

K131131

510(k) Submission – E.G. Scan™ II Esophagoscope System

Section 05_510(k) Summary

JUN 21 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: April 05, 2012

1. Company and Correspondent making the submission:

Name – IntroMedic Co., Ltd.

Address – Suite 1104, E&C Venture Dream Tower 6-Cha, 197-28 Guro-Dong, Guro-Gu,
Seoul, 152-719 Korea

Telephone – +82-2-801-9300

Fax – +82-2-801-9330

Contact – JinYoung, Lee

Internet – <http://www.intromedic.com>

2. Device :

Proprietary name : E.G. Scan™ II Esophagoscope System

Common Name : Esophagoscope System

Classification Name : Esophagoscope System

3. Predicate Device :

Manufacturer : IntroMedic Co., Ltd,

Device : E.G. Scan™ II Esophagoscope System

510(k) Number : K120702

4. Classifications Names & Citations :

21CFR874.4710, EOX, Esophagoscope System, Class2

5. Description :

5.1 Introduction

E.G. Scan™ II Esophagoscope System and its accessories are used for diagnosis of patients. E.G. Scan™ II Probe takes pictures of the esophagus of human and sends

IntroMedic Co., Ltd.

510(k) Submission – E.G. Scan™ II Esophagoscope System

image data to E.G. Scan™ II Controller. E.G. Scan™ II Controller processes and converts image data and upload. E.G. View™ image displaying software displays the image for diagnosis.

The E.G Scan™ II Esophagoscope Probe is disposable.

5.2 General Technology

E.G. Scan™ II Esophagoscope system is a transnasal esophagoscope designed to capture images of the esophagus. Captured images are viewed via the E.G. View™ Software for diagnosis of diseases related to the esophagus.

6. Indication for use :

The E.G. Scan™ II Esophagoscope System is intended for use in endoscopic access and examination of the larynx, esophagus and gastroesophageal junction.

7. Comparison with predicate device :

The E.G. Scan™ II Esophagoscope System and predicate device are substantially equivalent in the areas of design, indication for use, technological characteristics, function, application and safety and effectiveness. This was determined by reviewing the information provided in the 510(k) in comparison to the content specified in the FDA guidance documents.

8. Safety, EMC and Performance Data :

The E.G. Scan™ II Esophagoscope System has the same device characteristics as the predicate device, E.G. Scan™ Esophagoscope System of IntroMedic Co., Ltd.; intended use, material, design and use concept are similar. The biocompatibility of the patient contact parts has been demonstrated through the cytotoxicity, sensitization and irritation testing by ISO 10993-1 Biological evaluation of medical devices. The E.G. Scan™ II Esophagoscope System conforms to IEC 60601-1 Medical electric equipment, Part 1: General requirements for safety, IEC 60601-2-18 Medical electrical equipment-Part 2: Particular requirements for the safety of endoscopic equipment and IEC 60601-1-2 Medical electric equipment, General requirements for safety collateral standard electromagnetic compatibility.

IntroMedic Co., Ltd.

510(k) Submission – E.G. Scan™ II Esophagoscope System

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification IntroMedic Co., Ltd. concludes that The E.G. Scan™ II Esophagoscope System is safe and effective and substantially equivalent to predicate devices as described herein.

IntroMedic Co., Ltd.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

June 21, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

IntroMedic Company, Limited
% Mr. Steve Kwon
Manager
IntroMedic USA Incorporated
3550 Wilshire Blvd. #738
Los Angeles, CA 90010

Re: K131131

Trade/Device Name: E.G. Scan™ II Esophagoscope System
Regulation Number: 21 CFR 874.4710
Regulation Name: Esophagoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOX
Dated: April 22, 2013
Received: May 24, 2013

Dear Mr. Kwon:

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.

Page 2 - Mr. Steve Kwon

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,

Deborah Falls -
S 

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

Enclosure

K13113J

Section 04.

Indications for Use

510(k) Number(if known):

Device Name: E.G. Scan™ II Esophagoscope System

Indications for Use:

E.G. Scan™ II Esophagoscope System is intended for use in endoscopic access and examination of the larynx, esophagus and gastroesophageal junction.

Prescription Use AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

Eric A. Mann -S

Page 1 of 1



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

June 21, 2013

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10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

IntroMedic Company, Limited
% Mr. Steve Kwon
Manager
IntroMedic USA Incorporated
3550 Wilshire Blvd. #738
Los Angeles, CA 90010

Re: K131131

Trade/Device Name: E.G. Scan™ II Esophagoscope System
Regulation Number: 21 CFR 874.4710
Regulation Name: Esophagoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOX
Dated: April 22, 2013
Received: May 24, 2013

Dear Mr. Kwon:

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Sincerely yours,

Deborah L. Falls -
S 

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

Enclosure

Page 3 - Mr. Steve Kwon

Concurrence & Template History Page

[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K131131

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Vasant Malshet, (6/20/13)
Branch Chief Sign-Off	Srinivas Nandkumar, (6/20/13)
Division Sign-Off	Deborah Falls 2013.06.27 16:53:02 -04'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1 st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format

Drafted: 6/1/13
Edited: 6/20/13
Final: 6/20/13
Typed: Amanda Rodriguez

K13113J

Section 04.

Indications for Use

510(k) Number(if known):

Device Name: E.G. Scan™ II Esophagoscope System

Indications for Use:

E.G. Scan™ II Esophagoscope System is intended for use in endoscopic access and examination of the larynx, esophagus and gastroesophageal junction.

Prescription Use
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
 (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

Eric A. Mann -S

Page 1 of 1

H131131



IntroMedic Co., Ltd.
Suite 1104, E&C Venture Dream Tower 6 Cha
197-28 Guro-Dong, Guro-Gu
Seoul, Korea
152-719

Special 510(k): Device Modification

FDA CDRH DMC

MAY 24 2013

Received

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

*Reference: Special 510(k) Premarket Notification
IntroMedic Co., Ltd. E.G. Scan™ II Esophagoscope System
Medical Device User Fee Payment Identification Number: MD6067939-956733*

This to notify you of the intention by IntroMedic Co., Ltd., to market the E.G. Scan™ II Esophagoscope System.

The eCopy is an exact duplicate of the paper copy.

Type of Submission	Special
Trade/Device Name	E.G. Scan™ II Esophagoscope System
Regulation Number	21 CFR 874.4710
Regulation Name	Esophagoscope (flexible or rigid) and accessories
Regulatory Class	II
Product Code	EOX
Panel	Ear Nose & Throat
510(k) Submitter	IntroMedic Co., Ltd. Suite 1104, E&C Venture Dream Tower 6-Cha, 197-28 Guro-Dong, Guro-Gu, Seoul, Korea, 152-719
Contact Person	JinYoung Lee / RA Manager
Confidentiality	IntroMedic Co., Ltd. consider our intent to market these devices as confidential commercial information and request that it be considered as such by FDA.
Reason for Submission	Device Modification

IntroMedic Co., Ltd.
E.G. Scan™ II Esophagoscope System, Special 510(k)



IntroMedic Co., Ltd.
 Suite 1104, E&C Venture Dream Tower 6 Cha
 197-28 Guro-Dong, Guro-Gu
 Seoul, Korea
 152-719

Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

Sincerely yours,

Signature:
 JinYoung Lee / RA Manager

April 05, 2013
 Date

Enclosure: 510(k) Submission

IntroMedic Co., Ltd.
 E.G. Scan™ II Esophagoscope System, Special 510(k)

K131131



IntroMedic Co., Ltd.
Suite 1104, E&C Venture Dream Tower 6 Cha
197-28 Guro-Dong, Guro-Gu
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E.G. Scan™ II Esophagoscope System, Special 510(k)

49



IntroMedic Co., Ltd.
 Suite 1104, E&C Venture Dream Tower 6 Cha
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Is the device implanted?		X

Sincerely yours,

Signature:
 JinYoung Lee / RA Manager

April 05, 2013
 Date

Enclosure: 510(k) Submission

IntroMedic Co., Ltd.
 E.G. Scan™ II Esophagoscope System, Special 510(k)



IntroMedic Co., Ltd.
Suite 1104, E&C Venture Dream Tower 6 Cha
197-28 Guro-Dong, Guro-Gu
Seoul, Korea
152-719

K131131

Special 510(k): Device Modification

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

FDA CDRH DMC
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E.G. Scan™ II Esophagoscope System, Special 510(k)



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Signature:
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April 05, 2013
 Date

Enclosure: 510(k) Submission

IntroMedic Co., Ltd.
 E.G. Scan™ II Esophagoscope System, Special 510(k)



IntroMedic Co., Ltd.
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152-719

K131131

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SG



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April 05, 2013
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Suite 1104, E&C Venture Dream Tower 6 Cha
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Seoul, Korea
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Special 510(k): Device Modification

Food and Drug Administration
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Rockville, MD 20850

FDA CDRH DMC

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JinYoung Lee / RA Manager

April 05, 2013
Date

Enclosure: 510(k) Submission

IntroMedic Co., Ltd.
E.G. Scan™ II Esophagoscope System, Special 510(k)

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. 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) 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) INTROMEDIC USA INC 3550 Wilshire Blvd # 738 Los Angeles CA 900102401 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)	2. CONTACT NAME Steve Kwon 2.1 E-MAIL ADDRESS skwon@intromedic.com 2.2 TELEPHONE NUMBER (include Area code) 408-747-9876 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:

<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
--	--

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

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:

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?
 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.

<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population
<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The 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 NO

PAPERWORK REDUCTION ACT STATEMENT
 Public reporting burden for this collection of information is estimated to average 18 minutes 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 the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 03-Apr-2013

Form FDA 3601 (01/2007)

["Close Window"](#) [Print Cover sheet](#)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		Form Approval OMB No. 0910-0120 Expiration Date: December 31, 2013 See PRA Statement on page 5.	
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET			
Date of Submission 04/05/2013	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)	
SECTION A TYPE OF SUBMISSION			
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Request for Feedback <input type="checkbox"/> Pre-Submission <input type="checkbox"/> Informational Meeting <input type="checkbox"/> Submission Issue Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Study Risk Determination <input type="checkbox"/> Other (specify):
		Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):
Have you used or cited Standards in your submission? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, please complete Section I, Page 5)			
SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Company / Institution Name IntroMedic Co., Ltd.		Establishment Registration Number (if known) 3007244125	
Division Name (if applicable)		Phone Number (including area code) 82.2.801.9300	
Street Address Suite 1104, E&C Venture Dream Tower 6-Cha, 197-28 Guro-Dong, Guro-Gu		FAX Number (including area code) 82.2.801.9330	
City Seoul	State / Province	ZIP/Postal Code 152-719	Country Republic of Korea
Contact Name JinYoung Lee			
Contact Title RA Manager		Contact E-mail Address jylee@intromedic.com	
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name IntroMedic USA INC		Establishment Registration Number (if known)	
Division Name (if applicable)		Phone Number (including area code) 408.747.9876	
Street Address 3550 Wilshire Blvd # 738		FAX Number (including area code) 82.2.801.9330	
City Los Angeles	State / Province CA	ZIP Code 900102401	Country US
Contact Name Steve Kwon			
Contact Title Manager		Contact E-mail Address skwon@intromedic.com	

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason (<i>specify</i>):					
SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Other Reason (<i>specify</i>):					
SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input checked="" type="checkbox"/> Other Reason (<i>specify</i>): Device modification					

SECTION E								ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS							
Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information							
1	EOX	2		3		4		<input checked="" type="checkbox"/> 510 (k) summary attached		<input type="checkbox"/> 510 (k) statement					
5		6		7		8									
Information on devices to which substantial equivalence is claimed (if known)															
	<i>510(k) Number</i>			<i>Trade or Proprietary or Model Name</i>				<i>Manufacturer</i>							
1	K120702	1		E.G. Scan™ II Esophagoscope System	1			IntroMeidc Co., Ltd.							
2		2			2										
3		3			3										
4		4			4										
5		5			5										
6		6			6										
SECTION F												PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS			
Common or usual name or classification name															
Esophagoscope System															
	<i>Trade or Proprietary or Model Name for This Device</i>							<i>Model Number</i>							
1	E.G. Scan™ II Esophagoscope System							1	E.G. Scan™ II						
2								2							
3								3							
4								4							
5								5							
FDA document numbers of all prior related submissions (regardless of outcome)															
1	2	3	4	5	6	7	8	9	10	11	12				
Data Included in Submission															
<input type="checkbox"/> Laboratory Testing <input type="checkbox"/> Animal Trials <input type="checkbox"/> Human Trials															
SECTION G												PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS			
Product Code		C.F.R. Section (if applicable)						Device Class							
EOX		874.4710						<input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified							
Classification Panel															
Ear Nose & Throat															
Indications (from labeling)															
E.G. Scan™ II Esophagoscope System is intended for use in endoscopic access and examination of the larynx, esophagus and gastroesophageal junction.															

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.		FDA Document Number <i>(if known)</i>	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name IntroMedic Co., Ltd.		Establishment Registration Number 3007244125	
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i> 82.2.801.9300	
Street Address Suite 1104, E&C Venture Dream Tower 6-Cha, 197-28 Guro-Dong, Guro-Gu		FAX Number <i>(including area code)</i> 82.2.801.9330	
City Seoul	State / Province	ZIP Code 152-719	Country Republic of Korea
Contact Name JinYoung Lee	Contact Title RA Manager	Contact E-mail Address jylee@intromedic.com	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i>	
Street Address		FAX Number <i>(including area code)</i>	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i>	
Street Address		FAX Number <i>(including area code)</i>	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

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	IEC 60601-1	IEC	Medical Electrical Equipment - Part 1: General Requirements for Safety	1988+A1:1991 +A2:1995	08/01/1988
2	IEC 60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	Ed.2+A1	09/01/2001
3	ISO 10993-1	ISO	Biological evaluation of medical devices - Part 1: Evaluation and Testing	Ed.4	01/01/2009
4	IEC 60601-2-18	IEC	Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment	1996+A2:2000	10/31/2005
5					
6					
7					
Please include any additional standards to be cited on a separate page.					
<p>This section applies only to requirements of the Paperwork Reduction Act of 1995.</p> <p>*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.*</p> <p>The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff 1350 Piccard Drive, Room 400 Rockville, MD 20850</p> <p style="text-align: center;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>					



IntroMedic Co., Ltd.
Suite 1104, E&C Venture Dream Tower 6 Cha
197-28 Guro-Dong, Guro-Gu
Seoul, Korea
152-719

Special 510(k): Device Modification

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

*Reference: Special 510(k) Premarket Notification
IntroMedic Co., Ltd. E.G. Scan™ II Esophagoscope System
Medical Device User Fee Payment Identification Number: MD6067939-956733*

This to notify you of the intention by IntroMedic Co., Ltd., to market the E.G. Scan™ II Esophagoscope System.

The eCopy is an exact duplicate of the paper copy.

Type of Submission	Special
Trade/Device Name	E.G. Scan™ II Esophagoscope System
Regulation Number	21 CFR 874.4710
Regulation Name	Esophagoscope (flexible or rigid) and accessories
Regulatory Class	II
Product Code	EOX
Panel	Ear Nose & Throat
510(k) Submitter	IntroMedic Co., Ltd. Suite 1104, E&C Venture Dream Tower 6-Cha, 197-28 Guro-Dong, Guro-Gu, Seoul, Korea, 152-719
Contact Person	JinYoung Lee / RA Manager
Confidentiality	IntroMedic Co., Ltd. consider our intent to market these devices as confidential commercial information and request that it be considered as such by FDA.
Reason for Submission	Device Modification

IntroMedic Co., Ltd.
E.G. Scan™ II Esophagoscope System, Special 510(k)



IntroMedic Co., Ltd.
Suite 1104, E&C Venture Dream Tower 6 Cha
197-28 Guro-Dong, Guro-Gu
Seoul, Korea
152-719

Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

Sincerely yours,

Signature:
JinYoung Lee / RA Manager

April 05, 2013
Date

Enclosure: 510(k) Submission

IntroMedic Co., Ltd.
E.G. Scan™ II Esophagoscope System, Special 510(k)

Section 04.

Indications for Use

510(k) Number(if known):

Device Name: E.G. Scan™ II Esophagoscope System

Indications for Use:

E.G. Scan™ II Esophagoscope System is intended for use in endoscopic access and examination of the larynx, esophagus and gastroesophageal junction.

Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

Page 1 of 1

510(k) Submission – E.G. Scan™ II Esophagoscope System

Section 05_510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: April 05, 2012

1. Company and Correspondent making the submission:

Name – IntroMedic Co., Ltd.

Address – Suite 1104, E&C Venture Dream Tower 6-Cha, 197-28 Guro-Dong, Guro-Gu,
Seoul, 152-719 Korea

Telephone – +82-2-801-9300

Fax – +82-2-801-9330

Contact – JinYoung, Lee

Internet – <http://www.intromedic.com>

2. Device :

Proprietary name : E.G. Scan™ II Esophagoscope System

Common Name : Esophagoscope System

Classification Name : Esophagoscope System

3. Predicate Device :

Manufacturer : IntroMedic Co., Ltd,

Device : E.G. Scan™ II Esophagoscope System

510(k) Number : K120702

4. Classifications Names & Citations :

21CFR874.4710, EOX, Esophagoscope System, Class2

5. Description :

5.1 Introduction

E.G. Scan™ II Esophagoscope System and its accessories are used for diagnosis of patients. E.G. Scan™ II Probe takes pictures of the esophagus of human and sends

IntroMedic Co., Ltd.

510(k) Submission – E.G. Scan™ II Esophagoscope System

image data to E.G. Scan™ II Controller. E.G. Scan™ II Controller processes and converts image data and upload. E.G. View™ image displaying software displays the image for diagnosis.

The E.G Scan™ II Esophagoscope Probe is disposable.

5.2 General Technology

E.G. Scan™ II Esophagoscope system is a transnasal esophagoscope designed to capture images of the esophagus. Captured images are viewed via the E.G. View™ Software for diagnosis of diseases related to the esophagus.

6. Indication for use :

The E.G. Scan™ II Esophagoscope System is intended for use in endoscopic access and examination of the larynx, esophagus and gastroesophageal junction.

7. Comparison with predicate device :

The E.G. Scan™ II Esophagoscope System and predicate device are substantially equivalent in the areas of design, indication for use, technological characteristics, function, application and safety and effectiveness. This was determined by reviewing the information provided in the 510(k) in comparison to the content specified in the FDA guidance documents.

8. Safety, EMC and Performance Data :

The E.G. Scan™ II Esophagoscope System has the same device characteristics as the predicate device, E.G. Scan™ Esophagoscope System of IntroMedic Co., Ltd.; intended use, material, design and use concept are similar. The biocompatibility of the patient contact parts has been demonstrated through the cytotoxicity, sensitization and irritation testing by ISO 10993-1 Biological evaluation of medical devices. The E.G. Scan™ II Esophagoscope System conforms to IEC 60601-1 Medical electric equipment, Part 1: General requirements for safety, IEC 60601-2-18 Medical electrical equipment-Part 2: Particular requirements for the safety of endoscopic equipment and IEC 60601-1-2 Medical electric equipment, General requirements for safety collateral standard electromagnetic compatibility.

IntroMedic Co., Ltd.

510(k) Submission – E.G. Scan™ II Esophagoscope System

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification IntroMedic Co., Ltd. concludes that The E.G. Scan™ II Esophagoscope System is safe and effective and substantially equivalent to predicate devices as described herein.

IntroMedic Co., Ltd.



IntroMedic Co., Ltd.
Suite 1104, E&C Venture Dream Tower 6 Cha
197-28 Guro-Dong, Guro-Gu
Seoul, Korea
152-719

Section 06.

TRUTHFUL AND ACCURATE STATEMENT

Premarket Notification

Truthful and Accurate Statement

(As required by 21 CFR 807.87(k))

I certify that, in my capacity as RA Manager of IntroMedic Co., Ltd., 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

JinYoung Lee

RA Manager

April 05, 2013

Date

IntroMedic Co., Ltd.

E.G. Scan™ II Esophagoscope System, Special 510(k)

Section 07_CLASS III SUMMARY AND CERTIFICATION

IntroMedic Co., Ltd. Has determined that the E.G. Scan™ II Esophagoscope System is a Class III device. Therefore this Section is not applicable.

IntroMedic Co., Ltd.

E.G. Scan™ II Esophagoscope System, Special 510(k)

Page 7-1

Section 08.

FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

Therefore this Section is not applicable.



IntroMedic Co., Ltd.
Suite 1104, E&C Venture Dream Tower 6 Cha
197-28 Guro-Dong, Guro-Gu
Seoul, Korea
152-719

Declaration of Conformity with Design Controls

Verification Activities To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Signature

April 5, 2013

Date

YoungDae Seo
R&D Director

Manufacturing Facility The manufacturing facility, IntroMedic Co., Ltd. is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

Signature

April 5, 2013

Date

ChangOk Kim
Management representative

IntroMedic Co., Ltd.

E.G. Scan™ II Esophagoscope System, Special 510(k)

Page 9-1

510(k) Submission – E.G. Scan™ II Esophagoscope System

Section 10_Substantial Equivalence Discussion

1) Manufacturer and trademark of the predicate device:

Manufacturer : IntroMedic Co., Ltd.
 Device : E.G. Scan™ II Esophagoscope System
 510(k) Number : K120702 (Decision Date - Jun. 20, 2012)

2) Promotional material and specifications for SE device:

510(k) SE Letter : See Appendix 10

3) Comparison of features and specifications of the device and SE device:

Characteristic	Proposed IntroMedic Co., Ltd. E.G. Scan™ II Esophagoscope System	Predicate IntroMedic Co., Ltd. E.G. Scan™ II Esophagoscope System
510(k) number		K120702
Intended use	The E.G. Scan™ Esophagoscope System is intended for use in endoscopic access and examination of the larynx, esophagus and gastroesophageal junction.	The E.G. Scan™ Esophagoscope System is intended for use in endoscopic access and examination of the larynx, esophagus and gastroesophageal junction.
Scope Working Length	950mm	950mm
Scope Insertion Tube OD	Optic 6mm ± 10% Tube 3.9mm ± 10%	Optic 6mm Tube 3.6mm
Articulation (Up/Down)	160°/160°	160°/160°
Angle of view (Field of View)	125°	125°
Depth of Field	3~50mm	3~50mm
Air Supply	Yes	Yes
Method of Disinfection	Cidex OPA	Cidex OPA

IntroMedic Co., Ltd.

510(k) Submission – E.G. Scan™ II Esophagoscope System

Software	Separately	Separately
Software Model	E.G. View 1.0	E.G. View 1.0
Probe reusable	Disposable	Disposable
Insertion of Probe	Trans Nasal	Trans Nasal
Light source	LED	LED
Image Reconstruction	Denoise + Bayer Interpolation	Denoise + Bayer Interpolation
Image Enhancement	ALICE + HDRi	ALICE
Image Conversion	Bayer → RGB → YUV422	Bayer → RGB → YUV422
Frame Buffer	SRAM (512Mbit)	Not Use

4) Summary of comparison:

The E.G. Scan™ II Esophagoscope System described in this 510(k) has the same intended use and similar technical characteristics as E.G. Scan™ II Esophagoscope System of IntroMedic Co., Ltd.. The similarities and differences between two systems are described in the table shown above.

The similarities are as follows.

1. *Similarity of **Intended use***
2. *Similarity of **Scope Working Length***
3. *Similarity of **Articulation***
4. *Similarity of **Angle of view***
5. *Similarity of **Depth of Field***
6. *Similarity of **Air Supply***
7. *Similarity of **Method of Disinfection***
8. *Similarity of **Software Model***
9. *Similarity of **Probe reusable***
10. *Similarity of **Insertion of Probe***
11. *Similarity of **Light source***
12. *Similarity of **Image Reconstruction***
13. *Similarity of **Image Conversion***

IntroMedic Co., Ltd.

510(k) Submission – E.G. Scan™ II Esophagoscope System

A few differences are as follows.

1. Difference in **Scope Insertion Tube OD**

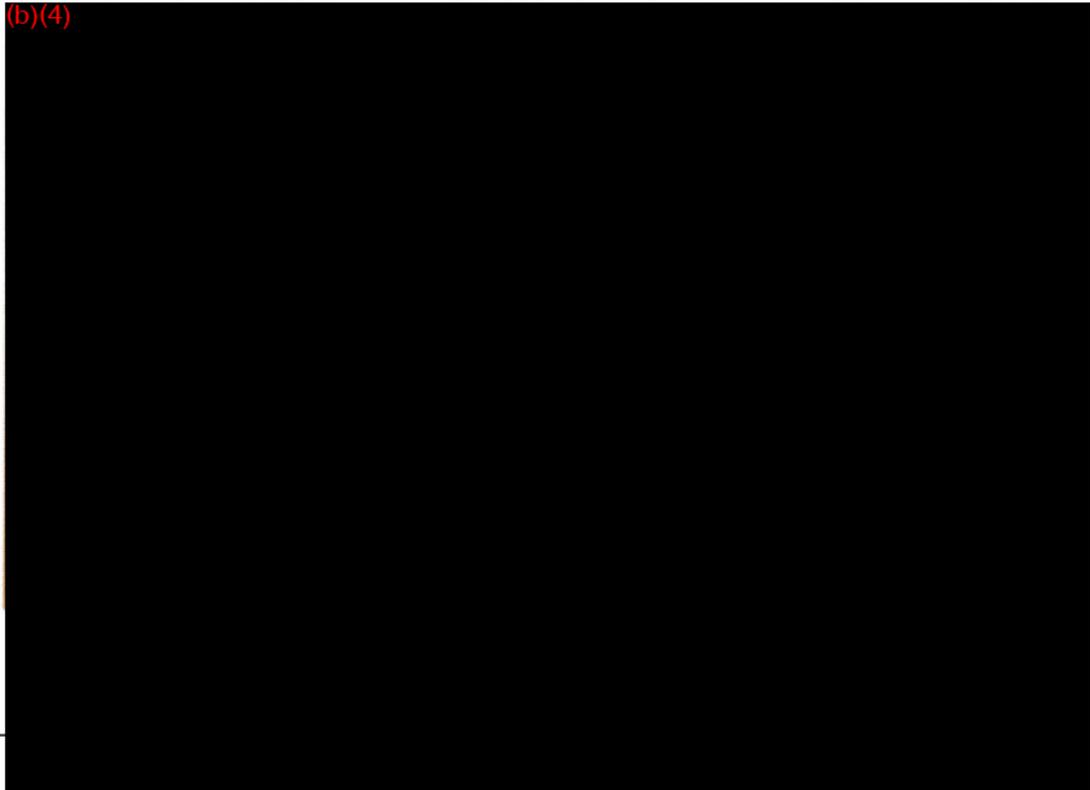
The size of optic is not changed but the size of tube got 8.3% bigger than the original size. The optic goes into patient's nasal cavity and its size is not changed, therefore there is no pressure on patients.

1. Difference in **Image Enhancement** and **Frame Buffer**

Only ELICE is included in Image Enhancement of Predicate device but HDRi is added to ELICE of Proposed device. ALICE (Augment Live-body Image Color-spectrum Enhancement) is the characterized technology of CMOS image sensor from IntroMedic Co., Ltd., which is Narrow Band Imaging technology. It is an image processing technology which extracts the images of Narrow Band from recorded images by white light.

HDRi (High Dynamic Range Imaging) is the technology that makes the parts of black and white visible on images. This image processing technology composes dark part and bright part into one image which makes whole part to be possibly identified.

(b)(4)

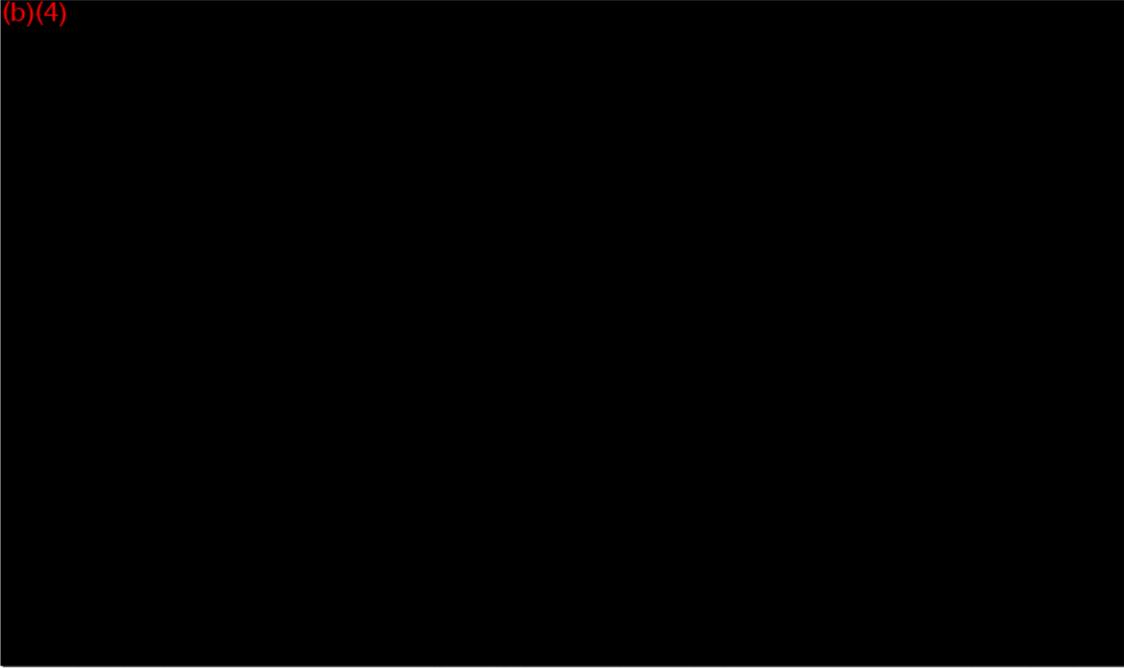


510(k) Submission – E.G. Scan™ II Esophagoscope System

Predicate device and proposed device, both of them use the same image processing technology. Probe records images using CMOS Image Sensor and transfers them to Processor in a form of analog signal. Processor uses Image Data Converter which can respond to CMOS image sensor to convert the analog signal to the digital data for image processing and it creates sync signal (pixel clock, horizontal sync, vertical sync) in each of images. It also eliminates the noise of black and white's Bayer Interpolation which is converted to the digital data (Denoise) and carries out Bayer Interpolation to convert them to color images. If it did not go through with Image Enhancement process, it converts the color images to compressed color images through Color Space Conversion and transfers them to Main processor and then to E.G. View™ in PC by USB Channel.

As an optional specification, it is possible to print out images of ALICE image processing technology. It extracts chosen images of a wavelength range from color images and converts them to compressed color images through Color Space Conversion to transfer them.

(b)(4)



Optionally, proposed device can perform HDRi image processing process. Saving one image and processing should be done at a time because HDRi

IntroMedic Co., Ltd.

510(k) Submission – E.G. Scan™ II Esophagoscope System

images have to be converted from recorded images to bright images and dark images. SRAM is attached outside Logic Processor because it does not have a separate space to save one image (100KByte). An image data being input 300KByte per second is being saved 2 Byte per unit to SRAM. When all the 100KByte images are saved, it converts the images through HDR image processing logic again.

In conclusion, the proposed device is substantially equivalent to the predicate device.

IntroMedic Co., Ltd.

JUN. 22. 2012 11:22AM

NO. 6814 P. 1/3



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

IntroMedic Company, Limited
% Mr. Marc M. Mouser
Underwriters Laboratories, Inc.
2600 NW Lake Road
Camas, WA 98607

JUN 20 2012

Re: K120702

Trade/Device Name: E.G. Scan™ II Esophagoscope System
Regulation Number: 21 CFR 874.4710
Regulation Name: Esophagoscope (flexible or rigid) and accessories
Regulatory Class: II
Product Code: EOX
Dated: May 25, 2012
Received: June 1, 2012

Dear Mr. Mouser:

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

06/22/2012 8:15AM

JUN. 22. 2012 11:23AM

NO. 6814 P. 2/3

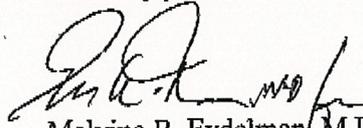
Page 2 – Mr. Marc M. Mouser

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

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

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

Sincerely yours,



Malvina B. Eydelman, M.D.

Director

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

Office of Device Evaluation Health

Center for Devices and Radiological Health

Enclosure

06/22/2012 8:15AM

JUN. 22. 2012 11:23AM

NO. 6814 P. 3/3
K120702

Indications for Use

510(k) Number(if known):

Device Name: E.G. Scan™ II Esophagoscope System

Indications for Use:

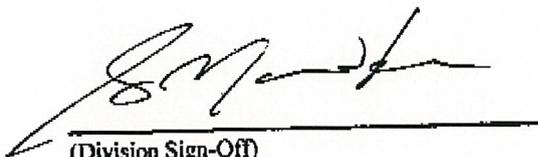
E.G. Scan™ II Esophagoscope System is intended for use in endoscopic access and examination of the larynx, esophagus and gastroesophageal junction.

Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

Page 1 of 1



(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

Prescription Use
(Per 21 CFR 801.109)

510(k) Number K120702

510(k) Submission – E.G. Scan™ II Esophagoscope System

Section 11_Device Description

1. Introduction: General description:

1.1 Introduction

E.G. Scan™ II Esophagoscope System and its accessories are used for diagnosis of patients. E.G. Scan™ II Esophagoscope System consists of probe, controller, processor and software. The probe takes pictures of esophagus and sends image data to processor through controller. The controller provides the function for movement of the probe and the processor reconstructs images, and sends that to the display software built in commercial computing system. The software (E.G. View™) displays that image for diagnosis.

The E.G. Scan™ II Esophagoscope Probe is disposable.

1.2 General Technology

E.G. Scan™ II Esophagoscope System is a transnasal esophagoscope designed to capture images of the esophagus. Captured images are viewed via the E.G. View™ Software for diagnosis of diseases related to the esophagus.

Generally, the transnasal esophagoscope has developed means to view the entire of esophagus, with a similar or higher diagnostic sensitivity than other transoral esophagoscope. Further, the transnasal esophagoscope avoid a great deal of discomfort with conventional transoral esophagoscope, because transnasal endoscopy dose not require the sedation.

1.3 Main Features

- 1) Probe – The E.G. Scan™ II Esophagoscope System Probe inserted into the esophagus through the nasal cavity and captures images of the esophagus at 30 frame/sec. It is disposable and it should be discarded after the procedure.

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510(k) Submission – E.G. Scan™ II Esophagoscope System

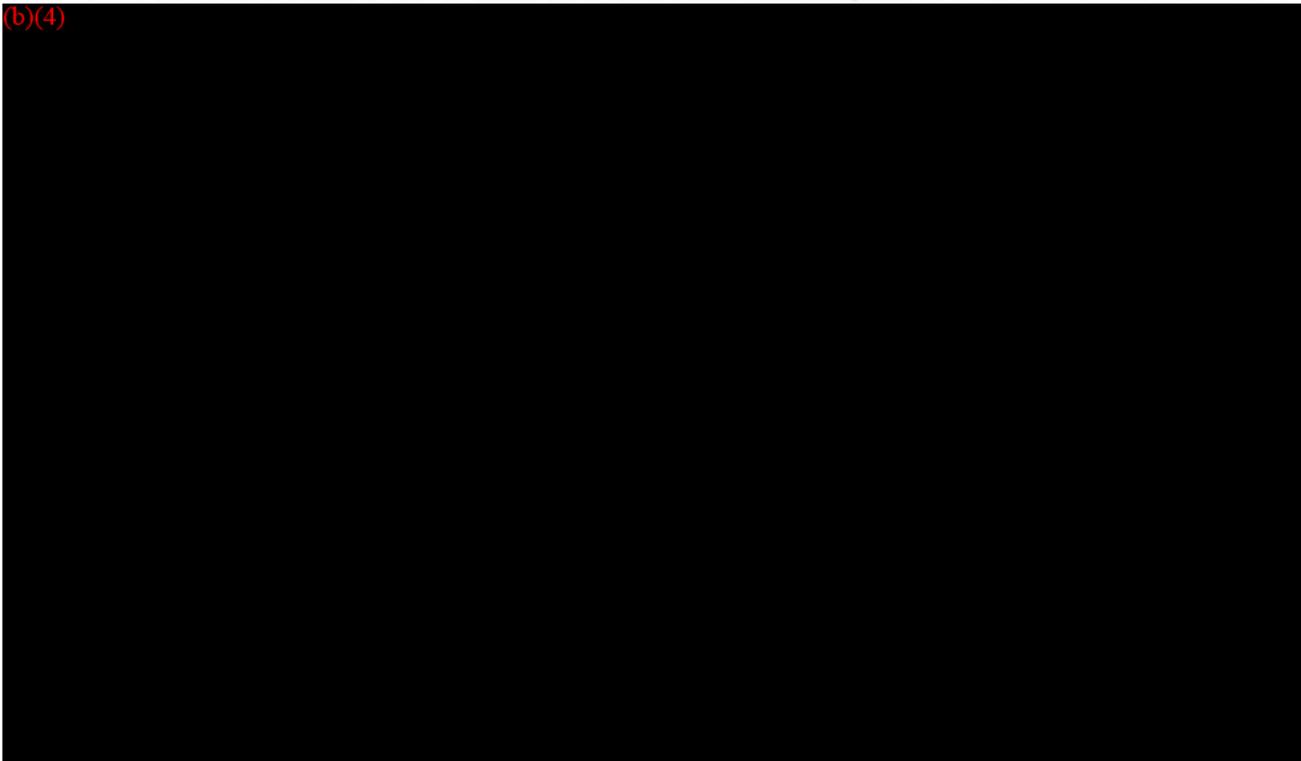
- 2) Controller – The E.G. Scan™ II Esophagoscope System Controller provides 2 way-bending wire and signal connection. The E.G. Scan™ II Esophagoscope System Controller has 3 function buttons which is 'capture', 'freezing' and 'air'.
- 3) Processor – The E.G. Scan™ II Esophagoscope System Processor reconstructs image data and has some image processing procedure. The captured images are processed to JPEG images and send to the application software built in commercial computing system.
- 4) Software – E.G. View™ displays the captured images and report the diagnosis results in the form of a report.

