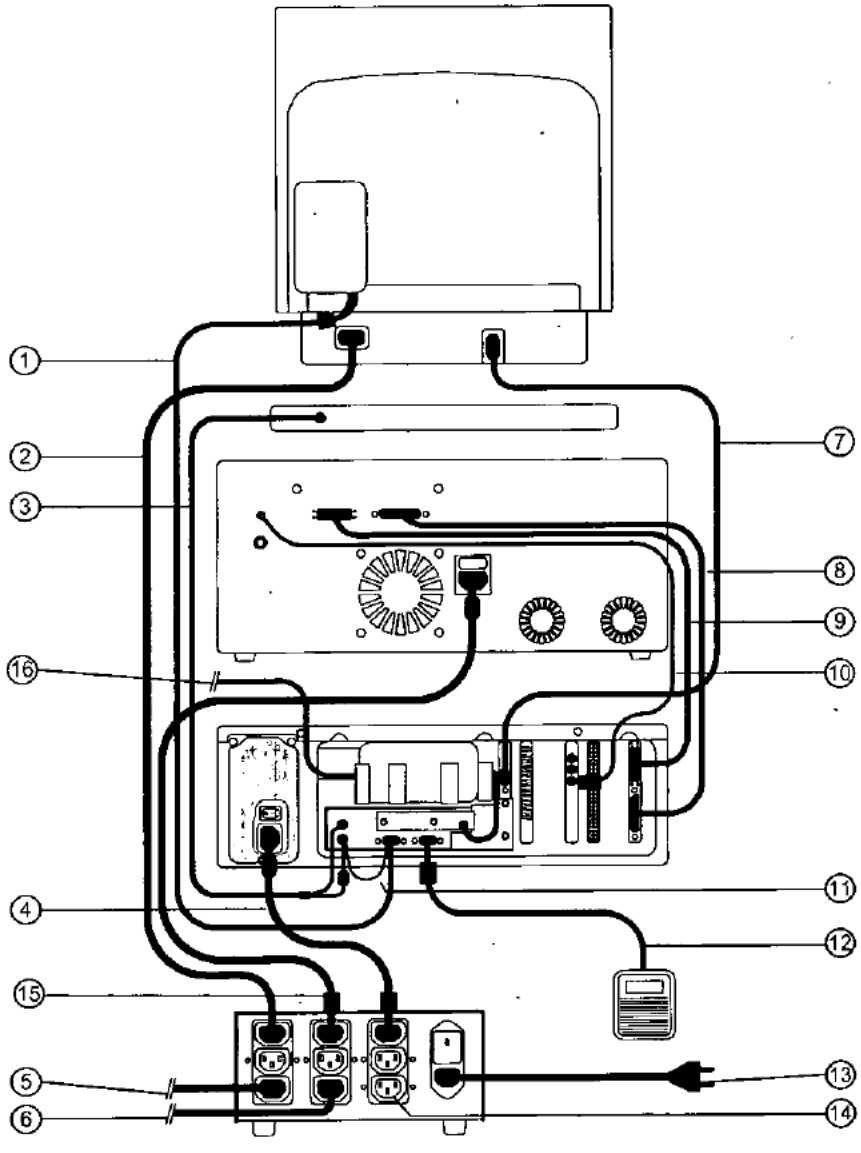

Figure 4-1 Connections of CEIS cabling.

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No.	NAME	FUNCTION
1.	Touch screen	Connects Touch screen signals to the CEIS-CU.
2.	Monitor Power	Supplies power to the Monitor from the Isolation Transformer
3.	Keyboard	Connects the Keyboard to the CEIS-CU via the Touch screen Power Adapter.
4.	CEIS-CU Power (EMI)	Supplies power to the CEIS-CU from the Isolation Transformer
5.	Accessory Outlets	Additional power outlets for connection to approved Accessories. Refer to Table 8-2
6.	Accessory Outlets	Additional power outlets for connection to approved Accessories. Refer to Table 8-2
7.	Monitor Video Signal	Connects Monitor Video signals from the CEIS-CU.
8.	Control Signal	Connects Control Signals between the CEIS-CU and the CEIS-OU.
9.	Control Data	Connects Control Data between the CEIS-CU and the CEIS-OU.
10.	Optical Signal	Connects the Optical Signal from the CEIS-OU and the CEIS-CU.
11.	Touch screen Power Adapter	Connects into the keyboard socket to supply power to the Touch screen.
12.	Footswitch	Connects the Footswitch to the CEIS-CU.
13.	Incoming Mains	Supplies incoming mains power to the Isolation Transformer.
14.	Accessory Outlets	Additional power outlets for connection to approved Accessories. Refer to Table 8-2
15.	CEIS-OU Power (EMI)	Supplies power to the CEIS-OU from the Isolation Transformer
16.	Network (if required)	Connects the CEIS-CU to a Local Area Network (UTP CAT5+)

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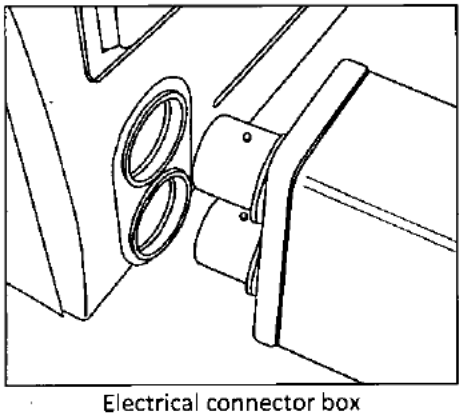
4.1.2 Connecting an Endomicroscope

Warning!

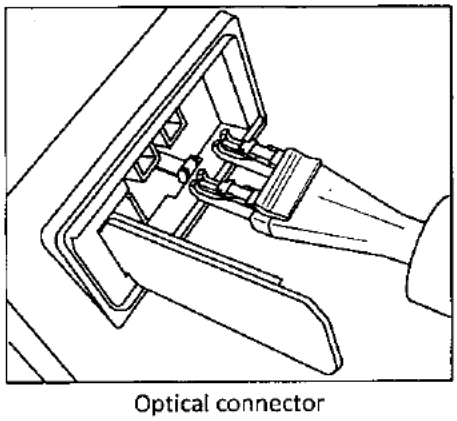
Only connect endomicroscopes that are listed in Table 8-2 and that meet the application required, and ensure that you consult the user instructions for the operational and installation instructions of any of these approved accessories to be used in conjunction with the CEIS System. Contact your local Optiscan representative if you require assistance.

Caution:

The endomicroscope **MUST NOT** be connected to or disconnected from the CEIS-OU whilst it is operating. Doing so may result in damage to the endomicroscope and the CEIS System.



Electrical connector box



Optical connector

Figure 4-2 Orientation of endomicroscope connectors

1. Ensure the CEIS is turned OFF.
2. Remove any caps from the endomicroscope connector box.
3. Align the endomicroscope Electrical Connector Box plugs with the CEIS-OU Electrical Connector as shown in Figure 4-2 and push the plugs fully into the sockets. Ensure that the connector is fully inserted.

Note:
This connector is keyed to ensure correct orientation. Ensure that the connector is fully inserted

4. Remove any caps from the confocal optical connector on the endomicroscope.
5. Hold open the Optical Connector door on the front of the CEIS-OU, align the dual optical connector with the dual socket inside the door as shown in Figure 4-2, and insert optical connector firmly into the mating CEIS-OU Optical Connector.

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4.2 Safety Check

Warning!

Before every use the following points should be checked. If any function or device in the CEIS does not perform properly, **DO NOT** perform the endomicroscopic procedure. Contact your local Optiscan representative before using the system for an endomicroscopic procedure.

1. Ensure the Isolation Transformer power switch is OFF.
2. Ensure that any approved accessory power switches are OFF.
3. Ensure the equipment is placed in a stable and level position.
4. Ensure all equipment is properly installed and interconnected.
5. Ensure the endomicroscope is properly connected.
6. Turn ON the Isolation Transformer.
7. Turn ON the approved accessory power switches, and follow any checklist instructions in the approved accessories manuals.
8. Turn ON the CEIS Monitor.
9. Turn ON the CEIS using the ON/OFF Button on either the CEIS-CU or the CEIS-OU. Note that both the power on indicators light.
10. Ensure that the CEIS-OU Laser ON indicator is not lit.
11. Ensure that the CEIS-OU Warning indicator is not lit.
12. Note that the CEIS Monitor displays a boot up sequence and presents a logon prompt. Logon and operating procedures are detailed in the CEIS Operator's Manual.
13. To prevent electrical shock, do not allow the CEIS or its approved accessories to be grounded to other electrical devices being used on the patient. Rubber gloves should always be worn to prevent grounding through user(s).

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5 OPERATION

Warning!

This equipment should **ONLY** be used under the supervision of a trained physician in a medical facility. **DO NOT** use in other locations or for any other purposes than the intended application.

Note:

Consult the user instructions for the operational instructions of any of the approved accessories used in conjunction with the CEIS System.

There are three instrument control devices on the CEIS. These are the keyboard and touch pad mouse, the monitor touch screen, and the footswitch. The footswitch triggers image capture during normal operation, and the other input devices provide multiple ways of performing similar functions. See the CEIS Operator's Manual for details on instrument control.

Note:

It is recommended that the Administrator and Service passwords not be changed from the factory default. Changing these passwords will cause delays in servicing and repair of this equipment, and may result in data loss.

Caution:

It is recommended that users do not log onto the CEIS as an Administrator. Administrator and service permissions allow access to parts of the instrument that should only be used by trained service technicians, and may change operating parameters to outside normal operating range.

5.1 Customer Site Install

When the system has been installed for the first time by your Optiscan In-Service Field Technician, the Microsoft XP End User License Agreement (EULA) will be displayed. The operation of the CEIS is not possible until the Customer has accepted the Windows XP EULA conditions on the screen. To agree with the terms of the Windows XP EULA simply click on the button "I accept this agreement" and then click on "Next" and the system will boot up automatically.

5.2 Principle of Operation

Confocal endomicroscope technology employs a laser to deliver highly focused beam of light to a specimen at controlled wavelengths via an optical fibre. A fluorophore is excited at the focus point of the confocal lens, and light of a longer wavelength is passed back through the same optical path used to illuminate the specimen. The collected light is transmitted by optical fibre to a light detection system which detects the light and converts it into a digital image displayed on the monitor.

By using an optical fibre as a spatial filter, only light returning from an exact plane of focus is permitted to pass through to the detection device. Light returning from other than the specific focal plane is not propagated by the optical fibre and omitted from detection. This process therefore rejects out-of-focus information to produce a thin optical section that can be positioned within a specimen to provide a sharp image with significantly higher resolution than a conventional light microscope. The optical section (image) obtained is oriented parallel to the surface of the specimen and optical window of the scanner.

This technique allows real time non-destructive high magnification imaging of living tissue.

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5.3 Performance Checks

Before using the endomicroscope in a clinical procedure, the following tests should be run to confirm that the system is running within normal operating parameters. These are tests for sensitivity, linearity and imaging depth control. Refer to the CEIS Operator's Manual for instruction on how to control the instrument.

5.3.1 Sensitivity Tests

1. Start the Clinical Application
2. Select "2. Green Fluoro - Normal gain" from the Procedure List and proceed to the Acquisition screen.
3. Set the Brightness to Min (0) and the Gamma to Mid (1.0)
4. Place a cloth test sample against the confocal imaging window of the endomicroscope tip.
5. Set the laser power to Mid (~500uW)
6. Operate the depth controls and ensure that the image changes accordingly. It should be possible to position the focal plane above the specimen (within the coverglass, where no fibres are visible), through the fluorescent fibres, and beyond the specimen at the deeper extreme. Fibres touching the confocal imaging window often have a "wet" appearance.
7. Bring into focus a field of view containing an array of fibres just beneath (touching) the confocal imaging window.
8. Adjust the laser power to produce an image on screen that ranges from completely black to brilliant white, representing the full dynamic range of the instrument imaging intensity. An example of a good full dynamic range image is shown in Figure 5-1, where the brightest parts of the image are just white. Large areas of saturation (Figure 5-2) suggest the laser power needs to be reduced. If the image is dim and does not fill the instrument's full dynamic range (Figure 5-3), the laser power should be increased.

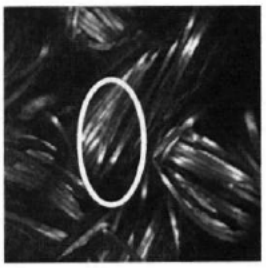

Figure 5-1

Figure 5-2

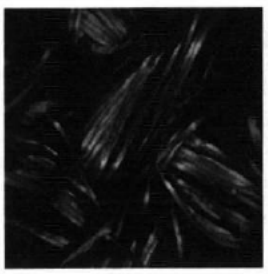

Figure 5-3

9. If the laser power required to obtain a full dynamic range image of the cloth test sample is:
   - **less than 650uW**, exit the procedure, select the procedure type "1. Green Fluoro – Low Gain" and repeat steps 3–9 of the sensitivity test.
   - **650–850uW**, see step 10
   - **higher than 850uW**, exit the procedure, select the procedure type "3. Green Fluoro – High Gain" and repeat steps 3–9 of the sensitivity test.
10. The procedure type used (low gain/ normal gain/ high gain) to obtain a full dynamic range image with 650–850uW laser power is recommended for routine in vivo imaging with the particular endoscope used.
    - If the High Gain procedure and maximum laser power still fail to produce a full dynamic range image, system sensitivity may be compromised and result in difficulty imaging human tissue. Note that the Maximum Gain procedure is reserved for imaging tissues known to have very dim fluorescence. It should not be necessary to proceed to the Maximum Gain procedure in order to obtain a full dynamic range image of the test cloth.
    - If the Optical Connection between the endomicroscope and the CEIS-OU is dirty, instrument sensitivity will be reduced. A sudden change in sensitivity when imaging the

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test cloth from one procedure to the next suggests that the Optical Connectors require cleaning to be performed by your Optiscan representative.

5.3.2 Image Linearity and Alignment

1. Use a cloth test sample to check that the linearity of the system is within normal operating range.
2. Rotate the test sample until the fibres in the cloth are orientated correctly.
3. Operate the depth controls to confirm the depth of view moves both up and down and to the Home position as expected.

5.4 During Use

Warning!

To avoid electric shock **NEVER** apply the attached endomicroscope or any other accessory device directly to the heart.

1. The attached endomicroscope is Class 3R Laser Product. During operation laser radiation is emitted from the endomicroscope tip. **DO NOT** stare into the laser beam or view directly with optical instruments.

Caution:

If the laser system has been operating for more than 30 minutes in air, care should be taken as the distal end may be hot. To avoid excessive heat at the distal end prior to inserting the endoscope place the distal end of the endoscope into a container of sterile water and suction. Lift the distal end out of the water and exercise the water delivery and air delivery functions.

2. During a procedure, use the minimum laser power required.
3. During clinical procedures, avoid unnecessary prolonged use which could compromise patient/user safety.
4. To avoid damage to the monitor display and membrane switches, do not press or impact with any hard or sharp objects.
5. Continually monitor this equipment and the patient for any signs of irregularities.
6. In the event that some type of irregularity is noted in the patient or this equipment, take the appropriate action to ensure patient safety.

Warning!

The CEIS should only be used according to the instruction and operating conditions described in this manual and the CEIS Operator's Manual. Failure to do so could result in compromised safety, equipment malfunction or instrument damage.

7. In the event that the system ceases to respond to operational commands, press and hold the Power ON/OFF button on the front of the CEIS-CU or CEIS-OU until the system shuts down. Restart the system as for normal operation.
8. After turning off the Isolation transformer it is recommended to let the Isolation Transformer "cool down" for approximately 1 minute, before the unit is turned on again. There may otherwise be a risk of blowing a fuse in the power entry module or possibly tripping the wall outlet circuit breaker.

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5.5 Connection to a Network or Peripherals

The CEIS may be connected to a network using the LAN Port (see Figure 3-2).
By default the instrument will automatically configure the network setting using DHCP.
While the LAN Port is available to allow printing to a network printer or for data transfer across a network, the CEIS has not been tested for operation with any specific network configuration or network device. Before you connect the LAN Port you should consult with your Hospital or Clinic IT Coordinator.

Caution:

Connecting the CEIS to a network may expose it to computer viruses and security vulnerabilities. Accordingly, it is the responsibility of the customer to ensure that the network is regularly updated with appropriate virus protection software and is configured with security features.

The CEIS is factory configured with the setting "not to accept Windows updates" as may be distributed to Windows users from time to time. It is recommended that this factory setting "not to accept Windows updates" be maintained as the CEIS would not have been tested for complete functionality against each Windows update.

Note:
The technician account provides administrator access, which is required to network connect the CEIS. You will need to contact your Optiscan technical support person for your area to obtain the password to access this Technician account.

It is recommended that the Technician password is not changed from the factory default. Changing the password will cause delays in servicing and repair of this equipment, and may result in data loss and/or damage to the instrument. Delays in servicing and repair caused by changes to passwords will incur additional costs.

Caution:

Once the CEIS has been networked connected, it is recommended that the user does not log onto the CEIS under the Technician account as Technician permissions allow access to parts of the instrument that should only be used by trained service technicians, and may change operating parameters to outside normal operating range.

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6 MAINTENANCE

6.1 After Use

Note:
Consult the user instructions for the after use handling and care of any of the approved accessories used in conjunction with the CEIS System.

1. Shut down the Clinical application and then shut down the equipment. Refer to the Operator's Manual for instructions on shutting down the application and the equipment.

Caution:
Unless in an emergency, The CEIS should only be shut down using the software method detailed in the Software User's Manual. Turning power off in any other way risks losing data and damaging the integrity of the software installation. Refer to the user instructions for the shutdown procedures of any of the approved accessories used in conjunction with the CEIS System.

2. Disconnect the endomicroscope. Disconnect the Optical Connector first. Replace the soaking caps over the endomicroscope connectors as they are disconnected.
3. Be sure connector interfaces and ventilation ports are not allowed to become wet or splashed with liquids.
4. Inspect the CEIS components for substance contamination and clean equipment enclosures as required. Refer to part 6.2 for cleaning guidelines.

6.2 Cleaning

6.2.1 Cleaning the CEIS Monitor and Touch Screen

1. Ensure the equipment has no power connected when cleaning is performed.
2. When necessary, wipe the surface of the monitor case with a mild non-abrasive detergent (non-ammonia and non-alcohol based) on a soft, clean lint-free cloth.
3. Clean the touch screen surface as required. For best results, use a pre-soaked wipe or towellette containing non-abrasive cleaning agent such as, isopropyl alcohol or ethyl alcohol.
4. If the connector between the plug and the pin is dusty or dirty, clean it properly with a dry cloth.

Caution:
- **DO NOT** spray cleaner directly onto the monitor case or the touch screen.
- **DO NOT** use abrasive, alcohol or alcohol based cleaning agents on the monitor case.
- **DO NOT** place open containers of water or chemicals on the monitor.
- **DO NOT** place any small metallic objects on the monitor.

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6.2.2 Cleaning the CEIS-CU and CEIS OU Enclosures

1. Ensure the equipment has no power connected when cleaning is performed.
2. When necessary, wipe the surface of the enclosure with a soft fabric slightly dampened with a dilute solution of detergent and water (1 part of detergent to 10 parts of water).

Caution:

- **DO NOT** spray cleaner directly onto the enclosure.

6.3 Service

Warning!

DO NOT make ANY alterations or modifications to the equipment.

1. There are no user serviceable parts inside the equipment.
2. Repairs should only be performed by an authorized Optiscan service agent.
3. Fuses for the Isolation Transformer and the CEIS-OU may be replaced provided only Optiscan supplied replacement fuses are used.

Warning!

Repeated fuse failure indicates faulty equipment. **DO NOT** use the equipment until it has been inspected by an Optiscan service agent.

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6.3.1 Replacing Isolation Transformer Fuses

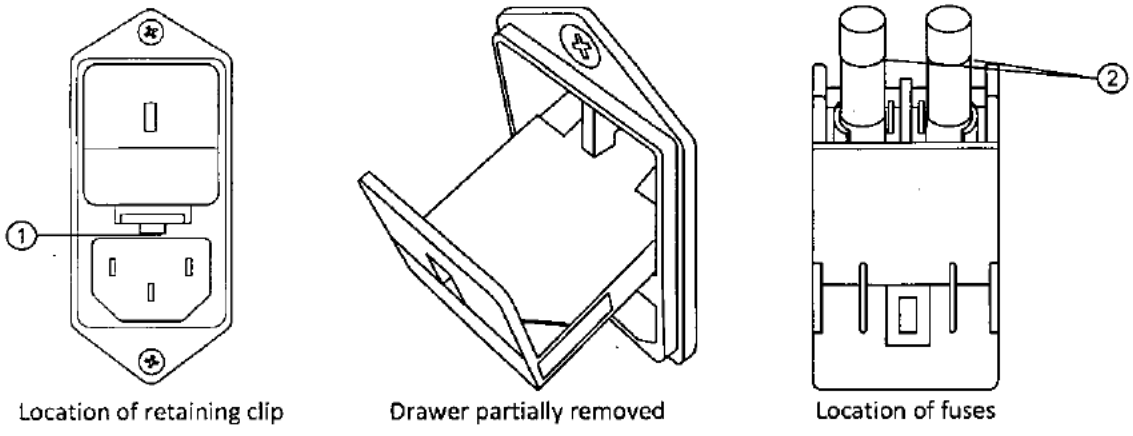

Figure 6-1 Isolation Transformer Fuse Replacement

Caution:
Make sure the mains power is turned off at the wall socket and the mains cord is unplugged.

1. Ensure the Isolation Transformer is turned off.
2. Unclip and unplug the mains power cord from the Isolation Transformer.
3. Remove the Fuse and Selector Drawer as shown in Figure 6-1 by raising the drawer retaining clip (1) with a small screwdriver or similar tool. The location of the drawer on the Isolation Transformer is shown in Figure 3-9.
4. Remove and replace the two fuses (2) with the same rated fuses supplied by Optiscan.
5. Reinstall the Fuse and Selector Drawer by placing it into its receptacle and pushing gently until the retaining clip engages.

Caution:
DO NOT apply significant force to the drawer.

6. Reinstall the mains power cord and ensure the clip is correctly in place.
7. Plug the mains cord back into the wall socket and turn the power on.
8. Turn the isolation transformer on and note that the switch indicator lights.
9. If the fuses blow again consult your Optiscan representative.

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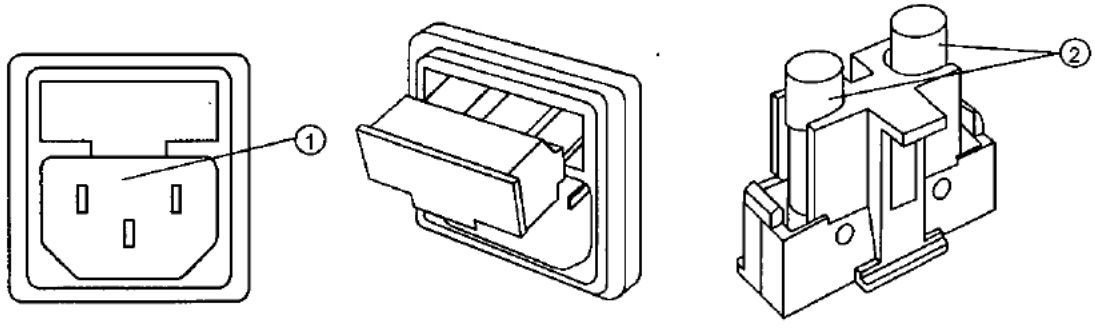
6.3.2 Replacing CEIS-OU Fuses



Location of drawer | Drawer partially removed | Location of fuses

Figure 6-2 CEIS-OU Fuse Replacement

Caution:
Make sure the power is turned off at the Isolation Transformer.

1. Unplug the power cord from the CEIS-OU.
2. Withdraw the Fuse Drawer as shown in Figure 6-2 by levering out the base of the drawer (1) with a small screwdriver or similar tool. The location of the drawer on the CEIS-OU is shown in Figure 3-4.
3. Remove and replace the two fuses (2) with the same rated fuses supplied by Optiscan.
4. Reinstall the Fuse Drawer by placing it into its receptacle and pushing gently until it is firmly home and flush with the surface of the connector. DO NOT apply significant force to the drawer.
5. Reinstall the power cord.
6. Turn on the CEIS following the checklist in part 0 and note that the CEIS-OU ON/OFF Indicator lights as it should.
7. If the fuses blow again consult your Optiscan representative.

6.4 Storage

1. **DO NOT** store the equipment in direct sunlight or where the unit could get wet or be exposed to any adverse environmental conditions such as high temperature, humidity, direct sunlight, dust, salt, etc.
2. **DO NOT** store the equipment where it can be exposed to liquids.
3. **DO NOT** store the equipment where it can be exposed to flammable or explosive gases or chemicals.
4. Power cords, cables and other accessories should be cleaned and neatly stored in bags or an appropriate container.
5. Equipment in storage should be periodically inspected for safety and tested for correct operation.

Caution:
For long term storage take precautions to prevent the ingress of dust and insects into the equipment. Accumulation of dust or insects within the equipment may cause malfunction, smoke or ignition when next turned on.

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6.5 Disposal

This equipment should be returned to Optiscan for disposal. Contact your Optiscan representative.

An Information on Disposal for users in the European Union

This product is a medical device. In accordance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment, this symbol indicates that the product must not be disposed off as unsorted waste, but should be collected separately. Contact your local Optiscan distributor for correct disposal and recycling.

By disposing of this product correctly you will help ensure that the waste undergoes the necessary treatment, recovery and recycling and thus prevent potential negative effects on the environment and human health which could otherwise arise due to inappropriate waste handling.

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7 TROUBLE SHOOTING GUIDE

CONDITION	CHECK	ACTION
No power at the isolation transformer	Mains power cord	Ensure proper connection at transformer and wall outlet.
	Fuses	Remove and inspect isolation transformer fuses. If unsure replace the fuses.
	Power outlet	Move the mains power cord to an outlet that is known to work.
CEIS-CU does not turn ON.	Isolation transformer	Ensure isolation transformer is turned ON. Note switch indicator light is lit.
	Power cord	Ensure proper connection at isolation transformer and CEIS-CU
CEIS-OU does not turn ON with CEIS-CU	Power cord	Ensure proper connection at isolation transformer and CEIS-OU
	Control data cable	Ensure proper connection at CEIS-CU and CEIS-OU
	Fuses	Remove and inspect CEIS-OU fuses. If unsure replace the fuses.
CEIS-OU ON/OFF switch does not work	Control data cable	Ensure proper connection at CEIS-CU and CEIS-OU
	Power cord	Ensure proper connection at isolation transformer and CEIS-CU
Monitor does not turn ON with CEIS-CU	Power cord	Ensure proper connection at isolation transformer and monitor
	ON/OFF switch	Ensure monitor ON/OFF switch is turned on

Table 7-1 Trouble Shooting Guide

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8 TECHNICAL SPECIFICATIONS

Power Requirements			
Rated Voltage		100 ~ 120 VAC	(USA, Canada & Japan)
		220 ~ 240 VAC	(Europe & Australia)
Rated Frequency		50 ~ 60 Hz	
Power Consumption		6A	(USA, Canada & Japan)
		3 A	(Europe & Australia)
Fuse Rating			
	CEIS – OU	T 3.15A	
	Transformer Fuse	T 5A	(Europe & Australia)
		T 10A	(USA/Canada)
		T 12.5A	(Japan)
Electrical Standard Requirements			
The system complies with IEC60601-1, EN 60601-1, UL 60601-1 & CAN/CSA-C22.2 No. 601.1 M90			
Protection against Electrical shock		Class One Equipment With Connected Endoscope Type BF Applied Part	
Degree of Ingress Protection		The CEIS is rated at IPX0 The CEIS Footswitch is rated at IP68.	
EMC Requirements			
The system meets the EMC requirements in accordance with IEC60601-1-2 & EN 60601-1-2. The system meets the RFI requirements of Group 1 Class B			
Product Classification			
As per Directive 93/42/EEC, Annex IX: Class IIa (Rule 10)			
Product Labelling / Approvals			
CE Labelling		The system meets the essential requirements stipulated in Annex I to the 93/42/EEC directive governing medical devices. The system is labelled with : CE 0197	
Electrical Safety (NRTL)		The system is labelled with:	
Operational Specifications			
Hard disk		80GB Total capacity ~70GB available for data storage	
Operating system & software		Windows XP, includes integrated control and image acquisition software	
Cooling		Forced Air Cooling	
Detection			
	Number channels	1	
	Dynamic range	12 bits	
	Bandwidth (User Selectable)	Filter HQS45 / 80M Chroma	Filter LP505 HE488
		505 nm – 585nm	505nm Long Pass (LP)

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Illumination Method		Class 3R Laser Output with Connected Endoscope	
	Laser Wavelength	488 nm ± 2 nm with connected Endomicroscope	
	Scanner Maximum Optical Output Power:	1 mw @ 488 nm with connected Endomicroscope	
Imaging			
	Transverse modes:	M^2 <1.1, TEMoo with connected Endomicroscope	
	Field of View (minimum):	~ 500 x 500 µm with connected Endomicroscope	
	Depth Range (minimum):	0 – 200 µm with connected Endomicroscope	
	Confocal Axis Response:	8 µm with connected Endomicroscope	
	Confocal Lateral Response:	1 µm with connected Endomicroscope	
	Scan Modes:	Scan Mode 1	Scan Mode 2
	(resolution/ Frame Rate (/sec):	1024 x 1024 / 0.7	1024 x 512/ 1.2
	Imaging Output Format	Compatible with BMP, TIF, JPG and OPZ (Optiscan Proprietary Imaging Format). Refer to CEIS Operators Manual for full details	
Ambient Requirements			
Operating Environment			
	Temperature	10 ~ 40 ºC	
	Relative Humidity (non-condensing)	0 ~ 85 %	
	Air Pressure	700 ~ 1060 hPa	
Storage/Transport Environment			
	Temperature	-20 ~ 60 ºC	
	Relative Humidity (non-condensing)	0 ~ 85 %	
	Air Pressure	700 ~ 1060 hPa	
Dimensions & Weight			
Size (WxHxD not packaged)			
	CEIS-CU	410 x 140 x 450 mm	
	CEIS-OU	430 x 180 x 470 mm	
	Monitor (with stand)	440 x 461 x 460 mm	
	Isolation Transformer	225 x 115x 310 mm	
	Keyboard (excluding cable)	415 x 35 x 193 mm	
Weight (not packaged)			
	CEIS-CU	10.8 kg	
	CEIS-OU	16.2 kg	
	Monitor (with stand)	21.0 kg	
	Isolation Transformer	11.0 kg	
	Keyboard (excluding cable)	1.0 kg	

Table 8-1 Specifications

Application	Compatible Confocal Endomicroscopes	Compatible Digital Video Processor	Compatible Trolley
Gastro Intestinal Examination	EC-3870CILK (PENTAX) EC-3870CIFK (PENTAX) EC-3870CIMK (PENTAX) EG-3770CIK (PENTAX)	EPK-1000 (PENTAX)	SMC-V10 (PENTAX)

Table 8-2 Approved Accessories

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NOTICE
This equipment is a Class B Medical Equipment (specified EN55011) and is intended for hospital or health care districts.
When used in clinical or residential areas near radio and TV receiver units, this equipment may be subjected to radio interference.
To reduce electromagnetic interference, do NOT keep turning on the main SWITCH of the equipment while a confocal endoscope is connected but not ready for use.
To avoid and resolve adverse electromagnetic effects, do NOT operate this equipment near the RF energy equipment.
Only connection cables and keyboard specified by OPTISCAN conform to the above standards.

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EC REP

Specifications are subject to change without notice and without any obligation on the part of the manufacturer.

CE 0197

Document (b) (Revision ((printed in AUSTRALIA)

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User Instructions
CEIS Operators Manual

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Revision: [redacted]
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Created from Template: Standard.Dotx

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Document Approval:

(b)(6) [redacted]

Signature: _____ Date: 13/5/09
Reviewer (Software Manager)

(b)(6) [redacted]

Signature: _____ Date: 20/5/2009
Approval (R&D [redacted]

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(b)(4)	(b)(6)	19/12/2005	Converted from 000420
		24/1/2007	CEIS Operators Manual updated by reference to the ISC-1000 Operators Manual which includes a number of changes requested by Pentax
		18/11/2008	Update to correspond with the ISC-1000 Owners Manual 000421 revision 19. All references to the ISC-1000 specific references have been changed to their CEIS equivalents.
		2/3/2009	Add new Cover Art Added Document and revision reference on all pages. Added a list of Tables and Figures
		14/5/2009	Add DIMDI Code to European Representative in last page Removed Declaration of Conformity from last page

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OptiScan|CEIS

Confocal Endoscopic Imaging System

Operator's Manual

Clinical Software Version 2.3
Reporter Software Version 2.3

Fluorescence In Vivo Endomicroscopy

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1 SCOPE AND CONTENT

1.1 CEIS Software Application

This Operators Manual describes the methods and procedures for operating the CEIS using the following releases of software.
Clinical Application Version 2.3
Reporter Application Version 2.3

This manual does not describe the use or operation of any of its approved accessories, and does not describe the general use or operation of an attached confocal endoscope.
This manual must be read in conjunction with the CEIS Owners Manual. Be sure to read and understand the Owners Manual before attempting to operate the CEIS equipment. All Operators must receive training before using the Clinical application and Reporter application to perform a clinical procedure.

1.2 Caution and Note Messages

The following conventions have been established in the text of this manual to aid in the identification of important information.

Warning!
The **warning triangle** indicates potential sources of danger which may constitute a risk of injury for the user or a health hazard.

Caution:
The **square** indicates situations which may lead to malfunction, defects, collision or damage of the instrument.

Note:
The **hand** indicates hints on the use of the instrument or other tips for the user.

1.3 Overview of the Imaging Modes

The CEIS software application operates in two image specific modes:
Acquisition (Section 4) and Review (Section 5).

The Image Acquisition mode allows images to be captured, reviewed, and stored as part of a Procedure Result. The types of information that may be found in Procedure Results are described further in Section 3.1.

The Image Review mode allows the review of previously collected Procedure Results. Procedure Results may be exported and imported for archival and retrieval purposes, and to allow the transfer of Procedure Results between CEIS systems. Image files can be exported and can also be used in other, third-party applications.

A work flow diagram showing the relationship between the stages of each of the Acquisition and Review modes is shown in at the start of each section.

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2 SOFTWARE OPERATION

2.1 Principles of Operation

The CEIS captures and displays endomicroscopy images of surface and subsurface layers of a tissue or organs site. The CEIS transmits light from a variable output laser via an optical fiber. The laser light is focused to a diffraction-limited spot within the tissue. A scanning mechanism in the tip of the endomicroscope is used to scan the focused point of laser light across an area of tissue (approximately 475 µm x 475 µm). Only light returning from the focal spot in the tissue is focused back onto the tip of the optical fiber, and propagated back to the detector. The detector is used to measure the intensity of the light returning from the tissue. An image is built up by sequentially measuring the intensity of light returning from each point within the scanned area. In other words, an image is comprised of an array of individual point intensity measurements.

When an image is captured, the CEIS stores the last complete image (not the partially complete image that is scrolling down the screen). The CEIS uses a Look Up Table (LUT) to display an image from the measured data. The Brightness value (Section 4.3.4) and the Gamma value (Section 4.3.5) can be modified to reveal different visual features of the image of the tissue site. The original image is always available.

2.2 Software Conventions

The following software conventions are used throughout this document:

- ALL CAPITALS indicate keyboard commands (e.g. press the ENTER key).
- Text in boxes indicates the labels of software buttons on the screen (e.g. [Start A New Procedure]).

Control of the Clinical application software is achieved in a number of ways. These include:

- touching controls directly on the touch screen,
- using the built-in touch pad on the keyboard to move the screen cursor,
- using the keyboard to type in information, and
- stepping on the footswitch.

Controls on the screen are either buttons to perform actions or sliders to adjust settings.

Buttons can be operated by any of the following ("press" means operating the button by any of these means):

- single-tapping the button on the screen,
- moving the screen cursor using the keyboard touch-pad and clicking using the touch-pad buttons (or double-tapping the touch-pad—ensure that the two taps are in the same spot otherwise they will register as two separate single taps),
- pressing the TAB key until the required button is highlighted and pressing ENTER on the keyboard (or single-tapping the touch-pad).

Items in a list can be selected or highlighted in the same way as buttons. Unlike buttons, more than one list item may be selected at a time. To select a block or continuous set of list items: highlight the first item; hold down SHIFT; highlight the last item. To select a discontinuous or random set of items: hold down CTRL and highlight each desired item in turn.

Sliders can be operated by any of the following:

- applying pressure to and dragging the slider pointer using the screen,
- clicking and holding the slider pointer with the screen cursor by the touch pad and drag the slider in the direction required, and
- pressing the increase [▶] button or the decrease [◀] button.

Displayed lists of previously entered information can be sorted by clicking on the column heading of interest. Click once to sort in ascending order. Click again to sort in descending order.

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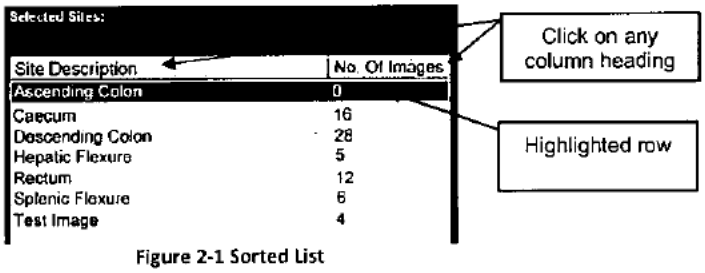

Figure 2-1 Sorted List

Data entry fields can be selected in the same way as buttons: touching the screen, clicking the touch-pad, and using the TAB key. Then type the required information in the field.
Where possible, error checking is performed on data entry. In the case where too much or the wrong type of information (e.g. an incorrect value in a date field) is entered into these fields then the operator will be prompted to correct the data entry when attempting to save the information.
One or more of the following buttons appears on each screen.

Next	Advance to the next screen
Back	Return to the previous screen
Save	Save any modified data and stay on the same screen—usually the button is dimmed to show it is inactive and becomes active when a change is made, otherwise it is always active
Done	Accept any input or editing changes and return to the main screen.
Exit	Go to **Save Procedure Result** screen (Section 4.6). If no information has been entered then go to **Start-up** (Section 0).

If there are unsaved changes on the screen then there is a prompt to do ***one*** of the following:

- save the change before returning
- discard (or abort) the change
- cancel the action and stay at the screen.

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3 CLINICAL APPLICATION OVERVIEW

The Clinical software application is used for imaging. When the CEIS equipment is turned on and has initialized, the Logon screen displays three user-accounts.

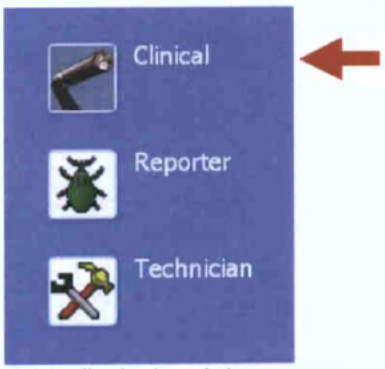

Figure 3-1 Application icons in Logon screen

Select the Clinical account icon to log on. The Clinical application automatically launches and displays the Start-Up screen (Section 0).

The Reporter account and its associated application are described in Section 6. The Technician account is password protected and is for servicing the CEIS equipment by trained service personnel only.

3.1 How the Information is Structured

The purpose of an Imaging Procedure (when a Subject is examined) is to capture images for subsequent analysis. All information associated with the procedure is stored in a Procedure Result. Each Procedure Result is part of a database. A Procedure Result is a collection of data comprising some or all of the following:

- contextual information entered by the operator during the procedure
- captured images
- range of instrument settings used at the time each image was captured
- Site Description of where each set of images was captured to allow identification
- associated data entered by the operator during the procedure.

Each procedure result is uniquely identified by the date and time the procedure result is created, and a unique session identification number that is generated by the CEIS. Each procedure result will always contain at least one imaging site (default site is **SITE_1**) unless otherwise named or additional sites entered.

Contextual information optionally entered includes additional notes and details pertaining to the Subject, Operator and imaging Site(s). Such Information is entered using the appropriate **Information Logging** screens (Section 4.2): Create Sites, General Notes, Operator Details, and Subject Details. To assist with data entry, the details of an Operator or Subject previously entered can subsequently be recalled from the database and used for a new Procedure.

Retrieval of stored procedure results is based on information entered about the Subject. Entering complete Subject details at the time a procedure is performed will assist in identifying stored procedure results at a later time.

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3.2 Start-up Screen

The Clinical application Start-up screen is shown in Figure 3-2

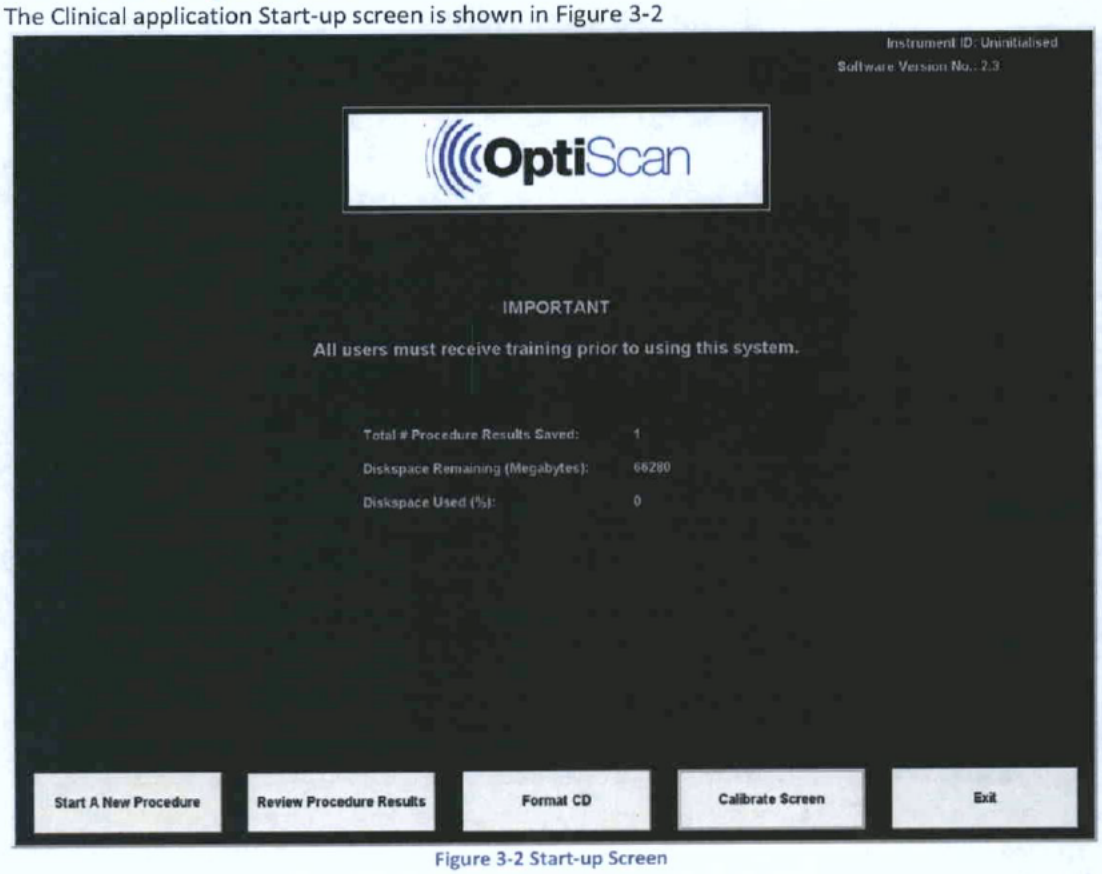

Figure 3-2 Start-up Screen

There are five menu buttons across the bottom of the screen. The action of each button is summarized as follows:

Start A New Procedure	The Acquisition mode (Section 5). Start a new Imaging Procedure to begin the acquisition and storage of new images. On initial instrument start up this button is dimmed during initial calibration. It becomes active after the system calibration and set-up has completed. If the system detects a fault then a message box is displayed (Figure 3-3). The button remains inactive.
Review Procedure Results	The Review mode (Section 5). Review and adjust images and information saved as a Procedure Result.
Format CD	Format a blank CD so it can be used to store user data (Section 3.3).
Calibrate Screen	Calibrate the touch screen (Section 3.4).
Exit	Exit the **Clinical** Application (Section 3.5).

The Review Procedure Results , Format CD , and Calibrate Screen button functionality is available during the initial set-up time.

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Note:
It is not necessary to have a confocal endomicroscope connected to the instrument to review stored Procedure Results. However if the **Clinical** application is started without a confocal endomicroscope connected, the error message in Figure 3-3 will be displayed because the instrument detects that there is no endomicroscope fitted and will therefore not allow a new imaging procedure to be started.

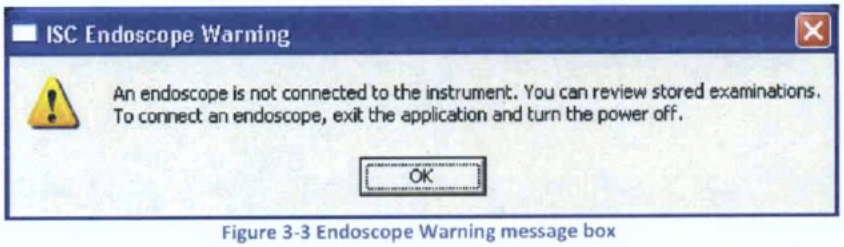

Figure 3-3 Endoscope Warning message box

3.3 Format CD

This button formats a blank CD using a third-party application, DirectCD. This allows user data, (images, procedures, and so on) to be written directly to a CD-Recordable (CD-R) or CD-ReWritable (CD-RW) disc in much the same way that files are copied to a floppy diskette or removable drive.
Ejecting the CD closes it so that it can be read in a normal CD-ROM drive. If the CD is not full, additional data can be added to the CD by re-inserting it into the CD writer. It does not need to be reformatted to add additional data.
The information on the CD is also accessible to CD-ROM (read-only) drives. The formatting application has its own extensive on-line help available.

Note:
The blank CD must be formatted before any data can be written to CD directly from the Clinical application and should be done ***before*** reviewing saved procedure results.

3.4 Calibrate Screen

This button allows the calibration of the touch-screen so the cursor accurately tracks where the screen is touched.
There are 2 buttons available that will commence the calibration of the touch-screen. Select the button labelled with the two (2) point (pt) number and follow the instructions on the screen

From a comfortable operating position, touch the screen at the points indicated and allow the calibration to complete.

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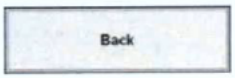
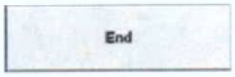
3.5 Shutting Down the System

Shut down the system by pressing the Exit button in the lower right corner of any screen in the application. The **Start Up** Screen (Figure 3-2) is displayed. Press the Exit button on the **Start Up** Screen to display the Exit Confirmation screen, (Figure 3-4).

Figure 3-4 Exit Confirmation Screen



Terminates the software application. Displays a **System Termination** splash screen, (Figure 3-5), that remains visible until all system termination activities are complete. The system then displays the **Logon** screen, (Figure 3-1).



Return to the **Start Up** screen.

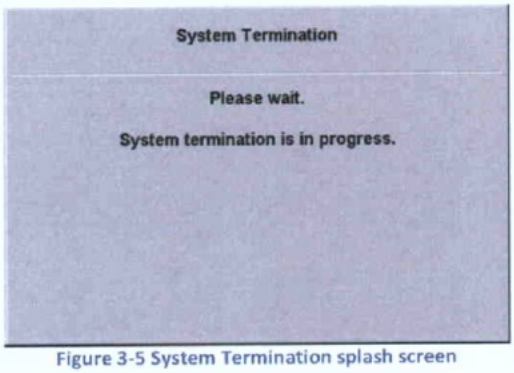


Figure 3-5 System Termination splash screen

Press Turn off computer on the screen to power down the system.

3.6 Backup and Archiving

It is strongly recommended to regularly back up the data stored on the CEIS by copying Procedure Results onto CD using the Export Procedure Results function (Section 5.2.1).

In the event that the data storage medium of the CEIS fails, the Procedure Results stored on CD may be used to rebuild the instrument database by importing the saved Procedure Results.

Caution:
Failure to make backup copies may result in data loss in the event of an instrument failure or malfunction.

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4 CLINICAL: ACQUISITION MODE

The Acquisition mode is used to collect images and contextual information of a Subject during a Procedure. The workflow through the acquisition screens is shown in Figure 4-1.

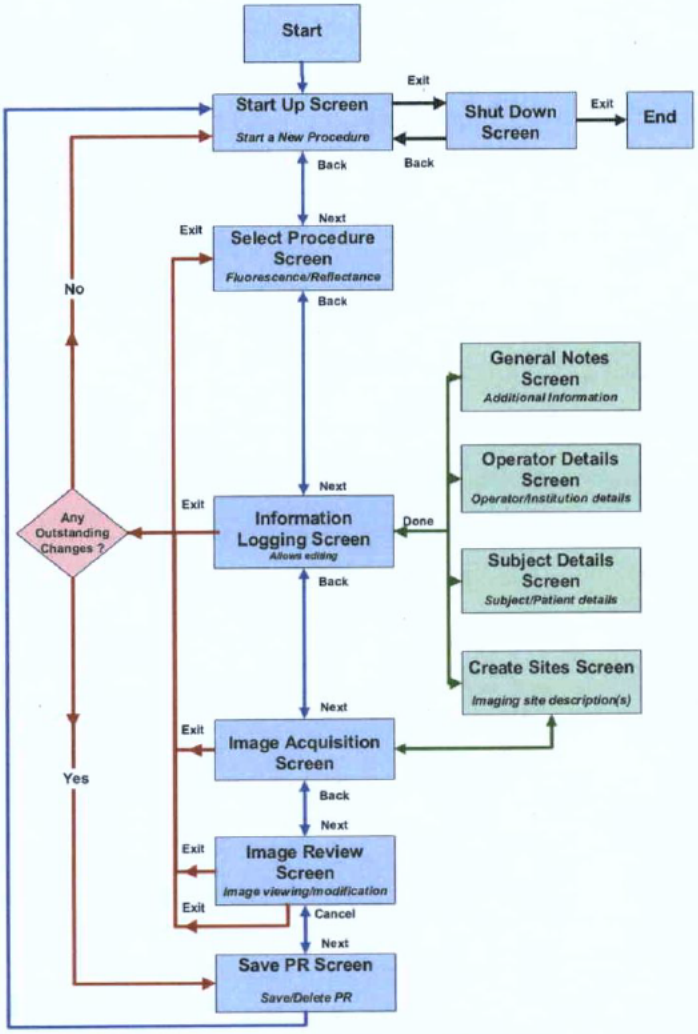

Figure 4-1 Clinical Acquisition mode flowchart

Press Start A New Procedure on the **Start-up** screen (Section 0) to start a new Imaging Procedure.

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4.1 Selecting a Procedure Name

Use the Select Procedure screen (Figure 4-2) to select the required imaging procedure from the Available Procedures list.

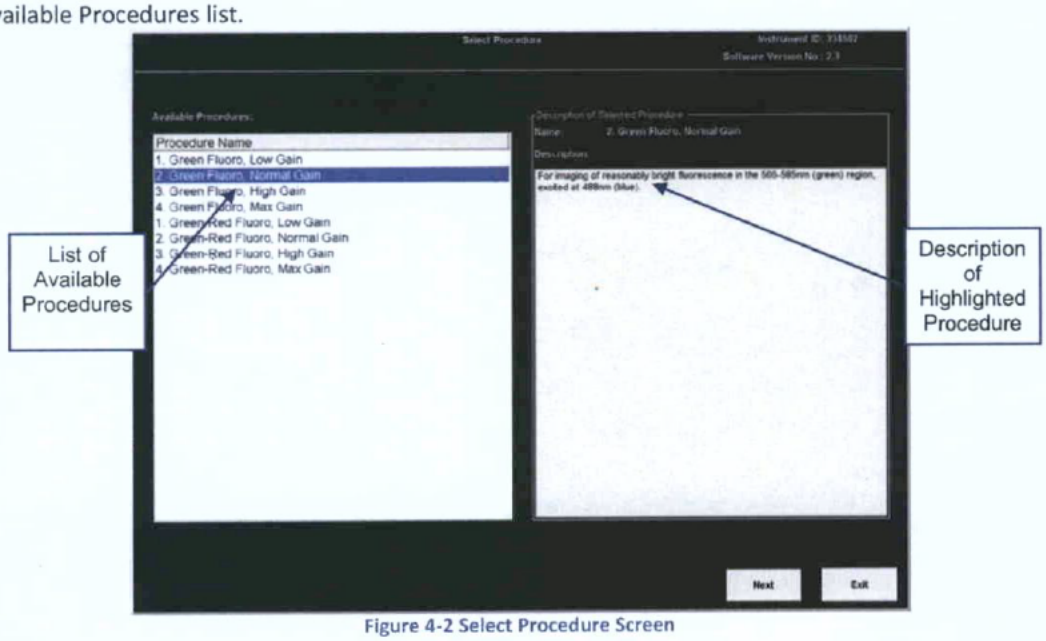

Figure 4-2 Select Procedure Screen

There are eight procedure types for acquiring images:

Green Fluro, Low Gain	Used for imaging unusually bright fluorescent emission from the specimen in the range 505-585nm, illuminated with 488nm incident light.
Green Fluro, Normal Gain	Used for imaging reasonably bright fluorescent emission from the specimen in the range 505-585nm, illuminated with 488nm incident light.
Green Fluro, High Gain	Used for imaging dim fluorescent emission from the specimen in the range 505-585nm, illuminated with 488nm incident light.
Green Fluro, Max Gain	Used for imaging very dim fluorescent emission from the specimen in the range 505-585nm, illuminated with 488nm incident light.
Green-Red Fluro, Low Gain	For imaging of unusually bright fluorescence in the 505-750nm (green-red) region, excited at 488nm (blue).
Green-Red Fluro, Normal Gain	For imaging of reasonably bright fluorescence in the 505-750nm (green-red) region, excited at 488nm (blue).
Green-Red Fluro, High Gain	For imaging of dim fluorescence in the 505-750nm (green-red) region, excited at 488nm (blue).
Green-Red Fluro, Max Gain	For imaging of very dim fluorescence in the 505-750nm (green-red) region, excited at 488nm (blue).

All procedures enable imaging of green fluorescence, using 488nm incident light to illuminate the specimen, with detection of fluorescent emission from the specimen in the range 505–585nm.

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The default procedure for capturing images is "Normal Gain". However, the appropriate level of gain required for each instrument combination should be determined by following the procedure for sensitivity testing using standard fluorescent test cloth outlined in the Owner's Manual (Section 5.3).

Select the required procedure by highlighting the Procedure Name from the **Available Procedures** list on the left side of the screen. A description of the highlighted Procedure Name is displayed on the right side of the screen. Press [Next] to continue when the required Procedure Name is highlighted. The **Information Logging** screen appears (Section 4.2).

4.2 Entering information about the Procedure

The **Information Logging** screen (Figure 4-3) is a menu selection screen to open other data-input screens and enter the optional identifying information (Section 3.1) associated with the current Imaging Procedure. It also displays a summary of the session information at the top left-hand corner of the screen. Any information entered may be reviewed or edited at any time during the Imaging Procedure by returning to the **Information Logging** screen.

Figure 4-3 Information Logging Screen

The four function buttons located in the top right-hand corner of the screen open further screens specific to each information type.

Create Sites	Create one or more new Sites for the current procedure (Section 4.2.1). By default, an imaging session must have a minimum of one site (**SITE_1**).
Subject Details	Enter or edit details about the Subject (Section 4.2.3).
Operator Details	Enter or edit details about the Operator (Section 4.2.2)
General Notes	Enter or edit general notes about the Procedure (Section 4.2.4).

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Press each function button to open another data-entry screen respectively. To edit previously entered data, highlight the information to be changed, and over-type it with the correct data using the keyboard. If the current information displayed requires editing, overtype it using the keyboard with the correct details. Some fields have a size limit that is appropriate for the kind of information normally entered. Closing a data-entry screen re-opens the **Information Logging** screen.
It is strongly recommended to create logical Site Descriptions and enter information such as Subject ID, Surname, First Name in the respective data-entry screens to better identify results and images at a later time.

When all relevant Site, Subject, Operator, and Note details have been entered using the respective data-entry screens, press Next to proceed to the **Image Acquisition** screen (Section 0).

Note:
Initially the Next button is inactive as the instrument self-calibrates. It becomes active when the calibration step is complete.
In Review Mode, the Create Sites button is replaced by a Site Details button. The Site Details button opens a **Create Sites** screen (Figure 4-4).
The session information at the top left-hand corner of the screen contains three additional text fields in Review Mode. These include **Session Unique ID**, **Procedure Results Creation Date** and **Instrument ID**.

4.2.1 Create Sites Screen

The **Create Sites** screen (Figure 4-4) is used to name or label one or more imaging sites where information may be entered about individual sites or features that are imaged during the current Imaging Procedure.

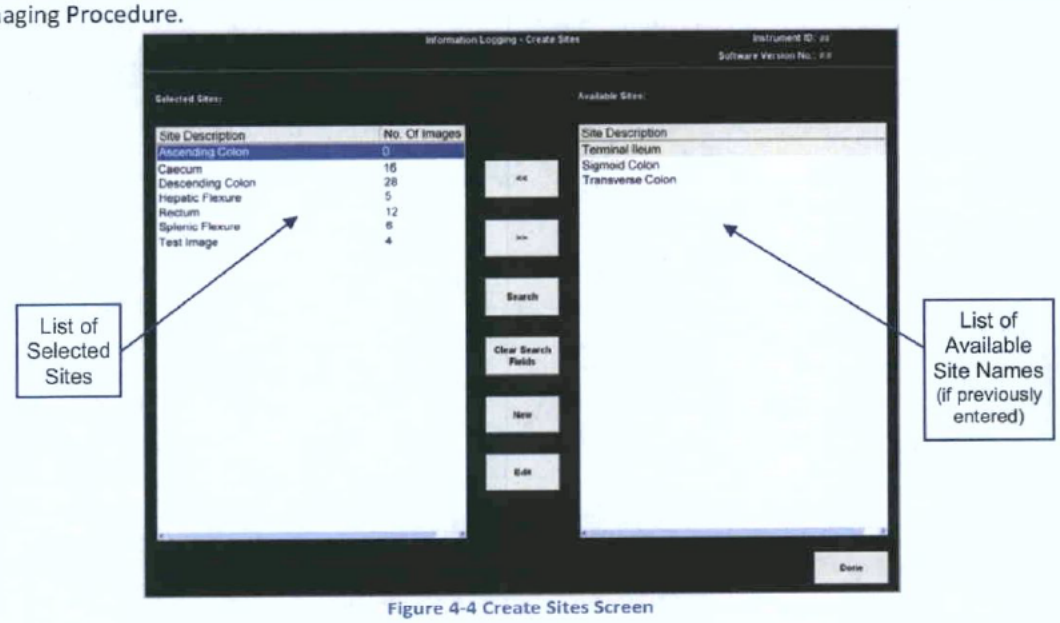

Figure 4-4 Create Sites Screen

Each Imaging Procedure may include several imaging Sites. When images are captured, they are associated with an imaging site to allow the operator to identify where images were captured (e.g. names of anatomical sites may be used). Multiple Site Names may be entered for any session, and multiple images can be captured and associated with the respective Sites.
Previously entered Site names are shown in the **Available Sites** list. They may be searched for, selected and added to the **Selected Sites** list for the current procedure. Alternatively new names may be added.

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The six buttons located down the centre of the screen control the selection, searching, creation, and editing of Sites.

<<	Select the highlighted Site name from the **Available Sites** list and add it to the **Selected Sites** list for the current procedure.
>>	Deselect the highlighted Site name from the **Selected Sites** window to remove unwanted Site names for the current procedure.
Search	Search for Site names in the **Available Sites** list. Type the required Site name into the **Site Description** field and press the ENTER key. Any partial matches found will be displayed. If there are no matching entries in the database, a message box appears. All the search fields are cleared and all available Site names in the database are shown.
Clear Search Fields	Clear the **Search Fields** to reset the search filter applied to the **Available Sites** list. All Site names in the system are now displayed in the **Available Sites** list.
New	Create a new Site name. Type the Site Description into the field provided in the **Edit Site** box and press OK. Any Site name that has been entered remains in the database and can be selected from the **Available Sites** list.
Edit	Edit the Site highlighted in the **Selected Sites** window. To rename Sites, highlight the desired Site name in the **Selected Sites** list and press Edit. Type the new Site Description into the field provided in the **Edit Site** box and press OK. Any images in the current procedure formerly associated with the original Site Description are now associated with the new Site Description instead. The original Site Description is removed from the current session, but remains in the **Available Sites** list. Stored Procedure Results are unaffected.

The **Create Sites** screen always has at least the default label **SITE_1**. If no Site Description is entered then all otherwise unidentified images are saved with this label. The **SITE_1** site name may be removed from the current procedure by using >>. Site Description names cannot be deleted from the database using this application. Use care when typing in names to avoid typographical errors.
It is recommended to create as many intended Sites as anticipated before commencing a procedure to minimize interruptions during imaging. If additional Sites are identified during imaging they may be created during imaging.

<u>Note:</u>
Initially the Next button is inactive as the instrument self-calibrates. It becomes active when the calibration step is complete.
In Review Mode, the New button is replaced by a Replace button.
The Replace button swaps the Site highlighted in the Selected Sites list, with that highlighted in the Available Sites list.

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4.2.2 Operator Details Screen

Operators can record their personal details to be associated with the current Imaging Procedure using the Operator Details screen (Figure 4-5).

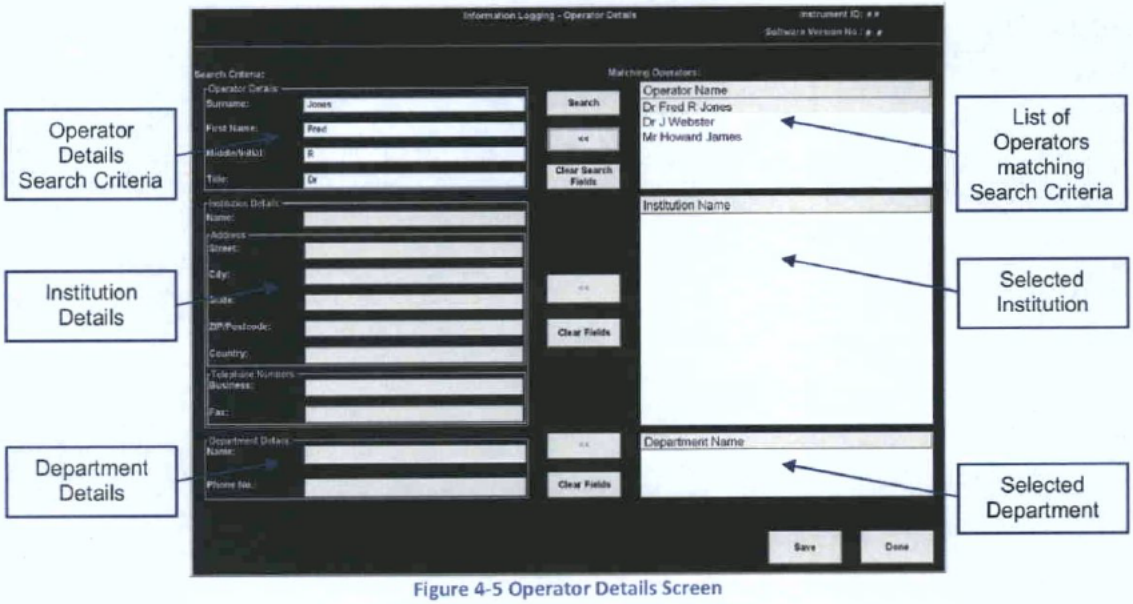

Figure 4-5 Operator Details Screen

Note:
New Operator details may be entered directly into the data fields. It is advisable to enter as many Operator details as possible to enable the correct Procedure Result to be identified and retrieved at a later time.

Search

Search for an Operator's details in the database. Type the search criteria into any of the **Operator Details** fields (e.g. **Surname**). The search function will accept partial details as search criteria. Press Search to display names that match the search criteria. If no match is found then the "No matching operator(s) found" message box is displayed.

<<

Copy an Operator's details from the database. Highlight the required Operator Name in the **Matching Operators** list and press << to fill in the **Operator Details** fields.

Clear Search Fields

Clear the search criteria fields and attempt another search.

Operator details can have Institution and Department details associated with them to better identify the Operator. It is not mandatory to select any Institution or Department details. Institution details that are available are listed in the **Institution Name** list. Department details that are available for a selected Institution are listed in the **Department Name** list.

