U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(smw)
FOLDER:	K101734 - 1812 pages
COMPANY:	VISION TECHNOLOGIES INTL., INC. (VISITECH)
PRODUCT:	ARTHROSCOPE (HRX)
SUMMARY:	Product: VISIONSCOPE HIGH DEFINITION ENDOSCOPY CAMERA SYSTEM WITH; CAMERA CONTR
DATE REQUESTED:	Jul 27, 2015
DATE PRINTED:	Jul 27, 2015

Note: Printed

VisionScope Technologies LLC
2352 Main Street, Suite 303
Concord, MA 01742
USA
T: 1-978-776-9512
F: 1-978-776-9511

K101734

VISIONSCOPE

SEP 0 8 2010

510(k) Summary of Safety and Effectiveness as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which Substantial Equivalence is based

1. **Date Prepared:** June 15, 2010

2. **510(k) Owner's Name:**
   VisionScope Technologies, LLC
   2352 Main Street, Suite 303
   Concord, MA 01742, USA

3. **Contact Information:**
   Lim Cheung, Ph.D.
   General Manager & CTO
   Telephone: 1-978-776-9512
   Fax: 1-978-776-9511
   Email: Lim.Cheung@visionscope-tech.com

4. **Device Name**

Trade Name: VisionScope High Definition Endoscopy Camera System with:

- Camera Control Unit
- Camera Handpiece
- Endoscopes (Accessories in four lengths)
- Sterile Procedure Kits (Accessories in four lengths)

Common Name: Endoscopes and Accessories: Video Systems, Image Capture, Light Source, Endoscopes, Fiber Optic

Classification Name: Endoscopes And/Or Accessories (21 CFR §876.1500): Video System, Image Capture, Light source, Endoscope, Fiber Optic
Arthroscope (21 CFR §888.1100)

5. **Predicate Devices:**

Primary:		
InnerVue Diagnostic Scope System	K072879	Arthrotek Inc. (Biomet)
Secondary:		
Smith & Nephew HD Camera System	K070266	Smith & Nephew Endoscopy
Smith & Nephew Arthroscope	K072675	Smith & Nephew Endoscopy
Stryker LED Light Source (L9000)	K082813	Stryker Endoscopy
EndoSheath	K990354	Vision Sciences Inc.
Smith & Nephew 660HD Image Management System	K060777	Smith & Nephew Endoscopy

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6. Description of Device

The VisionScope High Definition Endoscopy Camera System is made up of the following components:

- Integrated Camera Control Unit containing the camera control electronics, light source and image capture electronics
- Camera Handpiece
- VisionScope line of four Endoscopes of identical design except for the lengths
- VisionScope Disposable Sterile Procedure Kits in four matched lengths as the endoscopes

7. Indications for Use

The VisionScope High Definition Endoscopy Camera System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of an interior cavity of the body through a natural or surgical opening. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

Additionally, when used in conjunction with an appropriately indicated and FDA 510(k)-cleared endoscope and light source, the VisionScope High Definition Endoscopy Camera Control Unit and Camera Handpiece are indicated for use in arthroscopic and endoscopic surgical procedures to provide illumination, visualization and capture of still and motion pictures of articular cavities, body cavities, hollow organs and canals.

8. Comparison of Technological Characteristics

The VisionScope System similarities to the predicate devices are:

- Has the same intended use and indications for use
- Utilizes the same operating principle
- Incorporates the same basic design
- Incorporates the same technological characteristics
- Tested to the same electrical and electromagnetic safety standards for medical electrical equipment
- Manufactured under a quality system

9. Summary Performance Data

VisionScope conducted the verification and validation testing with the VisionScope High Definition Endoscopy Camera System to demonstrate safety and effectiveness and substantial equivalence to the predicate devices listed above. All verification and validation data demonstrate that the device is safe and effective and performs as intended.

The VisionScope System conforms to the following voluntary standards:

- ANSI/AAMI/ISO 11135-1:2007
- ISO 10993-7:2008
- ISO 10993-5:2009

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- ISO 10993-10:2002
- ISO 10993-11:2006
- UL 60601-1:2003 R4.06
- IEC 60601-1:1988 + A1:1991 + A2:1995,
- EN 60601-1:1990 + A1 + A2 + A13
- CAN/CSA 22.2 No. 601.1
- IEC 60601-1- 4 / EN60601-1-4:2000
- IEC 60601-1-6: 2004 (First Edition) for use in conjunction with IEC 60601-1:1988 + A1:1991 + A2:1995
- EN 60601-1-2:2007
- IEC 60601-2-18:1996 Second Edition + A1:2000

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

VisionScope Technologies, LLC
% Lim Cheung, Ph.D.
General Manager & CTO
2352 Main Street, Suite 303
Concord, Massachusetts 01742

SEP 0 8 2010

Re: K101734
Trade/Device Name: VisionScope High Definition Endoscopy Camera System with:

- Camera Control Unit
- Camera Handpiece
- Endoscopes (Accessories in four lengths)
- Sterile Procedure Kits (Accessories in four lengths)

Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, GCJ
Dated: June 15, 2010
Received: June 21, 2010

Dear Dr. Cheung:

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

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (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,

For Bob Phillips
Dep D.R.

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

Enclosure

Indications for Use

K101734

SEP 08 2010

510(k) Number (if known): K101734

Device Name:

VisionScope High Definition Endoscopy Camera System with:

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Prescription Use Yes (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)

Neil R P Ogden for

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

510(k) Number K101734

K101734/A1

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VISIONSCOPE

FDA CDRH DMC

JUN 25 2010

Received K56

June 22, 2010

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002
Attention: 510(k) Staff

Re: Incorrect Company Name in the Acknowledgment Letter of June 21, 2010
510(k) Number: K101734

Dear Sir or Madam:

Thank you for your letter dated June 21, 2010 acknowledging the receipt of our 510(k) submission (attached herein). Please note that the company name used in the acknowledgment letter is incorrect. It should be "VisionScope Technologies, LLC", and not "Vision Technologies Intl., Inc.".

The address and the contact information are correct.

Please enter the correct information in your record.

Sincerely,

Lim Cheung
General Manager & CTO
VisionScope Technologies, LLC
2352 Main Street, Suite 303
Concord, MA 01742
Voice: 978-776-9512
Fax: 978-776-9511
Mobile: 617-283-1906

Attachment: Ack Letter via e-mail

Li

Fr Lim Cheung
Se.... Monday, June 21, 2010 4:52 PM
To: 'Davis, Brittney *'
Subject: RE: (Ack Letter) - K101734

Brittney,

Thank you for your acknowledgment letter attached at the end of this email.

I would like to make one correction. The correct company name (and owner used throughout the submission) is VisionScope Technologies, LLC, and **NOT** Vision Technologies Intl., Inc. as indicated in your email.

Otherwise, both the contact information and the address are correct.

Please make a note of this and enter the correct information in your record.

Thanks!

Lim Cheung

Lim Cheung, Ph.D.,
General Manager & CTO
'isionScope Technologies, LLC
2352 Main Street, Suite 303
Concord, MA 01742
Voice: 978-776-9512
Fax: 978-776-9511
Mobile: 617-283-1906

CORRECT

From: Davis, Brittney * [mailto:Brittney.Davis@fda.hhs.gov]
Sent: Monday, June 21, 2010 4:09 PM
To: Lim Cheung
Subject: (Ack Letter)

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
June 21, 2010

Incorrect

ISION TECHNOLOGIES INTL., INC.
2352 MAIN STREET SUITE 303
CONCORD, MASSACHUSETTS 01742
UNITED STATES

ATTN: LIM CHEUNG PH.D
510k Number: K101734
Received: 6/21/2010
Product: VISIONSCOPE HIGH DEFINITION EN

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

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

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

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

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

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

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

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

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

Sincerely,

510(k) Staff

VisionScope Technologies LLC
2352 Main Street, Suite 303
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USA
T: 1-978-776-9512
F: 1-978-776-9511

K101734/A2

VISIONSCOPE

June 22, 2010

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002
Attention: 510(k) Staff

FDA CDRH DMC

JUL 07 2010

Received

Re: Incorrect Company Name in the Acknowledgment Letter of June 21, 2010
510(k) Number: K101734

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General Manager & CTO
VisionScope Technologies, LLC
2352 Main Street, Suite 303
Concord, MA 01742
Voice: 978-776-9512
Fax: 978-776-9511
Mobile: 617-283-1906

Attachment: FDA Ack Letter

KLIS

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

Correct name is
VisionScope Technologies, LLC

June 21, 2010

VISION TECHNOLOGIES INTL., INC.
2352 MAIN STREET SUITE 303
CONCORD, MASSACHUSETTS 01742
UNITED STATES
ATTN: LIM CHEUNG PH.D

510k Number: K101734
Received: 6/21/2010
Product: VISIONSCOPE HIGH DEFINITION EN

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VisionScope Technologies, LLC
% Lim Cheung, Ph.D.
General Manager & CTO
2352 Main Street, Suite 303
Concord, Massachusetts 01742

SEP 0 8 2010

Re: K101734
Trade/Device Name: VisionScope High Definition Endoscopy Camera System with:

- Camera Control Unit
- Camera Handpiece
- Endoscopes (Accessories in four lengths)
- Sterile Procedure Kits (Accessories in four lengths)

Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, GCJ
Dated: June 15, 2010
Received: June 21, 2010

Dear Dr. Cheung:

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.

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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,

For Petitioner Dep D.R.

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

Enclosure

Indications for Use

K101734

SEP 08 2010

510(k) Number (if known): K101734

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Prescription Use __Yes__ (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)

Neil R P Ogden for

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

510(k) Number K101734

3

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

June 21, 2010

VISION TECHNOLOGIES INTL., INC.
2352 MAIN STREET SUITE 303
CONCORD, MASSACHUSETTS 01742
UNITED STATES
ATTN: LIM CHEUNG PH.D

510k Number: K101734
Received: 6/21/2010
Product: VISIONSCOPE HIGH DEFINITION EN

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

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

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

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

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

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

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

Sincerely,

510(k) Staff

VISIONSCOPE Technologies LLC	Screening Checklist for Traditional Premarket Notification [510(k)] Submissions	Confidential

Section	Table of Contents / Checklist	Present	N/A
1	Medical Device User Fee Cover Sheet (Form FDA 3601)	✓	
2	CDRH Premarket Review Submission Cover Sheet	✓	
2.1	CDRH Premarket Review Submission Cover Sheet	✓	
2.2	Attachment 1 - UTILIZATION OF STANDARDS - Continuation	✓	
3	510(k) Cover Letter	✓	
4	Indications for Use Statement	✓	
5	510(k) Summary	✓	
6	Truthful and Accuracy Statement	✓	
7	Class III Summary and Certification – NA – Blank		✓
8	Financial Certification or Disclosure Statement – NA – Blank		✓
9	Declaration of Conformity and Summary Reports	✓	
9.1	VisionScope Declaration of Conformity	✓	
9.2	Form 3654 - ISO 11135-1	✓	
9.3	Form 3654 - ISO 10993-7	✓	
9.4	Form 3654 - ISO 10993-5	✓	
9.5	Form 3654 - ISO 10993-10	✓	
9.6	Form 3654 - ISO 10993-11	✓	
9.7	Form 3654 - UL 60601-1	✓	
9.8	Form 3654 - IEC 60601-1	✓	
9.9	Form 3654 - EN 60601-1	✓	
9.10	Form 3654 - CAN_CSA 22.2 601.1	✓	
9.11	Form 3654 - IEC 60601-1-4	✓	
9.12	Form 3654 - IEC 60601-1-6	✓	
9.13	Form 3654 - IEC 60601-1-2	✓	
9.14	Form 3654 - IEC 60601-2-18	✓	
10	Executive Summary	✓	
11	Device Description	✓	
11.1	VisionScope Endoscopy System Device Description	✓	
11.2	50006 Endoscope Engineering Drawing	✓	
11.3	50033 Sterile Procedure Kit Engineering Drawing	✓	
11.4	50023 Disposable Endoscope Sheath Engineering Drawing	✓	
11.5	50024 Canula Engineering Drawing	✓	
11.6	50027 Trocar Engineering Drawing	✓	
12	Substantial Equivalence Discussion	✓	
12.1	Substantial Equivalence – Summary	✓	
12.2	Substantial Equivalence Technical Features Comparison	✓	
12.3	InnerVue Reference Guide	✓	
12.4	Smith & Nephew 560 HD Camera System	✓	
12.5	Smith & Nephew 660 HD Image Management System	✓	
12.6	Smith and Nephew Arthroscopes	✓	
12.7	Stryker Evolution of HD Technology Brochure	✓	
12.8	VisionSciences Endosheath	✓	
12.9	VisionSciences Endosheath Urology Published Literature	✓	
13	Proposed Labeling	✓	
13.1	Proposed Labeling - Summary	✓	
13.2	VisionScope Labels and Markings	✓	
13.3	01112 - VisionScope System Instructions for Use	✓	
13.4	01113 - VisionScope Endoscope Instructions for Use	✓	
13.5	01114 - VisionScope Sterile Procedure Kit Instructions for Use	✓	
13.6	01115 - VisionScope Camera Handpiece Instructions for Use	✓	
13.7	80049 - VisionScope Brochure	✓	
13.8	InnerVue™ User Manual	✓	

14	Sterilization and Shelf Life	✓	
14.1	Sterilization and Shelf Life - Summary	✓	
14.2	80094 Supplemental Description of the Sterile Endoscope Illumination Sheath as a Protective Barrier	✓	
14.3	Camera & Endoscope ETO Sterilization Efficacy Validation Final Report (b)(4)	✓	
14.4	Camera & Endoscope Sterrad 100S Sterilization Efficacy Validation Final Report (b)(4)	✓	
14.5	Camera & Endoscope Sterrad NX Sterilization Efficacy Validation Final Report (b)(4)	✓	
14.6	Camera & Endoscope ETO & ECH Residual Test Report (b)(4)	✓	
14.7	Sterile Procedure Kit Tray Sealing (b)(4) Final Report	✓	
14.8	Sterile Procedure Kit Tray Sealing (b)(4) Final Report	✓	
14.9	Sterile Procedure Kit ETO Sterilization Protocol (b)(4)	✓	
14.10	Summary of Sterile Procedure Kit ETO Fractional Cycle per Protocol (b)(4)	✓	
14.11	Sterile Procedure Kit Fractional Cycle Sterilization Data	✓	
14.12	Sterile Procedure Kit Fractional Cycle Test Results	✓	
14.13	Sterile Procedure Kit ETO Fractional Cycle Biological Indicator Certificates	✓	
14.14	Sterile Procedure Kit Ship Test Final Report (b)(4)	✓	
14.15	Sterile Procedure Kit Aging Test Validation Protocol P(b)(4)	✓	
14.16	Sterile Procedure Kit Label Validation Final Report (b)(4)	✓	
15	Biocompatibility	✓	
15.1	Biocompatibility - Summary	✓	
15.2	513842 - ISO 10993-5 MEM Elution Cytotoxicity Test Report of Illumination Sheath	✓	
15.3	513848 - ISO 10993-10 Maximization Sensitization Report of Illumination Sheath	✓	
15.4	513849 - ISO 10993-10 Intracutaneous Reactivity Report of Illumination Sheath	✓	
15.5	513850 - ISO 10993-11 Acute Systemic Injection Report of Illumination Sheath	✓	
15.6	513851 - ISO 10993-11 Materials Mediated Rabbit Pyrogen Report of Illumination Sheath	✓	
15.7	ISO 10993 (b)(4) Plastic Fiber Report	✓	
15.8	ISO 10993 (b)(4) Loctitie 322 Report	✓	
15.9	ISO 10993 (b)(4) Biocompatibility Report	✓	
15.10	ISO 10993 (b)(4) Report	✓	
15.11	ISO 10993 (b)(4) Report	✓	
15.12	ISO 10993-5 Cytotoxicity Report for (b)(4)	✓	
15.13	517869 - ISO 10993-5 MEM Elution Cytotoxicity (b)(4)	✓	
15.14	520734 - ISO 10993 Part 5 MEM Elution Cytotoxicity Peek & Trocar Cover Report	✓	
15.15	Radel R-5100 NT 15 Biocompatibility Report	✓	
15.16	Eastman 6763 Biocompatibility Report	✓	
15.17	(b)(4) MSDS	✓	
15.18	(b)(4) Cytotoxicity Report	✓	
16	Software	✓	
16.1	Software - Summary	✓	
16.2	80071 VisionScope Software Architecture Design and Description	✓	
16.3	80020 VisionScope Risk Management Plan & Risk Management Summary	✓	
16.4	80013 VisionScope Risk Analysis	✓	
16.5	80014 VisionScope Design FMEA	✓	
16.6	80055 VisionScope Software FMEA	✓	
16.7	IEC60601-1-4 VisionScope Risk Management	✓	

16.8	IEC60601-1-6 VisionScope Usability	✓	
16.9	80016 VisionScope Software Requirements Specifications	✓	
16.10	80019 VisionScope Software Design Specifications	✓	
16.11	80072 VisionScope Traceability Analysis	✓	
16.12	80028 VisionScope Software Validation Document	✓	
16.13	80029 VisionScope Software Verification Document	✓	
16.14	80073 - Software Revision History Log	✓	
16.15	VisionScope Software Unresolved Anomalies	✓	
17	Electromagnetic Compatibility and Electrical Safety	✓	
17.1	Electromagnetic Compatibility and Electrical Safety - Summary	✓	
17.2	UL 60601-1 Certicate CU72100321.01	✓	
17.3	UL 60601-1 + CAN CSA Report	✓	
17.4	EN-IEC 60601-1 Report	✓	
17.5	EN 60601-1-2 EMI-EMC Report	✓	
17.6	IEC 60601-2-18 Endoscope Safety Report	✓	
17.7	Attachment 1 EN-IEC-UL 60601-1 Attachment - Constructional Data Form	✓	
17.8	Attachment 2 National Difference EN60601-1 CB 112A	✓	
17.9	Attachment 3 Test Pictures	✓	
18	Performance Testing – Bench	✓	
18.1	Performance Testing - Summary	✓	
18.2	80030 VisionScope System Validation Protocol & Report	✓	
18.3	80084 VisionScope System Validation in Cadaver labs	✓	
18.4	80099 Validation of Usability of Instructions for Use	✓	
18.5	80026 Verification of VisionScope Instructions for Use per UL60601 and IEC60601-2-18	✓	
18.6	80038 Verification of VisionScope Camera Head and CCU	✓	
18.7	80037 Verification of Endoscopes Illumination Sheath, Cannula and Trocar	✓	
18.8	80083 Sterilization Compatibility Validation Report for Endoscope and Camera Head	✓	
18.9	80082 ETO Sterilization Compatibility of Sterile Procedure Kit including Protective Barrier Effectiveness	✓	
19	Performance Testing – Animal – Not Applicable, Blank		N/A
20	Performance Testing – Clinical – Not Applicable, Blank		N/A

K101734

VisionScope Technologies LLC
2352 Main Street, Suite 303
Concord, MA 01742
USA
T: 1-978-776-9512
F: 1-978-776-9511
Email: Lim.Cheung@visionscope-tech.com

VISIONSCOPE

FDA CDRH DMC
JUN 21 2010
Received

June 7, 2010

Medical Device User Fee

The Company has paid the Medical Device User Fee of $2,004.00 for a Small Business on June 7th 2010, for this 510(k) submission to the Food and Drug Administration.

A copy of the Medical Device User Fee Cover Page along with the payment receipt is provided on the next two pages.

Lim Cheung
General Manager & CTO

25

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

VISIONSCOPE TECHNOLOGIES LLC
2352 Main Street
Suite 303
Concord MA 01742
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****1104

2. CONTACT NAME
Lim Cheung

2.1 E-MAIL ADDRESS
Lim.Cheung@visionscope-tech.com

2.2 TELEPHONE NUMBER (include Area code)
978-7769512

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number: SBD108270

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) [redacted]
07-Jun-2010

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

26

Lim Cheung

From: paygovadmin@mail.doc.twai.gov
Sent: Monday, June 07, 2010 8:48 AM
To: Lim Cheung
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Transaction Summary

(b)(4)

[redacted]

27

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
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)*
06/15/2010	(b)(4) [redacted]	

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: VisionScope Technologies, LLC	Establishment Registration Number *(if known)*: Will register within 30 days of 510(k) clearance		
Division Name *(if applicable)*:	Phone Number *(including area code)*: 1-978-776-9512		
Street Address: 2352 Main Street, Suite 303	FAX Number *(including area code)*: 1-978-776-9511		
City: Concord	State / Province: MA	ZIP/Postal Code: 01742	Country: USA
Contact Name: Lim Cheung, Ph.D.			
Contact Title: General Manager and Chief Technical Officer	Contact E-mail Address: Lim.Cheung@visionscope-tech.com		

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

Company / Institution Name: same as above			
Division Name *(if applicable)*:	Phone Number *(including area code)*:		
Street Address:	FAX Number *(including area code)*:		
City:	State / Province:	ZIP Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

PSC Graphics (301) 443-1090 EF

28

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

- ☐ New Device
- ☐ 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

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ 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

- ☐ Response 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)*:

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GCJ	2	HRX	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 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	K072879 (Primary)	1	InnerVue Diagnostic Scope System	1	Arthrotek Inc. (Biomet)
2	K070266 (Secondary)	2	560 High Definition Camera System	2	Smith & Nephew Endoscopy
3	K072675 (Secondary)	3	Smith & Nephew Arthroscope	3	Smith & Nephew Endoscopy
4	K082813 (Secondary)	4	Stryker LED Light Source L9000	4	Stryker Endoscopy
5	K990354 (Secondary)	5	VisionSciences Endosheath for Use with Flexible ENT Scopes	5	Vision Sciences Inc.
6	K060777 (Secondary)	6	Smith & Nephew Model 660HD Image Management System	6	Smith & Nephew Endoscopy

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Endoscope and Accessories: Video System, Light Source, Video Capture, Endoscope Sheath, Endoscope, Arthroscope

	Trade or Proprietary or Model Name for This Device		Model Number
1	VisionScope High Definition Endoscopy Camera System, with:	1	see below:
2	Camera Control Unit	2	50034
3	Camera Handpiece	3	50021
4	VisionScope Endoscopes (accessories with four lengths: 60 mm - 220 mm)	4	50060-XXX, XXX = length in mm = 060, 095, 160, 220
5	VisionScope Disposable Sterile Procedure Kits (accessories with four lengths: 60 mm - 220 mm)	5	50033-XXX, XXX = length in mm = 060, 095, 160, 220

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

1 N/A	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
HRX, GCJ	888.1100, 876.1500	☐ Class I ☒ Class II
Classification Panel: Orthopedic, General & Plastic Surgery		☐ Class III ☐ Unclassified

Indications *(from labeling)*

The VisionScope High Definition Endoscopy Camera System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of an interior cavity of the body through a natural or surgical opening. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.
Additionally, when used in conjunction with an appropriately indicated and FDA 510(k)-cleared endoscope and light source, the VisionScope High Definition Endoscopy Camera Control Unit and Camera Handpiece are indicated for use in arthroscopic and endoscopic surgical procedures to provide illumination, visualization and capture of still and motion pictures of articular cavities, body cavities, hollow organs and canals.

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**

(b)(4)

[redacted]

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	ISO 11135-1:2007	AAMI/ANSI/ISO	Sterilization of health care products -- Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2007	01/01/2007
2	ISO 10993-7:2008	AAMI/ANSI/ISO	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals	2008	01/01/2008
3	ISO 10993-5: 2009	AAMI/ANSI/ISO	Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity	2009	01/01/2009
4	ISO 10993-10:2002	AAMI/ANSI/ISO	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity	2002	01/01/2002
5	ISO 10993-11: 2006	AAMI/ANSI/ISO	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2006	1/1/2006
6	UL 60601-1:2003 R4.06	UL	Medical Electrical Equipment - Part 1: General Requirements for Safety	2003 R4.06	4/25/2003
7	IEC 60601-1:1988 + A1:1991 + A2:1995	IEC	Medical Electrical Equipment - Part 1: General Requirements for Safety	1995	01/01/1995

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:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

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.

SECTION I	UTILIZATION OF STANDARDS – CONTINUATION SHEET				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
8	Standards No.	Standards Organization	Standards Title	Version	Date
	EN 60601-1:1990 + A1:1993 + A2:1995 + A3:1996	EN	Medical Electrical Equipment - Part 1: General Requirements for Safety	1990 +A1:1993 +A2:1995 +A3:1996	1996
9	Standards No.	Standards Organization	Standards Title	Version	Date
	CAN/CSA-C22.2 No. 601.1-M90: 2005	CAN/CSA	Medical Electrical Equipment - Part 1: General Requirements for Safety	2005	2005
10	Standards No.	Standards Organization	Standards Title	Version	Date
	IEC 60601-1- 4 / EN60601-1-4:2000	IEC/EN	Medical electric equipment Part 1-4: General Requirements for Safety, Collaeral Standards: Programmable Electrical Medical Equipment	2000	2000
11	Standards No.	Standards Organization	Standards Title	Version	Date
	IEC 60601-1-6: 2004 (First Edition) for use in conjunction with IEC 60601-1:1988 + A1:1991 + A2:1995	IEC	Medical electrical equipment Part 1-6: General requirements for safety - Collateral Standard: Usability	Edition 1	2004
12	Standards No.	Standards Organization	Standards Title	Version	Date
	IEC/EN 60601-1-2:2007	IEC/EN	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility	2007	2007
13	Standards No.	Standards Organization	Standards Title	Version	Date
	IEC 60601-2-18:1996 Second Edition + A1:2000	IEC	Medical electrical equipment - Part 2: Particular Requirements for the Safety of Endoscopic Equipment	1996 + A1:2001	2001
14	Standards No.	Standards Organization	Standards Title	Version	Date

VisionScope Technologies LLC
2352 Main Street, Suite 303
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VISIONSCOPE

510(K) Cover Letter

June 15, 2010

FDA CDRH DMC
JUN 21 2010
Received

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Attention: Division of General, Restorative and Neurological Devices
Office of Device Evaluation

Re: Premarket Notification for VisionScope Technologies, LLC's High Definition Endoscopy Camera System

Dear Sir or Madam:

VisionScope Technologies, LLC. ("VisionScope" or "Company") is submitting the attached premarket notification ("510(k) Notification") prepared according to the requirements of 21CFR §807.87, for its High Definition Endoscopy Camera System ("Device").

Per the instructions accessed at 'Electronic Copies for Pre-Market Submissions', an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.

A Table of Contents / Screening Checklist is given at the beginning of the paper or electronic copy. It outlines all the major sections organized in a format in conformance with FDA's August 12, 2005, Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)'s.

A summary of the Device is given here:

Product Code:	GCJ (Endoscope and accessories); HRX (Arthroscope)
Panel:	General and Cosmetic Surgery; Orthopedic
Trade/Proprietary Name:	VisionScope High Definition Endoscopy Camera System
Establishment Registration No.:	To be registered within 30 days of clearance and commercial distribution
Device Class:	Class 2.
Basis for Submission:	A new device design that is substantially equivalent to predicate Endoscopy Imaging Devices on the market as described in Section 12
Intended Use:	Arthroscopic and endoscopic diagnostic and operative imaging, on the order of a licensed physician

Indications for Use:

The VisionScope High Definition Endoscopy Camera System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of an interior cavity of the body through a natural or surgical opening. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

Additionally, when used in conjunction with an appropriately indicated and FDA 510(k)-cleared endoscope and light source, the VisionScope High Definition Endoscopy Camera Control Unit and Camera Handpiece are indicated for use in arthroscopic and endoscopic surgical procedures to provide illumination, visualization and capture of still and motion pictures of articular cavities, body cavities, hollow organs and canals.

Bundling of Device Components that form the VisionScope High Definition Endoscopy Camera System:

Item	Device Components	Reasons for Bundling:
1	Camera Control Unit	• Same Indications for Use for all Device Components • Efficiency of the Review Process • Items (1) and (2) are always used together at all time. • Items (3) and (4) are accessories of Items (1) and (2). • Items (3) and (4) are intended to be used together at all time, and only with Item (1) and (2). • The technology, manufacturing processes and labeling for the four lengths of Items (3) and (4) are identical except for the lengths.
2	Camera Handpiece	
3	Endoscopes (in Four lengths, 60 - 220 mm)	
4	Sterile Procedure Kit (in Four Lengths, 60 - 220 mm)	

Design and Use of the Device

To conform with FDA's August 12, 2005, Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)'s, factors concerning the design and use of the Device are set forth in the following table.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	All four items	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		All four items
Does the device contain components derived from a tissue or other biologic source?		All four items
Is the device provided sterile?	Item 4 - Procedure Kits	Item 1 – Camera Control Unit Item 2 - Camera Handpiece Item 3 - Endoscopes
Is the device intended for single use?	Item 4 - Procedure Kits	Item 1 – Camera Control Unit Item 2 - Camera Handpiece Item 3 - Endoscopes
Is the device a reprocessed single use device?		All four items
If yes, does this device type require reprocessed validation data?	N/A	N/A

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Does the device contain a drug?		All four items
Does the device contain a biologic?		All four items
Does the device use software?	Item 1 - Camera Control Unit	Item 2 - Camera Handpiece Item 3 – Endoscopes Item 4 – Sterile Procedure Kits
Does the submission include clinical information?		All four items
Is the device implanted?		All four items

VisionScope considers its intent to market the Device as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employers, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company, therefore requests that FDA not disclose the existence of this application until such time as final action on the submission is taken.

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

Please contact the undersigned if any additional information is needed.

Sincerely,

Lim Cheung, Ph.D.
General Manager & CTO

VisionScope Technologies, LLC
2352 Main Street, Suite 303
Concord, MA 01742, USA
Telephone: 1-978-776-9512
Fax: 1-978-776-9511
e-mail: Lim.Cheung@visionscope-tech.com

Attachments:

- One set of printed paper copy of the 510(k) Notifications
- One CD-ROM containing the exact copy in electronic format

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2352 Main Street, Suite 303
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Indications for Use

510(k) Number (if known): Application in process, not yet assigned

Device Name:

VisionScope High Definition Endoscopy Camera System with:

- Camera Control Unit
- Camera Handpiece
- Endoscopes (Accessories in four lengths)
- Sterile Procedure Kits (Accessories in four lengths)

Indications for Use:

The VisionScope High Definition Endoscopy Camera System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of an interior cavity of the body through a natural or surgical opening. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

Additionally, when used in conjunction with an appropriately indicated and FDA 510(k)-cleared endoscope and light source, the VisionScope High Definition Endoscopy Camera Control Unit and Camera Handpiece are indicated for use in arthroscopic and endoscopic surgical procedures to provide illumination, visualization and capture of still and motion pictures of articular cavities, body cavities, hollow organs and canals.

Prescription Use __Yes__ (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)

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510(k) Summary of Safety and Effectiveness as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which Substantial Equivalence is based

1. **Date Prepared:** June 15, 2010

2. **510(k) Owner's Name:**
   VisionScope Technologies, LLC
   2352 Main Street, Suite 303
   Concord, MA 01742, USA

3. **Contact Information:**
   Lim Cheung, Ph.D.
   General Manager & CTO
   Telephone: 1-978-776-9512
   Fax: 1-978-776-9511
   Email: Lim.Cheung@visionscope-tech.com

4. **Device Name**

Trade Name: VisionScope High Definition Endoscopy Camera System with:

- Camera Control Unit
- Camera Handpiece
- Endoscopes (Accessories in four lengths)
- Sterile Procedure Kits (Accessories in four lengths)

Common Name: Endoscopes and Accessories: Video Systems, Image Capture, Light Source, Endoscopes, Fiber Optic

Classification Name: Endoscopes And/Or Accessories (21 CFR §876.1500): Video System, Image Capture, Light source, Endoscope, Fiber Optic
Arthroscope (21 CFR §888.1100)

5. **Predicate Devices:**

Primary:		
InnerVue Diagnostic Scope System	K072879	Arthrotek Inc. (Biomet)
Secondary:		
Smith & Nephew HD Camera System	K070266	Smith & Nephew Endoscopy
Smith & Nephew Arthroscope	K072675	Smith & Nephew Endoscopy
Stryker LED Light Source (L9000)	K082813	Stryker Endoscopy
EndoSheath	K990354	Vision Sciences Inc.
Smith & Nephew 660HD Image Management System	K060777	Smith & Nephew Endoscopy

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6. Description of Device

The VisionScope High Definition Endoscopy Camera System is made up of the following components:

- Integrated Camera Control Unit containing the camera control electronics, light source and image capture electronics
- Camera Handpiece
- VisionScope line of four Endoscopes of identical design except for the lengths
- VisionScope Disposable Sterile Procedure Kits in four matched lengths as the endoscopes

7. Indications for Use

The VisionScope High Definition Endoscopy Camera System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of an interior cavity of the body through a natural or surgical opening. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

Additionally, when used in conjunction with an appropriately indicated and FDA 510(k)-cleared endoscope and light source, the VisionScope High Definition Endoscopy Camera Control Unit and Camera Handpiece are indicated for use in arthroscopic and endoscopic surgical procedures to provide illumination, visualization and capture of still and motion pictures of articular cavities, body cavities, hollow organs and canals.

8. Comparison of Technological Characteristics

The VisionScope System similarities to the predicate devices are:

- Has the same intended use and indications for use
- Utilizes the same operating principle
- Incorporates the same basic design
- Incorporates the same technological characteristics
- Tested to the same electrical and electromagnetic safety standards for medical electrical equipment
- Manufactured under a quality system

9. Summary Performance Data

VisionScope conducted the verification and validation testing with the VisionScope High Definition Endoscopy Camera System to demonstrate safety and effectiveness and substantial equivalence to the predicate devices listed above. All verification and validation data demonstrate that the device is safe and effective and performs as intended.

The VisionScope System conforms to the following voluntary standards:

- ANSI/AAMI/ISO 11135-1:2007
- ISO 10993-7:2008
- ISO 10993-5:2009

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- ISO 10993-10:2002
- ISO 10993-11:2006
- UL 60601-1:2003 R4.06
- IEC 60601-1:1988 + A1:1991 + A2:1995,
- EN 60601-1:1990 + A1 + A2 + A13
- CAN/CSA 22.2 No. 601.1
- IEC 60601-1- 4 / EN60601-1-4:2000
- IEC 60601-1-6: 2004 (First Edition) for use in conjunction with IEC 60601-1:1988 + A1:1991 + A2:1995
- EN 60601-1-2:2007
- IEC 60601-2-18:1996 Second Edition + A1:2000

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VISIONSCOPE

Premarket Notification Truthful And Accurate Statement

[As Required by 21 CFR 807.87(k)]

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

(Signature)

Lim Cheung, Ph.D.
General Manager and CTO

June 15, 2010

(Date)

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

Not Applicable - Class III Summary and Certification - purposely left blank

Not Applicable - Financial Disclosure - purposely left blank

VisionScope Technologies LLC
2352 Main Street, Suite 303
Concord, MA 01742
USA
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Declaration of Conformity
VisionScope Technologies, LLC

Device: VisionScope High Definition Diagnostic and Operative Endoscopy System, consisting of:

- Camera Control Unit (PN 50034)
- Camera Handpiece (PN 50021)
- Endoscopes - Accessories (PN 50006-060, 50006-095, 50006-160, 50006-220)
- Disposable Procedure Kits - Accessories (PN 50033-060, 50033-095, 50033-160, 50033-220)

Consistent with FDA's guidance documents entitled "Use of Standards in Substantial Equivalence Determinations" (March 12, 2000) and "Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards" (September 17, 2007), VisionScope is including this statement that the Device complies with the recognized consensus standards listed in the following table.

A Data Standards Form (FDA Form 3654) is provided on the pages that follow for each standard listed. In addition, the test results or reports for the standards listed can be found in the Section Number indicated in the table below.

Standards	Form 3654 Attached	Test Reports Locations (Document No.)
ANSI/AAMI/ISO 11135-1:2007	✓	Document 14.1 & references therein
ISO 10993-7:2008	✓	Document 14.1 & references therein
ISO 10993-5: 2009	✓	Document 15.1 & references therein
ISO 10993-10: 2002	✓	Document 15.1 & references therein
ISO 10993-11: 2006	✓	Document 15.1 & references therein
UL 60601-1:2003 R4.06	✓	Documents 17.2, 17.3, 17.7, 17.8, 17.9
IEC 60601-1:1988 + A1:1991 + A2:1995	✓	Documents 17.4, 17.7, 17.8, 17.9
EN 60601-1:1990 + A1 + A2 + A3	✓	Documents 17.4, 17.7, 17.8, 17.9
CAN/CSA-C22.2 No. 601.1-M90	✓	Documents 17.3, 17.7, 17.8, 17.9
IEC 60601-1- 4 / EN60601-1-4:2000	✓	Documents 16.7, 17.3
IEC 60601-1-6: 2004 (First Edition) for use in conjunction with IEC 60601-1:1988 + A1:1991 + A2:1995	✓	Documents 16.8, 17.3
IEC/EN 60601-1-2:2007	✓	Document 17.5
IEC 60601-2-18:1996 Second Edition + A1:2000	✓	Document 17.6

Lim Cheung, Ph.D.
General Manager & CTO

9.2 - Form 3654 - ISO 11135-1

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]

ISO 11135-1:2007 Sterilization... - Ethylene oxide -- Part 1: Req'mts for dev., validat. and routine control of a sterilization process

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-228		
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: Dec 12, 2008 Draft Guidance for Industry and FDA Staff - Submission & Review of Sterility Information

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

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

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO 11135-1:2007 Sterilization... - Ethylene oxide -- Part 1: Req'mts for dev., validat. and routine control of a sterilization process

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 ◆	None	
DESCRIPTION	N/A	
JUSTIFICATION	N/A	

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☑ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆	None	
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.

9.3 - Form 3654 - ISO 10993-7

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]

AAMI/ANSI/ISO 10993-7:2008, Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-279		
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: Dec 12, 2008 Draft Guidance for Industry and FDA Staff - Submission & Review of Sterility Information

[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

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

AAMI/ANSI/ISO 10993-7:2008, Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals

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 ◆	None	
DESCRIPTION	N/A	
JUSTIFICATION	N/A	

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☑ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆	None	
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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Rockville, MD 20850

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9.4 - Form 3654 - ISO 10993-5

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]

AAMI/ANSI/ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 2-64		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
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: Blue Book Memo, G95-1, Use of ISO-10993, and Biological Evaluation of Med. Devices

[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

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

AAMI/ANSI/ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity

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 ◆	None	
DESCRIPTION	N/A	
JUSTIFICATION	N/A	

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☑ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆	None	
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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9.5 - Form 3654 - ISO 10993-10

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]

ISO 10993-10:2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 2-87		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
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: Blue Book Memo, G95-1, Use of ISO-10993, and Biological Evaluation of Med. Devices

[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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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

55

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-10:2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

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 ◆	None	
DESCRIPTION	N/A	
JUSTIFICATION	N/A	

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☑ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆	None	
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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56

9.6 - Form 3654 - ISO 10993-11

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]

AAMI/ANSI/ISO 10993-11:2006, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 2-118	
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: Blue Book Memo, G95-1, Use of ISO-10993, and Biological Evaluation of Med. Devices

[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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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

AAMI/ANSI/ISO 10993-11:2006, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

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 ◆	None	
DESCRIPTION	N/A	
JUSTIFICATION	N/A	

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☑ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆	None	
DESCRIPTION		
JUSTIFICATION		

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9.7 - Form 3654 - UL 60601-1

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]

UL 60601-1:2003 R4.06 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] # _____		
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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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

UL 60601-1:2003 R4.06 Medical Electrical Equipment - Part 1: General Requirements for Safety

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 ◆	None	
DESCRIPTION	N/A	
JUSTIFICATION	N/A	

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☑ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆	None	
DESCRIPTION		
JUSTIFICATION		

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G2

9.8 - Form 3654 - IEC 60601-1

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

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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: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601-1:1988 + A1:1991 + A2:1995 Medical Electrical Equipment - Part 1: General Requirements for Safety

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 ◆	None	
DESCRIPTION	N/A	
JUSTIFICATION	N/A	

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☑ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆	None	
DESCRIPTION		
JUSTIFICATION		

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65

9.9 - Form 3654 - EN 60601-1

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

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EN 60601-1:1990 + A1 + A2 + A3 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] # _____		
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.	☑	☐
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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: _____

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G7

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

EN 60601-1:1990 + A1 + A2 + A3 Medical Electrical Equipment - Part 1: General Requirements for Safety

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 *	None	
DESCRIPTION	N/A	
JUSTIFICATION	N/A	

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☑ N/A
TYPE OF DEVIATION OR OPTION SELECTED *	None	
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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9.10 - Form 3654 - CAN_CSA 22.2 601.1

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

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

CAN/CSA-C22.2 No. 601.1-M90 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] # _____		
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

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CAN/CSA-C22.2 No. 601.1-M90 Medical Electrical Equipment - Part 1: General Requirements for Safety

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*		
None		
DESCRIPTION		
N/A		
JUSTIFICATION		
N/A		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☑ N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
None		
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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9.11 - Form 3654 - IEC 60601-1-4

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-4:2000 Medical electric equipment Part 1-4: General reqm'ts for safety, Collat. Stds: Progm'ble. Elec. Med. Equip.

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 5-41	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary 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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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601-1-4:2000 Medical electric equipment Part 1-4: General reqm'ts for safety, Collat. Stds: Progm'ble. Elec. Med. Equip.

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 ◆	None	
DESCRIPTION	N/A	
JUSTIFICATION	N/A	

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☑ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆	None	
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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9.12 - Form 3654 - IEC 60601-1-6

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Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601–1–6 Medical electrical equipment Part 1-6: General requirements for safety - Collateral Standard: Usability

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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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

76

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601–1–6 Medical electrical equipment Part 1-6: General requirements for safety - Collateral Standard: Usability

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 ◆	None	
DESCRIPTION	N/A	
JUSTIFICATION	N/A	

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☑ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆	None	
DESCRIPTION		
JUSTIFICATION		

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9.13 - Form 3654 - IEC 60601-1-2

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Department of Health and Human Services
Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC/EN 60601-1-2:2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: EMC

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 5-34 (v. 2004)	
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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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

19

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

IEC/EN 60601-1-2:2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: EMC

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 ◆	None	
DESCRIPTION	N/A	
JUSTIFICATION	N/A	

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☑ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆	None	
DESCRIPTION		
JUSTIFICATION		

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9.14 - Form 3654 - IEC 60601-2-18

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

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Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC60601-2-18:1996+A1:2000 Medical electrical equipm't. 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: _____

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82

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

IEC60601-2-18:1996+A1:2000 Medical electrical equipm't. Part 2: Particular requirements for the safety of endoscopic equipment

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 ◆	None	
DESCRIPTION	N/A	
JUSTIFICATION	N/A	

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☑ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆	None	
DESCRIPTION		
JUSTIFICATION		

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83

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USA
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VISIONSCOPE

Executive Summary

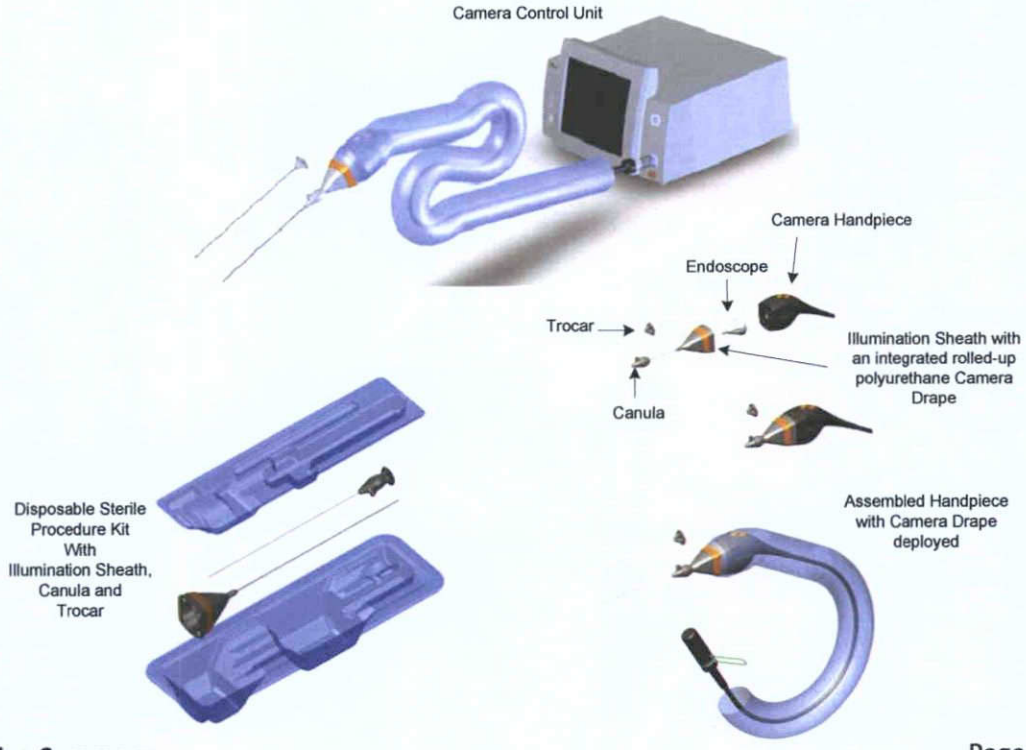
VisionScope High Definition Endoscopy Camera System 510(k) Notifications

VisionScope is an endoscopic imaging system designed to enable pre-operative and post-operative diagnosis in physician examination rooms. The device can also be used in operating rooms where smaller gauge endoscopes are important for minimally invasive surgical procedures. The key component of the VisionScope is a 1.4 mm diameter semi-rigid fiber-lens endoscope that fits within a disposable 1.7 mm diameter illumination sheath, which in turn is small enough to fit through a 2 mm portal or cannula. The disposable sterile illumination sheath is constructed of a leak-proof stainless steel tube with a hermetically sealed distal tip glass window that acts as a sterile protective barrier over the re-usable endoscope. VisionScope Technologies is able to miniaturize the endoscopes and illumination sheaths while still providing high clarity anatomical visualization. When used as an imaging device alone and without any resection or irrigation instrument, the system enables surgeons to perform direct visual clinical assessment without requiring re-sterilization or fluid disposal processing following a diagnostic imaging procedure.

The VisionScope High Definition Endoscopy Camera System is made up of four major components:

1) Camera Control Unit containing video electronics, LED light source, and an image recorder
2) Camera Handpiece with an imaging sensor and control buttons for image capture or camera setting adjustments
3) Endoscopes in four working lengths (60 mm, 95 mm, 160 mm, 220 mm) for different anatomical cavities (e.g., small and large articular joints or body cavities)
4) Sterile Procedure Kits in four matching lengths as the endoscopes, containing a set of disposable Illumination Sheath with an integrated Camera Drape, Cannula and Trocar.

A picture of the VisionScope System showing how the components are deployed is shown below.



84

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VISIONSCOPE

Indications for Use

1. The VisionScope High Definition Endoscopy Camera System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of an interior cavity of the body through a natural or surgical opening. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

2. Additionally, when used in conjunction with an appropriately indicated and FDA 510(k)-cleared endoscope and light source, the VisionScope High Definition Endoscopy Camera Control Unit and Camera Handpiece are indicated for use in arthroscopic and endoscopic surgical procedures to provide illumination, visualization and capture of still and motion pictures of articular cavities, body cavities, hollow organs and canals.

Predicate Device Comparison Table

The VisionScope System is substantially equivalent to several 510(k)-cleared predicate endoscopic imaging devices on the market. The primary predicate device is the InnerVue Diagnostic Scope System (K072879) manufactured by Biomet, with substantially the same Indications for Use as stated in the first statement (1) in the two-part VisionScope Indications for Use statement above.

Additionally, the VisionScope Camera Control Unit and Camera Handpiece are also designed to be compatible with the industry-standard C-mount endoscopes and light sources with standard fiber optic light cords. Therefore both the VisionScope Camera Control Unit and Camera Handpiece, without the disposable Procedure Kit, are substantially equivalent to several secondary generic predicate endoscopy camera systems, such as those manufactured by Smith & Nephew Endoscopy, Stryker Endoscopy and Karl Storz Endoscopy. One unique difference is that VisionScope managed to make use of advance microelectronics technology to integrate the functions of three separate predicate electronics devices (camera control unit, light source and image management unit) into one single integrated unit. These separate predicate devices are always used together in combination on a video tower or ceiling-mounted stack in an operating room. Therefore we use one example each of a generic camera, light source and image management device as our secondary predicate devices. The second statement (2) in the two-part VisionScope Indications for Use above shows the substantial equivalence to these secondary predicate devices.

An abbreviated Device Comparison Table is shown below, highlighting the similarities and differences. There is no difference in intended use, intended users, or use environments with these predicate devices. The imaging science, operating principle and basic underlying technology in electronics, video and optics, and safety and effectiveness of the sterile barrier, are substantially the same. Differences are mainly in the technological implementation and component packaging. A more detailed substantial equivalence comparison is given in Section 12.

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VISIONSCOPE

VisionScope System or Subsystems	Predicate Device Manufacturer, Model, and 510(k) Number	VisionScope Indications for Use closely track those of the following Predicate Devices:	Comparison of Technological Characteristics
VisionScope HD Endoscopy Camera System	Biomet Sports Medicine – Arthrotek InnerVue Diagnostic Scope System K072879 (Primary Predicate)	The InnerVue™ Diagnostic Scope System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening. Examples of generic surgical use include the visualization of joints within the body. These joints can include, joints located in the torso/trunk, upper/lower extremities, and the TMJ.	- Substantially same indications for use - Same operating principle - Same basic function design and use of technological components: imaging sensor, fiber optics, light source, image capture, disposable optics, camera handpiece, camera/cable drape
VisionScope High Definition Camera Control Unit (CCU) and Camera Handpiece	Smith and Nephew 560HD Camera System K070266 (Secondary Predicate)	The Smith & Nephew HD Camera System is indicated for use in endoscopic surgical procedures to allow visualization of the articular cavities, body cavities, hollow organs and canals when used with an appropriately indicated endoscope. Additionally, when used in conjunction with a Smith & Nephew light source and light cable the Smith & Nephew HD Camera System is indicated for use in endoscopic surgical procedures in the thoracic cavity when used with an appropriately indicated thoracoscope.	- Substantially same indications for use - Same operating principle - Same basic function design and use of technological components: imaging sensor, video electronics, C-mount optics adaptor - Reusable camera handpiece, sterilization efficacy validated to be compatible with ETO and Sterrad 100S and NX sterilization
VisionScope Endoscopes	Smith & Nephew Arthroscopes K072675 (Secondary Predicate)	The Smith & Nephew line of rigid Arthroscopes and ENT Endoscopes is indicated to provide illumination and visualization in diagnostic and operative arthroscopic procedures, endoscopic exam and treatment of the nasal cavities and nasal pharynx… In addition, the Smith & Nephew 4 mm diameter rigid Arthroscope/ENT Endoscopes are indicated to provide illumination and visualization in the removal of loose bodies and soft tissue within the hip joint as size /length appropriate.	- Substantially same indications for use - Same operating principle - Same basic function design and use of technological components: imaging sensor, fiber and lens optical design, C-mount optics - Reusable camera handpiece, sterilization efficacy validated to be compatible with ETO and Sterrad 100S and Sterrad NX sterilization
VisionScope LED Light Source module within the CCU	Stryker LED Light Source (L9000) K082813 (Secondary Predicate)	The Stryker LED Light Source is used to illuminate the site of surgery during minimally invasive surgical procedures in Arthroscopy (orthopedic surgery), Laparoscopy (general and gynecological surgery) and in Endoscopy (general, gastroenterological and ENT surgery). The light is transmitted from the source through an optical cable and a scope.	- Substantially same indications for use - Same operating principle - Same basic function design and use of technological components - Stryker's LED light source is in a separate unit while VisionScope's is an integrated unit with more efficient LED's
VisionScope Image Management module within the CCU	Smith & Nephew Model 660 HD Image Management System K060777 (Secondary Predicate)	The Smith & Nephew 660HD Image Management System is intended to capture intraoperative still and motion images.	- Substantially same indications for use - Same operating principle - Same basic function design and use of technological components - S&N's Image Management is in a separate unit while VisionScope's is an integrated unit with smaller micro-electronics
VisionScope Sterile Illumination Sheath & Camera Drape	Vision- Sciences EndoSheaths K990354 (Secondary Predicate)	The Vision-Sciences EndoSheaths® are indicated for use as a protective covering for the scope during endoscopic examination of the upper airway, vocal chords and/or nasal passages.	- Substantially same indications for use - Same basic function as sterile barrier - VisionScope's sheath is made of more robust stainless steel tubing and optical glass for direct patient contact surfaces and polyurethane film for indirect patient contact surfaces - Vision-Sciences EndoSheath is made of 100% plastic films for all surfaces

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Summary of Performance Testing

VisionScope conducts product development and manufacturing activities in conformance with a Quality System Manual and a set of Standard Operating Procedures (SOPs). The quality system are developed and audited by TUV Rheinland of North America to be in compliance with both FDA CFR820 and ISO-13485 requirements. As of this writing, TUV has completed a Stage 2 on-site audit and have sent the recommendation report to their Certification Committee to approve ISO-13485:2003 certification.

VisionScope conducted the verification and validation (V&V) testing to demonstrate safety and effectiveness and substantial equivalence to the predicate devices listed above. All V&V tests are traceable to the specification documents (User Needs, Product Requirements, Engineering Specifications, Labeling, Instructions for Use, Software Requirements & Specifications, and Software Design Specifications) and conducted according to documented protocols with quantifiable pass/fail criteria. Risk Analysis, Design Failure Mode and Effect Analysis (FMEA) and Risk Mitigation are conducted and verified in parallel with the development activities and updated when appropriate, in accordance with ISO 14971:2007 Risk Management requirements.

Final V&V are conducted with process-validated, production-equivalent and revision-controlled samples that are documented in the V&V reports and Device History Record.

Design Review and Design Transfer processes are documented in accordance with SOPs and maintained in the Design History File.

The following performance testing have been performed and documented in Sections 14 through 19 of this 510(k) Notification package:

- Verification Testing in Laboratory environment, both in-house and by outside test laboratories.
- Validation and Usability Testing in Cadaver Laboratories with multiple independent and unaffiliated surgeons
- EMI/EMC Testing by TUV Rheinland North America
- Electrical Safety Testing by TUV Rheinland North America
- Software Verification by engineers
- Software Validation by independent software QA staff
- Usability of Software and Instructions for Use validated by end users (surgeon and M.D. candidate)
- Biocompatibility Testing by outside independent test labs.
- ETO Sterilization Efficacy and Validation testing by outside independent test labs.
- Sterile Packaging & Sealing Validation by sterile packaging contractor and outside test labs.
- Sterilization Cycling, Compatibility & Efficacy Validation of reusable camera handpiece and endoscopes by outside sterilization contractor and independent test labs.
- Sterile Barrier Testing by in-house staff and outside independent contract sterilization contractor
- Ship Testing by two independent test labs.
- Shelf Life, Accelerated and Real-Time Aging Testing by sterile packaging contractor

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The VisionScope System conforms to the following voluntary standards and audited by TUV Rheinland of North America. Full test reports are included in Sections 14, 15, 16 and 17. There are no non-compliant items.

- ANSI/AAMI/ISO 11135-1:2007
- ISO 10993-7:2008
- ISO 10993-5:2009
- ISO 10993-10:2002
- ISO 10993-11:2006
- UL 60601-1:2003 R4.06
- IEC 60601-1:1988 + A1:1991 + A2:1995,
- EN 60601-1:1990 + A1 + A2 + A13
- CAN/CSA 22.2 No. 601.1
- IEC 60601-1- 4 / EN60601-1-4:2000
- IEC 60601-1-6: 2004 (First Edition) for use in conjunction with IEC 60601-1:1988 + A1:1991 + A2:1995
- EN 60601-1-2:2007
- IEC 60601-2-18:1996 Second Edition + A1:2000

Conclusions on Substantial Equivalence

All verification and validation data presented in this 510(k) Notification demonstrated that the device is safe and effective, and performs as intended.

Based on the above comparisons of intended use, intended users, use environments, indications for use, operating principles, technological characteristics, performance test data, compliance with consensus standards related to biocompatibility, sterilization, electrical safety and electromagnetic compatibility, we concluded that the VisionScope System is substantially equivalent to the primary and secondary predicate devices cited.

SECTION 11. DEVICE DESCRIPTION

TABLE OF CONTENTS

1. GENERAL DESCRIPTION 2

1.1. INTENDED USE 3
1.2. INDICATIONS FOR USE 3
1.3. INTENDED USERS 4
1.4. CONTRAINDICATIONS FOR USE 4

2. PRINCIPLES OF OPERATION 4

2.1. ENDOSCOPY PROCESS OVERVIEW 4
2.2. PRINCIPLES OF OPERATION OF VISIONSCOPE 5

3. SYSTEM COMPONENTS 7

3.1. VISIONSCOPE PART NUMBERS & FUNCTIONS 7
3.2. DEVICE CLASSIFICATION 8

4. TECHNOLOGICAL CHARACTERISTICS 9

4.1. VIDEO SUBSYSTEM 9
4.2. CAMERA CONTROL UNIT (PART NUMBER 50034) 10
4.3. CAMERA HANDPIECE (PART NUMBER 50021) 10
4.4. ENDOSCOPES (PART NUMBER 50006-XXX) 11
4.5. PATIENT ELECTRICAL ISOLATION SCHEME 12
4.6. DISPOSABLE STERILE PROCEDURE KIT (PART NUMBER 50033-XXX) 13
4.7. ILLUMINATION SHEATH & PROTECTIVE BARRIER 14
4.7.1. Physical Description 14
4.7.2. Material Composition of Patient Contact Surfaces of Disposable Procedure Kit including Illumination Sheath 16
4.8. STERILE PROCEDURE KIT PACKAGING 17

1. General Description

VisionScope is an endoscopic imaging system designed to enable pre-operative and post-operative diagnosis in physician examination rooms. The device can also be used in operating rooms where smaller gauge endoscopes are important for minimally invasive surgical procedures. The key component of the VisionScope is a 1.4 mm diameter semi-rigid fiber-lens endoscope that fits within a disposable 1.7 mm diameter illumination sheath, which in turn is small enough to fit through a 2 mm portal or cannula. The disposable sterile illumination sheath is constructed of a leak-proof stainless steel tube with a hermetically sealed distal tip glass window that acts as a sterile protective barrier over the re-usable endoscope. VisionScope Technologies is able to miniaturize the endoscopes and illumination sheaths while still providing high clarity anatomical visualization. When used as an imaging device alone and without any resection or irrigation instrument, the system enables surgeons to perform direct visual clinical assessment without requiring re-sterilization or fluid disposal processing following a diagnostic imaging procedure.

The VisionScope High Definition Endoscopy Camera System is made up of four major components:

1. Camera Control Unit
    a. Digital Video Processing Electronics
    b. Integrated Light Source
    c. A front panel with an LCD Touch Screen
    d. Image Capture and Management Electronics
    e. External video output connectors for external medical-grade LCD monitors (not part of the VisionScope system)

2. Camera Handpiece
    a. Imaging sensor
    b. Three buttons for image capture or camera setting adjustments
    c. 3.5 meter long cable that plugs into the Camera Control Unit

3. Endoscopes
    A family of endoscope in four lengths, with identical opto-mechanical design and indications for use, for different joints or body cavities requiring different working lengths

4. Disposable Sterile Procedure Kits
    A family of procedure kits in four lengths, matched to the VisionScope endoscopes, for use on different joints or body cavities, each kit containing:
        i. One-time use disposable endoscope sheath made up of an illuminator sheath with an integrated camera drape
        ii. One-time use disposable cannula
        iii. One-time use disposable trocar

A picture of the VisionScope System showing how the components are deployed is shown in Figure 1 below.

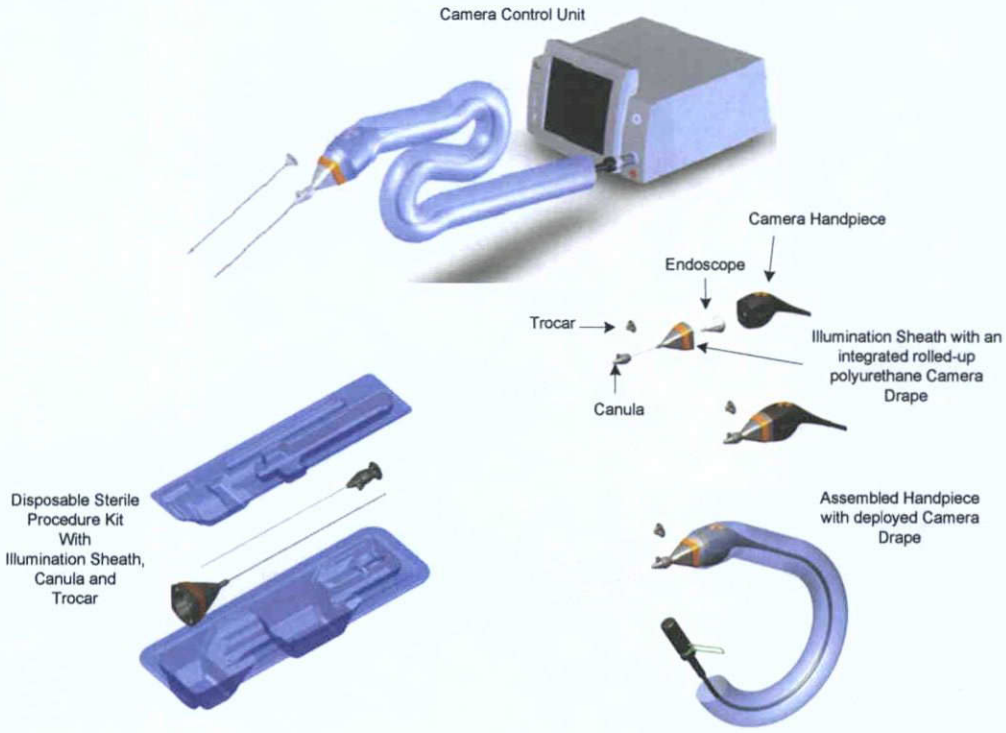

Figure 1 Components of the VisionScope System, showing how the camera handpiece, endoscope, illumination sheath and cannula are assembled together to form a complete handpiece for performing diagnostic imaging. The one-time use, disposable Sterile Procedure Kit is made up of an Illumination Sheath with an integrated Camera Drape, a Cannula and a Trocar. The camera control unit, camera handpiece and endoscopes are sold non-sterile. The preparation before, during and after a procedure is described in the Instructions for Use (VisionScope Part No. 01112, 01113, 01114, and 01115).

1.1. Intended Use

VisionScope is intended to be used for arthroscopic and endoscopic diagnostic and operative imaging, on the order of a licensed physician.

1.2. Indications for Use

The VisionScope High Definition Endoscopy Camera System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of an interior cavity of the body through a natural or surgical opening. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

Additionally, when used in conjunction with an appropriately indicated and FDA 510(k)-cleared endoscope and light source, the VisionScope High Definition Endoscopy Camera Control Unit and Camera Handpiece are indicated for use in arthroscopic and endoscopic surgical procedures to provide illumination, visualization and capture of still and motion pictures of articular cavities, body cavities, hollow organs and canals.

1.3. Intended Users

The VisionScope system is designed for use by licensed physicians for performing diagnostic or surgical procedures. Physician assistants may assist in the setup of the equipment and preparation of patients.

1.4. Contraindications for Use

None known

2. Principles of Operation

2.1. Endoscopy Process Overview

The typical work flow for using the VisionScope system, and for all the predicate endoscope systems cited in this 510(k) Notification, closely follows the flow chart illustrated in 2-1.

The Camera Control Unit is started up and the Camera Handpiece is connected. The patient is registered using the touch screen on the Image Management module. The patient is then prepared for the clinical procedure. The Endoscope is assembled. The Light Source is attached to the Endoscope. A small incision at the appropriate location is created with a trocar/cannula combination by the surgeon. The cannula is positioned at the area of interest. The trocar is removed, and the endoscope is inserted through the cannula to provide visualization of the interior anatomy. During the procedure, still images and video clips can be captured from the live video. For a purely diagnostic imaging procedure, no other surgical tool or entry portal is needed. For operative procedures, additional portals may be opened for insertion of resection, irrigation or repair tools.

After the patient has been discharged, the procedure can be reviewed. Still images and video recordings can be viewed, notes added, and audio recorded. The procedure report can be printed, e-mailed, and archived to a central storage facility maintained by the institution's IT infrastructure.

Instrument setup functions may be performed outside of the clinical procedure by an authorized and trained personnel, such as an OR technical staff, a service technician, a biomedical engineer, or a nurse.

The VisionScope system and all the Predicate Devices cited above are designed to support these functions. To the extent that predicate devices have been on the market for many years, and surgeons and nurses have been trained to perform endoscopy procedures using these types of devices, and that the VisionScope design approach is substantially equivalent, there are very few new training requirements for the operational work flow or principles of operation. The minor differences in the particular design and technical features of VisionScope do not raise new issue of safety and effectiveness compared with the predicate devices.

The step-by-step instruction on how to use the VisionScope system follow closely the above described workflow, and is explained in more details in the Instructions for Use (VisionScope Part Numbers 01112, 01113, 01114, 01115).

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2.2. Principles of Operation of VisionScope

All predicate endoscopy camera systems for arthroscopy and general surgery applications currently on the market, as well as the VisionScope system, contain the following key components as illustrated in Figure 2.2-1 below:

- Camera Control Unit (CCU) - to perform electronic video signal processing and display
- Camera Head (Handpiece) – to sense the image provided by the endoscope
- Endoscope – to form an in-vivo image inside the body, through a minimally invasive opening
- Light Source – to transfer light from the electronics box and to illuminate the body cavity
- Image Management Unit – to capture, store, retrieve and display still and motion video
- Display Monitors – to provide surgeons with a live view during a procedure (not part of the VisionScope system in this 510(k) submission)

Figure 2.2-1 clearly shows that the VisionScope system contains the same identical key components as other endoscopy camera systems on the market, delivering the same basic functions as those predicate devices, using similar electronic video and optical technology, and constructed using the similar manufacturing processes.

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Comparison w/ Predicate Endoscopy System

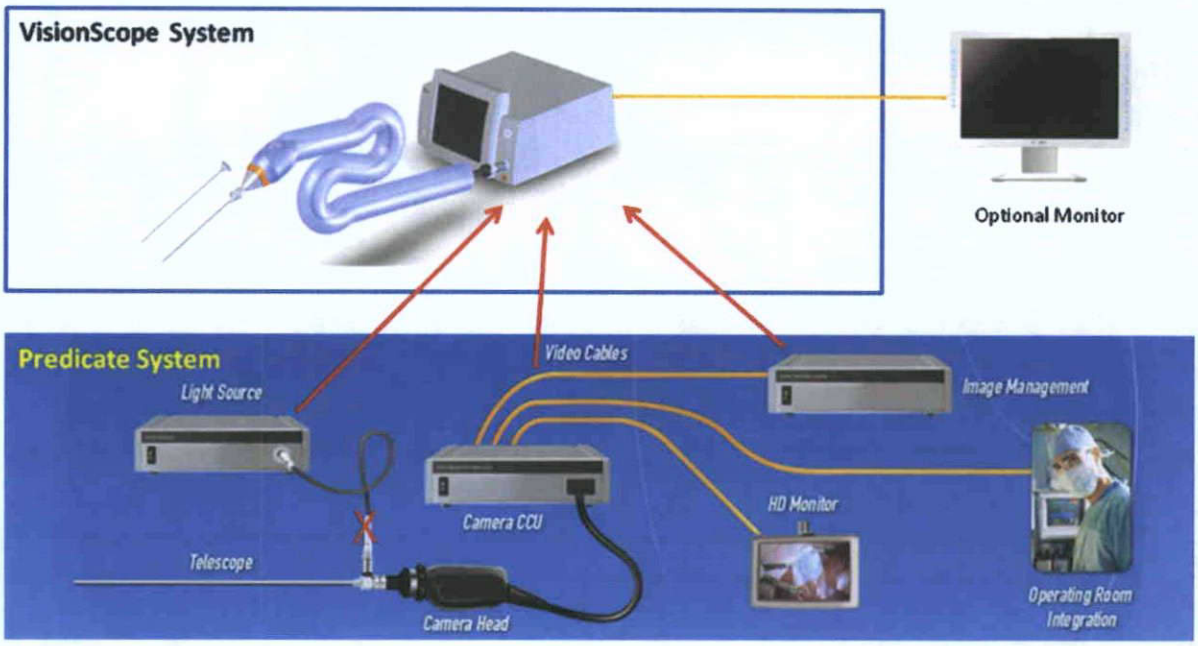

Figure 2.2-1 Comparison of the key components of VisionScope and predicate generic endoscopy camera systems

The differences of VisionScope from these predicate devices are due mainly to the technical advances in microelectronics, optics and packaging, including:

- VisionScope was able to consolidate the Camera Control Unit, Light Source and Image Management Unit from three boxes into one single integrated unit by using advance microelectronics, advance LED solid state lighting, and streamlined video routing. These three boxes are used together at all times, and never by itself in isolation. Therefore, they can be naturally combined into one integrated unit without loss of functionalities.
- One consequence of providing an integrated unit was the elimination of many interconnect electrical cables among these three boxes, and also the elimination of an external light cable for the endoscope, as shown in the above picture. This results in a substantial elimination of the clutter in the operating room, as well as reduction of a thick light cord near the patient operating area.
- VisionScope was able to use a higher sensitivity (>2X) imaging sensor with lower (>2X) noise than predicate imaging sensors. This allows VisionScope to translate the improvement into substantially smaller diameter endoscopes and smaller illumination source while still providing high image quality, enabling even less minimally invasive imaging diagnostic and operative procedures to be performed.
- VisionScope was able to substantially improve the optical throughput, image contrast and packing factors of imaging lens optics, fiber optics, and illumination fibers to optimize the optical chain, while enabling longer sub-2-mm semi-rigid endoscopes to be built. Previous endoscope based on rod-lens technology are too fragile when the diameter is smaller than 2.7 mm for lengths greater than 55 mm. VisionScope is able to produce sub-2-mm endoscopes of more than 200 mm and which can withstand repeated limited bending and flexing – limited only by the stainless steel tubing and not by the glass optics.

- With the reduction in diameter of the imaging optics and illumination light guide, VisionScope was able to separate the imaging optics and illumination fibers into two detachable concentric parts. Predicate endoscope design combined both the imaging optics and illuminating fibers together in one single integrated tube comprised of inseparable concentric elements.
- VisionScope was able to build an inexpensive detachable outer illumination sheath that fits over the more expensive inner endoscope with high quality optics. The illumination sheath is constructed of stainless steel and is hermetically sealed at the distal tip and critical joints, so that it provides an effective barrier against microbial penetration. In this way, the sterile outer illumination sheath and camera drape may be removed and disposed after each procedure. As stated in the Instructions for Use, for diagnostic imaging procedures that do not involve the use of resection instrument or any other instrument that may accidentally damage the illumination sheath, the VisionScope Instructions for Use allows the inner endoscope and camera handpiece to be used without deep sterilization in between procedures (but still requiring disinfectant wipes with 70% isopropyl alcohol after use). For applications in the operating rooms involving resection or any other instrument, the Instructions for Use requires that the endoscopes and camera handpiece be sterilized using traditional ETO, Sterrad 100S (H_2O_2), or Sterrad NX sterilization processes in accordance with established procedures by sterilization equipment vendors and the OR departments of the institutions. This aspect along with test data will be discussed further in Section 14 – Sterilization, of this 510(k) Notification File & Section 18 – Performance Testing – Bench.

3. System Components

3.1. VisionScope Part Numbers & Functions

The part numbers of the VisionScope components and a brief description of their functions are described in the table below:

VisionScope Part Name	VisionScope Part Number	Functions
Camera Handpiece	50021	• A hand-held device containing an imaging chip, housed in a camera body with an industry standard optical lens mount (C-mount) for receiving an image formed by an externally mounted endoscope. • The Camera Handpiece contains three buttons which may be customized and assigned by end users to perform capture of still and live video image, and to control the camera setting such as white balance, brightness and contrast. • The camera handpiece is connected to the Camera Control Unit via a 3.5 meter long cable.
Camera Control Unit	50034	• An electronic box that accepts video signals from the Camera Handpiece. • Perform video processing and display a live video image on a front panel touch screen and one or more external medical grade video monitors. • Record and play back still pictures or live video. • Provide a touch screen display to enable physician assistants to register patient information or adjust camera parameters. • The touch screen LCD display may also be used for viewing live or recorded video or still images.

		• An integrated LED light source that provides the illumination via a fiber-optic cable to the front bezel of the Camera Handpiece where the Illumination Light Sheath is mated and aligned.
Endoscopes	50006-XXX XXX is the length designator in mm = 060, 095, 160, 220	• A family of endoscopes with working lengths of 60 mm, 95 mm, 160 mm and 220 mm, for use in minimally invasive surgical procedures on different types of anatomy • When attached to the Camera Handpiece, forms an optical image onto an electronic imaging sensor.
Sterile Procedure Kits	50033-XXX Kit is made up of: 50023-XXX – Endoscope Sheath 50024-XXX – Cannula 50027-XXX – Trocar XXX is the length designator in mm = 060, 095, 160, 220	• A family of one-time use sterile procedure kits, to be used in conjuction with the family of endoscopes having working lengths of 60 mm, 95 mm, 160 mm and 220 mm • Each sterile procedure kit of a given length contains three items: o Endoscope Sheath = Illumination Sheath + Camera Drape o Cannula o Trocar • The Illumination Sheath provides a cover over the endoscope. The function is to channel the light output from the Camera Handpiece to illuminate the anatomy during a procedure, and to provide a clean sterile barrier to protect the patient and the underlying endoscope from contamination. • The Camera Drape is a sterile polyurethane plastic sleeve that is welded onto the Illumination Sheath and provides a sterile cover over the camera body and camera cable, to prevent contamination of the patient, the camera body and camera cable during a procedure in a physician examination room setting. • The cannula is a narrow tube through which the Illumination Sheath and Endoscope are inserted, whose function is to provide a portal to facilitate access to the patient anatomy. • The trocar is a sharp needle. When used in conjunction with the cannula, provides access to the patient anatomy.

3.2. Device Classification

USA - FDA:

VisionScope Trade/Device Name	VisionScope Part Number	FDA Product Code	FDA Device Class	FDA Regulation No.	FDA Device Name
High Definition Camera Handpiece	50021	GCJ	2	876.1500	Endoscope and accessories
High Definition Camera Control Unit	50034	GCJ	2	876.1500	Endoscope and accessories
Endoscopes	50006-XXX	GCJ HRX	2	876.1500 888.1100	Endoscope and accessories
Sterile Procedure Kits	50033-XXX	GCJ	2	876.1500	Endoscope and accessories
Kit Content – Endoscope Sheath	50023-XXX	GCJ	2	876.1500	Endoscope and accessories
Kit Content - Cannula	50024-XXX	GEA	1	878.4800	Cannula – surgical

Kit Content - Trocar	50027-XXX	KTE	1	874.4420	Trocar - ENT

European Union – Medical Device Directive:

Class IIa - MedDev Classification is made with reference to "*MEDDEV 2.4/1 – rev. 8 PART 2: GUIDELINES FOR THE CLASSIFICATION OF MEDICAL DEVICES (July 2001)", Rule 6 - Surgically invasive devices for transient use.*

4. Technological Characteristics

4.1. Video Subsystem

The Video Subsystem is made up of the following components:

- Camera Head with interconnect cable (Part Number 50021)
- Camera Control Unit (CCU) (Part Number 50034)
  - Digital Video Processing Electronics
  - Integrated LED Light Source
  - LCD Touch Screen & Display
  - Image Management Unit

A block diagram of the camera head, video processing electronics, light source, and external Physician Office and OR peripherals is shown in Figure 4.1-1. Further details are given in the document "80004 - Engineering Specifications of the VisionScope Camera Head and Camera Control Unit" maintained in the Device History File.

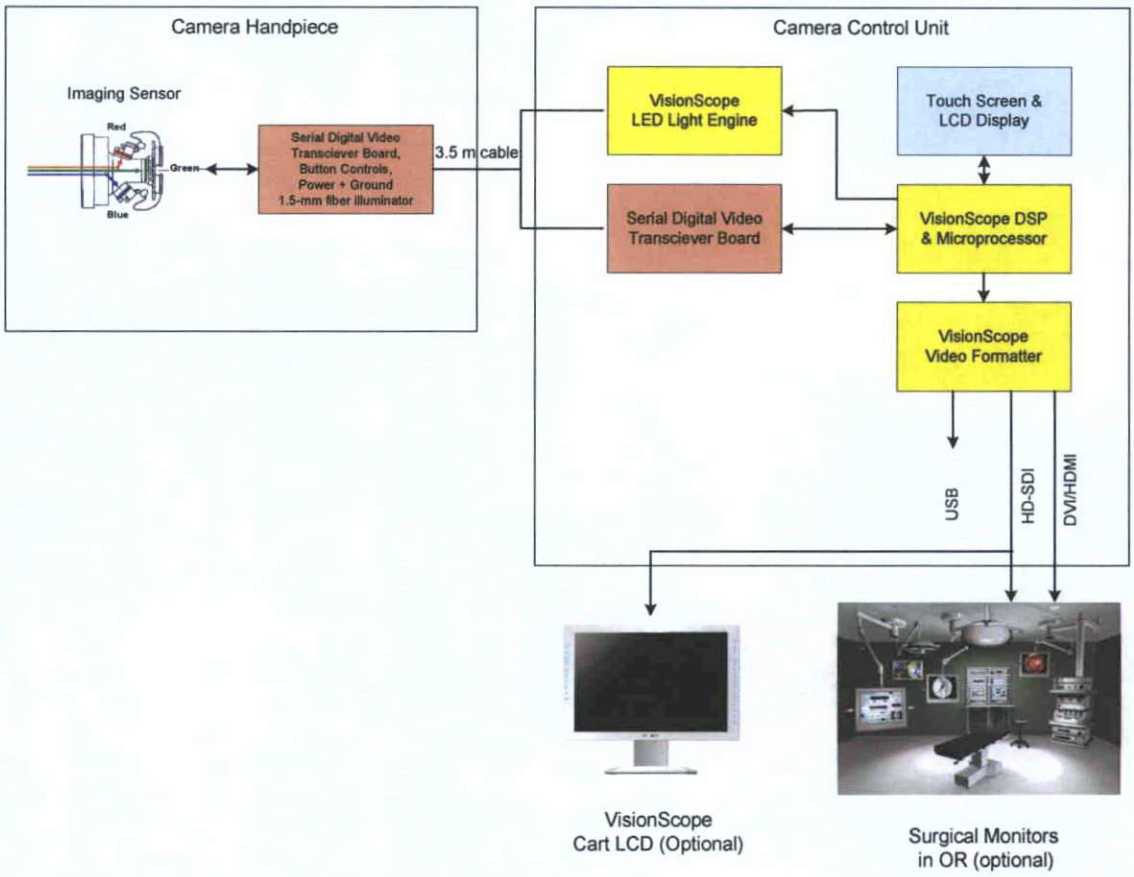

Figure 4.1-1 Overall Block Diagram of Camera Head and Camera Control Unit

4.2. Camera Control Unit (Part Number 50034)

The CCU is a single box containing multiple circuit boards, a LED light source, and an 8.4" LCD touch screen display. It supports the following functions:

- Provide power and electrical signals to support the function of the camera head
- To provide illumination inside the patient's anatomy via a fiber optic cable to the camera handpiece and endoscope
- To enable the end user to program and configure the CCU to suit individual preference
- To enable the patient ID data to be entered
- To enable the surgeons to capture still pictures and motion video files

A drawing of the CCU front and back is shown in Figure 4.2-1. Further details of the Camera Control Units are given in Document 80004, "Engineering Specifications of VisionScope Camera Control Unit and Camera Handpiece" located in the Design History File.

Figure 4.2-1 A drawing of the Camera Control Unit, with a 8.4" LCD Touch Screen. The symbols and markings are explained in full in the Instructions for Use (PN 01112).

4.3. Camera Handpiece (Part Number 50021)

The Camera Handpiece is a hand-held camera body that contains an imaging sensor and associated electronics, a 3.5 m long camera cable for connecting to the Camera Control Unit, and a front bezel with a combination of a C-mount and a bayonet mount. A picture of the Camera Handpiece is shown in Figure 4.3-1. Further details of the Camera Handpiece are given in Document 80004, "Engineering Specifications of VisionScope Camera Control Unit and Camera Handpiece" located in the Design History File.

Figure 4.3-1 Camera Handpiece

The C-mount on the front face of the Camera Handpiece is designed to accommodate both the VisionScope line of re-useable endoscopes as well as with 510(k)-cleared C-mount endoscopes manufactured by a number of medical endoscopy companies (e.g., Hanke-Sasse-Wolf, Smith & Nephew, Stryker, Storz, etc.). The use of these generic endoscopes was validated both in the laboratory and in cadaver laboratories and documented in Section 18 – Bench Testing of this 510(k) Notification File.

The Bayonet Mount that is concentric with the inner C-mount is a proprietary VisionScope feature that is designed to work with the VisionScope line of disposable Illumination Sheath described in the next section.

4.4. Endoscopes (Part Number 50006-XXX)

VisionScope manufactures a line of re-useable endoscopes in four different lengths: 60 mm, 95 mm, 160 mm and 220 mm, where the lengths is represented in the Part Number suffix XXX. Other than the length, there is no difference in the design, manufacturing process, material or indications for use. The endoscopes are specifically designed to be used with the VisionScope Disposable Procedure Kit (Section 4.5 below). As such, one unique feature of the VisionScope endoscopes is that there is no illumination element in the optical design, unlike almost all other medical endoscopes on the market that combine both the imaging optics and illumination fiber channel in one integrated piece.

The VisionScope endoscopes are designed to be re-useable. It is compatible with traditional chemical sterilization processes: ETO, Sterrad 100S and Sterrad NX. Sterilization efficacy data are included in Section 14 - Sterilization of this 510(k) submission.

A picture of the VisionScope endoscope is shown in Figure 4.4-1. An engineering drawing is given in the Document 11.2: "50006 Endoscope Engineering Drawing.pdf" in Section 11 - Device Description. Further details are given in VisionScope Document 80001, "Engineering Specifications of Endoscopes and Accessories" maintained in the Device History File.

Figure 4.4-1 VisionScope Endoscope

4.5. Patient Electrical Isolation Scheme

In order to comply with the electrical safety requirements for medical devices (IEC-60601-1 and IEC-60601-1-2), specifically to conform with the patient leakage current in accordance with the cardiac floating (CF) rating of the handpiece, certain electrical isolation scheme have to be observed. Conformance to the IEC-60601-1 standards is demonstrated in the IEC 60601-1 electrical safety test reports, tested and certified by TUV Rheinland and given in Section 17 – Electromagnetic Compatibility and Electrical Safety of this 510(k) Notification file. Figure 4.5-1 shows a schematic of the isolation scheme of the VisionScope Endoscopy System.

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Figure 4.5-1 Electrical Isolation and Ground Scheme of the VisionScope Endoscopy System

4.6. Disposable Sterile Procedure Kit (Part Number 50033-XXX)

The section here is intended to provide a general description and functions of the device. More detailed technical specification is given in VisionScope Document No. 80001 – Engineering Specifications of Endoscopes, Illumination Sheath, Cannula and Trocar located in the Design History File.

The Disposable Sterile Procedure Kit is a collection of the following three components packaged in a sealed sterile kit:

- One-time use disposable endoscope sheath made up of an Illuminator Sheath with a Camera Drape (PN 50023)
- One-time use cannula (PN 50024)
- One-time use trocar (PN 50027)

The Procedure kit is available in four different lengths (60 mm, 95 mm, 160 mm, and 220 mm), designated by the suffix XXX in the part number to match with the four different lengths of the VisionScope endoscopes described in the last section.

The Procedure Kit is a one-time use only set of accessories for use in conjunction with the re-useable camera handpiece and endoscope. It is distributed in a sealed sterile pack, using an ETO sterilization process described in Section 14 – "Sterilization and Shelf Life" of this 510(k) submission.

Figure 4.6-1 shows a picture of the Procedure Kit, and how the camera head, endoscope, disposable illumination sheath, camera drape and cannula are assembled together in a diagnostic imaging procedure. An engineering drawing of the Procedure Kit is given in the Document 11.3: "50033 Sterile Procedure Kit Engineering Drawing.pdf" in Section 11 - Device Description.

The Cannula and Trocar are relatively simple devices and do not serve any protective barrier function. The design and functions are identical to other predicate 510(k)-exempt cannulas and trocars widely used in surgical operations. Engineering drawings of these two components are given in Document 11.5 "50024 Cannula Engineering Drawing" and Document 11.6 "50027 Trocar Engineering Drawing" located in Section 11 – Device Description.

The description of the Illumination Sheath below is primarily intended to explain the functional characteristics including the protective barrier design. Further details, including sterility and protective barrier effectiveness validation are given in Documents 14.1 and 14.2 in Section 14 and references therein. A detailed explanation on how it is deployed and used in a procedure is explained in the four Instructions for Use located in Section 13 – Proposed Labeling (PN 01112 - System, 01113 - Endoscope, 01114 – Sterile Procedure Kit, and 01115 – Camera Handpiece).

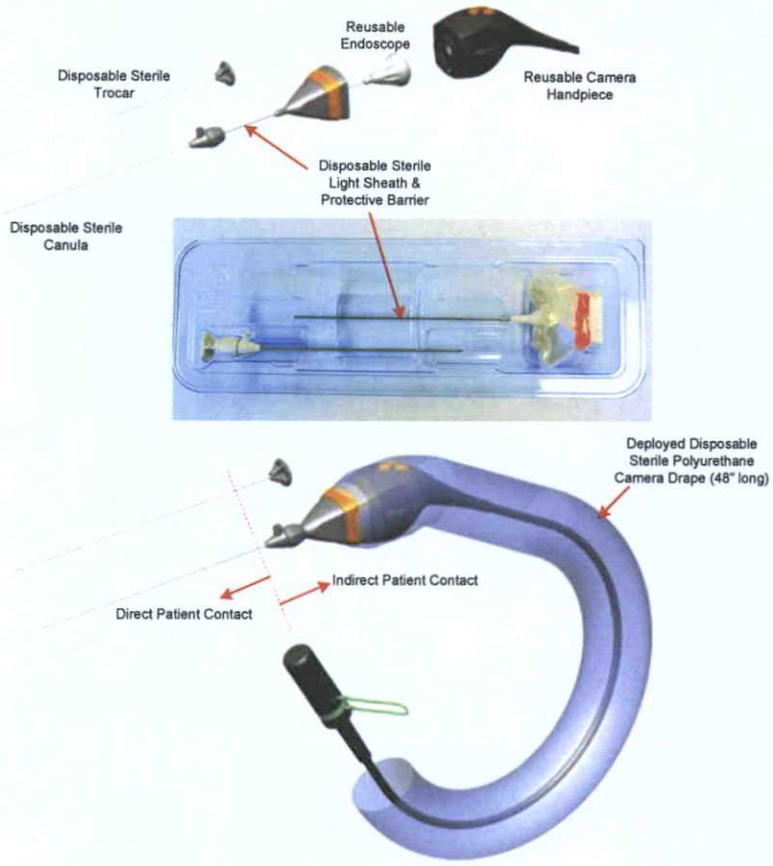


Figure 4.6-1 Picture of the Disposable Illumination Sheath, showing how it is used to provide a protective barrier over the endoscope and camera body. The patient-contact surfaces are in forward of the dotted red line shown.

4.7. Illumination Sheath & Protective Barrier

4.7.1. Physical Description

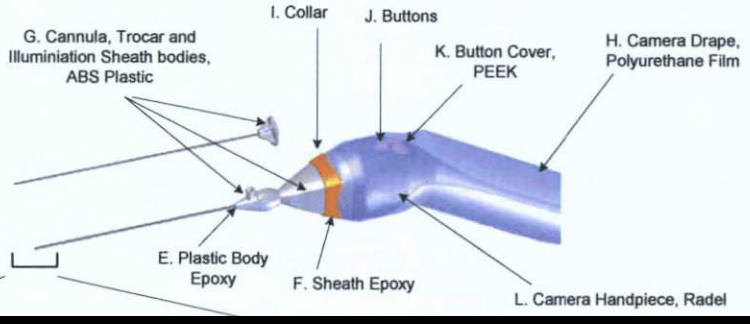
Prior to operation, the Endoscope is attached to the Camera Handpiece via a C-mount thread. The Sterile Illumination Sheath fits over the Endoscope, forming a protective barrier to isolate the Endoscope from the patient. It is fixed to the Camera Handpiece via a ¼-turn bayonet-mount that is concentric with the Endoscope's C-mount thread, as shown on the camera front bezel in Figure 4.3-1.

The parts that are in direct contact with the patient anatomy are the needle-shaped tubes of the Cannula, Trocar, and the front end of the Illumination Sheath. The stainless steel Cannula tube is hollow and open, within which the Trocar or Illumination Sheath needle can be inserted. Their function is to facilitate access and insertion of the Illumination Sheath and Endoscope combination. The deployment sequence is described in the Instructions for Use (PN 01112, 01113, 01114 and 01115).

The cross sections of the Cannula, the Illumination Sheath and the Endoscope are shown in Figure 4.7.1-1.

(b)(4)

[redacted]



(b)(4)

[redacted]

Figure 4.7.1-1 Cross Section Drawing of the distal end of the Cannula, Illumination Sheath, and Endoscope, showing how the Illumination Sheath forms a sterile protective barrier over the endoscope. The dimensions shown are in millimeters. The materials, identified and annotated in alphabets, are listed in Table 4.7.2-1 below.

4.7.2. Material Composition of Patient Contact Surfaces of Disposable Procedure Kit including Illumination Sheath

Table 4.7.2-1 lists all the materials that are in direct and indirect contact with the patient. Biocompatibility tests have been performed with all the exact material used in the construction of the components. The materials are annotated in Figure 4.7.1-1 above.

Sterilization and Biocompatibility are discussed in further details in Section 14 and 15 of this 510(k) submission package.

I.D. in pictures	Components (Items marked with * are protective barrier elements)	Material	Direct Patient Contact	Indirect Patient Contact
(b)(4) [redacted]			✓	
			✓	
			✓	
			✓	
			✓	
				✓
				✓
				✓
				✓
				✓
			Material does not touch patient either directly, or indirectly through other patient contact surfaces	
				✓
				✓
				✓

Table 4.7.2-1 List of Materials used in the Camera Handpiece Assembly

4.8. Sterile Procedure Kit Packaging

A picture of the disposable sterile Procedure Kit is shown in Figure 4.8-1 below. Inspection and packaging is performed by a contractor (Millstone Medical Outsourcing, ISO-13485 and FDA registered). All sterile packaging is performed in a controlled area (Class 7 per ISO 14644-1 clean room). Kits are packaged into a plastic tray and sealed with a Tyvek® lid. The sealed plastic tray is packaged inside a paper box, and multiple boxes are consolidated into a pellet and sterilized with 100% ETO gas. Further details on sterile packaging and sterilization are given in Section 14 - Sterilization and Shelf Life of this 510(k) submission.

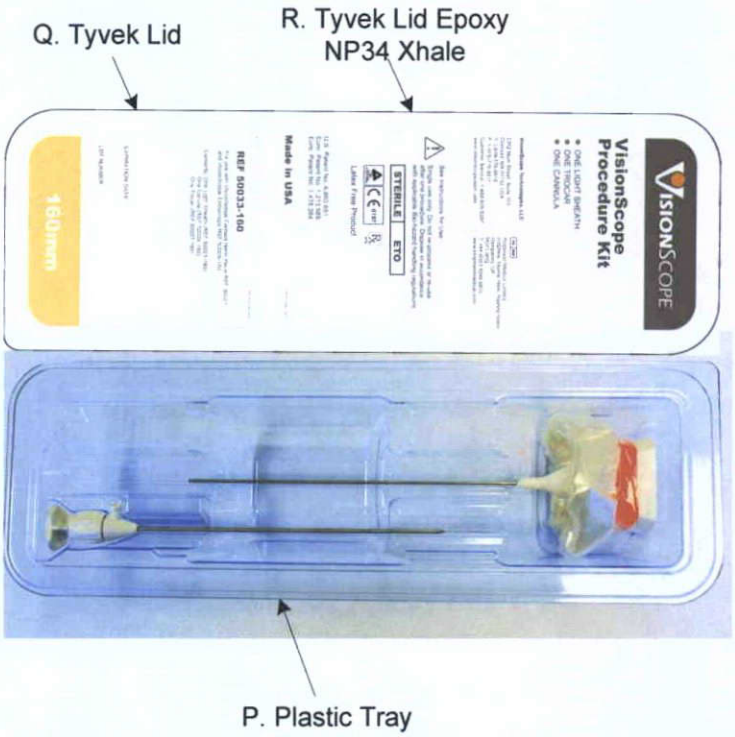


Figure 4.8-1 Packaging Tray and Tyvek lid of the Sterile Procedure Kit. The dimensions of the plastic tray are approximately 12 cm W x 37 cm L x 5 cm H.

11.2 - 50006 Endoscope Engineering Drawing.PDF

(b)(4)

[redacted]

11.3 - 50033 Sterile Procedure Kit Engineering Drawing

(b)(4)

11.4 - 50023 Disposable Endoscope Sheath Engineering Drawing

(b)(4)

[redacted]

11.5 - 50024 Canula Engineering Drawing

(b)(4)

[redacted]

11.6 - 50027 Trocar Engineering Drawing

(b)(4)

[redacted]

SECTION 12. SUBSTANTIAL EQUIVALENCE DISCUSSIONS

As explained in detail below, the VisionScope High Definition Endoscopy Camera System is substantially equivalent to other legally marketed endoscopy camera systems.

Specifically, the primary predicate device is the InnerVue Diagnostic Scope System (K072879) manufactured by Arthrotek, a Biomet Sports Medicine company, with substantially the same Indications for Use as stated in the first statement in the two-part VisionScope Indications for Use statement described below.

Additionally, each subsystem of the VisionScope High Definition Endoscopy Camera System is substantially equivalent to one or more 510(k)-cleared predicate endoscopy devices that are distributed individually, such as cameras, endoscopes, light sources and image management units manufactured by Smith & Nephew Endoscopy, Stryker Endoscopy and Karl Storz Endoscopy, with substantially the same Indications for Use as stated in the second statement in the two-part VisionScope Indications for Use statement described below. We use one example each of a 510(k)-cleared camera, endoscope, light source, image management device, endoscope, and disposable endoscope sheath as our secondary predicate devices:

- Smith & Nephew arthroscope (K072675)
- Smith and Nephew 560HD Camera System (K070266)
- Stryker LED Light Source L9000 (K082813)
- Smith & Nephew Model 660 HD Image Management System (K060777)
- Vision-Sciences EndoSheaths (K990354)

As explained in more detail below, VisionScope High Definition Endoscopy Camera System has the same general intended use and similar indications, principles of operation and technological characteristics, as the previously cleared predicate devices cited. Substantial equivalence charts comparing the similarities (Charts A-1 and C-1) and differences (Charts C-2 and C-3) between the VisionScope system and its predicate devices are provided in pages 2 and 5-8 below. More detailed supplementary comparisons of the Technological Characteristics are given in the following documents located in Section 12 of this submission:

- 12.2 - Substantial Equivalence Technical Features Comparison
- 12.3 - InnerVue Reference Guide
- 12.4 - Smith & Nephew 560 HD Camera System
- 12.5 - Smith & Nephew 660 HD Image Management System
- 12.6 - Smith and Nephew Arthroscopes
- 12.7 - Stryker Evolution of HD Technology Brochure
- 12.8 - VisionSciences Endosheath
- 12.9 - VisionSciences Endosheath Urology Published Literature

As is explained in more detail below, minor differences in the technological characteristics do not raise new questions of safety or efficacy. Bench and Cadaver Laboratories demonstrate that the VisionScope High Definition Endoscopy Camera System is as safe and effective as its predicate devices.

A. Indications for Use

VisionScope High Definition Endoscopy Camera System:

The VisionScope High Definition Endoscopy Camera System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion

pictures of an interior cavity of the body through a natural or surgical opening. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

Additionally, when used in conjunction with an appropriately indicated and FDA 510(k)-cleared endoscope and light source, the VisionScope High Definition Endoscopy Camera Control Unit and Camera Handpiece are indicated for use in arthroscopic and endoscopic surgical procedures to provide illumination, visualization and capture of still and motion pictures of articular cavities, body cavities, hollow organs and canals.

VisionScope System or Subsystems	**Predicate Device Manufacturer, Model, and 510(k) Number**	**VisionScope Indications for Use are substantially equivalent to those of the following Predicate Devices:**
VisionScope HD Endoscopy Camera System	Primary Predicate Device: Biomet Sports Medicine – Arthrotek InnerVue Diagnostic Scope System K072879	The InnerVue™ Diagnostic Scope System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening. Examples of generic surgical use include the visualization of joints within the body. These joints can include, joints located in the torso/trunk, upper/lower extremities, and the TMJ.
VisionScope High Definition Camera Control Unit (CCU) and Camera Handpiece	Secondary Predicate Device: Smith and Nephew 560HD Camera System K070266	The Smith & Nephew HD Camera System is indicated for use in endoscopic surgical procedures to allow visualization of the articular cavities, body cavities, hollow organs and canals when used with an appropriately indicated endoscope. Additionally, when used in conjunction with a Smith & Nephew light source and light cable the Smith & Nephew HD Camera System is indicated for use in endoscopic surgical procedures in the thoracic cavity when used with an appropriately indicated thoracoscope.
VisionScope Endoscopes	Secondary Predicate Device: Smith & Nephew Arthroscopes K072675	The Smith & Nephew line of rigid Arthroscopes ENT Endoscopes is indicated to provide illumination and visualization in diagnostic and operative arthroscopic procedures, endoscopic exam and treatment of the nasal cavities and nasal pharynx. In addition, the Smith & Nephew 4 mm diameter rigid Arthroscope/ENT Endoscopes are indicated to provide illumination and visualization in the removal of loose bodies and soft tissue within the hip joint as size /length appropriate.
VisionScope LED Light Source module within the CCU	Secondary Predicate Device: Stryker LED Light Source (L9000) K082813	The Stryker LED Light Source is used to illuminate the site of surgery during minimally invasive surgical procedures in Arthroscopy (orthopedic surgery), Laparoscopy (general and gynecological surgery) and in Endoscopy (general, gastroenterological and ENT surgery). The light is transmitted from the source through an optical cable and a scope.
VisionScope Image Management module within the CCU	Secondary Predicate Device: Smith & Nephew Model 660 HD Image Management	The Smith & Nephew 660HD Image Management System is intended to capture intraoperative still and motion images.

	System K060777	
VisionScope Illumination Sheath & Sterile Barrier	Secondary Predicate Device: Vision- Sciences EndoSheaths K990354	The Vision-Sciences EndoSheaths® are indicated for use as a protective covering for the scope during endoscopic examination of the upper airway, vocal chords and/or nasal passages.

Chart A-1 – Comparison of the Indications for Use with Primary and Secondary Predicate Devices

B. Principles of Operation

B.1. Endoscopy Process Overview

The typical work flow for using the VisionScope system, and for all the predicate endoscope systems cited above, closely follows the flow chart illustrated in B-1.

The Camera Control Unit is started up and the Camera Handpiece is connected. The patient is registered using the touch screen on the Image Management module. The patient is then prepared for the clinical procedure. The Endoscope is assembled. The Light Source is attached to the Endoscope, and applicable Endoscope Protective Sheath attached. A small incision at the appropriate location is created with a trocar/cannula combination by the surgeon. The cannula is positioned at the area of interest. The trocar is removed, and the endoscope including illumination source is inserted through the cannula to provide visualization of the interior anatomy. During the procedure, still images and video clips can be captured from the live video. For a purely diagnostic imaging procedure, no other surgical tool or entry portal is needed. For operative procedures, additional portals may be opened for insertion of resection, irrigation or repair tools.

After the patient has been discharged, the procedure can be reviewed. Still images and video recordings can be viewed, notes added, and audio recorded. The procedure report can be printed, e-mailed, and archived to a central storage facility maintained by the institution's IT infrastructure.

Instrument setup functions may be performed outside of the clinical procedure by an OR technical staff, a service technician, a biomedical engineer, or a nurse.

The VisionScope system and all the Predicate Devices cited above are designed to support these functions. To the extent that predicate devices have been on the market for many years, and surgeons and nurses have been trained to perform endoscopy procedures using these types of devices, and that the VisionScope design approach is substantially equivalent, there are very few new training requirements for the operational work flow or principles of operation. The minor differences in the particular design and technical features of VisionScope do not raise new issue of safety and effectiveness compared with the predicate devices.

(b)(4)

[redacted]

Figure B-1 Typical Workflow of an Endoscopy Procedure are applicable to the VisionScope system as well as to all predicate devices cited

B.2. Principles of Operation of VisionScope and the Predicate Devices are Similar

All predicate endoscopy camera systems for arthroscopy and general surgery applications currently on the market, as well as the VisionScope system, contain the following key components as illustrated in Figure 2.2-1 below:

- Camera Control Unit (CCU) - to perform electronic video signal processing and display
- Camera Head (Handpiece) – to sense the image provided by the endoscope
- Endoscope – to form an in-vivo image inside the body, through a minimally invasive opening
- Light Source – to transfer light from the electronics box and to illuminate the body cavity
- Image Management Unit – to capture, store, retrieve and display still and motion video
- Display Monitors – to provide surgeons with a live view during a procedure (not part of the VisionScope system in this 510(k) submission)

Figure B-2 clearly shows that the VisionScope system contains the same identical key components as other endoscopy camera systems on the market, delivering the same basic functions as those predicate devices, using similar electronic video and optical technology, and constructed using the similar manufacturing processes.

Comparison w/ Predicate Endoscopy System

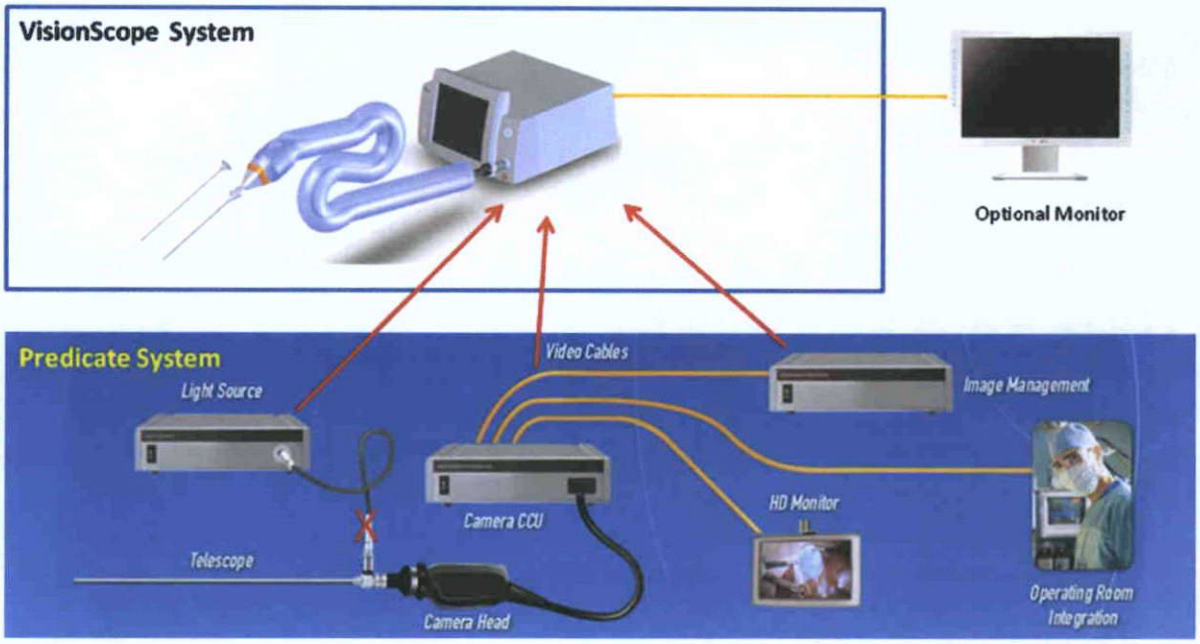


Figure B-2 Comparison of the key components of VisionScope and predicate generic endoscopy camera systems

C. Technological Characteristics

C.1. Similarities

Both the VisionScope system and the primary and secondary predicates cited above use similar technology based on i) CCD or CMOS imaging sensors, ii) Fiber optics and glass lens imaging optics, iii) fiber optics illumination light guide, iv) hermatically sealed camera housing that is compatible with ETO or other chemical sterilants, v) video signal processors conforming to high definition television (HDTV) standards, vi) LED solid state light source technology, vii) hermatically sealed endoscope barrier that have been validated to be effective against virus penetration, viii) sterile packaging technology using Tyvek sealed plastic trays that have been validated in accordance with applicable consensus AAMI/ANSI/ISO standards.

The table below shows that the major technological characteristics are shared by the primary predicate device and at least one secondary device.

VisionScope Components	Technological Characteristics	Shared by Primary and Secondary Predicates
Camera Handpiece PN 50021	• A hand-held device containing an imaging chip (CCD or CMOS). • Housed in a camera body with an optical lens mount for receiving an image formed by an externally mounted endoscope. • The Camera Handpiece contains buttons to capture of still and	• InnerVue™ Diagnostic Scope System • Smith & Nephew 560HD Camera System

	live video image, and to control the camera setting such as white balance, brightness and contrast. • The camera handpiece is connected to the Camera Control Unit via a 3.5 meter long cable. • Sterilization efficacy and material compatibility are validated with ETO, Sterrad 100S/NX/100NX	
Camera Control Unit PN 50034 Video Processing Module within	• An electronic box that accepts video signals from the Camera Handpiece. • Perform video processing and display a live video image on a front panel touch screen and one or more external medical grade video monitors. • System tested to conform with medical electrical safety (IEC-60601-1) and EMI/EMC standards (IEC-60601-1-2)	• InnerVue™ Diagnostic Scope System • Smith & Nephew 560HD Camera System
Camera Control Unit PN 50034 LED Light Source Module within	• An integrated LED light source • A light connector on the front panel of the chassis that allows a 4-meter long fiber optics cable to be connected to an exit light port that mates with the illumination fibers that are placed concentrically around the endoscope imaging optics	• Stryker LED Light Source L9000 • InnerVue™ Diagnostic Scope System has an integrated xenon light source which performs the same function as an LED light source
Camera Control Unit PN 50034 Image Management Module within	• Record and play back still pictures or live video upon receiving commands from the buttons located on the camera handpiece • Provide a touch screen or mouse-control display to enable physician assistants to register patient information or adjust camera parameters • The touch screen LCD display may also be used for viewing live or recorded video or still images.	• InnerVue™ Diagnostic Scope System • Smith & Nephew 660HD Image Management System
Endoscopes PN 50006-XXX where XXX = are length designators	• A family of endoscopes with different lengths for use in minimally invasive surgical procedures on different types of anatomy • When attached to the Camera Handpiece, forms an optical image onto an electronic imaging sensor • Conforms to endoscopy safety standard IEC60601-2-18	• InnerVue™ Diagnostic Scope System • Smith & Nephew arthroscopes, ENT endoscopes

Sterile Procedure Kits PN 50033-XXX where XXX are length designators Kit Content = Illumination Sheath & Camera Drape (PN 50023) + Cannula (Class 1) (PN 50024) + Trocar (Class 1) (PN 50027)	• A family of one-time use sterile procedure kits, to be used in conjuction with the family of endoscopes having different working lengths. • Each sterile procedure kit contains an Illumination Sheath/Camera Drape, a Cannula and a Trocar • The sterile Illumination Sheath provides a cover over the endoscope. The function is to channel the light output from the Camera Handpiece to illuminate the anatomy during a procedure, and to provide a clean sterile barrier to protect the patient and the underlying endoscope from contamination. • The Camera Drape is a sterile polyurethane plastic sleeve that is welded onto the Illumination Sheath and provides a sterile cover over the camera body and camera cable, to prevent contamination of the patient, the camera body and camera cable during a procedure in a physician examination room setting. • The cannula is a narrow and open tube through which the Illumination Sheath and Endoscope are inserted, whose function is to provide a portal to facilitate access to the patient anatomy. • The trocar is a sharp needle. When used in conjunction with the cannula, provides access to the patient anatomy. • Sterilization efficacy and shelf life of the disposable procedure kits have been validated to conform with the requirements of AAMI/ANSI/ISO 11135-1:2007 • All direct and indirect patient contact surfaces tested to conform with ISO-10993, Part 5, 10 and 11	• InnerVue™ Diagnostic Scope System • Vision-Sciences Inc. Endosheath™

Chart C-1 – Comparison of the Similarities with Primary and Secondary Predicate Devices

C.2. Differences

There is no single component or accessory that the VisionScope High Definition Endoscopy System has that NONE of the predicates has, although some VisionScope features are not present in one or more of the predicates.

The differences of VisionScope from these predicate devices are due mainly to the technical advances in microelectronics, optics and packaging. Otherwise there is no effect on Safety and Effectiveness. These are listed in the following two tables.

Items that VisionScope system has that are not shared by the primary predicate device and at least one secondary predicate device	**Impact on Safety and Effectiveness Relative to Predicate Devices****
VisionScope was able to consolidate the Camera Control Unit, Light Source and Image Management Unit from three boxes into one single integrated unit by using advance microelectronics, advance LED solid state lighting, and streamlined video routing. These three boxes are generally used together at all times, and never by itself. Therefore, they can be naturally integrated into one integrated unit without loss of functionalities.	No effect on S&E – convenience improvement
One consequence of providing an integrated unit was the elimination of many interconnected electrical cables among these three boxes, and also the elimination of	No effect on S&E – convenience

an external light cable for the endoscope, as shown in Figure B-2. This results in a substantial elimination of the clutter in the operating room, as well as reduction of a thick light cord near the patient surgical operating portal.	improvement
VisionScope was able to use a higher sensitivity (>2X) imaging sensor with lower (>2X) noise than predicate imaging sensors. This allows VisionScope to translate the improvement into substantially smaller diameter endoscopes and smaller illumination source while still providing high image quality, enabling even less minimally invasive imaging diagnostic and operative procedures to be performed.	No effect on S&E – image quality and performance improvement
VisionScope was able to substantially improve the optical throughput, image contrast and packing factors of imaging lens optics, fiber optics, and illumination fibers to optimize the optical chain, while enabling longer sub-2-mm semi-rigid endoscopes to be built. Previous endoscope based on rod-lens technology are too fragile when the diameter is smaller than 2.7 mm for lengths greater than 55 mm. VisionScope is able to produce sub-2-mm endoscopes of more than 200 mm and which can withstand repeated limited bending and flexing – limited only by the stainless steel tubing and not by the glass optics.	No effect on S&E – image quality and endoscope diameter reduction
With the reduction in diameter of the imaging optics and illumination light guide, VisionScope was able to separate the imaging optics and illumination fibers into two detachable concentric parts. Predicate endoscope design combined both the imaging optics and illuminating fibers together in one single integrated tube comprised of inseparable concentric elements.	No effect on S&E – based on bench testing and hermeticity /simulated virus penetration testing
VisionScope was able to build an inexpensive detachable outer illumination sheath that fits over the more expensive inner endoscope with high quality optics. The illumination sheath is constructed of stainless steel and is hermetically sealed at the distal tip and critical joints, so that it provides an effective barrier against virus penetration. In this way, the sterile outer illumination sheath may be removed and disposed after each procedure. For diagnostic imaging procedures that do not involve the use of resection instrument or any other instrument that may accidentally damage the illumination sheath, the VisionScope Instructions for Use allows the inner endoscope and camera handpiece to be used without sterilization in between procedures (but still requiring disinfectant wipes with 70% isopropyl alcohol after use). For applications in the operating rooms involving resection or any other instrument, the Instructions for Use requires that the endoscopes and camera handpiece be sterilized using traditional ETO, Sterrad 100S (H_2O_2), or Sterrad NX sterilization processes in accordance with established procedures by sterilization equipment vendors and the OR departments of the institutions. This aspect along with test data will be discussed further in Vol_14 - Sterilization of this 510(k) Notification File.	No effect on S&E – based on bench testing and hermeticity /simulated virus penetration testing
** Based on Bench Testing and Cadaver Lab Testing	

Chart C-2 – Comparison of the Similarities with Primary and Secondary Predicate Devices

Items that at least one predicate has but that the VisionScope system does not have	**Impact on Safety and Effectiveness Relative to Predicate Devices****
Analog video output (NTSC/PAL S-Video or Composite Video) in the Smith & Nephew 560HD Camera System. VisionScope only provides digital	No effect on S&E – convenience and backward compatibility issue, as analog video has largely been discontinued in the US and international regions,

TV output.	after transition to Digital TV broadcast worldwide. New television monitors are all equipped with digital TV input.
DVD/CD Writer in the Smith & Nephew 660HD Image Management System	No effect on S&E – convenience factor. VisionScope uses faster solid state flash media card or plug instead of DVD/CD Writer.
Optical light side-port on the Smith & Nephew endoscopes for attachment of a light cable	No effect on S&E – convenience factor. VisionScope uses an external illumination sheath that couples the light automatically when it is mounted on the camera handpiece.
Disposable Endoscopes in the InnerVue Diagnostic Scope System	No effect on relative S&E, based on Bench Testing and Cadaver Lab Testing – cost improvement factor. VisionScope uses a less expensive disposable light sheath, while retaining the expensive high quality imaging elements of the underlying endoscope.
External light port on the Stryker L9000 LED Light Source for connecting external light cord	No effect on relative S&E – when the VisionScope Camera Handpiece is used with the VisionScope Endoscopes, no external light post is needed. When the VisionScope Camera Handpiece is to be used with appropriately indicated and FDA 510(k) endoscopes by other manufacturers, an external light source such as the predicate Stryker light source will be used.
** Based on Bench Testing and Cadaver Lab Testing	

Chart C-3 – Comparison of the Similarities with Primary and Secondary Predicate Devices

D. Conclusion

The VisionScope High Definition Endoscopy Camera System and the Primary and Secondary Predicate Devices cited have the same intended use and similar indications, technological characteristics and principles of operation. The technological differences between the VisionScope system and its Predicate Devices have been reviewed in the previous sections. These differences do not present any new issues of safety or effectiveness based on the results of Bench Testing and Cadaver Lab Testing. Thus, the VisionScope system is substantially equivalent to the InnerVue Diagnostic Scope System and other Secondary Devices cited above.

12.2 - Substantial Equivalence Technical Features Comparison

SUBSTANTIAL EQUIVALENCE COMPARISON WITH PREVIOUSLY 510(K) CLEARED PREDICATE DEVICES

Features	VISIONSCOPE	ARTHROTEK® A Biomet Company	smith&nephew	Substantially Equivalent (Y/N)
Model	[redacted] (b)(4)	InnerVue Diagnostic Scope System	560HD Camera System	Y
510(k) Number	[redacted]	K072879 (Primary Predicate)	K070266 (Secondary Predicate)	Y
General Configuration	[redacted]	Camera Handpiece, proprietary mount endoscopes, Integrated Camera Control Unit with LED Light Source and Image Management unit	Camera Handpiece, C-mount endoscopes, Camera Control Unit, Light Source, and Image Capture Unit	Y
Indications for Use	[redacted]	The InnerVue™ Diagnostic Scope System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening. Examples of generic surgical use include the visualization of joints within the body. These joints can include, joints located in the torso/trunk, upper/lower extremities, and the TMJ.	The Smith & Nephew HD Camera System is indicated for use in endoscopic surgical procedures to allow visualization of the articular cavities, body cavities, hollow organs and canals when used with an appropriately indicated endoscope. Additionally, when used in conjunction with a Smith & Nephew light source and light cable the Smith & Nephew HD Camera System is indicated for use in endoscopic surgical procedures in the thoracic cavity when used with an appropriately indicated thoracoscope.	Y

127

SUBSTANTIAL EQUIVALENCE COMPARISON WITH PREVIOUSLY 510(K) CLEARED PREDICATE DEVICES

Features	VISIONSCOPE	ARTHROTEK® A Biomet Company	smith&nephew	Substantially Equivalent (Y/N)
Intended Users	[redacted] (b)(4)	Licensed physicians, assisted by physician assistants and OR nurses	Licensed physicians, assisted by physician assistants and OR nurses	Y
Where Used	[redacted]	Hospitals, Operating Rooms, Procedure Rooms	Hospitals, Operating Rooms, Procedure Rooms	Y
International Standards	[redacted]	IEC-60601-1, IEC60601-1-2, IEC-60601-2-18, ISO-10993, ISO-13485, FDA 510(k) and CE Mark	IEC-60601-1, IEC60601-1-2, IEC-60601-2-18, ISO-10993, ISO-13485, FDA 510(k) and CE Mark	Y

Camera Handpiece				Substantially Equivalent (Y/N)
	VisionScope Camera Headpiece Part Number 50021	InnerVue Camera Handpiece	S&N HD 560 Camera head	
501(k) Number	[redacted] (b)(4)	K072879 (Primary Predicate)	K070266 (Secondary Predicate)	N/A
Exterior Design	[redacted]			Y
Endoscope Mount	[redacted]	Proprietary Mount	C-mount	Y (no effect on S&E)
Sterilization	[redacted]	ETO, Sterrad 100S, Sterrad NX	ETO, Sterrad 100S, Sterrad NX	Y
Progammable Buttons	[redacted]	Yes	Yes	Y
Imaging Sensor	[redacted]	Single-chip	3-chip	Y (no effect on S&E)
Material	[redacted]	Plastic, glass, aluminum, polyurethane, silicone	Plastic, glass, aluminum, silicone	Y

128

SUBSTANTIAL EQUIVALENCE COMPARISON WITH PREVIOUSLY 510(K) CLEARED PREDICATE DEVICES

Features	VISIONSCOPE	ARTHROTEK® A Biomet Company	smith&nephew	Substantially Equivalent (Y/N)
Electrical Safety	[redacted] (b)(4)	CF, IEC/UL 60601-1, IEC 60601-1-2, CAN/CSA 22.2 No. 601.1	CF, IEC/UL 60601-1, IEC 60601-1-2, CAN/CSA 22.2 No. 601.1	Y
Biocompatibility	[redacted]	ISO-10933, Parts 5, 10, 11	ISO-10933, Parts 5, 10, 11	Y
Manufactured Under Quality System	[redacted]	ISO 13485	ISO 13485	Y
Human Factor	[redacted]	Hand-held piece, fit inside the surgeons' palms, with control buttons	Hand-held piece, fit inside the surgeons' palms, with control buttons	Y

Camera Control Unit				Substantially Equivalent (Y/N)
	VisionScope Camera Control Unit with integrated Image Management System and LED Light Source (Part Number 50034)	InnerVue Camera Control Unit	S&N HD 560 Camera head	
501(k) Number	[redacted] (b)(4)	K072879 (Primary Predicate)	K070266 (Secondary Predicate)	N/A
Exterior Design	[redacted]			Y
Digital Video Processing	[redacted]	Single-chip SD NTSC/PAL	3-chip HD 1080	Y (no effect on S&E)

129

SUBSTANTIAL EQUIVALENCE COMPARISON WITH PREVIOUSLY 510(K) CLEARED PREDICATE DEVICES

Features	VISIONSCOPE	ARTHROTEK® A Biomet Company	smith&nephew	Substantially Equivalent (Y/N)
Digital Video Output to external medical grade monitors	[redacted] (b)(4)	No	Yes	Y (no effect on S&E)
Design	[redacted]	Medical grade power supply, digital video processing circuitry, LCD display, control buttons, video output connectors on back panel	Medical grade power supply, digital video processing circuitry, front panel LCD display, control buttons, video output connectors on back panel	Y
Electrical Safety	[redacted]	CF, IEC/UL 60601-1, IEC 60601-1-2, CAN/CSA 22.2 No. 601.1	CF, IEC/UL 60601-1, IEC 60601-1-2, CAN/CSA 22.2 No. 601.1	Y
Material	[redacted]	Aluminum, steel, glass, ABS plastic, silicone	Aluminum, steel, glass, ABS plastic, silicone	Y
Manufactured Under Quality System	[redacted]	ISO 13485	ISO 13485	Y
Human Factor	[redacted]	Custom Cart with camera control unit inside one compartment	Desktop, cart mount or ceiling boom mount unit with User Inputs on Front Panel, Warning Labels, Label Annotations	Y (no effect on S&E)

Image Management System				Substantially Equivalent (Y/N)
	[redacted] (b)(4)	InnerVue Camera Control Unit with integrated Image Management System and Light Source	S&N 660HD	
501(k) Number	[redacted]	K072879 (Primary Predicate)	K060777 (Secondary Predicate)	N/A

130

SUBSTANTIAL EQUIVALENCE COMPARISON WITH PREVIOUSLY 510(K) CLEARED PREDICATE DEVICES

Features	VISIONSCOPE	ARTHROTEK® A Biomet Company	smith&nephew	Substantially Equivalent (Y/N)
Exterior Design	[redacted] (b)(4)			Y
Still Image Recording & Playback		Yes	Yes	Y
Motion Video Recording & Playback		Yes	Yes	Y
Procedure Image, Notes and Patient Information Management		Yes	Yes	Y
Patient Confidentiality Protection		Yes	Yes	Y
Touch Screen Control		No, w/keyboard and mouse	Yes	Y (no effect on S&E)
Removeable Recording Media		Yes	Yes	Y
Printer Interface		Yes	Yes	Y
Network Interface		No	Yes	Y
Operating System		Windows	Windows XP	Y

(3)

SUBSTANTIAL EQUIVALENCE COMPARISON WITH PREVIOUSLY 510(K) CLEARED PREDICATE DEVICES

Features	VISIONSCOPE	ARTHROTEK A Biomet Company	smith&nephew	Substantially Equivalent (Y/N)
Design	[redacted] (b)(4)	Medical grade power supply, digital video processing circuitry, LCD display, control buttons, video output connectors on back panel	Medical grade power supply, digital video processing circuitry, front panel LCD display, control buttons, video output connectors on back panel	Y
Electrical Safety	[redacted]	CF, IEC/UL 60601-1, IEC 60601-1-2, CAN/CSA 22.2 No. 601.1	CF, IEC/UL 60601-1, IEC 60601-1-2, CAN/CSA 22.2 No. 601.1	Y
Material	[redacted]	Aluminum, steel, glass, ABS plastic, silicone	Aluminum, steel, glass, ABS plastic, silicone	Y
Manufactured Under Quality System	[redacted]	ISO 13485	ISO 13485	Y
Human Factor	[redacted]	Custom Cart with image management unit inside one compartment	Desktop, cart mount or ceiling boom mount unit with User Inputs on Front Panel, Warning Labels, Label Annotations	Y

Light Source				Substantially Equivalent (Y/N)
	[redacted] (b)(4)	InnerVue Camera Control Unit with integrated Image Management System and Light Source	Stryker L9000 LED Light Source	
501(k) Number	[redacted]	K072879 (Primary Predicate)	K082813 (Secondary Predicate)	N/A

SUBSTANTIAL EQUIVALENCE COMPARISON WITH PREVIOUSLY 510(K) CLEARED PREDICATE DEVICES

Features	VISIONSCOPE	ARTHROTEK® A BIOMET COMPANY	smith&nephew	Substantially Equivalent (Y/N)
Exterior Design	[redacted] (b)(4)			Y
Illumination Source	[redacted]	Xenon	LED	Y (no effect on S&E)
Design	[redacted]	Medical grade power supply, xenon light source power supply, fiber optics connector, integrated into 3-In-1 unit with camera control unit and image management system	Medical grade power supply, low voltage LED light source power supply, fiber optics connector	Y
Electrical Safety	[redacted]	CF, IEC/UL 60601-1, IEC 60601-1-2, CAN/CSA 22.2 No. 601.1	CF, IEC/UL 60601-1, IEC 60601-1-2, CAN/CSA 22.2 No. 601.1	Y
Material	[redacted]	Aluminum, steel, glass, ABS plastic	Aluminum, steel, glass, ABS plastic	Y
Manufactured Under Quality System	[redacted]	ISO 13485	ISO 13485	Y
Human Factor	[redacted]	Custom Cart with light source unit inside one compartment	Desktop, cart mount or ceiling boom mount unit with User Inputs on Front Panel, Warning Labels, Label Annotations	Y

SUBSTANTIAL EQUIVALENCE COMPARISON WITH PREVIOUSLY 510(K) CLEARED PREDICATE DEVICES

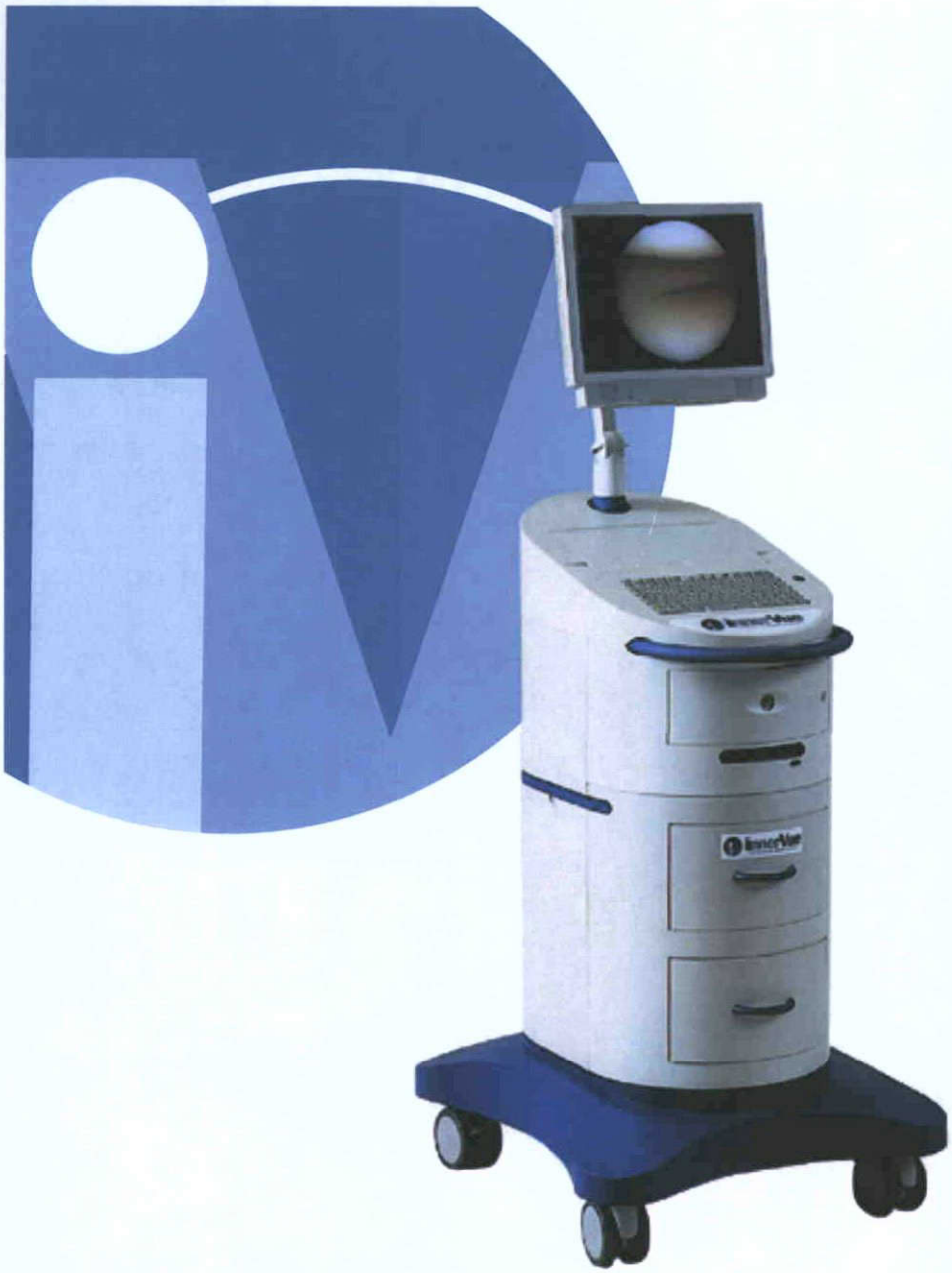
Features	VISIONSCOPE	ARTHROTEK® A Biomet Company	smith&nephew	Substantially Equivalent (Y/N)
Arthroscopes/Endoscopes				**Substantially Equivalent (Y/N)**
	VisionScope Camera Control Unit with integrated Image Management System and LED Light Source (Part Number 50034)	InnerVue Disposable Endoscope	Smith & Nephew Arthroscopes	
501(k) Number	[redacted] (b)(4)	K072879	K072675	N/A
Exterior Design				Y
Design		1.2 mm diameter, 60 - 120 mm working length	1.9 mm, 2.7 mm and 4 mm diameter, 60 mm - 250 mm working length	Y
Optical Components		Distal tip glass window, distal tip micro objective lens, image relay fiber optics, proximal end re-imaging lens	Distal tip glass window, distal tip micro objective lens, image relay optics, proximal end re-imaging lens	Y
Optical Mount to Camera Handpie		Proprietary Camera Mount	C-Mount	Y
Material		Stainless steel, glass, plastic, epoxy	Stainless steel, glass, epoxy	Y
Hermetic Sealing		Yes	Yes	Y
Biocompatibility		ISO-10933, Parts 5, 10, 11	ISO-10933, Parts 5, 10, 11	Y
Sterilization Method		ETO	ETO, Sterrad 100S, Sterrad NX	Y
Manufactured Under Quality System		ISO 13485	ISO 13485	Y
Light Source		External Light source	External Light source	Y

134

SUBSTANTIAL EQUIVALENCE COMPARISON WITH PREVIOUSLY 510(K) CLEARED PREDICATE DEVICES

Features	VISIONSCOPE	ARTHROTEK® A Biomet Company	smith&nephew	Substantially Equivalent (Y/N)
Human Factor	[redacted] (b)(4)	Manual attachment, no focus required	Manual attachment, manual focus may be required within focus range: 4 mm to 25 mm	Y

12.3 - InnerVue Reference Guide



innerVue™

DIAGNOSTIC SCOPE SYSTEM

Reference Guide

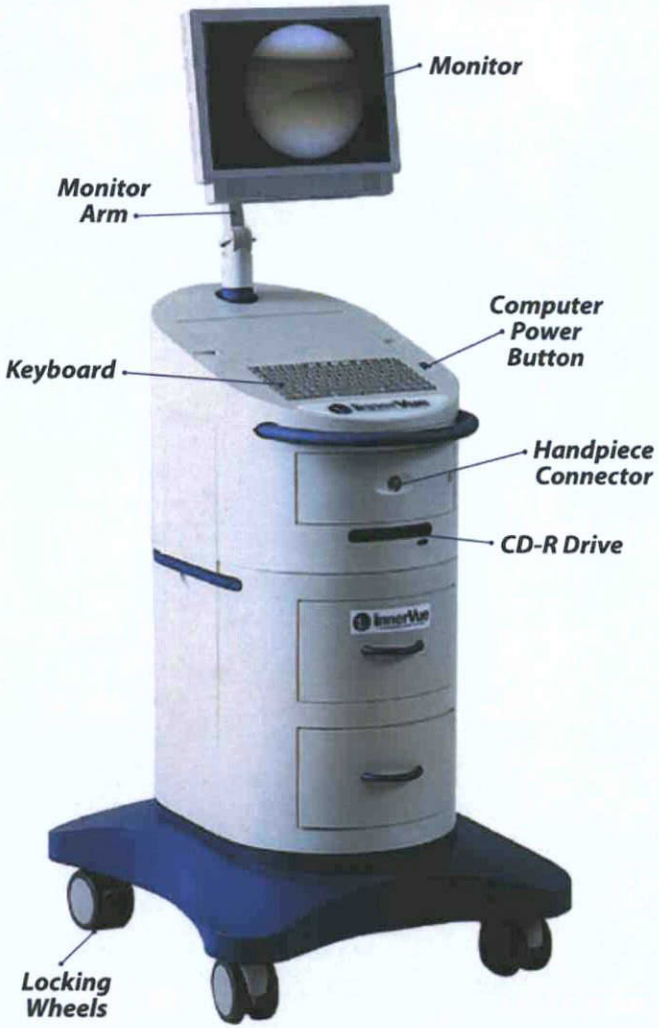
ARTHROCARE

A BIOMET COMPANY

B7

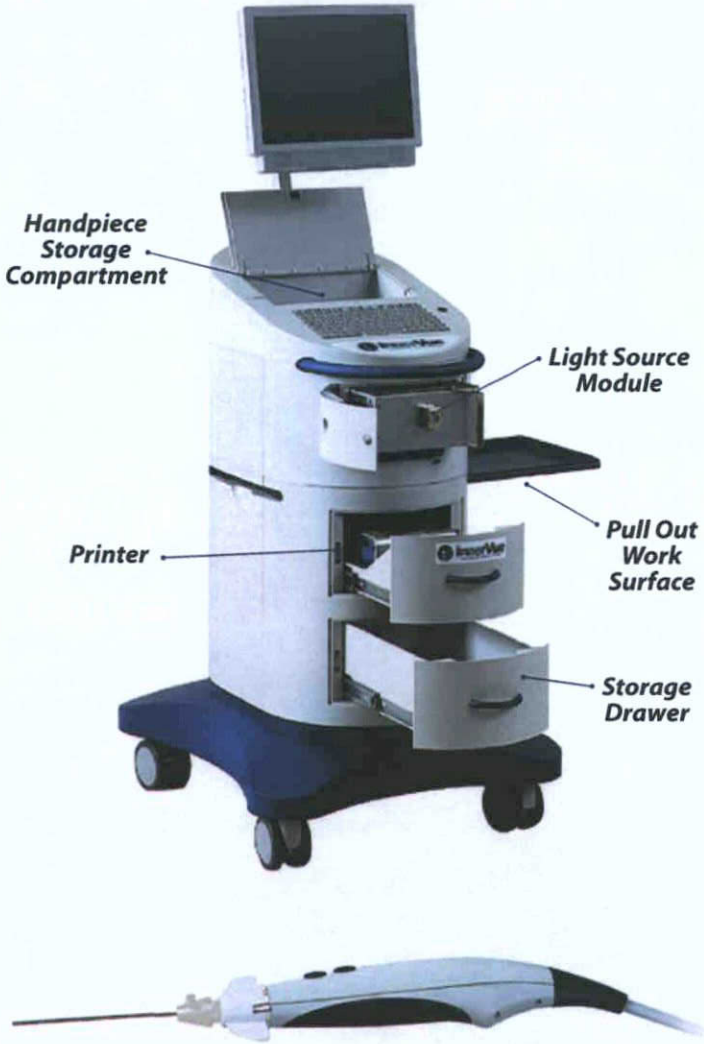
sleeve for
business card

The InnerVue™ Diagnostic Scope System Features



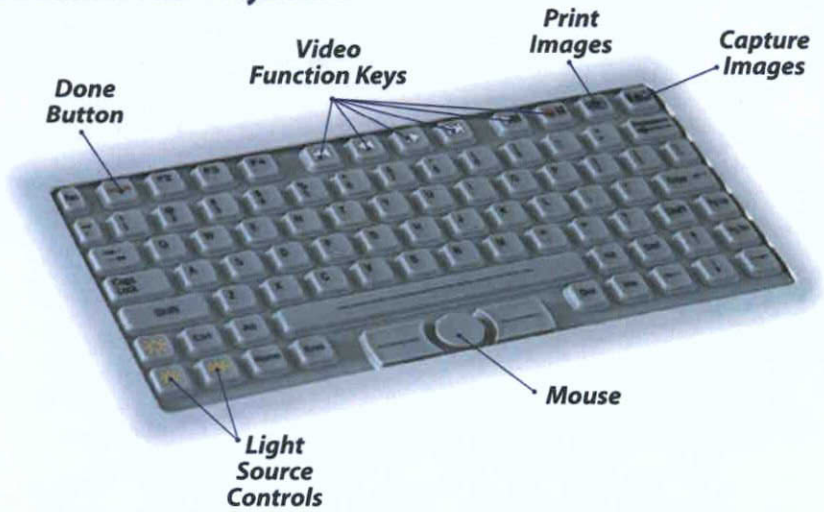
131

The InnerVue™ Diagnostic Scope System Features



InnerVue™ Handpiece, Scope and Cannula

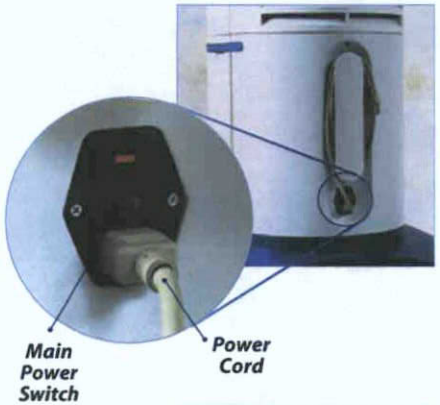
The InnerVue™ Keyboard

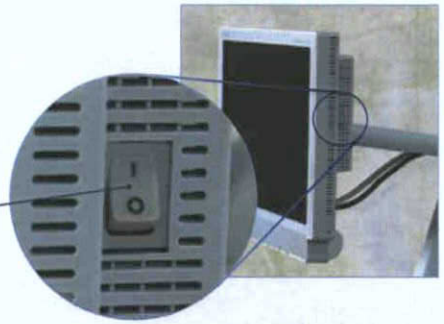


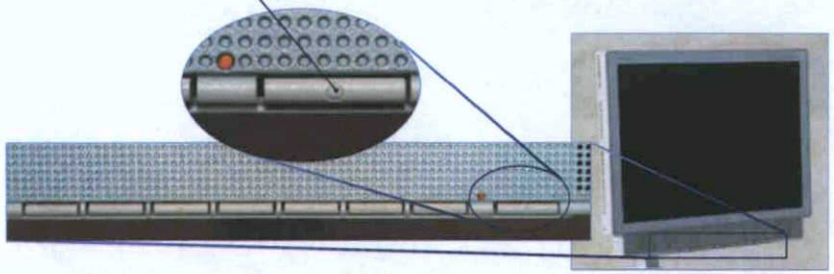
- Captures the current image (as a still image)
- Prints the current still image
- Records – or Pauses the Recording of – the current procedure
- Plays (or Pauses) the video
- Skips ahead ten (10) seconds within the video
- Goes back ten (10) seconds within the video
- Skips ahead to the next video marker
- Goes back to the last video marker
- DONE — Ends the current activity
- Turns light source On/Off
- Increases brightness of light source
- Decreases brightness of light source

Powering-Up the InnerVue™ Diagnostic Scope System

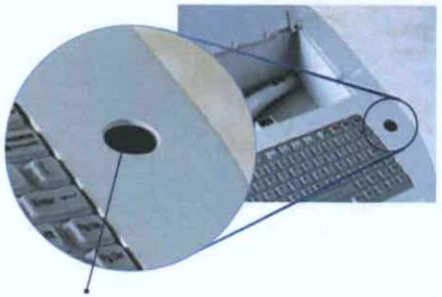
1. Ensure the InnerVue™ Diagnostic Scope System is on a flat, level, and secure surface and the wheels are properly locked.
2. Connect the power cord to the InnerVue™ Diagnostic Scope System. Connect the other end of this cord to a power outlet that has also been approved for medical use.
3. Push the InnerVue™ Diagnostic Scope System's Main Power Switch to the "On" position (on the back of the unit).
4. Ensure the monitor's power is turned on. Flip the power switch on, which is located on the side of the monitor, and press the power button on the front of the monitor. An indicator light will glow amber or green when the power is on.

