

K150271/A1



Access to Sustainable Surgical Solutions

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Blue Ash, Ohio 45242

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March 31, 2015

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Center for Devices and Radiological Health
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Silver Spring, MD 20993-0002

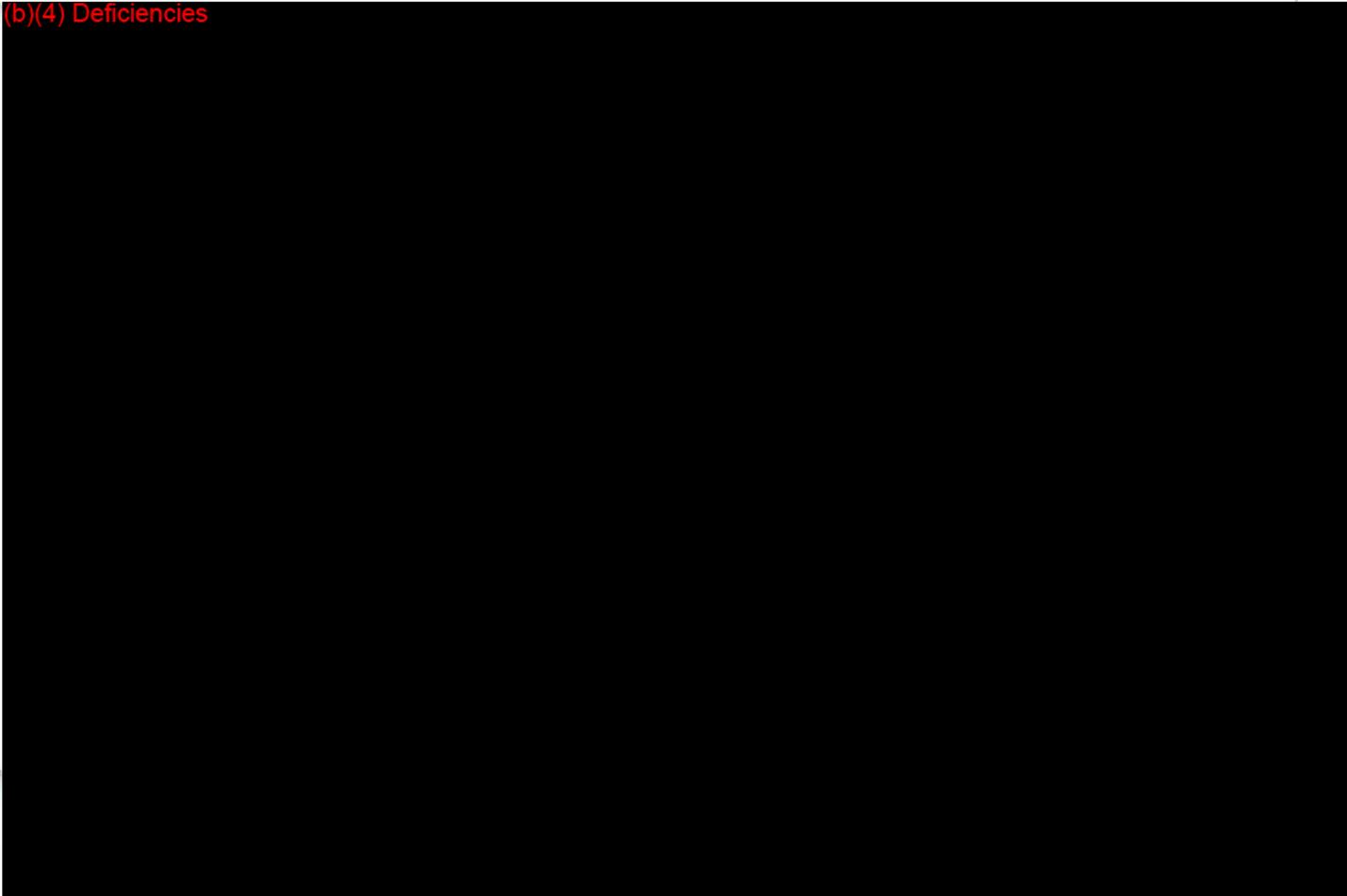
Attention: Dr. Thomas E. Claiborne

Re: K150271 S002 Response to Predicate vs Reference Device Question – EndoPrime Prime™ Adaptive Ultrasonic Scalpel System and Blades

Dear Dr. Claiborne,

EndoPrime is submitting this in response to your e-mail request dated March 27, 2015 regarding the use of K010309 Sonopet Ultrasonic Surgical Aspirator as a predicate device:

(b)(4) Deficiencies



1-0
602



(b)(4) Deficiencies



The electronic copy provided on a CD is exactly the same as the paper copy.

If additional information is needed, do not hesitate to contact me.

Best regards,

A handwritten signature in blue ink, appearing to read 'Rich Grant'.

Rich Grant, CEO
EndoPrime, Inc.

Attachments:

- Attachment 002 - Revised 510(k) Summary
- Attachment 003 - Revised Tables 8-2 and 9-3: Prime™ Adaptive Ultrasonic Scalpel Materials
- Attachment 004 - Revised Table 9-5: Prime™ Adaptive Ultrasonic Scalpel and Blades Specifications



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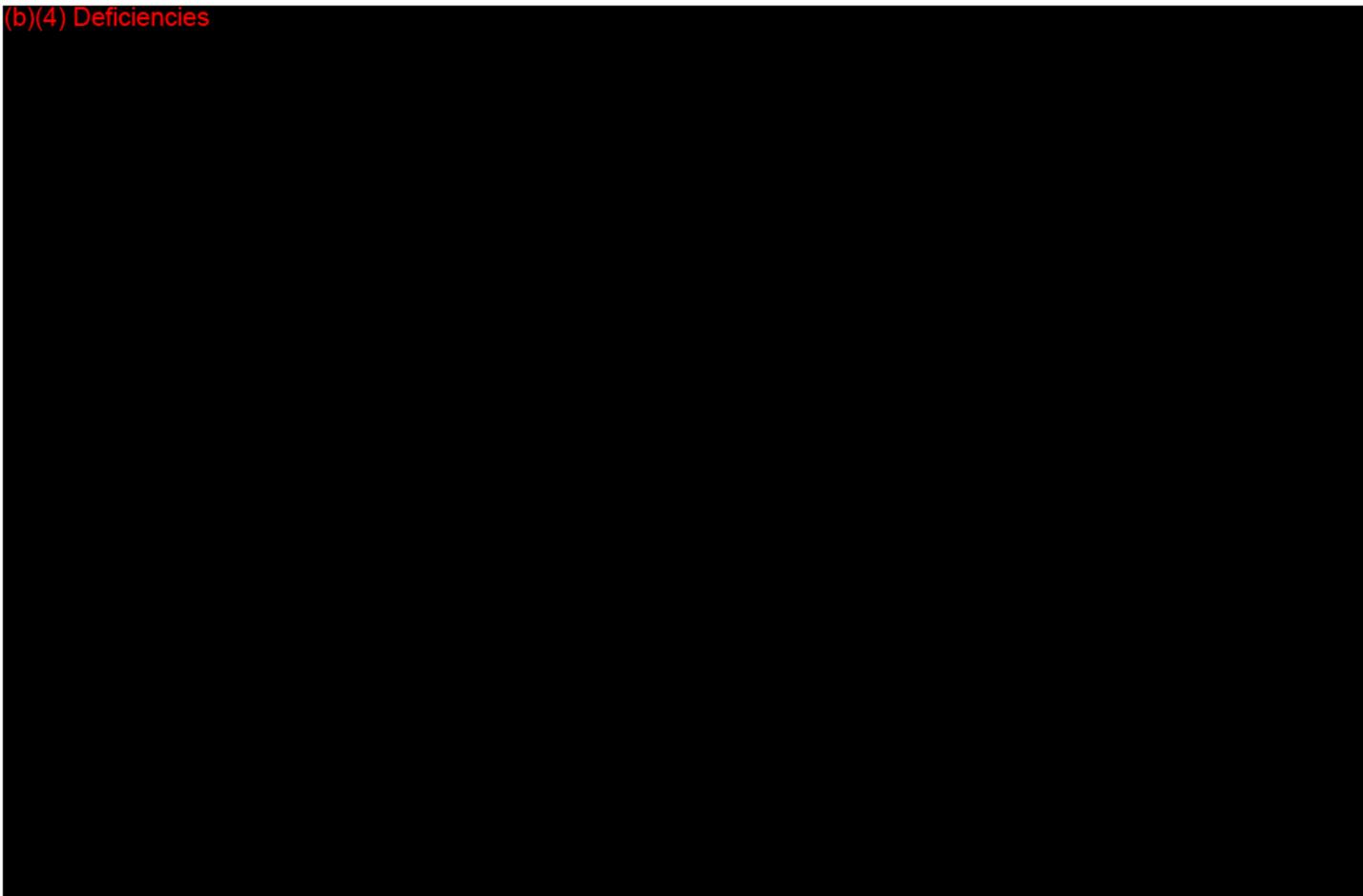
Attention: Dr. Thomas E. Claiborne

Re: K150271 S002 Response to Predicate vs Reference Device Question – EndoPrime Prime™ Adaptive Ultrasonic Scalpel System and Blades

Dear Dr. Claiborne,

EndoPrime is submitting this in response to your e-mail request dated March 27, 2015 regarding the use of K010309 Sonopet Ultrasonic Surgical Aspirator as a predicate device:

(b)(4) Deficiencies



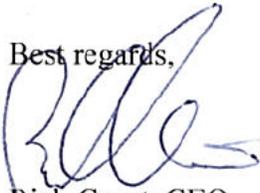
(b)(4) Deficiencies



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If additional information is needed, do not hesitate to contact me.

Best regards,



Rich Grant, CEO
EndoPrime, Inc.

Attachments:

Attachment 002 - Revised 510(k) Summary

Attachment 003 - Revised Tables 8-2 and 9-3: Prime™ Adaptive Ultrasonic Scalpel
Materials

Attachment 004 - Revised Table 9-5: Prime™ Adaptive Ultrasonic Scalpel and Blades
Specifications

510(k) Summary

Date Prepared: March 31, 2015
Submitter Contact: Rich Grant, CEO
EndoPrime, Inc.
4480 Lake Forest Drive, Suite 414
Cincinnati, OH 45242
513-769-1916

Regulatory Contact: Rich Grant
EndoPrime, Inc.
4480 Lake Forest Drive, Suite 414
Cincinnati, OH 45242
513-769-1916

Trade Name: Prime™ Adaptive Ultrasonic Scalpel System and Blades
Common or Usual Name: Electrosurgical Cutting and Coagulating Device
Product Class: Class II
Classification: Electrosurgical Cutting & Coagulation & Accessories
Product Codes: GEI
Panel Code: General & Plastic Surgery/79
Regulation Standard: 21 CFR 878.4400

AND

Trade Name: Prime™ Ultrasonic Scalpel Reusable Blades
Prime™ Reusable Transducer Handpiece
Prime™ Adaptive Ultrasonic Scalpel Generator
Common or Usual Name: Ultrasonic Surgical Instruments
Product Class: Class II
Classification: Instrument, Ultrasonic Surgical
Product Codes: GEI/LFL
Panel Code: General & Plastic Surgery
Regulation Standard: Unclassified

Reason for this Submission: This Traditional 510(k) involves one medical device system compiled of three individual medical device components.

No Prior Submissions: There were no prior submissions for the subject device by EndoPrime Inc.

Indications for Use:

The **Prime™ Adaptive Ultrasonic Scalpel System** is a cutting and coagulation system indicated for open, laparoscopic, and endoscopic surgery in soft tissue where control of hemostasis and thermal spread is desired. The system is indicated for dissection, sealing, transection,otomy creation and transection/coagulation of vessels as indicated for each cutting and coagulation instrument used (consult the instructions for use provided with each instrument). The system can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels.

Device Descriptions:

The **Prime™ Adaptive Ultrasonic Scalpel System** has three major components: Generator (with footswitch), Transducer Handpiece and instruments (or blades). The **Prime™ 6000 Generator** provides input/output control and operation interface to automatically adapt the ultrasonic power output for the tissue load encountered. The device system is compliant with the following consensus standards:

Performance Standards:	
IEC 60601-1 2005 + CORR. 1 (2006) + CORR. (2007)	International Standard-Medical Electrical Equipment-General Requirements for Basic Safety and Essential Performance.
CAN/CSA-C22.2 No. 60601-1:08	Medical Electrical Equipment-Part 1-6: General Requirements for Safety-Collateral Standard; General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems.
EN 60601-1-2:2007 CISPR 11:2009+A1	Medical Electrical Equipment-Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility-Requirements and Tests.
IEC 60601-1-2-18:2009 (Third Edition)	Medical electrical equipment-Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.
IEC 61000-4-8:2010	Medical Electrical Equipment: Part 1-4: General Requirements for Collateral Standard: Programmable Electrical Medical Systems.
IEC 61000-3-2:2006 +A1 +A2	Electromagnetic compatibility (EMC)-Part 3-2: Limits for harmonic current emissions (equipment input current \leq 16 A per phase).
IEC 61000-3-3:2008	Electromagnetic compatibility (EMC)-Part 3-3: Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current \leq 16 A per phase and not subject to conditional connection.
IEC 61000-4-3:2006 + A1:2007 + A2:2010	Electromagnetic compatibility (EMC)-Part 4-3: Limits-Limitation of emission of harmonic currents in low-voltage power supply systems for equipment with rated current greater than 16 A.

IEC 61000-4-4:2004+A1:2010	Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrical fast transient/burst immunity test.
IEC 61000-4-5:2005	Electromagnetic compatibility (EMC). Testing and measurement techniques. Surge immunity test.
IEC 61000-4-6:2003	Electromagnetic compatibility (EMC). Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields.
IEC 61000-4-11:2004	Electromagnetic compatibility (EMC). Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests.
ISO 10993-1:2009/AC2010	Biocompatibility Evaluation of medical Device Table A.1
ISO 10993-5:2009	Biological evaluation of medical devices--Part 5: Tests for vitro cytotoxicity.
ISO 10993-10:2009	Biological evaluation of medical devices--Part 10: Test for irritation and skin sensitivity.
ISO 10993-11:2009	Biological evaluation of medical devices--Part 11: Tests for systemic toxicity.
ISO 10993-4:2009	Biological evaluation of medical devices—Part 4: Test for Hemocompatibility.
AAMI TIR30:2011	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices. Association for Advancement of Medical Instrumentation, Arlington, VA. (CRD249).
EN/ISO 14971:2012	Risk Management for Medical Device
EN/IEC 62304:2006	Medical device software—Software life cycle processes.

Prime™ Adaptive Ultrasonic Scalpel System and Blades family of products consist of:

Prime™ G6000 Generator provides operation interface display, device condition monitoring and Input/Output control. The generator provides electrical energy output to the transducer, which is controlled by activating the footswitch. The **Prime™ G6000 Generator** is also validated to operate with hand switched devices and hand switched enabled transducer hand pieces. A built-in, automatic pre-check function verifies proper connection and operation of the system during startup and continuously monitors the system and instruments. Variable and Maximum (or Full) power levels (1 through 5) are displayed on the front panel and can be selected by pressing the VAR or FULL footswitch pedal (or if available the hand switch). The Variable Power setting can be selected throughout the procedure to provide corresponding energy outputs with the interacting instrument. Audible and visual alarms assist with identifying anomalies, error, and failures including generator, instrument or transducer that are at the end of their useful life. A Standby button is available to pause the system to avoid accidental activation when not in use, or conduct manual system checks and diagnostics.

Prime™ Ultrasonic Scalpel Reusable Blades vibrate ultrasonically, which enables its cutting ability. The same vibration seals small vessels ($\leq 2\text{mm}$) with coagulated blood and tissue proteins by producing local heating of tissue. Homeostasis occurs when tissue couples with the blade. The **Prime™ Ultrasonic Scalpel Reusable Blades** are designed for use with a transducer and a generator system as part of the **Prime™ Adaptive Ultrasonic Scalpel System** and family of products; these products are compatible with a limited number of other manufacturer's systems. The system instruments can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels with the advantages of limited heat/smoke generation and the lack of current flow through the patient. The blade instruments are provided with a reusable Torque Wrench to assure proper tightness when attaching the blade to the transducer. The generator will automatically check the tightness to assure proper function.

The **Prime™ Reusable Transducer Handpiece** cooperates with the **Prime™ Adaptive Ultrasonic Scalpel Blades** as a cutting and coagulation instrument. The **Prime™ Reusable Transducer Handpiece** is designed to convert electrical energy from the generator to mechanical motion of the instrument blades. When the transducer is used in conjunction with the **Prime™ Adaptive Ultrasonic Scalpel System**, the transducer provides ultrasonic vibration, which enables the blade's cutting ability. **Prime™ Adaptive Ultrasonic Scalpel System and Blades** family of products is compatible with a limited number of other manufacturer's systems.

Prime™ Adaptive Ultrasonic Scalpel System products are compatible with a limited number of other predicate systems.

Predicate Device(s):

K002981-Ultracision® Harmonic Scalpel®, Ethicon Endo-Surgery, Inc.
K990430-Ultracision® HARMONIC Scalpel® Hand Piece, Ethicon Endo-Surgery
K010898-Ultracision Harmonic Scalpel Blade, Ethicon Endo-Surgery
K053056-Harmonic Scalpel Blades and Shears, Ethicon Endo-Surgery, Inc.

Prime™ Adaptive Ultrasonic Scalpel System blade tips are finished identical to other ultrasonic devices:

Reference Device:

K010309-Sonopet® Surgical Aspirator, Mutoh America CO., LTD. (now Stryker) refinished for its blue anodized blade tip surface only.

Technological Characteristics:

The **Prime™ Adaptive Ultrasonic Scalpel System and Blades** technological characteristics are substantially equivalent to the predicated devices including automatically adapting the ultrasonic power output for the tissue load encountered to provide consistent vibration in differing loads and tissue thickness. The predicate device scalpel blades were predicated on reusable scalpel blades and the **Prime™ Ultrasonic Scalpel Reusable Blades** are designed to function similar to the predicate devices but are provided non-sterile and validated for disassembly, cleaning and sterilization. Another feature of the **Prime™ Adaptive Ultrasonic Scalpel System and Blades**

is the ability to disconnect the cable at the transducer handpiece. This feature allows the surgical scrub technician to quickly replace the transducer handpiece and/or ultrasonic blades without contact with the non-sterile surface of the generator or assistance from others. The cable disconnect was designed as a convenience feature similar to the ability to disconnect at the generator. The **Prime™ Ultrasonic Scalpel Reusable Blades** are designed similar to the predicate blades but have slightly different end effector designs. The **Prime™ Ultrasonic Curved Blades** have a compact design to improve access in narrow, delicate anatomy. The **Omni™ Ultrasonic Hook Blades** are curved for better visibility with a (b)(4) [REDACTED]. These technological improvements will not affect the overall device intended use, performance characteristics, substantial equivalence to the predicate, or raise any new issues regarding safety or efficacy.

Conclusion:

EndoPrime, Inc. concludes that the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** family of products, is substantially equivalent to the predicate devices, and raises no new questions of safety or effectiveness.

FDA CDRH DMC

FEB 04 2015

Received

K150271



4480 Lake Forest Dr.
Suite 414
Blue Ash, Ohio 45242

January 31, 2015

510(k) Document Control Center (WO66-G609)
U.S. Food and Drug Administration
General Surgery Devices Branch II
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attention: Joshua Nipper, M.D., Branch Chief

Re: Original Traditional 510(k) Premarket Submission Notification for the Prime™ Adaptive Ultrasonic Scalpel System and Blades

Dear Dr. Nipper:

In accordance with 21 CFR 807, Section E, EndoPrime, Inc., is submitting this Original Traditional Premarket Notification for the Prime™ Adaptive Ultrasonic Scalpel System and Blades.

EndoPrime, Inc. believes this device is substantially equivalent to predicate devices previously cleared by FDA. The primary predicate devices are:

K002981-Ultracision® Harmonic Scalpel®
K990430-Ultracision® HARMONIC Scalpel® Hand Piece
K010898-Ultracision Harmonic Scalpel Blade
K053056-Harmonic Scalpel Blades and Shears
K010300-Sonopet® Surgical Aspirator, Mutoh America Co., LTD. ***(now Stryker)
cited for its blade blue anodized surface only

EndoPrime, Inc. also believes that the device meets the criteria for a Traditional 510(k) in that the Indications for Use and technology are consistent with predicate device of the same genre, whose results of performance testing have demonstrated substantial equivalence.

To conform with the Food and Drug Administration's ("FDA" or the "Agency") August 12, 2005, Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, the principal factors concerning the design and use of the Prime™ Adaptive Ultrasonic Scalpel System are set forth in the following table of FDA questions.

01/13/16

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Page 2 of 3: Original Traditional 510(k) - Prime™ Adaptive Ultrasonic Scalpel System

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 a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	N/A	
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

In accordance with the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), EndoPrime, Inc. has submitted the required small business application fee of (b)(4). A copy of the User Fee Cover Sheet is provided on pages 4 and 5 of this submission, and the Small Business Designation letter is provided on page 6 of this submission.

EndoPrime, Inc. considers all the material provided herein as Privileged and Confidential. We request that the FDA handle this information as such per the provisions detailed in 21 CFR §807.9, §20.61 and § 20.45.

EndoPrime, Inc. has designated Rich Grant, CEO of EndoPrime, Inc., as the contact liaison for this submission. The FDA is authorized to discuss any matters related to this submission with Mr. Grant.

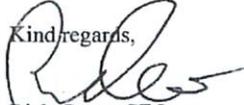
EndoPrime, Inc. is responsible for submission of the enclosed information to the Food and Drug Administration ("FDA" or the "Agency"). In addition, EndoPrime, Inc. is solely responsible for the completeness and accuracy of the submission. If there are any additional questions, please contact my office at (513) 769-1916.

An electronic copy (eCopy) of materials is provided on a CD for your assessment and review. The content of the CD are exactly the same as the paper copy.

Page 3 of 3: Original Traditional 510(k) - Prime™ Adaptive Ultrasonic Scalpel System

Notice of the FDA decision regarding this Premarket Notification should be faxed to my attention at (513-769-1921), and, please forward an electronic copy of the letter to my attention at rich.grant@endoprime.com . If there are any questions, or if additional information is needed during your review, do not hesitate to contact me at rich.grant@endoprime.com, or call me at (513) 769-1916 x11.

Kind regards,



Rich Grant, CEO
EndoPrime, Inc.

Original Traditional 510(k) Notification
For the

**Prime™ Adaptive Ultrasonic Scalpel System
And Blades**

Official Regulatory Contact:
Rich Grant, President of EndoPrime, Inc.
richgrantoh@gmail.com
(513) 769-1916

Submitted by:



EndoPrime, Inc.
4480 Lake Forest Drive, Suite 414
Cincinnati, OH 45242
Phone: 513-769-1916
Fax: 513-769-1921

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I. FORM MEDICAL DEVICE USER FEE

The following information is provided as required by 21 C.F.R. § 807.87 for EndoPrime, Inc.'s Prime™ Adaptive Ultrasonic Scalpel System and Blades Traditional 510 (k) Premarket Notification:

EndoPrime, Inc. is filing this traditional 510(k) Premarket Notification as eligible per regulation number 21 CFR 878.4400-Electrosurgical cutting and coagulation device and accessories/Product Code GEI/LFL.

The Company has remitted the Small Business Designation Medical Device User Fee of (b)(4) concurrent with this submission to the Food and Drug Administration. A copy of the Medical Device User Fee Cover Page is provided on the following page.

EndoPrime, Inc.'s Small Business Decision Number is SBD155035.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Room 4633 Building 66
Silver Spring, MD 20993-0002

EndoPrime Inc.
c/o Richard L Grant/President
4480 Lake Forest Drive, Suite 414
Cincinnati, OH 45242

Re: **Small Business Decision Number: SBD155035**
FDA User Fee Organization Number: **377209**
FY 2015 MDUFA Small Business Qualification
Approval Date: **October 20, 2014**
Expires: September 30, 2015

Dear Richard L Grant,

The Food and Drug Administration (FDA's) Small Business Determination (SBD) team has completed the review of your application eligibility as Small Business under the Medical Device User Fee Act (MDUFA). I am pleased to inform you that your firm qualifies under MDUFA as a Small Business for a reduced or waived fee for medical device submissions made during the fiscal year 2015.

Please include your Small Business Decision Number (see above) whenever you submit a Medical Device User Fee Coversheet (Form FDA 3601). This form is available at: <http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFeeandModernizationAct/ucm155274.htm>
When completing the User Fee Coversheet, you must locate your organization with the organization number **377209** stated in this letter. Your organization number, SBD number, and Business name and address must correspond to the information located above in this letter.

If you are registering as a new user to the User Fee System, please use the organization number assigned to you in this letter to register as an existing organization. If you currently have a User Fee account and the organization number in your profile does not match this organization number, please contact the User Fees Help Desk for further assistance at 301-796-7200 or at userfees@fda.gov.

Your Small Business status expires at the close of business September 30, 2015. FDA will provide information on how to qualify as a Small Business for FY2016 in a FEDERAL REGISTER Notice to be published on or about August 1, 2015. We will also provide this information on our MDUFA website at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

Sincerely,

A handwritten signature in black ink that reads "Geisha Rodriguez".

Geisha Rodriguez
Program Analyst
Premarket Programs Branch
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Site: null

https://userfees.fda.gov/OA_HTML/mdufmaCSocCfItemsPopup.jsp.

Form Approved OMB No. 0960-0046 Expires 04/30/2015 See Instructions for OMB Approval

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover-sheet.html	
1. COMPANY NAME AND ADDRESS (include name, street address, city, state, country, and post office code) ENDOPRIME INC 4480 LAKE FOREST DRIVE CINCINNATI OH 45242 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****4500	2. CONTACT NAME Richard Grant 2.1 E-MAIL ADDRESS richgrantoh@gmail.com 2.2 TELEPHONE NUMBER (include Area code) 513-769-1916 2.3 FACSIMILE (FAX) NUMBER (include Area code) 513-769-1821
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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm) 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"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input checked="" type="checkbox"/> 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: SBD155035	
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)	
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.	
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 361 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	
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.	

Site: null

https://userfees.fda.gov/OA_HTML/mdufmaCScdCfglItemsPopup.jsp

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colsonville Road, COLE-14-14253 Silver Spring, MD 20993-0002 [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)	28-Jan-2015

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

II. SCREENING CHECKLIST FOR TRADITIONAL PREMARKET 510(k) Submission

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm071360.htm>

Title	Related Information	eCopy Section #	Submission Section #	N/A
Title Page		001	1	
MDUFMA Cover Sheet	<u>Medical Device User Fee Cover Sheet</u>	001	6	
Screening Checklist		001	10	
CDRH Premarket Review Submission Cover Sheet	<u>CDRH Premarket Review Submission Cover Sheet</u>	001	13	
Table of Contents		001	2	
Compliance Certificate	FDA Form 3674	001	21	
Certificates of Conformance	FDA Form 3654	001	23	
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	001	62	
Sponsor Authorization Letter				
Indications for Use Statement	<u>Device Advice "Content of a 510(k)" Section D</u>	001	66	
510(k) Summary or 510(k) Statement	<u>Device Advice "Content of a 510(k)" Section E</u>	001	68	
Truthful and Accuracy Statement	<u>Device Advice "Content of a 510(k)" Section G</u>	001	74	
Class III Summary and Certification	<u>Class II Summary and Certification Form</u>			X
Financial Certification or Disclosure Statement	<u>FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators</u> <u>Financial Disclosure by Clinical Investigators-A clinical study was not conducted for this submission.</u>			X
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	<u>Use of Standards in Substantial Equivalence Determinations</u> <u>FDA Standards program</u> <u>Declaration of conformity</u> <u>Required Elements for Declaration of Conformity to Recognized Standard</u>	001	78	
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s"	001	103	

	updated November 17, 2005			
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	001	115	
Substantial Equivalence Discussion	<u>Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3)-</u>	001	139	
Proposed Labeling	IFUs (G6000/System, Scalpels, Transducer) G6000 front/back labels Package Labels- 3 sizes of boxes/color coded/6 sizes of blades Package Labels- Transducer box Package Labels- Adapter	012 015	150	
Sterilization/Shelf Life	Sterilization, packaging, storage (Shelf Life is n/a at this time)	001	154	
Biocompatibility	FDA Blue Book Memo, <u>G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"</u> -Previous (b)(4) testing will be used with agreement. (b)(4) Testing will be used with agreement.	001	169	
Software	<u>Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices</u>	001	175	
Electromagnetic Compatibility/Electrical Safety	<u>CDRH Medical Device Electromagnetic Compatibility Program</u> See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)	001	185	
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	001	191	
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	001	199	
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			X
Attachment 001	510(k) Document	001	Binder	
Attachment 002	(b) Testing	002	Binder	
Attachment 003	US0018 (b)(4) - Blade Animal Pathology	003	Binder	
Attachment 004	US-0002 Bench Test Ultrasonic Blades	004	Binder	
Attachment 005	US0020 Software Validation	005	Binder	
Attachment 006	Risk Analysis & FMEA	006	Binder	
Attachment 007	US0027 Torque Limit Study	007	Binder	
Attachment 008	US031 REV A WRENCH1 prototype torque test	008	Binder	
Attachment 009	US-0029 ADP Validation	009	Binder	
Attachment 010	Prime Generator/Accessory Cart Mechanical Testing	010	Binder	
Attachment 011	US0026 (b)(4) Cleaning and Sterilization Studies	011	Binder	
Attachment 012	EndoPrime IFUs	012	Binder	
Attachment 013	Design Drawings	013	Binder	
Attachment 014	EndoPrime Labels	014	Binder	
Attachment 015	Predicate Labeling	015	Binder	
Attachment 016	US0030 Protocol Transport Testing G6000	016	Binder	

Attachment 017	US016 TRN5 / TRA5 Reliability Report	017	Binder	
Attachment 018	018 (b)(4)	018	Binder	
Attachment 019	(b)(4)	019	Binder	
Attachment 020	DP0001-1 PRS & SDED	020	Binder	
Attachment 021	US-0015 Thermal Map Rev A	021	Binder	
Attachment 022	US-0019 Ultrasonic Scalpel Life Span Study	022	Binder	
Attachment 023	(b)(4) Electronics (b)(4) Power Cord	023	Binder	

III. FDA FORM 3514-CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET		Form Approval OMB No. 9010-0120 Expiration Date: May 31, 2007. See OMB Statement on page 5.	
Date of Submission 01/30/2015	User Fee Payment ID Number	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 checked="" type="checkbox"/> Traditional <input 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	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
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 EndoPrime, Inc.		Establishment Registration Number (if known)	
Division Name (if applicable)		Phone Number (including area code) (513) 769-1916	
Street Address 4480 Lake Forest Drive, Suite 412		FAX Number (including area code) (513) 769-1921	
City Cincinnati	State / Province OH	ZIP/Postal Code 45242	Country USA
Contact Name Richard Grant			
Contact Title CEO		Contact E-mail Address richgrantch@gmail.com	
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site <input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Response to FDA correspondence:	<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 (specify below) <input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packaging <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"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason (specify):					
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"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<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 (specify):					
SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input type="checkbox"/> Other Reason (specify):					

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	GEI	2	LFL	3		4	
5		6		7		8	
						<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	
Information on devices to which substantial equivalence is claimed (if known)							
510(k) Number	Trade or Proprietary or Model Name	Manufacturer					
1	K002981	1	Ultracision® Harmonic Scalpel®				
		1	Ethicon Endo-Surgery, Inc.				
2	K990430	2	Ultracision® HARMONIC Scalpel® Hand Piece				
		2	Ethicon Endo-Surgery				
3	K010898	3	Ultracision Harmonic Scalpel Blade				
		3	Ethicon Endo-Surgery				
4	K053056	4	Harmonic Scalpel Blades and Shears				
		4	Ethicon Endo-Surgery, Inc.				
5	K010309	5	Sonopet Model UST-2001 Ultrasonic Surgical Aspirator				
		5	Mutoh America Co., Ltd.				
6		6					
		6					
SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS							
Common or usual name or classification							
Ultrasonic Surgical Generator and Accessories							
Trade or Proprietary or Model Name for This Device				Model Number			
1	Prime™ Adaptive Ultrasonic Scalpel Generator			1	G6000		
2	Prime™ Reusable Transducer Handpiece			2	TRN5		
3	Prime™ Ultrasonic Scalpel Curved Blades Reusable			3	CB11R, CB37R, CB46R		
4	Omni™ Ultrasonic Scalpel Hook Blades Reusable			4	OHB11R, OHB37R, OHB46R		
5	Prime™ Accesories (Cart, Sterilization Tray, and Connector/Adapter)			5	PCART, TRAY1, ADP1		
FDA document numbers of all prior related submissions (regardless of outcome)							
1	Norte	2		3		4	
7		8		9		10	
11		12		13		14	
Data Included in Submission							
<input checked="" type="checkbox"/> Laboratory Testing <input checked="" type="checkbox"/> Animal Tests <input type="checkbox"/> Human Trials							
SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS							
Product Code	C.F.R. Section (if applicable)			Device Class			
GENUL	21 CFR 878.4400			<input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified			
Classification Panel							
General & Plastic Surgery							
Indications (from labeling)							
The Prime™ Adaptive Ultrasonic Scalpel System is a cutting and coagulation system indicated for open, laparoscopic, and endoscopic surgery in soft tissue where control of hemostasis and thermal spread is desired. The system is indicated for dissection, sealing, transection,otomy creation and transection/coagulation of vessels as indicated for each cutting and coagulation instrument used (consult the instructions for use provided with each instrument). The system can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels.							

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number (if known)	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name EndoPrime, Inc.		Establishment Registration Number	
Division Name (if applicable) N/A		Phone Number (including area code) (513) 769-1915	
Street Address 4480 Lake Forest Drive, Suite 412		FAX Number (including area code) (513) 769-1521	
City Cincinnati		State / Province OH	ZIP/Postal Code Country 45242 USA
Contact Name Rich Grant		Contact Title CEO	Contact E-mail Address richgrant@endoprime.com
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input checked="" type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler

(b)(4)



<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City		State / Province	ZIP/Postal Code Country
Contact Name		Contact Title	Contact E-mail Address

SECTION I UTILIZATION OF STANDARDS					
Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.					
1	Standards No. IEC 60601-1	Standards Organization International Electrotechnical Commission	Standards Title International Standard-Medical Electrical Equipment-General Requirements for Basic Safety and Essential Performance	Version 2007	Date 05/15/2007
2	Standards No. EN 60601-1-2:2007 CISPR 11:2009 +A1	Standards Organization European Standard	Standards Title Medical electrical equipment - Part 2-2: General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests.	Version 2007	Date 09/28/2007
3	Standards No. CAN/CSA-C22 .2 No. 60601-1:08	Standards Organization Canadian Standards Association	Standards Title Medical Electrical Equipment-Part 1-6: General Requirements for Safety-Collateral Standard; General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems. (R2013)	Version 2008	Date 03/14/2013
4	Standards No. ISO 10993-5	Standards Organization International Standards Organization	Standards Title Biological evaluation of medical devices--Part 5: Tests for vitro cytotoxicity	Version 2009	Date 07/30/2009
5	Standards No. ISO 10993-11	Standards Organization International Standards Organization	Standards Title Biological evaluation of medical devices--Part 11: Tests for systemic toxicity	Version 2006	Date 09/29/2006
6	Standards No. ISO 10993-10	Standards Organization International Standards Organization	Standards Title Biological evaluation of medical devices--Part 10: Test for irritation and skin sensitivity	Version 2010	Date 07/27/2010
7	Standards No. ISO 10993-4	Standards Organization International Standards Organization	Standards Title Biological evaluation of medical devices--Part 4: Selection of tests for interaction with blood	Version 2002	Date 11/14/2002
Please include any additional standards to be cited on a separate page.					
<p>Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:</p> <p style="text-align: center;">Food and Drug Administration CDRH (HFZ-342) 9200 Corporate Blvd. Rockville, MD 20850</p> <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</i></p>					

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.					
8	Standards No. ISO 10993-1	Standards Organization International Standards Organization	Standards Title Biocompatibility Evaluation of medical Device Table A.1	Version 2009	Date 10/13/2009
9	Standards No. IEC 61000-4-8	Standards Organization International Electrotechnical Commission	Standards Title Medical Electrical Equipment Part 1-4: General Requirements for Collateral Standard: Programmable Electrical Medical Systems	Version 2010	Date 04/30/2010
10	Standards No. IEC 61000-3-2	Standards Organization International Electrotechnical Commission	Standards Title Electromagnetic compatibility (EMC)-Part 3-2: Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)	Version 2006	Date 05/31/2006
11	Standards No. IEC 61000-3-3	Standards Organization International Electrotechnical Commission	Standards Title Electromagnetic compatibility (EMC)-Part 3-3: Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection.	Version 2008	Date 12/31/2008
12	Standards No. IEC 61000-4-3	Standards Organization International Electrotechnical Commission	Standards Title Electromagnetic compatibility (EMC)-Part 4-3: Limits-Limitation of emission of harmonic currents in low-voltage power supply system for equipment with rated current greater than 16 A	Version 2006	Date 07/31/2006
13	Standards No. IEC 61000-4-4	Standards Organization International Electrotechnical Commission	Standards Title Electromagnetic compatibility (EMC)-Part 4-4: Testing and measurement techniques: Electrical fast transient/burst immunity test	Version 2004	Date 07/08/2004
14	Standards No. IEC 61000-4-5	Standards Organization International Electrotechnical Commission	Standards Title Electromagnetic compatibility (EMC)-Part 4-5: Testing and measurement techniques: Surge immunity test	Version 2005	Date 11/29/2005
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. *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><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>					

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
15	IEC 61000-4-6	International Electrotechnical Commission	Electromagnetic compatibility (EMC) Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields	2003	02/28/2014
16	IEC 61000-4-11	International Electrotechnical Commission	Electromagnetic compatibility (EMC) Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests.	2004	10/26/2004
17	AAMI TIR 30:2011	Association for the Advancement of Medical Instrumentation	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices. Association for Advancement of Medical Instrumentation, Arlington, VA. (CRD249)	2011	05/02/2011
18	EN/ISO 14971	European and International Standards Organization	Risk Management for Medical Device	2007	11/02/2010
19	EN/IEC 62304:2006	International Electrotechnical Commission	Medical device software -- Software life cycle processes	2006	07/16/2010
	Standards No.	Standards Organization	Standards Title	Version	Date
	Standards No.	Standards Organization	Standards Title	Version	Date

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.
DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

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:

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

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.

IV. FDA FORM 3674-Certification of Compliance with ClinicalTrials.gov Data Bank

A completed copy of the Certification of Compliance with ClinicalTrials.gov Data Bank, FDA Form 3674, is provided below.

V. FDA FORM 3654-Certificates of Standards Conformance

Copies of the Certification of Conformance with test standards, FDA Form 3654, are provided below.

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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 checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ CAN/CSA-C22.2 No. 60601-1:08 Medical Electrical Equipment-Part 1-6: General Requirements for Safety-Collateral Standard; Gen. Require, Tests & Guidance for Alarm Systems in Medical Electrical Equipment & Medical Electrical Systems. March 14, 2013		
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	#5-76	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input checked="" 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], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm	

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE CAN/CSA-C22.2 No. 60601-1:08 Medical Electrical Equipment-Part 1-6: General Requirements for Safety-Collateral Standard; Gen. Require, Tests & Guidance for Alarm Systems in Medical Electrical Equipment & Medical Electrical Systems. March 14, 2013		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE See IEC 60601-1:2007	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * No deviation.		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>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 EMAIL ADDRESS BELOW.*</p> <p>The burden time for this collection of information is estimated to average 1 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> <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 Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov</p> </div> <div style="width: 35%; text-align: center;"> <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>		

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s (To be filled in by applicant)		
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TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ IEC 60601-1:2007 International Standard-Medical Electrical Equipment-General Requirements for Basic Safety and Essential Performance, May 15, 2007		
Please answer the following questions		
	Yes	No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number ³	#19-5	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input type="checkbox"/>
Title of guidance:		
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d]. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm	

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE IEC 60601-1:2007 International Standard-Medical Electrical Equipment-General Requirements for Basic Safety and Essential Performance, May 15, 2007		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 4.11 & 5.7	SECTION TITLE Power Input; Humidity Preconditioning treatment	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * No Deviation		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 5.9 & 7.1.2	SECTION TITLE Determination of applied parts & accessible parts; Legibility of markings	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * No Deviation		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 7.1.3	SECTION TITLE Durability of Markings	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * No Deviation		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>† Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>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 EMAIL ADDRESS BELOW.*</p> <p>The burden time for this collection of information is estimated to average 1 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>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov</p> <p style="text-align: right;"><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>		

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Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s (To be filled in by applicant)		
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TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ IEC 60601-1-2-18:2009 (Third Edition) Medical electrical equipment-Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.		
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		#19-1
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input 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?		<input checked="" type="checkbox"/> <input type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?		<input type="checkbox"/> <input checked="" type="checkbox"/>
Title of guidance: _____		
<small> ¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 390d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm </small>		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE IEC 60601-1-2-18:2009 (Third Edition) Medical electrical equipment-Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Part 2-18:	SECTION TITLE Particular requirements for the basic safety and essential performan	CONFORMANCE? <input checked="" 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>		
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Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s (To be filled in by applicant)		
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).		
TYPE OF 510(k) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ IEC 61000-4-8 Medical Electrical Equipment: Part 1-4: General Requirements for Collateral Standard: Programmable Electrical Medical Systems, April 30, 2010		
Please answer the following questions		
Is this standard recognized by FDA ² ?	Yes	No
.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
FDA Recognition number ³	# _____	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
if no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
if yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input type="checkbox"/>
Title of guidance: _____		
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d]. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm	

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE IEC 61000-4-8 Medical Electrical Equipment: Part 1-4: General Requirements for Collateral Standard: Programmable Electrical Medical Systems, April 30, 2010		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 62000-4-8	SECTION TITLE Power frequency magnetic field immunity	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * No deviations		
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>		
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TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ IEC 61000-3-2 Electromagnetic compatibility (EMC) - Part 3-2: Limits for harmonic current emissions (equipment input current ≤ 16 A per phase), May 31, 2006		
Please answer the following questions		Yes No
Is this standard recognized by FDA ² ?		<input type="checkbox"/> <input checked="" type="checkbox"/>
FDA Recognition number ³ #		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 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], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</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</p>	<p>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.</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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</p>	

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE IEC 61000-3-2 Electromagnetic compatibility (EMC) - Part 3-2: Limits for harmonic current emissions (equipment input current ≤ 16 A per phase), May 31, 2006		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Part 3-2	SECTION TITLE Emission in the frequency range up to 30 MHz	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * No deviation		
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.		
<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 EMAIL ADDRESS BELOW.*</p> <p>The burden time for this collection of information is estimated to average 1 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>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov</p> <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>		

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 checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ IEC 61000-3-3 Electromagnetic compatibility (EMC) - Part 3-3: Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16A per phase & not subject to conditional connection, 2008		
Please answer the following questions		
	Yes	No
Is this standard recognized by FDA ² ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
FDA Recognition number ³	# _____	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510(k)?	<input type="checkbox"/>	<input type="checkbox"/>
Title of guidance: _____		
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]	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.	
² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm	⁴ 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	
³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm	⁶ The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm	
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		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE IEC 61000-3-3 Electromagnetic compatibility (EMC) - Part 3-3: Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16A per phase & not subject to conditional connection, 2008		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Part 3-3	SECTION TITLE Voltage changes, voltage fluctuations and flicker on AC mains	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * No deviation		
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>		
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Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s (To be filled in by applicant)		
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TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ IEC 61000-4-3 Electromagnetic compatibility(EMC)-Part 4-3: Limits-Limitation of emission of harmonic currents in low-voltage power supply system for equipment with rated current greater than 16 A, July 31, 2006		
Please answer the following questions		Yes No
Is this standard recognized by FDA ² ?		<input type="checkbox"/> <input checked="" type="checkbox"/>
FDA Recognition number ³ # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? 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: N/A		
<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], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</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</p>	<p>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.</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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</p>	

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE IEC 61000-4-3 Electromagnetic compatibility(EMC)-Part 4-3: Limits-Limitation of emission of harmonic currents in low-voltage power supply system for equipment with rated current greater than 16 A. July 31, 2006		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Part 4-3	SECTION TITLE RF electromagnetic field immunity test	CONFORMANCE? <input checked="" 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>		
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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s (To be filled in by applicant)		
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TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ IEC 61000-4-4 Electromagnetic compatibility (EMC)-Part 4-4: Testing and measurement techniques: Electrical fast transient/burst immunity test, July 8, 2004		
Please answer the following questions		
	Yes	No
Is this standard recognized by FDA ² ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
FDA Recognition number ³	# _____	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input type="checkbox"/>
Title of guidance: <u>N/A</u>		
¹ The formatting convention for the title is: [SOO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm	

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE IEC 61000-4-4 Electromagnetic compatibility (EMC)-Part 4-4: Testing and measurement techniques: Electrical fast transient/burst immunity test, July 8, 2004		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Part 4-4	SECTION TITLE Fast Transients on AC Power Line, Signal Line and Interconnecting Line	CONFORMANCE? <input checked="" 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>		
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TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ IEC 61000-4-5 Electromagnetic compatibility (EMC)-Part-4-5: Testing and measurement techniques: Surge immunity test, November 29, 2005		
Please answer the following questions		
Is this standard recognized by FDA ² ?	Yes	No
.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
FDA Recognition number ³	# _____	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510(k)?	<input type="checkbox"/>	<input type="checkbox"/>
Title of guidance: N/A		
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE IEC 61000-4-5 Electromagnetic compatibility (EMC)-Part-4-5: Testing and measurement techniques: Surge immunity test, November 29, 2005		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Part 4-5	SECTION TITLE *Surges to Power Port, Signal Line and Interconnecting Line	CONFORMANCE? <input checked="" 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>		
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Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s (To be filled in by applicant)		
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TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ IEC 61000-4-6 Electromagnetic compatibility (EMC)-Part-4-6: Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields, February 28, 2014		
Please answer the following questions		Yes No
Is this standard recognized by FDA ² ?		<input type="checkbox"/> <input checked="" type="checkbox"/>
FDA Recognition number ³ # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input 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: N/A		
¹ The formatting convention for the title is: [SDC] [numeric identifier] [title of standard] [date of publication]		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.
² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm		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
³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm		⁶ The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm
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		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE IEC 61000-4-6 Electromagnetic compatibility (EMC)-Part-4-6: Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields, February 28, 2014		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Part 4-6	SECTION TITLE Injected Current into AC Power Line, Signal Line and Interconnecting Line	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "Justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p><small>This section applies only to requirements of the Paperwork Reduction Act of 1995.</small></p> <p>*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*</p> <p>The burden time for this collection of information is estimated to average 1 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> <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 Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov</p> </div> <div style="width: 35%; font-style: italic;"> <p><small>"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."</small></p> </div> </div>		

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
 Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
 (To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 61000-4-11 Electromagnetic compatibility (EMC)-Part-4-11: Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests, October 26, 2004

Please answer the following questions Yes No

Is this standard recognized by FDA ²? Yes No

FDA Recognition number ³ # _____

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? Yes No

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? Yes No
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? Yes No

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

Does this standard include more than one option or selection of tests? Yes No
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? Yes No
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? Yes No

Were deviations or adaptations made beyond what is specified in the FDA SIS? Yes No
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? Yes No
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard? Yes No
 If yes, was the guidance document followed in preparation of this 510k? Yes No

Title of guidance: N/A

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>
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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE IEC 61000-4-11 Electromagnetic compatibility (EMC)-Part-4-11: Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests, October 26, 2004		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Part 4-11	SECTION TITLE Voltage dips and interruptions to AC Power Port	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>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 EMAIL ADDRESS BELOW.*</p> <p>The burden time for this collection of information is estimated to average 1 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>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov</p> <p style="text-align: right;"><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>		

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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 checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ ISO 10993-1:2009(E) Biocompatibility Evaluation of medical device Table A-1, June 4, 2010		
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)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Title of guidance; FDA Guidance Document: Use of International Standard ISO-10993, "Biological Evaluation of Medical		
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] (date of publication) ² Authority [21 U.S.C. 360c], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm	

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993-1:2009(E) Biocompatibility Evaluation of medical device Table A-1, June 4, 2010		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>† Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>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 EMAIL ADDRESS BELOW.*</p> <p>The burden time for this collection of information is estimated to average 1 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> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov</p> </div> <div style="width: 45%; 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>		

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Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s (To be filled in by applicant)		
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).		
TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ ISO 10993-5-2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro Cytotoxicity (June 7, 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	#2-153	
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?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input checked="" 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], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm	

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993-5-2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro Cytotoxicity (June 7, 2009)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 5A	SECTION TITLE Test Specific Considerations-Cytotoxicity	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 5B	SECTION TITLE Test Specific Considerations Sensitizations	CONFORMANCE? <input checked="" 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>		
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Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s (To be filled in by applicant)		
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TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ ISO 10993-10 Biological evaluation of medical devices - Part 10: Test for irritation and skin sensitivity, July 27, 2010		
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		#2-173
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input 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 checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>
Title of guidance: _____		
<small> ¹ The formatting convention for the title is: [SDC] (numeric identifier) [title of standard] [date of publication] ² Authority [21 U.S.C. 360c], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm </small>		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993-10 Biological evaluation of medical devices - Part 10: Test for irritation and skin sensitivity, July 27, 2010		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" 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>		
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Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s (To be filled in by applicant)		
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).		
TYPE OF 510(k) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity, September 29, 2006		
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		#2-118
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510(k)?		<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>
Title of guidance: _____		
<small> ¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm </small>		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity, September 29, 2006		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>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 EMAIL ADDRESS BELOW.*</p> <p>The burden time for this collection of information is estimated to average 1 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>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov</p> <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>		

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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 checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ ISO 10993-4 Biological evaluation of medical devices - Part 4: Selection of tests for interaction with blood, November 14, 2002		
Please answer the following questions		
	Yes	No
Is this standard recognized by FDA ² ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
FDA Recognition number ³	# _____	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?		
	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?		
	<input type="checkbox"/>	<input type="checkbox"/>
Title of guidance: N/A		
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm	

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993-4 Biological evaluation of medical devices - Part 4: Selection of tests for interaction with blood, November 14, 2002		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" 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		
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SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	
STANDARD TITLE ¹ AAMI TIR30:2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices. Association for Advancement of Medical Instrumentation, Arlington, VA. (CRD249), May 2, 2011	
Please answer the following questions	
	Yes No
Is this standard recognized by FDA ² ?	<input type="checkbox"/> <input checked="" type="checkbox"/>
FDA Recognition number ³	# _____
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input checked="" type="checkbox"/> <input type="checkbox"/>
If no, complete a summary report table.	
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/> <input type="checkbox"/>
If no, include the results of testing in the 510(k).	
Does this standard include more than one option or selection of tests?	<input checked="" type="checkbox"/> <input type="checkbox"/>
If yes, report options selected in the summary report table.	
Were there any deviations or adaptations made in the use of the standard?.....	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/> <input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?.....	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.	
Were there any exclusions from the standard?	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.	
Is there an FDA guidance ⁶ that is associated with this standard?.....	<input checked="" type="checkbox"/> <input type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Title of guidance: FDA 2011 Draft Guide for Industry & FDA Staff-Processing/Reprocessing Medical Devices in HC Setting	
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d]. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" 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
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SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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DESCRIPTION		
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TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	
STANDARD TITLE ¹ EN/ISO 14971 Risk Management for Medical Device, November 2, 2010	
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	#5-40
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input type="checkbox"/> <input checked="" type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input checked="" type="checkbox"/> <input type="checkbox"/>
If no, complete a summary report table.	
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/> <input type="checkbox"/>
If no, include the results of testing in the 510(k).	
Does this standard include more than one option or selection of tests?	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, report options selected in the summary report table.	
Were there any deviations or adaptations made in the use of the standard?	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/> <input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.	
Were there any exclusions from the standard?	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.	
Is there an FDA guidance ⁶ that is associated with this standard?	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/> <input type="checkbox"/>
Title of guidance: N/A	
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d]. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE EN/ISO 14971 Risk Management for Medical Device, November 2, 2010		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" 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 *		
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TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ EN/IEC 62304:2006 Medical device software -- Software life cycle processes, July 16, 2010		
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		# 13-32
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		<input type="checkbox"/> <input checked="" type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard?..... If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input 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 checked="" type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
Title of guidance: <u>Guidance for the Content of Premarket submissions for Software Contained in Medical Devices-Guidance</u>		
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]		address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
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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 * 		
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1. Cover Letter



4480 Lake Forest Dr.
Suite 414
Blue Ash, Ohio 45242

January 31, 2015

510(k) Document Control Center (WO66-G609)
U.S. Food and Drug Administration
General Surgery Devices Branch II
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attention: Joshua Nipper, M.D., Branch Chief

Re: Original Traditional 510(k) Premarket Submission Notification for the **Prime™ Adaptive Ultrasonic Scalpel System and Blades**

Dear Dr. Nipper:

In accordance with 21 CFR 807, Section E, EndoPrime, Inc., is submitting this Original Traditional Premarket Notification for the Prime™ Adaptive Ultrasonic Scalpel System and Blades.

EndoPrime, Inc. believes this device is substantially equivalent to predicate devices previously cleared by FDA. The primary predicate devices are:

K002981-Ultracision® Harmonic Scalpel®
K990430-Ultracision® HARMONIC Scalpel® Hand Piece
K010898-Ultracision Harmonic Scalpel Blade
K053056-Harmonic Scalpel Blades and Shears
K010300-Sonopet® Surgical Aspirator, Mutoh America Co., LTD. ***(now Stryker)
(b)(4)

EndoPrime, Inc. also believes that the device meets the criteria for a Traditional 510(k) in that the Indications for Use and technology are consistent with predicate device of the same genre, whose results of performance testing have demonstrated substantial equivalence.

To conform with the Food and Drug Administration's ("FDA" or the "Agency") August 12, 2005, Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, the principal factors concerning the design and use of the Prime™ Adaptive Ultrasonic Scalpel System are set forth in the following table of FDA questions.

Page 2 of 3: Original Traditional 510(k) - Prime™ Adaptive Ultrasonic Scalpel System

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 a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	N/A	
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

In accordance with the Food and Drug Administration Amendments Act of 2007 (“FDAAA”), EndoPrime, Inc. has submitted the required small business application fee of (b)(4). A copy of the User Fee Cover Sheet is provided on pages 4 and 5 of this submission, and the Small Business Designation letter is provided on page 6 of this submission.

EndoPrime, Inc. considers all the material provided herein as Privileged and Confidential. We request that the FDA handle this information as such per the provisions detailed in 21 CFR §807.9, §20.61 and § 20.45.

EndoPrime, Inc. has designated Rich Grant, CEO of EndoPrime, Inc., as the contact liaison for this submission. The FDA is authorized to discuss any matters related to this submission with Mr. Grant.

EndoPrime, Inc. is responsible for submission of the enclosed information to the Food and Drug Administration (“FDA” or the “Agency”). In addition, EndoPrime, Inc. is solely responsible for the completeness and accuracy of the submission. If there are any additional questions, please contact my office at (513) 769-1916.

An electronic copy (eCopy) of materials is provided on a CD for your assessment and review. The content of the CD are exactly the same as the paper copy.

Page 3 of 3: Original Traditional 510(k) - Prime™ Adaptive Ultrasonic Scalpel System

Notice of the FDA decision regarding this Premarket Notification should be faxed to my attention at (513-769-1921), and, please forward an electronic copy of the letter to my attention at rich.grant@endoprime.com . If there are any questions, or if additional information is needed during your review, do not hesitate to contact me at rich.grant@endoprime.com, or call me at (513) 769-1916 x11.

Kind regards,

A handwritten signature in black ink, appearing to read 'Rich Grant', with a stylized flourish at the end.

Rich Grant, CEO
EndoPrime, Inc.

2. FDA FORM 3881-INDICATIONS FOR USE STATEMENT

The Company's Indications for Use Statement for Prime™ Adaptive Ultrasonic Scalpel System and Blades is provided on the following page.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)
Pending

Device Name
Prime™ Adaptive Ultrasonic Scalpel System

Indications for Use (Describe)
The Prime™ Adaptive Ultrasonic Scalpel System is a cutting and coagulation system indicated for open, laparoscopic, and endoscopic surgery in soft tissue where control of hemostasis and thermal spread is desired. The system is indicated for dissection, sealing, transection,otomy creation and transection/coagulation of vessels as indicated for each cutting and coagulation instrument used (consult the instructions for use provided with each instrument). The system can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels.

Type of Use (Select one or both, as applicable)

- Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours 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:

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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 number.

3. 510(K) SUMMARY

The Company's 510(k) Summary is provided on the following page.

510(k) Summary

Date Prepared: January 31, 2015
Submitter Contact: Rich Grant, CEO
EndoPrime, Inc.
4480 Lake Forest Drive, Suite 414
Cincinnati, OH 45242
513-769-1916

Regulatory Contact: Rich Grant
EndoPrime, Inc.
4480 Lake Forest Drive, Suite 414
Cincinnati, OH 45242
513-769-1916

Trade Name: Prime™ Adaptive Ultrasonic Scalpel System and Blades
Common or Usual Name: Electrosurgical Cutting and Coagulating Device
Product Class: Class II
Classification: Electrosurgical Cutting & Coagulation & Accessories
Product Codes: GEI
Panel Code: General & Plastic Surgery/79
Regulation Standard: 21 CFR 878.4400

AND

Trade Name: Prime™ Ultrasonic Scalpel Reusable Blades
Prime™ Reusable Transducer Handpiece
Prime™ Adaptive Ultrasonic Scalpel Generator
Common or Usual Name: Ultrasonic Surgical Instruments
Product Class: Class II
Classification: Instrument, Ultrasonic Surgical
Product Codes: GEI/LFL
Panel Code: General & Plastic Surgery
Regulation Standard: Unclassified

Reason for this Submission: This Traditional 510(k) involves one medical device system compiled of three individual medical device components.

Indications for Use:

The **Prime™ Adaptive Ultrasonic Scalpel System** is a cutting and coagulation system indicated for open, laparoscopic, and endoscopic surgery in soft tissue where control of hemostasis and thermal spread is desired. The system is indicated for dissection, sealing, transection,otomy creation and transection/coagulation of vessels as indicated for each cutting and coagulation instrument used (consult the instructions for use provide with each instrument). The system can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels.

Device Descriptions:

The **Prime™ Adaptive Ultrasonic Scalpel System** has three major components: Generator (with footswitch), Transducer Handpiece and instruments (or blades). The **Prime™ 6000 Generator** provides input/output control and operation interface to automatically adapt the ultrasonic power output for the tissue load encountered. The device system is compliant with the following consensus standards:

Performance Standards:	
IEC 60601-1 2005 + CORR. 1 (2006) + CORR. (2007)	International Standard-Medical Electrical Equipment-General Requirements for Basic Safety and Essential Performance
CAN/CSA-C22.2 No. 60601-1:08	Medical Electrical Equipment-Part 1-6: General Requirements for Safety-Collateral Standard; General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems.
EN 60601-1-2:2007 CISPR 11:2009+A1	Medical Electrical Equipment-Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility-Requirements and Tests.
IEC 60601-1-2-18:2009 (Third Edition)	Medical electrical equipment-Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.
IEC 61000-4-8:2010	Medical Electrical Equipment: Part 1-4: General Requirements for Collateral Standard: Programmable Electrical Medical Systems.
IEC 61000-3-2:2006 +A1 +A2	Electromagnetic compatibility (EMC)-Part 3-2: Limits for harmonic current emissions (equipment input current ≤ 16 A per phase).
IEC 61000-3-3:2008	Electromagnetic compatibility (EMC)-Part 3-3: Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection.
IEC 61000-4-3:2006 + A1:2007 + A2:2010	Electromagnetic compatibility (EMC)-Part 4-3: Limits-Limitation of emission of harmonic currents in low-voltage power supply systems for equipment with rated current greater than 16 A.
IEC 61000-4-4:2004+A1:2010	Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrical fast transient/burst immunity test.
IEC 61000-4-5:2005	Electromagnetic compatibility (EMC). Testing and measurement techniques. Surge immunity test.
IEC 61000-4-6:2003	Electromagnetic compatibility (EMC). Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields

IEC 61000-4-11:2004	Electromagnetic compatibility (EMC). Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests.
ISO 10993-1:2009/AC2010	Biocompatibility Evaluation of medical Device Table A.1
ISO 10993-5:2009	Biological evaluation of medical devices--Part 5: Tests for vitro cytotoxicity
ISO 10993-10:2009	Biological evaluation of medical devices--Part 10: Test for irritation and skin sensitivity
ISO 10993-11:2009	Biological evaluation of medical devices--Part 11: Tests for systemic toxicity
ISO 10993-4:2009	Biological evaluation of medical devices—Part 4: Test for Hemocompatibility
AAMI TIR30:2011	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices. Association for Advancement of Medical Instrumentation, Arlington, VA. (CRD249)
EN/ISO 14971:2012	Risk Management for Medical Device
EN/IEC 62304:2006	Medical device software—Software life cycle processes

Prime™ Adaptive Ultrasonic Scalpel System and Blades family of products consist of:

Prime™ G6000 Generator provides operation interface display, device condition monitoring and Input/Output control. The generator provides electrical energy output to the transducer, which is controlled by activating the footswitch. The **Prime™ G6000 Generator** is also validated to operate with hand switched devices and hand switched enabled transducer hand pieces. A built-in, automatic pre-check function verifies proper connection and operation of the system during startup and continuously monitors the system and instruments. Variable and Maximum (or Full) power levels (1 through 5) are displayed on the front panel and can be selected by pressing the VAR or FULL footswitch pedal (or if available the hand switch). The Variable Power setting can be selected throughout the procedure to provide corresponding energy outputs with the interacting instrument. Audible and visual alarms assist with identifying anomalies, error, and failures including generator, instrument or transducer that are at the end of their useful life. A Standby button is available to pause the system to avoid accidental activation when not in use, or conduct manual system checks and diagnostics.

Prime™ Ultrasonic Scalpel Reusable Blades vibrate ultrasonically, which enables its cutting ability. The same vibration seals small vessels ($\leq 2\text{mm}$) with coagulated blood and tissue proteins by producing local heating of tissue. Homeostasis occurs when tissue couples with the blade. The **Prime™ Ultrasonic Scalpel Reusable Blades** are designed for use with a transducer and a generator system as part of the **Prime™ Adaptive Ultrasonic Scalpel System** and family of products; these products are compatible with a limited number of other manufacturer's systems. The system instruments can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels with the

advantages of limited heat/smoke generation and the lack of current flow through the patient. The blade instruments are provided with a reusable Torque Wrench to assure proper tightness when attaching the blade to the transducer. The generator will automatically check the tightness to assure proper function.

The **Prime™ Reusable Transducer Handpiece** cooperates with the **Prime™ Adaptive Ultrasonic Scalpel Blades** as a cutting and coagulation instrument. The **Prime™ Reusable Transducer Handpiece** is designed to convert electrical energy from the generator to mechanical motion of the instrument blades. When the transducer is used in conjunction with the **Prime™ Adaptive Ultrasonic Scalpel System**, the transducer provides ultrasonic vibration, which enables the blade's cutting ability. **Prime™ Adaptive Ultrasonic Scalpel System and Blades** family of products is compatible with a limited number of other manufacturer's systems.

Prime™ Adaptive Ultrasonic Scalpel System products are compatible with a limited number of other predicate systems.

Predicate Device(s):

K002981-Ultracision® Harmonic Scalpel®, Ethicon Endo-Surgery, Inc.

K990430-Ultracision® HARMONIC Scalpel® Hand Piece, Ethicon Endo-Surgery

K010898-Ultracision Harmonic Scalpel Blade, Ethicon Endo-Surgery

K053056-Harmonic Scalpel Blades and Shears, Ethicon Endo-Surgery, Inc.

- **K010309**-Sonopet® Surgical Aspirator, Mutoh America CO., LTD. ***(now Stryker) cited for its blade blue anodized surface only.

Technological Characteristics:

The **Prime™ Adaptive Ultrasonic Scalpel System** technological characteristics are substantially equivalent to the predicated devices including automatically adapting the ultrasonic power output for the tissue load encountered to provide consistent vibration in differing loads and tissue thickness. The predicate device scalpel blades were predicated on reusable scalpel blades and the **Prime™ Ultrasonic Scalpel Reusable Blades** are designed to function similar to the predicate devices but are provided non-sterile and validated for disassembly, cleaning and sterilization. Another feature of the **Prime™ Adaptive Ultrasonic Scalpel System** is the ability to disconnect the cable at the transducer handpiece. This feature allows the surgical scrub technician to quickly replace the transducer handpiece and/or ultrasonic blades without contact with the non-sterile surface of the generator or assistance from others. The cable disconnect was designed as a convenience feature similar to the ability to disconnect at the generator. The **Prime™ Ultrasonic Scalpel Reusable Blades** are designed similar to the predicate blades but have slightly different end effector designs. The **Prime™ Ultrasonic Curved Blades** have a compact design to improve access in narrow, delicate anatomy. The **Omni™ Ultrasonic Hook Blades** are curved for better visibility with a dual hook design to permit easier change of direction without full rotation. These technological improvements will not affect the overall device intended use, performance characteristics, substantial equivalence to the predicate, or raise any new issues regarding safety or efficacy.

Conclusion:

EndoPrime, Inc. concludes that the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** family of products, is substantially equivalent to the predicate devices, and raises no new questions of safety or effectiveness.

4. Truthful and Accurate Statement

EndoPrime, Inc.'s signed Truthful and Accurate Statement is included on the following page.



Premarket Notification Truthful and Accurate Statement

[As Required by 21 C.F.R. 807.87(k)]

I certify that, in my capacity as CEO of EndoPrime, Inc, 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.

A handwritten signature in blue ink, appearing to read 'Rich Grant'.

Rich Grant, CEO
EndoPrime, Inc.

Date 1/31/2015

5. Class III Summary and Certification

A class III Summary and Certification is not applicable to the Prime™ Adaptive Ultrasonic Scalpel System and Blades, which is a Class II device.

6. Financial Certification or Disclosure Statement

The requirement for financial certification or disclosure as described in 21 CFR §807.87(i) does not apply to this submission because no clinical information is being submitted.

7. Declarations of Conformity and Summary Reports

A risk analysis and a Declaration of Conformity are found on the following pages.



Declaration of Conformity

Traditional 510(k)-Prime™ Adaptive Ultrasonic Scalpel System

All verification and validation activities for the Prime™ Adaptive Ultrasonic Scalpel System was performed by the designated individuals in EndoPrime, Inc. or (b)(4) (b)(4). The results of these activities demonstrated that the device meets or exceeds the predetermined acceptance criteria.

EndoPrime, Inc. is in conformance with the Design Control requirements as stated in 21 C.F.R. Part 820.30.

A handwritten signature in black ink, appearing to read 'Rich Grant'.

Rich Grant, CEO
EndoPrime, Inc.

1/30/15
Date

8. Executive Summary

8.1 Indications for Use

The **Prime™ Adaptive Ultrasonic Scalpel System** is a cutting and coagulation system indicated for open, laparoscopic and endoscopic surgery in soft tissue where control of hemostasis and thermal spread is desired. The system is indicated for dissection, sealing, transection,otomy creation and transection/coagulation of vessels as indicated for each cutting and coagulation instrument used (consult the instructions for use provided with each instrument). The system can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels.

8.2 Abbreviated Description

This Traditional 510(k) Premarket Submission is submitted for the **Prime™ Adaptive Ultrasonic Scalpel System and Blades**, which consist of:

- 1) Generator,
- 2) Transducer,
- 3) Blades or instruments, and
- 4) Accessories.

The following is a table of the components to be considered in this 510(k) submission:

Table 8-1: Prime™ Adaptive Ultrasonic Scalpel System and Blades Components

Description and Product Delivery	Model
Prime™ Adaptive Ultrasonic Scalpel Generator. Provided with Foot Switch, Power Cable and Instructions for Use	G6000
Prime™ Reusable Transducer Handpiece, for foot switch activation only. Provided with Test Tip, Cable and Instructions for Use	TRN5
Prime™ Ultrasonic Scalpel Reusable Blades – Each is Provided with a Torque Wrench and Instructions for Use:	
Prime™ Ultrasonic Curved Blade 5mm 11cm Length, Reusable	CB11R
Prime™ Ultrasonic Curved Blade 5mm 37cm Length, Reusable	CB37R
Prime™ Ultrasonic Curved Blade 5mm 46cm Length, Reusable	CB46R
Omni™ Ultrasonic Hook Blade 5mm 11cm Length, Reusable	OHB11R
Omni™ Ultrasonic Hook Blade 5mm 37cm Length, Reusable	OHB37R
Omni™ Ultrasonic Hook Blade 5mm 46cm Length, Reusable	OHB46R
Accessories: Provide Separately with Instructions for Use	
Prime™ Adaptive Ultrasonic Scalpel Sterilization Tray	TRAY1
Prime™ ADP Connector/Adaptor (for EES Generator GEN300 & G11)	ADP1
Prime™ Cart Generator/Accessory Cart	PCART

The Indications for Use are applicable to all of the components listed in Table 8-1.

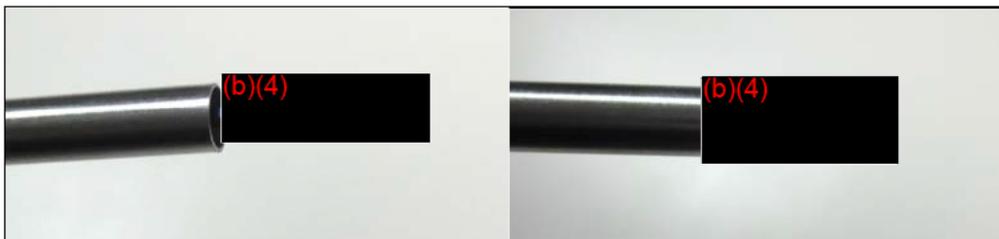
8.3 Technological Characteristics Summary

Prime™ Adaptive Ultrasonic Scalpel System and Blades are equivalent in technology to the predicate devices with regard to intended use of the device, materials of construction, safety and function. New and different technological characteristics not available in the predicate device include:

- (a) Hook blade with curved end effector to aid in visibility

- (b) Curved blade with compact end effector to aid in access
- (c) Transducer detachable cable to aid in changeover within the sterile field
- (d) (b)(4)
- (b)(4)

Figure 8-1: Photograph of the Curved and Hook Blades



Technological characteristics not available in the current version of scalpel blade predicate devices, but previously available in a predicates to the current predicate device (K010309-also listed in the predicate comparison) include:

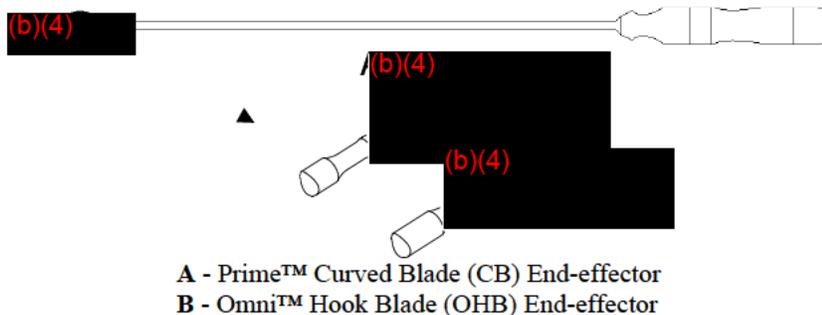
- (a) Blades are reusable rather than disposable
- (b) Sheath and blade are detachable for cleaning

These characteristics are further discussed later in this section. The introduction of these new and previously utilized features in the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** will not affect the overall device description or intended use, nor raise new questions of safety, or effectiveness, and were integrated as additional features to make the system operate more efficiently.

8.4 Prime™ Ultrasonic Scalpel Reusable Blades Summary

The blades are offered in two end effector configurations: **Prime™ Ultrasonic Curved Blades** and **Omni™ Ultrasonic Hook Blades** (see Figures 8-2 and 8-3)

Figure 8-2: Blade Assembly and End Effectors

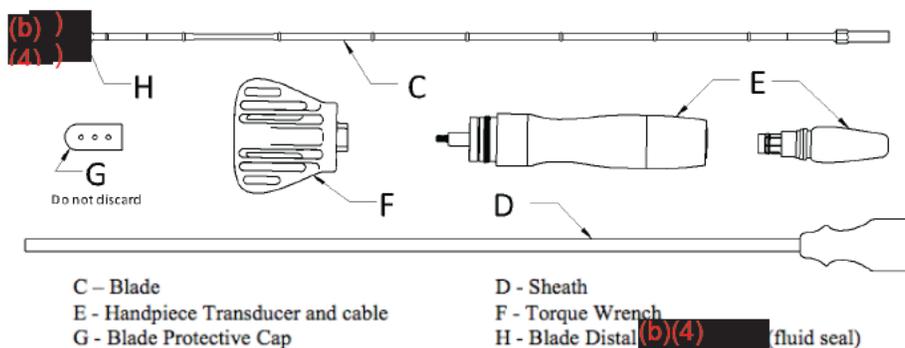


The curved blade has a compact design to improve access in narrow, delicate anatomy. The hook blade has a curved hook, as opposed to the predicate c-shaped hook, for better visibility. The hook blade has a (b)(4) (b)(4) Comparison pictures of the Prime™ and predicate blades are provided in this submission in Section 010: Substantial Equivalence.

There are two components of the scalpel system that come in contact with the patient tissue: the sheath and the blade. The sheath is a protective shield that slides over the blade device and remains in place during the surgical procedure. Both the blade and sheath are manufactured of materials that are well established and have a history of use in instrumentation for many years (See Section 13-Biocompatibility of this submission). The **Prime™ Ultrasonic Scalpel Reusable Blades** are secured to the transducer utilizing the reusable **Prime™ Torque Wrench** supplied with the scalpel blade assembly. The sheath is secured to the transducer handpiece by hand tightening to the transducer handpiece body. In addition, the blades are offered in three different lengths or a total of six options to provide the surgeon with a selection of blades for open, endoscopic, and barbaric procedures. Both the curved and hook scalpel blades work with the same technology and are equivalent to the predicate devices in providing a variety of cutting options for the user.

A reusable torque wrench is provided with the scalpel system (See Figure 8-3) and is used to secure the transducer hand piece to the blade (See Figure 8-2). The torque wrench is removed from the device once the scalpel is secured. The **Prime™ Torque Wrench** is validated for the same sterilization process of the instruments. Figure 8-3 is an illustration of the disassembled scalpel blade with the torque wrench, transducer handpiece and the cable (only the connector of the cable is illustrated):

Figure 8-3: Component Nomenclature Illustration



Current predicate device ultrasonic scalpel blades are validated for single patient use (SPU), and are recommended for disposal after use; however, predicates to those current blades are reusable. Materials of construction in the **Prime™ Ultrasonic Curved Blades** and **Omni™ Ultrasonic Hook Blades** have been validated for multiple reuse, cleaning, and steam sterilization per AAMI TIR30:2011

8.5 Prime™ Reusable Transducer Handpiece Summary

The **Prime™ Reusable Transducer Handpiece** converts electrical energy supplied by the generator to mechanical motion. The transducer houses several major components that generate, amplify and deliver ultrasonic energy to the scalpel end-effectors. The generator applies power to the transducer's piezoelectric material causing it to expand and contract to produce longitudinal motion.

The transducer is packaged with a Test Tip, Cable and Instructions for Use. The cable provided with the **Prime™ Reusable Transducer Handpiece** is detachable. The transducer hand piece detachable connection is designed as a convenience and will not affect the overall device description or intended use, and it raises no new questions of safety or effectiveness. The technological advantage is to allow the scrub nurse or surgeon to simply disconnect and reconnect the cable if a blade change is required rather than directing the circulating nurse to switch the generator to standby mode and then switching back to normal operating mode after changing blades. When the connector cable is re-connected, power is restored.

8.6 Prime™ G6000 Generator Summary

The **Prime™ G6000 Generator** controls electrical energy and therefore the motion or vibration generated by transducer. The user may set the generator's variable (VAR) power level from Level 1 to 5, with Level 5 power setting being the maximum (FULL) power. A higher generator power level is intended for greater tissue cutting speed and a lower generator power level is intended for greater coagulation capability.

Figure 8.4: Front Panel of Prime™ G6000 Generator Power Settings



The **Prime™ G6000 Generator** is the primary component used to power the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** and it is not a patient contacting device. A footswitch, power cord, and Instructions for Use are provided with the **Prime™ G6000 Generator**.

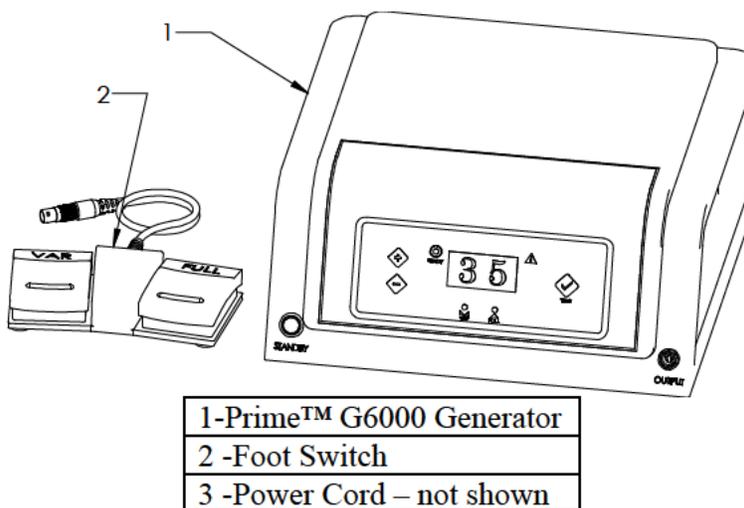
The **Prime™ G6000 Generator** was tested by (b)(4) for EMC reliability and safety in accordance with applicable standards (See Attachment 002) and meets the definition of an Energized Endotherapy Device, although it operates well below 200 kHz (50/60 kHz max) and is not considered a High Frequency Endotherapy Device. The **Prime™ G6000 Generator** consists of an isolation transformer, power transformer, switching power supply, main control board, a footswitch, and a hospital grade line cord (green dot-Type CF applied part).

The generator is designed to allow selective control of activation and power level from the footswitch provided with the **Prime™ G6000 Generator** (Ref: Section 9-Device Description). The **Prime™ G6000 Generator** is also validated for hand switch control (i.e. Hand Activation) when used with a hand activation enabled transducer/handpiece and hand switch enabled instrument. The **Prime™ Reusable Transducer Handpiece** is not hand activation enabled;

however, the generator is validated for use with hand activation enabled instruments and transducers from other manufactures (See Attachments 003, :US0018 (b)(4) -Acute Evaluation (b)(4), which includes cross product testing; Attachment 005-Software Validation which includes hand activation, and Attachment 009-US0029 ADP Connector/Adaptor Validation). The footswitch or a hand switch allows the user to select the VAR (selected variable power level) or FULL (maximum power level) by selecting the corresponding VAR or FULL switch. The VAR setting is preselected using the (+) and (-) buttons on the front face of the **Prime™ G6000 Generator**. A technological comparison between the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** and the predicate devices is provided in Table 10.2 on page 142.

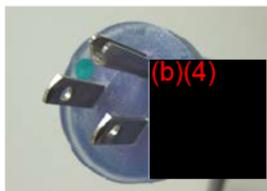
In addition, the **Prime™ G6000 Generator** provides operation interface display, device condition monitoring and input/output control. Features of the **Prime™ G6000 Generator** include audible and visual alarms, indicators, and a Standby Mode button to pause the system during use to allow for adjustments, instrument changeovers, and to assure the instrument will not be accidentally activated. The components are depicted in Figure 8.5:

Figure 8.5: Prime™ G6000 Generator



The Power Cord (or Line Cord) for the **Prime™ G6000 Generator** complies with IEC 60320/NEMA 5-15P - Type CF – Hospital Grade cord approximately 15 feet in length (4.5 Meters) and is depicted in Figure 8-6. The cord is OEM manufactured by (b)(4) and the power cord is CE Marked and UL Certified. The following is an illustration of the cord verifying it is UL green dot certified:

Figure 8-6: G6000 Power Cable



The foot switch is provided with a cord for connection with the back panel of the generator. Foot Switch has two pedals (“VAR” and “FULL”) to select Level 5 or the level selected by the

user. The **Prime™ G6000 Generator**, footswitch and Power Cable are intended to have no direct or indirect contact with the patient's body or tissue.

8.7 Accessories Summary

8.7.1 Prime™ Ultrasonic Adaptive Scalpel Sterilization Tray and Instrument Set

A sterilization tray is provided for sterilization of the reusable device instrument sets. The tray is designed specifically for the reusable Prime™ products that require sterilization. Figure 8-7 is an illustration of the sterilization tray, containing the two full sets of Prime™ instruments. The tray was validated for two full sets of instruments. Please refer to Section 016-Performance Testing for more information on testing.

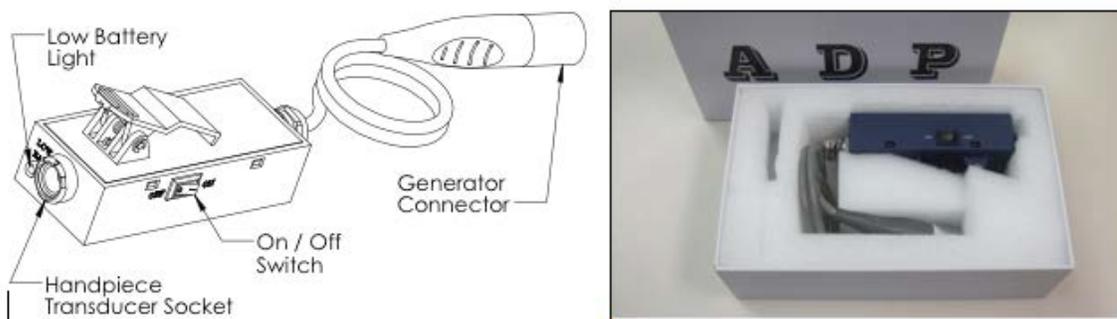
Figure 8-7: Prime™ Sterilization Tray and Instrument Sets



8.7.2 Prime™ ADP Connector/Adapter Summary

The **Prime™ ADP Connector/Adapter** is provided for connecting the hand piece transducer to generators manufactured by another manufacture and is available upon requests to EndoPrime Customer Service. Performance testing was conduct by EndoPrime Inc. (See Attachment 009-US0029 ADP Validation).

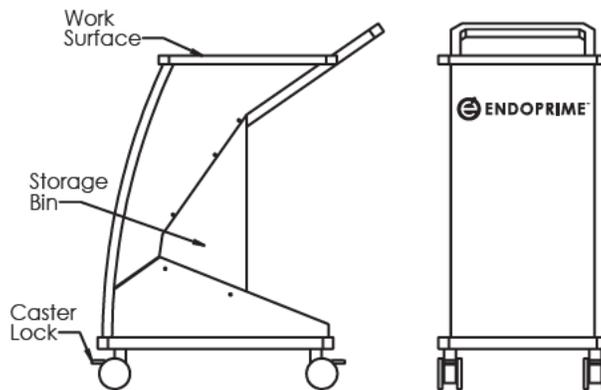
Figure 8-8: Prime™ ADP Connector Adapter



8.7.3 Prime™ Generator/Accessory Cart Summary

An optional accessory to the Prime™ ultrasonic family of devices is a generator/accessory cart, designed specifically for the Prime™ G6000 Generator (see Figure 8-9). The cart was tested for (b)(4) for more information regarding cart safety, please refer to Section 16-Performance Testing.

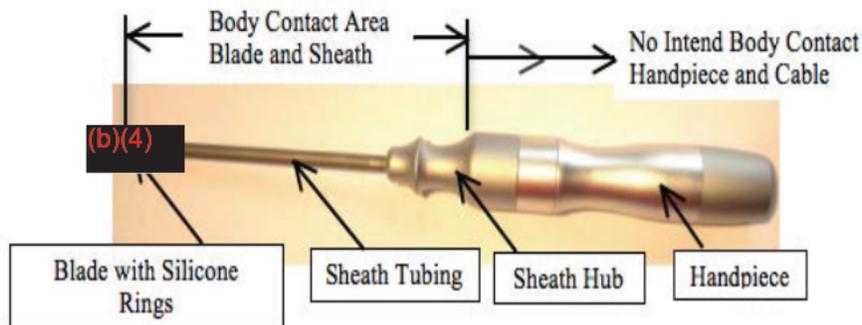
Figure 8-9: Prime™ Generator/Accessory Cart



8.8 Materials, Processes and Biocompatibility Summary

Figure 8-10 illustrates the portions of the Prime™ Adaptive Ultrasonic Scalpel System and Blades that are intended to have limited body contact:

Figure 8-10: Device Intended Tissue Contact Area



FDA's Guidance Document: *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"* dated April 23, 2013 was used to categorize the Prime™ Ultrasonic Scalpel Reusable Blades as a "Surface Device" that contacts mucosal and breached surfaces for less than 24 hours. The Prime™ Adaptive Ultrasonic Scalpel and Blades family of products, or any portion of the products which may come in contact with the patient, are made of implantable grade or medical grade materials. Contact includes Mucosal Membranes, Breached Surfaces, and blood vessels; however, contact is not intended to occur

directly or indirectly with circulating blood or within a blood or gas path. The following is a detailed list of the blade component sets, and materials of construction (see Table-8-2).

Table 8-2: Prime™ Adaptive Ultrasonic Scalpel and Blades Materials

Device Name	Model Number	Material(s)	Process (Process Material)
Prime™ Ultrasonic Curved Blade: 5mm 11cm Length 5mm 37cm Length 5mm 46cm Length	CB11R CB36R CB42R	(b)(4)	
Omni™ Ultrasonic Hook Blade: 5mm 11cm Length 5mm 37cm Length 5mm 46cm Length	HB11R HB36R HB42R		

Both the curved and hook blades, including the detachable sheath, are considered to be patient contacting devices, and are manufactured of materials that are well established and have a long history of use in instrumentation for many years. The materials include ASTM F899 Stainless Steel (Blade Sheath), and ASTM F136 Titanium Ti-6Al-4V ELI (Scalpel Blades). ASTM F899 Stainless Steel or (b)(4) may also be used in the Hub of the **Prime™ Ultrasonic Scalpel Reusable Blade** (Figure 8-10).

These materials are well established for use in medical device and patient contact use. The metallic materials of construction have the same manufacturing processes, chemical composition, body contact, and sterilization methods as the cited legally marketed predicate devices and therefore meet the biocompatible requirements. The (b)(4) was tested by the manufactures and the FDA Master File is cited or the test information provided to comply with biocompatibility requirements (See Attachment (b)(4)). Refer to Section-13 of this submission for a complete discussion regarding biocompatibility of all the materials of construction. Materials of construction are not considered in this discussion with regard to the **Prime™ Reusable Transducer Handpiece** and the **Prime™ G6000 Generator**, footswitch, and cord, as they are not intended for body contact.

8.9 Performance Testing Summary

Performance testing was successfully completed to verify and validate the design and performance of the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** and to ensure that the subject devices are substantially equivalent in safety and effectiveness to the predicate device. The testing was designed where applicable to worst-case mechanical conditions and to confirm that the system meets all regulatory standards and requirements. In addition to meeting regulatory requirements, the testing was consistently conducted under protocols and test plans with predetermined criteria for success and/or in comparison with the predicate devices. Please refer to Section 16-Performance Testing for a complete summary of performance testing.

8.9.1 Animal Testing Summary

Animal testing was conducted using the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** to demonstrate that it meets defined design requirements and can perform in a manner equivalent to predicate devices currently on the market for open laparoscopic, and endoscopic surgery in soft tissue. The **Prime™ Adaptive Ultrasonic Scalpel System and Blades**, both curved and hook configurations were equivalent to the predicate devices for cutting and hemostasis. Observations from the (b)(4) study report included slightly better mean bleeding scores (or hemostasis) for the **Prime™ Adaptive Ultrasonic Scalpel Blades** (test article) compared to the predicate blades. The slight difference was most pronounced for the hook blades at the ‘5’ power setting” (page 11, §7.2 of the report). A copy of the Animal Study Report conducted by (b)(4), *Evaluation of the Prime™ Adaptive Ultrasonic Scalpel System and of the Ultrasonic Shears in* (b)(4) is provided in Attachment 003-US018. Tissue samples were processed for (b)(4) report (Attachment 003) observed superficial thermal damage ranged from (b)(4) (b) for the predicate (or control) device vs. (b) (b)(b) for the **Prime™ Adaptive Ultrasonic Scalpel Reusable Blade** (or test device). Lateral thermal damage deeper within the incision ranged from (b)(4) for the Predicate (or control device) vs. (b)(4) for the **Prime™ Adaptive Ultrasonic Scalpel Reusable Blade** (or test device). The (b)(4) study concluded there was no biologically significant difference in the tissue damage between the control and test devices. Therefore, the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** are substantially equivalent in performance to the predicate devices in cutting/coagulating (b)(4) vessels. For a complete review of this testing, please refer to Section 17-Animal Testing.

8.9.2 Prime™ G6000 Generator Performance Testing Summary

Medical Electrical Equipment Safety and Performance testing was independently conducted by (b)(4) in accordance with the applicable sections of IEC 60601 and IEC 61000 Electromagnetic Compatibility and Endoscopic Equipment. The generator received the (b)(4) (b)(4) quality seal (similar to CSA or UL Seal for quality and safety). To review the complete test report, See Attachment 001-US0025, and see Section 15-EMC Reliability & Safety for a complete summary of the testing.

Bench testing was conducted utilizing the **Prime™ G6000 Generator** in combination with the **Prime™ Reusable Transducer Handpiece** and the **Prime™ Ultrasonic Scalpel Reusable Blades** (See Attachment 003-US002). During testing, the **Prime™ G6000 Generator** was capable of driving the **Prime™ Ultrasonic Scalpel Reusable Blades** with sufficient amplitude

for cutting and coagulation, which was equivalent to the predicate devices. The **Prime™ G6000 Generator** was utilized in all bench testing conducted for other **Prime™ Adaptive Ultrasonic Scalpel System** family of products. For a complete summary of performance bench testing, please refer to Section 16-Performance Testing.

8.9.3 Software Verification and Validation Summary

The **Prime™ G6000 Generator** contains resident software, which was reviewed throughout the design process for potential risk, was verified and validated. The software Verification and Validation testing included hand activated UltraCision™ devices (e.g. UltraCision Model ACE45E hand activated shears). All of the documentation associated with software development and testing is reviewed in Section 14-Software, and documentation is provided in Attachment 005. The **Prime™ G6000 Generator** is substantially equivalent to the predicate generator and the two systems are compatible.

8.9.4 Prime™ Reusable Transducer Handpiece Performance Testing Summary

The predicate UltraCision® HARMONIC Scalpel Shears-Handpiece Model HP054 is rated for (b)(4); therefore, the criteria for success for the **Prime™** transducer was over (b)(4) before it reached the end of usable life. The testing included repeated thermal cycle testing (steam sterilization) of the transducers for at least (b)(4) and monitoring for degradation after each cycle. The devices exceed the minimum success criteria with no failures related to performance. Therefore, the **Prime™** Transducer Reusable Handpiece has a useful life greater (b)(4) surgical procedures without degradation and this performance is substantially equivalent to the claimed life of the predicate UltraCision™ Model HP054. (See Attachment 017-US-016)

8.9.5 Prime™ Ultrasonic Scalpel Reusable Blade Performance Testing Summary

Blade Conformance Bench Testing was conducted to verify the mechanical design and electrical performance of the ultrasonic blades. To review the full test report, see Attachment 004-US0002. As described in Section 8.2, **Prime™** blades are provided with two styles or configurations of end effectors, and three different lengths. All of the blades were considered in the blade performance testing. The test method and results are summarized in Section 16-Performance Testing and all blade designs passed the performance testing. The amplitude for all blades is above the minimum (b)(4) to provide sufficient cutting and coagulation. The Frequency for all blades is within the (b)(4).

A *Thermal Map Study* was conducted to determine the potential for thermal injury over the full length of the **Prime™ Ultrasonic Scalpel Reusable Blades** and the **Prime™ Reusable Transducer Handpiece**. (See Section 16-Performance Testing for illustrations). The predicate device, UltraCision™ 32cm Hook Blade model HDH04, was included in the testing as a control test article. The study confirmed that the **Prime™** devices would not cause burn when used as intended and are substantially equivalent to the predicate.

A *Usable Life Study* was conducted to evaluate the fatigue life of the blades and determine if the user would be aware of the blades' end-of-usable-life. It was determined that the **Prime™ Ultrasonic Scalpel Reusable Blades** have a useful life greater than (b)(4) of activation time (b)(4) (b)(4)). Testing was completed for (b)(4) s using the **Prime™**

Adaptive Ultrasonic Scalpel System G6000 Generator and Prime™ Reusable Transducer Handpiece, and an additional (b)(4) using the predicate UltraCision™ transducer in combination with the UltraCision™ GEN300 Generator. None of the blades failed in fatigue even after repeated damage. In addition, the blades functioned normally even when moderately scratched or damaged from cutting through surgical staple lines or incidental contact with other metallic instruments.

After intentionally damaging the blades, both the **Prime™ G6000 Generator** and the predicate generators repeatedly detected the damage, providing the user with a clear indication that the blades were at the end of their useful life. Therefore, the **Prime™ Ultrasonic Scalpel Reusable Blades** have an acceptable usable life span as compared to the predicate devices, and the blades' end-of-usable-life can be detected by the **Prime™ G6000 Generator**, by the predicate generator or by visual inspection as described in the IFU. After testing, no new questions of safety or efficacy were raised.

8.9.6 Prime™ Reusable Torque Wrench Testing Summary

Prime™ Reusable Torque Wrench is provided with each **Prime™ Ultrasonic Scalpel Reusable Blade** to provide a method for tightening the blade to the transducer to assure the ultrasonic blade is not over tightening to where it may break the threaded stud that connects the transducer to the blade. Sufficient tightening must occur to be accepted by the **Prime™ G6000 Generator** diagnostic testing so that the blade is not loose resulting in degradation to the resulting power output. The blade performance and the successful use of the **Prime™ Torque Wrench** is tested by the **Prime™ G6000 Generator** each time the wrench is used. The **Prime™ G6000 Generator** will detect a loose blade and shut down the system insuring the wrench is functioning properly. Over or under tightening has no risk of harm to the patient or user but corrective action would be required (such as reapplying the torque wrench or replacing it). Specifications for the **Prime™ Torque Wrench** were established in a Torque Limit Study (See Attachment 007-US027).

The performance testing for the **Prime™ Torque Wrench** included verification of the mean torque, the minimum torque, and the maximum torque. A summary of the test results for performance testing is provided in Section 16-Performance Testing, and the full test results can be found in Attachment 008-US0031. The **Prime™ Torque Wrench** torque specification requirements were determined from this testing, will be maintained by the quality system, and the requirement is sufficiently broad to accommodate basic process controls. Within these parameters, the **Prime™ Torque Wrench** is capable of securing blades to the **Prime™ Reusable Transducer Handpiece**, or to Ethicon Endo-Surgery UltraCision™ compatible transducers without damaging the transducers.

8.9.7 Prime™ Accessory Testing Summary

- **Prime™ ADP Connector/Adapter (Model ADP1)**: The adapter was validated in combination with the **Prime™ Reusable Transducer Handpiece** as compatible with the Ethicon Endo-Surgery G300 and G11 generators and does not affect or interfere with the diagnostics or software for automatically conducted system checks. Complete *ADP1 Validation Testing* and *Compatibility with Predicate Generators* is provided in Attachment 009-US029.

- Prime™ Generator/Accessory Cart: *Mechanical Testing* was successfully completed under IEC 60601-1-2:2007/Section 9.4 for lateral movement, propulsion force, movement mover thresholds for potential tip over and wheel breaks on the Prime™ Cart Generator/Accessory. For complete test results and a summary, see Attachment 002-US024.
- Sterilization Tray: The Prime™ Adaptive Ultrasonic Scalpel Sterilization Tray was included in the Cleaning and *Sterilization Studies*. The cleaning validation was performed in accordance with the AAMI TIR30:2011 and the Prime™ Adaptive Ultrasonic Scalpel System and Blade's Instructions for Use. Validation testing was successfully completed for the full set of Prime™ Adaptive Ultrasonic Scalpel Reusable Blades, transducer handpiece, accessories and tray. The instrument set was validated to a sterility assurance level (SAL) of $\leq 10^{-6}$ using biological indicator overkill method. All test method criteria were met. The full test results and a summary are provided in Attachment 011-US0026.

9. Device Description

9.1 System Description

The **Prime™ Adaptive Ultrasonic Scalpel System and Blades** is a family of devices (or system components) that utilize ultrasonic energy to enable hemostatic cutting and/or coagulation of soft tissue in abdominal, pediatric, gynecologic, thoracic, urologic and general open and endoscopic procedures. The system consists of an ultrasonic generator, a reusable transducer handpiece and a variety of open and minimally invasive scalpel blade instruments. The generator controls the transducer handpiece, which drives the blade to vibrate longitudinally at approximately 55.5 kilohertz (kHz). This ultrasonic vibration enables the blades cutting ability. The same vibration seals small vessels with coagulated blood and tissue proteins. Hemostasis occurs when tissue couples with the instrument. This coupling causes collagen molecules within the tissue to vibrate and become denatured, forming a coagulum. The **Prime™ Adaptive Ultrasonic Scalpel System and Blades** provide input/output control and operation interface to automatically adapt the ultrasonic power output for the tissue load encountered.

9.2 Indications for Use

The **Prime™ Adaptive Ultrasonic Scalpel System** is a cutting and coagulation system indicated for open, laparoscopic and endoscopic surgery in soft tissue where control of hemostasis and thermal spread is desired. The system is indicated for dissection, sealing, transection,otomy creation and transection/coagulation of vessels as indicated for each cutting and coagulation instrument used (consult the instructions for use provided with each instrument). The system can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels.

9.3 Individual Device Descriptions and Product Delivery

Each of the products is described below and the family of devices (System Components) is tabulated in Table 9-1:

Table 9-1: Prime™ Adaptive Ultrasonic Scalpel System and Blades System Components

Description and Product Delivery	Model
Prime™ Adaptive Ultrasonic Scalpel Generator. Provided with Foot Switch, Power Cable and Instructions for Use	G6000
Prime™ Reusable Transducer Handpiece, for foot switch activation only. Provided with Test Tip, Cable and Instructions for Use	TRN5
Prime™ Ultrasonic Scalpel Reusable Blades – Each is Provided with a Torque Wrench and Instructions for Use:	
Prime™ Ultrasonic Curved Blade 5mm 11cm Length, Reusable	CB11R
Prime™ Ultrasonic Curved Blade 5mm 37cm Length, Reusable	CB37R
Prime™ Ultrasonic Curved Blade 5mm 46cm Length, Reusable	CB46R
Omni™ Ultrasonic Hook Blade 5mm 11cm Length, Reusable	OHB11R
Omni™ Ultrasonic Hook Blade 5mm 37cm Length, Reusable	OHB37R
Omni™ Ultrasonic Hook Blade 5mm 46cm Length, Reusable	OHB46R
Accessories: Provide Separately with Instructions for Use	
Prime™ Adaptive Ultrasonic Scalpel Sterilization Tray	TRAY1
Prime™ ADP Connector/Adaptor (for EES Generator GEN300 & G11)	ADP1
Prime™ Cart Generator/Accessory Cart	PCART

The following are Individual Device descriptions for the system components or the **Prime™ Adaptive Ultrasonic Scalpel System and Blades**:

9.3.1 Prime™ Adaptive Ultrasonic Scalpel Generator-Model G6000

The **Prime™ G6000 Generator** is a part of the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** family of devices. The generator provides electrical energy output to the transducer handpiece, which is controlled by activating the foot switch, which is provided with the generator. The system is also capable of hand switch activation of future EndoPrime products. The **Prime™ G6000 Generator** provides input/output control and operation interface to automatically adapt the ultrasonic power output for the tissue load encountered. Key aspects of operation are discussed below:

- **Startup:** The **Prime™ G6000 Generator** conducts an initial system test, continuously monitors device condition, provides system test results, displays troubleshooting information and deactivates the transducer handpiece and instrument operation when a fault or anomaly is detected. This includes faults or anomalies related to system components that have reached the end of their useful life.
- **Power Levels:** Variable and Full power levels are displayed and the variable power level can be adjusted throughout the procedure to provide the desired energy outputs.
- **Indicators:** Audible indications identify when an instrument is activated in FULL (rapid beeping) or VAR (slow beeping) power levels.
- **Alarms:** Audible and visual alarms assist with identifying when devices are improperly setup, damaged, or at the end of their useful life. Alarms immediately shutdown activation (transducer drive power) and will reset once the cause of the alarm is corrected to avoid unnecessary delay in surgery. Re-torquing the blade, restarting the generator, or replacing the indicated component can resolve most alarms. The instructions for use recommend keeping a backup cable, transducer handpiece, and blade in each instrument tray (See Attachment 012, G6000 IFU, page 19).
- **Normal (Ready), Standby and Test Modes:** The Standby Button is available to pause the system during use to allow for safely changing instruments, testing system components and avoiding accidental activation. The generator defaults to the Standby Mode when first started. Pressing the Standby Button allows entry or return to the Normal (Ready) Mode. Pressing the Test Button allows entry to the Test Mode, which is used for trouble shooting.