1.4 System Configuration

The E.G. Scan™ II Esophagoscope System consists of a probe, controller, processor and application software (E.G. View™). The overall system configuration is as follows:

E.G. Scan™ II Esophagoscope System Block Diagram

(b)(4)



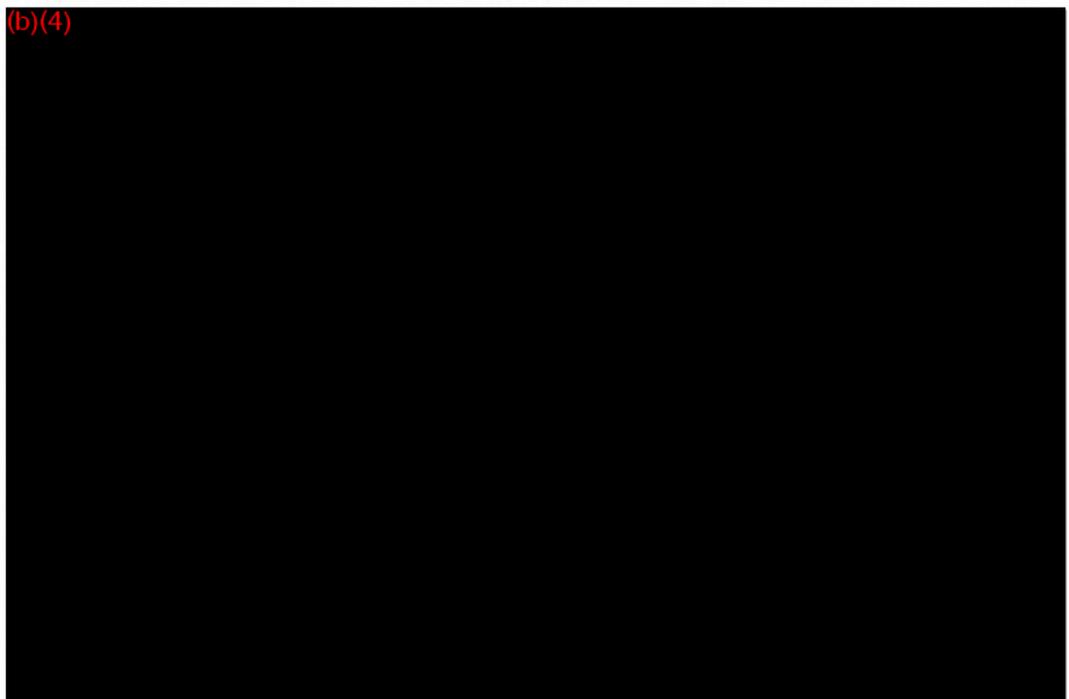
IntroMedic Co., Ltd.

510(k) Submission – E.G. Scan™ II Esophagoscope System

- Probe (Model No. EP2000)

The probe consists of an optical dome, LED module, imaging and communication module, bending module, air channel and connection module. The probe's insertion part can operate inside a human body for a moment. The insertion part's mechanical and electrical device is enclosed in a harmless plastic capsule and tube. The optical dome and the body are bonded with a medical grade adhesive. The bending module moves 2 directions and the air channel can expand esophagus.

(b)(4)

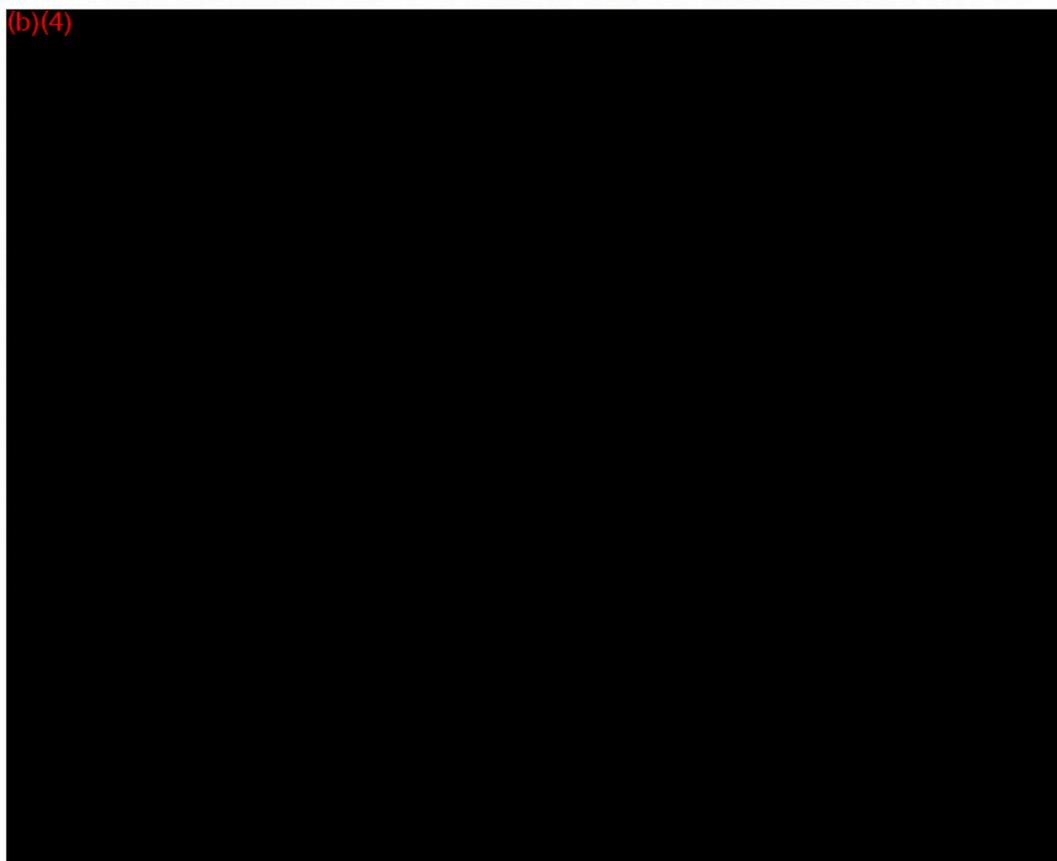


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510(k) Submission – E.G. Scan™ II Esophagoscope System

- Controller (Model No. EC2000)

The controller of the E.G. Scan™ II Esophagoscope System includes operating buttons and bending control knob. The operation functions of the controller are freezing, capture and air insertion. The direction of camera module is controlled by wheeling bending control knob. Some signals for Image data are sent to the processor by two buttons for the controller: 'Capture' and 'Freeze'. Images are captured by the 'Capture' button and frozen by the 'Freeze' button.



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510(k) Submission – E.G. Scan™ II Esophagoscope System

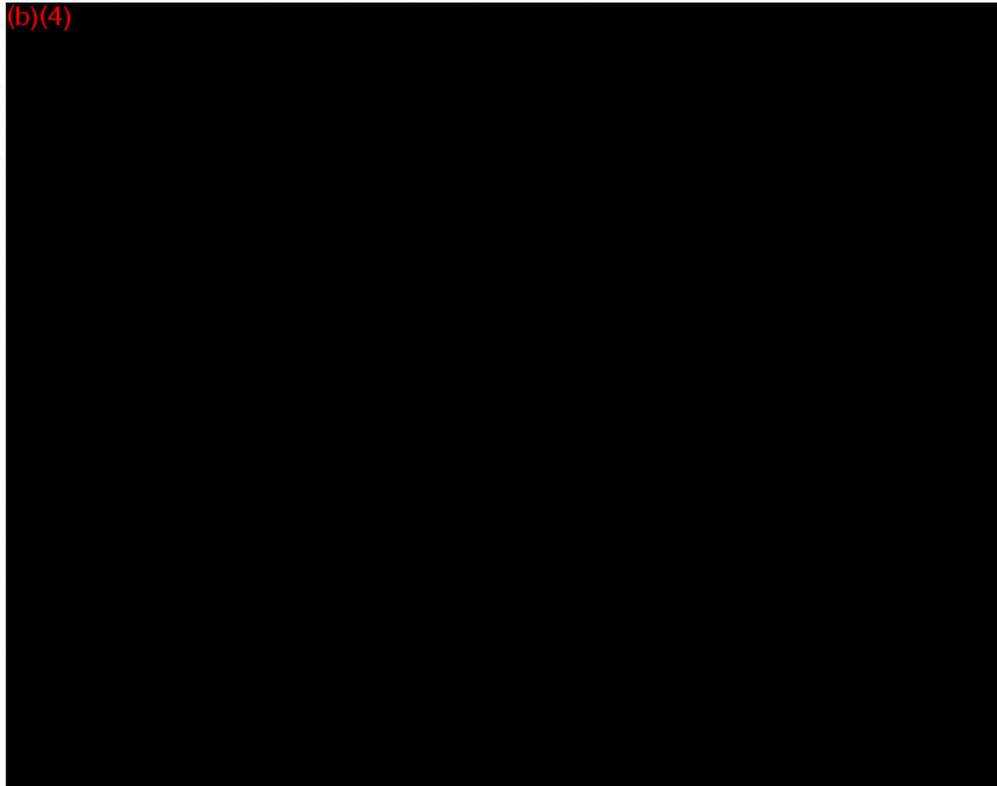
- Processor (Model No. ER2000)

The processor of the E.G. Scan™ II Esophagoscope System includes image processing module, air compressor module and power module. The image processing module includes the data converter, image processor and interface controller. The data converter converts image data transmitted by the probe to the digital image data and the image processor enhances the image quality. The interface controller transmits image data to the application software built in commercial computer via the USB communication channel.

The air compressor module includes air compressor and power control unit. The air compressor spouts air through air channel of probe into esophagus. The power control unit controls the volume of air.

The power module is medical grade switching mode power supply. The power module is connected to commercial AC power line through the AC power inlet and it is isolated any other power source.

(b)(4)



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510(k) Submission – E.G. Scan™ II Esophagoscope System

Only ELICE is included in Image Enhancement of Predicate device but HDRi is added to ELICE of Proposed device. ALICE (Augment Live-body Image Color-spectrum Enhancement) is the characterized technology of CMOS image sensor from IntroMedic Co., Ltd., which is Narrow Band Imaging technology. It is an image processing technology which extracts the images of Narrow Band from recorded images by white light.

HDRi (High Dynamic Range Imaging) is the technology that makes the parts of black and white visible on images. This image processing technology composes dark part and bright part into one image which makes whole part to be possibly identified.

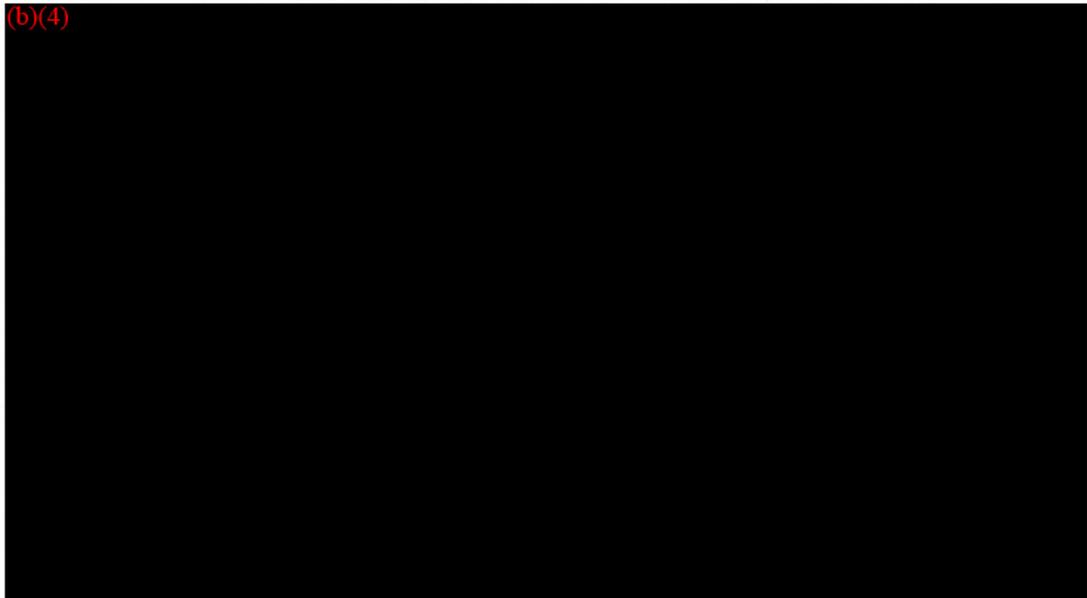


Figure 1. Block Diagram of Predicate Device

Predicate device and proposed device, both of them use the same image processing technology. Probe records images using CMOS Image Sensor and transfers them to Processor in a form of analog signal. Processor uses Image Data Converter which can respond to CMOS image sensor to convert the analog signal to the digital data for image processing and it creates sync signal (pixel clock, horizontal sync, vertical sync) in each of images. It also eliminates the noise of black and white's Bayer Interpolation which is converted to the digital data (Denoise) and carries out Bayer Interpolation to

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510(k) Submission – E.G. Scan™ II Esophagoscope System

convert them to color images. If it did not go through with Image Enhancement process, it converts the color images to compressed color images through Color Space Conversion and transfers them to Main processor and then to E.G. View™ in PC by USB Channel.

As an optional specification, it is possible to print out images of ALICE image processing technology. It extracts chosen images of a wavelength range from color images and converts them to compressed color images through Color Space Conversion to transfer them.

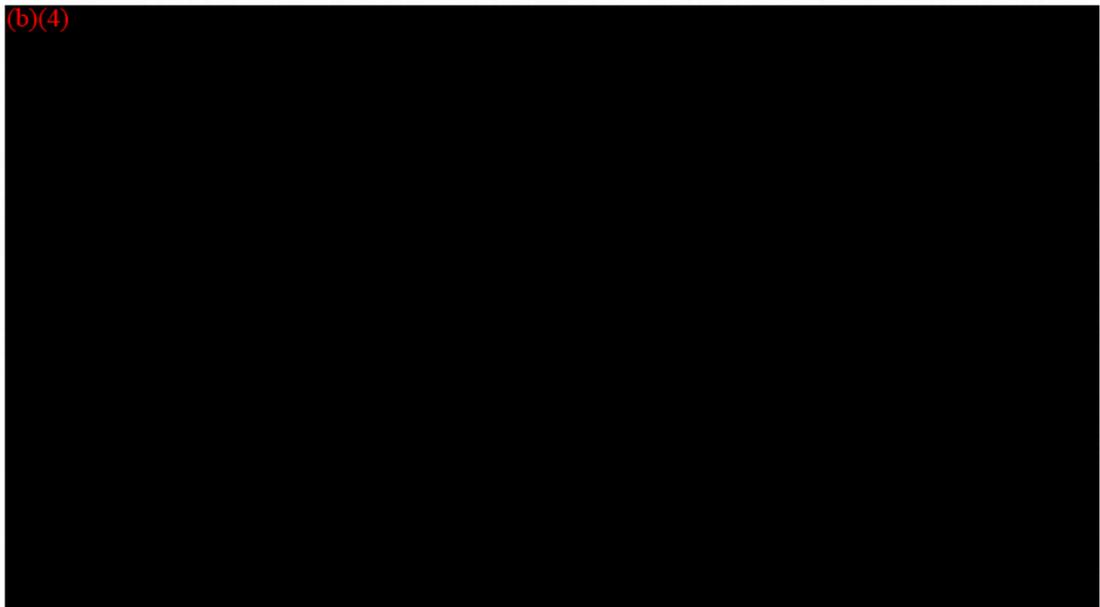


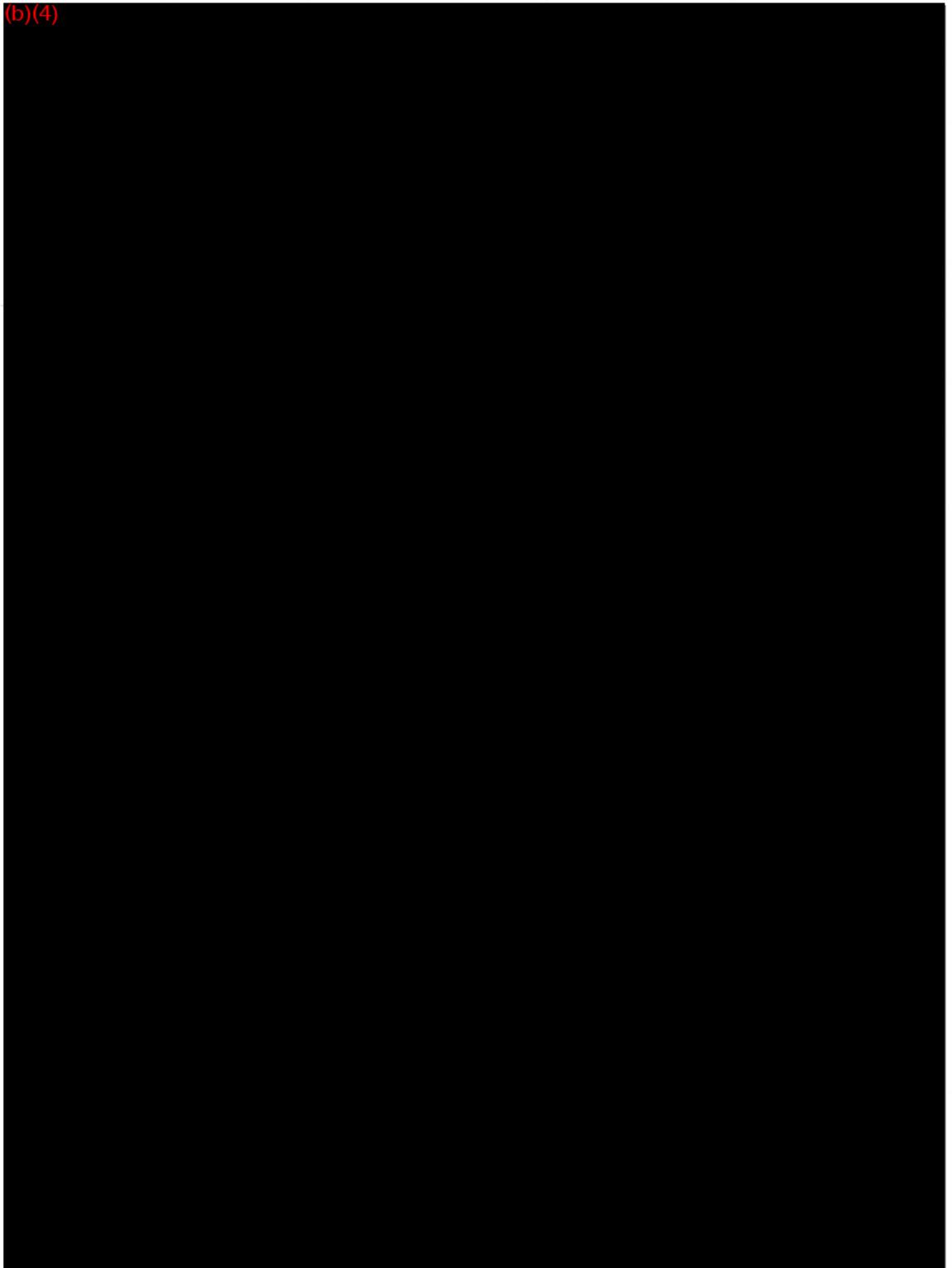
Figure 2. Block Diagram of Proposed device

Optionally, proposed device can perform HDRi image processing process. Saving one image and processing should be done at a time because HDRi images have to be converted from recorded images to bright images and dark images. SRAM is attached outside Logic Processor because it does not have a separate space to save one image (100KByte). An image data being input 300KByte per second is being saved 2 Byte per unit to SRAM. When all the 100KByte images are saved, it converts the images through HDRi image processing logic again.

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510(k) Submission – E.G. Scan™ II Esophagoscope System

(b)(4)



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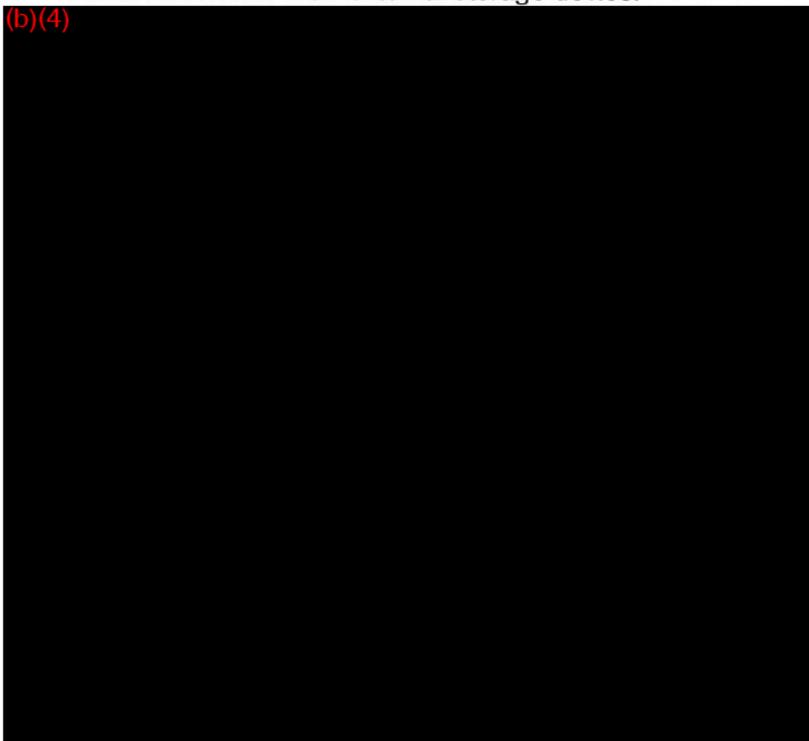
510(k) Submission – E.G. Scan™ II Esophagoscope System

- Image Displaying Software (E.G. View™)

E.G. View™, the application software for the E.G. Scan™ II Esophagoscope System, consists of an image displaying module and report module to export diagnosis data.

The software is compatible with Windows operating systems. Selected images can be edited and saved in an external storage device.

(b)(4)

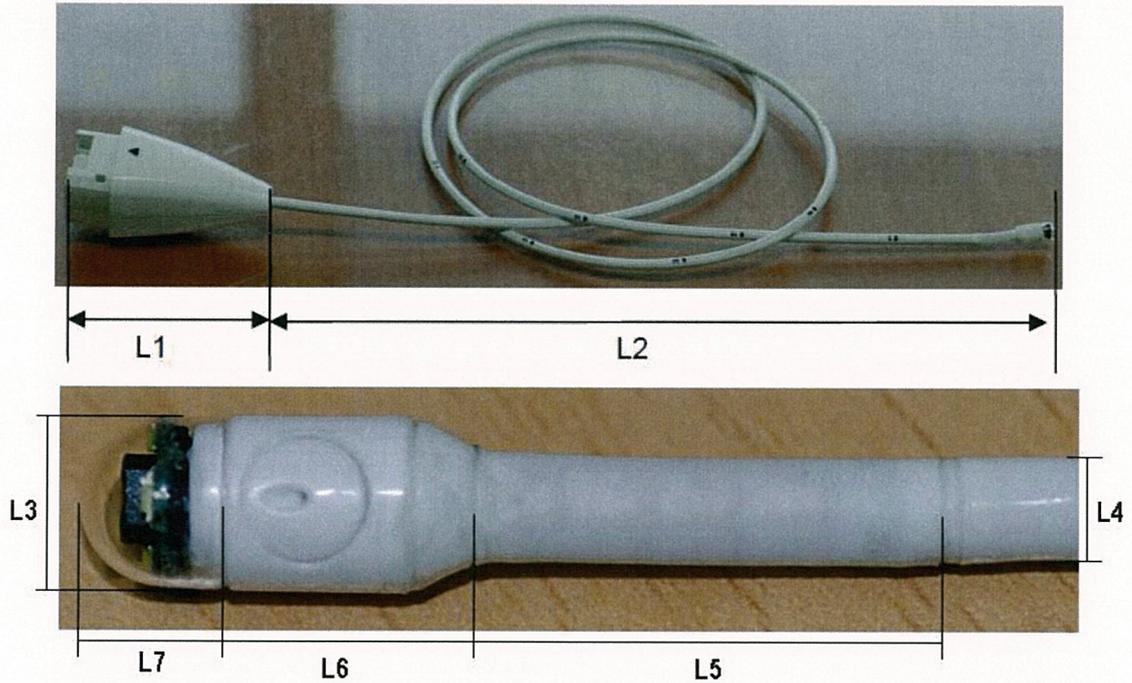


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510(k) Submission – E.G. Scan™ II Esophagoscope System

1.5 Probe (EP2000)

1.5.1 Dimension

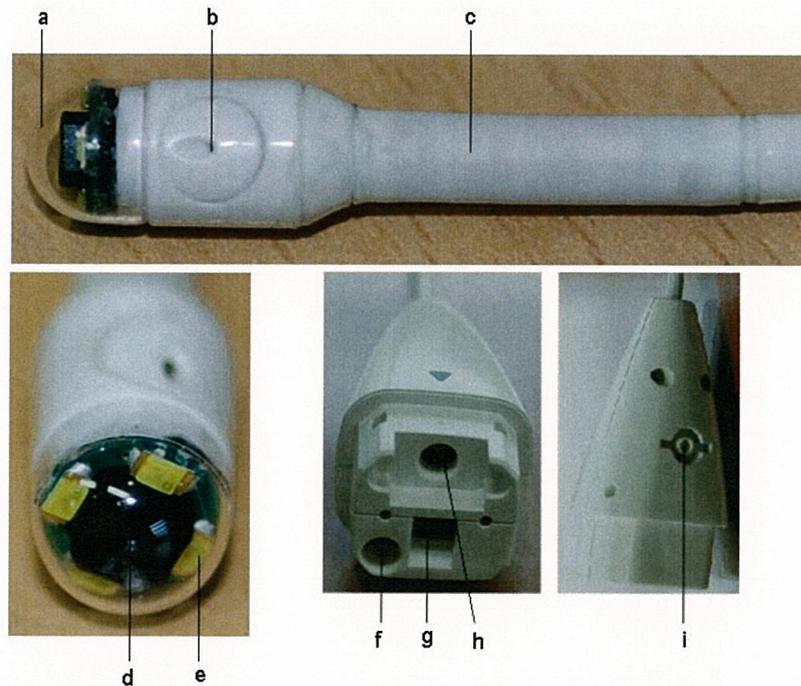


Model	Description	Size(mm) ± 10%	Weight(g)
EP2000	E.G. Scan™ II Esophagoscope System Probe	65.5(L1) * 1,022.5(L2) * 6.0(L3) * 3.9(L4) * 16.0(L5) * 8.2(L6) * 3.7(L7)	44

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510(k) Submission – E.G. Scan™ II Esophagoscope System

1.5.2 Description



No	Title	Function
a	Optical Dome	<ul style="list-style-type: none"> - Plastic window for light transmission. - This transmits light from LED to the outside of probe for illumination. - This transmits light from the outside of probe to camera for capture.
b	Air nozzle	<ul style="list-style-type: none"> - The air hole for expansion of the canal.
c	Bending	<ul style="list-style-type: none"> - Moving module for the camera
d	Lens	<ul style="list-style-type: none"> - This concentrates light for clear image of the range of vision which is secured by the illumination of LED light.
e	LED	<ul style="list-style-type: none"> - It illuminates a dark space of inside human body. - It accomplishes the role of the illumination which is the possibility of getting an image.
f	Air connector	<ul style="list-style-type: none"> - Air connection for the air-injection to Air nozzle
g	Locker	<ul style="list-style-type: none"> - Stick-like apparatus for sticking Probe on Controller.
h	Data connector	<ul style="list-style-type: none"> - Data connection for image data transmission to controller.
i	Air Tube connector	<ul style="list-style-type: none"> - Air valve connection for air tube connected with Processor

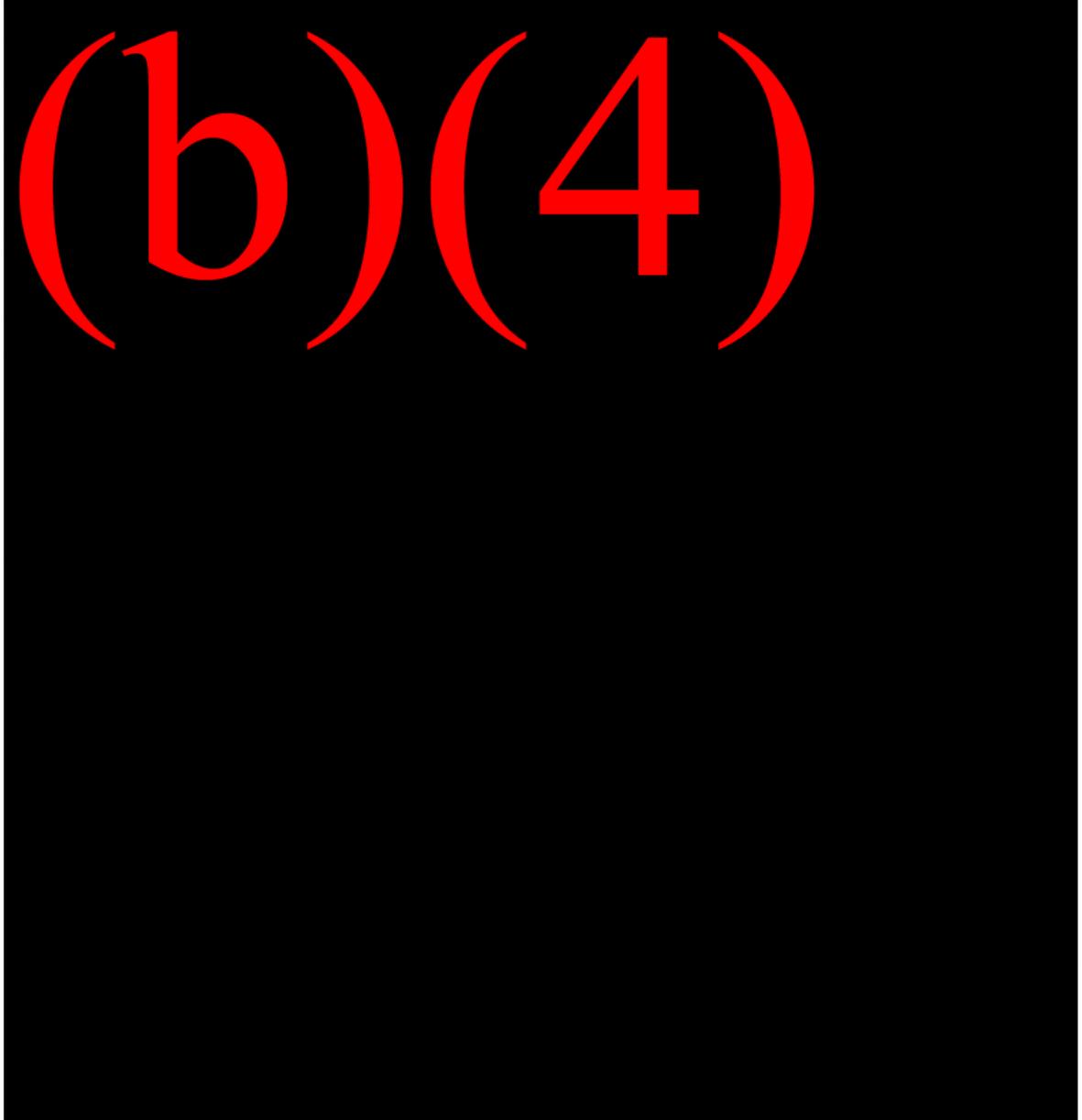
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510(k) Submission – E.G. Scan™ II Esophagoscope System

1.5.3 Specification

- Optic Diameter : 6.0 mm ± 10%
- Tube Diameter : 3.9mm ± 10%
- Length : 1,088mm ± 10%
- Weight : 44g ± 10%
- Material

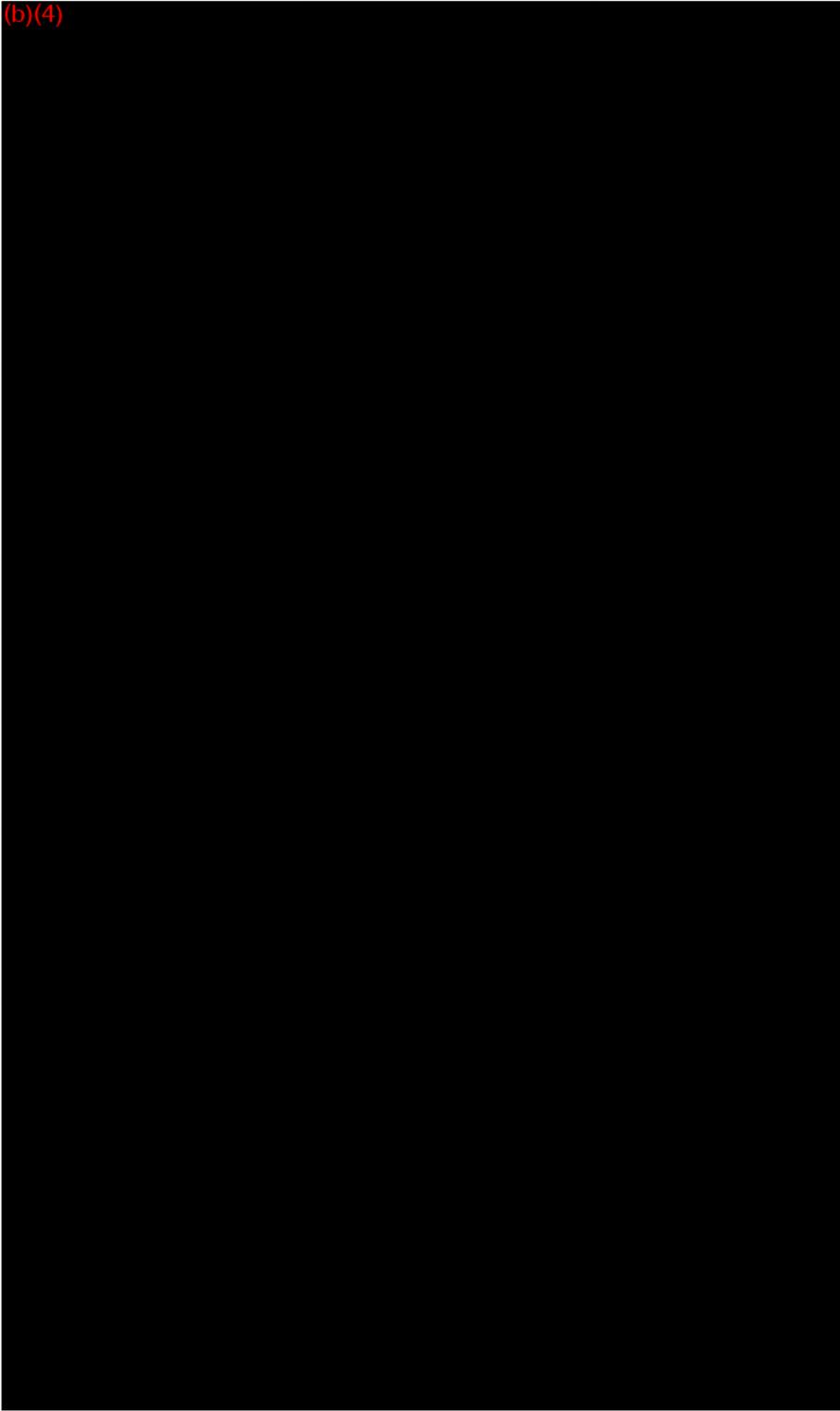
Component	Material	Ingredient	Remark
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510(k) Submission – E.G. Scan™ II Esophagoscope System

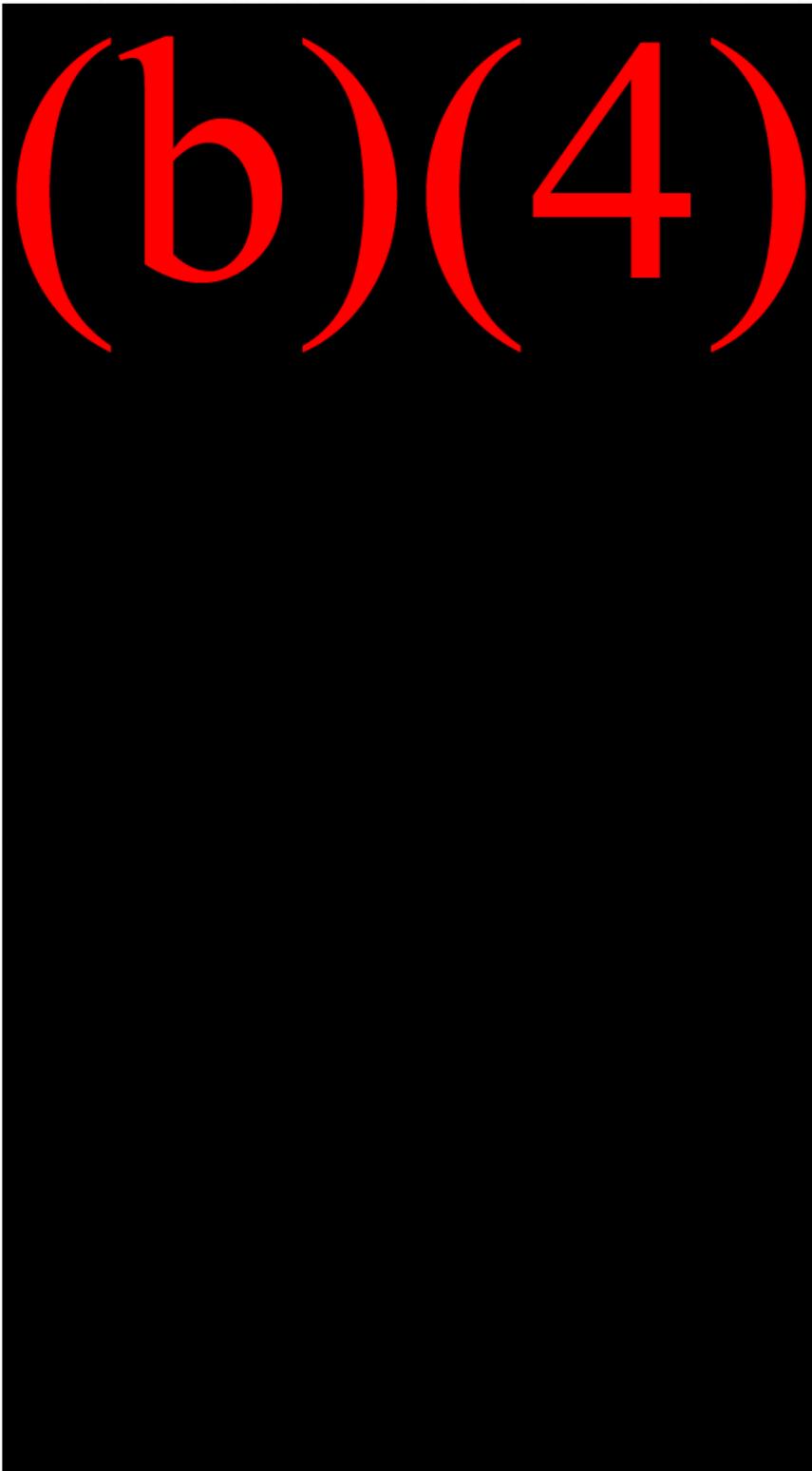
(b)(4)