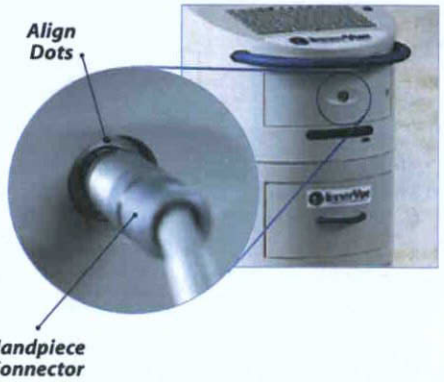






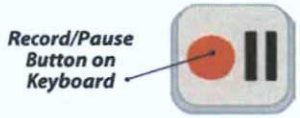
5. Turn on the InnerVue™ Diagnostic Scope System's Image Processor by pressing the power button (next to the Keyboard). An indicator light will glow when the power is on.
6. Connect the InnerVue™ Diagnostic Scope to the handpiece ensuring that they are properly aligned (Align the marks on the handpiece and scope.) Pull the drape over the handpiece.
7. Connect the handpiece cable to the cable connection on the front of the InnerVue™ Diagnostic Scope System, ensuring that the red dots are aligned. Insert the connector until a "click" is felt.
8. The InnerVue™ Diagnostic Scope System is now ready to use. You can begin a new procedure.

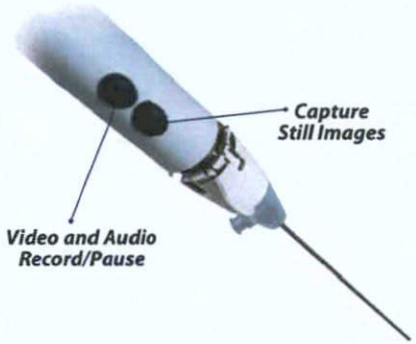




Performing a New Procedure

1. Power up system as shown on pages 4 & 5.
2. Place the InnerVue™ Patient Data CD in the CD drive.
3. From the InnerVue™ Main Menu, select Begin New Procedure.
4. Enter the Patient Data. You must enter information into the **bold** fields.
5. Enter the Surgical Data. You must enter information into the **bold** fields.
6. Click on Begin Procedure.
7. The screen will show the image through the camera. To record the procedure, either press the **Record/Pause** button on the keyboard or press and hold the second button on the handpiece for one second. A timer will start to count down in the lower left corner of the screen. To pause and resume recording, the same **Record/Pause** button is pushed. If the recorded video is paused, the timer will stop counting and begin flashing.



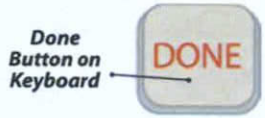


Note: If the procedure is longer than the allotted time, the system will halt recording but will continue to allow the use of the scope. The timer will display "0:00" in the lower left corner of the screen when record has been halted. Still Images can still be captured.

When the video record has been paused or a still image has been taken, the system sets markers for easy review of the video.

8. To capture still images, either press the **Camera** button on the keyboard or press the first button on the handpiece. There will be an indicator below the counter in the lower left corner of the screen representing the number of still images taken. Still images can be taken without recording video.

9. When finished recording the video, press the **Done** button on the keyboard.



10. The Review Session Menu will appear. You can choose from the following menu options:

Review the Video	View the video that was just recorded
Review the Images	View and print the images that were just taken **Print the desired images by pressing the print button on the keyboard.**
Archive Session	Burn the video and images that were just recorded onto the patient CD
Return to Main Menu	Returns to the Main Menu. **The recorded information is not stored on the hard drive. Information is only available on the archived CD**

11. If you would like to begin another new procedure, return to the main menu and refer to Step 1.

Note: If the procedure is not archived on the CD, you will not be able to retrieve any of the information once you return to the main menu.

Powering-Down the InnerVue™ Diagnostic Scope System

1. Remove the CD from the CD drive.
2. Remove all photos from the printer.
3. From the InnerVue™ Main Menu, select Power Off.
4. Press the power button on the front of the monitor to turn the display off.
5. Turn the main power off (on the bottom rear of the unit)

Note: It is not necessary to turn off the display power switch.

141

Cleaning of the InnerVue™ Diagnostic Scope System

Ensure the Main Power Switch on the lower back end of the system is turned OFF and disconnect all power cords before cleaning the system.

Note: Never immerse or soak any part of the InnerVue™ Diagnostic Scope System, including the handpiece, in any liquid, as this will cause significant damage.

The InnerVue™ Diagnostic Scope System and handpiece can be cleaned and disinfected with any cleaning agents meant for the cleaning of electrical equipment, used according to the instructions given by the manufacturer of the cleaning solution. Be sure to keep the following points in mind in order to ensure a long and effective life for the InnerVue™ Diagnostic Scope System:

- ***Do not allow excessive moisture or liquids to come in direct contact with the system or handpiece.***
- ***Do not use any cleaning agents that are not compatible with plastics, i.e. ammonia, acetone, other strong organic solvents, strong acids (HCl), etc.***
- ***Do not allow cleaning agents or liquids to enter the control unit outlets.***
- ***Do not use abrasive cleaning implements or compounds (e.g. tile cleaner, steel wool pads, fiber scrubbing pads, etc.) when cleaning the system.***

Replacement or Repair of the InnerVue™ Diagnostic Scope System

Cannula Set

If fluid flow has decreased through the cannula while the scope is inserted, the cannula may need to be repaired or replaced. For more information, please refer to the "Recommendations for the Care and Handling of Surgical Instruments and Instrument Cases" directions for use (included with the cannula set) for appropriate care, or contact your local Arthrotek® sales representative.

Light Source Replacement

If a new bulb for the InnerVue™ Diagnostic Scope System's Light Source is needed, then contact your Arthrotek representative for a replacement.

Re-Ordering Supplies

To re-order any supplies for the InnerVue™ Diagnostic Scope System, contact your local Arthrotek representative.

Technical Support

While the InnerVue™ System has no user serviceable parts, there are some error conditions that you can correct on your own. If difficulties occur with the InnerVue™ Diagnostic Scope System, refer to the Troubleshooting Guide in the User Manual to diagnose and solve the problem. If problems persist, call Arthrotek InnerVue™ Technical Support at 1-888-639-6886 during the hours of 8:00am to 5:00pm PDT. Twenty-four hour on-call emergency service is also available through this number.

Condensed Troubleshooting Guide

For more details, refer to the User Manual Troubleshooting guide or call **Arthrotek Technical Support at 1-888-639-6886** during the hours of 8:00am to 5:00pm PDT. Twenty-four hour on call emergency service is also available through this number.

Problem	Probable Cause
Main Menu does not appear	• Unit is not receiving electrical power • Unit is receiving electrical power, but monitor is turned off • Unit is receiving electrical power, but monitor cable is disconnected
"Incorrect Media Error" appears	• The software requires an unused InnerVue™ CD before it can proceed with the procedure
Printer does not print	• Paper tray is empty • Paper is improperly positioned in tray • Ink cassette is spent • Ink cassette is missing • Printer is disconnected from unit • Printer is not receiving electrical power
Screen is blue during procedure	• Handpiece cable is disconnected from unit
Sound is too low or absent	• Monitor volume is too low, volume controls are on the front bottom panel of the monitor • Speaker cable is unplugged
Scope illumination not present	• Handpiece cable is unplugged • Light source needs to be turned on. • Unit is out of procedure mode • Unit is too hot for light source to operate
Pushing the unit requires excessive force or is impossible	• Wheels are locked
Light source warning for number of hours remaining with the bulb appears	• Contact your sales representative to get your light source bulb replaced
Screen is frozen/system is unresponsive	• Software error, reboot system

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ARTHROTEK®

A BIOMET COMPANY

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Form No. Y-BMT-901/083104/K

INVENTING THE FUTURE OF ARTHROSCOPY

12.4 - Smith & Nephew 560 HD Camera System

300XL Xenon Light Source
450P and 460P Camera Control Units
460H 3-CCD Camera Head
470H Progressive Scan Autoclavable Camera Head
> 560 Series High Definition Camera System
560H 3-CCD High Definition Camera Head
660HD Image Management System
Arthroscopes and VideoArthroscopes
DORAWEB Surgical Documentation System
MULTIMODE COUPLER
SV420 Series Camera System

560 Series High Definition Camera System

Ordering Information

The defining moment in high definition has arrived

Smith & Nephew is proud to announce the all new, digital-broadcast quality 560 Series 3-CCD High Definition Camera System, producing pure HD 1080i imaging. It's a complete end-to-end, high definition system that keeps the HD format throughout the *entire* video chain – including optics, camera head, CCU and monitor. And it meets the ATSC broadcast standards for HDTV*. The result is a level of image quality and color never before possible, including picture clarity that's five times greater than the resolution of SDTV.

Native HD image data acquired by the 560 H camera is conveyed to the CCU via high speed digital interface, where the image data is processed and converted into HDTV images, which can then be displayed on a flat panel monitor in wide screen 16:9 format with either 1920 x 1080i or 1,280 x 720p pixels.

With our all-HD camera system, you'll see an extremely high-resolution and virtually distortion-free image. Colors look more realistic, with greater depth-of-field due to the wider bandwidth. The 560 H High Definition Camera System provides a level of image quality never before possible.

- Presents anatomical color and detail previously unseen with standard definition surgical cameras.
- Increases productivity and more confident diagnoses.

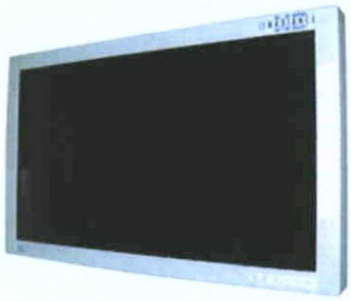
560H Camera Head

- Uses 3-CCD (Charge Coupled Device) design to acquire the digital HDTV image data.
- Captures more clinical information
- Breakthrough micro-electronic technology allows advanced ergonomic design: the 560 camera head is similar in size and weight to a standard camera head.
- 3-button, 6-function interface controls image and remote operation of compatible peripheral devices like CCU's, printers, and Smith & Nephew Image Management Systems.

145

560P Camera Control Unit

- Proprietary processing architecture handles 2 1/2 times more information than SDTV to achieve true high definition TV.



560 SYSTEM Flat Panel Monitor

- Outputs image in full 1920 x 1080i 16 x 9 format or traditional 4:3 format.
- Displays true high definition resolution and clarity.
- Displays true HD images when used with the Smith & Nephew 560 Series Camera System.
- Lightweight display for superior flexibility.

The 560 Series: the only definition that matters

*The Advanced Television Systems Committee (ATSC), an international non-profit organization that develops voluntary standards for digital television, defines the standard for HDTV as follows:

Aspect Ratio: Must be capable of displaying wide screen 16:9 format. Standard definition television (SDTV) has a 4:3 aspect ratio.

Pixel Quantity: Meets or exceeds 1280 x 720p, or 1920 x 1080i.

Scanning Pattern: 720p (progressive scan) or 1080i (interlaced scan).

Specifications
Subject to change without notice

560P High Definition Camera System

Power	100 - 240 VAC, 50/60 Hz;
Requirements	Dual Fuse
Classification	CISPR 11 Class A
Equipment Classification	Protection against electrical shock Class 1 with CF type applied part. Protection against harmful ingress of water. (Ordinary equipment, none provided) Degree of safety application in the presence of flammable anesthetics with mixture of air, oxygen, or nitrous oxide. (Not suitable)
CCU Dimensions	4.25" H x 12" W x 15" D
CCU Weight	9.9 pounds
Display Output	50/60 Hz
Resolution	1920 x 1080i (native)
Signal-to-Noise	>64 dB
Ratio Shutter	NTSC: 1/60 per second through 10,000 per second shutter speed PAL: 1/50 per second through 10,0000 per second shutter speed

HD Serial Digital Interface (HD-SDI) One serial digital interface (SDI) with 4:2:2 component digital video output on BNC connector

HD Digital Visual Interface (HD-DVI) Two digital visual interfaces supporting DVI-Digital (DVI-D) single-link interfaces on 29-pin DVI-I connector with 4:4:4 component digital video output on BNC connector

146

YPrPb Video Output One video output 1Vp-p, YPrPb or Component video into 75Ω, BNC coaxial connectors

IEEE-1394 Output One IEEE-digital video output, 4-pin connector; provides continuous DV-formatted (5:1) compressed 25 Mb/sec data rate

Y/C Video Outputs Two Y/C video outputs, combined luminance/chroma signal into 4-pin mini-DIN plug

Composite Output One analog, encoded video signal that includes vertical and horizontal synchronizing information

AC Leakage Current Camera control unit: less than 300 microamps earth leakage

Video Accessory Controls Two mini-phono connectors (3.5 mm)

560H High Definition Camera Head

Equipment	Protection against electrical shock
Classification	Class I, applied part Type CF
Video Imager	Three 1/3" Interline Transfer Micro-Lens high sensitivity CCD Image Sensors
Imaging Resolution	Vertical: 1080i native TV lines Horizontal: 1920 native TV lines
Signal-to-Noise Ratio	>64 dB
Video Data Acquisition	Three 14-bit RGB channels, digitized inside camera head
Video Data Transmission	High-speed, low-voltage differential serial (LVDS), uncompressed 42-bit RGB digital transmission via 12-foot camera cable
Video Output Format	Full HD 1080i, 100% compatible with SMPTE-274M:2005 HDTV broadcast standard when used with the 560P Camera Control Unit
Video Field Rate	60 Hz or 50 Hz universal camera head, software switchable
Operating Temperature	41° - 108° F (-20° -60° C)
Operating Humidity	38 - 75% non-condensing
Storage Temperature	-4° - 140° F (-20° -60° C)
Storage Humidity	20 - 90% non-condensing
Camera Head Dimensions	1.8" x 2.6" x 2.25" (width x depth x height)
Camera Head Weight	161 grams
Camera Head Cable	12' +/-3" (3.65 m +/- 7.6 cm)
Lens Mount	1"-32 UN C-mount thread
Compatible Control Units	Smith & Nephew 560P High Definition Camera System

For more information please contact:

Smith & Nephew Endoscopy
150 Minuteman Road, Andover, MA 01810
Phone: 1-800-343-5717
Email: *Click Here*

Ordering Information

560P Camera Control Unit (System, NTSC/PAL)	
72200571	English
72200572	Spanish
72200573	French
72200574	German
72200575	Italian
72200576	Swedish
72200577	Dutch
72200578	UK
72201380	Korean
72201381	Portuguese

147

72201382	Norwegian
72201383	Danish
72200579	International
560H 3-CCD HD Camera Head	
72200561	NTSC/PAL
High Definition Couplers	
72200315	5:4, 19.5 mm
72200422	16:9, 26.5 mm
High Definition Videoarthroscopes	
72200312	4 mm x 30°, Autoclavable
72200089	4 mm x 70°, Autoclavable

* Marque Déposée par Smith & Nephew
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148

12.5 - Smith & Nephew 660 HD Image Management System

300XL Xenon Light Source
450P and 460P Camera Control Units
460H 3-CCD Camera Head
470H Progressive Scan Autoclavable Camera Head
560 Series High Definition Camera System
560H 3-CCD High Definition Camera Head
660HD Image Management System
Arthroscopes and VideoArthroscopes
DORAWEB Surgical Documentation System
MULTIMODE COUPLER
SV420 Series Camera System

660HD

Image Management System

Ordering Information

High definition image management that puts you in complete control

The 660HD Image Management System increases OR efficiency by easily capturing and utilizing surgical images in true high definition (HD) format.

Manage Your Surgical Images with Ease

The Smith & Nephew 660HD Image Management System is an easy-to-use digital capture system that enables the OR staff to capture, edit, print, and store intraoperative surgical images and videos in true 1920 x 1080 high definition (HD) format.

Patient images and videos can be captured using camera head buttons or the graphical user interface. Images can be edited and printed on inkjet or laser printers. Patient data can be written to a data CD/DVD for a computer, or a video DVD for use in commercial DVD players. Images can also be saved to a USB drive or network folder. When used with the Smith & Nephew Integration Broker software, the 660HD System can save to PACS using DICOM or Electronic Medical Record (EMR) using HL7.

Capture

Enter the entire day's patients in the morning, or integrate with the electronic medical record for one-touch patient data import.

Capture images and video from any source in multiple formats

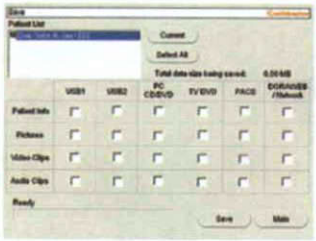
Capture audio either in combination with video, or as a audio clip.

Edit **Print** **Store**

150

Search history for previous patients, retrieve data and view, edit, print or save it.

Print patient data in any one of eight formats using only the desired images.



Store data to a USB device, CD, or DVD.

Rename images, videos and audios using the built-in keyboard or configurable drop-down menus.

Use the "Auto Print" feature and have images print as the case proceeds.

Send patient data to any network folder.

Enhance image brightness, contrast or color.

Include patient notes as well as the facility logo and address on the printouts.

Use the Integration Broker software to save to PACS using DICOM, or Electronics Medical Record (EMR) using HL7.

System Specifications

Video Inputs	S-Video (Y/C), Composite, HD-SDI, IEEE-1394
Video Outputs	S-Video (Y/C), Composite, HD-SDI, DVI
Video Formats	NTSC and PAL
USB 2.0 Ports	Type A receptacle, software compatible with NS16C550
Parallel Port	Bidirectional input/output with female DB-25 receptacle
Serial Ports	UART port with male DB-9 receptacle
VGA Port	15-pin female VGA port
Ethernet Ports	Auto-select 10Base-T/100Base-TX
Storage	Supports read/write of USB flash media of different sizes; CD-R/RW: 650 MB or 700 MB. Writes data in standard ISO 9660 CD-R format. DVD-R/RW: 4.7 GB. DVD+R: 4.7 GB.
Still Image File	24-bit RGB bitmap (.bmp) file
Formats	24-bit JPEG (.jpg) file
Still Image	NTSC/PAL
Resolution	Up to 1920 x 1080 @24 bit color depth 16.77 million True Color
Motion Video	MPEG1, MPEG2, MPEG4
File Format	AVI (For IEEE-1394 only)
Power Requirements	Input Voltage: 100-240 VAC, 50/60 Hz @90VA
Dimensions	(L x W x H) 14.0 x 12.0 x 8.0 inches 35.56 x 30.48 x 20.32 cm
Weight	16 lbs (7.25 kg)
Hard Drive	200 GB drive with Ultra DMA data transfer
Processor	Intel® Pentium® M 1.6 GHz
Operating System	Microsoft® embedded Windows® XP

For more information please contact:

Smith & Nephew Endoscopy
150 Minuteman Road, Andover, MA 01810
Phone: 1-800-343-5717
Email: *Click Here*

Ordering Information

Please contact Customer Service for product availability	
72200812	660HD Image Management System, English on-screen display and Operations/Service Manual, US power cord
72200814	660HD Image Management System, multi-language on-screen display and

151

	Operations/Service Manual, continental power cord.
72299816	660HD Image Management System, English on-screen display and Operations/Service Manual, UK power cord.
Accessories	
7210344	Touch panel, LCD, 15 inch (domestic)
7210345	Touch panel, LCD, 19 inch (domestic)
7209339	Single-pedal footswitch
7209340	Dual-pedal footswitch
7210534	DVD-R media, 4.7 G, single-sided
7209338	650 M or 700 MB CD-R media
72201464	Printer 6940, HP Inkjet Printer
7210533	Premium photo paper, glossy, 50 sheets
72200203	Everyday photo paper, semi-gloss, 100 sheets
72200204	High volume black ink cartridge, 21 ml
72200205	High volume color ink cartridge, 14 ml

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152

12.6 - Smith and Nephew Arthroscopes

300XL Xenon Light Source
450P and 460P Camera Control Units
460H 3-CCD Camera Head
470H Progressive Scan Autoclavable Camera Head
560 Series High Definition Camera System
560H 3-CCD High Definition Camera Head
660HD Image Management System
> Arthroscopes and VideoArthroscopes
DORAWEB Surgical Documentation System
MULTIMODE COUPLER
SV420 Series Camera System

Arthroscopes and VideoArthroscopes

Ordering Information

Delivering unparalleled image quality, superior brightness, clarity, and performance.
Engineered with wide angle lens construction and exceptional depth of field to keep the operative site in focus over a wide range of vision, reducing the need to refocus during surgery.

Direct view Arthroscopes provide optimal flexibility. Choice of viewing angles allows complete joint examination without compromising technique	VideoArthroscopes attach directly to camera for optimum clarity. Choice of viewing angles allows complete joint examination without compromising technique	High quality optical couplers team with direct view arthroscopes to offer procedural flexibility

For more information please contact:

Smith & Nephew Endoscopy
150 Minuteman Road, Andover, MA 01810
Phone: 1-800-343-5717
Email: *Click Here*

Ordering Information

VideoArthroscopes – Autoclavable

REF	NAME	DESCRIPTION
7210716	4.0 mm x 30° Autoclavable VideoArthroscope	160 mm working length
7209401	4.0 mm x 70° Autoclavable VideoArthroscope	160 mm working length
7209402	2.7 mm x 30° Autoclavable VideoArthroscope	120 mm working length
7205929	2.7 mm x 30° Autoclavable VideoArthroscope	67 mm working length

154

VideoArthroscopes - Non autoclavable
Blue Focus Ring, 35 mm focal length

7205922	4.0 mm x 30° Non-Autoclavable	160 mm working length
3766	4.0 mm x 30° Non-Autoclavable	160 mm working length
3628	4.0 mm x 70° Non-Autoclavable	160 mm working length
3632	2.7 mm x 30° Non-Autoclavable	120 mm working length
3768	2.7 mm x 30° Non-Autoclavable	120 mm working length
3863	1.9 mm x 30° Non-Autoclavable	67 mm working length

VideoArthroscopes - Non autoclavable
Black Focus Ring, 25 mm focal length

4125	4.0 mm x 30° Non-Autoclavable	160 mm working length
4126	4.0 mm x 70° Non-Autoclavable	160 mm working length
4130	2.7 mm x 30° Non-Autoclavable	120 mm working length
4131	2.7 mm x 30° Non-Autoclavable	67 mm working length
4132	2.7 mm x 70° Non-Autoclavable	70 mm working length

Direct-View Arthroscopes, Autoclavable

7205682	2.7 mm x 30° Autoclavable	67 mm working length
7205681	2.7 mm x 30° Autoclavable	120 mm working length
3894	4.0 mm x 30° Autoclavable	160 mm working length
7209403	4.0 mm x 30° Autoclavable	160 mm working length
3895	4.0 mm x 70° Autoclavable	160 mm working length
7208132	4.0 mm x 30° Autoclavable	175 mm working length
7205548	Aluminum oxide vial for cleaning autoclavable endoscope lenses	
7210721	Protective cap for autoclavable scopes. Fits 4.0 mm and 5.5 mm scopes. Package of 70.	

Direct-View Arthroscopes-Non autoclavable

3775	4.0 mm x 0° Arthroscope	160 mm working length
7205827	4.0 mm x 30° Arthroscope	160 mm working length
3623	4.0 mm x 70° Arthroscope	160 mm working length
3765	4.0 mm x 30° Arthroscope	160 mm working length
3625	2.7 mm x 30° Arthroscope	120 mm working length
3947	2.7 mm x 30° Arthroscope	120 mm working length
3948	2.7 mm x 70° Arthroscope	70 mm working length
4184	1.9 mm x 30° Arthroscope	65 mm working length

Accessories

7210192	18 mm Multimode coupler, for use with Smith & Nephew 1/4" CCD Camera Heads
7204613	Camera coupler, C-mount, 25 mm length
7204823	Camera coupler, C-mount, 30 mm length
7204614	Camera coupler, C-mount, 35 mm length
4466	Camera coupler, V-mount, 35 mm length
7205461	Zoom coupler, C-mount, 25-45 mm length
7209042	90° Urology coupler, for use with 4 and 5 mm endoscopes, C-mount, 25 mm length
4533	90° Urology coupler, C-mount, 35 mm length
4464	Rotateable beamsplitter coupler, C-mount, 25 mm
2985	Gemini Universal Fiber Optic Cable, 4 mm x 8 feet, for use with 4 mm and 2.7 mm Autoclavable Arthroscope line
2146	Versitip Adapter for use with Endoscopes and Gemini Universal Fiber Optic Cable
3642	Flexible Endoscope adaptor

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155

12.7 - Stryker Evolution of HD Technology Brochure

stryker

Endoscopy

Revolutionary HD Technology

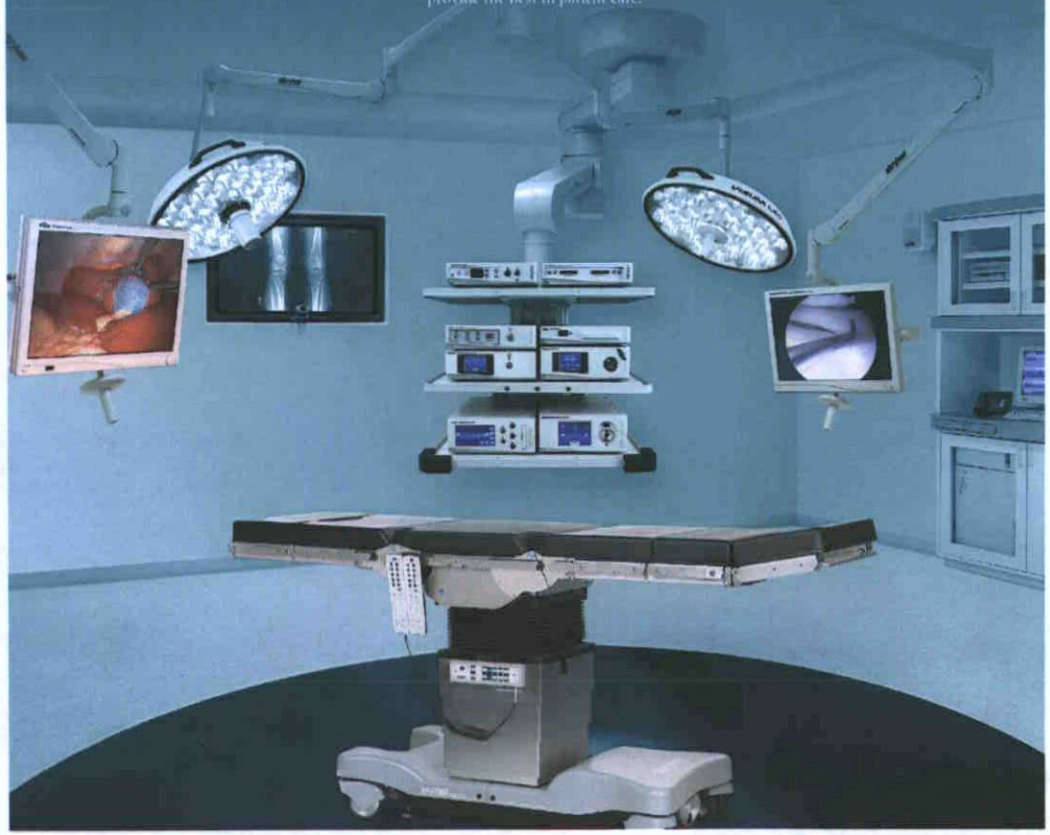
Introducing Wireless 1080p

- WiSe™ Wireless Platform
- 1288 HD 3-Chip® Camera
- L9000 LED Lightsource
- SIDNE® Device Control
- SDC Ultra Digital Capture

Simplifying
Today's OR

As medical video technology continues to evolve and the visual demands of today's operating room increase, Stryker has once again responded by raising the bar with revolutionary HD technology – the first wireless technology on the market and Stryker's third-generation of high definition (HD) video products.

This new visualization platform features the WiSe™ Wireless Platform, 1288 HD 3-Chip® Camera, and the L9000 LED Lightsource. This revolutionary platform, coupled with the SDC Ultra Digital Capture and SIDNE® Device Control Systems, offers hospitals an unparalleled and incredibly innovative video system which delivers exceptional results that will help surgical teams provide the best in patient care.



Restructuring
High Definition

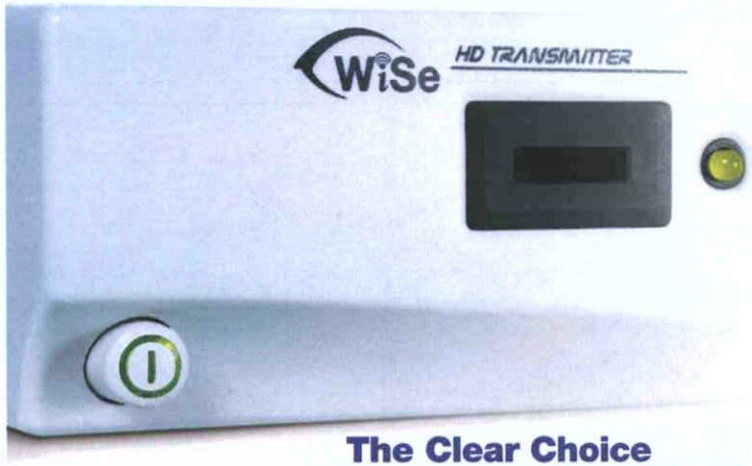
WiSe™ HDTV and Vision Elect™ HD Flat Panel Monitors
Designed specifically for the surgical environment, the WiSe™ HDTV and Vision Elect™ Flat Panel Monitors are the ideal complement to the 1288 HD Camera, offering exceptional video quality in both 21 inch and 26 inch displays thus providing a multitude of options. The WiSe™ HDTV and Vision Elect™ Flat Panel Monitors combine versatility with a brilliant picture to provide precise, lifelike images in the OR.

1288 HD 3-Chip® Camera
The 1288 HD, Stryker's third generation high definition 3-Chip camera, delivers an unsurpassed 1080p resolution with optimum depth of focus, and edge-to-edge clarity and sharpness for surgeons. It also features an intuitive touch screen, fully programmable camera head buttons and the ability to control the L9000 LED Lightsource from the camera head. The 1288 HD 3-Chip® sets a new standard in visualization products for the OR environment.

L9000 Lightsource
This new LED technology will completely change the perception of lightsources in the operating room. The long life expectancy of the LED bulbs will drastically reduce the overall cost of ownership while reducing the environmental waste and increasing the patient safety.

SDC Ultra
The SDC Ultra High Definition Information Management system provides cutting edge features and versatility to the Operating Room. Perfect for education and teaching purposes, the SDC Ultra captures both images and videos in Native Resolution High Definition. The Ultra supports dual channel video inputs, as well as the ability to save/archive information to multiple types of external media, including the 250 GB internal hard drive.

SIDNE® Suite
Ideal for the I-Suite® environment, SIDNE® Suite specifically provides system integration for device control. This intuitive system makes it possible to utilize device control functionality from a centralized station within the OR.



Introducing
Wireless 1080p

WiSe™ HDTV Transmitter

The WiSe™ HDTV Transmitter is the core of Stryker's ground breaking wireless 1080p video transmission platform. Combined with the WiSe™ HDTV Flat Panel Monitor, uncompressed 1080p video signals can be displayed wirelessly virtually anywhere within the OR. WiSe™ Token Keys create unique codes between monitors and transmitters to protect wireless signal quality from interference with other OR devices. This simplistic linking process provides secure and exclusive wireless video transmission channels.

Features & Benefits:

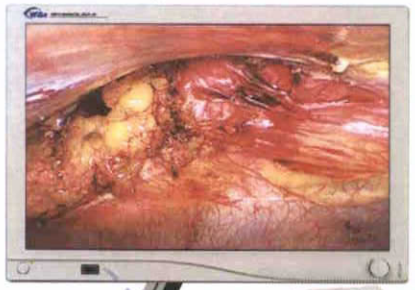
- Wireless 1080p HDTV resolution
- Simple linking system for wireless video transmission
- Increased visualization freedom
- Eliminates need for costly traditional cables

The Clear Choice
for HD Visualization

WiSe™ HDTV Surgical Display

Stryker builds upon its visualization expertise with the WiSe™ HDTV Flat Panel Monitor, the first wireless 1080p flat panel in the medical field. WiSe™ HDTV brings revolutionary technological advancement and financial benefits to the OR. Uncompressed 1080p is transmitted wirelessly to eliminate cable clutter and potential costly repairs to traditional flat panels. WiSe™ HDTV will deliver optimal surgical images with unsurpassed resolution, brightness, and optical clarity.

802.11n



Features & Benefits:

- 1st Wireless 1080p Flat Panel Monitor in the Medical Device Industry with FDA 510(k) clearance
- 26" high definition display provides bright and clear surgical footage
- Freedom to move the flat panel anywhere within the OR
- Ergonomic user interface allows consistent operation under any OR condition
- Multiple video inputs: DVI, VGA, HD/SD-SDI, C-Video/SOG, S-Video, Component, Optical (optional)

159

The Evolution
of High Definition Technology

1288 HD 3-Chip® Camera

As the third generation in Stryker's HD 3-Chip® camera line, the 1288 HD 3-Chip® Camera features a 1920x1080p resolution along with nine specialty settings, resulting in optimum color resolution and brightness. Additional benefits of the 1288 HD 3-Chip® Camera include wireless transmission capabilities, four fully programmable buttons on the camera head, HD and HDTV outputs, and a touch screen LCD interface for easy navigation. By allowing for backwards compatibility with past generation digital capture devices, scopes and various flat panels, while also offering future capabilities with an optional fiber optic board, the 1288 HD 3-Chip® Camera continues to offer new solutions for improved visualization within the OR.

Unparalleled Resolution
And Clarity for the OR

Features:

- 1920 x 1080p resolution
- Enhanced clarity, depth of focus and sharpness
- L9000 light source control from the camera head
- Intuitive touch screen LCD interface

Fully programmable buttons

20mm durable coupler with a single-hand focusing design

Ergonomic cable connector for reliable connection

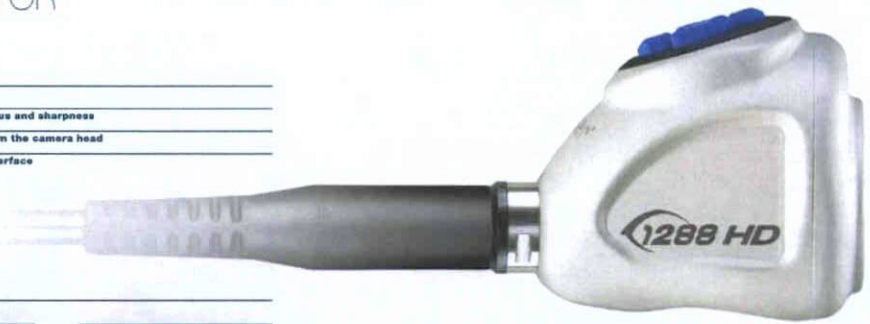
1288 HD 3-Chip® Camera Heads
High Definition Standardization

1288 HD 3-Chip® Regular Camera Head

- Ergonomic design for multi-specialty use
- Easy to rotate 20mm coupler design
- Fully programmable four buttons

1288 HD Urology 3-Chip® Camera Head

- 90° cable cable design for Urology, Gynecology & ENT procedures
- Rotating integrated 20mm coupler
- Built-in beam splitter provides direct eye viewing
- Ergonomic and light weight design



1288 HD Inline 3-Chip® Camera Head

- Optimum design for Endoscopic Vein Harvesting
- Fully programmable 4 buttons
- Easy to rotate 20mm coupler

Light
Unlike Ever Before

L9000 LED Lightsource

Now an eco-friendly and cost-savings OR device, the L9000 LED Light Source reduces the environmental waste by eliminating the need to change the LED light bulb. The new design and Safelight™ technology within this light source provides a cooler light emission during procedures, making the device safer and more efficient for both the patients and OR staff. As an added benefit, the Safelight™ technology ensures that the light source goes into standby mode when the light cable detaches from the Safelight™. This will minimize injury to the patient and provide added protection in the OR.

Features:

- Intutive simple user interface with LCD touch screen
- Control from the 1288 camera head
- Reduced lifetime ownership cost
- Increased patient and OR safety with Safelight ™ cable

OR Standardization
The 1288 HD Camera System continues to offer true standardization within the Operating Room

SIDNE® Suite...
The Ease of Integration

Simple Device Control

Ideal for the i-Suite® environment, SIDNE® Suite specifically provides touch panel integration for device control.

- Control from a centralized station within the i-Suite®
- Capable of additional methods of device control through voice activation and wireless tablet upgrades

SIDNE® Link...
The Freedom of Movement

Wireless Flexibility

SIDNE® Link is specifically designed for the unique needs of the cart market.

- Control from the completely wireless tablet's touch screen interface
- Capable of additional device control through voice activation upgrade

SIDNE® Voice...
The Essence of Control

Hands-Free Command of the OR

Hands free voice activation upgrades are available for both SIDNE® Suite and SIDNE® Link through the advancements in SIDNE® Voice. This modular piece brings flexibility to the OR with superior voice recognition to control surgical equipment from the sterile field.

Voice Recognition Technology
Using state-of-the-art voice recognition, SIDNE® eliminates the need for voice cards or voice training. Dual audio inputs allow two surgeons to use voice control simultaneously. In addition, SIDNE's superior video capability gives surgeons the ability to see text overlays while viewing high resolution video and analog signals.

Cutting Edge Technology
for the High Definition Operating Room

SDC Ultra
HD Information Management System

Native HD Video Capture

- **Record surgical footage in Native HD Resolution**
- **Perfect for use in teaching, conferences, and presentations**
- **Unprecedented quality in surgical video**

Redesigned Graphic User Interface

- **Control the SDC Ultra from the LCD Touch Screen**
- **Intuitive, easy to use**
- **Icon Driven user interface**

Dual Channel Input Support

- **Input/Display two separate video signals**
- **Capture images and record videos on two separate channels, in synchronized mode, or in PIP format**
- **On-Screen Picture in Picture to display multiple video signals**

SDC Ultra
The Final Piece to the Puzzle

Dual-Rotation Integrated Touchscreen

- Provide flexibility to OR workflow and design
- Dual Rotation Touchscreen for optimal visualization from any angle

Front-Load Patient Scheduling:
- Pre-load patient information for a day's worth of cases
- Easily select patient by convenient drop down menu in the capture screen
- Reduce time and effort between cases for surgical and nursing staff

Full Network Integration:
- Interface with Hospital PACS and FTP Networks
- Save and Retrieve case information from hospital networks/servers
- Auto-Populate patient information from hospital system for accurate medical records

Easily Customize Annotations, Specialty, & Procedure:
- Annotate images and videos from preloaded list in the album
- Organize annotations and case information by Specialty and Procedure
- Add customized procedures and annotations with one easy step

Archive:
- Archive every case with images and videos to the internal 250 GB Hard Drive
- Review, Reprint, and Resave case information from the archive
- Safeguard your hospital - Don't lose another important case

102

stryker

- Joint Replacements
- Trauma, Extremities & Deformities
- Craniomaxillofacial
- Spine
- Biologics
- Surgical Products
- Neuro & ENT
- Interventional Pain
- Navigation
- Endoscopy
- Communications
- Imaging
- Patient Handling Equipment
- EMS Equipment

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San Jose, CA 95138
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www.stryker.com

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VTD/FAW G 5k 01/09

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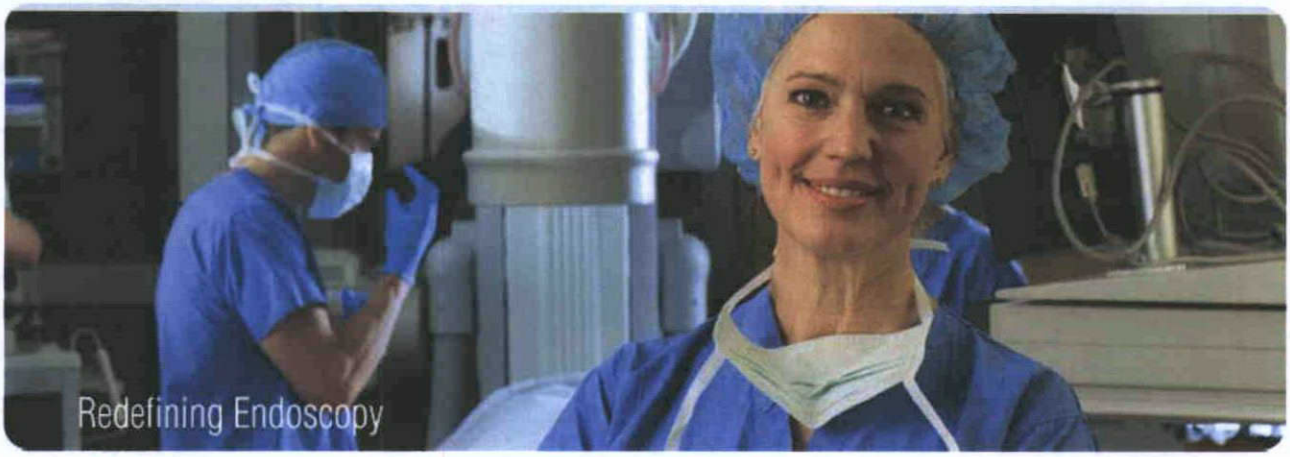
12.8 - VisionSciences Endosheath

Investors

VISION® sciences



Products/Catalog EndoSheath® Technology

PRODUCTS/CATALOG

ENDOSCOPY SYSTEMS

ENDOSCOPIC PERIPHERALS

ENDOSCOPY ACCESSORIES

ENDOSHEATH®

TECHNOLOGY

EndoSheath® Technology

How does EndoSheath® Technology work?

Prior to a flexible endoscopy procedure, an endoscope is placed inside a new, sterile sheath. Following the procedure, the endoscope is removed from the sheath, which is then discarded. The sheath eliminates the need for toxic high-level disinfection/sterilization routines between each patient. The result is a safe, sterile instrument for each patient and rapid equipment turnaround for the practice.

EndoSheath® Technology offers new advantages in endoscopy.

Image Gallery

Send to Colleague

Print Page

Contact Sales Rep

165

Cystoscopy

Bronchoscopy

Esophagoscopy

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166

12.9 - VisionSciences Endosheath Urology Published Literature

The Royal College of Surgeons of England

UROLOGY

Ann R Coll Surg Engl 2007; **89**: 426–430
doi 10.1308/003588407X183346

Out-patient flexible cystoscopy using a disposable slide-on™ endosheath system

MICHAEL KIMULI, STUART N LLOYD

Pyrah Department of Urology, St James's University Hospital, Leeds, UK

ABSTRACT

INTRODUCTION The aim of this study was to investigate the feasibility of out-patient flexible cystoscopy.

PATIENTS AND METHODS Twenty-seven patients awaiting diagnostic or check cystoscopy in Leeds, UK were invited to undergo out-patient flexible cystoscopy using a CST-2000 Flexible Cystoscope (Vision Sciences; Natick, MA, USA) using the sterile single-use slide-on™ disposable endosheath endoscope system (EndoSheath®; Vision Sciences). The performance of the cystoscope was evaluated, and the patients' experiences were documented using a questionnaire.

RESULTS The out-patient setting proved to be ideal for flexible cystoscopy. The cystoscope was rated highly for image quality, ease of use and handling. All patients complimented us on the service and preferred out-patients to a day-ward or theatre attendance.

CONCLUSIONS This study demonstrates that it is possible to perform out-patient flexible cystoscopy safely, economically and efficiently with the aid of a disposable endoscope system.

KEYWORDS

Flexible cystoscopy – Vision Sciences – Disposable endoscopy sheaths – Slide-on™ endosheath system

CORRESPONDENCE TO

Stuart N Lloyd, Consultant Urologist, Pyrah Department of Urology, St James's University Hospital, Leeds LS7 9TF, UK
E: slloyd140@btinternet.com

Flexible cystoscopy is the most frequently performed urological procedure both as a diagnostic and surveillance tool. Freely available facilities to flexible cystoscopy is fundamental to modern urological practice but this is often limited by access to facilities, sterilisation and instrumentation resulting in significant waiting times for the procedure delaying diagnosis and treatment. Most units perform flexible cystoscopy in a day-ward theatre setting, others in purpose-built endoscopy units, few in the out-patient setting. Within our unit, flexible cystoscopy is performed in day-ward theatres, waiting times for non-urgent flexible cystoscopy has reached 9 months. Purchasing and servicing a large number of instruments was considered costly. Moving flexible cystoscopy into an out-patient setting with the implementation of the new Vision Sciences flexible cystoscope using slide-on™ endosheath system may overcome these difficulties and provide an opportunity to improve efficiency.

This paper reports our initial experience with this new device comparing it with standard flexible cystoscopy in an out-patient setting.

Patients and Methods

Twenty-seven patients on the day-case waiting list for diagnostic flexible cystoscopy were randomly chosen to be part of the pilot for the out-patient flexible cystoscopy list. Initially, small numbers were listed to establish the processes; the last list accommodated 10 patients comfortably. All patients were given an information sheet in the waiting area prior to the procedure. They were interviewed using a simplified assessment sheet and consented by the operator (Appendix 1). Patients did not fully change as in the day-ward setting but removed their lower half garments in the treatment room behind a screen.

The Vision Science CST-2000 flexible cystoscopy was used for all procedures. At first glance, the flexible cystoscope looks similar to existing instruments but closer inspection reveals several key differences (Fig. 1A–D). The cross-section of the instrument is crescenteric and measures 13.8-F by 16.8-F. It has a lever to lock onto the disposable sheath and a depression valve for irrigation. The sheath incorporates a 6-F working channel for biopsy and ureteric stent removal.

168

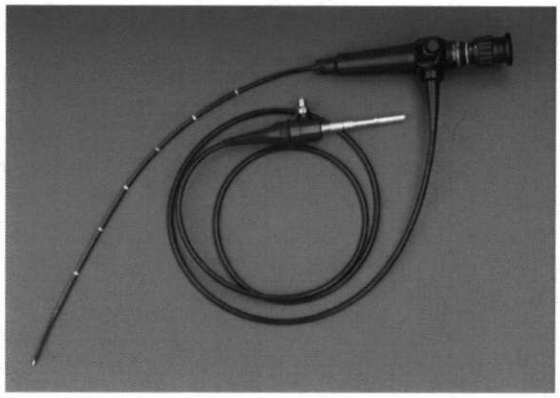

Figure 1 CST-2000 Flexible cystoscope with the sterile, single-use slide-on disposable endosheath.

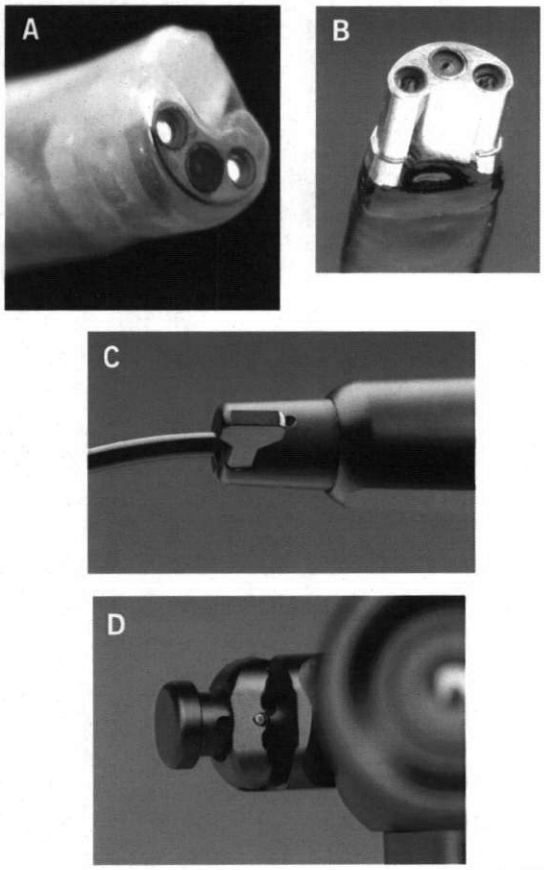

Figure 2 Crescent-shaped flexible cystoscope with (A) or without (B) an endosheath. (C) The lever that locks the cystoscope into the sheath. (D) The irrigation valve.

The cystoscope is sterilised at the beginning and end of the list with conventional techniques using peracetic acid. The single-use, slide-on sheath is employed between each patient. For each procedure, both the operator and the assistant wear double-layer, sterile gloves so as not to contaminate the instrument when re-sheathing. At the beginning of each procedure, the individually pre-packaged sheath is secured on a table-top fixed device. The instrument is inserted into the sheath and the two are locked together with a catch on the instrument (Fig. 2A–D). The sheath is pulled over to cover the rest of the cystoscope before attaching a camera. The instrument is introduced into the urethra in a standard fashion after cleaning and insertion of local anaesthetic jelly. At the end of the procedure, the assistant slides the sheath off the instrument, removes the outer gloves and inserts a new sterile sheath into the table-top holding device. The operator inserts the cystoscope into the new sheath, removes the outer gloves before pulling the sheath onto the rest of the instrument. The cystoscope is now ready for the next patient. The de-sheathing and re-sheathing process takes about 2 min. A standard catheterisation pack was used to provide the swabs and paper towel.

The assessment of the procedures was evaluated according to ease of use, flexibility and vision. Staffing ratios and patient flows were developed as the clinic progressed until the ideal levels were identified. The patients were asked to give feedback of the out-patient cystoscopy service.

Results

Out-patient setting

The out-patient setting proved to be ideal for flexible cystoscopy utilising a treatment room used for catheterisation and the main waiting area as pre-waiting and recovery area. The optimum staffing ratios were a receptionist, one trained (assistant) and one untrained nurse and the operator.

Instrumentation

EASE OF USE

Once the operator and assistant became familiar with the sheathing, the whole process of sheathing and re-sheathing became smooth and efficient. The whole process was more intricate than normal but the benefits outweighed the disadvantages. Care was taken not to put the instrument down after use until it was re-sheathed ready for use again. On four occasions, the sheath clung to the scope due to friction requiring the sheath to be cut off. Finally, there was no break in the integrity of the sheaths or damage to the instrument.

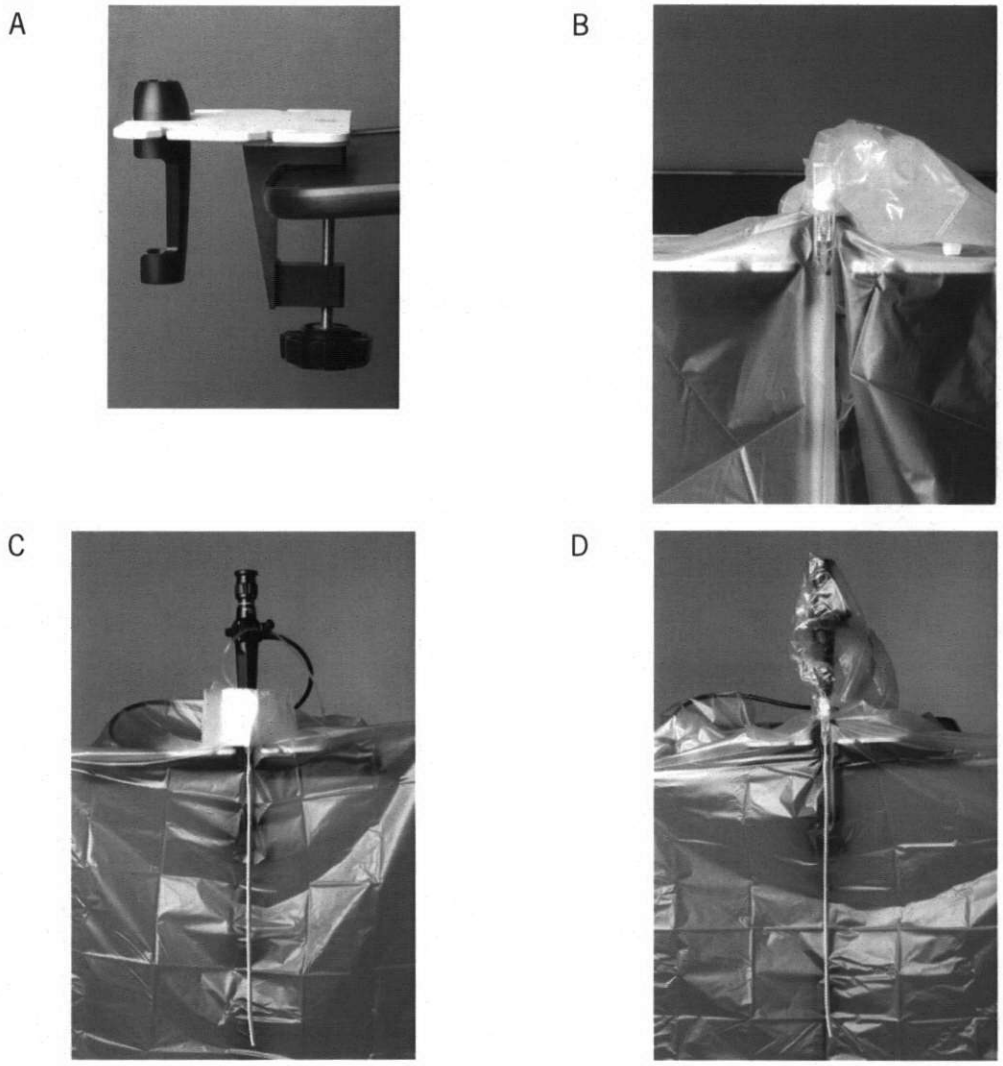

Figure 3 The installation stand attached onto a table (A) before securing the endosheath (B). The distal end of the cystoscope is inserted into the opening of the sheath (C) while the eye-piece is covered by the remainder of the sheath (D).

FLEXIBILITY

The instrument handled identically to conventional scopes with no restriction of movement (Fig. 3) or handling. The instrument is lighter than most, which is a distinct advantage when the camera was attached to the eyepiece. The working channel allowed passage of a biopsy forceps which, in one patient, facilitated retrieval of a foreign body (Fig. 4).

OPTICS

There was no noticeable reduction in quality of vision by looking through the transparent tip at the end of the scope.

Patient feedback

All patients complimented us on the service and preferred to come to out-patients rather than attend day-ward or day-theatre. They did have higher expectations of attending for

170

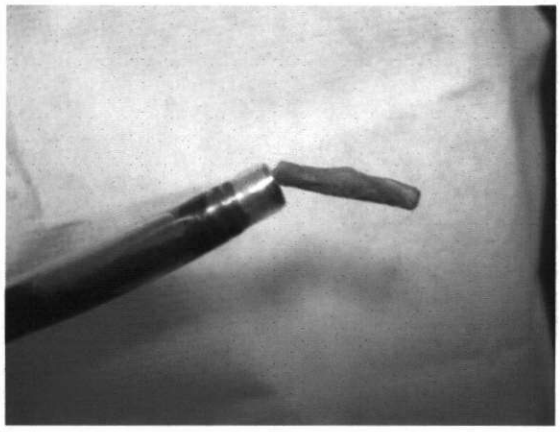

Figure 4 A foreign body retrieved from a patient.

an appointment whereas day-theatre patients seem to accept a longer wait for their procedure.

Discussion

Out-patient flexible cystoscopy is not a new concept but this requires either support with sterilisation units or several pre-packed scopes, which may limit the number of procedures that could be performed. The use of the re-sheathable, flexible cystoscopy overcomes most of these obstacles, potentially freeing up valuable day-theatre or endoscopy theatre time.

Vision Science also manufacture disposable sheaths for ENT instrumentation which have found favour in many centres including our own.[1] The disposable nasopharyngo-laryngoscopy sheath has proven cost-effective and has resulted in large numbers of procedures being performed in the community setting rather than in secondary care.

The US FDA-approved sheath is a proven effective barrier to micro-organisms as small as 27 nm (equivalent to a polio virus particle size) and is designed to isolate the patient from the cystoscope. Current, high-level disinfection of flexible cystoscopes uses either glutaraldehyde or peracetic acid. The efficacy of glutaraldehyde relies on 'meticulous', manual pre-cleaning. although symptomatic iatrogenic infection rates are low, this is likely to be due to under-reporting[2] as previous studies have shown a 15—17% positive culture rate in 'patient-ready' scopes.[3,4] Though more effective, peracetic acid disinfection is equally time-consuming, labour-intensive and, potentially, a costly process.[5] There have been scares about cross-contamination between patients undergoing endoscopies. Three-thousand patients had to be contacted recently due to problems with decontamination.[6]

Out-patient flexible cystoscopy is not a new concept. Each urology unit provides flexible cystoscopy in differing facilities with varying numbers of instruments and staffing levels. In Leeds, all flexible cystoscopies are performed within the day-theatre setting in four different hospitals with a total of eight lists per week. Transportation is needed before and after each list to move instruments around the city as well as the staff. This initiative has proven that all such lists could be moved into an out-patient setting. The cost of the Vision Science flexible cystoscopy is less than standard instrumentation; the cost of the disposable sheaths is £18 + VAT each from Dantec Dynamics Ltd.

All patients in our study preferred out-patient rather than day-case attendance. The next step would be to offer flexible cystoscopy at the time of out-patient attendance eliminating waiting times which can only improve the outcome of care. The flexible cystoscope could be pre-sterilised and ready for use; once used, it could be available for subsequent patients. This process could avoid costly instillations of sterilising equipment. These lists were carried out in a treatment room in the out-patient department adjacent to the day-theatre. There was no significant impact on the sterilising turnover of the existing endoscopy lists in this unit.

Conclusions

We would commend urologists and managers to consider the investment in out-patient flexible cystoscopy provision for both diagnostic and surveillance endoscopy and that the Vision Science CST-2000 with slide-on™ endosheath system be part of the planning.

Acknowledgement

The authors have no financial involvement or interest with Dantec Dynamics Ltd, Garonor Way, Royal Portbury, Bristol BS20 7XE, UK.

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6. BBC. Tests advised for 'scope patients'. In: BBC News UK edition. 21 June 2004.

171

APPENDIX 1

The simplified assessment sheet used to assess patients before undergoing cystoscopy

Leeds Teaching Hospitals NHS Trust Flexible Cystoscopy

Date of admission ----------

Name (addressograph)

Next of kin/carer ----------

Contact No ---- ----------

GP ----------

Transport home: Car, taxi, bus, ambulance. Accompanied or self

PAST MEDICAL HISTORY

Heart disease, Heart murmur --- Yes/No

Diabetes ---------- Yes/No

Possibility of pregnancy ------- Yes/No

MEDICATION

Warfarin ----------Yes/No

Antibiotics ----------Yes/No

Allergies to drugs, antibiotics, latex, *etc.* ---Yes/No

URINALYSIS

Protein ---------- Yes/No

Blood -------Yes/No

INFORMATION FOR CONSENT

Verbal/written ---------- Yes/No

PRE-OPERATIVE CHECK:

Signature ----------

Identity band applied ----------

Allergies noted ----------

Relevant blood results present ----------

Urine tested ---------- Pulse ------ BP ---/ ---

OPERATIVE PROCEDURE ----------

STERILISATION TRACKING

DISCHARGE CRITERIA

Passes urine

Clear/blood-stained

Has had something to eat/drink

Yes/No

GP discharge letter and information given Yes/No

Time of discharge

Print name of nurse ---------- **Signature of nurse** ----------

172

PROPOSED LABELING

The proposed labeling of the VisionScope High Definition Endoscopy Camera System is given in the attached documents, located in Section 13 of this 510(k) submission:

Document 13.2:	VisionScope's Labels and Markings
Document 13.3:	PN 01112 VisionScope System Instructions for Use
Document 13.4:	PN 01113 VisionScope Endoscope Instructions for Use
Document 13.5:	PN 01114 VisionScope Sterile Procedure Kit Instructions for Use
Document 13.6:	PN 01115 VisionScope Camera Handpiece Instructions for Use
Document 13.7:	80049 VisionScope Brochure

The labeling of the predicate device InnerVue Diagnostic is provided in:

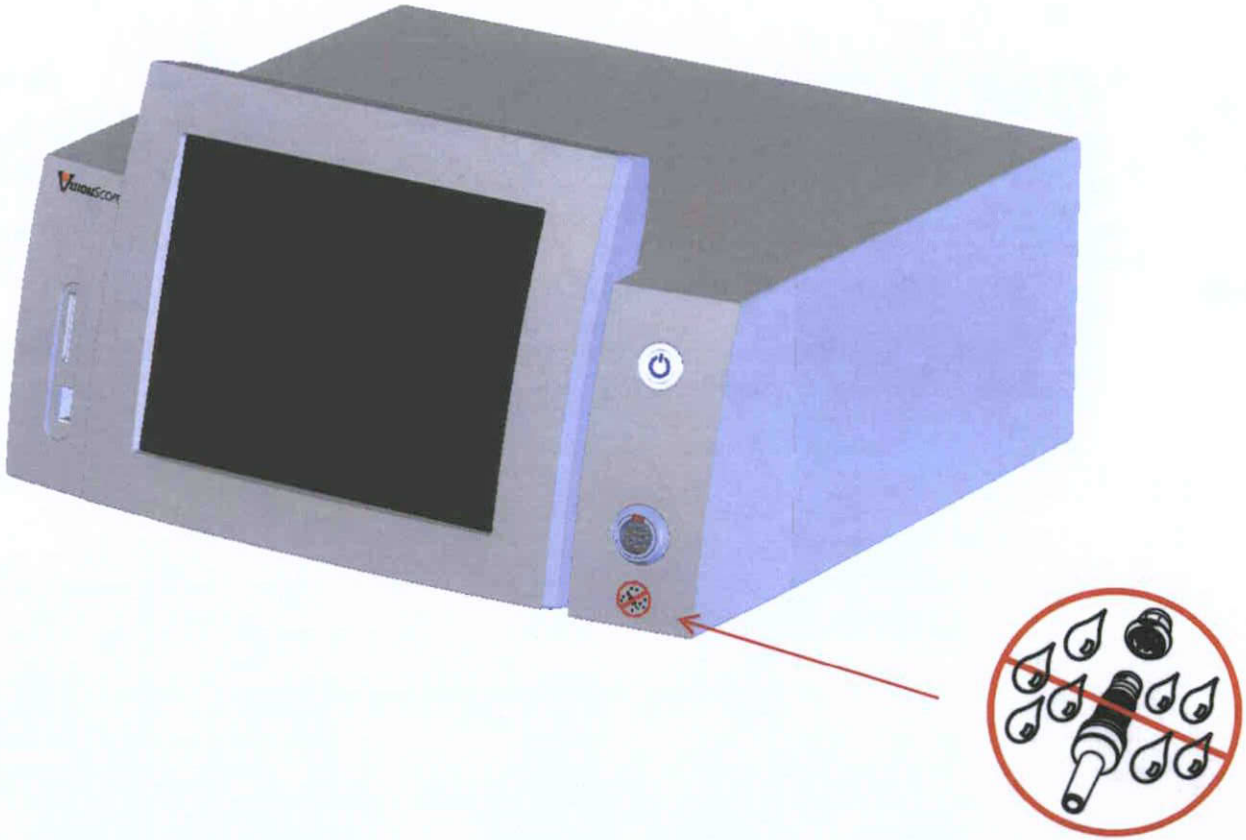
Document 13.8:	InnerVue Diagnostic Scope System User Manual

13.2 - VisionScope Labels and Markings

Proposed Markings and Labels

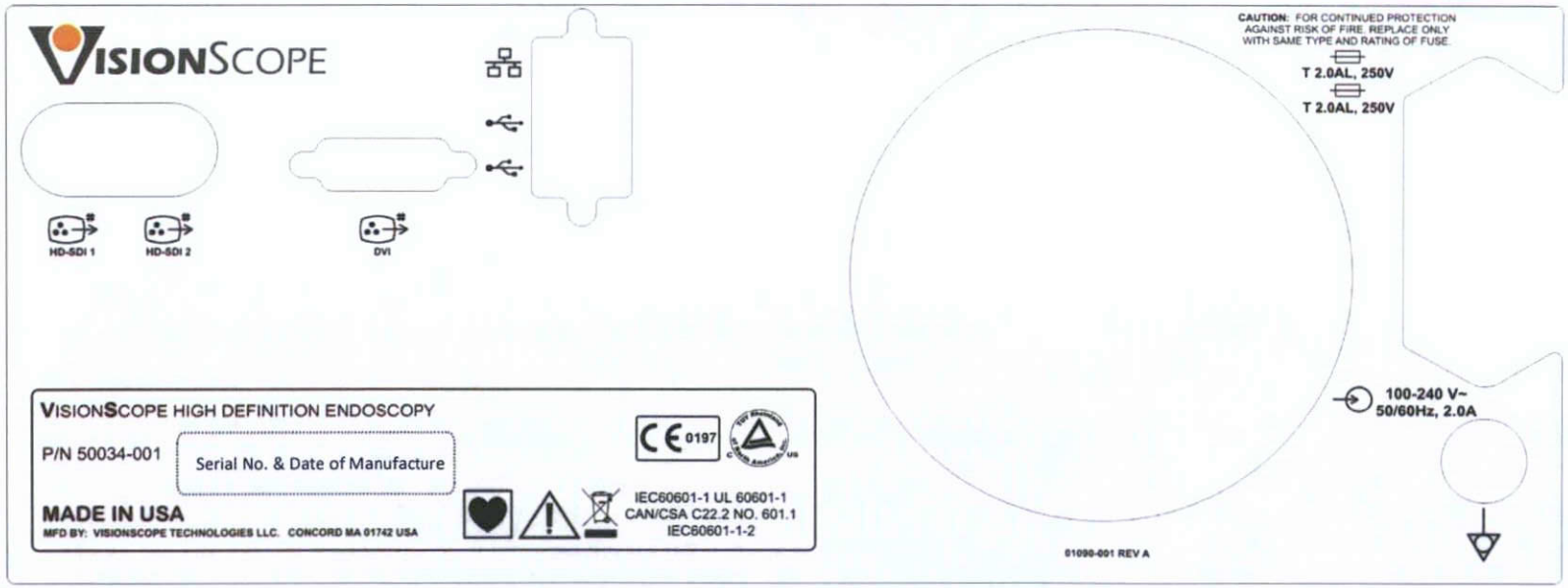
- This document contains illustrations and locations of all markings and labels
- Full explanation of all symbols are given in the Instructions for Use (IFU), Section 13:
  - PN 01112 – VisionScope System
  - PN 01113 – Endoscopes
  - PN 01114 – Sterile Procedure Kit
  - PN 01115 – Camera Handpiece

Camera Control Unit - Front

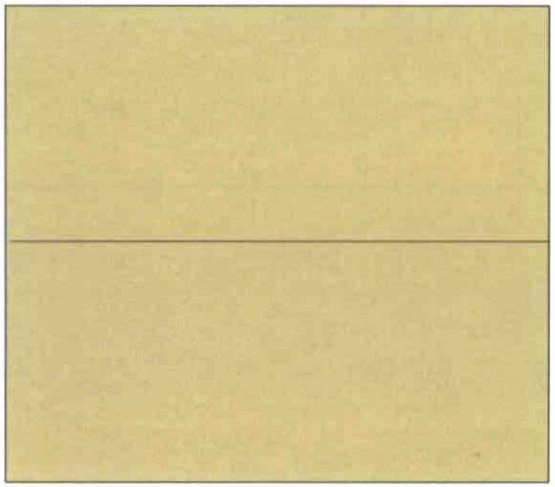


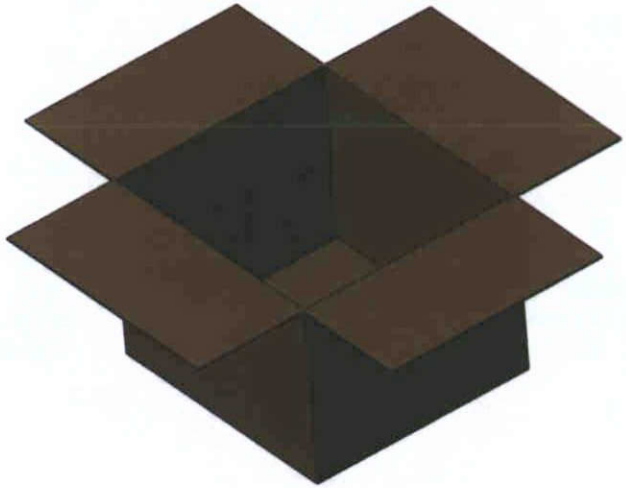
Do Not Plug in Wet Symbol

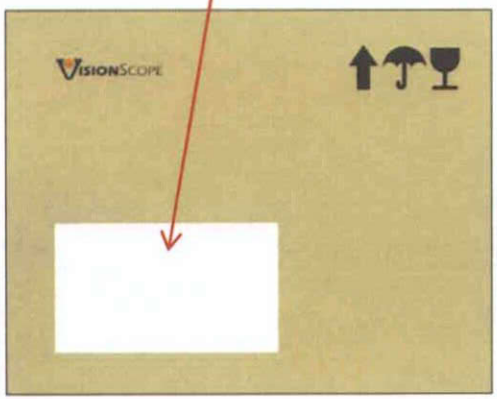
Camera Control Unit - Back

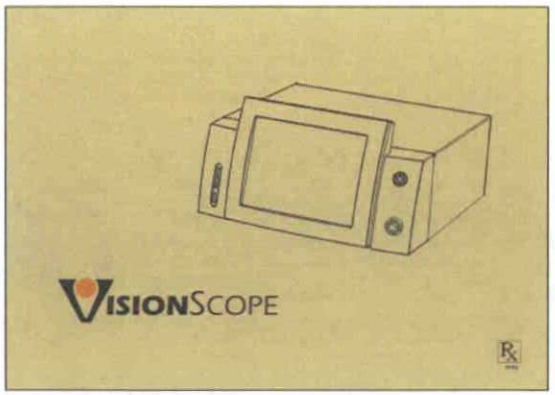


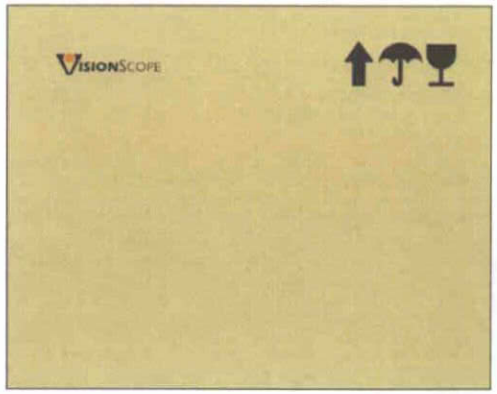
Camera Control Unit - Packaging











Camera Handpiece

179

Camera Handpiece - Packaging

180

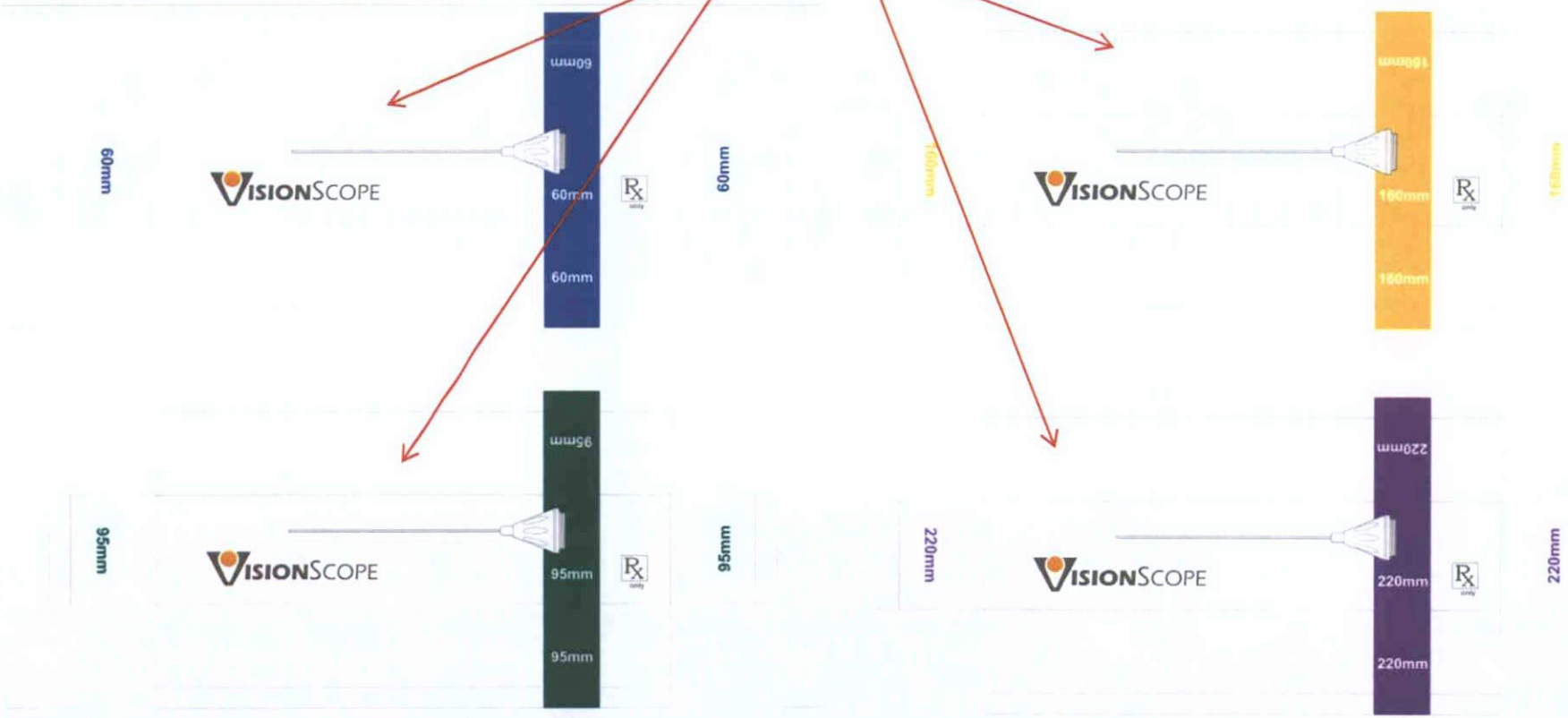
Endoscope

VISIONSCOPE
P/N 50006-095
S/N ENDOSCOPE

VISIONSCOPE
P/N 50006-095
S/N ENDOSCOPE

Endoscope Boxes - Unfolded

Adhesive Labels, see next page



182

Endoscope Boxes – Adhesive Labels

Locations shown in last page

VisionScope Endoscope - 060
For use with VisionScope Camera 50021-001
REF 50040-060, rev 1
See Instructions for Use
Lot No. 12345
VisionScope Technologies
2352 Main Street, Suite 303
Concord, MA 01742 USA
T: 1-978-776-9518
F: 1-978-776-9511
Customer Service:1-888-808-8357
www.visionscope-tech.com
Made in USA
CE 0197
Rx only
P/N: 01106-060 rev 1

VisionScope Endoscope - 160
For use with VisionScope Camera 50021-001
REF 50040-160, rev 1
See Instructions for Use
Lot No. 12345
VisionScope Technologies
2352 Main Street, Suite 303
Concord, MA 01742 USA
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F: 1-978-776-9511
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VisionScope Endoscope - 095
For use with VisionScope Camera 50021-001
REF 50040-095, rev 1
See Instructions for Use
Lot No. 12345
VisionScope Technologies
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F: 1-978-776-9511
Customer Service:1-888-808-8357
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P/N: 01106-095 rev 1

VisionScope Endoscope - 220
For use with VisionScope Camera 50021-001
REF 50040-220, rev 1
See Instructions for Use
Lot No. 12345
VisionScope Technologies
2352 Main Street, Suite 303
Concord, MA 01742 USA
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Sterile Procedure Kits
Tyvek Lid (60 mm)

Sterile Procedure Kits
Tyvek Lid (95 mm)

VISIONSCOPE

VisionScope Procedure Kit

- ONE LIGHT SHEATH
- ONE TROCAR
- ONE CANNULA

VisionScope Technologies, LLC
2352 Main Street, Suite 303
Concord, MA 01742 USA
T: 1-978-776-9510
F: 1-978-778-9511
Customer Service: 1-888-808-8357
www.visionscope-tech.com

EC REP
Kingsland Medical Limited
Dolphins, Marine Walk, Hayling Island
Hampshire, UK
PO11 9HJ
T: +44 (0)23 9246 6855
www.kingslandmedical.com

See Instructions for Use

Single use only. Do not re-process or re-use after one procedure. Dispose in accordance with applicable Bio-hazard handling regulations.

STERILE **ETO**

CE 0197 Rx only

Latex Free Product

U.S. Patent No. 6,863,651
Euro. Patent No. 1,213,988
Euro. Patent No. 1,470,264

Made in USA

REF 50033-095

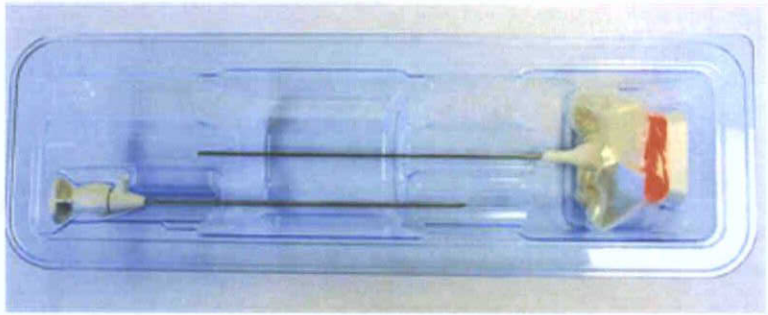
For use with VisionScope Camera Hand Piece REF 50021 and VisionScope Endoscope REF 50006-095

Contents: One Light Sheath (REF 50023-095)
One Cannula (REF 50024-095)
One Trocar (REF 50027-095)

EXPIRATION DATE

LOT NUMBER:

95mm



Sterile Procedure Kits
Tyvek Lid (160 mm)

VISIONSCOPE

VisionScope Procedure Kit

- ONE LIGHT SHEATH
- ONE TROCAR
- ONE CANNULA

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F: 1-978-776-9511
Customer Service: 1-888-808-8357
www.visionscope-tech.com

EC REP
Kingsland Medical Limited
Dolphins, Marine Walk, Hayling Island
Hampshire, UK
PO11 9HQ
T: +44 (0)23 9246 6855
www.kingslandmedical.com

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One Trocar (REF 50027-160)

EXPIRATION DATE:

LOT NUMBER:

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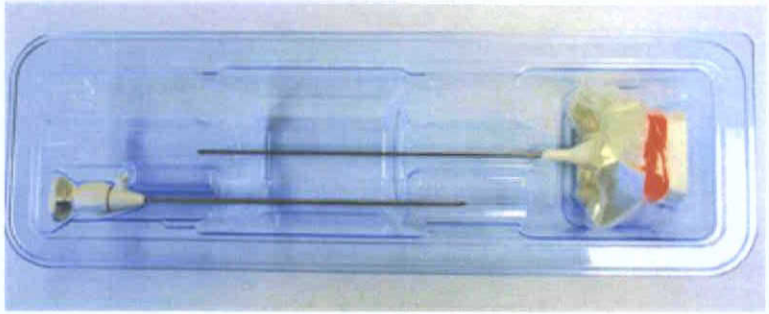
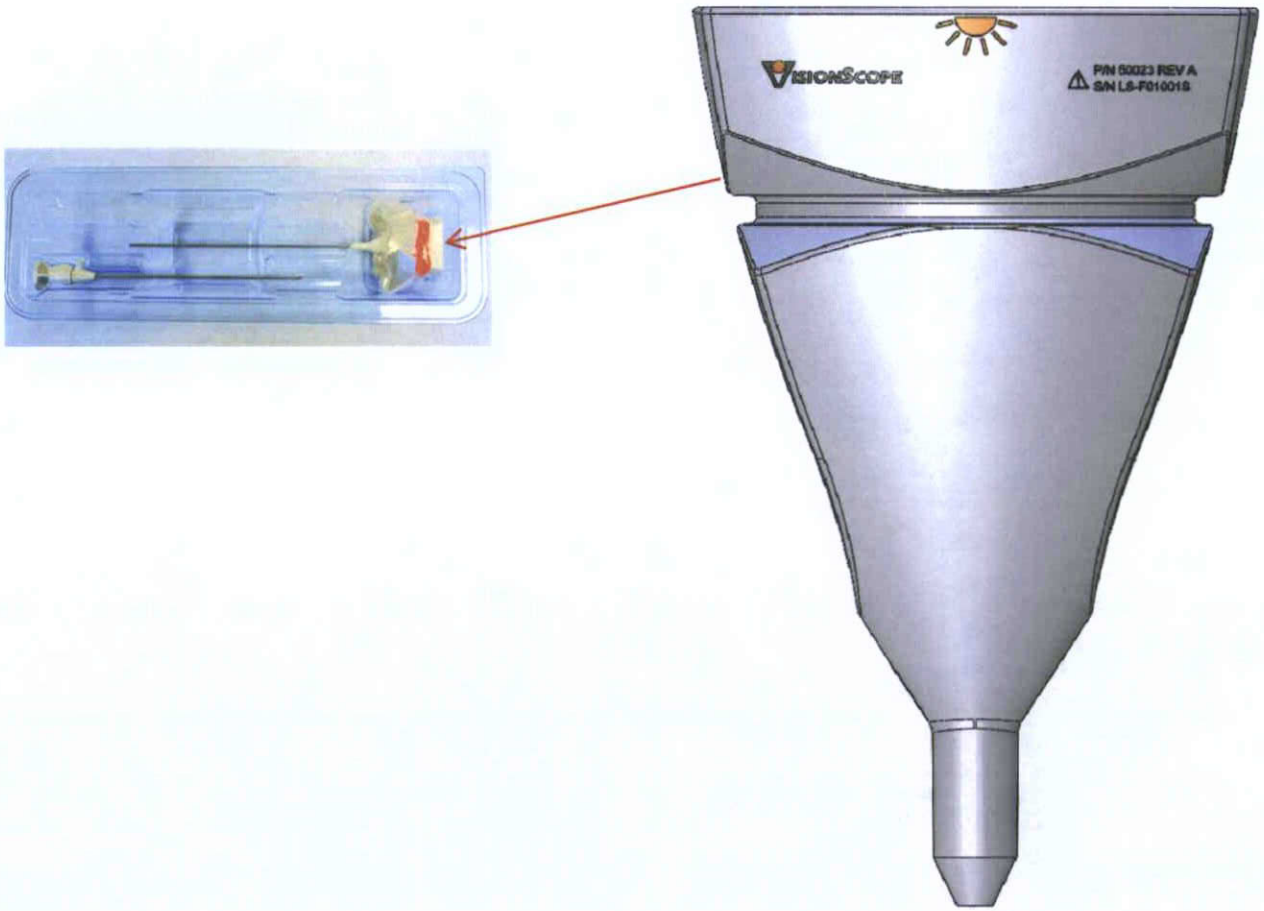


186

Sterile Procedure Kits
Tyvek Lid (220 mm)

187

Sterile Procedure Kits
Illumination Sheath Marking



188

Sterile Procedure Kit – Outer Package

VisionScope Procedure Kit - 060 - Single Use

For use with VisionScope Camera 50021-001
and VisionScope Endoscope Ref 50006-060

REF 50033-060, rev A

Contents: One Light Sheath (REF 50023-060)
One Canula (REF 50024-060)
One Trocar (REF 50027-060)

See Instructions for Use

Single use only. Do not re-process or re-use after one procedure. Dispose in accordance with applicable Bio-hazard handling regulations

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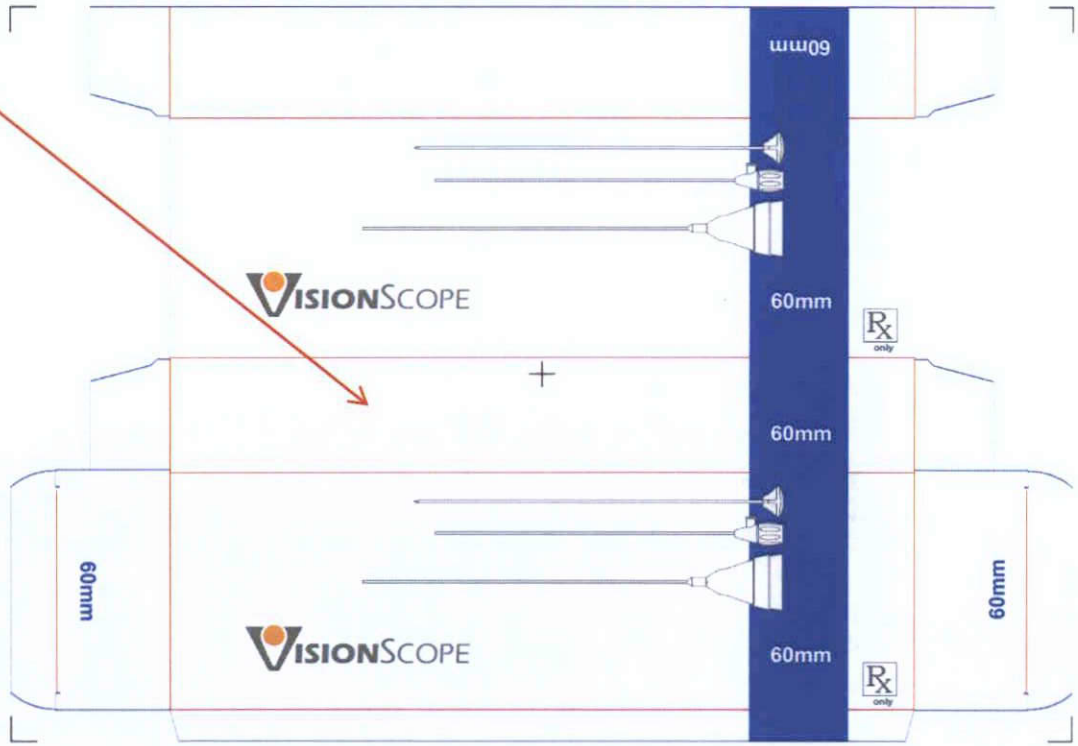

189

Sterile Procedure Kit – Outer Package

VisionScope Procedure Kit - 095 - Single Use

For use with VisionScope Camera 50021-001
and VisionScope Endoscope Ref 50006-095

REF 50033-095, rev A

Contents: One Light Sheath (REF 50023-095)
One Canula (REF 50024-095)
One Trocar (REF 50027-095)

See Instructions for Use

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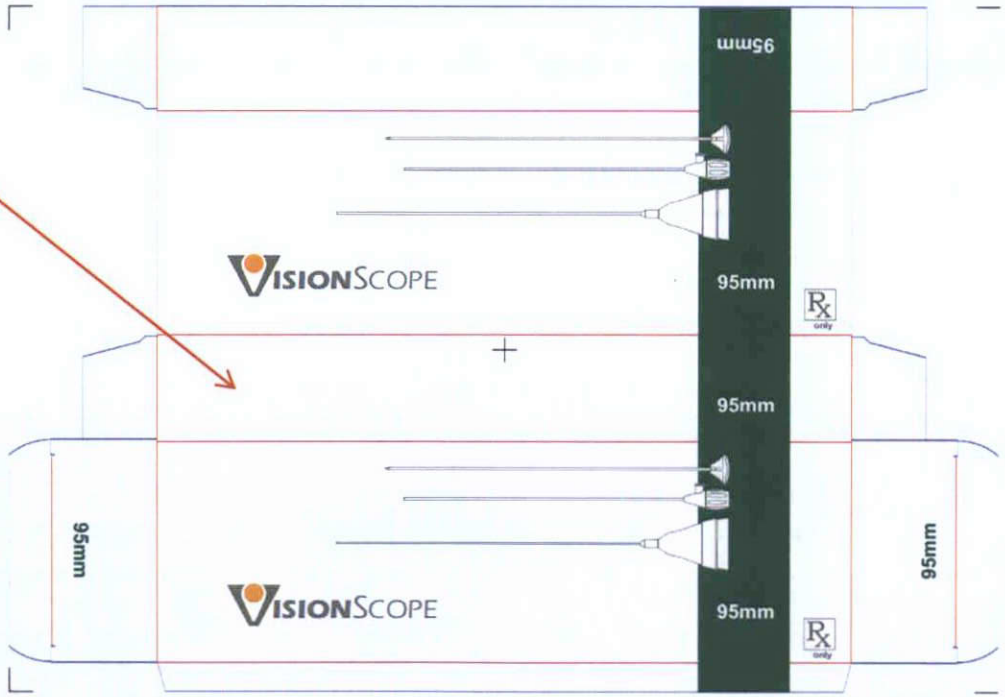

190

Sterile Procedure Kit – Outer Package

VisionScope Procedure Kit - 160 - Single Use

For use with VisionScope Camera 50021-001
and VisionScope Endoscope Ref 50006-160

REF 50033-160, rev A

Contents: One Light Sheath (REF 50023-160)
One Canula (REF 50024-160)
One Trocar (REF 50027-160)

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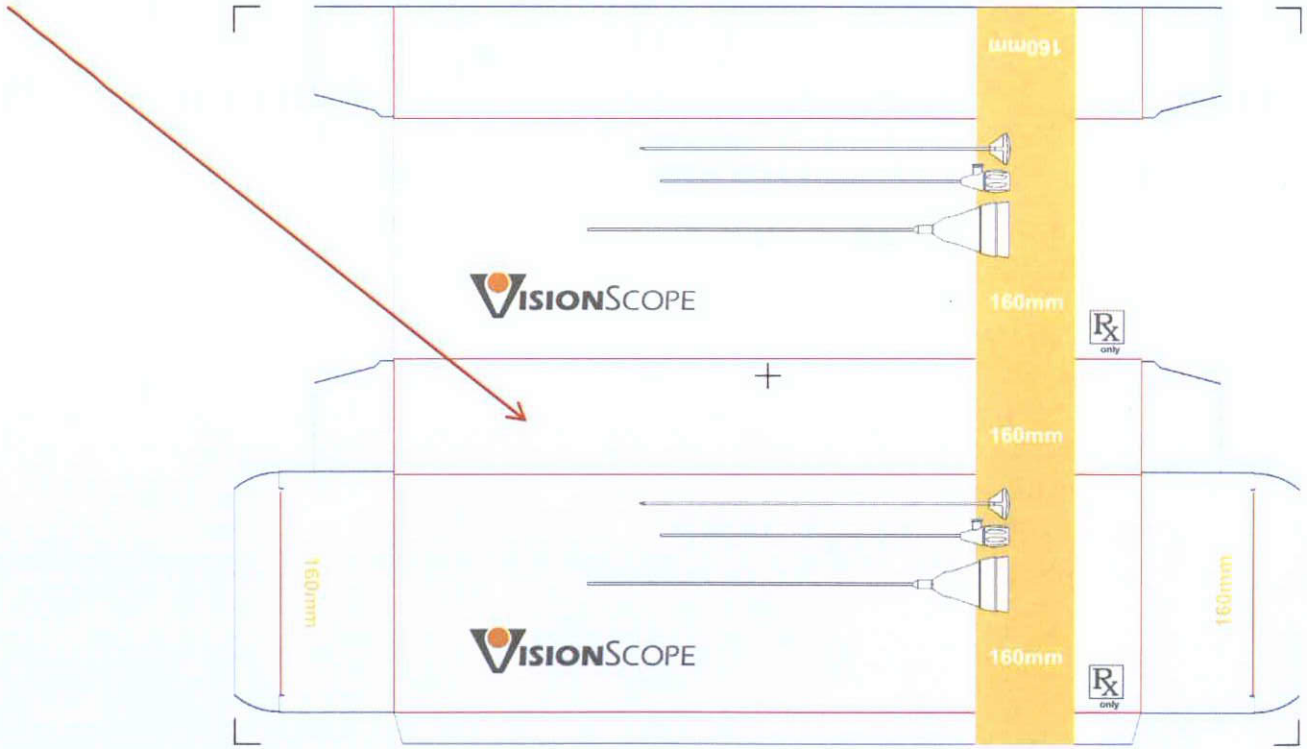

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Sterile Procedure Kit – Outer Package

VisionScope Procedure Kit - 220 - Single Use

For use with VisionScope Camera 50021-001
and VisionScope Endoscope Ref 50006-220
REF 50033-220, rev A

Contents: One Light Sheath (REF 50023-220)
One Canula (REF 50024-220)
One Trocar (REF 50027-220)

See Instructions for Use

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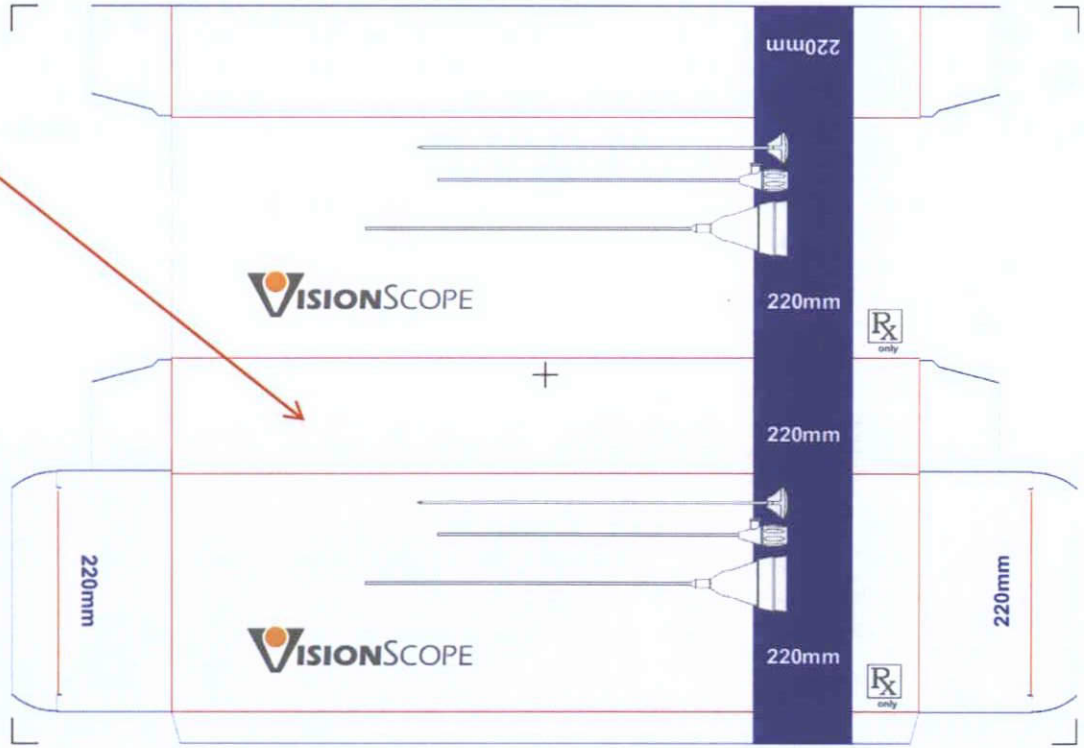

192

Sterile Procedure Kit – Patient Labels

To be affixed on the Instructions for Use (PN 01114), for easy peeling and application on patient file/record

VisionScope Procedure Kit - 060
Patient Label
REF 50033-060 rev A
Exp Date Lot No
01129-060 rev A LABEL 1 OF 3

VisionScope Procedure Kit - 060
Patient Label
REF 50033-060 rev A
Exp Date Lot No
01129-060 rev A LABEL 2 OF 3

VisionScope Procedure Kit - 060
Patient Label
REF 50033-060 rev A
Exp Date Lot No
01129-060 rev A LABEL 3 OF 3

VisionScope Procedure Kit - 160
Patient Label
REF 50033-160 rev A
Exp Date Lot No
01129-160 rev A LABEL 1 OF 3

VisionScope Procedure Kit - 160
Patient Label
REF 50033-160 rev A
Exp Date Lot No
01129-160 rev A LABEL 2 OF 3

VisionScope Procedure Kit - 160
Patient Label
REF 50033-160 rev A
Exp Date Lot No
01129-160 rev A LABEL 3 OF 3

VisionScope Procedure Kit - 095
Patient Label
REF 50033-095 rev A
Exp Date Lot No
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REF 50033-095 rev A
Exp Date Lot No
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01129-095 rev A LABEL 3 OF 3

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Exp Date Lot No
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Exp Date Lot No
01129-220 rev A LABEL 2 OF 3

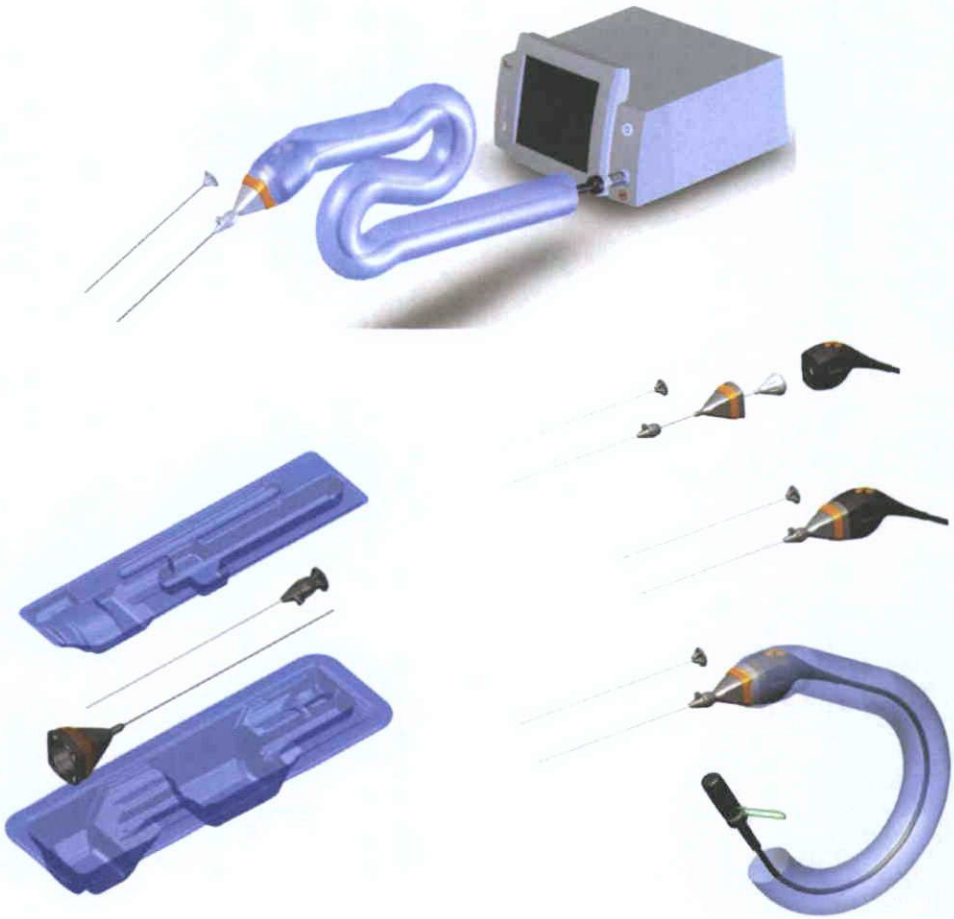
VisionScope Procedure Kit - 220
Patient Label
REF 50033-220 rev A
Exp Date Lot No
01129-220 rev A LABEL 3 OF 3

13.3 - 01112 - VisionScope System Instructions for Use

Instructions for Use

VISIONSCOPE

High Definition Endoscopy Camera System



CE 0197

Instructions for Use

VisionScope

High Definition Endoscopy Camera System

PN 01112 Rev. 2.5

Table of Contents

Introduction 1
- Indications for Use 1
- Intended Users 1
- Contraindications 1
- Warnings 1
- Precautions 2
- Glossary of Symbols 3
- Glossary of Terms 4

Device Description 7
- System Components and Part Numbers 8
- Unpacking, Inspection and Installation Qualification 9
- Front Panel Layout 10
- Rear Panel Layout 11
- Camera Handpiece Layout 12

Overview of the Endoscopy Process 13

Using the Camera Control Unit 14
- Starting Up and Shutting Down 14
- Using the Touch Screen Interface 15
- Entering Passwords 15

Performing a Patient Procedure 16
- Reprocessing Requirements of the Endoscope and Camera Handpiece 16
- Registering a New Patient and Starting a Procedure 17
- Starting a Procedure for a Previously Registered Patient 18
- Assembling the Endoscope and Camera Handpiece 19
- Installing the Endoscope Sheath 21
- White Balancing and Confirming Image Clarity 24
- Inserting the Cannula and Endoscope Assembly 25
- Using Full Screen Mode 26
- Capturing Still Images and Recording Video 27
- Finishing a Patient Procedure 28

Reviewing Media, Recording Audio, and Adding Notes 29
- Reviewing Media from the Current Procedure 29
- Reviewing Media from a Saved Procedure 30

Recording/Reviewing Still Images 31
Recording/Reviewing Video 31
Recording/Reviewing Audio 32
Deleting Media 33
Adding Notes 33
Managing Patient Records 34
E-Mailing a Patient Report 34
Printing a Patient Report 35
Backing Up/Copying a Patient Record 37
Monitoring Disk Usage 38
Adjusting Camera Settings 39
Adjusting Picture Settings 39
Color Bar 40
White Balance 40
Centering/Inverting the Image 40
Loading a Picture Profile 41
Customizing a Picture Profile 42
Editing the Surgeon, Procedure, and Patient Lists 43
Editing Surgeons 43
Retrieving a Forgotten Password 45
Editing Procedure Names 46
Deleting a Patient 47
Changing the Setup Options 48
Patient Data Options 49
Captured File Options 49
Surgical Display Options 50
Video Options 50
Audio Volume Control 50
Light Control Panel 50
System Information 51
Configuring Network Settings 51
E-mail Settings 52
Network IP Address 52
Date and Time 52
Passwords 52

Printers 53
E-mail Recipients 54
Daylight Savings 55
Hospital Info 55
Touch Screen Calibration 56
Reset Settings 56
Optional Accessories (Not Supplied by VisionScope) 56
External Monitors 57
Printers (USB and Network) 57
Network Port 57
Endoscopes 58
Periodic Maintenance, Cleaning and Sterilization 58
Service, Trouble Shooting, and Replacement 59
System Specifications 62
Electromagnetic Information 64
Limited Warranty 66
Contact Information 66

Introduction

VisionScope is an endoscopic imaging system designed to enable pre-operative and post-operative diagnosis in physician examination rooms. The device can also be used in intra-operative procedures in operating rooms where smaller gauge endoscopes are important for minimally invasive surgical procedures. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

The key component of the VisionScope is a 1.4 mm diameter semi-rigid fiber-lens endoscope that fits within a disposable sterile 1.7 mm diameter endoscope sheath (patented), which in turn is small enough to fit through a 2 mm portal or cannula. The disposable endoscope sheath, consisting of an illumination sheath with an integrated camera drape, also acts as a sterile barrier, thereby eliminating the need for full sterilization of the endoscope and camera handpiece following each procedure. VisionScope Technologies is able to miniaturize the endoscope diameter while still providing true High Definition (HD 1080) anatomical visualization, enabling Surgeons to obtain direct visual clinical assessment in a physician examination room without requiring sterilization or bio-hazard processing infrastructure when used as an imaging device alone and without any resection instrument.

Indications for Use

The VisionScope High Definition Endoscopy Camera System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of an interior cavity of the body through a natural or surgical opening. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

Additionally, when used in conjunction with an appropriately indicated and FDA 510(k)-cleared endoscope and light source, the VisionScope High Definition Endoscopy Camera Control Unit and Camera Handpiece are indicated for use in arthroscopic and endoscopic surgical procedures to provide illumination, visualization and capture of still and motion pictures of articular cavities, body cavities, hollow organs and canals.

Intended Users

The VisionScope system is designed for use by licensed physicians for performing diagnostic or surgical procedures. Physician assistants may assist in the setup of the equipment and preparation of patients.

Contraindications

None Known

⚠ Warnings

- Read this Instructions for Use (PN 01112) completely prior to use.

200

- Read the Instructions for Use for the applicable VisionScope Endoscope (PN 01113), Camera Handpiece (PN 01115) and Sterile Procedure Kit with Disposable Endoscope Sheath, Cannula, and Trocar (PN 01114) completely prior to use.
- It is the Surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- The VisionScope family of Camera Control Unit, Camera Handpiece, and Endoscope are designed to be used together with the one-time use sterile Endoscope Sheath, Cannula, and Trocar to ensure safety and effectiveness. Never mix or substitute any component with any other unauthorized product from any other unauthorized manufacturer.
- To ensure safety and effectiveness, do not re-process and re-use any product that is designed for one-time use only.
- Read the expiration date printed on the sterile Procedure Kit prior to use. Inspect the seal on the sterile tray before use to ensure that it is sealed and that it has never been peeled before (seal has been broken). Discard any Sterile Procedure Kit with an expired date code or a broken seal in accordance with institutional policy.
- Dispose of the Endoscope Sheath, Cannula, and Trocar that have been used once in a procedure following the institutional policy related to bio-hazard waste disposal.
- DANGER: Risk of explosion if used in the presence of flammable anesthetics.
- WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- To prevent electric shock, do not disassemble the VisionScope Camera Control Unit or the VisionScope Camera Handpiece. There are no user-serviceable parts. Dismantling the equipment will void your warranty.
- The Camera Control Unit and Camera Handpiece contain a light fiber that carries the output from a bright Light Emitting Diode (LED) light source. Like any light source in a hospital or residential environment, avoid looking directly at the light source for any length of time. Use an opaque object to block the direct line of sight if necessary. When the system is not in use, turn off the light with the software Light Switch on the Touch Screen LCD Panel. Do not attempt to service or clean the camera while the light is on.
- WARNING: Disregarding the information on safety of this device is considered ABNORMAL USE.

Rx Precautions

- U.S. Federal law restricts this device to sale by or on the order of a physician.
- When used for diagnostic imaging in a physician examination room solely without accompanying resection or surgical instrument, the Endoscope and the Camera Handpiece must be sheathed with the disposable sterile Endoscope Sheath to avoid infection.
- When used for intra-operative surgical procedure in an Operating Room, the Camera Handpiece and the Endoscope must be sterilized with validated chemical sterilants (100% Ethylene Oxide (ETO), Sterrad 100S, Sterrad NX, or Sterrad 100NX). This is to ensure that in the unlikely event that the exterior sterile Endoscope Sheath is accidentally damaged by resection or surgical instruments, the Endoscope and Camera Handpiece will not contribute to infection.
- Prior to sterilization with the above means, tighten the protective soak cap over the Camera Handpiece cable connector to prevent fluid or moisture to enter and damage the camera connector.
- Do not autoclave the Camera Handpiece, the Endoscope or the Procedure Kit.

- Prior to each use and insertion into a patient, ensure the system is functioning properly and is producing live video. Inspect the Endoscope, the disposable Illumination Sheath, Cannula, and Trocar to ensure that the tubes are not bent, the windows are not damaged, and there are no unintended rough surfaces, sharp edges or protrusions which may cause HARM. Do not use a damaged device.
- Handle any exposed sharp needle point at the distal tip of the Trocar, Cannula, Endoscope, and Illumination Sheath with care to avoid accidental injury or contamination.
- To avoid fogging during surgery, the Camera Handpiece and the Endoscope must be dry prior to attaching the one-time-use Endoscope Sheath.
- Prior to entering service, the system must be tested for electrical safety by a biomedical engineer or other qualified service staff.
- Do not plug the Camera Handpiece cable connector into the Camera Control Unit if wet. Moisture inside the protective cable connector will damage the electronic circuitry and void the product warranty.
- Do not operate or sterilize the equipment that is damaged. Use authorized hospital decontamination procedures to clean the Camera Handpiece or Endoscope optics prior to returning to the factory for service.
- Review the live video images to ensure that there is no deposit on the optical surfaces prior to a procedure.
- Carry and store the cable in loose coils with bend radius of not less than 5 cm (2 in) to prevent kinks and stress on the internal wires.
- Avoid pinching or damaging the camera cable (i.e., rolling heavy equipment over it, securing with clamps, pinching in drawers or doors, etc.).
- This equipment contains plastics, metals, electronic components, and printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national, local or institutional regulation and environmental policy.

Glossary of Symbols

⚠	Attention: Please Read Instructions for Use
℞	Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician.
100-240 VAC 50/60Hz, 2.0A	Input Power, Compatible with 100-240 VAC, 50 Hz/60 Hz, maximum 2.0 A
T2.0AL, 250V	Fuse, 250V, 2A rating, slow blow
	Equipotentiality
	Chassis Ground

202

	Type CF (Cardiac Floating) Equipment
	Network Connection
	USB Connection
USB	USB Memory Drive
SD	Secure Digital Multimedia Card
DVI	Digital Video Output Connection, Digital Visual Interface
HD-SDI	Digital Video Output Connection, High Definition Serial Digital Interface
	EU: Not for General Waste. When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling.
	Warning: Do not plug the connector into the electrical receptacle if it is wet.
	Date of Manufacture
CE 0197	CE Mark issued by TUV Rheinland
	Electrical Safety Testing Mark by TUV Rheinland of North America, Inc., a test laboratory and notified body
EC REP	European Representative
	Split Illumination icon for aiding alignment of Illumination Sheath to Camera Handpiece; Left – Starting Position; Right – Aligned.

Glossary of Terms

Audio Recording	Voice record (dictation) from a patient procedure saved as a G.711 file.
Brightness	Camera setting that controls lightness or darkness of the video.
Camera Control Unit	Integrated electronics unit with camera controller, light source, image management computer, and touch screen display.

Camera Drape	Sterile protective membrane tube, together with the Illumination Sheath, forms the Endoscope Sheath. It is deployed by pulling on the pull cord to form a enclosed drape over the Camera Handpiece and Camera Cable.
Camera Handpiece	Hand-held component combining high-definition camera and light source.
Cannula	Component of disposable Sterile Procedure Kit. A tube that can be inserted into the body, for the purpose of guiding the Endoscope, or for injecting or removing fluid including drug delivery.
CCU	Camera Control Unit.
C-Mount	Threaded connection used on camera lenses to ensure proper position for clear focus.
Color Bar Pattern	A video test pattern for confirming proper operation of the video electronics chain, when a camera with live video output is not conveniently available.
DVI	Digital Visual Interface (per Digital Video Working Group), a video signal interconnect format.
EMC	Electromagnetic Compatibility. Refers to the ability of the device being used to continue to function properly in the presence of outside electromagnetic interference.
EMI	Electromagnetic Interference. Refers to the possible electromagnetic radiation that a device under use may generate, thereby interfering with other devices in the vicinity.
Emission	Electromagnetic noise generated by a medical electronic device.
Endoscope	Endoscopy means *looking inside* and typically refers to looking inside the body for medical reasons using an instrument called an endoscope.
Endoscope Sheath	A patented Visionscope design that is made up of an Illumination Sheath and a Camera Drape. The Illumination Sheath is a hermatically sealed stainless steel tube with a glass window at the distal tip. It fits over an endoscope, forming a barrier to keep out body fluid or other contaminants. Integrated with the Illumination Sheath is a polyurethane Camera Drape to provide a cover around the camera handpiece and camera cable. The Camera Drape can be deployed by pulling on a pull string. (See *Illumination Sheath* below.)
HD-SDI	High Definition Serial Digital Interface (per SMPTE-292M:1998).
High Definition	Modern television broadcast standard, generally referring to video formed with 1920 x 1080 pixels.
Immunity	Response of an electronic product to external electrical noise.
Illumination Sheath	Light sheath. Component of disposable Sterile Procedure Kit that transmits LED light from Camera Head into body cavity, while also serving as a sterile barrier between the outside body cavity and the Endoscope within.
Media	Still images, video clips, and audio recordings captured during a patient procedure.

OR	Operating Room.
O-Ring	Toroid (donut-shaped) gasket that is compressed when connecting the Endoscope to create a water-proof seal between the Endoscope and Camera Handpiece.
OSD	On-screen display of video status information such as recording indicator (REC) and still image counter.
Patient Leakage Current	The current flowing from a medical device through the patient to ground when the device comes in contact with a patient.
PN	Part Number
Procedure	Procedure may have two meanings, depending on the context. The first meaning is a description of the type of surgical procedures, e.g., diagnostic arthroscopy, surgical arthroscopy, laparoscopy, or other customized surgical operations. The second meaning refers to the treatments that the patient may have received or is currently receiving. Patient information is a collection of data organized under a unique patient identification. For each unique patient ID, one or more procedures representing different instances of treatment may be present.
Protective Earth	Connection that ensures that all exposed conductive surfaces are at the same electrical potential as the surface of the Earth.
Record	Composite file from a patient procedure, including patient information, still images, video recordings, audio recordings, and notes.
REF	Reference number for ordering from VisionScope product catalog.
Report (e-mail)	Patient information, notes, video clips, still images, and audio files from a patient procedure, sent via network to a designated recipient.
Report (printed)	Patient information, notes, and still images from a patient procedure, sent to a local or networked printer (graphics format with text and images).
SN	Serial Number.
Soak Cap	A protective water-proof covering over the Camera Handpiece connector, to prevent the electronic metallic pins from contacting chemical sterilization agents during the sterilization process.
Sterile Procedure Kit	Sealed tray containing disposable supplies for patient preparation. Includes Endoscope Sheath, Cannula, and Trocar.
Still Image	Single frame captured from the live video during a patient procedure and saved as a JPG file.
Trocar	Component of disposable Sterile Procedure Kit. A thin metal rod with a sharply pointed end, used to introduce cannulas and other similar implements into blood vessels or body cavities.

Video Recording	Segment captured from the live video during a patient procedure and saved as an MPEG file (also called a video clip).
VisionScope	High Definition Diagnostic and Operative Needle Scope System including Camera Control Unit, Endoscope, and Sterile Procedure Kit.
WEEE	Waste of Electronic and Electrical Equipment per the European WEEE Directive 2002/96/EC.
White Balance	The process of matching the color of the video to ensure good color fidelity.

Device Description

VisionScope is an innovative, high quality, very minimally invasive imaging system made up of a Camera Control Unit, a Camera Handpiece, and a selection of four Endoscopes and Sterile Procedure Kits (60 mm, 95 mm, 160 mm or 220 mm operating lengths) for the intended patient procedure. The Endoscopes and Sterile Procedure Kits are color-coded to ensure that the correct components are selected.

The Camera Control Unit is designed to be able to perform its intended functions (camera control, illumination, display, patient information and image management) in a standalone manner without any other peripheral.

⚠ Warnings

Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this manual.

Portable and mobile RF communication equipments can affect Medical Electrical Equipment.

The system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the system should be observed for normal operation in the configuration it will be used.

The use of external accessories, transducers, and cables other than those specified by VisionScope, including medical grade external monitors or medical grade printers, may result in increased Emissions or decrease in Immunity of the VisionScope Camera Control Unit. Non-medical grade external accessories <u>must not</u> be used in the patient environment.

When the VisionScope Camera Handpiece (Type CF applied part) is used with appropriately indicated external energized endosurgery devices, patient leakage current may be additive. It is particularly important that a Type CF applied part endosurgery device be used in order to minimize total patient leakage current.

Any accessories equipment connected to the interfaces of this unit must be certified to the respective IEC standards (i.e. IEC 950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1.

Do not load any software into the VisionScope Camera Control Unit. Doing so will be contrary to the Indications for Use and will void the warranty.

System Components and Part Numbers

The VisionScope system consists of the following matched components:

Part Number	Description	Functions
50034	VisionScope Camera Control Unit Non-Sterile	An integrated electronics unit that replaces four separate boxes in a traditional endoscopy system: Camera Control, Light Source, Image Management, and Touch Screen Display. The innovative design results in a compact, power efficient and portable electronics that is ideally suited for use in both a physician examination room and an operating room environment.
50021	VisionScope Camera Handpiece Non-Sterile	Contains a three-chip, high sensitivity, low noise, HDTV broadcast-quality imaging sensor with full 1920 x 1080 pixels, optimized for use with narrow gauge needle scopes with unprecedented image clarity. The VisionScope Camera Handpiece is compatible with the following sterilization methods: ETO, Sterrad 100S, Sterrad NX. Do not autoclave.
50006-060	VisionScope Endoscope for small joints or body cavity, e.g., wrist, ENT. Non-Sterile	A family of four 17-gauge needle Endoscopes with operating lengths of 60 mm, 95 mm, 160 mm and 220 mm, optimized for visualization of articular or body cavities of different sizes. The innovative optics, working in conjunction with the Camera Handpiece and integrated Camera Control Unit, offers unprecedented light collecting efficiency, contrast resolution, and image clarity. VisionScope Endoscopes are compatible with the following sterilization methods: ETO, Sterrad 100S, Sterrad NX. Do not autoclave.
50006-095	VisionScope Endoscope for regular joint or body cavity, e.g., knee and regular shoulder Non-Sterile	
50006-160	VisionScope Endoscope for large cavity, e.g,., large shoulder or abdomen Non-Sterile	
50006-220	VisionScope Endoscope for very large cavity, e.g., hip or large abdomen Non-Sterile	

50033-060	Sterile Procedure Kit for Endoscope PN 50006-060	Sterile kit containing a matched set of one-time use components for supporting a procedure requiring a working length of 60 mm: • one Illumination Sheath with an integrated Camera Drape • one Cannula • one Trocar
50033-095	Sterile Procedure Kit for Endoscope PN 50006-095	Sterile Kit containing a matched set of one-time use components for supporting a procedure requiring a working length of 95 mm: • one Illumination Sheath with an integrated Camera Drape • one Cannula • one Trocar
50033-160	Sterile Procedure Kit for Endoscope PN 50006-160	Sterile Kit containing a matched set of one-time use components for supporting a procedure requiring a working length of 160 mm: • one Illumination Sheath with an integrated Camera Drape • one Cannula • one Trocar
50033-220	Sterile Procedure Kit for Endoscope PN 50006-220	Sterile Kit containing a matched set of one-time use components for supporting a procedure requiring a working length of 220 mm: • one Illumination Sheath with an integrated Camera Drape • one Cannula • one Trocar

Unpacking, Inspection and Installation Qualification

Examine the shipping containers for any sign of external damage. Open the packing boxes containing the re-useable components: Camera Control Unit, Camera Handpiece, Endoscopes and standard accessories. Set up the equipment following the instructions in this document to ensure that they are functional. Contact VisionScope or its authorized sales representatives to report any missing, damaged or non-functional items. Save the carton and packing material in the event that the equipment needs to be returned for repair or exchange.

The VisionScope High Definition Endoscopy System, like other Medical Electrical Equipment, should be installed and qualified for use by an authorized staff (typically a biomedical engineer) in accordance with any applicable institutional policy. In-service training of all users must be arranged by the responsible institutional staff.

Prior to using the VisionScope High Definition Endoscopy System, inspect all system components for damage. Inspection should include all equipment to be used in performing an imaging procedure, including the Camera Control Unit, the Camera Handpiece, the camera cable, and Endoscopes.

Inspection of the disposable devices may be carried out separately by examining the exterior of the Sterile Procedure Kit prior to use.

⚠ Warnings

Always use the Hospital Grade power cord and plug supplied with the Camera Control Unit (VisionScope Part No. 20079). Replace if necessary with a three-conductor (AWG 18 minimum, 300 VAC minimum rating), type SJT power cords and plugs that meets the special requirements contained in the following standards: UL 60601-1 and CAN/CSA C22.2 no 60601-1; Power supply cord standards: UL 817 and CAN/CSA C22.2 no 21; Attachment plug standards: UL 498 and CAN/CSA C22.2 no 42.

Front Panel Layout

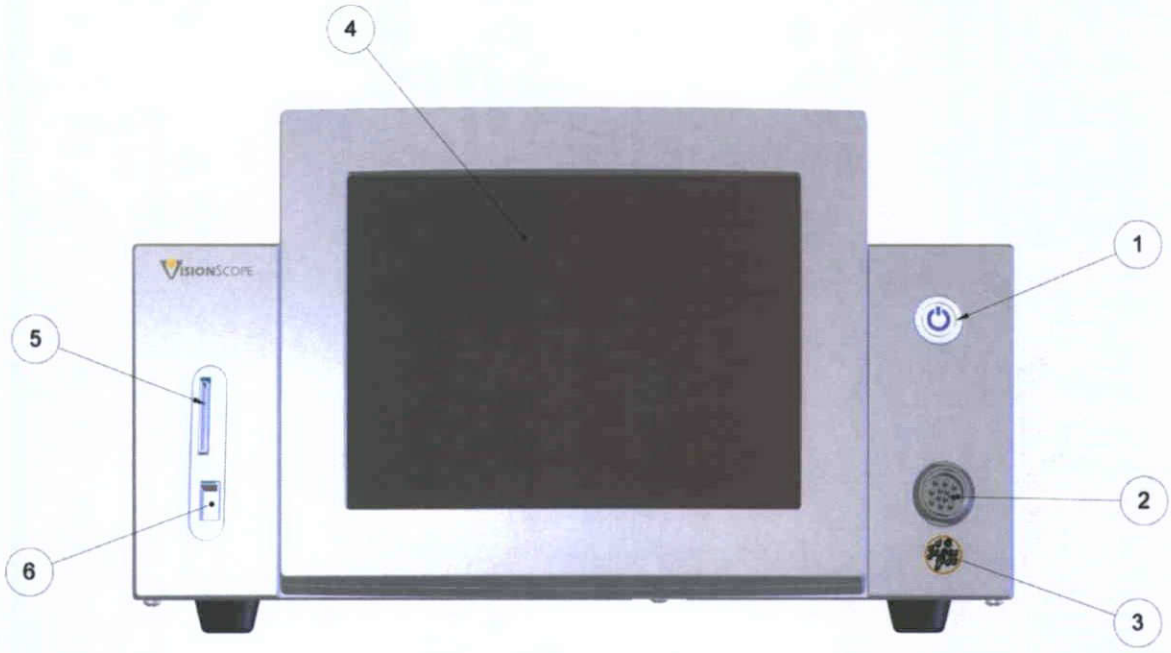


Figure 1 Front Panel Layout

Front Panel Control	Function
1. Power On/Off Switch	Turns the power to the System On or Off. When the switch is depressed, the power indicator light is green.
2. Camera Handpiece Cable Receptacle	Provides DC power and clock signals to the Camera Handpiece, and receive video data from the Camera Handpiece.
3.	⚠Warning: Do not plug connector into receptacle if it is wet.
4. LCD Touch Screen	Provides touch interface to allow users to control the camera operation.