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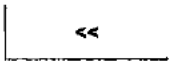
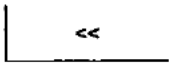


Copy an Institution's details from the database. Highlight the required Institution Name in the **Matching Operators** list and press << to fill in the **Institution Details** fields.



Copy a Department's details from the database. Highlight the required Department Name in the **Matching Operators** list and press << to fill in the **Department Details** fields.

Clear the fields—do not associate an Institution's or Department's details with the Operator.

Note:
Institution and Department details cannot be added or updated by the Operator. Only a system administrator or Service Technician can set up these details.

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4.2.3 Subject Details Screen

Operators can record details about the Subject of the current Imaging Procedure using the Subject Details screen (Figure 4-6).

Figure 4-6 Subject Details Screen

Note:
New Subject details may be entered directly into the data fields. It is advisable to enter as many Subject Details as possible to enable the correct Procedure Result to be identified and retrieved at a later time.

Search

Search for a Subject's details in the database. Subject details information includes the Subject's ID, Surname, First Name, Middle Initial, Title, date of birth (D.O.B), Sex, Address and other contact information. Type the search criteria into any of the **Operator Details** fields (e.g. **Surname**). The search function will accept partial details as search criteria. Press Search to display names that match the search criteria. If no match is found then the "No matching operator(s) found" message box is displayed.

<<

Highlight the required Subject Name in the **Matching Subjects** list to copy a Subject's details from the database into the **Subject Details** fields.

Clear Search Fields

Clear the search criteria fields and attempt another search.

Note:
Subject details cannot be deleted using this application. Use care when typing in names to avoid typographical errors. Take great care particularly when entering the D.O.B. Month and Day details.

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4.2.4 General Notes Screen

Operators can record additional details about the Subject or Operator, or other miscellaneous information relating to the current Imaging Procedure using the General Notes screen (Figure 4-7).

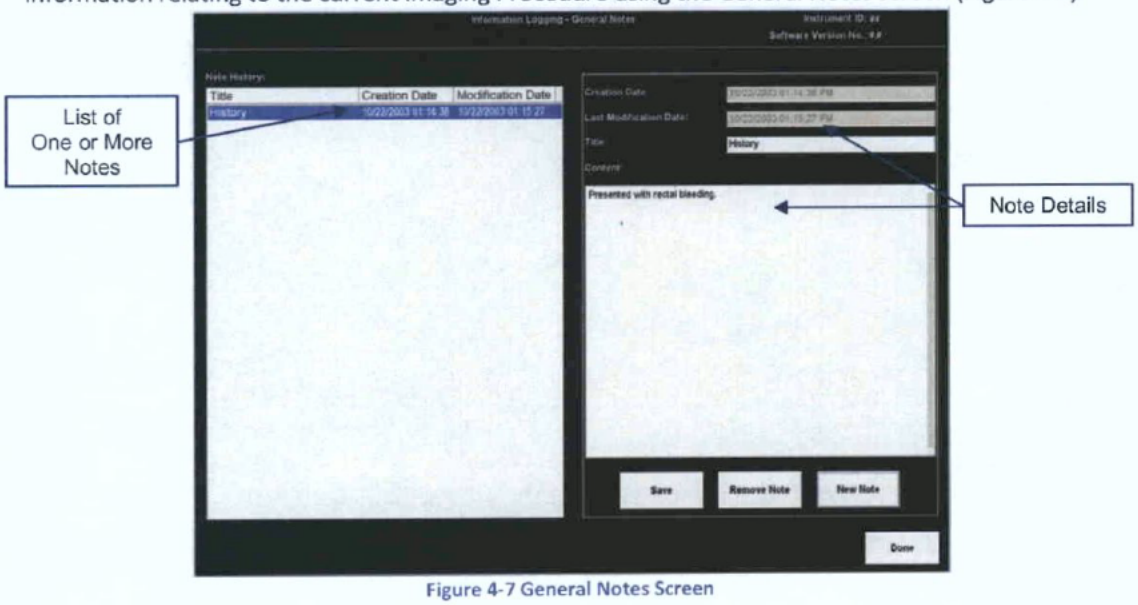

Figure 4-7 General Notes Screen

Notes may be viewed and edited by selecting the note of interest from the **Note History** list. The selected note is displayed, and may be edited directly. If a note is edited, the Modification Date (and time) will be updated to the current date and time.

New Note	Create a new note. A Title may be entered into the **Title** field, and free-form text typed into the **Content** field. More than one Note may be added, if required.
Remove Note	Delete unwanted Notes. Only one Note can be removed at a time.
Save	Store the Note. The stored Note will be added to the **Note History** list, and be displayed with an associated Creation Date (and time).

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4.3 Obtaining an Image

The **Image Acquisition** screen (Figure 4-8) is used to manage the acquisition of images relating to the current Imaging Procedure.

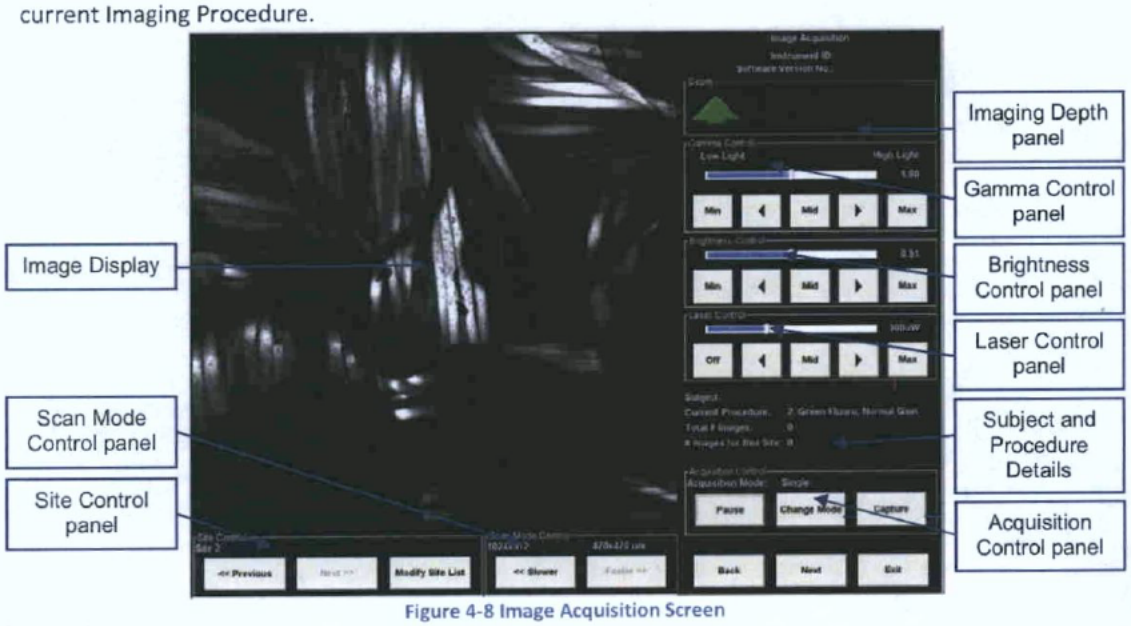

Figure 4-8 Image Acquisition Screen

The main functions relating to Image Acquisition are controlled by buttons and sliders grouped within function panels located on the right side and at the bottom of the screen.

Control Panel	Use	Section
Laser Brightness Gamma	Modify the appearance of the displayed image. Capture a displayed image when its appearance is satisfactory.	4.3.3 4.3.4 4.3.5
Scan Mode	Adjust the image update rate.	4.3.2
Acquisition	Pause updating and hold the displayed image. Select the capture mode. Capture the currently displayed image.	4.3.7
Site	Select Site where captured images are attached.	4.3.1
Imaging Depth	Information about focal plane depth.	4.3.6

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4.3.1 Site Control

Captured images are associated with Site Descriptions. Use the **Site Control** panel (Figure 4-9) to select the current Site for captured images.

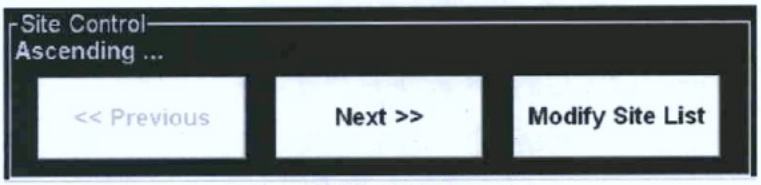

Figure 4-9 Site Control panel

Choose the desired image Site from those created previously (Section 4.2.1) using the << Previous and Next >> buttons. Once a site is selected, any images that are subsequently captured will be associated with the selected site (i.e. the desired site must be selected before the image is captured). It is possible to move between Sites whilst imaging in Single Mode to allow multiple sequences of imaging for a given Site.

Add or modify Site Descriptions (Section 4.2.1) by pressing the Modify Site List button to access the **Create Sites** screen. Modify the Site Descriptions as required and highlight the one to be used.

Press Done to return to the **Image Acquisition** screen and use the highlighted Site Description.

Note:

Images are associated with the ***currently*** selected site (created beforehand, Section 4.2.1) when captured, so it is important to select the correct site ***before*** capturing any images.

4.3.2 Scan Mode Control

The **Scan Mode Control** panel (Figure 4-10) located in the centre bottom of the **Image Acquisition** screen controls the image scan speed and the resulting resolution and field of view.

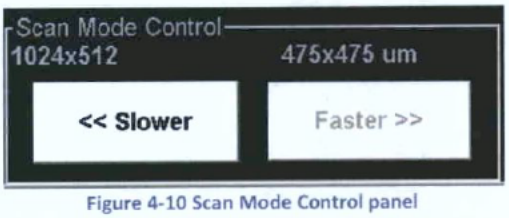

Figure 4-10 Scan Mode Control panel

Use the << Slower and Faster >> buttons to change the scan mode to decrease or increase the scan speeds available (Table 4-1). Switch to the **Faster** scan speed to search more efficiently for a region of interest. Switch back to the **Slower** scan speed to capture images with the higher resolution.

Resolution (pixels)	**Field of view** (µm approx.)	**Scan Speed** (frames per second approx.)
1024 x1024	475 x 475	0.7
1024 x 512	475 x 475	1.2

Table 4-1 Scan Modes available

The Field of View of approximately 475 x 475µm may vary by ±50µm when the system is operated in an environmental temperature range of 10°C to 30°C. If the system is operated at temperatures between 31°C to 40°C the system will continue to scan and obtain an image but with a Field of View that may exceed 475 x 475±50µm.

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4.3.3 Laser Control

The intensity of the detected signal is generally proportional to the intensity of the laser light used to illuminate the site, within the bounds of the fluorescence properties of the site.

The laser power setting is very important to obtain the best quality image. The "ideal" laser power setting gives a full dynamic range image (i.e. on-screen image features range from black to just white) when the brightness control is set to minimum (using the Min button). It may not always be possible to image under ideal conditions.

Note:
When operating in fluorescence mode, excessive laser power may cause photo-bleaching and saturation of fluorescence that can limit the contrast of the image regardless of increase in laser power and an associated reduction in image quality.

Use the Laser Control panel buttons and slider to set an appropriate laser output power level (Figure 4-11) located on the right side of the Image Acquisition screen.

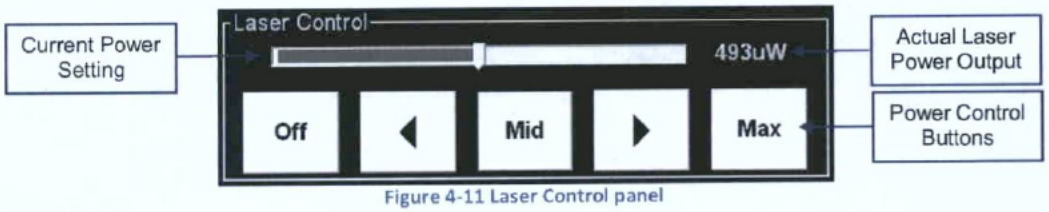

Figure 4-11 Laser Control panel

Laser power output at the confocal endomicroscope tip is displayed in microwatts (µW) to the right of the laser power slider control (Figure 4-11). The slider controls the overall output power linearly. Set the laser power output by using the buttons as follows.

▶	Press momentarily—to increase power output in approximately 5 µW increments. Hold—to increase laser power output continuously.
◀	Press momentarily—to decrease Power output in approximately 5 µW increments. Hold—to decrease power output continuously.
Off	Put the laser in standby mode and reduce laser power output to 0 µW at the endomicroscope tip. This is the Default setting.
Mid	Set laser power output to 50% of maximum.
Max	Set laser power output to maximum.

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4.3.4 Brightness Control

Set an appropriate brightness value of the displayed image using the **Brightness Control** panel buttons and slider (Figure 4-12) located on the right side of the Image **Acquisition** screen.

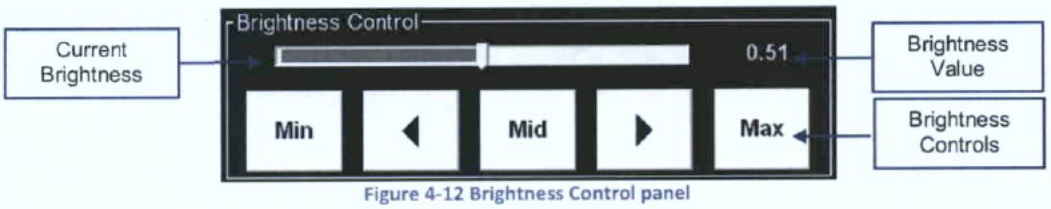

Figure 4-12 Brightness Control panel

The brightness value of the image is displayed to the right of the brightness slider control. The slider controls the overall brightness of the whole image linearly. Set the image brightness by using the buttons as follows.

▶	Press momentarily—to increase Image Brightness in small increments. Hold—to increase Image Brightness continuously.
◀	Press momentarily—to decrease Image Brightness in small increments. Hold—to decrease Image Brightness continuously.
Min	Set Image Brightness to minimum.
Mid	Set Image Brightness to 50% of maximum. This is the Default setting.
Max	Set Image Brightness to maximum.

The increase brightness ▶ button makes the whole image brighter, but may lead to saturation of the brightest structures. The decrease brightness ◀ button makes the whole image dimmer. Once the brightest structures are just displayed as pure white, lower intensity structures may be emphasized and de-emphasized using the **Gamma Control**.

☞ Note:
This control affects the way that the measured data is displayed. It does not affect the intensity of the signal being measured (as laser power does).

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4.3.5 Gamma Control

The Gamma value of an image controls the display of the mid-level grey regions of the image, without changing the lightest and darkest areas within the image. It can be used to emphasize or de-emphasize the middle grey values.

Use the **Gamma Control** panel controls to set the relative brightness value of lower intensity components of the displayed image (Figure 4-13) located on the right side of the **Image Acquisition** screen.

The default setting for the Gamma value is 1.00, which neither emphasizes nor de-emphasizes the mid-grey levels.

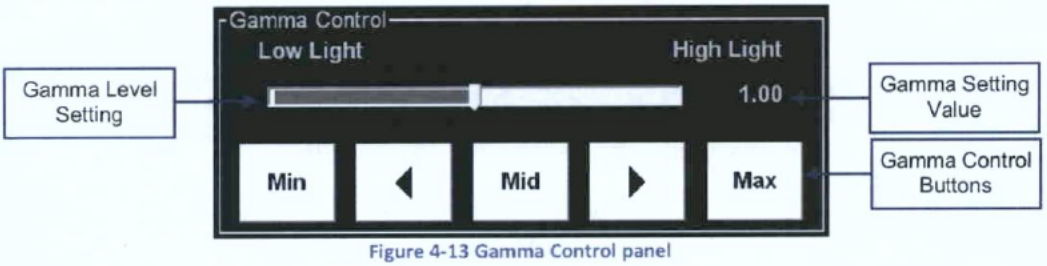

Figure 4-13 Gamma Control panel

The Gamma value of the image is displayed to the right of the gamma slider control. The slider controls the overall Gamma value of the image linearly. Set the image Gamma value by using the buttons as follows.

▶	Press momentarily—to increase Gamma value in small increments. Hold—to increase Gamma value continuously. Brightens the grey regions of the image, highlighting the lower intensity regions of the image (High Light), without altering the brightest structures.
◀	Press momentarily—to decrease Gamma value in small increments. Hold—to decrease Gamma value continuously. Darkens the grey regions of the image (Low Light), effectively reducing the overall contrast of the image.
Min	Sets Gamma value to minimum.
Mid	Set Gamma value to mid level. This is the Default setting.
Max	Set Gamma value to maximum.

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4.3.6 Image Depth

The appropriate controls on the confocal endomicroscope control body adjust the imaging depth of the of the focal plane in the tissue, which influences the appearance of the displayed image.

The operation of the depth controls is described in the relevant confocal endoscope Owner's Manual. The depth control footswitch has two functions. When clicked once, the "Home" button moves the imaging plane to the Home position near the surface of the tissue. The other footswitch button provides control of movement and direction of travel. It may be double-clicked to change direction, which will be indicated in the on screen Depth panel (Figure 4-14). The movement depth control may be operated using single clicks to move in small 4µm increments, or press and hold to move at approximately 10µm per second.

Figure 4-14 Depth panel

The icon or picture on the left of the Depth panel, displays the current direction of travel and position of the focal plane or the calibration mode of the Z Depth system.
A single text item may be displayed adjacent to the Depth Direction/motion arrow, indicating the Depth Position and Calibration Status. These depth indicators are summarised as follows:

Image Depth Status			
Direction UP	**Direction Down**	**Displayed Text**	**Position & Calibration Status**
		Home	Focal plane at the surface of the tissue positioned just in front of the external surface of the confocal imaging window.
		Upper Limit	At its fully retracted position within the confocal endoscope.
		Deep	Deepest imaging position.
		Calibrating	Performing calibration to ensure the accuracy of the displayed focal plane position.
		Uncalibrated	Unable to display an accurate focal plane position.
		Standby	Power saving mode, the focal plane will be at the deepest position.
		no text	Calibrated and operating normally. Focal plane position between Upper Limit and Deep and not at Home position.

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4.3.7 Acquisition Control

The **Acquisition Control** panel buttons (Figure 4-15) control the Image acquisition mode and capture images. Images are displayed on the screen but are not acquired unless Capture or Start Capture is pressed.

Figure 4-15 Acquisition Control panel

Images can be captured using either of two modes, Single mode (Section 4.3.7.1) and Movie mode (Section 4.3.7.2). Single mode captures a single image at a time. Movie mode acquires a continuous sequence of individual images. In both modes when images are captured the files are written directly to the hard disk, and the images are associated with the currently selected site (Section 4.2.1).

When sufficient images have been captured, press Next to proceed to the **Image Selection** screen to review and store images (Section 4.4).

4.3.7.1 Single Mode

Single mode acquires or captures displayed images one at a time.

Pause	Pause image updating and holds the current image. Button changes to Scan.
Scan	Continue updating images on the screen. Button changes to Pause.
Change Mode	Switch to **Movie** mode.
Capture	Capture the last fully scanned image. The footswitch can also be used.

☞ Note:
Scanning still occurs and laser light is been emitted from the confocal endomicroscope tip even when image updating is paused.

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4.3.7.2 Movie Mode

Movie mode acquires or captures displayed images sequentially when the capture is active. The result is a series of sequential single images (**not** a movie file) for the duration of the capture.

Pause	Pause image updating and holds the current image. Button changes to Scan.
Scan	Continue updating images on the screen. Button changes to Pause. Note: Movie capture mode does not re-start if paused previously.
Change Mode	Switch to **Single** mode.
Start Capture	Start a movie capture sequence. Button changes to Stop Capture. The time between each image depends on the Scan Mode selected (Section 4.3.2).
Stop Capture	Stop a movie capture sequence. Button changes to Start Capture. Images keep updating

Note:
Scanning still occurs and laser light is been emitted from the confocal endomicroscope tip even when image updating is paused.

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4.4 Reviewing Current Procedure Images

The **Image Selection** screen is reached by pressing Next on the **Image Acquisition** screen (Section 0). This screen initially displays a tiled view of all images captured during the current Imaging Procedure, the Multiple Images view (Section 4.4.1). Double-click an image to display it full screen in the Single Image view (Section 4.5).

The **Image Selection** screen always displays an **Acquired Images** tree structure down the left hand side of the screen comprising the current Imaging Procedure, Sites belonging to this Imaging Procedure, and all images associated with each of the Sites.

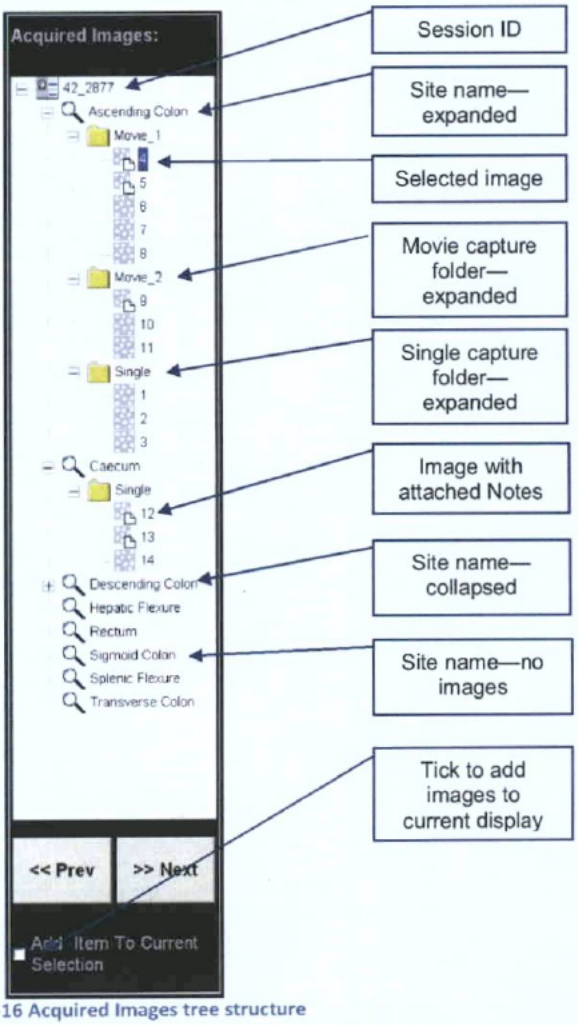

Figure 4-16 Acquired Images tree structure

Each Site in the image tree can contain one Single folder and one or more Movie folders. A Single folder holds Single Mode images. A Movie folder contains one set of Movie Mode images, i.e. a sequential set of still images captured over a period of time.

Choose between viewing multiple images together, or viewing and modifying individual images. Double-click the image of interest to toggle between single view and multiple view.

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4.4.1 Select and View Multiple Images

Selecting a Site name from the Acquired Images tree displays all of the images captured at that site in a tiled view in the middle section of the screen (Figure 4-17).

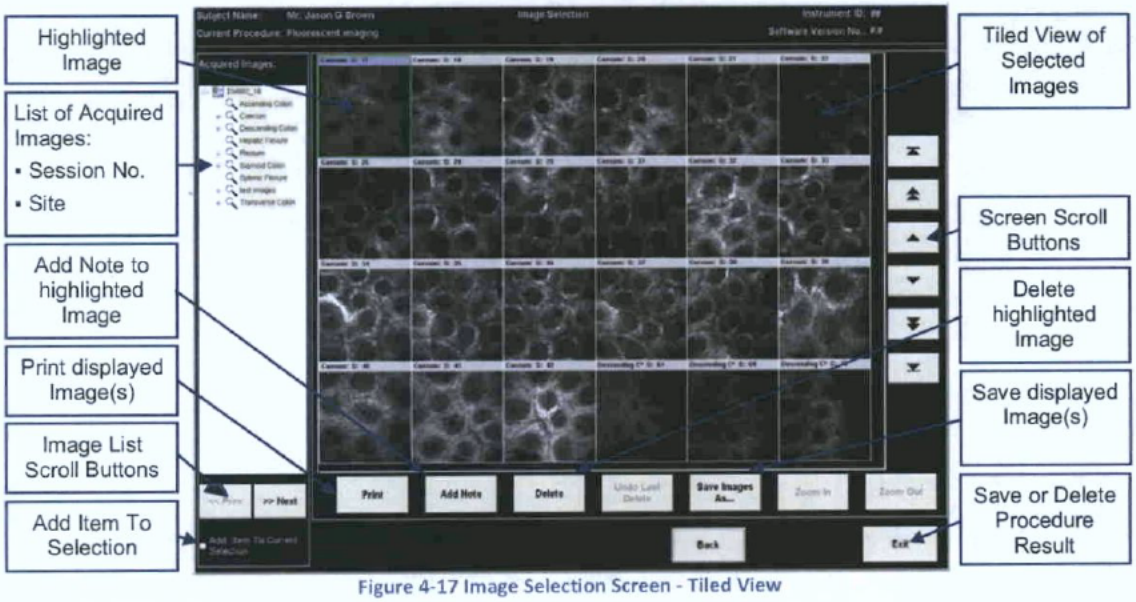

Figure 4-17 Image Selection Screen - Tiled View

Use the **Add Item To Current Selection** checkbox to select or deselect multiple images from anywhere within the **Acquired Images** tree. With the checkbox ***unticked***, each selection overwrites the display area. For instance, select (using the mouse pad, touch screen or keyboard) a folder to display all images in the folder, select a single image from the tree to display one image (full screen).

With the checkbox ***ticked***, each selection adds images or sites to the display area. As each folder or image is selected, images are added to the display. If a selected folder or image is re-selected then the highlight is removed and the associated image(s) are no longer displayed. Use this process to display only the images of interest, and to save them to image files (Section 0).

The **Image Selection** screen can display up to 24 images on the screen in the tiled view. If more than 24 images are selected, the scroll buttons on the right hand side of the screen (Figure 4-18) become active. Use these to scroll the screen through the images.

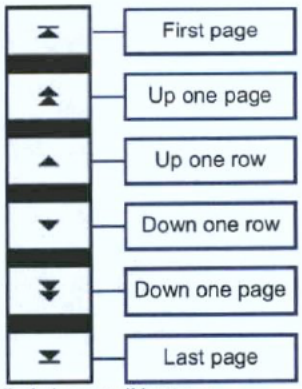

Figure 4-18 Tiled view scroll buttons

View single images within the selection by double-clicking on the desired image in the tiled display. Return to the tiled view by double-clicking on the single image.

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4.5 Select and View Single Images

The **Image Selection** screen (Figure 4-19) is used to review and modify single images from the **Acquired Images** tree.

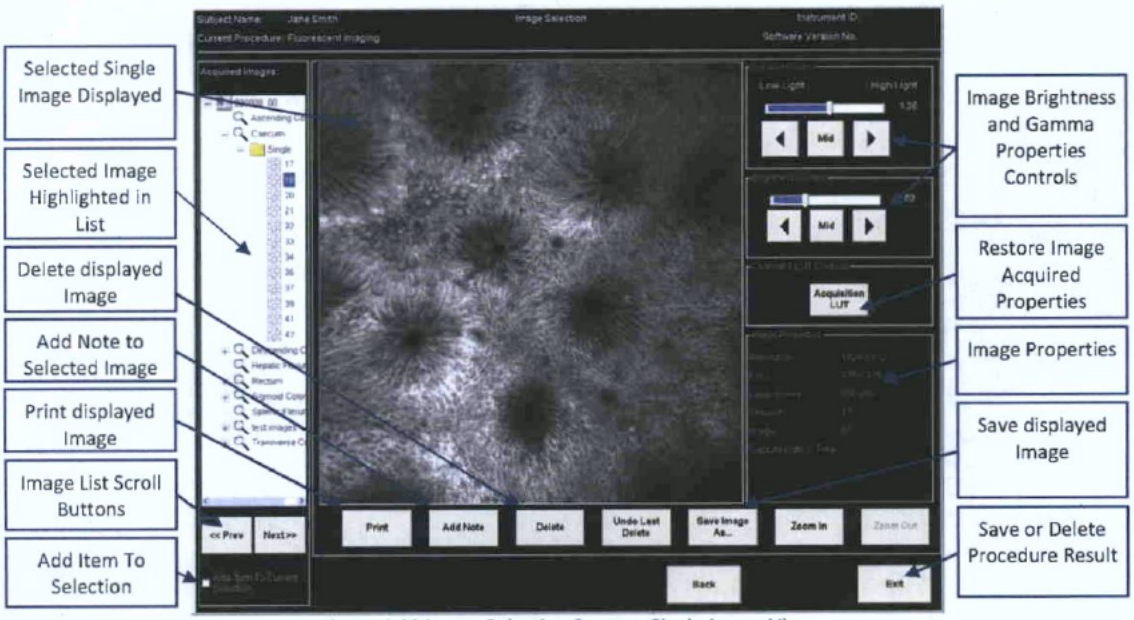

Figure 4-19 Image Selection Screen - Single Image View

Selecting one single image from the **Acquired Images** tree displays that image in large single image format (Figure 4-19) so it may be examined in more detail. The image properties (resolution, field of view, laser power, unique session identification number, image sequence number, and capture date and time) are displayed beside the image in the Image Properties panel.

<< Prev	Scroll backwards through each individual image in the **Acquired Images** tree. The Image Properties panel updates for each image.
Next>>	Scroll forwards through each individual image in the **Acquired Images** tree. The Image Properties panel updates for each image.
Brightness Controls	Modify the Brightness of the display properties of individual images (Section 4.3.4). Any changes made to the individual image are automatically saved upon exiting the screen.
Gamma Controls	Modify the Gamma value of the display properties of individual images (Section 4.3.5). Any changes made to the individual image are automatically saved upon exiting the screen
Acquisition LUT	Restore the Brightness and Gamma value settings of the original captured image
Zoom In	Enlarge digitally the displayed image.

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Zoom Out	Reduce digitally the displayed image.
Delete	In Multiple images view: Delete a selected image—one at a time. In Single image view: Delete a displayed image—one at a time. To select an image: • display the image in single display view, • select it from the **Acquired Images** tree, • select it within the tiled display view. Images saved with a Procedure Result can also be reviewed for deletion at a later time.
Undo Last Delete	Reverse the delete action, and recover multiple images—one at a time.
Print	A dialog box allows the selection of the target printer and other options and features associated with printing images. These printer functions are not supported on current release.
Add Note	Add Notes to the selected Image (Section 0).
Save Image As...	The **Save Image(s) As...** function allows displayed images to be saved as files at nominated locations in multiple formats (Section 0).
Add Item To Current Selection	When ticked, allows multiple images and folders to be selected in the **Acquired Images** tree, and associated images to be displayed.

Note:
The Brightness and Gamma settings of the original captured image are always saved with the image, and are exported with the image during the Export process (Section 5.2.1), along with other information (Section 3.1).

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4.5.1 Adding Notes to Images

The Image Notes screen (Figure 4-20) is used to attach notes to an individual image. This screen is available by pressing Add Notes on the Image Selection screen (Section 4.5). In contrast, General Notes (Section 4.2.4) attaches Notes to the Procedure Results. To select an image:

- display the image in single display view,
- select it from the Acquired Images tree,
- select it within the tiled display view.

Figure 4-20 Image Notes Screen

To edit a note, select the note from the **Image Note History** list (Section 4.5). This will display the notes details on the right hand pane of the screen. Enter changes in the **Title** and **Content** fields and press Save. Once an edited note is saved, the date and time of modification is updated in the **Modification Date** field.

New Note	Create a new note. A Title may be entered into the **Title** field, and free-form text typed into the **Content** field to identify and describe the image.
Remove Note	Delete unwanted Notes. Only one Note can be removed at a time.
Save	Store the note. The stored note is added to the **Note History** list, and displayed with an associated **Creation Date** and time.

Press Done to return to the Image Selection screen. All images with notes will appear in the Acquired Images tree with a note icon attached to them. This icon signifies that there are one or more notes associated with the image (Figure 4-16).

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4.5.2 Saving Images

The Save Image As function saves the image(s) displayed in the Image Selection screen (Figure 4-17 and Figure 4-19) to nominated locations in any of the supported image file formats (Table 4-2).

Note:
The Save Image As function does not backup or archive. Refer to Section 3.6 to backup or archive.

Select the multiple images (Section 4.4.1) or single image (Section 4.5) to be saved. Press Save Image As... on the **Image Selection** screen (Section 4.5) to bring up the **Save current image as...** prompt (Figure 4-21).

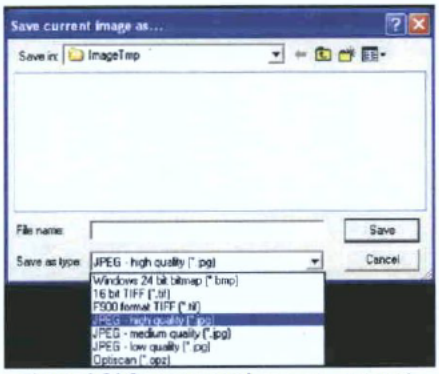

Figure 4-21 Save current image as... prompt

Enter a file name and optionally select a destination folder into the displayed message box. The default folder is ImageTmp on the D drive. Use the D drive for storing data temporarily. Alternatively use a formatted CD (Section 3.3). The **Save as type:** options are discussed in Table 4-2.

Caution:
Saving large numbers of image files to the instrument hard drive can result in an insufficient disk space condition (Section 7.4). Do not save any data in the C drive, as it only has enough space for the program and system files.

Images may be saved directly to a formatted CD (Section 3.3) by selecting the CD drive as the destination for the images to be saved. Leave the CD in the writer to allow multiple batches of images to be saved to the same CD.

When multiple images are selected (Section 2.2) the images are automatically saved as multiple separate files with a five digit incremented number appended to the file name specified (e.g. *Image00000.tif, Image00001.tif, ...*). The exception is the F900 format, which is a multi-image single-file format for backwards compatibility.

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This function ***only*** saves the image data and does not save any associated contextual information such as Subject Details, Operator Details, and so on. The available formats for the saved image files are standard so the files can also be electronically transported and used in other applications and documents such as reports and presentations. The 16-bit TIFF option is the best choice for image analysis and/or publication purposes.

File Type	Extension	Description of Image Format	Notes	File size[1]
Windows 24 bit bitmap	.BMP	Uncompressed Bitmap. 8x3 bit depth (so some loss of image information), single image. A very common image format in the Windows environment.	Saves the displayed image (8 bit) with some loss of image information. The saved image includes any brightness and gamma adjustments made by the Operator.	3 MB
16 bit TIFF	.TIF	Uncompressed Tagged Image File Format (TIFF). 16x1 bit depth (contains the maximum image information), single image.	This format saves the raw image data (12 bit) data only and is the best choice for image analysis and/or publication.	2 MB
F900 format TIFF	.TIF	Proprietary Uncompressed TIFF image format. 16x1 bit depth, multiple images.	Provided for compatibility with other proprietary instruments.	2.5 MB
JPEG – high quality	.JPG	Compressed jpeg format. 8x3 bit depth, single image. A compression algorithm reduces the file size at the cost of losing some quality. Best used when reduced file size is more important than the original image quality.	Minimal loss of quality.	~580 KB[2]
JPEG – medium quality	.JPG		Moderate loss of quality.	~90 KB[2]
JPEG – low quality	.JPG		Severe loss of quality.	~44 KB[2]
Optiscan proprietary	.OPZ	Optiscan proprietary image format.	All raw data is saved. Suitable for loading into ImageJ[3].	~2 MB[2]

[1] File sizes are given for a 1024 x 1024 image. Other image resolutions will result in different file sizes.

[2] These are nominal file sizes and may vary significantly. The actual file size depends on the compressible data content of the image.

[3] A third-party image analysis package.

Table 4-2 Supported Image File Types and Formats

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4.5.3 Printing Functions

A single image or a selection of images may be printed by selecting the Print button. The Print dialog box then opens, allowing the section of the target network printer, image print properties and options to print information associated with the selected images. A sample printed output is shown in Figure 4-24.

Note:
This option is only available if a printer is connected to the System.

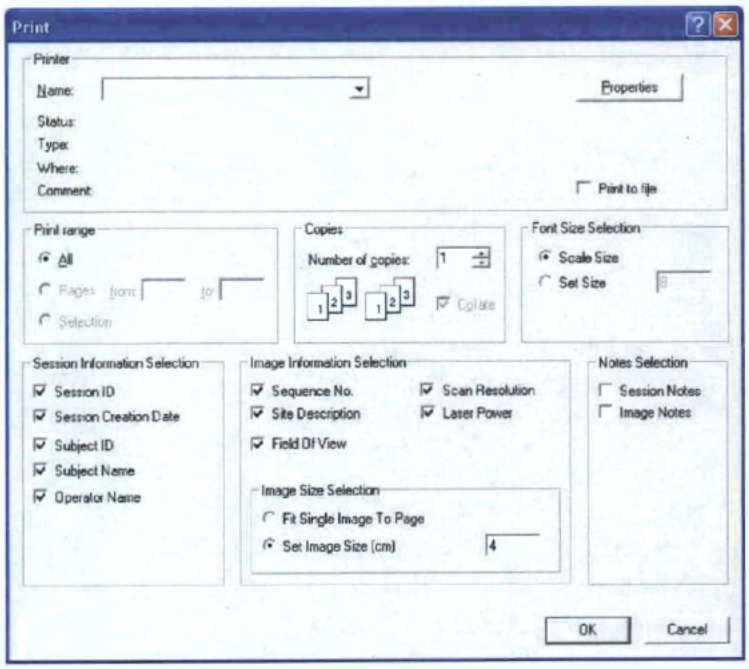

Figure 4-22 Print options

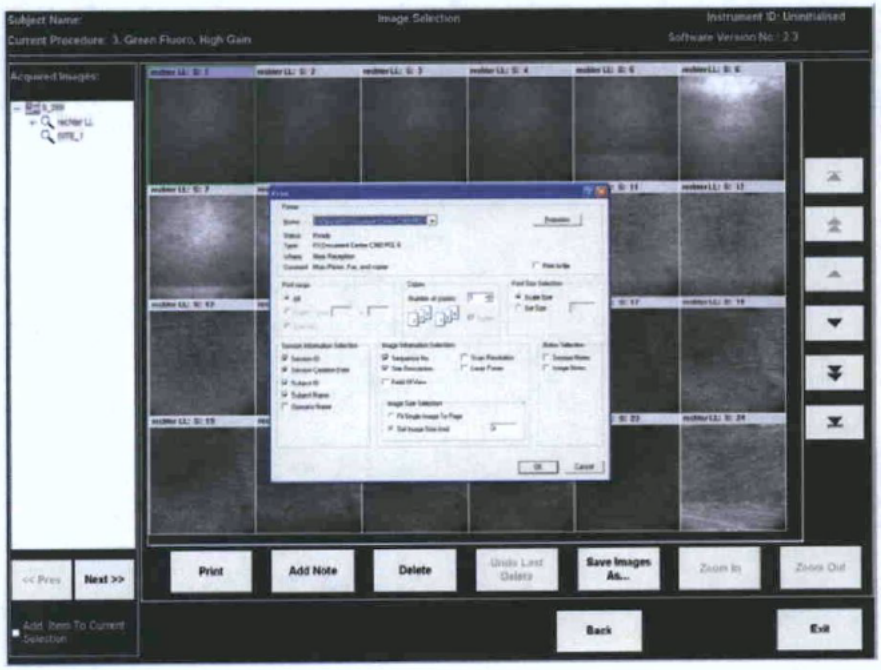

Figure 4-23 Print screen

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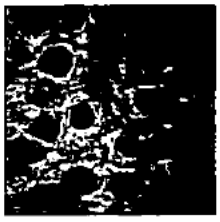
SESSION INFORMATION

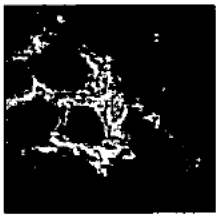
Session ID:	440000_10	Session Creation Date:	10/10/2006 08:00:15 AM
Subject ID:	012345	Subject Name:	
Operator Name:			

Seq No.:	119
Site:	Descending colon
FOV:	500x500 um
Scan:	1024x512
Laser:	578 uW

Seq No.:	121
Site:	Descending colon
FOV:	500x500 um
Scan:	1024x512
Laser:	578 uW



Seq No.:	47
Site:	Sigmoid colon
FOV:	500x500 um
Scan:	1024x512
Laser:	489 uW



Seq No.:	52
Site:	Sigmoid colon
FOV:	500x500 um
Scan:	1024x512
Laser:	295 uW

Figure 4-24 Print page

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4.6 Saving and Exiting the Procedure

Once a procedure is complete, decide whether it should be kept or discarded. Press Exit at the bottom right corner of the select screens to display the **Save Procedure Result** screen (Figure 4-25).

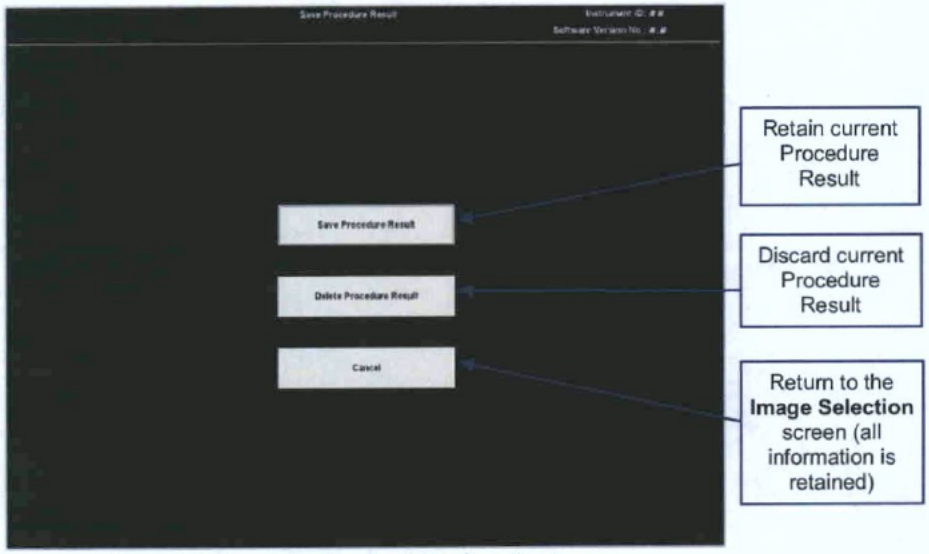

Figure 4-25 Save Procedure Result Confirmation Screen

Save Procedure Result

Save the Procedure Result and return to the **Start-up** screen (Section 0) to start a new Imaging Procedure. As a precaution, the current Procedure Result, including image changes and Notes, is automatically saved if there is a system failure prior to confirming the Procedure Result is to be kept.

Delete Procedure Result

Discard ***permanently*** the current Procedure Result and return to the **Start-up** screen (Section 0) to start a new Imaging Procedure.

Cancel

Return to the **Image Selection** screen without saving or deleting the Procedure Results.

Caution:
The **Delete Procedure Result** process is permanent—the Procedure Result is ***not*** saved and ***cannot*** be retrieved.

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5 CLINICAL: REVIEW MODE

Review mode is intended for examining and editing images and contextual information in a previously collected Procedure Result. The instrument itself does not need to have a confocal endomicroscope connected or operating. The workflow through the screens is shown in Figure 5-1.

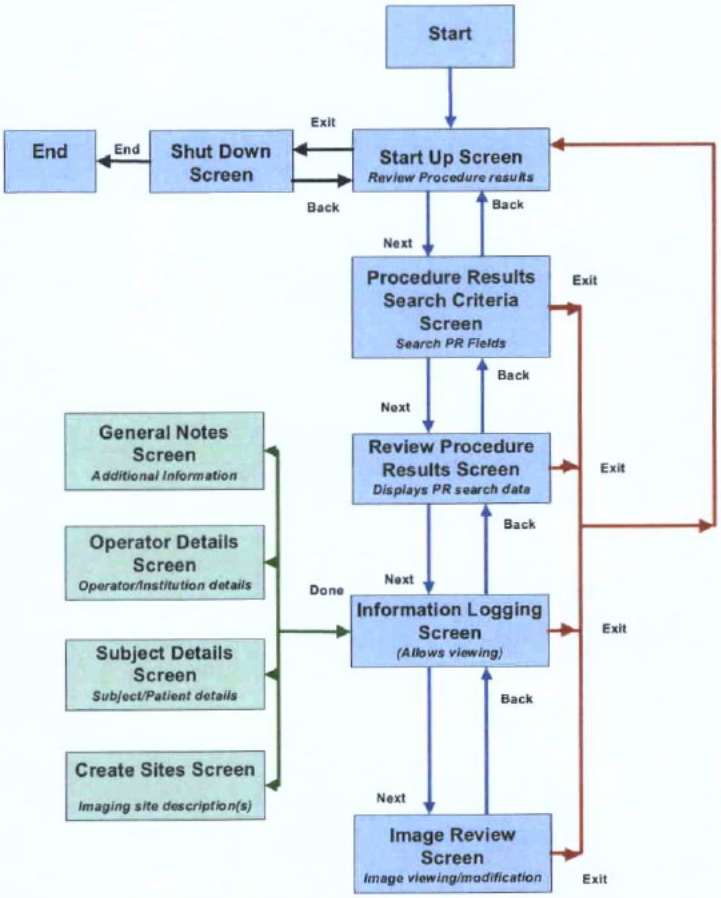

Figure 5-1 Save Procedure Result Confirmation Screen

Press Review Procedure Results on the Start-up screen (Section 0) to retrieve and review stored Procedure Results.

5.1 Searching for Procedure Results

Use the **Procedure Results Search Criteria** screen (Figure 5-2) to enter key words to search for Procedure Results.

To search the database for previously stored Procedure Results enter key subject details or partial details in the fields on this screen and press the Next button. To view the entire Subject database, simply press Next without entering any information in the search fields to proceed to the **Review Procedure Results** screen (Figure 5-3).

Note:
Entering partial search criteria will list more potential Procedure Results to review. Entering critical data such as Sex and Surname allows a more specific search to be performed. If a search does not result in any matches, a warning message is displayed with a request to re-enter valid search criteria. If no Procedure Results exist in the database, then a message will be displayed to indicate this.

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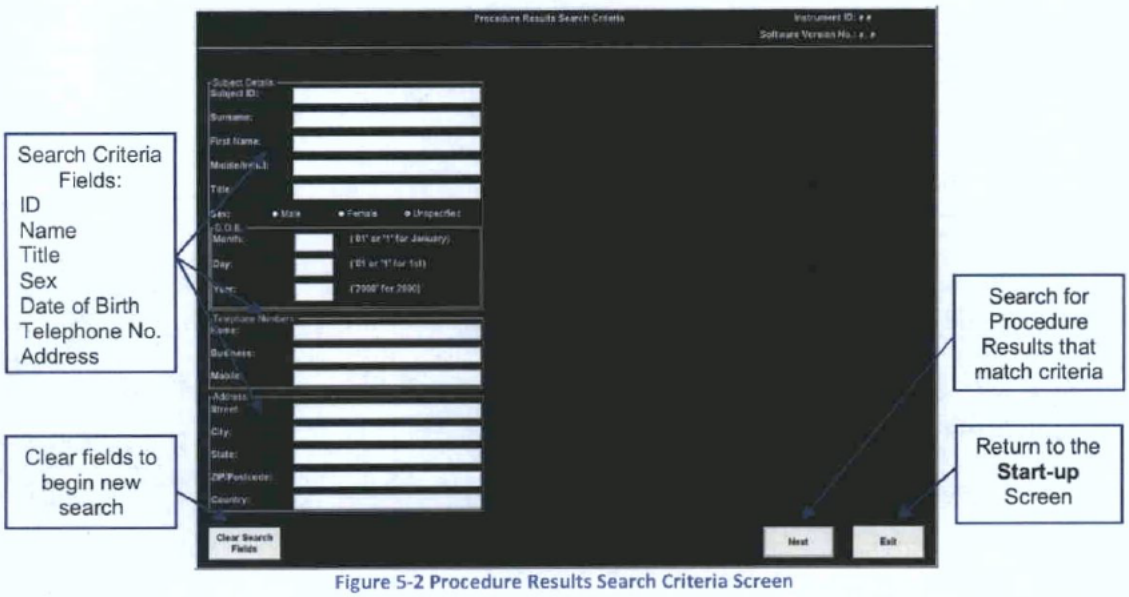

Figure 5-2 Procedure Results Search Criteria Screen

5.2 Managing Stored Procedure Results

The **Review Procedure Results** screen (Figure 5-3) displays the list of Procedure Results that match the search criteria entered at the **Procedure Results Search Criteria** screen (Section 5.1).

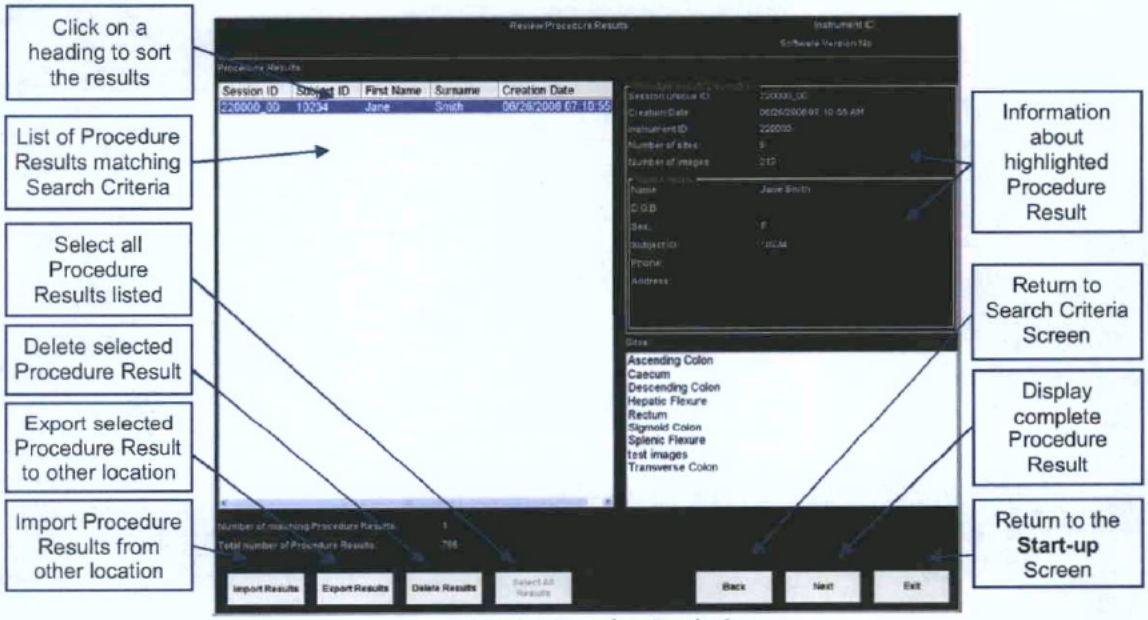

Figure 5-3 Review Procedure Results Screen

Use the arrow keys or the touch-pad to scroll through the Procedure Results list. Highlight a Procedure Result from the list to view its details. List entries may be sorted according to column headings by clicking on the column heading of interest.

To view and/or update the contextual information and images associated with a particular Procedure Result, highlight it from the list and press Next.

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Import Results	Import the Procedure Results from another location (Section 5.2.2).
Export Results	Saves or archives the selected Procedure Results to another location (Section 5.2.1). Button is inactive unless at least one Procedure Result is selected.
Delete Results	Deletes the selected Procedure Results (Section 0). Any Procedure Results no longer required may be removed from the database this way. Button is inactive unless at least one Procedure Result is selected.
Select All Results	Selects all the Procedure Results listed.
Next	Active only when a single Procedure Result is highlighted. Refer to Section 5.3. Allows review of the information in the highlighted Procedure Result.

5.2.1 Export Results

The Export function allows all data including images and contextual information (unlike the Save function, Section 2.2) contained in a Procedure Result on the local instrument's database to be copied to another location (e.g. formatted CD) for backup purposes, or transfer to another instrument.

Select one or more Procedure Results to be exported (using block or random select, Section 2.2). Alternatively press Select All Results function to select all displayed Procedure Results.

Note:
Selecting too many Procedure Results may generate a very large number of files that is difficult to manage.

Press Export Results to bring up the **Select Export Directory** prompt box. Enter the directory and drive where the files are to be stored. The filename used is a default and cannot be edited.

Click Save. The Procedure Results are saved as compressed .ZIP files. The default filename of any exported .ZIP file has the unique **Session ID** of the exported Procedure Result (generated by the instrument, see Figure 5-3 left-most column). The files within the .ZIP files are in a proprietary format that cannot be used by other applications.

Use this procedure on a regular basis as a backup against data loss.

5.2.2 Import Results

Procedure Results that have been previously exported may be imported to the local database from another instrument or location. Press Import Results to bring up the **Select Procedure Results to Import** prompt box. Locate the directory containing the exported Procedure Results files (.ZIP file type, or .XML file type for backwards compatibility). Highlight one or more filenames to import.

Click Open to add the selected Procedure Results to the database.

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5.2.3 Delete Results

Select one or more Procedure Results to be deleted (using block or random select, Section 2.2). Alternatively press Select All Results function to select all displayed Procedure Results.

Press Delete Results to display the **Delete Procedure Results** prompt box. Click Yes to remove permanently the selected Procedure Results from the database. Click No to cancel the operation.

Caution:

If the Select All Results button is pressed before pressing the Delete Results button, all the Procedure Results (all images and information) stored in the instrument's database will be deleted. Ensure this is the intended operation before clicking Yes.

5.3 Image Selection/Review

Pressing Next on the **Review Procedure Results** screen (Figure 5-3) displays the Information **Logging screen** (Section 4.2). Contextual information such as Subject details, Operator details, Site information and General Notes that were entered at the time the procedure was performed can be viewed and edited.

Pressing Next on the **Information Logging** screen (Figure 4-3) displays the **Image Selection** screen (Section 4.4). Images may be recalled and manipulated and have Notes added to them from this screen. Contextual information and images that were entered at the time the procedure was performed can be viewed and edited.

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5.4 Saving Modifications and Exiting

The **Save Procedure Result Modifications** screen (Figure 5-4) is displayed when closing the application (pressing Exit) and there are outstanding changes made to the reviewed Procedure Result. Changes include those made to contextual information such as Subject Details, Operator Details, Site Information, General Notes and images.

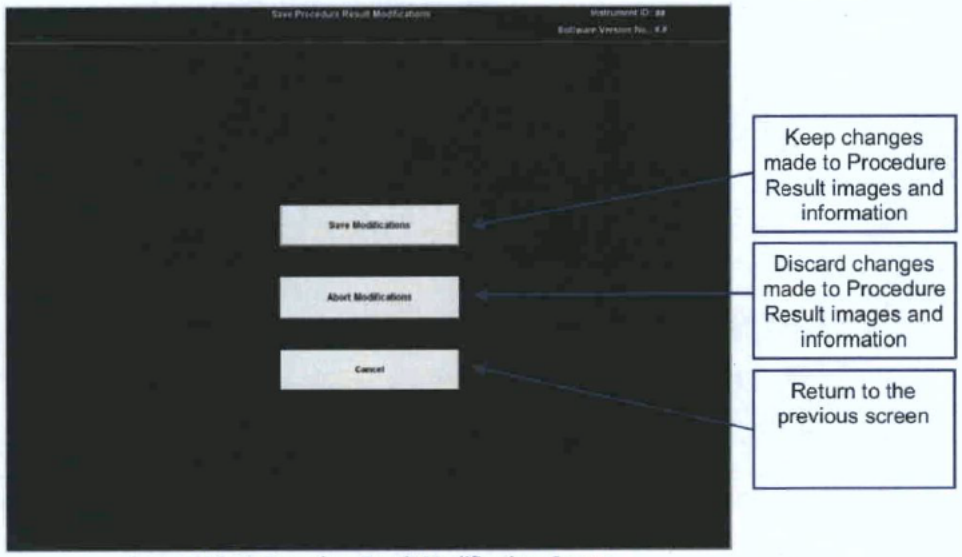

Figure 5-4 Save Procedure Result Modifications Screen

Save Modifications	Save the current modifications to the Procedure Result and return to the **Start-up** screen (Section 0).
Abort Modifications	Discard ***permanently*** the current modifications to the Procedure Result and return to the **Start-up** screen, (Section 0).
Cancel	Return to the previous screen without saving or deleting the changes.

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6 REPORTER APPLICATION

The CEIS automatically logs system parameters and performance including errors to aid Optiscan Technical Support personnel in the diagnosis and repair of instrument faults. Optiscan Technical Support may request access to this information.

The **Reporter** application is used to generate an instrument report comprising of instrument log files and other system information critical to the instrument function. The **Reporter** application compiles this information into a single compressed archive file that can be emailed or otherwise sent to Optiscan Technical Support for interpretation. If required, Optiscan Technical Support will guide you in the use of the application.

The **Reporter** application also allows manually selected files on the instrument to be included in the archive file. The resulting archive file may be very large. The **Reporter** application can also split the archive file into a number of smaller files, if required, which may then be sent by email or copied to a CD.

6.1 Before Starting

Decide what information is to be sent to Optiscan Technical Support. The **Reporter** application exports only the instrument parameters. If the concern is, for example, a suspected artifact in images then appropriate image files should also be included. View the required images with the Clinical application and save them as image files (high quality JPEG recommended) in a known location. Use care, as it is easy to generate very large files.

<u>Note:</u>
It is recommended to create a new directory on drive (D:\) for the use of storing such additional files. Under no circumstances should sub-directories be created under the designated system log directories C:\Log or D:\Database\MSSQL\LOG, doing so will cause Reporter to fail.

Decide how the information is to be sent to Optiscan Technical Support. This determines the maximum generated file size. A typical archive file with no additional files added is usually between 250 KB and 500 KB in size. Additional image files increase the size of the archive file. As a guide, a single 1024x1024 image adds approximately 1MB to the archive file size, depending on the image file format used. CDs can store approximately 650 MB. Email attachments are often limited to 1MB. Choosing too small a file size may result in an excessive number of output files, whereas too large a file size may cause a failure in transmitting the files.

6.2 Running Reporter

Run the Reporter application by following the steps below:

- Select the **Reporter** user account icon (Figure 6-1) from the **Logon** screen, described in Section 3.

Figure 6-1 Application icons in Logon screen

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The Reporter application is displayed.

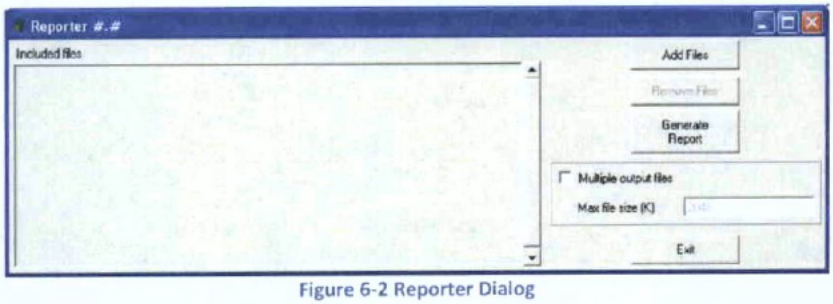

Figure 6-2 Reporter Dialog

- Optional: Press the Add Files button to add extra files, including image files. A file dialog will be displayed to allow single files to be selected. Selected files are added to the list displayed on the left hand side of the main dialog box.

Note:
The Add Files button only allows one file to be added at time. To add multiple files repeat the process to select and add a single file.
The Add Files button will not allow directories to be added.

- Optional: Press Remove Files to remove files from the list.

Note:
The list only displays the files to be added to the archive file. Removing files from the list does not delete the files.

- Optional: Tick the Multiple output files checkbox and enter the required maximum file size (in KB) in the **Max file size (K)** field. The default maximum file size is 512, which is the suggested size for archives that must be sent as email attachments.
- Press Generate Report. A file dialog box is displayed. Select the destination file or enter a new one for the report. The default directory is D:, which is the recommended directory if you are not sure.

Note:
Under no circumstances should the Reporter destination file be stored in the designated system log directories C:\Log or D:\Database\MSSQL\LOG. Doing so has the potential to cause Reporter to Fail.

A single output file has the extension .ZIP. If the Multiple output files checkbox is ticked then all the output files have extension .ZIA.

Note:
The .ZIA format is proprietary. All .ZIA files in a set are required to reassemble the original data files.

- Press Save. The Generate Report button is disabled until the report has been completed and the cursor changes to a busy icon whilst the archive is written. Progress can be seen via the Reporter console window, (Figure 6-3). Move the dialog box in order to see the console window as it may be behind the dialog box. If the Multiple output files checkbox is ticked then a five digit incremented number is appended to the file name specified, as before (Section 0).

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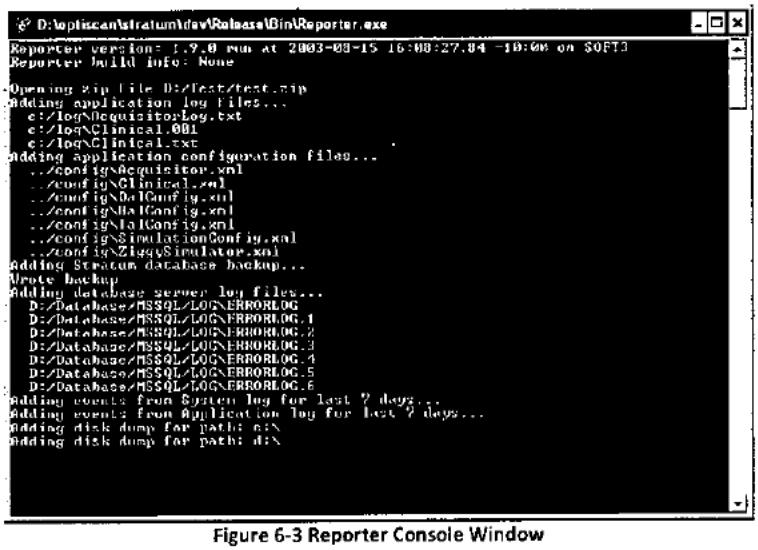

Figure 6-3 Reporter Console Window

Created files may be moved to an alternate location using the functions in a suitable file management program. When the archive is completely written (which may take several minutes, depending on system load and file system size), press **Exit** to close the **Reporter** dialog box.

Send the file(s) to Optiscan Technical Support either as email attachments or by burning the files onto CDs and mailing the CDs.

<u>Note:</u>
If the **Multiple output files** option was used, attach each .ZIA file in a set to a separate email. In the Subject line put File "n" of "m", where "m" is the total number of files in the set and "n" is the number added to the end of the original filename and is between 1 to "m". (For example, if the specified filename is "*myfile*" and the last file generated is *myfile00005.zia;* then five emails need to be sent, the first should have the attachment *myfile00001.zia* and the Subject line should be *"File 1 of 5"*, and so on). The recipient then knows how many files to expect and can request a resend of files, if necessary.

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7 TROUBLESHOOTING

Various status indicators are found on the front panel of the CEIS-CU and CEIS-OU respectively, Figure 7-1. The CEIS-OU has two indicators that must be noted: The Laser ON indicator and the Warning Indicator.

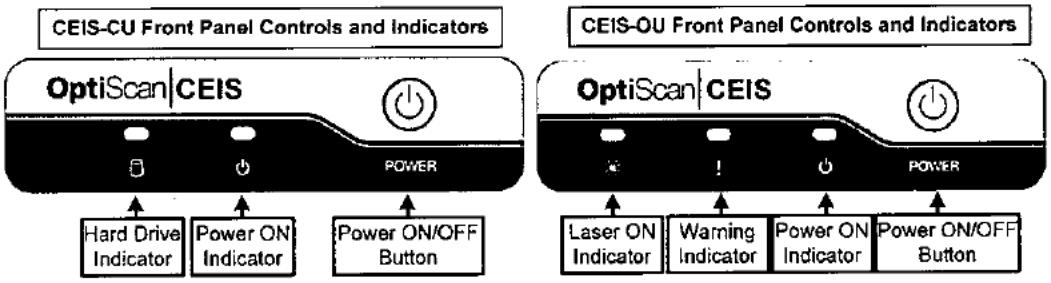

Figure 7-1 Front Panel Controls and Indicators

7.1 Warning Indicator

The Warning Indicator is located next to the Power ON Indicator on the CEIS–OU Front Panel and is labeled with the warning symbol !. The Warning Indicator is yellow in color and is illuminated in the event of a system error.

Caution:
Check the Warning Indicator if the instrument should malfunction. If the Warning indicator is on, close the application, power down the instrument, and wait for at least 60 seconds before restarting.

Turn the instrument power back on and restart the software. If the Warning Indicator is illuminated again, power down the instrument and contact the nearest Optiscan representative.

7.2 Laser Indicator

The Laser ON Indicator is located next to the Warning Indicator on the CEIS–OU Front Panel and is labeled with the laser symbol ✷. The Laser ON Indicator is blue in color and is illuminated while the laser is energized.