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510(k) Submission – E.G. Scan™ II Esophagoscope System

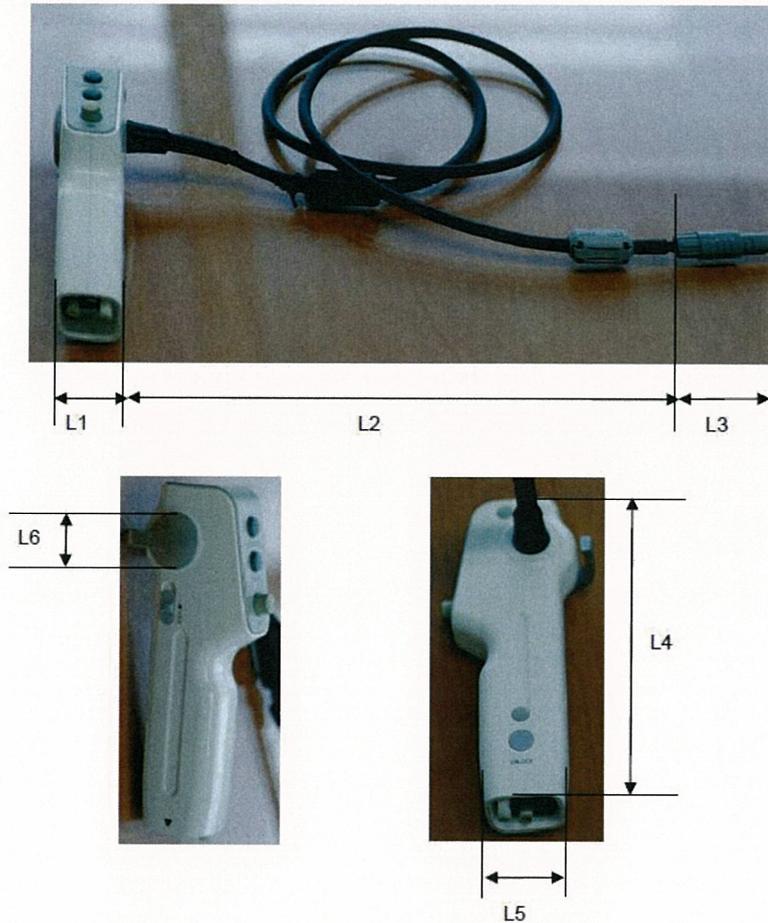


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510(k) Submission – E.G. Scan™ II Esophagoscope System

1.6 Controller (EC2000)

1.6.1 Dimension

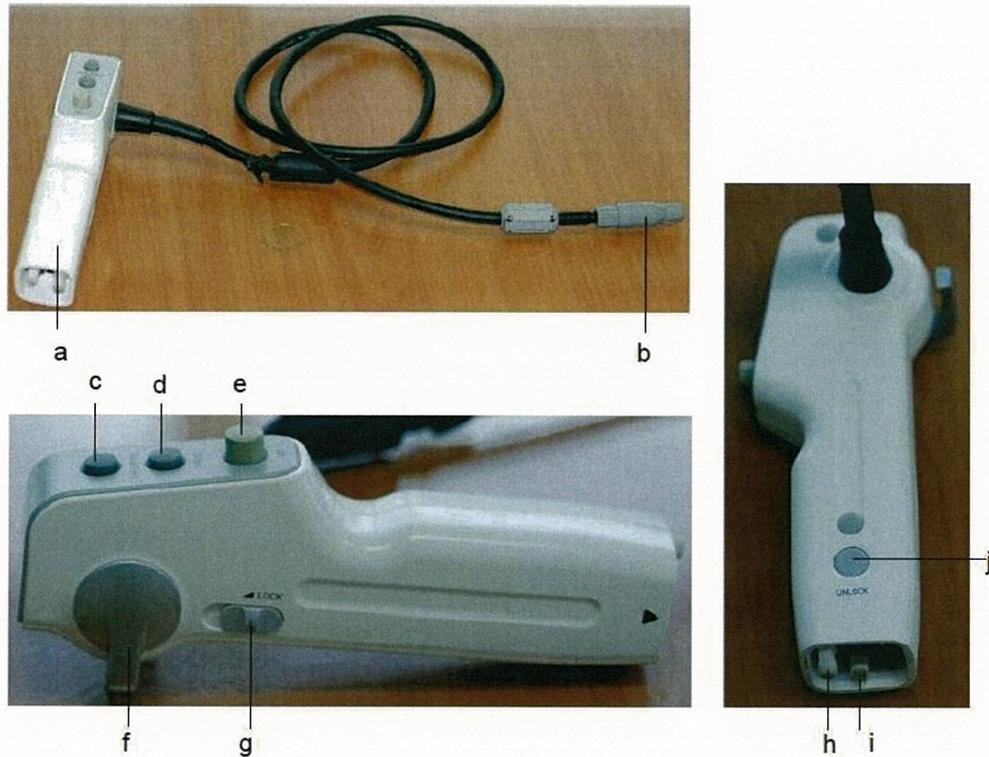


Model	Description	Size(mm) ± 10%	Weight(g)
EC2000	E.G. Scan™ II Esophagoscope System Controller	30.0(L1)*1,000(L2)*45.7(L3)*152.0(L4) *32.4(L5)*25.0(L6)	210

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510(k) Submission – E.G. Scan™ II Esophagoscope System

1.6.2 Description



No	Title	Function
a	Controller main body	- E.G. Scan™ II Controller Main Body
b	Connector	- Electrical connector between Controller and Processor
c	CAPTURE button	- Push button for capturing the displayed image
d	FREEZE button	- Push button for pushing the displayed image
e	AIR button	- Push and holding button for air-injection
f	Bending lever	- Wheel lever for moving the camera to up and down
g	Bending lock	- Push up for fixing the Bending lever
h	Air cork	- Cork and uncork air channel
i	Data connector	- Data connection for image data receiving from Controller
j	UNLOCK button	- Unlock the locker of the Probe and release the Probe

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510(k) Submission – E.G. Scan™ II Esophagoscope System

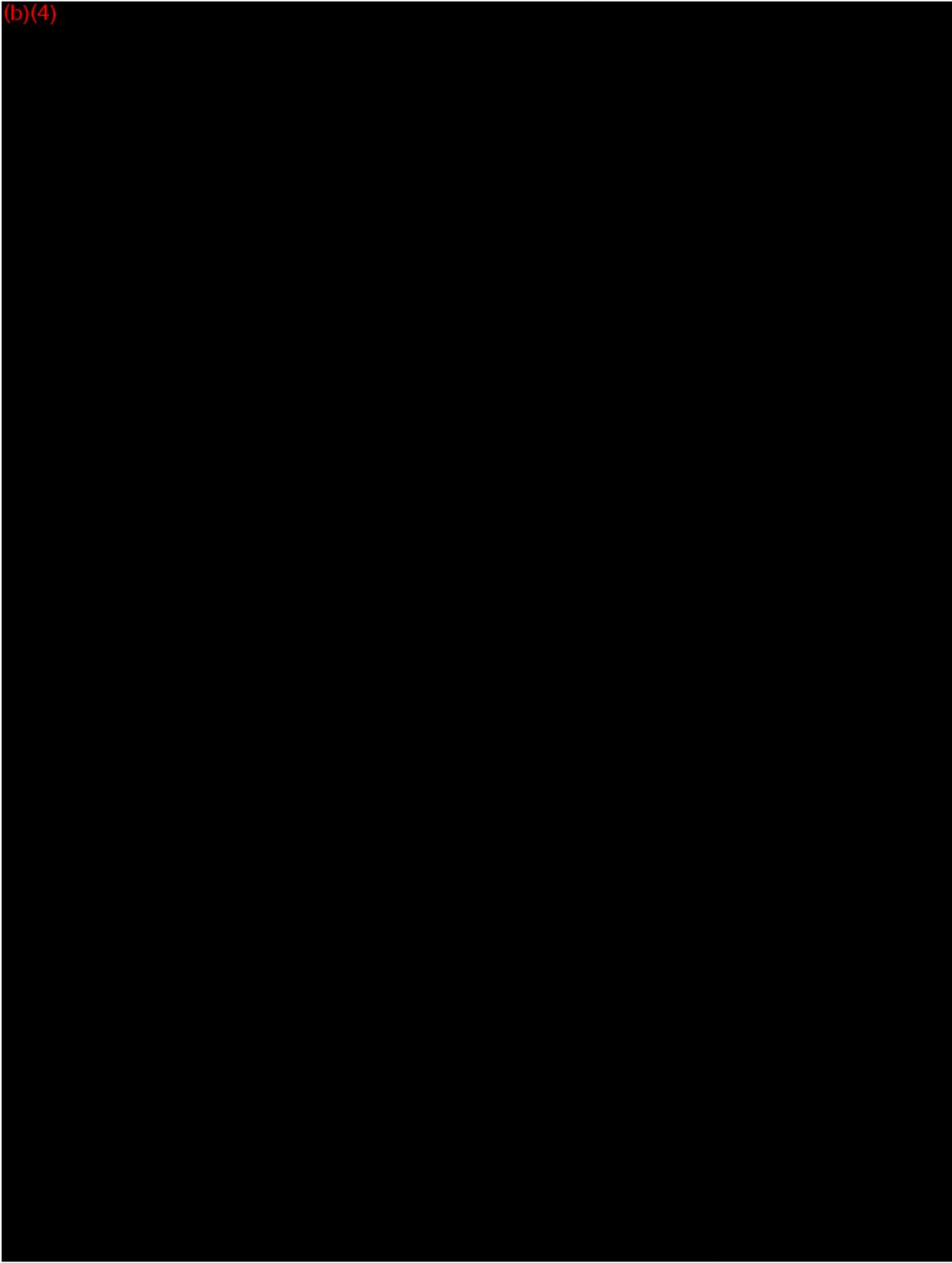
1.6.3 Specification

- Size : 152 X 30 X 32.4 mm \pm 10%
- Weight : 210g \pm 10%
- Rated Power : 3.3Vdc, 100mA)
- Operating Temperature : 0 ~ 40°C
- Storage Temperature : -10 ~ +70°C
- Button Function : Freezing, Capture, Air
- Protection against electric shock : Type BF

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510(k) Submission – E.G. Scan™ II Esophagoscope System

(b)(4)



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510(k) Submission – E.G. Scan™ II Esophagoscope System

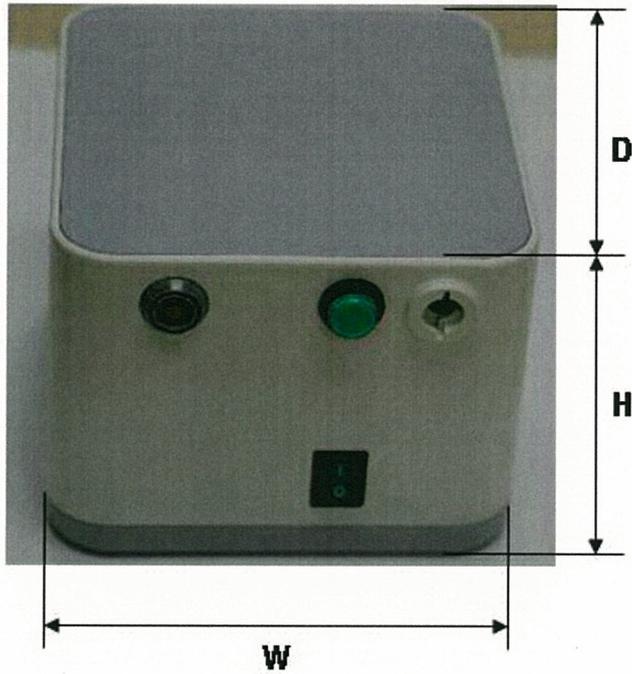
(b)(4)

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510(k) Submission – E.G. Scan™ II Esophagoscope System

1.7 Processor (ER2000)

1.7.1 Dimension

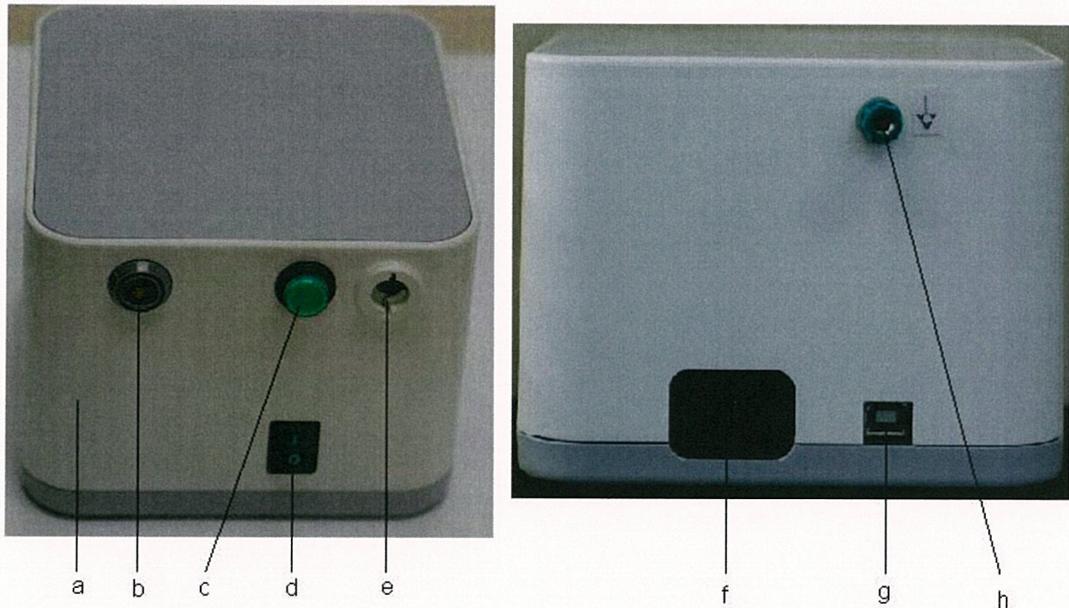


Model	Description	Size(mm) ± 10%	Weight(g)
ER2000	E.G. Scan™ II Esophagoscope System Processor	140(W) * 140(D) * 117(H)	840

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510(k) Submission – E.G. Scan™ II Esophagoscope System

1.7.2 Description



No	Title	Function
a	Main Body	- The main device for ER2000
b	Connector	- Electrical connector between Controller and Processor
c	Compressor switch	- Power of compressor
d	Power switch	- Control the main power of processor
e	Air tube connector	- Air valve connection for air tube connected with Probe
f	AC inlet	- Main power port - AC 100~240V, 50/60Hz, 0.5A
g	USB Port	- USB connection for image data transmission to the software built in commercial PC
h	Earth terminal	- Potential equalization terminal

1.7.3 Specification

- Operating System: Firmware
- Size: 140 * 140 * 117mm ± 10%
- Weight: 830g
- Rated Power: 100~240V, 50/60Hz, 0.5A
- Communication Channel: USB
- Attainable Air Vacuum: 200mmHg
- Free Air Displacement: 5l/min
- Maximum Air Pressure: 0.45kg/cm²
- Operation Temperature: 0~40 °C

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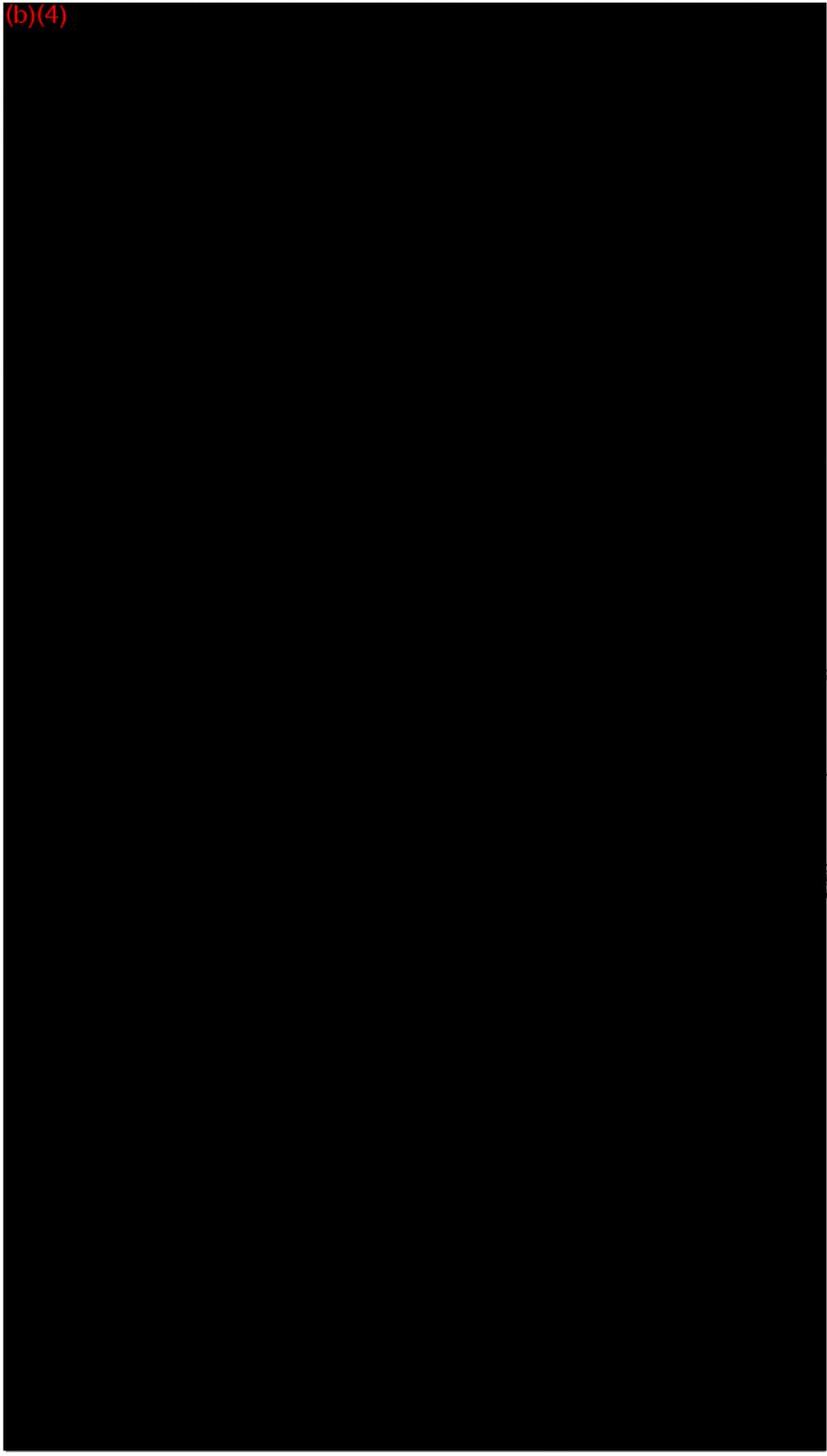
510(k) Submission – E.G. Scan™ II Esophagoscope System

- Storage Temperature: -10~70°C
- Protection against electric shock: Type BF

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510(k) Submission – E.G. Scan™ II Esophagoscope System

(b)(4)



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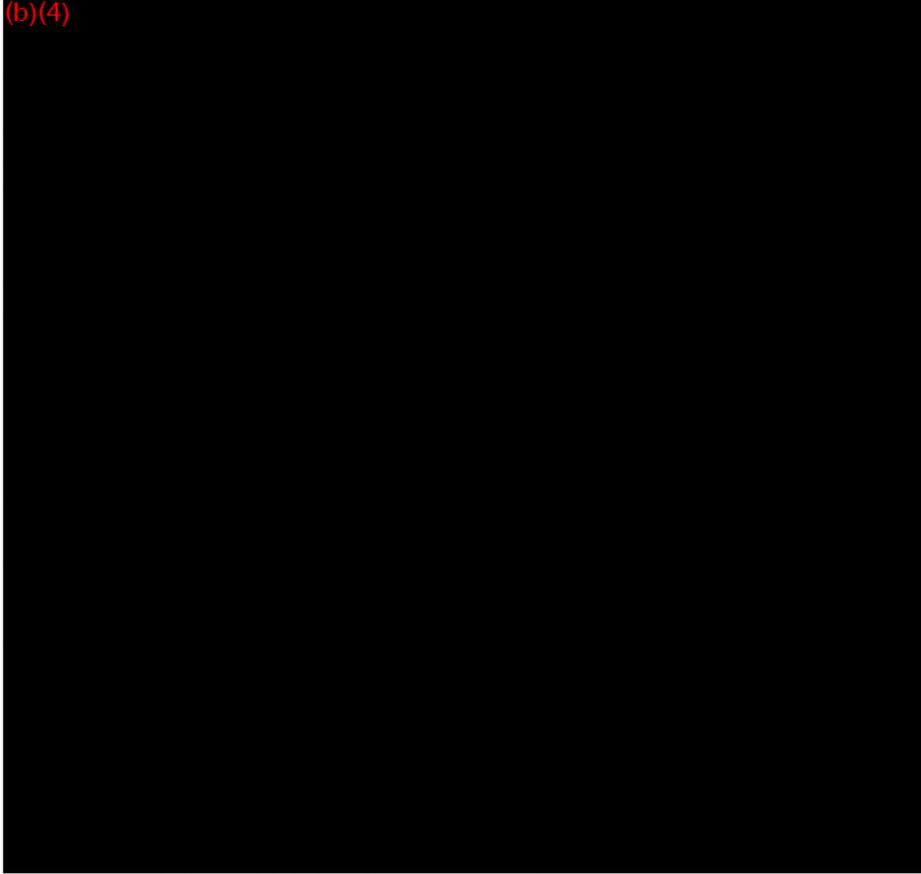
510(k) Submission – E.G. Scan™ II Esophagoscope System



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510(k) Submission – E.G. Scan™ II Esophagoscope System

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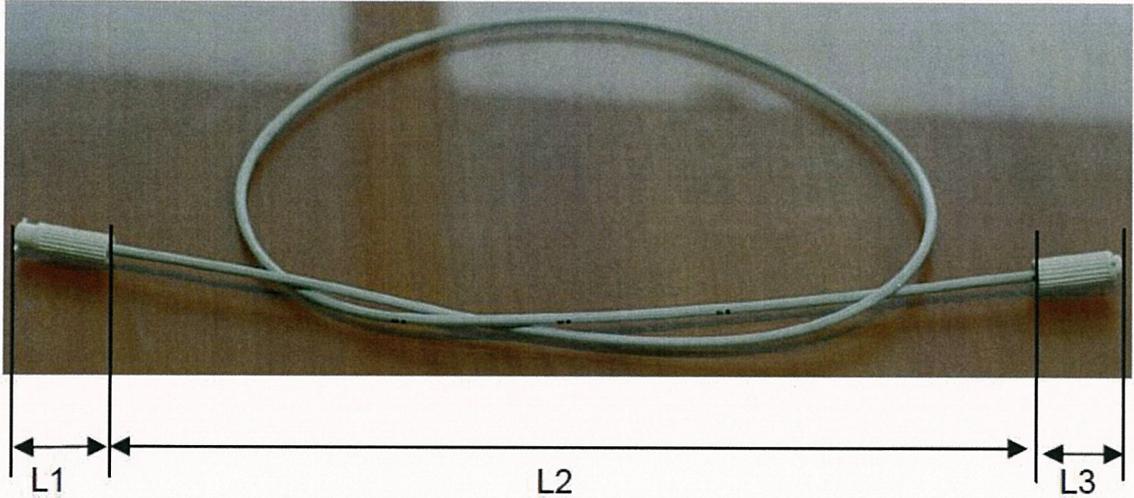


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510(k) Submission – E.G. Scan™ II Esophagoscope System

1.9 Accessories

1.9.1 Air Tube



Part No.	Description	Size(mm)	Weight(g)
ER2000-V	Balloon Air Valve	38(L1)*926.5(L2)*27.5(L3)	21

- Manufacturer : IntroMedic
- Manufacturer Code : ER2000-V

1.9.2 Syringe



Part No.	Description	Spec(mm)	Weight(g)
ER2000-U	USB 2.0 Data Cable	1,000	50

- Manufacturer: Various
- Intromedic Code: ER2000-U

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510(k) Submission – E.G. Scan™ II Esophagoscope System

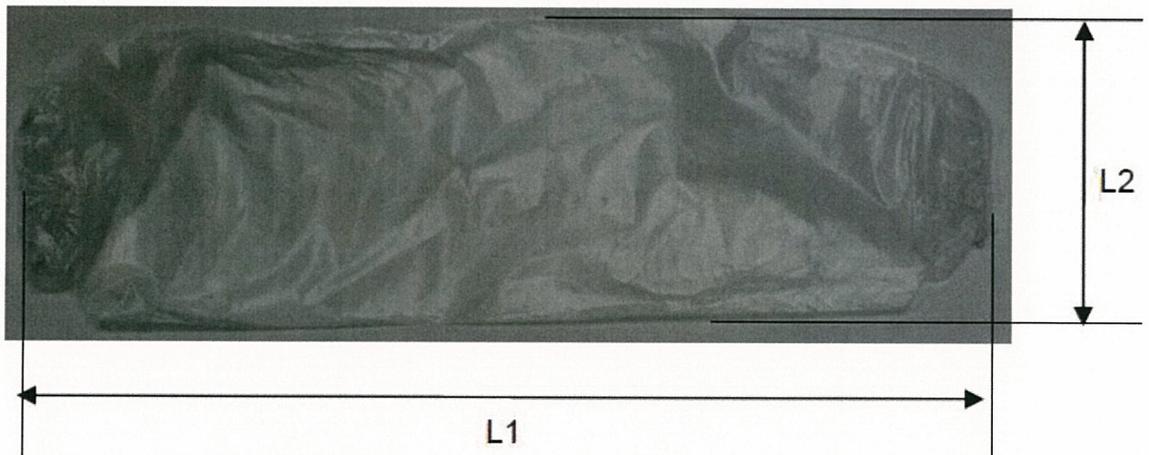
1.9.3 Power Cord



Part No.	Description	Size(mm)	Weight(g)
ER2000-O	AC Power Cord	1,000	100

- Manufacturer: Various
- Manufacturer Code: ER2000-V

1.9.4 Vinyl Cover



Part No.	Description	Size(mm)	Weight(g)
EC2000-V	Controller Vinyl Cover	350(L1)*100(L2)	1

- Manufacturer: Intromedic
- Manufacturer Code: EC2000-V

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510(k) Submission – E.G. Scan™ II Esophagoscope System

Section 12_Proposed labeling

1. Back Label & Packaging Information : Back Label and Drawings showing the method of packaging are provided in Appendix 12-1. All dimensions are in millimeters.
2. Draft Instructions for Use : The Instruction for Use that will be supplied to each purchaser of E.G. Scan II is provided in Appendix 12-2.

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510(k) Submission – E.G. Scan™ II Esophagoscope System

Labeling on product

- 1) Probe(EP2000)
: 60mm*70mm

EoGo Scan™ II

Probe
Part No. : EP2000

DATE OF MANUFACTURE:
SERIAL NUMBER:



0 1 2 0



CLASSIFIED
UL US

Medical Device Group
UL60601-1/CAN/CSA C22.2
No. 601.1
3LYL



CAUTION,
CONSULT ACCOMPANYING
DOCUMENTS

FCC ID: VAX INTROMEDIC4
IPX 8 Type BF Equipment
(ATTENTION, Consult instruction for use)
Caution: Federal law restricts this device to sale by
or on the order of a physician.

“DO NOT REUSE”

MANUFACTURER Suite 1104, E&C Venture Dream Tower 6-Cha,
197-28 Guro-Dong, Guro-Gu, Seoul, KOREA 152-719
Tel. +82-2-801-9300 Fax. +82-2-801-9330



www.intromedic.com

Made in Korea

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510(k) Submission – E.G. Scan™ II Esophagoscope System

- 2) Controller(EC2000)
: 102.0mm*22.6mm

E.G. Scan™ II
Controller
Part No. : EC2000

CE 0120
AC: 100-240V, 50/60Hz, 0.5A
FCC ID: VAX INTRAMEDICA

CLASSIFIED
UL us 3LYL
Medical Device Group
UL60601-1/CAN/CSA
C22.2 No. 601.1

DATE OF MANUFACTURE
SERIAL NUMBER

CAUTION, Federal law restricts this device to sale by
or on the order of a physician.
ATTENTION (Consult instructions for use)

Made in Korea
www.intramedic.com

Suite 1104, E&C Venture Dream Tower 6-Cha,
197-28 Guro-Dong, Guro-Gu, Seoul, KOREA 152-719
Tel. +82-2-801-9300 Fax. +82-2-801-9330

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510(k) Submission – E.G. Scan™ II Esophagoscope System

3) Processor(ER2000)

: 60mm*40mm

EoGo Scan™ II

Processor
Part No. : ER2000



0 1 2 0



Medical Device Group
UL60601-1/CAN/CSA C22.2
No. 601.1
3LYL



CAUTION,
CONSULT ACCOMPANYING
DOCUMENTS

**DATA OF
MANUFACTURE**

AC 100-240V, 50/60Hz, 0.5A

ATTENTION (Consult instructions for use)
(Limitted mechanical stability warning)

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

MANUFACTURER Suite 1104, E&C Venture Dream Tower 6-Cha, 197-28 Guro-Dong,
Guro-Gu, Seoul, KOREA 152-719
Tel +82-2-801-9300 Fax +82-2-801-9330

SERIAL NUMBER

FCC ID: VAX INTROMEDIC4

Made in Korea

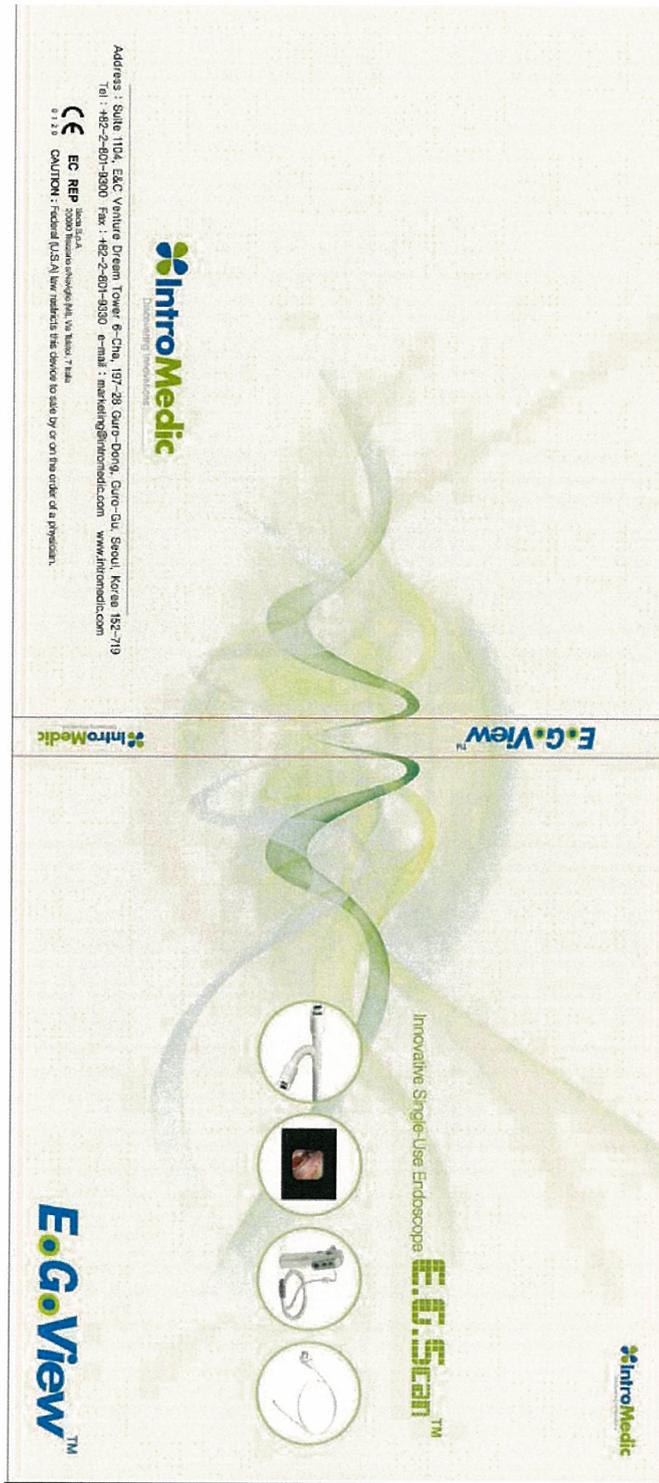
www.intromedic.com



IntroMedic Co., Ltd.

510(k) Submission – E.G. Scan™ II Esophagoscope System

4) Software(E.G. View):290mm*126mm



IntroMedic Co., Ltd.

510(k) Submission – E.G. Scan™ II Esophagoscope System

The image shows a screenshot of a document with a green background. At the top left, there is a small logo consisting of four colored squares (blue, green, yellow, red) followed by the text "Hardware Requirements". Below this is a table with two columns: a component name and its specifications. The components listed are OS, CPU, RAM, Graphic Card, Main Board, HDD, Interface, and Monitor. To the right of the table, there is a block of text providing a disclaimer and a website URL.

Component	Specifications
OS	Windows XP(32bit), Windows Vista(32bit), Windows 7(32bit)
CPU	Pentium IV 2GHz Dual Core (minimum)
RAM	1GB (minimum)
Graphic Card	Windows Compatible (3D acceleration)
Main Board	More than two IDE (or Serial ATA) slots required
HDD	Larger than 80GB
Interface	USB 2.0
Monitor	Resolution 1024x768 required, 1690x1050 recommended

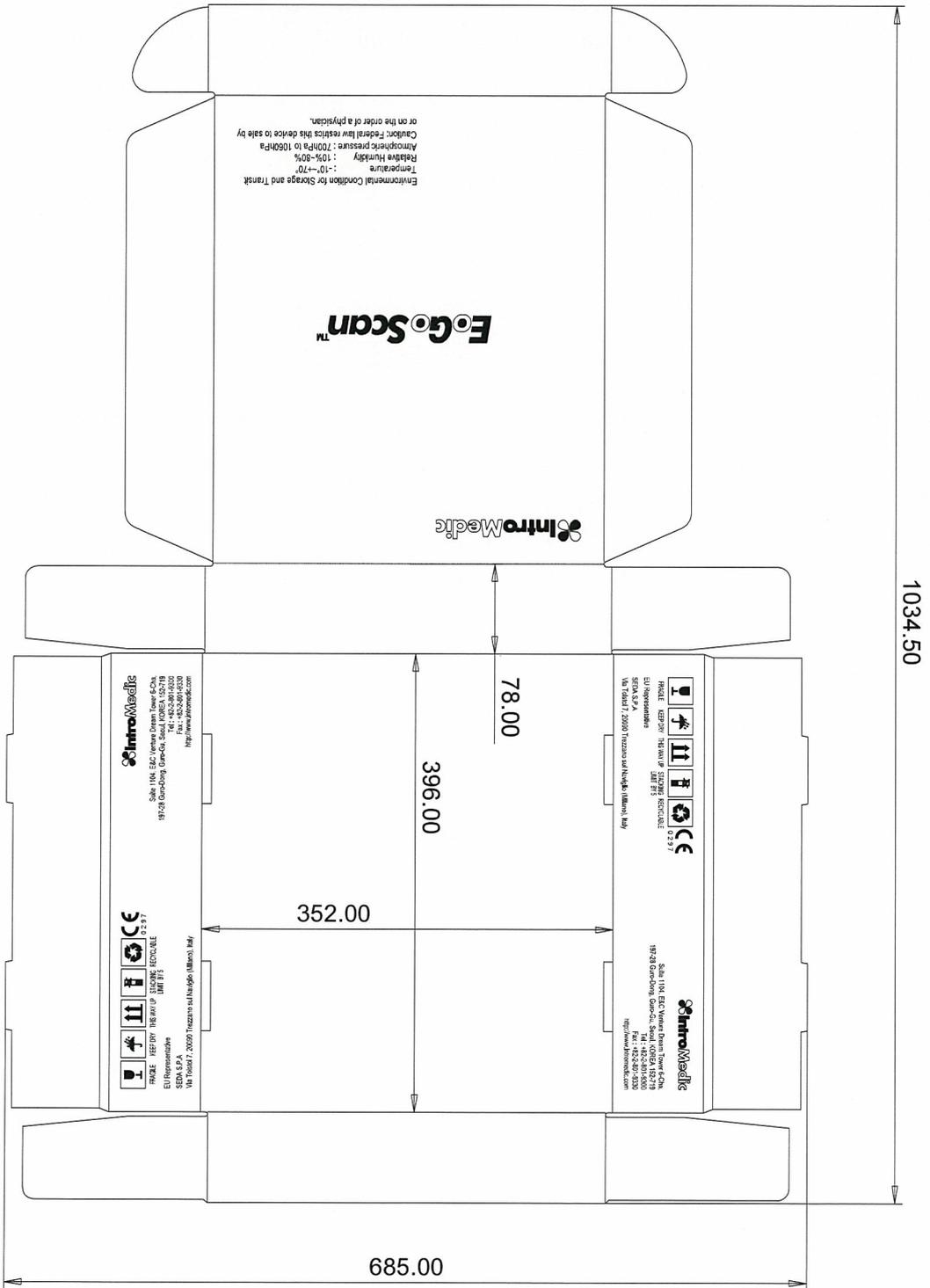
Software should only be installed by following the step by step procedure detailed in the Service Manual. Please contact Introtec with any comments or questions.
www.introtec.com

IntroMedic Co., Ltd.