5. Secure Digital Multi-Media Card Slot	Allows User to store still pictures and video clip on a removable SD MMC card. ⚠Warning: For use with passive media (such as an MMC card) only. Do not plug in any active electrical part or any device with a cable, such as a keyboard or an adapter cable. Do not use during a patient procedure.
6. USB Flash Memory Slot	Allows users to store still pictures and video clip on a removable USB Flash Memory Stick. ⚠Warning: For use with passive media (such as a memory stick) only. Do not plug in any active electrical part or any device with a cable, such as a keyboard or an adapter cable. Do not use during a patient procedure.

Rear Panel Layout

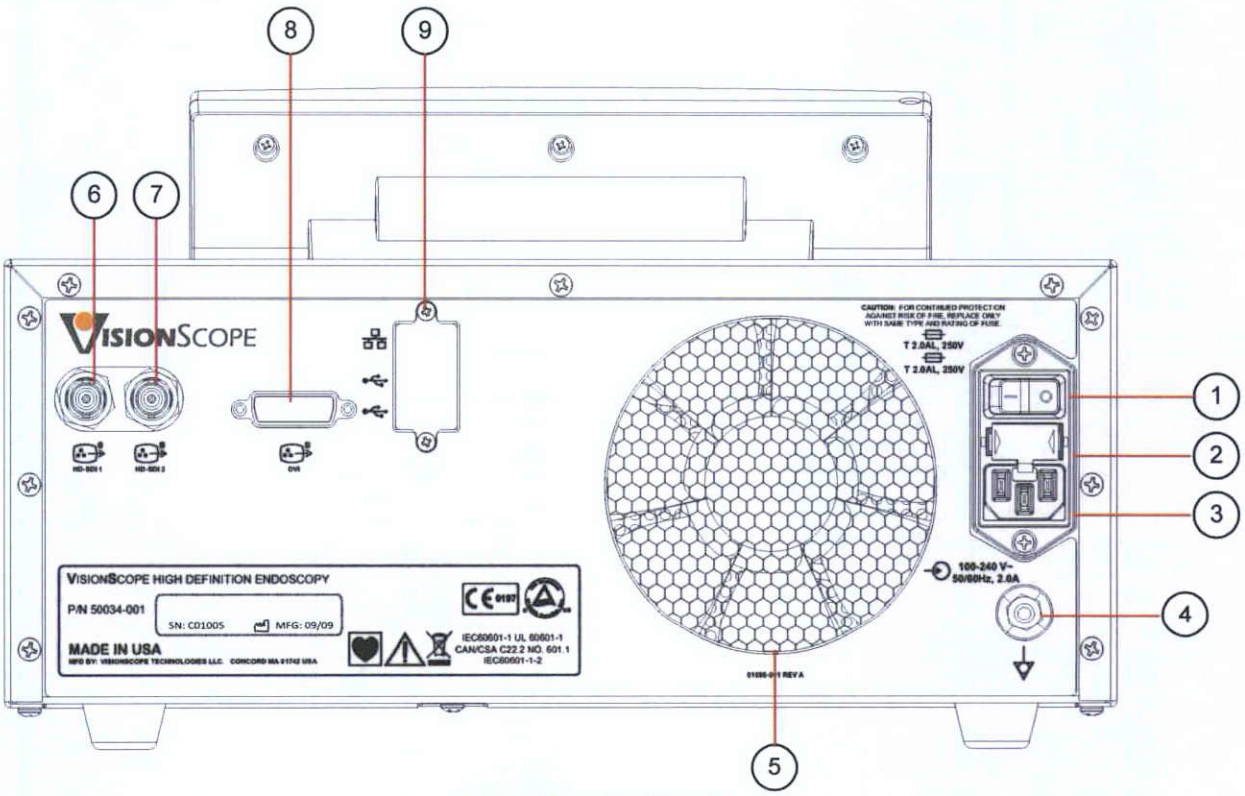


Figure 2 Rear Panel Layout

Rear Panel Connectors/Features	Functions
1. Main Power Switch	Supplies external AC power.
2. Fuse drawer	Contains two fuses in line with Live and Neutral of the AC input. Ratings of fuses shall be 2 Amps, 250 V, slow blow, low breaking capacity (T2.0AL, 250 V).
3. AC Power Plug Receptacle	Accepts AC power input.

4. Equipotential Plug	Enables connection to external equipotential connector.
5. Fan and EMI filter	Provides air circulation and EMI filtering.
6. HD-SDI connector No. 1	HD 1080i video output in Serial Digital Format
7. HD-SDI connector No. 2	HD 1080i video output in Serial Digital Format
8. DVI connector	HD 1080p video output in Digital Visual Format
9. Ethernet (1) and USB (2) receptacles	For Service Use only, do not use in patient environment. These receptacles are normally covered with a plate that can be removed only with a special tool.
Please refer to the Glossary of Symbols for an explanation of the labels on the Rear Panel.	

Camera Handpiece Layout

Three buttons are available on the Camera Handpiece to control the Camera Control Unit. During a sterile procedure, the buttons can be accessed through the sterile Camera Drape.

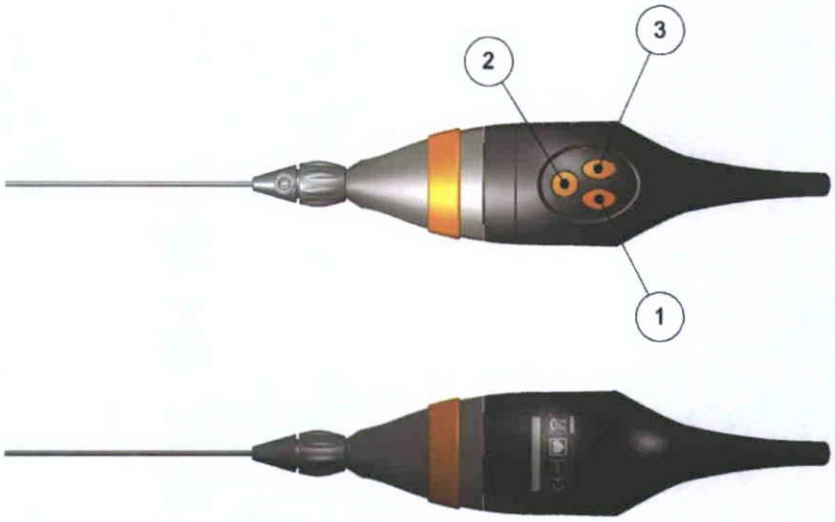


Figure 3 Camera Handpiece Button Layout

Each button serves two functions, depending on how long the button is pressed and released. Unless otherwise re-programmed by the users, the buttons serve the following functions:

Camera Handpiece Button	Short Press (< 1.0 second)	Long Press (≥ 1.0 second)
1. Left Button	Capture a Still Image.	Display last captured Still Image for 1 second.
2. Middle Button	Change video brightness by one step. Functions in a cyclic loop, from 0, +1, +2, +3, -3, -2, -1, 0...	Change video enhancement by one step. Functions in a cyclic loop, from 0, +1, +2, +3, -3, -2, -1, 0...
3. Right Button	Press once to start a video recording. Press again to stop	Change color saturation by one step.

211

	recording.	Functions in a cyclic loop, from 0, +1, +2, +3, -3, -2, -1, 0...
Please refer to the Glossary of Symbols for an explanation of the labels on the Camera Handpiece.		

The Camera Handpiece controls provide basic functions needed during a sterile procedure. If other functions are required, the Camera Handpiece controls can be re-programmed (see *Customizing a Picture Profile* on page 42).

Overview of the Endoscopy Process

The typical process flow for using the VisionScope system is illustrated in Figure 4. The Camera Control Unit is started up and the Camera Handpiece connected. The patient is registered using the touch screen on the Camera Control Unit.

The patient is then prepared for the clinical procedure. The Endoscope is assembled and inserted for visualization of the anatomy. During the procedure, still images and video clips can be captured from the live video.

After the patient has been discharged, the procedure can be reviewed. Still images and video recordings can be viewed, notes added, and audio recorded. The procedure report can be printed, e-mailed, and archived to an external storage device.

Instrument setup functions may be performed outside of the clinical procedure by an OR technical staff member, a service technician, a biomedical engineer, or a nurse.

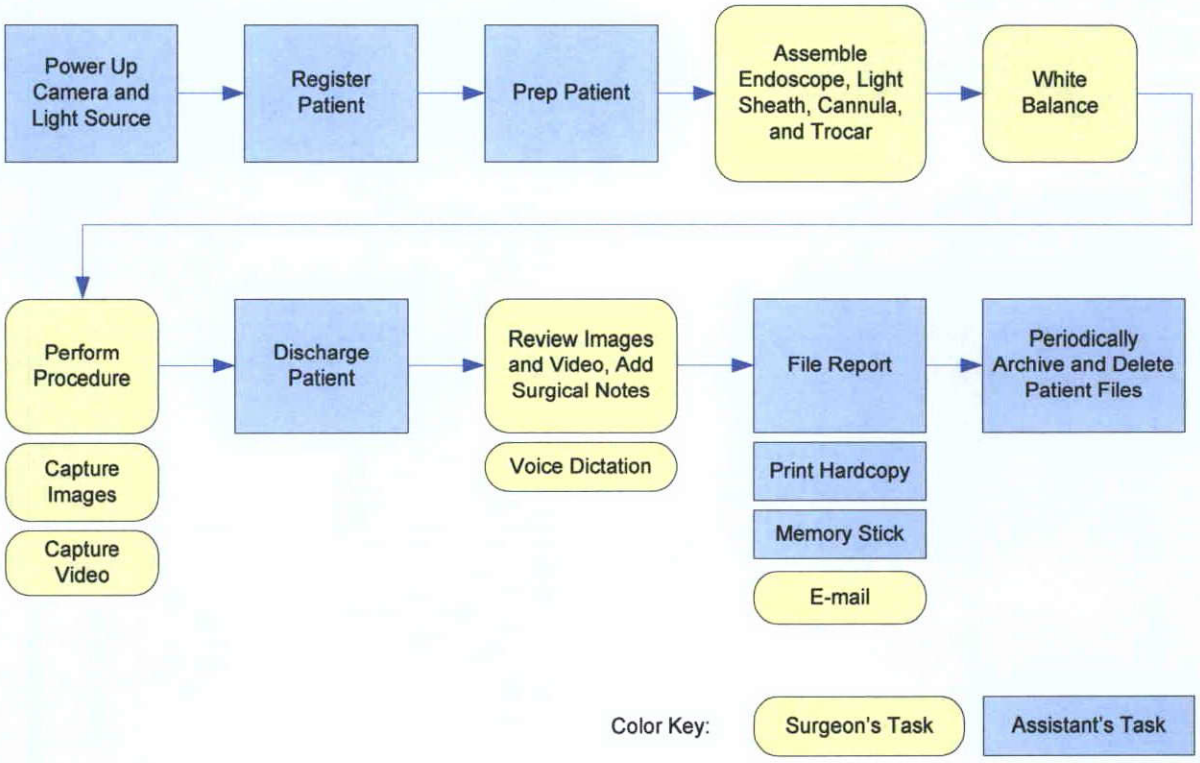


Figure 4 VisionScope Process Overview

212

Using the Camera Control Unit

The VisionScope High Definition Endoscopy System contains an integrated camera controller, light source, image management computer, and touch screen display (collectively called the Camera Control Unit). It may be used in a standalone configuration without an external display monitor or any other external peripherals.

⚠ Warning

The Camera Control Unit is intended to be used non-sterile. Do not touch Camera Control Unit with a sterile gloved hand.

To set up the Camera Control Unit:

1. Connect the medical grade power supply cord supplied as part of the system kit.
   The system is operable with a power source of 100-240 VAC, 50/60 Hz, at <120 watts.
2. Turn the main switch on the back panel to the ON position.
   When you turn on the main switch, the power switch on the front panel is also turned on. After initial setup, the main switch on the back panel can remain on, and the power turned on and off using the button on the front panel.

Starting Up and Shutting Down

To switch on the Camera Control Unit:

1. Press the power switch on the front panel.
   A green indicator light shows that the power is now applied.
2. Wait several moments for the computer to initialize and the touch screen to become active. When initialization is completed, a Patient Registration Screen is displayed on the Front Panel Touch Screen. (If the Camera Handpiece is not connected, a color bar test pattern appears, indicating the system is functioning properly.)

To turn off the Camera Control Unit:

1. After you have finished performing patient procedures, save all data and settings.
2. Tap the Close icon in the top right corner of the screen [ ].
3. Tap the Shutdown button (Figure 5).
4. Press the power button on the front panel.

Figure 5 Turning off the Camera Control Unit

Using the Touch Screen Interface

The Camera Control Unit is equipped with an 8.4" LCD touch screen that provides all the functions for viewing and managing a patient procedure. Operate the touch screen by touching or tapping on the glass using a clean finger or the plastic stylus provided in a slot on the top left of the unit.

To type data into a field, first tap the field to select it. A cursor blinks to indicate the field is active. Tap characters and functions on the virtual keyboard to enter them in the active field.

If a list of selections is available, tap the down arrow to access the pull-down list, and then tap the selection.

Note: If the tapping position on the screen appears to become inaccurate over time, it may be necessary to calibrate the alignment. See *Touch Screen Calibration* on page 56 for more information.

⚠ Warnings

Never touch the LCD touch screen, the stylus, or other parts of the non-sterile camera control unit with a gloved hand where bio-hazardous contamination may be transferred to screen.

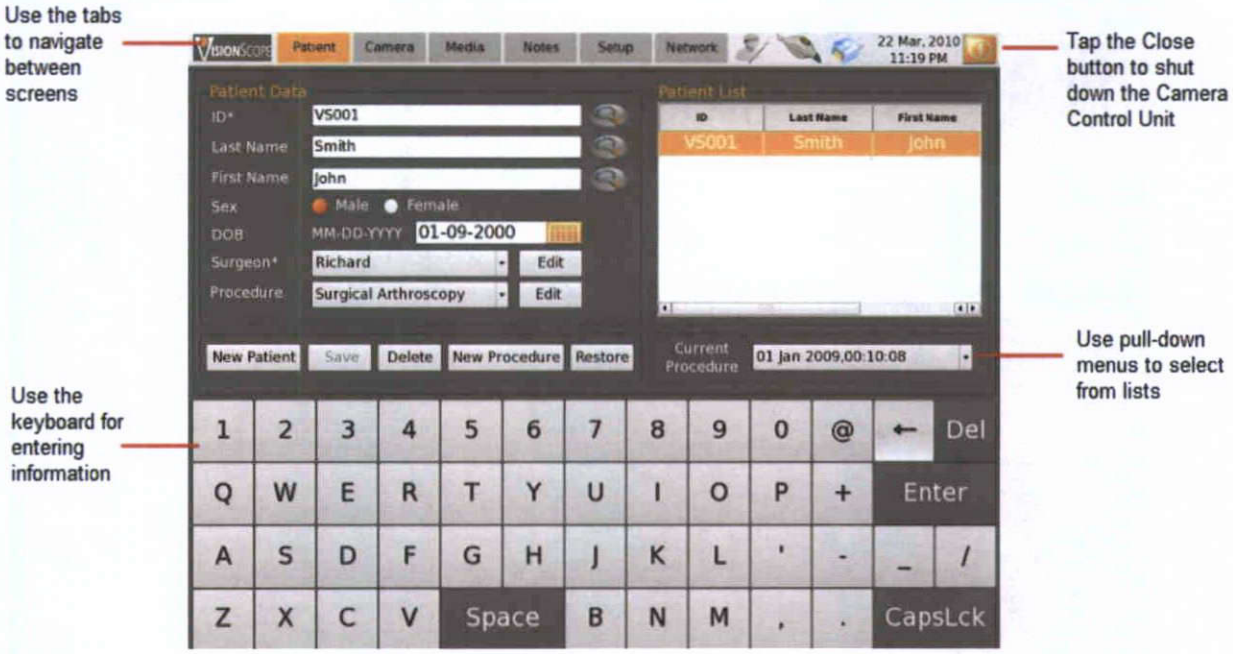


Figure 6 Using the Touch Screen

Entering Passwords

If the Camera Control Unit is configured with password security, you will be required to enter your password to perform specific operations. Passwords are case-sensitive.

- A **Surgeon** password (Figure 7) may be required for operations such as e-mailing and copying Patient Reports. See *Editing the Surgeon, Procedure, and Patient Lists* on page 43 for information on changing a Surgeon's password and retrieving a forgotten password.
- An **Administrator** password (Figure 8) may be required to access the Network tab and to edit the Surgeon and Procedure Lists. See *Passwords* on page 52 for information on changing an Administrator password.

214

See *Passwords* on page 52 for information on setting up Surgeon and Administrator password requirements.

To enter a password:

1. Tap in the box to activate the password field.
2. Tap the keyboard characters.
3. Tap the **Done** button.

Figure 7 Entering a Surgeon Password

Figure 8 Entering an Administrator Password

Performing a Patient Procedure

If VisionScope is prescribed to be used in a diagnostic imaging procedure without any resection tool, the one-time use sterile Endoscope Sheath (Illumination Sheath and integrated Camera Drape) may be used for protecting the patient as well as the Endoscope and Camera Handpiece from contamination.

Reprocessing Requirements of the Endoscope and Camera Handpiece

⚠ Warnings

Procedures with an accompanying in vivo resection tool: If VisionScope is prescribed to be used in a surgical procedure with an in vivo resection tool, the entire Camera Handpiece and the Endoscope must be sterilized before and after each procedure, using one of the sterilization methods specified in the Instructions for Use for the Camera Handpiece and the Endoscope (PN

01113, PN01115), to assure sterility in the unlikely event that the sterile Illumination Sheath or Camera Drape is accidentally damaged by the resection tool.

Diagnostic Imaging Procedures without any other tool: If VisionScope is prescribed to be used in a diagnostic imaging procedure without an in vivo resection tool or any other tool, and if used in conjunction with the VisionScope Disposable Sterile Procedure Kit in accordance with the Instructions for Use (PN 01114), the entire Camera Handpiece and the Endoscope may be used without full sterilization but must be disinfected by wiping with a 70% isopropyl alcohol soaked gauze pad before and after each procedure.

Registering a New Patient and Starting a Procedure

Before you can capture still images and record video, you must register the patient and start a procedure using the touch screen of the Camera Control Unit. Use the plastic stylus supplied in the storage slot on the top right of the Camera Control Unit or a non-sterile finger.

When you start a procedure on the Camera Control Unit, all data and media are collected and stored on the hard drive under the patient's identification. Each stored procedure can be easily identified by the starting date and time.

A procedure ends when you start a new procedure or open a saved procedure.

⚠ Warning

The touch screen and stylus are non-sterile. Do not touch the screen or stylus with a sterile gloved hand.

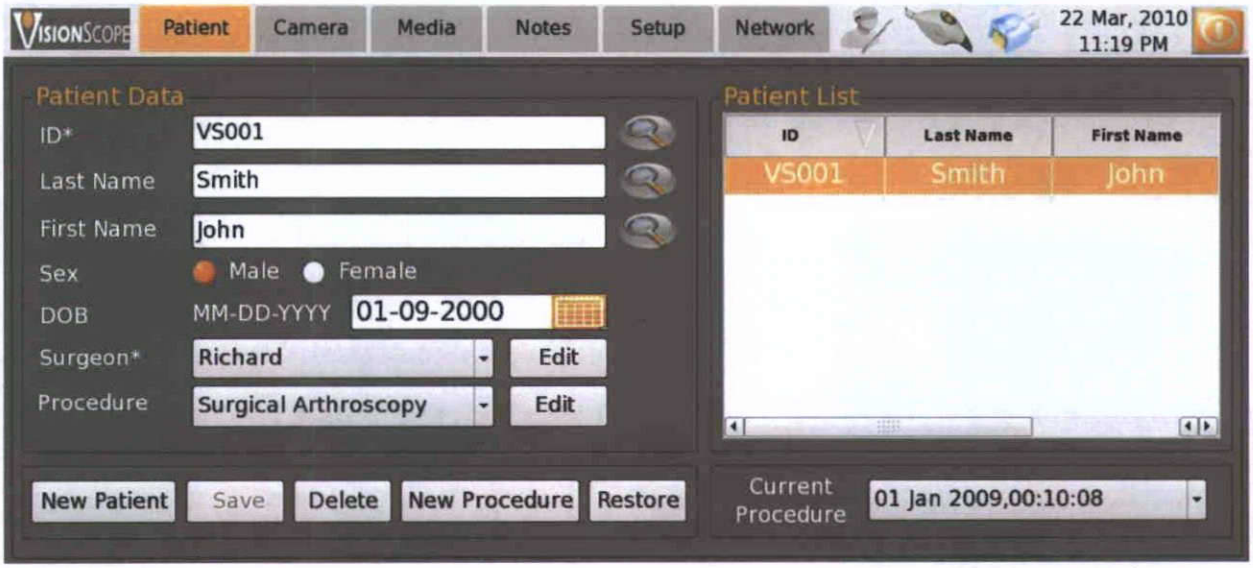


Figure 9 Registering a Patient

To register a new patient and start a procedure:

1. On the touch screen, tap the Patient tab (Figure 9).
2. Tap the **New Patient** button.
3. If prompted, close the current procedure.
4. (Required) Enter the Patient ID number, obtained from the surgical center.

5. (Optional) Enter the name, sex, and date of birth of the patient.
6. (Required) Select the attending Surgeon from the drop-down list.
7. (Optional) Select a Procedure from the pull-down list.
   The selected Procedure name will appear in any printed reports.
8. Tap the **Save** button.
   (If the **Save** button is disabled, you must enter additional required information.)
9. Review the Patient Data (Figure 10) and tap the **Save** button to confirm.

Figure 10 Saving Patient Data

The procedure is now started and you are prompted to white balance the camera. Before you proceed to white balancing, connect the Camera Handpiece, Endoscope, and Illumination Sheath.

Starting a Procedure for a Previously Registered Patient

If a patient has already been registered, you can select the patient from the Patient List and start a new procedure.

Note: You can also locate a patient by entering partial information in the ID, Last Name, or First Name field and tapping the Lookup icon [ ].

To start a procedure for a registered patient:

1. Select the patient from the Patient List (Figure 11).
   If the list is long, you can use the scroll bar to navigate. You can also sort the list using the column header.
2. (Optional) Edit the Patient Data.
3. Tap the **New Procedure** button.
4. If prompted, close the current procedure.

Figure 11 Selecting a Patient from the Patient List

The procedure is now started and you are prompted to white balance the camera. Before you proceed to white balancing, connect the Camera Handpiece, Endoscope, and Illumination Sheath.

Assembling the Endoscope and Camera Handpiece

Use the appropriate Endoscope (60 mm, 95 mm, 160 mm, or 220 mm operating length) for the intended patient procedure (see *System Components and Part Numbers* on page 8 for details and part numbers). If the same type of procedure (e.g., knee) is being performed, it is not necessary to change Endoscopes between procedures.

⚠ Warnings

The Endoscope and Camera Handpiece are non-sterile. Do not handle the Endoscope or Camera Handpiece with gloves that will be used for sterile procedures.

To verify correct viewing mode and image orientation:

Before each use or after a change of viewing modes/settings, the Operator should check to ensure the view observed through the Endoscope provides a live image (rather than a stored one) and has the correct image orientation. For instructions on changing from a stored image to a live image, see *Reviewing Media from the Current Procedure* on page 29. For instructions on inverting the image orientation, see *Centering/Inverting the Image* on page 40.

To connect the Endoscope to the Camera Handpiece:

1. Inspect the Camera Handpiece and cable connectors to make sure they are dry.
2. Inspect the window on the Camera Handpiece to make sure it is clean and dry. If necessary, use a lint free cotton cloth, lens tissue paper, or a Q-tip wetted with isopropyl alcohol to remove any dirt and smudge.
3. Select the appropriate Endoscope model with the desired working length.
4. Inspect the Endoscope to make sure that it is dry, the needle is not bent, and the windows on both ends are clean and free of dirt and smudge. Clean if necessary with a lint free cotton wipe or a Q-tip wetted with isopropyl alcohol.
5. Thread the Endoscope into the C-mount on the Camera Handpiece (Figure 12). Hand-tighten the Endoscope to ensure that the O-ring seal is compressed securely. Do not use hand tools to tighten the Endoscope.

Figure 12 Connecting the Endoscope to the Camera Handpiece

To connect the Camera Handpiece to the Camera Control Unit:

1. Unscrew and remove the connector soak cap from the Camera Handpiece cable (Figure 13).
2. Inspect the interior of the connector to make sure it is dry and free of water droplets. Blow dry with air if necessary.
3. Align the red dot on the Camera Handpiece cable connector with the red dot on the Camera Control Unit receptacle (Figure 14).
4. Plug the Camera Handpiece cable connector into the receptacle and push in tightly.

Figure 13 Removing the Soak Cap

Figure 14 Connecting the Camera Handpiece to the Receptacle on the Camera Control Unit

An icon at the top of the screen on the Camera Control Unit indicates the status of the Camera Handpiece connection:

Camera Handpiece is connected to the Camera Control Unit

Camera Handpiece is not connected to the Camera Control Unit

Note: If the Camera Handpiece will be idle for an extended period, you can set the Light to Standby mode (see *Light Control Panel* on page 50) to reduce the LED to a dim glow. Unplugging the Camera Handpiece cable from the receptacle on the Camera Control Unit also places the light in Standby mode.

Installing the Endoscope Sheath

The Sterile Procedure Kit includes an Illumination Sheath to provide illumination for endoscopic imaging. The Illuminated Sheath is integrated with a Camera Drape to keep the Camera Handpiece and camera cable in a sterile environment.

Physicians, Nurses or Physician Assistants should use their training for manipulating both sterile and non-sterile components when connecting the Illumination Sheath to the Endoscope and deploying the Camera Drape. In some cases, it may be helpful to lay the camera in a sterile field or have an assistant remove the outer glove.

Once the Illumination Sheath is installed and the Camera Drape is deployed, you are ready to white balance the camera. Prior to each use, confirm the image clarity of the Endoscope for suitability of reuse.

⚠ Warnings

Follow the reprocessing requirements of the Endoscope and Camera Handpiece (see *Reprocessing Requirements of the Endoscope and Camera Handpiece* on page 16).

You must select the correct Sterile Procedure Kit for the installed Endoscope (see *System Components* on page 8 for details and part numbers). All components are color-coded to indicate their working length.

Figure 15 Sterile Procedure Kit

To connect the Illumination Sheath to the Endoscope:

1. Select a Sterile Procedure Kit (Figure 15) with a disposable Illumination Sheath that has the same working length as the installed Endoscope.
2. Examine the Sterile Procedure Kit to ensure that the seal is not broken and the expiration date has not arrived. Discard the kit if either condition is true.
3. Wear two sterile gloves on the hand that will be used to handle the non-sterile Camera Handpiece. Wear a single sterile glove on the other hand that will be used to handle the Sterile Illumination Sheath.
4. Peel off the lid of the Sterile Procedure Kit.
5. While holding the non-sterile Camera Handpiece in the double-gloved hand, pick up the sterile Illumination Sheath in the single-gloved hand. Handle the Illumination Sheath by the base to avoid damaging the needle. Make sure the non-sterile (double-gloved) hand does not touch any sterile component, such as the needle on the Illumination Sheath, which will enter the patient.
6. Carefully insert the needle of the Endoscope into the funnel of the Illumination Sheath (Figure 16).
7. Orient the Illumination Sheath so that the Illumination icon on the Illumination Sheath aligns with the Half-Circle icon on the Camera Handpiece and engage the threaded mount.
8. Rotate the Illumination Sheath one-quarter turn in the clockwise direction (Figure 17) until the two Illumination icons align. The fiber optic light guide on the Illumination Sheath is now aligned with the Illumination port on the Camera Handpiece
9. Confirm that a bright light spot is seen at the distal tip of the Endoscope and that an adequately bright image appears on the touch screen LCD or an external monitor (if

connected) when the Endoscope is placed within 50 mm of a white piece of cotton gauze or bandage.

Note: Make sure the Light Control is set to Normal mode (full power) when verifying the image from the Endoscope (see Light Control Panel on page 50).

Figure 16 Inserting the Endoscope into the Illumination Sheath

Figure 17 Rotating the Illumination Sheath 1/4 Turn

To deploy the Camera Drape:

1. Using the hand with the single sterile glove, hold the Camera Handpiece/Endoscope assembly by the Illumination Sheath.
2. Using the double-gloved hand, pull back on the deployment cord of the Camera Drape. Continue pulling the cord until the Camera Drape is fully extended and covers both the Camera Handpiece and the camera cable (Figure 18).
3. Peel off the outer glove on the double-gloved hand, touching only the upper part of the glove that has not been contaminated by the Camera Handpiece.

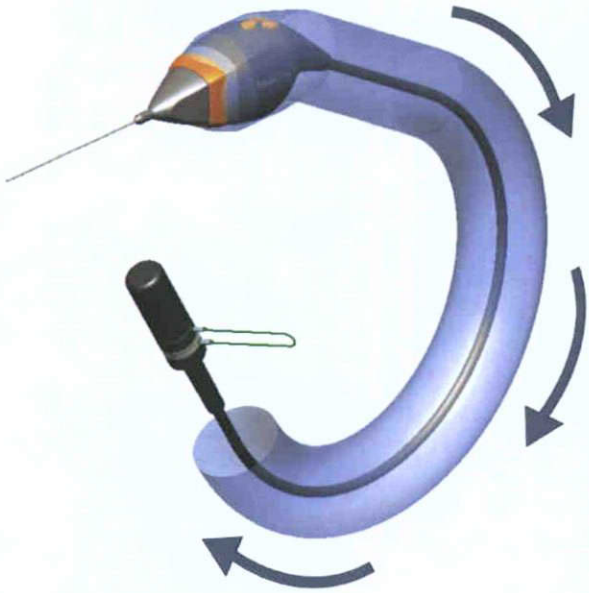


Figure 18 Deploying the Camera Drape

White Balancing and Confirming Image Clarity

Once you have assembled the Camera Handpiece, Endoscope, and Illumination Sheath, you are ready to white balance the camera.

Note: Make sure the Light Control is not set to Standby mode when white balancing the camera (see Light Control Panel on page 50).

To white balance the camera:

1. Point the Camera Handpiece at a white piece of cotton gauze or bandage. Press the middle button on the Camera Handpiece that has been pre-programmed (unless otherwise changed by the user) to produce a color-balanced image such that the white background is white.
2. The white balance process may take 1-2 seconds. During this time, hold the handpiece steady at the white background. The On-Screen Display shows the status of the white balancing.
3. Confirm that the On-Screen Display indicates that the white balance is completed successfully.

To confirm image clarity of the Endoscope for suitability of reuse prior to each use:

1. After successful white balance, point the Endoscope at a piece of white cotton gauze or bandage at a distance between 4 mm to 25 mm.
2. Confirm that the illumination level is bright, the color is correct, the fabric or threads are in sharp focus, and there is no foreign, nebulous object in the field of view.
3. If the image is not clear or is obstructed, replace the Illumination Sheath and Endoscope until a clear image is observed.

When white balancing is completed successfully, the Camera Control Unit switches to full screen mode (See *Using Full Screen Mode* on page 26).

The Camera Handpiece/Endoscope/Illumination Sheath assembly is now ready for surgical insertion. A Cannula and a Trocar with matched working length is provided for Surgeons to gain access to the anatomy.

Inserting the Cannula and Endoscope Assembly

Inserting the Camera Handpiece/Endoscope/Illumination Sheath assembly (the Endoscope assembly) into a patient requires the disposable sterile Cannula and Trocar included in the Sterile Procedure Kit. The Cannula and the Trocar should be inserted by qualified physicians only.

The Cannula is equipped with a fluid entry port for introducing a small volume (up to 50 ml) of liquid for flushing or drug delivery. An internal O-Ring prevents any leakage of fluid through the Cannula. If necessary, loosen the Cannula collar to relax the O-ring seal before inserting the Illumination Sheath and Endoscope.

⚠ Warnings

Prior to each use and insertion into a patient, ensure the system is functioning properly and is producing live video. Inspect the Endoscope, the disposable Illumination Sheath, Cannula, and Trocar to ensure that the tubes are not bent, the windows are not damaged, and there are no unintended rough surfaces, sharp edges, or protrusions which may cause harm. Do not use a damaged device.

Before starting this procedure, verify that the Cannula and Trocar have the same working length as the installed Endoscope and Illumination Sheath. In addition, verify that you are wearing sterile gloves and that the sterile Illumination Sheath and Camera Drape are installed over the Endoscope and Camera Handpiece.

To insert the Cannula and the Endoscope assembly:

1. Surgically insert the Cannula/Trocar combination into the patient cavity.
2. Remove the Trocar and discard.
3. Carefully insert the needle of the Camera Handpiece/Endoscope/Illumination Sheath assembly into the funnel of the Cannula (Figure 19). Continue inserting until the entire length of the needle is inserted and the base of the Illumination Sheath fits snugly into the Cannula collar.
4. Rotate the collar on the Cannula until the collar fits snugly on the Cannula body. Tightening this threaded connection compresses the internal O-Ring to prevent any leakage of fluid during the procedure.
5. If the procedure requires fluid injection, connect a syringe to the Cannula via the Luer-Lock port and inject.

Figure 19 Inserting the Endoscope Assembly into the Cannula

Using Full Screen Mode

Once a procedure has been started, the Camera Control Unit switches to Full Screen mode. If the Camera Head and Endoscope are connected and white balanced, the screen displays the live video from the Endoscope.

Full Screen mode provides the largest uncluttered viewing area for visualizing the anatomy. The tabs across the top of the touch screen are initially turned off to increase the viewing area. To turn the tabs on, tap the screen in the Live Video area. Tap again to turn the tabs off.

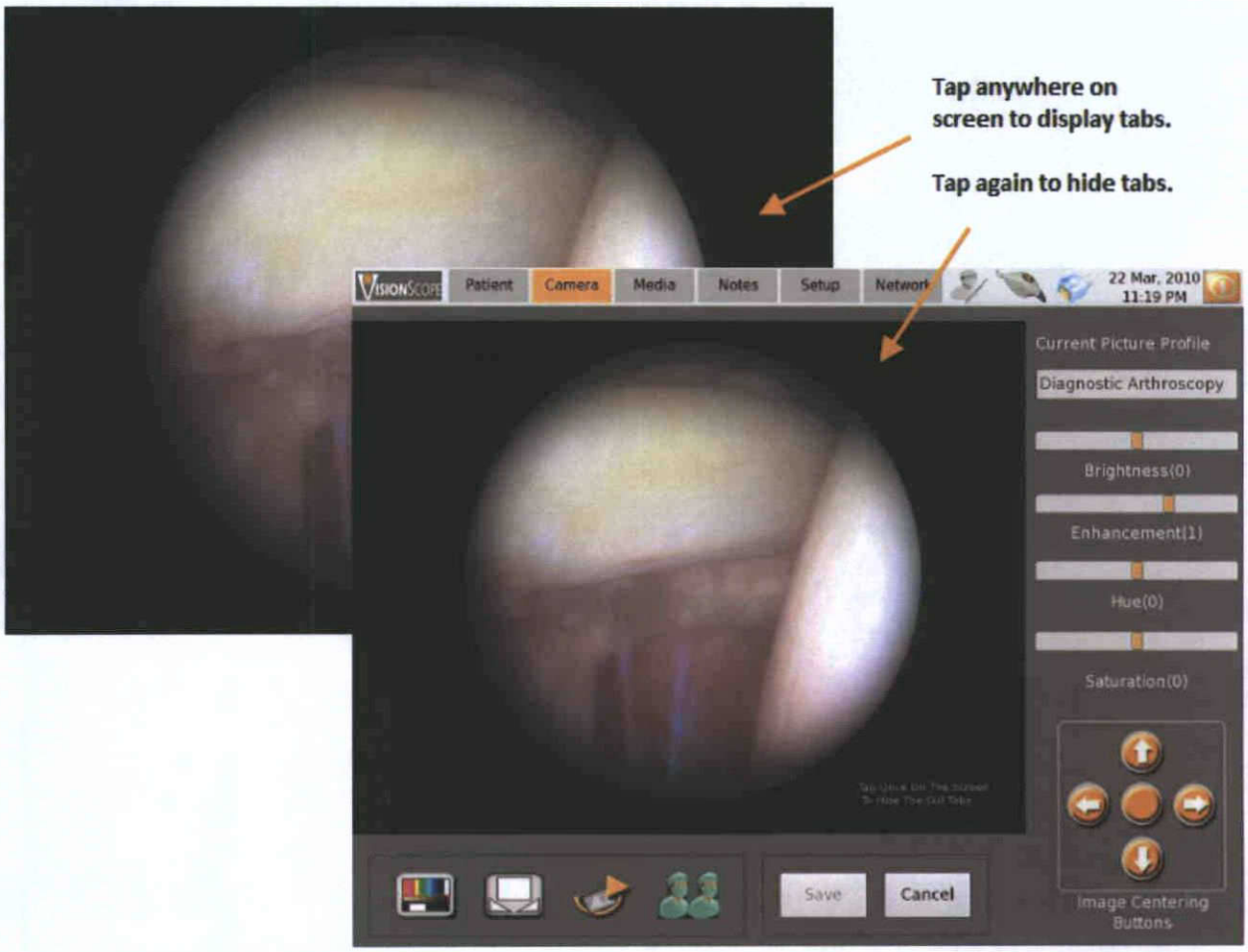


Figure 20 Hiding Tabs (Full Screen Mode) and Displaying Tabs

225

Live video can also be viewed on the Camera tab and the Media tab. The Camera tab includes controls for picture adjustment. The Media tab includes controls for reviewing and managing images and recordings. Tap the tabs at the top of the screen to move between screens.

Capturing Still Images and Recording Video

Three buttons are available on the Camera Handpiece to control the VisionScope system during a sterile procedure. The buttons can be accessed through the sterile Camera Drape. Unless otherwise pre-programmed by the user, the Camera Handpiece buttons control image capture, video recording, and camera settings. See *Camera Handpiece Layout* on page 12 for a description of the button functions.

Note: If the Camera Handpiece buttons do not function as expected, another user may have re-programmed the buttons in a Custom Picture Profile. Tap the Camera tab to see the currently loaded Picture Profile. See *Loading a Picture Profile* on page 41 for information on loading a standard Picture Profile.

⚠ Warning

During a sterile procedure, the Camera Handpiece control buttons should be used to capture images or make adjustments to the VisionScope video, unless an assistant is available to operate the touch screen.

Capturing a still image momentarily freezes the live video and saves the image in JPEG file format. Recording live video saves a video clip in MPEG file format. A maximum duration can be set for video recordings (see *Captured File Options* on page 49).

Captured still images and video recordings are stored with the Patient Record on a hard disk drive in the Camera Control Unit. An On-Screen Display shows the number of still images captured and the video recording status (Figure 21).

Figure 21 On-Screen Display

Finishing a Patient Procedure

If the proper procedure is followed during assembly and disassembly, the Camera Handpiece and attached Endoscope should be uncontaminated at the end of a procedure and ready for re-use in the next procedure.

To complete a procedure:

1. Remove the Endoscope and Cannula from the patient.
2. Turn the Illumination Sheath 90° counterclockwise to disengage the bayonet mount from the Camera Handpiece C-mount. Carefully slide the Camera Handpiece and the attached Endoscope out of the Illumination Sheath.
3. Carefully back the Camera Handpiece and the attached Endoscope out of the Camera Drape.
4. Set the Camera Handpiece and the attached Endoscope down on a clean work surface.
5. Dispose of the Illumination Sheath and Camera Drape, Cannula, Trocar, and any other patient-contact accessories or supplies in a bio-hazard waste bin per the hazard waste disposal policy of the facility. Refer to Instructions for Use of the Disposable Procedure Kit (PN 01114) for further disposal information.
6. **Follow the reprocessing requirements of the Endoscope and Camera Handpiece** (see *Reprocessing Requirements of the Endoscope and Camera Handpiece* on page 16).
7. If the Camera Handpiece and attached Endoscope have been contaminated during or after a procedure, send the devices through an approved sterilization cycle per the Instructions for

221

Use for those sub-systems (Document 80043). Acceptable sterilization methods include 100% ETO, Sterrad 100, Sterrad NX, or Sterrad 100 NX. Do not autoclave.

Reviewing Media, Recording Audio, and Adding Notes

The Media screen enables you to review the current procedure or a saved procedure. You can add voice dictation and select still images, video recordings, and audio recordings to play back for review. You can delete unwanted media files.

In addition, the Notes screen allows you to enter surgical notes that will be stored with the procedure.

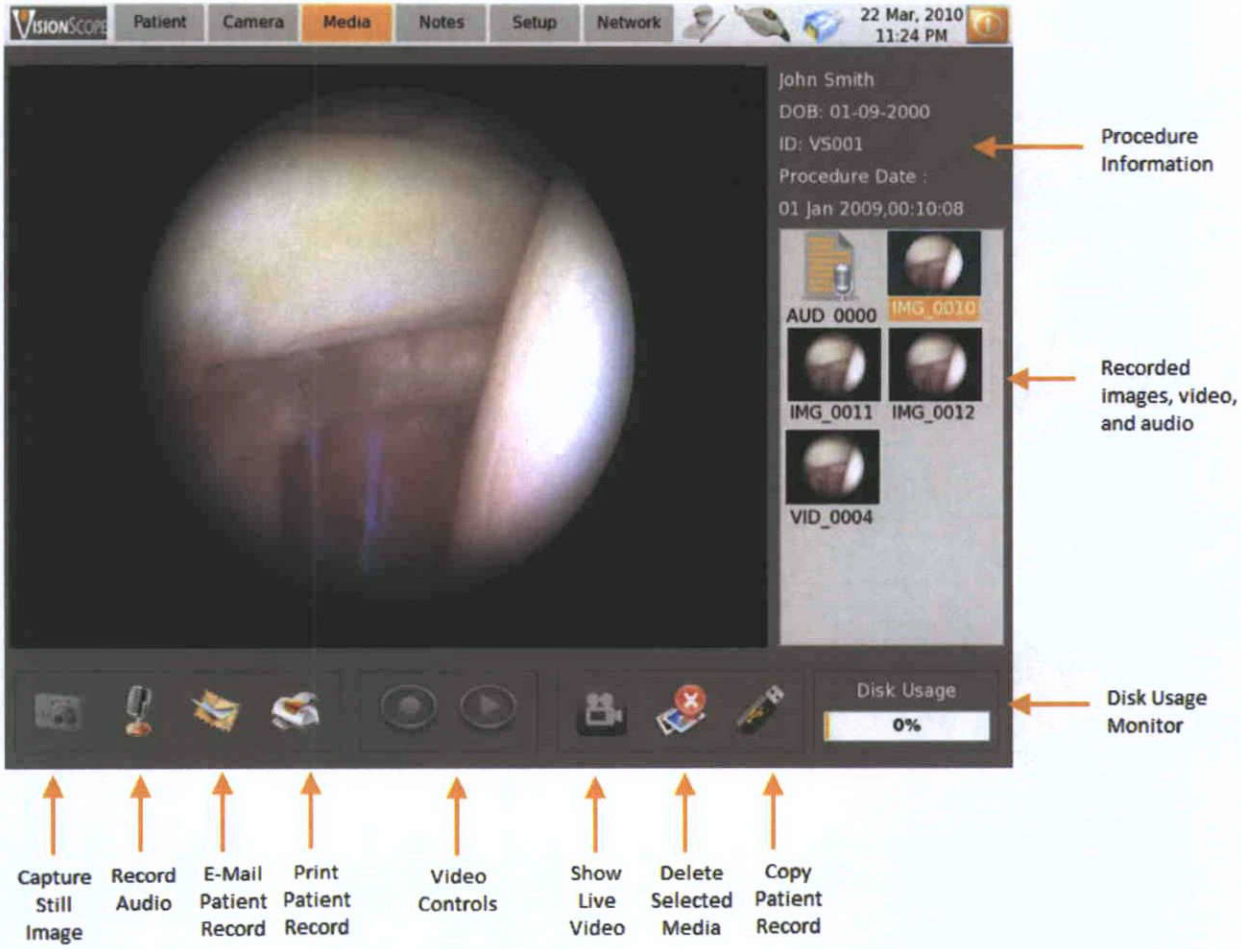


Figure 22 Using the Media Screen

Reviewing Media from the Current Procedure

You can you can use the Media screen to review media stored during the current procedure. While the procedure is running, you can switch back to Live Video to capture new still images and video recordings.

⚠ Warnings

Before each use or after a change of viewing modes/settings, the Operator should check to ensure the view observed through the Endoscope provides a live image (rather than a stored one) and has the correct image orientation.

To switch to live video:

1. On the Media screen, tap the Live Video icon [ ].
2. Tap the Live Video icon again to return to the recorded media.

An icon at the top of the screen indicates the mode:

Operating Mode – Screen is displaying live video

Review Mode – Screen is displaying recorded media

Reviewing Media from a Saved Procedure

You can use the Media screen to review any patient procedure stored in the Camera Control Unit system. Procedures are listed under the patient's name and can be identified by the date and time the procedure was started.

Note: Opening a saved procedure will close the current procedure.

To open a saved procedure:

1. On the Patient screen, select a patient from the Patient List.
   If another procedure is currently in session, you are prompted to close it before you can open a saved procedure.
2. Tap the down arrow to access the Procedure pull-down list.
3. Select the Procedure you want to review.
   The procedure is loaded along with all stored media and notes.
4. Tap the Media tab to review the still images and video recordings.

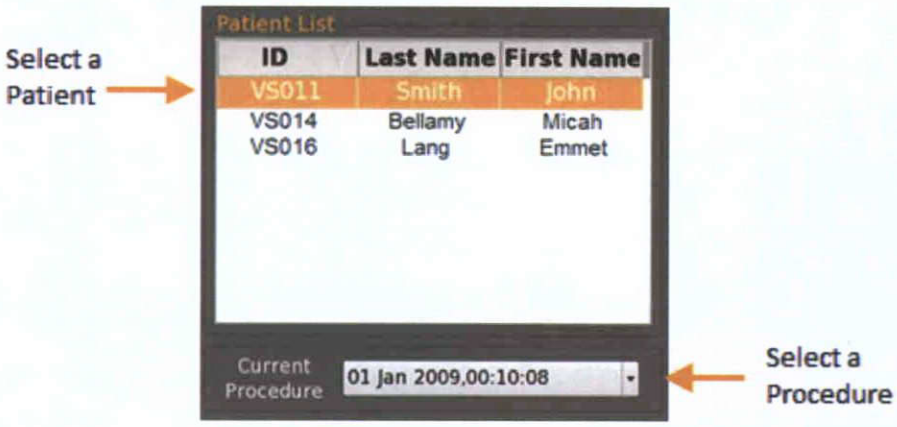


Figure 23 Opening a Saved Procedure

Note: You can also locate a patient by entering partial information in the ID, Last Name, or First Name field and tapping the Lookup icon [ ].

Recording/Reviewing Still Images

Captured still images appear as thumbnails in the right panel of the Media screen. You can review the still images on the Media screen.

If you are reviewing still images while a procedure is running, you can return to real-time video and capture additional still images.

⚠ Warning

During a sterile procedure, the Camera Handpiece control buttons should be used to capture images, unless an assistant is available to operate the touch screen.

To capture a still image:

1. While viewing live video, tap the Camera [ ] on the Media screen or press the designated button on the Camera Handpiece.
2. Tap OK to confirm image capture (or wait for the message to disappear).

To review a captured still image:

- Tap the thumbnail image in the right panel on the Media screen.

Recording/Reviewing Video

Video recordings appear as thumbnails in the right panel of the Media screen. You can ereplay the video recordings on the Media screen.

If you are reviewing video recordings while a procedure is running, you can return to real-time video and record additional video.

⚠ Warning

During a sterile procedure, the Camera Handpiece control buttons should be used to record video, unless an assistant is available to operate the touch screen.

230

To record video:

1. While viewing live video, tap the **Start Recording** (yellow) button on the Media screen. While video is recording, the **Recording** button flashes red. In addition, the REC symbol flashes in the On-Screen Display (if the Surgical Display Option is set to OSD).
2. Tap the **Stop Recording** (red) button to finish recording.
   The video recording appears as a thumbnail in the right panel of the Media screen.

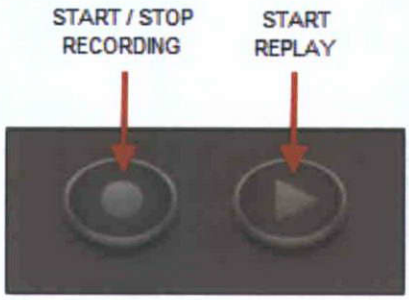


Figure 24 Video Recording Controls

To replay a video recording:

1. Tap the thumbnail image in the right panel of the Media screen.
2. Use the **Start/Pause** and **Stop** buttons to control the playback.

Figure 25 Replaying a Video Recording

Recording/Reviewing Audio

Voice dictation can be recorded using the microphone located in the front of the Camera Control Unit. Audio clips are saved in G.711 file format and stored with the patient's procedure record on a hard disk drive in the Camera Control Unit. Audio files may be played back on the Camera Control Unit's speaker.

You can adjust the recording and speaker volume using the Setup screen (see *Audio Volume Control* on page 50). In addition, you can set a time limit for audio recordings (see *Captured File Options* on page 49).

To record audio:

1. Tap the Microphone icon [ ] on the Media screen.
2. Speak in a normal voice. The Microphone icon blinks and a "Recording Audio" status appears in the OSD to indicate that audio is recording.
3. When finished speaking, tap the Microphone icon again to stop recording.
   The audio recording appears as a thumbnail in the right panel of the Media screen.

To replay an audio recording:

1. Tap the thumbnail image in the right panel of the Media screen.
2. Use the **Start/Pause** and **Stop** buttons to control the playback (Figure **26**).
3. Use the slider to control the playback volume.

Figure 26 Audio Playback Volume Controls

Deleting Media

As you review still images, video recordings, and audio recordings, you can select one or more media files to delete from the patient procedure record.

To delete media files:

1. Tap the thumbnail image in the right panel on the Media screen.
   To delete multiple files, touch and drag to draw a box around the thumbnail images.
2. Tap the Delete icon [ ].
3. Confirm the deletion.

Adding Notes

Use the **Notes** screen to add Surgeon notes that will be stored with the patient's procedure record. The notes will be included if a Procedure Report is e-mailed or printed.

To add notes:

1. Tap the Notes tab.
2. Enter the new text.
   Tap the **Clear Note** button, if necessary, to delete the text.

3. Tap the **Save** button.

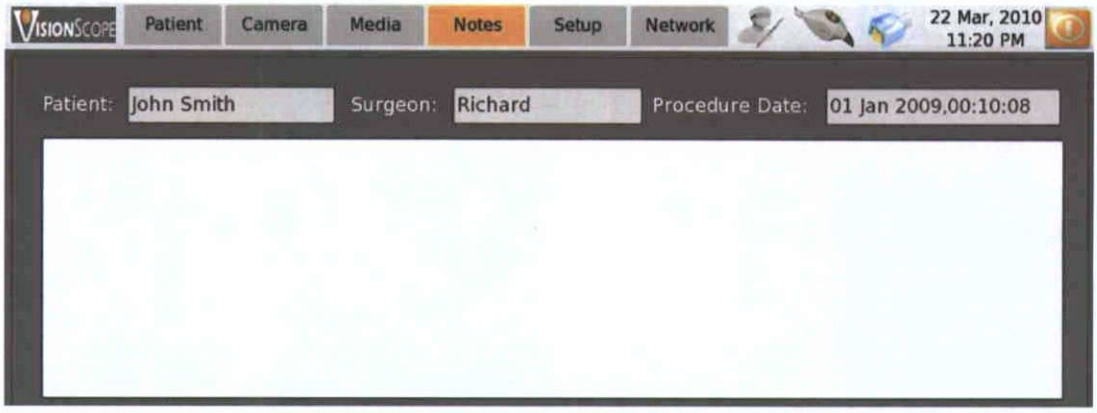


Figure 27 Adding Notes to a Patient Record

Managing Patient Records

The Media screen enables you to e-mail, print, and copy Patient Reports. The Media screen also provides a Disk Usage Meter for monitoring the available storage space on the Camera Control Unit hard drive. (See Figure 22 on page 29 for a key to the icons on the Media screen.)

E-Mailing a Patient Report

If your Camera Control Unit is connected to a local network and configured for e-mail, you can send a patient's Procedure Report to designated recipients. The report will include the Patient ID and other registration information, surgical notes, audio recordings, and any still images and video recordings you select.

Your system may be configured to require a Surgeon password for sending patient information by e-mail.

Note: An Administrator must configure e-mail on the Camera Control Unit. In addition, the Administrator must enter e-mail addresses for authorized recipients (see *E-mail Settings* on page 50 for more information). You cannot e-mail patient information to unauthorized addresses.

To e-mail a Patient Report:

1. Tap the Mail icon [ ] on the Media screen.
2. If requested, enter your Surgeon password and tap the **Done** button.
3. In the Send E-mail dialog box, select the recipient's e-mail address from the pull-down list.
4. Select still image, video recording, and audio recording files to include.
   Tap the Select All box if you want to include all files.
5. Tap the **Send** button.

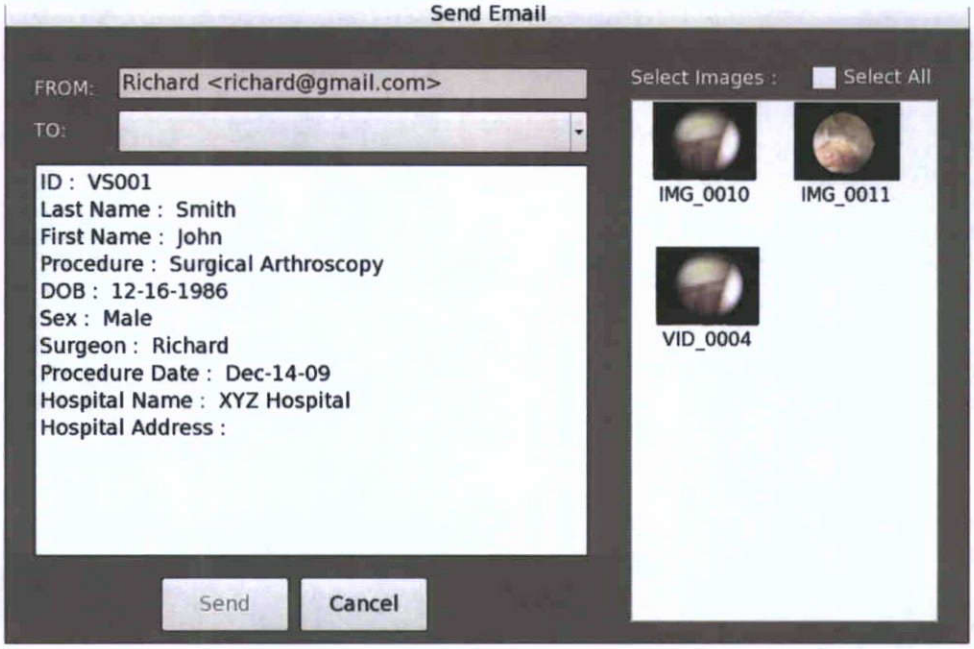


Figure 28 Sending a Patient Report via E-mail

Printing a Patient Report

If a VisionScope-approved medical grade and/or electrically-isolated inkjet or laser printer is connected to the Camera Control Unit, you can print a Patient Report. The printed report includes the Patient ID, additional registration information, surgical notes, and selected still images.

Note: Printers must be configured on the Camera Control Unit by an Administrator. (See *Printers* on page 50 for more information.)

To print a Patient Report:

1. Tap the Printer icon [ ] on the Media screen.
2. If more than one printer is connected, select a printer.
3. In the Print Patient Report dialog box, select the Image Size.
4. Select the still images to include in the printed report.
   Tap the Select All box if you want to include all files.
5. Tap the **Print** button.

Figure 29 Printing a Patient Report

Concord General Hospital

One Main Street Concord MA 01742

Patient ID:	123456789	DOB:	01/01/1960
Last Name:	McDonald	Sex:	F
First Name:	Elizabeth	Surgeon:	Welby, Marcus
Procedure:	Knee arthroscopy	Procedure Date:	01/01/2008

Procedure Notes:

A tear in the anterior cruciate ligament (ACL) is one of the most common knee injuries that may occur to a recreational, amateur, or professional athlete. This injury may result from twisting the knee too far in one direction, or by a sudden and forceful change in direction as may occur during football, soccer, skiing, basketball, racquetball, or tennis. Frequently, the injury occurs in those sports that require the foot to be planted in one spot, and the body to suddenly change direction or make a lateral movement.

Images:

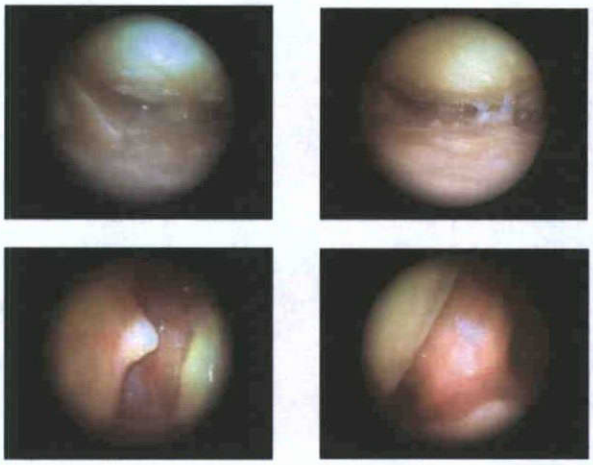


Figure 30 Sample Patient Report

Backing Up/Copying a Patient Record

The Camera Control Unit stores all Patient Records on the system's internal hard drive. You can copy patient data from the current procedure to several types of external storage devices:

- Memory stick inserted in a USB port
- SD/MMC inserted in the memory card slot (Secure Digital Multi-Media Memory Card 24x32x1.5 mm)
- External portable disk connected via a USB cable to a USB port

Note: For networked disk backup via connection to a hospital Local Area Network, consult your IT department.

Your system may be configured to require a Surgeon password for copying patient information.

To copy patient data:

1. Insert the storage device into the slot on the front of the Camera Control Unit.
2. On the Media screen, select thumbnails of the still images and video recordings you want to copy.
   You can also drag across to select multiple files.

3. Tap the USB icon [ ].
4. If requested, enter your Surgeon password and tap the **Done** button.
5. Select the device from the list.
6. Tap the **Save** button.
   A message displays when the data has been saved to the device.
7. Remove the external storage device from the Camera Control Unit.

Figure 31 Saving Data to a USB/MMC device

Monitoring Disk Usage

The Camera Control Unit is equipped with a 100 GB hard drive, providing storage capacity for approximately one million still images (approximately 100 KB per JPG) or 100 hours of recorded video (approximately 1 MB/second). In many cases, the Camera Control Unit's hard drive will be more than adequate for storing recordings for more than 100 hours of procedures.

A meter on the Media screen allows you to monitor the amount of disk space used.

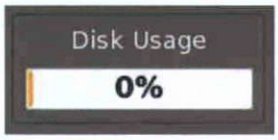


Figure 32 Disk Usage Meter

Several strategies are available if necessary to conserve disk space:

- Reduce the Data Retention Period for storing Patient Records (see *Patient Data Options* on page 49).
- Reduce the maximum length for video and audio recordings (see *Captured File Options* on page 49).
- Archive to an external storage device and then delete Patients that are no longer needed on the Camera Control Unit (see *Backing Up/Copying a Patient Record* on page 37 and *Deleting a Patient* on page 47).

Adjusting Camera Settings

The Camera screen provides controls for adjusting the picture settings, centering and rotating the image, white balancing, and viewing the color bar. The Camera screen also provides access to Picture Profiles, which contain picture settings as well as Camera Handpiece button settings.

Three pre-configured Picture Profiles are available for common procedures, as well as five Custom Picture Profiles that can be configured by the user.

Tap the **Camera** tab to access the camera controls.

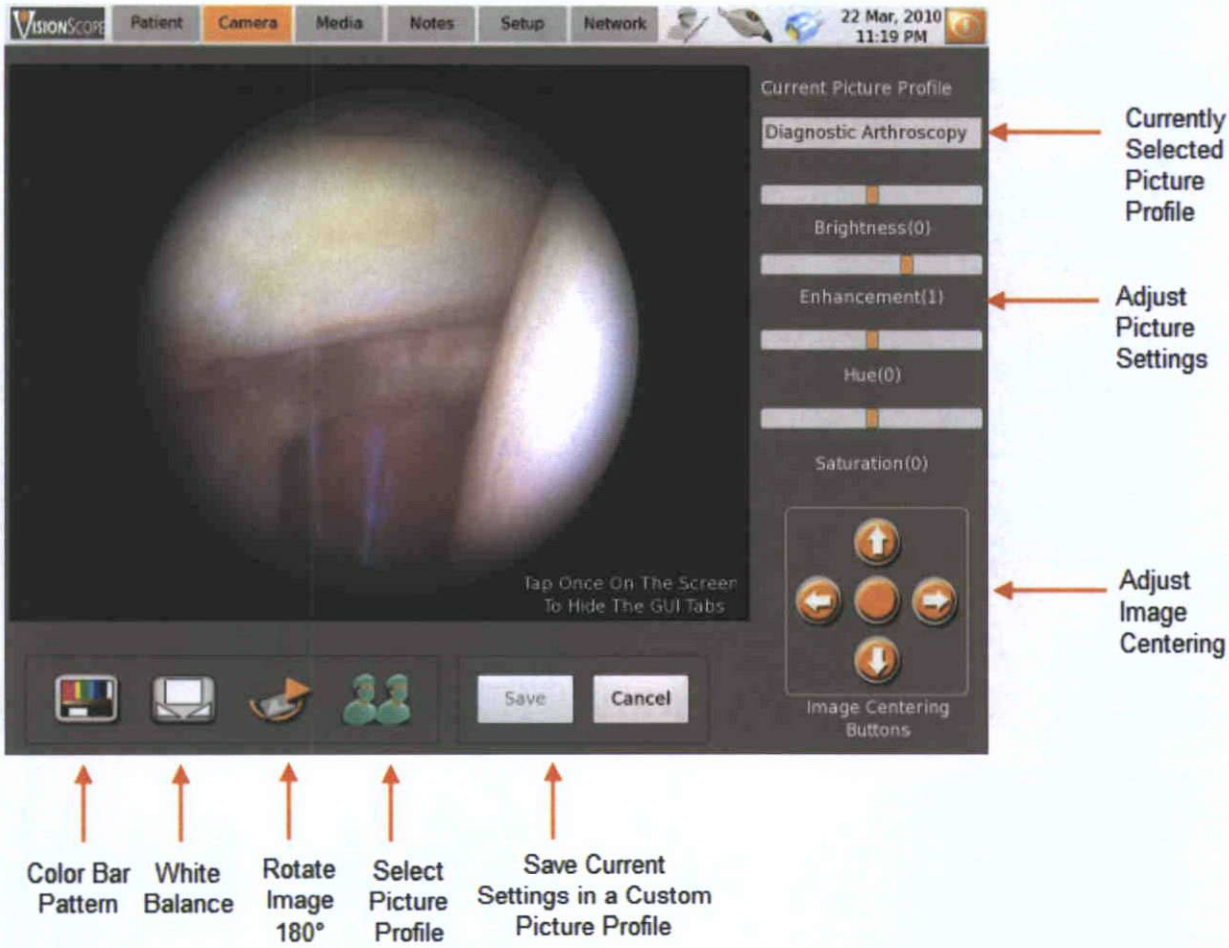


Figure 33 Using the Camera Screen

Adjusting Picture Settings

The Camera screen shows the Current Picture Profile with its camera settings. You can change the settings using the slider bars on the Camera screen.

Use the slider bars to adjust the following parameters:

Camera Parameter	Description	Value Range
Brightness	Adjust to lighter or darker (offset)	-3 to +3
Enhancement	Adjust to sharper or softer for visualizing more or less detail	-3 to +3
Hue	Adjust color balance	-3 to +3
Saturation	Adjust color intensity (full color to grey scale)	-3 to +3

If a Custom Picture Profile is currently selected, you can save the current picture settings by tapping the **Save** button. If you do not save the settings, the camera will return to the default settings the next time the Camera Control Unit is started up.

You cannot save settings to a Preconfigured Picture Profile.

Notes: In addition to adjusting picture settings, you can change the Camera Handpiece button assignments by editing a Custom Procedure (see *Customizing a Picture Profile* on page 42).

Color Bar

The color bar displays when the Camera Control Unit starts up, before a Camera Head is connected, to verify that internal electronics are functioning properly. If needed, you can display the Color Bar again from the Camera screen.

To display the Color Bar:

1. Tap the Color Bar icon on the Camera screen [ ].
2. Tap the Color Bar icon again to return close the display.

White Balance

White balancing is performed at the beginning of each procedure. If needed, you can white balance again by tapping the White Balance icon on the Camera screen.

To white balance the camera:

1. Point the Camera Handpiece at a white piece of cotton gauze or bandage.
2. Tap the White Balance icon on the Camera screen [ ].
   The white balance process may take 1-2 seconds.
3. Confirm that the On-Screen Display indicates that the white balance is completed successfully.

If for any reason the White Balance is not completed successfully, the Camera Control Unit will default to a color temperature of 3900 K, appropriate for a VisionScope Endoscope and light source combination. Reasons for unsuccessful white balance include using a target with color other than white, insufficient illumination because the light source is not turned on, or excessive illumination when the tip of the Illumination Sheath is too close to a white reflector.

Centering/Inverting the Image

The Camera screen provides controls for adjusting the image display position.

To move the image: Tap the **Image Centering** buttons (Up/Down/Left/Right arrows)

To rotate the image: Tap the **Rotate** icon [ ] to rotate the image 180°

Loading a Picture Profile

Picture Profiles are preconfigured settings that you can load and use for specific applications. Profiles include camera settings as well as button assignments for the Camera Handpiece controls.

The Camera Control Unit contains eight Picture Profiles: Three standard profiles and five customizable profiles that you can edit for specific applications.

To load a Picture Profile:

1. On the Camera screen, tap the Picture Profile icon [ ].
2. On the Select Custom Picture Profile Settings screen, select a Profile Name from the list. The Profile Settings are displayed.
3. Tap the **Load** button.
   The camera and Camera Handpiece button settings are loaded.
4. Tap the **Back** button to return to the Camera screen.

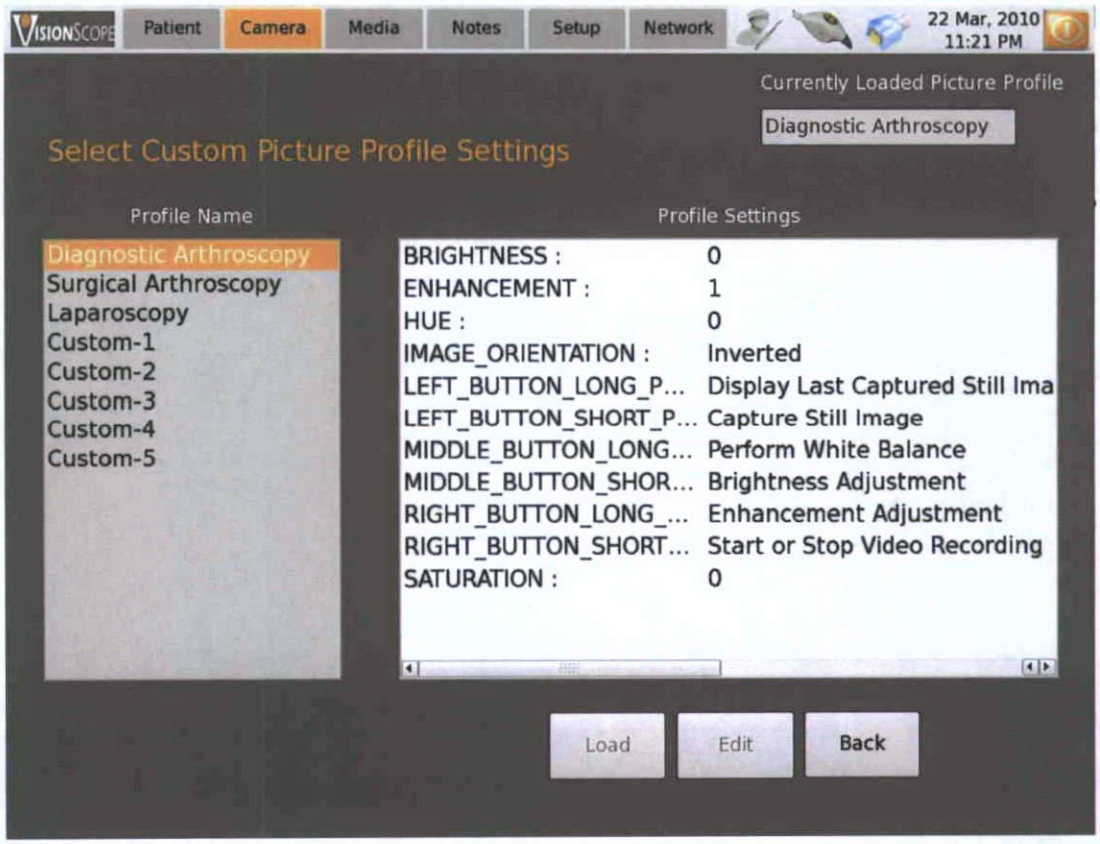


Figure 34 Selecting a Picture Profile

239

Customizing a Picture Profile

The Camera Control Unit provides five customizable Picture Profiles that you can edit for specific applications. By default, these profiles are named Custom 1 through Custom 5 and have the same settings as the Diagnostic Arthroscopy profile.

You can change the Picture Profile Name, the camera settings, and the Camera Handpiece button assignments for the Camera Handpiece controls (see *Adjusting Picture Settings* on page 39 and *Camera Handpiece Layout* on page 12 for more information).

You can also save the current settings for Brightness, Hue, Enhancement, and Saturation by tapping the **Save** button on the Camera screen (*Adjusting Picture Settings* on page 39).

Note: You cannot edit the three standard Picture Profiles (Diagnostic Arthroscopy, Surgical Arthroscopy, and Laparoscopy).

To edit a Custom Picture Profile:

1. On the Camera screen, tap the Picture Profile icon [ ].
2. On the Custom Picture Profile Settings screen, select a Custom Profile to edit.
3. Tap the **Edit** button.
4. (Optional) Enter a new name for the Picture Profile.
5. (Optional) Edit the Brightness, Hue, Enhancement, and Saturation settings.
6. (Optional) Select functions from the pull-down lists for short and long press of the right, left, and middle buttons of the Camera Handpiece. The following functions are available:
   - Capture Still Image
   - Start/Stop Video Recording
   - Brightness Adjustment
   - Contrast Adjustment
   - Perform White Balance
   - Display Last Captured Still Image
7. Tap the **Save** button.
   If you need to restore the default settings, tap the **Reset** button and tap **Yes** to confirm.
8. Tap the **Back** button to return to the Select Profile Settings screen.
9. Tap the **Back** button to return to the Camera screen.

Figure 35 Customizing a Picture Profile

The customized Picture Profile is saved and loaded.

Editing the Surgeon, Procedure, and Patient Lists

From the Patient screen, you can perform the following functions:

- Edit the list of Surgeons
- Edit the list of surgical Procedures
- Delete a Patient registration or restore deleted data that are temporarily held in a retaining area prior to being purged permanently

Note: Before editing the Surgeon, Procedure, or Patient List, you should save any patient data you have entered and finish the current procedure. A message warns you if the current procedure will be closed and any unsaved changes will be lost.

Editing Surgeons

You can add a Surgeon to the Surgeon list. The new Surgeon name will be available from the pull-down list on the Patient screen.

You can edit the name and e-mail address of any Surgeon on the list. You can change a Surgeon password or retrieve a forgotten password. You can activate or inactivate a Surgeon. An inactive Surgeon does not appear in the Surgeon list, but retains Surgeon data in the system and can be activated at any time.

Depending on your system settings, an Administrator password may be required to edit the Surgeon list.

To add a new Surgeon:

1. On the Patient screen, tap the **Edit** button next to the Surgeon field.
2. Tap the **New** button.
3. Enter the new Name, E-mail address, and Password and retype the Password.

4. Select the Activate Surgeon box if you want the Surgeon to appear in the list.
5. Tap the **Save** button.
   The new Surgeon Name appears in the Surgeon list.
6. Tap the **Back** button to return to the Patient screen.

Figure 36 Adding a New Surgeon

To edit a Surgeon's name, e-mail address, activation status, and password:

1. On the Patient screen, tap the **Edit** button next to the Surgeon field.
2. Select a Surgeon from the Surgeon Names list.
3. Tap the **Edit** button.
4. (Optional) Enter the new Name and E-mail.
7. (Optional) Select the Activate/Inactivate Surgeon box to change the Surgeon's status in the Surgeon list.
5. (Optional) Tap the Change Password box. Enter the current Password, enter a new Password, and confirm the new Password by retyping.
6. Tap the **Save** button.
7. Tap the **Back** button to return to the Patient screen.

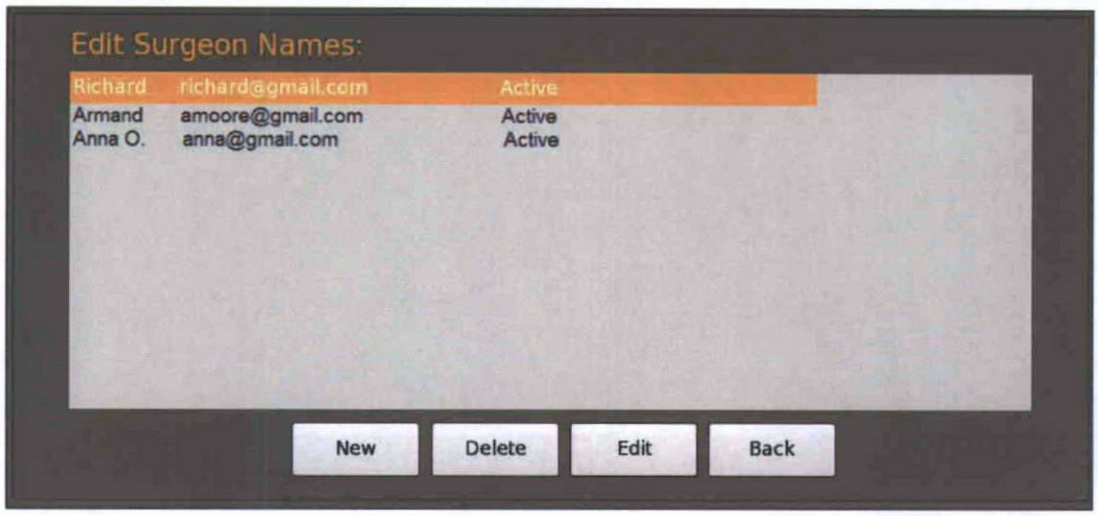


Figure 37 Selecting a Surgeon to Edit

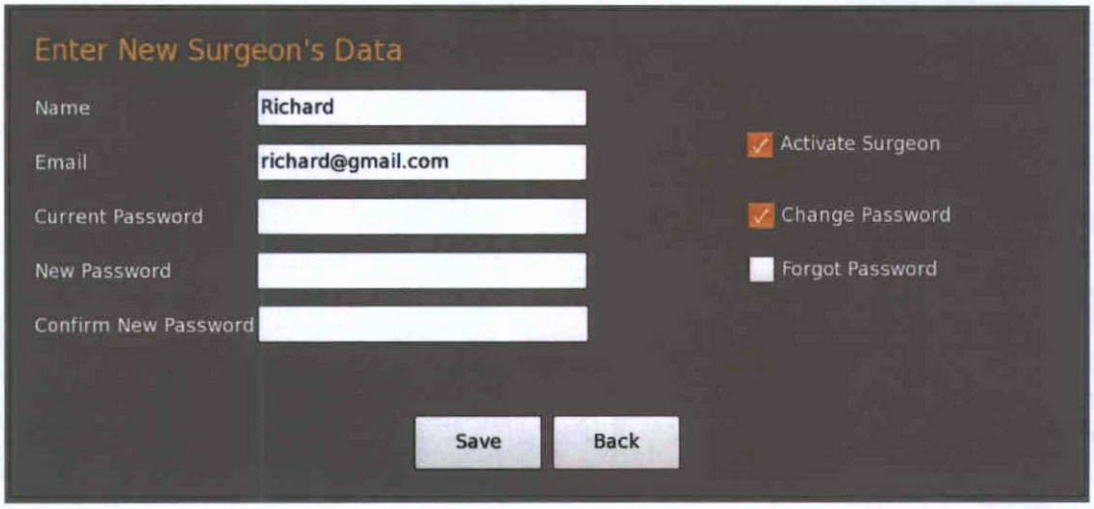


Figure 38 Editing Surgeon data

Retrieving a Forgotten Password

The Camera Control Unit includes a retrieval function in case a Surgeon forgets a password.

To retrieve a password:

1. On the Patient screen, tap the **Edit** button next to the Surgeon field.
2. Select a Surgeon from the list.
3. Tap the **Edit** button.
4. Tap the Change Password box.
5. Tap the Forgot Password box.
6. Enter and confirm the new password.
   (The current password is not required.)
7. Tap the **Back** button to return to the Patient screen.

Figure 39 Retrieving a Forgotten Password

Editing Procedure Names

You can add, edit, or delete Procedure names. Procedure names are fields that Surgeons can select from a pull-down list on the Patient screen to include in Patient Reports.

Depending on your system settings, an Administrator password may be required to edit the Procedure list.

To add a procedure:

1. On the Patient screen, tap the **Edit** button next to the Procedure field.
2. Tap the **New** button.
3. Enter the new Procedure Name.
4. Tap the **Back** button to return to the Patient screen.

To edit a procedure:

1. On the Patient screen, tap the **Edit** button next to the Procedure field.
2. Select the Procedure to edit.
3. Tap the **Edit** button.
4. Enter the new Procedure Name.
5. Tap the **Back** button to return to the Patient screen.

To delete a procedure:

1. On the Patient screen, tap the **Edit** button next to the Procedure field.
2. Select the Procedure to edit.
3. Tap the **Delete** button.
4. Tap the **Yes** button to confirm the deletion.
5. Tap the **Back** button to return to the Patient screen.

Figure 40 Adding, Editing, and Deleting Procedure Names

Deleting a Patient

Deleting a Patient removes all procedures including data, still images, and video recordings for the Patient currently displayed on the Patient screen. Before deleting a Patient, be absolutely sure that the correct patient is selected and that all important data has been backed up.

As protection against accidental data loss, the Camera Control Unit provides a "trash can" that retains the patient data for a specified number of days before deleting it permanently. A Restore function enables you to recover patient data from the trash can, if the Data Retention Period has not been exceeded (see *Patient Data Options* on page 49 for instructions on setting the Data Retention Period.)

Depending on your system settings, an Administrator password may be required to delete Patients.

To delete a patient:

1. On the Patient screen, select the name from the Patient List.
2. Tap the **Delete** button on the Patient screen.
3. Tap the **Yes** button to confirm.

To restore a deleted patient:

1. Tap the **Restore** button on the Patient screen.
2. In the Trash Can list (right side), select the patient you want to restore.
3. Tap the left arrow to move the patient to the Patient List (left side).
4. Tap the **Close** button.

   The patient now appears in the Patient list on the Patient screen.

Figure 41 Restoring Data to the Patient List

Changing the Setup Options

Tap the **Setup** tab to edit optional Camera Control Unit settings. When you finish editing, tap the **Save** button to apply the new settings.

Figure 42 Camera Control Unit Options Setup

Patient Data Options

Patient Data Options	Description
Print Patient File Options	Select from a list of available printers that have been tested to be compatible (see *Printers* on page 53 for more information).
Data Retention Period	Length of time a Patient Record is stored before deletion from hard drive (3 days/5 days/1 week/2 weeks/1 month).

Captured File Options

In many cases, the Camera Control Unit's hard drive will be more than adequate for storing media and data from more than 100 hours of procedures. If necessary, you can set a time limit to save disk space by controlling the maximum length of audio and video recordings. Recording will stop automatically when the time limit is reached.

Captured File Options	Description
Max. MPEG Length	Maximum length for recorded video (2 min/5 min/10 min/15 min/No Limit)
Audio Rec Length	Maximum length for recorded audio (2 min/5 min/10 min/15 min/No Limit)

Surgical Display Options

The On-Screen Display (OSD) superimposes a still image capture counter and "REC" indicator during recording. You can turn the OSD on or off according to your preferences.

Surgical Display Options	Description	Initial Setting
On-Screen Display	On - OSD characters are displayed on the 8" LCD touch screen and in DVI and HD-SDI output to external monitors Off - OSD characters are not visible on any display	On
OSD on Captured Images	ON - OSD characters appear on the captured JPEG or MPEG images during recording and playback OFF - OSD characters are not recorded	Off

Video Options

Use the Video Option to adjust for AC line frequency standards.

Video Options	Description
Video Frequency	Adjust for AC line frequency (50 HZ/60 Hz)

Audio Volume Control

Audio Volume Controls	Description
Record Volume	Adjusts the recording volume (0-100)
Speaker Volume	Adjusts the playback volume (0-100) A control is also available on the Media screen when playing back an audio recording.
Audio Assistant	Disable/enable sounds that provide audio cues during various functions (system startup, camera shutter, etc.)
Test Speaker	Tap the speaker icon to hear the speaker volume setting

Light Control Panel

If the Endoscope will be idle for an extended period, you can place the Light in Standby mode. (Unplugging the Camera Handpiece cable from the receptacle on the Camera Control Unit also places the light in Standby mode.)

Light Control Mode	Description
Normal	LED at full power
Standby	LED reduced to a dim glow

Figure 43 Light Control Panel

System Information

Tap the **System Information** button to see the VisionScope Serial Number, Software Version, Firmware Version, and other related information. Tap the **OK** button to close the dialog box.

Figure 44 System Information

Configuring Network Settings

An icon at the top of the screen indicates the status of the network connection:

Network is connected

Network is not connected

Tap the **Network** tab to configure computer and other system settings. Depending on the Camera Control Unit Network setting, an Administrator password may be required to log into the Network screen.

When you are finished configuring settings on the Network page, tap the **Save** button to apply the new settings. You can also tap the **Cancel** button at any time to exit the Network page without saving changes.

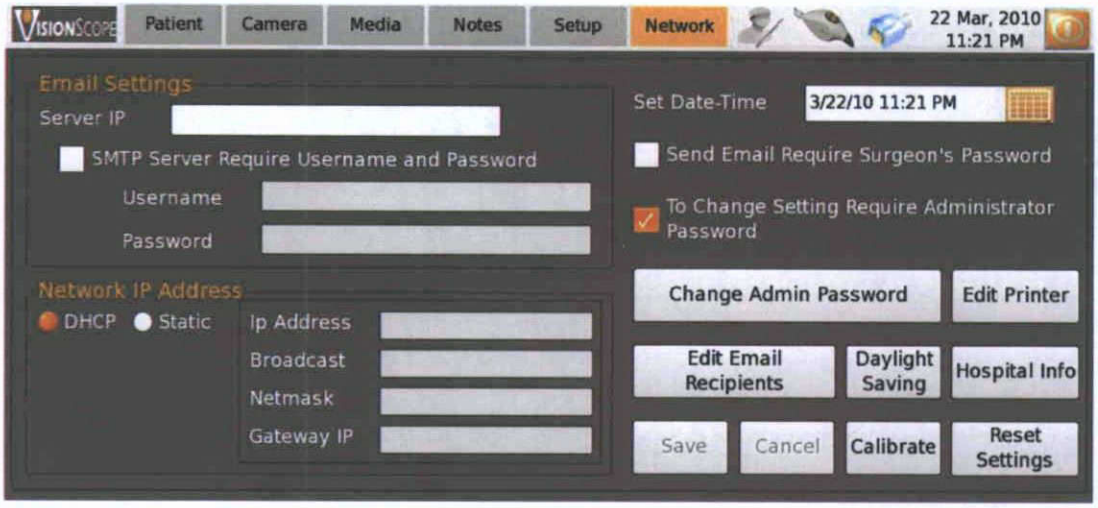


Figure 45 Camera Control Unit Network Screen

E-mail Settings

If you want users to be able to send patient data directly from the Camera Control Unit via e-mail, enter the Server IP of the e-mail server.

To provide access security for the e-mail server, select "SMTP Server requires user name and password" and enter a User Name and Password.

Note: E-mail recipients must be entered in the system before Surgeons can send messages to them (see *E-mail Recipients* on page 53). In addition, you can require a Surgeon password for sending e-mail (see *Passwords* on page 52).

Network IP Address

Select "DHCP" (Dynamic Host Configuration Protocol) if you want a different IP address to be assigned each time the Camera Control Unit connects to the network.

Select "Static" if you want an IT Administrator to assign the IP Address. Enter the IP information (IP Address, Broadcast, Netmask, Gateway IP).

Date and Time

Tap to change the internal clock or calendar.

Passwords

Select the "Send e-mail requires Surgeon's password" box to require a Surgeon password for operations such as e-mailing and copying Patient Reports.

Select the "To change setting requires Administrator password" box to require an Administrator password for logging onto the Network screen. The Administrator password is also required for editing the Surgeon and Procedure Lists

To enter a new Administrator Password:

1. Tap the **Change Admin Password** button.
2. Enter the current Password.
3. Type and retype the new Password.
4. Tap the **Done** button.

Figure 46 Changing Administrator Password

Printers

Tap the **Edit Printer** button to add or remove printers from the Camera Control Unit system or to edit printer settings. Once a printer has been added to the list, it can be selected on the Setup screen for use in printing Patient Reports.

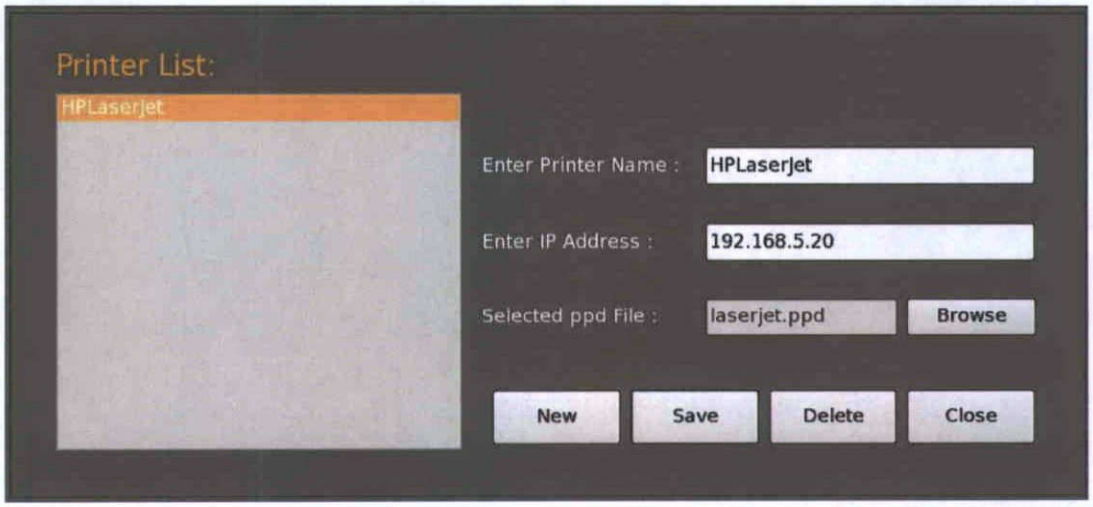


Figure 47 Adding, Deleting, or Editing a Printer

To add a printer:

1. Tap the **New** button.
2. Enter the Printer Name and IP Address.
3. Tap the **Browse** button to locate the Postscript Printer Description (ppd) file.
4. Tap the **Save** button.

5. Tap the **Close** button.

To edit a printer:

1. Select the printer from the Printer List.
2. Enter the Printer Name, IP Address, and ppd file.
3. Tap the **Save** button.
4. Tap the **Close** button.

To delete a printer:

1. Select the printer from the Printer List.
2. Tap the **Delete** button.
3. Verify the deletion.
4. Tap the **Close** button.

E-mail Recipients

Tap the **Edit E-mail Recipients** button to add or remove e-mail addresses from the Camera Control Unit system or to edit e-mail addresses. E-mail recipients will be available from a pull-down list when Surgeons e-mail Patient Reports. To maintain the security and privacy of patient information, only e-mail addresses entered in this list will be available as recipients.

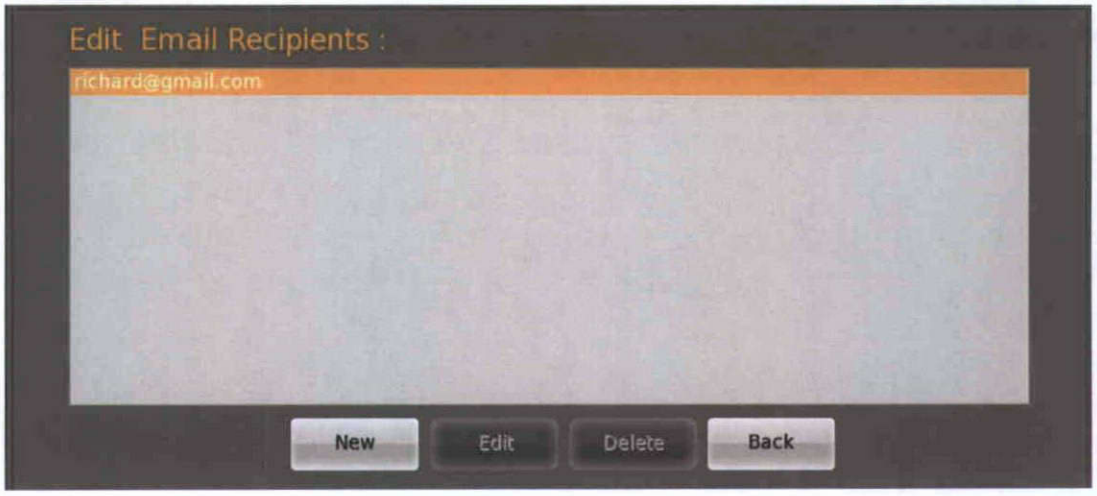


Figure 48 Selecting an E-mail Recipient to Edit

To add an e-mail recipient:

1. Tap the **New** button.
2. Enter the e-mail address in the highlighted field.
3. Tap the **Back** button to return to the Network screen.

To edit an e-mail recipient:

1. Select the recipient from the list.
2. Enter the new e-mail address in the highlighted field.
3. Tap the **Back** button to return to the Network screen.

To delete an e-mail recipient:

1. Select the recipient from the list.
2. Tap the **Delete** button.
3. Tap the **Yes** button to confirm the deletion.
4. Tap the **Back** button to return to the Network screen.

Daylight Savings

Tap the **Daylight Savings** button to enable/disable daylight savings, change the start and end times, and set the time difference. Tap the **Save** button to apply the new settings.

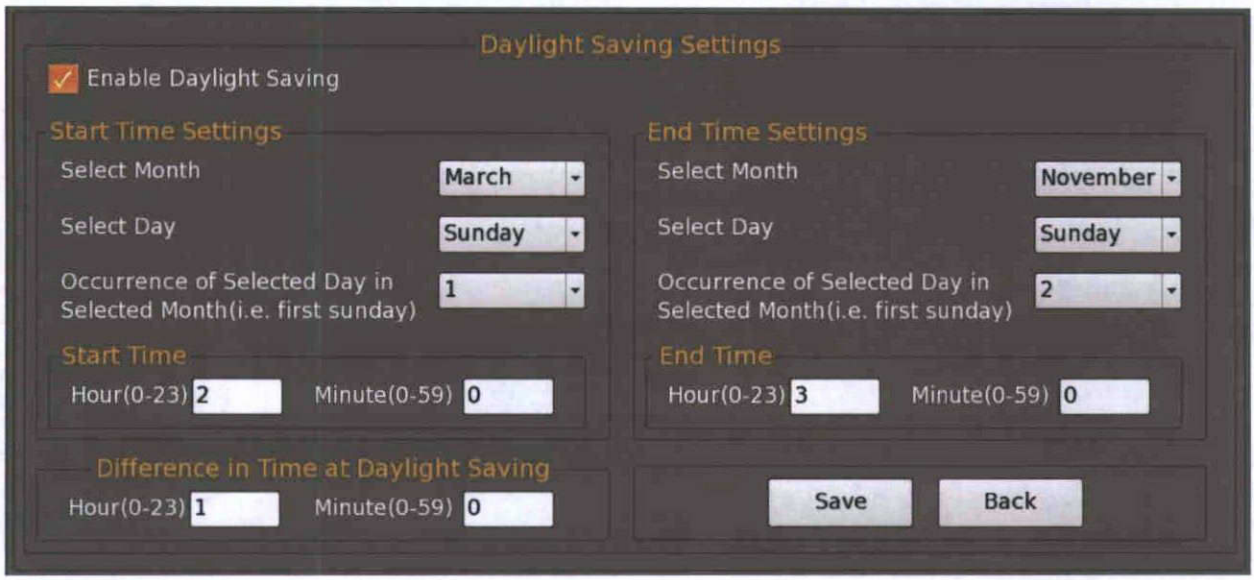


Figure 49 Daylight Savings Settings

Hospital Info

Tap the **Hospital Info** button to enter the name and address of the facility using the Camera Control Unit system. Tap the **Save** button to apply the new settings. The new information will appear in printed reports and e-mails.

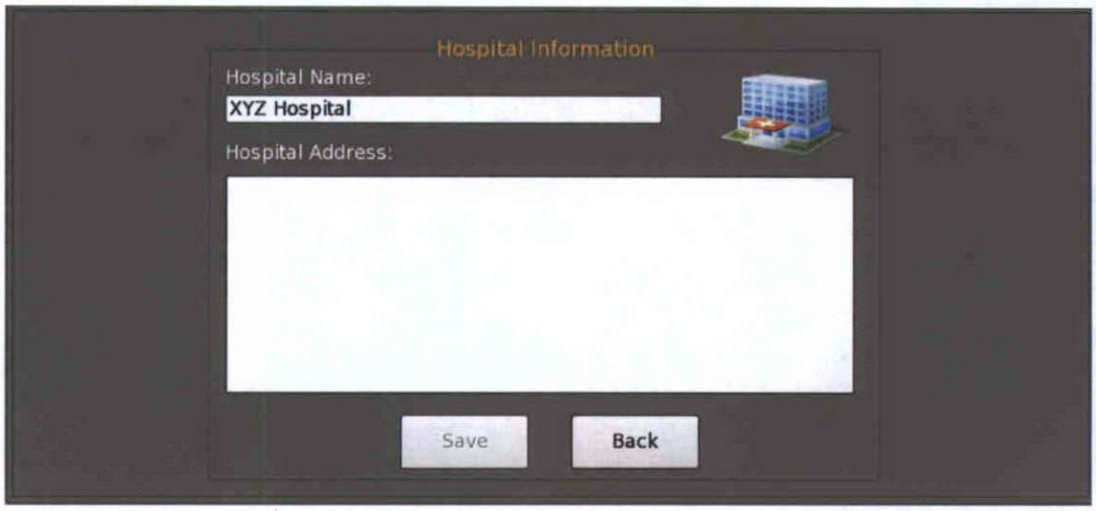


Figure 50 Entering Hospital Information

Touch Screen Calibration

If taps on the screen appear to become inaccurate over time, you may need to calibrate the touch screen. When you calibrate, a series of small targets appear on the screen that you tap with the stylus. The calibration process corrects the alignment of the coordinates in the screen digitizer.

To calibrate the touch screen:

1. Tap the **Calibrate** button on the Network page.
2. Tap the **Yes** button to overwrite the current calibration factor.
3. Using the stylus, tap the target at the center of the crosshairs.
4. Repeat for a total of five different screen positions.
5. Tap the **Yes** button to restart the system.
6. Tap **Restart**.

Reset Settings

Tap the **Reset Settings** button to restore the system to the default configuration. Tap **Shut Down** to restart the Camera Control Unit.

Optional Accessories (Not Supplied by VisionScope)

A medical grade 3 m (9') long power cord (VisionScope Part No. 20079) is supplied with the VisionScope Camera Control Unit as a standard accessory. No other Medical Electrical accessory is supplied. Proper operations with external accessories cannot be guaranteed.

The Camera Control Unit is designed to be able to perform its intended functions, including image acquisition, illumination, image display, patient information and image management, in a standalone manner without any other external peripheral.

To maintain backward compatibility with popular peripherals typically found in Operating Rooms, the Camera Control Unit is equipped with the following connectors on the back of the unit:

- Two HD-SDI connectors and one DVI connector for external medical grade video monitors on video towers or ceiling-mount booms in Operating Rooms.
- Two USB slots and one Ethernet connector for the purpose of system setup, maintenance and service. These slots are normally covered with a metal plate, removable only with a special tool, to prevent their use inside the patient treatment area.

See Figure 2 on page 11 for the rear panel layout of the Camera Control Unit.

⚠ Warning

The use of external accessories including medical grade external monitors or medical grade printers may result in increased Emissions or decrease in Immunity of the VisionScope Camera Control Unit. Non-medical grade external accessories must not be used in the patient environment.

External Monitors

Digital output video bit depth is 10-bit digital video per SMPTE 274M.

DVI-D: One output connector. 1920x1080 progressive scan output, 59.94 Hz/50 Hz. Digital receptacle connector per DDWG DVI spec. The video format follows Section 2-4 of the DDWG DVI spec.

HD-SDI: Two BNC connectors. HD 1080i, 60/50Hz. 60Hz/50Hz conforms to SMPTE 292 and ITU-R BT.709.

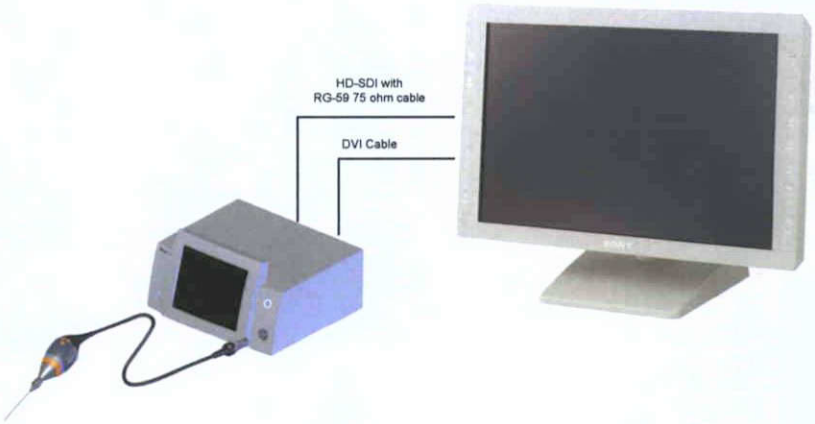


Figure 51 Options for Connecting an External LCD Monitor

Printers (USB and Network)

Two USB ports are provided for connecting medical grade inkjet or laser printers for printing Patient Reports. See *Printers* on page 53 for configuring a printer using the Network screen. Non-medical grade external accessories must not be used in the patient environment.

Network Port

An Ethernet port is provided for connection to a local network by an IT Administrator. See *Configuring Network Settings* on page 51 for configuring the Camera Control Unit to use a network

server for sending Patient Reports via E-mail and for printing Patient Reports to a networked printer. Non-medical grade external accessories must not be used in the patient environment.

Endoscopes

The Camera Handpiece is equipped with an industry-standard "C-Mount" thread that is nominally 1 inch (25.4 mm) in diameter, with 32 threads per inch, designated as "1-32 UN 2A" in the ANSI B1.1 standard for unified screw thread. An appropriately indicated third-party endoscope with C-mount screw thread and adjustable focus may be used with the VisionScope Camera Handpiece and Camera Control Unit. In this application, the VisionScope Disposable Sterile Procedure Kit (VisionScope PN 50033-XXX) cannot be used in conjunction with any third-party endoscope.

⚠ Warning

It is the responsibility of the Operator to ensure that the VisionScope Camera Handpiece and third-party endoscope and light cord are properly sterilized in accordance with the applicable Instructions for Use.

Before each use or after a change of viewing modes/settings, the Operator should check to ensure the view observed through the third party endoscope provides a live image (rather than a stored one) and has the correct image orientation. For instructions on changing from a stored image to a live image, see *Reviewing Media from the Current Procedure* on page 29. For instructions on inverting the image orientation, see *Centering/Inverting the Image* on page 40.

Periodic Maintenance, Cleaning and Sterilization

There are no user-serviceable parts inside any electronics or optical enclosure. The digital electronic circuitry does not require any periodic calibration. The following periodic maintenance or cleaning tasks are recommended. See the Sterilization instructions for the Camera Handpiece and the Endoscope in their respective Instructions for Use documents (PN 01113 and PN 01115).

VisionScope Camera Control Unit	The touch screen should be wiped on a weekly basis with a dry, clean lint-free cotton cloth. Use camera lens cleaning fluid or isopropyl alcohol when appropriate to remove hard-stained fingerprint grease and other smudges. Do not use cleaning fluids that are not compatible with plastics, such as acetone, ammonia or acids.
	The fan filter and ventilation holes on the electronics chassis should be vacuum-cleaned from the exterior surfaces once every six months (or more frequently in a dusty environment) to remove any blockages by lint and dirt.
	Fuses may need to be changed if the unit cannot start due to blown fuses. Caution: To prevent accidental electrical shock, always remove the power cord prior to changing the fuses. Replace the two fuses together in the fuse drawing with T2.0AL, 250 V slow-blow fuses, low breaking capacity (5 mm x 20 mm), Littelfuse slow blow 218 Series or equivalently UL rated fuses.
	Battery for Real Time Clock – If the date or time shown on the Patient Registration page stops running, an authorized technician or staff as approved by the facility's Manager should replace the battery on the

	microprocessor board with a lithium cell, CR1225 or equivalent. Normal battery life is approximately three years or more. To replace the battery, disconnect the AC power cord from the supply main, open the top chassis cover by removing all the screws using a Phillips screwdriver. The battery is located on the top of the video processor board and can be replaced easily.
Hard Disk Drive	The CCU is equipped with a hard disk drive with useable storage capacity in excess of 80 GB. The stored images need to be periodically off-loaded from the CCU (deleted or archived) according to the image retention policy of the facility. When a low-water mark is reached, the microprocessor will display a warning message periodically until the deficiency is corrected. It is the responsibility of the users to ensure that the disk is periodically purged and that there is enough free disk space available for the anticipated work load. Follow the Graphical User Menu on the touch screen and applicable local IT practice to restore the disk capacity.
Camera Handpiece	The window surface on the camera head should be dry and free of foreign objects or smudges in order to produce high quality images. The window should be inspected in between each procedure, and cleaned with a Q-tip wetted with isopropyl alcohol when necessary.
	If the camera head is contaminated with bio-fluid during any procedure, make sure that it is de-contaminated and sterilized after the procedure, following the sterilization steps given in the Instructions for Use manual (PN 01115) and any applicable institutional policy of the facility.
Endoscopes	Window surfaces on the Endoscopes should be dry and free of foreign objects or smudges in order to produce high quality images. The windows on both ends of the Endoscope should be inspected in between each procedure, and cleaned with a Q-tip wetted with isopropyl alcohol when necessary.
	Inspect the needle shaft of the Endoscope between each procedure, to make sure that it is not bent or kinked.
	If the Endoscope is contaminated with bio-fluid during any procedure, make sure that it is de-contaminated and sterilized after the procedure, following the sterilization directions and warnings given in the *Instructions for Use*, PN 01113, and any applicable institutional policy of the facility.

Service, Trouble Shooting, and Replacement

There are no user-serviceable parts except for the fuses and the clock battery. Do not disassemble any electronics assembly or optical instrument. The digital electronics circuitry does not require any periodic calibration.

Some common problems may occur that the end user can easily resolve. Use the following trouble shooting guide to diagnose and correct simple problems. If the problem persists, contact your authorized VisionScope representatives for further consultation or to arrange repair or replacement at an authorized Service Center.

⚠ Warning

Withdraw Endoscope if equipment loses images.

In the unlikely event that the live image is lost during an endoscopic procedure, immediately withdraw the Endoscope and Illumination Sheath from the patient, and follow the appropriate institutional procedures for managing the patient. It is highly recommended that a backup system be available should it be necessary to continue the procedure.

Problem: Image is soft, not clear, out of focus, or fuzzy.

Probable Cause	Possible Solution
Fluid or foreign object on the window of the Illumination Sheath	Clean and dry the exterior window on the Illumination Sheath with sterile surgical cotton gauze.
Fluid or foreign object on the window at the distal tip of the Endoscope	Clean and dry the distal tip window on the Endoscope with sterile surgical cotton gauze.
Fluid or foreign object on the window at the proximal end of the Endoscope	Clean and the proximal end window on the Endoscope with sterile surgical cotton gauze.
Fluid or foreign object on the window on the Camera Handpiece	Clean and dry the window on the Camera Handpiece.
Endoscope is not screwed all the way in the C-mount	Hand-tightened the Endoscope body all the way in the C-mount until the O-ring groove is compressed. Do not over-tighten with a tool.
Endoscope is damaged	Inspect the Endoscope to ensure that there is no play or possible movement between the needle shaft and the Endoscope body.

Problem: Color is not correct: white is not white; background is either too yellowish or too bluish.

Probable Cause	Possible Solution
Improper White Balance	Point the Camera Handpiece and Endoscope at a white background, depress the middle button on the Camera Handpiece for more than one second to perform a White Balance. Confirm from the On-Screen Display message that White Balance is successful.

Problem: Image is dark, image is too bright/showing excess glare, outer edge of the image is cut off or fuzzy, no image on Front Panel touch screen.

Probable Cause	Possible Solution
Illumination Sheath is not attached or aligned correctly.	Attach Illumination Sheath. Check to make sure that the Illumination Sheath is aligned with the Camera Handpiece, to ensure that the light fibers on both parts are in contact with each other.

Light source is turned off.	Check that the light source is turned on from the "Light" menu page.
Camera cable is damaged.	Inspect the cable to see if it is pinched or kinked.
Brightness setting is too low.	Check the "Brightness" setting on the "Camera" tab, increase if necessary.
	Check the "Brightness" or "Contrast" settings on the external monitor; make sure it is not set to a low level.
Light source is blown.	Unplug the Camera Handpiece cable connector, turn the power on, wait until the software starts. Go to the "Light" tab, turn the light source switch on and off. In the "On" position, confirm that there is a light beam exiting the Camera Handpiece connector on the front panel. Caution: do not look directly into the light source. If the light source fails to turn on, contact an authorized VisionScope representative and return the unit for repair.
AC Power Cord is damaged.	Order a replacement Hospital Grade power cord (VisionScope Part No. 20079). Replace if necessary with a three-conductor (AWG 18 minimum, 300 VAC minimum rating), type SJT power cords and plugs.
Endoscope has tunnel vision.	Cannula is not pushed all the way in and locked with the O-ring groove. Push the Cannula all the way back toward the Camera Handpiece.
Power is not on.	Make sure both the power switch on the back panel and the illuminated front panel push button switch are turned on.
Blown fuse	Check and replace both fuses in the fuse drawer on the power entry module.
Microprocessor has stopped working.	Turn off and turn on the power again to re-boot.
Camera cable is not plugged in all the way.	Make sure that the camera cable is pushed all the way into the receptacle on the front panel.

Problem: No image on external LCD monitor (HD-SDI output).

Probable Cause	Possible Solution
External LCD monitor is not compatible with HD-SDI input.	Confirm that the external LCD monitor can support 1920 x 1080i video format per SMTPE 292M standard.
Coaxial cable to LCD monitor is not the correct type.	Use a RG-59 coaxial cable with 75 ohm impedance. LCD may fail to synchronize if a RG-58 50 ohm cable is used.
Coaxial cable is plugged into the wrong connector on the external LCD monitor.	Check to make sure that the coaxial cable is connected to the HD-SDI input, and not to the Composite Video or the HD-SDI output.

Problem: No image on external LCD monitor (DVI output).

Probable Cause	Possible Solution
External LCD monitor is not compatible with 1920 x 1080 interlaced DVI signal	Confirm that the external LCD monitor can support 1920 x 1080 interlace video. Most medical grade surgical monitors can, many consumer grade LCD displays cannot.

Problem: DVI image is compressed in height, with a distorted vertical perspective.

Probable Cause	Possible Solution
External LCD monitor is not compatible with 1920 x 1080 interlaced DVI signal	Confirm that the external LCD monitor can support 1920 x 1080 interlace video. Most medical grade surgical monitors can, many consumer grade LCD displays cannot.

System Specifications

Parameters	**Specifications**
Imaging Functions	All-in-One Camera Control Unit with camera control electronics, light source, image recording and management, and touch screen display
Power Requirements	100 – 240 VAC, 50/60 Hz, 2 A max.
Fuse Ratings	Two, on neutral and live sides, T2.0AL, 250 V, slow blow, low breaking capacity, or Littelfuse Series 218 or equivalent
Camera Control Unit Dimensions	33 cm W x 33 cm W x 20 cm (13" W x 13" D x 8" H)
Camera Control Unit Weight	6 kg (13 lb)
Camera Handpiece Dimensions	7.6 cm L x 4.4 cm W x 5.1 cm H (3" L x 1.75" W x 2" H)
Camera Handpiece Weight	180 grams (0.4 lb)
Image Sensor Type	1920 x 1080 native pixel, ½" 3-chip HDTV CMOS
Imager Sensor Performance	100% digital transmission, Sensitivity = F10, Signal-to-noise ratio >54 db @ 1080 TV lines
HD Video Outputs	1920 x 1080 interlaced on two external HD-SDI and one DVI monitors
Camera Handpiece Cable	3.5 m (11 ft)
Touch Screen Display	21 cm (8.4") diagonal, 1024 x 768 pixels, 400:1 contrast ratio, 400 cd/m^2 brightness
Light Source	Built in white LED with color temperature at 5700 K

Video Capture	1920 x 1080 JPEG, 1280 x 960 MPEG4
Endoscope Optics Mount	Standard C-mount
Disposable Illumination Sheath Mount	Proprietary patent pending bayonet mount for disposable Illumination Sheath
Endoscope and Illumination Sheath Working Lengths	60 mm 95 mm 160 mm 220 mm
Operating Environment	10° C - 40° C 30 - 75 % Relative Humidity, non-condensing Atm. Pressure: 700 hpa -1060 hpa (525 mm Hg - 795 mm Hg)
Transport and Storage Environment	-20° to 60° C 10 – 95 % Relative Humidity, non-condensing Atm. Pressure: 700 hpa -1060 hpa (525 mm Hg - 795 mm Hg)
Medical Device Classifications	US FDA: Class II, per FDA Product Classification Database EU: Class IIa, per "MEDDEV 2.4/1- rev. 8 Part 2, Rule 6 – Surgically invasive device for transient use.
Classification in accordance with IEC60601-1:	According to the type of protection against electric shock: EQUIPMENT energized from an external electrical power source: – CLASS I EQUIPMENT; According to the degree of protection against electric shock: – TYPE CF APPLIED PART. According to the degree of protection against ingress of water as detailed in the current edition of IEC: - Not Protected According to the mode of operation: – CONTINUOUS OPERATION According to the degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE: – EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE;

Electromagnetic Information

Guidance and Manufacturer's Declaration – Electromagnetic Emission		
The VisionScope system is intended to be used in the electromagnetic environment specified below. The users should ensure that it is used under such an environment.		
Emission Test	Compliance	Electromagnetic Environment – Guidance
RF Emission CISPR11	Group 1	The VisionScope System uses RF energy only for its internal functions. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emission CISPR11	Class A	The VisionScope System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emission IEC 61000-3-2	Not applicable	
Voltage Fluctuations/flicker IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration – Separation Distances			
Recommended Separation Distances Between the VisionScope Camera Control Unit and Portable and Mobile RF Communications Equipment			
The VisionScope System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The users of VisionScope can help prevent electromagnetic interference by maintaining a minimum distance between the VisionScope system and portable and mobile RF communications equipment (transmitters) as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter	Separation Distance According to the Frequency of Transmitter (meter)		
	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	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The VisionScope System is intended for use in the electromagnetic environment specified below. The users of the VisionScope System 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	+/- 6 kV contact +/- 8 kV air	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	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	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	+/- 1 kV differential mode +/- 2 kV common mode	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% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec U_T is the a.c. mains voltage prior to application of the test level.	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec U_T is the a.c. mains voltage prior to application of the test level.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the VisionScope System requires continued operation during power mains interruptions, it is recommended that the VisionScope System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

2603

Limited Warranty

VisionScope warrants that the VisionScope products will be free from defects in material and workmanship, when properly installed, stored, maintained, and used for the intended purpose. The warranty period for all products except the Endoscopes is twelve (12) months, and six (6) months for Endoscopes, beginning from the date of invoice. VisionScope's warranty is extended only to the original purchaser of the products at the location where it is originally shipped.

This limited warranty is restricted to repair or replacement by VisionScope, at its option, of any product found to be defective during the warranty period without charge. Damage inflicted to a product by the user may result in additional charges, regardless of the status of warranty.

Any alteration, abuse, misuse, or modification of the product or any component thereof shall void this warranty. This warranty is null and void if the user attempts to service the product or if service is performed by unauthorized third parties. One-time use, disposable sterile products are not covered by this warranty after the first use or after the expiration date.

In no event shall VisionScope be liable for loss of profit, consequential damages, loss of time, or loss of business incurred by the buyer with the purchase or use of any product.

NO OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IS GIVEN.

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13.4 - 01113 - VisionScope Endoscope Instructions for Use

Instructions for Use

PN 01113 Rev 2.3

VISIONSCOPE

Endoscopes

Introduction

VisionScope is an endoscopic imaging system designed to enable pre-operative and post-operative diagnosis in physician examination rooms. The device can also be used in intra-operative procedures in operating rooms where smaller gauge endoscopes are important for minimally invasive surgical procedures. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

The key component of the VisionScope is a 1.4 mm diameter semi-rigid fiber-lens endoscope that fits within a disposable sterile 1.7 mm diameter endoscope sheath (patented), which in turn is small enough to fit through a 2 mm portal or cannula. The disposable endoscope sheath, consisting of an illumination sheath with an integrated camera drape, also acts as a sterile barrier, thereby eliminating the need for full sterilization of the endoscope and camera handpiece following each procedure. VisionScope Technologies is able to miniaturize the endoscope diameter while still providing true High Definition (HD 1080) anatomical visualization, enabling Surgeons to obtain direct visual clinical assessment in a physician examination room without requiring sterilization or bio-hazard processing infrastructure when used as an imaging device alone and without any resection instrument.

Indications for Use

The VisionScope High Definition Endoscopy Camera System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of an interior cavity of the body through a natural or surgical opening. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

Additionally, when used in conjunction with an appropriately indicated and FDA 510(k)-cleared endoscope and light source, the VisionScope High Definition Endoscopy Camera Control Unit and Camera Handpiece are indicated for use in arthroscopic and endoscopic surgical procedures to provide illumination, visualization and capture of still and motion pictures of articular cavities, body cavities, hollow organs and canals.

Intended Users

The VisionScope line of Endoscopes is designed for use by licensed physicians for performing diagnostic or surgical procedures. Physician assistants may assist in the setup of the equipment and preparation of patients.

Contraindications

None Known.

⚠ Warnings

- Read this *Instructions for Use* (PN 01113) completely prior to use.
- Read the *Instructions for Use* for the VisionScope System (PN 01112), VisionScope Camera Handpiece (PN 01115), and Sterile Procedure Kit with Disposable Endoscope Sheath, Cannula, and Trocar (PN 01114) completely prior to use.
- It is the Surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- The VisionScope family of Camera Control Unit, Camera Handpiece, and Endoscope are designed to be used together with one-time use sterile Illumination Sheath with Camera Drape, Cannula, and Trocar to ensure safety and effectiveness. Never mix or substitute any component with any other unauthorized product from any other unauthorized manufacturer.
- This product is shipped non-sterile. It must be used in conjunction of a matching piece of sterile disposable Endoscope Sheath manufactured by VisionScope to ensure sterility.
- WARNING: Disregarding the information on safety of this device is considered ABNORMAL USE.

℞ Precautions

- U.S. Federal law restricts this device to sale by or on the order of a physician.
- When used for diagnostic imaging in a physician examination room singly without accompanying resection or surgical instrument, the Endoscope and the Camera Handpiece must be sheathed with a disposable sterile Illumination Sheath and Camera Drape to avoid infection.
- When used for intra-operative surgical procedure in an Operating Room, the Camera Handpiece and the Endoscope must be sterilized with chemical sterilants (100% Ethylene Oxide (ETO), Sterrad 100S, Sterrad NX, or Sterrad 100 NX). This is to ensure that in the unlikely event that the exterior sterile Endoscope Sheath is accidentally damaged by resection or surgical instruments, the Endoscope and Camera Handpiece will not result in infection.
- Do not autoclave the Camera Handpiece or the Endoscope.
- Prior to each use and insertion into a patient, ensure the system is functioning properly and is producing live video. Inspect the Endoscope, the disposable Endoscope Sheath, Cannula, and Trocar to ensure that the tubes are not bent, the windows are not damaged, and there are no unintended rough surfaces, sharp edges or protrusions which may cause HARM. Do not use a damaged device.
- Handle any exposed sharp needle point at the distal tip of the Trocar, Cannula, and Endoscope with care to avoid accidental injury or contamination.
- To avoid fogging during surgery, the Camera Handpiece and the Endoscope must be dry prior to attaching the one-time-use sterile Illumination Sheath and Camera Drape.
- Do not operate or sterilize an Endoscope that is damaged. Use authorized hospital decontamination procedures to clean the Camera Handpiece and the Endoscope optics prior to returning to the factory for service.
- Review the live video images to ensure that there is no deposit on the optical surfaces prior to a procedure.
- The Endoscope contains plastics, metals, glass, and epoxy material. At the end of the useful life of the Endoscope it should be disposed of in accordance with any applicable national, local or institutional regulation and environmental policy.

Glossary of Symbols

⚠	Attention, Please Read Instructions for Use	℞	U.S. Federal law restricts this device to sale by or on the order of a physician.
	This WEEE symbol indicates that when the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling	CE 0197	CE Mark issued by TUV Rheinland
	Cardiac Floating Symbol, signifying that the equipment has a leakage current of less than 10 μA per IEC60601-1		Electrical Safety Testing Mark by TUV Rheinland of North America, Inc., a test laboratory and notified body
	Split Illumination Icon for aiding alignment of the Illumination Sheath to Camera Handpiece	EC REP	European Representative

Device Description

VisionScope Endoscopes are designed to be used with the VisionScope Camera Handpiece and matched line of Sterile Procedure Kits to provide illumination and access to articular cavities, body cavities, hollow organs, and canals.

Four Endoscopes (60 mm, 95 mm, 160 mm, or 220 mm operating lengths) are available. Endoscopes and Sterile Procedure Kits are color-coded to ensure that the correct components are selected.

Part Number	Description	Functions
50006-060	VisionScope Endoscope for small joint or body cavity, e.g. wrist or ENT. Non-Sterile	A family of four 17-gauge needle Endoscopes with operating lengths of 60 mm, 95 mm, 160 mm and 220 mm, optimized for visualization of of articular or body cavities of different sizes. The innovative optics, working in conjunction with the Camera Handpiece and integrated Camera Control Unit, offers unprecedented light collecting efficiency, contrast resolution, and image clarity. VisionScope endoscopes are compatible with the following sterilization methods: ETO, Sterrad 100S, Sterrad NX. Do not autoclave.
50006-095	VisionScope Endoscope for regular joints or body cavity, e.g. knee or shoulder. Non-Sterile	
50006-160	VisionScope Endoscope for large joint or body cavity, e.g., large Shoulder. Non-Sterile	
50006-220	VisionScope Endoscope for very large or deep body cavity, e.g., hip, abdomen Non-Sterile	

266

Unpacking and Inspection

Figure 1 Marking on Endoscope with Part Number and Serial Number

Prior to using the Endoscopes, inspect the Endoscope for signs of damage, including bent shaft, dented shaft, loose needles, missing glass windows on the distal tip and proximal end. Inspection should include all equipment to be used in performance an imaging procedure, including the Camera Control Unit, the Camera Handpiece, the camera cable and the Endoscopes. Inspection of the disposable devices may be carried out separately by examining the exterior of the Sterile Procedure Kit prior to use.

Check that the O-ring at the base of the Endoscope is in place and undamaged. If damaged or missing, a new O-ring can be ordered through VisionScope Customer Service.

Examine the shipping containers for any sign of external damage. Open the packing boxes containing the Endoscopes and standard accessories. Set up the equipment following the instructions in this document to ensure that they are functional. Contact VisionScope or its authorized sales representatives to report any missing, damaged or non-functional items. Save the carton and packing material in the event that the equipment needs to be returned for repair or exchange.

Performing a Patient Procedure

If VisionScope is prescribed to be used in a diagnostic imaging procedure without any resection tool, the one-time use sterile Illumination Sheath and Camera Drape may be used for protecting the patient as well as the Endoscope and Camera Handpiece from contamination.

⚠ Warning

Reprocessing Requirements of the Endoscope and Camera Handpiece

Procedures with an accompanying in vivo resection tool: If VisionScope is prescribed to be used in a surgical procedure with an in vivo resection tool, the entire Camera Handpiece and the Endoscope must be sterilized before and after each procedure, using one of the sterilization methods specified in the Instructions for Use for the Camera Handpiece and the Endoscope (PN 01113, PN01115), to assure sterility in the unlikely event that the sterile Illumination Sheath or Camera Drape is accidentally damaged by the resection tool.

Diagnostic Imaging Procedures without any other tool: If VisionScope is prescribed to be used in a diagnostic imaging procedure without an in vivo resection tool or any other tool, and if used in conjunction with the VisionScope Disposable Sterile Procedure Kit in accordance with the Instructions for Use (PN 01114), the entire Camera Handpiece and the Endoscope may be used without sterilization but must be disinfected by wiping with a 70% isopropyl alcohol soaked gauze pad before and after each procedure.

Assembling the Endoscope and Camera Handpiece

Use the appropriate Endoscope (60 mm, 95 mm, 160 mm, or 220 mm operating length) for the intended patient procedure (see *Device Description* for part numbers).

⚠ Warning

The Endoscope and Camera Handpiece are non-sterile. Do not handle the Endoscope or Camera Handpiece with gloves that will be used for sterile procedures.

Figure 2 Connecting the Endoscope to the Camera Handpiece

To connect the Endoscope to the Camera Handpiece:

1. Inspect the Camera Handpiece and cable connectors to make sure they are dry.
2. Inspect the window on the Camera Handpiece to make sure it is clean and dry. If necessary, use a lint free cotton cloth, lens tissue paper, or a Q-tip wetted with isopropyl alcohol to remove any dirt and smudge.
3. Select the appropriate Endoscope model with the desired working length.
4. Inspect the Endoscope to make sure that it is dry, the needle is not bent, and the windows on both ends are clean and free of dirt and smudge. Clean if necessary with a lint free cotton wipe or a Q-tip wetted with isopropyl alcohol.
5. Thread the Endoscope into the C-mount on the Camera Handpiece (Figure 2). Hand-tighten the Endoscope to ensure that the O-ring seal is compressed securely. Do not use hand tools to tighten the Endoscope.

⚠ Warning

To verify correct viewing mode and image orientation:

Before each use or after a change of viewing modes/settings, the Operator should check to ensure the view observed through the Endoscope provides a live image (rather than a stored one) and has the correct image orientation. Instructions for changing from a stored image to a live image and instructions for inverting the image orientation are provided in the Instructions for Use for the VisionScope System (PN 01112).

Installing the Endoscope Sheath

The Sterile Procedure Kit includes a Endoscope Sheath to provide illumination for arthroscopic imaging. The Endocope Sheath is made up of an Illumination Sheath with a integrated Camera Drape to enclose the Camera Handpiece and camera cable in a sterile environment.

Physicians, Nurses and Physician Assistants should use their training and preferred surgical techniques for manipulating both sterile and non-sterile components when connecting the Illumination Sheath to the Endoscope and deploying the Camera Drape. In some cases, it may be helpful to lay the camera in a sterile field or have an assistant remove the outer glove.

You must select the correct Sterile Procedure Kit for the installed Endoscope (see *Device Description* fo part numbers). All components are color-coded to indicate their working length.

Figure 3 Sterile Procedure Kit

To connect the Illumination Sheath to the Endoscope:

1. Select a Sterile Procedure Kit (Figure 3) with a disposable Illumination Sheath that has the same working length as the installed Endoscope.
2. Examine the Sterile Procedure Kit to ensure that the seal is not broken and the expiration date has not arrived. Discard the kit if either condition is true.
3. Wear two sterile gloves on the hand that will be used to handle the non-sterile Camera Handpiece. Wear a single sterile glove on the other hand that will be used to handle the Sterile Illumination Sheath.
4. Peel off the lid of the Sterile Procedure Kit.
5. While holding the non-sterile Camera Handpiece in the double-gloved hand, pick up the sterile Illumination Sheath in the single-gloved hand. Make sure the non-sterile (double-gloved) hand does not touch any sterile component, such as the needle on the Illumination Sheath, which will enter the patient.

Figure 4 Inserting the Endoscope into the Illumination Sheath

Figure 5 Rotating the Illumination Sheath 1/4

6. Carefully insert the needle of the Endoscope into the funnel of the Illumination Sheath (Figure 4).
7. Orient the Illumination Sheath so that the Illumination icon on the Illumination Sheath aligns with the Half-Circle icon on the Camera Handpiece and engage the threaded mount.
8. Rotate the Illumination Sheath one-quarter turn in the clockwise direction (Figure 5) until the two Illumination icons align. The fiber optic light guide on the Illumination Sheath is now aligned with the light port on the Camera Handpiece
9. Confirm that a bright light spot is seen at the distal tip of the Endoscope and that an adequately bright image appears on the touch screen LCD or an external monitor (if connected) when the Endoscope is placed within 50 mm of a light color object.

Note: Make sure the Light Control is set to full power (Normal) when verifying the image from the Endoscope.

To deploy the Camera Drape:

1. Using the hand with the single sterile glove, hold the Camera Handpiece/Endoscope assembly by the Illumination Sheath.
2. Using the double-gloved hand, pull back on the deployment cord of the Camera Drape (Figure 6). Continue pulling the cord until the Camera Drape is fully extended and covers both the Camera Handpiece and the camera cable.
3. Peel off the outer glove on the double-gloved hand, touching only the upper part of the glove that has not been contaminated by the Camera Handpiece.

To white balance the camera:

1. Point the Camera Handpiece at a white piece of cotton gauze or bandage. Press the middle button on the Camera Handpiece (pre-programmed by default, unless otherwise changed by the user) that has been pre-programmed to produce a color-balanced image such that the white background is white.

266

2. The whit ıce process may take 1-2 seconds. During this time, holo .. handpiece steady at the white background. Confirm that the On Screen Display indicates that the white balance is completed successfully.

Note: The middle button of the Camera Handpiece is the default setting for white balance. If picture settings have been customized, you may need to use another button to start white balance.

Figure 6 Deploying the Camera Drape

To confirm image clarity of the Endoscope for suitability of re-use prior to each use:

1. After successful white balance, point the Endoscope at a piece of white cotton gauze or bandage at a distance between 4 mm to 25 mm.
2. Confirm that the illumination level is bright, the color is correct, the fabric or threads are in sharp focus, and there is no foreign, nebulous object in the field of view.
3. If the image is not clear or is obstructed, replace the Illumination Sheath and Endoscope until a clear image is observed.

The Camera Handpiece/Endoscope/Illumination Sheath assembly is now ready for surgical insertion. A Cannula and a Trocar with matched working length is provided for Surgeons to gain access to the anatomy.

Inserting the Cannula and Endoscope Assembly

Inserting the Endoscope into a patient requires the disposable sterile Cannula and Trocar included in the Sterile Procedure Kit. The Cannula and the Trocar should be inserted by qualified physicians only.

The Cannula is equipped with a fluid entry port for introducing a small volume (up to 50 ml) of liquid for flushing or drug delivery. An internal O-ring prevents release of fluid through the Cannula. If necessary, loosen the Cannula collar slightly to relax the O-ring seal before inserting the Illumination Sheath and Endoscope.

⚠ Warnings

Prior to each use and insertion into a patient, ensure the system is functioning properly and is producing live video. Inspect the Endoscope, the disposable Illumination Sheath, Cannula and Trocar, to ensure that the tubes are not bent, the windows are not damaged, and there are no unintended rough surfaces, sharp edges or protrusions which may cause HARM. Do not use a damaged device.

Before starting this procedure, verify that the Cannula and Trocar have the same working length as the installed Endoscope and Illumination Sheath. In addition, verify that you are wearing sterile gloves and that the sterile Camera Drape is installed over the Endoscope and Camera Handpiece.

To insert the Cannula and Endoscope:

1. Surgically insert the Cannula/Trocar combination into the patient cavity.
2. Remove the Trocar and discard.
3. Carefully insert the needle of the Endoscope/Illumination Sheath assembly into the funnel of the Cannula (Figure 7). Continue inserting until the entire length of the needle is inserted and the base of the Illumination Sheath fits snugly into the Cannula collar.
4. Rotate the collar on the Cannula until the collar fits snugly on the Cannula body. Tightening this threaded connection compresses an internal O-Ring to prevent any leakage of fluid during the procedure.
5. If the procedure requires fluid injection, connect a syringe to the Cannula via the Luer-Lock port and inject.