Caution:
If the Laser ON Indicator is illuminated unexpectedly, power down the instrument and contact the nearest Optiscan representative.

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7.3 Missing Image Data

In the event that a Procedure Result is corrupt and/or any image data in a Procedure Result is missing, the image placeholder in the **Image Selection** screen (Figure 7-2) is displayed with a checkerboard pattern. This is a visual indication of missing data.

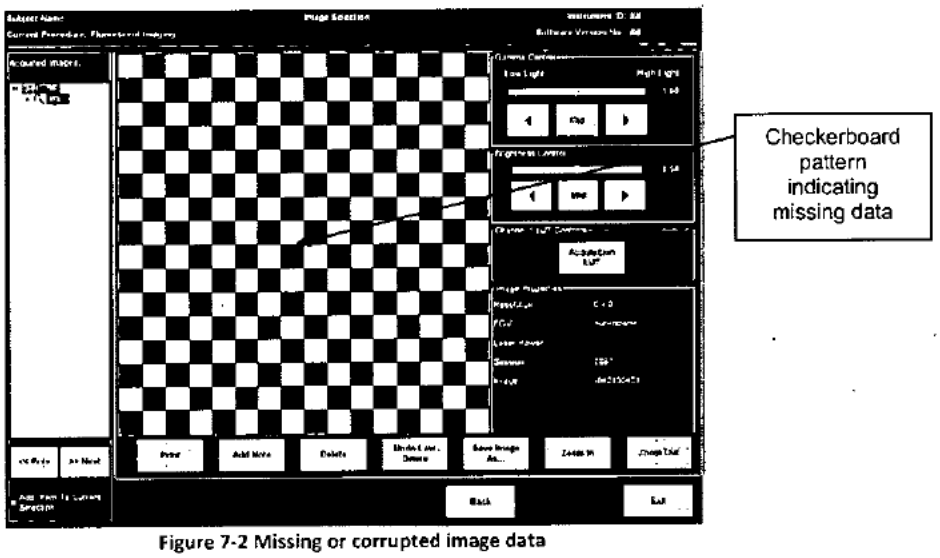

Figure 7-2 Missing or corrupted image data

7.4 Insufficient Disk Space

The **Clinical** application automatically stores image data to the instrument's hard disk. Image files are potentially very large. As a precaution, the Clinical application does not start a new Imaging Procedure if there is less than 500 MB of free disk space available on the instrument. (The **Clinical** application does not stop if the free disk space drops below 500 MB during a session.) Increase the amount of free disk space by deleting data or transferring data to an alternative storage medium, such as a CD.

Review of Procedure Results is possible with less than 500 MB of free disk space.

7.5 System Error

If the Clinical application detects a system error on start-up, or determines that a system parameter is out of range, it will automatically display an error message Figure 7-3) and shut down the application. Press End to exit the software.

Restart the **Clinical** application. Contact the nearest Optiscan representative if a System Error occurs again on restarting. Optiscan Technical Support may request running the **Reporter** application (Section 6).

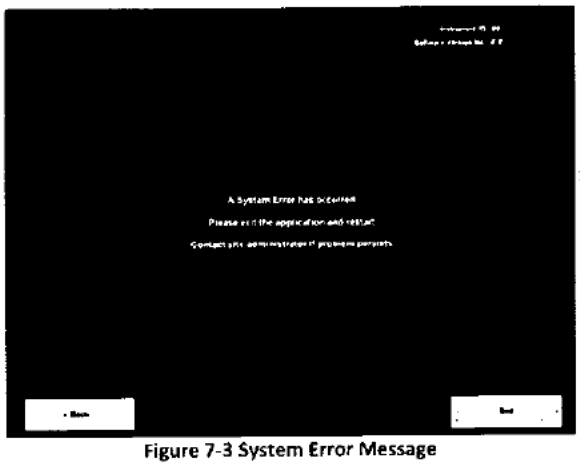

Figure 7-3 System Error Message

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NOTICE
This equipment is a Class B Medical Equipment (specified EN55011) and is intended for hospital or health care districts.
When used in clinical or residential areas near radio and TV receiver units, this equipment may be subjected to radio interference.
To reduce electromagnetic interference, do NOT keep turning on the main SWITCH of the equipment hanging a confocal endoscope on a scope-hanger when not operated.
To avoid and resolve adverse electromagnetic effects, do NOT operate this equipment near the RF energy equipment.
Only connection cables and keyboard specified by OPTISCAN conform to the above standards.

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EC REP

Specifications are subject to change without notice and without any obligation on the part of the manufacturer.

CE 0197

Document: [redacted] Revision [redacted] printed in AUSTRALIA)

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Appendix J:

Device Labelling Specification

The following documents have been attached to the submission in this section:

- (b)(4) Confirmation of Labelling for CEIS

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Confirmation of Labelling for CEIS

Documen[redacted]
Revision [redacted]
19 January 2009

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Document Approval

Signature [redacted] **Date** 19/1/2009

Reviewer (R&[redacted]

Signature [redacted] **Date** 19/1/2009

Approval ([redacted]

Revision History

Revision Number	Modified By	Release Date	Brief Change Summary
[redacted]	[redacted]	19-Dec-05	Initial Document
		23-Feb-06	Confirmation by Pentax of labels to be applied to the ISC-1000
		16-Nov-06	Addition of NRTL for the ISC-1000 and change of storage label from -40 C to -60 C
		24-Jan-07	Change of Address for European Representative
		6 Feb 07	Doc updated to include all labels and their placement
		17 Nov 08	Add NRTL Compliance Label (Section 3.12)
		19/1/2009	Updated labels in Section 2.3 and 2.4 (required for CEIS 510k Submission), Corrected error in part numbers throughout document. Updated Section 5.1 and 5.2 with new labels and corrected part numbers, Added Section 2.5 Shipping Symbols Label (102-205) mistakenly left off previous releases

Questions [redacted] tact FD[redacted] CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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1 INTRODUCTION

1.1 Scope

This document describes the labelling that will be placed on the CEIS. Note: Do not scale drawings from this document.

1.2 Responsibility and Authority

It is the responsibility of the regulatory manager to review this document

1.3 Definitions, Acronyms and Abbreviations

OU	Optical Unit
CU	Control Unit

1.4 References

Document ID	Document name
EN 980:2003	Labelling standard for medical devices
ISC Instrument	

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2 PACKAGING LABELLING

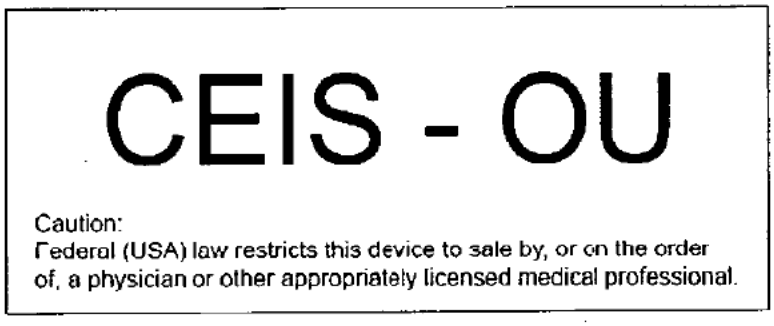
2.1 Optiscan Shipping label

Optiscan Item Number 102-226

2.2 CE Mark

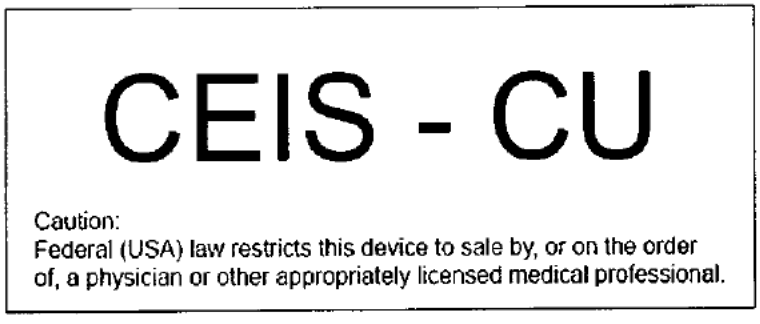
Optiscan Item Number: 102-227

2.3 CEIS OU Box Labels



Optiscan Item Number 110-222

2.4 CEIS CU Box Labels



Optiscan Item Number 110-221

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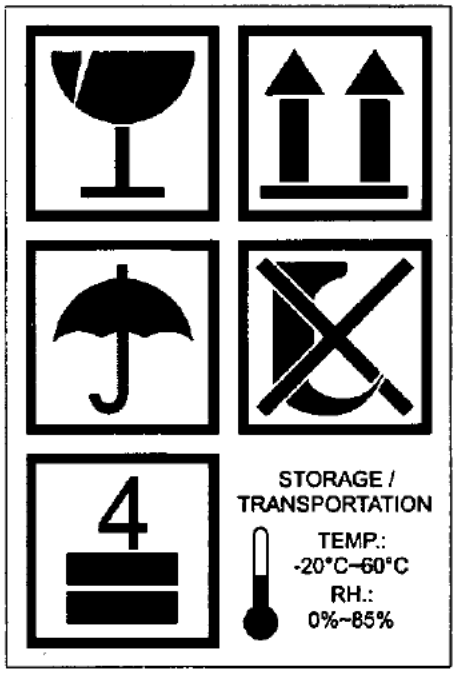
2.5 Shipping Symbols Label



Optiscan Item Number 102-205

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3 PRODUCT LABELLING – CONFOCAL CONTROL BOX

3.1 OU danger label

危険

爆発の恐れがあります。
揮発性可燃性物質を含む環境条件では
使用しないで下さい。

注意

感電の恐れがあります。
カバーは取外さないで下さい。
故障、修理は必ず弊社、あるいは弊社の
指定した専門家まで御連絡下さい。

DANGER

EXPLOSION HAZARD.
Do not use in the presence of
flammable anesthetics.

CAUTION

ELECTRIC SHOCK HAZARD.
Do not remove cover.
Refer servicing to qualified service
personnel.

ACHTUNG

EXPLOSIONSGEFAHR.
Nicht in der Nähe brennbarer
Flüssigkeiten betreiben.

VORSICHT

ELEKTRISCHER SCHLAG.
Gehäuse nicht öffnen.
Reparaturen nur durch PENTAX
Fachpersonal ausführen lassen.

DANGER

RISQUE D' EXPLOSION.
Ne pas employer en presence
d' anesthesiques inflammbles.

ATTENTION

RISQUE DE DECHARGE ELECTRIQUE.
Ne pas retirer le capot.
Contacter le service apresvent qualifile.

Optiscan Item Number: 102-214

3.2 Label Laser warning

LASER RADIATION
AVOID DIRECT EYE EXPOSURE
CLASS 3R LASER PRODUCT

Optiscan Item Number: 102-207

3.3 Caution Laser 3B Radiation Label

CAUTION - CLASS 3B LASER RADIATION WHEN OPEN
AVOID EXPOSURE TO THE BEAM

Optiscan Item Number: 102-213

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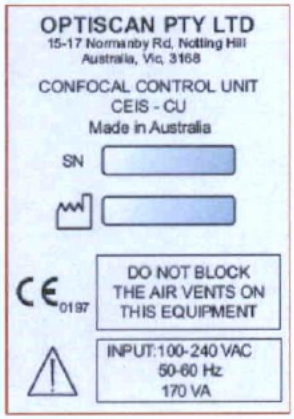
3.4 Laser Class and Standard Label

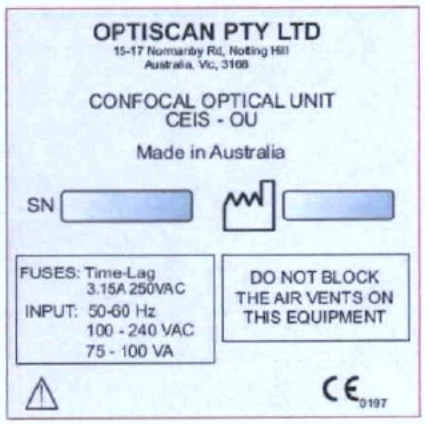
Optiscan Item Number: 102-212

3.5 CEIS CU ID Label



Optiscan Item Number:110-223

3.6 CEIS OU ID Label



Optiscan Item Number:110-224

3.7 CEIS System Label

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Optiscan Item Number: 110-225

3.8 European Representative Label

European Representative:
Medical Device Safety Service GmbH,
Schiffgraben 41
Hannover
GERMANY
D-30175

Optiscan Item Number: 110-226

3.9 Equipotential Earth Label

Optiscan Item Number: 102-209

3.10 Facia Hazard Label

Optiscan Item Number: 102-206

3.11 WEEE Compliance Label

[redacted]

Optiscan Item Number: 102-484

3.12 NRTL Compliance Label

Optiscan Part Number: 102-257

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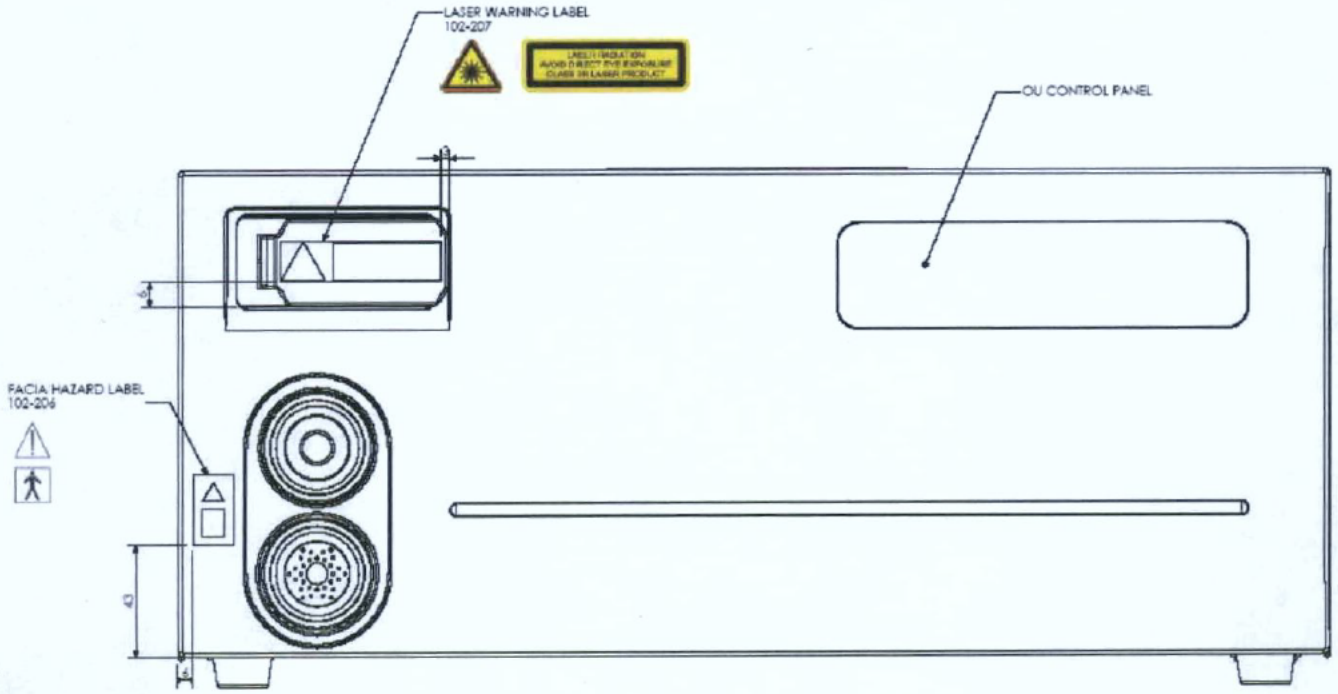
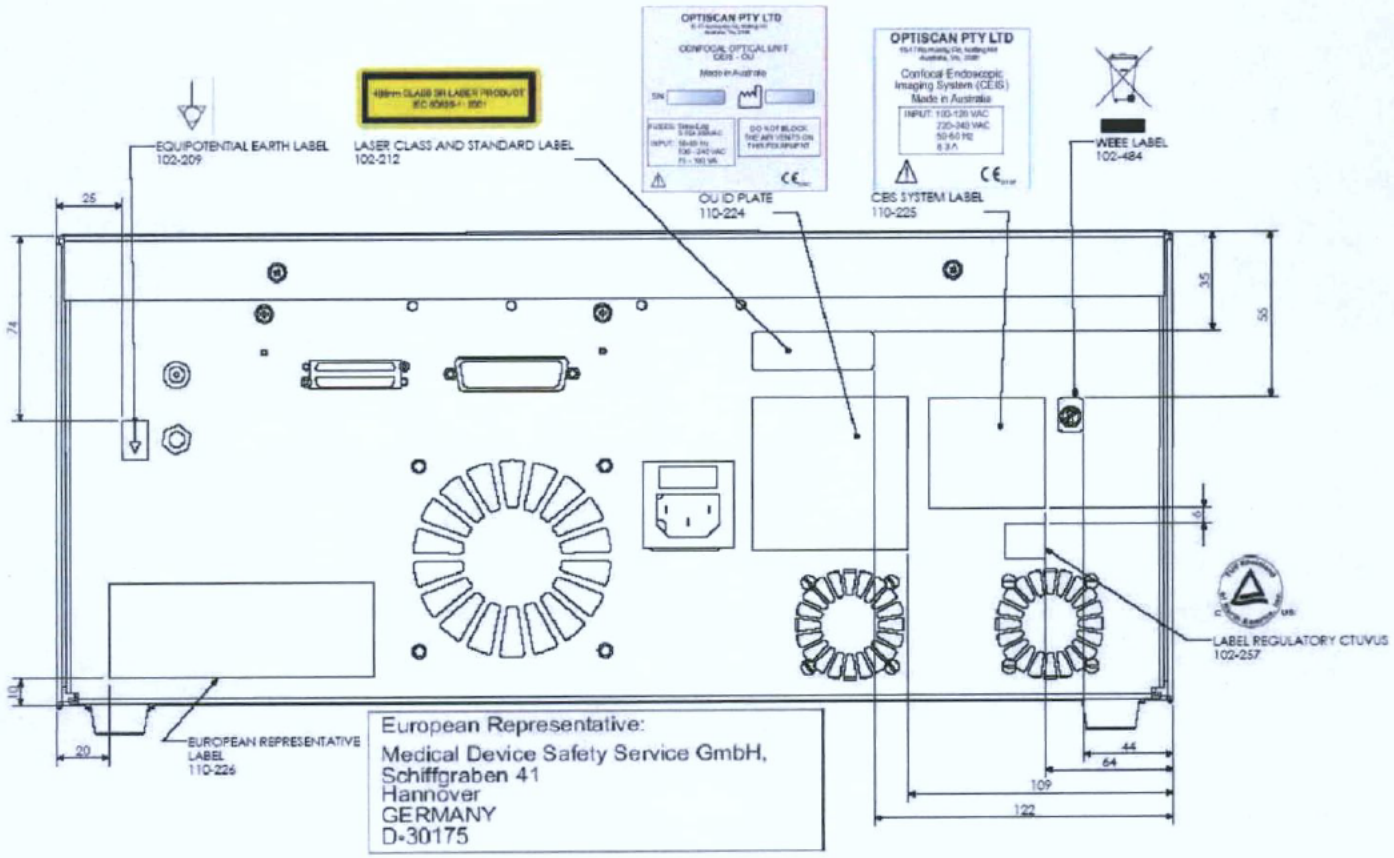
4 LABEL PLACEMENT – INSTRUMENT

4.1 Optical Unit (OU)





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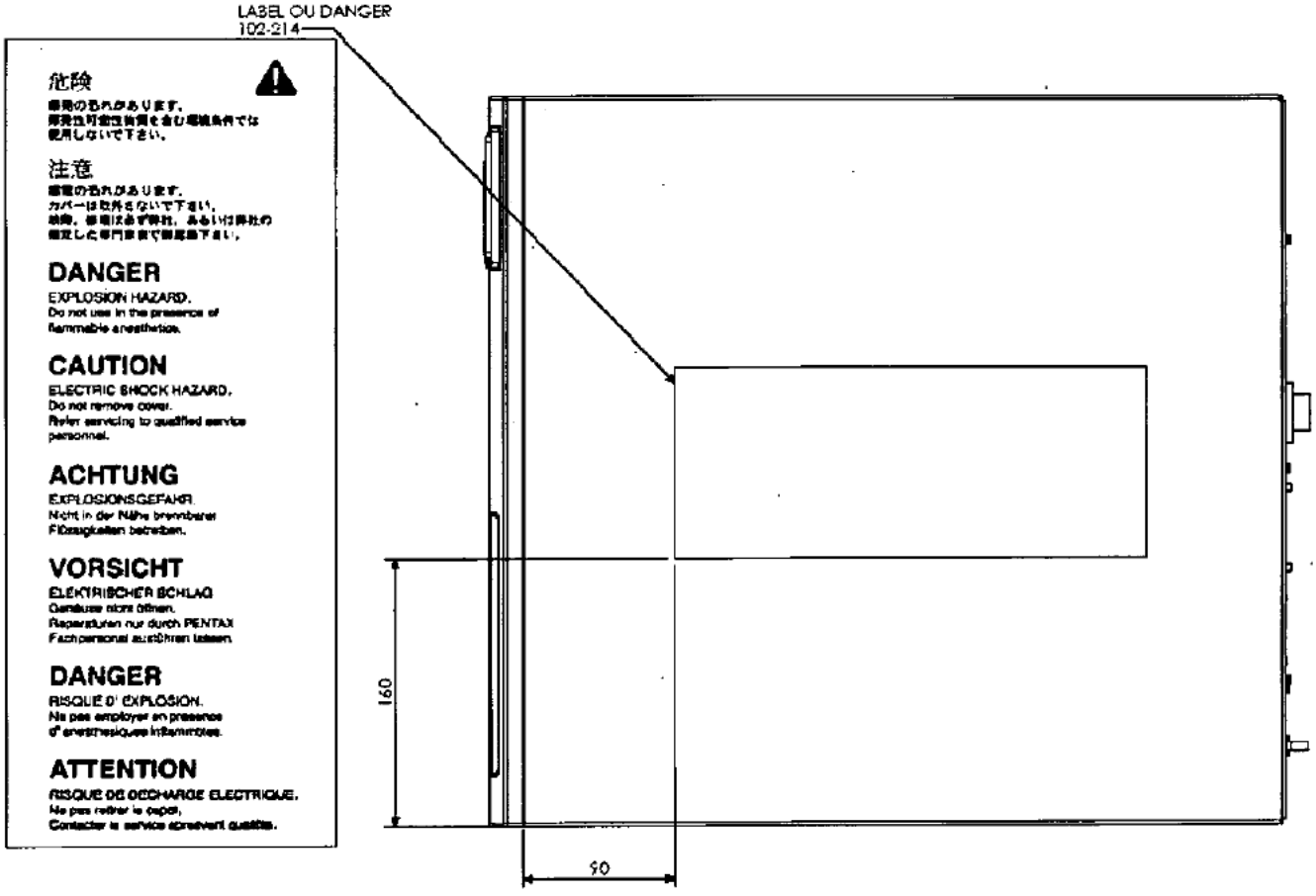

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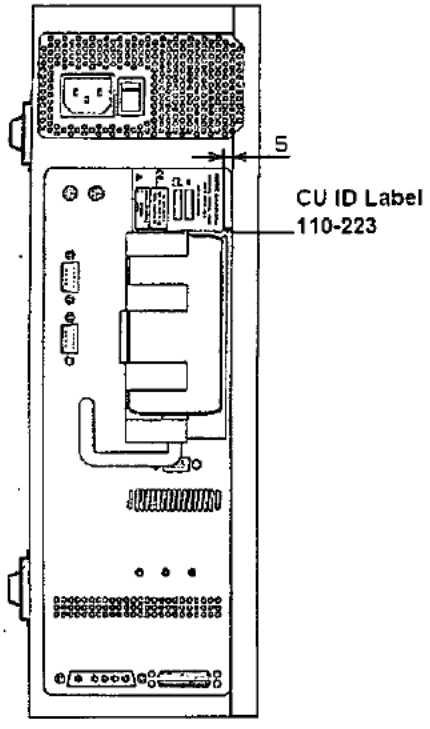
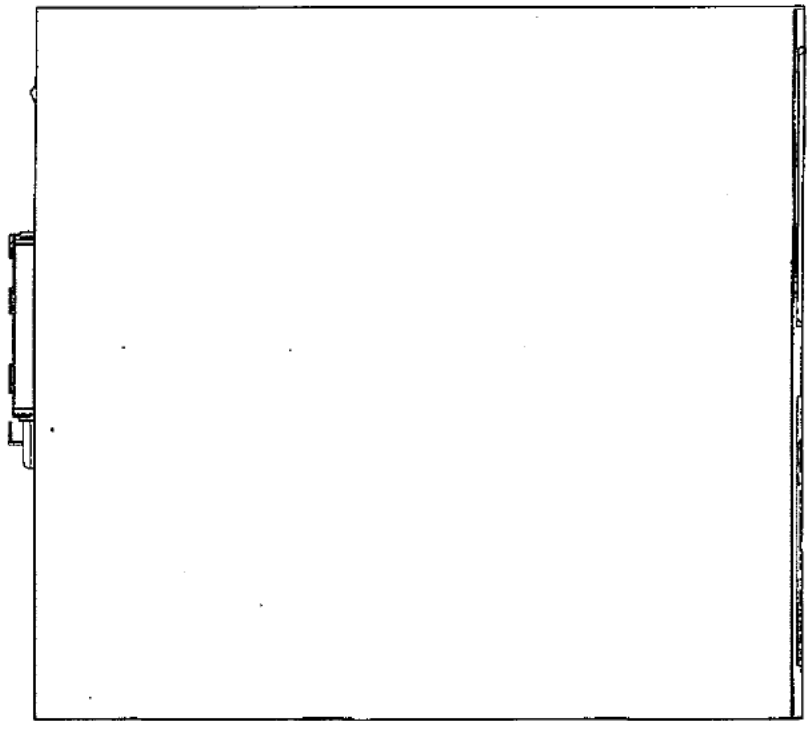
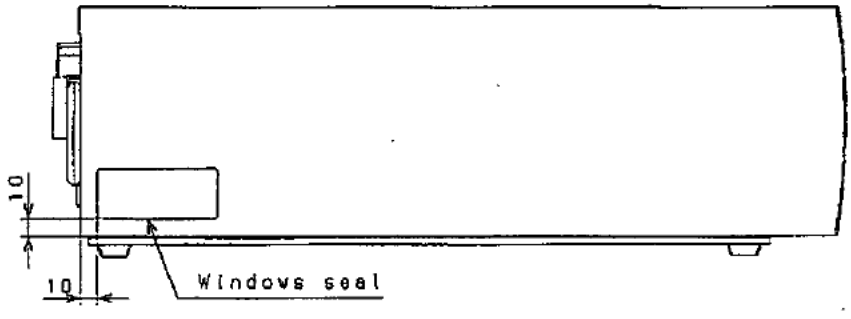
4.2 Control Unit (CU)





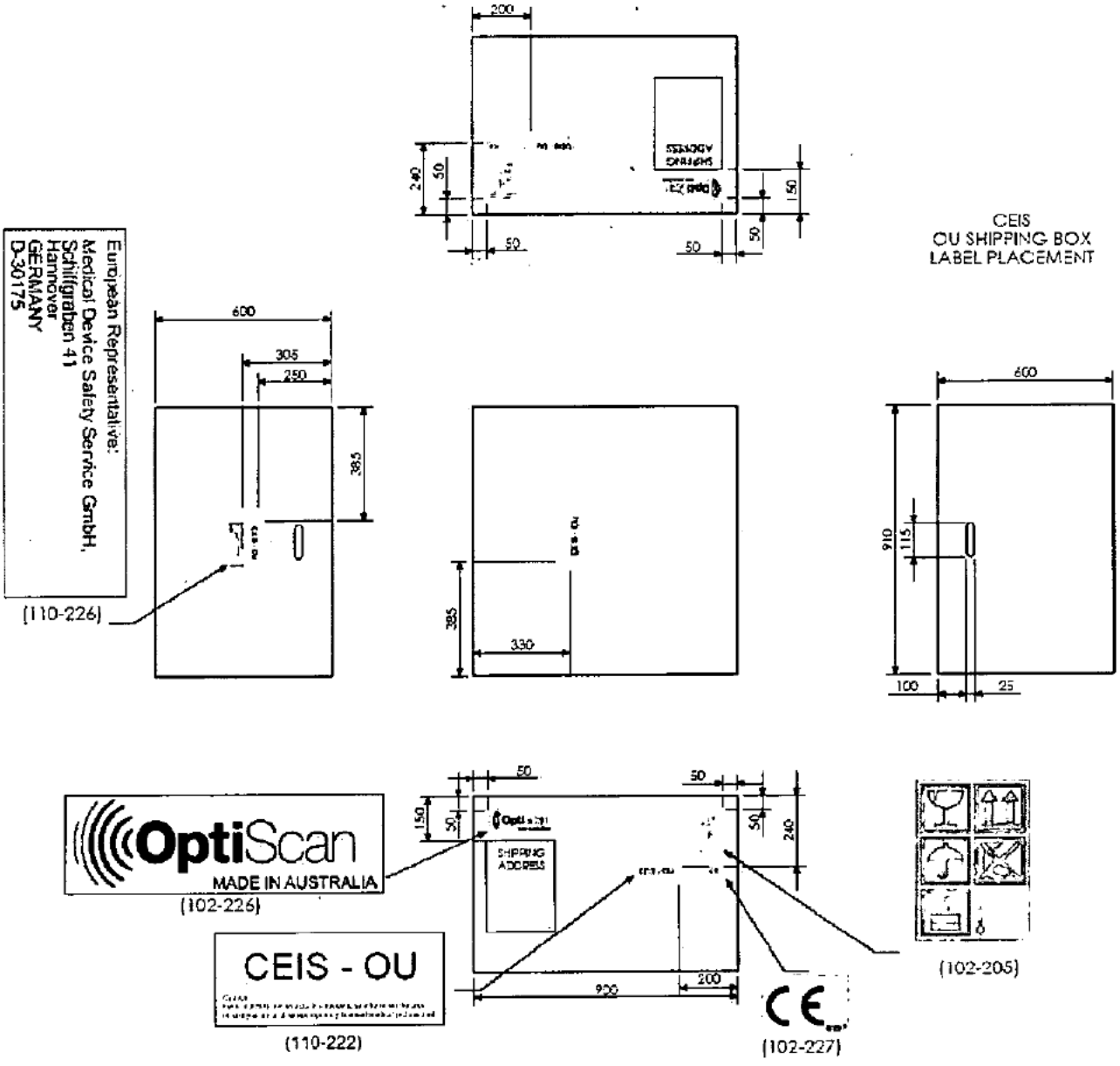


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

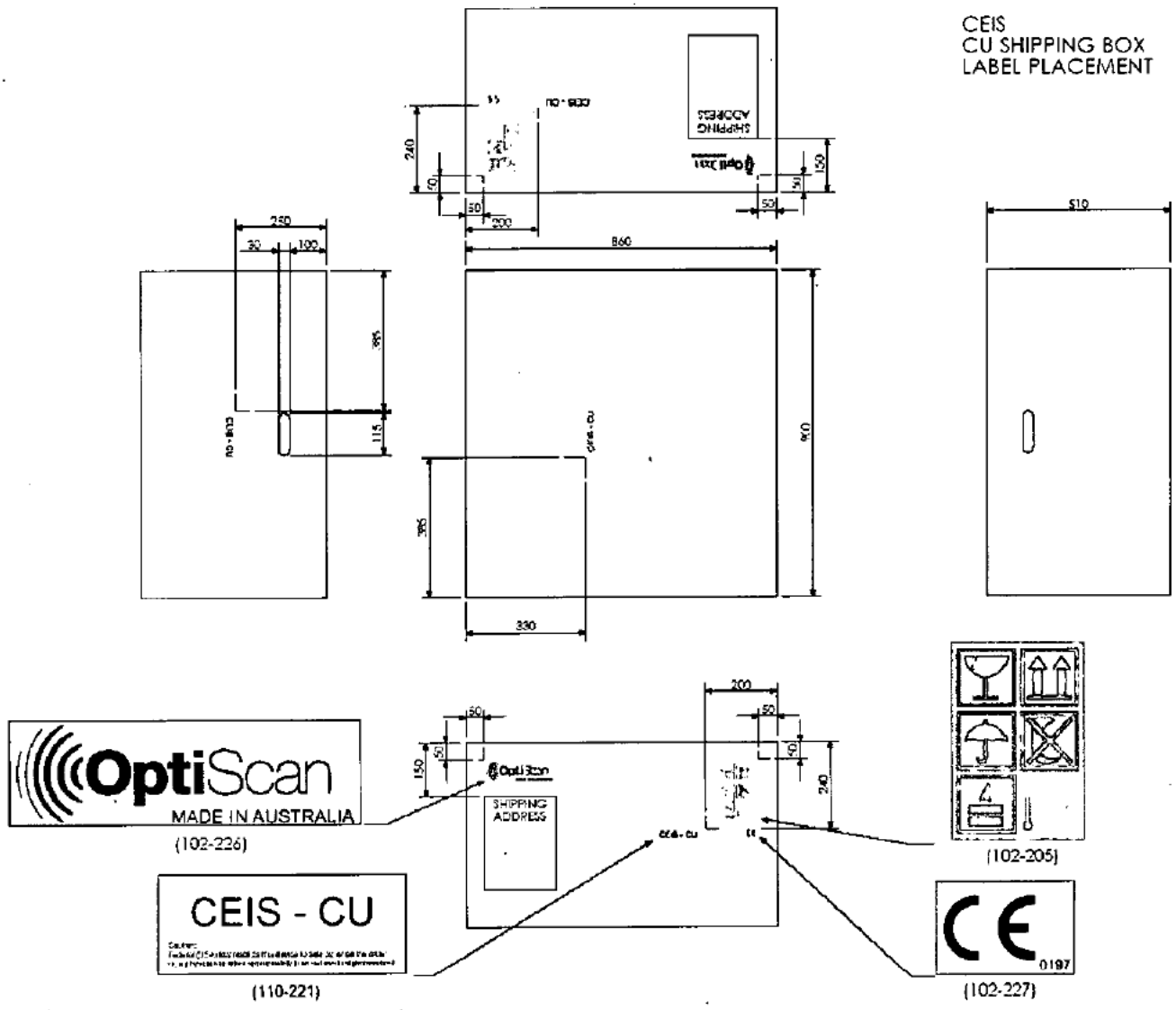
5 LABEL PLACEMENT – PACKAGING

5.1 CEIS OU Box Label Placement



Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

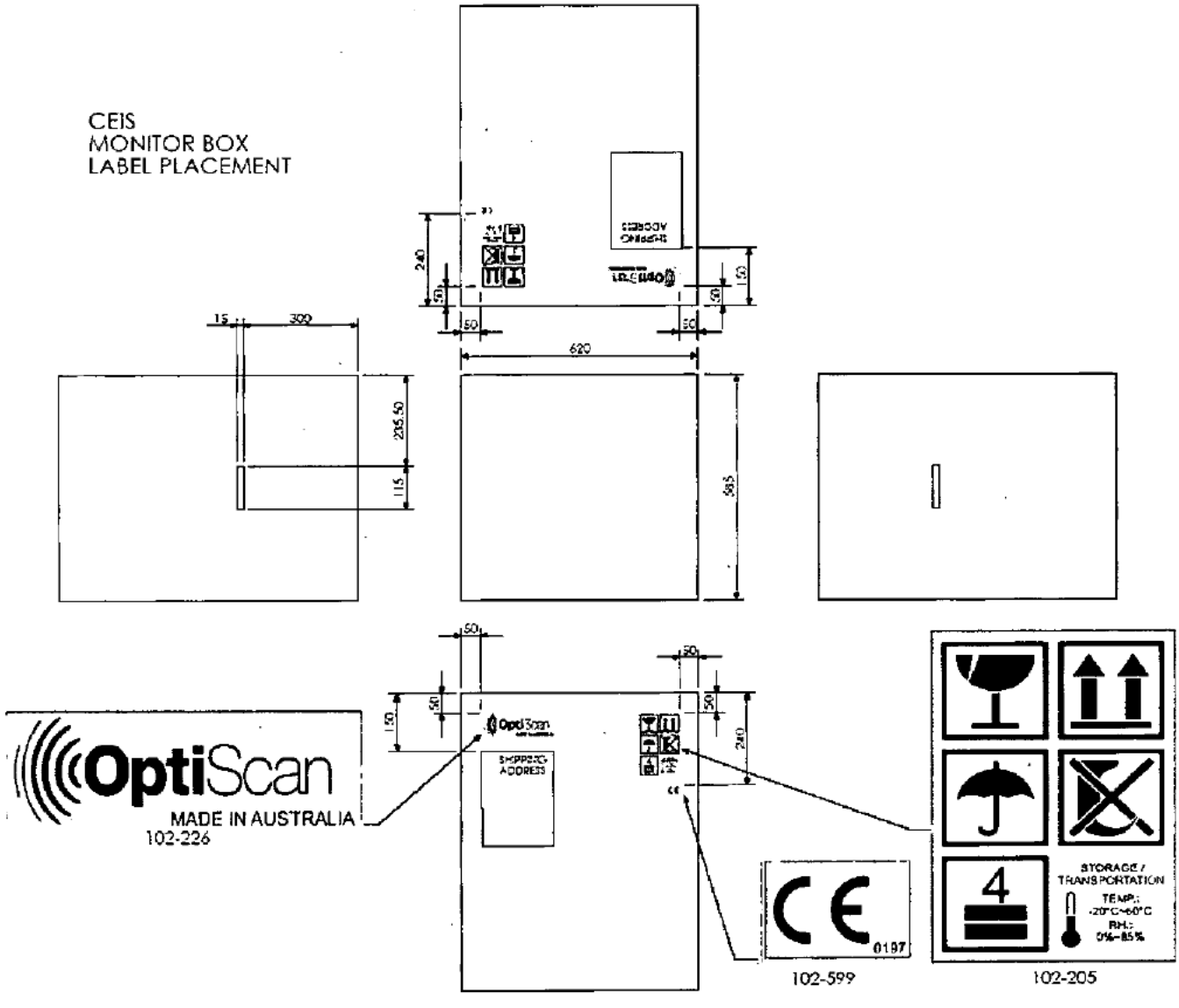
5.2 CEIS CU Box label placement



Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

5.3 CEIS Monitor / Transformer Box Label Placement



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
541

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

Appendix K:

Predicate Device Labelling Examples

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

510(k) Submission
Optiscan Confocal Endoscopic Imaging System

Labels Attached to the ISC-1000 Device and its Packaging

1. Total Rating Plate

⑤

HOYA Corporation
2-7-5 Naka-Ochiai, Shinjuku-ku
Tokyo 161-8525 Japan
Confocal Imaging System
PENTAX ISC-1000
Made in Australia
INPUT: 100-120VAC
220-240VAC
50-60Hz
6-3A

⑧ ※1 Label A or Label B

System lated label
(on PENTAX OU-1000)

⑤

European Representative:
PENTAX Europe GmbH
Julius Vesseler Strasse 104, 22527 Hamburg, Germany
EC REP

European Representative label
for OU backpanel or Packing box

③

⑧ CE 0123
※1 Label A
(CE0123)

⑧
※1 Label B
(Nothing)

2. PENTAX OU-1000

⑤

HOYA Corporation
2-7-5 Naka-Ochiai, Shinjuku-ku
Tokyo 161-8525 Japan
CONFOCAL OPTICAL UNIT
PENTAX ISC-OU 1000
Made in Australia
SN
FUSES: 250V, 3.15A
INPUT: 100-240VAC
50-60Hz
50-70VA
DO NOT BLOCK
THE AIR VENTS ON
THIS EQUIPMENT

⑧ ※1 Label A or Label B

OU lated label

Laser symbol

⑧

LASER RADIATION
AVOID DIRECT EYE EXPOSURE
CLASS 3R LASER PRODUCT
(English Ver.)

レーザ光
目への直接照射をさけること
クラス3Rレーザ製品
※2(Japanese Ver.)

Laser caution label

488nm CLASS 3R LASER PRODUCT
IEC 60825-1:2001

Laser label

⑤④ Do not change or disconnect
scope while power is on
(English Ver.)

⑧ 接続が故障する場合がありますので、電源をONにしたまま
スコープの接続／取り外しをしないでください。
詳しくは取扱説明書をお読みください。
※2(Japanese Ver.)

Hot swap caution label

543

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

④ WEEE seal

④ C TUV US label (Scale:1/2)

④ ※1 Chinese RoHS label

④ BF label

④ Equipotentiality label

④

製造販売元：HOYA株式会社
東京都新宿区中落合2－7－5
一般的名称：内視鏡用光源・プロセッサ装置
販　売　名：ペンタックス共焦点内視鏡用プロセッサ
ISC－1000

一般医療機器　特定保守管理医療機器

※2 YAKUJI Manufactures' label

危険
感電の恐れがあります。
保護性可能性物質を含む環境条件では
使用しないで下さい。

注意
感電の恐れがあります。
カバーは取外さないで下さい。
故障、修理は必ず弊社、あるいは弊社の
指定した専門家まで御連絡下さい。

DANGER
EXPLOSION HAZARD.
Do not use in the presence of flammable anesthetics.

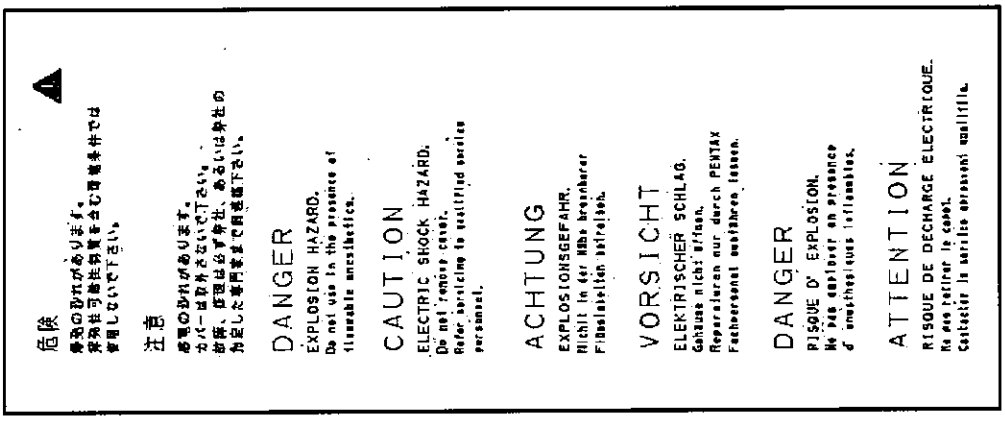
CAUTION
ELECTRIC SHOCK HAZARD.
Do not remove cover.
Refer servicing to qualified service personnel.

ACHTUNG
EXPLOSIONSGEFAHR.
Nicht in der Nähe brennbarer Flüsslabelten betreiben.

VORSICHT
ELEKTRISCHER SCHLAG.
Gehäuse nicht öffnen.
Reparaturen nur durch PENTAX Fachpersonal ausführen lassen.

DANGER
RISQUE D' EXPLOSION.
Ne pas employer en presence d' anesthesiques inflammables.

ATTENTION
RISQUE DE DECHARGE ELECTRIQUE.
Ne pas retirer le capot.
Contacter le service apresvent qualifie.



Caution label (Scale:1/2)

ISC-OU1000

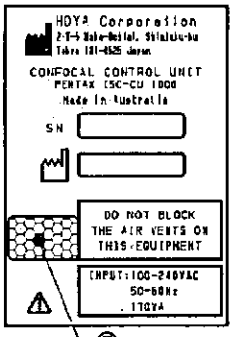
③ OU Label for Packing Box

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

3.PENTAX CU-1000

④



⑦ ※1 Label C or Label D

CU lated label

ISC-CU1000

CU Label for Packing Box

⑦ CE 0123

※1 Label C
(CE0123)

⑦

※1 Label D
(Nothing)

4.Package Box Scale:1/2

⑦ CE 0123

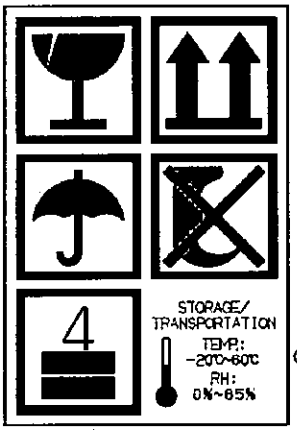
※2 CE mark

⑥ 包装材料 CB

※3 CB mark

⑧ Perchlorate Material-special handling may apply.
See www.dtsc.ca.gov/hazardouswaste/perchlorate.

※4 Perchlorate label for CU packing Box



Handling label

②③

④

PENTAX™
MADE IN AUSTRALIA
HOYA Corporation
2-7-5 Naka-Ochiai, Shinjuku-ku, Tokyo 161-8525 Japan

⑤

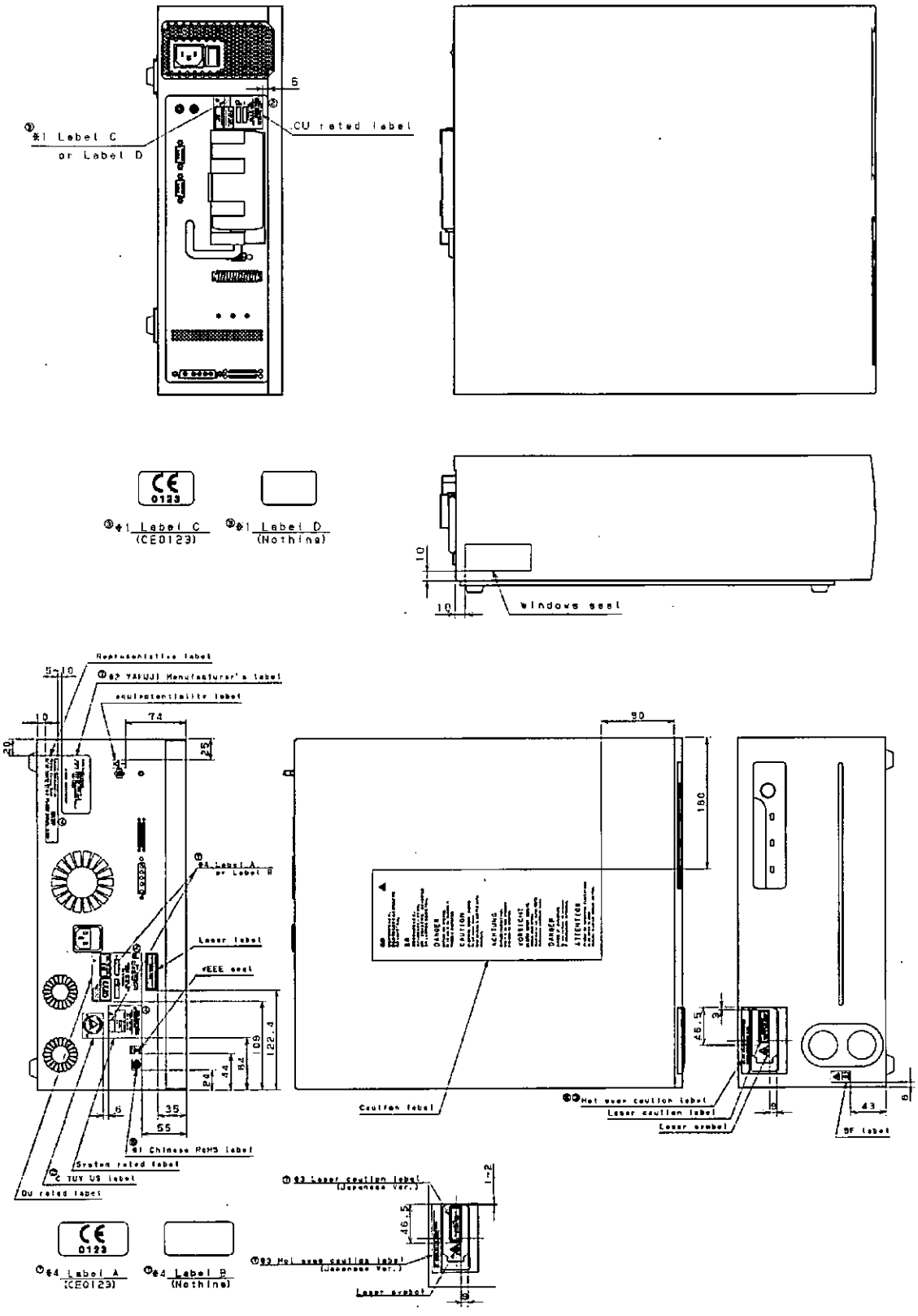
PENTAX label

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8148

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

510(k) Submission
Optiscan Confocal Endoscopic Imaging System

Labels Attached to the ISC-1000 CU and OU

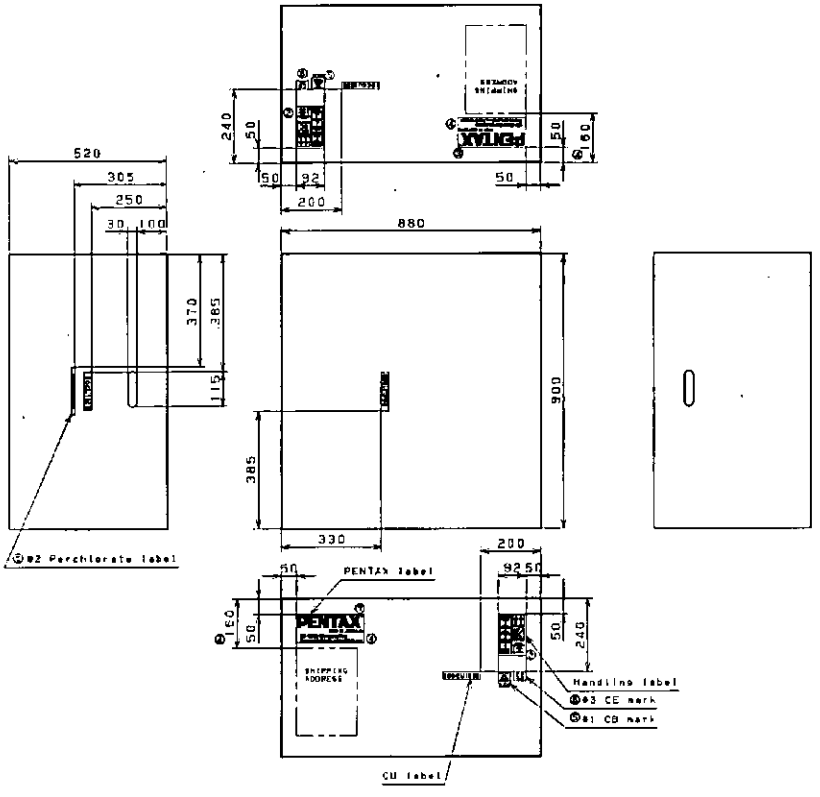


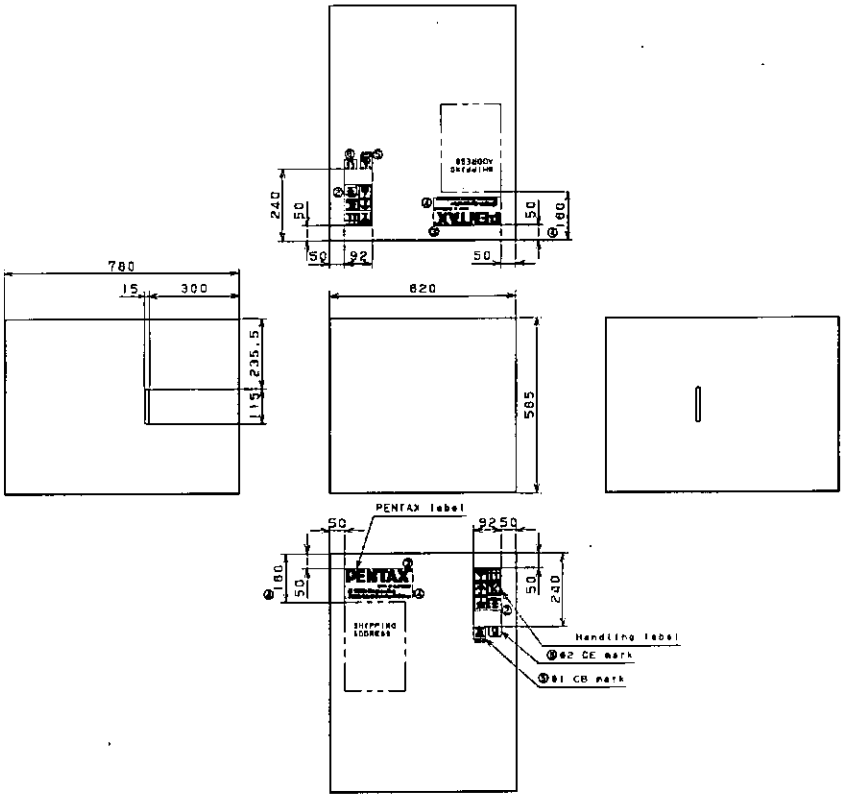
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

510(k) Submission
Optiscan Confocal Endoscopic Imaging System

Labels Attached to the Packaging Boxes

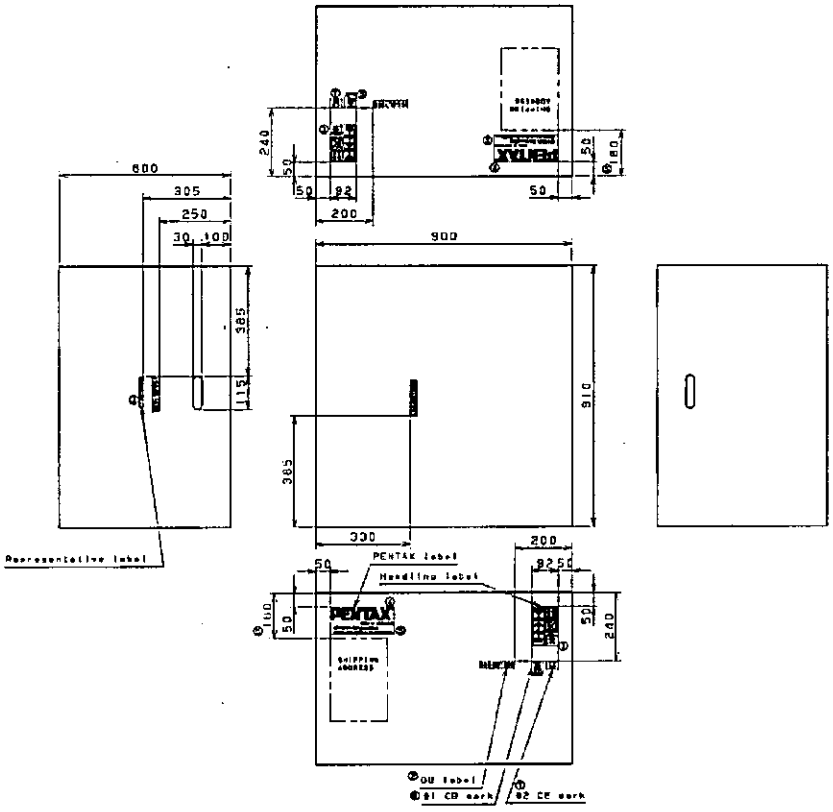




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

510(k) Submission
Optiscan Confocal Endoscopic Imaging System



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

Appendix L:

Software Release

The following documents have been attached to the submission in this section:

- (b)(4) 0 Software Release Form

Note: The Software utilised for the CEIS is identical to the ISC-1000 Software release with no changes.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OptiScan

Software Release Form

Product Information

Software Product	Imaging System Confocal (ISC)
Software Version	2.3
Release Candidate	5

Review Meeting

Date	Thursday 3rd November 2005
Time	10:00 am
Location	Optiscan Pty Ltd, Meeting Room 4
Attendees	[redacted] (b)(6) [redacted]

Validation

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OptiScan

Test Deliverables

(b)(4)

[redacted]

User manuals

User Manuals will be updated where required to reflect changes in the software.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
551

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OptiScan

Testers

Name	Signature	
(b)(6)	(b)(6)	3/11/2005
		3/11/2005
		3/11/2005
		03/11/2005
		03/11/2005
		3/11/05
		3/11/05
		3/11/05
		3/11/05
		03/11/05
		3/11/05

Approval

Permission to proceed with release: YES NO

(b)(6) Software Test Analyst	(b)(6)	3/11/2003
(b)(6) Software Manager		3/11/2005
(b)(6) R&D Manager		3/11/2005

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

Appendix M:

Standards Data Report for 510(k)s

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1] IEC 60601-1:1988+A1:1991+A2:1995
MEDICAL ELECTRICAL EQUIPMENT-PART 1: GENERAL REQUIREMENTS FOR SAFETY

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☑	☐
FDA Recognition number[3] # 5-4		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance[6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

555

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1] IEC 60601-1-1:2000
MEDICAL ELECTRICAL EQUIPMENT - PART 1 - SAFETY REQUIREMENTS FOR MEDICAL ELECTRICAL SYSTEMS

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☑	☐
FDA Recognition number[3] # 5-27		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance[6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1] IEC 60601-1-2:2004 (Edition 2.1)
MEDICAL ELECTRICAL EQUIPMENT - COLLATERAL STANDARD - ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☑	☐
FDA Recognition number[3]	# 5-34	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance[6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 559

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1] IEC 60601-2-18: 1996 + A1: 2000
MEDICAL ELECTRICAL EQUIPMENT – PART 2 – PARTICULAR REQUIREMENTS FOR THE SAFETY OF ENDOSCOPIC EQUIPMENT

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☑	☐
FDA Recognition number[3] # 9-42		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance[6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 560

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

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1350 Piccard Drive
Rockville, MD 20850

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 561

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1] IEC 60825-1: 2001
SAFETY OF LASER PRODUCTS - PART 1 - EQUIPMENT CLASSIFICATION, REQUIREMENTS AND USER'S GUIDE

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☐	☑
FDA Recognition number[3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance[6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

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[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 512

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

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1350 Piccard Drive
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 563

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Appendix N:

Declaration of Conformity to Standard

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

Declaration of Conformity to Standard

I, Peter Pavlicek certify that, in my capacity as Regulatory Affairs Manager with Optiscan Pty Ltd, believe to the best of my knowledge that the system Optiscan CEIS, Confocal Endoscopic Imaging System, complies with all applicable sections of:

- IEC 60825, Safety of Laser Products
- IEC 60601, Medical Electrical Equipment Safety Requirements

The unit testing was performed in accordance with the requirements as identified in the standards and the results demonstrated that the pre-determined acceptance testing criteria were met. A Risk Analysis and testing protocols including testing data are on file at Optiscan Pty. Ltd.

22/10/2009

Peter Pavlicek
Quality and Regulatory Affairs Manager
Optiscan Pty Ltd.

Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8716

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

Appendix O:

Requirements for Clinical Trials (Form 3674)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

Form Approved: OMB No. 0910-0616
Expiration Date: 06-30-2008
See OMB Statement on Reverse

SPONSOR/APPLICANT/SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER: OPTISCAN PTY. LTD.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES: 25th MAY, 2009

3. ADDRESS (*Number, Street, State, and Zip Code*): 15-17 NORMANBY ROAD NOTTING HILL, VICTORIA, 3168 AUSTRALIA

4. TELEPHONE AND FAX NUMBER (*Include Area Code*)
(T) +613 9538 3333
(F) +613 9562 7742

PRODUCT INFORMATION

5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(*Attach extra pages as necessary*)

OPTISCAN CETS

APPLICATION/SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (*If number previously assigned*)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT/INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES
(*See instructions for additional information and explanation*)

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN # 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
(*Attach extra pages as necessary*)

NCT Number(s)

567

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (SIGN)	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN #11 PETER PAULICEK QUALITY AND REGULATORY AFFAIRS MANAGER
13. ADDRESS (*Number, Street, State, and Zip Code*) *(of person identified in #11 & 12)* 15-17 NORMANBY ROAD NOTTING HILL, VICTORIA, 3168 AUSTRALIA	14. TELEPHONE AND FAX NUMBER (*Include Area Code*) (T) +613 9538 3348 (F) +613 9562 7742
15. DATE OF CERTIFICATION 25th MAY, 2009	

Paperwork Reduction Act Statement

Public Reporting Burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Form No. FDA 3674
5901-B Ammendale Road
Beltsville, MD 20705-1266

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
Center for Devices and Radiological Health
Program Operations Staff (HFZ-403)
9200 Corporate Blvd.
Rockville, MD 20850

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

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. Name of Sponsor/Applicant/Submitter - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.

2. Date - This is the date of the application/submission which the certification accompanies.

3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.

5. Product Information - For Drugs/Biologics: Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/ submission. Include all available names by which the product is known.
For Devices: Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.

6. Type of Application/Submission - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."

7. IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number - If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.

8. Serial Number - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field.

9. Certification - This section contains three different check-off boxes.

Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply to any of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply at the time of submission to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

10. National Clinical Trial (NCT) Numbers - If you have checked Box C in # 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as NCT will be added automatically before number. Include any and all NCT numbers assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

11. Signature of Sponsor/Applicant/Submitter or an Authorized Representative - The person signing the certification must sign in this field.

12. Name and Title of Person Who Signed in #11. - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/ submitter.

13. & 14. & 15. - Provide the full address, telephone and fax number of the person who is identified in number 11 and signs the certification in number 12. Provide the date the certification is signed. This date may be different from the date provided in #2.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

Appendix P:

Manufacturing Flowcharts

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Kejing Chen

Subject: 510(k) Number K093624/S1

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☑ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			✓
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank?* (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓

Rev. 7/2/07

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Transitional Adolescent B (18 -<= 21, No special considerations compared to adults => 21 years old) ✓

Nanotechnology ✓

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	Class*	Product Code
21 CFR 876.1500	II	GCJ

(*if unclassified, see 510(k) Staff)

Additional Product Codes: ~~KUR~~ KUG

Review: _____
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

3/5/10

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
WO Building 66
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional

K093624/s1

Date: March 3, 2010
To: The Record
From: Kejing Chen, Ph.D., Biomedical Engineer

Office: ODE
Division: DSORD/GSDB

510(k) Holder: (3rd party: TUV Rheinland of North America, Inc.)
Device Name: Optiscan Model Optiscan CEIS
Contact: Mr. Tamas Borsai
12 Commerce Rd.
Newton, Connecticut 06470
United States
Phone: 203-426-0888 Ext 707
Fax: 203-426-4009
E-mail: tborsai@us.tuv.com

Applicant: Optiscan PTY LTD
15-17 Normanby Rd.
Notting Hill VIC
Australia 3168
Phone: 613-953-83333

I. Purpose

The device is a confocal endoscopic imaging system. The illumination wavelength for the system (CEIS) is 488 nm and the power is in the order of hundreds of microwatts and the maximum illumination power is 1 mW. The illumination source is a solid state laser. The sponsor cited the K042740 from Pentax Medical Company as the predicate. The subject and predicate devices are the same in the areas of excitation wavelength, scanner maximum optical output power, transverse modes, field of view, axis and lateral response, and so on. The major differences are changes in labeling, a new software script, and an (b)(4) [redacted].

The original submission was evaluated by the third party reviewer. Upon the review on the 3rd party review as well as the submission from the sponsor, I found (b)(4) [redacted]s (b)(4) [redacted]s [redacted].

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

(b)(4) [redacted]

(b)(4) [redacted]. The response is acceptable. Also, the sponsor removed the long pass filter from the device. The response sufficiently addressed the concerns raised during the review on the original submission. Thus, I recommend an SE decision.

Consult: Mr. Neil Ogden, Branch Chief of GSDB/DSORD, Dr. Long Chen, Reviewer of GSDB/DSORD, and Dr. Josh Pfefer, were informally consulted frequently through the review process.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary	X		
Standards Form			X

III. Device Description

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

The device contains the following units: A control unit and an optical unit. The system is designed to take and display images of tissues or organs. The device transmits light from a variable output laser via an optical fiber and the laser light is focused to a diffraction-limited spot within the tissue.

The system is proposed to be used in either reflectance or fluorescence mode. The illumination wavelength for the system (CEIS) is 488 nm and the power is in the order of hundreds of microwatts and the maximum illumination power is 1 mW. The illumination source is a solid state laser. There are two scan modes. The confocal axis response is 8 µm

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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and the lateral response is 1 µm.

III. Indications for Use

	Company	Indications for use
K093624 (subject)	Optiscan PTY LTD	In original submission: The Optiscan Confocal Endoscopic Imaging System (CEIS) is intended to be used for confocal endomicroscopy of human tissue. The CEIS, its monitor, and a suitable confocal endomicroscope probe can provide microscopic visualization of the surface and subsurface of various body organs and tissues during endoscopic medical examination procedures. *The system is applied when indications consistent with the requirement of procedure are observed in adult and pediatric patient populations.* In Supplement I: The Confocal Endoscopic Imaging System (CEIS) is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by legally marketed video endoscopes (equipped with a confocal laser imaging module), during endoscopic medical examination procedures. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.
K042740	Pentax Medical Company	The Pentax confocal laser system is a required accessory for legally marketed video endoscopes equipped with a confocal laser imaging module. The system is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by the endoscope. *The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.*

The device is for prescription use only.