510(k) Submission – E.G. Scan™ II Esophagoscope System

Labeling on Carton box

1) E.G. Scan™ Probe Packaging Box



IntroMedic Co., Ltd.

510(k) Submission – E.G. Scan™ II Esophagoscope System

2) E.G. Scan™ Set Packaging Box



IntroMedic Co., Ltd.

510(k) Submission – E.G. Scan™ II Esophagoscope System

Packaging

1) Probe

- 1st. Packaging



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510(k) Submission – E.G. Scan™ II Esophagoscope System

- 2nd. Packaging



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- 3rd. Packaging



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2) Controller & Display System

- 1st. Packaging



IntroMedic Co., Ltd.

510(k) Submission – E.G. Scan™ II Esophagoscope System

- 2nd. Packaging



IntroMedic Co., Ltd.



E.G. Scan™ II User Manual

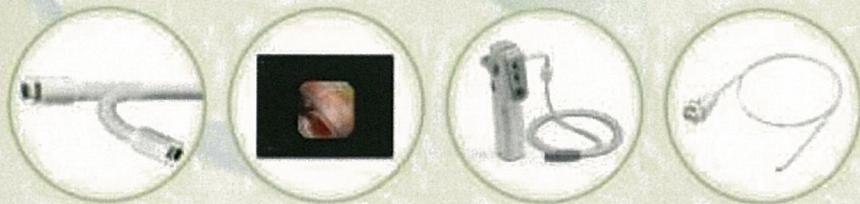
Innovative Single-Use Endoscope **E.G. Scan™ II**





E.G. Scan™ II User Manual

Innovative Single-Use Endoscope **E.G. Scan™ II**



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Version 1.10

EM2000-U-1303 (US)
Date: 2013-03-06

Trademarks

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Warranty

Every effort has been made to ensure the information contained in this User Manual is accurate, and is believed to be correct at time of printing. IntroMedic reserves the right to change any content contained with this User Manual without prior notice.

IntroMedic Co., Ltd. warrants the product against defects in material and workmanship for a period of twelve (12) months from the date of sale, unless different local regulations apply. IntroMedic Co., Ltd. will repair or replace products that are ascertained by IntroMedic to have defects during the warranty period. IntroMedic Co., Ltd. is not liable for the defects occurred by misuse, careless handling, unauthorized modifications or erroneous use, or any use that is non-compliant with instructions detailed within this User Manual. This includes use of the product in non-appropriate locations or conditions. Any other warranties are neither represented here nor recognized by implication.

To validate the warranty, please complete product registration with the local authorized IntroMedic distributor.

Warranty

Exclusive warranty service

The warranty service provided hereby is applicable exclusively to the purchaser of the product. IntroMedic will only warranty the product for purposes and usage as defined in this User Manual. Any usage not heeding the warnings, cautions and recommended usages as defined in this manual will nullify the warranty.

Support

For warranty or repair service please contact the local authorized IntroMedic distributor.

For customer service or support please contact your point of purchase or IntroMedic Co., Ltd. Service agreements are only applicable to products of IntroMedic Co., Ltd.

IntroMedic Customer Service

TEL: 82-2-801-9300

FAX: 82-2-801-9330

<http://www.intromedic.com>

E-mail: helpdesk@intromedic.com

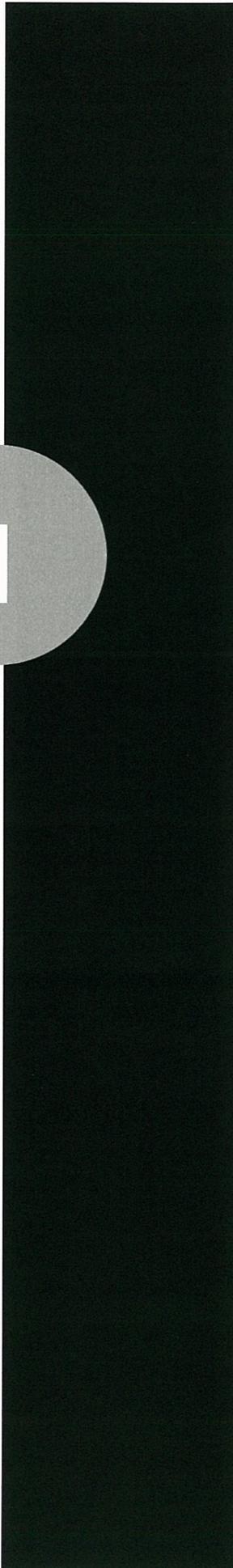
Safety

Non-compliance with the user's manual, unauthorized modifications of the product or replacement of parts, and/or opening of the product casing is prohibited and may be hazardous.

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Contents



1

Safety Information

1. SAFETY INFORMATION

1.1 Warnings

E.G. Scan™ II has been manufactured to conform to the International Standard for Medical Electrical Equipment: General Requirements for Safety IEC 60601-1, together with the Collateral Standard for Electromagnetic Compatibility Requirement and Tests IEC 60601-1-2.

E.G. Scan™ II has been manufactured to conform to the electric shock, fire and mechanical hazard standards as defined in CAN/CSA C22.2 NO.601.1.

Based on request of the buyer, IntroMedic will provide the labeling, such as ID labels and the User Manual in the national language(s) of European countries. Translated documents will be evaluated by a local language expert and will be confirmed by a native speaker of the respective national language.

Safety Symbols: The User Manual incorporates various safety symbols to ensure safe and correct use of the product and to prevent any personal injury or property damage. These symbols are defined in the following table:

	<p>WARNING</p> <p>WARNING indicates a potential hazard that, if not avoided, could result in serious personal injury or damage to the product.</p>
	<p>CAUTION</p> <p>CAUTION indicates a potential hazard that, if not avoided, could result in minor personal injury or damage to the product.</p>
	<p>NOTE</p> <p>NOTE does not indicate potential hazards as in Caution or Warning, but contains important information regarding the installation, operation or maintenance of the product.</p>

1.2 Symbols for Safety

This section describes a set of symbols that the IEC (International Electrotechnical Commission) has established for medical electronic equipment to classify connections warnings of any potential hazards.

	EN980: Attention. See instruction manual for use.
	IEC 878-02-03: Indicates that this is classified into Type BF equipment
	EN 980: Denotes Date of Manufacture
	EN 980: Denotes Address of Manufacture
SN	EN 980: Denotes serial number
	IEC60417-5008: Power Off (Power ; Connected to power source)
	IEC60417-5007: Power On (Power ; Connected to power source)
A	Denotes Ampere, the unit of current
V	Denotes Volt, the unit of Voltage
Hz	Denotes Herz, the unit of Frequency
	IEC 417-5021: Denotes potential equalization terminal
	Single Use Only
	Use by date
	EN980: Authorized representative in the European community

1.3 Function Symbols

1.3.1 E.G. View™ Function Symbols

The following table describes symbols or icons used in the E.G. View™.

Symbol	Description
	Enter Review Mode
	Enter Report Mode
	Enhance images
	Record videos
	Print report
	Preview report
	Save report as PDF file format
	Export captured images and reports
	Add selected captured images to report candidates
	Remove selected captured images from report candidates

1.3.2 Controller Function Symbols

Symbol	Description
FREEZE	 Button for freezing display image. First press means freezing and second press means release.
	 Button for Capturing current display image.
	 Button for putting air into body.

1.4 Remarks for Safe Use

- Follow the safety instructions included in this Service Manual and clinical precautions advised by medical professionals.
- The manufacturer is not liable for harm or damage caused by improper, unauthorized, unprofessional or inexperienced use of the device and/or product.
- IntroMedic Co., Ltd. is NOT responsible for physical harm or equipment problems caused by the user's careless operation or mismanagement of the device and/or product.
- Users MUST have read and understood the User Manual. ONLY trained and qualified medical professionals or authorized representatives of IntroMedic Co., Ltd. may operate the system.
- User Manual must ALWAYS be with the equipment. This is the USER'S RESPONSIBILITY.
- CAUTION: The processor, the controller, air channel and USB cable should not be exposed or come in contact with foreign substances including water, cleaning fluids, disinfecting cleanser; as such substances may harm the equipment
- ONLY authorized personnel may perform repairs. Never attempt to open covers, panels or casings.
- DO NOT crease, bend, fold or twist the probe and the air channels. Take care to guard them against mechanical stress (e.g. wheels or heels).
- The probe, the controller and the processor must not be exposed to mechanical shock (e.g. by dropping). IntroMedic Co., Ltd. will not take any responsibility for the damages caused by the improper use as mentioned above.
- CAUTION: Damage/injuries to the probe and cable may cause a safety hazard. Damaged items MUST be repaired IMMEDIATELY.
- DO NOT handle fluids around the system.

- DO NOT USE in moist or damp places.
- DO NOT operate the equipment with wet hands.
- Avoid using the equipment in extreme temperatures or humid environments.
- DO NOT keep the equipment or carry out the endoscopy procedure in places such as areas exposed to direct sunlight, vicinity of heaters, vicinity of chemical materials or gases, areas moist/damp or dusty, or poorly ventilated areas.
- DO NOT disassemble or open the equipment without permission. IntroMedic Co., Ltd. will not take any responsibility for the damages caused by the improper use as mentioned above.
- DO NOT carry out the endoscopy procedure in areas with high vibrations or in environments where high electro-magnetic waves are generated.
- DO NOT pull out the power cord by grabbing the cable. This may result in short-circuits, disconnection, or cord damage.
- CAUTION: Verify that all connection terminals are securely connected to the processor.
- CAUTION: Turn off the power switch of processor before connecting the controller and probes.
- DO NOT carry out the endoscopy procedure simultaneously with other procedures using medical products or equipment.
- DO NOT use for purposes other than medical treatment.
- The probe is disposable and should not be reused. If the probe is reused, it can cause cross infection.
- The probes, cables and vinyl coverings are medical waste, and should be disposed of according to local regulations or WEEE directive on waste disposal.
- Only use the probe, the controller and the processor in the medical environment condition.

- The mobile PC should have an adaptor with 100-240 V 50/60 Hz 0.5 A usage.
- For 120V applications, use only UL Listed detachable power cord with NEMA configuration 5-15P type (parallel blades) plug cap. For 240V applications use only UL Listed Detachable power supply cord with NEMA configuration 6-15P type (tandem blades) plug cap.
- Check the outer surface of the endoscope for rough surfaces, sharp edges, or protrusions which may cause a safety hazard.
- Take care to keep the end of probe from being heated, the temperature of the end of probe can be exceed 41 °C. Do not stay the end of probe at the same place for a long time, the temperature of the end of probe can cause the burning in the skin.
- Please do not try to cut the label.
- Please ground the earth terminals.
- DO NOT to touch signal input, signal output or other connectors, and the patient simultaneously.
- A mobile PC connected with E.G. Scan™ II Endoscope system should be complied with requirements of IEC/UL 60601-1 certifications.
- All products connected with E.G. Scan™ II Endoscope system should be complied with recommended specification.
- Turn the processor off, after the procedure finishes.

1.4.1 Environmental Conditions for Operation

- Temperature : 0 °C - 40°C
- Relative humidity : 45% - 75%
- Atmospheric pressure : 700hPa to 1060hPa

 **CAUTION** If the equipment has been brought in from a cold environment (stock room, airfreight) into a warm room, initial activation should take place after a few hours, to allow for temperature adjustment and balance and evaporation of condensed humidity.

 **WARNING** DO NOT operate the equipment around generators, power stations, X-ray devices, and broadcasting stations where high levels of electro-magnetic waves are generated. The electro-magnetic waves can cause equipment malfunctions.

 **WARNING** DO NOT operate the equipment around heat sources, strong electric or magnetic fields (close to a transformer), or near instruments generating high-frequency signals.

 **WARNING** DO NOT use E.G. Scan™ II around the medical device involving the electrical currents and/or during the endoscopy procedure which emits the electrical current radiation. DO NOT use the unit around (within 1m) short wave or microwave therapy equipment. This may cause instability in capturing images.

 **WARNING** E.G. Scan™ II is a Class A device according to EN60601-1-2 standards. This equipment can cause radio interference in residential areas. In this case, the owner (or operator) can be held responsible for the problem.

1.4.2 Safety Precaution

- Make sure the environment is without interference from electromagnetic fields.
- Make sure the environment is without noise and vibration.
- DO NOT carry out the endoscopy procedure while using all devices of except E.G.Scan™ II system.
- DO NOT use on patients with pacemakers or defibrillators.
- DO NOT use the probe if the package is not sealed.
- DO NOT reuse a used probe.
- To prevent unexpected accidents like fire or explosion, do not use any product around ignitable substances.
- DO NOT disassemble the equipment case. If there is a problem with E.G. Scan™ II, please contact customer service team of IntroMedic Co., Ltd. immediately.
- Only the accessories authorized and designed by IntroMedic Co., Ltd. should be used with this equipment. E.G. Scan™ II and the accessories are not guaranteed against problems caused by use of unapproved or undesignated accessories by IntroMedic Co., Ltd.
- This equipment may affect on other products or be affected by other products.
- Follow your doctor's instructions and the guidelines in the User Manual.
- Do Not carry out the endoscopy procedure around high frequency radiation sites (such as high voltage, radar, installation power plants, MRI, CT or electric blankets etc.) This may result in serious side effects requiring an emergency operation.)

- In case of any symptoms of abdominal pain, vomiting, fever, heart trouble, dizziness or seizure during or after the endoscopy procedure, please notify your doctor.
- Always check the connection between the probe, controller, processor and mobile PC.
- DO NOT use the probe if the package is damaged or already open before unsealing.
- If a patient has been diagnosed with diabetes, follow instructions of a medical professional to prevent medical accidents prior to the endoscopy procedure.
- For more accurate data and better analysis, patients should fast for 8 hours before the endoscopy procedure.
- If recommended by the physician, the patient may take a laxative prior to the endoscopy procedure.
- Always check whether USB is connected to the processor using E.G. View™.
- Always check the AC Power range before use of the processor.
- DO NOT touch AC power cord with wet hands.
- DO NOT use E.G. Scan™ II Endoscope system outside of the hospital.



WARNING

Before moving the system, always make sure to disconnect the mobile PC and accessories, and then safely move them separately. Connect the mobile PC and accessories only after the hardware is fully installed, secure and stable.

1.4.3 Cleaning and Maintenance

■ High-Level Disinfection Protocol

! **CAUTION** It is recommended to put on sterilized gloves during Disinfection Protocol which is shown as below.

! **NOTE** Only use disinfectant solution from disinfectant manufacturers that can ensure compatibility for E.G. Scan™ Probe's PVC material.
IntroMedic has confirmed Material Compatibility with Johnson & Johnson's Cidex® OPA (510K Number: K991487), a product equivalent or higher is recommended.

- Disinfection

- ① Soak the probe for 12 minutes at 20 °C to achieve high level disinfection in CIDEX OPA Solution.
- ② Following disinfection, remove the probe from the solution.

! **CAUTION** Ensure the probe is completely submersed in CIDEX OPA Solution.

- Rinsing

- ③ Following disinfection, rinse the probe thoroughly with sterilized water (23~25 °C).
- ④ Each rinse should be a minimum of 1 minute in duration and repeated three times with changing new sterilized water for each single time.
- ⑤ On a table, put a soft lint-free cloth and it should be dried and sterilized. Place a probe on the cloth and dry down the probe with sterilized gauze.

! **CAUTION** Used clothes, gauzes and gloves should be discarded to medical waste bin.

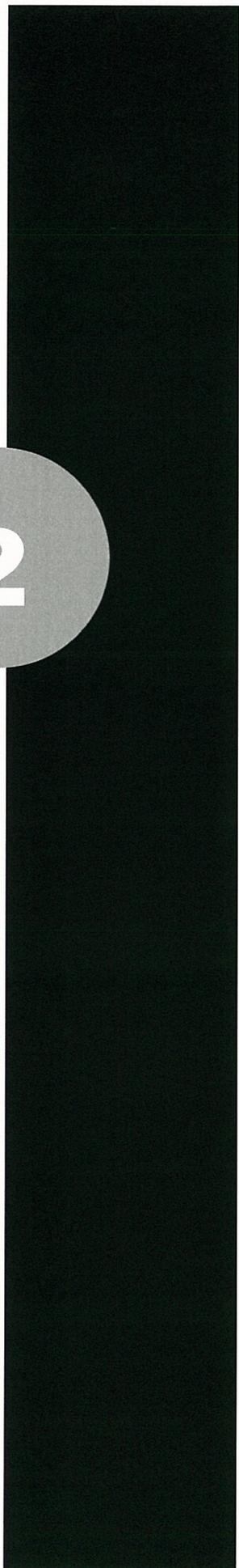
! **CAUTION** Never wipe dome surface.

! **NOTE** 99.74% of disinfection efficiency is confirmed when we did high level disinfection as shown as above.

- Controller, Display System and Accessories
 - The vinyl cover of controller is single use only. Please discard this cover after usage.
(Please refer to page 3-4~9 3.3 Examination Preparation for the usage and page 3-14~17 3.9.1 Remove Probe for the disuse.)
 - Controller, Display System and Accessories should be cleanly maintained. For cleaning them, wipe with a soft, lightly moistened cloth with warm water after use them. Do not use organic solvents such as lacquer, thinner, ethylene and oxide because they can damage the equipment. Be careful that foreign substances do not enter the main system when cleaning.
 - ALWAYS operate the equipment under sanitary environmental conditions.

- Service Document
 - If required, or upon request, the local IntroMedic Distributor (authorized IntroMedic Representative) may provide block diagrams, lists of spare parts, descriptions, adjustment instructions or other related information which may help qualified technical personnel in repairing specified parts of the equipment which have been defined repairable by IntroMedic Co., Ltd..

- Moving the Equipment
 - CAUTION when moving equipment.
 - WARNING: Excessive impact/shock causes internal damage.
 - If wiring is connected/disconnected when moving, check the exact wiring status after moving.
 - If damage to the equipment is discovered after moving, immediately contact IntroMedic or local Distributor.



2

Overview & Intended Usage

2. SYSTEM OVERVIEW

E.G. Scan™ II is a transnasal endoscope system to capture and transmit images of the esophagus. Captured images can be reviewed via the E.G. View™ for diagnosis of diseases related to the esophagus.

The E.G. Scan™ II endoscope system consists of probe, controller, processor, E.G. View™ and other accessories.

Generally, the commercial endoscope system has reusable probes, but the E.G. Scan™ II has single use probe. The E.G. Scan™ II use probes for single use only because reusable probes have the risk of infection and pollution.

2.1 Indications for Use

E.G. Scan™ II Esophagoscope System is intended for use in endoscopic access and examination of the larynx, esophagus and gastroesophageal junction.

2.1.1 Contraindications

- Not intended for patients who have history of broken nose or disease of nasal cavity.
- Not intended for patients who have severe back ground disease.
- Not intended for patients who are in a state after gastric surgery.
- Not intended for patients who have COPD, CHF, CRF and any disease with respiratory disturbances.
- Not intended for patients who have deviation of the nasal septum.

2.2 Observable Diseases

- 2.2.1 Gastroesophageal Reflux Disease**
- 2.2.2 Esophageal Cancer(adenoma)**
- 2.2.3 Esophageal Varix**
- 2.2.4 Barrett's Esophagus**
- 2.2.5 Esophageal Perforation**
- 2.2.6 Esophageal Stricture**
- 2.2.7 Esophageal Rings and Webs**
- 2.2.8 Obstruction of Esophagus**
- 2.2.9 Infectious Esophagitis, Esophagus Ulcer, Papilloma**
- 2.2.10 Esophageal Dissection**
- 2.2.11 Mallory-Weiss Syndrome**
- 2.2.12 Esophageal Deverticulum**

3

Performing E.G. Scan™ II Endoscopy

3. PERFORMING E.G. Scan™ II ENDOSCOPY

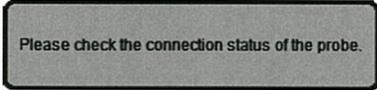
3.1 General Comments

This chapter describes how to perform an endoscopy procedure with the E.G. Scan™ II.

Installation must be performed by an authorized IntroMedic service technician.

3.2 Safety Messages

 **WARNING** DO NOT reuse the probe.
If a used probe is connected, an error message will appear



at the bottom-right on the screen.

 **WARNING** DO NOT touch the devices with wet hands or allow wet objects to come in contact with the device.

 **CAUTION** When moving the E.G. Scan™ II from a cold environment to a warmer one, wait several hours before running the processor. This will help prevent electrical malfunctions due to accumulated condensation.

 **CAUTION** Ensure that all peripheral devices, such as monitors and printers, are connected to independent power supplies that are properly grounded. Ensure that all peripheral equipment is properly shielded and approved for use in a medical environment.

 **CAUTION** DO NOT touch all of probe except for the connector with bare hands to prevent cross-contamination.

 **CAUTION** The probe and the vinyl are designed for single use and cannot be sterilized or reused.

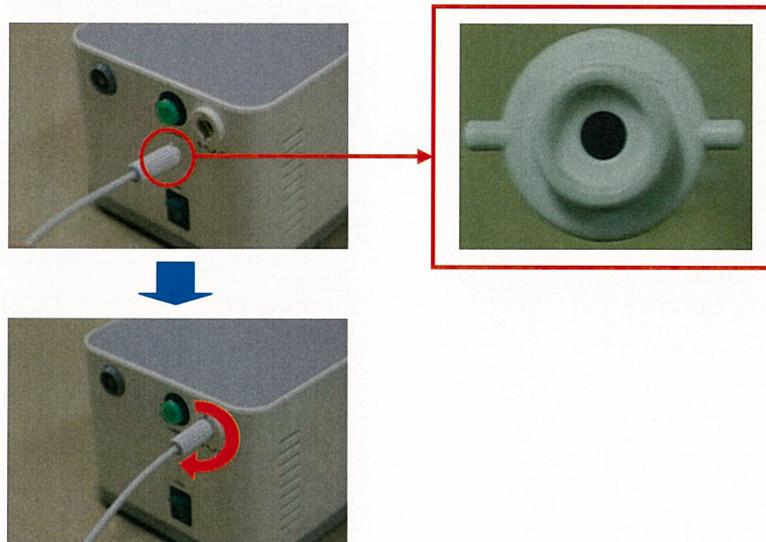
 **CAUTION** The mobile PC should have an adaptor with 100-240 V 50/60 Hz 0.5 A usage.

3.3 Prepare the System

Before performing an endoscopy procedure, connect the E.G. Scan probe and all verify all connections to prevent malfunctions.

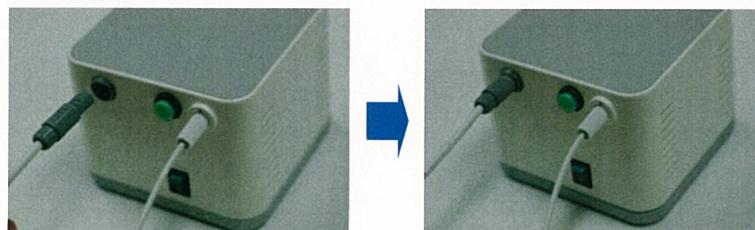
3.3.1 Set Up the E.G. Scan™ II System

- Fit one side of the connector of the air channel to the processor and then turn it to the right.

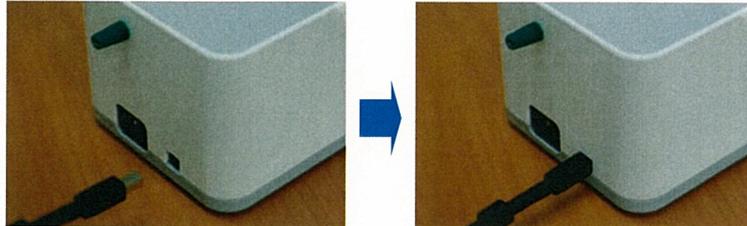


! **CAUTION** Please connect the air channel lock tight to avoid the connector separated from the processor during the procedure.

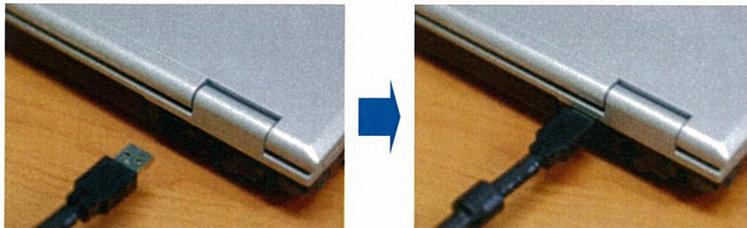
- Connect the controller connector to the processor.



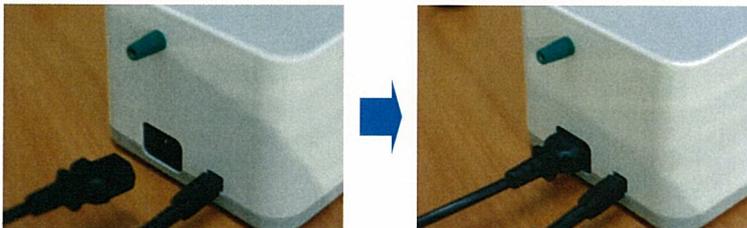
- Connect the USB cable to the processor.



- Connect the USB cable to the mobile PC.



- Connect the power cord to the processor.



- Connect the power cord for the processor to an AC outlet.

 **WARNING** Always check the AC Power range before connecting the power cord to an AC outlet.

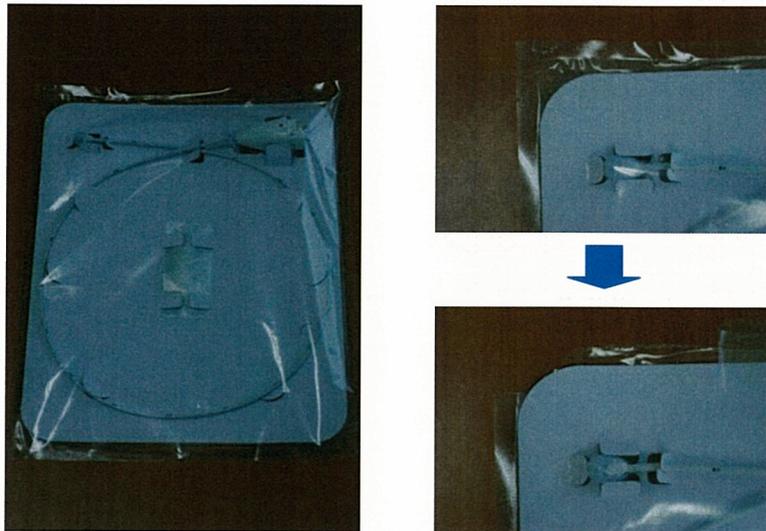
 **WARNING** DO NOT touch AC power cord with wet hands.

- Put on gloves.



3.3.2 Disinfect probe.

- Holding the groove, tear open the E.G. Scan™ II probe package.



- Remove the probe from probe holder.

! **CAUTION** DO NOT use the probe if the packaging is damaged.

! **CAUTION** To prevent any contaminations to the probe, please do not open the plastic package until the procedure.

- Disinfect the probe with CIDEX OPA Solution

! **CAUTION** It is recommended to put on sterilized gloves during Disinfection Protocol which is shown as below.

! **WARNING** Do Not immerse the probe connector into liquid.

Soak the probe for 12 minutes at 20°C to achieve high level disinfection in CIDEX OPA Solution.

! **CAUTION** Ensure the probe is completely submersed in CIDEX OPA Solution.

- Following disinfection, remove the probe from the solution.

- Rinse the probe.
 - Following disinfection, rinse the probe thoroughly with sterilized water (23~25°C).
 - Each rinse should be a minimum of 1 minute in duration and repeated three times. Each rinse should be done with new sterilized water.
 - On a table, put a soft lint-free cloth and it should be dried and sterilized. Place a probe on the cloth and dry down the probe with sterilized gauze.

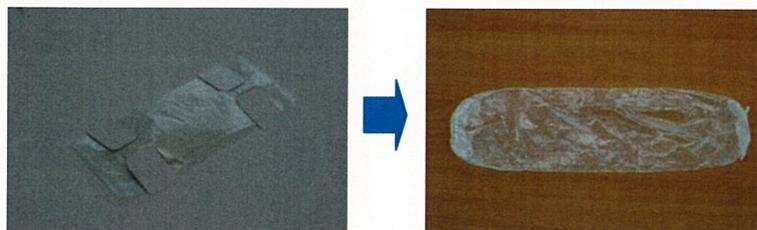
! **CAUTION** Used clothes, gauzes and gloves should be discarded to medical waste bin.

! **CAUTION** Never wipe dome surface.

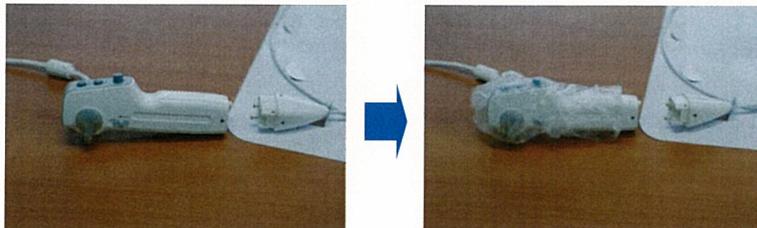
- Disinfected probe should be used immediately.
- Refer to the instrument manufacturer's labeling for additional storage and/or handling instruction.

3.3.3 Connect the Probe

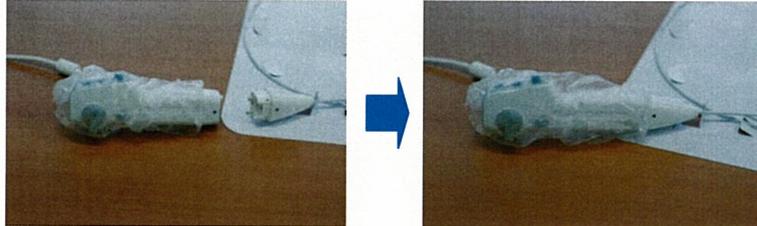
- Remove the probe holder from the vinyl packaging and then remove the vinyl covering of the controller from the probe holder.



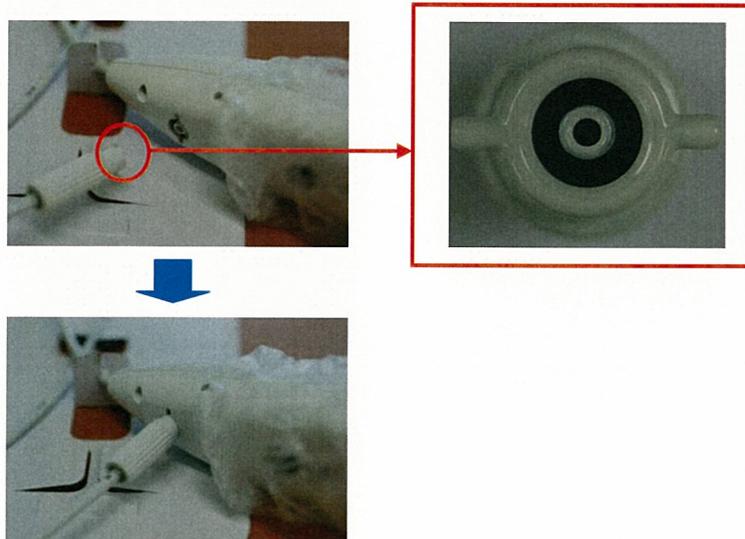
- Insert the connector of the controller through the vinyl covering to cover the controller with the vinyl covering.



- Firmly grasp the probe connector, align the slots with the tabs in the controller, and insert it into the controller as shown until a “click” sound is heard.



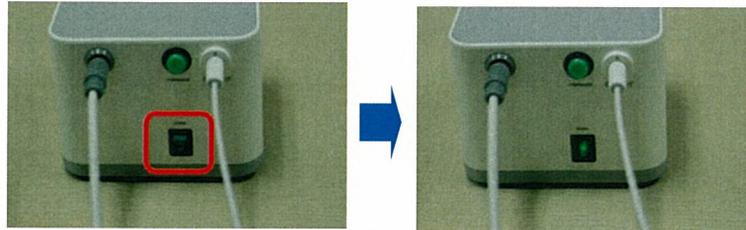
- Fit the otherside of the connector of the air channel to the probe and then turn it to the right.



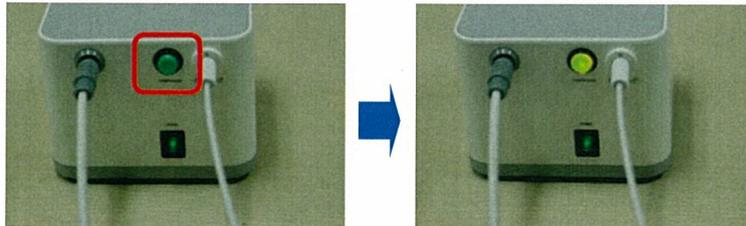
! **CAUTION** Please connect the air channel lock tight to avoid the connector separated from the probe during the procedure.

3.3.4 Check the Probe

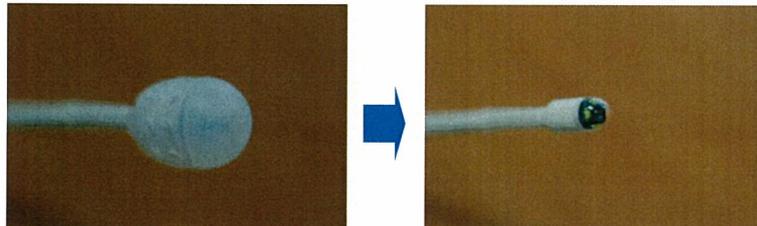
- Run the E.G. View™ on the screen of the mobile PC.
- Turn the processor switch on.



- Turn the compressor switch on.



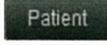
- After removing the probe from the package, remove the protective cap from the dome.

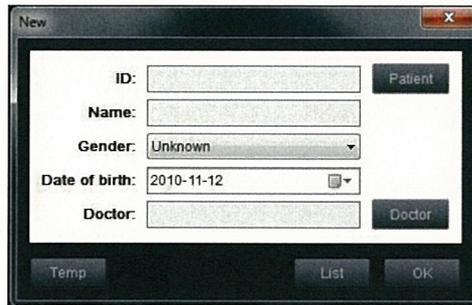


! **CAUTION** The dome is already clean. DO NOT touch or wash the dome.

- Verify that all four LEDs on the end of the probe are lighted.

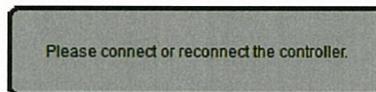


- When the New window appears, click  to select a patient.



 **NOTES**

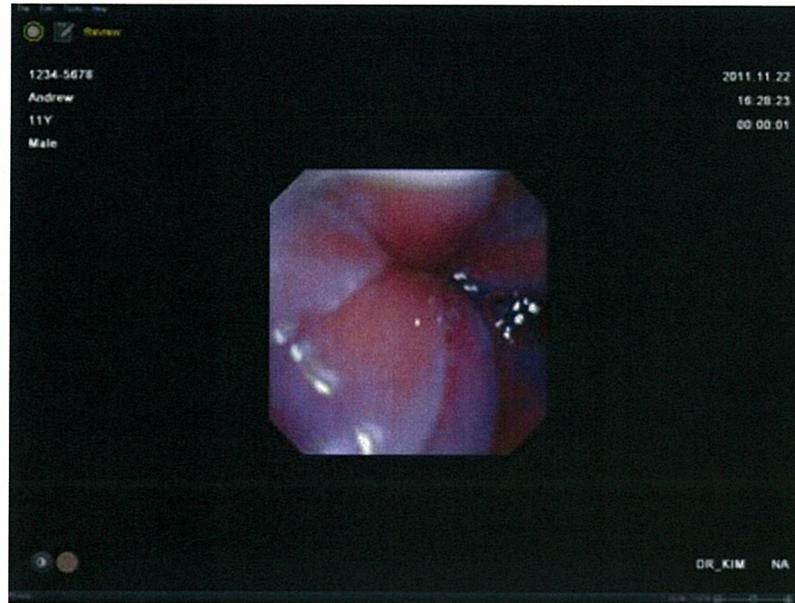
If the controller is not properly connected to the mobile PC, an error message will appear at the bottom-right of the screen:



Disconnect and reconnect the controller to continue.

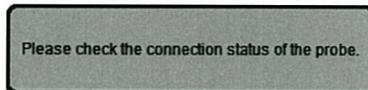
- Click  to select a doctor.
- Click .

- Verify that images are being transmitted to the mobile PC.



NOTES

If the probe is not connected properly, an error message will appear at the bottom-right of the screen:
Disconnect and reconnect the probe to continue.



- Verify the controller connection by pushing the lever upward or downward to manipulate the probe.

3.4 Prepare the Patient

Pretreatment of the patient's nasal cavity is necessary to prevent pain or discomfort and avoid epistaxis due to damage of the nasal mucosa. The most important role of pretreatment is to broaden the nasal cavity for easy insertion of the E.G. Scan™ II probe.

3.4.1 Interview the Patient

Interview the patient to determine the existence of the following conditions:

- Drug allergies that may prevent anesthetization of the nasal cavity.
- History of injuries or disease that may have compromised or blocked the nasal cavity.
- Use of anticoagulants or antiplatelets.
- Epistaxis, inflammation, or lesions in the nasal cavity.
- Unusually small nostrils or heavy nasal congestion.

3.4.2 Administer an Anti-foaming Agent

Administer Simethicone diluted with water to remove bubbles in the digestive canal and protect the probe lens from foreign substances.

3.4.3 Administer a Vasoconstrictor

Administer epinephrine diluted with lidocaine directly to the nasal cavity.

3.4.4 Administer Topical Anesthesia

Administer lidocaine spray directly to the nasal cavity.