Finishing a Patient Procedure

If the proper procedure is followed during assembly and disassembly, the Camera Handpiece and attached Endoscope should be uncontaminated at the end of a procedure and ready for re-use in the next procedure.

Figure 7 Inserting the Endoscope into the Cannula

To complete a procedure:

1. Remove the Endoscope and Cannula from the patient.
2. Turn the Illumination Sheath 90° counter-clockwise to disengage the bayonet mount from the Camera Handpiece C-mount. Carefully slide the Camera Handpiece and the attached Endoscope out of the Illumination Sheath.
3. Carefully back the Camera Handpiece and the attached Endoscope out of the Camera Drape.
4. Set the Camera Handpiece and the attached Endoscope down on a clean, uncontaminated work surface.
5. Dispose of the Illumination Sheath, Camera Drape, Cannula, Trocar, and any other patient-contact accessories or supplies in a bio-hazard waste bin per the hazard waste disposal policy of the facility.
6. **Follow the Reprocessing Requirements of the Endoscope and Camera Handpiece stated previously in this *Instructions for Use*.**
7. If the Camera Handpiece and attached Endoscope have been contaminated during or after a procedure, send the devices through an approved sterilization cycle per the Instructions for Use for those sub-systems (PN 01113 and PN01115). Acceptable sterilization methods include 100% ETO, Sterrad 100, Sterrad NX, or Sterrad 100 NX. Do not autoclave.

Periodic Maintenance, Cleaning and Sterilization

There are no user-serviceable parts inside any electronics or optical enclosure. The following periodic maintenance or cleaning tasks are recommended.

General	Procedures with an accompanying in vivo resection tool: If VisionScope is prescribed to be used in a surgical procedure with an in vivo resection tool, the entire Camera Handpiece and the Endoscope must be sterilized before and after each procedure, using one of the sterilization methods specified in the Instructions for Use for the Camera Handpiece and the Endoscope (PN 01113, PN01115), to assure sterility in the unlikely event that the sterile Illumination Sheath or Camera Drape is accidentally damaged by the resection tool. Diagnostic Imaging Procedures without any other tool: If VisionScope is prescribed to be used in a diagnostic imaging procedure without an in vivo resection tool or any other tool, and if used in conjunction with the VisionScope Disposable Sterile Procedure Kit in accordance with the Instructions for Use (PN 01114), the entire Camera Handpiece and the Endoscope may be used without sterilization but must be disinfected by wiping with a 70% isopropyl alcohol soaked gauze pad before and after each procedure.
Normal Cleaning and Inspection	The two window surfaces on the distal tip and proximal end of the Endoscopes should be dry and free of foreign objects or smudges in order to produce high quality images. These windows should be inspected in between each procedure, and cleaned with a Q-tip wetted with isopropyl alcohol when necessary.
	Inspect the needle shaft of the Endoscopes between each procedure, to make sure that it is not bent or kinked.
Deep Cleaning	VisionScope Endoscopes may be immersed in water for deep cleaning. Scrub each of the window surfaces with a 4" x 4" cotton surgical gauze pad soaked in enzymatic solution recommended for reprocessing of medical Endoscopes prepared in accordance with the manufacturers' instruction, when needed to break down any organic material. Rinse thoroughly with distilled or de-ionized water. Scrub again each of the window surfaces with a 4" x 4" cotton surgical gauze pad soaked in isopropyl alcohol. Rinse thoroughly with distilled or de-ionized water. Dry thoroughly. Use a clean, dry, lint-free cotton cloth to wipe the window surfaces to remove any streak residue. Caution: do not use any ultrasonic cleaning methods, as the energy will damage seals and optical surfaces and will void the warranty.
Sterilization	If the Endoscope is contaminated with bio-fluid during any procedure, make sure that it is de-contaminated and sterilized after the procedure. VisionScope Endoscopes may be sterilized with any of the following methods. • Sterrad 100S Sterilization System: Follow all directions and warnings from the Manufacturer. Put only one camera handpiece and one endoscope per tray. • Sterrad NX and Sterrad 100 NX Sterilization System: Follow all directions and warnings from the Manufacturer. Put only one camera handpiece and one endoscope per tray. • 100% ETO - Follow standard hospital procedures maintaining the following parameters: Temperature 55° C ± 3° C (131° F ± 5° F) Relative humidity >50% Gas concentration 725 mg/l Exposure time 60 minutes Aeration 11 hours minimum Caution: Disinfection is not a substitute for sterilization. VisionScope Endoscopes are not designed to be autoclaved.

Service, Troubleshooting, and Replacement

There are no user-serviceable parts. Do not disassemble any electronics assembly or optical instrument.

Some common problems may occur that the end user can easily resolve. Use the following trouble shooting guide to diagnose and correct simple problems. If the problem persists, contact your authorized VisionScope representatives for further consultation or to arrange repair or replacement at an authorized Service Center.

⚠ Warning

Withdraw Endoscope if equipment loses images.

In the unlikely event that the live image is lost during an endoscopic procedure, immediately withdraw the Endoscope and Illumination Sheath from the patient, and follow the appropriate institutional procedures for managing the patient. It is highly recommended that a backup system be available should it be necessary to continue the procedure.

Common Problem: Image is soft, not clear, out of focus, or fuzzy.

Probable Cause	Possible Solution
Fluid or foreign object on window of Illumination Sheath	Clean and dry the exterior window on the Illumination Sheath with sterile surgical cotton gauze.
Fluid or foreign object on window at distal tip of Endoscope	Clean and dry the distal tip window on the Endoscope with sterile surgical cotton gauze.
Fluid or foreign object on window at proximal end of Endoscope	Clean and the proximal end window on the Endoscope with sterile surgical cotton gauze.
Fluid or foreign object on window on Camera Handpiece	Clean and dry the window on the Camera Handpiece.
Endoscope not screwed all the way in C-mount	Hand-tightened the Endoscope body all the way in the C-mount until the O-ring groove is compressed. Do not over-tighten with a tool.
Endoscope is damaged	Inspect the Endoscope to ensure that there is no play or possible movement between the needle shaft and the Endoscope body.

Common Problem: Image is dark.

Probable Cause	Possible Solution
Fluid or foreign object on window of Illumination Sheath	Clean and dry the exterior window on the Illumination Sheath with sterile surgical cotton gauze.
Fluid or foreign object on the window at the proximal end of the Endoscope	Clean and the proximal end window on the Endoscope with sterile surgical cotton gauze.
Fluid or foreign object on window of Camera Handpiece	Clean and dry the window on the Camera Handpiece.
Endoscope is not screwed all the way in the C-mount.	Hand-tightened the Endoscope body all the way in the C-mount until the O-ring groove is compressed. Do not over-tighten with a tool.
Endoscope is damaged.	Inspect the Endoscope to ensure that there is no play or possible movement between the needle shaft and the Endoscope body.
Illumination Sheath is not attached or aligned correctly.	Attach Illumination Sheath. Check to make sure that the Illumination Sheath is aligned with the Camera Handpiece, to ensure that the light fibers on both parts are in contact with each other.
Light source is turned off.	Check that the light source is turned on from the "Light" menu page.
Camera cable is damaged.	Inspect the cable to see if it is pinched or kinked.
Brightness setting is too low.	Check the "Brightness" setting on the "Camera" tab, increase if necessary.
	Check the "Brightness" or "Contrast" settings on the external monitor, make sure it is not set to a low level.
Light source is blown.	Unplug the Camera Handpiece cable connector, turn the power on, wait until the software starts. Go to the "Light" tab, turn the light source switch on and off. In the "On" position, confirm that there is a light beam exiting the Camera Handpiece connector on the front panel. Caution: do not look directly into the light source. If the light source fails to turn on, contact an authorized VisionScope representative and return the unit for repair.

Endoscope Specifications

Part Numbers	50006-060, 50006-095, 50006-160, 50006-220
Working Lengths	60 mm 95 mm 160 mm 220 mm
Needle Diameter	1.4 mm (17 gauge)
Field of View	75° in air
Focus Distance	8.5 mm nominal from distal tip of window
Depth of Field	4 mm to 25 mm
Weight	36 g max. (1.3 oz)
Sterilization Compatibility	100% ETO, Sterrad 100S, Sterrad NX, Sterrad 100NX
Operating Environment	10° C - 40° C / 30 - 75 % Relative Humidity, non-condensing Atm. Pressure: 700 hpa -1060 hpa (525 mm Hg - 795 mm Hg)
Transport and Storage Environment	-20° to 60° C / 10 – 95 % Relative Humidity, non-condensing Atm. Pressure: 700 hpa -1060 hpa (525 mm Hg - 795 mm Hg)
Regulatory Classifications	US FDA: Class II, per FDA Product Classification Database EU: Class IIa, per "MEDDEV 2.4/1- rev. 8 Part 2, Rule 6 – Surgically invasive device for transient use.
Classification in accordance with IEC60601-2-18	Protection against electric shock: Type CF Applied Parts

Limited Warranty

VisionScope warrants that the VisionScope products will be free from defects in material and workmanship, when properly installed, stored, maintained, and used for the intended purpose. The warranty period for all products except the Endoscopes is twelve (12) months, and six (6) months for Endoscopes, beginning from the date of invoice. VisionScope's warranty is extended only to the original purchaser of the products at the location where it is originally shipped.

This limited warranty is restricted to repair or replacement by VisionScope, at its option, of any product found to be defective during the warranty period without charge. Damage inflicted to a product by the user may result in additional charges, regardless of the status of warranty.

Any alteration, abuse, misuse, or modification of the product or any component thereof shall void this warranty. This warranty is null and void if the user attempts to service the product or if service is performed by unauthorized third parties. One-time use, disposable sterile products are not covered by this warranty after the first use or after the expiration date.

In no event shall VisionScope be liable for loss of profit, consequential damages, loss of time, or loss of business incurred by the buyer with the purchase or use of any product.

NO OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IS GIVEN.

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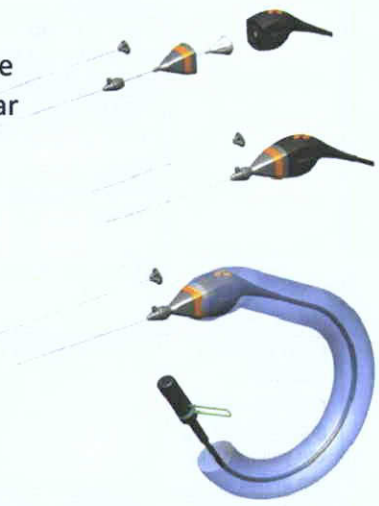
13.5 - 01114 - VisionScope Sterile Procedure Kit Instructions for Use

Instructions for Use

VISIONSCOPE

Sterile Procedure Kit
with Disposable Endoscope
Sheath, Cannula, and Trocar

PN 01114 Rev 2.3



Introduction

VisionScope is an endoscopic imaging system designed to enable pre-operative and post-operative diagnosis in physician examination rooms. The device can also be used in intra-operative procedures in operating rooms where smaller gauge endoscopes are important for minimally invasive surgical procedures. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

The key component of the VisionScope is a 1.4 mm diameter semi-rigid fiber-lens endoscope that fits within a disposable sterile 1.7 mm diameter endoscope sheath (patented), which in turn is small enough to fit through a 2 mm portal or cannula. The disposable endoscope sheath, consisting of an illumination sheath with an integrated camera drape, also acts as a sterile barrier, thereby eliminating the need for full sterilization of the endoscope and camera handpiece following each procedure. VisionScope Technologies is able to miniaturize the endoscope diameter while still providing true High Definition (HD 1080) anatomical visualization, enabling Surgeons to obtain direct visual clinical assessment in a physician examination room without requiring sterilization or bio-hazard processing infrastructure when used alone as an imaging device and without any resection instrument.

Indications for Use

The VisionScope High Definition Endoscopy Camera System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of an interior cavity of the body through a natural or surgical opening. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

Additionally, when used in conjunction with an appropriately indicated and FDA 510(k)-cleared endoscope and light source, the VisionScope High Definition Endoscopy Camera Control Unit and Camera Handpiece are indicated for use in arthroscopic and endoscopic surgical procedures to provide illumination, visualization and capture of still and motion pictures of articular cavities, body cavities, hollow organs and canals.

Intended Users

The VisionScope system is designed for use by licensed physicians for performing diagnostic or surgical procedures. Physician assistants may assist in the setup of the equipment and preparation of patients.

Contraindications

None Known.

Glossary of Symbols

- Attention, Please Read Instructions for Use
- CE Mark issued by TUV Rheinland
- This WEEE symbol indicates that when the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling.
- Electrical Safety Testing Mark by TUV Rheinland of North America, Inc., a test laboratory and notified body.
- Cardiac Floating Symbol, signifying that the equipment has a leakage current of less than 10 µA per IEC60601-1
- EC REP — European Representative
- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Split Illumination icon for aiding alignment of Illumination Sheath to Camera Handpiece

Warnings

- Read this *Instructions for Use (PN 01114)* for this Sterile Procedure Kit with Endoscope Sheath, Cannula, and Trocar completely prior to use.
- Read the *Instructions for Use* for the associated VisionScope Endoscopes (PN 01113), Camera Handpiece (PN 01115) and VisionScope System (PN 01112) completely prior to use.
- Read the expiration date printed on the Sterile Procedure Kit prior to use. Inspect the seal on the sterile tray before use to ensure that it is sealed and that it has never been peeled before. Discard any sterile Kit with an expired date code or a broken seal in accordance with institutional policy.
- This Kit is designed for one-time use only. Dispose the entire content of the Sterile Procedure Kit after a single procedure following the institutional policy related to bio-hazard waste disposal.
- It is the Surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- The VisionScope family of Camera Control Unit, Camera Handpiece, and Endoscope are designed to be used together with one-time use sterile Illumination Sheath with Camera Drape, Cannula, and Trocar to ensure safety and effectiveness. Never mix or substitute any component with any other unauthorized product from any other unauthorized manufacturer.
- To ensure safety and effectiveness, do not re-process and re-use any product that is designed for one-time use only.
- WARNING: Disregarding the information on safety of this device is considered ABNORMAL USE.

Precautions

- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Prior to each use and insertion into a patient, ensure the system is functioning properly and is producing live video. Inspect the Endoscope, the disposable Illumination Sheath, Cannula and Trocar, to ensure that the tubes are not bent, the windows are not damaged, and there are no unintended rough surfaces, sharp edges or protrusions which may cause HARM. Do not use a damaged device.
- Handle any exposed sharp needle point at the distal tip of the Trocar, Cannula, and Endoscope with care to avoid accidental injury or contamination.
- This equipment contains plastics, metals, and epoxy material. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national, local or institutional regulation and environmental policy.

Device Description

VisionScope Sterile Procedure Kits are one-time use, disposable pre-sterilized components designed to be used with the VisionScope Camera Handpiece and matched line of Endoscopes to provide illumination and access to articular cavities, body cavities, hollow organs, and canals. The Illumination Sheath and Camera Drape also act as a sterile barrier.

Four Sterile Procedure Kits (60 mm, 95 mm, 160 mm or 220 mm operating lengths) are available. Sterile Procedure Kits and Endoscopes are color-coded to ensure that the correct components are selected.

Figure 1 Markings on the Disposable Illumination Sheath

Part Number	Description	Functions
50033-060	Sterile Procedure Kit for small joint or body cavity, e.g., wrist, ENT.	Sterile kit containing a matched set of one-time use components for supporting a procedure requiring a working length of 60 mm: • one Illumination Sheath with integrated Camera Drape • one Cannula • one Trocar
50033-095	Sterile Procedure Kit for regular joint or body cavity, e.g., knee and shoulder	Sterile Kit containing a matched set of one-time use components for supporting a procedure requiring a working length of 95 mm: • one Illumination Sheath with integrated Camera Drape • one Cannula • one Trocar
50033-160	Sterile Procedure Kit for large joint or cavity, e.g., large shoulders	Sterile Kit containing a matched set of one-time use components for supporting a procedure requiring a working length of 160 mm: • one Illumination Sheath with integrated Camera Drape • one Cannula • one Trocar
50033-220	Sterile Procedure Kit for very large joint or deep body cavity, e.g, hip or large abdomen	Sterile Kit containing a matched set of one-time use components for supporting a procedure requiring a working length of 220 mm: • one Illumination Sheath with integrated Camera Drape • one Cannula • one Trocar

Unpacking and Inspection

Prior to using the VisionScope Sterile Procedure Kit, examine the shipping container for any sign of external damage. Make sure that the shipping box and the sealed Tyvek tray are not punctured or crushed. Visually look through the transparent plastic tray to ensure that no component is missing from the contoured interior compartments.

Read the Expiration Date on the top cover of the tray. Do not use the unit if the expiration date has passed.

Contact VisionScope or its authorized sales representatives to report any missing, damaged or non-functional items. Save the carton and packing material in the event that the equipment needs to be returned for repair or exchange.

Performing a Patient Procedure

If VisionScope is prescribed to be used in a diagnostic imaging procedure without any resection tool, the one-time use sterile Illumination Sheath and Camera Drape may be used for protecting the patient as well as the Endoscope and Camera Handpiece from contamination.

Warning

Reprocessing Requirements of the Endoscope and Camera Handpiece

Procedures with an accompanying in vivo resection tool: If VisionScope is prescribed to be used in a surgical procedure with an in vivo resection tool, the entire Camera Handpiece and the Endoscope must be sterilized before and after each procedure, using one of the sterilization methods specified in the Instructions for Use for the Camera Handpiece and the Endoscope (PN 01113, PN01115), to assure sterility in the unlikely event that the sterile Illumination Sheath or Camera Drape is accidentally damaged by the resection tool.

Diagnostic Imaging Procedures without any other tool: If VisionScope is prescribed to be used in a diagnostic imaging procedure without an in vivo resection tool or any other tool, and if used in conjunction with the VisionScope Disposable Sterile Procedure Kit in accordance with the Instructions for Use (PN 01114), the entire Camera Handpiece and the Endoscope may be used without sterilization but must be disinfected by wiping with a 70% isopropyl alcohol soaked gauze pad before and after each procedure.

Installing the Endoscope Sheath

The Sterile Procedure Kit includes a Illumination Sheath to provide illumination for arthroscopic imaging. The Illumination Sheath is equipped with a Camera Drape to enclose the Camera Handpiece and camera cable in a sterile environment.

Physicians should use their preferred surgical techniques for manipulating both sterile and non-sterile components when connecting the Illumination Sheath to the Endoscope and deploying the Camera Drape. In some cases, it may be helpful to lay the camera in a sterile field or have an assistant remove the outer glove.

You must select the correct Sterile Procedure Kit for the installed Endoscope (see *Device Description* for part numbers). All components are color-coded to indicate their working length.

Figure 2 Sterile Procedure Kit

Figure 3 Inserting the Endoscope into the Illumination Sheath

Figure 4 Rotating the Illumination Sheath 1/4

To connect the Illumination Sheath to the Endoscope:

1. Select a Sterile Procedure Kit (Figure 2) with a disposable Illumination Sheath that has the same working length as the installed Endoscope.
2. Examine the Sterile Procedure Kit to ensure that the seal is not broken and the expiration date has not arrived. Discard the kit if either condition is true.
3. Wear two sterile gloves on the hand that will be used to handle the Camera Handpiece. Wear a single sterile glove on the other hand that will be used to handle the Illumination Sheath.
4. Peel off the lid of the Sterile Procedure Kit.
5. While holding the non-sterile Camera Handpiece in the double-gloved hand, pick up the sterile Illumination Sheath in the single-gloved hand. Make sure the non-sterile (double-gloved) hand does not touch any sterile component, such as the needle on the Illumination Sheath, which will enter the patient.
6. Carefully insert the needle of the Endoscope into the funnel of the Illumination Sheath (Figure 3).
7. Orient the Illumination Sheath so that the Light icon on the Illumination Sheath aligns with the Half-Circle icon on the Camera Handpiece and engage the threaded mount.
8. Rotate the Illumination Sheath one-quarter turn in the clockwise direction (Figure 4) until the two Light icons align. The fiber optic light guide on the Illumination Sheath is now aligned with the light port on the Camera Handpiece
9. Confirm that a bright light spot is seen at the distal tip of the Endoscope and that an adequately bright image appears on the touch screen LCD or an external monitor (if connected) when the

Endosco[illegible] [illegible]aced within 50 mm of a light color object.

Note: Make sure the Light Control is set to Normal mode (full power) when verifying the image from the Endoscope.

Figure 5 Deploying the Camera Drape

To deploy the Camera Drape:

1. Using the hand with the single sterile glove, hold the Camera Handpiece/Endoscope assembly by the Illumination Sheath.
2. Using the double-gloved hand, pull back on the deployment cord of the Camera Drape (Figure 5). Continue pulling the cord until the Camera Drape is fully extended and covers both the Camera Handpiece and the camera cable.
3. Peel off the outer glove on the double-gloved hand, touching only the upper part of the glove that has not been contaminated by the Camera Handpiece.

To white balance the camera:

1. Point the Camera Handpiece at a white piece of cotton gauze or bandage. Press the middle button on the Camera Handpiece (pre-programmed by default, unless otherwise changed by the user) that has been pre-programmed to produce a color-balanced image such that the white background is white.
2. The white balance process may take 1-2 seconds. During this time, hold the handpiece steady at the white background. Confirm that the On Screen Display indicates that the white balance is completed successfully.

Note: The middle button of the Camera Handpiece is the default setting for white balance. If picture settings have been customized, you may need to use another button to start white balance.

To confirm image clarity of the Endoscope for suitability of reuse prior to each use:

1. After successful white balance, point the Endoscope at a piece of white cotton gauze or bandage at a distance between 4 mm to 25 mm.
2. Confirm that the illumination level is bright, the color is correct, the fabric or threads are in sharp focus, and there is no foreign, nebulous object in the field of view.
3. If the image is not clear or is obstructed, replace the Illumination Sheath and Endoscope until a clear image is observed.

The Camera Handpiece/Endoscope/Illumination Sheath assembly is now ready for surgical insertion. A Cannula and a Trocar with matched working length is provided for Surgeons to gain access to the anatomy.

Inserting the Cannula and Endoscope Assembly

Inserting the Endoscope into a patient requires the disposable sterile Cannula and Trocar included in the Sterile Procedure Kit. The Cannula and the Trocar should be inserted by qualified physicians only.

The Cannula is equipped with a fluid entry port for introducing a small volume (up to 50 ml) of liquid for flushing or drug delivery. An internal O-ring prevents release of fluid through the Cannula. If necessary, loosen the Cannula collar slightly to relax the O-ring seal before inserting the Illumination Sheath and Endoscope.

⚠ Warnings

Prior to each use and insertion into a patient, ensure the system is functioning properly and is producing live video. Inspect the Endoscope, the disposable Illumination Sheath, Cannula and Trocar, to ensure that the tubes are not bent, the windows are not damaged, and there are no unintended rough surfaces, sharp edges or protrusions which may cause HARM. Do not use a damaged device.

Before starting this procedure, verify that the Cannula and Trocar have the same working length as the installed Endoscope and Illumination Sheath. In addition, verify that you are wearing sterile gloves and that the sterile Camera Drape is installed over the Endoscope and Camera Handpiece.

To insert the Cannula and Endoscope:

1. Surgically insert the Cannula/Trocar combination into the patient cavity.
2. Remove the Trocar and discard.
3. Carefully insert the needle of the Endoscope/Illumination Sheath assembly into the funnel of the Cannula (Figure 6). Continue inserting until the entire length of the needle is inserted and the base of the Illumination Sheath fits snugly into the Cannula collar.

Figure 6 Inserting the Endoscope into the Cannula

4. Rotate the collar on the Cannula until the collar fits snugly on the Cannula body. Tightening this threaded connection compresses an internal O-Ring to prevent any leakage of fluid during the procedure.
5. If the procedure requires fluid injection, connect a syringe to the Cannula via the Luer-Lock port and inject.

Finishing a Patient Procedure

If the proper procedure is followed during assembly and disassembly, the Camera Handpiece and attached Endoscope should be uncontaminated at the end of a procedure and ready for re-use in the next procedure.

To complete a procedure:

1. Remove the Endoscope and Cannula from the patient.
2. Turn the Illumination Sheath 90° counterclockwise to disengage the bayonet mount from the Camera Handpiece C-mount. Carefully slide the Camera Handpiece and the attached Endoscope out of the Illumination Sheath.
3. Carefully back the Camera Handpiece and the attached Endoscope out of the Camera Drape.
4. Set the Camera Handpiece and the attached Endoscope down on a clean, uncontaminated work surface.
5. Dispose of the Illumination Sheath, Camera Drape, Cannula, Trocar, and any other patient-contact accessories or supplies in a bio-hazard waste bin per the hazard waste disposal policy of the facility.
6. **Follow the Reprocessing Requirements of the Endoscope and Camera Handpiece stated previously in this *Instructions for Use*.**
7. If the Camera Handpiece and attached Endoscope have been contaminated during or after a procedure, send the devices through an approved sterilization cycle per the Instructions for Use for those sub-systems (PN 01113 and PN01115). Acceptable sterilization methods include 100% ETO, Steris System 1, Sterrad 100, Sterrad NX, or Sterrad 100 NX. Do not autoclave.

Storage and Maintenance

Individual boxes of the Sterile Procedure Kit, once removed from the bulk shipping containers, should be stored inside a cabinet such that they will not be crushed. The boxes should preferably be stored in a temperature and humidity controlled environment in a clinic, surgery center or hospital.

There is no user-serviceable part inside the Sterile Procedure Kit. No periodic maintenance is needed. Do not peel open the sterile seal until immediately before a procedure.

Service, Trouble Shooting, and Replacement

Some common problems may occur that the end user can easily resolve. Use the following trouble shooting guide to diagnose and correct simple problems. If the problem persists, contact your authorized VisionScope representatives for further consultation or to arrange repair or replacement at an authorized Service Center.

⚠ Warning

Withdraw Endoscope if equipment loses Images.

In the unlikely event that the live image is lost during an endoscopic procedure, immediately withdraw the Endoscope and Illumination Sheath from the patient, and follow the appropriate institutional procedures for managing the patient. It is highly recommended that a backup system be available should it be necessary to continue the procedure.

Common Problem	Probable Cause	Possible Solution
Image is soft, not clear, out of focus or fuzzy	Fluid or foreign object on the window of the Illumination Sheath	Clean and dry the exterior window on the Illumination Sheath with sterile surgical cotton gauze.
	Fluid or foreign object on the window at the distal tip of the Endoscope	Clean and dry the distal tip window on the Endoscope with sterile surgical cotton gauze.
	Fluid or foreign object on the window at the proximal end of the Endoscope	Clean and the proximal end window on the Endoscope with sterile surgical cotton gauze.
	Fluid or foreign object on the window on the Camera Handpiece	Clean and dry the window on the Camera Handpiece.
	Endoscope is not screwed all the way in the C-mount.	Hand-tightened the Endoscope body all the way in the C-mount until the O-ring groove is compressed. Do not over-tighten with a tool.
	Endoscope is damaged.	Inspect the Endoscope to ensure that there is no play or possible movement between the needle shaft and the Endoscope body.
Color is not correct: white is not white; background is either too yellowish or too bluish	Improper White Balance	Point the Camera Handpiece and Endoscope at a white background, depress the middle button on the Camera Handpiece for more than one second to perform a White Balance. Confirm from the On Screen Display message that White Balance is successful.
Image is dark	Illumination Sheath is not attached or aligned correctly.	Attach Illumination Sheath. Check to make sure that the Illumination Sheath is aligned with the Camera Handpiece, to ensure that the light fibers on both parts are in contact with each other.
	Light source is turned off.	Check that the light source is turned on from the "Light" menu page.
	Camera cable is damaged.	Inspect the cable to see if it is pinched or kinked.
	Brightness setting is too low.	Check the "Brightness" setting on the "Camera" tab, increase if necessary.
		Check the "Brightness" or "Contrast" settings on the external monitor, make sure it is not set to a low level.
	Light source is blown.	Unplug the Camera Handpiece cable connector, turn the power on, wait until the software starts. Go to the "Light" tab, turn the light source switch on and off. In the "On" position, confirm that there is a light beam exiting the Camera Handpiece connector on the front panel. Caution: do not look directly into the light source. If the light source fails to turn on, contact an authorized VisionScope representative and return the unit for repair.
Image is too bright/showing excess glare	Brightness setting is too low.	Check the "Brightness" setting on the "Camera" tab, decrease if necessary.
		Check the "Brightness" or "Contrast" settings on the external monitor, make sure it is not set to a high level.
Outer edge of the image is cut off or fuzzy	Cannula is not pushed all the way in and locked with the O-ring groove. Endoscope has tunnel vision.	Push the Cannula all the way back toward the Camera Handpiece.

Sterile Procedure Kit Specifications

Part Numbers	50033-060, 50033-095, 50033-160, 50033-220
Working Lengths	60 mm 95 mm 160 mm 220 mm
Illumination Sheath Diameter	1.7 mm
Cannula Diameter	2.0 mm
Trocar Diameter	1.7 mm
Weight	180 g max. (6.4 oz)
Sterilization	ETO
Shelf Life	Expiration date is indicated on the packaging material
Operating Environment	10° C - 40° C / 30 - 75 % Relative Humidity, non-condensing Atm. Pressure: 700 hpa -1060 hpa (525 mm Hg - 795 mm Hg) altitude
Transport and Storage Environment	-20° to 60° C / 10 – 95 % Relative Humidity, non-condensing Atm. Pressure: 700 hpa -1060 hpa (525 mm Hg - 795 mm Hg)
Regulatory Classifications	US FDA: Class II, per FDA Product Classification Database EU: Class IIa, per "MEDDEV 2.4/1- rev. 8 Part 2, Rule 6 – Surgically invasive device for transient use.
Classification in accordance with IEC60601-2-18	Protection against electric shock: Type CF Applied Parts

Limited Warranty

VisionScope warrants that the VisionScope products will be free from defects in material and workmanship, when properly installed, stored, maintained, and used for the intended purpose. The warranty period for all products except the Endoscopes is twelve (12) months, and six (6) months for Endoscopes, beginning from the date of invoice. VisionScope's warranty is extended only to the original purchaser of the products at the location where it is originally shipped.

This limited warranty is restricted to repair or replacement by VisionScope, at its option, of any product found to be defective during the warranty period without charge. Damage inflicted to a product by the user may result in additional charges, regardless of the status of warranty.

Any alteration, abuse, misuse, or modification of the product or any component thereof shall void this warranty. This warranty is null and void if the user attempts to service the product or if service is performed by unauthorized third parties. One-time use, disposable sterile products are not covered by this warranty after the first use or after the expiration date.

In no event shall VisionScope be liable for loss of profit, consequential damages, loss of time, or loss of business incurred by the buyer with the purchase or use of any product.

NO OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IS GIVEN.

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13.6 - 01115 - VisionScope Camera Handpiece Instructions for Use

Instructions for Use

VISIONSCOPE

Camera Handpiece

TÜV Rheinland of North America, Inc. C US

CE 0197

Instructions for Use

VisionScope

Camera Handpiece

PN 01115 Rev. 2.4

272

Table of Contents

Introduction 1
- Indications for Use 1
- Intended Users 1
- Contraindications 1
- Warnings 1
- Precautions 2
- Glossary of Symbols 3
- Glossary of Terms 3

Device Description 6
- System Components and Part Numbers 6
- Unpacking and Inspection 8
- Camera Handpiece Layout 8

Performing a Patient Procedure 10
- Reprocessing Requirements of the Endoscope and Camera Handpiece 10
- Assembling the Endoscope and Camera Handpiece 10
- Installing the Endoscope Sheath 12
- White Balancing and Confirming Image Clarity 15
- Inserting the Cannula and Endoscope Assembly 16
- Capturing Still Images and Recording Video 17
- Finishing a Patient Procedure 17

Optional Accessories (Not Supplied by VisionScope) 18

Periodic Maintenance, Cleaning, and Sterilization 18

Service, Trouble Shooting, and Replacement 20

Camera Handpiece Specifications 22

Electromagnetic Information 23

Limited Warranty 25

Contact Information 26

Introduction

VisionScope is an endoscopic imaging system designed to enable pre-operative and post-operative diagnosis in physician examination rooms. The device can also be used in intra-operative procedures in operating rooms where smaller gauge endoscopes are important for minimally invasive surgical procedures. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

The key component of the VisionScope is a 1.4 mm diameter semi-rigid fiber-lens endoscope that fits within a disposable sterile 1.7 mm diameter endoscope sheath (patented), which in turn is small enough to fit through a 2 mm portal or cannula. The disposable endoscope sheath, consisting of an illumination sheath with an integrated camera drape, also acts as a sterile barrier, thereby eliminating the need for full sterilization of the endoscope and camera handpiece following each procedure. VisionScope Technologies is able to miniaturize the endoscope diameter while still providing true High Definition (HD 1080) anatomical visualization, enabling Surgeons to obtain direct visual clinical assessment in a physician examination room without requiring sterilization or bio-hazard processing infrastructure when used as an imaging device alone and without any resection instrument.

Indications for Use

The VisionScope High Definition Endoscopy Camera System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of an interior cavity of the body through a natural or surgical opening. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

Additionally, when used in conjunction with an appropriately indicated and FDA 510(k)-cleared endoscope and light source, the VisionScope High Definition Endoscopy Camera Control Unit and Camera Handpiece are indicated for use in arthroscopic and endoscopic surgical procedures to provide illumination, visualization and capture of still and motion pictures of articular cavities, body cavities, hollow organs and canals.

Intended Users

The VisionScope system is designed for use by licensed physicians for performing diagnostic or surgical procedures. Physician assistants may assist in the setup of the equipment and preparation of patients.

Contraindications

None known.

⚠ Warnings

- Read this Instruction for Use (PN 01115) completely prior to use.
- Read the Instructions for Use for the applicable VisionScope System (PN 01112), VisionScope Endoscope (PN 01113), and Sterile Procedure Kit with Disposable Endoscope Sheath, Cannula, and Trocar (PN 01114) completely prior to use.

- It is the Surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- The VisionScope family of Camera Control Unit, Camera Handpiece, and Endoscope are designed to be used together with the one-time use sterile Endoscope Sheath, Cannula, and Trocar to ensure safety and effectiveness. Never mix or substitute any component with any other unauthorized product from any other unauthorized manufacturer.
- DANGER: Risk of explosion if used in the presence of flammable anesthetics. To prevent electric shock, do not disassemble the VisionScope Camera Handpiece. There are no user-serviceable parts. Dismantling the equipment will void your warranty.
- The Camera Control Unit and Camera Head contain a light fiber that carries the output from a bright Light Emitting Diode (LED) light source. Like any light source in a hospital or residential environment, avoid looking directly at the light source for any length of time. Use an opaque object to block the direct line of sight if necessary. When the system is not in use, turn off the light with the Software Light Switch on the Touch Screen LCD Panel. Do not attempt to service or clean the camera while the light is on.
- WARNING: Disregarding the information on safety of this device is considered ABNORMAL USE.

℞ Precautions

- U.S. Federal law restricts this device to sale by or on the order of a physician.
- When used for diagnostic imaging in a physician examination room solely without accompanying resection or surgical instrument, the Endoscope and the Camera Handpiece must be sheathed with the disposable Endoscope Sheath to avoid infection.
- When used for intra-operative surgical procedure in an Operating Room, the Camera Handpiece and the Endoscope must be sterilized with validated chemical sterilants (100% Ethylene Oxide (ETO), Sterrad 100S, Sterrad NX, or Sterrad 100NX). This is to ensure that in the unlikely event that the exterior sterile Endoscope Sheath is accidentally damaged by resection or surgical instruments, the Endoscope and Camera Handpiece will not contribute to infection.
- Prior to sterilization with the above means, tighten the protective soak cap over the Camera Handpiece cable connector to prevent fluid or moisture to enter and damage the camera connector.
- Do not autoclave the Camera Handpiece or the Endoscope.
- Prior to each use and insertion into a patient, ensure the system is functioning properly and is producing live video. Inspect the Endoscope, the disposable Illumination Sheath, Cannula and Trocar, to ensure that the tubes are not bent, the windows are not damaged, and there are no unintended rough surfaces, sharp edges or protrusions which may cause HARM. Do not use a damaged device.
- Handle any exposed sharp needle point at the distal tip of the Trocar, Cannula, Endoscope and Illumination Sheath with care to avoid accidental injury or contamination.
- To avoid fogging during surgery, the Camera Handpiece and the Endoscope must be dry prior to attaching the one-time-use Endoscope Sheath.
- Prior to entering service, the system must be tested for electrical safety by a biomedical engineer or other qualified service staff.
- Do not plug the Camera Handpiece cable connector into the Camera Control Unit if wet. Moisture inside the protective cable connector will damage the electronic circuitry and void the product warranty.

- Do not operate or sterilize the equipment that is damaged. Use authorized hospital decontamination procedures to clean the Camera Handpiece and the Endoscope optics prior to returning to the factory for service.
- Review the live video images to ensure that there is no deposit on the optical surfaces prior to a procedure.
- Carry and store the cable in loose coils with bend radius of not less than 5 cm (2 in) to prevent kinks and stress on the internal wires.
- Avoid pinching or damaging the camera cable (i.e., rolling heavy equipment over it, securing with clamps, pinching in drawers or doors, etc.).
- This equipment contains plastics, metals, electronic components, and printed circuit assemblies. At the end of the useful life of the equipment, it should be disposed of in accordance with any applicable national, local or institutional regulation and environmental policy.

Glossary of Symbols

	Attention: Please Read Instructions for Use
Rx	Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician.
	Type CF (Cardiac Floating) Equipment
	EU: Not for General Waste. When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling.
	Warning: Do not plug the connector into the electrical receptacle if it is wet.
	Date of Manufacture
CE 0197	CE Mark issued by TUV Rheinland
	Electrical Safety Testing Mark by TUV Rheinland of North America, Inc., a test laboratory and notified body
EC REP	European Representative
	Split Illumination icon for aiding alignment of Illumination Sheath to Camera Handpiece; Left – Starting Position; Right – Aligned.

Glossary of Terms

Brightness	Camera setting that controls lightness or darkness of the video.

Camera Drape	Sterile protective membrane tube, together with the Illumination Sheath, forms the Endoscope Sheath. It is deployed by pulling on the pull cord to form a enclosed drape over the Camera Handpiece and Camera Cable.
Camera Control Unit	Integrated electronics unit with camera controller, light source, image management computer, and touch screen display.
Camera Handpiece	Hand-held component combining high-definition camera and light source.
Cannula	Component of disposable Sterile Procedure Kit. A tube that can be inserted into the body, for the purpose of guiding the Endoscope, or for injecting or removing fluid including drug delivery.
CCU	Camera Control Unit.
C-Mount	Threaded connection used on camera lenses to ensure proper position for clear focus.
Color Bar Pattern	A video test pattern for confirming proper operation of the video electronics chain, when a camera with live video output is not conveniently available.
DVI	Digital Visual Interface (per Digital Video Working Group), a video signal interconnect format.
EMC	Electromagnetic Compatibility. Refers to the ability of the device being used to continue to function properly in the presence of outside electromagnetic interference.
EMI	Electromagnetic Interference. Refers to the possible electromagnetic radiation that a device under use may generate, thereby interfering with other devices in the vicinity.
Endoscope	Endoscopy means looking inside and typically refers to looking inside the body for medical reasons using an instrument called an endoscope.
Endoscope Sheath	A patented VisionScope design that is made up of an Illumination Sheath and a Camera Drape. The Illumination Sheath is a hermatically sealed stainless steel tube with a glass window at the distal tip. It fits over an endoscope, forming a barrier to keep out body fluid or other contaminants. Integrated with the Illumination Sheath is a polyurethane Camera Drape to provide a cover around the camera handpiece and camera cable. The Camera Drape can be deployed by pulling on a pull string. (See *Illumination Sheath* below.)
Enhancement	Camera Setting that adjusts to sharper or softer for visualizing more or less detail.
HD-SDI	High Definition Serial Digital Interface (per SMPTE-292M:1998).
High Definition	Modern television broadcast standard, generally referred to video formed with 1920 x 1080 pixels.
Hue	Camera setting that controls color balance.

Illumination Sheath	Light sheath. Component of disposable Sterile Procedure Kit that transmits LED light from Camera Head into body cavity, while also serving as a sterile barrier between the outside body cavity and the Endoscope within.
OR	Operating Room.
O-Ring	Toroid (donut-shaped) gasket that is compressed when connecting the Endoscope to create a water-proof seal between the Endoscope and Camera Handpiece.
OSD	On-screen display of video status information such as recording indicator (REC) and image counter.
Patient Leakage Current	The current flowing from a medical device through the patient to ground when the device comes in contact with a patient.
PN	Part Number
Procedure	Procedure may have two meanings, depending on the context. The first meaning is a description of the type of surgical procedures, e.g., diagnostic arthroscopy, surgical arthroscopy, laparoscopy, or other customized surgical operations. The second meaning refers to the treatments that the patient may have received or is currently receiving. Patient information is a collection of data organized under a unique patient identification. For each unique patient ID, one or more procedures representing different instances of treatment may be present.
Protective Earth	Connection that ensures that all exposed conductive surfaces are at the same electrical potential as the surface of the Earth.
Record	Composite file from a patient procedure, including patient information, still images, video recordings, audio recording, notes.
REF	Reference number for ordering from VisionScope product catalog.
Saturation	Camera setting that controls color intensity (full color to grey scale).
SN	Serial Number.
Soak Cap	A protective water-proof covering over the Camera Handpiece connector, to prevent the electronic metallic pins to come into contact with chemical sterilization agents during the sterilization process.
Sterile Procedure Kit	Sealed tray containing disposable supplies for patient preparation. Includes Endoscope Sheath, Cannula, and Trocar.
Trocar	Component of disposable Sterile Procedure Kit that is a thin metal rod with a sharply pointed end, often three-sided, that is used to introduce cannulas and other similar implements into blood vessels or body cavities.
Video Recording	Segment captured from the live video during a patient procedure and saved as an MPEG file (also called a video clip).

VisionScope	High Definition Diagnostic and Operative Endoscopy System including Camera Control Unit, Endoscope, and Sterile Procedure Kit.
WEEE	Waste of Electronic and Electrical Equipment per the European WEEE Directive 2002/96/EC.
White Balance	The process of matching the color of the video to ensure good color fidelity.

Device Description

The VisionScope Camera Handpiece is designed to be used with a VisionScope Endoscope to provide illumination and visualization of articular cavities, body cavities, hollow organs, and canals.

VisionScope provides a line of Endoscopes and a matching line of Sterile Procedure Kits and that are designed to be used with the VisionScope Camera Handpiece. Each one-time-use Sterile Procedure Kit contains a disposable Cannula, Trocar, and an Endoscope Sheath that acts as a sterile barrier.

⚠ Warnings

Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this manual.

Portable and mobile RF communication equipments can affect Medical Electrical Equipment.

The System should not be used adjacent to and stacked with other equipment and that if adjacent or stacked use is necessary, the System should be observed for normal operation in the configuration it will be used.

The use of external Accessories, transducer and cables other than those specified by VisionScope, including medical grade external monitors or medical grade printers, may result in increase Emissions or decrease in Immunity of the VisionScope Camera Control Unit. Non-medical grade external accessories must not be used in the patient environment.

When the VisionScope Camera Handpiece (Type CF applied part) are used with appropriately indicated external energized endosurgery devices, patient leakage current may be additive. It is particularly important that a Type CF applied part endosurgery device be used in order to minimize total patient leakage current.

System Components and Part Numbers

This IFU describes primarily the Camera Handpiece, VisionScope Part No. 50021. This part is designed to be used with the following matched components and accessories:

Part Number	Description	Functions

50034	VisionScope Camera Control Unit Non-Sterile	An integrated electronics unit that replaces four separate boxes in a traditional endoscopy system: Camera Control, Light Source, Image Management, and Touch Screen Display. The innovative design results in a compact, power efficient and portable electronics that is ideally suited for use in both a physician examination room and an operating room environment.
50021	VisionScope Camera Handpiece Non-Sterile	Contains a three-chip, high sensitivity, low noise, HDTV broadcast-quality imaging sensor with full 1920 x 1080 pixels, optimized for use with narrow gauge needle scopes with unprecedented image clarity. The VisionScope Camera Handpiece is compatible with the following sterilization methods: ETO, Sterrad 100S, Sterrad NX. Do not autoclave.
50006-060	VisionScope Endoscope for small joint or body cavity, e.g., wrist Non-Sterile	A family of four 17-gauge needle Endoscopes with operating lengths of 60 mm, 95 mm, 160 mm and 220 mm, optimized for visualization of articular or body cavities of different sizes. The innovative optics, working in conjunction with the Camera Handpiece and integrated Camera Control Unit, offers unprecedented light collecting efficiency, contrast resolution, and image clarity. VisionScope Endoscopes are compatible with the following sterilization methods: ETO, Sterrad 100S, Sterrad NX. Do not autoclave.
50006-095	VisionScope Endoscope for regular joint or body cavity, e.g., knee and regular shoulder Non-Sterile	
50006-160	VisionScope Endoscope for large cavity, e.g,., large shoulder or abdomen Non-Sterile	
50006-220	VisionScope Endoscope for very large cavity, e.g., hip or large abdomen Non-Sterile	
50033-060	Sterile Procedure Kit for Endoscope PN 50006-060	Sterile kit containing a matched set of one-time use components for supporting a procedure requiring a working length of 60 mm: • one Illumination Sheath with an integrated Camera Drape • one Cannula • one Trocar

50033-095	Sterile Procedure Kit for Endoscope PN 50006-095	Sterile Kit containing a matched set of one-time use components for supporting a procedure requiring a working length of 95 mm: • one Illumination Sheath with an integrated Camera Drape • one Cannula • one Trocar
50033-160	Sterile Procedure Kit for Endoscope PN 50006-160	Sterile Kit containing a matched set of one-time use components for supporting a procedure requiring a working length of 160 mm: • one Illumination Sheath with an integrated Camera Drape • one Cannula • one Trocar
50033-220	Sterile Procedure Kit for Endoscope PN 50006-220	Sterile Kit containing a matched set of one-time use components for supporting a procedure requiring a working length of 220 mm: • one Illumination Sheath with an integrated Camera Drape • one Cannula • one Trocar

Unpacking and Inspection

Examine the shipping container for any sign of external damage. Save the carton and packing material in the event that the equipment needs to be returned for repair or exchange.

Set up the equipment following the instructions in this document to ensure that it is functional. Contact VisionScope or its authorized sales representatives to report any missing, damaged or non-functional items. Prior to using the VisionScope Camera Handpiece, inspect the hardware for damage.

Camera Handpiece Layout

Three buttons are available on the Camera Handpiece to control the Camera Control Unit. During a sterile procedure, the buttons can be accessed through the sterile Camera Drape.

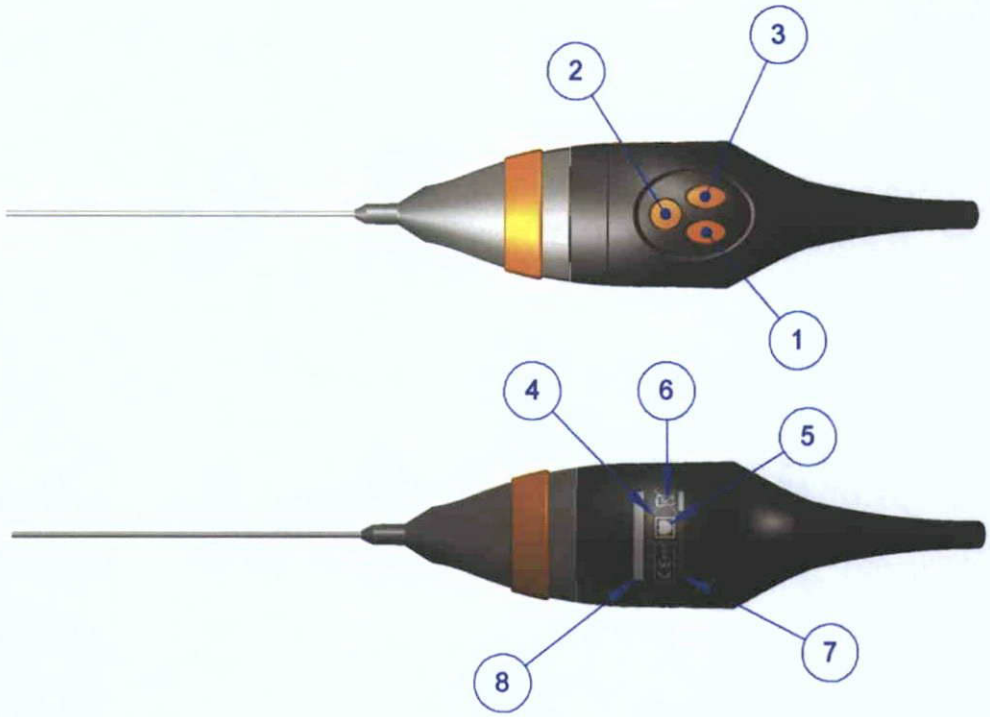

Figure 1 Camera Handpiece Layout

Each button serves two functions, depending on how long the button is pressed and released. Unless otherwise re-programmed by the users, the buttons serve the following functions:

Camera Handpiece Button	Short Press (< 1.0 second)	Long Press (≥ 1.0 second)
1. Left Button	Capture a Still Image.	Display last captured Still Image for 1 second.
2. Middle Button	Change video brightness by one step. Functions in a cyclic loop, from 0, +1, +2, +3, -3, -2, -1, 0...	Change video enhancement by one step. Functions in a cyclic loop, from 0, +1, +2, +3, -3, -2, -1, 0...
3. Right Button	Press once to start a video recording. Press again to stop recording.	Change color saturation by one step. Functions in a cyclic loop, from 0, +1, +2, +3, -3, -2, -1, 0...

Captured still images and video clips are stored on a hard disk drive located in the Camera Control Unit. The still images and video clips form part of the patient's procedure record, and may be reviewed or deleted from the Media screen of the Camera Control Unit (see Instructions for Use of the VisionScope System, PN 01112).

The Camera Handpiece controls provide basic functions needed during a sterile procedure. If other functions are required, the Camera Handpiece controls can be re-programmed (see the Instructions for Use of the VisionScope System, PN 01112).

Camera Handpiece Label	Explanation
4. REF No. and SN	Reference No. to VisionScope Sales Catalog, Part Number, and Serial Number.
5.	Type CF (Cardiac Floating) Equipment.
6.	EU: Not for General Waste. When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling.
7. USA	Made in USA.
8. CE	CE Mark, Conformity Mark for the European Economic Area.

Performing a Patient Procedure

If VisionScope is prescribed to be used in a diagnostic imaging procedure without any resection tool, the one-time use sterile Endoscope Sheath provided in the Sterile Procedure Kits may be used for protecting the patient as well as the Endoscope and Camera Handpiece.

Reprocessing Requirements of the Endoscope and Camera Handpiece

⚠ Warning

<u>Procedures with an accompanying in vivo resection tool</u>: If VisionScope is prescribed to be used in a surgical procedure <u>with</u> an in vivo resection tool, the entire Camera Handpiece and the Endoscope <u>must be sterilized</u> before and after each procedure, using one of the sterilization methods specified in the Instructions for Use for the Camera Handpiece and the Endoscope (PN 01113, PN01115), to assure sterility in the unlikely event that the sterile Illumination Sheath or Camera Drape is accidentally damaged by the resection tool.

<u>Diagnostic Imaging Procedures without any other tool</u>: If VisionScope is prescribed to be used in a diagnostic imaging procedure <u>without</u> an in vivo resection tool or any other tool, and if used in conjunction with the VisionScope Disposable Sterile Procedure Kit in accordance with the Instructions for Use (PN 01114), the entire Camera Handpiece and the Endoscope may be used without sterilization but <u>must be disinfected</u> by wiping with a 70% isopropyl alcohol soaked gauze pad before and after each procedure.

Assembling the Endoscope and Camera Handpiece

Use the appropriate Endoscope (60 mm, 95 mm, 160 mm, or 220 mm operating length) for the intended patient procedure (see *System Components and Part Numbers* on page 6 for part numbers). If the same type of procedure (e.g., knee) is being performed, it is not necessary to change Endoscopes between procedures.

⚠ Warning

The Endoscope and Camera Handpiece are non-sterile. Do not handle the Endoscope or Camera Handpiece with gloves that will be used for sterile procedures.

Verify correct viewing mode and image orientation:

Before each use or after a change of viewing modes/settings, the Operator should check to ensure the view observed through the Endoscope provides a live image (rather than a stored one) and has the correct image orientation. Instructions for switching to Live Video and for inverting the image are provided in the Instructions for Use of the VisionScope System (PN 01112).

To connect the Endoscope to the Camera Handpiece:

1. Inspect the Camera Handpiece and cable connectors to make sure they are dry.
2. Inspect the window on the Camera Handpiece to make sure it is clean and dry. If necessary, use a lint free cotton cloth, lens tissue paper, or a Q-tip wetted with isopropyl alcohol to remove any dirt and smudge.
3. Select the appropriate Endoscope model with the desired working length.
4. Inspect the Endoscope to make sure that it is dry, the needle is not bent, and the windows on both ends are clean and free of dirt and smudge. Clean if necessary with a lint free cotton wipe or a Q-tip wetted with isopropyl alcohol.
5. Thread the Endoscope into the C-mount on the Camera Handpiece (Figure 2). Hand-tighten the Endoscope to ensure that the O-ring seal is compressed securely. Do not use hand tools to tighten the Endoscope.

Figure 2 Connecting the Endoscope to the Camera Handpiece

To connect the Camera Handpiece to the Camera Control Unit:

1. Unscrew and remove the connector soak cap from the Camera Handpiece cable (Figure 3).
2. Inspect the interior of the connector to make sure it is dry and free of water droplets. Blow dry with air if necessary.
3. Align the red dot on the camera connector with the red dot on the receptacle of the Camera Control Unit (Figure 4).
4. Plug the camera connector into the receptacle and push in tightly.

Figure 3 Removing the Soak Cap

Figure 4 Connecting the Camera Handpiece to the Receptacle on the Camera Control Unit

Installing the Endoscope Sheath

The Sterile Procedure Kit includes an Illumination Sheath to provide illumination for endoscopic imaging. The Illuminated Sheath is integrated with a Camera Drape to keep the Camera Handpiece and camera cable in a sterile environment.

Physicians, Nurses or Physician Assistants should use their training and preferred surgical techniques for manipulating both sterile and non-sterile components when connecting the Illumination Sheath to the Endoscope and deploying the Camera Drape. In some cases, it may be helpful to lay the camera in a sterile field or have an assistant remove the outer glove.

Once the Illumination Sheath is installed and the Camera Drape is deployed, you are ready to white balance the camera. Prior to each use, confirm the image clarity of the Endoscope for suitability of reuse.

⚠ Warnings

Follow the reprocessing requirements of the Endoscope and Camera Handpiece (see *Reprocessing Requirements of the Endoscope and Camera Handpiece* on page 10).

You must select the correct Sterile Procedure Kit for the installed Endoscope (see *System Components and Part Numbers* on page 6 for part numbers). All components are color-coded to indicate their working length.

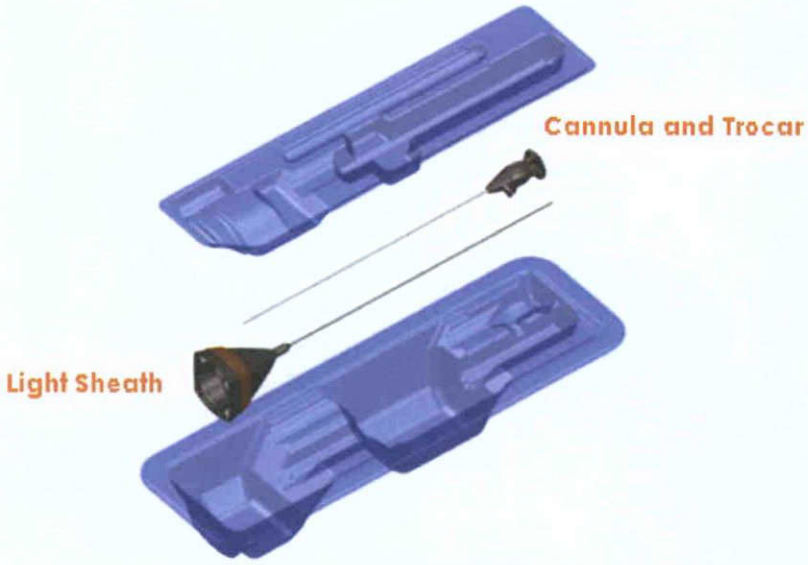

Figure 5 Sterile Procedure Kit

To connect the Illumination Sheath to the Endoscope:

1. Select a VisionScope Sterile Procedure Kit (Figure 5) with a disposable Illumination Sheath that has the same working length as the installed Endoscope.
2. Examine the Sterile Procedure Kit to ensure that the seal is not broken and the expiration date has not arrived. Discard the kit if either condition is true.
3. Wear two sterile gloves on the hand that will be used to handle the non-sterile Camera Handpiece. Wear a single sterile glove on the other hand that will be used to handle the sterile Illumination Sheath.
4. Peel off the lid of the Sterile Procedure Kit.
5. While holding the non-sterile Camera Handpiece in the double-gloved hand, pick up the sterile Illumination Sheath in the single-gloved hand. Make sure the non-sterile (double-gloved) hand does not touch any sterile component, such as the needle on the Illumination Sheath, which will enter the patient.
6. Carefully insert the needle of the Endoscope into the funnel of the Illumination Sheath (Figure 6).
7. Orient the Illumination Sheath so that the Illumination icon on the Illumination Sheath aligns with the Half-Circle icon on the Camera Handpiece and engage the threaded mount.
8. Rotate the Illumination Sheath one-quarter turn in the clockwise direction (Figure 7) until the two Illumination icons align. The fiber optic light guide on the Illumination Sheath is now aligned with the light port on the Camera Handpiece
9. Confirm that a bright light spot is seen at the distal tip of the Endoscope and that an adequately bright image appears on the touch screen LCD or an external monitor (if connected) when the Endoscope is placed within 50 mm of a light color object.

Note: Make sure the Light Control is set to Normal mode (full power) when verifying the image from the Endoscope.

Figure 6 Inserting the Endoscope into the Illumination Sheath

Figure 7 Rotating the Illumination Sheath 1/4 Turn

To deploy the Camera Drape:

1. Using the hand with the single sterile glove, hold the Camera Handpiece/Endoscope assembly by the Illumination Sheath.
2. Using the double-gloved hand, pull back on the deployment cord of the Camera Drape. Continue pulling the cord until the Camera Drape is fully extended and covers both the Camera Handpiece and the camera cable (Figure 7).
3. Peel off the outer glove on the double-gloved hand, touching only the upper part of the glove that has not been contaminated by the Camera Handpiece.

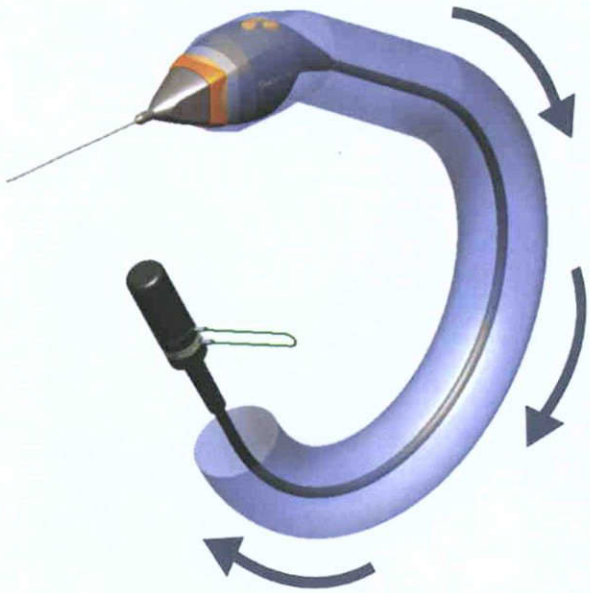

Figure 8 Deploying the Camera Drape

White Balancing and Confirming Image Clarity

Once you have assembled the Camera Handpiece, Endoscope, and Illumination Sheath, you are ready to white balance the camera.

Note: Make sure the Light Control is not set to Standby mode (reduced power) when white balancing the camera.

To white balance the camera:

1. Point the Camera Handpiece at a white piece of cotton gauze or bandage at a distance between 4 mm and 25 mm.
2. Press and release the middle button on the Camera Handpiece.
3. The white balance process may take 1-2 seconds. During this time, hold the handpiece steady at the white background.
4. Confirm that the On Screen Display indicates the white balance is completed successfully. This ensures the camera will produce a color-balanced image such that the white background is white.

Note: The middle button of the Camera Handpiece is the default setting for white balance. If the button settings have been customized, you may need to start white balance using another button.

To confirm image clarity of the Endoscope for suitability of reuse prior to each use:

1. After successful white balance, point the Endoscope at a piece of white cotton gauze or bandage at a distance between 4 mm to 25 mm.
2. Confirm that the illumination level is bright, the color is correct, the fabric or threads are in sharp focus, and there is no foreign, nebulous object in the field of view.
3. If the image is not clear or is obstructed, replace the Illumination Sheath and Endoscope until a clear image is observed.

The Camera Handpiece/Endoscope/Illumination Sheath assembly is now ready for surgical insertion. A Cannula and a Trocar with matched working length is provided for Surgeons to gain access to the anatomy.

Inserting the Cannula and Endoscope Assembly

Inserting the Camera Handpiece/Endoscope/Illumination Sheath assembly (the Endoscope assembly) into a patient requires the disposable sterile Cannula and Trocar included in the Sterile Procedure Kit. The Cannula and the Trocar should be inserted by qualified physicians only.

The Cannula is equipped with a fluid entry port for introducing a small volume (up to 50 ml) of liquid for flushing or drug delivery. An internal O-ring prevents release of fluid through the Cannula. If necessary, loosen the Cannula collar slightly to relax the O-ring seal before inserting the Illumination Sheath and Endoscope.

⚠ Warnings

Prior to each use and insertion into a patient, ensure the system is functioning properly and is producing live video. Inspect the Endoscope, the disposable Illumination Sheath, Cannula, and Trocar to ensure that the tubes are not bent, the windows are not damaged, and there are no unintended rough surfaces, sharp edges, or protrusions which may cause harm. Do not use a damaged device.

Before starting this procedure, verify that the Cannula and Trocar have the same working length as the installed Endoscope and Illumination Sheath. In addition, verify that you are wearing sterile gloves and that the sterile Illumination Sheath and Camera Drape are installed over the Endoscope and Camera Handpiece.

To insert the Cannula and Endoscope:

1. Surgically insert the Cannula/Trocar combination into the patient cavity.
2. Remove the Trocar and discard.
3. Carefully insert the needle of the Endoscope/Illumination Sheath assembly into the funnel of the Cannula (Figure 8). Continue inserting until the entire length of the needle is inserted and the base of the Illumination Sheath fits snugly into the Cannula collar.
4. Rotate the collar on the Cannula until the collar fits snugly on the Cannula body. Tightening this threaded connection compresses an internal O-Ring to prevent any leakage of fluid during the procedure.
5. If the procedure requires fluid injection, connect a syringe to the Cannula via the Luer-Lock port and inject.

Figure 9 Inserting the Endoscope Assembly into the Cannula

Capturing Still Images and Recording Video

Three buttons are available on the Camera Handpiece to control the VisionScope system during a sterile procedure. The buttons can be accessed through the sterile Camera Drape. Unless otherwise pre-programmed by the user, the Camera Handpiece buttons control image capture, video recording, and camera settings. See *Camera Handpiece Layout* on page 8 for a description of the button functions.

⚠ Warning

During a sterile procedure, the Camera Handpiece control buttons should be used to capture images or make adjustments to the VisionScope video, unless an assistant is available to operate the touch screen.

Finishing a Patient Procedure

If the proper procedure is followed during assembly and disassembly, the Camera Handpiece and attached Endoscope should be uncontaminated at the end of a procedure and ready for re-use in the next procedure.

To complete a procedure:

1. Remove the Endoscope and Cannula from the patient.
2. Turn the Illumination Sheath 90° counterclockwise to disengage the bayonet mount from the Camera Handpiece C-mount. Carefully slide the Camera Handpiece and the attached Endoscope out of the Illumination Sheath.
3. Carefully back the Camera Handpiece and the attached Endoscope out of the Camera Drape.
4. Set the Camera Handpiece and the attached Endoscope down on a clean, uncontaminated work surface.
5. Dispose of the Illumination Sheath and Camera Drape, Cannula, Trocar, and any other patient-contact accessories or supplies in a bio-hazard waste bin per the hazard waste disposal policy of the facility. Refer to Instructions for Use of the Disposable Procedure Kit (PN 01114) for further disposal information.
6. **Follow the reprocessing requirements of the Endoscope and Camera Handpiece** (see *Reprocessing Requirements of the Endoscope and Camera Handpiece* on page 10).
7. If the Camera Handpiece and attached Endoscope have been contaminated during or after a procedure, send the devices through an approved sterilization cycle per the Instructions for

290

Use for those sub-systems. Acceptable sterilization methods include 100% ETO, Sterrad 100, Sterrad NX, or Sterrad 100 NX. Do not autoclave.

Optional Accessories (Not Supplied by VisionScope)

The Camera Handpiece is equipped with an industry-standard "C-Mount" thread that is nominally 1 inch (25.4 mm) in diameter, with 32 threads per inch, designated as "1-32 UN 2A" in the ANSI B1.1 standard for unified screw thread. An appropriately indicated third-party endoscope with C-mount screw thread and adjustable focus may be used with the VisionScope Camera Handpiece and Camera Control Unit. In this application, the VisionScope Disposable Sterile Procedure Kit (VisionScope PN 50033) cannot be used in conjunction with any third-party endoscope.

⚠ Warnings

It is the responsibility of the Operator to ensure that the VisionScope Camera Handpiece and third-party endoscope and light cord are properly sterilized in accordance with the applicable Instructions for Use. Before each use or after a change of viewing modes / settings, the Operator should check to ensure the view observed through the third party endoscope provides a live image (rather than a stored one) and has the correct image orientation. Instructions for switching from a stored image to a live image and for inverting the image orientation are provides in the Instructions for Use for the VisionScope System (PN 01112).

Periodic Maintenance, Cleaning, and Sterilization

There are no user-serviceable parts inside any electronics or optical enclosure. The following periodic maintenance or cleaning tasks are recommended.

General	Procedures with an accompanying in vivo resection tool: If VisionScope is prescribed to be used in a surgical procedure with an in vivo resection tool, the entire Camera Handpiece and the Endoscope must be sterilized before and after each procedure, using one of the sterilization methods specified in the Instructions for Use for the Camera Handpiece and the Endoscope (PN 01113, PN01115), to assure sterility in the unlikely event that the sterile Illumination Sheath or Camera Drape is accidentally damaged by the resection tool. Diagnostic Imaging Procedures without any other tool: If VisionScope is prescribed to be used in a diagnostic imaging procedure without an in vivo resection tool or any other tool, and if used in conjunction with the VisionScope Disposable Sterile Procedure Kit in accordance with the Instructions for Use (PN 01114), the entire Camera Handpiece and the Endoscope may be used without sterilization but must be disinfected by wiping with a 70% isopropyl alcohol soaked gauze pad before and after each procedure.

Normal Cleaning and Inspection	The window surface on the Camera Handpiece should be dry and free of foreign objects or smudges in order to produce high quality images. The window should be inspected in between each procedure, and cleaned with a Q-tip wetted with isopropyl alcohol when necessary.
	If the Camera Handpiece is contaminated with bio-fluid during any procedure, make sure that it is de-contaminated and sterilized after the procedure, following the sterilization steps given in the Instructions for Use manual and any applicable institutional policy of the facility.
Deep Cleaning	The VisionScope Camera Handpiece may be immersed in water for deep cleaning. • Scrub each of the window surfaces with a 4" x 4" cotton surgical gauze pad soaked in enzymatic solution recommended for reprocessing of medical Endoscopes prepared in accordance with the manufacturers' instruction, when needed to break down any organic material. • Rinse thoroughly with distilled or de-ionized water. • Scrub again each of the window surfaces with a 4" x 4" cotton surgical gauze pad soaked in isopropyl alcohol. • Rinse thoroughly with distilled or de-ionized water. • Dry thoroughly. • Use a clean, dry, lint-free cotton cloth to wipe the window surfaces to remove any streak residue. Caution: do not use any ultrasonic cleaning methods, as the energy will damage seals and optical surfaces and will void the warranty.

Sterilization	If the VisionScope Camera Handpiece is contaminated with bio-fluid during any procedure, make sure that it is de-contaminated and sterilized after the procedure.
	
	The Camera Handpiece may be sterilized with any of the following methods.
	
	• Sterrad 100S Sterilization System: Follow all directions and warnings from the Manufacturer. Put only one camera handpiece and one endoscope per tray.
	• Sterrad NX and Sterrad 100 NX Sterilization System: Follow all directions and warnings from the Manufacturer. Put only one camera handpiece and one endoscope per tray.
	• 100% ETO - Follow standard hospital procedures maintaining the following parameters:
	  o Temperature 55° C ± 3° C (131 ± 5° F)
	  o Relative humidity >50%
	  o Gas concentration 725 mg/l
	  o Exposure time 60 minutes
	  o Aeration 11 hours minimum
	Caution:
	
	• Disinfection is not a substitute for sterilization
	• The VisionScope Camera Handpiece is not designed to be autoclaved.

Service, Trouble Shooting, and Replacement

There are no user-serviceable parts. Do not disassemble any electronics assembly or optical instrument.

Some common problems may occur that the end user can easily resolve. Use the following trouble shooting guide to diagnose and correct simple problems. If the problem persists, contact your authorized VisionScope representatives for further consultation or to arrange repair or replacement at an authorized Service Center.

⚠ Warnings

Withdraw Endoscope if equipment loses images.

In the unlikely event that the live image is lost during an endoscopic procedure, immediately withdraw the Endoscope and Illumination Sheath from the patient, and follow the appropriate institutional procedures for managing the patient. It is highly recommended that a backup system be available should it be necessary to continue the procedure.

Problem: Image is soft, not clear, out of focus, or fuzzy.

Cause	Solution
Fluid or foreign object on the window of the Illumination Sheath	Clean and dry the exterior window on the Illumination Sheath with sterile surgical cotton gauze.

Fluid or foreign object on the window at the distal tip of the Endoscope	Clean and dry the distal tip window on the Endoscope with sterile surgical cotton gauze.
Fluid or foreign object on the window at the proximal end of the Endoscope	Clean and the proximal end window on the Endoscope with sterile surgical cotton gauze.
Fluid or foreign object on the window on the Camera Handpiece	Clean and dry the window on the Camera Handpiece.
Endoscope is not screwed all the way in the C-mount.	Hand-tighten the Endoscope body all the way in the C-mount until the O-ring groove is compressed. Do not over-tighten with a tool.
Endoscope is damaged.	Inspect the Endoscope to ensure that there is no play or possible movement between the needle shaft and the Endoscope body.

Problem: Color is not correct: white is not white; background is either too yellowish or too bluish.

Cause	Solution
Improper White Balance	Point the Camera Handpiece and Endoscope at a white background and depress the middle button on the Camera Handpiece for more than one second to perform a White Balance. Confirm from the On Screen Display message that White Balance is successful.

Problem: Image is dark.

Cause	Solution
Illumination Sheath is not attached or aligned correctly.	Attach Illumination Sheath. Check to make sure that the Illumination Sheath is aligned with the Camera Handpiece, to ensure that the light fibers on both parts are in contact with each other.
Light source is turned off.	Check that the light source is turned on from the "Light" menu page.
Camera cable is damaged.	Inspect the cable to see if it is pinched or kinked.
Brightness setting is too low.	Check the "Brightness" setting on the "Camera" tab, increase if necessary.
	Check the "Brightness" or "Contrast" settings on the external monitor; make sure it is not set to a low level.

Light source is blown.	Unplugged the Camera Handpiece cable connector, turn the power on, wait until the software is started. Go to the "Light" tab, turn the light source switch on and off. In the "On" position, confirm that there is a light beam exiting the Camera Handpiece connector on the front panel. Caution: do not look directly into the light source. If the light source fails to turn on, contact an authorized VisionScope representative and return the unit for repair.

Problem: Image is too bright/showing excess glare.

Cause	Solution
Brightness setting is too low.	Check the "Brightness" setting on the "Camera" tab, decrease if necessary.
	Check the "Brightness" or "Contrast" settings on the external monitor, make sure it is not set to a high level.

Problem: Outer edge of the image is cut off or fuzzy.

Cause	Solution
Cannula is not pushed all the way in and locked with the O-ring groove. Endoscope has tunnel vision.	Push the Cannula all the way back toward the Camera Handpiece.

Camera Handpiece Specifications

Parameters	**Specifications**
Power Requirements	3.3 VDC@0.31A, 2.5 VDC@0.26A, 1.8 VDC@0.29A, 1.2 VDC@0.21A, supplied by VisionScope Camera Control Unit (P/N 50034) via custom connector.
Camera Handpiece Dimensions	7.6 cm L x 4.4 cm W x 5.1 cm H (3" L x 1.75" W x 2" H)
Camera Handpiece Weight	180 grams (0.4 lb)
Image Sensor Type	1920 x 1080 native pixel, ½" 3-chip HDTV CMOS
Imager Sensor Performance	100% digital transmission, Sensitivity = F10, Signal-to-noise ratio >54 db @ 1080 TV lines
Camera Handpiece Cable	3.5 m (11 ft)
Endoscope Optics Mount	Standard C-mount
Disposable Illumination Sheath Mount	Proprietary patent pending bayonet mount for disposable Illumination Sheath

Operating Environment	10° C - 40° C 30 - 75 % Relative Humidity, non-condensing Atm. Pressure: 700 hpa -1060 hpa (525 mm Hg - 795 mm Hg)
Transport and Storage Environment	-20° to 60° C 10 – 95 % Relative Humidity, non-condensing Atm. Pressure: 700 hpa -1060 hpa (525 mm Hg - 795 mm Hg)
Medical Device Classifications	US FDA: Class II, per FDA Product Classification Database EU: Class IIa, per "MEDDEV 2.4/1- rev. 8 Part 2, Rule 6 – Sugically invasive device for transient use.
Classification in accordance with IEC60601-1:	According to the type of protection against electric shock: EQUIPMENT energized from an external electrical power source: – CLASS I EQUIPMENT; According to the degree of protection against electric shock: – TYPE CF APPLIED PART. According to the degree of protection against ingress of water as detailed in the current edition of IEC: - Not Protected According to the mode of operation: – CONTINUOUS OPERATION According to the degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE: – EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE;

Electromagnetic Information

Guidance and Manufacturer's Declaration – Electromagnetic Emission		
The VisionScope system is intended to be used in the electromagnetic environment specified below. The users should ensure that it is used under such an environment.		
Emission Test	Compliance	Electromagnetic Environment – Guidance
RF Emission CISPR11	Group 1	The VisionScope System uses RF energy only for its internal functions. Its RF emissions are

		very low and are not likely to cause any interference in nearby electronic equipment.
RF Emission CISPR11	Class A	The VisionScope System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emission IEC 61000-3-2	Not applicable	
Voltage Fluctuations/flicker IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration – Separation Distances			
Recommended Separation Distances Between the VisionScope Camera Control Unit and Portable and Mobile RF Communications Equipment			
The VisionScope System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The users of VisionScope can help prevent electromagnetic interference by maintaining a minimum distance between the VisionScope system and portable and mobile RF communications equipment (transmitters) as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter	Separation Distance According to the Frequency of Transmitter (meter)		
	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	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The VisionScope System is intended for use in the electromagnetic environment specified below. The users of the VisionScope System 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	+/- 6 kV contact +/- 8 kV air	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	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	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	+/- 1 kV differential mode +/- 2 kV common mode	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% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec U_T is the a.c. mains voltage prior to application of the test level.	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec U_T is the a.c. mains voltage prior to application of the test level.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the VisionScope System requires continued operation during power mains interruptions, it is recommended that the VisionScope System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Limited Warranty

VisionScope warrants that the VisionScope products will be free from defects in material and workmanship, when properly installed, stored, maintained, and used for the intended purpose. The warranty period for all products except the Endoscopes is twelve (12) months, and six (6) months for Endoscopes, beginning from the date of invoice. VisionScope's warranty is extended only to the original purchaser of the products at the location where it is originally shipped.

This limited warranty is restricted to repair or replacement by VisionScope, at its option, of any product found to be defective during the warranty period without charge. Damage inflicted to a product by the user may result in additional charges, regardless of the status of warranty.

Any alteration, abuse, misuse, or modification of the product or any component thereof shall void this warranty. This warranty is null and void if the user attempts to service the product or if service is performed by unauthorized third parties. One-time use, disposable sterile products are not covered by this warranty after the first use or after the expiration date.

In no event shall VisionScope be liable for loss of profit, consequential damages, loss of time, or loss of business incurred by the buyer with the purchase or use of any product.

NO OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IS GIVEN.

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13.8 - InnerVue™ User Manual

innerVue™

DIAGNOSTIC SCOPE SYSTEM

User Manual

ARTHROTEK®

A BIOMET COMPANY

303

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Fax: 530-226-5803
www.InnerVueScope.com

InnerVue™ Diagnostic Scope System is a trademark of Arthrotek, Inc.

Caution: Federal (U.S.) law restricts this device for use by, or on the order of, a physician or properly licensed practitioner.

Pictures are for reference only.

Specifications are subject to change without notice.

Printed in the USA

Table of Contents

Introduction 2
- The InnerVue™ Diagnostic Scope System 2
- Regulatory Compliance 2
- How to Use This Manual 3
- Manual Conventions 3

System Specifications 4
- Contents 4
- Features and Specifications 5
- Safety Information 9

System Setup 10
- Introduction 10
- Moving the InnerVue™ Diagnostic Scope System 10
- Powering Up 10
- Attaching an External Video Monitor 11

Basic System Usage 12
- Before Beginning a New Procedure 12
- Beginning a New Procedure 12
- Attaching the Scope and Handpiece 13
- Light Source Operation 14
- Performing the Procedure 14
- Reviewing the Procedure 15
- Archiving the Procedure 16
- Reviewing an Archived Procedure 16
- Powering Down 17

Cleaning and Maintenance 18
- Cleaning of the InnerVue™ Diagnostic Scope System 18
- Cannula Set Replacement or Repair 18
- Changing Software Settings 18
- Light Source Life and Replacement 19
- Re-Ordering Supplies 20

Troubleshooting 21

End User License Agreement 25

Limited Warranty 29

CE Mark 29

Introduction

Congratulations on your purchase of the InnerVue™ Diagnostic Scope System from Arthrotek, Inc.! The InnerVue™ Diagnostic Scope System is a valuable addition to any practice, providing an active and dynamic visualization tool for rapid diagnosis of joint pathology.

1.1 The InnerVue™ Diagnostic Scope System

The InnerVue™ Diagnostic Scope System allows physicians to perform diagnostic arthroscopy in various diagnostic environments.

The InnerVue™ Diagnostic Scope System has several beneficial features:

- The InnerVue™ System gets a dynamic and active diagnostic test in the hands of the physician in various diagnostic environments.
- The ability to have an immediate diagnosis.
- The procedure consists of one needle poke (excluding local anesthetic) and the ability of the patient to walk out of the office immediately after the procedure.
- The InnerVue™ System is for viewing any interior cavity.
- A single unit on rolling casters that can be easily moved from one diagnostic area to another.
- A single, ergonomic, lightweight handpiece that combines the camera and light source.
- Pre-installed software that allows for the recording, printing and storing of the procedure video and still images.
- An adjustable LCD monitor for convenient viewing of the procedure video, still images and user interface.
- A photo-quality printer to print still images for the patient's records.
- A convenient slide out work surface to aid in efficiently performing a procedure.
- A storage drawer for conveniently stowing items used with the system.

1.2 Regulatory Compliance

Caution: Federal (U.S.) Law restricts this device for sale by, or on the order of, a physician or properly licensed practitioner.

DECLARATION OF CONFORMITY

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interferences in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio or television reception. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause interference to radio and television reception, which can be determined by turning the equipment on and off, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that which the receiver is connected.

This digital apparatus does not exceed the Class A limits for radio noise emissions from digital apparatuses as set out in the radio interference regulations of Industry Canada.

DÉCLARATION DE CONFORMITÉ

Cet appareil a été testé et déclaré conforme aux exigences d'un appareil numérique de Classe B, relative à la partie 15 des règles de FCC. Ces performances sont conçues pour fournir une protection raisonnable contre l'intervention nuisible dans une installation adéquate. Cet équipement émet des radiofréquences dans le cas où il n'est pas installé en conformité aux instructions. En conséquence, il peut causer des interférences nuisibles à la réception de radio ou télévision. Nous ne garantissons pas que ces interférences n'affecteront pas une installation particulière. Si cet équipement cause ces émissions à la réception de radio et télévision, ce qui peut être déterminé par la mise en tension ou non de l'équipement, l'utilisateur peut tenté de corriger ces nuisances par les mesures suivantes:

- Réorienter ou réinstaller l'antenne de réception.
- Augmenter la distance entre l'équipement et le récepteur.
- Connecter l'équipement dans une prise différente de celui où l'objet perturbé est connecté.

L'appareil est conforme, en matière électromagnétique, dans les tolérances applicables aux instruments numériques de Classe A, selon la norme appliquée par l'environnement Industrie Canada.

1.3 How to Use This Manual

Intended Usage

This device is to be used by a trained physician for viewing an interior cavity of the human body through either a surgical or natural opening.

Intended Audience

- Physicians
- Other health care professionals

1.4 Manual Conventions

Throughout this manual, any references to the "InnerVue™ Diagnostic Scope System," "InnerVue™ System," "InnerVue,™" should be considered synonymous.

System Specifications

The following section describes the components and features of the InnerVue™ Diagnostic Scope System.

2.1 Contents

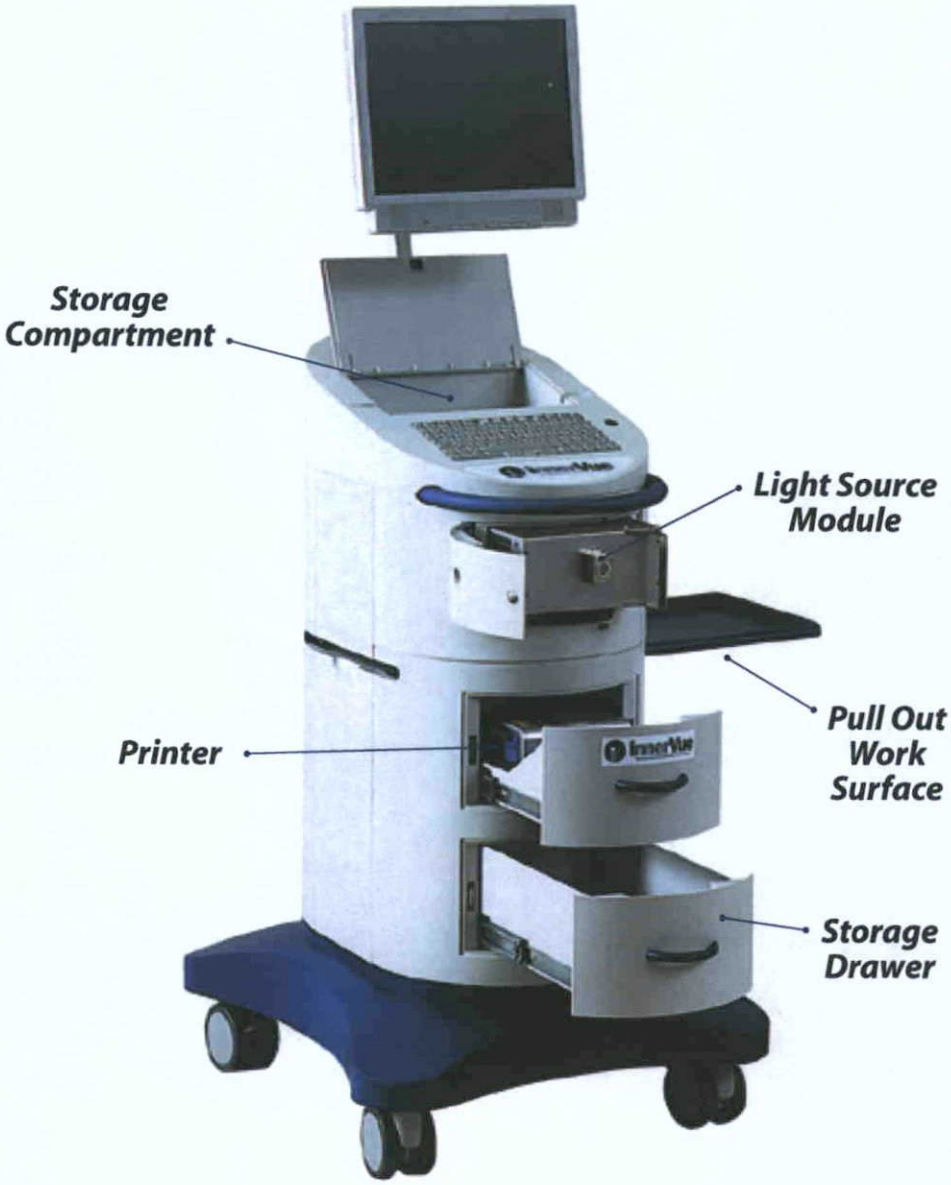
The following components are included in the InnerVue™ Diagnostic Scope System (See system schematic at right illustrating the locations of the items listed):

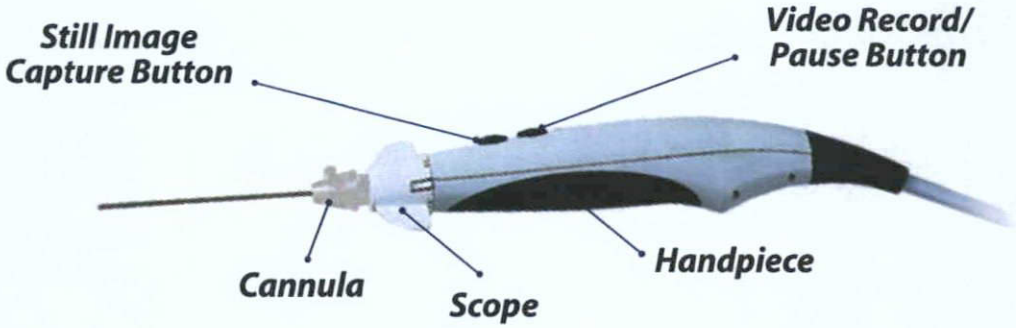
Verify that all the following components are included before proceeding. If any of these components are missing, contact your local Arthrotek® Sales Representative or Arthrotek Technical Support immediately.

- InnerVue™ Diagnostic Scope System:
  - *Removable Xenon Light Source Module*
  - *Keyboard*
  - *Monitor*
  - *Image Printer*
- Camera Handpiece
- Cables
  - *Hospital Grade Power Cord for InnerVue™ Diagnostic Scope System*
  - *Power Cord for LCD Monitor (with special male/female ends IEC 320)*
  - *VGA Cable*
  - *Audio Cable*
  - *Microphone*

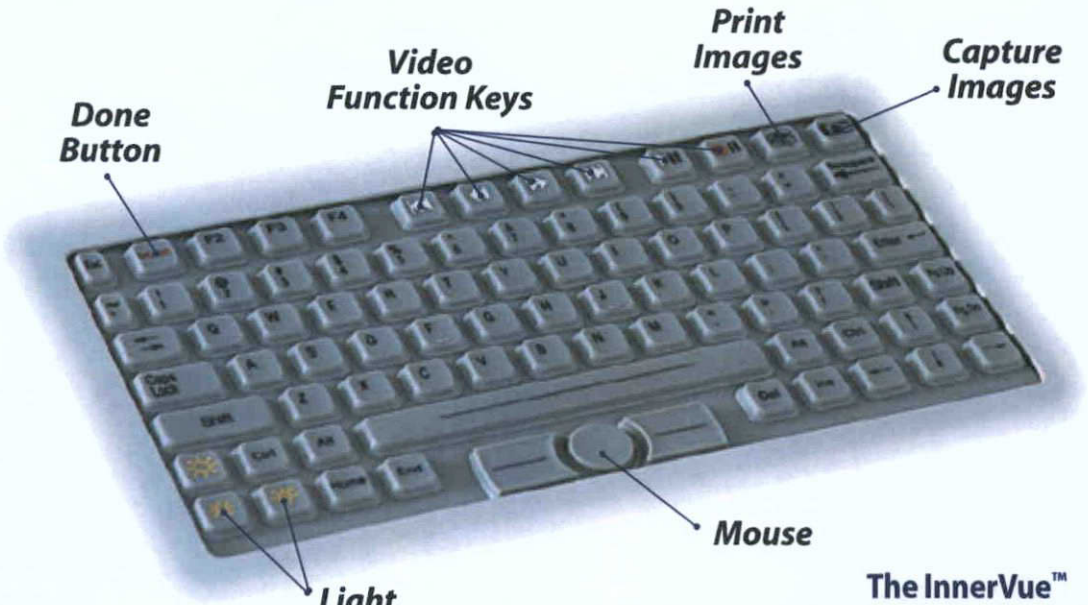
InnerVue™ Diagnostic Scope System

InnerVue™ Diagnostic Scope System





310



The InnerVue™ Diagnostic Scope System Keyboard

- Captures the current image (as a still image)
- Prints the current still image
- Records (or Pauses) the current procedure
- Plays (or Pauses) the video
- Skips ahead ten (10) seconds within the current video
- Skips back ten (10) seconds within the current video
- Jumps ahead to the next video marker
- Jumps back to the last video marker
- DONE — Ends the current activity
- Turns light source On/Off
- Increases light source intensity
- Decreases light source intensity

2.2 Technical Specifications

Dimensions
Overall dimensions: 25" wide x 29" deep x 61" tall
Approximate weight: 80 lb

Electrical
Power Input: 100-240VAC, 7.5 A, 60/50Hz.

Environmental
Operational Environment
Operating altitude: -1000 to 12000 ft MSL.
Operating temperature: 10°C to 40°C.
Operating humidity: 15%-95%, non-condensing.

Storage and Transport Environment:
Altitude: -1000ft to 35000ft MSL.
Temperature: -35°C to 60°C.
Humidity: 15% to 95% relative humidity, non-condensing.

Display Monitor
Type: Active matrix LCD
Viewable image size: 15" diagonal
Resolution: 1024 x 768 minimum
Display Colors: True Color (32 bit)
Viewing Angle: 70° minimum, up/down/left/right
Contrast Ratio: 450:1, typical.

Light Source
Xenon Short Arc Lamp, 100 to 300 W

Camera Handpiece
Cord Length 6.5 feet
Approximate weight: 1.5 lb
CCD imager with S-Video output

Printer
Dye sublimation
4 inch by 6 inch glossy prints

Video Viewer
Minimum requirements to view procedural video: Microsoft Windows™ Media 9 video codec

Still Image Viewer
Minimum requirements to view still images: JPEG format file viewer

2.3 Safety Information

It is important to read, understand, and comply with all of the following safety precautions.
Failure to follow these precautions could result in injury to the patient or user or damage to the InnerVue™ Diagnostic Scope System.

- All parts of the InnerVue™ Diagnostic Scope System are designed for use in standard medical environments. Components of the system that are meant for patient contact are constructed from biocompatible materials.
- To avoid fire hazard and electrical shock:
  - *Use only the power cord specified for this product.*
  - *Use only the fuse type and rating specified for this device.*
  - *Unplug the power cord from the outlet when performing any kind of cleaning or maintenance, particularly internal maintenance such as changing the light source.*
  - *Do not operate this product with covers or panels removed.*
  - *Do not apply an input voltage that is outside the specified range.*
  - *Do not operate in wet/damp conditions.*
  - *Do not operate the device in an explosive atmosphere.*
  - *Do not allow foreign objects inside the device.*
  - *Do not disassemble the device.*
  - *Never spill liquids of any kind on the device or immerse it in liquids.*
  - *Connect to a properly grounded hospital-grade outlet only.*
- To avoid personal injury and damage to this device:
  - *Do not place on an unstable surface, cart, stand or table. Always place and keep the InnerVue™ Diagnostic Scope System on a flat, level and secure surface so that it will not roll or tip over. Use the wheel locks to prevent the system from being moved accidentally.*
  - *Do not operate with suspected failures. If you suspect there is damage to this product, have it inspected by qualified personnel.*
  - *Do not block ventilation slots or openings—provide proper ventilation.*
- Unplug the device from the wall outlet if any of the following occur:
  - *The power cord is damaged.*
  - *Liquid has been spilled on the device or it has been exposed to rain or other moisture.*
  - *The device has been dropped.*
  - *The product displays a distinct change in performance.*
  - *The product does not operate properly when the operating instructions are followed.*
- The InnerVue™ Diagnostic Scope System is not intended to be used with high-frequency surgery equipment or laser equipment.
- Before each use, check the outer surface of the portions of the endoscope and any endoscopically-used accessories for unintended rough surfaces, sharp edges or protrusions that could create a hazard.
- Use caution not to damage the endoscope when it is used simultaneously with other surgical tools such as cutters or shavers.
- **Warning: possible explosion if used in the presence of flammable anesthetics.**
- **Warning: when endoscopes are used with energized endoscopically-used accessories, the patient leakage currents may be additive.**

System Setup

The following section describes how to set up the InnerVue™ Diagnostic Scope System for most basic surgical procedures:

3.1 Introduction

An authorized Arthrotek representative will perform the initial assembly and software setup of the InnerVue™ Diagnostic Scope System.

All internal components of the InnerVue™ Diagnostic Scope System are **NOT** user serviceable.

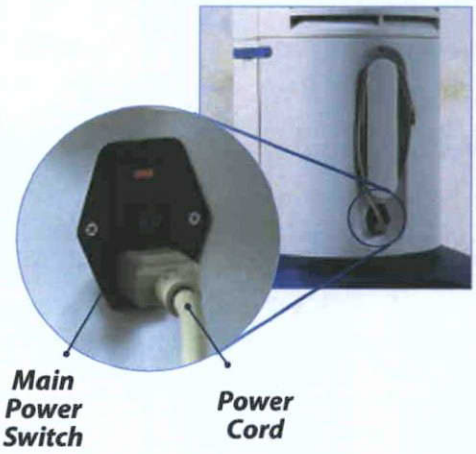
3.2 Moving the InnerVue™ System

The InnerVue™ system has been designed to be easily transportable within a single facility. To move the system from one area of a facility to another:

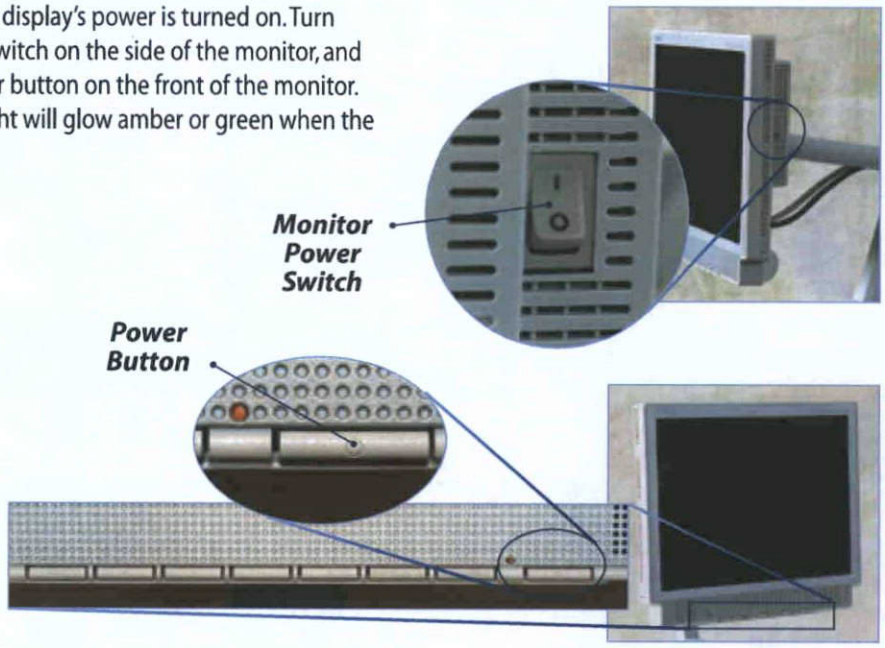
1. Begin by disconnecting any connections between the InnerVue™ System and other objects (e.g. disconnect power cord from the wall outlets, etc.). Coil and store the power cable.
2. Store the handpiece and its cable securely in the storage bin at the top of the system. Close the drawers and stow the tray.
3. Unlock all of the wheels on the bottom of the InnerVue™ System.
4. Use only the front semi-circular handle to transport the system within a facility. Never use a cable or connector to pull the system.
5. Place the InnerVue™ System on a flat, level and secure surface.
6. Finish by locking each of the wheels again.

3.3 Power-Up

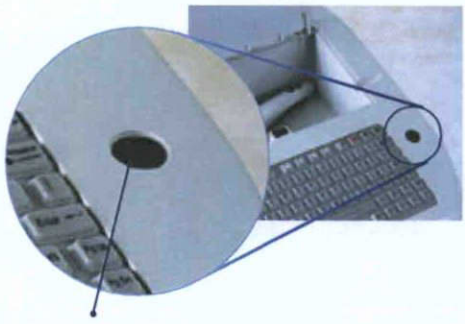
1. Ensure that the InnerVue™ Diagnostic Scope System is on a flat, level and secure surface and that the wheels are properly locked.
2. Connect the power cord to the InnerVue™ Diagnostic Scope System. Connect the other end of this cord to a power outlet that has also been approved for medical use.
3. Turn the InnerVue™ Diagnostic Scope System's Main Power Switch (on the back of the unit) to "On" (See inset photo at right).



4. Ensure that the display's power is turned on. Turn on the power switch on the side of the monitor, and press the power button on the front of the monitor. An indicator light will glow amber or green when the power is on.



5. Turn on the InnerVue™ Diagnostic Scope System's Image Processor by pressing the Power button (next to the Keyboard).
6. The InnerVue™ Diagnostic Scope System is now ready to use.



3.4 Attaching an External Video Monitor

To display video on a second monitor, use the S-Video output on the rear of the InnerVue™ Diagnostic Scope System:

1. Connect an S-Video cable (not provided) to the jack in the rear of the InnerVue™ System.
2. Connect the other end of the S-Video cable to a medical-grade monitor or other video device. *Note that poorly constructed or unshielded S-Video cables can cause degraded or "noisy" video.*

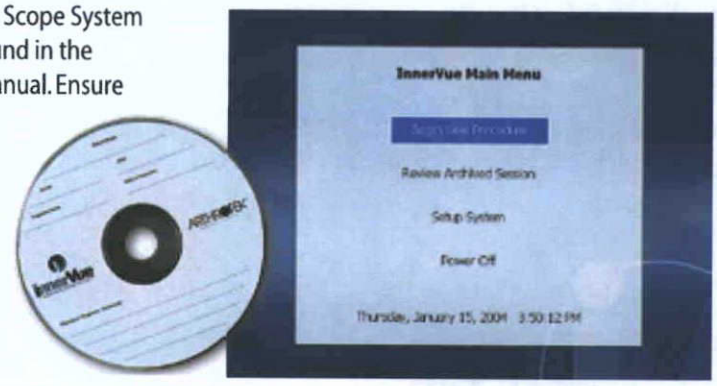
315

Basic System Usage

Note: These instructions are for basic usage of the InnerVue™ Diagnostic Scope System. For additional information, please refer to Arthrotek-certified training, or www.InnerVueScope.com.

4.1 Before Beginning a Procedure

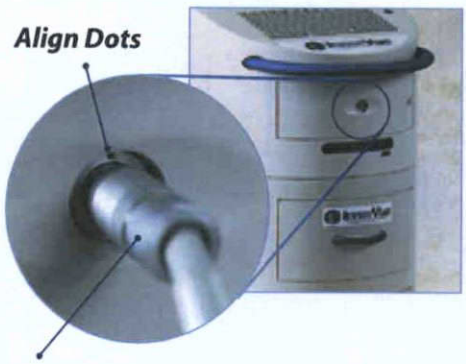
1. Set up the InnerVue™ Diagnostic Scope System according to the instructions found in the **System Setup** section of this manual. Ensure that the system is powered and turned on.
2. Gather all of the materials needed to perform the procedure, including sterile supplies such as an InnerVue™ scope, cannula set, and procedural kit.
3. Prepare the patient for this procedure according to facility Standard Operating Procedures or per physician order.

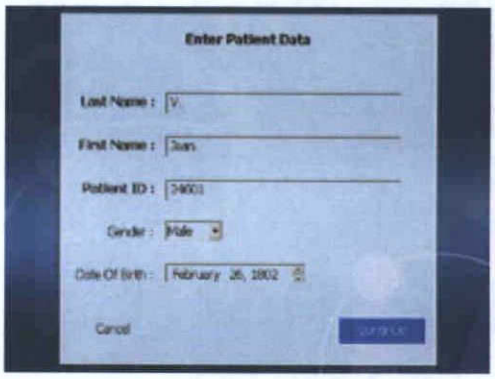


4.2 Beginning a New Procedure

At this point, the InnerVue™ System is ready to accept patient information and facility information.

1. The **InnerVue™ Main Menu** should be visible on the monitor.
2. Insert a new InnerVue™ Patient Data CD (provided with each disposable scope) into the CD drive.
3. Attach the InnerVue™ Scope to the InnerVue™ Handpiece. Connect the handpiece cable to the cable connection on the front of the InnerVue™ Diagnostic Scope System, ensuring that the red dots are aligned. Insert the connector until a "click" is felt. Refer to Section 4.3 of this manual for instructions.
4. From the **InnerVue™ Main Menu**, select the **Begin New Procedure** option.
5. The **Enter Patient Data** screen appears. Enter the following patient information using the TAB Key or the mouse to move to the next field (items in Bold are required entries, while all others are optional):
   - ***Last Name***
   - ***First Name***
   - ***Patient ID***
   - ***Gender*** *(select from the drop-down list)*



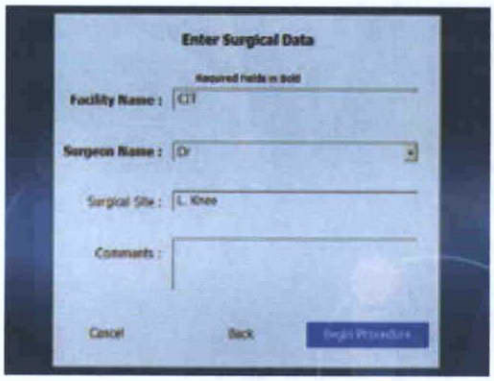


3/6

- ***Date of Birth*** *(Use the TAB key and the left and right arrow keys, or use the mouse and left mouse button, to position the cursor on the month field. Use the up and down buttons to the right of the date to change the month. Use the same technique to set the day and year. The day and year can also be changed by directly entering the numeric value from the keyboard. Note that the system will not allow an invalid date to be entered.)*

Check these entries for accuracy. If all of this information is correct, then click on the Continue button to accept this information. If any errors are found, then click on the Cancel button to reject this information and re-enter it.

6. After choosing to Continue, the **Enter Surgical Data** screen appears. Enter the following information on this screen using the TAB Key or the mouse to move to the next field; (items in Bold are required entries, while all others are optional):



- ***Facility Name*** *(if different from the default)*
- ***Surgeon Name*** *(if different from the default)*
- ***Surgical Site*** *(e.g. "left knee")*
- ***Comments*** *(up to 1000 characters)*

Check these entries, and then click on one of the following buttons:

- *Begin Procedure to accept this information and begin the actual surgical procedure (NOTE: the handpiece must be connected in order to proceed);*
- *Back to return to the previous screen;*
- *Cancel to reject this information and re-enter.*

The InnerVue™ Diagnostic Scope System is now ready to display and record the procedure.

4.3 Attaching Scope and Handpiece

The InnerVue™ Diagnostic Scope System is designed to have a user friendly connection system:

- The handpiece has only one cable, using a single connection for both illumination and video;
- The disposable scope and pre-assembled camera drape are sterile and pre-packaged with a patient data CD;
- The scope couples to the handpiece with a simple snap fit.

The system allows for rapid setup and takedown to minimize downtime between procedures.

1. Connect the scope to the handpiece. Align the marks on the handpiece and scope to connect properly. Using proper sterile technique, open the disposable scope package. Snap the scope onto the handpiece, ensuring that an audible click is heard.
2. Using proper sterile technique, pull the integrated handpiece drape over the handpiece and cable.
3. Connect the handpiece to the system. Align the red dots on the handpiece plug and the connector on the front of the system. A "click" is felt when the connection is seated properly.
4. Once the cannula is appropriately placed inside the patient, the scope is then inserted through the cannula. When inserting the scope into the cannula, ensure that the locking mechanisms (i.e. the groove on the scope and the pin in the cannula) are aligned.

   Gently press the cannula and scope together while turning the cannula to engage the locking mechanism.

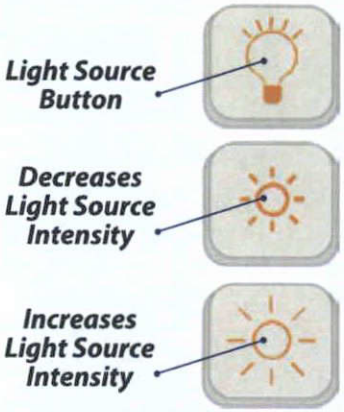
5. Upon completion of the procedure, disconnect the scope from the handpiece by breaking off the four tabs on the scope body and pulling the scope away from the handpiece.

   Discard the scope after each procedure, as with any other potentially bio-hazardous medical waste.

4.4 Light Source Operation

The light source will normally be off between procedures and will come on automatically when entering procedure mode.

- The **Light Source** button at the bottom left of the keyboard can be used to turn the light on or off.
- The **Decrease Light Source Intensity** button decreases the light intensity. The light intensity can be reduced to approximately 50% of its maximum value.
- The **Increase Light Source Intensity** button increases the light intensity.



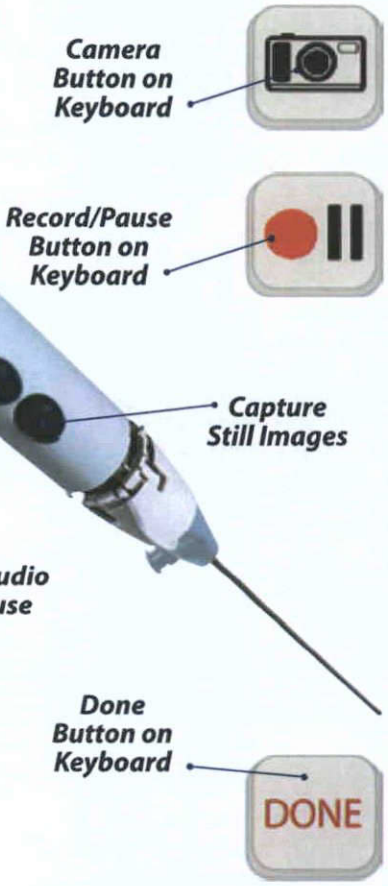
4.5 Performing the Procedure

The InnerVue™ Diagnostic Scope System is now ready to display and record the procedure:

- To capture still images, press the first handpiece button (closest to the scope) or press the **Camera** button on the keyboard. The display will indicate the number of images captured. There will be an opportunity to print these captured images after the procedure.
- To capture video, depress and hold the second handpiece button (closest to the cable) for two seconds, or press the **Record/Pause** button on the keyboard.

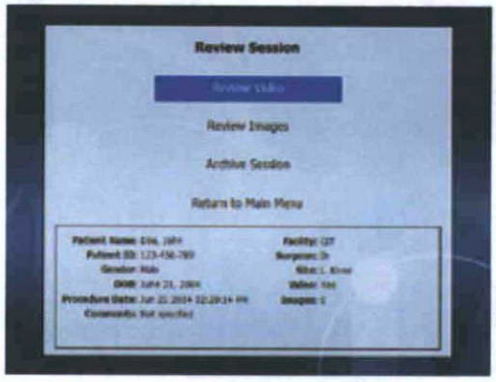
  To pause and resume video recording, depress and hold the second handpiece button (closest to the cable) for two seconds or press the **Record/Pause** button on the keyboard.

  While video is being recorded, a remaining record time indicator will count down on the bottom left corner of the display. When recording is paused, the indicator will stop counting down and will begin flashing.
- When finished performing the procedure, press the **Done** button on the keyboard. There will be a confirmation screen before procedure mode is actually completed. If video was recorded during the procedure, there may be a short delay while the video file is being prepared.



An image of the full keyboard is available in the "System Specifications" section of this User Manual.

When the procedure is complete, the **Review Session** menu appears.



4.6 Reviewing the Procedure

Now it is time to review the finished procedure, if desired.

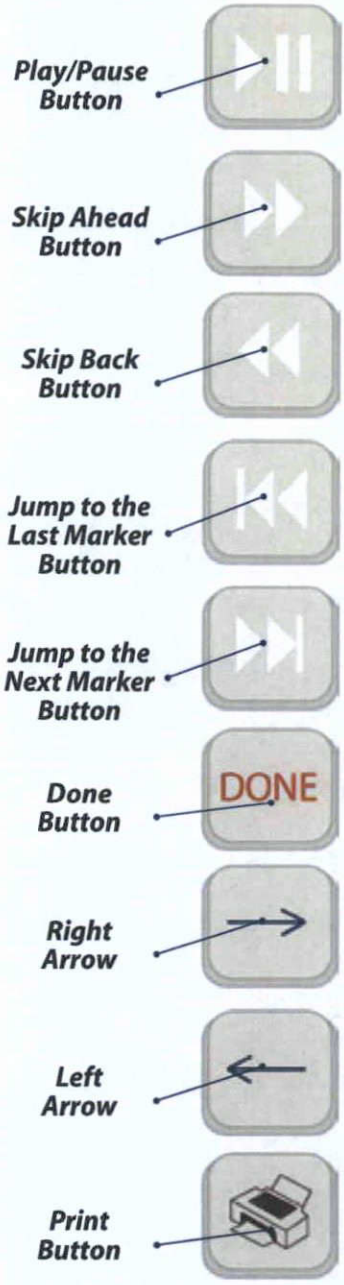
From the **Review Session** menu, select one of the following:

- **Review Video** (for streaming video of the procedure):
  - *If any video was captured during the procedure, it will begin to play automatically.*
  - *To pause the video, press the **Play/Pause** button on the keyboard. Also use this button to resume playback.*
  - *Use the **Skip** buttons on the keyboard to either **Skip Ahead** or **Skip Back** ten (10) seconds at a time.*
  - *Use the **Jump** buttons on the keyboard to navigate through the procedure by jumping to markers that were set during the procedure. A marker is set by pausing the video or by capturing an image.*
  - *Press the **Done** button on the keyboard to end playback and return to the **Review Session Menu**.*
  - *Note that the actual time during the original procedure is displayed during playback.*

An image of the full keyboard is available in the "System Specifications" section of this User Manual.

- **Review Images** (for still photos of the procedure):
  - *If any still images were captured during the procedure, the first image will appear automatically.*
  - *Press **Right Arrow** button on the keyboard to display the next image, or press the **Left Arrow** button on the keyboard to display the previous image.*
  - *To print the current image, press the **Print** button on the keyboard.*
  - *When finished reviewing images, press the **Done** button on the keyboard to return to the **Review Session** menu.*

An image of the full keyboard is available in the "System Specifications" section of this User Manual.



Note: In order to protect patient rights, no patient procedural information is recorded on the hard drive. Therefore, if the information is not archived, it will be lost.

319

4.7 Archiving the Procedure

To archive the procedural information, select **Archive Session** from the **Review Session** menu. The archiving process will automatically begin burning the recorded information to a recordable CD that has been inserted into the CD drive. This will archive not only the recorded video and audio but also the captured images and patient information.

The information screens (shown below) appear during the archiving process:

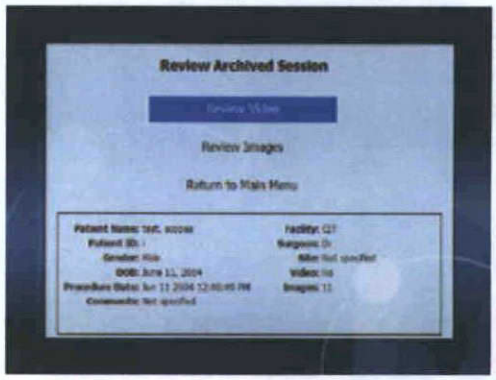
The process of writing to the CD will take several minutes. Do not eject the disk or power down the system while the CD is being created. In the event that an error occurred during CD writing, there will be an error message on the screen. Insert a blank CD-Recordable disk (not supplied) to attempt burning again. Once recording is complete, the disk will be ejected. Ensure that the disk is labeled correctly in the blanks provided using a felt tip pen. Close the CD tray by pressing the button next to the CD tray.

When the archiving process is finished, the Review Session Menu appears again. From there, the user can review additional videos or still images, print still images, burn additional CDs, or exit (by selecting the **Return to Main Menu** option).

4.8 Reviewing an Archived Session

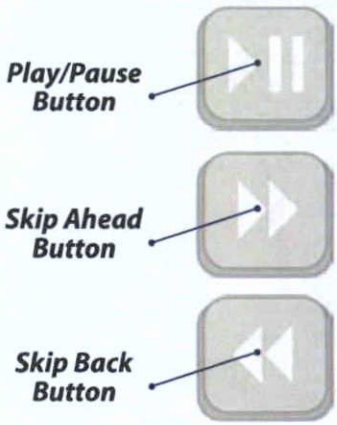
You can use the **Review Archived Session** option to review a pre-recorded procedure on the InnerVue™ Diagnostic Scope System.

1. Retrieve the CD to review and insert it into the InnerVue™ Diagnostic Scope System's CD drive.
2. From the **InnerVue™ Main Menu**, select the **Review Archived Session** option. The **Review Archived Session** menu appears as shown at right.



From the **Review Archived Session** menu, select from the following options:

- **Review Video** (for streaming video of the procedure):
  - *If any video was captured during the procedure, it will begin to play automatically.*
  - *To pause the video, press the **Play/Pause** button on the keyboard. Also use this button to resume playback.*
  - *Use the **Skip** buttons on the keyboard to either **Skip Ahead** or **Skip Back** ten (10) seconds at a time.*



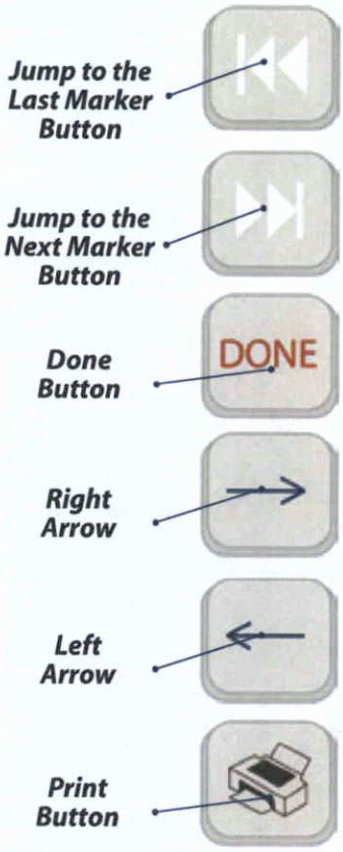
- *Use the **Jump** buttons on the keyboard to navigate through the procedure by jumping to markers that were set druing the procedure. A marker is set by pausing the video or by capturing an image.*
- *Press the **Done** button on the keyboard to end playback and return to the **Review Session Menu**.*
- *Note that the patient name and actual time during the original procedure are displayed during playback.*

An image of the full keyboard is available in the "System Specifications" section of this User Manual.

- **Review Images** (for still photos of the procedure):
  - *If any still images were captured during the procedure, the first image will appear automatically.*
  - *Press the **Right Arrow** button on the keyboard to display the next image, or press the **Left Arrow** button on the keyboard to display the previous image.*
  - *To print the current image, press the **Print** button on the keyboard.*

    If you encounter a printing error, please refer to the "Troubleshooting" section of this User Manual.
  - *When finished reviewing images, press the **Done** button on the keyboard to return to the **Review Archived Session** menu.*

3. When finished reviewing archived sessions, select the **Return to Main Menu** option.



An image of the full keyboard is available in the "System Specifications" section of this User Manual.

4.9 Powering Down

1. Before actually powering down the InnerVue™ Diagnostic Scope System, be sure to do the following:
   - *Remove any CDs from the CD drive;*
   - *Remove any photos from the printer.*
2. From the **InnerVue™ Main Menu**, select the Power Off option. The system will then power down.
3. It is not necessary to turn off the display power switch or the main power switch on the bottom rear of the unit. If the main switch is left on, the system will consume a very small amount of power.

321

Cleaning and Maintenance

The following section describes the proper method(s) for cleaning and maintaining the InnerVue™ Diagnostic Scope System.

Note: Always turn the Main Power Switch to "Off," and disconnect all power cords before cleaning the system.

Note: Never immerse or soak any part of the InnerVue™ Diagnostic Scope System, including the handpiece, in any liquid, as this will cause significant damage.

5.1 Cleaning of the InnerVue™ Diagnostic Scope System

The InnerVue™ Diagnostic Scope System and handpiece can be cleaned and disinfected with any cleaning agents meant for the cleaning of electric equipment, used according to the instructions given by the manufacturer of the cleaning solution.

Be sure to keep the following points in mind in order to ensure a long and effective life for the InnerVue™ Diagnostic Scope System:

- Do not allow excessive moisture or liquids to come in direct contact with the system or handpiece.
- Do not use any cleaning agents that are not compatible with plastics, i.e. ammonia, acetone, other strong organic solvents, strong acids (HCl), etc.
- Do not allow cleaning agents or liquids to enter the control unit outlets.
- Do not use abrasive cleaning implements or compounds (e.g. tile cleaner, steel wool pads, fiber scrubbing pads, etc.) when cleaning the system.

5.2 Cannula Set Replacement or Repair

If fluid flow has decreased through the cannula while the scope is inserted, the cannula may need to be repaired or replaced. For more information, please refer to the *Recommendations for the Care and Handling of Surgical Instruments and Instrument Cases* directions for use (included with the cannula set) for appropriate care, or contact your local Arthrotek® sales representative.

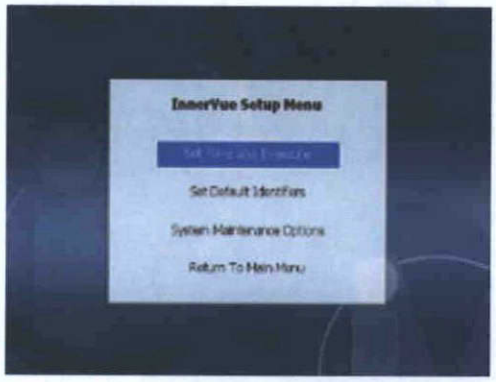
5.3 Changing Software Settings

The InnerVue™ System will be initially set up by an Arthrotek representative. However, the system clock and default identifiers can be changed by the user. The following sections describe how to perform these changes.

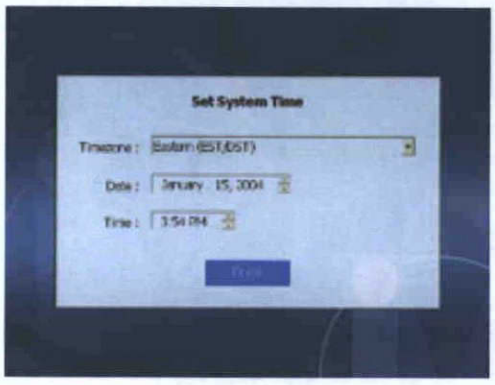
1. The **InnerVue™ Main Menu** should initially be visible on the monitor.

322

2. From the **InnerVue™ Main Menu**, select the **Setup System** option. The **InnerVue™ Setup Menu** appears.

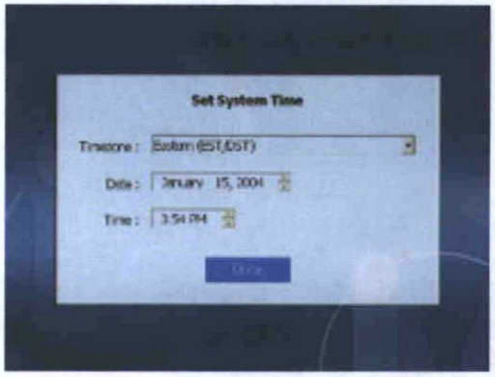


3. From the **InnerVue™ Setup Menu**, select the **Set Time** and **Timezone** option. The **Set System Time** screen appears.



- *Select the correct **Timezone** from the drop-down list. The InnerVue™ Diagnostic Scope System can adjust automatically for daylight savings time. For time zones that follow daylight savings time, choose a time zone that includes a daylight savings time code (e.g. "EST/DST"). To prevent the clock from adjusting to daylight savings time, choose the standard time code (e.g. "EST").*
- *Enter the current **Date**. Use the TAB key and the left and right arrow keys, or use the mouse and left mouse button, to position the cursor on the month field. Use the up and down buttons to the right of the date to change the month. Use the same technique to set the day and year. The day and year can also be changed by directly entering the numeric value from the keyboard. **Note that the system will not allow an invalid date to be entered.***
- *Enter the current **Time** using the same method as for setting the date (above). Note that the system will not allow an invalid time to be entered.*
- *Check these entries and then click on the **Done** button to accept them and return to the **InnerVue™ Setup Menu.***

4. From the **InnerVue™ Setup Menu**, select the **Set Default Identifiers** option. The **Set Default Identifiers** screen appears.



Note: The facility name and surgeon name entered here will come up automatically for each patient, but there will also be a chance to change what goes into each patient's record.

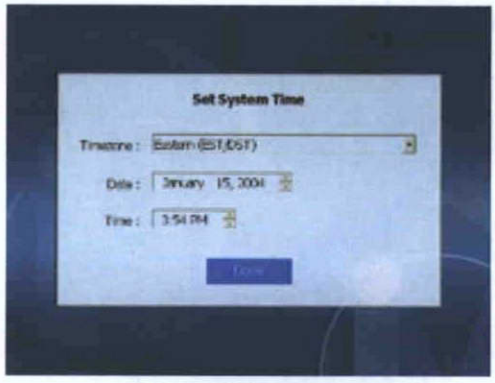
- *Enter the default name for this facility in the **Facility Name** field.*
- *Enter the default surgeon's name in the **Surgeon Name** field. Multiple users can be entered. The surgeon names are accessible from a drop down menu at the time of the procedure.*
- *Check these entries and then click on the **Done** button to accept them and return to the **InnerVue™ Setup Menu** screen.*

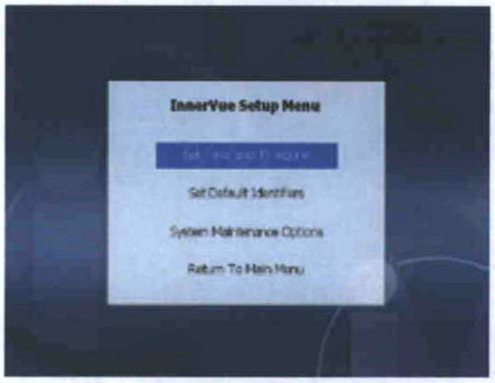
5.4 Light Source Life and Replacement

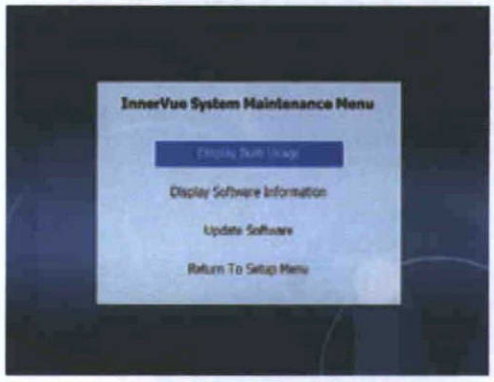
The InnerVue™ System tracks the number of hours that the light source has been in use. When the light source is nearing the end of its life, the system will provide a warning. The current number of usage hours can be checked at any time. The following sections describe how to perform this check:

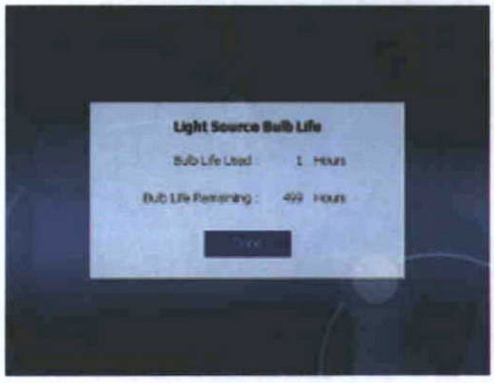
1. **The InnerVue™ Main Menu** should initially be visible on the monitor.
2. From the **InnerVue™ Main Menu**, select the **Setup System** option. The **InnerVue™ Setup Menu** appears.
3. From the **InnerVue™ Setup Menu**, select the **System Maintenance Options**. The **System Maintenance Menu** screen appears.
4. Select **Display Bulb Usage**.

If a new bulb for the InnerVue™ Diagnostic Scope System's Light Source is needed, then contact your Arthrotek representative for a replacement bulb. The bulb is not user serviceable.









5.5 Re-Ordering Supplies

To re-order any supplies for the InnerVue™ Diagnostic Scope System, contact your local Arthrotek representative.

Troubleshooting

While the InnerVue™ Diagnosic Scope System has no user serviceable parts, there are some error conditions that you can correct on your own. If difficulties occur with the InnerVue™ Diagnostic Scope System, use the following Troubleshooting Guide to diagnose and solve the problem.

If problems persist, call Arthrotek InnerVue™ Technical Support at 1-888-639-6886 during the hours of 8:00 A.M. to 5:00 P.M. PDT. 24-hour on-call emergency service is also available through this number.

Main Menu Does Not Appear

Probable Cause	Possible Solution
Unit is not receiving electrical power.	Verify that the power cable is plugged into both a live electrical outlet and to the InnerVue™ Diagnostic Scope System itself. Verify that the main power switch on the rear of the system is turned on.
Unit is receiving power, but monitor is turned off.	Turn on the monitor in both of these locations: 1. Facing the back of the monitor, on the left hand side, is a rocker switch. This switch must be in the on position, marked by a vertical line (I). 2. On the front of the monitor, the button farthest to the right is the power button. Press this button unti its LED glows either amber or green.
Unit is receiving power, but monitor cable is disconnected.	Verify that the monitor cable on the back of the unit is properly inserted (do not adjust it at this point). If the monitor cable is disconnected, then follow these steps: 1. Power down the InnerVue™ Diagnostic Scope System by pushing the Power button next to the keyboard. 2. Remove the power cable from the wall outlet. 3. Re-insert the monitor cable and tighten with thumbscrew. 4. Re-insert the power cable into the wall outlet. 5. Power up the system.
Unknown component failure.	If the main menu does not appear after attempting the steps above, contact technical support at 1.888.639.6886.

Incorrect Media Error Appears

Probable Cause	Possible Solution
The software requires an unused InnerVue™ disk before it can proceed with or archive a procedure.	Insert an unused InnerVue™ disk into the CD drive. If this error still occurs, it is possible that the disk inserted has been previously recorded, or is unused, but damaged.
The software can only review video or images from a valid InnerVue™ disk.	Verify that the disk in the CD drive contains a valid archived procedure.

326

Printer Does Not Print

Probable Cause	Possible Solution
Paper tray is empty.	Insert blank paper into the paper tray of the printer.
Paper is improperly positioned in tray.	1. Remove paper from printer. 2. Remove both printed and blank paper from tray. 3. Re-insert only blank paper into the tray. 4. Replace paper tray.
Ink cassette is spent.	Insert a new ink cassette into the ink cassette slot.
Ink cassette is missing.	Insert a new ink cassette into the ink cassette slot.
Printer is disconnected from unit.	Verify that the data cable of the printer is properly inserted and reconnect if necessary.
Printer is not receiving electrical power.	Verify that the power cable of the printer is properly inserted and reconnect if necessary.
Printer error is too obscure to be described within this manual.	Refer to the printer manual.
Unknown software error.	If the printer manual does not help, then contact technical support at 1.888.639.6886.

Screen is Blue During Procedure

Probable Cause	Possible Solution
Handpiece cable is disconnected from unit.	Re-connect handpiece cable to system. It is safe to do this while the unit is turned on.
Unknown error.	Contact technical support at 1.888.639.6886.

No Sound During Procedure Playback

Probable Cause	Possible Solution
Sound is too low or absent.	Adjust monitor volume using the + and – keys on the front of the monitor.
Speaker cable is unplugged.	Verify that the speaker cable is properly plugged into the port labeled "Audio Input" on the back of the monitor and to the audio output jack on the back of the system. If not, re-insert the cable. It is safe to do this while the unit is turned on.
Microphone is unplugged.	Verify that the microphone is properly plugged into the port with the picture of the microphone.

327

Scope Illumination Not Present

Probable Cause	Possible Solution
Handpiece cable is unplugged.	Plug handpiece cable into unit. It is safe to do this while the unit is turned on.
Unit is out of procedure mode.	Return to procedure mode. For more information on how to do this, please refer to "Begin New Procedure" in the "Basic System Usage" section of this User Manual.
Light source turned off.	The Light Source button at the bottom left of the keyboard can be used to turn the light on or off.
Unit is too hot for light source to operate.	Wait for unit to become cooler and try again.

Pushing the Unit Requires Excessive Force or is Impossible

Probable Cause	Possible Solution
Wheels are locked.	Unlock wheels.

Screen is Frozen/System is Unresponsive

Probable Cause	Possible Solution
Software error	Hold down the power button by the keyboard for several seconds. The system will power down. Press the power button by the keyboard again to re-start.

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INVENTING THE FUTURE OF ARTHROSCOPY

SECTION 14. STERILIZATION AND SHELF LIFE

The VisionScope High Definition Endoscopy Camera System components are intended to be distributed and use under different states of sterilization. The table below summarizes the conditions related to sterility and sterilization of all the components, along with references to the validation protocols and test reports.

In addition, Document 14.2 of Section 14 (VisionScope Document 80094) provides a supplemental description of the Sterile Procedure Kit including the Endoscope Illumination Sheath as a Protective Barrier.