9.3.2 Prime™ Reusable Transducer Handpiece

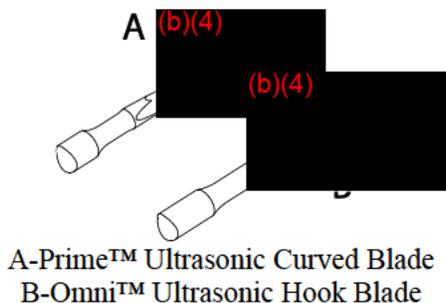
The **Prime™ Reusable Transducer Handpiece** is sold separately, provided non-sterile, and is designed to convert electrical energy from the generator to mechanical motion for the instrument blades. Detailed information on the assembly of the device can be found in the Instructions for

Use provided in Attachment 012 within this submission. Instructions for Use are part of labeling and are supplied with the packaged product. The transducer is also packaged with a detachable cable used to connect the instrument to the generator. In addition, the package includes a test tip for testing the system, and a torque wrench used to secure blade assemblies to the transducer. An adapter for connecting the **Prime™ Reusable Transducer Handpiece** to generators manufactured by others is available as a **Prime™ Accessory (ADP1)**. The instructions for use direct the user to contact Customer Service for information on obtaining a connector/adaptor.

9.3.3 Prime™ Ultrasonic Scalpel Reusable Blades

Prime™ Ultrasonic Scalpel Reusable Blades are sold non-sterile and are easily disassembled for cleaning and sterilization. Each blade is provided with one (1) **Prime™ Reusable Torque Wrench** and one (1) **Reusable Protective Cap**. The protective cap is reusable and designed to be reinstalled over the blade tip. Replacement parts are available upon request to EndoPrime Customer Service. Sterilization was validated with the cap in place on the blades. Blades are provided in two end effector styles, and three different lengths to offer adequate reach in different surgical situations. Examples of the two different end effectors are shown in Figure 9-1 below.

Figure 9-1: Prime™ Ultrasonic Scalpel Reusable Blade-Configuration Illustrations



The **Prime™ Adaptive Ultrasonic Scalpel System and Blades** family of devices are designed to work together; however, these products are validated to be compatible with UltraCision® Harmonic Scalpel® Blade devices and will continue to be validated in the future to be compatible with a limited number of other manufacturers' systems.

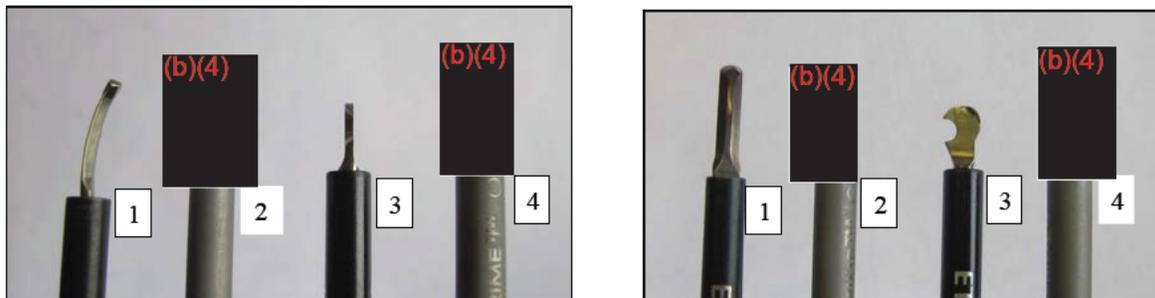
9.4 Technological Characteristics

The **Prime™ Adaptive Ultrasonic Scalpel System and Blades** technological characteristics are substantially equivalent to the predicate device referenced including automatically adapting the ultrasonic power output for the tissue load encountered to provide consistent performance (i.e. both are adaptive systems).

The **Prime™ Ultrasonic Scalpel Reusable Blades** are designed similar to the predicate blades except that the curved blade is more compact and balanced with the centroid of the end effector on the centerline of the blade. The predicate Ethicon EndoSurgery UltraCision™ hooked blades are balance with the centroid on the centerline; however, the Ethicon EndoSurgery UltraCision™

curved blades are wider (Figure 9-2) and are balanced such that the centroid falls to one side of the blade center line. These design choices raised no new questions regarding safety and effectiveness (discussed further in the next section). Comparison illustration of the subject and predicate blades is shown below in Figure 9-2.

Figure 9-2: Comparison to Predicate Blades (Profiles at 90°)



- | | |
|----------------------------|----------------------------|
| 1: Predicate Curved | 3: Predicate Hook |
| 2: Prime™ Curved | 4: Omni™ Hook Blade |

9.4.1 Predicate Blade Comparison

Curved Blades: The **Prime™ Ultrasonic Curved Blades** have a compact design to improve access in narrow, delicate anatomy.

Hook Blade: The **Omni™ Ultrasonic Hooked Blade** is curved for better visibility with a (b)(4)

Another technological characteristic is reusability of the entire system, including the blades. **Prime™ Ultrasonic Scalpel Reusable Blades** are reusable while the current predicate blades are single patient use (SPU) disposable; however, the current predicate device scalpels were predicated on reusable scalpels (such as UltraCision® Harmonic® Scalpel Blade System DH010, LC1004-2 and other reusable blades as discussed in Section 9.8.3 below). **Prime™ Ultrasonic Scalpel Reusable Blades** are designed to function the same as the predicate devices, but are validated for disassembly, cleaning and sterilization. The reusable design requires no different manufacturing process or materials – only the capability to clean and re-sterilize the blade. The sheath of the **Prime™ Ultrasonic Scalpel Reusable Blades** can be disassembled to allow access for cleaning, sterilization and reuse; where the sheath of the predicate SPU disposable blades cannot be disassembled. The reusable aspect of the scalpel blade will not affect the overall device description or intended use, and raises no new questions of safety or efficacy. Because all of the components of the system are reusable and have been validated for cleaning and sterilization as appropriate, the entire **Prime™ Adaptive Ultrasonic Scalpel System and Blades** are shipped non-sterile with instructions to clean and sterilize before use. Packaging is clearly labeled non-sterile (See Attachment 014-Labels); and the packaging is designed to allow the user to clearly understand the blades are non-sterile. The sheath of each reusable blade is also stainless steel in appearance and will be laser marked “Reusable” to distinguish it from predicate SPU disposable blades, which are black.

Another feature of the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** is the ability to disconnect the cable at the transducer handpiece. This feature allows the surgical scrub technician to quickly replace the transducer handpiece and/or an ultrasonic blade without contact with the non-sterile surface of the generator or assistance from others. Quickly dealing with alarms such as a device at the end of its useful life is important to avoid unnecessary surgical delay. Labeling instructions and common practice recommend keeping a backup cable, transducer handpiece, and blade in each instrument tray to avoid delay, in case corrective action is required during a procedure (See Attachment 012-G6000 Instructions for Use, Page 19). The cable disconnect was designed and added as a convenience feature and will not affect the overall device performance characteristics or intended use, and raises no new question of safety or equivalency to the predicate device.

9.5 Device Specifications and Materials

The **Prime™ Adaptive Ultrasonic Scalpel System and Blades** consist of the following components (For complete Assembly Design Drawings See **Attachment 013**):

9.5.1 Prime™ G6000 Generator

The main component of the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** is the **Prime™ G6000 Generator**, which is not a patient contacting device. A footswitch, power cord and instructions for use are provided with the **Prime™ G6000 Generator**, which is provided in non-sterile packaging, in a craft corrugated carton. The following Figure 9-3 is an illustration of the **Prime™ G6000 Generator**:

Figure 9-3: Illustration of Prime™ G6000 Generator



The Illustration of the **Prime™ G6000 Generator** reflects how the user of the generator can set the power produced by the generator using the VAR power setting from 1 to 5 by pressing the button on the interface display. Lower settings on the VAR power would slow the generator power, resulting in less friction and slower heating, useful in improved hemostatic implementation. The following are the approximate power distributions for each setting:

Level 1: 50% of FULL (Power Level 5)

Level 2:	62%	of FULL (Power Level 5)
Level 3:	75%	of FULL (Power Level 5)
Level 4:	87%	of FULL (Power Level 5)
Level 5:	100%	of FULL

FULL power is always maintained at level 5. When the highest power level (i.e. FULL power level 5) is used for the scalpel, faster tissue cutting can be obtained. The energy conveyed to the tissue and the tissue effect produced depend on many factors, including the selected VAR power level, scalpel shape, scalpel amplitude, clamping force (if applicable), tissue tension, tissue type, pathology and surgery method.

Simply put, the **Prime™ G6000 Generator** is designed to provide electrical energy that will be converted into mechanical motion through the use of a transducer handpiece. When a scalpel blade is connected to the transducer handpiece, and the generator is powered, the energy emitted through the transducer will cause the scalpel to vibrate longitudinally at 55.5 kilohertz (kHz). The ultrasonic vibration through the scalpel is used for cutting and coagulation. The same vibration can be used to seal small vessels with coagulated blood and tissue proteins. Hemostasis will occur when tissue couples with the scalpel, and this coupling causes collagen molecules within the tissue to vibrate and become denatured, forming a coagulum.

The following Figure 9-4 is taken from the Design Drawing for the **Prime™ G6000 Generator** and illustrates basic dimensional information, and system information is provided in Table 9-2:

Figure 9-4: Design Drawing of Generator (Units: mm)

(b)(4) Schematic Drawings

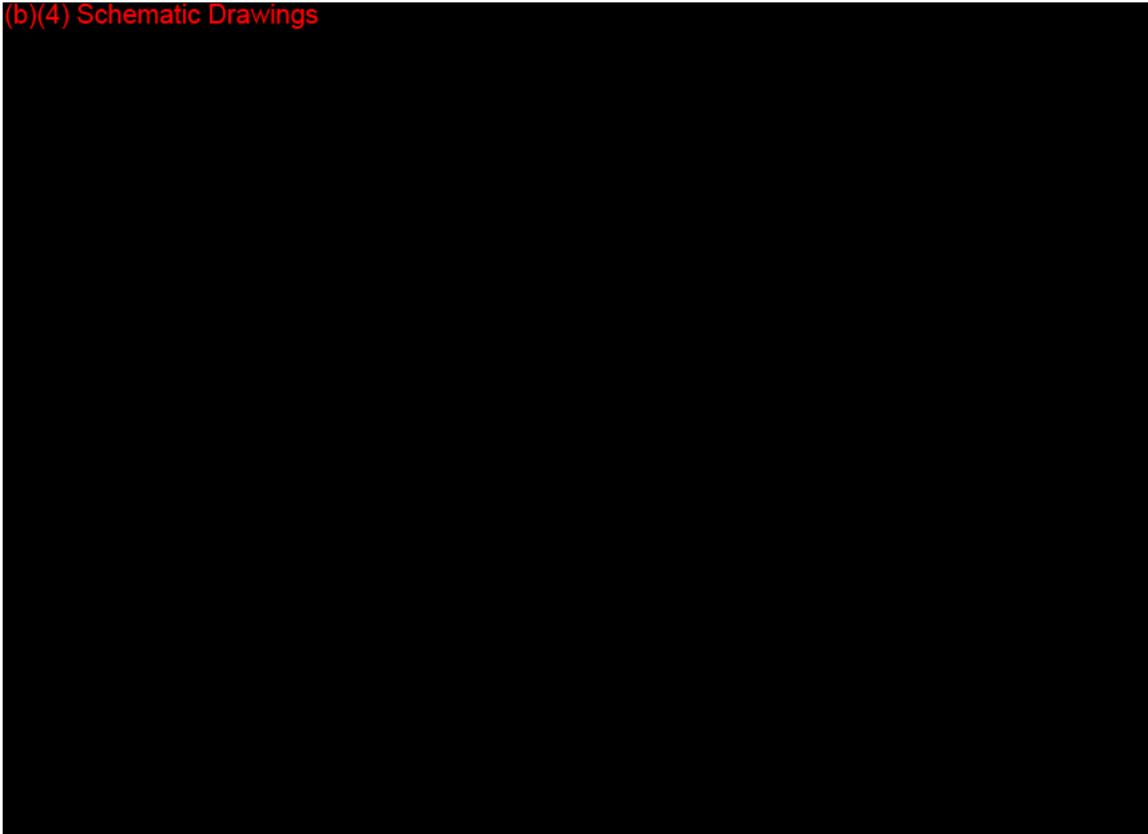


Table 9-2: Prime™ G6000 Generator System Specifications

Model Number	G6000
Performance	
Ultrasonic Frequency	55.5 KHz (range is (b)(4) kHz - range of resonance tracking of attached blades)
Over-Temperature Protection	Device automatically shuts down to prevent overheating. Fans will remain on during Over-Temperature Protection. Unit must be power cycled to reset.
Operation Mode	Variable and fixed Power Modes
Maximum Working Duty Cycle	Intervals of <(b)(4)
Electrical Input	
Input Line Voltage	90-264 VAC 50-60 Hz @ 1.5 Amps
Input Line Frequency	50/60 Hz
Line Cord	IEC 60320/NEMA 5-15 Type CF – Hospital Grade ~ 15 feet
Fuse	3.0 Amp Slow-Blow, 250 VAC, 5mm
Mechanical and Environmental	
Operating Temp	50° F to 86° F (10°C to 30°C)
Operating Humidity	<70% RH non-condensing
Storage Temperature	13°F to 156°F (-10°C to 70°C)
Storage Humidity	< 80% RH non-condensing
Weight	33 lbs. (15kg)
Case Size	H=6.3 (16 cm) Inches x W=14.2 (36 cm) Inches, D=15.0 (38 cm) Inches
Indicators	LCD display, LEDs
Safety, EMC, and Regulatory Compliance	<ul style="list-style-type: none"> • IEC/EN 60601-1 • IEC/EN 60601-1-2 • IEC/EN 60601-2-18 • CAN/CSA C22.2 No. 601.1 • CAN/CSA C22.2 No. 601.1.2
Equipment Class	Class 1
	Suitable for Continuous Operation
	Type CF Applied Part Class 1
	IPX0. Ordinary Equipment without the protection against ingress of water.
	Medical Electrical Equipment per IEC 60601-1/CAN/CSA C22.2 No. 601.1
	Not for use in presence of flammable mixtures

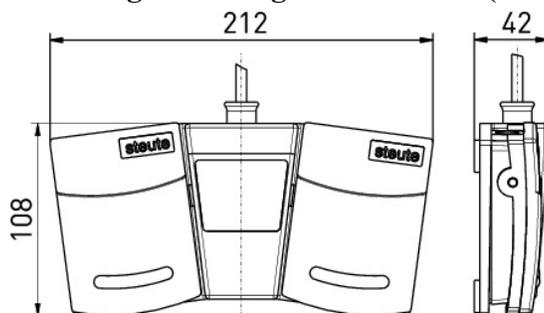
The generator is designed to allow selective control of activation and power level from the footswitch (Ref: Figures 9-5/9-6) provided with the **Prime™ G6000 Generator**. The **Prime™ G6000 Generator** is also validated for hand switch control (i.e. Hand Activation) when used with a hand activation enabled transducer/handpiece and hand switch enabled instrument. The **Prime™ Reusable Transducer Handpiece** is not hand activation enabled but the generator is validated for use with hand activation enabled instruments and transducers from other manufactures (including Software validation). The footswitch or a hand switch allows the user

to select the VAR (preset variable power level) or FULL (maximum power level) by selecting the corresponding VAR or FULL switch. The VAR setting is preselected using the (+) and (-) buttons on the front face of the **Prime™ G6000 Generator**. Refer to the instructions for use (Attachment 012) for directions to setup and operate the **Prime™ G6000 Generator**.

Figure 9-5: Illustration of Footswitch

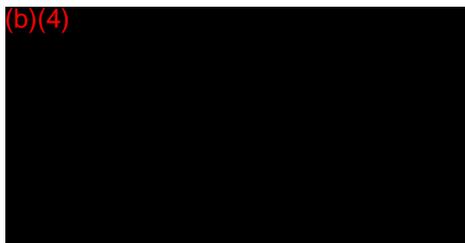


Figure 9-6: Design Drawing of Footswitch (Units: mm)



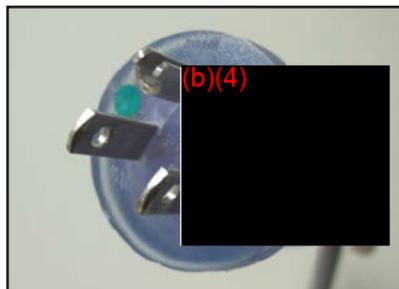
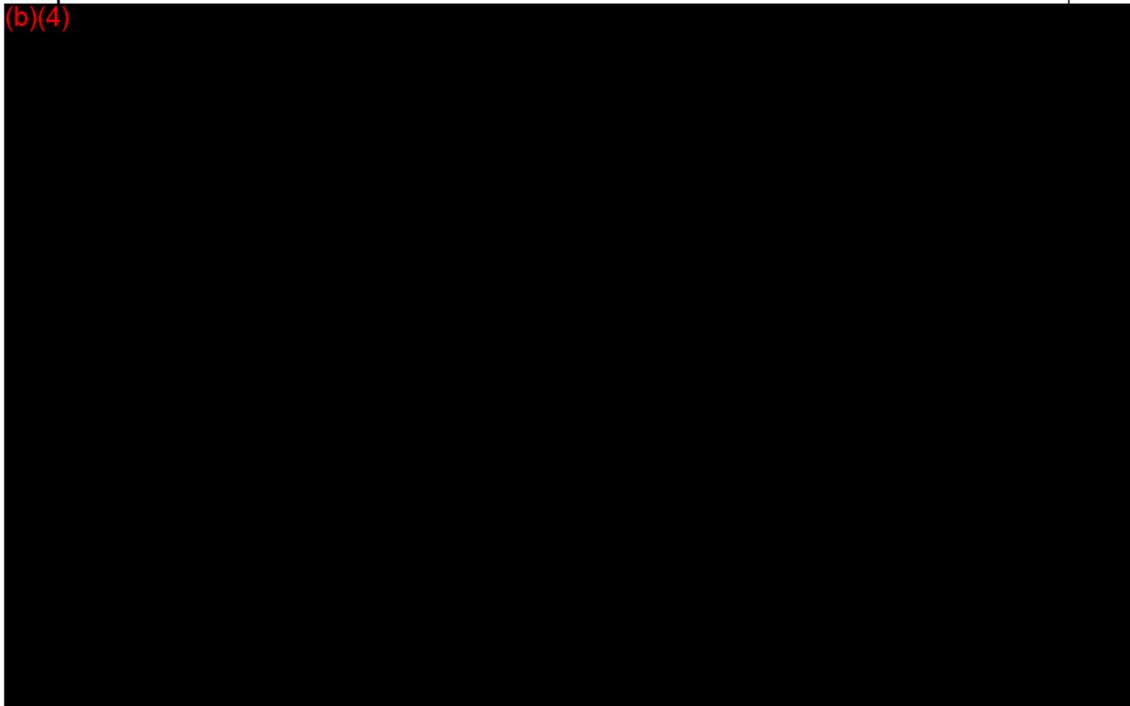
The foot switch is connected with the generator during the operation using the cord shown in the illustration above (Figures 9-5 and 9-6). The internal circuit, as shown in Figure 9-7 – Footswitch Internal Circuit Schematic, reflects that there are two switches in the circuit, and each switch refers to one pedal (S1 refers to “VAR”, S2 to “FULL”). If one pedal is pressed, the corresponding switch will be closed, the line 1 and line 3 (or line 2 and line 3) will form a closed loop in the circuit, the pedal activation is communicated to the microcontroller via the electrical signal of different loop to switch the output level.

Figure 9-7: Footswitch Internal Circuit Schematic



The Line Cord (or Power Cable) for the **Prime™ G6000 Generator** complies with IEC 60320/NEMA 5-15P – Type CF Hospital Grade cord approximately 15 feet in length (4.5 Meters). It is OEM manufactured by (b)(4) and the power cord is CE Marked and UL Certified.

Figure 9-8: Line Cable Schematic Drawing and Illustration



In addition, the **Prime™ G6000 Generator** can be used in conjunction with hand activation enabled transducer handpieces, ultrasonic shears and forceps. Hand activated devices are not currently offered with the **Prime™ Adaptive Ultrasonic Scalpel System and Blades**; however, the **Prime™ G6000 Generator** is compatible with other legally marketed USA hand activated scalpel products.

The **Prime™ G6000 Generator**, Footswitch and Line Cable are intended to have no direct or indirect contact with the patient's body or tissue.

9.5.2 Prime™ Reusable Transducer Handpiece

A list of **Prime™ Adaptive Ultrasonic Scalpel System and Blades** family of products that have patient tissue or fluids contact are provided in Table 9-3 below, along with the possible patient contacting materials and regulatory class for each.

Table 9-3: Prime™: Adaptive Ultrasonic Scalpel System-Patient Contacting Materials

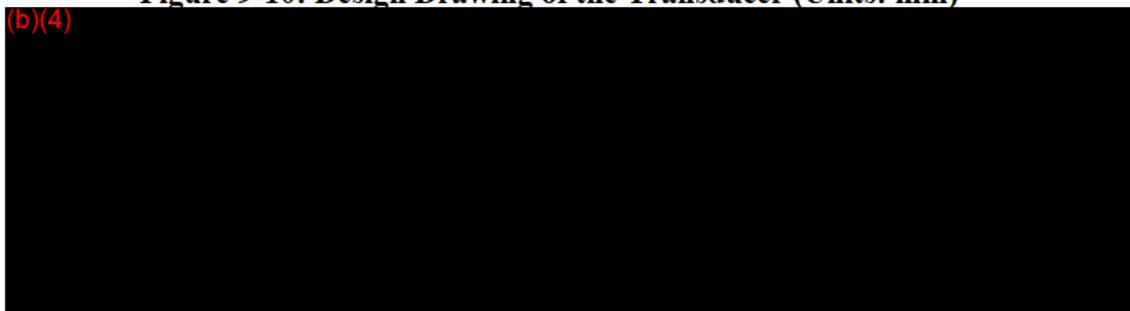
Device Name	Model Numbers	Material(s)	Regulatory Class
Prime™ Ultrasonic Scalpel Reusable Blades	CB11R CB37R CB46R OHB11R OHB37R OHB46R	(b)(4) [Redacted] (b)(4)	II

The following is an illustration, and a design drawing of the **Prime™ Reusable Transducer Handpiece** (Figures 9-9 and 9-10):

Figure 9-9: Photo of the Transducer



Figure 9-10: Design Drawing of the Transducer (Units: mm)



The **Prime™ Reusable Transducer Handpiece** components that could possibly come in contact with patient tissue are fabricated from ASTM F899 304 Stainless or (b)(4). These materials are used in (b)(4), are well established for use in this medical device application. This device is provided with a connector cable, a test tip and a torque wrench. The Prime™ Torque Wrench is used to set, attach and secure the scalpel blade. The following is an illustration and a design drawing of the Type CF hospital grade connector cable for the **Prime™ Reusable Transducer Handpiece** (Figure 9-11):

Figure 9-11: Illustrations and Design Drawing of Connector Cable



(b)(4) Schematic Drawings

The transducer converts the electrical energy supplied by the generator to mechanical motion. It is connected to an ultrasonic wave guide/amplifier, which amplifies the motion produced by the transducer and relays it to the scalpel. The transducer houses several major components that generate, amplify and deliver ultrasonic energy to the scalpel end-effector. When the generated waveform is applied to the transducer, the piezoelectric material expands and contracts to produce longitudinal motion. Adjusting the VAR power setting on the **Prime™ G6000 Generator** during use allows the user to control the level of this motion, or vibration. The user may adjust variable power level (VAR) on the generator from Level 1 to 5, with Level 5 power setting being the maximum power. Level 3 is the default level setting when the generator is first powered up. A higher generator power level would be used for greater tissue cutting speed, and a lower generator power level would be used for greater coagulation.

The power and waveform of Level 1 to Level 5 are presented in Figure 9-12 and the Generator power output power in Watts is provided in Table 9-4:

Figure 9-12: Generator Power Level Waveforms

(b)(4)

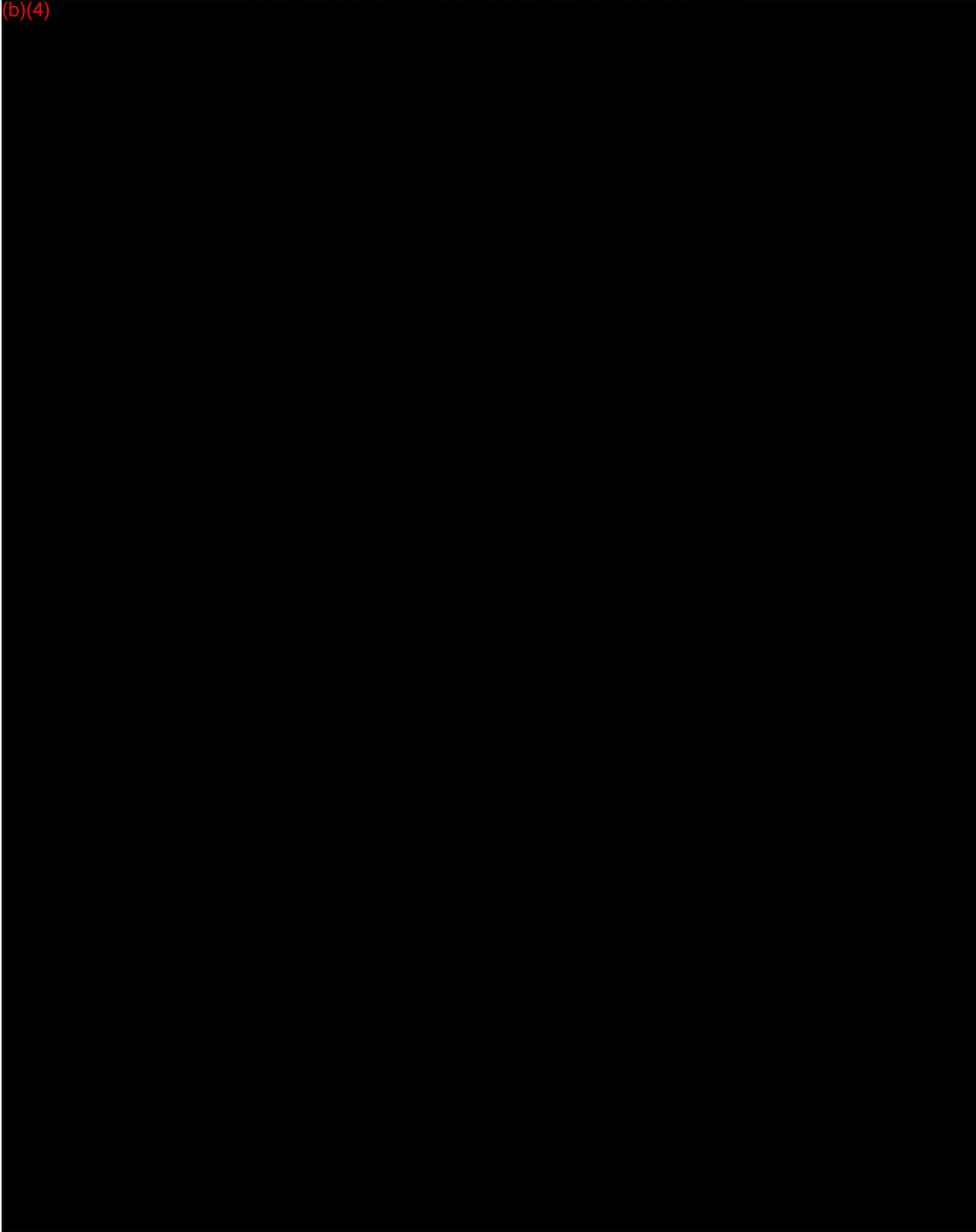


Table 9-4: Generator Maximum Power Levels (Watts)

Level Power	Level Power
1	(b)(4)
2	(b)(4)
3	(b)(4)
4	(b)(4)
5	(b)(4)

The **Prime™ Reusable Transducer Handpiece**, Test Tip, Cable and Instructions for Use have no direct or indirect contact with the patient’s body.

9.5.3 Prime™ Ultrasonic Scalpel Reusable Blades

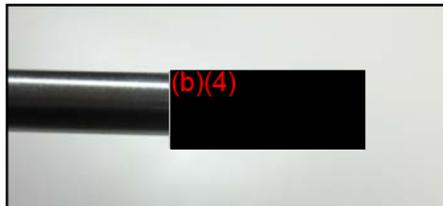
Prime™ Ultrasonic Scalpel Reusable Blades are provided in two types of end effectors and three lengths (See Table 9-1 above). The blades are designed to disassemble for easy cleaning in two pieces: a blade, which attaches to the transducer handpiece by a (b)(4) screw stud and a sheath, which slides over the blade and attaches to the transducer handpiece. The blade is secured to the transducer utilizing the reusable torque wrench supplied with the scalpel assembly. The sheath is secured to the transducer handpiece by hand tightening to the transducer handpiece body.

Both the blade and sheath are considered to be patient contacting devices, and are manufactured of materials that are well established and have a history of use in instrumentation for many years. The materials include ASTM F899 Stainless Steel (Blade Sheath), and ASTM F136 Titanium Ti-6Al-4V ELI (Scalpel Blades). These materials are also listed in Table 9-3 above. The following are illustrations of the curved and hook blades.

Figure 9-13: Photo of the Curved Blade



Figure 9-14: Photo of Hook Blade



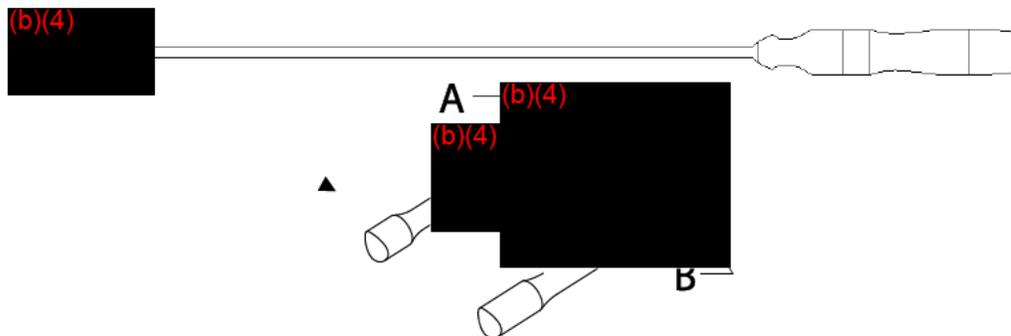
Both the curved and hook scalpel work with the same technology and offer equivalent variety of cutting options for the user. The parameters for use are stated in the original indications for use provided in the device description at the beginning of this section, and in the Instructions for Use (See Attachment 012).

All of the **Prime™ Ultrasonic Scalpel Reusable Blades** (curved and hook) can be used with the **Prime™ Reusable Transducer Handpiece**, which will supply the mechanical energy to the

scalpel. Mechanical energy is transferred to the tip of the scalpel blade through the shaft, to drive the tip to vibrate longitudinally at about 55.5 kilohertz (kHz) at five (5) power levels. The same vibration used at different power levels, seals small vessels with coagulated blood and tissue protein. Hemostasis occurs when the tissue couples with the scalpel blade. This coupling causes collagen molecules within the tissue to vibrate and become denatured, forming coagulum.

The following is a diagram example of each scalpel blade tip type:

Figure 9-15: Curved Blade Assembled and End effectors



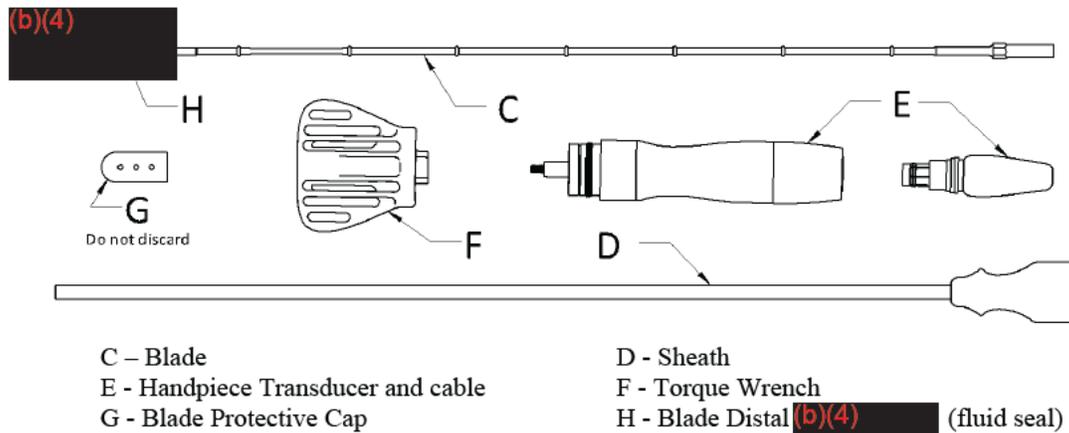
A - Prime™ Curved Blade (CB) End-effector
 B - Omni™ Hook Blade (OHB) End-effector

Table 9-5: Prime™ Adaptive Ultrasonic Scalpel and Blades Specifications

Device Name	Model Number	Material(s)	Regulatory Class
Prime™ Curved Blade 5mm 11cm Length, Ultrasonic	CB10R	(b)(4)	II
Prime™ Curved Blade 5mm 37cm Length, Ultrasonic	CB36R	Same	II
Prime™ Curved Blade 5mm 46cm Length, Ultrasonic	CB42R	Same	II
Prime™ Hook Blade 5mm 11cm Length, Ultrasonic	HB10R	Same	II
Prime™ Hook Blade 5mm 37cm Length, Ultrasonic	HB36R	Same	II
Prime™ Hook Blade 5mm 46cm Length, Ultrasonic	HB42R	Same	II

Figure 9-16 provides an example of the components used in assembly of the blade and the transducer for use:

Figure 9-16: Nomenclature and Illustration



Refer to the **Prime™ Ultrasonic Scalpel Reusable Blades Instructions For Use Attachment 012** for directions and diagrams on assembly.

9.5.4 Prime™ Adaptive Ultrasonic Scalpel Sterilization Tray

The **Prime™ Adaptive Ultrasonic Scalpel Sterilization Tray** is provided as an accessory to the Prime™ family of devices. The tray is designed specifically for the reusable Prime™ products that require sterilization. Figure 9-17 is an illustration and Figure 9-18 is a drawing of the sterilization tray, containing the Prime™ instruments:

Figure 9-17: Illustration of Prime™ Adaptive Ultrasonic Scalpel Sterilization Tray

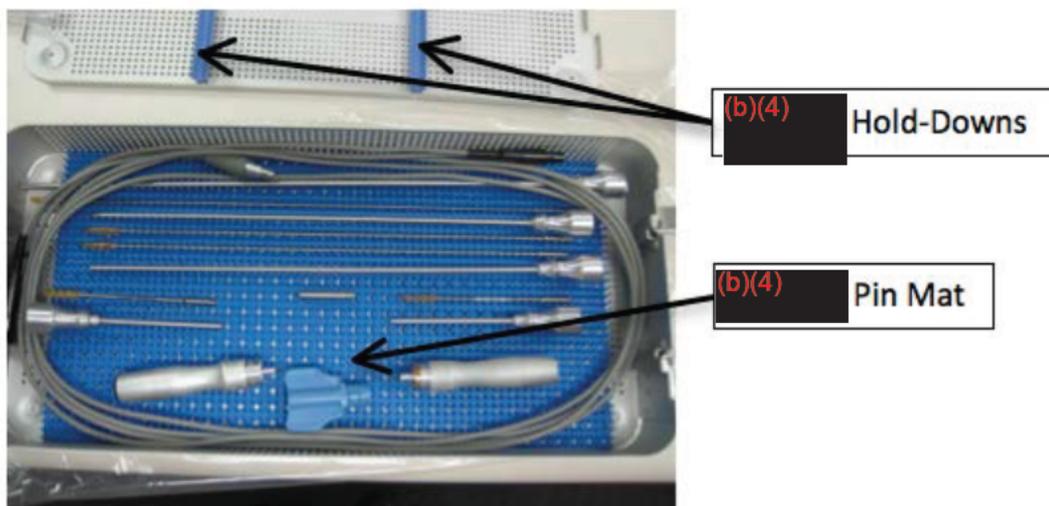
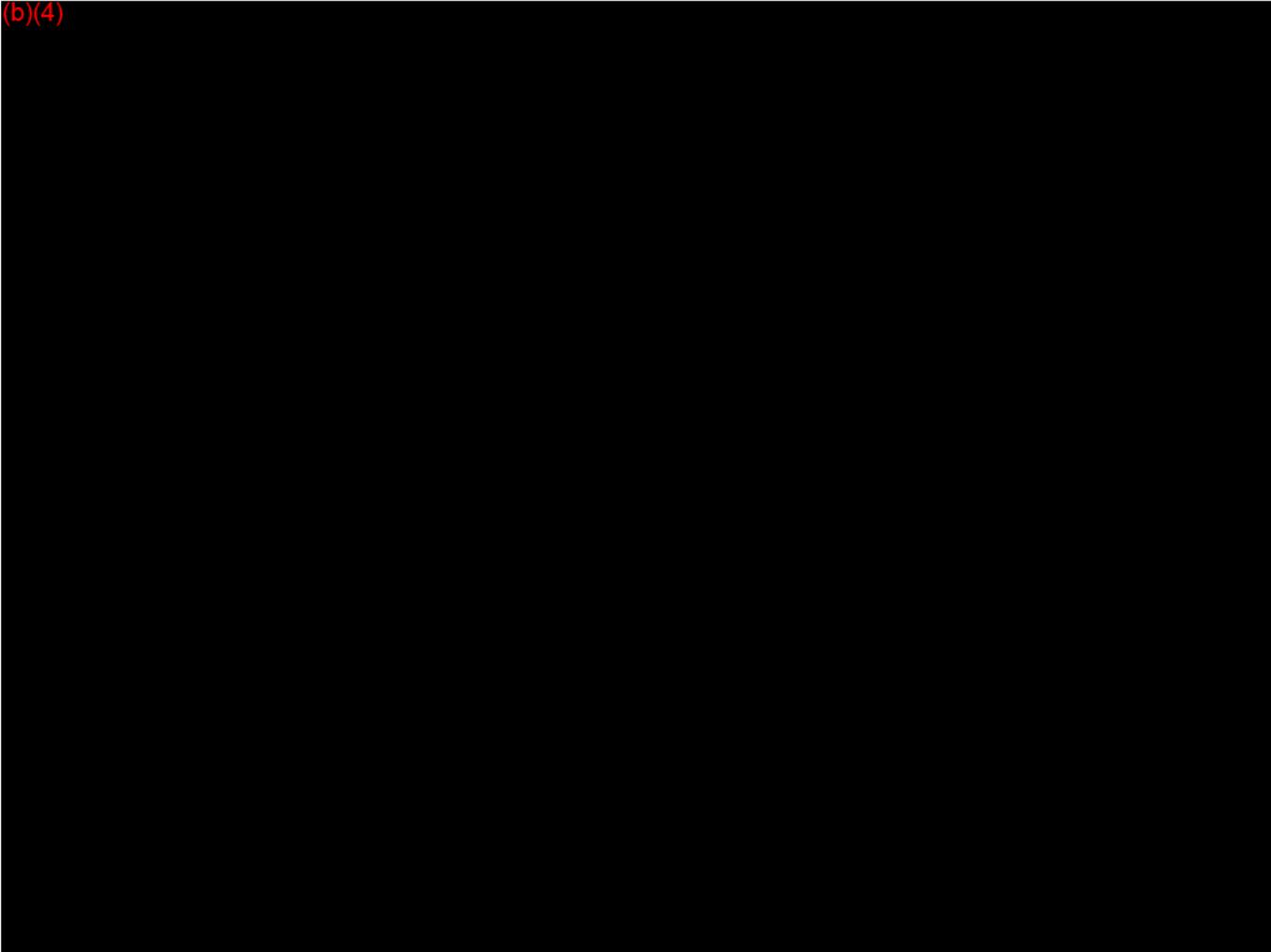


Figure 9-18: Drawing of Prime™ Adaptive Ultrasonic Scalpel Sterilization Tray

(b)(4)

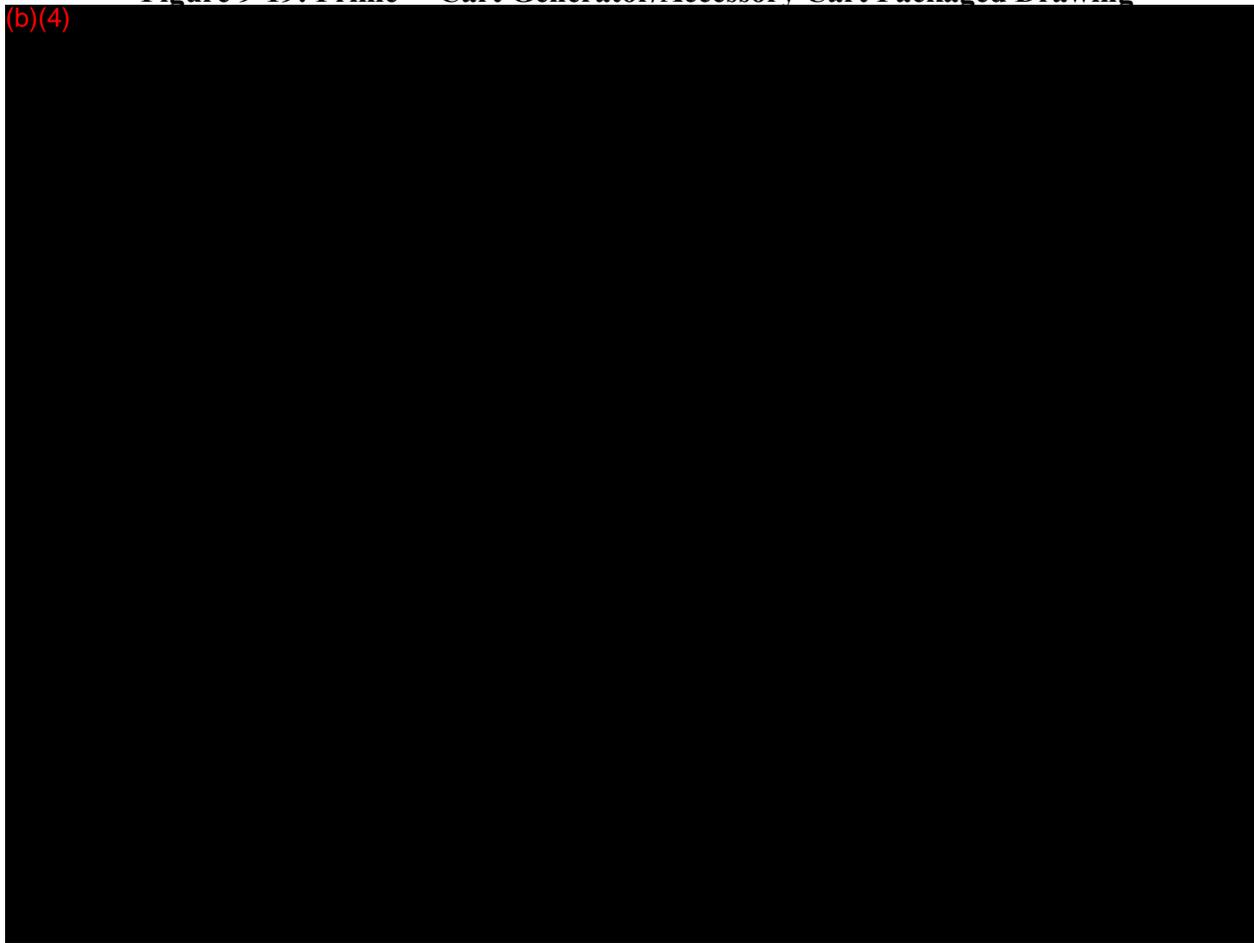


The Class I Device sterilization tray is fabricated from (b)(4) (b)(4). The latches are (b)(4). The Hold-Down Bars and Pin Mat are (b)(4). No latex is used in the construction. The **Prime™ Adaptive Ultrasonic Scalpel Sterilization Tray** has no body contact and therefore require no biocompatibility testing; however the materials of construction are also well established and have a long history of use in sterilization containers for many years.

9.5.5 Prime™ Generator/Accessory Cart

An optional accessory to the Prime™ family of devices is a generator/accessory cart, designed specifically to for the **Prime™ G6000 Generator**. The following is a packaged drawing of the cart:

Figure 9-19: Prime™ Cart Generator/Accessory Cart Packaged Drawing

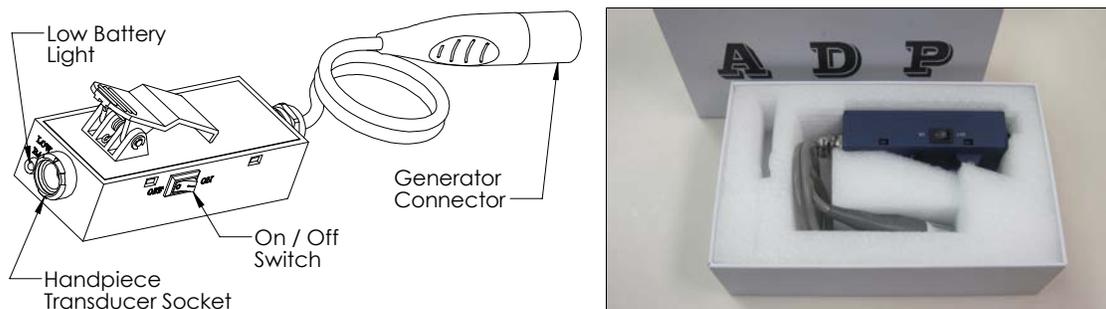


All drawings will also be provided in Attachment 013. The cart is not considered a medical device, and no further discussion of product technology, use, or safety will be discussed within this section. The cart was tested for lateral movement, propulsion force, movement mover thresholds for potential tip over and the wheel breaks; for more information regarding cart safety, please refer to Attachment 010 for the (b)(4) testing summary, which was conducted as part of compliance with IEC 60601-1:2007.

9.5.6 Prime™ ADP Connector/Adaptor

The **Prime™ ADP Connector/Adaptor** is available upon request as an accessory to the **Prime™ Reusable Transducer Handpiece**. The purpose of the connector is to provide the **Prime™ Reusable Transducer Handpiece** the ability to connect with the Ethicon Endo-Surgery Gen300 and Gen11 generators. Because the connector/adaptor is only needed in instances for use of connection, the accessory is available upon request to EndoPrime Customer Service. The following are a packaged illustration and drawing of the connector (Figure 9-20):

Figure 9-20: Prime™ ADP Connector/Adaptor Illustration and Packaged Drawing:



(b)(4)

The **Prime™ ADP Connector/Adaptor** allows electrical connection and adapts to the socket of the predicate device generators (UltraCision™ GEN300 and GEN11). Performance was validated to assure the UltraCision™ GEN300 and GEN11 would detect faults (including end-of-life faults) and the validation report is provided in Attachment 009-US-0029 ADP Validation, and further discussed in Section 016-Performance Testing.

9.6 Design Features

The **Prime™ Adaptive Ultrasonic Scalpel System and Blades** design features are outlined in this section. The system is designed to provide the user with a generator and footswitch that are also compatible with predicate hand activated devices and future EndoPrime hand activated devices. The current family of products includes a total of six options for scalpel blades to

provide the surgeon with a selection of blades for open procedures, endoscopic procedures and different soft tissue anatomy. These components are outlined in section 9.4-Technological Characteristics.

9.6.1 Prime™ Adaptive Ultrasonic Generator Design Features

- Fast and easy setup and operation: Matching methods, setup, operation and interface to predicate devices and other advanced energy systems.
- Diagnostics: Automatic diagnostics at start-up and continuous monitoring of all systems. Automatic reset of alarms when the fault is corrected, and the scrub technician without support can take most corrective actions. Test Diagnostics available at the touch of a button for trouble shooting components available.
- Adaptive Tissue Control: The Generator automatically adapts to tissue loading to maintain the selected power level. The generator power level can be changed at any time during use.
- Upgradeable Software Capability: Designed with a reserve microprocessor and memory capability to permit upgrades for future software maintenance, energy devices and continuous improvement under FDA's Special 510(k) submission process. Allows for future expansion to other products to limit the obsolescence of capital.

9.6.2 Prime™ Reusable Transducer Handpiece Design Features

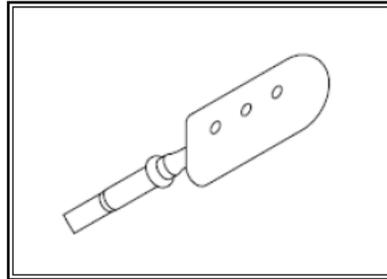
- Reusable: The Transducer is reusable because the cost of the piezoelectric actuator would be prohibitive to dispose after a single use. In addition, the device was validated for cleaning and sterilization and has demonstrated useful life beyond one hundred uses. The Prime™ G6000 Generator automated diagnostics combined with routine reuse-life inspection procedures provide in the IFU (Attachment 012) is the mechanism to ascertain that the device is still within specifications.
- Piezoelectric Technology: A piezoelectric actuator drives the ultrasonic vibration by converting electrical impulses to linear ultrasonic vibration.

9.6.3 Prime™ Ultrasonic Scalpel Reusable Blades Design Features

- Reusable: Reusable blades may provide lower cost-per-case compared to Single Patient Use (SPU) disposable blades/devices. Costs are lower because cleaning and sterilization overhead costs are incrementally low due to blades being cleaned and sterilized with other system components (i.e. the transducer and cable).
- Seals Vessels: Cutting and sealing of vessels up to (b)(4) as well as the lymphatics in endoscopic and open procedures.
- Open, Endoscopic and Bariatric Lengths: The 11 cm blade permits close control in open procedures, the 37 mm blade assures adequate length of reach in endoscopic procedures and the 46 mm blade permits adequate length for bariatric procedures or where additional length is needed to reach deep anatomy.
- Adaptive System: The system as well as predicate systems are designed to adjust the voltage and current delivered to the transducer handpiece when encountering differing tissue loads to maintain the blade motion at the selected power setting.
- Thermal Management: The surgeon can exercise control over hemostasis and thermal spread if desired by selecting the power level and duty cycle.

- Blade Tip Protectors: Blade tip protectors are provided to reduce potential damage during handling and sterilization (the Protective Tips were validated for use during sterilization see Attachment 011). The tip protectors are manufactured (b)(4)

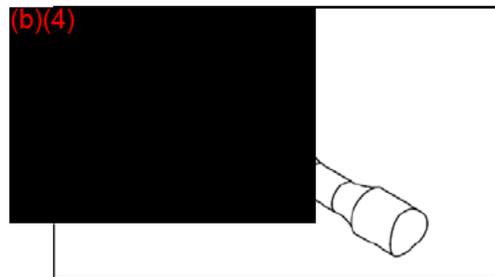
Figure 9-21: Blade Protective Tip



9.6.4 Prime™ Ultrasonic Curved Blade (Reusable) Design Features

- Curved: Allows visualization from a wide range of angles.
- Slender Design: Delicate cutting and coagulation in confined anatomy and delicate procedures.
- Delicate Blunt Tip: Blunt tip for small spot, precise and delicate coagulation.

Figure 9-22: Curved Blade



9.6.5 Omni™ Ultrasonic Hook Blade (Reusable) Design Features and Options

- Cutting Edges: Edges are provided for rapid cutting.
- (b)(4) Hook Curved Design: Allows visualization from a wide range of angles and reduced time (b)(4)
- Broad Coagulation Surfaces: Blunt convex surface achieves broadest area of coagulation for slower cutting and tissue plane separation.

Figure 9-23: Hook Blade



9.7 Principles of Operation

The **Prime™ G6000 Generator** converts the AC line voltage to a regulated DC level. The DC level is then switched at the resonant frequency of the transducer and blade. The switched signal is then filtered and delivered to the transducer, where it resonates the acoustic drive train (i.e. piezoelectric transducer). The foot switch (or hand switch when available in the further) controls activation of the transducer and the blade. In addition, the foot switch allows the user to select maximum power (Level 5) by depressing the FULL pedal or a variable power setting (between 1 and 5) by depressing the VAR pedal. The **Prime™** system like the predicate system is adaptive in its' design to adjust the voltage and current delivery to the transducer handpiece when encountering differing tissue loads to maintain the blade motion at the selected power setting.

Key technical components of the **Prime™ G6000 Generator** system include:

- Power Entry Module: Accepts a standard, hospital grade, and Type-CF line cord. The module allows selection of the line voltage for use in the USA (110 v) and International (220 v).
- Power Supply: Provides VDC to DC/DC Converter and Current/Power Regulator Circuit.
- Current and Power Regulator Circuits: Provides Current/Power regulation for all the ancillary generator circuits. Detection circuits detect and protect the transducer from out of range current, voltage and off frequency conditions. The acceptable range is (b)(4) the current, voltage, or frequency of the selected operating conditions.
- Circuit Isolation: Optical isolators and transformers provide the necessary isolation barrier to protect the patient and/or user from electrical shock.
- Organic Light Emitting Diode Display (OLED) and Front Panel: The OLED Display (or LED) and front panel are used as indicators for reporting the operating mode and condition of the System.
- Microcontroller: The microcontroller contains the software program that drives the Generator. The software provides the user interface, frequency drive signal, as well as drive signals to the Liquid Crystal Display, front panel indicators and generator audio circuit.

- **Fault Detection Circuitry:** Startup of the **Prime™ G6000 Generator** software will automatically conduct a system check including the condition of the generator, footswitch, (and hand switch where applicable), transducer and blade. The generator fault detection circuits continuously monitor the transducer's current, voltage and frequency. When a fault is detected, the transducer drive power is shut down and an alarm will sound. Alarms inform the user of transducer and other anomalies such as components that are at the end of their useful life or out of tolerance torque when connecting the blade to the transducer handpiece. Power is shut off to the transducer and cable when an alarm sounds and will reset when the cause of the alarm is corrected.

9.8 Comparison to Predicate Devices and Conclusion

The Prime™ Adaptive Ultrasonic Scalpel System and Blades are designed to be substantially equivalent to the predicate device with regard to dimensions, manufacturing processes, materials, non-sterile packaging and intended use of the device. Technological characteristics are equivalent to predicate devices including reusable scalpel blades (see supplemental predicate information below). Supplemental predicate systems are reusable including the previous legally marketed scalpel blades; therefore, the reusable **Prime™ Adaptive Ultrasonic Scalpel System and Blades** raise no new questions of safety or efficacy.

9.8.1 Predicate Devices:

K002981-UltraCision® Harmonic Scalpel®-GEN300 EES Generator and Footswitch, Ethicon Endo-Surgery, Inc.

K990430-Ultracision® HARMONIC Scalpel®-Shears (Hand Piece and 5 mm Hook Blades), Ethicon Endo-Surgery

K010898-UltraCision Harmonic Scalpel Blade-Hook Blade, Ethicon Endo-Surgery

K053056-Harmonic Scalpel Blades and Shears-Curved Blade, Ethicon Endo-Surgery, Inc.

K010309-Sonopet® Surgical Aspirator, Mutoh America CO., LTD. ***

***K010309 is listed as a predicate device in regard to (b)(4)

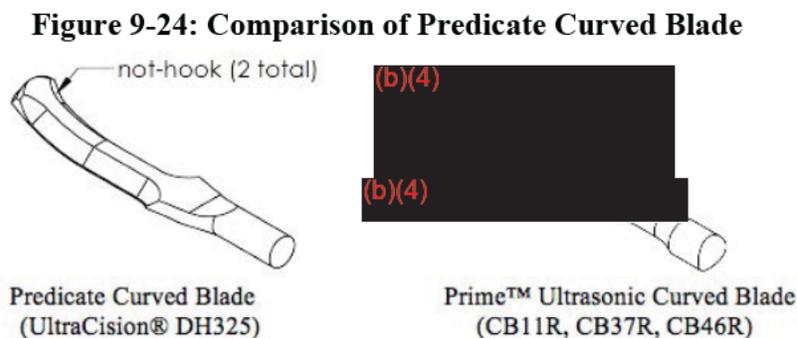
(b)(4)

Ultrasonic Scalpel Reusable Blades), and is not intended for comparison to the device technology, characteristics, or intended use.

9.8.2 Predicate Comparison

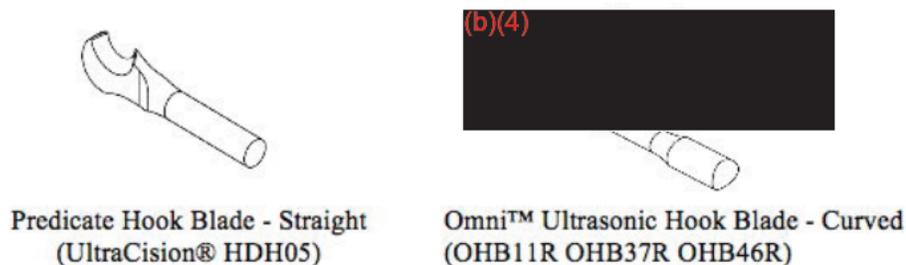
The materials and function of the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** is equivalent to the predicate device in terms of device indications for use, description, technology, specifications, features, and principles of operation. The differences between the predicates and the subject device are the additional features to improve upon the predicate design in order to accommodate a wider range of surgeon preferences. These improvements are:

- a) Curved Blade End Effector Compact Design: The reusable **Prime™ Ultrasonic Curved Blades** (see Figure 9-24) has a compact or slim profile that provides the surgeon with greater access in confined anatomy and delicate procedures.
- b) Centroidal Balanced End Effector Design – The compact **Prime™ Ultrasonic Curved Blade** is balanced with the centroid of the end effector on the centerline of the blade. This design was optimized using CAD Finite Element Analyses and validated in bench testing (Attachment 022-US-0019 Blade Life Testing). However, the predicate Ethicon EndoSurgery UltraCision® curved blades are wider as illustrated in Figure 9-4 and balanced such that the centroid falls to one side of the blade centerline. Balance is the key design parameter for an ultrasonic blade and the Ethicon EndoSurgery UltraCision® hooked blades are balance with the centroid on the centerline; therefore, the **Prime™ Ultrasonic Curved Blades** are substantially equivalent to the predicate device.



- c) Hook Blade End Effector Design: Although predicate devices are provided in both straight and curved designs, the predicate hook blade is provided only in a straight design (see Figure 9-25). The reusable **Omni™ Ultrasonic Hook Blade** (Figure 9-25) is curved to increase visibility when compared to the predicate straight hooked blade. In addition, the **Omni™ Ultrasonic Hook Blade** has a balanced, (b)(4) [redacted]. The hooked blade designs are compared in Figure 9-25 to show that the **Omin™ Ultrasonic Hook Blade** has (b)(4) [redacted] similar to the predicate curved blade in Figure 9-24. Combining these two predicate designs does not introduce new risks because of 1) similarity to the predicate curved blade, 2) durability with respect to incidental or unintended damage validated in life testing for fatigue (Ref: Attachment 022-US-0019 Blade Life Testing).

Figure 9-25: Comparison of Hook Blades



9.8.3 Supplementary Predicate Information

In addition to the cited predicate device (see Section 10-Substantial Equivalence, Predicate Comparison Table-10.2, on page 148), EndoPrime also examined reusable predicate devices for the purpose of filing this 510(k) Premarket Submission. The additional devices examined were the UltraCision® Harmonic® Scalpel Blade System, model number DH010, LC1004-2 and other reusable blades which are legally marketed devices under FDA clearance (e.g. K930352 HARMONIC SCALPEL REUSABLE LAPORASCOPIC BLADE SYSTEM). The DH010 and similar 10 mm reusable blades are predicates to the cited single patient use (SPU) predicates and therefore apply as predicates to the **Prime™ Ultrasonic Scalpel Reusable Blades**. These reusable predicate devices allowed for disassembly of the blade and sheath for cleaning, sterilization and reuse (See Section 13-Biocompatibility for more information on comparison of the reusable sterilization process between these predicates). **Prime™ Adaptive Ultrasonic Scalpel System and Blades** are designed to function the same as the predicate devices, but are validated for sterilization and reuse; therefore, the **Prime™ Ultrasonic Scalpel Reusable Blades** are substantially equivalent.

9.8.4 Conclusion

EndoPrime, Inc. concludes that the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** are substantially equivalent to the predicate systems and raises no new questions of safety or effectiveness. This conclusion is based upon the devices' similarities in functional design, materials, indications for use and methods of construction.

10. Substantial Equivalence

10.1 Predicate Summary

The **Prime™ Adaptive Ultrasonic Scalpel System and Blades**, and family of products, which are the subject of this submission, were compared successfully for substantial equivalence in indications for use, device descriptions, materials, technology, safety, and/or functions to the following devices:

- **K002981**-Ultracision® Harmonic Scalpel®, Ethicon Endo-Surgery, Inc.
- **K990430**-Ultracision® HARMONIC Scalpel® Hand Piece, Ethicon Endo-Surgery
- **K010898**-Ultracision Harmonic Scalpel Blade, Ethicon Endo-Surgery Inc.
- **K053056**-Harmonic Scalpel Blades and Shears, Ethicon Endo-Surgery, Inc.
- **K010309**-Sonopet® Surgical Aspirator, Mutoh America CO., LTD. ***(now Stryker)
(b)(4)

Because the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** include several different device components for the purpose of this 510(k) submission, the predicate comparison required the examination of four different Predicates. All of the predicate devices are currently legally marketed systems manufactured by Ethicon Endo-Surgery with the exception of the Sonopet® device which is manufactured by Stryker. This approach to predicate comparison was selected, rather than submitting several separate overlapping 510(k) submissions. Throughout the substantial equivalence discussion, evidence will be provided that the subject device and predicate devices have the same general indications for intended use, no technological differences that change the overall characteristics of the device components, and the principles of operations are all substantially equivalent.

10.2 Indications for Use/Intended Use

The **Prime™ Adaptive Ultrasonic Scalpel System and Blades** is a cutting and coagulation system indicated for open, laparoscopic, and endoscopic surgery in soft tissue where control of hemostasis and thermal spread is desired. The system is indicated for dissection, sealing, transection,otomy creation and transection/coagulation of vessels as indicated for each cutting and coagulation instrument (consult the instructions for use provide with each instrument). The system can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels.

When compared to the predicate indications and intended uses, all of the devices were indicated for use in soft tissue incisions when bleeding control and minimal thermal injury are desired. Both the subject device and predicates were intended as an adjunct to or substitute for electrosurgery instruments. One exception is K010309-Sonopet® Ultrasonic Aspirator (by Stryker) is provided as a predicate to the **Prime™ Ultrasonic Blades** (b)(4) blade in an ultrasonic blade and is indicated for aspiration of tissue, and is not intended for comparison to the device technology, characteristics, or intended use.

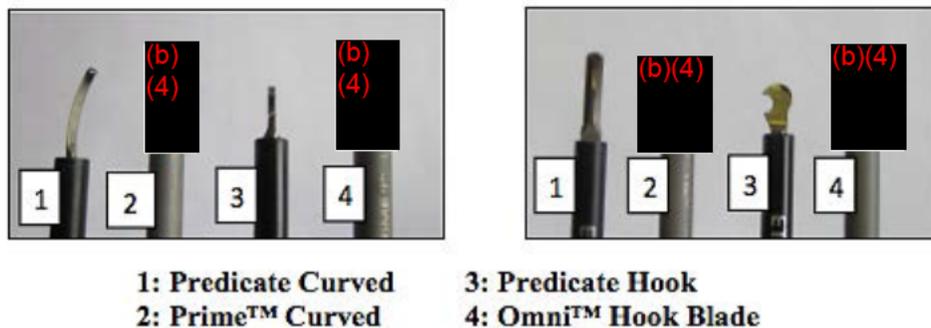
Conclusion: The indications for use/intended use for the subject device and the predicate device listed in this section, are substantially equivalent, and raise no new questions of safety or efficacy.

10.3 Technological Characteristics

With regard to the principle technological differences, there are four primary differences that will be discussed in this section: (1) the shape of the hook blade, (2) the blades are reusable rather than disposable, (3) the way the sheath attaches to the blade, and (4) a detachable Transducer connector cable. None of the technological differences that will be discussed in this section were shown in testing to alter the indication for intended use, or raise any new questions regarding the safety or effectiveness of the subject device. Before discussing the differences, a brief device-to-device technological comparison is provided.

The main component to the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** is the **Prime™ G6000 Generator**, which was compared to predicate **K002981**, the UltraCision® Harmonic Scalpel® system. The predicate system includes the GEN300 generator and footswitch, as well as a Scalpel Hook Blade, 5mm x 36 cm length (DH05). Both generators are ultrasonic and mechanical devices used as a power drive in conjunction with cutting and coagulation instruments used for soft tissue procedures. The only difference in technology to consider here is the shape of the hook blade, and how that would affect performance and safety. An illustration of the comparison blades is provided below:

Figure 10-1 Comparison of Subject & Predicate Blades



In addition to the **Omni™ Ultrasonic Hook Blades** have some design difference from the predicate blades, which have been compared to **K010898**-UltraCision Harmonic Scalpel Hook Blade, and the **K053056**-Harmonic Scalpel Blades and Shears. Overall, the Prime™ blade products are designed and tested to be reusable, while predicate blades are both reusable and single patient use (SPU) disposable. The following are the technological differences in the subject blades, when compared to the predicates:

Curved Blades: The **Prime™ Ultrasonic Curved Blades** have a compact design to improve access in narrow, delicate anatomy but are substantially equivalent in use and performance (Figure 10-1: blade profile 1 vs. 2).

Hook Blade: The **Omni™ Ultrasonic Hooked Blade** is curved for better visibility with a (b)(4) (Figure 10-1: blade profile 3 vs. 4). The **Omni™ Ultrasonic Hooked Blade** is very similar to the design of the predicate curved blade and is substantially equivalent in use and performance.

The Animal testing (reference Attachment 003) conducted using both the subject and predicate devices, shows that the **Omni™ Ultrasonic Hook Blade** stopped bleeding slightly more effectively in comparison to the control or predicate blade. Additional findings of substance during animal testing involved a full thickness cut approximately 5cm from the edge of the liver lobe of the porcine subject using the **Omni™ Ultrasonic Hook Blade** and predicate hook blades. Bleeding occurred during the entire procedure, and the predicate device was less effective in controlling the bleeding. The **Omni™ Ultrasonic Hook Blade** (test device) was used at the completion of the procedure to successfully control bleeding for the control site. In comparison procedures involving the curved blades, the **Prime™** blade took slightly less time to cut through the vessels of the small bowel.

In addition to the technological differences in the blades, the way the blades attach to the transducer handpiece is somewhat different than the predicate. Essentially, the **Prime™ Ultrasonic Scalpel Reusable Blades** sheath can be disassembled to allow access for cleaning, sterilization and reuse, where the sheath of the predicate SPU disposable blades cannot be disassembled. This technological change does not affect the description or intended use of the blades, nor does it raise any new questions of safety or effectiveness. Therefore, the **Prime™ Ultrasonic Scalpel Reusable Blades** are substantially equivalent in performance to the predicate devices

EndoPrime Inc. completed mechanical bench testing in-house for use with this 510(k) Premarket Submission (see Attachment 004), which used the predicate as a control device. The predicate transducer handpiece was tested against the **K990430-UltraCision® HARMONIC Scalpel Shears- Hand Piece**, the fourth predicate listed in the comparison table provided at the end of this section. Both the subject transducer and the predicate transducer were designed to convert electrical energy from the generator to mechanical motion for the instrument blades, and the devices are equivalent in safety and effectiveness.

There is one additional technological difference in the design of the **Prime™ Reusable Transducer Handpiece** and the predicate device, and that is the detachable connector cable used to connect the Transducer to the generator. The detachable connector cable presents only benefits to the **Prime™ Reusable Transducer Handpiece**, and raises no new questions of the safety or effectiveness of the device. The technological advantage of the detachable connector, is that the once the cable is disconnected, no further power is delivered from the generator until the connector is reengaged. As an example, if during a procedure a blade encounters an issue with performance, the surgeon or scrub technician may simply disconnect the cable until the blade is replaced rather than remotely placing the generator in standby mode to safely change blades. When the connector cable is re-connected, power will be reinstated. Therefore, the **Prime™ Reusable Transducer Handpiece** does not introduce any new risks beyond the predicate device designs referenced in Attachment 003-(b)(4) Animal Study.

Performance, Bench, and Animal testing was conducted that confirmed that the minor differences between the devices does not adversely impact performance, safety or effectiveness. A Predicate Comparison Table is provided to separate each component predicate comparison in detail, with an overview of all of the predicates (See Predicate Comparison Table 10-2 on page 148). Predicate labeling is provided in Attachment 015.

10.4 Materials of Construction

A comparison was conducted utilizing one additional predicate device with regard to the reusable aspect of the **Prime™ Ultrasonic Scalpel Reusable Blades**, materials of construction, and to address biocompatibility. The following predicate was reviewed for this limited capacity:

- **K010309-Mutoh America CO., LTD. (now Stryker), Sonopet® Surgical Aspirator - (b)(4) (b)(4) Ultrasonic Blades - provide non-sterile.**

All of the cited predicates are legally marketed devices in the US. The following table provides a predicate comparison of materials and processes considered, in addition to all of the information provided in the Master Predicate Comparison Table provided in this section:

Table 10-1: Comparisons of Sub-Predicate Device Materials and Processes

Prime™ Component	Material	Process (Process Material)	Predicate Component
Prime™ Ultrasonic Reusable Blade with (b)(4)	(b)(4)		K002981 -All UltraCision® Blades Including Model DH010 (b)(4)
			K010309-Sonopet® Model UST-2001 (b)(4) Ultrasonic Reusable Blades, Including Model: 5450-800-100 (b)(4)
Sheath Tubing			K002981 -UltraCision® Reusable Blade Model DH010 Sleeve Tubing
(b)(4) Rings (the rings suspend the blade inside the Sheath and provide a fluid seal)			K002981 -All UltraCision® Blades Including Model DH010
Sheath Hub (Or Sleeve)			304 SS: Same as all Predicate device Sleeve Tubing
			K002981 -Adapter (Hub) Reusable: Model HSA06

K002981 -UltraCision® Reusable Blade Model DH010 is cited here for its titanium alloy material of construction conforming to ASTM F136 Ti-6Al-4V ELI: *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*, a Recognized Consensus Standard (FDA Recognition Number 8-377). The ASTM F136 6AL4V-ELI is a refined grade of titanium approved for use in surgical and implantable medical device.

K010309-Sonopet® Model UST-2001 is cited here for its use of (b)(4) ASTM F136 6AL4V-ELI in an ultrasonic device. A second predicate device for this contact material was necessary because the **Prime™ Ultrasonic Scalpel Reusable Blades** are (b)(4) in the end effector area of the blade including the area exposed beyond the sheath; however, the Ethicon blades are not (b)(4), therefore the additional predicate was necessary to assure

(b)(4)

contact with the human body including implantation.

In all other aspects of biocompatibility, the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** family of products, were substantially equivalent to those predicates listed in the Primary Predicate Comparison Table in this section, and raised no new questions of safety or effectiveness.

10.5 Conclusion

EndoPrime, Inc. concludes that the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** are substantially equivalent to the predicates cited and discussed in this section, and the proposed submission does not raise any new issues of safety or effectiveness.

Continued on next page

Device Characteristics	Subject Device	Primary Predicate for Intended Use & Technology	Primary Predicate for Intended Use & Technology	Primary Predicate for Intended Use & Technology	Primary Predicate for Intended Use & Technology	Primary Predicate for Intended Use & Technology
Name and Identification	Prime™ Adaptive Ultrasonic Scalpel System and Blades	Predicate Device #1	Predicate Device #2	Predicate Device #3	Predicate Device #4	Predicate Device #5
	EndoPrime, Inc.	(K002981)	(K990430)	(K010898)	(K053056)	(K010309)
	Prime™ Adaptive Ultrasonic Scalpel System and Blades	UltraCision® Harmonic Scalpel® -GEN300 Generator & Footswitch	UltraCision® HARMONIC Scalpel® Shears- Hand Piece & 5mm Hook Blade	UltraCision Harmonic Scalpel Blades with Protective Sleeve- 5mm Hook Blade	Harmonic Scalpel Blades and Shears	Sonopet Modell UST-2001 Ultrasonic Surgical Aspirator
Manufacturer	EndoPrime, Inc. (OEM: Reach Surgical Inc.)	Ethicon Endo-Surgery, Inc.	Ethicon Endo-Surgery	Ethicon Endo-Surgery, Inc.	Ethicon Endo-Surgery, Inc.	Mutoh America Co LTD (now Stryker)
Trade Name	Prime™ Adaptive Ultrasonic Scalpel System and Blades	UltraCision® Harmonic Scalpel®	UltraCision® HARMONIC Scalpel® Shears	UltraCision Harmonic Scalpel Hook Blade	Harmonic Scalpel Blades and Shears	Ultrasonic Surgical Aspirator
510(k) Number	This Submission	K002981	K990430	K010898	K053056	K010309
Product Codes	GEI/LFL	GEI/LFL	LFL	LFL	LFL	LFL
Device Classification	Class II	Class II	Class II	Class II	Class II	Class II
Panel Code	79	79	79	79	79	79
Regulation	21 CFR § 878.4400	21 CFR § 878.4400	N/A	21 CFR § 878.4400	21 CFR § 878.4400	22 CFR § 878.4400
Device Classification	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery

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

Table 10-2: Predicate Comparison Table (Continued)						
510(k) Number	This Submission	K002981	K990430	K010898	K053056	K010309
Intended Use	The Prime™ Adaptive Ultrasonic Scalpel System is a cutting and coagulation system indicated for open, laparoscopic, and endoscopic surgery in soft tissue where control of hemostasis and thermal spread is desired. The system is indicated for dissection, sealing, transection,otomy creation and transection/coagulation of vessels as indicated for each cutting and coagulation instrument used (consult the instructions for use provide with each instrument). The system can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels.	The UltraCision® Harmonic Scalpel System is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electro-surgery, lasers, and steel scalpels in general, pediatric, gynecologic, urologic and other open and endoscopic procedures.	The UltraCision® Instruments are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electro-surgery, lasers and steel scalpels.	The UltraCision Harmonic Scalpel is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electro-surgery, lasers, and steel scalpels in general, plastic, gynecological ENT (Ear, Nose, Throat), thoracic surgery including mobilization of the Internal Mammary Artery (IMA).	The Harmonic Scalpel Shears Instruments are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electro-surgery, lasers, and steel scalpels in general, gynecologic, urologic and other open and endoscopic procedures.	Soft Tissue Ablation & Fine Bone Dissection (This predicate is cited for blade material equivalency only)

Continued on next page

Table 10-2: Predicate Comparison Table (Continued)						
510(k) Number	This Submission	K002981	K990430	K010898	K053056	K010309
Device Description	The Prime™ Adaptive Ultrasonic Scalpel System and Blades is a family of devices that utilize ultrasonic energy to enable hemostatic cutting and/or coagulation of soft tissue. The system consists of an ultrasonic generator, a reusable transducer handpiece and a variety of open and minimally invasive scalpel blade instruments.	The UltraCision® Harmonic Scalpel is an ultrasonic instrument for the cutting and coagulation of soft tissues. The device system has three essential parts: the generator/footswitch, the hand piece and the instruments, which are available in various lengths shapes and types.	The UltraCision® Hand Piece is the hand-held component of the Ultracision Instrumentation. The instrument is for cutting and coagulating soft tissues.	The protective sleeve is a cylindrical shaped silicone tube applied by the user to the blade sheath before a surgical procedure. The purpose of the protective sleeve is to provide a thermal barrier between the blade sheath and the patient.	The Harmonic Scalpel Blades and Shears are ultrasonic surgical instruments for the cutting and coagulation of soft tissue incisions when bleeding control and minimal thermal injury are desired. The device system has three essential parts: the generator/footswitch, the hand piece and the instruments, which are available in various lengths shapes and types. The selection of the appropriate instrument is a matter of surgeon preference.	The Stryker Sonopet Console, when used with the Handpiece, is intended for use in surgical procedures where fragmentation, emulsification, and aspiration of soft and hard tissue is desirable, including neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, plastic and reconstructive surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, and thoracoscopic surgery.

Continued on next page

Table 10-2: Predicate Comparison Table (Continued)						
510(k)	This Submission	K002981	K990430	K010898	K053056	K010309
Anatomy/ Approach	Soft Tissue	Soft Tissue	Soft Tissue	Soft Tissue	Soft Tissue	Soft Tissue and other tissues
Device System Components & Product Model	Generator, Footswitch & Cable: G6000	GEN300	-	-	-	-
	Transducer Handpiece: TRN5	-	HP054	-	-	-
	<u>Curved Blades - Length:</u> CB11R-11cm, CB37R-37cm, CB46R- 46cm	-	Not applicable	HC145-14cm	HC325-32cm HC105-10cm HF105-10cm	5450-800-100
	<u>Hook Blades-Length:</u> OHB11R-11cm, OHB37R-37cm,	DH05 Other Devices Range from 14 to 36cm	Not applicable	DH105, SH105-10cm DH145, SH145-	SH325-32cm	5450-800-100
Materials of Construction	(b)(4)					

Continued on next page

Table 10-2: Predicate Comparison Table (Continued)						
510(k) Number	This Submission	K002981	K990430	K010898	K053056	K010309
Frequency	Generator drive (b)(4)					
Blades & transducer resonant range: 55.5 ± 0.5 kHz	Generator drive (b)(4)	Transducer resonant range: 55.5 ± 0.5 kHz	Blade resonant range: 55.5 ± 0.5 kHz	Blade resonant range: 55.5 ± 0.5 kHz	-	
Amplitude	(b)(4)	Blades: <100 um at full power	Transducer: 20-24 um	Blades: <100 um at full power	Blades: <100 um at full power	-
Sterilization	Provided non-sterile	Blade sterilized by Irradiation	Hand Piece provided non-sterile	Sterilized by Irradiation	Sterilized by Irradiation	Provided non-sterile
	Transducer and blades are validated for cleaning and steam sterilization. Steam sterilization	Blades: Single use device	Steam sterilization cycle parameters are given in the IFU.	Single use device	Single use device	Not applicable
	Not applicable for the Generator and non-sterile equipment used outside sterile field.	Not applicable for Generator and non-sterile equipment used outside sterile field.	Not applicable	Not applicable	Not applicable	Not applicable

Continued on next page

*As measured by the Harmonic® Generator 300

Table 10-2: Predicate Comparison Table (Continued)						
510(k) Number	This Submission	K002981	K990430	K010898	K053056	K010309
Packaging	<u>Prime™ Reusable Transducer Handpiece</u> : Poly bag, support tray, and paperboard carton <u>Blades</u> : Poly bag that is open ended and paperboard carton	<u>Scalpel</u> : Blister pack with Tyvek® Lid <u>Hand Piece</u> : Information not available.	<u>Scalpel</u> : Blister pack with Tyvek® Lid	<u>Scalpel</u> : Blister pack with Tyvek® Lid	<u>Scalpel</u> : Blister pack with Tyvek® Lid	Not applicable
	G6000 Generator: poly bag, foam inserts in corrugated carton	Generator: poly bag, foam inserts in corrugated carton	Not applicable	Not applicable	Not applicable	Not applicable
Single Patent Use	No. Validated for cleaning, sterilization and multiple reuse.	Generator - No Scalpel - Yes	No	Yes	Yes	No
Shelf Life	N/A - All components are reusable	Disposables: 5 years Generator: N/A Foot Switch: N/A	Disposables: 5 years Handpiece: N/A Generator: N/A Foot Switch: N/A	Disposables: 5 years Handpiece: N/A Generator: N/A Foot Switch: N/A	Not applicable	N/A - All components are reusable
Electrical, Endoscopic & Magnetic Filed Safety	Compliant with: IEC 60601-1 Medical Equipment Safety; IEC60601-2-18 Endoscopic Equipment; and IEC 61000-4-8 Power Freq Mag Filed	IEC 60601-1 Compliant	IEC 60601-1 Compliant	Not applicable	Not applicable	Information Not Available
EMC	IEC 60601-1-2 & IEC 60601-2-2 Compliant	Information Not Available	Information Not Available	Information Not Available	Information Not Available	Information Not Available
Transport & Storage Conditions	Temperature: -13°F to 158°F (-25°C to 70°C).	Temperature -35 to +54°C	Temperature -35 to +54°C	Temperature -35 to +54°C	Temperature -35 to +54°C	Information Not Available
	Relative Humidity: <95%	Humidity: 10-95% non-condensing	Humidity: 10-100% Relative Humidity	Humidity: 10-100% Relative Humidity	Humidity: 10-100% Relative Humidity	Information Not Available

EndoPrime is releasing a new version for the US product

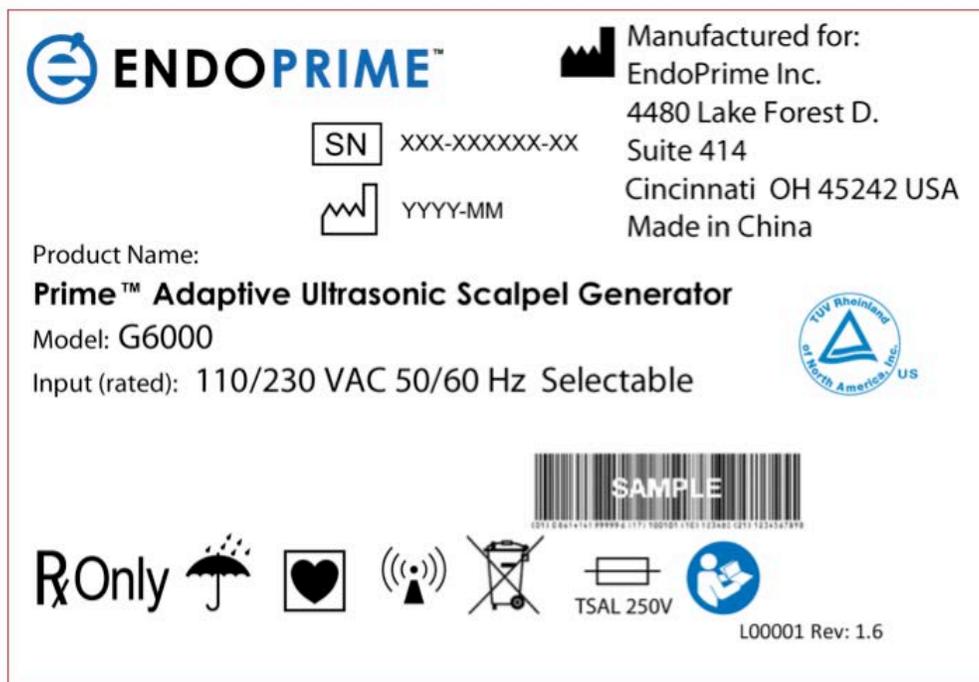
11. LABELING

This Section contains draft device and package labels, for the Prime™ Adaptive Ultrasonic Scalpel System. The package label and Instructions for Use (IFU) are provided with every shipment. The following Instructions for Use (IFUs) for each of the individual devices (system components) are provided in Attachment 012:

- **EPD0018-IFU: Prime™ G6000 Generator System Rev: A DRAFT**
- **EPD0019-IFU: Prime™ Reusable Transducer Handpiece Rev: A DRAFT**
- **EPD0020-IFU: Prime™ Ultrasonic Scalpel Reusable Blades Rev: A DRAFT**
- **EPD0021-IFU: Prime™ ADP Connector/Adapter Rev: A DRAFT**
- **EPD0022-IFU: Prime™ Adaptive Ultrasonic Scalpel Sterilization Tray Rev: A DRAFT**
- **EPD0023-IFU: Prime™ Cart Generator/Accessory Cart Rev: A DRAFT**

The following is the draft of the device label **Prime™ G6000 Generator** label:

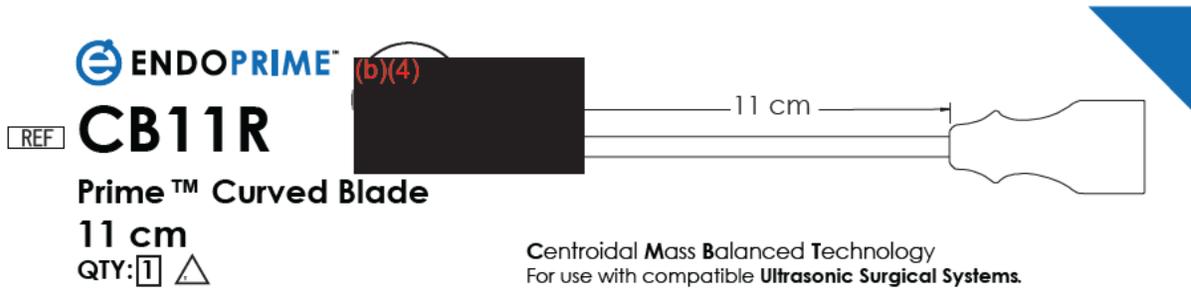
Figure 11.1: Prime™ G6000 Generator Label-L00001 Rev: 1.6



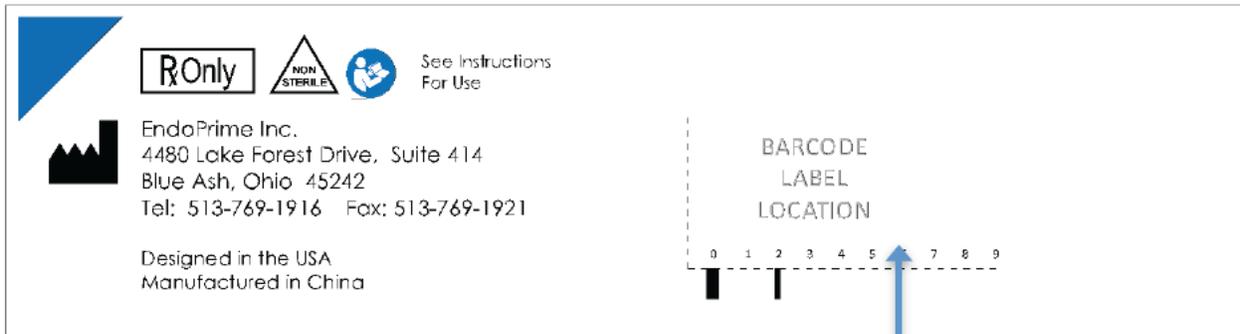
Examples of the Primary Carton labels are provided (Figure 11.2):

Figure 11.2: Prime™ Adaptive Ultrasonic Scalpel Reusable Blade Package Labeling

BOX TOP



BOX BOTTOM



BOX END 1



The remaining Prime Reusable blade label drawings differ only by product code, product name, and appropriate picture of device. These (provided in Attachment) drawings are:

- EPD0024 CB11R box labeling
- EPD0025 CB38R box labeling
- EPD0026 CB47R box labeling
- EPD0027 HB11R box labeling
- EPD0028 HB38R box labeling
- EPD0029 HB47R box labeling

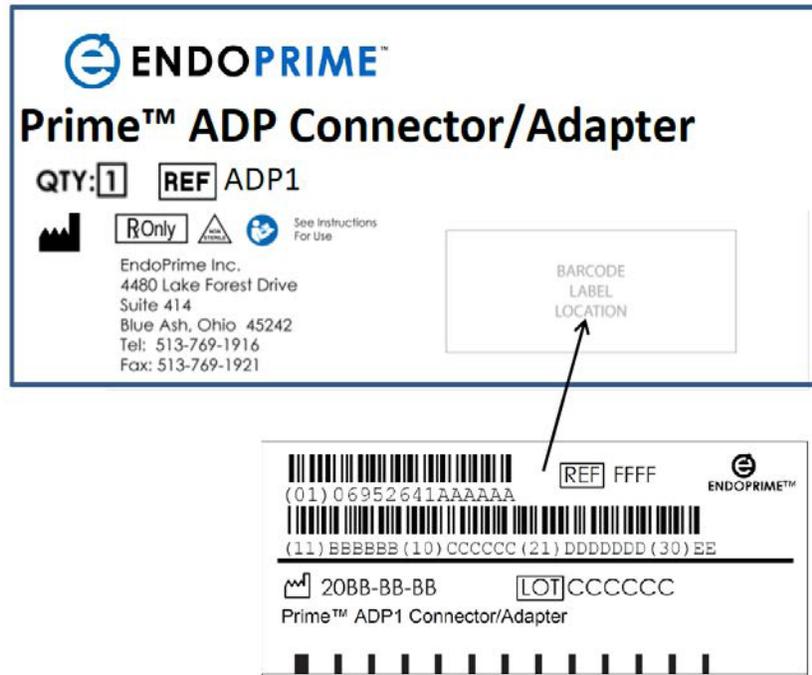
Figure 11.3: Prime™ Reusable Transducer Handpiece Draft Package Labeling



The Prime Reusable Transducer label drawings are referenced in drawing EDP0031.

The following is an example of package labeling for accessories and other devices:

Figure 11.4: Prime™ ADP Connector/Adapter Draft Package Labeling



The Prime™ ADP Connector/Adapter label drawings are referenced in drawing EDP0032.

Labeling in the form of Instructions for Use or User Manuals for the predicate devices are also provided with this submission in Attachment 014. The EndoPrime labeling is substantially equivalent to that of the predicate devices, and does not raise any new questions of safety or efficacy. The EndoPrime labeling has been written in accordance with the applicable FDA guidance document and standards:

- FDA Premarket Notification [510(k)} Submissions for Electrosurgical Devices for General Surgery: Draft Guidance for Industry and Food and Drug Administration Staff.
- FDA Device Labeling Guidance G91-1 (blue book memo) dated February 27, 1997.

12. Packaging, Cleaning, Sterilization and Storage

As previously described in Section 9-Device Description, all of the devices that make up the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** are provided non-sterile. The packaging is designed to protect and ship the device components, and in most instances, the packaging will be shipped in boxes with ancillary components. Detailed specifications regarding device packaging, sterilization, and storage is provided in the sections that follow.

12.1 Packaging Description

12.1.1 Prime™ G6000 Generator Packaging

The generator is packaged in a regular slotted container (RSC) style double wall corrugated shipper with poly foam inserts and poly bag liner. The footswitch, power cord, Transducer Handpiece (where applicable), and documentation are included in the container. The top and bottom of the container are sealed with tape. A shipping label is applied as appropriate. Figures 12-1, 12-2 and 12-3 below are drawings of the **Prime™ G6000 Generator** packaging.

Figure 12-1: Prime™ Ultrasonic Generator G6000 Corrugated Shipper Dimensions

(b)(4)



Figure 12-2: G6000 Generator Corrugated Shipper

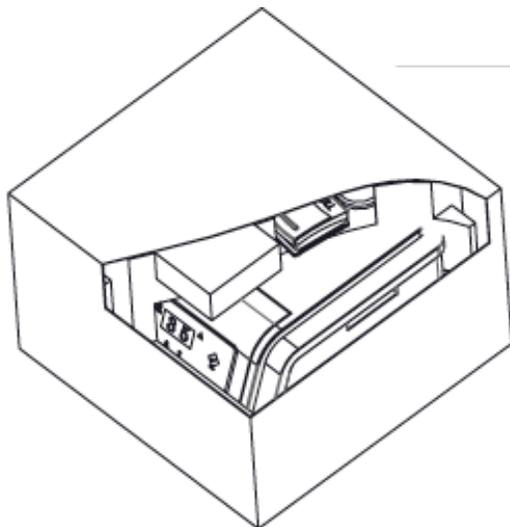
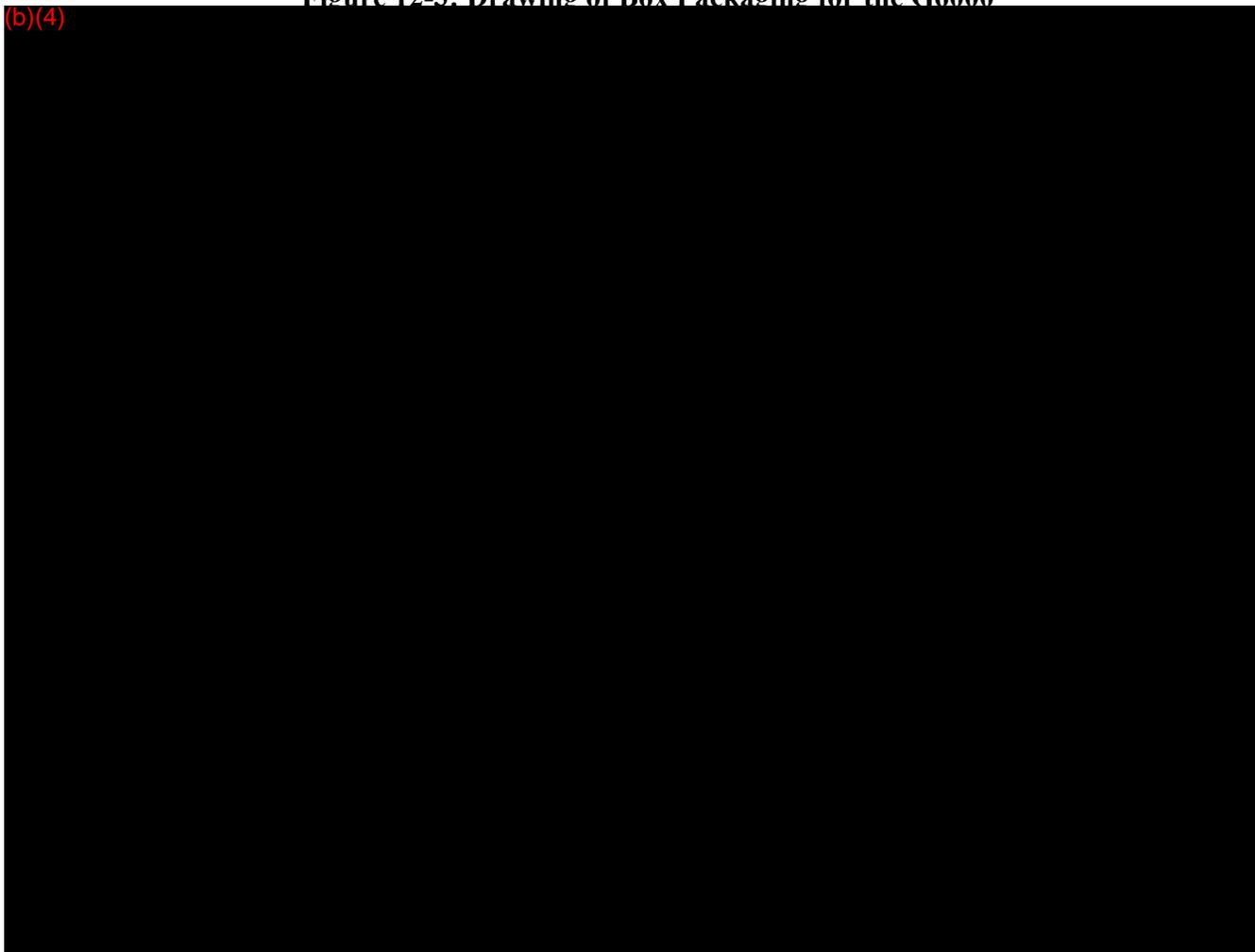


Figure 12-3: Drawing of Box Packaging for the G6000

(b)(4)



12.1.2 Footswitch Packaging

The footswitch is a **Prime™ G6000 Generator** accessory and is included in the Generator shipper described above. It is provided in its own primary package so it may also be sold and shipped as a replacement or for service. Figures 12-4 and 12-5 depict the dimensions and layout for the footswitch package.

Figure 12-4: Drawing of Box Package Dimensions for the Footswitch

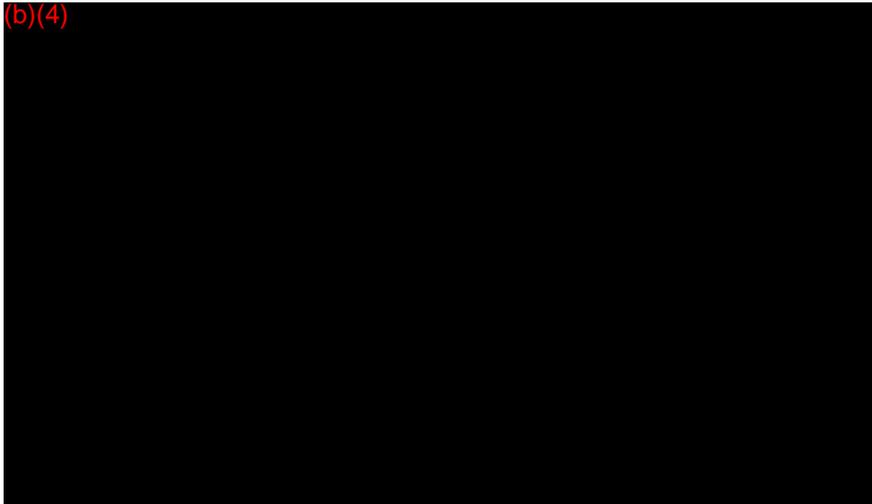
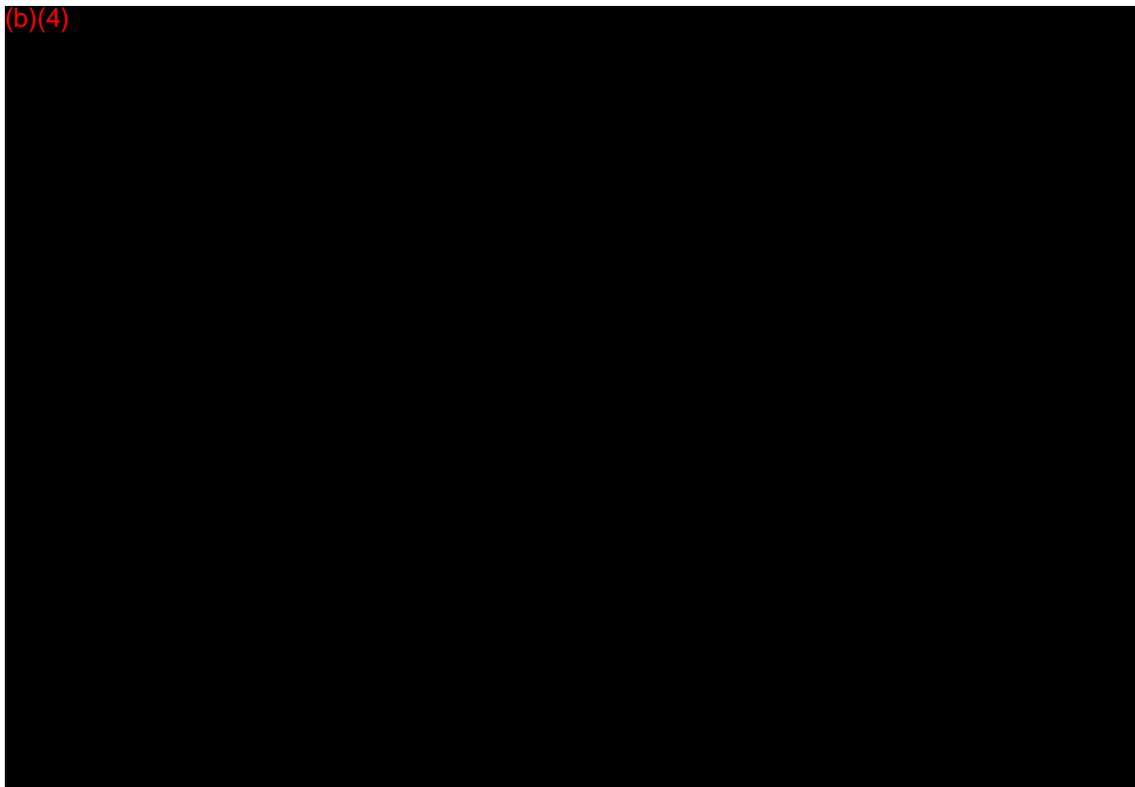


Figure 12-5: Drawing of Box Packaging for the Footswitch



12.1.3 Prime™ Reusable Transducer Handpiece Packaging

The transducer handpiece is packaged in a thermoformed tray, which is supported by a paperboard insert. This assembly is placed in a paperboard carton and sold as a unit of one. Labeling with printed graphics are placed on the carton (or printed on the carton) and overwrapped for shipping with shipping labels applied as needed. Examples of package labeling are provided in Attachment 014. The drawings in Figure 12-6, 12-7 and 12-8 depict the complete package assembly. Included in the carton are a Test Tip, Cable and Instructions for Use. The Test Tip is provided in a separate poly bag.