3.4.5 Administer Nasal Anesthesia

- ① Apply 10% lidocaine spray and 2% lidocaine jelly to a 7 fr Nelaton catheter.
- ② Insert the catheter about 10cm into the nasal cavity.
- ③ Leave the catheter in place for about 10 minutes.

 **CAUTION** DO NOT force the catheter into the nasal cavity, as this may cause pain or bleeding.

 **NOTE** The nostril for insertion is selected by the following test. Press the nasal cavity with fingers and select a well ventilated nasal.

3.4.6 Clear the Nasal Cavity

Remove any debris from the nasal cavity with a cotton swab.

3.5 Insert the Probe

Carefully insert the probe into the nostril, through the nasopharynx, and then into the esophagus.

3.5.1 Insert the Probe into the Nostril

Insert the probe into the nasal cavity, perpendicular to the face. If necessary, try multiple passes to comfortably insert the probe into the nostril. If severe resistance or pain occurs, remove the probe and try to insert it into the other nostril.

 **CAUTION** DO NOT insert the probe parallel to the bridge of the nose. This may result in contact with the superior turbinate and can cause pain or bleeding.

 **NOTE** The E.G. Scan™ II system allows patients to communicate during the endoscopy procedure. If the patient appears uncomfortable or distressed, ask the patient for feedback and respond directly to alleviate the pain or discomfort.

3.5.2 Thread the Probe into the Nasopharynx

- Pass the probe through the nostril into the nasal vestibule.
- Locate the middle turbinate and inferior turbinate.
- Pass the probe through the lower side of the middle turbinate or between the lower side of the inferior turbinate and the nasal septum.
- Pass the probe through the nasopharynx.
- Pass the probe through the oropharynx and hypopharynx.

 **CAUTION** Avoid contacting the nasal septum or turbinate, as this may result in pain or bleeding.

 **NOTE** When passing the probe through the turbinate, the nasal cavity should narrow. If the resistance is not great, continue passing the probe slowly through the turbinate.

3.5.3 Pass Probe into the Esophagus

When passing the probe through the esophagus, let the patient swallow the saliva to eliminate liquid in the pharynx. Remind the patient to breathe normally, as this will relax the laryngeal root and reduce the gag reflex.



CAUTION

Slowly insert the probe into the esophagus, continually checking the position of the probe. Avoid contacting the annular cartilage or straying from the opening of the esophagus, as this may cause pain.



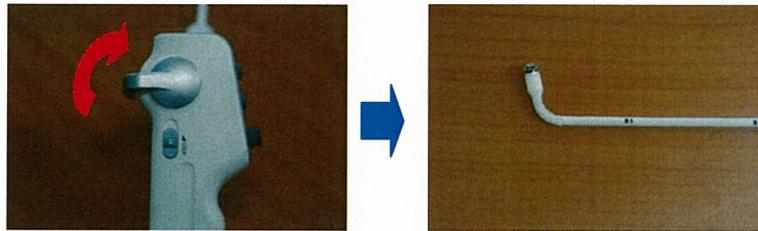
WARNING

Forcing the probe against the walls of the esophagus can cause perforations. Carefully insert the probe and do not force it against the esophagus.

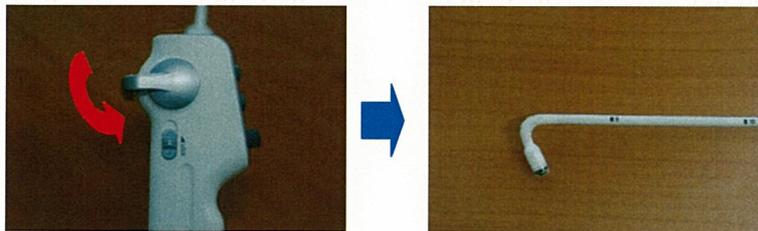
3.6 Use the E.G. Scan™ II during Endoscopy

3.6.1 Control the End of the Probe

- Push the lever upward to bend the probe upward.



- Pull the lever downward to bend the probe downward.



3.6.2 Capture Images

- To capture the frozen image, press 'CAPTURE' button.

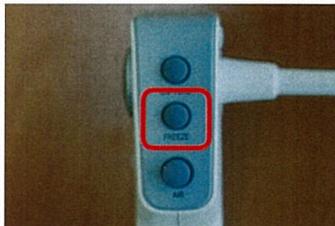


ⓘ **NOTE** Captured images are not deleted from internal memory.

ⓘ **NOTE** When saving captured images, save them to an external device.

3.6.3 Freeze Images

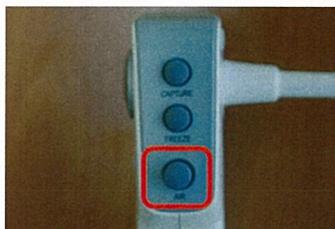
- To freeze the current image, press 'FREEZE' button.



! **NOTE** For more information about capturing and working with images, please refer to 4. *Using E.G. View™*.

3.6.4 Insert air

- To insert air into body, press 'AIR' button.



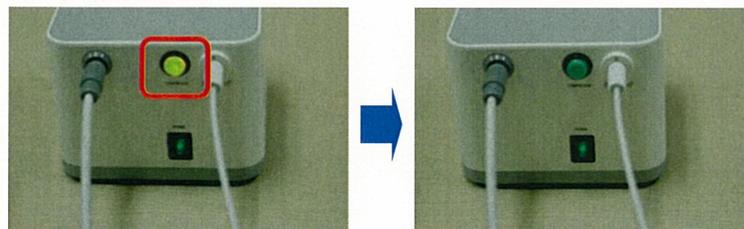
3.7 Remove the probe

Carefully remove the probe, using caution not to catch the end of the probe in the nasal cavity. If the end of the probe catches on the oropharynx, gently move the probe side to side and remove it slowly through the side with the least resistance.

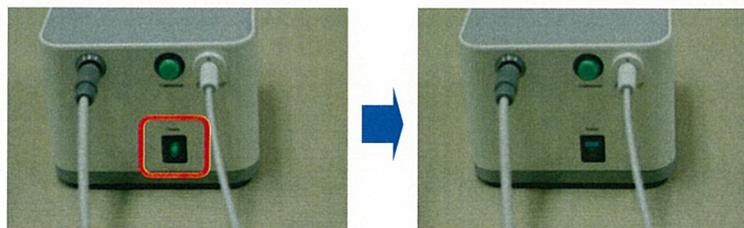
- !** **CAUTION** DO NOT remove the probe from the nasal cavity, as this may result in pain or bleeding.
- !** **CAUTION** When completed with the diagnosis and have saved all captured images, turn off the mobile PC and the processor.

3.8 Disassembling and Cleaning Up

3.8.1 Turn Compressor Off



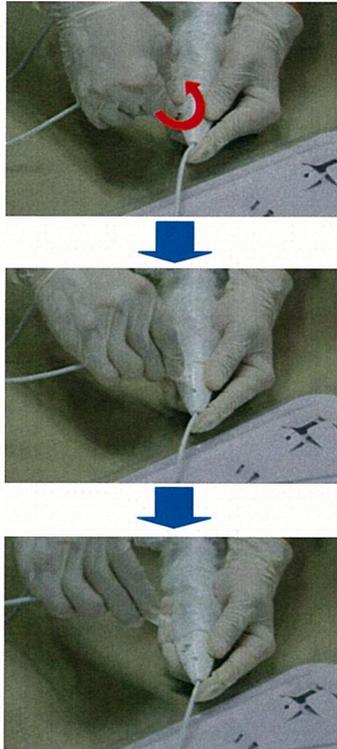
3.8.2 Turn Processor Off



- !** **CAUTION** When videos are being recorded, the recording icon on the Review screen will flash. DO NOT power off the device while the icon is flashing.

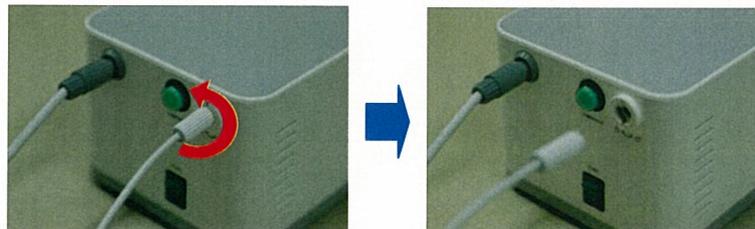
3.8.3 Disconnect Air Channel

- Grasp the air channel connector firmly, turn it and disconnect it from the probe connector.



! **CAUTION** Be sure to turn the air channel connector completely, to avoid damaging from the probe when disconnecting it.

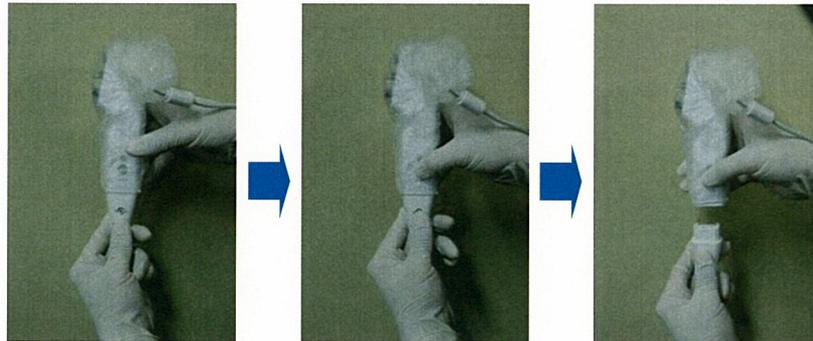
- Grasp the air channel connector firmly, turn it and disconnect it from the processor.



! **CAUTION** Be sure to turn the air channel connector completely, to avoid damaging from the processor when disconnecting it.

3.8.4 Disconnect Probe

- Grasp the probe connector firmly, press the 'UNLOCK' button on the controller, and disconnect the connector from the controller.



- ! **CAUTION** Be sure to press the 'UNLOCK' button completely, to avoid damaging the controller when disconnecting it.

3.8.5 Discard Medical Wastes

- Remove the vinyl covering of the controller from the controller and then discard the vinyl covering of the controller.



- ! **CAUTION** Do NOT touch used vinyl covering with bare hands to prevent cross-contamination.

- ! **CAUTION** The vinyl covering is designed for one-time use and cannot be sterilized or reused.

- Discard the probe as medical waste.



! **CAUTION** Do NOT touch the probe with bare hands to prevent cross-contamination.

! **CAUTION** The probe is designed for one-time use and cannot be sterilized or reused.

- Take off the gloves and then discard the gloves.

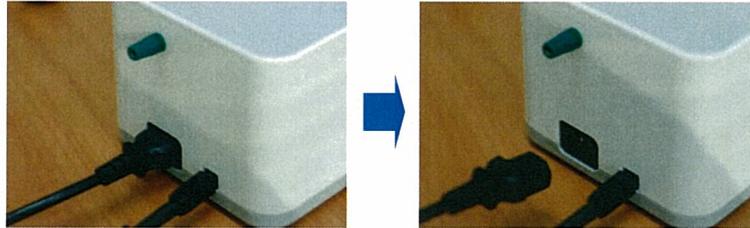


! **CAUTION** Do NOT touch the outer face of used gloves with bare hands to prevent cross-contamination.

! **CAUTION** The glove is designed for single use only and cannot be sterilized or reused.

3.8.6 Disconnect Power Cord

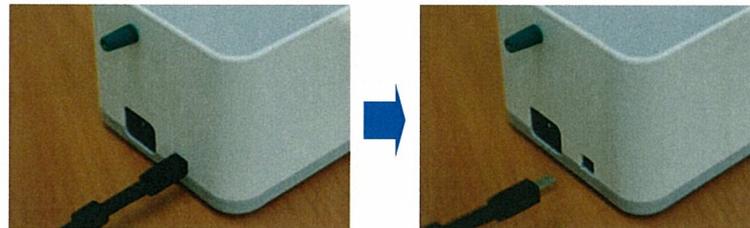
- Disconnect the AC power cord from processor.



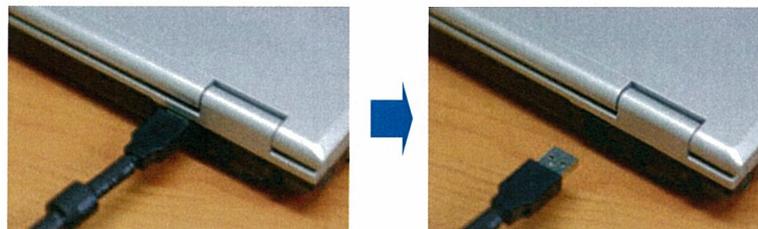
! **CAUTION** DO NOT twist the AC power cord to protect from mechanical damages.

3.8.7 Disconnect USB cable

- Disconnect the USB cable from the processor.



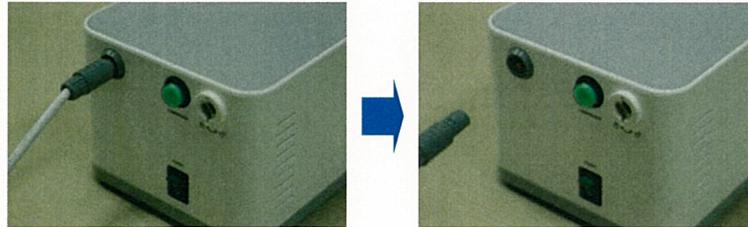
- Disconnect the USB connector from the mobile PC.



! **CAUTION** DO NOT twist the USB cable to protect from mechanical damages.

3.8.8 Disconnect Controller

- Grasp the probe connector firmly, press the release button on the controller, and disconnect the connector from the controller.



! **CAUTION** DO NOT twist the Controller to protect from mechanical damages.

- Clean E.G.Scan™ II

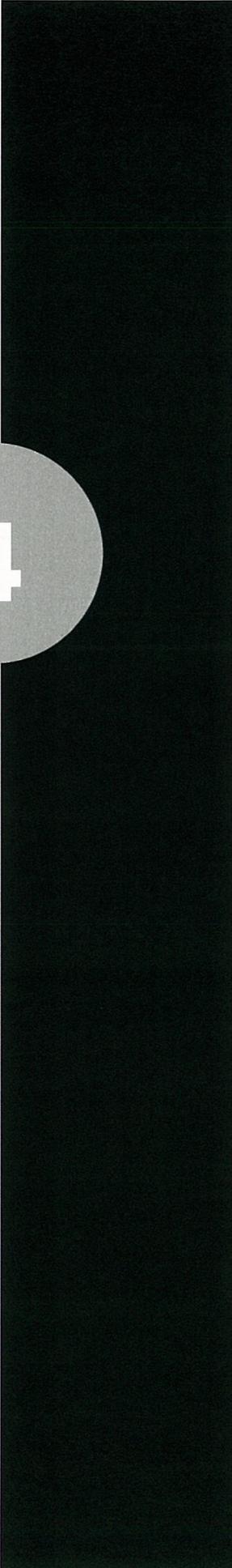
To clean the controller and the processor, dampen a soft cloth with warm water or a non-abrasive cleaner (such as a mild soap solution) and lightly wipe the exterior surface. Do not allow any liquids to come in contact with the power cord connector, or switches. Do not allow any liquids to penetrate connectors or openings in the system cover. Clean the system at least once a week.

! **CAUTION** DO NOT immerse the E.G. Scan™ II system or components in liquid or clean with caustic or abrasive cleaners.

! **CAUTION** DO NOT spray or pour any liquid on the system or components.

! **CAUTION** DO NOT use organic solvents, such as lacquers, thinners, ethylenes, and oxides.

! **CAUTION** DO NOT use abrasive cleaning tools, such as brushes or sandpaper to clean data cables.



4

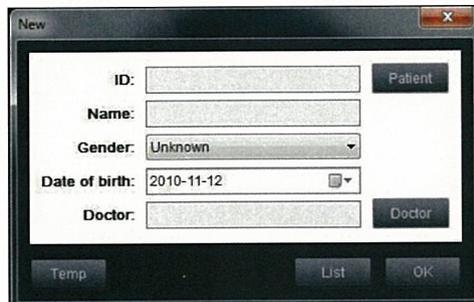
Using E.G. View™

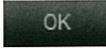
4. USING E.G. View™

E.G. View™ is a software that aids in the diagnosis of diseases of the esophagus by displaying, capturing, and allowing the manipulation and reporting of images obtained with the E.G. Scan™ II probe.

4.1 Start E.G. View™

- Connect the Probe, Controller and Processor to the Commercial PC (refer to 3.3 *Prepare the System*).
- Turn on the commercial PC and run E.G. View™. When started E.G. View™ registration window will appear.



- Click  to select a patient.
- Click  to select a doctor.
- Click  to access E.G. View™.

**CAUTION**

Ensure that the power cord is connected to a properly rated power supply.

4.1.1 E.G. View™ Icons

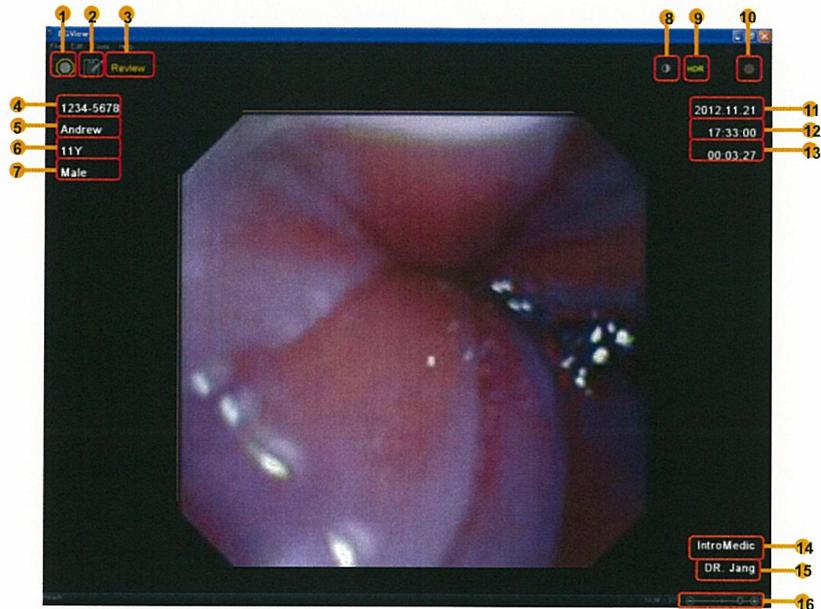
Symbol	Description
	Enter Review Mode
	Enter Report Mode
	Enhance images
	Replace images with High Dynamic Range images
	Record videos
	Input report summary
	Print report
	Preview report
	Save report as PDF file format
	Export captured images and reports
	Export videos
	Add selected captured images to report candidates
	Remove selected captured images from report candidates

4.1.2 E.G. View™ Menus

File Menu	
New	Create a new case
Open	Open a case
Save	Save a case
Close	Close
Edit Menu	
Undo	Undo the previous action
Redo	Redo the previous action
Copy	Copy
Delete	Delete
Complete	Mark the case complete (disables Undo, Redo, Copy, and Delete commands)
Tools Menu	
Patient Manager...	Manage the patient account
Doctor Manager...	Manage the doctor account
Preference...	Set a file path for saved images and enter hospital information
Help Menu	
About E.G. View...	View program version and IntroMedic contact information

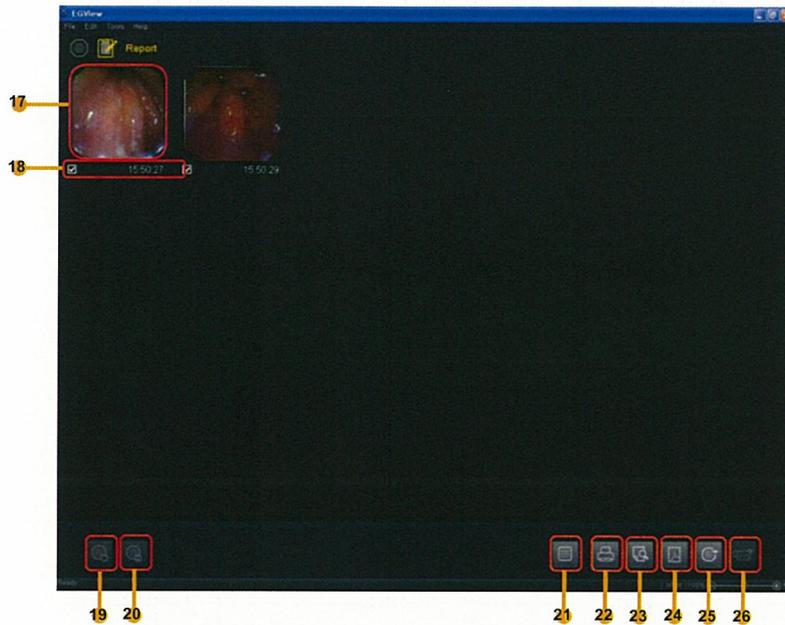
4.1.3 E.G. View™ Screen Layout

■ Review Mode



Item	Description
1.	Review Enter Review Mode
2.	Report Enter Report Mode
3.	Current Mode Shows current operating mode
4.	Patient ID Patient's identification number
5.	Patient Name Patient's name
6.	Patient Age Patient's age
7.	Patient Gender Patient's gender
8.	Image Enhancement Adjust image quality
9.	HDR High Dynamic Range image
10.	Record Record videos
11.	Date Current date
12.	Time Current time
13.	Elapsed Time Elapsed time of the endoscopy procedure
14.	Hospital/Clinic Name Name of hospital or clinic
15.	Doctor Name Doctor's name
16.	Magnification Control image magnification

■ Report Mode



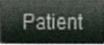
Item		Description
17.	Image Preview	Thumbnail of captured image
18.	Selected/Time	A check in the box denotes an image selected for the report. The capture time (during the endoscopy procedure) of the image is shown on the right.
19.	Add Selected	Add selected captured images to a report
20.	Remove Selected	Remove selected captured images from a report
21.	Save Report Summary	Input and save Report Summary
22.	Print	Print the report
23.	Preview	Preview the report
24.	Save as PDF	Save the report as a PDF file
25.	Export	Export captured images
26.	Save Video	Save video

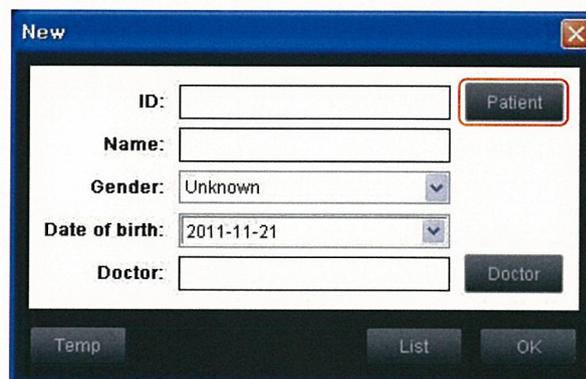
4.1.4 Basic Procedure

- Turn on the commercial PC.
- Run the E.G. View™.
- Enter the Review Mode. If the Probe & Controller are connected to the Display System properly, the Image from inside of human body will appear on the main image display area.
- Press 'FREEZE' and 'CAPTURE' button of controller for capturing current image.
- Click the  icon to enter the Report Mode.
- Add/Remove the captured image to/from Report candidate images and compose the report.
- Print out the report; Export the captured images / report; Save the report as PDF; save video.
- Turn off the commercial PC.

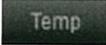
4.2 Diagnose with E.G. View™

4.2.1 Sequence of Operation

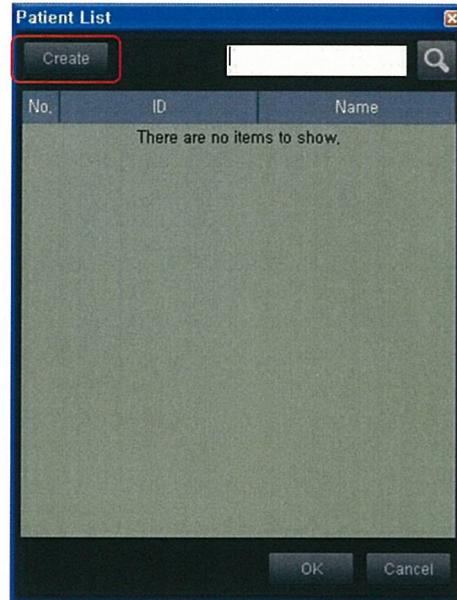
- Turn on the commercial PC.
- Run the E.G. View™.
- Connect the Probe to the Controller.
- Connect the Controller to the Processor
- Connect the Processor to the commercial PC with the USB cable.
- Turn on the Processor
- The registration window will appear if it starts at first time.
- Click  .



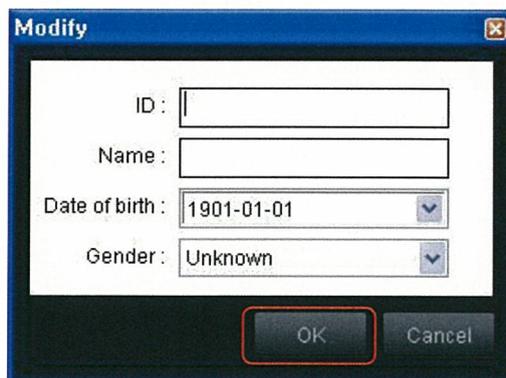
 **NOTE**

From the Registration window, user can click  to enter the temporary review. This mode allows for a quick verification that device is working, but does not allow to save images.

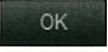
- When Patient List appears, click **Create** to start a new patient account.

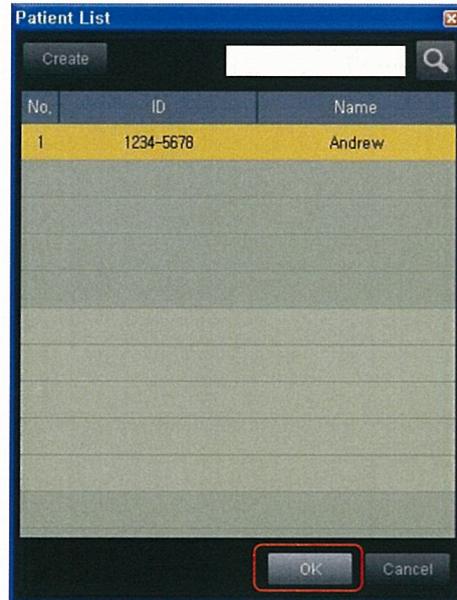


- Enter the patient's ID number and name, and then click **OK** to return to the Patient List.

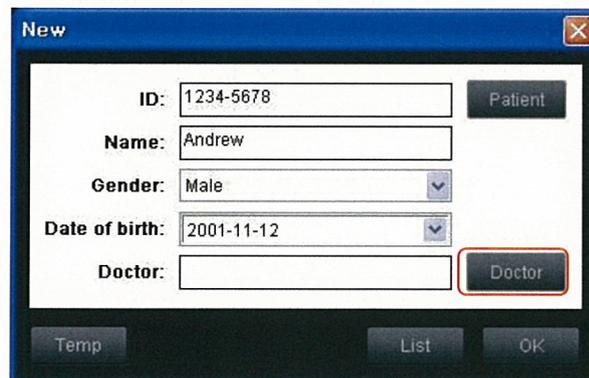


- Patient List will appear again. Select the patient and then

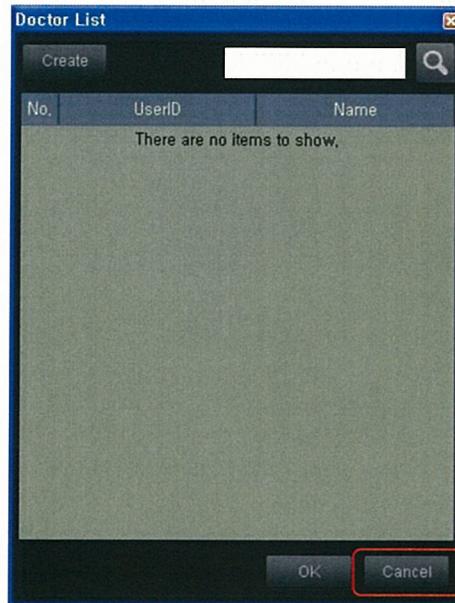
click .



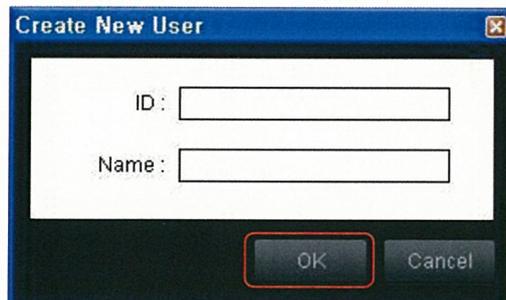
- Click  on New Dialog.

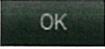


- Click **Create** to make a new doctor account.

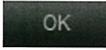


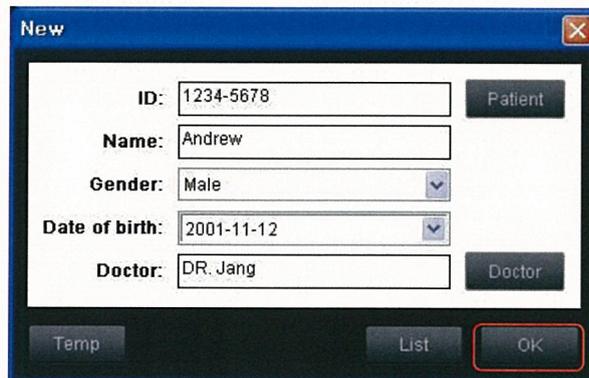
- Enter the doctor's ID number and Name, and then click **OK** to return to the Doctor List.



- Doctor List will appear again. Select the doctor and click .

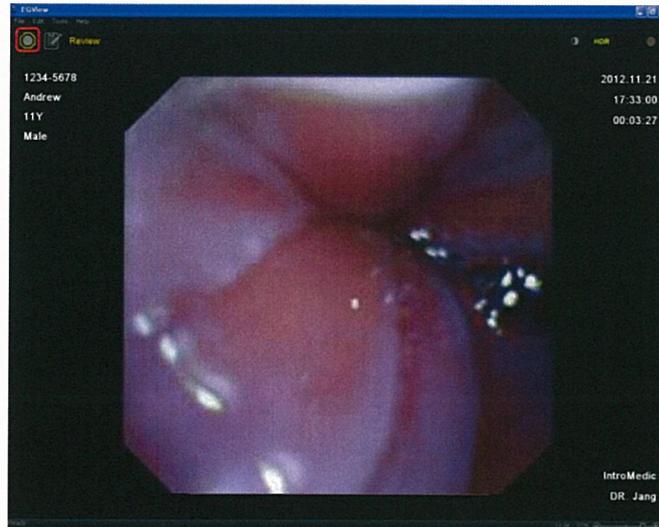


- Registration is complete and click .



4.2.2 Capture E.G. Scan™ II Images

- Click  to enter the Review Mode.

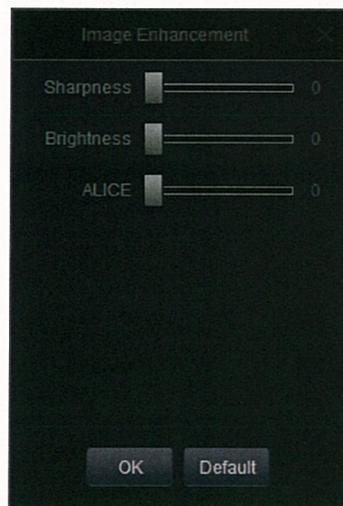
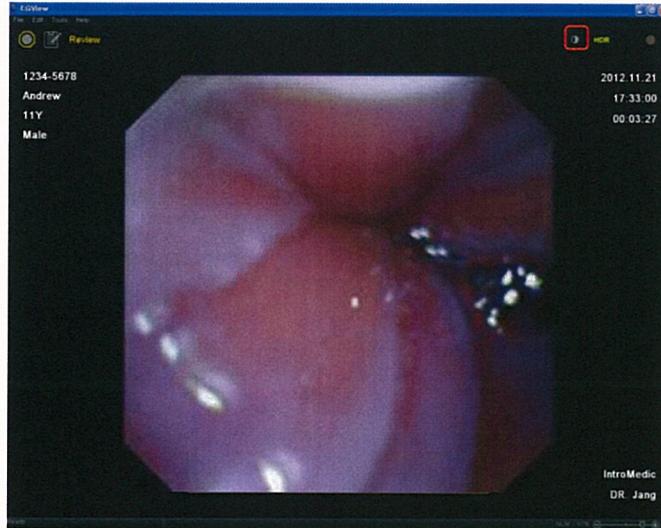


- On the controller, push the lever upward or downward to manipulate the probe. (Refer to *Chapter 3.6.1, Control the End of the Probe.*)
- On the controller, press  (the middle button) to freeze an image or  (the top button) to capture a frozen image. (Refer to *3.6.2 Capture Images and 3.6.3 Freeze Images.*)

 **NOTE** An image can be captured without freezing it.

 **NOTE** An image can be captured by double clicking on the screen.

- Click  at the top-right of the screen to enhance the images. You can adjust levels for sharpness, brightness, and ALICE.



- When you are finished capturing images, click  to enter the Report Mode.

 **NOTE** ALICE is IntroMedic's unique image processing technique based on narrow band image processing.

- Click icon below at the bottom-right on the screen to change size of images.



Enlarge size of images



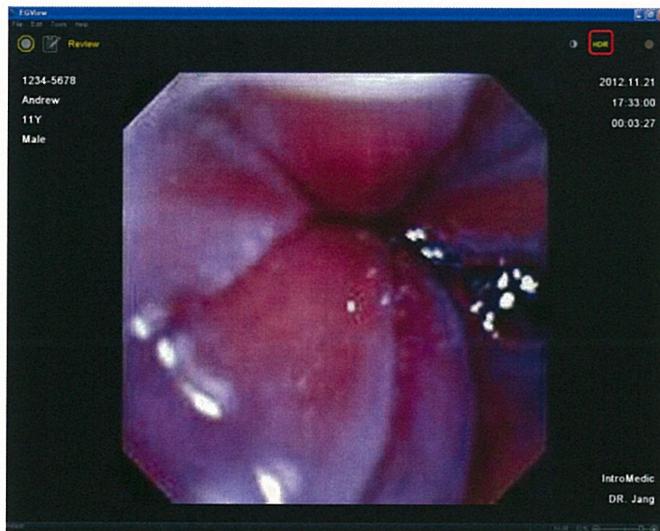
Reduce size of images



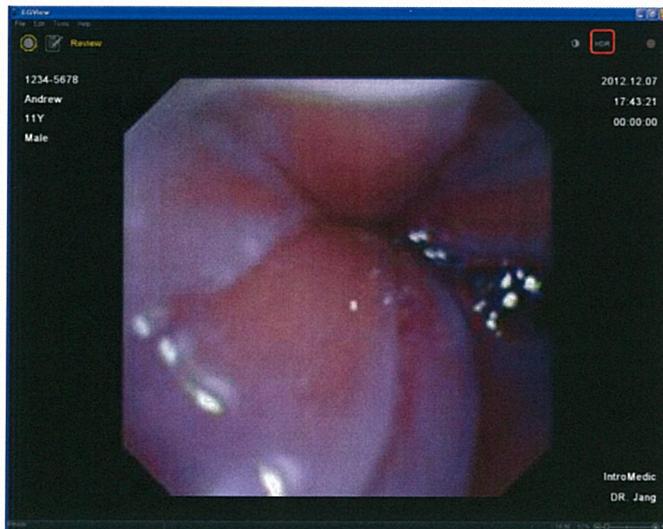
Go back to default size of images

4.2.3 Apply High Dynamic Range Image

- HDR is automatically applied when E.G. View™ run.
- Press  to stop HDR.



- Press  to apply HDR.



4.2.4 Record E.G. Scan™ II Videos

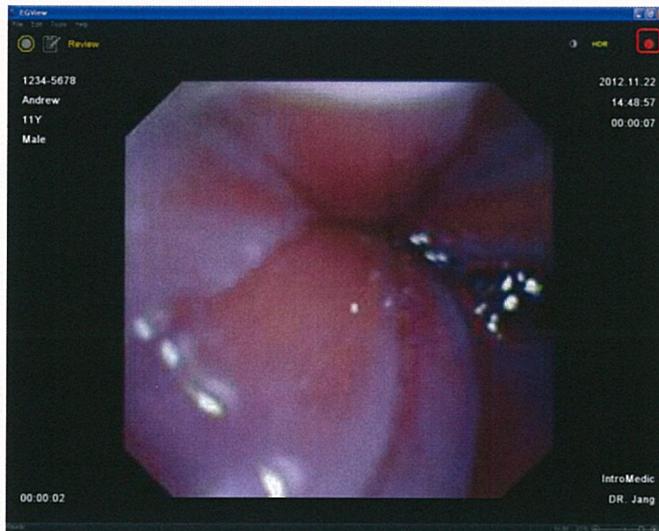
- Click  to enter the Review Mode.
- Click  at the top-right of the screen to begin video recording.

When the video recording is started,  will turn into bright red and a timer will appear at the bottom-left of that.



On the controller, push the lever upward or downward to manipulate the probe. (Refer to *Chapter 3.6.1, Control the End of the Probe.*)

- Press  to stop recording.