Summary of Sterilization Validation Reports

Based on a review of the Sterilization Protocols and Test Reports included in this section, the Camera Handpiece, Endoscopes and Sterile Procedure Kits are found to be safe and effective, and can perform their functions as intended after sterilization:

- The Camera Handpiece can be effectively sterilized by users to a SAL of better than 10^{-6}, using ETO, Sterrad 100S and Sterrad NX, in accordance with the procedures listed in the Instructions for Use.
- The Endoscopes can be effectively sterilized by users to a SAL of better than 10^{-6}, using ETO, Sterrad 100S and Sterrad NX in accordance with the procedures listed in the Instructions for Use.
- The Sterile Procedure Kit is validated to have a SAL of better than 10^{-6}, with a shelf life of one year, using validated manufacturing processes including sealing, packaging, and sterilization with ETO as described.

Additional sterilization information and supporting documents are summarized in the following table.

Subsystem & Part Number	Description of the Sterilization Requirements, Shelf Life, and Validation Reports
Camera Control Unit PN 50034	• This Camera Control Unit is distributed non-sterile. • Not intended to be used sterile by the users. • Periodic maintenance and surface cleaning is necessary. The Instructions for Use (PN 01112) provides the periodic maintenance and cleaning information that the user should follow. • The Instructions for Use is attached in Section 13 – Proposed Labeling of this 510(k) submission.
Camera Handpiece PN 50021	• The Camera Handpiece is distributed non-sterile. • May be used non-sterile in conjunction with the Sterile Procedure Kit for diagnostic imaging purpose only and when used without any other accompanying in-vivo surgical tools that may damage the endoscope sheath, in accordance with the Instructions for Use (PN 01112 and PN 01115). Must be cleaned and disinfected before and after each use in accordance with the Instructions for Use, when the device has not been contaminated by bio-hazard material. • Must be cleaned and re-sterilized by end-user when contaminated by bio-hazard material, or when used in conjunction with any additional tool in a surgical procedure, in accordance with the Instructions for Use (PN 01112 and PN 01115). This requirement is needed to prevent unintended infection risk in case the endoscope sheath is damaged accidentally in-vivo by powered resection instruments used during operative procedures. • Sterilization Efficacy validation to a minimum sterility assurance level (SAL) of 10^{-6} with one half of the expected full cycle was performed by (b)(4) [redacted]

	(b)(4) [redacted] in accordance with protocols conforming with AAMI/ANSI/ISO 14937:2000 - Sterilization of Health Care Products – General Requirements for Characterization of a Sterilizing Agent and the Development, Validation and Routine Control of a Sterilization Process. • Sterilization Protocols and Final Reports on the Sterilization Efficacy Validation are given in documents: ▪ 14.3 - Camera & Endoscope ETO Sterilization Efficacy Validation Final Report SPS-0909-329 ▪ 14.4 - Camera & Endoscope Sterrad 100S Sterilization Efficacy Validation Final Report SPS 0909-327-1 ▪ 14.5 - Camera & Endoscope Sterrad NX Sterilization Efficacy Validation Final Report SPS 0909-326 • In addition, VisionScope performed sterilization compatibility validation including imaging and functional tests on the Camera Handpiece & Endoscope combination before and after sterilization cycling to demonstrate that sterilization cycles do not adversely affect the performance of the devices (b)(4) [redacted] results are given in: ▪ 18.8 – 80083 Sterilization Compatibility Validation Report for Endoscope and Camera Head in Section 18 - Bench Testing. • The Camera Handpiece is a limited exposure device, as defined in FDA's recognized consensus standard AAMI/ANSI/ISO 10993-7:1995. As such, the maximum residual levels of ETO and ethylene chlorohydrin ("ECH") remaining on the product after sterilization, as measured using validated aqueous simulated use extraction methods shall not exceed an average daily (b)(4) [redacted] results are given in: ▪ 14.6 – Camera & Endoscope ETO & ECH Residual Test Final Report SPS 0909-330
Endoscopes PN 50006 – XXX XXX = working length designations = 060, 095, 160, 220 mm	• The Endoscopes are distributed non-sterile. • May be used non-sterile in conjunction with the Sterile Procedure Kit for diagnostic imaging purpose only and when used <u>without</u> any other accompanying in-vivo surgical tools that may damage the endoscope sheath, in accordance with the Instructions for Use (PN 01112 and PN 01115). Must be cleaned and disinfected before and after each use in accordance with the Instructions for Use, when the device has not been contaminated by bio-hazard material. • Must be cleaned and re-sterilized by end-user when contaminated by bio-hazard material, or when used in conjunction <u>with</u> any additional tool in a surgical procedure, in accordance with the Instructions for Use (PN 01112 and PN 01115). This requirement is needed to prevent unintended infection risk in case the endoscope sheath is damaged accidentally in-vivo by powered resection instruments used during operative procedures. • Sterilization Efficacy validation to a minimum sterility assurance level (SAL) of 10^{-6} with one half of the expected full cycle was performed by (b)(4) [redacted] (b)(4) [redacted] in accordance with protocols conforming with AAMI/ANSI/ISO 14937:2000 - Sterilization of Health Care Products – General Requirements for Characterization of a Sterilizing Agent and the Development, Validation and Routine Control of a Sterilization Process. • Sterilization Protocols and Final Reports on the Sterilization Efficacy Validation are given in documents: ▪ 14.3 - Camera & Endoscope ETO Sterilization Efficacy Validation Final Report

	SPS-0909-329 ▪ 14.4 - Camera & Endoscope Sterrad 100S Sterilization Efficacy Validation Final Report SPS 0909-327-1 ▪ 14.5 - Camera & Endoscope Sterrad NX Sterilization Efficacy Validation Final Report SPS 0909-326 • In addition, VisionScope performed sterilization compatibility validation including imaging and functional tests on the Camera Handpiece & Endoscope combination before and after sterilization cycling to demonstrate that sterilization cycles do not adversely affect the performance of the devices after 25 and 50 sterilization cycles. The results are given in: ▪ 18.8 – 80083 Sterilization Compatibility Validation Report for Endoscope and Camera Head in Section 18 - Bench Testing. • The Endoscope is a limited exposure device, as defined in FDA's recognized consensus standard AAMI/ANSI/ISO 10993-7:1995. As such, the maximum residual levels of ETO and ethylene chlorohydrin ("ECH") remaining on the product after sterilization, as measured using validated aqueous simulated use extraction methods, shall not exceed an average daily dose of 20 mg for ETO and 12 mg for ECH. The results are given in: ▪ 14.6 – Camera & Endoscope ETO & ECH Residual Test Final Report SPS 0909-330
Sterile Procedure Kit PN 50033-XXX XXX = working length designations = 060, 095, 160, 220 mm	• The Procedure Kit will be packaged and distributed in individual sterile packs, for Single Patient Use only, in accordance with the Instructions for Use (PN 01112 and PN 01114). • Must be disposed of after each use, in accordance with Instructions for Use (PN 01112 and PN 01114) and applicable biohazard disposal procedures as required by the Users' institutions. • The Procedure Kit will be sealed and packaged by (b)(4) [redacted] (b)(4) [redacted] prior to sterilization. Packaging & Sealing processes are validated by (b)(4) [redacted] following a Process Qualification (PQ) and an Operational Qualification (OQ) protocol. The PQ and OQ Validation Reports are given in: ▪ 14.7 - Sterile Procedure Kit Tray Sealing (b)(4) [redacted] Final Report ▪ 14.8 - Sterile Procedure Kit Tray Sealing (b)(4) [redacted] Final Report • Sealed Procedure Kits will be sterilized using a validated ETO sterilization cycle by (b)(4) [redacted] using the overkill method. The ETO sterilization cycles are designed and validated per the following references: ANSI/AAMI/ISO 11135:1994, ISO 11135-1:2007 and EN550:1994, AAMI TIR #14. • Half cycle sterilization validation was designed to provide a minimum sterility assurance level (SAL) of 10^{-6}, therefore a full cycle sterilization will lead to significantly better SAL. • PCS will conduct lot-by-lot sterilization and testing of biological indications located at various places of the product pellet under sterilization. VisionScope will review the sterility test results before releasing the device. • The ETO Sterilization Protocol is given in: ▪ 14.9 - Sterile Procedure Kit ETO Sterilization Protocol 10209014 • Summary Results of the Fractional Study to demonstrate the effectiveness of the ETO Sterilization Cycle to achieve SAL of 10^{-6} are given in: ▪ 14.10 - Summary of Sterile Procedure Kit ETO Fractional Cycle per Protocol

	10209014 ▪ 14.11 - Sterile Procedure Kit Fractional Cycle Sterilization Data ▪ 14.12 - Sterile Procedure Kit Fractional Cycle Test Results ▪ 14.13 - Sterile Procedure Kit ETO Fractional Cycle Biological Indicator Certificates • Sterile Packaging Ship Test was validated by (b)(4) [redacted] (b)(4) [redacted] Validation Reports are given in: ▪ 14.14 - Sterile Procedure Kit Ship Test Final Report 2008-126.pdf • The shelf life of the Sterile Procedure Kit is 1 year, established through a Sterile Packaging Aging Validation performed by (b)(4) [redacted] (b)(4) [redacted] Aging/Shelf Life Validation Report is given in: ▪ 14.15 - Sterile Procedure Kit Aging Test Validation Protocol PQ2008-121 • The final step of the Sterile Procedure Kit sterile packaging processes validation is the Label Generation validation performed at (b)(4) [redacted]. The Label Generation Validation Report is given in: ▪ 14.16 - Sterile Procedure Kit Label Validation Final Report 2008-112 Part 1 & 2.pdf • VisionScope performed barrier leakage, imaging and functional tests on the Sterile Procedure Kit to demonstrate that the sterilization cycle and normal articulation and deflection during clinical use does not affect the safety and effectiveness of the Endoscope Sheath. The verification protocol and test results are given in: ▪ 18.9 – 80082 ETO Sterilization Compatibility of Sterile Procedure Kit including Protective Barrier Effectiveness • The Sterile Procedure Kit is a limited exposure device, as defined in FDA's recognized consensus standard AAMI/ANSI/ISO 10993-7:1995. As such, the maximum residual levels of ETO and ethylene chlorohydrin ("ECH") remaining on the product after sterilization, as measured using validated aqueous simulated use extraction methods, shall not exceed an average daily dose of 20 mg for ETO and 12 mg for ECH. The requirement will be validated by (b)(4) [redacted] prior to product distribution by VisionScope.

14.2 - 80094 Supplemental Description of the Sterile Endoscope Illumination Sheath as a Protective Barrier

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SUPPLEMENTAL DESCRIPTION OF THE STERILE ENDOSCOPE ILLUMINATION SHEATH AS A PROTECTIVE BARRIER

Edit History

Revision	Date	Initials	Change Description
1.0	2/18/2010	LC	First version providing a detailed description of the Endoscope Sheath as a Virus Barrier
2.0	5/4/2010	LC	Remove several sections already discussed in other documents, e.g., Device Descriptions, Sterilization Summary, and Biocompatibility Summary.

Reviewed and Approved:

Jeff Lesica
Principal Mechanical Engineer

6/7/2010
Date

Lim Cheung, Ph.D.
General Manager & CTO, VisionScope

6/7/2010
Date

Table of Contents

1. INTRODUCTION **3**

2. SIMULATED VIRUS PENETRATION BENCH TESTING **3**

2.1. LIMITATIONS OF THE BACTERIOPHAGE INSIDE CHALLENGE METHOD DUE TO THE GEOMETRY OF THE VISIONSCOPE ILLUMINATION SHEATH 3
2.2. LIMITATIONS OF THE ASTM F1671-97A [3] DUE TO THE CONSTRUCTION MATERIAL OF THE VISIONSCOPE ILLUMINATION SHEATH 4
2.3. TRACER GAS (H_2, HE) INSIDE CHALLENGE LEAK DETECTION METHOD 4
2.3.1. Simulated Virus Penetration Tests of Illumination Sheath Using Inside Challenge Method with H_2 tracer gas .. *6*
2.4. CAMERA DRAPE LEAKAGE TEST 9
2.5. MANUFACTURING PROCESS VALIDATION 10
2.5.1. Illumination Sheath *10*
2.5.2. Sterile Packaging *11*
2.6. MANUFACTURING QUALITY CONTROL 11
2.6.1. Illumination Sheath *11*
2.6.2. Camera Drape *11*
2.6.3. Sterile Packaging *12*

3. REFERENCES **13**

1. Introduction

As noted in the Device Description Section (Section 11), the Endoscope Sheath, made up of a sub-2-mm Illumination Sheath with an integrated Camera Drape, also serves as a protective barrier that keeps outside body fluid, bacteria and virus away from the underlying endoscope and camera handpiece.

This document describes how VisionScope demonstrates the safety and effectiveness of this Endoscope Sheath, consistent with the discussions in the FDA Guidance document "Guidance for Manufacturers Seeking Marketing Clearance of Ear, Nose and Throat Endoscope Sheaths Used as Protective Barriers" [1, 2].

Based on the test data shown in this document, and consideration of the stainless-steel-and-glass construction material of the sheath, the manufacturing method, the quality assurance procedure, as well as a high-sensitivity leak check on 100% of all samples on the assembly line, we conclude that the VisionScope Illumination Sheath is safe and effective as a protective barrier.

2. Simulated Virus Penetration Bench Testing

(b)(4)

[redacted]

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(b)(4)

[redacted]

2.4. Camera Drape Leakage Test

Separately, we also tested the leak rate of the polyurethane Camera Drape. The purpose of the Camera Drape is to provide a sterile covering over the Camera Handpiece and electrical cable. The Camera Drape is not in direct contact with the patient. Under normal use condition, there is no differential pressure on both sides. The polyurethane film for the camera drape is constructed of the same material that has been used extensively in other FDA cleared medical products including male condoms, endoscope sheaths and balloon catheters. (b)(4)

(b)(4)

[redacted]

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(b)(4)

[redacted]

2.5. Manufacturing Process Validation

VisionScope completed the Final Design Review and Design Transfer Review (documented in the Design History File). Among the items on the Design Output Checklist are the Manufacturing Process Validation and Manufacturing Quality Control documents.

2.5.1. Illumination Sheath

The following tasks were carried out as part of the Illumination Sheath Manufacturing Process Validation. These tasks are in addition to the engineering verification tests of the Illumination Sheaths built for confirmation of that the devices meet the engineering design specifications (Document 80037, [4]).

Task No.	Purpose of Manufacturing Process Validation Sub-tasks	Illumination Sheaths Production Lot	Quantity
1	Protective Barrier Tests - (b)(4) [redacted] (b)(4) [redacted] to test for leaks, before and after ETO sterilization, and after agitation	(b)(4) [redacted]	
2	Protective Barrier Tests - (b)(4) [redacted] (b)(4) [redacted] to test for leaks, before and after ETO sterilization, and after agitation		
3	Protective Barrier Tests - (b)(4) [redacted] (b)(4) [redacted] to test for leaks, before and after ETO sterilization, and after agitation		
4	Biocompatibility Tests – ISO 10993-5, -10, -11		
5	Sterilization Validation Tests		
6	Sterile Packaging Sealing and Aging Tests		

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2.5.2. Sterile Packaging

The Sterilization Validation study is described fully in a separate set of documents, prepared by (b)(4) [redacted] consistent with the AAMI TRP14:2009. Briefly, the study contains the following steps:

- Process FMEA
- Package Sealing Process Qualification (PQ)
- Package Sealing Operational Qualification (OQ)
- Sterilization Validation using ETO in accordance with AAMI/ANSI/ISO-11135-1:2007
- ETO Residual Level validated in accordance with ISO-10993-7:2008
- Ship Test /Packaging Validation
- Aging Validation
- Label Validation

The validation protocols and the associated reports are listed in the Design History File and Technical File, Volume 2, and included in Section 14 – Sterilization and Shelf Life of the FDA 510(k) file.

2.6. Manufacturing Quality Control

2.6.1. Illumination Sheath

(b)(4) [redacted]

2.6.2. Camera Drape

(b)(4) [redacted]

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(b)(4)

[redacted]

2.6.3. Sterile Packaging

The Manufacturing Quality Control Processes for the Sterile Packing tasks include the following documents, steps and reports:

(b)(4)

[redacted]

Complete details can be found in the Design History File, Technical Files and Device Master Record.

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3. References

(b)(4)

[redacted]

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14.3 - Camera & Endoscope ETO Sterilization Efficacy Validation Final Report (b)(4) [redacted]

(b)(4) Testing

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14.4 - Camera & Endoscope Sterrad 100S Sterilization Efficacy Validation Final Report (b) (4) [redacted]

(b)(4) Testing

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(b)(4) Testing

14.5 - Camera & Endoscope Sterrad NX Sterilization Efficacy Validation Final Report (b) (4) [redacted]

(b)(4) Testing

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14.6 – Camera & Endoscope ETO & ECH Residual Test Report (b) (4) [redacted]

(b)(4) Testing

14.7 - Sterile Procedure Kit Tray Sealing (b) (4) [redacted], Final Report

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4)

[redacted]

ATTACHMENT 1

PEEL TEST RESULTS

(b)(4)

[redacted]

(b)(4) Testing

(b)(4) Testing

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14.8 - Sterile Procedure Kit Tray Sealing (b) (4) [redacted] Final Report

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14.9 - Sterile Procedure Kit ETO Sterilization Protocol (b) (4) [redacted]

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14.10 - Summary Report of Sterile Procedure Kit ETO Fractional Cycle per Protocol (b) (4) [redacted]

(b)(4) [redacted]

SUMMARY OF FRACTIONAL CYCLE

PER PROTOCOL (b)(4) [redacted]

FOR

VisionScope Technologies, LLC

(b)(4) [redacted]

Prepared By:

(b)(4) [redacted]

Copyright (b)(4) [redacted]

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

14.11 - Sterile Procedure Kit Fractional Cycle Sterilization Data

(b)(4) Testing

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14.12 - Sterile Procedure Kit Fractional Cycle Test Results

(b)(4) Testing

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14.13 - Sterile Procedure Kit ETO Fractional Cycle Biological Indicator Certificates

(b)(4) Testing

(b)(4) Testing

14.14 - Sterile Procedure Kit Ship Test Final Report (b) (4) [redacted]

(b)(4) [redacted]

SHIP TESTING VALIDATION FOR VISIONSCOPE TECHNOLOGIES DISPOSABLE KITS

PROCESS QUALIFICATION FINAL REPORT

PQ #: 2008-126

Equipment or Process Name: Ship Testing Validation

(b)(4) [redacted]

Applicable Product Codes or Product Families: Visionscope - Disposable Kits

Protocol Final Approvals:

The results of this Process Qualification have been reviewed and approved by the following parties. The equipment/process is ready for Production.

Originator's Department	Name	Signature	Date
Quality Engineering	(b)(4) [redacted]		

Department	
Quality Engineering	
Program Manager	
V.P. of Operations	
Training	
Visionscope Representative	

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: PQ # 2008-126

SHIP TESTING VALIDATION FOR VISIONSCOPE TECHNOLOGIES DISPOSABLE KITS

TO: Process Qualification File # 2008-126

FROM: (b) (6) [redacted]

SUBJECT: Ship Testing Validation Final Report – Visionscope Disposable Kits

DATE: 06/01/10

SUMMARY:

This Process Qualification was performed in strict adherence to the test procedure laid out in Section 6.0 of (b)(4) [redacted]

Sixty (60) samples provided by Visionscope, were trayed, boxed and labeled into their required packaging configurations. The fully packaged sample units were sent to (b)(4) [redacted] sterilization.

(b)(4) [redacted]

ISTA 2A Ship Testing.

Upon return from (b)(4) [redacted] all sixty (60) samples were inspected for damage and discoloration. Thirty (30) of the sixty (60) ship test samples were forwarded to (b)(4) [redacted] for bubble emission testing. The remaining thirty (30) samples were evaluated for peel strength. The results are included below.

RESULTS:

1) Peel Strength:

Thirty (30) tray (PM01081-001) test samples were evaluated for seal strength utilizing the Vinatoru Seal Strength Tester.

All thirty (30) trays showed a seal strength greater than 1lb/in. The average minimum peel strength was 1.55 lb/in, and The average maximum peel strength was 2.39 lb/in.

2) Materials and Product Inspection:

Shipping Container: All shipping Containers remained in good condition after ship testing. Refer to Figures shown in Ship testing section of this report to see actual condition of the shipping Containers.

Unit boxes: All unit boxes were thoroughly inspected for damage. All tamper seals were in place and undamaged. No discoloration was noticed on the unit, boxes, or tamper seals during inspection. Refer to Figures in Ship Testing section of this report to see pictures of actual samples.

Trays: There were no seal discontinuities on any of the trays. No physical damage was discovered for the trays used in the packaging of each product unit. Refer to figures shown in Ship testing section of this report to see actual condition of the trays

Product: Sixty (60) sample units were inspected for damage and discoloration. No units showed signs of damage or discoloration. Refer to figures shown in the ship testing section of this report for visual representation of the components.

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: PQ # 2008-126

SHIP TESTING VALIDATION FOR VISIONSCOPE TECHNOLOGIES DISPOSABLE KITS

3) Bubble Emission Testing:

Thirty (30) samples were submitted to (b)(4) [redacted] for Bubble Emission testing. None of the thirty (30) samples showed evidence of bubble emission. Refer to attached (b)(4) [redacted] Report for Bubble Emission Testing.

DEVIATIONS:

No deviations occurred during the execution of this protocol.

CONCLUSION:

Based on the achievement of acceptable results against the criterion stated in the approved protocol, the Visionscope Disposable Kits are approved for production and transit in their specified packaging configuration.

(b)(4) [redacted]

ATTACHMENT 1

POST STERILIZATION AND SHIP TEST SAMPLE PICTURES

(b)(4)

PROCESS QUALIFICATION: PQ # 2008-126

SHIP TESTING VALIDATION FOR VISIONSCOPE TECHNOLOGIES DISPOSABLE KITS

Shipping Container One

(b)(4)

(b)(4)

(b)(4) Testing

(b)(4) Testing

(b)(4)

[redacted]

ATTACHMENT 2

SAMPLE INSPECTION DATA:

(b)(4)

[redacted]

(b)(4)

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) [redacted]

ATTACHMENT 3

PEEL TEST RESULTS

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: PQ # 2008-126

SHIP TESTING VALIDATION FOR VISIONSCOPE TECHNOLOGIES DISPOSABLE KITS

Peel Test Results: Visionscope Disposable Kits - Ship Testing

Tray: PM VS01081-001 **Tray Lot :** 2544

SAMPLE	TEST LOT	SIDE	PEEL TEST RESULTS (LBS./IN) (b)(4)	VISUAL RESULTS	COMMENTS
1	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
2	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
3	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
4	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
5	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
6	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
7	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
8	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
9	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
10	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
11	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
12	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
13	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
14	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
15	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
16	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
17	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
18	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
19	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
20	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
21	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
22	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
23	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
24	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
25	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
26	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
27	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
28	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
29	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
30	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
31	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
32	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
33	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
34	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
35	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
36	A	A	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: PQ # 2008-126

SHIP TESTING VALIDATION FOR VISIONSCOPE TECHNOLOGIES DISPOSABLE KITS

37	(b)(4) [redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
38		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
39		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
40		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
41		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
42		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
43		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
44		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
45		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
46		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
47		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
48		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
49		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
50		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
51		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
52		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
53		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
54		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
55		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
56		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
57		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
58		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
59		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
60		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
61		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
62		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
63		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
64		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
65		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
66		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
67		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
68		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
69		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
70		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
71		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
72		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
73		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
74		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
75		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
76		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
77		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
78		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
79		☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: PQ # 2008-126

SHIP TESTING VALIDATION FOR VISIONSCOPE TECHNOLOGIES DISPOSABLE KITS

			(b)(4)		
80	B	B	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
81	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
82	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
83	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
84	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
85	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
86	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
87	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
88	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
89	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
90	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
91	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
92	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
93	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
94	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
95	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
96	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
97	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
98	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
99	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
100	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
101	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
102	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
103	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
104	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
105	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
106	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
107	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
108	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
109	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
110	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
111	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
112	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
113	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
114	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
115	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
116	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
117	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
118	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
119	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested
120	C	C	[redacted]	☒ ACCEPT ☐ REJECT	Sterilized @ 2 X ETO & Ship Tested

(b)(4) [redacted]

ATTACHMENT 4

PRODUCTION TRAVELERS AND COMPLETED TASK LISTS

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) [redacted]

ENGINEERING PACKAGE & LABEL CONTROL MATERIALS / PRODUCT USAGE

CLIENT: Vision scope

DATE: 04/05/10

PO #:

(b)(4) [redacted]

COMPONENT / MATERIAL #	DESCRIPTION	LOT #
PM VS01081-001	Blister Tray	2544
PM VS01082-001	Insert	2545
PM01118-001	Tyvek Lid	2543
50023-220	Sheath, hip	6102-10
50024-220	Cannula, hip	6102-10
50027-220	Trocars	6102-10
PM0117-220	Unit box	2630
PM01133-001	Tamper Label	2616
PM01114	IFU	2639
01136-001	15x20x10 shipper	NA
PM004	ETO Steri Dot	2357

NA MF 04/05/10

COMMENTS:

For Ship Testing Validation, PO 2008-126

(b)(4) [redacted]

(b)(4) [redacted]

F237 REV A
ECR # 1179

ENGINEERING PACKAGE & LABEL CONTROL TRAVELER

CLIENT: Vision scope DATE: 04/05/10

PO #: PQ 2008-126 FG Part Number (If required): NA

DESCRIBE REQUEST INCLUDING PRODUCT CODE AND LOT NUMBER IF REQUIRED:
Clean Room Package 60 Visionscope Units (P/N: 50023-220, sheath P/N 50024-220, Cannula and P/N 50027-220, Trocars) for ship testing Validation PQ 2008-126

If request is for Custom Product:

- Label proofs must be client approved prior to label printing.
- Label printing must be QA approved.
- A copy of the Prescription must be provided
- A signed copy of the Packaging Drawing

(b)(4) [redacted]

PRINTED BY: NA DATE: NA

QA APPROVED BY: NA DATE: NA

If QA approval is NA explain: generic Label

RECONCILED BY: NA DATE: NA

QA APPROVED BY: NA DATE: NA

If QA approval is NA explain: generic Label

☐ POUCH ☒ TRAY SEALER ID #: 50

INNER PARAMETERS:

OUTER PARAMETERS:

BOXING PERFORMED B

QA APPROVED BY:

If QA approval is NA e

PROVIDE A BRIEF EX

Packaged

(b)(4) [redacted]

(b)(4) [redacted]

ATTACHMENT 5
STERILIZATION CERTIFICATION

(b)(4)

[redacted]

VERIFICATION OF SAMPLE ETO EXPOSURE

(b) (6), (b) (4)

[redacted]

PACKING SLIP

(b)(4) [redacted]

DATE: APRIL 14, 2010

(b)(4) [redacted]

SHIP DATE	ORDER NUMBER	SHIPPED VIA
04/15/10	(b)(4) [redacted]	

ITEM #	DESCRIPTION	QUANTITY
1	ENGINEERING SAMPLES (b)(4) [redacted]	
	COMPANY NAME_____	
	PHONE NUMBER_____	
	DRIVER NAME (PRINT)_____	
	DRIVER SIGNATURE_____	
	TIME_____ DATE_____	

ATTACHMENT 6

(b)(4) [redacted] TEST REPORTS

(b)(4) [redacted]

Testing Certificate

Client: (b)(4) [redacted]

Procedure/Method: ISTA Test Procedure 2A for Individual Packaged Products 150lbs. or less, per MTL 1039S rev 004

Sample Description/Area: (b)(4) [redacted]

Box Dimensions:

(b)(4) [redacted]

(b)(4) [redacted]

Vibration Testing 1 and 2:

(b)(4) [redacted]

Shock Test (Drop Test):

(b)(4) [redacted]

Results:

After completion of the testing the exterior box was inspected and the following observations were made:

(b)(4) [redacted]

Reserve:

Sample(s) returned to client.

(b) (6) [redacted]

Analyst:

Approved by

(b)(4) [redacted]

ATTACHMENT 7

(b)(4) [redacted] TEST REPORTS

(b)(4) [redacted]

(b)(4)

[redacted]

BUBBLE EMISSION LEAK TEST – FINAL REPORT

Laboratory Number:	(b)(4) [redacted]
Procedure Number:	
Standard Method Based on:	
Sample Source:	
Sample Identification:	
Deviations:	
Statement of Uncertainty:	
Test Pressure:	
Package Size:	14 ½" x 5"
Package Type:	Porous
Product:	Present
Study Received Date:	11 May 2010
Lab Phase Start Date:	13 May 2010
Lab Phase Completion Date:	13 May 2010
Report Issue Date:	13 May 2010

(b) (6) [redacted]

14 MAY 2010
Study Completion Date

anl

(b)(4) [redacted]

524

(b)(4)

[redacted]

Bubble Emission Leak Test

TABLE 2. Results
VisionScope Technologies Disposable Kits / PQ 2008-126

PACKAGE IDENTIFICATION	RESULT
B1	0
B2	0
B8	0
B10	0
B11	0
B12	0
B14	0
B16	0
B19	0
B20	0

'0' No Evidence of Bubble Emission
'+' Evidence of Bubble Emission

525

(b)(4)

[redacted]

Bubble Emission Leak Test

TABLE 1. Results
VisionScope Technologies Disposable Kits / PQ 2008-126

PACKAGE IDENTIFICATION	RESULT
A2	0
A5	0
A11	0
A12	0
A14	0
A15	0
A16	0
A17	0
A18	0
A20	0

'0' No Evidence of Bubble Emission
'+' Evidence of Bubble Emission

526

(b)(4)

[redacted]

Bubble Emission Leak Test

TABLE 3. Results
VisionScope Technologies Disposable Kits / PQ 2008-126

PACKAGE IDENTIFICATION	RESULT
C1	0
C2	0
C4	0
C6	0
C8	0
C10	0
C11	0
C17	0
C7	0
C18	0

'0' No Evidence of Bubble Emission
'+' Evidence of Bubble Emission

14.15 - Sterile Procedure Kit Aging Test Validation Final Report (b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

PROCESS QUALIFICATION FINAL REPORT **PQ #: 2008-121**

Equipment or Process Name: Real Time & Accelerated Aging Validation

Manufacturer: (b)(4) [redacted] **Serial Number:** NA

PM Number: NA **Location:** NA

Applicable Product Codes or Product Families: Visionscope Disposable Kits

---

Protocol Final Approvals:

The results of this Process Qualification have been reviewed and approved by the following parties. The equipment and process are ready for production.

Originator's Department	Name	Signature	Date
Quality Engineering	(b) (6) [redacted]		06/15/10

Department		Date
Quality Engineering		6/16/10
V.P. of Operations		6/16/10
Training		6/16/10
Program Manager		6-16-10
Visionscope Representative		6/16/10

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

PROCESS QUALIFICATION FINAL REPORT

PQ #: 2008-121

Equipment or Process Name: Real Time & Accelerated Aging Validation

Manufacturer: (b)(4) [redacted]

Serial Number: NA

PM Number: NA **Location:** NA

Applicable Product Codes or Product Families: Visionscope Disposable Kits

Protocol Final Approvals:

The results of this Process Qualification have been reviewed and approved by the following parties. The equipment and process are ready for production.

Originator's Department	Name	Signature	Date
Quality Engineering	(b) (6) [redacted]		

Department
Quality Engineering
V.P. of Operations
Training
Program Manager
Visionscope Representative

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

TO: Process Qualification File # 2008-121

FROM: (b) (6) [redacted]

SUBJECT: Final Validation Report – 1 Year Accelerated Aging Validation for Visionscope – Disposable Kits

DATE: 06/15/10

SUMMARY:

This Process Qualification was performed in accordance to the test procedure laid out in Section 6.0 of PQ# 2008-121.

One hundred twenty (120) sample units were packaged in accordance with the approved work instructions for packaging, and sterilization of Visionscope Disposable Kits.

The bulk container employed for the aging studies was a 20x15x10 Uline shipper box (P/N S-11378). Dunnage such as bubble wrap, etc. was used to fill the extra space.

All product was forwarded through a 2x EtO (Ethylene Oxide) sterilization run representing a worst-case scenario dose for the product type in question.

After sterilization, sixty (60) samples for 1 Year Accelerated Aging were forwarded to (b)(4) [redacted] for 40 days in an (b)(4) [redacted] which is equivalent to 1 year of real time aging. The sixty (60) remaining samples were set aside for 1 year real time aging studies.

Upon completion of the 1 Year Accelerated Aging study, the sixty (60) samples were returned to (b)(4) [redacted] for analysis.

Upon completion of the visual integrity inspection at Millstone, thirty (30) of the sixty (60) samples were sent to (b)(4) [redacted] for bubble emission testing. The remaining thirty (30) samples were evaluated for peel strength.

Results for the 1 Year Accelerated Aging is listed below. Results for the 1 year Real Time Aging Study will be provided as an addendum at the appropriate time.

See attached pictures of post sterile, post accelerated aging samples.

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

RESULTS:

1) Materials and Product Inspection:

Shipping Box: The shipping box for the units did not experience any damage due to the aging process.

Unit Box: All of the unit boxes were thoroughly inspected. All tamper seals were in place and undamaged after the aging study. Refer to Figures in Attachment 2 of this report to see pictures of actual condition.

Trays: There was no evidence of seal discontinuities seen on visual inspection of any trays. No physical damage was discovered on the trays used in the packaging of the product unit.

Labels: The labels utilized remained intact and legible.

Product: No Product was utilized during the execution of this protocol.

2) Peel Strength:

Thirty (30) tray (PM01081-001) test samples were evaluated for seal strength utilizing the (b)(4) [redacted] Seal Strength Tester.

All thirty (30) trays showed a seal strength greater than 1lb/in. The average minimum peel strength was 1.45 lb/in, and The average maximum peel strength was 3.92 lb/in.

Peel testing results are attached.

3) Bubble Emission Testing:

Thirty (30) samples were submitted to (b)(4) [redacted] for Bubble Emission testing. None of the thirty (30) samples showed evidence of bubble emission. Refer to attached (b)(4) [redacted] Report for Bubble Emission Testing.

DEVIATIONS:

No deviations occurred during the execution of this validation.

CONCLUSION:

Based on the achievement of acceptable results against the criteria stated in the approved protocol, the Visionscope Disposable Kits are approved for packaging under the one (1) year expiration date. The Real Time Aging report will be added as an addendum to this report as the study is completed.

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

ATTACHMENT 1: Visionscope 1yr Accelerated Aging Peel Test Results

Tray Part Number: PM 01081-001 **Tray Lot #:** 2544

Lid Part Number: PM 01118-001 **Lid Lot #:** 2543

TEST#	SAMPLE	REPLICATE	CONDITION	AVERAGE	PEAK
1	1	1	1yr acc aging	(b)(4) [redacted]	
2	1	2	1yr acc aging		
3	1	3	1yr acc aging		
4	1	4	1yr acc aging		
5	2	1	1yr acc aging		
6	2	2	1yr acc aging		
7	2	3	1yr acc aging		
8	2	4	1yr acc aging		
9	3	1	1yr acc aging		
10	3	2	1yr acc aging		
11	3	3	1yr acc aging		
12	3	4	1yr acc aging		
13	4	1	1yr acc aging		
14	4	2	1yr acc aging		
15	4	3	1yr acc aging		
16	4	4	1yr acc aging		
17	5	1	1yr acc aging		
18	5	2	1yr acc aging		
19	5	3	1yr acc aging		
20	5	4	1yr acc aging		
21	6	1	1yr acc aging		
22	6	2	1yr acc aging		
23	6	3	1yr acc aging		
24	6	4	1yr acc aging		
25	7	1	1yr acc aging		
26	7	2	1yr acc aging		
27	7	3	1yr acc aging		
28	7	4	1yr acc aging		
29	8	1	1yr acc aging		
30	8	2	1yr acc aging		
31	8	3	1yr acc aging		
32	8	4	1yr acc aging		
33	9	1	1yr acc aging		
34	9	2	1yr acc aging		
35	9	3	1yr acc aging		
36	9	4	1yr acc aging		
37	10	1	1yr acc aging		
38	10	2	1yr acc aging		
39	10	3	1yr acc aging		
40	10	4	1yr acc aging		

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

TEST#	SAMPLE	REPLICATE	CONDITION	AVERAGE	PEAK
41	11	1	1yr acc aging	(b)(4) [redacted]	
42	11	2	1yr acc aging		
43	11	3	1yr acc aging		
44	11	4	1yr acc aging		
45	12	1	1yr acc aging		
46	12	2	1yr acc aging		
47	12	3	1yr acc aging		
48	12	4	1yr acc aging		
49	13	1	1yr acc aging		
50	13	2	1yr acc aging		
51	13	3	1yr acc aging		
52	13	4	1yr acc aging		
53	14	1	1yr acc aging		
54	14	2	1yr acc aging		
55	14	3	1yr acc aging		
56	14	4	1yr acc aging		
57	15	1	1yr acc aging		
58	15	2	1yr acc aging		
59	15	3	1yr acc aging		
60	15	4	1yr acc aging		
61	16	1	1yr acc aging		
62	16	2	1yr acc aging		
63	16	3	1yr acc aging		
64	16	4	1yr acc aging		
65	17	1	1yr acc aging		
66	17	2	1yr acc aging		
67	17	3	1yr acc aging		
68	17	4	1yr acc aging		
69	18	1	1yr acc aging		
70	18	2	1yr acc aging		
71	18	3	1yr acc aging		
72	18	4	1yr acc aging		
73	19	1	1yr acc aging		
74	19	2	1yr acc aging		
75	19	3	1yr acc aging		
76	19	4	1yr acc aging		
77	20	1	1yr acc aging		
78	20	2	1yr acc aging		
79	20	3	1yr acc aging		
80	20	4	1yr acc aging		
81	21	1	1yr acc aging		
82	21	2	1yr acc aging		
83	21	3	1yr acc aging		
84	21	4	1yr acc aging		
85	22	1	1yr acc aging		

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

TEST#	SAMPLE	REPLICATE	CONDITION	AVERAGE	PEAK
86	22	2	1yr acc aging	(b)(4) [redacted]	
87	22	3	1yr acc aging		
88	22	4	1yr acc aging		
89	23	1	1yr acc aging		
90	23	2	1yr acc aging		
91	23	3	1yr acc aging		
92	23	4	1yr acc aging		
93	24	1	1yr acc aging		
94	24	2	1yr acc aging		
95	24	3	1yr acc aging		
96	24	4	1yr acc aging		
97	25	1	1yr acc aging		
98	25	2	1yr acc aging		
99	25	3	1yr acc aging		
100	25	4	1yr acc aging		
101	26	1	1yr acc aging		
102	26	2	1yr acc aging		
103	26	3	1yr acc aging		
104	26	4	1yr acc aging		
105	27	1	1yr acc aging		
106	27	2	1yr acc aging		
107	27	3	1yr acc aging		
108	27	4	1yr acc aging		
109	28	1	1yr acc aging		
110	28	2	1yr acc aging		
111	28	3	1yr acc aging		
112	28	4	1yr acc aging		
113	29	1	1yr acc aging		
114	29	2	1yr acc aging		
115	29	3	1yr acc aging		
116	29	4	1yr acc aging		
117	30	1	1yr acc aging		
118	30	2	1yr acc aging		
119	30	3	1yr acc aging		
120	30	4	1yr acc aging		

Tested By: (b) (6) [redacted]

(b)(4) [redacted]

(b)(4)

[redacted]

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

Visionscope Disposable Kits - One Year Accelerated Aging

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

ATTACHMENT 2: POST STERILIZATION AND 1 YEAR ACCELERATED AGING SAMPLE PICTURES

Shipping Container:

Unit Boxes within Shipper:

(b)(4)

[redacted]

Unit Box:

Patient Labels, IFU, and Tray Configuration:

Figure 3

Figure 4

(b)(4)

[redacted]

(b)(4)

[redacted]

537

ATTACHMENT 3

(b)(4) [redacted]

Procedure Task List & Visual Inspection Results

(b)(4) Testing

(b)(4) Testing

(b)(4)

[redacted]

F556 Rev A
ECR 2268

PROCESS QUALIFICATION: PQ # 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE TECNOLOGIES DISPOSABLE KITS

ATTACHMENT 2: SAMPLE INSPECTION DATA: ☒ **Accelerated** ☐ **Real Time**

Sample	Item	Seal	Damage	Test	P/F	Initials	Date
1	Tray	Pass	No Damage	1 Year Aging	P	MF	05/02/10
	Unit Box						
2	Tray			1 Year Aging			
	Unit Box						
3	Tray			1 Year Aging			
	Unit Box						
4	Tray			1 Year Aging			
	Unit Box						
5	Tray			1 Year Aging			
	Unit Box						
6	Tray			1 Year Aging			
	Unit Box						
7	Tray			1 Year Aging			
	Unit Box						
8	Tray			1 Year Aging			
	Unit Box						
9	Tray			1 Year Aging			
	Unit Box						
10	Tray			1 Year Aging			
	Unit Box						
11	Tray			1 Year Aging			
	Unit Box						
12	Tray			1 Year Aging			
	Unit Box						
13	Tray			1 Year Aging			
	Unit Box						
14	Tray			1 Year Aging			
	Unit Box						
15	Tray			1 Year Aging			
	Unit Box						
16	Tray			1 Year Aging			
	Unit Box						
17	Tray	↓	↓	1 Year Aging	↓	↓	↓
	Unit Box	Pass	No Damage		P	MF	05/02/10

(b)(4)

[redacted]

(b)(4)

[redacted]

F556 Rev A
ECR 2268

PROCESS QUALIFICATION: PQ # 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE TECNOLOGIES DISPOSABLE KITS

ATTACHMENT 2: SAMPLE INSPECTION DATA: ☒ **Accelerated** ☐ **Real Time**

Sample	Item	Seal	Damage	Test	P/F	Initials	Date
18	Tray	Pass	No Damage	1 Year Aging	P	MF	05/02/10
	Unit Box						
19	Tray			1 Year Aging			
	Unit Box						
20	Tray			1 Year Aging			
	Unit Box						
21	Tray			1 Year Aging			
	Unit Box						
22	Tray			1 Year Aging			
	Unit Box						
23	Tray			1 Year Aging			
	Unit Box						
24	Tray			1 Year Aging			
	Unit Box						
25	Tray			1 Year Aging			
	Unit Box						
26	Tray			1 Year Aging			
	Unit Box						
27	Tray			1 Year Aging			
	Unit Box						
28	Tray			1 Year Aging			
	Unit Box						
29	Tray			1 Year Aging			
	Unit Box						
30	Tray			1 Year Aging			
	Unit Box						
31	Tray			1 Year Aging			
	Unit Box						
32	Tray			1 Year Aging			
	Unit Box						
33	Tray			1 Year Aging			
	Unit Box						
34	Tray			1 Year Aging			
	Unit Box	Pass	No Damage		P	MF	05/02/10

(b)(4)

[redacted]

(b)(4) [redacted]

F556 Rev A
ECR 2268

PROCESS QUALIFICATION: PQ # 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE TECNOLOGIES DISPOSABLE KITS

ATTACHMENT 2: SAMPLE INSPECTION DATA: ☒ **Accelerated** ☐ **Real Time**

Sample	Item	Seal	Damage	Test	P/F	Initials	Date
35	Tray	Pass	No Damage	1 Year Aging	P	MF	05/02/10
	Unit Box						
36	Tray			1 Year Aging			
	Unit Box						
37	Tray			1 Year Aging			
	Unit Box						
38	Tray			1 Year Aging			
	Unit Box						
39	Tray			1 Year Aging			
	Unit Box						
40	Tray			1 Year Aging			
	Unit Box						
41	Tray			1 Year Aging			
	Unit Box						
42	Tray			1 Year Aging			
	Unit Box						
43	Tray			1 Year Aging			
	Unit Box						
44	Tray			1 Year Aging			
	Unit Box						
45	Tray			1 Year Aging			
	Unit Box						
46	Tray			1 Year Aging			
	Unit Box						
47	Tray			1 Year Aging			
	Unit Box						
48	Tray			1 Year Aging			
	Unit Box						
49	Tray			1 Year Aging			
	Unit Box						
50	Tray			1 Year Aging			
	Unit Box						
51	Tray			1 Year Aging			
	Unit Box	Pass	No Damage		P	MF	05/02/10

(b)(4) [redacted]

(b)(4) [redacted]

F556 Rev A
ECR 2268

PROCESS QUALIFICATION: PQ # 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE TECNOLOGIES DISPOSABLE KITS

ATTACHMENT 2: SAMPLE INSPECTION DATA: ☒ **Accelerated** ☐ **Real Time**

Sample	Item	Seal	Damage	Test	P/F	Initials	Date
52	Tray	Pass	No Damage	1 Year Aging	P	MF	05/02/10
	Unit Box						
53	Tray			1 Year Aging			
	Unit Box						
54	Tray			1 Year Aging			
	Unit Box						
55	Tray			1 Year Aging			
	Unit Box						
56	Tray			1 Year Aging			
	Unit Box						
57	Tray			1 Year Aging			
	Unit Box						
58	Tray			1 Year Aging			
	Unit Box						
59	Tray			1 Year Aging			
	Unit Box						
60	Tray			1 Year Aging			
	Unit Box	Pass	No Damage		P	MF	05/02/10
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box		NA				
	Tray		MF 05/02/10	1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						

(b)(4) [redacted]

(b)(4) [redacted]

F237 REV A
ECR # 1179

ENGINEERING PACKAGE & LABEL CONTROL TRAVELER

CLIENT: Visionscope DATE: 03/22/10

PO #: PQ 2008-121 FG Part Number (If required): NA

(b)(4) [redacted]

- Label proofs must be client approved prior to label printing.
- Label printing must be QA approved.
- Box check must be QA approved
- A copy of the Prescription must be provided
- A signed copy of the Packaging Drawing

(b)(4) [redacted]

PRINTED BY: MF DATE: 03/25/10

QA APPROVED BY: NA DATE: NA

If QA approval is NA explain: generic Label

RECONCILED BY: MF DATE: 03/26/10

QA APPROVED BY: NA DATE: NA

If QA approval is NA explain: generic Label

☐ POUCH ☒ TRAY SEALER ID #: 50

INNER PARAMETERS: HEAT: 235 DWELL: 5.8 PRESSURE: 50 SEALING PERFORMED BY: MF DATE: 03/24/10

OUTER PARAMETERS: HEAT: NA DWELL: NA PRESSURE: NA SEALING PERFORMED BY: NA DATE: NA

BOXING PERFORMED BY: MF NA DATE: 03/26/10 QTY. BOXED: 120

QA APPROVED BY: NA DATE: NA

If QA approval is NA explain: engineering Run

PROVIDE A BRIEF EXPLANATION OF THE WORK PERFORMED:

cleanroom packaged 120 Visionscope - Disposable Kits in accordance with PQ 2008-121 for 1year Real Time & Accelerated aging

INITIALS: MF DATE: 03/30/10

(b)(4) [redacted]

F238 REV A
ECR # 1179

ENGINEERING PACKAGE & LABEL CONTROL MATERIALS / PRODUCT USAGE

CLIENT: Visionscope

DATE: 03/22/10

PO #: PQ 2008-121

COMPONENT / MATERIAL #	DESCRIPTION	LOT #	QTY.
PM 01114	IFU	2639	(b)(4) [redacted]
PM 01117-220	Unit box	2630	
PM 01118-001	Tyvek Lid	2543	
PM VS01081-001	PE Tray	2544	
PM VS01082-001	Insert	2545	
PM 004	EtO Steri Dot	2357	
PM 01133-001	Tamper Label	2616	
01136-001	15x20x10 Shipper	NA	

NA
MF 03/22/10

COMMENTS:
Visionscope Aging Study, PQ 2008-121
No Product Utilized
MF 03/22/10

(b)(4) [redacted]

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

PROCESS QUALIFICATION FINAL REPORT **PQ #: 2008-121**

Equipment or Process Name: Real Time & Accelerated Aging Validation

Manufacturer: (b)(4) [redacted] **Serial Number:** NA

PM Number: NA **Location:** NA

Applicable Product Codes or Product Families: Visionscope Disposable Kits

---

Protocol Final Approvals:

The results of this Process Qualification have been reviewed and approved by the following parties. The equipment and process are ready for production.

Originator's Department	Name	Signature	Date
Quality Engineering	(b) (6) [redacted]		

Department
Quality Engineering
V.P. of Operations
Training
Program Manager
Visionscope Representative

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

PROCESS QUALIFICATION FINAL REPORT **PQ #: 2008-121**

Equipment or Process Name: Real Time & Accelerated Aging Validation

Manufacturer: (b)(4) [redacted] **Serial Number:** NA

PM Number: NA **Location:** NA

Applicable Product Codes or Product Families: Visionscope Disposable Kits

---

Protocol Final Approvals:

The results of this Process Qualification have been reviewed and approved by the following parties. The equipment and process are ready for production.

Originator's Department	Name	Signature	Date
Quality Engineering	(b)(4) [redacted]		

Department
Quality Engineering
V.P. of Operations
Training
Program Manager
Visionscope Representative

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

TO: Process Qualification File # 2008-121

FROM: (b) (6) [redacted]

SUBJECT: Final Validation Report – 1 Year Accelerated Aging Validation for Visionscope – Disposable Kits

DATE: 06/15/10

SUMMARY:

This Process Qualification was performed in accordance to the test procedure laid out in Section 6.0 of PQ# 2008-121.

One hundred twenty (120) sample units were packaged in accordance with the approved work instructions for packaging, and sterilization of Visionscope Disposable Kits.

The bulk container employed for the aging studies was a 20x15x10 Uline shipper box (P/N S-11378). Dunnage such as bubble wrap, etc. was used to fill the extra space.

All product was forwarded through a 2x EtO (Ethylene Oxide) sterilization run representing a worst-case scenario dose for the product type in question.

(b)(4) [redacted]

Upon completion of the 1 Year Accelerated Aging study, the sixty (60) samples were returned to (b)(4) [redacted] for analysis.

Upon completion of the visual integrity inspection at (b)(4) [redacted] thirty (30) of the sixty (60) samples were sent to (b)(4) [redacted] for bubble emission testing. The remaining thirty (30) samples were evaluated for peel strength.

Results for the 1 Year Accelerated Aging is listed below. Results for the 1 year Real Time Aging Study will be provided as an addendum at the appropriate time.

See attached pictures of post sterile, post accelerated aging samples.

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

RESULTS:

1) Materials and Product Inspection:

Shipping Box: The shipping box for the units did not experience any damage due to the aging process.

Unit Box: All of the unit boxes were thoroughly inspected. All tamper seals were in place and undamaged after the aging study. Refer to Figures in Attachment 2 of this report to see pictures of actual condition.

Trays: There was no evidence of seal discontinuities seen on visual inspection of any trays. No physical damage was discovered on the trays used in the packaging of the product unit.

Labels: The labels utilized remained intact and legible.

Product: No Product was utilized during the execution of this protocol.

2) Peel Strength:

Thirty (30) tray (PM01081-001) test samples were evaluated for seal strength utilizing the (b)(4) [redacted] Seal Strength Tester.

(b)(4) [redacted]

3) Bubble Emission Testing:

Thirty (30) samples were submitted to (b)(4) [redacted] for Bubble Emission testing. None of the thirty (30) samples showed evidence of bubble emission. Refer to attached (b)(4) [redacted] Report for Bubble Emission Testing.

DEVIATIONS:

No deviations occurred during the execution of this validation.

CONCLUSION:

Based on the achievement of acceptable results against the criteria stated in the approved protocol, the Visionscope Disposable Kits are approved for packaging under the one (1) year expiration date. The Real Time Aging report will be added as an addendum to this report as the study is completed.

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

ATTACHMENT 1: Visionscope 1yr Accelerated Aging Peel Test Results

Tray Part Number: PM 01081-001 **Tray Lot #:** 2544

Lid Part Number: PM 01118-001 **Lid Lot #:** 2543

TEST#	SAMPLE	REPLICATE	CONDITION	AVERAGE	PEAK
1	1	1	1yr acc aging	(b)(4) [redacted]	
2	1	2	1yr acc aging		
3	1	3	1yr acc aging		
4	1	4	1yr acc aging		
5	2	1	1yr acc aging		
6	2	2	1yr acc aging		
7	2	3	1yr acc aging		
8	2	4	1yr acc aging		
9	3	1	1yr acc aging		
10	3	2	1yr acc aging		
11	3	3	1yr acc aging		
12	3	4	1yr acc aging		
13	4	1	1yr acc aging		
14	4	2	1yr acc aging		
15	4	3	1yr acc aging		
16	4	4	1yr acc aging		
17	5	1	1yr acc aging		
18	5	2	1yr acc aging		
19	5	3	1yr acc aging		
20	5	4	1yr acc aging		
21	6	1	1yr acc aging		
22	6	2	1yr acc aging		
23	6	3	1yr acc aging		
24	6	4	1yr acc aging		
25	7	1	1yr acc aging		
26	7	2	1yr acc aging		
27	7	3	1yr acc aging		
28	7	4	1yr acc aging		
29	8	1	1yr acc aging		
30	8	2	1yr acc aging		
31	8	3	1yr acc aging		
32	8	4	1yr acc aging		
33	9	1	1yr acc aging		
34	9	2	1yr acc aging		
35	9	3	1yr acc aging		
36	9	4	1yr acc aging		
37	10	1	1yr acc aging		
38	10	2	1yr acc aging		
39	10	3	1yr acc aging		
40	10	4	1yr acc aging		

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

TEST#	SAMPLE	REPLICATE	CONDITION	AVERAGE	PEAK
41	11	1	1yr acc aging	(b)(4) [redacted]	
42	11	2	1yr acc aging		
43	11	3	1yr acc aging		
44	11	4	1yr acc aging		
45	12	1	1yr acc aging		
46	12	2	1yr acc aging		
47	12	3	1yr acc aging		
48	12	4	1yr acc aging		
49	13	1	1yr acc aging		
50	13	2	1yr acc aging		
51	13	3	1yr acc aging		
52	13	4	1yr acc aging		
53	14	1	1yr acc aging		
54	14	2	1yr acc aging		
55	14	3	1yr acc aging		
56	14	4	1yr acc aging		
57	15	1	1yr acc aging		
58	15	2	1yr acc aging		
59	15	3	1yr acc aging		
60	15	4	1yr acc aging		
61	16	1	1yr acc aging		
62	16	2	1yr acc aging		
63	16	3	1yr acc aging		
64	16	4	1yr acc aging		
65	17	1	1yr acc aging		
66	17	2	1yr acc aging		
67	17	3	1yr acc aging		
68	17	4	1yr acc aging		
69	18	1	1yr acc aging		
70	18	2	1yr acc aging		
71	18	3	1yr acc aging		
72	18	4	1yr acc aging		
73	19	1	1yr acc aging		
74	19	2	1yr acc aging		
75	19	3	1yr acc aging		
76	19	4	1yr acc aging		
77	20	1	1yr acc aging		
78	20	2	1yr acc aging		
79	20	3	1yr acc aging		
80	20	4	1yr acc aging		
81	21	1	1yr acc aging		
82	21	2	1yr acc aging		
83	21	3	1yr acc aging		
84	21	4	1yr acc aging		
85	22	1	1yr acc aging		

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

TEST#	SAMPLE	REPLICATE	CONDITION	AVERAGE	PEAK
86	22	2	1yr acc aging	(b)(4) [redacted]	
87	22	3	1yr acc aging		
88	22	4	1yr acc aging		
89	23	1	1yr acc aging		
90	23	2	1yr acc aging		
91	23	3	1yr acc aging		
92	23	4	1yr acc aging		
93	24	1	1yr acc aging		
94	24	2	1yr acc aging		
95	24	3	1yr acc aging		
96	24	4	1yr acc aging		
97	25	1	1yr acc aging		
98	25	2	1yr acc aging		
99	25	3	1yr acc aging		
100	25	4	1yr acc aging		
101	26	1	1yr acc aging		
102	26	2	1yr acc aging		
103	26	3	1yr acc aging		
104	26	4	1yr acc aging		
105	27	1	1yr acc aging		
106	27	2	1yr acc aging		
107	27	3	1yr acc aging		
108	27	4	1yr acc aging		
109	28	1	1yr acc aging		
110	28	2	1yr acc aging		
111	28	3	1yr acc aging		
112	28	4	1yr acc aging		
113	29	1	1yr acc aging		
114	29	2	1yr acc aging		
115	29	3	1yr acc aging		
116	29	4	1yr acc aging		
117	30	1	1yr acc aging		
118	30	2	1yr acc aging		
119	30	3	1yr acc aging		
120	30	4	1yr acc aging		

Tested By: (b) (6) [redacted]

Date: 06/14/10

(b)(4) [redacted]

(b)(4)

[redacted]

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

Visionscope Disposable Kits - One Year Accelerated Aging

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

ATTACHMENT 2: POST STERILIZATION AND 1 YEAR ACCELERATED AGING SAMPLE PICTURES

Shipping Container:

Unit Boxes within Shipper:

(b)(4)

Unit Box:

Patient Labels, IFU, and Tray Configuration:

(b)(4)

(b)(4)

ATTACHMENT 3

(b)(4) [redacted]

Procedure Task List & Visual Inspection Results

(b)(4) Testing

(b)(4) Testing

(b)(4) [redacted]

F556 Rev A
ECR 2268

PROCESS QUALIFICATION: PQ # 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE TECNOLOGIES DISPOSABLE KITS

ATTACHMENT 2: SAMPLE INSPECTION DATA: ☒ **Accelerated** ☐ **Real Time**

Sample	Item	Seal	Damage	Test	P/F	Initials	Date
1	Tray	Pass	No Damage	1 Year Aging	P	MF	05/02/10
	Unit Box						
2	Tray			1 Year Aging			
	Unit Box						
3	Tray			1 Year Aging			
	Unit Box						
4	Tray			1 Year Aging			
	Unit Box						
5	Tray			1 Year Aging			
	Unit Box						
6	Tray			1 Year Aging			
	Unit Box						
7	Tray			1 Year Aging			
	Unit Box						
8	Tray			1 Year Aging			
	Unit Box						
9	Tray			1 Year Aging			
	Unit Box						
10	Tray			1 Year Aging			
	Unit Box						
11	Tray			1 Year Aging			
	Unit Box						
12	Tray			1 Year Aging			
	Unit Box						
13	Tray			1 Year Aging			
	Unit Box						
14	Tray			1 Year Aging			
	Unit Box						
15	Tray			1 Year Aging			
	Unit Box						
16	Tray			1 Year Aging			
	Unit Box						
17	Tray			1 Year Aging			
	Unit Box	Pass	No Damage		P	MF	05/02/10

(b)(4) [redacted]

(b)(4)

[redacted]

F556 Rev A
ECR 2268

PROCESS QUALIFICATION: PQ # 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE TECNOLOGIES DISPOSABLE KITS

ATTACHMENT 2: SAMPLE INSPECTION DATA: ☒ **Accelerated** ☐ **Real Time**

Sample	Item	Seal	Damage	Test	P/F	Initials	Date
18	Tray	Pass	No Damage	1 Year Aging	P	MF	05/02/10
	Unit Box						
19	Tray			1 Year Aging			
	Unit Box						
20	Tray			1 Year Aging			
	Unit Box						
21	Tray			1 Year Aging			
	Unit Box						
22	Tray			1 Year Aging			
	Unit Box						
23	Tray			1 Year Aging			
	Unit Box						
24	Tray			1 Year Aging			
	Unit Box						
25	Tray			1 Year Aging			
	Unit Box						
26	Tray			1 Year Aging			
	Unit Box						
27	Tray			1 Year Aging			
	Unit Box						
28	Tray			1 Year Aging			
	Unit Box						
29	Tray			1 Year Aging			
	Unit Box						
30	Tray			1 Year Aging			
	Unit Box						
31	Tray			1 Year Aging			
	Unit Box						
32	Tray			1 Year Aging			
	Unit Box						
33	Tray			1 Year Aging			
	Unit Box						
34	Tray			1 Year Aging			
	Unit Box	Pass	No Damage		P	MF	05/02/10

(b)(4)

[redacted]

(b)(4) [redacted]

F556 Rev A
ECR 2268

PROCESS QUALIFICATION: PQ # 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE TECNOLOGIES DISPOSABLE KITS

ATTACHMENT 2: SAMPLE INSPECTION DATA: ☒ **Accelerated** ☐ **Real Time**

Sample	Item	Seal	Damage	Test	P/F	Initials	Date
35	Tray	Pass	No Damage	1 Year Aging	P	MF	05/02/10
	Unit Box						
36	Tray			1 Year Aging			
	Unit Box						
37	Tray			1 Year Aging			
	Unit Box						
38	Tray			1 Year Aging			
	Unit Box						
39	Tray			1 Year Aging			
	Unit Box						
40	Tray			1 Year Aging			
	Unit Box						
41	Tray			1 Year Aging			
	Unit Box						
42	Tray			1 Year Aging			
	Unit Box						
43	Tray			1 Year Aging			
	Unit Box						
44	Tray			1 Year Aging			
	Unit Box						
45	Tray			1 Year Aging			
	Unit Box						
46	Tray			1 Year Aging			
	Unit Box						
47	Tray			1 Year Aging			
	Unit Box						
48	Tray			1 Year Aging			
	Unit Box						
49	Tray			1 Year Aging			
	Unit Box						
50	Tray			1 Year Aging			
	Unit Box						
51	Tray	↓	↓	1 Year Aging	↓	↓	↓
	Unit Box	Pass	No Damage		P	MF	05/02/10

(b)(4) [redacted]

(b)(4) [redacted]

F556 Rev A
ECR 2268

PROCESS QUALIFICATION: PQ # 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE TECNOLOGIES DISPOSABLE KITS

ATTACHMENT 2: SAMPLE INSPECTION DATA: ☒ **Accelerated** ☐ **Real Time**

Sample	Item	Seal	Damage	Test	P/F	Initials	Date
52	Tray	Pass	No Damage	1 Year Aging	P	MF	05/02/10
	Unit Box						
53	Tray			1 Year Aging			
	Unit Box						
54	Tray			1 Year Aging			
	Unit Box						
55	Tray			1 Year Aging			
	Unit Box						
56	Tray			1 Year Aging			
	Unit Box						
57	Tray			1 Year Aging			
	Unit Box						
58	Tray			1 Year Aging			
	Unit Box						
59	Tray			1 Year Aging			
	Unit Box						
60	Tray			1 Year Aging			
	Unit Box	Pass	No Damage		P	MF	05/02/10
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box		NA				
	Tray		MF 05/02/10	1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						

(b)(4) [redacted]

(b)(4) [redacted]

F237 REV A
ECR # 1179

ENGINEERING PACKAGE & LABEL CONTROL TRAVELER

CLIENT: Visionscope DATE: 03/22/10

PO #: PQ 2008-121 FG Part Number (If required): NA

DESCRIBE REQUEST INCLUDING PRODUCT CODE AND LOT NUMBER IF REQUIRED:

(b)(4) [redacted]

If request is for Custom Product:

- Label proofs must be client approved prior to label printing.
- Label printing must be QA approved.
- Box check must be QA approved
- A copy of the Prescription must be provided
- A signed copy of the Packaging Drawing

LABELS PRINTED				LABEL RECONCILIATION			
TYPE	QTY.	PM #	Lot #	USED	SAMPLES	SCRAP	TOTALS

(b)(4) [redacted]

PRINTED BY: MF DATE: 03/25/10

QA APPROVED BY: NA DATE: NA

If QA approval is NA explain: generic Label

RECONCILED BY: MF DATE: 03/26/10

QA APPROVED BY: NA DATE: NA

If QA approval is NA explain: generic Label

☐ POUCH ☒ TRAY SEALER ID #: 50

(b)(4) [redacted]

SEALING PERFORMED BY: MF DATE: 03/24/10

OUTER PARAMETERS: HEAT: NA DWELL: NA PRESSURE: NA

SEALING PERFORMED BY: NA DATE: NA

BOXING PERFORMED BY: MF NA DATE: 03/26/10 QTY. BOXED: 120

QA APPROVED BY: NA DATE: NA

If QA approval is NA explain: engineering Run

PROVIDE A BRIEF EXPLANATION OF THE WORK PERFORMED:

clean room packaged 120 Vision scope - Disposable Kits in accordance with PQ 2008-121 for 1 year Real Time & Accelerated aging

INITIALS: MF DATE: 03/30/10

(b)(4) [redacted]

F238 REV A
ECR # 1179

ENGINEERING PACKAGE & LABEL CONTROL MATERIALS / PRODUCT USAGE

CLIENT: Visionscope DATE: 03/22/10

PO #: PQ 2008-121

COMPONENT / MATERIAL #	DESCRIPTION	LOT #	QTY.
PM 01114	IFU	2639	120
PM 01117-220	Unit box	2630	121
PM 01118-001	Tyvek Lid	2543	142
PM VS01081-001	PE Tray	2544	142
PM VS01082-001	Insert	2545	142
PM 004	Eto Steri Dot	2357	8
PM 01133-001	Tamper Label	2616	243
01136-001	15x20x10 Shipper	NA	8

NA

MF 03/22/10

COMMENTS:
Visionscope Aging Study, PQ 2008-121
No Product Utilized
MF 03/22/10

ATTACHMENT 4

(b)(4) [redacted] CERTIFICATE OF PROCESSING

PACKING SLIP

(b)(4) [redacted]

DATE: APRIL 8, 2010

SHIP TO (b)(4) [redacted]

SHIP DATE	ORDER NUMBER	SHIPPED VIA
04/08/10	(b)(4) [redacted]	

ITEM #	DESCRIPTION	QUANTITY
1	ENGINEERING SAMPLES (b)(4) [redacted] COMPANY NAME_____ PHONE NUMBER_____ DRIVER NAME (PRINT)_____ DRIVER SIGNATURE_____ TIME_____ DATE_____	

(b)(4)

[redacted]

VERIFICATION OF SAMPLE ETO EXPOSURE

Note: Sample products are **"NOT FOR HUMAN USE"** only.

Special test product sample(s) designated by: VISION SCOPE

as Sterilization Lot# **ENGINEERING SAMPLE(S); VISIONSCOPE PROCEDURE KIT**

from P.O. **031610B** were ETO exposed on **04/05/10(1X) 04/07/10(2X)**

(b)(4)

[redacted]

All process parameters were within the requirement of specification (b)(4) unless otherwise noted. All original process control documentation has been returned to **PCS QA/QC DOCUMENTATION CENTER**.

(b) (6)

(b) Signature [redacted]

Date 4/13/10

(b)(4)

[redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

ATTACHMENT 5

(b)(4) [redacted] TEST REPORT

(b)(4) [redacted]

(b)(4) [redacted]

(b) (6) [redacted]

Testing Certificate

Client: [redacted]

Sample #: 10-02745
P.O. #: 3126
Date Started: 13Apr10
Date Completed: 24May10

Sample Description: (4) Boxes, Lot #PQ 2008-121, Visionscope Disposable Kits

Procedure(s): (b)(4) [redacted]

Aging Parameters:

Equipment #	(b)(4) [redacted]
Temperature (°C)	
Date In (Start Date)	
Aging Period	
Aging Equivalent Time	
Date Due	
Date Pulled	

Results:

Pre-Test Inspection: (4) boxes. Unopened

Post-Test Inspection: No change

There were no deviations from the above parameters for the aging period.

(b)(4) [redacted]

Reserve: Samples returned to client.

Technician: (b) (6) [redacted] **Date:** 02JUN10

Approved by: [redacted] **Date:** 03JUN10

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE – DISPOSABLE KITS

ATTACHMENT 6

(b)(4) [redacted] TEST REPORT

(b)(4) [redacted]

(b) (6), (b) (4)

[redacted]

Bubble Emission Leak Test Final Report

Test Article: VisionScope - Accelerated Aging, PQ 2008-121
Purchase Order: 3246
Laboratory Number: (b)(4) [redacted]
Study Received Date:
Test Procedure(s):

Summary: This procedure is designed to detect gross leaks, which may render the product non-sterile, in medical trays and pouch packages by internal pressurization. All test method acceptance criteria were met.

Standard Method Based On: ASTM F2096
Package Size: 14 ½" x 4 ½"
Package Type: Porous
Product: Not present

Results:

Package Identification	Result	Package Identification	Result
1	0	16	0
2	0	17	0
3	0	18	0
4	0	19	0
5	0	20	0
6	0	21	0
7	0	22	0
8	0	23	0
9	0	24	0
10	0	25	0
11	0	26	0
12	0	27	0
13	0	28	0
14	0	29	0
15	0	30	0

'0' = No Evidence of Bubble Emission '+' = Evidence of Bubble Emission

(b) (4), (b) (6)

[redacted]

(b)(4) [redacted]

F556 Rev A
ECR 2268

PROCESS QUALIFICATION: PQ # 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE TECNOLOGIES DISPOSABLE KITS

PROCESS QUALIFICATION PROTOCOL **PQ#: 2008-121**

Equipment or Process Name: Real Time & Accelerated Aging Validation

Manufacturer: (b)(4) [redacted] **Serial Number:** NA

PM Number: NA **Location:** NA

Applicable Product Codes or Product Families: VisionScope Technologies Disposable Kits

Protocol Pre-approvals:

Upon pre-approval, this document is authorized for execution.

Originator's Department	Name	Signature	Date
Quality Engineering	(b) (6) [redacted]		

Department	
Quality Engineer	
Program Manager	
V.P. of Operations	
Training	
VisionScope Technologies Representative	

(b)(4) [redacted]

(b)(4) [redacted]

F556 Rev A
ECR 2268

PROCESS QUALIFICATION: PQ # 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE TECNOLOGIES DISPOSABLE KITS

PROCESS QUALIFICATION PROTOCOL **PQ#: 2008-121**

Equipment or Process Name: Real Time & Accelerated Aging Validation

Manufacturer: (b)(4) [redacted] **Serial Number:** NA

PM Number: NA **Location:** NA

Applicable Product Codes or Product Families: VisionScope Technologies Disposable Kits

Protocol Pre-approvals:

Upon pre-approval, this document is authorized for execution.

Originator's Department	Name	Signature	Date
Quality Engineering	(b)(4) [redacted]		

Department
Quality Engineer
Program Manager
V.P. of Operations
Training
VisionScope Technologies Representative

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: PQ # 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE TECNOLOGIES DISPOSABLE KITS

1.0 PURPOSE

This validation will be executed utilizing a blister tray and tyvek lid. This protocol will provide test instructions for verifying the package and product integrity of VisionScope Technologies Disposable Kits post accelerated aging.

The objective of this Process Qualification is to provide pre-market accelerated aging validation of VisionScope Technologies Disposable Kits in post sterile, final packaged form. This qualification is to verify that the final, packaged and sterilized product can withstand the normal level of stress associated with the aging process. In addition, this validation will assess the integrity of the final sterile package configuration following accelerated aging at one (1) year. Completion of this protocol will occur prior to the shipment of any/all finished goods to the end user and will impact the assignment of product expiration to finished good labels.

This validation applies to all Sterile Product packaged in its approved package(s) per the controlled BOM for VisionScope Technologies Disposable Kits. Both individual package units (primary shelf box) and bulk package unit (secondary shipping container) will be evaluated.

(b)(4) [redacted]

This protocol requires that initial product testing, including all product & packaging components, be evaluated and approved prior to assembly and completion of the packaging.

2.0 SCOPE

The product family to be validated is VisionScope Technologies Disposable Kits. The Kits are available in a variety of sizes. The largest size will be utilized to complete this study. These Kits are distributed by VisionScope Technologies as a sterile packaged product.

Inspection and packaging is performed by (b)(4) [redacted]. All sterile packaging is performed in a controlled area (Class 7 per ISO14644-1clean room). Kits are packaged into a blister tray/tyvek lid configuration. This configuration is then boxed for follow-on ETO sterilization.

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: PQ # 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE TECNOLOGIES DISPOSABLE KITS

3.0 RESPONSIBILITIES

Activity	Responsible Department(s)
Protocol Execution	(b)(4) [redacted]
Report Preparation	
Report Approval	
Record Retention	
Team Member Training	
ETO Sterilization	
Accelerated Aging	
Bubble Emission Testing	
Seal Strength Testing	

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: PQ # 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE TECNOLOGIES DISPOSABLE KITS

4.0 REFERENCES

The following Standard Operating Procedures are applicable to the equipment or process described in scope of this Process Qualification.

Procedure Type	Procedure/Document Title	Document Number
Department Work Instruction	VisionScope Technologies Clean Room Packaging Procedure	DWI 040-012
(b)(4) [redacted]	(b)(4) [redacted]	(b) [redacted]
	Bubble Emission Testing	PKG260
Standard Company Procedure	Peel Testing Pouches & Trays	(b)(4) [redacted]
Standard Company Procedure	Process Validation Policy	
Standard Company Procedure	Process Qualification Procedure	
Standard Company Procedure	Operational Qualification Procedure	
Standard Company Procedure	Installation Qualification Procedure	
Standard Company Procedure	Environmental Controls for Clean Room Operations	
ISO	Packaging for Terminally Sterilized Medical Devices	ISO11607

5.0 TRAINING REQUIREMENTS

Training documentation for individuals performing specific tasks to execute this PQ may be found within the Quality Department.

6.0 TEST PLAN AND RATIONALE

Plan:

Three (3) lots will be packaged, with each lot consisting of forty (40) empty trays, totaling one-hundred twenty (120) samples. Each lot will be initiated by turning the tray sealer off for a period of at least five minutes between each run.

Twenty (20) units from each lot will be packaged and used for the one (1) year Accelerated Aging Validation. Twenty (20) units from each lot will be packaged and used for the one (1) year Real Time Aging Validation.

The bulk container employed for the aging studies is the (b)(4) [redacted] bulk shipper box. Dunnage such as Kraft paper, etc. will be used to fill the extra space.

All samples will be forwarded through ETO processing

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: PQ # 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE TECNOLOGIES DISPOSABLE KITS

The samples for Accelerated Aging will be forwarded to (b)(4) [redacted] for Accelerated Aging equivalent to one (1) year. Upon completion of the Accelerated Aging, the samples will be returned to (b)(4) [redacted] for analysis. All samples will be evaluated for peel strength, visual integrity, and package integrity by means of Bubble Emission testing.

Samples for Real Time Aging studies will be stored for one (1) year. After completion of Real Time Aging, all samples will be evaluated for peel strength, visual integrity and package integrity.

Equipment:

The table below lists the equipment/components used for the process qualification:

Required Equipment List		
1	(b)(4) [redacted]	
2		
3		
4		
5		
6		
7		
8		
9		

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: PQ # 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE TECNOLOGIES DISPOSABLE KITS

Equipment Continued:

Test Type	Accelerated Aging Equipment	In compliance With:
Atmospheric Conditioning	Environmental Chamber	ASTM D 4332-01

Required Test Samples and test requirements are detailed in the table below:

Condition	Test Type	Qty	Parameters
Sterile, Post 1 Year Accelerated Aging	Pull Strength Test	30 Total	Low, Low, Low Sealing
	Bubble Emission	30 Total	
Sterile, Post 1 Year Real Time Aging	Pull Strength Test	30 Total	Low, Low, Low Sealing
	Bubble Emission	30 Total	

Breakdown of Sample Designation is detailed below:

Seal Strength & Visual Integrity	Lots	Total Units
Post Sterile, Post 1 Year Accelerated Aging	3	60
Post Sterile, Post 1 Year Real Time Aging	3	60

Sample Size:

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

PROCESS QUALIFICATION: PQ # 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE TECNOLOGIES DISPOSABLE KITS

7.0 TEST PROCEDURE:

The table in Attachment 1 details the steps required to complete the Process Qualification and must be completed by the Operator at the time of completion.

8.0 RE-VALIDATION REQUIREMENTS:

Re-validation of the aging study must be considered if a specification, parameter, or component of the process is changed; if any non conformance is identified during or post processing; or if any compromise of the validated process becomes apparent.

9.0 ANALYSIS OF DATA/ACCEPTANCE CRITERIA:

General:

For a successful PQ, the equipment shall meet the conditions stated in the table below.

Test Type	Pass/Fail Criteria
Peel Strength	(b)(4) [redacted]
Materials Inspection	Packaging Materials: Product label must be readable. Damage to the product must not be visible (where actual product is employed). Visually, there shall not be evidence of seal discontinuity and no evidence of physical damage to the blister tray employed, i.e. holes, tears, channels. (b)(4) [redacted] result in a rejection per
Bubble Emission	There shall be no evidence of bubble emission through the package.

10.0 RESULTS:

A Final Report will be generated at the completion of this study. All final data, including test results and data sheets will be obtained and summarized providing the results and conclusion. The original report will be filed in the (b)(4) [redacted] Department Subject Files. A complete copy of this qualification will be provided to VisionScope Technologies.

Any deviation or abnormality observed during the execution of the protocol must be documented and will be discussed in the report. All required documentation must be filed in the validation report or appropriately referenced.

(b)(4) [redacted]

(b)(4) Testing

(b)(4) Testing

(b)(4) [redacted]

F556 Rev A
ECR 2268

PROCESS QUALIFICATION: PQ # 2008-121

1 YEAR REAL TIME & ACCELERATED AGING VALIDATION FOR VISIONSCOPE TECNOLOGIES DISPOSABLE KITS

ATTACHMENT 2: SAMPLE INSPECTION DATA: ☐ **Accelerated** ☐ **Real Time**

Sample	Item	Seal	Damage	Test	P/F	Initials	Date
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						
	Tray			1 Year Aging			
	Unit Box						

(b)(4) [redacted]

14.16 - Sterile Procedure Kit Label Validation Final Report (b) (4) [redacted]

(b)(4) [redacted]

F556 Rev A
ECR 2268

PROCESS QUALIFICATION: PQ # 2008-112

VISIONSCOPE TECHNOLOGIES LABEL SYSTEM GENERATION

PROCESS QUALIFICATION FINAL REPORT **PQ #: 2008-112**

Equipment or Process Name: VISIONSCOPE TECHNOLOGIES LABEL GENERATION

(b)(4) [redacted]

Applicable Product Codes or Product Families: VisionScope Technologies Product

Protocol Report Final Approval:

The results of this Process Qualification have been reviewed and approved by the following parties.
The equipment and process are ready for production.

Originator's Department	Name	Signature	Date
Label Designer	(b) (6) [redacted]		

Department	
Quality Engineer	
Program Manager	
V.P. of Operations	
Quality Training	
VisionScope Representative	

(b)(4) [redacted]

584

(b)(4) [redacted]

F556 Rev A
ECR 2268

PROCESS QUALIFICATION: PQ # 2008-112

VISIONSCOPE TECHNOLOGIES LABEL SYSTEM GENERATION

PROCESS QUALIFICATION FINAL REPORT **PQ #:** 2008-112

Equipment or Process Name: VISIONSCOPE TECHNOLOGIES LABEL GENERATION

Manufacturer: (b)(4) [redacted] **Serial Number:** (b)(4) [redacted]

PM Number: (b) [redacted] **Location:** Label Production Area

Applicable Product Codes or Product Families: VisionScope Technologies Product

Protocol Report Final Approval:

The results of this Process Qualification have been reviewed and approved by the following parties. The equipment and process are ready for production.

Originator's Department	Name	Signature	Date
Label Designer	Monie Rath		

Department	Name	Signature	Date
Quality Engineer	(b) (6) [redacted]		
Program Manager			
V.P. of Operations			
Quality Training			
VisionScope Representative			

(b)(4) [redacted]

585

(b)(4) [redacted]

F556 Rev A
ECR 2268

PROCESS QUALIFICATION: PQ # 2008-112

VISIONSCOPE TECHNOLOGIES LABEL SYSTEM GENERATION

TO: Process Qualification File # 2008-112

FROM: (b) (6) [redacted]

SUBJECT: Final Process Qualification Report / VisionScope Technologies Label Generation

DATE: 4/26/2010

SUMMARY:

This Process Qualification was performed in strict adherence to the test procedure laid out in Section 7.0 of the process protocol PQ # 2008-112.

Three trial runs were performed per printer (b)(4) [redacted]), see attachment 2 – label verification sheet for details. The total number of samples produced across all three trial runs equal to two hundred ten (210) labels in total.

RESULTS:

All label samples were verified for consistency, repeatability, and accuracy to VisionScope Technologies approved label-proofing documents. All fixed, printed information was clear and legible. Overall, the validation sample labels printed met visual standards for general aesthetic acceptability as specified in Section 9.0 of PQ # 2008-112. As a result, all VisionScope product codes (50033-060, 50033-095, 50033-160 and 50033-220) are proven to be acceptable and validated. Functionality of the label system proved reliable.

COMMENTS/DEVIATIONS/REVISION

There were no deviations reported.

CONCLUSION:

Since all labels passed inspection, the process for generating VisionScope Technologies labels is considered validated and ready for production.

Attached are printed label samples, inspection data sheets, and copies of proofing documents.

(b)(4) [redacted]

(b)(4) Report

[redacted] (b) (4)

PROCESS QUALIFICATION: 2008-112

VISIONSCOPE TECHNOLOGIES LABEL SYSTEM GENERATION

ATTACHMENT 2: Label Verification Sheet

[redacted] (b) (4)

[redacted] (b) (4)

LABEL OUTPUT VERIFICATION TABLE

TRIAL ONE										TRIAL TWO										TRIAL THREE										
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	P/F
P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
TRIAL ONE										TRIAL TWO										TRIAL THREE										
P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
TRIAL ONE										TRIAL TWO										TRIAL THREE										
P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P

[redacted] (b) (4)

225

(b) (4)

[redacted]

Patient label

VisionScope Procedure Kit - 220
Patient Label

REF 50033-220 rev A
Exp Date XX-XXX-XXXX Lot No XX-XXX-XXXX-A

01129-220 rev A

LABEL 1 OF 3

VisionScope Procedure Kit - 220
Patient Label

REF 50033-220 rev A
Exp Date XX-XXX-XXXX Lot No XX-XXX-XXXX-A

01129-220 rev A

LABEL 2 OF 3

VisionScope Procedure Kit - 220
Patient Label

REF 50033-220 rev A
Exp Date XX-XXX-XXXX Lot No XX-XXX-XXXX-A

01129-220 rev A

LABEL 3 OF 3

(b) (4)

[redacted]

(b) (4)

[redacted]

Tyvek Lid label

P/N 01120-220 rev A

REF 50033-220

For use with VisionScope Camera Hand Piece REF 50021
and VisionScope Endoscope REF 50006-220

Contents: One Light Sheath (REF 50023-220)
One Canula (REF 50024-220)
One Trocar (REF 50027-220)

EXPIRATION DATE: XX-XXX-XXXX

LOT NUMBER: XX-XXX-XXXX-A

Rx only Caution: Federal Law restricts this device to sale by or on the order of a physician.

220mm

(b) (4)

[redacted]

(b) (4)

[redacted]

Outer Box label

VisionScope Procedure Kit - 220 - Single Use

For use with VisionScope Camera 50021-001
and VisionScope Endoscope Ref 50006-220

REF 50033-220, rev A

Contents: One Light Sheath (REF 50023-220)
One Canula (REF 50024-220)
One Trocar (REF 50027-220)

See Instructions for Use

Single use only. Do not re-process or re-use after one procedure. Dispose in accordance with applicable Bio-hazard handling regulations

VisionScope Technologies
2352 Main Street, Suite 303
Concord, MA 01742 USA
T: 1-978-776-9518
F: 1-978-776-9511
Customer Service:1-888-808-8357
www.visionscope-tech.com

Latex Free Product

CE 0197

Rx only

Made in USA

STERILE | ETO

Expiration Date - use before:
XX-XXX-XXXX

Lot No. XX-XXX-XXXX-A

(b) (4)

[redacted]

VISIONSCOPE Technologies LLC	Screening Checklist for Traditional Premarket Notification [510(k)] Submissions	Confidential

Section	Table of Contents / Checklist	Present	N/A
1	Medical Device User Fee Cover Sheet (Form FDA 3601)	✓	
2	CDRH Premarket Review Submission Cover Sheet	✓	
2.1	CDRH Premarket Review Submission Cover Sheet	✓	
2.2	Attachment 1 - UTILIZATION OF STANDARDS - Continuation	✓	
3	510(k) Cover Letter	✓	
4	Indications for Use Statement	✓	
5	510(k) Summary	✓	
6	Truthful and Accuracy Statement	✓	
7	Class III Summary and Certification – NA – Blank		✓
8	Financial Certification or Disclosure Statement – NA – Blank		✓
9	Declaration of Conformity and Summary Reports	✓	
9.1	VisionScope Declaration of Conformity	✓	
9.2	Form 3654 - ISO 11135-1	✓	
9.3	Form 3654 - ISO 10993-7	✓	
9.4	Form 3654 - ISO 10993-5	✓	
9.5	Form 3654 - ISO 10993-10	✓	
9.6	Form 3654 - ISO 10993-11	✓	
9.7	Form 3654 - UL 60601-1	✓	
9.8	Form 3654 - IEC 60601-1	✓	
9.9	Form 3654 - EN 60601-1	✓	
9.10	Form 3654 - CAN CSA 22.2 601.1	✓	
9.11	Form 3654 - IEC 60601-1-4	✓	
9.12	Form 3654 - IEC 60601-1-6	✓	
9.13	Form 3654 - IEC 60601-1-2	✓	
9.14	Form 3654 - IEC 60601-2-18	✓	
10	Executive Summary	✓	
11	Device Description	✓	
11.1	VisionScope Endoscopy System Device Description	✓	
11.2	50006 Endoscope Engineering Drawing	✓	
11.3	50033 Sterile Procedure Kit Engineering Drawing	✓	
11.4	50023 Disposable Endoscope Sheath Engineering Drawing	✓	
11.5	50024 Canula Engineering Drawing	✓	
11.6	50027 Trocar Engineering Drawing	✓	
12	Substantial Equivalence Discussion	✓	
12.1	Substantial Equivalence – Summary	✓	
12.2	Substantial Equivalence Technical Features Comparison	✓	
12.3	InnerVue Reference Guide	✓	
12.4	Smith & Nephew 560 HD Camera System	✓	
12.5	Smith & Nephew 660 HD Image Management System	✓	
12.6	Smith and Nephew Arthroscopes	✓	
12.7	Stryker Evolution of HD Technology Brochure	✓	
12.8	VisionSciences Endosheath	✓	
12.9	VisionSciences Endosheath Urology Published Literature	✓	
13	Proposed Labeling	✓	
13.1	Proposed Labeling - Summary	✓	
13.2	VisionScope Labels and Markings	✓	
13.3	01112 - VisionScope System Instructions for Use	✓	
13.4	01113 - VisionScope Endoscope Instructions for Use	✓	
13.5	01114 - VisionScope Sterile Procedure Kit Instructions for Use	✓	
13.6	01115 - VisionScope Camera Handpiece Instructions for Use	✓	
13.7	80049 - VisionScope Brochure	✓	
13.8	InnerVue™ User Manual	✓	

FDA CDRH DMC
JUN 21 2010
Received

14	Sterilization and Shelf Life	✓	
14.1	Sterilization and Shelf Life - Summary	✓	
14.2	80094 Supplemental Description of the Sterile Endoscope Illumination Sheath as a Protective Barrier	✓	
14.3	Camera & Endoscope ETO Sterilization Efficacy Validation Final Report SPS-0909-329	✓	
14.4	Camera & Endoscope Sterrad 100S Sterilization Efficacy Validation Final Report SPS 0909-327-1	✓	
14.5	Camera & Endoscope Sterrad NX Sterilization Efficacy Validation Final Report SPS 0909-326	✓	
14.6	Camera & Endoscope ETO & ECH Residual Test Report SPS 0909-330	✓	
14.7	Sterile Procedure Kit Tray Sealing PQ-2008-111 Final Report	✓	
14.8	Sterile Procedure Kit Tray Sealing OQ-2008-068 Final Report	✓	
14.9	Sterile Procedure Kit ETO Sterilization Protocol 10209014	✓	
14.10	Summary of Sterile Procedure Kit ETO Fractional Cycle per Protocol 10209014	✓	
14.11	Sterile Procedure Kit Fractional Cycle Sterilization Data	✓	
14.12	Sterile Procedure Kit Fractional Cycle Test Results	✓	
14.13	Sterile Procedure Kit ETO Fractional Cycle Biological Indicator Certificates	✓	
14.14	Sterile Procedure Kit Ship Test Final Report 2008-126	✓	
14.15	Sterile Procedure Kit Aging Test Validation Protocol PQ2008-121	✓	
14.16	Sterile Procedure Kit Label Validation Final Report 2008-112	✓	
15	Biocompatibility	✓	
15.1	Biocompatibility - Summary	✓	
15.2	513842 - ISO 10993-5 MEM Elution Cytotoxicity Test Report of Illumination Sheath	✓	
15.3	513848 - ISO 10993-10 Maximization Sensitization Report of Illumination Sheath	✓	
15.4	513849 - ISO 10993-10 Intracutaneous Reactivity Report of Illumination Sheath	✓	
15.5	513850 - ISO 10993-11 Acute Systemic Injection Report of Illumination Sheath	✓	
15.6	513851 - ISO 10993-11 Materials Mediated Rabbit Pyrogen Report of Illumination Sheath	✓	
15.7	ISO 10993 (b)(4) [redacted] Fiber Report	✓	
15.8	ISO 10993 (b)(4) [redacted] Report	✓	
15.9	ISO 10993 (b)(4) [redacted] Biocompatibility Report	✓	
15.10	ISO 10993 (b)(4) [redacted] Report	✓	
15.11	ISO 10993 (b)(4) [redacted] Report	✓	
15.12	ISO 10993-5 Cytotoxicity Report for (b)(4) [redacted]	✓	
15.13	517869 - ISO 10993-5 (b)(4) [redacted]	✓	
15.14	520734 - ISO 10993 Part 5 (b)(4) [redacted] Cover Report	✓	
15.15	(b)(4) [redacted] Biocompatibility Report	✓	
15.16	(b)(4) [redacted] Biocompatibility Report	✓	
15.17	(b)(4) [redacted] MSDS	✓	
15.18	(b)(4) [redacted] Cytotoxicity Report	✓	
16	Software	✓	
16.1	Software - Summary	✓	
16.2	80071 VisionScope Software Architecture Design and Description	✓	
16.3	80020 VisionScope Risk Management Plan & Risk Management Summary	✓	
16.4	80013 VisionScope Risk Analysis	✓	
16.5	80014 VisionScope Design FMEA	✓	
16.6	80055 VisionScope Software FMEA	✓	
16.7	IEC60601-1-4 VisionScope Risk Management	✓	

16.8	IEC60601-1-6 VisionScope Usability	✓	
16.9	80016 VisionScope Software Requirements Specifications	✓	
16.10	80019 VisionScope Software Design Specifications	✓	
16.11	80072 VisionScope Traceability Analysis	✓	
16.12	80028 VisionScope Software Validation Document	✓	
16.13	80029 VisionScope Software Verification Document	✓	
16.14	80073 - Software Revision History Log	✓	
16.15	VisionScope Software Unresolved Anomalies	✓	
17	Electromagnetic Compatibility and Electrical Safety	✓	
17.1	Electromagnetic Compatibility and Electrical Safety - Summary	✓	
17.2	UL 60601-1 Certicate CU72100321.01	✓	
17.3	UL 60601-1 + CAN CSA Report	✓	
17.4	EN-IEC 60601-1 Report	✓	
17.5	EN 60601-1-2 EMI-EMC Report	✓	
17.6	IEC 60601-2-18 Endoscope Safety Report	✓	
17.7	Attachment 1 EN-IEC-UL 60601-1 Attachment - Constructional Data Form	✓	
17.8	Attachment 2 National Difference EN60601-1 CB 112A	✓	
17.9	Attachment 3 Test Pictures	✓	
18	Performance Testing – Bench	✓	
18.1	Performance Testing - Summary	✓	
18.2	80030 VisionScope System Validation Protocol & Report	✓	
18.3	80084 VisionScope System Validation in Cadaver labs	✓	
18.4	80099 Validation of Usability of Instructions for Use	✓	
18.5	80026 Verification of VisionScope Instructions for Use per UL60601 and IEC60601-2-18	✓	
18.6	80038 Verification of VisionScope Camera Head and CCU	✓	
18.7	80037 Verification of Endoscopes Illumination Sheath, Cannula and Trocar	✓	
18.8	80083 Sterilization Compatibility Validation Report for Endoscope and Camera Head	✓	
18.9	80082 ETO Sterilization Compatibility of Sterile Procedure Kit including Protective Barrier Effectiveness	✓	
19	Performance Testing – Animal – Not Applicable, Blank		N/A
20	Performance Testing – Clinical – Not Applicable, Blank		N/A

SECTION 15. BIOCOMPATIBILITY SUMMARY

Certification of the Biocompatibility of the VisionScope High Definition Endoscopy Camera System

I certify that:

1) The components of the VisionScope High Definition Endoscopy Camera System that contact the patient are fully listed in this Summary document.
2) The components are made from the materials described.
3) The materials used to manufacture the VisionScope system are identical to the listed material.
4) No other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.) to those materials in the device.
5) The biocompatibility test reports given in this Section are performed on the samples used for the production equivalent prototype units as described, and that any change of material in future production will follow applicable VisionScope Quality System Procedures and applicable Regulatory Requirements.

Signature

Lim Cheung

General Manager & CTO

April 26, 2010

Date

SECTION 15. BIOCOMPATIBILITY SUMMARY

The VisionScope High Definition Endoscopy Camera System contains direct and indirect patient-contact components. Specific biocompatibility safety evaluations programs follow the FDA Guidance and ISO 10993-1 standards. The specific set of biocompatibility test matrix is selected in accordance with the following guidance or standard documents:

1. FDA Guidance Document: Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' (Replaces #G87-1 #8294) (blue book memo)
2. ISO-10993-1:2009 - Biological evaluation of medical devices -- Part 1: Evaluation and testing
3. ASTM-2475-05 - Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials

Classification of VisionScope Patient Contact Parts:

- Duration: Limited (≤ 24 hours)
- Externally Communicating Devices
- Tissue/Bone/Dentin Communicating (include tissue fluid and subcutaneous spaces)

For direct patient contact materials, the following tests were performed in accordance with the FDA Guidance for the classification described above:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2002)
- Irritation/Intracutaneous Reactivity (ISO 10993-10:2002)
- Acute Systemic Toxicity (ISO 10993-11:2006)
- Materials Mediated Rabbit Pyrogen (ISO 10993-11:2006)

For indirect patient contact material, the Cytotoxicity test (ISO 10993-5) was performed as a minimum in accordance with the FDA Guidance and ASTM-2475-05 Standard Guide.

Post-sterilization Residual ETO level validation per ISO-10993-7 is discussed separately in Section 14 – Sterilization and Shelf Life.

This document contains an index and a locator Map to the Biocompatibility Test Reports. Figure 1 below shows the boundary line between direct and indirect patient contact components.

Figure 2 below describes the components and materials of the Camera Handpiece and Procedure Kit. The distal tip that enters the patient is enlarged to show the full details. The materials are itemized, described and classified further in Table 1.

Figure 3 shows the packaging material that may have indirect contact with the patient through the direct contact components.

SECTION 15. BIOCOMPATIBILITY SUMMARY

For all the materials labeled in Figures 1, 2 and 3 below, VisionScope has conducted biocompatibility testing and/or collected biocompatibility testing reports from the suppliers. The Biocompatibility Test Reports for Items A through R identified in Table 1 are attached in Section 15, documents 15.2 through 15.18.

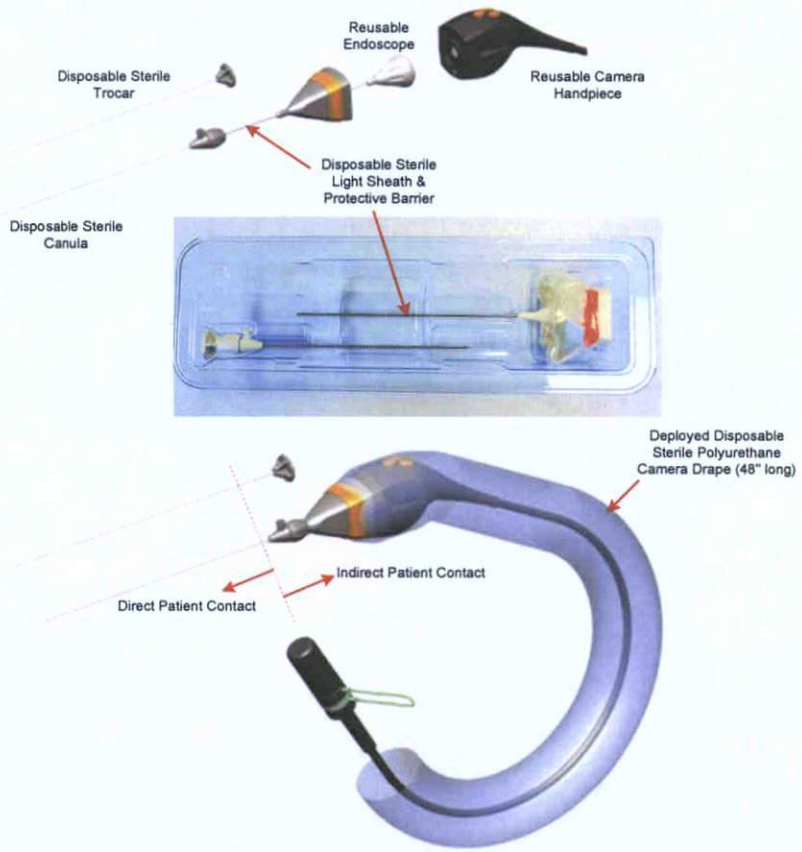

Figure 1. Identification of the separation line between the Direct and Indirect Patient Contact Components on the VisionScope Camera Handpiece and Procedure Kit.

597

(b)(4)

[redacted]

Figure 2. Identification of both direct and indirect patient contact information of the VisionScope Camera Handpiece and Procedure Kit

S48

(b)(4)

Q. Tyvek Lid

P. Plastic Tray

Figure 3. Identification of Indirect Patient Contact Packaging Materials of the VisionScope Procedure Kit.

S19

SECTION 15. BIOCOMPATIBILITY SUMMARY

Table 1: Identification and Description of Patient Contact Material and available Biocompatibility Test Reports

I.D. in Figures 2 and 3	Name of Components and Part Numbers Items marked with * are protective barrier elements	Material	Patient Contact: Direct or Indirect	ISO-10993 Part Number	Biocompatibility Test Report No. contained in Section 15
A	[redacted] (b)(4)	[redacted] (b)(4)	Direct	5, 10, 11	The entire illumination sheath with all the components A through G were tested as an assembly by VisionScope's contractor, [redacted] (b)(4) and reported in Documents 15.2 – 15.6: 15.2 - 513842 - ISO 10993-5 MEM Elution Cytotoxicity of Illumination Sheath.pdf 15.3 - 513848 - ISO 10993-10 Maximization Sensitization of Illumination Sheath.pdf 15.4 - 513849 - ISO 10993-10 Intracutaneous Reactivity of Illumination Sheath.pdf 15.5 - 513851 - ISO 10993-11 Materials Mediated Rabbit Pyrogen of Illumination Sheath.pdf 15.6 - 513850 - ISO 10993-11 Acute Systemic Injection of Illumination Sheath.pdf In addition, selected components were also tested by the material suppliers, and their certificates are given in Documents 15.7 – 15.11: 15.7 - B-10D2004 - Biocompatibility [redacted] (b)(4) Fiber.pdf (alternate construction for
B			Direct	5, 10, 11	
C			Direct	5, 10, 11	
D1			Direct	5, 10, 11	
D2			Direct	5, 10, 11	
E			Indirect	5, 10, 11	
F			Indirect	5, 10, 11	
G			Indirect	5, 10, 11	

SECTION 15. BIOCOMPATIBILITY SUMMARY

					[redacted] (b)(4)
H	[redacted] (b)(4) Camera Drape * (50023)	[redacted] (b)(4)	Indirect	5	15.12 - ISO 10993-5 Cytotoxicity Report [redacted] (b)(4)
I	Decorative Collar for concealing the bonding between the Illumination Sheath and the Camera Drape (50023)		Indirect	5	15.13 - 517869 - ISO 10993-5 MEM Elution Cytotoxicity PN 01091.pdf
J	Camera Buttons (50021)		No contact	5	Material does not touch patient either directly, or indirectly through other patient contact surfaces: 15.13 - 517869 - ISO 10993-5 MEM Elution Cytotoxicity PN 01091.pdf
K	Button Cover (50021)		No contact	5	Material does not touch patient either directly, or indirectly through other patient contact surfaces: 15.14 - 520734 - ISO 10993 Part 5 MEM Elution Cytotoxicity Peek & Trocar Cover [redacted] (b)(4)
L	Camera Handpiece Body (50021)		No contact	5	Material does not touch patient either directly, or indirectly through other patient contact surfaces: [redacted] (b)(4)

SECTION 15. BIOCOMPATIBILITY SUMMARY

M	Endoscope Window (50006)	[redacted] (b)(4)	No contact	5, 10, 11	Material does not touch patient either directly, or indirectly through other patient contact surfaces These materials are identical to and were tested as part of the completed Illumination Sheath assembly, and the test data are contained in the same test reports as in Items A through G (Documents 15.1 – 15.11)
N	Endoscope Tube (50006)		No contact	5, 10, 11	
O	Endoscope Epoxy (50006)		No contact	5, 10, 11	
P	Plastic Container Tray (50033)		Indirect	5, 10, 11	15.16 - [redacted] (b)(4) Biocompatibility.pdf
Q	Plastic Container Tray Lid (50033)		Indirect	5	[redacted] (b)(4)
R	Tyvek Lid epoxy (50033)		Indirect	5	

15.2 - 513842 - ISO 10993-5 MEM Elution Cytotoxicity Report of Illumination Sheath

(b)(4) [redacted]

FINAL REPORT

BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 5: TESTS FOR IN VITRO CYTOTOXICITY ISO 10993-5:2009

PROCEDURE NO. (b)(4) [redacted]
PROTOCOL DETAIL SHEET NO. (b)(4) [redacted]

(b)(4) [redacted]

PREPARED FOR:

LIM CHEUNG, PH.D.
VISIONSCOPE TECHNOLOGIES, LLC
2352 MAIN STREET, SUITE 303
CONCORD MA 01742

SUBMITTED BY:

(b)(4) [redacted]

604

(b)(4) [redacted]

(b)(4) [redacted]

QAU AUDIT STATEMENT

[X] USFDA (21 CFR PART 58) [ ] USEPA (40 CFR PART 160)

BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 5: TESTS FOR IN VITRO CYTOTOXICITY ISO 10993-5:2009

(b)(4) [redacted]

1. The test was conducted in accordance with the USFDA or USEPA Regulations as noted above.

2. In accordance with the Good Laboratory Practice Regulations, the Interpretation phase(s) of this study was inspected by the Quality Assurance Unit on: 15 Feb 2010. The findings of the inspection(s) were reported to the Study Director on: 16 Feb 2010 and to Management on: 15 Feb 2010.

3. The Quality Assurance Unit has reviewed this report and has determined that the methods and standard testing procedures are accurately described, and that the reported results accurately reflect the raw data.

4. The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel, involved in the study:

(b) (6) [redacted]

QUALITY ASSURANCE: (b) (6) [redacted]

(b)(4) [redacted]

BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 5: TESTS FOR IN VITRO CYTOTOXICITY ISO 10993-5:2009

LABORATORY NUMBER:	(b)(4) [redacted]
PROCEDURE NUMBER:	
PROTOCOL DETAIL SHEET NUMBER:	
SAMPLE SOURCE:	
TYPE OF TEST:	
SAMPLE IDENTIFICATION:	
DEVIATIONS:	
CELL LINE:	
CELL LINE JUSTIFICATION:	
CELL LINE SOURCE:	
INCUBATION PERIOD:	
METHOD OF SCORING:	Cytopathic Effect (0-4)
PROTOCOL APPROVAL DATE:	12 Feb 2010
STUDY RECEIVED DATE:	10 Feb 2010
LAB PHASE START DATE:	12 Feb 2010
LAB PHASE COMPLETION DATE:	16 Feb 2010
REPORT ISSUE DATE:	17 Feb 2010
STUDY COMPLETION DATE:	18 Feb 2010
AMENDED REPORT ISSUE DATE:	19 Apr 2010

AMENDMENT JUSTIFICATION:

At the request of the sponsor, the test title was changed from MEM Elution to Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity ISO 10993:2009.

INTRODUCTION:

The MEM Elution test was designed to determine the cytotoxicity of extractable substances. An extract of the sample was added to cell monolayers and incubated. The cell monolayers were examined and scored based on the degree of cellular destruction.

ACCEPTANCE CRITERIA:

The United States Pharmacopeia & National Formulary states that the sample meets the requirements if the reactivity grade is not greater than grade 2 or a mild reactivity. The USP/AAMI/ISO 10993-5 standard states that the achievement of a numerical grade greater than 2 is considered a cytotoxic effect. (b)(4) [redacted] acceptance criteria was based upon the negative and media controls receiving "0" reactivity grades and positive results receiving a 3-4 reactivity grades (moderate to severe).

(b)(4) [redacted]

PROCEDURE:

(b)(4) [redacted]

RESULTS:

The results are summarized in Table 1. The test is acceptable if all three of the negative control and medium control test wells have a score of 0 and all three of the positive control test wells have a score of 3 or higher.

The sample meets USP and ISO requirements if none of the cell culture exposed to the sample shows greater than a mild reactivity (grade 2).

(b)(4)

DATA DISPOSITION:

The raw data and final report from this study are archived at (b) or an approved off-site location.

STATEMENT OF UNCERTAINTY:

If applicable, the statement of uncertainty is available to sponsors upon request.

(b) (6)

rlf

608

(b)(4) [redacted]

TABLE 1. Results

IDENTIFICATION	AMOUNT TESTED / SAMPLE EXTRACT	SCORE #1	SCORE #2	SCORE #3	AVERAGE
Negative Control	4 g / 20 mL	0	0	0	0
Media Control	20 mL	0	0	0	0
Positive Control	4 g / 20 mL	4	4	4	4
VSLT000L	149.4 cm^2 / 49.8 mL	0	0	0	0

All reports and letters issued by (b)(4) [redacted]. are for the exclusive use of the sponsor to whom they are addressed. These results relate only to the samples tested. Reports may not be reproduced except in their entirety. No quotations from reports or use of the corporate name is permitted except as expressly authorized by (b)(4) [redacted]. in writing. The significance of any data is subject to the adequacy and representative character of the samples tendered for testing. (b)(4) [redacted] that all tests are performed in accordance with established laboratory procedures and (b)(4) [redacted]. makes no other warranties of any kind, express or implied. (b)(4) [redacted] states that it makes no representation or warranty regarding the adequacy of the samples tendered for testing for any specific use of application, that determination being the sole responsibility of the sponsor. (b)(4) [redacted] for any loss or damage resulting from its actions or failure to act shall not exceed the cost of tests performed, and it shall not be liable for any incidental or consequential damages. (b)(4) [redacted] a ten year record retention policy.

15.3 - 513848 - ISO 10993-10 Maximization Sensitization Report of Illumination Sheath

(b)(4)

[redacted]

26 Apr 2010

Lim Cheung, Ph.D.
VisionScope Technologies, LLC
2352 Main Street, Ste. 303
Concord, MA 01742

Dear Lim,

Enclosed is the final report for the testing we coordinated for you. The information is retained by the testing laboratory.

(b)(4)

[redacted]

TYPE OF TEST: Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-type Hypersensitivity ISO 10993-10:2002

SAMPLE IDENTIFICATION:
VSLT000L, VSLT001L, VSLT002L, VSLT003L, VSLT007, VSLT010, VSLT016, VSLT020, VSLT021, VSLT029, VSLT030, VSLT034, VSLT035L

(b)(4)

[redacted]

(b) (6)

[redacted]

612

(b)(4) Testing

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(b)(4) Testing

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15.4 - 513849 - ISO 10993-10 Intracutaneous Reactivity Report of Illumination Sheath

(b)(4) [redacted]

26 Apr 2010

Lim Cheung, Ph.D.
VisionScope Technologies, LLC
2352 Main St., Ste. 303
Concord, MA 01742

Dear Lim,

Enclosed is the final report for the testing we coordinated for you. The information is retained by the testing laboratory.

(b)(4) [redacted]

TESTING LAB: (b)(4) [redacted]

TYPE OF TEST: Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-type Hypersensitivity ISO 10993-10:2002

SAMPLE IDENTIFICATION:
VSLT000L, VSLT001L, VSLT002L, VSLT003L, VSLT007, VSLT010, VSLT016, VSLT020, VSLT021, VSLT029, VSLT030, VSLT034, VSLT035L

(b)(4) [redacted]

(b) (6) [redacted]

638

(b)(4) Testing

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15.5 - 513850 - ISO 10993-11 Acute Systemic Injection Report of Illumination Sheath

(b)(4) [redacted]

26 Apr 2010

Lim Cheung, Ph.D.
VisionScope Technologies, LLC
2352 Main St., Ste. 303
Concord, MA 01742

Dear Lim,

Enclosed is the final report for the testing we coordinated for you. The information is retained by the testing laboratory.

(b)(4) [redacted]

TESTING LAB: (b)(4) [redacted]

TYPE OF TEST: Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity ISO 10993-11:2006

SAMPLE IDENTIFICATION:
VSLT000L, VSLT001L, VSLT002L, VSLT003L, VSLT007, VSLT010, VSLT016, VSLT020, VSLT021, VSLT029, VSLT030, VSLT034, VSLT035L

(b)(4) [redacted]

(b) (6) [redacted]

(b)(4) Testing

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15.6 - 513851 - ISO 10993-11 Materials Mediated Rabbit Pyrogen Report of Illumination Sheath

(b)(4) [redacted]

26 Apr 2010

Lim Cheung, Ph.D.
VisionScope Technologies, LLC
2352 Main Street, Ste. 303
Concord, MA 01742

Dear Lim,

Enclosed is the final report for the testing we coordinated for you. The information is retained by the testing laboratory.

(b)(4) [redacted]

TESTING LAB: (b)(4) [redacted]

TYPE OF TEST: Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity ISO 10993-11:2006

SAMPLE IDENTIFICATION:
VSLT000L, VSLT001L, VSLT002L, VSLT003L, VSLT007, VSLT010, VSLT016, VSLT020, VSLT021, VSLT029, VSLT030, VSLT034, VSLT035L

(b)(4) [redacted]

(b) (6) [redacted]

(b)(4) [redacted]

17 Mar 2010

Lim Cheung, Ph.D.
VisionScope Technologies, LLC
2352 Main Street, Ste. 303
Concord, MA 01742

Dear Lim,

Enclosed is the final report for the testing we coordinated for you. The information is retained by the testing laboratory.

(b)(4) [redacted]

TESTING LAB: (b)(4) [redacted]

TYPE OF TEST: Materials Mediated Rabbit Pyrogen Test

SAMPLE IDENTIFICATION:
VSLT000L, VSLT001L, VSLT002L, VSLT003L, VSLT007, VSLT010, VSLT016, VSLT020, VSLT021, VSLT029, VSLT030, VSLT034, VSLT035L

(b)(4) [redacted]

(b) (6) [redacted]

680

(b)(4) [redacted]

FINAL STUDY REPORT

STUDY TITLE

Materials Mediated Rabbit Pyrogen Test

TEST ARTICLE IDENTIFICATION

VSLT000L, VSLT001L, VSLT002L, VSLT003L, VSLT007, VSLT010, VSLT016, VSLT020, VSLT021, VSLT029, VSLT030, VSLT034, VSLT035L

STUDY COMPLETION DATE

March 15, 2010

(b)(4) [redacted]

SPONSOR

(b)(4) [redacted]

PROTOCOL

(b)(4) [redacted]

PROJECT NUMBER

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

QUALITY ASSURANCE UNIT SUMMARY

STUDY: Materials Mediated Rabbit Pyrogen Test

The objective of the Quality Assurance Unit is to monitor the conduct and reporting of nonclinical laboratory studies. This study has been performed under Good Laboratory Practices regulations (FDA, 21 CFR, Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies) and in accordance to standard operating procedures and a standard protocol. The Quality Assurance Unit maintains copies of study protocols and standard operating procedures and has inspected this study on the dates listed below. Studies are inspected at time intervals to assure the quality and integrity of the study.

Critical Phase	Date	Study Director	Management
Test Article Preparation	03/01/10	03/01/10	03/15/10
Final Report	03/15/10	03/15/10	03/15/10

The findings of these inspections have been reported to management and the Study Director.

Quality Assurance Auditor: (b) (6) [redacted]

GOOD LABORATORY PRACTICES STATEMENT

The study referenced in this report was conducted in compliance with U.S. Food and Drug Administration Good Laboratory Practice (GLP) regulations set forth in 21 CFR part 58.

(b)(4) [redacted]

Study Director: (b) (6) [redacted]

Professional Personnel Involved:

(b) (6) [redacted]

Vice President of Process Improvement and Operations
Study Operations Manager
Associate Director, In-Life Studies
Study Director
Client Relations Manager

(b)(4) [redacted]

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) [redacted]

PROTOCOL TITLE: **MATERIAL MEDIATED RABBIT PYROGEN TEST**

TEST CODE: (b)(4) [redacted]

PERFORMING LABORATORY:

EFFECTIVE DATE: 18 February 2009

(b)(4) [redacted]

(b)(4) [redacted]

Exact Copy
Initials: SD Date: 3/16/10

(b)(4) [redacted]

(b)(4) [redacted]

Material Mediated Rabbit Pyrogen Test

1.0 PURPOSE

The purpose of this study is to determine if a saline extract of the test article causes a febrile response in rabbits.

2.0 TEST FACILITY: (b)(4) [redacted]

3.0 SCHEDULING AND DISCLAIMER OF WARRANTY

3.1 Test protocol initiation is generally within 10 working days after receipt of the test article, a signed Client Protocol Approval form, and a signed test request form. The Client Protocol Approval form and the test request form serve as addenda to this protocol. Written notification of the proposed initiation and completion dates will be provided at the time the test article and signed protocol is received by the laboratory. The estimated testing time is 1 – 3 days. Verbal results will be available from the Study Director upon completion of the study with the written quality assurance audited report to follow approximately 10 working days after completion of the study.

3.2 If a test, or a portion of it, must be repeated due to failure by (b)(4) [redacted] to adhere to specified procedures, it will be repeated free of charge. If a test must be repeated, or a portion of it, due to failure of internal controls or failure to meet assay validity requirements, it will be repeated free of charge. "Methods Development" fees shall be assessed, however, if the test article and test system require modifications due to complexity and difficulty of testing.

3.3 If the Sponsor requests a continued test, they will be charged for an additional test.

3.4 Neither the name of (b)(4) [redacted]

3.5 The Sponsor is responsible for any rejection of the final report by the regulatory agency concerning report format, pagination, etc. (b)(4) [redacted]

(b)(4) [redacted]

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4)

[redacted]

15.0 FINAL REPORT

The final report will include but will not be limited to: the date of the study initiation and completion, the purpose as stated in the approved protocol, changes in the approved protocol, identification of the test system, a description of the methods used and conclusion as it relates to the test.

(b)(4)

[redacted]

(b)(4)

[redacted]

17.0 REFERENCES

17.1 ISO 10993-11:2006. ANSI AAMI ISO 10993-11:2006. Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity.

17.2 ISO 10993-12:2007 Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials.

17.3 U.S. Pharmacopeia, Section 151, current revision.

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4) [redacted]

CLIENT PROTOCOL APPROVAL FORM

PLEASE NOTE THAT TESTING CANNOT BE INITIATED UNTIL THIS FORM IS COMPLETED WITH AN AUTHORIZED SIGNATURE AND THE ORIGINAL IS RETURNED TO WUXI APPTEC.

SPONSOR:

(b) (6), (b) (4) [redacted]

Primary Approval Statement

(b)(4) [redacted]

15.7 - ISO 10993 B-10D2004 (b) (4) Fiber Report

(b)(4)

[redacted]

TECHNICAL REPORT

FOR

Bio-Compatibility Test Summary Report

(b) (4), (b) (6)

[redacted]

699

(b)(4)

[redacted]

Contents

Item	Page Number
1. Test summary for irritation and delayed type hypersensitivity	2
2. Test summary for cytotoxicity using ISO elution method	3
3. Test summary for ISO intracutaneous study (extract)	4
4. Test summary for systemic toxicity: systemic injection	5
5. Test summary for systemic toxicity: material mediated pyrogenicity	6

(b)(4)

[redacted]

The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article extracts were not considered sensitizers in the guinea pig maximization model.

Supervisory Personnel:

(b) (6)

[redacted]

Approved by:

(b) (4), (b) (6)

[redacted]

(b)(4)

[redacted]

(b)(4) [redacted]

Summary

This *in vitro* study was conducted to evaluate (b)(4) [redacted] potential cytotoxic effects following the guidelines of International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity: *in vitro* Methods. (b)(4) [redacted]

The test extract showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

Supervisory Personnel: (b) (6) [redacted]

Approved by: (b) (4), (b) (6) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Summary

The potential for components from the test article, (b)(4) [redacted], to cause irritation following intracutaneous injection in rabbits was evaluated based on ISO 10993-10: Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. (b)(4) [redacted]

Supervisory Personnel: (b) (6) [redacted]

Approved by: (b) (4), (b) (6) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Summary

The test article, (b)(4) [redacted], was evaluated for systemic toxicity in mice based on International Organization for Standardization 10993-11, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity.

(b)(4) [redacted]

Supervisory Personnel: (b) (6) [redacted]

Approved by: (b) (4), (b) (6) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Summary

(b)(4) [redacted]

Supervisory Personnel:

(b) (6) [redacted]

Approved by:

(b) (4), (b) (6) [redacted]

(b)(4) [redacted]

15.8 - ISO 10993 (b) (4) [redacted] Report

(b)(4)

[redacted]

Messrs. (b)(4) */ VisionScope*

TECHNICAL REPORT

FOR

Bio-Compatibility Test Report of

Adhesive (b)(4)

(b) (6), (b) (4)

[redacted]

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Date of Test Completion: September 15, 2003
Project Numbers: 03-3122
Page: 1 of 2

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

Test Article: (b)(4) [redacted] Medical Device Adhesive

Lot Number: (b)(4) [redacted]

INTRACUTANEOUS INJECTION (ISO): The purpose of this test is to evaluate the irritation potential of the test article extracts in rabbits after intracutaneous injection. Test article extract in saline, cottonseed oil, polyethylene glycol 400 and alcohol in saline did not produce a significantly greater tissue reaction than blank extract when injected intracutaneously into rabbits. Additional extracts (PEG & Alcohol in Saline) were used to cover the requirements of United States Pharmacopeia 26, National Formulary 21, 2003; Monograph <88>: Biological Reactivity Tests, *In Vivo*. Based on the criteria set forth by the protocol, the test article is considered negligible or slight irritant-conforms. *Reference: Biological Evaluation of Medical Devices - Part 10: Irritation and Delayed-type Hypersensitivity, ISO 10993-10, 2002.*

ACUTE SYSTEMIC INJECTION (ISO): The purpose of this assay is to evaluate the test article extracts for potential toxic effects as a result of single dose systemic injection in mice. Test article extracted in saline, cottonseed oil, polyethylene glycol 400 and alcohol in saline did not produce a significantly greater systemic reaction than blank extract when injected into mice. Additional extracts (PEG & Alcohol in Saline) were used to cover the requirements of United States Pharmacopeia 26, National Formulary 21, 2003; Monograph <88>: Biological Reactivity Tests, *In Vivo*. The test article did not show greater biological reactivity compared to the control material-conforms.
Reference: Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity, ISO 10993-11:1993.

CYTOTOXICITY (ISO): The purpose of the MEM Elution is to determine biological reactivity of monolayer cell culture (L929) in response to the test article. The test article is considered non-cytotoxic and meets the requirements of the MEM Elution Test, ISO 10993-5.
Reference: Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity, ISO 10993-5:1999.

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Project Number: (b)(4) [redacted]
Page: 2 of 2

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

HEMOCOMPATIBILITY (ISO):
Hemolysis: This assay is designed to evaluate the hemolytic potential of the test article extracts. Hemolytic activity of the test article with rabbit blood indicated that the test article was non-hemolytic (<5%).
Reference: Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood, ISO 10993-4, 2002.

***In Vitro* Hemocompatibility Assay**: This assay is designed to ensure that the test material extract does not adversely affect the cellular components of blood. The test article was evaluated for its potential to adversely affect selected hematological parameters. The hematological parameters tested were complete blood count including platelets, hematocrit, erythrocyte indices and free plasma hemoglobin. The test article meets the requirements.
Reference: Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood, ISO 10993-4:2002.

IMPLANTATION TEST (ISO): The macroscopic and histological reaction of the test article, implanted in rabbit muscle for 2 weeks was not significant when compared to negative control sites-conforms.
Reference: Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects After Implantation, ISO 10993-6: 1994.

PHYSICOCHEMICAL TEST (USP): This test determines the physical and chemical properties of extracts of test material. The test article passes the USP Physiocochemical Tests for plastics.
Reference: United States Pharmacopeia 26, National Formulary 21, 2003.

These studies are in conformance to all applicable laws and regulations. Specific regulatory requirements include the current Good Laboratory Practice for Nonclinical Studies (GLP), FDA, 21 CFR, Part 58.

The adhesive bonded polycarbonate lap shears utilized to approximate typical medical device applications are disassembled prior to testing in order to maximize adhesive exposure during the respective tests. All test results reflect maximum exposure of the adhesive to the various test parameters and conditions. In this manner, the adhesive test results provide a higher margin of safety when compared to the tests involving only the bondline area and thickness.

(b) (4), (b) (6) [redacted]

(b)(4)

[redacted]

TEST RESULT CERTIFICATE

(b) (4), (b) (6)

[redacted]

Technical Initiation	06/20/97
Technical Completion	07/14/97
Report Date	07/16/97
Project Number	(b)(4)

(b) (4), (b) (6)

[redacted]

(b)(4)

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

Test Article: (b)(4) Medical Device Adhesive

Lot Number: (b)(4)

INTRACUTANEOUS INJECTION (ISO): The purpose of this test is to evaluate the irritation potential of the test article extracts in rabbits after intracutaneous injection. Test article extract in saline, cottonseed oil, polyethylene glycol 400 and alcohol in saline did not produce a significantly greater tissue reaction than blank extract when injected intracutaneously into rabbits. Additional extracts (PEG & Alcohol in Saline) were used to cover the requirements of United States Pharmacopeia 28, National Formulary 23, 2005; Monograph <88>: Biological Reactivity Tests, *In Vivo*. Based on the criteria set forth by the protocol, the test article is considered negligible or slight irritant-conforms. *Reference: Biological Evaluation of Medical Devices - Part 10: Irritation and Delayed-type Hypersensitivity, ISO 10993-10, 2002.*

ACUTE SYSTEMIC INJECTION (ISO): The purpose of this assay is to evaluate the test article extracts for potential toxic effects as a result of single dose systemic injection in mice. Test article extracted in saline, cottonseed oil, polyethylene glycol 400 and alcohol in saline did not produce a significantly greater systemic reaction than blank extract when injected into mice. Additional extracts (PEG & Alcohol in Saline) were used to cover the requirements of United States Pharmacopeia 28, National Formulary 23, 2005; Monograph <88>: Biological Reactivity Tests, *In Vivo*. The test article did not show greater biological reactivity compared to the control material-conforms.
Reference: Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity, ISO 10993-11:1993.

CYTOTOXICITY (ISO): The purpose of the MEM Elution is to determine biological reactivity of monolayer cell culture (L929) in response to the test article. The test article is considered non-cytotoxic and meets the requirements of the MEM Elution Test, ISO 10993-5.
Reference: Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity, ISO 10993-5:1999.

(b)(4)

(b)(4)

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

HEMOCOMPATIBILITY (ISO):
Hemolysis: This assay is designed to evaluate the hemolytic potential of the test article extracts. Hemolytic activity of the test article with rabbit blood indicated that the test article was non-hemolytic (<5%).
Reference: Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood, ISO 10993-4, 2002.

***In Vitro* Hemocompatibility Assay**: This assay is designed to ensure that the test material extract does not adversely affect the cellular components of blood. The test article was evaluated for its potential to adversely affect selected hematological parameters. The hematological parameters tested were complete blood count including platelets, hematocrit, erythrocyte indices and free plasma hemoglobin. The test article meets the requirements.
Reference: Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood, ISO 10993-4:2002.

IMPLANTATION TEST (ISO): The macroscopic and histological reaction of the test article, implanted in rabbit muscle for 2 weeks was not significant when compared to negative control sites-conforms.
Reference: Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects After Implantation, ISO 10993-6: 1994.

PHYSICOCHEMICAL TEST (USP): This test determines the physical and chemical properties of extracts of test material. The test article passes the USP Physicochemical Tests for plastics.
Reference: United States Pharmacopeia 28, National Formulary 23, 2005.

These studies are in conformance to all applicable laws and regulations. Specific regulatory requirements include the current Good Laboratory Practice for Nonclinical Studies (GLP), FDA, 21 CFR, Part 58.

(b) (4), (b) (6)

15.9 - ISO 10993 (b)(4) [redacted] Biocompatibility Report

(b)(4) Testing

15.10 - ISO 10993 (b)(4) [redacted] Report

(b)(4)

[redacted]

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

Test Article: (b)(4) [redacted] Medical Device Adhesive

Lot Number: (b)(4) [redacted]

INTRACUTANEOUS INJECTION (ISO): The purpose of this test is to evaluate the irritation potential of the test article extracts in rabbits after intracutaneous injection. Test article extract in saline, cottonseed oil, polyethylene glycol 400 and alcohol in saline did not produce a significantly greater tissue reaction than blank extract when injected intracutaneously into rabbits. Additional extracts (PEG & Alcohol in Saline) were used to cover the requirements of United States Pharmacopeia 28, National Formulary 23, 2005; Monograph <88>: Biological Reactivity Tests, *In Vivo*. Based on the criteria set forth by the protocol, the test article is considered negligible or slight irritant-conforms. *Reference: Biological Evaluation of Medical Devices - Part 10: Irritation and Delayed-type Hypersensitivity, ISO 10993-10, 2002.*

ACUTE SYSTEMIC INJECTION (ISO): The purpose of this assay is to evaluate the test article extracts for potential toxic effects as a result of single dose systemic injection in mice. Test article extracted in saline, cottonseed oil, polyethylene glycol 400 and alcohol in saline did not produce a significantly greater systemic reaction than blank extract when injected into mice. Additional extracts (PEG & Alcohol in Saline) were used to cover the requirements of United States Pharmacopeia 28, National Formulary 23, 2005; Monograph <88>: Biological Reactivity Tests, *In Vivo*. The test article did not show greater biological reactivity compared to the control material-conforms.
Reference: Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity, ISO 10993-11:1993.

CYTOTOXICITY (ISO): The purpose of the MEM Elution is to determine biological reactivity of monolayer cell culture (L929) in response to the test article. The test article is considered non-cytotoxic and meets the requirements of the MEM Elution Test, ISO 10993-5.
Reference: Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity, ISO 10993-5:1999.

(b)(4)

[redacted]

(b)(4)

[redacted]

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

HEMOCOMPATIBILITY (ISO):
Hemolysis: This assay is designed to evaluate the hemolytic potential of the test article extracts. Hemolytic activity of the test article with rabbit blood indicated that the test article was non-hemolytic (<5%).
Reference: Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood, ISO 10993-4, 2002.

***In Vitro* Hemocompatibility Assay**: This assay is designed to ensure that the test material extract does not adversely affect the cellular components of blood. The test article was evaluated for its potential to adversely affect selected hematological parameters. The hematological parameters tested were complete blood count including platelets, hematocrit, erythrocyte indices and free plasma hemoglobin. The test article meets the requirements.
Reference: Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood, ISO 10993-4:2002.

IMPLANTATION TEST (ISO): The macroscopic and histological reaction of the test article, implanted in rabbit muscle for 2 weeks was not significant when compared to negative control sites-conforms.
Reference: Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects After Implantation, ISO 10993-6: 1994.

PHYSICOCHEMICAL TEST (USP): This test determines the physical and chemical properties of extracts of test material. The test article passes the USP Physicochemical Tests for plastics.
Reference: United States Pharmacopeia 28, National Formulary 23, 2005.

These studies are in conformance to all applicable laws and regulations. Specific regulatory requirements include the current Good Laboratory Practice for Nonclinical Studies (GLP), FDA, 21 CFR, Part 58.

(b) (4), (b) (6)

[redacted]

15.11 - ISO 10993 (b) (4) [redacted] Report.pdf

(b)(4)

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

Test Article: (b)(4) Medical Device Adhesive

Lot Number: (b)(4)

INTRACUTANEOUS INJECTION (ISO): The purpose of this test is to evaluate the irritation potential of the test article extracts in rabbits after intracutaneous injection. Test article extract in saline, cottonseed oil, polyethylene glycol 400 and alcohol in saline did not produce a significantly greater tissue reaction than blank extract when injected intracutaneously into rabbits. Additional extracts (PEG & Alcohol in Saline) were used to cover the requirements of United States Pharmacopeia 28, National Formulary 23, 2005; Monograph <88>: Biological Reactivity Tests, *In Vivo*. Based on the criteria set forth by the protocol, the test article is considered negligible or slight irritant-conforms. *Reference: Biological Evaluation of Medical Devices - Part 10: Irritation and Delayed-type Hypersensitivity, ISO 10993-10, 2002.*

ACUTE SYSTEMIC INJECTION (ISO): The purpose of this assay is to evaluate the test article extracts for potential toxic effects as a result of single dose systemic injection in mice. Test article extracted in saline, cottonseed oil, polyethylene glycol 400 and alcohol in saline did not produce a significantly greater systemic reaction than blank extract when injected into mice. Additional extracts (PEG & Alcohol in Saline) were used to cover the requirements of United States Pharmacopeia 28, National Formulary 23, 2005; Monograph <88>: Biological Reactivity Tests, *In Vivo*. The test article did not show greater biological reactivity compared to the control material-conforms.
Reference: Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity, ISO 10993-11:1993.

CYTOTOXICITY (ISO): The purpose of the MEM Elution is to determine biological reactivity of monolayer cell culture (L929) in response to the test article. The test article is considered non-cytotoxic and meets the requirements of the MEM Elution Test, ISO 10993-5.
Reference: Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity, ISO 10993-5:1999.