The second part of the IFU statement is the same as the predicate ("The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations"). However, (b)(4) [redacted]

IV. Predicate Device Comparison

The subject and predicate devices are the same in the areas of excitation wavelength, scanner maximum optical output power, transverse modes, field of view, axis and lateral response, and so on. The major differences are changes in labeling, a new software script, and an (b)(4) [redacted] (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)4) [redacted] sponsor stressed that the (b)(4) [redacted] on the device do not change with the (b)(4) [redacted] and are identical to the predicate system.

However, (b)(4) [redacted]. Regarding this question, I talked with Mr. Neil Ogden, Branch Chief of GSDB/DSORD, on 12/4/09. It was agreed from the meeting that the sponsor (b)(4) [redacted].

In Supplement I, (b)(4) [redacted].

V. Labeling

The labeling is SE to that of the predicate. The third party review is sufficient.

VI. Sterilization/Shelf Life/Reuse

The device is not provided sterile. It will be connected to a suitable confocal endoscope. This is SE to the predicate. The third party review is sufficient.

VII. Biocompatibility

The sponsor stated that the device will not come into contact with patients directly or indirectly. Thus, there is no biocompatibility concern. The third party review is sufficient.

VIII. Software

Version:

Level of Concern: minor

	Yes	No
Software description:	X	
Device Hazard Analysis:	X	
Software Requirements Specifications:	X	
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:	X	
Development:		
Verification & Validation Testing:	X	
Revision level history:	X	
Unresolved anomalies:		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Software documentation is complete and the third party review on this section is sufficient.

VIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The sponsor claimed that the following standards apply to the device:

IEC 60825-1, Safety of Laser Products, Part 1
IEC 60601-1
IEC 60601-1-1
IEC60601-1-2
IEC60601-2-18

IX. Performance Testing – Bench

N/A

X. Performance Testing – Animal

N/A

XI. Performance Testing – Clinical

N/A

XII. Substantial Equivalence Discussion

	Yes	No	
1. Is Product A Device	X		If **NO** = Stop, see 510(k) staff
2. Is Device Subject To 510(k)?	X		If **NO** = Stop, see 510(k) staff
3. Same Indication Statement?		X	If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X	If **YES** = Stop **NSE**
5. Same Technological Characteristics?	X		If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?	X		If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification 510kProgram/0_4147/FLOWCHART 510K DECISION.PDF for Flowchart to assist in decision-

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Explain why not a device:

   This is a device.

2. Explain why not subject to 510(k):

   It is subject to 510(k).

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

   The IFU is SE to the predicate's.

4. Explain why there is or is not a new effect or safety or effectiveness issue:

   Please refer to Section IV.

5. Describe the new technological characteristics:

   Please refer to Section IV.

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

   Please refer to Sections IV and V.

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness question(s) raised or why the question(s) 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:

XIII. Deficiencies

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 15

(b)(4)

[redacted]

XIV. Contact History

1. 12/04/09: Tried to call the third party reviewer, Mr. (b)(6) [redacted], but he was not available. A message was left on his voice mail, followed by an e-mailed AI letter.
2. 12/23/09: Received draft response from the sponsor, Mr. (b)(6) [redacted]. Telephoned the sponsor and discussed their draft response the same day.
3. 01/06/10: The sponsor, Mr. (b)(6) [redacted], emailed a draft of letter that he was going to send to the company and sought informal comments. Telephoned him and discussed the questions the same day.

XV. Recommendation

I recommend that this submission be found substantially equivalent to the predicate device.

Regulation Number: 21 CFR 876.1500
Regulation Name: General and Plastic Surgery devices
Regulatory Class: Class II
Product Code: GCJ, KOG

Kejing Chen
Lead Reviewer, GSDB/DSORD

3/3/10
Date

Neil Ogden
Branch Chief, GSDB/DSORD

Date

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Record processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

COVER SHEET MEMORANDUM

From: Reviewer Name Kejing Chen

Subject: 510(k) Number K093624

To: The Record

Please list CTS decision code TH

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- ☑ Hold (Additional Information or Telephone Hold).
- ☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			✓
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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

Regulation Number	Class*	Product Code
21 CFR 876.1500	II	GCJ

(*If unclassified, see 510(k) Staff)

Additional Product Codes: KOG

Review: [signature] (Branch Chief) GSDB (Branch Code) 12/4/09 (Date)

Final Review: _____ (Division Director) _____ (Date)

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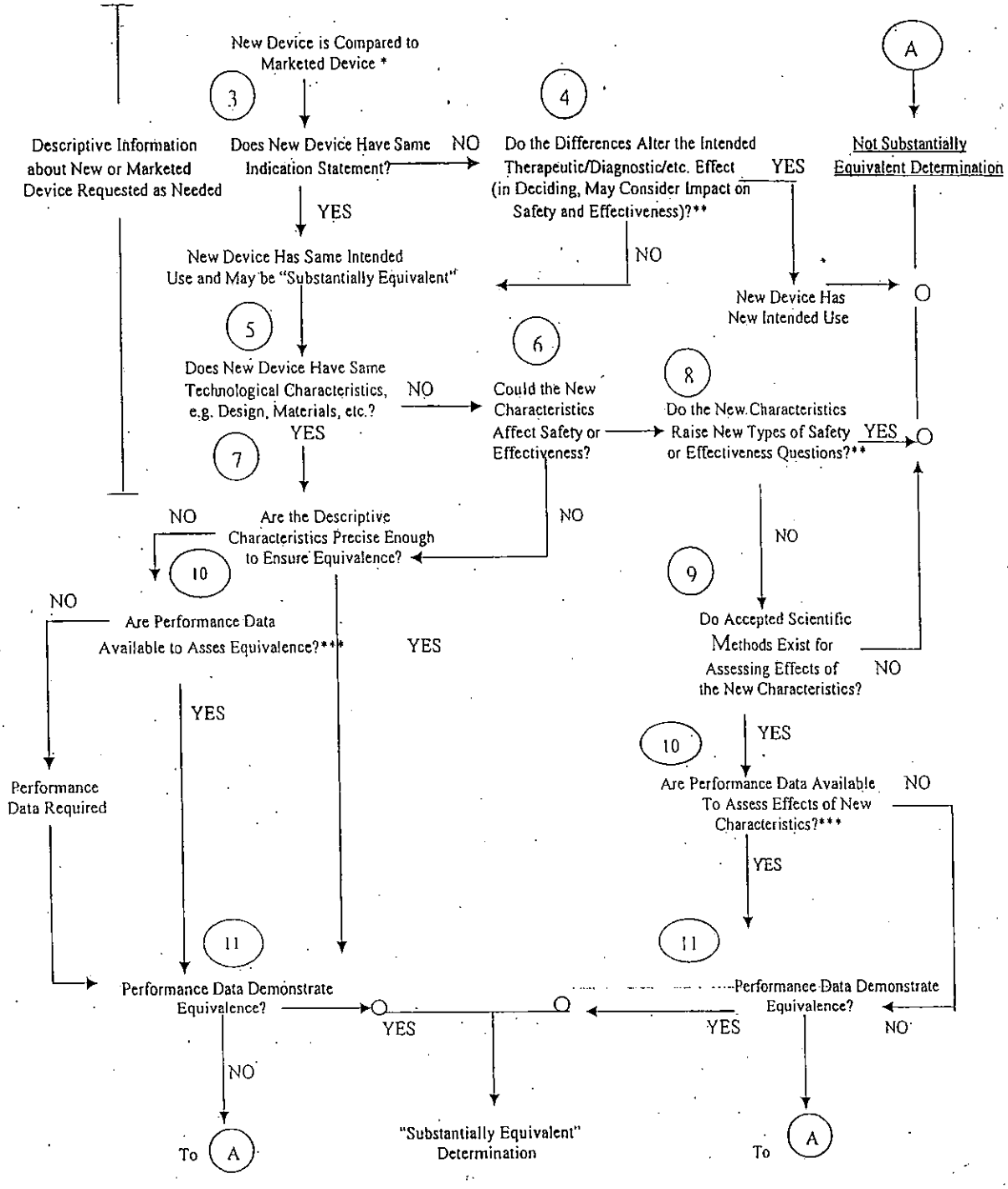
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

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.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
WO Building 66
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional

K093624

Date: December 1, 2009
To: The Record
From: Kejing Chen, Ph.D., Biomedical Engineer

Office: ODE
Division: DSORD/GSDB

510(k) Holder: (3rd party: TUV Rheinland of North America, Inc.)
Device Name: Optiscan Model Optiscan CEIS
Contact: Mr. Tamas Borsai
12 Commerce Rd.
Newton, Connecticut 06470
United States
Phone: 203-426-0888 Ext 707
Fax: 203-426-4009
E-mail: tborsai@us.tuv.com

Applicant: Optiscan PTY LTD
15-17 Normanby Rd.
Notting Hill VIC
Australia 3168
Phone: 613-953-83333

I. Purpose

The device is a confocal endoscopic imaging system. The illumination wavelength for the system (CEIS) is 488 nm and the power is in the order of hundreds of microwatts and the maximum illumination power is 1 mW. The illumination source is a solid state laser. The sponsor cited the K042740 from Pentax Medical Company as the predicate. The subject and predicate devices are the same in the areas of excitation wavelength, scanner maximum optical output power, transverse modes, field of view, axis and lateral response, and so on. The major differences are changes in labeling, a new software script, and an (b)(4) [redacted].

The submission was evaluated by the third party reviewer. Upon the review on the 3rd party review as well as the submission from the sponsor, I found that two questions were not sufficiently addressed: (b)(4) [redacted] (b)(4))(4) [redacted] (b)(4)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) [redacted]

(b)(4) [redacted]. See Deficiencies. I recommend that this submission be placed on hold pending receipt of the response to the above questions.

Consult: Mr. Neil Ogden, Branch Chief of GSDB/DSORD, Dr. Long Chen, Reviewer of GSDB/DSORD, and Dr. Josh Pfefer, were informally consulted frequently through the review process.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary	X		
Standards Form			X

III. Device Description

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

The device contains the following units: A control unit and an optical unit. The system is designed to take and display images of tissues or organs. The device transmits light from a variable output laser via an optical fiber and the laser light is focused to a diffraction-limited spot within the tissue.

The system is proposed to be used in either reflectance or fluorescence mode. The illumination wavelength for the system (CEIS) is 488 nm and the power is in the order of hundreds of microwatts and the maximum illumination power is 1 mW. The illumination source is a solid state laser. There are two scan modes. The confocal axis response is 8 μm and the lateral response is 1 μm.

III. Indications for Use

	Company	Indications for use
K093624 (subject)	Optiscan PTY LTD	The Optiscan Confocal Endoscopic Imaging System (CEIS) is intended to be used for confocal endomicroscopy of human tissue. The CEIS, its monitor, and a suitable confocal endomicroscope

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		probe can provide microscopic visualization of the surface and subsurface of various body organs and tissues during endoscopic medical examination procedures. *The system is applied when indications consistent with the requirement of procedure are observed in adult and pediatric patient populations.*
K042740	Pentax Medical Company	The Pentax confocal laser system is a required accessory for legally marketed video endoscopes equipped with a confocal laser imaging module. The system is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by the endoscope. *The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.*

The device is for prescription use only.

The second part of the IFU statement is the same as the predicate ("The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations"). However, (b)(4) [redacted] (b)(4) [redacted]

IV. Predicate Device Comparison

The subject and predicate devices are the same in the areas of excitation wavelength, scanner maximum optical output power, transverse modes, field of view, axis and lateral response, and so on. The major differences are changes in labeling, a new software script, and (b)(4) [redacted]

(b)(4) [redacted]. Regarding this question, I talked with Mr. Neil Ogden, Branch Chief of GSDB/DSORD, on 12/4/09. It was agreed from the meeting that the sponsor should (b)(4) [redacted]

V. Labeling

The labeling is SE to that of the predicate. The third party review is sufficient.

VI. Sterilization/Shelf Life/Reuse

The device is not provided sterile. It will be connected to a suitable confocal endoscope. This is SE to the predicate. The third party review is sufficient.

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VII. Biocompatibility

The sponsor stated that the device will not come into contact with patients directly or indirectly. Thus, there is no biocompatibility concern. The third party review is sufficient.

VIII. Software

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

Software documentation is complete and the third party review on this section is sufficient.

VIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The sponsor claimed that the following standards apply to the device:

IEC 60825-1, Safety of Laser Products, Part 1
IEC 60601-1
IEC 60601-1-1
IEC60601-1-2
IEC60601-2-18

IX. Performance Testing – Bench

X. Performance Testing – Animal

N/A

XI. Performance Testing – Clinical

N/A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 269

XII. Substantial Equivalence Discussion

	Yes	No	
1. Is Product A Device	X		If **NO** = Stop, see 510(k) staff
2. Is Device Subject To 510(k)?	X		If **NO** = Stop, see 510(k) staff
3. Same Indication Statement?			If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
5. Same Technological Characteristics?			If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?			If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification 510kProgram/0_4147/FLOWCHART 510K DECISION.PDF for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Explain why not a device:

2. Explain why not subject to 510(k):

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

At present, need explanation from the sponsor to determine the answer to this question.

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 question(s) raised or why the question(s) are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

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11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XIII. Deficiencies

(b)(4)

[redacted]

XIV. Contact History

1. 12/04/09: Tried to call the third party reviewer, Mr. (b)(6) [redacted], but he was not available. A message was left on his voice mail, followed by an e-mailed AI letter.

XV. Recommendation

I recommend that this submission be placed on hold pending receipt of the response to the above questions.

Regulation Number: 21 CFR 876.1500
Regulation Name: General and Plastic Surgery devices
Regulatory Class: Class II
Product Code: GCJ, KOG

Kejing Chen — 12/4/09
Lead Reviewer, GSDB/DSORD — Date

Neil Ogden — 12/4/09
Branch Chief, GSDB/DSORD — Date

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Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

Chen, Kejing

From: Chen, Kejing
Sent: Friday, December 04, 2009 1:19 PM
To: (b)(4) [redacted]
Cc: Ogden, Neil
Subject: 510(k) Submission – Optiscan Model Optiscan CEIS (K093624)

Attachments: K093624_email.1AI.doc

Dear Mr (b)(6) [redacted],

We have completed the review of your subject submission and a copy of the additional information request is attached for your information. Feel free to contact me for any further clarification.

Sincerely,
Kejing Chen

K093624_email.1AI
.doc (50 KB)

--
Kejing Chen, Ph.D.
General Surgery Devices Branch
Division of Surgical, Orthopedic, and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
White Oak #66 Room 1449
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 301-796-6390
kejing.chen@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 272

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

December 4, 2009

Mr. (b)(6) [redacted]
(b)(4) [redacted]

Re: 510(k) Submission – Optiscan Model Optiscan CEIS (K093624)

Dear Mr. (b)(6) [redacted],

In reviewing the subject submission, we have the following additional questions that need to be clarified to facilitate our review process:

(b)(4) [redacted]

The subject submission will be placed on hold pending your response with the requested information. If you need more than 30 days to provide a full and complete response, you should submit a request for an extension of time to Document Mail Center. For further information on how to apply for an extension and for general 510(k) information, please visit the FDA Website at:
http://www.fda.gov/cdrh/devadvice/31435.html#link_6

Sincerely,

Kejing Chen, Ph.D.
Biomedical Engineer

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

Phone#: (301)796-6390, Fax#: (301)847-8117
General Surgery Devices Branch
Division of Surgical, Orthopedic, and Restorative Devices
FDA/ODE
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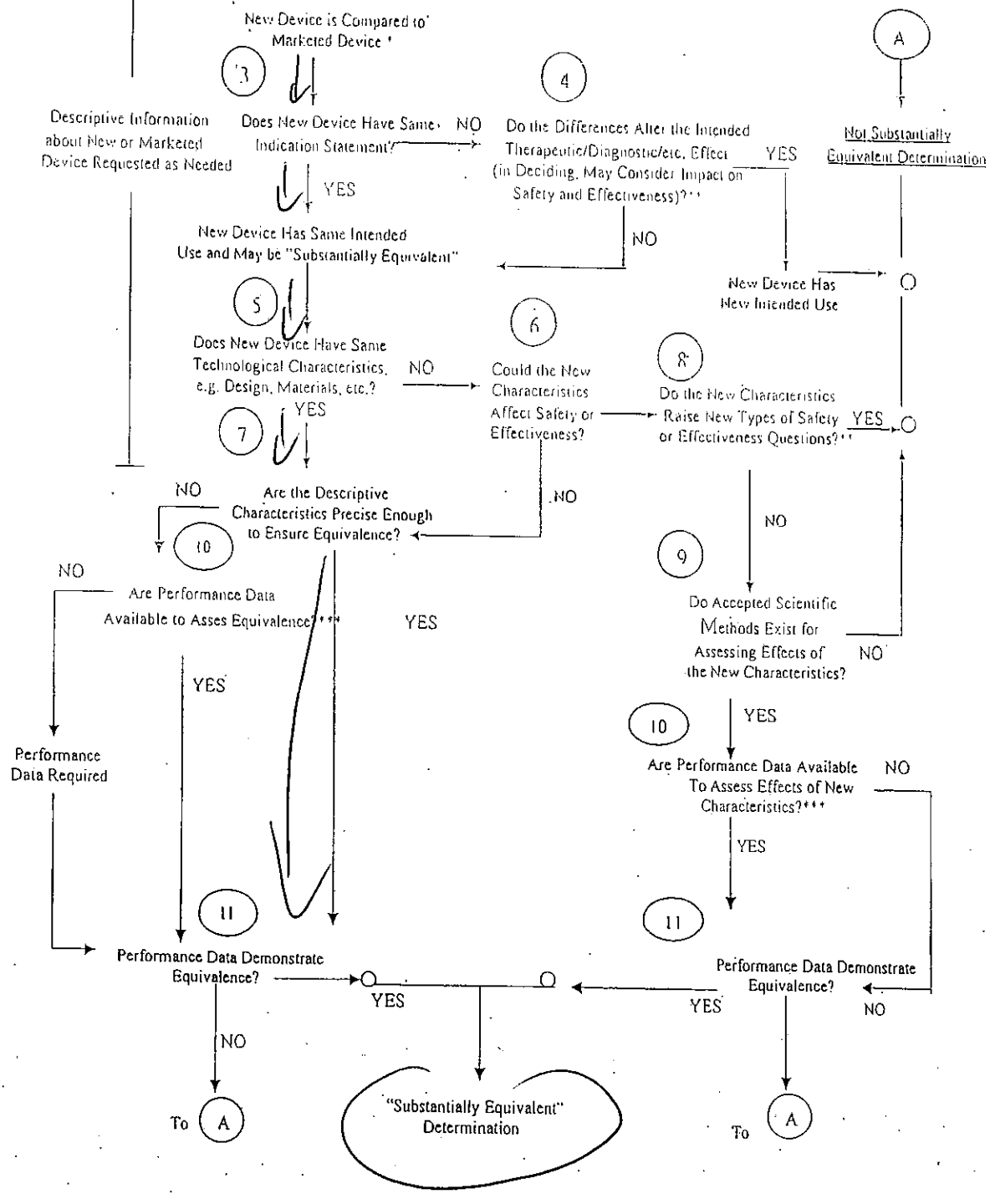
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Rel(b)(4)

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

K093624/S1

Subject: Response to FDA Deficiency Report 510(k) Notification reviewed by Third Party (K093624)

Dear Document Control Clerk:

(b)(4) as Third Party reviewer is submitting the revised previewed 510(k) of Optiscan Pty Ltd. for the Optiscan Confocal Endoscopic Imaging System (CEIS), Model: Optiscan CEIS.

The following information is being submitted in accordance with the Third Party Preview Manual.

1. Purpose of Submission:
   New Submission (Response to Deficiency Report)

2. Name and Address of Third Party:
   (b)(4)

FDA CDRH DMC
FEB 24 2010
Received

3. Name and Address of Manufacturer:
   Optiscan Pty Ltd.
   15-17 Normanby Road
   Notting Hill, Victoria 3168
   Australia

4. Trade Name: **Optiscan Confocal Endoscopic Imaging System (CEIS), Model: Optiscan CEIS**
5. Common Name: **Confocal Endoscopic Imaging System**
6. Classification Name: **Endoscope and Accessories**
7. Classification No.: 21 CFR 876.1500 (Code: GCJ & KOG)
8. SE Recommendation:
   (b)(4) is recommending that the **Optiscan Confocal Endoscopic Imaging System (CEIS), Model: Optiscan CEIS** is Substantially Equivalent (SE) to the legally marketed device ISC-1000 Pentax Confocal Laser System (K042740).

K2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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9. Date documents were received:
   Original Submission: 12-02-2008
   Additional documents (if applicable): 02-08-2010 (Response to FDA Deficiency Report)
10. Pre-Review documentation
    (See attachment 1)

11. Owner's letter authorizing (b)(4) [redacted] (b)(4) [redacted] to submit their 510(k) to FDA and discuss its content with FDA
    (See attachment 2)

12. Owner's 510(k) submission as reviewed by (b)(4) [redacted]
    (See attachment 3)

13. Personnel Qualification and Prevention of Conflict of Interest Criteria Statement: (b)(4) [redacted] will continue to meet the personnel qualification and prevention of conflict of interest criteria as reviewed by FDA.

14. True and accurate statement
    (b)(4) [redacted] certifies that the preview is based on the submitted 510(k), that it is true and accurate to the best of our knowledge, and it is understood that the submission of false information to the government is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q)

Primary Third Party Reviewer:

(b)(6) [redacted]

February 15, 2010
Date

Responsible Third Party Official (or Designee):

(b)(6) [redacted]

Title:
Division Manager, Medical Division

(b)(6) [redacted]

Tel: (b)(4) [redacted]
Fax: (b)(4) [redacted]
Email: (b)(4) [redacted]

Feb 19/2010
Date

Records processed under FOIA Request # 2015-7106; Release (b)(4)

510(k) Review Program
Response to FDA Deficiency Report [redacted]

Review Memorandum (K093624)

(b)(4) Report number: (b)(4) [redacted]

Response to Deficiency Report Review Memorandum for Traditional 510(k) Submission (K093624)

1.0 Submission / Administrative Information

510(k) Submitter:	**Optiscan Pty Ltd.**			
Common device name:	**Confocal Endoscopic Imaging System**			
Trade name:	**Optiscan Confocal Endoscopic Imaging System (CEIS), Model: Optiscan CEIS**			
Type of Submission:	Traditional			
Reason for the submission:	New Device Submission			
Classification:	21 CFR 876.1500			
Product Code:	GCJ			
Subsequent Product Code:	KOG			
Classification Name:	**Endoscope and Accessories**			
Legally Marketed Device(s):	**ISC-1000 Pentax Confocal laser System**			**K042740**
Truthful and Accuracy Cert:	Section#:	Appendix A	Page#:	1 page
510(k) Summary:	Section#:	Appendix D	Page#:	2 pages
510(k) Statement:	Section#:	N/A	Page#:	N/A
Indication for Use Statement:	Section#:	Appendix F	Page#:	1 page
Form FDA 3654	Section#:	Appendix M	Page#:	10 pages
Form FDA 3674	Section#:	Appendix O	Page#:	3 pages

2.0 Intended Use (Changed)

Per owner's submission the indication for use statement states, "The Optiscan Confocal Endoscopic Imaging System is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by legally marketed video endoscopes (equipped with a confocal laser imaging module), during endoscopic medical examination procedures. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations".

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-7106; Release

510(k) Review Program
Response to FDA Deficiency Report

Review Memorandum (K093624)

(b)(4) Report number (b)(4)

The Indications for Use Statement is consistent with the labeling in the owner's submission. The labeling sufficiently describe the device, its intended use and directions for its use as required by 21 CFR 807.87(e).
There is a warning statement on the User Manual (P/N: 001686 Rev. 7, page 8) that states, "Do not use the video images for diagnosis purpose".

The device is intended for prescriptions use per 21 CFR 801.109

3.0 FDA Deficiencies:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Releas

(b)(4) [redacted]

510(k) Review Program
Response to FDA Deficiency Report [redacted]

Review Memorandum (K093624)

(b)(4) Report number [redacted]

4.0 Reviewer's Analysis

The sponsor has response to the 2 FDA deficiencies and submitted revised documentation to back up their responses. The following changes have been made to the submission and reviewed by us:

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

510(k) Review Program
Response to FDA Deficiency Report

(b)(4) [redacted]

Review Memorandum (K093624)

[redacted] (b) Report number: (b)(4) [redacted]

(b)(4) [redacted]

Labeling review

The following information is included in various attachments of the submission:

- CEIS Owners Manual (Doc. (b)(4) [redacted], Rev. (b) [redacted]: Appendix I
- CEIS Operators Manual (Doc. #: (b)(4) [redacted], Rev. (b) [redacted]: Appendix I
- Device Labeling Specification (Doc. #(b) [redacted], Rev. (b) [redacted]: Appendix J
- Predicate Device Labeling Example: Appendix K

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-7106; Release (b)(4)

510(k) Review Program
Response to FDA Deficiency Report

Review Memorandum (K093624)

(b)(4) Report number: (b)(4)

5.0 Reviewer's Recommendation

The documents submitted allow for the decision that the Optiscan Confocal Endoscopic Imaging System (CEIS) is substantially equivalent to the legally marketed device, the ISC-1000 Pentax Confocal Laser System (K042740).

Based on my analysis of the Optiscan Pty. Ltd submission, I recommend that the device be determined substantially equivalent to the previously cleared devices.

Primary Third Party Reviewer:

(b)(6)

2/15/2010
Date

Responsible Third Party Official (or Designee): (b)(6)

Title: (b)(6) Medical Division

Tel: (b)(4)
Fax: (b)(4)
Email: (b)(4)

Feb/19/2010
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OptiScan Pty Ltd
ABN 15 080 668 764

27 January 2010

Mr [redacted] (b [redacted]
(b)(4) [redacted])

Re: 510(k) Submission – Optiscan Model Optiscan CEIS (K093624)

Dear Mr (b)(6) [redacted],

Based upon the questions and feedback that the FDA and (b)(4) [redacted] have provided through email correspondence, I have supplied you with a complete triplicate copy of the revised 510k application.

The following amendments have been made to the enclosed documentation,

(b)(4) [redacted]

(b)(4) [redacted]

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OptiScan Pty Ltd
ABN 18 050 658 764

(b)(4)

[redacted]

All other declarations have been signed with the date 27th January, 2010 to match the submission date.

I hope that the modifications are sufficient to allow for the successful completion of the project.

If you have any further queries please let me know.

Best Regards

Peter Pavlicek
Quality and Regulatory Affairs Manager

Optiscan Pty. Ltd.

(b)(4)

[redacted]

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OptiScan Pty Ltd
ABN 18 090 656 784

22 December 2009

Mr (b)(6) [redacted]
(b)(4) [redacted]

Re: 510(k) Submission – Optiscan Model Optiscan CEIS (K093624)

Dear Mr (b)(6) [redacted]

In response to the two questions raised by the FDA (Kejing Chen) in their letter dated 4th December, 2009 regarding the 510(k) application for the CEIS (K093624), we provide the following;

(b)(4) [redacted]

(b)(4) [redacted]

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OptiScan Pty Ltd
ABN 18 060 658 784

(b)(6)

[redacted]

(b)(6)

[redacted]

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OptiScan Pty Ltd
ABN 18 [illegible]

(b)(6)

[redacted]

Please advise and we will make the appropriate changes if required.

Yours Sincerely

Peter Pavlicek

Quality and Regulatory Affairs Manager

(b)(6)

[redacted]

(b)(6) (b)(4)
01/07/2010 08:00 AM

To (b)(6) (b)(4)
cc (b)(4)
bcc
Subject Re: Urgent - Optiscan! FDA 510(k) project

Dea(b)(6),

I will request 30 days additional time from FDA in order to be at the safe side.

Please confirm it with your client.

Thanks,

(b)(6)

(b)(6) (b)(4)

(b)(6) (b)(4)
01/06/2010 10:46 PM

To (b)(6) (b)(4)
cc (b)(6) (b)(4)
Subject Re: Urgent - Optiscan! FDA 510(k) project

Dear (b)(6)

Peter Pavlicek (Optiscan QA manager) will be on holiday from 11-15 Jan 2010 inc. Can he respond on the 19-22 Jan 2010 or does this exceed allowable time limits for the FDA?

A prompt response to this email would be appreciated by Peter.

Best regards

(b)

(b)(6) (b)(4)

(b)(6) (b)(4) (b)(4)
07/01/2010 09:04 AM

To (b)(6) (b)(4) (b)(4)
cc (b)(6) (b)(4)
Subject Re: Urgent - Optiscan! FDA 510(k) project

Dear (b)(6),

We reviewed the submitted documents and we consulted with the FDA reviewer as well. We need some additional clarification in the case of both questions.

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(b)(4)

[redacted]

Regards,

(b)(6)
Division Manager

[redacted] (b)
Medical Division

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(6))(4)

(b)(6) (b))(4)
12/23/2009 06:43 PM

To (b) e/(b)(4)
cc (b)(6) (b)(4)
Subject Re: Urgent - Optiscan! FDA 510(k) project

28

Dear (b)(6)

I forwarded the below document to the FDA reviewer.

Regards and merry Christmas.

(b)(6)

(b)(6) (b)(4)

(b)(6) (b)(4)
12/22/2009 05:05 PM

To (b)(6) (b)(4) (b)
cc [redacted], (b)(4) [redacted]
Subject Re: Urgent - Optiscan! FDA 510(k) project

Dear (b)(6)

Here are Optiscan's responses...

I have provided the raw Word document along with a signed pdf copy.

[attachment "K093624 - Response to FDA Questions.docx" deleted by (b)(6) /US/TUV]
[attachment "K093624 - Response to FDA Questions.pdf" deleted by (b)(6) i/US/TUV]

The originals will be available when I receive them in the post. Do you need the original letter?

Best regards

(b)

Dr (b)(6)
Project Manager
(b)(4)

Wishing you a merry Christmas and a prosperous new year!

This email message and any attachments is confidential and intended only for the use of an individual or entity named above and may contain information that is privileged, confidential or exempt from disclosure under applicable law. If you are not the intended recipient, you are notified that any dissemination, distribution or copying of this email is strictly prohibited. (b)(4) does not accept liability for any errors, omissions, corruption or virus in the contents of this message or any

attachments that arise as a result of e-mail transmission. If you have received this communication in error, please notify the sender immediately and delete the original message and its attachments immediately.

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(b)(6) (b)(4)
07/01/2010 09:04 AM

To (b)(6) (b)(4)
cc (b)(4)
Subject Re: Urgent - Optiscan! FDA 510(k) project

Dear (b)(6)

We reviewed the submitted documents and we consulted with the FDA reviewer as well. We need some additional clarification in the case of both questions.

(b)(4)

Regards,

(b)(6)
Division Manager

(b)(4)

Are You Ready for complying with the 2007/47/EC Directive Due on 3/21/2010 and effecting all the manufacturers certified under the 93/42EEC Medical Devices Directive?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sign up or call us at (b)(4) [redacted]
(b)(4) [redacted]

(b)(6) [redacted] (b)(4) [redacted]

(b)(6) [redacted] (b)(4) [redacted]
12/23/2009 06:43 PM

To (b)(6) [redacted] (b)(4) [redacted]
cc (b)(4) [redacted]
Subject Re: Urgent - Optiscan! FDA 510(k) project

Dear (b)(6) [redacted]

I forwarded the below document to the FDA reviewer.

Regards and merry Christmas.

(b)(6) [redacted]

(b)(6) [redacted] (b)(4) [redacted]

(b)(6) [redacted] (b)(4) [redacted]
12/22/2009 05:05 PM

To (b)(4) [redacted]
cc (b)(4) [redacted]
Subject Re: Urgent - Optiscan! FDA 510(k) project

Dear (b)(6) [redacted]

Here are Optiscan's responses...

I have provided the raw Word document along with a signed pdf copy.

[attachment "K093624 - Response to FDA Questions.docx" deleted by (b)(6) [redacted] (b)(4) [redacted]
[attachment "K093624 - Response to FDA Questions.pdf" deleted by (b)(6) [redacted] (b)(4) [redacted]

The originals will be available when I receive them in the post. Do you need the original letter?

Best regards

(b) [redacted]

Dr (b)(6) [redacted]
Project Manager
(b)(4) [redacted]

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(b)(4) [redacted]

Wishing you a merry Christmas and a prosperous new year!

This email message and any attachments is confidential and intended only for the use of an individual or entity named above and may contain information that is privileged, confidential or exempt from disclosure under applicable law. If you are not the intended recipient, you are notified that any dissemination, distribution or copying of this email is strictly prohibited. (b)(4) [redacted], does not accept liability for any errors, omissions, corruption or virus in the contents of this message or any attachments that arise as a result of e-mail transmission. If you have received this communication in error, please notify the sender immediately and delete the original message and its attachments immediately.

(b)(6) (b)(4)
02/10/2010 07:29 PM

To (b)(4)
cc (b)(4)
bcc
Subject Re: Urgent - Optiscan! FDA 510(k) project

History: This message has been replied to.

(b)(6)

I believe that Optiscan also sent a letter together with the submission which clarifies exactly the changes made. Please confirm you read this letter.

In any case here is the letter again. Please let me know if this is not clear. You shouldn't need to read the whole 510k again.

I don't think the client needs to be billed for reading the whole thing again.

510 (b)(4)

Best regards

(b)

(b)(6)
Project Manager

(b)(4)

This email message and any attachments is confidential and intended only for the use of an individual or entity named above and may contain information that is privileged, confidential or exempt from disclosure under applicable law. If you are not the intended recipient, you are notified that any dissemination, distribution or copying of this email is strictly prohibited. (. does not accept liability for any errors, omissions, corruption or virus in the contents of this message or any attachments that arise as a result of e-mail transmission. If you have received this communication in error, please notify the sender immediately and delete the original message and its attachments immediately.

(b)(6) (b)(4)

(b)(6) (b)(4)
11/02/2010 10:23 AM

To (b)(6) (b)(4) (b)
cc (b)(4)
Subject Re: Urgent - Optiscan! FDA 510(k) project

(b)(6)

We received the response submission from your client to the FDA deficiency. Going through the response I notice that the sponsor send us a full submission instead of documentation to the 2 FDA concerns. Also client needs to include in the submission a letter to address what have been change in the new submission compare to the old submission.

For me to review the complete submission without the letter of what have been change will take 5 days again. For now, I will put this project on hold until I get the letter from your client or we have to bill for the new review.

Regards

(b)(6)
Sr. Engineer/3rd Party FDA 510(k) Reviewer/Lead Auditor
(b)(4)

(b)(4)

(b)(6) (b)(4)

(b)(6) (b)(4)
01/07/2010 08:36 PM

To (b)(4)
cc (b)(4)
Subject Re: Urgent - Optiscan! FDA 510(k) project

(b)(6)

Client has also requested...

(b)(4) [redacted]

Best regards

(b) [redacted]

(b)(6) [redacted] (b)(4) [redacted]

(b)(6) [redacted] (b)(4) [redacted]
08/01/2010 12:00 AM

To (b)(4) [redacted]
cc [redacted], (b)(4) [redacted]
Subject Re: Urgent - Optiscan! FDA 510(k) project

Dear (b)(6) [redacted]

I will request 30 days additional time from FDA in order to be at the safe side.

Please confirm it with your client.

Thanks,

(b)(6) [redacted]

(b)(6) [redacted] (b)(4) [redacted]

(b)(6) [redacted] (b)(4) [redacted]
01/06/2010 10:46 PM

To (b)(4) [redacted]
cc [redacted], (b)(4) [redacted]
Subject Re: Urgent - Optiscan! FDA 510(k) project

Dear (b)(6) [redacted]

Peter Pavlicek (Optiscan QA manager) will be on holiday from 11-15 Jan 2010 inc. Can he respond on the 19-22 Jan 2010 or does this exceed allowable time limits for the FDA?

A prompt response to this email would be appreciated by Peter.

Best regards

(b) [redacted]

(b)(6) [redacted] (b)(4) [redacted]

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

27 January 2010

To whom it may concern,

Please find attached the "510(k) Notification" (21CFR 807.90(e)) for the Optiscan Confocal Endoscopic Imaging System (CEIS) Medical Device.

The submission includes required declarations which are provided in the main submission document. These include:

- Truthful and Accuracy Statement (See Appendix A)
- 510(k) Summary of Safety and Effectiveness (See Appendix D)
- Declaration of Conformity to Standard (See Appendix N)

Summary information about the submission is provided below for convenience.

Submitter Information:

Company Name:	Optiscan Pty Ltd
Address:	15-17 Normanby Road, Notting Hill, Victoria, 3168, AUSTRALIA
Telephone:	(+61 3) 95383333
Fax:	(+61 3) 9562 7742
Contact Person:	Mr Peter Pavlicek
E-Mail Address:	peterp@optiscan.com
FDA Establishment Registration No.:	3003562930
Date of Submission:	27 January, 2010

(b)(4)

[redacted]

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OptiScan Pty Ltd
ABN 18 000 658 784

Administrative Information:

CFR21 Section: 21CFR876.1500 **Product Code:** GCJ, KOG

Classification Panel: General & Plastic Surgery, Gastroenterology/Urology

Device Class: ☐ Class I ☑ Class II

Legally Marketed Comparison Device(s) – at least one legally marketed device must be listed:

1. Pentax Confocal Laser System K #: K042740
2. K #:

Common Device Name: Confocal Endoscopic Imaging System

Trade or Proprietary Device Name: Optiscan CEIS

Submission Type:

☐ Abbreviated

☑ Traditional

☐ Special

☑ Third Party Review

Reviewer: TUV RHEINLAND OF NORTH AMERICA, INC.

Purpose:

☑ New Device

☐ Change in

☐ Technology

☐ Design

☐ Material

☐ Manufacturing Process

☐ Other

(b)(4)

[redacted]

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OptiScan Pty Ltd
ABN 18 000 658 764

Design and Use of the Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)? [A]		✓
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?[A]		✓
Does the device contain components derived from a tissue or other biologic source?		✓
Is the device provided sterile?		✓
Is the device intended for single use?		✓
Is the device a reprocessed single use device?		✓
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		✓
Does the device contain a biologic?		✓
Does the device use software?	✓	
Does the submission include clinical information?		✓
Is the device implanted?		✓

[A] A device may be intended for both prescription and over-the-counter use. If so, the answer to both of these questions is yes.

Peter Pavlicek
Quality and Regulatory Affairs Manager

Optiscan Pty. Ltd.

(b)(4)

[redacted]

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
01/27/2010		

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☑ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☑ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☑ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

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

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Optiscan Pty. Ltd.	Establishment Registration Number *(if known)*: 3003562930		
Division Name *(if applicable)*:	Phone Number *(including area code)*: ( ) (+61 3) 95383333		
Street Address: 15-17 Normanby Road	FAX Number *(including area code)*: ( ) (+ 61 3) 9538 7742		
City: Notting Hill	State / Province: Victoria	ZIP/Postal Code: 3168	Country: Australia
Contact Name: Peter Pavlicek			
Contact Title: Quality & Regulatory Affairs Manager	Contact E-mail Address: peterp@optiscan.com		

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

Company / Institution Name:			
Division Name *(if applicable)*:	Phone Number *(including area code)*: ( )		
Street Address:	FAX Number *(including area code)*: ( )		
City:	State / Province:	ZIP/Postal Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

PSC Graphics: (301) 443-1090 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*
- ☐ Response to FDA correspondence:
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing
- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☑ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☐ Other Reason *(specify)*:

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SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GCJ	2	KOG	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K042740	1	ISC-1000 Pentax Confocal Laser	1	Pentax Medical Company
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Endoscope and Accessories (21CFR876.1500)

	Trade or Proprietary or Model Name for This Device		Model Number
1	Optiscan CEIS	1	Optiscan CEIS
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [ ] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
GCJ, KOG	21CFR876.1500	[ ] Class I [x] Class II [ ] Class III [ ] Unclassified

Classification Panel

General & Plastic Surgery, Gastroenterology/Urology

Indications *(from labeling)*

The Optiscan Confocal Endoscopic Imaging System (CEIS) is intended to be used for confocal endomicroscopy of human tissue. The CEIS, its monitor, and a suitable confocal endomicroscope probe can provide microscopic visualization of the surface and subsurface of various body organs and tissues during endoscopic medical examination procedures. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☑ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number	☑ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name: Optiscan Pty Ltd		Establishment Registration Number: 3003562930		
Division Name *(if applicable)*		Phone Number *(including area code)*: ( ) (+61 3) 95383333		
Street Address: 15-17 Normanby Road		FAX Number *(including area code)*: ( ) (+ 61 3) 9538 7742		
City: Notting Hill		State / Province: Victoria	ZIP/Postal Code: 3168	Country: Australia
Contact Name: Peter Pavlicek	Contact Title: Quality & Regulatory Manager		Contact E-mail Address: peterp@optiscan.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*: ( )		
Street Address		FAX Number *(including area code)*: ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*: ( )		
Street Address		FAX Number *(including area code)*: ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60825-1	IEC	Medical electrical equipment Part 1: General Requirements for Safety	1993+A1:1997 +A2:2001	
2	60601-1	IEC	Medical electrical equipment Part 1: General Requirements for Safety	1998+A1:1991 +A2:1995	
3	60601-1-1	IEC	Medical electrical equipment Part 1-1 - General requirements for safety - Safety requirements for medical electrical systems	2000	
4	60601-2-18	IEC	Medical electrical equipment Part 1-2: General Requirements for Safety - Electromagnetic Compatibility - Requirements and Tests	1996+A1:2000	
5	60601-1-2	IEC	Medical electrical equipment Part 1-2: General Requirements for Safety - Electromagnetic Compatibility - Requirements and Tests	2001	
6					
7					

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

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

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

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510(k) Submission

Optiscan Confocal Endoscopic Imaging System (CEIS)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix B: Quality System Information

Appendix C: Company Layout

Appendix D: 510(k) Summary of Safety and Effectiveness

Appendix E: Current CEIS Product Certifications

Appendix F: Indications for Use Statement

Appendix G: Declaration of Equivalence to the ISC-1000

Appendix H: Isolation Transformer Specification

Appendix I: Device User Instructions/Manuals

Appendix J: Device Labelling Specification

Appendix K: Predicate Device Labelling Examples

Appendix L: Software Release

Appendix M: Standards Data Report for 510(k)s

Appendix N: Declaration of Conformity to Standard

Appendix O: Requirements for Clinical Trials (Form 3674)

Appendix P: Manufacturing Flowcharts

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1 Submitter Information

1.1 Submitter/ Applicant:

Optiscan Pty. Ltd.
15-17 Normanby Road
Notting Hill, Victoria, 3168
Australia
Establishment Registration Number: 3003562930
Owner/Operator Number: 9044050
Phone: (+61 3) 95383333
Fax: (+ 61 3) 9538 7742
Website: http://www.optiscan.com

1.2 Contact Person:

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Quality and Regulatory Affairs Manager
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1.3 US Agent:

Grace Holland
Regulatory Specialists, Inc.
3722 Ave Sausalito
Irvine, CA 92606
United States of America
Phone: 949 262
Fax: 949 552
Email: grace@regulatoryspecialists.com

1.4 Premarket Notification Truthful and Accurate Statement:

The Premarket Notification Truthful and Accurate Statement is provided in Appendix A.

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2 Manufacturer Information

2.1 Manufacturer Details

Optiscan Pty. Ltd.
15-17 Normanby Road
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Australia
Establishment Registration Number: 3003562930
Owner/Operator Number: 9044050
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Email: peterp@optiscan.com

2.3 Manufacturer Quality System Details

Optiscan Pty Ltd is a quality certified company with ISO13485 certification. The current certifications for the company are listed below.

1. EN ISO 13485:2003 Certificate Registration Number SX 60014014 0001. Date of expiry: 1/3/2011, by TUV Rheinland.

This certificate is provided in Appendix B, along with a list of the Standard Operating Procedures of the Quality System.

2.4 Manufacturer Layout

A floor plan of Optiscan Pty Ltd is provided in Appendix C detailing the Production, inspection and despatch areas.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8148

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3 Device Registration Information

3.1 510(k) Summary of Safety and Effectiveness:

The 510(k) Summary of Safety and Effectiveness is provided in Appendix D.

3.2 Device Classification

Classification Name:	Endoscope Accessories
Classification Code:	GCJ, KOG
21 CFR Identification:	876.1500 Endoscope and Accessories
Common Name:	Pentax Confocal Laser System
Trade Name:	Optiscan CEIS
Establishment Operations:	Manufacturer

Table 1 –Device Classification details for the CEIS

3.2.1 Current Product Certifications

The CEIS has currently a CE Mark Certification and NRTL certification. The certificate is listed below and copies of the certifications are provided in Appendix E.

1. Annex II 93/42/EEC Certificate Number: (b)(4) [redacted] (b)(4) [redacted] with Date of Issue 2/3/2006
2. NRTL License. Certificate Number (b)(4) [redacted] Date of issue 7/10/2008.

3.3 Identification of Predicated Device(s)

1. Sponsor Name:	Pentax Medical Company
2. Product Description:	ISC-1000 Pentax Confocal Laser System
3. Product Classification Code:	GCJ, Laparoscope, general & plastic surgery KOG, Endoscope and/or accessories
4. Date of Substantial Equivalence:	10-19-2004
5. 510(k) Number:	K042740

Table 2 –Identification Details of the Predicate Device

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3.4 Performance Standard:

To the best of our knowledge, no performance standards have been established for the device classification. The following consensus standards apply to the product:

1. IEC 60825-1, Safety of Laser Products, Part 1- Equipment classification, requirements and user's guide
2. IEC 60601-1 Medical electrical equipment Part 1: General Requirements for Safety
3. IEC 60601-1-1 Medical electrical equipment Part 1-1 - General requirements for safety - Safety requirements for medical electrical systems
4. IEC 60601-1-2 Medical electrical equipment Part 1-2: General Requirements for Safety - Electromagnetic Compatibility - Requirements and Tests
5. IEC 60601-2-18 Medical electrical equipment Part 2-18: Particular Requirements for the safety of endoscopic equipment

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4 Intended Use and Comparisons/ Differences to Predicate(s)

4.1 Intended Use

The Confocal Endoscopic Imaging System (CEIS) is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by legally marketed video endoscopes (equipped with a confocal laser imaging module), during endoscopic medical examination procedures. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

4.2 Indications for Use Statement

The Indications for Use Statement is provided in Appendix F.

4.3 Substantial Equivalence Discussion

4.3.1 Criteria for Predicated Device(s) Selection

The Criterion used to demonstrate Substantial Equivalence are listed below.

- Intend Use
- Materials
- Manufacture
- Performance Specifications

4.3.2 Similarities between the Submission and Predicate Device(s)

Optiscan acts as the OEM manufacturer of the Confocal Imaging System (also known as the ISC-1000) which is the Predicate device listed:

- Both devices are intended to allow confocal laser imaging of human tissue during endoscopic medical examination procedures.
- The device components and the suppliers that supply those components for ISC-1000 are identical to those that are used within the CEIS.
- The manufacturing processes and tests that are used to determine conformance of the ISC-1000 are identical to those that are used within the CEIS. An outline of these are provided in Appendix I.
- The processing of information collected by the device and the resultant output are identical.

A declaration of equivalence of the Optiscan Confocal Endoscopic Imaging System (CEIS) to the Confocal Imagng System (also known as the ISC-1000) is provided in Appendix G. The ISC-1000 and the CEIS are essentially identical in performance and construction except for the differences as outlined below in Section 3.2.3

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4.3.3 Differences between the Submission and Predicate Device(s)

Differences between the predicate devices and the submission device are described below:

- the labels that are applied to the above named Products differ only in respect of the Manufacturer's Names, the European Representatives and the Product Names and Model Numbers. The CEIS Device Labeling Specification is provided in Appendix J and, examples of the predicate device labeling are provided in Appendix K.

- A software script that provides the logos within the software has been added to the system to provide the Optiscan Logo rather than the ISC-1000 logo.

- The manuals supplied to the end user have been modified to be specific to Optiscan and the CEIS rather than Pentax and the ISC-1000. Copies of the two CEIS Manuals are provided in Appendix I.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4.4.4 Summary Table of Predicate Device Substantial Equivalence

	Predicate Device (ISC-1000)	Submitted Device (CEIS)
Intended Use	• Is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by the endoscope. • Is intended to be used with the Pentax EC-3870CILK Video Endoscope • Is Intended to be applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations	• Is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by the endoscope. • Is intended to be used with any suitable confocal endomicroscope probe. This includes the Pentax EC-3870CILK Video Endoscope • The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.
Materials	The materials used to manufacture the ISC-1000 and the CEIS are identical apart from the • device labelling • user instructions	
Manufacture	The Manufacturing of the ISC-1000 and the CEIS utilise the same Work Instructions and In Process test specifications to ensure conformance. All actions are performed at Optiscan Pty Ltd.	
Performance Specifications Confocal Laser Scanning	**ISC-1000 with scope EC-3870CILK**	**CEIS with scope EC-3870CILK**
Wavelength:	488 nm ± 2 nm	488 nm ± 2 nm
Scanner Maximum Optical Output Power:	1 mw @ 488 nm	1 mw @ 488 nm
Transverse modes:	M^2 <1.1, TEMoo	M^2 <1.1, TEMoo
Field of View (minimum):	500 x 500 µm	500 x 500 µm
Depth Range (minimum):	0 – 200 µm	0 – 200 µm
Confocal Axis Response:	8 µm	8 µm
Confocal Lateral Response:	1 µm	1 µm
Scan Modes:	2	2
Scan Mode 1 resolution/ Frame Rate (/sec):	1024 x 1024 / 0.7	1024 x 1024 / 0.7
Scan Mode 2 resolution/ Frame Rate (/sec):	1024 x 512/ 1.2	1024 x 512/ 1.2

Table 4 –Summary Table of Predicate Device Substantial Equivalence

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5 Device Description

5.1 Principle of Operation:

In the Optiscan CEIS, light from a laser is launched into an optical fibre which is used for both illumination and detection. The fibre is attached to a scanning mechanism in the distal end of a compatible endoscope. The scanning mechanism within this endoscope scans a low power focussed point of laser light over the field of view in the translucent specimen. On emerging from fibre tip in the scanning mechanism, the light is focussed to a point within the specimen. Only light returning from the focal plane within the specimen is collected back at the fibre tip to be transmitted back into the Optiscan CEIS system.

In the CEIS system, the returning light is detected by an optical detector in the Optical Unit (CEIS-OU) and converted into an electrical signal. A computer in the Control Unit (CEIS-CU) digitises the signal and position information from the scanner, and then processes and displays the resulting information as a 2 dimensional real time image on the confocal monitor.

Once a suitable image is identified from the real time screen image it may be captured by operating a foot switch or a button displayed on the touch screen of the confocal monitor. Each captured image is stored on the hard disc of the CU1000 for later review. Each image may have information associated with it including patient details and image property information.

The main user interface is via a touch screen on the confocal monitor. Navigation between screens is achieved by operating buttons on the touch screen or by operation of the touch-pad that is located on the keyboard of the CEIS-CU.

The focal plane within the specimen that the image is collected from can be varied by the user by adjusting the position of a lens in the tip of a compatible endoscope. This is done by actuating control buttons on the control body of the endoscope. The maximum depth of optical sectioning depends on the wavelength of light used and the translucency of the object.

The design of the distal end of the endoscope enables immobilisation of the tip in relation to the tissue by wet surface contact (very gentle surface pressure) so that the two move together and thereby allows clear images to be collected.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The CEIS can be used in either reflectance or fluorescence mode. Reflectance mode uses reflected light when imaging cellular structures and relies on the differences in the reflectivity of structures in order to differentiate between them. In fluorescence mode, fluorescence emitted by the tissue or exogenously applied fluorophores may be detected to provide contrast in the structures being investigated. A specific light source, at the appropriate wavelength, is used to illuminate the tissue structure or fluorophore distribution and the emitted fluorescence signal is measured at a longer wavelength. In the CEIS the illumination wavelength is 488nm (blue). The illumination power used is in the order of hundreds of microwatts of optical power and the maximum illumination power used is 1mW. The illumination source is a solid state laser. The CEIS does not have any patient contact components or surfaces.

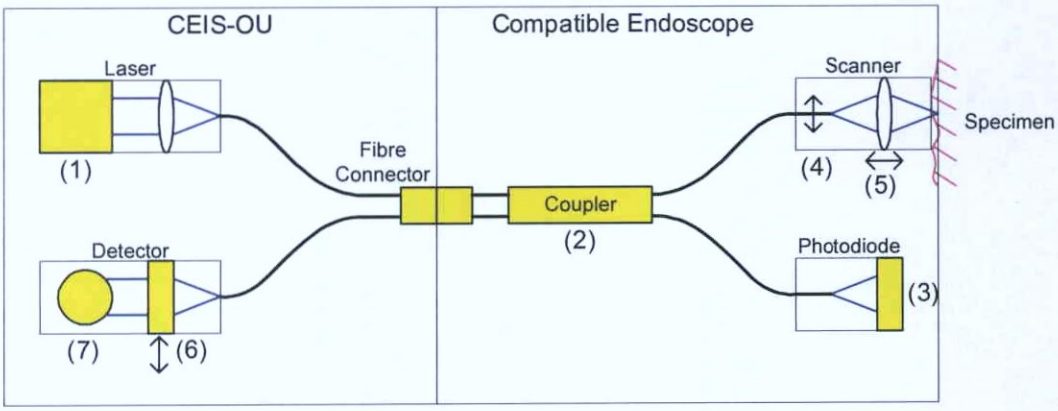

Figure 3 – Optical Schematic

Description of Figure:

1. A laser generates the illumination signal.
2. A fibre optic coupler is used to separate the illumination and detection signals.
3. A photodiode in the endoscope is used to determine the amount of illumination power being emitted by the scanner.
4. The scanning mechanism moves the illumination beam laterally across the specimen.
5. The objective lens in the scanner moves to vary the imaging depth within the specimen.
6. A filter in the detection unit is used to select fluorescence mode or reflectance mode.
7. A photo multiplier tube (PMT) is used to detect the intensity of the optical signal returning from the specimen.

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A typical example of a resultant image is shown below.

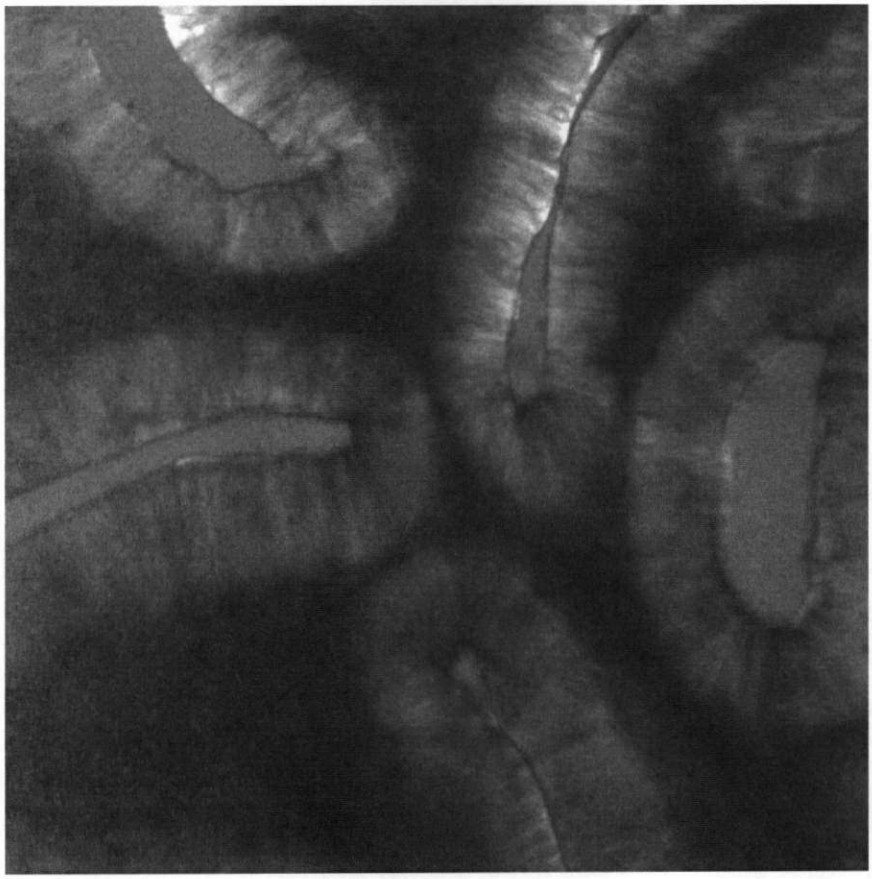

Figure 4 – A Typical Endoscopic Image of a polyp in the colonic mucosa. Image courtesy Professor Finlay Macrae, Cabrini Hospital, Melbourne, Australia.

The CEIS at present can only be used in the following applications using the Compatible Confocal endomicroscopes as indicated in the table below. Where a compatible endomicroscopes also utilises other standard endoscope functions that requires other processing equipment, these have also been indicated.

Application	Compatible Confocal Endomicroscopes	Compatible Digital Video Processor
Gastro Intestinal Examination	EC-3870CILK (PENTAX) EC-3870CIFK (PENTAX) EC-3870CIMK (PENTAX) EG-3770CIK (PENTAX)	EPK-1000 (PENTAX)

Table 5 –List of Compatible Applications and Endoscopes that can be used with the CEIS

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5.2 Components:

The Confocal Endomicroscopy Imaging System (CEIS) consists of three main units.

1. The Control Unit (CEIS-CU) together with its monitor, keyboard, and footswitch, is a computer based unit which performs the instrument control, and image capture and processing functions of the CEIS.
2. The Optical Unit (CEIS-OU) a specialised endomicroscope interface unit which performs the laser illumination and fluorescence detection functions of the CEIS.
3. The Isolation Transformer.

The overall block diagram of the CEIS is shown in the following figure. The block diagram shown also indicates the isolation barriers in the system.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Figure 5 – Overall Block Diagram of the CEIS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Software Information

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(b)(4) Software Information

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

(b)(4) Software Information

[redacted]

5.2.3 The Isolation Transformer

The Isolation Transformer is a Non-Proprietary Accessory which is used to provide electrical isolation to IEC 60601-1 safety standard for the CCB1.5 system. It is a Class I, Type B equipment with CE certification (CE003).

Refer to Appendix H for a complete specification as provided by the manufacturer of the Transformer.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8918

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6 Device Instructions

Details of the device labelling of the Optiscan Confocal Endoscopic Imaging System (CEIS) is provided in Appendix I.

7 Device Labelling

Details of the device labelling of the Optiscan Confocal Endoscopic Imaging System (CEIS) is provided in Appendix J.

Examples of the predicate device labelling have been provided in Appendix K.

8 Promotional Material

At present there is no promotional material that has been developed for the Optiscan Confocal Endoscopic Imaging System (CEIS).

9 Sterilization and Shelf Life

The Optiscan Confocal Endoscopic Imaging System (CEIS) is NOT labelled or sold as a sterile device and there are no Components that have a limited shelf life.

10 Biocompatibility

There are no Components of the Optiscan Confocal Endoscopic Imaging System (CEIS) that come into direct or indirect contact with patients and as a result no biocompatibility of materials is required.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

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11.2 Software Level of Concern:

In accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for software Contained in Medical device" Dated May 11, 2005,

We believe the level of Concern is **Minor** as any failures or latent design flaws are unlikely to cause any injury to the patient or operator. The Justifications are listed below.

- The function of the software is solely to control the scanning mechanisms of the device, and acquire the resulting scanned images (through interaction with a connected and compatible PENTAX Confocal Endoscope) and present these images (in a raw format absent of any post processing) to the end user via a monitor. The interaction with the connected endoscope is through laser power (of which the software can adjust) which by design cannot deliver an output greater than 3.5mw. This limit is controlled independently of the software, and as a result the software cannot cause any direct injury.

- With regard to potential misdiagnosis or delay of treatment (indirect injury), Optiscan have been explicitly clear that the device is an adjunct only to normal endoscopy (ie) providing additional information to an endoscopist, and is not to be used for diagnostic purposes (Please see the warning under the intended Use section 2.2 of the user manual 001686). A brief explanation of the typical workflow is attached

  The CEIS when attached to a compatible confocal endomicroscope provides confocal imaging capability over and above the normal video endoscope features as called upon in routine endoscopy. The confocal image is provided separately from the primary endoscopic view.

  The primary endoscopic view is used to guide the endoscopy including insertion, anatomical navigation, selection of sites of interest and positioning for biopsy or other minor surgical interventions conducted using accessories introduced via the working channel of the scope. It should be noted that none of these functions are dependent on confocal imaging to be performed as in routine endoscopic procedures where a confocal imaging capability is absent.

  The scope insertion part of the procedure does not usually involve any confocal imaging and certainly does not require it. Once fully inserted, the macroscopic (video) image produced by the endoscope is used for close examination of areas of interest within the anatomical tract. Any site may be selected for biopsy or other intervention based purely on this macroscopic view, and the confocal imaging capability may not be called upon at all.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Alternatively, areas of interest or randomly placed sites may be interrogated with the confocal imaging capability as an adjunct to the conventional visualisation. This provides high magnification images revealing fine structure not visible with the macroscopic view of the instrument. This has the possibility to unmask additional features of interest for documenting the in vivo microscopic appearance of the tissue (including in the case that biopsies would not be indicated, thereby providing additional information that would be absent from a typical endoscopy record from such a site) or in the case that exceptional structures are noticed at a given site, may give additional cause for suspicion leading to biopsy sampling (if already indicated within the course of the endoscopic procedure and considered safe to do so based on conventional endoscopy considerations) of that specific region. If the confocal capability is not called upon, the other features of the scope are used as per routine endoscopic examination as performed using an endoscope that does not have confocal imaging capability.

In the event that there are technical problems obtaining desirable confocal images (e.g. excessive movement artefacts; difficulty apposing tissue with imaging window; opaque residues/stool/food on surface of tissue; confocal imaging failure) the endoscopy would proceed as with a conventional endoscope not enabled with confocal imaging capability.

This would mean that there has been negligible delay in normal patient care and treatment suggesting there is a that there is a very low risk of indirect injury suggesting that the software should be a minor level of concern. To mitigate against possible malfunction of the device we deliberately included a pre test as per the user manual (document 001686 section 5.3) to check that the instrument is functioning and producing a acceptable image prior to it being used in any clinical procedure.

- The software is not intended to provide any function in the failure of which could result in any foreseeable injury to a patient or end user.

- The device and its software does not qualify as a Blood Establishment Computer Software.

- The device and its software is not intended to be used in combination with a drug or biologic outside the normal prescribed drugs provided in Surgical applications

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- The device and its software is not an accessory to any medical device that has software with a Major or Moderate Level of Concern

- The device and its software does not provide life supporting or life sustaining functions.

- The device provides a radiating laser energy to the soft tissue being scanned, however he inherit design would not allow the laser output at the probe of 3.5mw and in addition the system contains a Laser Safety Shut-off circuit independent of the software that trips at ≈3.5 mW, this is well below the Class 3R maximum power level 5 mW (IEC 60825).

- The device and its software does not provide any control of delivery or treatment

- The device and its software does not provide any diagnostic information that directly drives a decision regarding treatment or therapy

- The device and its software does not provide and monitoring of vital signs or alarms for any potentially life threatening situations where a medical intervention would be required.

- Any latent design flaw within the device that would cause a malfunction during the use of the device cannot cause any minor injury. The failure of the device would result in the device being unable to be used during a procedure and would provide inconvenience to the end user only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11.3 Software Hazards Analysis:

The hazard analysis to follow is prepared using the following definitions and criteria for Risk Level Assessment:

Table 6 - Probability of Occurrence	
Rating	**Description**
1	Improbable- possible but highly unlikely
2	Remote- possible but not normally expected
3	Occasional- expected as an infrequent occurrence
4	Probable- expected as a normal occurrence
5	Frequent- certain to occur most of the time

Table 7 - Severity of Harm	
Rating	**Description**
1	Negligible- little or no potential for injury
2	Marginal- has the potential to cause minor injury
3	Critical- has the potential to cause serious injury or death

Note: Serious injury = loss of body part, permanent impairment to a body function, or the need for medical intervention to preclude the loss of a body part or permanent impairment to a body function.