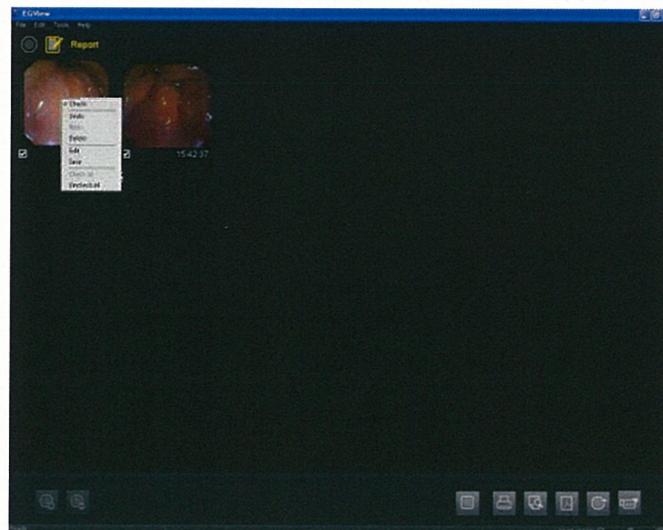
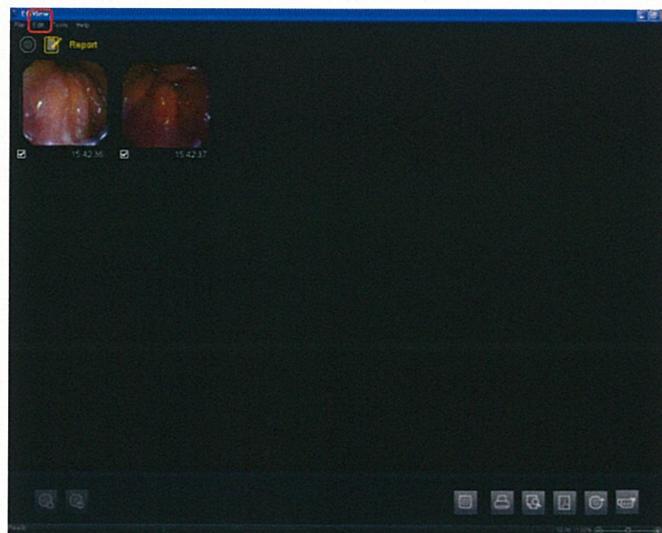
- When you are finished recording the endoscopy procedure, click

 to enter the Report Mode.

NOTE Videos will be saved in the EGScan \ MyVideos folder on the computer's hard drive. To view the videos, locate the destination folder and open them with Windows Media Player or another video playback utility. To change the destination folder, refer to *4.3.1 Manage Cases*.

4.2.5 Review and Comment on E.G. Scan™ II Images

- Right-click on an image and then click **'Edit'** to open the editing and commenting window.

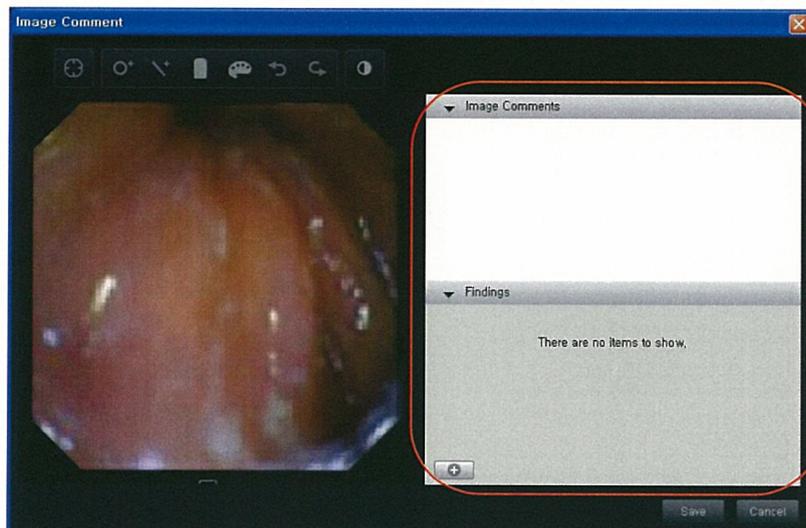


NOTE

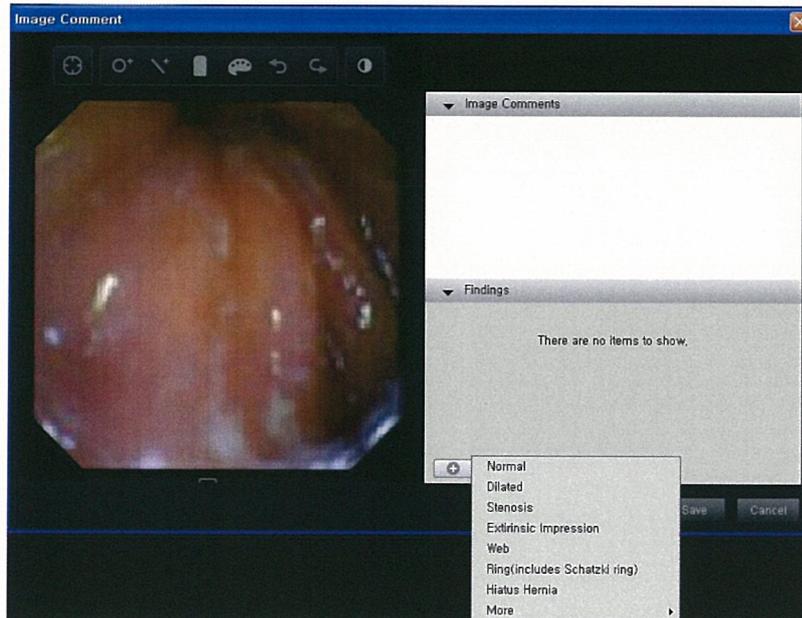
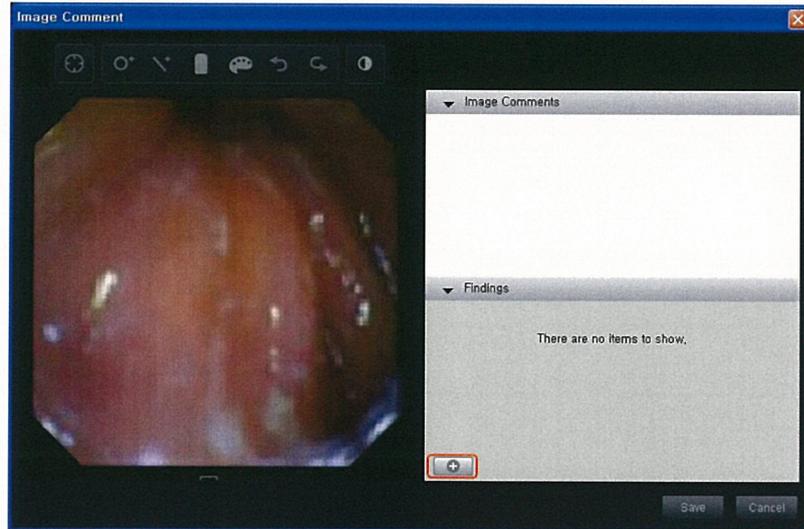
When you right-click images, the following menu commands are available:

- Check – add the selected image to the report.
- Undo – undo the previous action
- Redo – redo the previous action
- Delete – delete the selected image
- Edit – open the editing and commenting window
- Save – save the selected image
- Check all – add all selected images to the report
- Uncheck all – remove all selected images from the report

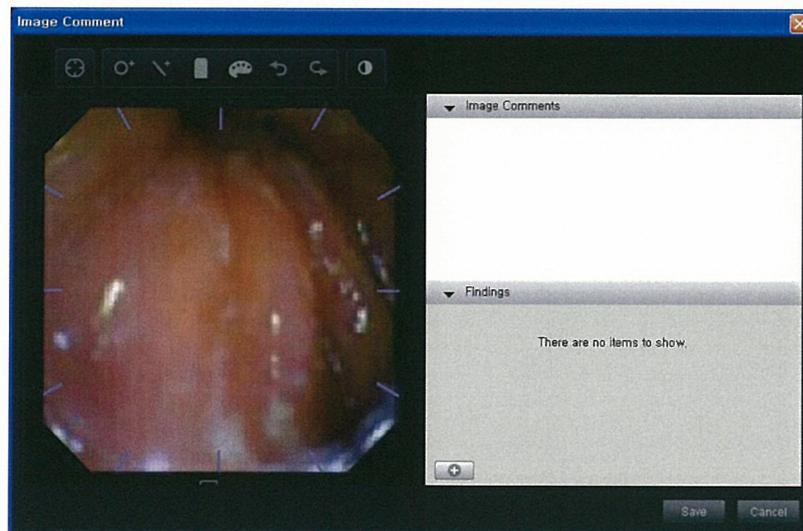
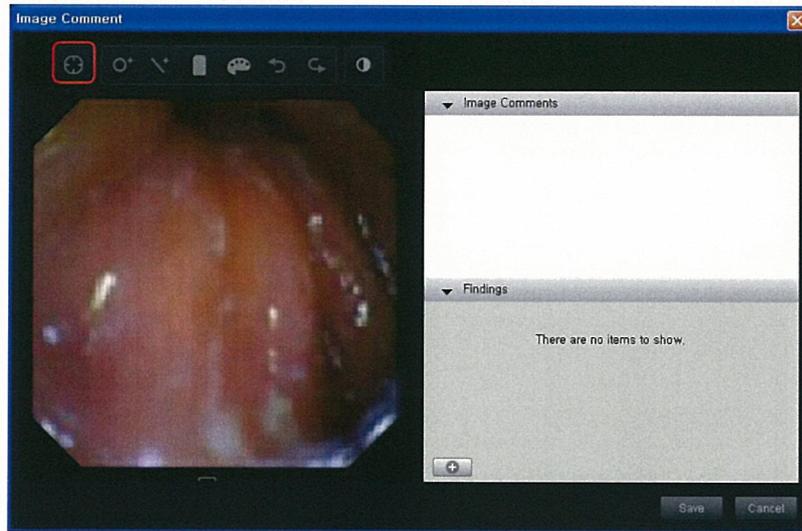
- In the Comments field, enter comments or notes.



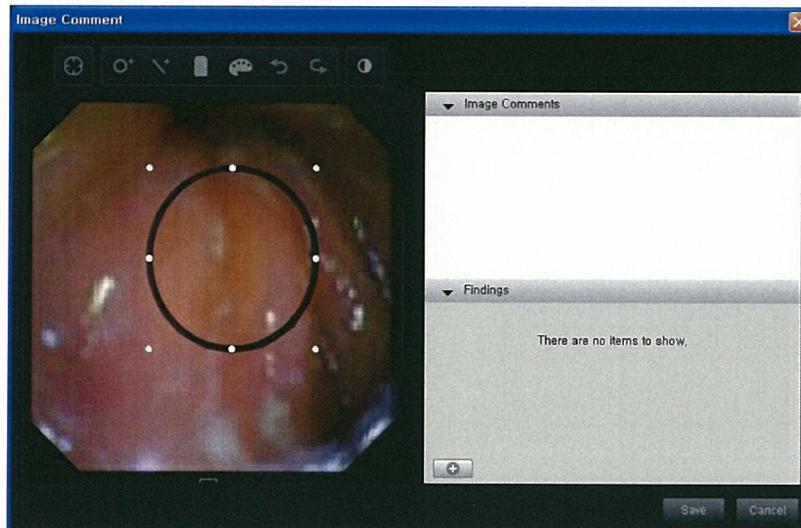
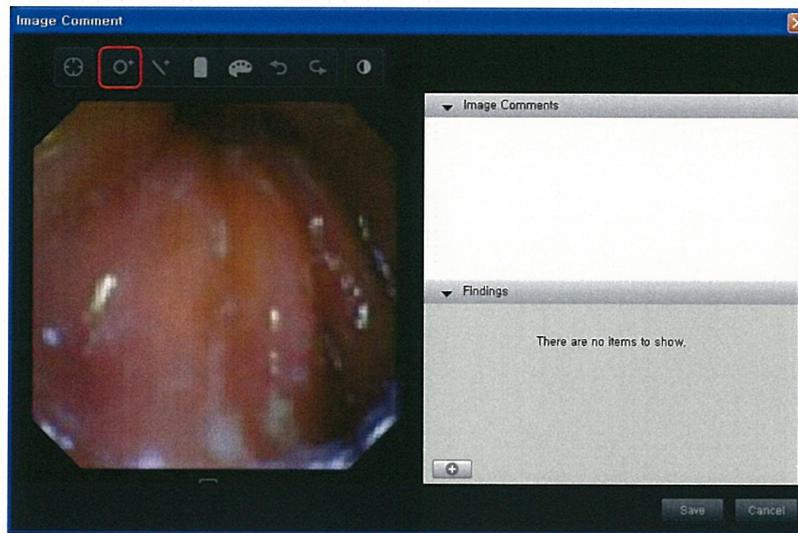
- In the Findings field, click the cross icon () to select findings from the pop-up list.



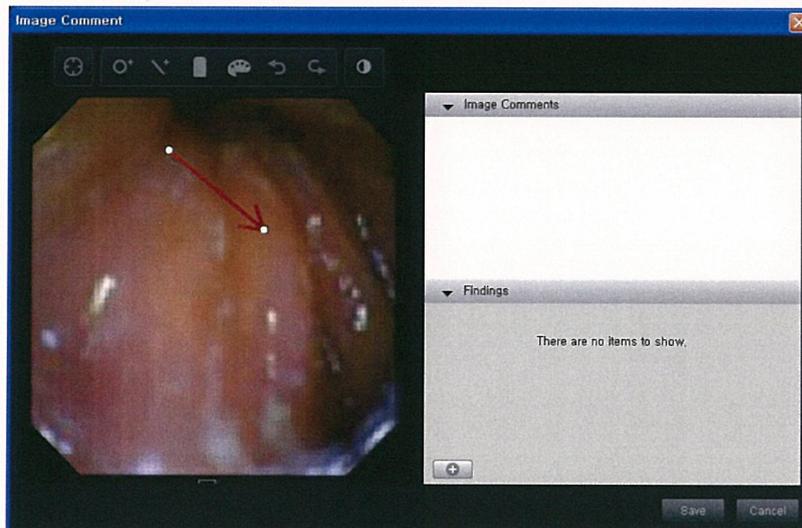
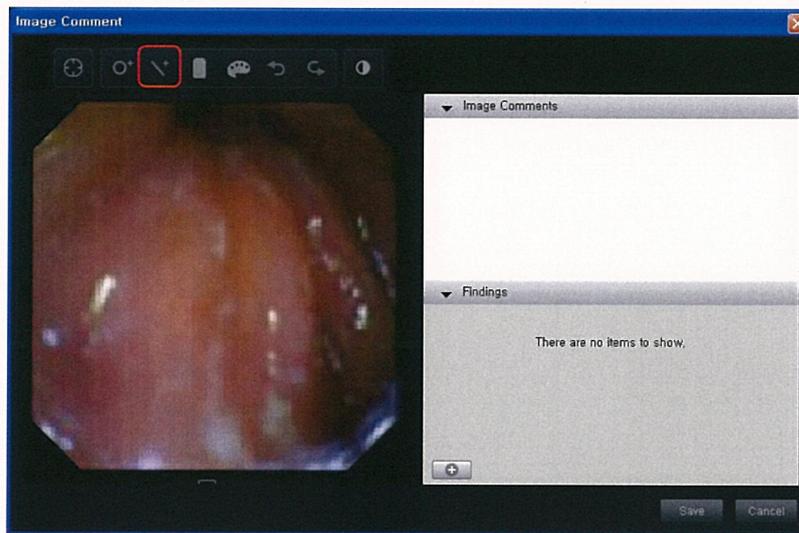
- To add circumference marks, click  and then drag the marks as needed.



- To add a circle, click  and then drag the mouse as needed to create the mark. After creating the mark, you can reposition or resize the mark as needed.



- To add an arrow, click  and then drag the mouse as needed to create the mark. After creating the mark, you can reposition or resize the mark as needed.



- While reviewing and commenting on images, use the following functions to manipulate the image or markings:

Icon	Description
	Show circumference marks
	Add a circle
	Add an arrow
	Erase a mark
	Choose a color for marks
	Undo the previous action
	Redo the previous action
	Enhance images

**NOTE**

To add or remove images, click an image and then click  (add) or  (remove) at the bottom-left of the screen of Report Mode.

- Click '**File \ Save**' to save the case. Captured images, comments, and findings will be saved with the patient and doctor information.

4.3 Manage and Report Cases

4.3.1 Manage Cases

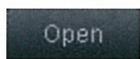
Saved cases contain patient and doctor information, captured images, comments, and findings. From the case list, open a case, delete a case, add or delete reviews for an existing case, and change the destination folder for saved videos.

With all cases closed, click **'File \ Open'** to open the case list.

No.	Procedure date	Name	ID	Doctor in charge	Video
2	Tuesday, November 22, 2011	Andrew	1234-5678	DR. KIM	
1	Tuesday, November 22, 2011	Andrew	1234-5678	DR. Jang	

- To open a case, double-click the case or click the case and then

click



- To delete a case, click a case, and then click



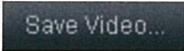
- To delete a review, click a case, and then click

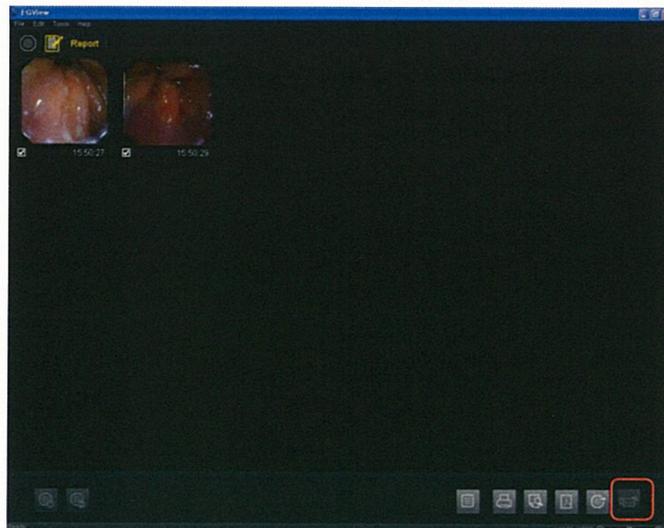


- To add a new review, click a case, and then click

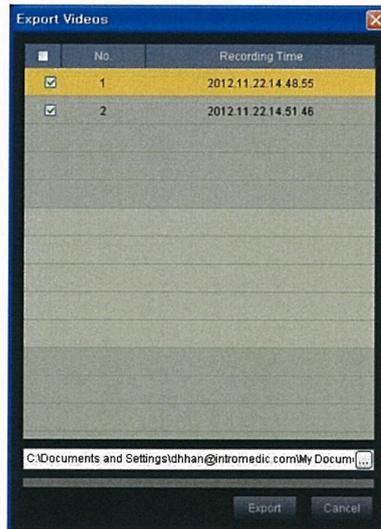


- To sort cases, click the drop-down menu, and then click a sort option ('Doctor Name,' 'Patient ID,' or 'Patient Name').

- To search for cases, enter some data in the search field (for example, part of the patient's name, patient's ID, or doctor's name), and then click .
- To show all cases, click .
- To change the location of video recordings:
 - 1) Method 1
 - I. From the case list, click a case that includes video recordings, and then click  at the bottom-left of the screen.
 - II. Select a new location for the videos and the videos will be relocated to the new **folder**.
 - 2) Method 2
 - I. In the Report Mode, click  at bottom-right of the screen if current case include video recordings.



II. Select video recordings.

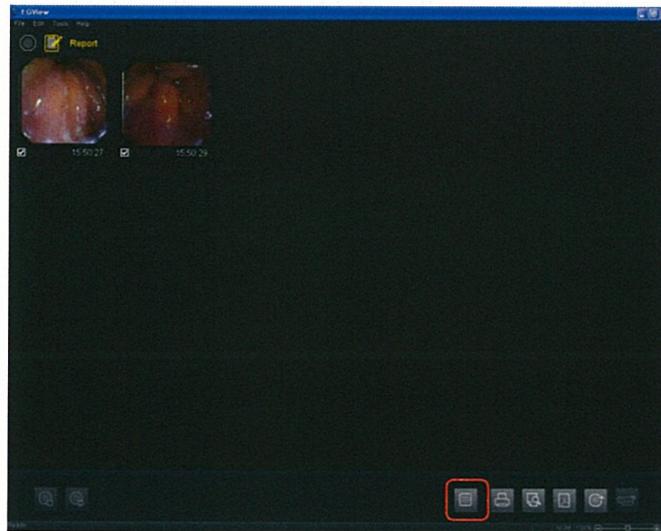


III. Select a new location for the videos after click .

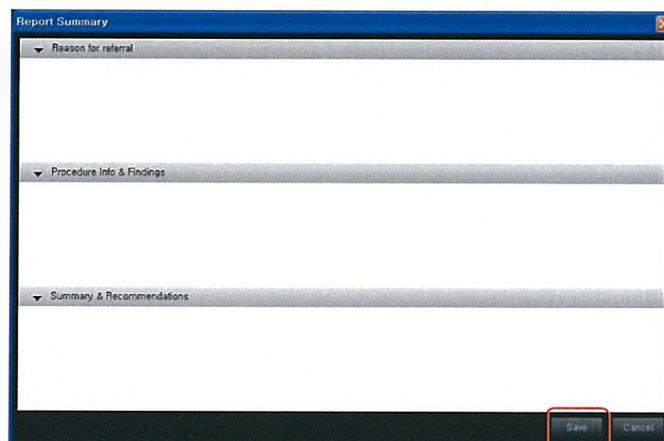
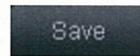
IV. Click  and the videos will be relocated to the new **folder**.

4.3.2 Print and Export Case Reports

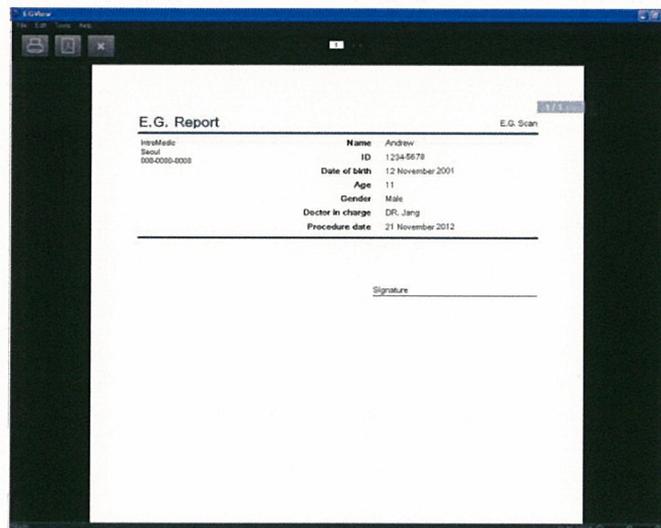
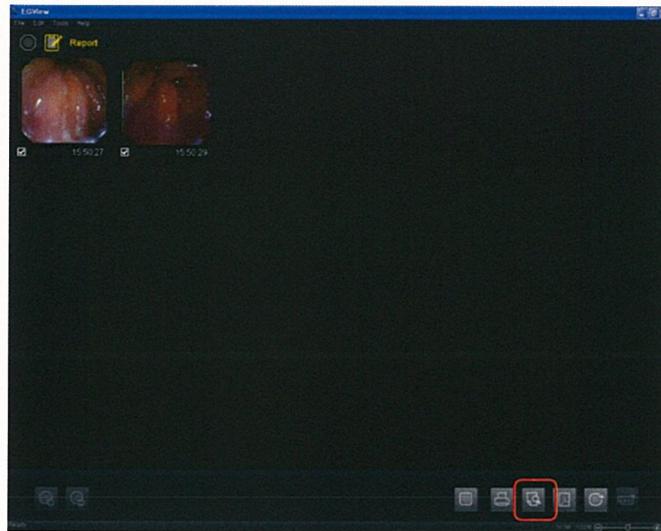
- In the Report Mode, click  to enter the report summary for the image.



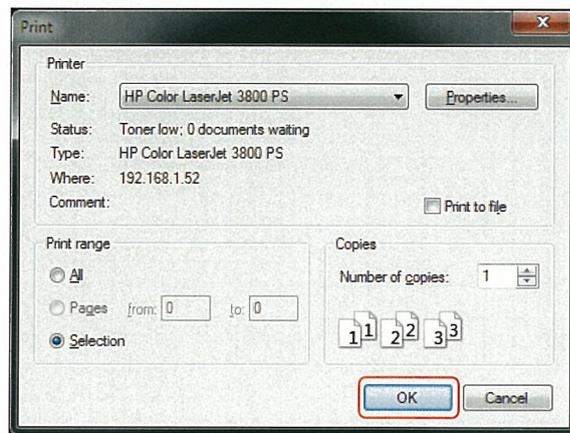
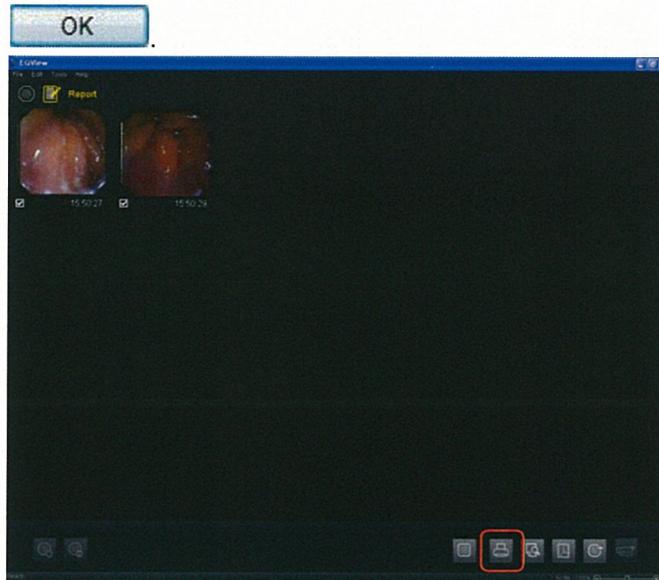
- In the Comments field, enter comments or notes and



- Click  to preview the report. The report will include captured images, comments, and findings.

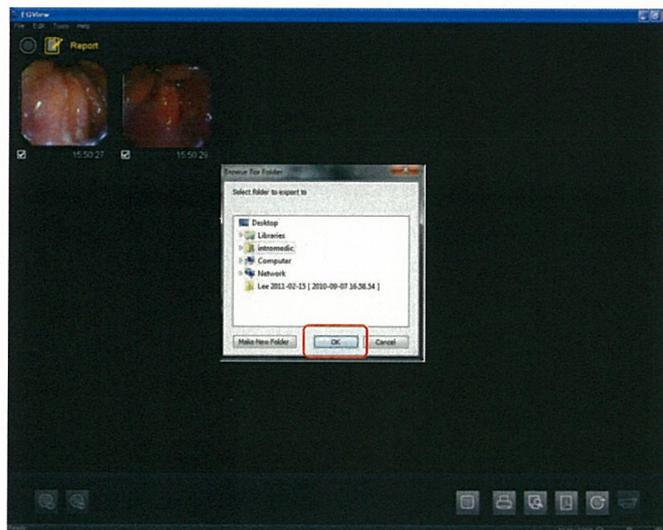
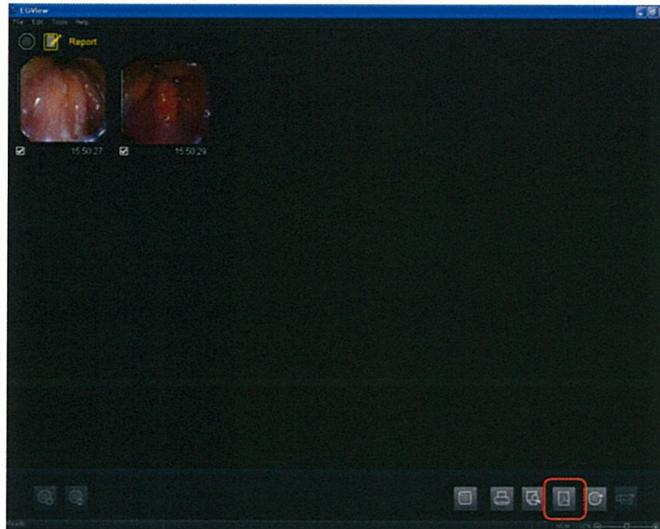


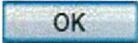
- To print the report, click , select a printer, and then click

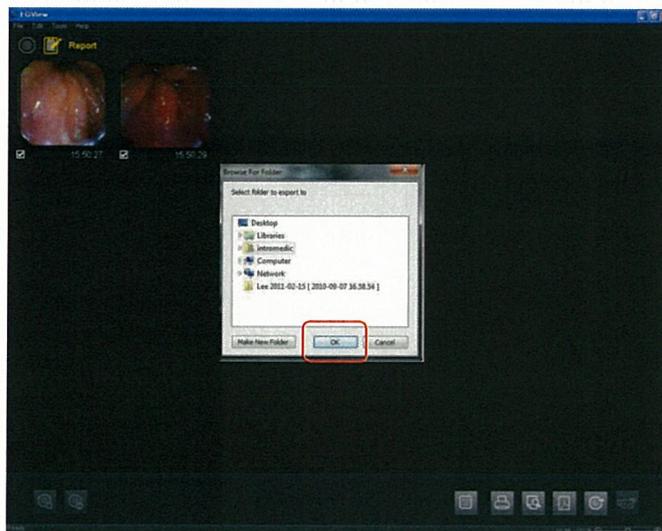
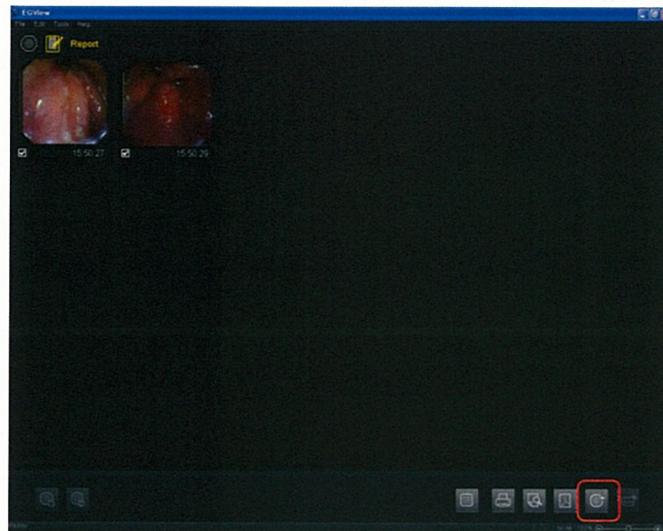


 **NOTE** If no printer is connected, the print function will be disabled. To set up a new printer, contact your network administrator.

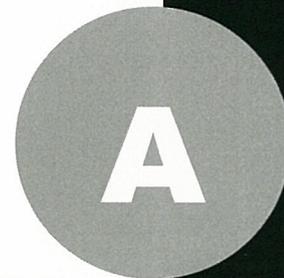
- To save the report as a PDF file, click , select new location for the PDF file, and then click .



- To export captured images, click , select new location for the images, and then click .



Appendix



Case Form Report

A- 2



Case Form Report

Trial ID :

Version No. : 1.0 : 07/01/2011

CASE REPORT FORM

Subject No.:	Subject Initials :	Center No.:
Principal Investigator	:	_____
Center Name	:	_____
Address	:	_____ _____
Telephone No.	:	_____
Fax No.	:	_____
E-mail	:	_____

CONFIDENTIAL

Case Form Report

Trial ID :

Version No. : 1.0 :

07/01/2011

Screening																			
Subject No.:	Subject Initials :	Center No.:																	
Date of Informed consent signed	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> </tr> <tr> <td style="text-align: center;">D</td> <td style="text-align: center;">M</td> <td style="text-align: center;">M</td> <td style="text-align: center;">Y</td> </tr> </table>									D	M	M	Y	Y	Y	Y	Y		
D	M	M	Y	Y	Y	Y	Y												
Inclusion Criteria																			
	Yes	No	N/A																
1. difficulty in swallowing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																
2. mouth and throat pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																
3. broken temporomandibular joint	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																
4. narrowing of the throat (strictures)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																
5. written informed consent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																
If there is one or more mark of 'No', you shall be contradicted for this clinical test.																			

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Case Form Report

Trial ID :

Version No. : 1.0 : 07/01/2011

Screening																			
Subject No.:	Subject Initials :	Center No.:																	
Date of visit :	<table border="1" style="margin: auto; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> </tr> <tr> <td style="text-align: center;">D</td> <td style="text-align: center;">M</td> <td style="text-align: center;">M</td> <td style="text-align: center;">Y</td> </tr> </table>											D	M	M	Y	Y	Y	Y	Y
D	M	M	Y	Y	Y	Y	Y												
Exclusion Criteria																			
	Yes	No	N/A																
1. history of broken nose or disease of the nasal cavity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																
2. Severe back ground disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																
3. State after gastric surgery	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																
4. COPD, CHF, CRF and any disease with respiratory disturbances.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																
5. Deviation of the nasal septum	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																
If there is one or more mark of 'Yes', you shall be contradicted for this clinical test.																			

CONFIDENTIAL

Case Form Report

A- 6





IntroMedic Co.,Ltd.

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Fax : +82-2-801-9330

<http://www.intromedic.com>

e-mail : helpdesk@intromedic.com





Address : Suite 1104, E&C Venture Dream Tower 6-Cha, 197-28 Guro-Dong, Guro-Gu, Seoul, Korea 152-719
Tel : +82-2-801-9300 Fax : +82-2-801-9330 e-mail : marketing@intromedic.com www.intromedic.com



EC REP

Soda S.p.A
20090 Trezzano s/Naviglio (MI), Via Tolstoi, 7 Italia

0 1 2 0

CAUTION : Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

510(k) Submission – E.G. Scan™ II Esophagoscope System

Section 13_Biocompatibility evaluation

Contact Material

The probe is intended to be in contact with internal organ of the nose and esophagus for a moment and thus this device is fall under Category A, according to ISO 10993-1.

1. Patient Contact

Item Part	Probe
Material	(b)(4)
Contact time	Less than 30 minute
Contact duration	one time
Contact site	Esophagus
Biocompatibility test and Aqueous extract test	<ol style="list-style-type: none"> 1. Cytotoxicity test (MEM Elution Test) Under the conditions of ISO 10993-5, Test for Cytotoxicity: In vitro method, the equipments should meet the test requirements. (Sample Preparation: 37°C for 24hours with MEM) 2. Maximization Sensitization Test Under the conditions of ISO 10993-10:[2010], 7.5 Guinea pig maximization test (GPMT), the test articles should meet the test requirements. 3. Intracutaneous Reactivity Test Under the conditions of ISO 10993-10:[2010], 6.4 Animal intracutaneous (intradermal) reactivity test, the test articles should meet the test requirements. 4. Aqueous extract test <ol style="list-style-type: none"> 4.1 Color and transparent The extract should yield clear and colorless preparations under specified test conditions. 4.2 pH The difference between the pH of the blank and that of extract, determined potentiometrically, is the pH change. The difference between the amounts obtained from the sample and blank should not exceed 1.5. 4.3 Heavy Metals as Lead The content of heavy metals is determined by color comparison with a 2 ppm lead standard. The color is measured after pH adjustment and the reaction with the

IntroMedic Co., Ltd.

510(k) Submission – E.G. Scan™ II Esophagoscope System

	<p>sulfide ion. The final sample color should not be darker than the lead standard.</p> <p>4.4 KMnO4 Consumption The KMnO4 consumption of a 10ml aliquot of the extract is determined by consumption in comparison with a distilled water. The difference of KMnO4 consumption between the amounts obtained from the sample and blank should not exceed 2ml.</p> <p>4.5 Non-Volatile Residue A 10ml aliquot of the extract is evaporated to dryness in the water bath and then dried for 1hr at 105°C. The residue weight is determined. The difference between the amounts obtained from the sample and blank should not exceed 1mg.</p> <p>4.6 Ultraviolet Absorption The extract and a reference solution are examined spectrophotometrically over the spectral range from 250nm~350nm. The maximum absorbance of extract should not exceed 0.1.</p>
Biocompatibility Test Report	KTL11-1712-80

2. User Contact

Item \ Part	Plastic (Controller)	Plastic (Processor)
Material	AF-312 (Flame Retardant ABS)	AF-312 (Flame Retardant ABS)
Contact time	Less than 30 minute	Less than 30 minute
Contact site	Skin	Skin
Manufacturer	LG Chem	LG Chem

3. Biocompatibility Requirement

In compliance with EN/ISO10993-1 Category A, IntroMedic Esophagoscope must be tested with ISO 10993-5[2002], ISO 10993-10[2002].