Figure 12-6: Drawing of Box Package Dimensions for the Transducer



Figure 12-7: Drawing of Packaged Transducer Device

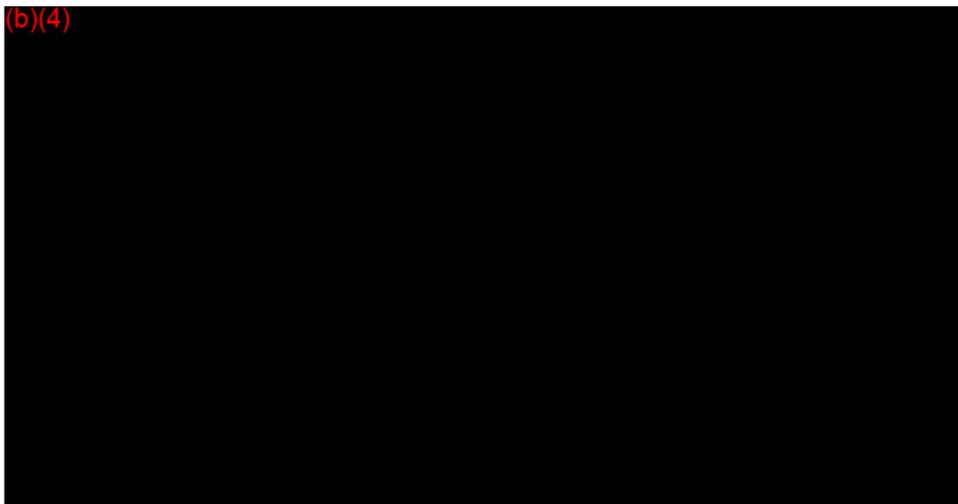
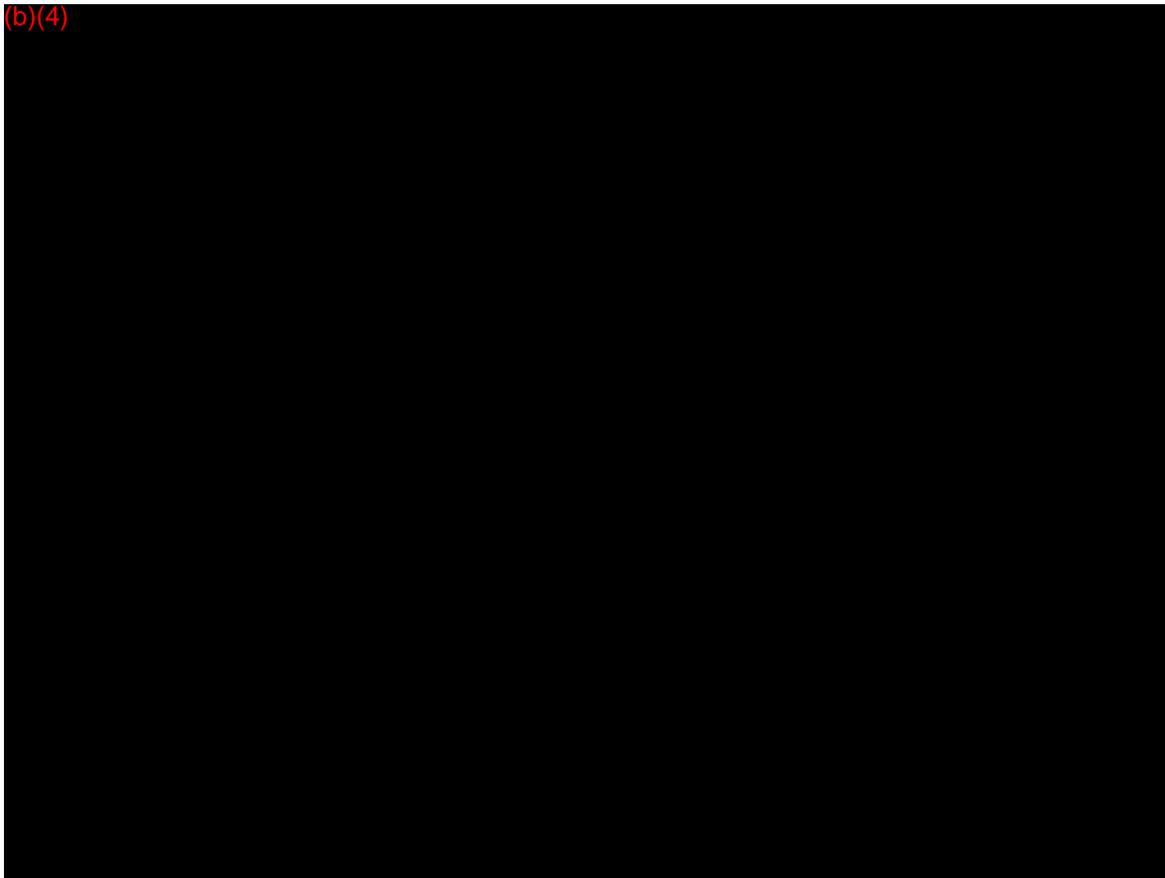


Figure 12-8: Drawing of Carton Packaging for the Transducer



12.1.4 Reusable Blade Packaging

Prime™ Ultrasonic Scalpel Reusable Blades have a total of six different product models (Section 9, Table 9-1), which will all have unique package dimensions and graphics, but the basic package design will be identical for all six models (See Figure 12-11 below for an example drawing). Each blade is provided as two components (Sheath and Blade) packaged together in a poly bag that is open ended and the end is folded over. Each blade is provided with one (1) **Prime™ Reusable Torque Wrench** and one (1) Reusable Protective Cap. The Torque Wrench and Protective Cap are packaged in the same polybag with the Protective Cap over the distal tip of the blade. The bagged blade and ancillary components are placed in a paperboard (or alternatively SBS) carton (Figure See 12-11). **Prime™ Ultrasonic Scalpel Reusable Blades** are sold non-sterile and clearly marked; however, the open-end of the poly bag provides a clear indication that sterilization is required before use. Graphics are printed on the carton and a pressure sensitive adhesive label with Barcodes, Lot Number and Date information is placed on each Carton. The devices may be provided in sets of three (3) and overwrapped for shipping. Shipping labels are applied as needed.

Figure 12-9: Prime™ Reusable Blade Carton Sizes



Figure 12-10: Sample Illustration of Packaged Blade

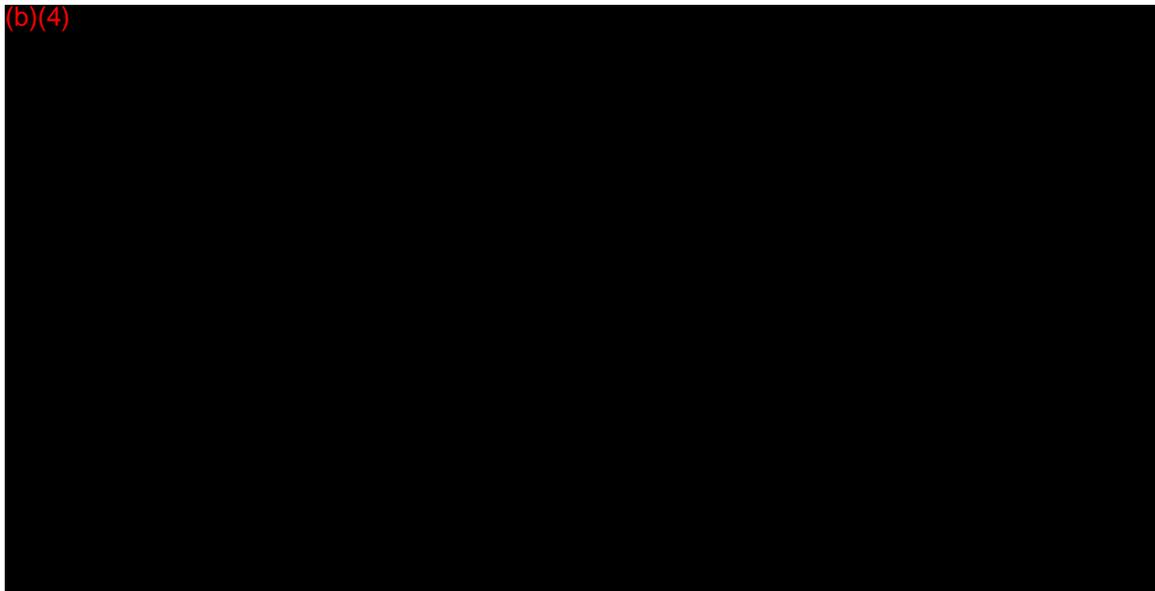
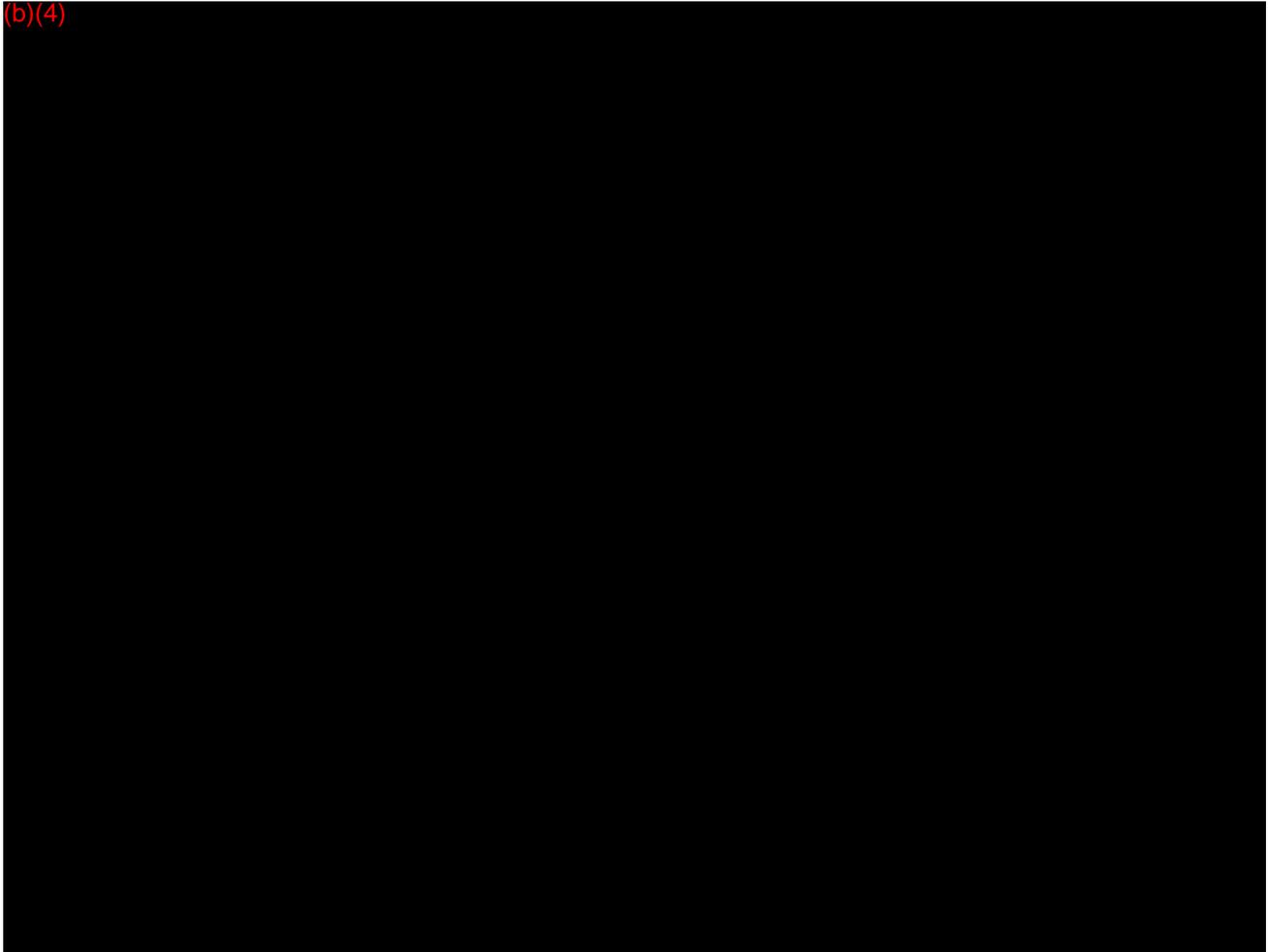


Figure 12-11: Sample Drawing of Packaging for the Scalpel Blade



12.1.5 Prime™ ADP Connector/Adaptor (for the UltraCision® GEN300 & G11)

The **Prime™ ADP Connector/Adaptor** assembly is placed in a die-cut foam insert (or equivalent thermoformed insert or paper board insert) and placed in a paperboard carton. Labeling with printed graphics is placed on the carton (or printed on the carton) and overwrapped for shipping with shipping labels applied as needed.

Figure 12-12: Photo of Packaged

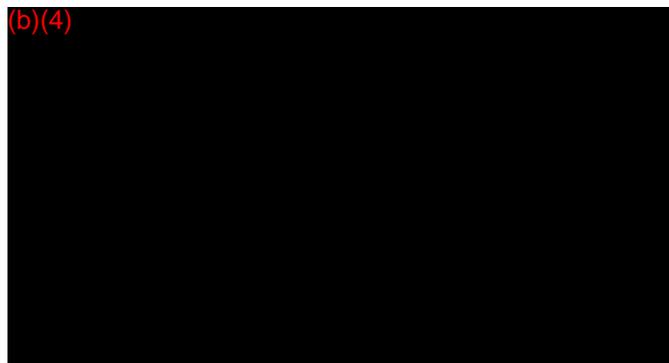


Figure 12-13: Prime™ ADP Connector/Adaptor Carton Sizes

(b)(4)

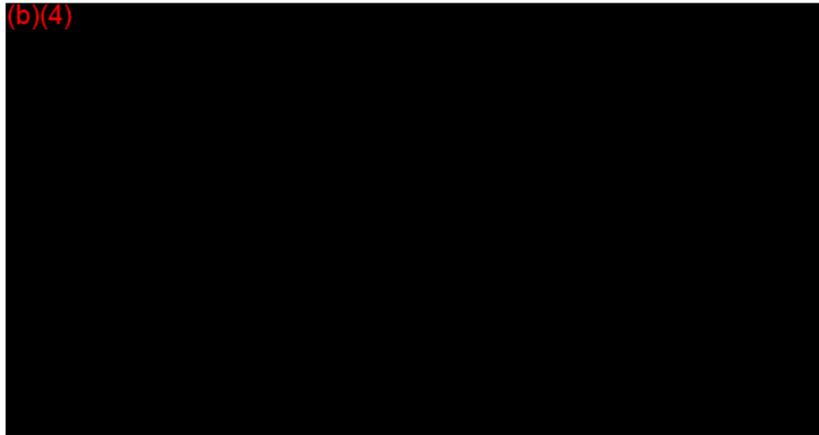
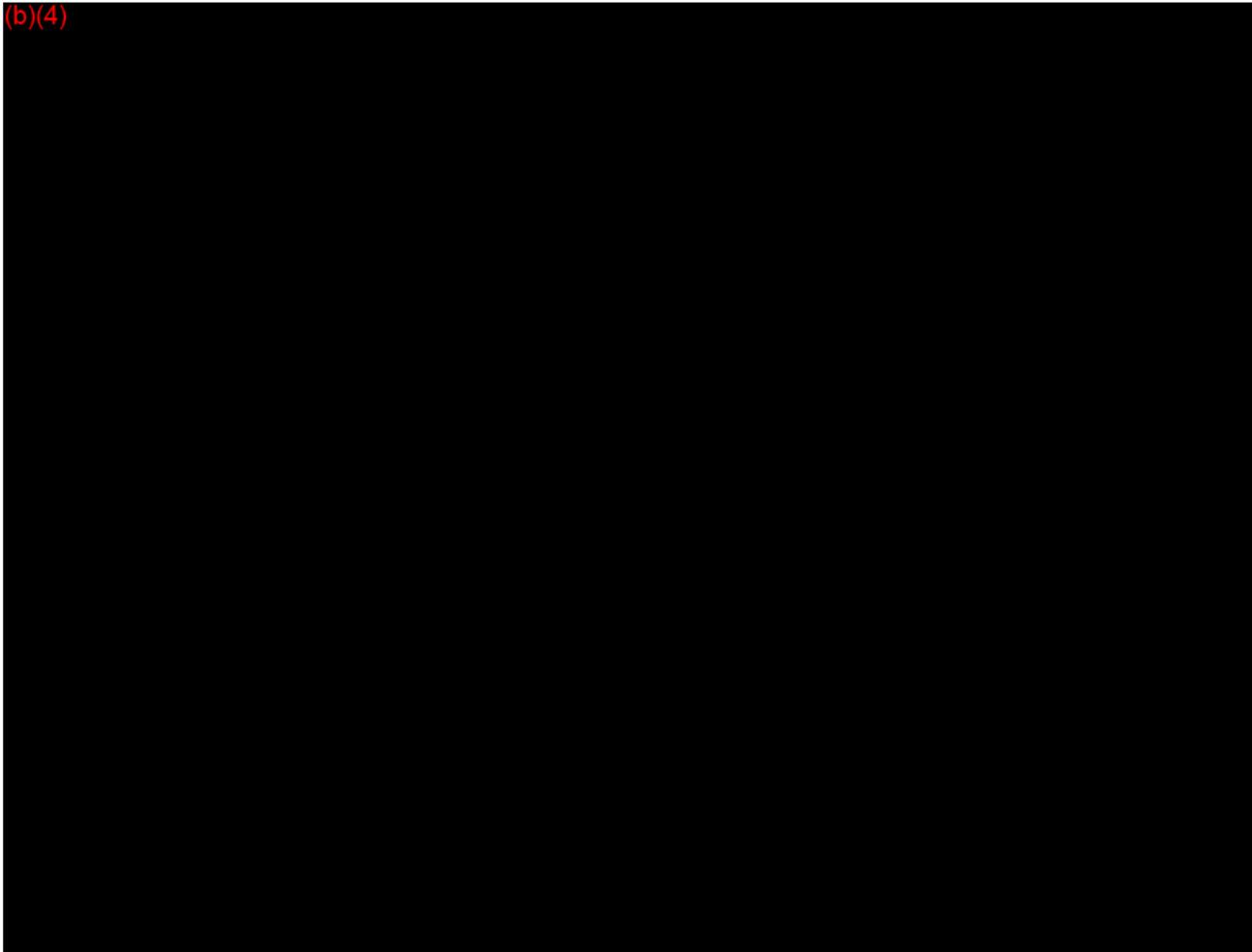
A large black rectangular redaction box covers the content of Figure 12-13. The text "(b)(4)" is printed in red at the top left corner of the redacted area.

Figure 12-14: Sample Illustration of Packaged Connector

(b)(4)

A large black rectangular redaction box covers the content of Figure 12-14. The text "(b)(4)" is printed in red at the top left corner of the redacted area.

12.1.6 Sterilization Tray

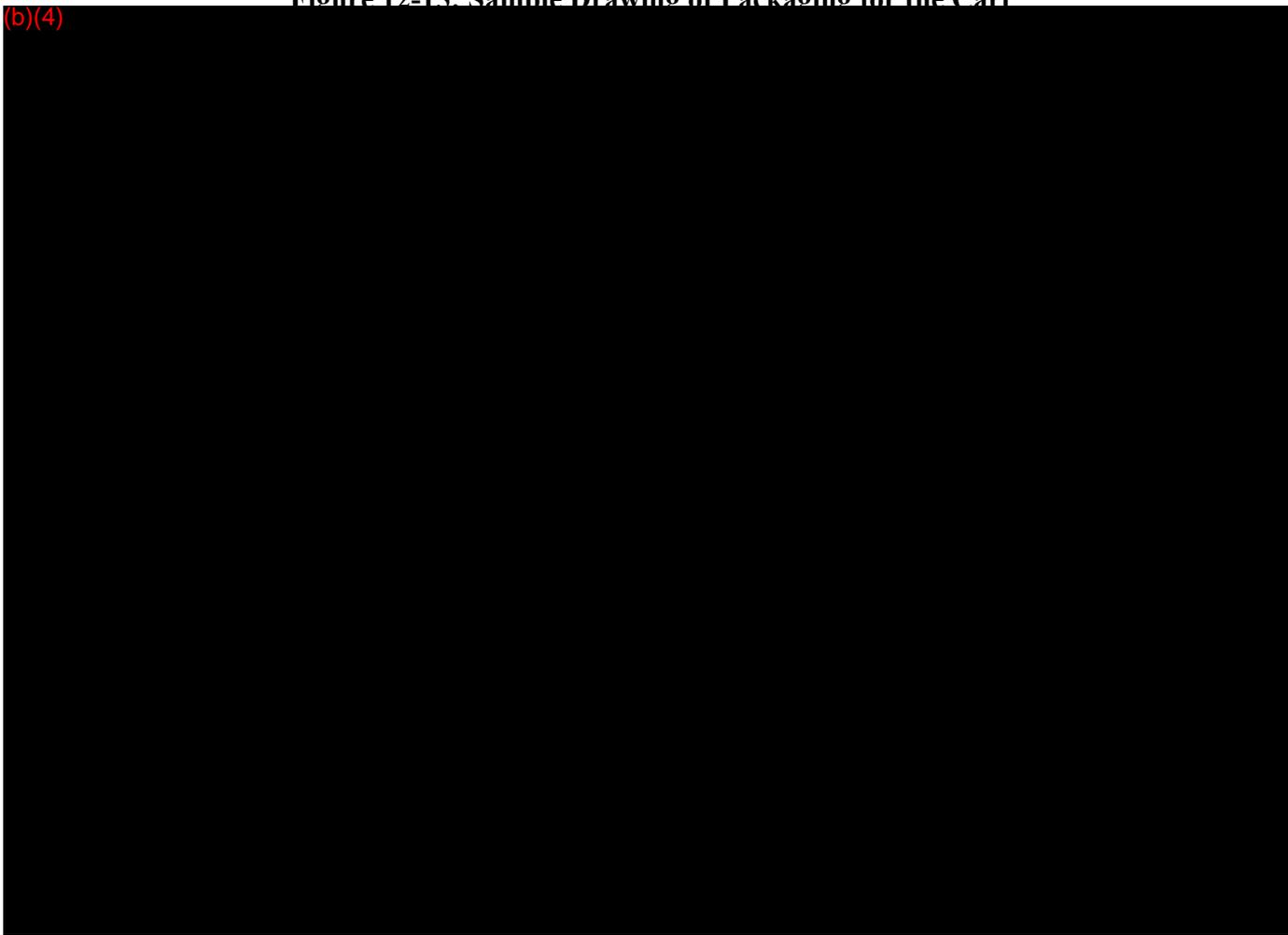
The Prime™ Adaptive Ultrasonic Scalpel Sterilization Tray is placed in a poly bag, packed in a corrugated shipper and sealed with tape. Labeling with printed graphics is placed on the carton. Shipping labels are applied as needed. The OEM Supplier (b)(4) will package the sterilization tray for shipping.

12.1.7 Prime™ Generator/Accessory Cart

The Prime™ Adaptive Ultrasonic Scalpel Sterilization Cart is provided in a poly bag, packed in a corrugated shipper, in a die-cut foam inserts (or equivalent thermoformed insert or paper board insert) and sealed with tape. Labeling is placed on the carton (or printed on the carton). Shipping labels are applied as needed.

Figure 12-15: Sample Drawing of Packaging for the Cart

(b)(4)



12.2 Cleaning

12.2.1 Generator and Accessory Cleaning:

The Prime™ G6000 Generator, and related footswitch and power cord are shipped non-sterile, and do not require sterilization before use. The generator is provided with a Foot Switch and

Line Cable which are all cleaned as follows: Wipe down the generator, foot switch and line cable using a damp cloth. Only Non-flammable disinfection agents should be used. Inspect to assure the devices are not damaged or worn, are properly functioning and available for the next surgery. The Instructions for Use also reflect a warning regarding not immersing or steam sterilizing the generator or related accessories such as the line cable and footswitch (See Attachment 012-Prime™ G6000 Generator Instructions for Use, page 31).

12.2.2 Blades and Transducer Handpiece

The **Prime™ Ultrasonic Scalpel Reusable Blades; Prime™ Reusable Transducer Handpiece** (with Test Tip, and Torque Wrench) and the **Prime™ Sterilization Tray** are shipped non-sterile, and must be cleaned and sterilized by the hospital before use. Validated cleaning and Sterilization methods for the sterile instruments are provided in the Instructions for Use and these methods provide protection from cross contamination, damage to the instruments, and injury to personnel (Refer to Attachments 011 US0026-(b)(4) Cleaning and Sterilization Study).

The validated cleaning and sterilization process is provided in the Instructions for Use for the **Prime™ and Omni™ Ultrasonic Scalpel Reusable Blades and Reusable Transducer Handpiece** (See Attachment 012-Prime™ G6000 Generator Instructions for Use, page 31). The **Prime™** devices were designed and validated in accordance with the *FDA's updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA (dated August 20, 2001)* and comply with the following applicable standards:

- **AAMI TIR30:2011.** A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices. Association for Advancement of Medical Instrumentation, Arlington, VA. (CRD249)

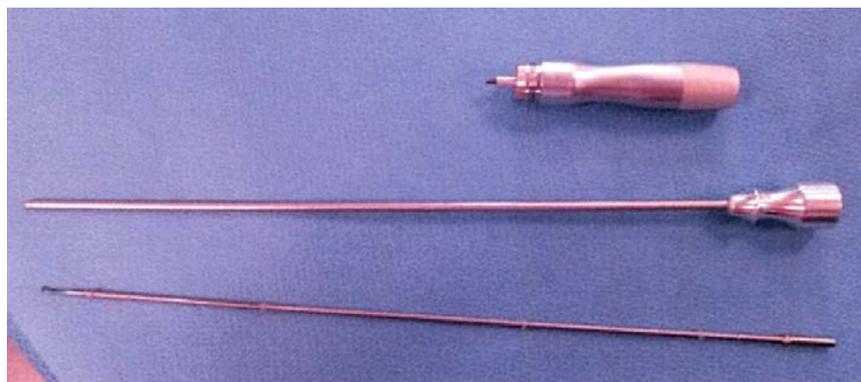
References:

- **AAMI TIR12:2010.** Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers. Association for Advancement of Medical Instrumentation, Arlington, VA. (CRD033)
- **ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013.** Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Association for the Advancement of Medical Instrumentation, Arlington, VA. (CRD204)
- **ANSI/AAMI ST81:2004/(R2010).** Sterilization of Medical Devices-Information to be provided by the manufacturer for the processing of resterilizable medical devices. Association of Advancement Medical Instrumentation, Arlington, VA. (CRD174)
- **ISO 17664:2004.** Sterilization of Medical Devices-Information to be provided by the manufacturer for the processing of resterilization medical devices. International Organization for Standardization, Geneva, Switzerland. (CRD184)

- **United States Pharmacopeia 37 & National Formulary 32. 2014. <851>** Spectrophotometry and Light Scattering. Unites States Pharmacopeial Convention, Inc., Rockville, MD. (CRD258)
- **AAMI TIR30:2011.** A compendium of processes, materials, test methods, and acceptance criteria fro cleaning reusable medical devices. Association for Advancement of Medical Instrumentation, Arlington, VA. (CRD249)
- **ANSI/AAMI ST35:2003.** Good Hospital Practice: Safe handling and biological decontamination of reusable medical devices in health care facilities and in nonclinical settings. Association for the Advancement of Medical Instrumentation, Arlington, VA. (CRD250 Archived)
- **ASTM E 1837-96 R2007.** Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test). ASTM International, West Conshohocken, PA. (CRD253)

The EndoPrime Cleaning Evaluation Validation study was conducted by (b)(4) (b)(4) simulate three or four use cycles consisting of contamination, cleaning, and sterilization. The worst-case test articles (longest ultrasonic scalpels and most complex transducers) were used. One set of articles was extracted as the negative control, and then replicates were contaminated and treated as the positive control. The positive control test articles were contaminated with protein and hemoglobin to simulate sample contamination during normal use as outlined in the Cleaning Evaluation Validation Protocol and Report (See Attachment 011-STP0083, 10). Figure 12-16 below is a Photograph of the test contamination articles.

Figure 12-16: Test Articles



Following the protocol dwell time after contamination, the contaminated test articles were brushed inside the sheath with a 5mm brush, processed through the automated cleaning procedure, sterilization procedure, extraction procedure, inspection, and final contamination testing (See Attachment 011–(b)(4)). Upon final examination of the test articles, no

visible soil remained, [REDACTED] (b) (4) [REDACTED] for the processed test articles and passed.

Based on the Cleaning Evaluation Testing performed by [REDACTED] (b)(4), the **Prime™ Ultrasonic Scalpel Reusable Blades** have been validated for the following cleaning procedures:

Reusable Blades are to be thoroughly cleaned according to the following steps:

- a. Manually scrub the Sheath with a channel cleaning brush to remove all debris (use 5mm or larger diameter nylon bristles or equivalent). Flush with water.
- b. Machine wash using a neutral pH detergent or neutral pH enzyme detergent according to the instructions of the detergent manufacturer. Use only nonabrasive materials.

12.3 Sterilization

The sterilization and dry time cycle for the **Prime™ Ultrasonic Scalpel Reusable Blades**, the **Prime™ Reusable Transducer Handpiece**, and the accessories (Test Tips, Torque Wrenches, and the Sterilization Tray) were validated by [REDACTED] (b)(4) (See Attachment [REDACTED] (b)(4) Steam Sterilization Validation GLP Report [REDACTED] (b)(4)) The methodology used for this validation is based on the following applicable standards:

- **AAMI TIR12:2010**. Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers. Association for Advancement of Medical Instrumentation, Arlington, VA. (CRD033)
- **ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013**. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Association for the Advancement of Medical Instrumentation, Arlington, VA. (CRD204)
- **ANSI/AAMI ST67:2011**. Sterilization of health care products-Requirements for products labeled “STERILE”. Association of Medical Instrumentation, Arlington, VA. (CRD170)
- **ANSI/AAMI ST8:2013**. Hospital Stem Sterilizers. Association for Advancement of Medical Instruments, Arlington, VA. (CRD 173)
- **ANSI/AAMI ST81:2004/(R2010)**. Sterilization of Medical Devices-Information to be provided by the manufacturer for the processing of resterilizable medical devices. Association of Advancement Medical Instrumentation, Arlington, VA. (CRD174)
- **ANSI/AAMI/ISO 17665-1:2006**. Sterilization of health care products-Moist Heat-Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices. Association for Advancement of Medical Instrumentation, Arlington, VA. (CRD169)

- **ANSI/AAMI/ISO 17665-2:2009.** Sterilization of health care products-Moist Heat-Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1. Association for the Advancement of Medical Instrumentation, Arlington, VA. (CRD373)
- **ISO 17664:2004.** Sterilization of Medical Devices-Information to be provided by the manufacturer for the processing of resterilization medical devices. International Organization for Standardization, Geneva, Switzerland. (CRD184)
- **EN556-2:2003.** Sterilization of medical devices. Requirements for medical devices to be designated “STERILE”. Requirements for aseptically processed medical devices. European Committee for Standardization, Brussels, Belgium. (CRD182)
- **ANSI/AAMI ST77:2013.** Containment devices for reusable medical device sterilization. Association for Advancement of Medical Instrumentation, Arlington, VA. (CRD273)
- **ANSI/AAMI/ISO 14937:2009.** Sterilization of health care products-General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices. Association for Advancement of Medical Instrumentation, Arlington, VA. (CRD100)
- **United States Pharmacopeia 37 & National Formulary 32. 2014. <71>** Sterility Tests. Unites States Pharmacopeial Convention, Inc., Rockville, MD. (CRD258)
- **United States Pharmacopeia 37 & National Formulary 32. 2014. <55>** Biological indicators-Resistance Performance Tests. Unites States Pharmacopeial Convention, Inc., Rockville, MD. (CRD258)

Each test article was evaluated to a Sterility Assurance Level (SAL) of 10^{-6} using the biological indicator overkill method. In addition to the SAL Validation, dry time was validated independently of the SAL validation using full cycle parameters. Two layers of 1-ply Kinguard KC600 Sterilization Wrap (a legally marketed FDA-cleared Wrap – ref: K082554) were used to wrap the tray and test articles. The protocol includes a diagram of the Inoculation Sites.

Based on the Steam Sterilization Validation Testing performed by (b)(4), the **Prime™ Ultrasonic Scalpel Reusable Blades**, the **Prime™ Reusable Transducer Handpiece**, and accessories (Test Tips, Torque Wrenches, and the Sterilization Tray) have been validated for the sterilization and dry time cycle provided in the IFUs (Attachment 012):

Steam Sterilization Cycle: After thoroughly cleaning, sterilize according to hospital procedures. The **Prime™ Reusable Transducer Handpiece** sterilization has been validated for sterilization as follows:

Cycle Type: Pre- Vacuum – 3 Pulses
Temperature: 270F (132°C)
Sterilization Time: 4 minutes
Dry Time: 20 minutes

Use with the **Prime™ Adaptive Ultrasonic Scalpel System Sterilization Tray** or equivalent.

EndoPrime intends to further validate the **Prime™ Ultrasonic Scalpel Reusable Blades**, the **Prime™ Reusable Transducer Handpiece**, and accessories (Test Tips, Torque Wrenches, and the Sterilization Tray) for sterilization using STERRAD® and other low temperature sterilization systems to provide the user options for sterilization. The Instructions for Use will be revised to reflect the sterilization options once the validation studies are successfully completed.

12.4 Storage and Transport Requirements

12.4.1 Transport Testing

The **Prime™ Adaptive Ultrasonic Scalpel System and Blades** have been shipped internationally and between test labs via air and truck carrier in the final specified packaging without damage or determination. Unpackaged shock and vibration testing was included in the IEC 60601-1 testing and passed (Attachment 002-IEC 60601-1 Testing Sections 15.3 and 15.4). Shock and Vibration testing will be successfully completed on the **Prime™ G6000 Ultrasonic Generator** prior to sale under the Protocol US0030 (See Attachment 016-Protocol US0030 Transportation Testing of the Prime™ Adaptive Ultrasonic Scalpel System and Blades Testing) following ASTM D 4169-05 Cycle 13 Assurance Level I.

12.4.2 Transporting, Handling and Storage

The **Prime™ Adaptive Ultrasonic Scalpel System and Blades'** materials of construction and solid state electronics are known to be stable under normal handling and environmental conditions for medical devices. Environmental conditions specifications were taken from IEC60601-1 and are reasonable for any user or transport company to maintain. The following are the Storage and Transport environmental conditions included in the labeling to assure compliance with IEC60601-1 and 21CFR § 809.10(d)(1)(v) as follows:

Temperature: -13°F to 131°F (-10°C to 55°C).
Relative Humidity: ≤ 80% non-condensing

Excessive environmental conditions, mechanical strength, electromagnetic compatibility, and spillage compliance was completed as a part of the IEC 60601-1 and -2 testing and were accepted (Attachment 002-IEC 60601-1 testing Sections 15.3 and 15.4 and IEC 60601-2-18 – Sections § 201.10-201.15). The labeling instructs the user to carefully handle, clean, sterilize, transport, and store the **Prime™ Adaptive Ultrasonic** family of devices to avoid unintentional damage. Routine inspections for damage, wear and tear to the devices (including the threaded and electrical connections), are also included in the G6000 instructions (See the G6000 Instructions for Use, page 19 in Attachment 011).

12.4.3 Shelf Life

The **Prime™ Adaptive Ultrasonic Scalpel System and Blades** are reusable devices that do not degrade over time, interact with components or packaging, nor do they contain radioactive or process altered materials. The devices are constructed of recognized consensus standard materials for medical device applications (i.e. Stainless, Titanium, Silicone, Aluminum, Plastic and electrical components) that are well known to be stable chemically, physically, microbiologically, toxicologically and therefore will retain operational therapeutic capability

over time. Therefore, no shelf life statement has been included in the labeling. Materials of construction are discussed in more detail in Section 9-Device Description.

12.4.4 Useful Life and Routine Inspection

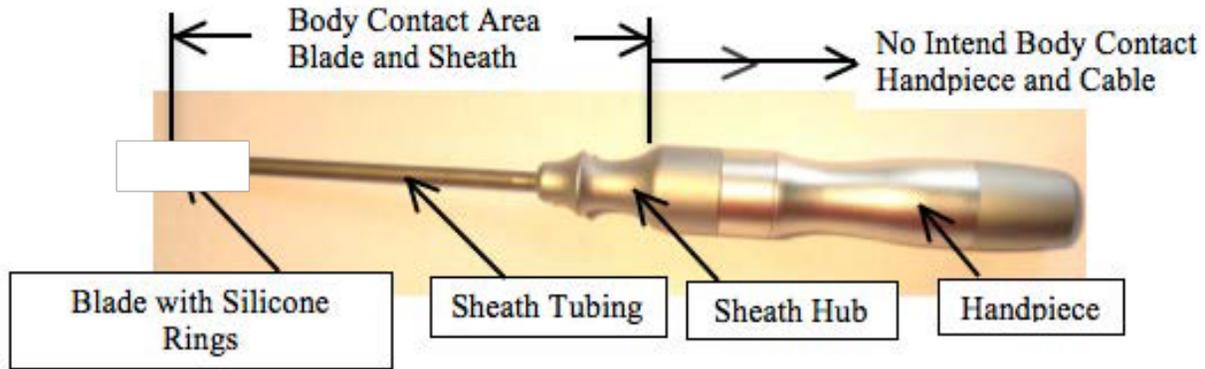
The **Prime™ Adaptive Ultrasonic Scalpel System and Blades** are reusable, provided non-sterile, and therefore do not require package integrity and stability testing for sterility. The **Prime™ G6000 Generator** automatically conducts an initial system test, monitors device condition, provides system test results, and deactivates the transducer handpiece and instrument operation when a fault or anomaly is detected. This includes faults or anomalies related to system components that have reached the end of their useful life. Validation Lifespan Testing showed that the only method found to reach failure is to successively abuse or deform the ultrasonic blade, which are faults detectable by the generator (Ref: Attachment 017-US0016 Transducer Reliability and US0019 Blade Lifespan Testing). The instructions for use require routine inspection for function, discoloration, corrosion, overheating, audible noise, damage, wear and tear to provide the user an endpoint for each devices' useful life and to allow the user to determine unacceptable deterioration at the end of each of the devices' useful life (See G6000 Instructions for Use, page 19, Attachment 012). The **Prime™ Ultrasonic Scalpel Reusable Blades** were validated for (b)(4) of operation and include use and compatibility with the predicate generator (e.g. UltraCision® Gen300) and transducers. The predicate generator provides the same system testing and monitoring for faults and anomalies including end of life faults.

13. Biocompatibility

13.1 Device Human Body Contact Classification & Materials of Construction

The **Prime™ Adaptive Ultrasonic Scalpel System** blades and sheath have or could have limited body contact as illustrated in Figure 13-1:

Figure 13-1: Intend Tissue Contact Area



FDA Guidance Document: *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"* dated April 23, 2013 was used to categorize the **Prime™ Ultrasonic Scalpel Reusable Blades** as a “Surface Device” that contacts mucosal and breached surfaces for less than 24 hours. None of the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** family of products or any portion of the products is intended to be implanted. Contact includes Mucosal Membranes, Breached Surfaces, and blood vessels; however, contact is not intended to occur directly or indirectly with circulating blood or within a blood or gas path.

Each of the body contact components of the **Prime™ Ultrasonic Scalpel Reusable Blade** assembly is classified below in Table 13-1 in accordance with the FDA Guidance as follows:

Table 13-1: Materials of Construction and Body Contact
Category: External Communicating Device

Component	Material	Duration	Body Contact
Ultrasonic Blade with Silicone Rings	(b)(4)	A	Direct: Mucosal membrane & Breached or Compromised Surfaces
		A	Fluids Contact: Mucosal membrane & Breached or Compromised Surfaces
		A	
Sheath Tubing	(b)(4)	A	Direct: Mucosal membrane and Breached or Compromised Surfaces
Sheath Hub		A	
Handpiece	(b)(4)	N/A	The cable and handpiece are not intended for Body Contact

Therefore when required, biocompatibility testing should include: (1) Cytotoxicity, (2) Sensitization, (3) Irritation (or Intracutaneous Reactivity) and (4) consideration for Acute Systemic Toxicity.

13.2 Predicate Devices Cited

The following Predicate devices are cited in this Biocompatibility Section and are legally marketed devices in the US:

- a) **K002981** and others cited in Section 010-Substantial Equivalence, and their predicates- Ethicon UltraCision® Harmonic Scalpel® Blades including Model DH010 and Adapter Model HS or HSA08 Reusable Ultrasonic Blades and Blade Adapter.
- b) **K010309**-Mutoh America CO., LTD. (now Stryker), Sonopet® Surgical Aspirator - (b)(4) Ultrasonic Blades - provide non-sterile.

13.3 Body Contact Materials of Construction Predicate Device Comparison

All materials of construction used in the Prime™ Ultrasonic Scalpel Reusable Blades are commonly used in medical devices and are the same materials used in the predicate devices. Therefore, there are no novel materials used and substantially the same manufacturing processes are used in manufacturing the devices. Table 13-2 provides a comparison of the predicate materials and processes and Illustrations 13-2 & 13-3 provide a visual comparison:

Table 13-2: Comparison of Predicate Device Materials and Processes
 Prime™ Blade Models: CB11R, OHB11R, CB37R, OHB37R, CB46R, OHB46R

Prime™ Component	Material	Process (Process Material)	Predicate Component
Prime™ Ultrasonic Reusable Blade with (b)(4)	Ti-6Al-4V ELI per ASTM F136	(b)(4)	K002981 -All UltraCision® Blades Including Model DH010 K010309-Sonopet® Model UST-2001 (b)(4) Ultrasonic Reusable Blades, Including Model: 5450-800-100
Sheath Tubing	304 Stainless Steel per ASTM F899	(b)(4)	K002981 -UltraCision® Reusable Blade Model DH010 Sleeve Tubing
(b)(4) Rings (the rings suspend the blade inside the Sheath and provide a fluid seal)	(b)(4)	(b)(4)	K002981 -All UltraCision® Blades Including Model DH010
Sheath Hub (Or Sleeve)	(b)(4) (b)(4)(b)(4) (b)(4)	(b)(4)	304 SS: Same as all Predicate device Sleeve (b)(4)
			K002981 -Adapter (Hub) Reusable (b)(4)

		(b)(4)	(b)(4) : Model HSA06
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Figure 13-2 Predicate Blade Comparison:
The Predicate and Prime™ Blades are constructed of

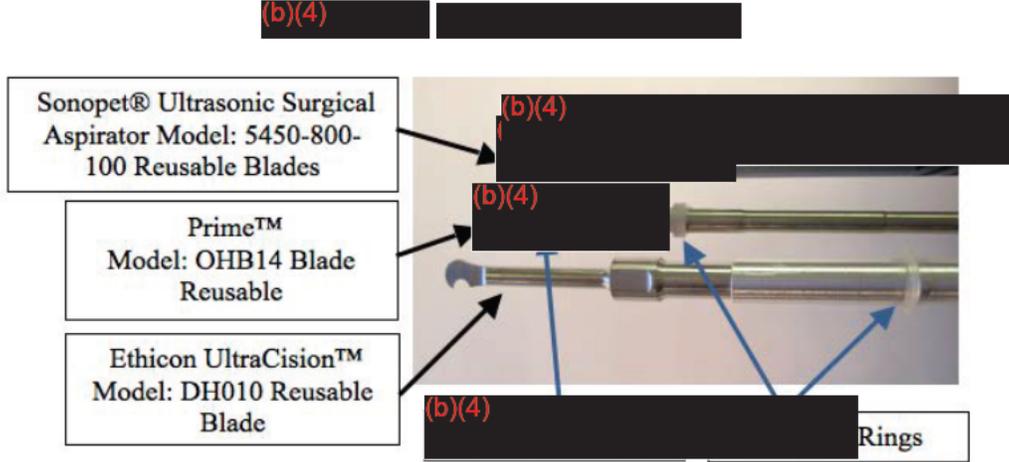
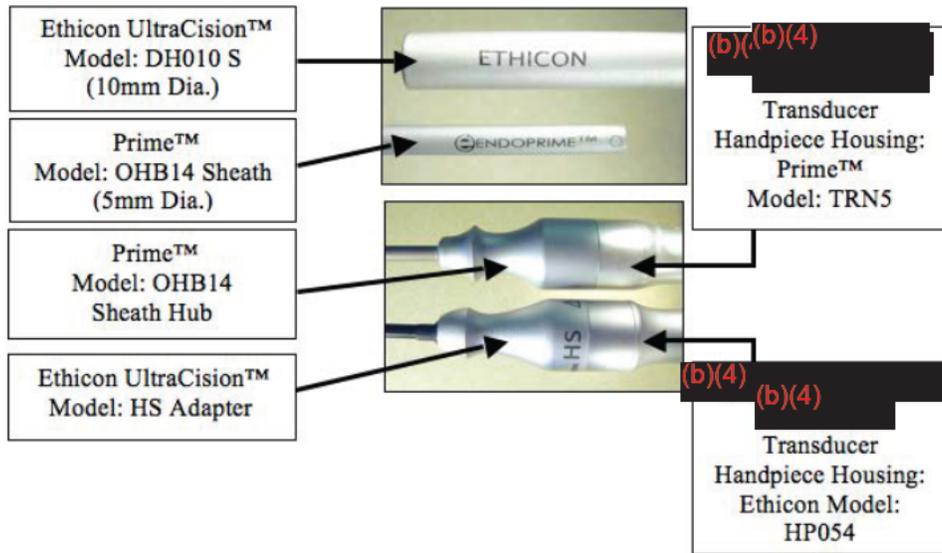


Figure 13-3 Predicate Sheath Comparison:
The Predicate Sleeves and the Prime™ Sheaths are made of ASTM F899 Stainless Steel and Laser Marked



13.4 Biocompatibility of ASTM F136 Titanium Blades

The **Prime™ Ultrasonic Scalpel Reusable Blades** and predicate devices are constructed of titanium alloy conforming to ASTM F136 Ti-6Al-4V ELI: *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*, a Recognized Consensus Standard (FDA Recognition Number 81377). Two predicate devices are cited for this contact material because the **Prime™ Ultrasonic Scalpel Reusable Blades** are (b)(4) of the blade including the

area exposed beyond the sheath (the tissue contact area) (b)(4) when (b)(4) used in the process. This end (b)(4)

inspection for damage (such as scratches). As can be seen in **Figure 13-3** the **Prime™ Ultrasonic Scalpel Reusable Blades** have areas that (b)(4) that could come in contact with body fluids. However, the Ethicon blades are not (b)(4) and therefore a second predicate is cited below to assure the device meets the biocompatibility requirements:

- All Ethicon UltraCision® Scalpel Blades including Model DH010 (pictured above in Illustration 13-2 and 13-3) are:
 - a) Constructed of the same material ASTM F136 Ti-6Al-4V ELI,
 - b) Use the same manufacturing process except (b)(4) (see next bullet),
 - c) Have the same chemical composition,
 - d) Are indicated for the same body contact, and
 - e) Are validated for steam sterilization method.
- All Stryker Sonopet® Ultrasonic Aspirator Reusable Blades including Model 5450-800- (b)(4) (b)(4) :
 - a) Constructed of the same material ASTM F136 Ti-6Al-4V ELI,
 - b) Use the same manufacturing process including (b)(4) (See Figure 13-3),
 - c) Have the same chemical composition,
 - d) Are indicated for the same body contact (also, some Sonopet® blades are indicated for additional body contact), and
 - e) Are validated for steam sterilization.

The Sonopet® Ultrasonic Aspirator Reusable Blades and numerous other examples can be cited where (b)(4) ASTM F136 Ti-6Al-4V ELI is used in medical devices including implanted devices; are supplied non-sterile; and are validated for steam sterilization.

Conclusion: ASTM F136 Ti-6Al-4V ELI (b)(4) (b) are identical to the materials of construction, manufacturing processes, chemical composition, body contact (or for a worst case body contact), and sterilization method (Steam Sterilization) are used in the legally marketed predicate devices cited above. ISO 10993-1, Clause 6 states, “Evaluation may include both a study of the relevant experience and actual testing. Such an evaluation may result in the conclusion that no testing is needed if the material has a demonstrable history of use in a specified role that is equivalent to that of the device under design.” Therefore, the use of ASTM F136 Ti-6Al-4V ELI in the **Prime™ Adaptive Ultrasonic Scalpel Blades** meet the biocompatibility requirements under FDA Guidance: *Use of International Standard ISO- 10993, "Biological Evaluation of 2 Medical Devices Part 1: Evaluation 3 and Testing;"* and no additional testing is required.

13.4 Biocompatibility of ASTM F899 Stainless Protective Sheath and Hub

The **Prime™ Ultrasonic Scalpel Reusable Blade-Sheath and Hub** have the same material of construction as the predicate device “sleeve” (or sheath) of the UltraCision® Harmonic Scalpel® Blades including Model DH010 (cited in 13.2 above). Both devices are constructed of 304 Stainless Steel conforming to ASTM F899-12b *Standard Specification for Wrought Stainless*

Steels for Surgical Instruments, a Recognized Consensus Standard (FDA Recognition Number 8-343). Also, (b)(4)

(see Figure 13-3 above). The **Prime™ Ultrasonic Scalpel Reusable Blade-Sheath and Hub** and the Sleeve of the Ethicon UltraCision® Scalpel Model DH010 are:

- a) Constructed of the same material: 304 Series Stainless Steel conforming to ASTM F899,
- b) Use the same manufacturing process (b)(4)
- c) Have the same chemical composition,
- d) Are indicated for the same body contact, and
- e) Are validated for steam sterilization method.

Conclusion: 304 Series Stainless Steel conforming to ASTM F899 is identical to the materials of construction, manufacturing process, chemical composition, body contact and sterilization method as the materials in the legally marketed predict devices cited above. ISO 10993-1, Clause 6 states, "Evaluation may include both a study of the relevant experience and actual testing. Such an evaluation may result in the conclusion that no testing is needed if the material has a demonstrable history of use in a specified role that is equivalent to that of the device under design." Therefore, the use of 304 Series Stainless Steel components conforming to ASTM F899 in the **Prime™ Ultrasonic Scalpel Reusable Blades** meet the biocompatibility requirements under FDA Guidance: *Use of International Standard ISO- 10993, "Biological Evaluation of 2 Medical Devices Part 1: Evaluation 3 and Testing* and no additional testing is required.

13.5 Biocompatibility of (b)(4) **Hub**

The **Prime™ Ultrasonic Scalpel Reusable Blades-Hub** may alternatively be constructed of (b)(4) as discussed above in (b)(4)

(b)(4) used in the construction of the Ethicon UltraCision® HS Adapter (Figure 13-3), Model HSA06 Adapter, the Ethicon UltraCision® HP054 Harmonic® Hand Piece (K990430) and other Ethicon Harmonic® Hand Pieces. The (b)(4) **Prime™ Ultrasonic Scalpel Reusable Blade-Hub** is lighter in weight and matches exactly the texture, color and finish of the **Prime™ Reusable Transducer Handpiece** housing which is constructed of the (b)(4); therefore, the (b)(4)

(b)(4) **Prime™ Ultrasonic Scalpel Reusable Blade-Hub** is preferred over the stainless steel hub but both may be provided. The (b)(4) hub has been validated in animal testing (See Attachment 003), is used in the predicate device and provides adequate strength. The (b)(4) (b)(4) is applied to the **Prime™ Scalpel Reusable Blade-Hub** using (b)(4) (b)(4) was selected because it (b)(4) (b)(4)

Prime™ Ultrasonic Scalpel Reusable Blade-Hub (as well as the **Prime™ Reusable Transducer Handpiece**) and the Ethicon UltraCision® HS Adapter are:

- a) Constructed of the same materials (b)(4) (b)(4)
- b) Use the same manufacturing process (b)(4)
- c) Have the same chemical composition (b)(4) (b)(4)
- d) Are indicated for the same body contact, and

e) Are validated for steam sterilization method.

The manufacturing process for the predicate devices is known by observing machining marks on the interior and the matt finish on the exterior created by grit blasting. Also, (b)(4); therefore, the processes are known to be the same.

Conclusion: (b)(4) identical to the materials of construction, manufacturing process, chemical composition, body contact and sterilization method as the materials in the legally marketed predict devices cited above. ISO 10993-1, Clause 6 states, "Evaluation may include both a study of the relevant experience and actual testing. Such an evaluation may result in the conclusion that no testing is needed if the material has a demonstrable history of use in a specified role that is equivalent to that of the device under design." Therefore, (b)(4) components in the **Prime™ Ultrasonic Scalpel Reusable Blades** meet the biocompatibility requirements under FDA Guidance: *Use of International Standard ISO- 10993, "Biological Evaluation of 2 Medical Devices Part 1: Evaluation 3 and Testing"* and no additional testing is required.

13.6 Biocompatibility of Reusable Blade Silicone Rings

The **Prime™ Ultrasonic Scalpel Reusable Blades** and the predicate device have silicone rings spaced along the length of each blade. The Silicone Rings maintain the blade centered in the protective sheath (or sleeve) and also provide a fluid seal to prevent body fluids from migrating up the blade. Each S (b)(4) Ring is cured on the blade after (b)(4) (b)(4) provide the required testing in the FDA Master Files and EndoPrime was given Right to Reference letters provided in Attachment 019. (b)(4) (b)(4) Biocompatibility Data and test summary was provided by (b)(4) and is provide in Attachment 018. The biocompatibility testing includes the four required tests discussed Section 13.1 above: Cytotoxicity, Sensitization, Irritation, and Acute Systemic Toxicity.

Conclusion: The **Prime™ Ultrasonic Scalpel Reusable Blades-Silicone Rings** meet the biocompatibility requirements under FDA Guidance: *Use of International Standard ISO- 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing."* (b)(4) are biocompatible and meet the biocompatibility requirements for use in the **Prime™ Ultrasonic Scalpel Reusable Blades**.

14. Software

14.1 Level of Concern

Software development and validation were completed in compliance with applicable standards and guidance as outlined in Table 14-1:

Table 14-1 Referenced Standards and Guidance Documents

ISO 62304:2006	Medical Device Software-Software Life Cycle Processes
FDA Guidance (January 11, 2002)	General Principles of Software Validation; Final Guidance for Industry and FDA Staff
IEC60601-1 Section 14.	"PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)"
FDA Guidance (May 11, 2005)	Guidance for the Content of Pre-market Submission of Software Contained in Medical Devices

In consideration of the FDA's Guidance Document entitled "*Content of Premarket Submissions for Software Contained in Medical Device*" dated May 11, 2005 the **Prime™ G6000 Generator System** Level of Concern with regard to the software contained in the proposed device is determined to be:

- Major Level of Concern
 Moderate Level of Concern
 Minor Level of Concern

In determining the Level of Concern, the following questions were considered from the FDA Guidance:

Major Level of Concern Questions (FDA's Guidance Table 1):

1. *Does the Software Device qualify as Blood Establishment Computer Software?*

No, the **Prime™ G6000 Generator** software controls a soft tissue cutting and coagulating device in a variety of surgical procedures.

2. *Is the Software Device intended to be used in combination with a drug or biologic?*

No

3. *Is the Software Device an accessory to a medical device that has a Major Level of Concern?*

No, the **Prime™ G6000 Generator** software controls the transducer handpiece and scalpel blades, which are mechanical; are only used for cutting and coagulating of soft tissue; do not use or have software; and are not consider to be at a Major Level of Concern.

4. *Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:*

a. *Does the Software Device control a life supporting or life sustaining function?*

No, the **Prime™ G6000 Generator** is a soft tissue cutting and coagulating device and does not support or sustain life.

- b. *Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators and ablation generators?*

No, the device software does not control the delivery of potentially harmful energy, which could result in death or serious injury. Mechanical (ultrasonic) vibrations of the **Prime™ Adaptive Ultrasonic Reusable Scalpel** instruments are used to cut and coagulate soft tissue in a variety of surgical procedures.

- c. *Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?*

No, the device software does not control treatment or therapy delivery; it is intended only for cutting and coagulation of soft tissue. The software controls the device:

- switching
- power level
- keyboard interface
- system diagnostics
- LED display
- audible signals

These software functions control the power supply to the transducer, which converts the electrical signal to mechanical vibration of the blade. Electrical energy is not in contact with, or in close proximity to patient tissue as with most other electrosurgical or tissue ablation devices. Patients, users and healthcare providers are insulated from the electrical energy by way of the transducer housing and CF rated cable assembly. Therefore, risk of harm is related to the mechanical energy of the blade. It is not foreseeable how this failure would result in death or serious injury.

- d. *Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?*

No, the system does not collect or provide patient related information.

- e. *Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?*

No, the system does not monitor vital signs nor provide alarms for potentially life-threatening situations.

Moderate Level of Concern (FDA's Guidance Table 2):

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

Yes, the **Prime™ Ultrasonic Scalpel Reusable Blades** are an “accessory” to the **Prime™ G6000 Generator** software. The software controls the transducer handpiece and scalpel blades, which are mechanical, but could be considered as having a

Moderate Level of Concern although the hand held devices are only used for cutting and coagulating of soft tissue and have no software. To be conservative the questions was answered yes.

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

Yes, before mitigations, if the software allowed continuation of activation after the user releases the activation switch and simultaneously a failure of the activation tone signal occurs, these highly unlikely failures could result in an inadvertent burn should the user allow the blade to contact tissue before becoming aware of the active blade. No occurrences of software failures that resulted in continuing activation were reported in the FDA TPLC for predicate and other systems under Product Code LFL. Reported software related complaints were for system shutdowns and failure of the generator to exit the test mode. However, to be conservative the question was answered yes.

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

No, the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** is only used for cutting and coagulating of soft tissues and does not provide diagnostic information. Also, a failure of the software could lead to a delay in surgery while the surgeon utilizes backup equipment or traditional methods such as steel blades for cutting and suture ties to control of bleeding; however, it is unlikely for this delay to lead to harm or injury.

Conclusion: Based on the previous information we conclude that the software used in the Prime™ Adaptive Ultrasonic Scalpel System and Blades is of a **Moderate Level of Concern**.

14.2 Development Approach and Compliance

The OEM manufacturer for international distribution initially developed the **Prime™ Adaptive Ultrasonic Scalpel System and Blades**, including the **Prime™ G6000 Generator** software. Therefore, planning and development of the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** including the **Prime™ G6000 Generator** software were built on the original verified products (b)(4)

The Software Development Environment Description provides specific descriptions and requirements used in the development project and documentation. Table 14-2 provides a summary of the records generated as a part of the development continuation and revalidation of the software:

Table 14-2 FDA Guidance Related Summary

Requirement:	Document Reference	Attachment Number	Discussion in Submission
Software Description:	DP001-1 Product Requirements Specification (PRS)	Attachment-020	Section 14.3

Software Development Environment Description	DP001-1 Attachment 3: Software Development Environment	Attachment-020	Section 14.2
Device Hazard Analysis:	Risk Management File including FMEA	Attachment-006	Section 14.8
Software Requirements Specifications (SRS):	US0020-3 Rev C: G6000 – SRS	Attachment-005	Section 14.9
Architecture Design Chart (ADC):	US0020-13: Software ADC	Attachment-005	Section 14.10
Software Architecture Description	US0020-1: (PRS) contains a description of the Architecture.	Attachment-005	Section 14.3
Architecture Design Chart (ADC)	US0020-13: Software ADC	Attachment-005	Section 14.10
Software Design Specification (SDS)	US0020-15: SDS	Attachment-005	Section 14.15
Software Flow Chart	US0020-3 Rev C G6000 - SRS Architecture Design Chart	Attachment-005	Section 14.10
Traceability Analysis:	US0020-11 Software Traceability Analysis	Attachment-005	Section 14.11
Software Development Environment Description	US0020-14 Software Development Environment Description	Attachment-005	Section 14.3
Software and Hardware Validation Documentation	US0020 -7 Hardware Validation Plan US0020-8 Software Validation Plan US0020-9 Validation Test Procedure, US0020-10 Validation Test Report	Attachment-005 Attachment-005 Attachment-005 Attachment-005	Section 14.14
Software Revision History	US0020-12 Software Revision Log	Attachment-005	Section 14.12
Unresolved Anomalies	None, all anomalies were investigated, resolved and validated.	N/A	Section 14.13
Additional Sections	Location in Submission		
Software Architecture Description	US0020-1 (PRS) contains a description of the Architecture.	Attachment-005	Section 14.10
Hardware Requirements:	US0020-2 Hardware Requirements Specification (HRS)	Attachment-005	Section 14.4

Programming Language	US0020-3 Software Requirements Specification (SRS)	Attachment-005	Section 14.5
Off-The-Shelf Software	No off-the-shelf software used	N/A	Section 14.6
Purpose of Software-Functions	US0020-3 Software Requirements Specification (SRS)	Attachment-005	Section 14.7
Equipment List	US0020-9 Validation Test Procedure	Attachment-005	Section 14-14

Each of the sections outlined will provide a summary of the information. Objective evidence of the validation and compliance is provided in the referenced attachments to this submission including test protocols or reports of verification and validation activities and other supporting diagrams, tables, or documents that support the design, testing, and validation of the **Prime™ G6000 Generator** software.

14.3 Software Description

The **Prime™ G6000 Generator System** is best described as a hardware and software-based device that incorporates software for controlling all functions of the generator. The development environment is described in the Attachment 020-DP001-1 Software Development Environment Description, which defines the software Design Control processes that are an adjunct to the EndoPrime Quality Management Systems and the Quality Systems of OEM Developers and Suppliers. However, the Generator functions are relatively simple and traditional methods for programming were selected for the software design process. (b)(4)

(b)(4)

(b)(4) however, the software was verified and validated manually. The microcontroller software was developed using the (b)(4)

(b)(4). The software resides in the microcontroller and controls the Organic Light-Emitting Diode display (OLED or LED in some documents or the display may be referred to as LCD), and other control mechanisms for the generator operation.

Table 14-3: G6000 Software Specifications

Current Version	(b)(4)
Operational Environment	(b)(4)

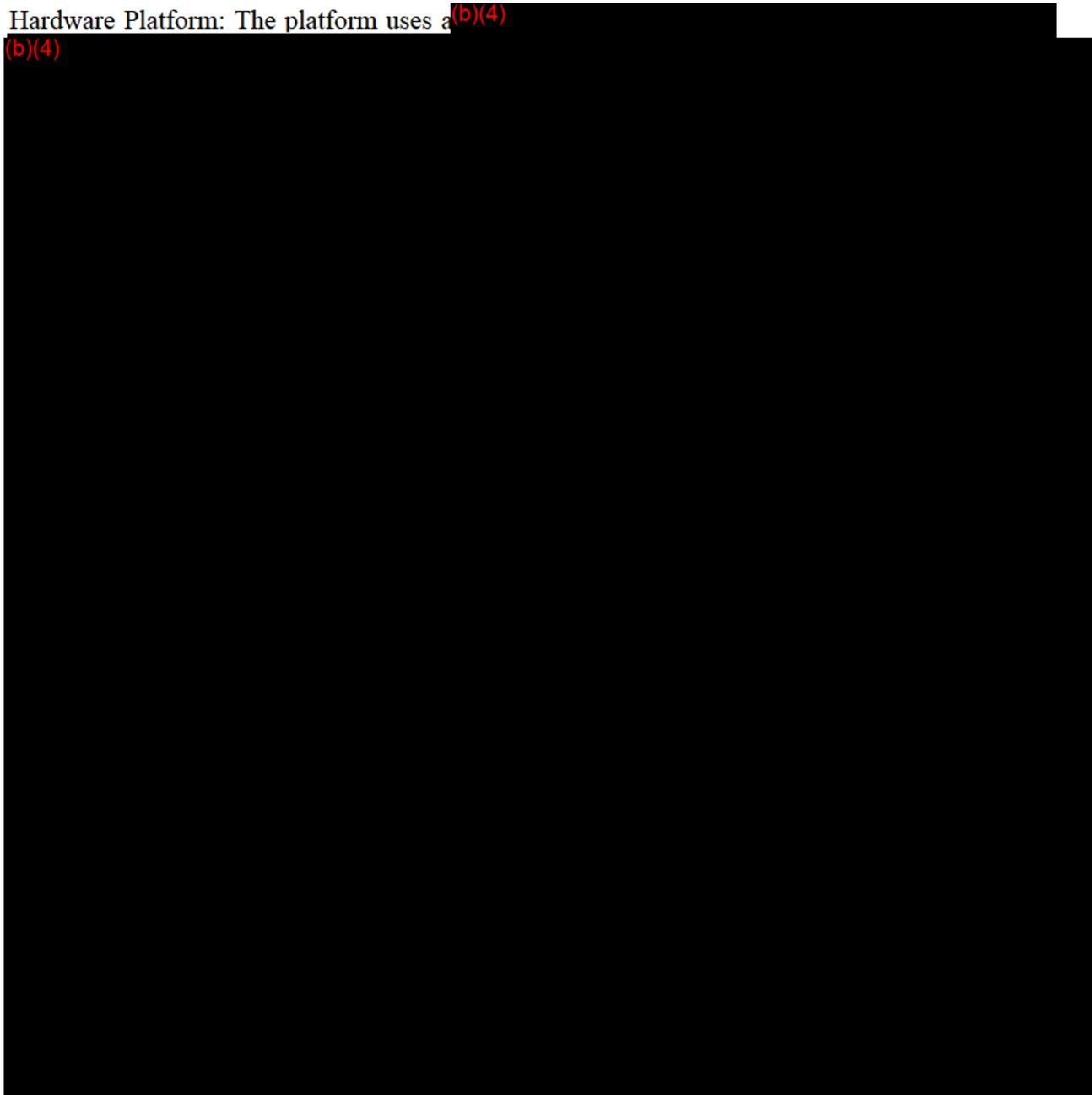
Programming Language	Assembly Language
Off The Shelf Software	N/A

14.4 Hardware Requirements

The hardware platform for the **Prime™ G6000 Generator** is an (b)(4) hardware design Block Diagram (Attachment 005-US0020-4), Hardware Schematics (Attachment 005-US0020-5) and Hardware Bill of Materials (Attachment 005-US0020-6) are provided in this submission.

Hardware Platform: The platform uses a (b)(4)

(b)(4)



14.5 Programming Language

The **Prime™ G6000 Generator System** utilizes software, which is written using (b)(4)

(b)(4)

14.6 Off-The-Shelf Software

No off-the-shelf software is included in the **Prime™ G6000 Generator** systems.

14.7 Purpose of Software-Functions

During the design of the **Prime™ G6000 Generator**, software was written for four primary purposes:

- System initialization
- Command data processing
- Timing function processing
- Operation function processing

The following is a summary of the functions that the software was designed to carry out, and a brief description of each:

- Responding to input signals provided by ancillary circuits and displaying on the LED, the operating mode message associated with desired operation.
- To supply data for power levels on the LED which will be used for the VAR and FULL functions during the working mode of operation.
- Provide the data for the testing mode of operation including all text messages to be displayed.
- To act upon errors and fault conditions in the generator, transducer, scalpel, footswitch, and hand switch.
- To test the Increment, Decrement, Test, and Standby switches.
- To store set A-D values for current and voltage levels for the 5 variable (VAR) power levels and the full (FULL) power level parameters.
- To control the audio transducer operation.
- To detect footswitch or hand switch operation.
- To control the VAR, FULL, Ready and Caution LED indicators operation.

14.8 Software and System Hazard Analysis

A full, product system wide risk analysis was conducted for the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** that included hardware and software as a part of a comprehensive risk management system that is in compliance with *ISO 14971:2007 Medical devices -- Application of risk management to medical devices* (See Attachment 005). The analysis included a full hazard analysis including software and hardware. The residual risk was accepted in a Risk-Benefit Analysis (See Attachment 005). The analysis includes a FMEA (See Attachment 006) that contains a specific software section. A Traceability Analysis (Attachment 005-US0020-11) was conducted to link the identified hazards and risk control measure (or mitigations) with the validation tests conducted.

Tabulated Device Hazard Analysis: Tabular arrangement that identifies the locations for each hazard analysis, description of the hazards, severity assessment and mitigations is provided in the Traceability Analysis US-0020-11 Software Traceability Analysis (Attachment 005). This document is an extract of the software-related items from the comprehensive risk management documents and ISO 14971 Hazard Analysis. Tabulated analysis is also provided in the software section of the DFMEA (Attachment 005).

14.9 Software Requirements Specifications (SRS)

The Software Requirement Specifications (SRS) is provided in Attachment 004: US0020-3. The SRS was generated to develop a software version that met US standards and design inputs. For example, one of the improvements identified and implemented was to display all faults on the LED screen as a text message in English rather than a code that required the user to refer to the IFU. Also, the software version and checksum are displayed at startup for easy reference (and is also menu assessible).

The Software Traceability Analysis (Attachment 005: US0020-11) was conducted to verify that the product design requirements and design specifications were include in the test procedures. The SRS and Traceability Analysis also addressed the identified hazards for the software. Hazards and risks were identified in the Risk Analysis (Attachment 006) and risk control measures (mitigations) were verified in the Software Traceability Analysis (Attachment 005: US0020-11) to assure testing was completed. Fault detection tolerances, fault recovery and interrupt recovery were tested and validated in the Validation Test Report (Attachment 005: US0020-10).

14.10 Software Architecture

The software architecture is defined in the Software Architecture Design Chart (Attachment 005-US0020 - 13). This Architecture Design Chart document provides a high level overview of the major functions supported and implemented by the microcontroller software. It also provides guidance for the design and development, verification and validation process. The development and documentation requirements are based on a moderate level of concern. Verification and validation documentation include V&V activities at the unit system level. Also, see the Product Requirements Specification (PRS) (Attachment 005 - US0020-1) for a more full description of the Architecture. The Software Architecture was developed as described in the Product Design Specifications (PDS) and the Software Requirements Specification (SRS). A full set of Software Flow Charts that better describes the final design and architecture is provided in the SRS (Attachment 005: US0020-3).

14.11 Traceability Analysis

The Software Traceability Analysis (Attachment 005-US0020-11) links together design, implementation, testing & risk management in a tabular format. It also identifies hazards and risk control measures (mitigations), and validation testing.

14.12 Revision History

The software was originally developed and implemented for Asian and international use by the (b)(4). Also, the entire system was verified and validated by the OEM. The current version of the software was developed and upgraded for the United States

market and will be sold worldwide. The Software Revision History Log (Attachment 005: US020-12) documents the changes implanted for the U.S product as well as worldwide release. The redesign work started with version 2.2d and was modified for engineering and user evaluation using an alpha suffix. The software was originally developed and implemented for Asian and international use where the entire system was verified and validated. This version of the software was undertaken for the U.S. market and this revision log represents the changes needed and implemented for U.S. as well as worldwide release. Version 2.3a was modified and evaluated as revision 2.3b, 2.3.b, ...2.3f; the final software was then validated and released as version 2.4.

14.13 Unresolved Anomalies

All hardware and software anomalies were resolved and this was verified in repeated testing as well as the final Validation Testing (See Attachment 005: US0020-9 Procedure and US0020-10 Report). The device was evaluated in animal testing and human factors were determined to be acceptable. A human interface related improvement was implemented where numbered fault codes were replaced with text messages. The full set of side-by-side studies including simulated surgery, animal study, and performance testing shows the device to be substantially equivalent to the predicate devices. No new unresolved anomalies have occurred at this time.

14.14 Verification and Validation Documentation

Based on the hardware and software requirements specifications, Section 14.4 and Section 14.9, hardware and software validation plans were developed. These plans detail the purpose, objectives, and process for ensuring the testing and assessment of all the requirements will be met. These plans include details of the testing process, the team that will conduct the testing and how the testing will be completed. For details and further review the plans can be found in Attachment 005: US0020-7 Hardware Validation Plan and Attachment 005: US0020-8 Software Validation Plan.

From the detailed plans in US0020-9 G6000 Validation Test Procedure (Attachment 005) was developed. This procedure details the equipment used and test setup for all the testing to be completed. The procedure then goes into detail describing the execution of each test. Once testing has been completed a final report was written (Attachment 005: US0020-10 G6000 Validation Test Report). The testing included compatibility with hand-activated predicate devices. (b)(4) conducted the final software testing. The report documents the conclusion and analysis of each test including, test description, specification, acceptance criteria, results, and documentation of testing evidence. After review and approval of the report the conclusion was the software is verified and validated for production use.

14.15 Software Design Specification (SDS)

The Software Design Specification (SDS) describes the implementation of the requirements for the Software Device (Attachment 005: US0020-15). It describes how the requirements were implemented. The analysis that went into developing and maintaining this document and other analyses assured that all anomalies and ambiguities were cleared and references are available for future maintenance or continued improvement.

Based on this objective evidence, EndoPrime, Inc. concludes that the **Prime™ G6000 Generator Software** raises no questions of safety or effectiveness and is substantially equivalent to the predicate system.

15. Electromagnetic Compatibility and Electrical Safety

Electromagnetic compatibility (EMC) and electrical safety testing of the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** was successfully completed by (b)(4) internationally accredited testing organization. EndoPrime Inc. cooperatively conducted testing (b)(4)

Parts to the Report). (b)(4) certified the test results for use with either the Prime™ G6000 (and the (b)(4)). All system components provided to (b)(4) were fully processed and representative of the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** production units; including generator, footswitch, cables, handpiece transducers, test tip, blades, cart, and similar representative instruments.

15.1 Background

(b)(4) was selected to complete the EMC, electrical safety, magnetic field immunity, endoscopic equipment and mechanical testing for the **Prime™ Adaptive Ultrasonic Scalpel System and Blades**, including the **Prime™ G6000 Generator**. Previous EMC and electrical safety testing was conducted by (b)(4) test facilities; however that testing was expanded to include additional IEC 60601 Third Edition, endoscopic and magnetic immunity testing requirements in anticipation of this Premarket 510(k) Submission. Power frequency, magnetic immunity and other testing (EN 60601-1-2 and EN 61000-2-18 & -4-8) was conducted by TUV Rheinland Inc. of North America's Newtown, CT test facility. Endoscopic testing (IEC 60601-2-18) was conducted by the Intertek Semko AB (USA) test facility under the direction of TUV Rheinland of North America, Inc. The completed reports (a total of four) are included in this submission (See Attachment 002).

TUV Rheinland concluded that the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** is not an Endoscope, nor is it a Light Source, although it can be used in conjunction with an Endoscope during various surgical procedures. It operates at approximately 55 KHz well below the 200 KHz for it to be considered a HF (hi frequency) Endotherapy Device. Therefore, TUV Rheinland concluded that the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** meets the definition of an Energized Endotherapy Device and tested it under EN IEC 60601-2-18 for endoscopic equipment.

The following is a list of standards the **Prime™ G6000 Generator**, in conjunction with the **Prime™ Adaptive Ultrasonic Scalpel System and Blades**, were tested to:

TUV cited Testing Standards for Report Part 1-IEC 60601-1 Med Equipment Safety

- **IEC 60601-1:2005 + CORR. 1 (2006) + CORR. (2007):** International Standard-Medical Electrical Equipment-General Requirements for Basic Safety and Essential Performance
- **BS EN 60601-1:2006/AC: 2010:** Medical electrical equipment. General requirements for basic safety and essential performance.

- **ANSI/AAMI ES60601-1: 2005/A2: 2010:** Medical Electrical Equipment-Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility-Requirements and Tests.
- **CAN/CAS-C22.2 No. 60601-1:08:** Medical Electrical Equipment-Part 1-6: General Requirements for Safety-Collateral Standard; General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems.

TUV cited Testing Standards for Report Part 2-IEC 60601-1-2:2007 IEC EMC Report

- **EN 60601-1-2:2007/CISPR 11:2009:** Medical Electrical Equipment-Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility-Requirements and Tests.
- **IEC 61000-3-2:2006+A1+A2:** Electromagnetic compatibility (EMC)-Part 3-2: Limits for harmonic current emissions (equipment input current ≤ 16 A per phase).
- **IEC 61000-3-3:2008:** Electromagnetic compatibility (EMC)-Part 3-3: Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection.
- **IEC 61000-4-3:2006+A1:2007+A2:2010:** Electromagnetic compatibility (EMC)-Part 3-4: Limits-Limitation of emission of harmonic currents in low-voltage power supply systems for equipment with rated current greater than 16 A.
- **IEC 61000-4-4:2004+A1:2010:** Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrical fast transient/burst immunity test.
- **IEC 61000-4-6:2003+A1+A2:2006:** Electromagnetic compatibility (EMC). Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields.
- **IEC 61000-4-5:2005:** Electromagnetic compatibility (EMC). Testing and measurement techniques. Surge immunity test.
- **IEC 61000-4-11:2004** Electromagnetic compatibility (EMC). Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests.

TUV cited Testing Standards for Report Part 3-IEC 60601-2-18 Endoscopic Equipment Test

- **IEC 60601-1-2-18:2009 (Third Edition):** Medical electrical equipment-Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.

TUV cited Testing Standards for Report Part 4-IEC 61000-4-8:2010

- **EN60601-4-8: 2010 Medical Electrical Equipment: Part 1-4: General Requirements for Collateral Standard: Programmable Electrical Medical Systems.**
- **EN 60601-1-2:2007: Medical Electrical Equipment-Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility-Requirements and Tests.**
- **IEC 60601-1-2-18:2009 (Third Edition): Medical electrical equipment-Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.**

15.2 Testing Summary

In consideration of the EMC and electrical safety testing, the **Prime™ G6000 Generator** consists of an isolation transformer, power transformer, switching power supply, main control board, ultrasound drive board, footswitch, and ultrasound scalpel. The ultrasonic scalpel connector cable and generator power cable were defined as a Type CF applied part, which is connected to the generator output connector. In addition, the system has a selectable input voltage of AC 110V and 230V, 50/60Hz, with rated power of 250VA. This is a Class A/Protection Class I power source. The isolation between the secondary and primary circuit of the equipment is maintained through the (b)(4) (b)(4). It is noted that there are no communication connections with other equipment during use. Also, the device has no wireless connection capability or external ports for interconnection. All enclosures on the equipment are fixed together by screw fixings.

The **Prime™ G6000 Generator** provides two modes of output, variable (VAR) and maximum (FULL). The user can set the variable power level from 1 to 5 by pressing the (+) or (-) keys according to the interface display. Further, the maximum power level is always maintained at position 5. High power levels provide fast cutting while lower power levels provide a larger range of coagulation options. The information regarding operation of the **Prime™ G6000 Generator** was provided to TUV Rheinland via the Instructions for Use (See Attachment 002).

Mechanical Testing of the whole unit (tested on wheels of the **Prime™ Cart** including footswitch and accessories) was tested for instability (including lateral movement, propulsion force, movement mover thresholds) with no issues including tip over in door thresholds (Reference: Attachment 002- IEC 60601-1-2:2007 Section 9.4.2).

The following is a comprehensive table of the complete TUV Rheinland Test Results:

Table 15-1: Summary of EMC & Electrical Safety Testing

Testing Part 1-IEC60601-1 Med Equipment Safety			
Standards	Description	Attachment 002 Section & Page Reference	Test Results
IEC60601-1-1: 2005/A2: 2010	Power Input	4.11/Page 12	Pass
	Humidity Preconditioning Treatment	5.7/Page 15	Pass
CAN/CSA-C22 2 No.	Determination of applied parts & accessible parts	5.9/Page 15	Pass

60601-1:08 IEC 60601-1-2:2007	Legibility of markings	7.1.2/Page 17 & Appended Table 7.1.2/Page 115	Pass
	Durability of Markings	7.1.3/Page 17 & Appended Table 7.1.3/Page 116	Pass
	Impedance & current-carrying capability of protective earth connections	8.6.4/Page 39 & Appended Table 8.6.4/Page 125	Pass
	Leakage currents & Patient auxiliary currents	8.7/Page 40 & Appended Table 8.7/Page 127	Pass
	Dielectric Strength	8.8.3/Page 43 & Appended Table 8.8.3/Page 143	Pass
	Measurement of creepage	8.9/Page 44 & Tables 11/Page & 15/Page	Pass
	Components & Wiring	8.10/Page 48 & Appended Tables 8.10.1/Page 151 & 8.10.2Page 151	Pass
	Gaps	9.2.2.2/Page 56	Pass
	Instability-from overbalance/unwanted lateral movement	9.4.2/Page 59	Pass
	Instability in transport position	9.4.2.1/Page 59	Pass
	Instability excluding transport	9.4.2.2/Page 59	Pass
	Force for propulsion	9.4.2.4.2/Page 60 & Appended Table 9.4.2.4.2/Page 157	Pass
	Movement over a threshold	9.4.2.4.3/Page 60 & Appended Table 9.4.2.4.3/Page 157	Pass
	Instability from unwanted lateral movement	9.4.3/Page 61	Pass
	Instability in transport position (including sliding)	9.4.3.1/Page 61	N/A
	Instability excluding transport (including sliding)	9.4.3.2/Page 61	Pass
	Audible acoustic energy	9.6.2.1/Page 63	Pass
	Excessive Temperatures in ME EQUIPMENT	11.1/Page 70 & Appended Table 11.1.1/Page 167	Pass
	Single fault conditions	13.2/Page 79 & Appended Tables 13.2/Page 186	Pass
	Mechanical strength tests	15.3/Page 86 & Appended Tables 15.3/Page 192 & 15.3.2/Page 192, 15.3.3/Page 193	Pass
Testing Part 2-IEC60601-2-3 IEC EMC Report			
IEC 61000-3-2:2006+A1+A2	Harmonics on AC Mains	4.1.1/Page 8	Pass
	Voltage Changes, Voltage Fluctuations and Flicker on AC Mains	4.1.2/Page 10	Pass
IEC 61000-3-3:2008	Mains Terminal Continuous Disturbance Voltage	4.1.3/Page 11	Pass
	Radiated Emission	4.2.1/Page 14	Pass
IEC 61000-4-2:2008	Electrostatic Discharge	5.1.1/Page 17	Pass
	RF Electromagnetic Field Immunity Test	5.1.2/Page 18	Pass

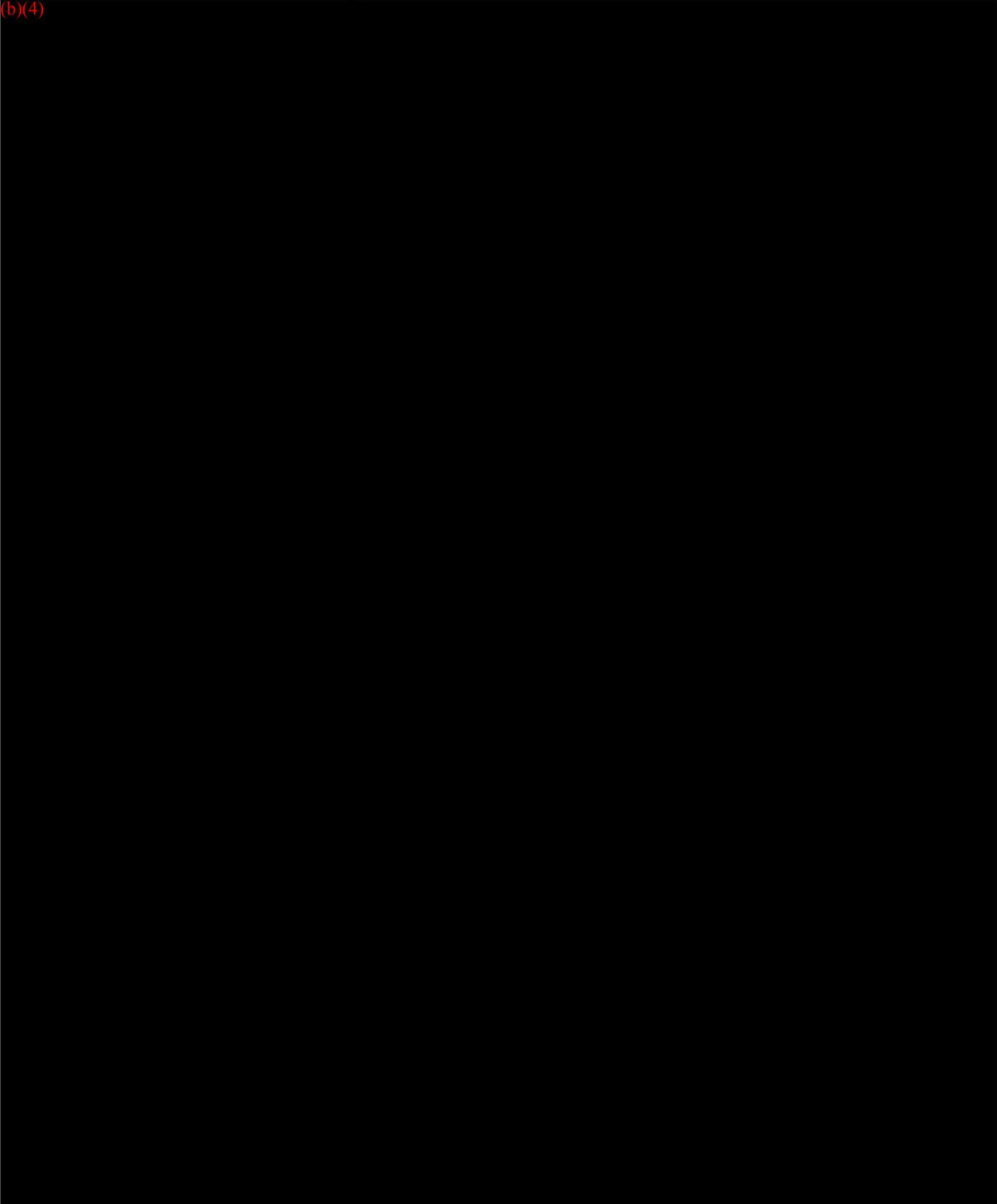
	Power Frequency Magnetic Field	5.1.3/Page 19	Pass
	Fast Transients on AC Power Line, Signal Line and Interconnecting Line	5.2.1/Page 20	Pass
	Injected Current into AC Power Line, Signal Line and Interconnecting Line	5.2.2/Page 21	Pass
	Surges to AC Power Port, Signal Line and Interconnecting Line	5.2.3/Page 22	Pass
	Voltage Dips and Interruptions to AC Power Port	5.2.4/Page 23	Pass
	Variations of Power Frequency	5.2.5/Page 24	Pass
Testing Part 3-IEC60601-2-18 Endoscopic Equipment Test			
IEC 60601-1-2-18:2009 (Third Edition)	Single Fault Condition for ME Equipment	201.4/7/Page 8	Pass
	Energized Endoscopes and Energized Endotherapy Devices which are subject to disinfection and/or sterilization processes prior to use are excluded from humidity preconditioning treatment, but shall instead be subjected to sub clause 11.6.6 and/or 11.6.7 of the general standard	201.5.7/Page 8	Pass
	Protection against electric shock-applied parts of Endoscopic Equipment shall be classified as Type BF or type CF applied parts	201.6.2/Page 8	Pass
	ME Equipment identification, marking and documents	201.7/Page 8-9	Pass
	Applied Parts	201.7.2.10/Page 9	Pass
	Symbols	201.7.6.2/Page 10	Pass
	Accompanying Documents-Instructions for Use, Warning & Safety Notices,	201.7.9.2 & 7.9.2.2 Pages 10-12	Pass
	Cleaning, disinfection and sterilization	201.7.9.2.12/Pages 12-13	Pass
	Accessories-supplementary equipment, used material	201.7.9.14/Pages 13	Pass
	Protection against electrical Hazards from ME Equipment	201.8 & 8.3/Page 14	Pass
	Patient Leads	201.8.5.2.3/Page 14	Pass
	Protection against Mechanical Hazards of ME Equipment and ME Systems	201.9/Page 15	Pass
	Protection against excessive temperature and other Hazards	201.11, 11.1, 11.1.2, 11.2.2.2/Page 18	Pass
	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME Equipment	201.11.6/Page 18	Pass
	Ingress of water or particulate matter in ME Equipment and ME Systems	201.11.6.5/Page 18	Pass
	Protection against hazardous output	201.12.4/Page 20	Pass
Construction of ME Equipment	201.15/Page 20	Pass	
ME Equipment components and general assembly	201.15.4/Page 21	Pass	
Testing Part 4-IEC60601-4-8 Power Frequency Magnetic Field Test			
IEC 60601-4-8:2010	Power Frequency Magnetic Field Immunity Test	6.2.1.10/Page 8	Pass

15.3 Conclusion

The **Prime™ Adaptive Ultrasonic Scalpel System and Blades**, including the **Prime™ G6000 Generator** was found to be in compliance with all of the applicable sections of IEC 60601-1-1, IEC 60601-4-8 IEC 61000 Parts 3 & 4 Electromagnetic compatibility reference in Table 15-1. All pertinent test criteria listed in this section were met or met by an equivalent reference test. Based on the outcome of the testing, the appropriate Electromagnetic Emissions Testing, Immunity, and Rated Maximum Power Outage information have been provided in the **Prime™ G6000 Generator** Instructions for Use (See Attachment 012, Page 37). The Prime™ Adaptive Ultrasonic Scalpel System and Blades is substantially equivalent to the predicate devices for medical electronic equipment.

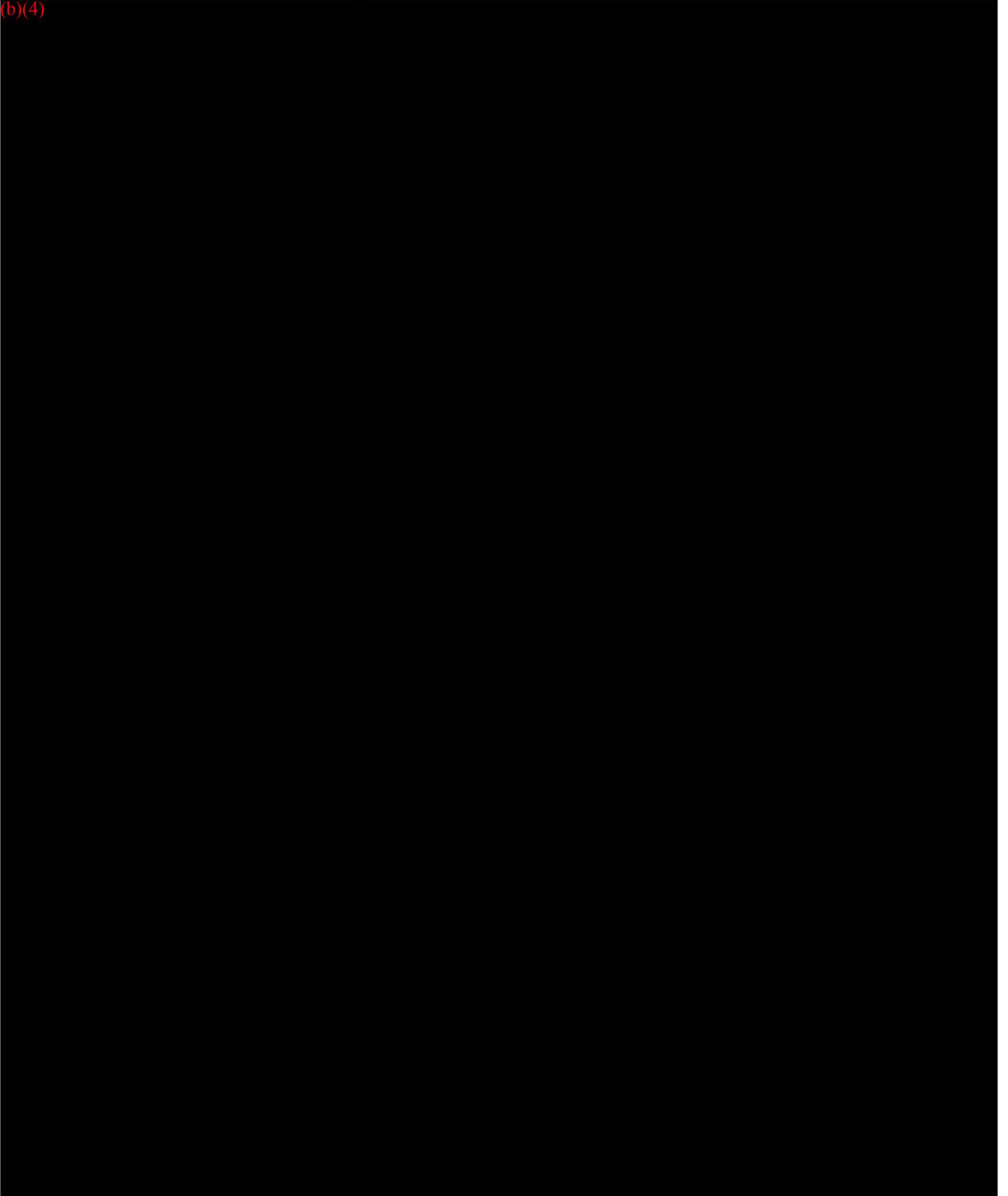
16. Performance Testing – Bench

(b)(4)



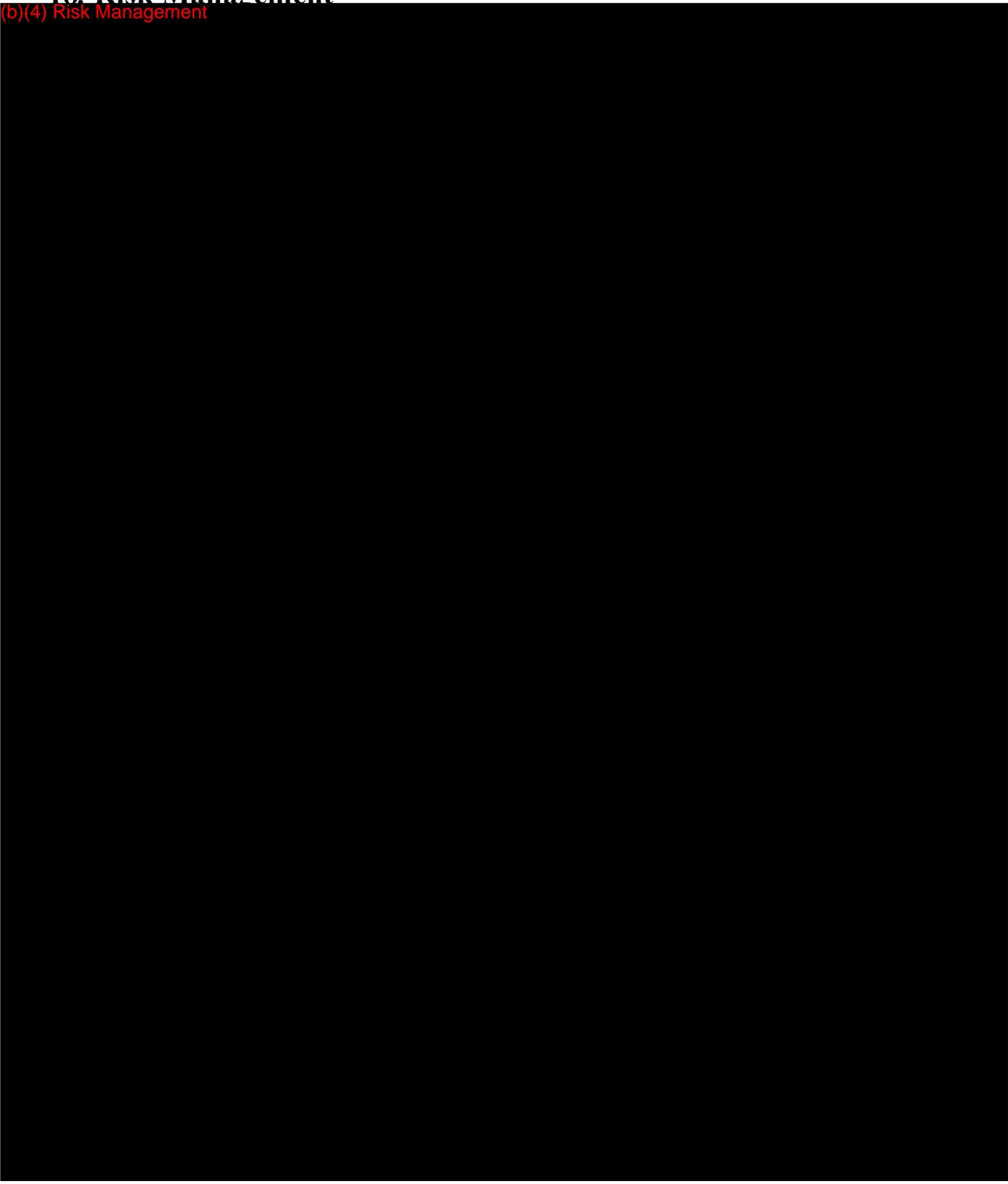
17. Performance Testing – Animal

(b)(4)

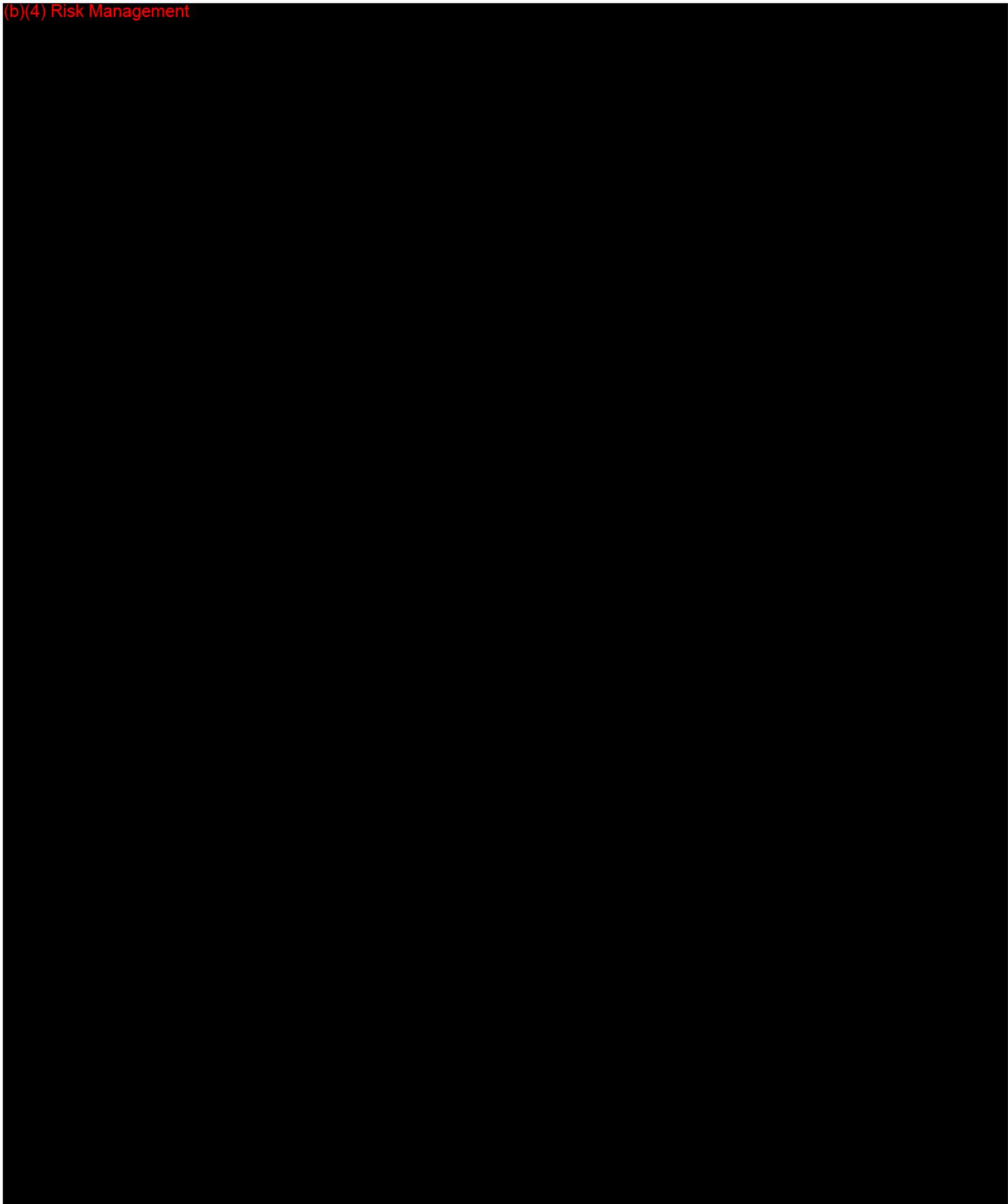


18. Risk Management

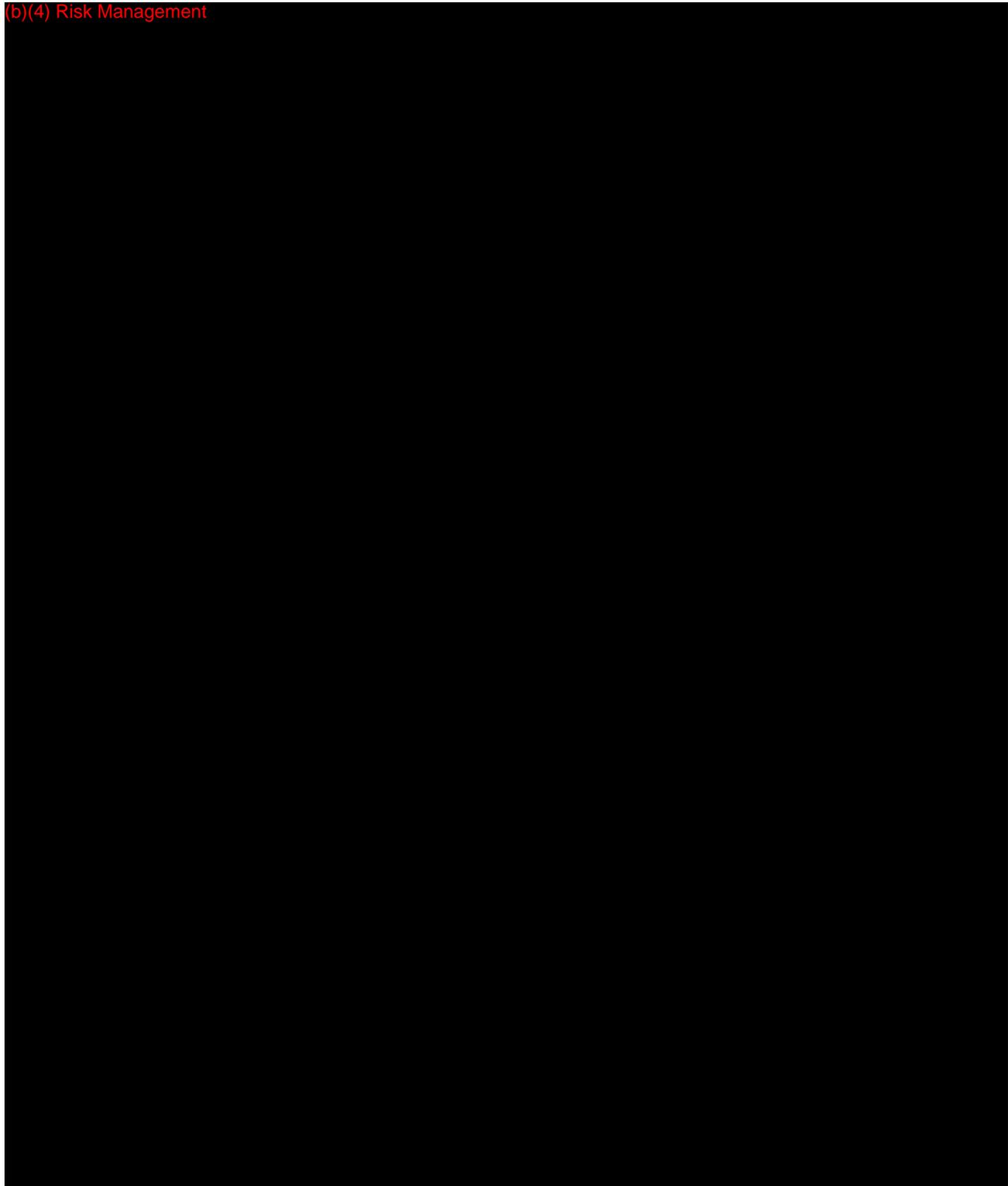
(b)(4) Risk Management



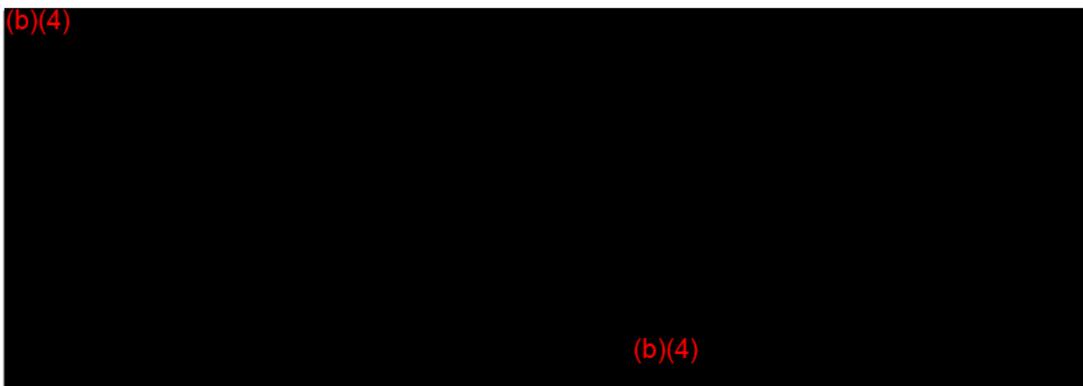
(b)(4) Risk Management

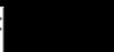


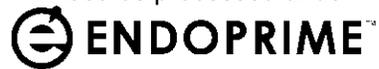
(b)(4) Risk Management



(b)(4)



Protocol: 



Prime™ G6000 Generator System

Operator's Manual REV A



EndoPrime
4480 Lake Forest Drive
Suite 414
Cincinnati, OH 45242
Telephone: (513) 769-1916
Fax: (513) 769-1921

Contact EndoPrime Customer Service for more information at the number above between the hours of 8:00 a.m. to 5:00 p.m. Eastern Time.