Table 8 – Risk Levels	
Level	**Description**
Minor	No other mitigation measures required
Moderate	Mitigation is recommended where it is possible to do so
Major	Mitigation is required to reduce the risk level of concern

Table 9 – Risk Level Calculation	
Probability*Severity	**Risk**
≤5	Minor
6 - 8	Moderate
≥9	Major

Table 10 – Risk Level Lookup			
Probability	**Severity**		
	1 - Negligible	2 - Marginal	3 - Critical
1 – Improbable	Minor	Minor	Minor
2 – Remote	Minor	Minor	Moderate
3 – Occasional	Minor	Moderate	Major
4 - Probable	Minor	Moderate	Major
5 - Frequent	Minor	Major	Major

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Figure 10 – System Block Diagram of Modules Evaluated under Hazards Analysis

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

(b)(4) Software Functional Requirements and Traceability Matrix

(b)(4) Software Functional Requirements and Traceability Matrix

(b)(4) Software Functional Requirements and Traceability Matrix

(b)(4) Software Functional Requirements and Traceability Matrix

(b)(4) Software Functional Requirements and Traceability Matrix

(b)(4) Software Functional Requirements and Traceability Matrix

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12 Electromagnetic Compatibility and Electrical Safety

The unit testing was performed in accordance with the requirements as identified in the standards and the results demonstrated that the pre-determined acceptance testing criteria were met. These reports are held on file at Optiscan Pty Ltd.

The CEIS System was tested to the following standards.

- IEC 60601-1:1988+A1:1991 + A2:1995
- IEC 60601-1-1:2000
- IEC 60601-1-2: 2001
- IEC 60601-2-18: 1996 + A1:2000
- IEC 60825-1:1993 + A1:1997 + A2:2001

Standards Data Report forms (FDA 3654) for each of the listed standards above are provided in Appendix M

A Declaration of Conformity to Standard is provided in Appendix N.

Safety Standards

IEC60601-1:1998 +A1 :1991 + A2:1995
IEC 60601-1-1:2000
IEC 60601-2-18:1996 +A1:2000
IEC 60825-1:1993 + A1:1997 + A2:2001

The CEIS system is physically and functionally equivalent to the ISC-1000 system. The ISC-1000 system was tested to the above standard(s) by (b)(4) with the US national deviations.

Test Report for Electrical Safety report Number: (b)(4).

The system complied with the standard without any performance deviations. No alternative test methods were selected during the compliance testing apart from the test methods described within the standard.
The equipment under submission

- is a class 1 equipment with respect toelectrical safety.
- Has one BF applied part
- Not suitable for use in the presence of flammable mixtures.
- Not an AP and APG equipment
- Intended for Continuous Operation

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- Not permanently installed equipment
- No medical gas connections
- Does not contain any carrying handles or grips
- Does not contain any patient support or immobilisation system
- Does not contain any external/accessible moving parts
- Does not contain any suspended masses
- Does not contain any pressurized parts or pressure vessels
- Does not contain any other batteries except for the small lithium battery in the control unit.
- Does not contain multiple socket outlet

All the clauses and sub-clauses that are applicable to the device with the above characteristics have been applied and the device was evaluated accordingly against the standard set criteria.

Electromagnetic Compatibility

IEC60601-1-2:2001

The ISC-1000 system was tested for compliance with the above standard with the following classification:

- Group 1 Class B for radiated and conducted emissions (CISPR 11)
- Class A for harmonic emissions (IEC 61000-3-2)

The system was tested by (b)(4) [redacted] for the above standard and found to be compliant. Test Report for Electromagnetic Compatibility report Number: (b)(4) [redacted].

All the clauses and sub-clauses that are applicable to the device with the above characteristics have been applied and the device was evaluated accordingly against the standard set criteria.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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13 Performance Testing - Bench

No Performance Testing (Bench) results have been submitted to support Substantial Equivalence.

14 Performance Testing - Animal

No Performance Testing (Animal) results have been submitted to support Substantial Equivalence.

15 Performance Testing - Clinical

No Performance Testing (Clinical) results have been submitted to support Substantial Equivalence.

A certificate of Compliance for Requirements for Clinical Trials (FDA Form 3674) has been attached and is provided in Appendix O

16 Manufacturing

Detailed manufacturing Work Instructions describing the assembly and testing of the CEIS is on file and held at Optiscan.

Flowcharts of the manufacturing steps in producing the Optiscan Confocal Endoscopic Imaging System (CEIS) are provided in Appendix P.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 9-

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Appendix A:

Premarket Notification Truthful And Accurate Statement

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Premarket Notification Truthful And Accurate Statement
(As required by 21 CFR 807.87(j))

I certify that, in my capacity as Regulatory Affairs Manager of Optiscan Pty Ltd that I believe to the best of my knowledge, that all data and information submitted in the premarket notification, attached, are truthful and accurate and that no material fact has been omitted.

27th January, 2010

Peter Pavlicek
Quality and Regulatory Affairs Manager
Optiscan Pty Ltd.

Date

Device: CEIS, Optiscan Confocal Laser System
510(k) Premarket Notification Number (Assigned by FDA):

_____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix B:

Quality System Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) [redacted]

Certificate

The Certification Body of

(b)(4) [redacted]

hereby certifies that the organization

Optiscan Pty. Ltd.
15-17 Normanby Road
Notting Hill Victoria 3168
Australia

has established and applies a quality management system for medical devices for the following scope:

Design, Development, Manufacture and Servicing of Rigid and Flexible Confocal Endoscopic Imaging Systems

Proof has been furnished that the requirements specified in

EN ISO 13485:2003

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: (b)(4) [redacted]

An audit was performed. Report No.: (b)(4) [redacted]

This Certificate is valid until: 2011-03-01 (b)(4) [redacted]

(b)(4) [redacted]

Figure - Optiscan ISO13485:2003 Quality System Certificate

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Policies and Standard Operating Procedures

(b)(4) Policies and Standard Operating Procedures

(b)(4) Policies and Standard Operating Procedures

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Appendix C:

Company Layout

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix D:

510(k) Summary of Safety and Effectiveness

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K093624 (1) of (2)

510(k) Summary of Safety and Effectiveness
Optiscan Confocal Endoscopic Imaging System

Submitter Information:

Optiscan Pty Ltd
15-17 Normanby Rd,
Notting Hill, Victoria, 3168
Australia
Tel: (+61 3) 9538 3333
Fax: (+61 3) 9562 7742

Date Summary Prepared: 27 January 2010

Name of Device:

Trade Name:	Optiscan CEIS
Classification Name	Endoscope and Accessories (21CFR876.1500)
Product Code	GCJ, KOG

Predicated Device(s) Information:

Model, Description	Manufacturer	PMN #
Pentax Confocal Laser System	Pentax	K042740

Device Description:

The Optiscan Confocal Endoscopic Imaging System (CEIS) is a software controlled device which is intended for use as a required accessory with a legally marketed and compatible video endoscope system that is equipped with confocal imaging module.

The Confocal Endomicroscopy Imaging System (CEIS) consists of three main units.

1. The Control Unit (CEIS-CU) together with its monitor, keyboard, and footswitch, is a computer based unit which performs the instrument control, and image capture and processing functions of the CEIS.
2. The Optical Unit (CEIS-OU) a specialised endomicroscope interface unit which performs the laser illumination and fluorescence detection functions of the CEIS.
3. The Isolation Transformer.

A video endoscope equipped with a confocal imaging module is connected to the CEIS-OU. Under control by the endoscopist, the CEIS-OU transmits visible laser light into the connected endoscope. The endoscope transmits this light to and then subsequently receives return light signals from the subject tissue. The returned light is detected by the CEIS-OU and converted into an electrical signal. The detected signal is sent to the System Computer (CEIS-CU) which processes the confocal image information for display on the system monitor, and allows still images of the tissue to be captured and stored.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Intended Use:
The Confocal Endoscopic Imaging System (CEIS) is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by legally marketed video endoscopes (equipped with a confocal laser imaging module), during endoscopic medical examination procedures. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

Comparison to Predicated Device(s):
The submission for substantial equivalence included Optiscan Confocal Endoscopic Imaging System (CEIS) literature including intended use and specifications. Comparison tables were provided to illustrate the comparisons to the predicated devices for intended use, technical specifications and materials. The submission for substantial equivalence was not based on an assessment of clinical performance data.

Conclusion:
Because the Optiscan Confocal Endoscopic Imaging System (CEIS) possesses the same or similar intended use, indications, and technological characteristics as the identified predicate device, with no additional questions of safety or effectiveness, the company submits that the device can be found to be substantially equivalent.

Prepared By:

Peter Pavlicek
Quality and Regulatory Affairs Manager

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix E:

Current CEIS Product Certifications

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

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Appendix F:

Indications for Use Statement

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K093624

Indications for Use

510(k) Number (if known):

Device Name: Optiscan CEIS

Indications for Use:

The Confocal Endoscopic Imaging System (CEIS) is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by legally marketed video endoscopes (equipped with a confocal laser imaging module), during endoscopic medical examination procedures. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix G:

Declaration of Equivalence to the ISC-1000

The following documents have been attached to the submission in this section:

- 002188 CEIS Declaration of Equivalence to ISC-1000

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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OptiScan

DECLARATION OF EQUIVALENCE

Council Directive 93/42/EEC on Medical Devices

We;

Optiscan Pty Ltd
15 to 17 Normanby Rd
Notting Hill
Victoria 3168
AUSTRALIA
Telephone: +61 (0)3 9538 3333
Fax: +61 (0)3 9562 7742

Declare that the Product Name:

Confocal Endoscopic Imaging System and related accessories, which is the medical device listed under an Optiscan Pty Ltd Declaration of Conformance, signed 27 January 2010, pursuant to the provisions of Council Directive 93/42/EEC (MDD)

is identical with the Product Name:

Confocal Imaging System, which is the medical device listed under a Pentax Corporation Declaration of Conformity, signed 26 October 2004, pursuant to the provisions of Council Directive 93/42 EEC (MDD)

which is manufactured at the premises of Optiscan Pty Ltd and supplied to Pentax Corporation, with the exception that:

- the labels that are applied to the above named Products differ only in respect of the Manufacturer's Names, the European Representatives and the Product Names and Model Numbers.

Signed this day 27th of January 2010

Peter Pavlicek
Regulatory Manager
Optiscan Pty Ltd

(b)(4) [redacted]

© Optiscan Pty Ltd

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8418

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Appendix H:

Isolation Transformer Specification

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

INSTALLATION AND OPERATING INSTRUCTIONS
OF THE INTERNATIONAL ISOBOX SERIES ISOLATION TRANSFORMERS.

Before installing and/or using this product, please check for any visual damage of the enclosure, power cord and plug. If any damage is observed, do not use this product. Contact Toroid Corporation of Maryland or its authorized agent for instructions to return the product for repair or replacement.

The ISOBOX Series Isolation transformers are intended for applications where medical devices require improved electrical isolation and/or reduced leakage current to comply with existing safety standards. With the ISOBOX connected between the device(s) and the wall outlet, the leakage current and the electrical isolation of the installed device will be that of the ISOBOX. (See data on following pages).

DANGER: Risk for explosion exists if used in the presence of flammable anesthetics, or other flammable gases or liquids.

CAUTION: Grounding continuity should be checked periodically

CAUTION: To reduce the risk of electrical shock, do not open enclosure. There are no serviceable parts inside. Refer service to Toroid Corporation of Maryland or its authorized agent only. Do not expose this equipment to rain or moisture.

NOTE: USA and Canada, Grounding reliability can only be achieved when this equipment is connected to a matching receptacle marked "Hospital Only", or, "Hospital Grade".

CAUTION: This product requires convection cooling. Adequate ventilation is therefore required. When installing this product, a minimum clearance of 2" should be provided to all sides, except mounting surface.

EXPLANATION OF GRAPHICS SYMBOLS

The exclamation point with an equilateral triangle is intended to alert the users to the presence of important operating and maintenance (servicing) instructions in the literature accompanying the product.

This apparatus is a Type B equipment.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

(b)(4)

[redacted]

TRANSPORT CONDITIONS:
Do not expose to temperatures below -30 Degr.C (-22F) or above 70 Degr.C (158F).
Do not expose this apparatus to relative humidity in excess of 95% RH (non-condensing).

MOUNTING INSTRUCTIONS:
For high traffic areas, carts and unstable surfaces, it is recommended to use the provided mounting brackets. For wall mounting, use appropriate wall anchors unless fastened into wall stud(s) or other forms of reinforcement available to support the weight of the enclosure. Appropriate air clearance for ventilation of ISOBOX is required (see CAUTION paragraph on previous page).

OPERATING INSTRUCTIONS:
This isolation transformer has eight (8) voltage combinations. To achieve the desired voltage in and out, please refer to this table

Input voltage provided (VAC 50/60Hz)	Power entry module setting	Output desired (VAC)	Output voltage selector setting
100	100	115-125	115
115-120	120	115-125	115
220	220	115-125	115
230-240	240	115-125	115
100	100	230-240	230
115-120	120	230-240	230
220	220	230-240	230
230-240	240	230-240	230

The correct fuse value must be used with the selected input voltage.
SERIOUS DAMAGE AND INJURY MAY RESULT IF INCORRECT INPUT AND OR OUTPUT VOLTAGES ARE SELECTED. VERIFY ISOBOX SELECTED INPUT AND OUTPUT VOLTAGES, AS WELL AS, WALL OUTLET SUPPLIED AND EQUIPMENT VOLTAGES.

Recommended initial installation procedure:
1. Verify power switch on the ISOBOX is in the OFF (0) position.
2. In Canada and USA, when connecting the ISOBOX to the wall outlet, plug only into a Hospital Grade Wall Outlet to ensure reliable grounding. Connect ISOBOX to Wall outlet.
3. Verify equipment to be connected to the ISOBOX is turned OFF (0).
4. Connect the devices to the receptacles of the ISOBOX.
5. Turn ON (1) the power switch of the ISOBOX.
6. The devices connected to the ISOBOX are now ready to be turned ON (1) and operated.

Note power cord requirements on next page.

The total power consumption equals the sum of all devices connected to the ISOBOX. The total power consumption must not exceed the maximum power rating of the ISOBOX, as shown on the product rating label or table below.

To reduce inrush currents, the M series employs a thermistor. After turning off the IsoBox unit it is recommended to let the ISO-BOX "cool down" for approximately 1 minute. There may otherwise be a risk of blowing a fuse in the power entry module or possibly tripping the wall outlet circuit breaker.

For power cord retention clip and clamp installation, please refer to separate instruction sheet.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

(b)(4)

[redacted]

ISOBOX SPECIFICATIONS.

All ISOBOX models listed in this document are intended for 100 or 115-120 or 220 or 230-240 VAC and 50/60Hz input frequency. DO NOT USE OTHER VOLTAGES OR FREQUENCIES. See previous paragraph for voltage selector settings on the ISOBOX and Datasheets mechanical data.

Model No.	Output voltage (Vac, 50/60 Hz)	Output current (Amps)	Output Power * (VA)	Leakage current 132V Nom/Max **	Leakage current 264V Nom/Max **	Regulation % ***
ISB-030M	115-120/230-240	2.50/1.25	300	50/100	50/100	6.8
ISB-060M	115-120/230-240	5.00/2.50	600	50/100	50/100	5.0
ISB-100M	115-120/230-240	8.33/4.17	1000	50/100	50/100	3.2

* Maximum total output power of the ISOBOX, whether one or more outlets are used.

** Nominal leakage current is measured at normal use and in no fault condition. Maximum leakage current is measured as Non-Patient connected, with reversed polarity and under single fault condition.

This transformer is a Class I, Type B equipment.

POWER CORD REQUIREMENTS:

Input: All power cords must be appropriately approved by testing agency for the country where the ISOBOX is installed, such as UL/CSA/VDE/SEMKO/<HAR> etc. For the US and Canadian Market, a HOSPITAL GRADE Plug is required.

The cord must have one end suitable for the wall receptacle and the other end must be of appliance type, IEC-320 female plug. All power cords must have grounding contacts.

	Minimum wire Diameter	Length Recommended
ISB-030M	AWG 18 (0.75mm^2)	12 ft or less
ISB-060M	AWG 18 (0.75mm^2)	12 ft or less
ISB-100M	AWG 16 (1.00mm^2)	12 ft or less

FUSE REQUIREMENTS:

These ISOBOX transformers have been tested, approved and deemed to be safe under certain conditions. The fuse in the power entry module is protecting the ISOBOX from overloads and short circuits. If the incorrect fuse is used, there may be danger to operator(s) or patient(s), or damage to equipment. Fuses must be UL and CSA approved and marked for North American use and VDE/EN approved and marked for European use. Use only SLOW BLOW type (T-type) fuse rated 250V. We also recommend the fuses to be ceramic bodied.

Model	Input Setting:	100V	120V	220V	240V
ISB-030M	Fuse rating:	4.0AT	3.15 AT	1.6 AT	1.6 AT
ISB-060M		8.0AT	6.3 AT	3.15 AT	3.15 AT
ISB-100M		12.5AT	10.0 AT	5.0 AT	5.0 AT

DO NOT USE FUSES WITH HIGHER AMP RATING THAN THOSE LISTED ABOVE.

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[redacted]

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[redacted]

TROUBLE SHOOTING:
DO NOT ATTEMPT TO REPAIR. WARRANTY WILL BE VOID IF UN-AUTHORIZED REPAIR WORK HAS BEEN CARRIED OUT.

No output power:

1. Verify that the ISOBOX is connected and that the power switch is ON (I).
2. Verify fuses in power entry module (disconnect ISOBOX from Power first)
3. Use another wall outlet.
4. Check wall outlet circuit breaker.
5. If you have any other problems with the ISOBOX, please call Toroid Corporation of Maryland, from US/CAN: 800-274-5793 other; 410-860-0300.

If you need to return the ISOBOX for any reason, call the factory for return instructions.

If you notice any Mechanical Damage: Call Toroid Corporation of Maryland for instructions.

LIMITED WARRANTY:
The ISOBOX series enclosed isolation transformers are backed by Toroid Corporation of Maryland's 36 month warranty. For complete information, please refer to the warranty card enclosed with this package.

SAFETY AGENCY LISTINGS:

Listee	Cert./Rep.No's	Standards	Markings
ITS Report No:	3021409_US/CAN	UL2601-1	ETL
	3021409_US/CAN	CSA C22.2 No. 601.1	cETL
SEMKO Certificate:	TDB	EN60601.1	S
CB Certificate No:	US/920/ITS	EN60601.1	-
CE mark Self Declared	CE003	Low Voltage Directive	CE

MECHANICAL DATA:
See Individual Data Sheets.

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Appendix I:

Device User Instructions/Manuals

The following documents have been attached to the submission in this section:

- 001686 CEIS Owners Manual
- 001685 CEIS Operators Manual

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User Instructions
CEIS Owners Manual

Document Number: 001686
Revision: 7
Release Date: 27/01/2010
Created from Template: Standard.Dotx

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Document Approval:

(b)(6)

Signature: [redacted] Date: 27th Jan 2010
Reviewer (

Signature: [redacted] Date: 27/1/2010
Approval (

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Revision History:

Revision	Modified	Release	Description
(b)(4)	(b)(6)	19/12/2005	Converted from 000421
		24/1/2007	CEIS Owner's manual Updated to reference to the ISC-1000 Owners Manual which includes a number of changes requested from Pentax
		15/1/2008	Update to correspond with the ISC-1000 Owners Manual 000421 revision 19. All references to the ISC-1000 specific references have been changed to their CEIS equivalents.
		17/11/2008	Amendment to Intended Use statement to remove the word prototype Fixed up some Mistaken references of ISC-1000 and CCB1.5 to CEIS Amended Section 3.2.2 to add NRTL Compliance Label
		2/3/2009	Converted to new template and added New Manual Cover Art. Added additional safety warnings in section "safety precautions" including connection of equipment non 60601 equipment and network connections. Change the Attention conventions to be consistent with the Operators Manual 001685. Moved the Intended Use Section to a more prominent position (See Section 2.2) and added additional warning and Contraindication and intended user section. Moved warnings, cautions and notes in section 3 from various tables into the text as per the attention conventions. Added warning in section 4.1.2 regarding connection of only approved endomicroscopes. Inclusion of a tables of Figures and Tables in the contents section. Inclusion of Document reference and revision on all pages.
		20/5/2009	Added symbols to section 1.2 Remove Declaration of Conformity from Last Page Updated the Technical Specifications with more detail Table 8 All Standards quoted have had the release date removed. Included where relevant standards citing both IEC and EN where applicable. Removed Section 4.1.2 as this was contradictory to other warnings within the manual. Added label to Footswitch Section 3.5 with IP explanation Added DIMDI Code to European Representative (Last page)
		27/1/2010	The Following Changes are in response to the FDA queries regarding 510k Submission. - Change Intended use Statement in Section 2.2 from to match the indications for Use (IFU) in the 510k Summary - Update Technical Specification Table in Section 8 to remove the LP505 Filter.

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OptiScan|CEIS

Confocal Endoscopic Imaging System

Owners Manual

Fluorescence In Vivo Endomicroscopy

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CE 0197

このCEマーキングはEC指令への適合宣言マークです。

The CE marking assures that this product complies with the requirements of the EC directive for safety.

Das CE Zeichen garantiert, daß dieses Produkt die in der EU eforderlichen Sicherheitsbestimmungen efüllt.

Le logo CE certifie que ce produit est conforme aux normes de sécurité prévues par la Commuunatuté Européenne.

Il marchio CE assicura che questo prodotto è conforme alle direttive CE alla sicurezza.

La marca CE asegura que este producto cumple todas las directivas de seguridad de la cE.

CE 标志意味着保证该类产品遵从欧洲共同体安全法规.

IMPORTANT

Read this manual before operating and retain this book for future reference.

This manual describes the recommended procedures for inspecting and preparing the CEIS system prior to its use and the care and maintenance after its use. It does not describe how to use the equipment or operate the software loaded on the system, nor does it attempt to teach the beginner proper techniques or any medical aspects regarding the use of the equipment. Do not use this equipment for any purpose other than that for which it has been designed.

If you have any questions regarding any information in this manual or concerns pertaining to the safety and/or use of this equipment, please contact your Optiscan representative.

CAUTION:

Federal (USA) law restricts this device to sale by, or on the order of, a physician or other appropriately licensed medical professional.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1 SAFETY PRECAUTIONS

The CEIS is **MEDICAL ELECTRICAL EQUIPMENT** as defined in IEC/EN 60601-1.

We would like to provide you with information about safety aspects which must be observed when handling this device, to ensure safety to all involved parties including patients and operators. This chapter contains a summary of the most important information concerning matters relevant to instrument safety.

Important safety information has been incorporated in this manual and is marked with a warning triangle accordingly. Please give this information your special attention. Attention conventions for this manual are provided below in Figure 1-1.

The correct use of the system is absolutely vital for safe operation. Please make yourself totally familiar with the contents of this manual prior to startup of the instrument. Please also observe the user manuals of any additional equipment. Further information is available from our service department or from authorized representatives.

- Please observe all applicable accident prevention regulations.

1.1 Attention Conventions

The following conventions have been established in the text of this manual to aid in the identification of important information.

Warning!
The **warning triangle** indicates potential sources of danger which may constitute a risk of injury for the user or a health hazard.

Caution:
The **square** indicates situations which may lead to malfunction, defects, collision or damage of the instrument.

Note:
The **hand** indicates hints on the use of the instrument or other tips for the user.

Figure 1-1 Attention Conventions

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1.2 Symbols and Markings

The following Symbols and Markings have been established in the text of this manual and also on the labelling provided with the device to aid in the identification of important information.

~	Alternating current
	This product emits laser radiation.
	Type BF applied part (Safety degree specified in IEC 60601-1)
	ON-OFF Power switch or indicator
	Attention
	Protective earth (ground)
	Equipotentiality
	Waste in Electrical and Electronic Equipment
EC REP	Authorised Representative in the European Community
	Manufacturer of the Device
	Manufacturing Date of the Device
SN	Device Serial Number

Figure 1-2 Symbols and Markings

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1.3 Laser Safety

The CEIS is a **CLASS 3R LASER PRODUCT** as defined in IEC/EN 68025-1

Warning!
LASER RADIATION is emitted from any connected endomicroscope.
- **DO NOT** stare into the beam or view directly with optical instruments.

Warning!
LASER RADIATION is generated inside the CEIS-OU.
- **DO NOT** operate the CEIS-OU with the cover removed.
- **DO NOT** operate the CEIS-OU with any optical fibres disconnected.
- **DO NOT** bypass or otherwise make inoperative the CEIS-OU Optical Connector interlock switch

Laser energy is coupled outside the CEIS-OU to the endomicroscope via the Optical Connector. The cover for the Optical Connector on the CEIS-OU is labelled with the labels shown in Figure 1-3

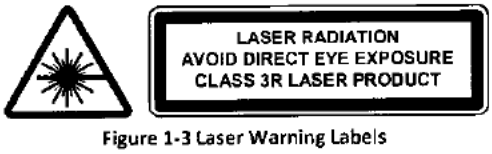

Figure 1-3 Laser Warning Labels

Laser operation and operating energy levels are controlled by the CEIS software applications. Procedures for using the software are covered in the Operator's Manual.

Warning!
Use of controls or adjustments or performance of procedures other than those specified in the Operator's Manual may result in hazardous radiation exposure.

1.4 Electrical & General Safety

The CEIS is **MEDICAL ELECTRICAL EQUIPMENT** as defined in IEC/EN 60601-1.
According to the degree of protection against electric shock as defined in IEC/EN 60601-1, the CEIS is Class One equipment. The CEIS has a fully isolated connection allowing the endomicroscope to be classified as a Type BF Applied Part. The CEIS is designed for continuous operation.

All parts of the CEIS system are suitable for use in the Patient Environment.
The CEIS is classified as IPX0 equipment in regard to the level of protection against the ingress of water. The CEIS Footswitch is rated at IP68.

Warning!
The CEIS is **NOT SUITABLE** for use in the presence of FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.
- **DO NOT** use in potentially flammable surroundings
- **DO NOT** splash or spray equipment with any liquid
- **DO NOT** expose equipment to dusty environments
- **DO NOT** operate the CEIS in an environment outside its operating limits as described in Table 8-1.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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There are no special sterilisation or disinfection requirements for the CEIS. See Section 6.2 of this manual for general equipment cleaning instructions.

Correct connection of the power for the CEIS system and accessories is very important for the safety of the patient and the operator.

Warning!
Connect the CEIS mains inlet power cord directly to a medical grade outlet ONLY.

- **DO NOT** connect the CEIS mains inlet power cord to a portable multiple socket outlet.
- **DO NOT** connect a portable multiple socket outlet or any extension cord to the CEIS Isolation Transformer.

Warning!
DO NOT connect the power cord for any component of the CEIS to any power outlet other than the CEIS Isolation Transformer as shown in Figure 4-1. ***Failure to comply with this instruction bypasses the electrical safety isolation provided by the Isolation Transformer causing seriously compromised electrical safety for the patient and the operator.***

Warning!
DO NOT connect any other external equipment to the CEIS system other than the approved equipment specified in this manual.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8418

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1.5 Electromagnetic Compatibility

The CEIS is **MEDICAL ELECTRICAL EQUIPMENT** as defined in IEC/EN 60601-1. Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility (EMC).

Warning!
Install and operate this equipment in strict accordance with the instructions contained in this Owner's Manual.
DO NOT take any actions that could compromise the EMC shielding of the equipment or the interconnecting cables.
DO NOT replace any supplied cable with any cable that is not a genuine replacement cable supplied by Optiscan. Use of non-genuine cables may result in increased emission levels and/or a decreased immunity to radiated fields

- Separate cables supplied for the CEIS by Optiscan are:
  - One interconnecting Control Data cable one metre long.
  - One interconnecting Control Signal cable one metre long.
  - One interconnecting Optical Signal cable one metre long.
  - Two interconnecting IEC C13 to C14 power cords with EMI suppression two metres long.
  - One interconnecting IEC C13 to C14 power cords without EMI suppression two metres long. Additional cables may be required based upon endoscope used.
  - One incoming mains supply plug to IEC C13 power cord two to three metres long.

Warning!
Mobile phones and other portable or mobile RF equipment can interfere with the operation of the equipment. **DO NOT** operate mobile phones and other portable or mobile RF equipment in close proximity to the equipment.

Warning!
The CEIS must not be operated stacked with or adjacent to any foreign equipment. **DO NOT** operate the CEIS stacked with or adjacent to equipment other than specified in Table 8-2

Guidance and Manufacturer's declaration – electromagnetic emissions		
The CEIS is intended for use in the electromagnetic environment specified below. The customer or the user of the CEIS should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The CEIS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The CEIS is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 1-1 Guidance and Manufacturer's declaration – electromagnetic emissions

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Guidance and Manufacturer's declaration – electromagnetic immunity

The CEIS is intended for use in the electromagnetic environment specified below. The customer or the user of the CEIS should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95% dip in UT) for 0,5 cycle 40 % UT (60% dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles <5 % UT (>95% dip in UT) for 5 seconds	Complies Complies Complies Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CEIS requires continued operation during power mains interruptions, it is recommended that the CEIS be powered from an uninterruptible power supply or battery.
Power Frequency (50-60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
			Portable and mobile RF communications equipment should be used no closer to any part of the CEIS system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 kHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 Mhz to 800 MHz
			$d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 U_T is the a.c. mains voltage prior to application of the test level

NOTE 2 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 3 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CEIS system is used exceeds the applicable RF compliance level above, the CEIS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CEIS.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 1-2 Guidance and Manufacturer's declaration – electromagnetic immunity

Recommended separation distances between portable and mobile RF communications equipment and the CEIS

The CEIS is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CEIS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CEIS as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0,01	0,12 m	0,12 m	0,23 m
0,1	0,38 m	0,38 m	0,73 m
1	1,2 m	1,2 m	2,3 m
10	3,8 m	3,8 m	7,3 m
100	12 m	12 m	23 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 1-3 Recommended separation distances

1.6 Protective Measures for IT Systems and Networks

The user (or IT officer) is responsible for ensuring that no viruses are transferred to the CEIS system via the network connection. It is the user's responsibility to ensure that the media used for data communication (CD, USB stick) are free from viruses.

Responsibilities for data protection and information security

The user (or IT officer) must ensure that the national laws and regulations relating to data protection are complied with.

The operators of IT systems and IT networks are responsible for the definition of the safety standards required, i.e. for the creation of the necessary technical and organizational framework.

Definition of terms

- Personal data means any information concerning the personal or material circumstances of an identified or identifiable individual. All data directly attributable to a person (employee, customer, supplier), e.g. marital status, type of employment, religion, income, etc., must be protected.
- Data processing means the storage (entry, recording or preservation), transfer (transmission to third parties outside the organization), modification (alteration of the substance, including anonymization and aliasing), erasure (deletion) and blocking (labelling so as to restrict further processing or use) of data.
- Use means any utilization of data (e.g. in-house transmission).
- Recipient means any person or body receiving data. Third party means any person or body other than the controller (legal entity). The transmission of data to third parties is deemed to constitute data transfer.

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2 CONFOCAL ENDOSCOPIC IMAGING SYSTEM

2.1 Introduction

The instrument described in this manual is designed for use by trained personnel only. This manual should be read thoroughly before using the CEIS.
Failure to read this manual thoroughly and understand the contents of the manual may result in injury to the patient and/or user. It is essential to follow the instructions in this and other manuals which pertain to any equipment or accessories used in conjunction with the CEIS. Failure to follow these instructions may also result in damage to and/or malfunction of the CEIS.
There are no user serviceable parts inside the CEIS. Adjustment, maintenance and repair of the CEIS should only be conducted by qualified and authorised personnel.

2.2 Intended Use

The Confocal Endoscopic Imaging System (CEIS) is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by legally marketed video endoscopes (equipped with a confocal laser imaging module), during endoscopic medical examination procedures. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

The CEIS is indicated for use as an aid or adjunct to a mode of therapy or diagnosis.

Warning!
DO NOT use the video images for diagnostic purposes, as the resulting images and the monitor have not been calibrated. The visualized images may therefore include deviations in shape, contrast and colour.

2.2.1 Contraindications

None Known.

2.2.2 Intended User(s)

The system must only be operated by physicians, nurses and other medically trained OR staff who have received appropriate briefing and observe the instructions of the user's manual. The installation conditions and the use of the system must meet surgical requirements:

- low vibration
- dust-free environment
- level, horizontal positioning
- avoidance of extreme mechanical stress.

Caution:
Federal (USA) law restricts this device to sale by, or on the order of, a physician or other appropriately licensed medical professional.

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2.3 System Overview

The Confocal Endomicroscopy Imaging System (CEIS) consists of three main units.

1. The Control Unit (CEIS-CU) incorporating a monitor, keyboard and footswitch.
2. The Optical Unit (CEIS-OU).
3. The Isolation Transformer.

The CEIS is always installed and operated in conjunction with a Confocal Endomicroscope and Video Processor. The full equipment set may be installed on an optional Trolley system. Refer to Table 8-2 for approved and compatible devices.

The Confocal Endomicroscope connects into the CEIS-OU, and contains a fully integrated fluorescence confocal microscope. This microscope provides high magnification, sub-cellular resolution images at and below the surface in living tissue.

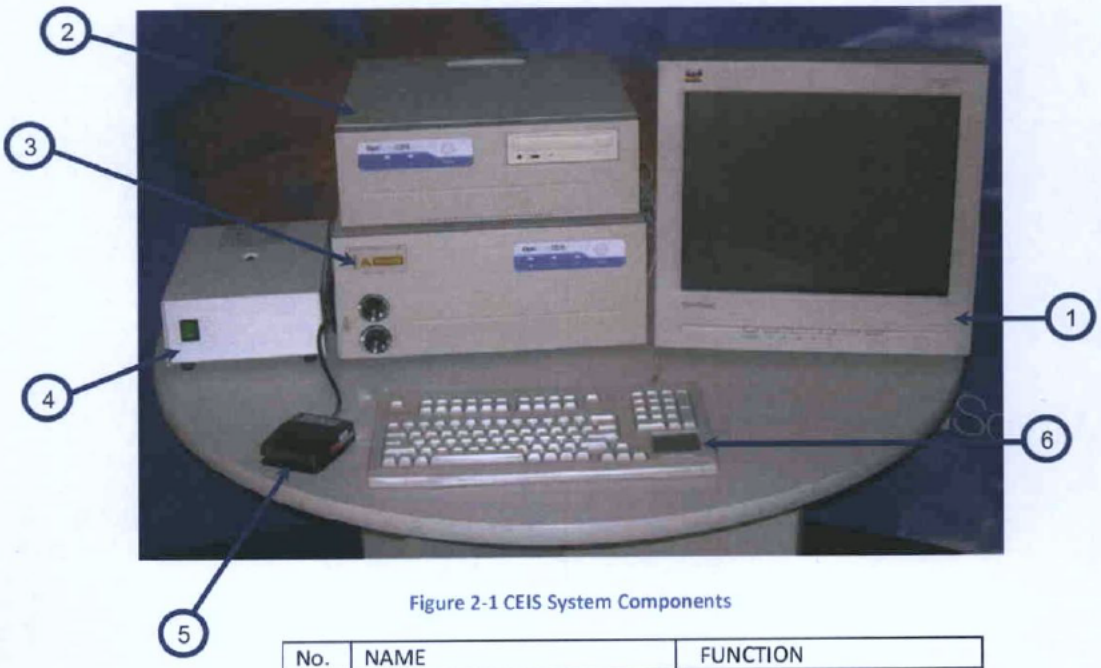

Figure 2-1 CEIS System Components

No.	NAME	FUNCTION
1.	CEIS Monitor	Refer to Section 3.3
2.	CEIS-CU	Refer to Section 3.1
3.	CEIS-OU	Refer to Section 3.2
4.	Isolation Transformer	Refer to Section 3.6
5.	Footswitch Control	Refer to Section 3.5
6.	Keyboard	Refer to Section 3.4

2.3.1 Control Unit (CEIS-CU)

The Control Unit (CEIS-CU) together with its monitor, keyboard, and footswitch, is a computer based unit which performs the instrument control, and image capture and processing functions of the CEIS.

2.3.2 Optical Unit (CEIS-OU)

The Optical Unit (CEIS-OU) is a specialised endomicroscope interface unit which performs the laser illumination and fluorescence detection functions of the CEIS.

2.3.3 Isolation Transformer

The Isolation Transformer is a mandatory safety component of the CEIS System which supplies power to all components of the CEIS System.

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Warning!
ALL components of the CEIS and approved accessories associated equipment electrically connected to the Endomicroscope, **MUST** be supplied from this Isolation Transformer.

2.4 Shipping Containers

Note:
It is recommended that you keep the instrument's shipping containers and packing materials. If you need to transport the instrument at a later time and have not retained the original packaging, you may be required to purchase replacement shipping containers.

2.4.1 Contents

The shipping components of the CEIS consists of 3 boxes containing the following items:

Box 1 – Control Unit (CEIS-CU), keyboard and cover, footswitch, manuals, cables, Operating System CD and licence.
Box 2 – Optical Unit (CEIS-OU)
Box 3 – Monitor, Isolation Transformer

2.4.2 Unpacking

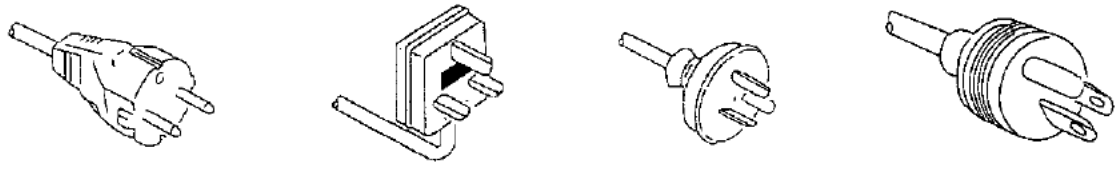
When unpacking the contents of the shipping containers each container should be checked to ensure that all items are present and that there is no obvious physical damage to any item. If any shortage or damage is detected contact your Optiscan representative as soon as possible.

Warning!
DO NOT connect or operate any damaged equipment.

Caution:
The following precautions should be observed when unpacking the equipment.

1. Ensure the equipment is never dropped or jarred when unpacking or setting up.
2. Ensure the screen of the monitor is never facing downward.
3. Check that the Isolation Transformer is set to the correct input and output voltages Figure 3-9 shows the location of the Input Voltage Selector. Figure 3-10 shows the location of the Output Voltage Selector. The voltage settings can be readily seen on both of these selectors without removing any covers. Ensure the enclosed mains input cord is the correct type.
4. Check the standard power plug configurations that are used in your country. If the appropriate power cord is not included in your product, notify your local Optiscan distributor.

Figure 2-2 shows the power plug types supplied for each country or region.



Continental Europe (Use a SEV approved plug for Switzerland) | U.K | Australia and New Zealand | U.S.A. and Canada (Hospital Grade)

Figure 2-2 Power Cord Plug Types

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3 NOMENCLATURE, CONTROLS AND FUNCTIONS

3.1 Control Unit

3.1.1 Front Panel

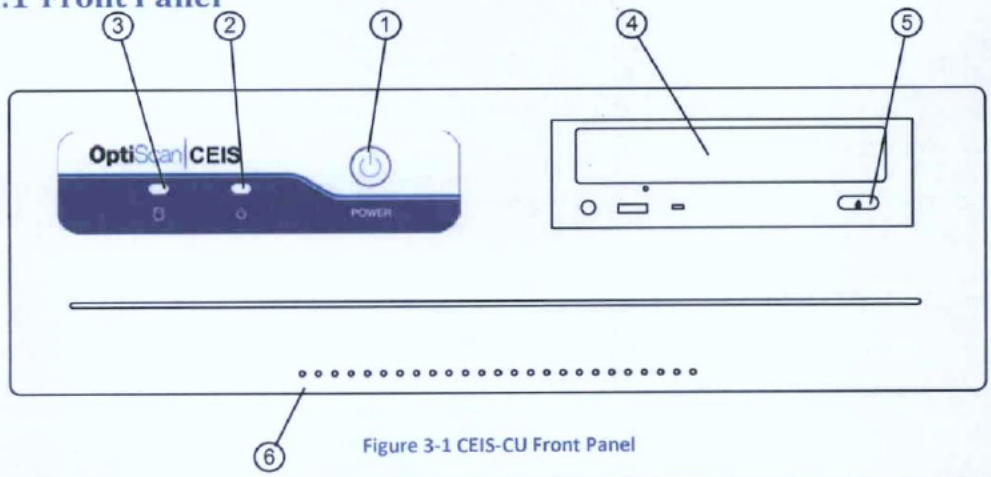

Figure 3-1 CEIS-CU Front Panel

No.	NAME	FUNCTION
1.	ON/OFF Button	Controls the power for both the CEIS-CU and the CEIS-OU. Press to turn on and press to turn off.
2.	ON/OFF Indicator	Indicates with a green light when power is on. The indicator lights when the power is turned on.
3.	Disk Indicator	Indicates with a green light when the disk is active. The indicator lights when the disk is active.
4.	CD/RW Drive	Drive unit for the reading and writing of Compact Disks.
5.	CD/RW Open/Shut Button	Opens and closes the CD/RW Drive. Press to open and press to close.
6.	Ventilation Holes	Allows adequate ventilation and cooling for the CEIS-CU.

Note:
For normal operation, press the ON/OFF Button to turn on. When turning the equipment off, use the "shutdown" control from the Start menu in the CEIS-CU. The ON/OFF Button should only be used to turn the equipment off in the case of a system malfunction or emergency. The Button should be operated with a finger and should not be hit or operated with any hard or sharp object.

Caution:
DO NOT block any of the Ventilation Holes.

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3.1.2 Rear Panel

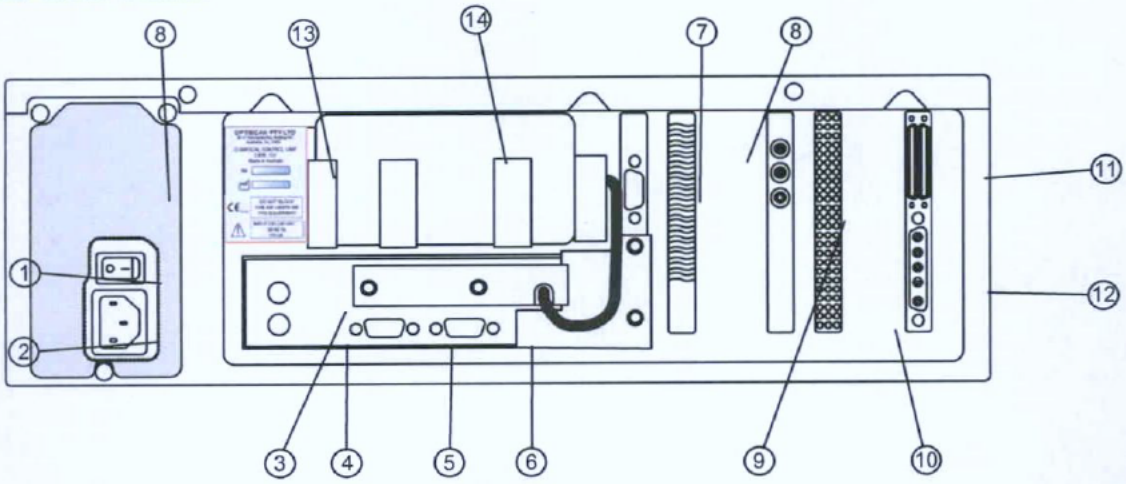

Figure 3-2 CEIS-CU Rear Panel

No.	NAME	FUNCTION
1.	Power Switch	Power isolating switch for the CEIS-CU. **I** is ON and **O** is OFF. This switch must be ON before the ON/OFF Button on the front panel will operate correctly.
2.	Power Cord Inlet	Receptacle for the power inlet cord from the Isolation Transformer.
3.	Mouse Socket	Socket for the Green Mouse Plug from the Keyboard.
4.	Keyboard Socket	Socket for the Purple Keyboard Plug from the Keyboard.
5.	Touch screen Connector	Socket for the Monitor Touch screen connector from the Monitor.
6.	Footswitch Connector	Socket for the Footswitch connector.
7.	Monitor Connector	Socket for Monitor connector.
8.	Ventilation Fan Grilles	Allows exit of forced ventilation and cooling for the CEIS-CU.
9.	Optical Signal Connector	Connector for the Optical Signal cable from the CEIS-OU.
10.	Ventilation Grille	Allows adequate ventilation and cooling of the CEIS-CU.
11.	Control Data Connector	Connector for the Control Data cable from the CEIS-OU.
12.	Control Signal Connector	Connector for the Control Signal cable from the CEIS-OU.
13.	Rating Plate	Displays unit model number, serial number and power requirements.
14.	Network Isolator	Network Isolation device with socket for 10/100 UTP network connection.

Warning!
The Power inlet cord **MUST** be connected to the Isolation Transformer **ONLY**.

Caution:
DO NOT obstruct the flow of air from any of the Ventilation grilles.

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3.2 Optical Unit

3.2.1 Front Panel

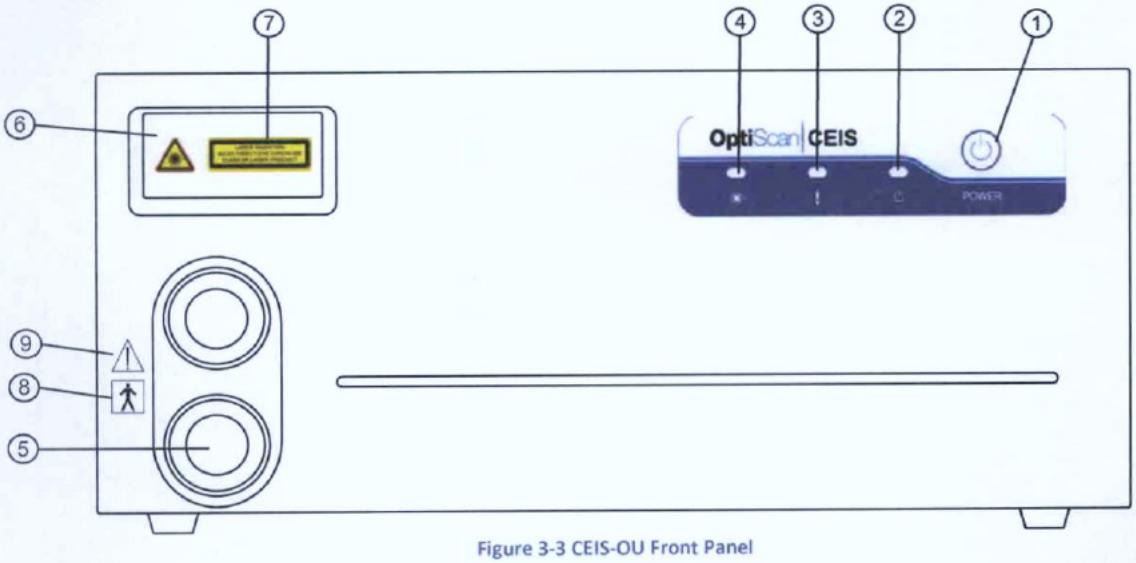

Figure 3-3 CEIS-OU Front Panel

No.	NAME	FUNCTION
1.	ON/OFF Button	Controls the power for both the CEIS-CU and the CEIS-OU. Press to turn on and press to turn off.
2.	ON/OFF Indicator	Indicates with a green light when power is on. The indicator lights when the power is turned on.
3.	Warning Indicator	Indicates with a yellow light when a problem exists. The indicator lights when a problem exists.
4.	Laser ON Indicator	Indicates with a blue light when the laser is on. The indicator lights when the laser is on.
5.	Endomicroscope Electrical Connector	Accepts the electrical connector from the Endomicroscope.
6.	Endomicroscope Optical Connector	Accepts the optical connector from the Endomicroscope. Open the cover door to access the connector.
7.	Laser Radiation Label	Label identifying that the product emits laser radiation and is a Class 3R laser product.
8.	Type BF Applied Part Label	Label identifying classification: Type BF applied part (Safety degree specified in IEC 60601-1)
9.	Warning Label	Label identifying: Attention, Consult owner's manual

<u>Note:</u>
For normal operation, press ON/OFF Button to turn on. When turning the equipment off, use the "shutdown" control from the Start menu in the CEIS-CU. The ON/OFF Button should only be used to turn the equipment off in the case of a system malfunction or emergency. The Button should be operated with a finger and should not be hit or operated with any hard or sharp object.

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3.2.2 Rear Panel

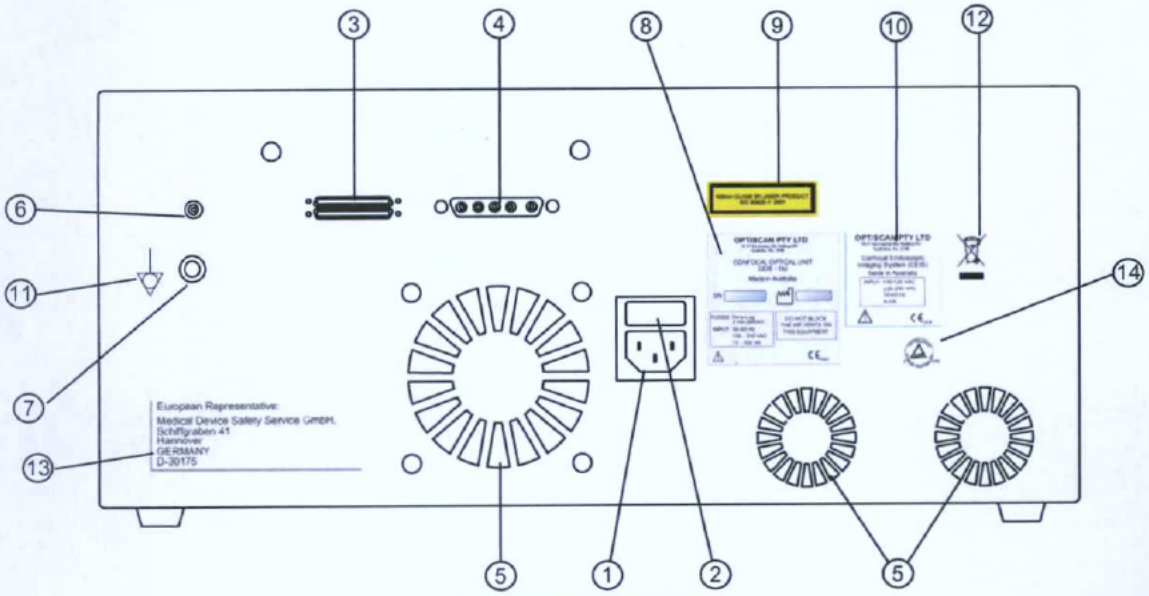

Figure 3-4 CEIS-OU Rear Panel

No.	NAME	FUNCTION
1.	Power Cord Inlet	Receptacle for the power inlet cord from the Isolation Transformer.
2.	Power Fuses	Drawer for the power fuses.
3.	Control Data Connector	Connector for the Control Data cable from the CEIS-CU.
4.	Control Signal Connector	Connector for the Control Signal cable from the CEIS-CU.
5.	Ventilation Fan Grilles	Allows exit of forced ventilation and cooling for the CEIS-OU.
6.	Optical Signal Connector	Connector for the Optical Signal cable from the CEIS-CU.
7.	Equipotential Connector	Connector for equipotentiality.
8.	Rating Plate	Displays unit model number, serial number and power requirements.
9.	Laser Class Label	Displays laser product class and wavelength
10.	System Label	Displays system power requirements.
11.	Equipotential Label	Label denoting a connector for equipotentiality.
12.	WEEE Label	Label denoting Waste in Electrical and Electronic Equipment
13.	European Representative Label	The Contact Name and address of the European Representative of the System (For use by EC Community Member Countries Only)
14.	NRTL Compliance Label	Label denoting Compliance to the Requirements of NRTL

Warning!
The Power inlet cord **MUST** be connected to the Isolation Transformer **ONLY**.

Warning!
Use only the correctly rated power fuses.

Caution:
Do not obstruct the flow of air from any of the Ventilation Fan Grilles.

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3.3 Monitor Display Screen

3.3.1 Front of Monitor

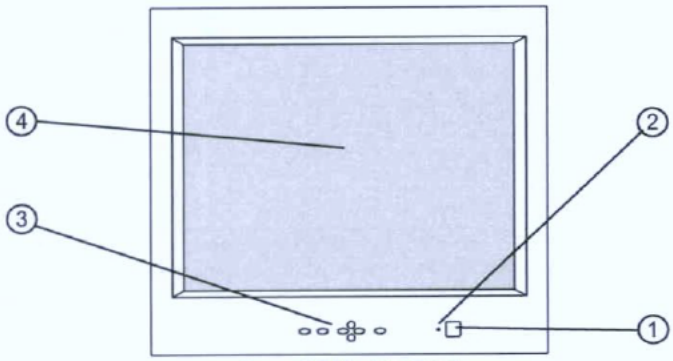

Figure 3-5 Monitor Front

No.	NAME	FUNCTION
1.	ON/OFF Switch	Turns the Monitor ON and OFF. Press for ON and press again for OFF.
2.	Power Indicator	Indicator lights when the power is ON.
3.	Adjustment Controls	Controls to adjust the characteristics of the screen image.
4.	Touch screen	Touch sensitive sensor over the whole screen area.

Caution:
To maintain the clarity of the front surface of the touch screen, keep it free of dirt, dust, fingerprints and other materials that could degrade optical properties. Long term contact with abrasive materials will scratch the front surface, decreasing image quality.
The touch screen may be cleaned or disinfected with non-abrasive agents such as, isopropyl alcohol or ethyl alcohol. We recommend that pre-soaked wipes or towelettes should be used to avoid applying excessive amounts of liquids.

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3.3.2 Rear of Monitor

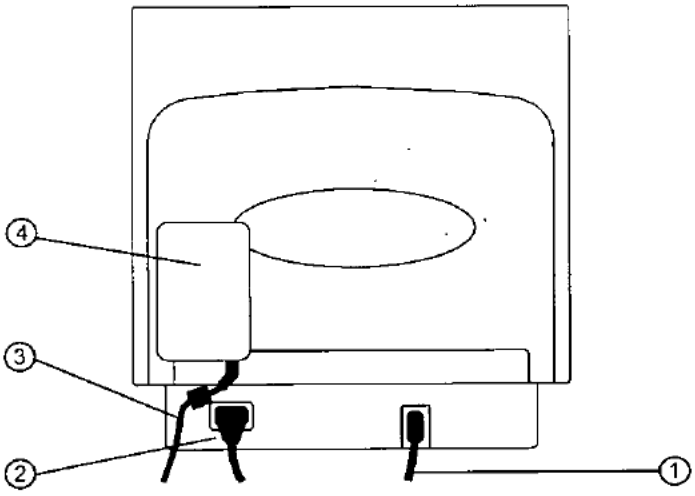

Figure 3-6 Monitor Rear

No.	NAME	FUNCTION
1.	Video Signal Cable	Cable that connects to the CEIS-CU Monitor Connector.
2.	Power Cord and Socket	Receptacle for the power inlet cord from the Isolation Transformer.
3.	Touch screen Cable	Cable that connects to the CEIS-CU Touch screen Connector.
4.	Touch screen Controller	Control unit for the touch screen.

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3.4 Keyboard

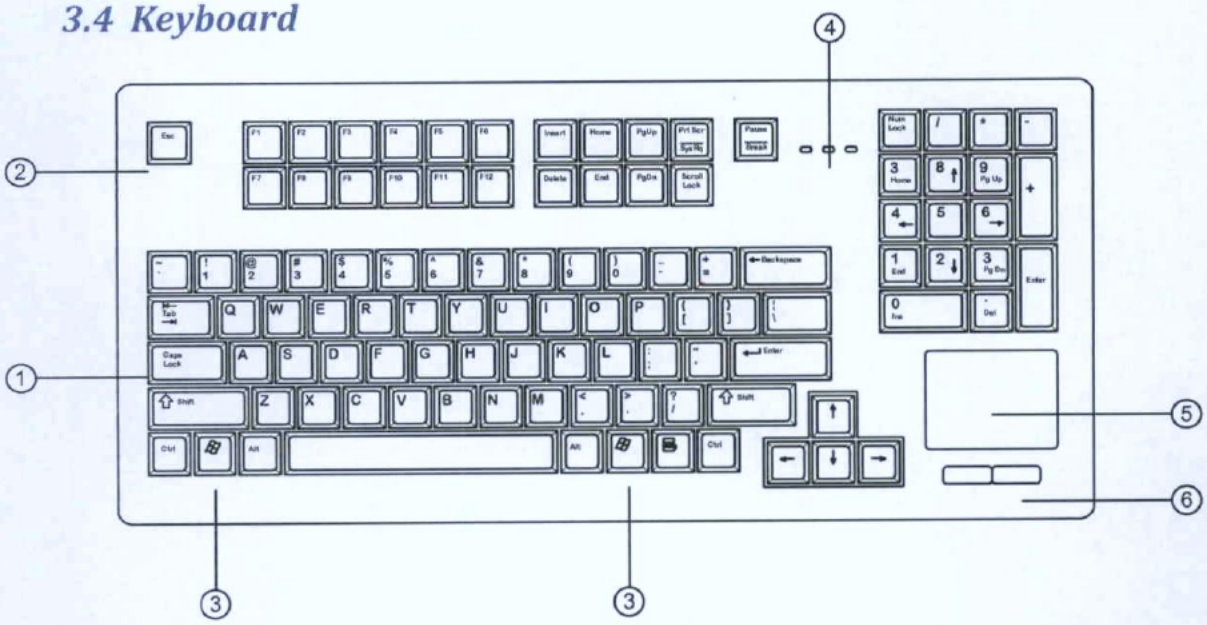

Figure 3-7 Keyboard

No.	NAME	FUNCTION
1.	QWERTY Keyboard	Standard QWERTY Layout Keyboard
2.	Escape key	Escape function key
3.	"Windows" keys	Microsoft Windows function keys
4.	Keyboard Status Indicators	Indicate status of Caps Lock, Num Lock and Scroll Lock functions
5.	Mouse Pad	Pressure sensitive mouse pad pointing device
6.	Mouse Buttons	Left and Right mouse buttons

3.5 Footswitch

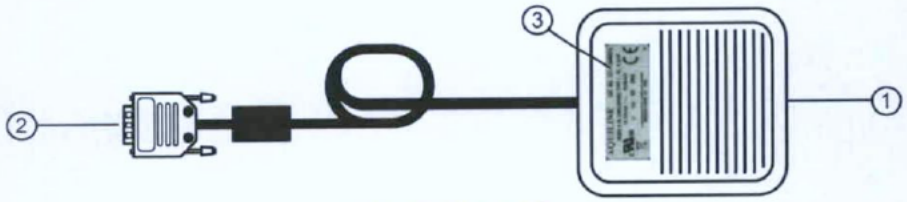

Figure 3-8 Footswitch

No.	NAME	FUNCTION
1.	Footswitch	Footswitch unit used to trigger image capture
2.	Footswitch Connector	Connector for connection to the CEIS-CU
3.	Footswitch Label	Contains the relevant Safety data and Ingress Protection Rating (IP68)

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3.6 Isolation Transformer

3.6.1 Front and Rear Panels

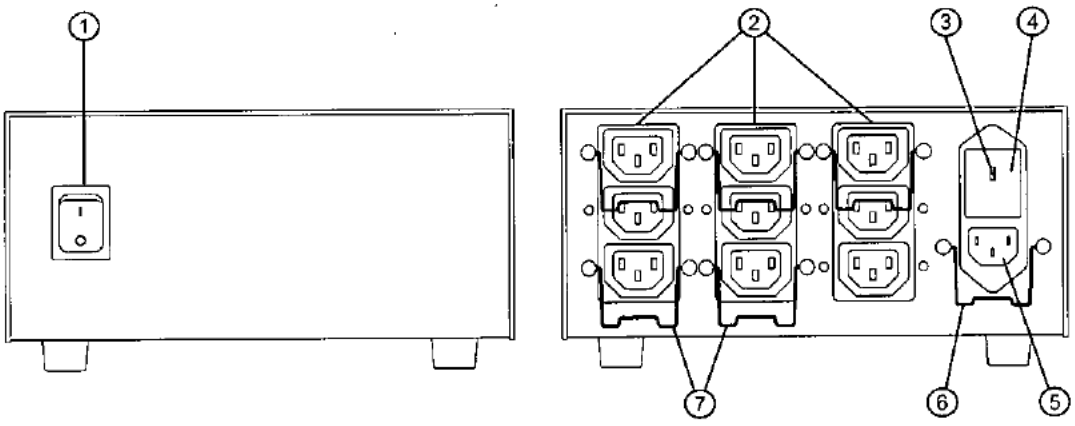

Figure 3-9 Isolation Transformer Front and Rear Panels

No.	NAME	FUNCTION
1.	ON/OFF Switch	Turns the system ON and OFF. Operate **I** for ON and **O** for OFF.
2.	System Cord Connectors	Connectors for power cords to the system equipment.
3.	Input Voltage Selector	Device to select the Isolation Transformer input (primary) voltage.
4.	Fuse and Selector Drawer	Drawer that contains the input fuses and the mains (input) voltage selector.
5.	Mains Cord Connector	Connector for the incoming mains cord.
6.	Mains Cord Clip	Clip to retain the incoming mains cord against accidental removal.
7.	System Cords Clips	Clips to retain the system equipment power cords against accidental removal.

Warning!
Use only the correctly rated fuses.

Warning!
All Power cords **MUST** be clipped.

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3.6.2 Base

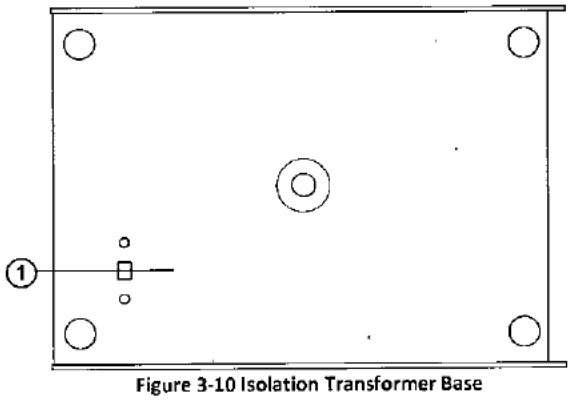

Figure 3-10 Isolation Transformer Base

No.	NAME	FUNCTION
1.	Output Voltage Selector	Switch to select the Isolation Transformer output (secondary) voltage.

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4 PREPARATION AND SAFETY CHECK

Warning!
The CEIS Control Unit and Optical Unit are medical electrical equipment incorporating delicate components and sophisticated circuitry that should not be subjected to harsh conditions, including strong vibrations or impact.

If the equipment is mishandled or dropped, **DO NOT** use it. Contact your Optiscan representative to arrange inspection.

4.1.1 Setting up the System

Note:
TO THE INSTALLER: The CEIS should be installed as described in this section to enable the user to achieve optimal use of the system.

Note:
If the CEIS and the associated Endomicroscope are to be used in a portable or moveable configuration then it is recommended that the components be installed onto a trolley system, so that the components can be securely mounted and transported without hindering the proper operation of the system. Refer to Table 8-2 for recommended trolley systems.

1. Place all equipment on a stable and level surface.
2. Place equipment in locations and positions that are suitable for convenient and safe operation.

Caution:

- **DO NOT** locate the CEIS Monitor and the Isolation Transformer directly adjacent to each other.
- **DO NOT** locate the Isolation Transformer on top of any other equipment.
- **DO NOT** install or use this equipment in areas where the unit could get wet or be exposed to adverse environmental conditions such as high temperature, humidity, direct sunlight, dust, salt, etc.
- **DO NOT** install or use this equipment in the presence of flammable or explosive gases of chemicals

3. Ensure all ventilation grilles are clear of obstructions.
4. Connect power cords from each piece of equipment to the Isolation Transformer as shown in Figure 4-1. The two EMI suppression cords supplied must be used for the CEIS-CU and the CEIS-OU. Use the supplied clips to secure the cords into the Isolation Transformer sockets.
5. Connect any power cords for peripheral equipment used with the CEIS to the Isolation Transformer.
6. Connect the mains power cord to the Isolation Transformer. Use the supplied clip to secure the cord into the Isolation Transformer socket. **DO NOT** plug the mains cord into the wall socket until instructed.

Warning!

- This equipment **MUST** be properly grounded. In the U.S.A. and Canada this equipment MUST be connected to a three (3) prong hospital grade outlet.
- Only power cords supplied with the CEIS equipment may be used for the CEIS equipment.
- Connect the power cords from all components of the CEIS System and accessories into the Isolation Transformer **ONLY**.
- Connect any peripheral equipment into the Isolation Transformer **ONLY**.

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(Refer to Table 8-2 for approved equipment)

Warning!

- When additional peripheral equipment is connected to the Isolation Transformer, check that the total power consumption of all connected equipment does not exceed 1000VA.
- **DO NOT** allow power cords or other cables to become twisted, crushed or pulled taut.