(b)(4)

(b)(4)

[redacted]

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

HEMOCOMPATIBILITY (ISO):
Hemolysis: This assay is designed to evaluate the hemolytic potential of the test article extracts. Hemolytic activity of the test article with rabbit blood indicated that the test article was non-hemolytic (<5%).
Reference: Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood, ISO 10993-4, 2002.

***In Vitro* Hemocompatibility Assay**: This assay is designed to ensure that the test material extract does not adversely affect the cellular components of blood. The test article was evaluated for its potential to adversely affect selected hematological parameters. The hematological parameters tested were complete blood count including platelets, hematocrit, erythrocyte indices and free plasma hemoglobin. The test article meets the requirements.
Reference: Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood, ISO 10993-4:2002.

IMPLANTATION TEST (ISO): The macroscopic and histological reaction of the test article, implanted in rabbit muscle for 2 weeks was not significant when compared to negative control sites-conforms.
Reference: Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects After Implantation, ISO 10993-6: 1994.

PHYSICOCHEMICAL TEST (USP): This test determines the physical and chemical properties of extracts of test material. The test article passes the USP Physicochemical Tests for plastics.
Reference: United States Pharmacopeia 28, National Formulary 23, 2005.

These studies are in conformance to all applicable laws and regulations. Specific regulatory requirements include the current Good Laboratory Practice for Nonclinical Studies (GLP), FDA, 21 CFR, Part 58.

(b) (4), (b) (6)

[redacted]

15.12 - ISO 10993-5 Cytotoxicity Report for (b) (4) [redacted] Camera Drape.pdf

Confidential

(b)(4) [redacted]

(b)(4) [redacted]

STUDY TITLE:

CYTOTOXICITY STUDY USING THE ISO ELUTION METHOD

TEST ARTICLE:

(b)(4) [redacted]

IDENTIFICATION NO.:

(b)(4) [redacted]

(b) (4), (b) (6) [redacted]

(b)(4)

[redacted]

TABLE OF CONTENTS

	Page Number
SUMMARY	3
INTRODUCTION	4
MATERIALS	4
METHODS	5
RESULTS	6
CONCLUSION	7
RECORD STORAGE	7

(b)(4)

[redacted]

(b)(4) [redacted]

SUMMARY

An *in vitro* biocompatibility study, based on the International Organization for Standardization (ISO 10993-5) guidelines, was conducted on the test article, (b)(4) [redacted], in order to determine the potential for cytotoxicity. Triplicate extracts of the test article were prepared using Minimum

(b)(4) [redacted]

Under the conditions of this study, the MEM test extracts showed no evidence of causing cell lysis or toxicity. The MEM test extracts were not cytotoxic and met the requirements of the test. The negative controls, reagent controls, and the positive controls performed as anticipated.

Study and Supervisory Personnel: (b) (6) [redacted]

Approved by: (b) (6) [redacted]

/las

(b)(4) [redacted]

(b)(4) [redacted]

INTRODUCTION

The test article identified below was extracted, and the extracts were subjected to an *in vitro* cytotoxicity study for biocompatibility based on the requirements of the International Organization for Standardization: Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity. The test was performed in order to determine whether leachables extracted from the material would cause cytotoxicity. The test article was received on April 9, 1999. The cells were first exposed to the extract on April 13, 1999, and the observations were concluded on April 15, 1999.

MATERIALS

The sample provided by the sponsor was identified and handled as follows:

Test Article:	(b)(4) [redacted]
Identification No.:	(b)(4) [redacted]
Storage Conditions:	Room temperature
Extraction Vehicle:	(b)(4) [redacted]
Test Article Preparation:	
Negative Control:	
Reagent Control:	
Positive Control:	
Condition of Extracts:	Test: clear Negative Controls: clear Reagent Controls: clear Positive Controls: clear

(b)(4) [redacted]

(b)(4) [redacted]

METHODS

Test System Management:

L-929 mouse fibroblast cells (ATCC CCL1, NCTC Clone 929, of strain L, or equivalent source) were propagated at

(b)(4) [redacted]

Experimental Procedure:

(b)(4) [redacted]

Grade	Reactivity	Condition of Culture
0	None	Discrete intracytoplasmic granules; no cell lysis.
1	Slight	Not more than 20% of the cells are round, loosely attached, and without intracytoplasmic granules; some lysed cells are present.
2	Mild	Not more than 50% of the cells are round and devoid of intracytoplasmic granules; no extensive cell lysis and empty areas between cells.
3	Moderate	Not more than 70% of the cell monolayer contains rounded cells or is lysed.
4	Severe	Nearly complete destruction of the cell monolayer.

For the suitability of the system to be confirmed, the reagent and negative controls must have been a grade of 0 (reactivity none) and the positive controls must have been a grade 3 or 4. The test article passed the test if all three of the monolayers exposed to the test medium showed no greater than a grade of 2 (mild reactivity). The test would have been repeated if the controls did not perform as anticipated and/or if all three test wells did not yield the same conclusion.

(b)(4) [redacted]

(b)(4) [redacted]

RESULTS

The observations and scores obtained were as follows:

Well	Confluent Monolayer	% Cells Without Intracellular Granulation	% Rounding	% Lysis	Grade Score	Reactivity
Test (1)	(+)	0	0	0	0	None
Test (2)	(+)	0	0	0	0	None
Test (3)	(+)	0	0	0	0	None
Negative Control (1)	(+)	0	0	0	0	None
Negative Control (2)	(+)	0	0	0	0	None
Negative Control (3)	(+)	0	0	0	0	None
Reagent Control (1)	(+)	0	0	0	0	None
Reagent Control (2)	(+)	0	0	0	0	None
Reagent Control (3)	(+)	0	0	0	0	None
Positive Control (1) 1:2 Dilution	(-)	100	100	100	4	Severe
Positive Control (2) 1:2 Dilution	(-)	100	100	100	4	Severe
Positive Control (3) 1:2 Dilution	(-)	100	100	100	4	Severe

(+) = Present (-) = Absent

pH Observation: The test medium was similar to the negative control medium at 48 hours.

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

CONCLUSION

Under the conditions of this study, the MEM test extracts showed no evidence of causing cell lysis or toxicity. The MEM test extracts were not cytotoxic and met the requirements of the test. The negative controls, reagent controls, and the positive controls performed as anticipated.

RECORD STORAGE

All raw data pertaining to this study and a copy of the final report are to be retained in designated (b)(4) [redacted] files.

(b)(4) [redacted]

15.13 - 517869 - ISO 10993-5 MEM Elution Cytotoxicity PN 01091

(b)(4) Testing

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(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

15.14 - 520734 - ISO 10993 Part 5 MEM Elution Cytotoxicity Peek & Trocar Cover Report

(b)(4) [redacted]

FINAL REPORT

MEM ELUTION

PROCEDURE NO. (b)(4) [redacted]
PROTOCOL DETAIL SHEET NO. (b)(4) [redacted]

LABORATORY NO. (b)(4) [redacted]

PREPARED FOR:

JEFF LESICA
VISIONSCOPE TECHNOLOGIES, LLC
2352 MAIN ST. STE. 303
CONCORD MA 01742

SUBMITTED BY:

(b)(4) [redacted]

738

(b)(4) [redacted]

(b)(4) [redacted]

QAU AUDIT STATEMENT

[X] USFDA (21 CFR PART 58) [ ] USEPA (40 CFR PART 160)

MEM ELUTION

LABORATORY NO. (b)(4) [redacted]

1. The test was conducted in accordance with the USFDA or USEPA Regulations as noted above.

2. In accordance with the Good Laboratory Practice Regulations, the Sample Preparation phase(s) of this study was inspected by the Quality Assurance Unit on: 30 Mar 2010. The findings of the inspection(s) were reported to the Study Director on: 05 Apr 2010 and to Management on: 02 Apr 2010.

3. The Quality Assurance Unit has reviewed this report and has determined that the methods and standard testing procedures are accurately described, and that the reported results accurately reflect the raw data.

4. The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel, involved in the study:

(b) (6) [redacted]

QUALITY ASSURANCE: (b) (6) [redacted]

(b)(4) [redacted]

MEM ELUTION

LABORATORY NUMBER:	(b)(4) [redacted]
PROCEDURE NUMBER:	
PROTOCOL DETAIL SHEET NUMBER:	
SAMPLE SOURCE:	VisionScope Technologies, LLC
TYPE OF TEST:	Solid
SAMPLE IDENTIFICATION:	Refer to Table 1
	P.O. #032410A
DEVIATIONS:	None
CELL LINE:	(b)(4) [redacted]
CELL LINE JUSTIFICATION:	Industry Standard
CELL LINE SOURCE:	(b)(4) [redacted]
INCUBATION PERIOD:	
METHOD OF SCORING:	
PROTOCOL APPROVAL DATE:	30 Mar 2010
STUDY RECEIVED DATE:	26 Mar 2010
LAB PHASE START DATE:	30 Mar 2010
LAB PHASE COMPLETION DATE:	05 Apr 2010
REPORT ISSUE DATE:	05 Apr 2010

INTRODUCTION:

The MEM Elution test was designed to determine the cytotoxicity of extractable substances. An extract of the sample was added to cell monolayers and incubated. The cell monolayers were examined and scored based on the degree of cellular destruction.

ACCEPTANCE CRITERIA:

The United States Pharmacopeia & National Formulary states that the sample meets the requirements if the reactivity grade is not greater than grade 2 or a mild reactivity. The USP/AAMI/ISO 10993-5 standard states that the achievement of a numerical grade greater than 2 is considered a cytotoxic effect. Nelson Laboratories acceptance criteria was based upon the negative and media controls receiving "0" reactivity grades and positive results receiving a 3-4 reactivity grades (moderate to severe).

PROCEDURE:

The amount of test material extracted was based on ANSI/AAMI/ISO and USP surface area recommendations or weight (0.20 g/mL extract fluid for polymers and plastic). The sample was extracted with agitation for 24-25 hours at 37 ± 1°C in 1X Minimal Essential Media with 5% bovine serum. Positive (Latex Natural Rubber) and negative (Polypropylene Pellets) controls were extracted and included in the assay. A blank of extraction media (media control) was also included in the assay.

(b)(4) [redacted]

(b)(4) [redacted]

The cell monolayers were examined microscopically. The wells were scored as to the degree of discernable morphological cytotoxicity on a relative scale of 0 to 4:

CONDITIONS OF ALL CULTURES	REACTIVITY	GRADE
No cell lysis, intracytoplasmic granules.	NONE	0
Not more than 20% rounding, occasional lysed cells.	SLIGHT	1
Not more than 50% rounding, no extensive cell lysis.	MILD	2
Not more than 70% rounding and lysed cells.	MODERATE	3
Nearly complete cell destruction.	SEVERE	4

The results from the three wells were averaged to give a final cytotoxicity score.

RESULTS:

The results are summarized in Table 1. The test is acceptable if all three of the negative control and medium control test wells have a score of 0 and all three of the positive control test wells have a score of 3 or higher.

The sample meets USP and ISO requirements if none of the cell culture exposed to the sample shows greater than a mild reactivity (grade 2).

DATA DISPOSITION:

The raw data and final report from this study are archived at (b)(4) [redacted] or an approved off-site location.

(b)(4) [redacted]

STATEMENT OF UNCERTAINTY:

If applicable, the statement of uncertainty is available to sponsors upon request.

(b) (6) [redacted]

ke

(b)(4) [redacted]

VisionScope Technologies, LLC
Lab Number (b)(4) [redacted]

MEM Elution

TABLE 1. Results

IDENTIFICATION	AMOUNT TESTED / SAMPLE EXTRACT	SCORE #1	SCORE #2	SCORE #3	AVERAGE
Negative Control	4 g / 20 mL	0	0	0	0
Media Control	20 mL	0	0	0	0
Positive Control	4 g / 20 mL	4	4	4	4
Lot 1 - Pooled Together P/N 01056-001 8 grams P/N 01071-001 6 grams	12.4 g / 62 mL	0	0	0	0

743

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4)

[redacted]

PREPARED FOR SPONSOR		LABORATORY / CONTRACTOR
CONTACT:	Jeff Lesica	(b)(4) [redacted]
COMPANY:	VisionScope Technologies, LLC	
EMAIL:	jeff.lesica@visionscope-tech.com	
PHONE:	978-776-9502	
FAX:	978-776-9502	

PROTOCOL SPECIFICATIONS			
PARENTAL DOCUMENT:	MEM Elution, STP0032, 5		
SECTION:	Biocompatibility		
PDS INITIATION DATE:	29-Mar-2010	EXPIRATION DATE:	29-Mar-2012

JUSTIFICATION:

No changes to the Standard Testing Protocol.

PROTOCOL SPECIFICATIONS:

Test according to Standard Test Protocol.

(b) (4), (b) (6)

[redacted]

15.15 (b) (4) [redacted] Biocompatibility Report

(b)(4) [redacted]

October 26, 2007

Re: ISO 10993 - (b)(4) [redacted]

Dear Valued Customer:

Thank you for your interest in (b)(4) [redacted]
(b)(4) [redacted]

(b)(4) [redacted]

Please refer to the attached tables for a summary of the results.

(b)(4) [redacted] presenting this information as a courtesy and does not intend for this letter and attached information to be viewed as final representation of the applicability of the test results in regards to the resin of interest. Properties of materials and their lots can vary in their biological response due to a variety of factors including different types and concentration of additives as well as local manufacturing conditions.

(b)(4) [redacted]

(b)(4) [redacted]

Sincerely,

(b) (6) [redacted]

Summary results for (b)(4) [redacted]:
The test article was steam sterilized prior to testing. Testing was initiated in June of 2006.

ISO Test Method	Test Description	Result/Comments
10993:5: 1999	Cytotoxicity using the ISO elution method	No evidence of causing cell lysis or toxicity
10993:10: 2002	Maximization Sensitization with sodium chloride extract	No evidence of causing delayed dermal contact sensitization in the guinea pig
10993:10: 2002	Maximization Sensitization with sesame oil extract	No evidence of causing delayed dermal contact sensitization in the guinea pig
10993:10: 2002	Intracutaneous Reactivity with sodium chloride extract	No erythema and no edema from the sodium chloride extract injected intracutaneously into rabbits. The primary irritation index characterization for the extracts was negligible.
10993:10: 2002	Intracutaneous Reactivity with sesame oil extract	Very slight erythema and no edema from the sesame oil extract injected intracutaneously into rabbits. The primary irritation index characterization for the extracts was negligible.
10993:11: 1993	USP & ISO Systemic Toxicity Study with sodium chloride extract	No mortality or evidence of systemic toxicity from the extracts.
10993:11: 1993	USP & ISO Systemic Toxicity Study with sesame oil extract	No mortality or evidence of systemic toxicity from the extracts.
10993:18: 2005	Physico-Chemical Testing with water extract	Non-volatile residue: < 1 mg Residue on ignition: < 1 mg Heavy metals: < 1 ppm Buffering capacity: < 1 ml
10993:18: 2005	Physico-Chemical Testing with isopropyl alcohol extract	Non-volatile residue: < 1 mg Residue on ignition: < 1 mg Turbidity: 0.2 NTU UV Absorption: O.D. 0.9332 λ Maximum: 275.1 nm

Equivalency Test Results Summary for (b)(4) [redacted]
The test article was steam sterilized prior to testing. Testing was initiated in June of 2006.

ISO Test Method	Test Description	Result/Comments
10993:5: 1999	Cytotoxicity using the ISO elution method	No evidence of causing cell lysis or toxicity
10993:18: 2005	Physico-Chemical Testing with water extract	Non-volatile residue: < 1 mg Residue on ignition: < 1 mg Heavy metals: < 1 ppm Buffering capacity: < 1 ml
10993:18: 2005	Physico-Chemical Testing with isopropyl alcohol extract	Non-volatile residue: < 1 mg Residue on ignition: < 1 mg Turbidity: 0.5 NTU UV Absorption: O.D. 1.0690 λ Maximum range: 275.1 nm

Equivalency Test Results Summary for (b)(4) [redacted]
The test article was steam sterilized prior to testing. Testing was initiated in June of 2006.

ISO Test Method	Test Description	Result/Comments
10993:5: 1999	Cytotoxicity using the ISO elution method	No evidence of causing cell lysis or toxicity
10993:18: 2005	Physico-Chemical Testing with water extract	Non-volatile residue: < 1 mg Residue on ignition: < 1 mg Heavy metals: < 1 ppm Buffering capacity: < 1 ml
10993:18: 2005	Physico-Chemical Testing with isopropyl alcohol extract	Non-volatile residue: < 1 mg Residue on ignition: < 1 mg Turbidity: 0.4 NTU UV Absorption: O.D. 0.8406 λ Maximum range: 250.1 nm

Summary results for Additive Packages A-J:
The test article was steam sterilized prior to testing. Testing was initiated in June of 2006.

ISO Test Method	Test Description	Result/Comments
10993:5: 1999	Cytotoxicity using the ISO elution method	No evidence of causing cell lysis or toxicity
10993:18: 2005	Physico-Chemical Testing with water extract	Non-volatile residue: < 1 mg Residue on ignition: < 1 mg Heavy metals: < 1 ppm Buffering capacity: < 1 ml
10993:18: 2005	Physico-Chemical Testing with isopropyl alcohol extract	Non-volatile residue: < 1 mg Residue on ignition: < 1 mg Turbidity ranges: < 0.1 to 1.8 NTU UV Absorption ranges: O.D. 0.1504 to 1.8756 λ Maximum range: 240 to 275.1 nm

15.16 - (b) (4) [redacted] Biocompatibility Report

APPENDIX IV - FDA/ISO 10993 and UPS Biological Evaluation Testing Results, (b)(4) [redacted]

(b)(4) [redacted]

Prior to testing, samples sterilized by:	Gamma & EtO
Cytotoxicity	√
Sensitization	√
Hemocompatibility *In vitro* hemocompatibility assay Hemolysis (direct contact)	 √ √
USP Physico-chemical	√
USP Systemic Injection	√
USP Intracutaneous Injection	√
USP Implantation	√

(b)(4) [redacted]

15.17 - (b) (4) [redacted] MSDS

(b)(4)

[redacted]

Properties

Attribute	Test method	Typical value (US)		Typical value (Int'l)	
Substrate basis weight	ASTM D3776	2.2	oz/yd²	75	g/m²
Adhesive coat weight	ASTM F2217-02	13.0	lbs/ream	21.2	g/m²
Total weight	—	58.8	lbs/ream	95.7	g/m²
Yield	—	7,347	in²/lb	10.4	m²/kg
Mullen burst	ASTM D774	178	psi	1,227	kPa
Elmendorf tear (MD)	ASTM D1424	0.77	lb	3,425	mN
Elmendorf tear (CD)	ASTM D1424	0.79	lb	3,514	mN
Tensile (MD)	ASTM D5035	43.4	lb/in	193	N/2.54cm
Tensile (CD)	ASTM D5035	46.8	lb/in	208	N/2.54cm
Porosity-Gurley	TAPPI T460	33	sec	—	—
Porosity-Bendtsen	ISO 5636-3	—	—	380	ml/min
Peel strength-180°	ASTM F88	2.0	lbs/in width	5.3	N/15mm
Thickness	ASTM D1777	8.3	mil	210	µm
Thickness range	ASTM D1777	4.5-12.1	mil	114-307	µm

Values shown above are typical results Values are not to be used in place of final product specifications.

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4) Testing

15.18 - (b) (4) [redacted] ISO-10993-5 NP34 Cytotoxicity Report

(b)(4) [redacted] FINAL REPORT: 03-3341-G1

AGAR DIFFUSION TEST - ISO

Author

(b) (6) [redacted]

(b)(4) [redacted]

MANAGEMENT OF THE STUDY

Performing Laboratory

(b)(4) [redacted]

Sponsor

(b)(4) [redacted]

(b)(4) [redacted]

TABLE OF CONTENTS

Title Page

Table of Contents

Study Summary

Quality Assurance Statement

Study Director Signature and Verification Dates

1.0 Purpose

2.0 References

3.0 Compliance

4.0 Identification of Test and Control Articles

5.0 Identification of Test System

6.0 Justification of Test System and Route of Administration

7.0 Experimental Design

8.0 Dosage

9.0 Evaluation Criteria

10.0 Results

11.0 Conclusion

12.0 Records

13.0 Confidentiality Agreement

(b)(4) [redacted]

STUDY SUMMARY

No biological reactivity (Grade 0) was observed in the L929 mammalian cells at 48 hours, post exposure to the test article. The observed cellular response obtained from the positive control article (Grade 3) and negative control article (Grade 0) confirmed the suitability of the test system. The test article, (b)(4) [redacted] is considered non-cytotoxic and meets the requirements of the Agar Diffusion Test, ISO 10993-5.

(b)(4) [redacted]

QUALITY ASSURANCE STATEMENT

This study was conducted in compliance with U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of (b)(4) [redacted] Corporation, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Parts 58.105 and 58.113.

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to (b)(4) [redacted].

INSPECTIONS	DATE OF INSPECTION	DATE REPORTED STUDY DIRECTOR	DATE REPORTED MANAGEMENT
DOSING	07/03/03	07/03/03	07/03/03
RAW DATA	07/14/03	07/14/03	07/14/03
FINAL REPORT	07/14/03	07/14/03	07/14/03

(b) (6) [redacted]

761

(b)(4) [redacted]

STUDY DIRECTOR SIGNATURE AND VERIFICATION DATES

This study meets with the technical requirements of the protocol. The study also meets with the requirements of the Good Laboratory Practice Regulations, 21 CFR, Part 58, with the exemptions as stated in the Quality Assurance Statement.

Protocol Number: (b)(4) [redacted]

Study Director:

Company:

Signature: (b) (6) [redacted]

Date: 07/14/03

Study Supervisor: (b) (6) [redacted]

VERIFICATION DATES:

The [redacted] (b)(4) [redacted]. The study dates were as follows:

Protocol Effective Date:	04/16/03
Test Article Receipt:	07/03/03
Project Log Date:	07/03/03
Technical Initiation:	07/03/03
Technical Completion:	07/05/03

(b)(4) [redacted]

1.0 PURPOSE

(b)(4) [redacted]

2.0 REFERENCES

The study was conducted based on the following references:

2.1 Biological Evaluation of Medical Devices-Part 5: Tests for *In Vitro* Cytotoxicity, ISO 10993-5, 1999.

2.2 Biological Evaluation of Medical Devices-Part 12: Sample Preparation and Reference Materials, ISO 10993-12, 2002.

2.3 General Requirements for the Competence of Testing and Calibration Laboratories, ISO 17025, 1999.

3.0 COMPLIANCE

The present study conformed to all applicable laws and regulations. Specific regulatory requirements included the current Good Laboratory Practice for Nonclinical Laboratory Studies, FDA, 21 CFR, Part 58.

4.0 IDENTIFICATION OF TEST AND CONTROL ARTICLES

The following information was supplied by the Sponsor wherever applicable; it did not apply to confidential information. The Sponsor was responsible for all test article characterization data as specified in the GLP regulations. Test and control articles (exclusive of extracts) that are mixed with carriers require verification of concentration, homogeneity and stability. Samples of test and control article mixtures were not returned to the Sponsor for characterization and verification.

4.1 Test Article

4.1.1 Test Article Name: NP-34
CAS/Code #: Not Supplied by Sponsor (N/S)
Lot/Batch #: Lot# 030623462
Physical State: Solid Polymer
Color: White
Stability: N/S

(b)(4) [redacted]

Solubility: N/S
Expiration Date: N/S
Storage Conditions: Room Temperature
Safety Precautions: Standard Toxikon Laboratory Safety Precautions

4.2 Control Articles (b)(4) [redacted]

4.2.1 Positive Control Article Name: Natural Rubber
Toxikon QC #: CSC-03-02-001-CC
Physical State: Solid
Stability: Stable
Storage: Room Temperature
Safety Precautions: Standard Laboratory Safety Precautions

4.2.2 Negative Control Article Name: Negative Control Plastic
Toxikon QC #: CSC-00-07-002-CC
Physical State: Solid
Stability: Stable
Storage: Room Temperature
Safety Precautions: Standard Laboratory Safety Precautions

5.0 IDENTIFICATION OF TEST SYSTEM

Mouse fibroblast L929 cells are classically used for cytotoxicity studies. The cell line was obtained from the American Type Tissue Collection, Manassas, Virginia.

6.0 JUSTIFICATION OF TEST SYSTEM AND ROUTE OF ADMINISTRATION

6.1 Historically, mouse fibroblast L929 cells have been used for cytotoxicity studies because they demonstrate sensitivity to leachable cytotoxic articles.

6.2 The test article was administered *in vitro*, directly to the test system. This was the optimal route of administration available in this test system as recommended by ISO 10993-5.

7.0 EXPERIMENTAL DESIGN

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

8.0 DOSAGE

(b)(4) [redacted]

9.0 EVALUATION CRITERIA

The response of the cell monolayer is evaluated under a microscope for cytotoxicity. The zone of biological reactivity (cellular degeneration and malformation) under and around the test and control articles is measured and rated on a scale of 0 to 4. The test system is considered suitable if no signs of cellular reactivity (Grade 0) are noted for the negative control article, and the positive control article shows greater than a Mild reactivity (Grade 2). The test article meets the requirements of the test if none of the cultures treated with the test article shows greater than a Mild reactivity (Grade 2). If the suitability of the system is not confirmed, the test should be repeated.

Grade	Reactivity	Description of Reactivity Zone
0	None	No detectable zone around or under specimen
1	Slight	Some malformed or degenerated cells under specimen
2	Mild	Zone limited to the area under the specimen
3	Moderate	Zone extends 0.5 to 1.0 cm beyond specimen
4	Severe	Zone extends greater than 1.0 cm beyond the specimen but does not involve entire dish

(b)(4) [redacted]

10.0 RESULTS

REACTIVITY GRADES

TIME (hours)	DISH	TEST ARTICLE		POSITIVE CONTROL		NEGATIVE CONTROL	
		Zone size (cm)	Grade	Zone size (cm)	Grade	Zone size (cm)	Grade
0	A	0.0	0	0.0	0	0.0	0
	B	0.0	0	0.0	0	0.0	0
	C	0.0	0	0.0	0	0.0	0
24	A	0.0	0	0.5	3	0.0	0
	B	0.0	0	0.5	3	0.0	0
	C	0.0	0	0.5	3	0.0	0
48	A	0.0	0	0.7	3	0.0	0
	B	0.0	0	0.7	3	0.0	0
	C	0.0	0	0.7	3	0.0	0

11.0 CONCLUSION

No biological reactivity (Grade 0) was observed in the L929 mammalian cells at 48 hours, post exposure to the test article. The observed cellular response obtained from the positive control article (Grade 3) and negative control article (Grade 0) confirmed the suitability of the test system. The test article, NP-34, is considered non-cytotoxic and meets the requirements of the Agar Diffusion Test, ISO 10993-5.

12.0 RECORDS

12.1 Original raw data is archived at (b)(4) [redacted].

12.2 A copy of the final report and any amendments is archived at (b)(4) [redacted].

12.3 The original final report and a copy of any protocol amendments or deviations is forwarded to the Sponsor.

12.4 All unused test article shall be disposed of by (b)(4) [redacted] Sponsor's specifications.

12.5 Final reports shall not be reproduced, except in full, without the written authorization/approval from Toxikon.

13.0 CONFIDENTIALITY AGREEMENT

Statements of confidentiality were as agreed upon prior to study initiation.

SECTION 16. SOFTWARE

As discussed in greater detail below, the controlling software for the VisionScope High Definition Endoscopy Camera System (Device) presents a "moderate" level of concern as defined in FDA's *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices* (May 11, 2005) (Hereinafter *Guidance Document.*) According to the *Guidance Document*, software for a device has a "moderate" level of concern when "the operation of the software associated with device function directly affects the patient and/or operator so that failures or latent design flaws could result in non-serious injury to the patient and/or operator, or if it indirectly affects the patient and/or operator (e.g., through the action of a care provider) where incorrect or delayed information could result in non-serious injury of the patient and/or operator." Using FDA's "Approach to Deciding Level of Concern" as detailed in the *Guidance Document*, the Device software has a moderate level of concern for the following reasons:

1. The software does not qualify as Blood Establishment Computer Software.

2. The software is not intended to be used in combination with a drug or biologic.

3. The software is not an accessory to a medical device that has a Major Level of Concern.

4. Prior to mitigation of hazards, a failure of the software could not result in death or serious injury, either to a patient or to a user of the device.

    a. The software does not control a life supporting or life sustaining function.
    b. The software does not control the delivery of potentially harmful energy that could result in death or serious injury.
    c. The software does not control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury.
    d. The software does not provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death.
    e. The software does not provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary.

Accordingly, this software documentation includes the following information that is required for a software controlled device that presents a moderate level of concern:

A. a description of the software;
B. a hazard analysis;
C. the software requirements specification documentation;
D. an architectural design chart providing a detailed depiction of functional units and software modules;
E. the Software Design Specification document;
F. a traceability analysis;
G. a summary of the software life cycle development plan;
H. a description of verification and validation activities at the unit, integration, and system level, and the system level test protocol, including pass/fail criteria, and tests results;
I. a revision level history log; and
J. a list of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors.

Table 1 below lists the locations and titles of the supporting documents attached in Section 16 – Software. Additional Summary Overviews of each document are given in Table 1 below.

Table 1. Supporting Software Documents

Software Documentation	Document References
A. Software Description	16.2 - 80071 VisionScope Software Architecture and Description
B. Device Hazard Analysis	16.3 - 80020 Risk Management Plan and Summary 16.4 - 80013 VisionScope Risk Analysis 16.5 - 80014 VisionScope System Design FMEA & Verification 16.6 - 80055 VisionScope Software Design FMEA & Verification 16.7 - 80089 IEC60601-1-4 VisionScope Risk Management 16.8 - 80090 IEC60601-1-6 Usability Test Report
C. Software Requirements Specification (SRS)	16.9 - 80016 VisionScope Software Requirements Specifications
D. Architecture Design Chart	16.2 - 80071 VisionScope Software Architecture and Description 16.10 - 800019 VisionScope Software Design Specification
E. Software Design Specification (SDS)	016.10 - 80019 VisionScope Software Design Specifications
F. Traceability Analysis	16.11 - 80072 VisionScope Traceability Analysis 16.12 - 80028 VisionScope Software Validation Protocol and Report 16.13 – 80029 VisionScope Software Verification Protocol and Report
G. Software Development Environment Description	16.2 - 80071 VisionScope Software Architecture and Description
H. Verification and Validation Documentation	16.12 - 80028 VisionScope Software Validation Protocol and Report 16.13 – 80029 VisionScope Software Verification Protocol and Report
I. Revision Level History	16.14 - 80073 VisionScope Software Revision History Log
J. Unresolved anomalies	16.15 - VisionScope Software Unresolved Anomalies None as of Rev. B of April 13, 2010

A. Software Description

Document 16.2 – 80071 VisionScope Software Architecture and Description contains the following:

- Brief description of device
- Purpose of software
- Specific software functions
- Architecture Design
- Software Development Environment
- Hardware requirements
- Programming languages used
- Life Cycle Development Plan
- Software Operating Environment including Off-the-Shelf Software

B. Hazard Analysis

The Hazard Analysis covers both the hardware and software aspects of the system per the FDA Guidance Document, as hardware and software are closely interconnected and inseparable. The procedures also closely follow ISO 14971 Application of Risk Management to Medical Devices.

Documents 16.3 – 80020 provides an overview of the Risk Management Plan

Document 16.4 – 80013 provides an overview of the Risk Analysis

Document 16.5 – 80014 provides the Design FMEA mostly from a hardware perspective but also relates to software when the hardware provides backup mitigation in case of software failure

Document 16.6 – 80055 provides the Software Design FMEA including Usability aspects

Document 16.7 – Provides a summary including the Risk Management and Development Cycle processes of Programmable Electrical Medical Systems per IEC 60601-1-4.

Document 16.8 – Provides a Summary Report including the assessment and mitigation of uses caused by usability problems associated with correct use and use errors, i.e., normal use, per IEC 60601-1-6.

C. Software Requirements Specifications (SRS)

The SRS describes what the software will do. The SRS were based on a value analysis approach, consisting of discussions with potential users, site visits, and a review of current, similar systems. The SRS was developed to comply with the VisionScope User Needs and Product Requirements document (80002). The SRS include the following:

- Device Description
- System Components
- Hardware Requirements
- Software Performance and Functional Requirements
- Internal and External Interface Requirements
- Off-the-shelf Software
- Acceptance Criteria
- Standards
- Change Management

D. Architecture Design Chart

The Device software architecture design chart can be found in two documents:

- 16.2 - 80071 VisionScope Software Architecture and Description – contains top level architecture design charts
- 16.10 - 80019 VisionScope Software Design Specification – contains more detailed, lower level modular architecture design charts

E. Software Design Specifications (SDS)

The SDS describes how the SRS is to be implemented. It contains is a very detailed description of what the software program should do and how it should do it. It is the specification that a programmer will use to produce the program the software.

The SDS includes the following:

- Reference to SRS
- Development standards and programming standards
- Reference to hazard analysis
- Internal software tests and checks
- Error and interrupt handling
- Fault detection, tolerance and recovery
- Program logic
- Data structures and data flow
- Variable definitions
- Error and alarm messages
- Off-the-shelf software
- Internal and External Communications
- Security

F. Traceability Analysis

Traceability Analysis is given in three documents:

i. 16.11 - 80072 VisionScope Traceability Analysis contains a top level overview of the traceability. It includes a table relating the requirements, specifications, verification, validation and hazard analysis in the following table format:

User Needs and Product Requirements Description **Section Title**	**VisionScope User Needs and Product Requirement Document 80002 Section Reference**	**System and Subsystem Specification Documents & Section Reference (Document # & Section #)**	**System and Subsystem Verification & Validation Documents & Section Reference (Document # & Section #)**	**Risk Analysis and Design FMEA (Document # & Section #)**

Additionally, detailed section-by-section software traceability relating requirements and specifications to validation and verification items are part of the Software Verification and Validation reports:

ii. 16.12 - 80028 VisionScope Software Validation Protocol and Report – contains test cases that are traceable to the SRS

iii. 16.13 – 80029 VisionScope Software Verification Protocol and Report – contains test cases that are traceable to the SDS

G. Summary of the Software Life Cycle Development Plan

As stated above, the requirements for the Device were based on a value analysis approach, consisting of discussions with potential users, site visits, and a review of the currently available devices. The System

Requirements were formulated together with the System Master Validation Plan to list what would be tested during the system verification and validation phase and how testing would be conducted.

After the system requirements phase, a preliminary hazard analysis was conducted (1) to identify the potential hazards, such as patient risks, operator risks and interrupted or delayed procedures due to any single electrical or mechanical part failure; and (2) to determine how each risk will be addressed. Additional hazard analyses were conducted throughout the design process and new safety features were incorporated into the software program or hardware design to avoid these additional risks. Hazard analysis, risk mitigation, and mitigation verification are performed in parallel with hardware and software design, verification and validation in an interactive loop. According to the system requirements, the software requirements were developed prior to the software development stage. During the software design, different software modules were defined from a waterfall structured approach and was presented to other engineering team members working on the project. After modification, the software modular structure was accepted by all of the team members and signed off by the Program Manager.

The coding then began using a structured approach, meaning that the coding of the high level routines was made prior to those of the lower level modules. Code "walk-throughs," whereby both software programmers and electrical engineers check the codes written by another programmer, were conducted interactively. The purpose of the "walk-throughs" is (1) to review the code for consistency, error handling and correctness; (2) to check the fulfillment of design goals; and (3) to detect problems with the software and hardware design early in the development process.

After the coding was completed, unit testing was conducted using the same waterfall and structured approach. The unit testing was deemed complete only when the results corresponded to the expected results. The expected results were defined by a priori in accordance with the SDS and SRS. Lower level software module was first tested separately from the rest of the controlling software before integration testing was conducted. As explained below, this software was subsequently integrated and tested on the system as a whole.

After the unit testing was completed, the modules of the software were integrated and tested on a module per module basis in order to obtain the final software package. The integration testing was deemed complete only when all the modules worked correctly on this simulation system.

All of the software modules were then tested on a production-equivalent mechanical, electrical, and hardware system to perform the software system level testing. Test cases were developed to test one or more functions of the software, either in isolation or in combination, corresponding to the functions described in the SDS and SRS. All of the variations of the user inputs were also tested to detect unexpected conditions. Special stress test cases and failure recovery test cases were developed where appropriate to test unusual and potential fault conditions. The software safety features resulting from the hazard analysis were also tested.

The final system verification and validation was conducted in-house, following the final system test protocol. The test results were recorded in the software verification as well as validation test report.

In addition, using initially released software and hardware, the VisionScope system was taken out to cadaver laboratories on several occasions and tested with the several surgeons to obtain user feedbacks on both the hardware and software requirements and performance. The comments were reviewed and analyzed, and where necessary, incorporated into the revised specifications and subsequent verification and validation steps.

Finally, a final design review and a design transfer review, in which the management, Quality Assurance, engineering and manufacturing team take part, was held both to present the results of the final system verification and validation and to decide whether design changes were needed before pre-production begins. Design Review

checklist and Design Transfer checklist were reviewed for completeness. The process was documented in the Final Design Review and Design Transfer meeting, maintained in the Design History File DHF-VS1.

H. Verification and Validation Documentation

Based on the Software Requirements Specification (SRS) found in Section 16.9, a software validation test plan was devised to verify that the software meets the requirements. Each element of the SRS was tested and found to meet the requirements. The complete system level test plan with pass/fail criteria and testing results can be found in the following attached documents:

- 16.12 - 80028 VisionScope Software Validation Protocol and Report
- 16.13 – 80029 VisionScope Software Verification Protocol and Report

I. Revision History Log

A software history revision log is provided in Document 16.14 - 80073 VisionScope Software Revision History Log.

J. Unresolved Anomalies

As of April 13, 2010, in the released Revision B of the software, there is no known unresolved software anomaly that will have impact on Safety and Effectiveness, as described in the following attached document:

- 16.15 - VisionScope Software Unresolved Anomalies as of April 13, 2010

16.2 - 80071 VisionScope Software Architecture Design and Description

VISIONSCOPE

VISIONSCOPE SOFTWARE ARCHITECTURE DESIGN AND DESCRIPTION

Edit History

Revision	Date	Initials	Change Description
1.0	5/29/08	LC	First version (combined with 80006)
2.0	7/7/2009	LC	Revised to conform with latest design (combined with 80006)
3.0	11/12/2009	LC	Separate out from Document 80006 the Software Architecture Design and Description into this document

Reviewed and Approved:

Sumukh Pathare
Principal Electrical Engineer

02/17/2010
Date

Lim Cheung, PhD.
General Manager & CTO,
VisionScope

2/17/2010
Date

Table of Contents

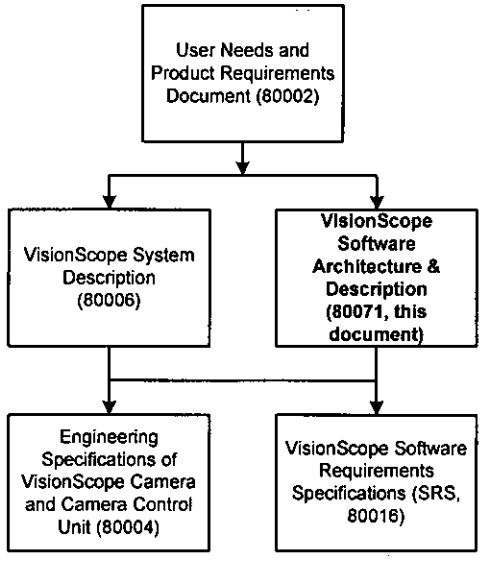
1. DOCUMENT SCOPE **3**
1.1. REFERENCES 3
2. GENERAL DESCRIPTION **4**
3. SOFTWARE ARCHITECTURE DESIGN AND DESCRIPTION **5**
3.1. SOFTWARE FUNCTIONS 5
3.2. ARCHITECTURE DESIGN 6
3.2.1. Procedure Sequence *6*
3.2.2. Hardware Architecture Chart *7*
3.2.3. Risk Control Requirements in Architecture Design *6*
3.2.4. Software Architecture Chart *8*
3.3. SOFTWARE DEVELOPMENT ENVIRONMENT 9
3.3.1. Host Processor and Software Elements *9*
3.3.2. Software Level of Concern *9*
3.3.3. Life Cycle Development Plan *9*
3.4. SOFTWARE OPERATING ENVIRONMENT 10
3.4.1. Configuration Management *10*
3.4.2. Software Maintenance Plan *10*
3.4.3. Cyber Security Threat Management *10*

1. Document Scope

The purpose of this document is to summarize the overall Software Architecture and narrative Description and VisionScope Endoscopy System Product, specifically the Camera Control Unit:

- Provides guidance for product design, prototyping and verification.
- Supports the VisionScope User Needs and Product Requirements document which describes the product from an end-user and marketing perspective
- Provide information to enable engineering specifications of major subsystems to be developed
- Serves as the basis for defining the statement of work, budget and schedule with suppliers
- Provides traceability for subsequent product verification and acceptance criteria, on a point-by-point basis against each stated specification.
- Constitute part of the Technical File per the EU Medical Device Directive

This Software Architecture and Description document represents one of the Design Input components of VisionScope's product development and design control processes. The relationship of this document to other specification documents is shown in the diagram below.



1.1. References

- VisionScope Quality System Manual (QSM-01)
- VisionScope User Needs and Product Requirements document (Document No. 80002)
- VisionScope System Description (80006)
- Engineering Specifications of VisionScope Endoscopes and Accessories (Document No. 80001)
- Engineering Specifications of VisionScope Camera Head and Camera Control Unit (Document No. 80004)
- VisionScope Software Requirements Specifications (SRS, Document No. 80016)
- VisionScope Software Design Specifications (SDS, Document No. 80019)
- VisionScope Standard Operating Procedure SOP-019 - Technical File Procedures

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2. General Description

(b)(4)

[redacted]

Indications for Use

The VisionScope High Definition Endoscopy Camera System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of an interior cavity of the body through a natural or surgical opening. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

Additionally, when used in conjunction with an appropriately indicated and FDA 510(k)-cleared endoscope and light source, the VisionScope High Definition Endoscopy Camera Control Unit and Camera Handpiece are indicated for use in arthroscopic and endoscopic surgical procedures to provide illumination, visualization and capture of still and motion pictures of articular cavities, body cavities, hollow organs and canals.

Intended Users

The VisionScope system is designed for use by licensed physicians for performing diagnostic or surgical procedures. Physician assistants may assist in the setup of the equipment and preparation of patients.

Contraindications for Use

None known

Warnings and Precautions

The VisionScope System and its components and accessories are to be used only under the order of licensed physicians and in accordance with the Instructions for Use included with all components. Please see additional warnings and precautions included in the Instructions for Use.

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3. Architecture Design and Description

3.1. Software Functions

Detail descriptions of the VisionScope software functional requirements and specifications are described in Document 80016 – "VisionScope Software Functional Requirements and Specifications." A top level view is provided here.

(b)(4)

[redacted]

Functions performed by VisionScope Software

(b)(4)

[redacted]

Functions not performed by VisionScope Software

(b)(4)

[redacted]

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3.2. Architecture Design

(b)(4)

[redacted]

Figure 3.2.1-1 VisionScope Procedure Typical Process Flow

3.2.2. Risk Control Requirements in Architecture Design

(b)(4)

[redacted]

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3.2.3. Hardware Architecture Chart

The hardware architecture of the VisionScope system is shown in Figure 3.2.3-1. For more details, please see VisionScope Document 80004, "Engineering Specifications of VisionScope Camera Head and Camera Control Unit".

(b)(4)

[redacted]

Figure 3.2.3-1 VisionScope Top Level System Hardware Architecture

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3.2.4. Software Architecture Chart

The top level software block diagram and its interaction with the hardware elements are shown in Figure 3.2.4-1. Please see the VisionScope Document 80019 "Software Design Specifications" for a more detailed discussion of the software elements.

(b)(4)

[redacted]

Figure 3.2.4-1 VisionScope Top Level System Software Architecture

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3.3. Software Development Environment

3.3.1. Host Processor and Software Elements

(b)(4)

[redacted]

3.3.2. Software Level of Concern

Classification: Moderate

Please see VisionScope Document 80012 for an analysis of the Software Level of Concern

3.3.3. Life Cycle Development Plan

The VisionScope software development plan follows the VisionScope Quality System Policy, Quality System Manual and Standard Operating Procedures related to Design Control, Change Control, Risk Management, Corrective and Preventive Actions, Recall, and other applicable procedures. In the Software Development process, VisionScope also follows closely with the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005.

The VisionScope software development follows these steps:

- User Needs and Product Requirement Document (PRD) are prepared. These documents define the top level description of what user needs and functions the product is designed to meet.
- The User Needs and PRD in turn drive the System Level Engineering Specifications, which in turn drives both hardware and software requirements and specifications.
- Software Requirements Specification ("SRS") – A SRS was written to define high-level system architecture, interfaces and functions. SRS defines what the software is supposed to do.
- Software Design Specification ("SDS") – A SDS was written to define lower-level design of data, architecture, interfaces and functions. SDS defines how the software is supposed to implement and support the SRS.

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- Risk Analysis, Software FMEA, Risk Mitigation activities are carried out in parallel during the hardware and software development cycle.
- Software Design Implementation – Software was written, tested and modified by engineering staff to comply with the SRS and SDS.
- Software Verification Test Plan – A Software Verification Test Plan was written to describe a means of verifying that the Software Design Implementation complies with the SDS.
- Software Verification Testing – The Software Verification Test Plan was executed.
- Software Validation Test Plan – A Software Validation Test Plan was written to describe a means of verifying that the Software Design Implementation complies with User Need requirements and SRS.
- Software Validation Testing – The Software Validation Test Plan was executed.
- Where necessary, the above steps involve multiple feedback and iterative loops to provide refinement of specifications, implementation, risk mitigation, verification and validation processes.
- Software Release – All software revisions for end customer use are released following the VisionScope Engineering Change Order and Notification (ECO/ECN) Procedure, prior to release into production in the end product.

3.4. Software Operating Environment

3.4.1. Configuration Management

(b)(4)

[redacted]

3.4.2. Software Maintenance Plan

(b)(4)

[redacted]

3.4.3. Cyber Security Threat Management

External cyber security threat is minimized in the software architecture and software functional design in two ways:

1. The VisionScope system is an embedded system, and the users can only perform certain functions in a controlled manner. The user cannot use the system as a general purpose computer, use the computer as

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783

a general purpose web browser, or load any software into the microprocessor without bypassing the very limited Input/Output hardware capability and without bypassing password-protected elaborate procedures. This greatly limits the chance that externally introduced malware or virus may be introduced.

2. The software functions are either all internally directed or deals with outgoing messages only. Connection with outside network is one-way – push but no pull. The system is not set up to service incoming requests of any kind beyond those provided by the front panel touch screen. The software controls capture and storage of internally generated still picture or video, send print request, send outgoing emails under password protection only to a limited set of pre-authorized recipients, and has no other provision to service any incoming signals or messages that may slow or interrupt normal functions of the VisionScope system.

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16.3 - 80020 VisionScope Risk Management Plan & Risk Management Summary

REVISION HISTORY

REV	DESCRIPTION OF CHANGES	DATE	BY
1	Initial Release	7/22/2008	AK
2	Updated to conform with IEC60601-1-4 requirements	11/5/2009	AK/LC

Reviewed and Approved:

Alex. Kreiz

Alex Kreizman, MSEE, NCE
Director QA/RA

11/5/2009
Date

Lim Cheung

Lim Cheung
General Manager & CTO

11/5/2009
Date

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Purpose

This Risk Management Plan provides a summary of the planning documents to be included as part of The Risk Management File in accordance with IEC 601-1-4 for the VisionScope System.

Applicable Project or Products

- VisionScope Camera (50021)
- Camera Control Unit (50034)
- Endoscopes (50006)
- Procedure Kits (50033)

Life Cycle Phases

This plan is applicable to the following life cycle phases:

- Concept Phase
- Development & Prototype Phase
- Design Transfer & Production
- Post-sales Monitoring

Responsibility

It is the Project Manager's responsibility to form a team with experts from the appropriate areas (e.g., QA, RA, R&D, Marketing, Sales, Operations, etc.) in addition to individuals who are knowledgeable about the quality risk management process. The team should review the Risk Management requirements and practices described in ISO 14971 and FDA Guidance for Industry on Risk Management:

- FDA Guidance for Industry on Quality Risk Management, http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073511.pdf

- ISO 14971 ISO 14971:2007 **Application of risk management to medical devices**

- IEC 60601-1-4 Medical electric equipment, Part 1-4: General requirements for safety Collateral Standard: Programmable electrical medical systems

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Risk Management Plan

The Risk Management Plan should contain the following elements:

- Risk Analysis
- Risk Evaluation
- Risk Control
- Risk Information and Communication

Procedures and documentations to support compliance with the FDA, ISO and IEC Guidance should be developed.

Risk Management Summary & Referenced VisionScope Documents

IEC 601-1-4 Requirements	Referenced VisionScope Documents
52.202.2 a) scope of the plan, defining the project or product and the development life-cycle phases for which the plan is applicable	80020 – VisionScope Risk Management Plan & Summary 80013 – VisionScope Risk Analysis
b) the development life-cycle to be applied (see 52.203), including a verification plan and a validation plan	80007 - VisionScope Design and Development Plan 80072 – Traceability Analysis 80027 - VisionScope Verification & Validation Master Plan
c) management responsibilities in accordance with 4.1 of ISO 9001	Quality System Manual QSM-01 and 80007 Design and Development plan
d) risk management process	Risk Management Procedure SOP-018
e) requirements for reviews	Design Review held per Design and Development Plan 80007, Design Control Procedure SOP-004
52.202.3 If the plan changes during the course of development, a record of the changes is kept	VisionScope Design and Development Plan 80007
Instructions for Use 6.8.201	User's Manual, PN 01112, 01113, 01114, 01115
Risk Estimation 52.204.3.2	Risk Control Procedure, SOP-018
Risk Control 52.204.4	Risk Management File, RM-01
Architecture 52.207	System Block Diagrams, 80071

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Risk Management Summary 52.201.3	Risk Analysis Doc. No. 80013
a. Identify hazards	Design FMEA Doc. No. 80014, 80055
b. Estimation of risk	Design FMEA Doc. No. 80014, 80055
c. Safety measures	Design FMEA Doc. No. 80014, 80055
d. Risk control	Design FMEA Doc. No. 80014, 80055
e. Verification	80027 - VisionScope System Validation Master Plan and references therein, Verification protocol and reports: 80014, 80037, 80038, 80029
f. Validation	80027 - VisionScope System Validation Master Plan.doc and references therein; Validation protocol and reports: 80014, 80028, 80030, 80084

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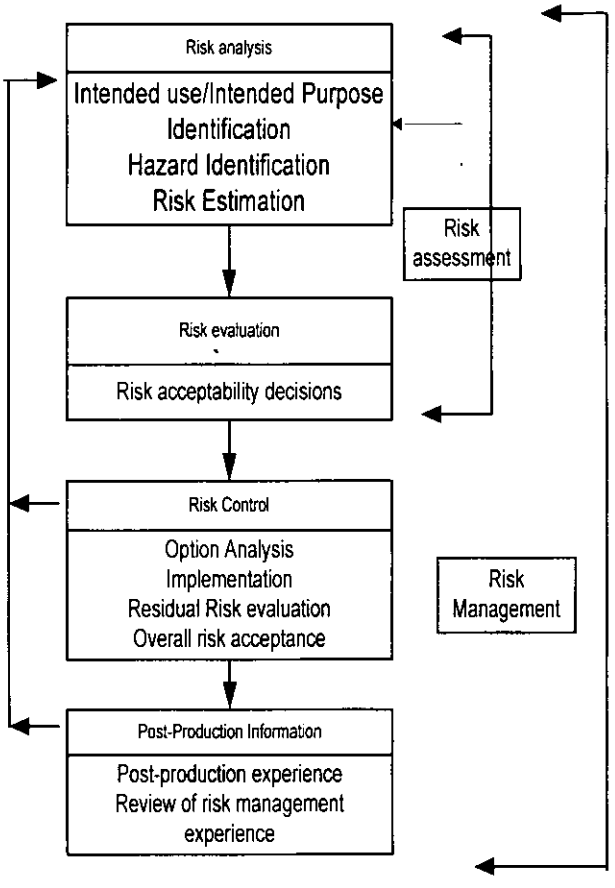

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16.4 - 80013 VisionScope Risk Analysis

VisionScope System Risk Analysis

REVISION HISTORY

REV	DESCRIPTION OF CHANGES	DATE	BY
1	First draft	6/4/08	AK
1.1	Revised with VisionScope Specific content	6/28/08	LC
1.2	Updated with information from Sterilization providers, material from subsystem manufacturers	6/4/2009	LC

Reviewed and Approved:	**Signature**	**Date**
R&D	Lomlley	6/5/2009
Quality	Alex. Kerr	6/5/2009

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This Risk Analysis is applicable to four major parts:

- Endoscope
- Procedure Kit including Light Sheath, Cannula and Trocar
- Camera Head
- Camera Control Unit (CCU)

I. Identification of Qualitative and Quantitative Characteristics	**II. Possible Associated Hazards**
1. What is the intended use / intended purpose and how is the device to be used?	(b)(4) [redacted]
2. Is the device intended to contact the patient or other persons?	
3. What materials and/or components are incorporated in the medical device, are used with, or are in contact with, the medical device?	
4. Is energy delivered to and/or extracted from the patient?	
5. Are substances delivered to and/or extracted from the patient?	
6. Are biological materials processed by the device for subsequent re-use?	
7. Is the device supplied sterile or intended to be sterilized by the user or are other microbiological controls applicable?	

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I. Identification of Qualitative and Quantitative Characteristics	II. Possible Associated Hazards
	(b)(4) [redacted]
8. Is the medical device intended to be routinely cleaned and disinfected by the user?	
9. Is the medical device intended to modify the patient environment?	
10. Are measurements made?	
11. Is the device interpretative?	
12. Is the device intended for use in conjunction with medicines or other medical technologies?	
13. Are there unwanted outputs of energy or substances?	
14. Is the device susceptible to environmental influences?	
15. Does the medical device influence the environment?	
16. Are there essential consumables or accessories associated with the device?	
17. Is maintenance and/or calibration necessary?	
18. Does the device contain software?	
19. Does the device have a restricted shelf life?	
20. Are there any delayed and/or long term use effects?	
21. To what mechanical forces will the device be subjected?	
22. What determines the lifetime of the device?	

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I. Identification of Qualitative and Quantitative Characteristics	II. Possible Associated Hazards
	(b)(4) [redacted]
23. Is the device intended for single use?	
24. Is safe decommissioning or disposal of the medical device necessary?	
25. Does installation or use of the medical device require special training?	
26. Will new manufacturing processes need to be established or introduced?	
27. Is successful application of the medical device critically dependent on human factors such as user interface?	
27.1 Does the medical device have connecting parts or accessories?	
27.2 Does the medical device have a control interface?	
27.3 Does the medical device display information?	
27.4 Is the medical device controlled by a menu?	
28. Is the medical device intended to be mobile or portable?	

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III. Design FMEA Reference: *Doc. No. 80014, 80055*

V. Risk/Benefit Analysis:

(b)(4)

[redacted]

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16.5 - 80014 VisionScope Design FMEA

REVISION HISTORY

REV	DESCRIPTION OF CHANGES	DATE	BY
1.0	Initial Release	6/4/08	AK
1.1	Reformat; add DFMEA for system and subsystems	6/17/08	LC
1.2	Reviewed and updated prior to design review	6/4/09	LC
1.3	Add Usability Items per IEC-60601-1-6; re-organize section number, re-organize to facilitate comparison with Traceability Analysis (80072)	1/15/2010	AK & LC
1.4	Add verification and review of risks after biocompatibility and sterilization tests	6/9/2010	LC

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Reviewed and Approved:

[redacted] (b) (6)

6/9/2010
Date

6/9/2010
Date

6/9/2010
Date

6/9/2010
Date

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Risk Analysis & DFMEA

NOTE: The Risk Analysis table below is divided into four sections:

1. **System**
2. **Endoscopes, Light Sheath and accessories**
3. **Camera Head**
4. **Camera Control Unit**

Software Design FMEA is discussed in a separate document (80055)

Abbreviations:

Hazard identification and mode – Brief description of potential hazard, Brief description of failure that may occur

Severity	Critical	(C)
	Serious	(S)
	Moderate	(M)
	Negligible	(N)
Probability of Occurrence	Frequent	(F)
	Probable	(P)
	Occasional	(O)
	Remote	(R)
	Improbable	(I)

[redacted] (b)(4)

Risk Level	(Numeric value determined in section based on Severity and Probability)	
	High	(1)
	Moderate	(2)
	Low	(3)

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Negligible (4)

Section 1. VisionScope VSI-01 System

Hazard					Risk Evaluation (Step4)	Risk Control				
#	Identification and mode (Step2)		Estimation (Step3)			Options (Step5)	Implementation (Step6)	Residual Risk (Step7)	Risk/ Benefit Analysis Req.?	Result
	Cause	Effect	Severity	Probability						
[redacted]									(b)(4)	✓
										✓
										✓
										✓
										✓

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108

Hazard					Risk Evaluation (Step4)	Risk Control				
#	Identification and mode (Step2)		Estimation (Step3)			Options (Step5)	Implementation (Step6)	Residual Risk (Step7)	Risk/ Benefit Analysis Req.?	Result
	Cause	Effect	Severity	Probability						
[redacted]									(b)(4)	✓
[redacted]										✓

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802

Hazard					Risk Evaluation (Step4)	Risk Control				
#	Identification and mode (Step2)		Estimation (Step3)			Options (Step5)	Implementation (Step6)	Residual Risk (Step7)	Risk/ Benefit Analysis Req.?	Result
	Cause	Effect	Severity	Probability						
[redacted]									(b)(4)	✓
[redacted]										✓

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(b)(4) System Design

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(b)(4) System Design

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16.6 - 80055 VisionScope Software FMEA

REVISION HISTORY

REV	DESCRIPTION OF CHANGES	DATE	BY
1.0	Initial Release	9/3/2009	LC
1.1	Updated based on more verification tests	11/22/2009	LC
1.2	Updated following Software Validation Report Rev. 2.2, and Verification Report, Rev. 2.0	1/13/2010	LC

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[redacted] (b) (6)

2/17/10
Date

02/17/10
Date

02/17/2010
Date

2/17/10
Date

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Risk Analysis & DFMEA

NOTE: The Risk Analysis table below is divided into two sections:

1. **User Interface Software**
2. **Digital Signal Processing Software**

Abbreviations:

Hazard identification and mode – Brief description of potential hazard, Brief description of failure that may occur

Severity	Critical	(C)
	Serious	(S)
	Moderate	(M)
	Negligible	(N)

Probability of Occurrence	Frequent	(F)
	Probable	(P)
	Occasional	(O)
	Remote	(R)
	Improbable	(I)

[redacted] (b)(4)

Risk Level	(Numeric value determined in section based on Severity and Probability)	
	High	(1)
	Moderate	(2)
	Low	(3)
	Negligible	(4)

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Section 1. VisionScope User Interface Software

[redacted] (b)(4)

Note: For a validation of the Risk Control steps, please see the Software Validation Document 80028, containing several hundred Functional Test Cases, Stress Test Cases, and Failure Recovery Test Cases. See also Document 80014 for verification of hardware related Risk Controls.

Hazard					Risk Evaluation (Step 4)	Risk Control				
#	Identification and mode (Step2)		Estimation (Step3)			Options (Step5)	Implementation (Step6)	Residual Risk (Step7)	Risk /Benefit Analysis Required ?	Result
	Cause	Effect	Severity	Probability						
[redacted] (b)(4)										✓
										✓

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Hazard					Risk Evaluation (Step 4)	Risk Control				
#	Identification and mode (Step2)		Estimation (Step3)			Options (Step5)	Implementation (Step6)	Residual Risk (Step7)	Risk /Benefit Analysis Required ?	Result
	Cause	Effect	Severity	Probability						
[redacted]										✓
										✓
										✓
										✓

(b)(4)

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Hazard					Risk Evaluation (Step 4)	Risk Control				
#	Identification and mode (Step2)		Estimation (Step3)			Options (Step5)	Implementation (Step6)	Residual Risk (Step7)	Risk /Benefit Analysis Required ?	Result
	Cause	Effect	Severity	Probability						
[redacted]										✓
										✓
										✓
										✓

(b)(4)

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(b)(4) Software Design

(b)(4) Software Design

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(b)(4) Software Design

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(b)(4) Software Design

(b)(4) Software Design

16.7 - IEC60601-1-4 VisionScope Risk Management

TEST REPORT

IEC 60601-1- 4 / EN60601-1-4:2000

Medical electric equipment

Part 1-4: General requirements for safety

Collateral Standard: Programmable electrical medical systems

Report

Reference No. ..... : 80089 Rev. 1

Tested by (+ signature) ..... : (b) (6) [redacted]

Approved by (+ signature) ..... : (b) (6) [redacted]

Date of issue ..... : Jan. 25. 2010

Contents ..... : Risk Management file review for VisionScope Technologies, LLC

(b) (6) [redacted]

(b)(4) [redacted]

Testing laboratory

Name ..... : VisionScope Technologies, LLC

Address ..... : 2352 Main Street, Suite 303, Concord, MA 01742 USA

Testing location / procedure ..... : CBTL ☐ SMT ☐ TMP ☐

Client

Name ..... : VisionScope Technologies, LLC

Address ..... : 2352 Main Street, Suite 303, Concord, MA 01742 USA

Manufacturer Same

Test specification

Standard ..... : IEC 60601-1-4:2000 / EN60601-1-4:2000

Test procedure ..... : (b) (6) [redacted]

Procedure deviation ..... : N.A.

Non-standard test method ..... : N.A.

Test Report Form/blank test report

Test Report Form No. ..... : IEC60601_1_4B

TRF originator. ..... : (b)(4) [redacted]

Master TRF ..... :

Test item	
Description	VisionScope High Definition Endoscopy Camera System
Trademark	VisionScope®
Model and/or type reference	VisionScope® Camera Handpiece (REF 50021-0XX) and Camera Control Unit (REF 50034-0XX) (X=0-9, A-Z; not safety relevant)
Manufacturer	VisionScope Technologies, LLC
Rating(s)	AC 120-240V 60Hz / 50Hz, 2.0A
Particulars: test item vs. test requirements	
Type of end product	VisionScope High Definition Endoscopy Camera System
End product	Same
Trademark	VisionScope®
End product model and/or type reference	VisionScope® Camera Handpiece (REF 50021-0XX) and Camera Control Unit (REF 50034-0XX) (X=0-9, A-Z; not safety relevant)
End product manufacturer	VisionScope Technologies, LLC
End product address	2352 Main Street, Suite 303, Concord, MA 01742 USA
End product rating(s)	AC 120-240V 60Hz / 50Hz, 2.0A
PEMS/PESS configuration information	Release A
Software designer (if different than end product manager)	(b) (6) [redacted]
Address	2352 Main Street, Suite 303, Concord, MA 01742 USA
Method of identification of software (e.g. revision level, date of release/issue)	Revision level via Doc. Control System, also visible on Touch Screen, under Setup/System Information
Particular risks addressed by software	See Software Design FMEA (80055) and Software Verification (80029) and Software Validation (80028)
Testing	
Date of receipt of test item	January 20, 2010
Date(s) of performance of test	January 20, 2010

General remarks

(b)(4) [redacted]

The test results presented in this report relate only to the item(s) tested. This report shall not be reproduced except in full without the written approval of the testing laboratory.

"(see remark #)" refers to a remark appended to the report.

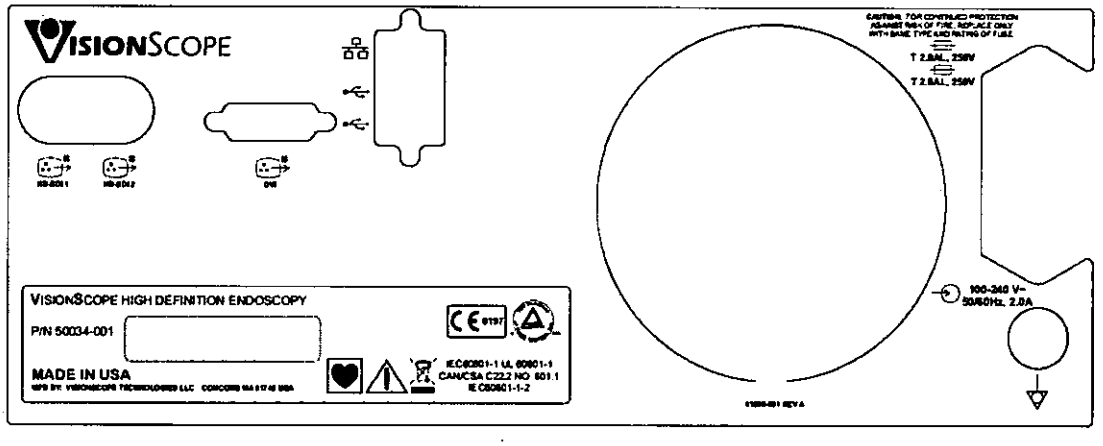
"(see Annex #)" refers to an annex appended to the report.

"(see appended table)" refers to a table in the CB Test Report.

Throughout this report a point is used as the decimal separator

Copy of marking plate:

Marking for VisionScope Camera Control Unit (located on the rear panel)



Marking for VisionScope Camera Hand Piece [located on the bottom (Ref. number & symbols) and side (Trademark) of the camera head]

Marking for Light Sheath (located on the side of plastic holder)

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict

6	IDENTIFICATION, MARKING AND DOCUMENTS	
6.8	Accompanying documents	
6.8.201	All relevant information regarding significant residual risk including descriptions of the hazards and actions by the operator or the user necessary to avoid/mitigate them shall be placed in both the instruction for use and the risk management file.	
6.8.202	ACCOMPANYING DOCUMENTS for the PEMS shall identify, as a minimum, the MANUFACTURER and a unique identifier such as revision level and date of release/issue	

52	ABNORMAL OPERATION AND FAULT CONDITI
52.201	DOCUMENTATION
52.201.1	Documents produced from application of this standard are maintained and are part of the quality records; see fig. 201. This should be done in accordance with 6.3 of ISO 9000-3
52.201.2	These documents, herein referred to as the risk management file, are approved, issued and changed in accordance with a formal configuration management system. This should be done in accordance with 6.2 of ISO 9000-3
52.201.3	A risk management summary is developed throug as part of the risk management file. It contains:
	a) identified hazards and their initiating causes (see 52.204.3.1.10)

(b)(4)

[redacted]

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
		(b)(4) [redacted]	
	b) estimation of risk (see 52.204.3.2.5)		
	c) reference to the safety measures, used to eliminate or control the risk of hazard (see 52.204.4.5)		
	d) evaluation of effectiveness of risk control (see 52.204.4.6)		
	e) reference of verification (see 52.209.3)		
52.202	RISK MANAGEMENT PLAN		
52.202.1	The manufacturer has prepared a risk management plan		
52.202.2	The plan includes the following:		
	a) scope of the plan, defining the project or product and the development life-cycle phases for which the plan is applicable		
	b) the development life-cycle to be applied (see 52.203), including a verification plan and a validation plan		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
		(b)(4) [redacted]	
	c) management responsibilities in accordance with 4.1 of ISO 9001		
	d) risk management process		
	e) requirements for reviews		
52.202.3	If the plan changes during the course of development, a record of the changes is kept		
52.203	DEVELOPMENT LIFE-CYCLE		
52.203.1	A development life-cycle is defined for the design and development of the PEMS		
52.203.2	The development life-cycle is divided into phases and tasks, with a well-defined input, output and activity for each		
52.203.3	The development life-cycle includes integral processes for risk management		
52.203.4	The development life-cycle includes documentation requirements		
52.203.5	Risk management activities have been applied throughout the development life-cycle as appropriate (see 52.204)		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
52.203.6	Where appropriate, a defined system for problem resolution within and between all phases and tasks of the development life cycle shall be developed and maintained as part of risk management file	(b)(4) [redacted]	
	Depending upon the problem, the system may hav		
	- be defined as a part of the development life cycle;		
	- allow the reporting of potential or existing safety and/or performance problems;		
	- include an assessment of each problem for associated risks;		
	- identify the criteria (safety and/or performance) that have to be met for the issue to be closed		
	- identify the action to be taken to resolve each problem;		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
	- identify validation methods for each action;	(b)(4) [redacted]	
	- identify the steps taken for verification of continuing compliance.		
52.204	RISK MANAGEMENT PROCESS		
52.204.1	A risk management process is used that has the		
	- Risk analysis		
	- Risk control		
52.204.2	The process is applied throughout the development life-cycle		
52.204.3	RISK ANALYSIS		
52.204.3.1	HAZARD ANALYSIS		
52.204.3.1.1	Hazard identification is carried out as defined in the risk management plan (see 52.202)		
52.204.3.1.2	Hazards are identified for all reasonably foreseea		
	- Normal use		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
		(b)(4) [redacted]	
	- Incorrect use		
52.204.3.1.3	The hazards considered include, as appropriate:		
	- Hazards to patients		
	- Hazards to operators		
	- Hazards to service personnel		
	- Hazards to bystanders		
	- Hazards to the environment		
52.204.3.1.4	Reasonably foreseeable sequences of events, which may result in a hazard, are considered		
52.204.3.1.5	Initiating causes considered include, as appropriate		
	- human factors including ergonomic limitations		
	- hardware faults		
	- software faults		
	- integration errors		
	- environmental conditions		
52.204.3.1.6	Matters considered include, as appropriate:		
	- compatibility of system components, including hardware and software		
	- user interface, including command language, warning and error messages		
	- accuracy of translation of text used in the user interface and instructions for use		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
		(b)(4) [redacted]	
	- data protection from human intentional or unintentional causes		
	- Risk/benefit criteria		
	- third party software		
52.204.3.1.7	Hazard identification methods appropriate to the development life-cycle phase are used		
52.204.3.1.8	The method used (e.g. fault tree analysis, failure modes and effects analysis) are documented in the risk management file		
52.204.3.1.9	The results of the application of the methods are documented in the risk management file		
52.204.3.1.10	Each identified hazard and its initiating causes are recorded in the risk management summary		

IEC 60601-1-4			
Clause	Requirement -- Test	Result - Remark	Verdict
52.204.3.2	RISK ESTIMATION	(b)(4) [redacted]	
52.204.3.2.1	For each identified hazard the risk is estimated		
52.204.3.2.2	The estimation of the risk is based on an estimation of the likelihood of each hazard and/or the severity of the consequences of each hazard		
52.204.3.2.3	The severity level categorization method is recorded in the risk management file		
52.204.3.2.4	The likelihood estimation method is either quantitative or qualitative and is recorded in the risk management file		
52.204.3.2.5	The estimated risk is recorded against each hazard in the risk management summary		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
52.204.4	RISK CONTROL	(b)(4) [redacted]	
52.204.4.1	Risk is controlled so that the estimated risk of each identified hazard is made acceptable		
52.204.4.2	A risk is acceptable if the risk is less than or equal to the maximum tolerable risk and the risk is made as low as reasonably practicable		
52.204.4.3	Methods of risk control reduce the likelihood of the hazard or reduce the severity of the hazard or both		
	The likelihood that the means for risk reduction will perform correctly shall be specified quantitatively		
52.204.4.4	Risk control methods are directed at the cause of the hazard (e.g. by reducing its likelihood) or by introducing protective measures which operate when the cause of the hazard is present, or both, using the following priority: inherent safe design; protective measures including alarms; adequate user information on the residual risk		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
52.204.4.5	The requirement(s) to control the risk is documented in the risk management summary (directly or as a cross reference)	(b)(4) [redacted]	
52.204.4.6	An evaluation of the effectiveness of the risk controls is recorded in the risk management summary		
52.205	QUALIFICATION OF PERSONNEL		
	The design and modification of a PEMS is considered as an assigned task in accordance with 4.18 of ISO 9001		
52.206	REQUIREMENT SPECIFICATION		
52.206.1	For the PEMS and each of its subsystems (e.g. for a PESS) there is a requirement specification		
52.206.2	The requirement specification details the functions includes functions that control risks arising from:		
	a) causes arising from environmental conditions		
	b) causes elsewhere in the PEMS		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
	c) possible malfunctions	(b)(4) [redacted]	
52.206.3	The requirement specification shall include the information necessary to assure that risk control measures satisfactorily reduce the identified risks.		
52.207	ARCHITECTURE		
52.207.1	The architecture satisfies the requirement specification		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
52.207.2	For the PEMS and each of its subsystems, an architecture is specified	(b)(4) [redacted]	
52.207.3	Where appropriate, the architecture specification of a PEMS and its subsystem shall address the risk control requirements by reducing the corresponding likelihood of the hazard or by reducing the severity of the hazard or both		
52.207.4	Where appropriate, to reduce the likelihood of the specification shall make use of:		
	a) highly reliable components;		
	b) fail-safe functions;		
	c) redundancy;		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
	d) diversity;	(b)(4) [redacted]	
	e) defensive design;		
	f) limits on potentially hazardous effects, for example by restricting the available output power and/or by introducing means to limit the travel of actuators		
52.207.5	Where appropriate the specification includes requir		
	a) allocation of risk control measures to subsystems and components of the PEMS		
	b) failure modes of components and their effects		
	c) common causes failures		
	d) systematic failures		
	e) test interval, test duration and diagnostic coverage		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
		(b)(4) [redacted]	
	f) maintainability		
	g) protection from human intentional or unintentional causes		
52.208	DESIGN AND IMPLEMENTATION		
52.208.1	Where appropriate, the design is decomposed into subsystems, each having a design and test specification		
52.208.2	Descriptive data regarding the design environment shall be included in the risk management file		
52.209	VERIFICATION		
52.209.1	Verification of the implementation of safety requirements is carried out		
52.209.2	A verification plan is produced to show how the safety requirements for each development life-cycle phase will be verified		
	The plan shall include:		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
	a) the selection and documentation of verification strategies, activities and techniques	(b)(4) [redacted]	
	b) the selection and utilization of verification tools		
	c) coverage criteria for verification		
52.209.3	The verification shall be performed according to verification plan		
	The results of the verification activities shall be documented, analyzed and assessed		
52.209.4	A reference to the methods, techniques and results of the verification shall be included in the risk management summary		
52.210	VALIDATION		
52.210.1	Validation of the safety of PEMS under the conditions of the intended use shall be carried out		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
52.210.2	A validation plan is produced to show that correct safety requirements have been implemented	(b)(4) [redacted]	
52.210.3	The validation shall be performed according to the validation plan		
	The results of validation activities shall be documented, analyzed and assessed		
52.210.4	The leader of the team carrying out the validation is independent of the design team		
52.210.5	All professional relationships of the members of the validation team with members of the design team are documented in the risk management file		
52.210.6	No member of a design team shall be responsible for the validation of his own design		
52.210.7	A reference to the methods and results of the validation is include in the risk management file		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict

52.211	MODIFICATION	
52.211.1	If any or all of a design results from a modification of an earlier design then either all of this standard applies as if it were a new design or the continued validity of any previous design documentation is assessed under a modification/change procedure	(b)(4) [redacted]
52.211.2	All relevant documents in the development life-cycle are revised, amended, reviewed, approved under a document control scheme in accordance with 4.5.2 of ISO 9001 or equivalent (see 52.201.1)	

52.212	ASSESSMENT	
52.212.1	Assessment is carried out to ensure that the PEMS has been developed in accordance with the requirements of this standard and recorded in the risk management file. This may be carried out by internal audit	

	NATIONAL DIFFERENCES	
	UNITED STATES: National differences available upon request	

52.201.1	Table: mapping of required evidence and client documents			
Standard Clause	Deliverables	title	revision #:	date:

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
6.8.201	Instructions for use	(b)(4) [redacted]	
6.8.201	Statements of residual risk in risk management file		
52.201.1	Quality record procedures		
52.201.2	Document control/configuration management procedures		
52.201.3	Risk management summary record		
52.202.1	Risk management plan		
52.202.2c	Statement of quality policy		
52.202.2c	Definition of responsibility and authority for all development personnel		
52.202.2c	Identification of verification resources and personnel		
52.202.2c	Identification of management representative		
52.202.2c	Records of management review		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
52.203.1	Life-cycle definition	(b)(4) [redacted]	
52.204.3.1	Hazard analysis procedures		
52.204.3.1.8	Hazard identification methods		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
52.204.3.1.9	Record of results of hazard identification methods	(b)(4) [redacted]	
52.204.3.1.10	Hazard list and initiating causes		
52.204.3.2	Risk estimation procedures		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
52.204.3.2.3	Severity categorization methods	(b)(4) [redacted]	
Standard Clause	Deliverables		
52.204.3.2.4	Likelihood estimation methods		
52.204.3.2.5	Record of estimated risk for each hazard		
52.204.4	Risk control procedures		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
52.204.4.5	Risk control method for each hazard	(b)(4) [redacted]	
52.204.4.6	Record of estimation for effectiveness of each risk control method		
52.205	Training procedures		
52.205	Training records		
52.206.1	PEMS requirements specification		
52.206.1	Subsystems requirements specification		
52.207.2	PEMS architecture specification		
52.207.2	Subsystems architecture specification		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
52.208.1	Design specification	(b)(4) [redacted]	
52.208.1	Test specification		
52.208.2	Descriptive data regarding the design environment		
52.209.2	Verification plan		
52.209.3	Verification methods and results for each hazard		
52.210.2	Validation plan		

IEC 60601-1-4			
Clause	Requirement – Test	Result - Remark	Verdict
52.210.7	Validation methods and results for each hazard	(b)(4) [redacted]	
52.211.1	Modification/ change procedures		
52.212.1	Assessment report		

1	Table: instructions for use/guidance	

INSTRUCTIONS FOR USE/GUIDANCE

The following has been developed based on input from other National Certification Bodies, authorities having jurisdiction and industry trade groups.

1. The section on page 2 "Particular Risks Addressed by Software" is intended to list the risks that are mitigated by software derived from addressed risks in IEC 60601-1 and the appropriate particulars (IEC 60601-2-X).

2. The table, "Mapping of Required Evidence and Other Documents" per Cl. 52.201.1, is intended to indicate the existence or performance of the process or activity.

3. The section headed by Clause, Requirement, Result-Remark and Verdict is intended to represent the evaluator's review of the scope of the underlying procedures.
Documents or guidance utilized by the manufacturer are identified.

4. One method to evaluate Cl. 52.209.1 and 52.210.1 is to trace the hazards, that are mitigated by software, from generation in the risk analysis documents through all the documents generated in the development life-cycle. An example of how this can be documented is the attached hazards/requirements traceability matrix. Some hints in using this are:

a. Number the requirements and the identified hazards.
b. Identify the documents with an alphanumeric identifier, a revision number and a date.
c. Know where each referenced document is kept.
d. Use the defined life-cycle phases, per Cl. 52.203.1, and trace each requirements and identified hazard to and from each phase. Should be traceable backwards and forwards.

5. The assessment of conformance with the standard is intended to be conducted with the manufacturer.

Remarks

16.8 - IEC60601-1-6 VisionScope Usability

VISIONSCOPE

TEST REPORT
IEC 60601–1–6
Medical electrical equipment
Part 1-6: General requirements for safety - Collateral Standard: Usability

Report Reference No. ..... :	80090 Rev. 1
Date of issue ..... :	Jan. 25. 2010
Total number of pages	15
Testing Laboratory ..... :	VisionScope Technologies, LLC
Address ..... :	2352 Main Street, Concord, MA 01742 USA
Applicant's name ..... :	VisionScope Technologies, LLC
Address ..... :	2352 Main Street, Suite 303, Concord, MA 01742 USA
Test specification:	
Standard ..... :	IEC 60601-1-6: 2004 (First Edition) for use in conjunction with IEC 60601-1:1988 + A1:1991 + A2:1995
Test procedure ..... :	TUV Mark
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	IEC60601_1_6B
Test Report Form(s) Originator ..... :	Underwriters Laboratories Inc.
Master TRF ..... :	Dated 2006-07

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This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

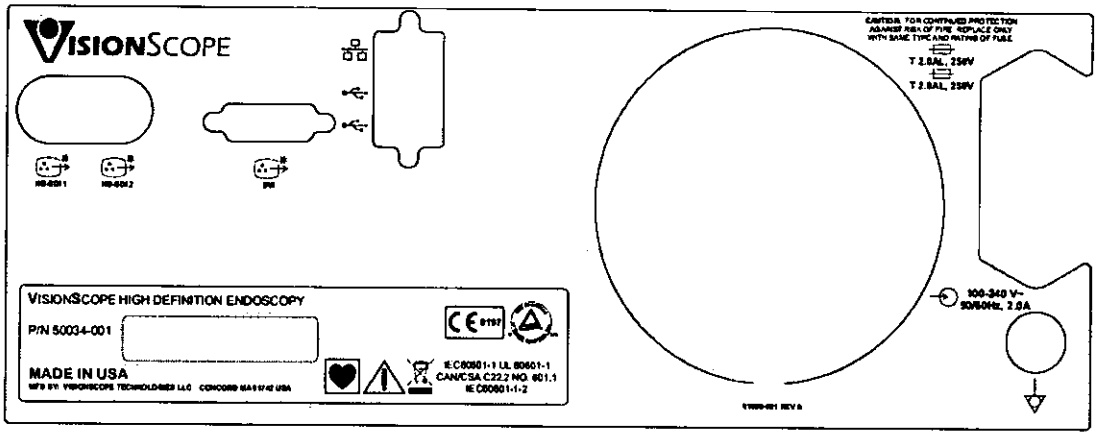
Test item description ..... :	VisionScope High Definition Endoscopy Camera System
Trade Mark ..... :	VisionScope®
Manufacturer ..... :	VisionScope Technologies, LLC
Model/Type reference ..... :	VisionScope® Camera Handpiece (REF 50021-0XX) and Camera Control Unit (REF 50034-0XX), where XX is configuration number not related to safety and has the value of 0-9 and A-Z
Ratings ..... :	AC 120-240V 60Hz / 50Hz, 2.0A

Testing procedure and testing location:	
☐ **Testing Laboratory**:	VisionScope Technologies, LLC
Testing location/ address.....:	2352 Main Street, Suite 303, Concord, MA 01742 USA
☐ **Associated Laboratory:**	
Testing location/ address.....:	
Tested by (name + signature)..... :	(b) (6) [redacted]
Approved by (+ signature)..... :	
☐ Testing procedure: TMP	
Tested by (name + signature)..... :	
Approved by (+ signature)..... :	
Testing location/ address.....:	
Testing procedure: WMT	N/A
Tested by (name + signature)..... :	
Witnessed by (+ signature)..... :	
Approved by (+ signature)..... :	
Testing location/ address.....:	
☐ Testing procedure: SMT	N/A
Tested by (name + signature)..... :	
Approved by (+ signature)..... :	
Supervised by (+ signature)..... :	
Testing location/ address..... :	
☐ Testing procedure: RMT	N/A
Tested by (name + signature)..... :	
Approved by (+ signature)..... :	
Supervised by (+ signature)..... :	
Testing location/ address.....:	

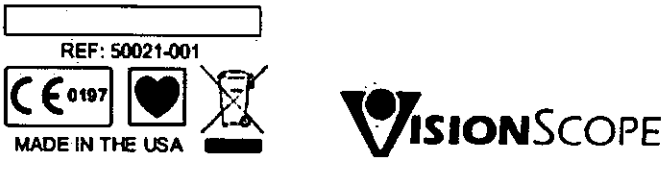
Summary of testing:	
Tests performed (name of test and test clause): **see IEC60601-1 test report and review of the Risk Management File and associated Risk Management Summary Analysis, Failure Modes and Effects Analysis (FMEA) and Hazard and Safety Analysis documents.**	**Testing location:** VisionScope Technologies, LLC 2352 Main Street, Concord, MA 01742 USA
Summary of compliance with National Differences: US, Canadian , European **See TUV Certifcate CU72100321.01**	

Copy of marking plate:

Marking for VisionScope Camera Control Unit (located on the rear panel)



Marking for VisionScope Camera Hand Piece [located on the bottom (Ref. number & symbols) and side (Trademark) of the camera head]



Marking for Light Sheath (located on the side of plastic holder)

Test item particulars ..... :	
Classification of installation and use ..... :	
Clinical application ..... :	Endoscopy
Mode of operation ..... :	Continuous
Surface temperature of APPLIED PART ..... :	25° C
Possible test case verdicts:	
- test case does not apply to the test object ..... :	N/A
- test object does meet the requirement ..... :	P (Pass)
- test object does not meet the requirement ..... :	F (Fail)
Testing ..... :	
Date of receipt of test item ..... :	Jan. 20, 2010
Date (s) of performance of tests ..... :	Jan. 20, 2010

General remarks:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.
"(see Enclosure #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.

Throughout this report a comma (point) is used as the decimal separator.

This Test Report contains the general safety requirements as related to the usability of Medical Electrical Equipment. It can only be used together with IEC 60601-1 Test Report.

General product information:

The VisionScope is a family of products designed to enable pre-operative and post-operative clinical imaging and diagnostics in physician examination rooms. The device can also be used in the operating rooms where smaller gauge arthroscopes are important for certain minimally invasive surgical procedures. In the orthopedic field, this includes but is not limited to arthroscopic surgery for small joints such as the ankle, wrist and elbow. VisionScope also opens the field for new access to hip diagnostics and hip arthroscopy. (b)(4) [redacted] (b)(4) [redacted] (b)(4) [redacted], a size that fits within the current standard of needle syringe applications within the initial targeted orthopedic surgeon market. The disposable component includes a proprietary sterile barrier that eliminates the need for endoscope and camera head reprocessing following each procedure. VisionScope Technologies is able to miniaturize the arthroscope without sacrificing image quality and high clarity anatomical visualization, producing the first viable sub-2 mm endoscope enabling surgeons to perform office-based direct visual clinical assessment without requiring re-sterilizing processing. This same endoscope could then be placed in a briefcase, and brought to a surgi-center where it could be used intra-operatively.

IEC 60601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
3	**General requirements**		
3.1	EQUIPMENT provides adequate USABILITY, and the RISKS resulting from NORMAL USE and USE ERRORS are acceptable	(b)(4) [redacted]	
6	**IDENTIFICATION, MARKING AND DOCUMENTS**		
6.8	ACCOMPANYING DOCUMENTS		
	A brief description of EQUIPMENT, its physical operating principles, and significant physical and performance characteristics relevant to its USABILITY included in the instructions for use		
	The same information, when provided as a separate document, included in the technical description		
	ACCOMPANYING DOCUMENTS for equipment are, optionally, provided electronically, e.g., by electronic file format or CD-ROM.....:		
	USABILITY ENGINEERING PROCESS includes the information that will need to be provided as a hard copy or as markings on EQUIPMENT (e.g., to cover emergency operation) when ACCOMPANYING DOCUMENTS are provided electronically		
	ACCOMPANYING DOCUMENTS include a description of the OPERATOR PROFILE		
	ACCOMPANYING DOCUMENTS are written at a level consistent with the intended OPERATOR PROFILE		
6.8.201	– necessary TRAINING materials provided in the instructions for use when EQUIPMENT specific TRAINING is required for PRIMARY OPERATING FUNCTIONS of EQUIPMENT;		
	– instructions for use indicate and ensure TRAINING materials are available; or		
	– the manufacturer provides TRAINING		
	EQUIPMENT-specific TRAINING provides knowledge and skills required for safe and effective use of EQUIPMENT in addition to the OPERATOR PROFILE		

IEC 60601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	INTENDED USE/INTENDED PURPOSE is the basis for TRAINING and TRAINING material	(b)(4) [redacted]	
	Instructions for use indicate the available TRAINING options and when specific TRAINING for the EQUIPMENT is required		
46	**USE ERROR AND USABILITY**		
46.201	A USABILITY ENGINEERING PROCESS related to USABILITY of OPERATOR-EQUIPMENT INTERFACE was conducted to provide SAFETY for PATIENT, OPERATOR, and other persons		
46.202.1	Results of the USABILITY ENGINEERING PROCESS recorded in the USABILITY ENGINEERING FILE		

IEC 60601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	Records and other documents making up the USABILITY ENGINEERING FILE form a part of other documents and files such as manufacturer's product file or RISK MANAGEMENT FILE.....:	(b)(4) [redacted]	
	When design of existing EQUIPMENT was modified, USABILITY ENGINEERING PROCESS was scaled based on the significance of the modification, and depending on the results of the RISK ANALYSIS		
46.202.2.1	Application of the EQUIPMENT is specified in the USABILITY ENGINEERING FILE, and the specifications include the following information:		
	– medical purpose such as conditions(s) or disease(s) to be screened, monitored, treated, or diagnosed.....:		

IEC 60601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	– PATIENT population such as age, weight, region of body, health, and condition .....:	(b)(4) [redacted]	
	– part of the body or type of tissue applied to or interacted with .....:		
	– intended OPERATOR PROFILE .....:		
	– application such as environment, frequency of use, location, and mobility.....:		
	A summary of the EQUIPMENT application specification is included in the instructions for use		
46.202.2.2	PRIMARY OPERATING FUNCTIONS are recorded in the USABILITY ENGINEERING FILE		
46.202.2.3	A RISK ANALYSIS or part of a RISK ANALYSIS focusing on USABILITY performed according to Clause 4 of ISO 14971:2007		
	During RISK ANALYSIS, the following items were taken into consideration:		
	– application specification		

IEC 60601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	– OPERATOR PROFILE	(b)(4) [redacted]	
	– predictable USE ERRORS		
	– task related requirements		
	– context of use		
	– information on HAZARDS known for existing OPERATOR-EQUIPMENT INTERFACES for EQUIPMENT of a similar type, when available		

IEC 60601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	– results of the review of the OPERATOR-EQUIPMENT INTERFACE	(b)(4) [redacted]	
	Information on safety for RISK CONTROL relative to USABILITY such as warnings or limitation of use are included in ACCOMPANYING DOCUMENTS, markings, and the like, and were subjected to the USABILITY ENGINEERING PROCESS		
	A statement indicates disregarding the information on safety considered ABNORMAL USE		
46.202.3	USABILITY SPECIFICATION developed by the manufacturer is recorded in USABILITY ENGINEERING FILE, and integrated into other specifications		
	USABILITY SPECIFICATION is based on the following:		
	– application specification		

IEC 60601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	– HAZARDS related to the use of EQUIPMENT (results from RISK ANALYSIS in 46.202.2.3)	(b)(4) [redacted]	
	– predictable USE ERRORS associated with EQUIPMENT		
	USABILITY SPECIFICATION describes at least the following:		
	– USE SCENARIOS for EQUIPMENT		
	– OPERATOR actions related to PRIMARY OPERATING FUNCTIONS		

IEC 60601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	– OPERATOR-EQUIPMENT INTERFACE requirements for PRIMARY OPERATING FUNCTIONS	(b)(4) [redacted]	
	– requirements to determine if PRIMARY OPERATING FUNCTIONS are easily recognizable by the OPERATOR		
46.202.4	Manufacturer verified the OPERATOR-EQUIPMENT interface design according to the USABILITY SPECIFICATION, and the results of the verification are recorded in the USABILITY ENGINEERING FILE		
46.202.5	Manufacturer has developed and maintains a USABILITY VALIDATION plan specifying the following:		
	– method used for VALIDATION of the USABILITY of PRIMARY OPERATING FUNCTIONS		

IEC 60601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	– criteria for determining successful VALIDATION of the USABILITY of PRIMARY OPERATING FUNCTIONS	(b)(4) [redacted]	
	– involvement of representative intended OPERATORS		
	Quantitative or qualitative method used for USABILITY VALIDATION ..... :		

IEC 60601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	USABILITY VALIDATION performed in a laboratory setting, in a simulated use environment, or in the actual use environment..... :	(b)(4) [redacted]	
	USABILITY VALIDATION plan addresses the following:		
	– worst case USE SCENARIOS derived from the application specification, predictable USE ERRORS, and results of the RISK ANALYSIS		

IEC 60601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
	– USE SCENARIOS representing frequent application situations identified in the USABILITY SPECIFICATION	(b)(4) [redacted]	
	USABILITY VALIDATION plan is recorded in the USABILITY ENGINEERING FILE		

IEC 60601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
46.202.6	Manufacturer validated OPERATOR-EQUIPMENT INTERFACE design according to USABILITY VALIDATION plan, and the results, including the required design modifications to satisfy the criteria in the USABILITY VALIDATION plan, are recorded	(b)(4) [redacted]	

16.9 - 80016 VisionScope Software Requirements Specifications

VISIONSCOPE SYSTEM

VISIONSCOPE SOFTWARE REQUIREMENTS SPECIFICATIONS

Edit History

Revision	Date	Initials	Change Description
1.0	6/18/08	LC	(b)(4) [redacted]
1.1	7/6/08	LC	
1.2	7/15/08	LC	
1.3	8/19/08	LC	
1.4	9/12/08	LC	
1.5	10/24/08	LC	
1.6	12/8/08	LC	
1.7	4/17/09	LC	
1.8	12/1/09	LC	
1.9	12/9/09	LC	

Reviewed and Approved:

(b) (6) [redacted]	Signature	19/Feb/2010 Date
(b) (6) [redacted]	Signature	Feb. 20, 2010 Date

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Table of Contents

1. DOCUMENT SCOPE **5**

1.1. REFERENCES 5

2. DEFINITIONS **5**

2.1. ACRONYMS AND ABBREVIATIONS 6

3. SYSTEM OVERVIEW & DESCRIPTION **7**

3.1. USE ENVIRONMENT 7
3.2. USER CHARACTERISTICS 7
3.3. OVERVIEW OF SYSTEM COMPONENTS 7

(b)(4) [redacted]

8
8
8
8
8
8
8
9
9

3.4. HARDWARE BLOCK DIAGRAM 9
3.5. CAMERA HEAD BUTTONS 11

4. FUNCTIONAL REQUIREMENTS **12**

(b)(4) [redacted]

12
12
13
13
14
15
15
16
16
17
17
18
18
19

5. EXTERNAL INTERFACE SPECIFICATIONS **20**

(b)(4) [redacted]

20
20
23
24
26
27
28
30
32
32
33

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33
33
34
34
34
35
36
36
36
36
36
36
37
38
39
39
40
40
41
43
44
45
45
45
45
46

6. ACCEPTANCE CRITERIA **47**

OVERALL ACCEPTANCE CRITERIA 47
6.1. ACCEPTANCE TEST SCENARIOS 47
6.2. ACCEPTANCE DOCUMENTATION 47
6.2.1. Acceptance for Engineering Development Purpose: *47*
6.2.2. Acceptance for Product Installation for Shipment to End Users *47*

7. STANDARDS **49**

8. CHANGE MANAGEMENT **50**

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916

1. Document Scope

The purpose of this document is to describe the Software Functional Requirements and Specifications (SRS) of the VisionScope Camera Controller User Interface. The document serves the following purposes:

- Provide guidance for the software design, prototyping, verification and validation
- Provide guidance for the hardware design such that the software may be supported
- Support the VisionScope User Needs and Product Requirements document which describes the product from an end-user and marketing perspective
- Serve as the basis for defining the statement of work, budget and schedule between VisionScope management and software team
- Provides traceability for subsequent product verification, validation and acceptance criteria, on a point-by-point basis against each stated specification.

(b)(4) [redacted]

These interface specifications are covered in separate documents included in the References section.

1.1. References

(b)(4) [redacted]

2. Definitions

The measurable parameters with respect to product acceptance are defined as follows:

Functional Requirements are descriptive functions that the equipment is required to perform. *Functional Requirements* are judged subjectively based on usual and customary practice, and acceptance is based on a binary scoring process: presence/absence, pass/fail or yes/no. Evidence of compliance is given in verification documents.

Performance Specifications are quantitative standards that the equipment is required to meet. *Performance Specifications* are measured quantitatively, and acceptance is based on a minimum passing standard expressed in the engineering units under specified operating conditions. Evidence of compliance is given in verification documents.

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Performance Goals are quantitative attributes that the designers will aim to achieve on a best effort basis. The designers are strongly encouraged to meet or exceed the goal, but the achievement cannot be guaranteed.

"*Shall or Must*":
indicates a requirement is mandatory for compliance

"*Should*":
indicates a strong recommendation that is not mandatory, but deviation must be justified

"*May*":
indicates a permitted manner of complying with a particular requirement

2.1. Acronyms and Abbreviations

CCU	Camera Control Unit
DVI	Digital Video Interface, per Digital Video Working Group Revision 1
(b)(4) [redacted]	
SDS	Software Design Specification
SRS	Software Requirement Specification

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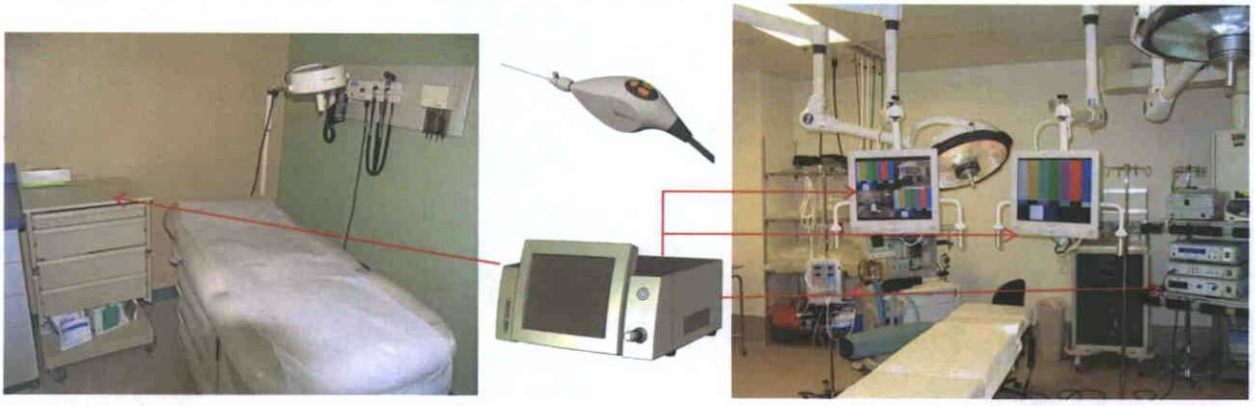
918

3. System Overview & Description

3.1. Use Environment

The system is intended to be used in both Physicians' examination rooms and Surgical Operating Rooms. Figure 3.1-1 shows a picture of the use environment.



Physicians' Clinics

Operating Rooms

Figure 3.1-1 Use Environment of the Endoscope System

3.2. User Characteristics

- **Main Intended Users are clinical staff who may not be expert computer users**
  Nurses, Physicians and Surgeons

- **Other Supporting and Infrequent Users may include:**
  Hospital's biomedical engineering staff, IT staff, distributors' service staff

3.3. Overview of System Components

A picture of the Camera Head and CCU is shown in Figure 3.1-1 above.

On the camera head there are three buttons to enable the surgeon to remotely control the operation of the CCU. Each button shall control two functions, depending on the length of time it is depressed. One function will be invoked following a short depression and release (< 1.5 seconds). The other function will be activated following a long depression (> 1.5 seconds) whether or not the button has been released. The type of functions that can be controlled may be customized to suit individual surgeon's preference. The following functions are available for head button control:

- Capture Still Picture and Activate Accessory Port 1
- Capture Video Clip and Activate Accessory Port 2

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919

- Increase/Decrease Brightness
- Increase/Decrease Enhancement
- White Balance
- Recall Last Captured Image

The CCU is an all-in-one unit that performs the following major types of functions:

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920

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3.4. Hardware Block Diagram

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Figure 3.4-1 Hardware Block Diagram of User Interface Processor

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921

The major functions of each block are described below.

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922

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3.5. Camera Head Buttons

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4. Functional Requirements

4.1. Overview of Process Flow

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[redacted]

Figure 4.1-1 VisionScope Procedure Typical Process Flow

4.2. Patient management

Term	Description
Purpose	To manage the data for a patient
Input(s)	None
Output(s)	A folder containing all details and history of patient

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5. External Interface Specifications

All pictures, diagrams and graphical user interface (GUI) objects used in this section are intended for reference use only. (b)(4) [redacted]

(b)(4) [redacted]

5.1. Initialization & Patient Registration

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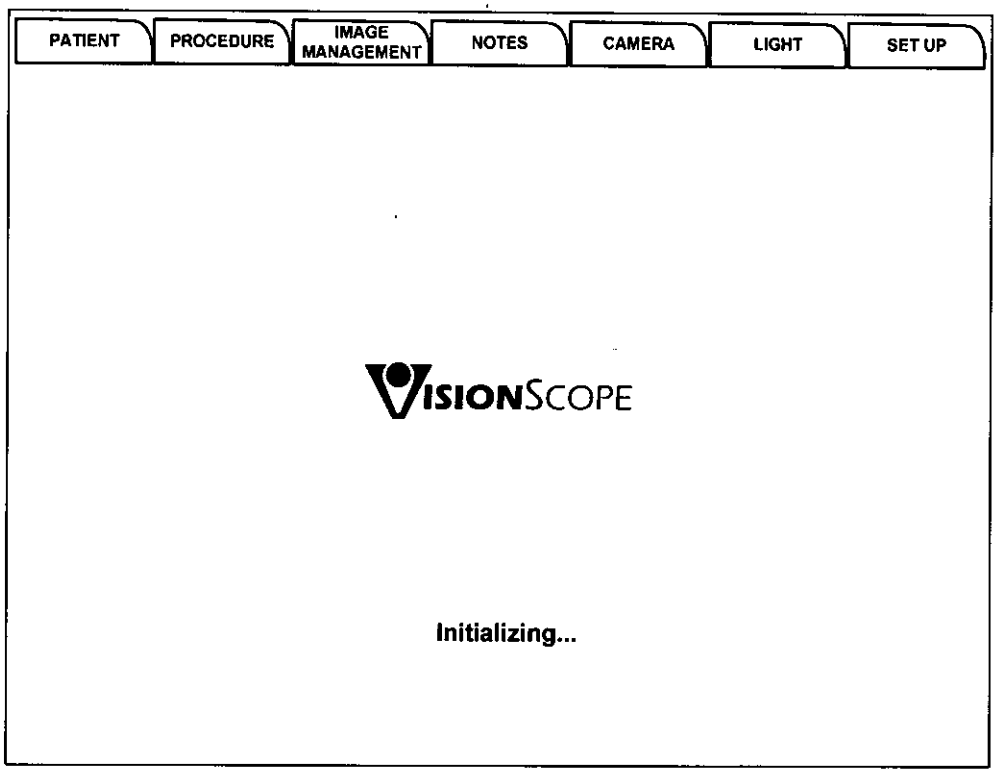

Figure 5.1.1-1 Touch Screen: Power Up Initialization Screen

After the microprocessor is finished with initializing, and if the camera head is not plugged in, the Touchscreen will switch to a standby mode with a color bar pattern, as shown in Figure 5.1.1-2 similar to that on the OR Screen shown in Figure 5.1.1-3.

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933

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Figure 5.1.1-3 OR Screen: Power Up Standby Screen before camera head is connected with the text message alternating between black and white at 0.5 Hz. The color bar is in 16:9 HD aspect ratio.

Sony Imaging Module Power Up Initialization
On Power Up, execute the "Power Up Initialization Sequence" sheet as described in the Sony Imaging Module Command Sequence Spreadsheet.

5.1.2. Patient Registration

Touch Screen
Upon successful power up, the first screen to appear is the Patient Registration Screen, shown in Figure 5.1.2-1.

A new patient must be registered, or an existing patient on the Patient List box must be selected, before the "PROCEDURE" and "NOTES" pages are enabled, enabling patient ID to be associated with the still images or video clips or notes to be part of the patient record. If a new patient has not been registered or selected, the tabs labeled "PROCEDURE" and "NOTE" will be disabled and grayed out.

If the surgeon presses the camera head buttons (and camera head buttons only) to capture JPEG or MPEG images before performing Patient Registration, an advisory message will be displayed on the screen for three second: "Please REGISTER or SELECT Patient", and the screen will be reverted to the Patient Registration page.

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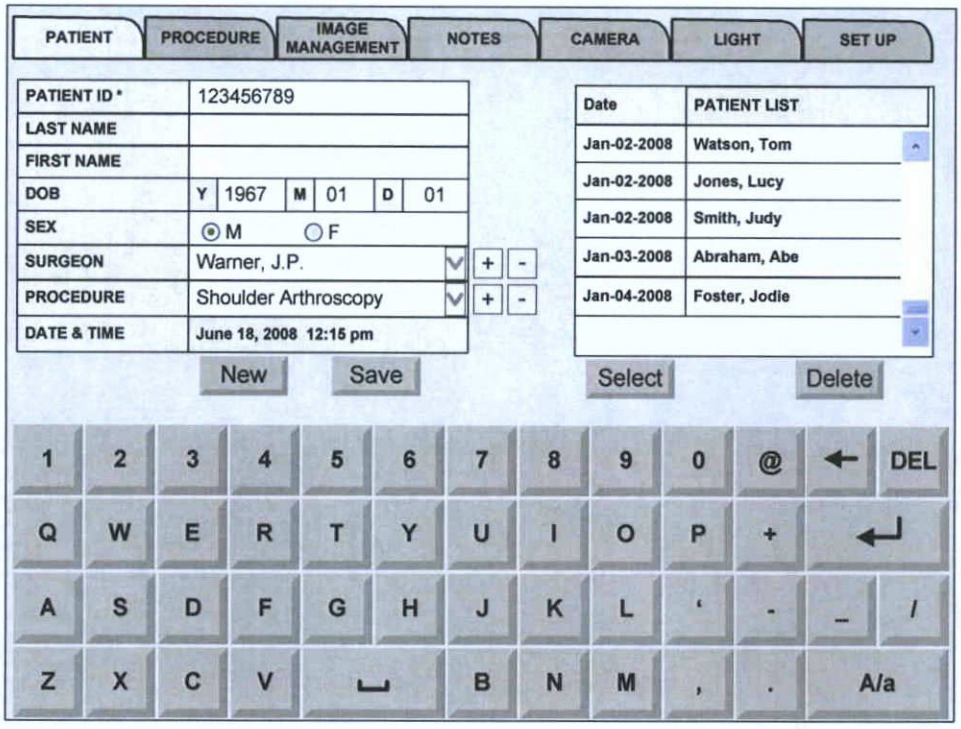

Figure 5.1.2-1 Touch Screen: Patient Registration Page

5.1.2.1. Descriptions of the Patient Registration Fields

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following messages, generated by the VisionScope FPGA, will appear on both the Touch Screen and the OR Screen:

During White Balance:	"White Balance in Process"
White Balance is Successful:	"White Balance Completed"
White Balance fails:	"White Balance Incomplete Please Repeat White Balance Again"

The "White Balance In Process" message will be displayed until the Imager DSP sends a success or failure signal.

The "White Balance Completed" message will be displayed for three seconds, afterward, it is turned off. The message will alternate between black and white at a frequency of 0.5 Hz.

The "White Balance Incomplete, Please Repeat White Balance Again" will remain on or five seconds, afterward it is turned off. It is recommended that the surgeon performs the white balance again, but it is not mandatory, in order not to slow down the surgery. The message will alternate between black and white at a frequency of 0.5 Hz. If the surgeon chooses not to repeat White Balance, the image may be slightly off-color, and white may not be white in appearance.

White Balance may fail due to one of several reasons, such as using a colored cloth instead of a white cloth, or there is not enough light or too much light.

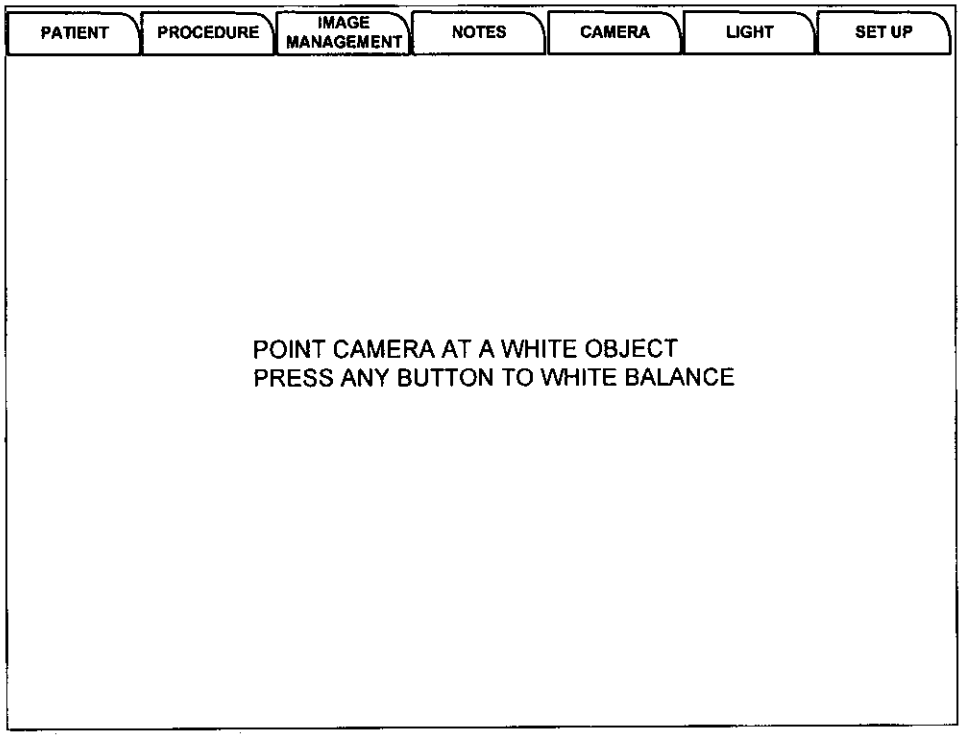

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Figure 5.2.2-1 Touch Screen: White Balance

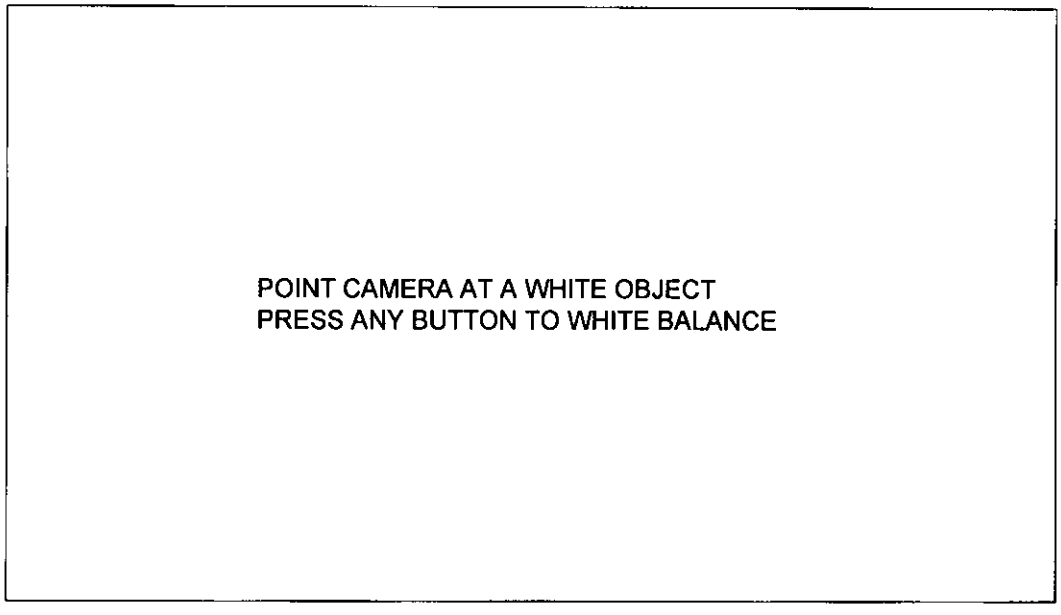

Figure 5.2.2-2 OR Screen: White Balance

Sony Imaging Module White Balance Sequence
On White Balance command, execute the "White Balance Sequence" sheet as described in Sony Imaging Module Command Sequence Spreadsheet.

5.2.3. Diagnostic or Surgical Mode

Touch Screen
After successful white balance, the camera is ready to provide live video of the diagnostic or surgical procedure. During this phase of the procedure, it is desirable to visualize the anatomy with the least amount of clutter and distraction. The GUI widgets on the Touch Screen may be optionally turned on or off by touching the main image below the row of top widgets, outside the GUI widgets, as illustrated in Figure 5.2.3-1.

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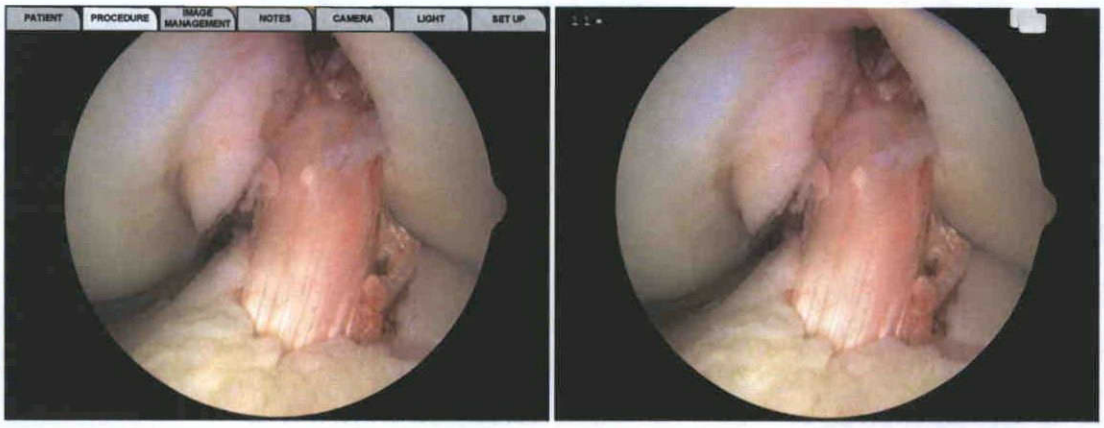

Figure 5.2.3-1 Touch Screen: Left – with GUI widgets on the top; Right – GUI widget may be turned off or turned back on by repeatedly touching the main area of the Touch Screen

OR Screen

The OR Screen, illustrated in Figure 5.2.3-2, will show the live image without the GUI widgets. Optionally, if enabled in the SET UP page, the FPGA will maintain a counter of the number of still image captured on the top left corner, and a "REC" symbol alternating in black and white while a video movie in MPEG4 is being captured. The GUI widgets will not appear on the OR Screen at all times.

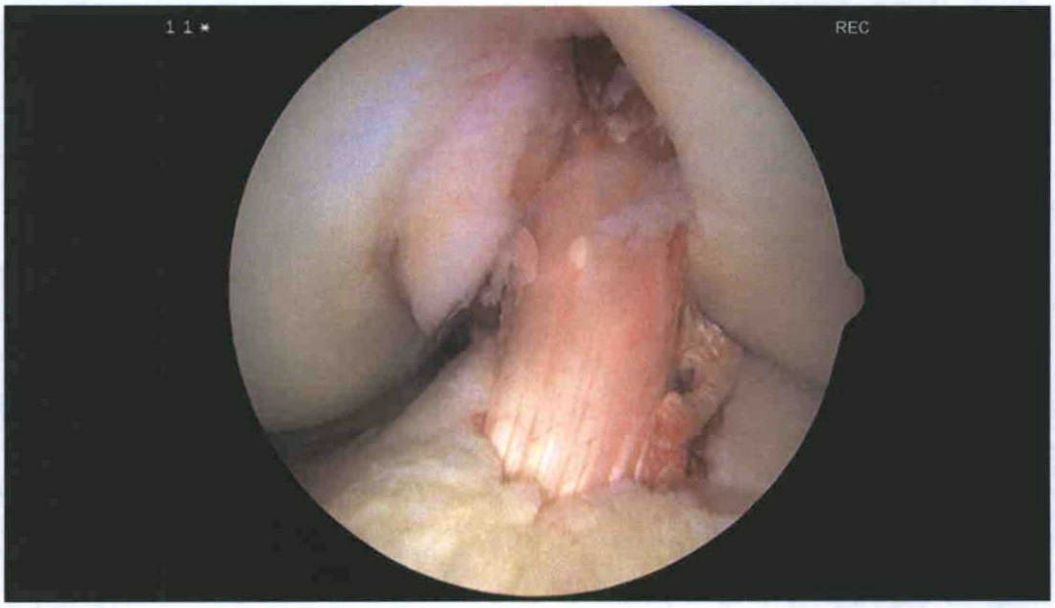

Figure 5.2.3-2 OR Screen, showing the live video during a Diagnostic or Surgical procedure. The number on the upper left corner indicates the number of still images that have been captured during this procedure. A "REC" OSD message will appear on the upper right corner during video capture.

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943

5.2.4. Still Picture or Video Clip Capture during Procedure

During a diagnostic or surgical procedure, a surgeon may occasionally capture a still picture or a short video clip by pressing on the camera head buttons. The default action for capturing a still picture is a short press on the left button, while a short press on the right button will start a video clip capture, and another short press on the same button will stop the video clip capture.

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5.3. Image Management (Media)

The Image Management Screen, shown in Figure 5.3-1, enables the user to perform a number of functions, including:

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Massachusetts General Hospital

1 Cambridge Street, Boston, MA 02138

Patient ID:	123456789	DOB:	01/01/1960
Last Name:	McDonald	Sex:	F
First Name:	Elizabeth	Surgeon:	Warner, J. P.
Procedure:	ACL	Procedure Date:	01/01/2008

Surgical Notes:

A tear in the anterior cruciate ligament (ACL) is one of the most common knee injuries that may occur to a recreational, amateur, or professional athlete. This injury may result from twisting the knee too far in one direction, or by a sudden and forceful change in direction as may occur during football, soccer, skiing, basketball, racquetball, or tennis. Frequently, the injury occurs in those sports that require the foot to be planted in one spot, and the body to suddenly change direction or make a lateral movement.

Images:

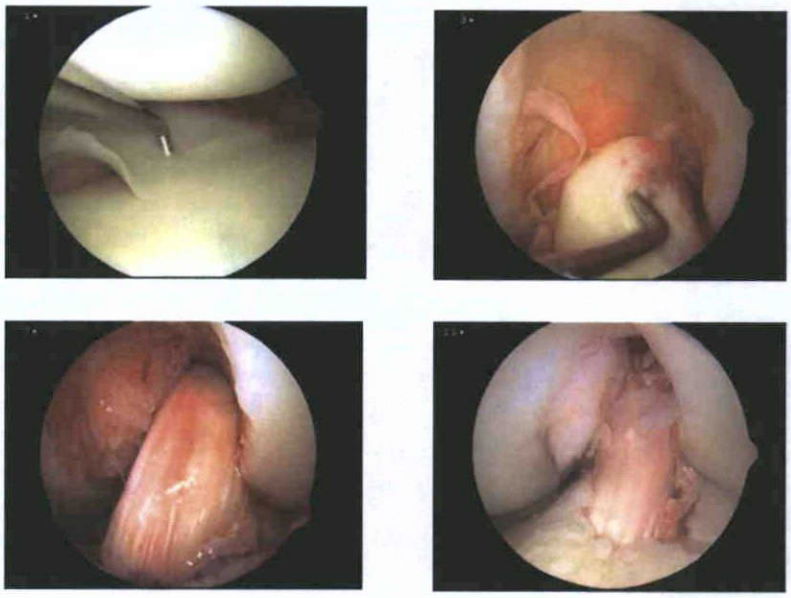

Figure 5.3.6-1 Sample Procedure Report

5.3.7. Email Button

If the CCU is connected to a LAN, pressing the Email button will cause a pop up dialog box to appear, prompting the user to enter an email address. Pressing the Send button will cause a Procedure Report in the standard XTML format to be sent.

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When the Notes page is selected, a text editor box is opened, enabling the user to type in short text notes, ASCII text format. The screen layout is shown in Figure 5.4-1. The maximum number of characters is limited to 1080 and the maximum number of lines is 15, whichever comes first. A scroll bar on the right vertical edge may be included to allow scrolling of the text beyond the visible window.

A patient must have been registered and New Procedure must have been created or any existing procedure must have been selected before NOTES page is enabled.

Whenever user first time enter notes and click on save button a notes file in .txt format will be stored on the disk.

Pressing the "CLEAR" will cause a pop up dialog box to open, requesting the user to confirm with "Yes" or "No". If confirmed, all the text entered in the box will be erased, and the file stored on the disk will be deleted. The cursor is positioned at the starting position within the text box.

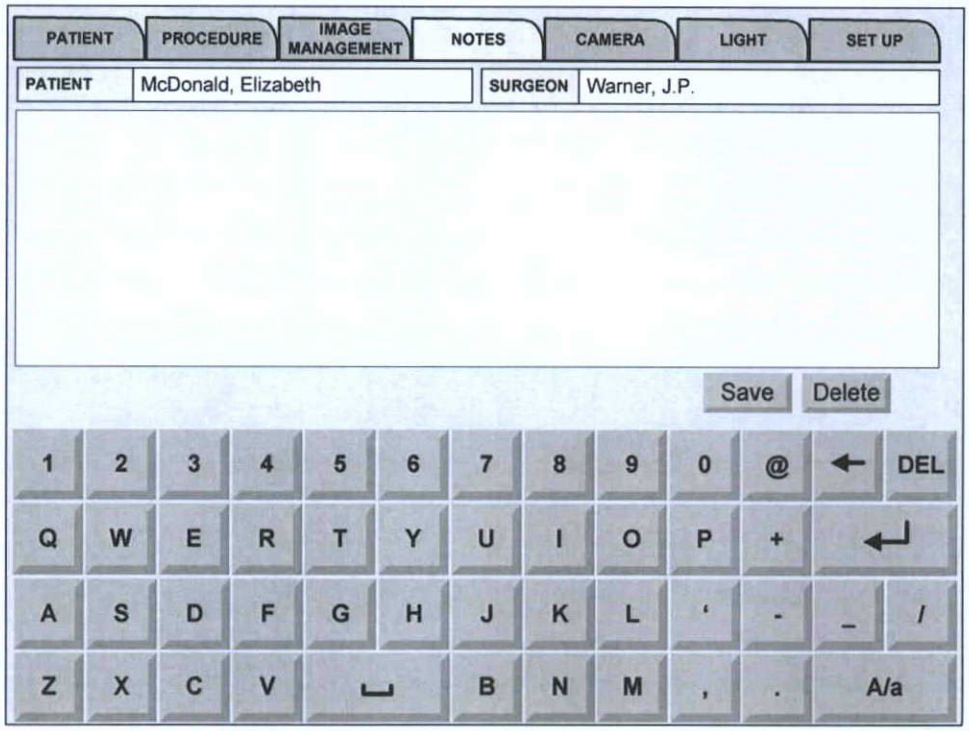

Figure 5.4-1 Screen Appearance of the NOTES page.

5.5. Camera Control

The Camera Control serves as the virtual front panel for the video camera. The layout of the Camera page is shown in Figure 5.5-1. The button icons should be designed such that a live image is shown running in the background.

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5.5.6. Customize Picture Profile

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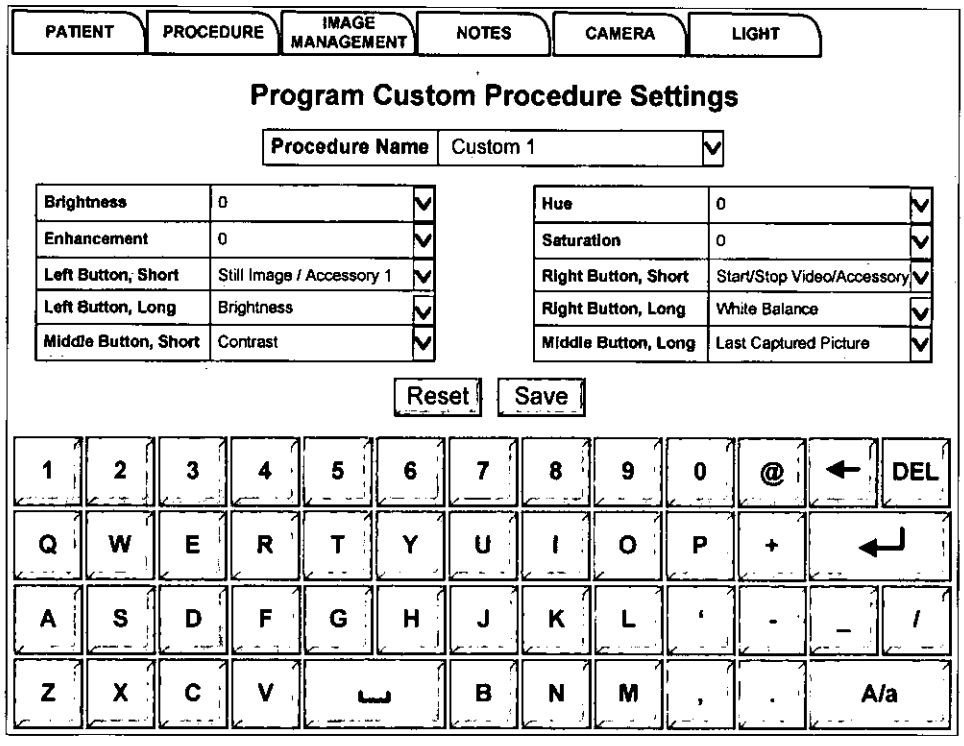

Figure 5.5.6-1 Custom Procedure page, showing the default settings as shipped from the factory before they are modified by the users.

5.5.6.1 Custom Picture Profile Name

Five entries are presented in this pull down menu: Custom 1 to Custom 5. The user may highlight one of these five names and use the keyboard to delete or modify the original names. This is the only field that requires typing on the keyboard.

5.5.6.2 Brightness, Enhancement, Hue and Saturation

These are pull down menus with seven choices: -3, -2,...0, ...2, 3.

5.5.6.3 Camera Head Button Settings

Each of the three camera head buttons may be programmed to perform two functions, depending on the duration of the press and release cycle. A short press is defined as 50 msec $\leq t \leq$ 1.0 second. A long press is defined as $t >$ 1.0 second. Any signal shorter than 50 mec is treated as noise and ignored. The functions are executed on the falling edge or release of the button.

The available functions associated with each pull down menu are:

- Still frame capture (tied to the Accessory 1 Contact Closure switch on the back panel)

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- Start/Stop video clip capture (tied to the Accessory 2 Contact Closure switch on the back panel)
- Brightness adjustment
- Enhancement adjustment
- White Balance
- Display last captured still image for 3 seconds

5.5.6.4 Reset

Pressing this button while one of the five Custom Procedures is selected will reset the parameters to the factory default setting, with the customized name restored to "Custom N", where N is the numerical order of the Custom Procedure on the pull down menu.

The default parameters as set in the factory are shown in Figure 3.4.6-1.

5.5.6.5 Save

Pressing the Save button will cause the microprocessor to load the currently set parameters into the memory area of the VisionScope microprocessor.

Afterward, the page will revert to the Select Custom Procedure page shown in Figure 3.5.5-1.

5.6. LED Light Source Control

There is only one controllable parameter on the Light Source page: NORMAL or STANDBY. The screen page is shown in Figure 5.6-1. The two buttons are mutually exclusive. When the STANDBY button is pressed, a signal is sent from the microprocessor to the FPGA, causing the LED current to be reduced to a small value just enough to make the LED glow dimly. Pressing the NORMAL button will cause a signal to be sent from the microprocessor to the FPGA to restore the LED to full power.

Pulling the camera head cable out of the socket on the front panel of the CCU will have the same effect as pushing the STANDBY button. In this case, the FPGA will detect that the camera head cable has been detached. The FPGA will set a register bit, so the microprocessor will toggle the LCD touch screen button accordingly.

The interface details between the microprocessor and the FPGA will be defined in a separate interface specification document.

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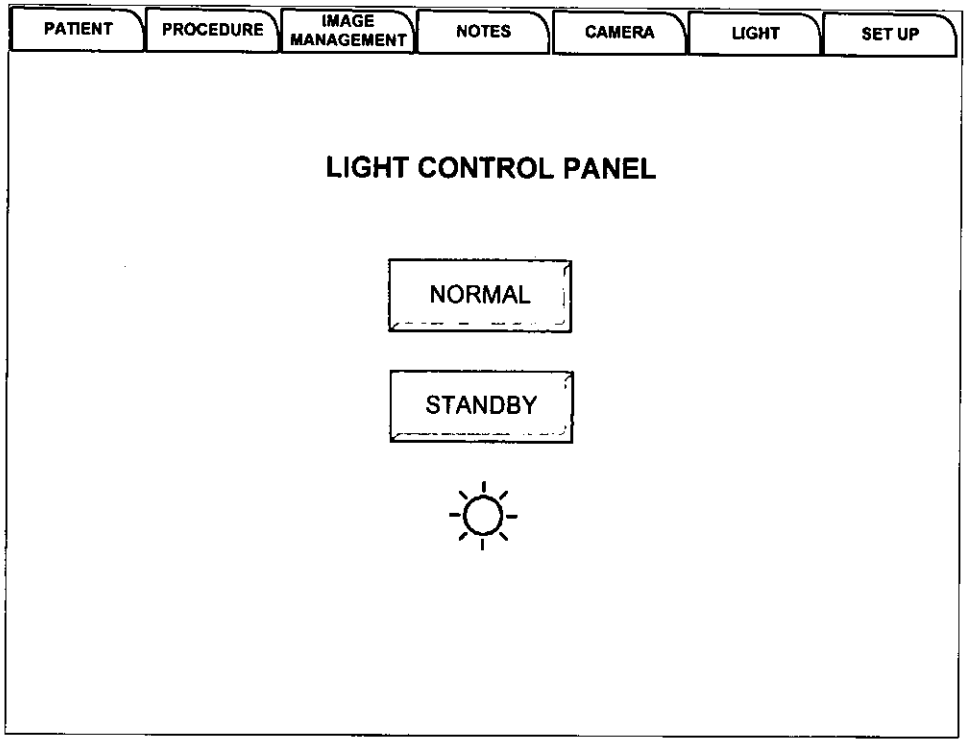

Figure 5.6-1 LED Light Source Control Panel

5.7. Setup

The Set-Up page enables the users to select options for file storage, printing, On-Screen Display, maximum record lengths, and network address. Figure 5.7-1 shows the Set-Up page.