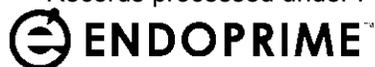
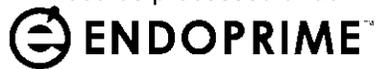


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Section 1 - Indications for Use

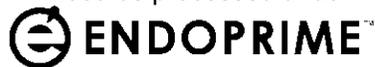
1.1 Indications for Use

The Prime™ G6000 Generator is used in conjunction with Prime™ **Adaptive Ultrasonic Scalpel System** cutting and coagulation instruments indicated for open, laparoscopic, and endoscopic surgery in soft tissue where control of hemostasis and thermal spread is desired. The system is indicated for dissection, sealing, transection,otomy creation and transection/coagulation of vessels as indicated for each cutting and coagulation instrument used (consult the instructions for use provide with each instrument). The system instruments can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels.

1.2 Contraindications

- The **Prime™ G6000 Generator** will not support instruments indicated for incising bone.
- The **Prime™ G6000 Generator** will not support instruments intended for contraceptive tubal ligation.

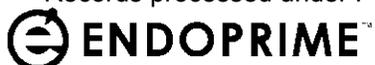
	<p>This manual is not a reference to surgical technique. Information provided in this manual is provided as a guide for setup and use of the Prime™ G6000 Generator (see Section 6). Also refer to the Instructions for Use provide with each Prime™ Adaptive Ultrasonic family of products used with the Prime™ G6000 Generator.</p>
	<p>Caution! Federal law restricts this system to sale on the order of a physician.</p>



1.3 Prime™ Adaptive Ultrasonic Scalpel System Family of Products

The Prime™ Adaptive Ultrasonic Scalpel System family of products are provided separately. Refer to the Instructions for Use provide with each of the Prime™ Adaptive Ultrasonic family of products used with the Prime™ G6000 Generator. The Prime™ Adaptive Ultrasonic Scalpel System and family of products include the following:

- **Prime™ G6000 Generator set** - generator, foot switch, power cord and operators manual.
- **Prime™ Transducer Handpiece set** - transducer, cable, test tip, and torque wrench.
- **Instrument sets:**
 - **Prime™ Ultrasonic Scalpel Reusable Blades** - includes a Reusable Torque Wench with each blade.
 - **Endoscopic Shears-** Pistol Grip with Hand Activation, includes cable, and torque wrench (contact Customer Service for availability).
 - **Open Shears-** Scissor Grip with Hand Activation, including cord, and torque wrench (contact Customer Service for availability).
- **Accessories:**
 - **Prime™ Generator/Accessory Cart**
 - **Prime™ Sterilization Tray**
 - **Adapter Connector** – for connecting to other manufactures generators systems (contact Customer Service for availability).

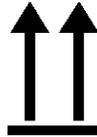
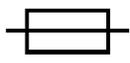


Section 2 - Symbol Legend

2.1 Symbols Used in Instruction Manual and on Device Labeling

 WARNING	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or property.
 DANGER! HIGH VOLTAGE	To identify hazards arising from dangerous voltages.
 OPERATING INSTRUCTIONS	Consult instructions for use.
 KEEP DRY	Keep away from direct contact with water.
 DO NOT COVER	To identify equipment that should not be draped with clothing or other material.
 RF ENERGY EMITTED	To identify an RF emitting energy.
 SALE ON ORDER OF PHYSICIAN ONLY	Caution: restricts this device to Caution: Federal (USA) law prohibits dispensing without prescription



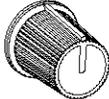
	Type CF Applied Part		Lot or Batch Number
	Temperature Limitation		Humidity limitation
	Precaution -Attention - Consult Accompanying Documents		Catalog Number
	Non-Sterile		Fragile
	Manufacturer		Date of Manufacture
	Do Not Use if package is damaged		This end up
	Serial Number		Equipotential
	On		Off
	Foot Switch		Hand activation
	Fuse		Category AP/(Anesthetic Proof) Equipment

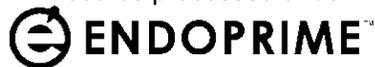


2.2 Control Illustrations and Symbols:

Illustrations and Symbols used for the Prime™ G6000 Generator controls are shown below for reference:

 VAR	<p>Variable (VAR)</p>
 TEST	<p>Test</p>
 STANDBY	<p>Standby</p>
 	<p>Increase</p> <p>Decrease</p> <p>(Or: move curse in Standby Mode)</p>

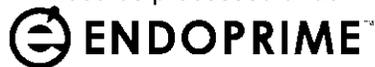
 FULL	<p>Full (FULL)</p>
 READY	<p>Ready</p>
 OUTPUT	<p>Transducer Socket</p>
 	<p>Volume</p>



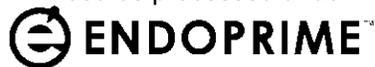
Section 3 - Warnings and Precautions

3.1 Precautions

1. The products described in this document are recommended for open and endoscopic procedures, which should ONLY be executed by a licensed physician familiar with endoscopic techniques. This equipment is for use only by medical professionals trained in the use, principles and techniques of ultrasonic, laser or electrosurgical procedures.
2. The physician is responsible for referral to relevant literature regarding techniques, complications, and hazards.
3. Users should consult this booklet in order to:
 - Avoid shock and burn hazards to both patient and medical personnel
 - Avoid damage to the device or other medical instrumentation
 - Ensure that electrical insulation or grounding is not compromised during the use of the instrumentation
4. The Prime™ Reusable Transducer Handpiece and cable; reusable blades and torque wrench are shipped non-sterile. These system components must be cleaned and sterilized according to Section 8 – System Cleaning and Sterilization prior to each use.
5. DO NOT USE instruments or transducer if damaged. Damage to the transducer or cable may result in device failure during use. Routinely inspect and replace system components when damaged or if performance is questioned.
6. Prolonged activation of device, especially at high power levels, can result in increased temperatures of the end effector and distal sheath. If prolonged activation is required, frequent pauses to allow the device to cool may be required. Avoid unintended contact with tissue or other sites at all times. Activating the blade in sterile saline may be used to clean and cool the blade's distal tip. Instruments and blades have an intermittent operation of ≤ 15 seconds on and ≥ 15 seconds off unless specified otherwise in the individual instrument instructions.
7. To prevent burn injury, discontinue use and replace the transducer handpiece if the handpiece temperature becomes uncomfortable to hold.
8. If the Prime™ Reusable Transducer is used in conjunction with products outside the Prime™ Adaptive Ultrasonic Scalpel System, verify the compatibility of all instruments and accessories prior to use.
9. Carefully handle instruments, avoid bending and contact with hard surfaces with the blade tip when removing the protective cap and when sliding the torque wrench onto or off the blade assembly. Scratches, dents or distortion of the blade or sheath will significantly shorten the instrument's useable life. Handle the instruments and handpiece with care to avoid damage by dropping or banging the instrument. The handpiece and cable should be inspected for damage before each use.

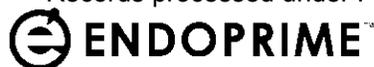


10. DO NOT USE instruments if the sheath or blade is bent or damaged. Both the sheath and blade must be straight to function safely.
11. The entire blade length is active and will cut or burn tissue when the instrument is activated. DO NOT USE or activate the Prime™ Ultrasonic Blade without fully assembling the protective Sheath over the shaft of the Blade. The shaft of the blade is active and can cause injury if not covered by the Sheath.
12. Blades should be inspected for damage before use. DO NOT USE blades with any damage or suspected damage. Damage to the blades may result in device failure during use. Examples of damage would include any scratches, deviations in shape, discoloration, overheating and audible screeching noise.
13. DO NOT USE torque wrench with evidence of damage. Damage to the torque wrench may result in device failure and inability to properly secure the blade assembly.
14. Always ensure that the instrument being used is clear of other instruments, drapes, retractors, the patient, or other objects when activated or when pressing TEST.
15. As in any laser, electrosurgical, and ultrasonic procedures, the potential exists for personnel to be exposed to carcinogenic and infectious by-products, such as tissue residue, smoke clouds and aerosols. When using the Prime™ Adaptive Ultrasonic Scalpel System protective eyewear, filtration masks, and effective smoke evacuation equipment should be used. Safety measures in accordance with hospital protocol in the presence of smoke and aerosols should be in effect while in use. Additional sterile instruments should be kept available for all surgical procedures in the event that any component becomes inoperable.
16. Immersing the generator, steam sterilizing the generator or contact with liquids or fluids may result in damage, risk of electrical shock or fire hazard.
17. Error or Check messages are indicators that a system component is malfunctioning or at the end of its usable life. Error and Check messages should always be addressed immediately according the Section 6.2 of this manual. Failure to follow the instructions in Section 6.2 could result in system failure and possible injury to the patient or user.
18. The system and generator must be operated under the specified environmental conditions listed in the Appendix.
19. The equipment should not be used in the presences of flammable anesthetic gasses mixed with air, oxygen, or nitrogen oxide. Non-flammable agents ONLY should be used for cleaning and disinfection. Sparks may be generated due to collision with other metal apparatuses and may ignite flammable fluids or gases.
20. To reduce the hazard of interference, electrosurgical equipment and the Prime™ G6000 Generator, cable and handpiece, should be located at a distance of at least 1 meter from other electrosurgical or similar equipment.



3.2 Warnings

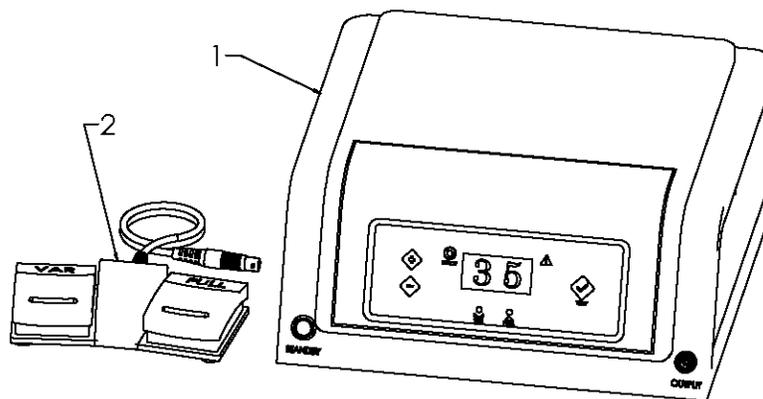
1. DO NOT USE the product if homeostasis cannot be achieved or observed. Monitor for bleeding during use of the device; if a small amount of or uncontrollable bleeding occurs, manually stop the bleeding.
2. Verify that the scalpel blade is clear of tissue, other instruments, and other objects before activating the system to avoid damage or injury. Only activate when the end effector (exposed blue blade) can be fully visualized. Lack of full visibility may result in unintended cutting of tissue or damage to other devices. Avoid blade contact with any and all metal surfaces especially while the instrument is activated. Contact with staples, clips, or other instruments may result in damaged resulting in broken blades during use.
3. Blood and tissue build up between the Blade and Sheath may also result in abnormally high temperatures at the distal end of the sheath. To prevent the potential of burn injury, remove visible tissue buildup or disassemble sheath to remove tissue. Dry blade assembly to remove moisture before reassembling sheath.
4. DO NOT attempt to bend or sharpen the blade. Deformed, damaged, cracked or broken blades may be identified by a warning tone from the generator and could lead to the blade breaking during use.
5. Attention should be paid to stop activation of device upon completion of tissue cutting. Excess activation may result in heat generation or injury during unintended tissue contact.
6. Excess lateral force on the blade, especially without the sheath attached, may result in damage to transducer handpiece or blade.
7. Interconnection with other medical electrical equipment for endoscopic application is to be type CF applied parts ONLY.
8. The Prime™ Adaptive Ultrasonic System does not insufflate or use inert gases; however, gas embolism caused by, for example, over-insufflation of air, use of inert gas prior to surgery, or the use of laser assist gas is a risk when used with the Prime™ Adaptive Ultrasonic System.
9. When other energized endotherapy devices are used with the Prime™ G6000 Generator or other Prime™ Adaptive Ultrasonic Scalpel System products, refer to the endotherapy device's safe use provided in the instructions for use or seek advice from the manufacturer before proceeding.
10. To avoid injury to the patient or user, keep the scalpel away from tissue, other instruments and other objects before system activation.



Section 4 - Elements of Basic System Function

4.1 Product Description

Figure 1- Prime™ G6000 Generator



1- G6000 Generator 2 - Foot Switch 3 - Power Cord -
not shown

4.1.1 Prime™ G6000 Generator

The **Prime™ G6000 Generator** is a part of the **Prime™ Adaptive Ultrasonic Scalpel System** family of products. The generator provides electrical energy output to the handpiece transducer, which is controlled by activating the foot switch, or hand switch, depending on the handpiece being utilized. The **Prime™ G6000 Generator** provides input/output control and operation interface to automatically adapt the ultrasonic power output for the tissue load encountered. Key aspects of operation are discussed below:

- **Startup:** The **Prime™ G6000 Generator** conducts an initial system test, monitors device condition, provides system test results, displays troubleshooting messages, and deactivates the instrument operation when an anomaly is detected.
- **Power Levels:** Variable and Full power levels are displayed and the variable power level can be adjusted throughout the procedure to provide the desired energy output.
- **Alarms and Indicators:** Audible indication identifies when an instrument is activated in FULL or VAR power levels. Audible and visual alarms and indicators assist with identifying when devices are improperly setup, damaged, or at the end of their usable life.
- **Ready, Standby and Test Modes:** The Standby Button is available to pauses the system during use to allow for safely changing instruments, testing system components and avoiding accidental activation. The Generator defaults to the Standby Mode when first started – press the Standby Button



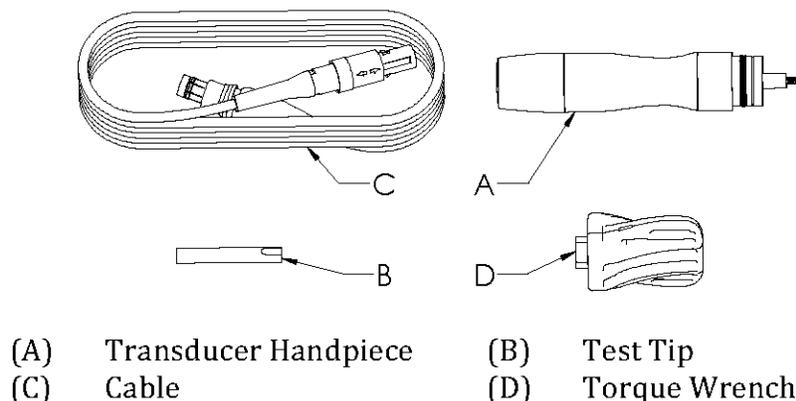
to enter the Ready Mode (see Section 5 below). The system is in the Ready Mode when the Power Levels (3 and 5) are on the screen.

4.1.2 Handpiece Transducer

The **Prime™ Reusable Transducer Handpiece** is sold separately and is designed to convert electrical energy from the generator to ultrasonic motion for the instrument blades. Consult the instructions for use supplied with each of these produces.

The transducer is packaged with a detachable cable used to connect the instrument to the generator. In addition, the package includes a Test Tip for testing the system and a torque wrench used to secure blade assemblies and the Test Tip to the transducer. An adapter for connecting the **Prime™ Reusable Handpiece Transducer** to generators manufactured by others is available (Contact Customer Service for adapter information).

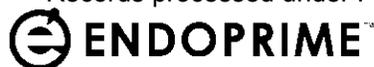
Figure 2- The Prime™ Reusable Transducer Handpiece is provided with the following:



	<p>Precaution! The Transducer Handpiece, Cable, Test Tip and Torque Wrench are provided Non-Sterile, Clean and sterilize before each use.</p>
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4.1.3 Scalpel Blades and Instruments

Prime™ Reusable Ultrasonic Scalpel Blades and other Prime™ Adaptive Ultrasonic Scalpel instruments are sold separately. Consult the instructions for use supplied with each of these devices for assembly and used with the Transducer Handpiece. The scalpel blade vibrates ultrasonically, which heats the tissue by friction and provides the cutting ability. The same vibration seals vessels with coagulated blood and tissue proteins by producing local heating of tissue resulting in homeostasis. See the individual instrument instructions for use for assembly, indications and use of the instruments with the Prime™ G6000 Generator and family of instruments.

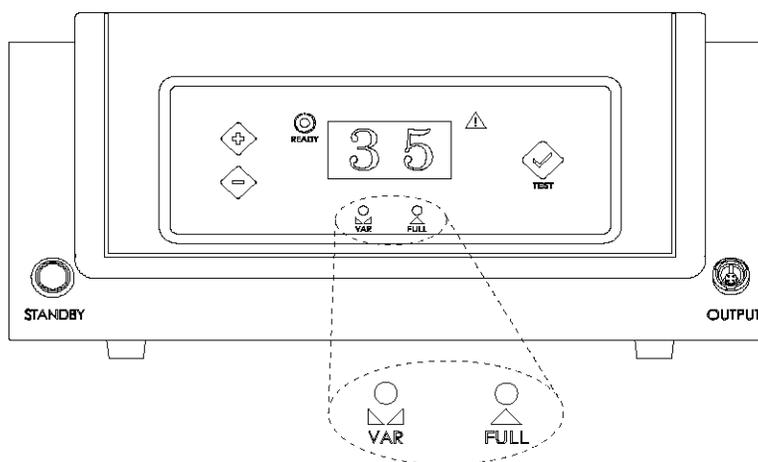


Precaution! The products described in this booklet are designed for use as part of the **Prime™ Adaptive Ultrasonic Scalpel System** and family of products; however, these products are compatible with a limited number of other manufacturer's systems. Verify and test compatibility before use.

4.2 Generator Power Settings

The Prime™ G6000 provides two power settings for the user to select using either the foot switch or hand activation switch. The digital display reflects the two setting as: VAR and FULL (See Figure 3).

Figure 3- Front Panel



The user can set the VAR power from 1 to 5 by pressing the Increase  / Decrease  Buttons on the front panel when in the Ready Mode. Lower settings for the VAR power result in less friction and more heat, which are useful in improved hemostasis. The following are the power distributions for each setting:

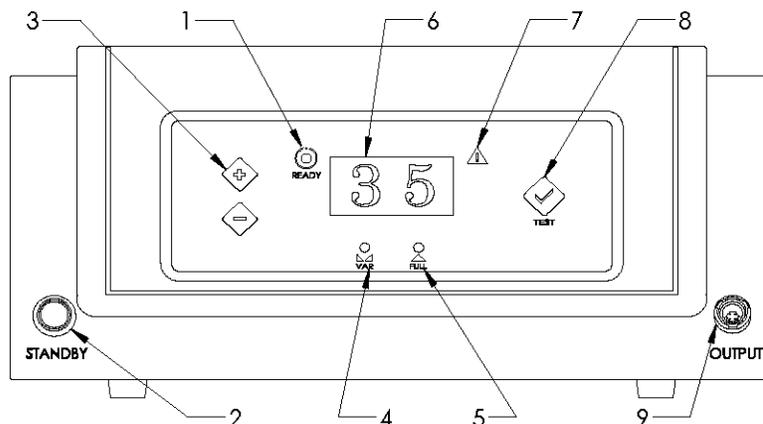
Level 1:	50%	of Full Power
Level 2:	62.5%	of Full Power
Level 3:	75%	of Full Power
Level 4:	87.5%	of Full Power
Level 5:	100%	of Full Power

FULL power is always maintained at level 5. FULL or the 5 power level is often used to obtain fast tissue cutting. The energy conveyed to the tissue and the tissue effect produced depends on many factors, including the selected power level, scalpel shape, clamping force (if applicable), tissue tension, tissue type, pathology and surgical technique.



4.3 Controls, Indicators, and Connections

Figure 4- Front Panel Diagram

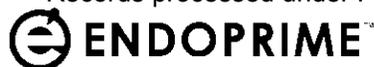


Front Panel Features and Controls

Refer to Figure 4 above

 READY	<p>1 Ready - If this indicator light is green, it indicates that the equipment is Ready for use. This indicator light goes off in the Standby mode.</p>
 STANDBY	<p>2. Standby - Press the Standby Button to shift between modes of Standby and Ready. In Standby mode, the transducer has no power output. Neither the foot switch nor instrument switches (if present) can activate the equipment output power. When the equipment is connected to the power supply and switched on, it enters the default Standby mode. An alternative to pushing Standby, if a medical technician is not available outside the sterile surgical field, simply disconnect the transducer power cable from the generator. The green Ready light will go out, and the power will discontinue until the transducer cable is reconnected to the generator.</p>

Continued on next Page



Front Panel Features and Controls Continued

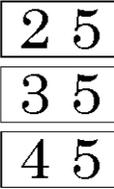
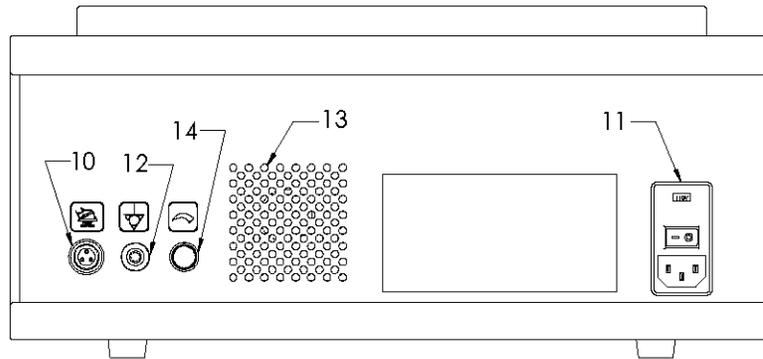
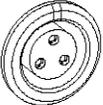
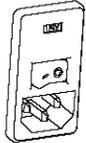
	<p>3. Increase/Decrease of Power Level - Press the  button to increase, or the  button to decrease minimum power to the desired level (from 1 to 5). The selected level will be displayed on the display screen on the left. The power level can be adjusted when the generator is in the Ready mode. When the equipment is in Test mode, these Buttons are used to move the cursor up and down.</p>
	<p>4. Variable Indicator Light - Indicates minimum power level, which can be set by the user. When this power level is activated (through the foot switch or instrument activation), the "VAR" indicator light flashes. The default setting for "VAR" power level is "3".</p>
	<p>5. Full Indicator Light- This indicates maximum power level. This setting is always "5". When it is activated (through the foot switch or instrument activation), the "FULL" indicator light flashes.</p>
	<p>6. Display Screen - displays error messages should errors occur and the power level when in the Ready Mode:</p> <p>Power Level: the variable, VAR , (set by the user from Level 1 to 5) and maximum, FULL, (Level 5) power levels. In case of fault of the equipment or an element or component, the error message will be displayed on this screen.</p>
	<p>7. Warning Indicator Light - The yellow indicator lights up red only when the equipment gives an alarm due to the fault of an element of the generator or equipment.</p>
	<p>8. TEST - In Standby mode, press to enter equipment Test mode. Components and menu functions that can be tested one by one. In the Test mode, use "TEST" as the "enter" Button.</p>
	<p>9. Transducer Socket - The socket on the lower right corner, which is used to connect the transducer to the generator.</p>

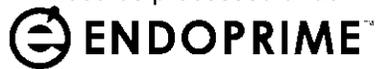


Figure 5- Back Panel: Diagram



Back Panel Features and Controls

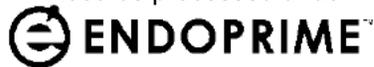
 	<p>10. Foot Switch Socket - Circular socket - connection for the foot switch by the user.</p>
	<p>11. Power Socket and Switch - The socket is used to connect the power cord to the generator. I is ON, O is OFF. The switch controls the main power supply of the generator. A fuse  is located in the fuse box in the power socket. (See Section 9.2 System Technical Specifications for replacement fuse specifications).</p>
 	<p>12. Equipotential Terminal - This terminal is used when connecting together with other like terminals to bring the same voltage potential, not necessarily the earth ground, to each component or equipment connected to a main source of power (e.g. for local bonding).</p>
<p>See Fig 5</p>	<p>13. Vents – The vents located on the back of the generator should be kept clean and free of any debris. During the system function, air will circulate through the vent to assist with cooling the system. DO NOT block the air vents to avoid generator overheating.</p>
 	<p>14. Volume adjust – The generator produces a sound upon activation, sounds for different power levels, and warning sounds when the system is in different failure modes. Volume will allow the user to adjust these sounds.</p>



4.4 System Component Verification

The **Prime™ Adaptive Ultrasonic Scalpel System** family of products are provided separately for purchase. Prior to use, verify if there is any visible transportation damage. In case of any damage, please contact the customer service or the local agent. The Prime™ G6000 Generator will automatically verify proper connection and function of the system during startup and operation by running a built-in, automatic pre-check function (See Section 5 System Inspection and Testing).

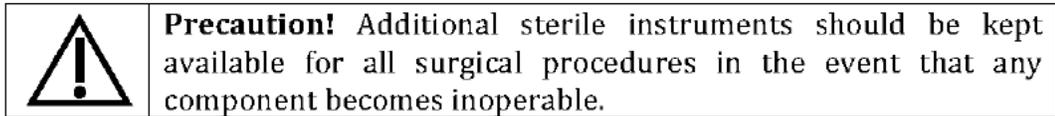
	Precaution! Always test instruments before use to ensure the system is operational to avoid unnecessary delays during surgical procedures. See Section 5 – Testing before Use.
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Section 5 - System Inspection and Testing

5.1 Routine System Inspection

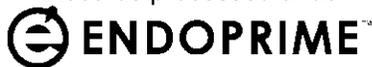
The following system inspection is to be carried out prior to use of the **Prime™ Adaptive Ultrasonic Scalpel System** to ensure user and patient safety:



5.1.1 Routine Inspection for Wear and Tear:

Inspect the generator, cables, foot switch, cable connectors, torque wrench, reusable blades and other equipment for any damage or wear and to ensure there is no liquid present. Any damaged cord, transducer handpiece, or reusable instrument must be replaced before use.

- **Inspect Scalpel Blade:** Inspect the ultrasonic scalpel for damage before and after each use. Also, the outer surface should be checked to ensure there are no unintended rough surfaces, sharp edges or protrusions which may cause harm. The scalpel blade cutting tip is (b) to aid in the detection of scratches and other damage. A damaged or suspect scalpel should be replaced before use.
- **Be Aware and Replace:** The transducer handpiece, blades and other components are rated for multiple reuse, but not infinite life. If the handpiece, sheath or blade makes noise, quickly becomes hot, or blades have degraded cutting performance, the transducer or blade may be beyond its usable life and should be replaced. Examples of damage include any tear in the insulation, deep scratches, deviations in shape, damage to the blade or its mounting surface, corrosion or discoloration. Such degradation may occur or be detected before, during or after a procedure. Older functional blades may also stop functioning during a procedure without warning and should be replaced. Scratches, dents or distortion of the blade or sheath will significantly shorten the instrument's useable life.
- **Indication of End of Blade or Handpiece Life:** A continuous tone or error message from the generator indicates the blade may be at the wrong torque setting or the blade may be at the end of its usable life. If reapplying the torque wrench to the blade does not resolve the error, the blade may be damaged and must be replaced. An audible screeching tone emanating from the blade or transducer is an indicator that the blade or transducer handpiece is beyond its useful life and should be replaced.



Proximity to other Equipment:

Ultrasound surgical equipment, including the transducer cable, should be located at a distance of at least 1 meter from other electrosurgical equipment, cable and handle (such as electrosurgical devices).

	<p>Precaution! To reduce the hazard of interference, electrosurgical equipment and the Prime™ G6000 Generator, cable and handpiece, should be located at a distance of at least 1 meter from other electrosurgical or similar equipment.</p>
---	---

Safety Equipment:

Ensure that protective eyewear, filtration masks, and effective smoke evacuation equipment are available for use.

Clear Tissue Buildup:

Verify that the scalpel is clear of tissue, other instruments, and other objects before activating the system to avoid damage or injury.

5.2 Routine System Function Testing

Prior to any surgical procedure using the **Prime™ Adaptive Ultrasonic Scalpel System**, the following functional testing steps should be conducted:

- **Connect** the scalpel and the Transducer Handpiece as described in Section 6 – Instructions for Use. Connect the desired scalpel instrument (blade or shears) following the instructions supplied with the instrument. Or, the generator and transducer handpiece may be tested by installing the Test Tip on the transducer (use the Torque Wrench supplied to tighten the Test Tip until the Torque Wrench clicks at least twice).
- **Verify:**
 - System can enter the READY mode. Press the STANDBY button to exit the standby mode and enter the READY mode.
 - Indicators are on.
 - Display VAR power level (default is 3) and the FULL power level 5.
- **Press the power** increase  and decrease  buttons to adjust the VAR power level between 1 and 5.
- **Turn off** the generator power (Back Panel). Wait for five seconds, and then switch on the generator power. The generator will automatically run a built-in, automatic pre-check function system wide test. Wait for another 10 seconds, press STANDBY button, and verify that the VAR power level 3 and the FULL power level 5 are displayed. Confirm that the generator is not activated during this process.
- **Standby Mode:** Press the STANDBY button to enter the STANDBY mode.
- **Ready Mode:** Press the STANDBY button to enter the READY mode.

	<p>Warning! To avoid injury to the patient or user, keep the scalpel away from tissue, other instruments and other objects before system activation.</p>
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- **Activate:** Hold the Transducer Handpiece with its distal end in the air and step on the VAR foot pedal of the foot switch (or Hand Switch where applicable). Check to see whether the VAR power level indicator on the control panel is flashing and the sound of the VAR activation is heard (slow beeping). Repeat by stepping on the FULL pedal, observing the FULL indicator and a rapid beeping is heard.

Successful completion indicates the system is ready to use.

5.3 Individual Component Functional Testing

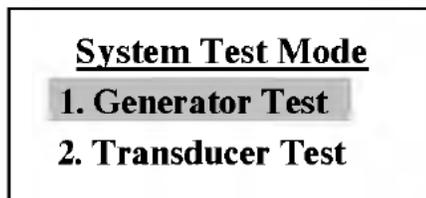
The equipment detects system failures of the generator, transducer or scalpel using a built-in, automatic pre-check function during startup and monitors the system during operation. Individual components may be tested manually anytime or for troubleshooting:

- **Press TEST Button in the Standby mode to enter the System Test mode.**
- **Press the \blacklozenge or \blacktriangleleft Button to move the cursor and select the corresponding component to perform a test.**

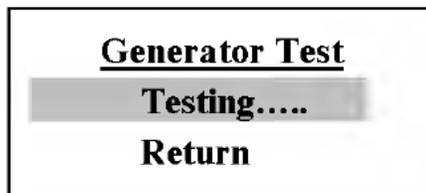
The following are test methods and screen displays of the functional tests available that may be use to conduct individual testing of components and are useful in trouble shooting (see Section 7 - Troubleshooting).

5.3.1 Generator Test:

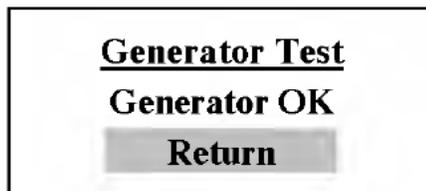
With the generator in Standby Mode press the TEST button on the Front Panel to activate the Test Mode. The screen will change as follows:



Press the TEST Button again to start a full test of the generator. The normal test screen is shown as follows:



After the generator has passed the test, the following screen will be display:



Press the TEST Button to return to the Test Mode.



****ERROR:** When any functional component has been found to be faulty during a test, the following screen is displayed and flashes on and off for 5 seconds. After the 5 seconds the screen will return to the following screen:

Generator Test
Generator Failure

After the 5 seconds the screen will return to the following screen:

System Test Mode
1. Generator Test
2. Transducer Test

Check all connections; inspect cables, transducer, and instruments. Retest and if the failure persists, call Customer Service for repair the Prime™ 6000 Generator if faulty.

5.3.2 Transducer Handpiece Test:

With the generator in Standby Mode press TEST to activate the Test Mode. The screen is shown as follows:

System Test Mode
1. Generator Test
2. Transducer Test

Press the Button, to highlight the transducer test menu. The screen is shown as follows:

System Test Mode
1. Generator Test
2. Transducer Test

Press the TEST Button to start the test of the functional components of the transducer automatically. The normal test screen is shown as follows:

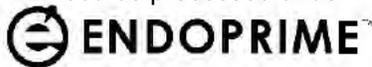
Transducer Test
Testing...
Return

After the transducer has passed the test, the following screen will display:

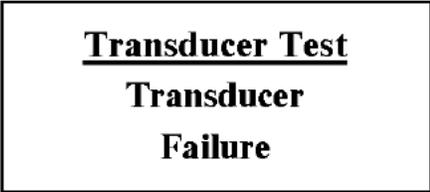
Transducer Test
00XXXX OK
Return

OK = the Transducer is within the acceptable range.

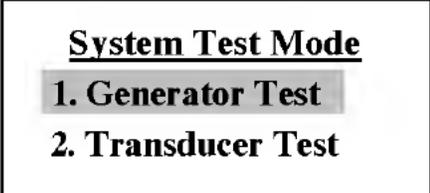
00XXXX = the capacitance in nanofarads is displayed for servicing reference.



****ERROR:** When any functional component of the transducer has been found to be faulty during a test, the following screen is displayed and flashes on and off for 5 seconds.



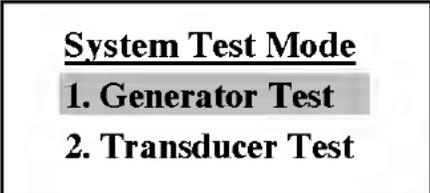
After the 5 seconds the screen will return to the following screen:



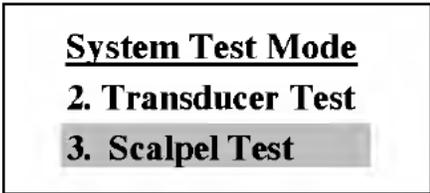
Other fault messages and audible alarms are shown in Section 7, Table 1- Troubleshooting Audible Indicators and Alarms

5.3.3 Instrument Scalpel Test:

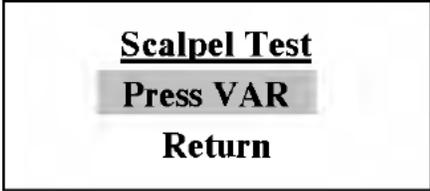
With the generator in Standby Mode press TEST to activate the Test Mode. The screen is shown as follows:



Press the DOWN ⇩ Button, to highlight the scalpel test menu. The screen is shown as follows:



Press the TEST Button to start the test of the scalpel automatically. The test screen is shown as follows:

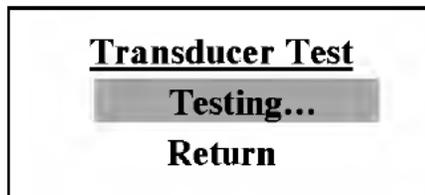


Press the Footswitch VAR pedal (or hand switch). The test screens are shown as follows:

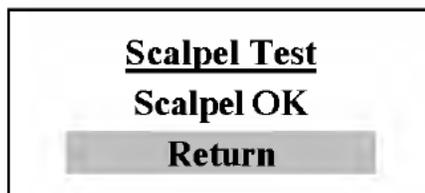




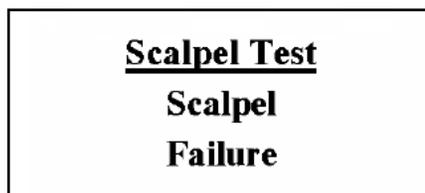
Followed by:



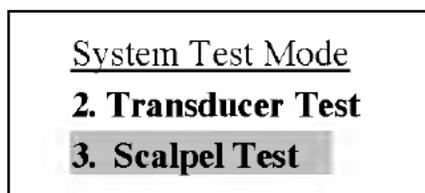
After the scalpel has passed the test, the following screen will display:



****ERROR:** If a scalpel fault has been detected during a test, the following screen is displayed and flashes on and off for 5 seconds (i.e. scalpel abnormality):



After the 5 seconds the screen will return to the following screen:

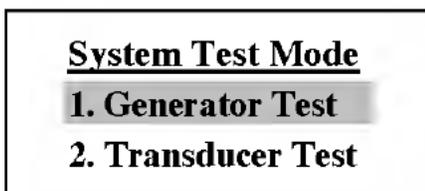


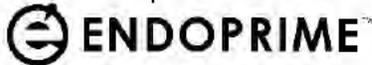
Press the **TEST** Button to return to the **Standby** mode of the equipment, and then refer to Section 7 – Troubleshooting, to address the Error message. Other fault messages and audible alarms are shown in Section 7, Table 1- Troubleshooting Audible Indicators and Alarms. Replace the Prime™ Transducer Handpiece if faulty.

5.3.4 Exit System Function Testing:

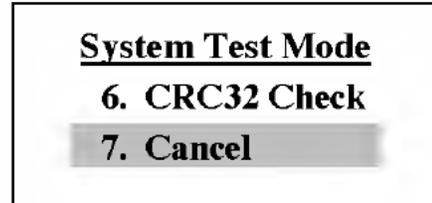
When the desired system component(s) or have been tested utilizing the steps above and all of the error messages have been resolved, the following are the steps to exit the system test mode:

The Test Mode menu is shown as follows (or the cursor may be on one of the tests):





Press the DOWN  Button until the cursor is over "Cancel". The screen is shown as follows:



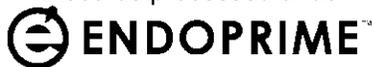
Press the TEST Button to exit the TEST Mode and return to the Standby mode.

5.3.5 Service Menu Selections:

Additional Test Mode Menu Selections are available for servicing. These functions provide Customer Service information and are selected similar to the steps above. The Customer Service functions are:

4. "S-Power" = provides Customer Service information regarding power.
5. "HandAD Define" = provides Customer Service information for hand activated devices.
6. "CRC Check" = provides Customer Service information for software version and check sum to insure software integrity.

Contact EndoPrime Customer Service for use of these menu items.



Section 6 - Instructions for Use

6.1 System Setup and Test



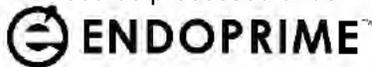
Precaution! Read and follow all instructions for use during setup, installation, and system interaction. Not following instructions may prevent the Prime™ adaptive ultrasonic scalpel system from being able to perform its intended actions.

1. **Switch off** the generator power switch before setup.
2. **Connect** the power cord to the AC power socket on the rear panel of the generator. Connect to power outlet that meets the voltage requirements of the generator.
 - If the power cord is wound around the handle of the cart or other holder, it must be removed completely from the handle before inserted into the power output socket.
3. **Inspections and testing** must routinely be completed for all equipment before use - Refer to Section 5.
4. **Connect** the foot switch cable to the foot switch socket on the rear panel of the generator.
 - Ensure that the connector socket is dry and clean.
 - Be careful not to introduce any liquids during connection in order to prevent accidental activation.
5. **Connect** the scalpel to the Transducer Handpiece in accordance with the operating instruction.
6. **Connect** the Transducer Cable to the socket on the front panel. Before connecting the Transducer to the generator:
 - Ensure that the Transducer connector is dry and clean.
 - Insert the Transducer connector completely to ensure that it is connected to the generator correctly.
7. **Turn on** the power switch of the generator and observe the initialization sequence. When the power is switched on, the following indicator lights on the front panel will light up for a moment: READY, FAULT, VAR, FULL



Warning! To avoid injury to the user or patient during equipment inspection, use caution to keep the distal end of the instrument away from other apparatuses, the surgical drape, the patient or other objects.

8. The **startup sequence** will be run by the equipment automatically. It will give an audible indication during the initial sequence. The complete power-on sequence lasts about 20 seconds. **If the startup sequence is different from that described above, please contact EndoPrime Customer Service.**



9. **Standby:** After completion of the startup sequence, the equipment will enter standby mode.
- If the equipment detects a fault of the generator, the error detected will be displayed on the display screen and an alarm will be heard.
 - See Section 7 - Troubleshooting.

	Precaution! Prior to use of the system, component and system testing should be completed. See Section 5 – Testing, for the appropriate steps.
--	--

10. **Power level:** When the equipment starts up, the default power level of the generator is 3 (VAR) and 5 (FULL).
- The user can adjust the minimum (VAR) power level from levels 1 to 5.
 - To adjust the minimum power level, press the / buttons on the left of the display screen.
 - Set the power level according to the preference of the surgeon and/or the recommendation of the scalpel operating instruction
 - For more details, please see the power level portion of Section 4.2 – Power Settings.

11. **Audible Activation Indication:** The generator uses different sounds to indicate activation power level. A dial located on the back of the generator can set the sound volume.

After inspecting and startup, the equipment is ready for use.

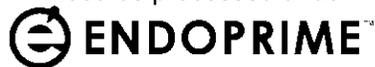
	Warning! The generator must be operated under the specified environmental conditions.
	Warning! If the Prime™ G6000 generator is damaged or it is suspected that it has fallen or that water has got into it, a Customer Service or other evaluation must be carried out before deciding whether it can continue to be used.

6.2 System Functions

	Precaution! Before use of the Prime™ G6000 and other ultrasonic surgical equipment or components, the user should refer to the Instructions for Use for the other component, instrument, scalpel, and Transducer Handpiece if appropriate.
--	---

1. Press the STANDBY Button to exit **Standby**.
2. The generator will enter **Ready** mode and the VAR and FULL Power levels will be displayed.
3. Step on the foot switch to activate the ultrasonic output.

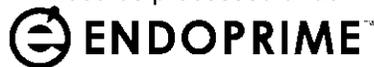
Press the STANDBY Button to exit **Standby**. The generator will enter **Ready** mode. Step on the foot switch to activate the ultrasonic output and test the instrument.



6.3 System Shutdown and Storage

Upon completion of the surgical procedure, the following steps should be followed to shutdown the **Prime™ Adaptive Ultrasonic Scalpel System**:

1. Turn off the power switch of the PRIME™ G6000 and pull the power cord out of the outlet socket.
2. Disconnect the transducer and the scalpel cords handling according to their instructions for use.
3. Wipe off and place the Transducer Handpiece and cable in the sterilization tray.
4. Disconnect the Reusable Sheath and Blade (or other instrument) from the Transducer Handpiece using a torque wrench.
5. When using reusable blades: Remove blood/debris from the Sheath and Blade. Replace protective caps on reusable blades.
6. Place cables, reusable blades with caps, and torque wrench in sterilization tray.
7. Replace any equipment that is not performing, worn, corroded, deteriorated, damaged, nonfictional or at the end of its usable life. Ensure that two of each item is in the tray as backup for the next surgery.
8. Clean the PRIME™ G6000, cart, foot switch, transducer and reusable instruments according to the procedures listed in Section 8 – System Cleaning and Sterilization.
9. The foot switch should be stored on the Cart with the Prime™ G6000 Generator or stored off the floor. The power cable should remain with the generator.

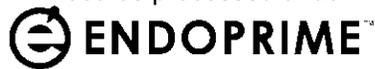


Section 7 - Troubleshooting

The PRIME™ G6000 generator has a series of alarm signals and error messages to help to recognize and detect faults of elements and components. Signals and messages are available as a resource to alert the medical professional when a device or system failure is occurring, and a system check or corrective action should be implemented. The following is a guide to audible indicators, alarms, and error messages.

7.1 Table 1: Troubleshooting Audible Indicators and Alarms

Sound	Possible Cause and Troubleshooting
No audible indications is given when the equipment is activated	<ul style="list-style-type: none"> • Assure the volume is adequate by adjusting the volume control. • Test function of the blade by placing the tip in sterile saline. • Make sure the Foot Switch and Transducer Handpiece cables are connected correctly and not damaged. • Restart the system and follow all recommended testing before use (See Section 5 – Testing).
Continuous Sound (>10 seconds)	<ol style="list-style-type: none"> 1) The scalpel has contacted/grasped too much tissue. <ul style="list-style-type: none"> • Reduce the amount of tissue in contact with the scalpel. • If continuous sound continues, remove the tissue buildup at the end of the scalpel and end effectors. 2) Transducer and/or scalpel error message or fault. <ul style="list-style-type: none"> • Press the TEST Button to find out the fault source. • When determined what device is failing, replace the device while the system is in STANDBY mode or with the Transducer Handpiece disconnected..
Alarm (two sequences)	Fault of a system component. See ERROR MESSAGES Chart in this section for more troubleshooting.

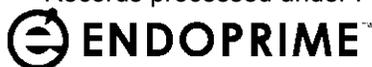


7.2 Troubleshooting and using Error Messages

The Prime™ G6000 Generator will automatically and continuously test the generator, transducer, scalpel, and foot switch to recognize faults. When a fault is recognized, an alarm will sound and an Error Message will appear on the display screen of the generator. The error message can be traced to a component listed below (i.e. the Foot switch, generator, transducer, or scalpel instrument). Replacing the component and restarting the system should resolve the problem.

The following are three Error messages to pay particular interest to:

- **Generator Failure or Check Generator:** indicates that the generator has a function problem, or that a Button on the control panel or the foot switch is activated when the power is switched on. In case of persistent generator fault, contact the manufacturer for repair or replacement of the faulty component.
- **Check Transducer or Scalpel:** indicates that the transducer or scalpel has a problem. Replacement scalpels should always be available during a procedure, and any scalpel with a fault should be replaced.



Section 8 - System Cleaning, Sterilization and Maintenance

8.1 Generator Cleaning

The Prime™ G6000 Generator and the related parts are shipped non-sterile. The generator is provided with a Foot Switch and Cable and use of the Prime™ Generator/Accessory Cart is recommended.

Generator Cleaning: Wipe down the generator and power cable using a damp cloth. Only Non-flammable disinfection agents should be used. Inspect to assure the devices will be properly functioning and available for the next surgery.



Warning! DO NOT immerse or Seam Sterilize the Prime™ G6000 Generator or Foot switch.

8.2 Reusable Instruments & Transducer Cleaning and Sterilization



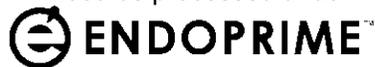
Precaution! Reusable Prime™ Adaptive Ultrasonic Scalpel System products are provided non-sterile.

Reusable Prime™ Scalpel Instruments, Transducer Handpieces, Cables, Test Tips, Torque Wrenches and Sterilization Trays are shipped non-sterile and must be sterilized by the hospital before use. The cleaning method must provide protection from cross contamination, damage to the instruments, and injury to personnel. All of the Prime™ reusable products have been approved for the following cleaning and sterilization procedure:

Remove Blood and Debris: Following each surgical procedure, clean as soon as reasonably possible. Disassemble and wipe down the Blade, Sheath, Transducer and cables with a damp cloth. Manually rinse and scrub the Sheath channel (or cannula) with a soft-bristle or nylon brush to remove any blood or debris. Inspect devices for damage, improper mechanical function, cracks, wear or corrosion. Replace if worn, damaged (including sharp or rough surfaces), or lack of integrity is suspect. For reusable blades: reinstall the Protective Tip Caps to reduce the potential of damaging the tip.

Cleaning: Clean instruments, cables and accessories according to the following steps:

- Use a neutral pH detergent or neutral pH enzyme detergent according to the instructions of the detergent manufacturer.



- Use only nonabrasive materials.
- Immerse in the detergent solution for a minimum of 5 minutes and manually scrub the cannula of the Sheath with a channel cleaning brush until all tissue, blood and debris is removed (use a 5mm or larger diameter nylon-bristles brush or equivalent).
- Machine-wash to remove all visible blood, debris, soil and contamination.

Sterilization Cycle: Double-wrap the tray with an FDA-cleared wrap using standard wrapping techniques such as those described in ANSI/AAMI ST79:2010 and A1:2010 and A2:2011. Steam Sterilize using the following cycle:

Cycle	Temperature	Exposure Time	Minimum Drying Time
Steam Pre-Vacuum 3 pluses	270°F (132°C)	4 minutes	30 minutes

No Lubrication is required for the devices.

8.3 Generator Customer Service

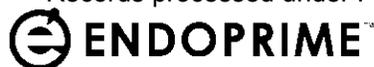
Customer Service and Maintenance

For repair service call (513) 769-1916 and ask for Customer Service. Ask about how to package the generator and other products for return or package in the original packaging. The Prime™ G6000 warranty and other warranties may be voided if the product is not returned in the original packaging or equivalent to protect the products during shipment.

Maintenance of the Prime™ G6000 Generator, Foot Switch, and other accessories requires inspection cleaning, and replacement or repair if damaged. Calibration is not required for the Prime™ G6000 Generator. The software revision level is displayed on the front panel and software may be upgraded when available upon request.

Disposal and Recycling

For environmental protection the Prime™ G6000 Generator, Prime™ Transducer Handpiece and accessories should not be disposed of at their end of life. Contact EndoPrime Customer Service or your local recycling center for instructions to recycle waste equipment. The Prime™ G6000 Generator disposal risks are similar to computers and other electronics. The Prime™ Transducer Handpiece contains lead -recycle or dispose in accordance with local regulations or return to EndoPrime for recycling. The products and accessories contain no radioactive substances, or hazardous liquids that may leak.



Section 9 - System Specifications and Technical Requirements

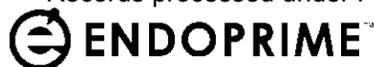
9.1 System Specifications

9.1.1 Table 2: The Prime™ Adaptive Ultrasonic Scalpel System Components

Product	Product Description
Generator	Prime™ Ultrasonic Generator , Sold with Foot Switch
Transducer Handpiece	Prime™ Reusable Transducer, Sold with Test Tip, and Cable
Ultrasonic Scalpel Blades Reusable -	Prime™ Ultrasonic Curved Blade Instrument Sets 5mm Diameter sold with Torque Wrench Unit sold
	Prime™ Omni™ Hook Blade Instrument Set 5mm Diameter sold with Torque Wrench
Accessories sold separately	Prime™ Generator/Accessory Cart
	Prime™ Sterilization Tray

9.1.2 Table 2b: Additional Products in the Prime™ Ultrasonic Family

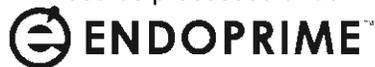
Prime™ Endo 5mm Ultrasonic Shears:	Contact EndoPrime Customer Service for information regarding availability of these products
Prime™ Open Curved Ultrasonic Shears	



9.2 System Technical Specifications

Model Number	G6000
Performance	
Ultrasonic Frequency	55 kHz +/- 1 kHz
Over-Temperature Protection	Device automatically shuts down to prevent overheating. Fans will remain on during Over-Temperature Protection. Unit must be power cycled to reset.
Operation Mode	Variable and fixed Power Modes
Maximum Duty Cycle	Intervals of < 15 seconds on; > 15 seconds off
Electrical Input	
Input Line Voltage	90-264 VAC 50-60 Hz @ 6 Amps
Input Line Frequency	50/60 Hz
Line Cord	IEC 60320/NEMA 5-15 - Hospital Grade ~ 15 feet
Fuse	3.0 Amp Slow-Blow, 250 VAC, 5mm
Mechanical and Environmental	
Operating Temp	50°F to 86°F (10°C to 30°C)
Operating Humidity	<70% RH non-condensing
Storage Temperature	13°F to 131°F (-10°C to 55°C)
Storage Humidity	< 80% RH non-condensing
Weight	33 lbs (15kg)
Case Size	H=6.3 (16 cm) Inches x W=14.2 (36 cm) Inches, D=15.0 (38 cm) Inches
Indicators	LED display, LEDs
Safety, EMC, and Regulatory Compliance	<ul style="list-style-type: none"> • IEC/EN 60601-1 • IEC/EN 60601-1-2 • CAN/CSA C22.2 No. 601.1 • CAN/CSA C22.2 No. 601.1.2
Equipment Class	Class 1
	Suitable for Continuous Operation
	Type CF Applied Part Class 1
	IPX0. Ordinary Equipment without the protection against ingress of water.
	Medical Electrical Equipment per IEC 60601-1/CAN/CSA C22.2 No. 601.1
	Not for use in presence of flammable mixtures

	Precaution! The ultrasonic surgical equipment must be operated within the specified ambient temperature range.
	Precaution! Verify that the voltage of the output socket meets the requirements of the generator. Incorrect connection of the power supply may damage the generator and cause shock or fire hazard.



Section 10 - Warranty

WARRANTY COVERAGE:

EndoPrime, Inc. ("**EndoPrime**") warrants this Generator (**the "Product"**), and only the Product, against defects in materials and workmanship under normal use for a period of one year from the date of retail purchase by the original purchaser ("**Limited Warranty Period**").

Consumer's sole and exclusive remedy, and EndoPrime's sole and exclusive responsibility under this warranty, shall be that EndoPrime will repair the Product at no charge, using new or refurbished replacement parts if a defect arises and a valid claim, as determined in the sole discretion of EndoPrime, is received by EndoPrime within the Limited Warranty Period, at EndoPrime's option and to the extent permitted by law. A replacement part(s) assumes the remaining warranty of the original Product or **NINETY (90) days** from the date of replacement or repair, whichever is longer.

INSTRUCTIONS TO OBTAIN WARRANTY SERVICE:

To obtain warranty service Consumer must notify EndoPrime to obtain a **Return Material Authorization ("RMA")** and return the defective Product together with proof of purchase to the address specified by EndoPrime. Consumer will pre-pay all return shipping charges and shall assume all risk of loss or damage to product while in transit to and from EndoPrime. Any Product returned to EndoPrime without an RMA or without proof of purchase will be returned to Consumer at Consumer's cost. EndoPrime will not be responsible for any such damage or loss.

EXCLUSIONS AND LIMITATIONS:

This Limited Warranty applies only to the Product manufactured by EndoPrime. The Limited Warranty does not apply to any EndoPrime products and services other than the Product. This warranty does not apply to a Product or part of the Product that has been altered or modified (e.g., to alter functionality or capability) by anyone who is not a representative of EndoPrime. In addition, this Limited Warranty does not apply: (a) to damage caused by accident, abuse, misuse, flood, fire, earthquake or other external causes; (b) to damage caused by operating the Product outside the permitted or intended uses not in accordance with the documentation by EndoPrime; or (c) to damage caused by service performed by anyone who is not a representative of EndoPrime.

EndoPrime reserves the right to upgrade and make other necessary changes to the Product at any time without incurring any obligation or liabilities to make the same or similar changes to other EndoPrime products.

No EndoPrime reseller, agent, or employee is authorized to make any modification, extension, or addition to this Limited Warranty. If any term is held to be illegal or unenforceable, the legality or enforceability of the remaining terms shall not be affected or impaired.

DISCLAIMER:

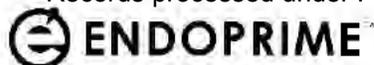
EXCEPT AS SPECIFIED IN THIS LIMITED WARRANTY, ALL EXPRESS OR IMPLIED CONDITIONS, REPRESENTATIONS, AND WARRANTIES INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, SATISFACTORY QUALITY, NON-INTERFERENCE, ACCURACY OF INFORMATIONAL CONTENT, OR ARISING FROM A COURSE OF DEALING, LAW, USAGE, OR TRADE PRACTICE, ARE HEREBY EXCLUDED TO THE EXTENT ALLOWED BY APPLICABLE LAW AND ARE EXPRESSLY DISCLAIMED BY ENDOPRIME TO THE EXTENT AN IMPLIED WARRANTY CANNOT BE EXCLUDED, SUCH WARRANTY IS LIMITED IN DURATION TO THE EXPRESS WARRANTY PERIOD. BECAUSE SOME STATES OR JURISDICTIONS DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, THE ABOVE LIMITATION MAY NOT APPLY. THESE WARRANTIES GIVE CONSUMER SPECIFIC LEGAL RIGHTS, AND CONSUMER MAY ALSO HAVE OTHER RIGHTS WHICH VARY FROM JURISDICTION TO JURISDICTION.



This disclaimer and exclusion shall apply even if the express warranty set forth above fails of its essential purpose.

GOVERNING LAW AND ARBITRATION:

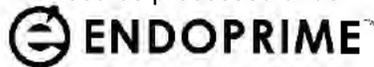
This Limited Warranty shall be governed by the laws of the State of Ohio without giving effect to any conflict of laws principles that may provide the application of the law of another jurisdiction. Any claim or dispute in connection with this Limited Warranty shall be resolved in a cost effective manner through binding non-appearance-based arbitration. The arbitration shall be initiated through an established alternative dispute resolution provider mutually agreed upon by the parties. The alternative dispute resolution provider and the parties must comply with the following rules: a) the arbitration shall be conducted by telephone, online and/or be solely based on written submissions, the specific manner shall be chosen by the party initiating the arbitration; b) the arbitration shall not involve any personal appearance by the parties or witnesses unless otherwise mutually agreed by the parties; and c) any judgment on the award rendered by the arbitrator may be entered in any court of competent jurisdiction. If the foregoing arbitration clause does not apply for any reason, you agree to submit to the personal jurisdiction of the state courts located within Hamilton County, Ohio and the federal courts in the Southern District of Ohio for the purpose of litigating all such claims or disputes, which courts shall have exclusive jurisdiction of such claims or disputes. Notwithstanding the foregoing, EndoPrime may seek injunctive or other equitable relief to protect its intellectual property rights in any court of competent jurisdiction.



Section 11 - APPENDIX

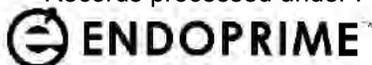
11.1 Table 3: Electromagnetic Emissions Testing

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS		
Adaptive Ultrasonic Scalpel System is intended for use in the electromagnetic environment specified below. The customer or the user of Adaptive Ultrasonic Scalpel System should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	Adaptive Ultrasonic Scalpel System uses RF energy only for its normal operation. Therefore, its unwanted RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Adaptive Ultrasonic Scalpel System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes



11.2 Table 4: Electromagnetic Immunity

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
Adaptive Ultrasonic Scalpel System is intended for use in the electromagnetic environment specified below. The customer or the user of Adaptive Ultrasonic Scalpel System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV contact 8 kV air	6 kV contact 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth	1 kV line(s) to line(s) 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 s	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of Adaptive Ultrasonic Scalpel System requires continued operation during power mains interruptions, it is recommended that Adaptive Ultrasonic Scalpel System be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE <i>UT</i> is the A.C. mains voltage prior to application of the test level.			



RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE MODEL

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

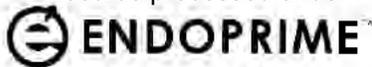
RATED MAXIMUM OUTPUT POWER OF TRANSMITTER IN WATTS	SEPARATION DISTANCE IN METERS ACCORDING TO FREQUENCY OF TRANSMITTER		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.38
1.0	1.2	1.2	2.3
10.0	3.8	3.8	7.6
100.0	12	12	23

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

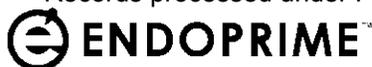
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. Interference may occur in the vicinity of equipment marked with the following symbol:





GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
Adaptive Ultrasonic Scalpel System is intended for use in the electromagnetic environment specified below. The customer or the user of Adaptive Ultrasonic Scalpel System should assure that it is used in such an environment.			
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2,5 GHz</p>	<p>3Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of Adaptive Ultrasonic Scalpel System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
^a Field strengths from fixed transmitters, such as base stations for radio			



(cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Adaptive Ultrasonic Scalpel System is used exceeds the applicable RF compliance level above, Adaptive Ultrasonic Scalpel System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Adaptive Ultrasonic Scalpel System .

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

The system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.

11.3 Table 5: Rated Maximum Power Outage

Ultrasound surgical equipment aims at application under an electromagnetic environment in which radiated RF disturbances are controlled. Customers/users of the Ultrasound surgical equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Ultrasound surgical Equipment as recommendations follow, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m.		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.117	0.117	0.233
01	0.36999	0.36999	0.73681
1	1.17	1.17	2.33
10	3.69986	3.69986	7.36811
100	11.7	11.7	23.33

Document #: EPD0018-P01 Revision



Prime™ Adaptive Ultrasonic Scalpel System

Prime™ Reusable Transducer Handpiece

This booklet is designed to assist in using the product and is not a reference to surgical technique. Before using this product, read the following information for setup and use of the following models:

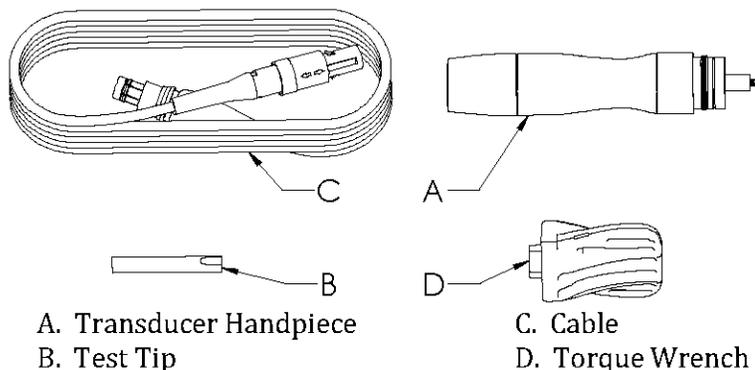
How Provided: Non-sterile -

Model TRN5: The Prime™ Reusable Transducer Handpiece (the transducer) is for foot switch activated devices only. Each transducer is sold with one Prime™ Reusable Torque Wrench, Test Tip and Cable.

	The transducers are designed, tested, and approved for multiple use, and are provided non-sterile. Refer to the steps for use regarding sterilization of the Prime™ Reusable Transducer Handpiece prior to use. The information provided in this booklet is provided as a guide for setup and use of the transducer, and is not provided as a surgical reference.
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Nomenclature and Illustration

Each Prime™ Reusable Transducer Handpiece is provided with Cable, Test Tip and Torque Wrench:



Device Description:

The Prime™ Reusable Transducer Handpiece cooperates with the Prime™ Ultrasonic Scalpel Reusable Blade as a cutting and coagulation instrument. The Prime™ Reusable Transducer Handpiece is designed to convert electrical energy from the generator to mechanical motion of the instrument blades. When the transducer is used in conjunction with the Prime™ Adaptive Ultrasonic Scalpel System, the transducer provides ultrasonic vibration, which enables the blade's cutting ability. Prime™ Adaptive Ultrasonic Scalpel System and family of products are compatible with a limited number of other manufacturers' systems.

The Prime™ Reusable Transducer Handpiece is packaged with a detachable cable used to connect the instrument to the generator. In addition, the package includes a test tip for testing the system and a torque wrench used to secure blade assemblies to the transducer.



Indications for Use

The Prime™ Reusable Transducer Handpiece interacts with the Prime™ Adaptive Ultrasonic Scalpel System as a cutting and coagulation instrument indicated for open laparoscopic, and endoscopic surgery in soft tissue when bleeding control, and minimal thermal injury is desired. The system is indicated for dissection, sealing, transection,otomy creation and transection/coagulation of vessels up to 5mm. The system instruments can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels with the advantages of limited heat/smoke generation and the lack of current flow through the patient.

Contraindications

- The instruments are not indicated for incising bone.
- The instruments are not intended for contraceptive tubal ligation.

Instructions for Use:

Step 1: Transducer Handpiece Cleaning and Sterilization

	The transducer, cable, test tip and torque wrench are shipped non-sterile. These system components must be thoroughly cleaned and sterilized according to hospital standards prior to each use.
	It is highly recommended that additional sterile instruments be kept available for all surgical procedures in the event that any system component becomes inoperable.

Cleaning: The Prime™ Reusable Transducer Handpiece and accessories are to be thoroughly cleaned by machine-washing according to the following steps (to avoid loss of usable life, do not immerse the handpiece in cleaning fluid for more than 60 minutes):

- Use a neutral PH detergent or neutral PH enzyme detergent according to the instruction of the detergent manufacturer. Use only nonabrasive materials.
- Wipe all the surfaces (including the generator screen) manually with a clean soft cloth soaked with a small amount of cleaning solution.

Steam Sterilization Cycle: After thoroughly cleaning, sterilize according to hospital procedures. The Prime™ Reusable Transducer Handpiece sterilization has been validated for sterilization as follows:

Cycle Type: Pre- Vacuum – 3 Pulses
Temperature: 270F (132°C)
Sterilization Time: 4 minutes
Dry Time: 20 minutes

Use with the Prime™ Sterilization Tray or equivalent.

Step 2: Assembly

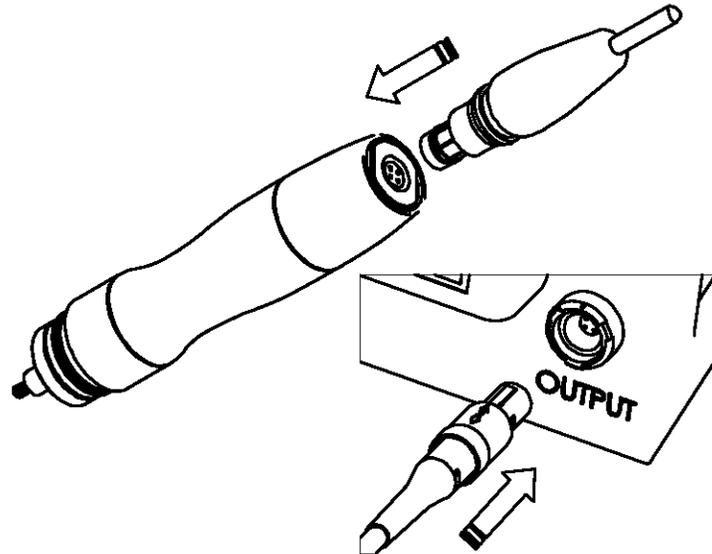
Assemble instrument to the transducer See the appropriate Prime™ Adaptive Ultrasonic Scalpel device Instructions for Use.

- | |
|---|
| <p>a. Inspect transducer for damage. The handpiece and cable should be inspected for damage before each use. DO NOT USE instruments or the transducer if damaged. Damage to the transducer or cable may result in device failure during use. Examples of damage to the transducer include any tear in the cable insulation, deep scratches, deviations in shape, discoloration, corrosion, and obvious damage to the threads or blade-mounting surface.</p> |
|---|



b. Assemble instrument to transducer. See the appropriate Prime™ Ultrasonic Scalpel Reusable Blade device Instructions for Use.

c. Connect the cable to the transducer first and then to the generator.



Step 3: Use of the Ultrasonic Assembly

Refer to the Prime™ Adaptive Ultrasonic Transducer Handpiece Instructions for Use and or the generator Instructions for Use.

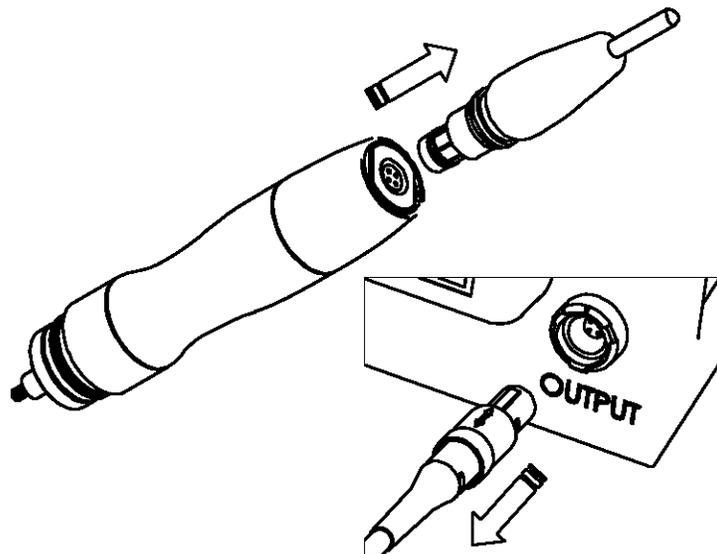


If the Prime™ Transducer Handpiece is used in conjunction with products outside the Prime™ Adaptive Ultrasonic Scalpel System verify the compatibility of all instruments and accessories prior to use.

Step 4: Disassembly

a. Place the generator in standby mode and disconnect the cable from the transducer or generator.

DO NOT activate the generator (i.e. step on the foot switch) with the transducer disconnected. Reboot the generator if a generator error occurs. Call Customer Service if the generator error persists.





b. Disassemble the instrument from the transducer. See the appropriate Prime™ Ultrasonic Scalpel Reusable Blade device Instructions for Use.

c. Place the transducer, cable, and all reusable Prime™ Adaptive Ultrasonic Scalpel System accessories and devices that are serializable in the sterilization tray.



Warnings and Precautions:

1. The Prime™ Reusable Transducer Handpiece, cable, test tip, and torque wrench are shipped non-sterile. These system components must be steam, flash, or otherwise sterilized according to hospital standards prior to each use.
2. If the Prime™ Reusable Transducer Handpiece is used in conjunction with products outside the Prime™ Adaptive Ultrasonic Scalpel System, verify the compatibility of all instruments and accessories prior to use.
3. Handle the instruments and handpiece with care to avoid damage by dropping or banging the instrument. The handpiece and cable should be inspected for damage before each use. DO NOT USE instruments or transducer if damaged. Damage to the transducer or cable may result in device failure during use. Examples of damage to the transducer handpiece would include any tear in the cable insulation, deep scratches, deviations in shape, obvious damage to the blade-mounting surface, or discoloration.
4. DO NOT USE torque wrench with evidence of damage. Damage to the torque wrench may result in device failure and inability to properly secure the blade assembly.
5. Transducers are rated for multiple reuse, but not infinite life. If the transducer makes noise, quickly becomes hot, or attached blades have degraded cutting or coagulation performance, the transducer may be beyond its usable life and should be replaced. Such degradation may occur or be detected before, during or after a procedure. Older functional transducers may also stop functioning during a procedure without warning and should be regularly replaced.
6. Additional sterile instruments should be kept available for all surgical procedures in the event that any system component becomes inoperable.
7. The products described in this document are recommended for endoscopic procedures, which should ONLY be executed by a licensed physician familiar with endoscopic techniques. The physician is responsible for referral to relevant literature regarding techniques, complications, and hazards.
8. All medical professionals handling the instrumentation should be trained and have a thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures in order to:
 - Avoid shock and burn hazards to both patient and medical personnel,
 - Avoid damage to the device or other medical instrumentation.
 - Ensure that electrical insulation or grounding is not compromised during the use of the instrumentation.
9. As with all ultrasonic, laser, and electrosurgery devices, DO NOT immerse the Prime™ Reusable Transducer Handpiece or Cable in liquid when connected to the Generator to avoid the potential for burns or electrical shock.
10. To prevent burn injury, DO NOT continue use of the handpiece if the handpiece temperature becomes uncomfortable to hold.
11. As in any laser, electrosurgical, and ultrasonic procedures, the potential exists for personnel to be exposed to carcinogenic and infectious by-products, such as tissue residue, smoke clouds and aerosols. When using the Prime™ Adaptive Ultrasonic Scalpel System



protective eyewear, filtration masks, and effective smoke evacuation equipment should be available and used.

12. Disposal: Contains lead – dispose in accordance with local regulations.

Storage and Transport Requirements:

Carefully handle, clean, sterilize, transport, and store the Prime™ Reusable Transducer Handpiece to avoid unintentional damage. Damage to the threaded connection or electrical connection will significantly shorten the instrument's useable life.

Store or transport at no more than 95% Relative Humidity, -13°F to 158°F (-25°C to 70°C).

EndoPrime, Inc. Limited Warranty

Warranty Coverage:

EndoPrime, Inc. ("EndoPrime") warrants this Transducer Handpiece (the "Product"), and only the Product, against defects in materials and workmanship under normal use for a period of **Nine (9) Months** from the date of retail purchase by the original purchaser ("Limited Warranty Period").

Consumer's sole and exclusive remedy, and EndoPrime's sole and exclusive responsibility under this warranty, shall be that EndoPrime will repair the Product at no charge, using new or refurbished replacement parts if a defect arises and a valid claim, as determined in the sole discretion of EndoPrime, is received by EndoPrime within the Limited Warranty Period, at EndoPrime's option and to the extent permitted by law. A replacement part assumes the remaining warranty of the original Product, or **90-days** from the date of replacement or repair, whichever is longer.

Instructions to Obtain Warranty Service:

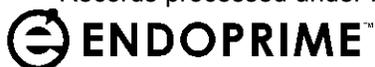
To obtain warranty service Consumer must notify EndoPrime to obtain a **Return Material Authorization ("RMA")** and return the defective Product together with proof of purchase to the address specified by EndoPrime. Consumer will pre-pay all return shipping charges and shall assume all risk of loss or damage to product while in transit to and from EndoPrime. Any Product returned to EndoPrime without an RMA or without proof of purchase will be returned to Consumer at Consumer's cost. EndoPrime will not be responsible for any such damage or loss.

Exclusions and Limitations:

This Limited Warranty applies only to the Product manufactured by EndoPrime. The Limited Warranty does not apply to any EndoPrime products and services other than the Product. This warranty does not apply to a Product or part of the Product that has been altered or modified (e.g., to alter functionality or capability) by anyone who is not a representative of EndoPrime. In addition, this Limited Warranty does not apply: (a) to damage caused by accident, abuse, misuse, flood, fire, earthquake or other external causes; (b) to damage caused by operating the Product outside the permitted or intended uses not in accordance with the documentation by EndoPrime; or (c) to damage caused by service performed by anyone who is not a representative of EndoPrime.

EndoPrime reserves the right to upgrade and make other necessary changes to the Product at any time without incurring any obligation or liabilities to make the same or similar changes to other EndoPrime products.

No EndoPrime reseller, agent, or employee is authorized to make any modification, extension, or addition to this Limited Warranty. If any term is held to be illegal or unenforceable, the legality or



enforceability of the remaining terms shall not be affected or impaired.

DISCLAIMER:

EXCEPT AS SPECIFIED IN THIS LIMITED WARRANTY, ALL EXPRESS OR IMPLIED CONDITIONS, REPRESENTATIONS, AND WARRANTIES INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, SATISFACTORY QUALITY, NON-INTERFERENCE, ACCURACY OF INFORMATIONAL CONTENT, OR ARISING FROM A COURSE OF DEALING, LAW, USAGE, OR TRADE PRACTICE, ARE HEREBY EXCLUDED TO THE EXTENT ALLOWED BY APPLICABLE LAW AND ARE EXPRESSLY DISCLAIMED BY ENDOPRIME TO THE EXTENT AN IMPLIED WARRANTY CANNOT BE EXCLUDED, SUCH WARRANTY IS LIMITED IN DURATION TO THE EXPRESS WARRANTY PERIOD. BECAUSE SOME STATES OR JURISDICTIONS DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, THE ABOVE LIMITATION MAY NOT APPLY. THESE WARRANTIES GIVE CONSUMER SPECIFIC LEGAL RIGHTS, AND CONSUMER MAY ALSO HAVE OTHER RIGHTS, WHICH VARY FROM JURISDICTION TO JURISDICTION.

This disclaimer and exclusion shall apply even if the express warranty set forth above fails of its essential purpose.

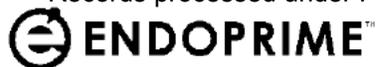
Governing Law and Arbitration:

The laws of the State of Ohio shall govern this Limited Warranty without giving effect to any conflict of laws principles that may provide the application of the law of another jurisdiction. Any claim or dispute in connection with this Limited Warranty shall be resolved in a cost effective manner through binding non-appearance-based arbitration. The arbitration shall be initiated through an established alternative dispute resolution provider mutually agreed upon by the parties. The alternative dispute resolution provider and the parties must comply with the following rules: a) the arbitration shall be conducted by telephone, online and/or be solely based on written submissions, the specific manner shall be chosen by the party initiating the arbitration; b) the arbitration shall not involve any personal appearance by the parties or witnesses unless otherwise mutually agreed by the parties; and c) any judgment on the award rendered by the arbitrator may be entered in any court of competent jurisdiction. If the foregoing arbitration clause does not apply for any reason, you agree to submit to the personal jurisdiction of the state courts located within Hamilton County, Ohio and the federal courts in the Southern District of Ohio for the purpose of litigating all such claims or disputes, which courts shall have exclusive jurisdiction of such claims or disputes. Notwithstanding the foregoing, EndoPrime may seek injunctive or other equitable relief to protect its intellectual property rights in any court of competent jurisdiction.



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Document #: EPD0019-P01 Revision A



Prime™ Adaptive Ultrasonic Scalpel System

Prime™ Ultrasonic Scalpel Reusable Blades

This booklet is designed to assist in using the product and is not a reference to surgical technique. Before using this product, read the following information for setup and use:

Indications for Use

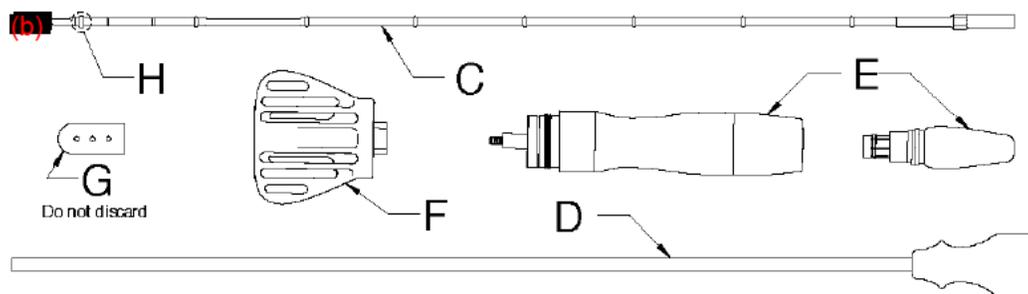
The **Prime™ Ultrasonic Reusable Blade** is a cutting and coagulation instrument indicated for open, laparoscopic, and endoscopic surgery in soft tissue when control of hemostasis and thermal spread is desired. The system is indicated for dissection, sealing, transection,otomy creation and transection/coagulation of vessels up to 2mm.

How Provided:

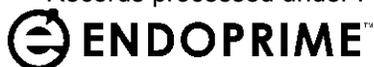
Prime™ Ultrasonic Scalpel Reusable Blades are sold non-sterile and are easily disassembled for cleaning and sterilization. Each blade is provided with one (1) **Prime™ Reusable Torque Wrench** and one (1) **Reusable Protective Cap** (save the cap and reinstall over the blade tip after each use). Blades are provided in different lengths to offer adequate reach in different surgical situations. Blades are provided in two end effector styles:

- (A) **Prime™ Curved Ultrasonic Reusable Blade**
- (B) **Omni™ Hook Blade Ultrasonic Reusable Blade**

Nomenclature and Illustration



- | | |
|--|---|
| (A) Prime™ Curved Blade (CB) End-effector | (B) Omni™ Hook Blade (OHB) End-effector |
| (C) Blade | (D) Sheath |
| (E) Handpiece Transducer and cable plug
(sold separately) | (F) Torque Wrench |
| (G) Blade Protective Cap | (H) Blade Distal Silicone Ring (fluid seal) |



The **Prime™ Reusable Ultrasonic Scalpel Blades** and Torque Wrench are designed, tested, and approved for multiple use, and are provided non-sterile. Refer to the steps for use regarding cleaning and sterilization prior to use.



The information provided in this booklet is provided as a guide for setup and use of the **Prime™ Reusable Ultrasonic Scalpel Blades** and Torque Wrench, and is not provided as a surgical reference.

Device Description

Prime™ Ultrasonic Scalpel Reusable Blades vibrate ultrasonically, which enables its cutting ability. The same vibration seals small vessels with coagulated blood and tissue proteins by producing local heating of tissue. Homeostasis occurs when tissue couples with the blade. The **Prime™ Ultrasonic Scalpel Reusable Blades** are designed for use with a transducer and a generator system as part of the **Prime™ Adaptive Ultrasonic Scalpel System** and family of products; these products are compatible with a limited number of other manufacturer's systems. The system instruments can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels with the advantages of limited heat/smoke generation and the lack of current flow through the patient.

Contraindications

- The instruments are not intended for contraceptive tubal ligation
- The instruments are not indicated for incising bone



This manual is not a reference to surgical technique. Information provided in this manual is provided as a guide for setup and use of the Prime™ G6000 Generator (see Instructions for Use - Section 6). Also refer to the Instructions for Use provide with each Prime™ Adaptive Ultrasonic family of products used with the Prime™ G6000 Generator.



Caution! Federal law restricts this system to sale on the order of a physician.

Instructions for Use

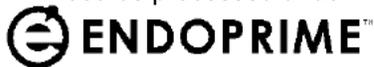


It is highly recommended that additional sterile instruments be kept available for all surgical procedures in the event that any component becomes inoperable.

Step 1: Blade Cleaning and Sterilization

Cleaning: Thoroughly cleaned each blade according to the following steps:

- a. Manually scrub the Sheath with a channel cleaning brush to remove all debris (use 5mm or larger diameter nylon bristles or equivalent). Flush with water.
- b. Machine wash using a neutral pH detergent or neutral pH enzyme detergent according to the instructions of the detergent manufacturer. Use only nonabrasive materials.



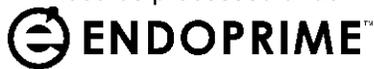
Steam Sterilization Cycle: After thoroughly cleaning, sterilize according to hospital procedures. Prime™ Ultrasonic Scalpel Reusable Blades have been validated for sterilization as follows:

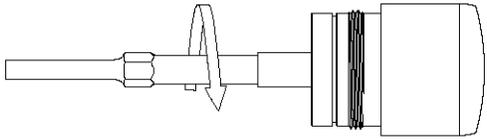
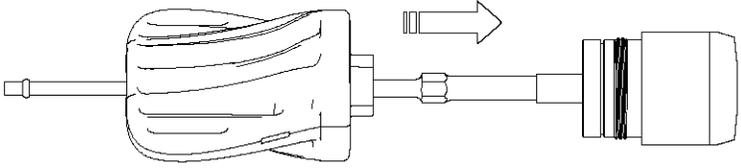
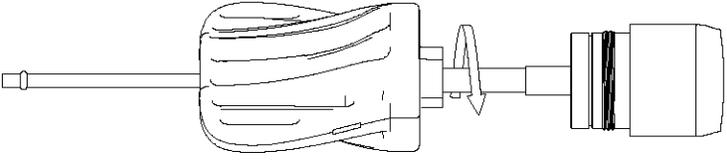
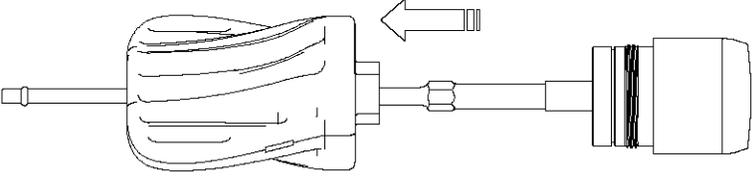
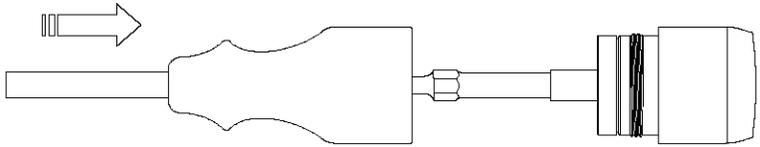
- Cycle Type: Pre-Vacuum – 3 Pulses
- Temperature: 270F (132°C)
- Sterilization Time: 4 minutes
- Dry Time: 20 minutes

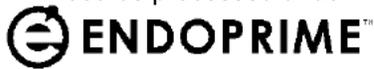
Use with the **Prime™ Adaptive Ultrasonic Scalpel System Sterilization Tray** or equivalent.

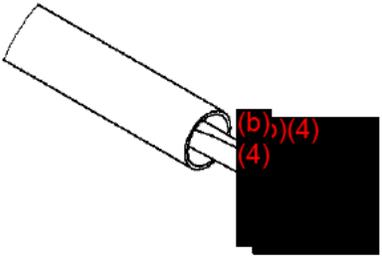
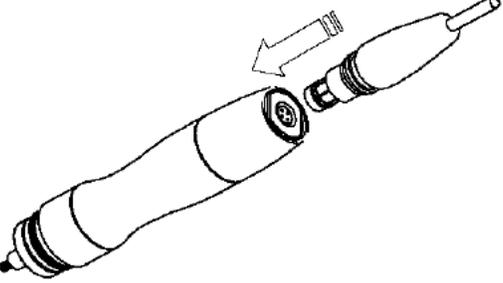
Step 2: Assembly

<p>a. Disconnect the cable from the transducer or generator before assembling the blade with the transducer hand piece or if the blade is being replaced during a procedure.</p>	
<p>b. Remove the Blade Protective Cap from sterile blade assembly and place the Cap back in the sterilization tray for use after the procedure.</p>	
<p>c. Routinely Inspect the Prime™ Reusable Blades, torque wrench and other equipment for any damage or wear and to ensure there is no liquid present. The end effector is blue to aid in observing scratches or other damage. DO NOT USE instruments if damaged. Damage may result in device failure during use. Examples of damage include any tear in the cable insulation, deep scratches on blade, deviations in shape, obvious damage to the blade-mounting surface, missing or broken silicone ring, corrosion or discoloration. Blades or Transducer Handpieces that make noise, quickly become hot, are uncomfortable to hold, have degraded cutting performance or do not pass the generator function test may be beyond the usable life and should be replaced.</p>	
<p>d. Insert the thread end of the transducer into the proximal screw hole of the blade.</p>	



<p>e. While holding the transducer with one hand and the blade with the other hand, gently turn the blade clockwise until the blade comes to a complete stop.</p>	
<p>f. Slide the torque wrench over the blade assembly with the round end crossing the blade first.</p>	
<p>g. When the torque wrench stops at the bottom of the assembly, engage it with the blade and turn clockwise until it clicks twice, indicating that the blade assembly is secure.</p>	
<p>h. Remove the torque wrench by sliding it back over the blade assembly and place it back in the sterilization tray. Do not dispose of the torque wrench provided with the blade assembly, it is reusable and is compatible with all Prime™ Reusable Blades, Test Tips, and is compatible with a limited number of other manufacturer's ultrasonic systems.</p>	
<p>i. Slide the Sheath over the blade. Assure the correct Sheath length is paired with the blade.</p>	



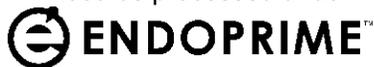
<p>j. While holding the transducer with one hand and the blade with the other hand, gently turn the Sheath clockwise until the Sheath comes to a complete stop. It is not necessary to continue to tighten the Sheath firmly once it stops turning.</p>	
<p>k. Inspect tip to see that end effector is properly exposed. No silicone rings should be exposed. Confirm blade exposure is sufficient for proper visualization and shielding prior to use.</p>	
<p>l. Reconnect the cable to the transducer or generator.</p>	

	<p>The blade should always be inspected before each use for any damage to the blade, including: scratches, deviations in shape, or discoloration. Damage to the blade could result in failure during the procedure.</p>
	<p>Avoid rough handling and do not allow the blade tip to contact metallic surfaces during assembly, disassembly, handling, and use.</p>

Step 3: Test

Confirm proper function and that the Prime™ Reusable Blades has not exceeded its useful life by activating according to the generator Instructions for Use. The generator will conduct a test of the system to confirm proper function.

Be Aware and Replace: The **Prime™ Reusable Blades** and other components are rated for multiple reuse, but not infinite life. If the Transducer Handpiece, Sheath or Blade makes noise, quickly becomes hot and is uncomfortable to hold, or blades have degraded cutting performance, the transducer or blade may be beyond its usable life and should be replaced. Examples of damage include scratches, dents, distortion of the blade, any tear in



the insulation, any deep scratches, deviations in shape, or damage to the mounting surfaces. Such degradation may occur or be detected before, during or after a procedure. Damaged or worn blades may also stop functioning during a procedure without warning and should be replaced. Replace the torque wrench when replacing the blade.

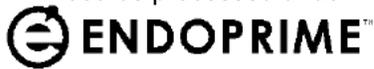
Use of the Blade Assembly

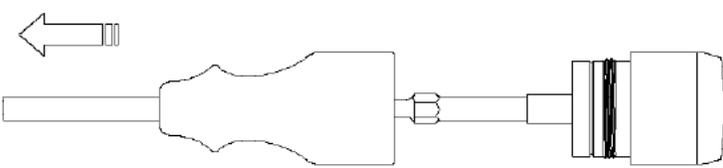
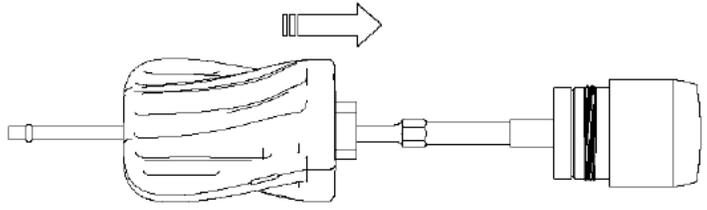
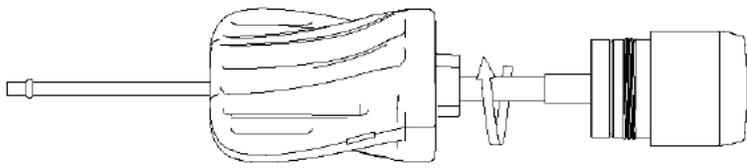
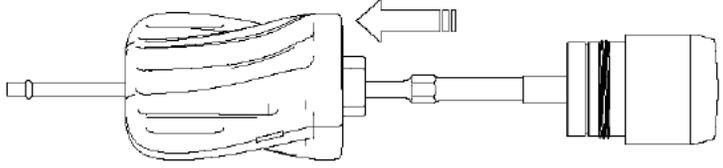
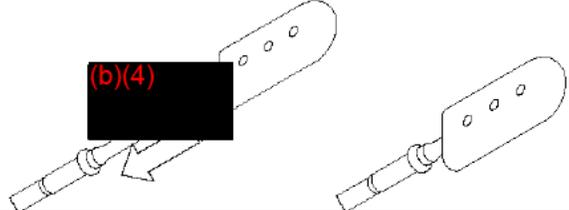
For instructions on use of the Ultrasonic Scalpel Blades, refer to the Prime Adaptive Ultrasonic Sonic Scalpel System-Generator 6000 Instructions for Use.

	<p>Only activate when end effector can be fully visualized. Lack of full visibility may result in unintended cutting of tissue or other devices.</p>
	<p>Prolonged use of the device, especially at high power levels, can result in increased temperatures of the end effector and distal Sheath. If prolonged use is required, frequent pauses to allow the device to cool may be required. Sterile saline may also be used to rapidly cool the device. Blood and tissue build up between the blade and shaft may also result in abnormally high temperatures at the distal end of the Sheath. To prevent the potential of burn injury, remove visible tissue buildup or disassemble the Sheath to remove tissue.</p>
	<p>The Prime™ Ultrasonic Scalpel Blade is a part of the Prime™ Adaptive Ultrasonic Scalpel System and is also compatible with other manufacturer's systems. Verify the compatibility of all instruments and accessories prior to initiating the procedure.</p>

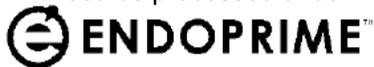
Step 3: Disassembly

<p>a. Disconnect the cable from the transducer or generator before disassembling the blade from the transducer hand piece or if the blade is being replaced during a procedure.</p>	
<p>b. Remove the Sheath from the transducer by gripping the base of the Sheath where the Sheath screws onto the transducer, and manually turning it clockwise until it completely unscrews.</p>	



<p>c. Slide the Sheath distally to remove, placing the Sheath in the sterilization tray.</p>	
<p>d. Slide the torque wrench over the end of the blade assembly, with the round end of the wrench going over the blade first.</p>	
<p>e. When the torque wrench stops at the base of the transducer, loosen the blade assembly by turning the wrench counterclockwise. Continue to loosen by turning the wrench or the blade assembly manually to unscrew it completely.</p>	
<p>f. Remove the torque wrench by sliding it back over the blade assembly.</p>	
<p>g. Inspect blade for damage, in particular the distal portion. Scratches, dents or distortion of the Blade or Sheath will significantly shorten the instrument's useable life. Damage may result in device failure during future uses.</p>	
<p>h. Place the Blade Protective Cap over the distal end of sterile blade assembly.</p>	
<p>i. Place the blade and torque wrench in the sterilization tray. Do not dispose of the torque wrench.</p>	

	<p>Handle the handpiece and blade with care to avoid damage by dropping or banging the instrument on metallic surfaces.</p>
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Warnings and Precautions

1. The Prime™ Ultrasonic Scalpel Blade assemblies (with Sheath), Blade Protective Cap and Torque Wrench are shipped non-sterile. These components must be sterilized according to these Instructions for Use and to hospital standards prior to each use.
2. The reusable blade assemblies, sheath, Blade Protective Cap and torque wrench are reusable and must be thoroughly cleaned, sterilized and stored for reuse. If the Prime™ Reusable Transducer is used in conjunction with products outside the Prime™ Adaptive Ultrasonic Scalpel System, verify the compatibility of all instruments and accessories prior to use.
3. The Prime™ Adaptive Ultrasonic Scalpel System includes blades of different lengths to provide adequate reach in different surgical situations. Confirm that the correct length is selected before attempting surgery. In the event two or more lengths are available for use, the appropriate Sheath length should be paired with the blade assembly.
4. Prolonged use of the device, especially at high power levels, can result in increased temperatures of the end effector and distal Sheath. If prolonged use is required, frequent pauses to allow the device to cool may be required. Sterile saline may also be used to rapidly cool the device. Blood and tissue build up between the blade and shaft may also result in abnormally high temperatures at the distal end of the Sheath. To prevent the potential of burn injury, remove visible tissue buildup or disassemble Sheath to remove tissue. Dry blade assembly to remove moisture before reassembling Sheath.
5. DO NOT USE blades with any damage. Damage to the blades may result in device failure during use. Blades should be inspected for damage before use. Examples of damage would include any scratches, deviations in shape, or discoloration. The (b)(4)
6. Avoid blade contact with any and all metal surfaces especially while the instrument is activated. Contact with staples, clips, or other instruments may result in damaged or broken blades. DO NOT attempt to bend or sharpen the blade. Deformed, damaged, cracked or broken blades may be identified by a continuous tone from the generator.
7. DO NOT USE the Torque Wrench with evidence of damage. Damage to the torque wrench may result in device failure and inability to properly secure the blade assembly.
8. DO NOT USE the product if homeostasis cannot be achieved or observed.
9. DO NOT USE the product if the Sheath or Blade is bent. Both components must be straight to function safely.
10. Components are rated for multiple reuse, but not infinite life. If the blade makes noise, quickly becomes hot, or blades have degraded cutting or coagulation performance, the transducer or blade may be beyond its usable life and should be replaced. Such degradation may occur or be detected before, during or after a procedure. To prevent burn injury, DO NOT continue use of the Blade or Transducer Handpiece if the handpiece temperature becomes uncomfortable to hold. Damaged or worn blades may also stop functioning during a procedure without warning and should be replaced. Replace the Torque Wrench when replacing the Blade.



11. Additional sterile instruments should be kept available for all surgical procedures in the event that any component becomes inoperable.
12. The products described in this document are recommended for endoscopic procedures, which should ONLY be executed by a licensed physician familiar with endoscopic techniques. The physician is responsible for referral to relevant literature regarding techniques, complications, and hazards.
13. All medical professionals handling the instrumentation should be trained and have a thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures in order to:
 - Avoid shock and burn hazards to both patient and medical personnel,
 - Avoid damage to the device or other medical instrumentation.
 - Ensure that electrical insulation or grounding is not compromised during the use of the instrumentation.
14. DO NOT USE or activate the Prime™ Ultrasonic Blade without fully assembling the protective Sheath over the blade. The entire blade length is active and will cut/coagulate tissue when the instrument is activated.
15. Monitor for bleeding during use of the device. If a small amount of bleeding occurs, manually stop the bleeding.
16. Avoid prolong use. Stop activation upon completion of tissue cutting. Excess activation may result in excess heat generation.
17. Only activate when the end effector can be fully visualized. Lack of full visibility may result in unintended cutting of tissue or other devices.
18. Excess lateral force on the blade, especially without the Sheath attached, may result in damage to transducer, blade assembly, or Sheath.
19. Scratches, dents or distortion of the Blade or Sheath will significantly shorten the instrument's useable life. An audible screeching tone emanating from the blade or transducer is an indicator that the blade or transducer is beyond its useful life and should be replaced.
20. As with all electrosurgery, laser or ultrasonic energy sources, there are concerns about the carcinogenic and infectious potential of the by-products from cutting and coagulation, such as smoke, plume or aerosols. Appropriate protective filtration masks, eye shields, local exhaust, and/or smoke-evacuation system should be used to prevent exposure to vapors or smoke when using laser, electrosurgery and ultrasonic cutting and coagulation systems.

Storage and Transport Requirements:

Carefully handle, clean, sterilize, transport, and store the Prime™ Ultrasonic Blades and Sheath to avoid bending or contact with hard surfaces. Scratches, dents or distortion of the Blade or Sheath will significantly shorten the instrument's useable life. Store or transport at no more than 95% Relative Humidity, -31°F to 158°F (-35°C to 70°C).

Limited Warranty

Warranty Coverage:

EndoPrime, Inc. ("EndoPrime") warrants these Reusable Blades (**the "Product"**), and only the Product, against defects in materials and workmanship under normal use for a period of **Three (3) months** from the date of retail purchase by the original purchaser ("**Limited Warranty Period**").

Consumer's sole and exclusive remedy, and EndoPrime's sole and exclusive responsibility under this warranty, shall be that EndoPrime will, if a defect arises and a valid claim, as



determined in the sole discretion of EndoPrime, is received by EndoPrime within the Limited Warranty Period, at EndoPrime's option and to the extent permitted by law, either (1) repair the Product at no charge, using new or refurbished replacement parts; or (2) replace the Product. A replacement part assumes the remaining warranty of the original Product or **NINETY (90) days** from the date of replacement or repair, whichever is longer.

INSTRUCTIONS TO OBTAIN WARRANTY SERVICE:

To obtain warranty service Consumer must notify EndoPrime to obtain a **Return Material Authorization ("RMA")** and return the defective Product together with proof of purchase to the address specified by EndoPrime. Consumer will pre-pay all return shipping charges and shall assume all risk of loss or damage to product while in transit to and from EndoPrime. Any Product returned to EndoPrime without an RMA or without proof of purchase will be returned to Consumer at Consumer's cost. EndoPrime will not be responsible for any such damage or loss.

EXCLUSIONS AND LIMITATIONS:

This Limited Warranty applies only to the Product manufactured by EndoPrime. The Limited Warranty does not apply to any EndoPrime products and services other than the Product. This warranty does not apply to a Product or part of the Product that has been altered or modified (e.g., to alter functionality or capability) by anyone who is not a representative of EndoPrime. In addition, this Limited Warranty does not apply: (a) to damage caused by accident, abuse, misuse, flood, fire, earthquake or other external causes; (b) to damage caused by operating the Product outside the permitted or intended uses not in accordance with the documentation by EndoPrime; or (c) to damage caused by service performed by anyone who is not a representative of EndoPrime.

EndoPrime reserves the right to upgrade and make other necessary changes to the Product at any time without incurring any obligation or liabilities to make the same or similar changes to other EndoPrime products.

No EndoPrime reseller, agent, or employee is authorized to make any modification, extension, or addition to this Limited Warranty. If any term is held to be illegal or unenforceable, the legality or enforceability of the remaining terms shall not be affected or impaired.

DISCLAIMER:

EXCEPT AS SPECIFIED IN THIS LIMITED WARRANTY, ALL EXPRESS OR IMPLIED CONDITIONS, REPRESENTATIONS, AND WARRANTIES INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, SATISFACTORY QUALITY, NON-INTERFERENCE, ACCURACY OF INFORMATIONAL CONTENT, OR ARISING FROM A COURSE OF DEALING, LAW, USAGE, OR TRADE PRACTICE, ARE HEREBY EXCLUDED TO THE EXTENT ALLOWED BY APPLICABLE LAW AND ARE EXPRESSLY DISCLAIMED BY ENDOPRIME TO THE EXTENT AN IMPLIED WARRANTY CANNOT BE EXCLUDED, SUCH WARRANTY IS LIMITED IN DURATION TO THE EXPRESS WARRANTY PERIOD. BECAUSE SOME STATES OR JURISDICTIONS DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, THE ABOVE LIMITATION MAY NOT APPLY. THESE WARRANTIES GIVE CONSUMER SPECIFIC LEGAL RIGHTS, AND CONSUMER MAY ALSO HAVE OTHER RIGHTS WHICH VARY FROM JURISDICTION TO JURISDICTION.



This disclaimer and exclusion shall apply even if the express warranty set forth above fails of its essential purpose.