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(b)(4)



2011.06.23

Page 1 of 29

COPY

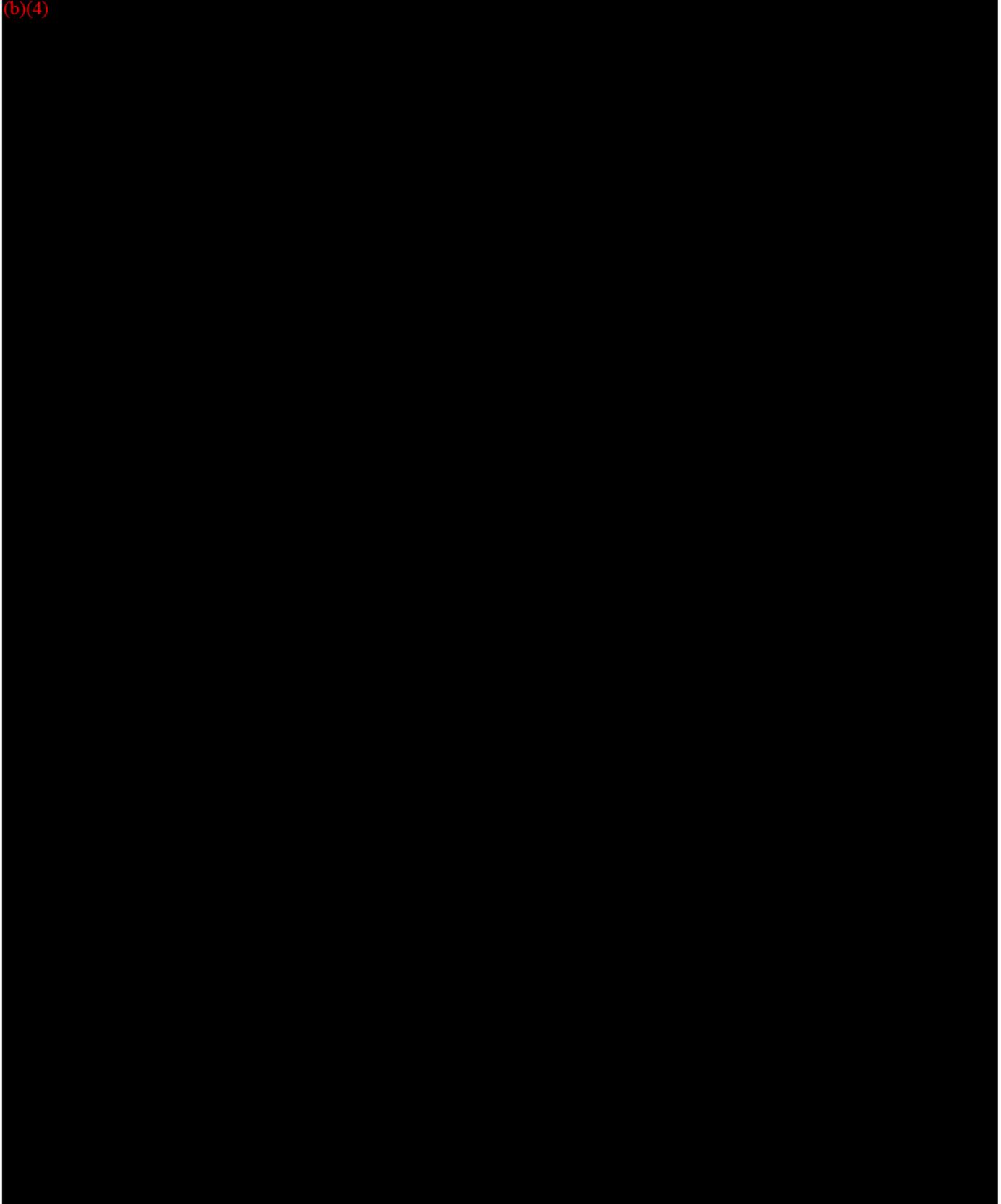
TEST REPORT

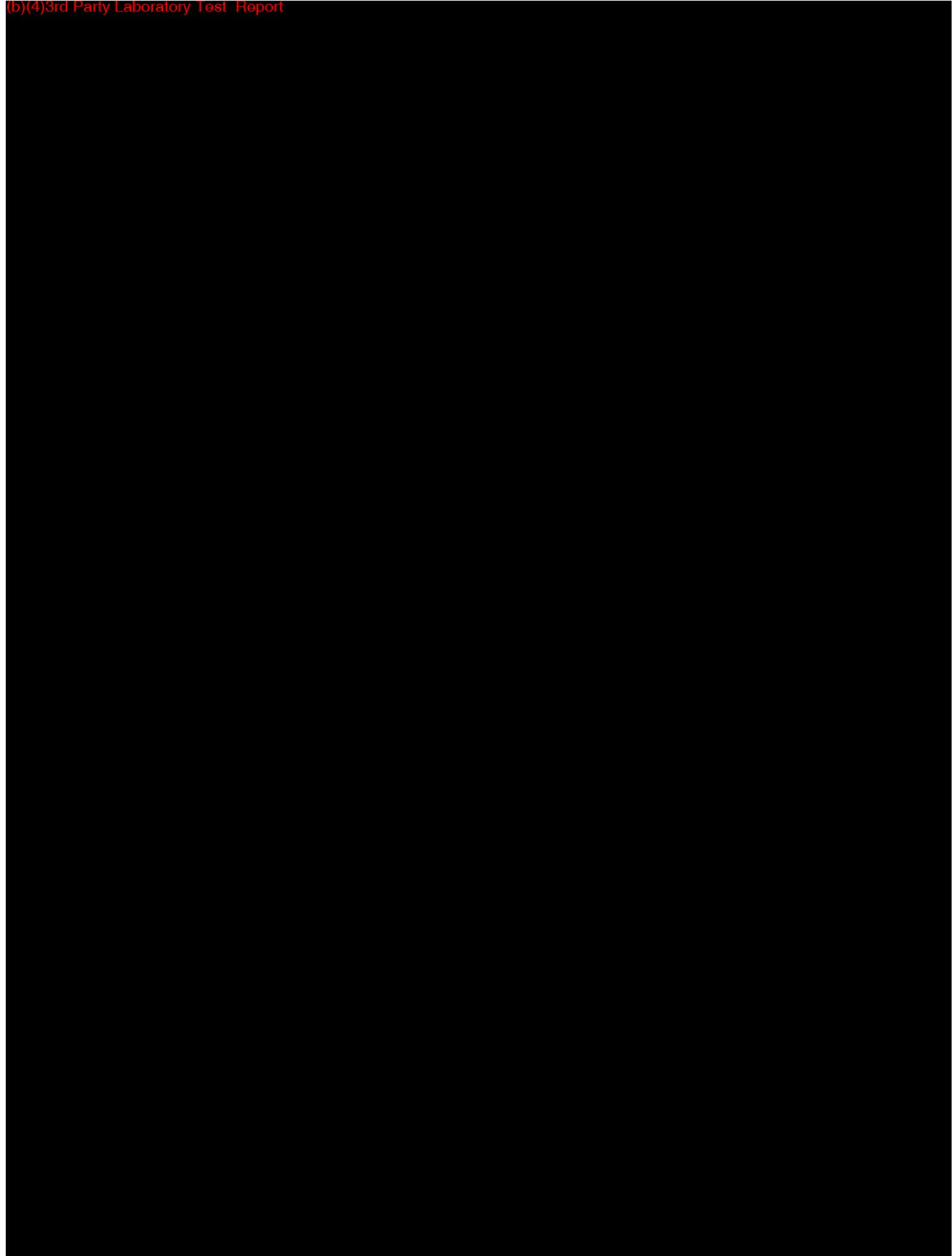
Report ref. No.

(b)(4)



(b)(4)





E.G. Scan™ Esophagoscope System Software Validation Report E.G. View™

Report No. : (b)(4)

IntroMedic. Co., Ltd.

<p>FE-3 Export Report FE-4 Save the report as PDF</p>	<p>4 2 Layer Diagram</p>	<p>5.7.1.2.2.4 ILBase.dll 5.7.1.2.2.5 ILCodec.dll 5.7.1.2.2.6 ILData.dll 5.7.1.2.2.7 ILFrameWork.dll 5.7.1.2.2.8 ILGraphic.dll 5.7.1.2.2.9 ILIP.dll 5.7.1.2.2.10 ILMath.dll 5.7.1.2.2.11 ILReport.dll 5.7.1.2.2.12 ILSystem.dll 5.7.1.2.2.13 ILUI.dll 5.7.1.2.2.14 ILUIBase.dll 5.7.1.2.3.2.21 CSLReportEditManager 5.7.1.2.3.2.22 CSLReportImageWnd 5.7.1.2.3.2.24 CSLMReport 5.7.1.2.3.2.42 CSLReportToolDlg</p>	<p>1. Unit Testing 2.1 Unit Test 5.7.1.2.3.2.21 CSLReportEditManager 5.7.1.2.3.2.22 CSLReportImageWnd 5.7.1.2.3.2.24 CSLMReport 5.7.1.2.3.2.42 CSLReportToolDlg 2.2 Module Test Report Module 2.3 Integration Test Report Module Test Criteria Client Report-1~10 CL4-1~CL4-47</p>	<p>N/A</p>
<p>FE-5 Backup</p>	<p>4 2 Layer Diagram</p>	<p>5.7.1.2.2.4 ILBase.dll 5.7.1.2.2.5 ILCodec.dll 5.7.1.2.2.6 ILData.dll 5.7.1.2.2.7 ILFrameWork.dll 5.7.1.2.2.8 ILGraphic.dll 5.7.1.2.2.9 ILIP.dll 5.7.1.2.2.10 ILMath.dll 5.7.1.2.2.11 ILReport.dll 5.7.1.2.2.12 ILSystem.dll 5.7.1.2.2.13 ILUI.dll 5.7.1.2.2.14 ILUIBase.dll 5.7.1.2.3.3.11 CSLMExportMode</p>	<p>1. Unit Testing 2.1 Unit Test 5.7.1.2.3.3.11 CSLMExportMode 2.2 Module Test Review Module 2.3 Integration Test Review Module Test Criteria</p>	<p>N/A</p>
<p>FE-6 ALICE</p>	<p>4 2 Layer Diagram</p>	<p>5.7.1.2.2.4 ILBase.dll 5.7.1.2.2.5 ILCodec.dll 5.7.1.2.2.6 ILData.dll 5.7.1.2.2.7 ILFrameWork.dll 5.7.1.2.2.8 ILGraphic.dll 5.7.1.2.2.9 ILIP.dll 5.7.1.2.2.10 ILMath.dll 5.7.1.2.2.11 ILReport.dll 5.7.1.2.2.12 ILSystem.dll 5.7.1.2.2.13 ILUI.dll 5.7.1.2.2.14 ILUIBase.dll 5.7.1.2.3.4.3 CSLImageWnd 5.7.1.2.3.4.8 CSLReviewImageWndRange 5.7.1.2.3.4.9 CSLReviewImageWndMulti 5.7.1.2.3.4.17 CSLMonitorStatic</p>	<p>1. Unit Testing 2.1 Unit Test 5.7.1.2.3.4.3 CSLImageWnd 5.7.1.2.3.4.8 CSLReviewImageWndRange 5.7.1.2.3.4.9 CSLReviewImageWndMulti 5.7.1.2.3.4.17 CSLMonitorStatic 2.2 Module Test Review Module 2.3 Integration Test Review Module Test Criteria Client Review-17 CL3-84~CL3-85</p>	<p>N/A</p>
<p>FE-7 Account Manager</p>	<p>4 2 Layer Diagram</p>	<p>5.7.1.2.2.4 ILBase.dll 5.7.1.2.2.5 ILCodec.dll 5.7.1.2.2.6 ILData.dll 5.7.1.2.2.7 ILFrameWork.dll 5.7.1.2.2.8 ILGraphic.dll 5.7.1.2.2.9 ILIP.dll 5.7.1.2.2.10 ILMath.dll</p>	<p>1. Unit Testing 2.1 Unit Test 5.7.1.2.3.9.2 CSLUser 2.2 Module Test Receiver Module 2.3 Integration Test</p>	<p>N/A</p>

Software Validation Report for E.G. Scan™ II Esophagoscope System

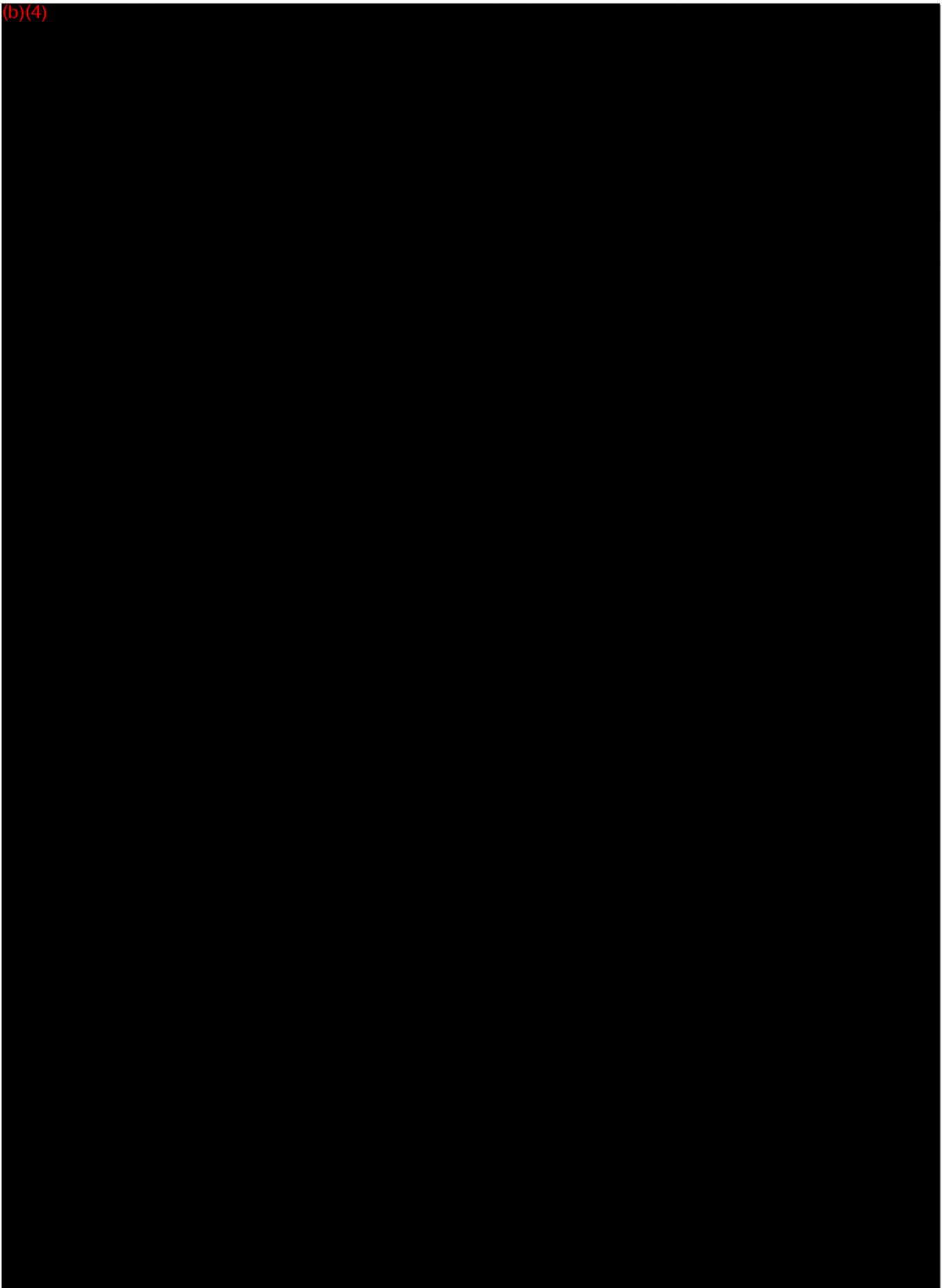
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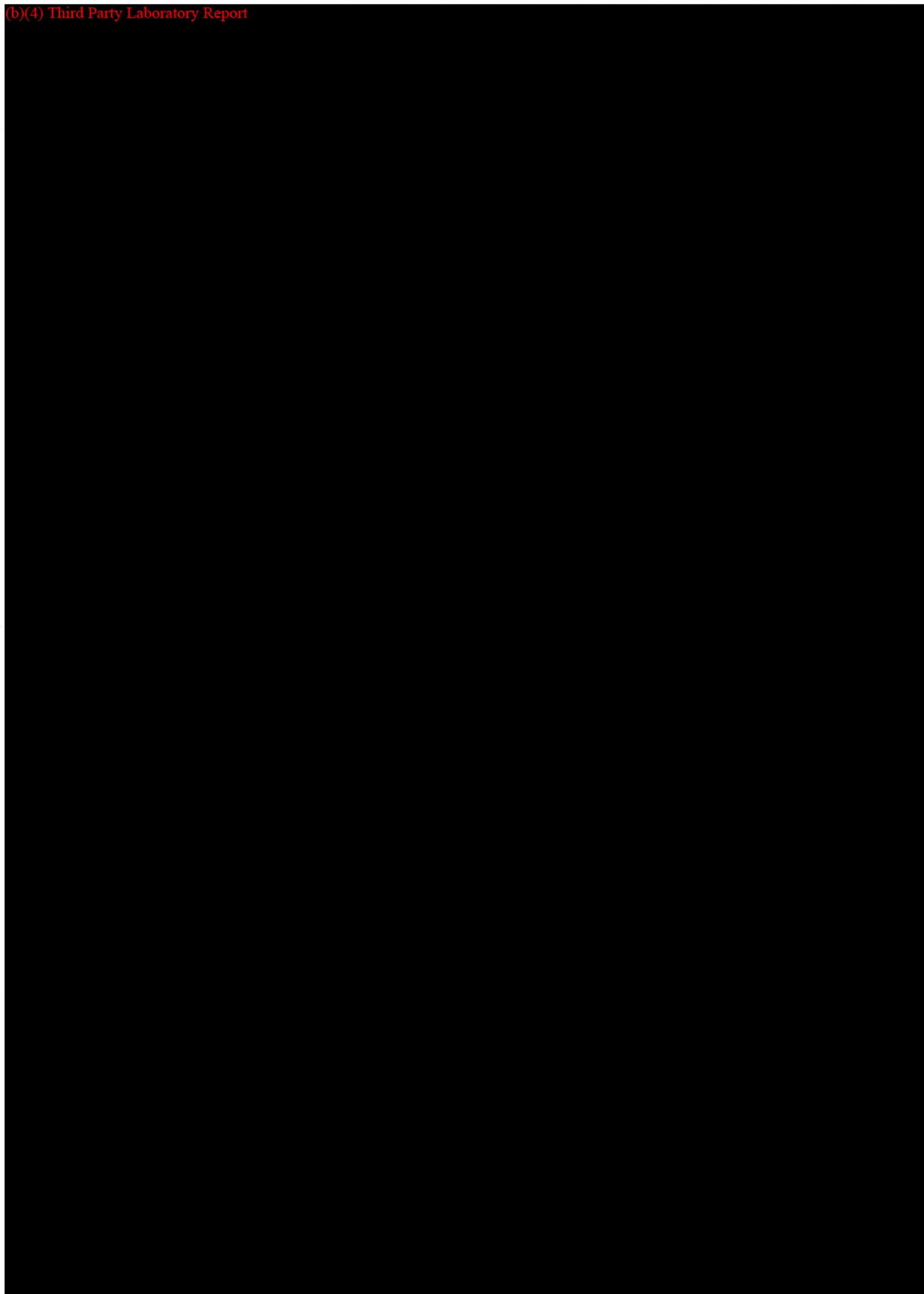
Report No. :

(b)(4)

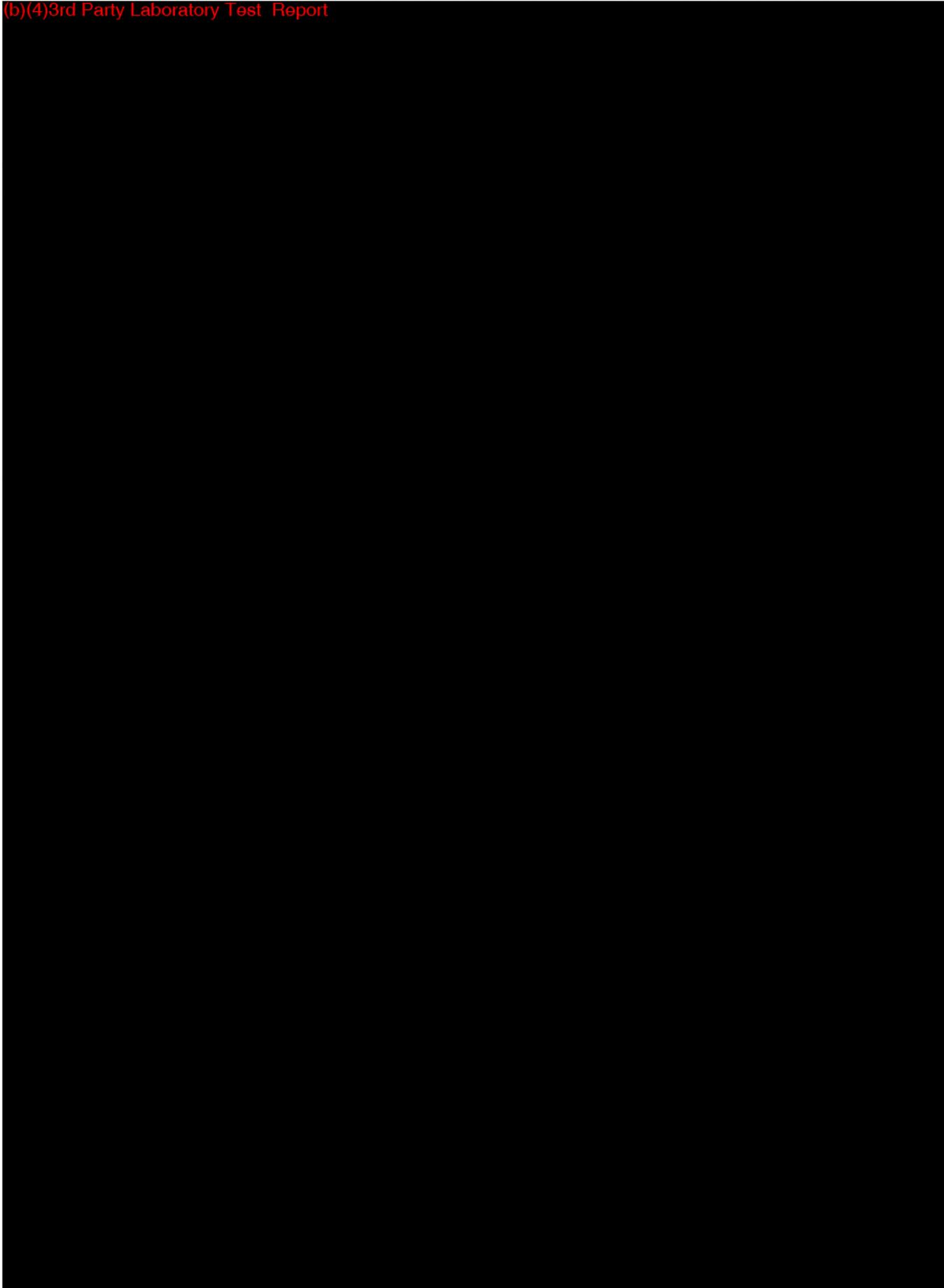
IntroMedic Co., Ltd.

(b)(4)

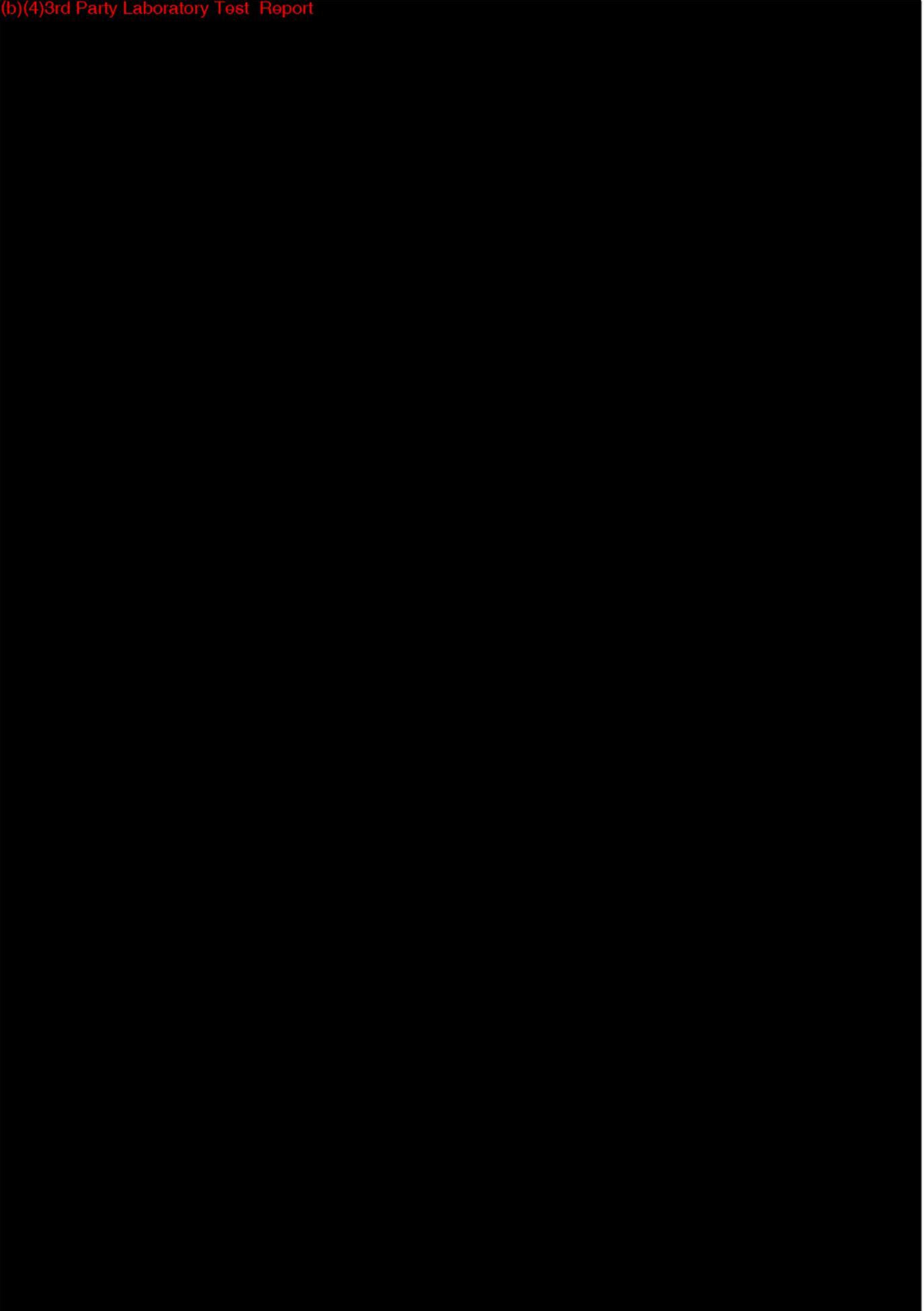




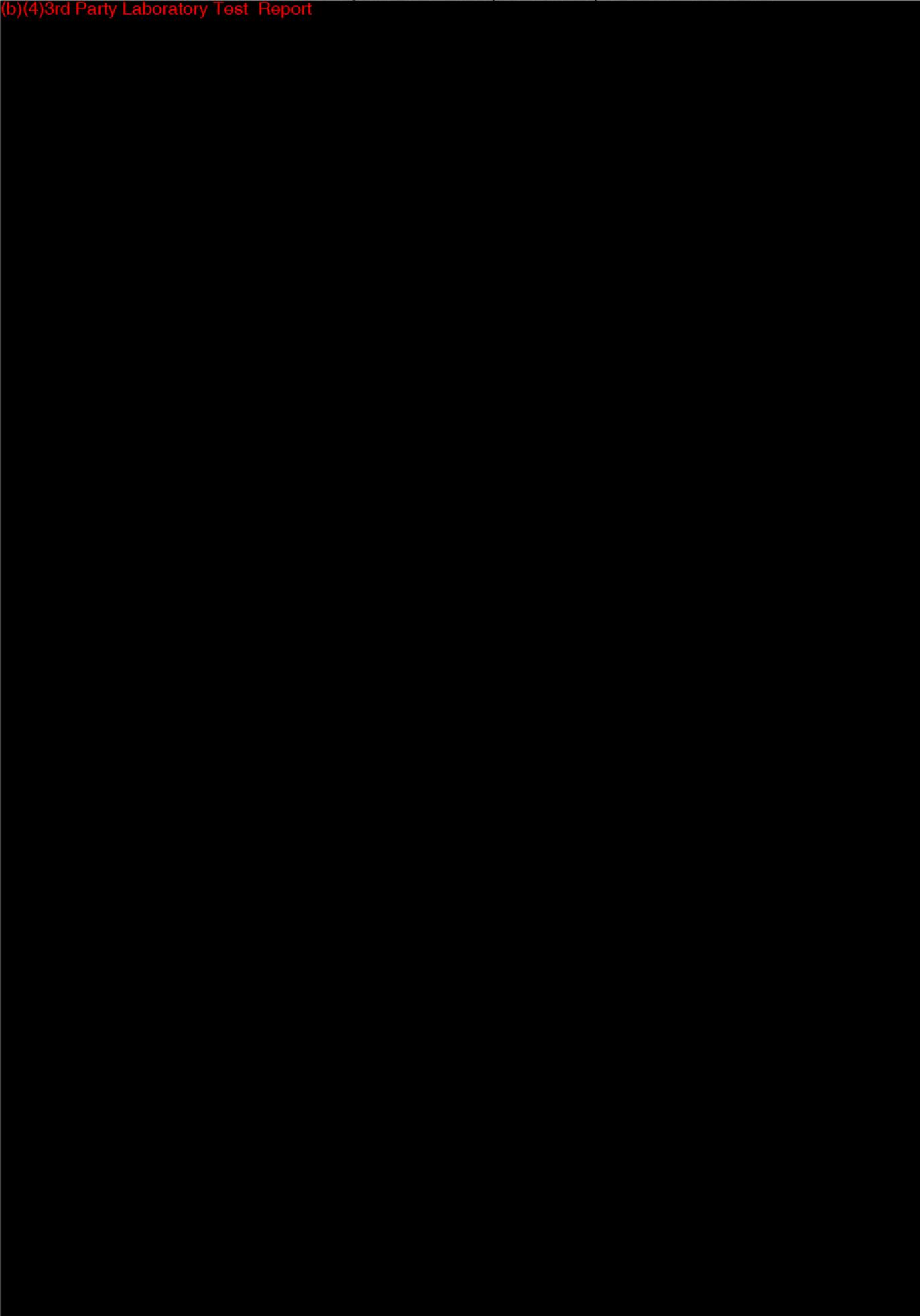
(b)(4)3rd Party Laboratory Test Report



(b)(4)3rd Party Laboratory Test Report



(b)(4)3rd Party Laboratory Test Report



(b)(4)



Electromagnetic Compatibility Test Report

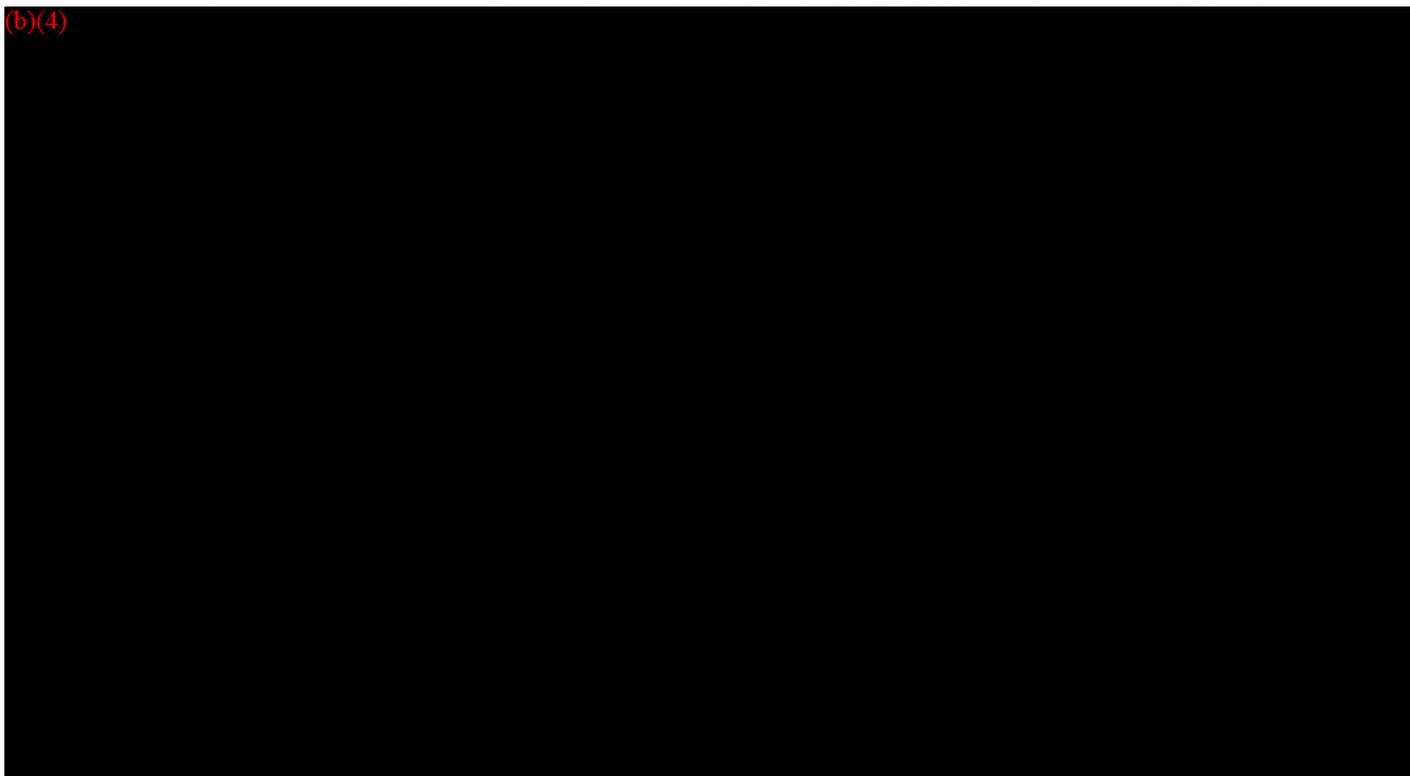
For

Esophagoscope system

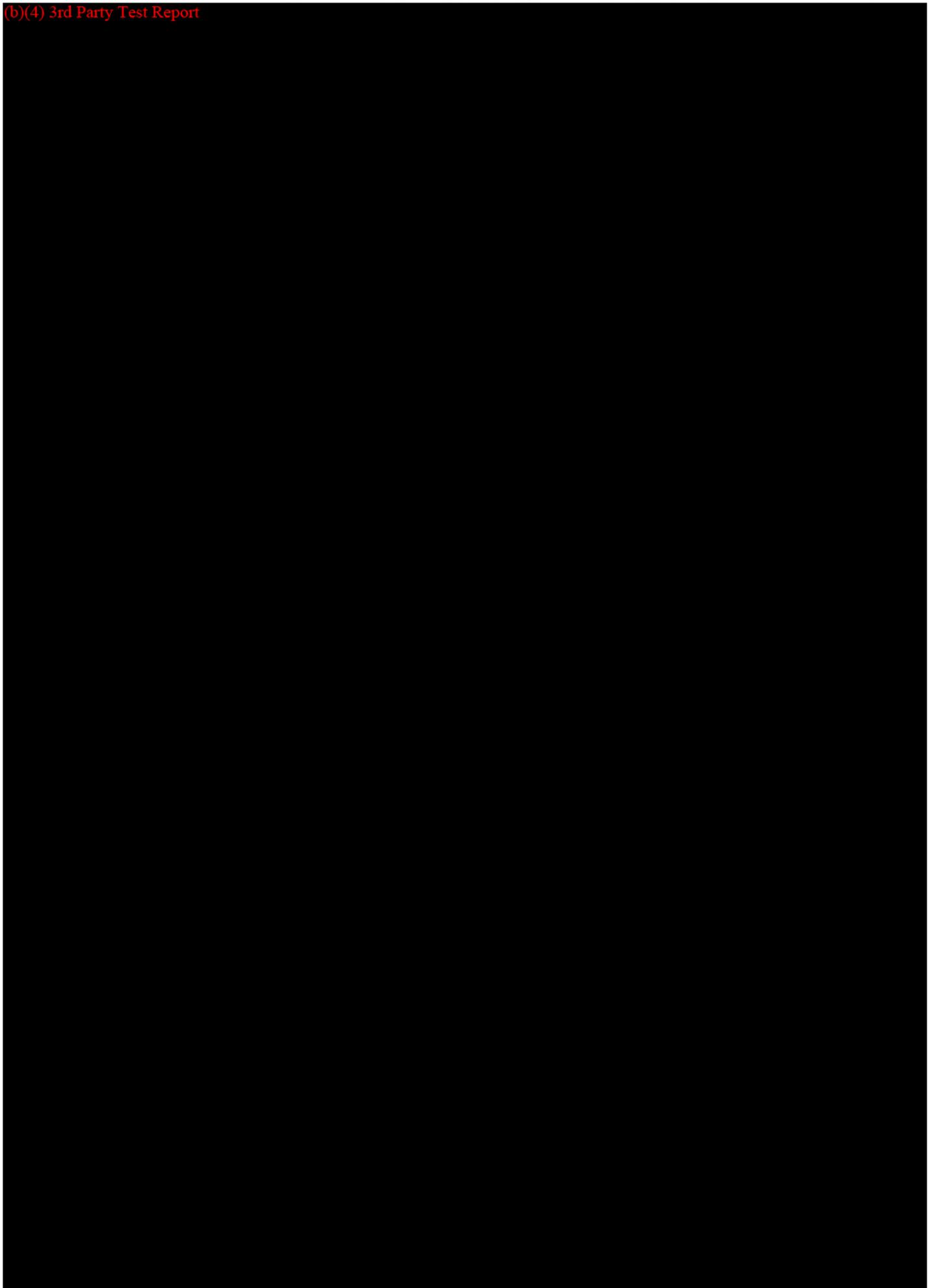
INTROMEDIC CO., LTD.