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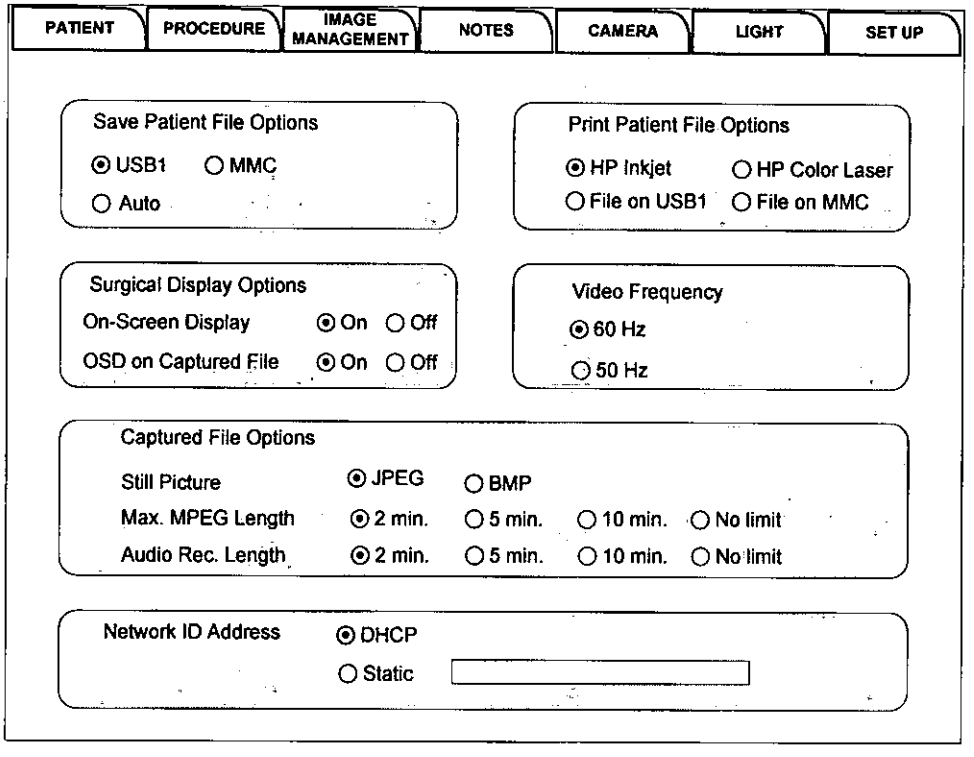

Figure 5.7.1 Setup Page

5.7.1. Print Patient File Options

This allows the user to print patient files onto a designated printer. To keep the system simple, only a small number of selected printers are supported.

If there is no printer attached to the CCU, an error message will pop-up.

5.7.2. Surgical Display Options

These options affect how the OSD appears on the Surgical Monitors connected only to the HD-SDI and the DVI connectors attached to the back panel. It has no effect on the appearance of images on the Touch Screen.

5.7.3. Video Frequency

(b)(4) [redacted]

5.7.4. (b)(4) [redacted]

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(b)(4)

[redacted]

5.7.5. Network Components

The following Network Components should be supported:

- Edit Email Recipient
- Add / Delete printer
- Email server configuration (IPaddress, Username and Password)
- Static/ DHCP(default) IP configuration
- Reset to factory settings
- Touch screen calibration
- Admin password
- Hospital Information
- Date & Time Setting
- Day Light Saving

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6. Acceptance Criteria

Overall Acceptance Criteria

All the requirements mentioned in Section 4 and 5 should be met.

6.1. Acceptance Test Scenarios

(b)(4) [redacted]

6.2. Acceptance Documentation

6.2.1. Acceptance for Engineering Development Purpose:

Final acceptance and approval of the software deliverables shall be based on a formal Verification Report (b)(4) [redacted]. The Verification Report may be in a (b)(4) [redacted] the following elements as a minimum:

- List of equipment, hardware and software configuration, revision number and unique identifier (e.g., checksum, byte size, and/or date code of source code, make file, and binary executable file) of software under test, serial number of test units and any test equipment
- A traceability table listing either the SRS or SDS specification document section number against the item that is being verified, section by section.
- For each specification item, list a brief summary of the verification procedure and test conditions. Include a pointer to a separate verification report if necessary.
- For each specification item, list the result of the verification: pass, fail, and if any, include any conditional qualifiers or exceptions. For items that continue to fail after reasonable remedial effort, provide suggestions on a resolution plan, including proposed changes of specifications or features, with the goal that all specifications in the final verification report can be verified successfully, reproducibly and reliably.
- Initial of person performing the test and date

Interim informal verifications or e-mail communications at major milestones may be provided.

6.2.2. Acceptance for Product Installation for Shipment to End Users

Release of the software into production units intended for use by the end users in a clinical environment shall be based on a formal Validation Report (against SRS traceable to the User Needs document) to be prepared by VisionScope and reviewed at a formal Design Review and Design Transfer session. The Validation Report should contain the following elements as a minimum:

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- List of equipment, hardware and software configuration, revision number and unique identifier (e.g., checksum, byte size, and/or date code of source code, make file, and binary executable file) of software under test, serial number of test units and any test equipment
- A traceability table listing the SRS section number against the items that is being validated, section by section.
- For each specification item, list a brief summary of the validation procedure and test conditions. Include a pointer to a separate validation report if necessary.
- For each specification item, list the result of the validation: pass, fail, and if any, include any conditional qualifiers or exceptions. For items that continue to fail after reasonable remedial effort, provide suggestions on a resolution plan, including proposed changes of specifications or features, with the goal that all specifications in the final validation report can be validated successfully, reproducibly and reliably.
- Initial of person performing the test and date
- Cover Page with a Sign-off block containing the Signature of tester and reviewer (normally supervisor of the person performing the test) and date

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7. Standards

(b)(4)

[redacted]

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8. Change Management

Once SRS gets base line after that if any change comes, change management will be followed. Impact analysis will be done.

A Documentation Change Order form shall be used for this purpose. A copy of VisionScope's form is provided for reference.

For software engineering development, software releases are to be numbered with a numerical designation, e.g., Release 1, 2, 3.0, 3.1, ... etc.

Not all engineering releases are intended for product use in shippable units for the intended final users in commercial products.

From time to time, based on the maturity of the software, certain software releases are designated to be used in commercial shippable products. Such releases are designated with a alphabetic revision number, e.g., Revision A, Revision B, B1, C, etc., per the VisionScope Quality System Manual (QSM-01) and associated Standard Operating Procedures (SOP's). Such releases are revision-controlled following the VisionScope Design Control Procedure (SOP-004) and Document and Data Control Procedure (SOP-001).

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16.10 - 80019 VisionScope Software Design Specifications

VisionScope Technologies LLC VisionScope Software Design Specifications (SDS)	
Document No. 80019 Rev. **0.04**	
Code Identification: File: VisionScope Software Design Specifications.doc	Date: December 19, 2009

VISIONSCOPE SOFTWARE DESIGN SPECIFICATIONS

REV. 0.04

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Reviewed and Approved:

(b) (6)

[redacted]

19/Feb/2010
Date

Feb. 20. 2010
Date

Table of Contents

1 DOCUMENT DETAILS 8

1.1 Document History 8
1.2 Review History 8
1.3 Acronyms 8
1.4 References 9

2 DESIGN OVERVIEW 10

2.1 Top Level System Diagram 10
2.2 Description 10
2.3 Criteria 11
2.3.1 System Performance Criteria 11
2.3.2 Acceptance Criteria 11
2.3.3 Compliance Criteria 11

3 SYSTEM CONFIGURATION 12

3.1 Hardware Configuration 12
3.2 Software Configuration 12

4 DETAIL DESIGN 13

(b)(4)
[redacted]

5 MODULE DESIGN 17

(b)(4)
[redacted]

6 DATA DESIGN 29

(b)(4)
[redacted]

966

(b)(4)

[redacted]

7 FUNCTION DESCRIPTION 53

(b)(4)

[redacted]

8 USER INTERFACE DESIGN 103

(b)(4)

[redacted]

9 ASSUMPTIONS 138

10 LIMITATIONS AND CONSTRAINTS 139

FIGURES

(b)(4)

[redacted]

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[redacted]

TABLES

Table 1 Hardware Configuration 12
Table 2 Software Configuration 12

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910

1 DOCUMENT DETAILS

1.1 Document History

(b)(4)

[redacted]

1.2 Review History

Version	Date	Author	Description
0.02	24 Dec 2008	Lim Cheung	Review comments marked with track changes on
0.04	19 Dec 2009	Lim Cheung	Review comments marked with track changes

1.3 Acronyms

(b)(4)

[redacted]

(b)(4) [redacted]

1.4 References

(b)(4) [redacted]

2 DESIGN OVERVIEW

2.1 Top Level System Diagram

(b)(4)

[redacted]

Figure 1. 2.1-1 : Top level system diagram

2.2 Description

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

975

(b)(4) Software Design Specifications

(b)(4) Software Design Specifications

(b)(4) Software Design Specifications

(b)(4) Software Design Specifications

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16.11 - 80072 VisionScope Traceability Analysis

1. Overview

The purpose of this document is to provide traceability among Specifications, Verification, Validation, Risk Analysis and Mitigation documents located in the VisionScope Design History File.

2. Traceability Tree

Figure 2.1 shows the traceability tree of a number of Specification documents. All specification documents are ultimately derived from the User Needs and Product Requirements Document (80002).

The major subsystems are the Camera Head, Camera Control Unit, Endoscopes, Illumination Sheaths, Cannulas and Trocars. The Camera Control Unit subsystem has its own hardware and software requirement specifications. These are described in top level specifications which in turn drive the specifications on building blocks or component levels.

Each of the System or Subsystem, Hardware or Software Specification document is associated with a System or Subsystem, Hardware or Software Verification report. Each of the verification items is traceable to the specifications. The traceability of verifications against specifications is summarized in a Traceability matrix, given in Section 3. The User Needs and Product Requirements are validated in the System Validation Report, System Validation Report in Cadaver Labs by Surgeons and the Software Validation Report by Software QA. Instructions per Use are also validated for Usability by end users.

Risk Analysis and Design FMEA are carried out on a system and sub-system level.

(b)(4)

[redacted]

Figure 2.1 Traceability Tree of Specifications, Verifications, Validations, and Risk Analysis

3. Trace Matrix

The Specifications of the VisionScope Camera Head, Camera Control Unit, Endoscopes, Illumination Light Sheaths, Cannulas, and Trocars, Software Requirements and Specifications and Software Design Specifications are traceable to the User Needs and Product Requirements Document.

The Hardware and Software Verifications of the VisionScope system and sub-systems are traceable to the System and Sub-systems Specifications.

Table 3.1 summarizes the traceability of the top-level Users Needs and Product Requirements, System Level Specifications, Verification, Risk Analysis and Design FMEA.

Both the Specifications and Verification documents are written at the same time, and to the extent possible, with the section numbers identical in both documents so as to facilitate the tracing of the verification items to the corresponding specification items.

Traceability of verification against specifications of lower-level subsystems is included in the individual verification documents of the subsystems. In these lower level verification documents, a summary table is provided to trace the section number of the corresponding specification document.

Table 3.1 Top Level Traceability Matrix

User Needs and Product Requirements Description Section Title	VisionScope User Needs and Product Requirement Document 80002 Section Reference	System and Subsystem Specification Documents & Section Reference (Document # & Section #)	System and Subsystem Verification & Validation Documents & Section Reference (Document # & Section #)	Risk Analysis and Design FMEA (Document # & Section #)
Clinical Needs	(b)(4) [redacted]			
User Needs				
Features – Outer diameter				
Working Lengths				
Interchangeable of endoscopes				
Focusing				
Field of View				
Direction of View				
Fluid Flush Port				
Sterilization Barrier				

	(b)(4) [redacted]
Access	
Sterilization Requirements	
Single Use Sterile Barrier	
Image Quality	
Surface Temperature	
Compatibility with current visualization equipment	
Product Features	
Product Family	
System Interconnect	
Patient Information Management Software	
Reuseable Parts Usability	
Diagnostic Use	
Surgical Use	
Sterilization	

VisionScope High Definition Endoscopy System

80072 - TRACEABILITY ANALYSIS REV. 1

Compatibility	(b)(4) [redacted]
EMC	
EMI	
Product Family & Components	
Warranty	
Environmental Conditions	
Markings and Labels	
User Manuals	
Power Requirements	
Service	

16.12 - 80028 VisionScope Software Validation Document

VISIONSCOPE

VISIONSCOPE SOFTWARE VALIDATION PROTOCOL AND REPORT

Edit History

Revision	Date	Initials	Change Description
1.0	12/1/2008	[redacted]	
2.0	10/29/2009		
2.1	12/23/2009		
2.2	2/12/2010		
3	4/12/2010		

(b) (4), (b) (6)

Performed by:

[redacted] (b) (6) 4/14/2010
Date

Independently Performed by:

[redacted] (b) (6) 4/13/2010
Date

Reviewed and Approved by:

[redacted] (b) (6) 4/14/2010
Date

4/13/2010
Date

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Table of Contents

TABLE OF CONTENTS 3
1. DOCUMENT SCOPE 4
1.1. REFERENCES 4
1.2. TERMINOLOGY 5
1.3. ABBREVIATION AND ACRONYM 5
2. VALIDATION EQUIPMENT RECORD 6
3. SOFTWARE VALIDATION PLAN, RISK ANALYSIS & EXECUTION SUMMARY 8
3.1. SUMMARY OF SOFTWARE VALIDATION TEST RESULTS 9
4. VALIDATION OF FUNCTIONAL REQUIREMENTS & EXTERNAL INTERFACE SPECIFICATIONS 10
5. STRESS TESTS 10
6. FAILURE RECOVERY TESTS 10
APPENDIX A SOFTWARE VALIDATION TEST CASES 12
APPENDIX B STRESS TEST 42
APPENDIX C FAILURE RECOVERY 47

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1112

1. Document Scope

This purpose of this document is to describe the Validation of the VisionScope System Software. The document provides the following information:

- Traceability of Validation against Software Functional Requirements and Specifications (SRS, Document 80016, Rev. 1.9), on an item-by-item basis
- Validation method and procedures
- Pass/fail or acceptance criteria
- Summary of the validation results, and where appropriate, points to additional documents or laboratory notebooks for more detailed results

Verification of the underlying software building blocks, traceable to the Software Design Specifications (SDS, Document 80019), is described in the VisionScope Software Verification Report (Document 80029).

1.1. References

- VisionScope Software Requirements Specifications (SRS, 80016 Rev. 1.9)
- VisionScope Software Design Specifications (SDS, 80019 Rev. 0.04)
- VisionScope Software Verification Document (80029 Rev. 2.0)
- VisionScope Software Revision History Log (80089)
- VisionScope Software FMEA (80055)
- VisionScope Quality System Manual (QSM-01)
- VisionScope Design History File DHF-VS1
- VisionScope System Validation Master Plan (80027)
- VisionScope Traceability Analysis (80072)
- VisionScope Endoscope System Description (80006)
- VisionScope User Needs and Product Requirements document (80002)
- Instructions for Use, VisionScope System (PN 01112)

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1113

1.2. Terminology

We use the term Software Verification and Validation in accordance with the definition provided in the FDA Guidance Document titled "General Principles of Software Validation, January 11, 2002", downloaded from the FDA web link:

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126955.pdf

Software verification provides objective evidence that the design outputs of a particular phase of the software development life cycle meet all of the specified requirements for that phase. Software verification looks for consistency, completeness, and correctness of the software and its supporting documentation, as it is being developed, and provides support for a subsequent conclusion that software is validated. Software testing is one of many verification activities intended to confirm that software development output meets its input requirements. Other verification activities include various static and dynamic analyses, code and document inspections, walkthroughs, and other techniques.

Software validation is a part of the design validation for a finished device, but is not separately defined in the Quality System regulation. For purposes of this guidance, FDA considers software validation to be "**confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled.**"

1.3. Abbreviation and Acronym

CCU	Camera Control Unit
DSP	Digital Signal Processing
FTC	Functional Test Case
LCD	Light Crystal Display
SDS	Software Design Specification
SRS	Software Requirement & Specification

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2. Validation Equipment Record

	[redacted] (b)(4)
Camera Head Assembly Part Number:	
Revision No.:	
Serial Number(s):	
[redacted] (b)(4)	
Camera Control Unit Assembly Part Number:	
Revision No.:	
Serial Number(s):	
[redacted] (b)(4)	
VisionScope Software Part Number:	
[redacted] (b)(4)	

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115

[redacted] (b)(4)

Supporting Test Equipment

Equipment Used	Model	VisionScope Tool Number
[redacted]		

(b)(4)

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1116

3. Software Validation Plan, Risk Analysis & Execution Summary

[redacted] (b)(4)

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3.1. Summary of Software Validation Test Results

(b)(4)

[redacted]

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16.13 - 80029 VisionScope Software Verification Document

VISIONSCOPE

VISIONSCOPE SOFTWARE VERIFICATION

Edit History

Revision	Date	Initials	Change Description
1.0	10/29/2009	[redacted]	
2.0	2/12/2010		
3.0	4/12/2010		

(b) (4)

1(a)

Performed by:

[redacted] (b) (6) _____ 4/14/2010
Date

Reviewed and Approved by:

[redacted] (b) (6) _____ 4/14/2010
Date

[redacted] (b) (6) _____ 4/13/2010
Date

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1102

Table of Contents

TABLE OF CONTENTS 3
1. DOCUMENT SCOPE 4
1.1. REFERENCES 4
1.2. TERMINOLOGY 4
1.3. ABBREVIATION AND ACRONYM 5
2. VERIFICATION EQUIPMENT RECORD 5
3. SUMMARY &STATISTICS 8
4. FUNCTIONAL TESTS 9
5. STRESS TESTS 92
6. FAILURE RECOVERY TESTS 98
APPENDIX A. BUG TRACKING & RESOLUTION 102

1103

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1. Document Scope

This purpose of this document is to describe the Verification of the VisionScope User Software against the Software Design Specification (SDS), VisionScope Document No. 80019, Rev. 0.04. The document provides the following information:

- Traceability of Verification against Specifications, on an item-by-item basis,
- Verification method and procedures
- Pass/fail or acceptance criteria
- Summary of the verification results, and where appropriate, points to additional documents or laboratory notebooks for more detailed results

Validation of the software, traceable to the Software Requirements Specifications (SRS, Document 80016), is described in the VisionScope Software Validation Report (Document 80028).

1.1. References

- VisionScope Software Design Specifications (SDS, 80019 – Rev. 0.04)
- VisionScope Software FMEA (80055)
- VisionScope Software Requirements Specifications Documents (80016, Re. 1.9)
- VisionScope Software Validation Document (80029 Rev. 3.0)
- VisionScope Software Revision History Log (80089)

1.2. Terminology

We use the term Software Verification and Validation in accordance with the definition provided in the FDA Guidance Document titled "General Principles of Software Validation, January 11, 2002", downloaded from the FDA web link:

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126955.pdf

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Software verification provides objective evidence that the design outputs of a particular phase of the software development life cycle meet all of the specified requirements for that phase. Software verification looks for consistency, completeness, and correctness of the software and its supporting documentation, as it is being developed, and provides support for a subsequent conclusion that software is validated. Software testing is one of many verification activities intended to confirm that software development output meets its input requirements. Other verification activities include various static and dynamic analyses, code and document inspections, walkthroughs, and other techniques.

Software validation is a part of the design validation for a finished device, but is not separately defined in the Quality System regulation. For purposes of this guidance, FDA considers software validation to be "**confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled.**"

1.3. Abbreviation and Acronym

CCU	Camera Control Unit
DSP	Digital Signal Processing
FTC	Functional Test Case
LCD	Light Crystal Display
SDS	Software Design Specification
SRS	Software Requirement & Specification

2. Verification Equipment Record

	[redacted] (b)(4)
Camera Head Assembly Part Number:	
Revision No.:	
Serial Number(s):	
[redacted] (b)(4)	

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1165

VisionScope Button Board Revision:	[redacted] (b)(4)
Camera Control Unit Assembly Part Number:	
Revision No.:	
Serial Number(s):	
[redacted] (b)(4)	
VisionScope Software Part Number:	
[redacted] (b)(4)	

Supporting Test Equipment

Equipment Used	Model	VisionScope Tool Number
[redacted] (b)(4)		70002
		70041

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16.14 - 80073 - Software Revision History Log

VisionScope Software Revision Log

Software Revision	Date of Release	Initial	Brief Description	Release Type	Detail Log Reference	Verification and Validation	Production Release Engineering Change Order (ECO) Number	Impact on Safety & Effectiveness
[redacted]								

(b) (4)

1273

[redacted] (b) (4)

16.15 - VisionScope Software Unresolved Anomalies as of April 13 2010

VisionScope Technologies LLC
2352 Main Street, Suite 303
Concord, MA 01742
USA
T: 1-978-776-9512
F: 1-978-776-9511

VISIONSCOPE

To: VisionScope FDA 510(k) Submission File

Copy: VisionScope Design History File DHF-VS1

Subject: Unresolved Anomalies (Bugs or Defects) that Affect Safety And Effectiveness

Date: April 13, 2010

References:

- VisionScope Document 80028 Rev. 3 – VisionScope Software Validation Protocol and Report
- VisionScope Document 80029 Rev. 3 - VisionScope Software Verification
- VisionScope Document 80016 Rev. 1.9 – VisionScope Software Requirements Specifications (SRS)
- VisionScope Document 80019 Rev. 0.04 – VisionScope Software Design Specifications (SDS)

The software in the VisionScope system has been verified and validated against the SDS and SRS in the above Verification and Validation documents.

There is no unresolved anomalies (bugs or defects) that will have impact on safety and effectiveness.

The bug tracking and resolution list in Appendix A of VisionScope Software Verification Document 80029 provides support for the above statement.

Lim Cheung
General Manager & CTO

VISIONSCOPE Technologies LLC	Screening Checklist for Traditional Premarket Notification [510(k)] Submissions	Confidential

Section	Table of Contents / Checklist	Present	N/A
1	Medical Device User Fee Cover Sheet (Form FDA 3601)	✓	
2	CDRH Premarket Review Submission Cover Sheet	✓	
2.1	CDRH Premarket Review Submission Cover Sheet	✓	
2.2	Attachment 1 - UTILIZATION OF STANDARDS - Continuation	✓	
3	510(k) Cover Letter	✓	
4	Indications for Use Statement	✓	
5	510(k) Summary	✓	
6	Truthful and Accuracy Statement	✓	
7	Class III Summary and Certification – NA – Blank		✓
8	Financial Certification or Disclosure Statement – NA – Blank		✓
9	Declaration of Conformity and Summary Reports	✓	
9.1	VisionScope Declaration of Conformity	✓	
9.2	Form 3654 - ISO 11135-1	✓	
9.3	Form 3654 - ISO 10993-7	✓	
9.4	Form 3654 - ISO 10993-5	✓	
9.5	Form 3654 - ISO 10993-10	✓	
9.6	Form 3654 - ISO 10993-11	✓	
9.7	Form 3654 - UL 60601-1	✓	
9.8	Form 3654 - IEC 60601-1	✓	
9.9	Form 3654 - EN 60601-1	✓	
9.10	Form 3654 - CAN_CSA 22.2 601.1	✓	
9.11	Form 3654 - IEC 60601-1-4	✓	
9.12	Form 3654 - IEC 60601-1-6	✓	
9.13	Form 3654 - IEC 60601-1-2	✓	
9.14	Form 3654 - IEC 60601-2-18	✓	
10	Executive Summary	✓	
11	Device Description	✓	
11.1	VisionScope Endoscopy System Device Description	✓	
11.2	50006 Endoscope Engineering Drawing	✓	
11.3	50033 Sterile Procedure Kit Engineering Drawing	✓	
11.4	50023 Disposable Endoscope Sheath Engineering Drawing	✓	
11.5	50024 Canula Engineering Drawing	✓	
11.6	50027 Trocar Engineering Drawing	✓	
12	Substantial Equivalence Discussion	✓	
12.1	Substantial Equivalence – Summary	✓	
12.2	Substantial Equivalence Technical Features Comparison	✓	
12.3	InnerVue Reference Guide	✓	
12.4	Smith & Nephew 560 HD Camera System	✓	
12.5	Smith & Nephew 660 HD Image Management System	✓	
12.6	Smith and Nephew Arthroscopes	✓	
12.7	Stryker Evolution of HD Technology Brochure	✓	
12.8	VisionSciences Endosheath	✓	
12.9	VisionSciences Endosheath Urology Published Literature	✓	
13	Proposed Labeling	✓	
13.1	Proposed Labeling - Summary	✓	
13.2	VisionScope Labels and Markings	✓	
13.3	01112 - VisionScope System Instructions for Use	✓	
13.4	01113 - VisionScope Endoscope Instructions for Use	✓	
13.5	01114 - VisionScope Sterile Procedure Kit Instructions for Use	✓	
13.6	01115 - VisionScope Camera Handpiece Instructions for Use	✓	
13.7	80049 - VisionScope Brochure	✓	
13.8	InnerVue™ User Manual	✓	

FDA CDRH DMC
JUN 21 2010
Received

14	Sterilization and Shelf Life	✓	
14.1	Sterilization and Shelf Life - Summary	✓	
14.2	80094 Supplemental Description of the Sterile Endoscope Illumination Sheath as a Protective Barrier	✓	
14.3	Camera & Endoscope ETO Sterilization Efficacy Validation Final Report SPS-0909-329	✓	
14.4	Camera & Endoscope Sterrad 100S Sterilization Efficacy Validation Final Report SPS 0909-327-1	✓	
14.5	Camera & Endoscope Sterrad NX Sterilization Efficacy Validation Final Report SPS 0909-326	✓	
14.6	Camera & Endoscope ETO & ECH Residual Test Report SPS 0909-330	✓	
14.7	Sterile Procedure Kit Tray Sealing PQ-2008-111 Final Report	✓	
14.8	Sterile Procedure Kit Tray Sealing OQ-2008-068 Final Report	✓	
14.9	Sterile Procedure Kit ETO Sterilization Protocol 10209014	✓	
14.10	Summary of Sterile Procedure Kit ETO Fractional Cycle per Protocol 10209014	✓	
14.11	Sterile Procedure Kit Fractional Cycle Sterilization Data	✓	
14.12	Sterile Procedure Kit Fractional Cycle Test Results	✓	
14.13	Sterile Procedure Kit ETO Fractional Cycle Biological Indicator Certificates	✓	
14.14	Sterile Procedure Kit Ship Test Final Report 2008-126	✓	
14.15	Sterile Procedure Kit Aging Test Validation Protocol PQ2008-121	✓	
14.16	Sterile Procedure Kit Label Validation Final Report 2008-112	✓	
15	Biocompatibility	✓	
15.1	Biocompatibility - Summary	✓	
15.2	513842 - ISO 10993-5 MEM Elution Cytotoxicity Test Report of Illumination Sheath	✓	
15.3	513848 - ISO 10993-10 Maximization Sensitization Report of Illumination Sheath	✓	
15.4	513849 - ISO 10993-10 Intracutaneous Reactivity Report of Illumination Sheath	✓	
15.5	513850 - ISO 10993-11 Acute Systemic Injection Report of Illumination Sheath	✓	
15.6	513851 - ISO 10993-11 Materials Mediated Rabbit Pyrogen Report of Illumination Sheath	✓	
(b) (4)	[redacted]		
16	Software	✓	
16.1	Software - Summary	✓	
16.2	80071 VisionScope Software Architecture Design and Description	✓	
16.3	80020 VisionScope Risk Management Plan & Risk Management Summary	✓	
16.4	80013 VisionScope Risk Analysis	✓	
16.5	80014 VisionScope Design FMEA	✓	
16.6	80055 VisionScope Software FMEA	✓	
16.7	IEC60601-1-4 VisionScope Risk Management	✓	

16.8	IEC60601-1-6 VisionScope Usability	✓	
16.9	80016 VisionScope Software Requirements Specifications	✓	
16.10	80019 VisionScope Software Design Specifications	✓	
16.11	80072 VisionScope Traceability Analysis	✓	
16.12	80028 VisionScope Software Validation Document	✓	
16.13	80029 VisionScope Software Verification Document	✓	
16.14	80073 - Software Revision History Log	✓	
16.15	VisionScope Software Unresolved Anomalies	✓	
17	Electromagnetic Compatibility and Electrical Safety	✓	
17.1	Electromagnetic Compatibility and Electrical Safety - Summary	✓	
17.2	UL 60601-1 Certicate CU72100321.01	✓	
17.3	UL 60601-1 + CAN CSA Report	✓	
17.4	EN-IEC 60601-1 Report	✓	
17.5	EN 60601-1-2 EMI-EMC Report	✓	
17.6	IEC 60601-2-18 Endoscope Safety Report	✓	
17.7	Attachment 1 EN-IEC-UL 60601-1 Attachment - Constructional Data Form	✓	
17.8	Attachment 2 National Difference EN60601-1 CB 112A	✓	
17.9	Attachment 3 Test Pictures	✓	
18	Performance Testing – Bench	✓	
18.1	Performance Testing - Summary	✓	
18.2	80030 VisionScope System Validation Protocol & Report	✓	
18.3	80084 VisionScope System Validation in Cadaver labs	✓	
18.4	80099 Validation of Usability of Instructions for Use	✓	
18.5	80026 Verification of VisionScope Instructions for Use per UL60601 and IEC60601-2-18	✓	
18.6	80038 Verification of VisionScope Camera Head and CCU	✓	
18.7	80037 Verification of Endoscopes Illumination Sheath, Cannula and Trocar	✓	
18.8	80083 Sterilization Compatibility Validation Report for Endoscope and Camera Head	✓	
18.9	80082 ETO Sterilization Compatibility of Sterile Procedure Kit including Protective Barrier Effectiveness	✓	
19	Performance Testing – Animal – Not Applicable, Blank		N/A
20	Performance Testing – Clinical – Not Applicable, Blank		N/A

SECTION 17. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY - SUMMARY

VisionScope's electromagnetic compatibility and electrical safety test methodology and results are provided in the documents attached in Section 17.

TUV Rheinland of North America has been retained to perform the testing of the VisionScope Camera Control Unit, Camera Handpiece, and Endoscope. The results indicate that the VisionScope system complies with the following recognized consensus standards listed in the following table.

Standards	Form 3654 Attached	Test Reports Locations (Document No.)
UL 60601-1:2003 R4.06	✓	Documents 17.2, 17.3, 17.7, 17.8, 17.9
IEC 60601-1:1988 + A1:1991 + A2:1995	✓	Documents 17.4, 17.7, 17.8, 17.9
EN 60601-1:1990 + A1 + A2 + A3	✓	Documents 17.4, 17.7, 17.8, 17.9
CAN/CSA-C22.2 No. 601.1-M90	✓	Documents 17.3, 17.7, 17.8, 17.9
IEC/EN 60601-1-2:2007	✓	Document 17.5
IEC 60601-2-18:1996 Second Edition + A1:2000	✓	Document 17.6

17.2 - UL 60601-1 Certificate CU72100321.01

- Zweitschrift (Copy) -

TÜVRheinland

Certificate

Certificate no. CU 72100321 01

License Holder:
VisionScope Technologies, LLC
2352 Main Street, Suite 303
Concord MA 01742
USA

Manufacturing Plant:
VisionScope Technologies, LLC
2352 Main Street, Suite 303
Concord MA 01742
USA

Test report no.: USA-JAK 30993481 003 **Client Reference:** Lim Cheung

Tested to: UL 60601-1:2003 R4.06
CAN/CSA-C22.2 No. 601.1-M90

Certified Product: High Definition Diagnostic and Operative Needle Scope System
License Fee - Units

Model Designation:
1) 50034-0XX (VisionScope Camera Control Unit), 7
2) 50021-0XX (VisionScope Camera Hand Piece)
(X = 0-9, A-Z; not safety-relevant)

Rated Voltage: 1) AC 100-240V, 50/60Hz
Rated Current: 1) 2.0A
Protection Class: 1) I, Type CF applied part

7

Appendix: 1, 1-4
Inh. = 791795 / Deb. = 791795 / Fert. = 791795

Licensed Test mark:

TÜV Rheinland of North America, Inc. C US

Signature

Dipl.-Ing. M. Glagla
QA Certification Officer

Date of Issue (day/mo/yr)
08/02/2010

TÜV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, Tel (203) 426-0888 Fax (203) 426-4009

1282

17.3 - UL 60601-1 + CAN CSA Report

TÜVRheinland®
Precisely Right.

TEST REPORT IEC 60601-1 Medical electrical equipment Part 1: General requirements for safety	
Report reference No. .....:	30993481.003
Compiled by (+ signature).....:	Jan Komarzynski
Reviewed by (+ signature) .....:	Peter Namisnak
Date of issue.....:	January 29, 2010
Testing laboratory.....:	TUV Rheinland of North America Inc.
Address .....:	12 Commerce Road, Newtown, CT 06470, USA
Testing location.....:	CBTL ☒ RMT ☐ SMT ☐ WMT ☐ TMP ☐
Testing location Address.....:	TUV Rheinland of North America Inc. 12 Commerce Road, Newtown, CT 06470, USA
Applicant.....:	VisionScope Technologies, LLC
Address .....:	2352 Main Street, Suite 303 Concord, MA 01742, USA
Standard .....:	IEC 60601-1:1988 + A1:1991 + A2:1995, UL 60601-1:2003 R4.06, CAN/CSA-C22.2 No. 601.1-M90
Test Report Form No. .....:	I601-1_C/97-04
TRF Originator.....:	Underwriters Laboratories Inc.
Master TRF.....:	dated 97-04
Copyright blank test report.....:	the bodies participating in the Committee of Certification Bodies (CCB). This report is based on a blank test report that was prepared by KEMA using information obtained from the TRF originator.
Test procedure.....:	cTUVus Mark
Procedure deviation.....:	AU, CA, DK, IL, KR, US
Non-standard test method .....:	N/A
Type of test object .....:	High Definition Diagnostic and Operative Needle Scope System
Trademark .....:	VISIONSCOPE
Model/type reference .....:	VISIONSCOPE HIGH DEFINITION ENDOSCOPY (1) 50034-0XX (VisionScope Camera Control Unit) (2) 50021-0XX (VisionScope Camera Hand Piece) X=0-9, A-Z (represent non-safety related features such as different configurations, variations or additional marking, etc.)

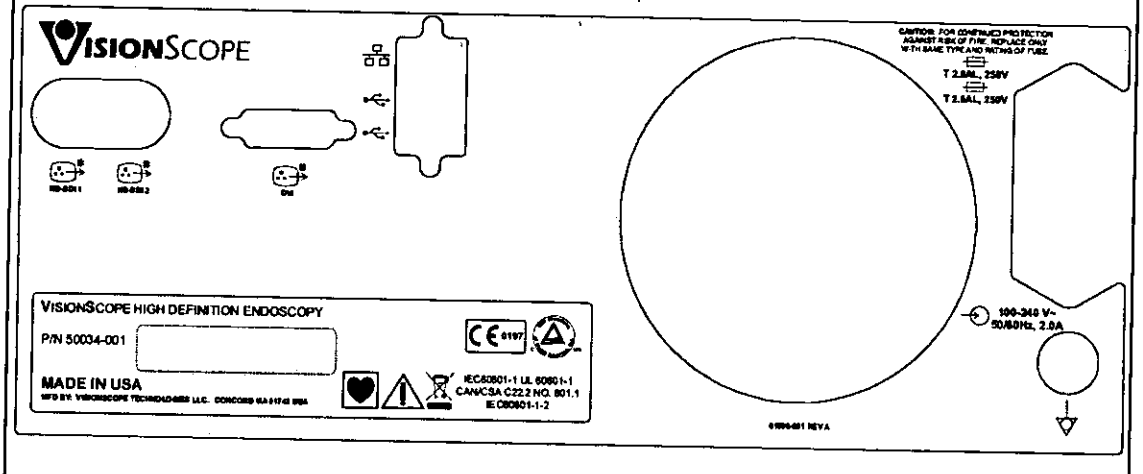
TÜVRheinland®
Precisely Right.

Manufacturer .....:	VisionScope Technologies, LLC
Manufacturer Address .....:	2352 Main Street, Suite 303, Concord MA 01742, USA
Factory.....:	VisionScope Technologies, LLC
Factory Address.....:	2352 Main Street, Suite 303 Concord, MA 01742, USA
Rating .....:	(1) Input: AC 100-240V, 50/60Hz, 2.0A; Protection Class: I (2) Supplied from 50034-0XX (VisionScope Camera Control Unit)

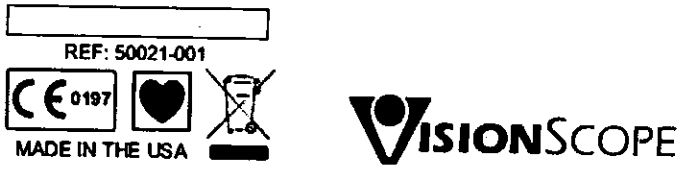
IEC 60601+ Am. 1 & 2

Copy of marking plates

Marking for VisionScope Camera Control Unit (located on the rear panel)



Marking for VisionScope Camera Hand Piece [located on the bottom (Ref. number & symbols) and side (Trademark) of the camera head]



Marking for Light Sheath (located on the side of plastic holder)

1286

IEC 60601+ Am. 1 & 2

GENERAL INFORMATION

Test item particulars (see also clause 5):	Class I
Classification of installation and use ..... :	~~transportable /~~ portable ~~/ stationary / mobile / fixed / permanently installed / hand-held~~
Supply connection .....:	~~internally powered /permanently installed /~~ appliance coupler ~~/ non-detachable cord~~
Accessories and detachable parts included in the evaluation :	Camera Hand Piece (camera head) with attached cable Part Number 50021-0XX (X=0-9, A-Z)
Options included .....:	None

Possible test case verdicts:

- test case does not apply to the test object .....:N / A
- test object does meet the requirement.....:Pass
- test object does not meet the requirement.....:Fail

Abbreviations used in the report:

- normal condition .....:N.C.
- operational insulation.....:OP
- basic insulation between parts of opposite polarity.....:BOP
- double insulation .....:DI
- single fault condition .....:S.F.C.
- basic insulation .....:BI
- supplementary insulation .....:SI
- reinforced insulation.....:RI

Additional Remarks:

1. In this test report the following names are used for the same camera accessory: "Camera Hand Piece" or "Camera Head".
2. The abbreviation IFU refers to "Instructions for Use"

Testing

Date of receipt of test item .....:	November 18, 2009
Date(s) of performance of test .....:	November 18, 2009 – January 29, 2010
.....:	-

IEC 60601+ Am. 1 & 2

General remarks:

"This report is not valid as a CB Test Report unless appended to a CB Test Certificate issued by a NCB, in accordance with IECEE 02".
"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
Throughout this report a point is used as the decimal separator.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of TÜV Rheinland of North America Inc.
List of test equipment must be kept on file and available for review.
Summary of contents provided on the last page of this report.

Summary of compliance with National Differences (for explanation of codes see below):
AU, CA, DK, IL, KR, US

Explanation of Codes:

AU=Australia, CA=Canada, DK=Denmark, IL=Israel, KR=Korea, US=United States of America.

Revision history:

Date:	Amendment No.	Technical/ non-technical	Amendment Description
01/29/2010	30993481.003	Technical	Original Test Report

General product information and considerations:

The medical equipment is VisionScope High Definition Diagnostic and Operative Needle System for medical endoscopy.

The VisionScope System is a family of products designed to enable office-based pre-operative and post-operative arthroscopic imaging and diagnostics. The equipment can also be used in the operating rooms for arthroscopy procedures. In the orthopedic field, this includes but is not limited to diagnostics and treatment of small joints such as the knee, shoulder, ankle, wrist, and elbow.

The key component of the VisionScope is a proprietary 1.4 mm diameter semi-rigid/fiber-lens Endoscope system, which is small enough to fit through a 2 mm portal, a size that fits within the current range of syringe applications. The disposable component includes a proprietary sterile barrier that eliminates the need for Endoscope and camera head reprocessing following each procedure.

VisionScope System is able to miniaturize the arthroscope while still providing High Definition (HD 1080) anatomical visualization, enabling Surgeons to obtain direct visual clinical assessment in a physician examination room without requiring sterilization or bio-hazard processing infrastructure.

The system model designation **VISIONSCOPE HIGH DEFINITION ENDOSCOPY** is made up of:

1. **VisionScope Camera Control Unit** (part number 50034-0XX), which include the following:

(b) (4) [redacted]

- Integrated Light Source and a LCD Touch Screen
- Digital Video Processing Electronics
- Image Management Electronics

1288

IEC 60601+ Am. 1 & 2

The Camera Control Unit is connected to AC mains via appliance inlet (part of power entry module) and detachable power supply cord set.

2. **VisionScope Camera Hand Piece** (part number 50021-0XX) , which include the following:

- Reuseable interchangeable endoscopes
- One-time use disposable illuminator sheaths associated with each endoscope
- One-time use disposable camera head flexible barrier
- One-time use canula
- One-time use trocar

The Camera Hand Piece is connected to Camera Control Unit SELV receptacle via camera cable.

The drawing below shows the system subassemblies

1289

IEC 60601+ Am. 1 & 2

The drawing below shows the System Block Diagram

(b) (4)

[redacted]

1290

The controls, connectors and features for the system subassemblies are shown on Figures 1-3.

Front Panel Layout

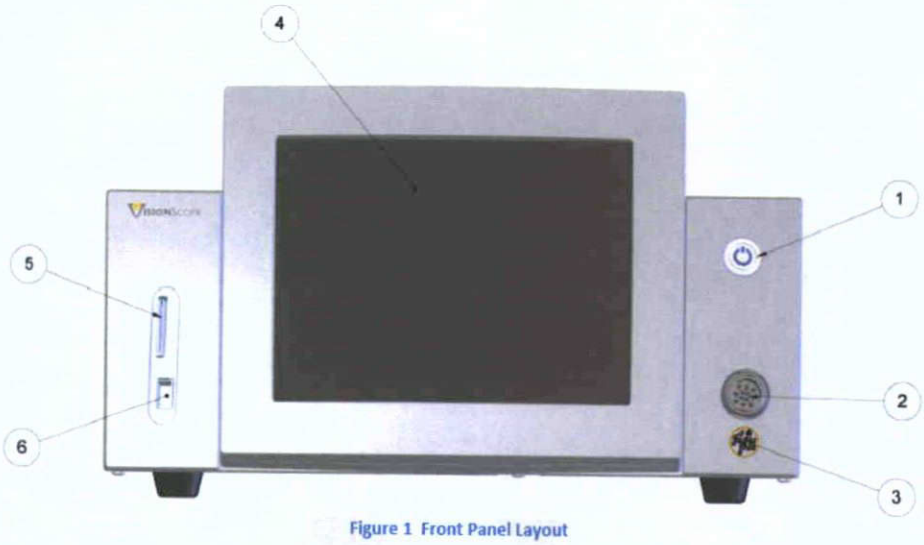


Figure 1 Front Panel Layout

Front Panel Control	Function
1. Power On/Off Switch	Turns the power to the System On or Off. When the switch is depressed, the power indicator light is green.
2. Camera Handpiece Cable Receptacle	Provides DC power and clock signals to the camera handpiece, and receive video data from the camera handpiece.
3.	⚠Warning: Do not plug connector into receptacle if it is wet.
4. LCD Touch Screen	Provides touch interface to allow User to control the camera operation.
5. Secure Digital Multi-media Card Slot	Allows User to store still pictures and video clip on a removable SD MMC card. ⚠Warning: for use with passive media only, do not plug in any active electrical part or cable. Do not use in patient environment.
6. USB Flash Memory Slot	Allows User to store still pictures and video clip on a removable USB Flash Memory Stick. ⚠Warning: for use with passive media only, do not plug in any active electrical part or cable. Do not use in patient environment.

Rear Panel Layout

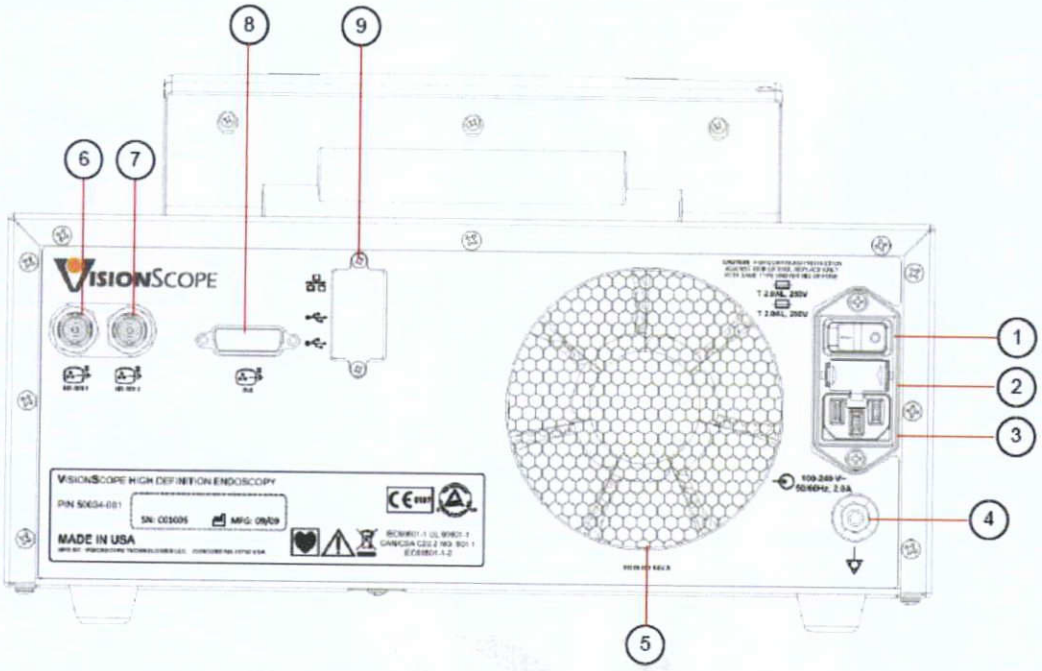


Figure 2 Rear Panel Layout

Rear Panel Connectors/Features	Functions
1. Main Power Switch	Supplies external AC power.
2. Fuse drawer	Contains two fuses in line with Live and Neutral of the AC input. Ratings of fuses shall be 2 Amps, 250 V, slow blow, low breaking capacity (T2.0AL, 250 V).
3. AC Power Plug Receptacle	Accepts AC power input.
4. Equipotential Plug	Enables connection to external equipotential connector.
5. Fan and EMI filter	Provides air circulation and EMI filtering.
6. HD-SDI connector No. 1	HD 1080i video output in Serial Digital Format
7. HD-SDI connector No. 2	HD 1080i video output in Serial Digital Format
8. DVI connector	HD 1080p video output in Digital Visual Format
9. Ethernet (1) and USB (2) receptacles	For Service Use only, do not use in patient environment. These receptacles are normally covered with a plate that can be removed only with a special tool.

Camera Handpiece Layout

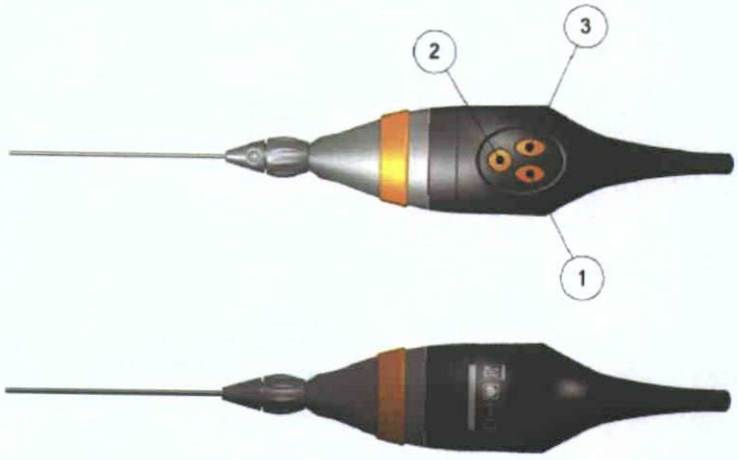


Figure 3 Camera Handpiece Button Layout

Each button serves two functions, depending on how long the button is pressed and released. Unless otherwise re-programmed by the users, the buttons serve the following functions:

Camera Handpiece Button	Short Press (< 1.0 second)	Long Press (≥ 1.0 second)
1. Left Button	Capture a Still Image. Pressing and releasing also closes contact closure switch #1 on the back panel momentarily (100 msec.).	Display last captured Still Image for 1 second.
2. Middle Button	Change video brightness by one step. Functions in a cyclic loop, from 0, +1, +2, +3, -3, -2, -1, 0...	Change video enhancement by one step. Functions in a cyclic loop, from 0, +1, +2, +3, -3, -2, -1, 0...
3. Right Button	Press once to start a video recording. Press again to stop recording. Pressing and releasing also closes contact closure switch #2 on the back panel momentarily (100 milliseconds).	Change color saturation by one step. Functions in a cyclic loop, from 0, +1, +2, +3, -3, -2, -1, 0...

IEC 60601+ Am. 1 & 2

Notes:

1. EMC evaluation is outside the scope of this evaluation and covered by separate test report.
2. On request additional documentation will be provided separately from this report.

This test report includes the following documents:

1. IEC 60601-1Test Report - 68 pages
2. IEC 60601-2-18 Test Report - Attachment 1; 8 pages
3. National Differences - Attachment 2; 20 pages
4. Photographs of Equipment – Attachment 3; 10 pages

Engineering considerations:

When installed, consideration must be given to the following:

- The plastic Camera Hand Piece contains threads that are used to attach endoscope accessory. These parts are considered the applied part.
- Equipment has not been evaluated for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide; end-use requirement.
- Equipment has not been evaluated for use with Oxygen enriched atmospheres; end-use requirement.
- Accessories equipment connected to the digital interfaces of this unit must be certified to the respective IEC standards (i.e. IEC 950 for data processing equipment and IEC 60601-1 for medical equipment.) Furthermore all configurations shall comply with the system standard IEC 60601-1-1. In addition, endoscopic accessories used in conjunction with this equipment are required to comply with the endoscopic equipment standard IEC 60601-2-18.

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
3	**GENERAL REQUIREMENTS**		
3.1	Equipment when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, causes no safety hazard which could reasonably be foreseen and which is not connected with its intended application in normal condition (N.C.) and in single fault condition (S.F.C.)	Unit causes no safety hazard in normal condition and in single fault condition	Pass
3.4	An alternative means of construction is used to that detailed in this standard and it can be demonstrated that an equivalent degree of safety is obtained	No alternative means of construction used	N/A

5	**CLASSIFICATION**		
5.1	Type of protection against electric shock		
	Class I equipment	The equipment is classified as Class I; appliance inlet IEC 60320 C14 provided	Pass
	Class II equipment	See above	N/A
	Internally powered equipment	Energized from external electrical power source	N/A
5.2	Degree of protection against electric shock		
	Type B applied part		N/A
	Type BF applied part		N/A
	Type CF applied part	Type CF applied part	Pass
	Not classified - no applied parts	See above	N/A
5.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1.1)..... :	IPX0	Pass
5.4	Methods of sterilization or disinfection	Methods are specified in the Instruction for Use	Pass
5.5	Equipment not suitable for use in the presence of flammable mixtures	Not suitable for use in the presence of flammable mixtures	Pass
	Category AP equipment	See above	N/A
	Category APG equipment	See above	N/A

1295

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
5.6	Mode of operation:		
	-continuous operation	Suitable for continuous operation	Pass
	-short-time operation, specified operation; period ...:	See above	
	-intermittent operation, specified operation; rest period .....:	See above	
	-continuous operation with short-time, stated permissible loading time ..... :	See above	
	-continuous operation with intermittent, stated permissible loading/rest time .....:	See above	

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

INSULATION DIAGRAM

(b)(4)

[redacted]

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

(b)(4)

[redacted]

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

(b)(4)

[redacted]

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
6	**IDENTIFICATION, MARKING AND DOCUMENTS**		
6.1	Marking on the outside of equipment or equipment parts		
	c) Markings of the specific power supply affixed	(b)(4) [redacted]	
	d) If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents		
	e) Name and/or trademark of the manufacturer or supplier		
	f) Model or type reference.....		
	g) Rated supply voltages or voltage range(s)		
	Number of phases		
	Type of current.....		
	h) Rated frequency or rated frequency range(s) (Hz)		
	j) Rated power input (VA, W or A)		
	k) Power output of auxiliary mains socket-outlets		
	l) Class II symbol		
	Symbol for degree of protection against ingress of water provided		
	Symbol for protection against electric shock		
	If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets		
	Symbol for protection of defibrillation-proof applied parts		
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable		
	m) Mode of operation (if no marking, suitable for continuous operation)		
	n) Types and rating of external accessible fuses....:		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	p) Ratings of external output.....	(b)(4) [redacted]	
	q) Symbol for physiological effect(s):		
	- attention, consult accompanying documents		
	- non-ionizing radiation, or symbols as adopted by ISO or IEC 417		
	r) Anaesthetic-proof symbol: AP or APG.....		
	s) Dangerous voltage symbol		
	t) Special cooling requirements		
	u) Limited mechanical stability		
	v) Protective packing requirement(s)		
	- Marking(s) for unpacking safety hazard(s)		
	- Equipment or accessories, marked as sterile		
	y) Potential equalization terminal		
	- Functional earth terminal		
	z) Removable protective means		
	Durability of marking test		
6.2	Marking on the inside of equipment or equipment p		
	a) Nominal voltage of permanently installed equipment		
	b) Maximum power loading for heating elements or holders for heating lamps		
	c) Dangerous voltage symbol		
	d) Type of battery and mode of insertion		
	- Marking referring to accompanying documents used for battery not intended to be changed by the operator		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	e) Fuses accessible with a tool identified either b type and rating or by a reference to diagram	(b)(4) [redacted]	
	f) Protective earth terminal		
	g) Functional earth terminal		
	h) Supply neutral conductor in permanently installed equipment (N)		
	j) Markings required in 6.2 f), h), k) ,and l) remain visible after connection and are not affixed to parts which have to be removed		
	- Markings comply with IEC 445		
	k) For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for sma equipment)		
	l) Statement for suitable wiring materials at temperatures over 75 °C		
	n) Capacitors and/or circuit parts marked as required in Sub-clause 15c		
6.3	Marking of controls and instruments		
	a) Mains switch clearly identified		
	- ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light		
	b) Indication of different positions of control devices and switches		
	c) Indication of the direction in which the magnitude of the function changes, or an indicating device		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	f) The functions of operator controls and indicators are identified	(b)(4) [redacted]	
	g) Numeric indications of parameters are in SI units except for units listed in Am. 2		
6.4	Symbols		
	Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)		
6.5	Colors of the insulation of conductors		
	a) Protective earth conductor has green/yellow insulation		
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations		
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow		
	d) Color of neutral conductor .....:		
	e) Colors of phase conductor(s) .....:		
	- Compliance with IEC 227 and IEC 245		
	f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors		
6.6	Medical gas cylinders and connections		
	a) In accordance with ISO ISO/R 32		
	b) Identification of connection point		
6.7	Indicator lights and push-buttons		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action	(b)(4) [redacted]	
	- Yellow used to indicate caution or attention required		
	- Green used to indicate ready for action		
	b) Color red used only for push-buttons by which a function is interrupted in case of emergency		
6.8	ACCOMPANYING DOCUMENTS		
6.8.1	Equipment accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer		
	Classifications specified in Clause 5 included in both the instructions for use and the technical description		
	Markings specified in Sub-clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment		
	Warning statements and the explanation of warning symbols provided in the accompanying documents		
6.8.2	Instructions for use		
	a) General information provided in instructions for use		
	- state the function and intended application of the equipment		
	- include an explanation of: the function of controls, displays and signals		
	- the sequence of operation		
	- the connection and disconnection of detachable parts and accessories		
	- the replacement of material which is consumed during operation		
	- information regarding potential electromagnetic or other interference and advice regarding avoidance		

1304

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety	(b)(4) [redacted]	
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance		
	General information provided in instructions:		
	- information for the safe performance or routine maintenance		
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied		
	- explanation of figures, symbols, warning statements and abbreviations on the equipment		
	c) Signal output or signal input parts intended only for connection to specified equipment described		
	d) Details about acceptable cleaning, disinfection or sterilization methods included		
	e) Warning statement for mains operated equipment with additional power source		
	f) A warning to remove primary batteries if equipment is not likely to be used for some time		
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries		
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1		
	j) Identification of any risks associated with the disposal of waste products, residues, etc.		
	- Advice in minimizing these risks		
6.8.3	Technical description		
	a) All characteristics essential for safe operation provided		
	b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment		

1 305

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
		(b)(4) [redacted]	
	- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use		
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided		
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging		
7	**POWER INPUT**		
	Power Input Measurements		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
		(b)(4) [redacted]	
10	**ENVIRONMENTAL CONDITIONS**		
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer		
10.2.2a	Rated voltage not exceeding 250 V for hand-held equipment		
	Rated voltage not exceeding 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for equipment up to 4kVA		
	Rated voltage not exceeding 500 V for all other equipment		
	Rated input frequency not more than 1kHz		
10.2.2b	Internal replaceable electrical power source specified		
14	**REQUIREMENTS RELATED TO CLASSIFICATI**		
14.4a	Class I and Class II equipment in addition to basic insulation provided with an additional protection		
14.4b	Equipment supplied from external dc source of reverse polarity results in no safety hazard		
14.5b	Internally powered equipment complies with requirements for Class I or Class II equipment while connected to supply mains, and with requirements for internally powered equipment when not connected		
14.6c	Applied parts intended for direct cardiac application are of type CF		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
15	**LIMITATION OF VOLTAGE AND/OR ENERGY**	(b)(4) [redacted]	
15b	Voltage measured one sec after disconnection of the mains plug does not exceed 60V		
15c	For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceed 2 mJ		
	Marking provided for manual discharging		
16	**ENCLOSURES AND PROTECTIVE COVERS**		
16a	Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)		
	Insertion or removal of lamps - protection against contact with live parts provided		
16b	Opening in a top cover positioned that accessibility of live parts by a test rod is prevented		
16c	Conductive parts accessible after the removal of h		
	- have a resistance of not more than 0.2 Ω		
	- separated from live parts by one of the means described in Sub-clause 17g		
16d	Parts with voltage exceeding 25V a.c. or 60V d.c. which cannot be disconnected by external mains switch or plug protected against contact		
16e	Removable enclosures protecting against contact		
	- Removal possible only with the aid of a tool		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- Use of automatic device making parts not live when the enclosure is opened or removed	(b)(4) [redacted]	
	- Exception 16e applied to the following parts		
16f	Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts		
17	**SEPARATION**		
17a	Separation method of the applied part from live par		
	1) basic insulation: applied part earthed		
	2) by protectively earthed conductive part (e.g. screen)		
	3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure		
	4) by double or reinforced insulation		
	5) by protective impedances limiting current to applied part		
	- Additional leakage current test in single fault conditions		
17c	There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed		
17d	Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)		
17g	Separation method of accessible parts other than a		
	1) basic insulation: accessible part earthed		
	2) by protectively earthed conductive part (e.g. screen)		
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure		

1309

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	4) by double or reinforced insulation	(b)(4) [redacted]	
	5) by protective impedances limiting current to accessible part		
	- Additional leakage current test in single fault conditions		
17h	Arrangements used to isolate defibrillation-proof ap		
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator		
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function		
18	**PROTECTIVE EARTHING, FUNCTIONAL EARTH EQUALIZATION**		
18a	Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal		
18b	Protective earth terminals suitable for connection to the protective earth conductor		
18e	Potential equalization conductor		
	- Readily accessible		
	- Accidental disconnection prevented in normal use		
	- Conductor detachable without the use of a tool		
	- Power supply cord does not incorporate a potential equalization conductor		
	- Connection means marked with Symbol 9, Table DI		
18f	For equipment without power supply cord, impedance between protective earth terminal and accessible metal part ≤ 0.1 Ω		
	- For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part ≤ 0.1 Ω		

1310

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part ≤ 0.2 Ω	(b)(4) [redacted]	
18g	If the impedance of protective earth connections other than in Cl. 18 f) exceeds 0.1 Ω, the allowable value of the enclosure leakage current is not exceeded in single fault condition		
18k	Functional earth terminal not used to provide protective earthing		
18l	Class II equipment with isolated internal screens		
	- insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation		
	- functional earth terminal clearly marked		
	- explanation of functional earth terminal provided in the accompanying documents		
19	**CONTINUOUS LEAKAGE CURRENTS AND PAT**		
19.1b	Leakage currents		
	- earth leakage current		
	- enclosure leakage current		
	- patient leakage current		
	- patient auxiliary current		
20	**DIELECTRIC STRENGTH**		
	Overall compliance with Clause 20		
21	**MECHANICAL STRENGTH**		
21a	Sufficient rigidity of an enclosure tested by: force of 45 N		
21b	Sufficient strength of an enclosure tested by: impact hammer		
21c	On portable equipment carrying handles or grips withstand the requirements of the loading test		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
21.3	No damage to parts of patient support and/or immobilization system after the loading test	(b)(4) [redacted]	
21.5	Hand held equipment or equipment parts are safe after drop test		
21.6	Portable and mobile equipment is able to withstand rough handling		
22	**MOVING PARTS**		
22.2a	Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment		
22.2b	Moving parts of a stationary equipment are provided with similar guards as above, unless it is evident that equivalent protection is separately provided during installation		
22.3	Cords (ropes), chains and bands are provided with guides to prevent them from running off or from jumping out of their guiding devices		
	Guides or other safeguards are removable only with a tool		
22.4	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation by the operator		
22.6	Parts of equipment subject to mechanical wear are accessible for inspection		
22.7	Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard		
	The means for emergency switching is readily identifiable and accessible and does not introduce a further safety hazard		
	Devices for emergency stopping able to break the full load current of the relevant circuit, taking into account possible stalled motor currents		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Means for stopping of movements operate as a result of one single action	(b)(4) [redacted]	
23	**SURFACES, CORNERS AND EDGES**		
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered		
24	**STABILITY IN NORMAL USE**		
24.1	Equipment does not overbalance during normal use when tilted through an angle of 10°		
24.3	Equipment overbalances when tilted through an an		
	- does not overbalance when tilted through an angle of 5° in any position excluding transport		
	- carry a warning notice stating that transport should only be undertaken in a certain position		
	- in the position specified for transport does not overbalance when tilted to an angle of 10°		
24.6a	Equipment or its parts with a mass of more than 20 k		
	- suitable handling devices (grips etc.), or		
	- instructions for lifting and handling during assembly		
24.6b	b) On portable equipment with a mass of more than 20 kg carrying handle(s) is (are) so situated that equipment may be carried by 2 or more persons		
25	**EXPELLED PARTS**		
25.1	Protective means are provided where expelled parts of the equipment could be a hazard		
25.2	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion		
28	**SUSPENDED MASSES**		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
28.3	Suspension system with safety device	(b)(4) [redacted]	
	Safety device provided where the integrity of a suspension depends on parts which may have hidden defects, or on parts having safety factors not complying with Sub-clause 28.4		
	Safety device has safety factors complying with Sub-clause 28.4.2		
	Clear indication to the operator that the safety device has been activated after failure of suspension means		
28.4	Suspension systems of metal without safety device		
	1) Total load does not exceed the safe working load		
	2) Safety factors not less than 4 where it is unlikely that supporting characteristics will be impaired		
	3) Safety factors not less than 8 where impairment is expected		
	4) Safety factors multiplied by 1.5 for metal having an elongation at break of less than 5%		
	5) Sheaves, sprockets, band wheels and guides so constructed that the safety factors maintained till replacement		
29	**X-RADIATION**		
29.2	EQUIPMENT not intended to produce X-radiation produces an exposure ≤ 130 nC/kg (0.5 mR)		
36	**ELECTROMAGNETIC COMPATIBILITY**		
	Equipment complies with IEC 601-1-2		
37	**COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT**		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Requirements for category AP and APG equipment (Cl. 37 - 41)	(b)(4) [redacted]	
42	**EXCESSIVE TEMPERATURES**		
42.1	Equipment does not attain temperatures exceeding the values given in Table Xa over the range of ambient temperatures per Clause 10.2.1		
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25°C ambient		
42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41°C		
42.5	Guards to prevent contact with hot surfaces removable only with a tool		
43	**FIRE PREVENTION**		
	Strength and rigidity necessary to avoid a fire hazard		
44	**OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, CLEANING, STERILIZATION AND DISINFECTIO**		
44.2	Equipment contain a liquid reservoir:		
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min		
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15° in the least favorable direction(s) (if necessary with refilling)		
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)		
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard		
44.5	Equipment sufficiently protected against the effects of humidity		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
		(b)(4) [redacted]	
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529		
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions		
45	**PRESSURE VESSELS AND PARTS SUBJECT T**		
45.2	Pressure vessel with pressure volume greater than 200 kPa x l and pressure greater than 50 kPa withstand the hydraulic test pressure		
45.3	Maximum pressure does not exceed the maximum permissible working pressure for individual parts		
45.7	Unless excessive pressure can not occur, pressure-relief device provided		
45.7a	Pressure-relief device connected as close as possible to the pressure vessel		
45.7b	Readily accessible for inspection		
45.7c	Not capable of being adjusted or rendered inoperative without a tool		
45.7d	Discharge opening located that the released material is not directed towards person		
45.7e	Discharge opening located that operation will not deposit material which may cause a safety hazard		
45.7f	Adequate discharge capacity to ensure pressure does not exceed the maximum permissible working pressure		
45.7g	No shut-off valve between a pressure-relief device and the parts intended to be protected		
45.7h	Minimum number of cycles of operation: 100.000		
48	**BIOCOMPATIBILITY**		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Parts of equipment and accessories intended to come into contact with biological tissues, cells or body fluids are evaluated in accordance with ISO 10993-1	(b)(4) [redacted]	
49	**INTERRUPTION OF THE POWER SUPPLY**		
49.1	Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard		
49.2	Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function		
49.3	Means are provided for removal of mechanical constraints on patient in case of a supply mains failure		
51	**PROTECTION AGAINST HAZARDOUS OUTPU**		
51.4	Equipment furnishing both low-intensity and high-intensity outputs provided with means minimizing possibility of a high intensity output being selected accidentally		
52	**ABNORMAL OPERATION AND FAULT CONDIT**		
52.1	Equipment is so designed and manufactured that even in single fault condition no safety hazard as described under 52.4 exists (see 3.1 and Cl. 13)		
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4		
52.5.2	Failure of thermostats presents no safety hazards		
52.5.3	Short-circuiting of either part of double insulation presents no safety hazard		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
52.5.5	Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5°C	(b)(4) [redacted]	
52.5.6	Locking of moving parts presents no safety hazard		
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard		
52.5.8	Duration of motors locked rotor test in compliance with Cl. 52.5.8		
52.5.9	Failure of one component at a time presents no safety hazard		
52.5.10	Overload of heating elements presents no safety hazard		
	f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection		
	h) Equipment with three-phase motors can safely operate with one phase disconnected		
56	**COMPONENTS AND GENERAL ASSEMBLY**		
	List of critical components		
56.1b	Ratings of components not in conflict with the conditions of use in equipment		
	Ratings of mains components are identified		
56.1d	Components, movements of which could result in a safety hazard mounted securely		
56.1f	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard		
56.3a	Connectors provide separation required by Sub-clause 17g		
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment		
	Medical gas connections not interchangeable		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
56.3b	Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken	(b)(4) [redacted]	
56.3c	Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.		
56.4	Connections of capacitors		
	Not connected between live parts and non-protectively earthed accessible parts		
	If connected between mains part and protectively earthed metal parts comply with: IEC Publication 384-14		
	Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts		
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs		
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment		
56.6	Temperature and overload control devices		
	a) Thermal cut-outs which have to be reset by a soldering not fitted in equipment		
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits		
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard		
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard		
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times		
	Non-self resetting over-current releases operated 10 times		
56.6b	Thermostats with varying temperature settings clearly indicated		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Operating temperature of thermal cut-outs indicated	(b)(4) [redacted]	
56.7	Batteries		
	a) Battery compartments:		
	- adequately ventilated		
	- accidentally short-circuiting is prevented		
	b) Incorrect polarity of connection prevented		
56.8	Indicators - unless indication provided by other me position), indicator lights are used (color see 6.7):		
	- to indicate that equipment is energized		
	- to indicate the operation of non-luminous heaters if a safety hazard could result		
	- to indicate when output exists if a safety hazard could result		
	- charging mode indicator provided		
56.10	Actuating parts of controls		
56.10b	Actuating parts are adequately secured to prevent them from working loose during normal use		
	Controls are secured to prevent the movement relative to scale marking (safety related only)		
	Detachable indicating devices are prevented from incorrect connection without the use of tool		
56.10c	Stops are provided on rotating controls:		
	- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard		
	- to prevent damage to wiring		
56.11	Cord-connected hand-held and foot-operated contr		

1320

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17g	(b)(4) [redacted]	
	b) Hand-held control devices comply with the requirement and test of Sub-clause 21.5		
	- Foot-operated control devices designed to support the weight of an adult human being		
	c) Devices not change their setting when inadvertently placed		
	d) Foot-operated control devices are at least IPX 1		
	- For surgical use, electrical switching parts are IPX 8		
	e) Adequate strain relief at the cord entry provided		

57	**MAINS PARTS, COMPONENTS AND LAYOUT**		
57.1	Isolation from supply mains	(b)(4) [redacted]	
	a) Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously		
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents		
	d) Switches used to comply with Sub-clause 57.1a comply with the creepage distances and air clearances as specified in IEC Publication 328		
	f) Mains switches not incorporated in a power supply cord		
	h) Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a		
	m) Fuses and semiconductor devices not used as isolating devices		
57.2	Mains connectors and appliance inlets		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	e) Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a mains plug	(b)(4) [redacted]	
	g) Unless functional earth needs to be provided, Class I appliance inlet is not used in Class II equipment		
57.3	Power supply cords		
	a) Not more than one connection to a particular supply mains		
	If alternative supply allowed, no safety hazards when more than one connection is made simultaneously		
	The mains plug has only one power supply cord		
	Non-permanently connected equipment provided with power supply cord or appliance inlet		
	b) Power supply cords sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53		
	Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75°C		
	c) Nominal cross-sectional area of conductors of power supply cords not less than in Table XV		
	d) Stranded conductors not soldered if fixed by any clamping means		
57.4	Connection of power supply cords		
57.4a	Cord anchorages		
(b)(4) [redacted]			

1322

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting	(b)(4) [redacted]	
	Tying the cord into a knot or tying the ends with string not used		
	Cord anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation		
	Cord anchorages made of metal provided with an insulating lining		
	Clamping screws do not bear directly on the cord insulation		
	Screws associated with cable replacement are not used to secure other components		
	Conductors of the power supply cord arranged that the protective earth conductor is not subject to strain as long as the phase conductors are in contact with their terminals		
57.4b	Power supply cord protected against excessive bending		
57.4c	Adequate space inside equipment to allow the supply cable conductors to be introduced and connected		
57.5	Mains terminal devices and wiring of mains part		
	Mains connected equipment other than those with a detachable supply cord provided with mains terminals, where connections are made with screws, nuts or equally effective methods		
	If a conductor breaks away, barriers are provided such that creepage distances and air clearances cannot be reduced		
	Screws and nuts which clamp external conductors not serve to fix any other component		
	b) Terminals closely grouped with any protective earth terminal		
	Mains terminal devices accessible only with use of a tool		
	Mains terminal devices located or shielded that, should a wire of a stranded conductor escape when the conductors are fitted, there is no risk of accidental contact		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	c) Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened	(b)(4) [redacted]	
	d) Cord terminals not require special preparation of the conductor		
57.6	Mains fuses and overcurrent releases		
	Fuses or over-current releases provided accordingly for Class I and Class II		
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current		
	Protective earth conductor not fused		
	Neutral conductor not fused for permanently installed equipment		
57.8	Wiring of the mains part		
	a) Individual conductor in the mains part with insulation not at least electrically equivalent to that of the individual conductors of flexible supply cords complying with IEC 227 or 245, treated as bare conductor		
	b) Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply cord		
	Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits sufficient to prevent any fire hazard		
57.9	Mains supply transformers		
	(b)(4) [redacted]		
57.9.1	Overheating		(b)(4) [redacted]
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative		
57.9.1a	Short-circuit of secondary windings not caused excessive temperature		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
57.9.1b	Overload of secondary windings not caused excessive temperature	(b)(4) [redacted]	
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests		
57.9.4	Construction		
	a) Separation of primary and secondary windings		
	- separate bobbins or formers		
	- one bobbin with insulating partition		
	- one bobbin with concentric windings and having copper screen with a thickness of not less than 0.13 mm		
	- concentrically wound on one bobbin with windings separated by double insulation		
	c) Means provided to prevent displacement of end turns		
	d) Insulated overlap of not less than 3 mm if a protective earthed screen has only one turn		
	e) Insulation between the primary and secondary ir insulation		
	- 1 insulation layer with thickness of at least 1 mm		
	- at least 2 insulation layers with a total thickness of at least 0.3 mm		
	- three layers provided that each combination of two layers can withstand the dielectric strength test for reinforced insulation		
	g) Exit of the wires of toroidal transformers provided with double sleeving complying with requirements for double insulation and having total thickness at least 0.3 mm extending at least 20 mm outside the winding		
57.10	Creepage distances and air clearances		
	a) Values: compliance with at least the values of Table XVI		
	Creepage distances for slot insulation of motors at least 50% of the specified values		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	b) Minimum creepage distances and air clearances in the mains part between parts of opposite polarity not required if short-circuting does not produce a safety hazard	(b)(4) [redacted]	
	c) Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts		
58	**PROTECTIVE EARTHING - TERMINALS AND C**		
58.1	Clamping means of the protective earth terminal		
	Not be able to loosen without the aid of a tool		
	Screws for internal earth connections are covered or protected against loosening from outside		
58.7	Earth pin of the appliance inlet regarded as the protective earth terminal		
58.8	The protective earth terminal not used for the mechanical connection or the fixing of any component not related to earthing		
58.9	Where the protective earth connections are made via a plug or socket device the protective earth connection is made before and interrupted after the supply connections during connection and interrupting		
59	**CONSTRUCTION AND LAYOUT**		
59.1	Internal wiring		
	a) Cables and wiring protected against contact with a moving part		
	Wiring having basic insulation only protected by additional fixed sleeving		
	Components are not likely to be damaged in the normal assembly or replacement of covers		
	b) Movable leads are not bent around a radius of less than five times the outer diameter of the lead		
	c) Insulating sleeving adequately secured		
	If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC 245 and dielectric test		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material	(b)(4) [redacted]	
	d) Aluminum wires of less than 16 mm^2 cross-section not used		
	f) Connecting cords between equipment parts considered as belonging to the equipment		
59.2	Insulation		
	b) Mechanical strength and resistance to heat and fires retained by all types of insulation		
	c) Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts		
	Parts of rubber resistant to ageing		
59.3	Excessive current and voltage protection		
	Internal electrical power source provided with device for protection against fire hazard		
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuseholder		
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.		
59.4	Oil containers		
	Oil containers adequately sealed		
	Container allow for the expansion of the oil		
	Oil containers in mobile equipment sealed to prevent the loss of oil during transport		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level	(b)(4) [redacted]	

IEC 60601+ Am. 1 & 2

6.1	TABLE: marking durability	Pass
Marking tested	Remarks	
Rating marking; distilled water.	Clearly legible and did not curl on the edges	
Rating marking; methylated spirit.	Clearly legible and did not curl on the edges	
Rating marking; isopropyl alcohol.	Clearly legible and did not curl on the edges	
Supplementary information: Test applied to all labels and silk screens.		

7	TABLE: power input				Pass
Operating condition	Voltage	Frequency	Current	Power	Remarks

(b)(4)

[redacted]

15b	TABLE: residual voltage in attachment plug	Pass

(b)(4)

[redacted]

IEC 60601+ Am. 1 & 2

Supplementary information:

1.The tests were performed (b)(4) [redacted] was disconnected at the peak voltage or close to the peak voltage.

2. The tests were performed for ON and OFF positions of the power entry module switch.

15c	TABLE: residual voltage or energy in capacitors				N/A
Capacitor and its location	Residual voltage (V)	Time after disconnection (s)	Capacitance value (μF)	Residual energy (mJ)	Remarks

Supplementary information:

No such hazard accessible to the operator. No access cover provided; refer to clause 15c for details.

17h1	TABLE: defibrillation-proof applied parts				N/A
Test Condition: Fig. 50 or 51	Accessible part of measurement:	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks

Supplementary information: No defibrillation-proof applied parts.

17h2	TABLE: defibrillation-proof recovery time			N/A
Applied part with test voltage	Test voltage polarity	Recovery time from accompanying documents (s)	Measured recovery time (s)	Remarks

Supplementary information: No defibrillation-proof applied parts.

18	TABLE: protective earthing			Pass
Test location	Test current (A)	Measured voltage (V)	Resistance (ohms)	Remarks

(b)(4) [redacted]

1330

IEC 60601+ Am. 1 & 2

(b)(4) [redacted]

Supplementary information: All tests were performed for 2 minutes.

19	TABLE: leakage current				Pass
Type of leakage current and test condition (including single faults)		Supply voltage (VAC)	Supply frequency (Hz)	Measured max. value (uA)	Remarks

(b)(4) [redacted]

IEC 60601+ Am. 1 & 2

(b)(4)

[redacted]

1332

IEC 60601+ Am. 1 & 2

(b)(4)

[redacted]

1333

IEC 60601+ Am. 1 & 2

(b)(4)

[redacted]

1334

IEC 60601+ Am. 1 & 2

(b)(4) [redacted]

Abbreviations used:	
ER - Earth leakage current EN - Enclosure leakage current P - Patient leakage current PM - Patient leakage current with mains on the applied parts PA -Patient auxiliary current Fig. 15 - refers to Fig. 15 in IEC601-1 MD - Measuring device	A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition

20	TABLE: dielectric strength				Pass
Insulation under test (area from insulation diagram)	Insulation type: (OP-operational / BI-basic / SI-supplementary / DI-double / RI-reinforced)	Reference voltage (VAC)	Test voltage (VAC)	Remarks	
A	A-f: (BOP), Mains (Line to Neutral)	(b)(4) [redacted]			
B	A-e: (DI/RI), Mains to SIP/SOP				
C	A-a1: (BI), Mains to protectively earthed metal parts				
E	B-a: (RI), Camera internal circuitry to outside camera enclosure, cable insulation and endoscope				

1335

IEC 60601+ Am. 1 & 2

		(b)(4) [redacted]
E	B-d: (BI), Camera internal circuitry to outside camera enclosure, cable insulation and endoscope	
F	B-d: (BI), Protectively earthed metal parts to entire camera assembly and endoscope	
G	B-a: (DI), Mains to entire camera assembly and endoscope	
H	A-a2: (DI), Mains to accessible parts not protectively earthed	

Supplementary information:
Maximum reference voltage is mains supply voltage 240Vac. The tests have been performed before humidity, after humidity requirements of clause 44.5 and after cleaning/disinfection requirements of clause 44.7.

21	TABLE: mechanical strength	Pass
Part under test	Test (impact, drop, force, handle, rough handling, mobile)	Remarks
Enclosure	21a) 45N Force	No hazard
Enclosure	21b) 0.5J Impact	No hazard
Camera Hand Piece	21.5) 1m Drop	No Hazard
Camera Control Unit	21.6) 5cm Drop	No hazard
Camera Hand Piece	1.22m Drop	No hazard (clause 55 for US national differences)
Enclosure	Impact test 6.78Nm; from height 1.3m	No hazard (clause 55 for US national differences)
Enclosure (plastic parts)	Stress relief test at 70°C for 7h	No deformation (clause 55 for US national differences)

IEC 60601+ Am. 1 & 2

Supplementary information: Where applicable the tests were performed on top, side and bottom part of the enclosure.

24	TABLE: - stability		Pass
Part under test	Test condition	Remarks	
Power supply unit	Tilt to 10°	Remains stable	
Supplementary information: --			

29	TABLE: X – radiation		N/A
Part under test	Test condition	Measured radiation (mR)	Remarks
Supplementary information: No such hazard			

IEC 60601+ Am. 1 & 2

(b)(4)

[redacted]

1338

IEC 60601+ Am. 1 & 2

(b)(4)

[redacted]

1339

IEC 60601+ Am. 1 & 2

(b)(4)

[redacted]

Notes:
See supplementary information below.

Notations: A: (measured); B: linear calculated for 40°C; C: linear calculated for 25°C ; COR - indicates measurements taken using change-of-resistance method

1340

IEC 60601+ Am. 1 & 2

(b)(4)

[redacted]

1341

IEC 60601+ Am. 1 & 2

(b)(4)

[redacted]

Supplementary information:

(b)(4)

[redacted]

1342

IEC 60601+ Am. 1 & 2

(b)(4)

[redacted]

1343

IEC 60601+ Am. 1 & 2

(b)(4)

[redacted]

1344

IEC 60601+ Am. 1 & 2

(b)(4)

[redacted]

1345

IEC 60601+ Am. 1 & 2

(b)(4)

[redacted]

1346

IEC 60601+ Am. 1 & 2

(b) (4)

[redacted]

(b) (4)

[redacted]

IEC 60601+ Am. 1 & 2

(b) (4)

[redacted]

IEC 60601+ Am. 1 & 2

(b) (4)

[redacted]

IEC 60601+ Am. 1 & 2

(b) (4)

[redacted]

End of Report

17.4 - EN-IEC 60601-1 Report

TÜVRheinland®
Precisely Right.

TEST REPORT
IEC 60601-1
Medical electrical equipment
Part 1: General requirements for safety

Report reference No.	(b) (6), (b) (4) [redacted]
Compiled by (+ signature).....	
Reviewed by (+ signature).....	
Date of issue.....	January 29, 2010
Testing laboratory.....	TUV Rheinland of North America Inc.
Address	12 Commerce Road, Newtown, CT 06470, USA
Testing location.....	CBTL ☒ RMT ☐ SMT ☐ WMT ☐ TMP ☐
Testing location Address.....	TUV Rheinland of North America Inc. 12 Commerce Road, Newtown, CT 06470, USA
Applicant.....	VisionScope Technologies, LLC
Address	2352 Main Street, Suite 303 Concord, MA 01742, USA
Standard	IEC 60601-1:1988 + A1:1991 + A2:1995, EN 60601-1:1990 + A1 + A2 + A13
Test Report Form No.	I601-1_C/97-04
TRF Originator.....	Underwriters Laboratories Inc.
Master TRF.....	dated 97-04
Copyright blank test report.....	the bodies participating in the Committee of Certification Bodies (CCB). This report is based on a blank test report that was prepared by KEMA using information obtained from the TRF originator.
Test procedure.....	CE Marking
Procedure deviation.....	AU, CA, DK, IL, KR, US
Non-standard test method	N/A
Type of test object	High Definition Diagnostic and Operative Needle Scope System
Trademark	VISIONSCOPE
Model/type reference	VISIONSCOPE HIGH DEFINITION ENDOSCOPY (1) 50034-0XX (VisionScope Camera Control Unit) (2) 50021-0XX (VisionScope Camera Hand Piece) X=0-9, A-Z (represent non-safety related features such as different configurations, variations or additional marking, etc.)

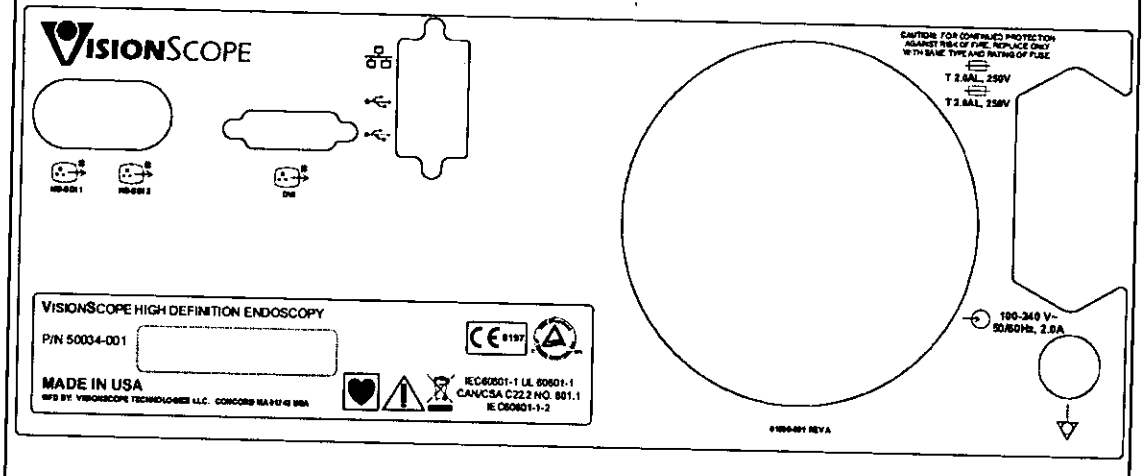
TÜVRheinland®
Precisely Right.

Manufacturer .....:	VisionScope Technologies, LLC
Manufacturer Address .....:	2352 Main Street, Suite 303, Concord MA 01742, USA
Factory.....:	VisionScope Technologies, LLC
Factory Address.....:	2352 Main Street, Suite 303 Concord, MA 01742, USA
Rating .....:	(1) Input: AC 100-240V, 50/60Hz, 2.0A; Protection Class: I (2) Supplied from 50034-0XX (VisionScope Camera Control Unit)

IEC 60601+ Am. 1 & 2

Copy of marking plates

Marking for VisionScope Camera Control Unit (located on the rear panel)



Marking for VisionScope Camera Hand Piece [located on the bottom (Ref. number & symbols) and side (Trademark) of the camera head]

Marking for Light Sheath (located on the side of plastic holder)

IEC 60601+ Am. 1 & 2

GENERAL INFORMATION

Test item particulars (see also clause 5):	Class I
Classification of installation and use ..... :	~~transportable /~~ portable ~~/ stationary / mobile / fixed / permanently installed / hand-held~~
Supply connection ..... :	~~internally powered /permanently installed /~~ appliance coupler ~~/ non-detachable cord~~
Accessories and detachable parts included in the evaluation :	Camera Hand Piece (camera head) with attached cable Part Number 50021-0XX (X=0-9, A-Z)
Options included ..... :	None

Possible test case verdicts:

- test case does not apply to the test object ..... :N / A
- test object does meet the requirement..... :Pass
- test object does not meet the requirement..... :Fail

Abbreviations used in the report:

- normal condition ..... :N.C.
- operational insulation..... :OP
- basic insulation between parts of opposite polarity..... :BOP
- double insulation ..... :DI
- single fault condition ..... :S.F.C.
- basic insulation ..... :BI
- supplementary insulation ..... :SI
- reinforced insulation..... :RI

Additional Remarks:

1. In this test report the following names are used for the same camera accessory: "Camera Hand Piece" or "Camera Head".
2. The abbreviation IFU refers to "Instructions for Use"

Testing

Date of receipt of test item ..... :	November 18, 2009
Date(s) of performance of test ..... :	November 18, 2009 – January 29, 2010
..... :	-

IEC 60601+ Am. 1 & 2

General remarks:

"This report is not valid as a CB Test Report unless appended to a CB Test Certificate issued by a NCB, in accordance with IECEE 02".
"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
Throughout this report a point is used as the decimal separator.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of TÜV Rheinland of North America Inc.
List of test equipment must be kept on file and available for review.
Summary of contents provided on the last page of this report.

Summary of compliance with National Differences (for explanation of codes see below):
AU, CA, DK, IL, KR, US

Explanation of Codes:

AU=Australia, CA=Canada, DK=Denmark, IL=Israel, KR=Korea, US=United States of America.

Revision history:

Date:	Amendment No.	Technical/ non-technical	Amendment Description
01/29/2010	30993481.001	Technical	Original Test Report

General product information and considerations:

(b) (4)

[redacted]

The system model designation **VISIONSCOPE HIGH DEFINITION ENDOSCOPY** is made up of:

1. **VisionScope Camera Control Unit** (part number 50034-0XX), which include the following:

- Approved Medical Power Supply (provides 12V d.c. SELV output voltages)
- Integrated Light Source and a LCD Touch Screen
- Digital Video Processing Electronics
- Image Management Electronics

IEC 60601+ Am. 1 & 2

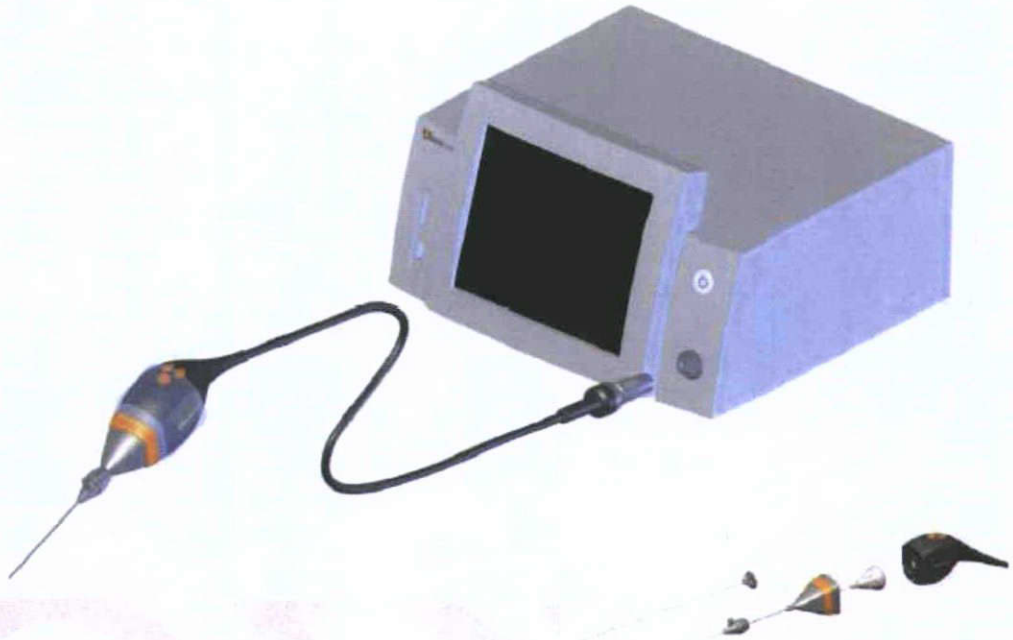
The Camera Control Unit is connected to AC mains via appliance inlet (part of power entry module) and detachable power supply cord set.

2. **VisionScope Camera Hand Piece** (part number 50021-0XX) , which include the following:

- Reuseable interchangeable endoscopes
- One-time use disposable illuminator sheaths associated with each endoscope
- One-time use disposable camera head flexible barrier
- One-time use canula
- One-time use trocar

The Camera Hand Piece is connected to Camera Control Unit SELV receptacle via camera cable.

The drawing below shows the system subassemblies



1358

IEC 60601+ Am. 1 & 2

The drawing below shows the System Block Diagram

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[redacted]

1359

IEC 60601+ Am. 1 & 2

The controls, connectors and features for the system subassemblies are shown on Figures 1-3.

Front Panel Layout

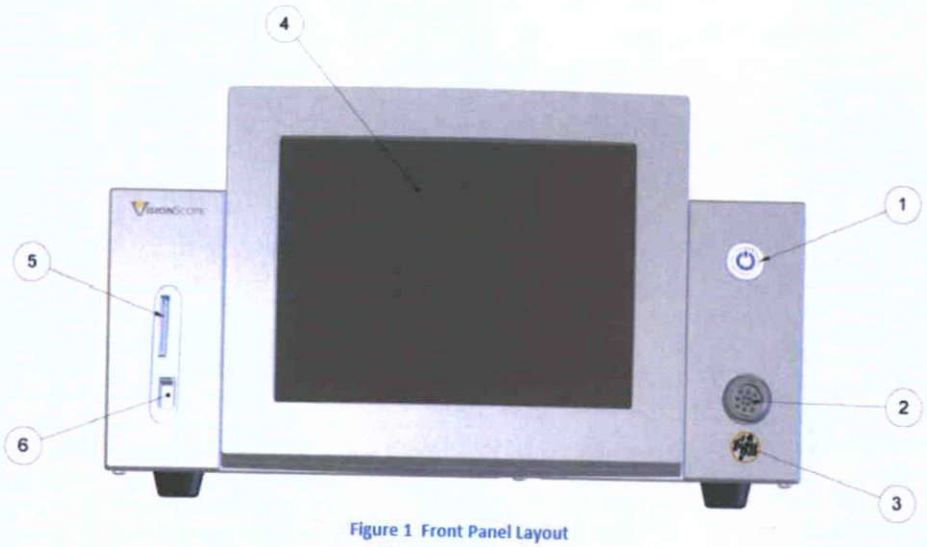

Figure 1 Front Panel Layout

Front Panel Control	Function
1. Power On/Off Switch	Turns the power to the System On or Off. When the switch is depressed, the power indicator light is green.
2. Camera Handpiece Cable Receptacle	Provides DC power and clock signals to the camera handpiece, and receive video data from the camera handpiece.
3.	⚠Warning: Do not plug connector into receptacle if it is wet.
4. LCD Touch Screen	Provides touch interface to allow User to control the camera operation.
5. Secure Digital Multi-media Card Slot	Allows User to store still pictures and video clip on a removable SD MMC card. ⚠Warning: for use with passive media only, do not plug in any active electrical part or cable. Do not use in patient environment.
6. USB Flash Memory Slot	Allows User to store still pictures and video clip on a removable USB Flash Memory Stick. ⚠Warning: for use with passive media only, do not plug in any active electrical part or cable. Do not use in patient environment.

1360

Rear Panel Layout

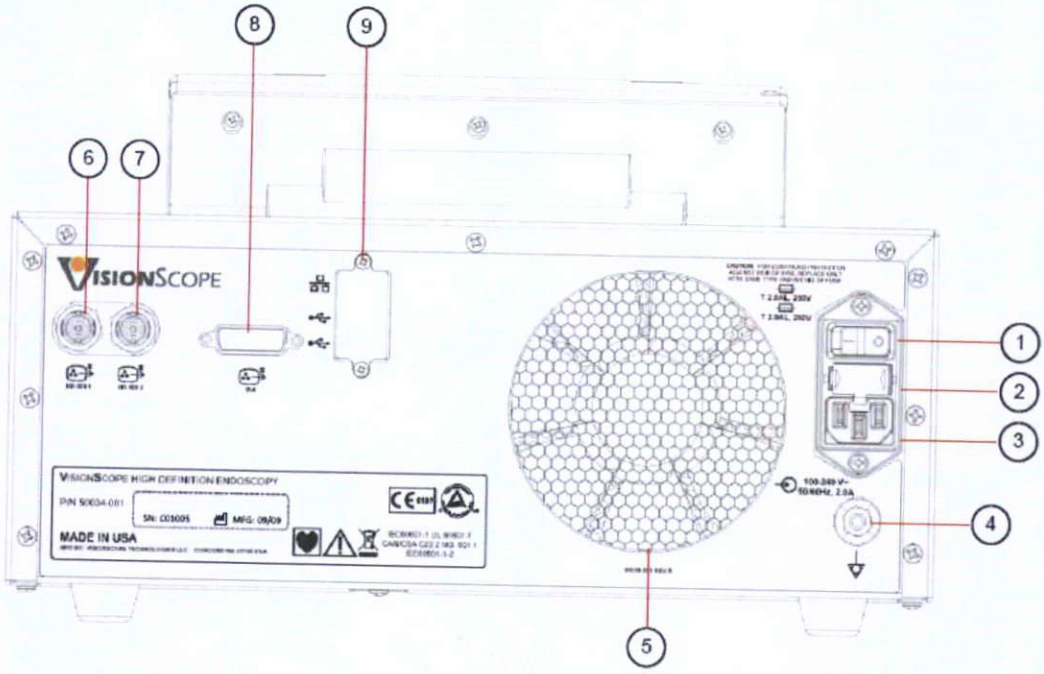

Figure 2 Rear Panel Layout

Rear Panel Connectors/Features	Functions
1. Main Power Switch	Supplies external AC power.
2. Fuse drawer	Contains two fuses in line with Live and Neutral of the AC input. Ratings of fuses shall be 2 Amps, 250 V, slow blow, low breaking capacity (T2.0AL, 250 V).
3. AC Power Plug Receptacle	Accepts AC power input.
4. Equipotential Plug	Enables connection to external equipotential connector.
5. Fan and EMI filter	Provides air circulation and EMI filtering.
6. HD-SDI connector No. 1	HD 1080i video output in Serial Digital Format
7. HD-SDI connector No. 2	HD 1080i video output in Serial Digital Format
8. DVI connector	HD 1080p video output in Digital Visual Format
9. Ethernet (1) and USB (2) receptacles	For Service Use only, do not use in patient environment. These receptacles are normally covered with a plate that can be removed only with a special tool.

Camera Handpiece Layout

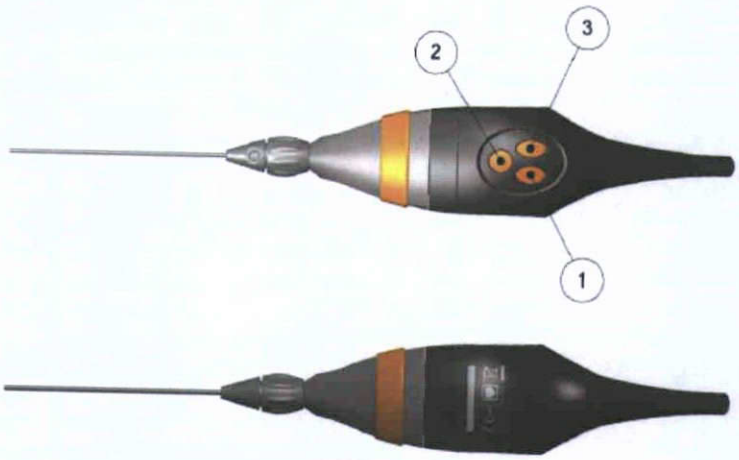

Figure 3 Camera Handpiece Button Layout

Each button serves two functions, depending on how long the button is pressed and released. Unless otherwise re-programmed by the users, the buttons serve the following functions:

(b)(4)

[redacted]

IEC 60601+ Am. 1 & 2

(b)(4)

[redacted]

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
3	**GENERAL REQUIREMENTS**		
3.1	Equipment when transported, stored, installed, operated in normal use and maintained accordi to the instructions of the manufacturer, causes r safety hazard which could reasonably be forese and which is not connected with its intended application in normal condition (N.C.) and in sing fault condition (S.F.C.)	(b)(4) [redacted]	
3.4	An alternative means of construction is used to that detailed in this standard and it can be demonstrated that an equivalent degree of safet is obtained	[redacted]	
5	**CLASSIFICATION**	[redacted]	
5.1	Type of protection against electric shock	[redacted]	
	Class I equipment	[redacted]	
	Class II equipment	[redacted]	
	Internally powered equipment	[redacted]	
5.2	Degree of protection against electric shock	[redacted]	
	Type B applied part	[redacted]	
	Type BF applied part	[redacted]	
	Type CF applied part	[redacted]	
	Not classified - no applied parts	[redacted]	
5.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1.1).....	[redacted]	
5.4	Methods of sterilization or disinfection	[redacted]	
5.5	Equipment not suitable for use in the presence of flammable mixtures	[redacted]	
	Category AP equipment	[redacted]	
	Category APG equipment	[redacted]	

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
5.6	Mode of operation:	(b)(4) [redacted]	
	-continuous operation		
	-short-time operation, specified operation; period		
	-intermittent operation, specified operation; rest period		
	-continuous operation with short-time, stated permissible loading time		
	-continuous operation with intermittent, stated permissible loading/rest time		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

INSULATION DIAGRAM

(b)(4)

[redacted]

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

(b)(4)

[redacted]

1367

(b)(4) Testing Reports

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17.5 - EN 60601-1-2 EMI-EMC Report

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17.6 - IEC 60601-2-18.Endoscope Safety Report

TÜVRheinland®
Precisely Right.

TEST REPORT
IEC 60601-2-18:1996 + A1: 2000
Medical electrical equipment
Part 2: Particular requirements for the safety of endoscopic equipment

Report Reference No. .....:	(b)(4) [redacted]	
Compiled by (+ signature) .....:	(b) (6) [redacted]	See cover page of test report (b)(4) [redacted]
Approved by (+ signature).....:	(b) (6) [redacted]	See cover page of test report (b)(4) [redacted]
Date of issue.....:	January 29, 2010	

CB Testing Laboratory.....:	TUV Rheinland of North America Inc.
Address .....:	12 Commerce Road, Newtown, CT 06470, USA
Testing location .....:	Same as above
Address .....:	Same as above
Applicant's name.....:	VisionScope Technologies, LLC
Address .....:	2352 Main Street, Suite 303 Concord, MA 01742, USA
Test specification:	
Standard.....:	IEC 60601-2-18:1996 Second Edition + A1:2000
Test procedure .....:	IEC/EN
Non-standard test method.....:	N/A
Test Report Form No.....:	IEC60601_2_18C
TRF Originator.....:	Underwriters Laboratories Inc.
Master TRF.....:	Dated 07-2001

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Test item description .....:	High Definition Diagnostic and Operative Needle Scope System
Trade Mark.....:	VISIONSCOPE
Manufacturer .....:	VisionScope Technologies, LLC
Address .....:	2352 Main Street, Suite 303 Concord, MA 01742, USA

Model/Type reference .....:	VISIONSCOPE HIGH DEFINITION ENDOSCOPY (1) 50034-0XX (VisionScope Camera Control Unit) (2) 50021-0XX (VisionScope Camera Hand Piece) X=0-9, A-Z (represent non-safety related features such as different configurations, variations or additional marking, etc.)
Ratings .....:	Input: AC 100-240V, 50/60Hz, 2.0A Protection Class: I
Factory.....:	VisionScope Technologies, LLC
Address .....:	2352 Main Street, Suite 303 Concord, MA 01742, USA

Test item particulars ..... :	See test report 30993481.003

Possible test case verdicts:

- test case does not apply to the test object ..... :	N/A
- test object does meet the requirement ..... :	Pass (P)
- test object does not meet the requirement ..... :	Fail (F)

Abbreviations used in the report:

- normal condition:	N.C.	- single fault condition:	S.F.C.
- operational insulation:	OP	- basic insulation:	BI
- double insulation:	DI	- supplementary insulation:	SI
- basic insulation between parts of opposite polarity:	BOP	- reinforced insulation:	RI
- Instructions for Use:	IFU		

Testing ..... :

Date of receipt of test item ..... :	November 18, 2009
Date (s) of performance of tests ..... :	November 18, 2009 – January 29, 2010

General remarks:

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by a NCB, in accordance with IECEE 02.

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.
"(see Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.

Throughout this report a point is used as the decimal separator.

This Test Report Form is intended for the investigation of endoscopic equipment in accordance with IEC 60601-2-18. It can only be used together with IEC 60601-1.

General product information and considerations: See IEC 60601-1 Test Report

The medical equipment is VisionScope High Definition Diagnostic and Operative Needle System for medical endoscopy.

The VisionScope System is a family of products designed to enable office-based pre-operative and post-operative arthroscopic imaging and diagnostics. The equipment can also be used in the operating rooms for arthroscopy procedures. In the orthopedic field, this includes but is not limited to diagnostics and treatment of small joints such as the knee, shoulder, ankle, wrist, and elbow.

The key component of the VisionScope is a proprietary 1.4 mm diameter semi-rigid/fiber-lens Endoscope system, which is small enough to fit through a 2 mm portal, a size that fits within the current range of syringe applications. The disposable component includes a proprietary sterile barrier that eliminates the need for Endoscope and camera head reprocessing following each procedure.

VisionScope System is able to miniaturize the arthroscope while still providing High Definition (HD 1080) anatomical visualization, enabling Surgeons to obtain direct visual clinical assessment in a physician examination room without requiring sterilization or bio-hazard processing infrastructure.

IEC 60601-2-18

(b)(4)

5	**CLASSIFICATION**	
5.2	Degree of protection against electric shock	
	Equipment is Type BF or CF	Type CF applied part

6	**IDENTIFICATION, MARKING AND DOCUMENTS**	
	ENDOSCOPIC EQUIPMENT with illumination lamps marked with lamp model or reference type	No illumination lamps; LED used as light source
	For illumination lamps built into the distant end of endoscope model information provided in the instruction for use	No serviceable LED light source built into Camera Control Unit
6.1	Marking on the outside of EQUIPMENT or EQUIPMENT parts	
	d) Minimum requirements for marking on the outside of EQUIPMENT or EQUIPMENT parts	Marking provided on the enclosure of Camera Hand Piece
	- at least markings required in 6.1e, 6.1f and 6.1g provided on not permanently installed equipment	See below
	- at least marking required in 6.1l and 6.1g provided on equipment	See test report 30993481.003
	e) Indication of origin	
	Name and/or trademark provided on the APPLIED PART	VISIONSCOPE
	f) MODEL or TYPE REFERENCE	
	MODEL or TYPE REFERENCE marked on the APPLIED PART.....:	Ref: 50021 and 50023 (see test report 30993481.003)
	Symbols used to denote functions of equipment explained in the accompanying documents.	All symbols are described in the IFU manuals

6.8.2	Instructions for use	
	aa) Instructions for use containing information concerning safety equipment	
	1) Prevention of SAFETY HAZARDS if ENDOSCOPIC EQUIPMENT loses functions	Based on the applications and construction of the endoscope, there is no safety hazard if the equipment looses functions
	2) Instructions to check the outer surface of the ENDOSCOPE and any ENDOSCPICALLY-USED ACCESSORIES for rough surfaces, sharp edges, or protrusions which may cause a SAFETY HAZARD	Contained in IFU manuals
	3) Warnings if surface temperatures on an APPLIED PART are likely to exceed 42 ° C.	The surface temperatures on endoscope / light sheath are not likely to exceed 42 ° C

IEC 60601-2-18		
	4) Warnings about high energy radiated light from the light emission window of the ENDOSCOPE and advice on how to minimize associated SAFETY HAZARDS	(b)(4) [redacted]
	5) Replacement of the illumination lamp and prevention of SAFETY HAZARDS such as burns and eye damage to the OPERATOROR and USER	
	6) Warnings regarding SAFETY HAZARDS resulting from gas embolism	
	7) Information whether there are any applicable INTERCONNECTION CONDITIONS	
	8) Warnings that when ENDOSCOPES are used with energized ENDOSCOPICALLY-USED ACCESSORIES, the PATIENT LEAKAGE CURRENTS may be additive	
	bb) Instructions for use with HIGH FREQUENCY SURGIC	
	1) The high frequency compatibility of endoscopes and ENDOSCOPICALLY-USED ACCESSORIES, by stating the maximum RATED recurring peak voltage of the ENDOSCOPE or ENDOSCOPICALLY-USED ACCESSORY for each mode of intended use	
	2) Avoidance of a SAFETY HAZARD in the event of explosive gas concentrations in the area of use of HIGH FREQUENCY ENDOSCOPICALLY-USED ACCESSORIES	
	cc) Instructions for use with laser equipment	
	For ENDOSCOPIC EQUIPMENT and ENDOSCOPICALLY-USED ACCESSORIES used with laser equipment, advice concerning their safe use, including potential eye damage to the OPERATOR.	
	dd) Instructions for use with other MEDICAL EQUIPMEN	
	For ENDOSCOPIC EQUIPMENT used with other MEDICAL ELECTRICAL EQUIPMENT, advise on the avoidance of potential SAFETY HAZARDS caused by their use together	

20	**DIELECTRIC STRENGTH**
20.2	Requirements for EQUIPMENT with an APPLIED PART
	B-a - between the APPLIED PART (PATIENT CIRCUIT) and LIVE parts; and between the outer surface of the ENDOSCOPE and any LIVE circuit in the ENDOSCOPE
	B-d - between an F-TYPE APPLIED PART (PATIENT CIRCUIT) and the ENCLOSURE

IEC 60601-2-18

(b)(4)

	B-d - between PROTECTIVELY EARTHED parts or parts connected to a FUNCTIONAL EARTH TERMINAL enclosing any LIVE circuit in the ENDOSCOPE and the outer surface of the ENDOSCOPE

36	**ELECTROMAGNETIC COMPATIBILITY**
	Ultrasonic ENDOSCOPE and its SUPPLY UNIT tested as Group 2 of CISPR 11
	ENDOSCOPICALLY-USED ACCESSORY and its associated MEDICAL ELECTRICAL EQUIPMENT for intracorporeal lithotripsy tested as Group 2 of CISPR 11
	ENDOSCOPICALLY-USED ACCESSORY and its associated MEDICAL ELECTRICAL EQUIPMENT for ultrasonic aspiration of tissue tested as Group 2 of CISPR 11

42	**EXCESSIVE TEMPERATURES**
42.3	APPLIED PARTS of ENDOSCOPIC EQUIPMENT not intended to supply heat to a PATIENT
	a) Portions held by the OPERATOR for short periods not exceeding applicable maximum temperatures for accessible surfaces of handles in table Xa of the General Standard
	For light guide connectors connecting to either a SUPPLY UNIT or an ENDOSCOPE exceeding max. allowed temperatures, warnings to avoid SAFETY HAZARDS included in the instructions for use
	b) Portions continuously held by the OPERATOR not exceeding the applicable maximum temperatures for accessible surfaces of handles in table Xa of the General Standard
	c) The temperature of the insertion portion, except for the LIGHT EMISSION PART not exceeding 41 °C
	For insertion portion used with an ENDOSCOPICALLY-USED ACCESSORY surface temperature of maximum of 50 °C
	For LIGHT EMISSION PART exceeding 41 °C, appropriate warnings to avoid risks to the PATIENT and OPERATOR provided in the instructions for use
42.5	Guards
	Doors providing access to lamps may be opened for lamp replacement without the use of a TOOL

IEC 60601-2-18		
42.101	**Thermal hazards from the use of ENDOSCOPES ar ACCESSORIES which are the APPLIED PARTS of HIGH**	(b)(4) [redacted]
42.101a)	INTERCONNECTION CONDITIONS for high frequency app	[redacted]
	Sufficient protection provided between ENDOSCOPE and ENDOSCOPICALLY-USED ACCESSORIES which are the APPLIED PARTS of HIGH FREQUENCY SURGICAL EQUIPMENT when used together	[redacted]
	Test voltage related to the RATED high frequency recurring peak voltage(s) stated by manufacturer ..:	[redacted]
	Insulation types and configurations used in the EQUIPMENT.....:	[redacted]
	Preconditioning of samples	[redacted]
	1) Insulation material thermal stability test	[redacted]
	Test in cut mode	[redacted]
	Test voltage (110%) and test frequency .....:	[redacted]
	Test in coagulation burst mode	[redacted]
	Test voltage (110%) and test frequency .....:	[redacted]
	Repetition rate (kHz) .....:	[redacted]
	Test in coagulation spray mode	[redacted]
	Test voltage (110%) and test frequency .....:	[redacted]
	Repetition rate (kHz) .....:	[redacted]
	No breakdown of insulation material in any mode	[redacted]
	2) Dielectric strength test	[redacted]
	Test voltage AC or DC (V):	[redacted]
42.101b)	CAPACITIVELY COUPLED HF CURRENT from the eyepiec	[redacted]
	The eyepiece of an ENDOSCOPE intended for use with ENDOSCOPICALLY-USED ACCESSORIES which are the APPLIED PARTS of HIGH FREQUENCY SURGICAL EQUIPMENT are isolated	[redacted]
	Coatings, such as lacquer not used for isolation of the eyepiece	[redacted]
	Eyepiece made of non-conductive material	[redacted]
	No CAPACITIVELY COUPLED HF CURRENT from the ENDOSCOPICALLY-USED ACCESSORY to the eyepiece under NORMAL USE and SINGLE FAULT CONDITION	[redacted]
	Measured CAPACITIVELY COUPLED HF CURRENT of isolated eyepiece (not exceeding 50 mA) .....:	[redacted]

44	**OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY,** (b)(4) [redacted], **CLEANING, STERILIZATION AND DISINFECTION**	

IEC 60601-2-18		
44.7	Cleaning, sterilization and disinfections	
	Method used for sterilization and/or disinfections of the EQUIPMENT .....:	Proper instructions are provided in IFU manuals
	Test of INTER CONNECTION CONDITIONS according to 42.101	
56	**COMPONENTS AND GENERAL ASSESMBLY**	
56.3c)	This clause is not applied to ENDOSCOPES, ENDOSCOPICALLY-USED ACCESSORIES and their ACCESSORIES	
57	**MAINS PARTS, COMPONENTS AND LAYOUT**	
57.10	Creepage distances and air clearances	
	aa) Secondary LIVE circuits isolated from MAINS VOLTAGE by REINFORCED or DOUBLE INSULATION meet the requirements of IEC 60664-1, pollution degree 1	Reinforced/double insulation is provided by IEC 60601-1 approved power supply

(b)(4) [redacted]

17.7 - Attachment 1 EN-IEC-UL 60601-1 Attachment - Constructional Data Form

Constructional Data Form for Electrical Products

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Precisely Right.

(For TUV Rheinland of N.A., Inc. use only)

Certificate # (b)(4) [redacted] File # (b)(4) [redacted]

License Holder: VisionScope Technologies, LLC

Type of Product: High Definition Diagnostic and Operative Needle Scope System

Model Number: VISIONSCOPE HIGH DEFINITION ENDOSCOPY

(1) 50034-0XX (VisionScope Camera Control Unit)

(2) 50021-0XX (VisionScope Camera Hand Piece)

where X=0-9, A-Z (represent non-safety related features such as different configurations, variations or additional marking, etc.)

List of Critical Components:

Object/part no.	Manufacturer/ Trademark	Type/Model	Technical Data	Standard	Mark(s) of Conformity
(b)(4) [redacted]				IEC/EN 60320-1, IEC/EN 60939-2, UL 498, CAN/CSA 22.2	UL, CSA, VDE UL Report E72928
				UL 498	UL E93617
				IEC 60127-2	UL E10480
				UL 62,CSA LR-89281	UL, CSA UL Report E99973
				EN/IEC/UL 60601-1 CSA 22.2 No. 601.1	cULus, CSA, D UL CB Test Certificate E116994A-A35-CB-1
				UL, CSA LR 19980	UL,CSA UL Report E29179
				-	Evaluated / tested in the application

Newtown, CT USA	January 29, 2010	2352 Main Street, Concord, MA 01742 USA	September 15, 2009 Updated January 26, 2010
		(Place)	(Date)
TUV Rheinland of North America, Inc.		VISIONSCOPE (Stamp and signature of applicant)	

1533

Constructional Data Form for Electrical Products

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(For TUV Rheinland of N.A., Inc. use only)

Certificate # (b)(4) [redacted] File # (b)(4) [redacted]

Object/part no.	Manufacturer/ Trademark	Type/Model	Technical Data	Standard	Mark(s) of Conformity
(b)(4) [redacted]				UL 310, CSA C22.2 No. 153, DIN VDE 0627/09.91	UL,CSA UL Report E66717 VDE Reg. No. 5193
				UL 310, CSA C22.2 No. 153, DIN VDE 0627/09.91	UL,CSA UL Report E66717 VDE Reg. No. 5193
				UL 497B	UL E163070
				UL 1414	UL E63802
				UL 94, UL796	UL E122342
				Insulation E Class (UL Class A)	UL E89936 CSA 174363 VDE 15073-2611
				DIN 42801/04.80, 42801-2/01.84	TUV Rheinland, UL E2013022E04
				UL248-1, UL248-14	UL E19180
				UL248-1, UL248-14	UL E19180
				UL1434	UL E174545

Newtown, CT USA	January 29, 2010	2352 Main Street, Concord, MA 01742 USA	September 15, 2009 Updated January 26, 2010
		(Place)	(Date)
TUV Rheinland of North America, Inc.		VISIONSCOPE	(Stamp and signature of applicant)

1534

Constructional Data Form for Electrical Products

TÜVRheinland®
Precisely Right.

(For TUV Rheinland of N.A., Inc. use only)

Certificate #(b)(4) [redacted] File #(b)(4) [redacted]

Object/part no.	Manufacturer/ Trademark	Type/Model	Technical Data	Standard	Mark(s) of Conformity
(b)(4) [redacted]				UL1642	MH12210
				IEC60695-11-10 IEC60695-11-20	UL E121562
				IEC60695-11-10	UL E121562
				UL94, UL796	UL E199875
				UL94, UL796	UL E122342
				UL AWM/STYLE 1015 CSA TEW-105	UL E-163880 CSA 81241
				UL AWM/STYLE 1015 CSA TEW-105	UL E-177303 CSA 163715
				UL AWM/STYLE 1015 CSA TEW-105	UL E-163880 CSA 81241
				UL AWM/STYLE 1015 CSA TEW-105	UL E-174416 CSA 109360

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TUV Rheinland of North America, Inc.		VISIONSCOPE (Stamp and signature of applicant)	

1535

Constructional Data Form for Electrical Products

TÜVRheinland®
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(For TUV Rheinland of N.A., Inc. use only)

Certificate # (b)(4) [redacted] File # (b)(4) [redacted]

Object/part no.	Manufacturer/ Trademark	Type/Model	Technical Data	Standard	Mark(s) of Conformity

Routine Safety Testing:

Required: ☒ **Not Required:** ☐ ***Reason:*** ***Class III product:*** ☐

Other:

Test Details:	Test Points:	Test Values
☒ **Dielectric Strength:**	**BI: L/N – Chassis**	(b)(4) [redacted]
☒ **Ground Continuity:**	**AC-inlet - Chassis**	
☐ **Insulation Resistance:**		
☐ **Leakage Current:**		
☐ **Other:**		

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1536

17.8 - Attachment 2 National Difference EN60601-1 CB 112A

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict

European Deviations from EN 60601-1: 1990 + A1 + A2 + A13		
	ANNEX ZC	
6.8.1	Finland (Resolution of the Ministry of Trade and Industry on Electrical Safety Regulations, 205/74)	
	Warnings and instructions for use, required to be on the outside of the equipment, shall be in Finnish and Swedish.	
56.3a	Austria (Dampfkesselverordnung, BGBl. 510/1986)	
	The identification of medical gas cylinders and connections are regulated according to the Dampfkesselverordnung, BGBl. 510/1986 in compliance with the Austria standards ÖNORM K 3010, M 7375, M 7387 and M 7886, which are not in conformity with ISO recommendation ISO/R407.	
57.10a	Finland (Resolution of the Ministry of Trade and Indust Regulations, 205/74)	
	Distance through solid insulation between metal parts for U higher than 60V: separated by supplementary insulation 0.4 mm or separated by reinforced insulation 0.4 mm.	
	ANNEX ZD	
6.6	Austria, Germany, Switzerland	
	The national color coding (informative) in Austria, Germany and Switzerland is as follows:	

(b)(4) [redacted]

GAS	GERMANY	AUSTRIA	SWITZERLAND	ISO 32
OXYGEN	Blue	Blue	Blue	White
NITROUSOXIDE	Grey	Grey / Yellow	Green / Yellow	Blue
AIR	Yellow	Grey	Brown	White / Black
OXYGEN/AIR	Blue / Yellow	Grey		
CO2		Grey / Black		
OXYGEN/CO2		Grey / Blue		

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict

AU

(b)(4)

6.1.g)	Insert the following sub-clause between the first and second dashes: For low voltage equipment rated at 200 V or more, a voltage marking (which may be part of a voltage range) of not less than 230V. Supply frequency ratings which include 60 Hz must also include 50 Hz.	[redacted]
6.6	Replace the existing text of Item a) with the following: a) Identification of the content of gas cylinders used in medical practice as part of electrical EQUIPMENT shall be in accordance with AS 1944, (see also Sub-clause 56.3a).	[redacted]
28.2	Replace the existing text with the following: Support (a) Ceiling-supported EQUIPMENT EQUIPMENT shall comply with the following requirements:	[redacted]
	(i) EQUIPMENT shall be fitted with an anticrash device or have suspension cables duplicated and independently anchored.	[redacted]
	(ii) Motorized drives shall be designed to prevent the driven part from becoming hazardous in the event of a power failure.	[redacted]
	(iii) Carriages, brakes and supports shall be designed such that any single failure will not constitute a hazard to the PATIENT.	[redacted]
	(iv) Effective means shall be incorporated to prevent carriages running off supporting rails.	[redacted]
	(v) Effective means shall be incorporated to facilitate adequate inspection of cables and anchorages.	[redacted]
	(vi) Proximity or pressure switches may be used to minimize hazards.	[redacted]

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict
	(vii) Ceiling-supported EQUIPMENT or parts thereof connected by electrical supply cables shall be provided with stops (e.g. for limitation of rotation or linear movement) to restrict movement in a manner which avoids any undue strain on the wiring termination or damage to the wiring.	(b)(4) [redacted]	
	(b) Floor and floor-to-ceiling supported (including mobile) EQUIPMENT EQUIPMENT shall comply with the following requirements:		
	(i) Anticrash devices shall be fitted to cable, chains, etc.		
	(ii) Means shall be incorporated to facilitate adequate inspection of cables and anchorages.		
	(iii) Cross-arms or pivots shall be fitted with adequate stops, locknuts, grub screws or similar devices to prevent supported masses being dislodged.		
42.3	Item 2) Add the following prior to the first dash: For this clause only, low voltage equipment rated at greater than 200 V is regarded as having a maximum rated voltage of 230 V.		
Table XII	In second row, first dash, after 'if impedance protected,' add 'maximum value'.		
56.3a)	Replace the text in the 3rd dash by the following: Medical gas connections on EQUIPMENT shall, if operating at positive pressures greater than 50 kPa in NORMAL USE comply with AS 2472, AS 2473 or AS 2896, as appropriate.		
57.2a)	Replace 'not used' with: Supply plugs -- Provision for inspection Where a supply flexible cord is fitted with a rewirable plug of a type complying with the requirements of AS 3112 for 3-pin plugs, the plug shall be clear-backed to facilitate inspection of the core colors and the condition of the terminations.		

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict

CA

(b)(4)

2.4.1	High Voltage	[redacted]
	Any voltage in excess of 750 V a.c. rms, 1050 V peak, or in excess of 750 V d.c.	
6.6 (b)	Identification of Medical Gas Cylinders and Connections	
	The point of connection of gas cylinders to EQUIPMENT shall be gas specific	
	The point of connection of gas cylinders to EQUIPMENT shall be non-interchangeable	
	The point of connection of gas cylinders to EQUIPMENT shall be identified so that errors are avoided when a replacement is made	
56.3 (a)	Construction of Connectors	
	Medical gas inlet connectors on EQUIPMENT shall be gas specific	
	Medical gas inlet connectors on EQUIPMENT shall be non-interchangeable	
	Medical gas inlet connectors on EQUIPMENT shall be DISS type complying with CGA V-5	
	Medical gas inlet connectors on EQUIPMENT shall be configured to permit the supply of medical gases from low pressure connecting assemblies complying with CAN/CSA - Z305.2 (Refer to Note below)	
	Note: *Users of this Standard should consult the Z305 Series of CSA Standards, CAN/CSA-Z9170-1, CAN/CSA-Z10524, and CAN/CSA-Z15002 for further information regarding inlet connectors, and ISO Recommendation 407 for requirements addressing yoke-type valve connections.*	
56.6 (a)	Application	
	Where the consequent loss of function of equipment caused by operation of a thermal cut-out presents a safety hazard, both visible and audible warnings are given	
57.2 (g)	The MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENT shall:	
	(i) if molded on type - hospital grade attachment plug (mains plug) complies with CSA C22.2, No. 21; or	

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict
	(ii) hospital grade disassembly type attachment plug (mains plug) complies with CSA C22.2, No. 42; or	(b)(4) [redacted]	
	(iii) if Class II equipment - CSA configuration 1-15P with polarized blade and meets all applicable requirements for hospital grade in C22.2 No. 21 and C22.2 No. 42		
57.3 (b)	Detachable power supply cord for non-permanently installed equipment (cord-connected equipment) shall be of a type that:		
	(i) can be shown to be unlikely to become detached accidentally, unless it can be shown that detachment will not constitute a safety hazard to a patient or operator;		
	(ii) can be shown that the impedance of the earth (ground) circuit contacts will not constitute a safety hazard to a patient or operator; and		
	(iii) has a terminal configuration or other constructional feature that will minimize the possibility of its replacement by a detachable power supply cord which could make the equipment hazardous		
	A Detachable power supply cord complies with the following requirements:		
	(i) it shall comply with the applicable requirements of CSA Std. C22.2 No. 21		
	(ii) the flexible cord shall not be smaller than No. 18 AWG, and the mechanical serviceability shall be:		
	(iii) not less than that of Type SJ for mobile equipment such as hospital beds and instruments carts;		
	(iv) not less than that of Type SV, (or Type HPN if required because of temperature) for other equipment		
	Note: See CSA Standard C22.2 No. 49 for requirements on the cord types mentioned in item (ii)		
59.1	Internal Wiring		
	Connecting cords between equipment parts shall meet the requirements of the *Canadian Electrical Code, Part I, as applicable.*		

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict

DK

(b)(4)

	For plugs and socket outlets the national standard SB 107-2-D1 3rd edition applies	[redacted]
	For Class I equipment:	
	Plugs: DK 2-la, DK 2-la with flat phase pin or DK 2-5a	
	Socket Outlets: DK 1-3a	
	For Class II equipment:	
	Plugs: DKA 2la, DKA 2-1b,Clb,C5, C6 or according to EN50075	

IL

4.7	A. Equipment that is to be connected to the mains, shall be intended for one of the following voltages and frequencies: Nominal frequency of 50Hz. Nominal voltage of 230V for portable and hand-held equipment. Nominal voltage 230V, for one phase equipment with input power not exceeding 4kVA. Nominal voltage 400V, for multiphase equipment.	
	B. It is allowed to connect to the mains other equipment, with the following ratings: One phase equipment, for the range of 220 to 240 Volts. Multiphase equipment, for the range of 380 to 440 Volts.	

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict
	The equipment shall comply with all the requirements of the standard, while being connected to the above mentioned mains frequencies and voltages, as if it was marked for 50Hz and 230 or 400 Volts.	(b)(4) [redacted]	
36	Change clause 36. - EMC – to: The equipment shall comply with the requirements of SI 1011 part 1.2 (IEC 60601-1-2).		

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict

KR

(b)(4)

	Supply Voltage Rating: National supply voltages are 110V, 220V and 380V.	[redacted]
	Frequency: Only appliances having supply frequency of 60 Hz or a frequency range including 60 Hz are accepted.	[redacted]
	Instruction: Instruction manuals and appliance markings related safety, including nameplate shall be in Korean or graphical symbols in accordance with IEC 60417.	[redacted]
	Plug: Plugs for the connection of the equipment to the supply mains shall comply with the Korean Standard (KSC 8305 and 8300).	[redacted]
6.1j)	Equipment for one or several rated voltage or frequency ranges, the rated input for 220V, 60Hz or if applicable for 110V, 60Hz shall be separately marked.	[redacted]
6.1s)	HIGH VOLTAGE TERMINAL DEVICES on the outside of equipment which are accessible without the use of a tool shall be marked with the symbol "dangerous voltage" (Appendix D, Table DII, Symbol 6) and with Korean language.	[redacted]
6.2c)	The presence of HIGH VOLTAGE PARTS shall be marked with symbol "dangerous voltage" (Appendix D, Table DII, Symbol 6) and with Korean language. 고압주의	[redacted]
6.8.1	Language of accompanying documents shall be included Korean.	[redacted]

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict

US

(b)(4)

* 1.1	Safety hazards resulting from intended physiological functions of and ionizing radiation resulting form equipment covered by this standard are not consider	[redacted]
	Such equipment is subject to US FDA requirements and US Federal Radiation Standards (21 CFR Part 1020) promulgated under the radiation control for health and safety act of 1968	[redacted]
	In addition to the requirements in the base standa	[redacted]
* 2.12.100	ANSI/AAMI Safety Current Limits (SCL) and	[redacted]
* 2.12.101	ANSI/NFPA 99 Health Care Facilities Standards	[redacted]
* 2.4.1	HIGH VOLTAGE > than 600 V	[redacted]
* 2.10.100	X-Ray Installations, (Long-Time Rating)	[redacted]
	A rating based on an operating interval of 5 minutes or longer	[redacted]
* 2.10.101	X-Ray Installations, (Momentary Rating)	[redacted]
	A rating based on an operating interval that does not exceed 5 seconds	[redacted]
* c) 10.2.2	High voltage x-ray installations long time and momentary ratings definitions clause 6, 6.2 and product markings shall agree with the NEC	[redacted]
3.10DV.1.1 * 3.100	The following shall meet nationally recognized sta	[redacted]
3.100.1 * 3.100.1	a) Printed wiring boards	[redacted]
3.100.1 * 3.101	b) Lithium batteries	[redacted]
3.100.1 * 3.101.1	c) Optical isolators	[redacted]
3.100.1 * 3.101.2	d) Wiring and tubing	[redacted]
* 3.102	e) CRTs > 5 inches	[redacted]

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict
3.100.1	Items a), c), and d) are exempt from this requirement if they are connected totally in an SELV circuit limited to 15 W, or less, maximum available power and whose failure will not result in a safety hazard	(b)(4) [redacted]	
3.10 DV.2 * 3.10.2	Primary Circuit Components		
3.10 DV.2.1 * 3.10.2.1	In addition to compliance with this basic standard, components in the primary circuit up to the isolation transformer shall meet nationally recognized standards (such as ANSI/UL standards) or Internationally Harmonized Component Standards		
3.10 DV.3	Annex DVA tabulates UL component Standards covering components as specified in subclause 3.10DV.1 and 3.10DV.2.		
6DV.1	Markings on the outside		
* 6	The text of the marking prefaced with an upper case signal word "CAUTION", "WARNING", or "DANGER, shall consist of upper and lower case letters, in English, that comply with the following:		
a)	All words comprising the text of the marking, excluding the signal word, shall be in letters not less than 1,6 mm (1/16 inch) high, based upon upper case,		
b)	The signal word shall be in letters at least 2,8 mm (7/64 inch),		
c)	The letters shall be in contrast color to the background. Letters that are raised or indented and do not have a contrasting color to the background are not acceptable.		
* 6	A "WARNING" Statement is required for ionizing radiation producing equipment		
6DV.2	EQUIPMENT capable of emitting ionizing radiation shall bear a warning statement concerning the risk of injury to persons from X-radiation. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view:"WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."		