7. Connect the interconnecting Control Data, Control Signal and Optical Signal cables between the CEIS-CU and the CEIS-OU as shown in Figure 4-1. Ensure all interconnecting cables are not stretched tight and that all connectors are properly inserted. Ensure all the retaining screws are tightened.
8. Connect the Monitor Signal and Touch screen cables to the CEIS-CU as shown in Figure 4-1. Ensure all the retaining screws are tightened.
9. Connect the Keyboard cables to the CEIS-CU as shown in Figure 4-1.
10. Connect the Footswitch cable to the CEIS-CU as shown in Figure 4-1. Ensure the retaining screws are tightened.

Warning!

Ensure all interconnecting cabling is secured off the floor and away from trafficked areas to remove potential trip risks. Ensure the mains cord is routed away from trafficked areas to reduce the trip risk.

11. Ensure the Isolation Transformer is turned OFF.
12. Plug the mains cord into the wall socket and turn the wall socket ON.

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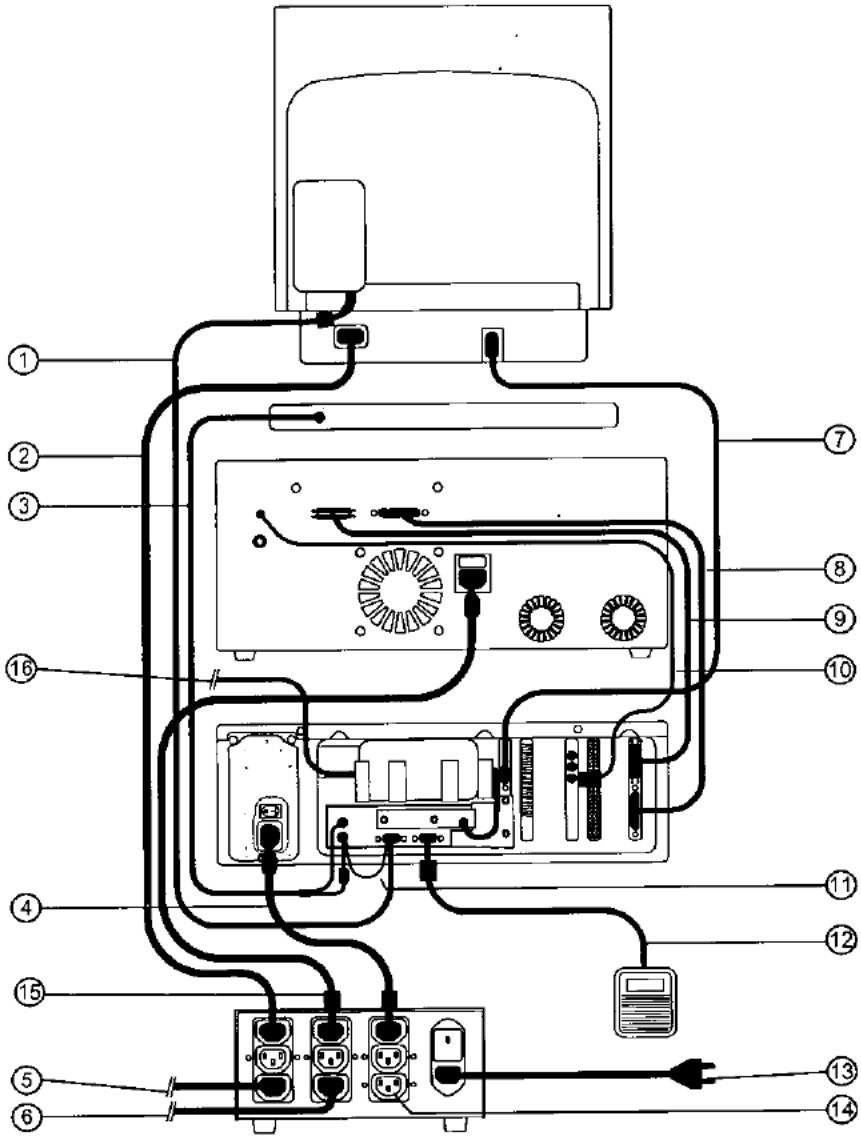

Figure 4-1 Connections of CEIS cabling.

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No.	NAME	FUNCTION
1.	Touch screen	Connects Touch screen signals to the CEIS-CU.
2.	Monitor Power	Supplies power to the Monitor from the Isolation Transformer
3.	Keyboard	Connects the Keyboard to the CEIS-CU via the Touch screen Power Adapter.
4.	CEIS-CU Power (EMI)	Supplies power to the CEIS-CU from the Isolation Transformer
5.	Accessory Outlets	Additional power outlets for connection to approved Accessories. Refer to Table 8-2
6.	Accessory Outlets	Additional power outlets for connection to approved Accessories. Refer to Table 8-2
7.	Monitor Video Signal	Connects Monitor Video signals from the CEIS-CU.
8.	Control Signal	Connects Control Signals between the CEIS-CU and the CEIS-OU.
9.	Control Data	Connects Control Data between the CEIS-CU and the CEIS-OU.
10.	Optical Signal	Connects the Optical Signal from the CEIS-OU and the CEIS-CU.
11.	Touch screen Power Adapter	Connects into the keyboard socket to supply power to the Touch screen.
12.	Footswitch	Connects the Footswitch to the CEIS-CU.
13.	Incoming Mains	Supplies incoming mains power to the Isolation Transformer.
14.	Accessory Outlets	Additional power outlets for connection to approved Accessories. Refer to Table 8-2
15.	CEIS-OU Power (EMI)	Supplies power to the CEIS-OU from the Isolation Transformer
16.	Network (if required)	Connects the CEIS-CU to a Local Area Network (UTP CAT5+)

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4.1.2 Connecting an Endomicroscope

Warning!

Only connect endomicroscopes that are listed in Table 8-2 and that meet the application required, and ensure that you consult the user instructions for the operational and installation instructions of any of these approved accessories to be used in conjunction with the CEIS System. Contact your local Optiscan representative if you require assistance.

Caution:

The endomicroscope **MUST NOT** be connected to or disconnected from the CEIS-OU whilst it is operating. Doing so may result in damage to the endomicroscope and the CEIS System.

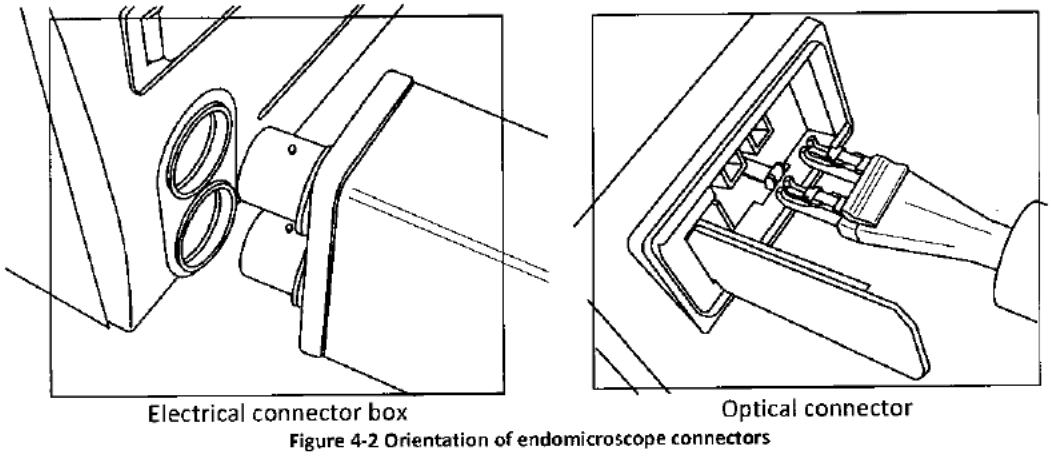

Figure 4-2 Orientation of endomicroscope connectors

1. Ensure the CEIS is turned OFF.
2. Remove any caps from the endomicroscope connector box.
3. Align the endomicroscope Electrical Connector Box plugs with the CEIS-OU Electrical Connector as shown in Figure 4-2 and push the plugs fully into the sockets. Ensure that the connector is fully inserted.

Note:
This connector is keyed to ensure correct orientation. Ensure that the connector is fully inserted

4. Remove any caps from the confocal optical connector on the endomicroscope.
5. Hold open the Optical Connector door on the front of the CEIS-OU, align the dual optical connector with the dual socket inside the door as shown in Figure 4-2, and insert optical connector firmly into the mating CEIS-OU Optical Connector.

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4.2 Safety Check

Warning!

Before every use the following points should be checked. If any function or device in the CEIS does not perform properly, **DO NOT** perform the endomicroscopic procedure. Contact your local Optiscan representative before using the system for an endomicroscopic procedure.

1. Ensure the Isolation Transformer power switch is OFF.
2. Ensure that any approved accessory power switches are OFF.
3. Ensure the equipment is placed in a stable and level position.
4. Ensure all equipment is properly installed and interconnected.
5. Ensure the endomicroscope is properly connected.
6. Turn ON the Isolation Transformer.
7. Turn ON the approved accessory power switches, and follow any checklist instructions in the approved accessories manuals.
8. Turn ON the CEIS Monitor.
9. Turn ON the CEIS using the ON/OFF Button on either the CEIS-CU or the CEIS-OU. Note that both the power on indicators light.
10. Ensure that the CEIS-OU Laser ON indicator is not lit.
11. Ensure that the CEIS-OU Warning indicator is not lit.
12. Note that the CEIS Monitor displays a boot up sequence and presents a logon prompt. Logon and operating procedures are detailed in the CEIS Operator's Manual.
13. To prevent electrical shock, do not allow the CEIS or its approved accessories to be grounded to other electrical devices being used on the patient. Rubber gloves should always be worn to prevent grounding through user(s).

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5 OPERATION

Warning!

This equipment should **ONLY** be used under the supervision of a trained physician in a medical facility. **DO NOT** use in other locations or for any other purposes than the intended application.

Note:

Consult the user instructions for the operational instructions of any of the approved accessories used in conjunction with the CEIS System.

There are three instrument control devices on the CEIS. These are the keyboard and touch pad mouse, the monitor touch screen, and the footswitch. The footswitch triggers image capture during normal operation, and the other input devices provide multiple ways of performing similar functions. See the CEIS Operator's Manual for details on instrument control.

Note:

It is recommended that the Administrator and Service passwords not be changed from the factory default. Changing these passwords will cause delays in servicing and repair of this equipment, and may result in data loss.

Caution:

It is recommended that users do not log onto the CEIS as an Administrator. Administrator and service permissions allow access to parts of the instrument that should only be used by trained service technicians, and may change operating parameters to outside normal operating range.

5.1 Customer Site Install

When the system has been installed for the first time by your Optiscan In-Service Field Technician, the Microsoft XP End User License Agreement (EULA) will be displayed. The operation of the CEIS is not possible until the Customer has accepted the Windows XP EULA conditions on the screen. To agree with the terms of the Windows XP EULA simply click on the button "I accept this agreement" and then click on "Next" and the system will boot up automatically.

5.2 Principle of Operation

Confocal endomicroscope technology employs a laser to deliver highly focused beam of light to a specimen at controlled wavelengths via an optical fibre. A fluorophore is excited at the focus point of the confocal lens, and light of a longer wavelength is passed back through the same optical path used to illuminate the specimen. The collected light is transmitted by optical fibre to a light detection system which detects the light and converts it into a digital image displayed on the monitor.

By using an optical fibre as a spatial filter, only light returning from an exact plane of focus is permitted to pass through to the detection device. Light returning from other than the specific focal plane is not propagated by the optical fibre and omitted from detection. This process therefore rejects out-of-focus information to produce a thin optical section that can be positioned within a specimen to provide a sharp image with significantly higher resolution than a conventional light microscope. The optical section (image) obtained is oriented parallel to the surface of the specimen and optical window of the scanner.

This technique allows real time non-destructive high magnification imaging of living tissue.

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5.3 Performance Checks

Before using the endomicroscope in a clinical procedure, the following tests should be run to confirm that the system is running within normal operating parameters. These are tests for sensitivity, linearity and imaging depth control. Refer to the CEIS Operator's Manual for instruction on how to control the instrument.

5.3.1 Sensitivity Tests

1. Start the Clinical Application
2. Select "2. Green Fluoro - Normal gain" from the Procedure List and proceed to the Acquisition screen.
3. Set the Brightness to Min (0) and the Gamma to Mid (1.0)
4. Place a cloth test sample against the confocal imaging window of the endomicroscope tip.
5. Set the laser power to Mid (~500uW)
6. Operate the depth controls and ensure that the image changes accordingly. It should be possible to position the focal plane above the specimen (within the coverglass, where no fibres are visible), through the fluorescent fibres, and beyond the specimen at the deeper extreme. Fibres touching the confocal imaging window often have a "wet" appearance.
7. Bring into focus a field of view containing an array of fibres just beneath (touching) the confocal imaging window.
8. Adjust the laser power to produce an image on screen that ranges from completely black to brilliant white, representing the full dynamic range of the instrument imaging intensity. An example of a good full dynamic range image is shown in Figure 5-1, where the brightest parts of the image are just white. Large areas of saturation (Figure 5-2) suggest the laser power needs to be reduced. If the image is dim and does not fill the instrument's full dynamic range (Figure 5-3), the laser power should be increased.

Figure 5-1

Figure 5-2

Figure 5-3

9. If the laser power required to obtain a full dynamic range image of the cloth test sample is:
   - **less than 650uW**, exit the procedure, select the procedure type "1. Green Fluoro – Low Gain" and repeat steps 3–9 of the sensitivity test.
   - **650–850uW**, see step 10
   - **higher than 850uW**, exit the procedure, select the procedure type "3. Green Fluoro – High Gain" and repeat steps 3–9 of the sensitivity test.
10. The procedure type used (low gain/ normal gain/ high gain) to obtain a full dynamic range image with 650–850uW laser power is recommended for routine in vivo imaging with the particular endoscope used.
    - If the High Gain procedure and maximum laser power still fail to produce a full dynamic range image, system sensitivity may be compromised and result in difficulty imaging human tissue. Note that the Maximum Gain procedure is reserved for imaging tissues known to have very dim fluorescence. It should not be necessary to proceed to the Maximum Gain procedure in order to obtain a full dynamic range image of the test cloth.
    - If the Optical Connection between the endomicroscope and the CEIS-OU is dirty, instrument sensitivity will be reduced. A sudden change in sensitivity when imaging the

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test cloth from one procedure to the next suggests that the Optical Connectors require cleaning to be performed by your Optiscan representative.

5.3.2 Image Linearity and Alignment

1. Use a cloth test sample to check that the linearity of the system is within normal operating range.
2. Rotate the test sample until the fibres in the cloth are orientated correctly.
3. Operate the depth controls to confirm the depth of view moves both up and down and to the Home position as expected.

5.4 During Use

Warning!

To avoid electric shock **NEVER** apply the attached endomicroscope or any other accessory device directly to the heart.

1. The attached endomicroscope is Class 3R Laser Product. During operation laser radiation is emitted from the endomicroscope tip. **DO NOT** stare into the laser beam or view directly with optical instruments.

Caution:

If the laser system has been operating for more than 30 minutes in air, care should be taken as the distal end may be hot. To avoid excessive heat at the distal end prior to inserting the endoscope place the distal end of the endoscope into a container of sterile water and suction. Lift the distal end out of the water and exercise the water delivery and air delivery functions.

2. During a procedure, use the minimum laser power required.
3. During clinical procedures, avoid unnecessary prolonged use which could compromise patient/user safety.
4. To avoid damage to the monitor display and membrane switches, do not press or impact with any hard or sharp objects.
5. Continually monitor this equipment and the patient for any signs of irregularities.
6. In the event that some type of irregularity is noted in the patient or this equipment, take the appropriate action to ensure patient safety.

Warning!

The CEIS should only be used according to the instruction and operating conditions described in this manual and the CEIS Operator's Manual. Failure to do so could result in compromised safety, equipment malfunction or instrument damage.

7. In the event that the system ceases to respond to operational commands, press and hold the Power ON/OFF button on the front of the CEIS-CU or CEIS-OU until the system shuts down. Restart the system as for normal operation.
8. After turning off the Isolation transformer it is recommended to let the Isolation Transformer "cool down" for approximately 1 minute, before the unit is turned on again. There may otherwise be a risk of blowing a fuse in the power entry module or possibly tripping the wall outlet circuit breaker.

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5.5 Connection to a Network or Peripherals

The CEIS may be connected to a network using the LAN Port (see Figure 3-2).
By default the instrument will automatically configure the network setting using DHCP.
While the LAN Port is available to allow printing to a network printer or for data transfer across a network, the CEIS has not been tested for operation with any specific network configuration or network device. Before you connect the LAN Port you should consult with your Hospital or Clinic IT Coordinator.

Caution:

Connecting the CEIS to a network may expose it to computer viruses and security vulnerabilities. Accordingly, it is the responsibility of the customer to ensure that the network is regularly updated with appropriate virus protection software and is configured with security features.

The CEIS is factory configured with the setting "not to accept Windows updates" as may be distributed to Windows users from time to time. It is recommended that this factory setting "not to accept Windows updates" be maintained as the CEIS would not have been tested for complete functionality against each Windows update.

Note:

The technician account provides administrator access, which is required to network connect the CEIS. You will need to contact your Optiscan technical support person for your area to obtain the password to access this Technician account.

It is recommended that the Technician password is not changed from the factory default. Changing the password will cause delays in servicing and repair of this equipment, and may result in data loss and/or damage to the instrument. Delays in servicing and repair caused by changes to passwords will incur additional costs.

Caution:

Once the CEIS has been networked connected, it is recommended that the user does not log onto the CEIS under the Technician account as Technician permissions allow access to parts of the instrument that should only be used by trained service technicians, and may change operating parameters to outside normal operating range.

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6 MAINTENANCE

6.1 After Use

Note:
Consult the user instructions for the after use handling and care of any of the approved accessories used in conjunction with the CEIS System.

1. Shut down the Clinical application and then shut down the equipment. Refer to the Operator's Manual for instructions on shutting down the application and the equipment.

Caution:
Unless in an emergency, The CEIS should only be shut down using the software method detailed in the Software User's Manual. Turning power off in any other way risks losing data and damaging the integrity of the software installation. Refer to the user instructions for the shutdown procedures of any of the approved accessories used in conjunction with the CEIS System.

2. Disconnect the endomicroscope. Disconnect the Optical Connector first. Replace the soaking caps over the endomicroscope connectors as they are disconnected.
3. Be sure connector interfaces and ventilation ports are not allowed to become wet or splashed with liquids.
4. Inspect the CEIS components for substance contamination and clean equipment enclosures as required. Refer to part 6.2 for cleaning guidelines.

6.2 Cleaning

6.2.1 Cleaning the CEIS Monitor and Touch Screen

1. Ensure the equipment has no power connected when cleaning is performed.
2. When necessary, wipe the surface of the monitor case with a mild non-abrasive detergent (non-ammonia and non-alcohol based) on a soft, clean lint-free cloth.
3. Clean the touch screen surface as required. For best results, use a pre-soaked wipe or towellette containing non-abrasive cleaning agent such as, isopropyl alcohol or ethyl alcohol.
4. If the connector between the plug and the pin is dusty or dirty, clean it properly with a dry cloth.

Caution:
- **DO NOT** spray cleaner directly onto the monitor case or the touch screen.
- **DO NOT** use abrasive, alcohol or alcohol based cleaning agents on the monitor case.
- **DO NOT** place open containers of water or chemicals on the monitor.
- **DO NOT** place any small metallic objects on the monitor.

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6.2.2 Cleaning the CEIS-CU and CEIS OU Enclosures

1. Ensure the equipment has no power connected when cleaning is performed.
2. When necessary, wipe the surface of the enclosure with a soft fabric slightly dampened with a dilute solution of detergent and water (1 part of detergent to 10 parts of water).

Caution:

- **DO NOT** spray cleaner directly onto the enclosure.

6.3 Service

Warning!

DO NOT make ANY alterations or modifications to the equipment.

1. There are no user serviceable parts inside the equipment.
2. Repairs should only be performed by an authorized Optiscan service agent.
3. Fuses for the Isolation Transformer and the CEIS-OU may be replaced provided only Optiscan supplied replacement fuses are used.

Warning!

Repeated fuse failure indicates faulty equipment. **DO NOT** use the equipment until it has been inspected by an Optiscan service agent.

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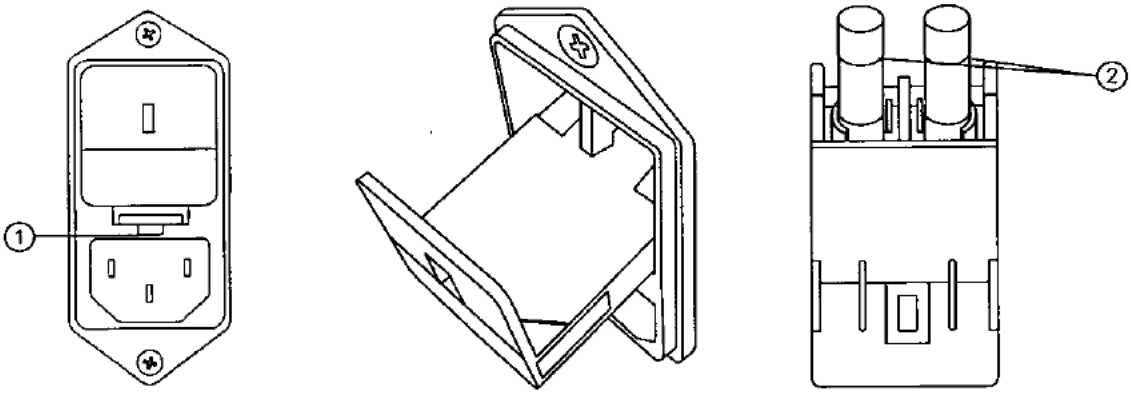
6.3.1 Replacing Isolation Transformer Fuses



Location of retaining clip | Drawer partially removed | Location of fuses

Figure 6-1 Isolation Transformer Fuse Replacement

Caution:
Make sure the mains power is turned off at the wall socket and the mains cord is unplugged.

1. Ensure the Isolation Transformer is turned off.
2. Unclip and unplug the mains power cord from the Isolation Transformer.
3. Remove the Fuse and Selector Drawer as shown in Figure 6-1 by raising the drawer retaining clip (1) with a small screwdriver or similar tool. The location of the drawer on the Isolation Transformer is shown in Figure 3-9.
4. Remove and replace the two fuses (2) with the same rated fuses supplied by Optiscan.
5. Reinstall the Fuse and Selector Drawer by placing it into its receptacle and pushing gently until the retaining clip engages.

Caution:
DO NOT apply significant force to the drawer.

6. Reinstall the mains power cord and ensure the clip is correctly in place.
7. Plug the mains cord back into the wall socket and turn the power on.
8. Turn the isolation transformer on and note that the switch indicator lights.
9. If the fuses blow again consult your Optiscan representative.

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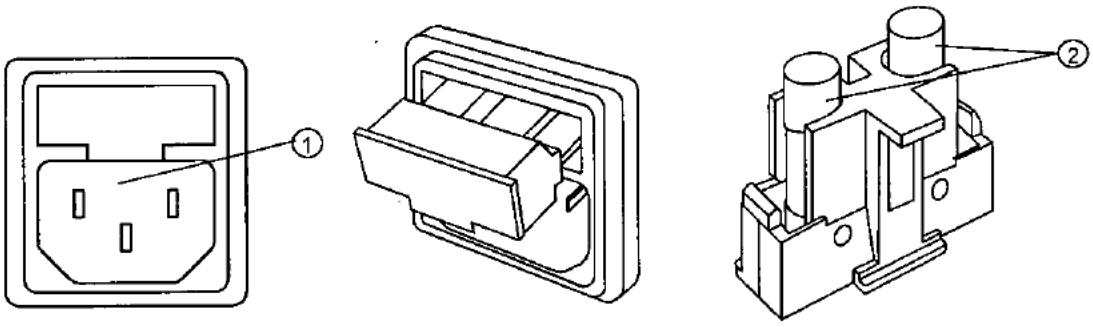
6.3.2 Replacing CEIS-OU Fuses



Location of drawer | Drawer partially removed | Location of fuses

Figure 6-2 CEIS-OU Fuse Replacement

Caution:
Make sure the power is turned off at the Isolation Transformer.

1. Unplug the power cord from the CEIS-OU.
2. Withdraw the Fuse Drawer as shown in Figure 6-2 by levering out the base of the drawer (1) with a small screwdriver or similar tool. The location of the drawer on the CEIS-OU is shown in Figure 3-4.
3. Remove and replace the two fuses (2) with the same rated fuses supplied by Optiscan.
4. Reinstall the Fuse Drawer by placing it into its receptacle and pushing gently until it is firmly home and flush with the surface of the connector. DO NOT apply significant force to the drawer.
5. Reinstall the power cord.
6. Turn on the CEIS following the checklist in part 0 and note that the CEIS-OU ON/OFF Indicator lights as it should.
7. If the fuses blow again consult your Optiscan representative.

6.4 Storage

1. **DO NOT** store the equipment in direct sunlight or where the unit could get wet or be exposed to any adverse environmental conditions such as high temperature, humidity, direct sunlight, dust, salt, etc.
2. **DO NOT** store the equipment where it can be exposed to liquids.
3. **DO NOT** store the equipment where it can be exposed to flammable or explosive gases or chemicals.
4. Power cords, cables and other accessories should be cleaned and neatly stored in bags or an appropriate container.
5. Equipment in storage should be periodically inspected for safety and tested for correct operation.

Caution:
For long term storage take precautions to prevent the ingress of dust and insects into the equipment. Accumulation of dust or insects within the equipment may cause malfunction, smoke or ignition when next turned on.

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6.5 Disposal

This equipment should be returned to Optiscan for disposal. Contact your Optiscan representative.

[redacted]

An Information on Disposal for users in the European Union

This product is a medical device. In accordance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment, this symbol indicates that the product must not be disposed off as unsorted waste, but should be collected separately. Contact your local Optiscan distributor for correct disposal and recycling.

By disposing of this product correctly you will help ensure that the waste undergoes the necessary treatment, recovery and recycling and thus prevent potential negative effects on the environment and human health which could otherwise arise due to inappropriate waste handling.

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7 TROUBLE SHOOTING GUIDE

CONDITION	CHECK	ACTION
No power at the isolation transformer	Mains power cord	Ensure proper connection at transformer and wall outlet.
	Fuses	Remove and inspect isolation transformer fuses. If unsure replace the fuses.
	Power outlet	Move the mains power cord to an outlet that is known to work.
CEIS-CU does not turn ON.	Isolation transformer	Ensure isolation transformer is turned ON. Note switch indicator light is lit.
	Power cord	Ensure proper connection at isolation transformer and CEIS-CU
CEIS-OU does not turn ON with CEIS-CU	Power cord	Ensure proper connection at isolation transformer and CEIS-OU
	Control data cable	Ensure proper connection at CEIS-CU and CEIS-OU
	Fuses	Remove and inspect CEIS-OU fuses. If unsure replace the fuses.
CEIS-OU ON/OFF switch does not work	Control data cable	Ensure proper connection at CEIS-CU and CEIS-OU
	Power cord	Ensure proper connection at isolation transformer and CEIS-CU
Monitor does not turn ON with CEIS-CU	Power cord	Ensure proper connection at isolation transformer and monitor
	ON/OFF switch	Ensure monitor ON/OFF switch is turned on

Table 7-1 Trouble Shooting Guide

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8 TECHNICAL SPECIFICATIONS

Power Requirements			
Rated Voltage		100 ~ 120 VAC	(USA, Canada & Japan)
		220 ~ 240 VAC	(Europe & Australia)
Rated Frequency		50 ~ 60 Hz	
Power Consumption		6A	(USA, Canada & Japan)
		3 A	(Europe & Australia)
Fuse Rating			
	CEIS – OU	T 3.15A	
	Transformer Fuse	T 5A	(Europe & Australia)
		T 10A	(USA/Canada)
		T 12.5A	(Japan)
Electrical Standard Requirements			
The system complies with IEC60601-1, EN 60601-1, UL 60601-1 & CAN/CSA-C22.2 No. 601.1 M90			
Protection against Electrical shock		Class One Equipment With Connected Endoscope Type BF Applied Part	
Degree of Ingress Protection		The CEIS is rated at IPX0 The CEIS Footswitch is rated at IP68.	
EMC Requirements			
The system meets the EMC requirements in accordance with IEC60601-1-2 & EN 60601-1-2. The system meets the RFI requirements of Group 1 Class B			
Product Classification			
As per Directive 93/42/EEC, Annex IX: Class IIa (Rule 10)			
Product Labelling / Approvals			
CE Labelling		The system meets the essential requirements stipulated in Annex I to the 93/42/EEC directive governing medical devices. The system is labelled with : CE 0197	
Electrical Safety (NRTL)		The system is labelled with:	
Operational Specifications			
Hard disk		80GB Total capacity ~70GB available for data storage	
Operating system & software		Windows XP, includes integrated control and image acquisition software	
Cooling		Forced Air Cooling	
Detection			
	Number channels	1	
	Dynamic range	12 bits	
	Bandwidth	Filter HQ545 / 80M Chroma	
		505 nm – 585nm	

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Illumination Method		Class 3R Laser Output with Connected Endoscope	
	Laser Wavelength	488 nm ± 2 nm with connected Endomicroscope	
	Scanner Maximum Optical Output Power:	1 mw @ 488 nm with connected Endomicroscope	
Imaging			
	Transverse modes:	M^2 <1.1, TEMoo with connected Endomicroscope	
	Field of View (minimum):	~ 500 x 500 µm with connected Endomicroscope	
	Depth Range (minimum):	0 – 200 µm with connected Endomicroscope	
	Confocal Axis Response:	8 µm with connected Endomicroscope	
	Confocal Lateral Response:	1 µm with connected Endomicroscope	
	Scan Modes:	Scan Mode 1	Scan Mode 2
	(resolution/ Frame Rate (/sec):	1024 x 1024 / 0.7	1024 x 512/ 1.2
	Imaging Output Format	Compatible with BMP, TIF, JPG and OPZ (Optiscan Proprietary Imaging Format). Refer to CEIS Operators Manual for full details	
Ambient Requirements			
Operating Environment			
	Temperature	10 ~ 40 ºC	
	Relative Humidity (non-condensing)	0 ~ 85 %	
	Air Pressure	700 ~ 1060 hPa	
Storage/Transport Environment			
	Temperature	-20 ~ 60 ºC	
	Relative Humidity (non-condensing)	0 ~ 85 %	
	Air Pressure	700 ~ 1060 hPa	
Dimensions & Weight			
Size (WxHxD not packaged)			
	CEIS-CU	410 x 140 x 450 mm	
	CEIS-OU	430 x 180 x 470 mm	
	Monitor (with stand)	440 x 461 x 460 mm	
	Isolation Transformer	225 x 115x 310 mm	
	Keyboard (excluding cable)	415 x 35 x 193 mm	
Weight (not packaged)			
	CEIS-CU	10.8 kg	
	CEIS-OU	16.2 kg	
	Monitor (with stand)	21.0 kg	
	Isolation Transformer	11.0 kg	
	Keyboard (excluding cable)	1.0 kg	

Table 8-1 Specifications

Application	Compatible Confocal Endomicroscopes	Compatible Digital Video Processor	Compatible Trolley
Gastro Intestinal Examination	EC-3870CILK (PENTAX) EC-3870CIFK (PENTAX) EC-3870CIMK (PENTAX) EG-3770CIK (PENTAX)	EPK-1000 (PENTAX)	SMC-V10 (PENTAX)

Table 8-2 Approved Accessories

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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NOTICE
This equipment is a Class B Medical Equipment (specified EN55011) and is intended for hospital or health care districts.
When used in clinical or residential areas near radio and TV receiver units, this equipment may be subjected to radio interference.
To reduce electromagnetic interference, do NOT keep turning on the main SWITCH of the equipment while a confocal endoscope is connected but not ready for use.
To avoid and resolve adverse electromagnetic effects, do NOT operate this equipment near the RF energy equipment.
Only connection cables and keyboard specified by OPTISCAN conform to the above standards.

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EC REP

Specifications are subject to change without notice and without any obligation on the part of the manufacturer.

CE 0197

Documen[redacted] Revision [redacted]nted in AUSTRALIA)

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User Instructions
CEIS Operators Manual

Document Number: (b)(4) [redacted]
Revision [redacted]
Release Date: 27/01/2010
Created from Template: Standard.Dotx

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(b)(6) [redacted] (b)(6)

Signature: _____ Date: 27/01/10
Reviewer [redacted]

Signature: _____ Date: 27/1/2010
Approval [redacted]

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Revision History:

Revision	Modified	Release	Description
(b)(4)	(b)(6)	19/12/2005	Converted from 000420
		24/1/2007	CEIS Operators Manual updated by reference to the ISC-1000 Operators Manual which includes a number of changes requested by Pentax
		18/11/2008	Update to correspond with the ISC-1000 Owners Manual 000421 revision 19. All references to the ISC-1000 specific references have been changed to their CEIS equivalents.
		2/3/2009	Add new Cover Art Added Document and revision reference on all pages. Added a list of Tables and Figures
		14/5/2009	Add DIMDI Code to European Representative in last page Removed Declaration of Conformity from last page
		27/1/2010	Update Section 4.1 to remove procedures types that were previously linked to the LP505 filter which has been removed based on feedback from the FDA during the 510k Submittal process

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OptiScan|CEIS

Confocal Endoscopic Imaging System

Operator's Manual

Clinical Software Version 2.3
Reporter Software Version 2.3

Fluorescence In Vivo Endomicroscopy

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1 SCOPE AND CONTENT

1.1 CEIS Software Application

This Operators Manual describes the methods and procedures for operating the CEIS using the following releases of software.
Clinical Application Version 2.3
Reporter Application Version 2.3

This manual does not describe the use or operation of any of its approved accessories, and does not describe the general use or operation of an attached confocal endoscope.
This manual must be read in conjunction with the CEIS Owners Manual. Be sure to read and understand the Owners Manual before attempting to operate the CEIS equipment. All Operators must receive training before using the Clinical application and Reporter application to perform a clinical procedure.

1.2 Caution and Note Messages

The following conventions have been established in the text of this manual to aid in the identification of important information.

Warning!
The **warning triangle** indicates potential sources of danger which may constitute a risk of injury for the user or a health hazard.

Caution:
The **square** indicates situations which may lead to malfunction, defects, collision or damage of the instrument.

Note:
The **hand** indicates hints on the use of the instrument or other tips for the user.

1.3 Overview of the Imaging Modes

The CEIS software application operates in two image specific modes:
Acquisition (Section 4) and Review (Section 5).

The Image Acquisition mode allows images to be captured, reviewed, and stored as part of a Procedure Result. The types of information that may be found in Procedure Results are described further in Section 3.1.

The Image Review mode allows the review of previously collected Procedure Results. Procedure Results may be exported and imported for archival and retrieval purposes, and to allow the transfer of Procedure Results between CEIS systems. Image files can be exported and can also be used in other, third-party applications.

A work flow diagram showing the relationship between the stages of each of the Acquisition and Review modes is shown in at the start of each section.

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2 SOFTWARE OPERATION

2.1 Principles of Operation

The CEIS captures and displays endomicroscopy images of surface and subsurface layers of a tissue or organs site. The CEIS transmits light from a variable output laser via an optical fiber. The laser light is focused to a diffraction-limited spot within the tissue. A scanning mechanism in the tip of the endomicroscope is used to scan the focused point of laser light across an area of tissue (approximately 475 µm x 475 µm). Only light returning from the focal spot in the tissue is focused back onto the tip of the optical fiber, and propagated back to the detector. The detector is used to measure the intensity of the light returning from the tissue. An image is built up by sequentially measuring the intensity of light returning from each point within the scanned area. In other words, an image is comprised of an array of individual point intensity measurements.

When an image is captured, the CEIS stores the last complete image (not the partially complete image that is scrolling down the screen). The CEIS uses a Look Up Table (LUT) to display an image from the measured data. The Brightness value (Section 4.3.4) and the Gamma value (Section 4.3.5) can be modified to reveal different visual features of the image of the tissue site. The original image is always available.

2.2 Software Conventions

The following software conventions are used throughout this document:

- ALL CAPITALS indicate keyboard commands (e.g. press the ENTER key).
- Text in boxes indicates the labels of software buttons on the screen (e.g. [Start A New Procedure]).

Control of the Clinical application software is achieved in a number of ways. These include:

- touching controls directly on the touch screen,
- using the built-in touch pad on the keyboard to move the screen cursor,
- using the keyboard to type in information, and
- stepping on the footswitch.

Controls on the screen are either buttons to perform actions or sliders to adjust settings.

Buttons can be operated by any of the following ("press" means operating the button by any of these means):

- single-tapping the button on the screen,
- moving the screen cursor using the keyboard touch-pad and clicking using the touch-pad buttons (or double-tapping the touch-pad—ensure that the two taps are in the same spot otherwise they will register as two separate single taps),
- pressing the TAB key until the required button is highlighted and pressing ENTER on the keyboard (or single-tapping the touch-pad).

Items in a list can be selected or highlighted in the same way as buttons. Unlike buttons, more than one list item may be selected at a time. To select a block or continuous set of list items: highlight the first item; hold down SHIFT; highlight the last item. To select a discontinuous or random set of items: hold down CTRL and highlight each desired item in turn.

Sliders can be operated by any of the following:

- applying pressure to and dragging the slider pointer using the screen,
- clicking and holding the slider pointer with the screen cursor by the touch pad and drag the slider in the direction required, and
- pressing the increase [▶] button or the decrease [◀] button.

Displayed lists of previously entered information can be sorted by clicking on the column heading of interest. Click once to sort in ascending order. Click again to sort in descending order.

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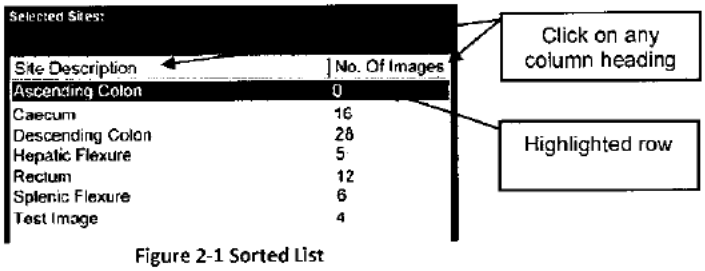

Figure 2-1 Sorted List

Data entry fields can be selected in the same way as buttons: touching the screen, clicking the touch-pad, and using the TAB key. Then type the required information in the field.
Where possible, error checking is performed on data entry. In the case where too much or the wrong type of information (e.g. an incorrect value in a date field) is entered into these fields then the operator will be prompted to correct the data entry when attempting to save the information.
One or more of the following buttons appears on each screen.

Next	Advance to the next screen
Back	Return to the previous screen
Save	Save any modified data and stay on the same screen—usually the button is dimmed to show it is inactive and becomes active when a change is made, otherwise it is always active
Done	Accept any input or editing changes and return to the main screen.
Exit	Go to **Save Procedure Result** screen (Section 4.6). If no information has been entered then go to **Start-up** (Section 0).

If there are unsaved changes on the screen then there is a prompt to do ***one*** of the following:

- save the change before returning
- discard (or abort) the change
- cancel the action and stay at the screen.

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3 CLINICAL APPLICATION OVERVIEW

The Clinical software application is used for imaging. When the CEIS equipment is turned on and has initialized, the Logon screen displays three user-accounts.

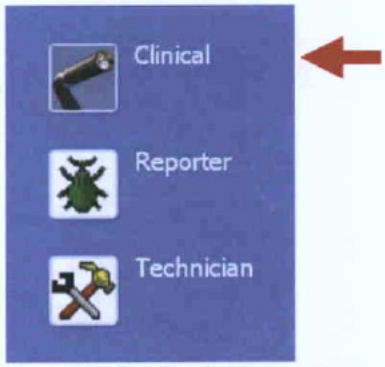

Figure 3-1 Application icons in Logon screen

Select the Clinical account icon to log on. The Clinical application automatically launches and displays the Start-Up screen (Section 0).

The Reporter account and its associated application are described in Section 6. The Technician account is password protected and is for servicing the CEIS equipment by trained service personnel only.

3.1 How the Information is Structured

The purpose of an Imaging Procedure (when a Subject is examined) is to capture images for subsequent analysis. All information associated with the procedure is stored in a Procedure Result. Each Procedure Result is part of a database. A Procedure Result is a collection of data comprising some or all of the following:

- contextual information entered by the operator during the procedure
- captured images
- range of instrument settings used at the time each image was captured
- Site Description of where each set of images was captured to allow identification
- associated data entered by the operator during the procedure.

Each procedure result is uniquely identified by the date and time the procedure result is created, and a unique session identification number that is generated by the CEIS. Each procedure result will always contain at least one imaging site (default site is **SITE_1**) unless otherwise named or additional sites entered.

Contextual information optionally entered includes additional notes and details pertaining to the Subject, Operator and imaging Site(s). Such Information is entered using the appropriate **Information Logging** screens (Section 4.2): Create Sites, General Notes, Operator Details, and Subject Details. To assist with data entry, the details of an Operator or Subject previously entered can subsequently be recalled from the database and used for a new Procedure.

Retrieval of stored procedure results is based on information entered about the Subject. Entering complete Subject details at the time a procedure is performed will assist in identifying stored procedure results at a later time.

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3.2 Start-up Screen

The Clinical application Start-up screen is shown in Figure 3-2

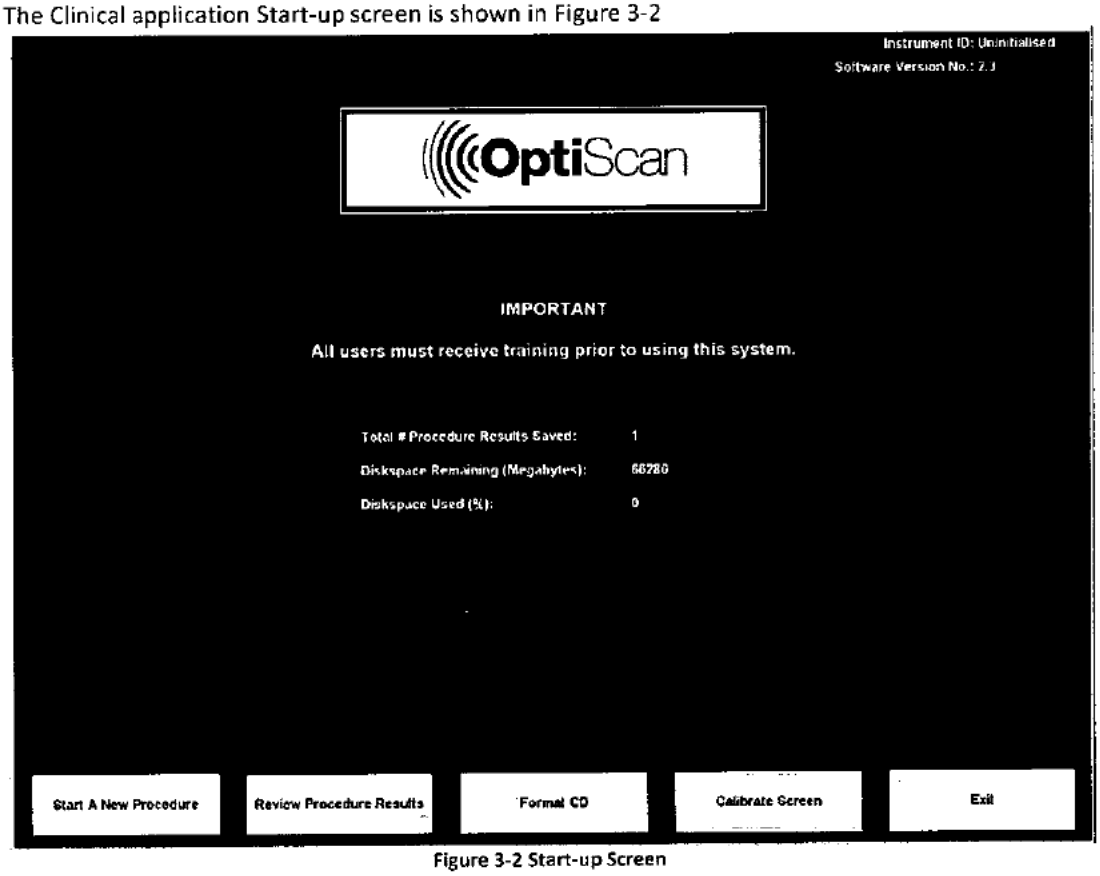

Figure 3-2 Start-up Screen

There are five menu buttons across the bottom of the screen. The action of each button is summarized as follows:

Start A New Procedure	The Acquisition mode (Section 5). Start a new Imaging Procedure to begin the acquisition and storage of new images. On initial instrument start up this button is dimmed during initial calibration. It becomes active after the system calibration and set-up has completed. If the system detects a fault then a message box is displayed (Figure 3-3). The button remains inactive.
Review Procedure Results	The Review mode (Section 5). Review and adjust images and information saved as a Procedure Result.
Format CD	Format a blank CD so it can be used to store user data (Section 3.3).
Calibrate Screen	Calibrate the touch screen (Section 3.4).
Exit	Exit the **Clinical** Application (Section 3.5).

The Review Procedure Results , Format CD , and Calibrate Screen button functionality is available during the initial set-up time.

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Note:
It is not necessary to have a confocal endomicroscope connected to the instrument to review stored Procedure Results. However if the **Clinical** application is started without a confocal endomicroscope connected, the error message in Figure 3-3 will be displayed because the instrument detects that there is no endomicroscope fitted and will therefore not allow a new imaging procedure to be started.

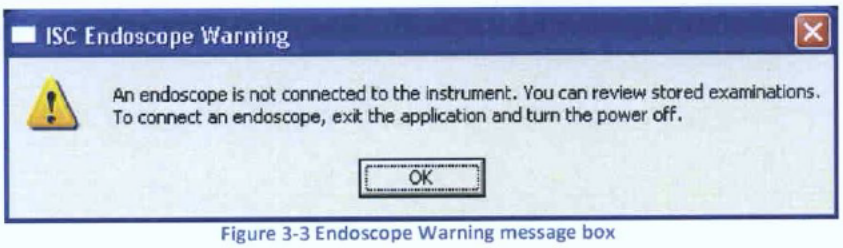

Figure 3-3 Endoscope Warning message box

3.3 Format CD

This button formats a blank CD using a third-party application, DirectCD. This allows user data, (images, procedures, and so on) to be written directly to a CD-Recordable (CD-R) or CD-ReWritable (CD-RW) disc in much the same way that files are copied to a floppy diskette or removable drive.
Ejecting the CD closes it so that it can be read in a normal CD-ROM drive. If the CD is not full, additional data can be added to the CD by re-inserting it into the CD writer. It does not need to be reformatted to add additional data.
The information on the CD is also accessible to CD-ROM (read-only) drives. The formatting application has its own extensive on-line help available.

Note:
The blank CD must be formatted before any data can be written to CD directly from the Clinical application and should be done ***before*** reviewing saved procedure results.

3.4 Calibrate Screen

This button allows the calibration of the touch-screen so the cursor accurately tracks where the screen is touched.
There are 2 buttons available that will commence the calibration of the touch-screen. Select the button labelled with the two (2) point (pt) number and follow the instructions on the screen

From a comfortable operating position, touch the screen at the points indicated and allow the calibration to complete.

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3.5 Shutting Down the System

Shut down the system by pressing the Exit button in the lower right corner of any screen in the application. The **Start Up** Screen (Figure 3-2) is displayed. Press the Exit button on the **Start Up** Screen to display the Exit Confirmation screen, (Figure 3-4).

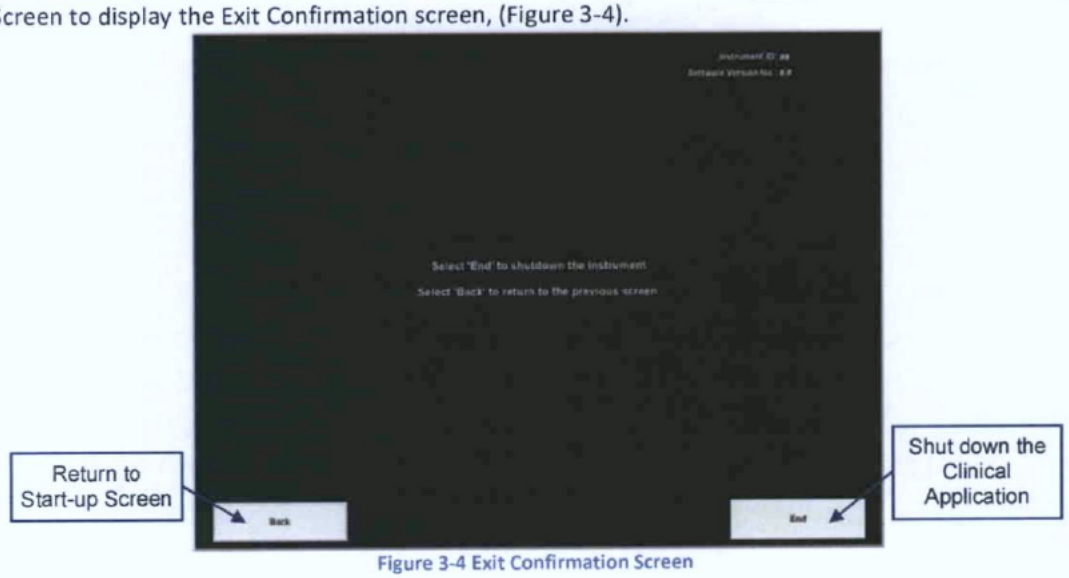
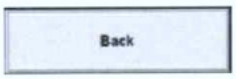
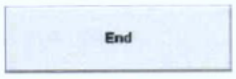


Figure 3-4 Exit Confirmation Screen



Terminates the software application. Displays a **System Termination** splash screen, (Figure 3-5), that remains visible until all system termination activities are complete. The system then displays the **Logon** screen, (Figure 3-1).



Return to the **Start Up** screen.

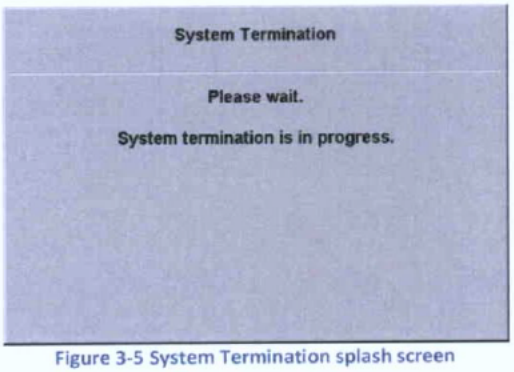


Figure 3-5 System Termination splash screen

Press Turn off computer on the screen to power down the system.

3.6 Backup and Archiving

It is strongly recommended to regularly back up the data stored on the CEIS by copying Procedure Results onto CD using the Export Procedure Results function (Section 5.2.1).

In the event that the data storage medium of the CEIS fails, the Procedure Results stored on CD may be used to rebuild the instrument database by importing the saved Procedure Results.

Caution:
Failure to make backup copies may result in data loss in the event of an instrument failure or malfunction.

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4 CLINICAL: ACQUISITION MODE

The Acquisition mode is used to collect images and contextual information of a Subject during a Procedure. The workflow through the acquisition screens is shown in Figure 4-1.

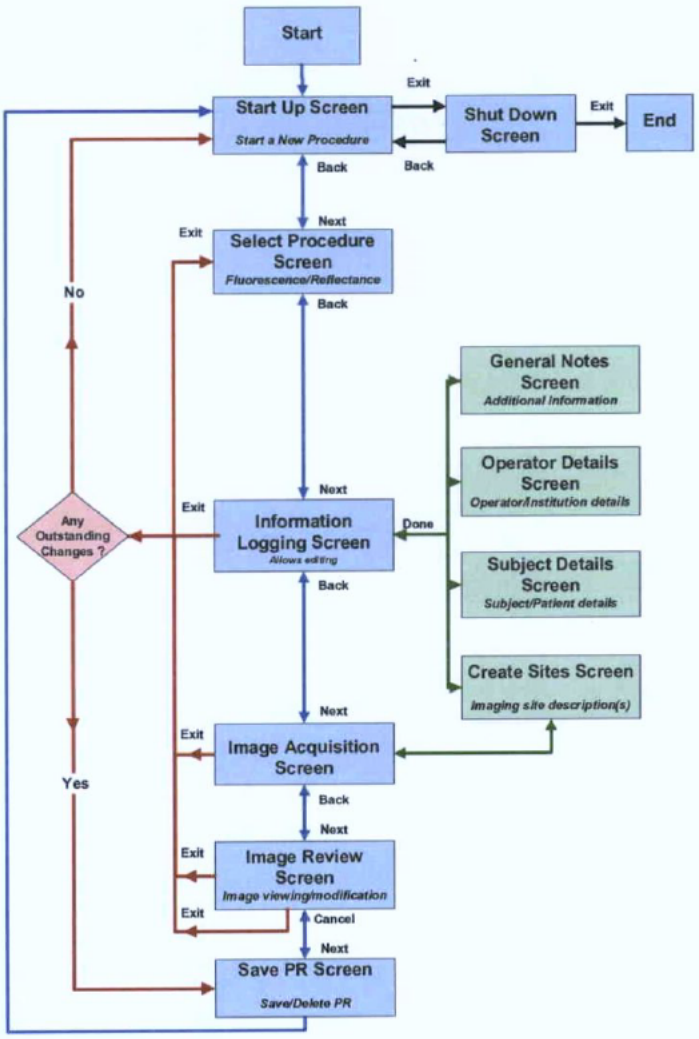

Figure 4-1 Clinical Acquisition mode flowchart

Press Start A New Procedure on the **Start-up** screen (Section 0) to start a new Imaging Procedure.

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4.1 Selecting a Procedure Name

Use the Select Procedure screen (Figure 4-2) to select the required imaging procedure from the Available Procedures list.

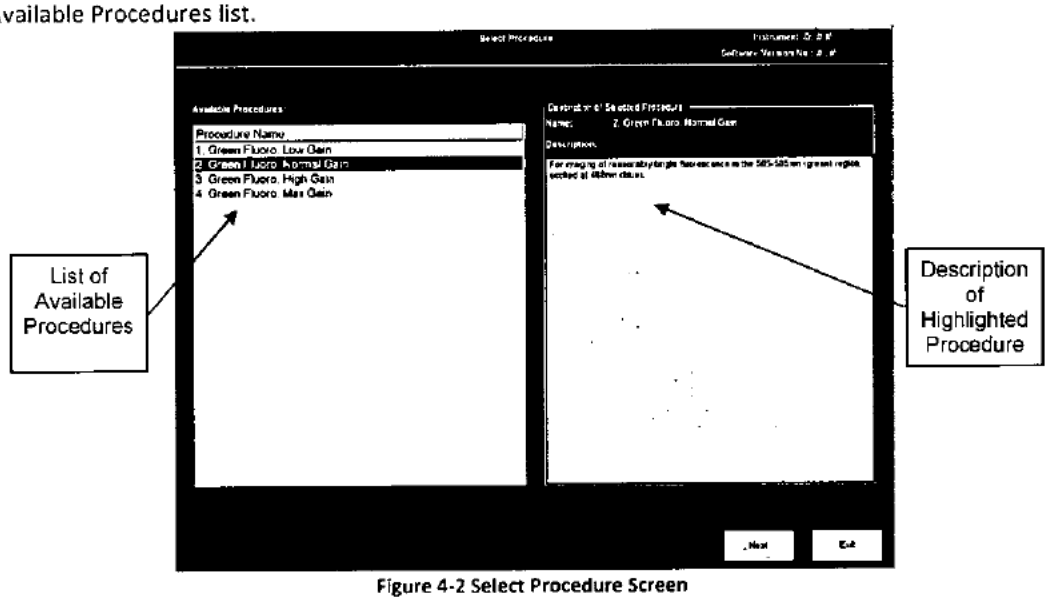

Figure 4-2 Select Procedure Screen

There are four procedure types for acquiring images:

Green Fluro, Low Gain	Used for imaging unusually bright fluorescent emission from the specimen in the range 505-585nm, illuminated with 488nm incident light.
Green Fluro, Normal Gain	Used for imaging reasonably bright fluorescent emission from the specimen in the range 505-585nm, illuminated with 488nm incident light.
Green Fluro, High Gain	Used for imaging dim fluorescent emission from the specimen in the range 505-585nm, illuminated with 488nm incident light.
Green Fluro, Max Gain	Used for imaging very dim fluorescent emission from the specimen in the range 505-585nm, illuminated with 488nm incident light.

All procedures enable imaging of green fluorescence, using 488nm incident light to illuminate the specimen, with detection of fluorescent emission from the specimen in the range 505–585nm.

The default procedure for capturing images is "Normal Gain". However, the appropriate level of gain required for each instrument combination should be determined by following the procedure for sensitivity testing using standard fluorescent test cloth outlined in the Owner's Manual (Section 5.3).

Select the required procedure by highlighting the Procedure Name from the **Available Procedures** list on the left side of the screen. A description of the highlighted Procedure Name is displayed on the right side of the screen. Press Next to continue when the required Procedure Name is highlighted. The **Information Logging** screen appears (Section 4.2).

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4.2 Entering information about the Procedure

The **Information Logging** screen (Figure 4-3) is a menu selection screen to open other data-input screens and enter the optional identifying information (Section 3.1) associated with the current Imaging Procedure. It also displays a summary of the session information at the top left-hand corner of the screen. Any information entered may be reviewed or edited at any time during the Imaging Procedure by returning to the **Information Logging** screen.

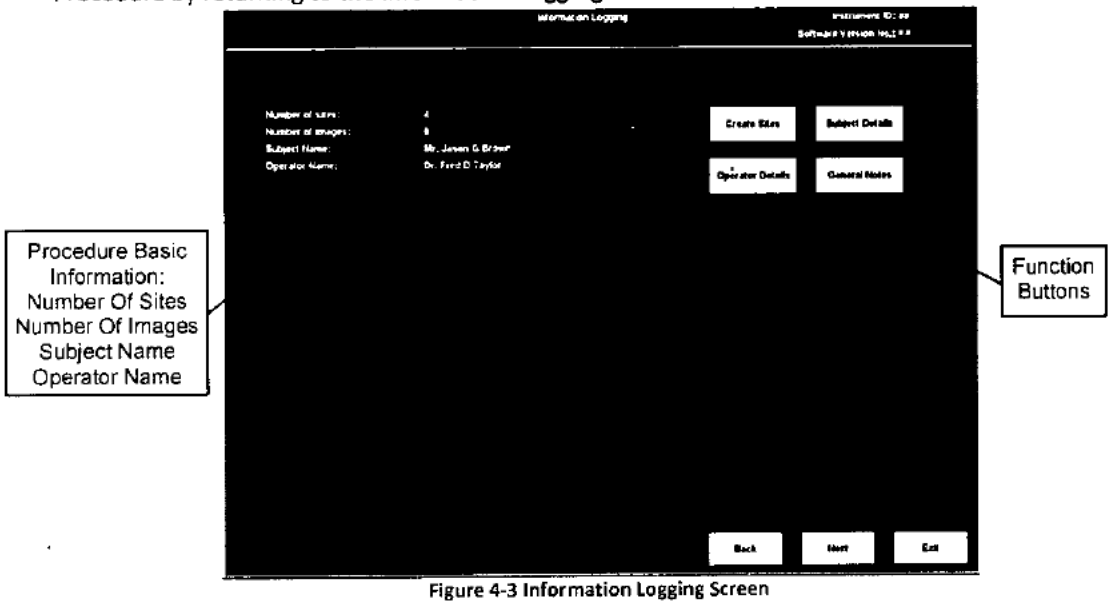

Figure 4-3 Information Logging Screen

The four function buttons located in the top right-hand corner of the screen open further screens specific to each information type.

Create Sites	Create one or more new Sites for the current procedure (Section **4.2.1**). By default, an imaging session must have a minimum of one site (**SITE_1**).
Subject Details	Enter or edit details about the Subject (Section 4.2.3).
Operator Details	Enter or edit details about the Operator (Section 4.2.2)
General Notes	Enter or edit general notes about the Procedure (Section 4.2.4).

Press each function button to open another data-entry screen respectively. To edit previously entered data, highlight the information to be changed, and over-type it with the correct data using the keyboard. If the current information displayed requires editing, overtype it using the keyboard with the correct details. Some fields have a size limit that is appropriate for the kind of information normally entered. Closing a data-entry screen re-opens the **Information Logging** screen.
It is strongly recommended to create logical Site Descriptions and enter information such as Subject ID, Surname, First Name in the respective data-entry screens to better identify results and images at a later time.

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When all relevant Site, Subject, Operator, and Note details have been entered using the respective data-entry screens, press Next to proceed to the **Image Acquisition** screen (Section 0).

Note:
Initially the Next button is inactive as the instrument self-calibrates. It becomes active when the calibration step is complete.
In Review Mode, the Create Sites button is replaced by a Site Details button. The Site Details button opens a **Create Sites** screen (Figure 4-4).
The session information at the top left-hand corner of the screen contains three additional text fields in Review Mode. These include **Session Unique ID**, **Procedure Results Creation Date** and **Instrument ID**.

4.2.1 Create Sites Screen

The **Create Sites** screen (Figure 4-4) is used to name or label one or more imaging sites where information may be entered about individual sites or features that are imaged during the current Imaging Procedure.

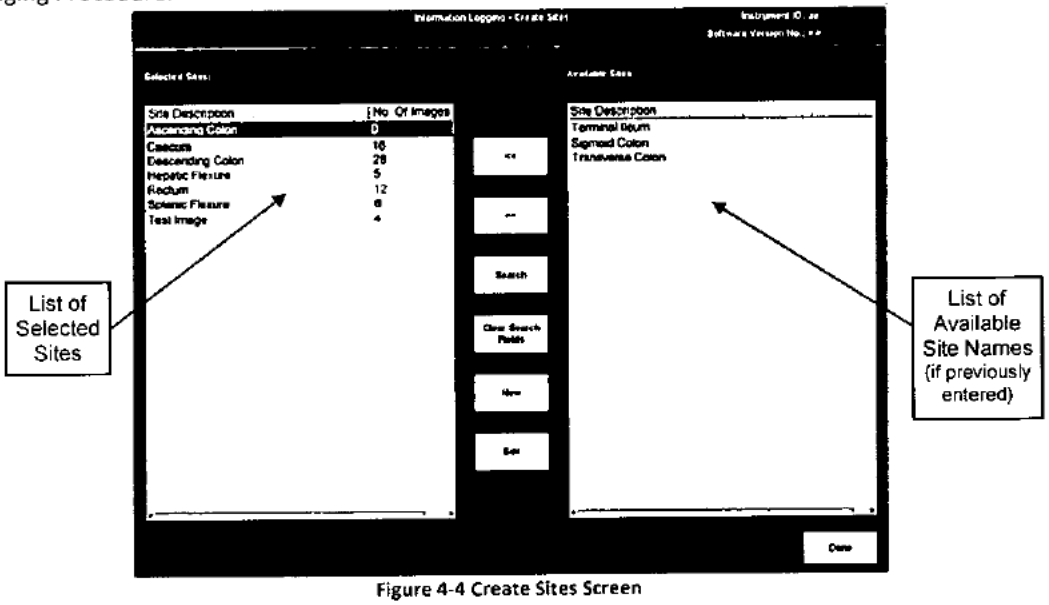
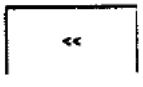


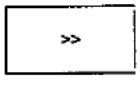
Figure 4-4 Create Sites Screen

Each Imaging Procedure may include several imaging Sites. When images are captured, they are associated with an imaging site to allow the operator to identify where images were captured (e.g. names of anatomical sites may be used). Multiple Site Names may be entered for any session, and multiple images can be captured and associated with the respective Sites.
Previously entered Site names are shown in the **Available Sites** list. They may be searched for, selected and added to the **Selected Sites** list for the current procedure. Alternatively new names may be added.

The six buttons located down the centre of the screen control the selection, searching, creation, and editing of Sites.



Select the highlighted Site name from the **Available Sites** list and add it to the **Selected Sites** list for the current procedure.



Deselect the highlighted Site name from the **Selected Sites** window to remove unwanted Site names for the current procedure.

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Search

Search for Site names in the **Available Sites** list. Type the required Site name into the **Site Description** field and press the ENTER key. Any partial matches found will be displayed. If there are no matching entries in the database, a message box appears. All the search fields are cleared and all available Site names in the database are shown.

Clear Search Fields

Clear the **Search Fields** to reset the search filter applied to the **Available Sites** list. All Site names in the system are now displayed in the **Available Sites** list.

New

Create a new Site name. Type the Site Description into the field provided in the **Edit Site** box and press OK. Any Site name that has been entered remains in the database and can be selected from the **Available Sites** list.