GOVERNING LAW AND ARBITRATION:

This Limited Warranty shall be governed by the laws of the State of Ohio without giving effect to any conflict of laws principles that may provide the application of the law of another jurisdiction. Any claim or dispute in connection with this Limited Warranty shall be resolved in a cost effective manner through binding non-appearance-based arbitration. The arbitration shall be initiated through an established alternative dispute resolution provider mutually agreed upon by the parties. The alternative dispute resolution provider and the parties must comply with the following rules: a) the arbitration shall be conducted by telephone, online and/or be solely based on written submissions, the specific manner shall be chosen by the party initiating the arbitration; b) the arbitration shall not involve any personal appearance by the parties or witnesses unless otherwise mutually agreed by the parties; and c) any judgment on the award rendered by the arbitrator may be entered in any court of competent jurisdiction. If the foregoing arbitration clause does not apply for any reason, you agree to submit to the personal jurisdiction of the state courts located within Hamilton County, Ohio and the federal courts in the Southern District of Ohio for the purpose of litigating all such claims or disputes, which courts shall have exclusive jurisdiction of such claims or disputes. Notwithstanding the foregoing, EndoPrime may seek injunctive or other equitable relief to protect its intellectual property rights in any court of competent jurisdiction.



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Document #: EPD0020-P01 Revision A



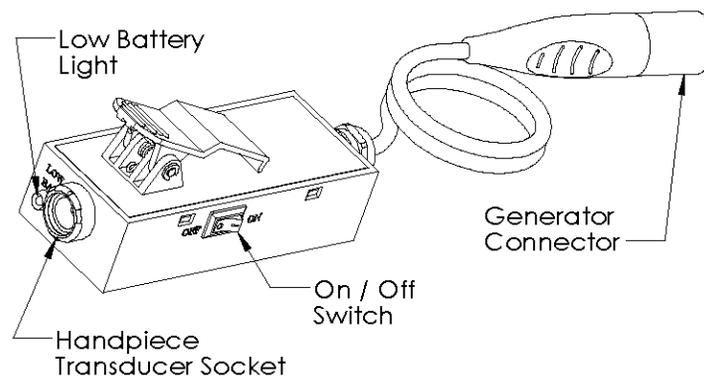
Prime™ Adaptive Ultrasonic Scalpel System

Prime™ ADP Connector/Adaptor For use with UltraCision® Generator (GEN300 & G11)

This booklet is designed to assist in using the product. Before using this product, read the following information and information provided with all devices.

The Prime™ ADP Connector/Adaptor is an accessory provided for connection of the Prime™ Reusable Transducer Handpiece to Ethicon Endo-Surgery UltraCision® Generators (Models Gen300 or G11).

Nomenclature and Illustration



Device Description:

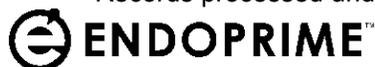
The Prime™ ADP Connector/Adaptor is an accessory for connecting and operating the Prime™ Reusable Transducer Handpiece and instruments with Ethicon UltraCision® Generators (Models Gen300 or G11), and the product is provided non-sterile. The Prime™ ADP Connector/Adaptor is compatible with all Prime™ Adaptive Ultrasonic Scalpel System components.

Instructions for Use:

Step 1: Connections: Connect the corded end of the Prime™ ADP Connector/Adaptor to the Generator (see Illustration above). Connect the Prime™ Transducer cable to the Handpiece Transducer Socket.

Step 2: Operation: Turn the Prime™ ADP Connector/Adaptor switch on and then turn on the Generator. Restart the Generator if the generator indicates an error or if the Prime™ ADP Connector/Adaptor switch was not in the on position.

Step 3: Power Off: To conserve battery life, the Prime™ ADP Connector/Adaptor should always be turned off when not in use. The Prime™ ADP Connector/Adaptor switch may also be turned off once the Generator has completed its initial diagnostics and is ready for use. This will further extend battery life.



Battery Replacement:

Disconnect the Prime™ ADP Connector/Adaptor from the Generator. Remove the screw and the access panel. Remove the Battery by slipping it out from under the contact arm. Replace with a CR2477 Lithium 3V Battery. Assure the positive (+) side of the Battery is up. Replace access panel and screw. Properly dispose of the spent battery.

Cleaning:

Wipe all surfaces manually using a damp, clean cloth. The Prime™ ADP Connector/Adaptor is provided non-sterile, and not intended for sterilization; however, should be cleaned before use in the operating suite.



Warnings and Precautions

1. DO NOT immerse or sterilize.
2. To avoid electrical injury:
 - DO NOT OPEN the access cover when connected to a generator.
 - DO NOT USE if damaged – inspect the case and cable insulation to assure it is not worn, torn or damaged.
 - Ensure that electrical insulation or grounding is not compromised during the use or when connected.

Storage and Transport Requirements:

Store or transport at no more than 95% Relative Humidity, -13°F to 158°F (-25°C to 70°C).

EndoPrime, Inc. Limited Warranty

Warranty Coverage:

EndoPrime, Inc. ("EndoPrime") warrants this Contactor/Adapter (the "Product"), and only the Product, against defects in materials and workmanship under normal use for a period of One (1) Year from the date of retail purchase by the original purchaser ("Limited Warranty Period").

Consumer's sole and exclusive remedy, and EndoPrime's sole and exclusive responsibility under this warranty, shall be that EndoPrime will repair the Products at no charge, using new or refurbished replacement parts if a defect arises and a valid claim, as determined in the sole discretion of EndoPrime, is received by EndoPrime within the Limited Warranty Period, at EndoPrime's option and to the extent permitted by law. A replacement part assumes the remaining warranty of the original Products or 90 days from the date of replacement or repair, whichever is longer.

Instructions to Obtain Warranty Service:

To obtain warranty service Consumer must notify EndoPrime to obtain a **Return Material Authorization ("RMA")** and return the defective Product together with proof of purchase to the address specified by EndoPrime. Consumer will pre-pay all return shipping charges and shall assume all risk of loss or damage to Product while in transit to and from EndoPrime. Any Products returned to EndoPrime without an RMA or without proof of purchase will be returned to Consumer at Consumer's cost. EndoPrime will not be responsible for any such damage or loss.

Exclusions and Limitations:

This Limited Warranty applies only to the Products manufactured by EndoPrime. The Limited Warranty does not apply to any EndoPrime products and services other than the Product. This warranty does not apply to the Product or parts of the Product that have been altered or modified (e.g., to alter functionality



or capability) by anyone who is not a representative of EndoPrime. In addition, this Limited Warranty does not apply: (a) to damage caused by accident, abuse, misuse, flood, fire, earthquake or other external causes; (b) to damage caused by operating the Product outside the permitted or intended uses not in accordance with the documentation by EndoPrime; or (c) to damage caused by service performed by anyone who is not a representative of EndoPrime.

EndoPrime reserves the right to upgrade and make other necessary changes to the Product at any time without incurring any obligation or liabilities to make the same or similar changes to other EndoPrime products.

No EndoPrime reseller, agent, or employee is authorized to make any modification, extension, or addition to this Limited Warranty. If any term is held to be illegal or unenforceable, the legality or enforceability of the remaining terms shall not be affected or impaired.

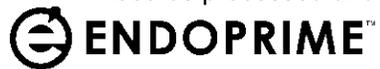
DISCLAIMER:

EXCEPT AS SPECIFIED IN THIS LIMITED WARRANTY, ALL EXPRESS OR IMPLIED CONDITIONS, REPRESENTATIONS, AND WARRANTIES INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, SATISFACTORY QUALITY, NON-INTERFERENCE, ACCURACY OF INFORMATIONAL CONTENT, OR ARISING FROM A COURSE OF DEALING, LAW, USAGE, OR TRADE PRACTICE, ARE HEREBY EXCLUDED TO THE EXTENT ALLOWED BY APPLICABLE LAW AND ARE EXPRESSLY DISCLAIMED BY ENDOPRIME TO THE EXTENT AN IMPLIED WARRANTY CANNOT BE EXCLUDED, SUCH WARRANTY IS LIMITED IN DURATION TO THE EXPRESS WARRANTY PERIOD. BECAUSE SOME STATES OR JURISDICTIONS DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, THE ABOVE LIMITATION MAY NOT APPLY. THESE WARRANTIES GIVE CONSUMER SPECIFIC LEGAL RIGHTS, AND CONSUMER MAY ALSO HAVE OTHER RIGHTS, WHICH VARY FROM JURISDICTION TO JURISDICTION.

This disclaimer and exclusion shall apply even if the express warranty set forth above fails of its essential purpose.

GOVERNING LAW AND ARBITRATION:

The laws of the State of Ohio shall govern this Limited Warranty without giving effect to any conflict of laws principles that may provide the application of the law of another jurisdiction. Any claim or dispute in connection with this Limited Warranty shall be resolved in a cost effective manner through binding non-appearance-based arbitration. The arbitration shall be initiated through an established alternative dispute resolution provider mutually agreed upon by the parties. The alternative dispute resolution provider and the parties must comply with the following rules: a) the arbitration shall be conducted by telephone, online and/or be solely based on written submissions, the specific manner shall be chosen by the party initiating the arbitration; b) the arbitration shall not involve any personal appearance by the parties or witnesses unless otherwise mutually agreed by the parties; and c) any judgment on the award rendered by the arbitrator may be entered in any court of competent jurisdiction. If the foregoing arbitration clause does not apply for any reason, you agree to submit to the personal jurisdiction of the state courts located within Hamilton County, Ohio and the federal courts in the Southern District of Ohio for the purpose of litigating all such claims or disputes, which courts shall have exclusive jurisdiction of such claims or disputes. Notwithstanding the foregoing, EndoPrime may seek injunctive or other equitable relief to protect its intellectual property rights in any court of competent jurisdiction.



SERVICE:

For service or more information, contact EndoPrime Inc. Customer Service during normal business hours 8:00 AM to 5:00 PM Eastern Time at the address below:



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Fax: (513) 769-1921

Document #: EPD0021-P01 Revision A



Prime™ Adaptive Ultrasonic Scalpel System

Prime™ Sterilization Tray

This booklet is designed to assist in using the product and is not a reference to surgical technique. Before using this product, read the following information for setup and use.

How Provided: Non-sterile

Prime™ Sterilization Tray is provided non-sterile. Clean and sterilize before each use.

Nomenclature and Illustration

The following Figure 1 and Figure 2 identify the components of the tray.

Figure 1: Prime™ Sterilization Tray

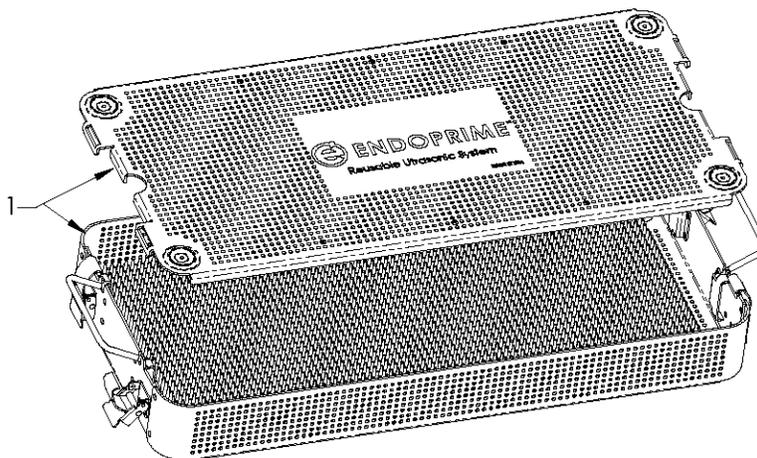
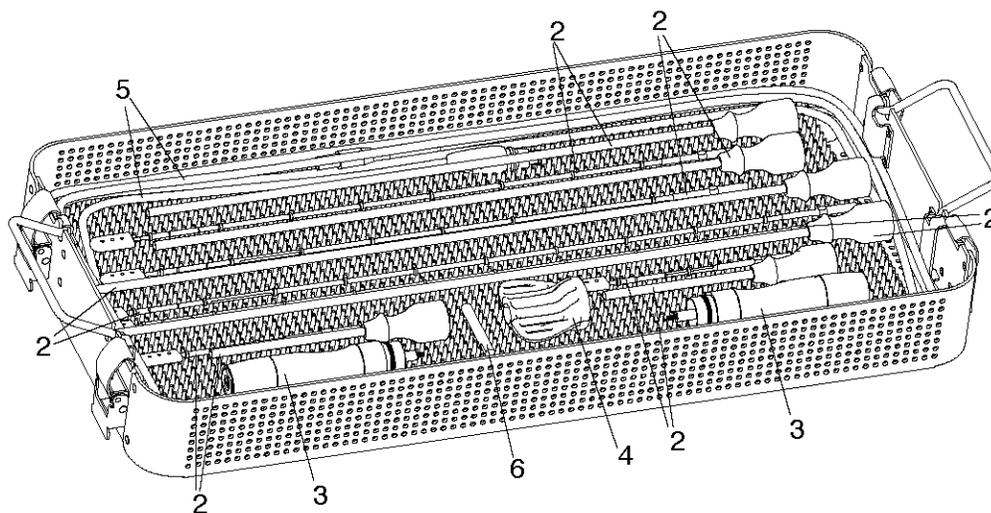


Figure 2: Placement of Devices in the Prime™ Sterilization Tray



1 Tray with Lid

2 Blade and Sheath Set

3 Transducer Handpiece

4 Torque Wrench

5 Handpiece Cables

6 Test Tip



Device Description:

The Prime™ Sterilization Tray is designed to hold and transport medical instruments during pre-vacuum steam sterilization and subsequent storage. The sterilization trays consist of an anodized aluminum tray and lid with stainless steel handles and latches. Each tray includes a silicone pin-mat insert and silicone retainer bars in the lid to separate and hold instruments in place. The tray and lid are perforated to facilitate steam sterilant penetration. The Prime™ Sterilization Tray, silicone mat, and retainers are latex-free.

Indications for Use:

The Prime™ Sterilization Tray is indicated for use in the sterilization of reusable ultrasonic blades, transducer hand pieces, test tip, and torque wrench.

Limits of Reuse:

The materials used in Prime™ Sterilization Tray may be sterilized for an indefinite number of cycles. The life of the tray is limited only by irreparable physical damage from mishandling. Always inspect the tray between each use.

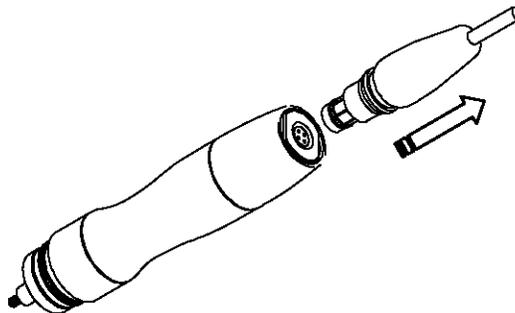
	<p>Instruments and devices used with the Prime™ Sterilization Tray include transducer, cable, test tip, and torque wrench and are provided non-sterile. The tray, instruments, and devices must be inspected, thoroughly cleaned, and sterilized according to hospital standards prior to each use.</p>
	<p>It is highly recommended that additional sterile instruments be kept available for all surgical procedures in the event that any component becomes inoperable.</p>

Instructions for Use:

Disassemble

Disassemble the devices and open any hinged devices according to the manufacture’s instructions for use. For the Prime™ Adaptive Ultrasonic Scalpel System and family of products, disconnect the cable from the transducer (Figure 3). Disassemble the sheath and remove from the blade (Figure 4). Use the torque wrench to loosen and remove the blade (Figure 5).

Figure 3: Disconnect the Transducer



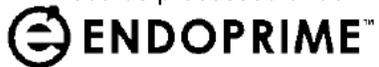


Figure 4: Disconnect the Transducer

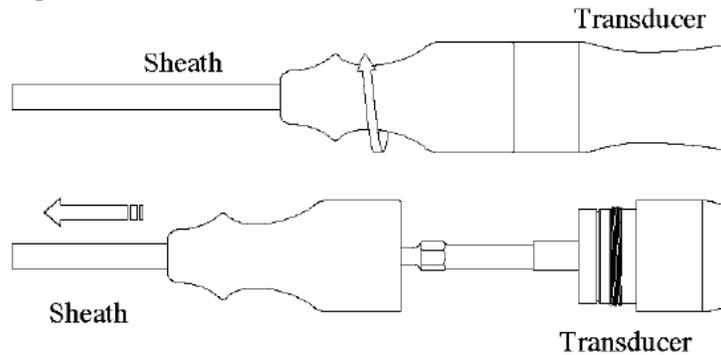
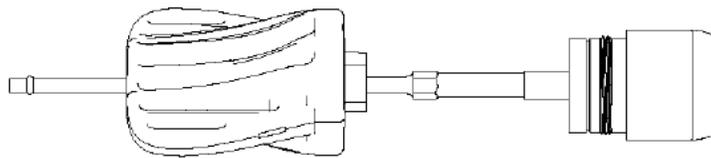


Figure 5: Remove the Blade from the Transducer

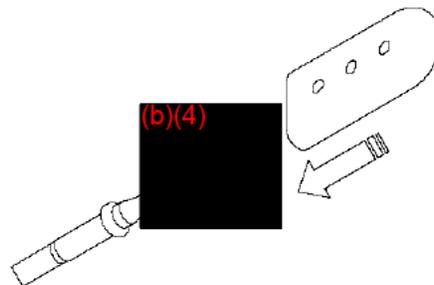


Cleaning

The Prime™ Sterilization Tray and devices are to be thoroughly cleaned following the instructions for use for each device. Prime™ reusable ultrasonic devices may be cleaned according to the following steps:

1. Manually scrub the sheath with a channel cleaning brush to remove all debris (use 5 mm or larger diameter nylon bristles or equivalent). Flush with water.
2. Wipe all the surfaces manually with a clean soft cloth soaked with a small amount of cleaning solution.
3. Machine wash using a neutral PH detergent or neutral PH enzyme detergent according to the instruction of the detergent manufacturer. Use only nonabrasive materials.
4. Place the reusable Prime™ Adaptive Ultrasonic Scalpel System accessories and devices in the sterilization tray. To avoid damage, replace the Blade Protective Caps over the Ultrasonic Blade Tips (Figure 6).

Figure 6: Replace the Blade Protective Cap(s)

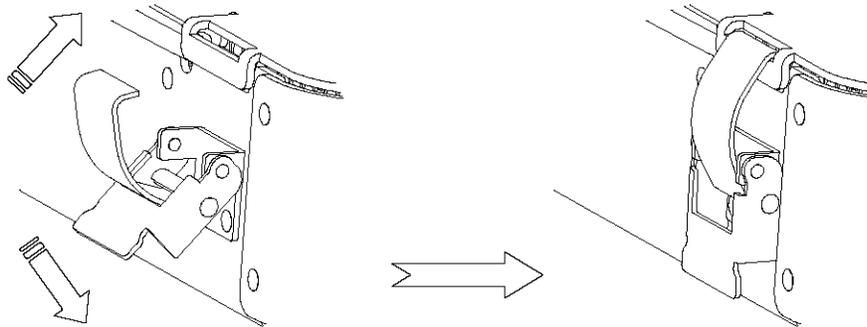


5. Organize the devices within the tray (Figure 2).



6. **Sterilization Tray Latching:** Carefully place the Prime™ Sterilization Tray lid on the tray and securely close the stainless steel latches. Handles and latches should be stowed inward before wrapping (Figure 7). Wrap with a USFDA cleared wrap.

Figure 7: Latch Closure Configuration



7. After thoroughly cleaning, sterilize according to hospital procedures. Sterilize as follows:
Steam Sterilization Cycle:
Cycle Type: Pre-Vacuum – 3 Pulses
Temperature: 270°F (132°C)
Sterilization Time: 4 minutes
Dry Time: 30 minutes



Warnings and Precautions

1. Always follow the manufacturer's instructions when sterilizing complex instruments requiring disassembly.
2. Instruments with hinges should have the hinges in the open position during sterilization.
3. Total weight of the tray and its contents (including all accessories) must not exceed 25 lbs.
4. The cover must be securely latched to the base during handling, wrapping and sterilization.
5. Only a legally marketed and USFDA cleared sterilization wrap should be used.
6. Allow adequate room on all sides to ensure proper sterilization and drying.
7. Wet-raps must be considered non-sterile and must be re-sterilized. Always inspect the tray for evidence of moisture upon completion of the sterilization/drying cycle.
8. If the Prime™ Sterilization Tray is used in conjunction with products outside the Prime™ Adaptive Ultrasonic Scalpel System, verify the compatibility of all instruments and accessories prior to use.
9. Additional sterile instruments should be kept available for all surgical procedures in the event that any component becomes inoperable.
10. DO NOT USE instruments if damaged. Damage to the transducer or cable may result in device failure during use. Examples of damage include any tear in electrical cable insulation, deep scratches, deviations in shape, corrosion, or discoloration.



If the Prime™ Sterilization Tray is used in conjunction with products outside the Prime™ Adaptive Ultrasonic Scalpel System, verify the compatibility of all instruments and accessories prior to use.



Storage and Transport Requirements:

Carefully handle, clean, sterilize, transport, and store the Prime™ Sterilization Tray to avoid unintentional damage. For best results, store or transport at no more than 95% relative humidity, -13°F to 158°F (-25°C to 70°C).

EndoPrime, Inc. Limited Warranty

Warranty Coverage:

EndoPrime, Inc. (“**EndoPrime**”) warrants this Prime™ Sterilization Tray (**the "Product"**), and only the Product, against defects in materials and workmanship under normal use for a period of **twelve (12) months** from the date of retail purchase by the original purchaser ("**Limited Warranty Period**"). Cosmetic damage from routine handling, damage resulting from abuse or mishandling, or damage resulting from the use of cleaning or sterilization methods incompatible with anodized aluminum is not covered under warranty.

Consumer's sole and exclusive remedy, and EndoPrime's sole and exclusive responsibility under this warranty, shall be that EndoPrime will repair the Product at no charge, using new or refurbished replacement parts if a defect arises with a valid claim, as determined in the sole discretion of EndoPrime, is received by EndoPrime within the Limited Warranty Period, at EndoPrime's option and to the extent permitted by law. A replacement part assumes the remaining warranty of the original Product or 90-days from the date of replacement or repair, whichever is longer.

Instructions to Obtain Warranty Service:

To obtain warranty service, the customer must notify EndoPrime to obtain a **Return Material Authorization ("RMA")** and return the defective Product together with proof of purchase to the address specified by EndoPrime. The customer will pre-pay all return shipping charges and shall assume all risk of loss or damage to product while in transit to and from EndoPrime. Any Product returned to EndoPrime without an RMA or without proof of purchase will be returned to the customer at the customer's cost. EndoPrime will not be responsible for any such damage or loss.

Exclusions and Limitations

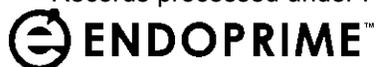
This Limited Warranty applies only to the Product manufactured by EndoPrime. The Limited Warranty does not apply to any other EndoPrime products and services. This warranty does not apply to a Product or part of the Product that has been altered or modified (e.g., to alter functionality or capability) by anyone who is not a representative of EndoPrime. In addition, this Limited Warranty does not apply: (a) to damage caused by accident, abuse, misuse, flood, fire, earthquake or other external causes; (b) to damage caused by operating the Product outside the permitted or intended uses not in accordance with the documentation by EndoPrime; or (c) to damage caused by service performed by anyone who is not a representative of EndoPrime.

EndoPrime reserves the right to upgrade and make other necessary changes to the Product at any time without incurring any obligation or liabilities to make the same or similar changes to other EndoPrime products.

No EndoPrime reseller, agent, or employee is authorized to make any modification, extension, or addition to this Limited Warranty. If any term is held to be illegal or unenforceable, the legality or enforceability of the remaining terms shall not be affected or impaired.

DISCLAIMER:

EXCEPT AS SPECIFIED IN THIS LIMITED WARRANTY, ALL EXPRESS OR IMPLIED CONDITIONS, REPRESENTATIONS, AND WARRANTIES INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, SATISFACTORY QUALITY, NON-INTERFERENCE, ACCURACY OF INFORMATIONAL CONTENT, OR ARISING FROM A COURSE OF DEALING, LAW, USAGE, OR TRADE PRACTICE, ARE HEREBY EXCLUDED TO THE EXTENT ALLOWED BY APPLICABLE LAW AND ARE EXPRESSLY DISCLAIMED BY ENDOPRIME TO THE EXTENT AN IMPLIED WARRANTY CANNOT BE EXCLUDED, SUCH WARRANTY IS LIMITED IN DURATION TO THE EXPRESS



WARRANTY PERIOD. BECAUSE SOME STATES OR JURISDICTIONS DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, THE ABOVE LIMITATION MAY NOT APPLY. THESE WARRANTIES GIVE CONSUMER SPECIFIC LEGAL RIGHTS, AND THE CONSUMER MAY ALSO HAVE OTHER RIGHTS, WHICH VARY FROM JURISDICTION TO JURISDICTION.

This disclaimer and exclusion shall apply even if the express warranty set forth above fails of its essential purpose.

Governing Law and Arbitration:

The laws of the State of Ohio shall govern this Limited Warranty without giving effect to any conflict of laws and principles that may provide the application of the law of another jurisdiction. Any claim or dispute in connection with this Limited Warranty shall be resolved in a cost effective manner through binding non-appearance-based arbitration. The arbitration shall be initiated through an established alternative dispute resolution provider mutually agreed upon by the parties. The alternative dispute resolution provider and the parties must comply with the following rules: a) the arbitration shall be conducted by telephone, online and/or be solely based on written submissions, the specific manner shall be chosen by the party initiating the arbitration; b) the arbitration shall not involve any personal appearance by the parties or witnesses unless otherwise mutually agreed by the parties; and c) any judgment on the award rendered by the arbitrator may be entered in any court of competent jurisdiction. If the foregoing arbitration clause does not apply for any reason, you agree to submit to the personal jurisdiction of the state courts located within Hamilton County, Ohio and the federal courts in the Southern District of Ohio for the purpose of litigating all such claims or disputes, which courts shall have exclusive jurisdiction of such claims or disputes. Notwithstanding the foregoing, EndoPrime may seek injunctive or other equitable relief to protect its intellectual property rights in any court of competent jurisdiction.

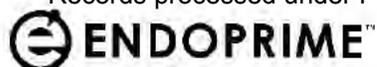
Service

For service or more information, contact EndoPrime Inc. Customer Service during normal business hours 8:00 AM to 5:00 PM Eastern Time at the address below:



EndoPrime Inc.
4480 Lake Forest Drive
Suite 414
Cincinnati, OH 45242
Telephone: (513) 769-1916
Fax: (513) 769-1921
Website: endoprime.com

Document #: EPD0022-P01 Revision A



Prime™ Adaptive Ultrasonic Scalpel System

Prime™ Generator Cart for use with the Prime™ G6000 Ultrasonic Generator

This booklet is designed to assist in using the product. Before using this product, read the following information and information provided with all devices.

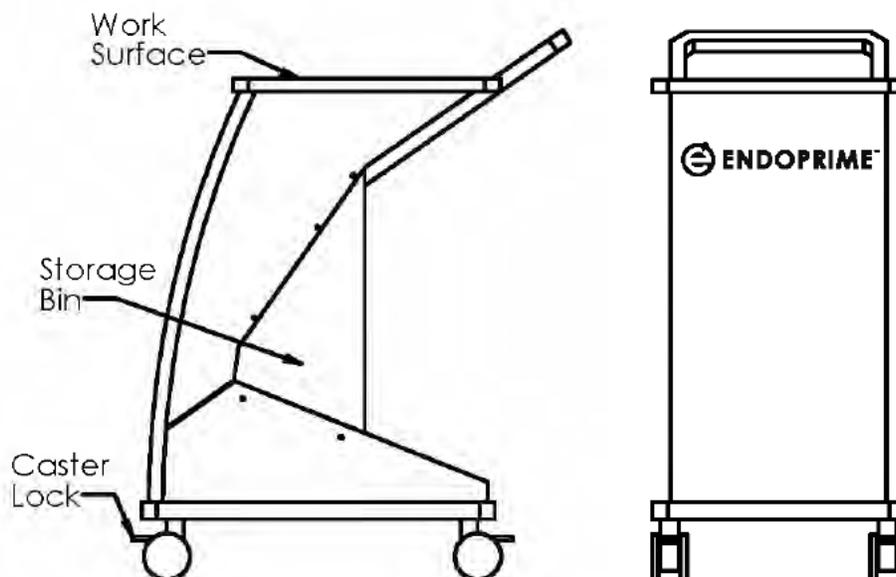


Description: The **Prime™ Generator Cart** is a work surface accessory for support, conveyance and storage of the **Prime™ Ultrasonic Generator** and the **Prime™ Adaptive Ultrasonic Scalpel System**. The cart is best suited for the hospital surgical department.

Features:

- Locking Casters: High-grade, locking Casters for easy moving and secure storage.
- Accessory Bin: Provides ample storage for the footswitch, extra blade, extra handpiece, Instruction manuals, reference books, general supplies, clipboards, etc.
- Easy Cleaning: Smooth, non-porous surfaces for easy cleaning and durability

Nomenclature and Illustration:



How Provided: The **Prime™ Generator Cart** is an accessory provided without generator and footswitch.



Instructions for Use: Place Generator on cart for convenient access and storage. Follow the instructions for use of the generator and other products.

Cleaning:

Wipe all surfaces manually using a damp, clean cloth and nonabrasive solutions. Never use steel wool or any other abrasive material as these could damage the surface finish.



Warnings and Precautions

1. DO NOT immerse in liquid or sterilize.
2. Because of the close proximity of electrical power and equipment, flammable cleaners should never be used!
3. Never cover the cart or its components in liquid.
4. DO NOT USE if damaged – inspect to assure the cart and casters are not worn or damage.
5. INDOOR use only. DO NOT OPERATE OUTDOORS.

Storage and Transport Requirements:

For best results, store or transport at no more than 95% Relative Humidity, -13°F to 158°F (-25°C to 70°C).

Tested to comply with: EN 60601-1 (3rd Edition)–Medical Electrical Equipment, Part 1: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

EndoPrime, Inc. Limited Warranty

Warranty Coverage:

EndoPrime, Inc. (“EndoPrime”) warrants this **Generator Cart (the “Products”)**, and only the Product, against defects in materials and workmanship under normal use for a period of **One (1) Year** from the date of retail purchase by the original purchaser (“**Limited Warranty Period**”).

Consumer's sole and exclusive remedy, and EndoPrime's sole and exclusive responsibility under this warranty, shall be that EndoPrime will repair the Products at no charge, using new or refurbished replacement parts if a defect arises and a valid claim, as determined in the sole discretion of EndoPrime, is received by EndoPrime within the Limited Warranty Period, at EndoPrime’s option and to the extent permitted by law. A replacement part assumes the remaining warranty of the original Products or **NINETY (90) days** from the date of replacement or repair, whichever is longer.



Instructions to Obtain Warranty Service:

To obtain warranty service Consumer must notify EndoPrime to obtain a **Return Material Authorization ("RMA")** and return the defective Products together with proof of purchase to the address specified by EndoPrime. Consumer will pre-pay all return shipping charges and shall assume all risk of loss or damage to Products while in transit to and from EndoPrime. Any Products returned to EndoPrime without an RMA or without proof of purchase will be returned to Consumer at Consumer's cost. EndoPrime will not be responsible for any such damage or loss.

Exclusions and Limitations:

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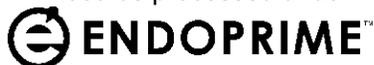
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GOVERNING LAW AND ARBITRATION:

This Limited Warranty shall be governed by the laws of the State of Ohio without giving effect to any conflict of laws principles that may provide the application of the law of another jurisdiction. Any claim or dispute in connection with this Limited Warranty shall be resolved in a cost effective manner through binding non-appearance-based arbitration. The arbitration shall be initiated through an established alternative dispute resolution provider mutually agreed upon by the parties. The alternative dispute resolution provider and the parties must comply with the following rules: a) the arbitration shall be conducted by telephone, online and/or be solely based on written submissions, the specific manner shall be chosen by the party initiating the arbitration; b) the arbitration shall not involve any personal appearance by the parties or witnesses unless otherwise mutually agreed by the parties; and c) any judgment on the award rendered by the arbitrator may be entered in any court of competent jurisdiction. If the foregoing arbitration clause does not apply for any reason, you agree to submit to the personal jurisdiction of the state courts located within Hamilton County, Ohio and the federal courts in the Southern District of Ohio for the purpose of litigating all such claims or disputes, which courts shall have exclusive jurisdiction of such claims or disputes. Notwithstanding the foregoing, EndoPrime may seek injunctive or other equitable relief to protect its intellectual property rights in any court of competent jurisdiction.

SERVICE:

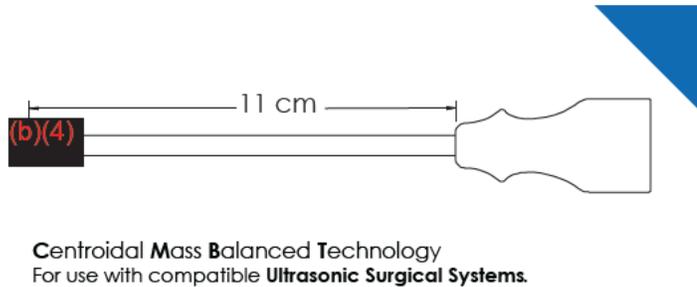
For service or more information, contact EndoPrime Inc. Customer Service during normal business hours 8:00 AM to 5:00 PM Eastern Time at the address below:



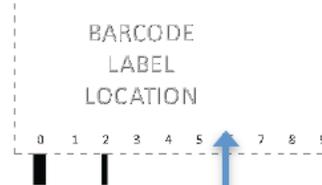
EndoPrime Inc.
4480 Lake Forest Drive
Suite 414
Cincinnati, OH 45242
Telephone: (513) 769-1916
Fax: (513) 769-1921

Primary Carton labels are provided:

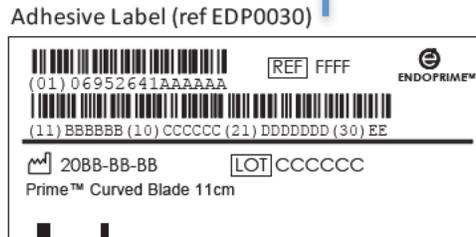
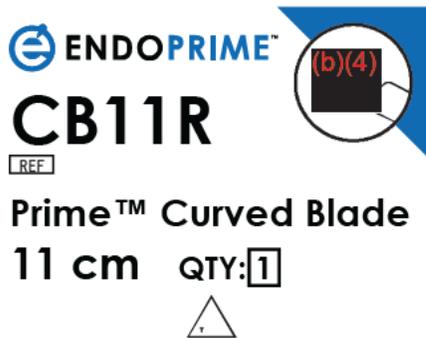
BOX TOP



BOX BOTTOM



BOX END 1



The remaining Prime Reusable blades label drawings differ only by product code, product name, and appropriate picture of device. These drawings are:

- EPD0024 CB11R box labeling
- EPD0025 CB38R box labeling
- EPD0026 CB47R box labeling
- EPD0027 HB11R box labeling
- EPD0028 HB38R box labeling
- EPD0029 HB47R box labeling



ENDOPRIME™

Records processed under FOIA Request # 2015-6843; Released by CDRH on 12-30-2015

Prime™ Adaptor / Connector

QTY: **1**  **REF ADP1**

Rx Only



See Instructions
For Use



EndoPrime Inc.
4480 Lake Forest Drive, Suite 414
Blue Ash, Ohio 45242

Tel: 513-769-1916 Fax: 513-769-1921

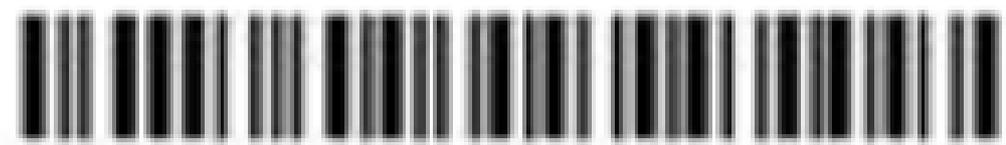
BARCODE
LABEL
LOCATION



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

Manufactured in China





REF ADP1



(01)06952641AAAAAA

under FOIA Request # 2015-6843 Released by CD



(11)BBBBBB (10)CCCCC (21)DDDDDD (30)EE

20BB-BB-BB

LOT CCCCCC

DA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs

Prime™ Connector / Adaptor

Transducer Box Top



ENDOPRIME™

REF

TRN5

**Ultrasonic Transducer
Hand Piece**

QTY: **1**



Piezoelectric Technology
For use with compatible **Ultrasonic Surgical Systems and Instruments.**

Transducer Box Side

R Only



See Instructions
For Use



EndoPrime Inc.
4480 Lake Forest Drive, Suite 414
Blue Ash, Ohio 45242
Tel: 513-769-1916 Fax: 513-769-1921

Ultrasonic Transducer Hand Piece
Manufactured in China

BARCODE
LABEL
LOCATION



Adhesive Label (Ref EDP0030)

REF FFFF **ENDOPRIME™**

(01) 06952641AAAAAA

(11) BBBB (10) CCCCC (21) DDDDDD (30) EE

20BB-BB-BB **LOT** CCCCC

Prime™ Reusable Transducer

The Prime Reusable Transducer label drawings are referenced in EDP0031



P40313P08



JHC124578

ULTRACISION®
HARMONIC SCALPEL®



5 mm Instruments
 Instruments de 5 mm
 5 mm Instrumente
 Strumenti da 5 mm
 Instrumentos de 5 mm
 Instrumentos de 5 mm
 5 mm Instrumenten
 5 mm Instrumenter
 5 mm Instrumentit
 Εργαλεία 5 mm
 5 mm Instrument
 Urządzenia o średnicy 5 mm
 5 mm-es eszköz nagyság
 5 mm nástroje
 5 mm nástroje
 ウルトラシジョン* ハーモニック スカルペル*
 5 mm ブレード

REF
HC325, HDH05, HSH05, HBC05



Ethicon Endo-Surgery (Europe) GmbH
Hummelsbuetteler Steindamm 71
22851 Norderstedt
GERMANY

Johnson & Johnson AG
CH-8957 Spreitenbach
SWITZERLAND

輸入・発売元: ジョーンソン・エンド・ジョーンソン 株式会社
〒135-0016 東京都江東区東陽 6 丁目 3 番 2 号 Tel: 03 (5632) 7206



ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company



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Cincinnati, OH 45242-2839 USA P40313P08

Please read all information carefully.

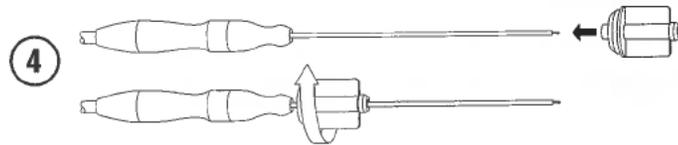
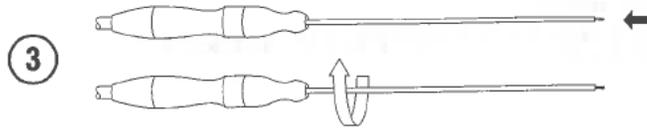
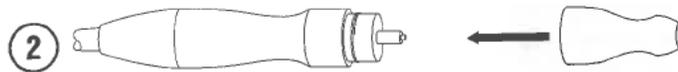
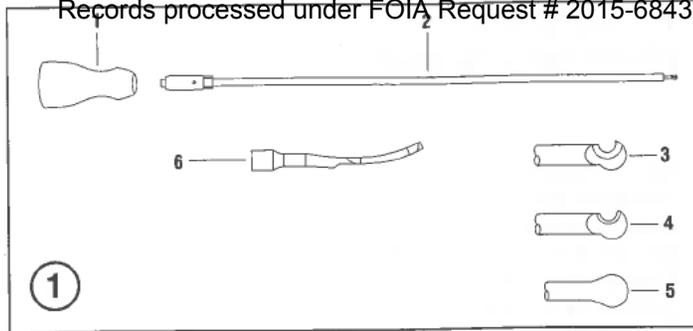
Failure to properly follow the instructions may lead to serious surgical consequences.

Important: This package insert is designed to provide instructions for use of the ULTRACISION® HARMONIC SCALPEL® 5 mm Instruments. It is not a reference to surgical techniques.

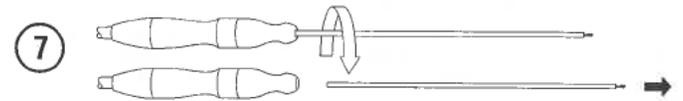
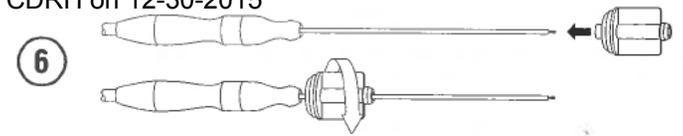


ETHICON ENDO-SURGERY, INC.
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Instructions, Instructions, Gebrauchsanweisung, Istruzioni, Instruções, Instrucciones,
Gebruiksaanwijzing, Brugsvejledning, Ölje, Οδηγίες, Bruksanvisning, Instrukcja,
Utasítások, Návod k použití, Navod, 説明書



2



3

Indications

The ULTRACISION HARMONIC SCALPEL 5 mm Instruments are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, gynecologic, and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

Contraindications

- The instruments are not indicated for incising bone.
- The instruments are not intended for contraceptive tubal occlusion.

Device Description

The ULTRACISION HARMONIC SCALPEL 5 mm Instruments are sterile, single patient use instruments consisting of a titanium blade with a non-removable sheath.

Four types of 5 mm Instrument blades are offered: a sharp hook, a dissecting hook, a ball coagulator, and a curved blade. The working length of the sharp hook, the dissecting hook, and the curved blade is 320 mm. The working length of the ball coagulator is 310 mm. Selection of the appropriate blade type is a matter of surgeon preference based on the procedure or application.

The 5 mm Instruments must be used with the 5 mm Adaptor or Hand-Switching Adaptor and connected to the ULTRACISION HARMONIC SCALPEL Hand Piece and Generator prior to use.

The ULTRACISION HARMONIC SCALPEL 5 mm Instruments are designed for use exclusively with the ULTRACISION HARMONIC SCALPEL Generator and Hand Piece. Refer to the Generator Manual before using these instruments.

Illustration and Nomenclature (Illustration 1)

- | | |
|---|-----------------------------|
| 1. 5 mm Adaptor or Hand-Switching Adaptor | 4. Dissecting Hook (320 mm) |
| 2. 5 mm Blade and Sheath | 5. Ball Coagulator (310 mm) |
| 3. Sharp Hook (320 mm) | 6. Curved Blade (320 mm) |

Instructions for Use

Verify compatibility of all instruments and accessories prior to using the instrument (refer to **Warnings and Precautions**).

The hand piece, adaptor, and blade wrench are reusable and shipped non-sterile. These components must be sterilized per their insert instructions prior to each use.

Attachment of 5 mm Blade to Hand Piece

- Attach the 5 mm adaptor or hand switching adaptor to the hand piece. (Illustration 2)
- Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
- Remove the protective cap from the blade tip.
Note: Take care to avoid injury from the blade tip when removing the protective cap.
- Attach the blade manually to the hand piece by turning it clockwise (finger tight only).
Note: Take care to avoid injury from the blade tip when attaching the blade to the hand piece and while sliding the blade wrench onto or off of the blade. (Illustration 3)
- Use the blade wrench to tighten the blade. Slide the wrench over the blade until it stops at the Hand Piece adaptor. Turn the wrench and continue to push it gently until the wrench nose is adjacent to the adaptor. Turn the wrench clockwise until it "snaps," indicating that sufficient torque has been applied to secure the blade. (Illustration 4)
Note: Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.
- Remove the blade wrench by sliding it straight back over the blade. (Illustration 5)
Do not dispose of the reusable blade wrench. It is used for removal of the blade following the procedure.

4

Operation of the 5 mm Blade

Refer to the ULTRACISION HARMONIC SCALPEL Generator Manual and hand piece package insert for hand piece attachment and system operation instructions.

- Connect the assembled hand piece, adaptor, and blade to the generator and turn the generator power on.
Note: Do not turn the generator power on before the hand piece, adaptor, and blade are connected to the generator.
- Select the desired power level using the INCREASE and DECREASE buttons on the generator.
- The blade is ultrasonically energized when either foot switch pedal is depressed.
Note: Scratches on the blade may lead to premature blade failure.
 - Avoid accidental contact with other instruments during use.
 - Do not use any other means than the blade wrench to attach or detach the blade.
- After inserting the blade through a trocar or an incision, press the blade against tissue during ultrasonic activation to cut and/or coagulate tissue under direct visualization.
Note: In general, sharper ultrasonically activated edges cut faster with less hemostasis, while more blunt edges and surfaces coagulate more and cut less rapidly. The amount of energy delivered to the tissue and resultant tissue effects are a function of many factors, including the power level selected, blade characteristics, tissue tension, tissue type, pathology, and surgical technique.

5 mm Blade Disassembly

- Turn the Generator **OFF** at the power switch or enter **STANDBY** mode.
- Slide the wrench over the blade to the base of the hand piece. Align the flats on the wrench with the flats on the blade. Loosen the blade by turning the wrench counterclockwise. Continue to loosen by turning the wrench or blade manually to unscrew it completely. (Illustration 6)
- Remove the blade wrench by pulling it straight back over the blade. **Save the blade wrench for future use.**
Note: Take care to avoid injury from the blade tip while sliding the blade wrench onto or off of the blade.
- Remove the blade and dispose of it in an appropriate container. (Illustration 7)
- Remove the adaptor and save it for future use.

Warnings and Precautions

- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- Minimally invasive instruments may vary from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. Do not immerse instruments in liquid unless the instruments are designed and labeled to be immersed.
- Audible high-pitched tones, resonating from the blade or hand piece, are an abnormal condition and an indicator that the blade or hand piece is not operating properly. The tones may be an indicator that the hand piece is beyond its useful life or that the blade has not been attached properly, which may result in abnormally high sheath temperatures and user or patient injury.
- Do not use the ULTRACISION HARMONIC SCALPEL blades without the proper adaptor. Failure to use the proper adaptor as described in the device description may result in user or patient burn injury.
- The blade has been designed to meet the international safety standard EN60601-1 based on an **intermittent operation of 15 second on/off intervals**. For activation time of longer duration and under certain fault conditions, the blade sheath may become hot. To prevent burn injury, avoid direct tissue contact with the blade sheath or take preventative measures to protect tissue that comes in contact with the sheath.
- Blood and tissue buildup between the blade and sheath may result in abnormally high temperatures at the distal end of the sheath. To prevent burn injury, remove any visible tissue buildup at the distal end of the sheath.

5

- As with all energy source instruments, the ULTRACISION HARMONIC SCALPEL 5 mm Instruments should be used with caution to avoid the carcinogenic and infectious potential of the by-products, such as tissue smoke plume and aerosols. Appropriate measures such as protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
- In case of system failure, ensure the availability of the appropriate backup equipment relevant to the specific procedure.
- Do not attempt to bend, sharpen or otherwise alter the shape of the blade. Doing so may cause blade failure and user or patient injury.
- To avoid user or patient injury in the event that accidental activation occurs, the instrument blades should not be in contact with the patient, drapes or flammable materials while not in use. During prolonged activation in tissue, the instrument blades may become hot. Avoid unintended blade contact with tissue, drapes, surgical gowns, or other unintended sites after activation.
- Use only the ULTRACISION HARMONIC SCALPEL Foot Switch, Hand Piece, blade accessories, and power cord to ensure that they are compatible with the Generator.
- Products manufactured or distributed by companies not authorized by Ethicon Endo-Surgery, Inc. may not be compatible with the ULTRACISION HARMONIC SCALPEL System. Use of such products may lead to unanticipated results and possible injury to the user or patient.
- After removing the instrument, examine the tissue for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- Avoid contact with any and all metal or plastic instruments or objects when the instrument is activated. Contact with staples, clips, or other instruments while the instrument is activated may result in cracked or broken blades which may be identified by generator solid tone or instrument error.
- This device is packaged and sterilized for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury, illness or death. Cleaning and resterilization of single patient use ULTRACISION HARMONIC SCALPEL 5 mm Instruments can also result in abnormally high sheath temperatures and burn injury to user or patient when the blade is activated. Also, reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

How Supplied

The ULTRACISION HARMONIC SCALPEL 5 mm Instruments are supplied sterile for single patient use. Discard after use.

**ULTRACISION® HARMONIC SCALPEL®
Instruments de 5 mm**

Lire attentivement toutes les informations suivantes.

Ne pas respecter les précautions d'emploi peut entraîner des conséquences chirurgicales graves.

Important : cette notice a pour but de donner des informations sur l'utilisation des Instruments de 5 mm HARMONIC SCALPEL® ULTRACISION®. Elle ne constitue pas une référence de techniques chirurgicales.

Indications

Les Instruments de 5 mm HARMONIC SCALPEL ULTRACISION sont conçus pour effectuer des incisions dans les tissus mous lorsqu'il est souhaité un minimum de saignements et de lésions thermiques. Ces instruments peuvent être utilisés en complément ou en substitution de l'électrochirurgie, des lasers ou des scalpels en acier dans les interventions de chirurgie générale, gynécologique et thoracique, y compris la mobilisation de l'arrière mammaire interne.

Contre-indications

- Ces instruments ne doivent pas être utilisés pour l'accès à l'utérus.
Ces instruments ne doivent pas être utilisés pour ligaturer les trompes à des fins contraceptives.

Description de l'instrument

Les Instruments de 5 mm HARMONIC SCALPEL ULTRACISION sont fournis stériles pour un usage unique. Ils sont constitués d'une lame en titane recouverte d'une gaine fixe.

L'instrumentation de 5 mm propose quatre types de lames : un crochet à bord biseauté, un crochet dissecteur, une sphère coagulante et une lame courbe. Le crochet à bord biseauté, le crochet dissecteur et la lame courbe existent en longueur utile de 320 mm. La longueur utile de la sphère coagulante est de 310 mm. Le chirurgien choisit le type de lame en fonction de l'intervention chirurgicale et de l'emploi envisagé.

Les instruments de 5 mm doivent être utilisés avec l'adaptateur de 5 mm ou l'adaptateur pour commande manuelle et connectés à la Poignée de Connexion et au Générateur HARMONIC SCALPEL ULTRACISION avant leur utilisation.

Les Instruments de 5 mm HARMONIC SCALPEL ULTRACISION sont conçus pour être utilisés exclusivement avec la Poignée de Connexion et le Générateur HARMONIC SCALPEL ULTRACISION. Se reporter au manuel du générateur avant d'utiliser ces instruments.

Illustration et nomenclature (Illustration 1)

- | | |
|--|--------------------------------|
| 1. Adaptateur de 5 mm ou adaptateur pour commande manuelle | 4. Crochet dissecteur (320 mm) |
| 2. lame et gaine de 5 mm | 5. Sphère coagulante (310 mm) |
| 3. Crochet à bord biseauté (320 mm) | 6. lame courbe (320 mm) |

Mode d'emploi

Vérifier la compatibilité de tous les instruments et accessoires avant d'utiliser ce dispositif (se référer au chapitre **Précautions d'emploi**).

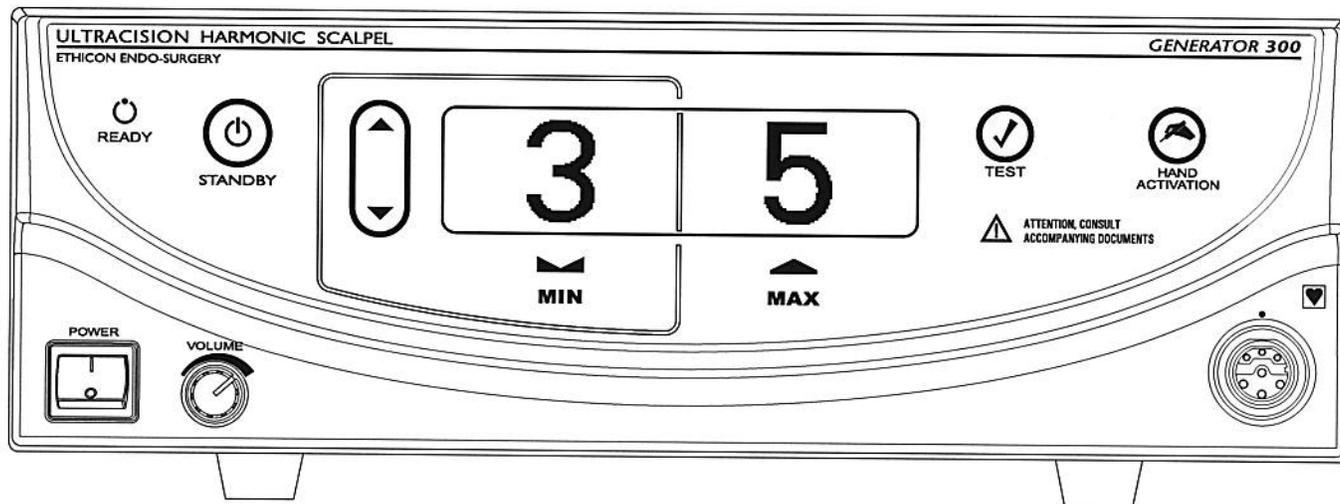
La poignée de connexion, l'adaptateur et la clé de fixation sont fournis non stériles et peuvent être réutilisés. Les composants de ces produits doivent être stérilisés conformément aux directives indiquées dans leur notice de conditionnement avant chaque utilisation.

Fixation d'une lame de 5 mm à la poignée de connexion

- Fixer l'adaptateur de 5 mm ou l'adaptateur pour commande manuelle à la poignée de connexion. (Illustration 2)
- Ôter l'instrument de son protecteur individuel de stérilité à l'aide des techniques stériles. Ne pas faire basculer l'instrument sur le champ stérile pour éviter de l'endommager.
- Enlever la protection de la pointe de la lame.
Remarque : cette procédure doit être réalisée avec précaution afin d'éviter toute blessure.
- Visser manuellement la lame à la poignée de connexion en tournant dans le sens des aiguilles d'une montre (du bout des doigts).
Remarque : fixer la lame à la poignée de connexion avec précaution afin d'éviter toute blessure. Prendre les mêmes précautions lors de l'introduction et du retrait de la clé de fixation. (Illustration 3)
- Utiliser la clé de fixation pour bien fixer la lame. Faire glisser la clé de fixation sur la lame jusqu'à ce qu'elle vienne buter l'adaptateur vissé à la poignée de connexion. Tourner soigneusement la clé de fixation de manière à enclencher la butée dans l'adaptateur. Tourner ensuite la clé de fixation dans le sens des aiguilles d'une montre jusqu'à entendre le « clic » qui indique la fixation correcte de la lame. (Illustration 4)
Remarque : vérifier l'absence de fissures et d'usure sur l'embase de la clé de fixation avant usage. En cas de dommage visible, remplacer la clé de fixation. Après l'autoclavage, laisser revenir la clé de fixation à la température ambiante pendant au moins 45 minutes ou la tremper dans de l'eau stérile à la température ambiante pendant 5 minutes avant usage.

ULTRACISION® HARMONIC SCALPEL®

Generator 300 System Service Manual



Scope

This manual and the equipment it describes are for use only by qualified Biomedical Service Personnel. It is intended only as a guide for technical maintenance of the ULTRACISION® HARMONIC SCALPEL® Generator 300.

This manual is intended to be a companion to the ULTRACISION® HARMONIC SCALPEL® Generator 300 User Manual. A thorough understanding of the User Manual is required to properly utilize the information in this manual.

Installation Guidelines

The person installing the device shall ensure that the installation, inspection, and any required testing are performed in accordance with the instructions in this and the ULTRACISION® HARMONIC SCALPEL® Generator 300 User Manual. The inspection shall be documented along with any test results to demonstrate proper installation.

Ethicon Endo-Surgery, Inc. reserves the right to change the electrical/electronic or mechanical configurations and components without notice. Schematic revisions may not match PCB revisions in the unit being maintained; consult Ethicon Endo-Surgery, Inc. before making any changes. When necessary, amendments to this manual will be made available by request only.

Product Information

Product Name: ULTRACISION HARMONIC SCALPEL Generator 300 System

Model Number/Product Code: GEN04

Voltage: 100 – 240 VAC

This manual is subject to revision. When referring to this manual please include the following:

Document Type: Service Manual

Document Number: P40401P0X (on back cover of manual)

Manufactured by:

Ethicon Endo-Surgery, Inc.

4545 Creek Road

Cincinnati, Ohio 45242-2839 USA

1-800-USE-ENDO (U.S. Customers)

<http://www.harmonicscalpel.com>

Service

1-800-USE-ENDO (U.S. Customers)

Customers outside the U.S. should contact their Ethicon Endo-Surgery, Inc. representative for assistance.

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Warnings and Precautions

- This equipment, in conjunction with the accessories, is intended to produce high-frequency mechanical energy which enables hemostatic cutting and/or coagulation of soft tissue.
- Safe and effective ultrasonic surgery is dependent not only upon equipment design, but also, to a large extent, upon factors under control of the operator. It is important that the instructions supplied with this equipment be read, understood, and followed in order to enhance safety and effectiveness.
- The ULTRACISION HARMONIC SCALPEL system, including the hand piece, is not Magnetic Resonance safe and is not Magnetic Resonance compatible.
- Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. It is possible to create sparks by hitting other metal instruments. Sparks may ignite flammable gases such as bowel gas.
- The ULTRACISION HARMONIC SCALPEL system must be operated within the required ambient operating conditions. Refer to Chapter 10 – System Specifications.
- The ULTRACISION HARMONIC SCALPEL system should be tested on a periodic basis by qualified biomedical maintenance personnel to ensure proper and safe operation.
- Refer all servicing to qualified biomedical personnel. Your Ethicon Endo-Surgery, Inc. representatives are available to assist in having your equipment serviced.
- Removing the top cover of the generator unit may expose the user to parts within the generator unit which may have high surface temperatures and high voltage. These surfaces are potentially dangerous and should be treated with extreme caution.
- Always unplug the generator from the wall outlet prior to opening the cover for servicing. This poses a potential electric shock hazard.
- After removing the cover, inspect the internal components for obvious damage or foreign debris. Never power ON a suspected problem unit.
- Never remove or install any parts with power on.
- To avoid user or patient injury in the event that accidental activation occurs, the ULTRACISION HARMONIC SCALPEL Generator 300 System instrument blades should not be in contact with the patient, drapes, or flammable materials while not in use. During prolonged activation in tissue, the instrument blade, clamp arm and distal end of the shaft may become hot. Avoid unintended blade contact with tissue, drapes, surgical gowns, or other unintended sites after activation.
- The user should verify that the power receptacle with which this unit is used is properly grounded and is correctly polarized. Do not use ground cheater plugs or extension cords. Do not connect the ULTRACISION HARMONIC SCALPEL Generator 300 System to an ungrounded outlet. Grounding reliability can only be achieved when this equipment is connected to a hospital-grade receptacle. (Refer to Chapter 10 – System Specifications.)
- Verify that the outlet voltage correctly corresponds to the generator's requirements. (Refer to Chapter 10 – System Specifications.) Connection to an improper power supply may result in damage to the generator and risk of shock or fire hazard.

- Do not connect the ULTRACISION HARMONIC SCALPEL Generator 300 to an ungrounded outlet. Grounding reliability can only be achieved when this equipment is connected to a hospital-grade receptacle.
- Spilling or spraying fluids on or into the generator or immersing the generator may result in damage to the generator and risk of shock or fire hazard.
- Do not place liquid containers on top of the unit. Wipe spilled liquids off the unit immediately. To avoid inadvertent penetration of liquids, do not operate this unit in a tilted position.
- Locate the ULTRACISION HARMONIC SCALPEL system, including the hand piece cable, at least 3 ft. (approximately 1 m) from electrosurgical systems and their hand piece (e.g., pencil) cables. The generator should not be on the same circuit as other equipment and machines. Please note that different outlets may not necessarily mean different circuits.
- To prevent overheating during use, ensure that the air vents found on the generator's bottom and back panels are not blocked and that they allow adequate clearance from obstructions to allow air to flow freely through the generator enclosure. Avoid placing the generator on a soft surface.
- Use proper electrical safety and hospital procedures when working on the generator unit.

Notes

- Use only Ethicon Endo-Surgery, Inc. approved replacement parts. Contact the Ethicon Endo-Surgery, Inc. representative for assistance in obtaining replacement parts by calling 1-800-USE-ENDO for customers in the United States. Customers outside the U.S. should contact their Ethicon Endo-Surgery, Inc. representative for assistance.
- Minimizing operating temperature and extreme thermal cycles will extend the life of the equipment.
- Throughout this manual "instrument(s)" refers to ULTRACISION HARMONIC SCALPEL blades, ball coagulators, or coagulating shears.

System Description

The ULTRACISION HARMONIC SCALPEL System utilizes ultrasonic energy to enable hemostatic cutting and/or coagulation of soft tissue. The system consists of an ultrasonic generator, a foot switch, an optional hand switching adaptor, a hand piece, and a variety of open and minimally invasive instruments.

Note: Throughout this manual “instrument(s)” refers to ULTRACISION HARMONIC SCALPEL blades, ball coagulators, or coagulating shears.

The ULTRACISION instruments vibrate longitudinally at 55.5 kilohertz. This ultrasonic vibration at the blade enhances its cutting ability. The same vibration seals small vessels with coagulated blood and tissue proteins. Hemostasis occurs when tissue couples with the instrument. This coupling causes collagen molecules within the tissue to vibrate and become denatured, forming a coagulum.

Indications

The ULTRACISION HARMONIC SCALPEL System is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The ULTRACISION HARMONIC SCALPEL System instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels.

System Components

Generator 300

The generator supplies the hand piece with electrical energy and facilitates selection of power levels, system monitoring, and system diagnostics.

Power is delivered by activating the foot switch or hand switching adaptor.

Hand Piece

The hand piece contains an acoustic transducer that converts the electrical energy supplied by the generator to mechanical motion. The transducer is connected to an ultrasonic wave guide/amplifier which amplifies the motion produced by the transducer and relays it to the instrument.

Instrument

The mechanical motion from the hand piece advances to the instrument, transmitting ultrasonic energy which enables hemostatic cutting and/or coagulation of tissue.

Power Levels

The generator delivers two power levels: minimum (MIN) and maximum (MAX). The minimum power level may be adjusted by the user from Level 1 to 5. The maximum power level is always Level 5. With all instruments except the ball coagulator, use a higher generator power level for greater tissue cutting speed and a lower generator power level for greater coagulation. For the ball coagulator, higher generator power levels will provide greater coagulation. The amount of energy delivered to the tissue and resultant tissue effects are a function of many factors including the power level selected, instrument characteristics, grip force (when applicable), tissue tension, tissue type, pathology, and surgical technique.

Note: Refer to the instruments' package inserts for additional power level information.

The ULTRACISION® HARMONIC SCALPEL® Generator 300 System consists of the following components: Generator (GEN04), hand piece, instruments, foot switch, and hand switching adaptor (if used). The generator produces an electric signal, which is transmitted via a coaxial cable to the hand piece, which then converts the electrical signal into ultrasonic, mechanical motion.

Hand Piece

The hand piece houses several major components that generate, amplify, and deliver ultrasonic energy to the instrument end-effector. When each component is attached to the other and tuned, an acoustic drive train is formed. Two key parts of the acoustic system or acoustic drive are:

Acoustic Transducer: Converts the electrical energy into motion. When an AC waveform is applied to the transducer, the piezoelectric material expands and contracts to produce longitudinal motion.

Instrument: Couples the ultrasonic energy to the tissue and amplifies motion. In a laparoscopic configuration, the instrument is elongated by means of a "Laparoscopic Extension." This extension allows the ultrasonic energy to propagate from the hand piece to the instrument with minimal loss.

Generator

The generator converts the AC line voltage to a controlled DC level. The DC level is then modulated at the resonant frequency of the hand piece. The modulated signal is then filtered and delivered to the hand piece, where it resonates the acoustic drive train. A more detailed description follows.

Power Entry Module: Accepts a standard, hospital grade utility cord. Refer to Chapter 10 – System Specifications for details. Provides susceptibility filtering from the external environment as well as suppressing electromagnetic emissions produced by the generator that could be conducted back through the power cord.

Power Supply: Provides 48 VDC to DC/DC Converter and Current/Power Regulation Circuit.

Current and Power Regulation Circuit: Provides Current/Power regulation. Current limit circuits protect these assemblies and others from overload conditions.

Patient Isolation Circuit: Provides a safety isolation barrier to patient and/or user. The voltage generated on the secondary of the transformer is isolated from the primary and thereby not referenced to earth ground.

Microprocessor: The microprocessor contains the software program that drives the ULTRACISION HARMONIC SCALPEL Generator 300 System. The software provides the user interface, frequency drive signal, as well as drive signals to the Liquid Crystal Display, front panel indicators, and generator audio circuit.

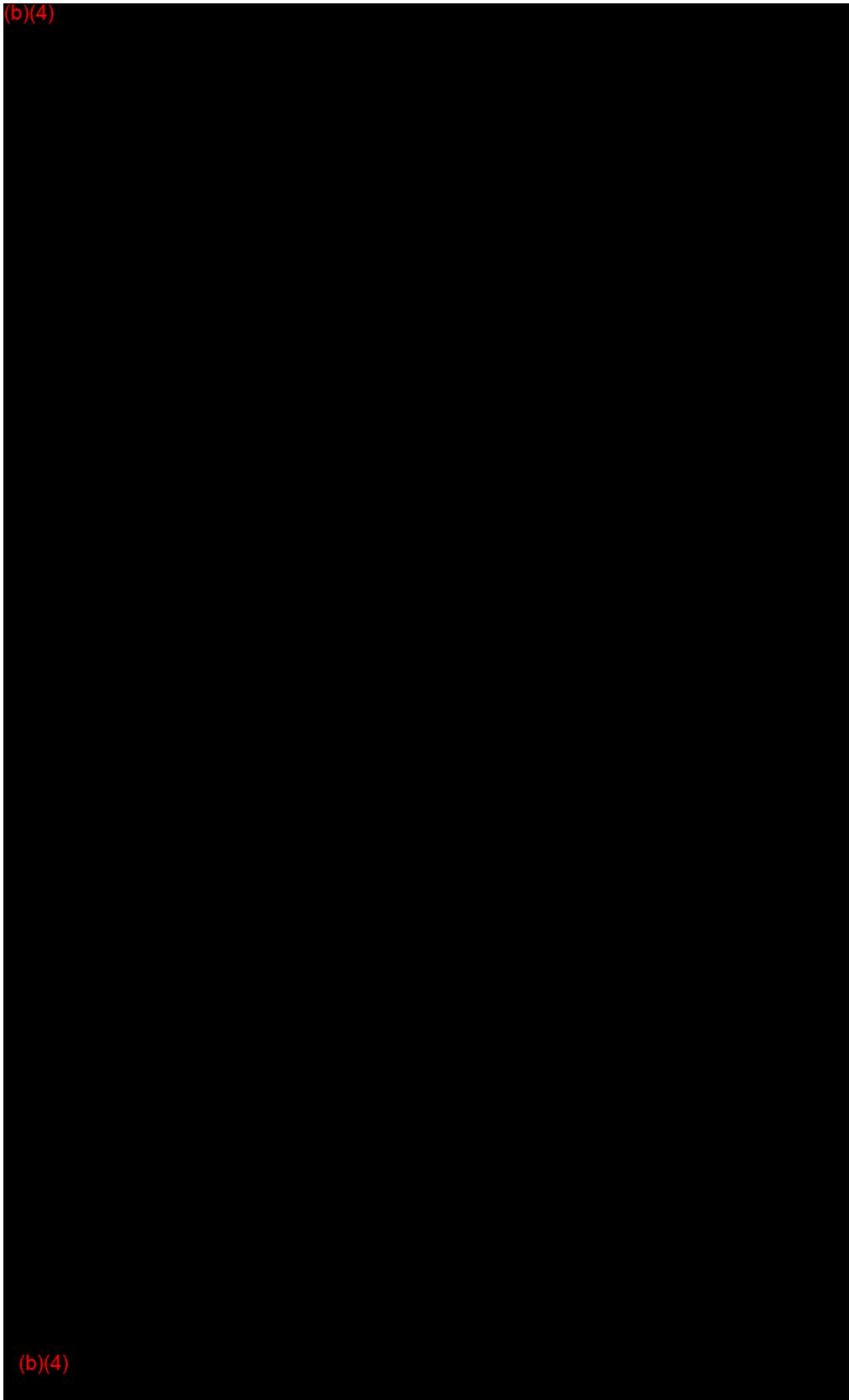
Liquid Crystal Display and Front Panel: The Liquid Crystal Display and front panel indicators report the operating mode of the ULTRACISION HARMONIC SCALPEL Generator 300 System. They are driven by the microprocessor.

Foot Switch and Hand Switching Adaptor

Foot Switch(es): The foot switch(es) allow(s) the user to activate the system in either the minimum (MIN) or maximum (MAX) modes based on which foot pedal is being pressed. Pedal activations are communicated to the microprocessor.

Hand Activation Circuit: The hand switching adaptor allows the user to activate the system in either the minimum (MIN) or maximum (MAX) modes based on which button is being pressed. Hand activations are communicated to the microprocessor.

(b)(4)



(b)(4)

Fig. 3-1 Block Diagram

Unpacking Instructions

The ULTRACISION HARMONIC SCALPEL Generator 300 System includes several components that are purchased separately. Upon receiving the ordered components, check for visible shipping damage. Do not attempt to use any component if it appears damaged. If damage is seen, contact your Ethicon Endo-Surgery representative.

Note: The original packaging should be saved for future storing and/or transporting of the device. Warranty may be voided if the unit is not returned to the service center in the original packaging or equivalent packaging which will protect the unit from damage during shipment.

System components may include the following parts (for product codes, see Chapter 10 – System Specifications):

Generator 300 - includes the generator, power cord, user manual, and service manual.

Note: The User Manual includes a troubleshooting guide (see back pocket of manual binder). Remove the self-adhesive guide's backing and adhere the guide to the top panel of the generator. Placement guides for the Troubleshooting Guide are found on the generator's top panel.

Foot Switch - includes the foot switch and detachable cable assembly.

Note: The foot switch is required if the system will be used with coagulating shears or instruments that are not compatible with the hand switching adaptor. Since the generator has receptacles for two foot switches, two foot switches may have been shipped.

Cart - the cart is optional. It is designed to hold one ULTRACISION HARMONIC SCALPEL Generator. The cart requires assembly; instructions are included with the cart.

Initial Setup

- 1 Confirm that the generator power switch is OFF during setup.

Caution: To avoid injury, in the event that accidental activation occurs, the ULTRACISION HARMONIC SCALPEL instrument blades should not be in contact with drapes or flammable materials while not in use. During prolonged activation, the instrument blades may become hot. Avoid unintended blade contact with drapes, surgical gowns, or other unintended sites after activation.

- 2 Secure the generator on its cart or on another suitable fixture. To secure the generator on its cart, place the generator's rubber feet into the corresponding holes on the cart. Push down on the generator's top panel.

Caution: To prevent overheating during use, ensure that the air vents found on the generator's bottom and back panels are not blocked and that they allow adequate clearance from obstructions to allow air to flow freely through the generator enclosure. Avoid placing the generator on a soft surface.

Warning: The ULTRACISION HARMONIC SCALPEL system must be operated within the required ambient operating conditions. (Refer to Chapter 10 – System Specifications for requirements.)

- 3 Connect the line cord into the AC inlet located on the generator's rear panel and into an appropriately-grounded outlet. If the power cord is wrapped around the cart handle, it must be completely removed from the cart handle prior to plugging it into the power outlet.

Warning: Verify that the outlet voltage correctly corresponds to the generator's requirements (Refer to Chapter 10 – System Specifications). Connection to an improper power supply may result in damage to the generator and risk of shock or fire hazard.

Caution: Do not connect the ULTRACISION HARMONIC SCALPEL Generator 300 to an ungrounded outlet. Grounding reliability can only be achieved when this equipment is connected to a hospital-grade receptacle.

- 4
 - a. Attach the foot switch cable to the foot switch:

Note: Although installation of the foot switch is optional when using the hand switching adaptor, installing the foot switch is recommended in case its use is needed during the procedure.

- Confirm that the connector and receptacle are dry and clean.
- Orient the slot on the foot switch cable's larger connector at 12 o'clock.
- Seat the connector in the foot switch receptacle.
- Turn the connector collar clockwise until tight. Ensure the collar is finger-tight to prevent inadvertent activation that may result from fluid ingress.

b. Connect the foot switch cable's smaller connector to the foot switch receptacle on the rear panel of the generator.

- Confirm that the connector and receptacle are dry and clean.
- Align the red dot on the foot switch 4-pin connector with the red dot on the 4-pin receptacle on the generator back panel.

Note: The generator has two identical foot switch receptacles. If one foot switch is used, either receptacle may be used.

Repeat steps 4a and 4b if a second foot switch will be used.

- 5 Connect the instrument and adaptor (or hand switching adaptor), if required, to the hand piece following instructions in their package inserts.

Note: The hand switching adaptor must be at room temperature to function properly. Do not immerse in water to cool rapidly. After steam sterilization, allow hand switching adaptor to air cool for at least 15 minutes prior to use.

- 6 Connect the hand piece connector to the receptacle on the front panel. Align the white dot on the connector with the white dot on the generator. Ensure the hand piece connector is clean and dry before connecting the hand piece to the generator. Fully insert the hand piece connector to assure complete, proper connection to the generator. (To disconnect the hand piece, firmly grasp the connector and pull the connector away from the generator.)

- 7** Turn the generator power switch on and observe the power-up sequence. During power-up, the following indicators on the front panel will briefly illuminate:
- **READY, STANDBY, MIN, MAX, TEST, ATTENTION, HAND ACTIVATION**

The system will run its start-up sequence and display the software version. An audible tone will sound during the initiation sequence.

Note: The entire power-up initiation sequence should not exceed ten seconds.

If the start-up sequence deviates from the description above, contact qualified service personnel following hospital protocol.

When the initiation sequence is complete, the system will go to Standby. If the system senses a generator, hand piece, or instrument fault during use, an audible alarm (tone with long pulses) will sound and a visual alarm indicator will appear on the control panel. (Refer to Chapter 8 – Troubleshooting or the Troubleshooting Guide located on top of the generator unit to resolve the problem.)

Controls, Indicators, and Connections

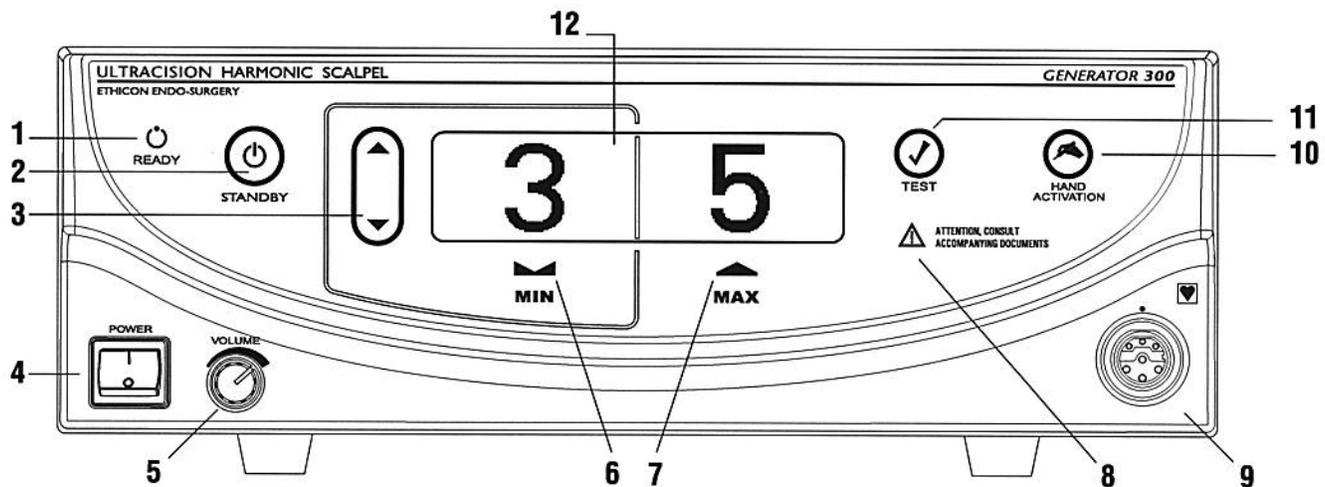


Fig. 5-1 Front Panel

- | | | |
|---|---|---|
| 1 | READY | When this indicator is green, the system is ready for activation. |
| <p>Note: In the Ready mode, for self-diagnostic purposes, the system sends a low-amplitude signal to the blade, causing the blade to vibrate slightly. This vibration does not pose a risk to the user.</p> | | |
| 2 | STANDBY | Push this button to toggle between Standby and Ready modes. In Standby mode, this button, and the STANDBY icon, light up and all power is removed from the hand piece. Both the foot switch and hand switch are disabled. Upon power-up, the system defaults to Standby mode enabled. |
| 3 | INCREASE/
DECREASE POWER
LEVEL | Push this button to increase or decrease the minimum (MIN) power setting to the desired level (from 1 to 5). The level chosen will be shown on the graphic display. The power level may be adjusted when the generator is in Ready or Standby mode. |
| 4 | POWER | This switch controls the main electrical power to the generator. |
| 5 | VOLUME | Turn this knob to adjust the volume of the activation tones. A tone will sound indicating the volume level selected. |
| 6 | MIN | Indicates the user-settable MIN power level setting. When this power level is activated (by foot switch or hand switch), the MIN indicator will flash. On power-up the system defaults to MIN power level 3. Refer to the instruments' package inserts for the recommended MIN power level. |
| 7 | MAX | Indicates the maximum power level setting. This setting is always "5". When this power level is activated (by foot switch or hand switch), the MAX indicator will flash. |
| 8 | ALARM INDICATOR | This red indicator appears only if a system alarm occurs in response to a component or generator problem. |

Screen Descriptions**Power-Up Screen**

Below is an **example** of the Software Version displayed during power-up.

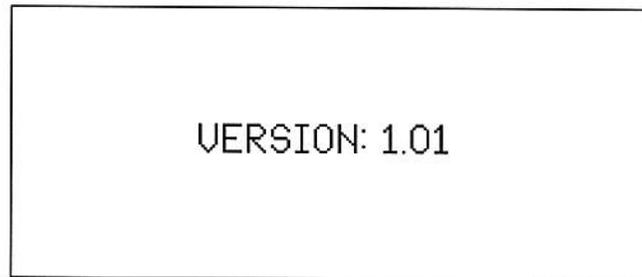


Fig. 5-3 Power-Up Screen

Tone Selection Screen

Refer to Chapter 11 – Adjustments for descriptions of the Tone Selection Screens.

User-Initiated and Pre-Activation Test Screens

The generator will cycle between the following two screens, displaying each screen briefly, for the duration of the time that the system is in the User-Initiated Test state and Pre-Activation Test state. Refer to Chapter 7 – Safety and Function Testing for details.

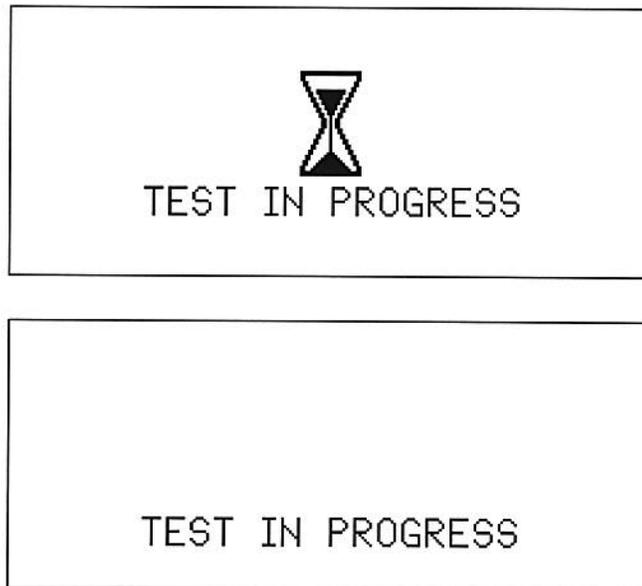


Fig. 5-4 Test in Progress Screens

Standby, Ready and Run Screens

The Standby, Ready, and Run screen appearances depend on the mode in which the system is running. In Normal mode, the Standby, Ready, and Run screens are the same and indicate the MAX power level of 5 on the right, and the user selected MIN power level on the left (1 to 5). In Developer/Biomed mode, the Standby screen indicates the user selected MIN power level on the left, and a subset of system parameters on the right. In Developer/Biomed mode, the Ready screen displays the user selected MIN Power level on the left (1 to 5) and the system run time parameters on the right. Developer/Biomed Run screen is identical to the Developer/Biomed Ready screen.

The following are all possible screens for the Standby, Ready, and Run states in Normal mode. The number on the left indicates the power level for MIN activation (1 to 5), and the number on the right is the power level for MAX activation.

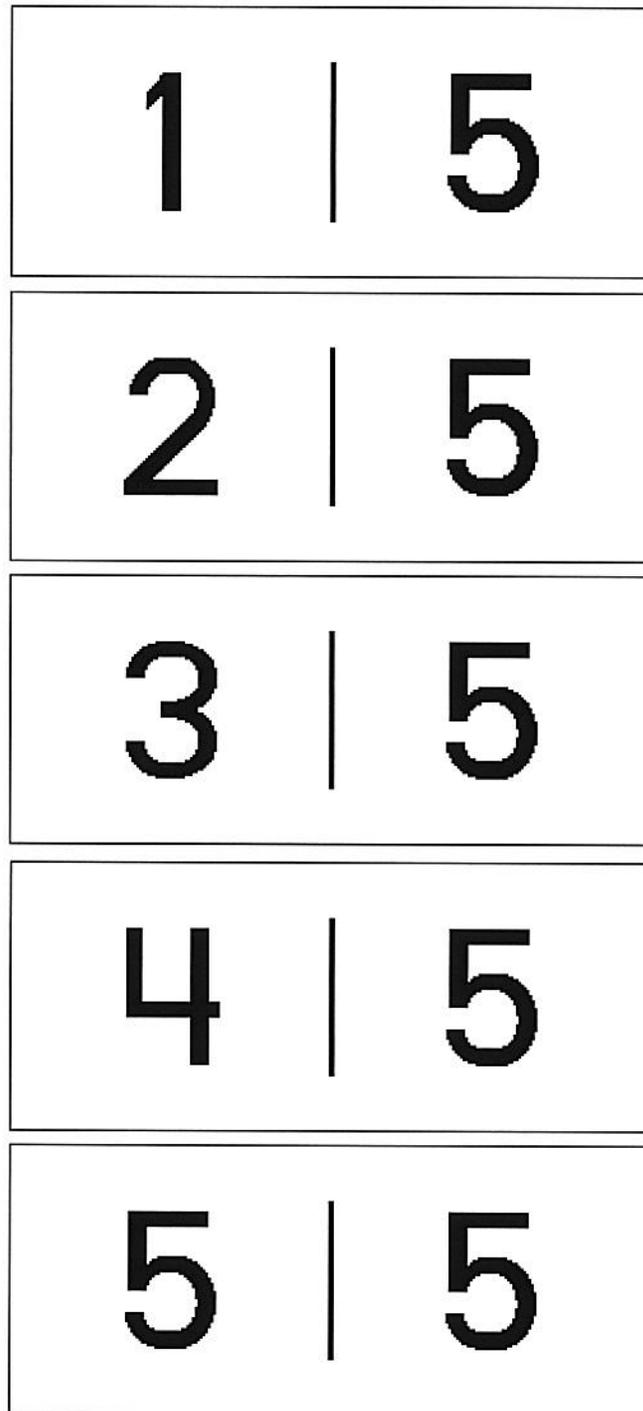


Fig. 5-5 Standby, Ready and Run Screens in Normal Mode

Error Screens

Refer to Chapter 9 – Troubleshooting for examples of each of these screens.

Generator 300 System Service Manual

System Operation

For an understanding of system operation, refer to the ULTRACISION HARMONIC SCALPEL Generator 300 User Manual for instructions and specifications for use of the ULTRACISION HARMONIC SCALPEL Generator 300, Foot Switch, and Cart. Refer to package inserts provided separately for information about the Hand Piece, Hand Switching Adaptor, Adaptors, Test Tip and Instruments prior to using the system. This manual is not a reference to surgical techniques.

After completing system setup, the system may be operated.

- 1 Place the generator in Ready mode by depressing the STANDBY button.

Note: In the Ready mode, for self-diagnostic purposes, the system sends a low-amplitude signal to the blade, causing the blade to vibrate slightly. This vibration does not pose a risk to the user.

- 2 System check and activation:

Each time the generator is activated after exiting Standby, hold the instrument in the air (if coagulating shears are used, open the clamp arm) and depress the MIN or MAX power level on the foot switch or hand switching adaptor. "TEST IN PROGRESS" will appear on the graphic display and a rapid two-tone pulse will sound while the test is occurring. During this five-second period, a system check is being performed.

- If the system is operating properly, the activation tone corresponding to the power level activated will be heard when the check is complete. Stop activation, position the instrument on tissue, and resume activation.
- If the system is not operating properly, an error code will appear (refer to Chapter 8 – Troubleshooting or the Troubleshooting Guide located on top of the generator unit).

Warning: To avoid user or patient injury, ensure that the instrument is clear of other instruments, drapes, the patient or other objects during the system check. Safety measures (in accordance with hospital protocol) taken in the presence of aerosols should be in effect during the system check.

Note: The foot switch or hand switch must be depressed until the system check is complete. If the switch is released prematurely, the check will reinitiate at the next activation.

Note: The HAND ACTIVATION button on the generator control panel must be illuminated for the hand switch to be active. To deactivate the hand switch, depress the HAND ACTIVATION button (if the HAND ACTIVATION button is not illuminated, hand switch will be inactive).

Note: If the hand switch will not turn off during operation, depress the button corresponding to the power level opposite that being activated to turn it off - an alarm will sound. Press the HAND ACTIVATION button to disable the hand switching adaptor. Place the generator in Standby, and replace the hand switch; or, continue using the foot switch after deactivating the hand switch.

- 3 If the system senses a generator, hand piece, or instrument fault during use, an audible alarm (tone with long pulses) will sound and a visual alarm indicator will appear on the control panel. (Refer to Chapter 8 – Troubleshooting or the Troubleshooting Guide on top of the generator unit to resolve the problem.)

Warning: Place the generator in Standby before removing or replacing an instrument, hand switching adaptor or hand piece or when the system is not in use.

Generator 300 System Service Manual

System Shutdown

- 1 Turn the generator power switch off and remove power cord from outlet.
- 2 Disconnect the hand piece, instrument, and adaptor or hand switching adaptor (if used) and process them as indicated in their respective package inserts.
- 3 Clean the generator and cart and disinfect the foot switch(es) following hospital protocol (for recommendations, refer to Chapter 6 – Cleaning and Disinfection).
- 4 Store foot switch(es) on the cart shelves provided. Each shelf will hold one foot switch.
- 5 Wrap foot switch cable(s) and the power cord on the cart's back handle for storage.

Generator and Cart Cleaning

Clean generator and cart following hospital protocol. Before cleaning, turn the generator main power off and unplug the power cord from the grounded electrical outlet.

Warning: Spilling or spraying fluids on or into the generator or immersing the generator may result in damage to the generator and risk of shock or fire hazard.

Proceed with cleaning as follows:

- 1 Prepare a neutral pH detergent or neutral pH enzymatic detergent according to the detergent manufacturer's directions.
- 2 Use a soft, clean cloth lightly moistened with the cleaning solution to manually clean all surfaces (including the generator's display).
- 3 Rinse thoroughly using a soft, clean cloth lightly moistened with warm tap water.
- 4 Dry with a clean, soft cloth.

Foot Switch Cleaning

The foot switch and cable should be cleaned after each use as follows:

- 1 Disconnect the foot switch from the generator.
- 2 Prepare a neutral pH enzymatic detergent according to the detergent manufacturer's directions.
- 3 With the cable securely attached to the foot switch, soak the foot switch and cable in the detergent solution for two minutes.

Note: Keep the foot switch cable connector that connects to the generator dry at all times to prevent inadvertent activation.
- 4 After soaking, use a soft-bristled brush to manually clean the foot switch and cable keeping them immersed in the detergent solution.
- 5 Thoroughly rinse the foot switch and cable – with the cable securely attached to the foot switch – with warm, running tap water for at least one minute.
- 6 Dry all surfaces with a clean, soft cloth.

Test the hand piece, generator, and foot switch for safety and function according to hospital protocol. Refer to individual package inserts for safety and function testing for other multi-patient use components.

Safety Test

Generator: A qualified hospital technician should perform a leakage current test.

Foot Switch: Examine the foot pedals, cable connectors, and cable for cracks or other damage and replace if damaged.

Other Components: Examine the components by following the instructions in their individual package inserts.

Function Test

- 1 Attach the hand piece to the generator as described in Chapter 4 – System Setup, then attach the test tip rather than an instrument.
- 2 Verify that the orange STANDBY indicator is illuminated.
- 3 Push the STANDBY button to leave Standby mode and enter Ready mode.

Note: In the Ready mode, for self-diagnostic purposes, the system sends a low-amplitude signal to the blade, causing the blade to vibrate slightly. This vibration does not pose a risk to the user.

- 4 Verify that the green READY indicator is illuminated.
- 5 Verify that MIN Power Level 3 and MAX Power Level 5 are displayed.
- 6 Push the Increase and Decrease Power Level button up and down to confirm the MIN Power Level changes from 1 to 5.
- 7 Turn the generator off. Wait five seconds, then turn the generator back on. Wait ten seconds, then confirm MIN Power Level 3 and MAX Power Level 5 are displayed. Confirm the generator is not being activated unexpectedly.
- 8 Press the TEST button to perform a User-Initiated Test. The system will run a series of tests to ensure the generator and hand piece are in proper working condition.
- 9 Place the generator in Ready mode by depressing the STANDBY button. Hold the hand piece so that the distal portion is in the air and step on the MAX foot switch pedal (before activation begins, a five-second system check will be performed – “TEST IN PROGRESS” will appear on the display). After the test is completed, verify that the MAX Power Level indicator on the control panel flashes and that the MAX activation tone is heard.

Warning: To avoid user injury, ensure that the test tip is clear of tissue, other instruments, or other objects before activating the system.

- 10 Hold the hand piece so that the distal portion is in air and step on the MIN foot switch pedal. Verify that the MIN Power Level indicator on the control panel flashes and that the MIN activation tone is heard.

Warning: To avoid user injury, ensure that the test tip is clear of tissue, other instruments, or other objects before activating the system.

The ULTRACISION HARMONIC SCALPEL Generator 300 System supports a series of audible and visual alarms, as well as error codes displayed on the unit's LCD, to help in the identification and troubleshooting of problems down to the assembly level (i.e. generator, hand piece, foot switch, hand switching adaptor, etc.). These guides are meant as an adjunct to, but not a substitute for, clinical judgment and observations.

If the problem cannot be resolved using the corrective actions below, contact the Ethicon Endo-Surgery, Inc. Customer Response Center at 1-800-USE-ENDO for assistance. Please have the model number, serial number from the rear panel of the generator, and a detailed description of the problem. The description of the problem should include power settings, accessories used, procedure being performed, and software revision of the unit.

Warning: Electric shock hazard. Always unplug the generator from the wall outlet prior to opening the cover for servicing.

Warning: After removing the cover, inspect the internal components for obvious damage or foreign debris. Never power ON a suspected problem unit.

Generator Power-Up Problems

Ensure the generator unit is plugged into a functioning wall outlet and that the power cord is attached to the rear panel of the generator. If the unit still does not respond, verify that the fuses are intact and properly installed. Note: There are both external and internal fuses in the generator unit. Refer to the Replacement Parts drawings in the back of the manual for fuse locations.

Audible Indicators and Alarms

Tone	Possible Cause and Corrective Action
No tone during power-up.	Generator failure. Contact service personnel.
No tone when system is activated.	<p>Confirm foot switch is fully connected (if hand switching adaptor is not being used).</p> <p>Confirm foot switch is not faulty.</p> <p>If hand switching adaptor is used, confirm it is connected and not faulty.</p> <p>Confirm hand activation is enabled if hand switching adaptor is being used.</p>
Activation (brief pulses)	System is being activated or is in Test mode. System is operating properly. MIN and MAX power have unique tones.
Alert (three-tone sequence)	<p>Activation is attempted while generator is in Standby mode. Push the STANDBY button to return the generator to Ready mode.</p> <p>Two or more foot or hand activation switches are recognized by the generator as being activated simultaneously. Release all activation switches and reactivate using only one switch.</p>

Constant tone	1) Instrument is in contact with too much tissue. Reduce the amount of tissue in contact with the instrument. If tone persists, carefully remove any tissue that has collected in the distal end of the instrument shaft. 2) Hand piece and/or blade fault. Press TEST to identify source of fault.
Prolonged solid tone during activation (exceeds 10 seconds)	Hand piece and/or blade fault. Press TEST to identify source of fault.
Alarm (two-tone sequence)	A component or system problem has occurred. Refer to the Error Codes section in this chapter or the Troubleshooting Guide.

Note: This alarm will activate for three seconds, then will silence itself for 30 seconds. This cycle will continue until the error is resolved or the main power switch is turned off.

Error Codes and Displays

The generator will recognize specific faults in five areas: generator, hand piece, instrument, foot switch or hand switch. When a fault is identified, an alarm will sound, the alarm indicator will appear on the generator control panel, and the source of the problem will appear on the graphic display (the power levels will not be displayed).

Note: For each error code, the generator will cycle between each of the two screens shown in the examples below, with the faulty component flashing.

Follow the procedures outlined below (or in the Troubleshooting Guide on the top of the generator unit) to resolve the problem.

Error Code 1: Generator

Error Code 1 indicates either there is a functional problem with the generator or the front panel button(s) were activated during power-up sequence.
 Cycle the power OFF then ON. If error persists, power off system and contact service.

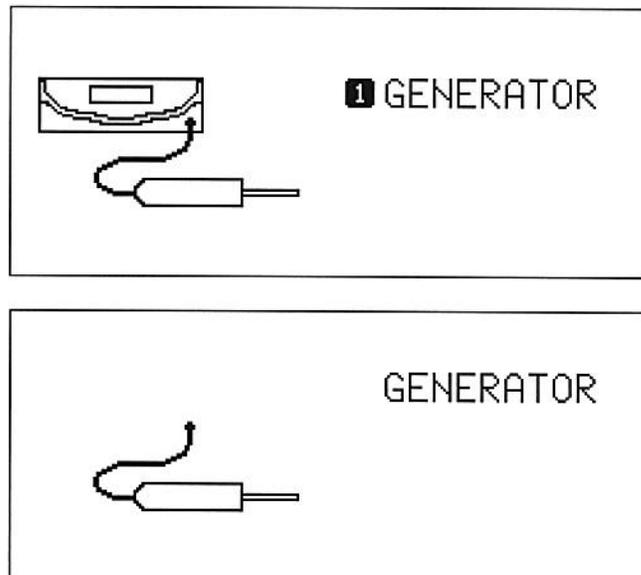


Fig. 8-1 Generator Failure Screens

Error Code 2: Generator Temperature

Error Code 2 indicates that the generator is overheating.

- 1 Power off system. Remove any obstructions blocking the air vents on the generator's bottom and back panels. If there is no apparent obstruction or external heat source, contact service.
- 2 Power on the system and wait for up to 30 minutes for generator error to clear.
- 3 If error code persists, contact service.

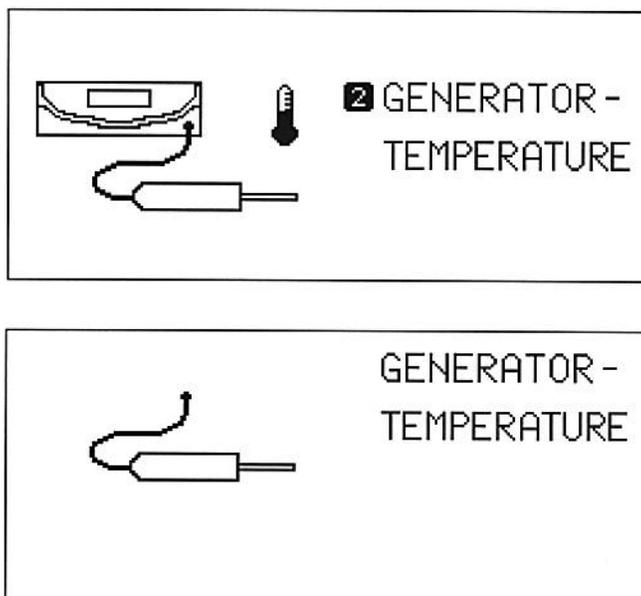


Fig. 8-2 Generator Over-Temperature Error Screens

Error Code 3: Hand Piece

Error Code 3 indicates a problem with the hand piece.

- 1 Confirm that the hand piece connector is fully inserted and properly oriented – white dot on hand piece is aligned with white dot on front panel. If the error code does not clear within three seconds after the hand piece is properly connected, press TEST.
- 2 The instrument may not be tightened properly or tissue may have collected in the distal end of the instrument shaft. Tighten instrument using blade wrench and carefully remove tissue from distal end of instrument sheath. Press STANDBY to clear error code and return to Ready mode. Activate system. If the pre-run test is running, ensure instrument is in air. If using shears, ensure jaws are open and not in contact with any objects during pre-run test.

Note: Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.

- 3 If the error persists, install a test tip to isolate the problem. Press TEST button.
 - If system indicates a hand piece error, hand piece is bad or test tip is bad. Replace hand piece or install a new test tip and press TEST.
 - If no error occurs with test tip attached, replace instrument.
- 4 Press STANDBY to return to Ready mode. Activate system.

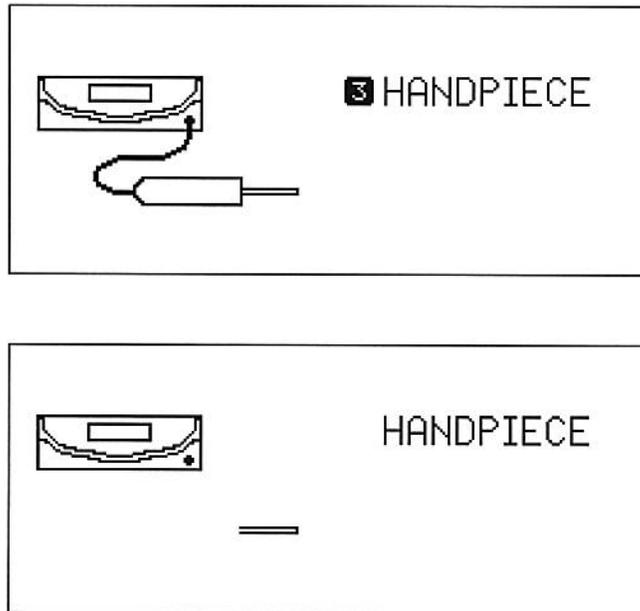


Fig. 8-3 Hand Piece Generic Error Screens

Error Code 4: Hand Piece Temperature

Error Code 4 indicates that the hand piece has exceeded its specified operating temperature. For immediate recovery, use another hand piece; or, follow the steps below to determine the cause of the error condition and alternate recovery methods.

The following are possible causes of an increase in hand piece temperature. To correct, complete the appropriate steps below and *allow the hand piece to cool before resuming operation.*

- 1 The hand piece is still warm from recent steam sterilization. Allow the hand piece to cool at room temperature for at least 45 minutes or, for rapid cooling, soak it in room-temperature sterile water for 5 minutes before resuming operation.

Note: The hand switching adaptor (HSA07) should not be submerged for rapid cooling purposes. This may render the hand switching adaptor inoperable for an extended of time. After steam sterilization, allow the hand switching adaptor to air cool at least 15 minutes prior to use.

- 2 The instrument may not be tightened properly or tissue may have collected in the distal end of the instrument shaft. Tighten instrument using blade wrench and carefully remove tissue from distal end of instrument sheath. Press STANDBY to clear error code and return to Ready mode. Activate system. If the pre-run test is running, ensure instrument is in air. If using shears, ensure jaws are open and not in contact with any objects during pre-run test.

Note: Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.

- 3 If the error persists, install a test tip to isolate the problem. Press TEST button.
 - If system indicates a hand piece error, hand piece is bad or test tip is bad. Replace hand piece or install a new test tip and press TEST.
 - If no error occurs with test tip attached, replace instrument.
- 4 Press STANDBY to return to Ready mode. Activate system.
- 5 If the hand piece does not show evidence of overheating and troubleshooting steps 1-4 above do not appear to resolve the problem, perform the following:
 - a. Leave the hand piece at room temperature for 24 hours or more.
 - b. Remove any test tip or instrument from the hand piece.
 - c. With the generator turned off, plug the hand piece into any Generator 300.
 - d. Power up the generator in Biomed mode.
 - Press and hold down the STANDBY button and down arrow key.
 - Wait for a steady display – approximately 10 seconds.
 - If a “Generator” error occurs, then one of the buttons was not properly held down. If this happens, repeat the power up procedure in Biomed mode.

- e. Record the "XDUCER CAPACITANCE" value.
 - Press the STANDBY button, if necessary, until it illuminates.
 - Use the increase/decrease arrow keys to get to "Page 2 of 21".
 - Record the number opposite "XDUCER CAPACITANCE".
 - Press the STANDBY button until the Standby light turns off.
 - Leave the hand piece plugged into the generator. Do not remove hand piece during entire procedure. Do not activate the MIN or MAX activation buttons on the foot switch or hand switch if either is attached.
 - After a period of time that exceeds 30 or more minutes, press the STANDBY button until the STANDBY icon is illuminated.
 - Again, read the "XDUCER CAPACITANCE" on Page 2 of 21.
 - If the number has changed, the update was successful.
 - If the number has not changed, then this update attempt did not succeed. Power down the generator and repeat Step 5.