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict
6DV.3	When a manufacturer produces or assembles equipment at more than one factory, the equipment shall have a distinctive marking – which may be in code – by means of which it may be identified as the product of a particular factory	(b)(4) [redacted]	
6DV.4	Multiple voltage equipment for permanent connection to the branch circuit shall be marked to indicate the particular voltage for which it is connected when shipped from factory. The marking may be in the form of a paper tag or any other nonpermanent material.		
6*.6.2l)	Replace 75°C with 60°C		
6.8DV	Cord-connected equipment shall be provided with instructions to indicate the type of attachment plug used for alternate voltages		
10.2.2DV	Modification of item a) in 10.2.2:		
	Replace "500 V with "600 V in both locations in the text associated with the first dash. In the text of the last dash of this sub-clause, add		
10.2.2 a)	and the National Electrical Code, ANSI/NFPA 70 after the reference to IEC Publication 364		
14DV	Classification		
	Fixed and permanently installed equipment shall be Class I		
* 14, 18	The Class of high voltage parts of equipment shall be in accordance with the provisions of the NEC		
18DV	Protective earthing, functional earthing and potenti		
	m) All parts of X-ray equipment operating at over 600 V ac, 850 V dc, or 850 V peak shall be enclosed within protectively earthed (grounded) enclosures. The connections from the high-voltage equipment to X-ray tubes and other high-voltage components shall be made with high-voltage shielded cables intended for operation at over 600 V ac, 850 V dc, or 850 V peak.		
	n) All accessible non-current carrying conductive parts, likely to become energized, of X-ray and associated equipment (controls, tables, transformer tanks, shields of shielded cables, tube heads and supports, etc.) shall be protective earthed (grounded) in accordance with clause 18.		

548

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict
* 19	X-Ray equipment need only comply with the clause 19 requirements in 60601-1	(b)(4) [redacted]	
19.5DV	Continuous Leakage Currents and Patient Auxiliar		
19.5DV.1	In addition to Clause 19 requirements, the followin X-ray equipment and equipment covered by note 3		
19.5DV.2	The Leakage currents specified in Tables 19.100 and 19.101 are not to be exceeded when the equipment is tested in accordance with Clause 19 except: - The equipment is to be connected to the highest rated mains voltage (minimum 120VAC and 240VAC for equipment with marked voltage ranges of 105-120 VAC and 210-240 VAC respectively) - The footnotes of Tables 19.5DV.1 and 19.5DV.2 apply.		
22DV	Moving Parts		
* 22 and 28	In addition to the requirements in this standard, equipment shall be found to be in compliance with the Standards for X-ray equipment, ANSI/UL 187, 5th edition, Section 31 and 34 with respect to the movement control and supporting masses		
22DV.1	Where a risk of injury to the patient or operator can occur as a result of a moving part, in addition to the other requirements in this clause, there shall be end stops or other mechanical means to act as the ultimate travel limiting means (example: the end points of a movable ceiling suspension).		
22DV.2	End stops or other mechanical means shall have the mechanical strength to withstand the conditions of maximum intended loading and reasonably foreseeable abusive operation.		
22DV.4	The equipment shall be loaded with (1) the maximum intended load, (2) unloaded, or (3) loaded to any intermediate level that is likely to provide the most severe test result. The moving part is to be driven against each end stop or other mechanical means for the number of cycles and conditions shown in Table 22DV1. The end stops or other mechanical means required shall be capable of performing their intended function upon completion of the following tests.		
	Results of test		

1541

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict
22.4DV	In addition to 'patient' add 'or operator'	(b)(4) [redacted]	
22.7DV	Emergency Stops		
	A device intended to be designated as an emergency off, emergency switching or stopping device shall comply with each of the following:		
	a) The device shall be constructed in accordance with all of the following:		
	1) The device shall have an actuator, colored red as per 6.7, designed to be distinctive and easily identifiable from that of other controls, and that will open the circuit(s) when actuated,		
	2) The device, once actuated, shall maintain the equipment in the off (open) condition until a deliberate action, different from that used to actuate it, is performed, and,		
	3) Actuators shall be readily accessible to the operator and positioned at each operating station.		
	b) An actuator that interrupts/opens mechanical movements shall be marked with the word "STOP" or with symbol 5110 from IEC 878 (shown below) on or immediately adjacent to, the face of the actuator and shall be marked in compliance with all the requirements (permanence, letter height, and the like) for cautionary markings in Clause 6. A switch need not be marked with the word "STOP" or the equivalent symbol, if the switch interrupts all movements, including the generation of X-rays and any other condition that could result in a risk of injury.		
	The emergency switching means, in the first dashed paragraph shall be separate and independent of the intended movement control.		
28DV	Suspended Masses		
28.3DV	To comply with the requirements of 28.3, the equipment relying on a safety device shall additionally be tested as follows:		

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict
	A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hoses, or the like, employed to support a load, is to be defeated by any convenient means, thereby causing the maximum normal load to fall from the most adverse position permitted by the construction of the equipment. There shall be no evidence of damage to a safety catch or other restraining means that would affect its ability to perform its intended function. If it cannot be demonstrated that a safety catch or other restraining means can perform its intended function after the test, a permanent marking shall be provided in accordance with paragraph below. If the load is a patient, the load is to be as specified by the manufacturer, or 1,33 kN or 136 kgf (300 lbf) if not specified.	(b)(4) [redacted]	
	The equipment shall be marked with signal word "WARNING" and the following text or the equivalent - "For Continued Protection Against Injury to Persons, Repair or Replace Safety Catch (or specific restraining means, as appropriate) After It Has Been Activated. Refer to Instructions in the Service Manual Provided With the Equipment." The marking shall be readily visible during any approach to servicing or resetting of the safety catch. More than one such marking may be required.		
28DV.4.1	Compliance with the requirements of 28.3 and 28.4 is checked by test performance, design data and inspection of any maintenance instructions. Where the complexity of the system is such that the design data can be reasonably evaluated so as to determine that compliance is met, demonstration of test performance may not be necessary.		
28.4DV.2	To comply with the required safety factors, the suspensions shall be subjected to a loading test. The suspension shall be loaded as in normal use with its safe working load multiplied by the applicable safety factors. There shall be no damage to structural parts that would create a risk of injury to a patient or operator. The support system shall be in equilibrium one minute after application of the test load. The test may be conducted on previously untested samples.		

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict
29DV	The requirements of 29.2 shall be considered when evaluating equipment. The remaining section five items are considered the responsibility of the proper authorities. See 1.1DV	(b)(4) [redacted]	
42DV	Excessive Temperatures		
* 42	Insulating systems (such as on transformers, motors, solenoids, inductors and the like) where the measured temperatures exceed Class A (105°C) limits during normal use and normal condition shall comply with the requirements in the Standard for Systems of Insulating Materials - General, UL 1446.		
43DV	Oxygen enriched atmospheres		
	These requirements only apply to equipment that is normally used or recommended for use with oxygen or oxygen enriched atmospheres and for which no particular requirements exist that address the equipment's use with oxygen or oxygen enriched atmospheres. Sub-clause 43.2DV.9 is relevant to installation and the product's end use and can be addressed by their inclusion in the product's operation and installation manual. The manual's reference should cover those details needed to reduce the risk of oxygen related hazards.		
	If this applies add this to add the rest of the clause otherwise remove this row		
52	Abnormal Operation and Fault conditions		
52.4.1DV	The requirements of sub-clause 52.1 and the corresponding tests shall not be applied to components 15W or less in Single Fault Condition		
55DV.1	The following requirements are additionally used enclosures and covers:		
55DV.2 * 55	Conductive coatings applied to nonmetallic surfaces comply with UL746C unless it can be determined by investigation that flaking or peeling of the coating does not result in the reduction of spacings or the bridging of live parts that may present a risk of injury.		
55DV.3.1	An external surface of combustible material having an area of more than 9,47 m2 (100 ft2) or a single dimension of 3,7 m (12 ft), including a diagonal, shall have a flame spread rating of 75 or less when subjected to the ASTM E 84		

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict
	Steiner tunnel test	(b)(4) [redacted]	
55DV.3.2 * 55	An external surface of combustible material having an area of more than 4,74 m2 (50 ft2) but not exceeding 9,47 m2 (100 ft2) shall have a flame spread rating of 75 or less when subjected to the radiant panel test ASTM E 162, Test Method for Surface Flammability of Materials Using a Radiant Heat Energy Source, or the ASTM E 84 Steiner tunnel test		
55DV.4.1	Compliance with Flammability, mechanical abuse and mold stress relief Reference UL 746C 94V-2 for Transportable equipment 94V-0 for fixed or stationary equipment		
55DV.4.2	Flammability tests are not required for enclosures housing only circuits supplied from a source, which is separated from the supply mains, by one of the methods described in 17 g), and where the available power does not exceed 15 W.		
55DV.4.3	Steel Ball Test		
55DV.4.4	Hand-held or hand-guided shall withstand drop test		
* 55	Polymeric enclosures and covers shall be considered for flammability characteristics and be resistant to mold stress relief and impact/drop safety hazards consistent with their use		
56.3DV	Connections		
56.3DV.1	Connector, plug, pin, or the like that is attached to a patient-connected lead or contact shall be constructed such that it cannot engage any part of the equipment - including a separable cord set - that can introduce a risk of electric shock, fire, or injury to persons.		
56.3DV.2	In addition to the above requirement a connector, plug, pin or the like that is attached to a patient-connected lead or contact, and that is used with a product that may be used without professional supervision, shall be constructed so that it cannot be inserted or manipulated to make contact with live parts of a power receptacle outlet or separate cord set.		
* 56.3	The likelihood of a patient connected lead or		

1553

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict
	part being misused so as to introduce a safety hazard shall be investigated	(b)(4) [redacted]	
57DV	Mains part		
57DV.1.1	Permanently connected equipment shall have provision for the connection of one of the wiring systems that is in accordance with NEC 70		
* 57	All equipment installations are required to be in accordance with the NEC		
57DV.1.2	Fixed and stationary X-ray equipment supplied from a branch circuit rated at 30 A or less, and equipment that is not strictly portable but obviously is intended to be stationary, may be acceptable if provided with a length of attached hard service flexible cord – such as Type S, or the equivalent, for supply connection.		
57.2DV	Mains connectors and appliance inlets		
57.2DV.1	For Patient care equipment Where a "Hospital Grade" or "Hospital Only" mains plug exists for the particular electrical rating in question, the mains plug of non-permanently installed equipment with a protective earth connection shall comply with the requirements for hospital grade attachment plug (Mains Plug) or the non-hazardous location locking type designated "Hospital Only" as specified in UL 498 and the product shall comply with 57.2DV.2		
57.2DV.2 * 57.2	Cord connected equipment employing "Hospital Only" or Hospital Grade" attachment plugs shall be provided with instructions to indicate that grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Only" or Hospital Grade". The necessary instructions shall be included on the equipment itself or on a tag attached to the supply cord or the equipment.		
57.2DV.3 * 57.2	For Radiography equipment the plug shall be rated not less than 50 % of the maximum current input to the equipment for radiographic settings.		
57.2DV.4 * 57.2	Except for X-ray Equipment, the plug must rated for at least 125 % of the rated current		

554

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict
57.2DV.5 * 57.2	Polarized plugs shall be connected such applicable devices shall be connected to the ungrounded side of the line for an edison-base lampholder, single pole switch, automatic control with off position, solitary fuseholder, and any other single-pole overcurrent protective device	(b)(4) [redacted]	
57.2DV.6	When a second fuseholder or other overcurrent protective device is provided in the application, it may be placed in the grounded side of the line.		
57.3DV	Power supply cords		
* 57.3, 57.9	Power supply cords and internal wiring including interconnection cords between equipment shall meet the requirements of NEC		
57.3DV b) * 57.3, 57.9	Detachable power supply cord for non-permanently installed equipment shall be of a type that can be shown to be unlikely to become detached accidentally, unless detachment does not cause a safety hazard to patient or operator:		
1)	A power supply cord shall:		
	Acceptable for application		
	Acceptable for use at voltage not less than the rated voltage of the appliance		
	Have ampacity of not less than the current rating of the appliance		
	Comply with UL62		
2)	Power cord no smaller than 18 AWG		
i)	Not less than SJE, SJT, SJO, or equivalent for transportable equipment		
ii)	Not less than SV for light-duty equipment where extreme flexibility or weight is a factor		
iii)	An oil-resistant cord if equipment is likely to be subjected to grease or oil		
57.5DV	Mains terminal devices and wiring of mains parts		
57.5 b)	The free end of leads provided for branch circuit connection shall be located in a separate enclosure		
	Free length of the lead shall be at least 6 inches		

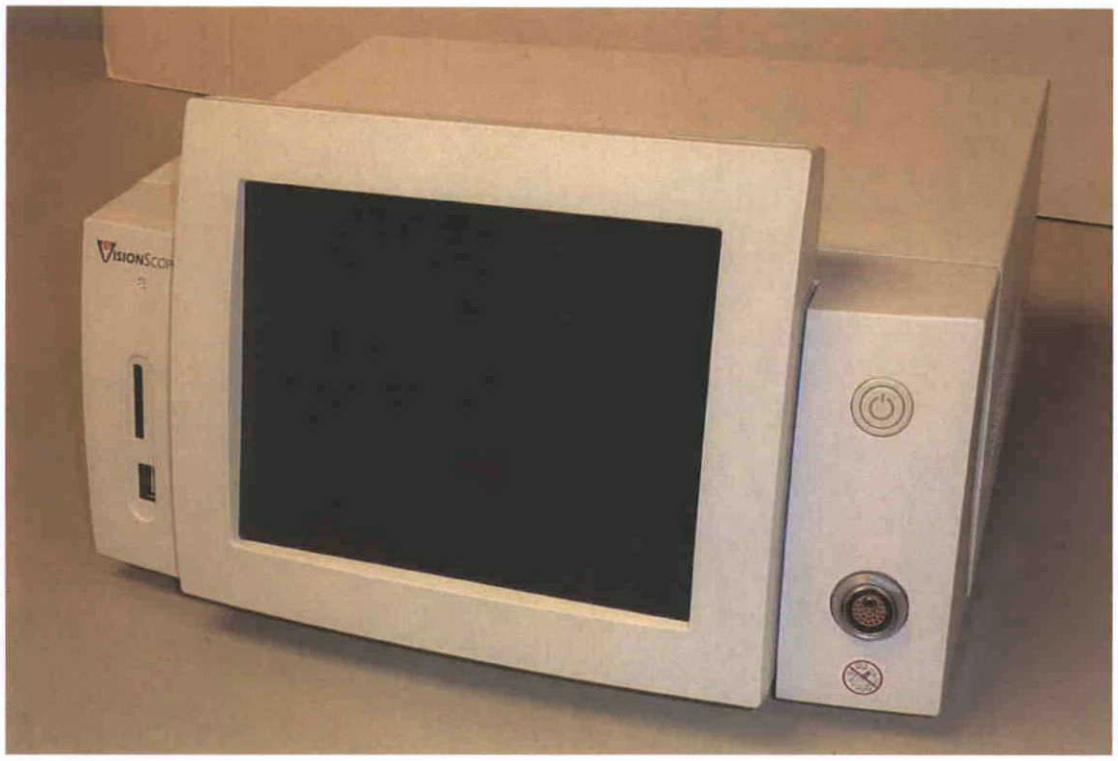
55

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict
* 57.5	Components shall be used in accordance with their intended use and in consideration to their inherent limitations	(b)(4) [redacted]	
58.2DV	Protective Earthing Terminals		
* 58.2	Soldering alone shall not be used. Connections shall be made mechanically secure as well as being soldered.		
59.1DV	Internal Wiring Methods		
59.1	Connecting cords between equipment parts shall comply with the National Electric Code		
59.1	If exposed to abuse the cable shall be SJT, SJTO, SJO, ST, SO, STO or equivalent		
59.1	If not exposed to abuse the cable shall be as indicated above or shall be SPT-2, SP-2, SPE-2, or equivalent or SVT, SVTO, SVE or equivalent, or insulation of 0.8 mm or more		
	Interconnecting cables operating at a voltage not exceeding 25 vac rms or 60 vdc or peak supplied from a source which is separated from the supply mains by one of the methods described in subclause 17g)		
59.1	If exposed to abuse, flexible cord or cable is considered protected from abuse from a rolling table or similar equipment at a time when such equipment is likely to be used in the vicinity of the equipment if one or more of the following conditions are met:		
59.1 a)	The entire cord or cable is 3 ft or more above the floor,		
59.1 b)	The cord or cable is guarded from contact by such equipment. A cord or cable that may touch the floor under any condition of intended use is to be considered exposed to abuse, or		
59.1 c)	The entire cord or cable, which may be retractable helically coiled type constructed so as to retain retractability, supplies a hand-held device. The cord length is limited to not contact the floor while positioned in stored position or 2 ft above the floor		
* 400	For equipment which uses oxygen, special safety hazards associated with use of oxygen should be addressed in accordance with		

556

National Differences from CB Bulletin 112A dated December 2006			
Clause	Requirement + Test	Result - Remark	Verdict
	clause 400	(b)(4) [redacted]	
	These requirements are based on oxygen-related requirements from IEC 601-2-19, particular requirements for the safety of baby incubators		
60DV.1.1.1	General		
* 600	A separate power unit employing a separable connector for supplying the equipment shall be packaged with the equipment Or Labeled with required markings (Refer to standard for labeling requirements)		
60DV.1.2.2.1 * 600	A direct plug-in unit shall comply with the mechanical assembly, enclosure, input connections, accessibility of live parts, and grounding requirements specified in the standard for class 2 power units, UL 1310		
60DV.1.2.3.1	A direct plug-in unit shall comply with the direct plug-in requirements for blade secureness, security of input contacts, and abuse tests specified in the Standard or Class 2 Power Units, UL 1310		
60DV.1.2.3.2	During the tests specified in Sub-clause 57.9.1 a) and 57.9.1 b), the external enclosure temperature rise of a direct plug-in unit shall not exceed 65°C, except a temperature rise of 125°C is acceptable in the unit permanently opens within one hour after initiation of the test.		
60DV.1.2.4.1	A direct plug-in unit provided with a mounting tab shall be marked in accordance with the requirements for semi-permanent mounted units specified in the Standard for Class 2 Power Units, UL 1310.		

17.9 - Attachment 3 Test Pictures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[redacted]

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[redacted]

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[redacted]

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[redacted]

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[redacted]

SECTION 18. PERFORMANCE TESTING SUMMARY - BENCH

Summary of Performance Testing

All verification and validation data presented in this 510(k) submission demonstrated that the device is safe and effective, and performs as intended.

VisionScope conducts product development and manufacturing activities in conformance with a Quality System Manual and a set of Standard Operating Procedures (SOPs). The quality system was audited by TUV Rheinland of North America to be in compliance with both FDA CFR820 and ISO-13485:2003 requirements. As of this writing, TUV has completed a Stage 2 on-site audit and have sent the recommendation report to their Certification Committee to approve ISO-13485:2003 certification.

VisionScope conducted the verification and validation (V&V) testing to demonstrate safety and effectiveness and substantial equivalence to the predicate devices listed in Section 12. All V&V tests are traceable to the specification documents (User Needs, Product Requirements, Engineering Specifications, Labeling, Instructions for Use, Software Requirements & Specifications, and Software Design Specifications) and conducted according to documented protocols with quantifiable pass/fail criteria. Risk Analysis, Design Failure Mode and Effect Analysis (FMEA) and Risk Mitigation are conducted and verified in parallel with the development activities and updated when appropriate, in accordance with ISO 14971:2007 Risk Management requirements.

Final V&V are conducted with process-validated, production-equivalent and revision-controlled samples that are documented in the V&V reports and Device History Record.

Design Review and Design Transfer processes are documented in accordance with SOPs and maintained in the Design History File.

Appendix A of this document provide a list of a Verification and Validation reports done in a Laboratory Bench as well as Cadaver Laboratory environment, along with a short summary of the objectives and conclusions. The individual test reports are attached in Section 18 of this 510(k) submission.

All verification and validation test reports follow the same general table format:

- Document the device under test (S/N, part number, etc.), along with other equipment used and test conditions
- List the specific bench tests conducted
- Provide a reference to the specification (section numbers of the appropriate documents)
- Describe the test protocol
- List the pre-defined pass/fail or acceptance criteria
- State the actual test result
- List any other comment or provide a reference to more detailed reports or notes
- Initial and date of the tester

Appendix A. Summary of Performance Bench Testing Reports

18.2 – 80030 VisionScope System Validation Protocol & Report

Validation is carried out to demonstrate that Device meets the User Needs. This validation testing is carried under simulated conditions in the laboratory, traceable on a section-by-section basis to the User Needs and Product Requirements (VisionScope Document 80002). The pass/fail criteria are either quantifiable parameters or can be answered in the form of presence/absence of certain feature sets.

The conclusion from this validation test is that the device meets the User Needs and Product Requirements on an item-by-item basis.

18.3 – 80084 VisionScope System Validation in Cadaver Laboratories

This validation is carried in three separate Cadaver Laboratories involving six surgeons. The main objective is to access the safety and effectiveness under a simulated endoscopic procedure environment. The main evaluation and acceptance criteria are the image quality and the ability of the surgeon to visualize various compartments inside the articular joints, using the small diameter VisionScope endoscope, light sheath and cannula.

The conclusion of this validation test is that all six surgeons are highly satisfied with the image quality, and find the device to be safe and effective. They see an advantage in the smaller diameter (smaller incision) of the VisionScope endoscope. They are able to access and visualize the interior of the cavity easily, and to perform the diagnostic functions that they normally perform using predicate endoscopes which have substantially larger diameters.

18.4 – 80099 Validation of Usability of Instructions for Use

This validation is carried out in a physician office environment by a surgeon and a M.D. candidate. The main objective is to validate the usability of the Instructions for Use, that the instructions are written clearly and that they can follow and carry out the procedures as written to perform the intended functions of the device. The evaluation is performed on a section-by-section basis through the Instructions for Use. Where appropriate, they provided feedbacks so that the instructions can be improved.

Additionally, the Instructions for Use have also been evaluated by TUV Rheinland as part of their testing of the device to ensure compliance with the labeling and instructions requirements of the IEC 60601-1 Electrical Safety standard for electrical medical devices, as documented in Section 17.

The conclusion of this validation is that the Instructions for Use are acceptable by the medical professional end-users, and are in compliance with the IEC60601-1 requirements.

18.5 - 80026 Verification of VisionScope Instructions for Use per UL/IEC 60601-1 and IEC 60601-2-18

This report contains an item-by-item review of the compliance of the Instructions for Use to the requirements of UL/IEC 60601-1 and IEC 60601-2-18.

This verification has been reviewed and accepted by TUV Rheinland of North America as part of the certification of the VisionScope system to these two IEC standards for electrical medical equipment.

18.6 – 80038 Verification of VisionScope Camera Head and Camera Control Unit

This report is an Engineering Verification of the VisionScope Electronics, comprising the Camera Head and Camera Control Unit. The verification is traceable to the specification documents, VisionScope Document 80004 Engineering Specifications of the VisionScope Camera Head and Camera Control Unit.

The verification is traceable to the specification on an item-by-item basis.

The conclusion of this verification is that the Camera Head and Camera Control Unit meet the engineering specifications and perform as intended.

18.7 – 80037 Verification of Endoscopes Illumination Sheath, Cannula and Trocar

This report is an Engineering Verification of the VisionScope Endoscopes and the Procedure Kit containing the Illumination Sheath, Cannula and Trocar. The verification is traceable to the specification documents, VisionScope Document 80001 Engineering Specifications of the VisionScope Camera Head and Camera Control Unit.

The verification is traceable to the specification on an item-by-item basis.

The conclusion of this verification is that the Camera Head and Camera Control Unit meet the engineering specifications and perform as intended.

18.8 - 80083 - Test Report for Endoscope and Camera Head Test Items before and after Sterilization Cycling

This verification report shows that the camera heads and endoscopes are compatible with sterilization with ETO, Sterrad 100S, and Sterrad NX. The report also contains references to sterilization efficacy tests of the camera head and endoscopes by an outside test laboratory, (b) [redacted] validating that Sterilization Assurance Level of at least 10^{-6} can be achieved using one half of the expected full cycle of sterilization, following the procedures as detailed in the reports and summarized in the Instructions for Use.

Two sets of three cameras and three endoscopes were used for each sterilization modalities. One set underwent 25 cycles of sterilization using ETO, and a second set underwent 25 cycles of Sterrad 100S, followed by 25 cycles of Sterrad NX for a cumulative total of 50 cycles of hydrogen peroxide.

There is no measurable performance degradation of the endoscopes and camera heads after undergoing 25 cycles of ETO and 50 combined cycles of Sterrad 100S and NX sterilization. The mechanical adhesive of all epoxy joints were examined under a high power microscope and were not found to exhibit detectable damage. The imaging camera and endoscope pairs were tested for resolution, sensitivity and color rendition, and no noticeable degradation trend has been detected.

The conclusion of this sterilization validation test is that the reusable cameras and endoscopes are compatible with the ETO, Sterrad 100S and Sterrad NX sterilization processes commonly used in hospitals, and can be sterilized to a SAL of $<10^{-6}$ following the prescribed processes.

18.9 - 80082 - ETO Sterilization Compatibility of Sterile Procedure Kit including Protective Barrier Effectiveness

This set of verification tests demonstrate: i) the compatibility of the Sterile Procedure Kit with ETO sterilization, and ii) the effectiveness of the Illumination Sheaths against penetration by hydrogen molecules, which by inference, bacteria and virus, after the Illumination Sheaths were subjected to ETO sterilization and a continuous agitation of 1 hour.

We followed a modified approach along the guidelines of the FDA Guidance for Manufacturers Seeking Market Clearance of Ear, Nose, and Throat Endoscope Sheaths Used as Protective Barriers, March 12, 2000. Due to the very small diameter of the endoscope sheath (<1.8 mm) and small enclosed volume, two independent biological test companies reported that it is not feasible to introduce the appropriate amount and concentration of agents required by Inside Challenge Method using bacteriophages as discussed in the Guidance document. In place of the bacteriophages, we used hydrogen gas molecules.

The rationale of this approach is explained more fully in VisionScope Document 80094, "Supplemental Description of the Sterile Endoscope Illumination Sheath as a Protective Barrier", also located in Section 14 – Sterilization and Shelf Life the FDA 510(k) file.

Three lots of seven samples, along with positive and negative control samples were tested prior to agitation and ETO sterilization. The samples are then sent for ETO sterilization. After sterilization, the endoscope sheaths are then agitated continuously and vigorously using a mechanical motor-driven test jig table for one hour (about 10,800 cycles of deflections). The leakage rate was measured using an Inside Challenge method with pressurized hydrogen at one standard atmosphere overpressure.

Both before and after ETO sterilization and agitation, the leakage rate was below the detection limit of 5×10^{-7} std. atm. cc/sec of the hydrogen leak detector. This gaseous leakage level was previously validated in refereed journal to correlate well with biological microbial detection method as described in VisionScope Document 80094.

Separately the polyurethane camera drapes were also tested in accordance with the ASTM-D6324-08 "Standard Test Methods for Male Condoms Made from Polyurethane" to be free of pin-hole water leaks.

The results of this validation test demonstrate that the Endoscope Sheaths are an effective barrier against bacteria and virus penetration.

18.2 - 80030 VisionScope System Validation Protocol & Report

VISIONSCOPE

SYSTEM VALIDATION PROTOCOL & TEST REPORT

Edit History

Revision	Date	Initials	Change Description
1.0	2/17/10	[redacted]	
2.0	6/4/2010		

(b)(4)

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Reviewed and Approved:

Camera and Optics System Functional Validation:

[redacted] (b) (6)

8/17/2010
Date

2/17/2010
Date

Sterilization Compatibility Validation:

6/9/2010
Date

6/9/2010
Date

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1575

1. Validation Purpose & Scope

This purpose of this document is to describe the Validation Protocol of the VisionScope System.

The Validation Protocol is traceable to the User Needs and Product Requirements (Document 80002).

The Validation process is made up of the following components:

- In-house Validation Testing under simulation conditions (this document)
- Testing by outside Independent Laboratories and Contractors (Test reports by [redacted] (b4)
- Cadaver Lab testing with Surgeons (end users) (VisionScope document 80084)
- Validation of Usability of the VisionScope Instructions for Use (by end users) (VisionScope document 80099)

1.1. Definition

We use the term Validation to mean *"**confirmation by examination and provision of objective evidence that specifications conform to user needs and intended uses, and that the particular requirements implemented through can be consistently fulfilled.**"*

Validation is a process of establishing evidence that provides a high degree of assurance that a product, service or system accomplishes its intended requirements. This involves acceptance of fitness for purpose with end users.

Validation can be expressed by the query "Are you building the right thing?", and verification by "Are you building the thing right?" It is required to have written requirements as well as formal procedures or protocol for determining compliance.

1.2. Validation Plan

Please refer to VisionScope System Verification and Validation Master Plan (80027).

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1576

Validation of the VisionScope System is made up of the following components:

Test Environment	Test Elements	Purpose
[redacted] (b)(4)	• Image Quality necessary to support diagnostic and surgical procedures • Access and visualization of different joint areas • Ease of Use • Areas for Future Improvements	Effectiveness (Primary) Safety (Secondary)
	• Electrical safety • Endoscope safety • Bio-burden • Sterilization efficacy • Sterile packaging effectiveness	Safety (Primary) Effectiveness (Secondary)
	• Product Features • Ease of Use • Usability • Software • Risk Assessment • Areas for Future Improvements • Instructions for Use	Meeting user needs - safety and effectiveness

1.3. Validation Traceability

Please refer to VisionScope Traceability Analysis (80072). This Validation report is traceable to the User Needs and Product Requirements Document (80002).

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1577

1.4. Validation Environment

For validation of safety, effectiveness and usability under simulated clinical conditions, tests are to be performed by orthopedic surgeons (actual end users) in a cadaver laboratory using knee, shoulder and hip specimens.

All validation tests are to be done in environmental conditions comparable to a physician examination room or an operating room.

- Temperature = 25 C ± 5 C
- Relative Humidity = 50% ± 25%

1.5. Other References

- VisionScope System Verification and Validation Master Plan (80027)
- VisionScope System Validation in Cadaver Labs (80084)
- VisionScope Software Validation (80028)
- VisionScope Traceability Analysis (80072)
- VisionScope Quality System Manual (QSM-01)
- VisionScope Design History File (DHF-VS1)
- VisionScope Endoscope System Description (80006)
- VisionScope User Needs and Product Requirements document (80002)
- Engineering Verification of Endoscopes, Illumination Sheaths, Cannulas and Trocars (80037)
- Engineering Verification of Camera Head and Camera Control Unit (80038)
- Instructions for Use, VisionScope System (PN 01112), VisionScope Camera Handpiece (PN 01115), Endoscopes (PN 01113) and VisionScope Procedure Kit (PN 01114)

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1578

2. Equipment and Material

Validation of the VisionScope System is carried out using equipment and material that are substantially equivalent to production. This means that the equipment and material have the following attributes:

- All engineering design details have been formally documented and released in accordance with the VisionScope Quality System Manual (QSM-01) and applicable Standard Operating Procedures (SOP).
- Engineering Design Details are located in the Design History File (DHF-VS1)
- The equipment and material are built under documented Work Instructions and Testing Procedures in accordance with the VisionScope Quality System Manual and applicable Standard Operating Procedures.
- Hardware and Software Configuration details of the units are tracked and traceable in the Device History Record (DMR) maintained at the VisionScope facility.

A listing of the Equipment used is given in the following table.

Equipment	Components	Part Number, Serial Number, or Lot Number
System 1	Camera Head (PN 50021-001)	[redacted] (b)(4)
	Camera Control Unit (PN 50034-001)	
	Endoscope (PN 50006-095)	
	Procedure Kit (PN 50033-095)	
	Firmware (PN 40001)	
	Instructions for Use (PN 01112, 01113, 01114, 01115)	
System 2	Camera Head (PN 50021-001)	
	Camera Control Unit (PN 50034-001)	
	Endoscope (PN 50006-095)	
	Procedure Kit (PN 50033-095)	
	Firmware (PN 40001)	
	Instructions for Use (PN 01112, 01113, 01114, 01115)	

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1579

Devices used in Sterilization Validation	Camera Heads (PN 50021-001)	[redacted] (b)(4)
	Endoscopes (PN 50006-220)	
	Procedure Kit (PN 50033-060) Procedure Kit (PN 50033-220)	

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3. Validation Traceability, Procedures & Results

Validation Category	Traceable to 80002 – User Needs and Product Reqmts Section No.	Description of Validation Items	Description of Procedures and Protocols	Expected results or endpoints	Actual Results	Initial & Date
Indications for Use Intended Users	3	VisionScope In-house Validation Testing under simulated conditions	• Use Production-equivalent equipment • Assembly camera, camera control unit, endoscope, disposable light sheaths, cannula and trocar, per Instructions For Use (PN 01112, 01113, 01114, 01115). • Perform Software Validation per 80028. • Perform simulated procedures by exercising the test cases per the Software Validation Protocol.	Software Validation Report documenting all the results of the Test Cases, Document No. 80028. Other supporting documents: • 80026 - VisionScope Instructions for Use Checklist per UL60601 and IEC60601-2-18.doc" • Verification Reports 80037, 80038, 80029.	[redacted] (b)(4)	LC 2/5/10
		Cadaver Lab Testing with multiple surgeons	• VisionScope System Validation Protocol & Report in Cadaver Labs. (Document 80084) • Cadaver Lab User Feedback Questionaire (FRM-018)	Surgeons should be able to perform simulated diagnostics and surgical procedures using VisionScope system on cadaver specimens.		LC 2/5/10
Clinical Needs	[redacted] (b)(4)					LC 2/5/10

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				[redacted] (b)(4)		
Clinical Needs	4.1.2	Correct lengths for: Short joints Knee Shoulder Hip	Consult surgeons on the necessary lengths for these joints and confirm in cadaver lab.	Working lengths: 60 mm 95 mm 160 mm 220 mm	Pass, surgeons in cadaver lab sessions confirmed that the lengths are appropriate. See Report 80084.	LC 2/5/10
Clinical Needs	4.1.3	Interchangeable needle endoscopes	Confirm that endoscopes of different lengths are compatible with the camera handpiece.	Endoscopes may be detached in between procedures for different anatomies.	Pass, all endoscopes and illumination sheaths are designed with the same attachment mechanism, more than 30 endoscopes and light sheaths have been attached without problems. See also Verification document 80037 and 80038	LC 2/5/10
Clinical Needs	4.1.4	[redacted] (b)(4)				LC 2/5/10

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1583

Needs			[redacted] (b)(4)	6/4/10
Clinical Needs	4.1.9	Access – cannula and trocar provided	[redacted]	LC 2/9/10
Clinical Needs	4.1.10	Sterilization Requirements	[redacted]	LC 6/4/10

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			[redacted] (b)(4)	
Clinical Needs	4.1.11	Means for assuring single-use of sterile barrier		LC 6/4/10
Clinical Needs	4.1.12	Image Quality - Resolution		LC 2/9/10

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	[redacted]
Environmental Conditions	[redacted]
	[redacted]
Regulatory Requirements	[redacted]

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1502

				ISO 10993-5 (2009) ISO 10993-10 (2007) ISO 10993-11 (2007)	the FDA 510(k) submission file, for a breakdown of the tests for all material used in the device, and for a collection of ISO 10993-5, -10, -11 certificates.	6/4/10
Marking, Labeling	9	[redacted]	(b)(4)	80026 - VisionScope Instructions for Use Checklist per UL60601 and IEC60601-2-18	Pass, see 80026, and TUV report: IEC/UL/CSA 60601-1: 30993481.001_Report.pdf 30993481.003_Report.pdf and attachments IEC60601-2-18: 30993481.001_Report_Att 1_60601-2-18.pdf and attachments 30993481.003_Report_Att 1_60601-2-18.pdf and attachments IEC60601-1-2: IEC 60601-1-2 30962774.001_Report 10-30-09.pdf	LC 2/10/10
				Issuance of IEC/UL/CSA-60601-1, IEC 60601-2-18 reports	IEC/UL/CSA 60601-1: 30993481.001_Report.pdf 30993481.003_Report.pdf and attachments IEC60601-2-18: 30993481.001_Report_Att 1_60601-2-18.pdf and attachments 30993481.003_Report_Att 1_60601-2-18.pdf and attachments IEC60601-1-2: IEC 60601-1-2 30962774.001_Report	LC 2/10/10

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1593

					10-30-09.pdf	
Manuals and Instructions for Use	10	VisionScope staff	Checklist is developed to assure compliance with the applicable sections per IEC/UL/CSA 60601-1 and IEC 60601-2-18, related to Manuals and Instructions for Use	80026 - VisionScope Instructions for Use Checklist per UL60601 and IEC60601-2-18	Pass, checklist prepared traceable to IEC 60601-1 and 60601-2-18. See document 80026 - VisionScope Instructions for Use Checklist per UL60601 and IEC60601-2-18.	LC 2/10/10
		Review by TUV	Review of all Instructions For Use to ensure that the standards per IEC/UL/CSA 60601-1 and IEC 60601-2-18 are met, and that the Markings and Symbols are correctly applied.	Issuance of IEC/UL/CSA-60601-1, IEC 60601-2-18 reports	Pass, IFU reviewed independently by TUV. See TUV certificate CU72100321.01.	LC 2/10/10
		Review by End-Users	Read IFU, and perform simulated surgical procedures in Cadaver lab settings	Cadaver Lab Testing Reports & Acquire Images; Surgeons are able to perform procedures per IFU.	Pass, IFU reviewed and followed in Cadaver Lab. See Reports 80084 – Validation in Cadaver Lab, and 80099 - Validation of Usability of Instructions for Use by End Users	LC 4/15/10

[redacted] (b)(4)

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1594

		tolerance levels between 90 VAC and 264 VAC line voltage			and attachments	
	11.1.3	Product shall be compatible with AC line frequencies between 50Hz AC and 60Hz AC at any voltage between 100VAC and 240VAC.	Testing by TUV.	IEC/UL/CSA 60601-1 report.	Pass, please see TUV Reports: IEC/UL/CSA 60601-1: [redacted] (b)(4)	LC 2/10/10

[redacted] (b)(4)

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1545

		users' institution. Unauthorized service shall void the warranty.				

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1596

18.3 - 80084 VisionScope System Validation in Cadaver Labs

VISIONSCOPE

SYSTEM VALIDATION REPORT IN CADAVER LABORATORIES

Edit History

Revision	Date	Initials	Change Description
1	12/06/09	[redacted]	
2	12/21/09		
3	1/29/10		

(b)(4)

1548

Reviewed and Approved:

[redacted] (b) (6)

2/4/10
Date

2/5/2010
Date

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1599

1. Introduction

This purpose of this report is to document the validation of the VisionScope System under simulated use environment by surgeons in cadaver laboratories, using a knee, shoulder and hip specimen.

Validation of the VisionScope System is made up of the following components:

Test Environment	**Test Elements**	**Purpose**
Cadaver Lab testing with Surgeons – **this report**	• Image Quality necessary to support diagnostic and surgical procedures • Access and visualization of different joint areas • Ease of Use • Areas for Future Improvements	Effectiveness (Primary) Safety (Secondary)
Outside Independent Laboratories	• Electrical safety and electromagnetic compatibility • Endoscope safety • Biocompatibility • Sterilization efficacy • Sterile packaging effectiveness	Safety (Primary) Effectiveness (Secondary)
VisionScope Laboratories (Report 80030)	• Product Features • Ease of Use • Usability • Software • Risk Assessment • Areas for Future Improvements	Meeting user needs - safety and effectiveness

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1.1. Validation Plan & Protocol

Validation in Cadaver Laboratories follow a Protocol traceable to the User Needs and Product Requirements Document (80002).

- VisionScope System Verification and Validation Master Plan (80027)
- VisionScope System Validation Protocol (80030)
- Cadaver Lab User Feedback Form (FRM-018)

1.2. Validation Traceability

Please refer to VisionScope Traceability Analysis (80072).

2. Personnel, Equipment and Material

For validation of safety, effectiveness and usability under simulated clinical conditions, the validation tests were performed by orthopedic surgeons (intended end users) using knee, shoulder and hip specimens in three cadaver lab sessions. The VisionScope system was further evaluated side by side and compared with predicate endoscopes previously 501(k)-cleared by FDA.

Validation was carried out using equipment and material that are substantially equivalent to production. The VisionScope equipment and material have the following attributes:

- All engineering design details have been formally documented and released in accordance with the VisionScope Quality System Manual (QSM-01) and applicable Standard Operating Procedures (SOP).
- Engineering Design and Manufacturing Specifications are located in the Design History File (DHF-VS1)
- The equipment and material are built under documented Work Instructions and Testing Procedures in accordance with the VisionScope Quality System Manual and applicable Standard Operating Procedures.

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- Hardware and Software Configuration details of the units are tracked and traceable in the Device History Record (DHR) maintained at the VisionScope facility.

Summary of Cadaver Lab Sessions:

Date	Location	Participants' Names & Affiliations	Specimen & Purpose	Equipment Serial Numbers/ Part Number of Procedure Kit (identified by Lot No. but not serialized individually)
1/27/2010	[redacted] (b)(4)		Knee – Diagnostic imaging without fluid irrigation	Camera: H-01008 CCU: C-01008 Firmware: Rev. A-11-01 Endoscope: EN01016K Procedure Kits: 50033-095 (Lot 01252010) Camera: H-01009 CCU: C-01009 Firmware: Rev. A-11-01 Endoscope: EN01019K Procedure Kits: 50033-095 (Lot 01252010)

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1602

12/18/2009	[redacted] (b)(4)	Shoulder – Diagnostic imaging without fluid irrigation	Camera: H-01004 CCU: C-01000 Firmware: Rev. A Endoscope: EN01014K Procedure Kit: 50033-095 (Lot 12032009)
12/4/2009	[redacted] (b)(4)	Hip – Diagnostic and surgical imaging: • With fluid irrigation • Without fluid irrigation • Test Compatibility with existing C-mount 4 mm endoscopes on the market • Compare image quality of VisionScope 1.4 mm endoscope with traditional 4 mm endoscope	Camera: H-01004 CCU: C-01000 Firmware: Rev. A Endoscope: EN01052H Procedure Kit: 50033-220 (Lot 12032009) Predicate Device being compared [redacted] (b)(4)

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1603

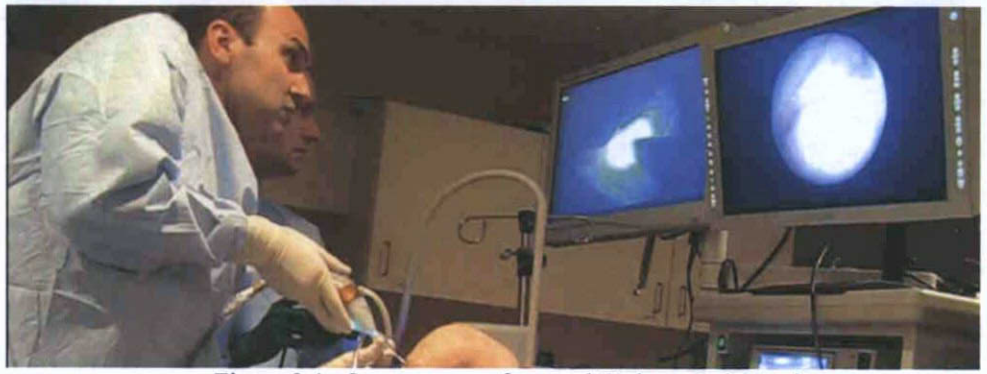

Figure 2.1 Setup at one of several Cadaver Lab Sessions

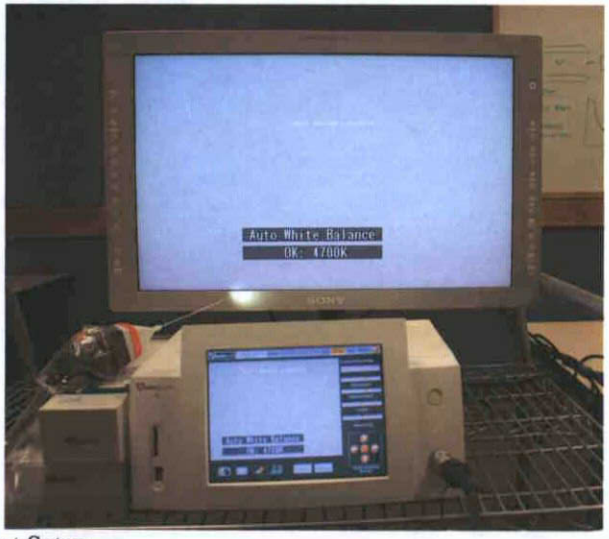

Figure 2.2 Equipment Setup

3.

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1604

3. Validation Procedures and Results

3.1. Knee Session on January 27, 2010

[redacted] (b)(4)

Test Step	Procedures	Purpose and Expected Results	Actual Results	Initial and Date
1	Set up Camera, Camera Control Unit, Endoscopes, Procedure Kit for Knee, per Instructions for Use (IFU) PN01112. Connect to external Monitor via HD-SDI cable.	Confirm that equipment can be setup as described in IFU. Live Images should be observed on both the front panel touch screen and the external monitor without artifacts. Image should be in focus	Pass. Equipment functions as expected, all parts fits together, camera and CCU displays live image on both the front panel touch screen and external monitor without artifacts. Image is in focus.	LC 1/27/10
2	Register patient, enter surgeon name and other optional parameters	Associate patient demographics with images recorded. System will prevent images to be recorded without a patient and surgeon ID. When patient data is saved, system will allow user to proceed, and prompt user to perform White Balance.	Pass. Images can be displayed on the front panel and external monitors, but cannot be recorded without patient I.D. association. Once patient and surgeon information was saved, system activates the "Procedure" and "Media" tab, allowing images to be saved and tagged with the patient I.D. System displayed a flashing on-screen display message, prompting user to point the camera at a white object and press any button to white balance.	LC 1/27/10
3	Surgeons take turn to make a portal to access	To test the sharpness of the trocar, and the fit of the trocar through	Pass, a portal on the knee was successfully made, and the cannula can be inserted into the knee with no difficulty.	LC

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5091

	knee, using the trocar and cannula supplied in the Procedure Kit, and to perform a diagnostic procedure.	the cannula. A portal should be easily made with the sharp point of the trocar, and that the trocar fits inside the cannula and can move freely.		1/27/10
4	Without any fluid distention and irrigation, insert the VisionScope 1.4 mm endoscope and light sheath into the cannula. Surgeon to perform a diagnostic imaging procedure inside the knee, in accordance with the normal standard of knee arthroscopy practice. Record still pictures as well as short video clips as needed by using the buttons on the camera handpiece or, with an assistant, the touch screen on the electronics unit.	Evaluate image quality for suitability of use in performing diagnostics, without fluid distention: - Clarity - Focus - Color Image should be clear enough to support decision making by surgeons.	Surgeon commented that image is clear, and image quality with the much smaller diameter VisionScope is as good as other endoscopy systems in the market. The image quality is good enough for him to make diagnosis. [redacted] (b)(4) VisionScope video with 1.4 mm diameter, 95 mm long endoscope (PN 50006-095) and light sheath (PN 50033-095), with no fluid distention.	LC 1/27/10

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1606

		Evaluate ability to see different compartments, without any fluid distention.	Surgeon commented that they were able to move around to see different compartment easily. Please see picture below.	LC 1/27/10

[redacted]

(b)(4)

VisionScope can image different compartments of the knee from one single portal, as illustrated in the picture above. Equipment: 1.4 mm diameter, 95 mm long endoscope (PN 50006-095) and light sheath (PN 50033-095), with no fluid distention.

Summary of Validation in this Cadaver knee session of January 27, 2010:

The VisionScope product meets the surgeons' need of high quality imaging to support diagnostic and surgical procedures. All four surgeons were satisfied with the image quality and the ability to see all he needs to see in a knee from one single portal. Their comments are summarized below:

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1607

(b)(4)

[redacted]

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1608

3.2. Shoulder Session on December 18, 2009

[redacted] (b)(4)

Test Step	Procedures	Purpose and Expected Results	Actual Results	Initial and Date
1	Set up Camera, Camera Control Unit, Endoscopes, Procedure Kit for Knee/Shoulder, per Instructions for Use (IFU) PN01112. Connect to external Monitor via HD-SDI cable.	Confirm that equipment can be setup as described in IFU. Live Images should be observed on both the front panel touch screen and the external monitor without artifacts. Image should be in focus	Pass. Equipment functions as expected, all parts fits together, camera and CCU displays live image on both the front panel touch screen and external monitor without artifacts. Image is in focus.	LC 12/18/09
2	Register patient, enter surgeon name and other optional parameters	Associate patient demographics with images recorded. System will prevent images to be recorded without a patient and surgeon ID. When patient data is saved, system will allow user to proceed, and prompt user to perform White Balance.	Pass. Images can be displayed on the front panel and external monitors, but cannot be recorded without patient I.D. association. Once patient and surgeon information was saved, system activates the "Procedure" and "Media" tab, allowing images to be saved and tagged with the patient I.D. System displayed a flashing on-screen display message, prompting user to point the camera at a white object and press any button to white balance.	LC 12/18/09
3	Surgeon to make a portal to access shoulder, using the trocar and cannula supplied in	To test the sharpness of the trocar, and the fit of the trocar through the cannula.	Pass, a portal on the shoulder was successfully made, and the cannula can be inserted into the shoulder with no difficulty.	LC

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	the Procedure Kit.	A portal should be easily made with the sharp point of the trocar, and that the trocar fits inside the cannula and can move freely.		12/18/09
4	Without any fluid distention and irrigation, insert the VisionScope 1.4 mm endoscope and light sheath into the cannula. Surgeon to perform a diagnostic imaging procedure inside the shoulder, in accordance with the normal standard of shoulder arthroscopy practice. Record still pictures as well as short video clips as needed by using the buttons on the camera handpiece or, with an assistant, the touch screen on the electronics unit.	Evaluate image quality for suitability of use in performing diagnostics, without fluid distention: - Clarity - Focus - Color Image should be clear enough to support decision making by surgeons.	Surgeon commented that image is clear, and image quality with the much smaller diameter VisionScope is as good as other endoscopy systems in the market. The image quality is good enough for him to make diagnosis. [redacted] (b)(4) VisionScope video with 1.4 mm diameter, 95 mm long endoscope (PN 50006-095) and light sheath (PN 50033-095), with no fluid distention.	LC 12/18/09

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1610

		Evaluate ability to see different compartments, without any fluid distention.	Surgeon commented that he was able to move around to see different compartment easily. He also stated that it will be easier to move around inside a knee. [redacted] (b)(4) VisionScope video with 1.4 mm diameter, 95 mm long endoscope (PN 50006-095) and light sheath (PN 50033-095), with no fluid distention.	LC 12/18/09

Summary of Validation in this Cadaver Shoulder session of Dec. 18, 2009:

The VisionScope product meets the surgeon's need of high quality imaging to support diagnostic and surgical procedures. The surgeon was satisfied with the image quality and the ability to see all he needs to see in a shoulder from one single portal.

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Other Comments from the Surgeon:

- The VisionScope images are excellent and more than adequate for diagnosis and procedures

Areas for Improvement for future product releases:

[redacted] (b)(4)

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3.3. Hip Session on Dec. 4, 2009

[redacted] (b)(4)

Test Step	Procedures	Purpose and/or Expected Results	Actual Results	Initial and Date
1	Set up Camera, Camera Control Unit, Endoscopes, Procedure Kit for Hip, per Instructions for Use (IFU) PN01112. Connect to external Monitor via HD-SDI cable.	Confirm that equipment can be setup as described in the Instructions for Use (IFU). Live Images should be observed on both the front panel touch screen and the external monitor without artifacts. Image should be in focus	Pass. Equipment functions as expected, all parts fits together, camera and CCU displays live image on both the front panel touch screen and external monitor without artifacts. Image is in focus.	LC 12/4/09
3	Register patient, enter surgeon name and other optional parameters	Associate patient demographics with images recorded. System will prevent images to be recorded without a patient and surgeon ID. When patient data is saved, system will allow user to proceed, and prompt user to perform White Balance.	Pass. Images can be displayed on the front panel and external monitors, but cannot be recorded without patient I.D. association. Once patient and surgeon information was saved, system activates the "Procedure" and "Media" tab, allowing images to be saved and tagged with the patient I.D. System displayed a flashing on-screen display message, prompting user to point the camera at a white object and press any button to white balance.	LC 12/04/09
3	Surgeon to make a portal to access hip, using the trocar and cannula supplied in the	To test the sharpness of the trocar, and the fit of the trocar through the cannula.	Pass, a portal on the hip was successfully made, and the cannula can be inserted into the hip with no difficulty.	LC 12/04/09

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[613

	Procedure Kit.	A portal should be easily made with the sharp point of the trocar, and that the trocar fits inside the cannula and can move freely.		
4	Surgeon to evaluate the stiffness of the cannula/trocar for access to hip.	Test the stiffness of the 4X stiffened cannula/trocar combination for hip arthroscopy.	Surgeon was able to move the cannula-trocar combination to the intended part of the hip anatomy. Surgeon commented that the 4X stiffened cannula-trocar combination for the Hip Procedure Kit was sufficient for him to place the tip of the cannula at the intended position.	LC 12/04/09
5	With the specimen under irrigation (surgical mode), and under distraction, insert the VisionScope 1.4 mm endoscope and light sheath into the cannula. Surgeon to perform a diagnostic imaging procedure inside the hip, in accordance	Evaluate image quality for suitability of use in performing diagnostics: - Clarity - Focus - Color Image should be clear enough to support decision making by surgeons.	Surgeon commented that image is clear, and image quality is very good for the very small size of the endoscope. The image quality is good enough for him to make diagnosis. The small diameter VisionScope was able to provide access and visualization of different areas of the hip with less distraction than with the 4 mm predicate endoscope.	LC 12/04/09

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	with their normal standard of hip arthroscopy practice. Record still pictures as well as short video clips as needed by using the buttons on the camera handpiece or, with an assistant, the touch screen on the electronics unit. The distraction of the hip was gradually relaxed from 50 lb to zero, while under observations by VisionScope.		[redacted] (b)(4) VisionScope video with 1.4 mm diameter, 220 mm long endoscope (PN 50006-220) and light sheath (PN 50033-220)	
		Evaluate ability to see different compartments, with and without distraction.	[redacted] (b)(4)	LC 12/04/09

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1615

			[redacted] (b)(4) VisionScope video with 1.4 mm diameter, 220 mm long endoscope (PN 50006-220) and light sheath (PN 50033-220)	
6	With the VisionScope Handpiece and Electronics, attach a traditional Smith & Nephew 4 mm x 160 mm x 30 degree videoarthroscope. Surgeon to perform a diagnostic imaging procedure inside the hip, in accordance with their normal standard of practice. Record still pictures as well as short video clips as needed by using the buttons on the	To evaluate the compatibility of the VisionScope electronics with traditional endoscopes currently on the market, and to demonstrate the superior image quality obtainable with the VisionScope electronics compared with current generation of HD video electronics.	Surgeon commented that the image quality was excellent. Video movies were recorded to document the scanning of the specimen in the hip (video files stored in directory "Cadaver Lab 12042009").	LC 12/04/09

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	camera handpiece or, with an assistant, the touch screen on the electronics unit.		[redacted] (b)(4)	
7	Operate a shaver blade tool to perform resection.	To conform that there is no electromagnetic interface causing artifacts in the video images. No video artifact should be seen.	Pass, no video artifact or electromagnetic interference is seen. (See picture above with shaver blade tool.)	LC 12/04/09

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1617

(b)(4)

[redacted]

Comparison of video images obtained with the VisionScope camera handpiece, camera control electronics, with (a) Left - Smith & Nephew predicate 4 mm x 160 mm x 70° video-arthroscope (Smith & Nephew Catalog Ref. 4126), and (b) Right – VisionScope 1.4 mm x 220 mm x 0° video-arthroscope.

Summary of Validation in this Cadaver Hip session of Dec. 4, 2009:

The VisionScope product meets the surgeons' need of high quality imaging to support diagnostic and surgical procedures. The VisionScope camera is compatible with both the smaller diameter VisionScopes and light sheaths (sub-2 mm), as well as with predicate 501(k) cleared 4.0 mm diameter

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1618

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[redacted]

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1619

18.4 - 80099 Validation of Usability of Instructions for Use

VISIONSCOPE

VALIDATION OF USABILITY OF THE VISIONSCOPE INSTRUCTIONS FOR USE

Edit History

Revision	Date	Initials	Change Description
1.0	3/15/2010	LC	First version
2.0	4/2/2010	JW	Minor revisions

1621

Reviewed and Approved:

[redacted] (b) (6)

April 12, 2010
Date

April 12, 2010
Date

1. Purpose

This purpose of this document is to describe the Validation of the Usability of the VisionScope Instructions for Use, by the end users who are healthcare professionals (physicians, nurses, physician assistants, medical students, or biomedical engineers).

The Validation is traceable to the Instructions for Use (IFU), on a section-by-section basis:

- Validation method and procedures
- Pass/fail or acceptance criteria
- Summary of the validation results, and where appropriate, points to additional documents or laboratory notebooks for more detailed results

The end point of the validation is ***"confirmation by examination and provision of objective evidence that the IFU conforms to user needs and intended uses, and that the particular requirements implemented through the IFU can be consistently fulfilled"***.

1.1. Reference Documents

- Instructions for Use, VisionScope System, PN 01112
- Instructions for Use, VisionScope Endoscope, PN 01113
- Instructions for Use, VisionScope Procedure Kit, PN 01114
- Instructions for Use, VisionScope Camera Handpiece, PN 01115

Note: The information in the IFU of the accessories (PN 01113, 01114, 01115) is duplicated and consolidated in the System IFU (PN 01112) of the entire system. Therefore, a full validation is performed only with the System IFU (PN 01112). The other IFU's are verified with an editorial process by the technical writer and the engineers performing complete system verification, and reviewed and approved by the General Manager.

1623

2. Validation Record

[redacted] (b)(4)

Equipment Record:

All validation tests are done using production units that are under revision control, with configurations documented in the Device History Record.

Equipment Description	Equipment Part Number	Serial Number	Revision Number
Camera Handpiece	50021-001	H01008	1
Camera Control Unit	50034-001	C01011	1
Endoscope	50006-060	EN01002S	A
Procedure Kit	50033-060	N/A	A
Software	40001	N/A	A
Instructions for Use, VisionScope System	01112	N/A	2.4
Instructions for Use, VisionScope Endoscopes	01113	N/A	2.2
Instructions for Use, VisionScope Procedure Kit	01114	N/A	2.2
Instructions for Use, VisionScope Camera Handpiece	01115	N/A	2.3

A picture of the setup of the validation equipment is shown in Figure 2.1.

1624

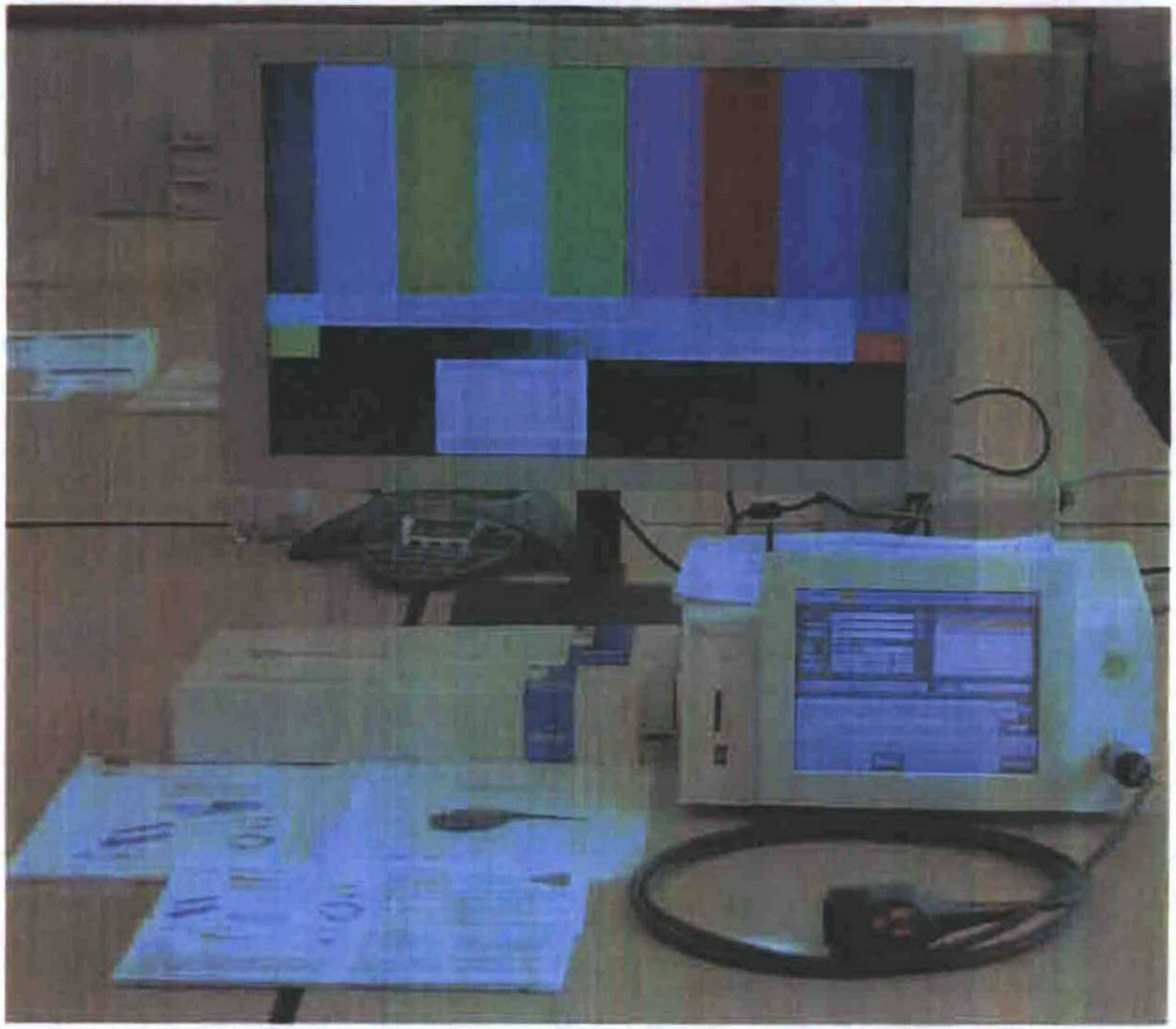

Figure 2.1 Validation Equipment Setup

1625

3. Validation Procedures, Summary Results and Additional Supporting Information

Provide additional supporting documents and references where appropriate when the full details cannot be accommodated in the table below.

Page No. IFU PN 01112	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
1	Indications for Use	[redacted]				
1	Intended Users					
1	Contraindications					

(b)(4)

1026

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
		[redacted]				
1	Warnings & Precautions					
3	Glossary of Symbols					
4	Glossary of Terms					
6	Device Description					

(b)(4)

(627)

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
		[redacted]				
7	System Components					
9	Unpacking, Inspection and Installation					
9	Front Panel Layout					

(b)(4)

1628

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
		[redacted]				
11	Rear Panel layout					
12	Camera Handpiece Layout					
12	Overview of the Endoscopy Process					
13	Using the Camera Control Unit					
14	Starting Up and Shutting Down					

(b)(4)

1629

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
14	Using the Touch Screen	[redacted]				
15	Entering the Password					
16	Performing a Patient Procedure - Reprocessing Requirements					
17	Registering a Patient and Starting a Procedure					
19	Assembling the Endoscope and Camera Handpiece					
21	Installing the Light Sheath					

(b)(4)

1630

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
		[redacted]				
23	Deploy the Flexible Camera Sheath					
24	Inserting the Cannula and Endoscope					
25	Viewing Live Video in Full-Screen Mode and Tab Mode					
26	Capturing Still Images and Recording Video					
27	Finishing a Patient Procedure					

(b)(4)

1631

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
		[redacted]				
28	Reviewing Media Recording Audio, and Adding Notes					
29	Switching between Live Video and Recorded Media					
29	Opening a Saved Procedure					
30	Reviewing / Deleting/ Capturing Still Images					
31	Reviewing / Deleting/ Capturing Video Recordings					
33	Recording/ Deleting/ Replaying Audio					

(b)(4)

1632

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
33	Adding Notes	[redacted]				
33	E-mailing a Patient Record					
34	Printing Patient Report					
36	Backing Up / Copy a Patient Record					
37	Monitoring Disk Usage					
38	Adjusting the Camera Settings					
38	Adjusting Picture Settings					
39	Color Bar					
39	White Balance					

(b)(4)

1673

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
		[redacted]				
39	Centering and Inverting Image					
40	Loading a Picture Profile					
41	Customizing a Picture Profile					
42	Editing the Surgeon List					
44	Retrieving a Forgotten Password					
45	Editing procedure names					
46	Deleting a Patient					

(b)(4)

1094

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
47	Setting Options	[redacted]				
48	Patient Data Options					
48	Captured File Options					
49	Surgical Display Options					
49	Video Options					
49	Controlling Audio Volume					
49	Placing the Light on Standby					

(b)(4)

1635

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
50	System Information	[redacted]				
50	Configuring Network Settings					
51	E-mail Settings					
51	Network IP Address					
51	Date and Time					
51	Passwords					
52	Printers					
53	E-mail Recipients					

(b)(4)

1036

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
		[redacted]				
54	Daylight Savings					
54	Hospital Information					
55	Touch Screen Calibration					
55	Reset Settings					
55	Optional Accessories – External Monitors					
56	Printers					
57	Network Port					

(b)(4)

1637

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
		[redacted]				
57	Endoscopes					
57	Periodic Maintenance, Cleaning and Sterilization					
58	Service, Trouble Shooting, and Replacement					
61	System Specifications					
63	Electromagnetic Information					

(b)(4)

1638

(b)(4)

[redacted]

VisionScope System

A picture of the setup of the validation equipment is shown in Figure 2.1.

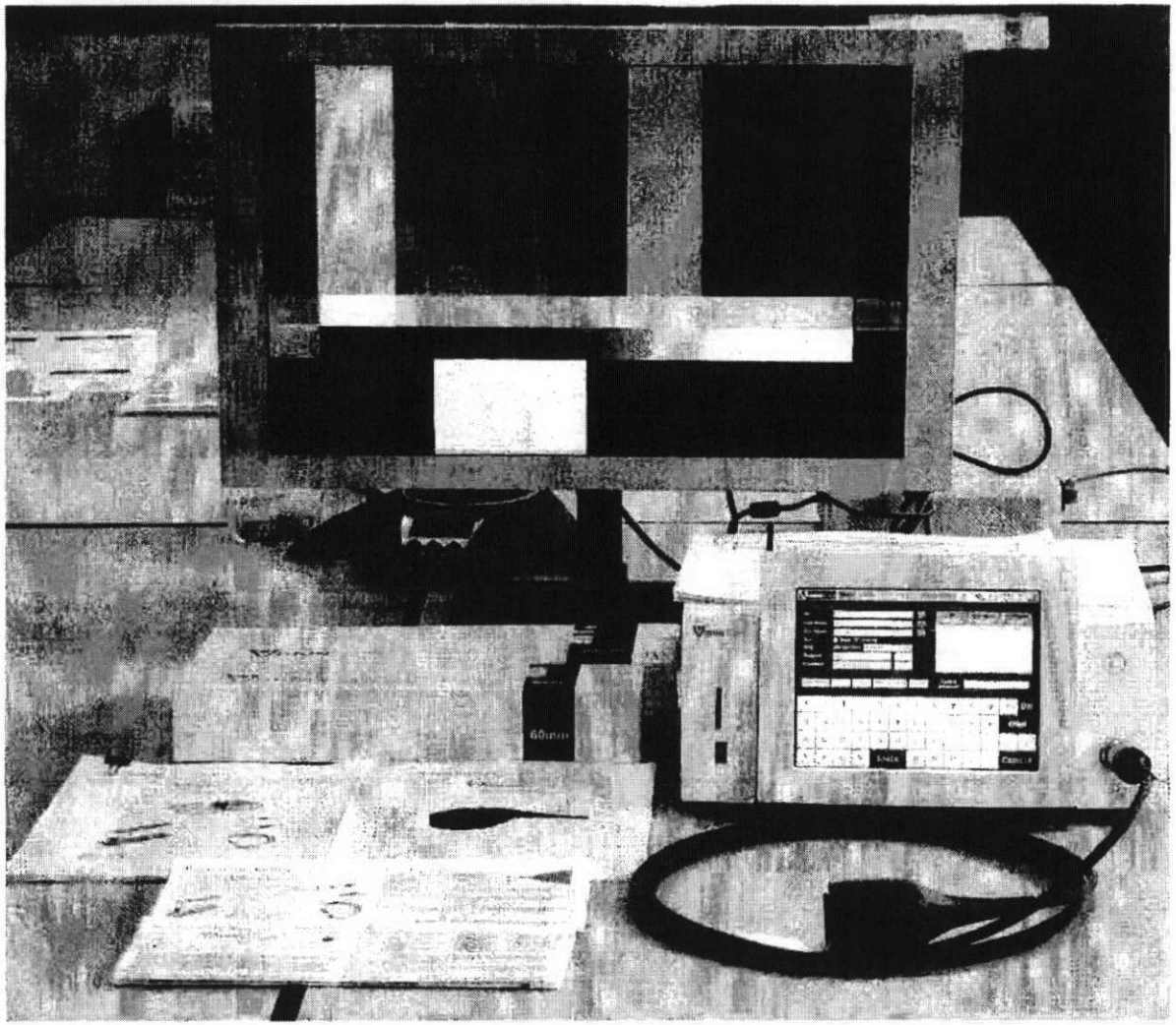

Figure 2.1 Validation Equipment Setup

1640

3. Validation Procedures, Summary Results and Additional Supporting Information

Provide additional supporting documents and references where appropriate when the full details cannot be accommodated in the table below.

Page No. IFU PN 01112	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
1	Indications for Use	[redacted]				
1	Intended Users					
1	Contraindications					

(b)(4)

1641

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
		[redacted]				
1	Warnings & Precautions					
3	Glossary of Symbols					
4	Glossary of Terms					
6	Device Description					

(b)(4)

1642

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
		[redacted]				
7	System Components					
8	Unpacking, Inspection and Installation					
9	Front Panel Layout					

(b)(4)

1643

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
		[redacted]				
10	Rear Panel layout					
11	Camera Handpiece Layout					
12	Endoscope Process Overview					
13	Using the Camera Control Unit					
14	Starting Up and Shutting Down					

(b)(4)

1644

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
14	Using the Touch Screen	[redacted]				
15	Placing the Light on Standby					
16	Entering the Password					
17	Performing a Patient Procedure - Reprocessing Requirements					
17	Registering a Patient and Starting a Procedure					
19	Assembling the Endoscope and Camera Handpiece					

(b)(4)

1645

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
21	Installing the Light Sheath	[redacted]				
23	Deploy the Flexible Camera Sheath					
24	Inserting the Cannula and Endoscope					
25	Viewing Live Video					
26	Capturing Still Images and Recording Video					
27	Finishing a Patient Procedure					

(b)(4)

1646

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
		[redacted]				
27	Reviewing Media and Adding Notes					
28	Switching to Live Video					
28	Opening a Saved Procedure					
29	Reviewing / Capturing Still Images					
30	Reviewing / Capturing Video Recordings					

(b)(4)

1047

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
31	Recording Audio	[redacted]				
31	Adding Notes					
32	E-mailing a Patient Records					
33	Printing Patient Report					
35	Backing Up / Copy a Patient Record					
36	Monitoring Disk Usage					
37	Adjusting the Camera Settings					
37	Adjusting Picture Settings					
38	Centering and Inverting Image					

(b)(4)

1648

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
		[redacted]				
38	Color Bar					
38	White Balance					
39	Loading a Picture Profile					
39	Customizing a Picture Profile					
41	Editing the Surgeon List					
43	Retrieving a Forgotton Password					
43	Editing procedure names					

(b)(4)

1449

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
44	Deleting a Patient	[redacted]				
45	Setting Options					
46	Patient Data Options					
46	Captured File Options					
47	Surgical Display Options					
47	Video Options					
47	System Information					

(b)(4)

1050

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
48	Configuring Network Settings	[redacted]				
48	E-mail Settings					
48	Network IP Address					
48	Date and Time					
49	Passwords					
49	Printers					
50	E-mail Recipients					
51	Daylight Savings					

(b)(4)

(b5)

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
51	Hospital Information	[redacted]				
52	Touch Screen Calibration					
52	Reset Settings					
53	Optional Accessories – External Monitors					
53	Printers					
54	Network Port					
54	Endoscopes					

(b)(4)

1652

Page No.	Section Headings	Validation Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Validation Result	Comments or References to supporting documents	Initial & Date
54	Periodic Maintenance, Cleaning and Sterilization	[redacted]				
56	Service, Trouble Shooting, and Replacement					
59	System Specifications					
61	Electromagnetic Information					

(b)(4)

1453

18.5 - 80026 Verification of VisionScope Instructions for Use per UL60601 and IEC60601-2-18

VISIONSCOPE

Verification of Instructions for Use for Compliance with UL60601:2003 & IEC 60601-2-18:2009

Edit History

Revision	Date	Initials	Change Description
1	1/12/10	LC	First version for TUV Rheinland review

1655

Document 80026 - Instructions for Use Verification per UL 60601:2003 & IEC 60601-2-18:2009

UL 60601-1:2003 Section No.	Description	VisionScope System IFU (PN 01112), Page No.	VisionScope Camera Head IFU (PN 01115), Page No.	VisionScope Endoscope IFU (PN 01113), Page No.	VisionScope Disposable Procedure Kit IFU (PN 01114), Page No.
6.8.2 a	– Instructions for use shall state the function and intended application of the EQUIPMENT	Page 1 – Introduction, Indications for Use, Intended Users	Page 1 – Introduction, Indications for Use, Intended Users	Page 1 – Introduction, Indications for Use, Intended Users	Page 1 – Introduction, Indications for Use, Intended Users
6.8.2 a	– Instructions for use shall contain all information necessary to operate the EQUIPMENT in accordance with its specification. This shall include explanation of the function of controls, displays and signals, the sequence of operation, connection and disconnection of detachable parts and ACCESSORIES, replacement of material which is consumed during operation.	Page 1 - 66	Page 1 – Page 26	Page 1 - 2	Page 1 - 2
6.8.2 a	– Instructions for use shall provide the USER or OPERATOR with information regarding potential electromagnetic or other interference between the EQUIPMENT and other devices together with advice regarding avoidance of such interference.	Page 63 - 65	Page 23 - 25	N/A, not electrical equipment	N/A, not electrical equipment
6.8.2 a	– Instructions for use shall include indications on recognized ACCESSORIES, detachable parts and materials, if the use of other parts or materials can degrade minimum safety.	Page 8, 9 , 12, Page 19 -25, Page 56 – 57	Page 6, 7, 10 - 18	Page 1, 2	Page 1, 2
6.8.2 a	– Instructions for use shall instruct the USER or OPERATOR in sufficient detail concerning cleaning, preventive inspection and maintenance to be performed by him,	Page 56 - 62	Page 18 - 22	Page 2	Page 1 on Inspection; One time use device, no

1658

Document 80026 - Instructions for Use Verification per UL 60601:2003 & IEC 60601-2-18:2009

UL 60601-1:2003 Section No.	Description	VisionScope System IFU (PN 01112), Page No.	VisionScope Camera Head IFU (PN 01115), Page No.	VisionScope Endoscope IFU (PN 01113), Page No.	VisionScope Disposable Procedure Kit IFU (PN 01114), Page No.
	including the frequency of such maintenance.				maintenance needed.
6.8.2 a	Such instructions shall provide information for the safe performance of routine maintenance. Additionally, instructions for use shall identify the parts on which preventive inspection and maintenance shall be performed by other persons, including the periods to be applied, but not necessarily including details about the actual performance of such maintenance.	Page 56-62	Page 18 - 22	Page 2	Page 1 on inspection; One time use device, no maintenance needed.
6.8.2 a	– The meaning of figures, symbols, warning statements and abbreviations on EQUIPMENT shall be explained in the instructions for use.	Page 3 - 7	Page 3 - 6	Page 1	Page 1
6.8.2 c	If a SIGNAL OUTPUT or SIGNAL INPUT PART is intended only for connection to specified EQUIPMENT complying with the requirements of this Standard, this shall be stated in the instructions for use (see Sub-clauses 19.2b) and 19.2c)).	Input: Page 10, 20, 59 - 61 Output: Page 11, 61 - 62	Input: Page 18 Output: Page 12	N/A	N/A
6.8.2 d	Cleaning, disinfection and sterilization of parts in contact with the PATIENT For EQUIPMENT parts which come into contact with the PATIENT during NORMAL USE, instructions for use shall contain details about cleaning or disinfection or sterilization methods that may be used (see also Sub-clause 44.7) or, where necessary, identify suitable sterilization agents, and list the temperature, PRESSURE,	Page 58 - 59, and References to Camera Head IFU (PN 01115) and Endoscope IFU (PN 01113)	Page 18 - 22	Page 2	Page 1 One time use sterile pack

1457

Document 80026 - Instructions for Use Verification per UL 60601:2003 & IEC 60601-2-18:2009

UL 60601-1:2003 Section No.	Description	VisionScope System IFU (PN 01112), Page No.	VisionScope Camera Head IFU (PN 01115), Page No.	VisionScope Endoscope IFU (PN 01113), Page No.	VisionScope Disposable Procedure Kit IFU (PN 01114), Page No.
	humidity and time limits which such EQUIPMENT parts can tolerate.				
6.8.2 e	Mains operated EQUIPMENT with additional power source Instructions for use of mains operated EQUIPMENT containing an additional power source not automatically maintained in a fully usable condition shall contain a warning statement referring to the necessity for periodical checking or replacement of such an additional power source. If CLASS I EQUIPMENT is specified for operation connected to a SUPPLY MAINS and alternatively using an INTERNAL ELECTRICAL POWER SOURCE, instructions for use shall contain a statement saying that where the integrity of the external protective conductor in the installation or its arrangement is in doubt, EQUIPMENT shall be operated from its INTERNAL ELECTRICAL POWER SOURCE.	N/A	N/A	N/A	N/A
6.8.2 f	Removal of primary batteries Instructions for use of EQUIPMENT containing primary batteries shall contain a warning to remove these batteries if EQUIPMENT is not likely to be used for some time, unless there is no risk of a SAFETY HAZARD arising.	Page 58 for replacement of backup watch-type battery	N/A	N/A	N/A
6.8.2 g	Rechargeable batteries Instructions for use of EQUIPMENT containing rechargeable batteries shall contain instructions to ensure safe use and adequate	N/A, no rechargeable battery	N/A	N/A	N/A

1458

Document 80026 - Instructions for Use Verification per UL 60601:2003 & IEC 60601-2-18:2009

UL 60601-1:2003 Section No.	Description	VisionScope System IFU (PN 01112), Page No.	VisionScope Camera Head IFU (PN 01115), Page No.	VisionScope Endoscope IFU (PN 01113), Page No.	VisionScope Disposable Procedure Kit IFU (PN 01114), Page No.
	maintenance.				
6.8.2 h	EQUIPMENT with a specified power supply or battery charger Instructions for use shall identify power supplies or battery chargers necessary to ensure compliance with the requirements of this Standard.	N/A	N/A	N/A	N/A
6.8.2 j	Environmental protection Instructions for use shall: – identify any risks associated with the disposal of waste products, residues, etc. and of the EQUIPMENT and ACCESSORIES at the end of their useful lives; **APRIL 25, 2003 UL 60601-1 51** – provide advice on minimizing these risks.	Page 4 – WEEE Symbol and explanation; Page 2, 3 – Disposal at end of useful life; Page 2, 28 – disposal of biohazards	Page 3 – WEEE Symbol and explanation; Page 3 – Disposal at end of useful life; Page 17 – disposal of biohazards	N/A: No environmental hazardous material, stainless steel, aluminium and glass only	N/A: No environmental hazardous material, stainless steel and glass only
6.8.3 a	General The technical description shall provide all data, which is essential for safe operation. This shall include: – data mentioned in subclause 6.1; – all characteristics of the EQUIPMENT, including range(s), accuracy, and precision of the displayed values or an indication where they can be found. In addition to details required to be included in instructions for use, the technical description shall state whether particular measures or particular conditions are to be observed for installing EQUIPMENT and bringing EQUIPMENT into use.	Page 7 – 12; Page 12, 14, 19 – 25; Page 50; Page 56 – 57; Page 62 - 65	Page 3, 9 - 25	Page 2	Page 2

1659

Document 80026 - Instructions for Use Verification per UL 60601:2003 & IEC 60601-2-18:2009

UL 60601-1:2003 Section No.	Description	VisionScope System IFU (PN 01112), Page No.	VisionScope Camera Head IFU (PN 01115), Page No.	VisionScope Endoscope IFU (PN 01113), Page No.	VisionScope Disposable Procedure Kit IFU (PN 01114), Page No.
6.8.3 b	Replacement of fuses and other parts – If the type and rating of fuses utilized in the mains supply circuit external to PERMANENTLY INSTALLED EQUIPMENT is not apparent from the information concerning RATED current and mode of operation of EQUIPMENT, the required type and rating of fuses shall be indicated in at least the technical description. – The technical description shall contain instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during NORMAL USE.	Fuses: Page 58 – 62 Endoscopes & Light Sheaths: Page 9 – 12; 19 - 26	N/A Endoscopes and Light sheaths: Page 9 - 18	N/A Light Sheaths: Page 1, 2	N/A Endoscopes: Page 1, 2
6.8.3 c	Circuit diagrams, component part lists, etc. The technical description shall contain a statement that the supplier will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the USER'S appropriately qualified technical personnel to repair those parts of EQUIPMENT which are designated by the manufacturer as repairable.	N/A; Page 58 states: "There are no user-serviceable parts.... "	N/A; Page 18 states: "There are no user-serviceable parts.... "	N/A; Page 2 states: "There are no user-serviceable parts.... "	N/A
6.8.3 d	Environmental conditions for transport and storage The technical description shall contain a specification of the permissible environmental conditions for transport and storage which shall be repeated on the	Page 63	Page 23	Page 2	Page 2

0941

Document 80026 - Instructions for Use Verification per UL 60601:2003 & IEC 60601-2-18:2009

UL 60601-1:2003 Section No.	Description	VisionScope System IFU (PN 01112), Page No.	VisionScope Camera Head IFU (PN 01115), Page No.	VisionScope Endoscope IFU (PN 01113), Page No.	VisionScope Disposable Procedure Kit IFU (PN 01114), Page No.
	outside of the packaging of the EQUIPMENT (see Sub-clause 6.1 v)).				

1661

Document 80026 - Instructions for Use Verification per UL60601:2003 & IEC 60601-2-18 :2009

IEC 60601-2-18:2009 Section No.	Description	VisionScope System IFU (PN 01112), Page No.	VisionScope Camera Head IFU (PN 01115), Page No.	VisionScope Endoscope IFU (PN 01113), Page No.	VisionScope Disposable Procedure Kit IFU (PN 01114), Page No.
201.7.9.2.2	**Warning and safety notices**				
a)	Warnings if surface temperatures on an APPLIED PART are likely to exceed 41 °C (see also 201.11.1.2.2).	N/A	N/A	N/A	N/A
b)	Warnings that high energy radiated light may be transmitted from the light emission window of the ENDOSCOPE, giving rise to high temperatures in front of the light emission window, and advice on how to minimize associated RISKS.	N/A	N/A	N/A	N/A
c)	Prevention of unacceptable RISKS if ENDOSCOPIC EQUIPMENT loses functions.	Page 60	Page 20	Page 1	Page 1
d)	Prevention of HAZARDOUS SITUATIONS, WHICH MAY CAUSE HARM, SUCH AS, burns and eye damage, by the replacement of the illumination lamp.	Page 2 – Bright LED light	Page 2 – Bright LED light	N/A	N/A
e)	Warning that the TYPE F APPLIED PART status of ENERGIZED ENDOSCOPES intended for use with a multiplicity of SUPPLY UNITS and/or light guide cables is ensured by, for instance, using only SUPPLY UNITS having isolated light guide output sockets.	N/A	N/A	N/A	N/A
f)	That before each use, the outer surface of the portions of ENERGIZED ENDOSCOPES which are intended to be inserted into a PATIENT should be checked to ensure there are no unintended rough surfaces, sharp edges or protrusions which may cause HARM.	Pages 2, 3, 25	Pages 2, 8, 16	Pages 1	Pages 2
g)	That before each use or after a change of viewing modes / settings, the OPERATOR	Pages 19, 24, 25, 59 -	Page 11, 15	Page 1, 2	N/A

1662

Document 80026 - Instructions for Use Verification per UL60601:2003 & IEC 60601-2-18 :2009

IEC 60601-2-18:2009 Section No.	Description	VisionScope System IFU (PN 01112), Page No.	VisionScope Camera Head IFU (PN 01115), Page No.	VisionScope Endoscope IFU (PN 01113), Page No.	VisionScope Disposable Procedure Kit IFU (PN 01114), Page No.
	should check to ensure the view observed through the ENDOSCOPE provides a live image (rather than a stored one) and has the correct image orientation.	61			
h)	Warning that INTERCONNECTIONS CONDITIONS require the APPLIED PARTS of other ME EQUIPMENT used within the CONFIGURATION FOR ENDOSCOPIC APPLICATION to be TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.	Page 7	Page 6	N/A	N/A
i)	Warnings regarding RISKS resulting from gas embolism caused by, for example, overinsufflation of air, inert gas prior to HIGH FREQUENCY surgery, or laser assist gas.	N/A	N/A	N/A	N/A
j)	Warnings that when ENERGIZED ENDOSCOPES are used with ENERGIZED ENDOTHERAPY DEVICES, PATIENT LEAKAGE CURRENTS may be additive. It should be noted that this is particularly important if a TYPE CF APPLIED PART ENDOSCOPE is used, in which case a TYPE CF APPLIED PART ENERGIZED ENDOTHERAPY DEVICE should be used in order to minimize total PATIENT LEAKAGE CURRENT.	Page 7	Page 6	N/A	N/A
k)	Avoidance of risks in the event of explosive gas concentrations being present in the area of use of HF ENERGIZED ENDOTHERAPY DEVICES.	Page 2	Page 2	N/A	N/A
l)	When ENERGIZED ENDOSCOPES and/or ENERGIZED ENDOTHERAPY DEVICES is/are used with laser equipment, advice	N/A	N/A	N/A	N/A

1663

Document 80026 - Instructions for Use Verification per UL60601:2003 & IEC 60601-2-18 :2009

IEC 60601-2-18:2009 Section No.	Description	VisionScope System IFU (PN 01112), Page No.	VisionScope Camera Head IFU (PN 01115), Page No.	VisionScope Endoscope IFU (PN 01113), Page No.	VisionScope Disposable Procedure Kit IFU (PN 01114), Page No.
	concerning their safe use shall be given, including avoidance of potential eye damage to the OPERATOR by, for example, wearing suitable protective filtering spectacles, or by inserting a suitable filter in the eyepiece of the ENERGIZED ENDOSCOPE.				
m)	That before each use, the compatibility of the ENDOSCOPIC EQUIPMENT with any ACCESSORIES and/or ENERGIZED ENDOTHERAPY DEVICES should be checked according to any criteria for safe use defined in the instructions for use.	Pages 2-3, 7, 9, 56 - 57	Pages 6, 18	N/A	N/A
n)	That before each use, the outer surface of the portions of any ENERGIZED ENDOTHERAPY DEVICES which are intended to be inserted into a PATIENT should be checked to ensure there are no unintended rough surfaces, sharp edges or protrusions which may cause HARM.	N/A	N/A	N/A	N/A
o)	Advice when ENDOSCOPIC EQUIPMENT is used with ACCESSORIES, other ME EQUIPMENT and/or non-ME EQUIPMENT within a CONFIGURATION FOR ENDOSCOPIC APPLICATION, on the avoidance of RISKS caused by their use together (see also 16.2 of the general standard and 201.15.4.1 of this particular standard).	Page 7, 56 - 57	Page 6	N/A	N/A

1664

Document 80026 - Instructions for Use Verification per UL60601:2003 & IEC 60601-2-18 :2009

IEC 60601-2-18:2009 Section No.	Description	VisionScope System IFU (PN 01112), Page No.	VisionScope Camera Head IFU (PN 01115), Page No.	VisionScope Endoscope IFU (PN 01113), Page No.	VisionScope Disposable Procedure Kit IFU (PN 01114), Page No.
201.7.9.2.12	**Cleaning, disinfection and sterilization** *Addition:* If the ACCOMPANYING DOCUMENTS provide instructions for visual and/or other inspection by the OPERATOR or the RESPONSIBLE ORGANIZATION to enable checking the suitability for reuse prior to each use, then the number of cycles the ENDOSCOPIC EQUIPMENT parts or ACCESSORIES can tolerate need not be given.	Page 19 – Instructions to Confirm Image Clarity of the Endoscope for Suitability of Reuse Prior to Each Use	Page 11 – Instructions to Confirm Image Clarity of the Endoscope for Suitability of Reuse Prior to Each Use	Page 2 – Instructions to Confirm Image Clarity of the Endoscope for Suitability of Reuse Prior to Each Use	Page 2 – Instructions to Confirm Image Clarity of the Endoscope for Suitability of Reuse Prior to Each Use
201.7.9.2.14	**ACCESSORIES, supplementary equipment, used material** *Addition:* When ENERGIZED ENDOTHERAPY DEVICES are used with HF SURGICAL EQUIPMENT, advice concerning their safe use shall be given in the instructions for use in accordance with the relevant requirements of IEC 60601-2-2.	N/A	N/A	N/A	N/A

18.6 - 80038 Verification of VisionScope Camera Head and CCU

VISIONSCOPE

ENGINEERING VERIFICATION OF VISIONSCOPE CAMERA HEAD AND CCU

Edit History

Revision	Date	Initials	Change Description
1.2	5/4/2009	[redacted]	
1.4	11/3/09		
1.5	12/31/09		

(b)(4)

1 of 7

Reviewed and Approved:

[redacted] (b) (6)

2/17/10
Date

2/17/10
Date

lity and Efficacy Verification:

6/9/2010
Date

6/9/2010
Date

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1. Document Scope

This purpose of this document is to describe the Verification of the VisionScope Camera and Camera Control Unit (CCU). The document provides the following information:

- Traceability of Verification against Specifications, on an item-by-item basis,
- Verification method and procedures
- Pass/fail or acceptance criteria
- Summary of the verification results, and where appropriate, points to additional documents or laboratory notebooks for more detailed results

This verification of the optics, including endoscopes, disposable light sheaths, and other accessories are given in separate documents.

1.1. References

- VisionScope Quality System Manual
- VisionScope Design History File DHF-VS1
- VisionScope Endoscope System Description (80006)
- VisionScope User Needs and Product Requirements document (80002)
- Engineering Specifications of Camera Head and Camera Control Unit (80004)
- Engineering Specifications of Endoscopes, Illumination Sheaths, Cannula and Trocars (80001)
- Instructions for Use, VisionScope System (PN 01112), VisionScope Camera Handpiece (PN 01115)

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1069

2. Verification Equipment Record

Test Articles being verified

Camera Head Assembly Part Number:	[redacted] (b)(4)
Revision No.:	
Serial Number(s):	
[redacted] (b)(4)	
Camera Control Unit Assembly Part Number:	
Revision No.:	
Serial Number(s):	

[redacted] (b)(4)

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16 70

Test Equipment

Equipment Used	Model	Serial Number
[redacted]		

(b)(4)

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/671

[redacted] (b)(4)

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3. Verification Procedures, Summary Results and Additional Supporting Information

Reference Specification Document: 80004 - Engineering Specifications of VisionScope Camera Head and CCU

Provide additional supporting documents and references where appropriate when the full details cannot be accommodated in the table below.

Doc. 80004 Spec. No.	Item	Verification Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Verification Result	Comments or References to additional Verification Document	Initial & Date
General Description						
3.1	Indications for Use	Check that the Indications for Use and Contraindications are contained in the Instructions for Use (PN 01112, 01113, 01114, 01115)	IFU's (PN 01112, 01113, 01114, 01115) contains the Indications for Use and Contraindications.	Pass. Indications for Use and Contraindications have been written clearly in the Instructions for Use, PN 01112 (System), as well as IFU's of subsystens PN 01113, PN 01114 and PN 01115.	Refer to Instructions for Use, PN 01112, 01113, 01114 and 01115. Also see 80026 - VisionScope Instructions for Use Checklist per UL60601 and IEC60601-2-18.doc	LC 1/23/10
3.2	Intended Users	Check that the Intended Users are described in the Instructions for Use (PN 01112, 01113, 01114, 01115)	IFU's (PN 01112, 01113, 01114, 01115) contains the description of the Intended Users.	Pass. The Intended Users have been specified in the Instructions for Use, PN 01112, Page 5, as well as in IFU of subsystems PN 01113, 01114 and 01115.	See Instructions for Use, PN 01112, 01113, 01114, and 01115. Also see 80026 - VisionScope Instructions for Use Checklist per UL60601 and IEC60601-2-18.doc	LC 1/23/10

1675

Doc. 80004 Spec. No.	Item	Verification Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Verification Result	Comments or References to additional Verification Document	Initial & Date
Engineering Specifications						
4.1	System Components	N/A	N/A	N/A	General Description of the System, for reference only, verification not applicable	LC 2/11/01
4.2 Essential Performance						
4.2.1	[redacted] (b)(4)				Pass	LC 1/23/10
4.2.2	[redacted]				See also Software Validation Report (80028)	LC 1/23/10

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(674)

Doc. 80004 Spec. No.	Item	Verification Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Verification Result	Comments or References to additional Verification Document	Initial & Date
4.2.3	[redacted]					LC 1/23/10
4.2.4						LC 2/11/10
4.2.5						LC 1/23/10
4.2.6						LC 2/11/10

(b)(4)

1675

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Doc. 80004 Spec. No.	Item	Verification Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Verification Result	Comments or References to additional Verification Document	Initial & Date
[redacted]					(b)(4)	
						LC 1/23/10
						LC 1/23/10
4.3.3 Image Centering						

1676

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Doc. 80004 Spec. No.	Item	Verification Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Verification Result	Comments or References to additional Verification Document	Initial & Date
[redacted]						(b)(4) LC 2/4/10

1677

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Doc. 80004 Spec. No.	Item	Verification Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Verification Result	Comments or References to additional Verification Document	Initial & Date
[redacted] (b)(4)						
Centering of Camera+Endoscope Image (H01008) = 0 %			Centering of Camera + Endoscope Image (H01009) [redacted] (b)(4)			
4.3.4 Hermeticity		[redacted] (b)(4)				
4.3.4.1	Hermeticiy of camera head				See test report 80083 for results before and after sterilization cycling.	JL/LC 2/8/10

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1678

Doc. 80004 Spec. No.	Item	Verification Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Verification Result	Comments or References to additional Verification Document	Initial & Date
		[redacted]			(b)(4)	LC 6/4/201 0
4.3.4.2	Hermeticity of camera head and endoscopy C-mount interface	[redacted]				LC 1/23/20 10
4.3.5 Imaging Sensor Module S		[redacted]				
4.3.5.1	Image sensor optics size	[redacted]				LC /23/10

1679

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Doc. 80004 Spec. No.	Item	Verification Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Verification Result	Comments or References to additional Verification Document	Initial & Date
		[redacted]				
4.3.5.2	Aspect ratio					LC 1/23/10
4.3.5.3	Imager matrix size					LC 1/23/10
4.3.5.4	Unit pixel size					LC 1/23/10
4.3.5.5	Readout format					LC 1/23/10

(b)(4)

1680

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Doc. 80004 Spec. No.	Item	Verification Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Verification Result	Comments or References to additional Verification Document	Initial & Date
[redacted]					(b)(4)	LC 1/23/10
[redacted]						LC 1/23/10
[redacted]						
[redacted]						LC 1/23/10
[redacted]						LC 1/23/10
[redacted]						LC 1/23/10
[redacted]						LC 1/23/10

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1681

Doc. 80004 Spec. No.	Item	Verification Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Verification Result	Comments or References to additional Verification Document	Initial & Date
[redacted]					(b)(4)	2/11/10
						LC 1/23/10
						LC 6/4/2010

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1682

Doc. 80004 Spec. No.	Item	Verification Method or Procedures	Acceptance or Pass/Fail Criteria	Summary of Verification Result	Comments or References to additional Verification Document	Initial & Date

[redacted]

(b)(4)

1683

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18.7 - 80037 Verification of Endoscopes Illumination Sheath, Cannula and Trocar

VISIONSCOPE

ENGINEERING VERIFICATION OF ENDOSCOPES, ILLUMINATION SHEATHS, CANNULAS AND TROCARS

Edit History

Revision	Date	Initials	Change Description
1.3	5/4/2009	[redacted]	(b) (4)
1.5	12/29/09		
1.6	2/12/10		
1.7	5/20/10		

1707

Reviewed and Approved:

Opto-Mechanical Verification:

[redacted] (b) (6)

After Biocompatibility, Sterilization Efficacy & Sterilization Compatibility Verification:

[redacted] (b) (6)

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1. Document Scope

This purpose of this document is to describe the Engineering Verification of the Endoscopes, Illumination Sheaths and Accessories. The document provides the following information:

- Traceability of Verification against Specifications, on an item-by-item basis,
- Verification method and procedures
- Pass/fail or acceptance criteria
- Summary of the verification results, and where appropriate, points to additional documents or laboratory notebooks for more detailed results

This document describes only the endoscopes, disposable illumination sheaths, cannulas and trocars in four different lengths for the four types of applications. Except for the lengths, all other engineering parameters for the four endoscope families are identical. The engineering specifications and verification of the camera head, camera control unit and the LED illuminator source are given in separate documents.

1.1. References

- VisionScope Quality System Manual
- VisionScope Design History File DHF-VS1
- VisionScope Endoscope System Description (80006)
- VisionScope User Needs and Product Requirements document (80002)
- Engineering Specifications of Camera Head and Camera Control Unit (80004)
- Engineering Specifications of Endoscopes, Illumination Sheaths, Cannulas and Trocars (80001)
- Instructions for Use, VisionScope System (PN 01112), VisionScope Camera Handpiece (PN 01115)

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1709

2. Verification Equipment Record

Test Equipment

(b) (4)

[redacted]

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Test Articles being Verified

[redacted] (b) (4)

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3. Verification Traceable to Specifications

Reference Specification Document: 80001 - Engineering Specifications of Endoscopes, Illumination Sheaths, Cannulas and Trocars

Provide additional supporting documents and references where appropriate when the full details cannot be accommodated in the table below.

Doc. 80001 Spec. No.	Specification Item (Refer to Document 80001)	Verification Method or Procedures (Refer to additional document where needed)	Acceptance or Pass/Fail Criteria	Summary of Verification Result (Refer to additional verification report where needed)	Comments (Refer to additional document where needed)	Initial & Date
System Level - Capability						
3.1	Indications for Use	Check that the Indications for Use and Contraindications are contained in the Instructions for Use (PN 01112, 01113, 01114, 01115)	IFU's (PN 01112, 01113, 01114, 01115) contains the Indications for Use and Contraindications.	Pass. Indications for Use and Contraindications have been written clearly in the Instructions for Use, PN 01112 (System), as well as IFU's of subsystens PN 01113, PN 01114 and PN 01115.	Refer to Instructions for Use, PN 01112, 01113, 01114 and 01115. Also see 80026 - VisionScope Instructions for Use Checklist per UL60601 and IEC60601-2-18.doc	LC 1/23/10
3.2	Intended Users	Check that the Intended Users are described in the Instructions for Use (PN 01112, 01113, 01114, 01115)	IFU's (PN 01112, 01113, 01114, 01115) contains the description of the Intended Users.	Pass. The Intended Users have been specified in the Instructions for Use, PN 01112, Page 5, as well as in IFU of subsystems PN 01113, 01114 and 01115.	See Instructions for Use, PN 01112, 01113, 01114, and 01115. Also see 80026 - VisionScope Instructions for Use Checklist per	LC 1/23/10

1712

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18.8 - 80083 Sterilization Compatibility Validation Report for Endoscope and Camera Head

(b)(4) Sterilization Compatibility Validation Report

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(b)(4) Sterilization Compatibility Validation Report

Appendix A. 80083 – Pre-Sterilization Pictures

Summary: These series of pictures show the image quality, specifically resolution, of the six matched pairs of camera heads and endoscopes prior to sterilization cycling. All are able to resolve Target (3, 6) of the USAF 1951 Test Target.

(b)(4) Sterilization Compatibility Validation Report

(b)(4) Sterilization Compatibility Validation Report

(b)(4) Sterilization Compatibility Validation Report

(b)(4) Sterilization Compatibility Validation Report

(b)(4) Sterilization Compatibility Validation Report

(b)(4) Sterilization Compatibility Validation Report

Appendix B. 80083 – Post-Sterilization-Cycling Pictures

(b)(4) Sterilization Compatibility Validation Report

(b)(4) Sterilization Compatibility Validation Report

(b)(4) Sterilization Compatibility Validation Report

(b)(4) Sterilization Compatibility Validation Report

(b)(4) Sterilization Compatibility Validation Report

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(b)(4) Sterilization Compatibility Validation Report

Appendix C: SPS Medical Camera & Endoscope ETO Sterilization Cycling Certificate 0909-326-1.pdf

1778

(b)(4) Sterilization Compatibility Validation Report

Appendix D: SPS Medical Camera & Endoscope Sterrad 100S Sterilization Cycling Certificate 0909-326-1.pdf

1180

(b)(4) Sterilization Compatibility Validation Report

Appendix E: SPS Medical Camera & Endoscope Sterrad NX Sterilization Cycling Certificate 0909-326-1.pdf

1782

(b)(4) Sterilization Compatibility Validation Report

18.9 - 80082 ETO Sterilization Compatibility of Sterile Procedure Kit including Protective Barrier Effectiveness

ETO-Sterilization Compatibility of Sterile Procedure Kit, including Protective Barrier Effectiveness		
VISIONSCOPE	Document Number:	80082
	Date:	6/4/2010 – Test Report date
	Author:	[redacted] (b) [redacted]

Revision	Date	Initials	(b) (4)
1.0	2/18/2010	JL	[redacted]
1.1	3/23/2010	JL & LC	
1.2	6/4/2010	JL & LC	

Reviewed and Approved:

(b) (6)

[redacted]

6/8/2010
Date

6/8/2010
Date

1.0 Purpose – Specification Verification

This document provides the supporting data to VisionScope Document 80094 – "Supplemental Description of the Sterile Endoscope Illumination Sheath as a Protective Barrier", and describes the protocol to be used for verification of the following specifications, especially on the effectiveness of the illumination sheath as a protective barrier:

1.1 80001 – Specification 5.1.1 "Illumination Sheath Leak Rate"
1.2 80001 – Specification 5.1.4 "Illumination Sheath Rigidity"
1.3 80001 – Specification 5.2.2.4 "Illumination Characteristics"
1.4 80001 – Specification 3.4.2 "Condom (Camera Drape) Leak Rate"
1.5 80001 – Specification 5.2.3 "Sterilization Compatibility of Illumination Sheath and Sterile Barrier"
1.6 80001 – Specification 6.2.2 "Sterilization Compatibility of Trocar"
1.7 80001 – Specification 7.2.2 "Sterilization Compatibility of Canula"

2.0 Reference Documents

2.1 FDA Guidance for Manufacturers Seeking Marketing Clearance of Ear, Noise, and Throat Endoscope Sheaths Used as Protective Barrier
2.2 80094 – "Supplemental Description of the Sterile Endoscope Illumination Sheath Sheath Used as a Protective Barrier"
2.3 80001 – "Engineering Specifications of Endoscopes, Illumination Sheaths, Canulas and Trocars
2.4 80037 – "Verification of Endoscopes Illumination Sheath, Cannula and Trocar"
2.5 50023-XXX – "Illumination Sheath Assembly Drawing", XXX = 060, 095, 160, 220 for the four lengths of the Illumination Sheaths
2.6 50024-XXX – "Canula Assembly Drawing", XXX = 060, 095, 160, 220
2.7 50027-XXX – "Trocar Assembly Drawing" , XXX = 060, 095, 160, 220
2.8 50033-XXX – "Disposable Kit Assembly Drawing" , XXX = 060, 095, 160, 220
2.9 QR-020-0808-1 - (b) (4) [redacted]
2.10 #10209014 - "PCS ETO Sterilization Protocol"

3.0 Overview of Verification Process Flow

The rationale and detailed justification for using the Inside Challenge Method with hydrogen trace gas detector instead of with bacteriophages as described in the FDA Guidance Document [Ref. 2.1] as a means for establishing the effectiveness of virus penetration barrier is discussed in VisionScope document 80094 – "Supplemental Description of Sterile Procedure Kit and Endoscope Illumination Sheath Used as a Protective Barrier" [Ref. 2.2].

(b) (4)

[redacted]

4.0 Simulation Virus Penetration Testing

The Simulated Virus Penetration Test is based on the (b) (4) [redacted]

(b) (4) [redacted]

5.0 Verification Protocol

Protocol Results can be of the following forms:

- Pass
- Fail
- Complete
- Incomplete
- See Attached Documentation

(b) (4)

[redacted]

(b)(4) Sterilization Compatibility

[redacted]

(b) (4) [redacted]	
Pass/fail criteria (b) (4) [redacted] (b) (4) [redacted]	
5.4 Send samples to (b) (4) [redacted] ETO Sterilization.	Complete JL 6/4/10 (b) (4) [redacted]

	Record (DHR)

(b) (4)

[redacted]

(b) (4)

5.6 VisionScope to perform (b) (4) Test on Light Sheaths after the (b) (4) test. 5.6.1 Repeat steps 5.3.2 through 5.3.13.	(b) (4)
5.7 VisionScope to perform Trocar and Canula Rigidity Test.	

(b) (4)

1791

(b) (4)

[redacted]

5.8 VisionScope to perform Illumination Sheath Rigidity Test.	

(b) (4)

[redacted]

5.9 VisionScope to perform Condom (Polyurethane Camera Drape) Leak Rate Test per the ASTM-D6324-08 "Standard Test Methods	Pass, see Section 3.4.2 of VisionScope Document 80037

(b) (4)

[redacted]

5.10 VisionScope to perform illumination characteristics verification	Pass, see data in Appendix C as well as in Section 5.2.2.4 of

Measurement light output in lumens:	VisionScope Document 80037 LC 6/4/2010
(b) (4) [redacted]	

Appendix A – Parts Pre-ETO Sterilization

(b) (4)

[redacted]

Lot Number	Serial Number	Pass/Fail Criteria	Actual Result Pass/Fail Leak Check

(b) (4)

[redacted]

Appendix B – Parts Post-ETO Sterilization and Articulation

(b) (4)

[redacted]

Appendix C – Illumination output of Pre- and Post-ETO Sterilization and Articulation

(b) (4)

[redacted]

Lot Number	Serial Number	Pass/Fail Criteria	Light Output (lumens) before ETO Sterilization 5/27/2010	Light Output (lumens) after ETO Sterilization 6/4/2010	Light Output (lumens) after ETO & Articulation 6/4/2010	Pass/Fail
(b) (4) [redacted]						Pass
						Pass
						Pass
						Pass
						Pass
						Pass
						Pass
						Pass
						Pass
						Pass
						Pass
						Pass
						Pass
						Pass
						Pass
						Pass
						Pass
						Pass
						Pass
						Pass
						Pass
						Pass

Animal Test - Intentionally Left Blank – Not Applicable

Clinical Test - Intentionally Left Blank – Not Applicable

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Keying Chen

Subject: 510(k) Number K101734

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%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/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

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 888.1100	II	HRX
	(*If unclassified, see 510(k) Staff)	

Additional Product Codes: GCJ

Review: [signature] (Branch Chief) GSDB (Branch Code) 9/8/10 (Date)

Final Review: [signature] (Division Director) MD DD DR 9/8/10 (Date)

5

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

K101734

Date: September 2, 2010
To: The Record
Office: ODE
From: Kejing Chen, Ph.D., Biomedical Engineer
Division: DSORD/GSDB

510(k) Holder: VisionScope Technologies, LLC
Device Name: Visionscope High Definition Endoscopy Camera System With Camera
Contact: Dr. Lim Cheung
2353 Main Street, Suite 303
Concord, Massachusetts 01742
Phone: 978-776-9512
Fax: 978-776-9511
Email: lim.cheung@visionscope-tech.com

I. Purpose

The submission is for an endoscopy camera system, which has four individual components: Camera Control Unit, Camera Handpiece, Endoscopes, and Sterile Procedure Kit. Among the four components, the Camera Control Unit and the Camera Handpiece are used together and Endoscopes and Sterile Procedure Kit are accessories of the first two components. To support the safety and effectiveness, the sponsor cited five predicates and compared the entire system and each of the four components to the predicates. Regarding the bundling of multiple components, I had a meeting with Mr. Neil Ogden, Branch of GSDB/DSORD, on August 27, 2010. We concluded that since the system consists of multiple components and there are similar cleared products to the entire system, this "bundling" was acceptable.

The sponsor compared the entire system to a predicate device that is a camera system; moreover, the sponsor compared each individual component to predicate devices, such as Endoscopes, the Procedure Kit, etc. The Indications For Use are substantially equivalent to the IFUs of the predicates combined. In addition to the Indications For Use, the subject device and the predicates share similar technological characteristics, such as the imaging sensor, fiber optics and glass lens, illumination light guide, video signal processors, etc. There are some differences between the subject and predicate devices. However, the differences are mainly on the area of microelectronics implementation, optics and packaging. The sponsor also conducted risk analysis, design failure mode and effect analysis and risk mitigation and provided validation and verification documents including real images obtained using the camera system. In summary, the subject device has the substantially equivalent indications for use, same principles of operation, and the same technological characteristics as the predicate devices. The

differences do not raise new safety and effectiveness concerns. I thus recommend that the subject device be found substantially equivalent to the predicate devices cited.

An administrative note: after the receipt of the original submission, the company sent in two amendments, in both of which the sponsor stressed that the company's name should be "VisionScope Technologies, LLC", rather than the name "Vision Technologies Intl., Inc." listed in the 510(k) acknowledgement letter.

Consult: Dr. Long Chen, Reviewer of GSDB/DSORD, was 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 is an endoscopic imaging system. There are four pieces included for the device: camera control unit, containing video electronics/LED light source/an image recorder, a camera handpiece with an imaging sensor and control buttons, endoscopes in four lengths, and sterile procedure kit in four lengths. A 1.4 mm diameter semi-rigid fiber-lens endoscope fits within a disposable 1.7 mm diameter illumination sheath, which in turn fits through a 2 mm protal or cannula.

The disposable sterile procedure kit contains the illumination sheath, canula and trocar. When the device is used, the Camera Control Unit is first started up, and then the Camera Handpiece is connected. The patient will be registered using the touch screen on the Image Management module. Then the Endoscope is assembled, with the Light Source attached to the Endoscope and applicable Endoscope Protective Sheath attached. When the doctor operates the device, a small incision at the appropriate location is created with a trocar/cannula combination by the surgeon. The cannula is positioned at the area of interest. The trocar is removed, and the endoscope including illumination sources is inserted through the cannula to provide visualization of the interior anatomy. During the procedure, still images and video clips

8

can be captured from the live video.

Note that the procedure kit is provided sterile and intended for single use only.

III. Indications for Use

	Company	Indications for use
K101734 (subject)	Vision Technologies Intl., Inc.	*The VisionScope High Definition Endoscopy Camera System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization* and capture of still and motion pictures of an interior cavity of the body through a natural or surgical opening. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals. Additionally, when used in conjunction with an appropriately indicated and FDA 510(k)-cleared endoscope and light source, the VisionScope High Definition Endoscopy Camera Control Unit and Camera Handpiece are indicated for use in arthroscopic and endoscopic surgical procedures to provide illumination, visualization and capture of still and motion pictures of articular cavities, body cavities, hollow organs and canals.
K072879	InnerVue	*The InnerVueTM Diagnostic Scope System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening.* Examples of generic surgical use include the visualization of joints within the body. These joints can include, joints located in the torso/trunk, upper/lower extremities, and the temporomandibular joint.
K072675	Smith & Nephew	The line of rigid Arthroscopes/ENT Endoscopes is indicated to provide illumination and visualization in: Diagnostic and operative arthroscopic procedures. Endoscopic examination and treatment of the nasal cavities and nasal pharynx. In addition, the Smith & Nephew 4 mm diameter rigid Arthroscopes/ENT Endoscopes are indicated to provide illumination and visualization in: The removal of loose bodies and soft tissue within the hip joint as size/length appropriate.
K070266	Smith & Nephew	The Smith & Nephew HD Camera System is indicated for use in endoscopic surgical procedures to allow visualization of the articular cavities, body cavities, hollow organs and canals when used with an appropriately indicated endoscope. Additionally, when used in conjunction with a Smith & Nephew light source and light cable the Smith & Nephew HD Camera System is indicated for use in endoscopic surgical procedures in the thoracic cavity when used with an appropriately indicated thoracoscope.
K082813	Stryker	The Stryker LED Light Source is used to illuminate the site of surgery during minimally invasive surgical procedures in arthroscopy (orthopedic surgery), laparoscopy (general and

9

		gynecblogical surgery) and in Endoscopy (general, gastroenterological and ENT surgery). The light is transmitted from the source through an optical cable and a scope. The light source is an integral component of a visualization system which consists of a video camera, video monitor, video recorder, video printer, light cable and scope.
K060777	Smith & Nephew	The Smith & Nephew 660HD Image Management System is intended to capture intraoperative still and motion images.
K990354	Vision-Sciences EndoSheaths	The EndoSheath provides a sterile, disposable protective covering for the scope to be used during flexible endoscopic examination of the upper airway, vocal chords and/or nasal passages.

The subject device is for prescription use.

As discussed above, the device system includes the camera system as well as individual components such as the control unit, the camera handpiece, and the endoscope. The sponsor compared the entire system to a predicate device that is a camera system; moreover, the sponsor compared each individual component to predicate devices, such as Endoscopes, the Image Management System, etc. The Indications For Use are SE to the IFUs of the predicates combined.

(b) (4)

[redacted]

IV. Predicate Device Comparison

The submission is for an endoscopy camera system. In addition to this camera system, the submission also describes four individual components: Camera Control Unit, Camera Handpiece, Endoscopes, and Sterile Procedure Kit. Among the four components, the Camera Control Unit and the Camera Handpiece are used together and Endoscopes and Sterile Procedure Kit are accessories of the first two components. In the original submission, the sponsor compared the Camera System to a predicate K072879 by InnerVue, which consists of components such as camera handpiece, light source, cannula, and a procedural kit. In addition, the sponsor compared each component to other predicates: The Control Unit and Camera Handpiece vs. K070266 by Smith and Nephew; Endoscopes vs. K072675 by Smith and Nephew; LED Light Source within the Camera Control Unit vs. K082813 by Stryker; Image Management module within the Camera Control Unit vs. K060777 by Smith and Nephew; and the illumination sheath and sterile barrier vs. K990354 by Vision-Sciences.

The subject device and the predicates share similar technological characteristics, such as the imaging sensor, fiber optics and glass lens, illumination light guide, video signal processors, etc. There are some differences between the subject and predicate devices. For example, the camera control unit, the light source, and the image management unit in the subject device are integrated intone unit while the predicates have them in separate units; some predicates have analog video output while the subject only provides digital output. The differences are mainly on the area of microelectronics implementation, optics and packaging. The sponsor also provided bench testing and validation/verification documents. In summary, the subject device has the same principles of operation and the same technological characteristics as the predicate

devices. The differences do not raise new safety and effectiveness concerns.

V. Labeling

The sponsor provided the labels, marketing materials, and instructions for use for the camera system and individual components (Endoscope, Sterile Procedure Kit, Camera Handpiece). The labeling information includes necessary directions for use, indications for use, contraindications, warnings, sterility, and warranty statements. The labeling information is sufficient.

VI. Sterilization/Shelf Life/Reuse

As described above, there are four components in the system. Some of them are provided sterile, some are provided non-sterile but need to be sterilized between each use, and some are not intended to be used sterile by the users.

The Camera Control Unit – provided non-sterile and not intended to be used sterile by users. Periodic maintenance and surface cleaning is needed and corresponding instructions are provided. SE to the instructions for the control unit under K070266.

The Camera Handpiece – distributed non-sterile. It must be cleaned and re-sterilized by users when contaminated by bio-hazard material. (b)(4) [redacted] The sponsor also performed tests on the sterilization compatibility validation including imaging and functional tests on the camera handpiece and endoscope combination before and after sterilization. (b)(4) [redacted]

The Endoscopes – distributed non-sterile. It must be cleaned and re-sterilized by users when contaminated by bio-hazard material. . The sterilization method is using ETO, Sterrad 100S and Sterrad NX with a minimum sterility assurance level of 10^{-6}. Sterilization protocols and final reports are reported. In addition, the sponsor conducted sterilization compatibility validation including imaging and functional tests on the Camera Handpiece & Endoscope combination before and after sterilization cycling. The results are provided as well. SE to K072675.

The Sterile Procedure Kit – packaged and distributed sterile. The Kit is for single patient use only. The sponsor contacts (b)(4) [redacted] seal and package the Kit, prior to sterilization. The Kits then will be sterilized using ETO sterilization. The ETO Sterilization Protocol and the summary results of the Fractional Study showing SAL of 10^{-6} result are provided. Also, the shelf life for the Kit is 1 year and the validation file is provided.

In addition, the sponsor performed simulated virus penetration bench testing on the protective sheath, drape in conjunction with the camera or endoscope. The test data showed no leakage.

Note that one of the recommended sterilization methods is Sterrad NX. Dr. Long Chen, Reviewer of GSDB/DSORD, pointed out that there was being a recall from FDA to certain manufacturers of the sterilizer. Dr. Long Chen further contacted Dr. Elaine Mayhall, Reviewer/Chemist of Infection Control Devices Branch at Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices, on 9/2/10. Dr. Mayhall pointed out that "ASP received a warning letter about the Sterrads and the CycleSure BI and was directed to make

corrections. The sterilizers have not been recalled. Use of the devices in healthcare facilities has not been affected. So it is ok for a firm to recommend use of the Sterrad NX in their labeling for sterilization of their device". Thus, the recommended and validated sterilization methods by the sponsor are still valid.

VII. Biocompatibility

The sponsor listed all the materials used to manufacture the device and its each component and claimed that no other chemicals had been added to those materials. The sponsor conducted biocompatibility tests on the materials based on ISO 10993 standards. For direct patient contact materials, the following tests were performed: Cytotoxicity, Sensitization, Irritation/Intracutaneous Reactivity, Acute Systemic Toxicity, and Materials Mediated Rabbit Pyrogen. For indirect patient contact material, the Cytotoxicity test was performed. All the test reports are provided in the submission and the results are acceptable. There are no biocompatibility concerns.

VIII. Software

Version: 1.4		
Level of Concern: Moderate.		
	Yes	No
Software description:	X	
Device Hazard Analysis:	X	
Software Requirements Specifications:	X	
Architecture Design Chart:	X	
Design Specifications:	X	
Traceability Analysis/Matrix:	X	
Development:	X	
Verification & Validation Testing:	X	
Revision level history:	X	
Unresolved anomalies:		

The sponsor determined the level of concern of the software as MODERATE, which is acceptable and comparable to that of the predicate K072879. Based on the level of concern, the sponsor provided the following documents: software description, software requirement specification, architecture design chart, software design specification, traceability analysis, software development environment description, hazards and definition of safety-relevant functions, revision level history, unresolved anomalies, and validation.

The hazard analysis covers both the hardware and software aspects of the camera system. The analysis includes an overview of the risk management plan, risk analysis, the design FMEA, the software design FMEA including usability aspects, etc. System has been validated and verified. The documentation is sufficient and there are no further concerns on software.

VIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The sponsor declared the conformity to the following standards:

ANSI/AAMI/ISO 11135-1:2007
ISO 10993-7:2008
ISO 10993-5:2009
ISO 10993-11:2006
UL 60601-1:2003 R4.06
IEC 60601-1:1988 + A1:1991 + A2:1995
EN 60601-1:1990 + A1 + A2 + A3
CAN/CSA-C22.2 No. 601.1-M90
IEC 60601-1-4 / EN60601-1-4:2000
IEC 60601-1-6: 2004 for use in conjunction with IEC 60601-1:1998 + A1:1991 + A21995
IEC/EN 60601-1-2:2007
IEC 60601-2-18:1996 Second Edition + A1:2000

The sponsor retained TUV Rheinland of North America that performed the testing of the device according to a number of standards referred above. The test results are provided with the submission and the results are acceptable.

IX. Performance Testing – Bench

The sponsor conducted validation tests regarding biocompatibility, sterilization, and software. The sponsor also conducted risk analysis, design failure mode and effect analysis and risk mitigation. Documents from the sponsor show that final validation and verification were performed with revision-controlled samples. Real images obtained using the camera system were provided.

X. Performance Testing – Animal

N/A

XI. Performance Testing – Clinical

N/A

13

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-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:

   Please refer to Section III.

4. Explain why there is or is not a new effect or safety or effectiveness issue:

   Please refer to Sections III and IV.

5. Describe the new technological characteristics:

   Please refer to Sections II and IV.

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

7. Explain how descriptive characteristics are not precise enough:

14

Please refer to Sections II and IV.

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

XIV. Contact History

1. 09/02/2010: Telephoned the sponsor, Dr. Lim Cheung and we discussed the IFU statement which was not in correct form because it was on a business letterhead of the company. Dr. Lim Cheung agreed to change the format of the IFU statement. A copy of the revised IFU was received on 9/2/2010 via email.

XV. Recommendation

I recommend that this submission be found substantially equivalent to the predicate devices cited.

Regulation Number: 21 CFR 888.1100, 21 CFR 876.1500
Regulation Name: General and Plastic Surgery devices
Regulatory Class: Class II
Product Code: HRX, GCJ

Kejing Chen — 9/2/10
Lead Reviewer, GSDB/DSORD — Date

Neil Ogden — I concur with — 9/8/10
Branch Chief, GSDB/DSORD — Date

15

Chen, Kejing

From: Lim Cheung [lim.cheung@visionscope-tech.com]
Sent: Thursday, September 02, 2010 4:15 PM
To: Chen, Kejing
Subject: RE: K101734 IFU statement
Attachments: 4.1 - Statement of Indications for Use.pdf

Dear Dr. Chen,

Please see attached, and let me know if this is OK.

Best regards,

Lim

Lim Cheung, Ph.D.,
General Manager & CTO
VisionScope Technologies, LLC
2352 Main Street, Suite 303
Concord, MA 01742
Voice: 978-776-9512
Fax: 978-776-9511
Mobile: 617-283-1906

From: Chen, Kejing [mailto:Kejing.Chen@fda.hhs.gov]
Sent: Thursday, September 02, 2010 4:14 PM
To: Lim Cheung
Subject: K101734 IFU statement

Dear Dr. Cheung,

As we just discussed through the phone, could you please email me a copy of the Indications For Use statement in a correct format? Thanks.

Regards,

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

16

Indications for Use

510(k) Number (if known): K101734

Device Name:

VisionScope High Definition Endoscopy Camera System with:

- Camera Control Unit
- Camera Handpiece
- Endoscopes (Accessories in four lengths)
- Sterile Procedure Kits (Accessories in four lengths)

Indications for Use:

The VisionScope High Definition Endoscopy Camera System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of an interior cavity of the body through a natural or surgical opening. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

Additionally, when used in conjunction with an appropriately indicated and FDA 510(k)-cleared endoscope and light source, the VisionScope High Definition Endoscopy Camera Control Unit and Camera Handpiece are indicated for use in arthroscopic and endoscopic surgical procedures to provide illumination, visualization and capture of still and motion pictures of articular cavities, body cavities, hollow organs and canals.

Prescription Use __Yes_ (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)

Chen, Kejing

From: Mayhall, Elaine
nt: Thursday, September 02, 2010 4:08 PM
.o: Chen, Long H
Cc: Chen, Kejing; Turtil, Steven; Panguluri, Ramesh K; Claverie, Elizabeth F
Subject: RE: Sterrad 100S

Hi Long,

ASP received a warning letter about the Sterrads and the CycleSure BI and was directed to make corrections. The sterilizers have not been recalled. Use of the devices in healthcare facilities has not been affected. So it is ok for a firm to recommend use of the Sterrad NX in their labeling for sterilization of their device.

Elaine

Elaine Schalk Mayhall, Ph.D.
Chemist/Reviewer
Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health
WO66 Room 2612
10903 New Hampshire Ave.
Silver Spring, MD 20993
(301) 796-6301
laine.mayhall@fda.hhs.gov

From: Chen, Long H
Sent: Thursday, September 02, 2010 3:57 PM
To: Mayhall, Elaine
Cc: Chen, Kejing; Turtil, Steven; Panguluri, Ramesh K; Claverie, Elizabeth F
Subject: RE: Sterrad 100S

Elaine,

Do you know whether their recall is due to the FDA warning letter (http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm212230.htm)?

Long

From: Mayhall, Elaine
Sent: Thursday, September 02, 2010 3:51 PM
To: Chen, Long H
Cc: Chen, Kejing; Turtil, Steven; Panguluri, Ramesh K; Claverie, Elizabeth F
Subject: RE: Sterrad 100S

Hi Long,

I got your messages. From the attached link to the Class 2 Recall for the Sterrad NX, it appears that the sterilizers required new plugs and that all sterilizers were being repaired.

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/resCollection_2.cfm?ID=80228&CREATE_DT=2009-06-15

18

Does this answer your question?

Elaine

Elaine Schalk Mayhall, Ph.D.
Chemist/Reviewer
Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health
WO66 Room 2612
10903 New Hampshire Ave.
Silver Spring, MD 20993
(301) 796-6301
elaine.mayhall@fda.hhs.gov

From: Chen, Long H
Sent: Thursday, September 02, 2010 3:41 PM
To: Mayhall, Elaine
Cc: Chen, Kejing
Subject: Sterrad 100S

Elaine,

I understand we have an outstanding FDA warming on the Sterrad 100S, NX, 100NX sterilizer. Do you know whether the issue has been resolved? And what should we do if the sponsor recommends using these sterilizers in their labeling? Please advise. Thanks.

Long
Long Chen, Ph.D.
(301)796-6389
GSDB/DSORD/ODE/FDA
long.chen@fda.hhs.gov

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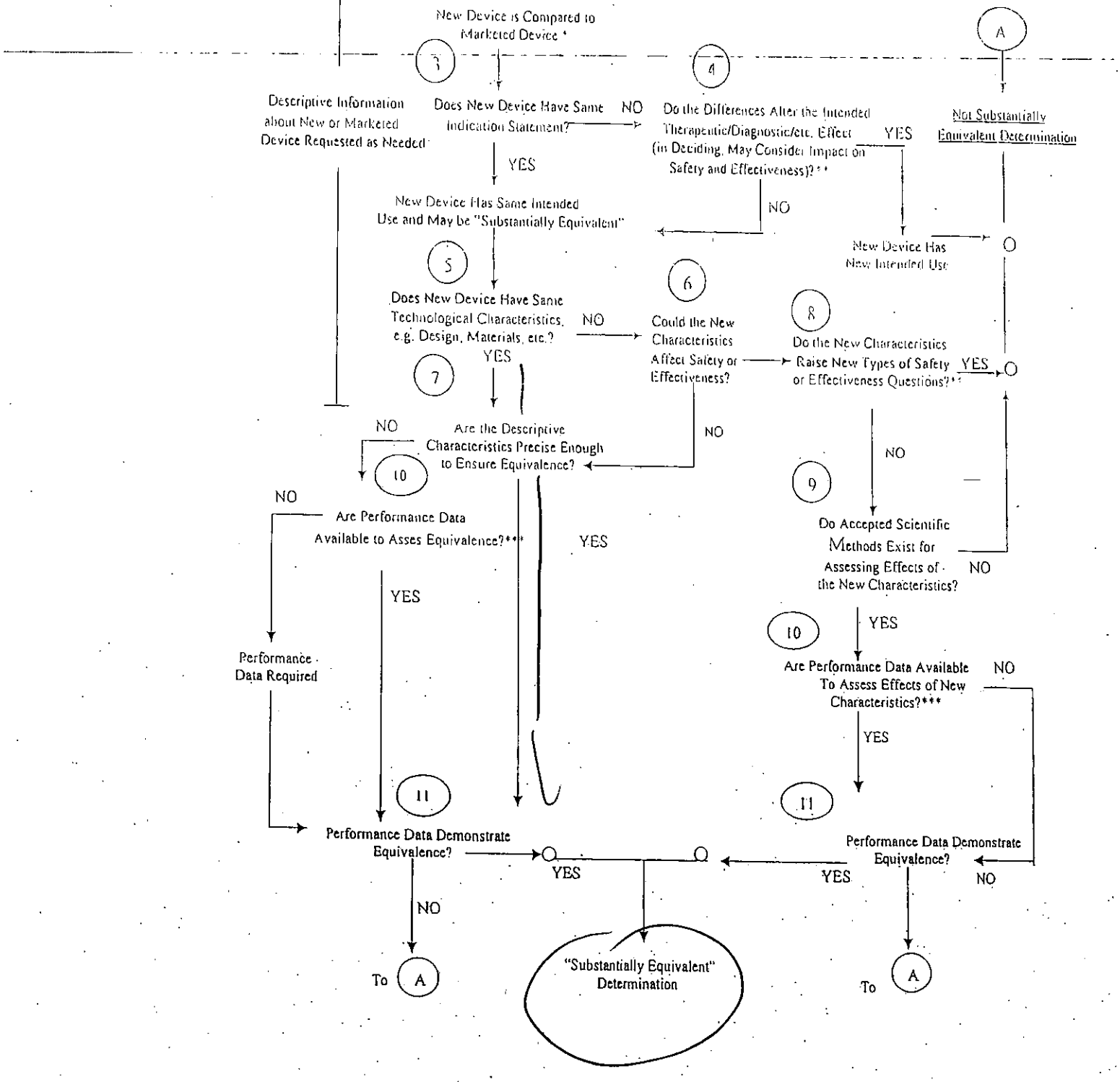
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 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.