Edit

Edit the Site highlighted in the **Selected Sites** window. To rename Sites, highlight the desired Site name in the **Selected Sites** list and press Edit. Type the new Site Description into the field provided in the **Edit Site** box and press OK. Any images in the current procedure formerly associated with the original Site Description are now associated with the new Site Description instead. The original Site Description is removed from the current session, but remains in the **Available Sites** list. Stored Procedure Results are unaffected.

The **Create Sites** screen always has at least the default label **SITE_1**. If no Site Description is entered then all otherwise unidentified images are saved with this label. The **SITE_1** site name may be removed from the current procedure by using >>. Site Description names cannot be deleted from the database using this application. Use care when typing in names to avoid typographical errors.
It is recommended to create as many intended Sites as anticipated before commencing a procedure to minimize interruptions during imaging. If additional Sites are identified during imaging they may be created during imaging.

<u>Note:</u>
Initially the Next button is inactive as the instrument self-calibrates. It becomes active when the calibration step is complete.
In Review Mode, the New button is replaced by a Replace button.
The Replace button swaps the Site highlighted in the Selected Sites list, with that highlighted in the Available Sites list.

4.2.2 Operator Details Screen

Operators can record their personal details to be associated with the current Imaging Procedure using the Operator Details screen (Figure 4-5).

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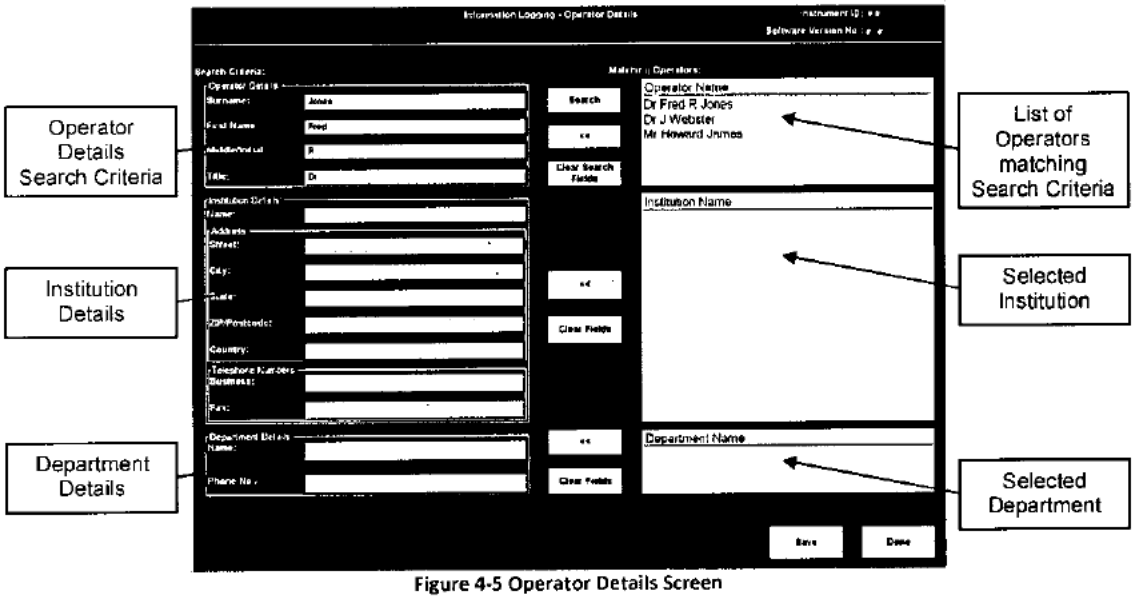

Figure 4-5 Operator Details Screen

<u>Note:</u>

New Operator details may be entered directly into the data fields. It is advisable to enter as many Operator details as possible to enable the correct Procedure Result to be identified and retrieved at a later time.

Search

Search for an Operator's details in the database. Type the search criteria into any of the **Operator Details** fields (e.g. **Surname**). The search function will accept partial details as search criteria. Press Search to display names that match the search criteria. If no match is found then the "No matching operator(s) found" message box is displayed.

<<

Copy an Operator's details from the database. Highlight the required Operator Name in the **Matching Operators** list and press << to fill in the **Operator Details** fields.

Clear Search Fields

Clear the search criteria fields and attempt another search.

Operator details can have Institution and Department details associated with them to better identify the Operator. It is not mandatory to select any Institution or Department details. Institution details that are available are listed in the **Institution Name** list. Department details that are available for a selected Institution are listed in the **Department Name** list.

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<<	Copy an Institution's details from the database. Highlight the required Institution Name in the **Matching Operators** list and press << to fill in the **Institution Details** fields.
<<	Copy a Department's details from the database. Highlight the required Department Name in the **Matching Operators** list and press << to fill in the **Department Details** fields.
Clear Search Fields	Clear the fields—do not associate an Institution's or Department's details with the Operator.

<u>Note:</u>
Institution and Department details cannot be added or updated by the Operator. Only a system administrator or Service Technician can set up these details.

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4.2.3 Subject Details Screen

Operators can record details about the Subject of the current Imaging Procedure using the Subject Details screen (Figure 4-6).

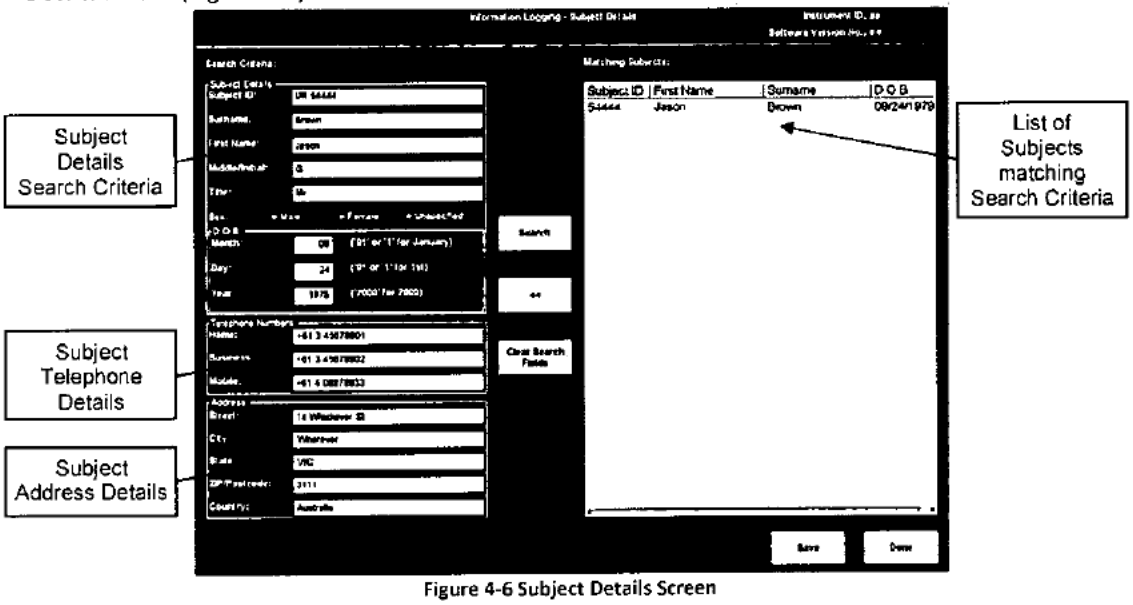

Figure 4-6 Subject Details Screen

Note:
New Subject details may be entered directly into the data fields. It is advisable to enter as many Subject Details as possible to enable the correct Procedure Result to be identified and retrieved at a later time.

Search

Search for a Subject's details in the database. Subject details information includes the Subject's ID, Surname, First Name, Middle Initial, Title, date of birth (D.O.B), Sex, Address and other contact information. Type the search criteria into any of the **Operator Details** fields (e.g. **Surname**). The search function will accept partial details as search criteria. Press Search to display names that match the search criteria. If no match is found then the "No matching operator(s) found" message box is displayed.

<<

Highlight the required Subject Name in the **Matching Subjects** list to copy a Subject's details from the database into the **Subject Details** fields.

Clear Search Fields

Clear the search criteria fields and attempt another search.

Note:
Subject details cannot be deleted using this application. Use care when typing in names to avoid typographical errors. Take great care particularly when entering the D.O.B. Month and Day details.

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4.2.4 General Notes Screen

Operators can record additional details about the Subject or Operator, or other miscellaneous information relating to the current Imaging Procedure using the General Notes screen (Figure 4-7).

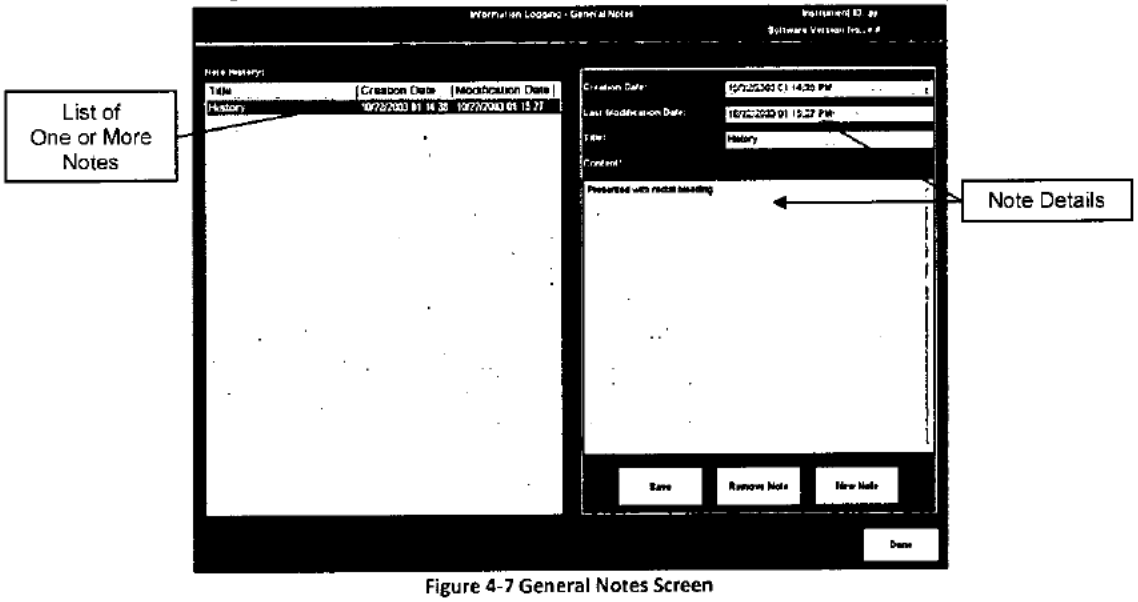

Figure 4-7 General Notes Screen

Notes may be viewed and edited by selecting the note of interest from the **Note History** list. The selected note is displayed, and may be edited directly. If a note is edited, the Modification Date (and time) will be updated to the current date and time.

New Note	Create a new note. A Title may be entered into the **Title** field, and free-form text typed into the **Content** field. More than one Note may be added, if required.
Remove Note	Delete unwanted Notes. Only one Note can be removed at a time.
Save	Store the Note. The stored Note will be added to the **Note History** list, and be displayed with an associated Creation Date (and time).

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4.3 Obtaining an Image

The **Image Acquisition** screen (Figure 4-8) is used to manage the acquisition of images relating to the current Imaging Procedure.

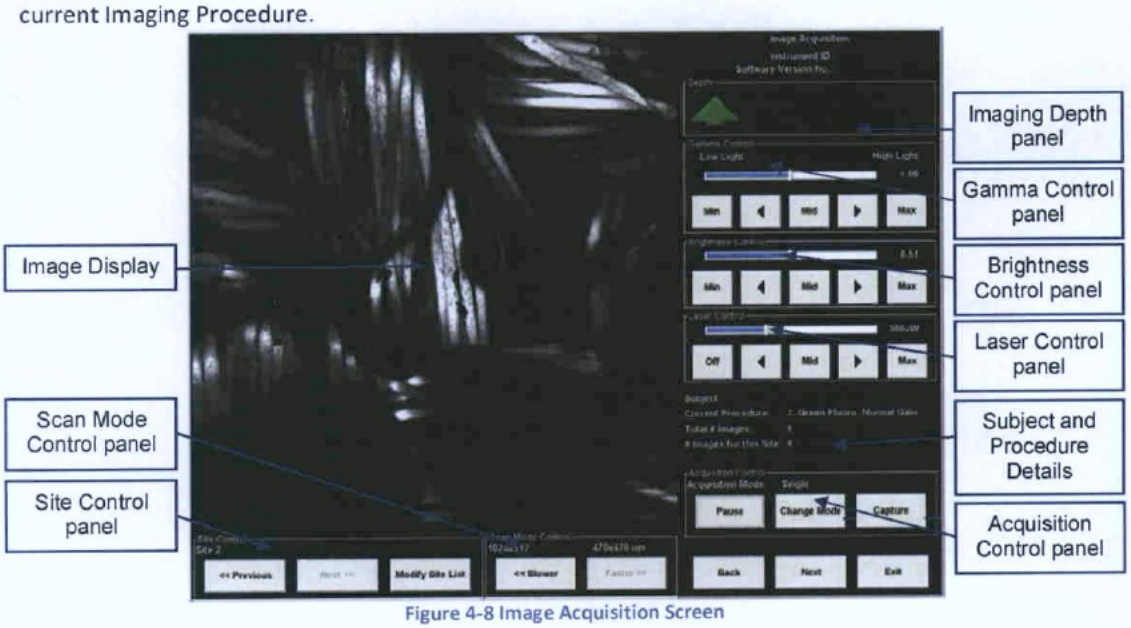

Figure 4-8 Image Acquisition Screen

The main functions relating to Image Acquisition are controlled by buttons and sliders grouped within function panels located on the right side and at the bottom of the screen.

Control Panel	Use	Section
Laser Brightness Gamma	Modify the appearance of the displayed image. Capture a displayed image when its appearance is satisfactory.	4.3.3 4.3.4 4.3.5
Scan Mode	Adjust the image update rate.	4.3.2
Acquisition	Pause updating and hold the displayed image. Select the capture mode. Capture the currently displayed image.	4.3.7
Site	Select Site where captured images are attached.	4.3.1
Imaging Depth	Information about focal plane depth.	4.3.6

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4.3.1 Site Control

Captured images are associated with Site Descriptions. Use the **Site Control** panel (Figure 4-9) to select the current Site for captured images.

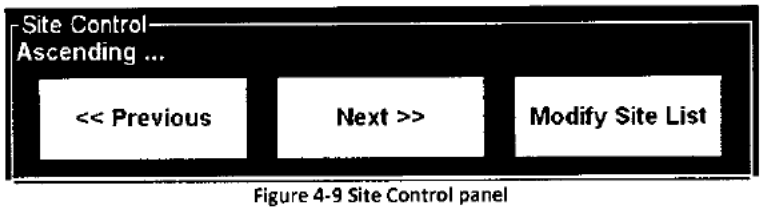

Figure 4-9 Site Control panel

Choose the desired image Site from those created previously (Section 4.2.1) using the << Previous and Next >> buttons. Once a site is selected, any images that are subsequently captured will be associated with the selected site (i.e. the desired site must be selected before the image is captured). It is possible to move between Sites whilst imaging in Single Mode to allow multiple sequences of imaging for a given Site.

Add or modify Site Descriptions (Section 4.2.1) by pressing the Modify Site List button to access the **Create Sites** screen. Modify the Site Descriptions as required and highlight the one to be used.

Press Done to return to the **Image Acquisition** screen and use the highlighted Site Description.

Note:
Images are associated with the ***currently*** selected site (created beforehand, Section 4.2.1) when captured, so it is important to select the correct site ***before*** capturing any images.

4.3.2 Scan Mode Control

The **Scan Mode Control** panel (Figure 4-10) located in the centre bottom of the **Image Acquisition** screen controls the image scan speed and the resulting resolution and field of view.

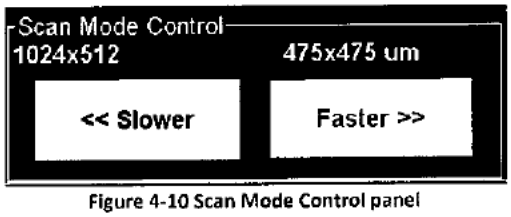

Figure 4-10 Scan Mode Control panel

Use the << Slower and Faster >> buttons to change the scan mode to decrease or increase the scan speeds available (Table 4-1). Switch to the **Faster** scan speed to search more efficiently for a region of interest. Switch back to the **Slower** scan speed to capture images with the higher resolution.

Resolution (pixels)	**Field of view** (µm approx.)	**Scan Speed** (frames per second approx.)
1024 x1024	475 x 475	0.7
1024 x 512	475 x 475	1.2

Table 4-1 Scan Modes available

The Field of View of approximately 475 x 475µm may vary by ±50µm when the system is operated in an environmental temperature range of 10°C to 30°C. If the system is operated at temperatures between 31°C to 40°C the system will continue to scan and obtain an image but with a Field of View that may exceed 475 x 475±50µm.

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4.3.3 Laser Control

The intensity of the detected signal is generally proportional to the intensity of the laser light used to illuminate the site, within the bounds of the fluorescence properties of the site.

The laser power setting is very important to obtain the best quality image. The "ideal" laser power setting gives a full dynamic range image (i.e. on-screen image features range from black to just white) when the brightness control is set to minimum (using the Min button). It may not always be possible to image under ideal conditions.

<u>Note:</u>
When operating in fluorescence mode, excessive laser power may cause photo-bleaching and saturation of fluorescence that can limit the contrast of the image regardless of increase in laser power and an associated reduction in image quality.

Use the Laser Control panel buttons and slider to set an appropriate laser output power level (Figure 4-11) located on the right side of the Image Acquisition screen.

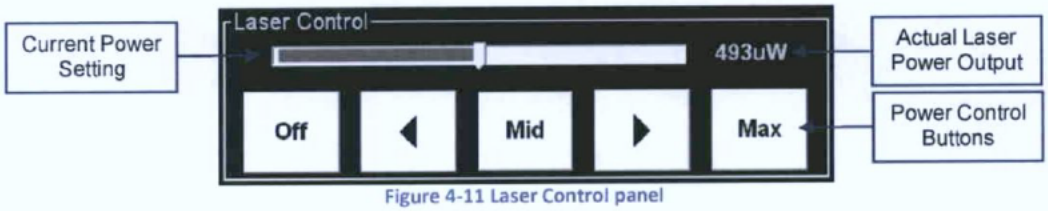

Figure 4-11 Laser Control panel

Laser power output at the confocal endomicroscope tip is displayed in microwatts (µW) to the right of the laser power slider control (Figure 4-11). The slider controls the overall output power linearly. Set the laser power output by using the buttons as follows.

▶	Press momentarily—to increase power output in approximately 5 µW increments. Hold—to increase laser power output continuously.
◀	Press momentarily—to decrease Power output in approximately 5 µW increments. Hold—to decrease power output continuously.
Off	Put the laser in standby mode and reduce laser power output to 0 µW at the endomicroscope tip. This is the Default setting.
Mid	Set laser power output to 50% of maximum.
Max	Set laser power output to maximum.

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4.3.4 Brightness Control

Set an appropriate brightness value of the displayed image using the **Brightness Control** panel buttons and slider (Figure 4-12) located on the right side of the Image **Acquisition** screen.

Figure 4-12 Brightness Control panel

The brightness value of the image is displayed to the right of the brightness slider control. The slider controls the overall brightness of the whole image linearly. Set the image brightness by using the buttons as follows.

▶	Press momentarily—to increase Image Brightness in small increments. Hold—to increase Image Brightness continuously.
◀	Press momentarily—to decrease Image Brightness in small increments. Hold—to decrease Image Brightness continuously.
Min	Set Image Brightness to minimum.
Mid	Set Image Brightness to 50% of maximum. This is the Default setting.
Max	Set Image Brightness to maximum.

The increase brightness ▶ button makes the whole image brighter, but may lead to saturation of the brightest structures. The decrease brightness ◀ button makes the whole image dimmer. Once the brightest structures are just displayed as pure white, lower intensity structures may be emphasized and de-emphasized using the **Gamma Control**.

<u>Note:</u>
This control affects the way that the measured data is displayed. It does not affect the intensity of the signal being measured (as laser power does).

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4.3.5 Gamma Control

The Gamma value of an image controls the display of the mid-level grey regions of the image, without changing the lightest and darkest areas within the image. It can be used to emphasize or de-emphasize the middle grey values.

Use the **Gamma Control** panel controls to set the relative brightness value of lower intensity components of the displayed image (Figure 4-13) located on the right side of the **Image Acquisition** screen.

The default setting for the Gamma value is 1.00, which neither emphasizes nor de-emphasizes the mid-grey levels.

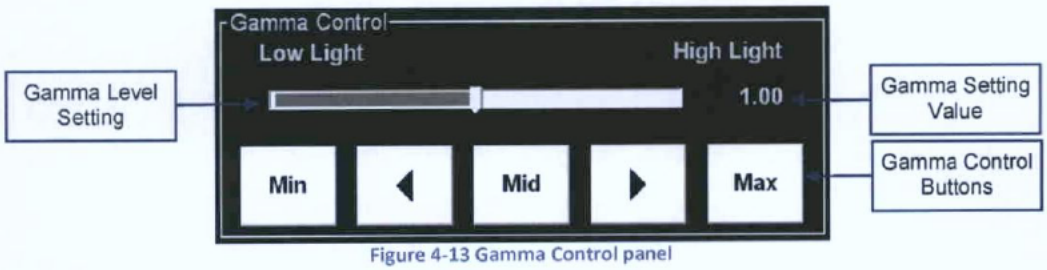

Figure 4-13 Gamma Control panel

The Gamma value of the image is displayed to the right of the gamma slider control. The slider controls the overall Gamma value of the image linearly. Set the image Gamma value by using the buttons as follows.

▶	Press momentarily—to increase Gamma value in small increments. Hold—to increase Gamma value continuously. Brightens the grey regions of the image, highlighting the lower intensity regions of the image (High Light), without altering the brightest structures.
◀	Press momentarily—to decrease Gamma value in small increments. Hold—to decrease Gamma value continuously. Darkens the grey regions of the image (Low Light), effectively reducing the overall contrast of the image.
Min	Sets Gamma value to minimum.
Mid	Set Gamma value to mid level. This is the Default setting.
Max	Set Gamma value to maximum.

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4.3.6 Image Depth

The appropriate controls on the confocal endomicroscope control body adjust the imaging depth of the of the focal plane in the tissue, which influences the appearance of the displayed image.

The operation of the depth controls is described in the relevant confocal endoscope Owner's Manual. The depth control footswitch has two functions. When clicked once, the "Home" button moves the imaging plane to the Home position near the surface of the tissue. The other footswitch button provides control of movement and direction of travel. It may be double-clicked to change direction, which will be indicated in the on screen Depth panel (Figure 4-14). The movement depth control may be operated using single clicks to move in small 4µm increments, or press and hold to move at approximately 10µm per second.

Figure 4-14 Depth panel

The icon or picture on the left of the Depth panel, displays the current direction of travel and position of the focal plane or the calibration mode of the Z Depth system.
A single text item may be displayed adjacent to the Depth Direction/motion arrow, indicating the Depth Position and Calibration Status. These depth indicators are summarised as follows:

Image Depth Status			
Direction UP	**Direction Down**	**Displayed Text**	**Position & Calibration Status**
		Home	Focal plane at the surface of the tissue positioned just in front of the external surface of the confocal imaging window.
		Upper Limit	At its fully retracted position within the confocal endoscope.
		Deep	Deepest imaging position.
		Calibrating	Performing calibration to ensure the accuracy of the displayed focal plane position.
		Uncalibrated	Unable to display an accurate focal plane position.
		Standby	Power saving mode, the focal plane will be at the deepest position.
		no text	Calibrated and operating normally. Focal plane position between Upper Limit and Deep and not at Home position.

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4.3.7 Acquisition Control

The **Acquisition Control** panel buttons (Figure 4-15) control the Image acquisition mode and capture images. Images are displayed on the screen but are not acquired unless Capture or Start Capture is pressed.

Figure 4-15 Acquisition Control panel

Images can be captured using either of two modes, Single mode (Section 4.3.7.1) and Movie mode (Section 4.3.7.2). Single mode captures a single image at a time. Movie mode acquires a continuous sequence of individual images. In both modes when images are captured the files are written directly to the hard disk, and the images are associated with the currently selected site (Section 4.2.1).

When sufficient images have been captured, press Next to proceed to the **Image Selection** screen to review and store images (Section 4.4).

4.3.7.1 Single Mode

Single mode acquires or captures displayed images one at a time.

Pause	Pause image updating and holds the current image. Button changes to Scan.
Scan	Continue updating images on the screen. Button changes to Pause.
Change Mode	Switch to **Movie** mode.
Capture	Capture the last fully scanned image. The footswitch can also be used.

<u>Note:</u>
Scanning still occurs and laser light is been emitted from the confocal endomicroscope tip even when image updating is paused.

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4.3.7.2 Movie Mode

Movie mode acquires or captures displayed images sequentially when the capture is active. The result is a series of sequential single images (**not** a movie file) for the duration of the capture.

Pause	Pause image updating and holds the current image. Button changes to Scan.
Scan	Continue updating images on the screen. Button changes to Pause. Note: Movie capture mode does not re-start if paused previously.
Change Mode	Switch to **Single** mode.
Start Capture	Start a movie capture sequence. Button changes to Stop Capture. The time between each image depends on the Scan Mode selected (Section 4.3.2).
Stop Capture	Stop a movie capture sequence. Button changes to Start Capture. Images keep updating

Note:
Scanning still occurs and laser light is been emitted from the confocal endomicroscope tip even when image updating is paused.

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4.4 Reviewing Current Procedure Images

The **Image Selection** screen is reached by pressing Next on the **Image Acquisition** screen (Section 0). This screen initially displays a tiled view of all images captured during the current Imaging Procedure, the Multiple Images view (Section 4.4.1). Double-click an image to display it full screen in the Single Image view (Section 4.5).

The **Image Selection** screen always displays an **Acquired Images** tree structure down the left hand side of the screen comprising the current Imaging Procedure, Sites belonging to this Imaging Procedure, and all images associated with each of the Sites.

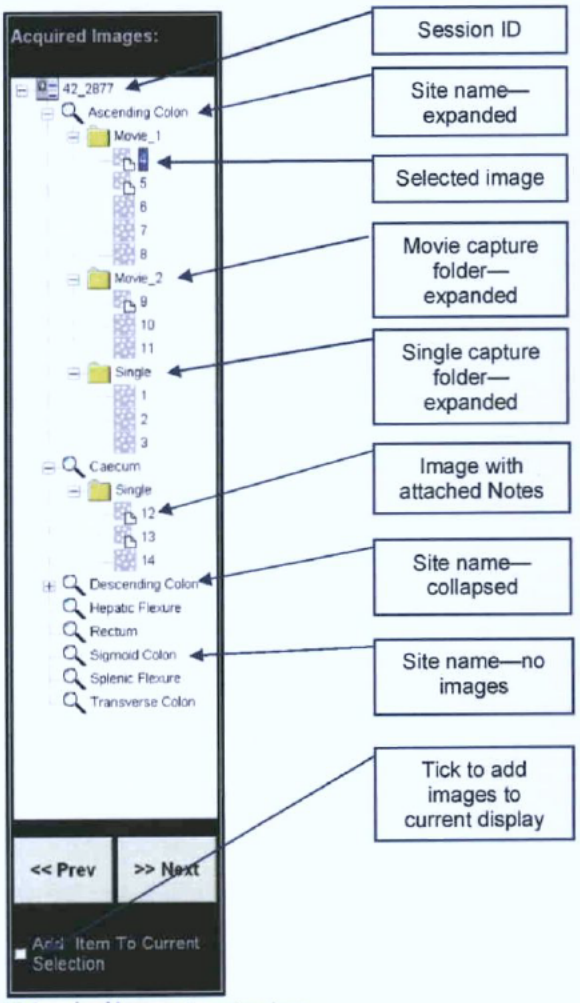

Figure 4-16 Acquired Images tree structure

Each Site in the image tree can contain one Single folder and one or more Movie folders. A Single folder holds Single Mode images. A Movie folder contains one set of Movie Mode images, i.e. a sequential set of still images captured over a period of time.

Choose between viewing multiple images together, or viewing and modifying individual images. Double-click the image of interest to toggle between single view and multiple view.

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4.4.1 Select and View Multiple Images

Selecting a Site name from the Acquired Images tree displays all of the images captured at that site in a tiled view in the middle section of the screen (Figure 4-17).

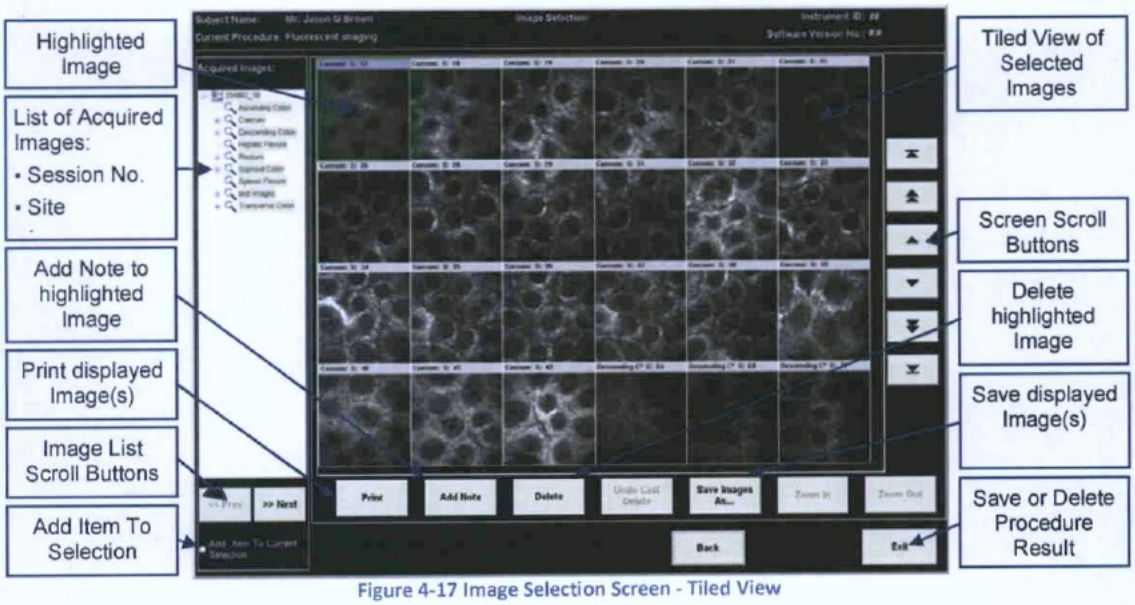

Figure 4-17 Image Selection Screen - Tiled View

Use the **Add Item To Current Selection** checkbox to select or deselect multiple images from anywhere within the **Acquired Images** tree. With the checkbox ***unticked***, each selection overwrites the display area. For instance, select (using the mouse pad, touch screen or keyboard) a folder to display all images in the folder, select a single image from the tree to display one image (full screen).

With the checkbox ***ticked***, each selection adds images or sites to the display area. As each folder or image is selected, images are added to the display. If a selected folder or image is re-selected then the highlight is removed and the associated image(s) are no longer displayed. Use this process to display only the images of interest, and to save them to image files (Section 0).

The **Image Selection** screen can display up to 24 images on the screen in the tiled view. If more than 24 images are selected, the scroll buttons on the right hand side of the screen (Figure 4-18) become active. Use these to scroll the screen through the images.

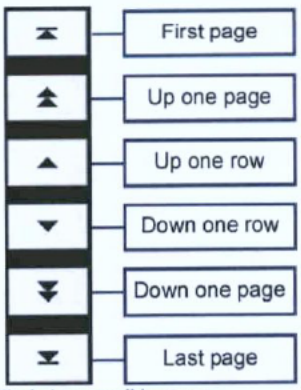

Figure 4-18 Tiled view scroll buttons

View single images within the selection by double-clicking on the desired image in the tiled display. Return to the tiled view by double-clicking on the single image.

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4.5 Select and View Single Images

The **Image Selection** screen (Figure 4-19) is used to review and modify single images from the **Acquired Images** tree.

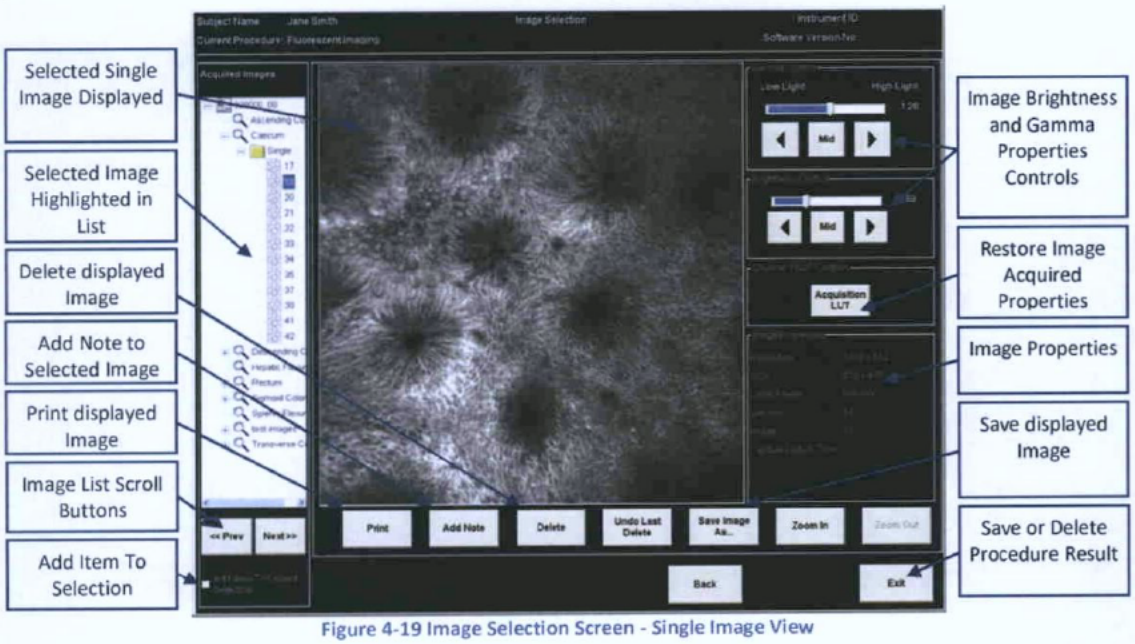

Figure 4-19 Image Selection Screen - Single Image View

Selecting one single image from the **Acquired Images** tree displays that image in large single image format (Figure 4-19) so it may be examined in more detail. The image properties (resolution, field of view, laser power, unique session identification number, image sequence number, and capture date and time) are displayed beside the image in the Image Properties panel.

<< Prev	Scroll backwards through each individual image in the **Acquired Images** tree. The Image Properties panel updates for each image.
Next >>	Scroll forwards through each individual image in the **Acquired Images** tree. The Image Properties panel updates for each image.
Brightness Controls	Modify the Brightness of the display properties of individual images (Section 4.3.4). Any changes made to the individual image are automatically saved upon exiting the screen.
Gamma Controls	Modify the Gamma value of the display properties of individual images (Section 4.3.5). Any changes made to the individual image are automatically saved upon exiting the screen
Acquisition LUT	Restore the Brightness and Gamma value settings of the original captured image
Zoom In	Enlarge digitally the displayed image.

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Zoom Out	Reduce digitally the displayed image.
Delete	In Multiple images view: Delete a selected image—one at a time. In Single image view: Delete a displayed image—one at a time. To select an image: • display the image in single display view, • select it from the **Acquired Images** tree, • select it within the tiled display view. Images saved with a Procedure Result can also be reviewed for deletion at a later time.
Undo Last Delete	Reverse the delete action, and recover multiple images—one at a time.
Print	A dialog box allows the selection of the target printer and other options and features associated with printing images. These printer functions are not supported on current release.
Add Note	Add Notes to the selected Image (Section 0).
Save Image As...	The **Save Image(s) As...** function allows displayed images to be saved as files at nominated locations in multiple formats (Section 0).
Add Item To Current Selection	When ticked, allows multiple images and folders to be selected in the **Acquired Images** tree, and associated images to be displayed.

Note:
The Brightness and Gamma settings of the original captured image are always saved with the image, and are exported with the image during the Export process (Section 5.2.1), along with other information (Section 3.1).

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4.5.1 Adding Notes to Images

The Image Notes screen (Figure 4-20) is used to attach notes to an individual image. This screen is available by pressing Add Notes on the Image Selection screen (Section 4.5). In contrast, General Notes (Section 4.2.4) attaches Notes to the Procedure Results. To select an image:

- display the image in single display view,
- select it from the Acquired Images tree,
- select it within the tiled display view.

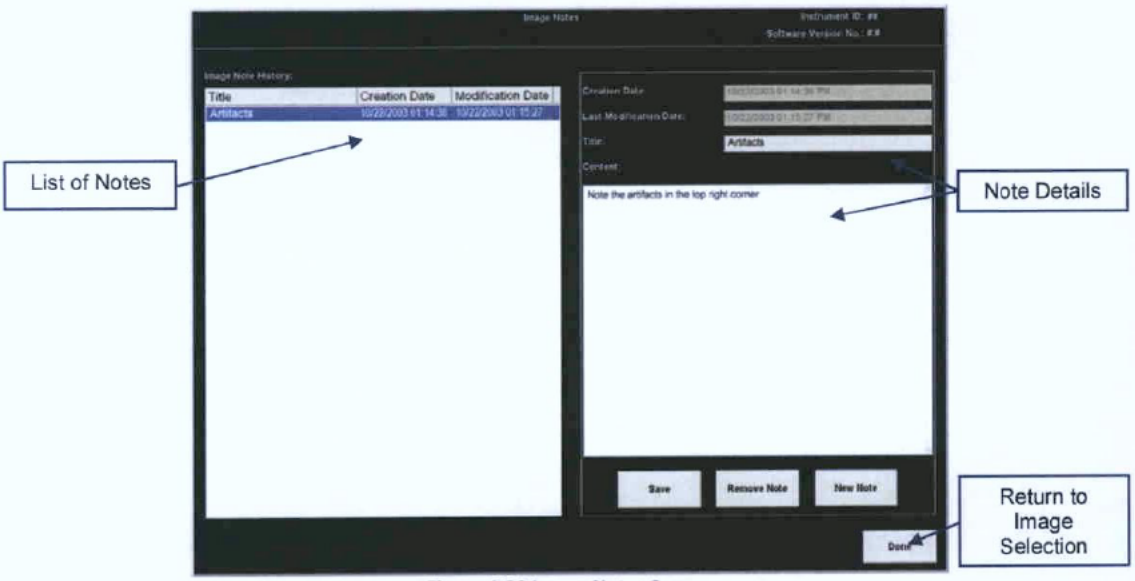

Figure 4-20 Image Notes Screen

To edit a note, select the note from the **Image Note History** list (Section 4.5). This will display the notes details on the right hand pane of the screen. Enter changes in the **Title** and **Content** fields and press Save. Once an edited note is saved, the date and time of modification is updated in the **Modification Date** field.

New Note	Create a new note. A Title may be entered into the **Title** field, and free-form text typed into the **Content** field to identify and describe the image.
Remove Note	Delete unwanted Notes. Only one Note can be removed at a time.
Save	Store the note. The stored note is added to the **Note History** list, and displayed with an associated **Creation Date** and time.

Press Done to return to the Image Selection screen. All images with notes will appear in the Acquired Images tree with a note icon attached to them. This icon signifies that there are one or more notes associated with the image (Figure 4-16).

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4.5.2 Saving Images

The Save Image As function saves the image(s) displayed in the Image Selection screen (Figure 4-17 and Figure 4-19) to nominated locations in any of the supported image file formats (Table 4-2).

Note:
The Save Image As function does not backup or archive. Refer to Section 3.6 to backup or archive.

Select the multiple images (Section 4.4.1) or single image (Section 4.5) to be saved. Press Save Image As... on the **Image Selection** screen (Section 4.5) to bring up the **Save current image as...** prompt (Figure 4-21).

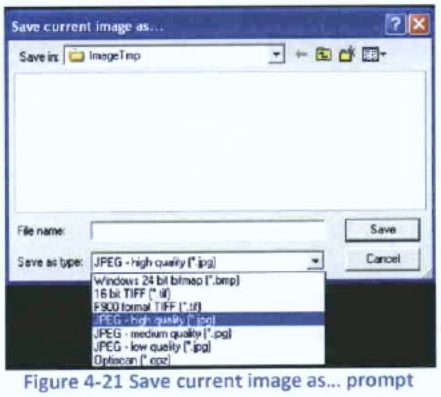

Figure 4-21 Save current image as... prompt

Enter a file name and optionally select a destination folder into the displayed message box. The default folder is ImageTmp on the D drive. Use the D drive for storing data temporarily. Alternatively use a formatted CD (Section 3.3). The **Save as type:** options are discussed in Table 4-2.

Caution:
Saving large numbers of image files to the instrument hard drive can result in an insufficient disk space condition (Section 7.4). Do not save any data in the C drive, as it only has enough space for the program and system files.

Images may be saved directly to a formatted CD (Section 3.3) by selecting the CD drive as the destination for the images to be saved. Leave the CD in the writer to allow multiple batches of images to be saved to the same CD.

When multiple images are selected (Section 2.2) the images are automatically saved as multiple separate files with a five digit incremented number appended to the file name specified (e.g. *Image00000.tif, Image00001.tif, ...*). The exception is the F900 format, which is a multi-image single-file format for backwards compatibility.

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This function ***only*** saves the image data and does not save any associated contextual information such as Subject Details, Operator Details, and so on. The available formats for the saved image files are standard so the files can also be electronically transported and used in other applications and documents such as reports and presentations. The 16-bit TIFF option is the best choice for image analysis and/or publication purposes.

File Type	Extension	Description of Image Format	Notes	File size[1]
Windows 24 bit bitmap	.BMP	Uncompressed Bitmap. 8x3 bit depth (so some loss of image information), single image. A very common image format in the Windows environment.	Saves the displayed image (8 bit) with some loss of image information. The saved image includes any brightness and gamma adjustments made by the Operator.	3 MB
16 bit TIFF	.TIF	Uncompressed Tagged Image File Format (TIFF). 16x1 bit depth (contains the maximum image information), single image.	This format saves the raw image data (12 bit) data only and is the best choice for image analysis and/or publication.	2 MB
F900 format TIFF	.TIF	Proprietary Uncompressed TIFF image format. 16x1 bit depth, multiple images.	Provided for compatibility with other proprietary instruments.	2.5 MB
JPEG – high quality	.JPG	Compressed jpeg format. 8x3 bit depth, single image. A compression algorithm reduces the file size at the cost of losing some quality. Best used when reduced file size is more important than the original image quality.	Minimal loss of quality.	~580 KB[2]
JPEG – medium quality	.JPG		Moderate loss of quality.	~90 KB[2]
JPEG – low quality	.JPG		Severe loss of quality.	~44 KB[2]
Optiscan proprietary	.OPZ	Optiscan proprietary image format.	All raw data is saved. Suitable for loading into ImageJ[3].	~2 MB[2]

[1] File sizes are given for a 1024 x 1024 image. Other image resolutions will result in different file sizes.

[2] These are nominal file sizes and may vary significantly. The actual file size depends on the compressible data content of the image.

[3] A third-party image analysis package.

Table 4-2 Supported Image File Types and Formats

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4.5.3 Printing Functions

A single image or a selection of images may be printed by selecting the Print button. The Print dialog box then opens, allowing the section of the target network printer, image print properties and options to print information associated with the selected images. A sample printed output is shown in Figure 4-24.

Note:
This option is only available if a printer is connected to the System.

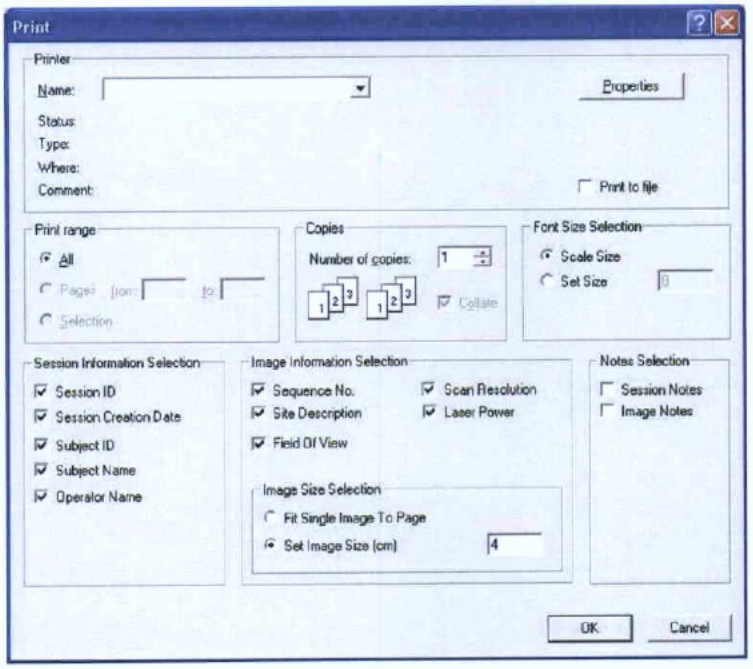

Figure 4-22 Print options

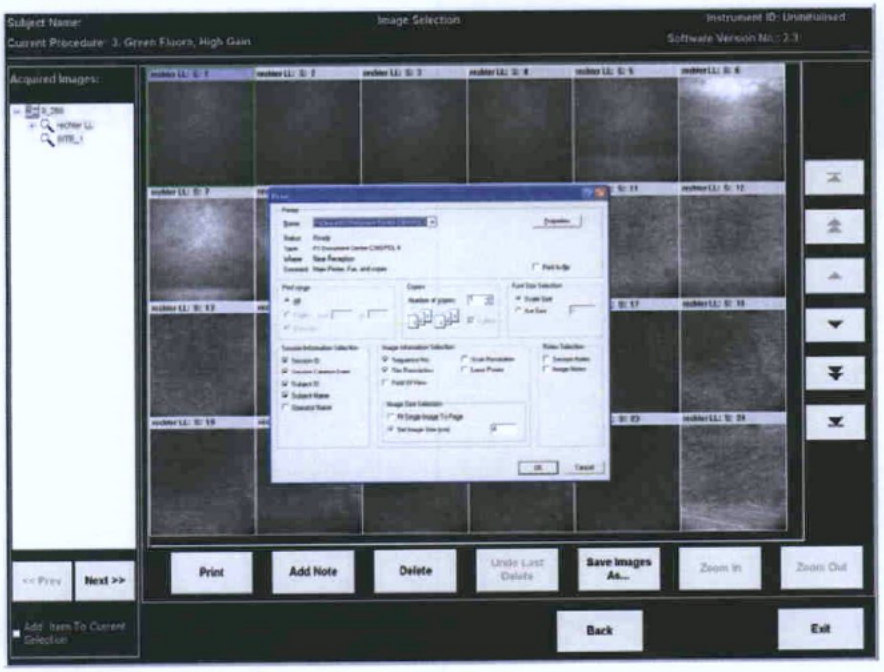

Figure 4-23 Print screen

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CEIS

SESSION INFORMATION

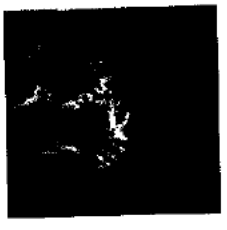
Session ID: 440000_10
Subject ID: 012345
Operator Name:

Session Creation Date: 10/10/2006 08:00:15 AM
Subject Name:

Seq No.: 119
Site: Descending colon
FOV: 500x500 um
Scan: 1024x512
Laser: 578 uW

Seq No.: 121
Site: Descending colon
FOV: 500x500 um
Scan: 1024x512
Laser: 578 uW

Seq No.: 47
Site: Sigmoid colon
FOV: 500x500 um
Scan: 1024x512
Laser: 489 uW



Seq No.: 52
Site: Sigmoid colon
FOV: 500x500 um
Scan: 1024x512
Laser: 295 uW

Figure 4-24 Print page

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4.6 Saving and Exiting the Procedure

Once a procedure is complete, decide whether it should be kept or discarded. Press Exit at the bottom right corner of the select screens to display the **Save Procedure Result** screen (Figure 4-25).

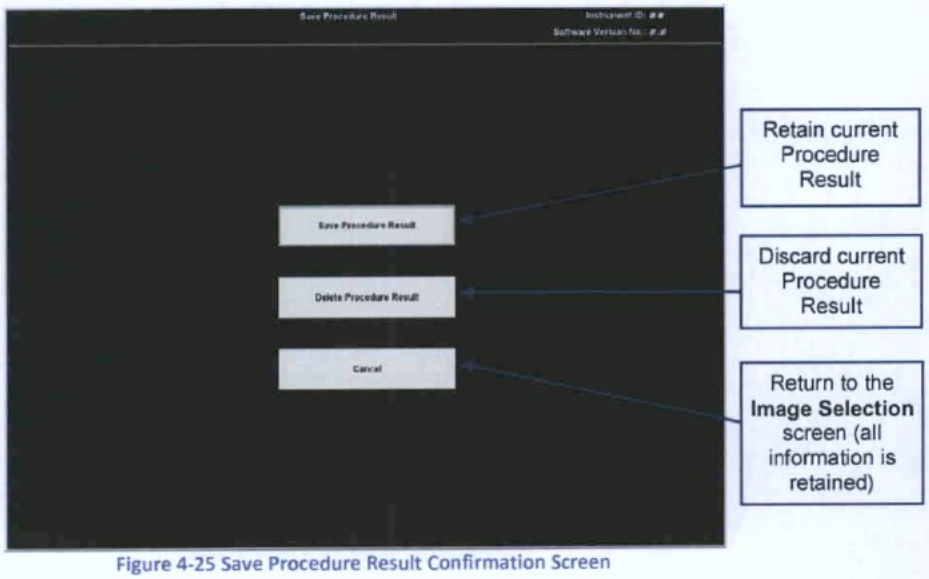

Figure 4-25 Save Procedure Result Confirmation Screen

Save Procedure Result	Save the Procedure Result and return to the **Start-up** screen (Section 0) to start a new Imaging Procedure. As a precaution, the current Procedure Result, including image changes and Notes, is automatically saved if there is a system failure prior to confirming the Procedure Result is to be kept.
Delete Procedure Result	Discard ***permanently*** the current Procedure Result and return to the **Start-up** screen (Section 0) to start a new Imaging Procedure.
Cancel	Return to the **Image Selection** screen without saving or deleting the Procedure Results.

Caution:
The **Delete Procedure Result** process is permanent—the Procedure Result is ***not*** saved and ***cannot*** be retrieved.

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5 CLINICAL: REVIEW MODE

Review mode is intended for examining and editing images and contextual information in a previously collected Procedure Result. The instrument itself does not need to have a confocal endomicroscope connected or operating. The workflow through the screens is shown in Figure 5-1.

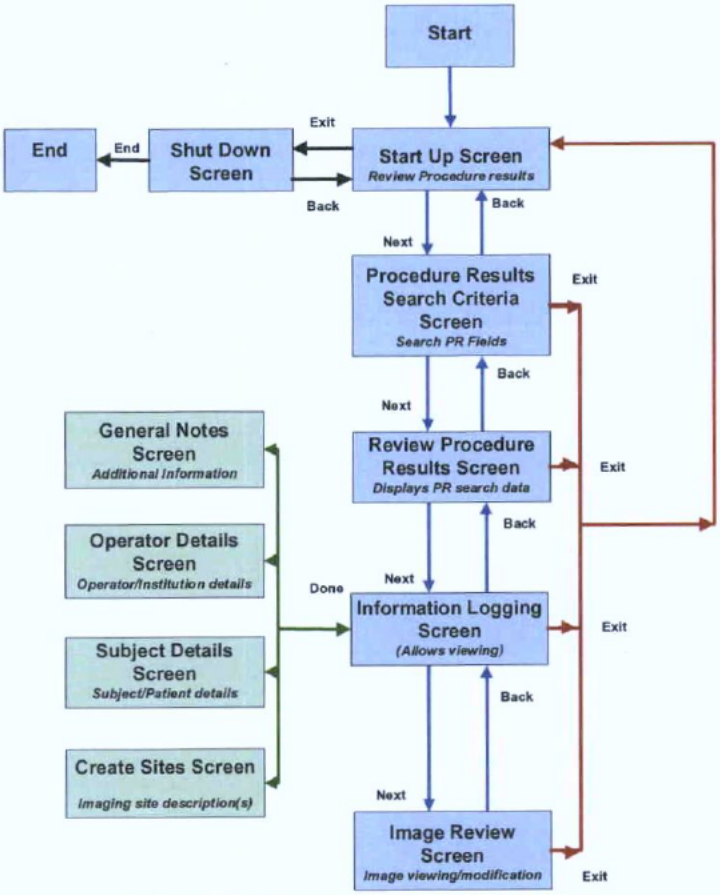

Figure 5-1 Save Procedure Result Confirmation Screen

Press Review Procedure Results on the Start-up screen (Section 0) to retrieve and review stored Procedure Results.

5.1 Searching for Procedure Results

Use the **Procedure Results Search Criteria** screen (Figure 5-2) to enter key words to search for Procedure Results.

To search the database for previously stored Procedure Results enter key subject details or partial details in the fields on this screen and press the Next button. To view the entire Subject database, simply press Next without entering any information in the search fields to proceed to the **Review Procedure Results** screen (Figure 5-3).

Note:
Entering partial search criteria will list more potential Procedure Results to review. Entering critical data such as Sex and Surname allows a more specific search to be performed. If a search does not result in any matches, a warning message is displayed with a request to re-enter valid search criteria. If no Procedure Results exist in the database, then a message will be displayed to indicate this.

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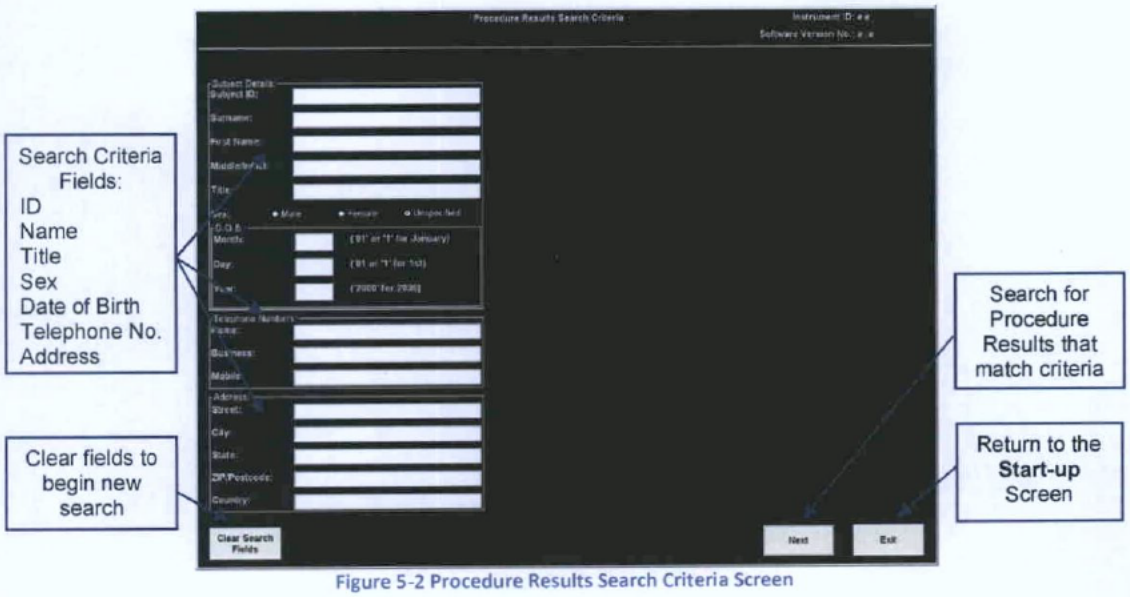

Figure 5-2 Procedure Results Search Criteria Screen

5.2 Managing Stored Procedure Results

The **Review Procedure Results** screen (Figure 5-3) displays the list of Procedure Results that match the search criteria entered at the **Procedure Results Search Criteria** screen (Section 5.1).

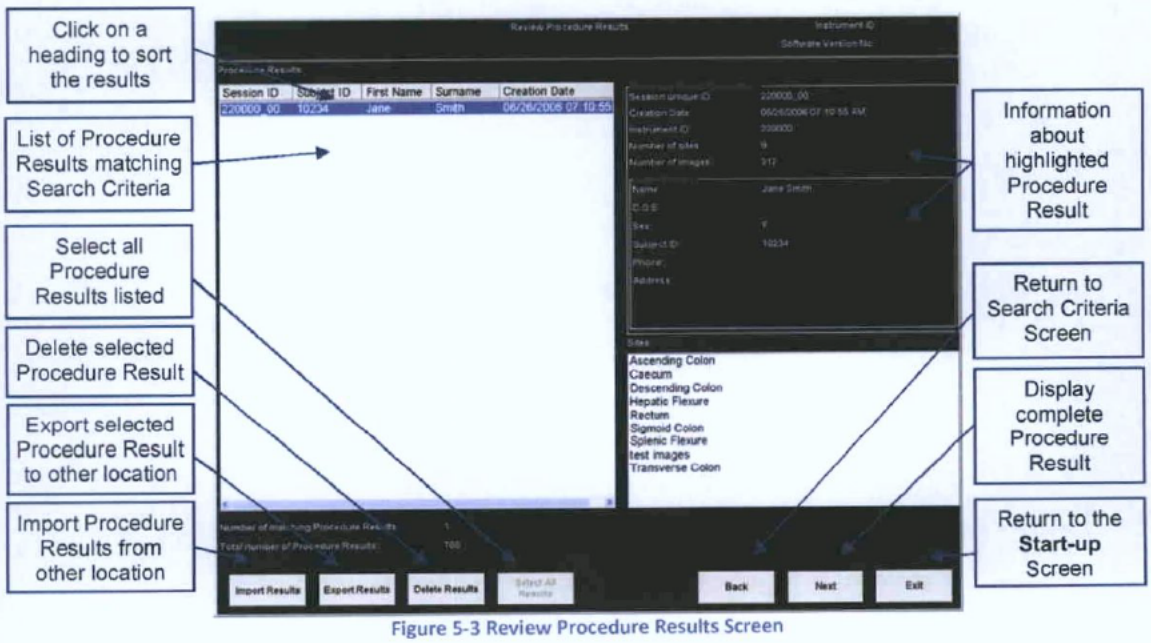

Figure 5-3 Review Procedure Results Screen

Use the arrow keys or the touch-pad to scroll through the Procedure Results list. Highlight a Procedure Result from the list to view its details. List entries may be sorted according to column headings by clicking on the column heading of interest.

To view and/or update the contextual information and images associated with a particular Procedure Result, highlight it from the list and press Next.

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Import Results	Import the Procedure Results from another location (Section 5.2.2).
Export Results	Saves or archives the selected Procedure Results to another location (Section 5.2.1). Button is inactive unless at least one Procedure Result is selected.
Delete Results	Deletes the selected Procedure Results (Section 0). Any Procedure Results no longer required may be removed from the database this way. Button is inactive unless at least one Procedure Result is selected.
Select All Results	Selects all the Procedure Results listed.
Next	Active only when a single Procedure Result is highlighted. Refer to Section 5.3. Allows review of the information in the highlighted Procedure Result.

5.2.1 Export Results

The Export function allows all data including images and contextual information (unlike the Save function, Section 2.2) contained in a Procedure Result on the local instrument's database to be copied to another location (e.g. formatted CD) for backup purposes, or transfer to another instrument.

Select one or more Procedure Results to be exported (using block or random select, Section 2.2). Alternatively press Select All Results function to select all displayed Procedure Results.

Note:
Selecting too many Procedure Results may generate a very large number of files that is difficult to manage.

Press Export Results to bring up the **Select Export Directory** prompt box. Enter the directory and drive where the files are to be stored. The filename used is a default and cannot be edited.

Click Save. The Procedure Results are saved as compressed .ZIP files. The default filename of any exported .ZIP file has the unique **Session ID** of the exported Procedure Result (generated by the instrument, see Figure 5-3 left-most column). The files within the .ZIP files are in a proprietary format that cannot be used by other applications.

Use this procedure on a regular basis as a backup against data loss.

5.2.2 Import Results

Procedure Results that have been previously exported may be imported to the local database from another instrument or location. Press Import Results to bring up the **Select Procedure Results to Import** prompt box. Locate the directory containing the exported Procedure Results files (.ZIP file type, or .XML file type for backwards compatibility). Highlight one or more filenames to import.

Click Open to add the selected Procedure Results to the database.

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5.2.3 Delete Results

Select one or more Procedure Results to be deleted (using block or random select, Section 2.2). Alternatively press Select All Results function to select all displayed Procedure Results.

Press Delete Results to display the **Delete Procedure Results** prompt box. Click Yes to remove permanently the selected Procedure Results from the database. Click No to cancel the operation.

Caution:
If the Select All Results button is pressed before pressing the Delete Results button, all the Procedure Results (all images and information) stored in the instrument's database will be deleted. Ensure this is the intended operation before clicking Yes.

5.3 Image Selection/Review

Pressing Next on the **Review Procedure Results** screen (Figure 5-3) displays the Information **Logging screen** (Section 4.2). Contextual information such as Subject details, Operator details, Site information and General Notes that were entered at the time the procedure was performed can be viewed and edited.

Pressing Next on the **Information Logging** screen (Figure 4-3) displays the **Image Selection** screen (Section 4.4). Images may be recalled and manipulated and have Notes added to them from this screen. Contextual information and images that were entered at the time the procedure was performed can be viewed and edited.

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5.4 Saving Modifications and Exiting

The **Save Procedure Result Modifications** screen (Figure 5-4) is displayed when closing the application (pressing Exit) and there are outstanding changes made to the reviewed Procedure Result. Changes include those made to contextual information such as Subject Details, Operator Details, Site Information, General Notes and images.

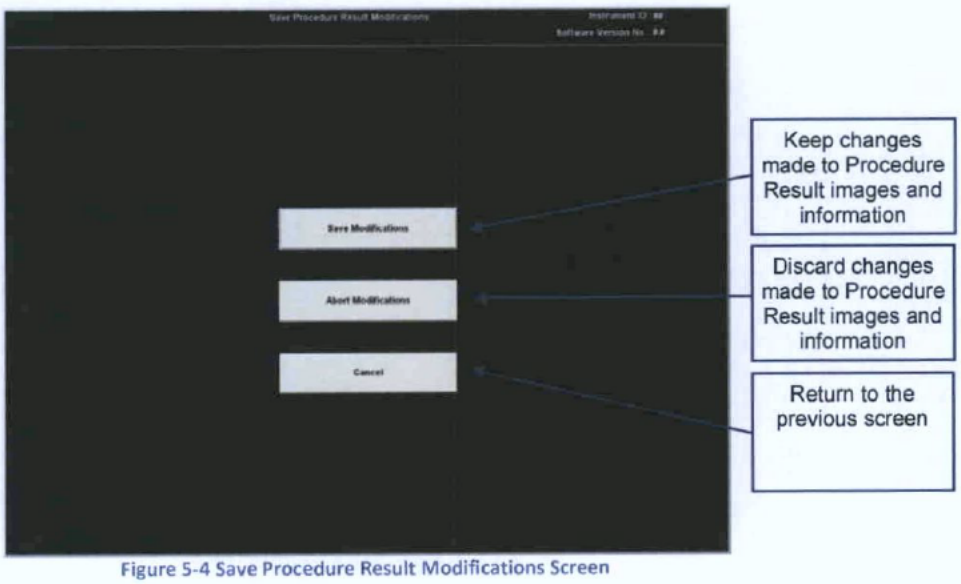

Figure 5-4 Save Procedure Result Modifications Screen

Save Modifications	Save the current modifications to the Procedure Result and return to the **Start-up** screen (Section 0).
Abort Modifications	Discard ***permanently*** the current modifications to the Procedure Result and return to the **Start-up** screen, (Section 0).
Cancel	Return to the previous screen without saving or deleting the changes.

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6 REPORTER APPLICATION

The CEIS automatically logs system parameters and performance including errors to aid Optiscan Technical Support personnel in the diagnosis and repair of instrument faults. Optiscan Technical Support may request access to this information.

The **Reporter** application is used to generate an instrument report comprising of instrument log files and other system information critical to the instrument function. The **Reporter** application compiles this information into a single compressed archive file that can be emailed or otherwise sent to Optiscan Technical Support for interpretation. If required, Optiscan Technical Support will guide you in the use of the application.

The **Reporter** application also allows manually selected files on the instrument to be included in the archive file. The resulting archive file may be very large. The **Reporter** application can also split the archive file into a number of smaller files, if required, which may then be sent by email or copied to a CD.