Note: As the hand piece ages, the generator performs measurements and updates a key hand piece parameter. This function is performed when the internal temperature of the hand piece is stable at room temperature. Certain usage patterns may prevent this update from occurring and subsequently make the hand piece diagnostics more sensitive to temperature. The steps above will cause an update of the hand piece parameter and return the system to designed sensitivity.

Warning: To avoid user or patient injury, ensure that the instrument is clear of other instruments, drapes, the patient or other objects before pressing TEST. Safety measures (in accordance with hospital protocol) taken in the presence of aerosols should be in effect while in Test mode.

Note: Do not run the Test mode while an electro-surgical generator is being activated in the room. Interference from the electro-surgical generator may affect test results.

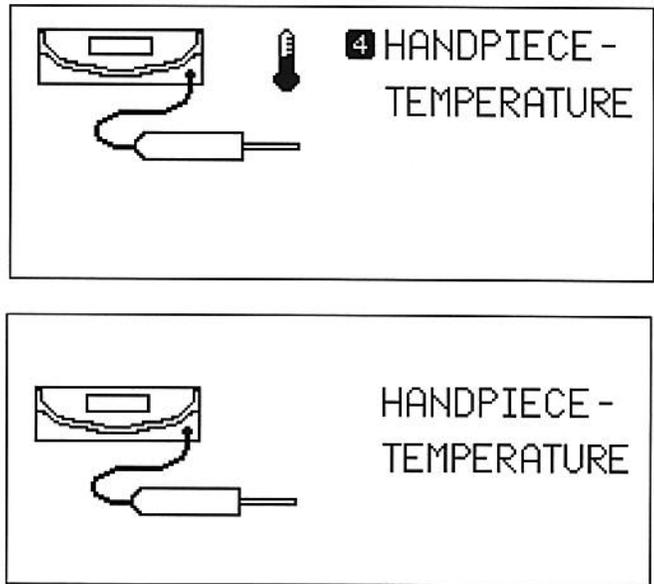


Fig. 8-4 Hand Piece Over-Temperature Error Screens

Error Code 5: Instrument

Error Code 5 indicates a problem with the instrument.

- 1 The instrument may not be tightened properly or tissue may have collected in the distal end of the instrument shaft. Tighten instrument using blade wrench and carefully remove tissue from distal end of instrument sheath. Press **STANDBY** to clear error code and return to Ready mode. Activate system. If the pre-run test is running, ensure instrument is in air. If using shears, ensure jaws are open and not in contact with any objects during pre-run test.

Note: Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.

- 2 If the error persists, install a test tip to isolate the problem. Press **TEST** button.
 - If system indicates a hand piece error, hand piece is bad or test tip is bad. Replace hand piece or install a new test tip and press **TEST**.
 - If no error occurs with test tip attached, replace instrument.
- 3 Press **STANDBY** to return to Ready mode. Activate system.

Note: Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.

Warning: To avoid user or patient injury, ensure that the instrument is clear of other instruments, drapes, the patient, or other interference before pressing TEST. Safety measures (in accordance with hospital protocol) taken in the presence of aerosols should be in effect while in Test mode.

Note: Do not run the Test mode while an electrosurgical generator is being activated in the room. Interference from the electrosurgical generator may affect test results.

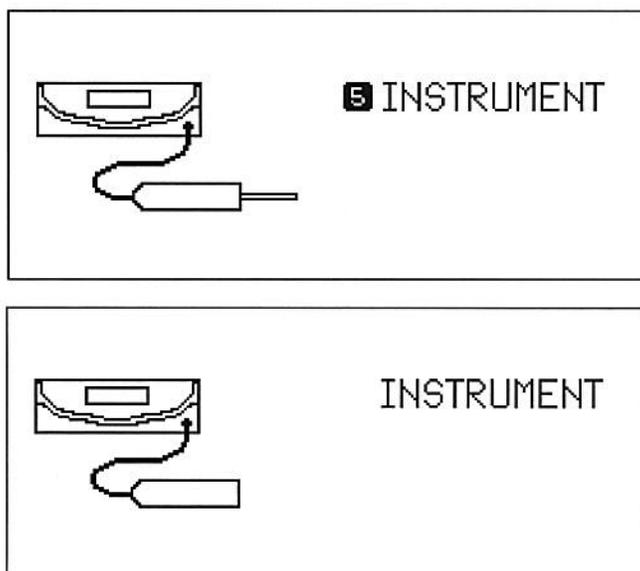


Fig. 8-5 Instrument Generic Error Screens

Error Code 6: Foot Switch

Error Code 6 indicates a foot switch pedal is stuck in the ON position. Confirm generator receptacle, foot switch receptacles and cable connectors are clean and dry or replace the foot switch.
Note: If the error persists, replace foot switch.

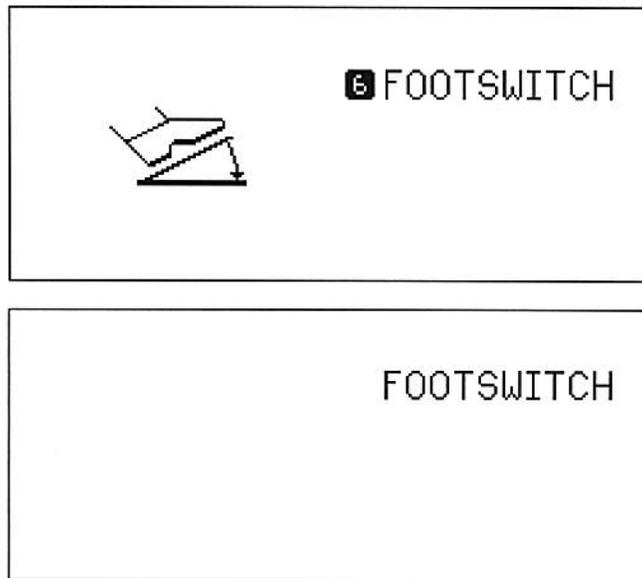


Fig. 8-6 Foot Switch Assembly Error Screens

Error Code 7: Hand Switch

Error Code 7 indicates the hand switch is stuck in the ON position. Confirm contacts in the distal end of hand piece and in the proximal end of the hand switching adaptor are dry or replace the hand switching adaptor.
 Note: If the error persists, replace hand switch.

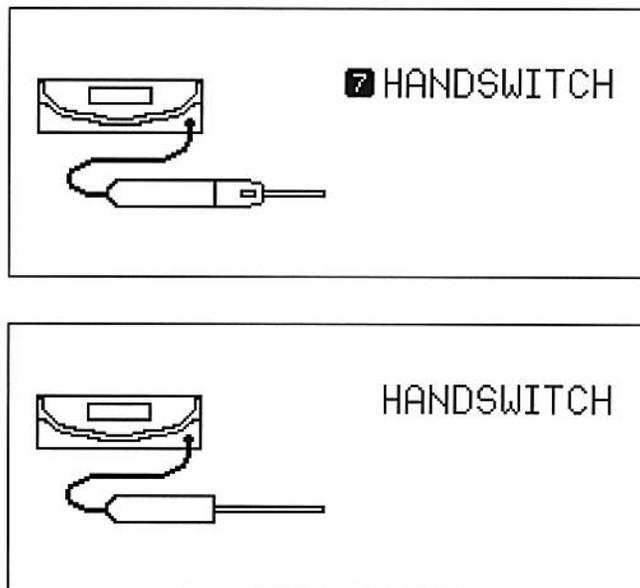


Fig. 8-7 Hand Activation Assembly Error Screens

Components Needed

- 1 ULTRACISION HARMONIC SCALPEL Hand Piece (HP054/HP055)
- 1 ULTRACISION HARMONIC SCALPEL Hand Piece Test Tip (HST02)
- 1 ULTRACISION HARMONIC SCALPEL Foot Switch (FSW01) or Hand Switching Adaptor (HSA07)
- Torque Blade Wrench (TLB01)

Equipment Needed

- DMM (Digital Multi-Meter) with the following specifications:
 - True RMS Voltage Measurements
 - 300 kHz Minimum Bandwidth
 - 4 Digits Minimum Resolution
 - ACRMS Tolerance
- Screwdriver

Required Schedule

Calibration is **required** on the ULTRACISION HARMONIC SCALPEL Generator 300 every **twelve months**.

Proof of calibration should be documented according to hospital procedures.

Generators can be returned to Ethicon Endo-Surgery, Inc. for calibration, but this is not covered in the warranty. A minimal charge will be assessed. This can be done by calling 1-800-USE-ENDO (U.S. Customers). International Customers should contact their Ethicon Endo-Surgery, Inc. representative for assistance.

Calibration Procedures

Complete the following Calibration procedures every 12 months according to hospital procedures.

Caution: Use proper hospital safety procedures when performing a calibration.

Calibration One

The Calibration One procedure is used to enter/input the Level 3 current read by an external, calibrated meter.

Step		Result
1	Unplug all connections to the generator. Remove the generator cover by removing the casing screws and sliding the cover towards the back of the unit.	<input type="checkbox"/>
2	Connect hand piece and foot switch (or hand switching adaptor) to their respective connections on the uncovered generator. Attach a test tip to the hand piece, and torque on using a torque blade wrench.	<input type="checkbox"/>
3	Connect a power cord to the uncovered generator. Use caution when working around generator components while the generator is powered ON.	<input type="checkbox"/>
4	Enter Developer/BME mode by simultaneously holding the STANDBY button and DOWN arrow button on the generator while powering ON. The Developer/BME mode screen will be displayed. The buttons can be released when the indicator icons light up.	<input type="checkbox"/>
5	Scroll to Page 2, using the UP and DOWN arrow buttons. Record the 'Current Setpoint' value.	____mA
6	75% of the value recorded in Step 5 is the Level 3 current. Calculate and record this value by multiplying the Step 5 value above by 0.75 .	____mA
7	Press the STANDBY button to enter READY state.	<input type="checkbox"/>
8	Set the MIN level to Level 3 (this is the default level).	<input type="checkbox"/>
9	Activate the hand piece at Level 3 by pressing the MIN foot switch pedal, or activating the MIN hand switching adaptor button. Ensure the test tip is activating in air and is not in contact with anything. Allow the Pre-Run tests to complete.	<input type="checkbox"/>
10	While continuing to press the MIN Level 3 foot switch pedal or MIN hand switching adaptor button, measure the RMS voltage across both current-sense resistors on the main board, R233 and R234 (which are in series). To measure using probes, place the positive and negative probes on the outside of each of the resistors R233 and R234, respectively. To measure using alligator clips, clip to the post of R229 closest to R233, and to the post of C177 closest to R234. Either of these connection schemes (probes or clips) will measure the voltage across R234 and R233 as required. Note: This measurement MUST be taken with a Digital Multi-Meter (DMM) consistent with the specifications listed in the Equipment Needed section of this manual. Using a DMM that does not meet these specifications will cause errors in the calibration procedure.	<input type="checkbox"/>
11	Record the DMM voltage from Step 10, to four digits of precision. The two resistors in series are a total of 1 ohm, so the value measured in volts is equivalent to the current in amperes. ($V=IR$) Record this equivalent current.	____mA
12	Deactivate the hand piece by releasing the foot switch or hand switch MIN or MAX button.	<input type="checkbox"/>

- 13 While in Developer/BME mode, press STANDBY to enter the Standby state.
- 14 Scroll to Page 17 by using the UP and DOWN arrow buttons.
- 15 Adjust the VOLUME knob to obtain the Level 3 current recorded in Step 11. Press the TEST button when this value is displayed on the screen.
- 16 The text 'Value Accepted!' should flash twice if the calibration was successful.
- 17 Power OFF the generator for a few seconds. Power ON the generator and enter Developer/BME mode by simultaneously holding down the STANDBY button and the DOWN arrow button on the generator while powering ON. The buttons can be released when the indicator icons light up.
- 18 Press the STANDBY button to enter the Ready state.
- 19 Activate the hand piece using the MIN foot switch pedal or MIN hand switching adaptor button at Level 3. Allow the Pre-Run tests to complete.
- 20 While continuing to press the MIN Level 3 footswitch pedal or MIN hand switching adaptor button, again, measure the VAC RMS output voltage simultaneously across **both** of the current-sense resistors, R233 and R234, as in Step 10 above.
- 21 Verify the current in Step 20 is within 1% of the Step 6 calculated value. ____mA
- 22 Power OFF the generator and continue to the Calibration Two procedure.

Serial Number _____ Results _____ Pass _____ Fail
 Software Version _____

Completed By _____ Date _____

Calibration Two

The Calibration Two procedure is used to confirm the output read by the generator is correct and to enter this confirmation. This procedure is performed without an external meter. The Calibration One procedure must be performed prior to the Calibration Two procedure.

Step		Result
1	Connect hand piece and foot switch (or hand switching adaptor) to their respective connections on the generator. Attach a test tip to the hand piece, and torque on using a torque blade wrench.	<input type="checkbox"/>
2	Enter Developer/BME mode by simultaneously holding the STANDBY button and DOWN arrow button on the generator while powering up. The Developer/BME mode screen will be displayed. The buttons can be released when the indicator icons light.	<input type="checkbox"/>
3	Scroll up to Page 2, using the UP and DOWN arrow buttons. Record the 'Current Setpoint' value.	____mA
4	75% of the value recorded in Step 3 is the anticipated Level 3 current. Calculate and record this value by multiplying the Step 3 value above by 0.75.	____mA
5	Go to Ready mode and activate the generator at Level 3 for more than one second after the pre-run test is completed, using the MIN foot switch or hand switching adaptor button. Ensure the test tip is activating in air and is not in contact with anything.	<input type="checkbox"/>
6	Deactivate the hand piece by releasing the foot switch or hand switching adaptor buttons.	<input type="checkbox"/>
7	While in Developer/BME mode, press the STANDBY button.	<input type="checkbox"/>
8	Scroll to Page 18 using the UP or DOWN arrow buttons.	<input type="checkbox"/>
9	Press the TEST button to accept the Level 3 calibration current value. Record the current displayed on the screen.	____mA
10	The text 'Value Accepted!' should flash twice if the calibration procedure was successful.	<input type="checkbox"/>
11	Power OFF the generator. Enter Developer/BME mode by simultaneously holding down the STANDBY button and the DOWN arrow button while powering ON generator.	<input type="checkbox"/>
12	Press the STANDBY button to enter the Ready state.	<input type="checkbox"/>
13	Activate the hand piece at Level 3 by pressing the MIN foot switch pedal, or activating the MIN hand switching adaptor button for more than one second. Ensure The test tip is activating in air and not in contact with anything. Press the STANDBY button to enter the Standby state.	<input type="checkbox"/>
14	Record the current displayed on Page 18.	____mA
15	Verify that the reading in Step 13 is within 1% of the the value from Step 4. If not, carefully re-execute both the Calibration One and Calibration Two test procedures again.	<input type="checkbox"/>

Serial Number _____ Results _____ Pass _____ Fail
 Software Version _____

Completed By _____ Date _____

Product Codes**Required Components for System Operation:**

GEN04: Generator 300

HP054/HP055: Hand Piece (includes HST02 Test Tip and

TLB01 Torque Blade Wrench)¹**Instruments and Adaptors:**

Contact your Ethicon Endo-Surgery representative for information about instruments available for use with this system. Some instruments may require use of an adaptor.

Optional Components:FSW01: Foot Switch²HSA07: Hand Switch^{1,2}

CRT01: Cart

¹ Refer to separate product insert supplied with this component.² At a minimum, either the foot switch or the hand switching adaptor is required to operate the generator. When the hand switching adaptor is used, availability of the foot switch is recommended.**Degree of Protection
Against Electric Shock**

Type CF Applied Part

**Class of Protection
Against Electric Shock**

Class I

Safety Standards

EN 60601

**Degree of Protection
Against Harmful Ingress
of Water**

Generator: Ordinary equipment

Footswitch: IPX8

Safety Classification

UL 2601-I

CSA C22.2 601.1

EN 60601-I

Mains Input

Voltage: 100-240 VAC

Frequency: 50/60 Hz

Current Consumption: 3 amp

**Ambient Operating
Conditions**

Temperature: 18°C to 23°C

Humidity: 10-90% non-condensing

Atmospheric Pressure Range: 700hPa-1060hPa

**Transport and Storage
Conditions**

Temperature: -35°C to +54°C

Humidity: 10-95% non-condensing

Atmospheric Pressure Range: 700hPa-1060hPa

Date of Manufacture	The date of manufacture may be determined by viewing the serial number on the rear panel of the generator. The fourth and fifth characters indicate the year of manufacture as follows: GN401 = year 2001 GN402 = year 2002 GN403 = year 2003 GN404 = year 2004 GN405 = year 2005
Power Cord	North American removable power cord set with the following characteristics: Plug Style: NEMA 5-15 (clear) North American Hospital Grade Receptacle: IEC 60320 C13 with straight non-angled cord entry Cord Length: 4.6 meters nominal Current Rating: 13A Voltage Rating: 125 VAC minimum Wiring Code: North American Cordage Description: SJT (UL) or SJT (CSA) Conductors: 16 AWG 3C Agency Approvals Required: UL and CSA International removable power cord set with the following characteristics: Plug Style: as needed by particular country requirements Receptacle: IEC 60320 C13 with straight non-angled cord entry Cord Length: 2.44 - 4.6 meters nominal Current Rating: 10A Minimum conductor size cross-sectional area: 1.0 mm ² copper Voltage Rating: 250 VAC minimum Wiring: international Cordage Type: HAR Item to have certification by at least one of the following agencies: VDE, ASTA, SEMKO, KEMA, LCIE, DFT, IMQ, SEV
Duty Cycle	Duty Cycle is determined by hand piece and instrument in use. For duty cycle information, refer to applicable instrument(s) and hand piece inserts and/or Chapter 7 – Warnings and Precautions of the Generator 300 System User Manual.
Weight (unpacked)	Generator: 7.48 kg nominal Cart: 42.0 kg nominal
Overall Dimensions	Generator 300 (HxWxD): 5.3" (13 cm) x 14.5" (37 cm) x 15.2" (39 cm) Cart (HxWxD): 37.3" (95 cm) x 17.7" (45 cm) x 27.6" (70 cm), including handle
Disposal	Some internal components of the generator, foot switch and foot switch cable contain lead. Disposal should be performed according to local requirements and regulations.
Torque Requirements	

Item	Torque	Units	Thread Locker	QTY	Comments
Front Bezel, Volume Control	6	In-Lb	No	1	long socket required
Front Bezel, Handpiece Receptacle	24	In-Lb	No	1	torqued with open-end torque wrench
Front Bezel, LCD	7	In-Oz	Yes	4	Phillips, Loctite 222
Front Bezel to Chassis	11	In-Lb	No	5	Phillips
Fan to Chassis	11	In-Lb	No	4	standard socket
Footjack Connectors to Chassis	11	In-Lb	No	2	long socket required
Speaker to Chassis	11	In-Lb	No	4	Phillips
Silver Ribbon Cable from Front Panel Switches	11	In-Lb	No	1	Phillips
Fuse Holders to Chassis	6	In-Lb	No	2	long socket required
Power Entry Module to Chassis	6	In-Lb	No	2	Phillips & hold the nut
Ground Pin-to-Chassis	6	In-Lb	No	1 nut	Special tool used to engage
Ground Pin Nut	18	In-Lb	No	1	standard socket
Ground Wires to Chassis	18	In-Lb	No	2	Phillips
Power Supply to Chassis	7	In-Lb	Yes	2	Phillips, Loctite 222
Generator PC Board to Chassis	18	In-Lb	No	15	Phillips
Cover to Chassis	18	In-Lb	No	11	Phillips

Power Level Adjustment

Upon start-up, the generator defaults to power level 3 (MIN) and 5 (MAX). The minimum (MIN) power level is user-settable from power levels 1 to 5. To adjust the power level, depress the UP/DOWN arrow button to the left of the MIN power level display. Set the power level based on surgeon preference and/or recommendations provided in the instrument's package insert (for more information, see Power Levels section in Chapter 2 – General Description).

Audible Activation Tone Adjustment

The generator has three activation tone sets from which to choose (the mid-pitch tone is factory set). To choose another tone:

- 1 Switch power off.
- 2 Switch power on. Then immediately depress and hold both the STANDBY and HAND ACTIVATION buttons. When the graphic shown in Fig. 11-1 appears on the display, release the STANDBY and HAND ACTIVATION buttons.
- 3 While in the Tone Selection mode, the generator will automatically sequence through the available tone pitches. To select a tone, depress any button on the control panel. The generator will return to Standby mode. The tone chosen will be saved until it is changed again by accessing the Tone Selection mode.
- 4 Adjust tone volume by turning the knob on the lower left corner of the control panel. A tone will sound to indicate the volume level selected.

Note: For safety reasons, the audible tone may not be disabled. The audible tone volume for alarms cannot be changed.

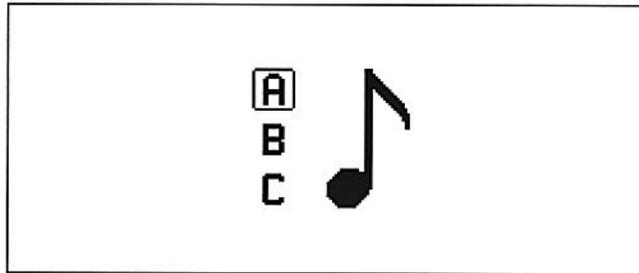


Fig. 11-1 Display: Tone Selection A

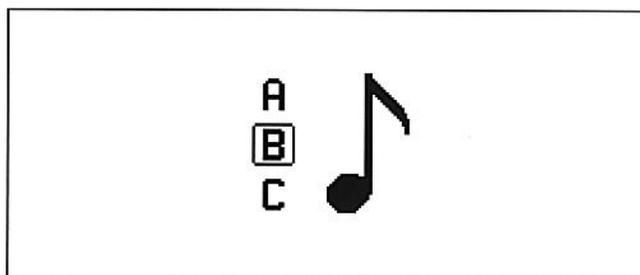


Fig. 11-2 Display: Tone Selection B

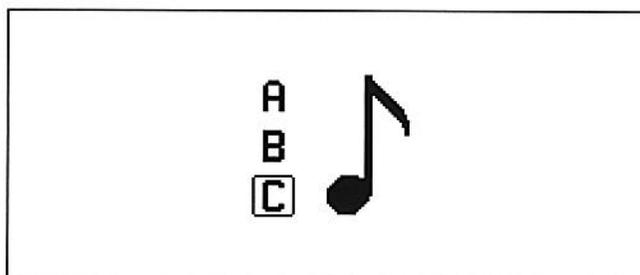


Fig. 11-3 Display: Tone Selection C

Repair Strategy

- Thorough knowledge of the ULTRACISION HARMONIC SCALPEL Generator 300 System User Manual and this manual is mandatory prior to attempting any repair.
- Loaner units may be provided free of charge for units which are being repaired under warranty.
- Calibration is not covered by any warranty. There will be a nominal charge for the manufacturer to perform the Calibration Procedure.
- Only those replacement parts designated in the Spare Parts List below are available for sale.
- Use only Ethicon Endo-Surgery, Inc. approved replacement parts. Your Ethicon Endo-Surgery, Inc. representative will be happy to assist you in obtaining replacement parts.
- Replacement parts can be purchased from Ethicon Endo-Surgery, Inc. by calling 1-800-USE-ENDO (U.S. Customers) or by contacting an Ethicon Endo-Surgery, Inc. representative (outside the U.S.).

Spare Parts List

Below is a list of spare parts which can be ordered through Ethicon Endo-Surgery, Inc. for the ULTRACISION HARMONIC SCALPEL Generator 300 System. The reference numbers below correspond to reference numbers on the Main Assembly Drawing in the back cover of this manual and the Package Assembly Drawing on p. 51 of the manual.

Reference No.	Part No.	Description
1	D06358P01	Fuse Label
2	D06363P01	Back Panel Label
3	3583.036	Bezel Sub-Assembly
4	3583.038	Cover Enclosure
5	3583.053	Cable Assembly, Hand Piece Receptacle
6	3583.060	Cable Assembly, Earth Terminal – Chassis
7	3583.061	Cable Assembly, Power Entry – Chassis
8	3583.062	Cable Assembly, Fuse Holder – AC Switch
9	3583.064	Cable Assembly, Volume Control – Generator Board
10	3583.065	Cable Assembly, Fan with Cable Assembly
11	3583.066	Cable Assembly, Speaker with Cable Assembly
12	3583.067	Cable Assembly, Power Supply – Generator Board
13	3583.070	Cable Assembly, Power Entry – Fuse Holder
14	3583.073	Cable Assembly, Foot Switch - Generator Board
15	3583.079	LCD Display PCB
16	3583.112	Wire Assembly, AC Switch – Power Supply
17	3583.123	Power Cord, 13 Amps, 125 Volts, 15 feet
18	3583.125	Label, Tamper Evident
19	600-000234	Power-on Rocker Switch
20	620-000243	Fuse 3.15 Amps, 250 Volts, Slo-Blo
21	640-000268	Ferrite Clamp/Bracket 279 @100MHz
22	700-000038	Hardware, Nut 8-32 (for fan assembly)
23	700-000394	Hardware, Phillips 8 – 32 x 5/16 (for ground to chassis)
24	700-000504	Hardware, Phillips 4 – 40 x 3/8
25	700-000884	Hardware, KNut 4-40
26	700-001497	Hardware, Ground Pin
27	700-001653	Hardware, Knob
28	700-001662	Hardware, Feet, Rubber Black, with screw
29	700-001663	Hardware, Fuseholder, 5 x 20 PNL MNT

30	700-001664	Hardware, Phillips 8 – 32 x 5/16
31	700-001665	Hardware, Phillips 8 – 32 x 1-1/4 (for fan assembly)
32	700-001666	Hardware, Lockwasher, for Hand Piece
33	700-001667	Hardware, Bushing (Wire Protectors)
34	700-001668	Hardware, Grommet
35	700-001749	Hardware, Phillips 6 – 32 x 5/16
36	700-001767	Hardware, Hnut 3/4 – 16 x 7, 8 x 5/32
37	700-001806	Hardware, Standoffs for fan
38	800-003007	Power Entry Module
39	875-000358	Power Supply, 48 Volt
40	950-000443	Packaging, Bag, Anti-Static 24 x 30; Pink
41	950-000530	Packaging, End Caps
42	950-000531	Packaging Carton, 18 x 19
43	700-000250	Hardware, Phillips 8 – 32 x 1/2, Secure Main Board
44	900-000266	Tystrap
45	3583.047	Generator PCB, Main
46	3583.042	Chassis Sub-Assembly
47	997-Q8	Quick Disconnect Foot Switch (GEN04)
48	N/A	Power Supply Fuse, 5 Amp, 250 Volt

Note: Refer to Chapter 10 - System Specifications for torque requirements.

Available Resources

- An Ethicon Endo-Surgery, Inc. Sales Representative is available for assistance.
- The Ethicon Endo-Surgery, Inc. Customer Response Center is available for Biomedical engineering support by calling 1-800-USE-ENDO (U.S. Customers). Customers outside the U.S. should contact their Ethicon Endo-Surgery, Inc. representative for assistance.

Service and Repair Returns

U.S. - All service inquiries in the US should be initiated by calling 1-800-USE-ENDO. A Customer Service representative will walk the customer through the equipment return process and identify the location where to ship the equipment.

Outside the U.S. – Customers should contact their Ethicon Endo-Surgery, Inc. representative for instructions.

Prior to sending your generator in for service:

- Obtain a Return Goods Authorization Number by calling 1-800-USE-ENDO.
- Package the generator in the original packaging with the tag indicating the return address information, a description of the problem, and your Return Goods Authorization Number.

Note: Warranty may be voided if the unit is not returned to the service center in the original packaging or equivalent packaging which will protect the unit during shipment.

- Ship the generator prepaid to Ethicon Endo-Surgery, Inc. Service Department.

This warranty and the rights and obligations hereunder shall be construed under and governed by the laws of the State of Ohio, U.S.A.

Ethicon Endo-Surgery, Inc. warrants this product to be free from defects in material and workmanship under normal use and preventive maintenance for the respective warranty period shown below. Ethicon Endo-Surgery's obligation under this warranty is limited to the repair or replacement, at its option, of any product, or part thereof, which has been returned to Ethicon Endo-Surgery, Inc. or its Distributor within the applicable time period shown below and which examination disclosed, to Ethicon Endo-Surgery's satisfaction, to be defective. This warranty does not apply to any product, or part thereof, that has been: (1) adversely affected due to use with devices manufactured or distributed by parties not authorized by Ethicon Endo-Surgery, Inc. (2) repaired or altered outside Ethicon Endo-Surgery's factory in a way so as to, in Ethicon Endo-Surgery's judgement, affect its stability or reliability, (3) subjected to improper use, negligence or accident, or (4) used other than in accordance with the design and use parameters, instructions and guidelines for the product or with functional, operational or environmental standards for similar products generally accepted in the industry.

Ethicon Endo-Surgery's products are warranted for the following periods after delivery to the original purchaser:

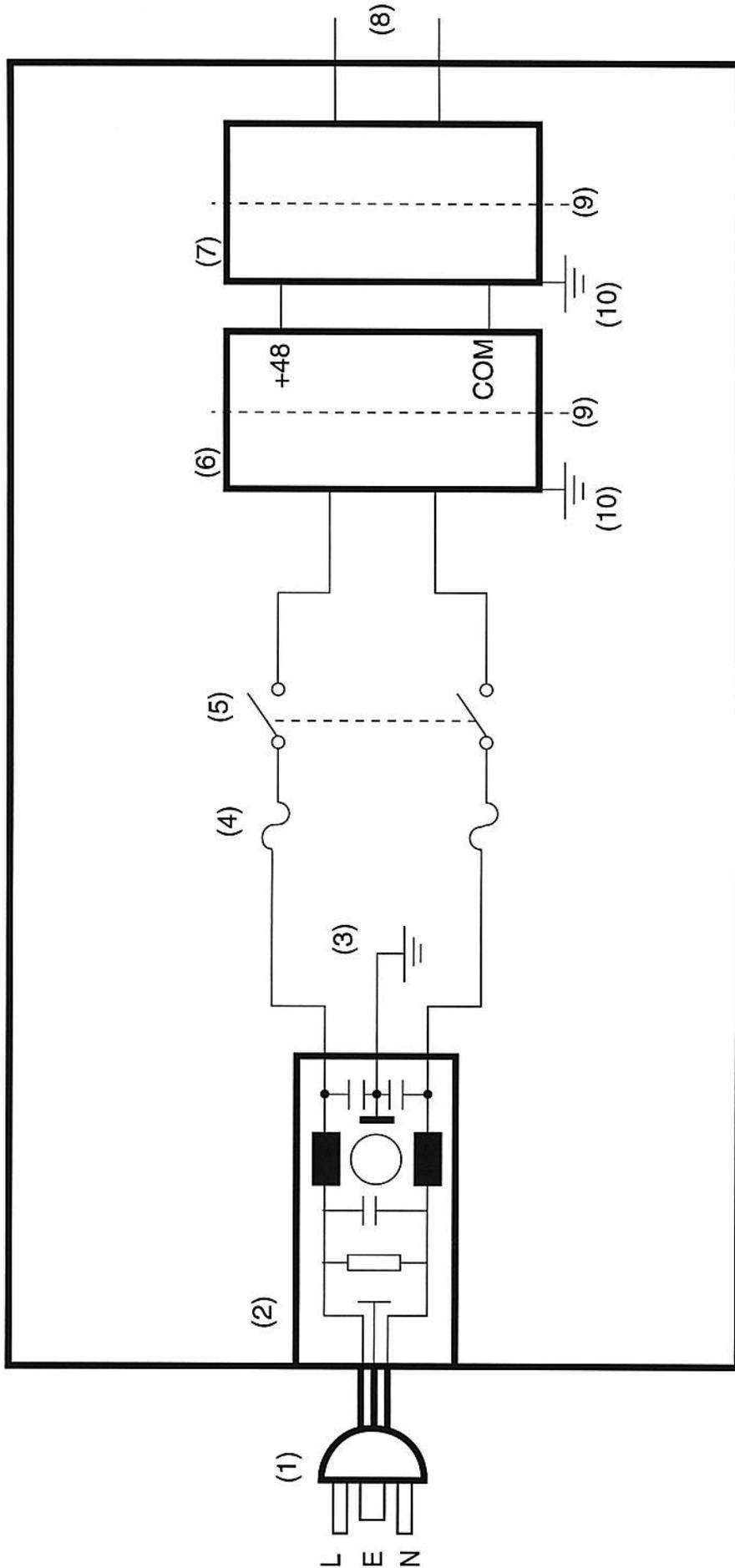
Hand Pieces	Nine (9) Months, Parts and Labor
Generators	One (1) Year, Parts and Labor
Carts	One (1) Year, Parts and Labor
Foot Switches and Cables	One (1) Year, Parts and Labor
Sterilization Tray	One (1) Year, Parts and Labor

UNLESS SUPERCEDED BY APPLICABLE LOCAL LAW, THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON THE PART OF ETHICON ENDO-SURGERY, INC. AND IS A PURCHASER'S EXCLUSIVE REMEDY. IN NO EVENT SHALL ETHICON ENDO-SURGERY, INC. BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES INCLUDING, WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, PROFITS, BUSINESS OR GOODWILL, OTHER THAN AS EXPRESSLY PROVIDED BY A SPECIFIC LAW. Ethicon Endo-Surgery, Inc. neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any of Ethicon Endo-Surgery Inc. products. There are no warranties that extend beyond the terms hereof.

Ethicon Endo-Surgery, Inc. reserves the right to make changes to products built and/or sold by them at any time without incurring any obligation to make the same or similar changes on products previously built and/or sold by them.

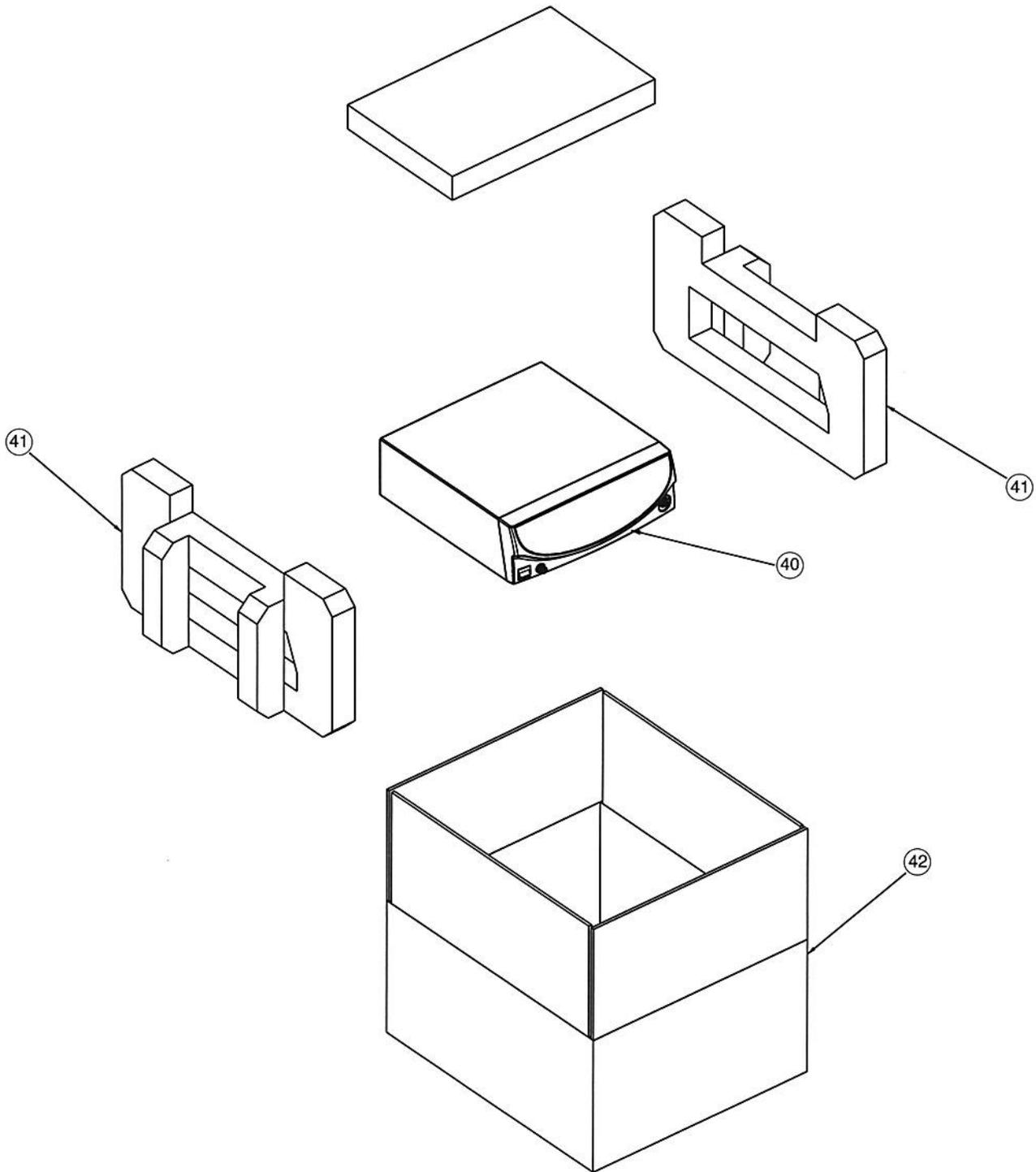
	On		Fuse
	Off		Safe working load
	Type CF Applied Part		Test
LOT	Lot		Hand Activation
	Temperature		Volume
	Relative Humidity		Minimum
	Attention - Consult Accompanying Documents/See Instructions For Use		Maximum
NON-STERILE	Non-Sterile		Ready
	Date of Manufacture		Standby
	Fragile	REF	Reorder Number
	This end up		Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Keep dry		ON/OFF Time for Intermittent Operation. Refer to the individual package insert and/or Chapter 1 – Warnings and Precautions for additional specifications.
	Increase/Decrease		Foot switch
SN	Serial Number		
	Equipotential		

Mains Power Wiring Diagram for Harmonic Scalpel Generator 300



- (1) - Universal AC Mains Input
- (2) - Power Entry Module
- (3) - Protective Earth Copnnection to Chassis
- (4) - Mains Fuses, 3.15A, 250V, IEC Type 'T'
- (5) - DPDT Mains Switch

- (6) - 48VDC Medical Grade Power Supply
- (7) - Generator PCB
- (8) - Isolated Transducer Drive / Patient Connection
- (9) - Isolation Barriers
- (10) - Functional Earth Connections to Chassis





(REF)
GEN04

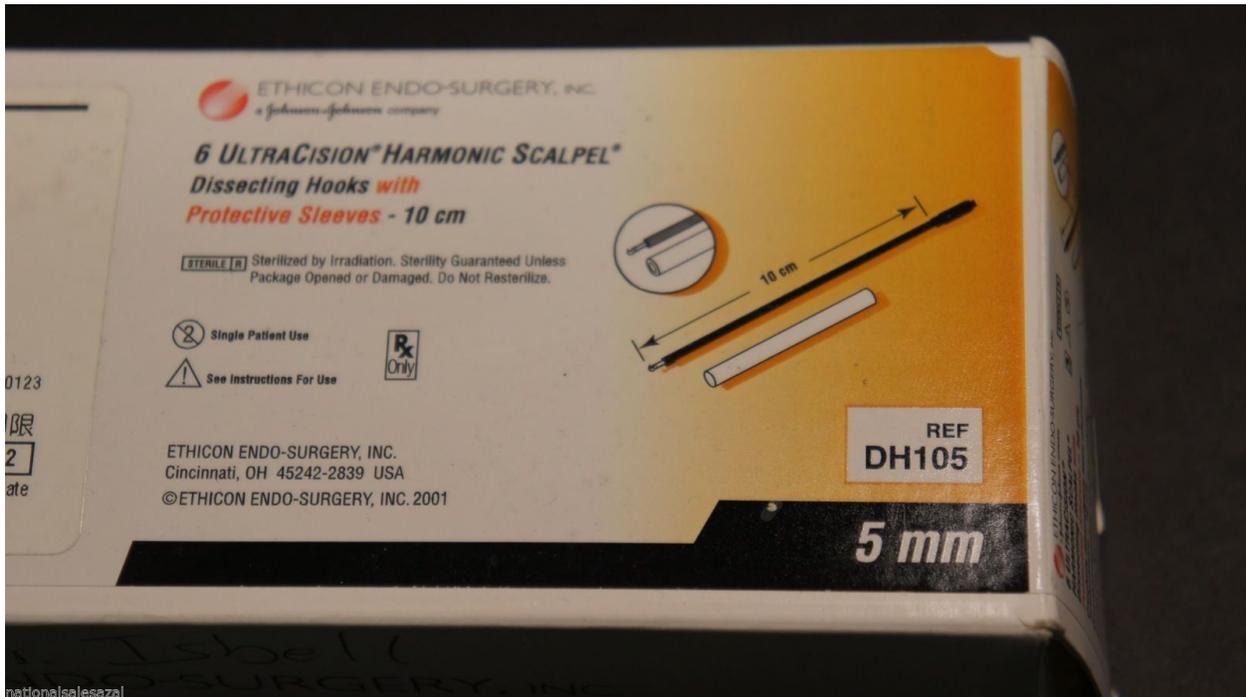
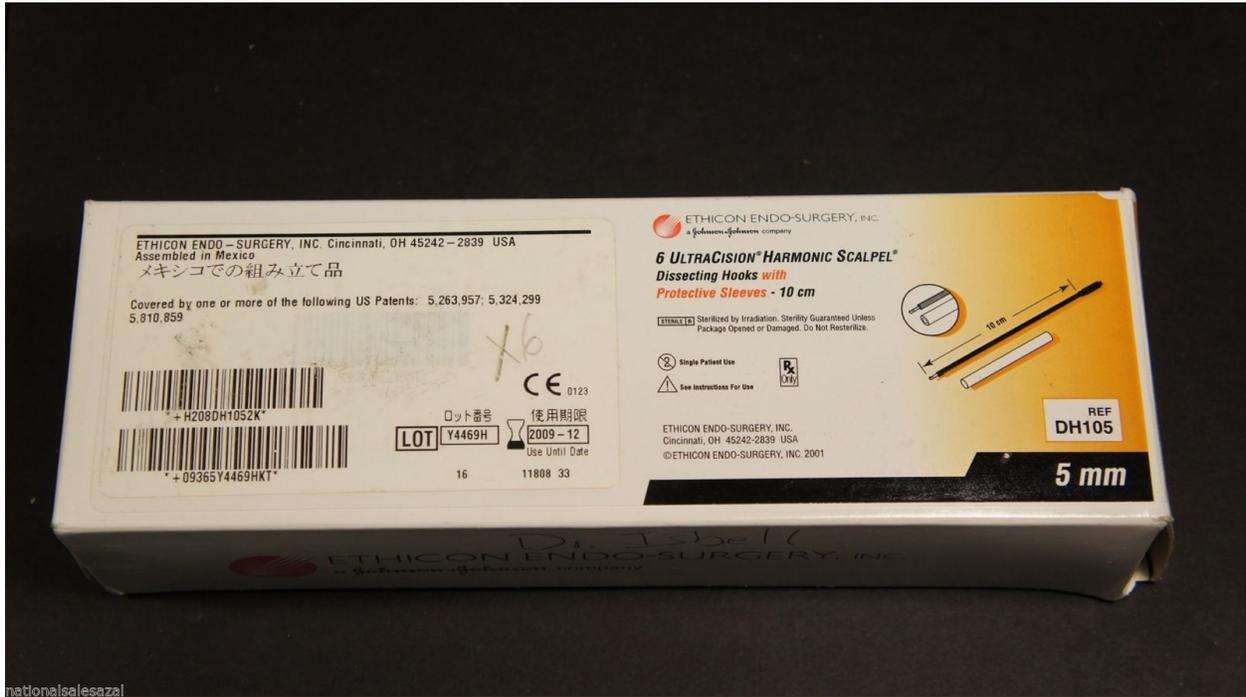


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ETHICON ENDO-SURGERY, INC.
Cincinnati, OH 45229-0001

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



DH105 Box Labeling

PRODUCT CATALOG



*Harmonic*TM

Harmonic™ Product Catalog

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Harmonic™ Capital	9
Harmonic™ Accessories	11

Advancing Smooth Surgery

Harmonic™



Now!
for your **Open** and
Laparoscopic Procedures



Harmonic ACE™ and **NOW** Harmonic WAVE™

- **Increased transection speed** —
moves through tissue quickly while maintaining hemostasis¹
- **Increased vessel-sealing capability** —
effectively seals vessels up to 5mm and decreases the need for instrument exchanges¹
- **Minimal lateral thermal tissue damage** —
safer dissection near vital structures²
- **A truly versatile instrument** —
cuts, coagulates, grasps and dissects without exchanging instruments
- **Seals lymphatics** —
for your open and laparoscopic procedures³

1 When compared with previous Harmonic™ shears

2 When compared with electrocautery

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

Product Code	Product Description	Pieces/Sales Unit
--------------	---------------------	-------------------

Laparoscopic Harmonic™ Shears

ACE36P	Harmonic ACE™, Pistol Grip, 5mm diameter, 36cm length (compatible with GEN04 only)	6
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ACE36S	Harmonic ACE™, Scissor Grip, 5mm diameter, 36cm length (compatible with GEN04 only)	6
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LCSC5L	Long Curved Shears (LCS), Pistol Grip, 5mm diameter, 45cm length (compatible with GEN04 only)	6
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LCSC5HA	LCS, Hand Control, Pistol Grip with Integrated Push Buttons, 5mm diameter, 36cm length (compatible with GEN04 only)	6
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LCSCIHA	LCS, Hand Control, Pistol Grip with Integrated Push Buttons, 5mm diameter, 36cm length (compatible with GEN04 only)	1
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LCSC5	LCS, Pistol Grip, 5mm diameter, 36cm length, curved active blade	6
LCSCI	LCS, Pistol Grip, 5mm diameter, 36cm length, curved active blade	1



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

Product Code	Product Description	Pieces/Sales Unit
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Laparoscopic Harmonic™ Shears (continued)

LCSK5	LCS, Pistol Grip, 5mm diameter, 35cm length, knife down active blade	6
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LCSB5*	LCS, Pistol Grip, 5mm diameter, 35cm length, blunt active blade	6
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*LCSB5 to be discontinued July, 2007. Substitute with LCSK5.



LCSI5	LCS, Pistol Grip, 10mm diameter, 34cm length	6
LCSI6	LCS, Pistol Grip, 10mm diameter, 34cm length	1



LCS6S	LCS, Scissor Grip, 10mm diameter, 34cm length	6
LCSI5	LCS, Scissor Grip, 10mm diameter, 34cm length	1



Introducing a NEW device
for open colorectal surgery

The **WAVE** of Certainty

- **Reliably** seals and divides 5mm vessels

- **Simultaneously** cuts and coagulates vessels and tissue

- **Multifunctionality** that may reduce instrument exchanges vs clamp/cut/tie

- **Minimal** lateral thermal spread*

Specifically designed for:

- colectomy
- total colectomy
- left hemi-colectomy
- right hemi-colectomy



Advancing Smooth Surgery



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

Product Code	Product Description	Pieces/Sales Unit
--------------	---------------------	-------------------

Open Harmonic™ Shears

ACE23P	Harmonic ACE™, Pistol Grip, 5mm diameter, 23cm length (compatible with GEN04 only)	6
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ACE23S	Harmonic ACE™, Scissor Grip, 5mm diameter, 23cm length (compatible with GEN04 only)	6
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ACE14S	Harmonic ACE™, Scissor Grip, 5mm diameter, 14cm length (compatible with GEN04 only)	6
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WAVE18S	NOW! Harmonic WAVE™, Scissor Grip, 8.5mm diameter, 18cm length, 18mm blade (compatible with GEN04 only)	6
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CSI4C	Coagulating Shears (CS), Scissor Grip, 5mm diameter, 14cm length, curved active blade	6
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CSI4I	CS, Scissor Grip, 5mm diameter, 14cm length, curved active blade	1
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Product Code	Product Description	Pieces/Sales Unit
--------------	---------------------	-------------------

Open Harmonic™ Shears (continued)

CS23C	Coagulating Shears (CS), Scissor Grip, 5mm diameter, 23cm length, curved active blade	6
CS23I	CS, Scissor Grip, 5mm diameter, 23cm length, curved active blade	1



CS150	CS, Pistol Grip, 10mm diameter, 20cm length	6
CS15I	CS, Pistol Grip, 10mm diameter, 20cm length	1



CS6S	CS, Scissor Grip, 10mm diameter, 20cm length	6
CSIS	CS, Scissor Grip, 10mm diameter, 20cm length	1



Harmonic™ Blades

DH105	Dissecting Hook, 5mm diameter, 10cm length with Protective Sleeve	6
DH145	Dissecting Hook, 5mm diameter, 14cm length with Grip and Protective Sleeve	6
DH010	Dissecting Hook, 10mm diameter, 30cm length	6



Product Code	Product Description	Pieces/Sales Unit
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Harmonic™ Blades (continued)

HDH05	Dissecting Hook, 5mm diameter, 32cm length	6
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SHI05*	Sharp Hook, 5mm diameter, 10cm length with Protective Sleeve	6
SHI45†	Sharp Hook, 5mm diameter, 14cm length with Grip and Protective Sleeve	6
HSH05§	Sharp Hook, 5mm diameter, 32cm length	6



*SHI05 to be discontinued July, 2007. Substitute with DH105.

†SHI45 to be discontinued July, 2007. Substitute with DH145.

§HSH05 to be discontinued July, 2007. Substitute with HDH05.

HCI05	Curved Blade, 5mm diameter, 10cm length	6
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HCI45	Curved Blade, 5mm diameter, 14cm length with Grip and Protective Sleeve	6
HC325	Curved Blade, 5mm diameter, 32cm length	6



HFI05	Sharp Curved Blade, 5mm diameter, 10cm length	6
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HBC05	Ball Coagulator, 5mm diameter, 31cm length	6
DBC10*	Ball Coagulator, 10mm diameter, 29cm length	6



*DBC10 to be discontinued July, 2007. Substitute with HBC05.

Advancing Smooth Surgery

Harmonic[™]

Generator[®] 300



Harmonic[™] Generator 300 offers:

Improved Performance

- Improved power delivery supports consistent cutting performance*
- Maintains power delivery under greater tissue loads*

Ease of Use

- Rotating hand-switching adaptor with min/max switches enables precise operation of system by hand
- System diagnostics and troubleshooting guide pinpoint system issues for quicker resolution of alert/alarm conditions*
- Intuitive control panel with large graphic display, configurable audio tones, and dual ergonomic foot controls

*When compared with previous Harmonic[™] systems



Product Code: GEN04



Product Code	Product Description	Pieces/Sales Unit
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Harmonic™ Capital

GEN04	Generator (110v)	1
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CRT01	Generator Cart	1
-------	----------------	---



FSW01	Footswitch and Cable	1
-------	----------------------	---



HP054	Hand Piece	1
-------	------------	---



NOW!
With
Spring Action
for Ease of
Dissection, Cutting
and Coagulation



Improved Ergonomic Design*

Advancing Smooth Surgery

Harmonic
ACE™

*When compared to previous ACE14S and ACE23S

Technology for Open Procedures

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

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Product Code	Product Description	Pieces/Sales Unit
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Harmonic™ Accessories

ADP03	Blade System Adaptor	2
ADPI0	10mm Blade System Adaptor	2
ADPI5	CS/LCS Blade System Adaptor	2
HST01	Sterilization Tray	1



HST02	Test Tip	1
TLB01	Torque Lock Blade Wrench	2



TWGREEN	NOW! Harmonic WAVE™ Torque Wrench	3
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HSA06	5mm Blade System Adaptor	2
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HSA07	Hand Switching Adaptor	1
WAREX	One-Year Harmonic™ Extended Warranty	1

*“It’s like
smooth sailing”*

**Discover Harmonic ACE™ —
designed for improved performance**

- *Increased transection speed* — move through tissue quickly while maintaining hemostasis¹
- *Expanded use* — seal larger vessels (up to 5mm) reliably with fewer instrument exchanges²

Harmonic ACE™ offers the multifunctionality and minimal surrounding tissue damage you trust from the Harmonic™ name.

¹When compared with LCSC5.

²When compared with previous Harmonic™ shears.



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Advancing Smooth Surgery

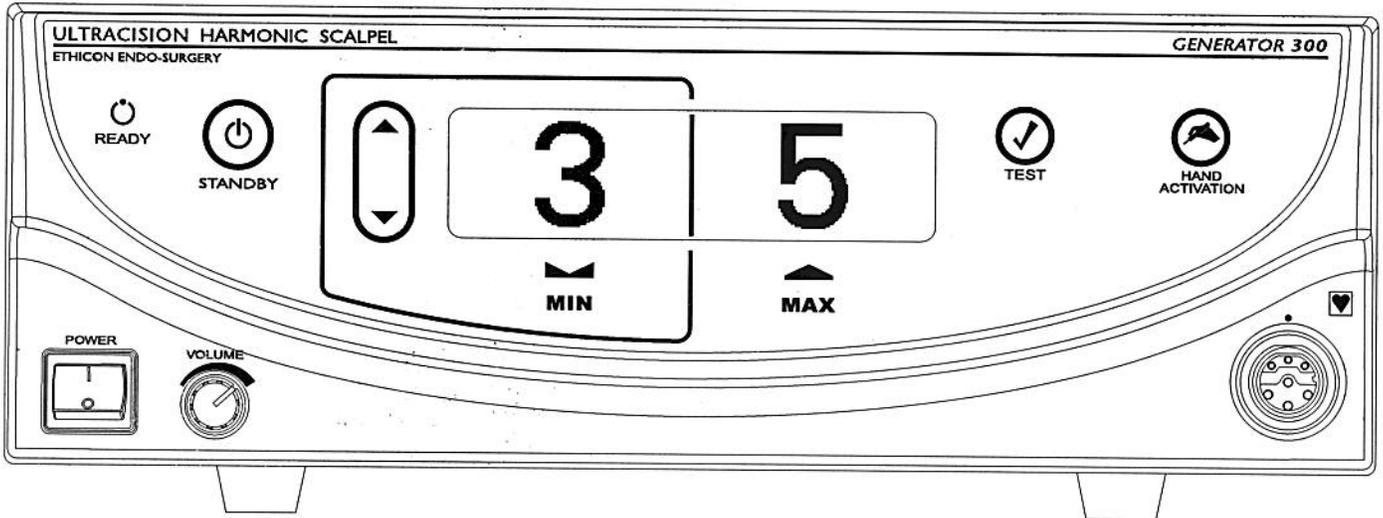
**Harmonic
ACE™**

back cover of folder
w/die cut for business card

flood w/blue

ULTRACISION® HARMONIC SCALPEL®

Generator 300 System User Manual



Manuel d'utilisation du Système de Générateur 300

Bedienungsanleitung für das Generator 300 System

Manuale dell'operatore del sistema generatore 300

Manual do utilizador do Sistema Gerador 300

Manual del usuario del sistema generador 300

Gebruikershandleiding generator 300-systeem

Brugermanual til generator 300 system

Generaattorijärjestelmän 300 käyttöopas

Εγχειρίδιο Χρήσης του Συστήματος Γεννήτρια 300

Användarhandledning för generator 300-systemet

ウルトラシジョン* ハーモニック スカルペル*

ジェネレーター 300 システム取扱説明書

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Please read all information carefully.

Failure to properly follow the instructions may lead to serious surgical consequences.

Important: The UltraCision® Harmonic Scalpel® Generator 300 System User Manual is designed to provide instructions for use of the UltraCision Harmonic Scalpel Generator 300, Foot Switch, and Cart (see Chapter 8 – System Specifications - for applicable product codes). This manual is not a reference to surgical techniques.

Note: Refer to package inserts provided separately for information about the Hand Piece, Hand Switching Adaptor, Adaptors, Test Tip and Instruments prior to using the system.

Indications

The UltraCision Harmonic Scalpel System is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The UltraCision Harmonic Scalpel System instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels.

Contraindications

- The instruments are not indicated for incising bone.
 - The instruments are not intended for contraceptive tubal occlusion.
-
-

The UltraCision Harmonic Scalpel System utilizes ultrasonic energy to enable hemostatic cutting and/or coagulation of soft tissue. The system consists of an ultrasonic generator, a foot switch, an optional hand-switching adaptor, a hand piece, and a variety of open and minimally invasive instruments.

Important: The UltraCision Harmonic Scalpel Generator 300 System User Manual is designed to provide instructions for use of the UltraCision Harmonic Scalpel Generator 300, Foot Switch, and Cart (see Chapter 8 – System Specifications for applicable product codes). This manual is not a reference to surgical techniques.

Note: Refer to package inserts provided separately for information about the Hand Piece, Hand Switching Adaptor, Adaptors, Test Tip and Instruments prior to using the system.

System Components

Generator 300

The generator supplies the hand piece with electrical energy and facilitates selection of power levels, system monitoring, and system diagnostics.

Power is delivered by activating the foot switch or hand switch.

Hand Piece

The hand piece contains an acoustic transducer that converts the electrical energy supplied by the generator to mechanical motion. The transducer is connected to an amplifier which amplifies the motion produced by the transducer and relays it to the instrument.

Instrument

The mechanical motion from the hand piece advances to the instrument, transmitting ultrasonic energy which enables hemostatic cutting and/or coagulation of tissue.

Note: Throughout this manual “instrument(s)” refers to UltraCision Harmonic Scalpel blades, ball coagulators, or coagulating shears.

Power Levels

The generator delivers two power levels: minimum (MIN) and maximum (MAX). The minimum power level may be adjusted by the user from Level 1 to 5. The maximum power level is always Level 5. With all instruments except the ball coagulator, use a higher generator power level for greater tissue cutting speed and a lower generator power level for greater coagulation. For the ball coagulator, higher generator power levels will provide greater coagulation. The amount of energy delivered to the tissue and resultant tissue effects are a function of many factors including the power level selected, instrument characteristics, grip force (when applicable), tissue tension, tissue type, pathology, and surgical technique.

Note: Refer to the instruments’ package inserts for additional power level information, including recommended starting power levels.

Controls, Indicators, and Connections

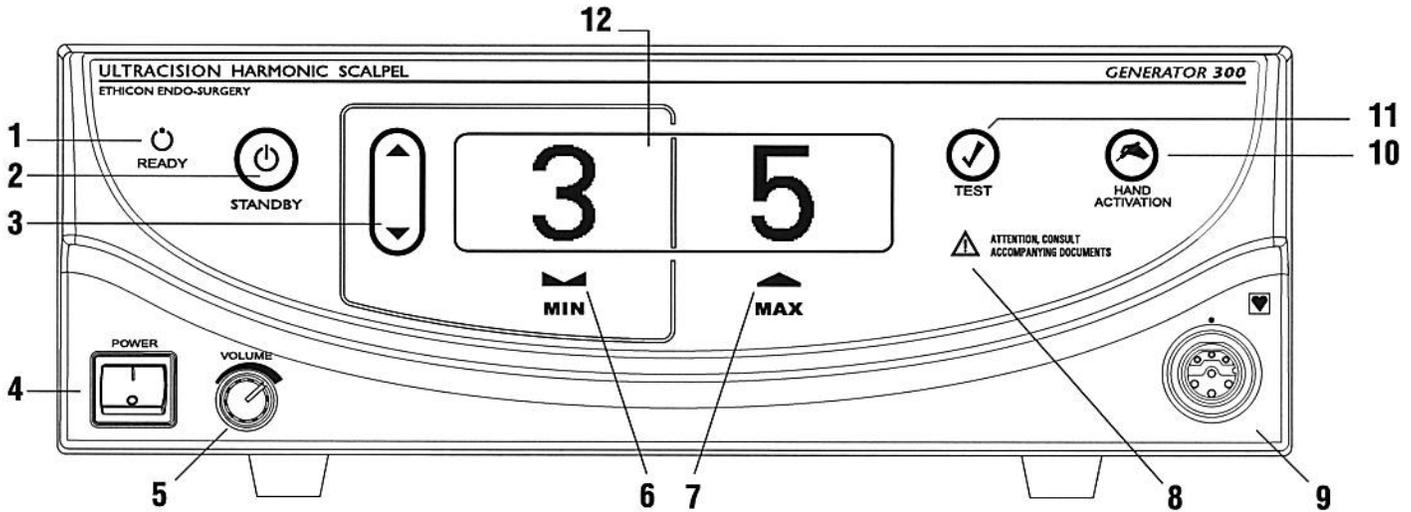


Fig. 2-1 Front Panel

- | | | |
|---|---|---|
| 1 | READY | When this indicator is green, the system is ready for activation. |
| 2 | STANDBY | Push this button to toggle between Standby and Ready modes. In Standby mode, this button, and the STANDBY icon, light up and all power is removed from the hand piece. Both the foot switch and hand switch are disabled. Upon power-up, the system defaults to Standby mode enabled. |
| 3 | INCREASE/
DECREASE POWER
LEVEL | Push this button to increase or decrease the minimum (MIN) power setting to the desired level (from 1 to 5). The level chosen will be shown on the graphic display. The power level may be adjusted when the generator is in Ready or Standby mode. |
| 4 | POWER | This switch controls the main electrical power to the generator. |
| 5 | VOLUME | Turn this knob to adjust the volume of the activation tones. A tone will sound indicating the volume level selected. |
| 6 | MIN | Indicates the user-settable minimum power level setting. When this power level is activated (by foot switch or hand switch), the “MIN” indicator will flash. The system defaults to “MIN” power level 3. Refer to the instruments’ package inserts for the recommended minimum power level. |
| 7 | MAX | Indicates the maximum power level setting. This setting is always “5”. When this power level is activated (by foot switch or hand switch), the “MAX” indicator will flash. |
| 8 | ALARM INDICATOR | This red indicator appears only if a system alarm occurs in response to a component or generator problem. |

- 9 **HAND PIECE RECEPTACLE** This receptacle is used to connect the hand piece to the generator.
- 10 **HAND ACTIVATION** When the indicator is green, hand activation on the hand switching adaptor is enabled. To disable the Hand Activation mode, depress the button. Upon power-up, the system defaults to Hand Activation mode disabled.
- Note: If the foot switch is installed, the foot switch is always enabled.
- 11 **TEST** Depressing this button initiates the Test mode. This mode is used during troubleshooting. The generator will emit a tone when the Test mode is active and "TEST IN PROGRESS" will appear on the display.
- 12 **GRAPHIC DISPLAY** In Ready or Standby modes, this display indicates the minimum (user-settable level 1 to 5) and maximum (level 5) power levels. If a system or component problem exists, error codes will appear on this display.

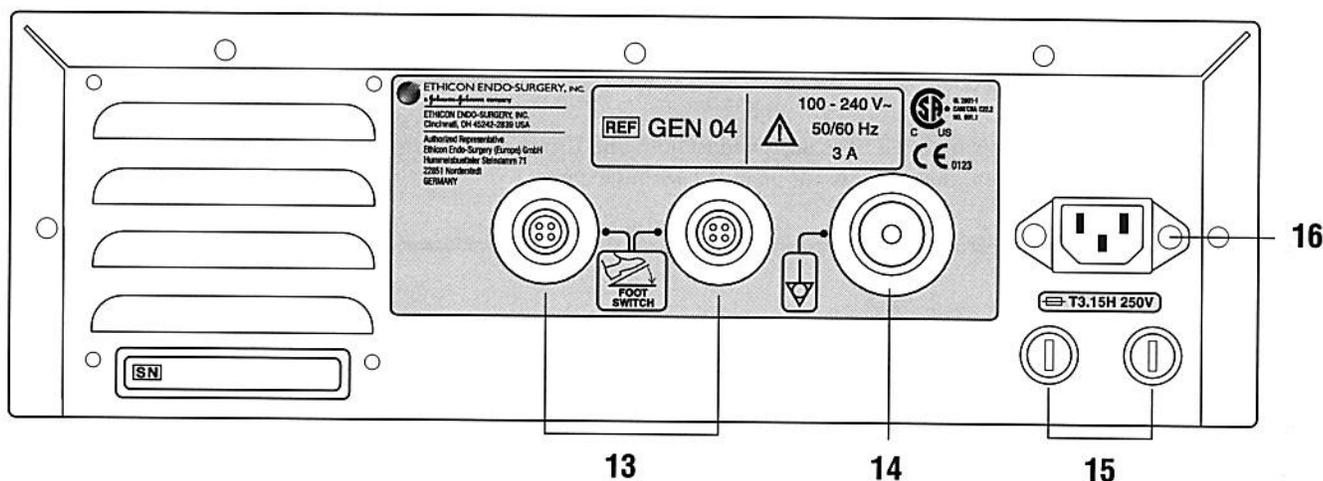


Fig. 2-2 Back Panel

- 13 **FOOT SWITCH RECEPTACLES** Identical receptacles allow connection of up to two foot switches for user convenience. If only one foot switch is used, connect to either receptacle.
- 14 **POTENTIAL EQUALIZATION TERMINAL** This terminal provides a means for connection to a Potential Equalization Conductor.
- 15 **FUSES** See the UltraCision Harmonic Scalpel Generator 300 Service Manual for additional information.
- 16 **POWER CORD RECEPTACLE** This receptacle is used to attach the power cord to the generator. For power cord requirements, see Chapter 8 – System Specifications.
- AUDIBLE SIGNALS** The generator delivers audible tones to signal activation and alarm states. The user may choose from three activation tone pitches. See Chapter 3 – System Setup and Operation for tone selection information. Upon power-up, the system defaults to the last tone chosen (the mid-pitch tone is factory-set).

Unpacking Instructions

The UltraCision Harmonic Scalpel Generator 300 System includes several components that are purchased separately. Upon receiving the ordered components, check for visible shipping damage. If damage is seen, contact your Ethicon Endo-Surgery representative.

System components may include the following parts (for product codes, see Chapter 8 – System Specifications):

Generator 300 – includes the generator, power cord, user manual, and service manual.

Note: The User Manual includes a troubleshooting guide (see back pocket of manual binder). Remove the self-adhesive guide's backing and adhere the guide to the top panel of the generator. Placement guides for the Troubleshooting Guide are found on the generator's top panel.

Foot Switch – includes the foot switch and detachable cable assembly.

Note: The foot switch is required if the system will be used with coagulating shears or instruments without the hand switching adaptor. Since the generator has receptacles for two foot switches, two foot switches may have been shipped.

Cart – the cart is optional. It is designed to hold one UltraCision Harmonic Scalpel Generator. The cart requires assembly; instructions are included with the cart.

System Startup

Warning: Products manufactured or distributed by companies other than Ethicon Endo-Surgery, Inc. may not be compatible with the UltraCision Harmonic Scalpel System. Use of such products may lead to unanticipated results and possible injury to the user or patient.

Caution: The UltraCision Harmonic Scalpel system includes components that are shipped non-sterile (e.g. hand piece, hand switching adaptor, adaptors, and blade wrench). Sterilize products as required before beginning system setup. Refer to individual package inserts for cleaning and sterilization instructions.

- 1 Confirm that the generator power switch is off during setup.
- 2 Secure the generator on its cart or on another suitable fixture. To secure the generator on its cart, place the generator's rubber feet into the corresponding holes on the cart. Push down on the generator's top panel.

Caution: To prevent overheating during use, ensure that the air vents found on the generator's bottom and back panels are not blocked and that they allow adequate clearance from obstructions to allow air to flow freely through the generator enclosure. Avoid placing the generator on a soft surface.

Warning: The UltraCision Harmonic Scalpel system must be operated within the required ambient operating conditions. Refer to Chapter 8 – System Specifications for requirements.

Caution: Do not simultaneously touch the patient and generator.

- 3 Connect the line cord into the AC inlet located on the generator's rear panel and into an appropriately-grounded outlet. If the power cord is wrapped around the cart handle, it must be completely removed from the cart handle prior to plugging it into the power outlet.

Warning: Verify that the outlet voltage correctly corresponds to the generator's requirements (see Chapter 8 – System Specifications). Connection to an improper power supply may result in damage to the generator and risk of shock or fire hazard.

- 4 a. Attach the foot switch cable to the foot switch:

Note: Although installation of the foot switch is optional when using the hand switching adaptor, installing the foot switch is recommended in case its use is needed during the procedure.

- Confirm that the connector and receptacle are dry and clean.
- Orient the slot on the foot switch cable's larger connector at 12 o'clock.
- Seat the connector in the foot switch receptacle.
- Turn the connector collar clockwise until tight. Ensure the collar is finger-tight to prevent inadvertent activation because of fluid ingress.

b. Connect the foot switch cable's smaller connector to the foot switch receptacle on the rear panel of the generator.

- Confirm that the connector and receptacle are dry and clean.
- Align the red dot on the foot switch 4-pin connector with the red dot on the 4-pin receptacle on the generator back panel.

Note: The generator has two identical foot switch receptacles. If one foot switch is used, either receptacle may be used.

Repeat steps 4a and 4b if a second foot switch will be used.

- 5 Connect the instrument and adaptor (or hand switching adaptor), if required, to the hand piece following instructions in their package inserts.
 Note: The hand switching adaptor must be at room temperature to function properly. Do not immerse in water to cool rapidly. After steam sterilization, allow hand switching adaptor to air cool for at least 15 minutes prior to use.
- 6 Connect the hand piece connector to the receptacle on the front panel. Align the white dot on the connector with the white dot on the generator. Ensure the hand piece connector is clean and dry before connecting the hand piece to the generator. Fully insert the hand piece connector to assure complete, proper connection to the generator.
- 7 Turn the generator power switch on and observe the power-up sequence. During power-up, the following indicators on the front panel will briefly illuminate:
 - **READY, STANDBY, MIN, MAX, TEST, ATTENTION, HAND ACTIVATION**

The system will run its start-up sequence and display the software version. An audible tone will sound during the initiation sequence.
 Note: The entire power-up initiation sequence should not exceed ten seconds.

If the start-up sequence deviates from the description above, contact qualified service personnel following hospital protocol.

When the initiation sequence is complete, the system will go to Standby. However, if the system detects a faulty generator or incorrect hand piece, a fault will appear on the graphic display (the power levels will not be visible) and an audible alarm will sound. Refer to Chapter 4 – Troubleshooting or the Troubleshooting Guide.

- 8 **Power Levels:** Upon startup, the generator defaults to power level 3 (MIN) and 5 (MAX). The minimum (MIN) power level is user-settable from power levels 1 to 5. To adjust the power level, depress the up/down arrow button to the left of the minimum power level display. Set the power level based on surgeon preference and/or recommendations provided in the instrument’s package insert (for more information, see Power Levels section in Chapter 2 – Principles of Operation).
- 9 **Audible tones:** The generator has three activation tone sets from which to choose (the mid-pitch tone is factory set). To choose another tone:
 - a. Switch power off.
 - b. Switch power on. Then immediately depress **and hold** both the STANDBY and HAND ACTIVATION buttons. When the graphic shown in Figure 3-1 appears on the display, release the STANDBY and HAND ACTIVATION buttons.
 - c. While in the Tone Selection mode, the generator will automatically sequence through the available tone pitches. To select a tone, depress any button on the control panel. The generator will return to Standby mode. The tone chosen will be saved until it is changed again by accessing the Tone Selection mode.



Fig. 3-1 Tone Selection Display

Adjust tone volume by turning the knob on the lower left corner of the control panel. A tone will sound to indicate the volume level selected. For safety reasons, the tone may not be disabled.

System Operation

Important: The UltraCision Harmonic Scalpel Generator 300 System User Manual is designed to provide instructions for use of the UltraCision Harmonic Scalpel Generator 300, Foot Switch, and Cart (see Chapter 8 – System Specifications - for applicable product codes). This manual is not a reference to surgical techniques.

Note: Refer to package inserts provided separately for information about the Hand Piece, Hand Switching Adaptor, Adaptors, Test Tip and Instruments prior to using the system.

After completing system setup, the system may be operated.

1 Place the generator in Ready mode by depressing the STANDBY button.

2 System check and activation:

Each time the generator is activated after exiting Standby, hold the instrument in the air (if coagulating shears are used, open the clamp arm) and depress the MIN or MAX power level on the foot switch or hand switching adaptor. “TEST IN PROGRESS” will appear on the graphic display and a rapid two-tone pulse will sound while the test is occurring. During this five-second period, a system check is being performed.

- If the system is operating properly, the activation tone corresponding to the power level activated will be heard when the check is complete. Stop activation, position the instrument on tissue, and resume activation.
- If the system is not operating properly, an error code will appear (refer to Chapter 4 – Troubleshooting or the Troubleshooting Guide).

Warning: To avoid user or patient injury, ensure that the instrument is clear of other instruments, drapes, the patient or other objects during the system check. Safety measures (in accordance with hospital protocol) taken in the presence of aerosols should be in effect during the system check.

Note: The foot switch or hand switch must be depressed until the system check is completed. If the switch is released prematurely, the check will reinitiate at the next activation.

Note: The system check will also be performed whenever the hand piece is removed and replaced or TEST is pressed.

Note: The hand activation button on the generator control panel must be illuminated for the hand switches to be active. To deactivate the hand switches, depress the hand activation button (if the hand activation button is not illuminated, hand switches will be inactive).

Note: If the hand switch will not turn off during operation, depress the button corresponding to the power level opposite that being activated to turn it off - an alarm will sound. Press the HAND ACTIVATION button to disable the hand switching adaptor. Place the generator in Standby, and replace the hand switch; or, continue using the foot switch after deactivating the hand switch.

If the foot switch will not turn off during operation, depress the pedal corresponding to the power level opposite that being activated to turn it off - an alarm will sound. Release the pedal to silence the alarm. Place the generator in Standby, and replace the foot switch.

- 3 If the system senses a generator, hand piece, or instrument fault during use, an audible alarm (tone with long pulses) will sound and a visual alarm indicator will appear on the control panel. (Refer to Chapter 4 – Troubleshooting or the Troubleshooting Guide to resolve the problem.)

Warning: Place the generator in Standby mode before removing or replacing an instrument, hand switching adaptor or hand piece or when the system is not in use.

System Shutdown

- 1 Turn the generator power switch off and remove power cord from outlet.
 - 2 Disconnect the hand piece, instrument, and adaptor or hand switching adaptor (if used) and process them as indicated in their respective package inserts.
 - 3 Clean the generator and cart and disinfect the foot switch(es) following hospital protocol (for recommendations, refer to Chapter 5 – Cleaning and Disinfection).
 - 4 Store foot switch(es) on the cart shelves provided. Each shelf will hold one foot switch.
 - 5 Wrap foot switch cable(s) and the power cord on the cart's back handle for storage.
-
-

The Generator 300 System supports a series of alarms and error codes to help in the identification and troubleshooting of component problems. These guides are meant as an adjunct to, but not a substitute for, clinical judgment and observations.

Audible Indicators and Alarms

Tone	Possible Cause and Corrective Action
No tone when system is activated.	<p>Confirm foot switch is fully connected (if hand switch is not being used).</p> <p>Confirm foot switch is not faulty.</p> <p>If hand switch is used, confirm it is connected and not faulty.</p> <p>Confirm hand activation is enabled if hand switching adaptor is being used.</p>
Activation (brief pulses)	System is being activated or is in Test mode. System is operating properly. MIN and MAX power have unique tones.
Alert (three-tone sequence)	<p>Activation is attempted while generator is in Standby mode. Push the STANDBY button to return the generator to Ready mode.</p> <p>Two or more foot or hand switches are recognized by the generator as being activated simultaneously. Reactivate using only one switch.</p>
Constant tone	<p>1) Instrument is in contact with too much tissue. Reduce the amount of tissue in contact with the instrument. If tone persists, carefully remove any tissue that has collected in the distal end of the instrument shaft.</p> <p>2) Hand piece and/or blade fault. Press TEST to identify source of fault.</p>
Prolonged solid tone during activation (exceeds 10 seconds)	Hand piece and/or blade fault. Press TEST to identify source of fault.
Alarm (two-tone sequence)	<p>A component or system problem has occurred. Refer to the Error Codes section in this chapter or the Troubleshooting Guide.</p> <p>Note: This alarm will activate for three seconds, then will silence itself for 30 seconds. This cycle will continue until the error is resolved or the main power switch is turned off.</p>

Error Codes

The generator will recognize specific faults in five areas: generator, hand piece, instrument, foot switch or hand switch. When a fault is identified, an alarm will sound, the alarm indicator will appear on the generator control panel, and the source of the problem will appear on the graphic display (the power levels will not be displayed). See Fig. 4-1 below for an example. Follow the procedures outlined below (or in the Troubleshooting Guide) to resolve the problem.



Fig. 4-1 Alarm Indicator (example)

Error Code 1: Generator

Error Code 1 indicates either there is a functional problem with the generator or the front panel button(s) were activated during power-up sequence.
Cycle the power OFF then ON. If error persists, power off system and contact service.

Error Code 2: Generator Temperature

Error Code 2 indicates that the generator is overheating.

- 1 Power off system. Remove any obstructions blocking the air vents on the generator's bottom and back panels. If there is no apparent obstruction or external heat source, contact service.
- 2 Power on the system and wait for up to 30 minutes for generator error to clear.
- 3 If error code persists, contact service.

Error Code 3: Hand Piece

Error Code 3 indicates a problem with the hand piece.

- 1 Confirm that the hand piece connector is fully inserted and properly oriented – white dot on handpiece is aligned with white dot on front panel. If the error code does not clear within three seconds after the hand piece is properly connected, press TEST.
- 2 The instrument may not be tightened properly or tissue may have collected in the distal end of the instrument shaft. Tighten instrument using blade wrench and carefully remove tissue from distal end of instrument sheath. Press STANDBY to clear error code and return to Ready mode. Activate system. If the pre-run test is running, ensure instrument is in air. If using shears, ensure jaws are open and not in contact with any objects during pre-run test.

Note: Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.

- 3 If the error persists, install a test tip to isolate the problem. Press TEST button.
 - If system indicates a hand piece error, hand piece is bad or test tip is bad. Replace hand piece or install a new test tip and press TEST.
 - If no error occurs with test tip attached, replace instrument.
- 4 Press STANDBY to return to Ready mode. Activate system.

Error Code 4: Hand Piece Temperature

Error Code 4 indicates that the hand piece has exceeded its specified operating temperature. For immediate recovery, use another hand piece; or, follow the steps below to determine the cause of the error condition and alternate recovery methods.

The following are possible causes of an increase in hand piece temperature. To correct, complete the appropriate steps below and *allow the hand piece to cool before resuming operation.*

- 1 The hand piece is still warm from recent steam sterilization. Allow the hand piece to cool at room temperature for at least 45 minutes or soak it in room-temperature sterile water for 5 minutes before resuming operation.

Note: The hand switching adaptor (HSA07) should not be submerged for rapid cooling purposes. This may render the hand switching adaptor inoperable for an extended period of time. After steam sterilization, allow the hand switching adaptor to air cool at least 15 minutes prior to use.

- 2 The instrument may not be tightened properly or tissue may have collected in the distal end of the instrument shaft. Tighten instrument using blade wrench and carefully remove tissue from distal end of instrument sheath. Press STANDBY to clear error code and return to Ready mode. Activate system. If the pre-run test is running, ensure instrument is in air. If using shears, ensure jaws are open and not in contact with any objects during pre-run test.

Note: Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.

- 3 If the error persists, install a test tip to isolate the problem. Press TEST button.
 - If system indicates a hand piece error, hand piece is bad or test tip is bad. Replace hand piece or install a new test tip and press TEST.
 - If no error occurs with test tip attached, replace instrument.
- 4 Press STANDBY to return to Ready mode. Activate system.
- 5 If the hand piece does not show evidence of overheating and troubleshooting steps 1-4 above do not appear to resolve the problem, perform the following:
 - a. Leave the hand piece at room temperature for 24 hours or more.
 - b. Remove any test tip or instrument from the hand piece.
 - c. With the generator turned off, plug the hand piece into any Generator 300.
 - d. Power up the generator in Biomed mode.
 - Press and hold down the STANDBY button and down arrow key.
 - Wait for a steady display – approximately 10 seconds.
 - If a “Generator” error occurs, then one of the buttons was not properly held down. If this happens, repeat the power up procedure in Biomed mode.

- e. Record the “XDUCER CAPACITANCE” value.
- Press the STANDBY button, if necessary, until it illuminates.
 - Use the increase/decrease arrow keys to get to “Page 2 of 21”.
 - Record the number opposite “XDUCER CAPACITANCE”.
 - Press the STANDBY button until the Standby light turns off.
 - Leave the hand piece plugged into the generator. Do not remove hand piece during entire procedure. Do not activate the MIN or MAX activation buttons on the foot switch or hand switch if either is attached.
 - After a period of time that exceeds 30 or more minutes, press the STANDBY button until the STANDBY light is illuminated.
 - Again, read the “XDUCER CAPACITANCE” on Page 2 of 21.
 - If the number has changed, the update was successful.
 - If the number has not changed, then this update attempt did not succeed. Power down the generator and repeat Step 5.

Note: As the hand piece ages, the generator performs measurements and updates a key hand piece parameter. This function is performed when the internal temperature of the hand piece is stable at room temperature. Certain usage patterns may prevent this update from occurring and subsequently make the hand piece diagnostics more sensitive to temperature. The steps above will cause an update of the hand piece parameter and return the system to designed sensitivity.

Warning: To avoid user or patient injury, ensure that the instrument is clear of other instruments, drapes, the patient or other objects before pressing TEST. Safety measures (in accordance with hospital protocol) taken in the presence of aerosols should be in effect while in Test mode.

Note: Do not run the Test mode while an electrosurgical generator is being activated in the room. Interference from the electrosurgical generator may affect test results.

Error Code 5: Instrument

Error Code 5 indicates a problem with the instrument.

- I The instrument may not be tightened properly or tissue may have collected in the distal end of the instrument shaft. Tighten instrument using blade wrench and carefully remove tissue from distal end of instrument sheath. Press STANDBY to clear error code and return to Ready mode. Activate system. If the pre-run test is running, ensure instrument is in air. If using shears, ensure jaws are open and not in contact with any objects during pre-run test.

Note: Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.

- 2 If the error persists, install a test tip to isolate the problem. Press TEST button.
 - If system indicates a hand piece error, hand piece is bad or test tip is bad. Replace hand piece or install a new test tip and press TEST.
 - If no error occurs with test tip attached, replace instrument.
- 3 Press STANDBY to return to Ready mode. Activate system.

Note: Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.

Warning: To avoid user or patient injury, ensure that the instrument is clear of other instruments, drapes, the patient, or other interference before pressing TEST. Safety measures (in accordance with hospital protocol) taken in the presence of aerosols should be in effect while in Test mode.

Note: Do not run the Test mode while an electro-surgical generator is being activated in the room. Interference from the electro-surgical generator may affect test results.

Error Code 6: Foot Switch

Error Code 6 indicates a foot switch pedal is stuck in the ON position. Confirm generator receptacle, foot switch receptacles and cable connectors are clean and dry or replace the foot switch.
Note: If the error persists, replace foot switch.

Error Code 7: Hand Switch

Error Code 7 indicates the hand switch is stuck in the ON position. Confirm contacts in the distal end of hand piece and in the proximal end of the hand switching adaptor are dry or replace the hand switching adaptor.
Note: If the error persists, replace hand switch.

Generator and Cart Cleaning

Clean generator and cart following hospital protocol. Before cleaning, turn the generator main power off and unplug the power cord from the grounded electrical outlet.

Warning: Spilling or spraying fluids on or into the generator or immersing the generator may result in damage to the generator and risk of shock or fire hazard.

Proceed with cleaning as follows:

- 1 Prepare a neutral pH detergent or neutral pH enzymatic detergent according to the detergent manufacturer's directions.
- 2 Use a soft, clean cloth lightly moistened with the cleaning solution to manually clean all surfaces (including the generator's display).
- 3 Rinse thoroughly using a soft, clean cloth lightly moistened with warm tap water.
- 4 Dry with a clean, soft cloth.

Foot Switch Cleaning

The foot switch and cable should be cleaned after each use as follows:

- 1 Disconnect the foot switch from the generator.
- 2 Prepare a neutral pH enzymatic detergent according to the detergent manufacturer's directions.
- 3 With the cable securely attached to the foot switch, soak the foot switch and cable in the detergent solution for two minutes.

Note: Keep the foot switch cable connector that connects to the generator dry at all times to prevent inadvertent activation.

- 4 After soaking, use a soft-bristled brush to manually clean the foot switch and cable keeping them immersed in the detergent solution.
- 5 Thoroughly rinse the foot switch and cable – with the cable securely attached to the foot switch – with warm, running tap water for at least one minute.
- 6 Dry all surfaces with a clean, soft cloth.

Test hand piece, generator, and foot switch for safety and function according to hospital protocol. Refer to individual package inserts for safety and function testing for other multi-patient use components.

Safety Test

Generator: A qualified hospital technician should perform a leakage current test.

Foot Switch: Examine the foot pedals, cable connectors, and cable for cracks or other damage and replace if damaged.

Other Components: Examine the components by following the instructions in their individual package inserts.

Function Test

- 1 Perform complete instrument preparation and hand piece attachment as described in Chapter 3 – System Setup and Operation. Attach the test tip rather than an instrument.
- 2 Verify that the orange STANDBY indicator is illuminated.
- 3 Push the STANDBY button to leave Standby mode and enter Ready mode.
- 4 Verify that the green READY indicator is illuminated.
- 5 Verify that MIN Power Level 3 and MAX Power Level 5 are displayed.
- 6 Push the Increase and Decrease Power Level button up and down to confirm the MIN Power Level changes from 1 to 5.
- 7 Turn the generator off. Wait five seconds, then turn the generator back on. Wait ten seconds, then confirm MIN Power Level 3 and MAX Power Level 5 are displayed. Confirm the generator is not being activated unexpectedly.
- 8 Place the generator in Ready mode by depressing the STANDBY button. Hold the hand piece so that the distal portion is in the air and step on the MAX foot switch pedal (before activation begins, a five-second system check will be performed – “TEST IN PROGRESS” will appear on the display). Verify that the MAX Power Level indicator on the control panel flashes and that the MAX activation tone is heard.

Warning: To avoid user injury, ensure that the test tip is clear of tissue, other instruments, or other objects before activating the system.

- 9 Hold the hand piece so that the distal portion is in air and step on the MIN foot switch pedal. Verify that the MIN Power Level indicator on the control panel flashes and that the MIN activation tone is heard.

Warning: To avoid user injury, ensure that the test tip is clear of tissue, other instruments, or other objects before activating the system.

Calibration

Refer to the Generator 300 System Service Manual for system calibration information.

System Warnings and Precautions

- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- Minimally invasive instruments may vary from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. Do not immerse electrosurgical instruments in liquid unless the instruments are designed and labeled to be immersed.
- Safe and effective ultrasonic surgery is dependent not only upon equipment design, but also, to a large extent, upon factors under control of the operator. It is important that the instructions supplied with this equipment be read, understood, and followed in order to enhance safety and effectiveness.
- As with all energy sources (Electrosurgery, Laser, or Ultrasound), there are concerns about the carcinogenic and infectious potential of the by-products, such as tissue smoke plume and aerosols. Appropriate measures such as protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
- To avoid user or patient injury in the event that accidental activation occurs, the ULTRACISION HARMONIC SCALPEL instrument blades should not be in contact with the patient, drapes, or flammable materials while not in use. During prolonged activation in tissue, the instrument blade, clamp arm and distal end of the shaft may become hot. Avoid unintended blade contact with tissue, drapes, surgical gowns, or other unintended sites after activation.
- To avoid user or patient injury, the ULTRACISION HARMONIC SCALPEL Generator should not be used prior to biomedical evaluation if it shows signs of damage or is suspected of being dropped or having fluids spilled on it.
- After removing the instrument, examine the tissue for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- Products manufactured or distributed by companies other than Ethicon Endo-Surgery, Inc. may not be compatible with the ULTRACISION HARMONIC SCALPEL system. Use of such products may lead to unanticipated results and possible injury to the user or patient.
- The ULTRACISION HARMONIC SCALPEL system, including the hand piece, is not Magnetic Resonance safe and is not Magnetic Resonance compatible.
- To reduce the risk of interference, electrosurgical systems and the ULTRACISION HARMONIC SCALPEL system should be plugged into separate electrical power circuits. Locate the ULTRACISION HARMONIC SCALPEL system, including the hand piece cable, at least 3 ft. (approximately 1 m) from electrosurgical systems and their hand piece (e.g., pencil) cables.
- Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. It is possible to create sparks by hitting other metal instruments. Sparks may ignite flammable gases such as bowel gas.
- The ULTRACISION HARMONIC SCALPEL system must be operated within the required ambient operating conditions. Refer to Chapter 8 – System Specifications for requirements.
- To prevent overheating during use, ensure that the air vents found on the generator's bottom and back panels are not blocked and that they allow adequate clearance from obstructions to allow air to flow freely through the generator enclosure. Avoid placing the generator on a soft surface.
- Verify that the outlet voltage correctly corresponds to the generator's requirements (see Chapter 8 – System Specifications). Connection to an improper power supply may result in damage to the generator and risk of shock or fire hazard.
- The ULTRACISION HARMONIC SCALPEL system includes components that are shipped non-sterile (e.g. hand piece, hand switching adaptor, adaptors, and blade wrench). Sterilize products as required before beginning system setup. Refer to individual package inserts for cleaning and sterilization instructions.
- To avoid user or patient injury, ensure that the instrument is clear of other instruments, drapes, the patient, or other objects before pressing TEST and during the system check. Safety measures (in accordance with hospital protocol) taken in the presence of aerosols should be in effect during the system check and while in Test mode.

- To avoid user injury, ensure that the test tip is clear of tissue, other instruments, or other objects before activating the system.
- Do not simultaneously touch the patient and generator.
- Place the generator in the Standby mode before removing or replacing an instrument, hand switching adaptor or hand piece or when system is not in use.
- Spilling or spraying fluids on or into the generator or immersing the generator may result in damage to the generator and risk of shock or fire hazard.

Instrument Warnings and Precautions

Blades

All blades have an intermittent operation of 15 second on/off intervals, unless the duty cycle is explicitly specified otherwise in the individual instrument package inserts.

Coagulating Shears

During prolonged activation in tissue, the instrument blade, clamp arm, and the distal 7 cm of the shaft may become hot. Avoid unintended contact with tissue, drapes, surgical gowns, or other unintended sites at all times.

Note: Refer to individual package inserts for additional warnings and precautions.

Product Codes

Required Components for System Operation:

GEN04: Generator 300
 HP054/HP055: Hand Piece (includes HST02 Test Tip and TLB01 Blade Wrench)¹

Instruments and Adaptors:

Contact your Ethicon Endo-Surgery representative for information about instruments available for use with this system. Some instruments may require use of an adaptor.

Optional Components:

FSW01: Foot Switch²
 HSA07: Hand Switch^{1,2}
 CRT01: Cart

¹ Refer to separate product insert supplied with this component.
² At a minimum, either the foot switch or the hand switch is required to operate the generator. When the hand switch is used, availability of the foot switch is recommended.

Degree of Protection Against Electric Shock

Type CF Applied Part

Class of Protection Against Electric Shock

Class I

Safety Standards

EN 60601-1

Degree of Protection Against Harmful Ingress of Water

Generator: Ordinary equipment
 Footswitch: IPX8

Safety Classification

UL 2601-1
 CSA C22.2 601.1
 EN 60601-1

Mains Input

Voltage: 100-240 VAC
 Frequency: 50/60 Hz
 Current Consumption: 3 amp

Ambient Operating Conditions

Temperature 18°C to 23°C
 Humidity: 10-90% non-condensing
 Atmospheric Pressure Range: 700hPa-1060hPa

Transport and Storage Conditions

Temperature: -35°C to +54°C
 Humidity: 10-95% non-condensing
 Atmospheric Pressure Range: 700hPa-1060hPa

Date of Manufacture	<p>The date of manufacture may be determined by viewing the serial number on the rear panel of the generator. The fourth and fifth characters indicate the year of manufacture as follows:</p> <p>GN401 = year 2001 GN402 = year 2002 GN403 = year 2003 GN404 = year 2004 GN405 = year 2005</p>
Power Cord	<p>North American removable power cord set with the following characteristics:</p> <p>Plug Style: NEMA 5-15 (clear) North American Hospital Grade Receptacle: IEC 60320 C13 with straight non-angled cord entry Cord Length: 4.6 meters nominal Current Rating: 13A Voltage Rating: 125 VAC minimum Wiring Code: North American Cordage Description: SJT (UL) or SJT (CSA) Conductors: 16 AWG 3C Agency Approvals Required: UL and CSA</p> <p>International removable power cord set with the following characteristics:</p> <p>Plug Style: as needed by particular country requirements Receptacle: IEC 60320 C13 with straight non-angled cord entry Cord Length: 2.44 - 4.6 meters nominal Current Rating: 10A Minimum conductor size cross-sectional area: 1.0mm² copper Voltage Rating: 250 VAC minimum Wiring: international Cordage Type: HAR Item to have certification by at least one of the following agencies: VDE, ASTA, SEMKO, KEMA, LCIE, DFT, IMQ, SEV</p>
Duty Cycle	<p>Duty Cycle is determined by hand piece and instrument in use. For duty cycle information, refer to applicable instrument(s) and hand piece inserts and/or Chapter 7 – Warnings and Precautions.</p>
Weight (unpacked)	<p>Generator: 7.48 kg nominal Cart: 42.0 kg nominal</p>
Overall Dimensions	<p>Generator 300 (HxWxD): 5.3" (13 cm) x 14.5" (37 cm) x 15.2" (39 cm) Cart (HxWxD): 37.3" (95 cm) x 17.7" (45 cm) x 27.6" (70 cm), including handle</p>
Disposal	<p>Some internal components of the generator, foot switch and foot switch cable contain lead. Disposal should be performed according to local requirements and regulations.</p>

This warranty and the rights and obligations hereunder shall be construed under and governed by the laws of the State of Ohio, U.S.A.

Ethicon Endo-Surgery, Inc. warrants this product to be free from defects in material and workmanship under normal use and preventive maintenance for the respective warranty period shown below. Ethicon Endo-Surgery's obligation under this warranty is limited to the repair or replacement, at its option, of any product, or part thereof, which has been returned to Ethicon Endo-Surgery, Inc. or its Distributor within the applicable time period shown below and which examination disclosed, to Ethicon Endo-Surgery's satisfaction, to be defective. This warranty does not apply to any product, or part thereof, that has been: (1) adversely affected due to use with devices manufactured or distributed by parties not authorized by Ethicon Endo-Surgery, Inc. (2) repaired or altered outside Ethicon Endo-Surgery's factory in a way so as to, in Ethicon Endo-Surgery's judgement, affect its stability or reliability, (3) subjected to improper use, negligence or accident, or (4) used other than in accordance with the design and use parameters, instructions and guidelines for the product or with functional, operational or environmental standards for similar products generally accepted in the industry.

Ethicon Endo-Surgery's products are warranted for the following periods after delivery to the original purchaser:

Hand Pieces	Nine (9) Months, Parts and Labor
Generators	One (1) Year, Parts and Labor
Carts	One (1) Year, Parts and Labor
Foot Switches and Cables	One (1) Year, Parts and Labor
Sterilization Tray	One (1) Year, Parts and Labor

UNLESS SUPERCEDED BY APPLICABLE LOCAL LAW, THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON THE PART OF ETHICON ENDO-SURGERY, INC. AND IS A PURCHASER'S EXCLUSIVE REMEDY. IN NO EVENT SHALL ETHICON ENDO-SURGERY, INC. BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES INCLUDING, WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, PROFITS, BUSINESS OR GOODWILL, OTHER THAN AS EXPRESSLY PROVIDED BY A SPECIFIC LAW. Ethicon Endo-Surgery, Inc. neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any of Ethicon Endo-Surgery Inc. products. There are no warranties that extend beyond the terms hereof.

Ethicon Endo-Surgery, Inc. reserves the right to make changes to products built and/or sold by them at any time without incurring any obligation to make the same or similar changes on products previously built and/or sold by them.

	On
	Off
	Type CF Applied Part
	Lot
	Temperature
	Relative Humidity
	Attention - Consult Accompanying Documents/See Instructions For Use
	Non-Sterile
	Date of Manufacture
	Fragile
	This end up
	Keep dry
	Increase/Decrease
	Serial Number
	Equipotential

	Fuse
	Safe working load
	Test
	Hand Activation
	Volume
	Minimum
	Maximum
	Ready
	Standby
	Reorder Number
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	ON/OFF Time for Intermittent Operation. Refer to the individual package insert and/or Chapter 7 – Warnings and Precautions for additional specifications.
	Foot switch
	Category AP (Anaesthetic Proof) Equipment

ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company
1 ULTRACISION®
HARMONIC SCALPEL®
Hand Piece



REF HP054

Hand Piece

ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

1 ULTRACISION®
HARMONIC SCALPEL®
Hand Piece

Poignée de connexion

Handstück

Manipolo

Peça de mão

Mango transductor

Handstük

-35°C - +54°C

10% - 100%

カルトラジション® ハーモニック スカルペル®
ハンドピース (1個入り) (15Vジェネレーター用)
ハーモニック スカルペル® II 承認番号: 21300BZ100662000
※キヤノコでの組み立て品 * 商標
※ 販売文書参照

See Instructions for Use

NON-STERILE

R Only

ETHICON ENDO-SURGERY, INC. ©ETHICON ENDO-SURGERY, INC. 2001
Cincinnati, OH 45242-2839 USA Assembled in Mexico



A93491P00

ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

1 ULTRACISION®
HARMONIC SCALPEL®
Hand Piece

Poignée de connexion

Handstück

Manipolo

Peça de mão

Mango transductor

Handstük

カルトラジション®
ハーモニック スカルペル®
ハンドピース (1個入り)

NON-STERILE

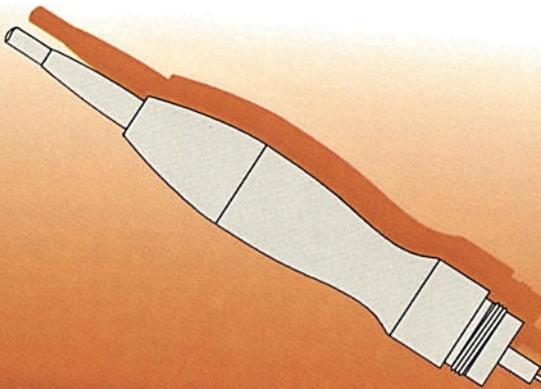
See Instructions for Use

R Only



REF HP054

Hand Piece



REF HP054

Hand Piece

ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

1 ULTRACISION®
HARMONIC SCALPEL®
Hand Piece



REF HP054

Hand Piece



130898J

1

Covered by one or more of the following US Patents:
 6,278,218B1; 6,338,657B1; 6,491,708 B2; 6,608,270 B2
 6,623,500 B1; 6,678,621 B2; 6,679,899 B2; D486,127 S

1376 32

ロット番号 X93D6009

製造年月日 2004-12

CE 0123

LOT

Date of Manufacture



ETHICON ENDO-SURGERY, INC. Cincinnati, OH 45242-2839 USA

輸入・販売元: エシコン・エンド・サージェリ株式会社
 〒135-0016 東京都江東区東陽6丁目3番2号 電話: 03 (5632) 7206

EC REP

Ethicon Endo-Surgery (Europe) GmbH
 Hummelsbuehler, Steindamm 71
 22851 Norderstedt, GERMANY

Ethicon Endo-Surgery, Inc.
 4545 Creek Road, Cincinnati, OH 45242-2839 USA

Rx Only

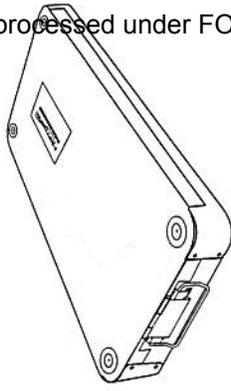
See Instructions For Use



ETHICON ENDO-SURGERY, INC.
 a Johnson & Johnson company

Harmonic*

- Sterilization Tray
- Boîte de stérilisation
- Sterilisationsersatz
- Vassoio di sterilizzazione
- Tabuleiro de esterilização
- Bandeja de esterilización
- Sterilisatietray
- Sterilisierungsbakke
- Sterilointikori
- Δίσκος Αποστείρωσης
- Sterilisierungsbrücke
- Tacka do sterylizacji
- Sterilizációs tábla
- Sterilizaci táč
- Sterilizacijski zasobnik
- 灭菌盘



Please read all information carefully.

Important: This package insert is designed to provide instructions for use of the HARMONIC® Sterilization Tray. It is not a reference to surgical techniques.

The Sterilization Tray is intended for use in the sterilization and resterilization of the HARMONIC reusable blades, sheaths, adaptors, hand pieces, test tips and blade wrench.

*Formerly known as *UltraCision® Harmonic Surgit®*

HARMONIC, ULTRACISION and HARMONIC SCALPEL are trademarks of Ethicon Endo-Surgery.