SUITE 1104, E&C VENTURE DREAM TOWER 6-CHA
197-28 GURO-DONG, GURO-GU, SEOUL, KOREA

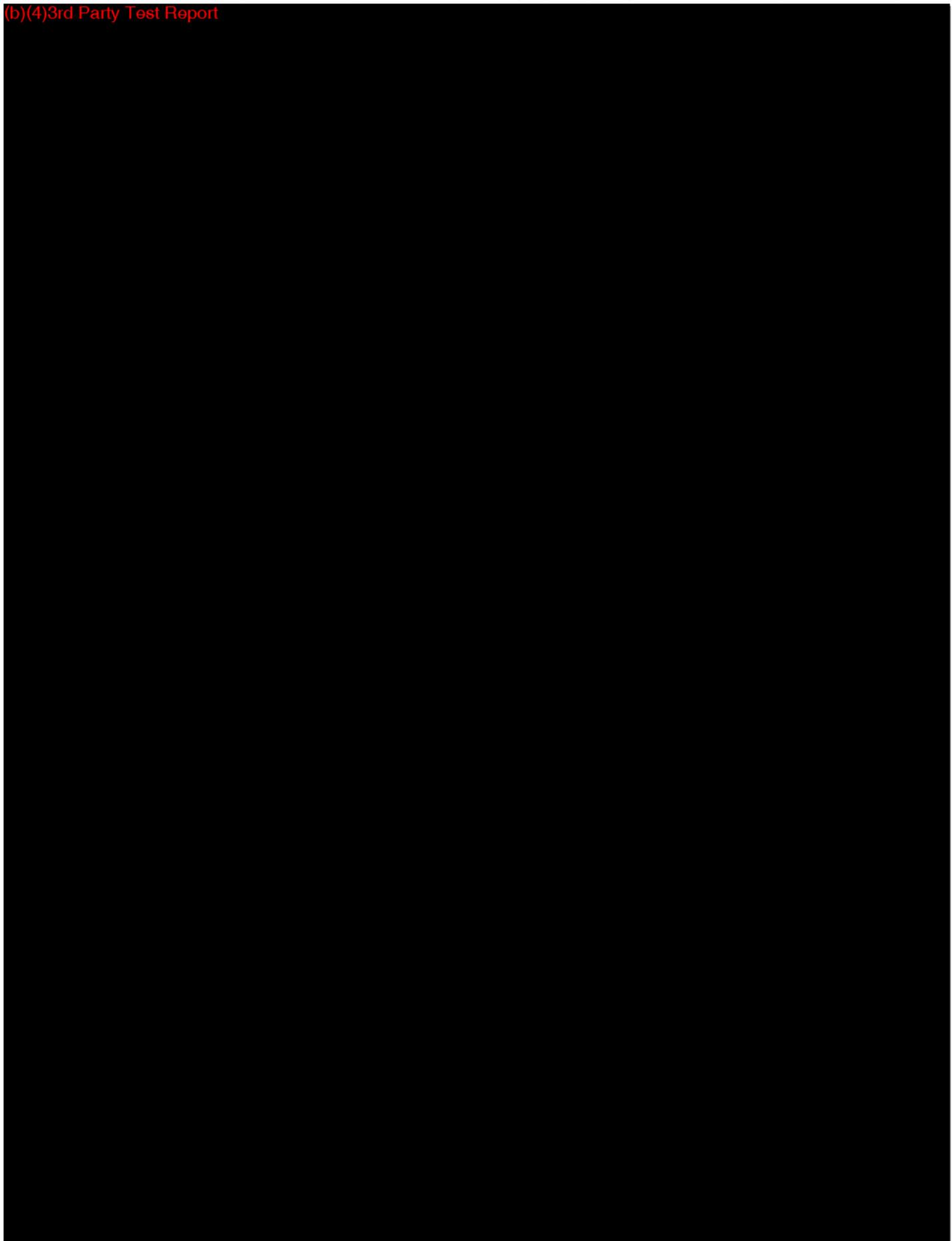
(b)(4)

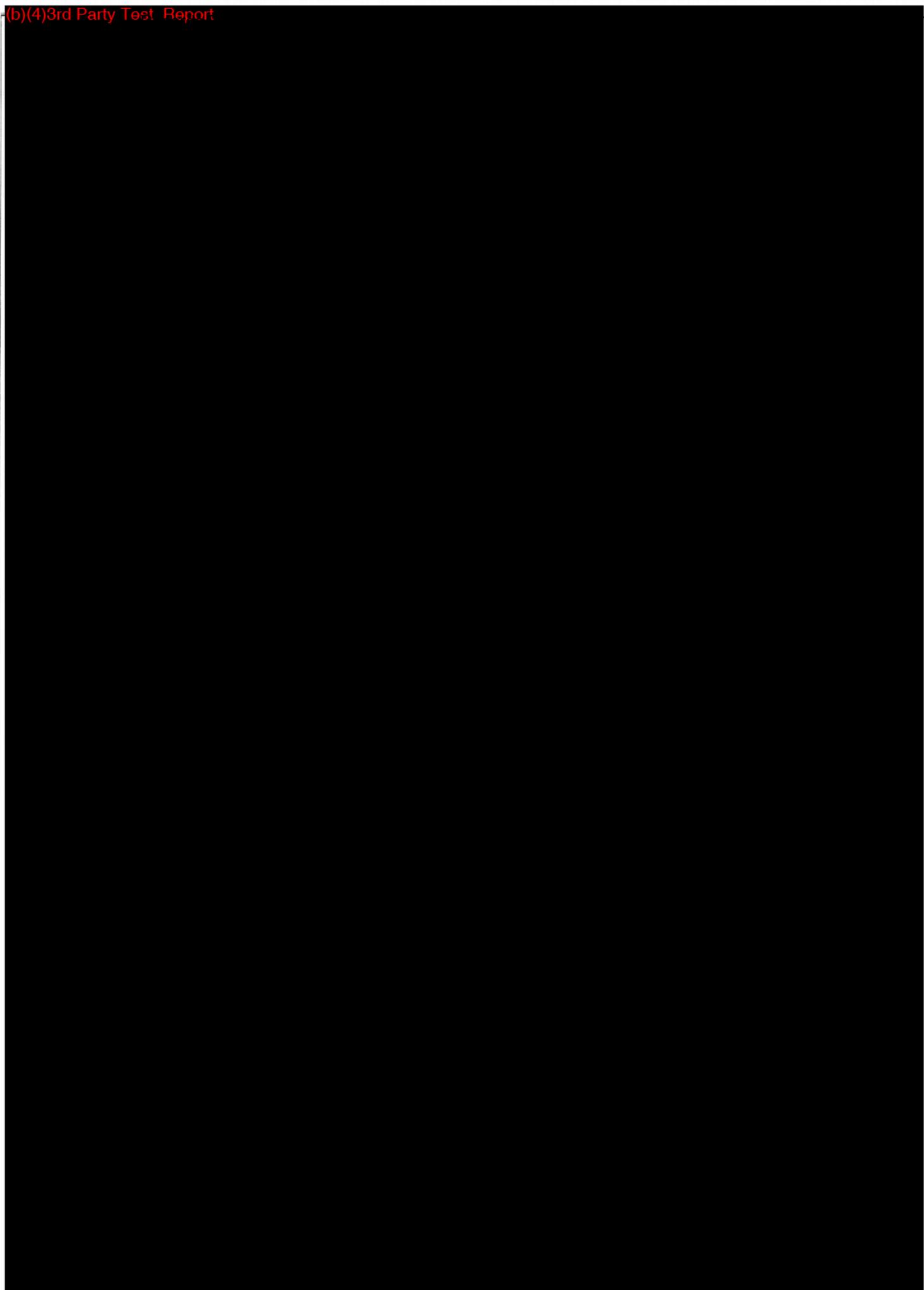


(b)(4) 3rd Party Test Report



(b)(4)3rd Party Test Report





INTROMEDIC	LABORATORY REPORT FOR		File No.	(b)(4)
	(b)(4)	PERFORMANCE TEST	Date(Rev.)	(b)(4)
	E.G. Scan Probe - EP1000		Page	1 of 10

Laboratory Report

for

(b)(4)

Performance Test

IntroMedic

E.G. Scan Probe - EP1000

(Approval Signatures / Dates)				
Issued by	Position	Name	Signature	Date
	(b)(4)	(b)(4)	(b)(4)	(b)(4)
Reviewed by	(b)(4)	(b)(4)	(b)(4)	(b)(4)
	(b)(4)	(b)(4)	(b)(4)	(b)(4)
Approved by	(b)(4)	(b)(4)	(b)(4)	(b)(4)
	(b)(4)	(b)(4)	(b)(4)	(b)(4)

INTROMEDIC	LABORATORY REPORT FOR	File No.	(b)(4)
	(b)(4) TEST	Date(Rev.)	(b)(4)
	E.G. Scan Probe - EP1000	Page	1 of 5

Laboratory Report for (b)(4) Test

IntroMedic

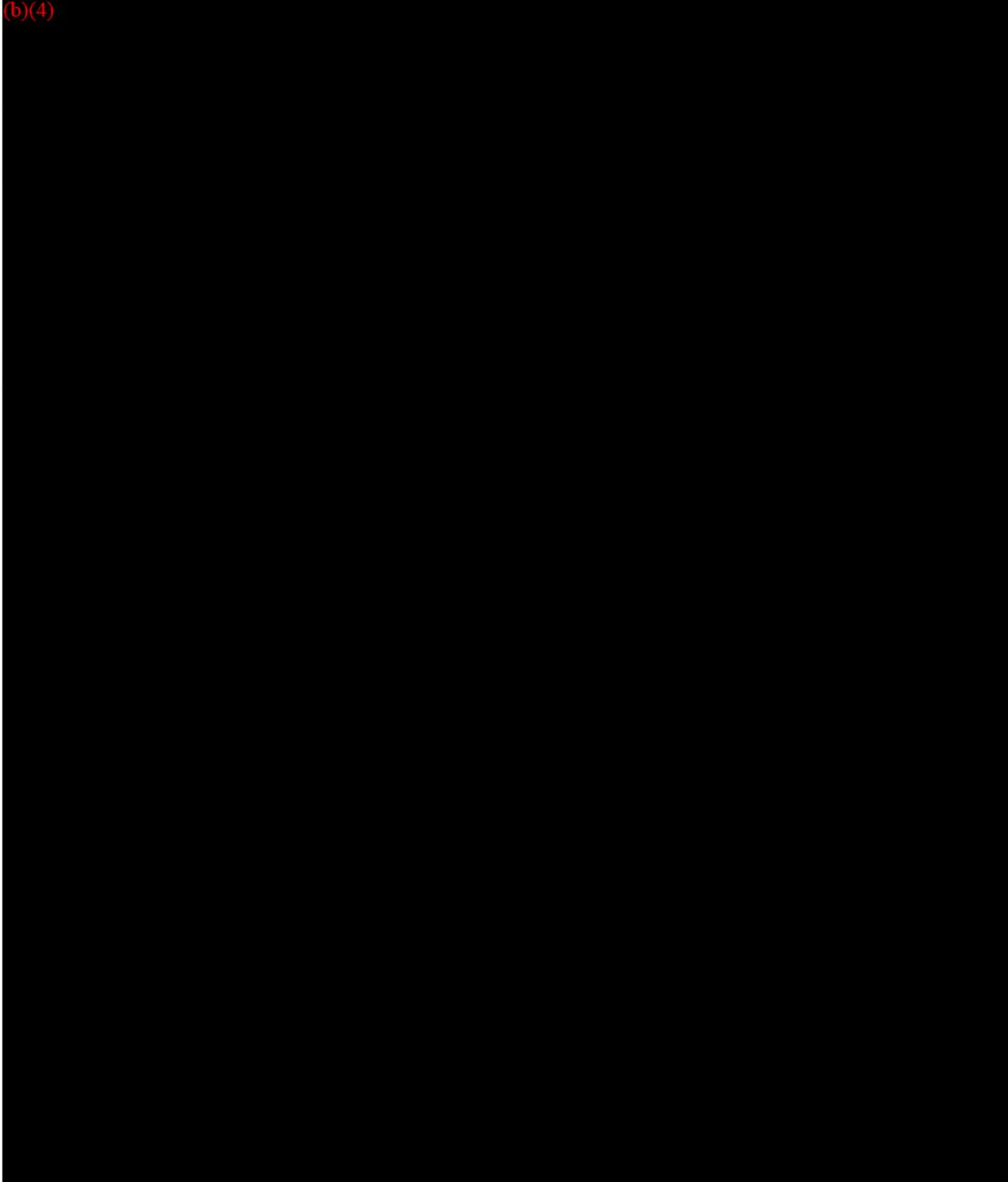
E.G. Scan Probe - EP1000

(Approval Signatures / Dates)				
Issued by	Position	Name	Signature	Date
	(b)(4)			
Reviewed by				
Approved by				

510(k) Submission – E.G. Scan™ II Esophagoscope System

Section 16_Risk Analysis

(b)(4)

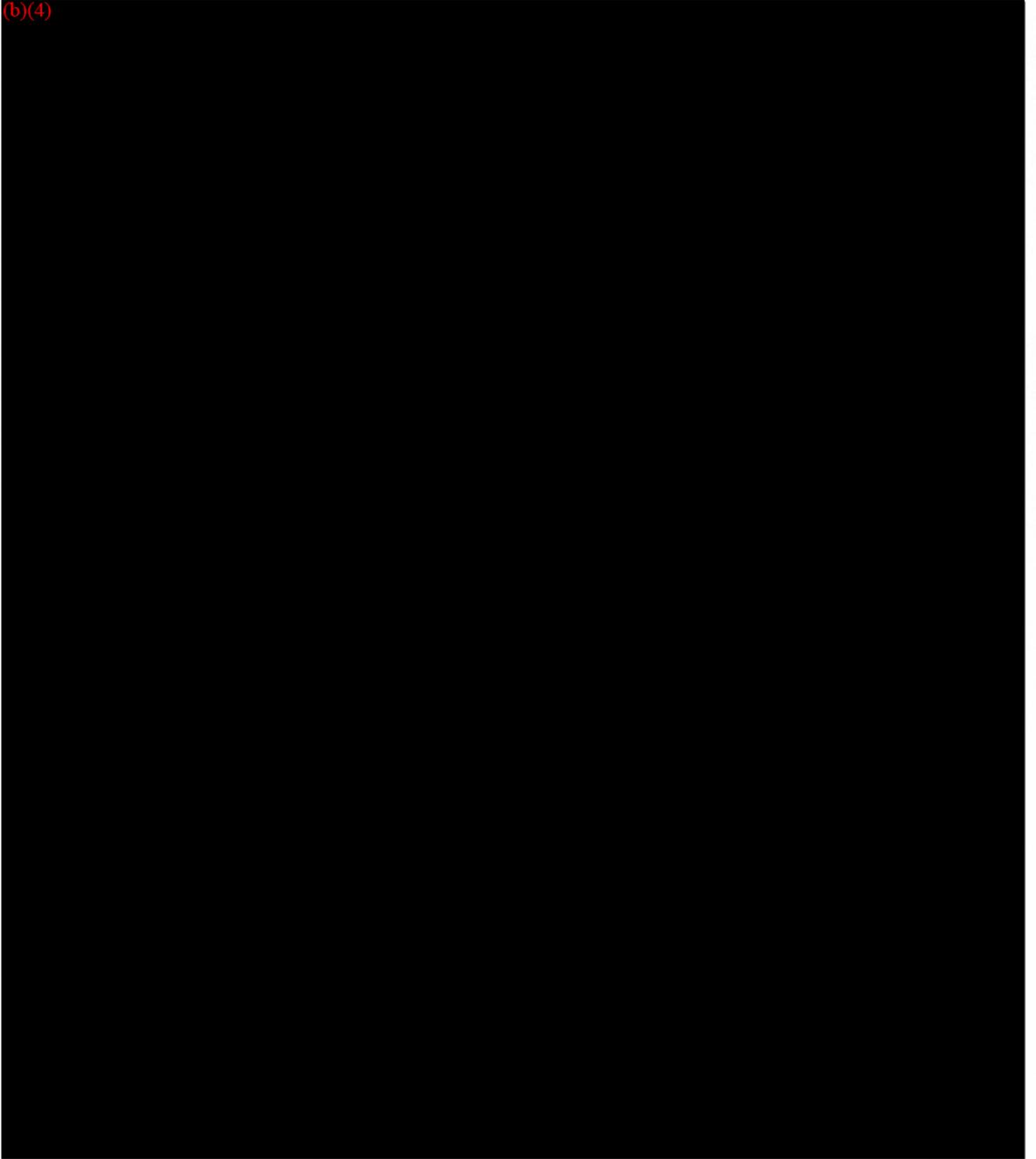


IntroMedic Co., Ltd.

510(k) Submission – E.G. Scan™ II Esophagoscope System

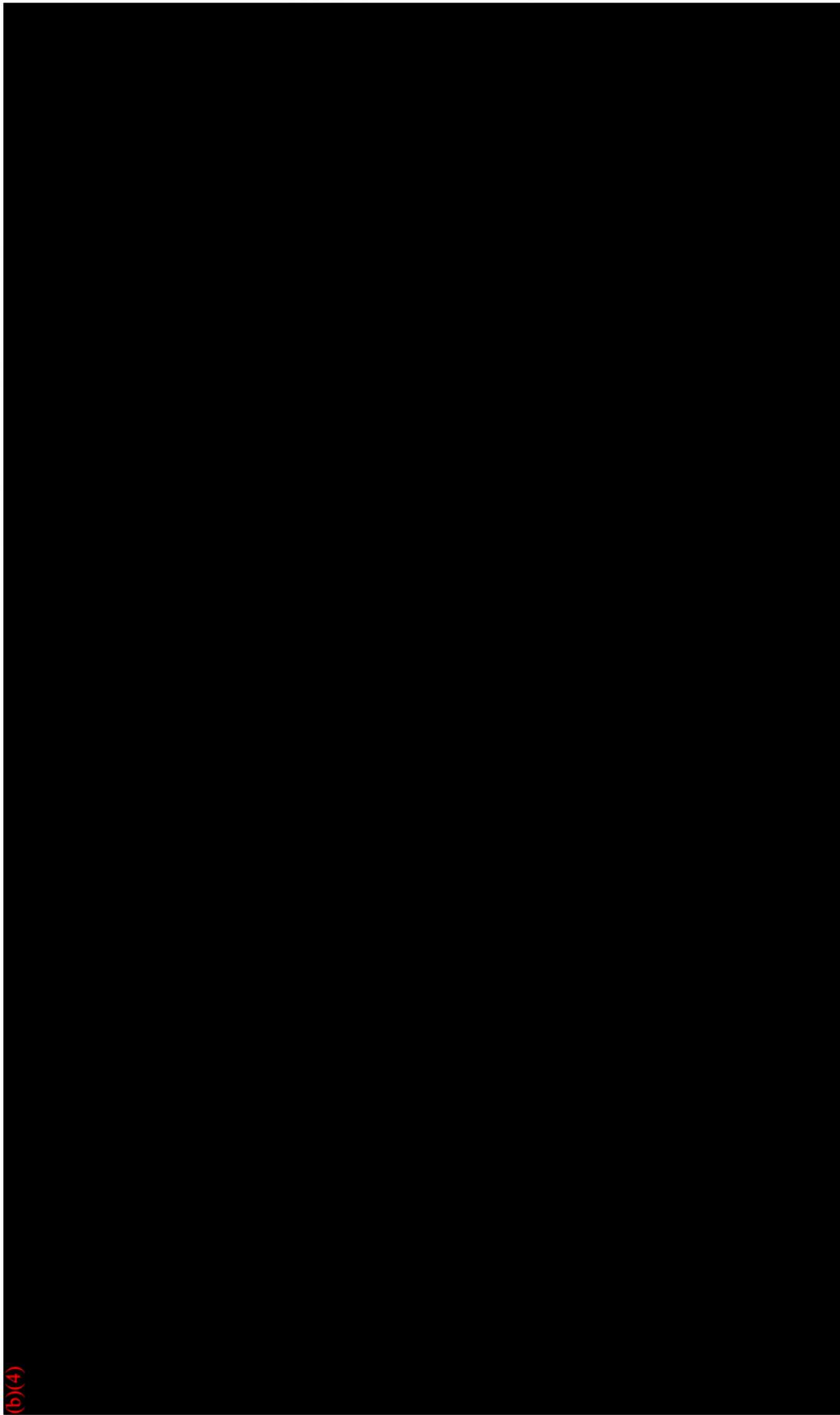
Risk Assessment

(b)(4)



IntroMedic Co., Ltd.

510(k) Submission – E.G. Scan™ II Esophagoscope System



(b)(4)

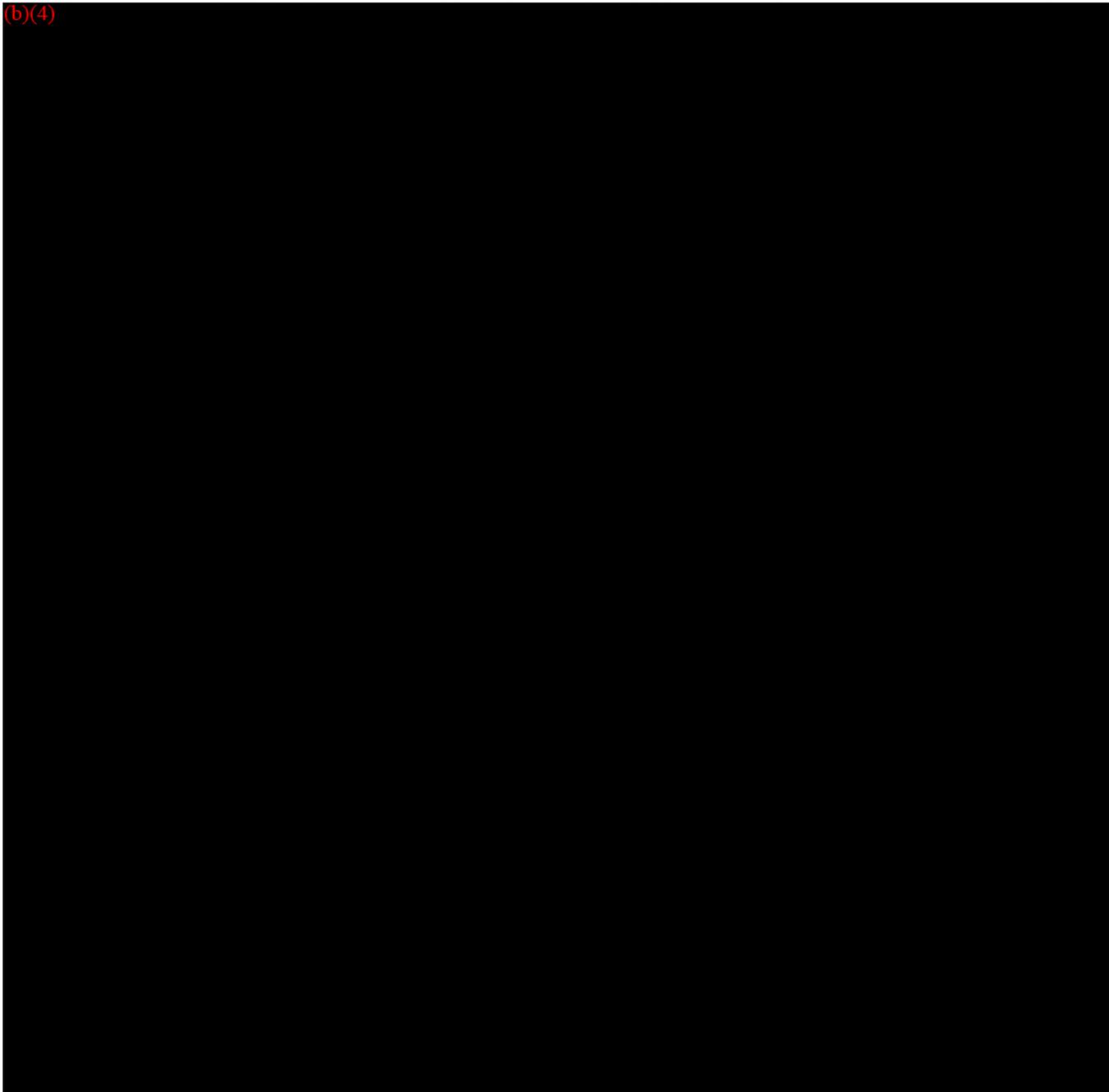
IntroMedic Co., Ltd.

Document No.:

(b)(4)

Test Report

(b)(4)



- Contents -

1. Purpose and Background
2. Test Content
3. Test Standards
4. Results
5. Conclusion

(b)(4)



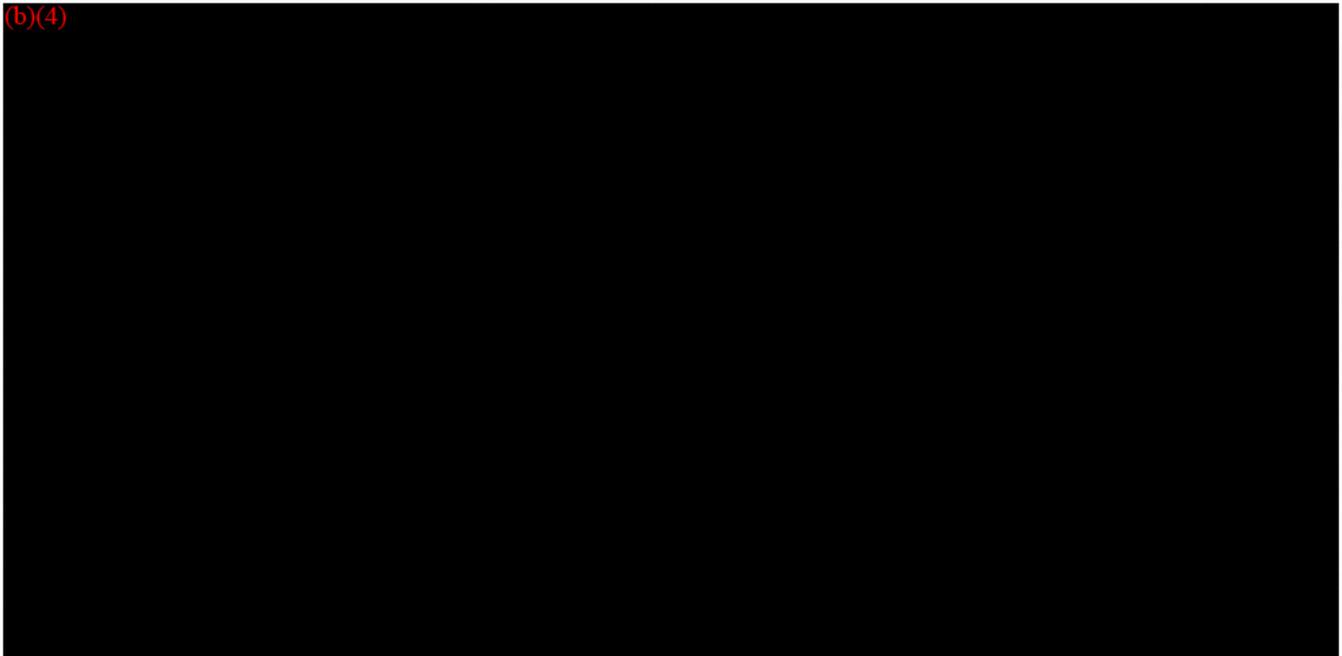
1. Purpose

(b)(4)

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2. Test content

(b)(4)

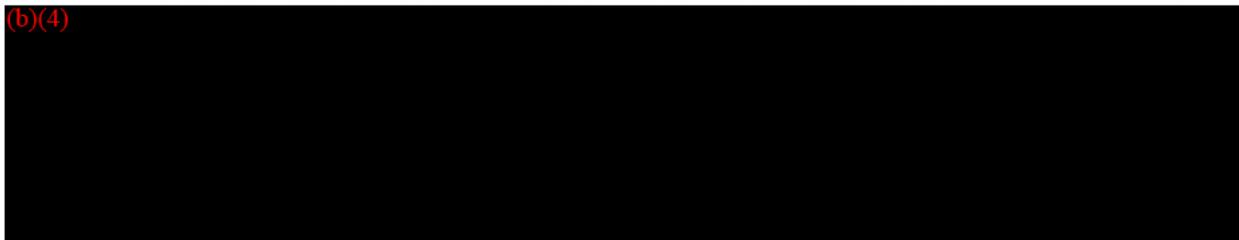
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(b)(4)

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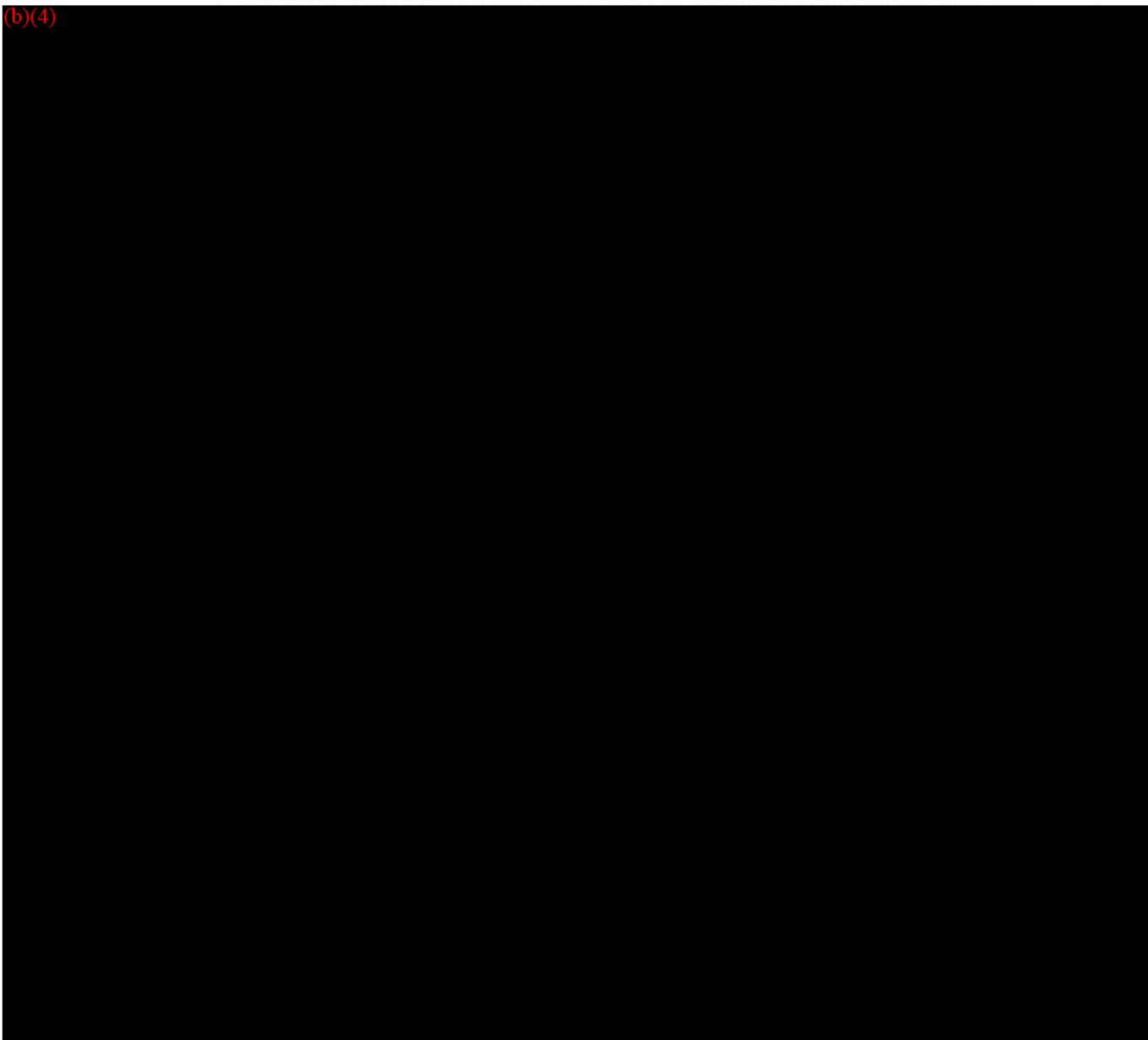
3. Experiment criterion

(b)(4)

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4. Results

(b)(4)

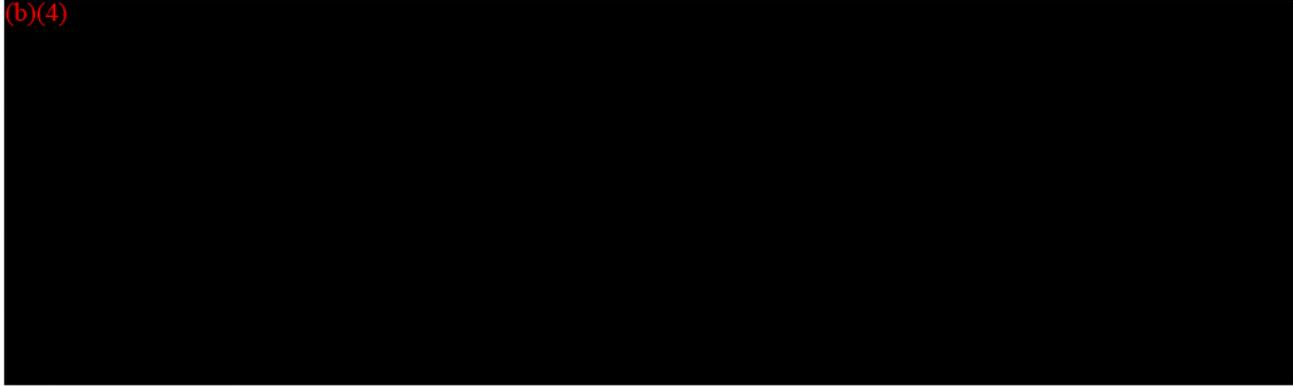
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(b)(4)

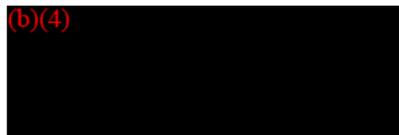
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5. Conclusion

(b)(4)



(b)(4)



See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 2-28-2015

 DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))		
(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)		
SPONSOR / APPLICANT / SUBMITTER INFORMATION		
1. NAME OF SPONSOR/APPLICANT/SUBMITTER IntroMedic Co., Ltd.	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES 04/05/2013	
3. ADDRESS (Number, Street, State, and ZIP Code) Suite 1104, E&C Venture Dream Tower 6-Cha, 197-28 Guro-Dong, Guro-Gu, Seoul, Korea, 152-719	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) +82.2.801.9300 (Fax) +82.2.801.9330	
PRODUCT INFORMATION		
5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s) FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s) (Attach extra pages as necessary) Esophagoscope System E.G. Scan™ II		
APPLICATION / SUBMISSION INFORMATION		
6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES <input type="checkbox"/> IND <input type="checkbox"/> NDA <input type="checkbox"/> ANDA <input type="checkbox"/> BLA <input type="checkbox"/> PMA <input type="checkbox"/> HDE <input checked="" type="checkbox"/> 510(k) <input type="checkbox"/> PDP <input type="checkbox"/> Other		
7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)		
8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES		
CERTIFICATION STATEMENT / INFORMATION		
9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation) <input checked="" type="checkbox"/> A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial. <input type="checkbox"/> B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies. <input type="checkbox"/> C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.		
10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary) NCT Number(s):		
The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.		
11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) JinYoung Lee (Title) RA Manager	
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) Suite 1104, E&C Venture Dream Tower 6-Cha, 197-28 Guro-Dong, Guro-Gu, Seoul, Korea, 152-719	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) +82.2.801.9300 (Fax) +82.2.801.9330	15. DATE OF CERTIFICATION 04/05/2013

Form FDA 3674 (3/12) (FRONT)

PSC Publishing Services (301) 443-6740 EF

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.
Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.
Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.
Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
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.

Form FDA 3674 (3/12) (BACK)

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 <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ [IEC 60601-1][Medical Electrical Equipment-Part 1: General Requirements for Safety][1988+A1:1991+A2:1995]		
Please answer the following questions		Yes No
Is this standard recognized by FDA ² ?		<input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number ³		#5-4
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard?..... If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?..... If yes, report these deviations or adaptations in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard?..... If yes, was the guidance document followed in preparation of this 510k?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Title of guidance: _____		
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or	certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html	

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE [IEC 60601-1][Medical Electrical Equipment-Part 1: General Requirements for Safety][1988+A1:1991+A2:1995]		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
* 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:		
Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850		<i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i>

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s (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 <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ [IEC 60601-1-2][Medical Electrical Equipment-Part 1-2: Collateral Standard: Electromagnetic Compatibility][2001/9/1, Ed.2+A1]		
Please answer the following questions		Yes No
Is this standard recognized by FDA ² ?		<input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number ³		#5-34
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard?..... If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?..... If yes, report these deviations or adaptations in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard?..... If yes, was the guidance document followed in preparation of this 510k?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Title of guidance: _____		
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or	certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html	

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE [IEC 60601-1-2][Medical Electrical Equipment-Part 1-2: Collateral Standard: Electromagnetic Compatibility][2001/9/1, Ed.2+A1]		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement		
<p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <p>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850</p> </div> <div style="width: 35%; text-align: right;"> <p><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p> </div> </div>		

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 <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated	
STANDARD TITLE ¹ [IEC 60601-2-18][Medical Electrical Equipment-Part 2: Particular requirements for the safety of endoscopic equipment][1996+A2: 2000]	
Please answer the following questions	
	Yes No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number ³	#4-122
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard?..... If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?..... If yes, report these deviations or adaptations in the summary report table.	<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	<input type="checkbox"/> <input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard?..... If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Title of guidance: _____	
<p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or</p>	<p>certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.</p> <p>⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html</p>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE [IEC 60601-2-18][Medical Electrical Equipment-Part 2: Particular requirements for the safety of endoscopic equipment][1996+A2: 2000]		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
* 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:		
Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850		<i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i>

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s (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 <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ [ISO 10993-1][Biological evaluation of medical devices - Part 1: Evaluation and testing][2009]		
Please answer the following questions		Yes No
Is this standard recognized by FDA ² ?		<input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number ³		#2-156
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard?..... If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?..... If yes, report these deviations or adaptations in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard?..... If yes, was the guidance document followed in preparation of this 510k?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Title of guidance: _____		
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or	certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html	

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE [ISO 10993-1][Biological evaluation of medical devices - Part 1: Evaluation and testing][2009]		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
* 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		
<p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <p>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850</p> </div> <div style="width: 35%; text-align: right;"> <p><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p> </div> </div>		

Chin, Yeuly *

From: Chin, Yeuly *
Sent: Monday, June 24, 2013 9:10 AM
To: 'skwon@intromedic.com'
Subject: K131131 Correspondence Letter

Attachments: K131131 Correspondence Letter.pdf



K131131
Correspondence Letter



COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

From: Reviewer Name Vasant G. Malshet, MS, Ph.D., DABT
Subject: 510(k) Number K131131
To: The Record

Please list CTS decision code: SE - Substantially Equivalent

- Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)
- Hold (Additional Information or Telephone Hold)
- Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page (<i>Attach IFU</i>)	X	X
510(k) Summary or 510(k) Statement (<i>Attach Summary or Statement</i>)	X	X
Truthful and Accurate Statement (<i>Must be present for a Final Decision</i>)	X	X
Is the device Class III?		X
Does firm reference standards? (If yes, please attach Form 3654.)	X	
Is this a combination product?		X
Is this a reprocessed single use device? (See <u>Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices.</u>)	X	
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		X
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X
Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)		X
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from its age >= 21 (different device design or testing, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		X

Nanotechnology		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		X

Regulation Number: 21 CFR 874.4710
Class: II
Product Code: EOX
Additional Product Codes:

Digital Signature Concurrence Table
(Not all signatures may be required)

Branch Chief Sign-Off	Srinivas Nandkumar -S 2013.06.20 11:46:07 -04'00'
Division Sign-Off	Eric A. Mann -S