6.1 Before Starting

Decide what information is to be sent to Optiscan Technical Support. The **Reporter** application exports only the instrument parameters. If the concern is, for example, a suspected artifact in images then appropriate image files should also be included. View the required images with the Clinical application and save them as image files (high quality JPEG recommended) in a known location. Use care, as it is easy to generate very large files.

<u>Note:</u>
It is recommended to create a new directory on drive (D:\) for the use of storing such additional files. Under no circumstances should sub-directories be created under the designated system log directories C:\Log or D:\Database\MSSQL\LOG, doing so will cause Reporter to fail.

Decide how the information is to be sent to Optiscan Technical Support. This determines the maximum generated file size. A typical archive file with no additional files added is usually between 250 KB and 500 KB in size. Additional image files increase the size of the archive file. As a guide, a single 1024x1024 image adds approximately 1MB to the archive file size, depending on the image file format used. CDs can store approximately 650 MB. Email attachments are often limited to 1MB. Choosing too small a file size may result in an excessive number of output files, whereas too large a file size may cause a failure in transmitting the files.

6.2 Running Reporter

Run the Reporter application by following the steps below:

- Select the **Reporter** user account icon (Figure 6-1) from the **Logon** screen, described in Section 3.

Figure 6-1 Application icons in Logon screen

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The Reporter application is displayed.

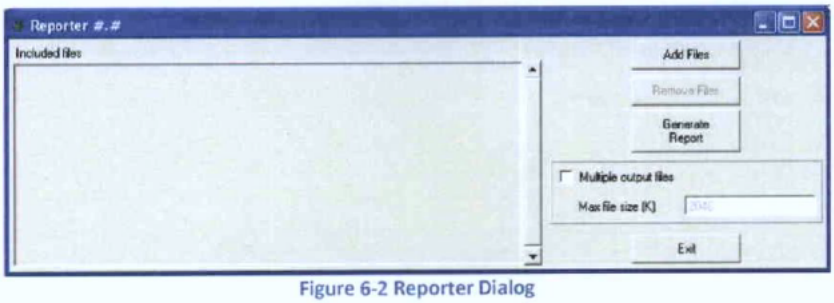

Figure 6-2 Reporter Dialog

- Optional: Press the Add Files button to add extra files, including image files. A file dialog will be displayed to allow single files to be selected. Selected files are added to the list displayed on the left hand side of the main dialog box.

Note:
The Add Files button only allows one file to be added at time. To add multiple files repeat the process to select and add a single file.
The Add Files button will not allow directories to be added.

- Optional: Press Remove Files to remove files from the list.

Note:
The list only displays the files to be added to the archive file. Removing files from the list does not delete the files.

- Optional: Tick the Multiple output files checkbox and enter the required maximum file size (in KB) in the **Max file size (K)** field. The default maximum file size is 512, which is the suggested size for archives that must be sent as email attachments.
- Press Generate Report. A file dialog box is displayed. Select the destination file or enter a new one for the report. The default directory is D:, which is the recommended directory if you are not sure.

Note:
Under no circumstances should the Reporter destination file be stored in the designated system log directories C:\Log or D:\Database\MSSQL\LOG. Doing so has the potential to cause Reporter to Fail.

A single output file has the extension .ZIP. If the Multiple output files checkbox is ticked then all the output files have extension .ZIA.

Note:
The .ZIA format is proprietary. All .ZIA files in a set are required to reassemble the original data files.

- Press Save. The Generate Report button is disabled until the report has been completed and the cursor changes to a busy icon whilst the archive is written. Progress can be seen via the Reporter console window, (Figure 6-3). Move the dialog box in order to see the console window as it may be behind the dialog box. If the Multiple output files checkbox is ticked then a five digit incremented number is appended to the file name specified, as before (Section 0).

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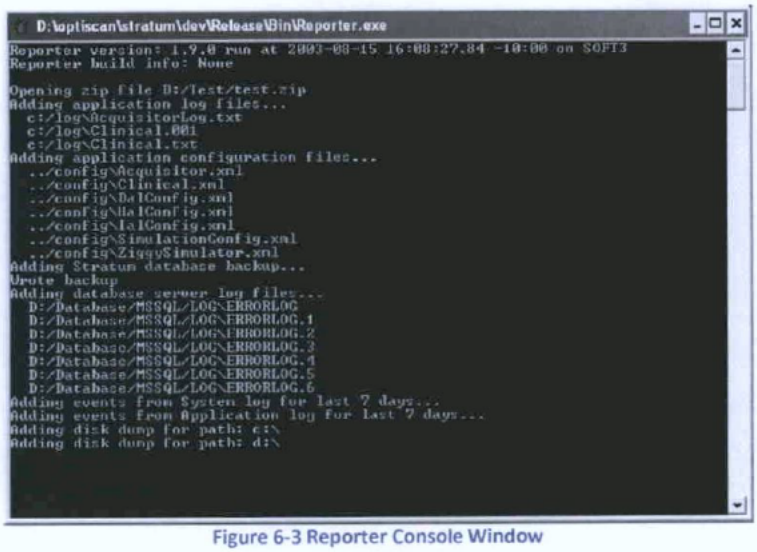

Figure 6-3 Reporter Console Window

Created files may be moved to an alternate location using the functions in a suitable file management program. When the archive is completely written (which may take several minutes, depending on system load and file system size), press Exit to close the **Reporter** dialog box.

Send the file(s) to Optiscan Technical Support either as email attachments or by burning the files onto CDs and mailing the CDs.

<u>Note:</u>

If the **Multiple output files** option was used, attach each .ZIA file in a set to a separate email. In the Subject line put File "n" of "m", where "m" is the total number of files in the set and "n" is the number added to the end of the original filename and is between 1 to "m". (For example, if the specified filename is "*myfile*" and the last file generated is *myfile00005.zia*; then five emails need to be sent, the first should have the attachment *myfile00001.zia* and the Subject line should be *"File 1 of 5"*, and so on). The recipient then knows how many files to expect and can request a resend of files, if necessary.

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7 TROUBLESHOOTING

Various status indicators are found on the front panel of the CEIS-CU and CEIS-OU respectively, Figure 7-1. The CEIS-OU has two indicators that must be noted: The Laser ON indicator and the Warning Indicator.

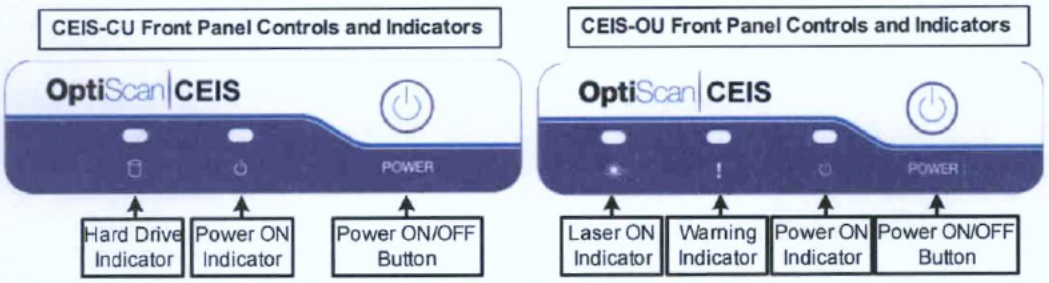

Figure 7-1 Front Panel Controls and Indicators

7.1 Warning Indicator

The Warning Indicator is located next to the Power ON Indicator on the CEIS–OU Front Panel and is labeled with the warning symbol **!**. The Warning Indicator is yellow in color and is illuminated in the event of a system error.

Caution:
Check the Warning Indicator if the instrument should malfunction. If the Warning indicator is on, close the application, power down the instrument, and wait for at least 60 seconds before restarting.

Turn the instrument power back on and restart the software. If the Warning Indicator is illuminated again, power down the instrument and contact the nearest Optiscan representative.

7.2 Laser Indicator

The Laser ON Indicator is located next to the Warning Indicator on the CEIS–OU Front Panel and is labeled with the laser symbol ✷. The Laser ON Indicator is blue in color and is illuminated while the laser is energized.

Caution:
If the Laser ON Indicator is illuminated unexpectedly, power down the instrument and contact the nearest Optiscan representative.

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7.3 Missing Image Data

In the event that a Procedure Result is corrupt and/or any image data in a Procedure Result is missing, the image placeholder in the **Image Selection** screen (Figure 7-2) is displayed with a checkerboard pattern. This is a visual indication of missing data.

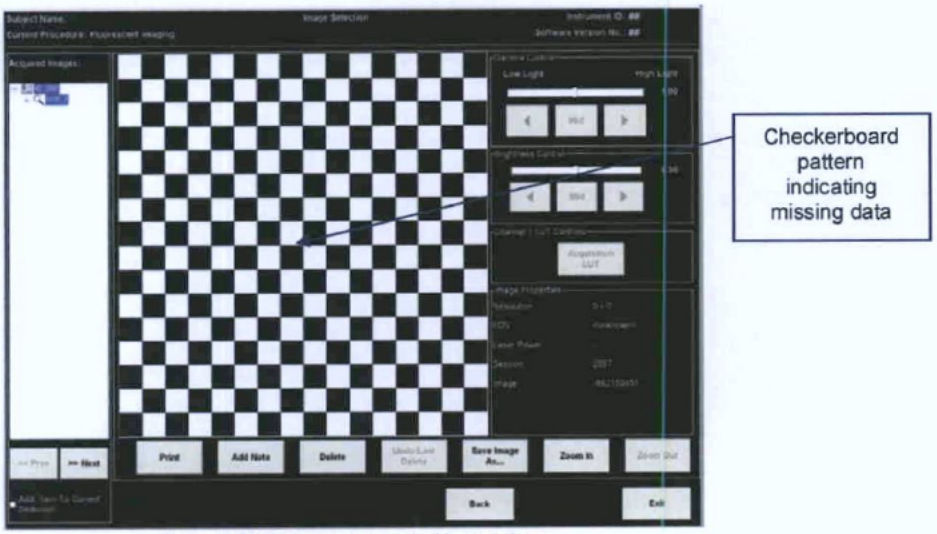

Figure 7-2 Missing or corrupted image data

7.4 Insufficient Disk Space

The **Clinical** application automatically stores image data to the instrument's hard disk. Image files are potentially very large. As a precaution, the Clinical application does not start a new Imaging Procedure if there is less than 500 MB of free disk space available on the instrument. (The **Clinical** application does not stop if the free disk space drops below 500 MB during a session.) Increase the amount of free disk space by deleting data or transferring data to an alternative storage medium, such as a CD.

Review of Procedure Results is possible with less than 500 MB of free disk space.

7.5 System Error

If the Clinical application detects a system error on start-up, or determines that a system parameter is out of range, it will automatically display an error message Figure 7-3) and shut down the application. Press End to exit the software.

Restart the **Clinical** application. Contact the nearest Optiscan representative if a System Error occurs again on restarting. Optiscan Technical Support may request running the **Reporter** application (Section 6).

Figure 7-3 System Error Message

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NOTICE
This equipment is a Class B Medical Equipment (specified EN55011) and is intended for hospital or health care districts.
When used in clinical or residential areas near radio and TV receiver units, this equipment may be subjected to radio interference.
To reduce electromagnetic interference, do NOT keep turning on the main SWITCH of the equipment hanging a confocal endoscope on a scope-hanger when not operated.
To avoid and resolve adverse electromagnetic effects, do NOT operate this equipment near the RF energy equipment.
Only connection cables and keyboard specified by OPTISCAN conform to the above standards.

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EC REP

Specifications are subject to change without notice and without any obligation on the part of the manufacturer.

CE 0197

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Appendix J:

Device Labelling Specification

The following documents have been attached to the submission in this section:

- (b)(4) Confirmation of Labelling for CEIS

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Confirmation of Labelling for CEIS

Document (b)(4)
Revisio (b)(4)
19 January 2009

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Document Approval

Signature (b)(6) Date 19/1/2009

Reviewer (R

Signature Date 19/1/2009

Approval (R

Revision History

Revision Number	Modified By	Release Date	Brief Change Summary
(b)(4)	(b)(6)	19-Dec-05	Initial Document
		23-Feb-06	Confirmation by Pentax of labels to be applied to the ISC-1000
		16-Nov-06	Addition of NRTL for the ISC-1000 and change of storage label from -40 C to -60 C
		24-Jan-07	Change of Address for European Representative
		6 Feb 07	Doc updated to include all labels and their placement
		17 Nov 08	Add NRTL Compliance Label (Section 3.12)
		19/1/2009	Updated labels in Section 2.3 and 2.4 (required for CEIS 510k Submission), Corrected error in part numbers throughout document. Updated Section 5.1 and 5.2 with new labels and corrected part numbers, Added Section 2.5 Shipping Symbols Label (102-205) mistakenly left off previous releases

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1 INTRODUCTION

1.1 Scope

This document describes the labelling that will be placed on the CEIS. Note: Do not scale drawings from this document.

1.2 Responsibility and Authority

It is the responsibility of the regulatory manager to review this document

1.3 Definitions, Acronyms and Abbreviations

OU	Optical Unit
CU	Control Unit

1.4 References

Document ID	Document name
(b)(4) [redacted]	Labelling standard for medical devices
ISC Instrument	

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2 PACKAGING LABELLING

2.1 Optiscan Shipping label

Optiscan Item Number 102-226

2.2 CE Mark

Optiscan Item Number: 102-227

2.3 CEIS OU Box Labels

CEIS - OU

Caution:
Federal (USA) law restricts this device to sale by, or on the order of, a physician or other appropriately licensed medical professional.

Optiscan Item Number 110-222

2.4 CEIS CU Box Labels

CEIS - CU

Caution:
Federal (USA) law restricts this device to sale by, or on the order of, a physician or other appropriately licensed medical professional.

Optiscan Item Number 110-221

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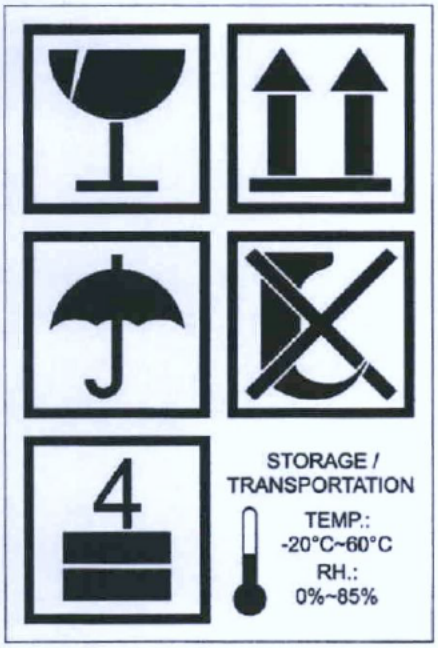
2.5 Shipping Symbols Label



Optiscan Item Number 102-205

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3 PRODUCT LABELLING – CONFOCAL CONTROL BOX

3.1 OU danger label

危険

爆発の恐れがあります。
揮発性可燃性物質を含む環境条件では
使用しないで下さい。

注意

感電の恐れがあります。
カバーは取外さないで下さい。
故障、修理は必ず弊社、あるいは弊社の
指定した専門家まで御連絡下さい。

DANGER

EXPLOSION HAZARD.
Do not use in the presence of
flammable anesthetics.

CAUTION

ELECTRIC SHOCK HAZARD.
Do not remove cover.
Refer servicing to qualified service
personnel.

ACHTUNG

EXPLOSIONSGEFAHR.
Nicht in der Nähe brennbarer
Flüssigkeiten betreiben.

VORSICHT

ELEKTRISCHER SCHLAG.
Gehäuse nicht öffnen.
Reparaturen nur durch PENTAX
Fachpersonal ausführen lassen.

DANGER

RISQUE D' EXPLOSION.
Ne pas employer en presence
d' anesthesiques inflammbles.

ATTENTION

RISQUE DE DECHARGE ELECTRIQUE.
Ne pas retirer le capot.
Contacter le service apresvent qualifile.

Optiscan Item Number: 102-214

3.2 Label Laser warning

LASER RADIATION
AVOID DIRECT EYE EXPOSURE
CLASS 3R LASER PRODUCT

Optiscan Item Number: 102-207

3.3 Caution Laser 3B Radiation Label

CAUTION - CLASS 3B LASER RADIATION WHEN OPEN
AVOID EXPOSURE TO THE BEAM

Optiscan Item Number: 102-213

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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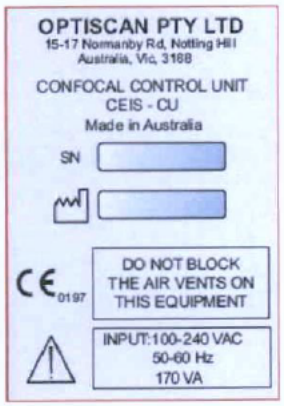
3.4 Laser Class and Standard Label

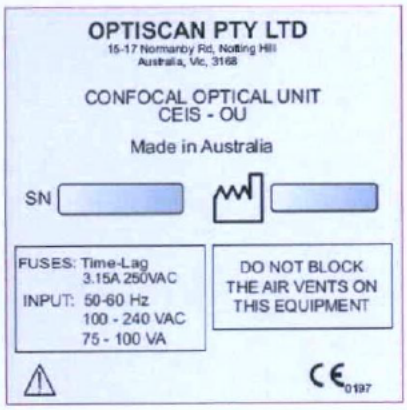
Optiscan Item Number: 102-212

3.5 CEIS CU ID Label



Optiscan Item Number:110-223

3.6 CEIS OU ID Label



Optiscan Item Number:110-224

3.7 CEIS System Label

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 222

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Optiscan Item Number: 110-225

3.8 European Representative Label

European Representative:
Medical Device Safety Service GmbH,
Schiffgraben 41
Hannover
GERMANY
D-30175

Optiscan Item Number: 110-226

3.9 Equipotential Earth Label

Optiscan Item Number: 102-209

3.10 Facia Hazard Label

Optiscan Item Number: 102-206

3.11 WEEE Compliance Label

[redacted]

Optiscan Item Number: 102-484

3.12 NRTL Compliance Label

Optiscan Part Number: 102-257

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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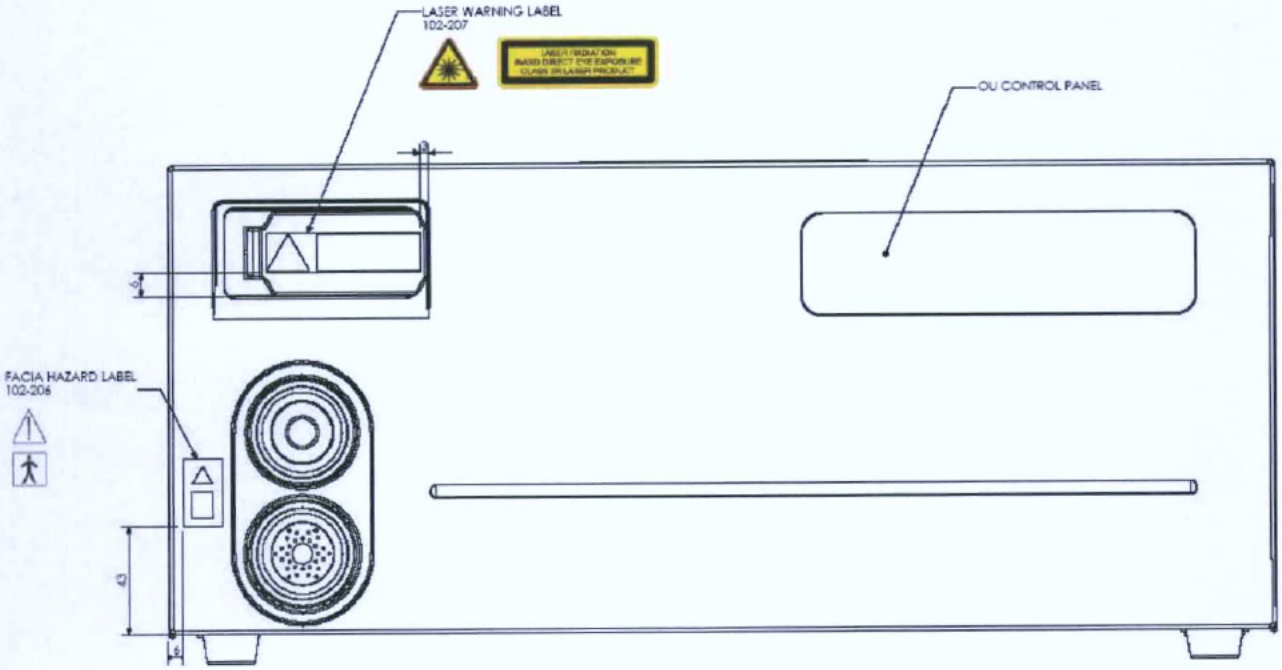
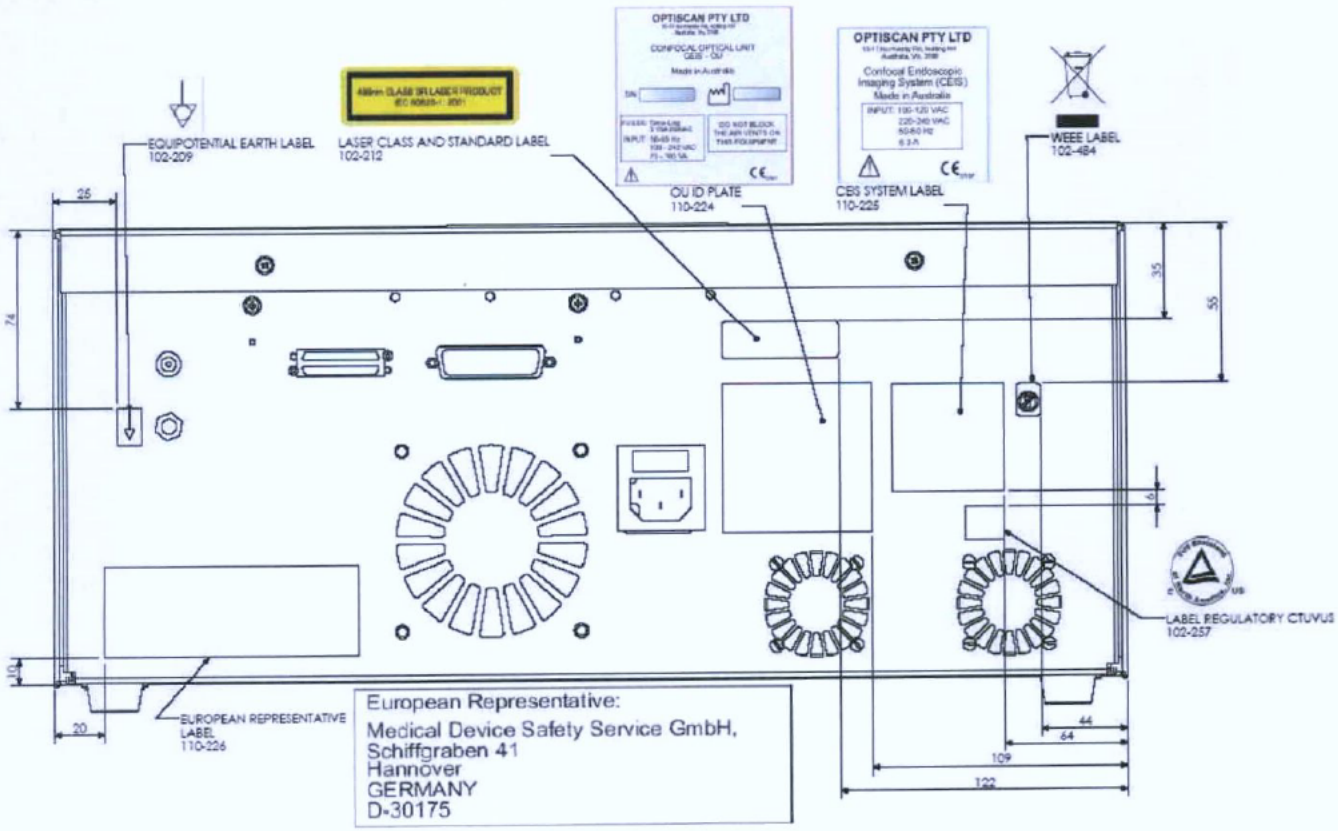
4 LABEL PLACEMENT – INSTRUMENT

4.1 Optical Unit (OU)





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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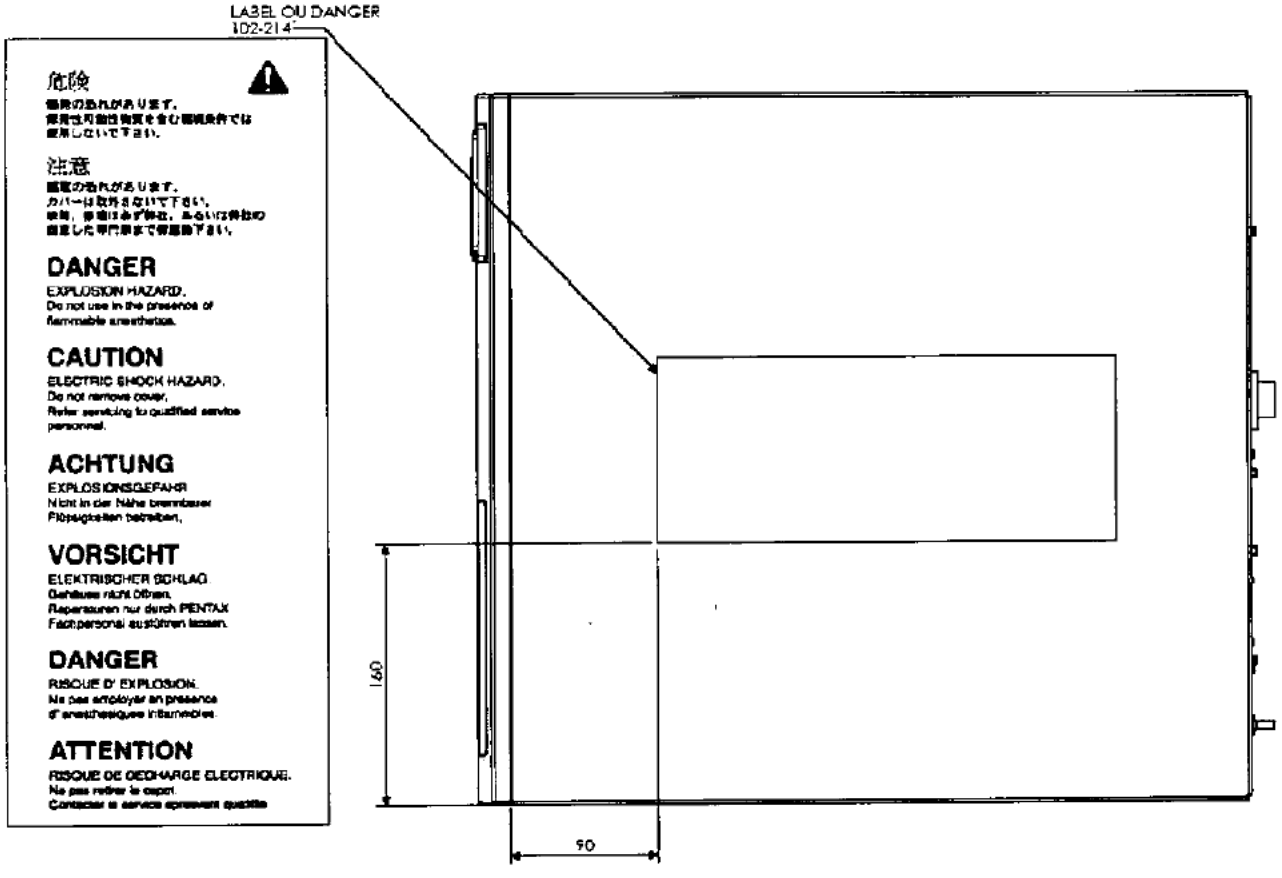

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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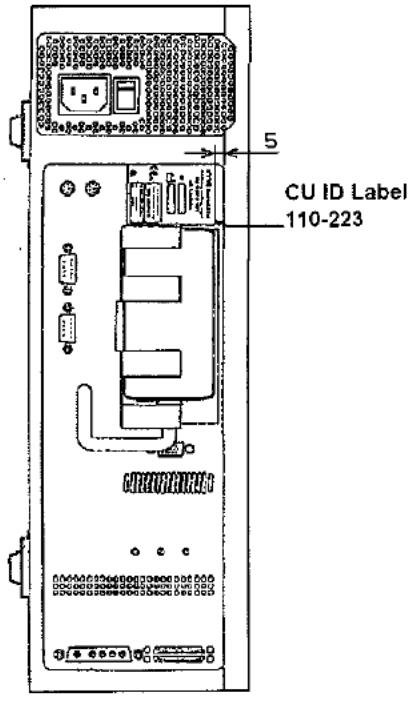
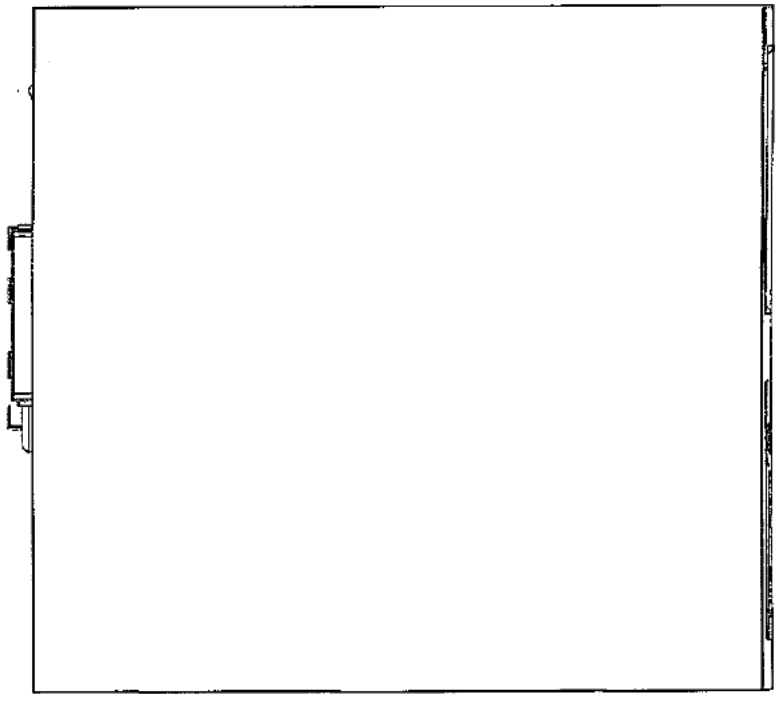
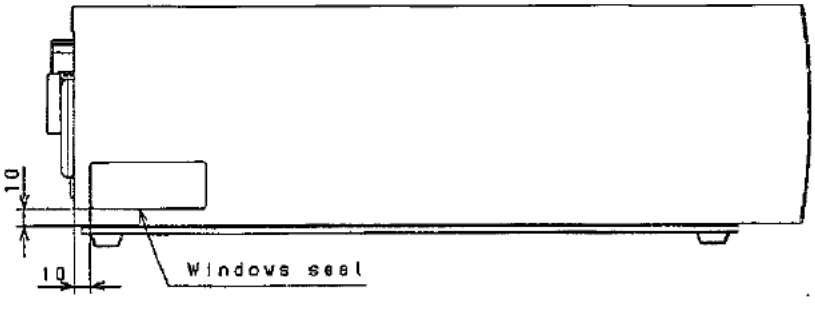
4.2 Control Unit (CU)







Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 226

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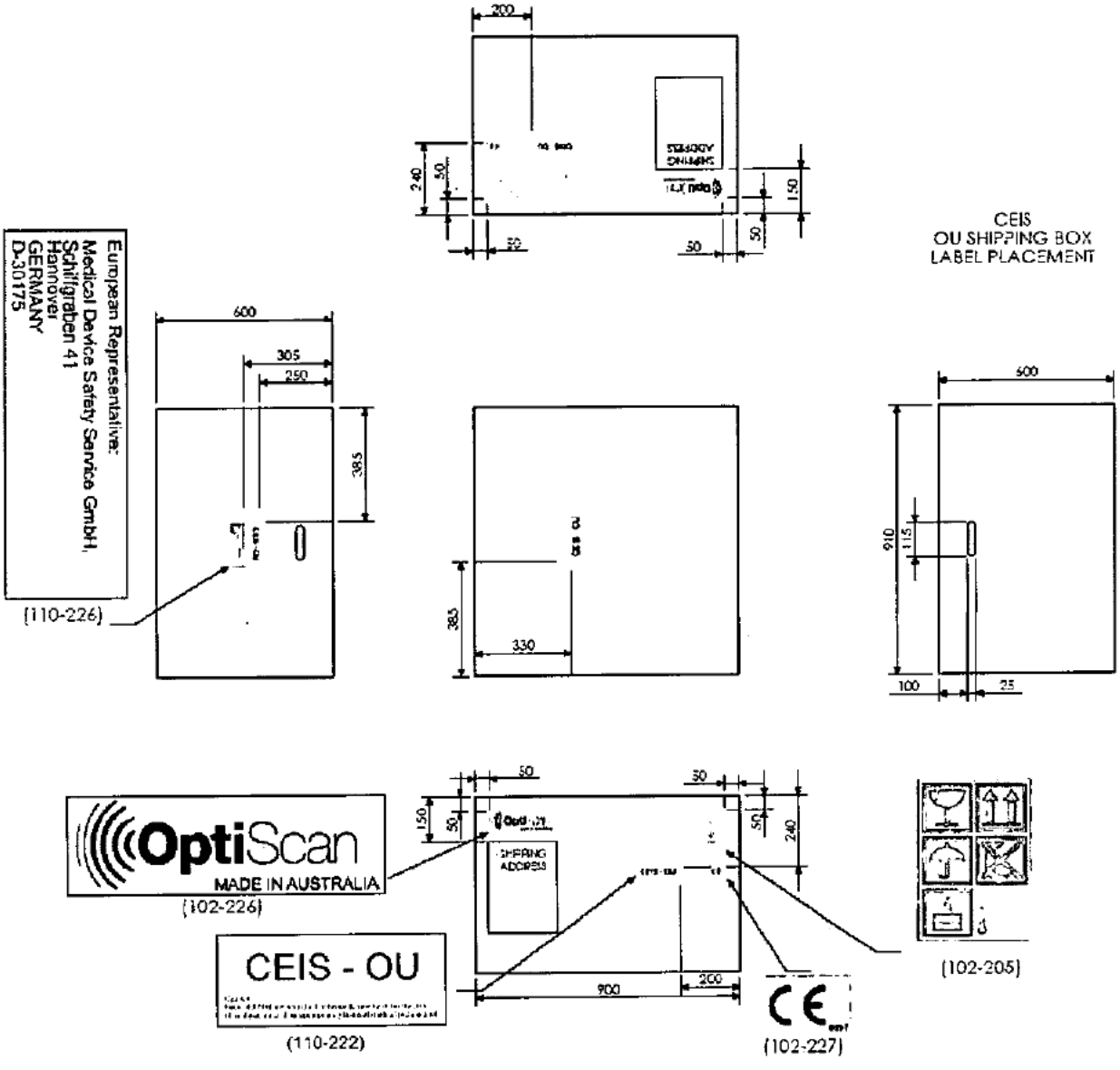
5 LABEL PLACEMENT – PACKAGING

5.1 CEIS OU Box Label Placement



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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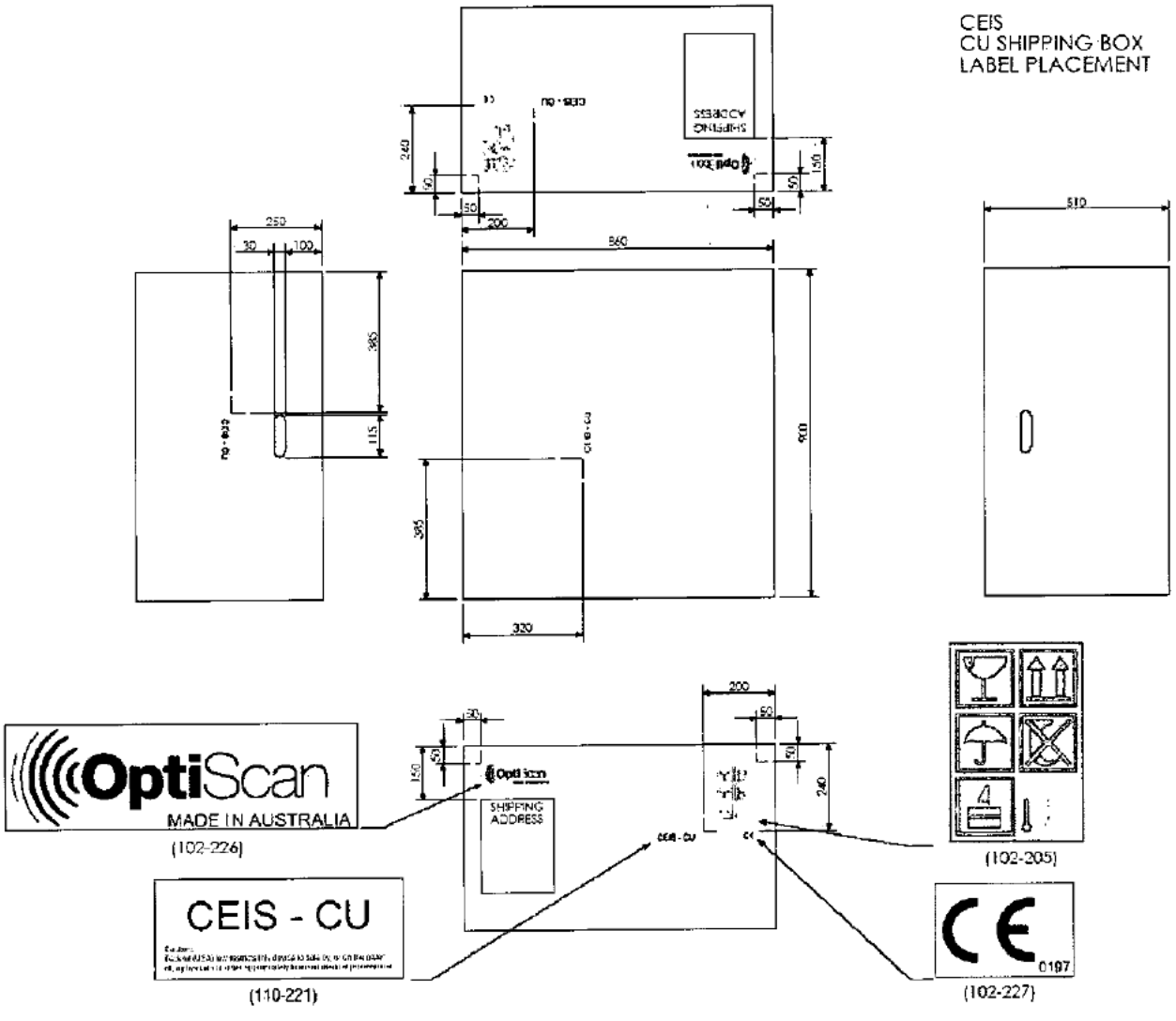
5.2 CEIS CU Box label placement



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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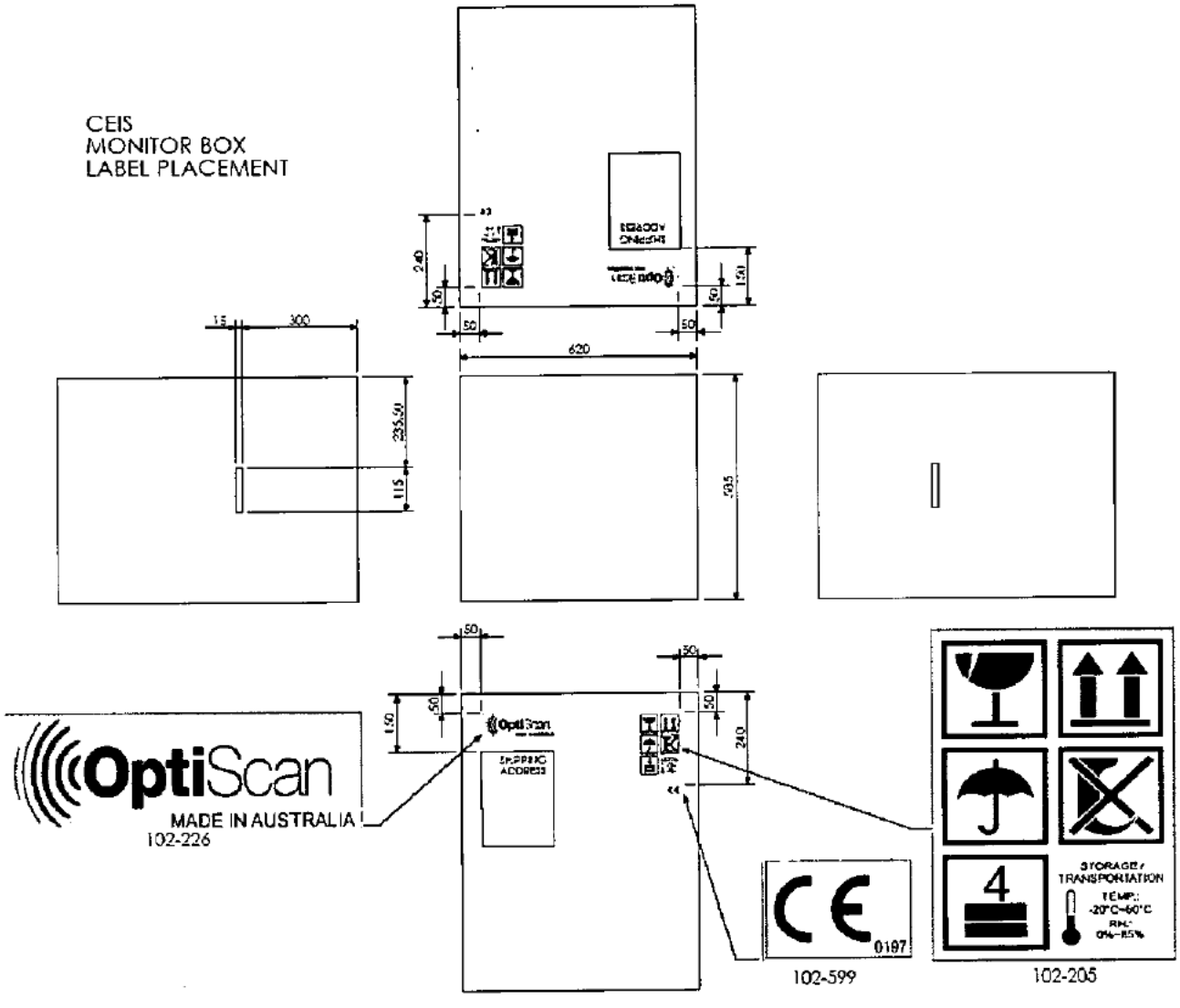
5.3 CEIS Monitor / Transformer Box Label Placement



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix K:

Predicate Device Labelling Examples

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Submission
Optiscan Confocal Endoscopic Imaging System

Labels Attached to the ISC-1000 Device and its Packaging

1. Total Rating Plate

⑤

HOYA Corporation
2-7-5 Naka-Ochiai, Shinjuku-ku
Tokyo 161-8525 Japan
Confocal Imaging System
PENTAX ISC-1000
Made in Australia
INPUT: 100-120VAC
220-240VAC
50-60Hz
6-3A

⑧ ※1 Label A or Label B

System lated label
(on PENTAX OU-1000)

⑤

European Representative:
PENTAX Europe GmbH
Julius Vesseler Strasse 104, 22527 Hamburg, Germany
EC REP

European Representative label
for OU backpanel or Packing box

③

⑧ CE 0123 ※1 Label A (CE0123)

⑧ ※1 Label B (Nothing)

2. PENTAX OU-1000

⑤

HOYA Corporation
2-7-5 Naka-Ochiai, Shinjuku-ku
Tokyo 161-8525 Japan
CONFOCAL OPTICAL UNIT
PENTAX ISC-OU 1000
Made in Australia
SN
FUSES: 250V, 3.15A
INPUT: 100-240VAC
50-60Hz
50-70VA
DO NOT BLOCK THE AIR VENTS ON THIS EQUIPMENT

⑧ ※1 Label A or Label B

OU lated label

Laser symbol

LASER RADIATION
AVOID DIRECT EYE EXPOSURE
CLASS 3R LASER PRODUCT
(English Ver.)

⑧ レーザ光
目への直接照射を避けること
クラス3Rレーザ製品
※2(Japanese Ver.)

Laser caution label

488nm CLASS 3R LASER PRODUCT
IEC 60825-1:2001

Laser label

⑥④ **Do not change or disconnect scope while power is on**
(English Ver.)

⑧ 装置が故障する場合がありますので、電源をONにしたまま
スコープの接続／取り外しをしないでください。
詳しくは取扱説明書をお読みください。
※2(Japanese Ver.)

Hot swap caution label

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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④

WEEE seal

④

C TUV US label
(Scale:1/2)

④

※1 Chinese RoHS label

④

BF label

④

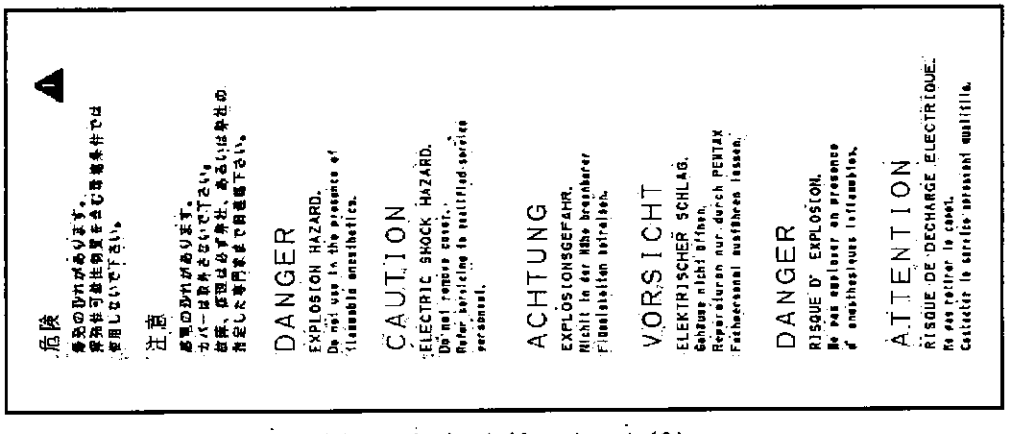
Equipotentiality label

④

製造販売元：HOYA株式会社
東京都新宿区中落合2－7－5
一般的名称：内視鏡用光源・プロセッサ装置
販売名：ペンタックス共焦点内視鏡用プロセッサ
ISC－1000

一般医療機器　特定保守管理医療機器

※2 YAKUJI Manufactures' label



Caution label (Scale:1/2)

ISC-OU1000

③ OU Label for Packing Box

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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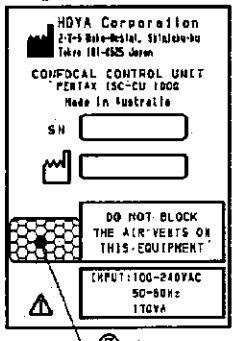
3. PENTAX CU-1000

④



⑦ ※1 Label C or Label D

CU lated label

CU Label for Packing Box

⑦ ※1 Label C (CE0123)

⑦ ※1 Label D (Nothing)

4. Package Box Scale: 1/2

⑦

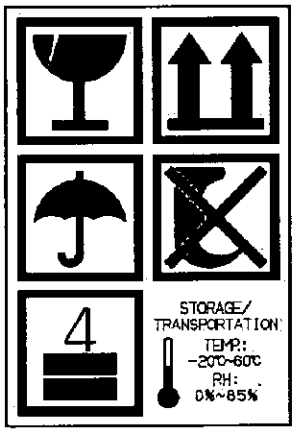
※2 CE mark

⑧

※3 CB mark

⑧

※4 Perchlorate label for CU packing Box



②③

Handling label

④

⑤

PENTAX label

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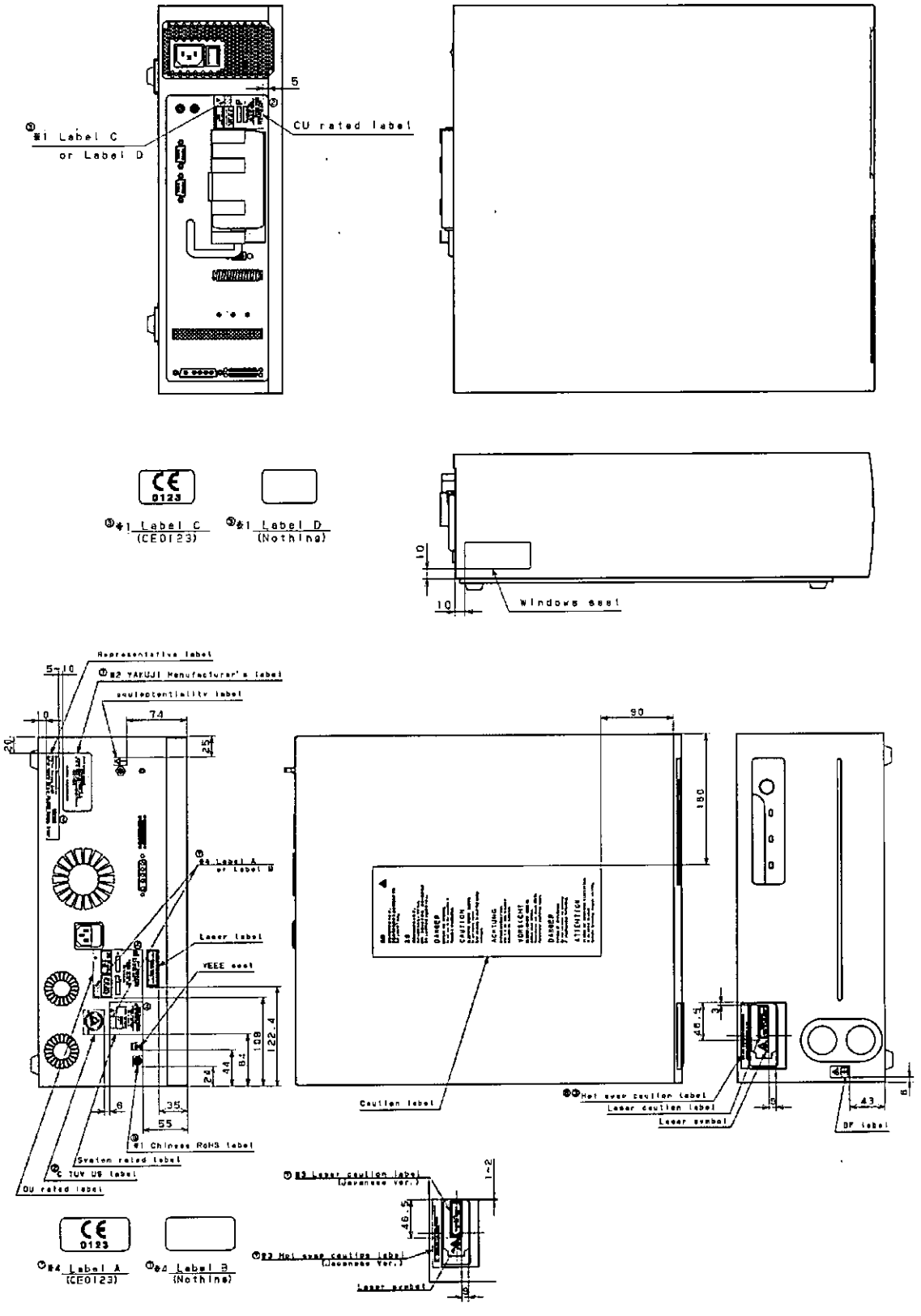
510(k) Submission
Optiscan Confocal Endoscopic Imaging System

Labels Attached to the ISC-1000 CU and OU



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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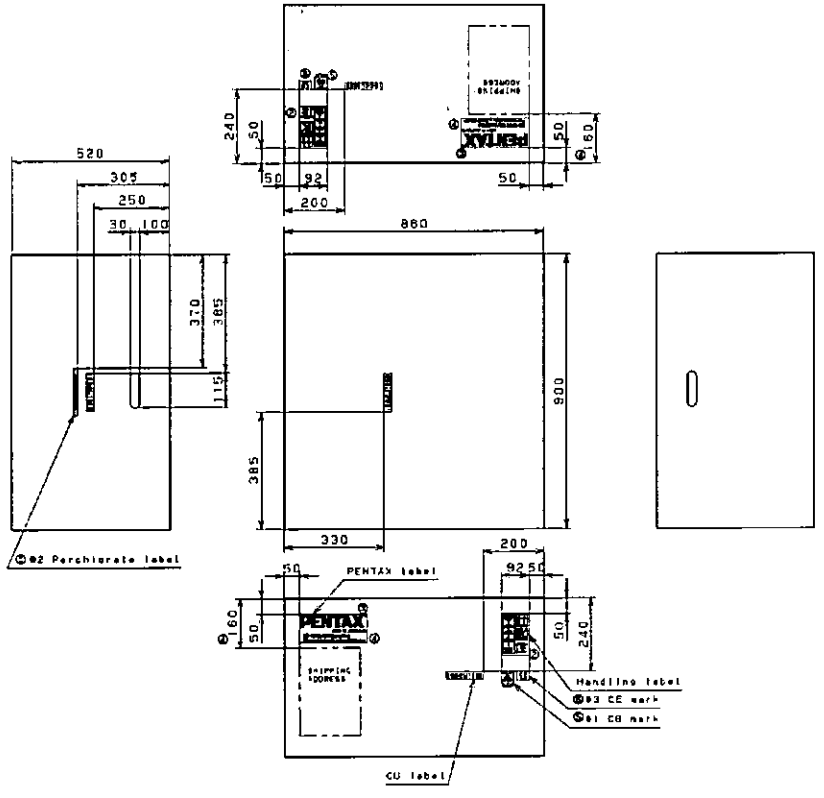
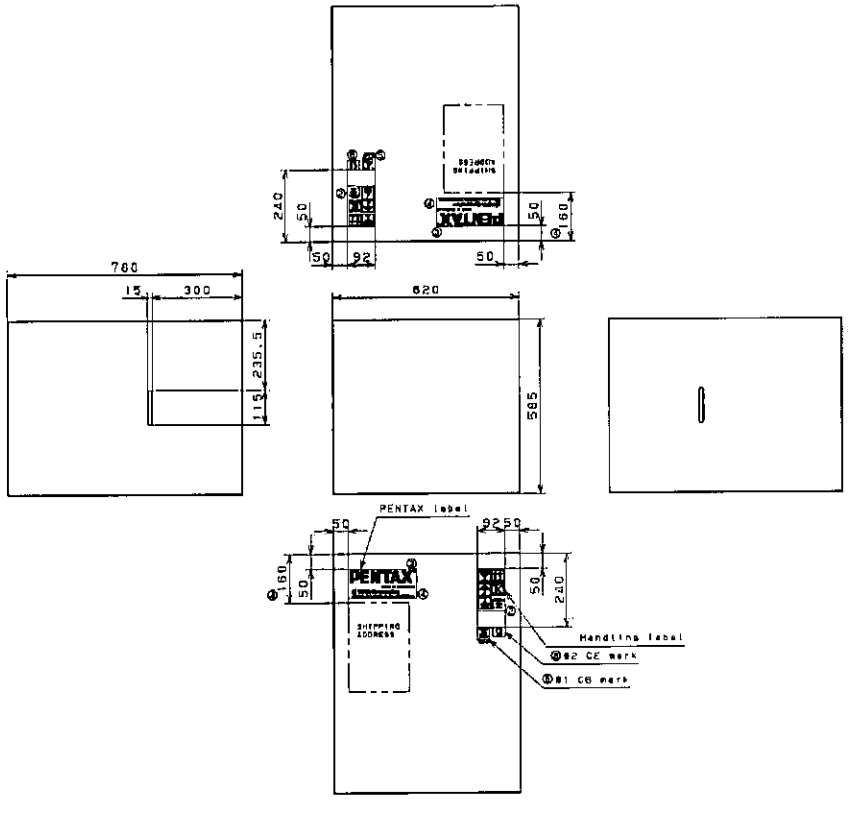
510(k) Submission
Optiscan Confocal Endoscopic Imaging System

Labels Attached to the Packaging Boxes

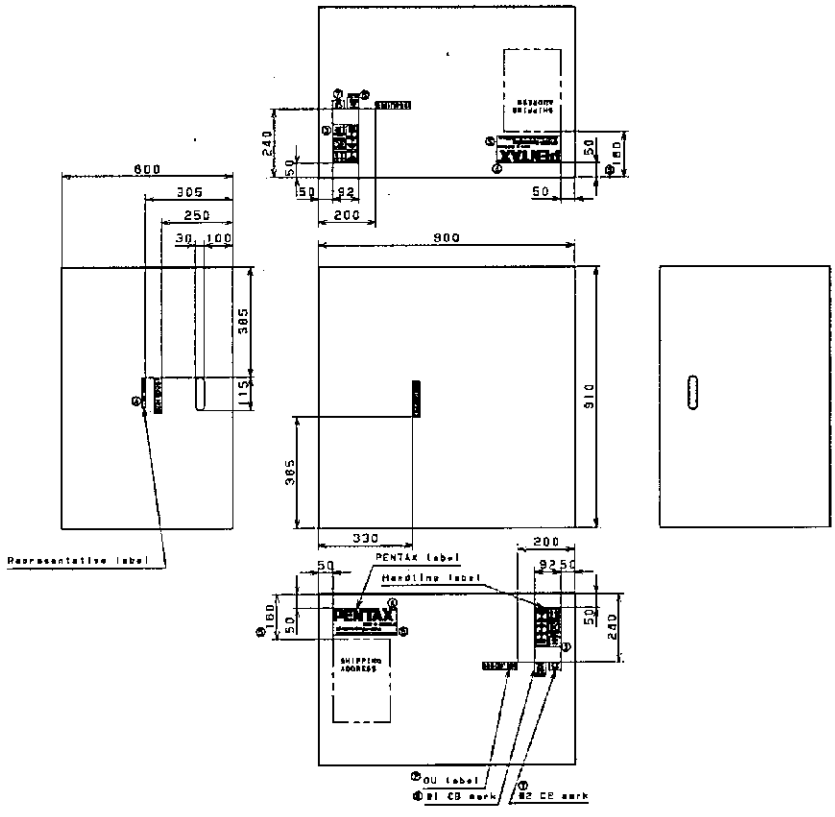




Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

510(k) Submission
Optiscan Confocal Endoscopic Imaging System



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix L:

Software Release

The following documents have been attached to the submission in this section:

- (b)(4) Software Release Form

Note: The Software utilised for the CEIS is identical to the ISC-1000 Software release with no changes.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OptiScan

Software Release Form

Product Information

Software Product	Imaging System Confocal (ISC)
Software Version	2.3
Release Candidate	5

Review Meeting

Date	Thursday 3rd November 2005
Time	10:00 am
Location	Optiscan Pty Ltd, Meeting Room 4
Attendees	(b)(6) [redacted]

Validation

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

OptiScan

Test Deliverables

(b)(4)

[redacted]

User manuals

User Manuals will be updated where required to reflect changes in the software.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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OptiScan

Testers

Name	Signature	
(b)(6) [redacted]	(b)(6) [redacted]	3/11/2005.
		3/11/2005.
		3/11/2005
		03/11/2005
		03/11/2005
		3/11/05
		3/11/05
		3/11/05
		3/11/05
		03/11/05
		3/11/05

Approval

Permission to proceed with release: YES NO

Darren Gage Software Test Analyst	(b)(6) [redacted]	3/11/2003
Bill Farrow Software Manager		3/11/2005.
Rob Pattie R&D Manager		3/11/2005

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix M:

Standards Data Report for 510(k)s

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1] IEC 60601-1:1988+A1:1991+A2:1995
MEDICAL ELECTRICAL EQUIPMENT – PART 1: GENERAL REQUIREMENTS FOR SAFETY

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☑	☐
FDA Recognition number[3] # 5-4		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance[6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8418

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1] IEC 60601-1-1:2000
MEDICAL ELECTRICAL EQUIPMENT - PART-1 - SAFETY REQUIREMENTS FOR MEDICAL ELECTRICAL SYSTEMS

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☑	☐
FDA Recognition number[3] # 5-27		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance[6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Paperwork Reduction Act Statement

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Rockville, MD 20850

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Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1] IEC 60601-1-2: 2004 (Edition 2.1)
MEDICAL ELECTRICAL EQUIPMENT - COLLATERAL STANDARD - ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☑	☐
FDA Recognition number[3] # 5-34		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance[6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED °		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED °		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED °		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Paperwork Reduction Act Statement

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1] IEC 60601-2-18: 1996 + A1: 2000
MEDICAL ELECTRICAL EQUIPMENT - PART 2 - PARTICULAR REQUIREMENTS FOR THE SAFETY OF ENDOSCOPIC EQUIPMENT

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☑	☐
FDA Recognition number[3] # 9-42		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance[6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

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PSC Graphics (301) 443-1090 EF

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1] IEC 60825-1: 2001
SAFETY OF LASER PRODUCTS - PART 1 - EQUIPMENT CLASSIFICATION, REQUIREMENTS AND USER'S GUIDE

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☐	☑
FDA Recognition number[3] #		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance[6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

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Appendix N:

Declaration of Conformity to Standard

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

Declaration of Conformity to Standard

I, Peter Pavlicek certify that, in my capacity as Regulatory Affairs Manager with Optiscan Pty Ltd, believe to the best of my knowledge that the system Optiscan CEIS, Confocal Endoscopic Imaging System, complies with all applicable sections of:

- IEC 60825, Safety of Laser Products
- IEC 60601, Medical Electrical Equipment Safety Requirements

The unit testing was performed in accordance with the requirements as identified in the standards and the results demonstrated that the pre-determined acceptance testing criteria were met. A Risk Analysis and testing protocols including testing data are on file at Optiscan Pty. Ltd.

27th January, 2010

Peter Pavlicek
Quality and Regulatory Affairs Manager
Optiscan Pty Ltd.

Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

Appendix O:

Requirements for Clinical Trials (Form 3674)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-7106; Released by CDRH on 02-01-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

Form Approved: OMB No. 0910-0616
Expiration Date: 06-30-2008
See OMB Statement on Reverse

SPONSOR/APPLICANT/SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER: OPTISCAN PTY LTD

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES: 27th January, 2010

3. ADDRESS (*Number, Street, State, and Zip Code*)
15-17 Normanby Road
Notting Hill, Victoria, 3168
AUSTRALIA

4. TELEPHONE AND FAX NUMBER (*Include Area Code*)
(T) +613 9538 3333
(F) +613 9562 7742

PRODUCT INFORMATION

5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(*Attach extra pages as necessary*)

OPTISCAN CEIS

APPLICATION/SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (*If number previously assigned*)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT/INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES
(*See instructions for additional information and explanation*)

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN # 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
(*Attach extra pages as necessary*)

NCT Number(s)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 255

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The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (SIGN)	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN #11 PETER PAVLICEK QUALITY & REGULATORY AFFAIRS MANAGER
13. ADDRESS (*Number, Street, State, and Zip Code*) *(of person identified in #11 & 12)* 15-17 Normanby Road Notting Hill, Victoria, 3168 AUSTRALIA	14. TELEPHONE AND FAX NUMBER (*Include Area Code*) (T) +613 9538 3348 (F) +613 9562 7742
15. DATE OF CERTIFICATION 27th, January, 2010	

Paperwork Reduction Act Statement

Public Reporting Burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Form No. FDA 3674
5901-B Ammendale Road
Beltsville, MD 20705-1266

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
Center for Devices and Radiological Health
Program Operations Staff (HFZ-403)
9200 Corporate Blvd.
Rockville, MD 20850

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 25C

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Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. Name of Sponsor/Applicant/Submitter - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.

2. Date - This is the date of the application/submission which the certification accompanies.

3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.

5. Product Information - For Drugs/Biologics: Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/ submission. Include all available names by which the product is known.
For Devices: Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.

6. Type of Application/Submission - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."

7. IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number - If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.

8. Serial Number - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field.

9. Certification - This section contains three different check-off boxes.

Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply to any of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply at the time of submission to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

10. National Clinical Trial (NCT) Numbers - If you have checked Box C in # 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as NCT will be added automatically before number. Include any and all NCT numbers assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

11. Signature of Sponsor/Applicant/Submitter or an Authorized Representative - The person signing the certification must sign in this field.

12. Name and Title of Person Who Signed in #11. - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/ submitter.

13. & 14. & 15. - Provide the full address, telephone and fax number of the person who is identified in number 11 and signs the certification in number 12. Provide the date the certification is signed. This date may be different from the date provided in #2.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 257

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Appendix P:

Manufacturing Flowcharts

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Manufacturing Information

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