Instrucciones, Instrucciones, Gebrauchsanweisung, Istruzioni, Instruccões, Instrucciones, Gebrauchsanweisung, Brugsvejledning, Ohje, Öbnytt, Bruksanvisning, Instruckcja, Uputstvo, Návod k použití, Návod, 使用説明



JHC1592564G

REF
HS101

Ethicon Endo-Surgery (Europe) GmbH
Hummelsbütteler Steinweg 71
22851 Nordstedt
GERMANY

Johnson & Johnson AG
CH-8957 Spreitenbach
SWITZERLAND

USA REP
ETHICON ENDO-SURGERY, INC.
Cincinnati, OH 45242-2839 USA
1-800-USA-ENDO

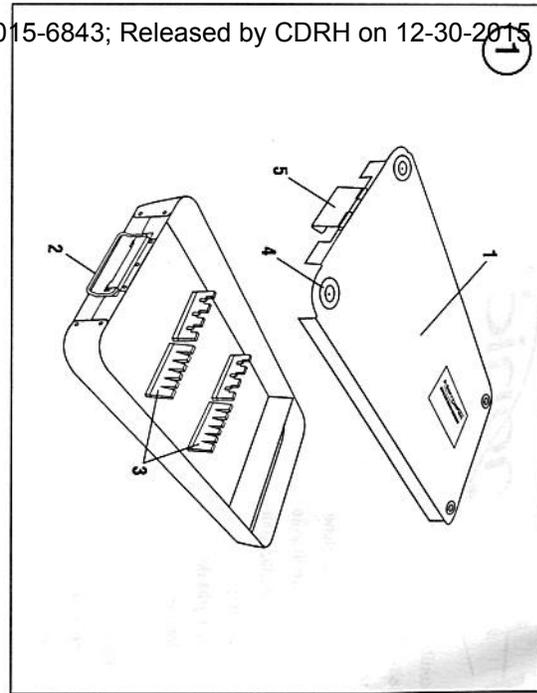
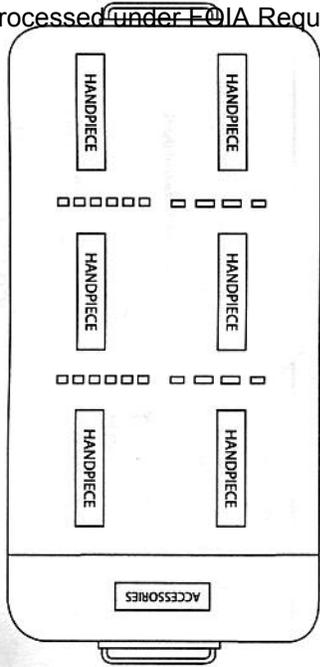
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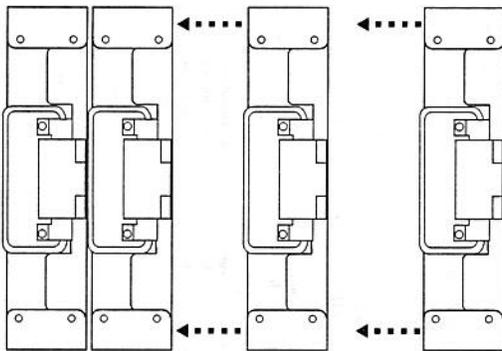


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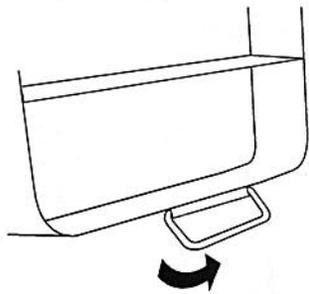
Rev. 2010-12



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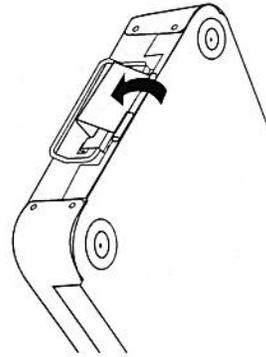
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4

5

3



- Illustration and Nomenclature (Illustration 1)
1. Tray Cover
 2. Handle
 3. Hold-It
 4. Foot Indentation
 5. Tray Latch

Prepping for Sterilization

The user must ensure that cleaning and sterilization are conducted in accordance with the appropriate guidelines, standards or national Health Authorities' requirements. These trays have been designed to allow for thorough cleaning and safe sterilization.

1. Thoroughly decontaminate the instruments to be sterilized according to instructions in the instruments' package inserts or the Decontamination and Sterilization insert.
2. Place the instruments in hold-its so that all instrument surfaces will be exposed to the sterilant. Do not have them open or disassembled. Be sure nothing will interfere with the flow of air and sterilant. **Important:** Reliable sterilization and instrument protection depends on properly orienting and spacing the instruments. **Do Not Overload** hold-its and trays.

The following organization of instruments within the Sterilization Tray is recommended, and that each tray contain the following: (Illustration 2) Align the instruments according to the diagrams in the Sterilization Tray.

- Up to 6 Haemovac® Hand Pieces
- Reusable instrument blades and sheaths per surgeon preference
- 1 of each type of Blade Adaptor
- 1 Blade Wrench
- 1 Test Tip

3. Close and latch the tray cover. (Illustration 3)
4. Stack trays according to Illustration 4. **Note:** When stacking trays, ensure that the feet on the underside of the tray rest securely within the foot indentations on the tray cover of the bottom tray. Do not stack trays without first securing the tray cover to the bottom tray.
5. Wrap the tray with CSR wrap or place in a sterilization container (following the container manufacturer's instructions).

Standard Procedure

The Sterilization Tray is not recommended for use with STERAD® sterilizers. Instruments that are wrapped or stored in containers can be sterilized using steam or gas sterilization methods. Follow the instructions listed in the instruments' package inserts or the Decontamination and Sterilization insert.

Removing trays from a sterile container

To maintain sterility when removing trays from a sterilized container, grasp the handles firmly and lift straight up out of the container. Do not touch the top edges of the container. (Illustration 5)

Cleaning

Before cleaning, thoroughly inspect the device for any signs of damage, cracks, or improper mechanical function. Do not use the instrument if it shows signs of damage. Discard and replace the instrument if damage or degradation is present. Trays and hold-its may be cleaned as needed with a mild detergent solution or alcohol. The silicone hold-its may be removed for cleaning if necessary. Use only neutral (pH 7-9) solutions, mildy alkaline, and free of sodium carbonate to avoid damaging finish. Do not use scouring pads or abrasive cleaners on metal parts. Do not store trays or hold-its in liquid.

Disinfection

If the Sterilization Tray becomes contaminated with blood or bodily fluid, a disinfection step must follow the cleaning of the tray.

The Sterilization Tray can be thermally disinfected in an automated washer-disinfector cycle of up to 21.00° (100°C) for a maximum of 10 minutes. Drying can be accomplished in an automated cycle as well. Drying temperatures remain under 273°F (134°C).

The following chemical disinfectants are approved for use with the Sterilization Tray:

Disinfectant	Recommended Concentration	Minimum Contact Time
Gler® OPA	100% - No preparation	12 minutes
Dreoner® S1 Plus	1.5% solution	30 minutes
Gigasept®	10% solution	30 minutes
Gigasept® HF	6% solution	15 minutes
Kehrolin®	3% solution	60 minutes
Aspibol®	4% solution	30 minutes

Disinfectants should be prepared and used according to the manufacturer's recommendations for use, concentration and contact time.

Use of other detergents: The use of detergents, other than those specified in this letter, should be assessed for equivalency before using. Technical data sheets are typically available through the manufacturer's web pages to assist in this assessment. Any cleaning process, including tools and solutions, may influence the wear and tear on a device. In some instances, changing to another detergent may be required. As the Haemovac® Sterilization Tray is comprised of anodized aluminum, care should be taken to choose an alkaline cleaner which is appropriate for anodized aluminum instruments/parts.

Any disinfection process, including tools and solutions, may influence the wear and tear on a device or equipment. In some instances, changing to another disinfectant may be required.

Within the applied decontamination process, ensure that detergent and disinfectant residuals are sufficiently removed. Purified or deionized water should be used during final rinsing processes, where applicable (multiple rinses may be required). Refer to the manufacturer's recommendations for the removal of disinfectant residuals.

Seeding baskets in a container

The number of Sterilization Trays which can be placed in a sterilization container is limited by the height of the container. Any combination should allow an additional 1 1/2" to 2" (3.81 cm to 5.08 cm) to compensate for the tray foot and cover. Weight must also be considered and should not exceed 17 lbs. (7.71 kg) (or the recommended weight specified by the manufacturer of the sterilizer). Use covers on all trays to afford the maximum protection for the instruments in case the tray is accidentally overturned or dropped.

Haemovac®

Boîte de stérilisation

Lire attentivement toutes les informations suivantes.

Important : Cette notice a pour but de donner des informations sur l'utilisation de la Boîte de stérilisation Haemovac®. Elle ne constitue pas une référence de techniques chirurgicales.

La boîte de stérilisation est destinée à la stérilisation et à la reconditionnement des lames, des gaines, des adaptateurs, des poignées de connexion, des embouts testeurs et des cils de fixation reutilisables Haemovac®.

* Anciennement appelé **Ultradisc® Haemovac Square®**

Haemovac®, Ultradisc® et Haemovac Square® sont des marques commerciales d'Ethicon Endo-Surgery.



4480 Lake Forest Dr.
Suite 414
Blue Ash, Ohio 45242

FDA CDRH DMC

FEB 18 2015

Received *196*

K150271/S001

February 17, 2015

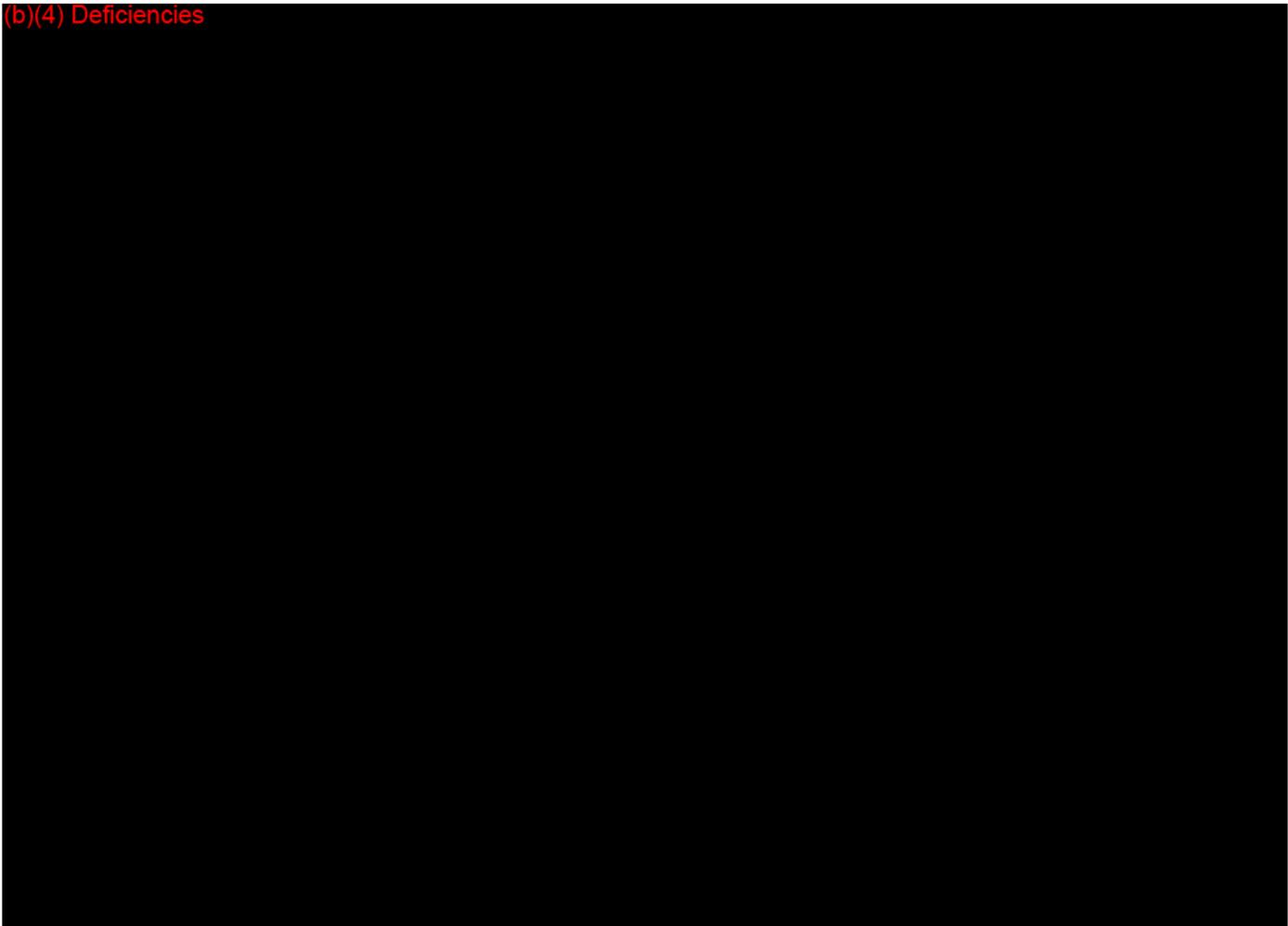
510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K150271 S001 RTA Checklist Response – EndoPrime Prime™ Adaptive Ultrasonic Scalpel System and Blades

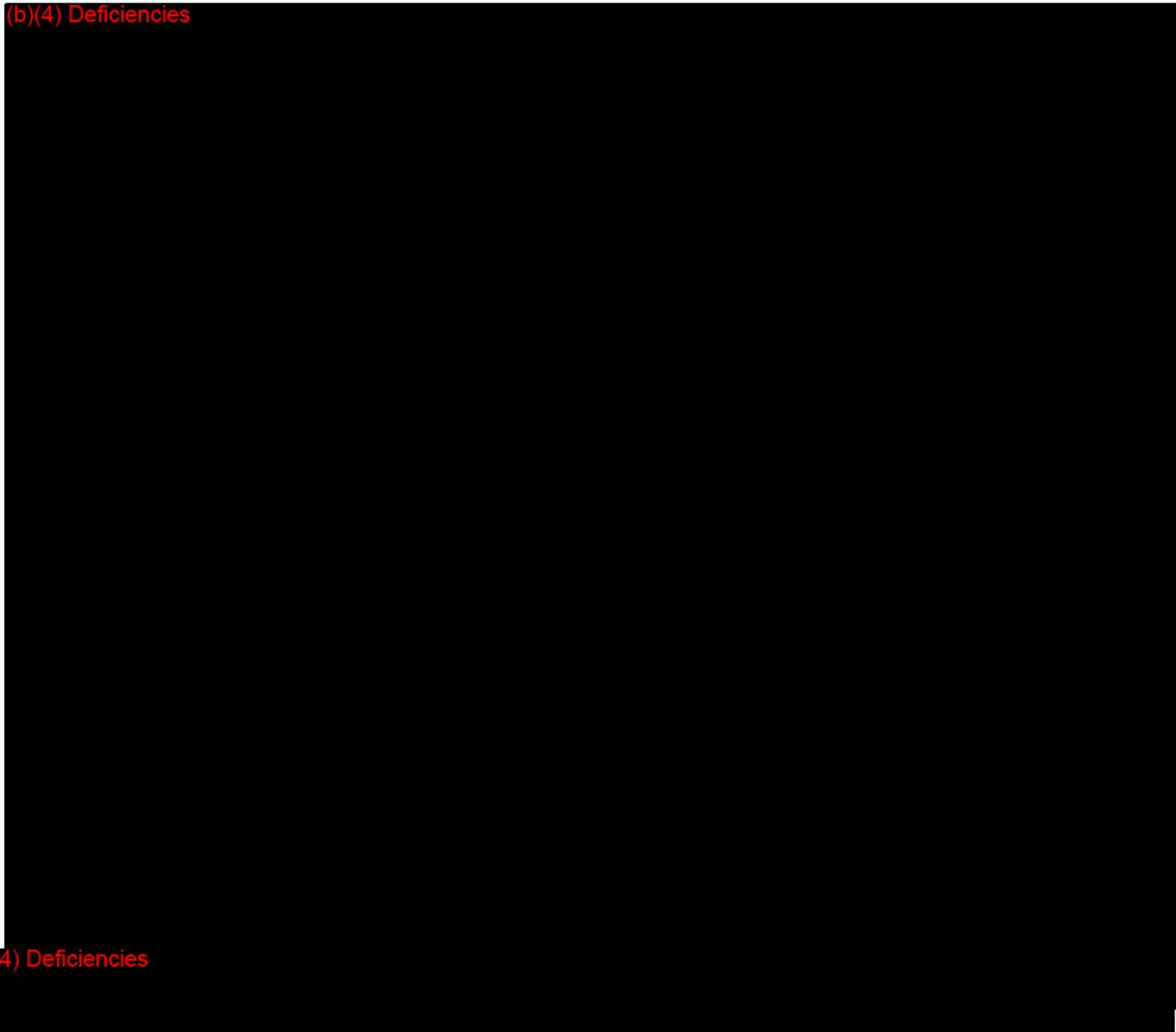
Dear Dr. Claiborne,

EndoPrime is submitting this in response to the Acceptance Checklist for the Prime™ Adaptive Ultrasonic Scalpel System and Blades. The request for additional information is provided below in *italic print*, followed by our response. The electronic copy provided on a CD is exactly the same as the paper copy.

(b)(4) Deficiencies



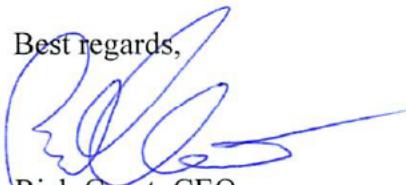
(b)(4) Deficiencies



(b)(4) Deficiencies

If additional information is needed, do not hesitate to contact me.

Best regards,



Rich Grant, CEO
EndoPrime, Inc.

Attachments:

- 1) Attachment 002 - Translated Engineering Drawings
- 2) Attachment 003 - Revised 510(k) Summary
- 3) Attachment 004 - Revised Labeling Instructions for Use



4480 Lake Forest Dr.
Suite 414
Blue Ash, Ohio 45242

February 17, 2015

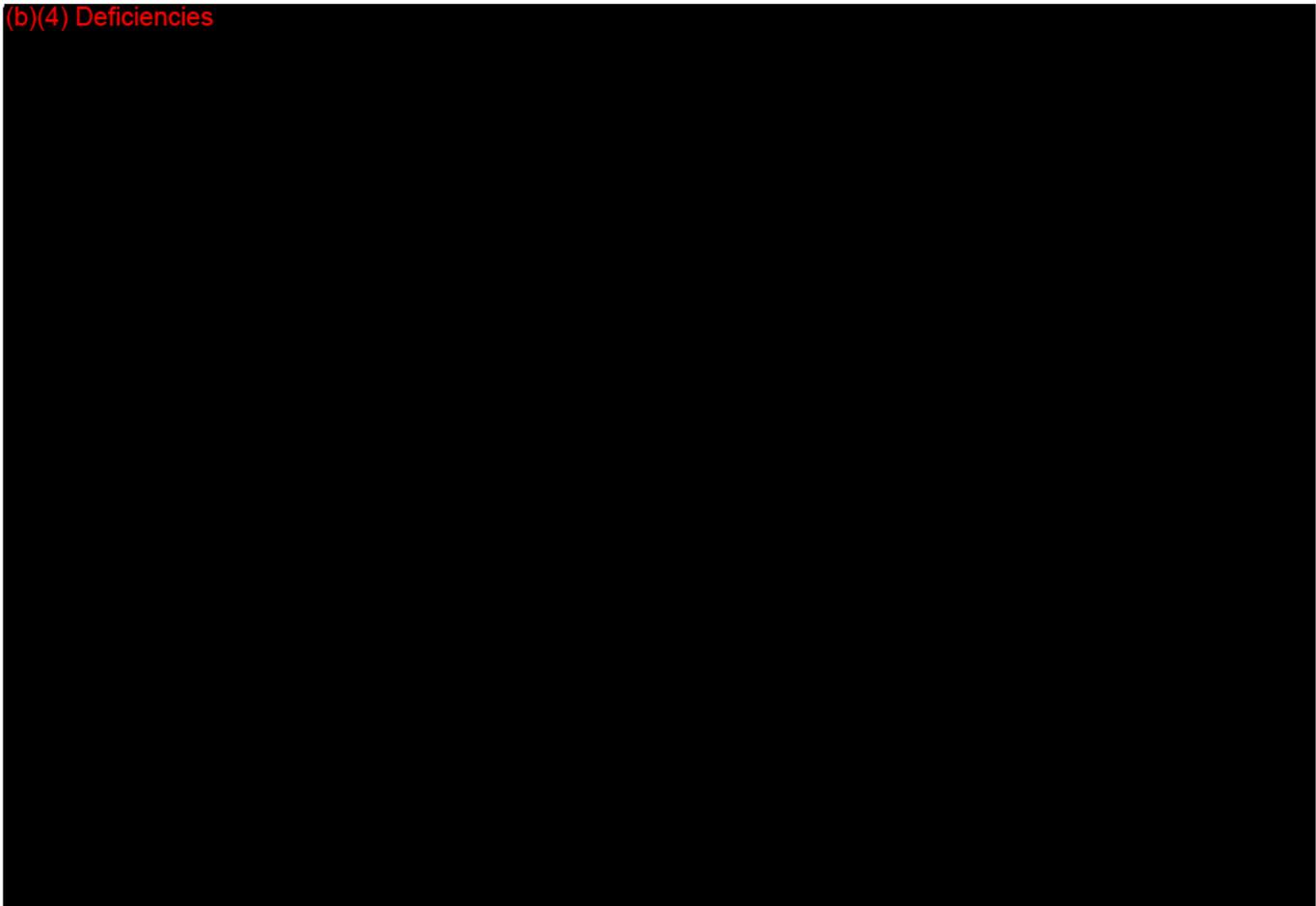
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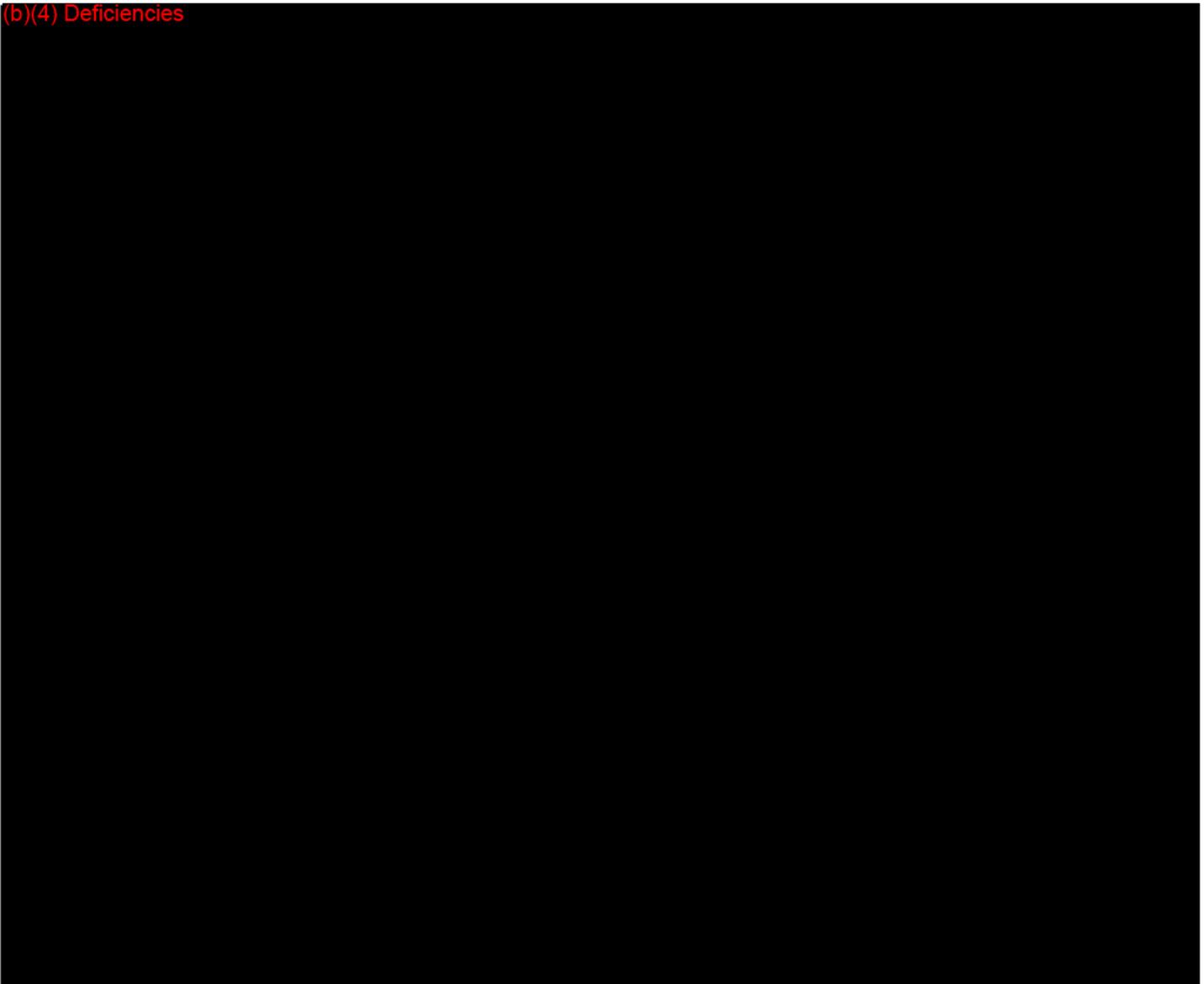
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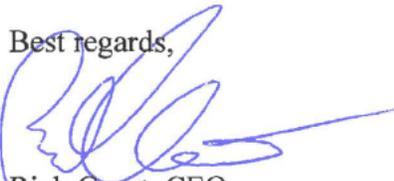


(b)(4) Deficiencies



If additional information is needed, do not hesitate to contact me.

Best regards,



Rich Grant, CEO
EndoPrime, Inc.

Attachments:

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- 2) Attachment 003 - Revised 510(k) Summary
- 3) Attachment 004 - Revised Labeling Instructions for Use

510(k) Summary

Date Prepared: February 17, 2015
Submitter Contact: Rich Grant, CEO
EndoPrime, Inc.
4480 Lake Forest Drive, Suite 414
Cincinnati, OH 45242
513-769-1916

Regulatory Contact: Rich Grant
EndoPrime, Inc.
4480 Lake Forest Drive, Suite 414
Cincinnati, OH 45242
513-769-1916

Trade Name: Prime™ Adaptive Ultrasonic Scalpel System and Blades
Common or Usual Name: Electrosurgical Cutting and Coagulating Device
Product Class: Class II
Classification: Electrosurgical Cutting & Coagulation & Accessories
Product Codes: GEI
Panel Code: General & Plastic Surgery/79
Regulation Standard: 21 CFR 878.4400

AND

Trade Name: Prime™ Ultrasonic Scalpel Reusable Blades
Prime™ Reusable Transducer Handpiece
Prime™ Adaptive Ultrasonic Scalpel Generator
Common or Usual Name: Ultrasonic Surgical Instruments
Product Class: Class II
Classification: Instrument, Ultrasonic Surgical
Product Codes: GEI/LFL
Panel Code: General & Plastic Surgery
Regulation Standard: Unclassified

Reason for this Submission: This Traditional 510(k) involves one medical device system compiled of three individual medical device components.

No Prior Submissions: There were no prior submissions for the subject device by EndoPrime Inc.

Indications for Use:

The **Prime™ Adaptive Ultrasonic Scalpel System** is a cutting and coagulation system indicated for open, laparoscopic, and endoscopic surgery in soft tissue where control of hemostasis and thermal spread is desired. The system is indicated for dissection, sealing, transection,otomy creation and transection/coagulation of vessels as indicated for each cutting and coagulation instrument used (consult the instructions for use provide with each instrument). The system can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels.

Device Descriptions:

The **Prime™ Adaptive Ultrasonic Scalpel System** has three major components: Generator (with footswitch), Transducer Handpiece and instruments (or blades). The **Prime™ 6000 Generator** provides input/output control and operation interface to automatically adapt the ultrasonic power output for the tissue load encountered. The device system is compliant with the following consensus standards:

Performance Standards:	
IEC 60601-1 2005 + CORR. 1 (2006) + CORR. (2007)	International Standard-Medical Electrical Equipment-General Requirements for Basic Safety and Essential Performance
CAN/CSA-C22.2 No. 60601-1:08	Medical Electrical Equipment-Part 1-6: General Requirements for Safety-Collateral Standard; General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems.
EN 60601-1-2:2007 CISPR 11:2009+A1	Medical Electrical Equipment-Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility-Requirements and Tests.
IEC 60601-1-2-18:2009 (Third Edition)	Medical electrical equipment-Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.
IEC 61000-4-8:2010	Medical Electrical Equipment: Part 1-4: General Requirements for Collateral Standard: Programmable Electrical Medical Systems.
IEC 61000-3-2:2006 +A1 +A2	Electromagnetic compatibility (EMC)-Part 3-2: Limits for harmonic current emissions (equipment input current \leq 16 A per phase).
IEC 61000-3-3:2008	Electromagnetic compatibility (EMC)-Part 3-3: Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current \leq 16 A per phase and not subject to conditional connection.
IEC 61000-4-3:2006 + A1:2007 + A2:2010	Electromagnetic compatibility (EMC)-Part 4-3: Limits-Limitation of emission of harmonic currents in low-voltage power supply systems for equipment with rated current greater than 16 A.

IEC 61000-4-4:2004+A1:2010	Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrical fast transient/burst immunity test.
IEC 61000-4-5:2005	Electromagnetic compatibility (EMC). Testing and measurement techniques. Surge immunity test.
IEC 61000-4-6:2003	Electromagnetic compatibility (EMC). Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields
IEC 61000-4-11:2004	Electromagnetic compatibility (EMC). Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests.
ISO 10993-1:2009/AC2010	Biocompatibility Evaluation of medical Device Table A.1
ISO 10993-5:2009	Biological evaluation of medical devices--Part 5: Tests for vitro cytotoxicity
ISO 10993-10:2009	Biological evaluation of medical devices--Part 10: Test for irritation and skin sensitivity
ISO 10993-11:2009	Biological evaluation of medical devices--Part 11: Tests for systemic toxicity
ISO 10993-4:2009	Biological evaluation of medical devices—Part 4: Test for Hemocompatibility
AAMI TIR30:2011	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices. Association for Advancement of Medical Instrumentation, Arlington, VA. (CRD249)
EN/ISO 14971:2012	Risk Management for Medical Device
EN/IEC 62304:2006	Medical device software—Software life cycle processes

Prime™ Adaptive Ultrasonic Scalpel System and Blades family of products consist of:

Prime™ G6000 Generator provides operation interface display, device condition monitoring and Input/Output control. The generator provides electrical energy output to the transducer, which is controlled by activating the footswitch. The **Prime™ G6000 Generator** is also validated to operate with hand switched devices and hand switched enabled transducer hand pieces. A built-in, automatic pre-check function verifies proper connection and operation of the system during startup and continuously monitors the system and instruments. Variable and Maximum (or Full) power levels (1 through 5) are displayed on the front panel and can be selected by pressing the VAR or FULL footswitch pedal (or if available the hand switch). The Variable Power setting can be selected throughout the procedure to provide corresponding energy outputs with the interacting instrument. Audible and visual alarms assist with identifying anomalies, error, and failures including generator, instrument or transducer that are at the end of their useful life. A Standby button is available to pause the system to avoid accidental activation when not in use, or conduct manual system checks and diagnostics.

Prime™ Ultrasonic Scalpel Reusable Blades vibrate ultrasonically, which enables its cutting ability. The same vibration seals small vessels ($\leq 2\text{mm}$) with coagulated blood and tissue proteins by producing local heating of tissue. Homeostasis occurs when tissue couples with the blade. The **Prime™ Ultrasonic Scalpel Reusable Blades** are designed for use with a transducer and a generator system as part of the **Prime™ Adaptive Ultrasonic Scalpel System** and family of products; these products are compatible with a limited number of other manufacturer's systems. The system instruments can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels with the advantages of limited heat/smoke generation and the lack of current flow through the patient. The blade instruments are provided with a reusable Torque Wrench to assure proper tightness when attaching the blade to the transducer. The generator will automatically check the tightness to assure proper function.

The **Prime™ Reusable Transducer Handpiece** cooperates with the **Prime™ Adaptive Ultrasonic Scalpel Blades** as a cutting and coagulation instrument. The **Prime™ Reusable Transducer Handpiece** is designed to convert electrical energy from the generator to mechanical motion of the instrument blades. When the transducer is used in conjunction with the **Prime™ Adaptive Ultrasonic Scalpel System**, the transducer provides ultrasonic vibration, which enables the blade's cutting ability. **Prime™ Adaptive Ultrasonic Scalpel System and Blades** family of products is compatible with a limited number of other manufacturer's systems.

Prime™ Adaptive Ultrasonic Scalpel System products are compatible with a limited number of other predicate systems.

Predicate Device(s):

K002981-Ultracision® Harmonic Scalpel®, Ethicon Endo-Surgery, Inc.

K990430-Ultracision® HARMONIC Scalpel® Hand Piece, Ethicon Endo-Surgery

K010898-Ultracision Harmonic Scalpel Blade, Ethicon Endo-Surgery

K053056-Harmonic Scalpel Blades and Shears, Ethicon Endo-Surgery, Inc.

- **K010309-Sonopet®** Surgical Aspirator, Mutoh America CO., LTD. ***(now Stryker) cited for its blade blue anodized surface only.

Technological Characteristics:

The **Prime™ Adaptive Ultrasonic Scalpel System and Blades** technological characteristics are substantially equivalent to the predicated devices including automatically adapting the ultrasonic power output for the tissue load encountered to provide consistent vibration in differing loads and tissue thickness. The predicate device scalpel blades were predicated on reusable scalpel blades and the **Prime™ Ultrasonic Scalpel Reusable Blades** are designed to function similar to the predicate devices but are provided non-sterile and validated for disassembly, cleaning and sterilization. Another feature of the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** is the ability to disconnect the cable at the transducer handpiece. This feature allows the surgical scrub technician to quickly replace the transducer handpiece and/or ultrasonic blades without contact with the non-sterile surface of the generator or assistance from others. The cable

disconnect was designed as a convenience feature similar to the ability to disconnect at the generator. The **Prime™ Ultrasonic Scalpel Reusable Blades** are designed similar to the predicate blades but have slightly different end effector designs. The **Prime™ Ultrasonic Curved Blades** have a compact design to improve access in narrow, delicate anatomy. The **Omni™ Ultrasonic Hook Blades** are curved for better visibility with a dual hook design to permit easier change of direction without full rotation. These technological improvements will not affect the overall device intended use, performance characteristics, substantial equivalence to the predicate, or raise any new issues regarding safety or efficacy.

Conclusion:

EndoPrime, Inc. concludes that the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** family of products, is substantially equivalent to the predicate devices, and raises no new questions of safety or effectiveness.



Prime™ G6000 Generator System

Operator's Manual REV A



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Contact EndoPrime Customer Service for more information at the number above between the hours of 8:00 a.m. to 5:00 p.m. Eastern Time.



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Section 1 - Indications for Use

1.1 Indications for Use

The Prime™ **Adaptive Ultrasonic Scalpel System** is a cutting and coagulation system indicated for open, laparoscopic, and endoscopic surgery in soft tissue where control of hemostasis and thermal spread is desired. The system is indicated for dissection, sealing, transection,otomy creation and transection/coagulation of vessels as indicated for each cutting and coagulation instrument used (consult the instructions for use provide with each instrument). The system instruments can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels.

1.2 Contraindications

- The **Prime™ G6000 Generator** will not support instruments indicated for incising bone.
- The **Prime™ G6000 Generator** will not support instruments intended for contraceptive tubal ligation.

	<p>This manual is not a reference to surgical technique. Information provided in this manual is provided as a guide for setup and use of the Prime™ G6000 Generator (see Section 6). Also refer to the Instructions for Use provide with each Prime™ Adaptive Ultrasonic family of products used with the Prime™ G6000 Generator.</p>
	<p>Caution! Federal law restricts this system to sale on the order of a physician.</p>



1.3 Prime™ Adaptive Ultrasonic Scalpel System Family of Products

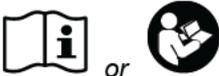
The Prime™ Adaptive Ultrasonic Scalpel System family of products are provided separately. Refer to the Instructions for Use provide with each of the Prime™ Adaptive Ultrasonic family of products used with the Prime™ G6000 Generator. The Prime™ Adaptive Ultrasonic Scalpel System and family of products include the following:

- **Prime™ G6000 Generator set** - generator, foot switch, power cord and operators manual.
- **Prime™ Transducer Handpiece set** - transducer, cable, test tip, and torque wrench.
- **Instrument sets:**
 - **Prime™ Ultrasonic Scalpel Reusable Blades** - includes a Reusable Torque Wench with each blade.
 - **Endoscopic Shears-** Pistol Grip with Hand Activation, includes cable, and torque wrench (contact Customer Service for availability).
 - **Open Shears-** Scissor Grip with Hand Activation, including cord, and torque wrench (contact Customer Service for availability).
- **Accessories:**
 - **Prime™ Generator/Accessory Cart**
 - **Prime™ Sterilization Tray**
 - **Adapter Connector** - for connecting to other manufactures generators systems (contact Customer Service for availability).



Section 2 - Symbol Legend

2.1 Symbols Used in Instruction Manual and on Device Labeling

 WARNING	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or property.
 DANGER! HIGH VOLTAGE	To identify hazards arising from dangerous voltages.
 OPERATING INSTRUCTIONS	Consult instructions for use.
 KEEP DRY	Keep away from direct contact with water.
 DO NOT COVER	To identify equipment that should not be draped with clothing or other material.
 RF ENERGY EMITTED	To identify an RF emitting energy.
 SALE ON ORDER OF PHYSICIAN ONLY	Caution: restricts this device to Caution: Federal (USA) law prohibits dispensing without prescription



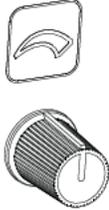
	Type CF Applied Part		Lot or Batch Number
	Temperature Limitation		Humidity limitation
	Precaution -Attention - Consult Accompanying Documents		Catalog Number
	Non-Sterile		Fragile
	Manufacturer		Date of Manufacture
	Do Not Use if package is damaged		This end up
	Serial Number		Equipotential
	On		Off
	Foot Switch		Hand activation
	Fuse		Category AP/(Anesthetic Proof) Equipment



2.2 Control Illustrations and Symbols:

Illustrations and Symbols used for the Prime™ G6000 Generator controls are shown below for reference:

 VAR	Variable (VAR)
 TEST	Test
 STANDBY	Standby
 	Increase Decrease (Or: move curse in Standby Mode)

 FULL	Full (FULL)
 READY	Ready
 OUTPUT	Transducer Socket
	Volume



Section 3 - Warnings and Precautions

3.1 Precautions

1. The products described in this document are recommended for open and endoscopic procedures, which should ONLY be executed by a licensed physician familiar with endoscopic techniques. This equipment is for use only by medical professionals trained in the use, principles and techniques of ultrasonic, laser or electrosurgical procedures.
2. The physician is responsible for referral to relevant literature regarding techniques, complications, and hazards.
3. Users should consult this booklet in order to:
 - Avoid shock and burn hazards to both patient and medical personnel
 - Avoid damage to the device or other medical instrumentation
 - Ensure that electrical insulation or grounding is not compromised during the use of the instrumentation
4. The Prime™ Reusable Transducer Handpiece and cable; reusable blades and torque wrench are shipped non-sterile. These system components must be cleaned and sterilized according to Section 8 – System Cleaning and Sterilization prior to each use.
5. DO NOT USE instruments or transducer if damaged. Damage to the transducer or cable may result in device failure during use. Routinely inspect and replace system components when damaged or if performance is questioned.
6. Prolonged activation of device, especially at high power levels, can result in increased temperatures of the end effector and distal sheath. If prolonged activation is required, frequent pauses to allow the device to cool may be required. Avoid unintended contact with tissue or other sites at all times. Activating the blade in sterile saline may be used to clean and cool the blade's distal tip. Instruments and blades have an intermittent operation of ≤ 15 seconds on and ≥ 15 seconds off unless specified otherwise in the individual instrument instructions.
7. To prevent burn injury, discontinue use and replace the transducer handpiece if the handpiece temperature becomes uncomfortable to hold.
8. If the Prime™ Reusable Transducer is used in conjunction with products outside the Prime™ Adaptive Ultrasonic Scalpel System, verify the compatibility of all instruments and accessories prior to use.
9. Carefully handle instruments, avoid bending and contact with hard surfaces with the blade tip when removing the protective cap and when sliding the torque wrench onto or off the blade assembly. Scratches, dents or distortion of the blade or sheath will significantly shorten the instrument's useable life. Handle the instruments and handpiece with care to avoid damage by dropping or banging the instrument. The handpiece and cable should be inspected for damage before each use.



10. DO NOT USE instruments if the sheath or blade is bent or damaged. Both the sheath and blade must be straight to function safely.
11. The entire blade length is active and will cut or burn tissue when the instrument is activated. DO NOT USE or activate the Prime™ Ultrasonic Blade without fully assembling the protective Sheath over the shaft of the Blade. The shaft of the blade is active and can cause injury if not covered by the Sheath.
12. Blades should be inspected for damage before use. DO NOT USE blades with any damage or suspected damage. Damage to the blades may result in device failure during use. Examples of damage would include any scratches, deviations in shape, discoloration, overheating and audible screeching noise.
13. DO NOT USE torque wrench with evidence of damage. Damage to the torque wrench may result in device failure and inability to properly secure the blade assembly.
14. Always ensure that the instrument being used is clear of other instruments, drapes, retractors, the patient, or other objects when activated or when pressing TEST.
15. As in any laser, electrosurgical, and ultrasonic procedures, the potential exists for personnel to be exposed to carcinogenic and infectious by-products, such as tissue residue, smoke clouds and aerosols. When using the Prime™ Adaptive Ultrasonic Scalpel System protective eyewear, filtration masks, and effective smoke evacuation equipment should be used. Safety measures in accordance with hospital protocol in the presence of smoke and aerosols should be in effect while in use. Additional sterile instruments should be kept available for all surgical procedures in the event that any component becomes inoperable.
16. Immersing the generator, steam sterilizing the generator or contact with liquids or fluids may result in damage, risk of electrical shock or fire hazard.
17. Error or Check messages are indicators that a system component is malfunctioning or at the end of its usable life. Error and Check messages should always be addressed immediately according the Section 6.2 of this manual. Failure to follow the instructions in Section 6.2 could result in system failure and possible injury to the patient or user.
18. The system and generator must be operated under the specified environmental conditions listed in the Appendix.
19. The equipment should not be used in the presences of flammable anesthetic gasses mixed with air, oxygen, or nitrogen oxide. Non-flammable agents ONLY should be used for cleaning and disinfection. Sparks may be generated due to collision with other metal apparatuses and may ignite flammable fluids or gases.
20. To reduce the hazard of interference, electrosurgical equipment and the Prime™ G6000 Generator, cable and handpiece, should be located at a distance of at least 1 meter from other electrosurgical or similar equipment.



3.2 Warnings

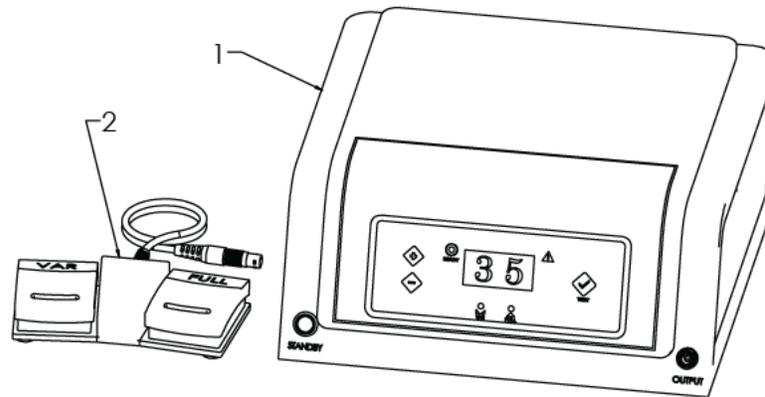
1. DO NOT USE the product if homeostasis cannot be achieved or observed. Monitor for bleeding during use of the device; if a small amount of or uncontrollable bleeding occurs, manually stop the bleeding.
2. Verify that the scalpel blade is clear of tissue, other instruments, and other objects before activating the system to avoid damage or injury. Only activate when the end effector (exposed (b)(4) [REDACTED]) can be fully visualized. Lack of full visibility may result in unintended cutting of tissue or damage to other devices. Avoid blade contact with any and all metal surfaces especially while the instrument is activated. Contact with staples, clips, or other instruments may result in damaged resulting in broken blades during use.
3. Blood and tissue build up between the Blade and Sheath may also result in abnormally high temperatures at the distal end of the sheath. To prevent the potential of burn injury, remove visible tissue buildup or disassemble sheath to remove tissue. Dry blade assembly to remove moisture before reassembling sheath.
4. DO NOT attempt to bend or sharpen the blade. Deformed, damaged, cracked or broken blades may be identified by a warning tone from the generator and could lead to the blade breaking during use.
5. Attention should be paid to stop activation of device upon completion of tissue cutting. Excess activation may result in heat generation or injury during unintended tissue contact.
6. Excess lateral force on the blade, especially without the sheath attached, may result in damage to transducer handpiece or blade.
7. Interconnection with other medical electrical equipment for endoscopic application is to be type CF applied parts ONLY.
8. The Prime™ Adaptive Ultrasonic System does not insufflate or use inert gases; however, gas embolism caused by, for example, over-insufflation of air, use of inert gas prior to surgery, or the use of laser assist gas is a risk when used with the Prime™ Adaptive Ultrasonic System.
9. When other energized endotherapy devices are used with the Prime™ G6000 Generator or other Prime™ Adaptive Ultrasonic Scalpel System products, refer to the endotherapy device's safe use provided in the instructions for use or seek advice from the manufacturer before proceeding.
10. To avoid injury to the patient or user, keep the scalpel away from tissue, other instruments and other objects before system activation.



Section 4 - Elements of Basic System Function

4.1 Product Description

Figure 1- Prime™ G6000 Generator



1- G6000 Generator 2 - Foot Switch 3 - Power Cord –
not shown

4.1.1 Prime™ G6000 Generator

The **Prime™ G6000 Generator** is a part of the **Prime™ Adaptive Ultrasonic Scalpel System** family of products. The generator provides electrical energy output to the handpiece transducer, which is controlled by activating the foot switch, or hand switch, depending on the handpiece being utilized. The **Prime™ G6000 Generator** provides input/output control and operation interface to automatically adapt the ultrasonic power output for the tissue load encountered. Key aspects of operation are discussed below:

- **Startup:** The **Prime™ G6000 Generator** conducts an initial system test, monitors device condition, provides system test results, displays troubleshooting messages, and deactivates the instrument operation when an anomaly is detected.
- **Power Levels:** Variable and Full power levels are displayed and the variable power level can be adjusted throughout the procedure to provide the desired energy output.
- **Alarms and Indicators:** Audible indication identifies when an instrument is activated in FULL or VAR power levels. Audible and visual alarms and indicators assist with identifying when devices are improperly setup, damaged, or at the end of their usable life.
- **Ready, Standby and Test Modes:** The Standby Button is available to pauses the system during use to allow for safely changing instruments, testing system components and avoiding accidental activation. The Generator defaults to the Standby Mode when first started – press the Standby Button



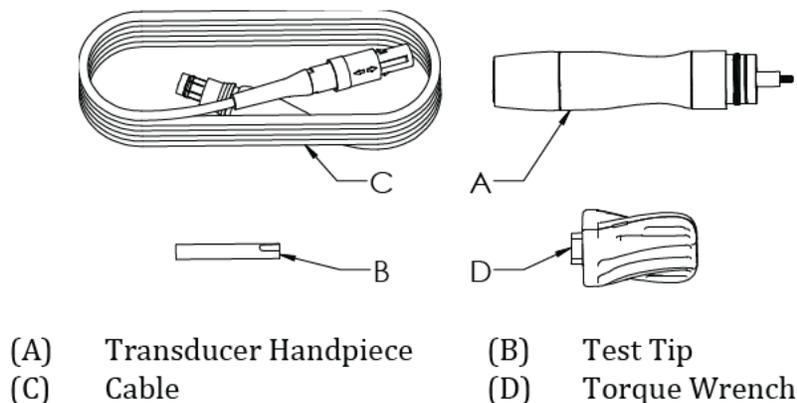
to enter the Ready Mode (see Section 5 below). The system is in the Ready Mode when the Power Levels (3 and 5) are on the screen.

4.1.2 Handpiece Transducer

The **Prime™ Reusable Transducer Handpiece** is sold separately and is designed to convert electrical energy from the generator to ultrasonic motion for the instrument blades. Consult the instructions for use supplied with each of these produces.

The transducer is packaged with a detachable cable used to connect the instrument to the generator. In addition, the package includes a Test Tip for testing the system and a torque wrench used to secure blade assemblies and the Test Tip to the transducer. An adapter for connecting the **Prime™ Reusable Handpiece Transducer** to generators manufactured by others is available (Contact Customer Service for adapter information).

Figure 2- The Prime™ Reusable Transducer Handpiece is provided with the following:



	<p>Precaution! The Transducer Handpiece, Cable, Test Tip and Torque Wrench are provided Non-Sterile, Clean and sterilize before each use.</p>
--	--

4.1.3 Scalpel Blades and Instruments

Prime™ Reusable Ultrasonic Scalpel Blades and other Prime™ Adaptive Ultrasonic Scalpel instruments are sold separately. Consult the instructions for use supplied with each of these devices for assembly and used with the Transducer Handpiece. The scalpel blade vibrates ultrasonically, which heats the tissue by friction and provides the cutting ability. The same vibration seals vessels with coagulated blood and tissue proteins by producing local heating of tissue resulting in homeostasis. See the individual instrument instructions for use for assembly, indications and use of the instruments with the Prime™ G6000 Generator and family of instruments.

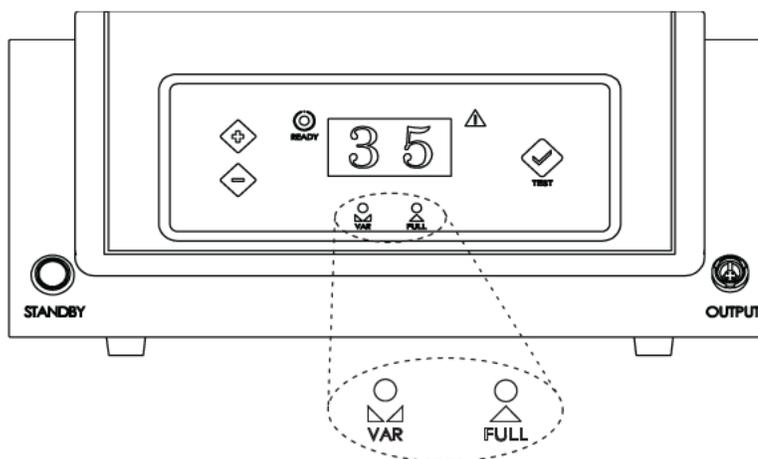


Precaution! The products described in this booklet are designed for use as part of the **Prime™ Adaptive Ultrasonic Scalpel System** and family of products; however, these products are compatible with a limited number of other manufacturer's systems. Verify and test compatibility before use.

4.2 Generator Power Settings

The Prime™ G6000 provides two power settings for the user to select using either the foot switch or hand activation switch. The digital display reflects the two setting as: VAR and FULL (See Figure 3).

Figure 3- Front Panel



The user can set the VAR power from 1 to 5 by pressing the Increase \blacklozenge / Decrease \blacklozenge Buttons on the front panel when in the Ready Mode. Lower settings for the VAR power result in less friction and more heat, which are useful in improved hemostasis. The following are the power distributions for each setting:

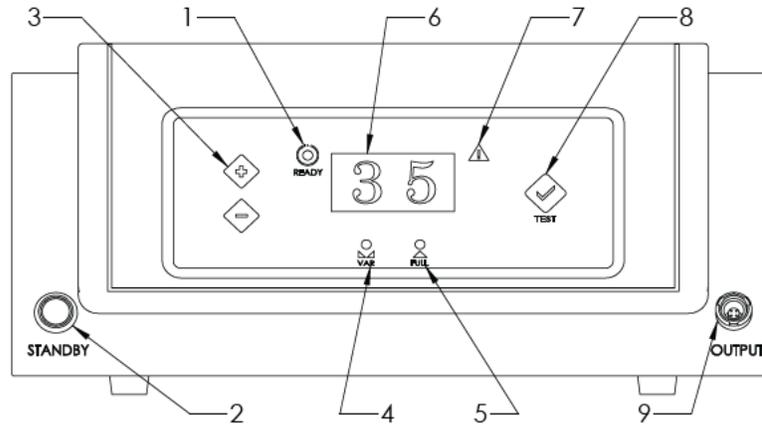
Level 1:	50%	of Full Power
Level 2:	62.5%	of Full Power
Level 3:	75%	of Full Power
Level 4:	87.5%	of Full Power
Level 5:	100%	of Full Power

FULL power is always maintained at level 5. FULL or the 5 power level is often used to obtain fast tissue cutting. The energy conveyed to the tissue and the tissue effect produced depends on many factors, including the selected power level, scalpel shape, clamping force (if applicable), tissue tension, tissue type, pathology and surgical technique.



4.3 Controls, Indicators, and Connections

Figure 4- Front Panel Diagram



Front Panel Features and Controls

Refer to Figure 4 above

 READY	<p>1 Ready - If this indicator light is green, it indicates that the equipment is Ready for use. This indicator light goes off in the Standby mode.</p>
 STANDBY	<p>2. Standby - Press the Standby Button to shift between modes of Standby and Ready. In Standby mode, the transducer has no power output. Neither the foot switch nor instrument switches (if present) can activate the equipment output power. When the equipment is connected to the power supply and switched on, it enters the default Standby mode. An alternative to pushing Standby, if a medical technician is not available outside the sterile surgical field, simply disconnect the transducer power cable from the generator. The green Ready light will go out, and the power will discontinue until the transducer cable is reconnected to the generator.</p>

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Front Panel Features and Controls Continued

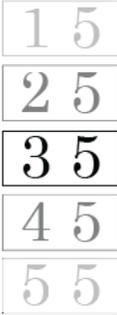
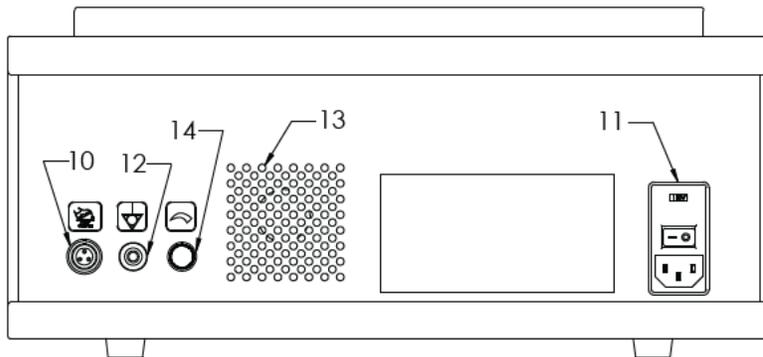
	<p>3. Increase/Decrease of Power Level - Press the  button to increase, or the  button to decrease minimum power to the desired level (from 1 to 5). The selected level will be displayed on the display screen on the left. The power level can be adjusted when the generator is in the Ready mode. When the equipment is in Test mode, these Buttons are used to move the cursor up and down.</p>
	<p>4. Variable Indicator Light - Indicates minimum power level, which can be set by the user. When this power level is activated (through the foot switch or instrument activation), the "VAR" indicator light flashes. The default setting for "VAR" power level is "3".</p>
	<p>5. Full Indicator Light- This indicates maximum power level. This setting is always "5". When it is activated (through the foot switch or instrument activation), the "FULL" indicator light flashes.</p>
	<p>6. Display Screen - displays error messages should errors occur and the power level when in the Ready Mode: Power Level: the variable, VAR, (set by the user from Level 1 to 5) and maximum, FULL, (Level 5) power levels. In case of fault of the equipment or an element or component, the error message will be displayed on this screen.</p>
	<p>7. Warning Indicator Light - The yellow indicator lights up red only when the equipment gives an alarm due to the fault of an element of the generator or equipment.</p>
	<p>8. TEST - In Standby mode, press to enter equipment Test mode. Components and menu functions that can be tested one by one. In the Test mode, use "TEST" as the "enter" Button.</p>
	<p>9. Transducer Socket - The socket on the lower right corner, which is used to connect the transducer to the generator.</p>



Figure 5- Back Panel: Diagram



Back Panel Features and Controls

 	<p>10. Foot Switch Socket - Circular socket - connection for the foot switch by the user.</p>
	<p>11. Power Socket and Switch - The socket is used to connect the power cord to the generator. I is ON, O is OFF. The switch controls the main power supply of the generator. A fuse  is located in the fuse box in the power socket. (See Section 9.2 System Technical Specifications for replacement fuse specifications).</p>
 	<p>12. Equipotential Terminal - This terminal is used when connecting together with other like terminals to bring the same voltage potential, not necessarily the earth ground, to each component or equipment connected to a main source of power (e.g. for local bonding).</p>
<p>See Fig 5</p>	<p>13. Vents – The vents located on the back of the generator should be kept clean and free of any debris. During the system function, air will circulate through the vent to assist with cooling the system. DO NOT block the air vents to avoid generator overheating.</p>
 	<p>14. Volume adjust – The generator produces a sound upon activation, sounds for different power levels, and warning sounds when the system is in different failure modes. Volume will allow the user to adjust these sounds.</p>



4.4 System Component Verification

The **Prime™ Adaptive Ultrasonic Scalpel System** family of products are provided separately for purchase. Prior to use, verify if there is any visible transportation damage. In case of any damage, please contact the customer service or the local agent. The Prime™ G6000 Generator will automatically verify proper connection and function of the system during startup and operation by running a built-in, automatic pre-check function (See Section 5 System Inspection and Testing).

	Precaution! Always test instruments before use to ensure the system is operational to avoid unnecessary delays during surgical procedures. See Section 5 – Testing before Use.
---	---



Section 5 - System Inspection and Testing

5.1 Routine System Inspection

The following system inspection is to be carried out prior to use of the **Prime™ Adaptive Ultrasonic Scalpel System** to ensure user and patient safety:

	<p>Precaution! Additional sterile instruments should be kept available for all surgical procedures in the event that any component becomes inoperable.</p>
---	---

5.1.1 Routine Inspection for Wear and Tear:

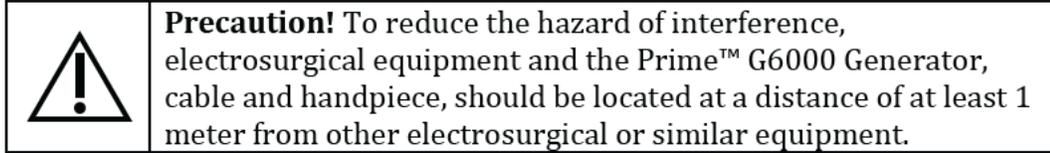
Inspect the generator, cables, foot switch, cable connectors, torque wrench, reusable blades and other equipment for any damage or wear and to ensure there is no liquid present. Any damaged cord, transducer handpiece, or reusable instrument must be replaced before use.

- **Inspect Scalpel Blade:** Inspect the ultrasonic scalpel for damage before and after each use. Also, the outer surface should be checked to ensure there are no unintended rough surfaces, sharp edges or protrusions which may cause harm. The scalpel blade cutting tip is (b) to aid in the detection of scratches and other damage. A damaged or suspect scalpel should be replaced before use.
- **Be Aware and Replace:** The transducer handpiece, blades and other components are rated for multiple reuse, but not infinite life. If the handpiece, sheath or blade makes noise, quickly becomes hot, or blades have degraded cutting performance, the transducer or blade may be beyond its usable life and should be replaced. Examples of damage include any tear in the insulation, deep scratches, deviations in shape, damage to the blade or its mounting surface, corrosion or discoloration. Such degradation may occur or be detected before, during or after a procedure. Older functional blades may also stop functioning during a procedure without warning and should be replaced. Scratches, dents or distortion of the blade or sheath will significantly shorten the instrument's useable life.
- **Indication of End of Blade or Handpiece Life:** A continuous tone or error message from the generator indicates the blade may be at the wrong torque setting or the blade may be at the end of its usable life. If reapplying the torque wrench to the blade does not resolve the error, the blade may be damaged and must be replaced. An audible screeching tone emanating from the blade or transducer is an indicator that the blade or transducer handpiece is beyond its useful life and should be replaced.



Proximity to other Equipment:

Ultrasound surgical equipment, including the transducer cable, should be located at a distance of at least 1 meter from other electrosurgical equipment, cable and handle (such as electrosurgical devices).



Safety Equipment:

Ensure that protective eyewear, filtration masks, and effective smoke evacuation equipment are available for use.

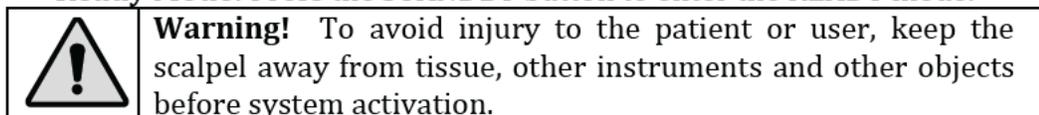
Clear Tissue Buildup:

Verify that the scalpel is clear of tissue, other instruments, and other objects before activating the system to avoid damage or injury.

5.2 Routine System Function Testing

Prior to any surgical procedure using the **Prime™ Adaptive Ultrasonic Scalpel System**, the following functional testing steps should be conducted:

- **Connect** the scalpel and the Transducer Handpiece as described in Section 6 – Instructions for Use. Connect the desired scalpel instrument (blade or shears) following the instructions supplied with the instrument. Or, the generator and transducer handpiece may be tested by installing the Test Tip on the transducer (use the Torque Wrench supplied to tighten the Test Tip until the Torque Wrench clicks at least twice).
- **Verify:**
 - System can enter the READY mode. Press the STANDBY button to exit the standby mode and enter the READY mode.
 - Indicators are on.
 - Display VAR power level (default is 3) and the FULL power level 5.
- **Press the power** increase  and decrease  buttons to adjust the VAR power level between 1 and 5.
- **Turn off** the generator power (Back Panel). Wait for five seconds, and then switch on the generator power. The generator will automatically run a built-in, automatic pre-check function system wide test. Wait for another 10 seconds, press STANDBY button, and verify that the VAR power level 3 and the FULL power level 5 are displayed. Confirm that the generator is not activated during this process.
- **Standby Mode:** Press the STANDBY button to enter the STANDBY mode.
- **Ready Mode:** Press the STANDBY button to enter the READY mode.





- **Activate:** Hold the Transducer Handpiece with its distal end in the air and step on the VAR foot pedal of the foot switch (or Hand Switch where applicable). Check to see whether the VAR power level indicator on the control panel is flashing and the sound of the VAR activation is heard (slow beeping). Repeat by stepping on the FULL pedal, observing the FULL indicator and a rapid beeping is heard.

Successful completion indicates the system is ready to use.

5.3 Individual Component Functional Testing

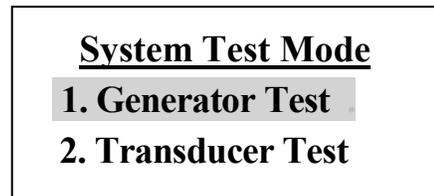
The equipment detects system failures of the generator, transducer or scalpel using a built-in, automatic pre-check function during startup and monitors the system during operation. Individual components may be tested manually anytime or for troubleshooting:

- **Press TEST Button in the Standby mode to enter the System Test mode.**
- **Press the \blacklozenge or \blacktriangleleft Button to move the cursor and select the corresponding component to perform a test.**

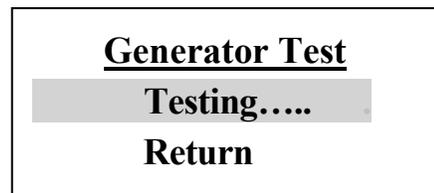
The following are test methods and screen displays of the functional tests available that may be use to conduct individual testing of components and are useful in trouble shooting (see Section 7 - Troubleshooting).

5.3.1 Generator Test:

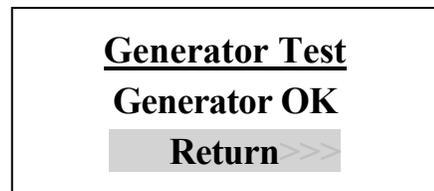
With the generator in Standby Mode press the TEST button on the Front Panel to activate the Test Mode. The screen will change as follows:



Press the TEST Button again to start a full test of the generator. The normal test screen is shown as follows:



After the generator has passed the test, the following screen will be display:



Press the TEST Button to return to the Test Mode.



****ERROR:** When any functional component has been found to be faulty during a test, the following screen is displayed and flashes on and off for 5 seconds. After the 5 seconds the screen will return to the following screen:

Generator Test
**Generator
Failure**

After the 5 seconds the screen will return to the following screen:

System Test Mode
1. Generator Test
2. Transducer Test

Check all connections; inspect cables, transducer, and instruments. Retest and if the failure persists, call Customer Service for repair the Prime™ 6000 Generator if faulty.

5.3.2 Transducer Handpiece Test:

With the generator in Standby Mode press TEST to activate the Test Mode. The screen is shown as follows:

System Test Mode
1. Generator Test
2. Transducer Test

Press the  Button, to highlight the transducer test menu. The screen is shown as follows:

System Test Mode
1. Generator Test
2. Transducer Test

Press the TEST Button to start the test of the functional components of the transducer automatically. The normal test screen is shown as follows:

Transducer Test
Testing...
Return

After the transducer has passed the test, the following screen will display:

Transducer Test
00XXXX OK
Return

OK = the Transducer is within the acceptable range.
00XXXX = the capacitance in nanofarads is displayed for servicing reference.



****ERROR:** When any functional component of the transducer has been found to be faulty during a test, the following screen is displayed and flashes on and off for 5 seconds.

Transducer Test
Transducer Failure

After the 5 seconds the screen will return to the following screen:

System Test Mode
1. Generator Test
2. Transducer Test

Other fault messages and audible alarms are shown in Section 7, Table 1- Troubleshooting Audible Indicators and Alarms

5.3.3 Instrument Scalpel Test:

With the generator in Standby Mode press TEST to activate the Test Mode. The screen is shown as follows:

System Test Mode
1. Generator Test
2. Transducer Test

Press the DOWN  Button, to highlight the scalpel test menu. The screen is shown as follows:

System Test Mode
2. Transducer Test
3. Scalpel Test

Press the TEST Button to start the test of the scalpel automatically. The test screen is shown as follows:

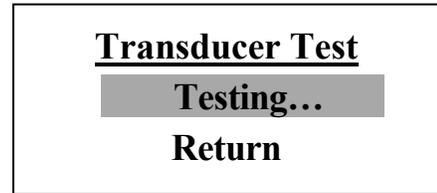
Scalpel Test
Press VAR
Return

Press the Footswitch VAR pedal (or hand switch). The test screens are shown as follows:

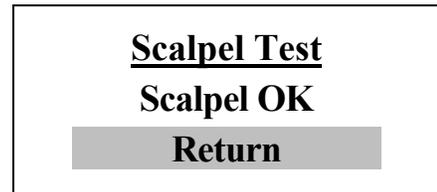
Scalpel Test
Initialization
Return



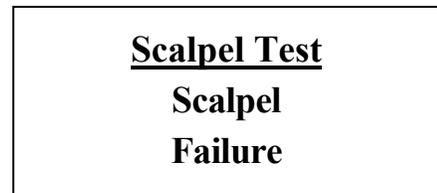
Followed by:



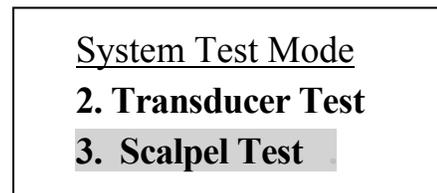
After the scalpel has passed the test, the following screen will display:



****ERROR:** If a scalpel fault has been detected during a test, the following screen is displayed and flashes on and off for 5 seconds (i.e. scalpel abnormality):



After the 5 seconds the screen will return to the following screen:

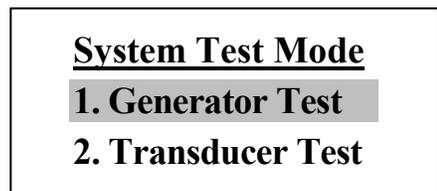


Press the **TEST** Button to return to the **Standby** mode of the equipment, and then refer to Section 7 – Troubleshooting, to address the Error message. Other fault messages and audible alarms are shown in Section 7, Table 1- Troubleshooting Audible Indicators and Alarms. Replace the Prime™ Transducer Handpiece if faulty.

5.3.4 Exit System Function Testing:

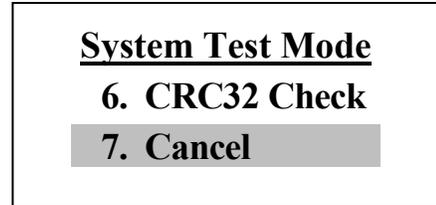
When the desired system component(s) or have been tested utilizing the steps above and all of the error messages have been resolved, the following are the steps to exit the system test mode:

The Test Mode menu is shown as follows (or the cursor may be on one of the tests):





Press the DOWN  Button until the cursor is over "Cancel". The screen is shown as follows:



Press the TEST Button to exit the TEST Mode and return to the Standby mode.

5.3.5 Service Menu Selections:

Additional Test Mode Menu Selections are available for servicing. These functions provide Customer Service information and are selected similar to the steps above.

The Customer Service functions are:

4. "S-Power" = provides Customer Service information regarding power.
5. "HandAD Define" = provides Customer Service information for hand activated devices.
6. "CRC Check" = provides Customer Service information for software version and check sum to insure software integrity.

Contact EndoPrime Customer Service for use of these menu items.



Section 6 - Instructions for Use

6.1 System Setup and Test



Precaution! Read and follow all instructions for use during setup, installation, and system interaction. Not following instructions may prevent the Prime™ adaptive ultrasonic scalpel system from being able to perform its intended actions.

1. **Switch off** the generator power switch before setup.
2. **Connect** the power cord to the AC power socket on the rear panel of the generator. Connect to power outlet that meets the voltage requirements of the generator.
 - If the power cord is wound around the handle of the cart or other holder, it must be removed completely from the handle before inserted into the power output socket.
3. **Inspections and testing** must routinely be completed for all equipment before use - Refer to Section 5.
4. **Connect** the foot switch cable to the foot switch socket on the rear panel of the generator.
 - Ensure that the connector socket is dry and clean.
 - Be careful not to introduce any liquids during connection in order to prevent accidental activation.
5. **Connect** the scalpel to the Transducer Handpiece in accordance with the operating instruction.
6. **Connect** the Transducer Cable to the socket on the front panel. Before connecting the Transducer to the generator:
 - Ensure that the Transducer connector is dry and clean.
 - Insert the Transducer connector completely to ensure that it is connected to the generator correctly.
7. **Turn on** the power switch of the generator and observe the initialization sequence. When the power is switched on, the following indicator lights on the front panel will light up for a moment: READY, FAULT, VAR, FULL



Warning! To avoid injury to the user or patient during equipment inspection, use caution to keep the distal end of the instrument away from other apparatuses, the surgical drape, the patient or other objects.

8. The **startup sequence** will be run by the equipment automatically. It will give an audible indication during the initial sequence. The complete power-on sequence lasts about 20 seconds. **If the startup sequence is different from that described above, please contact EndoPrime Customer Service.**



9. **Standby:** After completion of the startup sequence, the equipment will enter standby mode.
- If the equipment detects a fault of the generator, the error detected will be displayed on the display screen and an alarm will be heard.
 - See Section 7 - Troubleshooting.

	Precaution! Prior to use of the system, component and system testing should be completed. See Section 5 – Testing, for the appropriate steps.
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10. **Power level:** When the equipment starts up, the default power level of the generator is 3 (VAR) and 5 (FULL).
- The user can adjust the minimum (VAR) power level from levels 1 to 5.
 - To adjust the minimum power level, press the $\blacklozenge/\blacklozenge$ buttons on the left of the display screen.
 - Set the power level according to the preference of the surgeon and/or the recommendation of the scalpel operating instruction
 - For more details, please see the power level portion of Section 4.2 – Power Settings.

11. **Audible Activation Indication:** The generator uses different sounds to indicate activation power level. A dial located on the back of the generator can set the sound volume.

After inspecting and startup, the equipment is ready for use.

	Warning! The generator must be operated under the specified environmental conditions.
	Warning! If the Prime™ G6000 generator is damaged or it is suspected that it has fallen or that water has got into it, a Customer Service or other evaluation must be carried out before deciding whether it can continue to be used.

6.2 System Functions

	Precaution! Before use of the Prime™ G6000 and other ultrasonic surgical equipment or components, the user should refer to the Instructions for Use for the other component, instrument, scalpel, and Transducer Handpiece if appropriate.
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1. Press the STANDBY Button to exit **Standby**.
2. The generator will enter **Ready** mode and the VAR and FULL Power levels will be displayed.
3. Step on the foot switch to activate the ultrasonic output.

Press the STANDBY Button to exit **Standby**. The generator will enter **Ready** mode. Step on the foot switch to activate the ultrasonic output and test the instrument.



6.3 System Shutdown and Storage

Upon completion of the surgical procedure, the following steps should be followed to shutdown the **Prime™ Adaptive Ultrasonic Scalpel System**:

1. Turn off the power switch of the PRIME™ G6000 and pull the power cord out of the outlet socket.
2. Disconnect the transducer and the scalpel cords handling according to their instructions for use.
3. Wipe off and place the Transducer Handpiece and cable in the sterilization tray.
4. Disconnect the Reusable Sheath and Blade (or other instrument) from the Transducer Handpiece using a torque wrench.
5. When using reusable blades: Remove blood/debris from the Sheath and Blade. Replace protective caps on reusable blades.
6. Place cables, reusable blades with caps, and torque wrench in sterilization tray.
7. Replace any equipment that is not performing, worn, corroded, deteriorated, damaged, nonfictional or at the end of its usable life. Ensure that two of each item is in the tray as backup for the next surgery.
8. Clean the PRIME™ G6000, cart, foot switch, transducer and reusable instruments according to the procedures listed in Section 8 – System Cleaning and Sterilization.
9. The foot switch should be stored on the Cart with the Prime™ G6000 Generator or stored off the floor. The power cable should remain with the generator.



Section 7 - Troubleshooting

The PRIME™ G6000 generator has a series of alarm signals and error messages to help to recognize and detect faults of elements and components. Signals and messages are available as a resource to alert the medical professional when a device or system failure is occurring, and a system check or corrective action should be implemented. The following is a guide to audible indicators, alarms, and error messages.

7.1 Table 1: Troubleshooting Audible Indicators and Alarms

Sound	Possible Cause and Troubleshooting
No audible indications is given when the equipment is activated	<ul style="list-style-type: none"> • Assure the volume is adequate by adjusting the volume control. • Test function of the blade by placing the tip in sterile saline. • Make sure the Foot Switch and Transducer Handpiece cables are connected correctly and not damaged. • Restart the system and follow all recommended testing before use (See Section 5 – Testing).
Continuous Sound (>10 seconds)	<ol style="list-style-type: none"> 1) The scalpel has contacted/grasped too much tissue. <ul style="list-style-type: none"> • Reduce the amount of tissue in contact with the scalpel. • If continuous sound continues, remove the tissue buildup at the end of the scalpel and end effectors. 2) Transducer and/or scalpel error message or fault. <ul style="list-style-type: none"> • Press the TEST Button to find out the fault source. • When determined what device is failing, replace the device while the system is in STANDBY mode or with the Transducer Handpiece disconnected..
Alarm (two sequences)	Fault of a system component. See ERROR MESSAGES Chart in this section for more troubleshooting.



7.2 Troubleshooting and using Error Messages

The Prime™ G6000 Generator will automatically and continuously test the generator, transducer, scalpel, and foot switch to recognize faults. When a fault is recognized, an alarm will sound and an Error Message will appear on the display screen of the generator. The error message can be traced to a component listed below (i.e. the Foot switch, generator, transducer, or scalpel instrument). Replacing the component and restarting the system should resolve the problem.

The following are three Error messages to pay particular interest to:

- **Generator Failure or Check Generator:** indicates that the generator has a function problem, or that a Button on the control panel or the foot switch is activated when the power is switched on. In case of persistent generator fault, contact the manufacturer for repair or replacement of the faulty component.
- **Check Transducer or Scalpel:** indicates that the transducer or scalpel has a problem. Replacement scalpels should always be available during a procedure, and any scalpel with a fault should be replaced.



Section 8 - System Cleaning, Sterilization and Maintenance

8.1 Generator Cleaning

The Prime™ G6000 Generator and the related parts are shipped non-sterile. The generator is provided with a Foot Switch and Cable and use of the Prime™ Generator/Accessory Cart is recommended.

Generator Cleaning: Wipe down the generator and power cable using a damp cloth. Only Non-flammable disinfection agents should be used. Inspect to assure the devices will be properly functioning and available for the next surgery.



Warning! DO NOT immerse or Seam Sterilize the Prime™ G6000 Generator or Foot switch.

8.2 Reusable Instruments & Transducer Cleaning and Sterilization



Precaution! Reusable Prime™ Adaptive Ultrasonic Scalpel System products are provided non-sterile.

Reusable Prime™ Scalpel Instruments, Transducer Handpieces, Cables, Test Tips, Torque Wrenches and Sterilization Trays are shipped non-sterile and must be sterilized by the hospital before use. The cleaning method must provide protection from cross contamination, damage to the instruments, and injury to personnel. All of the Prime™ reusable products have been approved for the following cleaning and sterilization procedure:

Remove Blood and Debris: Following each surgical procedure, clean as soon as reasonably possible. Disassemble and wipe down the Blade, Sheath, Transducer and cables with a damp cloth. Manually rinse and scrub the Sheath channel (or cannula) with a soft-bristle or nylon brush to remove any blood or debris. Inspect devices for damage, improper mechanical function, cracks, wear or corrosion. Replace if worn, damaged (including sharp or rough surfaces), or lack of integrity is suspect. For reusable blades: reinstall the Protective Tip Caps to reduce the potential of damaging the tip.

Cleaning: Clean instruments, cables and accessories according to the following steps:

- Use a neutral pH detergent or neutral pH enzyme detergent according to the instructions of the detergent manufacturer.



- Use only nonabrasive materials.
- Immerse in the detergent solution for a minimum of 5 minutes and manually scrub the cannula of the Sheath with a channel cleaning brush until all tissue, blood and debris is removed (use a 5mm or larger diameter nylon-bristles brush or equivalent).
- Machine-wash to remove all visible blood, debris, soil and contamination.

Sterilization Cycle: Double-wrap the tray with an FDA-cleared wrap using standard wrapping techniques such as those described in ANSI/AAMI ST79:2010 and A1:2010 and A2:2011. Steam Sterilize using the following cycle:

Cycle	Temperature	Exposure Time	Minimum Drying Time
Steam Pre-Vacuum 3 pluses	270°F (132°C)	4 minutes	30 minutes

No Lubrication is required for the devices.

8.3 Generator Customer Service

Customer Service and Maintenance

For repair service call (513) 769-1916 and ask for Customer Service. Ask about how to package the generator and other products for return or package in the original packaging. The Prime™ G6000 warranty and other warranties may be voided if the product is not returned in the original packaging or equivalent to protect the products during shipment.

Maintenance of the Prime™ G6000 Generator, Foot Switch, and other accessories requires inspection cleaning, and replacement or repair if damaged. Calibration is not required for the Prime™ G6000 Generator. The software revision level is displayed on the front panel and software may be upgraded when available upon request.

Disposal and Recycling

For environmental protection the Prime™ G6000 Generator, Prime™ Transducer Handpiece and accessories should not be disposed of at their end of life. Contact EndoPrime Customer Service or your local recycling center for instructions to recycle waste equipment. The Prime™ G6000 Generator disposal risks are similar to computers and other electronics. The Prime™ Transducer Handpiece contains lead –recycle or dispose in accordance with local regulations or return to EndoPrime for recycling. The products and accessories contain no radioactive substances, or hazardous liquids that may leak.



Section 9 - System Specifications and Technical Requirements

9.1 System Specifications

9.1.1 Table 2: The Prime™ Adaptive Ultrasonic Scalpel System Components

Product	Product Description
Generator	Prime™ Ultrasonic Generator , Sold with Foot Switch
Transducer Handpiece	Prime™ Reusable Transducer, Sold with Test Tip, and Cable
Ultrasonic Scalpel Blades Reusable -	Prime™ Ultrasonic Curved Blade Instrument Sets 5mm Diameter sold with Torque Wrench Unit sold
	Prime™ Omni™ Hook Blade Instrument Set 5mm Diameter sold with Torque Wrench
Accessories sold separately	Prime™ Generator/Accessory Cart
	Prime™ Sterilization Tray

9.1.2 Table 2b: Additional Products in the Prime™ Ultrasonic Family

Prime™ Endo 5mm Ultrasonic Shears:	Contact EndoPrime Customer Service for information regarding availability of these products
Prime™ Open Curved Ultrasonic Shears	



9.2 System Technical Specifications

Model Number	G6000
Performance	
Ultrasonic Frequency	55 kHz +/- 1 kHz
Over-Temperature Protection	Device automatically shuts down to prevent overheating. Fans will remain on during Over-Temperature Protection. Unit must be power cycled to reset.
Operation Mode	Variable and fixed Power Modes
Maximum Duty Cycle	Intervals of < 15 seconds on; > 15 seconds off
Electrical Input	
Input Line Voltage	90-264 VAC 50-60 Hz @ 6 Amps
Input Line Frequency	50/60 Hz
Line Cord	IEC 60320/NEMA 5-15 - Hospital Grade ~ 15 feet
Fuse	3.0 Amp Slow-Blow, 250 VAC, 5mm
Mechanical and Environmental	
Operating Temp	50°F to 86°F (10°C to 30°C)
Operating Humidity	<70% RH non-condensing
Storage Temperature	13°F to 131°F (-10°C to 55°C)
Storage Humidity	< 80% RH non-condensing
Weight	33 lbs (15kg)
Case Size	H=6.3 (16 cm) Inches x W=14.2 (36 cm) Inches, D=15.0 (38 cm) Inches
Indicators	LED display, LEDs
Safety, EMC, and Regulatory Compliance	<ul style="list-style-type: none"> • IEC/EN 60601-1 • IEC/EN 60601-1-2 • CAN/CSA C22.2 No. 601.1 • CAN/CSA C22.2 No. 601.1.2
Equipment Class	Class 1
	Suitable for Continuous Operation
	Type CF Applied Part Class 1
	IPX0. Ordinary Equipment without the protection against ingress of water.
	Medical Electrical Equipment per IEC 60601-1/CAN/CSA C22.2 No. 601.1
	Not for use in presence of flammable mixtures

	Precaution! The ultrasonic surgical equipment must be operated within the specified ambient temperature range.
	Precaution! Verify that the voltage of the output socket meets the requirements of the generator. Incorrect connection of the power supply may damage the generator and cause shock or fire hazard.



Section 10 - Warranty

WARRANTY COVERAGE:

EndoPrime, Inc. ("EndoPrime") warrants this Generator (**the "Product"**), and only the Product, against defects in materials and workmanship under normal use for a period of one year from the date of retail purchase by the original purchaser ("**Limited Warranty Period**").

Consumer's sole and exclusive remedy, and EndoPrime's sole and exclusive responsibility under this warranty, shall be that EndoPrime will repair the Product at no charge, using new or refurbished replacement parts if a defect arises and a valid claim, as determined in the sole discretion of EndoPrime, is received by EndoPrime within the Limited Warranty Period, at EndoPrime's option and to the extent permitted by law. A replacement part(s) assumes the remaining warranty of the original Product or **NINETY (90) days** from the date of replacement or repair, whichever is longer.

INSTRUCTIONS TO OBTAIN WARRANTY SERVICE:

To obtain warranty service Consumer must notify EndoPrime to obtain a **Return Material Authorization ("RMA")** and return the defective Product together with proof of purchase to the address specified by EndoPrime. Consumer will pre-pay all return shipping charges and shall assume all risk of loss or damage to product while in transit to and from EndoPrime. Any Product returned to EndoPrime without an RMA or without proof of purchase will be returned to Consumer at Consumer's cost. EndoPrime will not be responsible for any such damage or loss.

EXCLUSIONS AND LIMITATIONS:

This Limited Warranty applies only to the Product manufactured by EndoPrime. The Limited Warranty does not apply to any EndoPrime products and services other than the Product. This warranty does not apply to a Product or part of the Product that has been altered or modified (e.g., to alter functionality or capability) by anyone who is not a representative of EndoPrime. In addition, this Limited Warranty does not apply: (a) to damage caused by accident, abuse, misuse, flood, fire, earthquake or other external causes; (b) to damage caused by operating the Product outside the permitted or intended uses not in accordance with the documentation by EndoPrime; or (c) to damage caused by service performed by anyone who is not a representative of EndoPrime.

EndoPrime reserves the right to upgrade and make other necessary changes to the Product at any time without incurring any obligation or liabilities to make the same or similar changes to other EndoPrime products.

No EndoPrime reseller, agent, or employee is authorized to make any modification, extension, or addition to this Limited Warranty. If any term is held to be illegal or unenforceable, the legality or enforceability of the remaining terms shall not be affected or impaired.

DISCLAIMER:

EXCEPT AS SPECIFIED IN THIS LIMITED WARRANTY, ALL EXPRESS OR IMPLIED CONDITIONS, REPRESENTATIONS, AND WARRANTIES INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, SATISFACTORY QUALITY, NON-INTERFERENCE, ACCURACY OF INFORMATIONAL CONTENT, OR ARISING FROM A COURSE OF DEALING, LAW, USAGE, OR TRADE PRACTICE, ARE HEREBY EXCLUDED TO THE EXTENT ALLOWED BY APPLICABLE LAW AND ARE EXPRESSLY DISCLAIMED BY ENDOPRIME TO THE EXTENT AN IMPLIED WARRANTY CANNOT BE EXCLUDED, SUCH WARRANTY IS LIMITED IN DURATION TO THE EXPRESS WARRANTY PERIOD. BECAUSE SOME STATES OR JURISDICTIONS DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, THE ABOVE LIMITATION MAY NOT APPLY. THESE WARRANTIES GIVE CONSUMER SPECIFIC LEGAL RIGHTS, AND CONSUMER MAY ALSO HAVE OTHER RIGHTS WHICH VARY FROM JURISDICTION TO JURISDICTION.



This disclaimer and exclusion shall apply even if the express warranty set forth above fails of its essential purpose.

GOVERNING LAW AND ARBITRATION:

This Limited Warranty shall be governed by the laws of the State of Ohio without giving effect to any conflict of laws principles that may provide the application of the law of another jurisdiction. Any claim or dispute in connection with this Limited Warranty shall be resolved in a cost effective manner through binding non-appearance-based arbitration. The arbitration shall be initiated through an established alternative dispute resolution provider mutually agreed upon by the parties. The alternative dispute resolution provider and the parties must comply with the following rules: a) the arbitration shall be conducted by telephone, online and/or be solely based on written submissions, the specific manner shall be chosen by the party initiating the arbitration; b) the arbitration shall not involve any personal appearance by the parties or witnesses unless otherwise mutually agreed by the parties; and c) any judgment on the award rendered by the arbitrator may be entered in any court of competent jurisdiction. If the foregoing arbitration clause does not apply for any reason, you agree to submit to the personal jurisdiction of the state courts located within Hamilton County, Ohio and the federal courts in the Southern District of Ohio for the purpose of litigating all such claims or disputes, which courts shall have exclusive jurisdiction of such claims or disputes. Notwithstanding the foregoing, EndoPrime may seek injunctive or other equitable relief to protect its intellectual property rights in any court of competent jurisdiction.



Section 11 - APPENDIX

11.1 Table 3: Electromagnetic Emissions Testing

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS		
Adaptive Ultrasonic Scalpel System is intended for use in the electromagnetic environment specified below. The customer or the user of Adaptive Ultrasonic Scalpel System should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	Adaptive Ultrasonic Scalpel System uses RF energy only for its normal operation. Therefore, its unwanted RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Adaptive Ultrasonic Scalpel System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes



11.2 Table 4: Electromagnetic Immunity

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY			
Adaptive Ultrasonic Scalpel System is intended for use in the electromagnetic environment specified below. The customer or the user of Adaptive Ultrasonic Scalpel System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV contact 8 kV air	6 kV contact 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth	1 kV line(s) to line(s) 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 s	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of Adaptive Ultrasonic Scalpel System requires continued operation during power mains interruptions, it is recommended that Adaptive Ultrasonic Scalpel System be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE <i>UT</i> is the A.C. mains voltage prior to application of the test level.			



RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE MODEL

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

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER IN WATTS	SEPARATION DISTANCE IN METERS ACCORDING TO FREQUENCY OF TRANSMITTER		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.38
1.0	1.2	1.2	2.3
10.0	3.8	3.8	7.6
100.0	12	12	23

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

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

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. Interference may occur in the vicinity of equipment marked with the following symbol:





GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

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

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2,5 GHz</p>	<p>3Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of Adaptive Ultrasonic Scalpel System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
 NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio



(cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Adaptive Ultrasonic Scalpel System is used exceeds the applicable RF compliance level above, Adaptive Ultrasonic Scalpel System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Adaptive Ultrasonic Scalpel System .

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

The system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.

11.3 Table 5: Rated Maximum Power Outage

Ultrasound surgical equipment aims at application under an electromagnetic environment in which radiated RF disturbances are controlled. Customers/users of the Ultrasound surgical equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Ultrasound surgical Equipment as recommendations follow, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m.		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.117	0.117	0.233
01	0.36999	0.36999	0.73681
1	1.17	1.17	2.33
10	3.69986	3.69986	7.36811
100	11.7	11.7	23.33

Document #: EPD0018-P01 Revision



Prime™ Adaptive Ultrasonic Scalpel System

Prime™ Reusable Transducer Handpiece

This booklet is designed to assist in using the product and is not a reference to surgical technique. Before using this product, read the following information for setup and use of the following models:

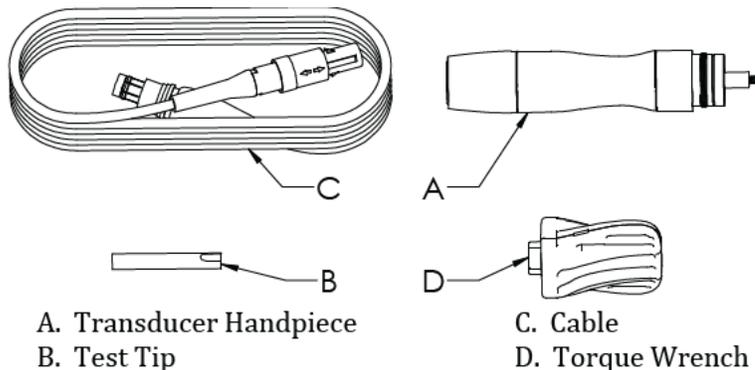
How Provided: Non-sterile -

Model TRN5: The Prime™ Reusable Transducer Handpiece (the transducer) is for foot switch activated devices only. Each transducer is sold with one Prime™ Reusable Torque Wrench, Test Tip and Cable.

	The transducers are designed, tested, and approved for multiple use, and are provided non-sterile. Refer to the steps for use regarding sterilization of the Prime™ Reusable Transducer Handpiece prior to use. The information provided in this booklet is provided as a guide for setup and use of the transducer, and is not provided as a surgical reference.
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Nomenclature and Illustration

Each Prime™ Reusable Transducer Handpiece is provided with Cable, Test Tip and Torque Wrench:



Device Description:

The Prime™ Reusable Transducer Handpiece cooperates with the Prime™ Ultrasonic Scalpel Reusable Blade as a cutting and coagulation instrument. The Prime™ Reusable Transducer Handpiece is designed to convert electrical energy from the generator to mechanical motion of the instrument blades. When the transducer is used in conjunction with the Prime™ Adaptive Ultrasonic Scalpel System, the transducer provides ultrasonic vibration, which enables the blade's cutting ability. Prime™ Adaptive Ultrasonic Scalpel System and family of products are compatible with a limited number of other manufacturers' systems.

The Prime™ Reusable Transducer Handpiece is packaged with a detachable cable used to connect the instrument to the generator. In addition, the package includes a test tip for testing the system and a torque wrench used to secure blade assemblies to the transducer.



Indications for Use

The **Prime™ Reusable Transducer Handpiece** interacts with the **Prime™ Adaptive Ultrasonic Scalpel System** as a cutting and coagulation system indicated for open, laparoscopic, and endoscopic surgery in soft tissue where control of hemostasis and thermal spread is desired. The system is indicated for dissection, sealing, transection,otomy creation and transection/coagulation as indicated for each cutting and coagulation instrument used (consult the instructions for use provide with each instrument). The system instruments can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels.

Contraindications

- The instruments are not indicated for incising bone.
- The instruments are not intended for contraceptive tubal ligation.

Instructions for Use:

Step 1: Transducer Handpiece Cleaning and Sterilization

	The transducer, cable, test tip and torque wrench are shipped non-sterile. These system components must be thoroughly cleaned and sterilized according to hospital standards prior to each use.
	It is highly recommended that additional sterile instruments be kept available for all surgical procedures in the event that any system component becomes inoperable.

Cleaning: The **Prime™ Reusable Transducer Handpiece** and accessories are to be thoroughly cleaned by machine-washing according to the following steps (to avoid loss of usable life, do not immerse the handpiece in cleaning fluid for more than 60 minutes):

- Use a neutral PH detergent or neutral PH enzyme detergent according to the instruction of the detergent manufacturer. Use only nonabrasive materials.
- Wipe all the surfaces (including the generator screen) manually with a clean soft cloth soaked with a small amount of cleaning solution.

Steam Sterilization Cycle: After thoroughly cleaning, sterilize according to hospital procedures. The **Prime™ Reusable Transducer Handpiece** sterilization has been validated for sterilization as follows:

Cycle Type: Pre- Vacuum – 3 Pulses
Temperature: 270F (132°C)
Sterilization Time: 4 minutes
Dry Time: 20 minutes

Use with the **Prime™ Sterilization Tray** or equivalent.

Step 2: Assembly

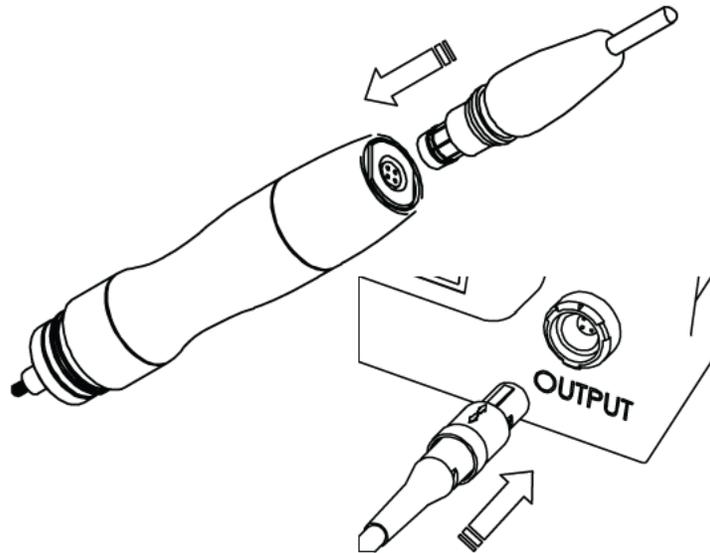
Assemble instrument to the transducer See the appropriate **Prime™ Adaptive Ultrasonic Scalpel** device Instructions for Use.

- | |
|---|
| <p>a. Inspect transducer for damage. The handpiece and cable should be inspected for damage before each use. DO NOT USE instruments or the transducer if damaged. Damage to the transducer or cable may result in device failure during use. Examples of damage to the transducer include any tear in the cable insulation, deep scratches, deviations in shape, discoloration, corrosion, and obvious damage to the threads or blade-mounting surface.</p> |
|---|



b. Assemble instrument to transducer. See the appropriate Prime™ Ultrasonic Scalpel Reusable Blade device Instructions for Use.

c. Connect the cable to the transducer first and then to the generator.



Step 3: Use of the Ultrasonic Assembly

Refer to the Prime™ Adaptive Ultrasonic Transducer Handpiece Instructions for Use and or the generator Instructions for Use.

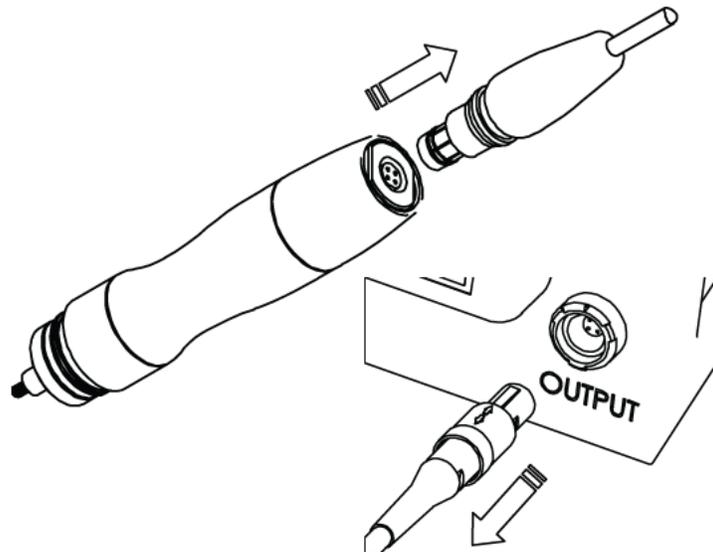


If the Prime™ Transducer Handpiece is used in conjunction with products outside the Prime™ Adaptive Ultrasonic Scalpel System verify the compatibility of all instruments and accessories prior to use.

Step 4: Disassembly

a. Place the generator in standby mode and disconnect the cable from the transducer or generator.

DO NOT activate the generator (i.e. step on the foot switch) with the transducer disconnected. Reboot the generator if a generator error occurs. Call Customer Service if the generator error persists.





b. Disassemble the instrument from the transducer. See the appropriate Prime™ Ultrasonic Scalpel Reusable Blade device Instructions for Use.

c. Place the transducer, cable, and all reusable Prime™ Adaptive Ultrasonic Scalpel System accessories and devices that are serializable in the sterilization tray.



Warnings and Precautions:

1. The Prime™ Reusable Transducer Handpiece, cable, test tip, and torque wrench are shipped non-sterile. These system components must be steam, flash, or otherwise sterilized according to hospital standards prior to each use.
2. If the Prime™ Reusable Transducer Handpiece is used in conjunction with products outside the Prime™ Adaptive Ultrasonic Scalpel System, verify the compatibility of all instruments and accessories prior to use.
3. Handle the instruments and handpiece with care to avoid damage by dropping or banging the instrument. The handpiece and cable should be inspected for damage before each use. DO NOT USE instruments or transducer if damaged. Damage to the transducer or cable may result in device failure during use. Examples of damage to the transducer handpiece would include any tear in the cable insulation, deep scratches, deviations in shape, obvious damage to the blade-mounting surface, or discoloration.
4. DO NOT USE torque wrench with evidence of damage. Damage to the torque wrench may result in device failure and inability to properly secure the blade assembly.
5. Transducers are rated for multiple reuse, but not infinite life. If the transducer makes noise, quickly becomes hot, or attached blades have degraded cutting or coagulation performance, the transducer may be beyond its usable life and should be replaced. Such degradation may occur or be detected before, during or after a procedure. Older functional transducers may also stop functioning during a procedure without warning and should be regularly replaced.
6. Additional sterile instruments should be kept available for all surgical procedures in the event that any system component becomes inoperable.
7. The products described in this document are recommended for endoscopic procedures, which should ONLY be executed by a licensed physician familiar with endoscopic techniques. The physician is responsible for referral to relevant literature regarding techniques, complications, and hazards.
8. All medical professionals handling the instrumentation should be trained and have a thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures in order to:
 - Avoid shock and burn hazards to both patient and medical personnel,
 - Avoid damage to the device or other medical instrumentation.
 - Ensure that electrical insulation or grounding is not compromised during the use of the instrumentation.
9. As with all ultrasonic, laser, and electrosurgery devices, DO NOT immerse the Prime™ Reusable Transducer Handpiece or Cable in liquid when connected to the Generator to avoid the potential for burns or electrical shock.
10. To prevent burn injury, DO NOT continue use of the handpiece if the handpiece temperature becomes uncomfortable to hold.
11. As in any laser, electrosurgical, and ultrasonic procedures, the potential exists for personnel to be exposed to carcinogenic and infectious by-products, such as tissue residue, smoke clouds and aerosols. When using the Prime™ Adaptive Ultrasonic Scalpel System



protective eyewear, filtration masks, and effective smoke evacuation equipment should be available and used.

12. Disposal: Contains lead – dispose in accordance with local regulations.

Storage and Transport Requirements:

Carefully handle, clean, sterilize, transport, and store the Prime™ Reusable Transducer Handpiece to avoid unintentional damage. Damage to the threaded connection or electrical connection will significantly shorten the instrument's useable life.

Store or transport at no more than 95% Relative Humidity, -13°F to 158°F (-25°C to 70°C).

EndoPrime, Inc. Limited Warranty

Warranty Coverage:

EndoPrime, Inc. ("EndoPrime") warrants this Transducer Handpiece (**the "Product"**), and only the Product, against defects in materials and workmanship under normal use for a period of **Nine (9) Months** from the date of retail purchase by the original purchaser ("**Limited Warranty Period**").

Consumer's sole and exclusive remedy, and EndoPrime's sole and exclusive responsibility under this warranty, shall be that EndoPrime will repair the Product at no charge, using new or refurbished replacement parts if a defect arises and a valid claim, as determined in the sole discretion of EndoPrime, is received by EndoPrime within the Limited Warranty Period, at EndoPrime's option and to the extent permitted by law. A replacement part assumes the remaining warranty of the original Product, or **90-days** from the date of replacement or repair, whichever is longer.

Instructions to Obtain Warranty Service:

To obtain warranty service Consumer must notify EndoPrime to obtain a **Return Material Authorization ("RMA")** and return the defective Product together with proof of purchase to the address specified by EndoPrime. Consumer will pre-pay all return shipping charges and shall assume all risk of loss or damage to product while in transit to and from EndoPrime. Any Product returned to EndoPrime without an RMA or without proof of purchase will be returned to Consumer at Consumer's cost. EndoPrime will not be responsible for any such damage or loss.

Exclusions and Limitations:

This Limited Warranty applies only to the Product manufactured by EndoPrime. The Limited Warranty does not apply to any EndoPrime products and services other than the Product. This warranty does not apply to a Product or part of the Product that has been altered or modified (e.g., to alter functionality or capability) by anyone who is not a representative of EndoPrime. In addition, this Limited Warranty does not apply: (a) to damage caused by accident, abuse, misuse, flood, fire, earthquake or other external causes; (b) to damage caused by operating the Product outside the permitted or intended uses not in accordance with the documentation by EndoPrime; or (c) to damage caused by service performed by anyone who is not a representative of EndoPrime.

EndoPrime reserves the right to upgrade and make other necessary changes to the Product at any time without incurring any obligation or liabilities to make the same or similar changes to other EndoPrime products.

No EndoPrime reseller, agent, or employee is authorized to make any modification, extension, or addition to this Limited Warranty. If any term is held to be illegal or unenforceable, the legality or



enforceability of the remaining terms shall not be affected or impaired.

DISCLAIMER:

EXCEPT AS SPECIFIED IN THIS LIMITED WARRANTY, ALL EXPRESS OR IMPLIED CONDITIONS, REPRESENTATIONS, AND WARRANTIES INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, SATISFACTORY QUALITY, NON-INTERFERENCE, ACCURACY OF INFORMATIONAL CONTENT, OR ARISING FROM A COURSE OF DEALING, LAW, USAGE, OR TRADE PRACTICE, ARE HEREBY EXCLUDED TO THE EXTENT ALLOWED BY APPLICABLE LAW AND ARE EXPRESSLY DISCLAIMED BY ENDOPRIME TO THE EXTENT AN IMPLIED WARRANTY CANNOT BE EXCLUDED, SUCH WARRANTY IS LIMITED IN DURATION TO THE EXPRESS WARRANTY PERIOD. BECAUSE SOME STATES OR JURISDICTIONS DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, THE ABOVE LIMITATION MAY NOT APPLY. THESE WARRANTIES GIVE CONSUMER SPECIFIC LEGAL RIGHTS, AND CONSUMER MAY ALSO HAVE OTHER RIGHTS, WHICH VARY FROM JURISDICTION TO JURISDICTION.

This disclaimer and exclusion shall apply even if the express warranty set forth above fails of its essential purpose.

Governing Law and Arbitration:

The laws of the State of Ohio shall govern this Limited Warranty without giving effect to any conflict of laws principles that may provide the application of the law of another jurisdiction. Any claim or dispute in connection with this Limited Warranty shall be resolved in a cost effective manner through binding non-appearance-based arbitration. The arbitration shall be initiated through an established alternative dispute resolution provider mutually agreed upon by the parties. The alternative dispute resolution provider and the parties must comply with the following rules: a) the arbitration shall be conducted by telephone, online and/or be solely based on written submissions, the specific manner shall be chosen by the party initiating the arbitration; b) the arbitration shall not involve any personal appearance by the parties or witnesses unless otherwise mutually agreed by the parties; and c) any judgment on the award rendered by the arbitrator may be entered in any court of competent jurisdiction. If the foregoing arbitration clause does not apply for any reason, you agree to submit to the personal jurisdiction of the state courts located within Hamilton County, Ohio and the federal courts in the Southern District of Ohio for the purpose of litigating all such claims or disputes, which courts shall have exclusive jurisdiction of such claims or disputes. Notwithstanding the foregoing, EndoPrime may seek injunctive or other equitable relief to protect its intellectual property rights in any court of competent jurisdiction.



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Document #: EPD0019-P01 Revision A



Prime™ Adaptive Ultrasonic Scalpel System

Prime™ Ultrasonic Scalpel Reusable Blades

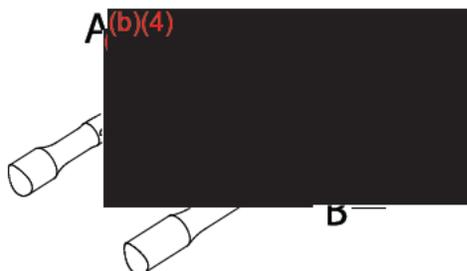
This booklet is designed to assist in using the product and is not a reference to surgical technique. Before using this product, read the following information for setup and use:

Indications for Use

The **Prime™ Ultrasonic Reusable Blade** is a cutting and coagulation instrument indicated for open, laparoscopic, and endoscopic surgery in soft tissue when control of hemostasis and thermal spread is desired. The instrument is indicated for dissection, sealing, transection,otomy creation and transection/coagulation of vessels up to 2mm.

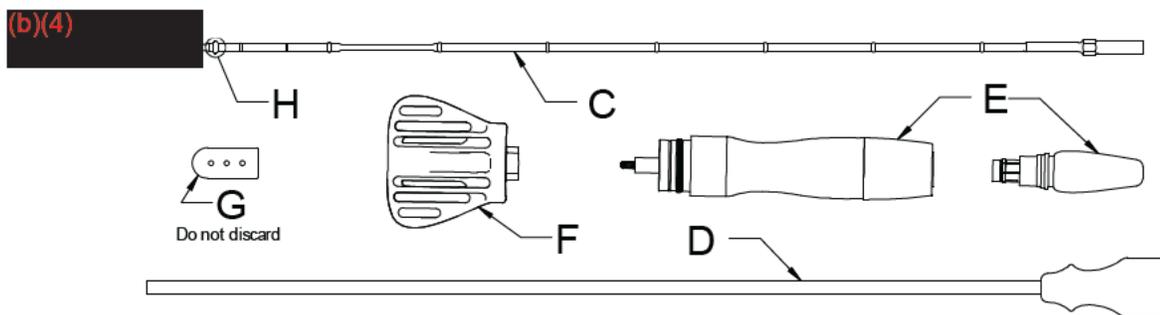
How Provided:

Prime™ Ultrasonic Scalpel Reusable Blades are sold non-sterile and are easily disassembled for cleaning and sterilization. Each blade is provided with one (1) **Prime™ Reusable Torque Wrench** and one (1) **Reusable Protective Cap** (save the cap and reinstall over the blade tip after each use). Blades are provided in different lengths to offer adequate reach in different surgical situations. Blades are provided in two end effector styles:



- (A) Prime™ Curved Ultrasonic Reusable Blade
- (B) Omni™ Hook Blade Ultrasonic Reusable Blade

Nomenclature and Illustration



- | | |
|--|---|
| (A) Prime™ Curved Blade (CB) End-effector | (B) Omni™ Hook Blade (OHB) End-effector |
| (C) Blade | (D) Sheath |
| (E) Handpiece Transducer and cable plug
(sold separately) | (F) Torque Wrench |
| (G) Blade Protective Cap | (H) Blade Distal Silicone Ring (fluid seal) |



	The Prime™ Reusable Ultrasonic Scalpel Blades and Torque Wrench are designed, tested, and approved for multiple use, and are provided non-sterile. Refer to the steps for use regarding cleaning and sterilization prior to use.
	The information provided in this booklet is provided as a guide for setup and use of the Prime™ Reusable Ultrasonic Scalpel Blades and Torque Wrench, and is not provided as a surgical reference.

Device Description

Prime™ Ultrasonic Scalpel Reusable Blades vibrate ultrasonically, which enables its cutting ability. The same vibration seals small vessels with coagulated blood and tissue proteins by producing local heating of tissue. Homeostasis occurs when tissue couples with the blade. The **Prime™ Ultrasonic Scalpel Reusable Blades** are designed for use with a transducer and a generator system as part of the **Prime™ Adaptive Ultrasonic Scalpel System** and family of products; these products are compatible with a limited number of other manufacturer's systems. The system instruments can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels with the advantages of limited heat/smoke generation and the lack of current flow through the patient.

Contraindications

- The instruments are not intended for contraceptive tubal ligation
- The instruments are not indicated for incising bone

Instructions for Use:

	It is highly recommended that additional sterile instruments be kept available for all surgical procedures in the event that any component becomes inoperable.
---	---

Step 1: Blade Cleaning and Sterilization

Cleaning: Instruments and accessories are to be thoroughly cleaned according to the following steps:

- a. Manually scrub the Sheath with a channel cleaning brush to remove all debris (use 5mm or larger diameter nylon bristles or equivalent). Flush with water.
- b. Machine wash using a neutral pH detergent or neutral pH enzyme detergent according to the instructions of the detergent manufacturer. Use only nonabrasive materials.

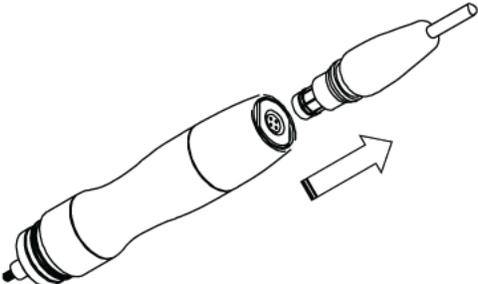
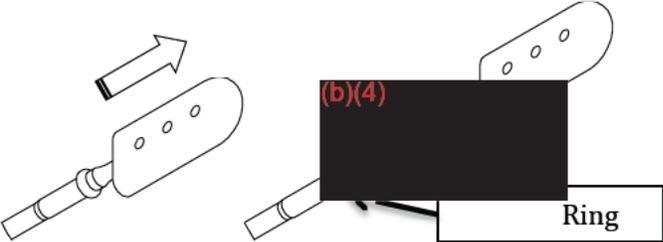
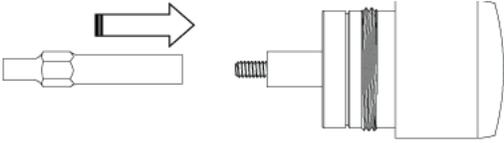
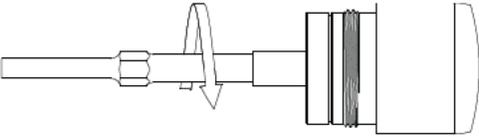
Steam Sterilization Cycle: After thoroughly cleaning, sterilize according to hospital procedures. **Prime™ Ultrasonic Scalpel Reusable Blades** have been validated for sterilization as follows:

Cycle Type: Pre-Vacuum – 3 Pulses
Temperature: 270F (132°C)
Sterilization Time: 4 minutes
Dry Time: 20 minutes

Use with the **Prime™ Adaptive Ultrasonic Scalpel System Sterilization Tray** or equivalent.



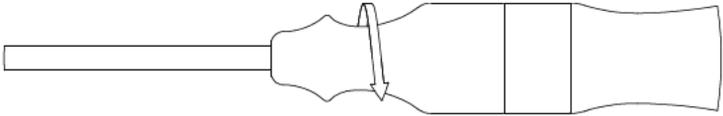
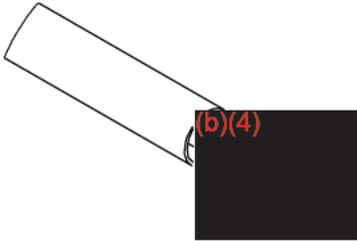
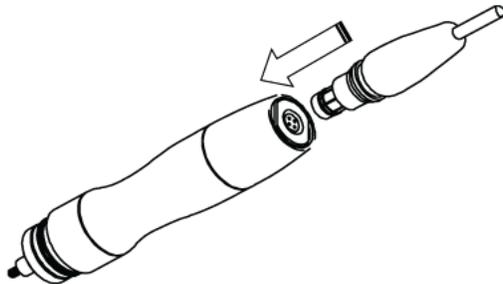
Step 2: Assembly

<p>a. Disconnect the cable from the transducer or generator before assembling the blade with the transducer hand piece or if the blade is being replaced during a procedure.</p>	
<p>b. Remove the Blade Protective Cap from sterile blade assembly and place the cap back in the sterilization tray for use after the procedure.</p>	
<p>c. Routinely Inspect the Prime™ Reusable Blades, torque wrench and other equipment for any damage or wear and to ensure there is no liquid present. The end effector is (b)(4) to aid in observing scratches or other damage. DO NOT USE instruments if (b)(4) damaged. Damage may result in device failure during use. Examples of damage include any tear in the cable insulation, deep scratches on blade, deviations in shape, obvious damage to the blade-mounting surface, missing or broken silicone ring, corrosion or discoloration. Blades or Transducer Handpieces that make noise, quickly become hot, are uncomfortable to hold, have degraded cutting performance or do not pass the generator function test may be beyond the usable life and should be replaced.</p>	
<p>d. Insert the thread end of the transducer into the proximal screw hole of the blade.</p>	
<p>e. While holding the transducer with one hand and the blade with the other hand, gently turn the blade clockwise until the blade comes to a complete stop.</p>	



<p>f. Slide the torque wrench over the blade assembly with the round end crossing the blade first.</p>	
<p>g. When the torque wrench stops at the bottom of the assembly, engage it with the blade and turn clockwise until it clicks, indicating that the blade assembly is secure.</p>	
<p>h. Remove the torque wrench by sliding it back over the blade assembly and place it back in the sterilization tray. Do not dispose of the torque wrench provided with the blade assembly, it is reusable and is compatible with all Prime™ Reusable Blades, Test Tips, and is compatible with a limited number of other manufacturer's ultrasonic systems.</p>	
<p>i. Slide the Sheath over the blade. Assure the correct Sheath length is paired with the blade.</p>	



<p>j. While holding the transducer with one hand and the blade with the other hand, gently turn the Sheath clockwise until the Sheath comes to a complete stop. It is not necessary to continue to tighten the Sheath firmly once it stops turning.</p>	
<p>k. Inspect tip to see that end effector is properly exposed. No silicone rings should be exposed. Confirm blade exposure is sufficient for proper visualization and shielding prior to use.</p>	
<p>l. Reconnect the cable to the transducer or generator.</p>	

	<p>The blade should always be inspected before each use for any damage to the blade, including: scratches, deviations in shape, or discoloration. Damage to the blade could result in failure during the procedure.</p>
	<p>Avoid rough handling and do not allow the blade tip to contact metallic surfaces during assembly, disassembly, handling, and use.</p>

Step 3: Test

Confirm proper function and that the Prime™ Reusable Blades has not exceed it useful life by activating according to the generator Instructions for Use. The generator will conduct a test of the system to confirm proper function.

Be Aware and Replace: The **Prime™ Reusable Blades** and other components are rated for multiple reuse, but not infinite life. If the Transducer Handpiece, Sheath or Blade makes noise, quickly becomes hot and is uncomfortable to hold, or blades have degraded cutting performance, the transducer or blade may be beyond its usable life and should be



replaced. Examples of damage include scratches, dents, distortion of the blade, any tear in the insulation, any deep scratches, deviations in shape, or damage to the mounting surfaces. Such degradation may occur or be detected before, during or after a procedure. Damaged or worn blades may also stop functioning during a procedure without warning and should be replaced. Replace the torque wrench when replacing the blade.

Use of the Blade Assembly

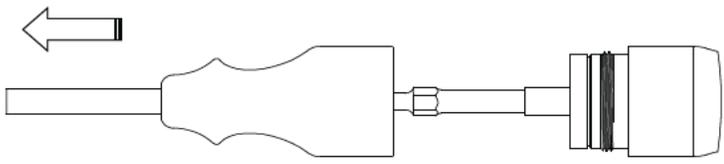
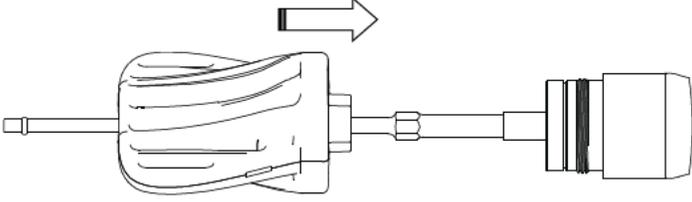
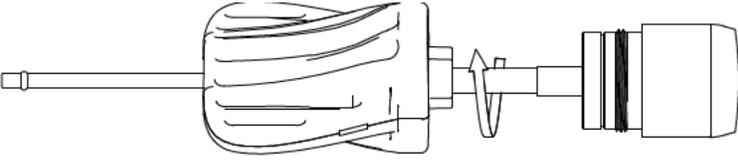
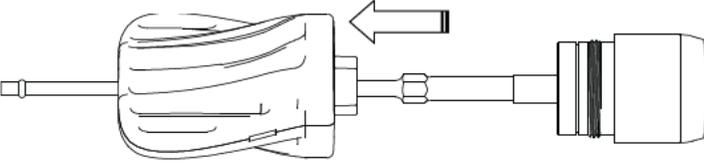
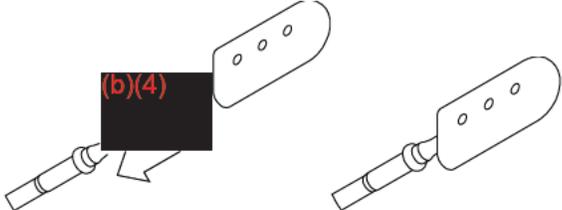
For instructions on use of the Ultrasonic Scalpel Blades, refer to the Prime Adaptive Ultrasonic Sonic Scalpel System-Generator 6000 Instructions for Use.

	<p>Only activate when end effector can be fully visualized. Lack of full visibility may result in unintended cutting of tissue or other devices.</p>
	<p>Prolonged use of the device, especially at high power levels, can result in increased temperatures of the end effector and distal Sheath. If prolonged use is required, frequent pauses to allow the device to cool may be required. Sterile saline may also be used to rapidly cool the device. Blood and tissue build up between the blade and shaft may also result in abnormally high temperatures at the distal end of the Sheath. To prevent the potential of burn injury, remove visible tissue buildup or disassemble the Sheath to remove tissue.</p>
	<p>The Prime™ Ultrasonic Scalpel Blade is a part of the Prime™ Adaptive Ultrasonic Scalpel System and is also compatible with other manufacturer’s systems. Verify the compatibility of all instruments and accessories prior to initiating the procedure.</p>

Step 3: Disassembly

<p>a. Disconnect the cable from the transducer or generator before disassembling the blade from the transducer hand piece or if the blade is being replaced during a procedure.</p>	
<p>b. Remove the Sheath from the transducer by gripping the base of the Sheath where the Sheath screws onto the transducer, and manually turning it clockwise until it completely unscrews.</p>	



<p>c. Slide the Sheath distally to remove, placing the Sheath in the sterilization tray.</p>	
<p>d. Slide the torque wrench over the end of the blade assembly, with the round end of the wrench going over the blade first.</p>	
<p>e. When the torque wrench stops at the base of the transducer, loosen the blade assembly by turning the wrench counterclockwise. Continue to loosen by turning the wrench or the blade assembly manually to unscrew it completely.</p>	
<p>f. Remove the torque wrench by sliding it back over the blade assembly.</p>	
<p>g. Inspect blade for damage, in particular the distal portion. Scratches, dents or distortion of the Blade or Sheath will significantly shorten the instrument's useable life. Damage may result in device failure during future uses.</p>	
<p>h. Place the Blade Protective Cap over the distal end of sterile blade assembly.</p>	
<p>i. Place the blade and torque wrench in the sterilization tray. Do not dispose of the torque wrench.</p>	



Handle the handpiece and blade with care to avoid damage by dropping or banging the instrument on metallic surfaces.



Warnings and Precautions

1. The Prime™ Ultrasonic Scalpel Blade assemblies (with Sheath), Blade Protective Cap and Torque Wrench are shipped non-sterile. These components must be sterilized according to these Instructions for Use and to hospital standards prior to each use.
2. The reusable blade assemblies, sheath, Blade Protective Cap and torque wrench are reusable and must be thoroughly cleaned, sterilized and stored for reuse. If the Prime™ Reusable Transducer is used in conjunction with products outside the Prime™ Adaptive Ultrasonic Scalpel System, verify the compatibility of all instruments and accessories prior to use.
3. The Prime™ Adaptive Ultrasonic Scalpel System includes blades of different lengths to provide adequate reach in different surgical situations. Confirm that the correct length is selected before attempting surgery. In the event two or more lengths are available for use, the appropriate Sheath length should be paired with the blade assembly.
4. Prolonged use of the device, especially at high power levels, can result in increased temperatures of the end effector and distal Sheath. If prolonged use is required, frequent pauses to allow the device to cool may be required. Sterile saline may also be used to rapidly cool the device. Blood and tissue build up between the blade and shaft may also result in abnormally high temperatures at the distal end of the Sheath. To prevent the potential of burn injury, remove visible tissue buildup or disassemble Sheath to remove tissue. Dry blade assembly to remove moisture before reassembling Sheath.
5. DO NOT USE blades with any damage. Damage to the blades may result in device failure during use. Blades should be inspected for damage before use. Examples of damage would include any scratches, deviations in shape, or discoloration. The (b) color of the end effector is an aid in observing scratches and other damage.
6. Avoid blade contact with any and all metal surfaces especially while the instrument is activated. Contact with staples, clips, or other instruments may result in damaged or broken blades. DO NOT attempt to bend or sharpen the blade. Deformed, damaged, cracked or broken blades may be identified by a continuous tone from the generator.
7. DO NOT USE the Torque Wrench with evidence of damage. Damage to the torque wrench may result in device failure and inability to properly secure the blade assembly.
8. DO NOT USE the product if homeostasis cannot be achieved or observed.
9. DO NOT USE the product if the Sheath or Blade is bent. Both components must be straight to function safely.
10. Components are rated for multiple reuse, but not infinite life. If the blade makes noise, quickly becomes hot, or blades have degraded cutting or coagulation performance, the transducer or blade may be beyond its usable life and should be replaced. Such degradation may occur or be detected before, during or after a procedure. To prevent burn injury, DO NOT continue use of the Blade or Transducer Handpiece if the handpiece temperature becomes uncomfortable to hold. Damaged or worn blades may also stop functioning during a procedure



- without warning and should be replaced. Replace the Torque Wrench when replacing the Blade.
11. Additional sterile instruments should be kept available for all surgical procedures in the event that any component becomes inoperable.
 12. The products described in this document are recommended for endoscopic procedures, which should ONLY be executed by a licensed physician familiar with endoscopic techniques. The physician is responsible for referral to relevant literature regarding techniques, complications, and hazards.
 13. All medical professionals handling the instrumentation should be trained and have a thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures in order to:
 - Avoid shock and burn hazards to both patient and medical personnel,
 - Avoid damage to the device or other medical instrumentation.
 - Ensure that electrical insulation or grounding is not compromised during the use of the instrumentation.
 14. DO NOT USE or activate the Prime™ Ultrasonic Blade without fully assembling the protective Sheath over the blade. The entire blade length is active and will cut/coagulate tissue when the instrument is activated.
 15. Monitor for bleeding during use of the device. If a small amount of bleeding occurs, manually stop the bleeding.
 16. Avoid prolong use. Stop activation upon completion of tissue cutting. Excess activation may result in excess heat generation.
 17. Only activate when the end effector can be fully visualized. Lack of full visibility may result in unintended cutting of tissue or other devices.
 18. Excess lateral force on the blade, especially without the Sheath attached, may result in damage to transducer, blade assembly, or Sheath.
 19. Scratches, dents or distortion of the Blade or Sheath will significantly shorten the instrument's useable life. An audible screeching tone emanating from the blade or transducer is an indicator that the blade or transducer is beyond its useful life and should be replaced.
 20. As with all electrosurgery, laser or ultrasonic energy sources, there are concerns about the carcinogenic and infectious potential of the by-products from cutting and coagulation, such as smoke, plume or aerosols. Appropriate protective filtration masks, eye shields, local exhaust, and/or smoke-evacuation system should be used to prevent exposure to vapors or smoke when using laser, electrosurgery and ultrasonic cutting and coagulation systems.

Storage and Transport Requirements:

Carefully handle, clean, sterilize, transport, and store the Prime™ Ultrasonic Blades and Sheath to avoid bending or contact with hard surfaces. Scratches, dents or distortion of the Blade or Sheath will significantly shorten the instrument's useable life. Store or transport at no more than 80% Relative Humidity, -31°F to 131°F (-35°C to 55°C).

Limited Warranty

Warranty Coverage:

EndoPrime, Inc. ("EndoPrime") warrants these Reusable Blades (**the "Product"**), and only the Product, against defects in materials and workmanship under normal use for a period of **Three (3) months** from the date of retail purchase by the original purchaser ("**Limited Warranty Period**").



Consumer's sole and exclusive remedy, and EndoPrime's sole and exclusive responsibility under this warranty, shall be that EndoPrime will, if a defect arises and a valid claim, as determined in the sole discretion of EndoPrime, is received by EndoPrime within the Limited Warranty Period, at EndoPrime's option and to the extent permitted by law, either (1) repair the Product at no charge, using new or refurbished replacement parts; or (2) replace the Product. A replacement part assumes the remaining warranty of the original Product or **NINETY (90) days** from the date of replacement or repair, whichever is longer.

INSTRUCTIONS TO OBTAIN WARRANTY SERVICE:

To obtain warranty service Consumer must notify EndoPrime to obtain a **Return Material Authorization ("RMA")** and return the defective Product together with proof of purchase to the address specified by EndoPrime. Consumer will pre-pay all return shipping charges and shall assume all risk of loss or damage to product while in transit to and from EndoPrime. Any Product returned to EndoPrime without an RMA or without proof of purchase will be returned to Consumer at Consumer's cost. EndoPrime will not be responsible for any such damage or loss.

EXCLUSIONS AND LIMITATIONS:

This Limited Warranty applies only to the Product manufactured by EndoPrime. The Limited Warranty does not apply to any EndoPrime products and services other than the Product. This warranty does not apply to a Product or part of the Product that has been altered or modified (e.g., to alter functionality or capability) by anyone who is not a representative of EndoPrime. In addition, this Limited Warranty does not apply: (a) to damage caused by accident, abuse, misuse, flood, fire, earthquake or other external causes; (b) to damage caused by operating the Product outside the permitted or intended uses not in accordance with the documentation by EndoPrime; or (c) to damage caused by service performed by anyone who is not a representative of EndoPrime.

EndoPrime reserves the right to upgrade and make other necessary changes to the Product at any time without incurring any obligation or liabilities to make the same or similar changes to other EndoPrime products.

No EndoPrime reseller, agent, or employee is authorized to make any modification, extension, or addition to this Limited Warranty. If any term is held to be illegal or unenforceable, the legality or enforceability of the remaining terms shall not be affected or impaired.

DISCLAIMER:

EXCEPT AS SPECIFIED IN THIS LIMITED WARRANTY, ALL EXPRESS OR IMPLIED CONDITIONS, REPRESENTATIONS, AND WARRANTIES INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, SATISFACTORY QUALITY, NON-INTERFERENCE, ACCURACY OF INFORMATIONAL CONTENT, OR ARISING FROM A COURSE OF DEALING, LAW, USAGE, OR TRADE PRACTICE, ARE HEREBY EXCLUDED TO THE EXTENT ALLOWED BY APPLICABLE LAW AND ARE EXPRESSLY DISCLAIMED BY ENDOPRIME TO THE EXTENT AN IMPLIED WARRANTY CANNOT BE EXCLUDED, SUCH WARRANTY IS LIMITED IN DURATION TO THE EXPRESS WARRANTY PERIOD. BECAUSE SOME STATES OR JURISDICTIONS DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, THE ABOVE



LIMITATION MAY NOT APPLY. THESE WARRANTIES GIVE CONSUMER SPECIFIC LEGAL RIGHTS, AND CONSUMER MAY ALSO HAVE OTHER RIGHTS WHICH VARY FROM JURISDICTION TO JURISDICTION.

This disclaimer and exclusion shall apply even if the express warranty set forth above fails of its essential purpose.

GOVERNING LAW AND ARBITRATION:

This Limited Warranty shall be governed by the laws of the State of Ohio without giving effect to any conflict of laws principles that may provide the application of the law of another jurisdiction. Any claim or dispute in connection with this Limited Warranty shall be resolved in a cost effective manner through binding non-appearance-based arbitration. The arbitration shall be initiated through an established alternative dispute resolution provider mutually agreed upon by the parties. The alternative dispute resolution provider and the parties must comply with the following rules: a) the arbitration shall be conducted by telephone, online and/or be solely based on written submissions, the specific manner shall be chosen by the party initiating the arbitration; b) the arbitration shall not involve any personal appearance by the parties or witnesses unless otherwise mutually agreed by the parties; and c) any judgment on the award rendered by the arbitrator may be entered in any court of competent jurisdiction. If the foregoing arbitration clause does not apply for any reason, you agree to submit to the personal jurisdiction of the state courts located within Hamilton County, Ohio and the federal courts in the Southern District of Ohio for the purpose of litigating all such claims or disputes, which courts shall have exclusive jurisdiction of such claims or disputes. Notwithstanding the foregoing, EndoPrime may seek injunctive or other equitable relief to protect its intellectual property rights in any court of competent jurisdiction.



EndoPrime
4480 Lake Forest Drive
Suite 414
Cincinnati, OH 45242
Telephone: (513) 769-1916
Fax: (513) 769-1921

K150271/52



4480 Lake Forest Dr.
Suite 414
Blue Ash, Ohio 45242

FDA CDRH DMC

May 18, 2015

MAY 20 2015

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

Received

Attn: Dr. Thomas Claiborne

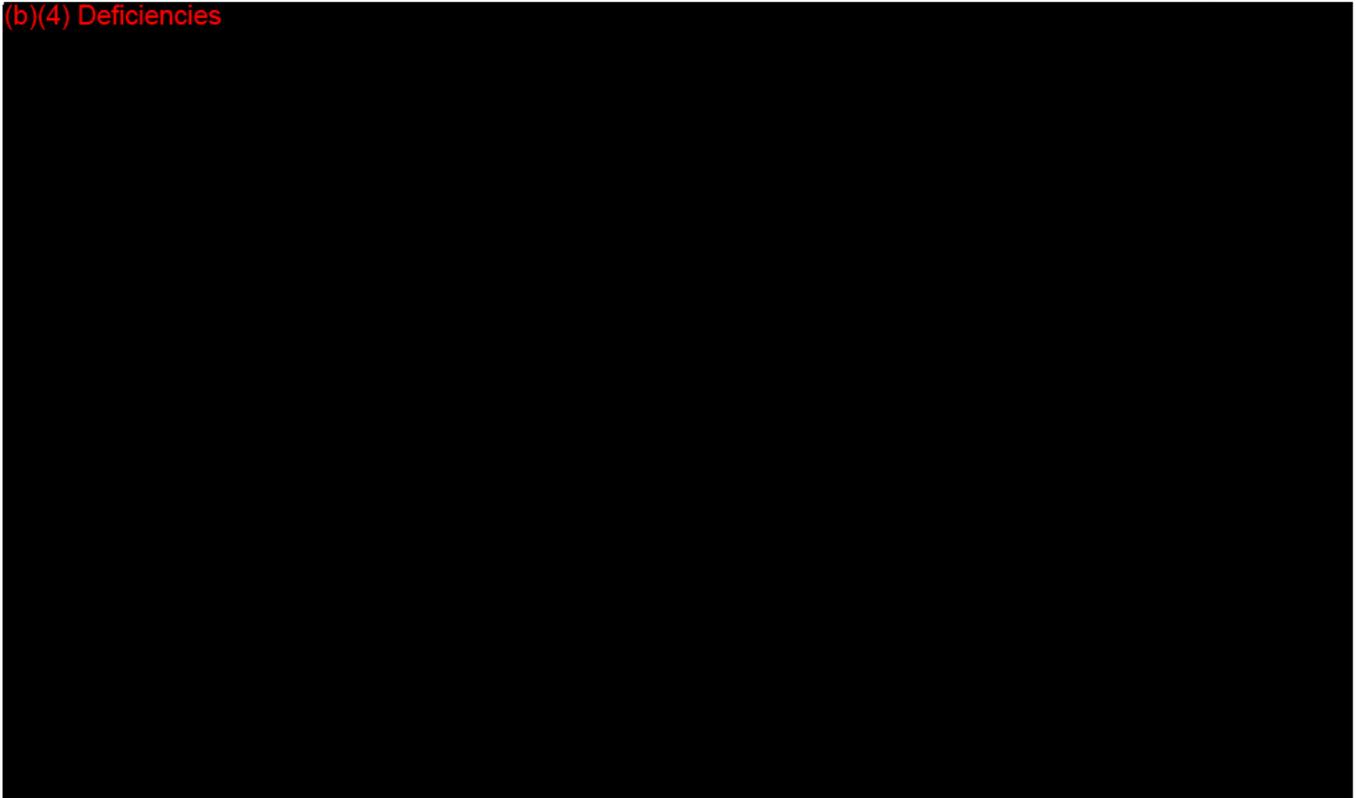
K150271/S002 - corrected naming convention of eCopy.
The eCopy is an exact duplicate of the paper copy.

Re: K150271/S001 Response to Product Code and Biocompatibility Deficiency – EndoPrime Prime™ Adaptive Ultrasonic Scalpel System and Blades

Dear Dr. Claiborne,

EndoPrime is submitting this in response to your Additional Information Letter received April 15, 2015 regarding the FDA Product Code and Biocompatibility Deficiencies:

(b)(4) Deficiencies

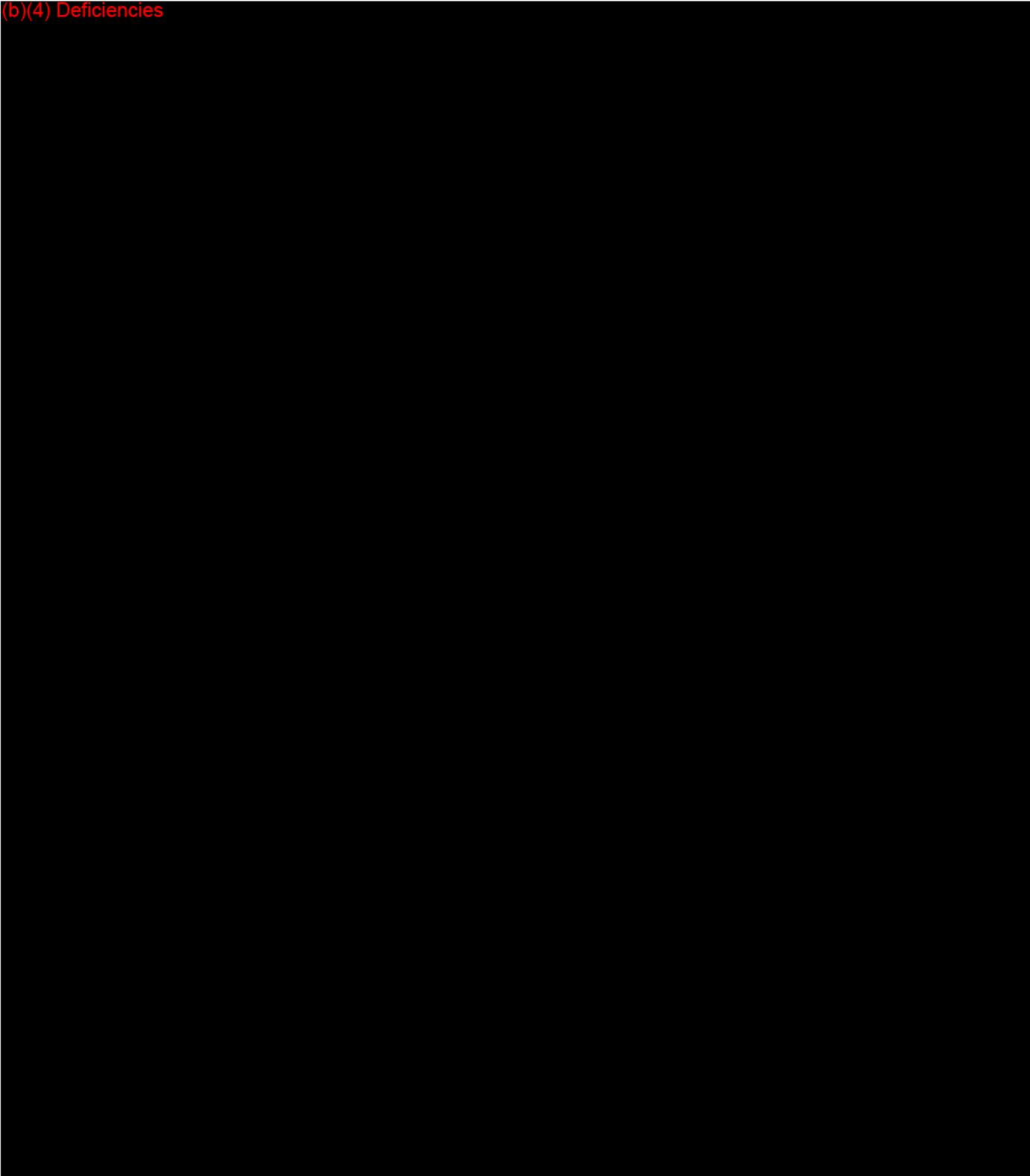


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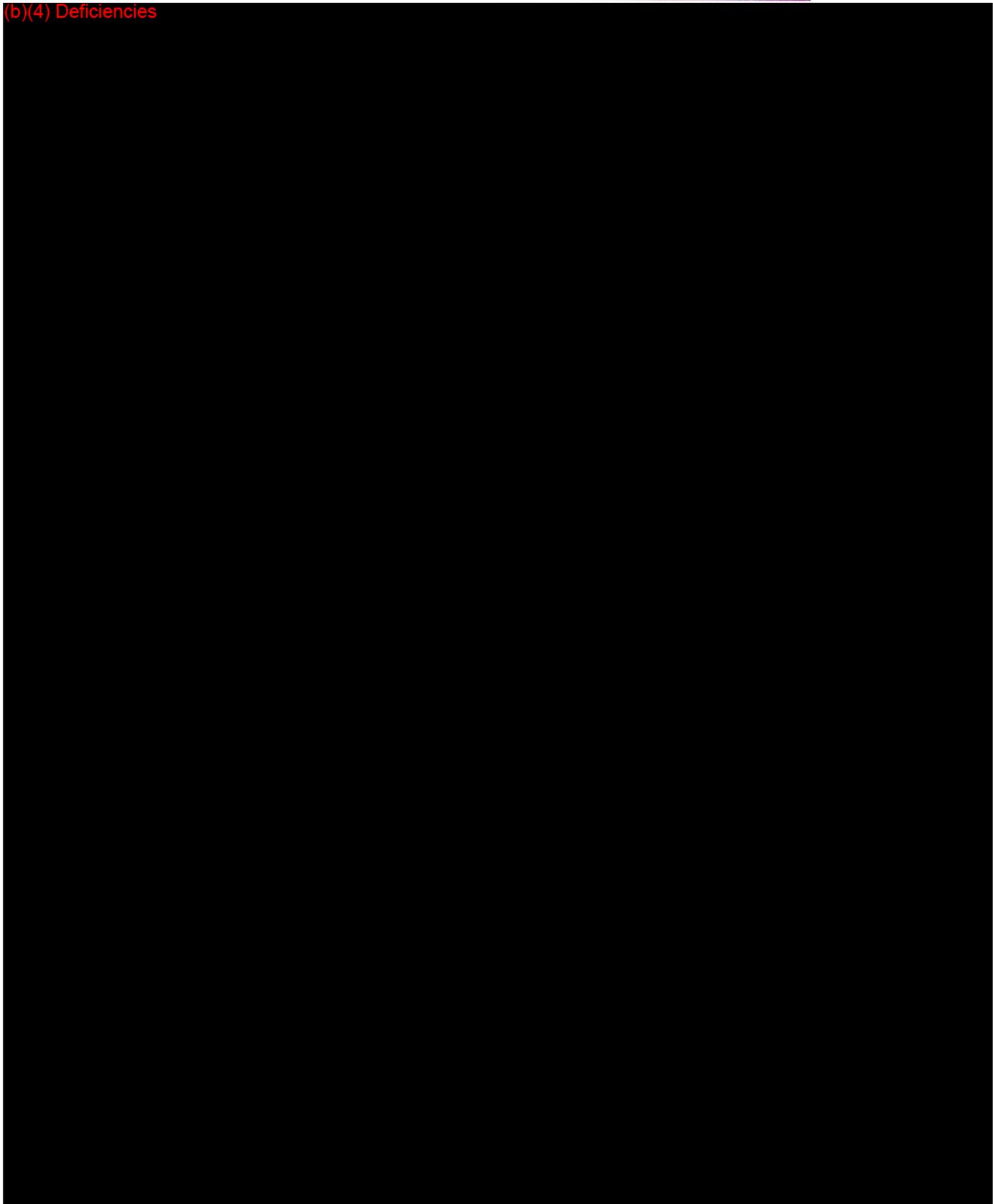
EndoPrime Response:

(b)(4) Deficiencies



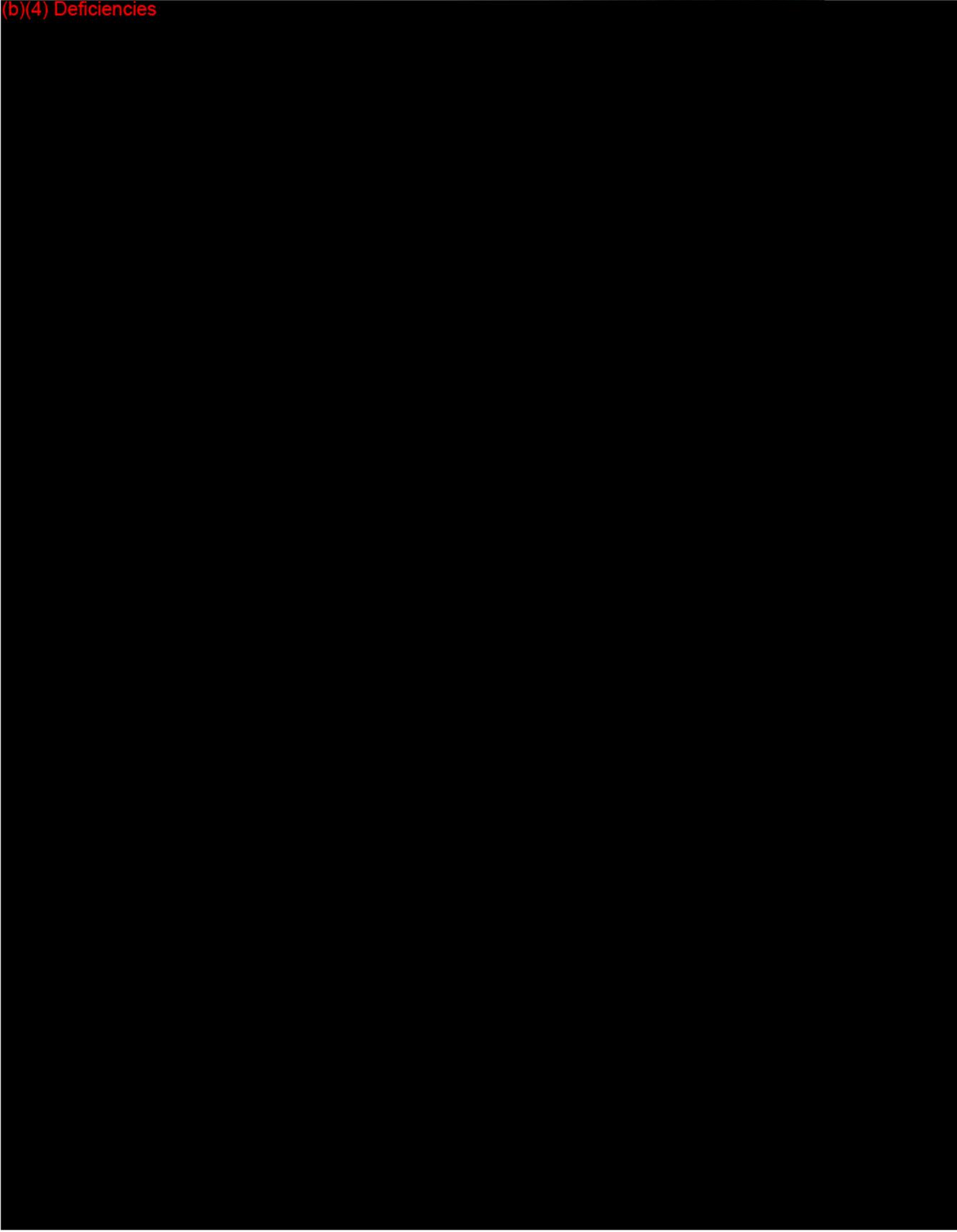


(b)(4) Deficiencies





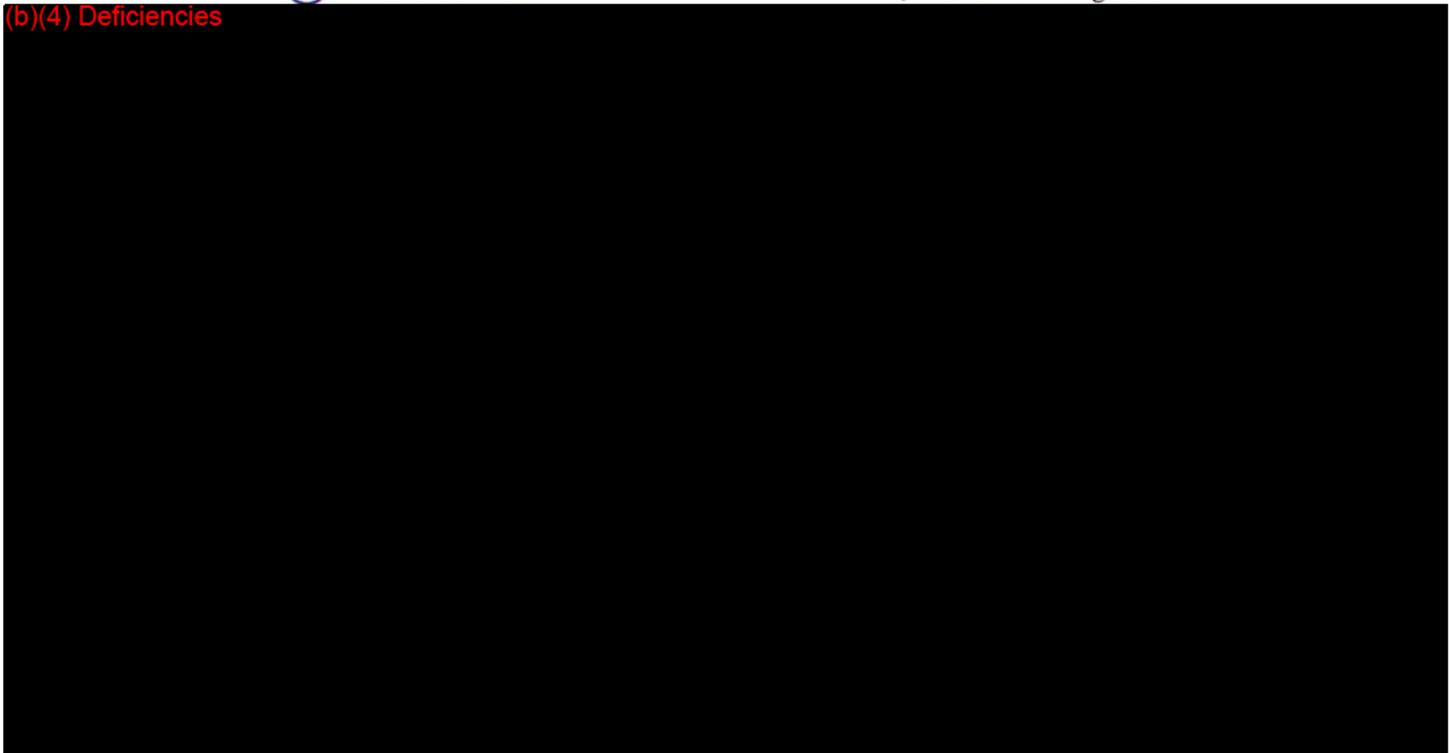
(b)(4) Deficiencies





May 18, 2015 Page 5 of 6

(b)(4) Deficiencies



If additional information is needed, do not hesitate to contact me.

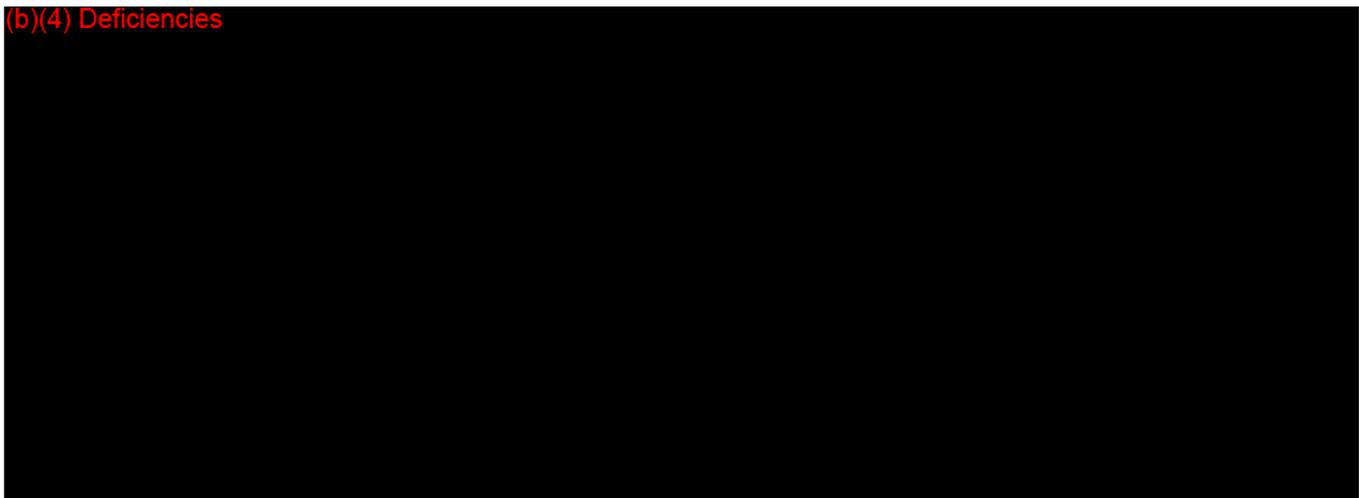
Best regards,

EndoPrime, Inc.

A handwritten signature in purple ink, appearing to read 'Rich Grant'.

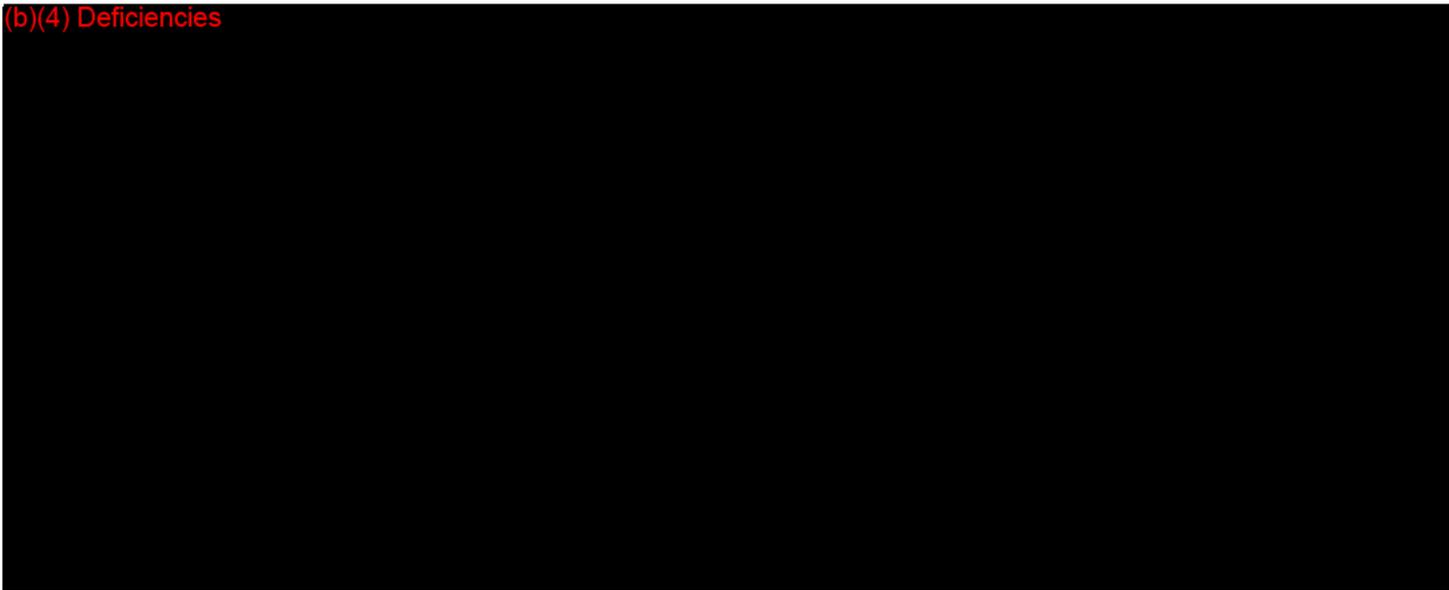
Rich Grant, CEO
Office: 513-769-1916x11
Mobile: 513-608-4017
rich.grant@endoprime.com

(b)(4) Deficiencies





(b)(4) Deficiencies





4480 Lake Forest Dr.
Suite 414
Blue Ash, Ohio 45242

May 18, 2015

U.S. Food and Drug Administration
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10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

K150271/S2

FDA CDRH DMC

MAY 19 2015

Received

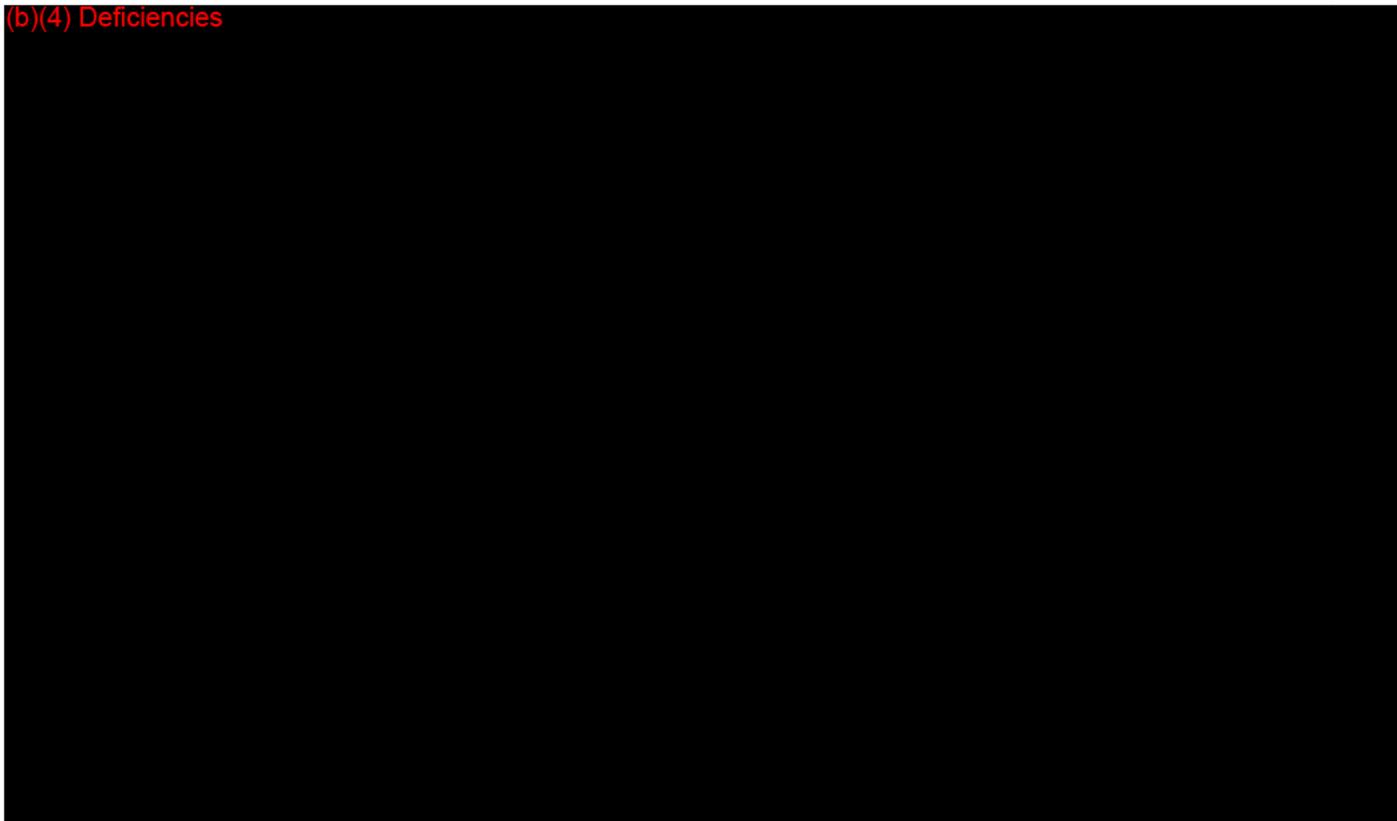
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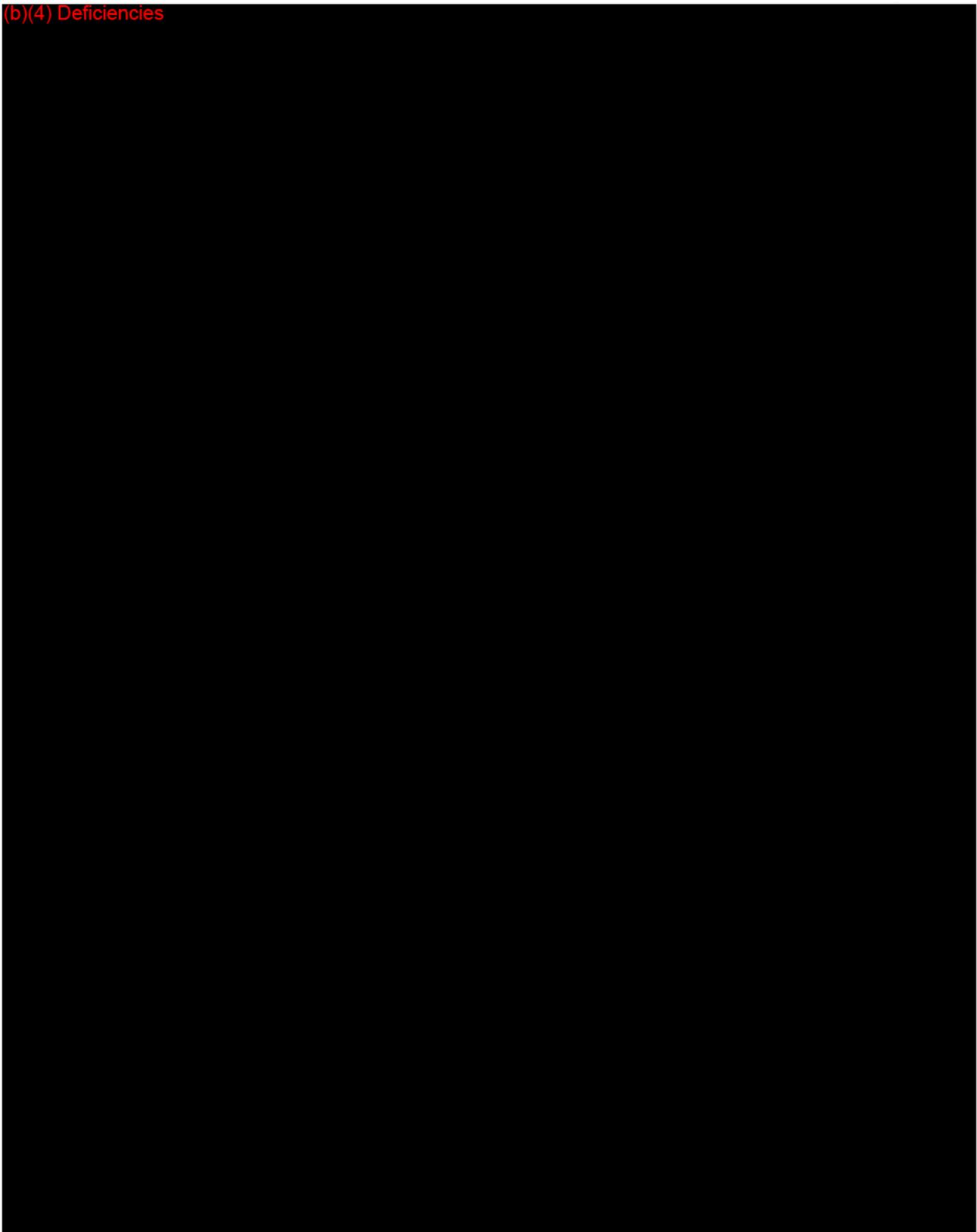
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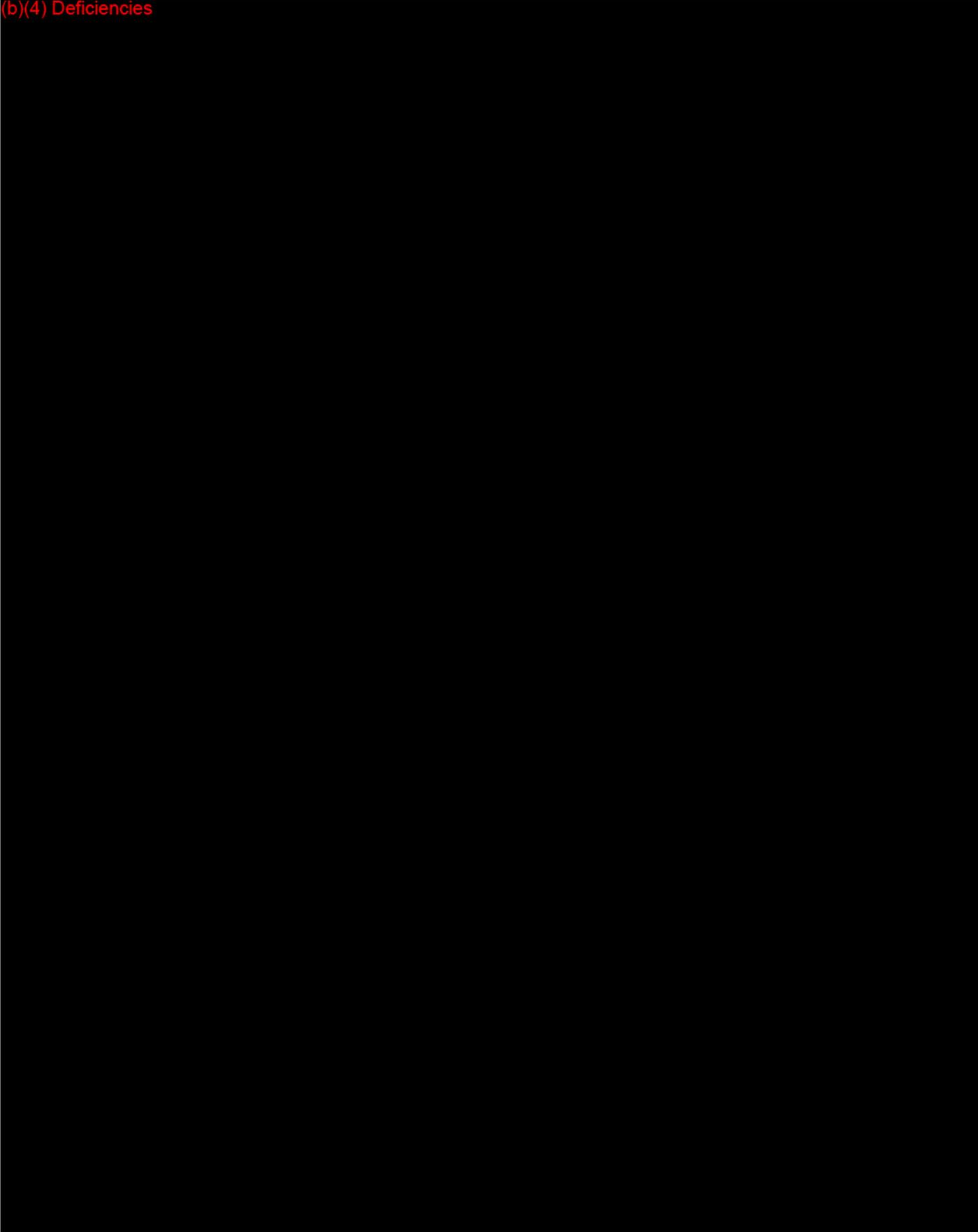


EndoPrime Response:

(b)(4) Deficiencies

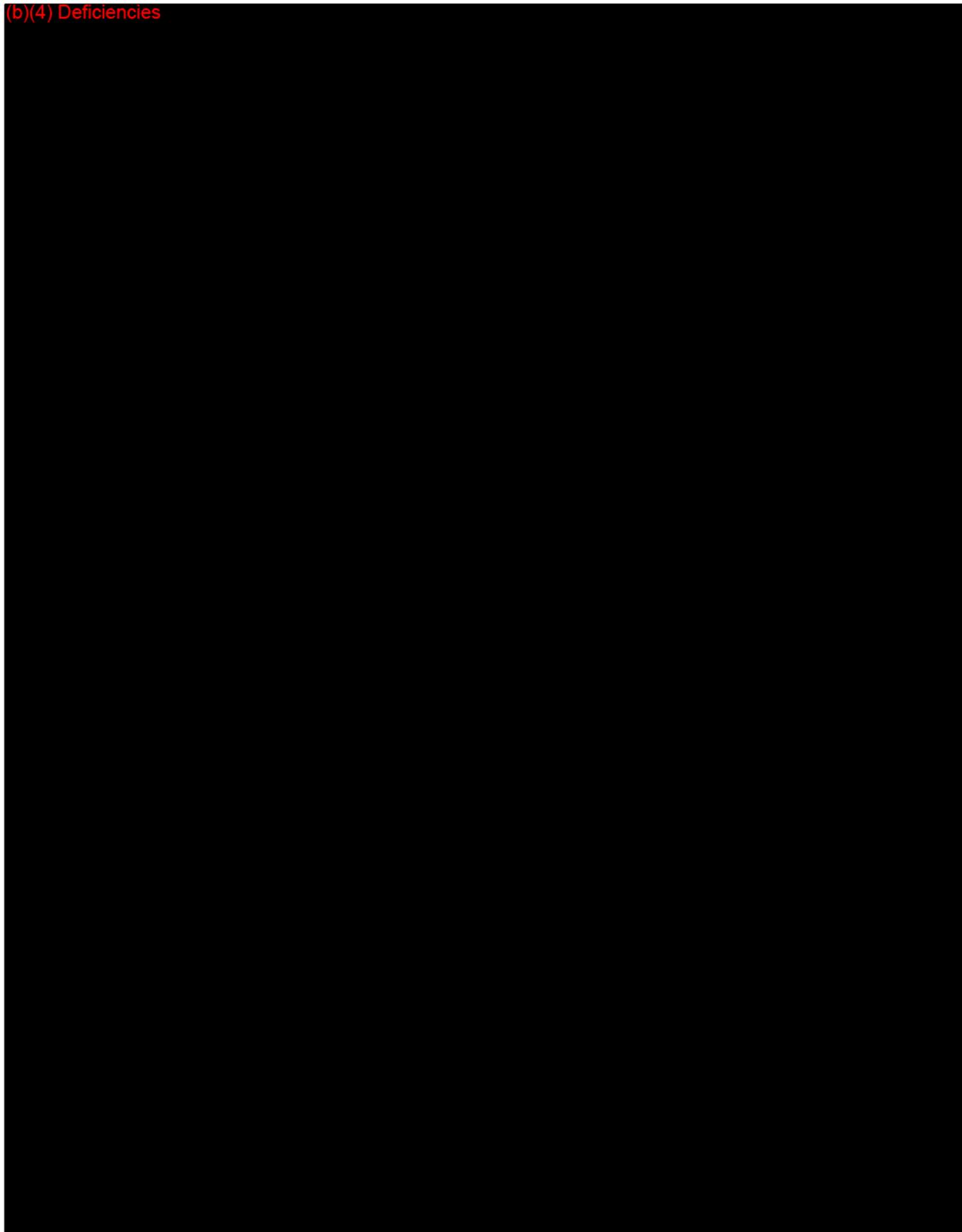


(b)(4) Deficiencies





(b)(4) Deficiencies





(b)(4) Deficiencies



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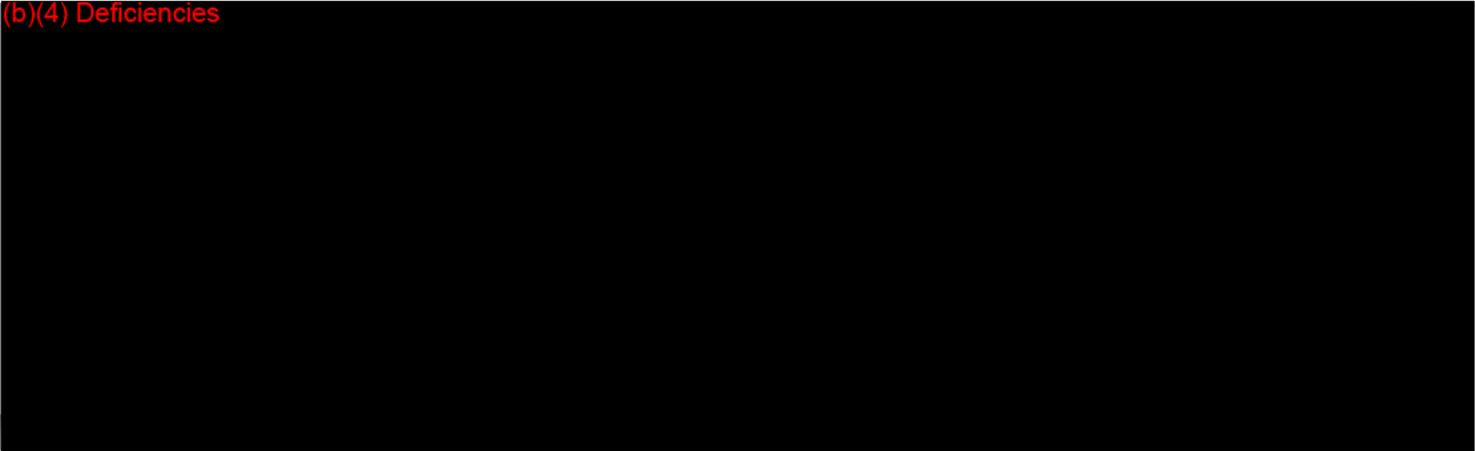
Best regards,

EndoPrime, Inc.



Rich Grant, CEO
Office: 513-769-1916x11
Mobile: 513-608-4017
rich.grant@endoprime.com

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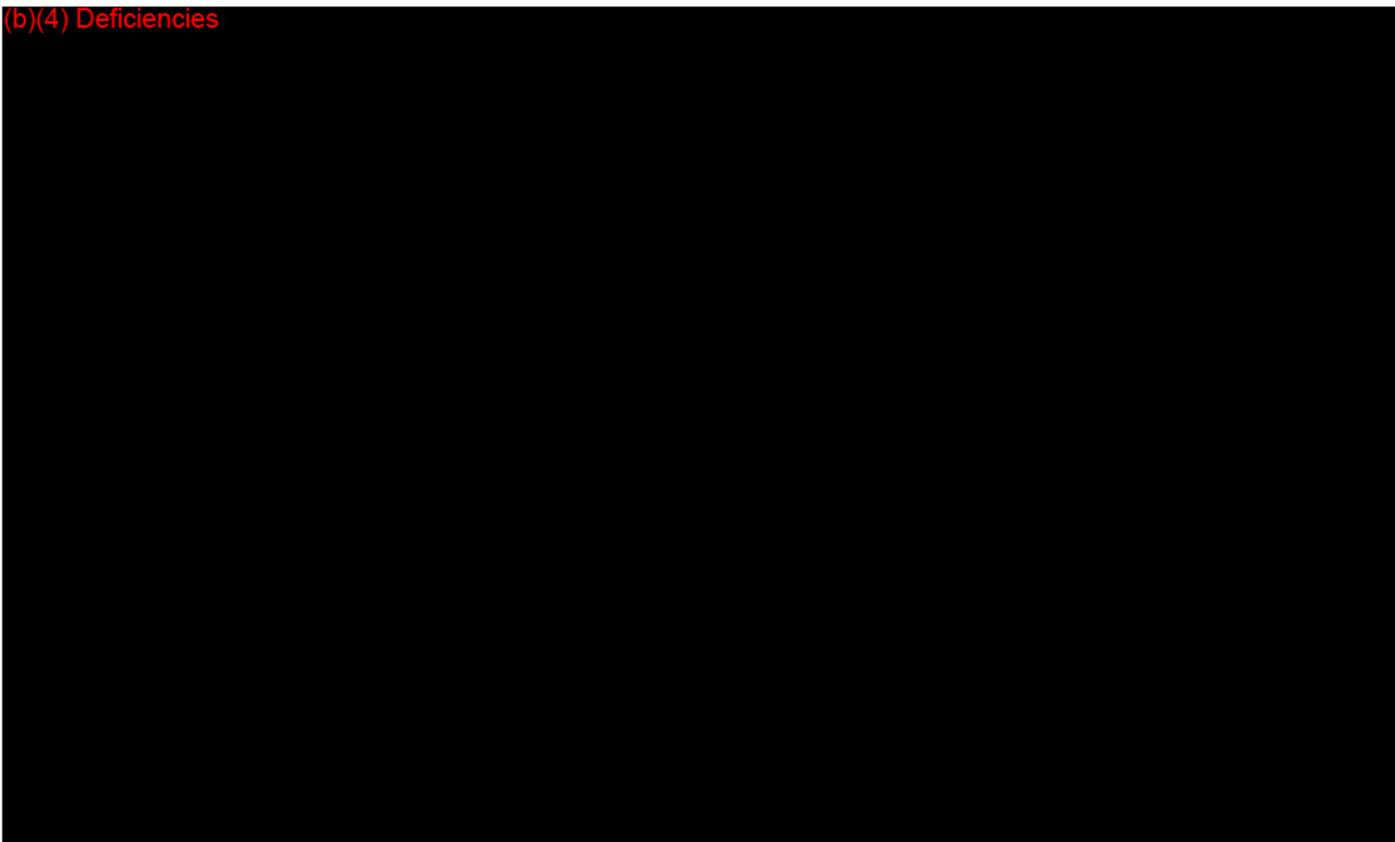
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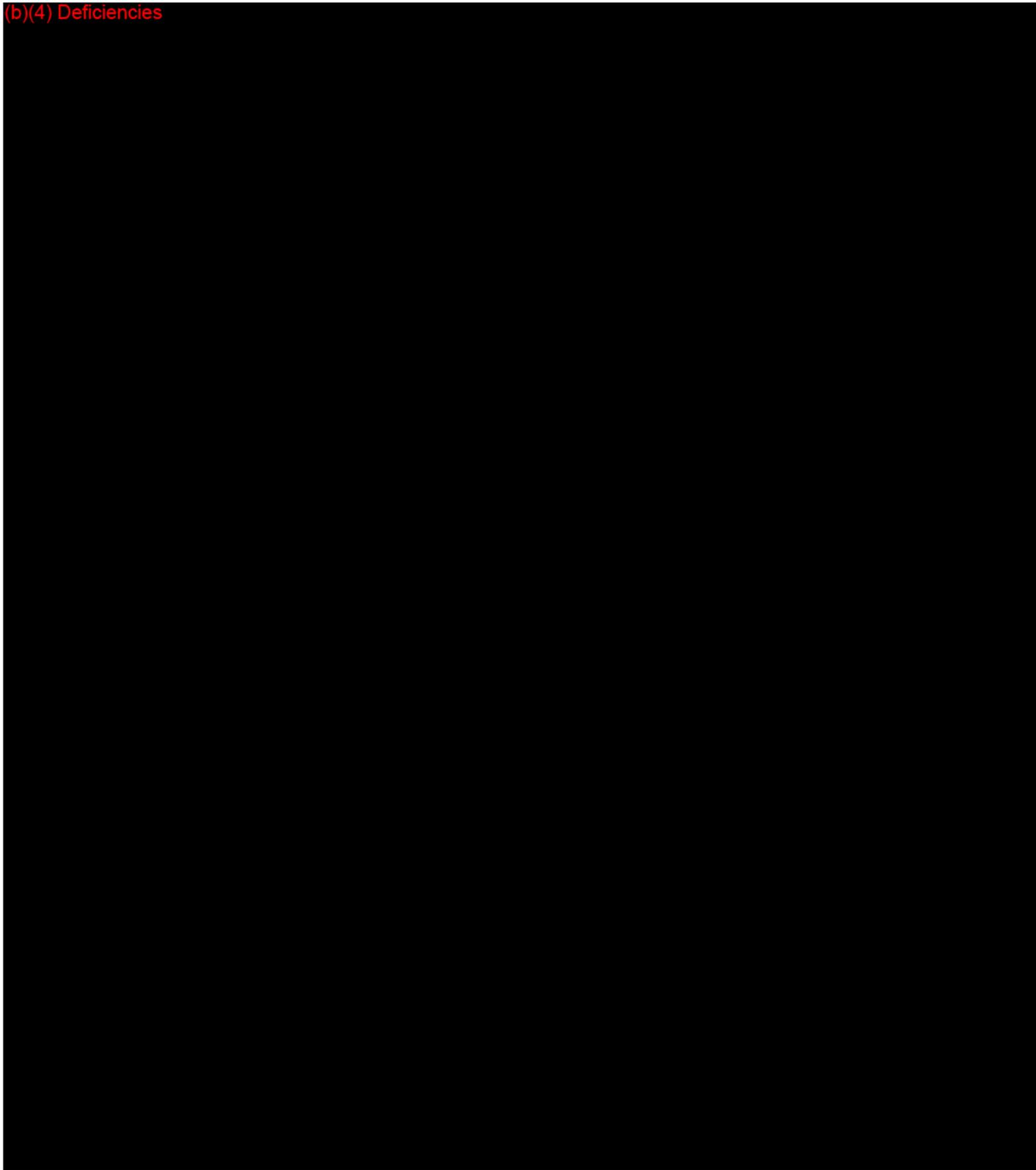
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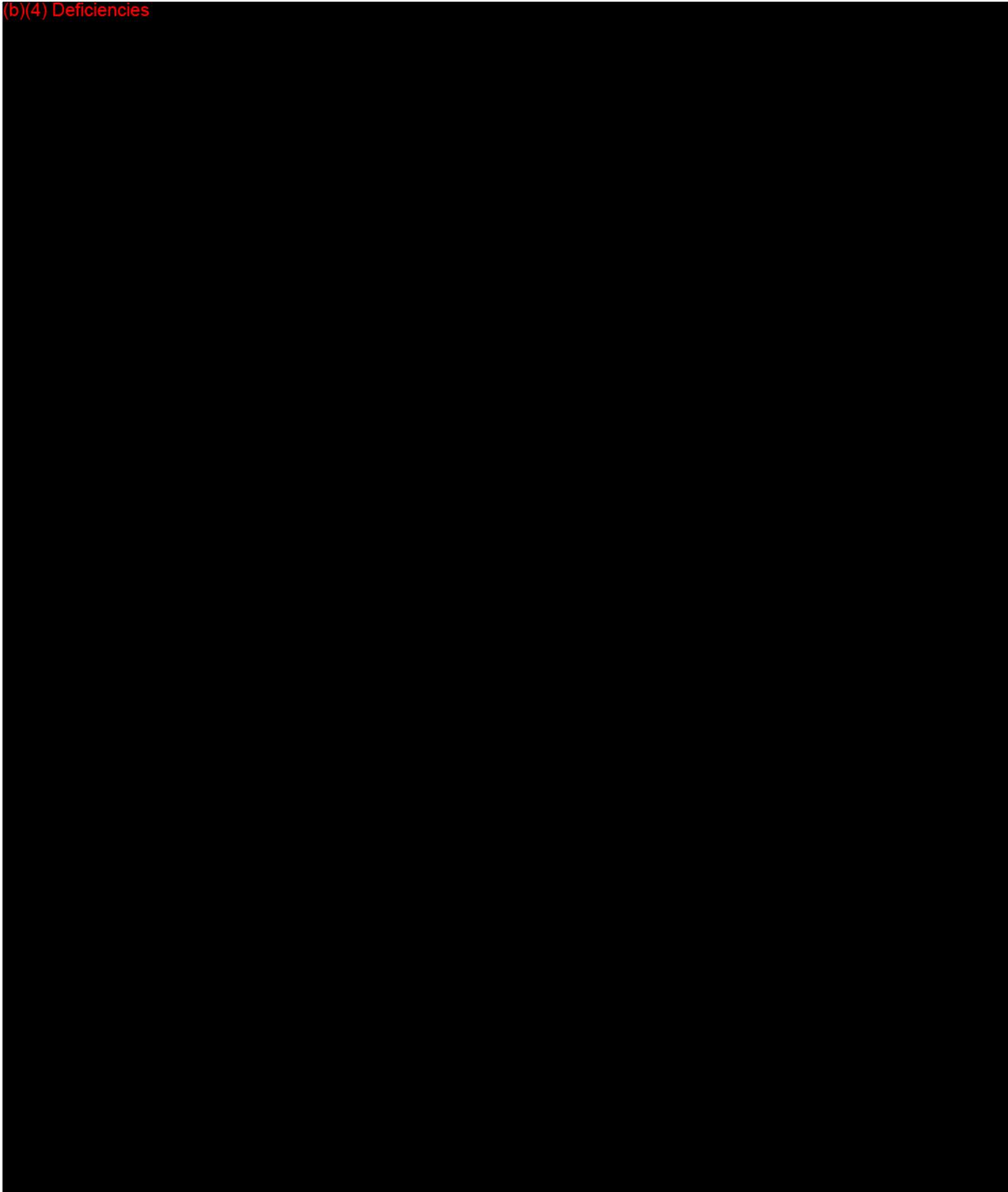
EndoPrime Response:

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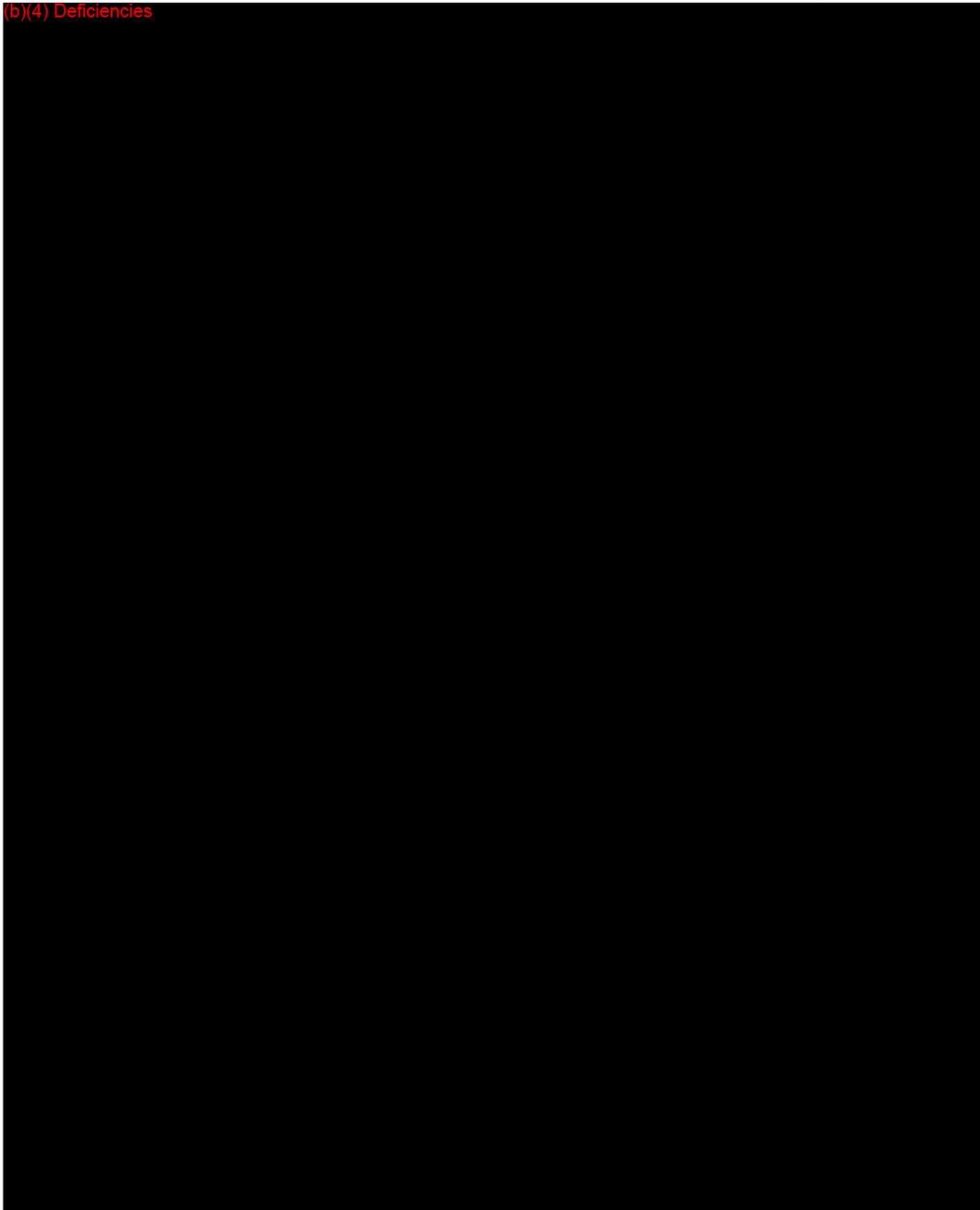


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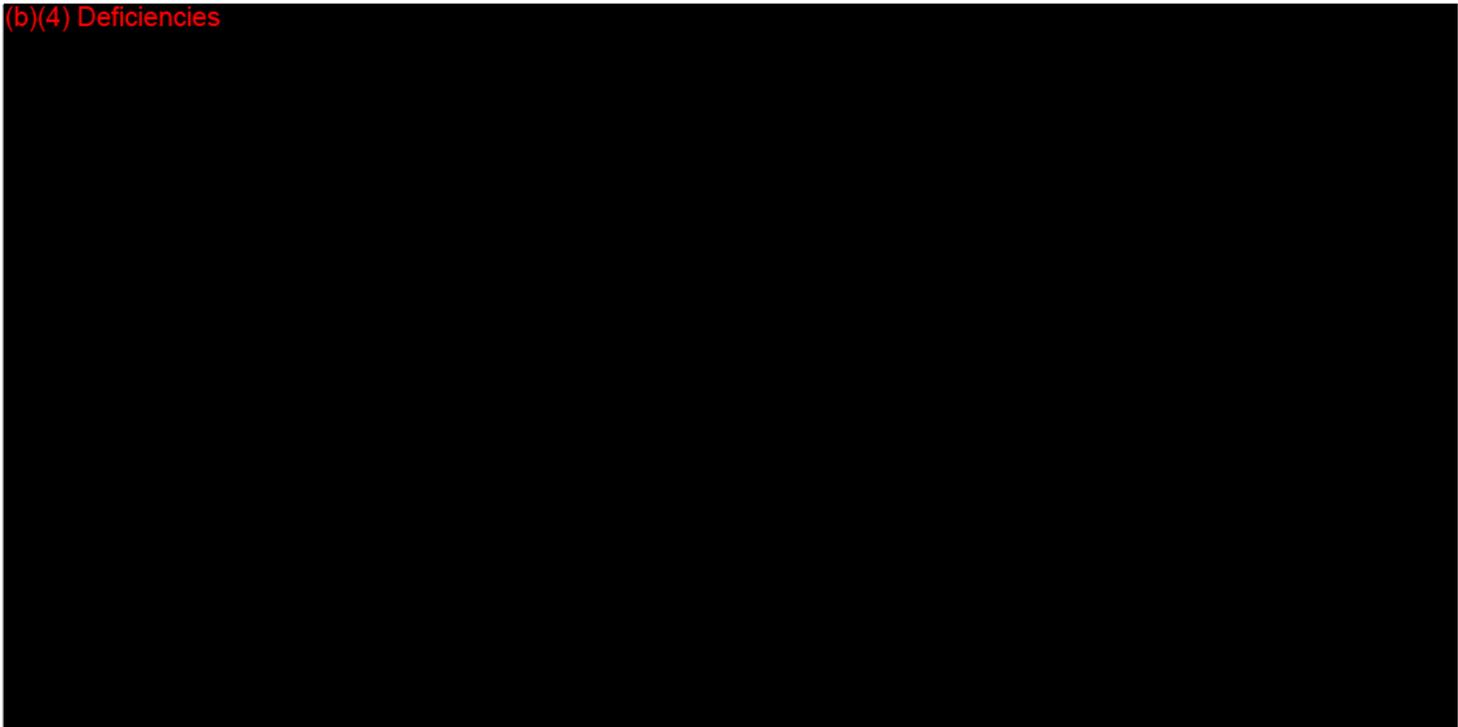


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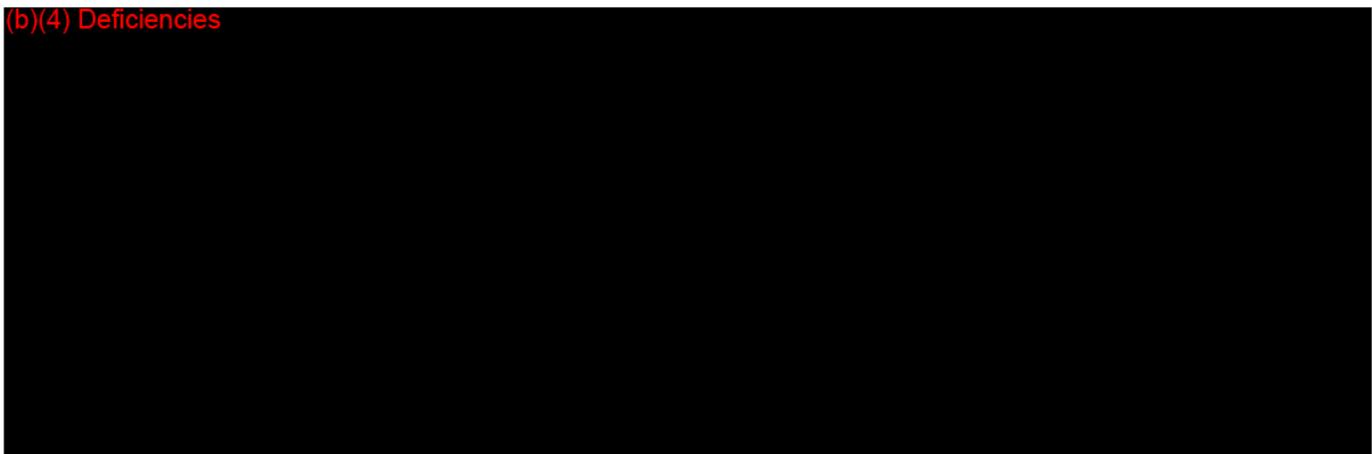
Best regards,

EndoPrime, Inc.

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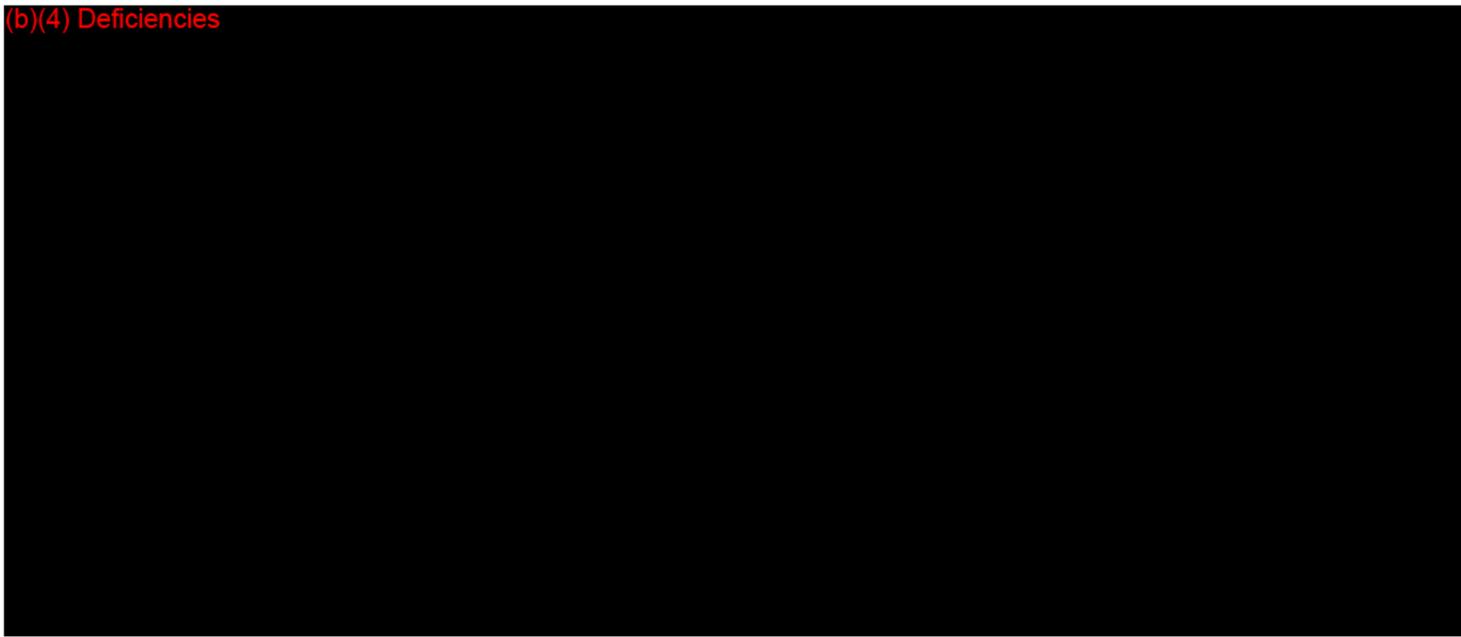
Rich Grant, CEO
Office: 513-769-1916x11
Mobile: 513-608-4017
rich.grant@endoprime.com

(b)(4) Deficiencies





(b)(4) Deficiencies



510(k) Summary

Date Prepared: May 14, 2015 (REVISED)
Submitter Contact: Rich Grant, CEO
EndoPrime, Inc.
4480 Lake Forest Drive, Suite 414
Cincinnati, OH 45242
513-769-1916

Regulatory Contact: Rich Grant
EndoPrime, Inc.
4480 Lake Forest Drive, Suite 414
Cincinnati, OH 45242
513-769-1916

Trade Name: Prime™ Ultrasonic Scalpel Reusable Blades
Prime™ Reusable Transducer Handpiece
Prime™ Adaptive Ultrasonic Scalpel Generator
Common or Usual Name: Ultrasonic Surgical Instruments
Product Class: Class II
Classification: Instrument, Ultrasonic Surgical
Product Codes: LFL
Panel Code: General & Plastic Surgery
Regulation Standard: Unclassified

Reason for this Submission: This Traditional 510(k) involves one medical device system compiled of three individual medical device components.

No Prior Submissions: There were no prior submissions for the subject device by EndoPrime Inc.

Indications for Use:

The **Prime™ Adaptive Ultrasonic Scalpel System** is a cutting and coagulation system indicated for open, laparoscopic, and endoscopic surgery in soft tissue where control of hemostasis and thermal spread is desired. The system is indicated for dissection, sealing, transection,otomy creation and transection/coagulation of vessels as indicated for each cutting and coagulation instrument used (consult the instructions for use provided with each instrument). The system can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels.

Device Descriptions:

The **Prime™ Adaptive Ultrasonic Scalpel System** has three major components: Generator (with footswitch), Transducer Handpiece and instruments (or blades). The **Prime™ 6000 Generator** provides input/output control and operation interface to automatically adapt the ultrasonic power output for the tissue load encountered. The device system is compliant with the following consensus standards:

Performance Standards:	
IEC 60601-1 2005 + CORR. 1 (2006) + CORR. (2007)	International Standard-Medical Electrical Equipment-General Requirements for Basic Safety and Essential Performance.
CAN/CSA-C22.2 No. 60601-1:08	Medical Electrical Equipment-Part 1-6: General Requirements for Safety-Collateral Standard; General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems.
EN 60601-1-2:2007 CISPR 11:2009+A1	Medical Electrical Equipment-Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility-Requirements and Tests.
IEC 60601-1-2-18:2009 (Third Edition)	Medical electrical equipment-Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.
IEC 61000-4-8:2010	Medical Electrical Equipment: Part 1-4: General Requirements for Collateral Standard: Programmable Electrical Medical Systems.
IEC 61000-3-2:2006 +A1 +A2	Electromagnetic compatibility (EMC)-Part 3-2: Limits for harmonic current emissions (equipment input current ≤ 16 A per phase).
IEC 61000-3-3:2008	Electromagnetic compatibility (EMC)-Part 3-3: Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection.
IEC 61000-4-3:2006 + A1:2007 + A2:2010	Electromagnetic compatibility (EMC)-Part 4-3: Limits-Limitation of emission of harmonic currents in low-voltage power supply systems for equipment with rated current greater than 16 A.
IEC 61000-4-4:2004+A1:2010	Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrical fast transient/burst immunity test.
IEC 61000-4-5:2005	Electromagnetic compatibility (EMC). Testing and measurement techniques. Surge immunity test.
IEC 61000-4-6:2003	Electromagnetic compatibility (EMC). Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields.
IEC 61000-4-11:2004	Electromagnetic compatibility (EMC). Testing and

	measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests.
ISO 10993-1:2009/AC2010	Biocompatibility Evaluation of medical Device Table A.1
ISO 10993-5:2009	Biological evaluation of medical devices--Part 5: Tests for vitro cytotoxicity.
ISO 10993-10:2009	Biological evaluation of medical devices--Part 10: Test for irritation and skin sensitivity.
ISO 10993-11:2009	Biological evaluation of medical devices--Part 11: Tests for systemic toxicity.
ISO 10993-4:2009	Biological evaluation of medical devices—Part 4: Test for Hemocompatibility.
AAMI TIR30:2011	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices. Association for Advancement of Medical Instrumentation, Arlington, VA. (CRD249).
EN/ISO 14971:2012	Risk Management for Medical Device
EN/IEC 62304:2006	Medical device software—Software life cycle processes.

Prime™ Adaptive Ultrasonic Scalpel System and Blades family of products consist of:

Prime™ G6000 Generator provides operation interface display, device condition monitoring and Input/Output control. The generator provides electrical energy output to the transducer, which is controlled by activating the footswitch. The **Prime™ G6000 Generator** is also validated to operate with hand switched devices and hand switched enabled transducer hand pieces. A built-in, automatic pre-check function verifies proper connection and operation of the system during startup and continuously monitors the system and instruments. Variable and Maximum (or Full) power levels (1 through 5) are displayed on the front panel and can be selected by pressing the VAR or FULL footswitch pedal (or if available the hand switch). The Variable Power setting can be selected throughout the procedure to provide corresponding energy outputs with the interacting instrument. Audible and visual alarms assist with identifying anomalies, error, and failures including generator, instrument or transducer that are at the end of their useful life. A Standby button is available to pause the system to avoid accidental activation when not in use, or conduct manual system checks and diagnostics.

Prime™ Ultrasonic Scalpel Reusable Blades vibrate ultrasonically, which enables its cutting ability. The same vibration seals small vessels ($\leq 2\text{mm}$) with coagulated blood and tissue proteins by producing local heating of tissue. Homeostasis occurs when tissue couples with the blade. The **Prime™ Ultrasonic Scalpel Reusable Blades** are designed for use with a transducer and a generator system as part of the **Prime™ Adaptive Ultrasonic Scalpel System** and family of products; these products are compatible with a limited number of other manufacturer's systems. The system instruments can be used as an adjunct to, or substitute for electro-surgery, lasers, or steel scalpels with the

advantages of limited heat/smoke generation and the lack of current flow through the patient. The blade instruments are provided with a reusable Torque Wrench to assure proper tightness when attaching the blade to the transducer. The generator will automatically check the tightness to assure proper function.

The **Prime™ Reusable Transducer Handpiece** cooperates with the **Prime™ Adaptive Ultrasonic Scalpel Blades** as a cutting and coagulation instrument. The **Prime™ Reusable Transducer Handpiece** is designed to convert electrical energy from the generator to mechanical motion of the instrument blades. When the transducer is used in conjunction with the **Prime™ Adaptive Ultrasonic Scalpel System**, the transducer provides ultrasonic vibration, which enables the blade's cutting ability. **Prime™ Adaptive Ultrasonic Scalpel System and Blades** family of products is compatible with a limited number of other manufacturer's systems.

Prime™ Adaptive Ultrasonic Scalpel System products are compatible with a limited number of other predicate systems.

Predicate Device(s):

K002981-Ultracision® Harmonic Scalpel®, Ethicon Endo-Surgery, Inc.
K990430-Ultracision® HARMONIC Scalpel® Hand Piece, Ethicon Endo-Surgery
K010898-Ultracision Harmonic Scalpel Blade, Ethicon Endo-Surgery
K053056-Harmonic Scalpel Blades and Shears, Ethicon Endo-Surgery, Inc.

Prime™ Adaptive Ultrasonic Scalpel System blade tips are finished identical to other ultrasonic devices:

Reference Device:

K010309-Sonopet® Surgical Aspirator, Mutoh America CO., LTD. (now Stryker) refinished for its blue anodized blade tip surface only.

Technological Characteristics:

The **Prime™ Adaptive Ultrasonic Scalpel System and Blades** technological characteristics are substantially equivalent to the predicated devices including automatically adapting the ultrasonic power output for the tissue load encountered to provide consistent vibration in differing loads and tissue thickness. The predicate device scalpel blades were predicated on reusable scalpel blades and the **Prime™ Ultrasonic Scalpel Reusable Blades** are designed to function similar to the predicate devices but are provided non-sterile and validated for disassembly, cleaning and sterilization. Another feature of the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** is the ability to disconnect the cable at the transducer handpiece. This feature allows the surgical scrub technician to quickly replace the transducer handpiece and/or ultrasonic blades without contact with the non-sterile surface of the generator or assistance from others. The cable disconnect was designed as a convenience feature similar to the ability to disconnect at the generator. The **Prime™ Ultrasonic Scalpel Reusable Blades** are designed similar to the predicate blades but have slightly different end effector designs. The **Prime™ Ultrasonic Curved Blades** have a compact design to improve access in narrow, delicate anatomy. The **Omni™ Ultrasonic Hook Blades** are curved for better visibility with a dual hook design to permit easier change of direction without full rotation. These technological improvements will

not affect the overall device intended use, performance characteristics, substantial equivalence to the predicate, or raise any new issues regarding safety or efficacy.

Conclusion:

EndoPrime, Inc. concludes that the **Prime™ Adaptive Ultrasonic Scalpel System and Blades** family of products, is substantially equivalent to the predicate devices, and raises no new questions of safety or effectiveness.

